

THE DRUG SAFETY RESEARCH TRUST

England & Wales · Charity number 327206

Details

Status Registered

Legal form Trust

Registered 1986-08-12

Register [View on the Charity Commission register](#)

Contact

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Blundell Lane
Bursledon
Southampton
SO31 1AA

Phone 02380408600

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Website <http://www.dsru.org>

Activities

Objects: TO ADVANCE EDUCATION AND BENEFIT THE COMMUNITY BY THE CONDUCT AND PROMOTION OF RESEARCH INTO AND THE ORGANISATION, DEVELOPMENT AND IMPROVEMENT OF EDUCATIONAL FACILITIES FOR THE STUDY OF THE SAFETY AND AFFICANCY OF DRUGS AND MEDICINES AND DRUG PHARMACOEPIDEMIOLOGY. TO PUBLISH OR PROCURE THE PUBLICATION OF AND OTHERWISE DISSEMINATE THE RESULTS OF SUCH RESEARCH. FOR FURTHER DETAIL SEE CLAUSE 5.

Activities: Post marketing surveillance of newly marketed medicines. Providing education and training in pharmacovigilance and related subjects.

Classification

- **How:** Sponsors Or Undertakes Research
- **What:** Education/training, The Advancement Of Health Or Saving Of Lives
- **Who:** The General Public/mankind

Geography

- Throughout England And Wales

Finances

Period end	Income	Expenditure	Assets	Employees
2024-12-31	£1,173,145	£2,478,401	£7,281,714	26
2023-12-31	£2,316,460	£2,688,576	£8,473,267	31
2022-12-31	£1,908,698	£2,683,345	£8,766,908	33
2021-12-31	£4,031,062	£2,794,787	£10,036,188	30
2020-12-31	£1,396,094	£1,635,153	£8,569,841	23

Trustees

Name	Role	Appointed
PROFESSOR KENNETH ROSS PATERSON	Chair	2020-05-07
PROFESSOR ALAN JOHN CAMM QHP BSC		
PROFESSOR MARTIN PATTERSON VESSEY CBE FRCP		
Professor Allan Hunter Young		2016-05-25
Professor Isla Shelagh Mackenzie MBChB		2019-10-11

THE DRUG SAFETY RESEARCH TRUST

England & Wales - Charity number 327206

Accounts

REGISTERED CHARITY NUMBER: 327206

**Trustees' Report and
Audited Financial Statements for the Year Ended 31 December 2024
for
Drug Safety Research Trust**

Drug Safety Research Trust

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Drug Safety Research Trust

Reference and Administrative Details for the Year Ended 31 December 2024

TRUSTEES

Professor Kenneth Ross Paterson MB ChB FRCP FFPM FBPhS (Chairman)
Professor John Camm QHP BSc MD FRCP FESC FACC FAHA FCGC CSTJ
Professor Martin Vessey CBE MD FRCP FRCOG FRCGP FFPH FMedSci FRS
Professor Allan Hunter Young MB, ChB, MPhil, PhD, FRCPC, FRCPsych
Professor Isla Mackenzie MB ChB PhD PGCertMedEd FRCP Edin FBPhS FBIHS

DIRECTOR

Dr Linda Harmark M.Pharm, M.Epi, Phd, MBA (appointed 22 April 2025)

PRINCIPAL ADDRESS

Drug Safety Research Unit
Bursledon Hall
Bursledon Lane
Bursledon
Southampton
SO31 1AA

REGISTERED CHARITY NUMBER

327206

INDEPENDENT AUDITORS

Cartwrights
Chartered Accountants and Business Advisors
Statutory Auditor
Regency House
33 Wood Street
Barnet
Hertfordshire
EN5 4BE

PROFESSIONAL ADVISERS

Solicitors
Paris Smith LLP
Number 1 London Road
Southampton
SO15 2AE

Investment advisers
Investec Wealth and Investment Limited
30 Gresham Street
London
EC2V 7QN

PRINCIPAL BANKERS

Lloyds Bank plc
92-94 Above Bar St
Southampton
SO14 7DT

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2024

The trustees present their report with the financial statements of the charity for the year ended 31 December 2024. The trustees have adopted the provisions of Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019).

Objectives and aims

Established in 1981, the Drug Safety Research Unit (DSRU) mission is to protect public health by studying the use and adverse effects of medicines and vaccines in real-world clinical use, working to the highest possible scientific standards. All of our work seeks to facilitate the health and wellbeing of patients by putting the interests of patients first and protecting people from the hazards of medicines.

To achieve this mission, the DSRU offer a range of observational studies to examine the safety of medicines, including new medicines, new formulations for existing medicines and when medicines are used for new indications or in new populations, or when safety issues or questions about the use, benefit-risk balance or effectiveness of medicines arise. In addition, the unit conducts utilisation studies for medicines and vaccines to enable understanding the use and effects of products on the healthcare system and behaviours and responses of patients and healthcare professionals.

The type of studies offered include CPRD studies, post-authorisation safety studies (PASS) in primary and secondary care, registries (including for the Early Access to Medicines Scheme, EAMS), European network studies, systematic reviews, drug utilization studies and benefit-risk assessments. It also offers services with regards to the design and implementation additional risk minimisation measures and to monitor their effectiveness.

In addition, DSRU seeks to contribute to the advancement of pharmacovigilance and pharmacoepidemiology by conducting methodological research, leading or participating in national and international research networks and scientific collaborative projects and by organising meetings and conferences to explore and develop new methods and innovations in pharmacovigilance and pharmacoepidemiology.

DSRU Consultancy provides advice on strategies, study designs and options for post-marketing pharmacovigilance, pharmacoepidemiology, risk minimisation and risk management planning for large and small pharmaceutical companies.

DSRU Education & Training is a leading European provider of training in pharmacovigilance, pharmacoepidemiology and risk management. Our portfolio of short courses can be used for one-off training, or as part of our postgraduate programme in Pharmacovigilance, leading to MSc.

OBJECTIVES AND ACTIVITIES

Objectives and aims

We continue to monitor developments in the UK relationship with the EU and make adjustments to our systems as appropriate to address relevant issues arising from these changes. In this regard the Trust has already opened a sub-office in Dublin to maintain and develop our links with the EU following the UK's severance of membership of the EU in 2020.

The Director keeps in regular contact with the Regulatory Agencies and our European colleagues to obtain information in order to shape our strategy and policy, particularly on matters related to the impact of Brexit on medicines regulations and medical research.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2024

OBJECTIVES AND ACTIVITIES

Significant activities

Research

The DSRU continues to function as one of the leading Units in the field of monitoring and studying the safety of medicines both in the UK and internationally, as well as being a leading organisation in teaching and training in these fields.

Progress of the scientific work of the Unit was satisfactory throughout 2024 and included post authorisation safety studies (PASS) (many of which use Clinical Practice Research Datalink (CPRD) data), systematic reviews, registries, structured benefit-risk evaluation, drug utilisation projects and methodological research. In addition, our programme of activities has included collaborating with a broad range of doctors in England through Health Research Networks from differing specialities as well as collaborating with colleagues in Europe. The policy to extend the range of scientific activities, as funding allows, will continue.

Applications for funding from bodies including grant-giving bodies, pharmaceutical companies and European initiatives, e.g., the European Commission, will continue.

The DSRU has a formal collaborative partnership programme agreement with the NHS Business Services Authority to receive prescription data that are necessary to conduct Modified Prescription-Event Monitoring studies to improve the understanding of the safety of new drugs used in the general population. This partnership has the support of the Department of Health and senior staff at NHS Business Services Authority.

Since application for Section 251 exemption of the NHS 2006 Act became a requirement, the Trust has applied annually to the Confidentiality Advisory Group (CAG) of the Health Research Authority for approval to use patient data without consent. In 2023 we were asked by the CAG to submit a refreshed Section 251 application as it had been 14 years since we obtained our approval. The application was submitted and continued approval was granted in 2024.

Education

The DSRU provides advice, education and training in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines. As one of the main providers of training and education in pharmacovigilance in Europe, its activities include:

- Providing a range of training courses in pharmacovigilance and pharmacoepidemiology. The DSRU currently provides 15 courses per year, as well as a Postgraduate Certificate, Diploma and a Master's degree in Pharmacovigilance in collaboration with University of Portsmouth and Pharmaceutical Medicine Specialty Training (PMST) for doctors specialising in pharmaceutical medicine in collaboration with the Faculty of Pharmaceutical Medicine.
- Providing external training and education when required.
- The DSRU is developing its postgraduate programme to be available via a distance learning route.
- Arranging national and international conferences in pharmacovigilance and pharmacoepidemiology.
- Providing postgraduate teaching and research opportunities at all levels including MSc.
- Providing training in pharmacovigilance and pharmacoepidemiology for pharmaceutical physicians.
- Supporting training and scientific communications on the safety of medicines in the UK and internationally.
- Providing advice on matters related to the safety of medicines.
- Producing newsletters and internet communications on matters to do with drug safety.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2024

OBJECTIVES AND ACTIVITIES

When required, reports on the results of studies are sent to the Medicines and Healthcare Products Regulatory Authority (MHRA) (an executive agency of the Department of Health) and to the European Medicines Agency (EMA) and other Regulatory Authorities in Europe to assist them in their regulatory and monitoring activities of medicines. The DSRU sends reports of its studies to Marketing Authorisation Holders of medicines and vaccines and also publishes findings of its work in scientific journals and at national and international conferences, newsletters and on its website.

Activities

The main objectives of the Unit for the next year are:

- Continuing with the core activities of the unit such as studies on the safety and utilisations of vaccines and medicinal products, benefit risk assessments and risk minimisation activities.
- Launch the postgraduate programme in pharmacovigilance as a distance learning programme.
- Develop a new business strategy for the coming years.
- Transition data analysis tools to keep up to date with the developments in the scientific world.
- To strengthen the organisational structure so the DSRU can fulfil its mission.
- To have increased attention for the organisational development so the DSRU is a place where employees can develop professionally and where they feel at home.
- Actively search for new business opportunities.
- To continue to try to secure sufficient funding from different sources (public and private) to enable the continuation of the charity's activities.
- Changing to a new platform for data capture.

Public benefit

The trustees confirm that the Charity Commission's general guidance on public benefit has been considered in relation to the objectives of the charity.

The objectives, activities, performance and achievement sections of this report clearly set out the activities which the charity undertakes for public benefit. The trustees confirm that they have complied with their duty in Section 4 of the Charities Act 2006 to have due regard to public benefits guidance published by the Charities Commission in determining the activities undertaken by the charity.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2024

ACHIEVEMENT AND PERFORMANCE

Charitable activities

The successful annual submission and subsequent approval and support of the Ethics and Confidentiality Committee of the Confidentiality Advisory Group (CAG) of the Health Research Authority for Section 251 exemption under the NHS Act 2006 was achieved for the fifteenth year running.

The Certificate, Diploma and Masters degree in Pharmacovigilance in collaboration with the University of Portsmouth continued, with 11 students enrolled at the end of the year.

Six scientific papers were published in medical literature. Nine abstracts/poster presentations on the results of studies were given by the Director and research staff at national and international medical and scientific conferences. One Vaccine Active Safety Surveillance study, one Disproportionality Analysis Study with Systematic Review and five Interim Reports were completed and delivered during 2024. In addition, the DSRU has provided pharmacovigilance consultancy support to pharmaceutical companies.

Education and Professional Capability

The educational training of staff has been maintained, including continuing professional development. In addition, the DSRU has provided advice on safety of medicines issues.

Teaching & Education

The Director taught at an MSc Course at Oxford University. The Head of Epidemiology and Research taught pharmacy students at the University of Portsmouth. In addition, teaching and presenting at national and international scientific meetings continued by both the Director and senior scientific staff enabling the scientific profile of the Unit and its work in public health and drug safety to be maintained.

Training Courses for Pharmaceutical Medicine Speciality Training

The DSRU continues to deliver teaching courses in pharmacovigilance, providing training on drug safety modules of Pharmaceutical Medicine Specialty Training (PMST), for pharmaceutical physicians on behalf of the Faculty of Pharmaceutical Medicine, Royal College of Physicians.

Partners and Stakeholders

Universities of Portsmouth

Collaborations with the University of Portsmouth on joint studentships and joint training continue.

Regulatory Agencies

Close links were maintained throughout the year with the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) with regular reports on safety issues submitted, contributing to the better understanding of the safety of a number of important medicinal products. The DSRU is a member of the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP), a project led by the European Medicines Agency and developed in collaboration with European experts in the fields of pharmacoepidemiology and pharmacovigilance. Senior staff of the DSRU regularly participate in meetings of the ENCePP network group.

VAC4EU

The DSRU is a member of VAC4EU which is a collaborative network of 46 units across Europe which conduct studies on the safety and effectiveness of vaccines. The network is led by Professor Miriam Sturkenboom (the University of Utrecht in the Netherlands). The DSRU is conducting seven studies on COVID-19 vaccines in collaboration with members of VAC4EU. The DSRU is using Clinical Practice Research Datalink (CPRD), the leading resource in the UK of primary care clinical data to conduct the studies on COVID-19 vaccines by AstraZeneca, Pfizer and Moderna, while our collaborators are using databases in a number of European countries. We continued to conduct work towards the final reports for VAC4EU COVID-19 vaccine studies relating to pregnancy and myocarditis/pericarditis for the Moderna and Pfizer vaccines.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2024

International scientific leadership collaboration

The DSRU is leading an International Working Group (IWG) for New Developments in Pharmacovigilance. The Group includes some of the best experts in the world in this field. The objective is to identify areas where contributions can be made to advance methods used in pharmacovigilance and pharmacoepidemiology. Such developments include artificial intelligence and machine learning, and the application of genetic knowledge in detecting and evaluating adverse drug reactions. The work has progressed well and the results of the first two workstreams are due to be published in 2025.

Investment performance

The trustees are satisfied that the current investment approach of the Trust is consistent with its investment needs, objectives and attitude to risk, which is to provide a balanced return on investment in the medium term with a moderate risk of capital loss.

The return on investment decreased from £67,032 to £66,907 in 2024.

FINANCIAL REVIEW

Financial position

The accounts have been prepared in accordance with the accounting policies set out in note 1 to the accounts and comply with the charity's Trust Deed, the Charities Act 1993 and the Statement of Recommended Practice, "Accounting and Reporting by Charities", issued in March 2005.

The Statement of Financial Activities for the year is set out on page 15 to these financial statements.

Principal funding sources

Principle funding sources come from donations received from pharmaceutical companies and other organisations in order to carry out charitable activities.

Whilst some costs are provided in advance by funders, the entitlement to income only arises when separately identifiable stages of the projects are completed. The charity monitors the progress of the projects closely and only includes the income and associated costs as and when these conditions are met. This treatment meets the charity's accounting policy regarding incoming resources as set out under accounting policy 1.2 in the notes to the financial statements..

Staffing costs (gross salaries plus employers' national insurance) in 2024 were £1,469,838 compared to £1,498,506 in 2023. Salaries still form the major part of the charity's expenses due to the specialist nature of employees, e.g., medical doctors and scientists needed to carry out the research activities. Total wage costs including national insurance and pension contributions therefore remain the highest expenditure for the Trust on a year-by-year basis.

The Chairman of Trustees and director maintained close scrutiny of incoming resources and expenditure during the year and kept the Board informed maintaining the same level of financial governance as in previous years.

Investment policy and objectives

The Trust has undertaken investment in equities and bonds through Rathbones (incorporating Investec Wealth & Investment Ltd). In order to monitor the investment portfolio performance, two trustees and the Director act as a sub-committee. This group, on behalf of the Board of Trustees, deals with all matters relating to the investment portfolio and meets with representatives of Rathbones (incorporating Investec Wealth & Investment Ltd) at appropriate intervals. It is the policy of the Board of Trustees that no investments in the pharmaceutical, armaments or tobacco industries should be undertaken.

Annually from a management perspective all other funds not immediately required from month to month for the normal running of the DSRU are routinely invested in fixed term deposit accounts to maximise return whenever possible.

The Trust's strategy to invest whenever possible to offset for leaner years when donations are reduced, will be maintained.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2024

FINANCIAL REVIEW

Reserves policy

It is the policy of the charity to maintain unrestricted funds, which are the free reserves of the charity. This provides sufficient funds to cover the cost of ongoing studies, management and administration costs. Considering expected fluctuations of future income, the financial reserves are necessary to maintain the future stability and viability of the DSRU. These reserves will be used when and if funds become too low to cover normal day to day activities. In these difficult economic times, the Trust is reaping the benefit of the prudent financial policy in the last decade. This approach will be continued in line with developments in the external economic environment.

Asset cover for funds

An analysis of the assets attributable to the various funds described is set out in the notes to these financial statements. These assets are sufficient to meet the charity's obligations on a fund by fund basis.

Going concern

The trustees consider the financial, operating and other risk factors when assessing whether there is any significant doubt over the Trust's ability to continue as a going concern.

During its 40 plus years, the Trust has established and followed a policy designed to ensure that, in the highly unlikely event of a significant drop in income, it has sufficient cash and cash equivalent reserves to enable it to continue its charitable activities for a period of at least 2 years. The trustees have considered the level of funds held and the expected level of income and expenditure for 12 months from authorising these financial statements. The budgeted income and expenditure is sufficient with the level of reserves for the charity to be able to continue as a going concern.

Since Brexit, there has been some uncertainty over the current regulatory environment and the impact this may have on the Trust's funding. The Trust is actively monitoring and planning for any changes, including repositioning itself to increase the number of studies being performed in the UK.

Because of the healthy level of "free reserves" and the operational steps taken to try and ensure that the Trust remains at the forefront of monitoring and research in the field of pharmacovigilance and pharmacoepidemiology, the trustees do not believe there is any such doubt and therefore believe it is appropriate to use the going concern basis of preparation in these financial statements.

FUTURE PLANS

Due to the new regulatory environment after Brexit the overall business strategy of the Unit will be reviewed and a new business strategy will be developed and implemented.

The Unit will continue to conduct a broad range of studies to address safety questions, including observational studies within our databases, pharmacoepidemiological studies using other data sources and a range of study designs, appropriate clinical trials, genetic studies, drug and vaccine utilisation studies, meta-analyses, systematic reviews, benefit-risk evaluations, other study methods to understand drugs and vaccines safety, effectiveness use and utilisation.

The DSRU will lead or participate in national and international collaborative projects that aim to improve the methods and advance the science of studying the safety of medicines. The DSRU will further develop its scientific communications programme to inform both the medical/scientific communities and the public about important pharmacovigilance issues.

The Unit will further develop its methods and capabilities in evidence-based pharmacovigilance and risk management and maintain its place as a leading Unit in providing advice, training and education in pharmacovigilance and drug safety.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2024

STRUCTURE, GOVERNANCE AND MANAGEMENT

Governing document

The Trust is governed by a charitable Trust Deed established on 23 July 1986 with a Board of Trustees five in number. The Mission of the Trust remains to monitor, study and communicate the safety of medicines independent from both Government and industry. The Trust by way of its operational unit, the Drug Safety Research Unit (DSRU), undertakes all forms of studies and evaluations on the safety of medicines. The DSRU provides advice, training and education in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines.

As an independent registered medical charity, its aim is to achieve the highest possible scientific and ethical standards by putting the interests of patients first and to work with integrity and fairness with all partners.

Recruitment and appointment of new trustees

As a charity specialising in drug safety, the trustees are identified for their expertise in areas which include drug regulation, epidemiology and medical statistics, experimental medicine and pharmacovigilance. Once appointed, the Trust ensures that any training required by the trustees is provided to enable them to fulfil their role.

Trustees of the charity

The trustees acknowledge their responsibilities as set out on the statement of trustees responsibilities.

The trustees who have served during the year and since the year end were as follows:

Professor Kenneth Ross Paterson MB ChB FRCP FFPM FBPhS (Chairman)
Professor John Camm QHP BSc MD FRCP FESC FACC FAHA FCGC CStJ
Professor Martin Vessey CBE MD FRCP FRCOG FRCGP FFPH FMedSci FRS
Professor Allan Hunter Young MB, ChB, MPhil, PhD, FRCPC, FRCPsychP
Professor Isla Mackenzie MB ChB PhD PGCertMedEd FRCP Edin FBPhS
FBIHS

There have been no changes to the trustees in the year nor to the date of signing of these financial statements.

Organisational structure

The Trust employs a Director, assisted by scientific, professional and administrative staff to conduct its day-to-day activities, ensuring that the charity's objectives are implemented. The Trust also retains the services of appropriate advisers and consultants depending upon the nature of the tasks required. During 2024 the average number of staff employed for the year was 26. In addition, 10 consultants were engaged, to advise and assist with additional medical/research input, IT and data protection, PR and planning matters.

Induction and training of new trustees

Induction is tailored to meet the needs of any new trustee and will be determined based on their own knowledge and experience. Where necessary, training is provided on charity, governance and financial matters.

Key management remuneration

The trustees, in conjunction with the director where appropriate, are responsible for setting the pay and remuneration of key management.

Drug Safety Research Trust

**Trustees' Report
for the Year Ended 31 December 2024**

STRUCTURE, GOVERNANCE AND MANAGEMENT

Risk management

The trustees have a duty to identify and review the risks to which the charity is exposed and to ensure appropriate controls are in place to provide reasonable assurance against fraud and error.

The trustees examine the major strategic, business and operational risks and confirm that systems are established to enable regular reports to be produced, so that necessary steps can be taken to control or lessen these risks. The variability of the funding of the Trust made it necessary to put in place processes to ensure that staff felt secure and motivated.

A Disaster Recovery Plan for the DSRU has been designed and completed. The plan is secured in off-site storage within a data safe.

Approved by order of the board of trustees on *20 MAY 2025* and signed on its behalf by:



.....
Professor K R Paterson MB ChB FRCP FFPM - Trustee

Drug Safety Research Trust

Statement of Trustees' Responsibilities for the Year Ended 31 December 2024

The trustees are responsible for preparing the Trustees' Report and the financial statements in accordance with applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice) including Financial Reporting Standard 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland".

The law applicable to charities in England and Wales, the Charities Act 2011, Charity (Accounts and Reports) Regulations 2008 and the provisions of the trust deed requires the trustees to prepare financial statements for each financial year which give a true and fair view of the state of affairs of the charity and of the incoming resources and application of resources, including the income and expenditure, of the charity for that period. In preparing those financial statements, the trustees are required to

- select suitable accounting policies and then apply them consistently;
- observe the methods and principles in the Charity SORP;
- make judgements and estimates that are reasonable and prudent;
- state whether applicable accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the charity will continue in business.

The trustees are responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the charity and to enable them to ensure that the financial statements comply with the Charities Act 2011, the Charity (Accounts and Reports) Regulations 2008 and the provisions of the trust deed. They are also responsible for safeguarding the assets of the charity and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Opinion

We have audited the financial statements of Drug Safety Research Trust (the 'charity') for the year ended 31 December 2024 which comprise the Statement of Financial Activities, the Statement of Financial Position, the Statement of Cash Flows and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice), including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'.

In our opinion the financial statements:

- give a true and fair view of the state of the charity's affairs as at 31 December 2024 and of its incoming resources and application of resources, for the year then ended;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice, including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'; and
- have been prepared in accordance with the requirements of the Charities Act 2011.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We are independent of the charity in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the trustees' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the charity's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the trustees with respect to going concern are described in the relevant sections of this report.

Other information

The trustees are responsible for the other information. The other information comprises the information included in the Annual Report, other than the financial statements and our Report of the Independent Auditors thereon.

Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Matters on which we are required to report by exception

We have nothing to report in respect of the following matters where the Charities (Accounts and Reports) Regulations 2008 requires us to report to you if, in our opinion:

- the information given in the trustees Report is inconsistent in any material respect with the financial statements; or
- sufficient accounting records have not been kept; or
- the financial statements are not in agreement with the accounting records and returns; or
- we have not received all the information and explanations we require for our audit.

**Report of the Independent Auditors to the Trustees of
Drug Safety Research Trust**

Responsibilities of trustees

As explained more fully in the Statement of Trustees' Responsibilities, the trustees are responsible for the preparation of the financial statements which give a true and fair view, and for such internal control as the trustees determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the trustees are responsible for assessing the charity's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the trustees either intend to liquidate the charity or to cease operations, or have no realistic alternative but to do so.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Our responsibilities for the audit of the financial statements

We have been appointed as auditors under Section 144 of the Charities Act 2011 and report in accordance with the Act and relevant regulations made or having effect thereunder.

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a Report of the Independent Auditors that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

The extent to which our procedures are capable of detecting irregularities, including fraud is detailed below:

We ensured that the engagement team collectively had the appropriate competence, capabilities and skills to identify or recognise non-compliance with applicable laws and regulations, and that they remained alert to instances of non-compliance throughout the audit.

Our approach to identifying and assessing the risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, was as follows:

- based on our understanding of the charity and sector, and through discussions with trustees and key management, we identified any specific laws and regulations which we considered may have a direct material effect on the financial statements or the operations of the charity, including the SORP 2015, Companies Act 2006, taxation legislation and data protection, anti-bribery, employment, environmental and health and safety legislation; and
- we assessed the extent of compliance with these laws and regulations through making enquiries of management and inspecting legal correspondence.

We assessed the susceptibility of the charity's financial statements to material misstatement, including obtaining an understanding of how fraud might occur, by:

- making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and
- considering the internal controls in place to mitigate risks of fraud and non-compliance with laws and regulations.

To address the risk of fraud through management bias and override of controls, we:

- performed analytical procedures to identify any unusual or unexpected relationships;
- tested journal entries, particularly focused around the year-end, to identify unusual transactions;
- assessed whether judgements and assumptions made in determining the accounting estimates in the notes to the financial statements were indicative of potential bias; and
- investigated the rationale behind significant or unusual transactions.

In response to the risk of irregularities and non-compliance with laws and regulations, we designed procedures which included, but were not limited to:

- agreeing financial statement disclosures to underlying supporting documentation;
- reading the minutes of meetings of those charged with governance;
- enquiring of management as to actual and potential litigation and claims; and
- reviewing correspondence with HMRC, relevant regulators and the charity's legal advisors.

There are inherent limitations in the audit procedures described above. We are less likely to become aware of instances of non-compliance with laws and regulations that are not closely related to events and transactions reflected in the financial statements. Also, the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at www.frc.org.uk/auditorsresponsibilities. This description forms part of our Report of the Independent Auditors.

**Report of the Independent Auditors to the Trustees of
Drug Safety Research Trust**

Use of our report

This report is made solely to the charity's trustees, as a body, in accordance with Part 4 of the Charities (Accounts and Reports) Regulations 2008. Our audit work has been undertaken so that we might state to the charity's trustees those matters we are required to state to them in an auditors' report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the charity and the charity's trustees as a body, for our audit work, for this report, or for the opinions we have formed.



Cartwrights
Chartered Accountants and Business Advisors
Statutory Auditor
Regency House
33 Wood Street
Barnet
Hertfordshire
EN5 4BE

Date:21/5/2025.....

Andrew Hill FCA (Senior Statutory Auditor) for and on behalf of Cartwrights

Drug Safety Research Trust

**Statement of Financial Activities
for the Year Ended 31 December 2024**

	Notes	Unrestricted funds £	Restricted fund £	31/12/24 Total funds £	31/12/23 Total funds £
INCOME AND ENDOWMENTS FROM					
Donations and legacies	2	704,584	-	704,584	1,665,967
Investment income	3	234,799	-	234,799	250,209
Other income	4	233,762	-	233,762	400,284
Total		<u>1,173,145</u>	<u>-</u>	<u>1,173,145</u>	<u>2,316,460</u>
EXPENDITURE ON					
Raising funds	5	24,633	-	24,633	22,956
Charitable activities	6				
Direct Charitable Expenditure		1,706,844	-	1,706,844	1,959,822
Other		728,144	18,780	746,924	705,798
Total		<u>2,459,621</u>	<u>18,780</u>	<u>2,478,401</u>	<u>2,688,576</u>
Net gains on investments		<u>113,703</u>	<u>-</u>	<u>113,703</u>	<u>78,475</u>
NET INCOME/(EXPENDITURE)		<u>(1,172,773)</u>	<u>(18,780)</u>	<u>(1,191,553)</u>	<u>(293,641)</u>
RECONCILIATION OF FUNDS					
Total funds brought forward		8,038,987	434,280	8,473,267	8,766,908
TOTAL FUNDS CARRIED FORWARD		<u><u>6,866,214</u></u>	<u><u>415,500</u></u>	<u><u>7,281,714</u></u>	<u><u>8,473,267</u></u>

The notes form part of these financial statements

Drug Safety Research Trust

**Statement of Financial Position
31 December 2024**

	Notes	Unrestricted funds £	Restricted fund £	31/12/24 Total funds £	31/12/23 Total funds £
FIXED ASSETS					
Tangible assets	11	44,204	415,500	459,704	480,674
Investments	12	4,311,066	-	4,311,066	4,066,828
		<u>4,355,270</u>	<u>415,500</u>	<u>4,770,770</u>	<u>4,547,502</u>
CURRENT ASSETS					
Debtors	13	500,400	-	500,400	1,211,314
Cash at bank		2,091,721	-	2,091,721	2,829,365
		<u>2,592,121</u>	<u>-</u>	<u>2,592,121</u>	<u>4,040,679</u>
CREDITORS					
Amounts falling due within one year	14	(81,177)	-	(81,177)	(114,914)
		<u>2,510,944</u>	<u>-</u>	<u>2,510,944</u>	<u>3,925,765</u>
NET CURRENT ASSETS					
		<u>6,866,214</u>	<u>415,500</u>	<u>7,281,714</u>	<u>8,473,267</u>
TOTAL ASSETS LESS CURRENT LIABILITIES					
		<u>6,866,214</u>	<u>415,500</u>	<u>7,281,714</u>	<u>8,473,267</u>
NET ASSETS					
		<u>6,866,214</u>	<u>415,500</u>	<u>7,281,714</u>	<u>8,473,267</u>
FUNDS					
	15			6,866,214	8,038,987
Unrestricted funds				415,500	434,280
Restricted funds				<u>7,281,714</u>	<u>8,473,267</u>
TOTAL FUNDS					

The financial statements were approved by the Board of Trustees and authorised for issue on 26 May 2025 and were signed on its behalf by:


K R Paterson MB ChB FRCP FFPM - Trustee

Drug Safety Research Trust

**Statement of Cash Flows
for the Year Ended 31 December 2024**

	Notes	31/12/24 £	31/12/23 £
Cash flows from operating activities			
Cash generated from operations	1	(902,420)	(1,571,029)
Net cash used in operating activities		<u>(902,420)</u>	<u>(1,571,029)</u>
Cash flows from investing activities			
Purchase of tangible fixed assets		(12,451)	(38,023)
Purchase of fixed asset investments		(130,535)	(156,434)
Sale of tangible fixed assets		1,109	-
Sale of fixed asset investments		113,703	78,475
Interest received		126,043	100,773
Dividends received		66,907	67,032
Net cash provided by investing activities		<u>164,776</u>	<u>51,823</u>
Change in cash and cash equivalents in the reporting period			
		<u>(737,644)</u>	<u>(1,519,206)</u>
Cash and cash equivalents at the beginning of the reporting period			
		<u>2,829,365</u>	<u>4,348,571</u>
Cash and cash equivalents at the end of the reporting period			
		<u><u>2,091,721</u></u>	<u><u>2,829,365</u></u>

The notes form part of these financial statements

Drug Safety Research Trust

**Notes to the Statement of Cash Flows
for the Year Ended 31 December 2024**

1. RECONCILIATION OF NET EXPENDITURE TO NET CASH FLOW FROM OPERATING ACTIVITIES

	31/12/24	31/12/23
	£	£
Net expenditure for the reporting period (as per the Statement of Financial Activities)	(1,191,553)	(293,641)
Adjustments for:		
Depreciation charges	31,669	30,389
Gain on investments	(227,406)	(156,950)
Interest received	(126,043)	(100,773)
Dividends received	(66,907)	(67,032)
Decrease/(increase) in debtors	711,557	(975,887)
Decrease in creditors	(33,737)	(7,135)
Net cash used in operations	<u>(902,420)</u>	<u>(1,571,029)</u>

2. ANALYSIS OF CHANGES IN NET FUNDS

	At 1/1/24	Cash flow	At 31/12/24
	£	£	£
Net cash			
Cash at bank	2,829,365	(737,644)	2,091,721
	<u>2,829,365</u>	<u>(737,644)</u>	<u>2,091,721</u>
Total	<u>2,829,365</u>	<u>(737,644)</u>	<u>2,091,721</u>

The notes form part of these financial statements

**Notes to the Financial Statements
for the Year Ended 31 December 2024**

1. ACCOUNTING POLICIES

Basis of preparing the financial statements

The financial statements of the charity, which is a public benefit entity under FRS 102, have been prepared in accordance with the Charities SORP (FRS 102) 'Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019)', Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland' and the Charities Act 2011. The financial statements have been prepared under the historical cost convention, with the exception of investments which are included at market value, as modified by the revaluation of certain assets.

Going concern

These financial statements are prepared on the going concern basis. The trustees have a reasonable expectation that the charity will continue in operational existence for the foreseeable future. The validity of this assumption depends on the continuing surplus in "free reserves". If the charity were unable to continue in existence for the foreseeable future, adjustments would be necessary to reduce the balance sheet values of assets to their recoverable amounts and to reclassify fixed assets as current assets.

Critical accounting judgements and key sources of estimation uncertainty

Judgements and estimates are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

Critical accounting estimates and assumptions

The charity makes estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results.

Property, plant and equipment - tangible fixed assets are depreciated over their useful lives taking into accounts residual value, where appropriate. The actual lives of the assets and residual values are assessed annually and may vary depending on a number of factors. Residual value assessments consider issues such as the remaining life of the asset and projected disposal values.

Recognition of income - income is recognised when receipt is probable and when the amount can be measured reliably. At the end of the financial year all ongoing studies are reviewed and accrued income estimated from the available information, based on the fulfilment of the study conditions and/or milestones.

Income

All income is recognised in the Statement of Financial Activities once the charity has entitlement to the funds, it is probable that the income will be received and the amount can be measured reliably.

For donations to be recognised the charity will have been notified of the amounts and the settlement date in writing. If there are conditions attached to the donation and this requires a level of performance before entitlement can be obtained then income is deferred until those conditions are fully met or the fulfilment of those conditions is within the control of the charity and it is probable that they will be fulfilled.

Investment income is earned through holding assets for investment purposes such as shares. It includes dividends, interest and unrealised gains or losses on shares held. Where it is not practicable to identify investment management costs incurred within a scheme with reasonable accuracy the investment income is reported net of these costs. It is included when the amount can be measured reliably. Interest income is recognised using the effective interest method and dividend income is recognised as the charity's right to receive payment is established.

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2024**

1. ACCOUNTING POLICIES - continued

Income

Other income represents management fees charged and donations received from the Trust's connected trading entity, DSRU Education and Research Limited. Management fees are included when charged and donations when received. Due to the connected nature of this entity, donation income is recorded within other income rather than within donations and legacy income in the Statement of Financial Activities.

Debtors are recognised when the charity is legally entitled to the income after any performance conditions have been met, the amount can be measured reliably and it is probable that the income will be received.

Expenditure

Liabilities are recognised as expenditure as soon as there is a legal or constructive obligation committing the charity to that expenditure, it is probable that a transfer of economic benefits will be required in settlement and the amount of the obligation can be measured reliably. Expenditure is accounted for on an accruals basis and has been classified under headings that aggregate all cost related to the category. Where costs cannot be directly attributed to particular headings they have been allocated to activities on a basis consistent with the use of resources.

Raising funds

Costs of raising funds represent investment manager costs incurred in dealing with the listed investment portfolio

Charitable activities

Expenditure on charitable activities includes the direct costs of carrying out and performing the studies and evaluations of medicines in order to meet the charity's objectives and aims.

Allocation and apportionment of costs

Support costs are those that assist the work of the charity but do not directly represent charitable activities and include office costs, governance costs, administrative payroll costs. They are incurred directly in support of expenditure on the objects of the charity. Where support costs cannot be directly attributed to particular headings they have been allocated to cost of raising funds and expenditure on charitable activities on a basis consistent with use of the resources.

Tangible fixed assets

Tangible fixed assets other than freehold land are stated at cost less depreciation. Depreciation is provided at rates calculated to write off the cost less estimated residual value of each asset over its expected useful life, as follow:

Freehold land	Not depreciated
Freehold buildings	2% Straight line on cost
Plant and machinery	20% straight line on cost
Fixtures, fittings and equipment	20% Straight line on cost
Motor vehicles	20% Straight line on cost

Taxation

The charity is an exempt charity within the meaning of schedule 3 of the Charities Act 2011 and is considered to pass the tests to ensure it is exempt from tax on its charitable activities.

Fund accounting

Unrestricted funds can be used in accordance with the charitable objectives at the discretion of the trustees.

Restricted funds can only be used for particular restricted purposes within the objects of the charity. Restrictions arise when specified by the donor or when funds are raised for particular restricted purposes.

Further explanation of the nature and purpose of each fund is included in the notes to the financial statements.

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2024**

1. ACCOUNTING POLICIES - continued

Foreign currencies

Assets and liabilities in foreign currencies are translated into sterling at the rates of exchange ruling at the statement of financial position date. Transactions in foreign currencies are translated into sterling at the rate of exchange ruling at the date of transaction. Exchange differences are taken into account in arriving at the operating result.

Pension costs and other post-retirement benefits

The charity operates a defined contribution pension scheme. Contributions payable to the charity's pension scheme are charged to the Statement of Financial Activities in the period to which they relate.

Donated goods

The charity does not receive any donated goods or gifts in kind.

Financial instruments

The charity only holds basic financial instruments as defined in FRS 102. The financial assets and financial liabilities of the charity and their measurement basis are as follows:

Financial assets

Fixed asset investments in publicly traded funds and shares are basic financial instruments and are measured at fair value with changes in fair value recognised in the Statement of Financial Activities.

Trade and other debtors are basic financial instruments and are debt instruments measured at amortised cost as detailed in the debtors note to these financial statements. Prepayments and accrued income are not financial instruments.

Cash at bank - is classified as a basic financial instrument and is measured at face value.

Financial liabilities

Trade creditors and other creditors are basic financial instruments, and are measured at amortised cost as detailed in the creditors note to these financial statements. Taxation and social security are not included in the financial instruments disclosure definition. Accruals and deferred income is not deemed to be a financial liability, as the cash settlement has already taken place and there is an obligation to deliver services rather than cash or another financial instrument.

Other balance sheet items

Cash at bank and in hand included cash and short term highly liquid investments with a short maturity of three months or less from the date of acquisition or opening of the deposit or similar account.

Provisions are recognised when the charity has an obligation at the reporting date as a result of a past event which it is probable will result in the transfer of economic benefits and the obligation can be estimated reliably. Provisions are measured at the best estimate of the amounts required to settle the obligation. Where the effect of the time value of money is material, the provision is based on the present value of those amounts, discounted at the pre-tax discount rate that reflects the risks specific to the liability. The unwinding of the discount is recognised within interest payable and similar charges.

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2024**

2. DONATIONS AND LEGACIES

	Unrestricted funds £	Restricted funds £	31/12/24 Total funds £	31/12/23 Total funds £
Donations	704,584	-	704,584	1,665,967

3. INVESTMENT INCOME

	Unrestricted funds £	Restricted funds £	31/12/24 Total funds £	31/12/23 Total funds £
Gain on disposal of investment	41,849	-	41,849	82,404
Listed income	66,907	-	66,907	67,032
Interest received	126,043	-	126,043	100,773
	<u>234,799</u>	<u>-</u>	<u>234,799</u>	<u>250,209</u>

4. OTHER INCOME

	Unrestricted funds £	Restricted funds £	31/12/24 Total funds £	31/12/23 Total funds £
Other income	233,762	-	233,762	400,284

5. RAISING FUNDS

Investment management costs

	Unrestricted funds £	Restricted funds £	31/12/24 Total funds £	31/12/23 Total funds £
Fund manager costs	24,633	-	24,633	22,956

6. CHARITABLE ACTIVITIES COSTS

	Direct Costs £
Direct Charitable Expenditure	<u>1,706,844</u>

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2024**

7. SUPPORT COSTS

	Governance costs
	£
Other resources expended	<u>746,924</u>

Support costs, included in the above, are as follows:

	31/12/24	31/12/23
	Other resources expended	Total activities
	£	£
Wages	178,021	167,640
Social security	150,351	150,333
Pensions	97,095	84,162
Auditors' remuneration	11,720	11,524
Rates and water	11,137	11,351
Insurance	22,780	21,952
Light and heat	26,079	23,719
Telephone and fax	4,612	6,052
PPS	765	1,754
Sundries	4,642	4,695
Repairs and maintenance	23,941	18,142
Staff medical costs	8,198	9,306
Motor and travel expenses	51,932	48,294
Computer costs	14,717	22,113
Subscriptions	62,363	37,623
Bank charges	(36)	1,277
Marketing costs	44,208	53,133
Equipment hire	2,730	2,339
Depreciation of tangible fixed assets	31,669	30,389
	<u>746,924</u>	<u>705,798</u>

8. AUDITORS' REMUNERATION

	31/12/24	31/12/23
	£	£
Fees payable to the charity's auditors for the audit of the charity's financial statements	<u>11,720</u>	<u>11,524</u>

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2024

9. TRUSTEES' REMUNERATION AND BENEFITS

There were no trustees' remuneration or other benefits for the year ended 31 December 2024 nor for the year ended 31 December 2023.

Trustees' expenses

Trustees indemnity insurance payable during the year amounted to £7,844 (2023: £7,323).

10. STAFF COSTS

The average number of employees during the year was 26 (2023 - 31).

The number of employees whose annual emoluments were £60,000 or more were:

	2024	2023
£230,001 - £300,000	1	1
£70,001 - £100,000	4	2
£60,001 - £70,000	2	3

11. TANGIBLE FIXED ASSETS

	Freehold property £	Plant and machinery £	Fixtures and fittings £	Computer system £	Totals £
COST					
At 1 January 2024	941,000	215,222	67,538	57,036	1,280,796
Additions	-	12,132	319	-	12,451
Disposals	-	(6,918)	-	-	(6,918)
	<u>941,000</u>	<u>220,436</u>	<u>67,857</u>	<u>57,036</u>	<u>1,286,329</u>
At 31 December 2024	941,000	220,436	67,857	57,036	1,286,329
DEPRECIATION					
At 1 January 2024	506,720	171,373	64,993	57,036	800,122
Charge for year	18,780	12,142	1,390	-	32,312
Eliminated on disposal	-	(5,809)	-	-	(5,809)
	<u>525,500</u>	<u>177,706</u>	<u>66,383</u>	<u>57,036</u>	<u>826,625</u>
At 31 December 2024	525,500	177,706	66,383	57,036	826,625
NET BOOK VALUE					
At 31 December 2024	<u>415,500</u>	<u>42,730</u>	<u>1,474</u>	<u>-</u>	<u>459,704</u>
At 31 December 2023	<u>434,280</u>	<u>43,849</u>	<u>2,545</u>	<u>-</u>	<u>480,674</u>

The freehold property was last revalued on 20 December 1999 by Messrs Daniells Harison, Chartered Surveyors, on the basis of open market value for current use. The freehold land and buildings valuation has not been updated since 1999. Under the transitional relief provisions under FRS 102, this value has been treated as the deemed cost in these financial statements. The estimated market value per the charity as at the balance sheet date, is in excess of £4 million.

Comparable historical cost for the land and buildings included at valuation:

	2024 £	2023 £
Cost	1,487,614	1,487,614
Accumulated Depreciation	<u>525,000</u>	<u>506,720</u>
At year end	<u>962,614</u>	<u>980,894</u>

Drug Safety Research Trust

**Detailed Statement of Financial Activities
for the Year Ended 31 December 2024**

	31/12/24 £	31/12/23 £
INCOME AND ENDOWMENTS		
Donations and legacies		
Donations	704,584	1,665,967
Investment income		
Gain on disposal of investment	41,849	82,404
Listed income	66,907	67,032
Interest received	126,043	100,773
	<hr/>	<hr/>
	234,799	250,209
Other income		
Other income	233,762	400,284
	<hr/>	<hr/>
Total incoming resources	1,173,145	2,316,460
EXPENDITURE		
Investment management costs		
Fund manager costs	24,633	22,956
Charitable activities		
Wages - direct	1,141,466	1,180,533
General Practitioner costs	109,683	44,627
Other direct costs	455,695	734,662
	<hr/>	<hr/>
	1,706,844	1,959,822
Support costs		
Governance costs		
Wages	178,021	167,640
Social security	150,351	150,333
Pensions	97,095	84,162
Auditors' remuneration	11,720	11,524
Rates and water	11,137	11,351
Insurance	22,780	21,952
Light and heat	26,079	23,719
Telephone and fax	4,612	6,052
PPS	765	1,754
Sundries	4,642	4,695
Repairs and maintenance	23,941	18,142
Staff medical costs	8,198	9,306
Motor and travel expenses	51,932	48,294
Computer costs	14,717	22,113
Subscriptions	62,363	37,623
Carried forward	668,353	618,660

This page does not form part of the statutory financial statements

Drug Safety Research Trust**Detailed Statement of Financial Activities
for the Year Ended 31 December 2024**

	31/12/24	31/12/23
	£	£
Governance costs		
Brought forward	668,353	618,660
Bank charges	(36)	1,277
Marketing costs	44,208	53,133
Equipment hire	2,730	2,339
Depreciation of tangible fixed assets	31,669	30,389
	<u>746,924</u>	<u>705,798</u>
Total resources expended	2,478,401	2,688,576
Net expenditure before gains and losses	(1,305,256)	(372,116)
Net losses on investments		
Net gains / losses on investments	113,703	78,475
	<u>(1,191,553)</u>	<u>(293,641)</u>

This page does not form part of the statutory financial statements

THE DRUG SAFETY RESEARCH TRUST

England & Wales - Charity number 327206

Accounts

**Trustees' Report and
Audited Financial Statements for the Year Ended 31 December 2023
for
Drug Safety Research Trust**

Drug Safety Research Trust

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Drug Safety Research Trust

Reference and Administrative Details for the Year Ended 31 December 2023

TRUSTEES

Professor Kenneth Ross Paterson MB ChB FRCP FFPM FBPhS (Chairman)
Professor John Camm QHP BSc MD FRCP FESC FACC FAHA FCGC CStJ
Professor Martin Vessey CBE MD FRCP FRCOG FRCGP FFPH FMedSci FRS
Professor Allan Hunter Young MB, ChB, MPhil, PhD, FRCPC, FRCPsych
Professor Isla Mackenzie MB ChB PhD PGCertMedEd FRCP Edin FBPhS FBIHS

DIRECTOR

Professor Saad Shakir MB ChB LRCP&S FRCP FFPM FISPE MRCGP

PRINCIPAL ADDRESS

Drug Safety Research Unit
Bursledon Hall
Bursledon Lane
Bursledon
Southampton
SO31 1AA

REGISTERED CHARITY NUMBER 327206

INDEPENDENT AUDITORS

Cartwrights
Chartered Accountants and Business Advisors
Statutory Auditor
Regency House
33 Wood Street
Barnet
Hertfordshire
EN5 4BE

PROFESSIONAL ADVISERS

Solicitors
Paris Smith LLP
Number 1 London Road
Southampton
SO15 2AE

Investment advisers
Investec Wealth and Investment Limited
30 Gresham Street
London
EC2V 7QN

PRINCIPAL BANKERS

Lloyds Bank plc
92-94 Above Bar St
Southampton
SO14 7DT

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2023

The trustees present their report with the financial statements of the charity for the year ended 31 December 2023. The trustees have adopted the provisions of Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019).

Objectives and aims

The Trust by way of its operational unit, the DSRU, undertakes all forms of studies and evaluations of the safety of medicines for the public benefit, including methodological research to improve existing methods including:

- Studies to examine the safety of medicines, including new medicines, new formulations for existing medicines and when medicines are used for new indications or in new populations, or when safety issues or questions about the use, benefit-risk balance or effectiveness of medicines arise. Frequently such DSRU studies are part of risk management plans for medicines which are now statutory requirements in the EU.
- Studies on established medicines when safety, scientific, utilisation or regulatory issues, questions, enquiries or needs for submissions arise. The issues include risk management & minimisation and methodological questions. The studies can be part of the UK and the EU regulatory requirements for risk management of medicines, though not exclusively.
- Conducting studies to address specific safety, public health, scientific, benefit-risk balance of medicines and vaccines, utilisation and usage and regulatory issues or concerns.
- Conducting utilisation studies for medicines and vaccines to enable understanding the use and effects of products on the healthcare system and behaviours and responses of patients and healthcare professionals.
- Use of healthcare databases to conduct drug safety studies.
- Establishing registries to conduct safety and utilisation studies.
- Working with doctors to undertake studies to examine specific safety questions and medical health research networks.
- Exploring the application of new methods such as clinical trials or database research, as well as other appropriate research methods, to understand the safety of medicines.
- Conducting methodological research in pharmacovigilance and pharmacoepidemiology.
- Conducting studies and other scientific activities such as organising meetings and conferences to explore and develop new methods and innovations in pharmacovigilance and pharmacoepidemiology.
- Undertaking reviews, systematic reviews, meta-analyses or benefit-risk studies to answer drug safety and drug utilisation questions.
- Establishing research entities for studying and communicating methodological issues in pharmacovigilance and pharmacoepidemiology and drug safety issues
- Leading or participating in national and international research networks and scientific collaborative projects.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2023

OBJECTIVES AND ACTIVITIES

Objectives and aims

We continue to monitor developments in the UK relationship with the EU and make adjustments to our systems as appropriate to address relevant issues arising from these changes. In this regard the Trust has already opened a sub-office in Dublin to maintain and develop our links with the EU following the UK's severance of membership of the EU in 2020.

The Director keeps in regular contact with the Regulatory Agencies and our European colleagues to obtain information in order to shape our strategy and policy, particularly on matters related to the impact of Brexit on medicines regulations and medical research.

Significant activities

The DSRU provides advice, education and training in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines. As one of the main providers of training and education in pharmacovigilance in Europe, its activities include:

- Providing a range of training courses in pharmacovigilance and pharmacoepidemiology. The DSRU currently provides 15 courses per year, including academically endorsed higher education in collaboration with University of Portsmouth for Postgraduate Certificate, Diploma and a Master's degree in Pharmacovigilance and with the Faculty of Pharmaceutical Medicine for providing Pharmaceutical Medicine Specialty Training (PMST) for doctors specialising in pharmaceutical medicine.
- Providing external training and education when required.
- Keeping up with technological progress the DSRU intends to periodically evaluate options such as providing distance learning and other internet based educational methods.
- Arranging national and international conferences in pharmacovigilance and pharmacoepidemiology.
- Providing postgraduate teaching and research opportunities at all levels including MSc and PhD students.
- Supporting postgraduate students who wish to undertake research at the DSRU.
- Providing training in pharmacovigilance and pharmacoepidemiology for pharmaceutical physicians. The DSRU has been selected by the Faculty of Pharmaceutical Medicine to provide Pharmaceutical Medicine Specialty Training (PMST) training in pharmacovigilance in the UK.
- Supporting training and scientific communications on the safety of medicines in the UK and internationally.
- Providing advice on matters related to the safety of medicines.
- Producing newsletters and internet communications to general practitioners on matters to do with drug safety.
- Providing information on drug safety which can be accessed by everyone on the DSRU website.

Routinely, reports on the results of studies are sent to the Medicines and Healthcare Products Regulatory Authority (MHRA) (an executive agency of the Department of Health) and to the European Medicines Agency (EMA) and other Regulatory Authorities in Europe to assist them in their regulatory and monitoring activities of medicines. The DSRU sends reports of its studies to Marketing Authorisation Holders of medicines and vaccines and also publishes findings of its work in scientific journals and at national and international conferences, newsletters and on its website.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2023

OBJECTIVES AND ACTIVITIES

Significant activities

Progress of the scientific work of the Unit was satisfactory throughout 2023 extending the breadth of activity to include research projects and collaborations other than Modified Prescription-Event Monitoring (MPEM). These include specialist and hospital-based studies (SCEMs), systematic reviews, registries, structured benefit-risk evaluation, drug utilisation projects and methodological research. In addition, our programme of activities has extended to include collaborating with a broad range of doctors in England through Health Research Networks from differing specialities as well as collaborating with colleagues in Europe. The policy to extend the range of scientific activities, as funding allows, will continue.

Applications for funding from grant-giving bodies, including the Department of Health Targeted Research Programme and other bodies such as the Medical Research Council (MRC), the Wellcome Trust, pharmaceutical companies and European initiatives, e.g., the European Commission, will continue as and when calls are advertised. The DSRU continues to function as one of the leading Units in the field of monitoring and studying the safety of medicines both in the UK and internationally, as well as being a leading organisation in teaching and training in these fields.

The DSRU has a long-standing partnership with the NHS Rx Services to receive prescription data that are necessary to conduct Modified Prescription-Event Monitoring studies to improve the understanding of the safety of new drugs used in the general population. This partnership has the support of the Department of Health and senior staff at NHS Rx Services.

Since application for Section 251 exemption of the NHS 2006 Act became a requirement, the Trust has applied annually to the Confidentiality Advisory Group (CAG) of the Health Research Authority for approval to use patient data without consent. In 2023 we were asked by the CAG to submit a refreshed Section 251 application as it had been 14 years since we obtained our approval. The application was submitted and has been successful.

The formal collaborative partnership programme agreement, required to develop the partnership with the NHS Rx Services, to supply improved prescription data is in place and we continue to maintain good communications. In the unlikely situation that the DSRU ceases to receive data for whatever reason from the NHS Rx Services, the DSRU is committed to continue its work on studying the safety of medicines by other methods and providing education and training in pharmacovigilance and drug safety.

The main objectives of the Unit for the next year are:

- To continue the monitoring and research programme on the safety and risk management of vaccines and medicinal products for the treatment COVID-19.
- To undertake all forms of studies and evaluations of the safety and benefit-risk of medicines and vaccines alone or in collaboration with other organisations.
- To plan and support organisations to implement risk minimisation measures for medicines and vaccines and monitor the effectiveness of these measures.
- To use its studies to support risk management, risk minimisation and monitoring the effectiveness of risk minimisation and utilisation of medicines and vaccines.
- To conduct studies to understand drug safety issues, undertake methodological research, and explore and conduct studies on new methodologies and innovations.
- To conduct studies to understand the utilisation (use) and effects of medicines and vaccines.
- To continue its scientific work in methodological aspects of drug safety including leading or participating in national and international collaborative projects.
- To continue its activities in advice, education and training in pharmacovigilance and pharmacoepidemiology.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2023

OBJECTIVES AND ACTIVITIES

- To consolidate its scientific communications programme such as the DSRU blogs to inform both the medical/scientific communities and the public about important pharmacovigilance issues.
- To continue to try to secure sufficient funding from different sources (public and private) to enable the continuation and growth of the charity's activities.

Public benefit

The trustees confirm that the Charity Commission's general guidance on public benefit has been considered in relation to the objectives of the charity.

The objectives, activities, performance and achievement sections of this report clearly set out the activities which the charity undertakes for public benefit. The trustees confirm that they have complied with their duty in Section 4 of the Charities Act 2006 to have due regard to public benefits guidance published by the Charities Commission in determining the activities undertaken by the charity.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2023

ACHIEVEMENT AND PERFORMANCE

Charitable activities

The successful annual submission and subsequent approval and support of the Ethics and Confidentiality Committee of the Confidentiality Advisory Group (CAG) of the Health Research Authority for Section 251 exemption under the NHS Act 2006 was achieved for the fourteenth year running.

The academically endorsed higher educational training in collaboration with the University of Portsmouth for Certificate, Diploma and Masters degree in Pharmacovigilance continued, with 20 students currently enrolled at the end of the year.

Four scientific papers were published in medical literature. Twelve abstracts/poster presentations on the results of studies were given by the Director and research staff at national and international medical and scientific conferences. One Vaccine Active Safety Surveillance study, one Pharmacy Survey Report and two Interim Reports were completed and delivered during 2023 as well as the provision of pharmacovigilance consultancy support to pharmaceutical companies.

Education and Professional Capability

The educational training of staff has been maintained, including continuing professional development. In addition, the DSRU has provided advice on safety of medicines issues.

Teaching & Education

The director taught at an MSc Course at Oxford University. In addition, teaching and presenting at national and international scientific meetings continued by both the director and senior scientific staff enabling the scientific profile of the Unit and its work in public health and drug safety to be maintained.

The DSRU and staff at the DSRU have provided training for general practitioners on effective and safe prescribing of medicines.

Training Courses for Pharmaceutical Medicine Speciality Training

The DSRU continues to deliver teaching courses in pharmacovigilance, providing training on drug safety modules of Pharmaceutical Medicine Specialty Training (PMST), for pharmaceutical physicians on behalf of the Faculty of Pharmaceutical Medicine, Royal College of Physicians. One student attended these modules during the year.

Partners and Stakeholders

Universities of Portsmouth

Collaborations with the University of Portsmouth on joint studentships and joint training continue.

Regulatory Agencies

Close links were maintained throughout the year with the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) with regular reports on safety issues submitted, contributing to the better understanding of the safety of a number of important medicinal products. The DSRU is a member of the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP), a project led by the European Medicines Agency and developed in collaboration with European experts in the fields of pharmacoepidemiology and pharmacovigilance. Senior staff of the DSRU regularly participate in meetings of the ENCePP network group.

VAC4EU

The DSRU is a member of VAC4EU which is a collaborative network of 46 units across Europe which conduct studies on the safety and effectiveness of vaccines. The network is led by Professor Miriam Sturkenboom (the University of Utrecht in the Netherlands). The DSRU is conducting three studies on COVID-19 vaccines in collaboration with members of VAC4EU. The DSRU is using Clinical Practice Research Datalink (CPRD), the leading resource in the UK of primary care clinical data to conduct the studies on COVID-19 vaccines by AstraZeneca, Pfizer and Moderna, while our collaborators are using databases in a number of European countries. In addition to the main PASS studies, we are also conducting work towards the final reports for another three separate VAC4EU COVID-19 vaccine studies relating to Pregnancy and myocarditis/pericarditis for AstraZeneca, Moderna and Pfizer.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2023

International scientific leadership collaboration

The DSRU is leading an International Working Group (IWG) for New Developments in Pharmacovigilance. The Group includes some of the best experts in the world in this field. The objective is to examine the impact of new developments in biomedical sciences on signal detection and management in pharmacovigilance. Such developments include artificial intelligence and machine thinking, the use of big data and the application of genetic knowledge in detecting and evaluating adverse drug reactions. The work of the IWG was interrupted for nearly two years because of the COVID-19 pandemic but the group re-started in October 2022 and has made good progress in its activities with broader objectives which are to address new developments in pharmacovigilance and pharmacoepidemiology.

Investment performance

The trustees are satisfied that the current investment approach of the Trust is consistent with its investment needs, objectives and attitude to risk, which is to provide a balanced return on investment in the medium term with a moderate risk of capital loss.

The return on investment increased from £63,666 in 2022 to £67,032 in 2023.

FINANCIAL REVIEW

Financial position

The accounts have been prepared in accordance with the accounting policies set out in note 1 to the accounts and comply with the charity's Trust Deed, the Charities Act 1993 and the Statement of Recommended Practice, "Accounting and Reporting by Charities", issued in March 2005.

The Statement of Financial Activities for the year is set out on page 16 to these financial statements.

Principal funding sources

Principal funding sources come from donations received from pharmaceutical companies and other organisations in order to carry out charitable activities.

Whilst some costs are provided in advance by funders, the entitlement to income only arises when separately identifiable stages of the projects are completed. The charity monitors the progress of the projects closely and only includes the income and associated costs as and when these conditions are met. This treatment meets the charity's accounting policy regarding incoming resources as set out under accounting policy 1.2 in the notes to the financial statements..

Staffing costs in 2023 were £1,498,506 compared to £1,485,552 in 2022. Salaries still form the major part of the charity's expenses due to the specialist nature of employees, e.g., medical doctors and scientists needed to carry out the research activities. Total wage costs including national insurance and pension contributions therefore remain the highest expenditure for the Trust on a year-by-year basis.

The Chairman of Trustees and director maintained close scrutiny of incoming resources and expenditure during the year and kept the Board informed maintaining the same level of financial governance as in previous years.

Investment policy and objectives

The Trust has undertaken investment in equities and bonds through Investec Wealth & Investment Ltd. In order to monitor the investment portfolio performance, two trustees and the director act as a sub-committee. This group, on behalf of the Board of Trustees, deals with all matters relating to the investment portfolio and meets with representatives of Investec Wealth & Investment Ltd at appropriate intervals. It is the policy of the Board of Trustees that no investments in the pharmaceutical, armaments or tobacco industries should be undertaken.

Annually from a management perspective all other funds not immediately required from month to month for the normal running of the DSRU are routinely invested in fixed term deposit accounts to maximise return whenever possible.

The Trust's strategy to invest whenever possible to offset for leaner years when donations are reduced, will be maintained.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2023

FINANCIAL REVIEW

Reserves policy

It is the policy of the charity to maintain unrestricted funds, which are the free reserves of the charity. This provides sufficient funds to cover the cost of ongoing studies, management and administration costs. Considering expected fluctuations of future income, the financial reserves are necessary to maintain the future stability and viability of the DSRU. These reserves will be used when and if funds become too low to cover normal day to day activities. In these difficult economic times, the Trust is reaping the benefit of the prudent financial policy in the last decade. This approach will be continued in line with developments in the external economic environment.

Asset cover for funds

An analysis of the assets attributable to the various funds described is set out in the notes to these financial statements. These assets are sufficient to meet the charity's obligations on a fund by fund basis.

Going concern

The trustees consider the financial, operating and other risk factors when assessing whether there is any significant doubt over the Trust's ability to continue as a going concern.

During its 40 plus years, the Trust has established and followed a policy designed to ensure that, in the highly unlikely event of a significant drop in income, it has sufficient cash and cash equivalent reserves to enable it to continue its charitable activities for a period of at least 2 years. The trustees have considered the level of funds held and the expected level of income and expenditure for 12 months from authorising these financial statements. The budgeted income and expenditure is sufficient with the level of reserves for the charity to be able to continue as a going concern.

Since Brexit, there has been some uncertainty over the current regulatory environment and the impact this may have on the Trust's funding. The Trust is actively monitoring and planning for any changes, including repositioning itself to increase the number of studies being performed in the UK. The Trust is also looking to move a currently dormant trading subsidiary from Ireland to the Netherlands to maintain a closer presence to the pharmaceutical presence in that country.

Because of the healthy level of "free reserves" and the operational steps taken to try and ensure that the Trust remains at the forefront of monitoring and research in the field of pharmacovigilance and pharmacoepidemiology, the trustees do not believe there is any such doubt and therefore believe it is appropriate to use the going concern basis of preparation in these financial statements.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2023

FUTURE PLANS

The overall strategy remains the same. As in previous years the DSRU will endeavour to ensure the preservation of Modified Prescription-Event Monitoring (MPEM) as a leading system to monitor the safety of medicines in the UK and to enhance and develop it.

The Unit will continue to conduct a broad range of studies to address safety questions, including observational studies within our databases, pharmacoepidemiological studies using other data sources and a range of study designs, appropriate clinical trials, genetic studies, drug and vaccine utilisation studies, meta-analyses, systematic reviews, benefit-risk evaluations, other study methods to understand drugs and vaccines safety, effectiveness use and utilisation. The DSRU will conduct methodological research to contribute to advance the science and methods of Pharmacovigilance. These are part of the DSRU's objective to explore conducting studies with different methods, including using a range of data sources and innovations that enable it to achieve its objective to monitor and study the safety of medicines. The DSRU will continue its recent successful expansion to conduct safety studies in secondary care as well as in primary care using appropriate and improved methods to answer the relevant safety questions.

The DSRU will lead or participate in national and international collaborative projects that aim to improve the methods and advance the science of studying the safety of medicines. The DSRU will further develop its scientific communications programme to inform both the medical/scientific communities and the public about important pharmacovigilance issues.

The DSRU continues to monitor IT and other developments in the NHS and elsewhere to ensure that it benefits from the opportunities provided by these developments. The Unit will further develop its methods and capabilities in evidence-based pharmacovigilance and risk management and maintain its place as a leading Unit in providing advice, training and education in pharmacovigilance and drug safety. The DSRU will try to review and improve where necessary its systems such as its IT database.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Governing document

The Trust is governed by a charitable Trust Deed established on 23 July 1986 with a Board of Trustees five in number. The Mission of the Trust remains to monitor, study and communicate the safety of medicines independent from both Government and industry. The Trust by way of its operational unit, the Drug Safety Research Unit (DSRU), undertakes all forms of studies and evaluations on the safety of medicines. The DSRU provides advice, training and education in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines.

As an independent registered medical charity, its aim is to achieve the highest possible scientific and ethical standards by putting the interests of patients first and to work with integrity and fairness with all partners.

Recruitment and appointment of new trustees

As a charity specialising in drug safety, the trustees are identified for their expertise in areas which include drug regulation, epidemiology and medical statistics, experimental medicine and pharmacovigilance. Once appointed, the Trust ensures that any training required by the trustees is provided to enable them to fulfil their role.

Trustees of the charity

The trustees acknowledge their responsibilities as set out on the statement of trustees responsibilities.

The trustees who have served during the year and since the year end were as follows:

Professor Kenneth Ross Paterson MB ChB FRCP FFPM FBPhS (Chairman)
Professor John Camm QHP BSc MD FRCP FESC FACC FAHA FCGC CStJ
Professor Martin Vessey CBE MD FRCP FRCOG FRCGP FFPH FMedSci FRS
Professor Allan Hunter Young MB, ChB, MPhil, PhD, FRCPC, FRCPsychP
Professor Isla Mackenzie MB ChB PhD PGCertMedEd FRCP Edin FBPhS FBIHS

There have been no changes to the trustees in the year nor to the date of signing of these financial statements.

Drug Safety Research Trust

**Trustees' Report
for the Year Ended 31 December 2023**

STRUCTURE, GOVERNANCE AND MANAGEMENT

Organisational structure

The Trust employs a Director, Professor Saad Shakir, assisted by scientific, professional and administrative staff to conduct its day-to-day activities, ensuring that the charity's objectives are implemented. The Trust also retains the services of appropriate advisers and consultants depending upon the nature of the tasks required. During 2023 the average number of staff employed for the year was 30. In addition, sixteen consultants were engaged, to advise and assist with additional medical/research input, IT and data protection, PR and planning matters.

Induction and training of new trustees

Induction is tailored to meet the needs of any new trustee and will be determined based on their own knowledge and experience. Where necessary, training is provided on charity, governance and financial matters.

Key management remuneration

The trustees, in conjunction with the director where appropriate, are responsible for setting the pay and remuneration of key management.

Risk management

The trustees have a duty to identify and review the risks to which the charity is exposed and to ensure appropriate controls are in place to provide reasonable assurance against fraud and error.

The trustees examine the major strategic, business and operational risks and confirm that systems are established to enable regular reports to be produced, so that necessary steps can be taken to control or lessen these risks. The variability of the funding of the Trust made it necessary to put in place processes to ensure that staff felt secure and motivated.

A Disaster Recovery Plan for the DSRU has been designed and completed. The plan is secured in off-site storage within a data safe.

EVENTS SINCE THE END OF THE YEAR

Information relating to events since the end of the year is given in the notes to the financial statements.

Approved by order of the board of trustees on and signed on its behalf by:

.....
Professor K R Paterson MB ChB FRCP FFPM - Trustee

Drug Safety Research Trust

Statement of Trustees' Responsibilities for the Year Ended 31 December 2023

The trustees are responsible for preparing the Trustees' Report and the financial statements in accordance with applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice) including Financial Reporting Standard 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland".

The law applicable to charities in England and Wales, the Charities Act 2011, Charity (Accounts and Reports) Regulations 2008 and the provisions of the trust deed requires the trustees to prepare financial statements for each financial year which give a true and fair view of the state of affairs of the charity and of the incoming resources and application of resources, including the income and expenditure, of the charity for that period. In preparing those financial statements, the trustees are required to

- select suitable accounting policies and then apply them consistently;
- observe the methods and principles in the Charity SORP;
- make judgements and estimates that are reasonable and prudent;
- state whether applicable accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the charity will continue in business.

The trustees are responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the charity and to enable them to ensure that the financial statements comply with the Charities Act 2011, the Charity (Accounts and Reports) Regulations 2008 and the provisions of the trust deed. They are also responsible for safeguarding the assets of the charity and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Opinion

We have audited the financial statements of Drug Safety Research Trust (the 'charity') for the year ended 31 December 2023 which comprise the Statement of Financial Activities, the Statement of Financial Position, the Statement of Cash Flows and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice), including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'.

In our opinion the financial statements:

- give a true and fair view of the state of the charity's affairs as at 31 December 2023 and of its incoming resources and application of resources, for the year then ended;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice, including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'; and
- have been prepared in accordance with the requirements of the Charities Act 2011.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We are independent of the charity in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the trustees' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the charity's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the trustees with respect to going concern are described in the relevant sections of this report.

Other information

The trustees are responsible for the other information. The other information comprises the information included in the Annual Report, other than the financial statements and our Report of the Independent Auditors thereon.

Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Matters on which we are required to report by exception

We have nothing to report in respect of the following matters where the Charities (Accounts and Reports) Regulations 2008 requires us to report to you if, in our opinion:

- the information given in the trustees Report is inconsistent in any material respect with the financial statements; or
- sufficient accounting records have not been kept; or
- the financial statements are not in agreement with the accounting records and returns; or
- we have not received all the information and explanations we require for our audit.

**Report of the Independent Auditors to the Trustees of
Drug Safety Research Trust**

Responsibilities of trustees

As explained more fully in the Statement of Trustees' Responsibilities, the trustees are responsible for the preparation of the financial statements which give a true and fair view, and for such internal control as the trustees determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the trustees are responsible for assessing the charity's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the trustees either intend to liquidate the charity or to cease operations, or have no realistic alternative but to do so.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Our responsibilities for the audit of the financial statements

We have been appointed as auditors under Section 144 of the Charities Act 2011 and report in accordance with the Act and relevant regulations made or having effect thereunder.

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a Report of the Independent Auditors that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

We ensured that the engagement team collectively had the appropriate competence, capabilities and skills to identify or recognise non-compliance with applicable laws and regulations, and that they remained alert to instances of non-compliance throughout the audit.

Our approach to identifying and assessing the risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, was as follows:

- based on our understanding of the charity and sector, and through discussions with trustees and key management, we identified any specific laws and regulations which we considered may have a direct material effect on the financial statements or the operations of the charity, including the SORP 2015, Companies Act 2006, taxation legislation and data protection, anti-bribery, employment, environmental and health and safety legislation; and
- we assessed the extent of compliance with these laws and regulations through making enquiries of management and inspecting legal correspondence.

We assessed the susceptibility of the charity's financial statements to material misstatement, including obtaining an understanding of how fraud might occur, by:

- making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and
- considering the internal controls in place to mitigate risks of fraud and non-compliance with laws and regulations.

To address the risk of fraud through management bias and override of controls, we:

- performed analytical procedures to identify any unusual or unexpected relationships;
- tested journal entries, particularly focused around the year-end, to identify unusual transactions;
- assessed whether judgements and assumptions made in determining the accounting estimates in the notes to the financial statements were indicative of potential bias; and
- investigated the rationale behind significant or unusual transactions.

In response to the risk of irregularities and non-compliance with laws and regulations, we designed procedures which included, but were not limited to:

- agreeing financial statement disclosures to underlying supporting documentation;
- reading the minutes of meetings of those charged with governance;
- enquiring of management as to actual and potential litigation and claims; and
- reviewing correspondence with HMRC, relevant regulators and the charity's legal advisors.

There are inherent limitations in the audit procedures described above. We are less likely to become aware of instances of non-compliance with laws and regulations that are not closely related to events and transactions reflected in the financial statements. Also, the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at www.frc.org.uk/auditorsresponsibilities. This description forms part of our Report of the Independent Auditors.

**Report of the Independent Auditors to the Trustees of
Drug Safety Research Trust**

Use of our report

This report is made solely to the charity's trustees, as a body, in accordance with Part 4 of the Charities (Accounts and Reports) Regulations 2008. Our audit work has been undertaken so that we might state to the charity's trustees those matters we are required to state to them in an auditors' report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the charity and the charity's trustees as a body, for our audit work, for this report, or for the opinions we have formed.

Cartwrights
Chartered Accountants and Business Advisors
Statutory Auditor
Regency House
33 Wood Street
Barnet
Hertfordshire
EN5 4BE

Date:

Andrew Hill FCA (Senior Statutory Auditor) for and on behalf of Cartwrights

Drug Safety Research Trust

**Statement of Financial Activities
for the Year Ended 31 December 2023**

	Notes	Unrestricted funds £	Restricted fund £	31/12/23 Total funds £	31/12/22 Total funds £
INCOME AND ENDOWMENTS FROM					
Donations and legacies	2	1,665,967	-	1,665,967	1,063,010
Investment income	3	250,209	-	250,209	132,385
Other income	4	400,284	-	400,284	713,303
Total		<u>2,316,460</u>	<u>-</u>	<u>2,316,460</u>	<u>1,908,698</u>
EXPENDITURE ON					
Raising funds	5	22,956	-	22,956	23,364
Charitable activities					
Direct Charitable Expenditure	6				
		1,959,822	-	1,959,822	2,012,954
Other		687,018	18,780	705,798	647,027
Total		<u>2,669,796</u>	<u>18,780</u>	<u>2,688,576</u>	<u>2,683,345</u>
Net gains/(losses) on investments		78,475	-	78,475	(494,633)
NET INCOME/(EXPENDITURE)		<u>(274,861)</u>	<u>(18,780)</u>	<u>(293,641)</u>	<u>(1,269,280)</u>
RECONCILIATION OF FUNDS					
Total funds brought forward		8,313,848	453,060	8,766,908	10,036,188
TOTAL FUNDS CARRIED FORWARD		<u><u>8,038,987</u></u>	<u><u>434,280</u></u>	<u><u>8,473,267</u></u>	<u><u>8,766,908</u></u>

The notes form part of these financial statements

Drug Safety Research Trust

**Statement of Financial Position
31 December 2023**

	Notes	Unrestricted funds £	Restricted fund £	31/12/23 Total funds £	31/12/22 Total funds £
FIXED ASSETS					
Tangible assets	11	46,394	434,280	480,674	473,040
Investments	12	4,066,828	-	4,066,828	3,831,919
		<u>4,113,222</u>	<u>434,280</u>	<u>4,547,502</u>	<u>4,304,959</u>
CURRENT ASSETS					
Debtors	13	1,211,314	-	1,211,314	235,427
Cash at bank		2,829,365	-	2,829,365	4,348,571
		<u>4,040,679</u>	<u>-</u>	<u>4,040,679</u>	<u>4,583,998</u>
CREDITORS					
Amounts falling due within one year	14	(114,914)	-	(114,914)	(122,049)
		<u>3,925,765</u>	<u>-</u>	<u>3,925,765</u>	<u>4,461,949</u>
NET CURRENT ASSETS					
		<u>8,038,987</u>	<u>434,280</u>	<u>8,473,267</u>	<u>8,766,908</u>
TOTAL ASSETS LESS CURRENT LIABILITIES					
		<u>8,038,987</u>	<u>434,280</u>	<u>8,473,267</u>	<u>8,766,908</u>
NET ASSETS					
		<u>8,038,987</u>	<u>434,280</u>	<u>8,473,267</u>	<u>8,766,908</u>
FUNDS					
	15			8,038,987	8,313,848
Unrestricted funds				434,280	453,060
Restricted funds				<u>8,473,267</u>	<u>8,766,908</u>
TOTAL FUNDS					
				<u>8,473,267</u>	<u>8,766,908</u>

The financial statements were approved by the Board of Trustees and authorised for issue on
and were signed on its behalf by:

.....
K R Paterson MB ChB FRCP FFPM - Trustee

Drug Safety Research Trust

Statement of Cash Flows for the Year Ended 31 December 2023

	Notes	31/12/23 £	31/12/22 £
Cash flows from operating activities			
Cash generated from operations	1	(1,571,029)	(240,785)
Net cash used in operating activities		<u>(1,571,029)</u>	<u>(240,785)</u>
Cash flows from investing activities			
Purchase of tangible fixed assets		(38,023)	(9,429)
Purchase of fixed asset investments		(156,434)	(101,643)
Sale of fixed asset investments		78,475	(494,633)
Interest received		100,773	27,364
Dividends received		67,032	63,666
Net cash provided by/(used in) investing activities		<u>51,823</u>	<u>(514,675)</u>
Change in cash and cash equivalents in the reporting period			
		(1,519,206)	(755,460)
Cash and cash equivalents at the beginning of the reporting period			
		<u>4,348,571</u>	<u>5,104,031</u>
Cash and cash equivalents at the end of the reporting period			
		<u>2,829,365</u>	<u>4,348,571</u>

The notes form part of these financial statements

Drug Safety Research Trust

Notes to the Statement of Cash Flows for the Year Ended 31 December 2023

1. RECONCILIATION OF NET EXPENDITURE TO NET CASH FLOW FROM OPERATING ACTIVITIES	31/12/23	31/12/22
	£	£
Net expenditure for the reporting period (as per the Statement of Financial Activities)	(293,641)	(1,269,280)
Adjustments for:		
Depreciation charges	30,389	30,339
(Gain)/losses on investments	(156,950)	989,266
Interest received	(100,773)	(27,364)
Dividends received	(67,032)	(63,666)
(Increase)/decrease in debtors	(975,887)	108,693
Decrease in creditors	(7,135)	(8,773)
Net cash used in operations	<u>(1,571,029)</u>	<u>(240,785)</u>

2. ANALYSIS OF CHANGES IN NET FUNDS

	At 1/1/23	Cash flow	At 31/12/23
	£	£	£
Net cash			
Cash at bank	4,348,571	(1,519,206)	2,829,365
	<u>4,348,571</u>	<u>(1,519,206)</u>	<u>2,829,365</u>
Total	<u>4,348,571</u>	<u>(1,519,206)</u>	<u>2,829,365</u>

The notes form part of these financial statements

**Notes to the Financial Statements
for the Year Ended 31 December 2023**

1. ACCOUNTING POLICIES

Basis of preparing the financial statements

The financial statements of the charity, which is a public benefit entity under FRS 102, have been prepared in accordance with the Charities SORP (FRS 102) 'Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019)', Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland' and the Charities Act 2011. The financial statements have been prepared under the historical cost convention, with the exception of investments which are included at market value, as modified by the revaluation of certain assets.

Going concern

These financial statements are prepared on the going concern basis. The trustees have a reasonable expectation that the charity will continue in operational existence for the foreseeable future. The validity of this assumption depends on the continuing surplus in "free reserves". If the charity were unable to continue in existence for the foreseeable future, adjustments would be necessary to reduce the balance sheet values of assets to their recoverable amounts and to reclassify fixed assets as current assets.

Critical accounting judgements and key sources of estimation uncertainty

Judgements and estimates are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

Critical accounting estimates and assumptions

The charity makes estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results.

Property, plant and equipment - tangible fixed assets are depreciated over their useful lives taking into account residual value, where appropriate. The actual lives of the assets and residual values are assessed annually and may vary depending on a number of factors. Residual value assessments consider issues such as the remaining life of the asset and projected disposal values.

Recognition of income - income is recognised when receipt is probable and when the amount can be measured reliably. At the end of the financial year all ongoing studies are reviewed and accrued income estimated from the available information, based on the fulfilment of the study conditions and/or milestones.

Income

All income is recognised in the Statement of Financial Activities once the charity has entitlement to the funds, it is probable that the income will be received and the amount can be measured reliably.

For donations to be recognised the charity will have been notified of the amounts and the settlement date in writing. If there are conditions attached to the donation and this requires a level of performance before entitlement can be obtained then income is deferred until those conditions are fully met or the fulfilment of those conditions is within the control of the charity and it is probable that they will be fulfilled.

Investment income is earned through holding assets for investment purposes such as shares. It includes dividends, interest and unrealised gains or losses on shares held. Where it is not practicable to identify investment management costs incurred within a scheme with reasonable accuracy the investment income is reported net of these costs. It is included when the amount can be measured reliably. Interest income is recognised using the effective interest method and dividend income is recognised as the charity's right to receive payment is established.

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2023

1. ACCOUNTING POLICIES - continued

Income

Other income represents management fees charged and donations received from the Trust's connected trading entity, DSRU Education and Research Limited. Management fees are included when charged and donations when received. Due to the connected nature of this entity, donation income is recorded within other income rather than within donations and legacy income in the Statement of Financial Activities.

Debtors are recognised when the charity is legally entitled to the income after any performance conditions have been met, the amount can be measured reliably and it is probable that the income will be received.

Expenditure

Liabilities are recognised as expenditure as soon as there is a legal or constructive obligation committing the charity to that expenditure, it is probable that a transfer of economic benefits will be required in settlement and the amount of the obligation can be measured reliably. Expenditure is accounted for on an accruals basis and has been classified under headings that aggregate all cost related to the category. Where costs cannot be directly attributed to particular headings they have been allocated to activities on a basis consistent with the use of resources.

Raising funds

Costs of raising funds represent investment manager costs incurred in dealing with the listed investment portfolio

Charitable activities

Expenditure on charitable activities includes the direct costs of carrying out and performing the studies and evaluations of medicines in order to meet the charity's objectives and aims.

Allocation and apportionment of costs

Support costs are those that assist the work of the charity but do not directly represent charitable activities and include office costs, governance costs, administrative payroll costs. They are incurred directly in support of expenditure on the objects of the charity. Where support costs cannot be directly attributed to particular headings they have been allocated to cost of raising funds and expenditure on charitable activities on a basis consistent with use of the resources.

Tangible fixed assets

Tangible fixed assets other than freehold land are stated at cost less depreciation. Depreciation is provided at rates calculated to write off the cost less estimated residual value of each asset over its expected useful life, as follow:

Freehold land	Not depreciated
Freehold buildings	2% Straight line on cost
Plant and machinery	20% straight line on cost
Fixtures, fittings and equipment	20% Straight line on cost
Motor vehicles	20% Straight line on cost

Taxation

The charity is an exempt charity within the meaning of schedule 3 of the Charities Act 2011 and is considered to pass the tests to ensure it is exempt from tax on its charitable activities.

Fund accounting

Unrestricted funds can be used in accordance with the charitable objectives at the discretion of the trustees.

Restricted funds can only be used for particular restricted purposes within the objects of the charity. Restrictions arise when specified by the donor or when funds are raised for particular restricted purposes.

Further explanation of the nature and purpose of each fund is included in the notes to the financial statements.

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2023

1. ACCOUNTING POLICIES - continued

Foreign currencies

Assets and liabilities in foreign currencies are translated into sterling at the rates of exchange ruling at the statement of financial position date. Transactions in foreign currencies are translated into sterling at the rate of exchange ruling at the date of transaction. Exchange differences are taken into account in arriving at the operating result.

Pension costs and other post-retirement benefits

The charity operates a defined contribution pension scheme. Contributions payable to the charity's pension scheme are charged to the Statement of Financial Activities in the period to which they relate.

Donated goods

The charity does not receive any donated goods or gifts in kind.

Financial instruments

The charity only holds basic financial instruments as defined in FRS 102. The financial assets and financial liabilities of the charity and their measurement basis are as follows:

Financial assets

Fixed asset investments in publicly traded funds and shares are basic financial instruments and are measured at fair value with changes in fair value recognised in the Statement of Financial Activities.

Trade and other debtors are basic financial instruments and are debt instruments measured at amortised cost as detailed in the debtors note to these financial statements. Prepayments and accrued income are not financial instruments.

Cash at bank - is classified as a basic financial instrument and is measured at face value.

Financial liabilities

Trade creditors and other creditors are basic financial instruments, and are measured at amortised cost as detailed in the creditors note to these financial statements. Taxation and social security are not included in the financial instruments disclosure definition. Accruals and deferred income is not deemed to be a financial liability, as the cash settlement has already taken place and there is an obligation to deliver services rather than cash or another financial instrument.

Other balance sheet items

Cash at bank and in hand included cash and short term highly liquid investments with a short maturity of three months or less from the date of acquisition or opening of the deposit or similar account.

Provisions are recognised when the charity has an obligation at the reporting date as a result of a past event which it is probable will result in the transfer of economic benefits and the obligation can be estimated reliably. Provisions are measured at the best estimate of the amounts required to settle the obligation. Where the effect of the time value of money is material, the provision is based on the present value of those amounts, discounted at the pre-tax discount rate that reflects the risks specific to the liability. The unwinding of the discount is recognised within interest payable and similar charges.

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2023**

2. DONATIONS AND LEGACIES

	Unrestricted funds £	Restricted funds £	31/12/23 Total funds £	31/12/22 Total funds £
Donations	1,665,967	-	1,665,967	1,063,010

3. INVESTMENT INCOME

	Unrestricted funds £	Restricted funds £	31/12/23 Total funds £	31/12/22 Total funds £
Gain on disposal of investment	82,404	-	82,404	41,355
Listed income	67,032	-	67,032	63,666
Interest received	100,773	-	100,773	27,364
	<u>250,209</u>	<u>-</u>	<u>250,209</u>	<u>132,385</u>

4. OTHER INCOME

	Unrestricted funds £	Restricted funds £	31/12/23 Total funds £	31/12/22 Total funds £
Other income	400,284	-	400,284	713,303

5. RAISING FUNDS

Investment management costs

	Unrestricted funds £	Restricted funds £	31/12/23 Total funds £	31/12/22 Total funds £
Fund manager costs	22,956	-	22,956	23,364

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2023**

6. CHARITABLE ACTIVITIES COSTS

	Direct Costs £
Direct Charitable Expenditure	
	1,959,822
	<u>1,959,822</u>

7. SUPPORT COSTS

	Governance costs £
Other resources expended	
	705,798
	<u>705,798</u>

Support costs, included in the above, are as follows:

	31/12/23 Other resources expended £	31/12/22 Total activities £
Wages	167,640	169,322
Social security	150,333	154,469
Pensions	84,162	65,396
Auditors' remuneration	11,524	10,773
Rates and water	11,351	10,559
Insurance	21,952	19,718
Light and heat	23,719	22,597
Telephone and fax	6,052	8,627
PPS	1,754	3,740
Sundries	4,695	3,284
Repairs and maintenance	18,142	12,718
Staff medical costs	9,306	11,080
Motor and travel expenses	48,294	18,690
Computer costs	22,113	15,567
Subscriptions	37,623	49,861
Bank charges	1,277	1,376
Marketing costs	53,133	35,690
Equipment hire	2,339	3,221
Depreciation of tangible fixed assets	30,389	30,339
	<u>705,798</u>	<u>647,027</u>

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2023**

8. AUDITORS' REMUNERATION

	31/12/23 £	31/12/22 £
Fees payable to the charity's auditors for the audit of the charity's financial statements	<u>11,524</u>	<u>10,773</u>

9. TRUSTEES' REMUNERATION AND BENEFITS

There were no trustees' remuneration or other benefits for the year ended 31 December 2023 nor for the year ended 31 December 2022.

Trustees' expenses

Trustees indemnity insurance payable during the year amounted to £7,323 (2022: £6,660).

10. STAFF COSTS

The average number of employees during the year was 31 (2022 - 33).

The number of employees whose annual emoluments were £60,000 or more were:

	2023	2022
£230,001 - £300,000	1	1
£70,001 - £100,000	2	-
£60,001 - £70,000	3	5

11. TANGIBLE FIXED ASSETS

	Freehold property £	Plant and machinery £	Fixtures and fittings £	Computer system £	Totals £
COST					
At 1 January 2023	941,000	178,369	66,368	57,036	1,242,773
Additions	-	36,853	1,170	-	38,023
	<u>941,000</u>	<u>215,222</u>	<u>67,538</u>	<u>57,036</u>	<u>1,280,796</u>
At 31 December 2023	941,000	215,222	67,538	57,036	1,280,796
DEPRECIATION					
At 1 January 2023	487,940	162,439	62,318	57,036	769,733
Charge for year	18,780	8,934	2,675	-	30,389
	<u>506,720</u>	<u>171,373</u>	<u>64,993</u>	<u>57,036</u>	<u>800,122</u>
At 31 December 2023	506,720	171,373	64,993	57,036	800,122
NET BOOK VALUE					
At 31 December 2023	<u>434,280</u>	<u>43,849</u>	<u>2,545</u>	-	<u>480,674</u>
At 31 December 2022	<u>453,060</u>	<u>15,930</u>	<u>4,050</u>	-	<u>473,040</u>

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2023

11. TANGIBLE FIXED ASSETS - continued

The freehold property was last revalued on 20 December 1999 by Messrs Daniells Harison, Chartered Surveyors, on the basis of open market value for current use. The freehold land and buildings valuation has not been updated since 1999. Under the transitional relief provisions under FRS 102, this value has been treated as the deemed cost in these financial statements. The estimated market value per the charity as at the balance sheet date, is in excess of £4 million.

Comparable historical cost for the land and buildings included at valuation:

	2023	2022
	£	£
Cost	1,487,614	1,487,614
Accumulated Depreciation	<u>506,720</u>	<u>487,940</u>
At year end	<u>980,894</u>	<u>999,674</u>

All other tangible fixed assets are stated at historical cost less accumulated depreciation.

12. FIXED ASSET INVESTMENTS

	Listed investments £
MARKET VALUE	
At 1 January 2023	3,831,919
Additions	156,434
Revaluations	78,475
	<hr/>
At 31 December 2023	4,066,828
	<hr/>
NET BOOK VALUE	
At 31 December 2023	4,066,828
	<hr/> <hr/>
At 31 December 2022	3,831,919
	<hr/> <hr/>

Fixed asset investments represent a managed fund portfolio run by Investec Wealth and Investments Limited. The asset allocation, including geographical location, of the portfolio is set out below:

	2023	2022
	£	£
UK fixed income	686,930	323,912
Overseas fixed income	291,461	345,384
UK equities	782,949	933,636
Overseas equities	1,657,440	1,369,423
Property	49,560	4,6800
Alternatives	543,330	648,730
Cash	55,158	164,034
	<hr/>	<hr/>
Total	<u>4,066,828</u>	<u>3,831,919</u>
	<hr/> <hr/>	<hr/> <hr/>

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2023**

12. FIXED ASSET INVESTMENTS - continued

Cost or valuation at 31 December 2023 is represented by:

	Listed investments £
Valuation in 2023	4,066,828
	<u>4,066,828</u>

Net additions at cost represent investment income reinvested at source in the relevant funds held.

Investments were valued by the Investment Fund Managers, Investec Wealth and Investment Limited, as at 31 December 2023.

13. DEBTORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	31/12/23 £	31/12/22 £
Trade debtors	1,168,415	202,409
Prepayments and accrued income	42,899	33,018
	<u>1,211,314</u>	<u>235,427</u>

14. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	31/12/23 £	31/12/22 £
Trade creditors	43,493	27,647
Taxation and social security	62,769	48,103
Other creditors	8,652	46,299
	<u>114,914</u>	<u>122,049</u>

15. MOVEMENT IN FUNDS

	At 1/1/23 £	Net movement in funds £	At 31/12/23 £
Unrestricted funds			
Unrestricted Fund	8,313,848	(274,861)	8,038,987
Restricted funds			
Restricted Fund	453,060	(18,780)	434,280
TOTAL FUNDS	<u>8,766,908</u>	<u>(293,641)</u>	<u>8,473,267</u>

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2023**

15. MOVEMENT IN FUNDS - continued

Net movement in funds, included in the above are as follows:

	Incoming resources £	Resources expended £	Gains and losses £	Movement in funds £
Unrestricted funds				
Unrestricted Fund	2,316,460	(2,669,796)	78,475	(274,861)
Restricted funds				
Restricted Fund	-	(18,780)	-	(18,780)
TOTAL FUNDS	<u>2,316,460</u>	<u>(2,688,576)</u>	<u>78,475</u>	<u>(293,641)</u>

Comparatives for movement in funds

	At 1/1/22 £	Net movement in funds £	At 31/12/22 £
Unrestricted funds			
Unrestricted Fund	9,564,348	(1,250,500)	8,313,848
Restricted funds			
Restricted Fund	471,840	(18,780)	453,060
TOTAL FUNDS	<u>10,036,188</u>	<u>(1,269,280)</u>	<u>8,766,908</u>

Comparative net movement in funds, included in the above are as follows:

	Incoming resources £	Resources expended £	Gains and losses £	Movement in funds £
Unrestricted funds				
Unrestricted Fund	1,908,698	(2,664,565)	(494,633)	(1,250,500)
Restricted funds				
Restricted Fund	-	(18,780)	-	(18,780)
TOTAL FUNDS	<u>1,908,698</u>	<u>(2,683,345)</u>	<u>(494,633)</u>	<u>(1,269,280)</u>

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2023

15. MOVEMENT IN FUNDS - continued

The restricted fund represents the net book values of the freehold land and buildings at Bursledon Hall, Southampton. The fund balances are reduced by the depreciation charged on the buildings.

Unrestricted funds represent donations and other incoming resources receivable or generated for the objects of the charity without further specified purpose and are available as general funds.

16. EMPLOYEE BENEFIT OBLIGATIONS

The company operates a defined contribution pension scheme. The assets of the scheme are held separately from those of the company in an independently administered fund. The pension cost charge represents contributions payable by the company to the fund. These amounted to £84,162 (2022 - £65,396). Contributions totalling £14,002 (2022 - £9,351) were payable to the fund at the year end and are included in creditors.

17. RELATED PARTY DISCLOSURES

Other income includes the following income received from DSRU Education and Research Trust, a company limited by guarantee, which is controlled by the charity and in which Professor Saad Shakir is sole company director. During the year:

Management fees totalling £92,400 (2022: £78,000) were charged to the company for use of shared premises and administrative resources;

Salary recharges totalling £34,884 (2022: 35,353) were made to the company for the use of shared staff; and

A donation of £273,000 (2022: £599,950) was received from the company. The value of the donation each year is determined such that the company reduces its profits chargeable to tax to £nil each year.

18. POST BALANCE SHEET EVENTS

A donation in the region of £173,500 is anticipated to be received in 2024 from DSRU Education and Research Limited, a company under the control of the charity. The value of this donation is not known or agreed until after the balance sheet date following preparation of the said company's financial statements, and is therefore considered to be a non-adjusting post balance sheet event.

19. FINANCIAL INSTRUMENTS

The charity's financial instruments include:

	2023	2022
	£	£
Financial assets that are debt instruments measured at amortised cost	1,168,415	202,409
Financial assets that are equity instruments measured at fair value	4,066,828	3,831,919
	<u>5,235,243</u>	<u>4,034,328</u>
Financial liabilities measured at amortised cost	<u>106,262</u>	<u>75,750</u>

Financial assets measured at amortised cost comprise trade and other debtors.

Financial assets that are equity instruments measured at fair value comprise of listed investments.

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2023**

19. FINANCIAL INSTRUMENTS - continued

Financial liabilities measured at amortised cost comprise of trade creditors, social security and other payroll taxes and other creditors.

Drug Safety Research Trust**Detailed Statement of Financial Activities
for the Year Ended 31 December 2023**

	31/12/23	31/12/22
	£	£
INCOME AND ENDOWMENTS		
Donations and legacies		
Donations	1,665,967	1,063,010
Investment income		
Gain on disposal of investment	82,404	41,355
Listed income	67,032	63,666
Interest received	100,773	27,364
	<hr/>	<hr/>
	250,209	132,385
Other income		
Other income	400,284	713,303
	<hr/>	<hr/>
Total incoming resources	2,316,460	1,908,698
EXPENDITURE		
Investment management costs		
Fund manager costs	22,956	23,364
Charitable activities		
Wages - direct	1,180,533	1,161,761
General Practitioner costs	44,627	51,932
Other direct costs	734,662	799,261
	<hr/>	<hr/>
	1,959,822	2,012,954
Support costs		
Governance costs		
Wages	167,640	169,322
Social security	150,333	154,469
Pensions	84,162	65,396
Auditors' remuneration	11,524	10,773
Rates and water	11,351	10,559
Insurance	21,952	19,718
Light and heat	23,719	22,597
Telephone and fax	6,052	8,627
PPS	1,754	3,740
Sundries	4,695	3,284
Repairs and maintenance	18,142	12,718
Staff medical costs	9,306	11,080
Carried forward	510,630	492,283

This page does not form part of the statutory financial statements

Drug Safety Research Trust**Detailed Statement of Financial Activities
for the Year Ended 31 December 2023**

	31/12/23	31/12/22
	£	£
Governance costs		
Brought forward	510,630	492,283
Motor and travel expenses	48,294	18,690
Computer costs	22,113	15,567
Subscriptions	37,623	49,861
Bank charges	1,277	1,376
Marketing costs	53,133	35,690
Equipment hire	2,339	3,221
Depreciation of tangible fixed assets	30,389	30,339
	<u>705,798</u>	<u>647,027</u>
Total resources expended	<u>2,688,576</u>	<u>2,683,345</u>
Net expenditure before gains and losses	(372,116)	(774,647)
Net losses on investments		
Net gains / losses on investments	<u>78,475</u>	<u>(494,633)</u>
Net expenditure	<u><u>(293,641)</u></u>	<u><u>(1,269,280)</u></u>

This page does not form part of the statutory financial statements

THE DRUG SAFETY RESEARCH TRUST

England & Wales - Charity number 327206

Accounts

REGISTERED CHARITY NUMBER: 327206

**Trustees' Report and
Audited Financial Statements for the Year Ended 31 December 2022
for
Drug Safety Research Trust**

Drug Safety Research Trust

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for the Year Ended 31 December 2022**

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Drug Safety Research Trust

**Reference and Administrative Details
for the Year Ended 31 December 2022**

TRUSTEES

Professor Kenneth Ross Paterson MB ChB FRCP FFPM FBPhS (Chairman)
Professor John Camm QHP BSc MD FRCP FESC FACC FAHA FCGC CSJ
Professor Martin Vessey CBE MD FRCP FRCOG FRCGP FFPH FMedSci FRS
Professor Allan Hunter Young MB, ChB, MPhil, PhD, FRCPC, FRCPsych
Professor Isla Mackenzie MB ChB PhD PGCertMedEd FRCP Edin FBPhS FBIHS

DIRECTOR

Professor Saad Shakir MB ChB LRCP&S FRCP FFPM FISPE MRCP

PRINCIPAL ADDRESS

Bursledon Hall
Blundell Lane
Southampton
SO31 1AA

REGISTERED CHARITY NUMBER 327206

INDEPENDENT AUDITORS

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Chartered Accountants and Business Advisors
Statutory Auditor
Regency House
33 Wood Street
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EN5 4BE

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Solicitors
Paris Smith LLP
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S015 2AE

Investment advisers
Investec Wealth and Investment Limited
30 Gresham Street
London
EC2V 7QN

PRINCIPAL BANKERS

Lloyds Bank plc
92-94 Above Bar St
Southampton
SO14 7DT

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2022

The trustees present their report with the financial statements of the charity for the year ended 31 December 2022. The trustees have adopted the provisions of Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019).

OBJECTIVES AND ACTIVITIES

Objectives and aims

The Trust by way of its operational unit, the DSRU, undertakes all forms of studies and evaluations of the safety of medicines for the public benefit, including methodological research to improve existing methods including:

- Studies to examine the safety of medicines, including new medicines, new formulations for existing medicines and when medicines are used for new indications or in new populations, or when safety issues or questions about the use, benefit-risk balance or effectiveness of medicines arise. Frequently such DSRU studies are part of risk management plans for medicines which are now statutory requirements in the EU.
- Studies on established medicines when safety, scientific, utilisation or regulatory issues, questions, enquiries or needs for submissions arise. The issues include risk management & minimisation and methodological questions. The studies can be part of the UK and the EU regulatory requirements for risk management of medicines, though not exclusively.
- Conducting studies to address specific safety, public health, scientific, benefit-risk balance of medicines and vaccines, utilisation and usage and regulatory issues or concerns.
- Conducting utilisation studies for medicines and vaccines to enable understanding the use and effects of products on the healthcare system and behaviours and responses of patients and healthcare professionals.
- Use of healthcare databases to conduct drug safety studies.
- Establishing registries to conduct safety and utilisation studies.
- Working with doctors to undertake studies to examine specific safety questions and medical health research networks.
- Exploring the application of new methods such as clinical trials or database research, as well as other appropriate research methods, to understand the safety of medicines.
- Conducting methodological research in pharmacovigilance and pharmacoepidemiology.
- Conducting studies and other scientific activities such as organising meetings and conferences to explore and develop new methods and innovations in pharmacovigilance and pharmacoepidemiology.
- Undertaking reviews, systematic reviews, meta-analyses or benefit-risk studies to answer drug safety and drug utilisation questions.
- Establishing research entities for studying and communicating methodological issues in pharmacovigilance and drug safety issues
- Leading or participating in national and international research networks and scientific collaborative projects.

We continue to monitor developments in the UK relationship with the EU and make adjustments to our systems as appropriate to address relevant issues arising from these changes. In this regard the Trust has already opened a sub-office in Dublin to maintain and develop our links with the EU following the UK's severance of membership of the EU in 2020. The Director keeps in regular contact with the Regulatory Agencies and our European colleagues to obtain information in order to shape our strategy and policy, particularly on matters related to the impact of Brexit on medicines regulations and medical research.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2022

OBJECTIVES AND ACTIVITIES

Significant activities

The DSRU provides advice, education and training in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines. As one of the main providers of training and education in pharmacovigilance in Europe, its activities include:

- Providing a range of training courses in pharmacovigilance and pharmacoepidemiology. The DSRU currently provides 18 courses per year, including academically endorsed higher education in collaboration with University of Portsmouth for Postgraduate Certificate, Diploma and a Master's degree in Pharmacovigilance and with the Faculty of Pharmaceutical Medicine for providing Pharmaceutical Medicine Specialty Training (PMST) for doctors specialising in pharmaceutical medicine.
- Providing external training and education when required.
- Keeping up with technological progress the DSRU intends to periodically evaluate options such as providing distance learning and other internet based educational methods.
- Arranging national and international conferences in pharmacovigilance and pharmacoepidemiology.
- Providing postgraduate teaching and research opportunities at all levels including MSc and PhD students.
- Supporting postgraduate students who wish to undertake research at the DSRU.
- Providing training in pharmacovigilance and pharmacoepidemiology for pharmaceutical physicians. The DSRU has been selected by the Faculty of Pharmaceutical Medicine to provide Pharmaceutical Medicine Specialty Training (PMST) training in pharmacovigilance in the UK.
- Supporting training and scientific communications on the safety of medicines in the UK and internationally.
- Providing advice on matters related to the safety of medicines.
- Producing newsletters and internet communications to general practitioners on matters to do with drug safety.
- Providing information on drug safety which can be accessed by everyone on the DSRU website.

Routinely, reports on the results of studies are sent to the Medicines and Healthcare Products Regulatory Authority (MHRA) (an executive agency of the Department of Health) and to the European Medicines Agency (EMA) and other Regulatory Authorities in Europe to assist them in their regulatory and monitoring activities of medicines. The DSRU sends reports of its studies to Marketing Authorisation Holders of medicines and vaccines and also publishes findings of its work in scientific journals and at national and international conferences, newsletters and on its website.

Progress of the scientific work of the Unit was satisfactory throughout 2022 extending the breadth of activity to include research projects and collaborations other than Modified Prescription-Event Monitoring (MPeM). These include specialist and hospital-based studies (SCeMs), systematic reviews, registries, structured benefit-risk evaluation, drug utilisation projects and methodological research. In addition, our programme of activities has extended to include collaborating with a broad range of doctors in England through Health Research Networks from differing specialities as well as collaborating with colleagues in Europe. The policy to extend the range of scientific activities, as funding allows, will continue.

Applications for funding from grant-giving bodies, including the Department of Health Targeted Research Programme and other bodies such as the Medical Research Council (MRC), the Wellcome Trust, pharmaceutical companies and European initiatives, e.g., the European Commission, will continue as and when calls are advertised. The DSRU continues to function as one of the leading Units in the field of monitoring and studying the safety of medicines both in the UK and internationally, as well as being a leading organisation in teaching and training in these fields.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2022

OBJECTIVES AND ACTIVITIES

The DSRU has a long-standing partnership with the NHS Rx Services to receive prescription data that are necessary to conduct Modified Prescription-Event Monitoring studies to improve the understanding of the safety of new drugs used in the general population. This partnership has the support of the Department of Health and senior staff at NHS Rx Services.

Since application for Section 251 exemption of the NHS 2006 Act became a requirement, the Trust has applied annually to the Confidentiality Advisory Group (CAG) of the Health Research Authority for approval to use patient data without consent. Application was again made in 2022 and was successful.

The formal collaborative partnership programme agreement, required to develop the partnership with the NHS Rx Services, to supply improved prescription data is in place and we continue to maintain good communications. In the unlikely situation that the DSRU ceases to receive data for whatever reason from the NHS Rx Services, the DSRU is committed to continue its work on studying the safety of medicines by other methods and providing education and training in pharmacovigilance and drug safety.

The main objectives of the Unit for the next year are:

- To continue the monitoring and research programme on the safety and risk management of vaccines and medicinal products for the treatment COVID-19.
- To undertake all forms of studies and evaluations of the safety and benefit-risk of medicines and vaccines alone or in collaboration with other organisations.
- To plan and support organisations to implement risk minimisation measures for medicines and vaccines and monitor the effectiveness of these measures.
- To use its studies to support risk management, risk minimisation and monitoring the effectiveness of risk minimisation and utilisation of medicines and vaccines.
- To conduct studies to understand drug safety issues, undertake methodological research, and explore and conduct studies on new methodologies and innovations.
- To conduct studies to understand the utilisation (use) and effects of medicines and vaccines.
- To continue its scientific work in methodological aspects of drug safety including leading or participating in national and international collaborative projects.
- To continue its activities in advice, education and training in pharmacovigilance and pharmacoepidemiology.
- To consolidate its scientific communications programme such as the DSRU blogs to inform both the medical/scientific communities and the public about important pharmacovigilance issues.
- To continue to try to secure sufficient funding from different sources (public and private) to enable the continuation and growth of the charity's activities.

Drug Safety Research Trust

**Trustees' Report
for the Year Ended 31 December 2022**

OBJECTIVES AND ACTIVITIES

Public benefit

The Trustees confirm that the Charity Commission's general guidance on public benefit has been considered in relation to the objectives of the Charity.

The objectives, activities, performance and achievement sections of this report clearly set out the activities which the charity undertakes for public benefit. The Trustees confirm that they have complied with their duty in Section 4 of the Charities Act 2006 to have due regard to public benefits guidance published by the Charities Commission in determining the activities undertaken by the Charity.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2022

ACHIEVEMENT AND PERFORMANCE

Charitable activities

The successful annual submission and subsequent approval and support of the Ethics and Confidentiality Committee of the Confidentiality Advisory Group (CAG) of the Health Research Authority for Section 251 exemption under the NHS Act 2006 was achieved for the thirteenth year running.

The academically endorsed higher educational training in collaboration with the University of Portsmouth for Certificate, Diploma and Masters degree in Pharmacovigilance continued, with 18 students currently enrolled at the end of the year.

Eight scientific papers were published in medical literature. Two poster presentations on the results of studies were given by the Director and research staff at national and international medical and scientific conferences. One Vaccine Active Safety Surveillance study, one Systematic Review and six Interim Reports were completed and delivered during 2022 as well as the provision of pharmacovigilance consultancy support to pharmaceutical companies.

Education and Professional Capability

The educational training of staff has been maintained, including continuing professional development. In addition, the DSRU has provided advice on safety of medicines issues.

Teaching & Education

The Director taught at an MSc Course at Oxford University. In addition, teaching and presenting at national and international scientific meetings continued by both the Director and senior scientific staff enabling the scientific profile of the Unit and its work in public health and drug safety to be maintained.

The DSRU and staff at the DSRU have provided training for general practitioners on effective and safe prescribing of medicines.

Training Courses for Pharmaceutical Medicine Speciality Training

The DSRU continues to deliver teaching courses in pharmacovigilance, providing training on drug safety modules of Pharmaceutical Medicine Specialty Training (PMST), for pharmaceutical physicians on behalf of the Faculty of Pharmaceutical Medicine, Royal College of Physicians. Eight students attended these modules during the year.

Partners and Stakeholders

Universities of Portsmouth

Collaborations with the University of Portsmouth on joint studentships and joint training continue.

Regulatory Agencies

Close links were maintained throughout the year with the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) with regular reports on safety issues submitted, contributing to the better understanding of the safety of a number of important medicinal products. The DSRU is a member of the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP), a project led by the European Medicines Agency and developed in collaboration with European experts in the fields of pharmacoepidemiology and pharmacovigilance. Senior staff of the DSRU regularly participate in meetings of the ENCePP network group.

VAC4EU

The DSRU is a member of VAC4EU which is a collaborative network of 46 units across Europe which conduct studies on the safety and effectiveness of vaccines. The network is led by Professor Miriam Sturkenboom (the University of Utrecht in the Netherlands). The DSRU is conducting three studies on COVID-19 vaccines in collaboration with members of VAC4EU. The DSRU is using Clinical Practice Research Datalink (CPRD), the leading resource in the UK of primary care clinical data to conduct the studies on COVID-19 vaccines by AstraZeneca, Pfizer and Moderna, while our collaborators are using databases in a number of European countries.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2022

Lareb

The DSRU is running the UK arm of the Covid Vaccine Monitor Study, a European-wide study organised by the Netherlands Pharmacovigilance Centre, Lareb. In this study a web app is used to monitor the safety of all COVID-19 vaccines amongst vaccinees in seven European countries. The aims of the study are to generate incidence rates of patient-reported ADRs for each COVID-19 vaccine brand in near real time and to describe differences in those incidence rates between different vaccine batches used across the participating countries. EU work package partners are using anonymised, aggregated data from all countries to produce a dashboard for the monitoring of side effects and signal detection.

International scientific leadership collaboration

The DSRU is leading an International Working Group (IWG) for New Developments in Pharmacovigilance. The Group includes some of the best experts in the world in this field. The objective is to examine the impact of new developments in biomedical sciences on signal detection and management in pharmacovigilance. Such developments include artificial intelligence and machine thinking, the use of big data, the application of genetic knowledge in detecting and evaluating adverse drug reactions. The work of the IWG was interrupted for nearly two years because of the COVID-19 pandemic but the group re-started in October 2022 and has made good progress in its activities with broader objectives which are to address new developments in pharmacovigilance and pharmacoepidemiology.

Investment performance

Special investment powers of the Trustees

The Trust has undertaken investment in equities and bonds through Investec Wealth & Investment Ltd. In order to monitor the investment portfolio performance, two Trustees and the Director act as a sub-committee. This group, on behalf of the Board of Trustees, deals with all matters relating to the investment portfolio and meets with representatives of Investec Wealth & Investment Ltd at appropriate intervals. It is the policy of the Board of Trustees that no investments in the pharmaceutical, armaments or tobacco industries should be undertaken. The Trustees are satisfied that the current investment approach of the Trust is consistent with its investment needs, objectives and attitude to risk, which is to provide a balanced return on investment in the medium term with a moderate risk of capital loss.

FINANCIAL REVIEW

Financial position

The accounts have been prepared in accordance with the accounting policies set out in note 1 to the accounts and comply with the charity's Trust Deed, the Charities Act 1993 and the Statement of Recommended Practice, "Accounting and Reporting by Charities", issued in March 2005.

The Statement of Financial Activities for the year is set out on page 14 to these financial statements.

Principal funding sources

Principle funding sources come from donations received from pharmaceutical companies and other organisations in order to carry out charitable activities.

Whilst some costs are provided in advance by funders, the entitlement to income only arises when separately identifiable stages of the projects are completed. The charity monitors the progress of the projects closely and only includes the income and associated costs as and when these conditions are met. This treatment meets the charity's accounting policy regarding incoming resources as set out under accounting policy 1.2 in the notes to the financial statements..

Staffing costs were higher in 2022 at £1,485,552 compared to £1,361,121 in 2021. Salaries still form the major part of the charity's expenses due to the specialist nature of employees, e.g., medical doctors and scientists needed to carry out the research activities. Total wage costs including national insurance and pension contributions therefore remain the highest expenditure for the Trust on a year-by-year basis.

The Chairman of Trustees and Director maintained close scrutiny of incoming resources and expenditure during the year and kept the Board informed maintaining the same level of financial governance as in previous years.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2022

FINANCIAL REVIEW

Investment policy and objectives

The Trust has undertaken investment in equities and bonds through Investec Wealth & Investment Ltd. In order to monitor the investment portfolio performance, two Trustees and the Director act as a sub-committee. This group, on behalf of the Board of Trustees, deals with all matters relating to the investment portfolio and meets with representatives of Investec Wealth & Investment Ltd at appropriate intervals. It is the policy of the Board of Trustees that no investments in the pharmaceutical, armaments or tobacco industries should be undertaken. The Trustees were satisfied that the current investment approach of the Trust is consistent with its investment needs, objectives and attitude to risk, which is to provide a balanced return on investment in the medium term with a moderate risk of capital loss.

Annually from a management perspective all other funds not immediately required from month to month for the normal running of the DSRU are routinely invested in fixed term deposit accounts to maximise return whenever possible.

The Trust's strategy to invest whenever possible to offset for leaner years when donations are reduced, will be maintained. The return on investment increased from £49,452 in 2021 to £63,666 in 2022.

Reserves policy

It is the policy of the charity to maintain unrestricted funds, which are the free reserves of the charity. This provides sufficient funds to cover the cost of ongoing studies, management and administration costs. Considering expected fluctuations of future income, the financial reserves are necessary to maintain the future stability and viability of the DSRU. These reserves will be used when and if funds become too low to cover normal day to day activities. In these difficult economic times, the Trust is reaping the benefit of the prudent financial policy in the last decade. This approach will be continued in line with developments in the external economic environment.

Asset cover for funds

An analysis of the assets attributable to the various funds described is set out in the notes to these financial statements. These assets are sufficient to meet the charity's obligations on a fund by fund basis.

FUTURE PLANS

The overall strategy remains the same. As in previous years the DSRU will endeavour to ensure the preservation of Modified Prescription-Event Monitoring (MPeM) as a leading system to monitor the safety of medicines in the UK and to enhance and develop it. The Unit will continue to conduct a broad range of studies to address safety questions, including add-on studies, such as case-control and case-series studies within our databases, pharmacoepidemiological studies using other data sources and a range of study designs, appropriate clinical trials, genetic studies, drug and vaccine utilisation studies, meta-analyses, systematic reviews, benefit-risk evaluation, other study methods to understand drugs and vaccines safety, effectiveness use and utilisation.

The DSRU will conduct methodological research to contribute to advance the science and methods of Pharmacovigilance. These are part of the DSRU's objective to explore conducting studies with different methods, including using a range of data sources and innovations that enable it to achieve its objective to monitor and study the safety of medicines.

The DSRU will continue its recent successful expansion to conduct safety studies in secondary care as well as in primary care using appropriate and improved methods to answer the relevant safety questions.

The DSRU will lead or participate in national and international collaborative projects that aim to improve the methods and advance the science of studying the safety of medicines. The DSRU will further develop its scientific communications programme to inform the both the medical/scientific communities and the public about important pharmacovigilance issues.

The DSRU continues to monitor IT and other developments in the NHS and elsewhere to ensure that it benefits from the opportunities provided by these developments. The Unit will further develop its methods and capabilities in evidence-based pharmacovigilance and risk management and maintain its place as a leading Unit in providing advice, training and education in pharmacovigilance and drug safety. The DSRU will try to review and improve where necessary its systems such as its IT database.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2022

STRUCTURE, GOVERNANCE AND MANAGEMENT

Governing document

The Trust is governed by a charitable Trust Deed established on 23 July 1986 with a Board of Trustees five in number. The Mission of the Trust remains to monitor, study and communicate the safety of medicines independent from both Government and industry. The Trust by way of its operational unit, the Drug Safety Research Unit (DSRU), undertakes all forms of studies and evaluations on the safety of medicines. The DSRU provides advice, training and education in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines.

As an independent registered medical charity, its aim is to achieve the highest possible scientific and ethical standards by putting the interests of patients first and to work with integrity and fairness with all partners.

Recruitment and appointment of new trustees

As a charity specialising in drug safety, the Trustees are identified for their expertise in areas which include drug regulation, epidemiology and medical statistics, experimental medicine and pharmacovigilance. Once appointed, the Trust ensures that any training required by the Trustees is provided to enable them to fulfil their role.

Organisational structure

The Trust employs a Director, Professor Saad Shakir, assisted by scientific, professional and administrative staff to conduct its day-to-day activities, ensuring that the charity's objectives are implemented. The Trust also retains the services of appropriate advisers and consultants depending upon the nature of the tasks required. During 2022 the average number of staff employed for the year was 33. In addition, fourteen consultants were engaged, to advise and assist with additional medical/research input, IT and data protection and PR.

Induction and training of new trustees

The Trustees acknowledge their responsibilities as set out on the statement of "Trustees responsibilities".

Changes to the Board of Trustees

There have been no changes during 2022.

Risk management

The Trustees have a duty to identify and review the risks to which the Charity is exposed and to ensure appropriate controls are in place to provide reasonable assurance against fraud and error.

The Trustees examine the major strategic, business and operational risks and confirm that systems are established to enable regular reports to be produced, so that necessary steps can be taken to control or lessen these risks. The variability of the funding of the Trust made it necessary to put in place processes to ensure that staff felt secure and motivated.

A Disaster Recovery Plan for the DSRU has been designed and completed. The plan is secured in off-site storage within a data safe.

Approved by order of the board of trustees on 30 MAY 2023 and signed on its behalf by:



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Professor K R Paterson MB ChB FRCP FFPM - Trustee

Drug Safety Research Trust

Statement of Trustees' Responsibilities for the Year Ended 31 December 2022

The trustees are responsible for preparing the Trustees' Report and the accounts in accordance with applicable law and Financial Reporting Standards (FRS102).

The law applicable to charities in England and Wales requires the trustees to prepare Accounts for each financial year which give a true and fair view of the charity's financial activities during the year and of its financial position at the end of the year (unless the charity is entitled to prepare accounts on the alternative receipts and payments basis).

In preparing accounts giving a true and fair view, the trustees should follow best practice and:

- Select suitable accounting policies and then apply them consistently;
- State whether applicable accounting standards and statements of recommended practice have been followed, subject to any departures and explained in the accounts.
- make judgements and estimates that are reasonable and prudent;
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the charity will continue in business.

The trustees are responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the charity and to enable them to ensure that the financial statements comply with the applicable law. They are also responsible for safeguarding the assets of the charity and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Opinion

We have audited the financial statements of Drug Safety Research Trust (the 'charity') for the year ended 31 December 2022 which comprise the Statement of Financial Activities, the Statement of Financial Position, the Statement of Cash Flows and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice), including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'.

In our opinion the financial statements:

- give a true and fair view of the state of the charity's affairs as at 31 December 2022 and of its incoming resources and application of resources, for the year then ended;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice, including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'; and
- have been prepared in accordance with the requirements of the Charities Act 2011.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We are independent of the charity in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the trustees' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the charity's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the trustees with respect to going concern are described in the relevant sections of this report.

Other information

The trustees are responsible for the other information. The other information comprises the information included in the Annual Report, other than the financial statements and our Report of the Independent Auditors thereon.

Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Matters on which we are required to report by exception

We have nothing to report in respect of the following matters where the Charities (Accounts and Reports) Regulations 2008 requires us to report to you if, in our opinion:

- the information given in the trustees Report is inconsistent in any material respect with the financial statements; or
- sufficient accounting records have not been kept; or
- the financial statements are not in agreement with the accounting records and returns; or
- we have not received all the information and explanations we require for our audit.

**Report of the Independent Auditors to the Trustees of
Drug Safety Research Trust**

Responsibilities of trustees

As explained more fully in the Statement of Trustees' Responsibilities, the trustees are responsible for the preparation of the financial statements which give a true and fair view, and for such internal control as the trustees determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the trustees are responsible for assessing the charity's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the trustees either intend to liquidate the charity or to cease operations, or have no realistic alternative but to do so.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Our responsibilities for the audit of the financial statements

We have been appointed as auditors under Section 144 of the Charities Act 2011 and report in accordance with the Act and relevant regulations made or having effect thereunder.

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a Report of the Independent Auditors that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

We ensured that the engagement team collectively had the appropriate competence, capabilities and skills to identify or recognise non-compliance with applicable laws and regulations, and that they remained alert to instances of non-compliance throughout the audit.

Our approach to identifying and assessing the risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, was as follows:

- based on our understanding of the charity and sector, and through discussions with trustees and key management, we identified any specific laws and regulations which we considered may have a direct material effect on the financial statements or the operations of the charity, including the SORP 2015, Companies Act 2006, taxation legislation and data protection, anti-bribery, employment, environmental and health and safety legislation; and
- we assessed the extent of compliance with these laws and regulations through making enquiries of management and inspecting legal correspondence.

We assessed the susceptibility of the charity's financial statements to material misstatement, including obtaining an understanding of how fraud might occur, by:

- making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and
- considering the internal controls in place to mitigate risks of fraud and non-compliance with laws and regulations.

To address the risk of fraud through management bias and override of controls, we:

- performed analytical procedures to identify any unusual or unexpected relationships;
- tested journal entries, particularly focused around the year-end, to identify unusual transactions;
- assessed whether judgements and assumptions made in determining the accounting estimates in the notes to the financial statements were indicative of potential bias; and
- investigated the rationale behind significant or unusual transactions.

In response to the risk of irregularities and non-compliance with laws and regulations, we designed procedures which included, but were not limited to:

- agreeing financial statement disclosures to underlying supporting documentation;
- reading the minutes of meetings of those charged with governance;
- enquiring of management as to actual and potential litigation and claims; and
- reviewing correspondence with HMRC, relevant regulators and the charity's legal advisors.

There are inherent limitations in the audit procedures described above. We are less likely to become aware of instances of non-compliance with laws and regulations that are not closely related to events and transactions reflected in the financial statements. Also, the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at www.frc.org.uk/auditorsresponsibilities. This description forms part of our Report of the Independent Auditors.

**Report of the Independent Auditors to the Trustees of
Drug Safety Research Trust**

Use of our report

This report is made solely to the charity's trustees, as a body, in accordance with Part 4 of the Charities (Accounts and Reports) Regulations 2008. Our audit work has been undertaken so that we might state to the charity's trustees those matters we are required to state to them in an auditors' report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the charity and the charity's trustees as a body, for our audit work, for this report, or for the opinions we have formed.



Cartwrights
Chartered Accountants and Business Advisors
Statutory Auditor
Regency House
33 Wood Street
Barnet
Hertfordshire
EN5 4BE

Date: 01/06/2023

Andrew Hill FCA (Senior Statutory Auditor) for and on behalf of Cartwrights

Drug Safety Research Trust

**Statement of Financial Activities
for the Year Ended 31 December 2022**

	Notes	Unrestricted funds £	Restricted fund £	31/12/22 Total funds £	31/12/21 Total funds £
INCOME AND ENDOWMENTS FROM					
Donations and legacies	2	1,063,010	-	1,063,010	3,375,220
Investment income	3	132,385	-	132,385	149,016
Other income		713,303	-	713,303	506,826
Total		<u>1,908,698</u>	<u>-</u>	<u>1,908,698</u>	<u>4,031,062</u>
EXPENDITURE ON					
Raising funds	4	23,364	-	23,364	21,974
Charitable activities					
Direct Charitable Expenditure	5				
		1,994,174	18,780	2,012,954	2,157,209
Other		647,027	-	647,027	615,604
Total		<u>2,664,565</u>	<u>18,780</u>	<u>2,683,345</u>	<u>2,794,787</u>
Net gains/(losses) on investments		<u>(494,633)</u>	<u>-</u>	<u>(494,633)</u>	<u>230,072</u>
NET INCOME/(EXPENDITURE)		<u>(1,250,500)</u>	<u>(18,780)</u>	<u>(1,269,280)</u>	<u>1,466,347</u>
RECONCILIATION OF FUNDS					
Total funds brought forward		9,564,348	471,840	10,036,188	8,569,841
TOTAL FUNDS CARRIED FORWARD		<u><u>8,313,848</u></u>	<u><u>453,060</u></u>	<u><u>8,766,908</u></u>	<u><u>10,036,188</u></u>

The notes form part of these financial statements

Drug Safety Research Trust

**Statement of Financial Position
31 December 2022**

	Notes	Unrestricted funds £	Restricted fund £	31/12/22 Total funds £	31/12/21 Total funds £
FIXED ASSETS					
Tangible assets	9	19,980	453,060	473,040	493,950
Investments	10	3,831,919	-	3,831,919	4,224,909
		<u>3,851,899</u>	<u>453,060</u>	<u>4,304,959</u>	<u>4,718,859</u>
CURRENT ASSETS					
Debtors	11	235,427	-	235,427	344,120
Cash at bank		4,348,571	-	4,348,571	5,104,031
		<u>4,583,998</u>	<u>-</u>	<u>4,583,998</u>	<u>5,448,151</u>
CREDITORS					
Amounts falling due within one year	12	(122,049)	-	(122,049)	(130,822)
NET CURRENT ASSETS					
		<u>4,461,949</u>	<u>-</u>	<u>4,461,949</u>	<u>5,317,329</u>
TOTAL ASSETS LESS CURRENT LIABILITIES					
		<u>8,313,848</u>	<u>453,060</u>	<u>8,766,908</u>	<u>10,036,188</u>
NET ASSETS					
		<u>8,313,848</u>	<u>453,060</u>	<u>8,766,908</u>	<u>10,036,188</u>
FUNDS					
	13				
Unrestricted funds				8,313,848	9,564,348
Restricted funds				453,060	471,840
TOTAL FUNDS					
				<u>8,766,908</u>	<u>10,036,188</u>

The financial statements were approved by the Board of Trustees and authorised for issue on 30 MAY 2023 and were signed on its behalf by:



.....
K R Paterson MB ChB FRCP FFPM - Trustee

The notes form part of these financial statements

Drug Safety Research Trust

**Statement of Cash Flows
for the Year Ended 31 December 2022**

	Notes	31/12/22 £	31/12/21 £
Cash flows from operating activities			
Cash generated from operations	1	(240,785)	703,704
Net cash (used in)/provided by operating activities		<u>(240,785)</u>	<u>703,704</u>
Cash flows from investing activities			
Purchase of tangible fixed assets		(9,429)	(8,614)
Purchase of fixed asset investments		(101,643)	(575,793)
Sale of fixed asset investments		(494,633)	230,072
Interest received		27,364	13,304
Dividends received		63,666	49,452
Net cash used in investing activities		<u>(514,675)</u>	<u>(291,579)</u>
Change in cash and cash equivalents in the reporting period		<u>(755,460)</u>	<u>412,125</u>
Cash and cash equivalents at the beginning of the reporting period		<u>5,104,031</u>	<u>4,691,906</u>
Cash and cash equivalents at the end of the reporting period		<u><u>4,348,571</u></u>	<u><u>5,104,031</u></u>

The notes form part of these financial statements

Drug Safety Research Trust

**Notes to the Statement of Cash Flows
for the Year Ended 31 December 2022**

1. RECONCILIATION OF NET (EXPENDITURE)/INCOME TO NET CASH FLOW FROM OPERATING ACTIVITIES

	31/12/22	31/12/21
	£	£
Net (expenditure)/income for the reporting period (as per the Statement of Financial Activities)	(1,269,280)	1,466,347
Adjustments for:		
Depreciation charges	30,339	33,547
Losses/(gain) on investments	989,266	(460,144)
Interest received	(27,364)	(13,304)
Dividends received	(63,666)	(49,452)
Decrease/(increase) in debtors	108,693	(332,629)
(Decrease)/increase in creditors	(8,773)	59,339
	<u>(240,785)</u>	<u>703,704</u>

2. ANALYSIS OF CHANGES IN NET FUNDS

	At 1/1/22	Cash flow	At 31/12/22
	£	£	£
Net cash			
Cash at bank	5,104,031	(755,460)	4,348,571
	<u>5,104,031</u>	<u>(755,460)</u>	<u>4,348,571</u>
Total	<u>5,104,031</u>	<u>(755,460)</u>	<u>4,348,571</u>

The notes form part of these financial statements

Drug Safety Research Trust

Notes to the Financial Statements for the Year Ended 31 December 2022

1. ACCOUNTING POLICIES

Basis of preparing the financial statements

The financial statements of the charity, which is a public benefit entity under FRS 102, have been prepared in accordance with the Charities SORP (FRS 102) 'Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019)', Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland' and the Charities Act 2011. The financial statements have been prepared under the historical cost convention, with the exception of investments which are included at market value, as modified by the revaluation of certain assets.

Income

All income is recognised in the Statement of Financial Activities once the charity has entitlement to the funds, it is probable that the income will be received and the amount can be measured reliably.

For donations to be recognised the charity will have been notified of the amounts and the settlement date in writing. If there are conditions attached to the donation and this requires a level of performance before entitlement can be obtained then income is deferred until those conditions are fully met or the fulfilment of those conditions is within the control of the charity and it is probable that they will be fulfilled.

Investment income is earned through holding assets for investment purposes such as shares. It includes dividends, interest and unrealised gains or losses on shares held. Where it is not practicable to identify investment management costs incurred within a scheme with reasonable accuracy the investment income is reported net of these costs. It is included when the amount can be measured reliably. Interest income is recognised using the effective interest method and dividend income is recognised as the charity's right to receive payment is established.

Other income represents management fees charged and donations received from the Trust's connected trading entity, DSRU Education and Research Limited. Management fees are included when charged and donations when received. Due to the connected nature of this entity, donation income is recorded within other income rather than within donations and legacy income in the Statement of Financial Activities.

Expenditure

Liabilities are recognised as expenditure as soon as there is a legal or constructive obligation committing the charity to that expenditure, it is probable that a transfer of economic benefits will be required in settlement and the amount of the obligation can be measured reliably. Expenditure is accounted for on an accruals basis and has been classified under headings that aggregate all cost related to the category. Where costs cannot be directly attributed to particular headings they have been allocated to activities on a basis consistent with the use of resources.

Raising funds

Costs of raising funds represent investment manager costs incurred in dealing with the listed investment portfolio

Charitable activities

Expenditure on charitable activities includes the direct costs of carrying out and performing the studies and evaluations of medicines in order to meet the Trust's objectives and aims.

Allocation and apportionment of costs

Support costs are those that assist the work of the charity but do not directly represent charitable activities and include office costs, governance costs, administrative payroll costs. They are incurred directly in support of expenditure on the objects of the charity and include project management carried out at Headquarters. Where support costs cannot be directly attributed to particular headings they have been allocated to cost of raising funds and expenditure on charitable activities on a basis consistent with use of the resources. Premises overheads have been allocated on an insert detail basis and other overheads have been allocated on an insert detail basis..

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2022

1. ACCOUNTING POLICIES - continued

Tangible fixed assets

Tangible fixed assets other than freehold land are stated at cost less depreciation. Depreciation is provided at rates calculated to write off the cost less estimated residual value of each asset over its expected useful life, as follows:

Freehold land	Not depreciated
Freehold buildings	2% Straight line on cost
Plant and machinery	20% straight line on cost
Fixtures, fittings and equipment	20% Straight line on cost
Motor vehicles	20% Straight line on cost

Taxation

The charity is exempt from tax on its charitable activities.

Fund accounting

Unrestricted funds can be used in accordance with the charitable objectives at the discretion of the trustees.

Restricted funds can only be used for particular restricted purposes within the objects of the charity. Restrictions arise when specified by the donor or when funds are raised for particular restricted purposes.

Further explanation of the nature and purpose of each fund is included in the notes to the financial statements.

Pension costs and other post-retirement benefits

The charity operates a defined contribution pension scheme. Contributions payable to the charity's pension scheme are charged to the Statement of Financial Activities in the period to which they relate.

Accumulated funds

The restricted fund represents the net book values of the freehold land and buildings at Bursledon Hall, Southampton. The fund balances are reduced by the depreciation charged on the buildings.

Unrestricted Funds

Unrestricted funds represent donations and other incoming resources receivable or generated for the objects of the charity without further specified purpose and are available as general funds.

Investments

Fixed asset investments are stated at market value.

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2022**

2. DONATIONS AND LEGACIES

	Unrestricted funds £	Restricted funds £	31/12/22 Total funds £	31/12/21 Total funds £
Donations	1,063,010	-	1,063,010	3,375,220

3. INVESTMENT INCOME

	Unrestricted funds £	Restricted funds £	31/12/22 Total funds £	31/12/21 Total funds £
Gain on disposal of investment	41,355	-	41,355	86,260
Listed income	63,666	-	63,666	49,452
Interest received	27,364	-	27,364	13,304
	<u>132,385</u>	<u>-</u>	<u>132,385</u>	<u>149,016</u>

4. RAISING FUNDS

Investment management costs

	Unrestricted funds £	Restricted funds £	31/12/22 Total funds £	31/12/21 Total funds £
Fund manager costs	23,364	-	23,364	21,974

5. CHARITABLE ACTIVITIES COSTS

	Direct Costs £
Direct Charitable Expenditure	
	<u>2,012,954</u>

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2022**

6. SUPPORT COSTS

	Governance costs
	£
Other resources expended	<u>647,027</u>

Support costs, included in the above, are as follows:

	31/12/22 Other resources expended £	31/12/21 Total activities £
Wages	169,322	167,080
Social security	154,469	134,680
Pensions	65,396	62,210
Auditors' remuneration	10,773	11,368
Rates and water	10,559	10,598
Insurance	19,718	17,634
Light and heat	22,597	16,242
Telephone and fax	8,627	17,409
PPS	3,740	11,251
Sundries	3,284	2,880
Repairs and maintenance	12,718	12,085
Staff training	-	8,660
Staff medical costs	11,080	10,140
Motor and travel expenses	18,690	5,837
Computer costs	15,567	12,715
Subscriptions	49,861	30,260
Bank charges	1,376	1,365
Marketing costs	35,690	47,063
Equipment hire	3,221	2,580
Depreciation of tangible fixed assets	30,339	33,547
	<u>647,027</u>	<u>615,604</u>

7. TRUSTEES' REMUNERATION AND BENEFITS

There were no trustees' remuneration or other benefits for the year ended 31 December 2022 nor for the year ended 31 December 2021.

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2022**

7. TRUSTEES' REMUNERATION AND BENEFITS - continued

Trustees' expenses

Travelling expenses amounting to £0 (2021 - £0) were reimbursed to the trustees for attending meetings.

Trustees indemnity insurance payable during the year amounted to £6,660 (2021: £6,858).

8. STAFF COSTS

The average number of employees during the year was 33 (2021 - 30).

The number of employees whose annual emoluments were £60,000 or more were:

	2022	2021
£230,001 - £300,000	1	-
£220,001 - £230,000	-	1
£60,001 - £70,000	5	1

9. TANGIBLE FIXED ASSETS

	Freehold property £	Plant and machinery £	Fixtures and fittings £	Computer system £	Totals £
COST					
At 1 January 2022	941,000	168,940	66,368	57,036	1,233,344
Additions	-	9,429	-	-	9,429
At 31 December 2022	<u>941,000</u>	<u>178,369</u>	<u>66,368</u>	<u>57,036</u>	<u>1,242,773</u>
DEPRECIATION					
At 1 January 2022	469,160	153,403	59,795	57,036	739,394
Charge for year	18,780	9,036	2,523	-	30,339
At 31 December 2022	<u>487,940</u>	<u>162,439</u>	<u>62,318</u>	<u>57,036</u>	<u>769,733</u>
NET BOOK VALUE					
At 31 December 2022	<u>453,060</u>	<u>15,930</u>	<u>4,050</u>	<u>-</u>	<u>473,040</u>
At 31 December 2021	<u>471,840</u>	<u>15,537</u>	<u>6,573</u>	<u>-</u>	<u>493,950</u>

The freehold property was last revalued on 20 December 1999 by Messrs Daniells Harison, Chartered Surveyors, on the basis of open market value for current use. The freehold land and buildings valuation has not been updated since 1999. Under the transitional relief provisions under FRS 102, this value has been treated as the deemed cost in these financial statements. The estimated market value as at the balance sheet date is in excess of £4 million.

Comparable historical cost for the land and buildings included at valuation:

	2022 £	2021 £
Cost	1,487,614	1,487,614
Accumulated Depreciation	487,940	469,160
At year end	<u>999,674</u>	<u>1,018,454</u>

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2022**

9. TANGIBLE FIXED ASSETS - continued

All other tangible fixed assets are stated at historical cost.

10. FIXED ASSET INVESTMENTS

	Listed investments £
MARKET VALUE	
At 1 January 2022	4,224,909
Additions	101,643
Revaluations	(494,633)
At 31 December 2022	<u>3,831,919</u>
NET BOOK VALUE	
At 31 December 2022	<u>3,831,919</u>
At 31 December 2021	<u>4,224,909</u>

There were no investment assets outside the UK.

Cost or valuation at 31 December 2022 is represented by:

	Listed investments £
Valuation in 2022	<u>3,831,919</u>

Net additions at cost represent investment income reinvested at source in the relevant funds held.

11. DEBTORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	31/12/22 £	31/12/21 £
Trade debtors	202,409	312,686
Prepayments and accrued income	33,018	31,434
	<u>235,427</u>	<u>344,120</u>

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2022**

12. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	31/12/22	31/12/21
	£	£
Trade creditors	27,647	23,881
Taxation and social security	48,103	75,968
Other creditors	46,299	30,973
	<u>122,049</u>	<u>130,822</u>

13. MOVEMENT IN FUNDS

	At 1/1/22	Net movement in funds	At 31/12/22
	£	£	£
Unrestricted funds			
Unrestricted Fund	9,564,348	(1,250,500)	8,313,848
Restricted funds			
Restricted Fund	471,840	(18,780)	453,060
TOTAL FUNDS	<u>10,036,188</u>	<u>(1,269,280)</u>	<u>8,766,908</u>

Net movement in funds, included in the above are as follows:

	Incoming resources	Resources expended	Gains and losses	Movement in funds
	£	£	£	£
Unrestricted funds				
Unrestricted Fund	1,908,698	(2,664,565)	(494,633)	(1,250,500)
Restricted funds				
Restricted Fund	-	(18,780)	-	(18,780)
TOTAL FUNDS	<u>1,908,698</u>	<u>(2,683,345)</u>	<u>(494,633)</u>	<u>(1,269,280)</u>

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2022**

13. MOVEMENT IN FUNDS - continued

Comparatives for movement in funds

	At 1/1/21 £	Net movement in funds £	At 31/12/21 £
Unrestricted funds			
Unrestricted Fund	8,079,221	1,485,127	9,564,348
Restricted funds			
Restricted Fund	490,620	(18,780)	471,840
TOTAL FUNDS	<u>8,569,841</u>	<u>1,466,347</u>	<u>10,036,188</u>

Comparative net movement in funds, included in the above are as follows:

	Incoming resources £	Resources expended £	Gains and losses £	Movement in funds £
Unrestricted funds				
Unrestricted Fund	4,031,062	(2,776,007)	230,072	1,485,127
Restricted funds				
Restricted Fund	-	(18,780)	-	(18,780)
TOTAL FUNDS	<u>4,031,062</u>	<u>(2,794,787)</u>	<u>230,072</u>	<u>1,466,347</u>

14. EMPLOYEE BENEFIT OBLIGATIONS

The company operates a defined contribution pension scheme. The assets of the scheme are held separately from those of the company in an independently administered fund. The pension cost charge represents contributions payable by the company to the fund. These amounted to £65,396 (2021 - £62,210). Contributions totalling £9,351 (2021 - £25,119) were payable to the fund at the year end and are included in creditors.

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2022

15. RELATED PARTY DISCLOSURES

Other income includes the following income received from DSRU Education and Research Trust, a company limited by guarantee, which is controlled by the Charity and in which Professor Saad Shakir is sole company director. During the year:

Management fees totalling £78,000 (2021: £78,000) were charged to the company for use of shared premises and administrative resources;

Salary recharges totalling £35,353 (2021: 33,276) were made to the company for the use of shared staff; and

A donation of £599,950 (2021: £395,550) was received from the company. The value of the donation each year is determined such that the company reduces its profits chargeable to tax to £nil each year.

Drug Safety Research Trust

**Detailed Statement of Financial Activities
for the Year Ended 31 December 2022**

	31/12/22	31/12/21
	£	£
INCOME AND ENDOWMENTS		
Donations and legacies		
Donations	1,063,010	3,375,220
Investment income		
Gain on disposal of investment	41,355	86,260
Listed income	63,666	49,452
Interest received	27,364	13,304
	<hr/>	<hr/>
	132,385	149,016
Other income		
Other income	713,303	506,826
	<hr/>	<hr/>
Total incoming resources	1,908,698	4,031,062
EXPENDITURE		
Investment management costs		
Fund manager costs	23,364	21,974
Charitable activities		
Wages - direct	1,161,761	1,059,361
General Practitioner costs	51,932	149,555
Other direct costs	799,261	948,293
	<hr/>	<hr/>
	2,012,954	2,157,209
Support costs		
Governance costs		
Wages	169,322	167,080
Social security	154,469	134,680
Pensions	65,396	62,210
Auditors' remuneration	10,773	11,368
Rates and water	10,559	10,598
Insurance	19,718	17,634
Light and heat	22,597	16,242
Telephone and fax	8,627	17,409
PPS	3,740	11,251
Sundries	3,284	2,880
Repairs and maintenance	12,718	12,085
Staff training	-	8,660
Carried forward	481,203	472,097

This page does not form part of the statutory financial statements

Drug Safety Research Trust**Detailed Statement of Financial Activities
for the Year Ended 31 December 2022**

	31/12/22	31/12/21
	£	£
Governance costs		
Brought forward	481,203	472,097
Staff medical costs	11,080	10,140
Motor and travel expenses	18,690	5,837
Computer costs	15,567	12,715
Subscriptions	49,861	30,260
Bank charges	1,376	1,365
Marketing costs	35,690	47,063
Equipment hire	3,221	2,580
Depreciation of tangible fixed assets	30,339	33,547
	<u>647,027</u>	<u>615,604</u>
Total resources expended	<u>2,683,345</u>	<u>2,794,787</u>
Net (expenditure)/income before gains and losses	(774,647)	1,236,275
Net losses on investments		
Net gains / losses on investments	<u>(494,633)</u>	<u>230,072</u>
Net (expenditure)/income	<u><u>(1,269,280)</u></u>	<u><u>1,466,347</u></u>

This page does not form part of the statutory financial statements

THE DRUG SAFETY RESEARCH TRUST

England & Wales - Charity number 327206

Accounts

REGISTERED CHARITY NUMBER: 327206

**Trustees' Report and
Audited Financial Statements for the Year Ended 31 December 2021
for
Drug Safety Research Trust**



Drug Safety Research Trust

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Drug Safety Research Trust

**Reference and Administrative Details
for the Year Ended 31 December 2021**

TRUSTEES

Professor Kenneth Ross Paterson MB ChB FRCP FFPM FBPhS (Chairman)
Professor John Camm QHP BSc MD FRCP FESC FACC FAHA FCGC CSTJ
Professor Martin Vessey CBE MD FRCP FRCOG FRCGP FFPH FMedSci FRS
Professor Allan Hunter Young MB, ChB, MPhil, PhD, FRCPC, FRCPsych
Professor Isla Mackenzie MB ChB PhD PGCertMedEd FRCP Edin FBPhS FBIHS

DIRECTOR

Professor Saad Shakir MB ChB LRCP&S FRCP FFPM FISPE MRCPG

PRINCIPAL ADDRESS

Bursledon Hall
Blundell Lane
Southampton
SO31 1AA

**REGISTERED CHARITY
NUMBER**

327206

INDEPENDENT AUDITORS

Cartwrights
Chartered Accountants and Business Advisors
Statutory Auditor
Regency House
33 Wood Street
Barnet
Hertfordshire
EN5 4BE

PROFESSIONAL ADVISERS

Solicitors
Paris, Smith & Randall
1 London Road
Southampton
SO15 2AE

Investment advisers
Investec Wealth and Investment Limited
30 Gresham Street
London
EC2V 7QN

PRINCIPAL BANKERS

Lloyds Bank plc
92-94 Above Bar Street
Southampton
SO14 7DT

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

The trustees present their report with the financial statements of the charity for the year ended 31 December 2021. The trustees have adopted the provisions of Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019).

OBJECTIVES AND ACTIVITIES

Objectives and aims

The Trust by way of its operational unit, the DSRU, undertakes all forms of studies and evaluations of the safety of medicines for the public benefit, including methodological research to improve existing methods including:

1. Studies to examine the safety of medicines, including new medicines, new formulations for existing medicines and when medicines are used for new indications or in new populations, or when safety issues or questions about the use, benefit-risk balance or effectiveness of medicines arise. Frequently such DSRU studies are part of risk management plans for medicines which are now statutory requirements in the EU.
2. Studies on established medicines when safety, scientific, utilisation or regulatory issues, questions, enquiries or needs for submissions arise. The issues include risk management & minimisation and methodological questions. The studies can be part of the UK and the EU regulatory requirements for risk management of medicines, though not exclusively.
3. Conducting studies to address specific safety, public health, scientific, benefit-risk balance of medicines and vaccines, utilisation and usage and regulatory issues or concerns.
4. Conducting utilisation studies for medicines and vaccines to enable understanding the use and effects of products on the healthcare system and behaviours and responses of patients and healthcare professionals.
5. Use of healthcare databases to conduct drug safety studies.
6. Establishing registries to conduct safety and utilisation studies.
7. Working with doctors to undertake studies to examine specific safety questions and medical health research networks.
8. Exploring the application of new methods such as clinical trials or database research, as well as other appropriate research methods, to understand the safety of medicines.
9. Conducting methodological research and pharmacovigilance and pharmacoepidemiology.
10. Undertaking reviews, systematic reviews, meta-analyses or benefit-risk studies to answer drug safety and drug utilisation questions.
11. Establishing research entities for studying and communicating methodological issues in pharmacovigilance and pharmacovigilance and drug safety issues
12. Lead or participate in national and international research networks and scientific collaborative projects.

We continue to monitor developments in the UK relationship with the EU and make adjustments to our systems as appropriate to address relevant issues arising from these changes. In this regard the Trust has already opened a sub-office in Dublin to maintain and develop our links with the EU following the UK's severance of membership of the EU in 2020.

The Director keeps in regular contact with the Regulatory Agencies and our European colleagues to obtain information in order to shape our strategy and policy, particularly on matters related to the impact of Brexit on medicines regulations and medical research.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

OBJECTIVES AND ACTIVITIES

Significant activities

The DSRU provides advice, education and training in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines. As one of the main providers of training and education in pharmacovigilance in Europe, its activities include:

1. Providing a range of training courses in pharmacovigilance and pharmacoepidemiology. The DSRU currently provides 17 courses per year, including academically endorsed higher education in collaboration with University of Portsmouth for Postgraduate Certificate, Diploma and a Master's degree in Pharmacovigilance and with the Faculty of Pharmaceutical Medicine for providing Pharmaceutical Medicine Specialty Training (PMST) for doctors specialising in pharmaceutical medicine.
2. Providing external training and education when required.
3. Keeping up with technological progress the DSRU intends to periodically evaluate options such as providing distance learning and other internet based educational methods.
4. Arranging national and international conferences in pharmacovigilance and pharmacoepidemiology.
5. Providing postgraduate teaching and research opportunities at all levels including MSc and PhD students.
6. Supporting postgraduate students who wish to undertake research at the DSRU
7. Providing training in pharmacovigilance and pharmacoepidemiology for pharmaceutical physicians. The DSRU has been selected by the Faculty of Pharmaceutical Medicine to provide Pharmaceutical Medicine Specialty Training (PMST) training in pharmacovigilance in the UK.
8. Supporting training and scientific communications on the safety of medicines in the UK and internationally.
9. Providing advice on matters related to the safety of medicines.
10. Producing newsletters and internet communications to general practitioners on matters to do with drug safety.
11. Providing information on drug safety which can be accessed by everyone on the DSRU website.

Routinely, reports on the results of studies are sent to the Medicines and Healthcare Products Regulatory Authority (MHRA) (an executive agency of the Department of Health) and to the European Medicines Agency (EMA) and other Regulatory Authorities in Europe to assist them in their regulatory and monitoring activities of medicines. The DSRU sends reports of its studies to Marketing Authorisation Holders of medicines and vaccines and also publishes findings of its work in scientific journals and at national and international conferences, newsletters and on its website.

Progress of the scientific work of the Unit was satisfactory throughout 2021 extending the breadth of activity to include research projects and collaborations other than Modified Prescription-Event Monitoring (MPeM). These include specialist and hospital-based studies (SCeMs), systematic reviews, registries, structured benefit-risk evaluation, drug utilisation projects and methodological research. In addition, our programme of activities has extended to include collaborating with a broad range of doctors in England through Health Research Networks from differing specialities as well as collaborating with colleagues in Europe. The policy to extend the range of scientific activities, as funding allows, will continue.

Applications for funding from grant-giving bodies, including the Department of Health Targeted Research Programme and other bodies such as the Medical Research Council (MRC), the Wellcome Trust, pharmaceutical companies and European initiatives, e.g. the European Commission, will continue as and when calls are advertised. The DSRU continues to function as one of the leading Units in the field of monitoring and studying the safety of medicines both in the UK and internationally, as well as being a leading organisation in teaching and training in these fields.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

OBJECTIVES AND ACTIVITIES

The DSRU has a long-standing partnership with the NHS Rx Services to receive prescription data that are necessary to conduct Modified Prescription-Event Monitoring studies to improve the understanding of the safety of new drugs used in the general population. This partnership has the support of the Department of Health and senior staff at NHS Rx Services.

Since application for Section 251 exemption of the NHS 2006 Act became a requirement, the Trust has applied annually to the Confidentiality Advisory Group (CAG) of the Health Research Authority for approval to use patient data without consent. Application was again made in 2021 and was successful.

The formal collaborative partnership programme agreement, required to develop the partnership with the NHS Rx Services, to supply improved prescription data is in place and we continue to maintain good communications. In the unlikely situation that the DSRU ceases to receive data for whatever reason from the NHS Rx Services, the DSRU is committed to continue its work on studying the safety of medicines by other methods and providing education and training in pharmacovigilance and drug safety.

The main objectives of the Unit for the next year are:

1. To continue the monitoring and research programme on the safety and risk management of vaccines and medicinal products for the treatment COVID-19
2. To undertake all forms of studies and evaluations of the safety and benefit-risk of medicines and vaccines alone or in collaboration with other organisations
3. To plan and support organisations to implement risk minimisation measures for medicines and vaccines
4. To use its studies to support risk management, risk minimisation and monitoring the effectiveness of risk minimisation and utilisation of medicines and vaccines
5. To conduct studies to understand drug safety issues
6. To conduct studies to understand the utilisation (use) and effects of medicines and vaccines
7. To continue its scientific work in methodological aspects of drug safety including leading or participating in national and international collaborative projects
8. To continue its activities in advice, education and training in pharmacovigilance and pharmacoepidemiology
9. To consolidate its scientific communications programme such as the DSRU international pharmacovigilance observatory to inform both the medical/scientific communities and the public about important pharmacovigilance issues
10. To continue to try to secure sufficient funding from different sources (public and private) to enable the continuation and growth of the charity's activities

Public benefit

The Trustees confirm that the Charity Commission's general guidance on public benefit has been considered in relation to the objectives of the Charity.

The objectives, activities, performance and achievement sections of this report clearly set out the activities which the charity undertakes for public benefit. The Trustees confirm that they have complied with their duty in Section 4 of the Charities Act 2006 to have due regard to public benefits guidance published by the Charities Commission in determining the activities undertaken by the Charity.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

ACHIEVEMENT AND PERFORMANCE

Charitable activities

The successful annual submission and subsequent approval and support of the Ethics and Confidentiality Committee of the Confidentiality Advisory Group (CAG) of the Health Research Authority for Section 251 exemption under the NHS Act 2006 was achieved for the twelfth year running.

The academically endorsed higher educational training in collaboration with the University of Portsmouth for Certificate, Diploma and Masters degree in Pharmacovigilance continued, with 22 students currently enrolled at the end of the year.

Eleven scientific papers were published in medical literature. Four oral and poster presentations on the results of studies were given by the Director and Research staff at national and international medical and scientific conferences. One Vaccine Active Safety Surveillance study, one Safety Profile Summary Report and six Spontaneous Data Reports were completed during 2021 as well as the provision of pharmacovigilance consultancy support to pharmaceutical companies.

Education and Professional Capability

The educational training of staff has been maintained, including continuing professional development. In addition, the DSRU has provided advice on safety of medicines issues.

Teaching & Education

The Director taught at an MSc Course at Oxford University. In addition, teaching and presenting at national and international scientific meetings continued by both the Director and senior scientific staff enabling the scientific profile of the Unit and its work in public health and drug safety to be maintained.

The DSRU and staff at the DSRU have provided training for general practitioners on effective and safe prescribing of medicines.

Training Courses for Pharmaceutical Medicine Speciality Training

The DSRU continues to deliver teaching courses in pharmacovigilance, providing training on drug safety modules of Pharmaceutical Medicine Specialty Training (PMST), for pharmaceutical physicians on behalf of the Faculty of Pharmaceutical Medicine, Royal College of Physicians. Eight students attended these modules during the year.

Partners and Stakeholders

Universities of Portsmouth

Collaborations with the University of Portsmouth on joint studentships and joint training continue.

Regulatory Agencies

Close links were maintained throughout the year with the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) with regular reports on safety issues submitted, contributing to the better understanding of the safety of a number of important medicinal products. The DSRU is a member of the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP), a project led by the European Medicines Agency and developed in collaboration with European experts in the fields of pharmacoepidemiology and pharmacovigilance. Senior staff of the DSRU regularly participate in meetings of the ENCePP network group.

VAC4EU

The DSRU is a member of VAC4EU which is a collaborative network of 46 units across Europe which conduct studies on the safety and effectiveness of vaccines. The network is led by Professor Miriam Sturkenboom (the University of Utrecht in the Netherlands). The DSRU is conducting three studies on COVID-19 vaccines in collaboration with members of VAC4EU. The DSRU is using Clinical Practice Research Datalink (CPRD), the leading resource in the UK of primary care clinical data to conduct the studies on COVID-19 vaccines by AstraZeneca, Pfizer and Moderna, while our collaborators are using databases in a number of European countries. We have been asked recently to join another multi-centre study on myocarditis and pericarditis with the Pfizer vaccine using CPRD.

Lareb

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

The DSRU is running the UK arm of the Covid Vaccine Monitor Study, a European-wide study organised by the Netherlands Pharmacovigilance Centre, Lareb. In this study a web app is used to monitor the safety of all COVID-19 vaccines amongst vaccinees in seven European countries. The aims of the study are to generate incidence rates of patient-reported ADRs for each COVID-19 vaccine brand in near real time and to describe differences in those incidence rates between different vaccine batches used across the participating countries. EU work package partners are using anonymised, aggregated data from all countries to produce a dashboard for the monitoring of side effects and signal detection.

International scientific leadership collaboration

The DSRU is leading an International Working Group (IWG) on Signal Detection and Management in Pharmacovigilance. The Group includes some of the best experts in the world in this field. The objective is to examine the impact of new developments in biomedical sciences on signal detection and management in pharmacovigilance. Such developments include artificial intelligence and machine thinking, the use of big data, the application of genetic knowledge in detecting and evaluating adverse drug reactions. The work of the IWG was interrupted for nearly two years because of the COVID-19 pandemic. The DSRU is working now to restart its activities with broader objectives which are to address new developments in pharmacovigilance and pharmacoepidemiology.

Investment performance

The Trust's strategy to invest whenever possible to offset for leaner years when donations are reduced, will be maintained. Full details of investment income and performance can be found in the notes to the financial statements.

Special investment powers of the Trustees

The Trust has undertaken investment in equities and bonds through Investec Wealth & Investment Ltd. In order to monitor the investment portfolio performance, two Trustees and the Director act as a sub-committee. This group, on behalf of the Board of Trustees, deals with all matters relating to the investment portfolio and meets with representatives of Investec Wealth & Investment Ltd at appropriate intervals. It is the policy of the Board of Trustees that no investments in the pharmaceutical, armaments or tobacco industries should be undertaken. The Trustees are satisfied that the current investment approach of the Trust is consistent with its investment needs, objectives and attitude to risk, which is to provide a balanced return on investment in the medium term with a moderate risk of capital loss.

Annually from a management perspective all other funds not immediately required from month to month for the normal running of the DSRU are routinely invested in fixed term deposit accounts to maximise return whenever possible.

FINANCIAL REVIEW

Asset cover for funds

An analysis of the assets attributable to the various funds described is set out in the notes to these financial statements. These assets are sufficient to meet the charity's obligations on a fund by fund basis.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

FUTURE PLANS

The overall strategy remains the same. As in previous years the DSRU will endeavour to ensure the preservation of Modified Prescription-Event Monitoring (MPEM) as a leading system to monitor the safety of medicines in the UK and to enhance and develop it. The Unit will continue to conduct a broad range of studies to address safety questions, including add-on studies, such as case-control and case-series studies within our databases, pharmacoepidemiological studies using other data sources and a range of study designs, appropriate clinical trials, genetic studies, drug and vaccine utilisation studies, meta-analyses, systematic reviews, benefit-risk evaluation, other study methods to understand drugs and vaccines safety, effectiveness, use and utilisation. The DSRU will conduct methodological research to contribute to advance the science and methods of Pharmacovigilance.

These are part of the DSRU's objective to explore conducting studies with different methods, including using a range of data sources that enable it to achieve its objective to monitor and study the safety of medicines.

The DSRU will continue its recent successful expansion to conduct safety studies in secondary care as well as in primary care using appropriate and improved methods to answer the relevant safety questions. The DSRU will lead or participate in national and international collaborative projects that aim to improve the methods and advance the science of studying the safety of medicines. The DSRU will further develop its scientific communications programme such as the DSRU international pharmacovigilance observatory to inform the both the medical/scientific communities and the public about important pharmacovigilance issues. The DSRU continues to monitor IT and other developments in the NHS and elsewhere to ensure that it benefits from the opportunities provided by these developments. The Unit will further develop its methods and capabilities in evidence-based pharmacovigilance and risk management and maintain its place as a leading unit in providing advice, training and education in pharmacovigilance and drug safety.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Governing document

The Trust is governed by a charitable Trust Deed established on 23 July 1986 with a Board of Trustees five in number. The Mission of the Trust remains to monitor, study and communicate the safety of medicines independent from both Government and industry. The Trust by way of its operational unit, the Drug Safety Research Unit (DSRU), undertakes all forms of studies and evaluations on the safety of medicines. The DSRU provides advice, training and education in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines.

As an independent registered medical charity, its aim is to achieve the highest possible scientific and ethical standards by putting the interests of patients first and to work with integrity and fairness with all partners.

Recruitment and appointment of new trustees

As a charity specialising in drug safety, the Trustees are identified for their expertise in areas which include drug regulation, epidemiology and medical statistics, experimental medicine and pharmacovigilance. Once appointed, the Trust ensures that any training required by the Trustees is provided to enable them to fulfil their role.

Organisational structure

The Trust employs a Director, Professor Saad Shakir, assisted by scientific, professional and administrative staff to conduct its day-to-day activities, ensuring that the charity's objectives are implemented. The Trust also retains the services of appropriate advisers and consultants depending upon the nature of the tasks required. During 2021 the average number of staff employed for the year was 28. In addition, nineteen consultants were engaged, to advise and assist with additional medical/research input, IT and data protection, PR/advertising and property planning matters.

Induction and training of new trustees

The Trustees acknowledge their responsibilities as set out on the statement of "Trustees responsibilities".

Changes to the Board of Trustees

There have been no changes during 2021.

Drug Safety Research Trust

**Trustees' Report
for the Year Ended 31 December 2021**

STRUCTURE, GOVERNANCE AND MANAGEMENT

Risk management

The Trustees have a duty to identify and review the risks to which the Charity is exposed and to ensure appropriate controls are in place to provide reasonable assurance against fraud and error.

The Trustees examine the major strategic, business and operational risks and confirm that systems are established to enable regular reports to be produced, so that necessary steps can be taken to control or lessen these risks. The variability of the funding of the Trust made it necessary to put in place processes to ensure that staff felt secure and motivated.

A Disaster Recovery Plan for the DSRU has been designed and completed. The plan is secured in off-site storage within a data safe.

Approved by order of the board of trustees on 16 Jan 2022 and signed on its behalf by:



.....
Professor K R Paterson MB ChB FRCP FFPM - Trustee

Drug Safety Research Trust

Statement of Trustees' Responsibilities for the Year Ended 31 December 2021

The trustees are responsible for preparing the Trustees' Report and the accounts in accordance with applicable law and Financial Reporting Standards (FRS102).

The law applicable to charities in England and Wales requires the trustees to prepare Accounts for each financial year which give a true and fair view of the charity's financial activities during the year and of its financial position at the end of the year (unless the charity is entitled to prepare accounts on the alternative receipts and payments basis).

In preparing accounts giving a true and fair view, the trustees should follow best practice and:

- Select suitable accounting policies and then apply them consistently;
- State whether applicable accounting standards and statements of recommended practice have been followed, subject to any departures and explained in the accounts.
- make judgements and estimates that are reasonable and prudent;
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the charity will continue in business.

The trustees are responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the charity and to enable them to ensure that the financial statements comply with the applicable law. They are also responsible for safeguarding the assets of the charity and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Opinion

We have audited the financial statements of Drug Safety Research Trust (the 'charity') for the year ended 31 December 2021 which comprise the Statement of Financial Activities, the Statement of Financial Position, the Statement of Cash Flows and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice), including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'.

In our opinion the financial statements:

- give a true and fair view of the state of the charity's affairs as at 31 December 2021 and of its incoming resources and application of resources, for the year then ended;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice, including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'; and
- have been prepared in accordance with the requirements of the Charities Act 2011.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We are independent of the charity in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the trustees' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the charity's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the trustees with respect to going concern are described in the relevant sections of this report.

Other information

The trustees are responsible for the other information. The other information comprises the information included in the Annual Report, other than the financial statements and our Report of the Independent Auditors thereon.

Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Matters on which we are required to report by exception

We have nothing to report in respect of the following matters where the Charities (Accounts and Reports) Regulations 2008 requires us to report to you if, in our opinion:

- the information given in the trustees Report is inconsistent in any material respect with the financial statements; or
- sufficient accounting records have not been kept; or
- the financial statements are not in agreement with the accounting records and returns; or
- we have not received all the information and explanations we require for our audit.

**Report of the Independent Auditors to the Trustees of
Drug Safety Research Trust**

Responsibilities of trustees

As explained more fully in the Statement of Trustees' Responsibilities, the trustees are responsible for the preparation of the financial statements which give a true and fair view, and for such internal control as the trustees determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the trustees are responsible for assessing the charity's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the trustees either intend to liquidate the charity or to cease operations, or have no realistic alternative but to do so.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Our responsibilities for the audit of the financial statements

We have been appointed as auditors under Section 144 of the Charities Act 2011 and report in accordance with the Act and relevant regulations made or having effect thereunder.

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a Report of the Independent Auditors that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

We ensured that the engagement team collectively had the appropriate competence, capabilities and skills to identify or recognise non-compliance with applicable laws and regulations, and that they remained alert to instances of non-compliance throughout the audit.

Our approach to identifying and assessing the risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, was as follows:

- based on our understanding of the charity and sector, and through discussions with trustees and key management, we identified any specific laws and regulations which we considered may have a direct material effect on the financial statements or the operations of the charity, including the SORP 2015, Companies Act 2006, taxation legislation and data protection, anti-bribery, employment, environmental and health and safety legislation; and
- we assessed the extent of compliance with these laws and regulations through making enquiries of management and inspecting legal correspondence.

We assessed the susceptibility of the charity's financial statements to material misstatement, including obtaining an understanding of how fraud might occur, by:

- making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and
- considering the internal controls in place to mitigate risks of fraud and non-compliance with laws and regulations.

To address the risk of fraud through management bias and override of controls, we:

- performed analytical procedures to identify any unusual or unexpected relationships;
- tested journal entries, particularly focused around the year-end, to identify unusual transactions;
- assessed whether judgements and assumptions made in determining the accounting estimates in the notes to the financial statements were indicative of potential bias; and
- investigated the rationale behind significant or unusual transactions.

In response to the risk of irregularities and non-compliance with laws and regulations, we designed procedures which included, but were not limited to:

- agreeing financial statement disclosures to underlying supporting documentation;
- reading the minutes of meetings of those charged with governance;
- enquiring of management as to actual and potential litigation and claims; and
- reviewing correspondence with HMRC, relevant regulators and the charity's legal advisors.

There are inherent limitations in the audit procedures described above. We are less likely to become aware of instances of non-compliance with laws and regulations that are not closely related to events and transactions reflected in the financial statements. Also, the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at www.frc.org.uk/auditorsresponsibilities. This description forms part of our Report of the Independent Auditors.

**Report of the Independent Auditors to the Trustees of
Drug Safety Research Trust**

Use of our report

This report is made solely to the charity's trustees, as a body, in accordance with Part 4 of the Charities (Accounts and Reports) Regulations 2008. Our audit work has been undertaken so that we might state to the charity's trustees those matters we are required to state to them in an auditors' report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the charity and the charity's trustees as a body, for our audit work, for this report, or for the opinions we have formed.



Cartwrights
Chartered Accountants and Business Advisors
Statutory Auditor
Regency House
33 Wood Street
Barnet
Hertfordshire
EN5 4BE

Date: 17/06/2022

Andrew Hill FCA (Senior Statutory Auditor) for and on behalf of Cartwrights

Drug Safety Research Trust

**Statement of Financial Activities
for the Year Ended 31 December 2021**

	Notes	Unrestricted funds £	Restricted fund £	31/12/21 Total funds £	31/12/20 Total funds £
INCOME AND ENDOWMENTS FROM					
Donations and legacies	2	3,375,220	-	3,375,220	767,131
Investment income	3	149,016	-	149,016	111,782
Other income		506,826	-	506,826	517,181
Total		<u>4,031,062</u>	<u>-</u>	<u>4,031,062</u>	<u>1,396,094</u>
EXPENDITURE ON					
Raising funds	4	21,974	-	21,974	18,748
Charitable activities	5				
Direct Charitable Expenditure		2,157,209	-	2,157,209	1,106,830
Other		596,824	18,780	615,604	509,575
Total		<u>2,776,007</u>	<u>18,780</u>	<u>2,794,787</u>	<u>1,635,153</u>
Net gains on investments		230,072	-	230,072	193,128
NET INCOME/(EXPENDITURE)		<u>1,485,127</u>	<u>(18,780)</u>	<u>1,466,347</u>	<u>(45,931)</u>
RECONCILIATION OF FUNDS					
Total funds brought forward		8,079,221	490,620	8,569,841	8,615,772
TOTAL FUNDS CARRIED FORWARD		<u><u>9,564,348</u></u>	<u><u>471,840</u></u>	<u><u>10,036,188</u></u>	<u><u>8,569,841</u></u>

The notes form part of these financial statements

Drug Safety Research Trust

Statement of Financial Position
31 December 2021

	Notes	Unrestricted funds £	Restricted fund £	31/12/21 Total funds £	31/12/20 Total funds £
FIXED ASSETS					
Tangible assets	9	22,110	471,840	493,950	518,883
Investments	10	4,224,909	-	4,224,909	3,419,044
		<u>4,247,019</u>	<u>471,840</u>	<u>4,718,859</u>	<u>3,937,927</u>
CURRENT ASSETS					
Debtors	11	344,120	-	344,120	11,491
Cash at bank		5,104,031	-	5,104,031	4,691,906
		<u>5,448,151</u>	<u>-</u>	<u>5,448,151</u>	<u>4,703,397</u>
CREDITORS					
Amounts falling due within one year	12	(130,822)	-	(130,822)	(71,483)
		<u>5,317,329</u>	<u>-</u>	<u>5,317,329</u>	<u>4,631,914</u>
NET CURRENT ASSETS					
		<u>5,317,329</u>	<u>-</u>	<u>5,317,329</u>	<u>4,631,914</u>
TOTAL ASSETS LESS CURRENT LIABILITIES					
		<u>9,564,348</u>	<u>471,840</u>	<u>10,036,188</u>	<u>8,569,841</u>
NET ASSETS					
		<u>9,564,348</u>	<u>471,840</u>	<u>10,036,188</u>	<u>8,569,841</u>
FUNDS					
	13				
Unrestricted funds				9,564,348	8,079,221
Restricted funds				471,840	490,620
				<u>10,036,188</u>	<u>8,569,841</u>
TOTAL FUNDS					
				<u>10,036,188</u>	<u>8,569,841</u>

The financial statements were approved by the Board of Trustees and authorised for issue on 16 June 2022 and were signed on its behalf by:


K R Paterson MB ChB FRCP FFPM - Trustee

Drug Safety Research Trust

**Statement of Cash Flows
for the Year Ended 31 December 2021**

	Notes	31/12/21 £	31/12/20 £
Cash flows from operating activities			
Cash generated from operations	1	703,704	(219,881)
Net cash provided by/(used in) operating activities		<u>703,704</u>	<u>(219,881)</u>
Cash flows from investing activities			
Purchase of tangible fixed assets		(8,614)	(3,971)
Purchase of fixed asset investments		(575,793)	(853,669)
Sale of fixed asset investments		230,072	873,932
Interest received		13,304	32,622
Dividends received		49,452	48,125
Net cash (used in)/provided by investing activities		<u>(291,579)</u>	<u>97,039</u>
Change in cash and cash equivalents in the reporting period		<u>412,125</u>	<u>(122,842)</u>
Cash and cash equivalents at the beginning of the reporting period		<u>4,691,906</u>	<u>4,814,748</u>
Cash and cash equivalents at the end of the reporting period		<u><u>5,104,031</u></u>	<u><u>4,691,906</u></u>

The notes form part of these financial statements

Drug Safety Research Trust

**Notes to the Statement of Cash Flows
for the Year Ended 31 December 2021**

**1. RECONCILIATION OF NET INCOME/(EXPENDITURE) TO NET CASH FLOW FROM
OPERATING ACTIVITIES**

	31/12/21	31/12/20
	£	£
Net income/(expenditure) for the reporting period (as per the Statement of Financial Activities)	1,466,347	(45,931)
Adjustments for:		
Depreciation charges	33,547	43,002
Gain on investments	(460,144)	(284,693)
Interest received	(13,304)	(32,622)
Dividends received	(49,452)	(48,125)
(Increase)/decrease in debtors	(332,629)	154,843
Increase/(decrease) in creditors	59,339	(6,355)
Net cash provided by/(used in) operations	<u>703,704</u>	<u>(219,881)</u>

2. ANALYSIS OF CHANGES IN NET FUNDS

	At 1/1/21	Cash flow	At 31/12/21
	£	£	£
Net cash			
Cash at bank	4,691,906	412,125	5,104,031
	<u>4,691,906</u>	<u>412,125</u>	<u>5,104,031</u>
Total	<u>4,691,906</u>	<u>412,125</u>	<u>5,104,031</u>

The notes form part of these financial statements

Drug Safety Research Trust

Notes to the Financial Statements for the Year Ended 31 December 2021

1. ACCOUNTING POLICIES

Basis of preparing the financial statements

The financial statements of the charity, which is a public benefit entity under FRS 102, have been prepared in accordance with the Charities SORP (FRS 102) 'Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019)', Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland' and the Charities Act 2011. The financial statements have been prepared under the historical cost convention, with the exception of investments which are included at market value, as modified by the revaluation of certain assets.

Income

All income is recognised in the Statement of Financial Activities once the charity has entitlement to the funds, it is probable that the income will be received and the amount can be measured reliably.

For donations to be recognised the charity will have been notified of the amounts and the settlement date in writing. If there are conditions attached to the donation and this requires a level of performance before entitlement can be obtained then income is deferred until those conditions are fully met or the fulfilment of those conditions is within the control of the charity and it is probable that they will be fulfilled.

Investment income is earned through holding assets for investment purposes such as shares. It includes dividends, interest and unrealised gains or losses on shares held. Where it is not practicable to identify investment management costs incurred within a scheme with reasonable accuracy the investment income is reported net of these costs. It is included when the amount can be measured reliably. Interest income is recognised using the effective interest method and dividend income is recognised as the charity's right to receive payment is established.

Other income represents management fees charged and donations received from the Trust's connected trading entity, DSRU Education and Research Limited. Management fees are included when charged and donations when received. Due to the connected nature of this entity, donation income is recorded within other income rather than within donations and legacy income in the Statement of Financial Activities.

Expenditure

Liabilities are recognised as expenditure as soon as there is a legal or constructive obligation committing the charity to that expenditure, it is probable that a transfer of economic benefits will be required in settlement and the amount of the obligation can be measured reliably. Expenditure is accounted for on an accruals basis and has been classified under headings that aggregate all cost related to the category. Where costs cannot be directly attributed to particular headings they have been allocated to activities on a basis consistent with the use of resources.

Raising funds

Costs of raising funds represent investment manager costs incurred in dealing with the listed investment portfolio

Charitable activities

Expenditure on charitable activities includes the direct costs of carrying out and performing the studies and evaluations of medicines in order to meet the Trust's objectives and aims.

Allocation and apportionment of costs

Support costs are those that assist the work of the charity but do not directly represent charitable activities and include office costs, governance costs, administrative payroll costs. They are incurred directly in support of expenditure on the objects of the charity and include project management carried out at Headquarters. Where support costs cannot be directly attributed to particular headings they have been allocated to cost of raising funds and expenditure on charitable activities on a basis consistent with use of the resources. Premises overheads have been allocated on an insert detail basis and other overheads have been allocated on an insert detail basis..

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2021

1. ACCOUNTING POLICIES - continued

Tangible fixed assets

Depreciation is provided at the following annual rates in order to write off each asset over its estimated useful life.

Freehold property	- 2% on cost
Plant and machinery	- Straight line over 5 years
Fixtures and fittings	- Straight line over 5 years

Tangible fixed assets other than freehold land are stated at cost less depreciation. Depreciation is provided at rates calculated to write off the cost less estimated residual value of each asset over its expected useful life, as follows:

Freehold Land	Not depreciated
Freehold Building	2% Straight Line
Plant & Machinery	20% Straight Line
Fixture, Fittings & Equipment	20% Straight Line
Motor Vehicles	20% Straight Line

Taxation

The charity is exempt from tax on its charitable activities.

Fund accounting

Unrestricted funds can be used in accordance with the charitable objectives at the discretion of the trustees.

Restricted funds can only be used for particular restricted purposes within the objects of the charity. Restrictions arise when specified by the donor or when funds are raised for particular restricted purposes.

Further explanation of the nature and purpose of each fund is included in the notes to the financial statements.

Pension costs and other post-retirement benefits

The charity operates a defined contribution pension scheme. Contributions payable to the charity's pension scheme are charged to the Statement of Financial Activities in the period to which they relate.

Accumulated funds

The restricted fund represents the net book values of the freehold land and buildings at Bursledon Hall, Southampton. The fund balances are reduced by the depreciation charged on the buildings.

Unrestricted Funds

Unrestricted funds represent donations and other incoming resources receivable or generated for the objects of the charity without further specified purpose and are available as general funds.

Investments

Fixed asset investments are stated at market value.

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2021**

2. DONATIONS AND LEGACIES

	Unrestricted funds £	Restricted funds £	31/12/21 Total funds £	31/12/20 Total funds £
Donations	3,375,220	-	3,375,220	767,131

3. INVESTMENT INCOME

	Unrestricted funds £	Restricted funds £	31/12/21 Total funds £	31/12/20 Total funds £
Gain on disposal of investment	86,260	-	86,260	31,035
Listed income	49,452	-	49,452	48,125
Interest received	13,304	-	13,304	32,622
	<u>149,016</u>	<u>-</u>	<u>149,016</u>	<u>111,782</u>

4. RAISING FUNDS

Investment management costs

	Unrestricted funds £	Restricted funds £	31/12/21 Total funds £	31/12/20 Total funds £
Fund manager costs	21,974	-	21,974	18,748

5. CHARITABLE ACTIVITIES COSTS

	Direct Costs £
Direct Charitable Expenditure	
	<u>2,157,209</u>

6. SUPPORT COSTS

	Governance costs £
Other resources expended	<u>615,604</u>

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2021

6. SUPPORT COSTS - continued

Support costs, included in the above, are as follows:

	31/12/21	31/12/20
	Other resources expended £	Total activities £
Wages	167,080	147,110
Social security	134,680	102,211
Pensions	62,210	48,358
Auditors' remuneration	11,368	10,723
Rates and water	10,598	10,659
Insurance	17,634	16,432
Light and heat	16,242	14,383
Telephone and fax	17,409	6,264
PPS	11,251	933
Sundries	2,880	4,117
Repairs and maintenance	12,085	13,565
Staff training	8,660	169
Staff medical costs	10,140	9,716
Motor and travel expenses	5,837	8,174
Trustees expenses	-	34
Computer costs	12,715	12,955
Subscriptions	30,260	35,115
Bank charges	1,365	952
Marketing costs	47,063	22,320
Equipment hire	2,580	2,383
Depreciation of tangible fixed assets	33,547	43,002
	<u>615,604</u>	<u>509,575</u>

7. TRUSTEES' REMUNERATION AND BENEFITS

There were no trustees' remuneration or other benefits for the year ended 31 December 2021 nor for the year ended 31 December 2020.

Trustees' expenses

Travelling expenses amounting to £0 (2020 - £34) were reimbursed to the trustees for attending meetings.

Trustees indemnity insurance payable during the year amounted to £6,858 (2020: £6,653).

8. STAFF COSTS

The average number of employees during the year was 30 (2020 - 24).

The number of employees whose annual emoluments were £60,000 or more were:

	2021	2020
£300,001 - £310,000	-	-
£220,001 - £230,000	1	1
£60,001 - £70,000	1	1

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2021**

9. TANGIBLE FIXED ASSETS

	Freehold property £	Plant and machinery £	Fixtures and fittings £	Computer System £	Totals £
COST					
At 1 January 2021	941,000	161,910	64,784	57,036	1,224,730
Additions	-	7,030	1,584	-	8,614
At 31 December 2021	<u>941,000</u>	<u>168,940</u>	<u>66,368</u>	<u>57,036</u>	<u>1,233,344</u>
DEPRECIATION					
At 1 January 2021	450,380	144,204	55,788	55,475	705,847
Charge for year	18,780	9,199	4,007	1,561	33,547
At 31 December 2021	<u>469,160</u>	<u>153,403</u>	<u>59,795</u>	<u>57,036</u>	<u>739,394</u>
NET BOOK VALUE					
At 31 December 2021	<u>471,840</u>	<u>15,537</u>	<u>6,573</u>	<u>-</u>	<u>493,950</u>
At 31 December 2020	<u>490,620</u>	<u>17,706</u>	<u>8,996</u>	<u>1,561</u>	<u>518,883</u>

The freehold property was last revalued on 20 December 1999 by Messrs Daniells Harison, Chartered Surveyors, on the basis of open market value for current use. The freehold land and buildings valuation has not been updated since 1999. Under the transitional relief provisions under FRS 102, this value has been treated as the deemed cost in these financial statements. The estimated market value as at the balance sheet date is in excess of £4 million.

Comparable historical cost for the land and buildings included at valuation:

	2021 £	2020 £
Cost	1,487,614	1,487,614
Accumulated Depreciation	<u>469,160</u>	<u>450,380</u>
At year end	<u>1,037,234</u>	<u>1,037,234</u>

All other tangible fixed assets are stated at historical cost.

10. FIXED ASSET INVESTMENTS

	Listed investments £
MARKET VALUE	
At 1 January 2021	3,419,044
Additions	575,793
Revaluations	230,072
At 31 December 2021	<u>4,224,909</u>
NET BOOK VALUE	
At 31 December 2021	<u>4,224,909</u>
At 31 December 2020	<u>3,419,044</u>

There were no investment assets outside the UK.

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2021**

10. FIXED ASSET INVESTMENTS - continued

Cost or valuation at 31 December 2021 is represented by:

Valuation in 2021	Listed investments £
	<u>4,224,909</u>

Net acquisitions at cost represent investment income reinvested at source in the relevant funds held.

11. DEBTORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	31/12/21	31/12/20
	£	£
Trade debtors	312,686	-
Prepayments and accrued income	31,434	11,491
	<u>344,120</u>	<u>11,491</u>

12. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	31/12/21	31/12/20
	£	£
Trade creditors	23,881	-
Taxation and social security	75,968	41,533
Other creditors	30,973	29,950
	<u>130,822</u>	<u>71,483</u>

13. MOVEMENT IN FUNDS

	At 1/1/21	Net movement in funds	At 31/12/21
	£	£	£
Unrestricted funds			
Unrestricted Fund	8,079,221	1,485,127	9,564,348
Restricted funds			
Restricted Fund	490,620	(18,780)	471,840
TOTAL FUNDS	<u>8,569,841</u>	<u>1,466,347</u>	<u>10,036,188</u>

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2021**

13. MOVEMENT IN FUNDS - continued

Net movement in funds, included in the above are as follows:

	Incoming resources £	Resources expended £	Gains and losses £	Movement in funds £
Unrestricted funds				
Unrestricted Fund	4,031,062	(2,776,007)	230,072	1,485,127
Restricted funds				
Restricted Fund	-	(18,780)	-	(18,780)
TOTAL FUNDS	<u>4,031,062</u>	<u>(2,794,787)</u>	<u>230,072</u>	<u>1,466,347</u>

Comparatives for movement in funds

	At 1/1/20 £	Net movement in funds £	At 31/12/20 £
Unrestricted funds			
Unrestricted Fund	8,106,372	(27,151)	8,079,221
Restricted funds			
Restricted Fund	509,400	(18,780)	490,620
TOTAL FUNDS	<u>8,615,772</u>	<u>(45,931)</u>	<u>8,569,841</u>

Comparative net movement in funds, included in the above are as follows:

	Incoming resources £	Resources expended £	Gains and losses £	Movement in funds £
Unrestricted funds				
Unrestricted Fund	1,396,094	(1,616,373)	193,128	(27,151)
Restricted funds				
Restricted Fund	-	(18,780)	-	(18,780)
TOTAL FUNDS	<u>1,396,094</u>	<u>(1,635,153)</u>	<u>193,128</u>	<u>(45,931)</u>

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2021

13. MOVEMENT IN FUNDS - continued

A current year 12 months and prior year 12 months combined position is as follows:

	At 1/1/20 £	Net movement in funds £	At 31/12/21 £
Unrestricted funds			
Unrestricted Fund	8,106,372	1,457,976	9,564,348
Restricted funds			
Restricted Fund	509,400	(37,560)	471,840
TOTAL FUNDS	<u>8,615,772</u>	<u>1,420,416</u>	<u>10,036,188</u>

A current year 12 months and prior year 12 months combined net movement in funds, included in the above are as follows:

	Incoming resources £	Resources expended £	Gains and losses £	Movement in funds £
Unrestricted funds				
Unrestricted Fund	5,427,156	(4,392,380)	423,200	1,457,976
Restricted funds				
Restricted Fund	-	(37,560)	-	(37,560)
TOTAL FUNDS	<u>5,427,156</u>	<u>(4,429,940)</u>	<u>423,200</u>	<u>1,420,416</u>

14. EMPLOYEE BENEFIT OBLIGATIONS

The company operates a defined contribution pension scheme. The assets of the scheme are held separately from those of the company in an independently administered fund. The pension cost charge represents contributions payable by the company to the fund. These amounted to £62,210 (2020 - £48,358). Contributions totalling £14,119 (2020 - £7,991) were payable to the fund at the year end and are included in creditors.

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2021

15. RELATED PARTY DISCLOSURES

Other income includes the following income received from DSRU Education and Research Trust, a company limited by guarantee, which is controlled by the Charity and in which Professor Saad Shakir is sole company director. During the year:

Management fees totalling £78,000 (2020: £78,000) were charged to the company for use of shared premises and administrative resources;

Salary recharges totalling £33,276 (2020: 32,017) were made to the company for the use of shared staff; and

A donation of £395,550 (2020: £407,164) was received from the company. The value of the donation each year is determined such that the company reduces its profits chargeable to tax to £nil each year.

Drug Safety Research Trust**Detailed Statement of Financial Activities
for the Year Ended 31 December 2021**

	31/12/21	31/12/20
	£	£
INCOME AND ENDOWMENTS		
Donations and legacies		
Donations	3,375,220	767,131
Investment income		
Gain on disposal of investment	86,260	31,035
Listed income	49,452	48,125
Interest received	13,304	32,622
	<u>149,016</u>	<u>111,782</u>
Other income		
Other income	506,826	517,181
	<u>4,031,062</u>	<u>1,396,094</u>
EXPENDITURE		
Investment management costs		
Fund manager costs	21,974	18,748
Charitable activities		
Wages - direct	1,059,361	777,162
General Practitioner costs	149,555	(200)
Other direct costs	948,293	329,868
	<u>2,157,209</u>	<u>1,106,830</u>
Support costs		
Governance costs		
Wages	167,080	147,110
Social security	134,680	102,211
Pensions	62,210	48,358
Auditors' remuneration	11,368	10,723
Rates and water	10,598	10,659
Insurance	17,634	16,432
Light and heat	16,242	14,383
Telephone and fax	17,409	6,264
PPS	11,251	933
Sundries	2,880	4,117
Repairs and maintenance	12,085	13,565
Staff training	8,660	169
Staff medical costs	10,140	9,716
Motor and travel expenses	5,837	8,174
Trustees expenses	-	34
Computer costs	12,715	12,955
Subscriptions	30,260	35,115
Carried forward	531,049	440,918

This page does not form part of the statutory financial statements

Drug Safety Research Trust**Detailed Statement of Financial Activities
for the Year Ended 31 December 2021**

	31/12/21	31/12/20
	£	£
Governance costs		
Brought forward	531,049	440,918
Bank charges	1,365	952
Marketing costs	47,063	22,320
Equipment hire	2,580	2,383
Depreciation of tangible fixed assets	33,547	43,002
	<u>615,604</u>	<u>509,575</u>
Total resources expended	<u>2,794,787</u>	<u>1,635,153</u>
Net income/(expenditure) before gains and losses	1,236,275	(239,059)
Net losses on investments		
Net gains / losses on investments	<u>230,072</u>	<u>193,128</u>
Net income/(expenditure)	<u><u>1,466,347</u></u>	<u><u>(45,931)</u></u>

This page does not form part of the statutory financial statements

THE DRUG SAFETY RESEARCH TRUST

England & Wales - Charity number 327206

Accounts

(Spare set)

REGISTERED CHARITY NUMBER: 327206

**Trustees' Report and
Audited Financial Statements for the Year Ended 31 December 2020
for
Drug Safety Research Trust**

Drug Safety Research Trust

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Drug Safety Research Trust

**Reference and Administrative Details
for the Year Ended 31 December 2020**

TRUSTEES

Professor Kenneth Ross Paterson MB ChB FRCP FFPM FBPhS (Chairman)
Professor John Camm QHP BSc MD FRCP FESC FACC FAHA FCGC CSTJ
Professor Martin Vessey CBE MD FRCP FRCOG FRCGP FFPH FMedSci FRS
Professor Allan Hunter Young MB, ChB, MPhil, PhD, FRCPC, FRCPsych
Professor Isla Mackenzie MB ChB PhD PGCertMedEd FRCP Edin FBPhS FBIHS

DIRECTOR

Professor Saad Shakir MB ChB LRCP&S FRCP FFPM FISPE MRCP

PRINCIPAL ADDRESS

Bursledon Hall
Blundell Lane
Southampton
SO31 1AA

**REGISTERED CHARITY
NUMBER**

327206

INDEPENDENT AUDITORS

Cartwrights
Chartered Accountants and Business Advisors
Statutory Auditor
Regency House
33 Wood Street
Barnet
Hertfordshire
EN5 4BE

PROFESSIONAL ADVISERS

Solicitors
Paris, Smith & Randall
1 London Road
Southampton
SO15 2AE

Investment advisers
Investec Wealth and Investment Limited
30 Gresham Street
London
EC2V 7QN

PRINCIPAL BANKERS

Lloyds Bank plc
19-21 High Street
Southampton
SO9 7AN

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2020

The trustees present their report with the financial statements of the charity for the year ended 31 December 2020. The trustees have adopted the provisions of Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019).

OBJECTIVES AND ACTIVITIES

Objectives and aims

The Trust by way of its operational unit, the DSRU, undertakes all forms of studies and evaluations of the safety of medicines for the public benefit, including methodological research to improve existing methods including:

1. Studies to examine the safety of medicines, including new medicines, new formulations for existing medicines and when medicines are used for new indications or in new populations, or when safety issues or questions about the use, benefit-risk balance or effectiveness of medicines arise. Frequently such DSRU studies are part of risk management plans for medicines which are now statutory requirements in the EU.
2. Studies on established medicines when new safety issues or scientific questions, regulatory questions (including risk management of medicines and methodological questions) arise, these are also frequently parts of the EU statutory requirements for risk management of medicines.
3. Conducting studies to address specific safety, public health, scientific, benefit-risk balance medicines usage and regulatory issues or concerns.
4. Population based drug utilisation studies.
5. Use of healthcare databases to conduct drug safety studies.
6. Establishing registries to conduct safety studies.
7. Working with hospital doctors to undertake studies to examine specific safety questions and medical and mental health research networks.
8. Exploring the application of new methods such as clinical trials or database research, as well as other appropriate research methods, to understand the safety of medicines.
9. Conducting methodological research and pharmacovigilance and pharmacoepidemiology.
10. Undertaking systematic reviews and meta-analyses or benefit-risk studies to answer drug safety and drug utilisation questions.
11. Lead or participate in national and international research and scientific collaborative projects.

We will monitor developments in the UK relationship with the EU and make adjustments to our systems as appropriate to address relevant issues arising from these changes. In this regard the Trust has already opened a sub-office in Dublin to maintain and develop our links with the EU following our severance of membership of the EU in 2020.

The Director keeps in regular contact with the Regulatory Agencies and our European colleagues to obtain information in order to shape our strategy and policy, particularly on matters related to the impact of Brexit on medicines regulations and medical research.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2020

OBJECTIVES AND ACTIVITIES

Significant activities

The DSRU provides advice, education and training in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines. As one of the main providers of training and education in pharmacovigilance in Europe, its activities include:

1. Providing a range of training courses in pharmacovigilance and pharmacoepidemiology. The DSRU currently provides 22 courses per year, including academically endorsed higher education in collaboration with University of Portsmouth for Postgraduate Certificate, Diploma and a Master's degree in Pharmacovigilance and with the Faculty of Pharmaceutical Medicine for providing Pharmaceutical Medicine Specialty Training (PMST) for doctors specialising in pharmaceutical medicine.
2. To keep up with technological progress the DSRU intends to periodically evaluate options such as providing distance learning and other internet based educational methods.
3. Arranging national and international conferences in pharmacovigilance and pharmacoepidemiology.
4. Providing postgraduate teaching and research opportunities at all levels including MSc and PhD students.
5. Support for postgraduate students who wish to undertake research at the DSRU.
6. Providing training in pharmacovigilance and pharmacoepidemiology for pharmaceutical physicians. The DSRU has been selected by the Faculty of Pharmaceutical Medicine to provide Pharmaceutical Medicine Speciality Training (PMST) training in pharmacovigilance in the UK.
7. Supporting training and scientific communications on the safety of medicines in the UK and internationally.
8. Providing advice on matters related to the safety of medicines.
9. Producing newsletters and internet communications to general practitioners on matters to do with drug safety.
10. Providing information on drug safety which can be accessed by everyone on the DSRU website.

Routinely, reports on the results of studies are sent to the Medicines and Healthcare Products Regulatory Authority (MHRA) (an executive agency of the Department of Health) and to the European Medicines Agency (EMA) and other Regulatory Authorities in Europe to assist them in their regulatory and monitoring activities of medicines. The DSRU also publishes the findings of its work in scientific journals and at national and international conferences, newsletters and on its website.

Progress of the scientific work of the Unit was satisfactory throughout 2020 extending the breadth of activity to include research projects and collaborations other than Modified Prescription-Event Monitoring (MPEM). These include specialist and hospital-based studies (SCEMs), systematic reviews, registries, structured benefit-risk evaluation, drug utilisation projects and methodological research. In addition, our programme of activities has extended to include collaborating with a broad range of doctors in England through Health Research Networks from differing specialities as well as collaborating with colleagues in Europe. The policy to extend the range of scientific activities, as funding allows, will continue.

Applications for funding from grant-giving bodies, including the Department of Health Targeted Research Programme and other bodies such as the Medical Research Council (MRC), the Wellcome Trust and European initiatives, e.g. the European Commission will continue as and when calls are advertised. The DSRU continues to function as one of the leading Units in the field of monitoring and studying the safety of medicines both in the UK and internationally, as well as being a leading organisation in teaching and training in these fields.

The DSRU has a long-standing partnership with the NHS Rx Services to receive prescription data that are necessary to conduct Modified Prescription-Event Monitoring studies to improve the understanding of the safety of new drugs used in the general population. This partnership has the support of the Department of Health and senior staff at NHS Rx Services.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2020

OBJECTIVES AND ACTIVITIES

Since application for Section 251 exemption of the NHS 2006 Act became a requirement, the Trust has applied annually to the Confidentiality Advisory Group (CAG) of the Health Research Authority for approval to use patient data without consent. Application was again made in 2020 and was successful.

The formal collaborative partnership programme agreement, required to develop the partnership with the NHS Rx Services, to supply improved prescription data is in place and we continue to maintain good communications. In the unlikely situation that the DSRU ceases to receive data for whatever reason from the NHS Rx Services, the DSRU is committed to continue its work on studying the safety of medicines by other methods and providing education and training in pharmacovigilance and drug safety.

The main objectives of the Unit for the next year are:

1. To continue the monitoring and research programme on the safety and risk management of vaccines and medicinal products for the treatment COVID-19.
2. To undertake all forms of studies and evaluations of the safety and benefit-risk of medicines alone or in collaboration with other organisations.
3. To use its studies to support risk management, risk minimisation and monitoring the effectiveness of risk minimisation of medicines.
4. To continue its scientific work in methodological aspects of drug safety including leading or participating in national and international collaborative projects.
5. To continue its activities in advice, education and training in pharmacovigilance and pharmacoepidemiology.
6. To consolidate its scientific communications programme such as the DSRU international pharmacovigilance observatory to inform the both the medical/scientific communities and the public about important pharmacovigilance issues.
7. To continue to try to secure sufficient funding to enable the continuation and growth of the charity's activities.

Public benefit

The Trustees confirm that the Charity Commission's general guidance on public benefit has been considered in relation to the objectives of the Charity.

The objectives, activities, performance and achievement sections of this report clearly set out the activities which the charity undertakes for public benefit. The Trustees confirm that they have complied with their duty in Section 4 of the Charities Act 2006 to have due regard to public benefits guidance published by the Charities Commission in determining the activities undertaken by the Charity.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2020

ACHIEVEMENT AND PERFORMANCE

Charitable activities

The successful annual submission and subsequent approval and support of the Ethics and Confidentiality Committee of the Confidentiality Advisory Group (CAG) of the Health Research Authority for Section 251 exemption under the NHS Act 2006 was achieved for the eleventh year running.

The academically endorsed higher educational training in collaboration with the University of Portsmouth for Certificate, Diploma and Masters degree in Pharmacovigilance continued, with 32 students currently enrolled at the end of the year.

Eight scientific papers were published in medical literature. Eleven oral and poster presentations on the results of studies were given by the Director and Research staff at national and international medical and scientific conferences. One MPEM network study, one Vaccine Active Safety Surveillance study, one CPRD Study and two Systematic Reviews were completed during 2020.

Education and Professional Capability

The educational training of staff has been maintained, including continuing professional development. In addition, the DSRU has provided advice on safety of medicines issues.

Teaching & Education

The Director taught at an MSc Course at Oxford University. In addition, teaching and presenting at national and international scientific meetings continued by both the Director and senior scientific staff enabling the scientific profile of the Unit and its work in public health and drug safety to be maintained.

The DSRU and staff at the DSRU have provided training for general practitioners on effective and safe prescribing of medicines.

Training Courses for Pharmaceutical Medicine Speciality Training

The DSRU continues to deliver teaching courses in pharmacovigilance, providing training on drug safety modules of Pharmaceutical Medicine Specialty Training (PMST), for pharmaceutical physicians on behalf of the Faculty of Pharmaceutical Medicine, Royal College of Physicians. Eleven students attended these modules during the year.

Partners and Stakeholders

Universities of Portsmouth

Collaborations with the University of Portsmouth on joint studentships and joint training continue.

Regulatory Agencies

Close links were maintained throughout the year with the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) with regular reports on safety issues submitted, contributing to the better understanding of the safety of a number of important medicinal products. The DSRU is a member of the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP), a project led by the European Medicines Agency and developed in collaboration with European experts in the fields of pharmacoepidemiology and pharmacovigilance. Senior staff of the DSRU regularly participate in meetings of the ENCePP network group in London.

International scientific leadership collaboration

The DSRU is leading an International Working Group (IWG) on Signal Detection and Management in Pharmacovigilance. The Group includes some of the best experts in the world in this field. The objective is to examine the impact of new developments in biomedical sciences on signal detection and management in pharmacovigilance. Such developments include, artificial intelligence and machine thinking, the use of big data, the application of genetic knowledge in detecting and evaluating adverse drug reactions.

Investment performance

The Trust's strategy to invest whenever possible to offset for leaner years when donations are reduced, will be maintained. Full details of investment income and performance can be found in the notes to the financial statements.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2020

FINANCIAL REVIEW

Financial position

Review of financial position

The statement of financial activities for the year is set out on page 12 in these financial statements.

Whilst some costs are provided in advance by grant-givers, the entitlement to income only arises when separately identifiable stages of the projects are completed. The charity monitors the progress of the projects closely and only includes the income and associated costs as and when these conditions are met. This treatment meets the charity's accounting policy regarding incoming resources as set out under the accounting policy in the notes to the financial statements.

Staffing costs were lower in 2020 at £1,074,841 compared to £1,159,721 in 2019. Salaries still form the major part of the charity's expenses due to the specialist nature of employees, e.g. medical doctors and scientists needed to carry out the research activities. Total wage costs including national insurance and pension contributions therefore remain the highest expenditure for the Trust on a year by year basis.

The reasons for the reduction in financial support in some years include the fact that fewer new drugs which are used in the primary care setting and can be studied by the Unit are launched in the UK. In addition, mergers and acquisitions in the pharmaceutical industry have resulted in fewer companies from which to obtain support and this has continued to have impact on sources of funding.

The Chairman of Trustees and Director maintained close scrutiny of incoming resources and expenditure during the year and kept the Board informed maintaining the same level of financial governance as in previous years.

Principal funding sources

Principle funding sources come from donations received from pharmaceutical companies and other organisations in order to carry out charitable activities.

Investment policy and objectives

The Trust has undertaken investment in equities and bonds through Investec Wealth & Investment Ltd. In order to monitor the investment portfolio performance, two Trustees and the Director act as a sub-committee. This group, on behalf of the Board of Trustees, deals with all matters relating to the investment portfolio and meets with representatives of Investec Wealth & Investment Ltd at appropriate intervals. It is the policy of the Board of Trustees that no investments in the pharmaceutical, armaments or tobacco industries should be undertaken. The Trustees were satisfied that the current investment approach of the Trust is consistent with its investment needs, objectives and attitude to risk, which is to provide a balanced return on investment in the medium term with a moderate risk of capital loss.

Annually from a management perspective all other funds not immediately required from month to month for the normal running of the DSRU are routinely invested in fixed term deposit accounts to maximise return whenever possible.

Reserves policy

It is the policy of the charity to maintain unrestricted funds, which are the free reserves of the charity. This provides sufficient funds to cover the cost of ongoing studies, management and administration costs. Considering expected fluctuations of future income, the financial reserves are necessary to maintain the future stability and viability of the DSRU. These reserves will be used when and if funds become too low to cover normal day to day activities. In these difficult economic times, the Trust is reaping the benefit of the prudent financial policy in the last decade. This approach will be continued in line with developments in the external economic environment.

Asset cover for funds

An analysis of the assets attributable to the various funds described is set out in the notes to these financial statements. These assets are sufficient to meet the charity's obligations on a fund by fund basis.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2020

FUTURE PLANS

The overall strategy remains the same.

As in previous years the Trust will endeavour to ensure the preservation of Modified Prescription-Event Monitoring (MPeM) as a leading system to monitor the safety of medicines in the UK and to enhance and develop it. The Trust will continue to conduct a broad range of studies to address safety questions, including add-on studies, such as case-control and case-series studies within our databases, pharmacoepidemiological studies using other data sources, appropriate clinical trials, genetic studies, drug utilisation studies, meta-analyses, systematic reviews, benefit-risk evaluation and conduct methodological research.

These are part of the Trust's objective to explore conducting studies with different methods, including utilisation of a range of data sources that enable it to achieve its objective to monitor and study the safety of medicines.

The Trust will:

1. Continue its recent successful expansion to conduct safety studies in secondary care as well as in primary care using appropriate and improved methods to answer the relevant safety questions.
2. Lead or participate in national and international collaborative projects that aim to improve the methods and advance the science of studying the safety of medicines.
3. Further develop its scientific communications programme such as the DSRU international pharmacovigilance observatory to inform the both the medical/scientific communities and the public about important pharmacovigilance issues.
4. Continue to monitor IT and other developments in the NHS and elsewhere to ensure that it benefits from the opportunities provided by these developments.
5. Further develop its methods and capabilities in evidence-based pharmacovigilance and risk management and maintain its place as a leading unit in providing advice, training and education in pharmacovigilance and drug safety.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Governing document

The Trust is governed by a charitable Trust Deed established on 23 July 1986 with a Board of Trustees five in number. The Mission of the Trust remains to monitor, study and communicate the safety of medicines independent from both Government and industry. The Trust by way of its operational unit, the Drug Safety Research Unit (DSRU), undertakes all forms of studies and evaluations on the safety of medicines. The DSRU provides advice, training and education in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines.

As an independent registered medical charity, its aim is to achieve the highest possible scientific and ethical standards by putting the interests of patients first and to work with integrity and fairness with all partners.

Recruitment and appointment of new trustees

As a charity specialising in drug safety, the Trustees are identified for their expertise in areas which include drug regulation, epidemiology and medical statistics, experimental medicine and pharmacovigilance.

Organisational structure

The Trust employs a Director, Professor Saad Shakir, assisted by scientific, professional and administrative staff to conduct its day-to-day activities, ensuring that the charity's objectives are implemented. The average number of staff employed for the year was 23. In addition, the Trust retains the services of appropriate advisers and consultants depending upon the nature of the tasks required. During 2020 eleven consultants were engaged, to advise and assist with IT, computer system validation, PR matters and additional medical/research input.

Induction and training of new trustees

Once appointed, the Trust ensures that any training required by the Trustees is provided to enable them to fulfil their roles.

The Trustees acknowledge their responsibilities as set out on the statement of "Trustees responsibilities".

Drug Safety Research Trust

**Trustees' Report
for the Year Ended 31 December 2020**

STRUCTURE, GOVERNANCE AND MANAGEMENT

Changes to Board of Trustees

Professor David Lawson tendered his resignation from the Board of Trustees and as Chairman of the Board of Trustees on 7th May 2020. Professor Ken Paterson was appointed as Chairman of the Board of Trustees on 7th May 2020.

Risk management

The Trustees have a duty to identify and review the risks to which the Charity is exposed and to ensure appropriate controls are in place to provide reasonable assurance against fraud and error.

The Trustees examine the major strategic, business and operational risks and confirm that systems are established to enable regular reports to be produced, so that necessary steps can be taken to control or lessen these risks. The variability of the funding of the Trust made it necessary to put in place processes to ensure that staff felt secure and motivated.

A Disaster Recovery Plan for the DSRU has been designed and completed. The plan is secured in off-site storage within a data safe.

Approved by order of the board of trustees on 21 July 2021 and signed on its behalf by:

Lee K.R. Paterson ✓

Professor K R Paterson MB ChB FRCP FFPM - Trustee

Drug Safety Research Trust

Statement of Trustees' Responsibilities for the Year Ended 31 December 2020

The trustees are responsible for preparing the Trustees' Report and the accounts in accordance with applicable law and Financial Reporting Standards (FRS102).

The law applicable to charities in England and Wales requires the trustees to prepare Accounts for each financial year which give a true and fair view of the charity's financial activities during the year and of its financial position at the end of the year (unless the charity is entitled to prepare accounts on the alternative receipts and payments basis).

In preparing accounts giving a true and fair view, the trustees should follow best practice and:

- Select suitable accounting policies and then apply them consistently;
- State whether applicable accounting standards and statements of recommended practice have been followed, subject to any departures and explained in the accounts.
- make judgements and estimates that are reasonable and prudent;
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the charity will continue in business.

The trustees are responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the charity and to enable them to ensure that the financial statements comply with the applicable law. They are also responsible for safeguarding the assets of the charity and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Opinion

We have audited the financial statements of Drug Safety Research Trust (the 'charity') for the year ended 31 December 2020 which comprise the Statement of Financial Activities, the Statement of Financial Position, the Statement of Cash Flows and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice), including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'.

In our opinion the financial statements:

- give a true and fair view of the state of the charity's affairs as at 31 December 2020 and of its incoming resources and application of resources, for the year then ended;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice, including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'; and
- have been prepared in accordance with the requirements of the Charities Act 2011.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We are independent of the charity in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the trustees' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the charity's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the trustees with respect to going concern are described in the relevant sections of this report.

Other information

The trustees are responsible for the other information. The other information comprises the information included in the Annual Report, other than the financial statements and our Report of the Independent Auditors thereon.

Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Matters on which we are required to report by exception

We have nothing to report in respect of the following matters where the Charities (Accounts and Reports) Regulations 2008 requires us to report to you if, in our opinion:

- the information given in the trustees Report is inconsistent in any material respect with the financial statements; or
- sufficient accounting records have not been kept; or
- the financial statements are not in agreement with the accounting records and returns; or
- we have not received all the information and explanations we require for our audit.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Responsibilities of trustees

As explained more fully in the Statement of Trustees' Responsibilities, the trustees are responsible for the preparation of the financial statements which give a true and fair view, and for such internal control as the trustees determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the trustees are responsible for assessing the charity's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the trustees either intend to liquidate the charity or to cease operations, or have no realistic alternative but to do so.

Our responsibilities for the audit of the financial statements

We have been appointed as auditors under Section 144 of the Charities Act 2011 and report in accordance with the Act and relevant regulations made or having effect thereunder.

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a Report of the Independent Auditors that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud is detailed below:

The engagement partner ensured that the engagement team collectively had the appropriate competence, capabilities and skills to identify or recognise non-compliance with applicable laws and regulations, and that they remained alert to instances of non-compliance throughout the audit.

Our approach to identifying and assessing the risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, was as follows:

- based on our understanding of the charity and sector, and through discussions with directors and key management, we identified the specific laws and regulations which we considered may have a direct material effect on the financial statements or the operations of the company, including the Charities Act 2011, taxation legislation and data protection, anti-bribery, employment, environmental and health and safety legislation; and
- we assessed the extent of compliance with these laws and regulations through making enquiries of management and inspecting legal correspondence.

We assessed the susceptibility of the company's financial statements to material misstatement, including obtaining an understanding of how fraud might occur, by:

- making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and
- considering the internal controls in place to mitigate risks of fraud and non-compliance with laws and regulations.

To address the risk of fraud through management bias and override of controls, we:

- performed analytical procedures to identify any unusual or unexpected relationships;
- tested journal entries, particularly focused around the year-end, to identify unusual transactions;
- assessed whether judgements and assumptions made in determining the accounting estimates in the notes to the financial statements were indicative of potential bias; and
- investigated the rationale behind significant or unusual transactions.

**Report of the Independent Auditors to the Trustees of
Drug Safety Research Trust**

In response to the risk of irregularities and non-compliance with laws and regulations, we designed procedures which included, but were not limited to:

- agreeing financial statement disclosures to underlying supporting documentation;
- reading the minutes of meetings of those charged with governance;
- enquiring of management as to actual and potential litigation and claims; and
- reviewing correspondence with relevant regulators and the charity's legal advisors.

There are inherent limitations in the audit procedures described above. We are less likely to become aware of instances of non-compliance with laws and regulations that are not closely related to events and transactions reflected in the financial statements. Also, the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at www.frc.org.uk/auditorsresponsibilities. This description forms part of our Report of the Independent Auditors.

Use of our report

This report is made solely to the charity's trustees, as a body, in accordance with Part 4 of the Charities (Accounts and Reports) Regulations 2008. Our audit work has been undertaken so that we might state to the charity's trustees those matters we are required to state to them in an auditors' report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the charity and the charity's trustees as a body, for our audit work, for this report, or for the opinions we have formed.



Cartwrights
Chartered Accountants and Business Advisors
Statutory Auditor
Eligible to act as an auditor in terms of Section 1212 of the Companies Act 2006
Regency House
33 Wood Street
Barnet
Hertfordshire
EN5 4BE

Date: 22/07/2021

Andrew Hill FCA (Senior Statutory Auditor) for and on behalf of Cartwrights

Drug Safety Research Trust

**Statement of Financial Activities
for the Year Ended 31 December 2020**

	Notes	Unrestricted funds £	Restricted fund £	31/12/20 Total funds £	31/12/19 Total funds £
INCOME AND ENDOWMENTS FROM					
Donations and legacies	2	767,131	-	767,131	1,279,171
Investment income	3	111,782	-	111,782	105,905
Other income		517,181	-	517,181	452,843
Total		<u>1,396,094</u>	<u>-</u>	<u>1,396,094</u>	<u>1,837,919</u>
EXPENDITURE ON					
Raising funds	4	18,748	-	18,748	17,466
Charitable activities					
Direct Charitable Expenditure	5				
		1,106,830	-	1,106,830	1,295,491
Other		490,795	18,780	509,575	605,134
Total		<u>1,616,373</u>	<u>18,780</u>	<u>1,635,153</u>	<u>1,918,091</u>
Net gains on investments		193,128	-	193,128	359,218
NET INCOME/(EXPENDITURE)		<u>(27,151)</u>	<u>(18,780)</u>	<u>(45,931)</u>	<u>279,046</u>
RECONCILIATION OF FUNDS					
Total funds brought forward		8,106,372	509,400	8,615,772	8,336,726
TOTAL FUNDS CARRIED FORWARD		<u><u>8,079,221</u></u>	<u><u>490,620</u></u>	<u><u>8,569,841</u></u>	<u><u>8,615,772</u></u>

The notes form part of these financial statements

Drug Safety Research Trust

**Statement of Financial Position
31 December 2020**

	Notes	Unrestricted funds £	Restricted fund £	31/12/20 Total funds £	31/12/19 Total funds £
FIXED ASSETS					
Tangible assets	9	28,263	490,620	518,883	557,914
Investments	10	3,419,044	-	3,419,044	3,154,614
		<u>3,447,307</u>	<u>490,620</u>	<u>3,937,927</u>	<u>3,712,528</u>
CURRENT ASSETS					
Debtors	11	11,491	-	11,491	166,334
Cash at bank		4,691,906	-	4,691,906	4,814,748
		<u>4,703,397</u>	<u>-</u>	<u>4,703,397</u>	<u>4,981,082</u>
CREDITORS					
Amounts falling due within one year	12	(71,483)	-	(71,483)	(77,838)
		<u>4,631,914</u>	<u>-</u>	<u>4,631,914</u>	<u>4,903,244</u>
NET CURRENT ASSETS					
		<u>8,079,221</u>	<u>490,620</u>	<u>8,569,841</u>	<u>8,615,772</u>
TOTAL ASSETS LESS CURRENT LIABILITIES					
		<u>8,079,221</u>	<u>490,620</u>	<u>8,569,841</u>	<u>8,615,772</u>
NET ASSETS					
		<u>8,079,221</u>	<u>490,620</u>	<u>8,569,841</u>	<u>8,615,772</u>
FUNDS					
	13			8,079,221	8,106,372
Unrestricted funds				490,620	509,400
Restricted funds					
				<u>8,569,841</u>	<u>8,615,772</u>
TOTAL FUNDS					

The financial statements were approved by the Board of Trustees and authorised for issue on 21 July 2021 and were signed on its behalf by:

 
K R Paterson MB ChB FRCP FFPM - Trustee

Drug Safety Research Trust

**Statement of Cash Flows
for the Year Ended 31 December 2020**

	Notes	31/12/20 £	31/12/19 £
Cash flows from operating activities			
Cash generated from operations	1	(219,881)	(394,889)
Net cash used in operating activities		<u>(219,881)</u>	<u>(394,889)</u>
Cash flows from investing activities			
Purchase of tangible fixed assets		(3,971)	(13,097)
Purchase of fixed asset investments		(853,669)	(549,582)
Sale of fixed asset investments		873,932	556,423
Interest received		32,622	48,582
Dividends received		48,125	51,318
Net cash provided by investing activities		<u>97,039</u>	<u>93,644</u>
Change in cash and cash equivalents in the reporting period			
		(122,842)	(301,245)
Cash and cash equivalents at the beginning of the reporting period			
		<u>4,814,748</u>	<u>5,115,993</u>
Cash and cash equivalents at the end of the reporting period			
		<u>4,691,906</u>	<u>4,814,748</u>

The notes form part of these financial statements

Drug Safety Research Trust

**Notes to the Statement of Cash Flows
for the Year Ended 31 December 2020**

1. RECONCILIATION OF NET (EXPENDITURE)/INCOME TO NET CASH FLOW FROM OPERATING ACTIVITIES

	31/12/20 £	31/12/19 £
Net (expenditure)/income for the reporting period (as per the Statement of Financial Activities)	(45,931)	279,046
Adjustments for:		
Depreciation charges	43,002	51,076
Gain on investments	(284,693)	(718,436)
Interest received	(32,622)	(48,582)
Dividends received	(48,125)	(51,318)
Decrease in debtors	154,843	71,253
(Decrease)/increase in creditors	(6,355)	22,072
Net cash used in operations	<u>(219,881)</u>	<u>(394,889)</u>

2. ANALYSIS OF CHANGES IN NET FUNDS

	At 1/1/20 £	Cash flow £	At 31/12/20 £
Net cash			
Cash at bank	4,814,748	(122,842)	4,691,906
	<u>4,814,748</u>	<u>(122,842)</u>	<u>4,691,906</u>
Total	<u>4,814,748</u>	<u>(122,842)</u>	<u>4,691,906</u>

The notes form part of these financial statements

Drug Safety Research Trust

Notes to the Financial Statements for the Year Ended 31 December 2020

1. ACCOUNTING POLICIES

Basis of preparing the financial statements

The financial statements of the charity, which is a public benefit entity under FRS 102, have been prepared in accordance with the Charities SORP (FRS 102) 'Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019)', Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland' and the Charities Act 2011. The financial statements have been prepared under the historical cost convention, with the exception of investments which are included at market value, as modified by the revaluation of certain assets.

Income

All income is recognised in the Statement of Financial Activities once the charity has entitlement to the funds, it is probable that the income will be received and the amount can be measured reliably.

For donations to be recognised the charity will have been notified of the amounts and the settlement date in writing. If there are conditions attached to the donation and this requires a level of performance before entitlement can be obtained then income is deferred until those conditions are fully met or the fulfilment of those conditions is within the control of the charity and it is probable that they will be fulfilled.

Investment income is earned through holding assets for investment purposes such as shares. It includes dividends, interest and unrealised gains or losses on shares held. Where it is not practicable to identify investment management costs incurred within a scheme with reasonable accuracy the investment income is reported net of these costs. It is included when the amount can be measured reliably. Interest income is recognised using the effective interest method and dividend income is recognised as the charity's right to receive payment is established.

Other income represents management fees charged and donations received from the Trust's connected trading entity, DSRU Education and Research Limited. Management fees are included when charged and donations when received. Due to the connected nature of this entity, donation income is recorded within other income rather than within donations and legacy income in the Statement of Financial Activities.

Expenditure

Liabilities are recognised as expenditure as soon as there is a legal or constructive obligation committing the charity to that expenditure, it is probable that a transfer of economic benefits will be required in settlement and the amount of the obligation can be measured reliably. Expenditure is accounted for on an accruals basis and has been classified under headings that aggregate all cost related to the category. Where costs cannot be directly attributed to particular headings they have been allocated to activities on a basis consistent with the use of resources.

Raising funds

Costs of raising funds represent investment manager costs incurred in dealing with the listed investment portfolio.

Charitable activities

Expenditure on charitable activities includes the direct costs of carrying out and performing the studies and evaluations of medicines in order to meet the Trust's objectives and aims.

Allocation and apportionment of costs

Support costs are those that assist the work of the charity but do not directly represent charitable activities and include office costs, governance costs, administrative payroll costs. They are incurred directly in support of expenditure on the objects of the charity and include project management carried out at Headquarters. Where support costs cannot be directly attributed to particular headings they have been allocated to cost of raising funds and expenditure on charitable activities on a basis consistent with use of the resources. Premises overheads have been allocated on an insert detail basis and other overheads have been allocated on an insert detail basis.

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2020

1. ACCOUNTING POLICIES - continued

Tangible fixed assets

Tangible fixed assets other than freehold land are stated at cost less depreciation. Depreciation is provided at rates calculated to write off the cost less estimated residual value of each asset over its expected useful life, as follows:

Freehold Land	Not depreciated
Freehold Building	2% Straight Line
Plant & Machinery	20% Straight Line
Fixture, Fittings & Equipment	20% Straight Line
Motor Vehicles	20% Straight Line

Taxation

The charity is exempt from tax on its charitable activities.

Fund accounting

Unrestricted funds can be used in accordance with the charitable objectives at the discretion of the trustees.

Restricted funds can only be used for particular restricted purposes within the objects of the charity. Restrictions arise when specified by the donor or when funds are raised for particular restricted purposes.

Further explanation of the nature and purpose of each fund is included in the notes to the financial statements.

Pension costs and other post-retirement benefits

The charity operates a defined contribution pension scheme. Contributions payable to the charity's pension scheme are charged to the Statement of Financial Activities in the period to which they relate.

Accumulated funds

The restricted fund represents the net book values of the freehold land and buildings at Bursledon Hall, Southampton. The fund balances are reduced by the depreciation charged on the buildings.

Unrestricted Funds

Unrestricted funds represent donations and other incoming resources receivable or generated for the objects of the charity without further specified purpose and are available as general funds.

Investments

Fixed asset investments are stated at market value.

2. DONATIONS AND LEGACIES

	Unrestricted funds	Restricted funds	31/12/20 Total funds	31/12/19 Total funds
	£	£	£	£
Donations	767,131	-	767,131	1,279,171

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2020**

3. INVESTMENT INCOME

	Unrestricted funds £	Restricted funds £	31/12/20 Total funds £	31/12/19 Total funds £
Gain on disposal of investment	31,035	-	31,035	6,005
Listed income	48,125	-	48,125	51,318
Interest received	32,622	-	32,622	48,582
	<u>111,782</u>	<u>-</u>	<u>111,782</u>	<u>105,905</u>

4. RAISING FUNDS

Investment management costs

	Unrestricted funds £	Restricted funds £	31/12/20 Total funds £	31/12/19 Total funds £
Fund manager costs	18,748	-	18,748	17,466
	<u>18,748</u>	<u>-</u>	<u>18,748</u>	<u>17,466</u>

5. CHARITABLE ACTIVITIES COSTS

	Direct Costs £
Direct Charitable Expenditure	
	<u>1,106,830</u>

6. SUPPORT COSTS

	Governance costs £
Other resources expended	<u>509,575</u>

Support costs, included in the above, are as follows:

	31/12/20 Other resources expended £	31/12/19 Total activities £
Wages	147,110	157,483
Social security	102,211	109,910
Pensions	48,358	45,086
Auditors' remuneration	10,723	10,609
Rates and water	10,659	10,885
Insurance	16,432	17,782
Light and heat	14,383	17,985
Telephone and fax	6,264	7,370
PPS	933	2,058
Sundries	4,117	4,920
Carried forward	<u>361,190</u>	<u>384,088</u>

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2020

6. SUPPORT COSTS - continued

	31/12/20	31/12/19
	Other resources expended	Total activities
	£	£
Brought forward	361,190	384,088
Repairs and maintenance	13,565	27,295
Staff training	169	7,355
Staff medical costs	9,716	7,800
Motor and travel expenses	8,174	34,927
Trustees expenses	34	1,516
Computer costs	12,955	16,739
Subscriptions	35,115	34,589
Bank charges	952	951
Marketing costs	22,320	25,809
Equipment hire	2,383	2,429
Legal and professional fees	-	10,560
Depreciation of tangible fixed assets	43,002	51,076
	<u>509,575</u>	<u>605,134</u>

7. TRUSTEES' REMUNERATION AND BENEFITS

There were no trustees' remuneration or other benefits for the year ended 31 December 2020 nor for the year ended 31 December 2019.

Trustees' expenses

Travelling expenses amounting to £34 (2019 - £1,516) were reimbursed to the trustees for attending meetings.

Trustees indemnity insurance payable during the year amounted to £6,653 (2019: £6,600).

8. STAFF COSTS

The average number of employees during the year was 23 (2019 - 24).

The number of employees whose annual emoluments were £60,000 or more were:

	2020	2019
£300,001 - £310,000	-	1
£220,001 - £230,000	1	-
£60,001 - £70,000	1	1

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2020**

9. TANGIBLE FIXED ASSETS

	Freehold property £	Plant and machinery £	Fixtures and fittings £	Computer System £	Totals £
COST					
At 1 January 2020	941,000	158,798	63,925	57,036	1,220,759
Additions	-	3,112	859	-	3,971
At 31 December 2020	<u>941,000</u>	<u>161,910</u>	<u>64,784</u>	<u>57,036</u>	<u>1,224,730</u>
DEPRECIATION					
At 1 January 2020	431,600	132,902	48,954	49,389	662,845
Charge for year	18,780	11,302	6,834	6,086	43,002
At 31 December 2020	<u>450,380</u>	<u>144,204</u>	<u>55,788</u>	<u>55,475</u>	<u>705,847</u>
NET BOOK VALUE					
At 31 December 2020	<u>490,620</u>	<u>17,706</u>	<u>8,996</u>	<u>1,561</u>	<u>518,883</u>
At 31 December 2019	<u>509,400</u>	<u>25,896</u>	<u>14,971</u>	<u>7,647</u>	<u>557,914</u>

The freehold property was last revalued on 20 December 1999 by Messrs Daniells Harison, Chartered Surveyors, on the basis of open market value for current use. The freehold land and buildings valuation has not been updated since 1999. Under the transitional relief provisions under FRS 102, this value has been treated as the deemed cost in these financial statements. The estimated market value as at the balance sheet date is in excess of £4 million.

Comparable historical cost for the land and buildings included at valuation:

	2020 £	2019 £
Cost	1,487,614	1,487,614
Accumulated Depreciation	<u>450,380</u>	<u>431,600</u>
At year end	<u>1,037,234</u>	<u>1,056,014</u>

All other tangible fixed assets are stated at historical cost.

10. FIXED ASSET INVESTMENTS

	Listed investments £
MARKET VALUE	
At 1 January 2020	3,154,614
Additions	853,669
Disposals	(680,804)
Revaluations	91,565
At 31 December 2020	<u>3,419,044</u>
NET BOOK VALUE	
At 31 December 2020	<u>3,419,044</u>
At 31 December 2019	<u>3,154,614</u>

There were no investment assets outside the UK.

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2020**

10. FIXED ASSET INVESTMENTS - continued

Net acquisitions at cost represent investment income reinvested at source in the relevant funds held.

11. DEBTORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	31/12/20	31/12/19
	£	£
Other debtors	-	140,847
Prepayments and accrued income	11,491	25,487
	<u>11,491</u>	<u>166,334</u>

12. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	31/12/20	31/12/19
	£	£
Taxation and social security	41,533	37,424
Other creditors	29,950	40,414
	<u>71,483</u>	<u>77,838</u>

13. MOVEMENT IN FUNDS

	At 1/1/20	Net movement in funds	At 31/12/20
	£	£	£
Unrestricted funds			
Unrestricted Fund	8,106,372	(27,151)	8,079,221
Restricted funds			
Restricted Fund	509,400	(18,780)	490,620
	<u>8,615,772</u>	<u>(45,931)</u>	<u>8,569,841</u>

Net movement in funds, included in the above are as follows:

	Incoming resources	Resources expended	Gains and losses	Movement in funds
	£	£	£	£
Unrestricted funds				
Unrestricted Fund	1,396,094	(1,616,373)	193,128	(27,151)
Restricted funds				
Restricted Fund	-	(18,780)	-	(18,780)
	<u>1,396,094</u>	<u>(1,635,153)</u>	<u>193,128</u>	<u>(45,931)</u>

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2020**

13. MOVEMENT IN FUNDS - continued

Comparatives for movement in funds

	At 1/1/19 £	Net movement in funds £	At 31/12/19 £
Unrestricted funds			
Unrestricted Fund	7,808,546	297,826	8,106,372
Restricted funds			
Restricted Fund	528,180	(18,780)	509,400
TOTAL FUNDS	<u>8,336,726</u>	<u>279,046</u>	<u>8,615,772</u>

Comparative net movement in funds, included in the above are as follows:

	Incoming resources £	Resources expended £	Gains and losses £	Movement in funds £
Unrestricted funds				
Unrestricted Fund	1,837,919	(1,899,311)	359,218	297,826
Restricted funds				
Restricted Fund	-	(18,780)	-	(18,780)
TOTAL FUNDS	<u>1,837,919</u>	<u>(1,918,091)</u>	<u>359,218</u>	<u>279,046</u>

A current year 12 months and prior year 12 months combined position is as follows:

	At 1/1/19 £	Net movement in funds £	At 31/12/20 £
Unrestricted funds			
Unrestricted Fund	7,808,546	270,675	8,079,221
Restricted funds			
Restricted Fund	528,180	(37,560)	490,620
TOTAL FUNDS	<u>8,336,726</u>	<u>233,115</u>	<u>8,569,841</u>

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2020

13. MOVEMENT IN FUNDS - continued

A current year 12 months and prior year 12 months combined net movement in funds, included in the above are as follows:

	Incoming resources £	Resources expended £	Gains and losses £	Movement in funds £
Unrestricted funds				
Unrestricted Fund	3,234,013	(3,515,684)	552,346	270,675
Restricted funds				
Restricted Fund	-	(37,560)	-	(37,560)
TOTAL FUNDS	<u>3,234,013</u>	<u>(3,553,244)</u>	<u>552,346</u>	<u>233,115</u>

14. EMPLOYEE BENEFIT OBLIGATIONS

The company operates a defined contribution pension scheme. The assets of the scheme are held separately from those of the company in an independently administered fund. The pension cost charge represents contributions payable by the company to the fund. These amounted to £48,358 (2019 - £45,086). Contributions totalling £7,991 (2019 - £7,617) were payable to the fund at the year end and are included in creditors.

15. RELATED PARTY DISCLOSURES

During the year management fees totalling £78,000 (2019: £78,000) were charged to DSRU Education and Research Limited, a company limited which shares its premises with the Trust and in which Professor Saad Shakir is sole company director. The management fees are charged to the company for its share of office costs.

Donation income of £407,164 (2019: £353,525) was received from the company during the year. The donations made are determined such that the company reduces its profits chargeable to tax to £nil each year.

Drug Safety Research Trust**Detailed Statement of Financial Activities
for the Year Ended 31 December 2020**

	31/12/20	31/12/19
	£	£
INCOME AND ENDOWMENTS		
Donations and legacies		
Donations	767,131	1,279,171
Investment income		
Gain on disposal of investment	31,035	6,005
Listed income	48,125	51,318
Interest received	32,622	48,582
	<hr/>	<hr/>
	111,782	105,905
Other income		
Other income	517,181	452,843
	<hr/>	<hr/>
Total incoming resources	1,396,094	1,837,919
EXPENDITURE		
Investment management costs		
Fund manager costs	18,748	17,466
Charitable activities		
Wages - direct	777,162	847,242
General Practitioner costs	(200)	9,503
Other direct costs	329,868	438,746
	<hr/>	<hr/>
	1,106,830	1,295,491
Support costs		
Governance costs		
Wages	147,110	157,483
Social security	102,211	109,910
Pensions	48,358	45,086
Auditors' remuneration	10,723	10,609
Rates and water	10,659	10,885
Insurance	16,432	17,782
Light and heat	14,383	17,985
Telephone and fax	6,264	7,370
PPS	933	2,058
Sundries	4,117	4,920
Repairs and maintenance	13,565	27,295
Staff training	169	7,355
Staff medical costs	9,716	7,800
Motor and travel expenses	8,174	34,927
Trustees expenses	34	1,516
Computer costs	12,955	16,739
Subscriptions	35,115	34,589
Carried forward	440,918	514,309

This page does not form part of the statutory financial statements

Drug Safety Research Trust

Detailed Statement of Financial Activities for the Year Ended 31 December 2020

	31/12/20	31/12/19
	£	£
Governance costs		
Brought forward	440,918	514,309
Bank charges	952	951
Marketing costs	22,320	25,809
Equipment hire	2,383	2,429
Legal and professional fees	-	10,560
Depreciation of tangible fixed assets	43,002	51,076
	<u>509,575</u>	<u>605,134</u>
Total resources expended	<u>1,635,153</u>	<u>1,918,091</u>
Net expenditure before gains and losses	(239,059)	(80,172)
Net losses on investments		
Net gains / losses on investments	<u>193,128</u>	<u>359,218</u>
Net (expenditure)/income	<u>(45,931)</u>	<u>279,046</u>

This page does not form part of the statutory financial statements