GMDN AGENCY

England & Wales · Charity number 1154418

Details

Status	Registered
Legal form	Charitable company
Company number	05392271
Registered	2013-10-31
Register	View on the Charity Commission register

Contact

Address	Hampden House Monument Park Chalgrove Oxford Oxfordshire OX44 7RW
Phone	01235799759
Email	admin@gmdnagency.org
Website	https://www.gmdnagency.org

Activities

Objects: TO PRESERVE AND PROTECT HEALTH AND TO RELIEVE SICKNESS FOR THE PUBLIC BENEFIT BY DEVELOPING AND MAINTAINING THE “GLOBAL MEDICAL DEVICE NOMENCLATURE”, A SYSTEM OF INTERNATIONALLY AGREED DESCRIPTORS USED TO IDENTIFY MEDICAL DEVICE PRODUCTS WHICH WILL MEET A GLOBAL NEED FOR IDENTIFICATION PURPOSES

Activities: To preserve and protect health and to relieve sickness for the public benefit by developing and maintaining the Global Medical Device Nomenclature, a system of internationally agreed descriptors used to identify medical device products which will meet a global need for identification purposes.

Classification

- **How:** Provides Advocacy/advice/information
- **What:** The Advancement Of Health Or Saving Of Lives
- **Who:** The General Public/mankind

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Geography

- Throughout England And Wales

Finances

Period end	Income	Expenditure	Assets	Employees
2025-03-31	£1,899,661	£1,296,883	£1,185,661	13
2024-03-31	£1,269,660	£1,638,076	£582,883	12
2023-03-31	£951,942	£1,517,547	£951,299	12
2022-03-31	£992,374	£1,171,442	£1,516,904	11
2021-03-31	£1,047,928	£1,250,520	£1,695,972	10

Trustees

Name	Role	Appointed
John Wilkinson OBE	Chair	2017-06-05
Deniz Bruce		2022-11-07
Dennis Donald Black		2023-12-06
Dr MEI WEN CHRISTINA TONG PHD		2013-02-06
Janet Trunzo BS MS		2013-02-06
Jo Goulding		2024-06-13
Melissa Tores		2026-05-07
Tai Chuan Alfred Kwek		2024-12-05

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GMDN AGENCY

England & Wales - Charity number 1154418

Accounts

Docusign Envelope ID: D938B470-57F9-4C79-817D-14998106EBFF

REGISTERED COMPANY NUMBER: 05392271 (England and Wales)
REGISTERED CHARITY NUMBER: 1154418

REPORT OF THE TRUSTEES AND

AUDITED FINANCIAL STATEMENTS

FOR THE YEAR ENDED 31 MARCH 2025

FOR

GMDN AGENCY

Docusign Envelope ID: D938B470-57F9-4C79-817D-14998106EBFF

GMDN AGENCY

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FOR THE YEAR ENDED 31 MARCH 2025

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The trustees who are also directors of the charity for the purposes of the Companies Act 2006, present their report with the financial statements of the charity for the year ended 31 March 2025. 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

Purposes and aims

Our charity's purposes, as set out in the objects contained in the company's memorandum of association, are to:

To preserve and protect health and to relieve sickness for the public benefit by developing and maintaining the 'Global Medical Device Nomenclature', a system of internationally agreed descriptors used to identify medical device products which will meet a global need for identification purposes. Our aims fully reflect the purposes that the charity was set up to further.

Our charity's purposes, as set out in the objects contained in the company's Articles of Association, are to:

To preserve and protect health and relieve sickness for the public benefit by developing and maintaining the "Global Medical Device Nomenclature", a system of internationally agreed descriptors used to identify medical device products which will meet a global need for identification purposes.

Our Strategic Aims, as identified in our Quality Policy, fully reflect the purposes that the charity was set up to further:

- Assist in the protection of patients by acting as a resource for healthcare regulators to help them identify trends and solve problems quickly;
- Facilitate collaborative efforts between regulators in different jurisdictions;
- Offer expertise and insight to the whole medical device supply chain;
- Increase transparency of the Agency through stakeholder engagement and communication of activities;
- Support the industry in the setting up of registries and learning communities;
- Demonstrate the advantages of greater global harmonisation and medical technology for patient care;
- Support users to reduce the risk of misuse or misassignment of GMDN terms by taking the lead on the quality of Terms assignment to ensure they are as accurate as possible for downstream use;
- Assisting stakeholders in the downstream use of GMDN data as a leveraging tool e.g., inventory management, real-world evidence analysis, vigilance and signal detection.

Ensuring our work delivers our aims

We review our Strategic Aims each year (The annual review took place in February 2025). This review looks at what we achieved and the outcomes of our work in the previous 12 months. The review looks at the success of each key activity and the benefits they have brought to those groups of people we are set up to help. The review also helps us ensure that our aims, objectives and activities remain focused on our stated purposes. We have referred to the guidance contained in the Charity Commission's general guidance on public benefit when reviewing our aims and objectives and in planning our future activities. In particular, the trustees consider how planned activities will contribute to the aims and objectives they have set.

The focus of our work

After extensive consultation, the Strategy 2022-2026 was published in early 2022. To deliver the GMDN Agency's core work of helping to meet the global need for accurate identification of medical devices, we have developed four ambitions, the aims for those areas of work and where we expect to be at the end of the five-year strategy period.

- Promote the value of global collaboration and harmonisation
- Continuously improve and innovate
- Provide excellent services which add value
- Be engaged, helpful and expert

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OBJECTIVES AND ACTIVITIES

Public benefit

Our main activities and who we try to help are described below. All our charitable activities focus on the accurate identification of medical devices by standardising their common description and sharing this information with Governments, Hospitals and device manufacturers worldwide for the public benefit.

Who used and benefited from our services?

Our objects and funding limit the services we provide to the maintenance, promotion and distribution of the Global Medical Device Nomenclature.

Equal access to our services is an important issue for us. All potential users of the GMDN can gain free access to the GMDN data.

Medical device regulators use the GMDN data to identify specific equipment accurately when they need to approve medical devices as part of their national regulatory framework.

When monitoring the safety of medical devices within the market, medical device regulators can use the GMDN to identify trends in the success and failure of a specific device or common technology, which is vitally important when systematic failures of devices from more than one manufacturer may occur.

Medical device manufacturers use GMDN data to sort their products into more manageable groups and provide more consistent device names to their customers.

Medical device users can use GMDN data to support decision-making within the healthcare environment.

We maintain our database to provide information to our members in 14 languages, thereby encouraging wider global access to the GMDN.

The GMDN Agency continues to maintain its Quality Management System compliance to standard ISO9001:2015 by a third-party audit.

To demonstrate our commitment to information security, the GMDN Agency was re-certified to the UK Government's Cyber Essentials scheme in October 2024.

FINANCIAL REVIEW

Principal funding sources

The principal funding sources for the charity are currently the licencing of services related to the maintenance of the GMDN to our members via our website.

Access is only available to members and membership is priced according to organisation type and size. The membership process is completed online and access to the GMDN database is immediate upon completion of the registration process. Over 91% of organisations access our membership services free of any cost, and some commercial organisations that make up the balance, volunteer to subscribe to our paid membership services.

Investment policy and objectives

Aside from retaining a prudent amount in reserves each year, most of the charity's funds are to be spent in the short term, so there are few funds for long-term investment. With the aid of sound financial management and the support of its staff and volunteers, the charity maintained a total of funds carried forward amounting to £1,185,661.

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FINANCIAL REVIEW

Reserves policy

The GMDN Agency, as a charitable activity designed to provide services to members, should operate on the basis of costs equating to income over the long term. Reserves will be held to ensure continuity of operation and provide a buffer for variations in income or respond to short-term expenditure needs not accommodated by the normal running of the organisation, as well as addressing anticipated future change costs associated with both environmental and operational necessities e.g. changes in business model, major recapitalisation of assets, etc.

The charity aims to hold around six months' of expenditure in general reserves in case the database were to go down (including from risk of cyber attack or global server failures) and if the funds exceeded this, they would be used for investing in the database recovery and building new infrastructure. If there was still an excess, funds would be returned to members via adjustments to the fees for the service.

Designated reserves are categorised as Operational and Strategic reserves.

The Operational reserve is to cover cash flow variability and anticipated short-term variations in either income or expenditure. It also needs to cover the cost of winding up the Agency, subject to the possibility that the Agency needs to be closed.

The Strategic reserve is to cover anticipated needs over and above those accommodated by the Operational reserve but required to support the long-term sustainability of the Agency. This needs to be consistent with the conditions applied above.

The level of these reserves is agreed on an annual basis by the Trustees as part of the financial budgeting process.

During the year, the charity received a £5,000 restricted grant. Restricted expenditure of £5,000 was subsequently incurred and there was therefore no restricted fund balance carried forward at 31 March 2025. There was no restricted income or restricted expenditure in the previous year and no restricted fund balance at 31 March 2024.

FUTURE DEVELOPMENTS

The effective use of the GMDN by national medical device regulators and other stakeholders throughout the world continues to be the primary objective of the Agency.

The Trustees deliberately build up the reserves in the past few years to meet the challenges and costs associated with the increasing use of the GMDN. Due to the long-term nature of adopting the GMDN, the timing of the use of funds can be challenging to predict. It is expected that the adoption of the GMDN will require the investment of substantial funds in supporting adoption and supporting users worldwide.

Our larger company members have remained loyal to the voluntary paid-for services we provide to support their management of the GMDN Terms they use and therefore our income has remained enough to allow the Trustees to be confident of our long-term financial sustainability. The membership schemes will be carefully monitored during the coming years to determine their ongoing suitability of purpose and amended as necessary.

With the increased global recognition and use of GMDN, several countries and NGOs have joined in adopting the use of the GMDN, and this is particularly important in countries with less-developed economies.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Governing document

The organisation is a charitable company limited by guarantee, incorporated on 14 March 2005 and registered as a charity on 31 October 2013. The company was established under a Memorandum of Association which established the objects and powers of the charitable company and is governed under its Articles of Association. In the event of the company being wound up members are required to contribute an amount not exceeding £10.

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STRUCTURE, GOVERNANCE AND MANAGEMENT

Recruitment and appointment of new trustees

The directors of the company are also charity trustees for the purposes of charity law and under the company's Articles are known as members of the Board of Trustees. Under the requirements of the Memorandum and Articles of Association the members of the Board of Trustees are elected to serve for a period of three years after which they must be re-elected at the next Annual General Meeting.

All members of the Board of Trustees give their time voluntarily and received no benefits from the charity. Any expenses reclaimed from the charity are set out in note 8 to the accounts.

Due to the nature of the medical device sector much of the charity's work inevitably focuses upon this subject. The Board of Trustees seeks to ensure that the needs of this sector are appropriately reflected through the members of the trustee body.

To enhance the potential pool of trustees, the charity, through selective networking with industry, regulators and healthcare providers, has sought to identify those individuals who would be willing to become members of the Agencies advisory committees and use their own experience to assist the charity.

In early 2022 following the launch of our new strategy, we established the Authorities Strategic Advisory Group (ASAG) as a standing advisory committee to the Board of Trustees. This committee strengthens the voice of regulators in the strategic planning of the Agency and has been very useful, with regulators from Australia, Brazil, Canada, the UK and the USA now actively participating. The Advisory Committee and the Board of Trustees meet three times a year.

The more traditional business and medical skills are well represented on the Board of Trustees. In an effort to maintain this broad skill mix, members of the Board of Trustees are requested to provide a list of their skills and in the event of particular skills being lost due to retirements, individuals are approached to offer themselves for election to the Board of Trustees. Two new Trustees joined the Board within the last year.

The Trustees as part of the recent strategic planning process, wish to increase the active involvement of regulators in our governance and therefore are engaging with them to see how this can be done in the coming year.

Organisational structure

The Board of Trustees consists of up to eight members who meet quarterly and are responsible for the charity's strategic direction and policy. At present, the Committee has eight members from a variety of professional backgrounds relevant to the charity's work.

A scheme of delegation is in place and day to day responsibility for the provision of the services rests with the Chief Executive Officer. The Chief Executive Officer is responsible for ensuring that the charity delivers the services specified and that key performance indicators are met. The Senior Clinical Lead and Term Development Team has overall responsibility for the maintenance of the Global Medical Device Nomenclature database, and the Office Administrators have responsibility for the customer services staff. The Chief Executive Officer has individual supervision of all staff and also ensures that the team continue to develop their skills in line with good working practice.

CEO, Deniz Bruce, was appointed in November 2022 and is now driving the Agency forward in its delivery of our strategic and operational plan. Focusing on expanding the use of the GMDN Database (currently used in around 140 countries) beyond the regulatory pre- and post-market use, building new partnerships and supporting global harmonisation for device naming and grouping of medical devices, as well as the business sustainability plans.

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STRUCTURE, GOVERNANCE AND MANAGEMENT

Induction and training of new trustees

Trustees are already familiar with the practical work of the charity, having been encouraged to have been a previous members of Agencies advisory committees.

Additionally, new trustees are invited and encouraged to attend a training session to familiarise themselves with the charity and the context within which it operates. This is led by the Chief Executive Officer of the charity and covers:

- The obligations of Board of Trustees members;
- The main documents which set out the operational framework for the charity including the Articles of Association;
- Resourcing and the current financial position as set out in the latest published accounts; and
- Future plans and objectives.

A resource pack has been prepared drawing information from the various Charity Commission publications. This is distributed to all new trustees along with the Articles of Association, Governance, Policy and reference documents and the latest management financial report.

Charity representation

In so far as it is complimentary to the charity's objects, the charity is guided by international forum for medical device safety, including the members of the International Medical Device Regulators Forum (IMDRF) and the Global Harmonisation Working Party (GHWP) as well as international medical device manufacturers' trade associations, including the Global Medical Technology Alliance (GMTA) and the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA). The representation of the GMDN Agency to these organisations has proved invaluable to the charity in establishing improved links with the medical device sector and identifying relevant policy improvements.

Risk management

The Board of Trustees has conducted a review of the major risks to which the charity is exposed. Our risk register is reviewed at every Board meeting. Where appropriate, systems or procedures have been established to mitigate the risks the charity faces. Significant external risks to funding have led to the development of a strategic plan which will allow for the planning of funding and activities. Internal control risks are minimised by the implementation of procedures for authorisation of all transactions and projects. Procedures are in place to ensure compliance with health and safety of staff, volunteers, clients and visitors to the GMDN Agency's offices. The third-party certification of our ISO 9001 Quality Management System supports a consistent quality of delivery for all operational aspects of the charity. All internal procedures are regularly audited to ensure that they continue to meet the needs of the charity.

REFERENCE AND ADMINISTRATIVE DETAILS

Registered Company number

05392271 (England and Wales)

Registered Charity number

1154418

Registered office

Hampden House
Monument Business Park
Chalgrove
Oxford
Oxfordshire
OX44 7RW

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Trustees
Dr E D Krell (resigned 4/9/2025)
Ms J Trunzo
Dr C M W Tong
Mr J Wilkinson
Mrs D Bruce
Mr D Black
Mr A Kwek (appointed 5/12/2024)
Ms J Goulding (appointed 13/6/2024)

Company Secretary
Mrs D Bruce

Auditors
MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

Solicitors
Mishcon de Reya LLP
Buxton Court
Minns Business Park, Unit 3 West Way
Botley
Oxford
OX2 0JB

STATEMENT OF TRUSTEES' RESPONSIBILITIES
The trustees (who are also the directors of GMDN Agency for the purposes of company law) are responsible for preparing the Report of the Trustees 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".

Company law requires the trustees to prepare financial statements for each financial year. Under that law, the trustees have elected to prepare the financial statements in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards and applicable law).

Under company law the trustees must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the charitable company and of the incoming resources and application of resources, including the income and expenditure, of the charitable company 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 Charities SORP;
- 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 charitable company 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 charitable company and to enable them to ensure that the financial statements comply with the Companies Act 2006. They are also responsible for safeguarding the assets of the charitable company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

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STATEMENT OF TRUSTEES' RESPONSIBILITIES - continued
In so far as the trustees are aware:

- there is no relevant audit information of which the charitable company's auditors are unaware; and
- the trustees have taken all steps that they ought to have taken to make themselves aware of any relevant audit information and to establish that the auditors are aware of that information.

AUDITORS
MGI Midgley Snelling LLP were appointed as the charitable company's auditors during the year and have expressed their willingness to continue in that capacity.

Approved by order of the board of Trustees on 16 October 2025 and signed on its behalf by:

.....
Mrs D Bruce - Trustee

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Opinion

We have audited the financial statements of GMDN Agency (the 'charitable company') for the year ended 31 March 2025 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 charitable company's affairs as at 31 March 2025 and of its incoming resources and application of resources, including its income and expenditure, 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 Companies Act 2006.

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 charitable company 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 charitable company'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.

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Opinions on other matters prescribed by the Companies Act 2006
In our opinion, based on the work undertaken in the course of the audit:
- the information given in the Report of the Trustees for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the Report of the Trustees has been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception
In the light of the knowledge and understanding of the charitable company and its environment obtained in the course of the audit, we have not identified material misstatements in the Report of the Trustees.

We have nothing to report in respect of the following matters where the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept, or returns adequate for our audit have not been received from branches not visited by us; or
- the financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit; or
- the trustees were not entitled to prepare the financial statements in accordance with the small companies' regime and take advantage of the small companies' exemptions in preparing the directors' report and from the requirement to prepare a strategic report.

Responsibilities of trustees
As explained more fully in the Statement of Trustees' Responsibilities, the trustees (who are also the directors of the charitable company for the purposes of company law) are responsible for the preparation of the financial statements and for being satisfied that they 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 charitable company'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 charitable company or to cease operations, or have no realistic alternative but to do so.

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Our responsibilities for the audit of the financial statements

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:

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.

In planning and designing our audit tests, we identify and assess the risks of material misstatements within the financial statements, whether due to fraud or error. Our assessment of these risks includes consideration of the nature of the industry and sector, the control environment and the business performance along with the results of our enquiries of management, about their own identification and assessment of the risks of irregularities. We are also required to perform specific procedures to respond to the risk of management override.

As a result of this assessment, we considered the opportunities and incentives that may exist within the company for fraud and identified that the greatest area of risk was in relation to management override and valuation of intangible assets.

We have obtained an understanding of the legal and regulatory frameworks that the company operates in from discussions with the directors and our knowledge of the company and its industry sector. We have focussed on the provisions of those laws and regulations that have a direct effect on the determination of material amounts and disclosures in the financial statements. The key laws and regulations we considered in this context included the UK Companies Act and local tax legislation.

We performed the following audit procedures after consideration of the above risks which included the following:

- evaluating the methodology used by management to assess the fair value of intangible assets;
- enquiry of management of actual and potential litigation and claims;
- reviewing correspondence with HMRC and the company's legal advisors;
- reviewing financial statement disclosures and testing to supporting documentation to assess compliance with applicable laws and regulations;
- performing analytical procedures to identify any unusual or unexpected relationships that may indicate risks of material misstatement due to fraud; and
- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

The engagement partner has assessed that all engagement team members were made aware of the relevant laws and regulations and potential fraud risks and were reminded to remain alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

Because of the inherent limitations of an audit, there is a risk that we will not detect all irregularities, including those leading to a material misstatement in the financial statements or non-compliance with regulation. The risk increases the more that compliance with a law or regulation is removed from the events and transactions reflected in the financial statements, as we will be less likely to become aware of instances of non-compliance. The risk is also greater regarding irregularities occurring due to fraud rather than error, as fraud involves intentional concealment, forgery, collusion, omission or misrepresentation.

A further description of our responsibilities is available on the Financial Reporting Council's website at: https://www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

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Use of our report

This report is made solely to the charitable company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the charitable company's members 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 charitable company and the charitable company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Sarah Squires

Sarah Squires BEng FCA (Senior Statutory Auditor)
for and on behalf of MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

Date: 16 October 2025

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GMDN AGENCY

STATEMENT OF FINANCIAL ACTIVITIES
(INCORPORATING AN INCOME AND EXPENDITURE ACCOUNT)
FOR THE YEAR ENDED 31 MARCH 2025

	Notes	Unrestricted funds £	Restricted fund £	2025 Total funds £	2024 Total funds £
INCOME AND ENDOWMENTS FROM					
Donations and legacies	3	1,876,034	5,000	1,881,034	1,260,956
Investment income	4	18,627	-	18,627	8,704
Total		1,894,661	5,000	1,899,661	1,269,660
EXPENDITURE ON					
Charitable activities	5				
Development and maintenance of database		1,291,883	5,000	1,296,883	1,638,076
NET INCOME/(EXPENDITURE)		602,778	-	602,778	(368,416)
RECONCILIATION OF FUNDS					
Total funds brought forward		582,883	-	582,883	951,299
TOTAL FUNDS CARRIED FORWARD		1,185,661	-	1,185,661	582,883

The notes form part of these financial statements

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GMDN AGENCY (REGISTERED NUMBER: 05392271)

STATEMENT OF FINANCIAL POSITION
31 MARCH 2025

	Notes	Unrestricted funds £	Restricted fund £	2025 Total funds £	2024 Total funds £
FIXED ASSETS					
Intangible assets	10	394,361	-	394,361	306,344
Tangible assets	11	7,702	-	7,702	10,014
		402,063	-	402,063	316,358
CURRENT ASSETS					
Debtors	12	63,047	-	63,047	54,615
Cash at bank		1,799,322	-	1,799,322	1,049,370
		1,862,369	-	1,862,369	1,103,985
CREDITORS					
Amounts falling due within one year	13	(1,078,771)	-	(1,078,771)	(837,460)
NET CURRENT ASSETS		783,598	-	783,598	266,525
TOTAL ASSETS LESS CURRENT LIABILITIES		1,185,661	-	1,185,661	582,883
NET ASSETS		1,185,661	-	1,185,661	582,883
FUNDS	14				
Unrestricted funds				1,185,661	582,883
TOTAL FUNDS				1,185,661	582,883

These financial statements have been prepared in accordance with the provisions applicable to charitable companies subject to the small companies regime.

The financial statements were approved by the Board of Trustees and authorised for issue on 16 October 2025 and were signed on its behalf by:

.....
Mrs D Bruce - Trustee

The notes form part of these financial statements

Docusign Envelope ID: D938B470-57F9-4C79-817D-14998106EBFF

GMDN AGENCY

STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 31 MARCH 2025

	Notes	2025 £	2024 £
Cash flows from operating activities			
Cash generated from operations	1	994,460	55,292
Net cash provided by operating activities		994,460	55,292
Cash flows from investing activities			
Purchase of intangible fixed assets		(258,277)	(149,571)
Purchase of tangible fixed assets		(4,858)	(5,082)
Interest received		18,627	8,704
Net cash used in investing activities		(244,508)	(145,949)
Change in cash and cash equivalents in the reporting period		749,952	(90,657)
Cash and cash equivalents at the beginning of the reporting period		1,049,370	1,140,027
Cash and cash equivalents at the end of the reporting period		1,799,322	1,049,370

The notes form part of these financial statements

Docusign Envelope ID: D938B470-57F9-4C79-817D-14998106EBFF

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

	2025 £	2024 £
Net income/(expenditure) for the reporting period (as per the Statement of Financial Activities)	602,778	(368,416)
Adjustments for:		
Depreciation charges	177,430	158,698
Interest received	(18,627)	(8,704)
Increase in debtors	(8,432)	(13,455)
Increase in creditors	241,311	287,169
Net cash provided by operations	994,460	55,292

2. ANALYSIS OF CHANGES IN NET FUNDS

	At 1.4.24 £	Cash flow £	At 31.3.25 £
Net cash			
Cash at bank	1,049,370	749,952	1,799,322
	1,049,370	749,952	1,799,322
Total	1,049,370	749,952	1,799,322

The notes form part of these financial statements

Docusign Envelope ID: D938B470-57F9-4C79-817D-14998106EBFF

1. GENERAL INFORMATION

GMDN Agency is a charitable company limited by guarantee and incorporated in England and Wales. The address of the company's registered office is Hampden House, Monument Business Park, Chalgrove, Oxford, OX44 7RW. The registered company number is 05392271 and the registered charity number is 1154418.

The principal activities of the charity are as disclosed within the Report of the Trustees.

The presentational currency of these financial statements is Sterling (£), being the currency of the primary economic market in which the entity operates. All amounts in these financial statements have been rounded to the nearest pound unless stated otherwise.

The significant accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all years presented unless otherwise stated.

2. ACCOUNTING POLICIES

Basis of preparing the financial statements
The financial statements of the charitable company, 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 Companies Act 2006. The financial statements have been prepared under the historical cost convention.

Going Concern
The trustees have considered the substantial net assets of the charity and the cash resources available as well as the charity's commitments. The trustees consider that the charity has adequate resources in place to continue in operation for a period of at least twelve months from the date of approval of the financial statements and therefore continue to adopt the going concern basis in preparing these financial statements.

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. Membership fees are recognised equally over the period of the 12 month subscription.

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 costs related to the category.

Allocation and apportionment of costs
Where costs cannot be directly attributed to particular headings they have been allocated to activities on a basis consistent with use of the resources.

Trustee salaries have been apportioned in accordance with the duties to which they relate.

Intellectual property
The cost of developing the company's database and associated systems is being capitalised and amortised through the Statement of Financial Activities in equal annual instalments over its estimated economic life of 5 years. The cost of development includes staff costs.

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2. 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.

Computers and furniture - straight line - 33%

Taxation
The charity is exempt from corporation 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.

All the charity's funds are unrestricted as at 31 March 2025.

Foreign currencies
Transactions in foreign currencies are recorded at the rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated at the rate of exchange ruling at the balance sheet date. All differences are taken to the Statement of Financial Activities.

Hire purchase and leasing commitments
Rentals paid under operating leases are charged to the Statement of Financial Activities on a straight line basis over the period of the lease.

Pension costs and other post-retirement benefits
The charitable company operates a defined contribution pension scheme. Contributions payable to the charitable company's pension scheme are charged to the Statement of Financial Activities in the period to which they relate.

Financial instruments
The charitable company only has financial assets and financial liabilities of a kind that qualify as basic financial instruments. Basic financial instruments are initially recognised at transaction value and subsequently measured at their settlement value.

Significant judgements and estimates
The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of income, expenditure, assets and liabilities. If in the future such estimates and assumptions, which are based on management's best judgment at the date of the financial statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate in the year in which the circumstances change.

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3. DONATIONS AND LEGACIES

	2025	2024
	£	£
Donations	-	19
Grants	5,000	-
Subscriptions	1,876,034	1,260,937
	1,881,034	1,260,956

Grants received, included in the above, are as follows:

	2025	2024
	£	£
Other grants	5,000	-

Further details of the grant received are disclosed in note 14.

4. INVESTMENT INCOME

	2025	2024
	£	£
Bank interest	18,627	8,704

5. CHARITABLE ACTIVITIES COSTS

	Direct Costs	Support costs (see note 6)	Totals
	£	£	£
Development and maintenance of database	1,157,444	139,439	1,296,883

6. SUPPORT COSTS

	Management	Finance	Governance costs	Totals
	£	£	£	£
Development and maintenance of database	100,983	30,316	8,140	139,439

Analysis of support and governance costs
The charity initially identifies the costs of its support function. It then identifies those costs which relate to the governance function. Having identified its governance costs and support costs these are apportioned between the key charitable activities undertaken in the year. Please refer to the table below for the basis of apportionment and the key analysis of support.

	General Support	Governance function	Basis of apportionment
	£	£	
Wages	100,983		The duties to which they relate
Audit fees		8,140	Governance
Accountancy	30,316		The duties to which they relate
Total	131,299	8,140	

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7. NET INCOME/(EXPENDITURE)

Net income/(expenditure) is stated after charging/(crediting):

	2025	2024
	£	£
Auditors' remuneration	8,140	7,595
Depreciation - owned assets	7,170	6,728
Other operating leases	7,861	24,719
Intellectual property amortisation	170,260	151,970
Foreign exchange (gains)/losses	10,827	18,045

8. TRUSTEES' REMUNERATION AND BENEFITS

	2025	2024
	£	£
Trustees' salaries	176,361	172,334
Trustees' social security	17,988	21,194
Trustees' pension contributions to money purchase schemes	8,752	8,498
	203,101	202,026

The trustees' remuneration relates to one trustee (2024: one), Mrs D Bruce, for services rendered as Chief Executive Officer of the charity.

Trustees' expenses

Trustees' expenses reimbursed for the year ended 31 March 2025 totalled £28,683 to five trustees (2024 - £16,586 to four trustees), of which £nil (2024: £2,451) was due at the year end. Expenses related to travel and conferences.

9. STAFF COSTS

	2025	2024
	£	£
Wages and salaries	691,881	731,737
Social security costs	72,649	84,203
Other pension costs	33,783	36,355
	798,313	852,295

During the year £211,970 (2024 - £121,652) of salaries and pension as well as £21,499 (2024 - £13,169) of social security costs were capitalised as part of the intangible fixed asset. These costs are not included in the figures above.

The average monthly number of employees during the year was as follows:

	2025	2024
Management	1	1
Technical	7	7
Administration	5	4
	13	12

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9. STAFF COSTS - continued

The number of employees whose employee benefits (excluding employer pension costs) exceeded £60,000 was:

	2025	2024
£60,001 - £70,000	2	2
£70,001 - £80,000	1	1
£80,001 - £90,000	-	1
£90,001 - £100,000	1	-
£110,001 - £120,000	1	-
£130,001 - £140,000	-	1
£170,001 - £180,000	1	1
	6	6

10. INTANGIBLE FIXED ASSETS

	Intellectual property £
COST	
At 1 April 2024	1,723,315
Additions	258,277
At 31 March 2025	1,981,592
AMORTISATION	
At 1 April 2024	1,416,971
Charge for year	170,260
At 31 March 2025	1,587,231
NET BOOK VALUE	
At 31 March 2025	394,361
At 31 March 2024	306,344

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11. TANGIBLE FIXED ASSETS

	Computers and furniture £
COST	
At 1 April 2024	44,884
Additions	4,858
Disposals	(4,004)
At 31 March 2025	45,738
DEPRECIATION	
At 1 April 2024	34,870
Charge for year	7,170
Eliminated on disposal	(4,004)
At 31 March 2025	38,036
NET BOOK VALUE	
At 31 March 2025	7,702
At 31 March 2024	10,014

12. DEBTORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	2025 £	2024 £
Trade debtors	31,304	31,198
Other debtors	25	3,423
Prepayments and accrued income	31,718	19,994
	63,047	54,615

13. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	2025 £	2024 £
Trade creditors	16,709	9,369
Social security and other taxes	27,634	28,075
Other creditors	9,645	7,114
Accruals and deferred income	1,024,783	792,902
	1,078,771	837,460

Included within accruals and deferred income is the following deferred income:

	£
Deferred income at 31 March 2024	770,539
Released in the year	(770,539)
Deferred in the year	1,000,661
Deferred income at 31 March 2025	1,000,661

The deferred income is in respect of the annual memberships to the database.

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14. MOVEMENT IN FUNDS

	At 1.4.24 £	Net movement in funds £	At 31.3.25 £
Unrestricted funds			
General fund	2,633	602,778	605,411
Designated cash flow fund	250,000	-	250,000
Designated reserve fund	330,250	-	330,250
	582,883	602,778	1,185,661
TOTAL FUNDS	582,883	602,778	1,185,661

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

	Incoming resources £	Resources expended £	Movement in funds £
Unrestricted funds			
General fund	1,894,661	(1,291,883)	602,778
Restricted funds			
Innovate UK fund	5,000	(5,000)	-
TOTAL FUNDS	1,899,661	(1,296,883)	602,778

Comparatives for movement in funds

	At 1.4.23 £	Net movement in funds £	Transfers between funds £	At 31.3.24 £
Unrestricted funds				
General fund	171,049	(368,416)	200,000	2,633
Designated cash flow fund	250,000	-	-	250,000
Designated reserve fund	530,250	-	(200,000)	330,250
	951,299	(368,416)	-	582,883
TOTAL FUNDS	951,299	(368,416)	-	582,883

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14. MOVEMENT IN FUNDS - continued

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

	Incoming resources £	Resources expended £	Movement in funds £
Unrestricted funds			
General fund	1,269,660	(1,638,076)	(368,416)
TOTAL FUNDS	1,269,660	(1,638,076)	(368,416)

The Charity has the following restricted funds:

The Innovate UK Fund is a grant received to be used towards labour costs for transforming postmarket intelligence to safely accelerate medical device innovation and adoption.

The Charity has the following designated funds:

The Designated Cash Flow Fund ("Operational Reserve") is held to cover cash flow variability and anticipated short-term variations in either income or expenditure. It also needs to cover the cost of winding up the Agency subject to the possibility that the Agency needs to be closed.

The Designated Reserve Fund ("Strategic Reserve") is held to cover anticipated needs over and above those accommodated by the Operational Reserve but required to support the long-term sustainability of the Agency. This needs to be consistent with the conditions applied above.

The level of these reserves will be agreed on an annual basis by the Trustees as part of the annual financial budgeting process.

15. EMPLOYEE BENEFIT OBLIGATIONS

The company operates a defined contribution pension scheme. The pension costs charged to the income statement represent contributions payable by the company to the fund in the year and amounted to £43,738 (2024 - £42,887). This is prior to any capitalisation of costs in respect of the development of the database. Pension commitments included on the statement of financial position at the year end date amount to £9,644 (2024: £7,114).

16. RELATED PARTY DISCLOSURES

There were no related party transactions for the year ended 31 March 2025 (2024: £Nil).

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17. ULTIMATE CONTROLLING PARTY

The charity was under the control of the trustees throughout the current and previous year.

18. COMPANY LIMITED BY GUARANTEE

The liability of each member is limited to an amount not exceeding £10.

GMDN AGENCY

England & Wales - Charity number 1154418

Accounts

Docusign Envelope ID: DFFB8044-A239-4AE7-B509-1C08EFE41471

REGISTERED COMPANY NUMBER: 05392271 (England and Wales)
REGISTERED CHARITY NUMBER: 1154418

REPORT OF THE TRUSTEES AND

AUDITED FINANCIAL STATEMENTS

FOR THE YEAR ENDED 31 MARCH 2024

FOR

GMDN AGENCY

Docusign Envelope ID: DFFB8044-A239-4AE7-B509-1C08EFE41471

GMDN AGENCY

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FOR THE YEAR ENDED 31 MARCH 2024

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The trustees who are also directors of the charity for the purposes of the Companies Act 2006, present their report with the financial statements of the charity for the year ended 31 March 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 ACTIVITIES

Purposes and aims

Our charity's purposes, as set out in the objects contained in the company's memorandum of association, are to:

To preserve and protect health and to relieve sickness for the public benefit by developing and maintaining the 'Global Medical Device Nomenclature', a system of internationally agreed descriptors used to identify medical device products which will meet a global need for identification purposes. Our aims fully reflect the purposes that the charity was set up to further.

Our Strategic Aims, as identified in our Quality Policy, fully reflect the purposes that the charity was set up to further:

- Assist in the protection of patients by acting as a resource for healthcare regulators to help them identify trends and solve problems quickly;
- Facilitate collaborative efforts between regulators in different jurisdictions;
- Offer expertise and insight to the whole medical device supply chain;
- Increase transparency of the Agency through stakeholder engagement and communication of activities;
- Support the industry in the setting up of registries and learning communities;
- Demonstrate the advantages of greater global harmonisation and medical technology for patient care;
- Support users to reduce the risk of misuse or misassignment of GMDN terms by taking the lead on the quality of Terms assignment to ensure they are as accurate as possible for downstream use;
- Assisting stakeholders in the downstream use of GMDN data as a leveraging tool, e.g., inventory management, real-world evidence analysis, vigilance and signal detection.

Ensuring our work delivers our aims

We review our Strategic Aims each year (The annual review takes place in February each year). This review looks at what we achieved and the outcomes of our work in the previous 12 months. The review looks at the success of each key activity and the benefits they have brought to those groups of people we are set up to help. The review also helps us ensure that our aims, objectives and activities remain focused on our stated purposes. We have referred to the guidance in the Charity Commission's general guidance on public benefit when reviewing our aims and objectives and planning our future activities. In particular, the trustees consider how planned activities will contribute to the aims and objectives they have set.

The focus of our work

After extensive consultation, the Strategy 2022-2026 was published in early 2022. To deliver the GMDN Agency's core work of helping to meet the global need for accurate identification of medical devices, we have developed four ambitions: the aims for those areas of work and where we expect to be at the end of the five-year strategy period.

- Promote the value of global collaboration and harmonisation
- Continuously improve and innovate
- Provide excellent services which add value
- Be engaged, helpful and expert

The next five-year strategy will be reviewed with the input of all relevant stakeholders and will be published in the last quarter of 2025.

Docusign Envelope ID: DFFB8044-A239-4AE7-B509-1C08EFE41471

OBJECTIVES AND ACTIVITIES

Public benefit

Our main activities and who we try to help are described below. All our charitable activities focus on the accurate identification of medical devices by standardising their common description and sharing this information with Governments, Hospitals and device manufacturers worldwide for the public benefit.

Who used and benefited from our services?

Our objects and funding limit the services we provide to maintaining, promoting, and disseminating the Global Medical Device Nomenclature.

Equal access to our services is an important issue for us. All potential users of the GMDN can gain free access to the GMDN data.

Medical device regulators use the GMDN data to identify specific equipment accurately when they need to approve medical devices as part of their national regulatory framework.

When monitoring the safety of medical devices within the market, medical device regulators can use the GMDN to identify trends in the success and failure of a specific device or common technology, which is vitally important when systematic failures of devices from more than one manufacturer may occur.

Medical device manufacturers use GMDN data to sort their products into more manageable groups and provide more consistent device names to their customers.

Medical device users can use GMDN data to support decision-making within the healthcare environment.

We maintain our website to provide information to our members in 14 languages, thereby encouraging wider global access to the GMDN. If necessary, more languages will be added each year.

The GMDN Agency continues to maintain its Quality Management System compliance to standard ISO9001:2015 by a third-party (BSI UK) audit.

To demonstrate our commitment to information security, the GMDN Agency was re-certified to the UK Government's Cyber Essentials scheme in October 2023.

FINANCIAL REVIEW

Principal funding sources

The principal funding sources for the charity are currently the licencing of services related to the maintenance of the GMDN to our members via our website.

Access is only available to members, and membership is priced according to organisation type and size. The membership process is completed online, and access to the GMDN database is immediate upon completion of the registration process. Approximately 91% of organisations access our membership services free of charge, and some commercial organisations that make up the balance, volunteer to subscribe to our paid membership services.

Investment policy and objectives

Aside from retaining a prudent amount in reserves each year, most of the charity's funds are to be spent in the short term, so there are few funds for long-term investment. With the aid of sound financial management and the support of its staff and volunteers, the charity maintained a total of funds carried forward amounting to £582,883.

Docusign Envelope ID: DFFB8044-A239-4AE7-B509-1C08EFE41471

FINANCIAL REVIEW

Reserves policy

The GMDN Agency, as a charitable activity designed to provide services to members, should operate on the basis of costs equating to income over the long term. Reserves will be held to ensure continuity of operation and provide a buffer for variations in income or respond to short-term expenditure needs not accommodated by the normal running of the organisation, as well as addressing anticipated future change costs associated with both environmental and operational necessities e.g. changes in business model, major recapitalisation of assets, etc.

Excess funds should be returned to members over the medium term via adjustments to the fees for service. Reserves are categorised as Operational and Strategic reserves.

The Operational reserve is to cover cash flow variability and anticipated short-term variations in either income or expenditure. It also needs to cover the cost of winding up the Agency, subject to the possibility that the Agency needs to be closed. In 2023-24 the investment IT/GMDN Database Software Coding did incur some substantial 'one-off' operational charges. This pushed the expenditure higher than expected in the year.

The Strategic reserve is to cover anticipated needs over and above those accommodated by the Operational reserve but required to support the long-term sustainability of the Agency. This needs to be consistent with the conditions applied above.

The Trustees agree on an annual basis to the level of these reserves as part of the financial budgeting process.

FUTURE DEVELOPMENTS

The Agency's primary objective continues to be the effective use of the GMDN by national medical device regulators and other stakeholders worldwide.

The Trustees deliberately build up the reserves in the past few years to meet the challenges and costs associated with the increasing use of the GMDN. Due to the long-term nature of adopting the GMDN, the timing of the use of funds can be challenging to predict. It is expected that the adoption of the GMDN will require the investment of substantial funds in supporting adoption and supporting users worldwide.

Our larger company members have remained loyal to the voluntary paid-for services we provide to support their management of the GMDN Terms they use. Therefore our income has remained enough to allow the Trustees to be confident of our long-term financial sustainability. The membership schemes will be carefully monitored during the coming years to determine their ongoing suitability of purpose and amended each year as necessary.

With the increased global recognition and use of GMDN, several countries have joined in adopting it, and the collaboration with the WHO started in March 2024; this is particularly important in countries with less-developed economies.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Governing document

The organisation is a charitable company limited by guarantee, incorporated on 14 March 2005 and registered as a charity on 31 October 2013. The company was established under a Memorandum of Association which established the objects and powers of the charitable company and is governed under its Articles of Association. In the event of the company being wound up members are required to contribute an amount not exceeding £10.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Recruitment and appointment of new trustees

The directors of the company are also charity trustees for the purposes of charity law and under the company's Articles are known as members of the Board of Trustees. Under the requirements of the Memorandum and Articles of Association the members of the Board of Trustees are elected to serve for a period of three years after which they must be re-elected at the next Annual General Meeting.

All members of the Board of Trustees give their time voluntarily and received no benefits from the charity. Any expenses reclaimed from the charity are set out in note 8 to the accounts.

Due to the nature of the medical device sector much of the charity's work inevitably focuses upon this subject. The Board of Trustees seeks to ensure that the needs of this sector are appropriately reflected through the members of the trustee body.

To enhance the potential pool of trustees, the charity, through selective networking with industry, regulators and healthcare providers, has sought to identify those individuals who would be willing to become members of the Agencies advisory committees and use their own experience to assist the charity.

In early 2022 following the launch of our new strategy, we established the Authorities Strategic Advisory Group (ASAG) as a standing advisory committee to the Board of Trustees. This committee strengthens the voice of regulators in the strategic planning of the Agency and has been very useful, with regulators from Australia, Brazil, Canada, the UK and the USA now actively participating.

The more traditional business and medical skills are well represented on the Board of Trustees. In an effort to maintain this broad skill mix, members of the Board of Trustees are requested to provide a list of their skills and in the event of particular skills being lost due to retirements, individuals are approached to offer themselves for election to the Board of Trustees. A new Trustee joined the Board within the last year.

The Trustees as part of the recent strategic planning process, wish to increase the active involvement of regulators in our governance and therefore are engaging with them to see how this can be done in the coming year.

Organisational structure

The Board of Trustees consists of up to eight members who meet quarterly and are responsible for the strategic direction and policy of the charity. At present, the Committee has six members from a variety of professional backgrounds relevant to the work of the charity.

A scheme of delegation is in place and day to day responsibility for the provision of the services rest with the Chief Executive Officer. The Chief Executive Officer is responsible for ensuring that the charity delivers the services specified and that key performance indicators are met. The Technical Lead has overall responsibility for the maintenance of the Global Medical Device Nomenclature database and the Office Administrator has responsibility for customer services staff. The Chief Executive Officer supervises all staff and ensures that the team continues to develop their skills in line with good working practice.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Induction and training of new trustees

Trustees are already familiar with the practical work of the charity, having been encouraged to have been a previous members of Agencies advisory committees.

Additionally, new trustees are invited and encouraged to attend a training session to familiarise themselves with the charity and the context within which it operates. This is led by the Chief Executive Officer of the charity and covers:

- The obligations of Board of Trustees members;
- The main documents which set out the operational framework for the charity including the Articles of Association;
- Resourcing and the current financial position as set out in the latest published accounts; and
- Future plans and objectives.

A resource pack has been prepared drawing information from the various Charity Commission publications. This is distributed to all new trustees along with the Articles of Association, Governance, Policy and reference documents and the latest management financial report.

Related parties

In so far as it is complimentary to the charity's objects, the charity is guided by international forum for medical device safety, including the members of the International Medical Device Regulators Forum (IMDRF) and the Global Harmonisation Working Party (GHWP) as well as international medical device manufacturers' trade associations, including the Global Medical Technology Alliance (GMTA) and the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA). The representation of the GMDN Agency to these organisations has proved invaluable to the charity in establishing improved links with the medical device sector and identifying relevant policy improvements.

Risk management

The Board of Trustees has conducted a review of the major risks to which the charity is exposed. Our risk register is reviewed at every Board meeting. Where appropriate, systems or procedures have been established to mitigate the risks the charity faces. Significant external risks to funding have led to the development of a strategic plan which will allow for the planning of funding and activities. Internal control risks are minimised by the implementation of procedures for authorisation of all transactions and projects. Procedures are in place to ensure compliance with health and safety of staff, volunteers, clients and visitors to the GMDN Agency's offices. The third-party certification of our ISO 9001 Quality Management System supports a consistent quality of delivery for all operational aspects of the charity. All internal procedures are regularly audited to ensure that they continue to meet the needs of the charity.

REFERENCE AND ADMINISTRATIVE DETAILS

Registered Company number

05392271 (England and Wales)

Registered Charity number

1154418

Registered office

Hampden House
Monument Business Park
Chalgrove
Oxford
Oxfordshire
OX44 7RW

Docusign Envelope ID: DFFB8044-A239-4AE7-B509-1C08EFE41471

Trustees
Dr E D Krell
Ms J Trunzo
Dr C M W Tong
Mr J Wilkinson
Mrs D Bruce
Mr D Black (appointed 6/12/2023)

Company Secretary
Mrs D Bruce

Auditors
MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

Solicitors
Mishcon de Reya LLP
Buxton Court
Minns Business Park, Unit 3 West Way
Botley
Oxford
OX2 0JB

STATEMENT OF TRUSTEES' RESPONSIBILITIES
The trustees (who are also the directors of GMDN Agency for the purposes of company law) are responsible for preparing the Report of the Trustees 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".

Company law 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 charitable company and of the incoming resources and application of resources, including the income and expenditure, of the charitable company 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;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the charitable company 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 charitable company and to enable them to ensure that the financial statements comply with the Companies Act 2006. They are also responsible for safeguarding the assets of the charitable company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

In so far as the trustees are aware:

- there is no relevant audit information of which the charitable company's auditors are unaware; and
- the trustees have taken all steps that they ought to have taken to make themselves aware of any relevant audit information and to establish that the auditors are aware of that information.

STATEMENT OF TRUSTEES' RESPONSIBILITIES - continued

AUDITORS

MGI Midgley Snelling LLP were appointed as the charitable company's auditors during the year and have expressed their willingness to continue in that capacity.

Approved by order of the board of Trustees on 4 September 2024 and signed on its behalf by:

DocuSigned by:
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05/09/2024

Mrs D Bruce - Trustee

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REPORT OF THE INDEPENDENT AUDITORS TO THE MEMBERS OF GMDN AGENCY

Opinion

We have audited the financial statements of GMDN Agency (the 'charitable company') for the year ended 31 March 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 charitable company's affairs as at 31 March 2024 and of its incoming resources and application of resources, including its income and expenditure, 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 Companies Act 2006.

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 charitable company 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 charitable company'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.

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Opinions on other matters prescribed by the Companies Act 2006
In our opinion, based on the work undertaken in the course of the audit:
- the information given in the Report of the Trustees for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the Report of the Trustees has been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception
In the light of the knowledge and understanding of the charitable company and its environment obtained in the course of the audit, we have not identified material misstatements in the Report of the Trustees.

We have nothing to report in respect of the following matters where the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept, or returns adequate for our audit have not been received from branches not visited by us; or
- the financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit; or
- the trustees were not entitled to prepare the financial statements in accordance with the small companies' regime and take advantage of the small companies' exemptions in preparing the directors' report and from the requirement to prepare a strategic report.

Responsibilities of trustees
As explained more fully in the Statement of Trustees' Responsibilities, the trustees (who are also the directors of the charitable company for the purposes of company law) are responsible for the preparation of the financial statements and for being satisfied that they 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 charitable company'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 charitable company or to cease operations, or have no realistic alternative but to do so.

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Our responsibilities for the audit of the financial statements

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:

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.

In planning and designing our audit tests, we identify and assess the risks of material misstatements within the financial statements, whether due to fraud or error. Our assessment of these risks includes consideration of the nature of the industry and sector, the control environment and the business performance along with the results of our enquiries of management, about their own identification and assessment of the risks of irregularities. We are also required to perform specific procedures to respond to the risk of management override.

As a result of this assessment, we considered the opportunities and incentives that may exist within the company for fraud and identified that the greatest area of risk was in relation to management override.

We have obtained an understanding of the legal and regulatory frameworks that the company operates in from discussions with the directors and our knowledge of the company and its industry sector. We have focussed on the provisions of those laws and regulations that have a direct effect on the determination of material amounts and disclosures in the financial statements. The key laws and regulations we considered in this context included the UK Companies Act and local tax legislation.

We performed the following audit procedures after consideration of the above risks which included the following:
- enquiry of management of actual and potential litigation and claims;
- reviewing correspondence with HMRC and the company's legal advisors;
- reviewing financial statement disclosures and testing to supporting documentation to assess compliance with applicable laws and regulations;
- performing analytical procedures to identify any unusual or unexpected relationships that may indicate risks of material misstatement due to fraud; and
- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

The engagement partner has assessed that all engagement team members were made aware of the relevant laws and regulations and potential fraud risks and were reminded to remain alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

Because of the inherent limitations of an audit, there is a risk that we will not detect all irregularities, including those leading to a material misstatement in the financial statements or non-compliance with regulation. The risk increases the more that compliance with a law or regulation is removed from the events and transactions reflected in the financial statements, as we will be less likely to become aware of instances of non-compliance. The risk is also greater regarding irregularities occurring due to fraud rather than error, as fraud involves intentional concealment, forgery, collusion, omission or misrepresentation.

A further description of our responsibilities is available on the Financial Reporting Council's website at: https://www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

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REPORT OF THE INDEPENDENT AUDITORS TO THE MEMBERS OF GMDN AGENCY

Use of our report

This report is made solely to the charitable company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the charitable company's members 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 charitable company and the charitable company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Sarah Squires BEng FCA (Senior Statutory Auditor)
for and on behalf of MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

9 September 2024

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GMDN AGENCY

STATEMENT OF FINANCIAL ACTIVITIES
(INCORPORATING AN INCOME AND EXPENDITURE ACCOUNT)
FOR THE YEAR ENDED 31 MARCH 2024

	Notes	2024 Unrestricted funds £	2023 Total funds £
INCOME AND ENDOWMENTS FROM			
Donations and legacies	3	1,260,956	951,466
Investment income	4	8,704	476
Total		1,269,660	951,942
EXPENDITURE ON			
Charitable activities	5		
Development and maintenance of database		1,638,076	1,517,547
NET INCOME/(EXPENDITURE)		(368,416)	(565,605)
RECONCILIATION OF FUNDS			
Total funds brought forward		951,299	1,516,904
TOTAL FUNDS CARRIED FORWARD		582,883	951,299

The notes form part of these financial statements

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GMDN AGENCY

STATEMENT OF FINANCIAL POSITION
31 MARCH 2024

	Notes	2024 Unrestricted funds £	2023 Total funds £
FIXED ASSETS			
Intangible assets	10	306,344	308,743
Tangible assets	11	10,014	11,660
		316,358	320,403
CURRENT ASSETS			
Debtors	12	54,615	41,160
Cash at bank		1,049,370	1,140,027
		1,103,985	1,181,187
CREDITORS			
Amounts falling due within one year	13	(837,460)	(550,291)
NET CURRENT ASSETS		266,525	630,896
TOTAL ASSETS LESS CURRENT LIABILITIES		582,883	951,299
NET ASSETS		582,883	951,299
FUNDS	14		
Unrestricted funds		582,883	951,299
TOTAL FUNDS		582,883	951,299

These financial statements have been prepared in accordance with the provisions applicable to charitable companies subject to the small companies regime.

The financial statements were approved by the Board of Trustees and authorised for issue on 4 September 2024 and were signed on its behalf by:

DocuSigned by:
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Mrs D Bruce - Trustee

The notes form part of these financial statements

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GMDN AGENCY

STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 31 MARCH 2024

	Notes	2024 £	2023 £
Cash flows from operating activities			
Cash generated from operations	1	55,292	(388,117)
Net cash provided by/(used in) operating activities		55,292	(388,117)
Cash flows from investing activities			
Purchase of intangible fixed assets		(149,571)	(138,954)
Purchase of tangible fixed assets		(5,082)	(10,790)
Interest received		8,704	476
Net cash used in investing activities		(145,949)	(149,268)
Change in cash and cash equivalents in the reporting period		(90,657)	(537,385)
Cash and cash equivalents at the beginning of the reporting period		1,140,027	1,677,412
Cash and cash equivalents at the end of the reporting period		1,049,370	1,140,027

The notes form part of these financial statements

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NOTES TO THE STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 31 MARCH 2024

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

	2024 £	2023 £
Net expenditure for the reporting period (as per the Statement of Financial Activities)	(368,416)	(565,605)
Adjustments for:		
Depreciation charges	158,698	158,949
Loss on disposal of fixed assets	-	762
Interest received	(8,704)	(476)
Increase in debtors	(13,455)	(21,542)
Increase in creditors	287,169	39,795
Net cash provided by/(used in) operations	55,292	(388,117)

2. ANALYSIS OF CHANGES IN NET FUNDS

	At 1.4.23 £	Cash flow £	At 31.3.24 £
Net cash			
Cash at bank	1,140,027	(90,657)	1,049,370
	1,140,027	(90,657)	1,049,370
Total	1,140,027	(90,657)	1,049,370

The notes form part of these financial statements

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1. GENERAL INFORMATION

GMDN Agency is a charitable company limited by guarantee and incorporated in England and Wales. The address of the company's registered office is Hampden House, Monument Business Park, Chalgrove, Oxford, OX44 7RW. The registered company number is 05392271 and the registered charity number is 1154418.

The principal activities of the charity are as disclosed within the Report of the Trustees.

The presentational currency of these financial statements is Sterling (£), being the currency of the primary economic market in which the entity operates. All amounts in these financial statements have been rounded to the nearest pound unless stated otherwise.

The significant accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all years presented unless otherwise stated.

2. ACCOUNTING POLICIES

Basis of preparing the financial statements
The financial statements of the charitable company, 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 Companies Act 2006. The financial statements have been prepared under the historical cost convention.

Going Concern
The trustees have considered the substantial net assets of the charity and the cash resources available as well as the charity's commitments. The trustees consider that the charity has adequate resources in place to continue in operation for a period of at least twelve months from the date of approval of the financial statements and therefore continue to adopt the going concern basis in preparing these financial statements.

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. Membership fees are recognised equally over the period of the 12 month subscription.

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 costs related to the category.

Allocation and apportionment of costs
Where costs cannot be directly attributed to particular headings they have been allocated to activities on a basis consistent with use of the resources.

Trustee salaries have been apportioned in accordance with the duties to which they relate.

Intellectual property
The cost of developing the company's database and associated systems is being capitalised and amortised through the Statement of Financial Activities in equal annual instalments over its estimated economic life of 5 years. The cost of development includes staff costs.

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2. 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.

Computers and furniture - straight line - 33%

Taxation
The charity is exempt from corporation 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.

All the charity's funds are unrestricted.

Foreign currencies
Transactions in foreign currencies are recorded at the rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated at the rate of exchange ruling at the balance sheet date. All differences are taken to the Statement of Financial Activities.

Hire purchase and leasing commitments
Rentals paid under operating leases are charged to the Statement of Financial Activities on a straight line basis over the period of the lease.

Pension costs and other post-retirement benefits
The charitable company operates a defined contribution pension scheme. Contributions payable to the charitable company's pension scheme are charged to the Statement of Financial Activities in the period to which they relate.

Financial instruments
The charitable company only has financial assets and financial liabilities of a kind that qualify as basic financial instruments. Basic financial instruments are initially recognised at transaction value and subsequently measured at their settlement value.

Significant judgements and estimates
The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of income, expenditure, assets and liabilities. If in the future such estimates and assumptions, which are based on management's best judgment at the date of the financial statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate in the year in which the circumstances change.

3. DONATIONS AND LEGACIES

	2024	2023
	£	£
Donations	19	11
Subscriptions	1,260,937	951,455
	1,260,956	951,466

4. INVESTMENT INCOME

	2024	2023
	£	£
Bank interest	8,704	476

5. CHARITABLE ACTIVITIES COSTS

	Direct Costs	Support costs (see note 6)	Totals
	£	£	£
Development and maintenance of database	1,502,723	135,353	1,638,076

6. SUPPORT COSTS

	Management	Finance	Governance costs	Totals
	£	£	£	£
Development and maintenance of database	100,570	27,188	7,595	135,353

Analysis of support and governance costs

The charity initially identifies the costs of its support function. It then identifies those costs which relate to the governance function. Having identified its governance costs and support costs these are apportioned between the key charitable activities undertaken in the year. Please refer to the table below for the basis of apportionment and the key analysis of support.

	General Support	Governance function	Basis of apportionment
	£	£	
Wages	100,570		The duties to which they relate
Audit fees		7,595	Governance
Accountancy	27,188		The duties to which they relate
Total	127,758	7,595	

7. NET INCOME/(EXPENDITURE)

Net income/(expenditure) is stated after charging/(crediting):

	2024	2023
	£	£
Auditors' remuneration	7,595	6,655
Depreciation - owned assets	6,728	6,412
Other operating leases	24,719	20,247
Deficit on disposal of fixed assets	-	762
Intellectual property amortisation	151,970	152,537
Foreign exchange (gains)/losses	18,045	(52,562)

8. TRUSTEES' REMUNERATION AND BENEFITS

	2024	2023
	£	£
Trustees' salaries	172,334	261,600
Trustees' social security	21,194	32,416
Trustees' pension contributions to money purchase schemes	8,498	12,916
	202,026	306,932

The trustees' remuneration is in respect of one (2023 - two) trustees, being Mrs D Bruce, for services as the Chief Executive Officer of the charity.

Trustees' expenses

Trustees' expenses reimbursed for the year ended 31 March 2024 totalled £16,586 to four trustees (2023 - £38,118 to five trustees), of which £2,451 (2023: £Nil) was due at the year end. Expenses related to travel, subscriptions and other sundry costs.

9. STAFF COSTS

	2024	2023
	£	£
Wages and salaries	731,737	772,271
Social security costs	84,203	88,947
Other pension costs	36,355	37,556
	852,295	898,774

During the year £121,652 (2023 - £108,141) of salaries and pension as well as £13,169 (2023 - £11,511) of social security costs were capitalised as part of the intangible fixed asset. These costs are not included in the figures above.

The average monthly number of employees during the year was as follows:

	2024	2023
Management	1	2
Technical	7	7
Administration	4	3
	12	12

9. STAFF COSTS - continued

The number of employees whose employee benefits (excluding employer pension costs) exceeded £60,000 was:

	2024	2023
£60,001 - £70,000	2	1
£70,001 - £80,000	1	1
£80,001 - £90,000	1	1
£130,001 - £140,000	1	1
£170,001 - £180,000	1	-
£190,001 - £200,000	-	1
	6	5

10. INTANGIBLE FIXED ASSETS

	Intellectual property £
COST	
At 1 April 2023	1,573,744
Additions	149,571
At 31 March 2024	1,723,315
AMORTISATION	
At 1 April 2023	1,265,001
Charge for year	151,970
At 31 March 2024	1,416,971
NET BOOK VALUE	
At 31 March 2024	306,344
At 31 March 2023	308,743

11. TANGIBLE FIXED ASSETS

	Computers and furniture £
COST	
At 1 April 2023	42,764
Additions	5,082
Disposals	(2,962)
At 31 March 2024	44,884
DEPRECIATION	
At 1 April 2023	31,104
Charge for year	6,728
Eliminated on disposal	(2,962)
At 31 March 2024	34,870
NET BOOK VALUE	
At 31 March 2024	10,014
At 31 March 2023	11,660

12. DEBTORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	2024 £	2023 £
Trade debtors	31,198	-
Other debtors	3,423	4,838
Prepayments and accrued income	19,994	36,322
	54,615	41,160

13. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	2024 £	2023 £
Trade creditors	9,369	23,346
Social security and other taxes	28,075	36,635
Other creditors	7,114	7,890
Accruals and deferred income	792,902	482,420
	837,460	550,291

Included within accruals and deferred income is the following deferred income:

	£
Deferred income at 31 March 2023	463,335
Released in the year	(463,335)
Deferred in the year	770,539
Deferred income at 31 March 2024	770,539

The deferred income is in respect of the annual memberships to the database.

14. MOVEMENT IN FUNDS

	At 1.4.23 £	Net movement in funds £	Transfers between funds £	At 31.3.24 £
Unrestricted funds				
General fund	171,049	(368,416)	200,000	2,633
Designated cash flow fund	250,000	-	-	250,000
Designated reserve fund	530,250	-	(200,000)	330,250
	951,299	(368,416)	-	582,883
TOTAL FUNDS	951,299	(368,416)	-	582,883

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

	Incoming resources £	Resources expended £	Movement in funds £
Unrestricted funds			
General fund	1,269,660	(1,638,076)	(368,416)
TOTAL FUNDS	1,269,660	(1,638,076)	(368,416)

Comparatives for movement in funds

	At 1.4.22 £	Net movement in funds £	At 31.3.23 £
Unrestricted funds			
General fund	736,654	(565,605)	171,049
Designated cash flow fund	250,000	-	250,000
Designated reserve fund	530,250	-	530,250
	1,516,904	(565,605)	951,299
TOTAL FUNDS	1,516,904	(565,605)	951,299

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

	Incoming resources £	Resources expended £	Movement in funds £
Unrestricted funds			
General fund	951,942	(1,517,547)	(565,605)
TOTAL FUNDS	951,942	(1,517,547)	(565,605)

14. MOVEMENT IN FUNDS - continued

The Charity has the following designated funds:

The Designated Cash Flow Fund ("Operational Reserve") is held to cover cash flow variability and anticipated short-term variations in either income or expenditure. It also needs to cover the cost of winding up the Agency subject to the possibility that the Agency needs to be closed.

The Designated Reserve Fund ("Strategic Reserve") is held to cover anticipated needs over and above those accommodated by the Operational Reserve but required to support the long-term sustainability of the Agency. This needs to be consistent with the conditions applied above.

The level of these reserves will be agreed on an annual basis by the Trustees as part of the annual financial budgeting process.

15. EMPLOYEE BENEFIT OBLIGATIONS

The company operates a defined contribution pension scheme. The pension costs charged to the income statement represent contributions payable by the company to the fund in the year and amounted to £42,887 (2023 - £41,923). This is prior to any capitalisation of costs in respect of the development of the database.

16. RELATED PARTY DISCLOSURES

During the year ended 31 March 2024, consultancy fees amounting to £8,400 (2023: £Nil) were paid to Mr M Wasmuth, who was a trustee during the prior year ended 31 March 2023.

There were no other related party transactions for the year ended 31 March 2024 (2023: £Nil).

17. ULTIMATE CONTROLLING PARTY

The charity was under the control of the trustees throughout the current and previous year.

18. COMPANY LIMITED BY GUARANTEE

The liability of each member is limited to an amount not exceeding £10.

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GMDN AGENCY

DETAILED STATEMENT OF FINANCIAL ACTIVITIES
FOR THE YEAR ENDED 31 MARCH 2024

	2024 £	2023 £
INCOME AND ENDOWMENTS		
Donations and legacies		
Donations	19	11
Subscriptions	1,260,937	951,455
	1,260,956	951,466
Investment income		
Bank interest	8,704	476
Total incoming resources	1,269,660	951,942
EXPENDITURE		
Charitable activities		
Trustees' salaries	85,724	130,248
Trustees' social security	10,597	16,208
Trustees' pension contributions	4,249	6,458
Wages	559,403	510,671
Social security	63,009	56,531
Pensions	27,857	24,640
Rent	24,719	20,247
Database costs	199,406	123,837
Travel and subsistence	51,124	61,380
Insurance	36,350	32,481
Telephone	351	790
Postage and stationery	300	316
Computer costs	204	95
Sundries	8,328	6,435
Consultancy	201,466	157,541
Bank charges	19,839	16,061
Foreign exchange (gains) / losses	18,045	(52,262)
PAYE interest	-	19
Training costs	24,307	20,424
Subscriptions	4,772	9,770
Recruitment fees	2,196	33,727
Marketing	1,779	4,350
Amortisation	151,970	152,537
Depreciation	6,728	6,412
Loss on sale of tangible fixed assets	-	762
	1,502,723	1,339,678
Support costs		
Management		
Trustees' salaries	85,724	130,248
Carried forward	85,724	130,248

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GMDN AGENCY

DETAILED STATEMENT OF FINANCIAL ACTIVITIES
FOR THE YEAR ENDED 31 MARCH 2024

	2024 £	2023 £
Management		
Brought forward	85,724	130,248
Trustees' social security	10,597	16,208
Trustees' pension contributions	4,249	6,458
	100,570	152,914
Finance		
Accountancy	27,188	18,300
Governance costs		
Auditors' remuneration	7,595	6,655
Total resources expended	1,638,076	1,517,547
Net expenditure	(368,416)	(565,605)

This page does not form part of the statutory financial statements

GMDN AGENCY

England & Wales - Charity number 1154418

Accounts

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REGISTERED COMPANY NUMBER: 05392271 (England and Wales)
REGISTERED CHARITY NUMBER: 1154418

REPORT OF THE TRUSTEES AND

AUDITED FINANCIAL STATEMENTS

FOR THE YEAR ENDED 31 MARCH 2023

FOR

GMDN AGENCY

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GMDN AGENCY

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FOR THE YEAR ENDED 31 MARCH 2023

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GMDN AGENCY

REPORT OF THE TRUSTEES
FOR THE YEAR ENDED 31 MARCH 2023

The trustees who are also directors of the charity for the purposes of the Companies Act 2006, present their report with the financial statements of the charity for the year ended 31 March 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 ACTIVITIES

Purposes and aims

Our charity's purposes, as set out in the objects contained in the company's memorandum of association, are to:

To preserve and protect health and to relieve sickness for the public benefit by developing and maintaining the 'Global Medical Device Nomenclature', a system of internationally agreed descriptors used to identify medical device products which will meet a global need for identification purposes. Our aims fully reflect the purposes that the charity was set up to further.

Our charity's purposes, as set out in the objects contained in the company's Articles of Association, are to:

To preserve and protect health and relieve sickness for the public benefit by developing and maintaining the "Global Medical Device Nomenclature", a system of internationally agreed descriptors used to identify medical device products which will meet a global need for identification purposes.

Our Strategic Aims, as identified in our Quality Policy, fully reflect the purposes that the charity was set up to further:

- Assist in the protection of patients by acting as a resource for healthcare regulators to help them identify trends and solve problems quickly;
- Facilitate collaborative efforts between regulators in different jurisdictions;
- Offer expertise and insight to the whole medical device supply chain;
- Increase transparency of the Agency through stakeholder engagement and communication of activities;
- Support the industry in the setting up of registries and learning communities;
- Demonstrate the advantages of greater global harmonisation and medical technology for patient care;
- Support users to reduce the risk of misuse or misassignment of GMDN terms by taking the lead on the quality of Terms assignment to ensure they are as accurate as possible for downstream use;
- Assisting stakeholders in the downstream use of GMDN data as a leveraging tool e.g., inventory management, real-world evidence analysis, vigilance and signal detection.

Ensuring our work delivers our aims

We review our Strategic Aims each year (The annual review took place in February 2023). This review looks at what we achieved and the outcomes of our work in the previous 12 months. The review looks at the success of each key activity and the benefits they have brought to those groups of people we are set up to help. The review also helps us ensure that our aims, objectives and activities remain focused on our stated purposes. We have referred to the guidance contained in the Charity Commission's general guidance on public benefit when reviewing our aims and objectives and in planning our future activities. In particular, the trustees consider how planned activities will contribute to the aims and objectives they have set.

The focus of our work

After extensive consultation, the Strategy 2022-2026 was published in early 2022. To deliver the GMDN Agency's core work of helping to meet the global need for accurate identification of medical devices, we have developed four ambitions, the aims for those areas of work and where we expect to be at the end of the five-year strategy period.

- Promote the value of global collaboration and harmonisation
- Continuously improve and innovate
- Provide excellent services which add value
- Be engaged, helpful and expert

OBJECTIVES AND ACTIVITIES

Public benefit

Our main activities and who we try to help are described below. All our charitable activities focus on the accurate identification of medical devices by standardising their common description and sharing this information with Governments, Hospitals and device manufacturers worldwide for the public benefit.

Who used and benefited from our services?

Our objects and funding limit the services we provide to the maintenance, promotion and distribution of the Global Medical Device Nomenclature.

Equal access to our services is an important issue for us. All potential users of the GMDN can gain free access to the GMDN data.

Medical device regulators use the GMDN data to identify specific equipment accurately when they need to approve medical devices as part of their national regulatory framework.

When monitoring the safety of medical devices within the market, medical device regulators can use the GMDN to identify trends in the success and failure of a specific device or common technology, which is vitally important when systematic failures of devices from more than one manufacturer may occur.

Medical device manufacturers use GMDN data to sort their products into more manageable groups and provide more consistent device names to their customers.

Medical device users can use GMDN data to support decision-making within the healthcare environment.

We maintain our website to provide information to our members in 33 languages, thereby encouraging wider global access to the GMDN, with more languages being added each year if necessary.

The GMDN Agency continues to maintain its Quality Management System compliance to standard ISO9001:2015 by a third-party audit.

To demonstrate our commitment to information security, the GMDN Agency was re-certified to the UK Government's Cyber Essentials scheme in October 2022.

FINANCIAL REVIEW

Principal funding sources

The principal funding sources for the charity are currently the licencing of services related to the maintenance of the GMDN to our members via our website.

Access is only available to members and membership is priced according to organisation type and size. The membership process is completed online and access to the GMDN database is immediate upon completion of the registration process. Over 91% of organisations access our membership services free of any cost, and some commercial organisations that make up the balance, volunteer to subscribe to our paid membership services.

Investment policy and objectives

Aside from retaining a prudent amount in reserves each year, most of the charity's funds are to be spent in the short term, so there are few funds for long-term investment. With the aid of sound financial management and the support of its staff and volunteers, the charity maintained a total of funds carried forward amounting to £951,299.

FINANCIAL REVIEW

Reserves policy

The GMDN Agency, as a charitable activity designed to provide services to members, should operate on the basis of costs equating to income over the long term. Reserves will be held to ensure continuity of operation and provide a buffer for variations in income or respond to short-term expenditure needs not accommodated by the normal running of the organisation, as well as addressing anticipated future change costs associated with both environmental and operational necessities e.g. changes in business model, major recapitalisation of assets, etc.

Excess funds should be returned to members over the medium term via adjustments to the fees for service. Reserves are categorised as Operational and Strategic reserves.

The Operational reserve is to cover cash flow variability and anticipated short-term variations in either income or expenditure. It also needs to cover the cost of winding up the Agency, subject to the possibility that the Agency needs to be closed. In 2022-23 the change of CEO did incur some substantial 'one-off' operational charges. This pushed the expenditure higher than expected in the year.

The Strategic reserve is to cover anticipated needs over and above those accommodated by the Operational reserve but required to support the long-term sustainability of the Agency. This needs to be consistent with the conditions applied above.

The level of these reserves is agreed on an annual basis by the Trustees as part of the financial budgeting process.

FUTURE DEVELOPMENTS

The effective use of the GMDN by national medical device regulators and other stakeholders throughout the world continues to be the primary objective of the Agency.

The Trustees deliberately build up the reserves in the past few years to meet the challenges and costs associated with the increasing use of the GMDN. Due to the long-term nature of adopting the GMDN, the timing of the use of funds can be challenging to predict. It is expected that the adoption of the GMDN will require the investment of substantial funds in supporting adoption and supporting users worldwide.

Our larger company members have remained loyal to the voluntary paid-for services we provide to support their management of the GMDN Terms they use and therefore our income has remained enough to allow the Trustees to be confident of our long-term financial sustainability. The membership schemes will be carefully monitored during the coming years to determine their ongoing suitability of purpose and amended as necessary.

With the increased global recognition and use of GMDN, several countries have joined in adopting the use of the GMDN and this is particularly important in countries with less-developed economies.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Governing document

The organisation is a charitable company limited by guarantee, incorporated on 14 March 2005 and registered as a charity on 31 October 2013. The company was established under a Memorandum of Association which established the objects and powers of the charitable company and is governed under its Articles of Association. In the event of the company being wound up members are required to contribute an amount not exceeding £10.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Recruitment and appointment of new trustees

The directors of the company are also charity trustees for the purposes of charity law and under the company's Articles are known as members of the Board of Trustees. Under the requirements of the Memorandum and Articles of Association the members of the Board of Trustees are elected to serve for a period of three years after which they must be re-elected at the next Annual General Meeting.

All members of the Board of Trustees give their time voluntarily and received no benefits from the charity. Any expenses reclaimed from the charity are set out in note 8 to the accounts.

Due to the nature of the medical device sector much of the charity's work inevitably focuses upon this subject. The Board of Trustees seeks to ensure that the needs of this sector are appropriately reflected through the members of the trustee body.

To enhance the potential pool of trustees, the charity, through selective networking with industry, regulators and healthcare providers, has sought to identify those individuals who would be willing to become members of the Agencies advisory committees and use their own experience to assist the charity.

In early 2022 following the launch of our new strategy, we established the Authorities Strategic Advisory Group (ASAG) as a standing advisory committee to the Board of Trustees. This committee strengthens the voice of regulators in the strategic planning of the Agency and has been very useful, with regulators from Australia, Brazil, Canada, the UK and the USA now actively participating.

The more traditional business and medical skills are well represented on the Board of Trustees. In an effort to maintain this broad skill mix, members of the Board of Trustees are requested to provide a list of their skills and in the event of particular skills being lost due to retirements, individuals are approached to offer themselves for election to the Board of Trustees. No new Trustees joined the Board within the last year.

The Trustees as part of the recent strategic planning process, wish to increase the active involvement of regulators in our governance and therefore are engaging with them to see how this can be done in the coming year.

Organisational structure

The Board of Trustees consists of up to eight members who meet quarterly and are responsible for the strategic direction and policy of the charity. At present, the Committee has five members from a variety of professional backgrounds relevant to the work of the charity.

A scheme of delegation is in place and day to day responsibility for the provision of the services rest with the Chief Executive Officer. The Chief Executive Officer is responsible for ensuring that the charity delivers the services specified and that key performance indicators are met. The Technical Lead has overall responsibility for the maintenance of the Global Medical Device Nomenclature database and the Office Administrator has responsibility for customer services staff. The Chief Executive Officer has individual supervision of all staff and also ensures that the team continue to develop their skills in line with good working practice.

After more than 13 years of service, Chief Executive Officer Mark Wasmuth decided to retire from the Agency, and we wish him well. Our new CEO, Deniz Bruce, was appointed in November 2022 and is now driving the Agency forward in its delivery of our strategic and operational plan.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Induction and training of new trustees

Trustees are already familiar with the practical work of the charity, having been encouraged to have been a previous members of Agencies advisory committees.

Additionally, new trustees are invited and encouraged to attend a training session to familiarise themselves with the charity and the context within which it operates. This is led by the Chief Executive Officer of the charity and covers:

- The obligations of Board of Trustees members;
- The main documents which set out the operational framework for the charity including the Articles of Association;
- Resourcing and the current financial position as set out in the latest published accounts; and
- Future plans and objectives.

A resource pack has been prepared drawing information from the various Charity Commission publications. This is distributed to all new trustees along with the Articles of Association, Governance, Policy and reference documents and the latest management financial report.

Related parties

In so far as it is complimentary to the charity's objects, the charity is guided by international forum for medical device safety, including the members of the International Medical Device Regulators Forum (IMDRF) and the Global Harmonisation Working Party (GHWP) as well as international medical device manufacturers' trade associations, including the Global Medical Technology Alliance (GMTA) and the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA). The representation of the GMDN Agency to these organisations has proved invaluable to the charity in establishing improved links with the medical device sector and identifying relevant policy improvements.

Risk management

The Board of Trustees has conducted a review of the major risks to which the charity is exposed. Our risk register is reviewed at every Board meeting. Where appropriate, systems or procedures have been established to mitigate the risks the charity faces. Significant external risks to funding have led to the development of a strategic plan which will allow for the planning of funding and activities. Internal control risks are minimised by the implementation of procedures for authorisation of all transactions and projects. Procedures are in place to ensure compliance with health and safety of staff, volunteers, clients and visitors to the GMDN Agency's offices. The third-party certification of our ISO 9001 Quality Management System supports a consistent quality of delivery for all operational aspects of the charity. All internal procedures are regularly audited to ensure that they continue to meet the needs of the charity.

REFERENCE AND ADMINISTRATIVE DETAILS

Registered Company number

05392271 (England and Wales)

Registered Charity number

1154418

Registered office

Hampden House
Monument Business Park
Chalgrove
Oxford
Oxfordshire
OX44 7RW

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Trustees
Mr M Wasmuth (resigned 23/3/2023)
Dr E D Krell
Ms J Trunzo
Dr C M W Tong
Mr J Wilkinson
Mrs D Bruce (appointed 7/11/2022)

Company Secretary
Mrs D Bruce

Auditors
MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

Solicitors
Mishcon de Reya LLP
Buxton Court
Minns Business Park, Unit 3 West Way
Botley
Oxford
OX2 0JB

STATEMENT OF TRUSTEES' RESPONSIBILITIES
The trustees (who are also the directors of GMDN Agency for the purposes of company law) are responsible for preparing the Report of the Trustees 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".

Company law 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 charitable company and of the incoming resources and application of resources, including the income and expenditure, of the charitable company 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;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the charitable company 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 charitable company and to enable them to ensure that the financial statements comply with the Companies Act 2006. They are also responsible for safeguarding the assets of the charitable company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

In so far as the trustees are aware:

- there is no relevant audit information of which the charitable company's auditors are unaware; and
- the trustees have taken all steps that they ought to have taken to make themselves aware of any relevant audit information and to establish that the auditors are aware of that information.

STATEMENT OF TRUSTEES' RESPONSIBILITIES - continued

AUDITORS

MGI Midgley Snelling LLP were appointed as the charitable company's auditors during the year and have expressed their willingness to continue in that capacity.

Approved by order of the board of Trustees on 8/10/2023 and signed on its behalf by:

DocuSigned by:
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Mrs D Bruce - Trustee

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Opinion
We have audited the financial statements of GMDN Agency (the 'charitable company') for the year ended 31 March 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 charitable company's affairs as at 31 March 2023 and of its incoming resources and application of resources, including its income and expenditure, 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 Companies Act 2006.

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 charitable company 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 charitable company'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.

Opinions on other matters prescribed by the Companies Act 2006
In our opinion, based on the work undertaken in the course of the audit:
- the information given in the Report of the Trustees for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the Report of the Trustees has been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception
In the light of the knowledge and understanding of the charitable company and its environment obtained in the course of the audit, we have not identified material misstatements in the Report of the Trustees.

We have nothing to report in respect of the following matters where the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept, or returns adequate for our audit have not been received from branches not visited by us; or
- the financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit; or
- the trustees were not entitled to prepare the financial statements in accordance with the small companies' regime and take advantage of the small companies' exemptions in preparing the directors' report and from the requirement to prepare a strategic report.

Responsibilities of trustees
As explained more fully in the Statement of Trustees' Responsibilities, the trustees (who are also the directors of the charitable company for the purposes of company law) are responsible for the preparation of the financial statements and for being satisfied that they 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 charitable company'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 charitable company or to cease operations, or have no realistic alternative but to do so.

Our responsibilities for the audit of the financial statements
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 an auditor's report 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:

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.

In planning and designing our audit tests, we identify and assess the risks of material misstatements within the financial statements, whether due to fraud or error. Our assessment of these risks includes consideration of the nature of the industry and sector, the control environment and the business performance along with the results of our enquiries of management, about their own identification and assessment of the risks of irregularities. We are also required to perform specific procedures to respond to the risk of management override.

As a result of this assessment, we considered the opportunities and incentives that may exist within the company for fraud and identified that the greatest area of risk was in relation to management override.

We have obtained an understanding of the legal and regulatory frameworks that the company operates in from discussions with the directors and our knowledge of the company and its industry sector. We have focussed on the provisions of those laws and regulations that have a direct effect on the determination of material amounts and disclosures in the financial statements. The key laws and regulations we considered in this context included the UK Companies Act and local tax legislation.

We performed the following audit procedures after consideration of the above risks which included the following:
- enquiry of management of actual and potential litigation and claims;
- reviewing correspondence with HMRC and the company's legal advisors;
- reviewing financial statement disclosures and testing to supporting documentation to assess compliance with applicable laws and regulations;
- performing analytical procedures to identify any unusual or unexpected relationships that may indicate risks of material misstatement due to fraud; and
- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

The engagement partner has assessed that all engagement team members were made aware of the relevant laws and regulations and potential fraud risks and were reminded to remain alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

Because of the inherent limitations of an audit, there is a risk that we will not detect all irregularities, including those leading to a material misstatement in the financial statements or non-compliance with regulation. The risk increases the more that compliance with a law or regulation is removed from the events and transactions reflected in the financial statements, as we will be less likely to become aware of instances of non-compliance. The risk is also greater regarding irregularities occurring due to fraud rather than error, as fraud involves intentional concealment, forgery, collusion, omission or misrepresentation.

A further description of our responsibilities is available on the Financial Reporting Council's website at: https://www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

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Use of our report

This report is made solely to the charitable company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the charitable company's members 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 charitable company and the charitable company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Sarah Squires BEng FCA (Senior Statutory Auditor)
for and on behalf of MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

Date: ...11.....August 2023

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GMDN AGENCY

STATEMENT OF FINANCIAL ACTIVITIES (INCORPORATING AN INCOME AND EXPENDITURE ACCOUNT) FOR THE YEAR ENDED 31 MARCH 2023

	Notes	2023 Unrestricted funds £	2022 Total funds £
INCOME AND ENDOWMENTS FROM			
Donations and legacies	3	951,466	992,306
Investment income	4	476	68
Total		951,942	992,374
EXPENDITURE ON			
Charitable activities	5		
Development and maintenance of database		1,517,547	1,171,442
NET INCOME/(EXPENDITURE)		(565,605)	(179,068)
RECONCILIATION OF FUNDS			
Total funds brought forward		1,516,904	1,695,972
TOTAL FUNDS CARRIED FORWARD		951,299	1,516,904

The notes form part of these financial statements

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GMDN AGENCY

STATEMENT OF FINANCIAL POSITION
31 MARCH 2023

	Notes	2023 Unrestricted funds £	2022 Total funds £
FIXED ASSETS			
Intangible assets	10	308,743	322,326
Tangible assets	11	11,660	8,044
		320,403	330,370
CURRENT ASSETS			
Debtors	12	41,160	19,618
Cash at bank		1,140,027	1,677,412
		1,181,187	1,697,030
CREDITORS			
Amounts falling due within one year	13	(550,291)	(510,496)
NET CURRENT ASSETS		630,896	1,186,534
TOTAL ASSETS LESS CURRENT LIABILITIES		951,299	1,516,904
NET ASSETS		951,299	1,516,904
FUNDS	15		
Unrestricted funds		951,299	1,516,904
TOTAL FUNDS		951,299	1,516,904

These financial statements have been prepared in accordance with the provisions applicable to charitable companies subject to the small companies regime.

The financial statements were approved by the Board of Trustees and authorised for issue on .....8/10/2023..... and were signed on its behalf by:

DocuSigned by:

.....EE4D0B79E5F7449:.....

Mrs D Bruce - Trustee

The notes form part of these financial statements

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STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 31 MARCH 2023

	Notes	2023 £	2022 £
Cash flows from operating activities			
Cash generated from operations	1	(388,117)	(32,271)
Net cash used in operating activities		(388,117)	(32,271)
Cash flows from investing activities			
Purchase of intangible fixed assets		(138,954)	(193,472)
Purchase of tangible fixed assets		(10,790)	(4,906)
Interest received		476	68
Net cash used in investing activities		(149,268)	(198,310)
Change in cash and cash equivalents in the reporting period		(537,385)	(230,581)
Cash and cash equivalents at the beginning of the reporting period		1,677,412	1,907,993
Cash and cash equivalents at the end of the reporting period		1,140,027	1,677,412

The notes form part of these financial statements

GMDN AGENCY

NOTES TO THE STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 31 MARCH 2023

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

	2023 £	2022 £
Net expenditure for the reporting period (as per the Statement of Financial Activities)	(565,605)	(179,068)
Adjustments for:		
Depreciation charges	158,949	157,848
Loss on disposal of fixed assets	762	-
Interest received	(476)	(68)
(Increase)/decrease in debtors	(21,542)	14,224
Increase/(decrease) in creditors	39,795	(25,207)
Net cash used in operations	(388,117)	(32,271)

2. ANALYSIS OF CHANGES IN NET FUNDS

	At 1.4.22 £	Cash flow £	At 31.3.23 £
Net cash			
Cash at bank	1,677,412	(537,385)	1,140,027
	1,677,412	(537,385)	1,140,027
Total	1,677,412	(537,385)	1,140,027

The notes form part of these financial statements

1. GENERAL INFORMATION

GMDN Agency is a charitable company limited by guarantee and incorporated in England and Wales. The address of the company's registered office is Hampden House, Monument Business Park, Chalgrove, Oxford, OX44 7RW. The registered company number is 05392271 and the registered charity number is 1154418.

The principal activities of the charity are as disclosed within the Report of the Trustees.

The presentational currency of these financial statements is Sterling (£), being the currency of the primary economic market in which the entity operates. All amounts in these financial statements have been rounded to the nearest pound unless stated otherwise.

The significant accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all years presented unless otherwise stated.

2. ACCOUNTING POLICIES

Basis of preparing the financial statements
The financial statements of the charitable company, 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 Companies Act 2006. The financial statements have been prepared under the historical cost convention.

Going Concern
The trustees have considered the substantial net assets of the charity and the cash resources available as well as the charity's commitments. The trustees consider that the charity has adequate resources in place to continue in operation for a period of at least twelve months from the date of approval of the financial statements and therefore continue to adopt the going concern basis in preparing these financial statements.

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. Membership fees are recognised equally over the period of the 12 month subscription.

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 costs related to the category.

Allocation and apportionment of costs
Where costs cannot be directly attributed to particular headings they have been allocated to activities on a basis consistent with use of the resources.

Trustee salaries have been apportioned in accordance with the duties to which they relate.

Intellectual property
The cost of developing the company's database and associated systems is being capitalised and amortised through the Statement of Financial Activities in equal annual instalments over its estimated economic life of 5 years. The cost of development includes staff costs.

2. 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.

Computers and furniture - straight line - 33%

Taxation
The charity is exempt from corporation 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.

All the charity's funds are unrestricted.

Foreign currencies
Transactions in foreign currencies are recorded at the rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated at the rate of exchange ruling at the balance sheet date. All differences are taken to the Statement of Financial Activities.

Hire purchase and leasing commitments
Rentals paid under operating leases are charged to the Statement of Financial Activities on a straight line basis over the period of the lease.

Pension costs and other post-retirement benefits
The charitable company operates a defined contribution pension scheme. Contributions payable to the charitable company's pension scheme are charged to the Statement of Financial Activities in the period to which they relate.

Financial instruments
The charitable company only has financial assets and financial liabilities of a kind that qualify as basic financial instruments. Basic financial instruments are initially recognised at transaction value and subsequently measured at their settlement value.

Significant judgements and estimates
The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of income, expenditure, assets and liabilities. If in the future such estimates and assumptions, which are based on management's best judgment at the date of the financial statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate in the year in which the circumstances change.

3. DONATIONS AND LEGACIES

	2023	2022
	£	£
Donations	11	21
Subscriptions	951,455	992,285
	951,466	992,306

4. INVESTMENT INCOME

	2023	2022
	£	£
Bank interest	476	68

5. CHARITABLE ACTIVITIES COSTS

	Direct Costs	Support costs (see note 6)	Totals
	£	£	£
Development and maintenance of database	1,339,678	177,869	1,517,547

6. SUPPORT COSTS

	Management	Finance	Governance costs	Totals
	£	£	£	£
Development and maintenance of database	152,914	18,300	6,655	177,869

Analysis of support and governance costs

The charity initially identifies the costs of its support function. It then identifies those costs which relate to the governance function. Having identified its governance costs and support costs these are apportioned between the key charitable activities undertaken in the year. Please refer to the table below for the basis of apportionment and the key analysis of support.

	General Support	Governance function	Basis of apportionment
	£	£	
Wages	152,914		The duties to which they relate
Audit fees		6,655	Governance
Accountancy	18,300		The duties to which they relate
Total	171,214	6,655	

7. NET INCOME/(EXPENDITURE)

Net income/(expenditure) is stated after charging/(crediting):

	2023	2022
	£	£
Auditors' remuneration	6,655	5,400
Depreciation - owned assets	6,412	5,859
Other operating leases	20,247	14,840
Deficit on disposal of fixed assets	762	-
Intellectual property amortisation	152,537	151,989
Foreign exchange (gains)/losses	(52,562)	11,042

8. TRUSTEES' REMUNERATION AND BENEFITS

	2023	2022
	£	£
Trustees' salaries	261,600	189,895
Trustees' social security	32,416	22,544
Trustees' pension contributions to money purchase schemes	12,916	9,603
	306,932	222,042

The trustees' remuneration is in respect of two (2022 - one) trustees, being Mr M Wasmuth and Mrs D Bruce, for services as the Chief Executive Officers of the charity.

Trustees' expenses

Trustees' expenses reimbursed for the year ended 31 March 2023 totalled £38,118 to five trustees (2022 - £644 to two trustees). Expenses related to travel, subscriptions and other sundry costs.

9. STAFF COSTS

	2023	2022
	£	£
Wages and salaries	772,271	582,140
Social security costs	88,947	64,235
Other pension costs	37,556	28,937
	898,774	675,312

During the year £108,141 (2022 - £150,048) of salaries and pension as well as £11,511 (2022 - £15,725) of social security costs were capitalised as part of the intangible fixed asset. These costs are not included in the figures above.

The average monthly number of employees during the year was as follows:

	2023	2022
Management	2	1
Technical	7	7
Administration	3	3
	12	11

9. STAFF COSTS - continued

The number of employees whose employee benefits (excluding employer pension costs) exceeded £60,000 was:

	2023	2022
£60,001 - £70,000	1	-
£70,001 - £80,000	1	2
£80,001 - £90,000	1	-
£120,001 - £130,000	-	1
£130,001 - £140,000	1	-
£190,001 - £200,000	1	1
	5	4

10. INTANGIBLE FIXED ASSETS

	Intellectual property £
COST	
At 1 April 2022	1,434,790
Additions	138,954
At 31 March 2023	1,573,744
AMORTISATION	
At 1 April 2022	1,112,464
Charge for year	152,537
At 31 March 2023	1,265,001
NET BOOK VALUE	
At 31 March 2023	308,743
At 31 March 2022	322,326

11. TANGIBLE FIXED ASSETS

	Computers and furniture £
COST	
At 1 April 2022	58,126
Additions	10,790
Disposals	(26,152)
At 31 March 2023	42,764
DEPRECIATION	
At 1 April 2022	50,082
Charge for year	6,412
Eliminated on disposal	(25,390)
At 31 March 2023	31,104
NET BOOK VALUE	
At 31 March 2023	11,660
At 31 March 2022	8,044

12. DEBTORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	2023 £	2022 £
Other debtors	4,838	1,081
Prepayments and accrued income	36,322	18,537
	41,160	19,618

13. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	2023 £	2022 £
Trade creditors	23,346	2,346
Social security and other taxes	36,635	32,988
Other creditors	7,890	-
Accruals and deferred income	482,420	475,162
	550,291	510,496

Included within accruals and deferred income is the following deferred income:

	£
Deferred income at 31 March 2022	454,721
Released in the year	(454,721)
Deferred in the year	463,335
Deferred income at 31 March 2023	463,335

The deferred income is in respect of the annual memberships to the database.

14. LEASING AGREEMENTS

Minimum lease payments under non-cancellable operating leases fall due as follows:

	2023	2022
	£	£
Within one year	-	13,924

15. MOVEMENT IN FUNDS

	At 1.4.22	Net movement in funds	At 31.3.23
	£	£	£
Unrestricted funds			
General fund	736,654	(565,605)	171,049
Designated cash flow fund	250,000	-	250,000
Designated reserve fund	530,250	-	530,250
	1,516,904	(565,605)	951,299
TOTAL FUNDS	1,516,904	(565,605)	951,299

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

	Incoming resources	Resources expended	Movement in funds
	£	£	£
Unrestricted funds			
General fund	951,942	(1,517,547)	(565,605)
TOTAL FUNDS	951,942	(1,517,547)	(565,605)

Comparatives for movement in funds

	At 1.4.21	Net movement in funds	At 31.3.22
	£	£	£
Unrestricted funds			
General fund	915,722	(179,068)	736,654
Designated cash flow fund	250,000	-	250,000
Designated reserve fund	530,250	-	530,250
	1,695,972	(179,068)	1,516,904
TOTAL FUNDS	1,695,972	(179,068)	1,516,904

15. MOVEMENT IN FUNDS - continued

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

	Incoming resources £	Resources expended £	Movement in funds £
Unrestricted funds			
General fund	992,374	(1,171,442)	(179,068)
TOTAL FUNDS	992,374	(1,171,442)	(179,068)

The Charity has the following designated funds:

The Designated Cash Flow Fund ("Operational Reserve") is held to cover cash flow variability and anticipated short-term variations in either income or expenditure. It also needs to cover the cost of winding up the Agency subject to the possibility that the Agency needs to be closed.

The Designated Reserve Fund ("Strategic Reserve") is held to cover anticipated needs over and above those accommodated by the Operational Reserve but required to support the long-term sustainability of the Agency. This needs to be consistent with the conditions applied above.

The level of these reserves will be agreed on an annual basis by the Trustees as part of the annual financial budgeting process.

16. EMPLOYEE BENEFIT OBLIGATIONS

The company operates a defined contribution pension scheme. The pension costs charged to the income statement represent contributions payable by the company to the fund in the year and amounted to £41,923 (2022 - £36,280). This is prior to any capitalisation of costs in respect of the development of the database.

17. RELATED PARTY DISCLOSURES

There were no related party transactions for the year ended 31 March 2023 (2022: £Nil).

18. ULTIMATE CONTROLLING PARTY

The charity was under the control of the trustees throughout the current and previous year.

19. COMPANY LIMITED BY GUARANTEE

The liability of each member is limited to an amount not exceeding £10.

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DETAILED STATEMENT OF FINANCIAL ACTIVITIES FOR THE YEAR ENDED 31 MARCH 2023

	2023 £	2022 £
INCOME AND ENDOWMENTS		
Donations and legacies		
Donations	11	21
Subscriptions	951,455	992,285
	951,466	992,306
Investment income		
Bank interest	476	68
Total incoming resources	951,942	992,374
EXPENDITURE		
Charitable activities		
Trustees' salaries	130,248	94,834
Trustees' social security	16,208	11,272
Trustees' pension contributions	6,458	4,802
Wages	510,671	392,245
Social security	56,531	41,691
Pensions	24,640	19,334
Rent and rates	20,247	14,840
Database costs	123,837	76,073
Travel and subsistence	61,380	1,808
Insurance	32,481	30,967
Telephone	790	730
Postage and stationery	316	908
Computer costs	95	262
Sundries	6,435	7,047
Consultancy	157,541	146,299
Bank charges	16,061	14,562
Foreign exchange (gains) / losses	(52,262)	11,042
PAYE interest	19	-
Training costs	20,424	5,148
Subscriptions	9,770	7,204
Recruitment fees	33,727	3,350
Marketing	4,350	-
Amortisation	152,537	151,989
Depreciation	6,412	5,859
Loss on sale of tangible fixed assets	762	-
	1,339,678	1,042,266
Support costs		
Management		
Trustees' salaries	130,248	94,833
Carried forward	130,248	94,833

GMDN AGENCY

DETAILED STATEMENT OF FINANCIAL ACTIVITIES
FOR THE YEAR ENDED 31 MARCH 2023

	2023 £	2022 £
Management		
Brought forward	130,248	94,833
Trustees' social security	16,208	11,272
Trustees' pension contributions	6,458	4,801
	152,914	110,906
Finance		
Accountancy	18,300	12,870
Governance costs		
Auditors' remuneration	6,655	5,400
Total resources expended	1,517,547	1,171,442
Net expenditure	(565,605)	(179,068)

GMDN AGENCY

England & Wales - Charity number 1154418

Accounts

REGISTERED COMPANY NUMBER: 05392271 (England and Wales)
REGISTERED CHARITY NUMBER: 1154418

REPORT OF THE TRUSTEES AND

AUDITED FINANCIAL STATEMENTS

FOR THE YEAR ENDED 31 MARCH 2022

FOR

GMDN AGENCY

MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

GMDN AGENCY

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FOR THE YEAR ENDED 31 MARCH 2022

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The trustees who are also directors of the charity for the purposes of the Companies Act 2006, present their report with the financial statements of the charity for the year ended 31 March 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

Purposes and aims

Our charity's purposes as set out in the objects contained in the company's memorandum of association are to:

To preserve and protect health and to relieve sickness for the public benefit by developing and maintaining the 'Global Medical Device Nomenclature', a system of internationally agreed descriptors used to identify medical device products which will meet a global need for identification purposes. Our aims fully reflect the purposes that the charity was set up to further.

Our charity's purposes as set out in the objects contained in the company's Articles of Association are to:

To preserve and protect health and relieve sickness for the public benefit by developing and maintaining the "Global Medical Device Nomenclature", a system of internationally agreed descriptors used to identify medical device products which will meet a global need for identification purposes.

Our Strategic Aims as identified in our Quality Policy, fully reflect the purposes that the charity was set up to further:

- Assist in the protection of patients by acting as a resource for healthcare regulators to help them identify trends and
  solve problems quickly;
- Facilitate collaborative efforts between regulators in different jurisdictions;
- Offer expertise and insight to the whole medical device supply chain;
- Increase transparency of the Agency through stakeholder engagement and communication of activities;
- Support industry in the setting up of registries and learning communities;
- Demonstrate the advantages of greater global harmonisation and medical technology for patient care;
- Support users to reduce the risk of misuse or misassignment of GMDN terms by taking the lead on the quality of
  Terms assignment, to ensure they are as accurate as possible for downstream use;
- Assisting stakeholders in the downstream use of GMDN data as a leveraging tool e.g., inventory management, real
  world evidence analysis, signal detection.

Ensuring our work delivers our aims

We review our Strategic Aims each year. This review looks at what we achieved and the outcomes of our work in the previous 12 months. The review looks at the success of each key activity and the benefits they have brought to those groups of people we are set up to help. The review also helps us ensure our aims, objectives and activities remained focused on our stated purposes. We have referred to the guidance contained in the Charity Commission's general guidance on public benefit when reviewing our aims and objectives and in planning our future activities. In particular, the trustees consider how planned activities will contribute to the aims and objectives they have set.

The focus of our work

After extensive consultation the Strategy 2022-2026 was published in early 2022. To deliver the GMDN Agency's core work of helping to meet the global need for accurate identification of medical devices, we have developed four ambitions, the aims for those areas of work and where we expect to be at the end of the five-year strategy period.

- Promote the value of global collaboration and harmonisation
- Continuously improve and innovate
- Provide excellent services which add value
- Be engaged, helpful and expert

Public benefit
Our main activities and who we try to help are described below. All our charitable activities focus on the accurate identification of medical devices by standardising their common description and sharing this information with Governments, Hospitals and the device manufacturers worldwide for the public benefit.

Who used and benefited from our services?
Our objects and funding limit the services we provide to the maintenance, promotion and distribution of the Global Medical Device Nomenclature.

Equal access to our services is an important issue for us. All potential users of the GMDN can gain free access to the GMDN data.

Medical device regulators use the GMDN data to accurately identify specific equipment, when they need to approve medical devices, as part of their national regulatory framework.

When monitoring the safety of medical devices within the market, medical device regulators can use the GMDN to identify trends in success and failure of a specific device or common technology, which is vitally important when systematic failures of devices from more than one manufacturer may occur.

Medical device manufacturers use the GMDN data to sort their products into more manageable groups and provide more consistent device names to their customers.

Medical device users can use GMDN data to support decision making within the healthcare environment.

We maintain our website to provide information to our members in 32 languages, thereby encouraging wider global access to the GMDN, with more languages being added each year if necessary.

The GMDN Agency continues to maintain its Quality Management System compliance to standard ISO9001:2015 by third-party audit.

To demonstrate our commitment to information security, the GMDN Agency was re-certified to the UK Government's Cyber Essentials Scheme in October 2021.

FINANCIAL REVIEW
Principal funding sources
The principal funding sources for the charity are currently the licencing of services related to the maintenance of the GMDN to our members via our website.

Access is only available to members and membership is priced according to organisation type and size. The membership process is completed online and access to the GMDN database is immediate upon completion of the registration process.

Investment policy and objectives
Aside from retaining a prudent amount in reserves each year most of the charity's funds are to be spent in the short term so there are few funds for long term investment. The charity, with the aid of sound financial management and the support of both its staff and volunteers maintained a total of funds carried forward amounting to £1,516,904.

FINANCIAL REVIEW

Reserves policy

The GMDN Agency, as a charitable activity designed to provide services to members, should operate on the basis of costs equating to income over the long-term. Reserves will be held to ensure continuity of operation and provide a buffer for variations in income or respond to short-term expenditure needs not accommodated by the normal running of the organisation, as well as addressing anticipated future change costs associated with both environmental and operational necessities e.g. changes in business model, major recapitalisation of assets, etc.

Excess funds should be returned to members over the medium-term via adjustments to the fees for service. Reserves are categorised as the Operational and Strategic reserves.

The Operational reserve is to cover cash flow variability and anticipated short-term variations in either income or expenditure. It also needs to cover the cost of winding up the Agency subject to the possibility that the Agency needs to be closed.

The Strategic reserve is to cover anticipated needs over and above those accommodated by the Operational reserve but required to support the long-term sustainability of the Agency. This needs to be consistent with the conditions applied above.

The level of these reserves is agreed on an annual basis by the Trustees as part of the financial budgeting process.

FUTURE DEVELOPMENTS

The effective use of the GMDN by national medical device regulators and other stakeholders throughout the world continues to be the primary objective of the Agency.

The Trustees deliberately build up the reserves in the past few years to meet the challenges and costs associated with the increasing use of the GMDN. Due to the long-term nature of the adoption of the GMDN the timing of the use of funds can be difficult to predict. It is expected that the adoption of the GMDN will require the investment of substantial funds in supporting adoption and supporting users worldwide.

In April 2019, following a consultation with Stakeholders, the Trustees decided to introduce a new band of Basic membership service that would provide the essential data components of the GMDN for no cost. The new membership band and financial impact has been carefully monitored by the Trustees during the intervening period and we are pleased to report that total concurrent membership at the end of the year was over 16,400, which is nearly 500% increase in 3 years. Our larger company members have remained loyal to the voluntary paid-for services we provide to support their management of the GMDN Terms they use and therefore our income has remained enough to allow the Trustees to be confident of our long-term financial sustainability. The membership schemes will be carefully monitored during the coming years to determine their ongoing suitability of purpose and amended as necessary.

With the introduction of the free membership band, several countries have joined in adopting the use of the GMDN and this is particularly important in countries with less-developed economies.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Governing document

The organisation is a charitable company limited by guarantee, incorporated on 14 March 2005 and registered as a charity on 31 October 2013. The company was established under a Memorandum of Association which established the objects and powers of the charitable company and is governed under its Articles of Association. In the event of the company being wound up members are required to contribute an amount not exceeding £10.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Recruitment and appointment of new trustees

The directors of the company are also charity trustees for the purposes of charity law and under the company's Articles are known as members of the Board of Trustees. Under the requirements of the Memorandum and Articles of Association the members of the Board of Trustees are elected to serve for a period of three years after which they must be re-elected at the next Annual General Meeting.

All members of the Board of Trustees give their time voluntarily and received no benefits from the charity. Any expenses reclaimed from the charity are set out in note 8 to the accounts.

Due to the nature of the medical device sector much of the charity's work inevitably focuses upon this subject. The Board of Trustees seeks to ensure that the needs of this sector are appropriately reflected through the members of the trustee body.

To enhance the potential pool of trustees, the charity, through selective networking with industry, regulators and healthcare providers, has sought to identify those individuals who would be willing to become members of the Policy Advisory Group and use their own experience to assist the charity.

The more traditional business and medical skills are well represented on the Board of Trustees. In an effort to maintain this broad skill mix, members of the Board of Trustees are requested to provide a list of their skills and in the event of particular skills being lost due to retirements, individuals are approached to offer themselves for election to the Board of Trustees. No new Trustees joined the Board within the last year.

The Trustees as part of the recent strategic planning process, wish to increase the active involvement of regulators in our governance and therefore are engaging with them to see how this can be done in the coming year.

Organisational structure

The Board of Trustees consists of up to eight members who meet quarterly and are responsible for the strategic direction and policy of the charity. At present the Committee has five members from a variety of professional backgrounds relevant to the work of the charity.

A scheme of delegation is in place and day to day responsibility for the provision of the services rest with the Chief Executive Officer. The Chief Executive Officer is responsible for ensuring that the charity delivers the services specified and that key performance indicators are met. The Technical Lead has overall responsibility for the maintenance of the Global Medical Device Nomenclature database and the Office Administrator has responsibility for customer services staff. The Chief Executive Officer has individual supervision of all staff and also ensures that the team continue to develop their skills in line with good working practice.

Induction and training of new trustees

Most trustees are already familiar with the practical work of the charity having been encouraged to have been a previous member of the Policy Advisory Group.

Additionally, new trustees are invited and encouraged to attend a training session to familiarise themselves with the charity and the context within which it operates. This is led by the Chief Executive Officer of the charity and cover:

- The obligations of Board of Trustees members;
- The main documents which set out the operational framework for the charity including the Articles of Association;
- Resourcing and the current financial position as set out in the latest published accounts; and
- Future plans and objectives.

A resource pack has been prepared drawing information from the various Charity Commission publications. This is distributed to all new trustees along with the Articles of Association, Governance, Policy and reference documents and the latest management financial report.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Related parties

In so far as it is complimentary to the charity's objects, the charity is guided by international forum for medical device safety, including the members of the International Medical Device Regulators Forum (IMDRF) and the Global Harmonisation Working Party (GHWP) as well as international medical device manufacturers' trade associations, including the Global Medical Technology Alliance (GMTA) and the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA). The representation of the GMDN Agency to these organisations has proved invaluable to the charity in establishing improved links with the medical device sector and identifying relevant policy improvements.

Risk management

The Board of Trustees has conducted a review of the major risks to which the charity is exposed. Our risk register is reviewed at every Board meeting. Where appropriate, systems or procedures have been established to mitigate the risks the charity faces. Significant external risks to funding have led to the development of a strategic plan which will allow for the planning of funding and activities. Internal control risks are minimised by the implementation of procedures for authorisation of all transactions and projects. Procedures are in place to ensure compliance with health and safety of staff, volunteers, clients and visitors to the GMDN Agency's offices. The third-party certification of our ISO 9001 Quality Management System supports a consistent quality of delivery for all operational aspects of the charity. All internal procedures are regularly audited to ensure that they continue to meet the needs of the charity.

REFERENCE AND ADMINISTRATIVE DETAILS

Registered Company number
05392271 (England and Wales)

Registered Charity number
1154418

Registered office
Hampden House
Monument Business Park
Chalgrove
Oxford
Oxfordshire
OX44 7RW

Trustees
Mr M Wasmuth
Dr E D Krell
Ms J Trunzo
Dr C M W Tong
Mr J Wilkinson

Company Secretary
Mr M Wasmuth

Auditors
MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

REFERENCE AND ADMINISTRATIVE DETAILS

Solicitors
Taylor Vinters LLP
Prama House
267 Banbury Road
Oxford
OX2 7HT

STATEMENT OF TRUSTEES' RESPONSIBILITIES

The trustees (who are also the directors of GMDN Agency for the purposes of company law) are responsible for preparing the Report of the Trustees 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"

Company law 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 charitable company and of the incoming resources and application of resources, including the income and expenditure, of the charitable company 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;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the charitable company 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 charitable company and to enable them to ensure that the financial statements comply with the Companies Act 2006. They are also responsible for safeguarding the assets of the charitable company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

In so far as the trustees are aware:

- there is no relevant audit information of which the charitable company's auditors are unaware; and
- the trustees have taken all steps that they ought to have taken to make themselves aware of any relevant audit information and to establish that the auditors are aware of that information.

AUDITORS

MGI Midgley Snelling LLP were appointed as the charitable company's auditors during the year and have expressed their willingness to continue in that capacity.

Approved by order of the board of Trustees on 11th OCTOBER 2022 and signed on its behalf by:

Mr M Wasmuth - Trustee

Opinion
We have audited the financial statements of GMDN Agency (the 'charitable company') for the year ended 31 March 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 charitable company's affairs as at 31 March 2022 and of its incoming resources and application of resources, including its income and expenditure, 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 Companies Act 2006.

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 charitable company 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 charitable company'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.

Opinions on other matters prescribed by the Companies Act 2006
In our opinion, based on the work undertaken in the course of the audit:
- the information given in the Report of the Trustees for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the Report of the Trustees has been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception
In the light of the knowledge and understanding of the charitable company and its environment obtained in the course of the audit, we have not identified material misstatements in the Report of the Trustees.

We have nothing to report in respect of the following matters where the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept, or returns adequate for our audit have not been received from branches not visited by us; or
- the financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit; or
- the trustees were not entitled to prepare the financial statements in accordance with the small companies' regime and take advantage of the small companies' exemptions in preparing the directors' report and from the requirement to prepare a strategic report.

Responsibilities of trustees
As explained more fully in the Statement of Trustees' Responsibilities, the trustees (who are also the directors of the charitable company for the purposes of company law) are responsible for the preparation of the financial statements and for being satisfied that they 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 charitable company'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 charitable company or to cease operations, or have no realistic alternative but to do so.

Our responsibilities for the audit of the financial statements
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 an auditor's report 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:

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.

In planning and designing our audit tests, we identify and assess the risks of material misstatements within the financial statements, whether due to fraud or error. Our assessment of these risks includes consideration of the nature of the industry and sector, the control environment and the business performance along with the results of our enquiries of management, about their own identification and assessment of the risks of irregularities. We are also required to perform specific procedures to respond to the risk of management override.

As a result of this assessment, we considered the opportunities and incentives that may exist within the company for fraud and identified that the greatest area of risk was in relation to management override.

We have obtained an understanding of the legal and regulatory frameworks that the company operates in from discussions with the directors and our knowledge of the company and its industry sector. We have focussed on the provisions of those laws and regulations that have a direct effect on the determination of material amounts and disclosures in the financial statements. The key laws and regulations we considered in this context included the UK Companies Act and local tax legislation.

We performed the following audit procedures after consideration of the above risks which included the following:
- enquiry of management of actual and potential litigation and claims;
- reviewing correspondence with HMRC and the company's legal advisors;
- reviewing financial statement disclosures and testing to supporting documentation to assess compliance with applicable laws and regulations;
- performing analytical procedures to identify any unusual or unexpected relationships that may indicate risks of material misstatement due to fraud; and
- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

The engagement partner has assessed that all engagement team members were made aware of the relevant laws and regulations and potential fraud risks and were reminded to remain alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

Because of the inherent limitations of an audit, there is a risk that we will not detect all irregularities, including those leading to a material misstatement in the financial statements or non-compliance with regulation. The risk increases the more that compliance with a law or regulation is removed from the events and transactions reflected in the financial statements, as we will be less likely to become aware of instances of non-compliance. The risk is also greater regarding irregularities occurring due to fraud rather than error, as fraud involves intentional concealment, forgery, collusion, omission or misrepresentation.

A further description of our responsibilities is available on the Financial Reporting Council's website at: https://www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

Use of our report

This report is made solely to the charitable company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the charitable company's members 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 charitable company and the charitable company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Sarah Squires BEng FCA (Senior Statutory Auditor)
for and on behalf of MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

Date: 12 Oct 2022

GMDN AGENCY

STATEMENT OF FINANCIAL ACTIVITIES
(INCORPORATING AN INCOME AND EXPENDITURE ACCOUNT)
FOR THE YEAR ENDED 31 MARCH 2022

	Notes	2022 Unrestricted funds £	2021 Total funds £
INCOME AND ENDOWMENTS FROM			
Donations and legacies	3	992,306	1,047,030
Investment income	4	68	898
Total		992,374	1,047,928
EXPENDITURE ON			
Charitable activities	5		
Development and maintenance of database		1,171,442	1,250,520
NET INCOME/(EXPENDITURE)		(179,068)	(202,592)
RECONCILIATION OF FUNDS			
Total funds brought forward		1,695,972	1,898,564
TOTAL FUNDS CARRIED FORWARD		1,516,904	1,695,972

The notes form part of these financial statements

GMDN AGENCY

STATEMENT OF FINANCIAL POSITION
31 MARCH 2022

	Notes	2022 Unrestricted funds £	2021 Total funds £
FIXED ASSETS			
Intangible assets	10	322,326	280,843
Tangible assets	11	8,044	8,997
		330,370	289,840
CURRENT ASSETS			
Debtors	12	19,618	33,842
Cash at bank		1,677,412	1,907,993
		1,697,030	1,941,835
CREDITORS			
Amounts falling due within one year	13	(510,496)	(535,703)
NET CURRENT ASSETS		1,186,534	1,406,132
TOTAL ASSETS LESS CURRENT LIABILITIES		1,516,904	1,695,972
NET ASSETS		1,516,904	1,695,972
FUNDS	15		
Unrestricted funds		1,516,904	1,695,972
TOTAL FUNDS		1,516,904	1,695,972

These financial statements have been prepared in accordance with the provisions applicable to charitable companies subject to the small companies regime.

The financial statements were approved by the Board of Trustees and authorised for issue on 11TH OCTOBER 2022 and were signed on its behalf by:

.....
Mr M Wasmuth - Trustee

The notes form part of these financial statements

GMDN AGENCY

STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 31 MARCH 2022

	Notes	2022 £	2021 £
Cash flows from operating activities			
Cash generated from operations	1	(32,271)	(83,306)
Net cash used in operating activities		(32,271)	(83,306)
Cash flows from investing activities			
Purchase of intangible fixed assets		(193,472)	(129,630)
Purchase of tangible fixed assets		(4,906)	(7,082)
Interest received		68	898
Net cash used in investing activities		(198,310)	(135,814)
Change in cash and cash equivalents in the reporting period		(230,581)	(219,120)
Cash and cash equivalents at the beginning of the reporting period		1,907,993	2,127,113
Cash and cash equivalents at the end of the reporting period		1,677,412	1,907,993

The notes form part of these financial statements

NOTES TO THE STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 31 MARCH 2022

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

	2022 £	2021 £
Net expenditure for the reporting period (as per the Statement of Financial Activities)	(179,068)	(202,592)
Adjustments for:		
Depreciation charges	157,848	152,270
Interest received	(68)	(898)
Decrease in debtors	14,224	1,417
Decrease in creditors	(25,207)	(33,503)
Net cash used in operations	(32,271)	(83,306)

2. ANALYSIS OF CHANGES IN NET FUNDS

	At 1.4.21 £	Cash flow £	At 31.3.22 £
Net cash			
Cash at bank	1,907,993	(230,581)	1,677,412
	1,907,993	(230,581)	1,677,412
Total	1,907,993	(230,581)	1,677,412

The notes form part of these financial statements

1. GENERAL INFORMATION

GMDN Agency is a charitable company limited by guarantee and incorporated in England and Wales. The address of the company's registered office is Hampden House, Monument Business Park, Chalgrove, Oxford, OX44 7RW. The registered company number is 05392271 and the registered charity number is 1154418.

The principal activities of the charity are as disclosed within the Report of the Trustees.

The presentational currency of these financial statements is Sterling (£), being the currency of the primary economic market in which the entity operates. All amounts in these financial statements have been rounded to the nearest pound unless stated otherwise.

The significant accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all years presented unless otherwise stated.

2. ACCOUNTING POLICIES

Basis of preparing the financial statements
The financial statements of the charitable company, 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 Companies Act 2006. The financial statements have been prepared under the historical cost convention.

Going concern
Given the spread of Coronavirus "COVID-19", the trustees have produced projections and budgets for the next twelve months in order to consider the charity's going concern status. Following this review, the trustees consider there to be little impact on the charity's ability to act as a going concern.

The trustees have considered the substantial net assets of the charity and the cash resources available as well as the charity's commitments. The trustees consider that the charity has adequate resources in place to continue in operation for a period of at least twelve months from the date of approval of the financial statements and therefore continue to adopt the going concern basis in preparing these financial statements.

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. Membership fees are recognised equally over the period of the 12 month subscription.

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 costs related to the category.

Allocation and apportionment of costs
Where costs cannot be directly attributed to particular headings they have been allocated to activities on a basis consistent with use of the resources.

Trustee salaries have been apportioned in accordance with the duties to which they relate.

2. ACCOUNTING POLICIES - continued

Intellectual property
The cost of developing the company's database and associated systems is being capitalised and amortised through the Statement of Financial Activities in equal annual instalments over its estimated economic life of 5 years. The cost of development includes staff costs.

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

Computers and furniture - straight line - 33%

Taxation
The charity is exempt from corporation 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.

All the charity's funds are unrestricted.

Foreign currencies
Transactions in foreign currencies are recorded at the rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated at the rate of exchange ruling at the balance sheet date. All differences are taken to the Statement of Financial Activities.

Hire purchase and leasing commitments
Rentals paid under operating leases are charged to the Statement of Financial Activities on a straight line basis over the period of the lease.

Pension costs and other post-retirement benefits
The charitable company operates a defined contribution pension scheme. Contributions payable to the charitable company's pension scheme are charged to the Statement of Financial Activities in the period to which they relate.

Financial instruments
The charitable company only has financial assets and financial liabilities of a kind that qualify as basic financial instruments. Basic financial instruments are initially recognised at transaction value and subsequently measured at their settlement value.

Significant judgements and estimates
The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of income, expenditure, assets and liabilities. If in the future such estimates and assumptions, which are based on management's best judgment at the date of the financial statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate in the year in which the circumstances change.

3. DONATIONS AND LEGACIES

	2022	2021
	£	£
Donations	21	-
Subscriptions	992,285	1,047,030
	992,306	1,047,030

4. INVESTMENT INCOME

	2022	2021
	£	£
Bank interest	68	898

5. CHARITABLE ACTIVITIES COSTS

	Direct Costs	Support costs (see note 6)	Totals
	£	£	£
Development and maintenance of database	1,042,266	129,176	1,171,442

6. SUPPORT COSTS

	Management	Finance	Governance costs	Totals
	£	£	£	£
Development and maintenance of database	110,906	12,870	5,400	129,176

Analysis of support and governance costs

The charity initially identifies the costs of its support function. It then identifies those costs which relate to the governance function. Having identified its governance costs and support costs these are apportioned between the key charitable activities undertaken in the year. Please refer to the table below for the basis of apportionment and the key analysis of support.

		General Support	Governance function	Basis of apportionment
		£	£	
Wages		110,906		The duties to which they relate
Audit fees			5,400	Governance
Accountancy		12,870		The duties to which they relate
	Total	123,776	5,400	

7. NET INCOME/(EXPENDITURE)

Net income/(expenditure) is stated after charging/(crediting):

	2022	2021
	£	£
Auditors' remuneration	5,400	6,680
Depreciation - owned assets	5,859	13,432
Other operating leases	14,840	55,357
Intellectual property amortisation	151,989	138,838
Foreign exchange losses	11,042	50,574

8. TRUSTEES' REMUNERATION AND BENEFITS

	2022	2021
	£	£
Trustees' salaries	189,895	186,845
Trustees' social security	22,544	23,310
Trustees' pension contributions to money purchase schemes	9,603	9,146
	222,042	219,301

The trustees' remuneration is in respect of one (2021 - one) trustee, being Mr M Wasmuth, for services as the Chief Executive Officer of the charity.

Trustees' expenses

Trustees' expenses reimbursed for the year ended 31 March 2022 totalled £644 to two trustees (2021 - £Nil). Expenses related to travel, subscriptions and other sundry costs.

9. STAFF COSTS

	2022	2021
	£	£
Wages and salaries	582,140	591,120
Social security costs	64,235	64,077
Other pension costs	28,937	29,027
	675,312	684,224

During the year £150,048 (2021 - £100,852) of salaries and pension as well as £15,725 (2021 - £9,251) of social security costs were capitalised as part of the intangible fixed asset. These costs are not included in the figures above.

The average monthly number of employees during the year was as follows:

	2022	2021
Management	1	1
Technical	7	7
Administration	3	2
	11	10

9. STAFF COSTS - continued

The number of employees whose employee benefits (excluding employer pension costs) exceeded £60,000 was:

	2022	2021
£60,001 - £70,000	-	1
£70,001 - £80,000	2	1
£120,001 - £130,000	1	1
£180,001 - £190,000	-	1
£190,001 - £200,000	1	-
	4	4

10. INTANGIBLE FIXED ASSETS

	Intellectual property £
COST	
At 1 April 2021	1,241,318
Additions	193,472
At 31 March 2022	1,434,790
AMORTISATION	
At 1 April 2021	960,475
Charge for year	151,989
At 31 March 2022	1,112,464
NET BOOK VALUE	
At 31 March 2022	322,326
At 31 March 2021	280,843

11. TANGIBLE FIXED ASSETS

	Computers and furniture £
COST	
At 1 April 2021	56,290
Additions	4,906
Disposals	(3,070)
At 31 March 2022	58,126
DEPRECIATION	
At 1 April 2021	47,293
Charge for year	5,859
Eliminated on disposal	(3,070)
At 31 March 2022	50,082
NET BOOK VALUE	
At 31 March 2022	8,044
At 31 March 2021	8,997

12. DEBTORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	2022 £	2021 £
Other debtors	1,081	601
Prepayments and accrued income	18,537	33,241
	19,618	33,842

13. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	2022 £	2021 £
Trade creditors	2,346	-
Social security and other taxes	32,988	23,219
Accruals and deferred income	475,162	512,484
	510,496	535,703

Included within accruals and deferred income is the following deferred income:

	£
Deferred income at 31 March 2021	480,843
Released in the year	(480,843)
Deferred in the year	454,721
Deferred income at 31 March 2022	454,721

The deferred income is in respect of the annual memberships to the database.

14. LEASING AGREEMENTS

Minimum lease payments under non-cancellable operating leases fall due as follows:

	2022	2021
	£	£
Within one year	13,924	3,782
Between one and five years	-	676
	13,924	4,458

15. MOVEMENT IN FUNDS

	At 1.4.21	Net movement in funds	At 31.3.22
	£	£	£
Unrestricted funds			
General fund	915,722	(179,068)	736,654
Designated cash flow fund	250,000	-	250,000
Designated reserve fund	530,250	-	530,250
	1,695,972	(179,068)	1,516,904
TOTAL FUNDS	1,695,972	(179,068)	1,516,904

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

	Incoming resources	Resources expended	Movement in funds
	£	£	£
Unrestricted funds			
General fund	992,374	(1,171,442)	(179,068)
TOTAL FUNDS	992,374	(1,171,442)	(179,068)

Comparatives for movement in funds

	At 1.4.20	Net movement in funds	At 31.3.21
	£	£	£
Unrestricted funds			
General fund	1,118,314	(202,592)	915,722
Designated cash flow fund	250,000	-	250,000
Designated reserve fund	530,250	-	530,250
	1,898,564	(202,592)	1,695,972
TOTAL FUNDS	1,898,564	(202,592)	1,695,972

15. MOVEMENT IN FUNDS - continued

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

	Incoming resources £	Resources expended £	Movement in funds £
Unrestricted funds			
General fund	1,047,928	(1,250,520)	(202,592)
TOTAL FUNDS	1,047,928	(1,250,520)	(202,592)

The Charity has the following designated funds:

The Designated Cash Flow Fund ("Operational Reserve") is held to cover cash flow variability and anticipated short-term variations in either income or expenditure. It also needs to cover the cost of winding up the Agency subject to the possibility that the Agency needs to be closed.

The Designated Reserve Fund ("Strategic Reserve") is held to cover anticipated needs over and above those accommodated by the Operational Reserve but required to support the long-term sustainability of the Agency. This needs to be consistent with the conditions applied above.

The level of these reserves will be agreed on an annual basis by the Trustees as part of the annual financial budgeting process.

16. EMPLOYEE BENEFIT OBLIGATIONS

The company operates a defined contribution pension scheme. The pension costs charged to the income statement represent contributions payable by the company to the fund in the year and amounted to £36,280 (2021 - £33,772). This is prior to any capitalisation of costs in respect of the development of the database.

17. RELATED PARTY DISCLOSURES

There were no related party transactions for the year ended 31 March 2022 (2021: £Nil).

18. ULTIMATE CONTROLLING PARTY

The charity was under the control of the trustees throughout the current and previous year.

19. COMPANY LIMITED BY GUARANTEE

The liability of each member is limited to an amount not exceeding £10.

GMDN AGENCY

DETAILED STATEMENT OF FINANCIAL ACTIVITIES
FOR THE YEAR ENDED 31 MARCH 2022

	2022 £	2021 £
INCOME AND ENDOWMENTS		
Donations and legacies		
Donations	21	-
Subscriptions	992,285	1,047,030
	992,306	1,047,030
Investment income		
Bank interest	68	898
Total incoming resources	992,374	1,047,928
EXPENDITURE		
Charitable activities		
Trustees' salaries	94,834	93,309
Trustees' social security	11,272	11,655
Trustees' pension contributions	4,802	4,573
Wages	392,245	404,275
Social security	41,691	40,767
Pensions	19,334	19,881
Rent and rates	14,840	55,357
Database costs	76,073	86,431
Travel and subsistence	1,808	32
Insurance	30,967	24,947
Telephone	730	2,066
Postage and stationery	908	1,225
Computer costs	262	777
Sundries	7,047	7,842
Consultancy	146,299	139,971
Bank charges	14,562	14,070
Foreign exchange	11,042	50,574
Training costs	5,148	6,485
Subscriptions	7,204	10,007
Recruitment fees	3,350	-
Amortisation	151,989	138,838
Depreciation	5,859	13,432
	1,042,266	1,126,514
Support costs		
Management		
Trustees' salaries	94,833	93,308
Trustees' social security	11,272	11,655
Trustees' pension contributions	4,801	4,573
	110,906	109,536

DETAILED STATEMENT OF FINANCIAL ACTIVITIES
FOR THE YEAR ENDED 31 MARCH 2022

	2022 £	2021 £
Management		
Finance		
Accountancy	12,870	7,790
Governance costs		
Auditors' remuneration	5,400	6,680
Total resources expended	1,171,442	1,250,520
Net expenditure	(179,068)	(202,592)

GMDN AGENCY

England & Wales - Charity number 1154418

Accounts

REGISTERED COMPANY NUMBER: 05392271 (England and Wales)
REGISTERED CHARITY NUMBER: 1154418

REPORT OF THE TRUSTEES AND

AUDITED FINANCIAL STATEMENTS

FOR THE YEAR ENDED 31 MARCH 2021

FOR

GMDN AGENCY

MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

GMDN AGENCY

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FOR THE YEAR ENDED 31 MARCH 2021

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REPORT OF THE TRUSTEES
FOR THE YEAR ENDED 31 MARCH 2021

The trustees who are also directors of the charity for the purposes of the Companies Act 2006, present their report with the financial statements of the charity for the year ended 31 March 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

Purposes and aims

Our charity's purposes as set out in the objects contained in the company's memorandum of association are to:

To preserve and protect health and to relieve sickness for the public benefit by developing and maintaining the 'Global Medical Device Nomenclature', a system of internationally agreed descriptors used to identify medical device products which will meet a global need for identification purposes. Our aims fully reflect the purposes that the charity was set up to further.

Our charity's purposes as set out in the objects contained in the company's Articles of Association are to:

To preserve and protect health and relieve sickness for the public benefit by developing and maintaining the "Global Medical Device Nomenclature", a system of internationally agreed descriptors used to identify medical device products which will meet a global need for identification purposes.

Our aims fully reflect the purposes that the charity was set up to further:

- Make it easy to identify the appropriate GMDN Term for any medical device;
- Where an appropriate GMDN Term is not available, make the request process simple and effective;
- Make the GMDN Term development process transparent to our stakeholders;
- Ensure translation of the GMDN is timely;
- Improve our website experience and improve our customer support in the international context;
- Promote worldwide utilisation of the GMDN and contribute to organisations that promote healthcare standards harmonisation;
- Continuously review the GMDN to ensure that it remains relevant, accurate and current;

Ensuring our work delivers our aims

We review our aims, objectives and activities each year. This review looks at what we achieved and the outcomes of our work in the previous 12 months. The review looks at the success of each key activity and the benefits they have brought to those groups of people we are set up to help. The review also helps us ensure our aims, objectives and activities remained focused on our stated purposes. We have referred to the guidance contained in the Charity Commission's general guidance on public benefit when reviewing our aims and objectives and in planning our future activities. In particular, the trustees consider how planned activities will contribute to the aims and objectives they have set.

The focus of our work

Our main objectives for the year continued to be the maintenance, promotion and distribution of the Global Medical Device Nomenclature. The strategies we use to meet these objectives included:

- Ensuring the GMDN is maintained regularly and represents most medical devices to be identified quickly and accurately;
- Presenting information about the GMDN at international conferences on medical device safety and encouraging all countries to adopt the GMDN as their national standard for medical device identification;
- Meeting customers and discussing their use of the GMDN and improving our services to them;
- Working in partnership with other organisations that share our objectives in improving patient care;
- Maintaining our Quality Management System and its certification to the ISO9001 standard; and
- Making our website easier to use and protecting our customers information.

OBJECTIVES AND ACTIVITIES

Public benefit

Our main activities and who we try to help are described below. All our charitable activities focus on the accurate identification of medical devices by standardising their common description and sharing this information with the device manufacturers, regulators and healthcare providers worldwide for the public benefit.

Who used and benefited from our services?

Our objects and funding limit the services we provide to the maintenance, promotion and distribution of the Global Medical Device Nomenclature.

Equal access to our services is an important issue for us. All potential users of the GMDN can gain access to the GMDN data.

Medical device regulators use the GMDN data to accurately identify specific equipment, when they need to approve medical devices, as part of their national regulatory framework.

When monitoring the safety of medical devices within the market, medical device regulators can use the GMDN to identify trends in success and failure of a specific device or common technology, which is vitally important when systematic failures of devices from more than one manufacturer may occur.

Medical device manufacturers use the GMDN data to sort their products into more manageable groups and provide more consistent device names to their customers.

Medical device users can use GMDN data to support decision making within the healthcare environment.

We maintain our website to provide information to our members in 32 languages, thereby encouraging wider global access to the GMDN database, with more languages being added each year if necessary.

The GMDN Agency completed our first three-year audit-cycle by third-party external audit to the Quality Management System standard ISO9001:2015 in February 2020.

To demonstrate our commitment to information security the GMDN Agency was re-certified to the UK Government's Cyber Essentials Scheme in October 2020.

FINANCIAL REVIEW

Principal funding sources

The principal funding sources for the charity are currently the licencing of access to the GMDN to our members via our website.

Access is only available to members and membership is priced according to organisation type and size. The membership process is completed online and access to the GMDN database is immediate upon completion of payment.

Investment policy and objectives

Aside from retaining a prudent amount in reserves each year most of the charity's funds are to be spent in the short term so there are few funds for long term investment. The charity, with the aid of sound financial management and the support of both its staff and volunteers maintained a total of funds carried forward amounting to £1,695,972.

FINANCIAL REVIEW

Reserves policy

The GMDN Agency, as a charitable activity designed to provide services to members, should operate on the basis of costs equating to income over the long-term. Reserves will be held to ensure continuity of operation and provide a buffer for variations in income or respond to short-term expenditure needs not accommodated by the normal running of the organisation, as well as addressing anticipated future change costs associated with both environmental and operational necessities e.g. changes in business model, major recapitalisation of assets, etc.

Excess funds should be returned to members over the medium-term via adjustments to the fees for service. Reserves are categorised as the Operational and Strategic reserves.

The Operational reserve is to cover cash flow variability and anticipated short-term variations in either income or expenditure. It also needs to cover the cost of winding up the Agency subject to the possibility that the Agency needs to be closed.

The Strategic reserve is to cover anticipated needs over and above those accommodated by the Operational reserve but required to support the long-term sustainability of the Agency. This needs to be consistent with the conditions applied above.

The level of these reserves is agreed on an annual basis by the Trustees as part of the financial budgeting process.

The impact of the Covid-19 pandemic is being carefully monitored by the Trustees and adjustments to the current operating plan are being introduced to ensure the GMDN is maintained and available for all users.

COVID-19

In light of the rapid global spread of the Coronavirus "COVID-19" since early 2020, the trustees have given consideration to the charity's operations, including its going concern status. Following this review, the trustees consider there to be little impact on the charity's ability to act as a going concern, given its net asset position and capital resources available, and consequently the trustees continue to adopt the going concern basis in preparing these financial statements.

Further details in respect of the impact of COVID-19 can be seen in the "Basis of preparing the financial statements" note within the accounting policies.

FUTURE DEVELOPMENTS

The effective use of the GMDN by national medical device regulators and other stakeholders throughout the world continues to be the primary objective of the Agency.

The Trustees deliberately build up the reserves in the past few years to meet the challenges and costs associated with the increasing use of the GMDN. Due to the long-term nature of the adoption of the GMDN the timing of the use of funds can be difficult to predict. It is expected that the adoption of the GMDN will require the investment of substantial funds in supporting adoption and supporting users worldwide.

In April 2019, following a consultation with Stakeholders, the Trustees decided to introduce a new band of Basic membership service that would provide the essential data components of the GMDN for no cost. The new membership band and financial impact has been carefully monitored by the Trustees during the intervening period and we are pleased to report that total concurrent membership at the end of the year was over 14,200, which is over a 50% increase in 12 months. Our larger company members have remained loyal to the voluntary paid-for services we provide to support their management of the GMDN Terms they use and therefore our income has remained enough to allow the Trustees to be confident of our long-term financial sustainability. The membership schemes will be carefully monitored during the coming years to determine their ongoing suitability of purpose and amended as necessary.

With the introduction of the free membership band, several countries have joined in adopting the use of the GMDN and this is particularly important in countries with less-developed economies.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Governing document

The organisation is a charitable company limited by guarantee, incorporated on 14 March 2005 and registered as a charity on 31 October 2013. The company was established under a Memorandum of Association which established the objects and powers of the charitable company and is governed under its Articles of Association. In the event of the company being wound up members are required to contribute an amount not exceeding £10.

Recruitment and appointment of new trustees

The directors of the company are also charity trustees for the purposes of charity law and under the company's Articles are known as members of the Board of Trustees. Under the requirements of the Memorandum and Articles of Association the members of the Board of Trustees are elected to serve for a period of three years after which they must be re-elected at the next Annual General Meeting.

All members of the Board of Trustees give their time voluntarily and received no benefits from the charity. Any expenses reclaimed from the charity are set out in note 8 to the accounts.

Due to the nature of the medical device sector much of the charity's work inevitably focuses upon this subject. The Board of Trustees seeks to ensure that the needs of this sector are appropriately reflected through the members of the trustee body.

To enhance the potential pool of trustees, the charity, through selective networking with industry, regulators and healthcare providers, has sought to identify those individuals who would be willing to become members of the Policy Advisory Group and use their own experience to assist the charity.

The more traditional business and medical skills are well represented on the Board of Trustees. In an effort to maintain this broad skill mix, members of the Board of Trustees are requested to provide a list of their skills and in the event of particular skills being lost due to retirements, individuals are approached to offer themselves for election to the Board of Trustees. No new Trustees joined the Board within the last year.

The Trustees as part of the recent strategic planning process, wish to increase the active involvement of regulators in our governance and therefore are engaging with them to see how this can be done in the coming year.

Organisational structure

The Board of Trustees consists of up to eight members who meet quarterly and are responsible for the strategic direction and policy of the charity. At present the Committee has five members from a variety of professional backgrounds relevant to the work of the charity.

A scheme of delegation is in place and day to day responsibility for the provision of the services rest with the Chief Executive Officer. The Chief Executive Officer is responsible for ensuring that the charity delivers the services specified and that key performance indicators are met. The Technical Lead has overall responsibility for the maintenance of the Global Medical Device Nomenclature database and the Office Administrator has responsibility for customer services staff. The Chief Executive Officer has individual supervision of all staff and also ensures that the team continue to develop their skills in line with good working practice.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Induction and training of new trustees

Most trustees are already familiar with the practical work of the charity having been encouraged to have been a previous member of the Policy Advisory Group.

Additionally, new trustees are invited and encouraged to attend a training session to familiarise themselves with the charity and the context within which it operates. This is led by the Chief Executive Officer of the charity and cover:

- The obligations of Board of Trustees members;
- The main documents which set out the operational framework for the charity including the Articles of Association;
- Resourcing and the current financial position as set out in the latest published accounts; and
- Future plans and objectives.

A resource pack has been prepared drawing information from the various Charity Commission publications. This is distributed to all new trustees along with the Articles of Association, Governance, Policy and reference documents and the latest management financial report.

Related parties

In so far as it is complimentary to the charity's objects, the charity is guided by international forum for medical device safety, including the members of the International Medical Device Regulators Forum (IMDRF) and the Global Harmonisation Working Party (GHWP) as well as international medical device manufacturers' trade associations, including the Global Medical Technology Alliance (GMTA) and the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA). The representation of the GMDN Agency to these organisations has proved invaluable to the charity in establishing improved links with the medical device sector and identifying relevant policy improvements.

Risk management

The Board of Trustees has conducted a review of the major risks to which the charity is exposed. Our risk register is reviewed at every Board meeting. Where appropriate, systems or procedures have been established to mitigate the risks the charity faces. Significant external risks to funding have led to the development of a strategic plan which will allow for the planning of funding and activities. Internal control risks are minimised by the implementation of procedures for authorisation of all transactions and projects. Procedures are in place to ensure compliance with health and safety of staff, volunteers, clients and visitors to the GMDN Agency's offices. The third-party certification of our ISO 9001 Quality Management System ensure a consistent quality of delivery for all operational aspects of the charity. These procedures are periodically reviewed to ensure that they continue to meet the needs of the charity.

REFERENCE AND ADMINISTRATIVE DETAILS

Registered Company number

05392271 (England and Wales)

Registered Charity number

1154418

Registered office

Hampden House
Monument Business Park
Chalgrove
Oxford
Oxfordshire
OX44 7RW

Trustees
Mr M Wasmuth
Dr E D Krell
Ms J Trunzo
Dr C M W Tong
Mr J Wilkinson

Company Secretary
Mr M Wasmuth

Auditors
MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

Solicitors
Taylor Vinters LLP
Prama House
267 Banbury Road
Oxford
OX2 7HT

STATEMENT OF TRUSTEES' RESPONSIBILITIES
The trustees (who are also the directors of GMDN Agency for the purposes of company law) are responsible for preparing the Report of the Trustees 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"

Company law 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 charitable company and of the incoming resources and application of resources, including the income and expenditure, of the charitable company 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;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the charitable company 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 charitable company and to enable them to ensure that the financial statements comply with the Companies Act 2006. They are also responsible for safeguarding the assets of the charitable company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

In so far as the trustees are aware:

- there is no relevant audit information of which the charitable company's auditors are unaware; and
- the trustees have taken all steps that they ought to have taken to make themselves aware of any relevant audit information and to establish that the auditors are aware of that information.

STATEMENT OF TRUSTEES' RESPONSIBILITIES - continued

AUDITORS

MGI Midgley Snelling LLP were appointed as the charitable company's auditors during the year and have expressed their willingness to continue in that capacity.

Approved by order of the board of Trustees on 13 October 2021 and signed on its behalf by:

Mr M Wasmuth - Trustee

Opinion

We have audited the financial statements of GMDN Agency (the 'company') for the year ended 31 December 2020 which comprise the profit and loss account, the statement of comprehensive income, the balance sheet, the statement of changes in equity, the statement of cash flows and notes to the financial statements, including significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and United Kingdom Accounting Standards, including FRS 102 The Financial Reporting Standard applicable in the UK and Republic of Ireland (United Kingdom Generally Accepted Accounting Practice).

In our opinion the financial statements:
- give a true and fair view of the state of the company's affairs as at 31 December 2020 and of its profit for the year then ended;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice; and
- have been prepared in accordance with the requirements of the Companies Act 2006.

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 Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the company 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 directors' 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 company'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 directors with respect to going concern are described in the relevant sections of this report.

Other information

The other information comprises the information included in the annual report other than the financial statements and our auditor's report thereon. The directors are responsible for the other information contained within the annual report. 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. 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 course of 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.

Opinions on other matters prescribed by the Companies Act 2006

In our opinion, based on the work undertaken in the course of our audit:
- the information given in the strategic report and the directors' report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the strategic report and the directors' report have been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception
In the light of the knowledge and understanding of the company and its environment obtained in the course of the audit, we have not identified material misstatements in the strategic report and the directors' report.

We have nothing to report in respect of the following matters where the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept, or returns adequate for our audit have not been received from branches not visited by us; or
- the financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

Responsibilities of trustees
As explained more fully in the statement of trustees' responsibilities, the trustees are responsible for the preparation of the financial statements and for being satisfied that they 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 company'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 directors either intend to liquidate the company or to cease operations, or have no realistic alternative but to do so.

Our responsibilities for the audit of the financial statements

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 an auditor's report 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.

In planning and designing our audit tests, we identify and assess the risks of material misstatements within the financial statements, whether due to fraud or error. Our assessment of these risks includes consideration of the nature of the industry and sector, the control environment and the business performance along with the results of our enquiries of management, about their own identification and assessment of the risks of irregularities. We are also required to perform specific procedures to respond to the risk of management override.

As a result of this assessment, we considered the opportunities and incentives that may exist within the company for fraud and identified that the greatest area of risk was in relation to management override.

We have obtained an understanding of the legal and regulatory frameworks that the company operates in from discussions with the directors and our knowledge of the company and its industry sector. We have focussed on the provisions of those laws and regulations that have a direct effect on the determination of material amounts and disclosures in the financial statements. The key laws and regulations we considered in this context included the UK Companies Act and local tax legislation.

We performed the following audit procedures after consideration of the above risks which included the following:

- enquiry of management of actual and potential litigation and claims;
- reviewing correspondence with HMRC and the company's legal advisors;
- reviewing financial statement disclosures and testing to supporting documentation to assess compliance with applicable laws and regulations;
- performing analytical procedures to identify any unusual or unexpected relationships that may indicate risks of material misstatement due to fraud; and
- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

The engagement partner has assessed that all engagement team members were made aware of the relevant laws and regulations and potential fraud risks and were reminded to remain alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

Because of the inherent limitations of an audit, there is a risk that we will not detect all irregularities, including those leading to a material misstatement in the financial statements or non-compliance with regulation. The risk increases the more that compliance with a law or regulation is removed from the events and transactions reflected in the financial statements, as we will be less likely to become aware of instances of non-compliance. The risk is also greater regarding irregularities occurring due to fraud rather than error, as fraud involves intentional concealment, forgery, collusion, omission or misrepresentation.

A further description of our responsibilities is available on the Financial Reporting Council's website at: https://www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

Use of our report

This report is made solely to the company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's 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 company and the company's members, as a body, for our audit work, for this report, or for the opinions we have formed.

Sarah Squires BEng FCA (Senior Statutory Auditor)
for and on behalf of MGI Midgley Snelling LLP
Ibex House
Baker Street
Weybridge
Surrey
KT13 8AH

18 October 2021

GMDN AGENCY

STATEMENT OF FINANCIAL ACTIVITIES (INCORPORATING AN INCOME AND EXPENDITURE ACCOUNT) FOR THE YEAR ENDED 31 MARCH 2021

	Notes	2021 Unrestricted funds £	2020 Total funds £
INCOME AND ENDOWMENTS FROM			
Donations and legacies	3	1,047,030	1,287,010
Investment income	4	898	4,291
Total		1,047,928	1,291,301
EXPENDITURE ON			
Charitable activities	5		
Development and maintenance of database		1,250,520	1,077,125
NET INCOME/(EXPENDITURE)		(202,592)	214,176
RECONCILIATION OF FUNDS			
Total funds brought forward		1,898,564	1,684,388
TOTAL FUNDS CARRIED FORWARD		1,695,972	1,898,564

The notes form part of these financial statements

GMDN AGENCY

STATEMENT OF FINANCIAL POSITION
31 MARCH 2021

	Notes	2021 Unrestricted funds £	2020 Total funds £
FIXED ASSETS			
Intangible assets	10	280,843	290,051
Tangible assets	11	8,997	15,347
		289,840	305,398
CURRENT ASSETS			
Debtors	12	601	5,668
Prepayments and accrued income		33,241	29,591
Cash at bank		1,907,993	2,127,113
		1,941,835	2,162,372
CREDITORS			
Amounts falling due within one year	13	(535,703)	(569,206)
NET CURRENT ASSETS		1,406,132	1,593,166
TOTAL ASSETS LESS CURRENT LIABILITIES		1,695,972	1,898,564
NET ASSETS		1,695,972	1,898,564
FUNDS	15		
Unrestricted funds		1,695,972	1,898,564
TOTAL FUNDS		1,695,972	1,898,564

These financial statements have been prepared in accordance with the provisions applicable to charitable companies subject to the small companies regime.

The financial statements were approved by the Board of Trustees and authorised for issue on 13 October 2021 and were signed on its behalf by:

Mr M Wasmuth - Trustee

The notes form part of these financial statements

GMDN AGENCY

STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 31 MARCH 2021

	Notes	2021 £	2020 £
Cash flows from operating activities			
Cash generated from operations	1	(83,306)	198,386
Net cash (used in)/provided by operating activities		(83,306)	198,386
Cash flows from investing activities			
Purchase of intangible fixed assets		(129,630)	(148,222)
Purchase of tangible fixed assets		(7,082)	(12,826)
Interest received		898	4,291
Net cash used in investing activities		(135,814)	(156,757)
Change in cash and cash equivalents in the reporting period		(219,120)	41,629
Cash and cash equivalents at the beginning of the reporting period		2,127,113	2,085,484
Cash and cash equivalents at the end of the reporting period		1,907,993	2,127,113

The notes form part of these financial statements

NOTES TO THE STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 31 MARCH 2021

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

	2021 £	2020 £
Net (expenditure)/income for the reporting period (as per the Statement of Financial Activities)	(202,592)	214,176
Adjustments for:		
Depreciation charges	152,270	136,290
Interest received	(898)	(4,291)
Decrease in debtors	1,417	31,691
Decrease in creditors	(33,503)	(179,480)
Net cash (used in)/provided by operations	(83,306)	198,386

2. ANALYSIS OF CHANGES IN NET FUNDS

	At 1.4.20 £	Cash flow £	At 31.3.21 £
Net cash			
Cash at bank	2,127,113	(219,120)	1,907,993
	2,127,113	(219,120)	1,907,993
Total	2,127,113	(219,120)	1,907,993

The notes form part of these financial statements

1. GENERAL INFORMATION

GMDN Agency is a charitable company limited by guarantee and incorporated in England and Wales. The address of the company's registered office is Hampden House, Monument Business Park, Chalgrove, Oxford, OX44 7RW. The registered company number is 05392271 and the registered charity number is 1154418.

The principal activities of the charity are as disclosed within the Report of the Trustees on pages 1 to 7.

The presentational currency of these financial statements is Sterling (£), being the currency of the primary economic market in which the entity operates. All amounts in these financial statements have been rounded to the nearest pound unless stated otherwise.

The significant accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all years presented unless otherwise stated.

2. ACCOUNTING POLICIES

Basis of preparing the financial statements
The financial statements of the charitable company, 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 Companies Act 2006. The financial statements have been prepared under the historical cost convention.

Going concern
In light of the rapid global spread of the Coronavirus "COVID-19" since early 2020, the trustees have produced projections and budgets for the next twelve months in order to consider the charity's going concern status. Following this review, the trustees consider there to be little impact on the charity's ability to act as a going concern.

The trustees have considered the substantial net assets of the charity and the cash resources available as well as the charity's commitments. The trustees consider that the charity has adequate resources in place to continue in operation for a period of at least twelve months from the date of approval of the financial statements and therefore continue to adopt the going concern basis in preparing these financial statements.

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. Membership fees are recognised equally over the period of the 12 month subscription.

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 costs related to the category.

Allocation and apportionment of costs
Where costs cannot be directly attributed to particular headings they have been allocated to activities on a basis consistent with use of the resources.

Trustee salaries have been apportioned in accordance with the duties to which they relate.

2. ACCOUNTING POLICIES - continued

Intellectual property
The cost of developing the company's database and associated systems is being capitalised and amortised through the Statement of Financial Activities in equal annual instalments over its estimated economic life of 5 years. The cost of development includes staff costs.

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

Computers and furniture - straight line - 33%

Taxation
The charity is exempt from corporation 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.

All the charity's funds are unrestricted.

Foreign currencies
Transactions in foreign currencies are recorded at the rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated at the rate of exchange ruling at the balance sheet date. All differences are taken to the Statement of Financial Activities.

Hire purchase and leasing commitments
Rentals paid under operating leases are charged to the Statement of Financial Activities on a straight line basis over the period of the lease.

Pension costs and other post-retirement benefits
The charitable company operates a defined contribution pension scheme. Contributions payable to the charitable company's pension scheme are charged to the Statement of Financial Activities in the period to which they relate.

Financial instruments
The charitable company only has financial assets and financial liabilities of a kind that qualify as basic financial instruments. Basic financial instruments are initially recognised at transaction value and subsequently measured at their settlement value.

Significant judgements and estimates
The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of income, expenditure, assets and liabilities. If in the future such estimates and assumptions, which are based on management's best judgment at the date of the financial statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate in the year in which the circumstances change.

3. DONATIONS AND LEGACIES

	2021	2020
	£	£
Subscriptions	1,047,030	1,287,010

4. INVESTMENT INCOME

	2021	2020
	£	£
Bank interest	898	4,291

5. CHARITABLE ACTIVITIES COSTS

	Direct Costs	Support costs (see note 6)	Totals
	£	£	£
Development and maintenance of database	1,126,514	124,006	1,250,520

6. SUPPORT COSTS

	Management	Finance	Governance costs	Totals
	£	£	£	£
Development and maintenance of database	109,536	7,790	6,680	124,006

Analysis of support and governance costs

The charity initially identifies the costs of its support function. It then identifies those costs which relate to the governance function. Having identified its governance costs and support costs these are apportioned between the key charitable activities undertaken in the year. Please refer to the table below for the basis of apportionment and the key analysis of support.

	General Support	Governance function	Basis of apportionment
	£	£	
Wages	109,536		The duties to which they relate
Audit fees		6,680	Governance
Accountancy	7,790		The duties to which they relate
Total	117,326	6,680	

7. NET INCOME/(EXPENDITURE)

Net income/(expenditure) is stated after charging/(crediting):

	2021	2020
	£	£
Auditors' remuneration	6,680	8,034
Depreciation - owned assets	13,432	1,697
Other operating leases	55,357	53,050
Intellectual property amortisation	138,838	134,593

8. TRUSTEES' REMUNERATION AND BENEFITS

	2021	2020
	£	£
Trustees' salaries	186,845	174,212
Trustees' social security	23,310	21,648
Trustees' pension contributions to money purchase schemes	9,146	8,710
	219,301	204,570

The trustees' remuneration is in respect of one (2020 - one) trustee, being Mr M Wasmuth, for services as the Chief Executive Officer of the charity.

Trustees' expenses

Trustees' travel expenses reimbursed for the year ended 31 March 2021 totalled £Nil (2020 - £10,926 reimbursed to four trustees).

9. STAFF COSTS

	2021	2020
	£	£
Wages and salaries	591,120	515,138
Social security costs	64,077	58,823
Other pension costs	29,027	25,774
	684,224	599,735

The average monthly number of employees during the year was as follows:

	2021	2020
Management	1	1
Technical	7	6
Administration	2	2
	10	9

9. STAFF COSTS - continued

The number of employees whose employee benefits (excluding employer pension costs) exceeded £60,000 was:

	2021	2020
£60,001 - £70,000	1	1
£70,001 - £80,000	1	1
£120,001 - £130,000	1	1
£180,001 - £190,000	1	1
	4	4

During the year £100,852 (2020 - £109,148) of salaries and pension as well as £9,251 (2020 - £11,544) of social security costs were capitalised as part of the intangible fixed asset. These costs are not included in the figures above.

10. INTANGIBLE FIXED ASSETS

	Intellectual property £
COST	
At 1 April 2020	1,111,688
Additions	129,630
At 31 March 2021	1,241,318
AMORTISATION	
At 1 April 2020	821,637
Charge for year	138,838
At 31 March 2021	960,475
NET BOOK VALUE	
At 31 March 2021	280,843
At 31 March 2020	290,051

11. TANGIBLE FIXED ASSETS

	Computers and furniture £
COST	
At 1 April 2020	78,326
Additions	7,082
Disposals	(29,118)
At 31 March 2021	56,290
DEPRECIATION	
At 1 April 2020	62,979
Charge for year	13,432
Eliminated on disposal	(29,118)
At 31 March 2021	47,293
NET BOOK VALUE	
At 31 March 2021	8,997
At 31 March 2020	15,347

12. DEBTORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	2021 £	2020 £
Other debtors	601	5,668

13. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	2021 £	2020 £
Social security and other taxes	23,219	22,015
Accruals and deferred income	512,484	547,191
	535,703	569,206

Included within accruals and deferred income is the following deferred income:

	£
Deferred income at 31 March 2020	529,080
Released in the year	(529,080)
Deferred in the year	480,843
Deferred income at 31 March 2021	480,843

14. LEASING AGREEMENTS

Minimum lease payments under non-cancellable operating leases fall due as follows:

	2021	2020
	£	£
Within one year	902	30,615
Between one and five years	676	1,578
	1,578	32,193

15. MOVEMENT IN FUNDS

	At 1.4.20	Net movement in funds	At 31.3.21
	£	£	£
Unrestricted funds			
General fund	1,118,314	(202,592)	915,722
Designated cash flow fund	250,000	-	250,000
Designated reserve fund	530,250	-	530,250
	1,898,564	(202,592)	1,695,972
TOTAL FUNDS	1,898,564	(202,592)	1,695,972

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

	Incoming resources	Resources expended	Movement in funds
	£	£	£
Unrestricted funds			
General fund	1,047,928	(1,250,520)	(202,592)
TOTAL FUNDS	1,047,928	(1,250,520)	(202,592)

Comparatives for movement in funds

	At 1.4.19	Net movement in funds	At 31.3.20
	£	£	£
Unrestricted funds			
General fund	904,138	214,176	1,118,314
Designated cash flow fund	250,000	-	250,000
Designated reserve fund	530,250	-	530,250
	1,684,388	214,176	1,898,564
TOTAL FUNDS	1,684,388	214,176	1,898,564

15. MOVEMENT IN FUNDS - continued

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

	Incoming resources £	Resources expended £	Movement in funds £
Unrestricted funds			
General fund	1,291,301	(1,077,125)	214,176
TOTAL FUNDS	1,291,301	(1,077,125)	214,176

The Charity has the following designated funds:

The Designated Cash Flow Fund ("Operational Reserve") is held to cover cash flow variability and anticipated short-term variations in either income or expenditure. It also needs to cover the cost of winding up the Agency subject to the possibility that the Agency needs to be closed.

The Designated Reserve Fund ("Strategic Reserve") is held to cover anticipated needs over and above those accommodated by the Operational Reserve but required to support the long-term sustainability of the Agency. This needs to be consistent with the conditions applied above.

The level of these reserves will be agreed on an annual basis by the Trustees as part of the annual financial budgeting process.

16. RELATED PARTY DISCLOSURES

There were no related party transactions for the year ended 31 March 2021 (2020: £Nil).

17. ULTIMATE CONTROLLING PARTY

The charity was under the control of the trustees throughout the current and previous year.

18. COMPANY LIMITED BY GUARANTEE

The liability of each member is limited to an amount not exceeding £10.

DETAILED STATEMENT OF FINANCIAL ACTIVITIES
FOR THE YEAR ENDED 31 MARCH 2021

	2021 £	2020 £
INCOME AND ENDOWMENTS		
Donations and legacies		
Subscriptions	1,047,030	1,287,010
Investment income		
Bank interest	898	4,291
Total incoming resources	1,047,928	1,291,301
EXPENDITURE		
Charitable activities		
Trustees' salaries	93,309	87,106
Trustees' social security	11,655	10,824
Trustees' pension contributions	4,573	4,355
Wages	404,275	340,926
Social security	40,767	37,175
Pensions	19,881	17,064
Rent and rates	55,357	53,050
Database costs	86,431	68,914
Travel and subsistence	32	29,793
Insurance	24,947	19,133
Telephone	2,066	2,882
Postage and stationery	1,225	691
Computer costs	777	834
Sundries	7,842	15,422
Consultancy	139,971	111,775
Bank charges	14,070	16,823
Foreign exchange	50,574	(29,664)
Trustees' meetings	-	19,675
Training costs	6,485	10,116
Subscriptions	10,007	9,475
Amortisation	138,838	134,593
Depreciation	13,432	1,697
	1,126,514	962,659
Support costs		
Management		
Trustees' salaries	93,308	87,106
Trustees' social security	11,655	10,824
Trustees' pension contributions	4,573	4,355
	109,536	102,285
Finance		
Accountancy	7,790	4,147

DETAILED STATEMENT OF FINANCIAL ACTIVITIES FOR THE YEAR ENDED 31 MARCH 2021

	2021 £	2020 £
Finance		
Governance costs		
Auditors' remuneration	6,680	8,034
Total resources expended	1,250,520	1,077,125
Net (expenditure)/income	(202,592)	214,176