GMDN

STRATEGY

2022 – 2026

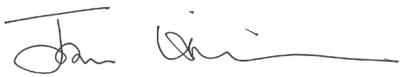
This new strategy is the culmination of very significant events in the development of the GMDN. The first of these was the decision to make GMDN terms available to all manufacturers free of charge in 2019. As a charity dedicated to serving the interests of patients and citizens of the world, GMDN has raised funding through contributions from manufacturers. We continue to be both grateful to, and reliant on, the manufacturers that support our activities and fund the services that we provide worldwide. What has become evident is that the number of users of GMDN continue to grow beyond the founding members who were the world's medical device regulators to include thousands of manufacturers, clinicians, and researchers.

The foundations of this strategy were built on an independent stakeholder consultation which was designed to help the Agency understand both historical performance and future needs. The results are a reflection of what we learned from stakeholders on where our future focus needs to be. I would like to express my personal thanks to those who gave up their time to inform the development of this strategy and provide us with candid feedback. I would also like to thank the team for their openness and positive response towards the need to evolve.

The GMDN was established as a keystone of global harmonisation and the Agency remains committed to supporting this collaboration. There are two key reasons why a globally harmonised and adopted nomenclature is important. The first is that it facilitates the unambiguous use, analysis and exchange of information about medical devices and their performance. This is critical to patient safety and a detailed understanding of how medical technologies are performing in everyday use. The second reason is more administrative and practical. Setting up and maintaining nomenclatures is a costly business, whether it be the authorities that establish them or the industry that feeds them with appropriate information. Several nomenclatures not only duplicate costs, but also undermine the potential benefits to patients of consistently structured databases.

Our new strategy marks a significant shift from just providing a well-constructed and maintained set of definitions to supporting the development and use of the nomenclature in a wide variety of applications. We are investing more of our time and efforts into helping with application development, exploring new uses with our community and ensuring that users can get the best from this unique resource. This is only possible through the generosity of our supporters, and we remain grateful for their loyalty and collaboration.

Finally, I would like to thank the Trustees for their continued and unremunerated commitment to the Agency and its goals. Without such selfless service the Agency would not be in the strong position that it now holds. The support of strong, independent Trustees and members is critical to the future of the Agency in delivering against its primary purpose of public good.



John Wilkinson
Chair

The last decade has seen great leaps forward in the identification of medical devices, including the introduction and global adoption of unique device identification. This means we are seeing more reliable methods of recording device use and experience. Naming and grouping medical devices to manage them more safely and efficiently is what the GMDN is all about. We are increasingly seeing the tangible benefits of our work at the GMDN Agency to realise the vision of those that instigated the global nomenclature many years ago.

This strategy document has been prepared in collaboration with our members. We have listened and reflected on their needs and aspirations and hope the support we provide them in the next few years meets their expectation.

We look forward to a new decade of exploring the use of GMDN with our members, because we believe we are part of something bigger than just us and better identification of devices is something we all aspire to. As we all know, better data makes better decisions.

Mark Wasmuth
Chief Executive

MEETING THE CHALLENGES AHEAD

As a charity, the GMDN Agency's charitable objects are clear. The agency has been established 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.

The Agency's role is an essential part of the global regulatory framework. Our role is primarily to assist in the protection of patients, by acting as a resource for healthcare regulators. The GMDN allows regulators to track the use of similar medical devices, helping to identify trends and solve problems quickly. Through greater global harmonisation, trends can be identified across borders, allowing for regulators in different jurisdictions to work together more effectively. Alongside patient protection, our mission is to offer expertise and insight to the whole medical device supply chain. Users benefit from our excellent data and expertise, as well as the efficiencies created through the widespread use of a global language for medical devices, which improves communication and in turn helps protect the public. In order to ensure that the GMDN Agency continues to achieve its aims, the Agency needs to be prepared for the future.

THREE DECADES OF INDEPENDENT EXPERTISE

From its inception in 1991, the Agency has brought together medical device experts from around the world (regulators, healthcare providers and manufacturers) to work together creating the Global Medical Device Nomenclature. This work was requested by the inter-governmental body, the Global Harmonisation Task Force (now the IMDRF) to help accelerate international medical device regulatory harmonization and cross-border collaboration. Initial work was mandated by the European Commission to support the implementation of the first European Medical Device Safety Directives, and over the last 20 years use of GMDN has spread throughout the world. As a globally trusted source of information, the independence and effective governance of the GMDN is essential.

The GMDN Agency is the non-profit organisation that is responsible for the management of the GMDN. It is a registered UK charity, subject to an independent audit each year and regulated by the UK Charites Commission. The Agency's work is overseen by a Board of Trustees comprising of members representing national regulators and healthcare authorities. There is also one place on the Board for a representative of medical device manufacturers.

The GMDN Agency is also guided in its work by dedicated standing committees, which provides advice to the Board of Trustees on matters of relevance to the satisfactory maintenance of the GMDN. This includes ways to ensure that the GMDN meets international requirements for exchange of regulatory information. It also covers new and emerging international needs for nomenclatures. The PAG also has an important role helping to ensure that developing technologies are monitored and incorporated as appropriate. Past Chairs of the PAG have included officials of the US FDA and European Commission.

OPEN AND TRANSPARENT

We recognise that responding to the needs of regulators, users and patients, while also maintaining and strengthening the independence of the GMDN, will be critical as we adapt to meet the challenges ahead. Central to this strategy will be increasing the transparency of the Agency, improving our engagement with stakeholders and communicating our activities.

The GMDN Agency has operated a Quality Management System registered to ISO9001 since 2017 and is confident its procedures are appropriate to allow all stakeholders to engage in its activities, but it will need to do more to improve the confidence of some critics.

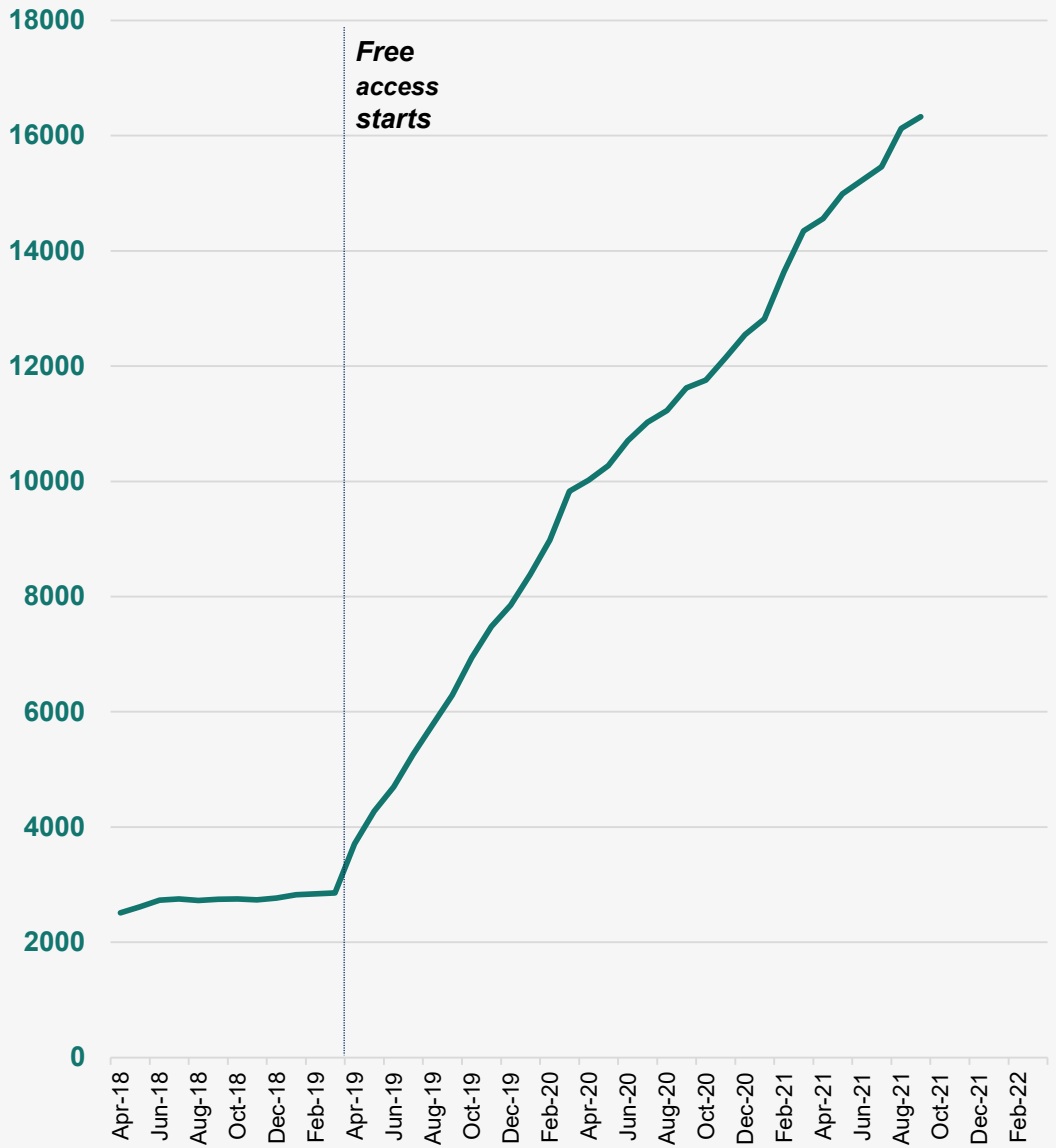
A RESOURCE FOR ALL

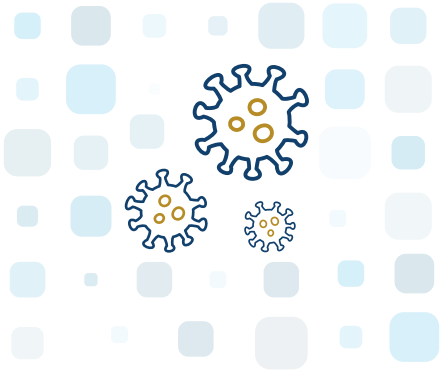
Since its establishment, the GMDN has been dedicated to improving cross-border collaboration, and meeting a global need for device identification. We are committed to helping regulators protect the public, and we believe greater global harmonisation of medical device standards is essential to allow regulators in every jurisdiction to track trends and identify issues in medical device use.

As part of our work to ensure the GMDN is a resource for all, regardless of means, we made access to the GMDN free for all users in 2019. Having free access to the world's most used, independent and trusted nomenclature for medical devices has benefited healthcare providers, regulators and patients across the globe, as well as meeting the demands of the World Health Organisation and the European Commission. Following this change, the number of people who subscribe to the GMDN has continued to grow.

Over many years, the GMDN has become a resource for all. As well as offering free access to the nomenclature for all users, the GMDN is now licensed for use to the government in over a hundred different countries, making it by far the most widely used medical device nomenclature in the world. However, we know we need to keep working to reduce barriers for use, to ensure the GMDN can be an effective, easy to use tool, which has utility for all. This strategy outlines how we intend to continue to make the GMDN easier to use, and help more users adopt and use it.

GMDN CONCURRENT SUBSCRIBERS





THE ONGOING IMPACT OF COVID-19

The medical devices sector has faced a particularly challenging period as regulators and medical device manufacturers have played a crucial role in responding to the Covid-19 pandemic. During this period, the Agency has responded immediately to the demands of regulators to identify specific devices needed to diagnose and treat patients with Covid-19. The additional demands on the medical devices sector will last into the future, and the GMDN Agency will continue to provide an essential service to the sector. The Agency will continue to reflect and act on our learning from this period and, as the healthcare sector returns to a more normal way of working, we will ensure lessons are learned for the future.

> *In short, the speed and affordability of set up of registries will be greatly helped by standardisation most notably the use of common data standards, which could enable complex data sets needed for a comprehensive and granular registry to be built. In addition, when things go wrong there needs to be a way of tracking the supply chain using GMDN.*
>
> **Written evidence to the Cumberlege Review, submitted by NHS Digital**

THE CHANGING FACE OF MEDICAL DEVICE REGULATION

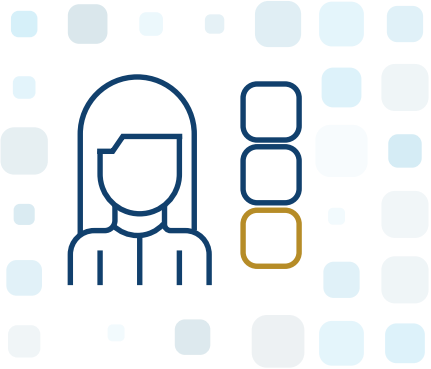
The global roll-out and use of Unique Device Identification systems is changing the way medical devices are identified and UDI systems will grow in importance as they continue to be adopted. The GMDN has an essential role within the UDI system, to provide the standardised names to enable consistent grouping of devices. We will ensure that we continue to provide regulators and manufacturers with the service they need to improve the identification of devices with UDI.

> *Use of the GMDN term assigned to UDI-DIs and their associated implantable collective codes supports the most accurate programmable approach to identifying implantable devices.*
>
> **Learning UDI Community - High-Risk Implants Work Group**

IMPROVING GLOBAL COMMUNICATION AND HARMONISATION

International cooperation and communication allow the medical devices sector to improve patient outcomes and protect the public globally. The Agency has a core role in facilitating greater harmonisation to benefit regulators, manufacturers, healthcare professionals and the public. The Agency will continue to promote international dialogue within the global medical devices sector and will maintain users' ability to communicate effectively and protect patient safety. The Agency will demonstrate the advantages of greater global harmonisation, and the benefits of medical technology for patient care.

> *Mapping our history and institutional knowledge of search and taxonomy to the GMDN database will enable users to quickly and easily find the information they need to prepare documentation for regulators – ultimately getting new and better devices to market so they can benefit patients.*
>
> **Medical Research Publisher**

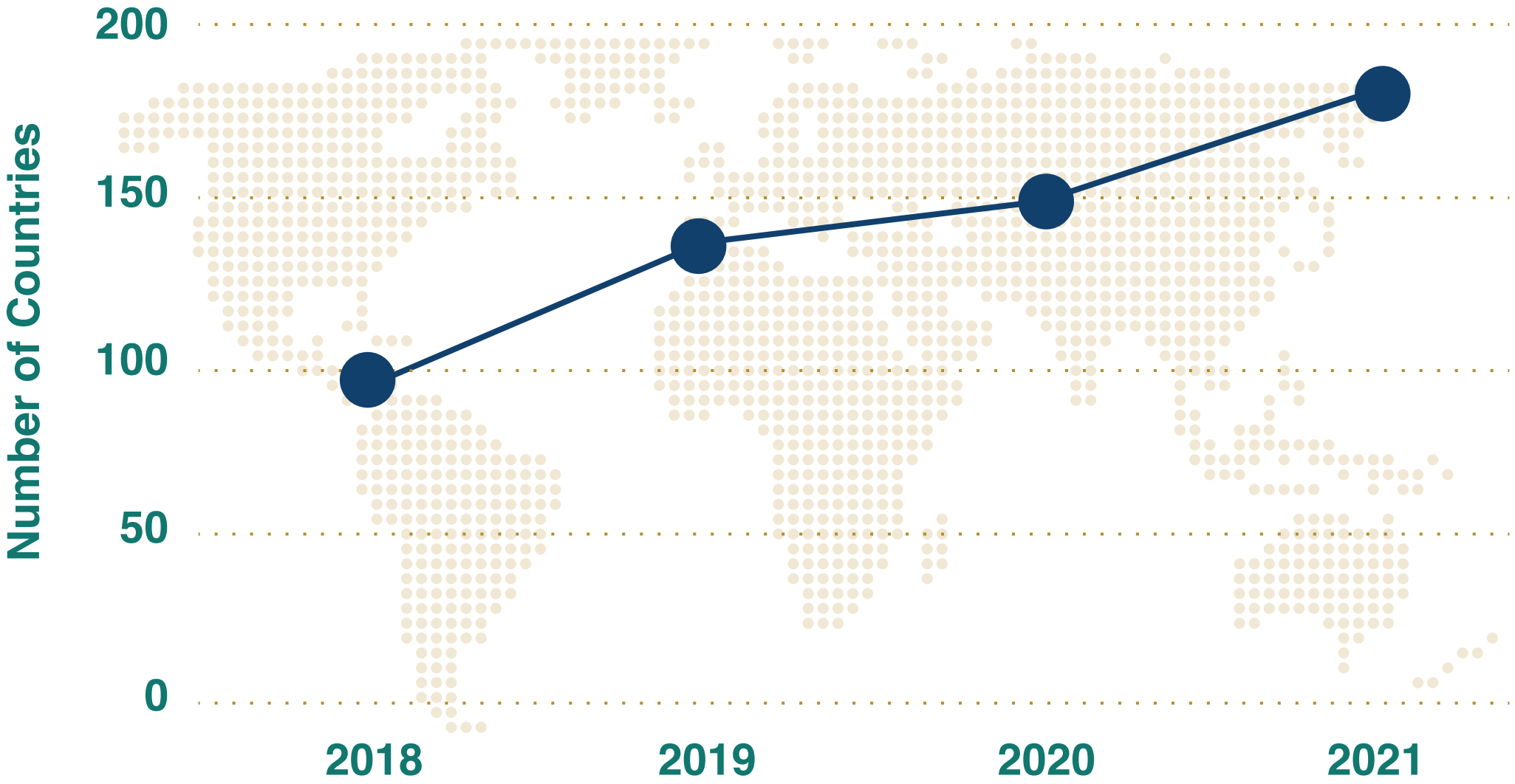


HELPING USERS TO EFFECTIVELY TAKE ADVANTAGE OF OUR SERVICES

The GMDN Agency is a rich repository of data, expertise and insight and we will continue to encourage users to take advantage of our services. The Agency will help users to improve efficiencies and achieve their aims more effectively. We will support users to reduce the risk of misuse or misassignment of GMDN terms, while also offering other services to add value for our users.

> *It appears that the GMDN data would be extremely useful in building further submission validation for the registry, which we could explore once we are in a position to develop the registry further.*
>
> **NHS Breast and Cosmetic Implant Registry (BCIR)**

GMDN GROWING IN USE AROUND THE WORLD



OUR VISION

To provide a single common language for all medical technology, and for it to be adopted by medical device regulators, manufacturers and other participants in healthcare systems worldwide

OUR MISSION

To be the global leader in naming, describing and unambiguously identifying medical devices for the protection of patients

OUR VALUES

TRUSTED

We will be accurate, reliable and transparent, confident in our independence and expertise.

INNOVATIVE

We will be ambitious and enterprising, responding to the needs of users with agility and creativity.

USEFUL

We will demonstrate the value of using GMDN, providing solutions to help users achieve their aims.

OUR PILLARS

NOMENCLATURE DEVELOPMENT

Continued development and hosting of the Nomenclature based on real devices and with close liaison with stakeholders.

GMDN ADOPTION

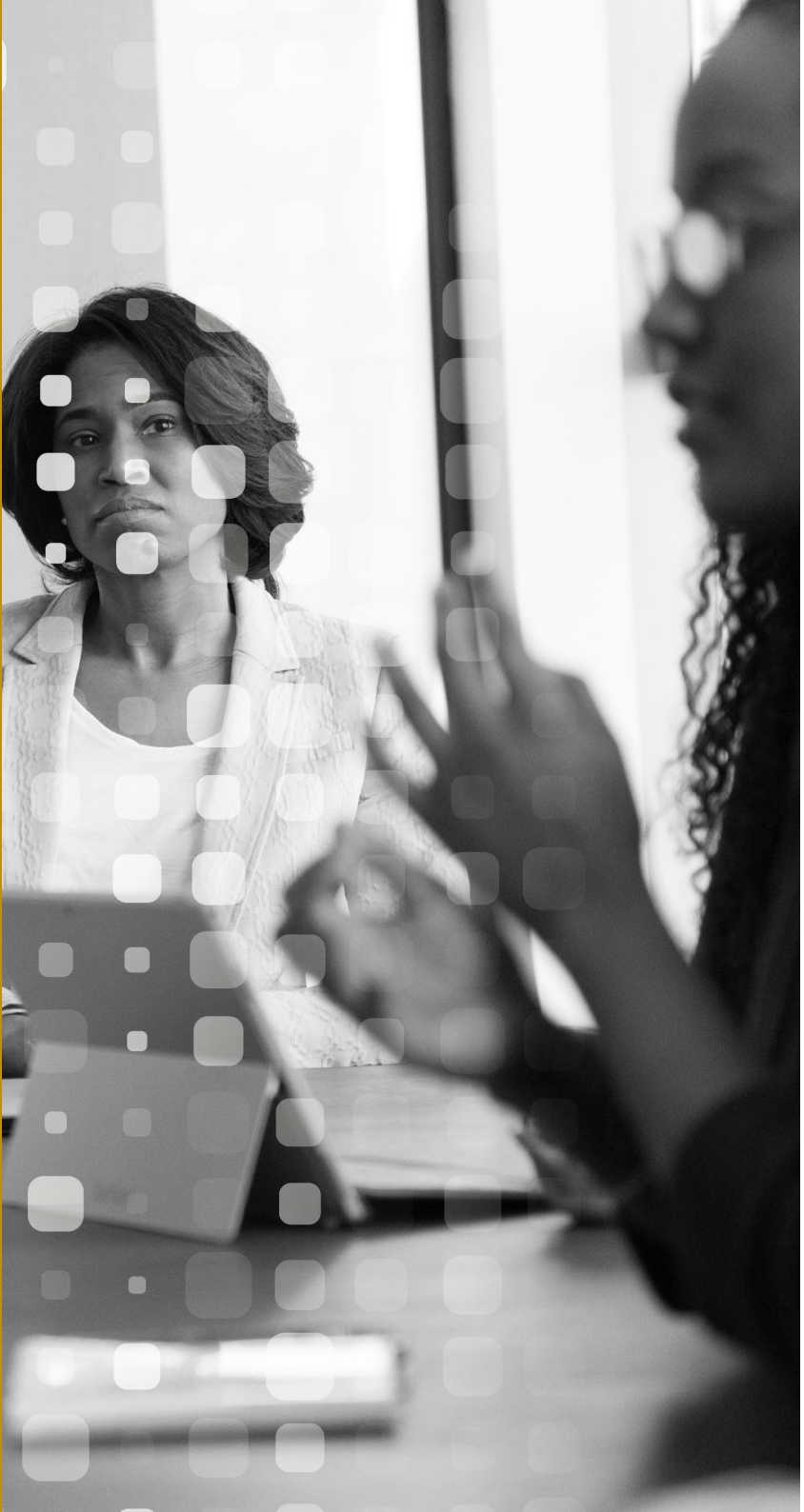
Actively seeking to help stakeholders adopt the GMDN into their internal work-flows through technical support and training.

DATA ANALYSIS

Assisting stakeholders in the downstream use of GMDN data as a leveraging tool for e.g., inventory management, real-world evidence analysis, signal detection.

TERM ASSIGNMENT QUALITY

Taking the lead in ensuring that GMDN assignments are as accurate as possible as a crucial step towards meaningful data analysis.



OUR AMBITIONS

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

PROMOTE THE VALUE OF GLOBAL COLLABORATION AND HARMONISATION

AIM

To improve international understanding and recognition of the benefits of greater global collaboration and harmonisation for regulators, manufacturers and patients.

ACTION

We will implement a programme to improve the way we communicate with all our stakeholders and the public. This will raise the profile of the GMDN as a key component of UDI development, patient safety, data science, the medical device supply chain and wider efforts to protect the public. Our communications programme will promote the value of global standards in the medical device sector, helping to explain the benefits of international cooperation in ensuring patient safety.

WHERE WE EXPECT TO BE BY 2026

The role a single global nomenclature plays in improving patient safety will be recognised and understood by key stakeholders globally.

There will be clear evidence for the utility of medical device nomenclature and better data management.

CONTINUOUSLY IMPROVE AND INNOVATE

AIM

To improve the accuracy, comprehensiveness, and utility of our services and to innovate across all our services, continuously improving the experience of our users.

ACTION

We will implement a programme to support quality assurance of Term assignment to products. The programme will reduce the burden on regulators when ascertaining the correct designation of codes for medical devices licensed in their jurisdiction. The programme will help manufacturers to ensure that the correct Terms are assigned to products, and that these are maintained and updated in a timely way.

WHERE WE EXPECT TO BE BY 2026

We will be recognised as a beacon of good practice, data leadership and innovation.

We will be adaptable and practical and will continue to meet the needs and uses of regulators and manufacturers.

We will be recognised as the nomenclature of choice globally, effectively integrated into international UDI systems.

We will have implemented a user experiences strategy which provides easily accessible processes and a positive user experience for those interacting with our services.

PROVIDE EXCELLENT SERVICES WHICH ADD VALUE

AIM

To increase the scope of the services we provide to users, according to their needs, and increase the use of our expertise, insight and high-quality data to help users achieve their aims.

ACTION

We will implement a series of programmes to increase the utility of the nomenclature and help our users to achieve their aims and protect the public. These programmes will include: Bespoke Device Grouping as part of the development of collective term architecture, to aid device grouping and analysis; Harmonisation Support for Regulators, to assist regulators in their efforts; and, Legacy Transition Tools, to facilitate the translation of data held on different systems.

WHERE WE EXPECT TO BE BY 2026

We will be recognised as a global expert on data management in the medical devices sector.

We will broaden the range of services we offer to users, providing greater consultancy and insight to help users adapt to changes in the medical devices sector, improve research and development, and protect the public.

We will continue to engage with regulators and other users to identify how these programmes are implemented and other programmes that would be of benefit to them and to the protection of the public.

BE ENGAGED, HELPFUL AND EXPERT

AIM

To improve the decision making within the medical devices sector and promote patient safety through greater application of our data, insight and expert understanding of the environment within which our users operate.

ACTION

We will implement a programme to intensify our engagement with international bodies, national regulators and other users of the GMDN. We will work with these key stakeholders, listening to their feedback to improve the services we offer. This will involve a range of developments, including increased levels of dialogue with stakeholders, renewal and augmentation of our Board and standing committees, as well as improving the ease with which users and others can make recommendations, comments and suggestions to the GMDN Agency.

WHERE WE EXPECT TO BE BY 2026

We will be recognised as a primary source for expert insight and input on data management and the medical devices sector. We will be recognised as accurate and trusted by users, well-regarded for being up to date, easy to use, and reliable.

We will have effective mechanisms for engaging with, and listening to, all our key stakeholder groups.

OUR PROGRAMMES

To build on GMDN's core purpose and meet the challenges ahead, we have identified four programmes which will be at the heart of our development. Each of these programmes will help us to better serve our users, improving the global regulatory device framework for all, and leading to better outcomes for medical device users, practitioners and patients.

BESPOKE DEVICE GROUPING

LEGACY TRANSITION TOOLS

HARMONISATION SUPPORT FOR REGULATORS

STAKEHOLDER OUTREACH

TERM ASSIGNMENT SUPPORT

BESPOKE DEVICE GROUPING

The GMDN has a device hierarchy, Collective Terms, which allows users to group devices by specific attributes. This is useful when aggregating data for better analysis for GMDN Terms linked to individual devices. Collective Terms are designed to be globally relevant. There are currently over 2,500 Collective Terms.

Often users want to create bespoke sets of GMDN Terms for a specific purpose that may have a limited or local application. These 'Private Collections' would allow users to make their own groups of GMDN Terms, which would be hosted and maintained on the GMDN website and made available to users and their local networks. An example of its use would be if a health authority needed to quickly assemble a set of GMDN Terms needed to represent the devices used to treat a local health crisis.

LEGACY TRANSITION TOOLS

The use of the GMDN globally is the goal of the Agency. We are aware that certain users may have a legacy nomenclature or classification system that they are familiar with and find the idea of changing to use the GMDN system a challenge.

We would support users to transition away from their legacy nomenclature, by providing a service to help convert their existing data to use GMDN Terms.

This may be converting an existing regulatory classification system into GMDN or supporting a hospital to convert from a proprietary classification system for the equipment they use.

HARMONISATION SUPPORT FOR REGULATORS

The GMDN was always intended to support regulators in their progress towards greater global harmonisation, but we know resources may not always be available to help with the transition to adopt the GMDN from their legacy systems.

With the cooperation of interested regulators, we will create resources to support international cooperation and help with difficult to manage device concepts or when new technology emerges, such as AI. The use of the GMDN will provide regulators with support and collaborative tools to help identify and group technology. It may help to cooperate on the development or shared search and analysis tools, so that regulators can identify device specific problems on a common platform, for example to help them quickly understand growth in populations of devices used in their local area.

Post-market surveillance has always been challenged when faced with a low-frequency incident of a generic nature.

Future development of this programme could share real-world evidence of device efficacy, to support the evaluation of new technology and monitor long-term device safety to improve confidence and accelerate technology uptake.

STAKEHOLDER OUTREACH

The development of the nomenclature to date has primarily been in collaboration with device regulators and manufacturers, as we have implemented the procedures and systems to effectively identify all the medical devices on the global market today.

Going forward there is a greater realisation that other stakeholders will need to be more directly involved in our activities as the work we do starts to have a greater impact on them.

We will initiate a programme which identifies stakeholder groups that can help shape the way their interests are met by the GMDN. This outreach work will provide a useful resource to find new ways of using the GMDN to support device identification, such as with patient groups.

As our support structure develops, we hope this will in turn create new programmes of support for our members.

TERM ASSIGNMENT SUPPORT

The selection of a correct GMDN Term for any single product has always relied on the knowledge and skills of our manufacturer members, and this will remain so in the future. The GMDN Agency will remain available to support manufacturers when they cannot find a GMDN Term suitable with our free enquiry service. We also understand regulators may not always have the resources necessary in their own organisations to monitor GMDN assignment quality, to ensure mis-assignment does not occur and to maintain confidence in the GMDN.

The GMDN Agency will implement a plan of surveillance to identify errors in GMDN / product assignment and feed this information back to members. We hope members will respond positively to our advice and use this information to update the device information they provide to regulators and other stakeholders.

GMDN

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