The Global Language of Business

GS1 Healthcare strategy 2023-2027

Better patient outcomes start with accelerated standards adoption and digital transformation.

November 2022

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Audience

This document has been developed as a reference for all stakeholders interested in the work of the GS1 Healthcare community.

Executive Summary

GS1 Healthcare envisions a future in which the healthcare sector achieves the harmonised implementation of global standards in business and clinical processes, enabling interoperability, optimal quality and efficiency of healthcare delivery to benefit patients.

GS1 is a global organisation comprised of local Member Organisations (MOs) in 116 countries. It provides a system of standards that enable unique identification, automated data capture (scanning) and sharing of information relating to actors, items and locations throughout multiple sectors, including healthcare.

GS1 Healthcare is a global user group that leads the healthcare sector in the successful development and implementation of global standards. This voluntary group brings together experts from all healthcare stakeholders who are focused on increasing awareness of the benefits of standards throughout the healthcare industry, and for patients and caregivers alike.

GS1 Healthcare is working to help healthcare organisations enable and accelerate their digital transformation by providing them with a set of global standards that can be used in both supply chain and clinical settings.

This GS1 Healthcare Strategy has been developed against a backdrop of unprecedented challenge and changes in healthcare delivery.

The COVID-19 pandemic has driven healthcare stakeholders throughout the supply chain to enact their digital transformation and innovation at a hyper-accelerated rate. Digital and e-health trends have empowered patients by delivering remote healthcare access via web and telemedicine technology. Personalised treatments and medicines, home-based care and specialised medical devices have quickly been adopted by patients. Added to this are changing climate patterns and strained natural resources that have increased healthcare stakeholders' focus on sustainability.

This strategy has been developed to build on 18 years of global work in healthcare. When GS1 healthcare was formed, the strategy mainly focussed on improving global supply chain efficiency. In 2016 and continuing in the 2018-2022 strategy, we expanded our work to ensure the patient was at the core of our standards implementation and the engagement with healthcare providers was one of the priorities of our work at the local level. The 2023-2027 strategy considers the reality of today's healthcare sector, and of patient safety after an unprecedented global health crisis. It is organised around 7 areas of focus that aim to improve patient outcomes with accelerated standards adoption and better data, to support the digital transformation of healthcare.

This strategy is in line with the GS1 strategy which aims to bridge the physical and digital worlds. Our ultimate goal is to address the new challenges in this quickly changing world.

The GS1 Healthcare Strategy comprises 7 focus areas designed to support all healthcare stakeholders.

GS1 STANDARDS AS THE FOUNDATIONS	GS1 HEALTHCARE COMMUNITY	ADDRESSING NEW NEEDS
GS1 Healthcare will continue to focus on driving the development and deployment of GS1 standards to provide consistent and solid foundations to the Healthcare sector.	*The GS1 Healthcare community is unique as it brings together healthcare stakeholders from around the world, including regulators and government agencies, healthcare providers and local GS1 Member Organisations, to enable a globally consistent implementation of our standards. GS1 Healthcare will further strengthen that collaboration.*	*GS1 Healthcare will leverage the learnings from the pandemic and ensure that the current needs of the GS1 Healthcare community are effectively addressed to support the acceleration of digitalisation, the call for simple and clear access to product data, and the emergence of new types of treatments.*
STANDARDS DEPLOYMENT Champion and support the deployment of GS1 standards across healthcare for the identification and sharing of data related to products, locations, subjects of care and individual providers. This will help to improve patient safety by facilitating accurate and automated global and local traceability of medical products, while continuing to enable all actors in the healthcare supply chain to grow and improve efficiency and sustainability.	**INTEROPERABLE IMPLEMENTATION** Work with regulators and government agencies to raise awareness of the importance of local implementation of globally harmonised standards. **INTERNATIONAL STAKEHOLDERS** Collaborate with strategic international stakeholders to support and help drive adoption of GS1 standards. **SOLUTION PARTNERS** Partner with solution providers to guide the implementation of GS1 standards in their systems to allow automated data capture and data exchange in both supply chain and clinical systems.	**SINGLE BARCODE** Champion and support the drive to eliminate multiple barcodes on healthcare product packs at the point of care, and work with industry to move towards a single GS1 barcode. **PRIMARY PACKAGING IDENTIFICATION** Champion and support the implementation of GS1 identifiers on primary packaging to enable point of care scanning and improve patient safety and traceability. **EMERGING TECHNOLOGIES** Determine if and how GS1 standards would apply to emerging technologies and healthcare treatments, including personalised and precision medicine, gene therapy and complex cold chain products.

Stakeholders throughout the healthcare system, including the patient, will benefit from the delivery of the GS1 Healthcare Strategy.

Caregivers, suppliers, development and collaboration partners will be able to increase operational efficiency and reduce costs with simpler processes based on one set of standards, and automated data capture and master data that can be exchanged quickly and securely. They can improve inventory management with authentic products accessible at the right times, based on the traceability and visibility of product movements, and will more easily achieve sustainability goals by reducing waste and increasing transport optimisation.

Regulators can align with the global direction, when making decisions about local or regional identification and traceability requirements for increased supply chain and inventory visibility. The authenticity of products can be verified, preventing falsified products from being given to patients. Customs processes can be enhanced with automated product clearance systems. Faster recalls and accurate reporting of adverse events will help to add trust in healthcare systems and increase patient safety.

Patient safety will be enhanced with quality clinical data used by care providers to make more informed decisions, as accurate data is captured throughout the care process.

The ultimate beneficiaries of GS1 standards will continue to be patients who receive better outcomes, safer care and treatments by caregivers, wherever they happen to be.

The GS1 Healthcare Strategy benefits all

Manufacturers

- **Increase operational efficiency, reduce costs and be more competitive** with simpler processes based on one set of global standards that enable interoperability and can be relied on in processes such as customs clearance. Master data is more accurate, exchanged quickly, securely and efficiently.
- **Increase customer satisfaction** with accurate and on-time product deliveries.
- **Improve inventory management** supply authentic products at the right times with traceability and visibility of product movements.

Regulators and development partners

- **Drive policy decision making** and support innovation with the ability to use an existing coordinated approach to develop traceability and identification systems around the world.
- **Verify the authenticity of products, and enable traceability and visibility**, preventing falsified products from moving across the globe and being dispensed to patients.
- **Gain interoperability** with access to quality data for overall population health analysis and decision making. Information on products and their

Collaboration partners

- **Help increase operational efficiency, traceability and visibility** for their users since data can be exchanged quickly, securely and efficiently between systems. This can help achieve data portability between locations due to standardised formats.
- **Help to provide interoperability and big data visibility** by facilitating access to complete and accurate data for overall population health analysis and decision making.

Care providers

- **Increase patient safety** through accurate documentation and scanning of medications, implants and devices. Captured data can facilitate data-informed clinical decision making.
- **Increase operational efficiency, planning and interoperability** with process improvements via automation. Data can be exchanged quickly, securely and efficiently, and becomes a valuable tool for policy decision making.

Patients

- **Receive safer care** since global standards enable the delivery of authentic products with traceability and visibility of product movements
- **Benefit from better outcomes** since their caregivers have access to accurate medical product data to make the best decisions.

The GS1 Healthcare Strategy offers multiple benefits to stakeholders throughout the healthcare system that enable them to better care for patients, while keeping them safe. Simply put, unique identification, automated data capture (scanning) and sharing of information relating to actors, items and locations throughout healthcare benefits every stakeholder.

- **Achieve sustainability goals** by reducing waste and enabling transport optimisation due to increased visibility across the product life cycle for all actors and patients in the healthcare supply chain.
- **Increase patient safety** with faster recalls and accurate reporting of adverse events and product shortages.
- **Be more competitive by protecting technology investments and improving planning** with the ability to anticipate the need for coding and scanning equipment, and related IT systems as well as processes to meet global requirements.
- **Help drive innovations to market** by enabling clear and consistent coding requirements, accelerating product launches.

usage can also be leveraged for insurance, tender requirements and more.

- **Increase consumer and patient safety** with faster recall actions, and accurate reporting of adverse events and product shortages.
- **Enhance customs processes** with automated product clearance systems allowing products to flow more swiftly to those in need.
- **Increase operational efficiency** since master data can be exchanged quickly and securely, ensuring inventory management processes can be more precise*.
- **Achieve sustainability goals** with access to more information that is increasingly standardised and accurate*.

**Relevant to development partners*

- **Protect their technology investments and improve planning** by using global standards approach that is aligned with traceability and identification systems and requirements across borders.
- **Increase consumer and patient safety actions for their users** by facilitating faster recalls and accurate reporting of adverse events and product shortages. Patient safety is also improved since accurate data is captured at points of care.

- **Reduce manual data entry and facilitate technology** by barcode scanning which is more accurate and much faster.
- **Improve inventory management**, with traceability and visibility of product movements. Accurate data enables faster recalls and accurate reporting of adverse events and product shortages.
- **Achieve sustainability goals** by reducing waste with access to more online information and better management of expiry dates.

- **Be treated by caregivers in different locations** that have access to standardised patients' clinical records containing standardised identification of products, locations, patients and caregivers regardless of where care is delivered.
- **Always receive up to date information** due to modern technology and innovation allowing access to product safety data, alerts in case of recalls, and the ability to use applications to help adherence to treatments.

	Increase consumer and / or patient safety	Increase operational efficiency and reduce manual processes	Enable traceability and visibility and verify product authenticity	Achieve sustainability goals	Gain interoperability and big data visibility	Improve inventory management	Be more competitive, protect technology and improving planning
Manufacturers	X	X	X	X	X	X	X
Regulators & Develpoment Partners	X	X	X	X	X	X	
Collaboration Partners	X	X	X		X		X
Care Providers	X	X	X	X	X	X	X
Patient							

Help drive innovation to market	Drive public policy decision making	Enhance customs processes	Receive safer care	Be treated by caregivers in different locations	Benefit from better outcomes	Increase customer satisfaction	Always receive up to date information
X		X				X	
X	X	X					
X							
	X						
			X	X	X		X

Introducing GS1

GS1 believes in the power of standards to transform the way we work and live.

GS1 is the not-for-profit and global standards development organisation that provides a system of unique numbers, data carriers (e.g., barcodes) and information sharing standards relevant to products, relationships, assets, locations, services, and processes.

GS1 standards enable identification, information capture and sharing throughout key sectors including healthcare, CPG, retail, apparel, transport and logistics, fresh foods and technical industries. (See Figure below.)

GS1 is a global organisation, comprised of local Member Organisations (MOs) in 116 countries. More than 2 million companies use GS1 standards across 150 countries. More than 100 million products carry barcodes with more than 6 billion barcodes scanned each day.

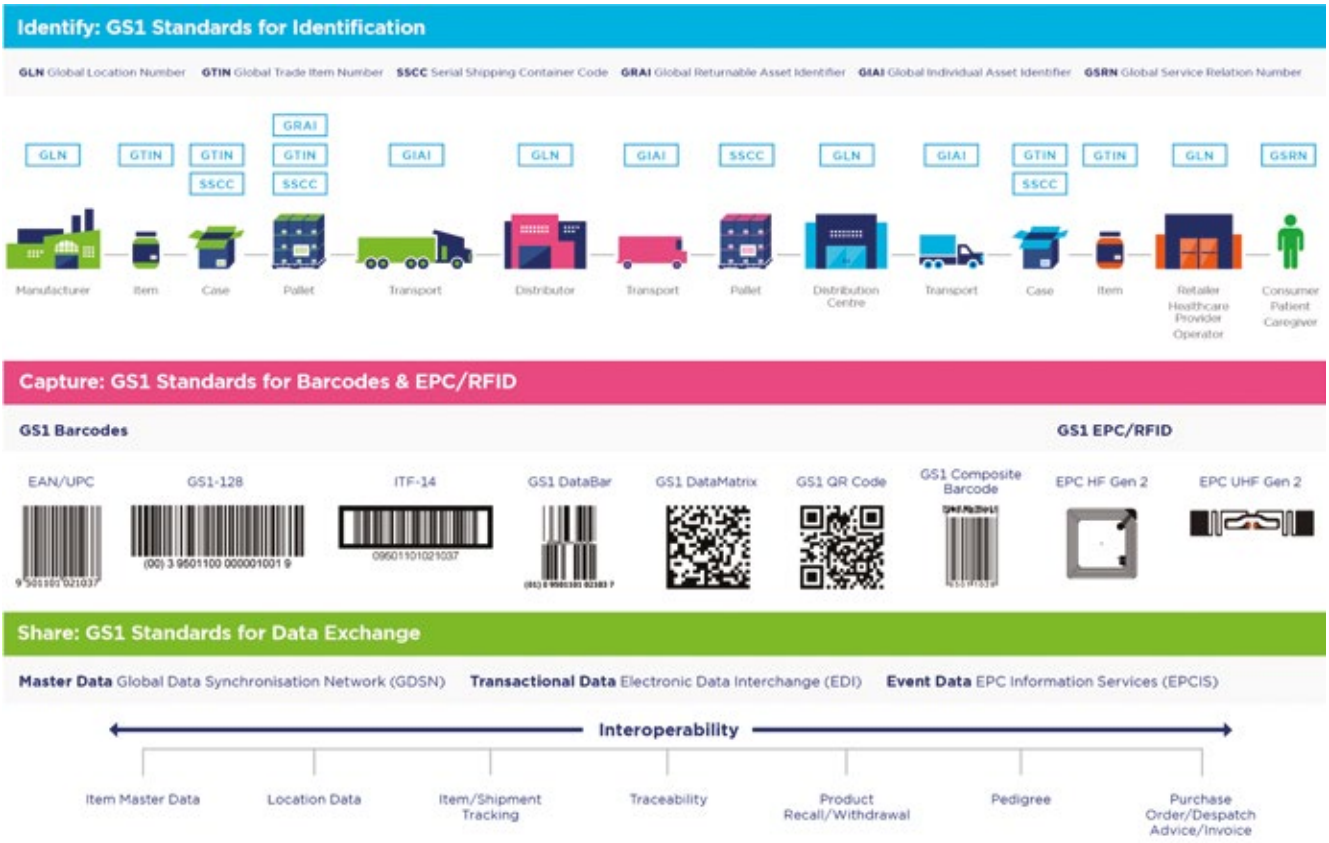
GS1 standards help companies and organisations improve the efficiency, safety and visibility across their physical and digital channels. They enable interoperability between stakeholder systems, support local regulatory compliance, and ultimately facilitate digitisation.

Inclusive & collaborative

Global & local

Neutral & not-for-profit

User-driven & governed



About GS1 Healthcare

GS1 Healthcare imagines a world where global standards enable optimal healthcare delivery to benefit patients.

GS1 Healthcare is a global user group that leads the healthcare sector in the successful global standards development and facilitates implementation of these global standards in the healthcare sector. This voluntary group brings together experts from all healthcare stakeholders who are focused on increasing awareness about the benefits of standards throughout the healthcare industry, and for patients and caregivers alike.

GS1 Healthcare is focused on multiple areas of standards development and adoption, including:

- Working to increase awareness in the healthcare sector around the role that GS1 standards play in creating a trusted and efficient healthcare supply chain.
- Communicating about how standards help patients access safer care and how they provide caregivers a mechanism to access data-driven decision support when working in high-pressure healthcare environments.
- Sharing information about how GS1 can play a role in the acceleration of healthcare's digital transformation. For example, during the pandemic, healthcare providers realised that their use of GS1 standards boosted the resilience of their operations.

Vision

GS1 Healthcare envisions a future in which the healthcare sector achieves harmonised implementation of global standards in business and clinical processes enabling interoperability, optimal quality and efficiency of healthcare delivery to benefit patients.

Mission

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards enhancing patient safety, operational and supply chain efficiencies.

Interested in learning more?

Visit www.gs1.org/healthcare and follow us on LinkedIn and Twitter @GS1Healthcare.

Healthcare trends, challenges and opportunities

This GS1 Healthcare strategy has been developed against a backdrop of unprecedented change in healthcare delivery. The COVID-19 pandemic has driven healthcare stakeholders throughout the supply chain to accelerate their digital transformation and innovation at a rate that was inconceivable only five years ago.

The world has seen that the last three years have stretched healthcare systems to their limits, accelerating the drive towards innovation, agility and adaptability. At the same time, the expectation of equal access to levels of care and medical products has increasingly become a focus, with discussions about COVID treatment and vaccine distribution.

Digital and e-health trends have spurred empowered patients by delivering remote healthcare access via web and telemedicine technology. Patients today expect more when it comes to personalised healthcare—personalised treatments and medicines, home-based care, specialised medical devices and other creative, customised approaches to healthcare delivery.

Changing climate patterns and an ever-evolving strain on natural resources are creating heightened awareness and focus on sustainability—from sustainable packaging to maximising resources and minimising waste.

Over the next 5 years, GS1 Healthcare will work to ensure the use of, and support for, GS1 standards is included in this rapidly changing world.

Digital health

Digital health is the top emerging topic for healthcare in the next five years, based on interviews and survey responses for this strategy. It also shows up strongly in industry publications and studies as a market trend to address—sooner rather than later. Major drivers include the continuous infusion of technology in healthcare and patient environments, along with the need to expand and creatively deliver "health care" spurred by the pandemic. According to the *HIMSS Future of Healthcare Report*[1], 80% of healthcare providers plan to increase investment in technology and digital solutions over the next five years. As part of this activity, there is a strong focus on enabling interoperability between systems and portability of data to ensure comprehensive patient information is available to the caregivers that require it. Another motivation is to increase visibility of all kinds of medical inventory throughout supply chains and healthcare facilities. In this space, accurate identification, data capture and information sharing for products, locations, subjects of care and individual providers, based on global standards, remains an important foundation.

Virtual healthcare and telehealth[2,3]

The pandemic has driven an increasing reliance by both patients and healthcare providers on the want to receive healthcare remotely – by video call or by telephone. We see wide ranging examples of innovation in this space and know that identification of products, locations and subjects of care is key in applications such as remote patient monitoring, virtual hospital wards, and the move to ePharmacies.

In-home care

In-home care is another area where global standards for identification and data sharing are necessary. Consumers are turning to self-care measures with the continued growth in nutritional sub-segments such as vitamins and dietary supplements, and increased acceptance of at-home diagnostics and tests[4]. At the same time, elderly people wish to stay in their homes rather than transitioning to care facilities. More seniors and their families are looking for higher acuity care in the home setting.[5,6]

1 HIMSS. Future of Healthcare Report: Exploring Healthcare Stakeholders' Expectations for the Next Chapter. https://www.himss.org/resources/future-healthcare-report-exploring-healthcare-stakeholders-expectations-next-chapter. August 11, 2021.
2 Forbes. The Five Biggest Healthcare Tech Trends In 2022. https://www.forbes.com/sites/bernardmarr/2022/01/10/the-five-biggest-healthcare-tech-trends-in-2022/?sh=686f465b54d0
3 Aratrika Dutta. Analytics Insight. Internet of Medical Things: Top IoMT Trends to Watch Out For in 2021. August 21, 2021. https://www.analyticsinsight.net/internet-of-medical-things-top-iomt-trends-to-watch-out-for-in-2021/#:~:text=The%20most%20common%20application%20of,to%20physically%20visit%20the%20hospital
4 Rivilin, Adrienne. Parkin, Geoff. LEK. Consumer Healthcare and Coronavirus: Three Trends That Will Continue to Drive Long-term Industry Growth. https://www.lek.com/insights/ei/consumer-healthcare-and-coronavirus-three-trends-will-continue-drive-long-term-industry, February 16, 2021.
5 Hammons, Cheryl CFE, CSA. Veterans Care. The SNF at Home Model and Home Care. https://www.vcchc.com/the-snf-at-home-model-and-home-care. March 10, 2021.
6 SYNZI. How the SNF-at-Home Model balances High-Touch and High-Tech. https://synzi.com/blog/how-the-snf-at-home-model-balances-high-touch-and-high-tech. December 2020.

Increasingly, GS1 is seeing the trend towards direct to patient delivery and clinical trials with in-home patients. This means the patient is able to participate in important trials, without the investment needed to travel to a caregiver location, such as a hospital.

Technology

Healthcare providers are increasingly investing in advanced IT systems as a solution to many major challenges in service delivery, including record management, remote care and reaching low-income patients. Successful implementations will require clear subject of care, individual provider, location and product identification. Providers worldwide are using such systems to manage electronic medical records efficiently and make real-time data available to healthcare professionals. Pharmaceutical manufacturers are making drugs that can be self-administered by the user—and that do not require a healthcare professional. This calls for the need for industry to provide simple access to online resources for the patient, including authentication, clear instructions, allergen alerts and more.

Innovative healthcare treatments

Technologies also play a major role in personalised healthcare, including genomic profiling, precision health and personalised drug therapies. Consider advances in gene therapy and the resulting need to accurately identify and capture data during every step, from collection of samples to the identification of the drug returned. The same applies for all categories of personalised healthcare. We also see opportunities for 3D printing of specialised medical devices which reflects patients' needs for customised products.

Cross-border care

The situation in Ukraine has caused many families to relocate to countries where they don't speak the local language. These refugees are provided with medicines donated from across the world with packaging and labelling in a language other than their own. There is currently an industry project leveraging GS1 standards, to allow access to the electronic product information leaflet (ePIL) in the Ukrainian language to prevent medicines misidentification and misuse due to language barriers.[7]

The increase of cross-border services such as ePrescription continues and more recently includes projects to address medico- or pharmaco-economic shortages. These services and projects require solutions to compare medical products, to enable replacements or substitutions. In the space of medicinal products, the set of Identification of Medicinal Product (IDMP) standards is gaining implementation progress. IDMP recognises the need to link the supply chain with clinical and regulatory information.

Increasing demand is also being seen in cross-border care - to access timely surgical procedures and/or diagnostics due to increasing waiting lists as a result of the pandemic. Not only people but their biological samples are also being sent across borders, requiring unique identification for the assurance of accurate results being provided to the correct patient.

This calls for healthcare policies and systems to be interconnected for accessible and accurate patient records, an area where global standards for product, location and subject of care identification could play an important role.

Sustainability

Maximising resources and minimising waste entails initiatives like using green packaging, e-leaflets, and renewable energy in manufacturing as well as efficient

7 https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/pharmaceutical-industry-launches-patient-information-initiative-for-displaced-ukrainians/

logistics – both forward and in reverse. Lack of traceability and visibility leads to unnecessary waste through expiry and loss of goods. This waste must be disposed of, as inefficient methods in the treatment of pharmaceutical waste and a lack of reverse logistics processes has led to unauthorised disposal and crucial environmental problems, including water pollution, soil contamination, and the production of toxic and non-toxic wastes. Therefore, traceability, visibility and forming a proper reverse logistics network, based on global standards, is essential for pharmaceutical supply chains.[8]

The use of electronic leaflets or e-leaflets enables manufacturers to keep frequently revised information about products up to date for improved patient safety —especially critical for high-risk drugs and medical devices. With the huge quantities of paper used in printed leaflets comes other waste. Consider that millions of dollars worth of medicines are discarded annually due to printed leaflet issues, either because they need to be updated or because there are errors in them [9]. The use of e-leaflets brings with it the need to provide user's a simple way to access the latest information online. Leveraging the product barcode is the key.

Conclusion

GS1 can (and will) play a role in these trends, through provision of unique identifiers, barcodes, and data sharing standards. We will prioritise our activities through the strategy development process and ensuing work. Yet, our challenge is to remain relevant in a changing world. Therefore, our strategy needs to be adaptable and flexible, as the rate of development and change over the past two years is expected to continue.

Through our efforts, the healthcare sector will have the opportunity to leverage GS1 standards in innovative ways, that have not been imagined before. the outcome will be what GS1 standards deliver – accuracy, visibility, trust in the supply chain, and increased patient safety.

One thing will not change. All of the innovations that result from these trends and challenges need to be supported by a strong, reliable, accurate and transparent supply chain right to the point of care. Patients are treated with products and by caregivers—many times across multiple locations—and information about all of these need to be identified, captured, stored and transmitted accurately and securely. The standards by which to do this are the role of GS1.

8 Sazvar, Z., Zokaee, M., Tavakkoli-Moghaddam, R., Al-sadat, S., Nayeri, S. Designing a sustainable closed-loop pharmaceutical supply chain in a competitive market considering demand uncertainty, manufacturer's brand and waste management. Annals of Operations Research. https://doi.org/10.1007/s10479-021-03961-0, February 8, 2021.
9 Stone, Andrew. Reuters Events. Making medicines sustainable. https://www.reutersevents.com/pharma/multichannel/making-medicines-sustainable. https://www.reutersevents.com/pharma/multichannel/making-medicines-sustainable. November 30, 2021.

GS1 Healthcare Strategy 2023–2027

Our GS1 Healthcare strategy consists of 7 areas of focus with 13 different workstreams based on guiding principles and tactical plans to help drive success. Some areas of focus are extensions of our current work and others are new initiatives foreseen to further increase uptake of GS1 standards.

This strategy has been developed to build on 18 years of global work in healthcare, and is in line with the GS1 strategy which aims to bridge the physical and digital worlds.

GS1 standards are already used in healthcare in more than 75 countries across all regions of the world, to meet regulations, government requirements or trading partner requirements. Use of the standards throughout global and local supply chains is extensive, and increasingly this is also occurring to the point of care with applications such as bedside scanning or scanning in the operating theatre. Whilst depth of standards implementation in these areas remains a focus for growth, breadth of implementation, for example, through increased applications for recall and post-market surveillance, or in the clinical trial supply chain, is key.

Collaboration remains a foundation for GS1. With development partners, this has enabled increased uptake of GS1 standards in emerging markets. With professional organisations, this has started to create awareness of clinicians and other specialised healthcare resources about the importance of global standards to their daily work. And with health IT organisations, this has started work to drive systems interoperability across healthcare. Each of these areas of collaboration exists today, and will remain to the end of this strategy and beyond.

Via existing initiatives, working with supply chain solution providers is a focus for GS1 Healthcare, and where we see strong support for the standards. Pairing this with a newer initiative to work with clinical systems providers, and work with supply chain solution providers in other areas of healthcare, such as clinical trials, will enhance the capability of all organisations to implement our standards.

Forward focussed activities relating to eliminating multiple barcodes on a healthcare product pack at the point of care, identification of the primary packaging to allow broader implementation of point of care scanning, and an overall programme to identify technology and developments in which GS1 standards can play a role, will set the groundwork for the future.

The framework

Each of the 7 areas of focus and their resulting 13 workstreams has a detailed plan of activity, with allocated resources confirmed. Overall assessment and task reallocation has been undertaken so that appropriate resourcing is available to ensure plans for each of these areas of focus are delivered, whilst at the same time the operational work of GS1 Healthcare continues.

Three focus areas are identified as "speed to lead" areas of focus, meaning these are crucial topics where GS1 standards should be deployed immediately.

7 areas of focus

STANDARDS DEPLOYMENT

Champion and support the deployment of GS1 standards across healthcare for the identification and sharing of data related to products, locations, subjects of care and individual providers. This will help to improve patient safety by facilitating accurate and automated global and local traceability of medical products, while continuing to enable all actors in the healthcare supply chain to grow and improve efficiency and sustainability.

What we will achieve

We will continue to collaborate with GS1 Member Organisations (MOs), or relevant stakeholders in countries without MOs, to roll out GS1 standards in established and emerging national and regional healthcare markets.

This work will be organised based on four major workstreams:

- From production to supply chain
- To point of care
- Product availability, recall and post-market surveillance
- Clinical trials

What success looks like

From production to supply chain

A. Stakeholders will endorse each task area from production and supply chain.

B. GS1 identifiers will be used in business and hospital processes, orders, invoices and more, on both sides of the trading relationship.

C. Necessary GS1 standards such as the Global Data Synchronisation Network (GDSN) for master data, EPCIS for traceability event data, EDI / electronic messaging standards and others will be evaluated and integrated as needed into shared business processes between manufacturers, distributors, and hospitals. Globally integrated implementation of GS1 standards for data sharing remains GS1's aspirational goal. In practice, data management systems for traceability are based on differing regional or national regulatory requirements. As a result, GS1 Healthcare's focus is to ensure that the GS1 standards for data sharing are used to support implementation of these regional/national requirements and to enable interoperability across these regional/national systems.

D. Pandemic learnings, supply chain shortages, lack of inventory visibility, and the ability to respond quickly and efficiently, will be leveraged to drive implementation and prevent or mitigate similar situations in the future.

At point of care

A. Healthcare providers will adopt GS1 standards within clinical processes and scanning at point of care to realise improved patient outcomes.

B. Healthcare providers will realise the benefits of point of care scanning to capture and store data to drive clinical decisions.

C. Manufacturers will generate real world evidence for product performance.

D. Patients and consumers will benefit from improved accuracy of clinical records and the potential for traceability, reduction in medication errors and reduction in potential for harm.

E. Healthcare systems will be enabled to eliminate errors and waste from the wrong product and/or medication being administered.

Product availability, recall and post-market surveillance

A. Product availability, recall and post-market surveillance will be improved, and greater efficiencies realised with the implementation of GS1 standards in partnering with the appropriate industry associations.

B. Pandemic learnings will be implemented to alleviate supply chain shortages, lack of inventory visibility and provide stakeholders the ability to respond quickly and efficiently.

Clinical trials

A. Stakeholders will be made aware of the efficiencies gained by the use of GS1 standards in clinical trials.

B. Sponsors will continue to implement the standards, and adoption by trial sites will be underway.

C. Case studies will illustrate the benefits of GS1 standards in providing consistent identification and data that is understood by all stakeholders.

INTEROPERABLE IMPLEMENTATION

Work with regulators and government agencies to raise awareness of the importance of local implementation of globally harmonised standards.

What we will achieve

- We will continue our work to inform about the benefits of global standards.
- By the end of 2023, we will develop tools for the use of GS1 MOs and others to provide one clear message about the benefits of GS1 standards for global implementation alignment.
- We will develop a matrix to demonstrate where the GS1 standards impact healthcare and their benefits worldwide.

What success looks like

- Regulators and government agencies will understand the value of GS1 standards in supporting globally interoperable implementation.
- MO colleagues will be able to translate the needs of the healthcare community into regulators' needs and vice-versa.
- Trust will be built on GS1 being a neutral, not-for-profit organisation, especially in emerging markets.

INTERNATIONAL STAKEHOLDERS

Collaborate with strategic international stakeholders to support and help drive adoption of GS1 standards.

What we will achieve

- Together with GS1 MOs, we will continue to engage:
  - international intergovernmental organisations,
  - professional healthcare organisations,
  - IT standards development organisations.

What success looks like

- International intergovernmental organisations will understand GS1 and will support the deployment of GS1 standards worldwide.
- Professional healthcare associations will advocate for the benefits of standardisation in the healthcare IT environment for improving patient outcomes.
- A framework of cooperation will be created with healthcare associations to promote GS1 standards implementation for improving patient safety and traceability.
- Healthcare providers will advocate for how standardisation improves accurate data capture and ultimately patient outcomes.
- IT standards development organisations will improve the integration of GS1 identifiers in healthcare IT standards, including primary packaging identification.
- IT standards development organisations will deliver education about GS1 and healthcare IT standards.

SOLUTION PARTNERS

Partner with solution providers to guide the implementation of GS1 standards in their systems to allow automated data capture and data exchange in both supply chain and clinical systems.

What we will achieve

Work with end users to define the criteria that solution providers should meet to deploy GS1 standards

We will continue to work with **supply chain solution providers**, specifically to:

A. Develop specific use cases—Electronic Product Information Leaflets (ePil) and Inventory Management Systems—with solution providers that illustrate how use of GS1 standards can accelerate improvements.

B. Identify and bring current global member solution providers along the customer journey, including showcasing best practices for the implementation of traceability.

C. Work with GS1 Member Organisations, as needed, to ensure they are able to engage and educate their solution provider communities.

Our work with **clinical solution providers** will enable electronic patient and health-record solution providers to adopt GS1 standards to drive implementation regionally and globally, leveraging newly released GS1 standards developed via the Global Standards Management Process (GSMP).

What success looks like

Supply chain solution providers

A. Increased engagement between solution providers and GS1 Member Organisations to ensure that interoperable solutions are developed and used locally, in particular, in emerging markets.

B. Supply chain solution providers will become one of the first ambassadors of GS1 standards, advocating for the need for one single barcode and supporting the integration of GS1 keys and AI in solution provider applications.

Clinical solution providers

A. Clinical system solution providers in regions and countries will adopt GS1 standards to drive implementation locally and globally.

B. Healthcare providers will be able to more quickly and cost effectively implement point of care scanning to realise patient safety benefits and deliver sustainable patient outcomes.

C. Manufacturers will benefit from products being scanned at point of care with the future potential to demonstrate value-based healthcare based on products used and patient outcomes achieved.

D. Health authorities will have the potential to capture surveillance data and identify concerning trends sooner.

E. Healthcare systems will have the capability to access real-time data of healthcare delivery to map trends for financing, operational efficiency, and patient outcomes.

SINGLE BARCODE

Champion and support the drive to eliminate multiple barcodes on a healthcare product pack at the point of care, and work with industry to move towards a single GS1 barcode.

What we will achieve

- We will work to eliminate multiple barcodes at point of care.

What success looks like

- Clear communication about the benefits of having only one GS1 barcode on pharmaceutical and medical device products at points of care - enabling patient safety and seamless, efficient care.
- Recognition that the GS1 barcode used will have to comply with relevant national or regional regulatory requirements which could mandate the use of a specific type of barcode symbol e.g., DataMatrix.
- Awareness that different types of GS1 barcodes may successfully function as the one barcode on medical products, depending on the region/ country, on the scanning environment and on the packaging level.
- Awareness of industry will be increased through communications and educational activities undertaken in partnership with GS1 Member Organisations.
- The required tools will be developed to drive and measure industry migration to a single GS1 barcode.
- We will build on the GS1 global work to transition other industries 2D barcodes and aim to align the healthcare sector.

PRIMARY PACKAGING IDENTIFICATION

Champion and support the implementation of GS1 identifiers on primary packaging to enable point of care scanning and improve patient safety and traceability.

What we will achieve

- By working with industry, and other relevant stakeholders, we will drive consensus for how to implement primary identification and develop a roadmap for implementation by 2027.

What success looks like

- We will increase the primary packaging identification of medicines and medical devices using GS1 standards that are scanned at the bedside and points of care.
- Awareness of industry will be increased through communications and educational activities undertaken in partnership with GS1 Member Organisations.

EMERGING TECHNOLOGIES

Determine if and how GS1 standards would apply to emerging technologies and healthcare treatments, including personalised and precision medicine, gene therapy and complex cold chain products.

What we will achieve

- Develop a horizon scanning process to identify areas in which GS1 should focus, taking into account the input of industry and GS1 Member Organisations.
- Create a roadmap for work in the selected areas to ensure necessary standards are available or developed.

What success looks like

- There will be a methodical six-month review to identify new and emerging technologies where GS1 should focus. New topics will be identified and prioritised with GS1 Healthcare users and GS1 MOs. They will be part of the GS1 Healthcare annual workplan, along with roll out and communication about GS1 standards in that area.
- The goal is that GS1 will have a standard or solution to provide to the topic within 12 months from work commencing.

Appendices

Appendix 1: GS1 Healthcare operating environment

Governance

GS1 Healthcare is governed as part of GS1, an international not-for-profit standards organisation, and reports to the GS1 Management Board. The full governance of GS1 Healthcare is explained in detail in its charter, available at www.gs1.org/healthcare/about.

Stakeholders

As described in Section 5 of the *GS1 Healthcare Governance Charter*, below are the stakeholders associated with GS1 Healthcare:

- **Global voting members** including stakeholders operating in the healthcare supply chain, such as suppliers, wholesalers, distributors, logistics service providers, hospitals, pharmacies and solution providers.
- **Global non-voting members** including trade associations, regulatory bodies and other governmental healthcare authorities, and educational institutions, as well as other standards organisations.
- **GS1 Member Organisations** are critical stakeholders of GS1 Healthcare since they provide the communication, support, and services necessary to ensure GS1 standards are positioned as relevant and valuable to their members (including small to medium enterprises) and local markets.

Leadership

The GS1 Healthcare Leadership Team (HCLT) is elected annually and is comprised of global members representing healthcare manufacturers, healthcare providers, solution providers, wholesalers/distributors, GS1 Member Organisations and special appointments, such as advisors that contribute important direction to leadership discussions.

Alignment with GS1's organisational goals

The GS1 Healthcare Strategy has been developed to build on 18 years of global work in healthcare, and is in line with the GS1 strategy which aims to bridge the physical and digital worlds.

It is also aligned with the GS1 Global Office three-year plan, so that our work fits with overall organisational goals, and that the organisation is aware of our activities to ensure appropriate support from other departments within GS1.

Annual planning and reporting

Each January, the GS1 Healthcare team prepares a set of strategic priorities detailing our more tactical work plan for the coming calendar year. This is approved by the GS1 Healthcare Leadership Team. These strategic priorities are driven by our strategy and the GS1 Healthcare operational needs (i.e., continuing to run GS1 Healthcare). A six-month report provides the GS1 HCLT with visibility of the status and progress of the workstreams in the June/July timeframe and an end-of-year report is delivered to the HCLT in December.

In addition, we communicate our progress to all GS1 Healthcare global members and GS1 Member Organisations through the GS1 Healthcare annual newsletter sent in January/February each year. This outlines achievements over the past calendar year and gives a view of the upcoming year's plans and priorities.

Appendix 2: Strategy development process

The strategy development process consisted of four major phases, with contributors working together each step of the way. The goal was to confirm the ongoing priorities established within the current 2018-2022 strategy and to explore new and emerging areas of focus.

A key objective was to prioritise those areas of focus that would impact the healthcare sector and fit within the scope of GS1 Healthcare. In doing this, strong focus was placed on where GS1 Healthcare would be uniquely capable of delivering solutions to meet pressing stakeholder needs, and to where activities would strengthen and expand core operations. At the same time the goals of the strategy needed to be sufficiently aspirational. It was essential to outline the scope, tasks, timelines, and execution plans to ensure transparency and sustained implementation.

GS1 Healthcare engaged an external consulting organisation to help us deliver the foundational strategy development programme over a 14-week period. The process was designed to be highly inclusive, ensuring that representatives from all healthcare stakeholder environments, and from within GS1, were able to share input.

Step 1: Setup

During this phase, work teams (called Core and Challenger Teams, see Core and Challenger Team contributors on page 27.) were established with timelines for the work ahead. The strategy development process was initiated with a kick-off meeting to launch the effort.

Step 2: Assessment

Online surveys and more than 50 video interviews were used to collect a comprehensive list of potential areas of focus from nearly 100 contributors from all regions of the world and representing all stakeholder functions and industries. (See contributors on page 28.)

Step 3: Design

The work teams prioritised and rationalised the list into a final set of areas of focus for detailed planning. Workshops, alternating between the Core Team and Challenger Teams, were conducted at every step to ensure comprehensive input and promote alignment across diverse perspectives.

Step 4: Report

Seven areas of focus were defined with 13 tactical workstreams. Opportunity charters that outlined objectives, scope, tasks, timelines, and execution plans were drafted, then refined to take into account inter-dependencies and resourcing capabilities. These were reviewed and approved by members of HCLT. Detailed working level plans have been created and will be updated annually, in line with the GS1 Healthcare annual planning processes.

CONTRIBUTORS

Thank you to the many industry stakeholders, the GS1 Healthcare Leadership Teams from 2021/22 and 2022/23 as well as the GS1 Member Organisation colleagues who contributed their expertise, insights, and knowledge to the development of the GS1 Healthcare Strategy. Thank you to OXYGY, the external consulting organisation who assisted us in this work.

Core strategy development team

- AbbVie
- ACT Health
- Bayer
- GS1 Australia
- GS1 UK
- Johnson & Johnson
- McKesson Corporation
- St. James's Hospital

Challenger strategy development team

- Abbott
- AmerisourceBergen
- Atrify
- Becton Dickinson
- Cook Medical
- DHL
- Dijklander Ziekenhuis
- F. Hoffmann-La Roche
- GHX
- GS1 Brazil
- GS1 Canada
- GS1 Germany
- GS1 Jordan
- GS1 Netherlands
- GS1 US
- International Hospital Federation
- Medtronic
- Pfizer
- Smith & Nephew
- WeDigit Consulting

Interviews

More than 50 contributors were interviewed from the following companies, organisations and MOs:

- Australian Capital Territory Health
- Alfred Health
- Association of Healthcare Providers (AHPI)
- Aventech Biobank
- B. Braun Gruppe
- Bayer
- Berlin Institute of Health at Charité Hospital
- Canberra Health Services
- Dedalus Group
- European Association of Hospital Pharmacists (EAHP)
- ecGroup Inc.
- First Affiliated Hospital of Zhengzhou University
- GIRP - European Healthcare Distribution Association
- GS1 Denmark
- GS1 Hong Kong
- GS1 Indonesia
- GS1 Ireland
- GS1 Japan
- GS1 Kenya
- GS1 Netherlands
- GS1 Singapore
- GS1 South Africa
- Guy's and St Thomas' NHS Foundation Trust
- Healthcare Leadership Team Group
- Healthscope
- HealthShare NSW
- Healthcare Information and Management Systems Society (HIMSS)
- Hospital Barmherzige Brüder,
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- International Hospital Federation (IHF)
- International Society for Quality in Health Care (ISQua)
- Johnson & Johnson
- Latin American GS1 Member Organisations Group
- Manchester University NHS Foundation Trust
- Medtronic
- Victorian Ministry of Health
- National Health Service (NHS), UK
- New South Wales Ministry of Health (NSW Health)
- Pfizer
- Royal College of Physicians and Surgeons of Canada
- Royal Papworth Hospital NHS Foundation Trust
- Saludax
- SNOMED International
- The Royal Women's Hospital, Australia
- United States Agency of International Development (USAID)
- USDM Life Sciences
- UZ Leuven
- WeDigit
- World Bank

Surveys

Contributors from the following companies, organisations and Member Organisations provided input via surveys.

- Abbott
- AbbVie
- Atrify
- Bayer AG
- Cook Medical
- DHL
- GS1 Algeria
- GS1 Australia
- GS1 Bulgaria
- GS1 Canada
- GS1 Chile
- GS1 China
- GS1 Denmark
- GS1 Germany GmbH
- GS1 Ghana
- GS1 Global Office
- GS1 Healthcare Global Office
- GS1 Indonesia
- GS1 Ireland
- GS1 Italy
- GS1 Japan
- GS1 Jordan
- GS1 Kenya
- GS1 Malaysia Berhad
- GS1 Malta
- GS1 Netherlands
- GS1 Pakistan
- GS1 Portugal
- Gs1 Saudi Arabia
- GS1 Singapore
- GS1 Slovenia
- GS1 South Africa
- GS1 Tunisia
- GS1 Turkey
- GS1 UK
- GS1 Vietnam
- Hoffmann-La Roche
- Johnson & Johnson
- McKesson
- Medtronic
- Smith and Nephew, Inc.
- St. James's Hospital
- USDM Life Sciences
- WeDigit Consulting

Appendix 3: Strategy tactics and timelines

The overall strategy work effort is highlighted below. In the first years of implementation, the resources allocated to the strategy focus on the "speed to lead" topics and those areas that are seen as immediately critical to the success of GS1 Healthcare. As mentioned previously, activities have been planned to ensure timing is appropriate with industry needs, GS1 Healthcare resourcing capabilities, and also to allow for leveraging work from each of these areas of focus, which are interdependent in many cases. The GS1 Healthcare Team ran a resource assessment exercise to ensure the balance between resources allocated to the implementation of the strategy and those working on business operational activities was appropriate. It should be noted that this assessment was based on the resources available at the time of strategy development and may require reassessment in the future.

	2023	2024	2025	2026	2027
Deploy GS1 standards					
Production to supply chain	●	●	●	◕	◕
To point of care	●	●	●	◕	◕
Product availability, recall and post market surveillance	●	●	●	●	◑
Clinical trials	●	●	◕	◕	◕
Solution partners					
Supply Chain	◕	●	●	◕	◕
Clinical Systems 🚀	●	●	◕	◕	●
Emerging technologies 🚀	●	◕	◕	◕	◕
Single barcode 🚀	●	◕	◕	◕	◕
Primary packaging	●	◕	◕	◕	◕
International stakeholders					
International governmental organisations	●	●	◕	◑	◑
Professional healthcare organisations	◕	●	◑	◑	●
IT standards development organisations	◕	●	◕	◑	◑
Interoperable implementation	●	◑	◕	◑	◑

Key

● **Low intensity of work effort**

● **High intensity of work effort**

🚀 **Speed to lead**

Appendix 4: GS1 Healthcare 2018-2022

As we look forward to our 2023-2027 GS1 Healthcare strategy, it is important to also reflect on what has been achieved during the previous 5 years. As a community, GS1 Healthcare has worked intensively to successfully drive standards uptake whilst focussing on the patient and healthcare providers. At the same time, we have kept a keen eye on new technologies and how these may be leveraged as part of our work. Below are just some of the major milestones specifically related to the elements from the 2018-2022 strategy.

In addition, we continue to strive to increase engagement and awareness of GS1 standards through initiatives such as:

- The **GS1 Board Committee for Healthcare (BCHC)**, established as a specialist governance committee of the GS1 Management Board to create increased awareness of the work of GS1 Healthcare in C-suites of key organisations.
- Our **Clinical Transformation Committee (formerly Clinical Advisory Committee)**, a group of thought leaders and early adopters of GS1 standards in healthcare – all representatives are from the clinical or standards implementation environment.
- Our annual **GS1 Healthcare Reference Book** which continues to be published, with the objective to bring together case studies of GS1 standards' implementations.
- GS1 Healthcare events – during 2018-2022 GS1 Healthcare held **four global conferences, two African regional conferences, three online summits, 3 Executive Dialogues, and one hybrid conference**. Through these events, more than 3000 people increased their awareness of GS1 standards in healthcare.

Successfully drive the current business

Operationalise implementation of identification and barcoding standards

MILESTONE	OUTCOME
A full revision of the Healthcare GTIN Allocation Rules was completed.	This document provides improved clarity about product identification for all healthcare stakeholders.
The GS1 Application Standard for Identification of Investigational Products in Clinical Trials was developed.	The clinical trials sector now has a concise standard detailing how to identify and barcode investigational products and kits.
The Healthcare Global Location Number Implementation Guide was updated.	This enhanced document includes implementation success stories from across the healthcare sector, shares details regarding application of Global Location numbers in the clinical trials environment, and a 10-step implementation checklist.
Updates were made to the GS1 2D Matrix Data Carriers in Healthcare paper.	There is clear guidance for the healthcare sector regarding use of 2D symbologies on medical product packaging.
Three new versions of the Healthcare Barcode Scanner App were released.	This tool helps users check the encoding of GS1 barcodes, facilitates surveys for the presence of GS1 barcodes on products, and demonstrates how a GS1 barcode can be used to access online information.

Trusted, complete quality master data / improve awareness of the role of quality master data

MILESTONE	OUTCOME
Completed a pilot to demonstrate how the GS1 Master Data Services programme.	The pilot demonstrated how improving data quality at source can help improve overall data quality across the supply chain.
A listing of Global Data Synchronisation Network™ (GDSN®) implementation support across the world in healthcare was created.	Users can now access a comprehensive support listing to help them move forward with GDSN.
The Pharmaceutical Serialisation and Traceability Use Case was published.	This is designed to help accelerate the sharing of trusted pharmaceutical product master data by providing a simple set of data and use case examples.
A Healthcare GDSN 'Deep Dive' initiative was conducted.	Designed to understand in detail how GS1 and GDSN data pools can further support healthcare in sharing quality data. Actions relating to this work will commence in 2023.

Exchange of information between trading partners

MILESTONE	OUTCOME
GS1 chaired the Joint Initiative Council for two years beginning February 2020.	Through collaboration with other standards development organisations in this forum, GS1 continues to work to ensure data interoperability across healthcare.
Continued education was provided about how GS1 standards interact with other health informatics standards, including classroom training, an interactive education tool, and an explanatory document.	Creating awareness of the role GS1 standards play in health informatics ensures better understanding of the value of interoperability for data exchange.
For clinical trials, an EDI implementation guideline was released, as well as a suite of GS1 XML standards for data exchange across the clinical trials supply chain.	The sector now has standardised EDI messages by which information about status and shipment of investigational products can be shared.

Traceability and preventing falsification

MILESTONE	OUTCOME
By February 2019, all EU Member States (except Italy that has until 2025) had moved forward in using GS1 standards for the identification of prescribed drugs.	GS1 standards can be used across Europe to meet the EU Falsified Medicines Directive.
The GS1 Regulatory Roadmap: Traceability of Medicinal Products document was released and translated into Chinese, French, and Spanish.	This document provides clear guidance for regulators looking for development guidance for traceability in their markets.
Foundational work was undertaken to help demonstrate EPCIS-enabled visibility in hospitals and to implement traceability requirements.	There are now projects in place that show how GS1 standards for traceability can extend into the four walls of the hospital. The US FDA released Guidance on the use of EPCIS to implement the US Drug Supply Chain Security Act (DSCSA).[10]
A range of traceability driven initiatives were realised in Africa, including two African GS1 Healthcare conferences (in Ethiopia and Nigeria), a Call to Action for medicines traceability signed at the 2019 GS1 Healthcare conference in Lagos, a traceability regulation released in Ethiopia, a traceability vision document from Botswana, draft regulatory requirements in Zambia, and a COVID-19 traceability vaccine pilot in Nigeria.	African nations, like the rest of the world, are moving to the use of GS1 global standards for medicines traceability.
Release of the International Coalition of Medicines Regulatory Authorities (ICMRA), technical denominator for the interoperability of medicine traceability systems and the World Health Organisation (WHO) policy paper on traceability of medical products.	These documents provide guidance to the 194 WHO Member States about policy and regulatory approaches to their traceability systems.
The 2019 announcement by the Gavi Alliance and UNICEF about the use of GS1 standards for the identification of vaccines they purchase, and the 2022 launch of the TrVst repository for vaccines traceability.	Through these initiatives, emerging markets will have the ability to leverage GS1 standards for traceability of vaccines and other products.
Board representation for the Fight the Fakes Alliance and foundation partnership status of the Sustainable Medicines Partnership.	Both organisations are focussed on medicines quality and effective use, which aligns strongly with the work of GS1 Healthcare.

Align with global regulatory requirements

MILESTONE	OUTCOME
Continued engagement of the GS1 Healthcare community through our public policy initiatives including bi-weekly meetings and publication of position papers and development of our Public Policy Interactive World Map.	From this work, developments are shared, knowledge is gained, and areas where education about global standards can be developed is identified.
Support for the Global Harmonisation Working Party's (GHWP) Unique Device Identification (UDI) activities.	Continued global harmonisation of UDI requirements remains an enabler of successful implementation by helping to prevent national divergence.
GS1 worked with international development partners such as USAID, Global Fund and Gavi and continued our participation on the World Bank Private Sector Advisory Council. GS1 Healthcare has become an official resource member of DCVMN (Developing Countries Vaccine Manufacturers Network) and delivered training about GS1 standards.	The important work of these organisations creates awareness of the need for global standards for medicines traceability and medical product identification across the world, and the importance of an aligned approach.
Standards development continued, in order to support the European Union Medical Device Regulations (MDR).	The industry now has clear guidance regarding how to use GS1 standards to meet the European Basic UDI-DI requirement, and work continues to support the Master UDI-DI.

10 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dscsa-standards-interoperable-exchange-information-tracing-certain-human-finished-prescription-drugs?utm_medium=email&utm_source=govdelivery

GDSN mapping guides were completed and updated as needed for the US Global UDI Database, the European EUDAMED UDI database and Chinese NMPA UDI database.	Resources are available to help the medical device sector understand the parallels between the GDSN data fields and UDI regulatory data fields – helping to maintain the need for quality master data.
GS1 worked with our local Member Organisations to support UDI regulations in South Korea, Australia, Brazil, Saudi Arabia, China, and more.	The need for global harmonisation to enable successful implementation of UDI continues to be emphasised.

Modernise training resources

MILESTONE	OUTCOME
The first healthcare provider-related eLearning module, GS1 standards in hospitals was released, as was a module introducing GS1 standards to all healthcare stakeholders.	Having a simple explanation of the role of GS1 standards and their application for healthcare providers is an important tool to help enable implementation.
A range of recorded healthcare learning courses were introduced, including application of standards for clinical trials, electronic data interchange, and the application of GS1 standards in healthcare.	These more detailed courses are designed to help the user understand the specifics of the use of GS1 standards.
The dedicated GS1 Healthcare eAcademy page was released.	There is now a simple way for stakeholders to access all the GS1 healthcare related training resources.
Promotion of the benefits of using GS1 standards in hospitals through virtual reality was undertaken.	For the use case of bedside scanning, a virtual reality experience has been created, bring the use of GS1 standards to life.
Bi-monthly Healthcare Provider Implementation webinars were delivered. A step-by-step implementation plan for use of GS1 standards in bedside scanning and for recording use of implants in the operating room has been released, and a Clinical Patient Pathway, which demonstrates the individual touch points throughout a patient's clinical journey where GS1 standards are used, has been published.	These tools help healthcare providers to understand how GS1 standards can be deployed in their organisations.
GS1 Healthcare contributed to a special edition of the International Hospital Federation Journal.	Ten articles from hospitals around the world, where GS1 standards are used to enhance efficiency and patient safety, were published. These are a valuable educational resource.

Focus on the patient and healthcare provider

Patient and caregiver identification

MILESTONE	OUTCOME
The updated CEN / ISO Technical Standard 18530 for subject of care and individual provider identification was approved through international standard ballot.	This standard provides a resource for users wishing to implement GS1 standards for patient and caregiver identification.

Primary packaging identification

MILESTONE	OUTCOME
Work commenced on how to use GS1 standards to accurately identify repackaged medicinal products.	The goal of this work is to provide guidance to the healthcare sector for how to identify these products.

Engage providers of other relevant solutions

MILESTONE	OUTCOME
Development of an inclusive Solution Partner Working Group composed of global solution providers and GS1 Member Organisations.	There are now best practices for how to engage with the solution partner community, education through webinars, case studies and solution provider podcasts, and the global solution provider finder tool, which identifies GS1 MOs solution provider programmes.
Continued engagement with electronic patient record / electronic health record solution providers to understand the barrier to adopting GS1 standards within their systems.	Hospitals need their clinical systems to support GS1 standards so processes such as barcode scanning at point of care can be implemented. We continue to work with clinical systems providers to enable that capability.

Engage with payers or reimbursement agencies

MILESTONE	OUTCOME
Initially planned to commence in 2021, this work was deprioritised due to the pandemic.	-

Achieve a single barcode

MILESTONE	OUTCOME
An updated version of the GS1 Healthcare ONE product ONE barcode paper has been published.	The goal of GS1 Healthcare is to have one GS1 barcode on the medical product packaging. This means the healthcare provider, at point of care, is presented with only one barcode which can be used for both product identification and access to electronic information. This reduces the risk of confusion in a high-pressure environment.
In Japan, GS1 Digital Link is now used to access electronic product information leaflets (ePILs) for medicines. A pilot of the same capability has also been undertaken in Singapore. GS1 Digital Link is also being used to allow Ukrainian refugees in Poland to access ePILs for donated medicines in Ukrainian.	All of these implementations leverage the one GS1 barcode on the medicines pack.

Strengthen the COVID-19 supply chain

MILESTONE	OUTCOME
Work was undertaken with Deloitte to explore how global standards can contribute to efficient distribution and administration of the COVID-19 vaccines globally. Two resulting discussion papers explored: how to build trust in the global supply chain for COVID-19 vaccines, as well as a look at what had been achieved one year later. The release of these papers was supported by a communication strategy and three Executive Dialogue events, bringing together key stakeholders in the vaccine supply chain.	The role of global standards in helping to ensure supply chain accuracy and security, in the context of the pandemic was communicated widely to provide education and guidance for those wishing to implement.
GS1 Healthcare supported GS1 Member Organisations to explore how GS1 standards can, and have, made a difference to the supply chain during COVID.	A range of implementation stories for medical products, medicines and vaccines were presented during GS1 Healthcare events and compiled in a library available on the GS1 Healthcare website.
GS1 worked with UNICEF, Gavi, the Vaccine Alliance, and with the Developing Countries Vaccine Manufactures Network (DCVMN) on implementation of GS1 standards as they relate to COVID vaccines.	The majority of COVID-19 vaccines are being identified with GS1 standards, sometimes to the individual vial, allowing traceability through the supply chain to the patient.
GS1 Healthcare published a white paper with the International Society for Quality in Healthcare (ISQua) discussing how the use of barcode technology can make a difference to patient safety in the post-COVID era.	This paper highlights how GS1 standards and barcodes can play an even greater role in helping to ensure patient safety, and is a useful resource for healthcare providers.

Develop a guideline for laboratory sample identification

MILESTONE	OUTCOME
Development of standards for identification and labelling of biological samples commenced.	Identified as an additional strategy focus due to the pandemic, this work is underway.

Leverage new technologies where appropriate and beneficial for our objectives

Monitor technology developments and engage digital innovators

MILESTONE	OUTCOME
Two editions of the biennial GS1 Innovation Board Trend Research report were published, including content about the innovation trends in healthcare that may impact GS1.	By contributing to these reports, GS1 Healthcare has been able to monitor key developments and assess how these may impact our current work, drive standards development, or provide new opportunities for existing standards implementation.
The GS1 Registry Platform is a foundational GS1 tool providing access to product and identifier information. Education about the requirements for validation of electronic record systems for regulated healthcare products, such as the GS1 Registry Platform, was provided.	GS1 Healthcare has actively worked to understand and communicate healthcare use cases in which the GRP can be used, and understand the applicability of requirements for validation of electronic record systems for regulated healthcare products.

Notes

Notes

About GS1 Healthcare

GS1 Healthcare is a neutral and open community bringing together all healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations.

Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefit to all stakeholders.

GS1 Healthcare members include more than 100 leading healthcare organisations worldwide.

For more information about GS1 standards in healthcare, go to **www.gs1.org/healthcare.**

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