



The Global Language of Business

GS1 Healthcare Strategy 2018-2022

Harnessing the power of open, global standards to address the challenges of healthcare and benefit patients worldwide

September 2018







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

Across 150 countries, GS1 standards are being used in 25 industry sectors, such as grocery, retail, DIY/hardware, transport and logistics, as well as healthcare. Implementation of the GS1 standards helps to enable interoperability between stakeholder systems and ultimately facilitate digitisation.

GS1 Healthcare, a community of healthcare experts working with GS1, 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. This neutral and open community brings together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards - enhancing patient safety, operational and supply chain efficiencies.

At a global level, GS1 has been working with the healthcare industry for over 13 years to develop the required GS1 standards, ensure successful implementation of those standards for all stakeholders, and maintain the relevance and timeliness of our work. During this time, the healthcare industry landscape has been changing at an ever-increasing pace as new technologies and quality data are made available for use in patient treatments, as well as all in parts of the healthcare supply chain.

GS1 Healthcare works to embrace the speed of change and continues to assist standards implementation, but at the same time recognises new developments that can influence and accelerate that implementation - all the way to the patient. As such, GS1 Healthcare must remain grounded in today's industry needs, but at the same time have a very focused eye on the future. Factors such as the aging population in some countries, the growing population in others, increasing healthcare costs, the continued risk of medication error, falsified and substandard medical products entering the supply chain, quality and safety during the last mile to the patient, the surge for information and finally, data quality, completeness and accuracy for effective decision making, must all be considered.

The 2018-2022 GS1 Healthcare strategy was developed to ensure GS1 Healthcare's direction addresses these key factors. The outcome is based on the expert guidance of more than 50 healthcare stakeholders and Member Organisations (MOs).

The strategy is specifically designed to ensure that the activities until 2022 deliver substantial progress towards the GS1 Healthcare vision and mission. It aims to:

- Ensure that current activities are maintained to drive deeper standards implementation
- Further enhance the already increased focus on healthcare providers (hospitals and retail pharmacies) and bring the patient increasingly into focus
- Allow monitoring, influencing and action, where appropriate, to engage with emerging technology developments

To represent the role of GS1 standards across the healthcare continuum today, and into the future, GS1 developed the Digital Thread. This is an interactive situational depiction that represents the application of GS1 standards in healthcare in a simple, yet powerful way. It demonstrates healthcare stakeholders and their inter-relationships, communicates how GS1 standards apply in healthcare today, and gives a view of the future in 2022 achieved through the activities of the strategy.

GS1 Healthcare has played a critical support role in transforming healthcare over the last years and with the 2018-2022 strategy, will continue to do so. Past achievements relating to public policy, providing a neutral platform for stakeholders to meet and exchange experiences and views, engagement of healthcare providers, and working with humanitarian organisations show the position GS1 Healthcare has attained already, but there are still many challenges ahead.

Working together to deploy the new strategy over the next 5 years the GS1 Healthcare community will continue to make a difference for all healthcare stakeholders worldwide and further support improvement of safety and quality for patients everywhere.

GS1 Healthcare

GS1 Healthcare is a voluntary and global user group leading the healthcare sector to the successful development and implementation of global standards. This group brings together experts in healthcare to enhance patient safety and supply chain efficiency.

Evidence available from industry clearly illustrates that the GS1 identification, data capture and data sharing standards, when implemented in healthcare, help to increase patient safety, provide the foundations for interoperability, drive supply chain efficiency, improve real-time data capture during care processes, and improve product traceability from manufacturer to patient.

The development and implementation of GS1 standards in healthcare is led by those stakeholders 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. Today, nearly 70 countries have healthcare related regulations or trading partner requirements where GS1 standards are being used - because visibility in the supply chain and the possibility to uniquely identify products is very important.

For more information about GS1 standards in healthcare refer to www.gs1.org/healthcare.

Vision and Mission

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.



The GS1 Healthcare Strategy 2018-2022

For the last 3 years, GS1 Healthcare has had a key focus on engaging healthcare providers – hospitals and retail pharmacies. As this important work has transitioned to business as usual, it became time to look to the future.

For the last 3 years, GS1 Healthcare has had a key focus on engaging healthcare providers – hospitals and retail pharmacies. As this important work has transitioned to business as usual, it became time to look to the future. As a result, the GS1 Healthcare strategy for 2018-2022 was developed. The strategy will leverage and extend activities already in process, as well as bring the activities of GS1 Healthcare into areas not previously in focus.

This comprises three main areas designed to:

- Ensure that current activities are maintained to drive deeper standards implementation
- Further enhance the already increased focus on healthcare providers (hospitals and retail pharmacies) and bring the patient increasingly into focus
- Allow monitoring, influencing and action, where appropriate, to engage with emerging technology developments

Successfully drive the current business

Further drive the implementation of GS1 standards within healthcare environments through education, focusing on the value of implementation. Keep doing what is important to the success of GS1 Healthcare, while at the same time looking to gain efficiencies and effectiveness by refining our structure and operations.

➔ Operationalise and link current standards to business needs

Continue to educate and help drive deeper implementations of GS1 identification keys (e.g., Global Trade Item Number, Global Location Number, Serial Shipping Container Code) and data carriers (e.g., GS1-128 barcode, GS1 DataMatrix barcode) to make their use commonplace across all healthcare stakeholder environments and increase interoperability.

➔ Increase awareness about and drive toward trusted, complete, quality master data

Promote the use of global standards such as the GS1 Global Data Synchronisation Network (GDSN) to enable accurate, consistent, complete and timely master data to be shared between healthcare stakeholders.

➔ Align with global regulatory requirements

Continue to be the open, neutral source for regulatory agencies and other government organisations to drive the harmonised uptake of global standards.

➔ Focus on security, traceability and preventing falsification

Continue to educate, support and assist with the implementation of global standards to ensure supply chain security and medical product traceability, and to help detect falsified products entering the legitimate supply chain.

➔ Engage and promote the exchange of information between trading partners

Continue to educate, support and assist with the implementation of global GS1 Electronic Data Interchange (EDI) standards for electronic interchange of transactional business messages between healthcare stakeholders.

Focus on the patient and healthcare provider

Drive the implementation of GS1 standards in hospitals and retail pharmacies with a continuous focus on patient care, outcomes and safety.

➔ Engage providers of electronic health records, enterprise resource planning, clinical systems and other relevant solutions

Increase collaboration with healthcare solution providers with the objective to ensure they support GS1 standards in their solutions and drive interoperability throughout healthcare systems.

➔ Increase focus to drive implementation of standardised patient and caregiver identification

Increase education and implementation of GS1 identifiers and barcodes for patient and caregiver identification to enable positive patient identification throughout the care process.

➔ Increase focus on primary packaging identification

Increase education and implementation of GS1 identifiers and barcodes on primary level packaging to enable safer and more accurate recording and management at the point of care which directly impacts patient care.

➔ Achieve a single barcode for identification, authentication and access to product information

Create an interoperable architecture, for example, by means of a digital bridge, to allow a single GS1 barcode on a medical product package to be scanned and have the user, depending on their characteristics (e.g., consumer, healthcare provider), be able to access the needed online product information, complementing the reliance on the label information. With that, drive the efforts towards ONE barcode on medical product packages.

➔ Engage with reimbursement agencies or payers

Engage more with reimbursement agencies (insurers and payers) to educate and connect the implementation of global standards with healthcare reimbursement processes.

Leverage new technologies where appropriate and beneficial for our objectives

Explore digital innovation, including developments in blockchain, Internet of Things (IoT), big data, analytics, GS1 Cloud or medical data clouds, and others as relevant, and at the same time develop partnerships with key stakeholders and influencers.

➔ Research and monitor technology developments and engage digital innovators

Look to advances that may impact GS1's role in the healthcare environment. Upon identifying these areas or opportunities of impact, engage the digital innovators to encourage them to use GS1 standards, as necessary. Undertake relevant standards development activities, where necessary, and support implementation activities.

The future GS1 Healthcare strategy is specifically designed to ensure that the activities until 2022 deliver substantial progress towards the GS1 Healthcare vision and mission. We aim for further implementation of GS1 standards across healthcare, together with an increasing focus on healthcare providers – hospitals and retail pharmacies – as well as the patient, whilst ensuring that time is spent to study and act upon developing technologies and innovators. Working together, over the next 5 years the GS1 Healthcare community will make a difference for all healthcare stakeholders.



Challenges and opportunities for GS1 Healthcare

The healthcare industry landscape is changing at an accelerated pace as new technologies and quality data are made available for use in patient treatments as well as in all parts of the healthcare supply chain.

GS1 Healthcare has been working with industry for over 13 years to continue to develop the required standards, ensure successful implementation of those standards for all stakeholders and maintain the relevance and timeliness of our work to meet industry's changing needs. Here lies the challenge for GS1 Healthcare for the next 5 years – to keep working to enable standards implementation, but at the same time embrace new developments that can influence and accelerate that implementation all the way to the patient. GS1 Healthcare must remain grounded in today's industry needs, but at the same time have a very focused eye on the future.

As GS1 Healthcare maintains this balance, influencers such as those below have shaped the direction of the future strategy.

The aging population and increasing healthcare costs

A 2018 study by Dieleman et al¹ published in the *Lancet*, estimates that healthcare spending across the globe is “expected to increase from US\$7.83 trillion in 2013 to \$18.28 (uncertainty interval 14.42–22.24) trillion in 2040 (in 2010 purchasing power parity-adjusted dollars)”. The report continues, estimating “per-capita health spending to increase annually by 2.7% (1.9–3.4) in high-income countries, 3.4% (2.4–4.2) in upper-middle-income countries, 3.0% (2.3–3.6) in lower-middle-income countries, and 2.4% (1.6–3.1) in low-income countries.” Such substantive increases in spending is a driver for efficiency, getting best value, and ultimately changed behaviour in the production and consumption of healthcare, both within and outside of hospital premises.

It is also well documented that the cost of healthcare increases, on average, as the population ages. Peterson Kaiser has estimated that over half of healthcare spending in the US can be attributed to people aged 55 and over². This is consistent with trends seen in many countries around the world. With an ageing population increasing in record-setting numbers this will only exacerbate healthcare costs. Add to this new and expanded services which are in increasing demand, longer life expectancy leading to longer treatments, and empowered patients expecting access to

advanced treatments such as gene therapies, there are multiple very significant forces driving up healthcare costs. Already we see GS1 standards relied upon to help address many healthcare economic factors and foresee that this will continue well into the future.

Medication errors

Medication errors continue to be an unfortunate occurrence that impact patients worldwide. As evidenced by the World Health Organisation's Third Global Patient Safety Challenge – Medication Without Harm³, stakeholders across the globe need to come together to address the medication safety challenge. The World Health Organization (WHO) states that “Unsafe medication practices and medication errors are a leading cause of injury and avoidable harm in health care systems across the world. Globally, the cost associated with medication errors has been estimated at \$42 billion USD annually.” The application of GS1 standards assists to prevent medication errors – scanning a barcode at the point of care and referring to a database containing accurate information, coupled with unambiguous patient identification, helps to ensure that the right medication is given to the right patient at the right time.

Falsified and substandard medical products

A disturbing trend is the increase in falsified medical products entering the healthcare supply chain. The report, WHO Global Surveillance and Monitoring System for Substandard and Falsified Medicines⁴, released in 2017 found the “failure rate of substandard and falsified medical products in low- and middle-income countries at approximately 10.5%.”

¹ National spending on health by source for 184 countries between 2013 and 2040 - Joseph L Dieleman, PhD, Tara Templin, BA, Nafis Sadat, MA, Patrick Reidy, BA, Abigail Chapin, BA, Kyle Foreman, PhD, Annie Haakenstad, MA, Tim Evans, MD, Prof Christopher J L Murray, MD, Christoph Kurowski, MD, *The Lancet*, Volume 387, No. 10037, p2521–2535, 18 June 2016

² Peterson-Kaiser Health System Tracker, <https://www.healthsystemtracker.org/chart-collection/health-expenditures-vary-across-population/#item-start>

³ Refer to <http://www.who.int/patientsafety/medication-safety/en/>

⁴ Refer to http://www.who.int/medicines/regulation/ssffc/publications/GSMS_Report.pdf?ua=1

The impact of such products to the patient, the healthcare system and the community is very significant, which is why we see an increasing regulatory and government demand for visibility and data sharing. Visibility aims to “shed light” on the supply chain, enabling end-to-end traceability for safer, more secure care. This is particularly important in emergency and humanitarian environments which will be stretched as needs around the world continue to grow. The GS1 standards have a clear role in helping to enable such visibility and traceability, by facilitating unique identification, data capture and data sharing for healthcare products across the globe.

Connecting to the patient (the last mile)

Patients are more informed and better able to participate in their own care with self-management systems. They are increasingly empowered as consumers of healthcare who expect effective communication within and between the healthcare system stakeholders, together with interoperability between clinical systems and processes. The expectation is that the healthcare system will work as that – an integrated system. When care is provided in a traditional setting, hospitals and retail pharmacies are implementing initiatives such as point of care scanning of medication and medical device identifiers, and positive patient identification during clinical processes. At the same time, as the centre of care transitions from hospitals and clinics to treating and monitoring patient health in the comfort of their homes, this drives increased information needs for caregivers. Many of these initiatives leverage the unique identification, data capture and data sharing capabilities that application of the GS1 standards can provide.

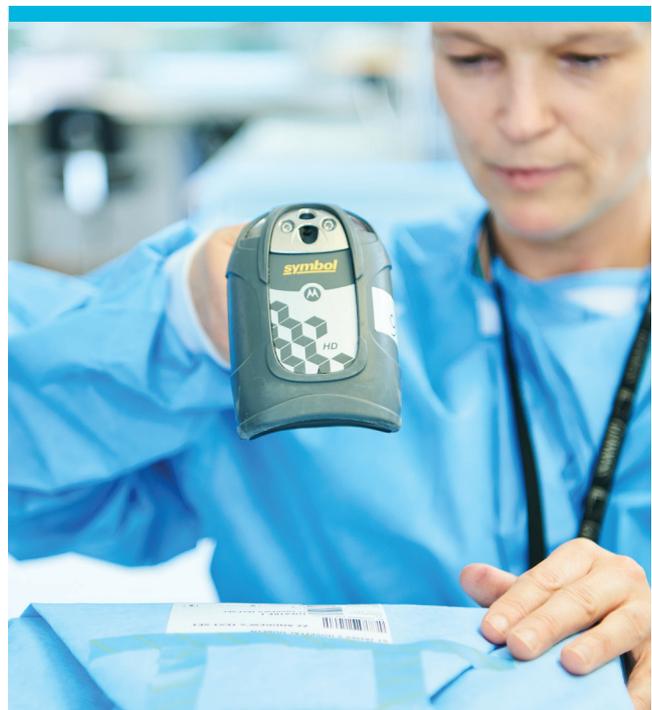
Data quality, completeness and accuracy is needed

Data is increasingly seen as a fundamental element in healthcare, whether this is product data, legal entity and location data, medical data, clinical trial data or transactional data. The quality of the data is sometimes seen as a reflection on the quality of the product. Data accuracy starts with the data source and is the responsibility of every healthcare stakeholder. It is an essential tool to help ensure any patient receives the most appropriate treatment. In healthcare, managing master data, including sharing this data with the appropriate stakeholders, is increasingly critical for enabling strategic decision-making, planning, research and development initiatives, and purchasing decisions. Interoperability of systems across all healthcare environments will be a top priority, especially

when moving to next-generation electronic health records. The standards administered by GS1 for master data exchange can go a long way to helping aid the healthcare environment’s need for consistent and accurate data.

Innovation is coming

As defined by the US Department of Commerce Advisory Committee, innovation is “the design, invention, development, and/or implementation of new or altered products, services, processes, systems, organizational structures, or business models for the purpose of creating new value for customers and financial returns for the firm⁵.” According to Sanjay Poonen writing for Forbes⁶, innovation in healthcare is occurring at a pace not seen before, and a lot of this is driven by patients and their expectations. Coupled with rapidly developing technologies such as Blockchain, the Internet of Things, wearable devices, cloud capacities, augmented reality and digital marketplaces such as Amazon moving into healthcare, to name a few, the potential for these innovations to disrupt the status quo of implementation of GS1 standards in healthcare is high. The future direction of GS1 Healthcare must embrace such developments, and at the same time be able to assess and influence those that will complement the implementation of global standards.



⁵ Refer to <http://www.esa.doc.gov/reports/innovation-measurement-tracking-state-innovation-american-economy>

⁶ Refer to <https://www.forbes.com/sites/forbestechcouncil/2018/04/02/health-care-innovation-harnessing-new-technologies-to-benefit-patients/#2d7d626b5a88>

GS1 standards enable healthcare's digital thread

The digital thread, Figure 2, is a situational depiction representing the application of GS1 standards in healthcare in a simple, yet powerful way. It demonstrates healthcare stakeholders and their inter-relationships, communicates graphically how GS1 standards apply in healthcare today and gives a view of the future in 2022 driven by the activities of the strategy.

The digital thread's multi-dimensional view encompasses:

1. Key healthcare stakeholders
2. Relationships and connections between stakeholders, and to the patient as the ultimate beneficiary
3. The role of GS1 standards that can enable these connections
4. The current status of implementation of GS1 standards
5. A look into the future, including the anticipated changes to implementation driven by the strategy activities

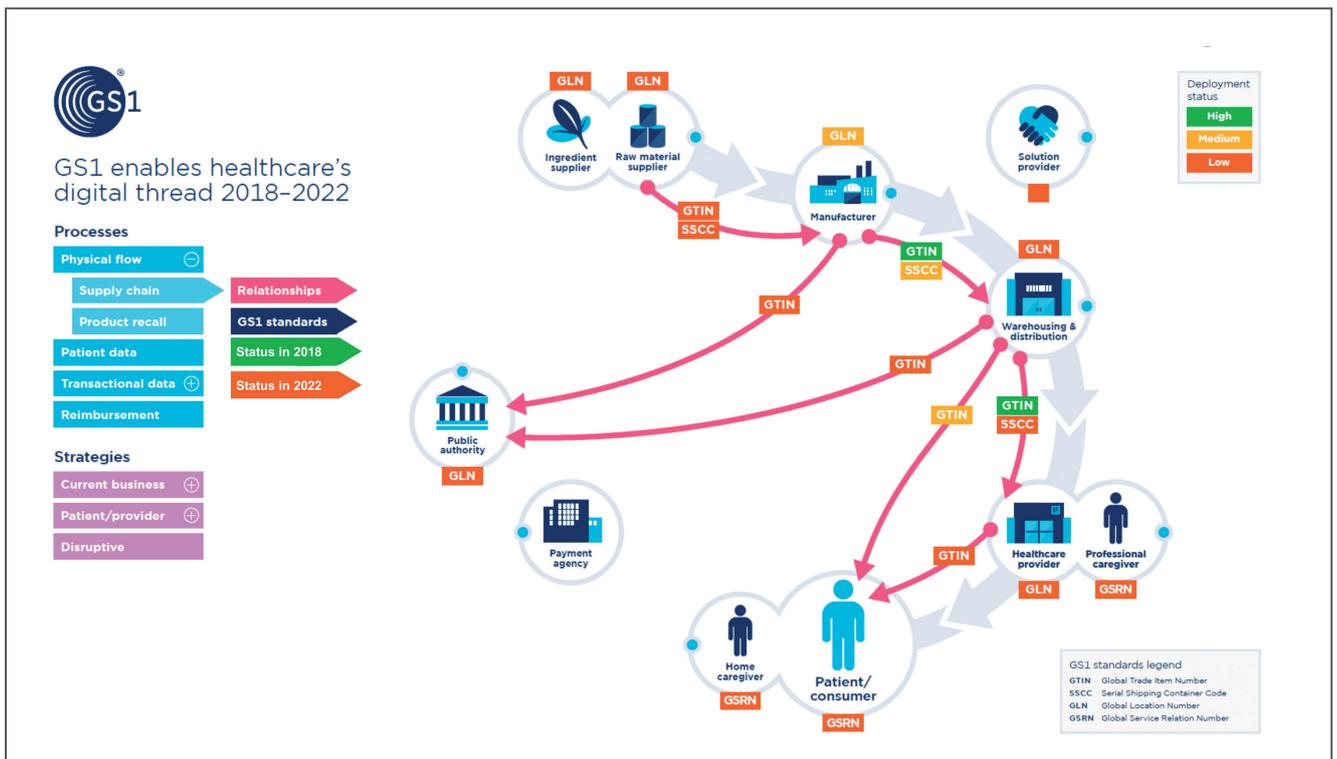


Figure 2: An illustrative view of one page of the digital thread

The interactive digital thread

can be accessed at

<https://www.gs1.org/healthcare/about/strategy#digital-thread>.

GS1 Healthcare's strategic framework

Figure 3 details how the GS1 Healthcare strategy relates to the vision and mission as well as specific projects and GS1 Global Office employee activities.

The GS1 Healthcare strategic priorities are determined based on the GS1 Healthcare 5-year strategy, whilst taking into account current workload, unplanned strategic projects and resourcing constraints. The strategic priorities are signed off by the GS1 Healthcare Leadership Team at the start of the calendar year. Progress relating to the strategic priorities is reported to the GS1 Healthcare Leadership Team every 6 months.

The GS1 Member Organisations (MOs) are responsible for uptake of GS1 standards in their local markets in line with market maturity, demand and local stakeholder requirements. At the same time, the GS1 MOs align, where possible, with the GS1 Healthcare global direction and can leverage the momentum and resources this provides.

Communication, and measurement of progress, are foundational elements of the GS1 Healthcare strategic framework and are business as usual activities.



Figure 3: GS1 Healthcare strategic framework



Appendices

The appendices of this report are designed to provide more information about GS1 Healthcare, the process and stakeholders involved in the development of the strategy, tactics and timelines for the strategy components, and lastly to reflect on the progress of GS1 Healthcare from 2015-2018, during the last healthcare strategy: project Imagine.

Appendix 1: GS1 Healthcare operating environment

Governance

GS1 Healthcare is governed as part of GS1, an international not-for-profit standards organisation, reporting 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, stakeholders to GS1 Healthcare include:

- Global voting members — all stakeholders operating in the healthcare supply chain, including, but not limited to, suppliers, wholesalers, distributors, logistics service providers, hospitals, pharmacies and solution providers. Voting members contribute to GS1 Healthcare activities and basic operational costs with an annual fee.

- Global non-voting members — trade associations, regulatory bodies and other governmental healthcare authorities, educational institutions and other standards organisations.
- GS1 Member Organisations (MOs) — GS1 Member Organisations are critical stakeholders of GS1 Healthcare since they provide the communication, support and services necessary to ensure that 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 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 industry advisors that contribute important direction to Leadership discussions.



Appendix 2: Strategy development process

Over 10 months, the development of the GS1 Healthcare Strategy brought together contributors from all functions across the healthcare sector in workshops and meetings designed to brainstorm, debate, create and ultimately finalise the five-year strategy.

- During the first strategy development workshop at the Cap Gemini Advanced Solutions Environment in Chicago during October 2017, 50 attendees brainstormed the future of the application of GS1 standards in Healthcare, delivering significant outputs.
- A work team (subset of stakeholders from the Chicago meeting) continued to refine the raw outputs of the strategy, streamlining this into manageable topics – major strategies and supporting components, as well as graphical representation of the GS1 standards in healthcare now and in the future – The Digital Thread.
- An intensive workshop with the Healthcare Leadership Team was held in Bogota, Colombia, in April 2018. Outputs from the workshop included the first draft of the tactics detailing the “what, when, how” of the strategy components.
- During April through July 2018, the Digital Thread was finalised along with refreshed GS1 Healthcare vision and mission statements and this final strategy report.
- Throughout the strategy development process, review and input was received from the GS1 Management Board members representing healthcare.

Contributors

Thank you to the many industry stakeholders, the GS1 Healthcare Leadership Teams from 2017/18 and 2018/19, and GS1 Member Organisation colleagues who contributed to development of this strategy.

- 1WorldSync
- 3M
- Abbott
- AmerisourceBergen
- Baxter
- Bayer
- B. Braun
- Becton Dickinson
- Bernhoven Hospital
- Carl Gustav Carus University Hospital
- Cook Medical
- DHL
- GHX
- GS1 Australia
- GS1 Brazil
- GS1 Canada
- GS1 Denmark
- GS1 France
- GS1 Netherlands
- GS1 UAE
- GS1 UK
- GS1 US
- GSK
- Innovit
- International Hospital Federation
- Johnson & Johnson
- Lansa
- McKesson
- Medtronic
- Northwestern University
- Pfizer
- Roche
- SAP
- Smith & Nephew
- St. James's Hospital
- Systec One
- Teleflex
- Tracelink
- University Hospitals of Derby and Burton NHS Foundation Trust
- University Medical Center Schleswig-Holstein
- USDM
- Zebra



Appendix 3: Strategy tactics and timelines

During the strategy development process, effort was made to plan anticipated activities and timelines for each of the strategy components. These plans are based on best estimates and current information as at the time of strategy development. In executing these plans, the GS1 Healthcare Leadership Team recognises that changes in the

healthcare environment, and as a result the GS1 Healthcare priorities, could mean the current plans are not achievable. Progress to the plan will be assessed each year during the process of planning strategic priorities and against agreed metrics for each strategy component.

➔ Operationalise and link current standards to business needs

Task	2018	2019	2020	2021	2022
Review and update value propositions per audience with messaging around value, not compliance, add use case information as necessary	✓	✓			
Stocktake current resource and identify needed application specific user guides	✓	✓			
Develop further education tools - for GS1 MO and global member use		✓	✓		
Deployment of new education tools for global members (within their own organisations and with partners) and GS1 MOs - to drive harmonised education			✓	✓	✓
Develop and deploy metrics to track progress of implementation		✓	✓	✓	✓

➔ Increase awareness about and drive toward trusted, complete, quality master data

Task	2018	2019	2020	2021	2022
Develop an industry data quality situational problem statement and the desired outcome as a result of actions to be taken	✓				
Develop the goals, components, and deliverables in order to achieve the desired outcome. The goal is data excellence for downstream, and to create or identify what is needed: - Components / tools - Activities - communication, education - Value propositions		✓			
Develop metrics in order to measure progress towards the goal. Develop a roll out plan		✓	✓	✓	✓
Execute the program and measure progress		✓	✓	✓	✓

In scope

Desired actions to be taken by the data sources, and recipients (i.e., manufacturers, distributors/wholesalers, hospitals and pharmacies) to ensure the data quality, accuracy and completeness is fit for purpose and maintained through the entire information sharing ecosystem. This creates a data quality chain of custody that is the responsibility of all stakeholders.

Out of scope

Internal and external technologies, infrastructures and data sharing mechanisms, e.g., the Global Data Synchronisation Network (GDSN). Suggestions for improvements to these systems and technologies are outside of the scope of this project.

➔ Align with global regulatory requirements

Task	2018	2019	2020	2021	2022
Review and identify the key decision makers for regulations in countries (to be accessible in the GS1 Community Room)		✓			
Review and update public policy strategy to include: <ul style="list-style-type: none"> - Increased GS1 Global Office and GS1 MO coordination (incl. better education of GS1 MOs about regulatory topics in healthcare) - Develop regional engagement strategies (e.g., Asia Pacific, Africa) - Cooperation with global/regional industry/trade associations - Develop and deploy metrics for assessing strategy impact 		✓	✓		
Deploy strategy			✓	✓	✓
Monitor regulatory developments and implementations (business as usual) including metrics to track progress	✓	✓	✓	✓	✓

➔ Focus on security, traceability and preventing falsification

Task	2018	2019	2020	2021	2022
Review and refine message definition leveraging GS1 multi-sector global traceability project Positioning this messaging: <ul style="list-style-type: none"> - At a global level - At a country specific GS1 MO/local level according to use cases: (1) brand protection/fighting illicit trade/diversion and (2) patient safety/security 		✓			
Deploy updated messaging - Building roadmap in 2019 and deployment as of 2020+		✓	✓	✓	✓
GS1 MO support and education starting 2019 together with deployment: <ul style="list-style-type: none"> - Training (webinars/presentations) - Development of communication materials 		✓	✓	✓	✓
Create awareness around and undertake GS1 MO proof of concepts (POC) or pilots, ensure monitoring of POCs, and measuring adoption of traceability, starting mid-2019		✓	✓	✓	✓
Develop and deploy metrics to track progress of implementation once the POCs are successful, starting 2020			✓	✓	✓

➔ Engage and promote the exchange of information between trading partners

Task	2018	2019	2020	2021	2022
Understand industry needs further			✓		
Clarify GS1 Healthcare positioning regarding EDI			✓		
Identify additional education needs for industry and GS1 MOs and develop tools as needed				✓	
Roll out education tools				✓	
Explore other possible areas of support (e.g., offering simple software solutions)				✓	✓
Develop and deploy metrics to track progress of implementation				✓	✓

➔ Engage providers of electronic health records, enterprise resource planning, clinical systems and other relevant solutions

Task	2018	2019	2020	2021	2022
Update the value proposition for Solution Providers to support GS1 standards	✓				
Create an inventory of hospital information technology (IT) systems currently being implemented	✓				
Agree a consistent approach to Solution Provider engagement – both global and local	✓	✓	✓		
Help industry to better communicate their needs to Solution Providers through communication tools and education	✓	✓	✓	✓	✓
Help smaller GS1 MOs and GS1 MOs not active in working with solution providers to gain knowledge and tools to help them engage		✓	✓	✓	✓
Develop and deploy metrics to track progress of implementation		✓	✓	✓	✓



➔ Increase focus to drive implementation of standardised patient and caregiver identification

Task	2018	2019	2020	2021	2022
Undertake information gathering regarding current practices and consolidate this for knowledge sharing	✓				
Develop a “how to” implement process guide and relevant communication tools	✓	✓	✓		
Develop value propositions or value statements based on role		✓			
Rollout/implementation for patient and caregiver identification		✓	✓	✓	✓
Develop and deploy metrics to track progress of implementation	✓	✓	✓	✓	✓

➔ Increase focus on primary packaging identification

Task	2018	2019	2020	2021	2022
Develop value propositions or value statements based on role		✓	✓		
Develop a “how to” implement process guide and relevant communication tools		✓	✓		
Rollout/implementation for primary packaging identification		✓	✓	✓	✓
Develop and deploy metrics to track progress of implementation		✓	✓	✓	✓

➔ Achieve a single barcode for identification, authentication and access to product information

Task	2018	2019	2020	2021	2022
Create a problem statement	✓				
Engage industry associations to understand if they support a digital bridge	✓				
Develop a 1-3-5 year plan, including a pilot (continuing to take into account other relevant GS1 projects, e.g., Digital Link project)		✓			
Execute plan year 1 and assess progress		✓	✓		
Develop and deploy metrics to track progress of implementation			✓	✓	✓
Continued plan deployment				✓	✓



→ Engage with reimbursement agencies or payers

Task	2018	2019	2020	2021	2022
Understand current landscape, create list of reimbursement agencies and schemes in 30 countries				✓	
Develop GS1's value proposition in this space				✓	
Develop education and communication materials including GS1 MO support					✓
Roll out					✓
Develop and deploy metrics to track progress of implementation.					✓

→ Research and monitor technology developments and engage digital innovations

Task	2018	2019	2020	2021	2022
Assess current situation to understand baseline	✓				
Deploy formal process of 'watching' developments		✓	✓	✓	✓
Commence building relationships with relevant healthcare innovators	✓	✓	✓	✓	✓
Develop and deploy metrics to track progress of initiative		✓	✓	✓	✓

Appendix 4: GS1 Healthcare 2015-2018

Prior to 2015, GS1 Healthcare had a primary focus to enable suppliers to use GS1 standards, and to communicate with health authorities. Yet, as requirements, costs and the need to better care for patients accelerated, so did the need to focus on healthcare providers – hospitals and retail pharmacies – as these organisations are the final users of the product before application to the patient. Whilst managing business as usual activities to work with suppliers, regulators and governments, GS1 Healthcare undertook project Imagine.

Project Imagine was a cohesive program designed to communicate the value of GS1 standards to healthcare providers – increasing patient safety, better managing healthcare costs, reducing the risk of error and improving overall efficiencies in hospitals.

Development of the tools and materials occurred throughout 2015, with a launch in 2016 and deployment ongoing.

Project Imagine has delivered:

- Hiring of a dedicated resource with clinical experience to lead project Imagine as this becomes business as usual.
- Formation of the GS1 Healthcare Clinical Advisory Committee, consisting of medical doctors as key leaders in discussing and advancing the implementation of GS1 standards in hospitals.
- Formation of the GS1 Healthcare Nurses in Leadership Group, to drive uptake of GS1 standards in clinical processes as nurses will always be involved in the processes of implementation and barcode scanning.
- Training of GS1 MOs to strengthen their knowledge of hospital operations such as detailed information about clinical and support processes.
- Tools and methodologies for GS1 MOs to effectively engage healthcare providers and support their implementations at local levels. These include a 'Go To Market' guideline, GS1 standards step-by-step implementation plans for certain business processes, other written communication materials, videos and images.
- The GS1 Healthcare Provider Database, developed to provide information about hospital and retail pharmacy implementations using GS1 standards. By the beginning of 2018, the

database contained more than 100 case studies and had attracted more than 360 registered users.

- GS1 Healthcare webinars, monthly presentations and discussions of hospital implementations of GS1 standards that attract an average audience of greater than 80 people. The recorded webinars are shared with the International Society for Quality in Healthcare (ISQua), and the World Continuing Education Alliance and are offered to their members and stakeholders.
- An increased focus on healthcare provider implementations at the global GS1 Healthcare conferences, with the first full day showcasing this content.
- A stronger representation of published hospital implementation case studies in GS1 Healthcare Reference Books – more than 50% of case studies are from hospitals in each of the 2016/2017, 2017/2018 and 2018/2019 editions.
- Deeper relationships with ISQua, including referencing the use of barcodes in hospital accreditation criteria and presentations at ISQua conferences.
- Closer collaboration with the International Hospital Federation (IHF), including participation at IHF Congresses (World Hospital Congress), participating in specific IHF groups, planning for inclusion of articles in the World Hospitals and Health Services Journal special edition relating to traceability and ongoing representation of the IHF on the GS1 Healthcare leadership team.
- Presentations at other conferences for a clinical/hospital audience such as the Conference for Intensive Care Specialists in 2016, and the World Congress of Clinical Safety in 2017 and 2018.
- A request from international plastic surgeons relating to the exchange of data on implants via the GS1 Global Data Synchronisation Network (GDSN). This is now work in progress.
- Increased engagement with relevant umbrella organisations such as European Hospital and Healthcare Federation (HOPE), Standing Committee of European Doctors (CPME), hospital associations, etc.

These are significant achievements over a 2 year deployment period with many more developments planned. Most outstandingly, more than 40 GS1 MOs are now leveraging the outputs of project Imagine in their markets and using the tools of project Imagine.

Business as usual, in parallel with project Imagine deployment

Whilst project Imagine was a key focus, GS1 Healthcare continued business as usual activities between 2015- 2018. These are grouped into 4 general areas:

- Public policy
- GS1 Healthcare conferences
- Ensuring GS1 standards relevance and implementation
- Working with humanitarian organisations

➔ Public policy

- A new version of the Public Policy database was launched in 2017, bi-weekly teleconferences were held, and sessions were included during the global conferences along with special work groups being formed.
- GS1 Healthcare continued as a Unique Device Identification (UDI) issuing agency for the U.S. Food and Drug Administration (FDA). By the end of 2016, more than 86 percent of the medical devices registered in the U.S. UDI Database (GUDID) used the GS1 GTIN as the primary identifier.
- GS1 released a new GS1 standard for the Global Model Number, to support the implementation of the Basic Unique Device Identifier-Device Identifier (BUDI-DI) in Europe. An implementation guide will be developed after further guidance from the EU Commission has been published. The final designation of GS1 as a UDI issuing agency in the EU is expected.
- Facilitated by GS1, research was completed in 2016 by the Track and Trace Systems Work Group, together with the outcome of the nine other work groups which resulted in the Asia Pacific Economic Community (APEC) Roadmap for Global Medical Product Quality and Supply Chain Security. The APEC Toolkit was published in 2017 and is being promoted to APEC countries. Two Centres of Excellence in the U.S. and one in South Korea are now providing training while additional centres are planned to be established in China, Japan, Chinese Taipei and Singapore.
- In 2016, the European (EU) Falsified Medicines Directive (FMD) position paper was released with recommendations for a harmonised implementation, using GS1 standards. By the implementation deadline in 2019, most of the EU Member States will

have moved forward with the use of the GTIN as the product code to implement the EU Falsified Medicines Directive (FMD).

- The relationships between health IT standards are complex, so a “high-level standards map” was finalised in 2016, showing how health informatics standards interoperate with GS1 standards. In 2017, a health informatics education program for GS1 MOs was started. Advanced training on the ISO Identification of Medicinal Products (IDMP) standards was conducted in December with more tools and education sessions planned in 2018.

➔ GS1 Healthcare Conferences

- In 2016, the GS1 Healthcare Conference was hosted for the first time in the Middle East Mediterranean and Africa (MEMA) region. Representing more than 40 countries, 295 participants travelled to Dubai for the April conference.
- In October 2016, the Beijing GS1 Healthcare conference saw 285 participants representing more than 30 countries.
- A record number of 394 participants from more than 40 countries shared information and networked during the conference in Berlin in April 2017.
- In October 2017, nearly 350 from 30 countries attended the global conference in Chicago.
- April 2018 commenced with the GS1 Healthcare conference in Bogota, Colombia, again attended by nearly 300 attendees from 30 countries.

➔ Ensuring GS1 standards relevance and implementation

- The 2016 publication of the Healthcare Electronic Data Interchange (EDI) Implementation Kit was completed as a business-level guide for implementers of GS1 standards for EDI.
- In the area of data quality, a Master Data Services and Brand Owner Certification Programme was completed to help improve data quality at the source.
- In 2017, a data strategy and roadmap was developed to address the growing need of pharmaceutical manufacturers, distributors and wholesalers to share trusted product data via the GS1 Global Data Synchronisation Network (GDSN).

- In 2017, work continued to align GS1 standards with the Systemised Nomenclature of Medicine-Clinical Terms (SNOMED-CT) to better manage health information and enhance clinical decision-making outcomes. Progress toward this goal was made with the publication and promotion of Global Trade Item Number® (GTIN®) to SNOMED-CT assignment principles.
- Several guidance documents were developed and published - about primary packaging level identification, a position paper about GS1 and IDMP and GS1's guidance on the use of identification keys in GS1's event data sharing solution EPCIS visibility events.
- As the use of mobile and digital devices increases in healthcare, an ecosystem vision was crafted by GS1 Healthcare that enables access to trusted product information via a simple scan of a Global Trade Item Number (GTIN). In 2017, we developed a strategic vision to address the industry's needs. The "Digital Bridge Service" concept is a proposed solution to address the evolution of mobile and digital technology as a "positive disruptor" in healthcare.
- From 2017 onwards, global solution providers who are members of GS1 Healthcare came together with GS1 MOs to develop tools and collateral that will help ensure GS1 standards are included in solutions used by manufacturers and healthcare providers. One guide developed advises how healthcare providers can articulate their needs to best select solution providers.
- Using GS1 standards in pharmaceutical clinical trials was explored with presentations conducted by GS1 at clinical trial conferences and at the GS1 Healthcare Conference in Chicago, as well as commencement of a work group to deliver a guideline for how GS1 standards apply in clinical trials.
- The GS1 Healthcare Reference Book, containing implementation case studies from around the world, was published annually.

Working with humanitarian organisations

- GS1 Healthcare increasingly worked to support humanitarian and aid organisations such as GAVI The Vaccine Alliance, United States Agency for International Development (USAID) and United Nations Population Fund (UNFPA). The primary intent was to develop supply chain visibility for vaccines and medicines and prevent counterfeits from entering the global supply chain.
- In 2017, USAID published its guidelines for the Identification of Reproductive Health products, relying on GS1 standards.
- GS1 has also become part of the Private Sector Advisory Council of the World Bank looking into implementing optimised and safe supply chains.
- In August 2017, the Interagency Supply Chain Group (ISG), an informal partnership of 15 major actors involved in providing supply chain support to countries, all formally endorsed GS1 standards. This included the Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, United Nations Development Programme (UNDP), UNFPA, UNICEF, USAID, World Bank, World Food Programme (WFP) and World Health Organization (WHO).
- GS1 Healthcare presented at the 2017 Developing Countries Vaccine Manufacturers Network annual meeting and then created an e-learning course for its website.
- In May 2018, the first African GS1 Healthcare conference was held in Addis Ababa, Ethiopia. Hosted by FMHACA (the Ethiopian healthcare regulator) and opened by the Minister of Health and Director General of FMHACA, the event welcomed 310 people from 38 countries, representing 45 regulatory bodies and 23 humanitarian organisations.

GS1 Healthcare is providing a critical role in transforming healthcare

As we plan for the future, our past achievements can be a useful barometer of how far we have come and how far we have yet to go. It can inform us, inspire us or simply remind us of the critical role that GS1 Healthcare and our standards are performing in the transformation of healthcare.

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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190018-Strategy Booklet-092018