

GS1 Healthcare

2018 Strategic Priorities



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.

Our Strategic Objectives are:

Healthcare Providers

- *Development of tools to assist healthcare provider roll-out*
- Continued cooperation with clinical stakeholders
- *Submit GS1 papers to healthcare provider journal*
- Constantly update and further improve healthcare provider database

Standards and Guidelines

- Solution Provider activities
- Extending Healthcare AIDC Solutions
- *Health informatics education program for MOs*
- *EPCIS in hospitals group*
- *Guideline for use of GS1 standards in pharma clinical trials*
- *GMN/BUDI-DI implementation guide*
- Traceability in healthcare

Future Vision

- *GS1 Healthcare Future Strategy*
- Monitor / drive global harmonization and support regulatory reporting
- *Pharma data strategy roll-out*
- *African regional conference*
- *Support inter-governmental orgs*
- *Digital bridge proof of concept*
- *Master data in healthcare*

Ongoing Activities

- Public Policy activities
- MO Support
- Global Member Activities
- Global GS1 Healthcare Conferences
- Presentation at conferences and events
- Liaising with other SDOs
- Participation in eHealth activities
- *Increase operational efficiency*

Our Strategic Measures are:

Total global number of pharma & medical device members reported by GS1 Member Organisations (MOs)

Number of Healthcare GTINs in Global Registry

% of products with GS1 barcodes in each country (surveyed at healthcare providers – hospital, retail pharmacy)



New tasks for 2018 in *italics*

The Global Language of Business

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Healthcare Providers

Development of tools to assist healthcare provider roll-out



- *Remote Healthcare Provider Training:* The training run for GS1 MOs in 2017, to provide detailed information about the structure and clinical processes of hospitals will be modified to be delivered remotely
- *Step-by-step process implementation plans:* Prioritise most important processes and develop top three step by step plans for implementation of GS1 standards in clinical processes, e.g., bedside scanning, implant traceability, etc. will be developed
- *Perfect hospital document:* Develop a document describing the “hospital of the future - using GS1 standards”
- *Continue monthly Healthcare Provider webinars:* to showcase examples of GS1 implementation in the Healthcare Provider environment

Continued engagement with clinical stakeholders



- International Society for Quality in Healthcare (ISQua) – global accreditation body for organisations such as JCI
 - Provide content for Fellowship Program
 - Reciprocal participation on the agenda at conferences
 - Explore how global standard barcodes may provide a role in helping hospitals to achieve accreditation
- International Hospital Federation (IHF)
 - Build stronger relationship
 - Working to plan collaboration activities
 - Reciprocal participation on the agenda at conferences
- European Association for Hospital Pharmacists
 - Drive identification on primary level packaging to enable bedside scanning
 - Joint activities at conferences in promoting global standards
- Clinical Advisory Committee and Nurses in Leadership Group will continue to operate with regular meetings
 - Two groups (1) of medical doctors and (2) nurses discussing implementation of GS1 standards

Submit GS1 papers healthcare provider journals



- The paper already developed and in review, then will be submitted to the ISQua Journal.
- GS1 will work with the International Hospital Federation to develop case studies related to traceability in hospitals and these will be submitted to a special IHF Traceability focused journal.

Healthcare Provider Database



- The healthcare provider database is a detailed repository to pool information about hospital implementation of GS1 standards worldwide was created
- Further activities include:
 - Commencing a video guide & webinar – leveraging Marketing support
 - Develop the statistical & analysis function in the database – leveraging IT support
 - Work with colleagues and stakeholders to continually update the database



Standards and Guidelines

Solution Provider activities



- Objective is to accelerate the global transformation of the healthcare industry by working to ensure that GS1 standards are included in solutions used by healthcare providers and manufacturers
- Will involve three focus areas:
 - Engagement of solution providers - Leverage existing tools to communicate the value
 - Make sure Healthcare Providers can articulate their needs relating to GS1 standards
 - Make sure the MOs have the tools needed to communicate to SPs
- Focus areas 1 and 2 have been delivered. Focus area 3 will be addressed during 2018.
- At the same time, GS1 Healthcare will work to more actively engage and collaborate with solution providers operating

Extending Healthcare AIDC Solutions



- As the use of AIDC and GS1 Standards has moved within reach of Healthcare providers and gets closer to the “bedside”... questions and discussions have arisen in regard to potential / needed “hospital identification” applications where as yet consensus on a global solution / approach has not been reached.
- Examples of such identification needs in the hospital environment include repacking products, tracking treatment equipment, custom products, biological samples, assistive technologies, products in med labs, diagnostic & other hospital services, hospital warehouse storage bins, procedure code ID, etc.
- Goals are to better understand these business need(s), determine community support & prioritize the needs, plan the path forward to the creation & publication of application & implementation recommendations.
- Bi-weekly calls are in place.

Health informatics education program for MOs



- Health IT standards are complex and difficult to understand
- Where does GS1 provide value to Health IT standards?
- Comprehensive training and reference tools for use face to face and via webinar / internet will be developed.
- Training delivered will include:
 - General health informatics
 - IDMP
 - IHE
 - Others upon request

Event-Based Hospital Visibility (EPCIS) in Hospitals – discussion group



- Considerations on applications of EPCIS for...
 - Events at bedside and in the operating theatre
 - Patient treatment incl. administration of medication
 - Identification of caregiver & recipient
- Potential for GS1 interest group of stakeholders
 - Align on requirements, charter workgroup to develop a global GS1 application standard
 - **Need:** common denominator of visibility requirements for event-based hospital visibility
 - **Need:** involvement by a critical mass of GS1 MOs and their caregivers to launch a workgroup

Guideline detailing the use of GS1 standards in pharma clinical trials



- An agreement to explore collaboration has been signed between GS1 and the Alliance for Clinical Research Excellence and Safety in Clinical Trials
- It is believed that GS1 standards have application for identification of products, patients and locations in clinical trials environments just like the overall healthcare environments
- During 2017 we explored opportunities to better articulate and document the role of GS1 in clinical trials through conference presentations and stakeholders
- During 2018/2019 a guideline discussing the role of GS1 standards in clinical trials will be developed and published

GMN / BUDI-DI - Details on implementation



- With the release of the GS1 standards for the Global Model Number, to support implementation of requirement in the EU for a new concept of identifier: the Basic UDI-DI for medical devices, implementation details need to be developed
- This will be actioned in 2018 after further guidance of EU Commission has been published

Traceability in Healthcare



- Various multi-industry traceability initiatives, as well as healthcare sector specific workgroups and projects, are occurring which could impact healthcare
- GS1 Healthcare will continue actively monitor and contribute to these activities in 2018



Future Vision

GS1 Healthcare future strategy



- During 2018 the next GS1 Healthcare 3-5 year strategy will be developed, under the guidance of the GS1 Healthcare Leadership Team.
- This strategy will govern the direction of the GS1 Healthcare focus and operations, including strategic priorities.
- At the time of finalisation of the strategy, communications will be made to all GS1 Healthcare stakeholders.

Drive strategic implementation of regulatory related global initiatives



UDI

- Working with GS1 US on the GS1 renewed accreditation as UDI Issuing Agency: [application submitted](#). [Renewed accreditation will be for 7 years](#).
- Working with MD industry, MedTech Europe and EU Commission on facilitating the implementation of the EU UDI system using GS1 standards (See slide 14)
- IMDRF: support work on the draft IMDRF Guide on UDI use and UDI application

EU FMD

- Working with PH industry, EFPIA and GS1 MOs on leveraging the use of the GS1 standards for implementing the EU unique identifier: [position papers and coordinated advocacy activities at the local, EU and global level](#).



Background

- The Pharmaceutical industry's use of the GDSN has lagged behind Medical Devices considerably. The objective of this project is to clearly define the master needs of the Pharma industry and develop a strategy to address them.

Strategy components

- A defined strategy including the use case and a minimum set of data elements to support its specific objective, in combination with users, GDSN Data Pools and MOs
- In 2018 the strategy will be rolled out in line with the agreed roadmap

African regional conference



- In May 2018, the first GS1 Healthcare Regional Conference, themed: Track and trace for access to safe medicines will be held in Addis Ababa, Ethiopia.
- The conference will be conducted in partnership between GS1 and aid organisations, including USAID and UNFPA.
- The objective will be to bring forward the necessity and benefits of global standards to stakeholders across the African healthcare environment, especially regulatory bodies.

Support inter-governmental organisations



WHO/GAVI - Vaccines

- Workgroup has closed down. Continuous cooperation with WHO, GAVI and DCVMN on implementation of recommendation for GS1 standards.

PATH – Vaccines

- Support PATH in developing a value proposition for global standards in identification and barcoding of vaccines

World Bank Advisory Group

- Continue to participate in Private Sector Advisory Council to build traceability capabilities in developing countries

Digital Bridge Service proof of concept



Objective

- The Digital Bridge Service concept is a proposed solution to address the evolution of mobile and digital technology as a “positive disruptor”
- In 2017 a strategy and solution framework was developed to address the sector’s needs, including a path forward as the use of mobile and digital devices increases in healthcare was developed
- In 2018, this strategy and roadmap will be tested via a proof of concept project and documented in a resulting report.



Public Policy Master Data Subgroup

- Under the auspices of the GS1 Healthcare Public Policy workgroup, form a work group to discuss and consider public policy requests for product master data (both medicines and medical devices) in healthcare

Healthcare Attributes for GS1 Cloud Phase II or later

- Work with industry stakeholders to define the healthcare attributes that would be useful for inclusion in a later phase of the GS1 Cloud
- Ensure understanding of healthcare specific requirements / validations for databases feeding and receiving data from the Cloud



Ongoing Activities



- All Public Policy activities are open to GS1 Healthcare **global members** and GS1 MOs
- Comprehensive and “real time” documentation about existing and developing regulatory and customer requirements from across the world relating to use of GS1 standards. Three levels of information:
 - [Overview slide deck summarizing the “country adoption” trends and overall roadmap](#)
 - [Country-level summary slides](#)
 - [Detailed information and references in GS1 Healthcare Public Policy Database](#)
- Development of position papers and input to requests for regulatory consultation to drive global harmonisation
- Public Policy Work Team meetings held every two weeks via teleconference
- Open face-to-face sessions twice per year during GS1 Healthcare Global Conferences

Member Organisation Support



- Support and information from GO subject matter experts both remotely and face-to-face as needed
- Monthly Healthcare Interest Group (HIG) meetings via teleconference, with face-to-face meetings during global GS1 Healthcare conferences and Global Forum
- Reference materials continuing to be developed based on issues raised by MOs
- “Real time” information sharing via Yammer
- For MOs with local user groups, annual voting and nomination rights for representatives on global GS1 Healthcare Leadership Team which drives the strategy and direction
- Enhanced regional support by allocation of healthcare team members to specifically support, e.g., APAC, Latin America, etc.

Global Member Activities



- Continued support, assistance and information to GS1 Healthcare members, with activities such as:
 - Weekly/monthly meetings with global updates about all GS1 Healthcare activities
 - Ensuring all documents are online in respective Community Rooms (LT and global members)
 - Providing discounted access to Global GS1 Healthcare Conferences as well as participation in strategic side meetings
 - Ensuring ready access to unique Public Policy network and work efforts
 - Facilitating annual nomination and voting for global GS1 Healthcare Leadership Team
- Continue Account Management programme to provide more value and better service for our users

Global GS1 Healthcare Conferences



- Two Global GS1 Healthcare Conferences on a geographically-rotating basis
- **2018 Bogota, Colombia (April),
Bangkok, Thailand (October)**
- A three-day event for healthcare leaders from private/public industry and government agencies to exchange information on the progress of worldwide efforts to improve patient safety, supply chain security and efficiency using GS1 standards
- Benefits of participation:
 - Sharing the latest news on industry and regulatory developments in automatic identification, traceability and electronic product catalogues
 - Learning more about existing supply chain data standards
 - Hearing how GS1 works with hospitals, pharmacies and patients
 - Networking with other stakeholders from around the world using this unique, neutral and global platform

Presentation at Conferences / Events



- In 2017 GS1 Healthcare presented at more than 55 conferences in 24 countries
- Some examples include:
 - IDMP Compliance Challenge: Navigating Through Uncertainty, 27-29 March, London, UK
 - Serialisation Event - Beyond FDM Compliance, 30 March, Etten-Leur, The Netherlands
 - Logipharma, 25 April, Montreux, Switzerland
 - 5th Annual Medical UDI & Traceability Forum, 16-18 May, Brussels, Belgium
 - SMI's Pharmaceutical Logistics conference, 18-19 May, London, UK
 - Seminario Internacional GS1 "HealthCare 2017, Santiago, Chile
 - Medforce, 6-7 June 2017, Hamburg, Germany
 - Clinical Trails Supply Nordics, 7-8 June 2017, Copenhagen, Denmark
 - Pharmco CMO Summit, 14 June 2017, Lisbon, Portugal
 - SMI In Vitro Diagnostics, 14-15 June 2017, London, UK

Detailed list available at:
www.gs1.org/healthcare/events

Liaising with other SDOs



- Liaising with standard development organisations to strengthen GS1's perception as the most used standard for supply chains
- Memorandums of Understanding with:
 - ICCBBA - terminology, coding and labeling of medical products of human origin (blood, tissue, organs)
 - HL7 (Health Level Seven International) – standards for electronic health information that supporting clinical practice (e.g., eHealth records)
 - IHTSDO (The International Health Terminology Standards Development Organization, Snomed) - global standards for health terms
 - JIC (Joint Initiative Council) – Group of key healthcare SDOs, ISO, CEN, HL7, CDISC, IHTSDO, IHE, DICOM, and GS1 working to ensure interoperability between their standards
 - ISO – facilitating collaboration with the European Medicines Agency and other regulators (FDA, Japan,...)
- Work in progress:
 - Revision of the technical specification about medicinal product barcoded identification (improve document, increase accuracy in highlighting junction points between regulatory data and supply chain data (such as for FMD)).
 - Development of a specification for digital information access with supply chain barcode.

Participation in eHealth Activities



- Educating Health Informaticians about GS1 standards and their applicability in the Healthcare industry
- Influencing standard developments so that GS1 identification key (and, where relevant GS1 EDI standards) are taken in consideration at least as examples in new / revised standards
- Participate to regulatory implementations for adverse event reporting, identification of medicinal products, so that GS1 standards are considered as the preferred enabler where applicable
- Participate to European projects to provide demonstrator of GS1's efficiency for cross-border prescription and dispensation (including EU-US)
- Active participation to EMA's IDMP implementation task force

Increase Operational Efficiency



- The growing GS1 Healthcare membership base, the increasing workload of the GS1 Healthcare team, and ever increasing activity of GS1 MOs in healthcare has lead to a need to look at internal processes and tools to drive efficiency
- In 2018 we will aim to:
 - Complete a review of the public website to increase ease of access to information
 - Update the GS1 Healthcare MO Zone (MO resource centre) to create easier access to materials by GS1 MOs
 - Implement the GS1 CRM (Dynamics) in healthcare for management of global member and MO data
 - Implement Microsoft Office 365 (i.e.Teams) to drive greater efficiency and information sharing between staff
 - Develop an interactive world map presenting an overview of regulatory developments in healthcare

Additional unplanned tasks

GS1 enables healthcare's digital thread 2018-2022



The digital thread's multi-dimensional view encompasses:

1. Key stakeholders
2. Relationships between stakeholders and to the patient as the ultimate beneficiary
3. The role of GS1 standards in enabling these connections
4. The current status of deployment of GS1 standards
5. The projected status in 2022 as a result of our strategic efforts

Processes

Physical flow ⊖

Supply chain

Product recall

Patient data

Transactional data ⊕

Reimbursement

Strategies

Current business ⊕

Patient/provider ⊕

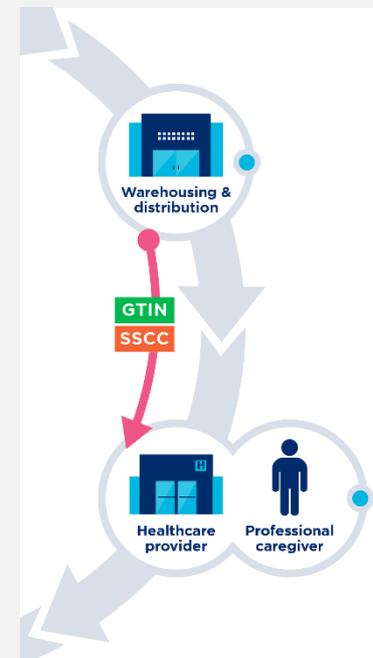
Disruptive

Relationships

GS1 standards

Status 2018

Status 2022



GS1 GSMP Mission Specific Workgroup: Messaging for Verification of Pharmaceutical Saleable Returns



Background:

- *Effective 27 November 2019, US DSCSA requires verification of saleable returns*
- *DSCSA expects supply chain parties to exchange information in an "interoperable, electronic manner... comply with widely recognized international standards development organization."*

Requested per GSMP WR 18-061 (GS1 HC US Rx workgroup)

Scope / Deliverable of MSWG:

- *Specification of a streamlined, GS1 messaging standard including Request & Response format for Verification of Pharma trade items identified by GTIN, Serial Number, Lot & Expiry*
- Approved by IESC on 21 May, call-to-action issued on 12 June, Workgroup kickoff on 21 June
- Roster (as of 12 July): > 25 active members
 - 4 Manufacturers, 4 Distributors, 10 SPs, 6 MOs, 1 Logistics Provider, 1 Data Pool, 1 HAD
 - Chairs: Jeff Denton (ABC), Allison Sheldon (Pfizer), Elizabeth Waldorf (Tracelink)
- BRAD community review 12-27 July; Solution Development planned for August-September
- Completion of standard development anticipated in Q4 2018

GDSN and implant registries



- ICOBRA: International Collaboration of Breast Registry Activities, 74 societies of Plastic Surgeons are members.
- ICOBRA decided to use GS1 as the barcode standard for identification of breast implants in various national registries.
- ICOBRA is looking for standardised data-exchange about breast implants for benchmarking and quality monitoring: to improve patient outcomes.
- ICOBRA defined a core data set to be used globally in breast implant registries and this will be submitted as a work request to GSMP to have necessary fields added to GDSN.

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