The Global Language of Business

GS1 Healthcare
2019 Strategic Priorities

February 2019

Note: The content contained within may be subject to change due to activity reprioritisation and resource availability.

GS1 Healthcare
2019 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.

Drive the current business

- Health informatics education program
- Roll out guideline for use of GS1 standards in pharma clinical trials
- *UDI standards and policy*
- Working with Africa
- Support inter-governmental orgs
- *Operationalise current AIDC standards, e.g GTIN allocation rules*
- *Accurate and trusted data*
- Solution Provider activities
- Drive strategic implementation of regulatory related global initiatives

Healthcare Providers

- Development of tools to assist healthcare provider roll-out
- GDSN and implant registries
- Continued cooperation with clinical stakeholders
- *Patient and caregiver ID*
- *Primary pack ID*

Leverage new technologies

- *Digital Link service*
- *Monitoring digital disruptors*
- Participation in eHealth activities
- *Develop Digital Thread 2.0*

Ongoing Activities

- Public Policy activities
- MO Support
- Global Member Activities (HRM)
- Global GS1 Healthcare Conferences
- Liaising with other SDOs
- 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 2019 in *italics*

Drive the current business

Health informatics education program for MOs

- Health IT standards are complex and difficult to understand
- Where does GS1 provide value to Health IT standards?
- Develop simple health informatics education videos explaining 3 health informatics topics designed to assist MOs gain knowledge but also explain to their industry stakeholders

Roll out of guideline detailing the use of GS1 standards in pharma clinical trials

- Using communication tools developed, work with industry and GS1 MOs to roll out the GS1 Application Standard for Identification of Investigational Products in Clinical Trials
- Based on industry feedback, work to develop further resources as needed and explore the need for developing an application standard for additional GS1 standards – beyond identification and barcodes, this may include EDI messages.
- Clearly position GS1 standards compared to IDMP for clinical trial investigational product identification.

UDI standards and policy

- 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.
- The GMN standard must be updated to align on NEW requirements from the EU Commission on the Basic UDI-DI structure (ie. Check-digit and maximum 25 characters) and definition, target date May 2019.
- A WG on Merger & Acquisition is meeting on a weekly basis to define the rules for the GMN and for the GMN/GTIN in this case.
- A specific Work Group on UDI in EU is meeting on a monthly basis + recorded webinar: lead by GO and composed by all GS1inEU MOs (PP, AIDC and GDSN experts + 1 dedicated coordinator from GS1inEU).
- Develop and deliver the UDI Certification Programme.
- Develop MO Manual to support implementation of the GS1 UDI Policy

Working in Africa

- **Regional coordination has been appointed to strengthen GS1 healthcare engagement in sub-Saharan Africa to:**
- Support and strengthen local GS1 MOs knowledge and capabilities.
- Support local governments and other initiatives with implementation of GS1 standards
- Better understand the country and regional specific challenges for standard implementation
- Together with local MOs develop a strategy to address these challenges and drive global harmonization

- In September 2019, the second GS1 Healthcare Regional Conference will be held in Nigeria, with the theme: Track and trace for access to safe medicines. The conference will be conducted in partnership between GS1 and international organisations, including World Bank, Global Fund and USAID, hosted by NAFDAC, the local regulatory authority. 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 and PATH – Vaccines

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

World Bank Advisory Group

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

USAID

- Continue to support USAID implementation of GS1 standards, including GDSN

Cooperate with and train humanitarian organisations to harmonise procurement requirements

- Continue, with partnership of GS1 MOs where appropriate, to support DCVMN, Global Fund, Gavi and other humanitarian organisations.
- Cooperate with DCVMN regarding training for vaccine manufacturers in China and Brazil

Operationalise and link current AIDC 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.

- In 2019:
  - Review and update value propositions per audience with messaging around value, not compliance, add use case information as necessary
  - Review and update the Healthcare GTIN Allocation Rules so they are aligned with the GTIN Management standard, as much as possible without negatively impacting the specificity needed in healthcare and support the Clinical Trials application standard
  - Stocktake current resources and identify needed application specific user guides
  - Start to develop further education tools – for GS1 MO and global member use
  - Start to develop and deploy metrics to track progress of implementation

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

- The goal is to improve the quality, accuracy, consistency, completeness and timeliness of master data shared between healthcare stakeholders. This project will consider best practices and actions which can be taken starting at the source and maintained through the healthcare value chain in order to ensure the data is fit for purpose. This includes GTIN construction and all associated master data attributes for both Medical Devices and Pharmaceutical products, the need for standardised data content and internal processes for ensuring quality data is maintained.
- In 2019:
  - Develop an industry data quality situational problem statement which will identify the areas that are in scope, specify the desired outcome for each area and the actions to be taken to achieve that outcome
  - Develop the goals, components, and deliverables in order to achieve the desired outcomes, these may include tools such as value propositions, communication activities and education
  - Start to develop metrics in order to measure progress towards the goal and a roll out plan
  - Start to execute the program and measure progress

Solution Providers 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

- The existing work plan takes into account areas of solution provider engagement that have been identified in the GS1 Healthcare 2018-2022 strategy

- Mission statement of the group:
  - Increasing the GS1 standards uptake
  - Improving the access of GS1 information for both MOs and SPs
  - Engaging with Solution Providers that do not yet use GS1 Standards
  - Leading to a more efficient and coordinated work at global and local levels

Drive strategic implementation of regulatory related global initiatives

UDI

- Working with the relevant MO on the GS1 accreditation as UDI Issuing Agency/Entity: application submitted for accreditation in the EU, first will be for 5 years. Renewed accreditation in the U.S.A. pending, will be for 7 years.
- Continue to work with MD industry, trade associations and regulators to support the implementation of UDI systems using GS1 standards (e.g. EU, China, Saudi, Australia, Brazil). Contribute to the IMDRF Guide on UDI use and UDI application.
- Ensure implementation of the GS1 UDI Policy, in particular on data quality of GS1 related information in the US FDA GUDID, on processes and automation to allow regular data verification, and on anticipating on future needed beyond USA.
- A Public Policy master data work group has been created to consider public policy requests for product master data (both medicines and medical devices) in healthcare. This will be launched as soon as the EUDAMED data definitions are available Click to join > http://xchange.gs1.org/cr/ig/hc/iehppwt/pmdag/Pages/Home-wg.aspx

PH traceability

- Working with PH industry, trade associations, GS1 MOs and regulators to leverage the use of the GS1 standards for implementing the drug traceability: position papers and coordinated advocacy activities at the local and global level. Current activities cover countries in all Regions. In the EU for the FMD implementation, all EU Members States have decided to use GS1 standards for identification (except Italy, who has until 2025).
- Increasing awareness around EPCIS and Event-Based Traceability, providing training and support to/for MOs where requested

European Association for Hospital Pharmacists

- Clarify the use of GS1 standards for aggregation and drive identification on primary level packaging for bedside scanning

Aggregation best practices

- Many questions are being asked about the best practice method to apply GS1 standards for aggregation of the contents of related packaging levels or logistics units. In 2019, a guideline detailing this best practice application will be finalised.

Overall activities will take into account the areas of work identified in the GS1 Healthcare strategy 2018-2022.

Healthcare Providers

Development of tools to assist healthcare provider roll-out

- *Perfect hospital document:* Develop a document describing the "hospital of the future - using GS1 standards"
- *Step-by-step process implementation plans:* Finalise the last two of the top three step by step plans for implementation of GS1 standards in clinical processes. Bedside scanning is complete. Implants in the OR and Patient Discharge will be completed in 2019.
- *Remote Healthcare Provider Training:* Develop the 2018 'hospital training' slide deck, to provide detailed information about the structure and clinical processes of hospitals, into interactive online training course. To be finalised by end of 2019.
- *Continue monthly Healthcare Provider webinars:* To showcase examples of GS1 implementation in the Healthcare Provider environment
- *Healthcare provider database:* Finalise the business requirements and open the database publicly for all healthcare stakeholders to access; Complete the 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

GDSN and clinical registries

- ICOBRA: International Collaboration of Breast Registry Activities, 17 societies of Plastic Surgeons are members.
- 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.
- Final work to be discussed with manufacturers (2019) and HC-LT. Work request will be prepared and submitted before the end of June 2019.
- Work has progressed as far as possible, manufacturers must now be consulted for their commitment for any work request to be able to be submitted.

Continued engagement with clinical stakeholders

- International Society for Quality in Healthcare (ISQua) – global accreditation body for organisations such as Joint Commission International (JCI)
  - Continue to provide content for Fellowship Program and have reciprocal participation on the agenda at conferences
  - Finalise the academic paper / literature review about the benefit of barcodes in hospitals submit to the ISQua Journal
  - Joint Commission International
  - Commence relationship and commence at least one area of collaboration
- International Hospital Federation (IHF)
  - Continue to build stronger relationship and have reciprocal participation on the agenda at conferences
  - Share with the HCLT a working plan for collaboration activities by end 2019
- 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
- World Health Organisation (WHO)
  - Map the WHO surgery safety checklist and identify the points where GS1 standards could play a role
- Use of GS1 standards
  - Leverage relationships with healthcare provider associations to create programs to drive hospitals to use GS1 standards, eg, barcodes or GLNs (where these are already present due to regulatory and other activity)
- Considerations on applications of EPCIS in Hospitals for
  - Events at bedside and in the operating theatre
  - Patient treatment incl. administration of medication

Patient and Caregiver ID

- Increase education and implementation of GS1 identifiers and barcodes for patient and caregiver identification to enable positive patient identification throughout the care process.
- In 2019:
  - Undertake information gathering regarding current practices and consolidate this for knowledge sharing
  - Start to develop a “how to” implement process guide and relevant communication tools
  - Develop value propositions or value statements based on role
  - Start to rollout/implementation for patient and caregiver identification
  - Start to develop and deploy metrics to track progress of implementation

- Considerations on applications of EPCIS in Hospitals with regard to identification of caregiver & recipient

Primary pack ID/ Single Unit ID

- 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.
- In 2019, start to:
  - 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
- Due to conflicting manufacture and hospital priorities relating to FMD implementation, this topic will be deprioritised until industry commitment is provided.

Leverage new technologies

Digital Link service

- 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.
  - A proof of concept demonstration App was developed.
  - The first half of the Digital Link standard was developed (i.e. URI data syntax and creation from a GTIN).
  - Phase 2 was launched in late 2018 to develop the functional requirements of the resolver service, with an expected completion in June 2019. Join here: https://www.gs1.org/standards/development-work-groups#DigitalLInk. Will need to identity additional HC use cases as phase 2 progresses.

- Positive discussions under way with Pharma.be (Belgium Luxembourg) on eLeaflet pilot, physical meeting was held on 15th January 2019. Moving to a demonstration project.

- Overall activities will take into account the areas of work identified in the GS1 Healthcare strategy 2018-2022.

Monitoring digital disruptors

- 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.
- In 2019:
  - Assess current situation to understand baseline
  - Start to deploy a formal process of 'watching' developments
  - Commence building relationships with relevant healthcare innovators
  - Start to develop and deploy metrics to track progress of initiative

Participation in eHealth Activities

- Educating Health Informaticians about GS1 standards and their applicability in the Healthcare industry and acting as a liaison with SDO by taking part in their respective meetings and providing GS1 tutorials
- 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, WEF Project about health informatics and the Horizon 2020 project.

GS1 Healthcare Digital Thread 2.0

Support healthcare stakeholders with simple and powerful tools that bring GS1 standards to life throughout healthcare processes all the way to the patient and support their implementation.

In 2019

- Update the GS1 Healthcare Digital Thread format to be an interactive webpage rather than the current PDF format
- Develop the first ‘virtual reality’ interactive educational tool to communicate the benefits of GS1 standards in healthcare provider environment
- Develop a business case for future examples / use cases to be demonstrated through virtual reality

Ongoing Activities

Public Policy Activities

- All Public Policy activities are open to GS1 Healthcare **global members** and GS1 MOs
- Introduction/training to (potential) global members
- Comprehensive and "real time" documentation about existing and developing regulatory and tender requirements from across the world relating to use of GS1 standards. Three levels of information:
  - Overview slide deck summarising the "country adoption" trends and overall roadmap
  - Country-level summary slides
  - Detailed information and references in GS1 Healthcare Public Policy Database
  - Healthcare Public Policy Interactive World Map
- 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
- Regulatory ThinkTank during the 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. Increased support in Africa will be facilitated by a staff member based in that region.

Global Member Activities (HRM)

- Continued support, assistance and information to GS1 Healthcare members, with activities such as:
  - Leading interactive 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
  - Facilitating relationships between global members and local GS1 Member Organisations
- Continue Relationship 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
- 2019 Noordwijk-Amsterdam, the Netherlands (March) and New Delhi, India (November)
- 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 about industry and regulatory developments in automatic identification, traceability and electronic product catalogues
  - Learning more about existing supply chain data standards
  - Hearing about best practice GS1 standards implementations in hospitals and pharmacies to increase patient safety
  - Networking with other stakeholders from around the world using this unique, neutral and global platform

Liaising with other SDOs

- Liaising with standard development organisations to strengthen GS1's perception as the most used standard for supply chains and enable interoperability.
- 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,…)
  - IHE – reciprocal membership between GS1 and IHE
- Work in progress:
  - Development of a specification for digital information access with supply chain barcodes to be delivered by end 2019.
  - Preparation to take the Chairperson role for the Joint Initiative Council (JIC) in 2020. Transition commences the year before official appointment as the chairperson.

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 2019 we will aim to:
  1. Complete a review of the GS1 Healthcare website to increase ease of access to information
  2. Update the GS1 Healthcare MO Zone (MO resource centre) to create easier access to materials by GS1 MOs
  3. Finalise the implementation of GS1 CRM (Dynamics) in healthcare for management of global member and MO data
  4. Use increasingly Microsoft Teams for an improved communication flow within the team
  5. Assess the value of SmartSheets in Teams to support the project management efficiency

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