GS1 Healthcare
2017 Strategic Priorities

January 2017

GS1 Healthcare
2017 Strategic Priorities

Vision: To be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders seeking input and direction for global standards in healthcare for patient safety, supply chain security & efficiency, traceability and accurate data synchronisation.

Mission: to lead the healthcare sector to the successful development and implementation of global standards by bringing together experts in healthcare to enhance patient safety and supply chain efficiencies.

Our Strategic Objectives are:

Healthcare Providers

- *Healthcare Provider (HCP) rollout and MO HCP training*
- Healthcare provider database
- Intensify cooperation with clinical stakeholders such as IHF, ISQua EAHP, patient safety organisations
- *Submit GS1 paper to clinical journal*

Standards and Guidelines

- Global Solution Provider activities
- Alignment between GS1 and Snomed
- *Extending Healthcare AIDC Solutions*
- *Health informatics standards map*
- *EPCIS in hospitals group*
- *Explore GS1's role with clinical trials*

Future Vision

- Drive strategic implementation of regulatory related global initiatives (e.g. UDI, EU FMD, GTFC, APEC Roadmap)
- Data Quality in Healthcare
- *Pharma data strategy*
- Support organisations, e.g., GAVI, USAID, UNFPA to develop supply chain visibility
- *Mobile scanning strategy and transition plan*

Ongoing Activities

- Public Policy activities
- MO Support – *account management*
- Global Member Activities – *roll out account management*
- Global GS1 Healthcare Conferences
- Presentation at conferences and events
- Liaising with other SDOs
- Participation in eHealth activities

Our Strategic Measures will be:

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 2017 in italics

Healthcare Providers

Healthcare provider roll out and MO Healthcare provider training

- GS1's activities will involve engagement of healthcare providers and patient safety organisations to drive understanding of the benefits of GS1 standards. A focus on patient safety, a safe working environment, supply chain and more time to actually spend with the patient.
- Specific training will be run for GS1 MOs to provide detailed information about the structure and clinical processes of hospitals

In 2017 even more support will be provided to GS1 MOs to engage healthcare providers, including via a training course.

Healthcare Provider Database

- In 2016, a detailed repository to pool information about hospital implementation of GS1 standards worldwide was created
- This combines sources of information from MOs, conferences, networks, publications, global members to create a common knowledge base
- Sharing what is happening and latest developments – between the MO's – with our users
- During 2017 we will develop:
  - A video guide & webinar
  - Develop the statistical & analysis function in the database
  - Update the database based on needs and feedback
  - Work with colleagues and stakeholders to continually update the database with the latest implementation information

Intensify cooperation with relevant hospital organisations:
ISQua, IHF and EAHP

- International Society for Quality in Healthcare (ISQua) – global accreditation body for organisations such as JCI
  - Provide content for Fellowship Program
  - Reciprocal participation and presentation at conferences
  - Explore how global standard barcodes may provide a role in helping hospitals to achieve accreditation
- International Hospital Federation (IHF)
  - Build stronger relationship
  - Mapping of existing GS1 activities on local level and future opportunities
  - Reciprocal participation and presentation at conferences
- European Association for Hospital Pharmacists
  - Existing MOU
  - Drive identification on primary level packaging to enable bedside scanning
  - Joint activities at conferences in promoting global standards

Submit GS1 standards paper to a peer reviewed healthcare journal

- Topic：How can Global Standards benefit healthcare providers
- A literature review using various sources:
  - GS1 Healthcare Reference Books
  - McKinsey report
  - Reports from US FDA, NHS, ANMAT, others
  - Healthcare Provider Database & Public Policy Database
  - GDSN & GUDID data in healthcare
  - Existing journal papers
- Methods：
  - Study the cases & public policy by timeline/region/country
  - Look into the benefits and ROI
  - Examine and explain how the sectors and processes in hospital can be benefit

The paper will be submitted in first half of 2017.

Standards and Guidelines

Global Solution Provider program

- 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
- 12 month program commencing November 2016
- 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
- Relevant working groups will be formed

This project will be finalised by December 2017

Alignment between GS1 and Snomed

- SNOMED: clinical terminology which enables computerisation of clinical observations, processes or decisions.
- SNOMED has local (country specific) extensions to meet local needs. One of these extensions is to support prescription-dispensation of medicinal products.
- There is a link between SNOMED and the prescribed physical items. How to ensure that this link is safe? How to avoid requirement to print some SNOMED code on medicinal product packages?
- Joint work agreed in May 2016, to prepare a guidance on how to link SNOMED to GTIN. Involvement of experts from AUS, NZ, UK, CA. Deliverable due by End 2016.
- Might be slightly delayed (because of public consultation)

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, at bedside 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.

The AIDC solutions work will start at the Beijing Conference HIG Meeting

Health informatics standards map and training

- Health IT standards are complex and difficult to understand
- Where does GS1 provide value to Health IT standards?
- Purpose of this task here is to provide a high level chart illustrating standards which benefit or should benefit of GS1 standards (ID keys, processes)
- Develop a training accordingly

- One specific Health IT standard is IDMP. A first training has been set-up in 2016. An advanced training is planed for 2017.

- Training audience: GS1 MO

Advanced training for GS1 MOs will be run in 2017

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

- MO interest: AE, AU, BE, CH, DE, DK, FI, GB, NL, SE, US

- Potential for GS1 interest group of stakeholders
  - Align on process steps and information required
  - Charter workgroup to develop an application standard
  - **MO input** needed: concrete visibility requirements around caregiving processes which MO users (clinics & caregivers) want to address in an event-based context

Explore GS1's role in 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 will explore opportunities to better articulate and document the role of GS1 in clinical trials
- Outcomes could include a guideline describing GS1 standards in clinical trials processes, clinical trials IT systems and others

Exploration of GS1's role in healthcare clinical trials will commence in November 2016 and extend during 2017

Future Vision

Drive strategic implementation of regulatory related global initiatives -1/2

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, Eucomed and EU Commission on facilitating the implementation of the EU UDI system using GS1: BASIC-DI concept and possibly new XML messages structure.

EU FMD:

- Working with PH industry, EFPIA and GS1 MOs on leveraging the use of the GTIN as the EU unique drug code, with potential national codes cross-referenced in a database: position papers and coordinated advocacy activities at the local, EU and global level.

Drive strategic implementation of regulatory related global initiatives -2/2

APEC Roadmap:

- Working with the US FDA, APEC WG leads and APEC Track & Trace WG on the final Roadmap: to be presented to APEC Q1 2017. Recommendation to use Global Data Standards (i.e. GS1) for drug traceability included.

Pharma Data Strategy

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.

Action

- Interview Data Pools, MOs and users where GDSN in succeeding to better understand what is working and what needs improvement
- Engage Pharma manufacturers and providers from the LT to determine a forward strategy
- Develop a Value Proposition including use cases
- Develop a strategy and roadmap which meets the needs identified, in combination with users, GDSN Data Pools and MOs

Develop a strategy and roadmap to address the Pharma data needs

Data Quality in Healthcare

Vision: Data fit for the intended purpose

Inconsistent, incomplete and incorrect data increases the risk of patient safety errors and the cost of healthcare across the entire supply chain.

Quality data means:

- Reduced rework caused by data correction and need for internal audits
- Improved care by ensuring data accuracy at the point of care
- Consistent use of data attributes across all stakeholders

Input and participation from providers is critical so that the programme meets the specific needs of the internal hospital processes, pharmacies and other data recipients.

Develop data quality programme for healthcare which increases the provides' trust and use of GDSN data

Potential savings from improved data quality[3]

By conservative estimates, more than $100 million in potential savings can be achieved by addressing product data quality issues by making only minor adjustments to existing processes.

Support organisations such as GAVI, USAID and UNFPA to develop supply chain visibility

- **WHO/GAVI - Vaccines**
  - Further hold Secretariat for VPPAG barcode subgroup on implementation of global standard for vaccines

- **USAID/UNFPA – Reproductive Health (RH) Products**
  - Secretariat for forum of subject matter experts from industry/public sector for to provide recommendations for usage of global standards in the RH supply chain to enable visibility
  - Development of procurement requirements for drugs and medical devices used for reproductive health

Mobile scanning strategy and transition plan

Objective

- Develop a strategy and roadmap to address current needs and establish a path to address the evolution of this technology as a "positive disruptor"

Action

- Engage LT members and identify issues, concerns and an ideal path forward
- Expand engagement to the broader user group and document the sector's current state and future vision
- Develop a strategy and roadmap to meet the sector's needs

Develop a strategy and roadmap to address the sector's needs including a path forward as the use of mobile devices increases in healthcare

Ongoing Activities

Public Policy 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

During 2017, Account Management of some MOs actively working in healthcare will commence

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
- Commence Account Management programme to provide more value and better service for our users

During 2017, Account Management of our Global Members will commence

Global GS1 Healthcare Conferences

- Two Global GS1 Healthcare Conferences on a geographically-rotating basis
- 2017 – Berlin (4-6 April), Chicago (17-19 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 2016 GS1 Healthcare presented at more than 35 conferences in 17 countries
- Some examples include:
  - Access to safe medicines, 19-20 January, London, UK
  - Pharma & Cosmetics in the GCC region, 10-11 February, Dubai, UAE
  - IDMP Compliance Challenge: Strategy and Practice, 15 April, Frankfurt, Germany
  - Clinical Trial Logistics, 18-19 May, London, UK
  - POLITICO Annual Health Care Summit, 11 October, Geneva, Switzerland
  - HDA Traceability conference, 10-11 November, Washington, USA

Detailed list available at http://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 Organisation, 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

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)

Unplanned strategic activities

Unplanned strategic activities

- Traceability – as reinvigorated activity with GSMP involvement
- Global Fund Advisory Group – opportunity to participate in activities to build traceability in developing countries
- Basic UDI-DI – standards development
- Implant registries (ICOBRA)
- Healthcare GTIN allocation rules updates
- Encoding NTIN in EPCIS 2 pager

The GS1 Healthcare Team

Ulrike Kreysa
Vice President
Healthcare

Chuck Biss
Senior Director,
AIDC Healthcare

Pete Alvarez
Senior Director Healthcare,
Master Data Management

Tania Snioch
Director Healthcare

Géraldine Lissalde-Bonnet
Director Public Policy

Craig Alan Repec
Senior Manager
EPC Global & Technology

Sophie Molle
Manager Healthcare

Els van der Wilden
Director Healthcare Providers

Christian Hay
Senior Consultant Healthcare