

GS1 Healthcare 2020 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

- Operationalise and link current AIDC standards to business need
- Increase awareness about and drive toward trusted, complete, quality master data
- Roll out of guideline detailing use of GS1 standards in pharma clinical trials
- Drive strategic implementation of regulatory related global initiatives (not UDI)
- UDI standards and policy
- Driving global standards implementation in Africa
- Support inter-governmental orgs

Healthcare Providers

- Collaboration
- Clinical engagement
- Training and tools
- Patient and caregiver ID

Leverage new technologies

- Digital Link service
- Monitoring digital disruptors

Ongoing Activities

- Global GS1 Healthcare Conferences
- MO Support
- Business development / services to global members
- Public Policy activities
- eHealth activities
- Interaction with other SDOs
- Solution Provider activities
- Increase communication

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)





Drive the current business

Operationalise & link current AIDC standards to business needs



Ensure GS1 AIDC standards, guides and Global Office position and value proposition papers reflect the current needs in healthcare. Update as needed.

Healthcare GTIN Allocation Rules

- 1) Complete the GTIN Allocation Rules
- 2) Identify & develop support tools that help use Rules
- 3) Develop training material to educate (what is new, what has changed and how it impacts the membership)

March 2020
March 2020
June 2020

Educate & help drive deeper implementations of GS1 identification Keys

- 1) With input from the HIG, evaluate current AIDC tools and resources and identify top needs
- 2) Determine what additional tools are needed to improve AIDC implementation

July 2020
October 2020

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



Improve the quality, accuracy, consistency, completeness and timeliness of master data shared between healthcare stakeholders.

Improving data quality at the source

Present draft strategy for data quality to leading MOs and gain buy in

Propose draft strategy for data quality to HCLT - gain their buy in

Commence strategy roll out

Report to GS1 Healthcare Leadership Team regarding progress

March 2020

May 2020

July 2020

Quarterly

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



Enable usage of GS1 standards in the specific supply chain for clinical trials in the pharmaceutical industry

Continue to roll out AIDC standard

Presentation at 4 external conferences in 2020
GS1 Forum education session
Session at GS1 Healthcare conference, Paris

End 2020
February 2020
March 2020

Deliver EDI guideline

Ratify EDI guideline
Deliver detailed mapping documents per message
Communicate new standards / pilot

February 2020
April 2020
April – December 2020

IDMP and Clinical Trials

Develop a clear communication about where GS1 standards and IDMP fit for clinical trials

June 2020

GLN allocation

Initial meeting to discuss GLN allocation at Paris GS1 Healthcare conference
Work group to deliver necessary guideline updates

March 2020
December 2020

Drive strategic implementation of regulatory related global initiatives (not UDI)



Ensure harmonisation across national/regional regulatory requirements by sharing education and good practices on the use of GS1 standards for traceability of medicines

Support regulators in developing harmonised of PH traceability requirements

Work on harmonisation for specific countries – e.g. Australia, China, Columbia, Egypt, EU, India, Malaysia – with users and MOs
Promote the use of the Regulatory Roadmap on traceability
ICMRA guidance and WHO policy on interoperability of T&T systems
APEC Roadmap on supply chain security

Work on the follow-up of the African Call to Action supporting donor and local authorities

Ongoing
At least 5 countries "trained"
Delivered by end 2020
Upon request – at least 1 workshop/year
see slides on Africa for more details

Facilitate implementation of PH traceability requirements

Working with PH industry, trade associations, GS1 MOs and regulators to leverage the use of the GS1 standards on specific topics: e.g. aggregation v.2, use of GLN to support traceability implementation

Ongoing – at least 3 advocacy docs/year

Increase awareness and education on data exchange standards

Increasing awareness around GDSN, providing training and support to/for MOs where requested
Increasing awareness around EPCIS and Event-Based Traceability, providing training and support to/for MOs where requested

Ongoing

UDI standards and policy – 1



Ensure GS1 is accredited (renewed) as issuing agency/entity of UDI in the relevant jurisdictions and is complying with the related obligations. Educate regulators, MOs and industry on the accurate use of the GS1 standards to implement UDI across the world.
Share good practices and expertise demonstrating the need for global harmonisation of UDI requirements.

UDI in the USA

Support in "correcting deficiencies" identified in AccessGUDID
Develop and submit the US FDA UDI Annual Report
Ensure renewed accreditation as Issuing Agency for 7 years

Ongoing, daily basis
Delivered end of 2020
Ongoing

Other UDI systems

Support the IMDRF work on UDI
Support AHWP UDI activities as Liaison Member
Support dev. in Australia, Brazil, China, Egypt, Saudi Arabia, South Korea and monitor dev. in other countries

Upon request
At least once per year
Ongoing

GS1 UDI Policy

Develop and deliver UDI Certification program via eLearning and face to face where required
UDI workshop for MOs

UDI Yammer group and UDI calls for MOs
GS1 UDI Policy Implementation Manual for MOS

Module 2 by end 2020

Session during the Global Forum (Feb. 2020) and one at each Regional Forum (Q3 2020)
Ongoing and monthly basis
Ongoing

UDI standards and policy – 2



Ensure GS1 is accredited (renewed) as issuing agency/entity of UDI in the relevant jurisdictions and is complying with the related obligations. Educate regulators, MOs and industry on the accurate use of the GS1 standards to implement UDI across the world. Share good practices and expertise demonstrating the need for global harmonisation of UDI requirements.

UDI in the EU

- Update GMN webpage to add a GMN generator
- Contribute to MedTech EU (MTE) Guidance on Basic UDI-DI
- Participate in EU COM UDI Expert Group and in MTE UDI Task Force
- Develop paper on "manufacturer vs. Brand owner"
- Support the GDSN and EUDAMED discussion
- Ensure GS1 role as Issuing Entity – assessed in 5 years

- Delivered by Q2 2020
- Delivered by Q1 2020
- Quarterly basis
- Delivered by Q2 2020
- As needed
- Ongoing

UDI in the EU - EUDAMED

- Develop GDSN mapping for the EUDAMED UDI attributes and keep current with each release of their data dictionary
- Add new attributes to the GDSN standard via GSMP (target approval in GSMP May 2020, depending entering a Work Request latest February 2020 and approval of attributes in GSMP)
- Add new attributes to the GDSN network release

- Complete Version 5 analysis February 2020
- Timing to be coordinated with the EUDAMED releases
- Work with community to determine release timing for HC attributes, develop implementation plan



Driving global standards implementation in Africa



Drive global standards implementation in Africa while strengthening MO knowledge and collaboration in the healthcare sector.

<p>Provide platform for MO communication and collaboration</p>	<p>Organise AHIG call Provide support via mail, calls & Yammer Organise meetings during GS1 and regional conferences</p>	<p>Monthly Ongoing Minimum Global Forum + GS1 HC</p>
<p>Build MO knowledge on GS1 standards in healthcare</p>	<p>Provide training during AHIG call Improve support and communication material (e.g. Deployment Kit, update pictures, workshop & training docs) Provide training in country and during conferences</p>	<p>Monthly Q2 2020 Deployment Kit Material Minimum 3 country visits</p>
<p>Provide support for AHIG project initiatives</p>	<p>Engagement regulatory bodies (led by GS1 Kenya) Shared approach master data & GDSN (led by GS1 SA) Engagement solution providers (led by GS1 Nigeria)</p>	<p>Ongoing, depending on actions by MOs, GO has facilitating and supporting role.</p>
<p>Provide support and build capacity for non-MO initiatives</p>	<p>Represent GS1 at conferences & workshops Support regulators and PP activities related to Lagos Call to Action Support financing and donor organisations (e.g. World Bank, USAID GHSC-PSM, Global Fund) Be the main point of contact for standards implementation for mosquito nets in sub-Saharan Africa</p>	<p>Ongoing Ongoing Ongoing Q1 2020</p>

Support inter-governmental organisations



Support donor and financing organisations in the drive for and implementation of GS1 standards in developing countries

UNICEF / Gavi / DCVMN (Vaccines)

Continuous cooperation with UNICEF, GAVI and DCVMN about implementation of GS1 standards
Help MOs resource DCVMN training sessions

Ongoing

2 per annum (June in Korea)

World Bank Advisory Group

Participate in Private Sector Advisory Council meetings to build traceability capabilities in developing countries

Quarterly

USAID / Global Fund

Participate at donor meetings and seminars
Provide training to donor organisations

Estimate 4 per annum
Estimate 2 per year

Other donor organisations

Attend meetings and support with needs as required

Ongoing



Healthcare Providers

Collaboration



Continuous work with relevant global healthcare organisations to enhance knowledge of GS1 implementations in the healthcare provider communities to support the furthering of GS1 standards in the clinical supply chain and beyond into clinical work.

Joint Commission International	Establish working relationship	End of the year continuous exchange realised
International Hospital Federation (IHF)	Develop new vision for collaboration Develop document on cooperation IHF-ISQua and GS1 Presenting slot at the IHF Conference 2020	April 2020 May 2020 November 2020
ISQua	Submit abstract together with HC-provider for the ISQua Conference Review MoU for collaboration Develop document on cooperation IHF-ISQua and GS1	January 2020 April 2020 May 2020
Primary pack ID	Identify key organisations and healthcare providers with policy on or implementing bedside scanning Addition to the HP database of >60% identified best practice bedside scanning initiatives using GS1 standards Set up a multi stakeholder project group to create 1) a Good Practice document and 2) a common strategy towards implementation of this document	May 2020 Ongoing Q3 invitations/Q4 first meeting

Clinical engagement



Continuous work with clinical representatives to support the connection between the clinical supply chain and the benefits of GS1 in clinical work and advise GS1 Healthcare on understanding issues faced and how these can be overcome.

Clinical Advisory Committee	Facilitate at least six meetings Participation at global GS1 HC conferences Meeting with medical directors from industry	December 2020 March & November 2020 March 2020
Execute the CAC-roadmap	CAC-communication strategy	Mid 2020
Medical directors working at manufacturers	Identify a pilot group Meet with CAC and pilot group on the topic VBHC (and GS1) Define and decide on further steps	January 2020 March 2020 Mid 2020

Training and tools



Develop materials and trainings to support the MO community in understanding implementations in the healthcare provider environment and maintain tools for sharing best practices with the general stakeholder community.

Healthcare Provider webinars

Showcase examples of GS1 implementation in the Healthcare Provider environment: six in 2020.
Share the content with ISQua and WCEA.

End of the year: six webinars completed
End of the year: six

Healthcare provider database

Statistical & analysis function of the database
Video-guide and webinar
Update and upload a minimum of 10 cases

July 2020
July 2020
December 2020

Measuring and monitoring

Develop validated set of measurements for hospital/healthcare provider implementations
Used by 2 MOs to find hospitals willing to implement

Pilot completed Mid-2020
December 2020

Understanding GS1 in connection to VBHC

Develop an educational paper about the role of GS1 in value based healthcare
Interactive webinar for GS1 MO's

August 2020
December 2020

Healthcare provider training

Workshop with MO's at Global Forum
As requested, at Regional Forums
Finalise the first e-learning module(delayed in 2019)
Initiate and complete a second e-learning module

February 2020
Q3 2020
March 2020
December 2020

Patient and Caregiver ID



Drive implementation of GS1 standards for patient and caregiver ID

Respond to questions

Reactively respond to questions from MOs and industry about this topic

Ongoing

ISO DTS 18530 (patient identification, etc.)

ISO Standard passed by international ballot
Publication

April 2020
September 2020



Leverage new technologies

Digital Link standard in healthcare



Enable patients and healthcare professionals to scan a single GS1 barcode on a medical product or pack to access a wealth of digital information about the product.

Standard & Implementation guide

- The Standard v1.1 and the Global Implementation guide were motioned to Community Review, through 27 January
Note: Separate implementation guide for North America

BCS ratification expected end of February 2020

End to end system validation

- Global Office resolver, to be integrated into the registries platform, will not be a validated system
- Developers of resolver functions (i.e. manufacturers, providers, solution providers, etc.) will determine validated system compliance requirements for their intended use and target markets

Prevents use of GO resolver in regulated Healthcare applications
Enables integration of resolver functionality within existing validated system infrastructure

QR Code situation statement

- QR Code use w/ URL, but no GTIN, to access digital content, such as patient leaflets, is increasing in healthcare and is becoming a threat to the position of 2D DataMatrix as the preferred barcode for healthcare, especially pharmaceuticals
- Ease of QR scanning with digital devices w/out an App, and predominant market use in the Asia Pacific region, presents a threat to the use of the Digital Link standard to access digital content

Both points require focused HLT discussion and agreement on:

- How to position the Digital Link standard in healthcare
- Increased use of QR Code's potential influence on regulations and regulatory bodies

Note: Proposed workshop for Paris HLT meeting. Sooner?



Monitoring digital disruptors

Monitor developments which could impact GS1 Healthcare strategy and work in cooperation with Innovation department and HC LT

GS1 Trend Research Report

Provide healthcare input to next edition of the GS1 Trend research report

Commence May 2020
Report to be released in March 2021

Relationships with innovators

Based on identified trends that impact GS1 in healthcare engage with innovative organisations

Ongoing; based on assessment of GS1 Healthcare Leadership Team



Ongoing Activities



Global GS1 Healthcare Conferences

Organise global GS1 Healthcare conference as tool to engage stakeholders, enable interaction and communication and provide training and education on GS1 standards in healthcare

Paris, France

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

24-26 March 2020 together with the 15th GS1 Healthcare anniversary

Cairo, Egypt

17-19th November 2020

Member Organisation Support



Maintain and further increase the GS1 MO Healthcare community, support the exchange of information, build knowledge, develop tools and assets to support their work and engage in local activities as requested.

MO support	Support and information from GO subject matter experts both remotely and face-to-face as needed	Ongoing
Healthcare Interest Group meetings	1.5 hour teleconference Face to face meeting at each GS1 Healthcare conference	Monthly March 2020 / November or December 2020
Reference materials	Develop new reference materials – based on support of 5 MOs	As requested
Enhanced regional support	Continue staff allocation to support the various regions: APAC, LATAM and Africa	Ongoing
General Healthcare E-learning	Continue professionalization of support material for GS1 Member Organisations and members	Ongoing

Business development / Services to global members



Maintain and further develop global membership		
Develop a plan to increase GS1 Healthcare membership	Commence a work group to drive membership growth activities Develop an engagement plan / approach and define necessary tools CRM used as a tool for recording updated and new contacts	February 2020 June 2020 March 2020
Identify potential new members	Identification of companies which are not yet global members Define an engagement process to build CRM accordingly Define an action plan (based on work group feedback) in order to grow the membership with this target	March 2020 May 2020 September 2020
Extend to new key areas	Extend our outreach to other areas: animal health, dental and generics Identify key people in those areas in order to start the customer journey	Ongoing
Current services to be continued	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 Facilitating relationships between global members and local GS1 Member Organisations Annual global member newsletter Run quarterly 'Meet our MOs' webinars	Ongoing Ongoing Ongoing Ongoing January 2020 January, April, July, October 2020

Global Healthcare Public Policy activities



Develop, manage and maintain the relevant tools, meetings, platforms in order to ensure complete and real-time information of the GS1 Global HC PP Community. Establish and ensure trusted relationship with regulators, and HC stakeholders.

Global Healthcare Public Policy Community

Public Policy Work Team teleconferences (Global members and MOs)
Sessions at the GS1 HC Global Conferences (open)
Yammer group and HIG calls (MOs only)

Every two weeks
2 sessions per conference
Ongoing

Global Healthcare Public Policy Tools

Overview slide deck summarising the "country adoption" trends
Healthcare Public Policy Interactive World Map
Detailed information and references in GS1 HC Public Policy Database
New PP section on public GS1 Healthcare website (part of GS1 Healthcare website review)

Ongoing
Improvements and updates on a regular basis

Ad-hoc country/topic specific activities

Sub-Work Groups and additional materials as required, for example China PH
Support other Working Group as required, e.g. review of the GTIN Allocation Rules

Ongoing, every two weeks
Ongoing and as needed

Interactions with regulators

Think-Tank at GS1 HC Conferences and follow-up (incl. Lagos Call to Action)
Reply to public consultations
Contribute, as requested, to guidance, roadmap, tender requirements, regulation to ensure harmonisation and a favourable global environment for GS1 (see previous slides on PP)
Participate in EMA advisory boards on IDMP
Follow-up adverse event reporting work at WHO/EMA

At each Conference
When relevant
Ongoing, on a daily basis
Ongoing according to schedule
Ongoing

eHealth Activities



Ensure involvement of GS1 in eHealth activities

eHealth projects

Follow / influence UNICOM project
Follow / influence WEF project about Health IT

On-going

Interaction with other SDOs



Interact with other SDO's to ensure interoperability and relevance/awareness of each other standards

Joint Initiative Council

Chair Joint Initiative Council
Define 2020 – 2022 work program
Increase cooperation with other SDOs

February 2020 onwards
July 2020 (TBC)
February 2020 onwards

ISO standards

Finalise ISO standards in revision (patient ID, medicinal product ID)
Develop ISO new standards (eLeaflet, bio-sample)

September 2020
Ongoing

Liaising with other SDO

Maintain / renew memorandums of understanding
Participate in SDO meetings, interface questions with GS1 specialists / MO

Ongoing
Ongoing



Solution Provider activities

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

Experts webinar from Solution Partners	1st expert webinar (Zebra) to Global members, MOs and MOs network Second webinar	End of February 2020 Mid-September 2020
New Solution Providers web pages under the HC website	Launch of new solution provider web pages at GS1 Global Forum Regular updates of those pages with new videos, quotes, case studies	February 2020 Every three months (April, June, Oct and Dec)
Finder tool (Solution Providers and MOs SP programmes)	Cleaning and updates of all data Interactive map linked to the map where solution providers and MOs SP programmes (19) + contacts are listed (based on PP and healthcare provider database map concept)	January and February 2020 December 2020
Strengthen awareness	Increase the global work group by 2 more solution providers Increase the data in the finder tool by 3 more MOs with solution provider programmes	By end of 2020
Educational material tools	2 pager on the implementation of GS1 standards for beginners 1 pager on the communication towards consultancies	February 2020 June 2020

Increase communication



Deliver best in class, differentiated and customer centric communication and marketing assets to better reach out to new and larger audiences and contribute to drive awareness of GS1 standards in Healthcare, and ultimately resulting in improving our overall efficiency and growing our membership.

GS1 Healthcare Marketing Plan	Marketing Plan & Calendar Social Media strategy, plan & roll out	Plan delivered, shared and approved with HCLT & HIG by March & roll out in 2020
Modernise and optimise healthcare website	Plan for 2020 approved HC Website modernisation / optimisation	January 2020 December 2020
GS1 Healthcare Reference Book	Deliver 2020/2021 GS1 Healthcare Reference Book	July 2020
GS1 Healthcare Digital Thread 2.0	Introduce Virtual Reality App to 20 GS1 MO representatives at Global Forum to test the concept Present consolidated MO feedback to the HIG Report out to HCLT for final Go/No Decision	17 Feb 2020 @Global Forum March 5 HIG meeting March 23 HCLT in Paris

The GS1 Healthcare Team at GO



Lara Abovsleiman
Assistant Manager Marketing
lara.abovsleiman@gs1.org



Pete Alvarez
Senior Director,
Master Data Management
peter.alvarez@gs1.org



Chuck Biss
Consultant, AIDC
Healthcare



Christian Hay
Senior Consultant
Healthcare
christian.hay@gs1.org



Maria Ingenito
PA, Internal Communication
& Office Administrator
maria.ingenito@gs1.org



Ulrike Kreysa
Senior Vice President
Healthcare
ulrike.kreysa@gs1.org



**Géraldine
Lissalde-Bonnet**
Director Public Policy
geraldine.lissalde@gs1.org



Nuran Mallya
Healthcare Manager Africa



Sophie Molle
Senior Manager
Healthcare
sophie.molle@gs1.org



Robert Moss
Director
Healthcare Engagement
Robert.moss@gs1.org



Philippe Neirinckx
Director Marketing
Healthcare
philippe.neirinckx@gs1.org



Laure Pontis
Assistant Manager
Public Policy
laure.pontis@gs1.org



Craig Alan Repec
Senior Manager
Supply Chain Visibility,
EPCIS & RFID
craig.alan.repec@gs1.org



Tania Snioch
Director Healthcare
tania.snioch@gs1.org



Els van der Wilden
Director
Healthcare Providers
els.vanderwilden@gs1.org



Elisa Zwaneveld
Consultant
elisa.zwaneveld@gs1.org