GS1 Healthcare
2020 Strategic Priorities

As approved by the GS1 Healthcare Leadership Team in February 2020

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

Our Strategic Measures are:
Total global number of pharma & medical device members reported by GS1 Member Organisations (MOs)

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

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.

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

| **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

**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

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

**Ongoing – at least 3 advocacy docs/year**
- Ongoing
### UDI standards and policy – 1

| 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

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 standards and policy – 2

**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

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<th>Activity</th>
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<td>Delivered by Q2 2020</td>
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<td>Contribute to MedTech EU (MTE) Guidance on Basic UDI-DI</td>
<td>Delivered by Q1 2020</td>
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<tr>
<td>Participate in EU COM UDI Expert Group and in MTE UDI Task Force</td>
<td>Quarterly basis</td>
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<tr>
<td>Develop paper on &quot;manufacturer vs. Brand owner&quot;</td>
<td>Delivered by Q2 2020</td>
</tr>
<tr>
<td>Support the GDSN and EUDAMED discussion</td>
<td>As needed</td>
</tr>
<tr>
<td>Ensure GS1 role as Issuing Entity – assessed in 5 years</td>
<td>Ongoing</td>
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**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

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<tr>
<td>Develop GDSN mapping for the EUDAMED UDI attributes and keep current with each release of their data dictionary</td>
<td>Complete Version 5 analysis February 2020</td>
</tr>
<tr>
<td>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)</td>
<td>Timing to be coordinated with the EUDAMED releases</td>
</tr>
<tr>
<td>Add new attributes to the GDSN network release</td>
<td>Work with community to determine release timing for HC attributes, develop implementation plan</td>
</tr>
</tbody>
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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 word. Share good practices and expertise demonstrating the need for global harmonisation of UDI requirements.

Delivered by Q2 2020
Delivered by Q1 2020
Quarterly basis
Delivered by Q2 2020
As needed
Ongoing
## Driving global standards implementation in Africa

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

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

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

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Activity</th>
<th>Frequency</th>
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</table>
| **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.

<table>
<thead>
<tr>
<th>Joint Commission International</th>
<th>Establish working relationship</th>
<th>End of the year continuous exchange realised</th>
</tr>
</thead>
</table>
| 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 | December 2020
|                           | Participation at global GS1 HC conferences | March & November 2020
|                           | Meeting with medical directors from industry | March 2020

| Execute the CAC-roadmap | CAC-communication strategy | Mid 2020

| Medical directors working at manufacturers | Identify a pilot group | January 2020
|                                           | Meet with CAC and pilot group on the topic VBHC (and GS1) | March 2020
|                                           | Define and decide on further steps | 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 webinars completed |
| **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

<table>
<thead>
<tr>
<th>Drive implementation of GS1 standards for patient and caregiver ID</th>
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<table>
<thead>
<tr>
<th><strong>Respond to questions</strong></th>
<th>Reactively respond to questions from MOs and industry about this topic</th>
<th>Ongoing</th>
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<table>
<thead>
<tr>
<th><strong>ISO DTS 18530 (patient identification, etc.)</strong></th>
<th>ISO Standard passed by international ballot Publication</th>
<th>April 2020 September 2020</th>
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</table>
Leverage new technologies
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

### 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

### 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

- BCS ratification expected end of February 2020
  Prevents use of GO resolver in regulated Healthcare applications
  Enables integration of resolver functionality within existing validated system infrastructure

- 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

<table>
<thead>
<tr>
<th>GS1 Trend Research Report</th>
<th>Relationships with innovators</th>
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<tbody>
<tr>
<td>Provide healthcare input to next edition of the GS1 Trend research report</td>
<td>Based on identified trends that impact GS1 in healthcare engage with innovative organisations</td>
</tr>
<tr>
<td>Commence May 2020 Report to be released in March 2021</td>
<td>Ongoing; based on assessment of GS1 Healthcare Leadership Team</td>
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Ongoing Activities
Global GS1 Healthcare Conferences

Oorganise 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

### 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

<table>
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<td>June 2020</td>
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<tr>
<td>March 2020</td>
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### 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

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<td>May 2020</td>
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<td>September 2020</td>
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### 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

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### 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

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<tr>
<td>January 2020</td>
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<tr>
<td>January, April, July, October 2020</td>
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## 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)

### 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)

### 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

### 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

### Timeline and Frequency
- Every two weeks
- 2 sessions per conference
- Ongoing

- Ongoing
- Improvements and updates on a regular basis

- Ongoing
- every two weeks
- Ongoing and as needed

- 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

<table>
<thead>
<tr>
<th>Joint Initiative Council</th>
<th>ISO standards</th>
<th>Liaising with other SDO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair Joint Initiative Council</td>
<td>Finalise ISO standards in revision (patient ID, medicinal product ID)</td>
<td>Maintain / renew memorandums of understanding</td>
</tr>
<tr>
<td>Define 2020 – 2022 work program</td>
<td>Develop ISO new standards (eLeaflet, bio-sample)</td>
<td>Participate in SDO meetings, interface questions with GS1 specialists / MO</td>
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<tr>
<td>Increase cooperation with other SDOs</td>
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<tr>
<td>February 2020 onwards</td>
<td>September 2020</td>
<td>Ongoing</td>
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<tr>
<td>July 2020 (TBC)</td>
<td>Ongoing</td>
<td>Ongoing</td>
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<tr>
<td>February 2020 onwards</td>
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## 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

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