The Global Language of Business



GS1 Healthcare Newsletter

2019-2020: A Year in Review and a New Decade of Opportunities

January 2020

As 2019 just ended and a new decade begins, I am reminded of how much our GS1 Healthcare community has accomplished—not only the quantity, but the quality of achievements that we are realising together. We are deeply grateful for your engagement and support.

Together, we are expanding our activities. In Lagos, Nigeria, GS1 Healthcare held its 2nd African GS1 Healthcare Conference to share powerful knowledge and compelling experiences about using GS1 standards to enable traceability and access to safe medicines for patients around the world.

A very inspirational moment during the conference occurred when Professor Moji Christianah Adeyeye, Director General, National Agency for Food and Drug Administration and Control in Nigeria (NAFDAC), issued a call to action for the Africa Strategy for Pharmaceutical Traceability. Twenty-five African regulatory authorities and six health financing and donor organisations responded—committing to pursue pharmaceutical traceability based on global supply chain standards.

Together, we are setting records. The global GS1 Healthcare conferences in Noordwijk-Amsterdam, Netherlands and New Delhi, India were memorable events with record-breaking participation. More than 400 healthcare leaders attended the conference in the Netherlands with over 330 in India—home to many large pharmaceutical manufacturers and one of the first countries to adopt GS1 standards in healthcare.

Together, we are taking the lead to improve patient safety worldwide. Strong engagement and actions by doctors and nurses in the Clinical Advisory

"Together we can embrace the opportunity to reach our healthcare vision of patient safety and efficiency."



Ulinhe Klypa

Ulrike Kreysa Senior Vice President GS1 Healthcare

Committee are helping to bring GS1 standards to life throughout clinical processes. Healthcare stakeholders up and down the supply chain are sharing compelling stories about GS1 standards in action via the GS1 Healthcare Reference Book. And, a growing number of GS1 Member Organisations—currently 78 worldwide—are actively working with healthcare professionals to successfully implement standards.

Together, we are looking to the future. In 2020, GS1 is honoured to be assuming the chair position of the Joint Initiative Council, a group of international Standard Organisations, working together towards interoperability. GS1 Healthcare will continue to make working with regulatory bodies a priority, supporting pharmaceutical traceability and Unique Device Identification (UDI) regulations, standards and policies in more than 70 countries globally.

Together, we are truly making a difference. I am excited about 2020—a new decade of discovery, hard work and progress. I know we will continue to come together as a community that is committed to making healthcare safer and more efficient for patients everywhere. And that is very exciting!

GS1 Heatlhcare



2019-2020: A Year in Review and a New Decade of Opportunities

With completion of the <u>GS1 Healthcare strategy</u>, 2019 activities were all about executing that strategy and, at the same time, supporting our global GS1 Healthcare members and GS1 Member Organisations (MOs). Progress continued as GS1 standards were implemented across clinical and business processes and deeper into healthcare provider environments. New developments in standards and digital tools helped to accelerate these implementations—all the way to the patient.

In 2020, efforts are being increased to ensure all healthcare stakeholders—providers, distributors/wholesalers, manufacturers, regulators, solution & logistics providers and GS1 MOs—have access to the necessary knowledge and assistance to implement GS1 standards. As a new decade begins, our community is determined more than ever to successfully

transform the global healthcare supply chain for the benefit and safety of patients around the world.

Keeping the spotlight on healthcare providers

For yet another year, we focused on the needs of healthcare providers and the GS1 MOs that work with them. 2019 was filled with activities to support healthcare providers' implementations of GS1 standards, including the creation of step-by-step implementation plans that address bedside scanning and implants in the operating room. In 2020, emphasis will be on the development of a validated set of measurements to capture outcomes from healthcare provider implementations.

More than **550 participants** attended or listened to recordings of monthly healthcare provider webinars that featured successful examples of implementations;

webinars will be offered bimonthly in 2020.

These valuable implementation stories will also continue to be shared with the International Society for Quality in Healthcare (ISQua) for its Fellowship Programme and the World Continuing Education Alliance (WCEA).

In 2019, we continued to collaborate with the International Hospital Federation (IHF), participating in each other's activities. GS1 hosted a session with four hospital presenters during the IHF conference in Oman.

The Clinical Advisory Committee (CAC) comprised of doctors, merged with the Nurses in Leadership group in 2019 to enable richer discussions about the implementation of GS1 standards in hospital settings. Notably, this group developed a document called Clinical Patient Pathway, which demonstrates the individual touch points throughout a patient's clinical journey where GS1 standards are used, linking it to the supply chain.

In addition, in 2020 we will explore the role of GS1 standards in value-based healthcare and publish our findings on this much discussed topic.

The updated CEN / ISO Technical Standard 18530 for patient and caregiver identification was approved in

In 2019, access to the healthcare provider database was extended to all healthcare stakeholders. The database continues to grow with more than 125 case studies about hospital implementations of GS1 standards worldwide. An updated version of the database was also launched with statistical and analysis functionalities.

In 2020, plans include adding a minimum of 10 case studies. A video guide and webinar will also be created to help users navigate the database.

2019 and moved to international standard ballot, with expected approval in 2020. This standard relates to relevant GS1 standards that identify the patient and caregiver such as the Global Service Relation Number (GSRN).

In 2019, an online interactive healthcare provider training course was created for MOs. The planned release is in 2020. The training course outlines detailed information about the structure and clinical processes in hospitals, further enriching MOs' knowledge about hospital environments.

Collaborations that help drive the use of GS1 standards

Solution providers help to facilitate the implementation of GS1 standards by integrating them into their solutions and supporting standards-based projects. In 2019, significant efforts were invested at both global and local levels to help engage and support these valuable partners.

Attendance of the global GS1 Healthcare Solution Provider work group has grown to include 25 solution providers and 30 MOs. In 2020, steps will be taken to drive further collaboration, including the development of an interactive "finder" tool that links to a map of solution providers and MO solution provider programmes.

To further improve access to GS1 standards information, new webpages for solution providers were created in 2019, with the launch scheduled for early 2020. Expert webinars presented by solution providers to GS1 MOs and their members are planned in 2020.

The <u>Digital Thread</u> was transformed in 2019 from a static PDF to an interactive online tool. It graphically shows the collaborative interrelationships and connections between healthcare stakeholders. and how the use of GS1 standards helps drive the physical flow of products and services and digital exchange of product and transactional data, supporting full traceability and patient care.





Strengthening our core business: standards

In 2019, a flyer that positions GS1 standards and their value among other healthcare IT standards was released. Additional learning activities and assets are planned in 2020.

The GS1 Application Standard for Identification of Investigational Products in Clinical Trials was launched in 2019, and a number of clinical trial sponsor organisations are already implementing the standard. To extend the standard beyond identification and barcoding, a GS1 Global Standards Management Process (GSMP) work group has been developing an electronic messaging standard, with plans for release in 2020. Next year, we will also develop clear communication about how GS1 standards relate to Identification of Medicinal Products (IDMP) standards in clinical trial processes.

A major work effort in 2019 was updating the Healthcare GTIN Allocation Rules so that they are aligned with the GS1 GTIN Management standard and refreshed based on relevant developments from past years. The Rules will be completed in 2020 along with training materials and other support tools.

In 2019, educational efforts about GS1 identification (AIDC) standards continued to help drive deeper and broader implementations across all healthcare stakeholder environments. Work to update how we communicate about GS1 AIDC standards in healthcare—to focus even more on how standards drive true value and benefits for stakeholders—is targeted to start in 2020. In order to better support the growing use of 2D symbologies, the GS1 2D Matrix Data Carriers in Healthcare paper was updated. This includes the use of GS1 Serial Shipping Container Codes (SSCCs) encoded in 2D barcodes on logistics labels as well as the role of the ONE barcode initiative in enabling the Digital Link standard to access digital content via the web. For more information, refer to the updated paper.

Implementing standards in global regulations

To enable pharmaceutical traceability, we worked with healthcare stakeholders, to leverage the use of GS1 standards when implementing drug traceability. Due to many inquiries, we published a guideline that details best practices to apply GS1 standards for the aggregation of contents of related packaging levels or logistics.

In 2020, we will continue to support stakeholders in developing harmonised pharmaceutical traceability requirements. Increased awareness and education about data exchange standards will also be a priority. Initiatives include creating a Public Policy master data work group to consider product master data requirements for both medicines and medical devices, and providing training and support for MOs and users about the GS1 EPCIS standard and event-based traceability.

The GS1 Regulatory Roadmap on Traceability of Medicinal Products that supports regulators in aligning with the global framework of medicines traceability, was translated into Chinese, French and Spanish in 2019.

In 2019, GS1's Unique Device Identification (UDI) standards and policy were supported in multiple ways. The Global Model Number (GMN) standard was updated to include the additional EU requirements for the Basic UDI-DI. In addition, a position paper was published to define the rules related to the use of the GS1 GMN in cases of mergers & acquisitions.

A new and improved listing of Global Data Synchronisation Network[™] (GDSN^{*}) implementation support across the world in healthcare was added to the GS1 website. This interactive page allows direct access to the various countries' implementation support tools and services.

A notable achievement: We are starting 2020 with 3.4 million Global Trade Item Numbers in the GS1 Global Registry for GDSN! This represents a 17% growth over the last 12 months. As the need and value of quality master data grows in healthcare so does the reliance on the GDSN as a trusted source of product information. Please refer to the GDSN Statistics & Facts for more information.

Other efforts are focused on GDSN mapping with EUDAMED, the European UDI database, and monitoring developments related to data submission to EUDAMED, in particular by third-party solution partners. In addition, support for the U.S., EU, China and South Korea requirements will be provided wherever appropriate, along with ongoing assistance for UDI systems in countries like Australia, Brazil, Egypt and Saudi Arabia. A new UDI Certification Programme and eLearning module for GS1 MOs resulted in

130 participants from

MOs being certified in

2019. We also communicated with regulators about how GS1

standards could be used in UDI implementations

As part of the International Coalition of Medicines Regulatory Authorities (ICMRA), we led the work effort to develop guidance on the technical denominator for the interoperability of medicine traceability systems that will be part of the policy guidelines of the World Health Organisation (WHO) in 2020.

Focusing on Africa for safer medicines

In 2019, working with healthcare leaders in Africa continued to be a major priority. During the 2nd African GS1 Healthcare Conference in Lagos, Nigeria, which was actively supported by the Global Fund, USAID and World Bank, 287 participants came together to share knowledge and compelling experiences about GS1 standards enabling traceability for access to safe medicines and to discuss how to use them in Africa.

In October 2019, an announcement was made by the <u>Gavi Alliance</u> and <u>UNICEF</u> about the use of GS1 standards for the identification of vaccines they purchase.

In partnership with GS1 MOs, we continued to cooperate with and train donor and financing organisations organisations on GS1 standards. As a result, five donor organisations now have harmonised requirements for GS1 standards in their procurement guidelines.



Other activities included MO training and support for Kenya, Ghana, Senegal, Ivory Coast, Cameroon, Mauritius, Nigeria and South Africa. Support related to GS1 standard implementation was provided to other initiatives in sub-Saharan Africa including in Ethiopia, Malawi and Zambia.

In cooperation with the Developing Countries Vaccine Manufacturers Network (DCVMN) and supported by GS1 MOs, we conducted training sessions for vaccine manufacturers in Vietnam, China and Brazil. In 2020, these activities will continue.

Leveraging new digital technologies

In 2019, the resolver functional requirements were completed for the <u>GS1 Digital Link</u>. The Digital Link will enable scanning a GS1 barcode on an item to point to appropriate digital information about that product, which is of great interest, e.g., to enable digital access to eLeaflets.

In 2019, the Healthcare Barcode Survey App was updated and will be re-introduced to healthcare stakeholders and MOs. The app offers an improved user interface and features to survey and check GS1 barcodes.

We continued to educate health informaticians about GS1 standards and liaise with other standards development organisations to strengthen awareness of GS1 as the standards for product and location identification, data capture, and information sharing in healthcare.

Increasing our leading role in this area, in 2019 GS1 began the transition to undertake a two-year term as chair of the Joint Initiative Council, and in 2020 will formally take this role.

Connecting with healthcare stakeholders around the globe

Our Public Policy activities are open to all GS1 Healthcare global members and MOs. In 2019, more than 60 participants regularly attended the Public Policy bi-weekly meetings. In the GS1 Healthcare Public Policy Database complete and real-time information is readily available on all existing and developing regulatory requirements related to the use of GS1 standards. The new Healthcare Public Policy Interactive World Map helps to navigate quickly to the relevant information and provides a great overview.

In 2020, priorities will continue to revolve around interactions with regulators and the global healthcare Public Policy community. A new Public Policy webpage on the GS1 Healthcare website will be released.

Support of GS1 global members continued throughout 2019, including leading interactive meetings, ensuring up-to-date online documentation and facilitating the relationship management programme to provide more value and better service

Continuing into 2020, we will work to become more efficient and provide even greater value for our global members and GS1 Member Organisations.

Looking forward to 2020, we will enhance communication with our members by modernising the GS1 Healthcare website, increasing communication through social media and delivering valuable member stories about successful implementations of GS1 standards in the next edition of the GS1 Healthcare Reference Book.

The details about our 2020 strategic priorities will be published in the first weeks of 2020.



In 2019, Global GS1 Healthcare Conferences were held in Noordwijk-Amsterdam, the Netherlands and New Delhi, India. More than 400 healthcare leaders shared best practices and networked during the conference in Noordwijk-Amsterdam in March. In November, more than 330 attended the conference in New Delhi, India. Both events resulted in very positive feedback by participants and helped to strengthen the GS1 Healthcare community.

In 2020, the global conferences are planned for Paris, France in March and Cairo, Egypt in November.

For questions or comments, please contact your GS1 Global Office Relationship Manager

About GS1 Healthcare

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, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefit to all stakeholders. Global members of GS1 Healthcare include more than 100 leading healthcare organisations worldwide.

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