![GS1 logo]

The Global Language of Business

GS1 Healthcare Reference Book 2021-2022

Stories of successful implementations of GS1 standards

GS1

" Safer, more
efficient care
starts with a
simple scan. "

What's inside

GS1 standards are enabling the transformation of healthcare around the world

US
- 1WorldSync & GDSN increase supply chain efficiencies and enhance patient safety with accurate, enriched data.
- Fresenius Kabi gives hospitals the ability to achieve more precise inventory management, by reading many RFID tags with one scan. many RFID tags in one scan.

Ireland
- St. James's Hospital has full visibility of the movement of laboratory specimens.
- Ireland's public health authority, HSE, achieved visibility of COVID-19 vaccine usage and traceability to the point of vaccination across all of its vaccination centres.

UK
- Recalls that could once take weeks now take only hours, saving significant time for medical staff at Hull University Teaching Hospital.
- CareScan+ at North Tees and Hartlepool NHS Foundation Trust provides patient safety alert in an instant.

France
- 50% reduction in time spent by Sanofi on labelling clinical trial kits for increased productivity.
- Cost reductions related to data errors, minimising or eliminating disputes, re-entries and more with Resah's eCat-Santé.

Denmark

North Denmark Region's Cardiac Laboratory saves €134,000 each year by scanning GS1 barcodes.

Bulgaria

Bulgarian Medicines Verification System virtually eliminates counterfeit drugs from being dispensed.

Poland

70% improvement in use of doctors' time at The University Clinical Centre of the Medical University of Warsaw.

Japan

Latest, up-to-date pharmaceutical and medical device information is now available to healthcare providers via e-leaflets on the Pharmaceuticals and Medical Devices Agency.

China

Johnson & Johnson Supply Chain deploys a cost optimised and localised solution benefiting healthcare providers and patients.

Australia

ACT Health quickly put in place new COVID-related processes, systems and contact tracing app based on GS1 standards.

Colombia

UDI enables traceability and improved management practices related to spending in Colombia's General System of Healthcare Social Security.

India

Traceability enabled by GS1 standards helps Serum Institute of India better manage inventory and distribution of its COVID vaccine exports.

South Africa

85% of products used by Netcare have GS1 barcodes applied by suppliers.

2021: A year of hope and the new normal

Last year at this time, we were all battling the first waves of the COVID-19 virus and the global healthcare industry was racing to find a vaccine. This year, while the world continues to grapple with this dangerous pandemic, 2021 has become a year of "hope" with the introduction of not one—but multiple vaccines—that we all hope will restore life to some semblance of normal.

At the same time, many argue that life is returning to a "new normal"—filled with changes in the ways we work, play and interact. Clearly, the healthcare sector has been especially challenged in this time, often pushed to its limits. Yet, it has also been transformed through innovation and adaptation. The way that all parts of the healthcare community have worked together to make change happen is inspirational—a collaboration that will ultimately benefit every patient.

What does this mean for GS1 standards, and how will we apply our learnings for a brighter future?

While the pandemic has challenged the digital foundation of our global healthcare supply chain and national care systems, investments in GS1 standards by healthcare suppliers and providers have strengthened these foundations. And, the further use of GS1 standards will make the foundations even more resilient when providing a secure and efficient supply chain.

GS1 standards are enabling healthcare systems to put in place processes and practices for COVID-19 testing, contact tracing, and vaccine identification and administration.

When Ireland's Health Service Executive (HSE), the country's health authority, needed to vaccinate its population of five million people, the HSE turned to GS1 Ireland as the traceability standard experts. The team collaborated to create a standardised label for vaccine packages, a scanning app for vaccine receipt and a full traceability system in the Central Vaccination Centres (CVCs) to identity, label, track and report on vaccines and give national visibility for informed, rapid decisions for the safe and efficient vaccination of the population.

In Japan, an amendment to the Pharmaceuticals and Medical Devices Act called for pharmaceutical and medical device marketing authorisation holders to transition from paper-based to electronic leaflets for their products. To date, nearly all pharmaceutical manufacturers and some of medical device manufacturers have completed the registration process so

that healthcare providers can simply scan a product's barcode and GS1 Digital Link directs them to the product's e-leaflet on the Ministry's website. This includes COVID vaccines.

Serum Institute of India adopted global standards to create a traceability system to fulfil the UNICEF mandate for supplying COVID vaccines to other countries. Now, the vaccine manufacturer has increased visibility of its vaccines in the supply chain in real-time to efficiently manage inventory and distribution.

> 📢 When ACT Health from Australia was faced with the COVID-19 virus, the health system lost no time making use of GS1 standards when developing a contact tracing app, identifying more than 27,000 sites with Global Location Numbers (GLNs). And, in only 15 days, the team developed the system and process for scanning vaccine barcodes to administer vaccinations, linking them to the electronic health records of patients.

Hospitals continue to drive toward greater efficiencies by automating processes.

In the North Denmark Region, hospitals are using GS1 standards to save 12 minutes on each surgery based on an automated replenishment process where staff scan barcodes on the products used in their surgical departments.

In Poland, The Paediatric Teaching Clinical Hospital automated its clinical and business processes, supported by GS1 standards. Now, medical orders can be automatically generated and, as medications are administered to patients, GS1 barcodes are scanned to ensure the right patient gets the right medicine, at the right time, recording this information in the patient's electronic medical record.

> 📢 St. James's Hospital in Dublin uses GS1 standards-based RFID technology to track the movement of laboratory samples throughout the hospital, a solution that is part of the hospital's broader traceability strategy called PATH (Patient and Asset Tracking in Healthcare).

Major benefits of using GS1 standards revolve around the patient's journey, safety and care.

The Netcare Group in South Africa is scanning GS1 barcodes on pharmaceutical drugs and medical devices as they are received in the hospital's pharmacy and theatre storage rooms, and as they are used throughout wards and operating theatres. With automated processes, Netcare nurses and staff can now focus more on patient care.

Hull University Teaching Hospital (HUTH) in the UK replaced its manual and paper-based processes with automated ones by implementing GS1 standards throughout the entire patient care journey. Transparent and real-time data collected at points of care has helped HUTH deliver better patient outcomes and identify the actual cost of care per patient.

North Tees and Hartlepool NHS Foundation Trust in the UK developed its own point-of-care tool called CareScan+ that uses GS1 standards to track and trace any product and asset used by staff during the delivery of care to patients. Patient safety alerts and decision support mechanisms are built in for clinicians.

Suppliers are standardising processes to better serve healthcare providers and patients.

Leveraging the Global Data Synchronisation Network™ (GDSN®), 1WorldSync has developed a unique solution—the 1WorldSync Playlist—to improve efficiencies and enable scalability in healthcare supply chain data exchange. A pilot program was undertaken with a major healthcare provider and medical product manufacturers.

Fresenius Kabi, a global healthcare company, launched an ambitious program to tag vials of medication using Electronic Product Code-enabled radio frequency identification (EPC/RFID) technology.

As a public purchasing organisation in France, Resah offers manufacturers and hospitals an interoperable electronic catalogue: eCat-Santé. The catalogue enables the input and output of comprehensive, standardised and up-to-date product information, reducing their time and costs associated with product information management.

Sanofi, a global biopharmaceutical company, worked with its supply chain stakeholders to transition from the use of seven proprietary barcodes to one standardised GS1 DataMatrix barcode. This standardised approach helps Sanofi's clinical trial supply chain manage clinical trial activities so that the right investigational kit goes to the right patient.

> 📢 Johnson & Johnson Supply Chain (JJSC) converted from national Chinese medicines identification and barcoding requirements to the use of a globally standardised approach, using GS1 standards. This has provided JJSC an opportunity to increase overall operational efficiency and product traceability.

Government initiatives are making significant strides in using GS1 standards for patient safety.

In Bulgaria, a massive project has been undertaken to implement GS1 standards for the identification of every pharmaceutical package, in compliance with the EU's Falsified Medicines Directive. The Bulgarian Medicines Verification System (BgMVS) was created so that when pharmacies dispense medicines, the medicine pack can be certified as "authentic," enabled by the GS1 Global Trade Item Number® (GTIN®).

Representatives from GS1 Colombia, the National Association of Businessmen of Colombia (ANDI) and National Federation of Merchants (FENALCO) have been working with Colombia's Ministry of Health and Social Protection to identify why and how it would implement Unique Device Identification for all medical devices.

Turning the corner into 2022

Looking ahead, we have much to be grateful and hopeful about . . . and much to do as we continue to digitally transform our global healthcare supply chain, hospital and other care environments.

At GS1 Healthcare, we will work together, continue to implement global standards, share best practices and collaborate to further improve healthcare around the world.

We're on the road to renewal and recovery, and whilst we know there will be twists and turns, GS1 standards are playing an active role in helping the healthcare sector adapt to the challenges that lie ahead and accelerate improvements and innovation further—for patient safety worldwide.

Pandemic stories

Learn how health agencies, manufacturers and hospitals are addressing the challenges of the pandemic with GS1 standards.
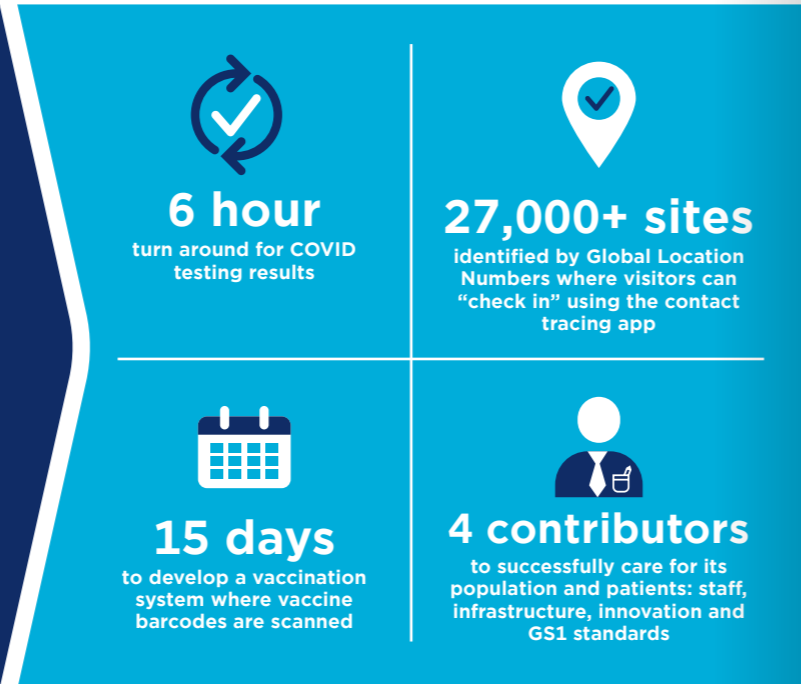
Australia

ACT Health uses GS1 standards to create innovative solutions to fight COVID and build trust with their population

Challenge

When the COVID-19 virus hit Australia, the Australian Capital Territory's health system (ACT Health) faced the challenge of containment, testing and administering vaccinations.

Solution

The ACT Health team acted quickly to leverage existing tools and, at the same time, put in place new processes, systems and a contact tracing app that took advantage of its knowledge and existing use of GS1 standards.

6 hour
turn around for COVID testing results

27,000+ sites
identified by Global Location Numbers where visitors can "check in" using the contact tracing app

15 days
to develop a vaccination system where vaccine barcodes are scanned

4 contributors
to successfully care for its population and patients: staff, infrastructure, innovation and GS1 standards

A very good foundation

ACT Health serves a population of approximately 440,000 people in the Australian Capital Territory and about 200,000 in the surrounding regional areas. Three hundred kilometres south of Sydney, ACT Health has three main hospitals with approximately 1,200 beds. The Canberra Hospital (the largest of the ACT Health hospitals) has the second busiest hospital helipad in Australia, receiving patients from rural New South Wales as a major trauma centre.

For more than 13 years, ACT Health has been on the forefront of implementing and using GS1 standards, integrating standards into many of its business and clinical processes. The health system has worked to assign GS1 identifiers for staff members and patients, as well as all its locations, from receiving points in pharmacies to ward storage closets. It also makes use of GS1 barcodes applied by manufacturers to pharmaceuticals and medical devices by scanning them at different points of care within its hospital environments.

"GS1 standards are providing a very good foundation for us," says Peter O'Halloran, Chief Information Officer, ACT Health. "I get excited by standards—not only for how they have helped us in the past, but how they are also making a difference for us in our COVID-19 response."

Testing with quick results

Throughout the pandemic, all the states and territories of Australia have focused on preventative and containment measures like testing and contact tracing and, at the same time, increasing vaccination rates in the population in readiness for the "new normal"– living with COVID.

ACT Health has followed that national direction. "We're using specimen labels, collected during tests in drive-through testing centres and other testing sites, and leveraging GS1 standards to actually get those specimens straight into the analyser in a machine-readable format," explains Mr. O'Halloran.

"Over time, we have been able to refine our processes, leveraging standards and the turnaround time for test results, which depending on demand, can be as little as 6 hours."

Peter O'Halloran,
CIO, ACT Health

Based on the health protocols, it is required that people quarantine as soon as they know they have had possible contact with a COVID positive person, have been at an exposure site or if they have symptoms. That quarantine period will end when they receive the appropriately timed negative test results, as defined by health protocols. "With test results reduced from 48 hours to now only taking overnight, this reduced time has had real-life implications for people and their families," says Mr. O'Halloran.

Building trust with contact tracing

Being able to identify the contacts of positive cases is a foundational pillar to the Australian response to COVID. Another GS1 standard, the Global Location Number or GLN, has supported the health system's contact tracing application. Using manual processes, such as sifting through handwritten records, produced a huge challenge for ACT Health staff when trying to trace people's whereabouts and visits to locations.

"ACT Health came up with a simple smartphone app that allowed people to 'check in' at locations and put our people in control," explains Mr. O'Halloran. "People can walk up to a venue, and scan a QR code to register their attendance. If needed due to a positive case visiting a location, the data can be provided

> When ACT Health from Australia was faced with the COVID-19 virus, the health system lost no time making use of GS1 standards when developing a contact tracing app, identifying more than 27,000 sites with Global Location Numbers (GLNs).
> And, in only 15 days, the team developed the system and process for scanning vaccine barcodes to administer vaccinations, linking them to the electronic health records of patients.

directly to our contact tracers. In the ACT with a population of about 440,000, as of October 2021, we've seen more than 27,000 venues registered and 75 million check-ins."

During recent COVID-19 outbreaks, the contact tracing app has proven to be highly useful. In fact, three other states and territories in Australia have adopted the app for their own contact tracing activities. The ACT team designed and developed the app for the three jurisdictions on a cost recovery basis, recognising the benefit of having an interoperable app able to be used across multiple states and territories. "Half of Australia is now using the app," explains Mr. O'Halloran. "Sharing the app means that when vaccination targets are met, we are helping to open up the country."

Since the app uses GLNs, the ACT Health team implemented a central registry, shared by all the states and territories leveraging the app. When someone scans the code, the system knows it's a code from the "XYX" location. The data is sent directly to the contact tracers in that jurisdiction.

"It's simple and easy, since we based the app on standards," says Mr. O'Halloran. "It's exciting— not just the technology and standards—but the outcomes are what's really exciting us. How can this help open up the country safely? How does this improve patient outcomes? How does this let us get on top of an outbreak quicker?"

ACT Health strongly promoted the app to ensure that people understood the benefits. "It's all about engaging with the community. Building their trust has been essential for all that we've done."

Getting jabs in arms

It was 27 December 2020 when Peter O'Halloran got the call from the head of ACT's Health Directorate saying that vaccines were arriving in February 2021, and it was "all hands on deck" to plan for their arrival and administration to ACT Health's waiting population.

Coincidentally, the team was in the process of implementing a new Epic electronic medical record system. This offered the ideal opportunity to create an electronic vaccination record, rather than introducing a new manual process.

"We implemented the entire system for vaccinations from start to finish in 15 days," recalls Mr. O'Halloran. "This included capabilities for scheduling and administering vaccinations."

When ACT Health received the first shipments of vaccines in February, the team was relieved to find the packages were labelled with GS1 identifiers encoded in GS1 barcodes. "Until we received them, we didn't have absolute surety that the vaccines' packaging would be marked with GS1 barcodes," says Mr. O'Halloran. "The supply chain in those early days was working very hard to ramp up capabilities to bring vaccines to many countries across the world. We had to react quickly when we received deliveries."

> "It was a relief that we could use our system and scanners to read the barcodes, do all the patient safety checks, and upload all patient and vaccine information into the EMR system. It was amazing."
>
> **Peter O'Halloran,**
> CIO, ACT Health

Peter O'Halloran and his team are working to ensure ACT Health's legacy pharmacy inventory management system is integrated in their vaccine management process. They have also developed capabilities to load data into the Australian Immunisation Register (AIR), which is a national database containing all the details about those who have been vaccinated. The registry will also be used to issue "vaccine passports" to Australians who are planning to travel.

As of 26 October 2021, ACT is leading the nation with in excess of 99% of the 12 years and older population having had a 1st vaccine dose and 89.3% having had their 2nd dose. In addition, the ACT has administered significant number of vaccinations to citizens from the surrounding region in New South Wales. The ACT has administered more than 800,000 doses.

Contributors of success

Even with all the challenges the ACT Health team has faced, Mr. O'Halloran is quick to point out that GS1 standards and barcodes have been a key foundation. "Standards help us deal with all we have to do."

"What has contributed to our success? One, we have a phenomenal workforce that met the COVID-19 challenge and continues to do so every day in what can be very challenging circumstances.

"Secondly, we have the infrastructure—not only the IT technology but also the infrastructure of GS1 standards for identifying people, locations and products. Standards have been key, helping us to ensure that the risk of patient-safety issues is reduced and, in fact, have not occurred. We've been able to use barcodes when we're injecting people to make sure it's the right product going to the right patient.

"And, the last ingredient that worked for us is innovation.

"Our overall response has been to plan, practice, refine the plan and then practice again. Our community is working together to fight a once-in-100-year battle, and I feel incredibly fortunate to be contributing."

About the authors

Peter O'Halloran,
CIO, ACT Health

Peter O'Halloran is the Chief Information Officer for ACT Health, the government agency responsible for the public health system in Canberra, Australia's capital. He is responsible for over 250 systems, serving 10,000 staff who operate across three public hospitals with over 1,200 beds and 40 community facilities.

Mr. O'Halloran joined the Australian Public Service in 2006 in the National Health and Medical Research Council before moving to the National Blood Authority where he was appointed as the inaugural Chief Information Officer and was responsible for the provision of services to all Australian hospitals. He joined ACT Health in 2016 and since that time has embarked on a complete overhaul of all ICT services and systems with a complete replacement of all core systems currently underway, guided by the Digital Health Strategy that was launched in May 2019.

Katrina Keep,
Senior Director,
ACT Health

Katrina Keep is the Senior Director, Office of the Chief Information Officer, Digital Solutions Division at ACT Health. Ms. Keep is an inclusive leader with a background in public relations, stakeholder engagement and executive management, with 20 years' experience working in the federal and territory governments, health and IT sectors. She has contributed to and led the delivery of a range of transformation projects throughout her career, including the design, development and implementation of the COVID-19 Check In apps for the ACT, Northern Territory, Tasmania and Queensland governments.

Peter McNiven,
Executive Branch
Manager, ACT Health

Peter McNiven is the Executive Branch Manager, Technology Operations for ACT Health, Digital Solutions Division at ACT Health. He is responsible for all ICT operational requirements for the territory's public health system covering over 42 established sites and numerous temporary and popup sites that have been required during the current public health emergency. Mr. McNiven has over 30 years in the Health industry, starting out as a Pathology scientist in remote areas before moving to the ACT and continuing to work in Pathology. He moved into ICT to run regional Pathology, covering the ACT and South East NSW Public Pathology network for 21 public and multiple private hospitals. He then moved into whole of ACT Government ICT leadership roles responsible for health systems and oversight of significant health building infrastructure development. He is now leading a significant overhaul of hosting and system delivery guided by the Digital Health Strategy.

About the organisation

ACT Health caters for a diverse population of over 400,000 that geographically encompasses Australia's national capital Canberra and its highly 'transient' population. There has been significant investment in key infrastructure via new technologies and new hospitals and The Canberra Hospital (TCH) campus in recent years to support the increasing requirements of digital health as well as ensuring continued improvements to safety.

www.health.act.gov.au

India

Serum Institute of India: Implementing UNICEF guidelines for distribution of COVID vaccines

Challenge

Serum Institute of India needed a to comply with the UNICEF mandate for seamless delivery of vaccine to various parts of the world.

Approach

SII adopted GS1 standards to create a traceability system for all COVID vaccines, meant for exports.

Increased visibility of vaccines in supply chain

Real-time monitoring and recording of vaccine temperature

Enables vaccine authentication at point of vaccination

Swift and targeted recalls, whenever needed

Supplying the world with COVID vaccines

Serum Institute of India (SII) is one of the world's largest vaccine producers when it comes to manufacturing and supplying the COVID vaccines both for India and globally. It needed a solution that ensured compliance with the UNICEF mandate for seamless delivery of vaccine to various parts of the world. The directive required that each vaccine should be uniquely identified to prevent falsified vaccine. SII needed to use global standards to effectively track and trace COVID vaccines throughout the supply chain—from production to healthcare providers.

Creating a traceability system

With support of GS1 India, SII adopted global standards as it enabled them to fulfil the UNICEF mandate for supplying vaccines to other countries. This required a GS1 standards-based track and trace system to be set up for all COVID vaccine exports.

To provide end-to-end traceability, SII started with the implementation of batch-level traceability. Over time, it moved to case-level traceability with the use of serialised barcodes on intermediate secondary packaging and Serialised Shipping Container Codes (SSCC) on tertiary packages of COVID vaccine supplies. By scanning serialised barcodes, the information captured included the vaccine's Global Trade Item Number® (GTIN®), batch number, serial number and expiry date.

"The adoption of GS1 standards not only enabled us to fulfil the UNICEF directive for traceability purposes but also for internal process optimisation and ensure targeted recalls, if required. GS1 India supported us during the whole implementation phase. We appreciate the support received from GS1 India. A long-standing relationship with GS1 India helped us adopt traceability requirements of UNICEF and other importing countries."

Dr. Sunil Gairola,
Executive Director, Serum Institute of India

To support implementation, GS1 India conducted various workshops and webinars to ensure a smooth transition of processes. This also included technical support to manage country-specific regulations and regulatory requirements in domestic supplies to various State Governments.

"Tracking each batch of vaccines as it moves through the supply chain is import-ant to secure the chain and ensure patient safety. GS1 standards help in ensuring safety and trust in COVID vaccines supply,"

Mr. Sachidanantham Swaminathan
CEO, GS1 India

Benefits realised by implementing GS1 standards

- Ensures increased visibility of the vaccines in the supply chain in real-time to efficiently manage inventory and distribution

- Enables real-time monitoring and recording of temperature to ensure that the right temperature is maintained throughout the supply chain – storage as well as transportation

- Ensures effective patient coverage, without wastage and pilferages

- Enables authentication of the vaccine at the point of inoculation

- Enables swift and targeted recalls, whenever required

- Enables a common platform for various regulatory bodies across the globe to work collaboratively to deliver vaccines

Future roadmap

With the requirement of global standards gaining precedence for track and trace of vaccines, SII has plans to barcode vaccines meant for domestic supplies as well.

About the organisation

Serum Institute of India Pvt. Ltd. is one of the world's largest vaccine manufacturers by the number of doses produced and sold globally.

Vaccines manufactured by the Serum Institute are accredited by the World Health Organization, Geneva and are being used in around 170 countries across the globe in their national immunization programs, saving millions of lives.

The Serum Institute of India (SII) and UNICEF have entered into a long-term supply agreement for the AstraZeneca/Oxford and the Novavax vaccines. UNICEF plays a key role in immunisation campaigns worldwide under the COVAX program. COVAX is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, and the World Health Organization (WHO), alongside key delivery partner UNICEF. It aims to accelerate the development and manufacturing of COVID-19 vaccines and to guarantee fair and equitable access for every country in the world.

www.hse.ie/eng/

About the authors

Dr. Sunil Gairola
EVP- packaging,
Serum Institute of India (SII)

Sunil Gairola, Ph.D, is the Executive Director of Serum Institute of India Pvt. Ltd. He has more than 38 years of experience in quality control of vaccines, adjuvant development, and managing quality control-related activities, and has significantly contributed towards the development and calibration of national reference Standards for vaccines and antisera. He is by training a microbiologist and joined SIIPL in 1994. Expertise in characterization of bacterial, viral, recombinant antigens using advanced analytical tools and implementation of newer technologies in quality control of vaccines. Leads a team of more than 400 Scientists. Collaborator to international initiatives of WHO, NVI, NIBSC, EDQM, and PATH, aimed at the harmonization of regulatory requirements, the establishment of international standards, and the development of quality control release assays for immunobiologicals. Served as IP Expert committee for many years and Member, Scientific Body. Also member to expert committee/panel of USP. Published research papers in National and International journals. Attended many National and International Conferences as well as WHO Consultations on scientific topics.

Mr. Sachidanantham Swaminathan
CEO, GS1 India

Mr. Swaminathan has been actively engaged with several government and industry projects related to track & trace, recall and supply chain management for adoption of global standards and best practices, which facilitate unique and universal product identification and authentication, and information exchange of product data between trading partners.

He has 29 years of experience across Automatic Data Capture Industry and software products & services sector in varied responsibilities incl. channel development, supply chain management, sales/marketing and project management for domestic and international markets. Mr. Swaminathan is an Engineering graduate in Computer Science from Bharathiar University and alumnus of IIFT Delhi.

Ireland

Traceability standards enabling a safer, more efficient rollout of the COVID-19 vaccine across Ireland

Challenge

As COVID-19 vaccines became available, Ireland's Health Service Executive (HSE) needed an efficient and effective way of receiving, administering, tracking and reporting vaccinations across its more than 40 Centralised Vaccination Clinics (CVCs). It was important for the HSE's National Immunisation Office (NIO) that no dose was wasted and that batches of vaccine could be tracked to the point of vaccination.

Approach

The HSE in collaboration with GS1 Ireland adopted a GS1 standards-based approach for the identification and tracking of vaccines to the point of vaccination. Following an intensive design phase with the HSE project team, two software applications were developed: ScanVax and TrackVax. ScanVax was installed on over 1,000 PCs across the country to allow for the receipt of vaccines. By scanning the barcode on each of the vaccine boxes, vaccine information is then uploaded to the national vaccine administration system. This means that vaccinators can select the correct batch when administering the vaccine. TrackVax has been installed in all CVCs across the country. This allows the CVC teams to identify, label, track and report on the vaccines in their centres, allowing a much easier vaccine reconciliation process locally and nationally. Both solutions are provided by GS1 Ireland.

Time savings - Estimated 0.5 - 1 full time employee (FTE) per CVC* and a total of 56 days across all sites to record vaccine details in the national vaccination administration system

Medication safety - Clear labelling (printed not handwritten) of vaccine type, discard time and batch for every vial or syringe

Reporting (locally and nationally) - Useful data on vial yields and stock expiry dates to assist in keeping wastage to a minimum. Estimated 75,000 doses were saved based on early detection of discrepancy on vial yield due to appropriateness of syringes used

Standardised and repeatable processes used at all sites

Staff engagement - Very easy to use system that adapted to working practices and assisted in standardisation across CVCs

Data quality improvements - Automated and reliable end-of-session reports prevented data inaccuracies from developing in the national vaccine administration system

Efficiency - CVCs were able to ramp up as numbers for vaccinations increased—a very challenging situation to support without TrackVax in place

* depending on size of CVC

An enormous challenge

In Ireland, GS1 standards are actively used in the country's healthcare system comprised of 7 hospital groups, 52 acute hospitals and 19 private hospitals. Serving Ireland's population of 5 million, HSE is the national authority for health, providing all of the public health services in Ireland.

Throughout the pandemic's first year, GS1 Ireland supported the HSE in responding to the pandemic, most notably in the design of the COVID-19 test and trace system to include a standardised barcode label with a GS1 identifier to assist in the tracking of the tests from test

centres to laboratories. Prior to the COVID-19 rollout, the NIO and GS1 Ireland were working to use barcode scanning in the Schools Immunisation System. With this collaboration as a backdrop, GS1 Ireland offered its support to the HSE to help with the COVID-19 national vaccination programme, starting in early December. Stepping up to the challenge, the GS1 team "rolled up their sleeves" to get involved in an intensive design phase during the early stages of the programme.

The overall task was complex and multi-dimensional. It involved answering questions
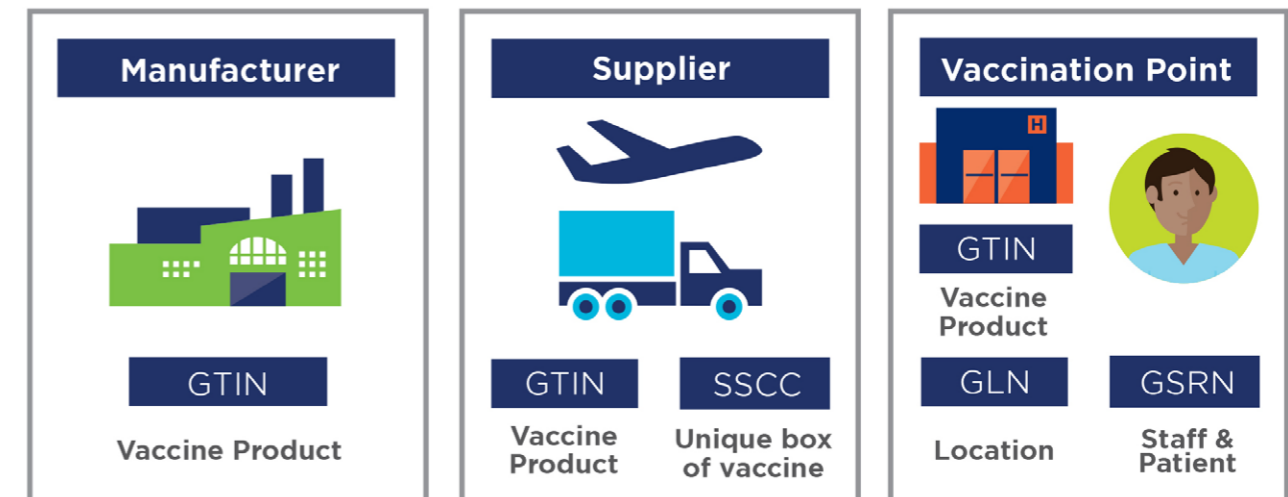
Figure 1: Unique identification is key to enabling full traceability of vaccines

about distributing the vaccines efficiently and effectively, getting insight into inventory levels, managing second doses, and managing the cold chain and expiry dates. It was also important for HSE's NIO that no dose was wasted and that batches of vaccines could be tracked to the point of vaccination for full accountability and oversight of every dose. GS1 Ireland's team was in a unique position to advise on the traceability elements of the project and develop software to address the traceability requirements.

Background

Over the last 15 years, HSE has worked with GS1 Ireland to implement traceability standards in areas such as National Haemophilia track and trace, National Instrument and Endoscope track and trace and the development of the Health Directory, which assigns GS1 identifiers to locations, people, assets and more. These identifiers all played a role in the establishment of the national vaccine administration system as identifiers were required for the people being vaccinated and the locations where the vaccination clinics were operating. Additionally, GS1 identifiers were assigned to staff using TrackVax and in some cases to boxes of vaccines to identify smaller pack sizes.

As a result of the EU's Falsified Medicines Directive (FMD), manufacturers of prescription medicines are required to assign a two-dimensional (2D) DataMatrix barcode on the secondary package of the product, which means traceability data can be captured in one scan. The barcode has four data elements: the Global Trade Item Number® (GTIN®), batch, expiry date and serial number. Although some of the vaccines didn't have a serial number due to a derogation for COVID-19 vaccines, which presented additional challenges in managing vaccines in the clinics.

"It was clear from early in the CVC design stage, that the ambitious vision for the scale of vaccination in the CVCs required a comprehensive in-CVC vaccine tracking tool to support a standardised medicines management process. Identification and tracking of vaccine at vial level enabled vaccine stewardship. Articulating this need was crucial for the successful approval of the business case for the development and rollout of TrackVax."

Fionnuala King,
Chief Pharmacist, Acute Hospitals Drug Management Programme, HSE Acute Operations

Designing in traceability standards

1- Standardised labelling to manage dynamic expiry dates

Within two days of the letter of offer from GS1 Ireland, HSE invited GS1 Ireland to join discussions on how to manage the change in expiry date for the Pfizer-BioNTech vaccine on removal from the Ultra Low Temperature (ULT) freezer prior to distribution. GS1 Ireland provided a label design for the distributor and subsequently worked very closely with the HSE and system implementation partners to advise on how to "design-in" traceability standards for the national COVID-19 vaccination programme.

2- ScanVax to capture vaccine details in one scan

The next challenge was how to capture the batch details of the vaccines on receipt in the vaccination clinics across Ireland. There was a backlog of vaccine data that needed to be transferred, so barcode scanning was the obvious choice. One scan can automatically capture the vaccine type, batch and expiry date details related to the COVID-19 vaccines. By

early January 2021, GS1 Ireland had developed ScanVax, an app that enables the receipt of vaccines by scanning the barcode on the vaccine boxes. The details from the barcode are then uploaded to the national vaccine administration system. This means that vaccinators can select the correct batch when administering the vaccine, thus minimising human error and greatly reducing the time required to record the vaccine details. ScanVax has been installed on more than 1,000 PCs and is used to record receipt of vaccines and upload vaccine information to the national vaccine administration system in locations across the country.

> "We had approximately 20,000 vaccine deliveries, 4 vaccine types and 20 complicated data fields for each vaccine type. ScanVax standardised everything and meant we could capture records both accurately and quickly. Vaccine data is now seamlessly reportable for the first time in a vaccine programme in Ireland."

Kerry Ryder,
ICT General Manager, HSE National Immunisation Office
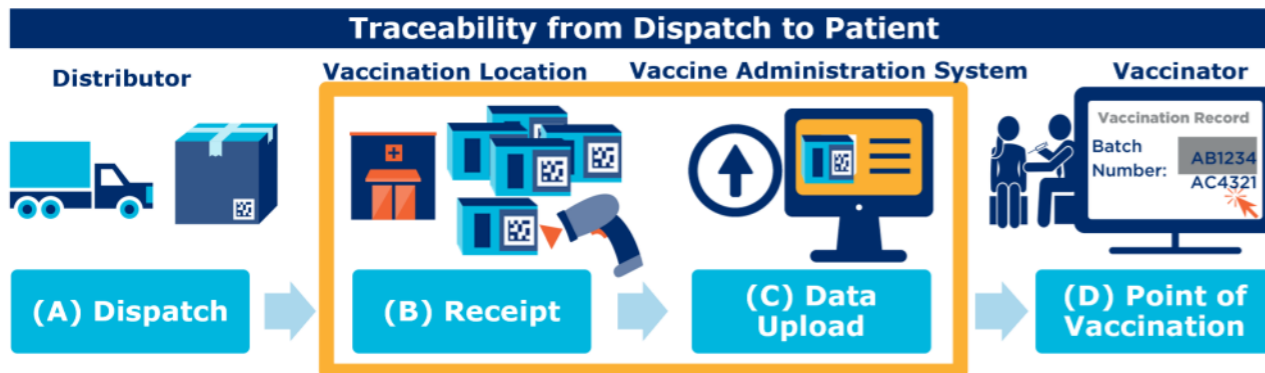
Figure 2: ScanVax is used to record receipt of COVID-19 vaccines by scanning the barcode on the box for upload to the national vaccine administration system.

Figure 3: One scan of 2D DataMatrix barcode automatically captures and uploads the vaccine type, batch and expiry date details related to the COVID-19 vaccine.
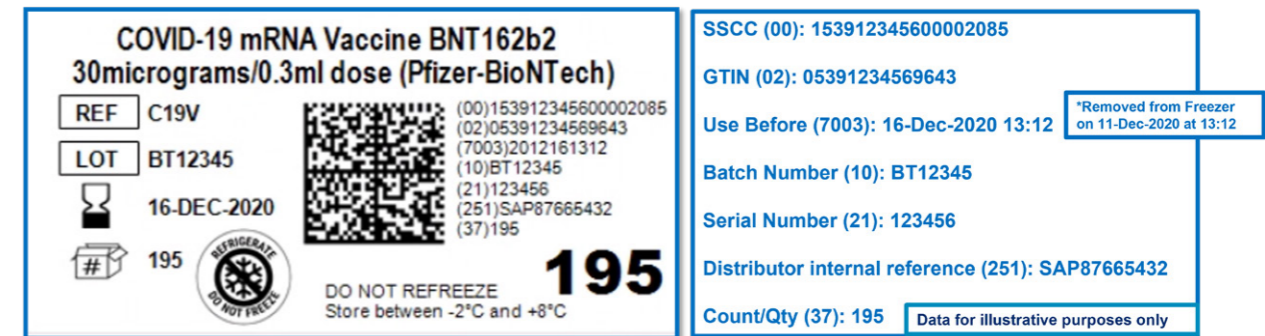
Figure 4: Example of label specification for the Pfizer-BioNTech vaccine

COVID-19 vaccines: Gaining efficiencies in special handling processes

The COVID-19 vaccines, based on the mRNA technology, are fragile and require special handling to ensure they maintain their effectiveness. For the Pfizer-BioNTech vaccine, on removal from the ULT freezer to storage between +2°C and +8°C, the expiry date must change and a "use before" date and time of 120 hours needed to be assigned to the product prior to distribution. This now has been increased to 31 days. For the Moderna vaccine, the expiry date changes on arrival at the vaccination centres and requires a new label "use before" for storage between +2°C and +8°C, which is assigned on receipt into TrackVax.

Consider the process for the Pfizer-BioNTech vaccine.

There is one distributor that delivers the National Cold Chain Service (NCCS) for the entire country. All vaccines arriving in Ireland are brought to a central warehouse in Dublin. Each package or box of Pfizer-BioNTech vaccines, containing 195 vials or 1,170 doses, is marked with a GS1 DataMatrix barcode as part of the requirements for the EU's FMD regulation. The boxes are stored in freezers at the designated temperature.

To prepare the vials for distribution to vaccination sites, the vials are re-packaged in smaller pack sizes with the exact number needed for these sites (e.g., nursing homes). From the distribution site, the packaged vials of vaccines are transported in refrigerated

vans to more than 600 locations throughout Ireland.

One of the first recommendations by the GS1 Ireland team was the design of a standardised, full box and break-pack label—for the secondary packages that contain the vaccine's unique identifier—the GTIN, its batch/lot number, and the revised expiry date and time based on the re-packaging activity—encoded in a GS1 DataMatrix barcode.

The "use before" date and time information was needed for the Pfizer-BioNTech and Moderna vaccines as their remaining shelf life reduced once stored between +2°C and +8°C.

> "Traceability is a key part of managing the vaccine process. The use of barcodes has been very beneficial and it is evident that while it has saved time and resources, more importantly it is giving time back to clinicians while providing accurate information for decisions. Patient safety is key and TrackVax has been a real enabler in this case."

John Swords,
National Director of Procurement, HSE
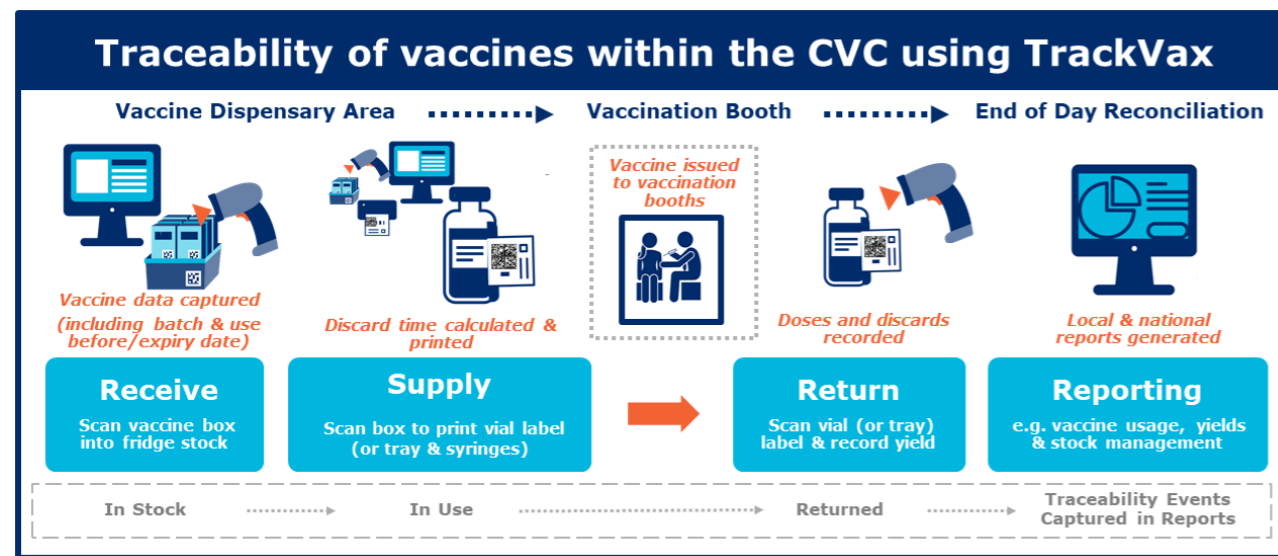
Figure 5: Traceability of vaccines within the CVC using TrackVax

3- TrackVax for safer medication management and more efficient vaccine reconciliation

The evolving situation with the pandemic meant it was a race to get people vaccinated. The HSE COVID-19 vaccination planning teams worked intensively on the design of the purpose-built CVCs. As part of this design phase, it was agreed that a standardised vial label was required, and GS1 Ireland was asked to provide the software to print these labels. This software ultimately evolved to become TrackVax, a full track and trace software to identify, label, track and report on the COVID-19 vaccines in the vaccination centres. **This proved invaluable for pharmacy staff as the CVCs were extremely busy during their peak when averaging 8 clients vaccinated per minute.**

The COVID-19 vaccines are received into stock in the CVC so that a full record is available for stock management. When a vial is required by vaccinators, the staff scans the box and the required number of vials are entered. TrackVax then prints a label for each vial with the key data, including a GTIN, batch and discard time, printed and encoded in a GS1 DataMatrix barcode. There is also the option to print syringe labels depending on the requirements of the CVC. The syringe mode is particularly helpful when approaching the end of the day to minimise the number of open vials and avoid wastage.

The vials or syringes are given to the vaccinators in the booths. There is also the option to assign a vial to a vaccination bay. Some sites used this option when they didn't have as many staff since it was easier to locate a vial when needed. The vaccinators like the standardised label as they can easily read the batch information and the discard time. When the vaccinator is finished administering the vaccine, the number of doses

drawn from the vial is written on the vial label and is then returned to the pharmacy so that the vial yield can be recorded in TrackVax. When in syringe mode, the tray is returned so the yield can be recorded. Each vaccine has different levels of yield. For example, for AstraZeneca the yield is typically between 11 and 12 vaccinations. For Pfizer-BioNTech the yield is between 6 and 7. Based on this wide range, TrackVax needed to be flexible to manage the yields.

TrackVax also allows for discarded vaccines to be accounted for. The system was designed so a discard code can be assigned. This is an important reporting requirement for the NIO in relation to vaccine usage and to detect any trends related to quality issues, or if additional training is required in sites.
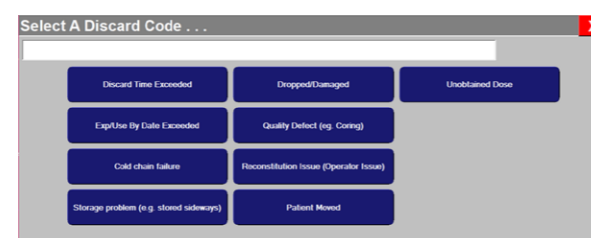
Figure 6: Table of Discard codes

The system provides a live dashboard for staff so that vaccine usage can be tracked throughout the day and oversight can be kept if a vial is close to expiration.

One of the challenges for staff in the early days was the reconciliation of the vaccine when using a paper-based process. CVCs use the data from TrackVax to keep a very close track of opened vials particularly as the end of the day

approaches which enables an accurate forecast of the number of additional vials that will be required for the remainder of the clinic. It is the combination of vial information or doses in open vials and remaining appointments that helps them manage this process.

TrackVax has made the vaccine reconciliation process much easier to manage since a full audit trail is available and an end-of-day report is automatically generated. This report is used to complete the vaccine reconciliation and confirm that the doses dispensed match the doses administered in the national vaccine administration system. The report also summarises the vaccine usage information and includes any discarded doses. This reporting was previously done manually by staff at the end of a busy day.

As all of the CVCs started to use TrackVax, the information related to vial yield was visible at local and national levels. The HSE can follow the yields by site and by vaccine type. And, because the vials are scanned and tracked as they are used in the CVC, the accuracy and timeliness of the data enables HSE and the individual CVC to make quick decisions.

TrackVax is giving the CVCs and HSE visibility of vaccine usage and stock management:

• What are current inventory levels of vaccines? What are the expiry dates?
• How many boxes and how many vials by vaccine type are in stock?
• How many doses have been administered in a given timeframe?
• What is the yield per vial? Are there any discarded doses?

Figure 7: Tracking vaccine vials in the CVC - sample labels paper vs electronic

Consider that one large CVC was experiencing a decrease in yield for the Pfizer-BioNTech vaccine. They immediately alerted the HSE's NIO. Using TrackVax, the team was able to check the yields for other sites and quickly identified that this decline was also happening in other CVCs. Upon closer examination, the HSE deduced very quickly that it was due to the type of syringes being used. Because the HSE had this data readily available, it immediately contacted the procurement team and arranged for the appropriate syringes to be provided to the sites to optimise the yield per vial. The data from TrackVax facilitated quick decision-making. The data wouldn't have been available using a paper-based system, and it is estimated that about 75,000 doses were saved due to this one change.

"The success of the implementation of TrackVax has demonstrated the importance of traceability, not just for the COVID-19 vaccine, but for all vaccines. It is truly exciting times for immunisation programmes which are ever changing and TrackVax will be integral to successful rollouts in the future."

Cliona Kiersey,
Chief Pharmacist, HSE National Immunisation Office

Throughout the roll out of the mass vaccination effort, the GS1 Ireland team has acted as an advisor to the HSE, helping to develop and put processes in place to sustain the support model. The team has also delivered onsite training as well as online training sessions as new versions of the software were rolled out and for new staff joining the CVCs. There are over 40 CVCs in Ireland and as these sites worked at full capacity, the GS1 Ireland team was busy supporting the teams on the ground. Additional GS1 Ireland staff members joined the support team to ensure every inquiry to the ticketing system was responded to in a timely manner, even during out of hours as sites worked 12 hour shifts, 7 days per week.

The feedback from the CVCs is very positive, and the traceability system is making their work easier. Reconciliation of the vials at the end of the day is a very time-consuming process when working with a manual process. The excellent data quality means that the NIO has oversight of vaccine usage and accurate stock level data. This means vaccines can be managed closely and wastage is kept to a minimum.

*"From a medication safety perspective, the use of Trackvax across our vaccination centres really helps to standardise our workflow, ensuring vaccines are labelled clearly with all relevant details, which is so important when delivering a programme on such a big scale.
The data from Trackvax is also informing evidence based decisions to ensure we achieve optimum yield from vaccine vials as it allows us to act quickly if any issues arise."*

Muriel Pate,
Medication Safety Specialist Pharmacist, HSE Quality and Patient Safety Directorate

Looking forward

TrackVax has been operational since 3 March 2021. The software has enabled the tracking and management of over 3 million vaccine doses, as of September 2021, or nearly 50% of Ireland's vaccination programme. TrackVax has been widely accepted across CVCs and has delivered value to the HSE through medicine safety, vaccine tracking, operational efficiency and programme integrity.

The TrackVax governance team recognises TrackVax using barcode scanning right to the

point of vaccination as an important foundation for the future management of vaccines across all vaccination centres, both large and small. The use of GS1 Traceability standards enable the tracking of vaccine type, batch and expiry date in one scan. This forms a working model for how traceability can be applied to many areas of care across the HSE.

While the benefits accrue during mass vaccination sites, further investigation is required to find ways to bring these benefits to smaller sites, such as nursing homes and general practitioners to enable end-to-end vaccine tracking and efficient, safe vaccine record creation through scanning barcodes at point of care. The next step is the development of a mobile app to facilitate the tracking of vaccines in the community based on a simpler version of TrackVax.

"History tells us that pandemics can last up to four years, and Ireland is now reopening society after 18 months. In order to do this, it has been critical that we have a safe and efficient vaccination programme. TrackVax has been instrumental in enabling a high level of quality assurance and traceability of the vaccine to every citizen. At our peak we were vaccinating 8 clients per minute, we couldn't have done that without TrackVax."

Joan Peppard,
Pharmacy Vaccination lead Dublin Mid-Leinster, HSE

Lessons learned

The pandemic and urgent need for mass vaccinations helped to drive the call for standardisation in how the vaccines were identified, scanned, administered and tracked. By "designing in" GS1 standards from the start, HSE and GS1 Ireland were able to act quickly and then monitor progress over time.

The GS1 Ireland team brought a significant amount of experience and knowledge about designing traceability into the vaccination process, systems and software needed to bring the vision to reality. It also meant putting easy-to-use, agile tools into the hands of the CVC staff to ensure accuracy and efficiency. The combination of this expertise and knowledge and GS1 Irelands' in-house ability to develop software based on user feedback was critical to the success of this project, particularly given the very tight timelines.

The strong relationship and collaboration between the HSE project teams and GS1 Ireland also proved to be a major success factor. The HSE appointed a TrackVax project lead who coordinated the meetings, sometimes multiple per day, actions and timelines which meant project milestones were achieved. Further to this the ICT teams and onsite engineers in the CVCs liaised closely with the TrackVax project team to ensure the smooth and efficient rollout and support of the ScanVax and TrackVax software. The TrackVax Governance group met weekly to review and take decisions, as required. The majority of the meetings took place online due to COVID-19 restrictions. Listening to and acting on feedback from pharmacists and

vaccinators on the front line as well as translating technical discussions into ones that were healthcare focused helped to keep everyone on the same page and moving forward.

"The feedback on TrackVax from the Senior Management Teams and the High Level Taskforce has been really positive in terms of enabling visibility of vaccine usage and it has been recognised that TrackVax has made a significant contribution to the efficient rollout of the COVID-19 vaccinations across Ireland."

Dr. Lucy Jessop,
Director of Public Health, HSE National Immunisation Office

- ➤ Vaccine Boxes (where necessary)
- ➤ Vaccine Vials, Trays and Syringes

- ➤ ScanVax for goods receipt and upload to vaccine locations (used on over 1,000 PCs)
- ➤ TrackVax, to identify, label, track and report on the vaccines (used in over 40 CVCs)
- ➤ Training and Support
- ➤ Continued development of system functionality

Labelling specification

Identification and Licensing

Software

Advisory

- ➤ SSCCs (vaccines boxes)
- ➤ GLNs (locations)
- ➤ GTINs (vaccine product)
- ➤ GSRNs (staff and patient identification)

- ➤ Technical expertise on barcode scanning and GS1 standards
- ➤ Traceability 'logic/processes' being designed into new vaccine administration system
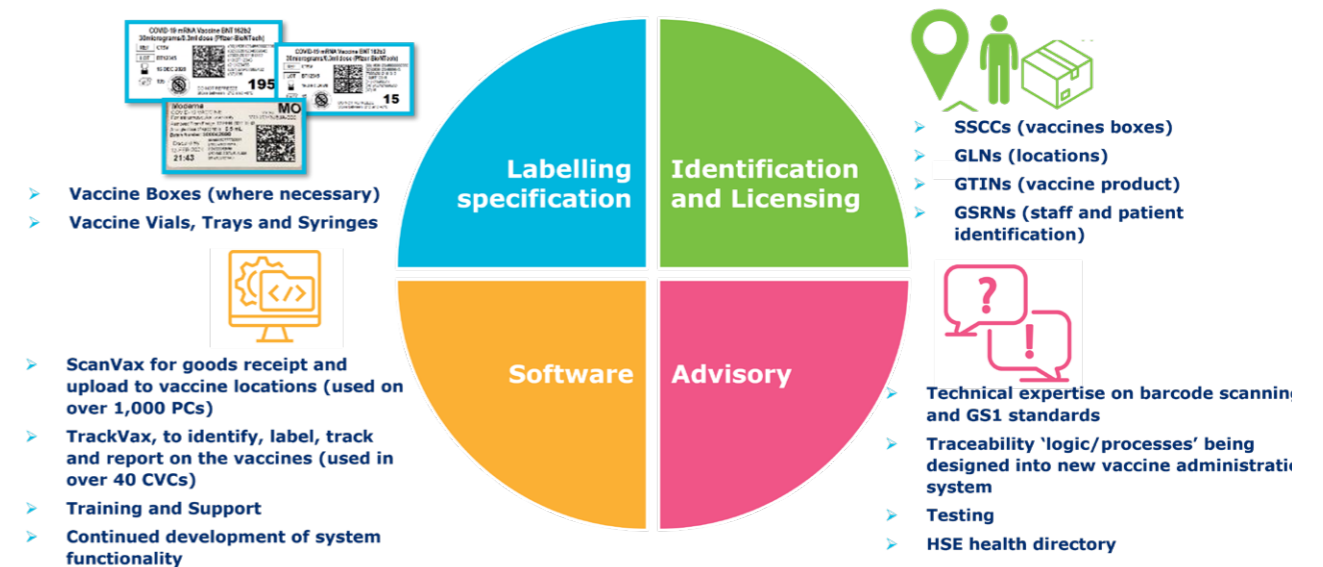- ➤ Testing
- ➤ HSE health directory

Figure 8: Overview of the areas where GS1 Ireland provided support to the HSE

TrackVax Project Governance & Project Management Team

Lucy Jessop,
Director of Public Health, NIO

Caralyn Horne,
National HSE Vaccination Programme

Cliona Kiersey,
Chief Pharmacist, NIO

Kerry Ryder,
ICT General Manager, NIO

Joseph McManus,
TrackVax Project Manager, HSE

Muriel Pate,
Medication Safety Specialist Pharmacist, HSE Quality and Patient Safety Directorate

Noreen Noonan,
ICT Delivery Director For Public Health, OoCIO, HSE

Fionnuala King,
Chief Pharmacist, Acute Hospitals Drug Management Programme, HSE Acute Operations

Mariangela Toma,
Chief II Pharmacist, NIO

Martin Wickham,
Covid-19 SO Support Lead, OoCIO, HSE

Joan Peppard,
Pharmacy Vaccination Lead Dublin Mid-Leinster, HSE

Justin McGoldrick,
Senior Project Manager, OoCIO, HSE

Amy Colgan,
Business & Administration Support, NIO

Aishwarya Vivekkumar,
Grade IV - ICT (Graduate Programme), NIO

Denis O'Brien,
Director of Standards and Solutions, GS1 Ireland

Amanda Creane,
Healthcare Manager, GS1 Ireland

Siobhain Duggan,
Director of Healthcare and Innovation, GS1 Ireland

Thank you to everyone from the many organisations both within the HSE and externally who have contributed to the successful implementation of the COVID-19 vaccine traceability programme including:

National Immunisation Office, Medicines Management Working Group, Office of the Chief Information Officer, Procurement, COVID-19 Vaccination planning and operations teams and all the staff in the CVCs

Special mention to the Hospital Pharmacy team at the Rotunda Hospital including Brian Cleary and Gavin Horan for their support in the early stages of design and testing of TrackVax, writing test scripts and for supporting the business case for the rollout of the system

About the authors

Dr. Lucy Jessop,
Director of Public Health, HSE National Immunisation Office

Dr. Lucy Jessop graduated from Cambridge University and worked in paediatrics before training in Public Health Medicine in London. She worked as a consultant in public health in Buckinghamshire for 5 years. In 2014, Dr. Jessop moved to work as a consultant in Health Protection in Northern Ireland and was the lead for childhood immunisation programmes. In 2019, she took up the position of Director of Public Health, HSE National Immunisation Office in Ireland, where she leads the implementation and improvement of all the national immunisation programme. She is now a member of the National Immunisation Advisory Committee (NIAC) in Ireland and is a passionate advocate for immunisations across the life course.

Siobhain Duggan,
Director of Healthcare and Innovation GS1 Ireland

Siobhain Duggan holds a Masters in Leadership and Management Practice and a Bachelors degree in International Commerce and German both from University College Dublin, and she has also completed all of her ACCA accounting exams. Ms. Duggan worked abroad in Germany and Switzerland in a variety of business development, supply chain and product marketing roles in BMW for one year and subsequently in Hewlett Packard for 11 years. She joined GS1 Ireland in 2010 and now leads the implementation of the healthcare strategy in Ireland. She brings a wealth of international supply chain experience to her role as well as a passion for patient safety in healthcare. She is also an Executive member of the Health Informatics Society of Ireland (HISI).

Kerry Ryder,
ICT General Manager, HSE National Immunisation Office

Kerry Ryder has been working with the NIO as ICT General Manager since 2016. She is an experienced application manager with a demonstrated history of working in the hospital and healthcare industry. Skilled in Business Process Design, Dashboard Requirements Analysis, Integration strategy, Standards, Healthcare Information Technology (HIT), and Management. Strong information technology professional graduated from Royal College of Surgeons in Ireland. Ms. Ryder is a passionate advocate for the utilisation of Information Technology to assist in the safer delivery of care. She has been a strong supporter of barcode standards and traceability to enable the safe and efficient rollout of the COVID-19 vaccination programme.

Cliona Kiersey,
Chief Pharmacist, HSE National Immunisation Office

Cliona Kiersey holds a Masters in Pharmaceutical Medicines and a Higher Diploma in Quality in Healthcare. She is the only pharmacist in Ireland (of 5 people internationally) to have been accepted to complete the internationally recognised Advanced Course of Vaccinology (ADVAC). Prior to joining the National Immunisation Office in 2005, she worked as a qualified pharmacist in both retail and hospital pharmacies. She is currently responsible for vaccination programme planning, through vaccine procurement, vaccine budget and management of the cold chain delivery service. She also represents Ireland at the EU level on the joint procurement of medical countermeasures and pandemic vaccine procurements, including the procurement of COVID-19 vaccines.

About the Health Service Executive and the National Immunisation Office

The HSE provides all of Ireland's public health and social services in hospitals and communities across the country. They are the largest employer and organisation in the Irish state, employing over 100,000 people.

The HSE National Immunisation Office is responsible for managing vaccine procurement and distribution, developing training and communication materials for the public and health professionals. The mission of the National Immunisation Office is to work with key stakeholders and support healthcare providers to maximise the uptake of all national immunisation programmes.

www.hse.ie/eng/

Japan

GS1 Digital Link helps deliver valuable e-leaflet information to healthcare providers and patients

Challenge

In November 2019, amendments were made by the Japanese government to the Pharmaceuticals and Medical Devices Act (PMDAct) with the aim to enhance patient safety. One amendment called for the transition from paper-based to electronic leaflets (e-leaflets) for pharmaceuticals and medical devices.

Approach

Nearly all pharmaceutical marketing authorisation holders (MAHs) have completed the registration process to link the GS1 Global Trade Item Number® (GTIN®) encoded in the GS1 barcode on the product's package to the product's e-leaflet on the Pharmaceuticals and Medical Devices Agency (PMDA) website. Healthcare providers and patients can scan a product's GTIN in the barcode and GS1 Digital Link directs them to product's e-leaflet on the PMDA website. For medical devices, some of the manufacturers have registered their e-leaflets on the PMDA website. Linking the GTINs is now in progress with the goal to complete the process in two years.

Most up-to-date information about pharmaceuticals and medical devices

Immediate access to critical product information for healthcare providers and patients

Eliminates paper waste for increased sustainability

Improves patient safety with simple scan of a product's barcode

Advancing patient safety

Today, all secondary packages of pharmaceutical products and medical devices contain paper leaflets for use by healthcare providers, and this leaflet information is registered on Japan's PMDA website.

One of the PMDAct amendments specifically mandated that pharmaceutical and medical device manufacturers and other types of marketing authorisation holders (MAHs) would need to transition from paper-based to e-leaflets (Over-the-counter drugs and medical devices are out of scope.) Each product's e-leaflet would need to be accessible via a barcode on the product's package—a barcode that healthcare providers and patients could scan to easily read the latest e-leaflet's information on the website.

As early as 2006, GS1 standards have been promoted by Japan's Ministry of Health, Labour and Welfare (MHLW) as the only standards for the unique identification of pharmaceuticals and medical devices. The unique product identifier— the Global Trade Item Number—is encoded in GS1 barcodes such as the GS1 DataBar and GS1-128 for pharmaceuticals and the GS1-128 and GS1 DataMatrix barcodes for medical devices.

Today, 100% of pharmaceuticals' packages have GS1 barcodes—from primary packages (e.g., vials and blisters) to tertiary packages. For medical devices, more than 95% have barcodes on secondary packages and most high-risk medical materials such as catheters and orthopedic products have barcodes applied on primary packages.

Mr. Masayuki Muraoka, the Ministry's Deputy Director, Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau is responsible for leading Japan's barcoding strategy of pharmaceuticals and medical devices.

"There were several advantages of using GS1-based barcodes. For example, one of the benefits is that GS1 barcodes can be used on the product's multiple layers of packaging— not just on secondary packages," explains Mr. Muraoka. "This precise level of identification ensures that pharmaceutical products can be scanned in various scenarios by healthcare providers and even patients, giving them critical information for patient safety."

Problems with using paper

While paper leaflets describing the potential side effects and other important information are inserted in secondary packages, these inserts are frequently revised as new information becomes available. The use of electronic leaflets enables manufacturers and other MAHs to keep published information about products up-to-date—especially critical for high-risk drugs and medical devices.

Another important consideration was the Ministry's goal to minimise the use of paper for a more environmentally friendly and sustainable approach. "We want to eliminate paper waste in favour of providing healthcare providers and patients with the latest information in a digital format," says Mr. Muraoka.

> "While QR codes were considered, the decision to use GS1 standards was made. "With GS1 standards already in place as a foundation, we knew it was possible to more easily extend the benefits of using standards to include e-leaflets."
>
> **Mr. Masayuki Muraoka,**
> Deputy Director, Pharmaceutical Safety Division, Pharmaceutical Safety & Environmental Health Bureau, Ministry of Health, Labour & Welfare

Figure 1: For pharmaceuticals, e-leaflets can be accessed from every type of package with a GS1 barcode.

Made possible by the GS1 Digital Link standard

As of August 2021, the vast majority of pharmaceutical manufacturers and some of the medical device manufacturers have completed the registration process to link the GTIN encoded in the GS1 barcode on the product's package to the product's e-leaflet on the PMDA website.

This is made possible with GS1 Digital Link standard. Healthcare providers and patients alike can scan a pharmaceutical package's GTIN in the barcode and the Digital Link's URI directs them to product's e-leaflet on the PMDA website.

For each product, there are three URIs:
• E-leaflet for healthcare providers
• Related information for healthcare providers
• E-leaflet (for pharmaceuticals only) for patients and consumers

E-leaflet for healthcare providers ⟩	https://www.pmda.go.jp/PmdaSearch/bookSearch/01/04912345678904
Related information for healthcare providers ⟩	https://www.pmda.go.jp/PmdaSearch/rdSearch/01/04912345678904?user=1
E-leaflet for patient and consumer: pharmaceuticals only ⟩	https://www.pmda.go.jp/PmdaSearch/rdSearch/01/04912345678904?user=2

Figure 2: GS1 Digital Link uses the GTIN encoded in GS1 barcodes on packages to re-direct users to e-leaflets. The GTIN in Figure 2 is an example.
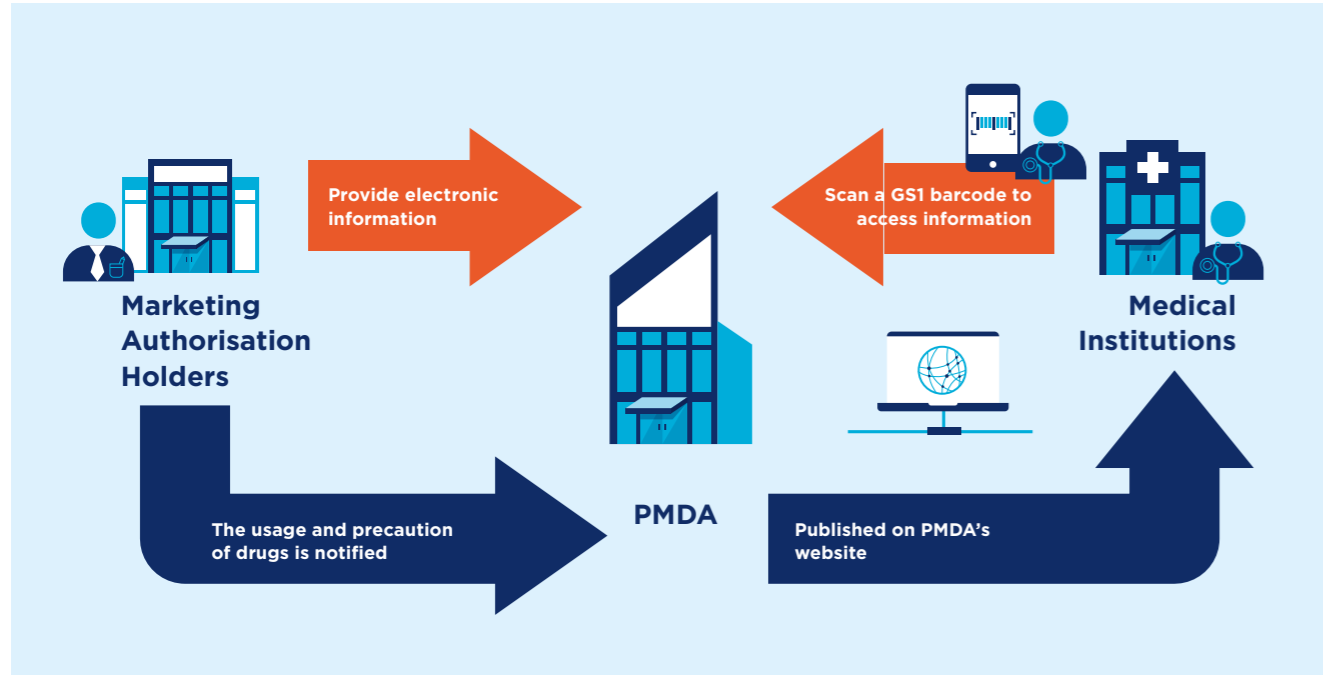
Figure 3: Now, healthcare providers and patients alike can scan a pharmaceutical package's barcode and the Digital Link's URI directs them to the PMDA website that then directs them to the product's e-leaflet.

Ease of scanning with a smartphone app

GS1 Japan in cooperation with the Federation of Pharmaceutical Manufacturer's Association of Japan (FPMAJ) and the Japan Federation of Medical Devices Association (JFMDA) developed a smartphone app called "Tenbun-Navi."

Available on the Apple App Store and Google Play, Tenbun-Navi is free to download and makes accessing e-leaflet information even easier. With the app, healthcare providers can use their smartphones and tablets (versus specialised scanning equipment) to scan barcodes and browse e-leaflets on the PMDA website.
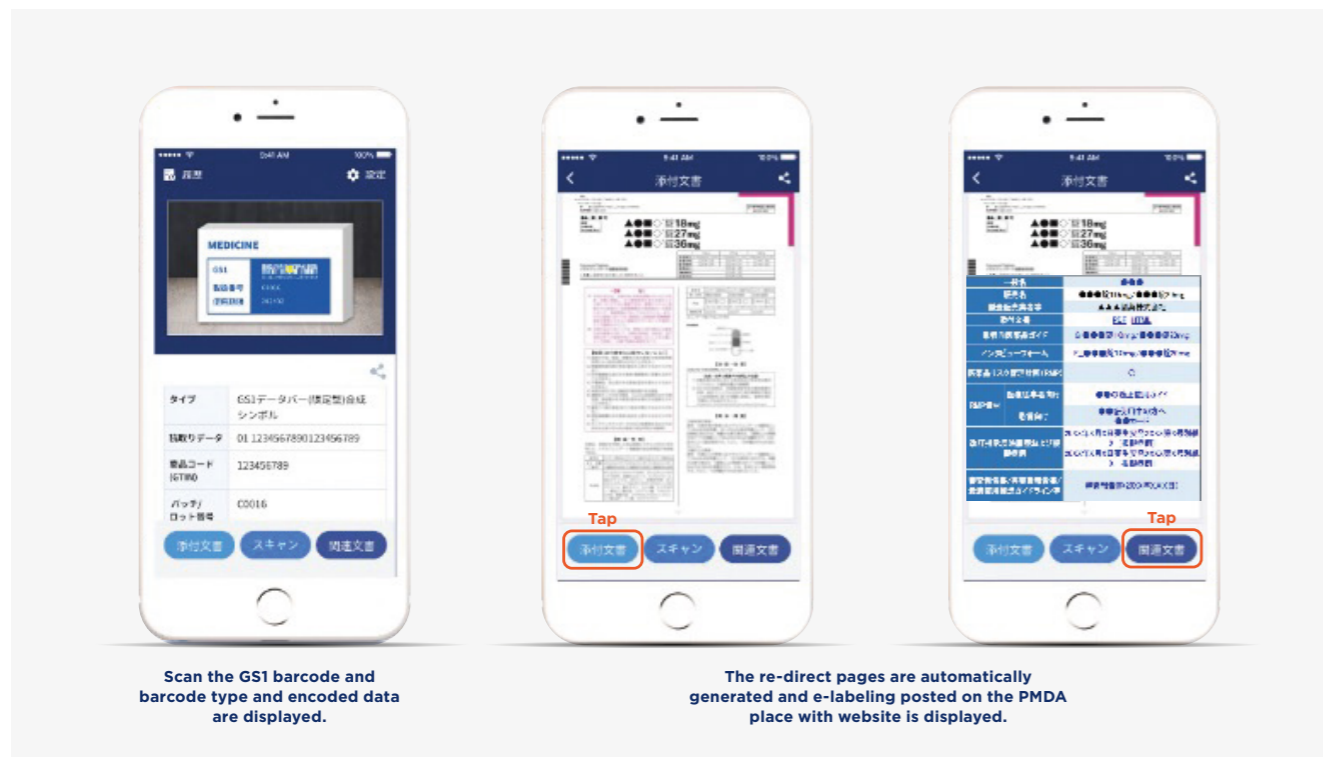
Scan the GS1 barcode and barcode type and encoded data are displayed.

The re-direct pages are automatically generated and e-labeling posted on the PMDA place with website is displayed.

Figure 4: The Tenbun-Navi app makes e-leaflet information easily accessible via a smartphone or tablet. (https://www.dsri.jp/standard/healthcare/tenbunnavi/app/index.html)

Accessing COVID-19 vaccine information

The fact that all primary packages have GS1 barcodes, such as vials, ampules and blisters, provides significant benefits for healthcare providers. Now, healthcare providers can check e-leaflets via these GS1 barcodes at all points of care: pharmacies, hospital wards, theatres or nursing homes. Access to e-leaflet information is also expected to be beneficial during the COVID-19 pandemic. One of the vaccines supplied to Japan has a GS1 barcode on the primary package (vial), which can be scanned by healthcare providers to be directed to the e-leaflet and other related information.

On the path to patient safety

In Japan, the use of GS1 standards to identify, label and barcode healthcare products has been promoted by the Ministry and GS1 Japan and implemented by manufacturers for more than a decade.

Thanks to this promotion, most healthcare products have GS1 barcodes on many levels of packaging, even on primary packages. This foundation of GS1 standards helped make the change from paper to e-leaflets a much more efficient transition.

"With GS1 barcodes on the primary packages of pharmaceutical products and medical devices, GS1 standards are increasingly being recognised in Japan's healthcare system as highly useful for improving patient safety as well as increasing operational efficiencies," says Mr. Muraoka. "With the introduction of the GS1 standards, especially GS1 Digital Link, to support ease of access to e-leaflets, we anticipate that healthcare stakeholders like electronic health record companies will become more and more interested in the use of GS1 standards for benefits like traceability."

Looking to the future, the Ministry along with manufacturers and healthcare providers will continue to leverage GS1 standards for the health and well-being of Japan's people.

About the author

Masayuki Muraoka is the Deputy Director, Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau with the Ministry of Health, Labour and Welfare. He is responsible for leading Japan's barcoding strategy of pharmaceuticals and medical devices. Since 2012, Mr. Muraoka has held numerous government positions, most recently the Deputy Director of the Forestry Agency Administration and Deputy Director to the Assistant Chief Cabinet Secretary.

Masayuki Muraoka, Deputy Director, Pharmaceutical Safety Division, Pharmaceutical Safety & Environmental Health Bureau, Ministry of Health, Labour & Welfare

Healthcare Providers

Healthcare institutions around the world are working to provide the best possible care for their patients, often under pressure to save time and money. GS1 standards are helping them do all this. Read the case studies over the next few pages to find out how.

Denmark

Improving inventory management and patient safety with simple scans

Challenge
The North Denmark Region has three hospitals with approximately 1,800 beds and more than 8,700 employees. The hospitals' surgery departments used non-standardised manual processes for the replenishment of goods, making them time-consuming with increased risk for human error. There was also an insufficient way to track and trace implants and their patients. Finally, the hospitals needed a better understanding of the total cost for surgeries.

Approach
North Denmark Region's IT department developed an automated process for replenishment that allows staff to scan GS1 barcodes on products used in surgery, directly from the operation theatre. The system was been expanded to include traceability capabilities for implants to patients, named the Implant Trace Module (ITM). Since the traceability system is scalable, it has been implemented in all Surgery departments.

€134,000
saved each year by the Cardiac Laboratory department

Out of stock situations have been eliminated

12 minutes saved on each surgery

Increased staff productivity and improved patient safety

One of five regions in Denmark, the North Denmark Region is the smallest with 578,839 citizens. Yet, the region provides health services for Greenland which makes it, from a geographical perspective, the largest area to serve. The North Denmark Region has three main areas of responsibility:

• Healthcare, including public hospitals
• Regional development
• Social services and special education

The region's public hospitals make up 95% of all hospital services. To make these services possible, the hospitals needed highly efficient inventory management of medical devices and implants. In particular, the region's surgical wards wanted to digitalise their inventory management by using GS1 barcodes for streamlined processes.

Inefficient and risk-prone manual processes

Prior to using barcodes, inventory management processes were manual. After surgeries, a nurse had to key in the medical devices and implants to be reordered via a computer—making it a time-

consuming and vulnerable process. Sometimes, multiple nurses reordered products and, at other times, products were not reordered at all. The process was also risk-prone; at times, the wrong devices were reordered. All this impacted the efficiency, accuracy and trustworthiness of the hospitals' inventory management system. It also meant that they had higher inventory levels than needed of very expensive devices and implants.

Together with the IT department, the Cardiology Laboratory and Orthopedic department planned a digital replenishment project, using GS1 Global Trade Item Numbers (GTINs) encoded in GS1 DataMatrix barcodes on packages of medical devices and implants.

In the beginning, the project was straightforward and required about 200 hours of development from the IT experts. When the new process was introduced, replenishment was performed directly from the operation theatre by scanning the GS1 barcodes available on packages. When used products reached a specific threshold defined by doctors and nurses, the products were reordered automatically.

As a result, nurses and doctors increasingly trusted the inventory management process.

Receiving and handling products became much more efficient, because these processes were accomplished without paper. It was also easier to replace products in the stock rooms, because staff knew where products were taken from.

Eventually, threshold levels declined and stock levels decreased, due to increased visibility and more efficient processes.

All this has led to improved financial benefits. The Cardiology Laboratory participating in the pilot saved approximately €134,000 annually (1 million Danish Krones) resulting from improved inventory management and processes.

Better inventory managed meant better planning with no out-of-stock situations. In turn, this prevented the cancellation of surgeries due to the lack of necessary products, a huge benefit for staff as well as patients. Because of the simpler processes, it also became easier to train back up staff for holidays and when staff were ill.

Region's Board approves full roll out

The pilot was considered a huge success for all involved with a high return based on a low investment in time. Because the system used GS1 standards, it was quite scalable. As a result, the Region's Board decided to focus on improving other important processes.

At that time, data for the traceability of implants to patients was generated, but in

a manual and time-consuming way. In case of a recall, data was not easy to work with, and required a significant number of hours of searching by the staff to find those patients impacted by the recall.

Therefore, the next phase of the project focused on creating a regional implant registry, where traceability information between patient and implants is stored.

Traceability data was generated by scanning GS1 barcodes on implant packages, capturing necessary information such as the implant's Global Trade Item Number® (GTIN®), batch/lot number and serial number. In the registry, user-friendly functions make it possible to match implants to patients in a matter of seconds, increasing patient safety and saving the staff valuable time.

In the new processes, more complete and accurate data is generated by scanning barcodes as part of the new processes. The fiscal department has started using the data as an input to better estimate the total cost of surgeries performed.

Based on a better overview of what products were used in surgeries, the department is able to better estimate the resources required to run a department. Furthermore, with access to accurate and complete data, the department can better negotiate with the national bodies that pay the regions for what they perform and the associated costs. The information is also used in tenders for greater precision on what

was actually purchased on a specific contract for a specific period.

Because of the numerous benefits the pilot project, the Board of the region decided that the new GS1 standards-based processes should be implemented in all Surgery departments at the hospitals.

Step-by-step roll out

Given the task, the clear decision from executives in the organisation to automate hospital processes enabled by GS1 standards was an important tool for the small team.

The project was approved for implementation in 26 departments in North Denmark Region's hospitals. It was decided to implement in phases—three departments at a time, completing implementation before starting a new one.

This approach provided the team with an opportunity to learn from each implementation, and bring these experiences and lessons learned to the next phase. At the same time, the team was able to ensure that each department realised the planned benefits within a certain timeframe.

The project's implementations were based on a step-by-step plan, to include:

1. Introduction by the Purchasing department, explaining the challenges with the existing replenishment and traceability processes for implants. The GS1 standards-based solution was explained with the Implant Traceability Module (ITM).
2. Technical introduction on the new inventory management process with the ITM and updated internal processes.
3. Roll-out plan development with the local team responsible for the department, including timelines, sourcing scanners, and recruiting champions and super users.
4. Education and training of the staff, including the training of super users who would help others (e.g. help them understand which barcodes to scan on packs, if multiple barcodes were on the pack).
5. Conducting the implementation, starting with getting an exact baseline inventory level.
6. Project evaluation and support of users until they were comfortable with the new system and processes.

It was important that training was very close to start of implementation. That helped the trained staff to remember the important messages in the training when they started to use the system. The surgery department has discovered it is now saving time with each surgery. The implementation staff once used 10-15 minutes to perform the replenishment process manually.

> **The Surgery department has discovered it is now saving time with each surgery. The implantation staff once used 10-15 minutes to perform the replenishment process manually. Now, by scanning GS1 barcodes, the process is completed in 3 minutes, and technical errors have been eliminated.**

Now, by scanning GS1 barcodes, the process is completed in 3 minutes, and technical errors have been eliminated.

Concept for National Implant Registry

For improved patient safety, it was decided in 2015 that Denmark should have a national implant registry where traceability information for each patient would be stored for all surgeries, with a few exemptions.

The project in North Denmark Region was an inspiration for this National Implant Registry concept. Before all other hospitals (public or private), the region participated in a pilot for one year that delivered traceability data to the implant registry as a proof of concept. Since July 2018, legislation has required that all hospitals deliver traceability data about implants used in all surgeries to the registry.

As a result, the importance of barcodes on packages has increased. As part of the system implementation in all region's departments, tenders now mandate that suppliers of implants must apply barcodes based on global standards, such as GS1. This step was necessary to ensure that the barcodes needed are available for users.

Next steps

Many benefits have been achieved and more are still to come, including increased patient safety and the productivity of users.

An obvious benefit is that most implants have expiration dates encoded in their GS1 barcodes. This information can be used for better inventory

management, helping staff work with the first in, first out (FIFO) concept and to reduce waste by keeping expired implants to a minimum. The ITM solution also contains data to provide a better overview of when back-order situations occur and find the needed products elsewhere to prevent the cancellation of surgeries. This can be achieved by giving departments access to information about levels of available products in other departments, making it more efficient to find needed stock internally.

A challenge today is that it is not always easy for the user to decide if an implant should be registered in the National Implant Registry, or if it is exempt. The classification standard, UNSPSC (United Nations Standard Products and Services Code), is used in different processes today, and this step could be an additional one in the future, using the classification standard to define if the product needs to be registered or not. This will require a continuous focus on high quality data by manufacturers, because their work will be used for compliance with legislative traceability requirements.

Greenland plans to soon use all IT systems for purchasing and warehouse management that the North Denmark Region uses. Implementing the ITM solution for surgical departments in Greenland is an important step.

Conclusion

Starting the journey from manual to automated processes, using technology and standards such as barcodes and GS1 standards, has been a great choice for North Denmark Region. Improved stock management, replenishment and traceability for implants has been achieved in ways that would not be possible without the use of GS1 standards and technology.

The benefits are much greater than the cost of implementation, when it comes to both economic and human resources, and increased patient safety.

An important learning has been that is essential to secure both local and top level management commitment when conducting projects that have a huge impact on how staff work in hospitals.

North Denmark has started a journey, and the journey will not end soon. The hospitals will continue to use technology and GS1 standards to achieve more and more benefits.

About the author

In 2002, Camilla Schnell Steen received a law degree from the University of Aalborg. After 11 years in the telecommunications industry working with LEAN manufacturing, she started at North Denmark Region as a Purchasing Controller, responsible for LEAN and e-commerce projects.

Camilla Schnell Steen, Purchasing Controller, North Denmark Region

About the organisation

North Denmark Region
The healthcare sector is the main responsibility for North Denmark Region. Over 90% of its budget is allocated for healthcare services. The hospitals in Northern Denmark represent practically all medical specialties, and offer most types of treatments. In particular, Aalborg University Hospital is of great importance to the high standard the regional hospitals possess.

North Denmark Region includes:
- 3 hospitals on 11 sites
- 1,753 beds plus an additional 50 beds in the patient hotel
- Approx. 8,700 employees working in the hospitals
- Budge of almost 7.2B DKK
- Pre-hospital force with approximately 50 ambulance alert units

rn.dk/service/english

Ireland

Implementing RFID-enabled technology for the transport of precious laboratory samples at St. James's Hospital

Challenge

Laboratory samples, such as cancerous tissues taken during a biopsy, are "precious" since a patient's care could be delayed if the sample was lost. It would be necessary to take another sample (perhaps by another potentially invasive operation) or the hospital might be unable to retrieve another sample, unnecessarily delaying the diagnosis and treatment for the patient.

Approach

St. James's Hospital in Dublin investigated GS1 standards-based RFID (radio frequency identification) technology in 2014 as a method of tracking anyone or anything that could move or be transferred within the hospital. By placing an RFID tag on an asset, person or item and installing an RFID infrastructure within the campus, it can now be tracked and located. The RFID project called PATH (Patient and Asset Tracking in Healthcare) is part of a broader overall traceability strategy in the hospital.

Full visibility of movement of specimens

Increased patient safety

Knowledge of information transfer

Standards-based RFID infrastructure is now in place

St. James's Hospital is a 60-acre campus with approximately 52 different buildings and 4,500 staff. Around 10,000 people walk through the hospital's front door each day—a level of activity that is comparable to that of a small town.

At any point in time, St. James's Hospital had low visibility as to where people, patients and assets were located. When considering a use case for RFID-enabled traceability, the hospital identified significant risks associated with the transport of precious samples from the theatre to laboratory. The traceability process in place was manual and paper-based. A sample could go missing, impacting patient safety and causing potential issues for the patient and hospital.

For example, without a safe and effective system of transporting samples, a missing sample might not be discovered until the end of the day or much later when the consultant was looking for the laboratory test results. The hospital had worked on a solution to track the samples using books to sign samples in and out but it was time consuming, open to error and posed a clinical risk should samples go missing.

"It's of fundamental importance to all at ASD that we deliver solutions that meet and exceed our customers' requirements. The GS1 standards are a core part of our products and they standardise and future-proof our solutions. The synergy between ASD, St. James's Hospital and GS1 Ireland was also a key element to this successful project implementation. We look forward to this continued working relationship and successful implementation of many more projects at St. James's."

Dave Browne,
Managing Director, Aerospace Software Developments (ASD)

The aim of the RFID-enabled solution was to improve patient safety by introducing a safer system for the transport of precious laboratory samples throughout the hospital by using RFID-enabled technology to automatically track the samples from theatre to laboratory.
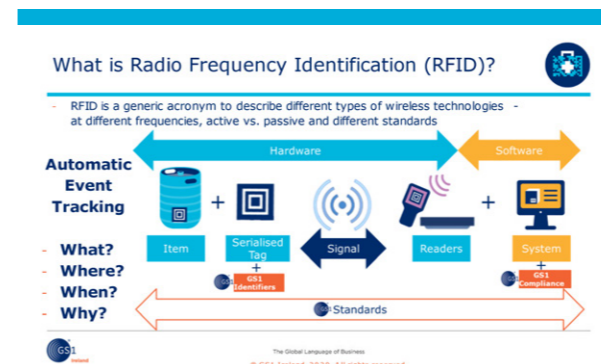
The hospital also took the opportunity to use the hardware put in place to extend the solution to allow for the tracking of vulnerable patients whose safety is at high risk*. The solution was then expanded to track valuable art and to protect it from theft.

Aerospace Software Developments (ASD), a GS1 Ireland Certified Solution Provider, was engaged by the hospital to implement the RFID solution. GS1 Ireland worked with ASD to provide guidance on the implementation of GS1 standards.

Revisiting RFID

St. James's Hospital had previously embarked on an RFID tracking project, using real-time tracking technology to track vulnerable patients, but there were issues with WiFi connectivity and the solution was not scalable. Furthermore, it was a proprietary solution that was not based on standards.

There were valuable lessons learned from this experience that the hospital used in the design of the new solution to help ensure its success. St. James's Hospital knew it would need:

- A coordinated approach across many departments
- Integration with other IT systems
- Buy-in from users and staff
- A clear chain of custody
- Most importantly, a standards-based solution based on a strong working relationship between ASD and GS1 Ireland

In addition, there were other considerations associated with working in a hospital theatre environment, such as mitigating infection control risks introduced by the new process.

A strategy group was formed to rebuild confidence in RFID as an enabling technology and to invest in a standards-based solution that would be future-proof and scalable.

The group investigated where RFID would be an immediate and worthwhile benefit. A plan

* in adherence with patient consent policy

was developed to identify current problems that RFID could solve quickly and without too much investment in infrastructure and software.

Two business pain points were immediately identified within the hospital: precious samples and vulnerable patients. The hospital started the ambitious project to track and trace all precious samples from theatres to the central pathology laboratory (CPL).

Working in conjunction with ASD, St. James's Hospital successfully completed a proof of concept, tracking precious samples taken in the main theatre, day surgery theatre, endoscopy and ultrasound departments. This was generally regarded as the most difficult use case scenario, demonstrating the complete value of using RFID technology in healthcare.

The before process

Before implementing the RFID-based solution, the transportation of precious samples from theatres to CPL required completing a paper-based register. The original system consisted of an unreliable chain of custody and offered zero visibility with no reliable data. In short, the system had the potential for patient samples taken in theatre to get lost when transported to the CPL.

Test results and diagnosis could be delayed with additional time spent looking for the sample, resulting in the completion of an Adverse Incident Report.
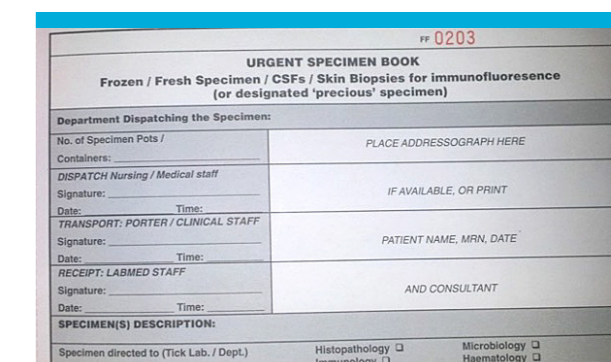
Figure 1: The original system was paper-based with an unreliable chain of custody.

The new process

Today, the RFID solution enabled by GS1 standards tracks the movement of precious samples by using RFID tags on sample bags and RFID readers installed at entry/exit points in the hospital.

The workflow starts with the nurse in the theatre who places and scans an RFID tag encoded with a GS1 unique identifier—the GS1 Serial Shipping Container Code (SSCC)—on the

bag of patient samples. The GS1 Global Service Relation Number (GSRN), the unique patient identifier, is also scanned to link that patient with the samples.

The samples are then left in a basket for collection by the porters. The porters also have RFID tags each encoded with a GS1 GSRN, a unique staff identifier, embedded in their staff ID cards. So, when a porter collects the samples, his identification is associated with the samples and the patient.

The porters have a pre-determined length of time to arrive in CPL. RFID readers and antennae have been installed at key points in the hospital and in CPL. The chain of custody is passed from the theatre nurse to the laboratory staff when the porter and samples arrive and are read by the RFID readers.

The theatre, exit doors and laboratory have all been assigned GS1 Global Location Numbers

(GLNs) that are used to identify RFID reader locations. All unique identifiers—the GSRNs, SSCCs and GLNs—are encoded in tags containing an RFID antenna, which can be encoded with the same information as printed on a two-dimensional (2D) GS1 DataMatrix barcode.

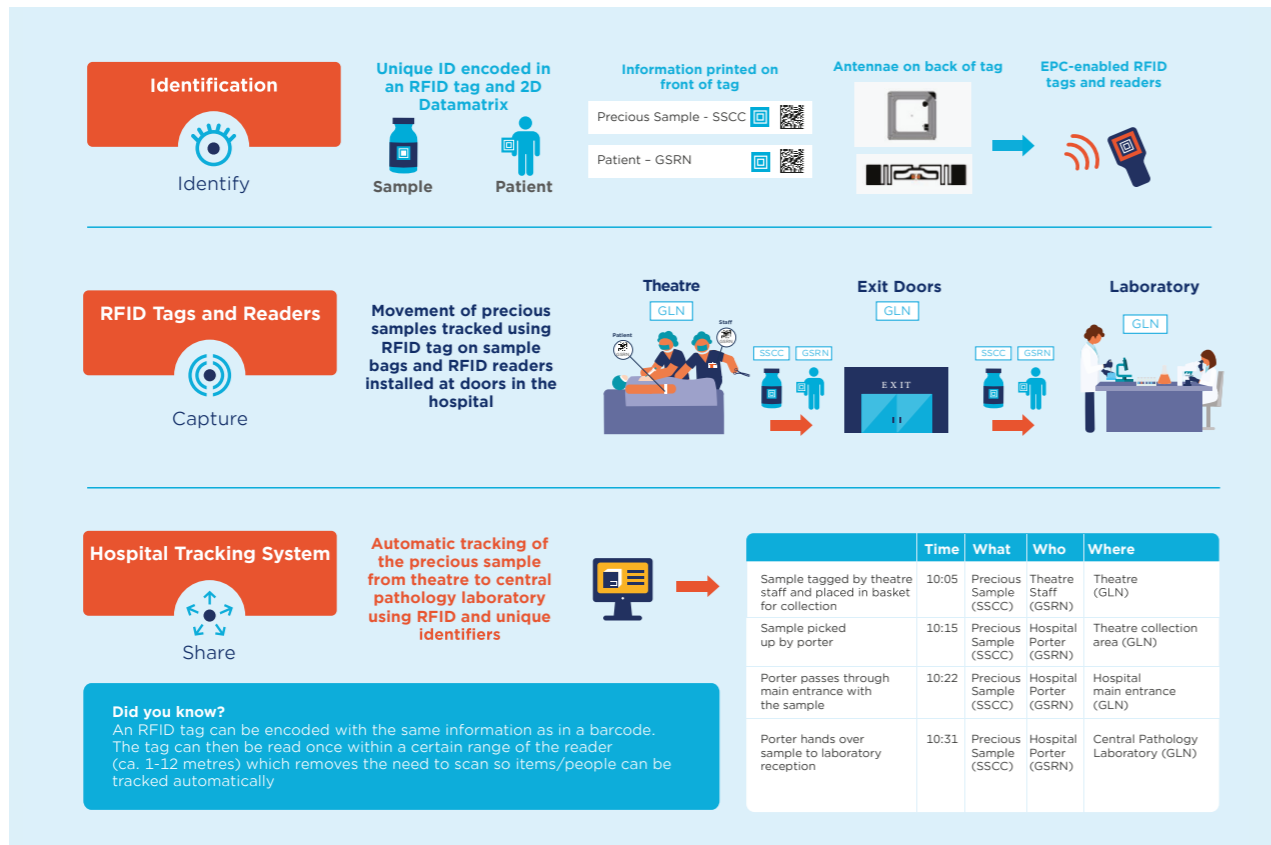The RFID tags are read when they come within a certain range of the readers installed at doors in the hospital (approximately 1-12 metres), enabling the automatic tracking of these samples throughout the hospital via the ASD-provided system.

If a sample doesn't arrive at CPL in a given amount of time, an alert is sent to the portering services manager, indicating a sample has not reached its destination. The tracking database is consulted to identify the point where the sample was last seen, and the relevant staff is contacted. Before the introduction of this system, it could be the following day before a search even started.

Figure 2: The RFID-enabled tracking system and RFID tags on sample bags

Figure 3: Precious Samples Movement List

Challenges

Technology

Previous experience in the hospital with RTLS technology had highlighted the challenges around costs and connectivity. The hospital was then introduced to ASD by GS1 Ireland as the only GS1-certified solution provider of passive RFID solutions in Ireland. ASD worked very closely with the project team to choose the most appropriate hardware (tags and readers) that would optimise the tracking of the precious samples. The software was also customised to link with the hospitals security system.

Change management

In developing the RFID-enabled system, the hospital had lengthy and widespread consultation sessions with all the staff involved. They had particularly detailed discussions with the portering staff who were a vital part of the chain of custody. Since this involved an additional level of tracking, there was initial fear that this may be a source of blame; however, It was very clear to everyone that the introduction of the new system was all about patient safety.

To date, feedback from the staff has been excellent and they have provided the hospital with many suggestions for improvement.

"The RFID infrastructure we now have in place has allowed us to expand our use of Standards-based RFID enabled technology and is now part of a broader overall traceability strategy at St. James's Hospital leading to safer care for our patients"

Vincent Callan,
Director, Campus Development Office,
St James's Hospital

Outcomes and benefits

The RFID-enabled transport of precious laboratory samples and a tracking system was implemented in the histopathology laboratory, day-surgery centre and main theatre in 2016. Over a two-year period, from June 2016 to 2018, 16,733 tagged bags were transported, equal to 24 bags per day.

As a result, the system has:
• Increased patient safety by eliminating the risks of not being able to track all precious samples
• Enhanced trust with staff through the visibility of sample movement
• Put in place a standards-based RFID infrastructure that provides the foundation for future standards-based patient and asset tracking solutions (which are in progress)

These solutions have enabled huge organisational efficiencies in patient care and quality as well as improvements in safety, security, portering services and waste management.

"These precious samples are biological samples that cannot be easily taken again. If these samples are lost it can be detrimental to a patients timely diagnosis. It is critical that we ensure we have safe and effective procedures in place so that we have an audit trail and visibility from when the sample is taken to when it is processed- and we have achieved that with the RFID solution!"

John Gibbons,
Laboratory Advisor, Campus Development Office, St James's Hospital

Figure 4: RFID readers installed at doors in the hospital.

Significant benefits

The introduction of the GS1 standards-based approach to RFID tracking has achieved the following:

- Significant cost savings and time savings for staff resources to redeploy to other value-added activities
- Reduction in re-keying and duplication of work, streamlining processes and improving productivity
- Decline in the hospital's reliance on paper-based processes
- Tighter controls throughout the lab sample process
- Scalable solution to track all assets, patients, providers, products, stock and more
- Maintenance of assets that can be actively tracked, enabling huge organisational efficiencies in patient care and quality as well as improvements in safety, security, portering services and waste management

In 2016-17, RFID projects included precious samples, staff including porters, public wheelchairs, Mercer's Institute for Successful Ageing (MISA) patients and fine art.

Projects in progress since 2018-19 have included: Medical Physics Bio Engineering (MBPE) equipment, beds, infusion pain pumps and ICU samples.

With the RFID infrastructure now in place, the hospital has been able to expand its use of standards-based RFID technology to track and trace assets, staff, patients and more, as they move throughout the entire hospital campus. The PATH project is now part of a broader overall traceability strategy at St. James's Hospital.

Other future initiatives include the tracking of patients in the emergency department and equipment on loan from other hospitals, as well as the integration of RFID tracking with the Scan4Safety Project.

Implementation timeline

May 2014 – June 2015

Kick off with GS1's introduction of ASD to St. James's Hospital. Formation of strategy group. Agreement of project-phased approach to begin RFID project based on GS1 standards to track precious samples.

Development of ASD software for the precious samples proof of concept. Training of all staff—nurses, porters and lab scientists.

Completion of infrastructure implementation and software development for precious samples. Completion of proof of concept for precious samples in main theatre, day surgery theatre, endoscopy and ultrasound.

December 2015

Go live with fine art. Completion of public wheelchair tagging and ASD software development modifications.

January – November 2016

Development of RFID solution for vulnerable patients, including creating a suitable bracelet and tag for patients to wear.

Three interfaces between separate software solutions were developed: ASD to read the tags once the patient passes through an egress point; ACT for access control; and SAR for alarm activation. Full system test in MISA.

January – June 2017

Full proof of concept of tracking vulnerable patients in MISA. Go live of tracking vulnerable patients in MISA.

2018 – 2019

Medical Physics Bio Engineering (MBPE) equipment, beds, infusion pain pumps and ICU samples.

2020 and beyond

St James's Hospital continues to explore and implement RFID solutions, utilising the standards-based RFID structure in place to provide safer and more efficient services for patients.

Conclusion

This RFID solution highlights the huge opportunity for traceability throughout the hospital (not just in clinical areas), the value of collaboration between healthcare providers, solution providers and local GS1 Member Organisations and how laying the foundation with standards-based capabilities is enabling St. James's Hospital to achieve traceability and visibility of staff, patients, samples and assets across the campus.

About the authors
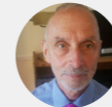
John Gibbons, Laboratory Advisor and Project Lead, Campus Development Office, St James's Hospital

Mr. John Gibbons was Laboratory Manager in Blackrock Clinic for 21 years (1985-2006) and latterly for 17 years in St. James's Hospital up to the end of 2020. His priority interests included the delivery of services to patients in a quality and safe manner, for example, regularly introducing patient focussed process improvements that enhanced the patient experience and continually improving operational systems and processes that ensured the timely and accurate reporting of laboratory results to the patient's medical team. He also supported his laboratory team, in consultation with clinical users, in the development of new and innovative services that had a local and national remit. He has now taken up a new position of Laboratory Advisor and Project Lead in the Hospital's Strategic Campus Development Office focusing on the Hospital's strategic vision of developing an Academic Health Science Campus.

Vincent Callan, Director, Campus Development Office, St James's Hospital

Vincent Callan, has 25 years Healthcare experience and has recently been appointed to lead the Strategic Office for Campus Developments at St James's Hospital. He has held various management and leadership positions within St James's Hospital and he has represented the Hospital on local community groups and business forums. The Campus Development Office is responsible for supporting the realisation of Irelands first Academic Health Science Campus including the development of an Innovation Healthcare District.

Vincent is a strong advocate of GS1 standards for safer, more efficient care and has been the project sponsor for the adoption of GS1 standards across the hospital over the last number of years including Scan4Safety and other ongoing projects. Vincent is also the Tri-Chair of the GS1 Ireland Healthcare User Group.

About the organisation

St. James's Hospital is the largest acute academic teaching hospital in the Republic of Ireland with 1,000 beds and provides a comprehensive range of diagnostic and treatment hospital services to a population in excess of 300,000 at local and regional level. SJH also deliver the majority of National Clinicals services with its enduring academic partner Trinity College by locating both their medical school and Health science centre on the SJH Campus.
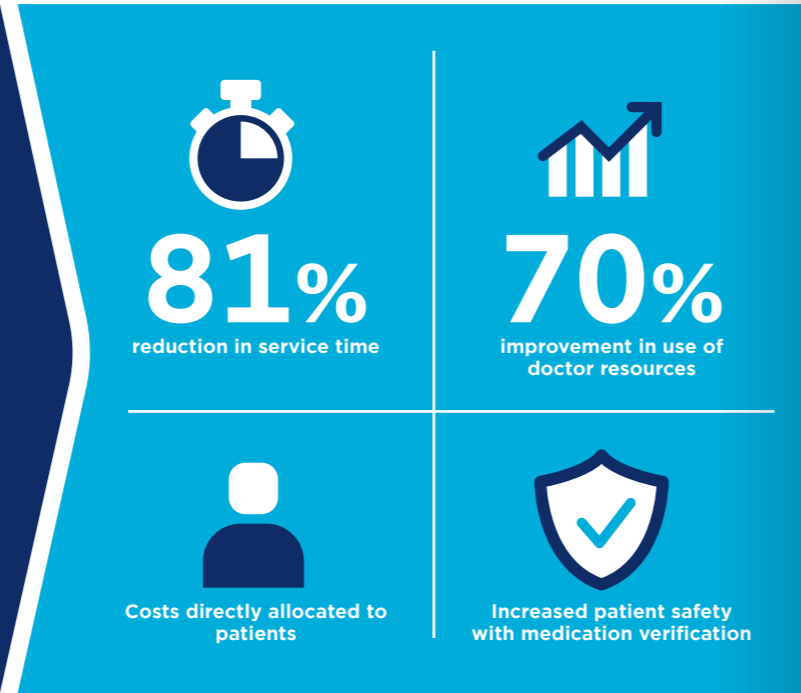
www.stjames.ie

Poland

Enhancing patient safety by implementing an electronic system for medical orders and GS1 barcode scanning

Challenge

The Paediatric Teaching Clinical Hospital wanted to transition from its manual, paper-based processes of ordering and administering medicines into automated ones, supported by GS1 standards. One major goal of the project was to improve patient safety and significantly minimise (or even eliminate) medication-related errors.

Approach

In collaboration with GS1 Poland and other partners, the hospital implemented new processes supported by GS1 identification standards encoded in GS1 DataMatrix barcodes. IT systems were integrated to support the new processes. Now medical orders can be automatically generated (called an e-order). As medications are administered to patients, GS1 barcodes are scanned to ensure the right patient takes the right medicine, at the right time. This information is also recorded in the patient's electronic medical record. As medicines as used, they are replenished for optimal inventory management.

81%
reduction in service time

70%
improvement in use of doctor resources

Costs directly allocated to patients

Increased patient safety with medication verification

Addressing medication-related errors

Medication-related errors are one of the most common, serious adverse drug events (ADEs) occurring in hospitals. These errors can be attributed to mistakes made by the medical staff or may result from organisational missteps. When administering medications, issues may include the wrong medication, patient, dose, route of administration and/or timing.

Regardless of the reasons, the consequences for patients can be severe or even fatal. It is estimated that 2-14% of patients are affected by adverse drug events. In Poland, healthcare experts have emphasised that the domestic data is substantially underestimated since ADEs are rarely reported by hospitals.

At The University Clinical Centre of the Medical University of Warsaw (formerly The

Paediatric Teaching Clinical Hospital in Warsaw) and The Department of Paediatrics with Observation and Insolation Ward sites where the project was conducted, hospitalisation data included:

The Paediatric Teaching Clinical Hospital (DSK)	2018	2019
All units/wards	123,970	126,019
The Department of Paediatrics with Observation and Insolation Ward	1,223	1,246

Figure 1: Total number of hospital patients (2018-2019)

Any risks associated with medication-related errors are significantly important, especially when treating paediatric patients. More effective control over the administration of medications in hospitals can not only improve patient safety, but also increase organisational efficiency and optimise medication costs—a major cost for hospitals.

The Paediatric Teaching Clinical Hospital (DSK)	2018	2019
All units/wards	PLN 32,453,645	PLN 38,734,746
The Department of Paediatrics with Observation and Insolation Ward	PLN 233,645	PLN 236,698

Figure 2: Total value (PLN or Polish Zloty, the local currency) of the consumed medications (2018 - 2019)

The Paediatric Teaching Clinical Hospital (DSK)	2018	2019
All units/wards	47,337	47,445
The Department of Paediatrics with Observation and Insolation Ward	1,157	1,129

Figure 3: Total number of consumed medications (2018-2019)

Assessing the situation

Before starting the pilot project, The Paediatric Teaching Clinical Hospital was preparing to implement the Accreditation Standards System for evaluation by the Health Care Quality Monitoring Centre in Poland. The hospital identified a problem with the incorrect management of patient medical records when ordering medicines.

Orders were being placed manually (written on paper) outside of the Clininet Health Information System (HIS) IT system. There were orders for products that were not available or even withdrawn from circulation. Drugs were ordered by different names. There was a lack of correct doctors' signatures under each prescription or there was a record

of signing orders all at the same time, which was also inappropriate.

Nurses who were executing orders had to visually verify the prescription, check the availability of inventory and inform the doctor if there was no inventory and the need to modify the prescription. The nurses updated patients' medical records after the orders were placed. With this inefficient and error-prone process, it was difficult to consistently update the inventory of medicines in the ward and also assign administered medications to patients in their medical records.

Defining the project strategy and goals

The hospital determined that some errors could be eliminated through systemic solutions and additional control points in the process. Ideally, they could optimise the process, using up-to-date IT tools and system resources.

The hospital decided to implement an electronic system for medical prescriptions, based on automatically verifying data accuracy with medical prescriptions and with the patient's identity by scanning the wristband. The new system would also automatically register the administration of medication to the patient's report, including the cost of treatment. Using an electronic system instead of paper-based prescriptions, the hospital could reduce the time required to place medical prescriptions and administer medications.

The hospital also wanted to transition from the internal labelling of medications to use GS1 Global Trade Item Numbers (GTINs) encoded in two-dimensional (2D) GS1 DataMatrix barcodes applied on medication labels. With the use of GS1 standards, they could confirm the authenticity of medicinal products in compliance with the European Union's Falsified Medicines Directive (FMD).

The project was planned to achieve several goals:

- Improve the safety of patients by eliminating the risk of medication-related errors, by scanning GS1 barcodes on each patient's wristband, at the time of administration.
- Prescribe medications only in the electronic system.
- Identify all participants in administering medications as well as the time and date stamps of particular activities.
- Automate and report these particular activities in administering medications.
- Allocate the costs associated with medications to each patient.
- Reduce the service time for medical staff.

Challenges were also identified and needed to be addressed:

- The hospital's medical personnel were used to old habits, to a paper-based process and, in worst case scenarios, to issuing verbal medical prescriptions.
- There were two, separate information systems—the HIS and Eurosoft Pharmacy Information System—that were not fully integrated nor were they interoperable.
- There would be a delay in implementing a pilot project due to needed modifications, systems' upgrades and integrations with separate modules by different IT system providers.
- There was a lack of infrastructure and tools such as barcode scanners, mobile versions of HIS and WiFi access points covering the entire ward.
- The hospital was labelling medications with internal hospital barcodes, in addition to manufacturer codes.
- It was not keeping complete electronic medical records.
- At the same time, the hospital was combatting the SARS-CoV-2 pandemic.

Implementing solutions and methods

The implementation process was in collaboration with the Institute of Logistics and Warehousing and GS1 Poland. The first element of process optimisation was process management and an analysis of the current status ("as is").

GS1 experts then prepared process maps that focused on the future state ("to be"). The solution included the transition from internal codes to using only GS1 identifiers encoded in GS1 DataMatrix barcodes.

The maps provided the team with an overview of the process and resources needed. The maps also supported discussions with the IT company that provided the IT system to the hospital.

The starting point for the updated process was to change the form of ordering medicines to an electronic order (e-order) in the HIS. With an e-order, it was possible to scan GS1 DataMatrix barcodes during the completion of administering medications to the patient and, before the administration of the medications, identifying the patient by scanning the GS1 barcode placed on his wristband. The new process required the integration of two different IT systems from different suppliers, making this step in the project time-consuming.

The ability to generate medical orders and confirm their execution in the system allowed the hospital to "close the process" by verifying the identity of the patient and the ordered medicines at each stage, as outlined below:

- Prescribe medicines by a doctor in the HIS.
- Confirm the ordered medicinal products in the ward or central pharmacy of the hospital.
- Accept the order in the system by a nurse for execution.
- Prepare the medication by a nurse by scanning the Global Trade Item Number® (GTIN®) encoded in the DataMatrix barcode.
- Confirm the patient's identity by scanning the GS1 identifier encoded in a barcode on the patient's wristband compared with the order in the system.
- Confirm the execution of the order by the nurse in the system with automatic registration.

Changes in the hospital's infrastructure were also needed. In the ward, additional WiFi antennas were installed to allow staff to use mobile scanners and laptops at patients' bedsides. The nurses were equipped with trolleys carrying medications prepared for patients, as well as scanners and laptops. Ultimately, medical tablets will be used, but currently the HIS does not have a fully functional mobile version.

The benefits and results of using the automated process

The new automated process has primarily minimised the risk of errors in the administration of medications to patients, during the processes of ordering medicines and their administration. In addition, the process has reduced the working time of staff in this process, which means additional, available time for other activities for patient care.

> Automating the prescription of medicines to patients and the automatic verification of compliance has enabled the recording of detailed information about the names of the administered products, their batch numbers, hours of administration, the amounts, doses and costs.

The introduction of a way to verify the correctness of completed medicines has also contributed to improving the safety and confidence of medical and nursing staff. Using GS1 DataMatrix barcodes has eliminated manual processes, reduced the risk of error and saved time for optimal productivity. Before the new process, the average service time was more than 1.5 hours; after implementation, it has been reduced to about 17 minutes, a savings up to 81%.

Average service time (minutes)

Difference **81%**

- Before implementation — 93
- Target — 56.4
- After implementation — 17.4
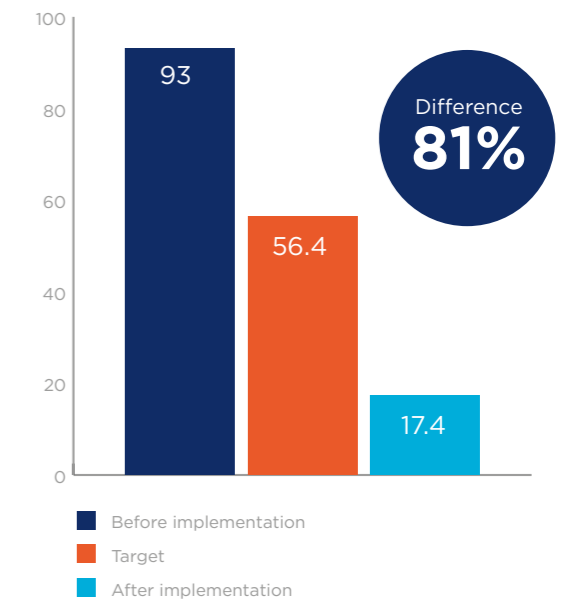
Average working time (minutes)

Difference **59%**

- Before implementation — 39.88
- Target — 19.97
- After implementation — 16.55
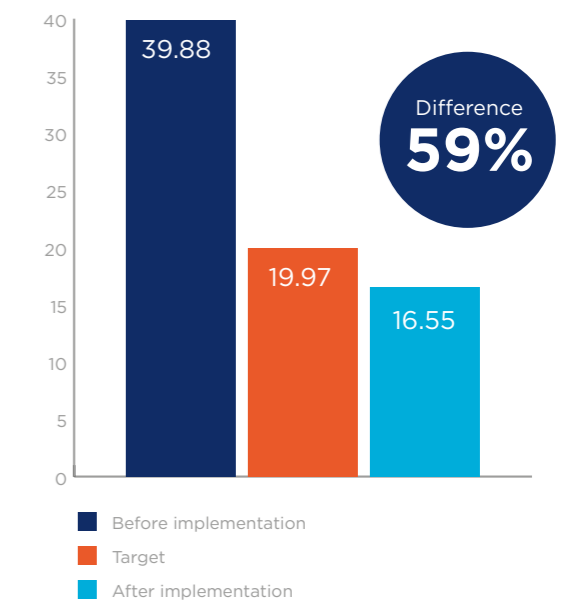
Figures 4 & 5: Data related to the process of preparing and administering medications
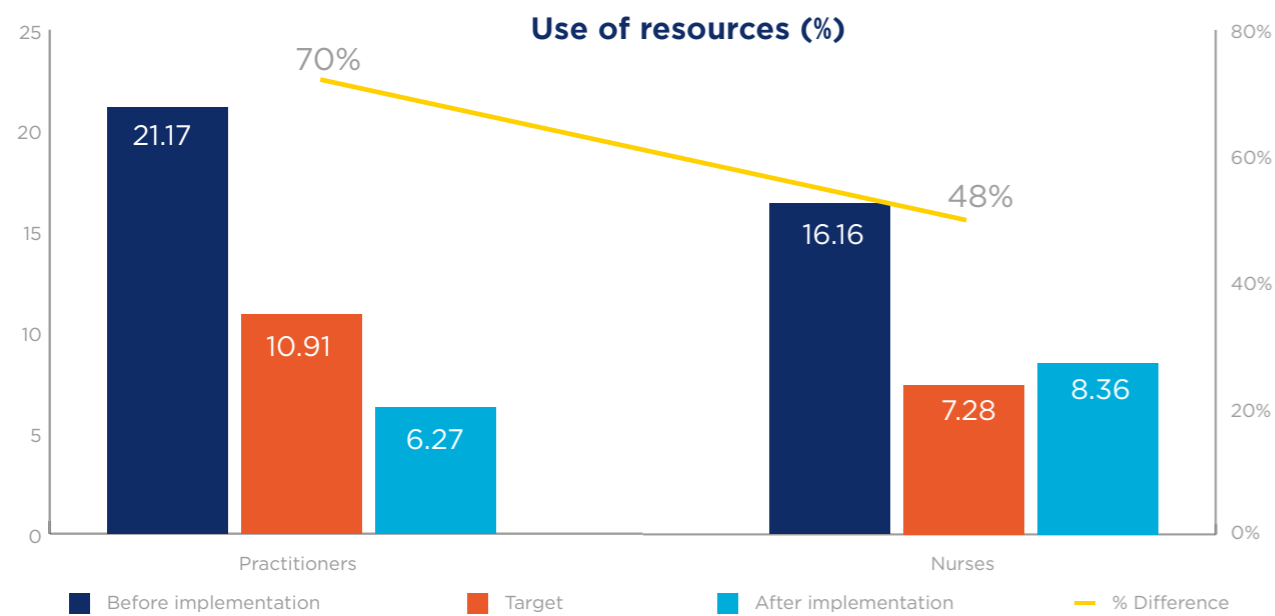
Use of resources (%)

Figure 6: Improvements in use of resources administering medications

Automating the confirmation of prescribed medications for the patient will also allow the direct assignment of those products, as well as their costs, to the individual patient. As a result, the hospital will be able to take into account all costs associated with treating individual patients.

More effective control of medications used and ongoing inventory updates in wards are expected to contribute to optimal resource utilisation and loss reduction. However, this area has not yet been tested during the pilot phase.

The implementation of the project during the SARS-CoV-2 pandemic revealed an additional benefit of using GS1 DataMatrix barcodes. The piloting unit was transformed into a COVID ward. To limit contact by the medical staff with isolated patients infected with the virus, barcodes from patient wristbands are used and placed on the door of the patient isolation room. The staff who transported the medications down the corridor on the trolley were able to deliver the necessary assorted medicines to patients without having to enter the room.

Conclusion

The hospital confirmed that the greatest challenge in implementing GS1 standards was the readiness of IT systems to use these standards. In the case of University Clinical Centre of the Medical University of Warsaw, the problem was to change the use of internal barcodes; yet, a positive aspect was the readiness of staff to use automatic identification techniques.

Cooperation with the IT companies required significant time and patience, which could be experienced during cooperation with other medical entities. Standardisation of expectations on the part of hospitals certainly contributes to a change in the perception of hospitals by IT companies.

The most advantageous are projects that improve the organisation of the hospital in several areas at the same time. By piloting the process of medication distribution at The Paediatric Teaching Clinical Hospital, this allowed for the automation of work performed by nurses and doctors in the execution of
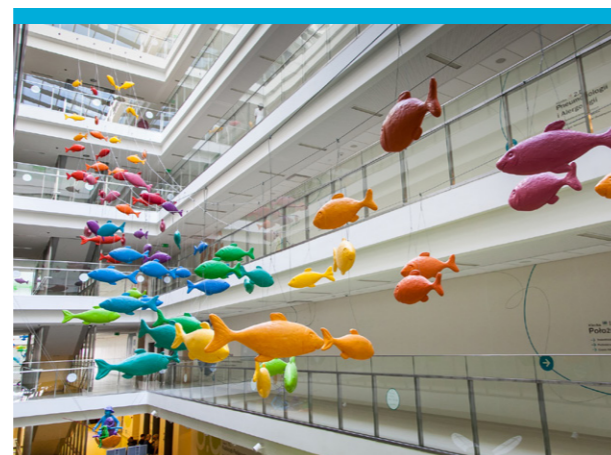
medical orders using GS1 barcodes. Thanks to this, the hospital has immediately gained several benefits such as increasing patient safety, reducing the working time of medical staff, increasing the comfort and safety of staff, automating medication administration to patients and recording administered medicines in the ward's inventory system.

Secondly, the need to scan GS1 barcodes applied on manufacturer's packaging in the process of administering the medication to the patient allowed the transition from paper orders to HIS IT systems. This, in turn, influenced medical staff to outsource medications to

patients only in electronic form. This is a key change in maintaining medical records, and the compliance of legal requirements and accreditation standards audited by the Health Care Quality Monitoring Centre in Poland.

The next step in the project will be the transition to only use GS1 barcodes from manufacturers' packaging—from the admission of medicines in the hospital's central pharmacy to their administration to patients at bedsides.

Ultimately, medical tablets will be used, but currently the HIS system does not have a fully functional mobile version.

About the author

Maciej Zabelski, Deputy Director of the University Clinical Centre of the Medical University of Warsaw and Director of the Central Clinical Hospital. Mr. Zabelski has extensive managerial experience in the field of public and private healthcare. He co-created the Program of Consolidation and Restructuring of the three Medical University of Warsaw clinical hospitals. He was also in charge of implementing suggested amendments at the operational level.

Mr. Zabelski has advised on restructuring processes of several dozen hospitals and co-managed mergers and acquisitions (M&A) in the private medical sector.

He is a lecturer of MBA healthcare programs at the Medical University of Warsaw, Warsaw School of Economics and Medical University of Lublin.

Maciej Zabelski, Deputy Director of the University Clinical Centre of the Medical University of Warsaw and Director of the Central Clinical Hospital
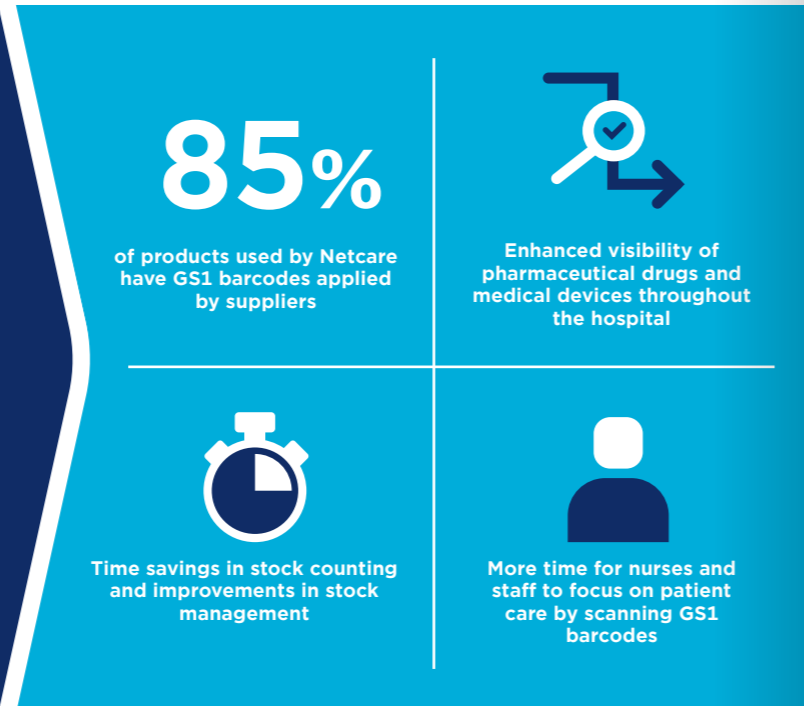
South Africa

Netcare: Investing in GS1 standards and quality product information for patient safety

Challenge

The Netcare Group (Netcare) in South Africa operates the largest private acute care hospital, primary healthcare, emergency medical services, mental health and renal care networks in the country. With a continuous focus on providing the best and safest health and care to each patient, Netcare wanted to transform its paper-based business and clinical processes to ones that are automated, digital and highly efficient.

Approach

Netcare is now scanning GS1 barcodes on products—pharmaceutical drugs and medical devices—as they are received in the hospital's pharmacy and theatre storage rooms, and as they are used throughout wards and operating theatres. Netcare, collaborating closely with GS1 South Africa, engaged with suppliers to start using GS1 standards on medical devices. For master data management, Netcare and its suppliers use the Global Data Synchronisation Network™ (GDSN®) to exchange accurate and complete product information.

85%

of products used by Netcare have GS1 barcodes applied by suppliers

Enhanced visibility of pharmaceutical drugs and medical devices throughout the hospital

Time savings in stock counting and improvements in stock management

More time for nurses and staff to focus on patient care by scanning GS1 barcodes

Leading the way

As a leading healthcare provider in South Africa, Netcare is continually investing in ways to better care for patients—the latest in medical technologies, professional expertise and the digitalisation of its processes. "Our strategy is to go digital throughout all of our operations within the Group," says Caroline Potgieter, Procurement E-Commerce Manager with Netcare. "Creating a standardised, fully mobile platform of capturing and sharing information is a vital part of this strategy."

Under the leadership of Chief Executive Officer Richard Friedland, Netcare is the first major healthcare provider in South Africa and throughout Sub-Saharan Africa, to adopt and integrate GS1 standards to support its digital transformation of business and clinical processes.

While global pharmaceutical regulations mandated the use of standardised barcodes on drugs, there was no national regulation focused on medical device traceability. Netcare decided to take a proactive stance and has been at the forefront of approaching medical device suppliers to implement GS1 standards.

With help from GS1 South Africa, Netcare developed a strategy for engaging suppliers about the benefits of using GS1 barcodes and sharing quality data. When these engagement efforts commenced, just over 28% of suppliers were using barcodes—GS1 standards-based and in-house created—to identify medical devices.

Success with suppliers

For Netcare, engaging and gaining buy-in from medical device suppliers to use GS1 barcodes has been a long, yet fruitful journey.

"Working with our team, GS1 South Africa took the lead to approach each supplier, one-by-one," explains Ms. Potgieter. "This meant visiting suppliers on their premises, touring their warehouses—taking a 'hands-on' approach with nearly every supplier in our network."

The effort was structured as a project with the establishment of key performance indicators (KPIs), measurements and a targeted timeframe to guide the work. Each supplier's progress was measured and reported throughout the project. An individualised assessment of the current situation, list of requirements and implementation best practices were formulated and shared with each supplier.

"Today, about 85% of the products we use, across most of our suppliers, are compliant by using GS1 standards to uniquely identify and barcode medical devices."

Caroline Potgieter,
Procurement E-Commerce Manager, Netcare

"Based on regular communication with GS1 South Africa, we understood at all times where suppliers were in their compliance journeys—who was fully compliant and who needed time to work on certain factors within their environment," says Ms. Potgieter.

Scanning with GS1 standards

For the vast majority of products used in Netcare's hospitals, each is identified with a GS1 Global Trade Item Number® or GTIN® encoded in a GS1 DataMatrix barcode, applied on the product's package. When barcodes are scanned at various points throughout the hospital, data about the pharmaceutical drugs and medical devices are captured in Netcare's information systems—information like the product's GTIN, batch number and expiry date.

"Using GS1 standards has been a game-changer for us since we can now scan barcodes that are standards based, across multiple processes like patient billing and stock management," says Ms. Potgieter. "Scanning GS1 barcodes has enhanced our visibility of products as they travel throughout our hospital environment."

As products come into the Netcare pharmacy and theatre storage rooms, staff scan the DataMatrix barcodes to register information about the products in Netcare's inventory management system. As drugs and devices are transferred and used in wards and operating theatres, the products' barcodes are scanned each step of the way.

"Using GS1 standards has been a game-changer for us since we can now scan barcodes that are standards based, across multiple processes like patient billing and stock management. Scanning GS1 barcodes has enhanced our visibility of products throughout our hospital environment."

Caroline Potgieter, Procurement E-Commerce Manager, Netcare

This enhances Netcare's ability to track its drugs and devices throughout the hospital and, if needed, trace the product back to the supplier.

Linking product information in electronic medical records

Netcare is currently implementing electronic patient medical records that will extend the value of GS1 standards-based information to patients' electronic medical records, captured in operating theatres and at bedsides.

When a medical device is used, its barcode is scanned in the theatre to link the device's identification information to the patient's electronic medical record. The same process can also apply to pharmaceutical drugs as they are administered to patients at bedside.

"We have three sites live now with nine more rolling out later this year (2021)," explains Ms. Potgieter. "This is especially important in case of a recall. With traceability built into our processes, we can more easily and quickly identify patients who received a medical device or was given a pharmaceutical drug."

Sharing medical device information

A key component of the Netcare digital transformation is its use of the 1WorldSync data pool and the Global Data Synchronisation Network or GDSN. Netcare's suppliers also use the GDSN to enter their product information once and have it published to all participating healthcare providers like Netcare.

GS1 South Africa provided GDSN services to Netcare and its suppliers for a smooth and seamless implementation. "GS1 South Africa has a trusted data program that includes onboarding support for GDSN and training on data quality," explains Ms. Potgieter.

In addition, GS1 South Africa has developed a "data-out" strategy for its data recipients like Netcare, developing application programming interfaces (APIs), supported by a solution provider called Trusted Source, so that product data can be easily shared through a front-in portal or through a data-to-data transfer process.

"With the GDSN common platform and data quality best practices in place, we can be assured the product data we are using from suppliers is complete and accurate."

Caroline Potgieter,
Procurement E-Commerce Manager, Netcare

"It's involved significant work and collaboration with all members of the GDSN, driving us to support a process of trusted data," says Ms. Potgieter.

Automation with a simple scan

Netcare's adoption of GS1 standards and the resulting enhanced visibility have contributed towards increased efficiencies and accuracy in the billing and stock management processes. The seamless exchange and accessibility of standards-based data has been achieved at Netcare with the implementation and use of the GDSN platform.

During the COVID-19 pandemic, Netcare used GS1 barcodes to enhance the sourcing of personal protective equipment (PPE), enabling a degree of assurance about the PPE products' origins.

With the automation of processes, clinicians, nurses and other healthcare staff are realising significant time savings and productivity gains. Furthermore, using GS1 standards, Netcare has ensured that information used within Netcare's systems is standards based.

"Our focus is providing patient centred the best and safest healthcare. By digitising processes, enhanced with standards-based data, our nurses now have more time to care for patients. It's about ensuring each patient is at the centre of their care, with the aim of reducing the burden of administration for nurses."

Caroline Potgieter,
Procurement E-Commerce Manager, Netcare
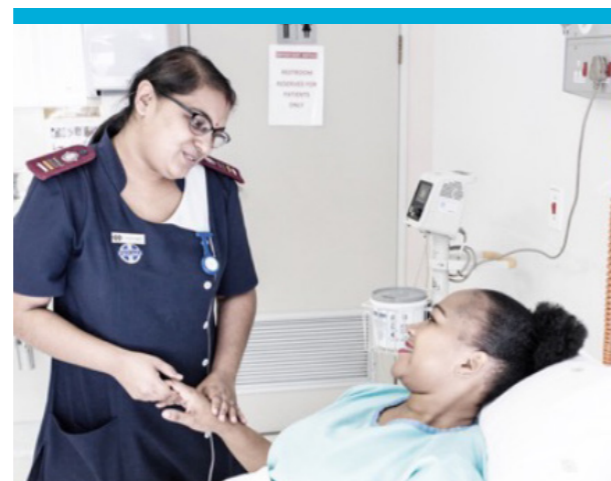
Visibility and assurance

Ms. Potgieter stresses the importance of implementing GS1 standards in hospitals and throughout the healthcare supply chain.

"Having visibility and quality product information is important to everyone. It's not only a benefit to a hospital, but to suppliers, regulators and, especially patients. Ultimately, it's about working together in a partnership between you, your suppliers and the entire supply chain of stakeholders."

"With GS1 standards in place, you can have the assurance knowing you are recording the right products with the right patients. The journey is not easy, but well worth it."

Caroline Potgieter,
Procurement E-Commerce Manager, Netcare

About the author
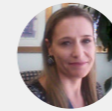
Caroline Potgieter,
Procurement E-Commerce Manager, Netcare

Caroline Potgieter has 27 years' experience in private healthcare. She is currently the Procurement E-Commerce Manager for Netcare. Ms. Potgieter is responsible for the e-procurement systems at Netcare, and the database used for both purchasing and billing purposes. She is responsible for supplier engagement for the Netcare Barcoding project.

About the organisation

In South Africa, **Netcare** operates the largest private acute care hospital, primary healthcare, emergency medical services, mental health and renal care networks. In addition to the operations mentioned above, the Group offers physical rehabilitation, sub-acute care, day surgery, occupational health, and employee wellness services. Netcare is a leading private trainer of emergency medical personnel and nurses in the country.

www.netcare.co.za

United Kingdom

CareScan+: Enabling safer more efficient patient care while reducing costs

Challenge

North Tees and Hartlepool NHS Foundation Trust began its GS1 standards-adoption journey as one of six selected demonstrator sites involved in the Department of Health and Social Care's Scan4Safety programme.

To fully meet the requirements of the Scan4Safety programme, a point-of-care scanning solution was necessary to facilitate the convenient and practical capture an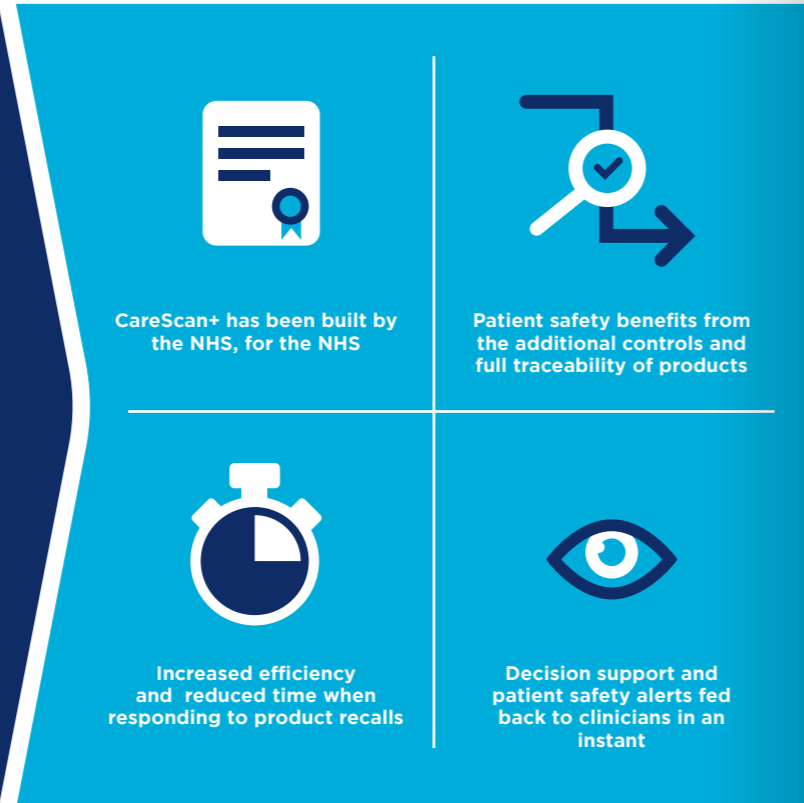d recording of events taking place during each episode of patient care. However, when implementing and using scanning at the point of care, staff found that there was no all-encompassing scanning solution available to meet their needs.

Approach

The trust decided to develop its own solution and looked to produce an easy-to-use, accessible app that staff could use for all of their scanning requirements – one where all of the data collected could be accessed and stored in one central repository so that the right investigational product and/or kit goes to the right patient.

CareScan+ has been built by the NHS, for the NHS

Patient safety benefits from the additional controls and full traceability of products

Increased efficiency and reduced time when responding to product recalls

Decision support and patient safety alerts fed back to clinicians in an instant

GS1 standards have long been a feature in retail – used to provide a standard and consistent means of sharing product data across industry.

In 2016, England's Department of Health and Social Care (DHSC) decided to apply these same standards in healthcare with the launch of the Scan4Safety programme.

North Tees and Hartlepool NHS Foundation Trust (NTH) became one of six trusts that formed part of the programme, which set out to establish the value of GS1-standards adoption across three main areas: patient identification (person), catalogue management (product) and location identification (place).

During the implementation of the Scan4Safety programme, it became clear to the trust that a point-of-care (POC) scanning solution – one that was patient-safety focused and would provide clinicians with immediate safety and decision support alerts – did not exist at the time.

Built by the NHS, for the NHS.

NTH decided the best solution would be to design and develop an app that would be able to accommodate all the trust's requirements. It is here where CareScan+ was born, the creation of a point-of-care scanning solution.

Shining a light

In 2016, NTH was selected by the DHSC to become one of only six demonstrator sites within the English National Health Service (NHS), tasked with the implementation of

GS1 standards and Pan-European Public Procurement Online (PEPPOL).

The Scan4Safety programme, as it is more commonly known, focused on improving patient safety, enabling clinical productivity and driving supply-chain efficiency. Trusts were required to standardise processes and capture data relating to people, products and places via the scanning of GS1 barcodes – the ultimate goal being to embed the "4Ps" within the organisation.

> *"As an organisation, our key aim is to put patients and the population at the centre of everything we do. This is no different when it comes to the development of innovative digital solutions. The challenge is to make simple solutions for complex problems, and our CareScan+ platform is such an example. We worked hard to make this simple."*

Professor Graham Evans,
Chief Information and Technology Officer/ SIRO, North Tees and Hartlepool NHS Foundation Trust

CareScan+ is a POC-scanning solution designed and developed by the trust to support the Scan4Safety requirements. With software underpinned by open standards, such as GS1 standards, it is a wholly interoperable and flexible solution that has the capacity to work with any trust's existing systems – including electronic patient records (EPRs), patient administration systems (PAS) and inventory management systems (IMSs).

CareScan+ is used to track and trace products used by staff during the delivery of care to patients. It uses established GS1

GS1 Traceability Standard

barcode standards that major industries have successfully shown can be relied upon to improve logistical processes.

The software provides a quick, easy and accurate means of collecting quality data in a consistent manner, and facilitates the instant reporting of this data via a single system.

CareScan+ is able to "shine a light" on the trust's "blind spots," and affords the trust the opportunity to make informed decisions based on an accurate, rich set of data.

Collect once and use often

When starting its Scan4Safety journey, the trust soon realised that there was a gap in the market when it came to scanning technology solutions that were patient-safety focused. Available products existed, but they were predominately focused on inventory management, whereas the trust required a solution to improve patient safety and provide clinicians with immediate decision support alerts.

The challenge facing all trusts is how to quickly, easily and consistently capture data. Accurate data capture improves visibility, interoperability and traceability across the healthcare system. NHS trusts should be looking to "collect once and use often" and "collect what matters."

NTH collects significant volumes of data across many different systems and in many different formats. Some of this data is captured using barcode-scanning techniques, but in most instances, data is manually entered using a keyboard.

This leads to data that can be inconsistent in its quality, accuracy and structure. Consequently, this leads to challenges when attempting to filter, process or report on this data. This is known to result in "blind spots" across the organisation due to a lack of accurate, quality and available data.

Barcode scanning is recognised for its accuracy, rapidity and reliability, and this was something the trust wanted to capitalise on.

The goal was to understand the what, where, who and when, so the trust would be better equipped to make intelligent decisions around its selection and utilisation of staff, products, assets and locations. The aim was to help influence the design of improved patient pathways and achieve better patient outcomes.

During the early implementation stages of POC scanning, the trust established that staff needed to use multiple scanning devices, which varied based on the area and the data they were collecting.

Alternative devices were required for patient identification, catalogue management and location identification – highly inefficient and impractical for staff to use.

Furthermore, as one of only six sites involved in the Scan4Safety programme, this also meant that there was a limited number of trusts adopting POC scanning as a major patient-safety initiative. With all trusts embarking on the journey at the same time, there were limited prior experiences to learn from.

Introducing CareScan+

In an effort to overcome this, NTH decided to develop a scanning solution that could be used by any hospital function, irrespective of which GS1 identification keys were being used. This could mean anything from capturing the Global Service Relation Number (GSRN) on a patient
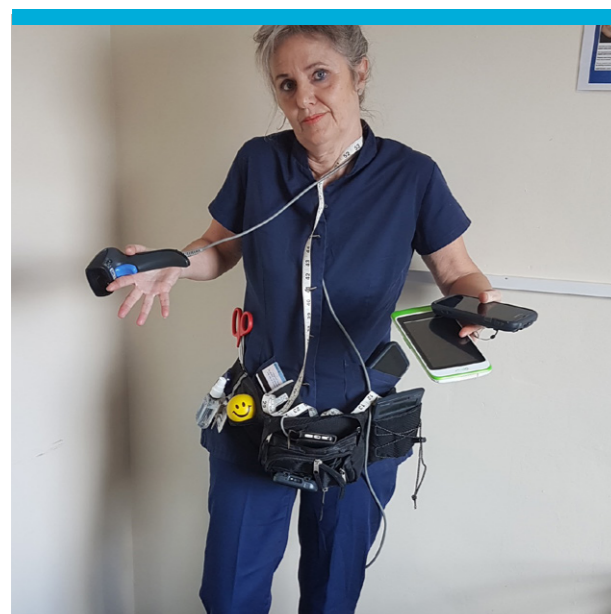

Figure 1: Multiple scanners required to scan different elements during episodes of patient care

Figure 2: Single scanner running CareScan+ app

wristband, to scanning the Global Location Number (GLN) at the site of care.

In collaboration with key stakeholders, the POC-scanning solution, trademarked as CareScan+, was developed to support all aspects of data capture required as part of the Scan4Safety programme.

Importantly, CareScan+ was built using open-source components to ensure that the trust was not tied to any proprietary systems and could be easily integrated into other trust frameworks, e.g., EPRs or inventory management, catalogue management and purchase-to-pay (P2P) systems. However, as a stand-alone system, it could also be used independently.

> "Compared to the current system, the major benefit is the ease of use. Overall, its efficiency gains are second to none.
>
> This frees up approximately 15 minutes of a theatre personnel's time per case, which, in turn, aids the turnaround time and associated benefits that this has on our patients and for the trust."

Sarah Todd,
Orthopaedic Sister, North Tees and Hartlepool NHS Foundation Trust

CareScan+ is now used to track and trace any product used by staff via the Global Trade Item Number® (GTIN®) during the delivery of care to patients. The data collected is instantly available for reporting and auditing purposes, and provides users with immediate feedback

on product recalls, product warnings and expiry dates. The collection of this data assists the trust in rapidly identifying patients in the event of a product recall. Prior to the use of CareScan+ the time taken to identify patients was measured in weeks and months. The measure is now minutes and hours.

During the pandemic, the trust also utilised CareScan+ to track and trace non-invasive ventilators (NIVs), giving clinicians the confidence of not just knowing the location of a ventilator, but, more importantly, its actual status (available/in use/out for cleaning/out for repair).

Finance teams are then provided with more accurate and timely patient-level information costing, which also gives insight into asset, staff and space utilisation – all achieved by simply scanning the associated GS1 barcode.

CareScan+ can also advise clinicians via a screen prompt or warning, of a specific site implant to prevent a "Never Event." These are events defined in the UK as: "Serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers."

For example, one such Never Event would be the use of a left-sided implant for a right-sided procedure. Using this solution, these real-time alerts provide clinicians with the relevant information to prevent and avoid harm to the patient. In turn, this provides the trust with an enhanced level of patient safety, ensuring that the patient's journey is the safest it can be whilst in the care of the hospital staff.

With CareScan+ in place, it also provides the ability to identify unwarranted variation that can cause inefficiency and risk, so that these elements can be targeted and eradicated to enable changes in clinical practice, if necessary.

Figure 3: Scanning products using CareScan+ in theatres

> "CareScan+ has the potential to shine a light on non-pay expenditure in theatres, which until now has been a blind spot in the organisation.
>
> "The availability of this kind of highly precise data is very rare in the NHS, and will enable a greater understanding of how staff deployment and medical equipment usage impacts patient care and the associated costs."

Neill Waters,
Senior Cost Accountant, North Tees and Hartlepool NHS Foundation Trust

The CareScan+ app is more than just about scanning GS1 barcodes; it is ultimately about driving patient-safety improvements through real-time access to vital data for each episode of patient care.

> "CareScan+ enables us to know 'who does what to whom, where, when and using what.'"

Chris Tulloch,
Deputy Medical Director & Orthopaedic Surgeon, North Tees and Hartlepool NHS Foundation Trust

Real-time, valuable data

Using CareScan+ enables valuable data to be captured in real time, and because it is captured at the point of care, it provides improved data quality for anyone that needs it. Instead of being collected and transcribed later, or being collated across several different devices, everything is captured, held and processed in one place, so there is a central repository for all data needed. This provides staff with greater oversight of all information, enhancing traceability and audit processes across the trust.

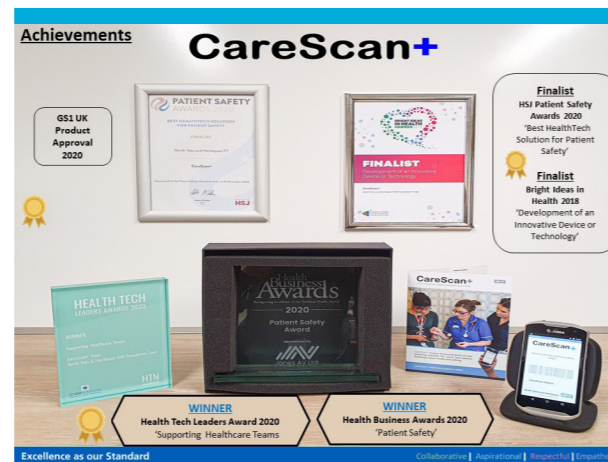Data collected is instantly available for reporting and auditing purposes and will facilitate an immediate response, to both patients and care providers, in the event of a Class III product recall.

Additionally, the instant alert feedback means that before a product or device is administered or used, the clinician is made aware if the product has been recalled, preventing unnecessary harm to patients.

Since its implementation, NTH has been able to improve the speed and efficiency of its product recalls, providing additional insight to procedure costs, and has a greater awareness of product consumption and asset utilisation.

An example of how valuable asset utilisation monitoring has been for the trust, can be seen throughout the coronavirus pandemic, in the form of understanding the capacity, availability and locations of non-invasive ventilators throughout the hospital.

The team rapidly adapted the CareScan+ software and produced a reporting dashboard to provide clinicians with insight into the location and status (availability) of the non-invasive ventilators (NIVs) throughout the organisation, which helped to coordinate the fight against COVID-19.

Built by the NHS, for the NHS

The Independent Medicines and Medical Devices Safety (IMMDS) Review, led by Baroness Cumberlege, published in July 2020, said that "a central patient-identifiable database should be created by collecting details of the implantation of all devices at the time of operation."
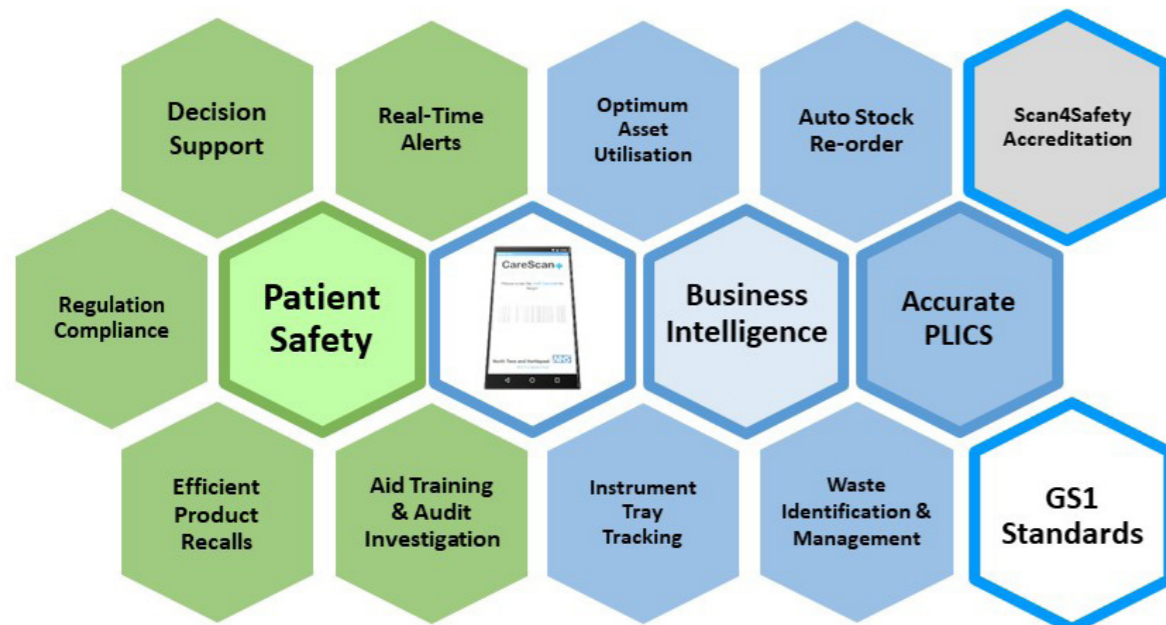
NHS Digital is developing an information system to collect, curate and analyse surgical device and implant data related to patients receiving surgical care in the UK. The system is known as the Medical Device Information System (MDIS) and forms part of a wider Medical Device Safety Programme (MDSP) – a collaboration between Getting It Right First Time (GIRFT), NHSX and NHS Digital. These organisations work jointly to enable the better use of technology to improve patient safety where medical devices are used.

Based on successful trials, CareScan+ is already demonstrating the capability to provide high-quality data for submission, according to the emerging MDIS data set standard. With one scanning solution in place, staff are no longer bound by the constraints of multiple devices, so they are able to work with a greater level of operational efficiency.

The trust's efforts were recognised in 2020 when CareScan+ won two prestigious awards; the HTN Health Tech Leaders Award 2020 for Supporting Healthcare Teams and the Health Business Awards 2020 for Patient Safety.

CareScan+ has been developed "by the NHS, for the NHS," and because of this, it has received great feedback from staff. In the future, NTH hopes to be able to make this available to other NHS trusts on their own adoption journey. The CareScan+ solution has also recently become a GS1 UK-approved product, as part of the GS1 UK partner programme.

About the authors

Anthony Kennerley, CareScan+ Project Manager, North Tees and Hartlepool NHS Foundation Trust

Anthony Kennerley has more than 30 years of experience in NHS procurement and supply-chain management. He joined the North Tees and Hartlepool NHS Foundation Trust in 2000, and has led numerous high-profile projects, including the successful adoption of e-procurement and e-tendering within the organisation. He was deputy head of procurement and supplies prior to his secondment into the Scan4Safety project in 2016.

A procurement professional with a proven track record of improving operational efficiency and delivering significant cost savings for the NHS, Mr. Kennerley brings with him a wealth of knowledge and experience of implementing e-procurement solutions and change management processes within the healthcare sector. He was influential in the trust achieving the Scan4Safety accreditation in 2018, and has been central to the design, development and successful implementation of CareScan+ within the trust.

Tony Naylor, Associate Director of ICT and CareScan+ Project Lead, North Tees and Hartlepool NHS Foundation Trust

Tony Naylor became the Associate Director of Information and Communication Technology (ICT) for NTH in 2008 having joined the trust in 2001 as Head of Information Technology (IT). This followed 14 years experience gained developing and supporting accounting and process management software applications within the private sector.

Working with an excellent team to implement and support myriad systems with optimum availability and resilience is not without its rewards, but Mr. Naylor will tell you that what motivates him most is applying technology to improve patient safety.

Mr. Naylor was the chief architect of CareScan+ and is credited with producing the original concept and design. He has been instrumental in successfully introducing point of care scanning into the trust.

He is a self-proclaimed Scan4Safety evangelist.

About the organisation

North Tees and Hartlepool NHS Foundation Trust is an integrated hospital and community services healthcare organisation, serving around 400,000 people in Hartlepool, Stockton and parts of County Durham.

Services are primarily offered from the University Hospital of North Tees (Stockton-on-Tees) and University Hospital of Hartlepool, with support from a wide range of community-based services.

In 2018, the trust was rated "Good" from the independent health and social care regulator, the Care Quality Commission (CQC), with elements of its A&E services being rated "Outstanding."

www.nth.nhs.uk

[1] *First Do No Harm.* (8 July 2020). Retrieved from: https://www.immdsreview.org.uk/Report.html

United Kingdom

Connected, continuous and complete: Implementing Scan4Safety using GS1 standards at the core of the patient pathway

Challenge

Hull University Teaching Hospital (HUTH) wanted to replace its manual and paper-based processes with automated ones that would capture data at points of patient care, connecting the data and linking it directly to each patient. Routine and recall processes took significant time away from staff caring for patients.

Solution

HUTH defined a new model focused on the patient and Scan4Safety principles, implementing GS1 identification standards and barcodes throughout the entire patient care journey. Barcodes are scanned to capture information such as date, time, staff member, patient and location of interventions—from the patient's admission to discharge.

Recalls that once could take weeks now take only hours, saving significant time for medical staff

Precise, efficient asset and inventory management for increased staff productivity and improved patient care

Clinical decision-making and resource planning with fact-based data centred on individual patient care

Transparent and real-time data collected at points of care for better patient outcomes and actual costs per patient

Launched in England by the UK's Department of Health and Social Care in 2016, the Scan4Safety programme became the start of a long-standing journey of GS1 standards adoption in clinical environments.

The premise of the programme centred on the adoption of GS1 unique identifiers for every person, product, place and process at touchpoints throughout the supply chain and patient pathway.

What started with six National Health Service (NHS) trusts involved in the pilot (called the "demonstrator sites"), has since gained traction with other NHS trusts across England.

Hull University Teaching Hospital embarked on an implementation roadmap for Scan4Safety, which commenced in September 2018 as a non-demonstrator site. This marked the start of one of many implementation projects for HUTH. The aim was to bring together data and transparency to improve the digital record of the patient

and, ultimately, to enable HUTH to make great decisions based on great data.

Understanding the details of patient care

Prior to adopting Scan4Safety principles, HUTH relied on manually recording procedural details for implants, estimating its costs on average patient experiences, without real costs based on individual patient-required levels of care.

With this process in place, routine execution of product recalls proved to be a challenge as the recall process was entirely manual. When recalls did occur, this monopolised nursing-staff time, which was spent physically tracing stock instead of tending to direct patient-care duties.

Scan4Safety provided HUTH the opportunity to realise a full patient pathway—all in a single system.

Take, for example, the patient care for a cardiac patient. The patient may have procedures

carried out in the Catheter Labs, leading to a surgical intervention in the theatres (which also required anaesthetics and perfusion), before being admitted to an intensive-care unit (ICU) for recovery, and then, before being transferred to a ward and eventually being discharged home.

HUTH wanted to be able to capture all of this information at the point of care, connecting the data and linking it directly to each patient.

Clinical staff at the trust wanted to be able to understand details from patient-care and budgeting perspectives across the department, to make informed decisions such as:

• Duration of procedures
• How many primary admissions (patients admitted as an emergency via ambulance)
• How many re-admissions occurred after a particular procedure

The trust needed a solution that would allow actual patient data to be compared across multiple surgeries, highlight particular patient pathways, identify specific products used and enable comparisons of procedure, process and patient-outcomes data from different surgeons.

With this in mind, HUTH decided to adopt GS1 standards based on their prevalence, quality and renown for bringing benefits to healthcare. GS1 standards are widely recognised for their ability to capture data accurately, at the point of care and in real time. GS1 standards and early findings from the Scan4Safety programme provided the evidence needed to proceed with the project.

Capturing valuable data along the entire patient pathway

HUTH defined an entirely new model of implementation that tracked the entire patient pathway to improve transparency and provide data. The scope went much further than implementing Scan4Safety within surgical theatres; it transcended the entire care journey.

This meant implementing the core Scan4Safety principles—the "4Ps":

• Patient identification, using the Global Service Relation Number (GSRN)
• Product identification, using the Global Trade Item Number® (GTIN®)
• Place, using the Global Location Number (GLN)
• Process, in this case, the patient pathway and the staff involved with the patient's care

This process was then followed for each and every patient, following their respective care pathway. Rachael Ellis, Scan4Safety Programme Director at HUTH, devised a new methodology that was simply captioned as the "3Cs" for leading the development of the new model.

If it was *connected* to the patient, *continuous* in relation to the patient pathway, and made the pathway *complete*, then it would be included in the implementation plan—a contrasting model to the majority of other NHS trusts that focus their implementation models on one department at a time.

Ms. Ellis explains, "Scan4Safety is ultimately a patient-safety programme. Therefore, it should absolutely follow the patient, as the patient should be kept at the centre of the programme. At HUTH, they are!

"It is the only way to truly establish what is needed operationally to cater for each patient's individual piece of care – and if it is not tracked, how do you know? How can you make bigger decisions around facilities, assets and resources if you do not understand where patients are going and what care they actually require? Data evidence is required to suggest trends that might not necessarily be known or reported."

> "Scan4Safety is ultimately a patient-safety programme. Therefore, it should absolutely follow the patient, as the patient should be kept at the centre of the programme. At HUTH, they are!"

Rachael Ellis
Scan4Safety Programme Director,
Hull University Teaching Hospital

The premise of the model was born out of early engagement with clinical teams and the trust's senior executives from the outset. This approach made it easier to identify the direct needs and challenges of the clinical staff members. It also enabled the Scan4Safety project team to understand the problems for resolution, pinpoint data-capture requirements for particular attributes, and uncover areas where support could be provided.

Early engagement also extended to the trust's executive team. The open and transparent culture at HUTH proved to be a significant contributing factor towards the projects' successes. Although different members of the executive team were focused on achieving different outputs from the projects, the patient-safety outcomes were key for all concerned.

The model's success has led to implementation projects across 19 specific care pathways, including anaesthetics, perfusion services, cardiology wards, lung function services, home ventilation services as well as ICUs.

All information that can possibly be scanned and captured is done at the point of care, recording the date, time, staff member and location of any interventions along the way, right through to the patient's discharge details. This information is attained in real time, using GS1 barcodes, to enhance accuracy and efficiency.

Informed and speedy decisions for patient safety

There have been many benefits, but one of the most obvious advantages has been the ability to see the entire patient pathway reflected in the data, including full patient-level costing.

HUTH also scans items, including assets, which has had a profound impact on the management of product recalls. During the COVID-19 pandemic, the trust had to deal with a ventilator product recall. On receiving the recall notice, HUTH was able to very quickly

identify 100% of the affected ventilators, using GS1-barcoded asset labels.

With each of the assets scanned to the patient (identified using the GSRN encoded in a GS1 DataMatrix barcode on the patient wristband) and the location (using the GLN), the Scan4Safety team was promptly able to ascertain which asset was with a patient, which was unused and sat in a storeroom, and which was held by clinical engineering. This data was reviewed. Patients who were impacted by the ventilator recall were identified, available ventilator assets were quarantined, the product-recall flags were added to the system, and all of this happened within two hours of receiving the official recall notice.

Crucially, not a single minute of nursing time was used to physically track down each piece of equipment. Before using GS1 standards, the recall process was expected to have taken more than 70 hours of nursing resource and would have taken several weeks to complete. Despite this effort, it would have remained unclear whether all of the recalled ventilators had been tracked down.

> **During the COVID-19 pandemic, the trust had to deal with a ventilator product recall. On receiving the recall notice, HUTH was able to very quickly identify 100% of the affected ventilators, using GS1-barcoded asset labels.**

Clinical decision-making and resource planning can now also be done using fact-based analysis. Access to the data provides the additional details needed to see how often a patient follows a particular pathway in comparison to another. Since this is evidence-based data centred on individual patient care, it removes any level of ambiguity and speculation. Actions can then be built on timely data, which provides opportunity to analyse and act quickly.

HUTH is now in a better position to be able to make tangible decisions based on patient needs specific to the trust's individual needs. All the data is regularly reviewed and used—a powerful tool for clinicians as all data is available at their fingertips without requesting patient notes and delaying patient care.

Clear patient data and benefits

Ms. Ellis at HUTH firmly believes that by putting the patient at the heart of a large-scale patient-safety programme, the benefits are clear to see.

The data is transparent, clinicians are able to view it, inventory can be managed much more effectively and, by digitising the patient pathway, it leads to quicker, smoother recalls of data and records. This information can then be used for producing data about the patient pathway, rather than just the patient's surgery, if conducted at department level.

Managing the enormous volume of data has been both the biggest benefit and the largest challenge. Connecting the data as part of the patient pathway builds further complexities into the process. There is data connected to theatre, recovery, ICU, the ward and discharge information. This is then layered with product, implant and staffing data in addition to procedure details and coding requirements—all of which presents its own challenges.

HUTH has already rolled out Scan4Safety to 19 patient pathways—soon to be 20 with RFID (radio frequency identification) planned next for all assets across all three sites. Doing so will allow for assets to be mapped and located with ease, saving huge amounts of nursing and portering time. This will bring coherence to the strategy of asset buying and planned preventative maintenance across the trust's sites.

About the author

Rachael Ellis worked within the NHS in senior procurement roles before becoming the UK's first Scan4Safety programme director.

Ms. Ellis is passionate about creating exceptional patient care, and ensuring patients' respective care journeys are transparent. Her goal is to make patient information readily available for clinicians and nursing staff, to ensure the best possible care and decisions are made for patients.

Before joining the NHS, Ms. Ellis worked in both the education and private sectors, all within procurement and large-scale project delivery programmes.

Rachael Ellis
Scan4Safety Programme Director,
Hull University Teaching Hospital

Suppliers & GPO

Responsible for the medicines and medical devices needed at all levels of patient care, manufacturers need to make sure they are doing this as safely and accurately as possible. Using GS1 standards helps to ensure they know where products have come from, where they're going, and that they are safe for use. Review the following case studies to see how they're doing this.

China

Johnson & Johnson Supply Chain: The evolution of pharmaceutical product traceability in China

Challenge

Transitioning to a GS1 standards-based solution, while desirable, requires changing systems and processes and impacts the entire supply chain. Could a transition occur effectively and efficiently?

Approach

Johnson & Johnson Supply Chain (JJSC) embraces the concept of standardisation and has invested in standard operating procedures, common platforms and GS1 standards. A portfolio of products was selected to be converted from the original track and trace technology used for China to a global standardised approach using GS1 standards.

Product traceability for the benefit of healthcare providers and patients alike

Opportunity to increase overall operational efficiency

Readily scalable GS1 standards-based model and platform

Ease of compliance with Chinese and other global regulations

In the 2000s, prior to its global recognition of GS1 standards, the China regulatory agency published its initial pharmaceutical track and trace regulation and a local technology company implemented a proprietary solution to meet the requirements. In 2019, China revised its regulations, allowing for the use of GS1 standards. However, most of the pharmaceutical industry had already complied and implemented the original proprietary solution.

China's path to GS1

The use of serialisation to track and trace pharmaceutical products to improve visibility throughout the supply chain is not a new concept. It has been long recognised that its potential benefits are multi-layered: improved patient safety, enhanced inventory transparency and increased operational efficiency.

At its core, serialisation and traceability are considered effective tools to combat the counterfeiting and diversion of products. Pharmaceuticals are potentially one of the largest markets for counterfeit goods globally, estimated to be worth $200 billion per year[1].

The China Food and Drug Administration (CFDA), an early adopter of product identification and traceability, began to establish regulations for pharmaceuticals in 2007[2]. In the absence of global alignment to GS1 standards, local standards and solutions were designed.

By 2013, other countries enacting serialisation and traceability regulations started aligning to GS1 standards as they provide a framework to implement consistent product identification and traceability by using a common language to uniquely identify, accurately capture and automatically share vital information about products, locations, assets and more.

The result was manufacturers implementing two different technologies and supply chain processes to manage both the Chinese traceability requirements and the requirements set forth by other countries using GS1 standards. This scenario also imposed complexities for Chinese manufacturers exporting to other countries.

Overall, with the focus mainly on manufacturing compliance and less on the additional benefits of product traceability, supply chain stakeholders (distributors, hospitals and healthcare professionals) were less inclined to adapt to a drug traceability system.

In 2019, the Chinese National Medical Products Administration (NMPA), formerly the CFDA, revised its pharmaceutical track and trace regulation, allowing the usage of GS1 standards – a notable achievement. The next step was to find manufacturers in the pharmaceutical industry willing to move from China's proprietary solution to GS1's global solution since it would require a significant change to IT systems and processes throughout the entire supply chain.

Johnson & Johnson Supply Chain begins transition in China

Embracing the concept of global standardisation, JJSC welcomed the opportunity to transition to GS1 standards in China, starting with a select portfolio of products.

The project scope included:

- Serialisation of eight stock-keeping units (SKUs) using a GS1 type of "license plate" that includes a Global Trade Item Number® (GTIN®), serial number, batch number and expiry date

- Identification of an IT solution provider that could deploy a cloud solution to enable track and trace in the market

- Funding and enablement of new automated capabilities through the track and trace cloud solution so enhancements could be explored, and supply chain efficiencies realised by the companies involved. Some examples of these enhancements are: mobile device connected real-time with the track and trace platform; possibility to develop business-to-business connectivity using webservices and operational process automation; leaner and more optimised end-user interface; exploration of relevant online content via mobile phone scanning by end customers and healthcare professionals (electronic leaflets, educational content and product information)

- Integration between JJSC and the solution provider platform, automating the electronic files exchange, supporting basic supply chain track and trace operations. One of the examples of files to be shared across platforms is the Advanced Shipping Notice (ASN) containing all serial numbers and hierarchies (carton > shipper case > pallets) communicated by the JJSC enterprise platform to the solution provider platform when products get shipped from global sites to the Chinese market

- Purchasing of warehouse mobile devices (PDAs) to be used by downstream distributors to scan the GS1 products in this first phase of the project

Solution provider selected

At the end of 2019, following an assessment of several solution providers, an agreement was formalised with a multinational technology company based in China. "One of the biggest advantages to having this technology company manage the track and trace process in China is that they have a multi-purpose mobile application that could be a useful tool for end customers and healthcare professionals scanning products and retrieving value-added online content," says Leandro Oliveira, Digital Identification & Traceability Asia Pacific Lead at Johnson & Johnson Supply Chain.

Distributors identified

"In 2018 and 2019, we conducted surveys with Tier 1 distributors. Results indicated a clear willingness to explore more innovative and effective approaches to handle product traceability. Distributors' interest in GS1 and global standards was gradually increasing. This is one of the factors that led us to make the change in China," adds Lindsay Tao, Corporate Director, Global Policy, Worldwide Government Affairs & Policy.

All distributors that would eventually handle the initial eight SKUs were identified. Focal points representing each distributor were engaged and trained, and a strong communication strategy was enabled.

Project deployment

Project deployment kicked-off in January 2020 with a core team comprised of members from both a cross-functional team led by JJSC and the technology company. Requirements were defined, aligned and implemented, and recurrent project meetings occurred throughout 2020.

[1] World Health Organization. (2020). Growing threat from counterfeit medicines. Retrieved from https://www.who.int/bulletin/volumes/88/4/10-020410/en/
[2] Rodgers, Dirk. (19 June 2019). China: NMPA Drug Traceability Guidance. Retrieved from https://www.rxtrace.com/2019/06/china-nmpa-drug-traceability-guidance.html/

In addition to internal business and IT functions, other external organisations were involved, including the Partnership for Safe Medicines, GS1 China, China Pharmaceutical Industry Association and the China Pharmaceutical Commerce Association—all willing to promote the use of global standards.

By the end of 2020, the technical implementation was finished, initial batches following GS1 standards were being commercialised, the entire supply chain handling these products was trained and the equipment was in place to start exploring the GS1 benefits.
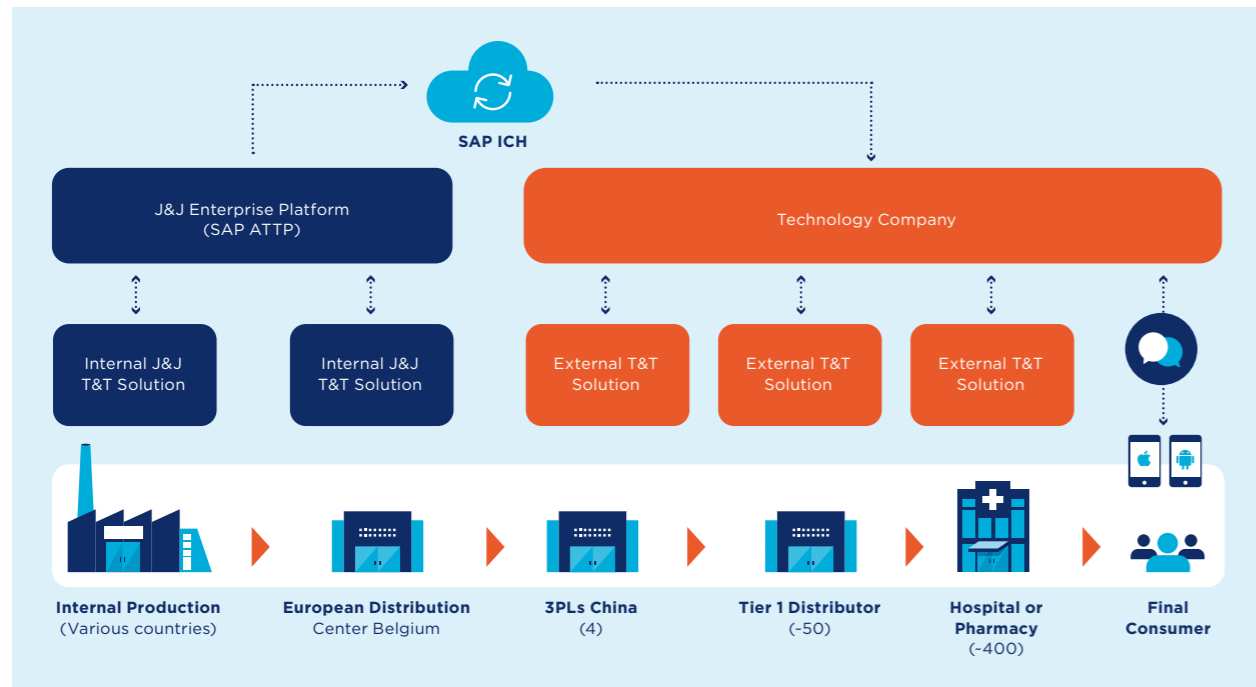
Figure 1: JJSC supply chain in China

Next steps

Moving to the next phase, JJSC is planning to expand the scope of products operating under the new business model and platform for China. The advantage to the new model and platform is that it is readily scalable, and no new infrastructure needs to be built.

"The development and deployment of a cost optimised and localised solution in China enabling GS1 standards is an important proof of concept that allows us to explore similar solutions in new and smaller markets globally," says Vivek Nadadur, Senior Director for Digital Identification & Traceability, Johnson & Johnson Supply Chain. Eventually this platform will integrate with the NMPA national platform where data can be shared with NMPA and supply chain partners, especially hospitals when needed.

Another feature being evaluated is a multi-purpose mobile application. It's an all-purpose 2D barcode scanner that could potentially

become a go-to tool for product scanning and provide relevant consumer and patient value-added information, such as verification, e-IFU, patient education and online medical services.

Impacting the regulatory landscape

In addition to Johnson & Johnson, other manufacturers started to transition to GS1 global standards in 2020 and the overall regulatory landscape in China appears to be more open to the exploration of benefits and the value added with the use of global standards and best practices for product traceability. Manufacturers, third-party logistic providers, distributors, hospitals and pharmacy chains investigating GS1 and standardisation are starting to see it as an opportunity to increase overall operational efficiency. Ultimately, these efficiencies will benefit healthcare professionals and patients throughout China.

About the authors

Lindsay Tao, M.D., Corporate Director, Global Policy, Worldwide Government Affairs & Policy, Johnson & Johnson.

Lindsay Tao provides cross sector leadership in regulatory policy focusing on safety, quality and efficacy of medicinal products. Before she moved to her current position in 2009, she was the Vice President of Strategic Medical Affairs, Johnson & Johnson Medical Greater China (including China, Hong Kong, Taiwan), responsible for regulatory, quality and compliance, clinical research & medical, health policy and government affairs. Besides her role in J&J, she also represents the healthcare industry and takes different roles in regional and global organisations, e.g., GHTS SG1, UDI ad hoc working group members, WHO medical device nomenclature expert group member, AHWP Vice Chair, and APEC RHSC industry coalition alternative coordinator to promote international regulatory best practices and regulatory convergence. Ms. Tao was trained as a clinical physician and worked as an Oncologist in Shanghai Cancer Hospital, Fu Dan University before she joined J&J.

Vivek Nadadur, Sr. Director, Digital Identification & Traceability, Johnson & Johnson Supply Chain

Vivek Nadadur leads Digital Identification & Traceability and the delivery of critical enterprise capabilities in the areas of regulatory compliance, customer compliance, standards and emerging technologies. He focuses his efforts on uniting the physical product to the digital thread, driving greater supply chain transparency, integrity and effectiveness. In support of Johnson & Johnson's partnership with GS1, Mr. Nadadur is a member of the GS1 Data Excellence Board and Committee of Standards Board. Since joining Johnson & Johnson in 2013, he has been responsible for driving several strategic initiatives, including ERP portfolio strategy and supply chain systems integrated roadmap. He also led Johnson & Johnson's global deployment of the serialisation and traceability program. Mr. Nadadur holds an MBA from the University of Chicago Booth School of Business and a bachelor's degree in physics from the University of Delhi.
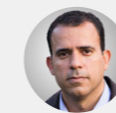
Leandro Oliveira, Asia Pacific Lead, Digital Identification & Traceability, Johnson & Johnson Supply Chain

Leandro Oliveira has spent most of his career in strategic supply chain functions, both in technology and business roles. He has lead global digitalisation programs for Johnson & Johnson Supply Chain, including end-to-end product traceability, UDI, RFID, cloud computing and e-Labelling. Prior to joining Johnson & Johnson Supply Chain, he worked in the energy, oil and gas industries, focusing on the deployment of technology to solve complex business problems. Mr. Oliveira has lived in three countries in different continents and is currently based out of Singapore. He has a bachelor's degree in system analysis, MBA in project management by FGV Brazil and UCI United States and holds PMP and APICS CSCP certifications.
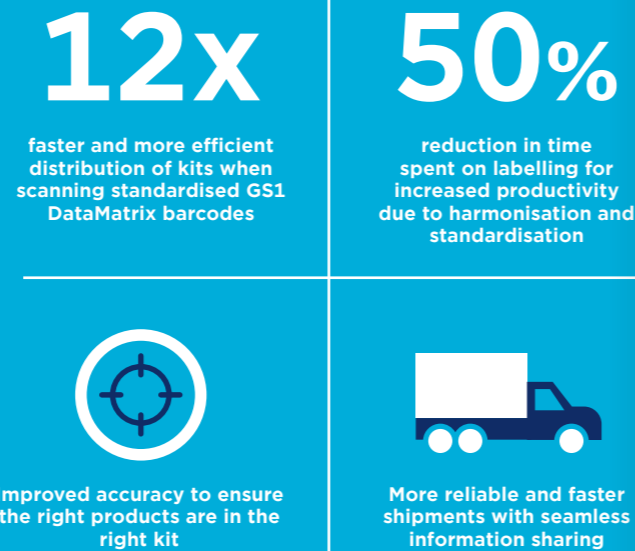
France

Sanofi uses GS1 standards in clinical trials for significant operational and human health benefits

Challenge

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe. The global biopharmaceutical company wanted to improve the efficiency of its operational processes related to investigational products that, in turn, would deliver numerous benefits for its healthcare providers and patients.

Approach

Sanofi worked with its supply chain stakeholders to transition from the use of multiple proprietary barcodes to global GS1 standards. Today, investigational products are uniquely identified with GS1 Global Trade Item Numbers (GTINs) encoded in GS1 DataMatrix barcodes. This standardised approach helps Sanofi's hospitals and trial sites better manage clinical trial activities so that the right investigational product and/or kit goes to the right patient.

12x faster and more efficient distribution of kits when scanning standardised GS1 DataMatrix barcodes

50% reduction in time spent on labelling for increased productivity due to harmonisation and standardisation

Improved accuracy to ensure the right products are in the right kit

More reliable and faster shipments with seamless information sharing

Introducing Sanofi

Sanofi is dedicated to supporting people through their health challenges. Focused on human health, Sanofi prevents illness with vaccines, and provides innovative treatments to fight pain and ease suffering. Sanofi also stands by the few who suffer from rare diseases and the millions with long-term chronic conditions.

Sanofi's clinical trial kits are designed to use inputs received from end-users of the supply chain, such as patient communities, physicians and hospitals where trials are conducted. As a result, Sanofi transitioned from taking an internal approach of identifying its investigational products and investigational product kits to adopting global standards for unique identification.

Sanofi's goals: Ensure that clinical trials' products are aligned with the relevant needs of patients and healthcare providers, and enhance internal efficiencies in identifying, handling and tracing products within multiple clinical trial protocols.

Global standards for clinical trials

Sanofi was the leader of an industry working group comprised of 57 organisations that, within

a nine-month period, drove the development of GS1 global standards for the identification and barcoding of investigational products for clinical trials.

Today, the safety of patients remains the main goal and key success indicator for Sanofi, and patient safety will be enhanced through end-to-end traceability and supply chain interoperability—both enabled by global standards.

Why did Sanofi implement global standards for its clinical trials? The aim of Sanofi is continuous improvement on all levels of its operations. The company wanted to improve the efficiency of its internal processes, using a less complex way of generating, identifying and capturing information about investigational products.

As its implementation of global standards moved forward, Sanofi's focus remained on maintaining and enhancing the accuracy of its clinical trial supply chain.

Since 2009 and prior to its implementation of global standards, Sanofi had used internal identifiers and barcodes. This led to the creation of multiple, different DataMatrix formats and the resulting complexity in managing numerous matrices since each barcode required specific processes to be generated and/or captured.

This situation also meant challenges for stakeholders in the supply chain, as they were unable to scan and interpret the different barcodes with their existing IT capabilities. This led to operational inefficiencies that potentially impacted the overall accuracy of information exchanged throughout the supply chain.

Despite Sanofi's intentions to provide the tools that all trial partners needed, Sanofi barcodes were limited to internal use only, leading to limited interoperability with other stakeholders. Sanofi recognised that a single standardised approach was needed.

Industry collaboration for a common benefit

As Sanofi worked on its vision, other stakeholders in the clinical trials supply chain had come to realise that using internal, proprietary identification and barcode schemas (that were different for each trial) was causing potential confusion for trial sites, hospitals and logistics providers.

Full-scale interoperability enabled by global standards and relevant IT systems across the supply chain would provide multiple benefits for all stakeholders. Clinical trial sponsors could provide enhanced service to both hospitals and patients that, in turn, could more efficiently manage and accurately document the multiple products of their clinical trials, and provide more timely feedback.

"By speaking a common language, we realised that hospitals could more efficiently manage clinical trials."

Pierre Fernandez-Barbereau,
R&D Clinical Supply Chain Operations, Industrial Development, Sanofi

The implementation process of GS1 standards

1 - Standardise the identifier and barcode.

The standardisation of clinical labels and information was a crucial step during the Label & Package Design phase of Sanofi's clinical trial methodology.

Before implementing GS1 standards, Sanofi used seven different DataMatrix formats with seven different formulas. Each DataMatrix format was encoded with data to pilot and direct every single investigational product through its assigned product line in the phase. These formulas had to be rewritten to leverage GS1 standards, including the allocation and encoding of a Global Trade Item Number® (GTIN®) in the GS1 barcode.

Sanofi used the GS1 Healthcare Barcode Scanner App (HBSA) to ensure the correct string of data was encoded in the GS1 DataMatrix barcode. The HBSA allows users to check if the encoding of data in a certain barcode is compliant with GS1 standards.

2 - Enable technologies to encode and decode GS1 barcodes.

Sanofi then needed to ensure its label printers, barcode scanners and other technologies were able to encode and decode GS1 barcodes. The camera controls, which are responsible for the synchronisation of what is scanned from the investigational product label with the visual recognition of labels in the Packaging Operations phase, had to be updated to comply with GS1 standards.

There were also updates made to IT systems and infrastructure, including hardware and equipment for the packaging re-design and accurate reading of the new GS1 DataMatrix. Since barcode scanning is widely used in the Distribution phase of Sanofi's operations, this function was also a key focus.

3 - Leverage the new identifiers and barcodes.

Sanofi's priority was to help hospitals and trial sites through the management of their activities at site level to ensure that the right investigational product or investigational product kit went to the right patient. At the same time, Sanofi was aware that various contract manufacturers, contract research organisations, contract packaging organisations, warehousing

providers and logistics providers would need to be able to handle the new GS1 identifiers and barcodes.

As a first step, Sanofi created a document that specifies and explains the content of its new standardised GS1 DataMatrix, and then distributed the document to all stakeholders and partners across the supply chain.

To advance standardisation in the clinical supply chain, Sanofi's vision, as a study sponsor, is to have every stakeholder along the supply chain equipped with barcode readers. With this addition, Sanofi and its stakeholders will be able to fully benefit from the implementation of the new GS1 standard. In short, hospitals and clinical sites can then adopt GS1 standards to identify, capture and use the identification of Investigational kits.

Figure 1: Sanofi implementation timeline and outcomes

since the manufacturers' IT systems need to be updated to accommodate the change to standards. At the same time, both Sanofi and the contract manufacturers realise the major benefits of investing in and adopting this standardised approach.

Giving patients access to investigational product information

As a top priority, Sanofi wanted to help patients use smart applications to scan GS1 barcodes easily and then share the scanned data with Sanofi. This could provide patients with stable home delivery of products and enhanced guidelines on how to use those products. Sanofi's E-product information application was developed

Successfully transitioning to standards

The implementation of global GS1 identifiers and DataMatrix barcodes meant that Sanofi's current IT systems needed to be able to accurately encode and decode GS1 barcodes. This was not a simple task given the wide range of legacy IT systems in place and IT providers' lack of knowledge regarding the technical structure of GS1 identifiers and barcodes. As such, significant transitional projects included a major systems upgrade as well as educating software providers about how to implement GS1 standards—efforts that proved to offer time savings benefits.

Sanofi is also requiring that its contract manufacturers use the GS1 DataMatrix barcode. This transition is taking some time and effort
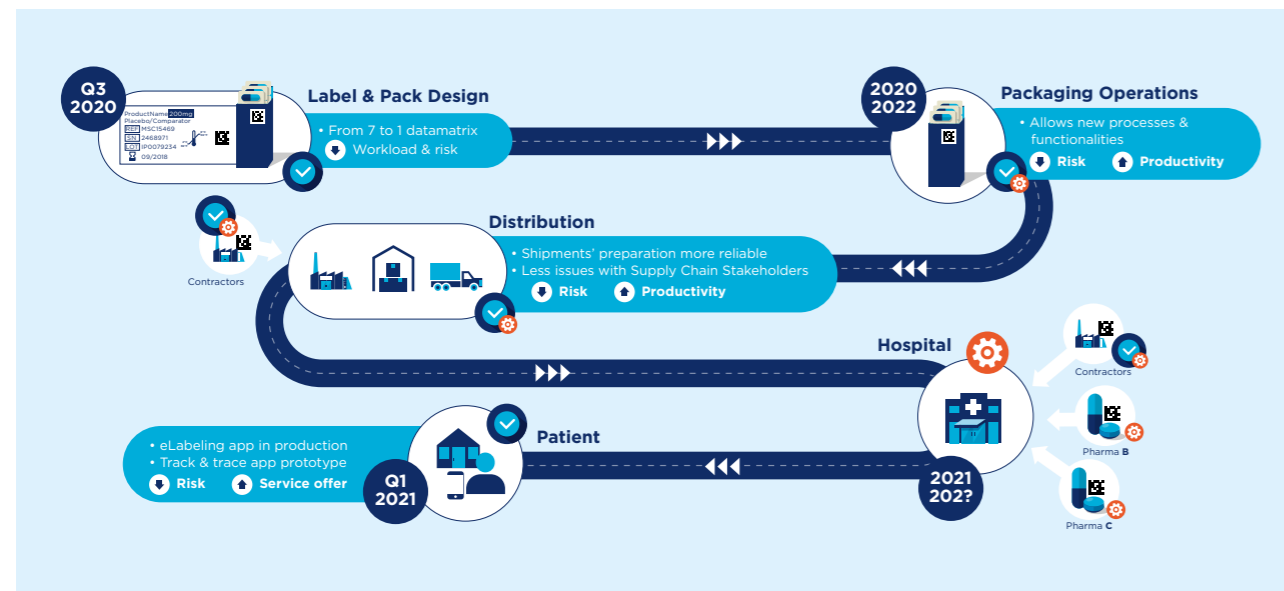
by solution provider, ClickTag. Now, a patient can simply scan the GS1 DataMatrix barcode on the product's e-label and the application retrieves digital information about the products while simultaneously helping Sanofi track and trace the product in the process. As of August 2021, the e-label app is being used for 4-6 trials with plans to use it for all trials, starting in 2022.

Operational benefits for Sanofi

GS1 standards are now being used throughout all operational phases at Sanofi, increasing efficiencies and reducing time and risks. And with a standardised structure for the GS1 DataMatrix barcode, Sanofi needs less support from IT, reducing its reliance on and time spent with IT resources.

In the label and package design phase, the time needed for processes has been cut by 50%, significantly reducing workload and improving overall productivity. This productivity hike due to harmonisation and standardisation efforts has improved Sanofi's ability to ensure the investigational products in a box are the right ones.

With its contract manufacturers using GS1 DataMatrix barcodes to label investigational kits, Sanofi also expects to realise significant time savings and operational efficiencies in its own distribution process. It will no longer need separate distribution processes to accommodate non-standardised and standardised barcode labels. Rather, Sanofi will be able to use a single, automated distribution process with no manual intervention.

GS1 standards have helped Sanofi with the re-modelling of its distribution and shipment management processes, which ensures standardised identification of products throughout the supply chain. Sanofi anticipates that the benefits associated with this standardised approach will enable its depots (3PLs) to streamline their processes and help ensure that the right kits get to the right healthcare providers.

Prior to the standardised approach, with multiple barcodes, Sanofi found it was time-consuming to scan and retrieve information based on all the formats.

The company also discovered how disruptive the manual preparation of kits could be.

When preparing 250 kits, it took two people working 2.5 hours compared to less than 10 minutes required when scanning standardised DataMatrix barcodes.

In short, the distribution process is now more efficient, resulting in more reliable and faster shipment preparation, as well as the seamless sharing and exchange of information across the supply chain.

Looking forward

Sanofi sees that the identification of investigational products and their kits is just the beginning in the overall transformation of its clinical trial operations. Currently, the company is engaging vendors to implement GS1 EDI (electronic data interchange aligned with GS1 standards) to guarantee an optimised flow of business data by "speaking with one common language."

Sanofi will start to implement just-in-time labelling that will allow sponsors and vendors to request labelling for a specific country. This late-stage customisation effort is expected to reduce product wastage, increase the efficiency of distributions, and maximise the usage of products with short expiration dates.

All of these benefits—for Sanofi, its hospitals and patients—are a result of leveraging global GS1 standards.

About the author

Pierre Fernandez-Barbereau,
R&D Clinical Supply Chain Operations, Industrial Development, Sanofi

Pierre Fernandez-Barbereau enables and coordinates the development of next-generation clinical supply chain technologies, taking into consideration new regulations and pharma trends. While remaining patient and clinical-site oriented, he is focused on continuous improvement and operations optimisation.

Previously, Mr. Fernandez-Barbereau held several positions in Clinical Supply Chain and IT departments in France and US, as Domain Leader in Technology and Innovation areas. He joined Sanofi in 2004 as IT Project Manager bringing more than five years of expertise and project management experience at Cap Gemini Ernst & Young. Mr. Fernandez-Barbereau holds a Master of Information Technology, Computer Science and Management.

About the organisation

Sanofi is dedicated to supporting people through their health challenges. As a global biopharmaceutical company, Sanofi is focused on human health, preventing illness with vaccines, providing innovative treatments to fight pain and ease suffering. The company stands by the few who suffer from rare diseases and the millions with long-term chronic conditions. With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.
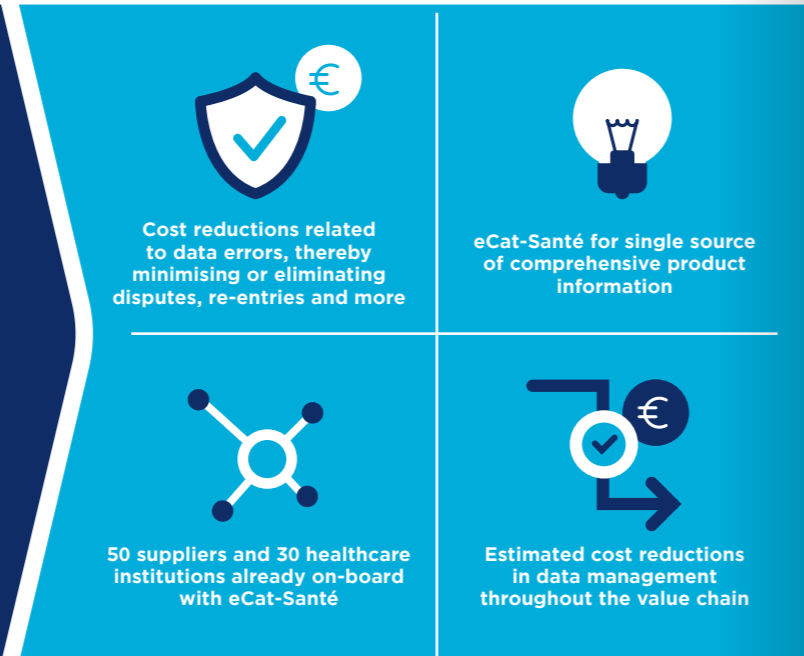
www.sanofi.com

France

Digitise healthcare product information to improve procurement and supply chain management

Challenge

As a public purchasing organisation, Resah aims to facilitate access to the ordering, management and identification of products exchanged between hospitals and manufacturers. For global consistency, it is essential to share global information on products directly from manufacturers to hospitals, using a single format.

Approach

To support manufacturers and hospitals in the digitisation of product information, Resah implemented the first interoperable electronic catalogue for the French health sector: eCat-Santé. Based on GS1 standards, this catalogue enables the input and output of comprehensive, standardised and up-to-date product information. The solution provides a win-win by reducing the time and costs associated with product information management.

Cost reductions related to data errors, thereby minimising or eliminating disputes, re-entries and more

eCat-Santé for single source of comprehensive product information

50 suppliers and 30 healthcare institutions already on-board with eCat-Santé

Estimated cost reductions in data management throughout the value chain

Today, French hospitals are challenged by new regulations such as European Union's Falsified Medicines Directive (EU-FMD), Unique Device Identification (UDI) and more—with requirements to uniquely identify all healthcare products. As a result, pharmacists and hospitals need reliable and complete trade item data for greater knowledge about the products they use in order to improve patient safety.

Created in 2007, Resah is a major public Group Purchasing Organisation (GPO) that leverages the purchasing power of hospitals and nursing homes in France, with over 4,000 public contracts covering all healthcare procurement fields.

After a successful proof of concept, Resah is now leveraging the GS1 Global Data Synchronisation Network™ (GDSN®) to enable manufacturers to send trusted data to its platform called eCat-Santé. Ultimately, eCat-Santé will cover not only medical devices and pharmaceutical drugs, but any product that Resah contracts for hospitals in France.

The eCat-Santé solution is expected to save time and money for hospitals and pharmacies, while ensuring increased data quality and improved

patient safety. The solution will also allow suppliers to share their updated data with all healthcare users in France, to receive orders based on registered product codes that can easily be integrated in hospitals' IT systems, and to share the product references in a secure environment.

Introducing eCat-Santé

Healthcare professionals need complete and accurate data related to healthcare products for efficient processes—order-to-cash, inventory management and dispensing of the products they use every day. In fact, data quality is especially critical when it comes to ensuring the quality of patient care and safety. For more than 10 years, French hospitals have been aware of this need and have tried multiple times to synchronise product information with suppliers and points of care.

For several years, suppliers have had to provide more and more information about their products (e.g., instructions, codes, descriptions, sizes) in formats specific to each of their customers. Gathering, managing and sending these data in proprietary formats has

required significant time and money for the medical device and pharmaceutical companies.

Resah, working in a dematerialised way with healthcare institutions and suppliers, has several goals:

- Anticipate the transformation linked to the dematerialisation and traceability of healthcare products in compliance with regulations (e.g.,UDI, EU-FMD, public procurement regulations).
- Ensure that hospitals have access to reliable and integrated product information at a very low cost.
- Secure the process via internationally recognised standards.

At the end of September 2020, Resah launched eCat-Santé, its first e-catalogue, developed with @GP, a solution provider. The catalogue is based on GS1 standards, recognised by the profession and defined in close collaboration with a multi-professional working group. eCat-Santé offers product information directly sourced and updated by manufacturers— providing a secure database that guarantees healthcare providers a comprehensive knowledge database for the traceability of healthcare products.

Implementing eCat-Santé

The eCat-Santé system brings together different stakeholders on one single platform. eCat-Santé's objective is to improve the reliability and consistency of data in the various healthcare information systems.

Launched in September 2020, more than 50 suppliers, including 12 suppliers via the GDSN, and 45,000 product records are shared with eCat-Santé.

More than 20 hospitals have already applied to eCat-Santé, which is planned for opening to healthcare institutions in November 2021.

Resah started the development of eCat-Santé by creating a task force with the different stakeholders, focusing on issues related to the quality of end-to-end product information. The group included representatives from:

- Medical device manufacturers - B.Braun, Bio-Rad, Vygon
- Pharmaceutical company - Roche
- Pharmaceutical database - CIP
- Hospital pharmacists - Hospitals of Argenteuil, Saint-Denis and Groupement Hospitalier de l'Est Francilien
- Medical service of the French Army - Service de Santé des Armées
- GS1 France

The objective of the task force was to collect users' needs that would conform to regulatory prerequisites, with the aim of getting responses from healthcare providers.

Once these prerequisites were established, Resah launched a call for tender in order to choose a solution provider that would support the technical development of the solution. The solution provider selected was @GP.

The eCat-Santé solution was launched in September 2020 to include medical devices and pharmaceutical products, the first products in scope. Today, more than 50 suppliers, including 12 suppliers via the GDSN, and 45,000 product records have been shared with eCat-Santé. More than 20 hospitals have already applied to eCat-Santé, which is planned for opening to healthcare institutions in November 2021.

Resah also intends to leverage eCat-Santé by opening it to other sectors such as catering in mid-2021.

Leveraging GS1 standards

For increased adoption by all stakeholders, eCat-Santé is based on several GS1 standards:

- GS1 global identifiers include the Global Trade Item Number® (GTIN®) and Global Location Number (GLN).
- GS1 data models for pharmaceutical products and medical devices include sharing data via the GDSN.
- The GS1 data model gathers product information in families and covers 160 attributes, to include product identification, packaging information, purchase order, marketing, prices / taxes, health / reimbursement, medical device or pharmaceutical, and danger.

The eCat-Santé solution is now integrated into Resah's application system and will enable the communication between several applications, in particular those associated

with enterprise resource planning (ERP), to ensure the consistency of product references, the healthcare provider's website to enable enhancements of online product information, and the supplier's web portal to ensure the proper digitisation of the purchasing process, from order to invoice.

One catalogue for all

The catalogue enables suppliers to provide and share product information in a single format. There are two available ways of sending information to eCat-Santé: (See Figure 1.)

- GDSN: Suppliers that have a data pool and product information management (PIM) software can directly share their product information with eCat-Santé. A link between the manufacturer and eCat-Santé has been set up by @GP, enabling the manufacturer to directly send data. The use of GDSN has proven to be an efficient way to share large product catalogues and to save time for manufacturers, Resah and healthcare providers.

- eCat-Santé suppliers web portal: Suppliers without PIM can use the supplier portal, structured in a GS1 format. The data can then be compiled manually or by importing via comma-separated values (CSV) files.

Resah receives the product information and improves it with tendering information, to include the tender number, and the start and end dates of the tender.

For hospitals, eCat-Santé provides a centralised data source for all healthcare professionals: pharmacists, purchasing assistants, logisticians and others. Therefore, everyone has access to the data they need on a daily basis.

Two access points are available for hospitals. (See Figure 1.)

> "Healthcare products are available in numerous references to specifically meet the needs of patients, according to their size, gender or age.
>
> "As a result, manufacturers have to manage catalogues that include several hundred or even several thousand references.
>
> The GDSN has proven its efficiency by allowing Resah suppliers to load such catalogues on eCat-Santé in only a few weeks, mobilising teams with lead times of less than two or three days."
>
> **Stéphane Ancel,**
> IT Editor, @GP

eCat Santé operating mode
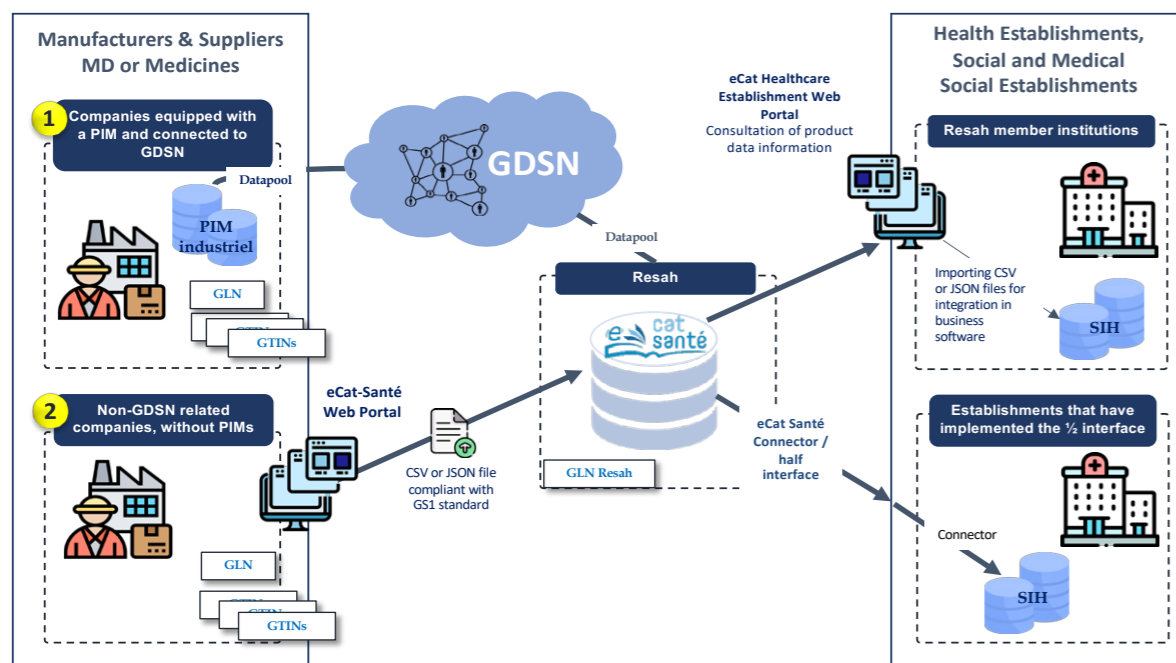
Figure 1: eCat-Santé operating model
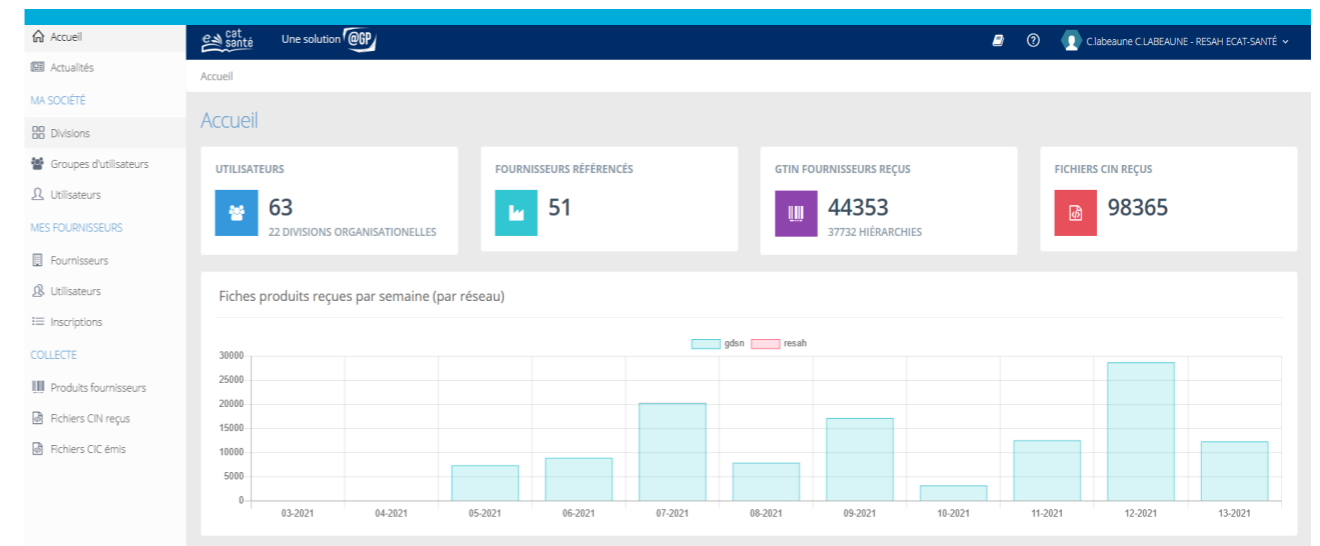
Figure 2: eCat-Santé dashboard
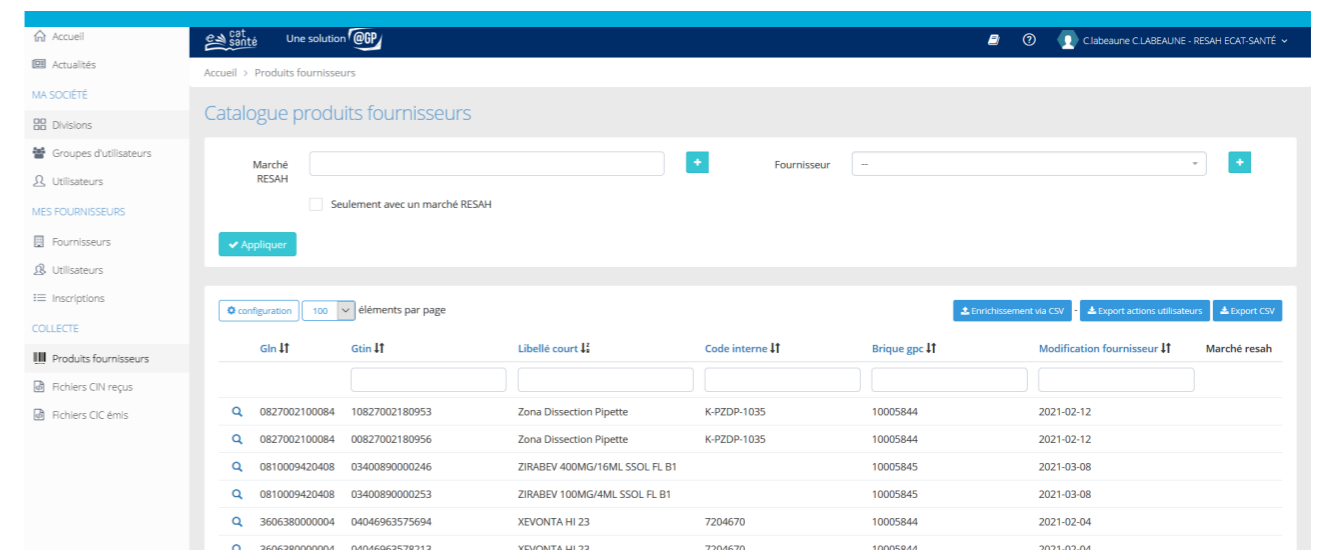
Figure 3: eCat-Santé product list

> "It was essential for us to enable the healthcare industry in France to share standardised product data in the most efficient and global way as possible, avoiding the use of proprietary data formats. The choice of the GDSN network gives us the opportunity to add a value proposition in the use of eCat-Santé for manufacturers."
>
> **Camille Labeaune,**
> Project Manager, Resah

Supporting manufacturers' digitalisation

Several webinars dedicated to eCat-Santé help to promote the use of the solution by suppliers. Since August 2020, different Resah calls for tender have included clauses requiring contract holders to provide eCat-Santé with information on selected products. Uploading data into eCat-Santé is free-of-charge for suppliers that are under contract with Resah.

Convinced that eCat-Santé is a solution that will allow healthcare institutions to better know and manage their products, suppliers are also using

eCat-Santé as a showcase for their entire product catalogue. Suppliers that do not have a contract with Resah can also use the catalogue under specific conditions.

Digitising information management in hospitals

The eCat-Santé catalogue will allow medical device suppliers to share their internal codes as well as their UDI codes for all their product catalogues. The use of these two identification systems, for both supply codes (e.g., order, dematerialised exchanges) and regulatory codes (e.g., traceability), will enable healthcare institutions to ensure compliance with the UDI regulation, which commenced in May 2021. Beyond that, eCat-Santé is built for the data expected in the European database for medical devices (EUDAMED) and will allow hospitals to enhance health product data directly from their IT systems. Healthcare institutions are also supported through eCat-Santé webinars that introduce and teach them how to use the solution.

> "
>
> *"eCat-Santé concerns the standardisation of logistic practices for the supply of medical products in different hospitals, working with Resah in order to optimise the execution of the contracts signed with the suppliers. As a consequence, this leads to better sustainability, time savings for healthcare practitioners and a lower number of errors in order processing."*

Jean-Michel Descoutures,
Hospital Pharmacist, Argenteuil Hospital

Next steps

For the future, Resah intends to offer healthcare organisations global coverage of all the products they use daily. Thus, Resah is already offering eCat-Santé for other sectors such as catering, textile, general services and more. The availability of the solution for the food industry is planned for mid-2021 in order to meet the tender schedule of the central purchasing organisation. The FMCG and out-of-home catering data models defined by GS1 France are already configured on eCat-Santé and are waiting for suppliers to complete their data.

Multiple benefits

Resah wants to reduce as much as possible the management costs associated with the data produced for suppliers and hospitals.

By using the eCat-Santé electronic catalogue, suppliers will be able to:
- Control the data transmitted to healthcare institutions.
- Enable the automation of transmitting data to everyone simultaneously.
- Receive order forms with recognised and updated codes.
- Minimise returns due to data errors.

The advantages for manufacturers are also important. A standard data model enables them to reduce the number of product record formats sent to their customers. Above all, manufacturers can control their own data.

For healthcare providers, eCat-Santé provides a way to:
- Secure the circulation of health products, thanks to reliable data.
- Provide access to exhaustive, standardised and updated product information without manual input into their information systems.
- Facilitate the integration of pricing data from notified contracts.

The French Army health system and many other institutions already use eCat-Santé for increased knowledge of healthcare products.

Conclusion

Resah hopes to involve more and more manufacturers and healthcare providers in eCat-Santé. By mid-2021, the GPO plans to launch the first eCat-Santé User Group, opening the possibility for everyone to improve the solution.

The promotion of a direct connection with hospital information systems is dependent on hospital solution providers. Resah also plans to use the data produced in its own IT systems by interfacing its e-commerce website and its supplier e-portal with eCat-Santé.

About the authors

Camille Labeaune,
Project Manager, Resah

Camille Labeaune is a project manager for supplier relationship transformation at Resah, with six years of experience in data quality management. She leads projects aimed at improving the performance of purchasing activities in hospitals.

Ms. Labeaune leads the eCat-Santé project, organising healthcare stakeholders and working to harmonise and optimise data management related to healthcare products (pharmaceuticals and medical devices) in hospitals.

Ms. Labeaune is a biomedical and informatical engineer graduated from the Ecole Centrale Electronique of Paris.

Stéphane Ancel,
IT Editor, @GP

In the health area for 20 years, Stéphane Ancel has held various positions in the management and optimisation of hospital organisations. He first managed private hospitals and then joined the purchasing sector by working for several purchasing groups.

It is within the framework of purchasing that Mr. Ancel focused on the development of new technologies and digitalisation, which is lagging behind in the health sector compared to other sectors of activity, by deploying an EDI platform on behalf of the health institutions of the Mutualité Française.

Based on his strong experience in these different areas, Mr. Ancel joined @ GP as the IT Editor, specialising in EDI to develop applications and enable the development of digitalised purchases.

Jean-Michel Descoutures,
Hospital Pharmacist, Argenteuil Hospital

Jean-Michel Descoutures is a hospital pharmacist, currently working in the Pharmacy department of Argenteuil Hospital in France. He joined the "Réseau des acheteurs hospitaliers" (Resah) in 2007, one of the major group purchasing organisations for hospitals in France. Because of his knowledge on how medications come on the market and how the price is established by the authorities, he has been appointed coordinator for the procurement of pharmaceuticals for over 100 hospitals, including the military hospitals.

Mr. Descoutures is part of the executive board of the "Club des Acheteurs de Produits de Santé," which is an association where all different public and private GPOs can discuss their issues regarding the environment of procurement of health products. In 2009, he was elected a Member of the French Academy of Pharmacy.

Mr. Descoutures represents the International Hospital Federation (IHF) on the leadership team of GS1 Healthcare.

About the organisation

resah

Resah – Réseau des Acheteurs Hospitaliers – is a public group purchasing organisation in France that supports high performance for all actors in the healthcare, medico-social and social sectors, thanks to mutualisation and professionalisation of purchasing and logistical activities. Its activities are organised around two major areas of services: a purchasing group and a resource and expertise centre.

www.resah.fr

United States

Fresenius Kabi: First to provide healthcare providers with GS1 EPC-enabled RFID tagging at the dosage level

Challenge

Fresenius Kabi, a global healthcare company, launched an ambitious program to support healthcare providers and become the first in its industry to tag vials of medication using Electronic Product Code-enabled radio frequency identification (EPC/RFID) technology.

The company's goals: Each container of medication would have an encoded EPC that carries the globally unique product code, unique serial number, expiration date and batch/lot number. The product code would consist of the Global Trade Item Number® (GTIN®) with an embedded National Drug Code (NDC), which identifies the manufacturer. The RFID tags would have to comport with the dielectric properties of the drugs, not impede manufacturing speed, and eventually be brought to scale across the company's extensive portfolio of pharmaceuticals.

Solution

Fresenius Kabi chose an EPC/RFID tagging system based on GS1 standards. Using no proprietary software or rules, GS1 standards enable any supply chain participant across the globe to read data with the proper RFID equipment, including hospitals and pharmacies that comprise Fresenius Kabi's primary customer base. By tagging each dose of medication, the healthcare provider and patient have an additional serialised measure of unique product identification.

Hospitals that are applying their own RFID tags to pharmaceuticals no longer need to expend that time-consuming effort (and avoid potential process-quality or security issues) when using drugs from manufacturers that supply their products with RFID tags embedded in the label of each dose.

Supplying the combination of the GTIN, serial number and tag ID, the RFID-tagged drug is virtually impossible to counterfeit, strengthening serialisation already in place in compliance with the U.S. Food and Drug Administration (FDA) Drug Supply Chain Security Act[1] (DSCSA).

In the event of a recall, the identity of target items can be pinpointed, with the item date, batch/lot, serial number or other related manufacturing details.

Hospitals can achieve more precise inventory management, with the ability to read many RFID tags in one scan. This could lead to better drug management overall, and improved charge capture in hospital settings where barcode scanning is not conducive to the workflow.

From the customer's perspective

Fresenius Kabi specialises in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. As a leading manufacturer of sterile injectable medications in the US, Fresenius Kabi believes that the company's values of collaboration and creativity are a strategic advantage, and using GS1 standards for traceability exemplify these values.

As Angie Lindsey, Vice President of Marketing, puts it, "Our responsibility as a healthcare company does not end at the hospital's loading dock. By including RFID

technology in the label of our medications, we are helping our customers manage their drug inventory with more precision and accuracy, tracking the medication all the way to the patient."

A few years ago, a senior executive from Fresenius Kabi was visiting a hospital customer in Chicago in the US when a pharmacist showed him how they were using the hospital's RFID system and manually tagging drug vials, associating the information for the medication with the tag, including its name, manufacturer and expiration date. It was clear that this very labour-intensive tagging process was something Fresenius Kabi could help with.

[1] Drug Supply Chain Security Act, Pub. Law No. 113-54, 127 Stat 599 (2013).

> "Our responsibility as a healthcare company does not end at the hospital's loading dock. By including RFID technology in the label of our medications, we are helping our customers manage their drug inventory with more precision and accuracy, tracking the medication all the way to the patient."

Angie Lindsey
Vice President of Marketing, Fresenius Kabi

After seeing firsthand the importance of RFID technology from a hospital's perspective, the executive asked, "What if we provided the vial with all the information already in the RFID tag?" The pharmacist's response was immediate and enthusiastic.

"Following this customer interaction, our team developed and presented the business case to our executive leadership to receive approval," says Ms. Lindsey. "It was apparent how adding RFID smart labels to products would serve a very important purpose for our customers."

"Throughout the implementation process, there was an opportunity to gain a variety of perspectives on RFID technology for medication tagging and educate our internal stakeholders," says Gwen Volpe, Director of Medication Technology and Analytics, serving as one of the project leads for implementing RFID tagging. "The teamwork within our organisation is exemplary. We are a global company of more than 35,000 people and share a common purpose of working together to serve our customers and communities in 150 countries around the world. It was great to see our cross-functional team converge on a common vision, and then make it a reality."

Jeanne Sirovatka who leads the Operational Excellence / Continuous Improvement team for all three of Fresenius Kabi's US manufacturing sites, was the logical choice to partner with Ms. Volpe.

"RFID certainly falls into the innovation category," Ms. Sirovatka says. "We completed our serialisation equipment installation prior to the DSCSA deadline; it was important to us to continue as a leader. And we were able to leverage our packaging engineering expertise on the RFID project."

Coming together to innovate

With over 600 unique NDCs in its product line of generics, leading on a groundbreaking technology is no small matter—or undertaking. "In our RFID project, having input from both the commercial and manufacturing sides of Fresenius Kabi was very important. Many people were involved," says Ms. Volpe, a trained pharmacist.

Ms. Sirovatka with her military background and training as an analytical chemist echoes and expands on the point: "We use a classic scientific method; can we disprove something as a way to challenge it? This project team required experts from Regulatory Affairs, Marketing, Engineering, Project Management and Quality Control. Everybody came together to make this project work."

"A generic manufacturer leading the way is maybe counterintuitive, in some ways. We usually follow the innovators. But in this case, we're the one innovating from a technology perspective," says Matt Farley, Senior Manager of Medication Technology and Analytics who serves on Ms. Volpe's team and like her is a pharmacist by training.

Voice of the customer

Before launching the RFID tagging project, the team's market research looked at both customers' and vendor partners' needs: pharmacies, hospitals, healthcare automation and wholesalers—with the patient always in mind. The marketing team even assembled advisory boards to inform its decision-making.

Going beyond DSCSA

From the moment of its very passage by the US FDA in 2013, it was easy to see how the DSCSA would improve patient safety.

The regulation enables traceability by specifying that pharmaceutical products must be marked with four data elements—an NDC (e.g., GTIN), serial number, lot number and expiration date. It also requires that packages must be marked with a two-dimensional (2D) barcode (e.g., GS1 DataMatrix barcode) and homogeneous cases with either a 2D barcode or linear barcode (e.g., GS1-128 barcode).

Throughout the DSCSA implementation, GS1 US, the neutral not-for-profit membership-based organisation, has been positioned to provide each participant in the pharmaceutical supply chain with the guidance needed to apply global GS1 standards in support of DSCSA.

Driven by DSCSA implementations, pharmaceuticals in packages or homogeneous cases can be tracked and traced from manufacturers to the receiving docks of healthcare providers. Yet, the management of medicines throughout hospitals—from receipt to administration—is not within the scope of DSCSA.

With its initial implementation of EPC/RFID tagging of Diprivan, Fresenius Kabi is going beyond DSCSA requirements by encoding an RFID tag with the four, DSCSA-required data elements at the unit-of-use level. The company is adding another layer of protection to pharmaceutical integrity for the sake of patients, while saving healthcare providers time and providing precise inventory control throughout hospitals.

"We talked to many hospital customers to gain their insights and understand their experiences with RFID technology for medication tracking. Safety and efficiency were the words we heard most often," recalls Mr. Farley.

"We looked at technologies that customers use every day," Ms. Volpe says. "We learned that standards were exceedingly important— in particular they specified GS1 standards. They wanted the products they use to be RFID-enabled with the tag embedded and the drug identification data locally encoded like a barcode. Once you scan a RFID-tagged product, all the information you need is there: GTIN/NDC, lot, expiration da and a unique serial number."

"Every barcode a customer scans is based on a GS1 standard, so it really informed our decisions. It was quite easy once our research bore that out," Ms. Volpe continues.

As a member of the GS1 community, Fresenius Kabi is very familiar with the solutions, standards and resources the organisation provides.

With the advent of the implementation, a Fresenius Kabi drug manufactured in Sweden would be the first in the industry to carry GS1 EPC/RFID tags.

Fresenius Kabi chose the drug Diprivan, a sedative used intravenously, as the first medication to be RFID tagged, primarily because, as the most utilised drug in its portfolio, hospitals were manually tagging it for the tightest possible inventory control.

Source: Fresenius Kabi

Open and interoperable

For its tag design, Fresenius Kabi steered away from vendors whose products relied on proprietary software for encoding. Fresenius Kabi chose a GS1 US Solution Partner—eAgile— to help them with tag and equipment design. "eAgile offered a custom design through a framework of experiments. With Diprivan as our product pilot, the RFID technology would have to adapt to the dielectric properties of the medication," Ms. Sirovatka says. "Essentially eAgile helped us create a new technology."

"All of our solutions are based upon open, interoperable standards," says Gary Burns, eAgile CEO. "It allows our solutions to be deployed globally at what we believe is a lower cost, because there aren't a lot of proprietary components to develop."

"eAgile was able to show us the process of RFID from end-to-end. It allowed us to see the process of creating an RFID tag, applying the tag, storing prior to shipping and so on. There was an emphasis on quality, which is really important to us," Ms. Volpe says.

Ms. Sirovatka agrees. "Quality and safety are always our top priorities. The fact that we're enabling quality and safety at the hospital is the fundamental driver for us to do this."

Disproving myths

With eAgile's help, Fresenius Kabi also upended some misconceptions along the way to reach its solution, such as encoding all of the product data within the EPC-enabled RFID tag rather than merely linking to a cloud-based database.

The company was cautioned that its proposed tagging protocols would not work at manufacturing speed, something else Fresenius Kabi disproved. Some revelations came as nice surprises; others as interesting curiosities.

"We thought you could only write to a tag at about 150 units a minute maximum, which is not sufficient for our manufacturing lines. That turns out to be false. It's much higher; we're approaching up to 600 units now," Ms. Sirovatka says.

"Finding out that every medicine can have a different RFID reflective transmission capability was unexpected. It's important to have an upfront understanding of how your medication affects the RFID environment. I thought we could make one tag per size of vial and we'd be good. That's not necessarily true."
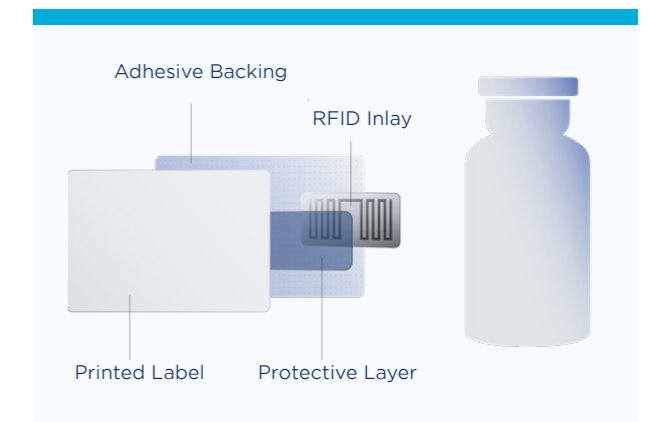

Image created by Fresenius Kabi

Standard project challenges were also addressed as part of the mix: equipment integration, managing an implementation team, readying the plant team when the equipment was ready, developing a change management process and obtaining buy-in of participants all along the line who may be reluctant for new technology to change their way of doing things.

"It's not just Fresenius Kabi that needs to provide medicines with RFID, it's all manufacturers," says Ms. Sirovatka. "This is a proven use case with more opportunities beyond operating room usage to become a global inventory management system."

"Manually maintaining the tray can be quite cumbersome for the pharmacy. With RFID tags identifying products, the pharmacist can scan all the tags and identify what's missing and what's about to expire. What once took a significant amount of time can now be done in a matter of seconds."

Matt Farley,
Senior Manager of Medication Technology and Analytics, Fresenius Kabi

Time and safety

RFID tracking tags are most often found in hospitals' operating rooms and procedural rooms where firm control over medication trays and carts is most needed. Applying individual tags to drugs, inputting relevant product data into the system, double checking and validating the data can be extremely time-consuming.

"Many hospitals use what's called a kit-and-tray system. Prior to the procedure, the anesthesiologist retrieves a tray with many drugs that may be needed for the case," explains Mr. Farley.

Under pressure in an emergency or operating room setting, selecting the right medication for the right patient has very real life-and-death implications. If the tray has not been precisely maintained, an expired drug could be used or absent entirely. Following a surgery, the tray is returned to the pharmacy for replenishment.

"Having the ability to track a product down to individual-use level is valuable. With RFID tagging, the pharmacy can close the loop on medication use, safety and inventory management with the ability to scan products at the point-of-care," Ms. Lindsey adds.

"As a leader in sterile injectable medications, we have a responsibility to tag our products so that they can be read easily and accurately by our customers in the US and abroad, and use standards that any pharmaceutical manufacturer can adopt for consistency. We are all in this together for patient care."

Gwen Volpe,
Director of Medication Technology and Analytics, Fresenius Kabi

Efficiency and authenticity

Fresenius Kabi has made that scenario a reality with Diprivan, a widely used medication, and anticipates other manufacturers will be doing the same in the near future.

"There are huge efficiency gains with RFID. Increased control is one of the biggest factors for hospitals, along with the entire medication management process. Having a pharmaceutical company that follows cGMP[2] processes helps with that," Ms. Volpe says. "Having items that are serialised check all the boxes for innovation and traceability."

And Fresenius Kabi is afforded 100% verification that the label is applied correctly and secondary quality verification of its core data—a correct batch/lot number, expiry date, serial number, GTIN—is pre-encoded during manufacturing, not having to rely on external parties to record attributes correctly.

Although Fresenius Kabi has not had a counterfeiting problem in the US, implementing DSCSA requirements was the first step in combatting counterfeiting. In addition, RFID adds an invisible anticounterfeit device, in that

not only is there a serial number embedded in the tag, there is a tag ID embedded by the chip manufacturer that is very difficult to duplicate. A combination of the GTIN, serial number and tag ID makes a tagged drug virtually impossible to counterfeit.

"We are working shoulder-to-shoulder with hospitals today, supporting them through the pandemic. Precise inventory management is even more important today than ever before. We specialise in 'ready-to-administer' products—prefilled syringes and premixed bags—with a goal to significantly reduce drug preparation at the point-of-care."

Angie Lindsey,
Vice President of Marketing, Fresenius Kabi

Looking forward

The success of the project is reflected in the future plans for EPC-enabled RFID. Three Fresenius Kabi facilities in the US across multiple product lines are being readied for the technology, with 21 medications planned for RFID in 2021, building out the technology to include more of its drugs in subsequent years.

"We'll be supporting our customers both from a sales and customer service standpoint, ensuring that they get the product properly and are able to start using it immediately. We're also working with RFID vendors to ensure that their systems properly interpret GS1 data standards.

"We are creating a lot of resources for support, including a website, information going out to customers, supporting education at conferences," Lindsey says. "It's a very important step to ensure customer satisfaction. All of these things are important to supporting the adoption of RFID in general."

EPC-enabled RFID tags on the Fresenius Kabi unit-of-use can ultimately eliminate inadvertent entry error changes to a medication's product data at the hospital and in the future along the supply chain.

A Pilot's Guide:
Advice from RFID Pioneers

Leadership support
It's critical to have C-suite support for any project that is as far-reaching as this technology.

Research
Talk to experts both inside and outside the organisation, especially customers, to examine all perspectives and make well-informed decisions.

Neutrality
Base your solutions on open GS1 standards so your technology is inclusive rather than exclusionary. GS1 standards enable interoperability among trading partners worldwide.

Breadth and depth of expertise
Everyone that touches the product should be involved in implementation. Regulatory affairs, marketing, engineers, project managers, quality control officers and manufacturing need to buy into the ultimate goal.

Leverage the investment
While the initial decision to pilot RFID technology may foster better customer service, do not ignore the potential for significant operational paybacks such as improved efficiencies and inventory control.

[2] FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (cGMP) regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.

About the authors
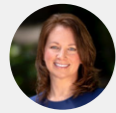
Angie Lindsey,
Vice President, Marketing
Pharmaceuticals, Region North
America, Fresenius Kabi

Angie Lindsey is Vice President of Marketing for Fresenius Kabi in the United States. In this role, Ms. Lindsey leads the marketing effort for the company's pharmaceutical portfolio of anesthesia and analgesia injectable medications, along with the prefilled syringes and +RFID smart-labeled products.

Ms. Lindsey has 25 years of experience in commercial roles of increasing responsibility and leadership within the pharmaceutical industry. She joined Fresenius Kabi in 2012 as National Sales Director, after serving in a variety of sales and marketing roles at Takeda and AstraZeneca.
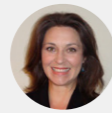
Gwen Volpe,
Director, Medication Technology
Pharmaceuticals, Region North
America, Fresenius Kabi

Gwen Volpe R.Ph., LSSBB, FASHP is the Director of Medication Technology at Fresenius Kabi in the United States, leading various health care technology initiatives and programs. Ms. Volpe oversees the company's +RFID commercialisation effort, and works with customers and technology companies to develop alliances to support safer and more efficient processes.

Ms. Volpe has more than 25 years of experience in healthcare and medication technology, working for various institutions and organisations including Omnicell and Swisslog. She joined Fresenius Kabi in 2017. She is a graduate of Butler University, a fellow of the American Society of Health-System Pharmacists, author, and speaker.
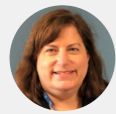
Jeanne Sirovatka, Ph.D.
Senior Director, Packaging Design
and Technical Projects Business Unit
Operations North America
Pharmaceuticals and Devices Division,
Fresenius Kabi

Jeanne Sirovatka is Senior Director, Packaging Design and Technical Projects for Fresenius Kabi in Business Unit Operations North America. In this role, Ms. Sirovatka leads the design and implementation of all packaging componentry for vials, pre-filled syringes, and freeflex® bags in Fresenius Kabi's US manufacturing plants. This includes the digital transformation of the company's pharmaceutical packaging to include RFID technology.

Ms. Sirovatka has 19 years of experience in development, quality and manufacturing roles of increasing responsibility and leadership within the pharmaceutical industry. She joined Fresenius Kabi in 2014 as Associate Director of Operational Excellence, after serving in a variety of pharmaceutical manufacturing roles at Roche and Sandoz.

Matthew Farley, Pharm.D.
Senior Manager of
Medication Technology and
Analytics, Fresenius Kabi

Matthew J. Farley, Pharm.D., CPHIMS is a Senior Manager of Medication Technology at Fresenius Kabi in the United States. In this role, Mr. Farley works on various healthcare technology initiatives and programs, including +RFID and Simplist pharmacy support services. Prior to joining Fresenius Kabi, Mr. Farley's work as a pharmacist focused on hospital operations, medication use systems, and EHRs. He joined Fresenius Kabi in 2018, is a graduate of the University of Iowa College of Pharmacy and is Epic Willow certified.

About the organisations

FRESENIUS KABI

Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. Its products and services are used to help care for critically and chronically ill patients.

www.fresenius-kabi.com/us

eAgile

Established in 2009, **eAgile** sets the industry standard for RFID based IoT solutions for the healthcare, pharmaceutical and nutraceutical markets. From a vertically integrated headquarters in Grand Rapids, Michigan and supporting sales office in Zurich, Switzerland, eAgile designs, tests, manufactures and distributes an expanding portfolio of customized RFID products. Shipping to over 40 countries across 5 continents, eAgile's clients range from emerging healthcare tech start-ups to established industry leaders whose brands have become household names.

www.eagile.com

United States

1WorldSync: Leveraging the GDSN to improve the healthcare supply chain

Challenge

Complete and accurate master product data are essential for healthcare providers to deliver the best possible care to their patients. Ideally, product master data should flow freely and efficiently from manufacturers to healthcare providers.

Approach

The Global Data Synchronisation Network™ (GDSN®) with its one-to-many model makes it possible for hospitals to efficiently receive product data. In an effort to improve the healthcare supply chain data exchange, 1WorldSync has developed a unique solution—the 1WorldSync Playlist—to leverage the GDSN to improve efficiencies and enable scalability. To ensure proof of concept, a pilot program was undertaken with a major healthcare provider and medical product manufacturers.

Lowered implementation barriers and simplified the data exchange process

Scalable solution that remains unchanged whether sharing one product or one million

Increases supply chain efficiencies and enhances patient safety with accurate and enriched data

Better product master, which translates to fewer errors and reduced manual effort

1WorldSync's Healthcare pilot program summary

This report summarises a recent pilot program to further enhance 1WorldSync's GDSN-based solution for product data exchange between manufacturers and healthcare providers.

1WorldSync is the leading provider of product content solutions, enabling more than 13,000 global companies in over 60 countries to share authentic, trusted product content. Through its highly advanced technology platform, which connects companies through the GDSN, 1WorldSync provides data exchange solutions that efficiently meet the diverse needs of the healthcare industry.

Participants in the pilot program included Geisinger Health as the data recipient, and three of the world's largest medical device manufacturers – the medical device segment of Johnson & Johnson Supply Chain (JJSC); Abbott Laboratories; and Teleflex Incorporated – as data suppliers. Each manufacturer has made a commitment to employ

GS1 standards and the GDSN for product data exchange. Manufacturers were eager to participate in this pilot program to help further the understanding of the GDSN and the benefits of adoption.

Case study: Pilot program participant Geisinger Health

Geisinger is an integrated health service organisation that provides care to thousands of patients in Pennsylvania and New Jersey. Geisinger agreed to participate in this pilot program because it has long sought a better system for product data exchange. In fact, just three years ago, as an active participant

in a similar GDSN-based discovery program aimed at identifying a solution for better data exchange, Geisinger found the data to be "clean and accurate," but the mapping exercise to match GDSN data to its own internal system data was too time-consuming.

For instance, it took "52 hours over a span of 6 months to map and load just 36 items," according to Tasha Gowin, Supply Chain System Analyst at Geisinger. Understandably, Geisinger was cautiously optimistic when agreeing to participate in 1WorldSync's new pilot program.
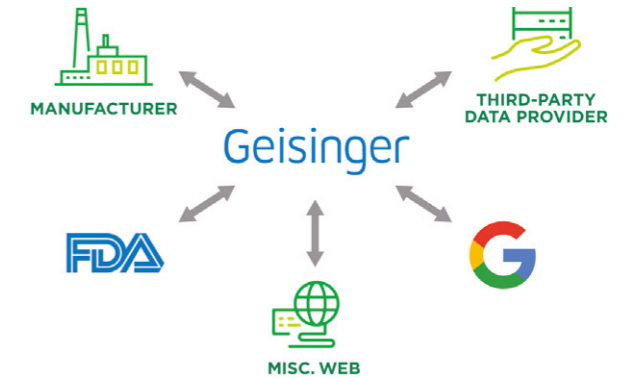
Geisinger's current process is to receive new item build requests through its internal Infor-Lawson Materials Management Information System (MMIS) where the manufacturer part number or model number is used as the key product identifier.

To confirm selection of the correct product, Geisinger searches for Global Trade Item Numbers (GTINs) to cross-reference and match part numbers. GS1 standards would recommend using a product's GTIN® as the unique identifier because, unlike manufacturer model numbers, GTINs cannot be duplicated. Outside of the GDSN, one source of data is rarely sufficient; therefore, Geisinger's analysts use multiple sites including the US Food and Drug Administration's (FDA) Global Unique Device Identification Database (GUDID), manufacturer sites (most of which do not provide GTIN information), third-party data sources and even Google to verify the data. After the collected information is validated, it is entered into the MMIS system. Because the data collected is from multiple sources, it must be pieced together by Geisinger supply chain data analysts.
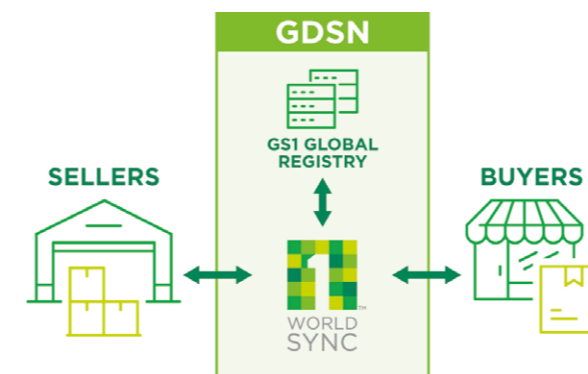
VEN_ITEM	ITEM	DESCRIPTION	MANUF_CODE	MANUF_NBR
2227	6072578	Character Sticker	MDBD	2227
2227	6027887	Surgical Device	Manufacturer A	2227

Figure 1: Export from Geisinger's internal system showing duplicate vendor/manufacturer's numbers between a surgical device and a child's sticker (character sticker has same SKU as surgical item)

Issues arise since these part numbers are not always unique and formats of part numbers vary across the disparate data sources. Special characters such as dashes and spaces create a huge risk for errors and potential duplication within the Geisinger item master, and ultimately add hours of unproductive work for data analysts.

In addition, if a product's GTIN can be located through a third-party source, often only the unit-of-use information and no other packaging level

data is included. Lack of packaging level data can cause problems when orderable and invoiced package levels are mismatched. Geisinger has experienced issues when, for example, it orders one box of 10 items, but is invoiced for 10 single units ("eaches"). Using the current process, this unit-of-use mismatch is hard to prevent, even after checking multiple sources. Once detected after the fact, it is even harder to correct, because the adjustments involve open transactions.

1WorldSync's versatile GDSN solution

Companies in the retail and consumer goods industries were facing the same problems as Geisinger turned to 1WorldSync for a solution. With its roots in the GDSN, 1WorldSync was already familiar with the challenges of mapping product attributes and understood the need to avoid unnecessary back-and-forth between recipients and suppliers. As a result, the 1WorldSync Playlist was created to simplify the data exchange process for both parties.

The 1WorldSync Playlist is essentially a filter that establishes a set of data validations to ensure that recipients get the exact product attribution needed. In addition, the Playlist simplifies the process for suppliers by narrowing down the attribute set to that requested by the specific recipient. For example, some recipients do not use the GTIN as an internal primary identifier, but the 1WorldSync Playlist still easily matches the GTIN to a manufacturer's product number.

Expansion of 1WorldSync's GDSN solution into healthcare

As 1WorldSync began deploying its GDSN solution in the healthcare industry, it realised that high-quality GDSN data from manufacturers paired with the 1WorldSync Playlist tool could be an ideal solution to address many of the data-related issues facing both suppliers and recipients. Another key ingredient to the success of the program was the application and use of GS1 standards that ensure that all parties are

using the same language to identify and share data within the supply chain.

In addition, hospitals and healthcare providers source many products essential for operations that are not specifically categorised as healthcare items. For example, there are millions of paper products, food service supplies and hardline items currently in use in healthcare organisations, and many are included in the GDSN.

Geisinger's pilot project results

As previously mentioned, Geisinger entered the pilot project cautiously, but optimistically. This new pilot project demonstrated significant improvement.
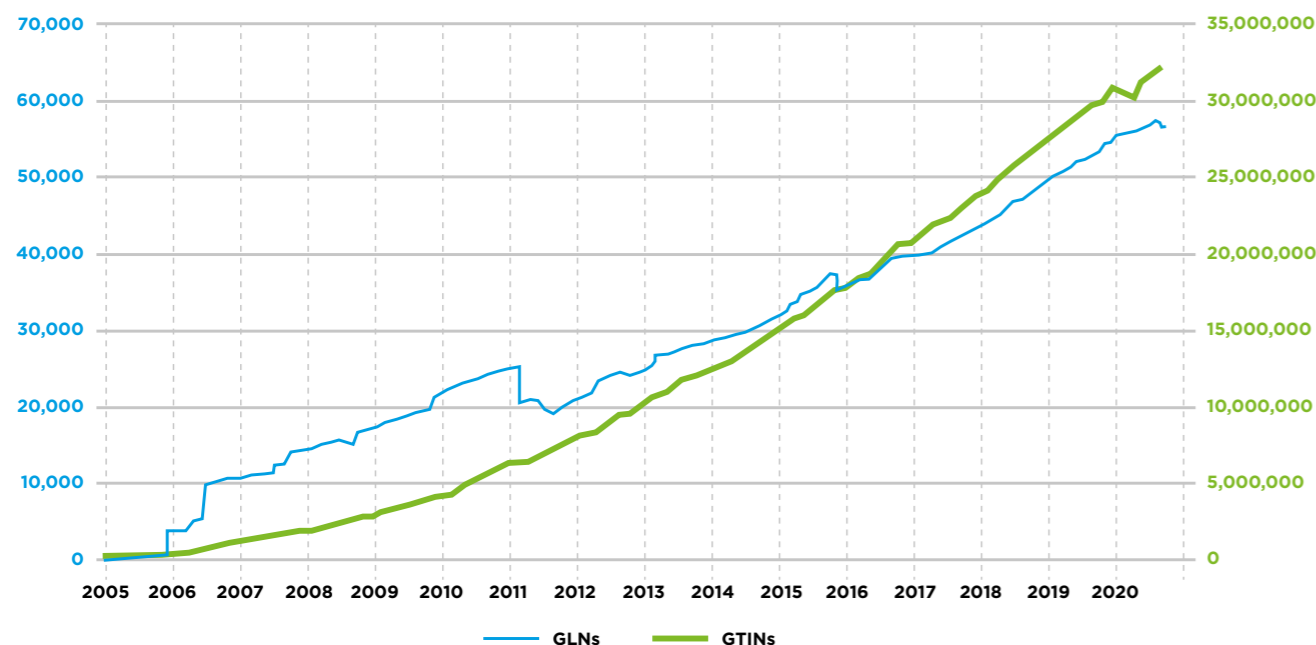
Figure 2: Exponential growth of GLNs and GTINs

Ms. Gowin mentioned that one of the reasons for the efficiency increase with the 1WorldSync Playlist was that she was able to "pull in only what was needed, and mapped those fields without a dictionary of definitions."

> "1WorldSync Playlist enables us to extract data from multiple vendors using one source to match up items and assign GTINs in less than an hour … a process that took over 52 hours before!"
>
> **Tasha Gowin,** Supply Chain System Analyst, Geisinger

She also noted that "once my system is mapped and fully set up, this will become even easier by using only one source to match. Today, I have to search manufacturer or model numbers from two-three sources, then I have to complete matches manually. Thanks to the 1WorldSync Playlist, I can easily, even without a machine, extract data from the GDSN and verify with my system to ensure all products are up to date. Once the legacy data is cleaned up, not only could one person handle this task, but it is also sustainable."

> **Adoption of GS1 standards and participation in the GDSN has rapidly grown within all industries, as evidenced in Figure 2. Within the healthcare industry specifically, GDSN and GS1 standards adoption has expanded exponentially in recent years. Currently, there are over 5,400 healthcare-specific global location numbers (GLNs) accounting for over four million GTINs.**

Manufacturers' findings on data exchange using the GDSN

Some hospitals are connected to more than 5,000 suppliers and purchase hundreds of thousands of individual items while other healthcare providers carry only a limited number of items. Thus, a flexible, scalable solution is necessary.

The manufacturers participating in the pilot project provided feedback on the practical implementation and use of the GDSN in the healthcare industry.

As part of the pilot, JJSC received current product listings from Geisinger MMIS. JJSC analysed and reconstructed the data leveraging GS1 GTINs and other standardised attributes. JJSC used the 1WorldSync Playlist to aggregate those files to update product data. The result is JJSC and Geisinger having a shared language for that product data, enabling JJSC to publish that data directly to Geisinger via 1WorldSync using the GDSN.

MJ Wylie, Senior Manager, GS1 Global Standards and Global Data Synchronisation at Johnson & Johnson Supply Chain noted, "Johnson & Johnson Supply Chain understands trusted product data begins with accurate, consistent, and complete product content. We support the use of GS1 standards as they provide the framework to implement consistent product identification and traceability. Trading partners demand this information to influence efficiencies across the entirety of their supply chain."

Final verdict: Improved implementation, scalability and efficiency

Improved data quality and efficiency in obtaining data is the ultimate goal that many organisations strive to achieve. Unfortunately many settle for less than ideal, because of the belief that implementation of an improved standard and system is a prohibitive cost or resource. While a data improvement project extends beyond the IT department, many times it is the IT aspect that applies the brakes and stalls the initiative. Major IT projects often involve installations and implementations that take months or even years to complete, requiring extensive consideration and trials before a solution is selected. JJSC's standard is to enter as much product information as possible into the master product record. Given this, there can be product attributes that are not relevant to every recipient. The 1WorldSync Playlist simplifies the process and guides both supplier and recipient to easily identify the needed product attributes in the proper format.

"The 1WorldSync Playlist lowered implementation barriers by simplifying the use of attributes through the creation of healthcare-specific data models."

Pilot participant,
Johnson & Johnson Supply Chain

In addition, scalability is a crucial factor when considering solution options. The ability to scale a solution is especially important in healthcare, where the size of organisations varies widely, and mergers and acquisitions are constantly changing the landscape.

This pilot program was completed in just four weeks, demonstrating that implementation can be an expeditious process. In addition, the solution remains unchanged whether sharing one product or one million.

"Teleflex believes in the GDSN. Rooted in innovation, data synchronisation of item information through the GDSN allows suppliers and customers to syndicate accurate and enriched information, driving efficiencies in the supply chain and enhancing patient safety. Teleflex is excited to offer a method to publish product information and make it available to our customers."

Mark Hoyle,
UDI Technical Director,
Teleflex Incorporated

"The GDSN provides detailed product information, easy visibility to all available products, and eliminates the need for multiple sources of product information. Customers that use GDSN data should have a better product master, which translates to fewer errors and reduced manual effort."

Pilot participant,
Abbott Laboratories

This project allowed manufacturers to see the value in 1WorldSync's GDSN solution. 1WorldSync's GDSN solution with its one-to-many concept has proven success in meeting the needs of the healthcare supply chain, from small to large providers and suppliers. In addition, the neutrality of the GDSN opens the door to suppliers around the world to efficiently syndicate product data.

The 1WorldSync Playlist solution improves accuracy and saves time in real-world use cases. With increased adoption of these GDSN tools, the healthcare industry can continue to improve patient care with easy access to complete master product data.

About the organisations

1WorldSync® is the leading provider of omnichannel product content solutions, enabling more than 14,000 companies in over 60 countries to share authentic, trusted content that empowers confident commerce and intelligent consumer purchasing decisions. Through its technology platform and expert services, 1WorldSync solves revenue-impacting product content challenges faced by leading brands and retailers in the CPG/retail, DIY, consumer electronics, healthcare and foodservice industries. 1WorldSync is one of the only product content providers and GDSN Data Pools to achieve ISO Certification 27001. For more information, please visit

www.1worldsync.com

Geisinger Health is committed to making better health easier for the more than 1.5 million consumers it serves. Founded more than 100 years ago by Abigail Geisinger, the system now includes 13 hospital campuses, a 600,000-member health plan, two research centers and the Geisinger Commonwealth School of Medicine. With 32,000 employees and 1,800 employed physicians, Geisinger boosts its hometown economies in Pennsylvania and New Jersey by billions of dollars annually.

www.geisinger.org

Abbott Laboratories is a global healthcare leader that helps people live more fully at all stages of life. Its portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines.

Its 107,000 colleagues serve people in more than 160 countries.

www.abbott.com

Teleflex Incorporated is a global provider of medical technologies designed to improve the health and quality of people's lives. It applies purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Its portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine, and respiratory care. Teleflex employees worldwide are united in the understanding that what they do every day makes a difference.

www.teleflex.com

Johnson & Johnson Supply Chain includes three business sector supply chains – Consumer Health, Medical Devices and Pharmaceuticals – that cover planning, sourcing, internal and external manufacturing, as well as the Supply Chain Strategy, Innovation & Deployment organization and the Deliver organization, which manages distribution and customer service. Additional enterprise-wide functions that are part of the Johnson & Johnson Supply Chain include Quality & Compliance, Environmental Health, Safety & Sustainability and Engineering & Property Services.
www.jnj.com

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• https://www.gs1.org/standards
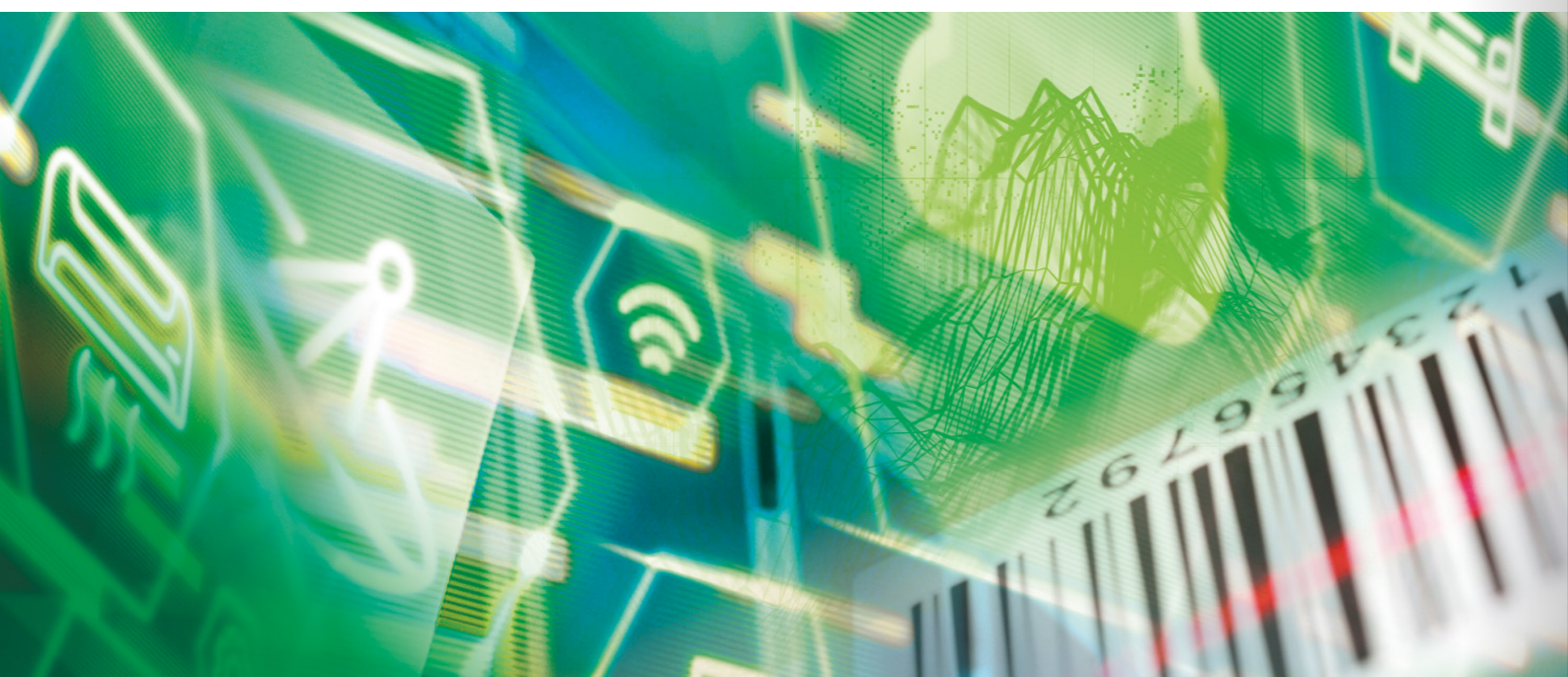
Government initiatives

New government initiatives for monitoring and enhancing supply chains are being created. As a neutral facilitator between healthcare stakeholders and regulators, GS1 plays an important role by enabling the harmonised implementation of regulatory requirements around the world. This is in everyone's best interest, because globally consistent policy frameworks supported by GS1 standards are good for patient safety, increasing productivity, combatting counterfeits, and streamlining business and clinical processes.

Bulgaria

Successful implementation of the Bulgarian Medicines Verification System

Challenge

In Bulgaria, projects to follow the European Union's (EU) Falsified Medicines Directive (FMD) were a massive undertaking that spanned all stakeholders in the supply chain—manufacturers, wholesalers, hospitals and pharmacies. GS1 standards, specifically a Global Trade Item Number® (GTIN®) encoded in GS1 DataMatrix barcode, would need to be applied to each and every prescribed pharmaceutical pack for scanning, from manufacturer to pharmacist when dispensing the medicine.

Approach

In addition to GS1 standards, the Bulgarian Medicines Verification System (BgMVS) was created and is connected to the European hub of the European Medicines Verification Organisation (EMVO). GTINs are uploaded by manufacturers to the European hub so that when pharmacies dispense medicines, the pack can be certified as an "authentic" medicine.

Enables pharmacies' ability to verify authenticity of dispensed medicines

Eliminates counterfeit drugs from being dispensed

Provides visibility and traceability of medicine packs throughout the supply chain

Increases overall patient safety

Following the 2011 European Union Falsified Medicines Directive, which became mandatory as of 9 February 2019, the Bulgarian Medicines Verification Organisation (BgMVO) projects all focused on patient safety. Based on the European Union's position to protect patients from falsified medicines, it was decided that all stakeholders in the supply chain should be included in this initiative.

The European Commission Delegated Regulation, (EU) 2016/161, supplements the directive, with rules regarding safety features for the packaging of medicinal products for human use. The regulation was adopted in October 2015.

Measures to counteract fake medicines include stricter record-keeping by wholesale distributors, tougher inspections by pharmaceutical producers, an EU-wide quality mark to identify online pharmacies and obligatory safety features on packages.

Using GS1 standards for identification

The main challenge associated with the project to address the FMD is that it is perhaps the largest ever European healthcare IT project. The project included all 32 European countries,

"In 2016, when the initiative through the EU was launched, the BgMVO was actually the second organisation of its kind to be legally established in Europe. We are aiming to be in the first five or six pilot countries for the project."

Illiana Paunova,
Executive Director and Founder, Bulgarian Medicines Verification Organisation

2,500 European pharmaceutical manufacturers, hundreds of thousands of public and hospital pharmacies across Europe and more than 10 billion packs per year. In Bulgaria, the FMD effort included 200 manufacturers, 150 wholesalers, 3,500 pharmacies and 180 million packs per year.

The main focus of the project was the supply chain, especially wholesalers and pharmacists. The most important action was to create the GS1 DataMatrix barcode for printing on every single pack of prescribed medicines. The barcode itself and the identification information encoded in it had to be standardised, and global standards were to be used. Ultimately, the GS1 system of standards would uniquely identify each medicine.

Verifying the authenticity of medicines

In early 2018, the pilot project started in Bulgaria. A GS1 DataMatrix barcode has been applied on each medicinal product pack and encoded with the product's GTIN, lot/batch number, expiry date and serial number. (For some other countries, an additional piece of information was needed - the National Reimbursement Number - encoded as the fifth element in the DataMatrix barcode.) Applied by the manufacturer, the DataMatrix barcode is then scanned at the pharmacy to authenticate the pack, when the medicine is dispensed to the patient.

The Bulgarian Medicines Verification System is connected to the European hub of the European Medicines Verification Organisation (EMVO). Drug manufacturers upload their product data, including product identifiers or GTINs to the European hub. This data is then automatically transferred to the National Medicines Verification System of the EU country for which the respective batch is intended.

"The BgMVO is actually the second organisation of its kind to be legally established in Europe," says Ms. Illiana Paunova, Executive Director and one of the founders, Bulgarian Medicines Verification Organisation. "We are aiming to be in the first five or six pilot countries for the project."

End-users such as pharmacies and wholesalers are connected to the corresponding National Medicines Verification System. When a medicinal product is dispensed, the DataMatrix barcode is scanned so that the identification code can be verified and decommissioned from the system. This is to ensure traceability of medicines—from manufacturers to patients. As a result, the pack dispensed to the patient is verified as an "authentic" medicine.

An alert is generated if there is discrepancy between the data captured when the DataMatrix code is scanned on the pack and the data that is uploaded in the National Medicines Verification System. This means that the unique identification code has not been uploaded into the system, or it has been uploaded but has already been decommissioned.

In case of an alert generated by the National Medicines Verification System, the pharmacist should not dispense the medicine to the patient, and it is required that the pharmacist inform the competent authorities. In the early phases of the implementation, users found challenges with scanners and pharmacy software applications.

BgMVO organises regular operational meetings with IT providers. The purpose of these meetings is to provide information on upcoming changes related to the implementation of new versions of the verification system. Discussions are also taking place about how to reduce alerts due to technical reasons in the software or barcode readers.

IT providers are informed about the standard requirements for developing verification applications, as well as the need to maintain an offline mode implemented in their applications.

An alert is generated if there is discrepancy between the data captured when the DataMatrix code is scanned on the pack and the data that is uploaded in the National Medicines Verification System. This means that the unique identification code has not been uploaded into the system, or it has been uploaded but has already been decommissioned.

Widespread acceptance

With the introduction of the unified systems of medicines verification in Europe, the origin and quality of prescribed medicines that patients receive are assured.

By February 2021 more than 3,100 or 83% of retail pharmacies, hospital pharmacies and wholesalers were connected to the BgMVS. Currently, about 30% of the prescribed and dispensed packs in the system are decommissioned.

Figure 1: Pilot packs ready to be verified

All Bulgarian manufacturers serialise and upload data for their products in the European hub. The coverage of COVID-19 vaccines is forthcoming.

The practical experience of pharmacists and other participants in solving specific cases with the application of the verification system has increased and the number of alerts generated due to technical issues with manufacturers and pharmacies has decreased.

Guidelines on managing alerts during the verification and decommissioning of medicines in the BgMVS were issued at the beginning of 2021. These instructions are published on the Bulgarian Drug Agency (BDA) website.

By February 2021 more than 3,100 or 83% of retail pharmacies, hospital pharmacies and wholesalers were connected to the Bulgarian Medicines Verification System. All Bulgarian manufacturers serialise and upload the data for their products in the European hub.
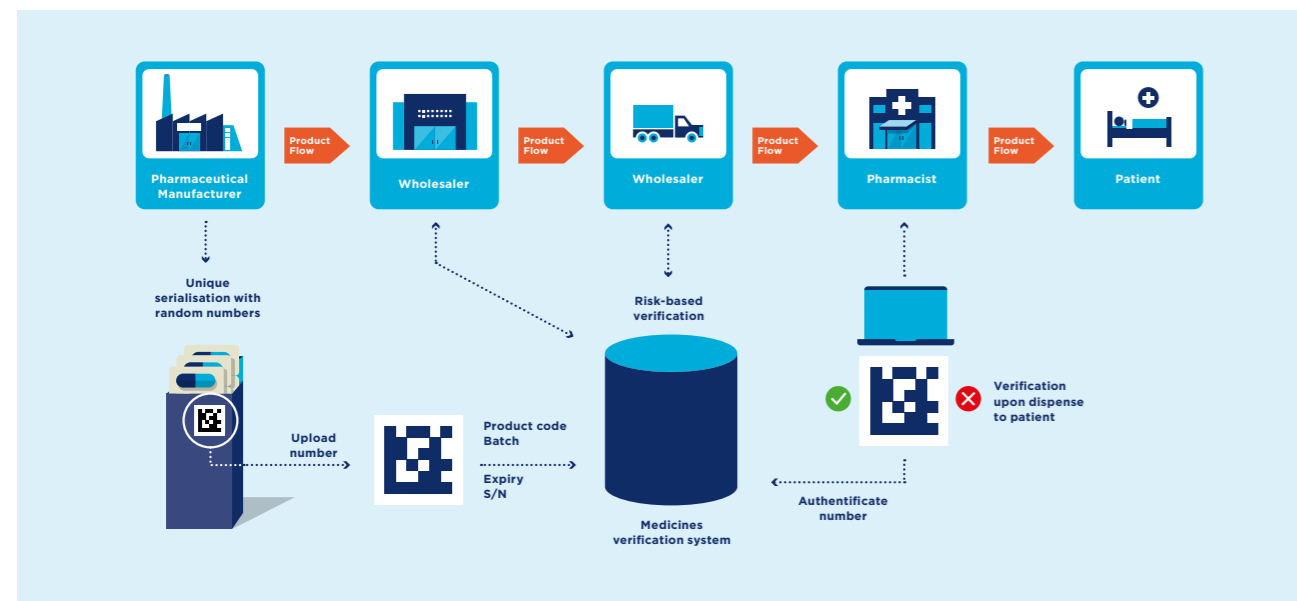
Looking ahead with BgMVS

The BgMVS helps to ensure the safety of patients. It also provides a high-level of security, but only when products are delivered to the supply chain in accordance with the EU FMD regulation.

To date, new on-time versions of the system are being implemented in Bulgaria, with work efforts to sustain progress.

"We are supported by society, state institutions and by the vast majority of stakeholders in the pharmaceutical supply chain. Protecting patients and delivering greater transparency of medicines throughout the supply chain—these are the benefits of the verification process that are well worth the effort," says Ms. Paunova.

In 2020, changes in Bulgarian legislation related to the verification of medicines were adopted and are already being enforced. These changes establish the verification responsibilities of all actors in the pharmaceutical supply chain, as well as the penalties for non compliance.

Thanks to the joint collaboration of BgMVO, GS1 Bulgaria and the Association of Research-based Pharmaceutical Manufacturers (ARPharM) in Bulgaria, the pharmaceutical drug law in Bulgaria has been amended so that the GS1 GTIN will not be replaced by National Trade Item Number (NTIN) on the drug pack, but only linked to it in internal systems.

Applying standards to COVID-19 vaccines

As of 1 April 2021, the requirements for serialisation and verification will apply to

COVID-19 vaccines, for which an initial grace period was given by the European Commission in order to facilitate the vaccines' distribution.

After this period, the vaccines will be produced with a unique identifier based on GS1 standards to be given to people at immunisation points. By using the GTIN, DataMatrix barcode and application of the verification requirements, COVID-19 vaccines will be able to be scanned throughout the supply chain and when they are given to people at immunisation points. With GS1 standards-based identification, vaccines will be protected from falsification attempts.

BgMVO works in close cooperation with GS1 Bulgaria in providing expert advice to National Competent Authorities about the GS1 GTIN, the product identifier and supports manufacturers in implementing safety features. They jointly organise training workshops and conferences to promote the importance of GS1 standards for the verification of medicines, for the protection of the supply chain from falsified medicines and, ultimately, for patient safety.

"We are supported by society, state institutions and by the vast majority of stakeholders in the pharmaceutical supply chain. Protecting patients and delivering greater transparency of medicines throughout the supply chain— these are the benefits of the verification process that are well worth the effort."

Illiana Paunova,
Executive Director and Founder, Bulgarian Medicines Verification Organisation

About the author

Desislava Dimitrova has more than seven years of experience as a GS1 expert in healthcare. She is responsible for business development within the healthcare sector and the implementation of the GS1 standards in healthcare. Ms. Dimitrova's mission is aligned with the overall mission of GS1 standards in the Healthcare sector: to increase patient safety, supply chain security and efficiency, traceability and accurate data synchronisation in healthcare.

Desislava Dimitrova, GS1 Healthcare

Figure 3: Launcing the system in hospital pharmacy

About the organisation

Bulgarian Medicines Verification Organisation was established on 14 March 2016 in Sofia as a non-profit association to support the implementation in Bulgaria of Directive 2011/62/EU for preventing the entry of falsified medicinal products into the legal supply chain.

The founders of the BgMVO include five organisations representing the stakeholders involved in the manufacturing and distribution of medicines: the Association of Research-Based Pharmaceutical Manufacturers in Bulgaria, Bulgarian Generic Pharmaceutical Association, Bulgarian Association of Medicines Parallel Trade Development, Bulgarian Association of Pharmaceutical Wholesalers and Bulgarian Pharmaceutical Union. This governance model is aligned with the set-up of the European Medicines Verification Organisation. It includes all five stakeholders: innovative industry, generics industry, pharmacies, wholesalers and parallel distributors. It is the most important public-private partnership in Bulgaria so far for any industry.

The main purpose of the Falsified Medicines Directive is to ensure that patients are supplied with authentic medicinal products by building, operating and maintaining an effective drug verification system in the Republic of Bulgaria. BgMVO works in close collaboration with healthcare authorities in Bulgaria, with all stakeholder organisations and partners such as GS1 Bulgaria, IT software providers, media and patient organisations.

www.bgmvo.org/bg
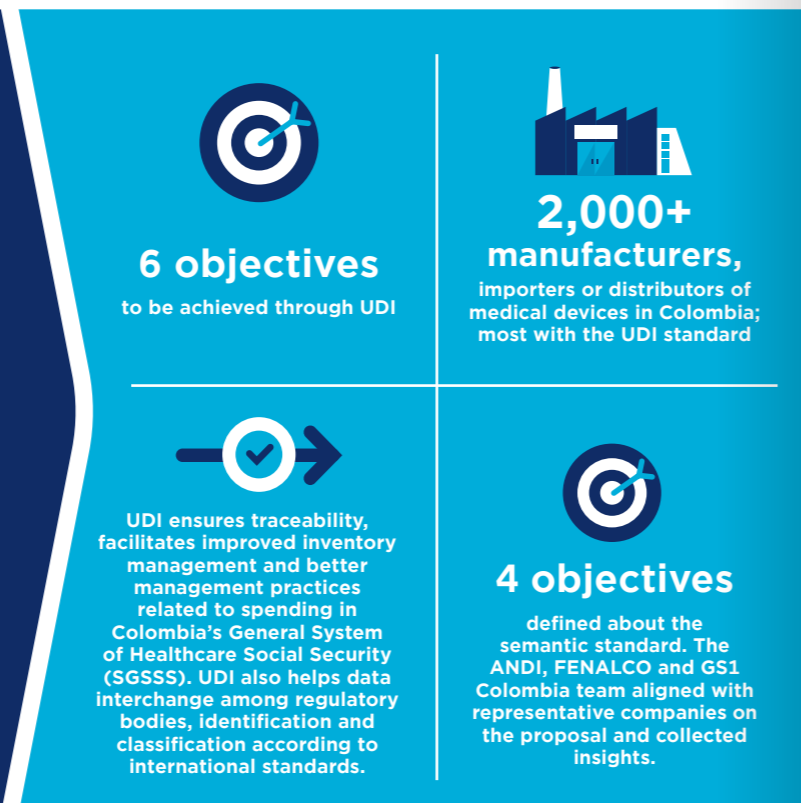

Figure 2: Preferred process

Colombia

UDI pilot proposal with Ministry of Health and Social Protection

Challenge

It was a challenge to validate the endorsement and approval of the Ministry of Health and Social Protection to carry out a pilot test and make use of the Unique Device Identification (UDI) device identifier (DI) to identify medical devices in Colombia, as well as align healthcare providers with the proposal.

Approach

A public consultation was held to review the draft resolution of the proposed semantic standard for UDI. Representatives from GS1 Colombia, the National Association of Businessmen of Colombia (ANDI) and National Federation of Merchants (FENALCO) started meeting with Colombia's Ministry of Health and Social Protection (MoH) to identify key points about why and how it would implement UDI, according to the needs of the government and healthcare industry.

6 objectives
to be achieved through UDI

2,000+ manufacturers,
importers or distributors of medical devices in Colombia; most with the UDI standard

UDI ensures traceability, facilitates improved inventory management and better management practices related to spending in Colombia's General System of Healthcare Social Security (SGSSS). UDI also helps data interchange among regulatory bodies, identification and classification according to international standards.

4 objectives
defined about the semantic standard. The ANDI, FENALCO and GS1 Colombia team aligned with representative companies on the proposal and collected insights.

Resolution 2535 of 2013, Article 3 states by semantic standard the process of continuously standardising and updating data related to health technologies in categories associated with procedures, medicines, inputs and medical devices. With diagnostics, these technologies align with the provisioning of services, whether individual or collective, as an essential source of the healthcare information system.

The MoH reference proposal aims to structure and implement the semantic standard and coding for medical devices for human use in the country. Its scope includes all medical devices, including biomedical equipment, in vitro diagnostic medical devices (IVDs) and medical devices (MDs), and vital biomedical equipment.

From the MoH's public consultation of the draft resolution of the semantic standard for MDs, "through which the semantic standard and coding for MDs for human use in Colombia is structured and implemented," the opportunity was identified to implement the UDI standard at

the national level. Regulated by the MoH, a pilot test was needed to demonstrate the benefits and solution points for the healthcare sector that align with the purpose of the semantic standard. This would become part of the regulation that all stakeholders in the healthcare value network would make use of this standard to identify their devices.

More than 47 stakeholders were nominated for the initiative, working in conjunction with the national government, MoH, ANDI, FENALCO and the Colombia National Food and Drug Surveillance Institute (INVIMA) for the planning, execution and monitoring the UDI pilot test, addressing government and industry needs.

This pilot test of the UDI standard was developed based on the needs in the draft resolution of the semantic standard of medical devices (Resolution 2535 of 2013), highlighting the need for alignment with international standards as outlined in Article 4, Number 6 of that resolution, "Facilitate identification

and classification according to international standards of medical inputs and devices."

The main objectives were to:

• Validate the application and functionality of the UDI-DI against the MoH's required semantic standard for medical devices.

• Perform a comparative analysis with medical device identification (IDM), for medical device identification.

The specific objectives were:

1. Facilitate the exchange of information and interoperability between actors and regulatory entities with the use of UDI-DI as a common identifier and language, including issuing an electronic Invoice).

2. Optimise the supply management and inventory control of medical devices for expense and consumption reports.

3. Strengthen mechanisms for traceability records along the value chain, in the final use and disposal of products, and strengthen patient safety processes.

4. Analyse the conceptual and structure definitions of UDI-DI compared to the local IDM, according to the guidelines of the semantic standard of medical devices.

READY FOR UDI!

Methodology

The methodology used for the development of the pilot consisted of evidence-based, concurrent mixed research. A field project and evaluation process of the current use state of the UDI standard were implemented, as well as the application and functionality against the semantic standard for MDs. In addition, the pilot compared this code with the local IDM, built by the MoH.

A series of interviews were conducted, evaluating the management of MDs using the UDI standard. This was done in order to validate its compliance with the specific objectives of the pilot.

At the end, compliance indicators were generated for each specific objective. This resulted in a comparative analysis of the international UDI standard versus the local IDM code. The project was divided into four phases: sensitisation, alignment, field project and results measurement.

> **Objective: Validate the application and functionality of UDI-DI against the requirement of a semantic standard for medical devices of the MoH. Perform a comparative analysis with local IDM for medical device identification.**

The pilot test's scope was defined as the implementation of the UDI standard within a period of eight weeks. During this time, it was evaluated as part of the flow of the product and information (including electronic invoicing) of medical risk classification devices I, II, IIA, IIB and III—from their coding at source to their delivery in the main warehouse, to the respective business partners.

For this part of the process, it was defined to require a minimum of:

• 3 local MD manufacturers
• 3 international MD manufacturers
• 3 healthcare service providers (IPS)
• 1 healthcare service promoter (EPS)
• 2 distributors of medical devices

The MoH suggested prioritising the following types of medical devices:

• Infusion pumps
• Pacemakers
• Syringes
• IVDs (e.g., Troponin)
• Anesthesia

Participants

For the development of the pilot, different stakeholders—manufacturers, distributors/ pharmaceutical managers, IPS and EPS—were identified. Interactions between them were defined, specifically the flow of products throughout the hospital value network. (See Figure 1.)

Participant roles: Manufacturers, Distributors, IPS and EPS.

Participant profiles: Project leaders, inventory leaders, staff in charge of tasks such as master data management, product marking and identification, internal logistics, distribution or related.

UDI pilot test

The stages in the pilot included:

Sensitisation: The objective of this stage was the call, planning and kickoff of the pilot with the participants. A communication plan, roadmap and an initial work schedule were put in place.

Field project: The field project stage focused on the current process by participants. It was designed for the monitoring or implementation of UDI (according to each stakeholder) via a process review checklist (e.g., coding, dispatch, receiving, and more). Documentation was also considered along with the step-by-step process according to the stakeholder's need.

The objective was to deliver a report of results and general documentation.

At this stage, multiple interviews were conducted with each company to create the necessary information survey to validate the compliance indicators aligned with specific objectives of the pilot.
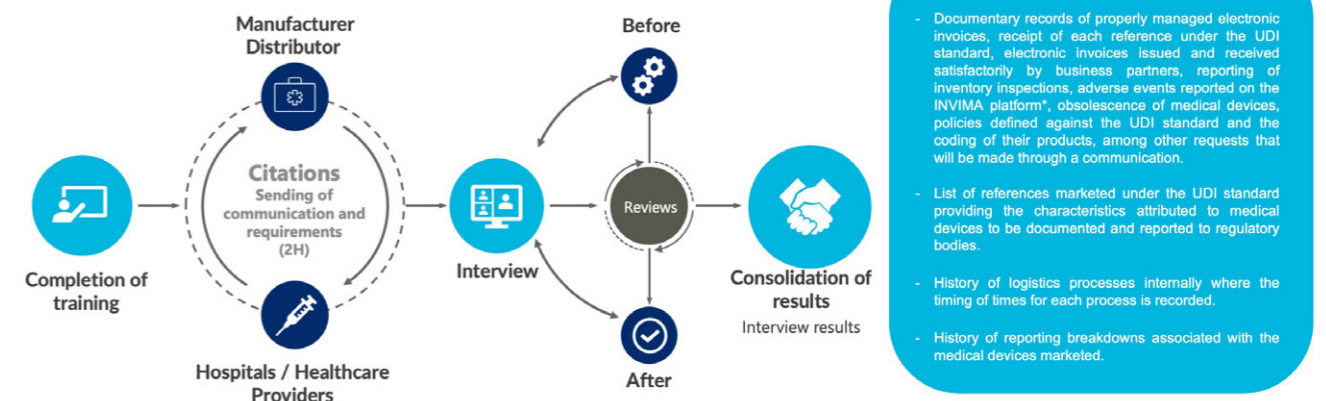

Figure 1: The flow of products across the healthcare sector value network

Figure 2: Interview flow for companies participating in the UDI pilot

"It is a unique opportunity that has been given to the industry for the construction of public policies around the healthcare sector. "

Marisol Sánchez González,
Director of the Sectorial Chamber of Medical Devices and Health Supplies, ANDI

At this stage, a call/presentation of the pilot test was conducted during which the step-by-step roadmap was defined by each stakeholder in the value network. Timelines were considered and mandatory participation requirements were determined.

Alignment: The objective of this stage was to understand any gaps in the sector and focus the work on creating joint improvements. Closing the gaps in the identification of MDs

would be achieved through evaluation and training in international standards and best practices. As a deliverable of this process, 16 hours of training, session learnings and technical evaluation were provided regarding the UDI standard.

During this stage, a series of technical trainings were conducted about standards and best logistics practices. They were divided by modules: identification, capture, and exchange and use. This was designed to align and educate all participating companies about the UDI standard. The training sessions were virtual. Therefore, it was essential that the participants had enough time to attend (2-4 hours / week), with a computer and quality network connection that enabled learning.

Participants of the sessions included leaders in inventory, master data management, product marking and identification, internal logistics, distribution and related.

Results measurement: The objective of this stage was to validate the fulfillment of the specific and general objectives of the pilot, and analyse their alignment with objectives 1, 2, 3, 5 and 6 of Resolution 2535/13. In addition, the qualitative and quantitative results of the pilot were measured. To do this, a compliance indicator was used for each specific objective along with the development of a tailored outreach plan. A results report, guide, manuals, infographics and outreach support were generated as deliverables of this process.

In this final stage, all participants received the results that were analysed quantitatively and qualitatively. Corresponding conclusions were made, and a final report was generated. All results and information was socialised with all stakeholders involved in the healthcare value network during a closing meeting.

UDI pilot test results

Following the official launch of the pilot on 17 December 2020, the industry expressed various doubts and suggestions regarding the pilot. That's why the rest of the phase was focused

on resolving doubts, making adjustments and re-defining the roles of the participants.

During this period (December 2020 to March 2021), the mandatory requirements for participation in the pilot were socialised, an assessment was carried out to select participating companies and observer companies, which would make up the pilot monitoring committee. More than 27 meetings with participants during which an estimated 100 hours of joint alignment were invested. Six work tables were held that focused exclusively on each of the medical devices that were prioritised by the MoH with the participation of approximately 150 people. As a result of this entire process, manufacturers from the following participants were defined: B. Braun, Baxter International, Mindray Medical International, GBarco, Abbott Laboratories, St. Jude Medical, Innomed, Medical Industries Sampedro, Stryker Corporation, Amarey Group, Roche Products, Cardinal Health, Medtronic, Siemens, Becton Dickinson, Alfa Trading, Rymco Medical and Ortho Clinical. These 18 participants were asked to read and sign an act of commitment for the development of the processes ahead.
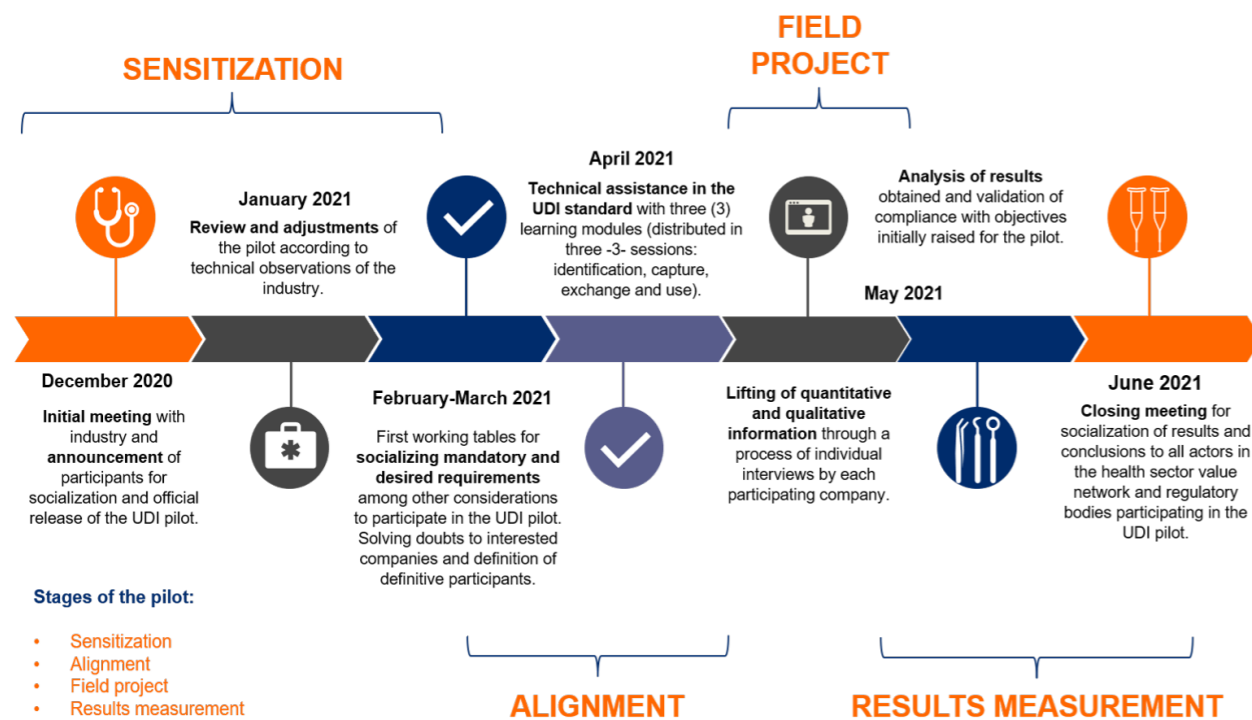
Next steps

Figure 3: Timeline of progress made and next steps of the UDI pilot

Benefits

The following benefits from the UDI pilot proposal were defined associated with the complete adoption of the UDI standard in Colombia, to include:

• Increased participation by GS1 Colombia in the healthcare sector

• Facilitation of the exchange of information and interoperability between stakeholders and regulatory entities with the use of UDI-DI as a common identifier and language

• Issuance of electronic invoices

• Optimisation of supply management and inventory control of medical devices as inputs for expense and consumption reports

• Improved mechanisms for traceability records along the value chain, in final use and disposal

• Stronger patient safety processes

Conclusions

The pilot has been well-received by the healthcare sector, which exceeded initial expectations. An example of this success was increasing the number of manufacturers participation from 6 to 18 companies.

At the clinical level, each medical device has different characteristics, components, risks and functions. Due to these differences, they must have specific protocols, classifications and management for each within the health factors. However, it is important to remember that at the level of identification, regardless of the type of medical device being marketed and the management of master data, it is essential that all products require an identifier as "key" to have the necessary information for decision-making. For this reason, it is possible to extrapolate the UDI standard and the associated information for all medical devices at the identification level.

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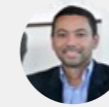
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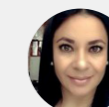
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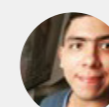
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About the organisations

ANDI is a non-profit organisation, which aims to divulgate and promote political, economic and social principles for a healthy system of free enterprise. It consists in a significant percentage of companies belonging to sectors such as industrial, financial, agro-industrial, food, commercial and services, among others.
www.andi.com.co

FENALCO is the guild that represents and defends the interests of trading; contributes to its sustainable development and continued growth through ongoing accompaniment and the provision of innovative services, which drive business competitiveness and innovation.
www.andi.com.co

GS1 Colombia is a GS1 Member Organisation of the global GS1 network. It is a meeting point where different economic sectors coordinate and achieve common technological solutions, in the face of the needs imposed by the market. Thanks to the effort, responsibility and desire to involve greater performance and efficiency in all processes of the value network, the management of technology and the possibility of sharing internationally, the results have become possible.
www.gs1co.org

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 benefits to all stakeholders. Global members of GS1 Healthcare members include more than 120 leading healthcare organisations worldwide.

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