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

Manufacturer	Supplier		Vaccination Point	
GTIN	GTIN	SSCC	GTIN Vaccine Product	
Vaccine Product	Vaccine Product	Unique box of vaccine	GLN Location	GSRN Staff & Patient

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
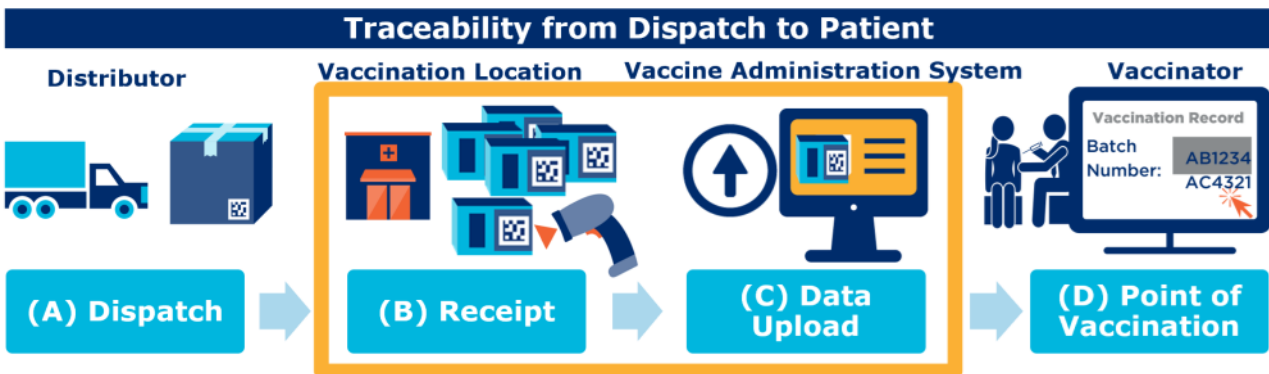
Figure 2: ScanVax is used to record receipt of COVID-19 vaccines by scanning the barcode on the box for upload to the national vaccine administration system.
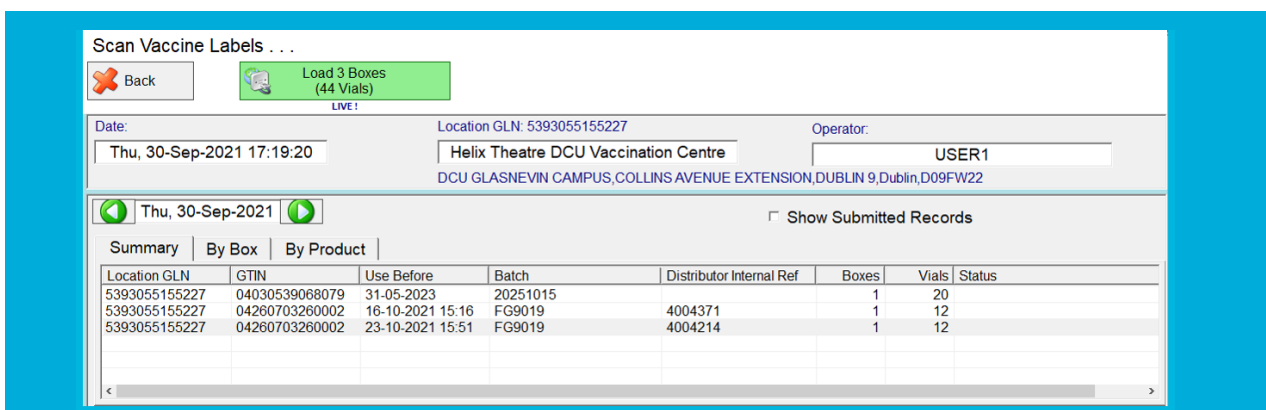
Figure 3: One scan of 2D DataMatrix barcode automatically captures and uploads the vaccine type, batch and expiry date details related to the COVID-19 vaccine.
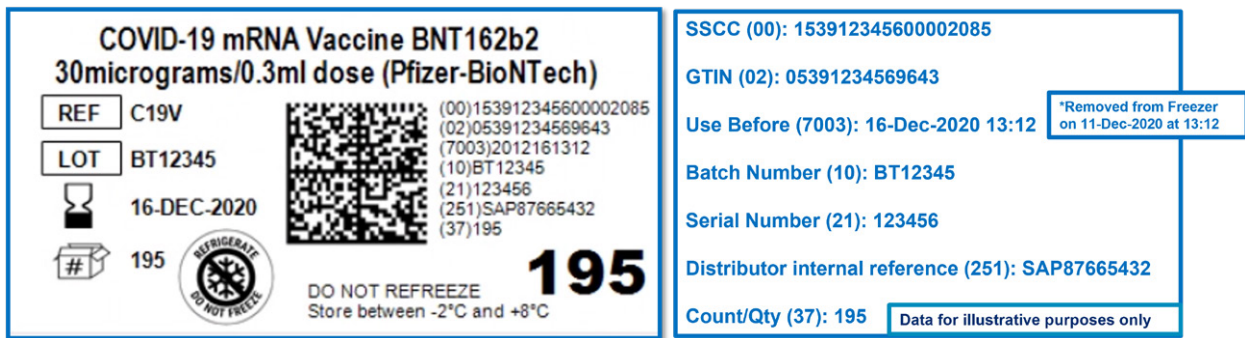
Figure 4: Example of label specification for the Pfizer-BioNTech vaccine

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,
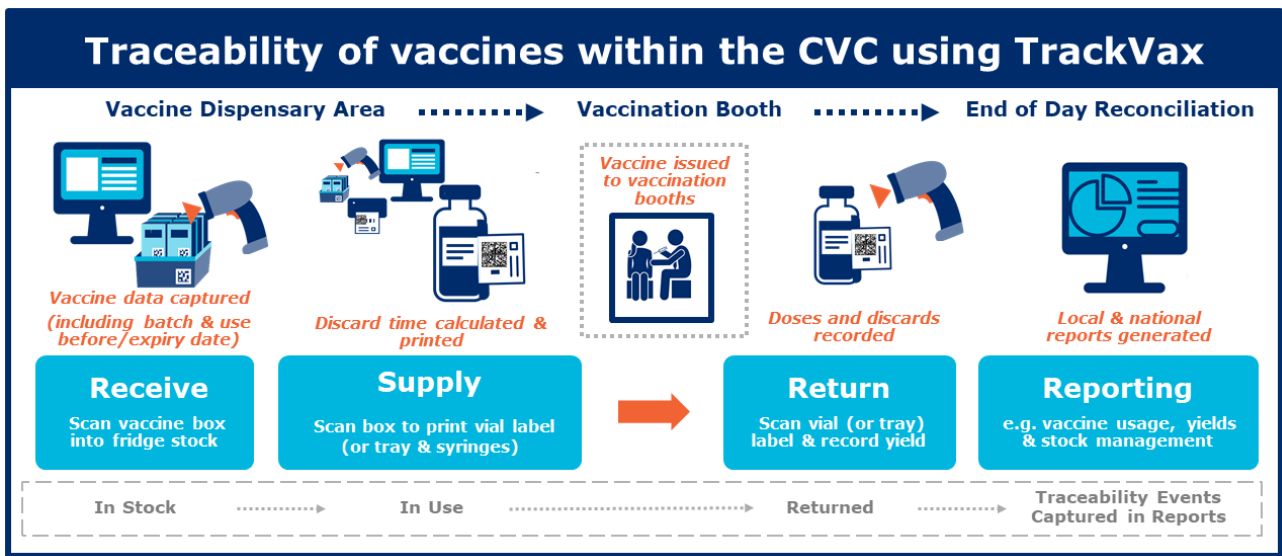National Director of Procurement, HSE

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.
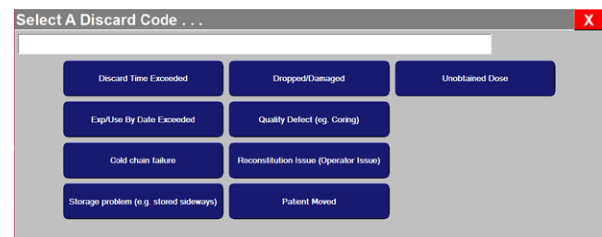

Figure 6: Table of Discard codes

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?

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.

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

"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.

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.

"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 s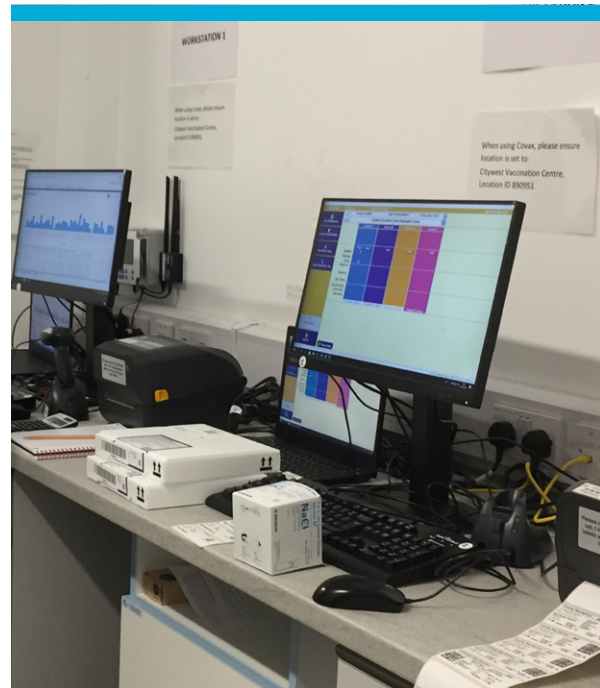o important when delivering a programme on such a big scale. The data from Trackvax is also informing evidence based decisions to ensure we achieve optimum yield from vaccine vials as it allows us to act quickly if any issues arise."

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

"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,
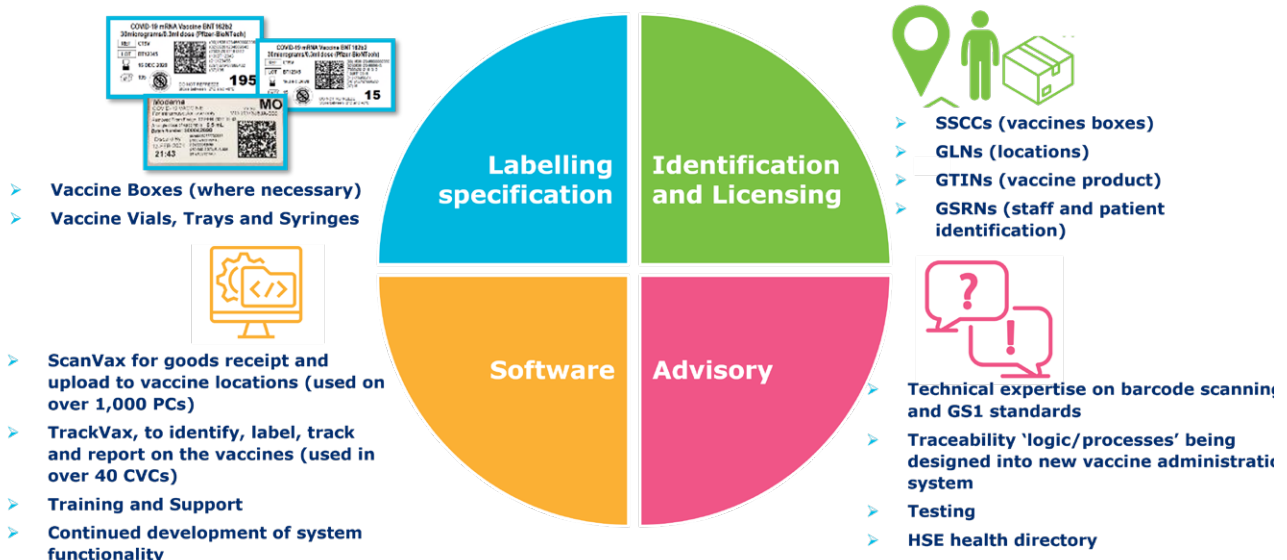Director of Public Health, HSE National Immunisation Office

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

Labelling specification

Identification and Licensing

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

- 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

Software

Advisory

- 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
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Noreen Noonan,
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Public Health, OoCIO, HSE

Fionnuala King,
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Drug Management Programme,
HSE Acute Operations

Mariangela Toma,
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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/