

Vaccine Information System for COVID-19 Vaccination Programme

Data Protection Impact Assessment

Version 1.8



Rialtas na hÉireann
Government of Ireland



An Roinn Sláinte
Department of Health



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Version History

Version	Date	Description
0.1	18/12/2020	First draft development.
0.2	21/12/2020	Second Draft following feedback from Chris Meehan and Peter Connolly.
0.3	23/12/2020	Third draft following feedback from Jim O’Sullivan (HSE DPO), Chris Meehan, Fran Thompson, Peter Connolly.
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0.7	21/01/2021	Seventh draft incorporating additional comments from Lucy Jessop, Jim O’Sullivan (HSE DPO), Chris Meehan, Fran Thompson, Peter Connolly.
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1.1	25/02/2021	Updated to include details of the Healthcare Worker Registration Portal
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1.6	15/04/2021	Updated prior to publishing in advance of the launch of the public portal

Version	Date	Description
1.7	20/04/2021	Updated following final review by Lucy Jessop and Fran Thompson. Incorporated additional comments from Niall Sinnott
1.8	22/04/2021	Final review and opinion by Jim O'Sullivan, HSE DPO

Vaccine Information System - Context

The overarching objective of this Vaccination Programme is:

‘To build on the public health response to COVID-19 to date through the efficient provision of safe and effective vaccines to the population and, in doing so, to reduce serious illness and death as a consequence of COVID-19.’

Necessary and accurate information of the right type in the right place at the right time is essential to the success of the Covid 19 vaccination programme for all for us, as individuals, and for Irish society as whole.

The Health Service Executive has been charged with the administration of the Covid-19 vaccination programme. This Data Protection Impact Assessment (DPIA) sets out details of the information systems that will be used and the information that the system needs to collect and process in order to ensure the vaccination programme delivers on its purpose.

As the name indicates, the focus of the DPIA is on the data protection (privacy) aspects of the information system but it also has the broader goal of helping to ensure public confidence in the programme.

The aim of any vaccination programme is to reduce morbidity and mortality in the population. Vaccines are critical public health interventions as they mitigate disease at the population level by offering protection to individuals and, depending on the mode of action of the vaccine, curbing community transmission.

The key function of a COVID-19 vaccination programme is to offer the vaccine to the whole of the population for whom it is indicated. The Irish COVID-19 Vaccination Programme is designed to ensure the safe, effective and efficient administration of a COVID-19 vaccine to all residents of Ireland who are indicated and wish to receive it.

The decision to receive the Covid-19 vaccine is for each individual to make on the basis of consent that is informed and voluntary. The consent to receive the Covid-19 vaccine is a ‘medical consent’ and derives from the principle of autonomy and forms an important part of medical and public-health ethics as well as international law. It will be achieved through an Information Leaflet to be produced by HSE that sets out in an open and objective way, in plain English, what the vaccine is, what it does and the reasons for taking it. It also addresses in the same way concerns that individuals may have about the vaccine. That information will allow every individual to decide in an informed manner where he or she wishes to receive the vaccine. The capture of an individual’s consent to receive the vaccine is a critical part of this process. Each individual receiving the vaccination will have a checklist completed¹.

The Covid-19 national vaccination programme can only work both for individuals and society if it is supported by information systems capable of capturing and processing relevant and necessary information. Where that relevant and necessary information is personal data (that is information about a living, identifiable individual) it falls under the EU General Data Protection Regulation (GDPR). Its processing must be compliant with the provisions of GDPR. In particular, there must be a lawful basis for processing. It is worth noting at this point in the DPIA that the GDPR recognises as lawful basis: processing for reasons of public interest, processing for reasons of a public health threat, processing for care and treatments and processing for health services management.

The Health Service Executive (“HSE”) will implement an end-to-end comprehensive digital solution to support the delivery and rollout of the nationwide COVID-19 vaccination programme. The ICT system will enable the planning and scheduling of vaccinations, the administration of the vaccine and support the monitoring and evaluation of the success and effectiveness of the vaccination programme.

¹ <https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/covid19vaccinechecklist.pdf>

The purpose of this document is to transparently assess the impact of the envisaged operations on the protection of personal data and how the rights to privacy and confidentiality of the users are appropriately protected. In light of the scale of the envisaged required data processing, types of data processing and use of new technology, the carrying out of this assessment is considered appropriate, necessary and desirable.

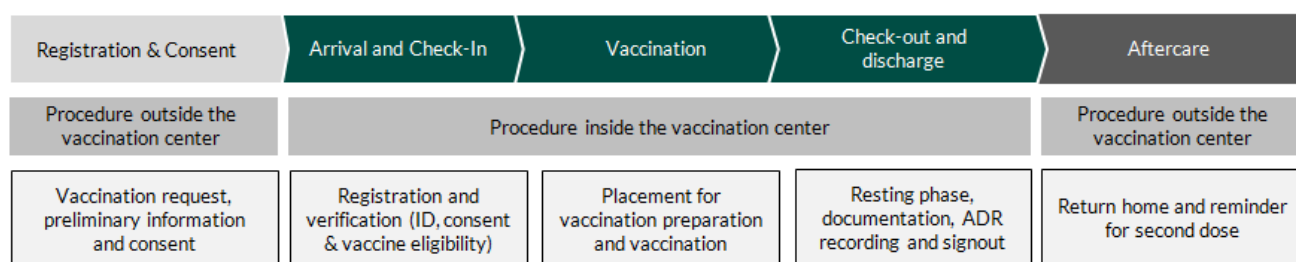
The assessment within this DPIA pertains to the administration of vaccines to individuals and the associated capture of personal and vaccine-related clinical data.

The data collected as part of the national vaccination programme, processed by the covid vaccination system and used for the creation of vaccinations records will also form part of broader electronic health records in the future, which themselves will be subject to separate DPIA, stakeholder engagement and compliance with legislation and regulations.

As the vaccine programme continues to evolve there are likely to be changes to the vaccine distribution strategy, the associated processes and operating model and the underlying technology solutions, this DPIA should be viewed as a living document that will be updated as necessary to ensure that its contents always reflect any material changes in the vaccination information system.

1. Overview

Regardless of where people receive the vaccine, the approach and process will be similar. The HSE is developing an end-to-end comprehensive digital solution to underpin this process and support the delivery of the vaccination programme. The diagram below sets out the process that everyone being vaccinated will go through.



It is critical for efficiency at scale and accurate record keeping and reporting that this process is systematically enabled, and key data elements are captured at the time of execution of each phase.

As per guidance from the European Centre for Disease Prevention and Control², “strong information systems to digitally record information about vaccination, immunisation information systems, are an integral part of well-functioning vaccine programmes. Immunisation information systems are an important tool for vaccination programmes. They hold data both at the personal and population levels, and are a valuable resource for individuals and the community: individuals are empowered to make informed decisions on vaccination, while improving the ability to detect patterns of vaccination in the community leads to better targeted vaccination programmes and consequently better public health.

The European Commission acknowledges vaccination as one of the most cost-effective public health tools and is keen to support cooperation between Member States on national immunisation programmes. In April 2018, the European Commission proposed a set of recommendations to increase vaccination coverage and ensure access to vaccines to respond to increased outbreaks of vaccine-preventable diseases and increasing level of distrust in vaccines in the EU. The development of comprehensive immunisation information systems is recognised as an essential tool to the

² <https://www.ecdc.europa.eu/en/immunisation-vaccines/immunisation-information-systems>

implementation of these recommendations.”

A key challenge in the process enablement is that Ireland does not have a national vaccination system, or similar. To support the delivery of the COVID-19 vaccination programme, a vaccine information system has been selected, procured and implemented.

The information system will have four primary purposes:

1. Ensure public confidence in the value and necessity of the information collected and processed.
2. To provide a method for people to register their details so that they can be scheduled to receive the Covid vaccine.
3. To support the safe administering of the vaccines through the capture and recording of required data and the creation of an underlying record of vaccination.
4. Facilitate the creation of a vaccine certificate in paper and digital format, should this be required.

It is essential that a Vaccine Information System can guarantee the security and privacy of personal health information. The public will rightly expect that to be the case. The system will be hosted in accordance with the appropriate standards for protected personal health information, i.e. security/encryption, disaster recovery, confidentiality and privacy practices, and policies based on pertinent laws or regulations that protect subjects whose data are recorded in the system.

Under the GDPR, processing of personal health data is generally prohibited, unless it falls into one of the expressly foreseen scenarios in Articles 6 and 9 of the GDPR (i.e. there is a ‘lawful basis’). The capturing and processing of personal health data (to the extent that it is necessary and proportionate) on the Vaccine Information System is required for the purpose of rolling out the COVID-19 vaccine to protect the health of individual citizens and the public generally. The impact of the operation of administering the vaccine on the protection of personal data and how the rights to privacy and confidentiality of users are protected will be formally assessed as part of this Data Protection Impact Assessment.

2. Scope

It is intended that individuals will receive vaccine through 5 administration channels:

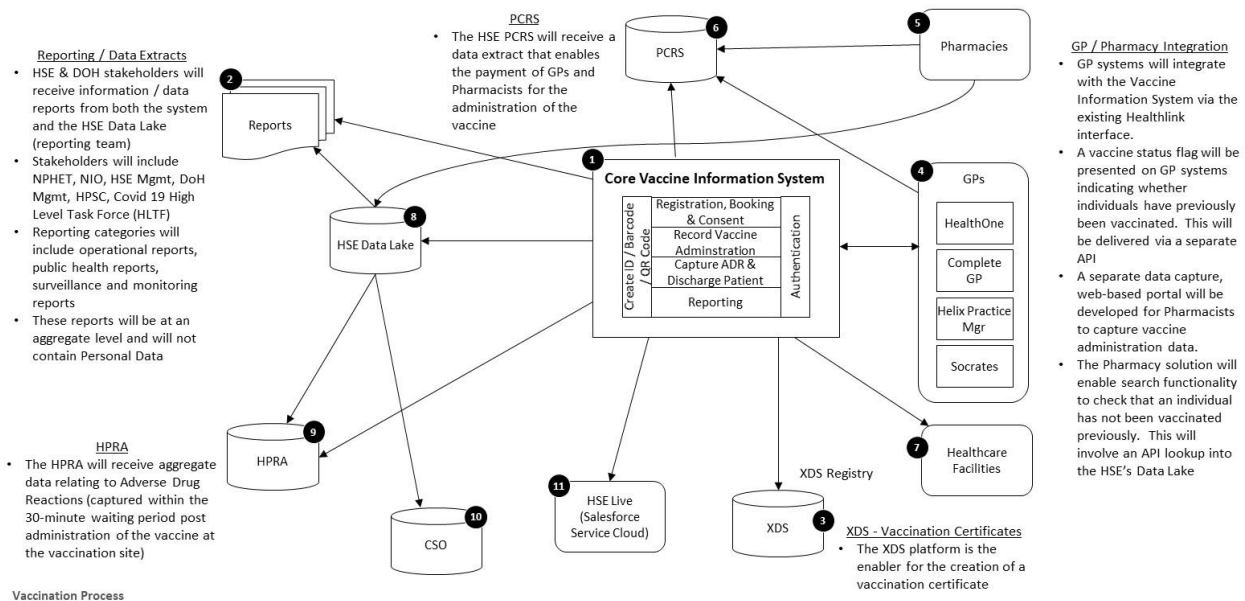
1. **GPs:** GPs will administer vaccine to nominated cohorts using their existing operational, clinical and technology infrastructure and processes. Data capture and flow will be consistent with current processes for existing vaccine administration. GP’s will use their proprietary systems to collect and store their patients Covid-19 vaccination details, and this data will be transferred to the Vaccine Information system (Covax) via integration between the GP proprietary system(s) and the Covax.
2. **Acute Settings:** Hospital staff and HSE vaccination teams will administer vaccine to nominated cohorts using their existing operational and clinical processes. The Vaccine Information System will be used to capture the appropriate data, details of which are described in this document under section 5. Individuals will self-register on the system via an online portal or will be registered via a batch upload of data directly onto the Vaccine Information System. A summary of the registration process is outlined in section 4.1.
3. **Residential Care Facilities:** HSE vaccination teams will administer vaccine to the residents of long-term care facilities (cohort 2) using existing operational and clinical processes. The Vaccine Information System will be used to capture the appropriate data, details of which are described in this document under section 5. Individuals will be registered on the system via a batch upload of data directly onto the Vaccine Information System. A summary of the registration

process is outlined in section 4.1.

4. **Mass Vaccination Centres (MVCs):** HSE vaccination teams will administer vaccine to nominated cohorts at dedicated MVCs located across the country. The Vaccine Information System will be used to capture the appropriate data, details of which are described in this document under section 5. Individuals will self-register on the system via an online portal. A summary of the registration process is outlined in section 4.1.
5. **Pharmacies:** Pharmacists will administer vaccine to nominated cohorts using their existing operational and clinical processes. A web-based data capture portal (separate to the Vaccine Information System) will be developed by the HSE for Pharmacists to record the vaccine administration record. A separate DPIA will be appended to cover this process prior to the deployment of this solution.

The functionality available to enable the administration of vaccines will include the registration of the individual via an online portal (which is a user facing interface to the Vaccine Information System), the booking or enrolment of an appointment, the capture of data relating to the administration of the vaccine, the ability to record an adverse drug reaction within 30 minutes of administration and the creation of operational and public health reports.

The diagram below shows the logical flow of data between the Vaccine Information System and the various other systems and stakeholders who will participate in the end-to-end process.



The table below summarises the roles of all key parties who will provide data or have access to data processed by the Vaccine Information System. Contracts are in place between the HSE and each of these parties which set out the processors' obligations and the HSE's obligations and rights with regard to the personal data that is being processed. These contracts comply with the legal requirements for processor contracts set out in the GDPR in Article 28. Where there is a legitimate business need and, where a lawful basis exists, authorised third parties will be provided with access to the Vaccine Information System. All third-party access to the Vaccine Information System shall be managed in accordance with the HSE IT Security Policies. The level of access and the access privileges will be agreed with the third party on a case by case basis.

Data Map Ref	Members	Data Role	Role Summary
n/a	HSE	Data Controller	The HSE is the Data Controller for the vaccination programme
4	GP's	Data Controller	GP's are data controllers in their own right independent from the HSE. They will use their own proprietary systems to collect patient/citizen data relating to the administration of the vaccine and will use this data for the ongoing management of the healthcare needs of their patients. Only information captured by GPs relating to the administration of the vaccine (Personal Data, Vaccinator/GP Data, Vaccine Data) will be integrated with the core HSE Vaccine Information System.
5	Pharmacists	Data Processor	<p>It is intended that Pharmacists will utilise an HSE-developed and hosted web-based portal to capture vaccine administration data. The final operating model for pharmacists and approach to data capture enabling vaccination is to be finalised.</p> <p>In the scenario where Pharmacists will utilise an HSE developed and hosted data capture solution, Pharmacies will be data processors. This is a bespoke application that will only be utilised by pharmacists. All information captured on this application will solely relate to the administration of the vaccine (Personal Data, Vaccinator/Pharmacist Data, Vaccine Data) and be integrated with the HSE's Data Lake.</p>
7	Healthcare Facilities (acting under Section 38 of the Health Acts 2004)	Data Processor	The Section 38 Voluntary hospitals are assisting the HSE with the rollout of the Covid-19 Vaccination Programme. They are assisting the HSE with the administration of Covid-19 vaccines to their staff and/or the staff of other healthcare providers on behalf of the HSE. The Section 38 Voluntary Hospitals will have direct access to the Vaccine Information System to record the details of individuals for which they have administered a Covid-19 vaccine.
7	Private Hospitals	Data Processor	The Private hospitals are assisting the HSE with the rollout of the Covid-19 Vaccination Programme. They are assisting the HSE with the administration of Covid-19 vaccines to their staff and/or the staff of other healthcare providers on behalf of the HSE. The Private Hospitals will be provided with direct access to the Vaccine Information System to them to record the details of individuals they have administered a Covid-19 vaccine to. There are existing data sharing agreements in place with the Private Hospitals.

Data Map Ref	Members	Data Role	Role Summary
3	DPER	Data Processor	Assisting the HSE with the distribution and delivery of the Vaccine Certificates and acting as a 'data processor' for the HSE.
9	IBM	Data Processor	Data Processor who is configuring and implementing the Vaccine Information System on behalf of the HSE
1	Salesforce	Data Sub Processor	Data sub processor for the Vaccine Information system working in conjunction with IBM to implement and host the system (and data). On instruction from the HSE, Salesforce will also send SMS messages to the phones of those who have registered to receive the vaccine. SMS messages will typically be used to provide confirmations and reminders about vaccine appointments, but may also be used to re-schedule appointments on short notice if this becomes necessary
9	Healthcare Products Regulatory Authority (HPRA)	Not a Processor	The HPRA are recipients of aggregated/ anonymised data for reporting purposes which is not personal data about identifiable individuals within the terms of GDPR. It is therefore outside of the scope of this DPIA
10	Central Statistics Office (CSO)	Independent Controller	The CSO are recipients of Personal data which they process for their own lawful purposes.
2	DOH	Not a Processor	The DOH are recipients of aggregated/ anonymised data which is not personal data about identifiable individuals within the terms of GDPR. It is therefore outside of the scope of this DPIA
11	Service Providers for HSELive <ul style="list-style-type: none"> • Capita Customer Solutions • Abtran • Rigney Dolphin • Covalen 	Data Processors	There are four 3 rd party service providers being used to provide online and telephone support to both Vaccination teams and the general public. Support agents from the four organisations will receive, manage and process calls via the HSE's service cloud platform. Support agents will also have access to the CoVax system to provide support to individuals who require support with the vaccination process.

3. Roles and Responsibilities

3.1 Overall Vaccination Program

The Government established the High-Level Task Force (HLTF) on COVID-19 Vaccination on November 10th, 2020 to ensure the requisite oversight, agility and specialist input is available to support the HSE and the Department of Health in the effective, efficient and agile delivery of the COVID-19 Vaccination Programme.

The overarching objective of this Vaccination Programme is:

‘To build on the public health response to COVID-19 to date through the efficient provision of safe and effective vaccines to the population and, in doing so, to reduce serious illness and death as a consequence of COVID-19.’

The table below lists the key members of the High-Level Task Force (HLTF) and their associate roles:

Members	Role
Health Service Executive	The Health Services Executive has statutory responsibility for the delivery of health and personal social services including the prevention of illness and infectious disease through immunisation and vaccinations services.
Department of Health	The Department of Health’s role includes formulating policy and providing direction on national health priorities; protecting the interests of patients and consumers; supporting practitioners and professionals to practice to the highest standards by providing a prudent and appropriate regulatory framework and providing effective stewardship of health resources. In respect of immunisation programmes and policy, the Department makes policy decisions based on advice from the National Immunisation Advisory Committee and these are then implemented by the HSE through the National Immunisation Office.
HSE COVID-19 Immunisation Programme Team	Lead on operational matters related to the roll-out of the vaccination programme. Overall lead on operational matters relating to HSE roll-out of the vaccination programme, resource and facilities management.
National Immunisation Office (NIO)	The HSE office responsible for managing vaccine procurement and distribution and developing training and communication materials for the public and health professionals. NIO develops immunisation training and has a role in communications to the public; manages logistic considerations for vaccine storage, distribution under validated cold chain conditions.
Health Protection Surveillance Centre (HPSC)	Collects immunisation data and is responsible for compiling and publishing uptake (coverage) statistics during the rollout of vaccine programmes in Ireland, liaising closely with the European Centre for

	Disease Control (ECDC). Data presented by the HPSC ultimately feedback to immunisation implementation planning and policy development.
Health Products Regulatory Authority (HPRA)	The national body which grants licences for medicines (other than those licensed centrally on the basis of an EMA opinion), in Ireland, following a review of their safety, quality and efficacy. The HPRA is also responsible for monitoring vaccine safety, quality and effectiveness post-authorisation, and, where medicines are licensed centrally for all EU member states, works closely with the European Medicines Agency (EMA) at the European level.
National Public Health Emergency Team	Oversees and provides national direction, guidance, support and expert advice on the development and implementation of a strategy to contain COVID-19 in Ireland. It advises the Government on the public health aspects of what is a cross-Government response to COVID-19.
High-Level Task Force on COVID-19 Vaccination	Established to support the Department of Health (DoH) and the Health Service Executive (HSE) to deliver a COVID-19 vaccination programme that meets best practice and good governance.

The HSE COVID-19 Immunisation Executive Oversight Group, the terms of reference for which are provided in Appendix A, has been formed to provide oversight to the COVID-19 Immunisation Programme, receive regular progress reports from the from the COVID-19 Immunisation Programme Implementation Working Group and provide assurance to the HSE on the progress of the Immunisation Programme Implementation.

The Vaccine Information System is discussed at this Oversight Group as well as the HSE implementation group. The system will also be included in the Data and Information Management group of the HSE

3.2 Vaccination Information System

With regard to the Vaccination Information System, the HSE has determined the means and purposes for the processing of personal data using the Vaccination Information System and as such is the data controller for the system. The vendors selected to provide the technology solution are IBM and Salesforce. The solution is based on Salesforce’s HealthCloud platform. IBM is the lead vendor in the relationship and responsible for configuring the platform to meet the requirements of the HSE. IBM is the data processor. Salesforce, as a subcontractor to IBM will act as a sub processor. The HSE alongside IBM and Salesforce is responsible for the development, testing, security, operation and maintenance of the system. System security will be managed by the HSE in conjunction with IBM/Salesforce. Following go live the system will be supported by IBM and the HSE OOCIO team.

With regards to training, all HSE employees have to complete mandatory data protection training. Specific training on the system is available in an ongoing basis and is updated as required. Hypercare support is available to sites when they first go live and a network of superusers is being set up.

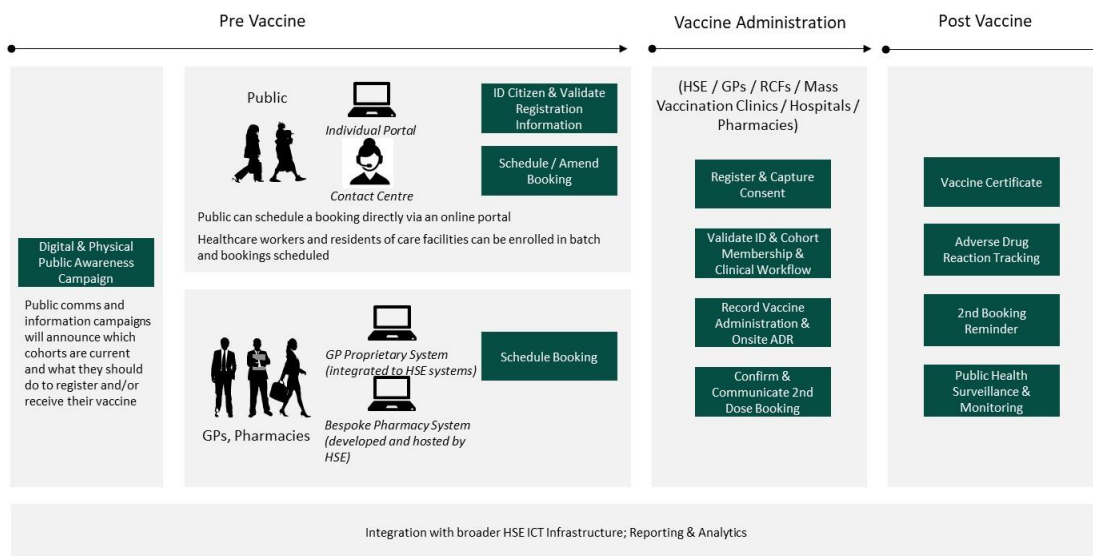
4. Processing Overview

The vaccine system will establish a standardised, national approach to the recording of patient vaccination data and a national dataset for national (and local) reporting, analysis and research purpose to inform responsive, clinical/public health intervention strategy. The system is ultimately intended for use in any health care vaccination settings where a vaccination is delivered i.e. clinic, care or residential home, patient's home (housebound), ward (long stay patients), community pharmacy and GP practices.

The system has been in use from 30 December 2020 to capture the data required to support the rollout of the COVID-19 Vaccination programme in the Republic of Ireland. Regardless of which vaccine is being administered and where people receive the vaccine, the approach and process will be similar. The system will underpin this process and support the delivery of the vaccination programme.

The table below sets out the core functionality for the IT system that will be required to support the COVID-19 vaccination programme.

Outline Workflow – Core Functionality (End State)



4.1 Pre-Vaccination

The solution supports the key functional and non-functional requirements of the clinical and operational stakeholders responsible for the delivery of Covid vaccines. An overview of the core processes within the Pre-Vaccination state are described below

Registration

The primary purpose of the registration process is as follows:

- 1) to capture details of the individual receiving the vaccine in order to validate that they are within the relevant cohort
- 2) to create the shell of the clinical record
- 3) to enable the scheduling of a vaccine appointment.

The registration process is dependent on the individual's cohort membership and the channel through which they will receive the vaccine (5 channels as summarised in section 2 above). While the process will be identical across several cohorts, there are variations in the registration process across the channels. The following sections outline the process for each channel.

GPs

Initially, individuals over the age of 70 (cohort 3) will be vaccinated by their GPs. GPs will contact their over 70s patients and schedule a booking as per their current vaccine and patient management processes. Patient and vaccine data will be captured on GP systems as per their current processes. This data will be integrated into the HSE systems (PCRS and the Vaccine Information System) via the current integration mechanism, Healthlink. A vaccine status flag will be presented on GP systems via an API into HSE systems, indicating whether an individual has been previously vaccinated. There is no requirement for individuals receiving vaccine via their GPs to pre-register on any system.

Acute Settings

Healthcare Workers (HCWs) are members of Cohorts 2 and 4 and will register on the Vaccine Information System in one of two possible ways – via a batch data upload or self-registration on an online portal. The batch data upload was used as the mechanism for registering HCWs in the early stages of the programme as the registration portal was not available.

The online portal is configured to enable the registration, and scheduling of an appointment for healthcare workers to receive a vaccination. Healthcare workers register their details and provide consent to receive the vaccine via this online portal. This enables the creation of an appointment at a healthcare facility. As part of this registration process, healthcare workers will provide personal data to the HSE including data related to their occupation and location of work. This data is required to uniquely identify the individual and validate that they are a healthcare worker at the point of vaccination and are therefore entitled to receive a vaccine as part of cohort 2 or 4. The data fields that are captured are described in the table in sub-section 5.5 below.

The registration portal is merely a user interface to the Vaccine Information System. It is not a separate system. Data is captured securely and encrypted when stored in the database of the Vaccine Information System.

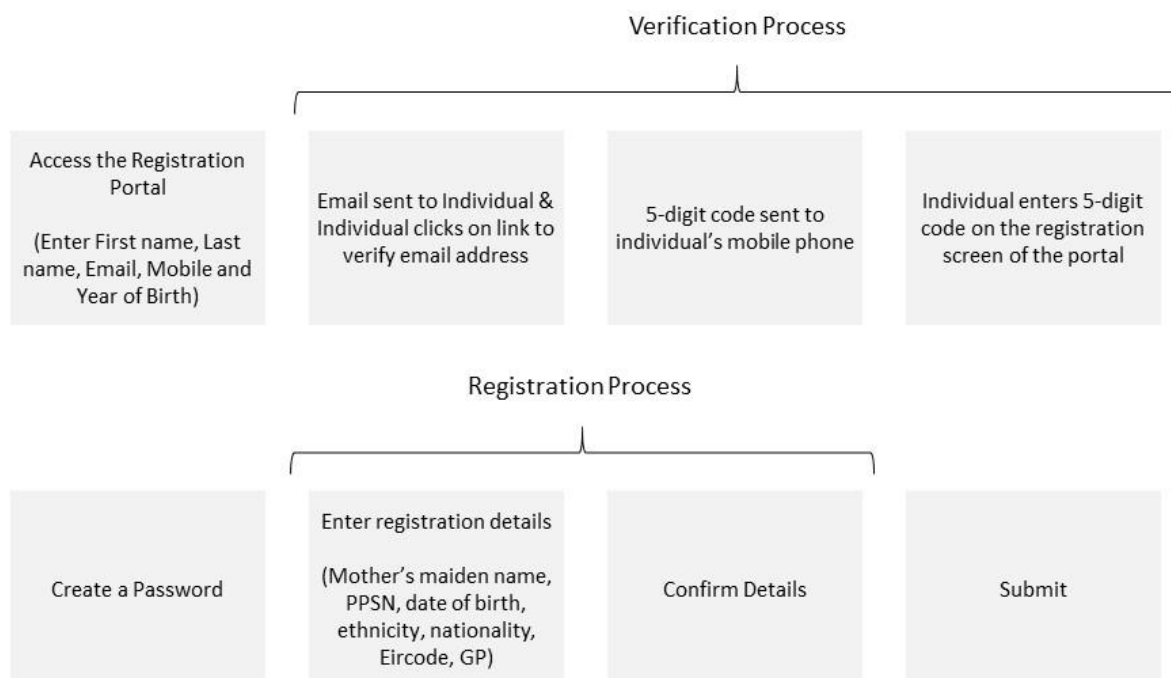
Residential Care Facilities

Residents of Care Facilities are members of Cohort 1 in the overall vaccine rollout strategy. Members of this cohort will be automatically registered on the Vaccine Information System via a secure batch data upload. This data will be limited to the key data fields required to create the vaccine clinical record. The data fields that are captured are described in the table in sub-section 5.5 below and are consistent with the data fields captured for members of all other cohorts.

Mass Vaccination Centres

The majority of individuals within the State will register to receive an appointment for a vaccine via an online public portal. As per the healthcare worker registration portal, the public portal is essentially a user interface into the Vaccine Information System. It is not a separate system. Data is captured securely and encrypted when stored in the database of the Vaccine Information System.

Individuals who register on the portal will provide personal data to the HSE. The purpose of capturing this data is to enable the unique identification of the individual, validate that the individual is within the cohort that has been called for vaccinations, and schedule an appointment. Additional validation and confirmation that the individual is within the appropriate cohort will happen at the point of vaccination. The outline process for registration for a vaccine appointment at a mass vaccination centre is illustrated in the diagram below.



The data fields that are captured as part of the registration process are described in the table in sub-section 5.5 below.

Pharmacies

It is intended that pharmacists will play a role in the overall vaccination programme rollout. It has not been determined which cohorts will be vaccinated in a pharmacy setting. Pharmacists will schedule appointments using their own operational and technology processes and systems for individuals who qualify to receive a vaccine through this channel. An HSE web-based data capture tool will be deployed for pharmacists to capture personal and vaccine data relating to the physical administration of the vaccine. This solution will be integrated via an API into the HSE Data Lake, enabling pharmacists search to determine if individuals have been previously vaccinated. A separate DPIA will be appended to this document prior to the Pharmacy web-based data capture tool being deployed to live.

Unique Identification of Individuals

A critical component of the registration process is the requirement to capture sufficient information that enables vaccinators uniquely identify individuals. This is important to validate that individuals are within their stated cohort and to ensure the integrity of the clinical record (in administering the correct vaccine for dose 2).

Where possible, the HSE will use a combination of the individual's name, their mother's maiden name, their date of birth and their PPSN to locate their Individual Health Identifier (IHI) on the National Register of Individual Health Identifiers. The lawful basis for this processing is contained in the Health Identifiers Act 2014.

Using a person's PPSN to accurately locate their Individual Health Identifier helps to ensure that an individual's particulars are being correctly assigned with the correct IHI which is required for patient safety. Utilisation of the Individual Health Identifier and its related dataset (as provided for in the Health Identifiers Act 2014) is critically important as it will ensure that each person is uniquely identified for full traceability of the vaccine administered to the individual. The PPSN and the IHI, through the highest level of authentication, will ensure the ongoing accuracy of the data with respect to individuals.

Under both the Health Identifiers Act 2014 and the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020, if a person does not have, or is unable to give, a personal public service number, they may provide other identifying particulars in order to help locate their IHI.

This means that no individual presenting to receive a COVID-19 Vaccine will be denied the vaccine because they are unable to provide their PPSN.

As part of this registration process, individuals must provide personal data to the HSE. This data is required in order to uniquely identify the individual, validate that they are within the cohort that is current at that time and register them for an appointment to receive the vaccine. This is an important and necessary measure to ensure the correct individual gets the right dose of the vaccine at the right time and ensure the HSE can be sure to whom they have provided the vaccine.

The overall vaccine programme is designed around the principle of equitable allocation of vaccine. As vaccine supplies are limited at the start of the programme, the allocation of doses is targeted at those population cohorts prioritised by Government. A public communication and information campaign will inform individuals what cohorts are current and entitled to register for an appointment to receive a vaccine. The campaign will also inform individuals of what action they must take to register or receive an appointment.

Vaccine Administration

The vaccine administration process ensures vaccine delivery to the public is efficient and that all required information is accurately recorded at the time the vaccine is administered. Validation of the person's identity is necessary prior to the vaccine being administered as well as confirmation that they are within the allocated cohort. Where individuals are attending an HSE organised clinic, this validation will occur at the appropriate vaccination centre. Administrators supporting the vaccination teams will validate individual's identification and cohort membership against the data provided by the individual as part of the pre-registration and booking process.

Any adverse reactions that occur post vaccination during the observation period will be recorded in a codified manner on the system. The solution may also need to cater for the creation of a paper or digital vaccine certificate.

Post-Vaccination

The HPRA, as part of the EU regulatory network of medicines agencies, together coordinated by the EMA, will closely monitor the safety profile of COVID-19 vaccines by reviewing the totality of available data, including reports of ‘suspected adverse reactions’. Through the HPRA’s suspected adverse reaction reporting system, members of the public, carers and healthcare professionals can report side effects by using the HPRA’s online reporting facility, by email or by phone. Should details of suspected adverse reactions be captured at the time of vaccination, this information will be provided to the HPRA electronically from the Vaccine Information System, in order to facilitate enhanced reporting by avoiding duplication of records at the point of care.

All reports received by the HPRA are processed and collated within the national pharmacovigilance database, according to established EU rules, with anonymised cases in turn reported to the European database Eudravigilance, with frequent analysis on cumulative data performed to detect potential signals.

The HPRA also closely monitors national cases and will publish safety summary reports. The EMA’s safety committee, in which the HPRA participates through an Irish delegate, will make safety recommendations, if necessary, following evaluation of the totality of post-marketing safety & effectiveness data contained in the system, including that from passive and active surveillance.

4.1 Necessity & Proportionality

The Vaccine Information System is both necessary and proportionate to:

- ✓ Ensure best practice in the care and safety of any person receiving the vaccine
- ✓ Reduce or eliminate the clinical and information governance risks associated with the existing vaccination systems and processes. Current systems are a mix of IT and paper-based solutions with no one system deployed nationally
- ✓ Ensure HSE meets its obligations regarding the protection of patient data and confidentiality
- ✓ Improve the accuracy of clinical/vaccine data recording and reporting
- ✓ Make vaccine data readily and securely accessible to those authorised to process it
- ✓ Provide standardised clinical and workflow management in all vaccination settings.
- ✓ Provide structured data relating to the vaccination of patients to be included into national datasets for improved reporting purposes
- ✓ Capture data relating to adverse drug reactions post administration of the vaccine and within the observation period

In addition, guidance from the European Centre for Disease Prevention and Control describes the importance of equivalent systems:

“Immunisation information systems (IIS) are an important tool for vaccination programmes. They hold data both at the personal and population levels, and are a valuable resource for individuals and the community: individuals are empowered to make informed decisions on vaccination, while improving the ability to detect patterns of vaccination in the community leads to better targeted vaccination programmes and consequently better public health. Vaccination programmes are complex public health interventions that produce major health benefits. They are vulnerable to changes in public confidence and opinion. Immunisation programmes may be subject to controversy that has prevented achieving high uptake for some vaccines. Mitigating these controversies requires near to real time demonstration of the efficacy and favourable safety profile of vaccines to reassure all concerned stakeholders, from the

patient to the healthcare professionals.³

It is the view of the HSE that in order to safely, effectively and efficiently manage the deployment of the vaccine to the population, there is not a less intrusive methodology to undertake this task. In addition to establishing the principle of necessity and proportionality we have adopted the principle of data minimisation.

4.2 Key System Functionality

The solution will be configured and supported to fulfil the following key functionalities:

- ✓ Vaccine client registration
- ✓ Client consent management
- ✓ Clinic preparation for vaccination
- ✓ Vaccination record management & history access
- ✓ Vaccine schedules and schedule rules set-up
- ✓ Clinic schedule management
- ✓ User administration control and maintenance
- ✓ Electronic integration of data with other systems (e.g. GP systems, etc.)
- ✓ Mass data upload management
- ✓ Flexible reporting and data analytics
- ✓ General information system functionality
- ✓ Record data relating to adverse drug reaction post administration of the vaccine within the observation period

4.3 Vaccination Certificates (XDS integration)

It is intended that your personal and special category data collected as part of the vaccine programme will be used only for the purposes of programme management and reporting. This will include at a future date your enablement to access a smart digital vaccination certificate as evidence of your COVID-19 vaccination in Ireland. This is in line with on-going co-ordinated European Council and WHO efforts in this area.

4.4 EU Interoperability

The Irish implementation system will leverage the EU-WHO based digitised smart vaccination certificate based on the information held in the Vaccine Information System. This is architected upon open standards and the principles of interoperability. The European Commission eHealth Network in conjunction with the WHO recognises that EU Member states are responsible for determining what architecture they wish to leverage for in-country implementations, as long as the architecture is interoperable with the decentralised trust framework established by WHO and the EU for interoperability.

Accordingly, the cross border architectural framework will be underpinned by XDS, as this is the common architectural base for eHealth record structure used by EU member states for healthcare interoperability.

³ <https://www.ecdc.europa.eu/en/publications-data/designing-and-implementing-immunisation-information-system-handbook>

4.5 Other Functions

Data privacy, data protection and information accuracy are at the very heart of the XDS platform. Key elements of the clinical dataset will be SNOMED coded to support the effective clinical recording of data and help avoid variability in the way data might be captured and recorded.

In terms of design assurance, the solution design gives regard to EU Commission Decision 2015/1302 for ICT standardisation and it embraces the relevant recommendations within the directive. These include the requisite standards and profiles required for identity, interoperability, privacy, consent and audit trail.

4.6 Customer / User Support

A Covid-19 helpline is available to individuals who cannot register online for their vaccination appointment. Contact details for the Covid-19 helpline can be found online at <https://www2.hse.ie/services/contact-the-hse/>. The Covid-19 helpline support team will capture the same details as per the online registration process. Support agents will receive, manage and process calls via the HSE's Service Cloud platform. Support agents will have access to the CoVax system to provide support to individuals who require support with the vaccination process.

Additionally, a HSE support team will be in place to support Vaccination teams. This support team (VOCC) will log tickets on Service Cloud to support vaccination teams for a variety of reasons e.g. user set up requests, consumables queries (needles, PPE etc), facility id requests etc. This team has access to CoVax to log calls against facilities (vaccination clinics) and vaccination team members. Security is role based.

5. Scope of Processing

This section of the document describes the data that will be processed, how much data is being collected and used, how often it will be processed, how long it will be retained for, and who the data relates to.

5.1 Data Subjects

The proposed data processing relates to all individuals in the Republic of Ireland that are administered the COVID-19 vaccination by the HSE.

- Data will be collected on individuals through each phase of the vaccine administration process. This includes during registration, the vaccination event and aftercare.
- Data will also be collected on administrators of the vaccine; the vaccination venue and additional data will be collected for healthcare staff that receive the vaccine for patient safety reasons.
- Personal data is not further processed beyond identified purposes.

5.2 Data Types

There are various different types of data to be processed by the system. The table below lists the data types and provides a definition for each. Examples are also provided for each data type. Please refer to the minimum dataset for a full list fields and their associated data type:

Data Type	Definition	Examples
Personal Data	Personal Data required to administer, manage and monitor the vaccination process	Forename, Surname, Address, PPSN, Date of Birth, Email, IHI, COVID-19 Identifier, GP Name, Vaccination Status, Healthcare workers will provide additional data to enable validate that they are legitimately part of cohorts 2 or 4 (healthcare workers). This personal data includes job specific details such as occupation type and priority, and the primary health care facility where the individual works
Vaccinator Data	Employee information required to administer, manage and monitor the vaccination process involving healthcare workers	Job Title, Service, HSE Grade, etc.
Booking Data	Non-personal information relevant to the vaccine appointment including date and time.	Booking Date, Booking Time, Booking Venue
Vaccine Data	Non-personal information relevant to the vaccine being administered to the patient	Vaccine Name, Vaccine Brand, Vaccine Batch Number, Vaccinator Expiry date, etc.

Post Vaccine Data	Additional data collected in the event of an adverse reaction to the vaccine	Adverse Reaction Description, Duration, etc.
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5.3 Data Collected/ Processed

The information processed by the system is a combination of personal data, special categories of personal data (health related data). Information is processed on the system by multiple parties along the vaccination journey as seen on the diagram on page 11. These will include but are not limited to- GPs, Vaccinators, HPRA (if you have an adverse reaction), Pharmacists and administrative staff.

5.4 Data Retention

There are various retention limits on different types of data being processed and these are outlined in the table below. Data about you will be retained on the HSE Vaccine Information System in accordance with the HSE Record Retention Policy⁴ or as long as legally required.

Data Type	Retention	Retention Justification	Retention Measure
Personal Data	Personal data will be securely held within the vaccine system throughout the duration of the vaccination programme and beyond. Post vaccination, patient personal data will be retained indefinitely as this created as an immunisation record.	The justification to store personal data in the system is to facilitate the availability of the data to those providing frontline care. Retention is also required for analysis, reporting and monitoring the vaccine across the population.	It is intended that data in relation to an individual's vaccination will be held in perpetuity
Vaccinator Data	Vaccinator data will be securely held within the vaccine system throughout the duration of the vaccination programme and beyond.	The justification to retain Vaccinator data is to ensure the ability to audit that a qualified vaccinator administered the vaccine.	It is intended that data in relation to the vaccinator will be held in perpetuity as part of the overall clinical record
Booking Data	Booking data will be securely held on the vaccine system indefinitely	Booking data is non-personal, therefore, can be retained in the system for as long as it is needed. The data will be retained for management, reporting and compliance purposes.	Booking data will be held in perpetuity. While it is not a core element of the clinical record, it would not be practical to purge these data elements from the overall clinical record. Booking data is non-personal

⁴ <https://www.hse.ie/eng/gdpr/data-protection-covid-19/record-retention-policy-2013.pdf>

Vaccine Data	Vaccine data will be securely held on the vaccine system indefinitely.	Vaccine data is non-personal, therefore, can be retained in the system for as long as it is needed. The data will be retained for stock management, reporting and compliance purposes.	It is intended that vaccine data will be held in perpetuity as part of the clinical record
Post Vaccine Data	Post vaccine data will only be captured in the event of an adverse reaction during the observation period following the administration of the vaccine.	The justification to retain post vaccine data is to facilitate the availability of the data to those providing frontline care. Retention is also required for analysis, reporting and monitoring purposes specific to the adverse reaction. This information is key in the analysis of the vaccine and will be reported to the HPRA. Post vaccine data is also an important element of an individual's clinical record	It is intended that post vaccine data will be held in perpetuity as part of the clinical record

5.5 Parties who will Access/Use Data

The HSE shall enter into the appropriate agreements with all third parties who are provided with direct access to the Vaccine Information System and/or are provided with personal data from the Vaccine Information System. These agreements will outline each parties' responsibilities and the scope, purpose, duration and means of processing undertaken by each party.

The National Immunisation Office (NIO) will use data from the system for business reporting purposes. As noted by the ECDC, monitoring uptake of COVID-19 vaccines will provide information about the performance and efficiency of the vaccination programme and its capability of reaching most of the population. In addition, it will help inform on how equitable (in terms of access to vaccines) and how acceptable the programme is to target populations. Data collected at the finest geographical level and in specific subgroups will allow for the identification of areas with low coverage and pockets of susceptible individuals (or specific groups that may pose a risk for the wider community, e.g. healthcare workers).

The data is shared with the Central Statistics Office ('CSO'). The CSO is Ireland's national statistics office and its purpose is to impartially collect, analyse and make available statistics about Ireland's people, society and economy.

The CSO will carry out statistical analysis on the information shared with it, which it will publish in line with its remit, including to the National Public Health Emergency Team (NPHE), Department of Health, the Health Protection Surveillance Centre, the HSE, and to the public as appropriate.

NPHET will review and report vaccination data at regular intervals and in line with its commitment to transparency will communicate the data publicly. Transparency is vital for ensuring that all aspects of the vaccination programme are worthy of trust and can promote the necessary solidarity and mutual responsibility needed for a successful strategy.

Vaccination uptake will be assessed in an ongoing manner to track the implementation of the programme and acceptance of the vaccination in the populations targeted in line with the prioritisation framework. Monitoring of the uptake by population group may be done where it is possible to obtain denominator data (e.g. census data for different age groups). Where denominators are not readily available, estimates will be made based on estimates of populations at risk. Analysis will be carried out on uptake by demographic characteristics, such as gender, age, area of residence, HSE region (CHO), workplace settings for HCWs (hospital groups, hospitals, long-term care facilities, primary care sites), occupational or clinical risk group.

Data obtained on vaccination will also be monitored at individual, target group, and population level, including specific vaccines administered, number of 1st doses and 2nd doses received, and calculation of completed vaccinations (1st and 2nd dose, if appropriate, and 'DNAs', who do not attend for scheduled appointments or who do not complete the required vaccination schedule (dual dose).

The ability to link COVID notification data with vaccination data will be a key feature of disease surveillance once the vaccination programme begins.

The table below details the level of access to the data that each of aforementioned groups will have.

Members	Data Role	Data Access
HSE	Controller	Patient Data
GP's	Controller	Patient Data
Pharmacists	Processor	Patient Data
Healthcare Facilities (acting under Section 38 of the Health Acts 2004)	Processor	Patient Data
Private Hospitals	Processor	Patient Data
DPER	Processor	Patient Data
IBM	Processor	Patient Data
Salesforce	Sub Processor	Patient Data
HPRA	Aggregate/ Anonymised data	Reporting Data

	for reporting purposes	
CSO	Independent Controller	Patient data subsequently anonymised for reporting purposes
DOH	Aggregate/ Anonymised data or Pseudo anonymised Data	Reporting Data

5.6 Personal Data

This section describes how personal data will be collected, used, transferred and if necessary, kept up to date. The Vaccine Information System, via secure sign-in, and IT/network security standards already established for the Vaccine Information system, will allow secure, dynamic data recording at the point-of care, by on-site administrators (rather than centralised teams) and vaccinators. Patient vaccine data will almost instantly enter the database within any vaccination setting and will be shareable with all healthcare staff that require access to vaccination information for the patient via the security models already in place for the relevant clinical systems e.g. GP IT systems.

The following scope for personal data processing has been determined. A rigorous data minimisation approach has been adopted to personal data processing and only personal data that is necessary and proportionate to administer the vaccine will be processed - Please refer to the Appendix B for further details.

The following table sets out the personal data that will be processed by the Vaccine Information system, including the Healthcare Worker and Public portal interfaces. The table provides a description of the data, the source, the type of data and how often the data is processed.

Data <i>Data Points to be collected within dataset</i>	Data Type <i>(Personal Data / Personal Health Data)</i>	Collection Activity <i>Event at which data will be captured</i>	Collection Frequency <i>Frequency at which data will be captured</i>
First Name	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Middle Name (optional)	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Surname	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.

Mother's Maiden Name	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Date of Birth	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
PPSN	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Sex	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Nationality	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Ethnicity	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
IHI (Individual Health Identifier)	Personal Data	Data entry during registration	This data set is generated for each person registered for a vaccination.
Contact Number (Mobile)	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Email	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Home Address (Line 1)	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Home Address (Line 2)	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Home Address (Line 3)	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
County	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Country	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.

Area Code (Dublin Region)	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Eircode	Personal Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
CHO/ Hospital	Personal Health Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
GP (name or name of practice)	Personal Health Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Permission for GP to access COVID19 vaccination	Personal Health Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Occupation (for HCWs only)	Personal Health Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Prioritisation Category	Personal Health Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Health Care Facility	Personal Data	Data entry during registration	This data is entered by Healthcare workers to capture their work location. It is captured as part of the pre-registration process and is collected to support the validation process that individuals are registering as bono fide healthcare workers
Vaccination Status	Personal Health Data	Populated by system based on vaccination event data	This data set is collected when a person is registered for a vaccination.
Contraindication to Vaccination	Personal Health Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Are you currently unwell?	Personal Health Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Are you pregnant?	Personal Health Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.

Covid infection in past 4 weeks?	Personal Health Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.
Have you received any other vaccine within the past 14 days?	Personal Health Data	Data entry during registration	This data set is collected when a person is registered for a vaccination.

5.7 Data Security

The Vaccine Information System, via secure sign-in and existing IT network security standards enables secure, dynamic data recording at the point-of care, by on-site administrators and vaccinators. Personal data enters the database almost instantaneously within any vaccination setting. A number of technical features and process controls have been implemented to ensure patient and vaccinator data protection, as follows:

- Role-based security model with restricted access
- Multi-factor authentication functionality for system administrators
- Full penetration testing across all potential access points (Portal and API integration points, e.g. IHI, Eircode/Address, PPSN)
- Additional security enhancements developed including the no ability to export data and removal of search functionality
- Use of QR codes (delivered to the individual post registration and presented by the individual to be vaccinated at the point of vaccination) to uniquely identify patients – eliminates search functionality and the ability of vaccinators to see lists of patients
- Approval process for all user accounts prior to setup
- Additional screens to remind people of rights in terms of access and legal obligations included in the logon process
- Hardening of the account set-up and user access process

6. Context of Processing

This section of the document sets out the relationship the HSE has with data subjects, how much control they have over the data processed, what type of people make up the data subjects. It also sets the context in regard to the privacy concerns that people may have with the system. It is important that a Vaccine Information System can guarantee the security and privacy of personal health information. The system will be hosted in accordance with the appropriate standards for protected personal health information, i.e. security/encryption, disaster recovery, confidentiality and privacy practices, and policies based on pertinent laws or regulations that protect subjects whose data are recorded in the system.

Under the GDPR, processing of personal health data is permitted subject to there being a valid lawful basis for the processing in Article 6 (Lawfulness of processing) and Article 9 (Processing of special categories of personal data) of GDPR. (The lawful basis for the processing of the personal data in the vaccination programme is discussed later in the DPIA). Processing must also be in accordance with the data protection principles set out in Article 5 (Principles relating to the processing of personal data).

The capturing and processing of personal health data on the Vaccine Information System is required for the purpose of rolling out the COVID-19 vaccine to protect the health of members of the public.

6.1 Privacy Model

As noted by the ECDC, monitoring uptake of COVID-19 vaccines will provide information about the performance and efficiency of the vaccination programme and its capability of reaching most of the population. In addition, it will help inform on how equitable (in terms of access to vaccines) and how acceptable the programme is to target populations. Data collected at the finest geographical level and in specific subgroups will allow for the identification of areas with low coverage and pockets of susceptible individuals (or specific groups that may pose a risk for the wider community, e.g. healthcare workers).

NPHET will review and report vaccination data at regular intervals and in line with its commitment to transparency will communicate the data publicly. Transparency, which is a key data protection principle (Article 5) is vital for ensuring that all aspects of the vaccination programme are worthy of trust and can promote the necessary solidarity and mutual responsibility needed for a successful strategy. Vaccination uptake will be assessed in an ongoing manner to track the implementation of the programme and acceptance of the vaccination in the populations targeted in line with the prioritisation framework. Monitoring of the uptake by population group may be done where it is possible to obtain denominator data (e.g. census data for different age groups).

Where denominators are not readily available, estimates will be made based on estimates of populations at risk. Analysis will be carried out on uptake by demographic characteristics, such as gender, age, area of residence, HSE region (LHO and CHO), workplace settings for HCWs (University hospital groups, hospitals, long-term care facilities, primary care sites), occupational or clinical risk group. Data obtained on vaccination will also be monitored at individual, target group, and population level, including specific vaccines administered, number of 1st doses and 2nd doses received, and calculation of completed vaccinations (1st and 2nd dose, if appropriate, and 'DNAs', who do not attend for scheduled appointments or who do not complete the required vaccination schedule (dual dose).

6.2 Children

Children aged 16-17 with underlying conditions that place them at very high risk of serious disease should they contract Covid-19 will be vaccinated (they will be vaccinated with Pfizer, the only EMA approved vaccine for under 18s). This cohort (which is part of cohort 4), will be vaccinated in a hospital setting. They will be referred by their care team and an appointment scheduled, and their personal data will be captured as part of the vaccine administration process.

The Vaccine will not be administered more broadly to under 18s at this moment and therefore not considered under review for this DPIA.

7. Stakeholder Engagement

Stakeholder engagement has been conducted to support and inform the development and deployment of the Vaccine Information Solution as part of the ongoing Covid-19 vaccine rollout project. The purpose of these consultations is to ensure the application is configured to reflect the clinical, operational, public health and reporting requirements that underpin the Covid-19 vaccination rollout. From a development perspective, the following considerations were addressed: system functionality, appropriate use of data, information security, accessibility.

Due to the time constraints regarding the roll out of the vaccine, a consultation process was not conducted with the public. The list of stakeholders involved in the covid-19 vaccination rollout process are listed in Section 3.1.

8. Compliance with data protection law and other regulatory guidance

The following sets out the lawful bases for the processing of personal data identified in Section 4 of this document. The processing activity is included in brief for convenience.

8.1 Lawful basis for processing of personal data in the Immunisation Programme

The administration of Covid-19 vaccines to individuals will involve the processing of the individual's personal data and special categories of personal data. While individuals must provide their consent to receive the Covid-19 vaccine, this consent is in the form of 'medical consent'. Consent as outlined under Articles 6 and 9 of the GDPR is not used as a lawful basis by the vaccination programme to process an individual's personal data.

The following lawful basis in Article 6 and Article 9 of the GDPR are appropriate to and suitable for the purposes of processing personal data for the vaccination programme.

Article 6 (Lawfulness of processing)

-Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller (Article 6.1(e); (processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller).

Article 9 (Processing of special categories of personal data)

-Processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3 (Article 9.2(h)); (Paragraph 3 provides that personal data processed for the purposes referred to in point (h) must be processed by or under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies or by another person also subject to an obligation of secrecy under Union or Member State law or rules established by national competent bodies).

-Processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy (Article 9.2(i));

Processing of Special Category Data

Data collected and processed for the purpose of the COVID-19 Vaccination Programme will only be shared

on a strict need-to-know basis for specific purposes relating to the management of the programme.

The data will only be accessed by:

- HSE staff involved in pre-vaccination, vaccine administration, and post vaccination tasks as well as general management of the programme;
- External professionals such as GPs and Pharmacists in relation to their patients;
- Service Providers (Section 38 agencies) administering vaccines;
- External suppliers for the purposes of managing and maintaining IT systems;
- Health Products Regulatory Authority for the purposes of monitoring vaccine safety;
- Other Government agencies for the purposes of preparing anonymised statistical reports.
- CSO for statistical purposes
- Private Hospitals administering vaccines

The HSE aims to ensure the highest level of safeguards regarding all personal and special category data that it processes in relation to the vaccine programme.

In addition to being fully compliant with GDPR and data protection legislation, the HSE ensures appropriate levels of professional secrecy and operates to the highest standards of ethical behaviour in relation to its data processing.

8.2 Legislative Framework

The proposed data processing relates to all individuals in the Republic of Ireland that are administered the COVID-19 vaccination by the HSE.

- Data will be collected on individuals through each phase of the vaccine administration process. This includes during registration, the vaccination event and aftercare.
- Data will also be collected on administrators of the vaccine; the vaccination venue and additional data will be collected for healthcare staff that receive the vaccine.

While the lawful basis for the processing of personal data for the vaccination programme is detailed in Article 6 and Article 9 of GDPR, it is helpful to set out legislative provisions that also support such processing by the HSE in carrying out its statutory functions under the Health Act 2004 as amended.

- a) Covid 19 is one of the diseases prescribed as an infectious disease (and scheduled in the Infectious Diseases Regulations 1981 (SI 390/1981) (as amended) by virtue of the Infectious Diseases (Amendment) Regulations 2020 (S.I. No. 53/2020).

- b) Section 31 of the Health Act 1947 provides for the making of Regulations inter alia for:

“providing for the prevention of the spread (including the spread outside the State) of an infectious disease or of infectious diseases generally and for the treatment of persons suffering therefrom and the regulations may, in particular, provide for any of the matters mentioned in the Second Schedule to this Act”

and the concept of “preventing the spread (including the spread outside the State) of an infectious disease or infectious diseases generally”, includes the concept of immunisation and vaccinations.

- c) The Infectious Diseases Regulations 1981 (SI 390/1981) is a Regulation which records as its lawful basis section 31 of the Health Act 1947. Regulation 10(1) of the 1981 Regulations provides that a “Health Board (HSE) shall make arrangements for the diagnosis and treatment of infectious diseases in persons in the functional area of that health board”
- d) Regulation 13 of the 1981 Regulations provides:

“(1) The Health Service Executive may, from time to time, in accordance with the advice of a medical officer of health and shall, if required by the Minister, do all or any of the following things: –

 - (a) purchase and keep a supply of such agents and ancillary instruments and equipment as may be approved by the Minister for ascertaining whether or not a person is infected with an infectious disease or for determining susceptibility to or for increasing resistance against or for producing immunity from infection with any infectious disease;
 - (b) make, subject to the Minister's approval, arrangements for the administration of any such agent to persons in each functional area of the Health Service Executive.
- e) Section 7 (Objects and functions of the Executive) of the Health Act 2004 provides in subsection (1) that “the object of the Executive is to use the resources available to it in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public”
- f) Section 2 of the Health Identifiers Act 2014 provides for the processing (collecting, using, storing and sharing) of the IHI and its identifying particulars for primary and secondary purposes by specified persons (mainly health services providers, including the HSE) and by authorised discloses (which includes the CSO) for secondary purposes.
 - i. “primary purpose” means the present, past or future provision of a health service to an individual;
 - ii. “secondary purpose” includes the identification or prevention of a threat to public health, the management of health services, the performance of any function conferred on a person under the 2014 Act or another enactment for which the processing of identifiers is necessary.
- g) Sections 38 (Processing for a task carried out in the public interest or in the exercise of official authority) and 49 (Processing of special categories of personal data for purposes of administration of justice and performance of functions) of the Data Protection Act 2018 allow the HSE to process such personal data as is necessary and proportionate for its functions and those functions include provision of care, combatting public health threats and health services management.
- h) Regulation 20 of the Infectious Diseases Regulations 1981 provides that “a Health Board shall keep such records as may be directed by the Minister from time to time in relation to the exercise of its powers and the performance of its duties under these Regulations”.

The following sets out the lawful basis for the processing of personal data identified in Section 4 of this document. The processing activity is included in brief for convenience.

8.3 Exercise of Data Subject Rights

Under certain circumstances, by law you have the right to

- **Right of access** – you have the right to request a copy of the information that we hold about you.
- **Right of rectification** – you have a right to correct data that we hold about you that is inaccurate or incomplete.
- **Right to be forgotten** – in certain circumstances, you can ask for the data we hold about you to be erased from our records, this does not usually apply to health care records and is not an absolute right.
- **Right to restriction of processing** – where certain conditions apply to have a right to restrict the processing.
- **Right of portability** – where certain conditions apply, you have the right to have the data you have provided to us in a structured, commonly used and machine-readable format, transferred to another organisation.
- **Right to object** – you have the right to object to certain types of processing such as direct marketing, however, please be assured that we will not be using your data for direct marketing.
- **Right to object** – including profiling – which produces legal effects concerning you or similarly significantly affects you. However please note that our IT systems will not be making decisions based on automated processing.
- **Right to review** – in the event that the HSE refuses your request under rights of access, we will provide you with a reason as to why. You have the right to complain as outlined below.

If you wish to exercise any of these rights, then please submit a request, to the relevant deputy Data Protection Officer. These details are available in Appendix C.

When submitting a request, the HSE may need information from you to confirm your identity.

Once your identity has been confirmed, the HSE will supply you with your information free of charge, however, we may charge a reasonable fee if we believe your request is clearly unfounded, excessive or repetitive.

8.4 International Transfers

Both IBM and Salesforce are providing support of the Vaccine Information System from outside the EEA. In compliance with the GDPR, the HSE and IBM and/or IBM and Salesforce have entered into the appropriate arrangements as set out in Chapter 5 of the GDPR in order to facilitate the transfer and/or processing vaccine data outside the EEA.

8.5 Appointment of Data Processors

All of the data processors are appointed under Data Processors Agreements in compliance with Article 28 of the GDPR.

8.6 Technical & Organisational Measures

The HSE, IBM and Salesforce have each implemented a number of technical and organisational measures to protect the integrity, availability and confidentiality of the Vaccine Information System.

The Vaccine Information System servers are hosted on the secure Salesforce Cloud and within Salesforce data centres within the European Economic Area (EEA).

The Vaccine Information System servers and the Salesforce Cloud are protected by a multitude of security controls including, server hardening, network firewalls, Intrusion Detections Systems (IDS), File Integrity Monitoring, anti-virus and malicious software protection, network traffic monitoring, network redundancy, automatic replication of data onto a secondary site and all transmissions between the HSE network and the Salesforce Cloud are encrypted via Transport Layer Security (TLS).

HSE, IBM and Salesforce each have their own comprehensive set of IT security policies which are applicable to each organisation respective employees. All access to the Vaccine Information System by the HSE employees and third parties is granted and managed in accordance with the HSE IT security policies.

IBM are ISO 27011 certified and Salesforce are ISO 27001, ISO 27017 and ISO 27018 certified.

9. Identify and Assess Risks

The table below sets out the risks that have been identified for the project and the levels for those risks if not mitigated. Overall risk score for each risk identified is calculated as the product of the risk likelihood score and the risk impact score (i.e. likelihood score X impact score). The following sets out the metrics used in documenting the risk assessment.

Likelihood	Score	Impact	Score	Overall	Score
Highly Unlikely	1	Negligible	1	Low	1 - 7
Unlikely	2	Minor	2		
Possible	3	Moderate	3	Medium	8 - 14
Likely	4	Major	4		
Highly Likely	5	Critical	5	High	15 - 25

No.	Risk	Likelihood	Impact	Likelihood Score	Impact Score	Overall Risk
1	Risk of insecure methods of data transfer are used that allow access to patient data, or any other data transferred to the HSE	Likely that attempts will be made to intercept transfers	Patient data from the Vaccine Information System needs to be transferred securely.	4	4	16
2	Risk of the system being hacked to obtain patient information.	Likely that attempts will be made to hack into the system.	Patient data from the Vaccine Information System needs to be held securely with the appropriate encryption at rest.	4	4	16
3	Users are not given sufficient information about how the system works, what data will be collected and for what purpose in a comprehensive way	The requirement to have excellent communications about the system is understood	If the transparency information is not provided in a comprehensive way, then this will impact the number of people who will use the system and as consent is used as a lawful basis can lead to it not being given without being fully informed	3	5	15
4	Risk that patient information has not been updated on the system (contact details, personal address)	It is likely that there will be occasions where the information provided by the patient needs to be updated.	There may be an increased clinical risk here if an individual is deemed vulnerable or 'high risk' should they contract Covid-19 and miss an immunisation.	4	3	12
5	Non-compliance with the relevant data protection legislation or other legislation can lead to sanctions, fines and reputational damage.	It is likely that there will be some level of non-compliance with the relevant data protection legislation.	This could undermine the credibility of the HSE, causing reputational issues, litigation and thus financial penalty.	4	3	12
6	The context in which information is used or disclosed can change over time, leading to it	It is possible that the information is used for different purposes.	If the transparency information is not provided in a comprehensive way,	3	4	12

	being used for different purposes without people's knowledge.		then could cause reputational damage and mistrust of the system.			
7	The sharing and merging of datasets can allow organisations to collect a much wider set of information than individuals might expect.	It is possible that shared information could allow organisation to collect a much wider set of information.	Patient data needs to be transferred appropriately with the correct control and policies in place.	3	3	9
8	Vulnerable people may be particularly concerned about the risks of identification or the disclosure of information.	It is possible that vulnerable people may be concerned about data sharing.	It is critical that the HSE treat all personal data of patients with the upmost care.	3	3	9
9	Collecting information and linking Data sets might mean that an organisation is no longer using information which is safely anonymised.	It is possible that personal data may not be appropriately anonymised in process of collecting information.	Systems need to be in place which ensure that patient data from the Vaccine Information System is held securely and anonymised.	3	4	12
10	If a retention period is not established information might be used for longer than necessary.	It is unlikely that information will be held longer than the agreed retention period.	Patient data must be retained in line with the appropriate retention period.	2	4	8
11	There is a risk that users of the Vaccine Information System may accidentally or otherwise access data on the system which they are not authorised to access.	The number of people with open access may be too high.	There is a potential to access information not required.	3	4	12

10. Identify Measures to Reduce Risks

An evaluation of the identified risks in the previous section has been carried out and a series of measures have been detailed that seek to mitigate those risks to an acceptable level. The table below sets out these mitigation measures and an assessment of the risk impact due to their introduction.

No.	Risk	Measures to Mitigate Risk	Likelihood with measures	Impact with measures	Residual Risk	Remaining risk to data subjects
1	Risk of insecure methods of data transfer are used that allow access to patient data, or any other data transferred to the HSE	- Ensure data is encrypted in transit over the network.	1	4	4	Virtually impossible to intercept data if these controls are implemented.
2	Risk of the system being hacked to obtain patient information.	- HSE, IBM and Salesforce have implemented a number of technical and operational measures (please see section 8.6)	1	4	4	Virtually impossible to intercept data if these controls are implemented.
3	Users are not given sufficient information about how the system works, what data will be collected and for what purpose in a comprehensive	- Implement a communications plan to inform people about the system, what it does and what data is processed	1	1	1	Correct implementation of all mitigations leaves little risk to data subjects
4	Risk that patient information has not been updated on the system (contact details, personal address)	- Specific training on the system is available in an ongoing basis and is updated as required. Hypercare support is available to sites when they first go live and a network of superusers is being set up.	2	2	4	With good training and processes in place any changes in details can be managed by the vaccinators to ensure the system is updated.

5	Non-compliance with the relevant data protection legislation or other legislation can lead to sanctions, fines and reputational damage.	<ul style="list-style-type: none"> - All HSE users are required to complete data protection training. -All data processors have entered into GDPR compliant data processing agreements with the HSE -All transfers of personal data outside the EEA are covered by the appropriate GDPR agreements 	2	2	4	There will be rigorous data protection training Third parties have to adhere to appropriate Data Processing Agreements
6	The context in which information is used or disclosed can change over time, leading to it being used for different purposes without people's knowledge.	- The DPIA covers the scope of administering vaccine to individuals and the associated data capture mechanisms. As the programme evolves, there are likely to be continued changes to the distribution strategy, the operating model and associated processes and the underlying technology solutions supporting the programme. Any material changes will be reflected in an updated version of the DPIA and communicated appropriately with the public.	1	2	2	Correct implementation of all mitigations leaves little risk to data subjects
7	The sharing and merging of datasets can allow organisations to collect a much wider set of information than individuals might expect.	- Third parties who receive the data have signed agreements which set out the lawful basis in which they can process the data.	2	2	4	With compliance to the DPA's there is lower risk.
8	Vulnerable people may be particularly concerned about the risks of identification or	- Implement a targeted communications plan to inform people about the system, what it does and what data is processed	1	1	1	Correct implementation of all mitigations leaves little risk to data subjects

	the disclosure of information.	-Extensive vaccine related information is available on the HSE website.				
9	Collecting information and linking Data sets might mean that an organisation is no longer using information which is safely anonymised.	- Data sets will not be linked on the Vaccine Information system. -For third parties (GPs/ Pharmacists), there are appropriate agreements in place on the sharing of patient data.	2	2	4	Correct implementation of all mitigations leaves little risk to data subjects
10	If a retention period is not established information might be used for longer than necessary.	- Data collected and processed on the HSE Vaccine Information System shall be retained in accordance with the HSE Record Retention Policy or as long as legally required. - It is intended that data in relation to an individual's vaccination will be held in perpetuity	1	3	3	Low risk with the implementation of the retention schedule.
11	There is a risk that users of the Vaccine Information System may accidentally or otherwise access data on the system which they are not authorised to access.	- The HSE is in the process of developing a role-based access control regime for the Vaccine Information System.	2	2	4	Low risk with the implementation of access policy.

11. Sign off and Record Outcomes

Item	Name/Date	Notes
Risk measures approved by:	Lucy Josephine Jessop- Business Owner Fran Thompson- System Owner	
Residual risks approved by:	Lucy Josephine Jessop- Business Owner Fran Thompson- System Owner	
HSE DPO advice provided:	Jim O’Sullivan (HSE DPO)	<p>“I have reviewed the second version of the DPIA for the COVID-19 Vaccination Information System and have engaged extensively with officials from the Office of the Chief Information Officer and the National Immunisation Office on relevant elements.</p> <p>I am satisfied that the revised version provides an appropriate update on developments in the system and processes that have occurred since the original DPIA was completed including details on the registration portal and the additional technical and operational control arrangements implemented.</p> <p>I acknowledge that the roll-out of the vaccine programme is dynamic and evolving in nature and that additional DPIAs will be required for the Pharmacy solution and Vaccination Certificates. These are currently underway and will be completed in due course.</p> <p>While my preference from a data protection perspective would be for a single application to cover all information aspects of the vaccination programme, I have been advised that as part of the overall governance of the process, it has been agreed that a separate Pharmacy system is the most effective solution.”</p>
DPO advice accepted or overruled by:	Lucy Josephine Jessop- Business Owner Fran Thompson- System Owner	
This DPIA will be kept under review by:	Lucy Josephine Jessop- Business Owner Fran Thompson- System Owner	

Appendix A - Governance

Covid-19 Immunisation Executive Oversight

1. Background:

The COVID-19 pandemic is an ongoing global crisis and key to the suppression and ultimately to the elimination of COVID-19 is the development of a safe and effective vaccine.

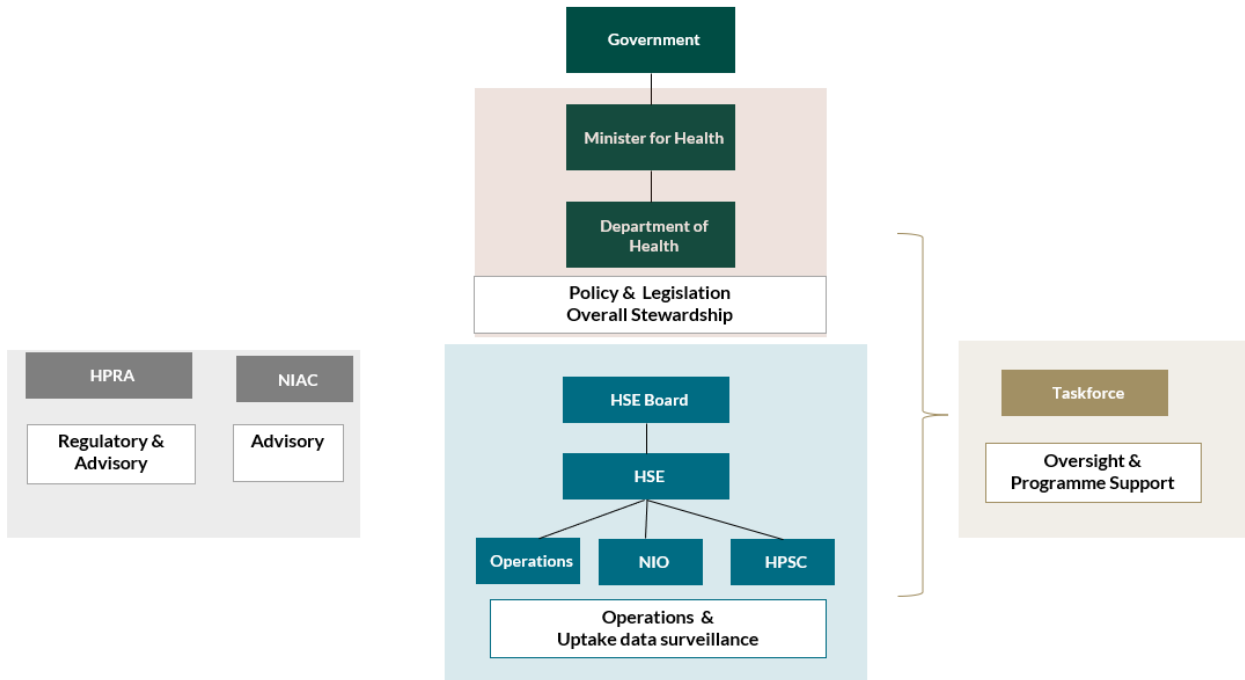
At national level, the development of a clearly defined governance and decision-making process is recognised as essential to the success of the national vaccine implementation programme. To that end, there will be a single, integrated work programme and plan and a single, robust and integrated programme governance structure. There will also be a clear apex of accountability for the implementation of the programme, with unambiguous responsibility for decision-making across all workstreams. A High-Level Taskforce on COVID-19 Vaccination (the “Task Force”) under the leadership of Professor Brian MacCraith was established and reports directly to the Department of the Taoiseach. The objective of the HLTF was to develop a strategy and implementation plan and to monitor the roll-out of a safe, effective, efficient and agile national COVID19 immunisation programme that plays a central role in Ireland’s exit from the pandemic.

The Task Force is supported by a Programme Management Office that has developed an integrated programme plan with seven key work streams;

- A. Governance and Operating Model;
- B. Population Definition and Sequencing;
- C. Public Engagement and Communication;
- D. Vaccine Supply and Chain Logistics;
- E. Vaccination Process and Workforce;
- F. Surveillance Monitoring and Reporting;
- G. Enabling Technology and Information.

The HSE provides leadership for workstreams D-G.

The implementation of the Strategy will rely in the normal way on the governance structures and statutory responsibilities of a range of existing bodies. However, there will be a need to augment and support existing arrangements given the range of responsibilities, actors and the responsiveness that will be demanded as the programme rolls out. The figure below shows the roles and responsibilities which are not replaced or displaced, but which will be supported by oversight role and programme management support of the High Level Task Force.



2. Role and Purpose:

The HSE CEO has convened a number of EMT members to establish the **HSE COVID-19 Immunisation Executive Oversight Group**. The Group will provide oversight to the COVID-19 Immunisation Programme, receive regular progress reports from the COVID-19 Immunisation Programme Implementation Working Group and provide assurance to the HSE on the progress of the Immunisation Programme implementation. The Implementation Working Group is supported by a programme office and working in coordination with the Task Force is tasked with the development and delivery of integrated plans for each cohort in line with the agreed national COVID-19 vaccination strategy and overarching implementation plan. The COVID-19 vaccination programme is clinically led and CCO and the Implementation Working Group are supported by a Clinical Advisory Support Group (CASG).

The HSE Implementation working group is jointly chaired by the HSE CCO and the Operational Programme Lead. The HSE Oversight Group will be chaired by the Chief Executive Officer who is also a member of the Task Force on COVID-19 Vaccination.

3. Membership:

The HSE Oversight Group membership is as follows:

Membership:

1. Paul Reid, **Chair**, Chief Executive Officer, Health Service Executive

2. Anne O'Connor, Chief Operations Officer, Health Service Executive

3. Stephen Mulvany, Chief Financial Officer, Health Service Executive

4. Colm Henry, Chief Clinical Officer, Health Service Executive

5. Fran Thompson, Chief Information Officer (SRO for Enabling Technology & Information Workstream)

6. Dean Sullivan, Chief Planning & Strategy and Planning Officer, Health Service Executive

7. John Kelly, Head of Corporate Affairs, Office of the CEO

In Attendance:

1. Sean Bresnan, SRO for Vaccine Supply Chain and Logistics Workstream

2. Lorraine Doherty, National Clinical Director for Health Protection, Health Service Executive

3. David Walsh, SRO for Vaccine Process and Workforce Workstream

4. John Cuddihy, SRO for Surveillance, Monitoring and Reporting Workstream

5. Deirdre McNamara, Director of Strategic Programmes, OCCO

6. Lucy Jessop, Director National Immunisation Office

7. Brian MacCraith, Head of the HLTF

8. Derek Tierney, Assistant Secretary Dept. of Justice seconded onto the HLTF as lead

9. Damien McCallion, Operational Programme Lead, HSE National Director Emergency Management & Director General CAWT

The group may, if circumstances require, co-opt other relevant experts throughout the duration of the project.

4. Objectives:

4.1. Oversee, monitor and support the progress of the HSE Implementation Working Group to plan and implement the COVID-19 Immunisation Programme in coordination with the High-Level Task Force on COVID-19 Vaccination and its delivery in line with the agreed national COVID-19 vaccination strategy and implementation plan.

4.2. Provide assurance to the HSE Board regarding the planning and implementation of the COVID-19 Immunisation Programme and its progress in line with the agreed COVID-19 vaccination strategy and implementation plan.

4.3. Consider and interrogate the information provided by the Implementation Working Group to ensure all objectives of the implementation plan are met.

4.4. Act as the escalation point for decisions and issues which cannot be resolved by the COVID-19 Implementation Working Group.

5. Meetings:

5.1. The HSE COVID-19 Immunisation Oversight Group will meet weekly and as required throughout the planning and implementation phases of the Programme.

6. Meeting Documentation:

6.1. Meeting papers, agenda and minutes will be prepared by the Office of the CCO and programme management structure and will be circulated electronically in advance of meetings.

6.2. Minutes will contain Actions and Decisions only. If required, additional discussion items will be included.

7. Governance

7.1 The COVID Immunisation Executive Oversight Group will report directly to the Board of the HSE.

Appendix B – Data Minimisation

The Vaccine Information system has been designed in a manner to minimise the amount of personal data processed in order to fulfil its defined purposes. The following are design approaches that highlight putting the principle of data minimisation into effect.

- The Vaccine Information System, via secure sign-in, and IT/network security standards already established for the Vaccine Information system, will allow secure, dynamic data recording at the point-of care, by on-site administrators (rather than centralised teams) and vaccinators. Patient vaccine data will almost instantly enter the database within any vaccination setting and will be shareable with all healthcare staff that require access to vaccination information for the patient via the security models already in place for the relevant clinical systems e.g. GP IT systems. The system will only capture patient vaccination and health data in relation to the administration of the vaccine. It will not access or capture any other personal or health related data.
- The retention period for all personal data is set out in Section 5.4 of this document and has been carefully examined to be only as long as is necessary for the fulfilling of its purpose.

Appendix C – Data Protection Officer and Deputy Data Protection Officers Contact Details

Contact Details for Data Protection Staff⁵ are as follows:

Data Protection Officer (DPO) HSE	Email: dpo@hse.ie Telephone: 087 - 908 2160
Deputy Data Protection Officer West (excluding voluntary agencies) <ul style="list-style-type: none"> • CHO 1 – Cavan, Donegal, Leitrim, Monaghan, Sligo • CHO 2 – Galway, Mayo, Roscommon • Mid-West Community Healthcare • Saolta Hospital Group 	Email: ddpo.west@hse.ie Telephone: 091-775 373
Deputy Data Protection Officer Dublin North-East (excluding voluntary hospitals and agencies) <ul style="list-style-type: none"> • Midlands, Louth, Meath Community Health Organisation • Community Health Organisation Dublin North City & County • CHO 6 – Dublin South East, Dublin South & Wicklow • RCSI Hospital Group 	Email: ddpo.dne@hse.ie Kells Office: 046-9251265 Cavan Office: 049-4377343
Deputy Data Protection Officer Dublin mid-Leinster (excluding voluntary hospitals and agencies) <ul style="list-style-type: none"> • Dublin Midlands Hospital Group • Ireland East Hospital Group • Community Healthcare Dublin South, Kildare & West Wicklow 	Email: ddpo.dml@hse.ie Tullamore Office: 057-93 57876 Naas Office 045-880496
Deputy Data Protection Officer South (excluding voluntary hospitals and agencies) <ul style="list-style-type: none"> • Cork & Kerry Community Healthcare • CHO 5 – Carlow, Kilkenny, South Tipperary, Waterford & Wexford • UL Hospital Group • South South-West Hospital Group 	Email: ddpo.south@hse.ie Cork Office 021-4928538 Kilkenny Office 056-7785598

⁵ <https://www.hse.ie/eng/gdpr/data-requests/data-protection-officer-and-deputy-data-protection-officer-contact-details.html>