

For posting on the Global Collaboration for Public Health Initiative Area of the LHC Website

The Global Information for Public Health Transformation (GIPHT)

A standard for COVID-19 vaccination data

Every day more people across the globe are receiving vaccinations to protect them from COVID-19. Any one of us may need to show proof that we have received these vaccines, which ones and on what dates we received them, when we travel abroad, and sometimes locally to access buildings and events. We may also need to show this information to our health professionals if they don't already have this. Every country has raced to create something like a vaccination certificate app that carries information about your vaccination status that can be shared with relevant authorities if you agree to show this. The problem is that countries have chosen different data structures and codes to document the COVID-19 vaccinations given in their country, and companies are collecting and storing vaccination data in different ways on apps and databases. This will make it increasingly difficult for vaccination data to be exchanged between countries, which may be needed for authorization to travel. This data is also importantly needed by research teams to study the effectiveness and the safety of the different vaccines that are being given across the world.

We need a vaccine data standard!

An international standard for the data that documents the administration of COVID-19 vaccinations was published in June 2021. This standard built on vaccination data structures that had been developed by the World Health Organisation, by the European Commission and by other bodies. It harmonises their different data structures into a single universal format. This standard has been published, is openly available, free to all. We now need to encourage everyone around the planet to utilise this standard rather than having our data stored in different incompatible formats by different countries and on different apps.

You can read more about the way in which the standard was developed, including the organisations that were involved and what the standard does, [here](#).

If you would like to download a copy of the standard yourself, you can find it [here](#).

CDISC Vaccine Administration Standard V1.0

As many emerge from being homebound during the Covid-19 pandemic, there is incentive to be able to prove in certain cases whether individuals have been fully vaccinated. One key use case is international travel. The European Commission has announced a Digital Green Certificate that is intended to facilitate safe travel among EU members countries using data elements recommended by the European eHealth Network. The Vaccine Credentialing Initiative and the Global Health Pass group are also working to address this use case. Many technology developers are creating apps that will enable digital vaccine 'passports'. Although there are many issues that must still be addressed, including privacy, security, ethics and ubiquitous access, one key requirement for facilitating the valid exchange of the necessary data to support these applications is broad adoption of an international data standard for interoperability of core data elements related to vaccine administration.

Considering the urgency during the global COVID-19 pandemic, the Learning Health Community's Global Initiative for Public Health Transformation (GIPHT) Initiative and the global standards development

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The Global Information for Public Health Transformation (GIPHT) organization, Clinical Data Interchange Standards Consortium (CDISC) have partnered to develop the V1.0 Vaccine Administration Standard.

The core elements were identified by referencing a) the eHealth Network Guidelines for proof of vaccination for medical purposes - basic interoperability elements; b) corresponding CDC-endorsed data elements posted by the American Immunization Registry Association; c) the EU Digital Green Certificate documentation; and d) the WHO Interim Guidance for Developing a Smart Vaccine Certificate (SVC).

These core data elements were then mapped/pointed to prevailing global standards from Clinical Data Interchange Standards Consortium (CDISC); Health Level 7 (HL7) and the International Standards Organization (ISO), ICD 10/11, SNOMED CT, WHODrug and the ATC Classification to create the Vaccine Administration Standard v1.0. The result can effectively ensure that data can flow efficiently and comprehensively among various applications that implement this standard. Global adoption will support safe and efficient global travel.

Vaccine Administration v1.0 – Mapping Curation

Developed in collaboration with
LEARNING HEALTH COMMUNITY
cdisc
Vaccine Administration v1.0 (Final)
Mapping Curation of Interim Data Elements and Metadata from Interoperability Elements
Harmonized in Collaboration with the Learning Health Community
CDISC, HL7, ISO, SNOMED CT, WHODrug, and ATC Classification
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Rationale & Goals

- Use case – International Travel
- Urgent need - global COVID-19 pandemic
- Support emerging applications with an international data standard for interoperability of core data elements and underlying metadata related to vaccine administration
- Harmonize a set of core vaccine administration data elements
- Deliver a short readily implementation standard that leverages and maps to available and widely used data standards and terminologies
- No new standards
- Follow endorsed governance process.

Activities

Harmonize a set of 20 core elements

- Based on European eHealth Network – Guidelines for proof of vaccination for medical purposes - basic interoperability elements

Align with:

- US CDC Endorsed Data Elements
- Digital Green Certificate
- WHO Interim Guidance for Developing a Smart Vaccine Certificate (SVC)

Map/point to:

- CDISC
- HL7-FHIR
- ISO Standards
 - ISO 8601
 - ISO 3166
 - IDMP
- ICD 10/11
- SNOMED CT
- WHODrug
- ATC Classification

Develop a CDISC Vaccine Administration v1.0 and mapping spreadsheet

Core Data Elements*

- **Vaccination Information**
 - Disease or agent targeted
 - Vaccine/Prophylaxis
 - Vaccine medicinal product
 - Marketing Authorization Holder
 - Manufacturer
 - Number in a series of vaccinations/doses
 - Batch/lot number
 - Date of Vaccination
 - Administering center
 - Health Professional identification
 - Country of vaccination
 - Next vaccination date
- **Patient Identification Information**
 - Person Name: First and last
 - Person Identifier
 - Sex/Gender
 - Date of Birth
- **Certificate Metadata**
 - Certificate issuer
 - Certificate Identifier
 - Certificate Valid from
 - Certificate Valid until

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*Source: eHealth Network, Guidelines on proof of vaccination for medical purposes - basic interoperability elements, V2, March 12, 2021. Retrieved from: https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

Photo by National Cancer Institute on Unsplash

Figure 1: Vaccine Administration v1.0 Project Summary

About CDISC

CDISC is a global non-profit charitable organization with over 500 member organizations from 30 countries. CDISC is incorporated as a 501(c)3 in the state of Massachusetts with an office in Austin, Texas and employees based in the US and Europe. CDISC Europe Foundation is based in Brussels, Belgium. CDISC Coordinating Committees (3Cs) strengthen international relationships in the EU, Japan, Asia Pacific and Korea and CDISC User Networks are located in Asia, Africa, EU, North America. These Networks discuss standards updates and developments, share implementation and learning experiences, participate in public review, and circulate feedback and new ideas to CDISC.

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CDISC standards are required for electronic submissions of study data to the US FDA [15] and Japan's PMDA [16] and are recommended by China's NMPA [17] regulators. In the European Union regulators, in rare instances where subject level data is requested [18], they also recommend the use the CDISC standards. EMA also incorporated CDISC requirements for eSource Data Interchange into their field auditor guidance. EMA and PMDA have provided input into the development of CDISC Therapeutic Area Standards through the Coalition For Accelerating Standards and Therapies (CFAST), which also included the Critical Path Institute and TransCelerate.

CDISC Europe Foundation has participated in a number of projects of the Innovative Medicines Initiative (IMI) in Europe, including EHR4CR, eTRIKS, Conect4children (a collaborative network for European Clinical trials) and DRAGON, (a consortium to secure AI imaging-based diagnosis, stratification, follow-up, and preparedness for coronavirus pandemics). CDISC has also provided courses on the CDISC standards to IMI members.

In the United States, CDISC has formed alliances across the National Institutes of Health (NIH) including a long-standing collaboration with the National Cancer Institute (NCI); National Institute of Allergy and Infectious Diseases (NIAID), which has used CDISC standards for pharmacovigilance studies and meta-analyses and requires them for new HIV research protocols; the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which was part of the consortium that developed CDISC's polycystic kidney disease consortium referenced above; the National Institute of Neurological Disorders and Stroke (NINDS), which has contributed common concepts to our Therapeutic Area (TA) standard development in collaboration with NCI; and The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), which developed pediatric controlled terminologies managed by the NCI's Enterprise Vocabulary Services (EVS) team.