2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Harmonizing Health and Research Data: Extending the IPS for Europe's EHDS Future

Peter Casteleyn, Clinical Data Strategy Advisor, i~HD
John Owen, Senior Director, Standards Operations, CDISC

Speakers

Peter Casteleyn
Clinical Data Strategy Advisor
i~HD

John Owen
Senior Director
CDISC

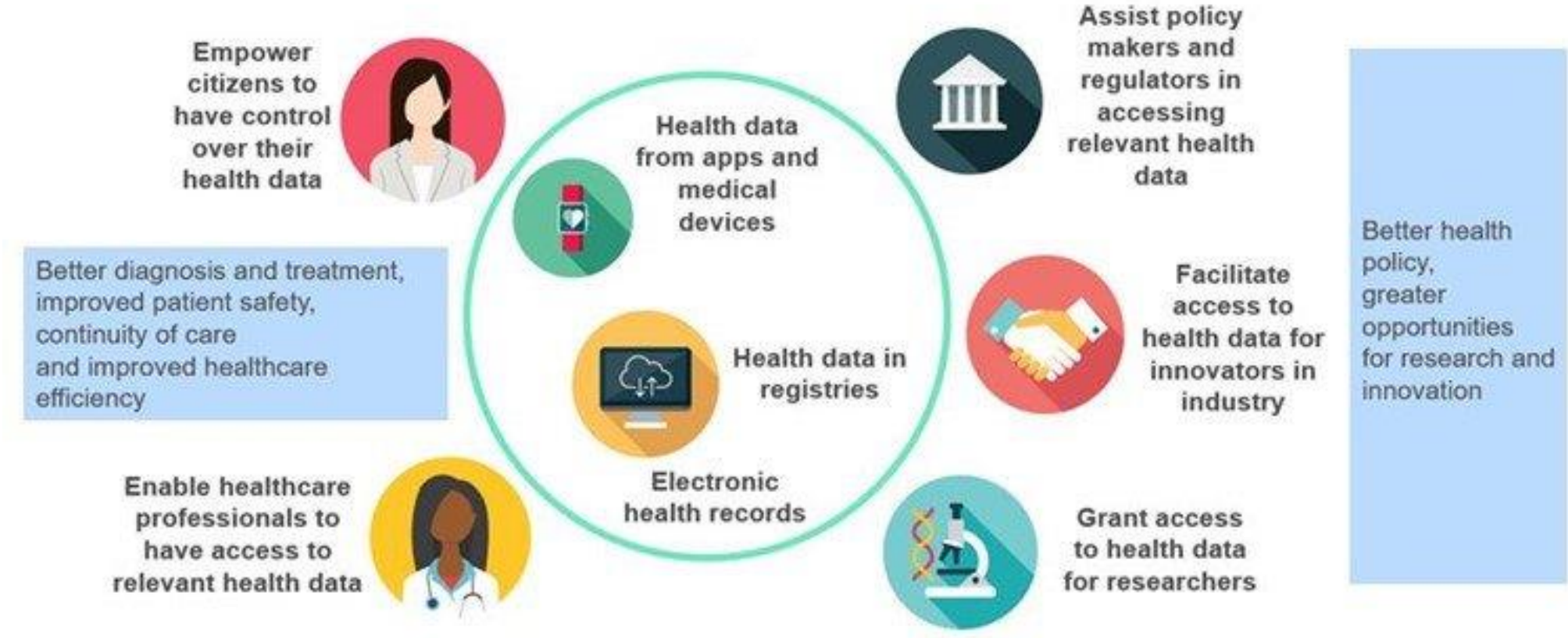
Agenda

1. Introduction to XShare
2. How CDISC standards have been incorporated into XShare
3. XShare open calls

Introduction to xShare

Subtitle

The European Health Data Space
Unlocking the future of health data in Europe (March 6, 2025)



The three pillars of xShare

The “Yellow button”

Everyone can **share their health data** in EEHRxF with a “**click-of-a-button**”

The Hub

Build a **European EHRxF Standards and Policy Hub** sustainable by design.

The Industry label

Explore the **feasibility** and **value** of an EU xShare Industry label

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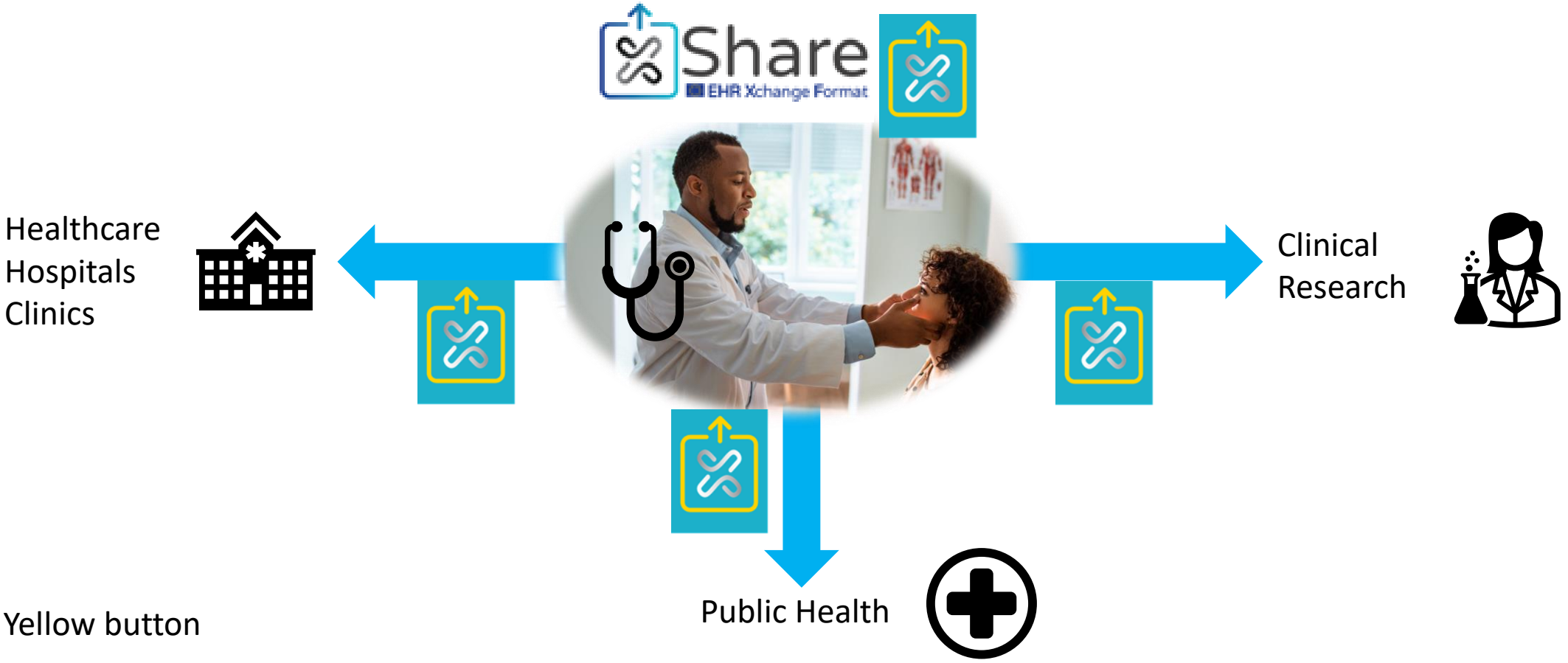
Sharing Data with the xShare Yellow Button

The Patient at the Center Supporting Primary and Secondary use



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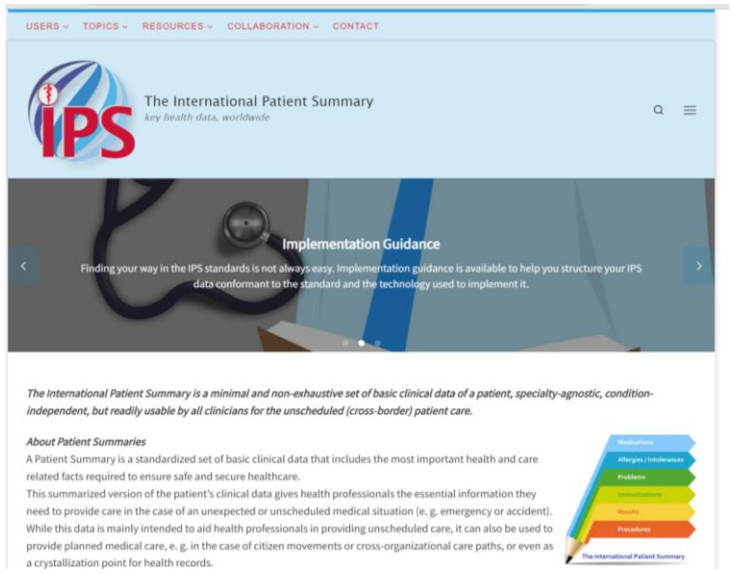
How CDISC standards have been incorporated into xShare

The International Patient Summary +

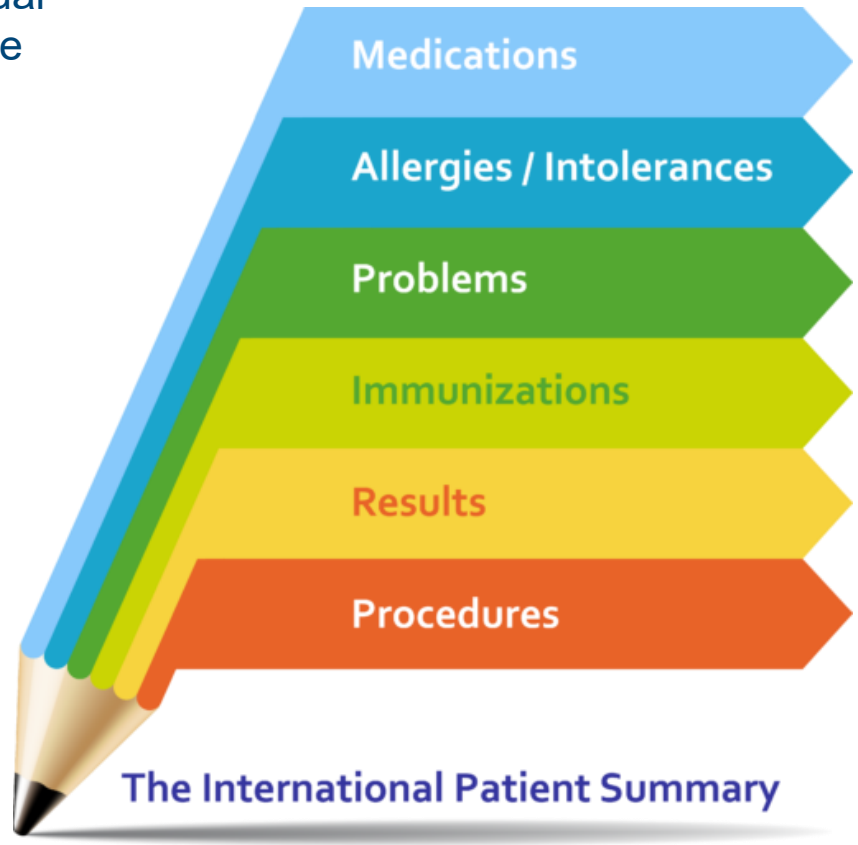
International Patient Summary: the elements

a health record extract comprising a standardized collection of clinical and contextual information (retrospective, concurrent, prospective) that provides a snapshot in time of a subject of care's health information and healthcare.

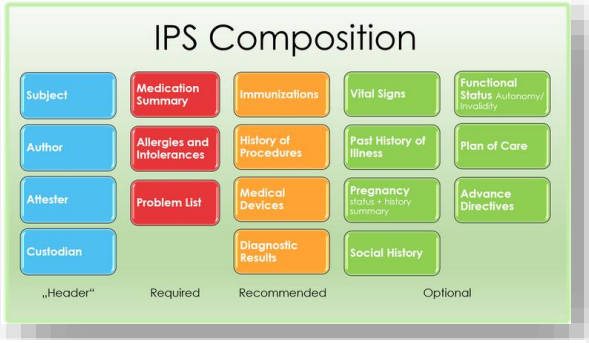
Source: ISO/TR 12773-1:2009 *Business requirements for health summary records — Part 1: Requirements*
https://www.iso.org/standard/51683.html



International-Patient-Summary.net



1) Data Element Sources → 2)Core Element Set → 3) Terminology Assessment



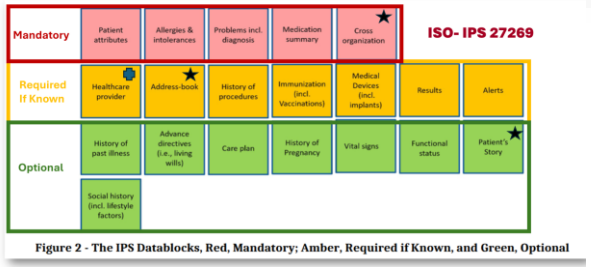
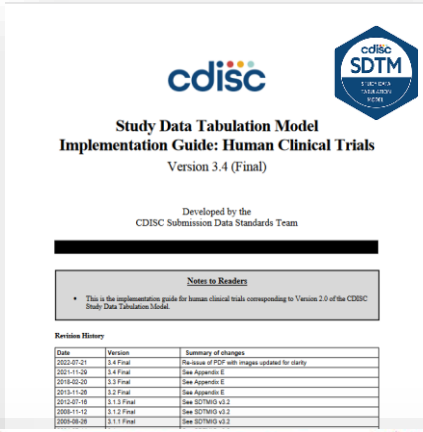
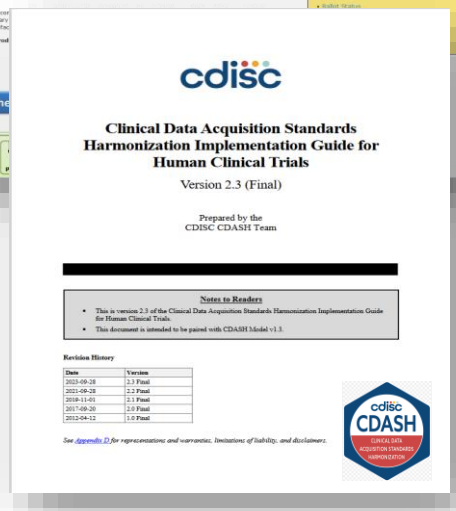
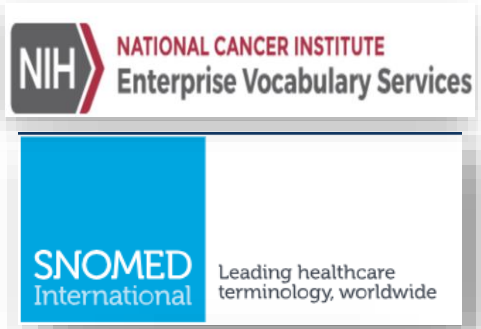


Figure 2 - The IPS Datablocks, Red, Mandatory; Amber, Required if Known, and Green, Optional







Published as the IPS+ data element inventory

Fed into the IPS+ Specification

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xShare vision: Everyone can share their health data in EEHRxF with a click-of-a-button

European Health Data Space

Global Standards

CEN Health Informatic TC251 · HL7 Europe · SNOMED International · IHE Europe · IEEE · cdisc

Global Digital Health Partnership

button

industry label

Industry Driven

DIGITALEUROPE · MedTech Europe from diagnosis to cure · EUCROF European CRO Federation

- Build the European EHRxF standards and Policy HUB sustainable by design: ESHIA
- Examine feasibility of the **xShare industry label** indicating EEHRxF capability

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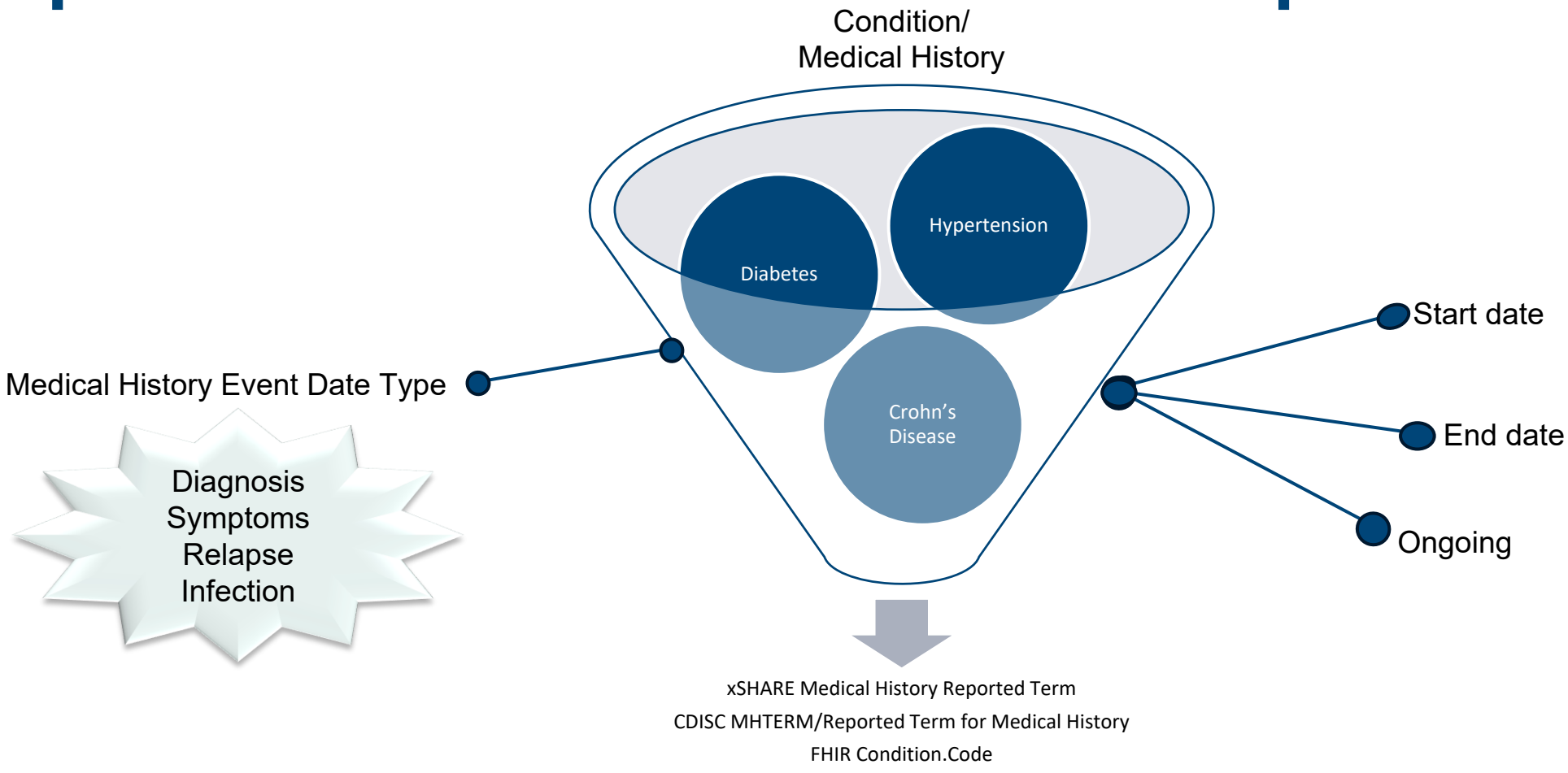
Terminology for Condition/Problem/Medical History Reported Term Data Element Concept



Standard

MHDECOD
=Standardized
terminology

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Title: General Medical History

Indicate if the subject experienced any medical conditions or events. If Yes, include the appropriate details where indicated on the CRF.	Has the subject had any medical conditions or events? MHYN Not Submitted	○ Yes ○ No <*NY codelist*>
	Medical History Category MHCAT *Pre-populated*	Sponsor Defin
Sponsor-Defined CRF Completion Instructions	What is the medical condition or event identifier? MHSPID	
Record all relevant medical conditions or events, as defined in the protocol. Record only one medical condition or event per line. Ensure that the medical conditions or events listed on the Medical History page do not meet any of the exclusion criteria.	What is the medical condition or event term? MHTERM	
Record the start date of the medical event or condition using this format (DD-MON-YYYY).	Start Date MHSTDAT MHSTDTC	
Record the medical condition or event as ongoing (Yes) if it has not ended at the time of data collection; the end date should be left blank.	Is the medical condition or event ongoing? MHONGO MHENRF/ MHENRTPT	○ Yes ○ No <*NY codelist*>
Record the end date of the medical event or condition using this format (DD-MON-YYYY).	End Date MHENDAT MHENDTC	

IPS DE	IPS Comp Cat	CDISC Domain	CDISC Variable	CDISC Variable Label
Diabetes	Problem List	MH	MHTERM; MHDECOD	Reported Term for the Medical History; Dictionary-Derived Term
Hypertension	Problem List	MH	MHTERM; MHDECOD	Reported Term for the Medical History; Dictionary-Derived Term
Chronic obstructive pulmor	Problem List	MH	MHTERM; MHDECOD	Reported Term for the Medical History; Dictionary-Derived Term
Acute myocardial infarctior	Problem List	MH	MHTERM; MHDECOD	Reported Term for the Medical History; Dictionary-Derived Term

FHIR Path Origin	SDTM Variable(s)	MedDRA Code	MedDRA Preferred Term
Condition.code	MHDECOD	10012601	Diabetes mellitus
Condition.onsetDateTime	MHSTDTC		
Condition.code	MHTERM		
Condition.code	MHDECOD	10020772	Hypertension
Condition.onsetDateTime	MHSTDTC		
	MHTERM		
Condition.code	MHDECOD	10009033	Chronic obstructive pulmonary disease
Condition.onsetDateTime	MHSTDTC		

For medical history, the term is as collected. It is then standardized using MedDRA codes.

The question

Condition in SNOMED = 404684003 – Clinical Finding

The answer

What condition =
73211009
Diabetes mellitus (disorder)

Medical History

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IPS-Subject = CDISC Demographics (DM) Subject Characteristics (SC)

- Subject Characteristic /Demographic Item
- Subject Characteristic/Demographic Result
- Collection Date

Demographics/Subject Characteristics – Specific Requested Items:

- Research Subject Identifier
- Research Study Identifier
- Age
  - Age Units
- Birth Date
- Gender/Sex*
- Death
  - Death Date
  - Death Time
  - Subject Death Flag

*Terms not precisely defined

IPS Diagnostic Results = CDISC Laboratory Results (LB); Microbiology Results (MB); Body Systems Findings Domains**

- Diagnostic/Laboratory/Micro Test Name
  - Diagnostic/Lab/Micro Result in Original Units Value
  - Diagnostic/Lab/Micro Original Units
  - Diagnostic/Lab/Micro Test/Specimen Collection Date
  - Diagnostic/Lab/Micro Test/Specimen Collection Time
  - Laboratory/Micro Specimen Type
  - Diagnostic /Laboratory Test Fasting Status
  - Diagnostic/Lab/Micro Test/Specimen Reference ID
  - Lab Ref Range Lower Limit in Original Unit
  - Lab Ref Range Upper Limit in Original Unit
  - Diagnostic/Lab/Micro Test Collection Location
  - Diagnostic/Lab/Micro Test Method of Test/Exam
  - Microbiology Examination Detail

**Body Systems Findings each have specific domain with the same variables (e.g., CVTEST/CVORRES for Cardiovascular).

IPS-Data Element = CDISC Adverse Encounters (AE)

- Allergies and Intolerances
  - Start Date
  - End Date
  - Reaction
  - Manifestation
  - Severity
- Adverse Event Term
  - Adverse Event Start Date
  - Ongoing Adverse Event
  - Adverse Event End Date
  - Adverse Event Severity
  - Serious Criteria Met
  - AE Result in Death
  - Death Date
  - AE Life Threatening
  - AE Hospitalization
  - AE Disability or Permanent Damage
  - AE Congenital Anomaly or Birth Defect
  - AE Needs Intervention to Prevent Impairment
  - AE Other Serious Important Medical Event
  - Action Taken with Study Treatment
  - Outcome

Section Not in HL7 FHIR IPS IG
Essential to research – likely not found in health care records

IPS-Problem List = CDISC Med History (MH)

- Problem/Condition/ MH Event Reported Term
- Medical History Event Collection Date
- Medical History Event Start Date
- Medical History Event End Date
- Hypertension
- Diabetes
- Chronic obstructive pulmonary disease
- Alcohol Abuse
- Drug Abuse
- Allergy

IPS-Medication Summary = CDISC Concomitant Meds (CM)

- Medication/Drug/Product Name
  - Medication Start Date
  - Medication End Date
  - Dose
  - Dose Units
  - Dose Form
  - Dose Frequency
  - Route of Administration
  - Medication Indication

IPS-Vital Signs = CDISC Vital Signs (VS)

- Vital Signs Test Name
- Vital Signs Date
- Vital Signs Time
- Vital Signs Result of Finding in Original Units
- Vital Signs Original Units

IPS Data Element =CDISC Healthcare Encounters (HO)

- Hospital Stay
  - Admission Date
  - Discharge Date
- Healthcare Encounter
  - Reason for Healthcare Encounter
  - Reported Term for Healthcare Encounter
  - Healthcare Encounter Start Date
  - Healthcare Encounter End Date

Section Not in HL7 FHIR IPS IG
ISO IPS and IPS IHE has discharge summary information

IPS-History of Procedures = CDISC Procedures (PR)

- Name of Procedure
- Procedure Start Date
- Procedure Indication
- Ongoing Procedure
- Procedure End Date

IPS Pregnancy status + history summary = CDISC Reproductive Findings (RP)

- Pregnancy Status
- Reproductive Finding Name
- Reproductive Result or Finding in Original Units
- Reproductive Result Original Units
- Reproductive System Finding Date

IPS Social History = CDISC Substance Use (SU)

- Tobacco Use (Smoking Status)
- Alcohol Use
- Name of Substance
- Never/Current/Former Usage
- Substance Dose
- Substance Dose Units
- Substance Use Frequency
- Substance Use Start Date
- Substance Use End Date
- Substance Use Duration
- Substance Use Duration Unit

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xShare Open Call

The IPS+ in action

Purpose of the Open Call for clinical research

- Scope

  Practical implementation of business use cases inspired by the identified BUCs demonstrating the benefits of a wide dissemination of the EHDS standards (EEHRxF, IPS+).

- Who could apply

  All affiliated members of EUCROF, either alone or in consortium with other stakeholders of clinical research such as hospital sites involved in clinical research or networks of hospital sites or other academic players, private players (pharma, biotechs, medtechs …).

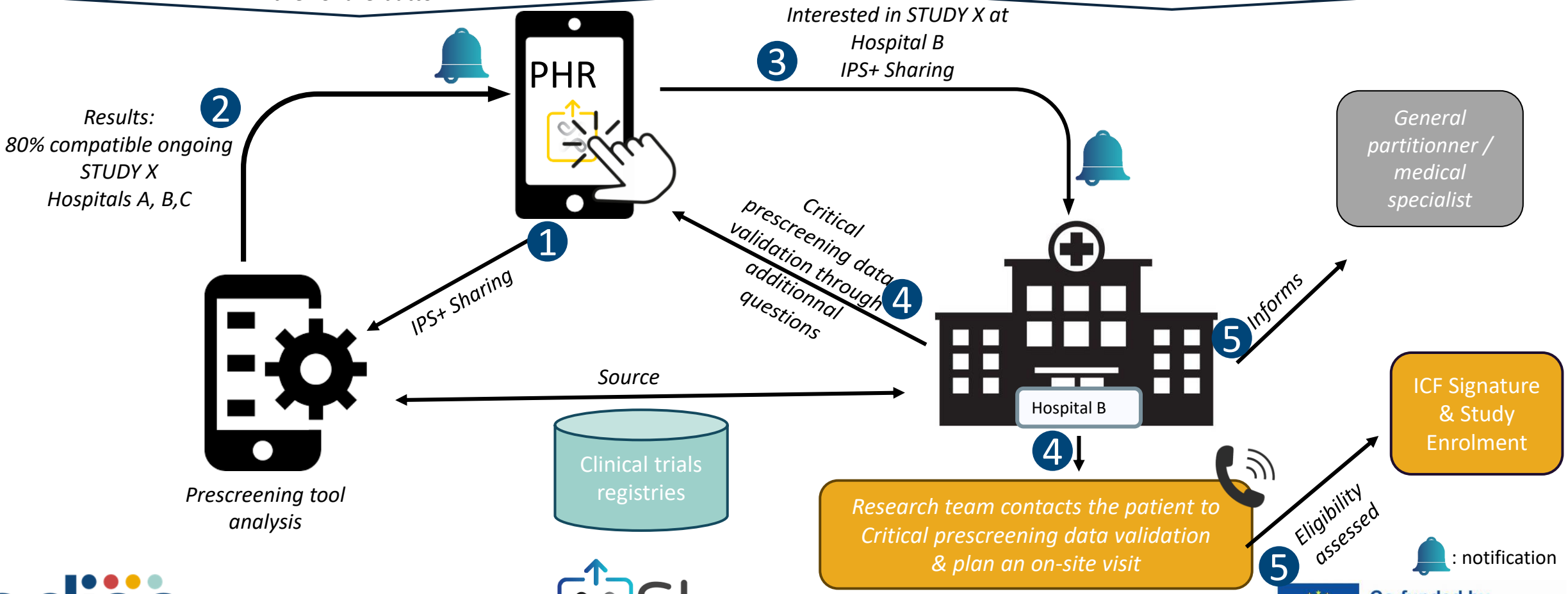
Business Use Cases

Nr	Description	Scope
1	Patient pre-screening in clinical trial through healthcare professional pre-screening tool	Prescreening
2	Patient self-nomination as possibly eligible for a trial	Prescreening
3	Protocol feasibility via a repository of IPS+ summaries, e.g. at hospital, regional or national level	Feasibility
4	Targeted patient recruitment via a repository of IPS+ summaries, e.g. at hospital, regional or national level	Prescreening
5	Clinical Study support – whole scenario (side effect reporting)	Study support
6	Longitudinal cohort tracking	Cohort
7	Clinical Study definition	Study support
8	Clinical Study follow-ups	Study support
9	Site feasibility guided by xShare Button	Feasibility
10	eCRF Filling Process through xShare Button	Study support

Use case example

STEP 1 : ELIGIBILITY ASSESSMENT
User triggers (and gives consent for) the sharing of their data with the xShare button

STEP 2 : PATIENT/HEALTHY VOLUNTEER FOLLOW-UP
User chooses the hospital of their choice where the STUDY X is running, and allows data sharing



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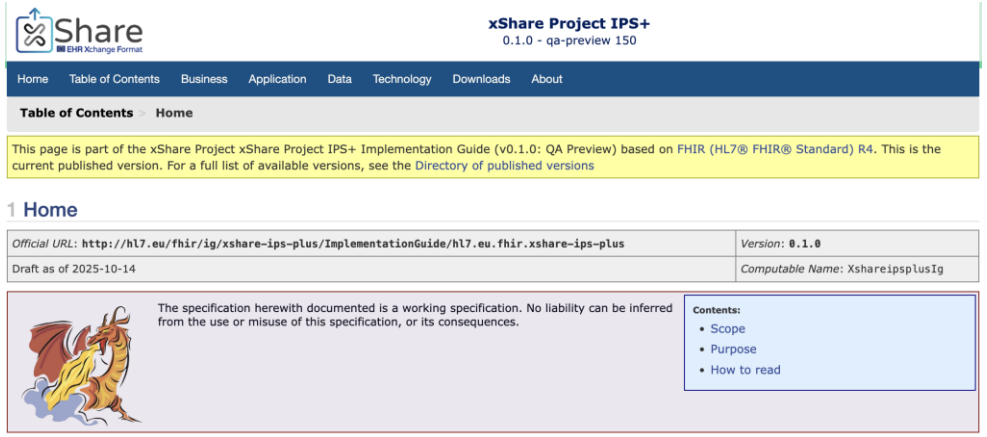
Structure of interoperability specification

IPS+ X-Bundle



IPS+ Implementation Guide

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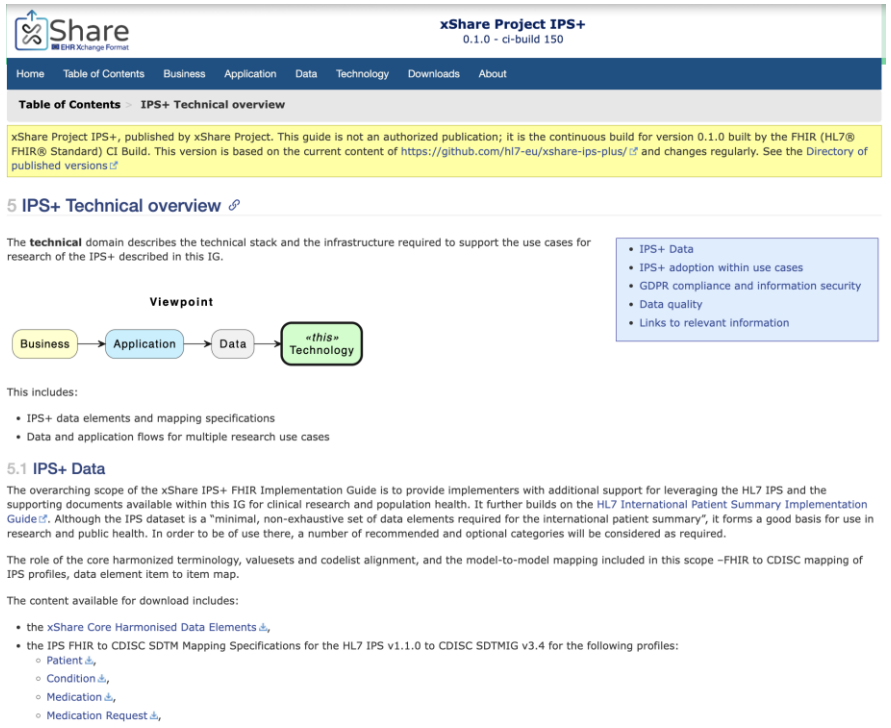
The IPS+ Implementation Guide

HL7 FHIR International Patient Summary

Implementer's will start with IPS

And use the IPS+ as a guide to enhance the specification for research

IPS+ provides tools to implement the HL7 IPS for clinical research and public health



Tools in IPS+

FHIR to CDISC Map	Core Harmonized Dataset	Value set alignment	Workflow to Trigger IPS+

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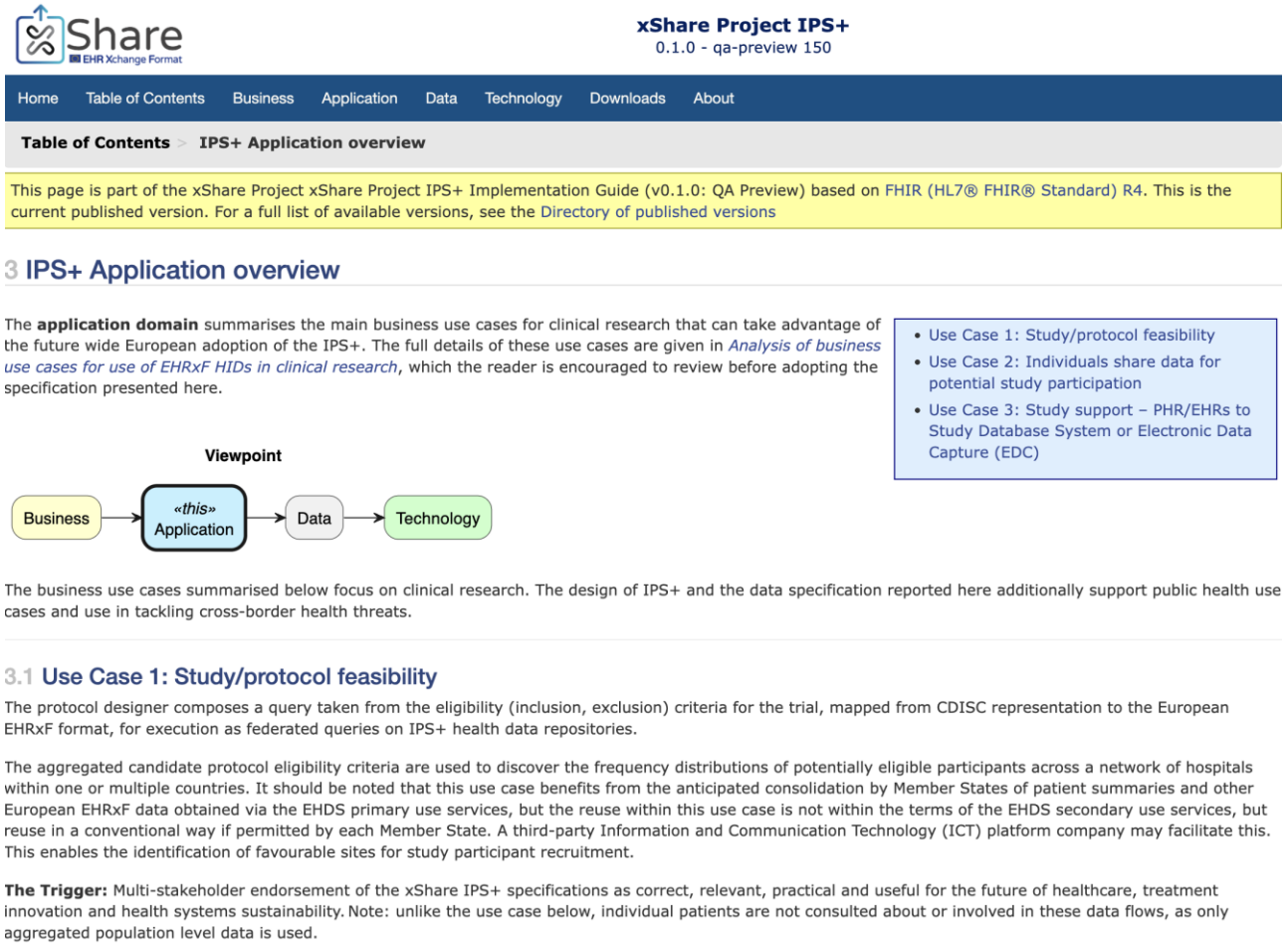
Use Case details in Implementation Guide

- Study/protocol feasibility (3)
  - Through federated queries on repositories of IPS+ summaries, e.g. at hospital, regional or national level
- Potential study participation (2)
  - Individuals explore potential clinical studies by leveraging their up-to-date IPS+ health data through a PHR via the xShare Yellow Button
- Study support (10)
  - Research question responses and eCRF filling



xShare Project IPS+
0.1.0 - qa-preview 150

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Table of Contents > **IPS+ Application overview**

This page is part of the xShare Project xShare Project IPS+ Implementation Guide (v0.1.0: QA Preview) based on FHIR (HL7® FHIR® Standard) R4. This is the current published version. For a full list of available versions, see the Directory of published versions

3 IPS+ Application overview

The **application domain** summarises the main business use cases for clinical research that can take advantage of the future wide European adoption of the IPS+. The full details of these use cases are given in *Analysis of business use cases for use of EHRxF HIDs in clinical research*, which the reader is encouraged to review before adopting the specification presented here.

- Use Case 1: Study/protocol feasibility
- Use Case 2: Individuals share data for potential study participation
- Use Case 3: Study support – PHR/EHRs to Study Database System or Electronic Data Capture (EDC)

The business use cases summarised below focus on clinical research. The design of IPS+ and the data specification reported here additionally support public health use cases and use in tackling cross-border health threats.

3.1 Use Case 1: Study/protocol feasibility

The protocol designer composes a query taken from the eligibility (inclusion, exclusion) criteria for the trial, mapped from CDISC representation to the European EHRxF format, for execution as federated queries on IPS+ health data repositories.

The aggregated candidate protocol eligibility criteria are used to discover the frequency distributions of potentially eligible participants across a network of hospitals within one or multiple countries. It should be noted that this use case benefits from the anticipated consolidation by Member States of patient summaries and other European EHRxF data obtained via the EHDS primary use services, but the reuse within this use case is not within the terms of the EHDS secondary use services, but reuse in a conventional way if permitted by each Member State. A third-party Information and Communication Technology (ICT) platform company may facilitate this. This enables the identification of favourable sites for study participant recruitment.

The Trigger: Multi-stakeholder endorsement of the xShare IPS+ specifications as correct, relevant, practical and useful for the future of healthcare, treatment innovation and health systems sustainability. Note: unlike the use case below, individual patients are not consulted about or involved in these data flows, as only aggregated population level data is used.

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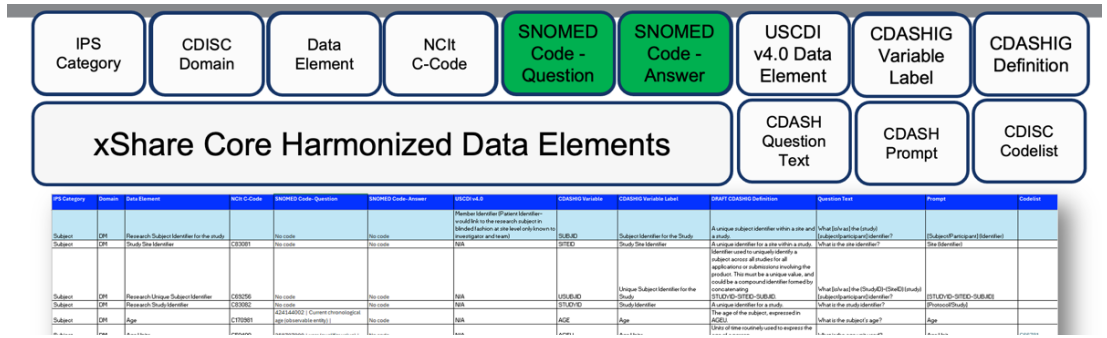
IPS+ details in Implementation Guide

- Core Harmonized Data Elements
- FHIR – CDISC SDTM mapping for IPS+ (example Observation Results Lab)
- SNOMED, LOINC mappings (subsets)



- the IPS FHIR to CDISC SDTM Mapping Specifications for the HL7 IPS v1.1.0 to CDISC SDTMIG v3.4 for the following profiles:
  - Patient,
  - Condition,
  - Medication,
  - Medication Request
  - Medication Stateme
  - Observation Results
  - Procedures,
  - Diagnostic Report
  - Allergy and Intoller
  - Immunization,
  - the base R4 FHIR re

This is the README for the StructuredDefinition-Observation-results-laboratory-uv-ips-v1.1.0 to SDTM LB generic spreadsheet.

In the description SDTM is the tabulation source for CDISC. The mapping is from FHIR to CDISC SDTM.

Tab	Topic	Description
Metadata	Original IPS Specification	http://hl7.org/fhir/uv/ips/StructureDefinition-Observation-results-laboratory-uv-ips.html
Elements	Original IPS Specification	http://hl7.org/fhir/uv/ips/StructureDefinition-Observation-results-laboratory-uv-ips.html
Elements_IPS Generic Lab - SDTM	Original IPS Spec to SDTM	Element tab from original IPS-Observation-results-laboratory to SDTM - written using the LB domain to aid understanding. Applicable to all specimen domains changing the two letter domain code and the test terminology to match that domain.
Lab Result Profile to SDTM	Brief source to target FHIR to SDTM specificallly for the LB domain	Lab result FHIR Path to SDTM using the LB domain to aid comprehension
IPS Generic Lab Result to SDTM	Brief source to target FHIR to SDTM providing a generic perspective	Lab result FHIR Path to SDTM using the "--" for the laboratory domain referencing the "Determining the domain" tab for guidance on how to determine the SDTM domain.
Determining the domain	How to determine the CDISC SDTM Findings domain	Provides guidance to determine the domain for the observation of the mapping.
Specimen Findings Domains	How to determine the Laboratory Findings domain related to the specimen of the observation.	Provides guidance to determine the domain for the observation of the mapping for laboratory specimens.
Common Rules	Rule or guidance that applies to all mappings regardless of the topic or object	Provides guidance for mapping from FHIR to CDISC SDTM for all content. This content applies to all domains pdated across all maps when updates applied.

- resourceTypeConceptMap_CDISC_to_SNOMED.txt
- resourceTypeConceptMap_LOINC_to_SNOMED.txt
- resourceTypeConceptMap_SNOMED_to_CDISC.txt
- resourceTypeConceptMap_SNOMED_to_LOINC.txt

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Open Call – awarded partners

- 8 consortia
- Covering 5 use cases
  - Some cover multiple

- Award levels
  - Platinum: 1
  - Gold: 2
  - Silver: 2
  - Bronze: 3

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Open call coverage of BUC for research

Nr	Description	Scope	Open Call
1	Patient pre-screening in clinical trial through healthcare professional pre-screening tool	Prescreening	
2	Patient self-nomination as possibly eligible for a trial	Prescreening	✓
3	Protocol feasibility via a repository of IPS+ summaries, e.g. at hospital, regional or national level	Feasibility	✓
4	Targeted patient recruitment via a repository of IPS+ summaries, e.g. at hospital, regional or national level	Prescreening	
5	Clinical Study support – whole scenario (side effect reporting)	Study support	
6	Longitudinal cohort tracking	Cohort	✓
7	Clinical Study definition	Study support	
8	Clinical Study follow-ups	Study support	
9	Site feasibility guided by xShare Button	Feasibility	✓
10	eCRF Filling Process through xShare Button	Study support	✓

Related initiative - eSource Scale Up Task Force

Coordinated by i~HD for member organizations to drive data interoperability and champion EHR as eSource

Purpose

- Drive and scale the adoption of Electronic Health Record (EHR) as eSource technology across pharma/biotech companies and hospitals
- Promote alignment across members and to networks to adopt harmonized and efficient practices and processes
- Engage with relevant organisations and stakeholders involved in eSource EHR initiatives

Outputs

- Published reports, publications, webinars, position papers, recommendation, presentations, meetings

eSource

Scale Up Task Force

Core Members

Cambridge University Hospitals NHS Foundation Trust

Memorial Sloan Kettering Cancer Center

University Medicine Essen

sanofi

Johnson&Johnson

Lilly

REGENERON A MEDICINE COMPANY

AstraZeneca

i~HD The European Institute for Innovation through Health Data

Reference Groups

Study Sites

Industry

Technology Network

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Questions?