Adapting the patient summary for clinical research and public health current and prospective use cases

IPS+ (formerly IPS+R)

Co-funded by the European Union

Key Points

- IPS+R (now IPS+) - a modest extension of the IPS to support Research and Public Health
- Learning Health Systems -rely on Research and Public Health to inform Clinical Decisions
- Workflow for “collect once – use many times” (examples/case studies from CDISC, HL7, IHE)
- IPS+ and yellow button - role for secondary use of data for Research and Public Health
- CDISC tools – can be leveraged to support Research and Public Health and LHSs
- xShare opportunity to make the desired workflow a reality – depends on harmonization of terminologies and adoption

Information from healthcare (private, aggregated) to enable research

Healthcare

- Quality healthcare
- Informed decisions
- Personalized medicine
- Patient safety and privacy
- Public health
- Improved therapies
- Efficiencies/reduced costs

Research

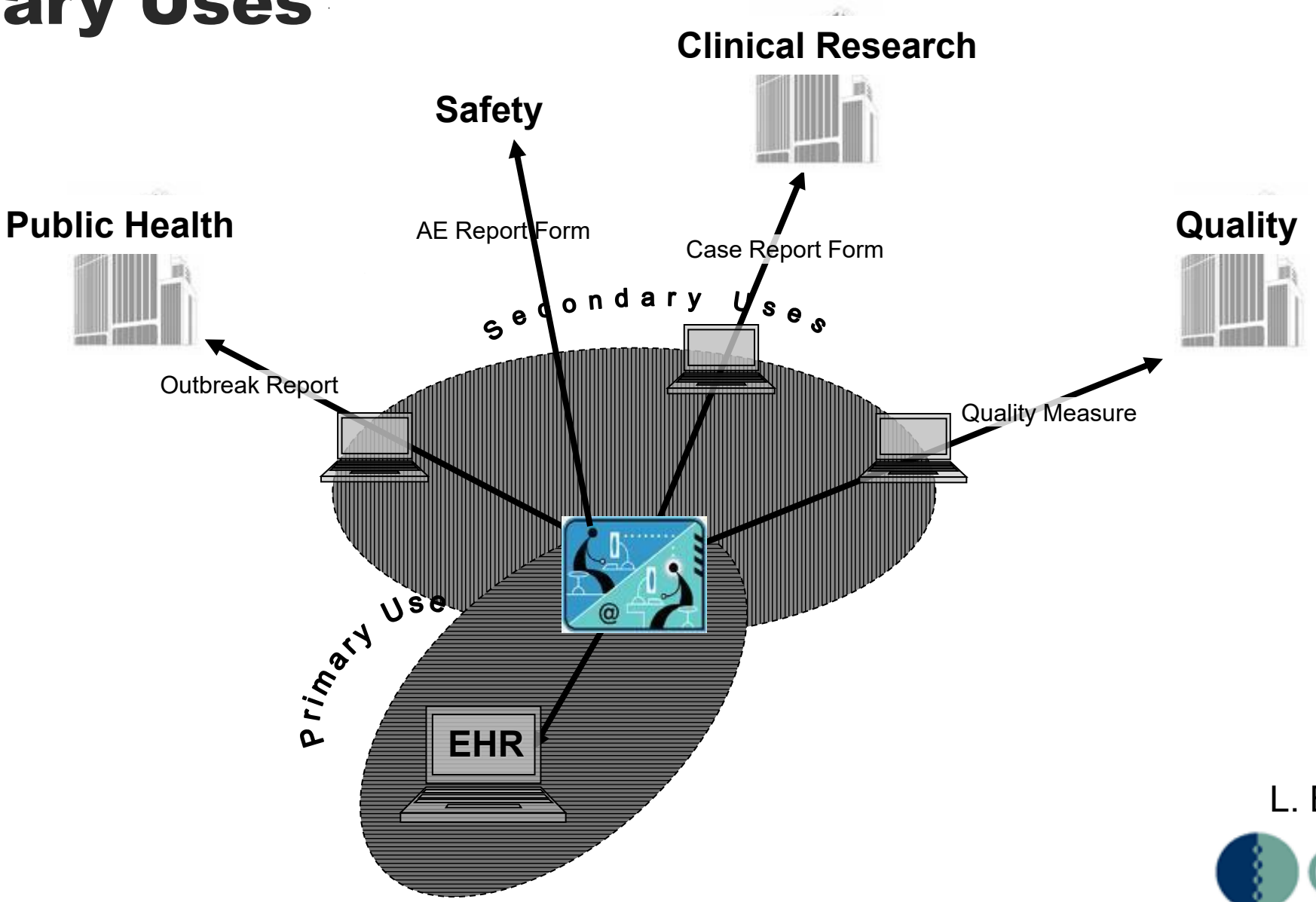
- Discovery of new therapies
- Understanding diseases
- Testing/comparing therapies (CER)
- Assessing efficacy
- Monitoring safety
- Understanding responses (genomics, biomarkers)
- **Public health/quality evaluations**
- Post-marketing surveillance

Research findings to inform healthcare decisions

CATALYSIS

R. D. Kush, 2009

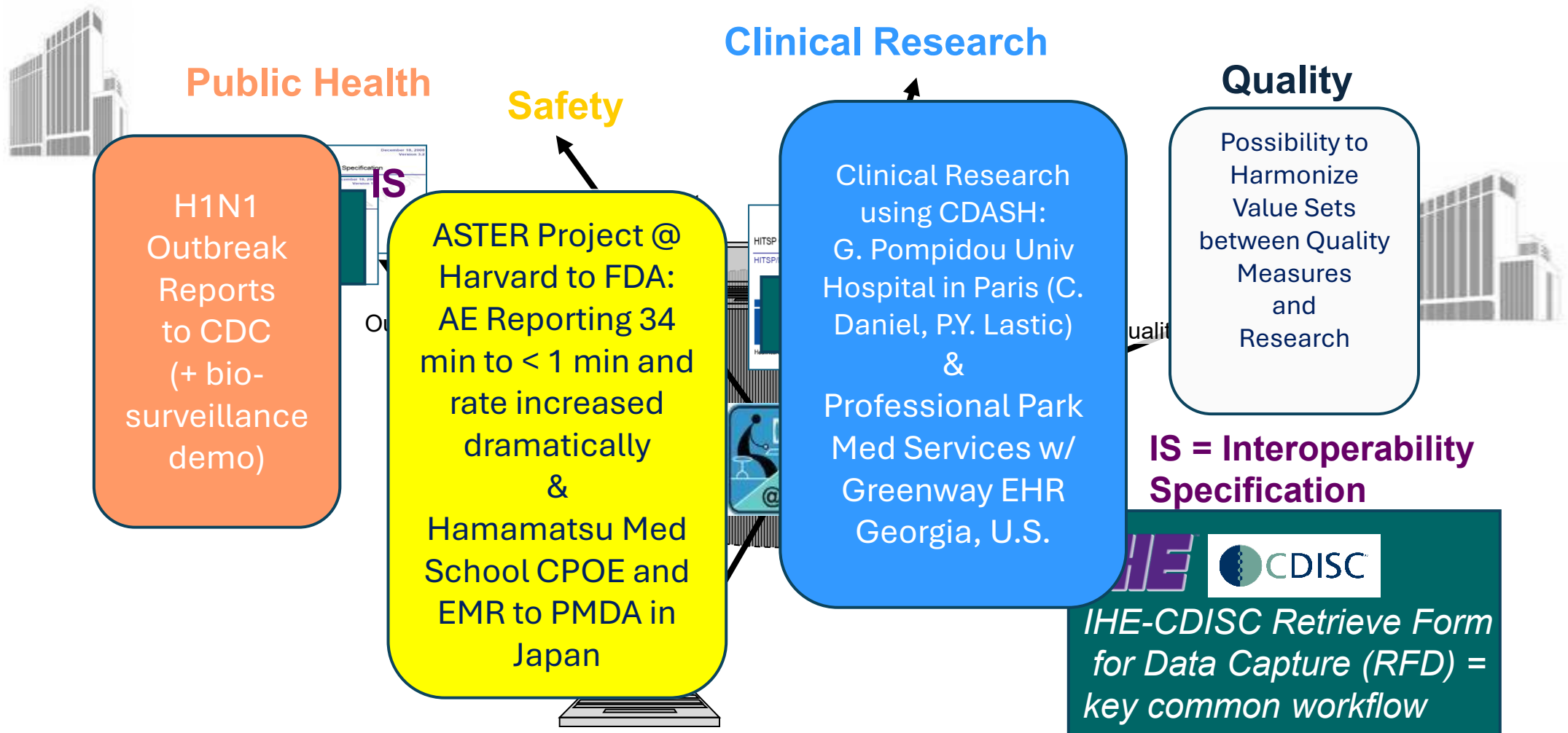
Integrating EHR Workflow for Secondary Uses



L. Bain, 2010

CDISC

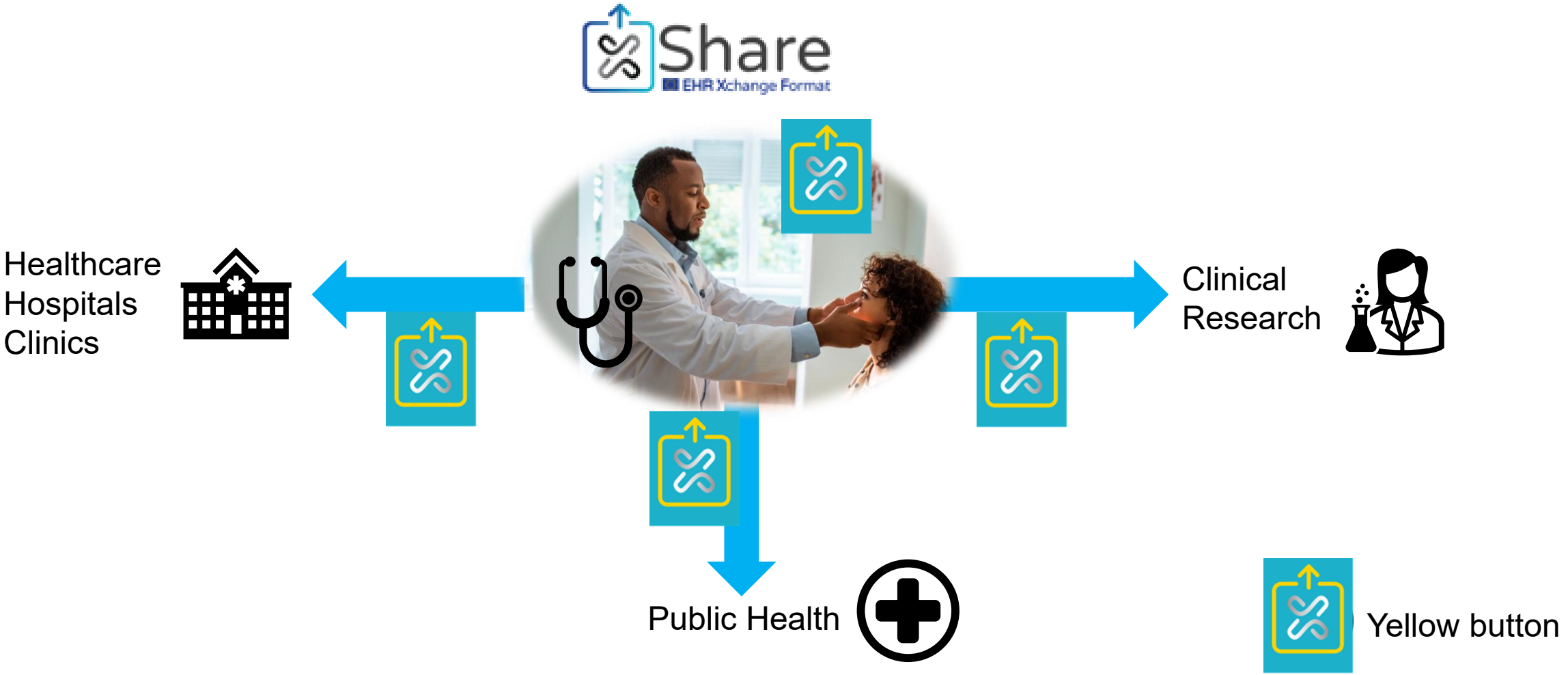
Integrating Workflow: EHRs and Clinical Research, Quality, Safety and Public Health Implementations (2010)



Implementation vs. Adoption

- From 2008 ~2014, the IHE-CDISC created integration profiles (leveraging HL7 CDA and CDISC standards). RFD was implemented in various settings for secondary use globally and displayed at HIMSS interoperability showcases; ROI was demonstrated. Interoperability Specifications were written.
- Why has there not been widespread adoption???
  - ~ 2014, HL7 formally agreed to introduce HL7 FHIR.
  - In the US, HITSP was replaced by the HITECH Act; blue button not broadly adopted
  - Terminologies were not aligned within healthcare, across IGs and among healthcare, public health and clinical research.
  - Regulators and industry were not ready?
- Why could we now succeed with xShare?
  - EHDS is committed to for the E EHRxF to support secondary use cases
  - HL7, IHE, CDISC, IHTSDO, CEN/ISO all working together as partners in the Consortium
  - Terminologies are being aligned/harmonized within the IPS and for the IPS+
  - Patients will be able to access their own health data with the yellow button

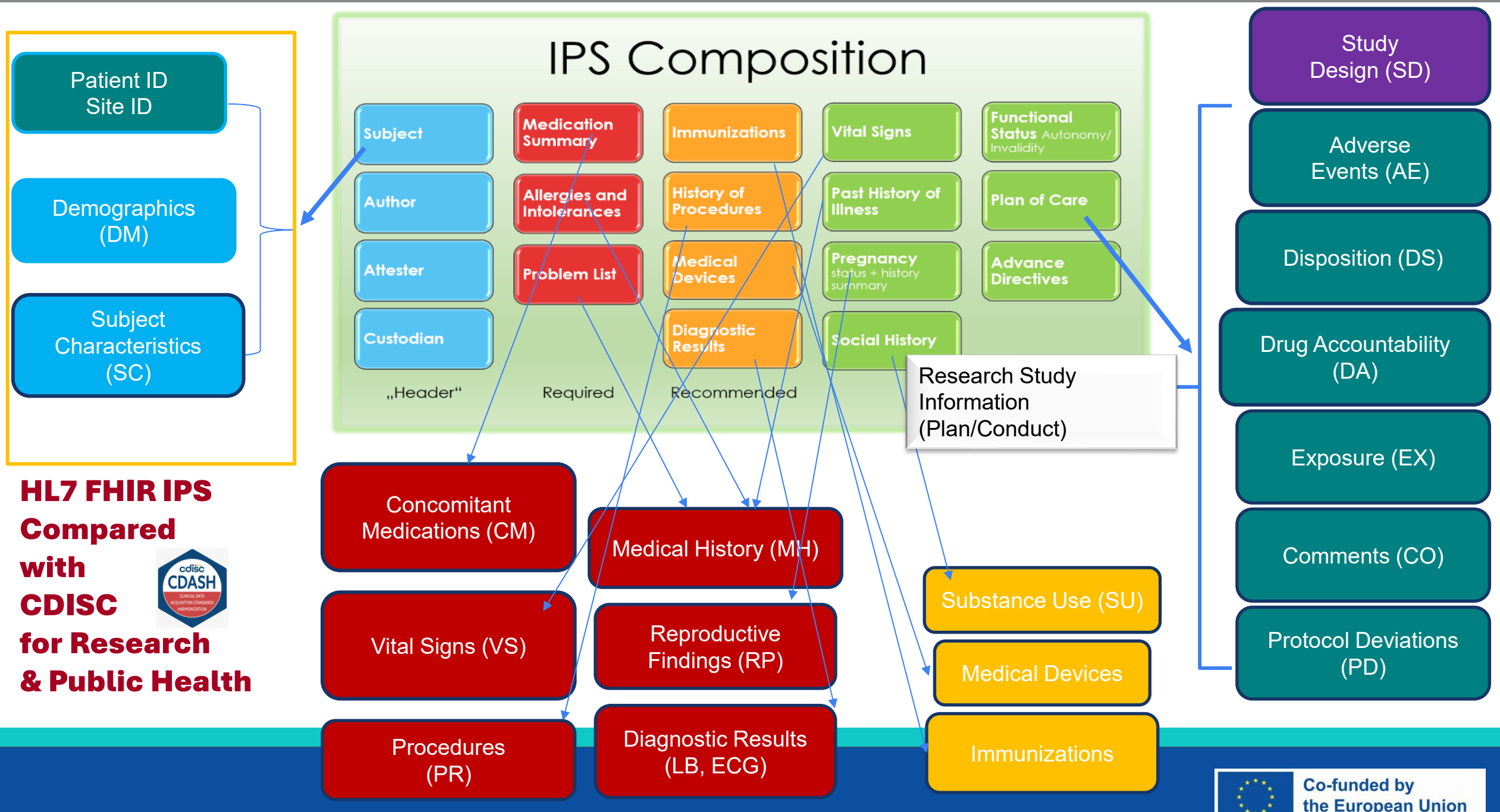
Sharing Data with the xShare Yellow Button and the Patient at the Center Supporting Primary and Secondary use



Co-funded by
the European Union

xShare WP5 Deliverables in Current Status

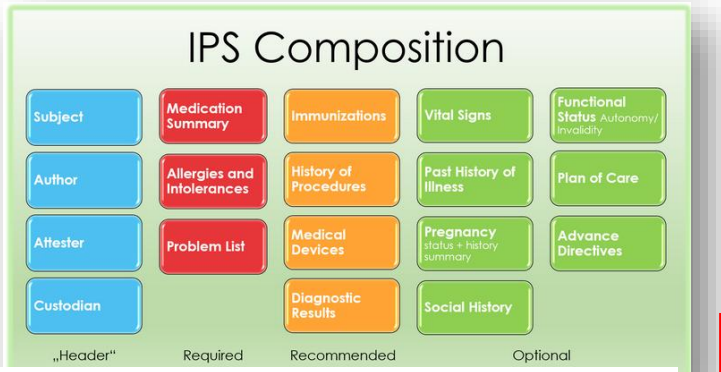
- D5.1 Proposal for a harmonized core data set across health care, population health and clinical research. **M6 – Completed June 2024**
  - **Core data element set of ~ 100 elements, very slightly expanding IPS → IPS+**
- D5.2 Analysis of business use cases for use of EHRxF HIDs in clinical research **M9-Completed Q4 2024**
  - **Support for case report form completion with EHR Data**
  - **Patients self-nominating for research study (sending data with yellow button)**
  - **Protocol feasibility via registry of IPS+ summaries**
- *D5.3 Proposed interoperability specification for an International Patient Summary for Research & Public Health mapped to international standards M18 - Completed May 2025*
  - *An interoperability specification (IPS+) mapped to international standards*
  - *Terminology harmonization to support research and public health*
- D5.4 Next iteration of D5.3 – M24- to be based on implementer feedback
- D5.5 Final iteration of D5.3 – M30- to be based on implementer feedback

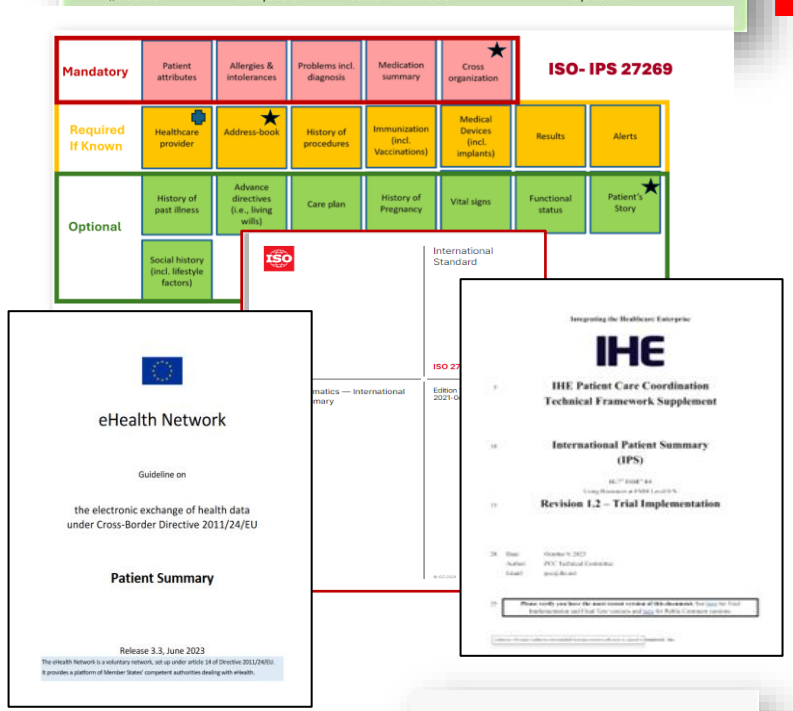


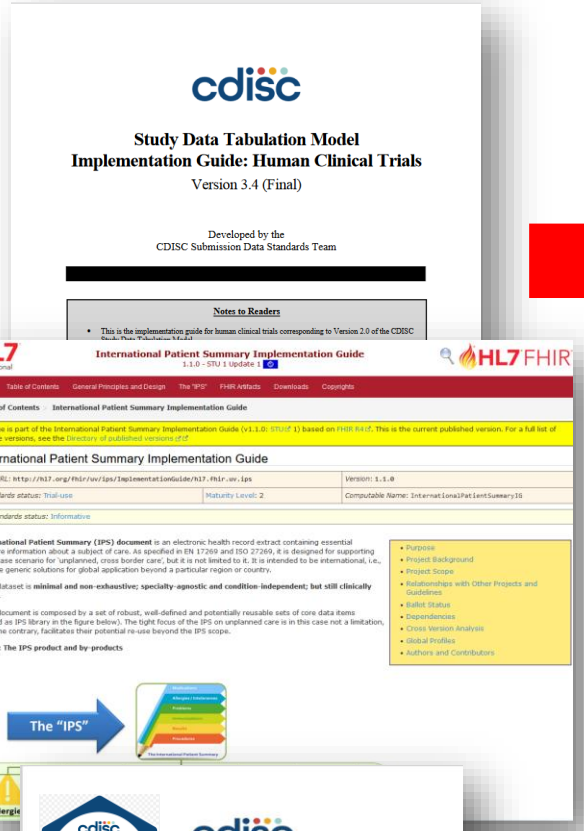
HL7 FHIR IPS Compared with CDISC for Research & Public Health

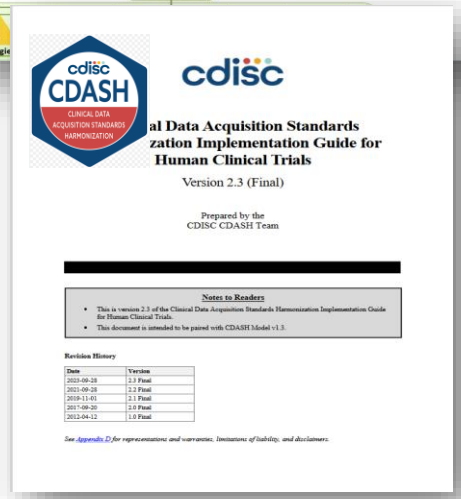
Co-funded by the European Union

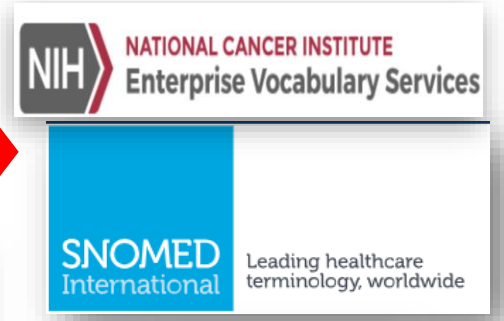
1) Data Element Sources → 2)Core Element Set → 3) Terminology "Harmonization"











Developing the xSHARE Core Data Element Set and IPS +

NEXT STEPS (Putting the Core Data Element Set into Use):

Consensus-building, Validation in New Health Information Domains (HIDs), e.g., IPS+ BUC, Care Plans, Telemonitoring, Public Health

DOMAIN/CATEGORY:
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

DOMAIN/CATEGORY:
IPS Diagnostic Results= CDISC- Laboratory Results (LB)
Microbiology Results (MB); Body Systems Findings**

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

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

PS-Data Element = Adverse Event**
CDISC- Adverse Events (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

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

IPS-Problem List = CDISC- Medication History (MH)**

- Problem/Condition/Medical History 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

DOMAIN/CATEGORY:
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

DOMAIN/CATEGORY:
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**

Category Not in HL7 FHIR IPS IG
ISO IPS and IPS IHE have 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 Original Units
- Reproductive System Finding Date
- There are a number of discrete pregnancy related outcomes that were mapped to CDISC SDTM since there were discrete data elements in IPS (code system/code/label) available – potential public health use case

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

IPS Category | CDISC Domain | Data Element | NCIt C-Code | SNOMED Code - Question | SNOMED Code - Answer | USCDI v4.0 Data Element | CDASHIG Variable Label | CDASHIG Definition

xShare Core Harmonized Data Elements

CDASH Question Text | CDASH Prompt | CDISC Codelist

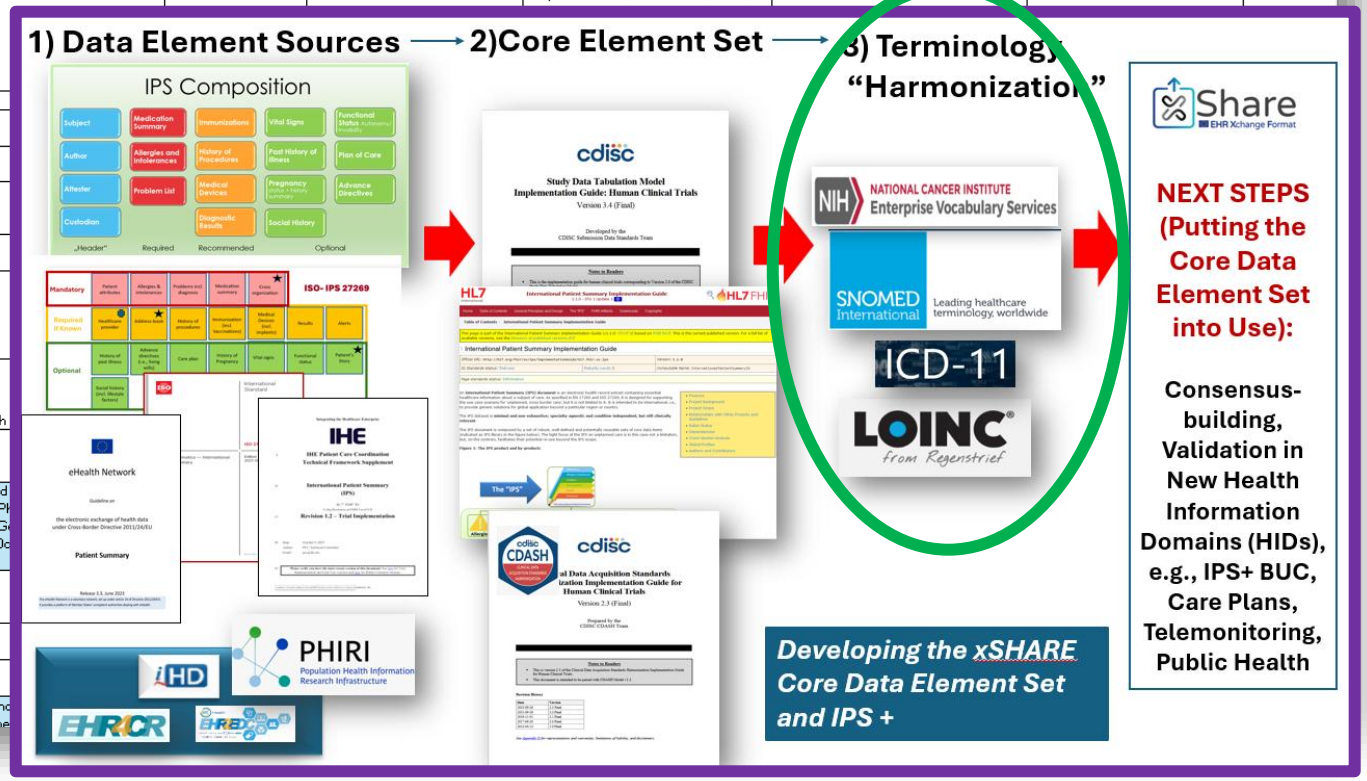
IPS Category	Domain	Data Element	NCIt C-Code	SNOMED Code- Question	SNOMED Code- Answer	USCDI v4.0	CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition	Question Text	Prompt	Codelist
Subject	DM	Research Subject Identifier for the study		No code	No code	Member Identifier (Patient Identifier- would link to the research subject in blinded fashion at site level only known to investigator and team)	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	
Subject	DM	Study Site Identifier	C83081	No code	No code	N/A	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	
Subject	DM	Research Unique Subject Identifier	C69256	No code	No code	N/A	USUBJID	Unique Subject Identifier for the Study	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique value, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	What [is/was] the (StudyID)-(SiteID) (study) [subject/participant] identifier?	[STUDYID-SITEID-SUBJID]	
Subject	DM	Research Study Identifier	C83082	No code	No code	N/A	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	
Subject	DM	Age	C170981	424144002 | Current chronological age (observable entity) |	No code	N/A	AGE	Age	The age of the subject, expressed in AGEU.	What is the subject's age?	Age	
Subject	DM	Age Units	C50400	258707000 | year (qualifier value) |	No code	N/A	AGEU	Age Units	Units of time routinely used to express the age of a person.	What is the age unit used?	Age Unit	C66781
Subject	DM	Demographics Collection Date	C83243	Information model	No code	N/A	DMDAT	Demographics Collection Date	The date of collection, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What is the date of collection?	Collection Date	
Subject	DM	Sex (Administrative/clinical use?)	C28421	184100006 | Patient sex (observable entity) |	< 429019009 | Finding related to biological sex (finding) |	Sex	SEX	Sex	Sex of the subject, as determined by the investigator.	What is the sex of the subject?	Sex	C66731
Subject	DM	Birth Date	C83217	184099003 | Date of birth (observable entity) |	No code	Date of Birth	BRTHDAT	Birth Date	A subject's date of birth (with or without the time of birth). The complete Date of Birth is made from the temporal components of Birth Year, Birth Month, Birth Day, and Birth Time..	What is the subject's date of birth?	Birth Date	
Subject	DM	Deceased Date	C117450	399753006 | Date of death (observable entity) |	No code	Date of Death	DTHDTC	Date/Time of Death	Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-trial database.	What was the subject's date/time of death?	Death Date	
Subject	DM	Deceased Flag	C117451	18632008 | Patient status determination, deceased (finding)	410515003 | Known present (qualifier value) | 410516002 | Known absent	N/A	DTHFL	Subject Death Flag	Indicates the subject died. Should be "Y" or null. Should be populated even when the death date is unknown	Was the subject dead?	Subject Death Flag	C66742
Subject	SC	Subject Characteristic	C103330	363789004 | General characteristic of patient (observable entity) |	363790008 | General characteristic of appearance (observable entity) |	Data included for individual patient information; Physical Activity; Sexual Orientation; Gender Identity; Preferred Language; Occupation; Occupation Industry	SCTEST	Subject Characteristic	Descriptive name of the subject characteristic of interest.	What is the subject characteristics name?	[Subject Characteristic Test Name]	C103330
Subject	SC	Subject Characteristic Collection Date	C83397	Information model	No code	N/A	SCDAT	Subject Characteristic Collection Date	The date of collection represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date the subject characteristics were collected?	Date	
Subject	SC	Subject Characteristic Finding Value	C83107	This could be a value set, but no individual code	No code	N/A	SCORRES	SC Result or Finding in Original Units	Result of the subject characteristic as originally received or collected.	What is the subject characteristic?	(Result)	
Subject	SC	Subject Characteristic Finding Value Units	C83400	This could be a value set, but no individual code	No code	N/A	[SCTESTCD]_SCORRES	SC Result or Finding in Original Units	Result of the subject characteristics as originally received or collected.	What is the subject's [SCTEST]?	[SCTEST] Result	
Problem List	MH	Medical History Reported Term	C83118	1003642006 | Past medical history section (record artifact) |	< 404684003 | Clinical finding (finding) |	Problem (Condition, diagnosis, or reason for seeking medical attention)	MHTERM	Reported Term for the Medical History	The reported or prespecified name of the medical condition or event	What is the medical condition or event term?	Medical History Term	

IPS Category | CDISC Domain | Data Element | NCIt C-Code | SNOMED Code - Question | SNOMED Code - Answer | USCDI v4.0 Data Element | CDASHIG Variable Label | CDASHIG Definition

xShare Core Harmonized Data Elements

CDASH Question Text | CDASH Prompt | CDISC Codelist

IPS Category	Domain	Data Element	NCIt C-Code	SNOMED Code- Question	SNOMED Code- Answer	USCDI v4.0	CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition	Question Text	Prompt	Codelist
Subject	DM	Research Subject Identifier for the study		No code	No code	Member Identifier (Patient Identifier- would link to the research subject in blinded fashion at site level only known to investigator and team)	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	
Subject	DM	Study Site Identifier	C83081	No code	No code	N/A	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	
Subject	DM	Research Unique Subject Identifier	C69256	No code	No code	N/A			Identifier used to uniquely identify a subject across all studies for all			
Subject	DM	Research Study Identifier	C83082	No code	No code	N/A						
Subject	DM	Age	C170981	424144002 | Current chronological age (observable entity) |	No code	N/A						
Subject	DM	Age Units	C50400	258707000 | year (qualifier value) |	No code	N/A						
Subject	DM	Demographics Collection Date	C83243	Information model	No code	N/A						
Subject	DM	Sex (Administrative/clinical use?)	C28421	184100006 | Patient sex (observable entity) |	< 429019009 |Finding related to biological sex (finding)|	Sex						
Subject	DM	Birth Date	C83217	184099003 | Date of birth (observabl entity) |	No code	Date of Birth						
Subject	DM	Deceased Date	C117450	399753006 | Date of death (observable entity) |	No code	Date of Death						
Subject	DM	Deceased Flag	C117451	18632008 | Patient status determination, deceased (finding)	410515003 |Known present (qualifier value)| 410516002 |Known absent	N/A						
Subject	SC	Subject Characteristic	C103330	363789004 | General characteristic of patient (observable entity) |	363790008 | General characteristic of appearance (observable entity) |	Data included information; Ph Orientation; Ge Language; Oc Industry						
Subject	SC	Subject Characteristic Collection Date	C83397	Information model	No code	N/A						
Subject	SC	Subject Characteristic Finding Value	C83107	This could be a value set, but no individual code	No code	N/A						
Subject	SC	Subject Characteristic Finding Value Un	C83400	This could be a value set, but no individual code	No code	N/A						
Problem List	MH	Medical History Reported Term		1003642006 |Past medical history section (record artifact)|	< 404684003 |Clinical finding (finding)|	Problem (Cond for seeking me						

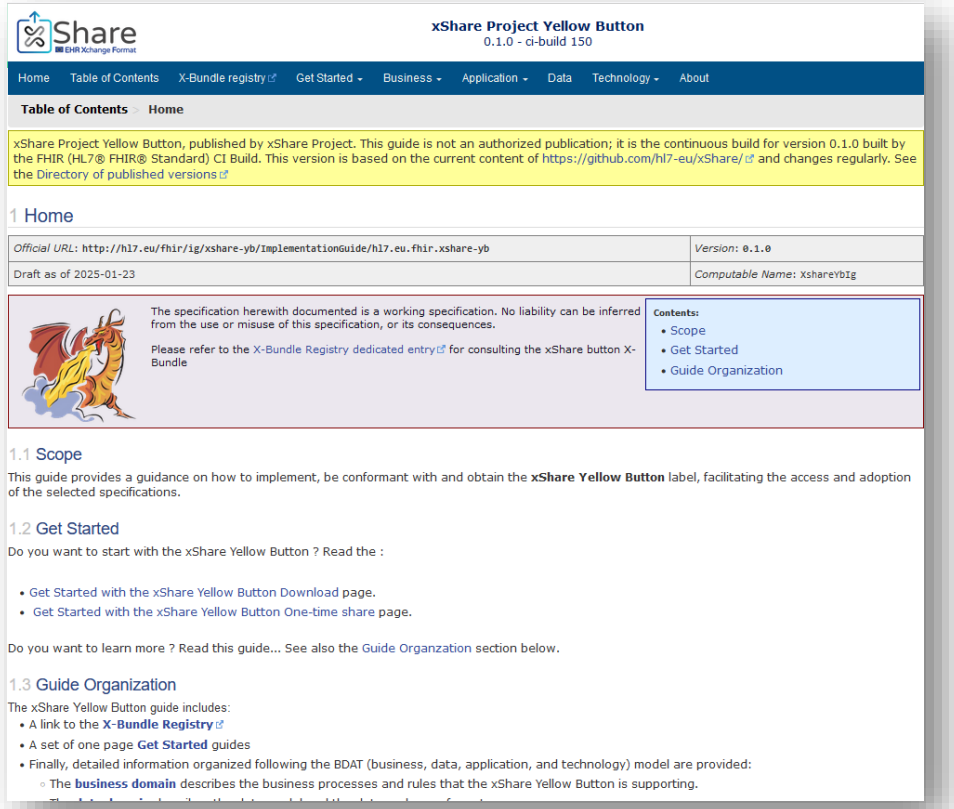


HL7 International Patient Summary

Implementer's will start with IPS

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

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

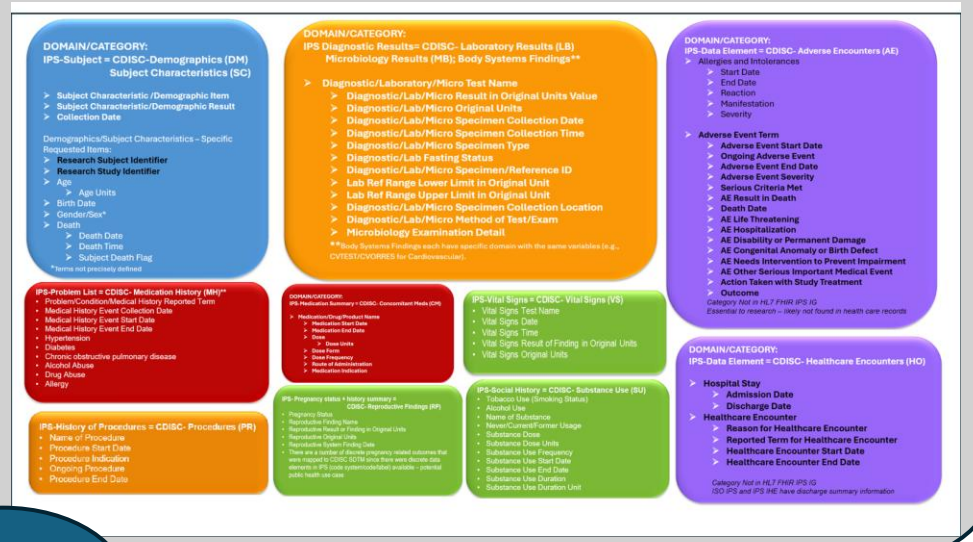


Tools in IPS+

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

Potential Glidepath Between IPS and IPS+ for Secondary Use

Core Data Element Set



EHR

IPS

HL7 FHIR

IPS Elements
for EHRxF
FHIR Paths
+ Terminology, (e.g. SNOMED, LOINC, ICD)

For global research, harmonize with USCDI/USCore

HL7 FHIR

***

harmonization of terminologies

***

cdisc

Patients receive own summary data (IPS+, no PHI) for Research and Public Health BUC

cdisc

IPS Elements
for Research
+ Terminology
(i.e. NCI EVS C-Codes used by FDA, ICH, Research Sponsors, NIH); also apply to Safety and Public Health

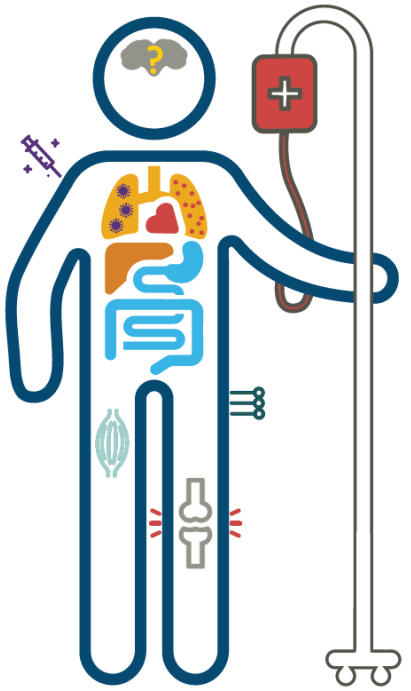
IPS+

- xShare Core Harmonized Data Elements
- Maps from FHIR to CDISC in support of the Core Harmonized Data Elements metadata
- Valueset alignment for routine laboratory and microbiology tests (public health)
- Workflow to trigger for IPS+
- Guidance for HL7 FHIR IPS for research
- Sources of HL7 FHIR IGs for research
- Sources for CDISC standards content

Clinical Research Supports Public Health

CDISC has Therapeutic Area User Guides (TAUGs) that provide example case report forms (CRFs) and guidance on how to use the standards for the core elements for a particular disease, including metadata standards and terminology

Infectious Disease	Chronic Disease	Rare Diseases
COVID-19	Asthma	
Ebola	Cardiovascular	
Hepatitis C	COPD	
HIV	Diabetes	
Influenza	Kidney	
Malaria	Depression	
Tuberculosis		



All TAUGs are available for download in multiple formats at:
www.cdisc.org/standards/therapeutic-areas

VACCINE ADMINISTRATION V1.0 – HARMONIZATION

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

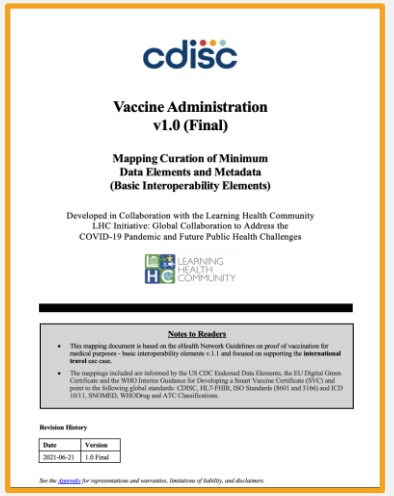
- Harmonize a set of 20 core elements
  - Based on European eHealth Network – Guidelines for proof of vaccination for medical purposes - basic interoperability elements*
- Align with:
  - US CDC Endorsed Data Elements
  - Digital Green Certificate
  - WHO Interim Guidance for Developing a Smart Vaccine 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

Developed in collaboration with

LEARNING HEALTH COMMUNITY


cdisc

Vaccine Administration
v1.0 (Final)

Mapping Curation of Minimum
Data Elements and Metadata
(Basic Interoperability Elements)

Developed in Collaboration with the Learning Health Community
LHC Initiative: Global Collaboration to Address the
COVID-19 Pandemic and Future Public Health Challenges

Notes to Readers

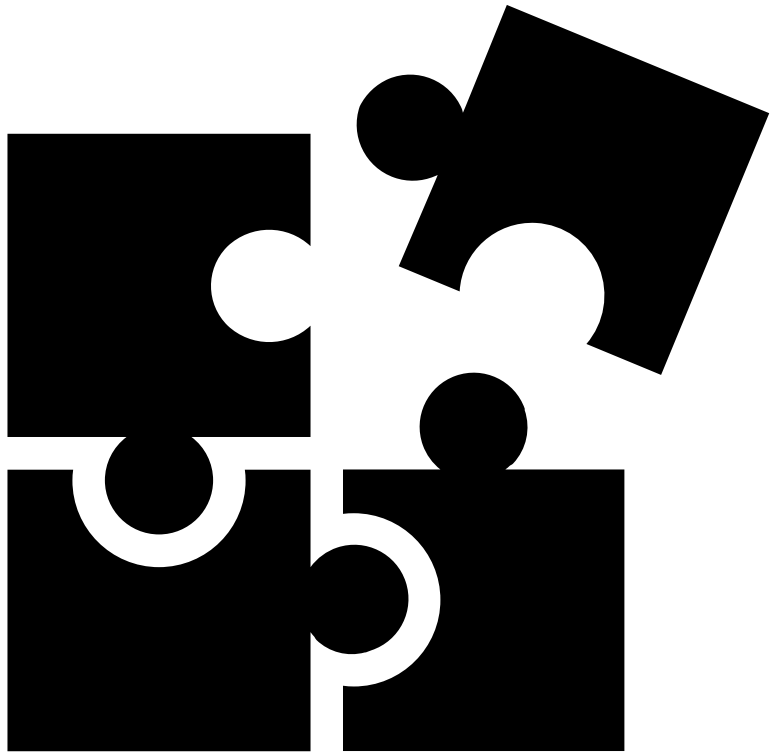
Revision History

Date	Version
2021-06-21	1.0 Final

*Source: eHealth Network, Guidelines on proof of vaccination for medical purposes - basic interoperability elements, V 2. 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

xShare as a missing piece of the puzzle
connecting the CDISC initiatives to healthcare



xShare IPS+

- Core Harmonised Data Element Set
- FHIR IPS Profiles to CDISC SDTM Mapping
- Valueset/Codelist Alignment – SNOMED & CDISC
- Guidance on implementation using the tools

Digital Data Flow –
-ICH M11
-CDISC/TransCelerate USDM
- relates to/connect to HL7 FHIR UDP

Biomedical Concepts

360i

https://xshare-project.eu/newsletter/

Summary

- IPS+ proposes to add a small number of elements to leverage IPS in use cases for clinical research and public health.
- IPS+ implementation AND adoption will support Learning Health Systems such that research data can more readily provide results to inform clinical decisions.
- No new standards are necessary. We need to use the available tools to align, harmonize and connect healthcare with research and public health.
- The IHE-CDISC integration profiles could be updated to use FHIR vs. HL7 CDA.
- The xShare Consortium can encourage and support widespread implementation and adoption for the benefit of patients.