



REUSING DATA OF AN EU-WIDE EHR SYSTEM FOR CLINICAL TRIALS: A CAPABILITIES ANALYSIS

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Motivation

- **Conventional acquisition of trial data** highly laborious
 - Feasibility checks slow and unprecise
 - Patient recruitment numbers low
 - Manual duplication of routine data for trial execution error prone



- **(Semi) automatic reuse** of electronic health record (EHR) data for trials



- **eHDSI** => Shared EHR System for cross-border document exchange in EU

RESEARCH QUESTION

Can eHDSI data be reused for clinical trials?



eHDSI

- eHDSI stands for “**eHealth Digital Service Infrastructure**,”
- Shared EHR System for cross-border document exchange in EU
- Based on results of epSOS project
- Already operative in 7 EU countries, 22 countries expected by 2021
- Currently patient summaries and medication data
- Documents represented in HL7 CDA format



Which data are needed for trials?

- Starting point: **EHR4CR data inventories**
 - Patient recruitment
 - 149 data elements
 - Clinical trial feasibility
 - 76 data elements
 - Clinical trial execution and serious adverse event reporting
 - 137 data elements

Which data are needed for trials?

- Example for EHR4CR data inventory for patient identification and recruitment*

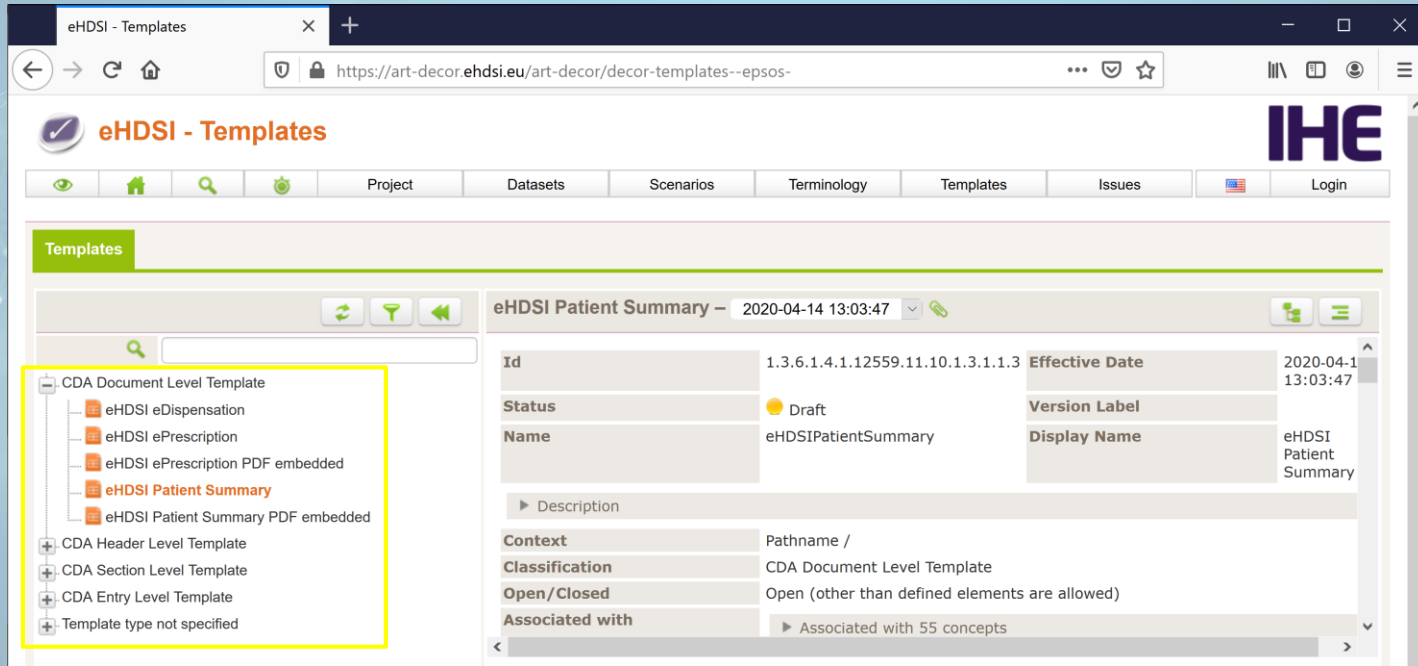


EHR4CR data inventory for patient identification and recruitment		
Name	Typ	Description Question Decode (Coded Value)
▼Demographics	Item Group	Patientendaten
Date of Birth	Item	Geburtsdatum
Gender	Item	Geschlecht
Admission date	Item	Aufnahmedatum
discharge date	Item	Entlassungsdatum
Case Status	Item	Fallstatus
▼Medical History	Item Group	Anamnese
▼Medical device	Item Group	Medizinprodukt
▼Diagnosis	Item Group	Diagnose
▼Procedure	Item Group	Prozeduren
► Findings	Item Group	Untersuchungsergebnisse
▼Laboratory Findings	Item Group	Laboregebnisse
► Medication	Item Group	Medikation
▼Scores&Classifications	Item Group	Scores&Classifications
▼Patient Characteristics	Item Group	Patient Characteristics

*Referenced by Doods, Justin, et al. "A European inventory of data elements for patient recruitment." *MIE*. 2015.

Does eHDSI contain these data?

- **Starting point:** eHDSI HL7 CDA template definitions in ART-DECOR



eHDSI - Templates

Project Datasets Scenarios Terminology Templates Issues Login

Templates

eHDSI Patient Summary - 2020-04-14 13:03:47

- CDA Document Level Template
 - eHDSI eDispensation
 - eHDSI ePrescription
 - eHDSI ePrescription PDF embedded
 - eHDSI Patient Summary**
 - eHDSI Patient Summary PDF embedded
- CDA Header Level Template
- CDA Section Level Template
- CDA Entry Level Template
- Template type not specified

Id	1.3.6.1.4.1.12559.11.10.1.3.1.1.3	Effective Date	2020-04-14 13:03:47
Status	Draft	Version Label	
Name	eHDSIPatientSummary	Display Name	eHDSI Patient Summary
Description			
Context	Pathname /		
Classification	CDA Document Level Template		
Open/Closed	Open (other than defined elements are allowed)		
Associated with	Associated with 55 concepts		

Method: Map EHR4CR data to eHDSI templates

1. Represent EHR4CR data as ART-DECOR concepts
2. Reference needed eHDSI CDA templates
3. Represent mappings as ART-DECOR “template associations”

Method: Map EHR4CR data to eHDSI templates



Datasets

- Demographics
 - Date of Birth
 - Gender
 - Admission Date
 - Discharge Date
 - Case Status
 - Ethnic Group
 - Racial Group
- Disease Characteristics
- Disposition
- Vital Signs
- Laboratory
- Laboratory Findings
- Laboratory Findings
- Laboratory Findings
- Surgery
- Disposition
- Patient Reported Outcome
- ECG
- Adverse Events
- Medical History
- Medical History

Template Associations

Concept: Date of Birth

Templates

Name	Id	Effective date	Element or attribute
eHDSI RecordTarget	2.16.840.1.113883.3.1937.777.11.10.100	2018-11-14 10:54:53	hi7:birthTime
epSOS CDA recordTarget	2.16.840.1.113883.3.1937.777.11.10.100	2018-11-14 10:54:53	

epSOS CDA recordTarget - 2018-11-14 10:54:53 (repository: epsos-)

Id: 2.16.840.1.113883.3.1937.777.11.10.100 (ref: epsos-)

Status: Retired

Name: epSOSCDArecordTarget

Classification: CDA Header Level Template

Open/Closed: Open (other than defined elements are allowed)

Associated with: Associated with 2 concepts

Relationship: Specialization: template 2.16.840.1.113883.3.1937.777.11.10.100 (ref: ad1bbr-)

Expand All Collapse All Search by name

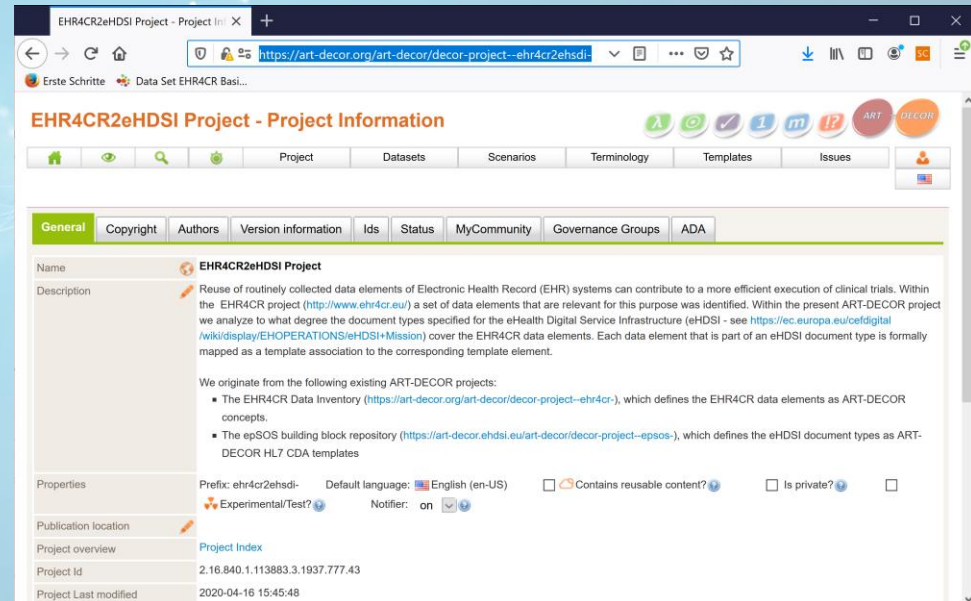
Item	DT	Card	Conf	Description
hi7:recordTarget		1 ... *	R	epSO--rget

Templates

- CDA Document Level Template
- CDA Header Level Template
 - eHDSI AssignedEntity
 - eHDSI Author
 - eHDSI Author Prescriber
 - eHDSI Contact/Preferred HP/Legal Organization
 - eHDSI Custodian
 - eHDSI DocumentationOf
 - eHDSI DocumentationOf PCPR
 - eHDSI LegalAuthenticator
 - eHDSI RecordTarget
 - eHDSI RelatedDocument
- CDA Section Level Template
 - eHDSI Active Problems
 - eHDSI Allergies and Other Adverse Reactions
 - eHDSI Coded Results
 - eHDSI Functional Status
 - eHDSI History Of Past Illness
 - eHDSI List of Surgeries
 - eHDSI Medical Devices
 - eHDSI Pregnancy History
 - eHDSI Social History

Mappings publicly accessible

- ART-DECOR project <https://art-decor.org/art-decor/decor-project--ehr4cr2ehsdi->
- Mappings specified in XML-format
- Easily transformed in computable query (see [Ott et al., 2019])



The screenshot shows a web browser window displaying the 'EHR4CR2eHDSI Project - Project Information' page. The page has a navigation bar with tabs for Project, Datasets, Scenarios, Terminology, Templates, and Issues. Below this is a sub-navigation bar with tabs for General, Copyright, Authors, Version information, Ids, Status, MyCommunity, Governance Groups, and ADA. The 'General' tab is selected, showing the following information:

- Name:** EHR4CR2eHDSI Project
- Description:** Reuse of routinely collected data elements of Electronic Health Record (EHR) systems can contribute to a more efficient execution of clinical trials. Within the EHR4CR project (<http://www.ehr4cr.eu>) a set of data elements that are relevant for this purpose was identified. Within the present ART-DECOR project we analyze to what degree the document types specified for the eHealth Digital Service Infrastructure (eHDSI - see <https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Mission>) cover the EHR4CR data elements. Each data element that is part of an eHDSI document type is formally mapped as a template association to the corresponding template element.

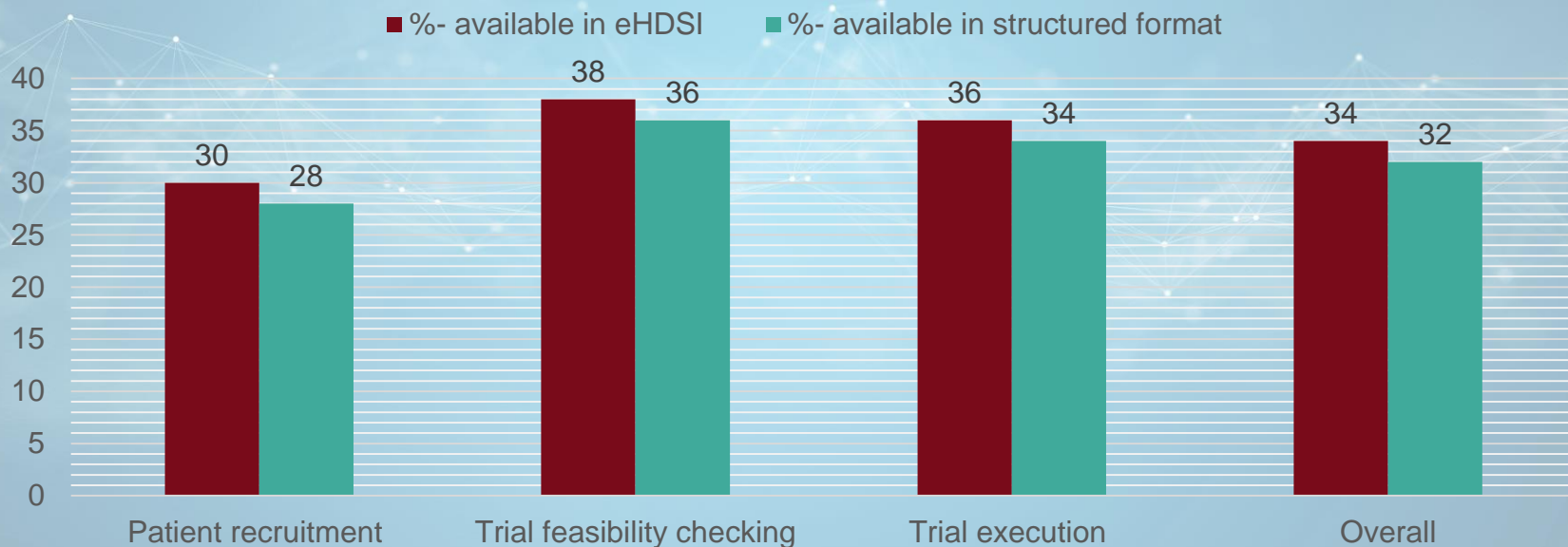
We originate from the following existing ART-DECOR projects:

 - The EHR4CR Data Inventory (<https://art-decor.org/art-decor/decor-project--ehr4cr->), which defines the EHR4CR data elements as ART-DECOR concepts.
 - The epSOS building block repository (<https://art-decor.ehdsi.eu/art-decor/decor-project--epsos->), which defines the eHDSI document types as ART-DECOR HL7 CDA templates
- Properties:** Prefix: ehr4cr2ehsdi- Default language: English (en-US) Contains reusable content? Is private? Experimental/Test? Notifier: on
- Publication location:** Project Index
- Project overview:** Project Id: 2.16.840.1.113883.3.1937.777.43 Project Last modified: 2020-04-16 15:45:48

Results



Proportion of mapable EHR4CR concepts



Discussion (1/2)

- Results (34% availability) **lower** than earlier work
 - [Ateya et al., 2016] \Rightarrow **74%** of recruitment criteria available in structured format in typical hospital EHR system
 - [Köpcke et al., 2013] \Rightarrow **55%** of recruitment criteria available in German university hospitals EHR systems
 - [Augustinov et al., 2019] \Rightarrow **61%** of EHR4CR recruitment criteria available in structured format in ELGA
- Main reason: currently **no lab data** in eHDSI
 - *Potential: If lab data available in eHDSI \Rightarrow **56%** of EHR4CR concepts would be available in eHDSI*

Discussion (2/2)

- eHDSI
 - [+] Multinational patient cohorts
 - [-] Degree of utilization
- Mapping only to eHDSI document structures
 - Many template elements optional
 - Actual frequency of recording unknown

Conclusion



eHDSI coverage of trial-specific concepts currently modest



eHDSI lab report will almost double current coverage (34% => 56%)



eHDSI then useful for multinational clinical trials

THANK YOU FOR YOUR ATTENTION!

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