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*

<table>
<thead>
<tr>
<th>EHR4CR data inventory for patient identification and recruitment</th>
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<tbody>
<tr>
<td>Name</td>
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<td>---------------------</td>
</tr>
<tr>
<td>▶ Demographics</td>
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<tr>
<td>Date of Birth</td>
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<td>Gender</td>
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<tr>
<td>Admission date</td>
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<tr>
<td>discharge date</td>
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<tr>
<td>Case Status</td>
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<td>▶ Medical History</td>
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<td>▶ Medical device</td>
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<td>▶ Diagnosis</td>
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<td>▶ Procedure</td>
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<td>▶ Findings</td>
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<td>▶ Laboratory Findings</td>
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<tr>
<td>▶ Medication</td>
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<tr>
<td>▶ Scores &amp; Classifications</td>
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<tr>
<td>▶ Patient Characteristics</td>
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</tbody>
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Does eHDSI contain these data?

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

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

Proportion of mapable EHR4CR concepts

- % available in eHDSI
- % available in structured format

<table>
<thead>
<tr>
<th></th>
<th>% available in eHDSI</th>
<th>% available in structured format</th>
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<tbody>
<tr>
<td>Patient recruitment</td>
<td>30</td>
<td>28</td>
</tr>
<tr>
<td>Trial feasibility checking</td>
<td>38</td>
<td>36</td>
</tr>
<tr>
<td>Trial execution</td>
<td>36</td>
<td>34</td>
</tr>
<tr>
<td>Overall</td>
<td>34</td>
<td>32</td>
</tr>
</tbody>
</table>
Discussion (1/2)

• Results (34% availability) **lower** than earlier work
  • [Ateya et al., 2016] ⇒ **74%** of recruitment criteria available in structured format in typical hospital EHR system
  • [Köpcke et al., 2013] ⇒ **55%** of recruitment criteria available in German university hospitals EHR systems
  • [Augustinov et al., 2019] ⇒ **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 ⇒ 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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