HL7 FHIR DevDays 2018

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FHIR for Clinical Research

Sebastiaan Knijnenburg

Amsterdam, 14-16 November | @HL7 @FirelyTeam | #fhirdevdays18 | www.fhirdevdays.com

Introduction – Who am I?

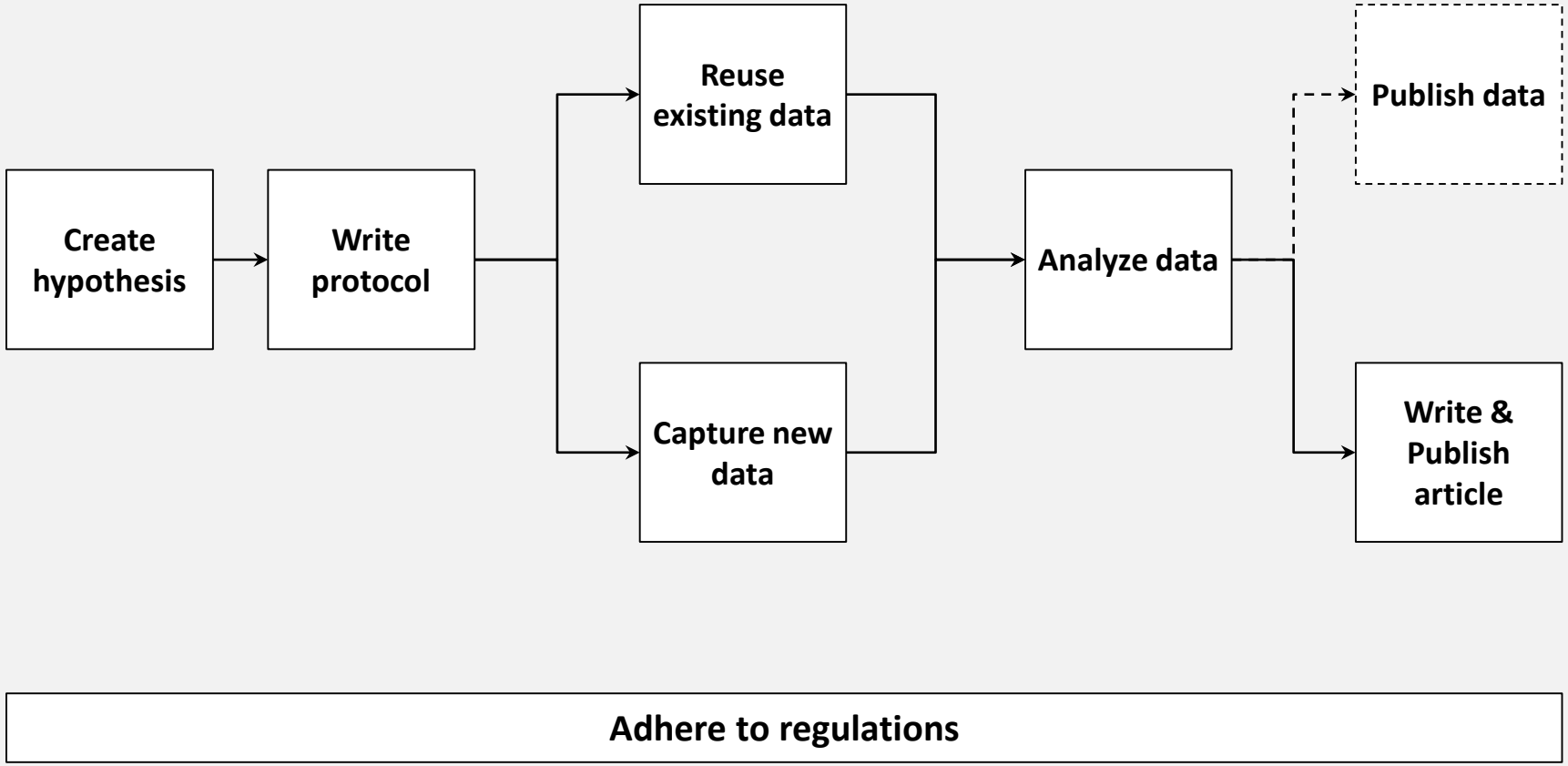
- Name: Sebastiaan Knijnenburg
- Background:
  - MSc in Medical Informatics (& some Medicine)
  - PhD in pediatric oncology
    - Website usability
    - Clinical epidemiology

- Currently Chief Technology Officer at Castor EDC

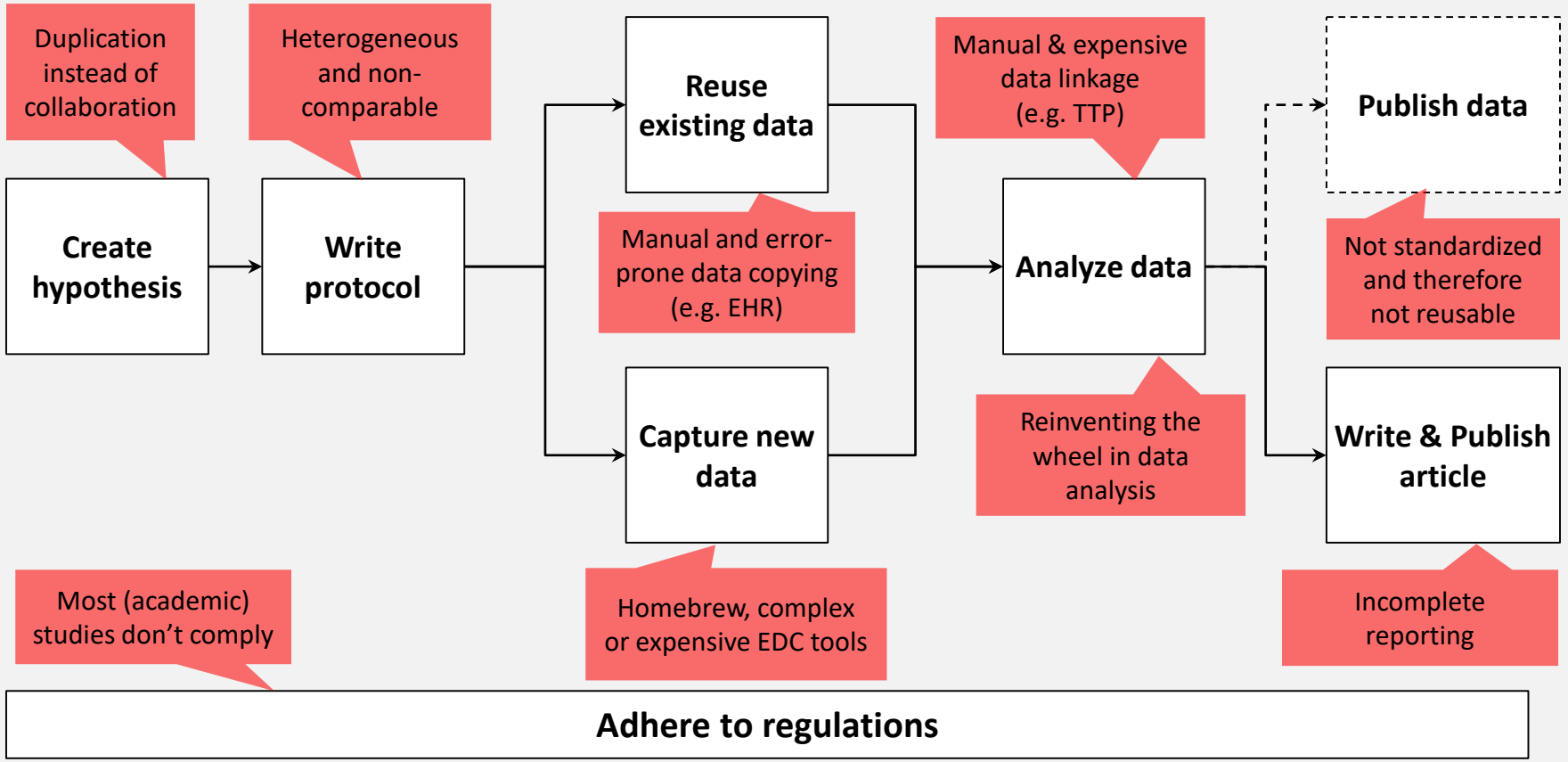
Introduction – Who are you?

- Who has hands-on experience with FHIR?
- Who is working with clinical data?
- Who is involved in research data management?
- Who has written a scientific paper?

The research process



The research process is broken



How can FHIR help to advance medical research?

- Automate electronic data capture via data exchange
- Improve FAIRness of data by facilitating standardization
- Patient recruitment
- Consent management
- Device integration

How can FHIR help to advance medical research?

- **Automate electronic data capture via data exchange**
- **Improve FAIRness of data by facilitating standardization**
- Patient recruitment
- Consent management
- Device integration

Using FHIR for data exchange

- Research data is highly structured
- Protocol defines the data requirements
- Data is often already available within the EHR

- Research database is (usually) standalone
  - Access / Excel
  - One-off databases
  - Electronic Data Capture tools

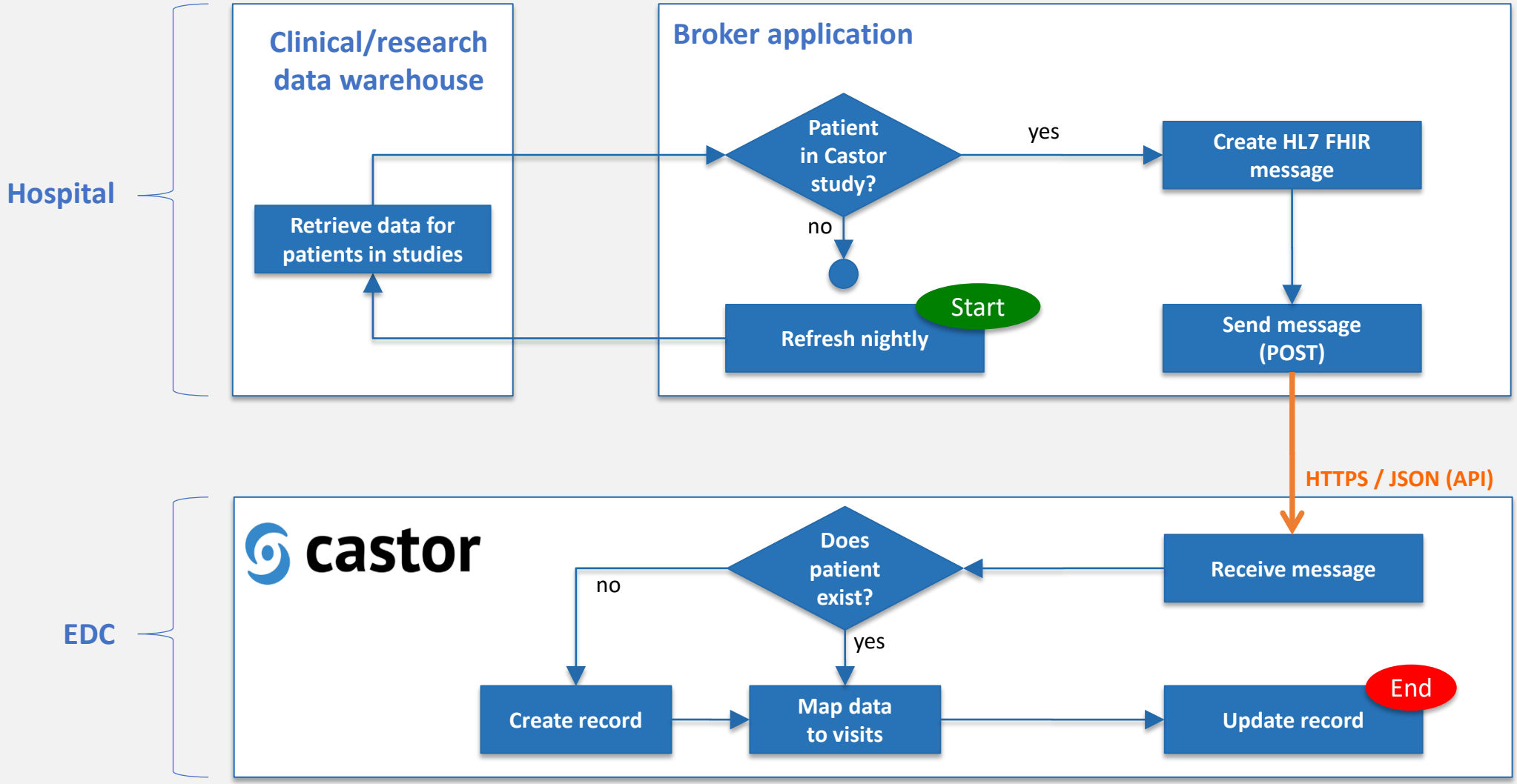
Using FHIR for data exchange

- High level of data duplication / transcription from EHR to research DB
- Study in Dutch UMC:
  - Approximately 70 FTE spent on transcribing data for research
  - High risk of transcription errors
- Manual data linkage often hard to achieve
- (Automated) data import via FHIR
  - Save time
  - Improve quality

Architecture: from EHR to EDC

- Experiences with connecting three Dutch UMCs to Castor
- Started with basic resources:
  - Patient
  - Observation
- Two approaches used:
  - Hospital pushes FHIR messages to the outside world
  - Hospital allows pulling FHIIR messages from the outside world

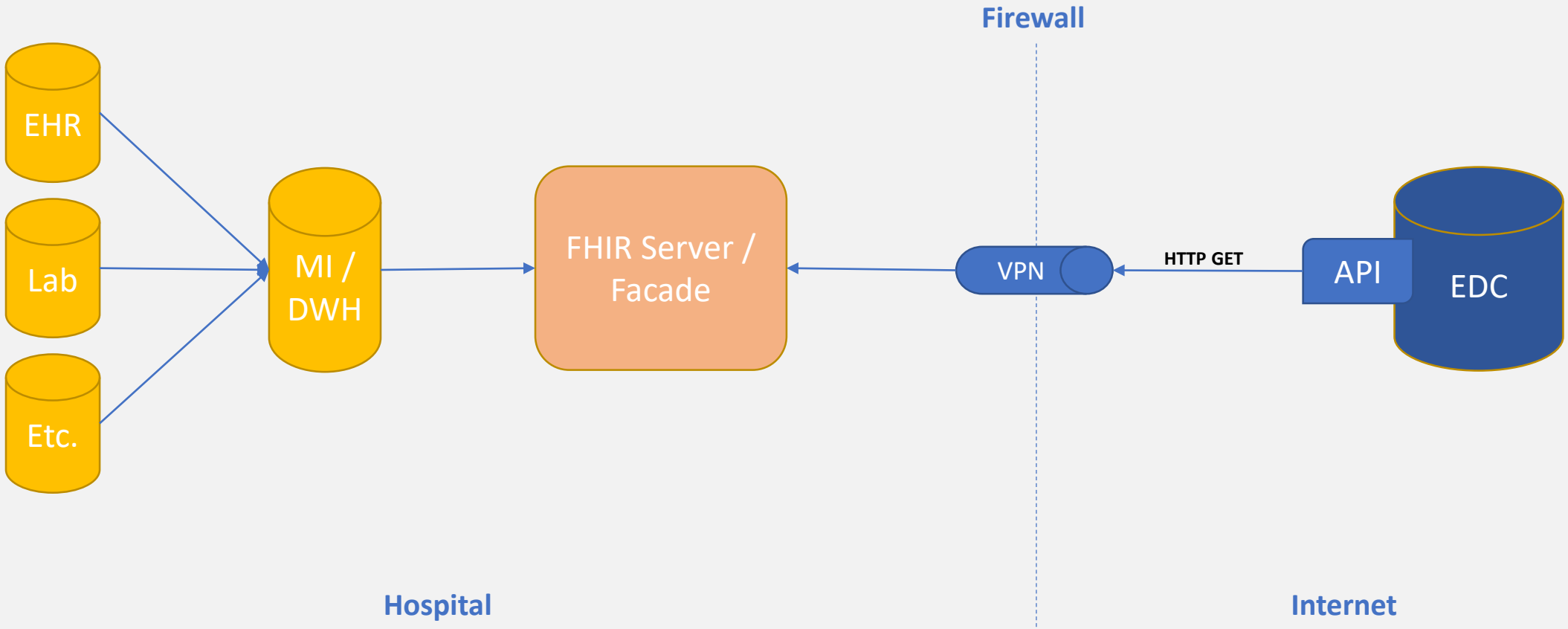
The push mechanism



The push mechanism

- Pros
  - Hospital has full control
  - Flexibility of data sources
  - Notifications when new data becomes available
  - Custom implementations:
    - C# FHIR components
    - MS BizTalk
    - Cloverleaf
    - Etc.
- Cons
  - Requires (internal) IT resources to build and maintain
  - ‘Data dump’ if no negotiation protocol in place
  - Recipient becomes responsible for storage & processing
  - What push-interval to use?

The pull mechanism



The pull mechanism

- Pros
  - Only retrieves necessary data
  - ‘Live’ view of the data
  - Data stays at the source
  - All functionality of a FHIR server available
- Cons
  - Access control
  - Pseudonymization
  - Requires FHIR server implementation in the hospital

Challenges: Identifying studies and patients

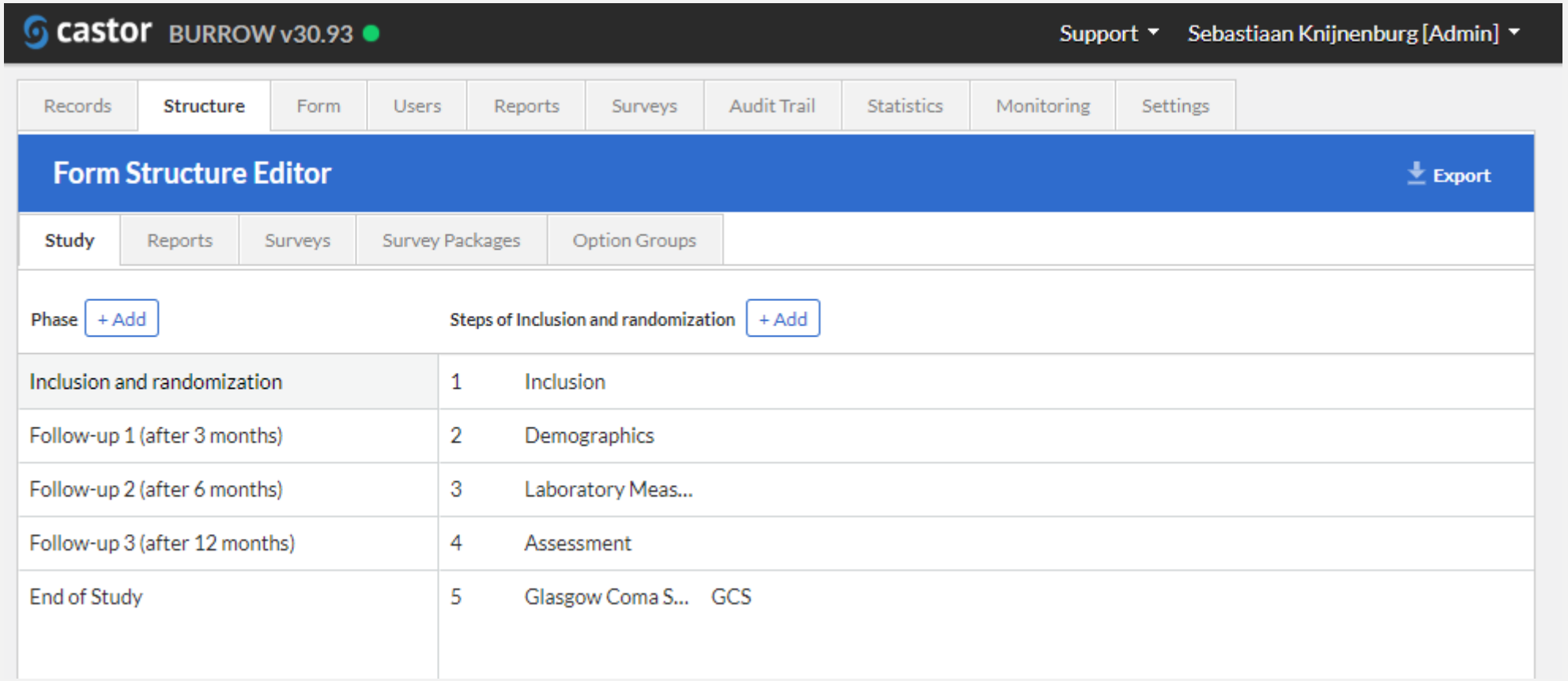
- Study management & patient enrollment differ per institute
- Research data is pseudonymized
- Hospital-specific implementations
  - Store research pseudonyms in the EHR
  - Store hospital identifier in EDC system
  - <StudyID>:<pseudonym> as Patient ID

- Potential use for ResearchStudy and ResearchSubject resources
  - Clinical Research Core IG offers starting point

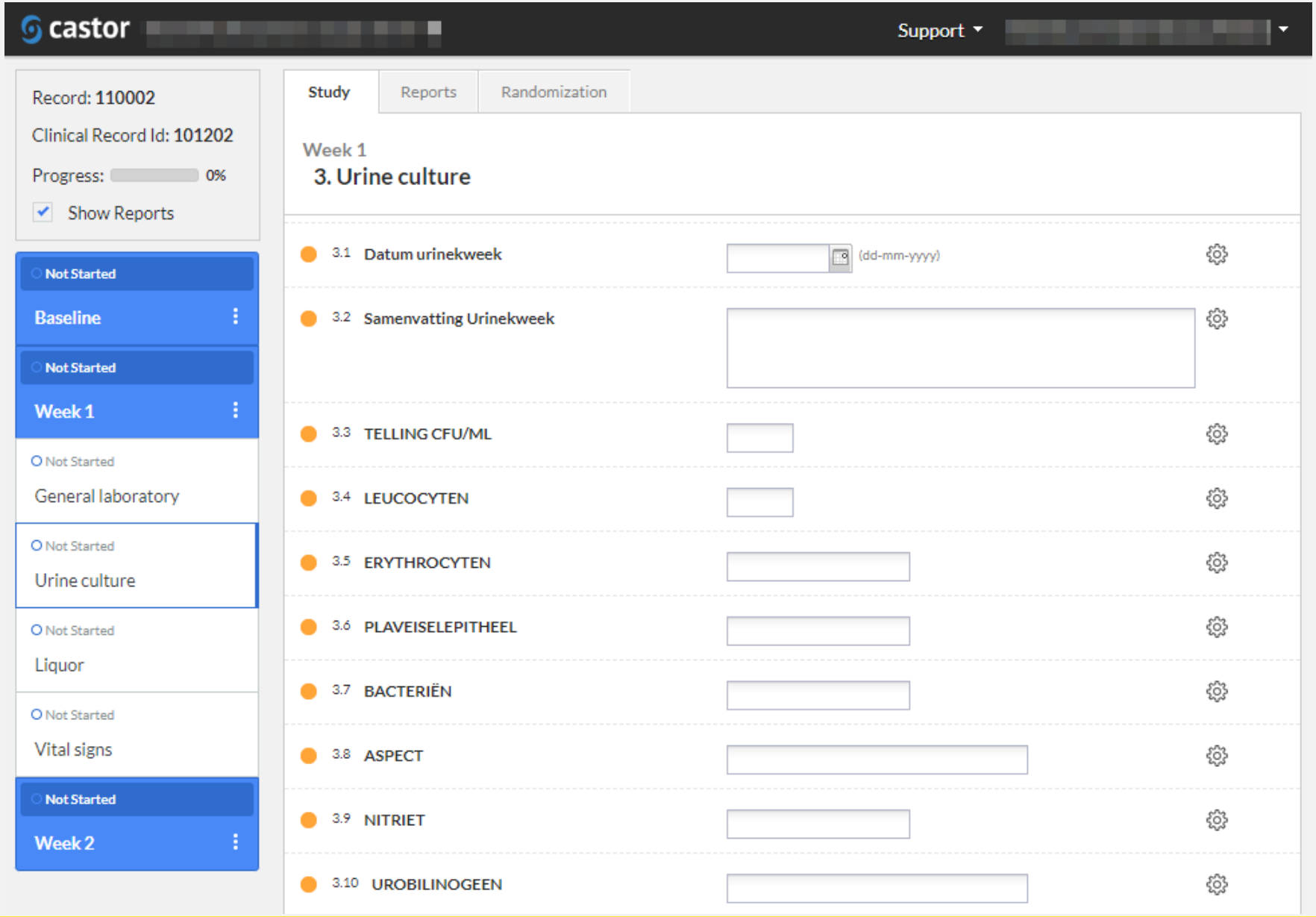
Challenges: mapping incoming data

- Incoming datapoints need to be stored in the right place in the study protocol

Study protocol

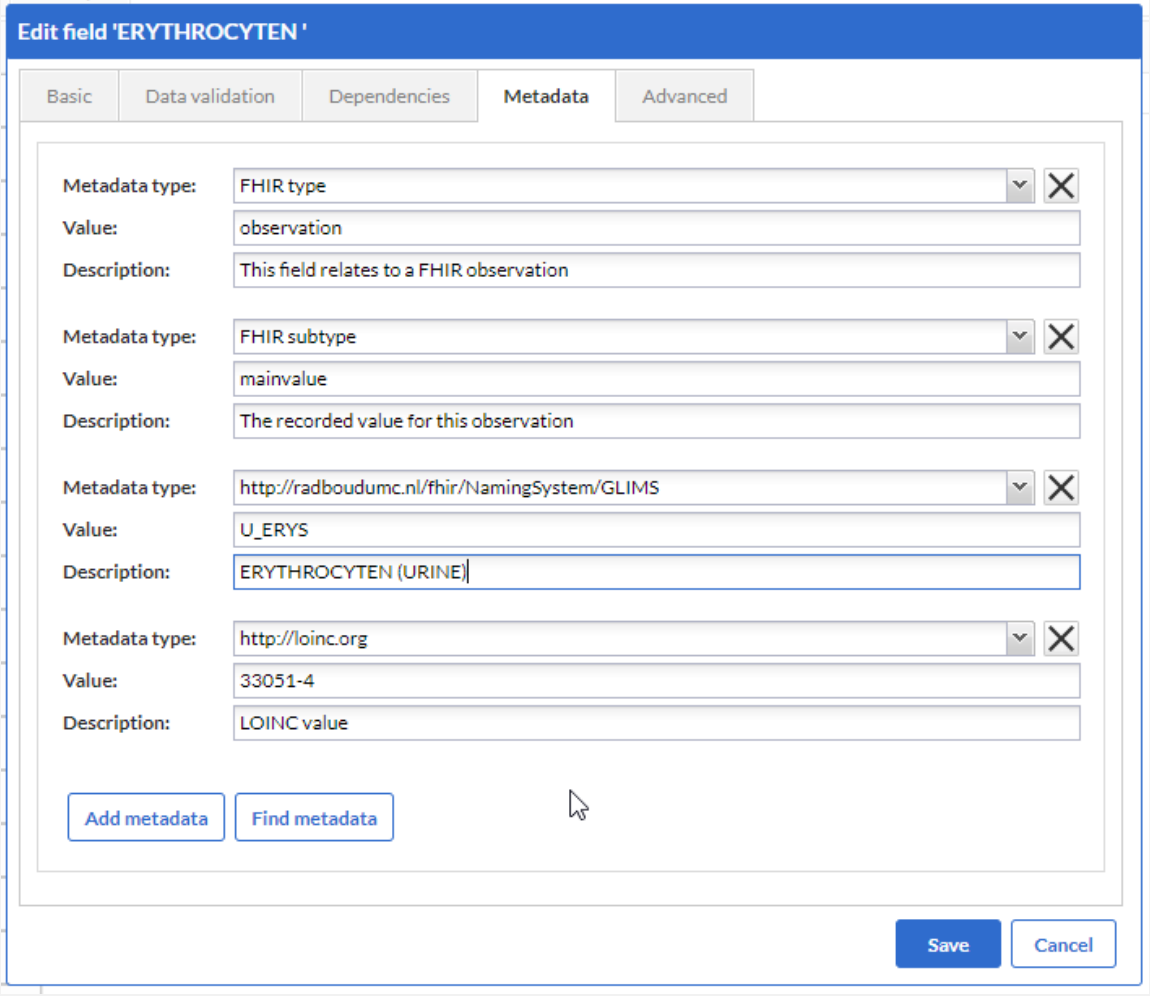


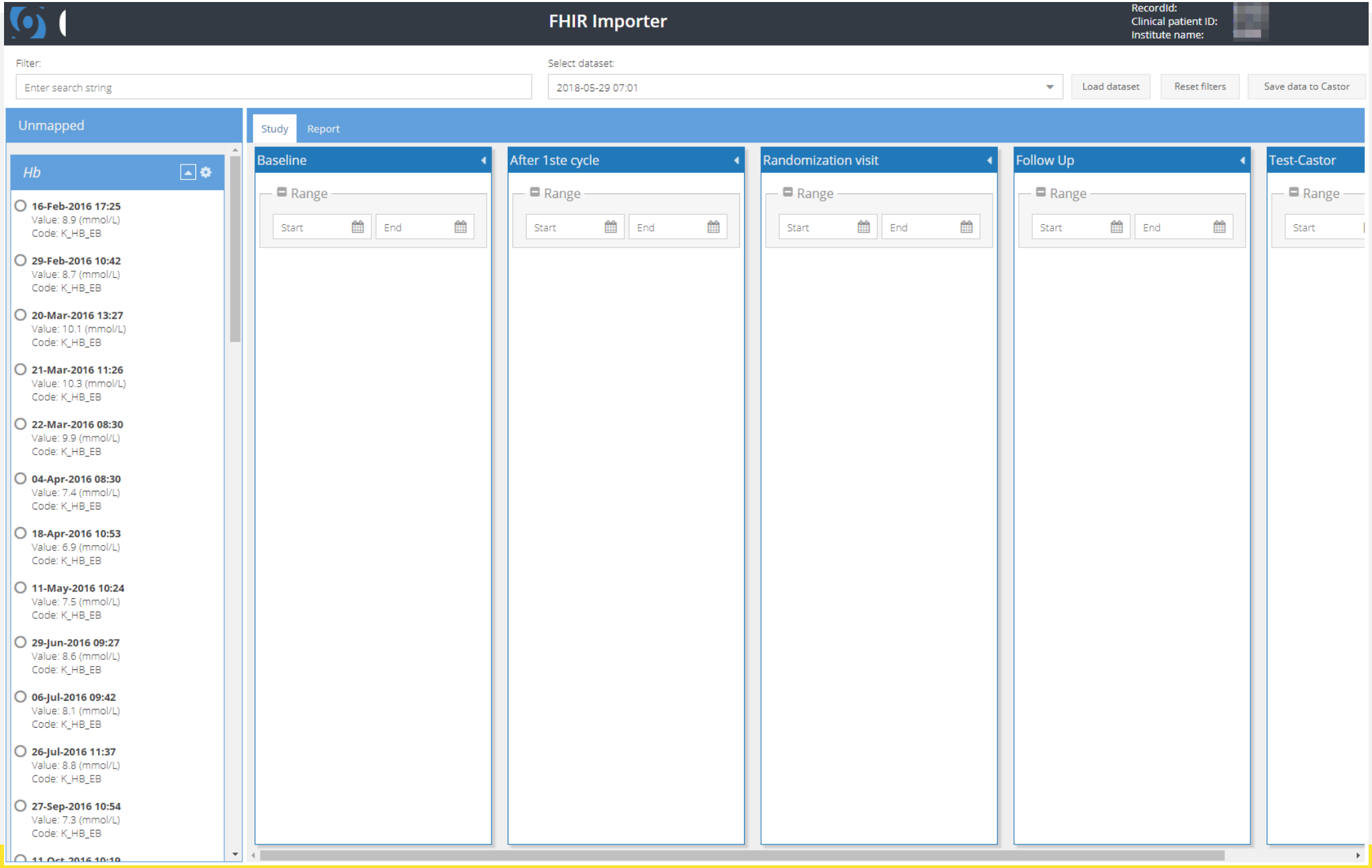
Study forms

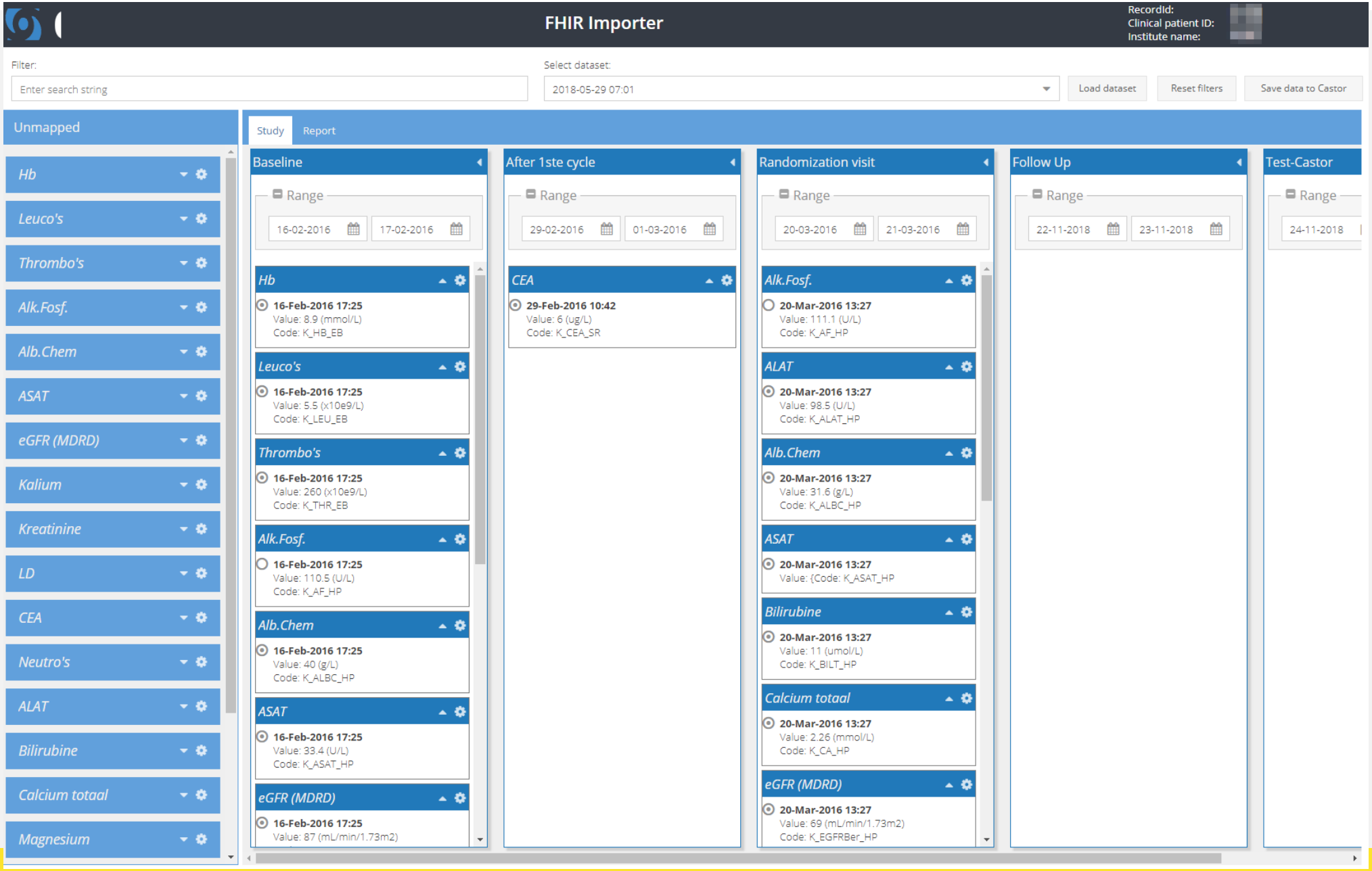

castor
Support
Record: 110002
Clinical Record Id: 101202
Progress: 0%
Show Reports
Not Started
Baseline
Not Started
Week 1
Not Started
General laboratory
Not Started
Urine culture
Not Started
Liquor
Not Started
Vital signs
Not Started
Week 2
Study
Reports
Randomization
Week 1
3. Urine culture
3.1 Datum urinekweek
(dd-mm-yyyy)
3.2 Samenvatting Urinekweek
3.3 TELLING CFU/ML
3.4 LEUCOCYTEN
3.5 ERYTHROCYTEN
3.6 PLAVEISELEPITHEEL
3.7 BACTERIËN
3.8 ASPECT
3.9 NITRIET
3.10 UROBILINOGEEN

Metadata mapping

- Define per data point:
  - Which FHIR resource (Observation)
  - What to store (main value)
  - Which CodableConcept
- Provide search tools for codes
- Allows for form re-use
- Effort required for standardization!



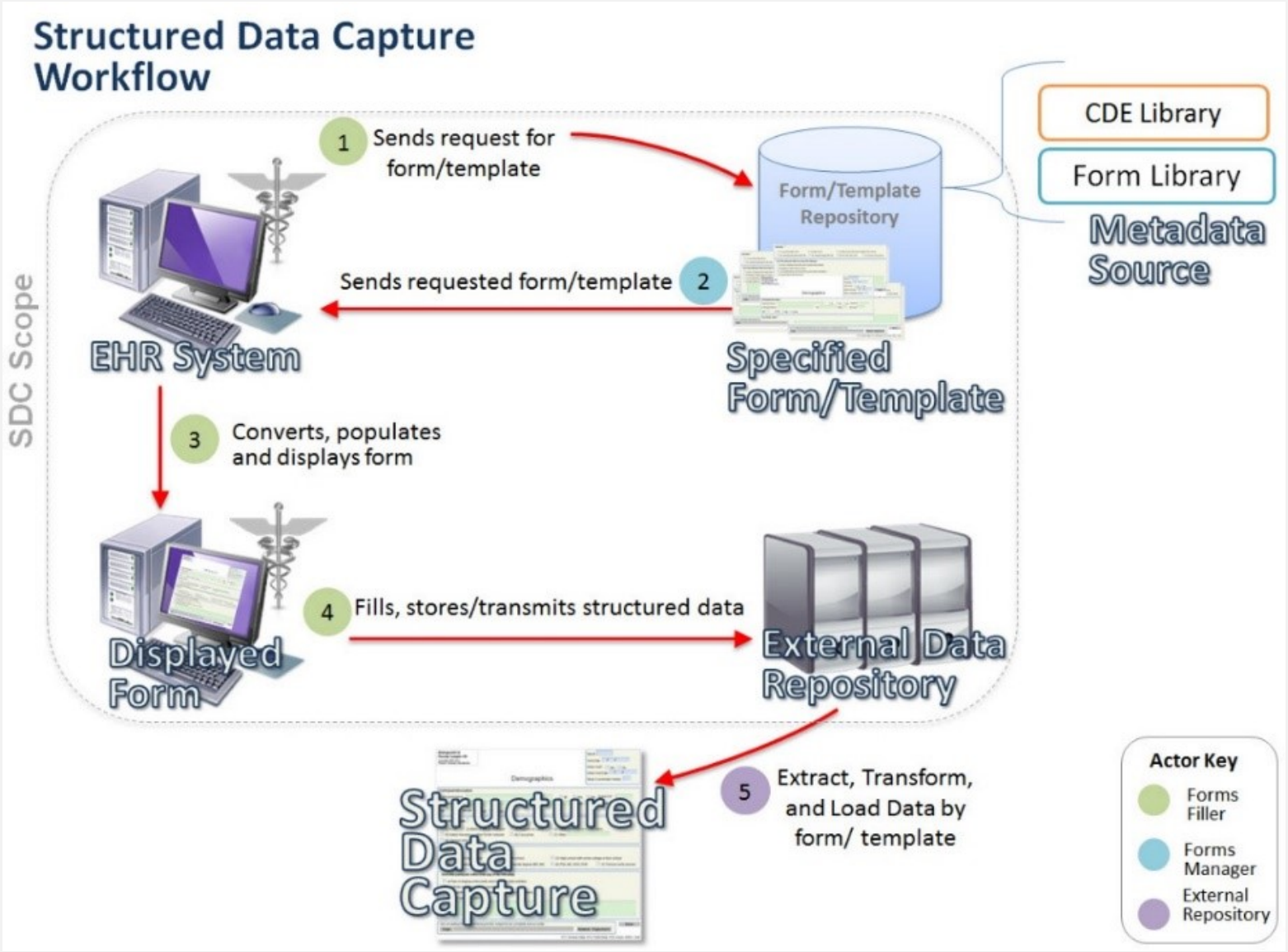

FHIR Importer
RecordId:
Clinical patient ID:
Institute name:
Filter:
Enter search string
Select dataset:
2018-05-29 07:01
Load dataset
Reset filters
Save data to Castor
Unmapped
Hb
16-Feb-2016 17:25
Value: 8.9 (mmol/L)
Code: K_HB_EB
29-Feb-2016 10:42
Value: 8.7 (mmol/L)
Code: K_HB_EB
20-Mar-2016 13:27
Value: 10.1 (mmol/L)
Code: K_HB_EB
21-Mar-2016 11:26
Value: 10.3 (mmol/L)
Code: K_HB_EB
22-Mar-2016 08:30
Value: 9.9 (mmol/L)
Code: K_HB_EB
04-Apr-2016 08:30
Value: 7.4 (mmol/L)
Code: K_HB_EB
18-Apr-2016 10:53
Value: 6.9 (mmol/L)
Code: K_HB_EB
11-May-2016 10:24
Value: 7.5 (mmol/L)
Code: K_HB_EB
29-Jun-2016 09:27
Value: 8.6 (mmol/L)
Code: K_HB_EB
06-Jul-2016 09:42
Value: 8.1 (mmol/L)
Code: K_HB_EB
26-Jul-2016 11:37
Value: 8.8 (mmol/L)
Code: K_HB_EB
27-Sep-2016 10:54
Value: 7.3 (mmol/L)
Code: K_HB_EB
Study
Report
Baseline
After 1ste cycle
Randomization visit
Follow Up
Test-Castor
Range
Start
End


FHIR Importer
RecordId:
Clinical patient ID:
Institute name:
Filter:
Enter search string
Select dataset:
2018-05-29 07:01
Load dataset
Reset filters
Save data to Castor
Unmapped
Hb
Leuco's
Thrombo's
Alk.Fosf.
Alb.Chem
ASAT
eGFR (MDRD)
Kalium
Kreatinine
LD
CEA
Neutro's
ALAT
Bilirubine
Calcium totaal
Magnesium
Study
Report
Baseline
Range
16-02-2016
17-02-2016
Hb
16-Feb-2016 17:25
Value: 8.9 (mmol/L)
Code: K_HB_EB
Leuco's
16-Feb-2016 17:25
Value: 5.5 (x10e9/L)
Code: K_LEU_EB
Thrombo's
16-Feb-2016 17:25
Value: 260 (x10e9/L)
Code: K_THR_EB
Alk.Fosf.
16-Feb-2016 17:25
Value: 110.5 (U/L)
Code: K_AF_HP
Alb.Chem
16-Feb-2016 17:25
Value: 40 (g/L)
Code: K_ALBC_HP
ASAT
16-Feb-2016 17:25
Value: 33.4 (U/L)
Code: K_ASAT_HP
eGFR (MDRD)
16-Feb-2016 17:25
Value: 87 (mL/min/1.73m2)
After 1ste cycle
Range
29-02-2016
01-03-2016
CEA
29-Feb-2016 10:42
Value: 6 (ug/L)
Code: K_CEA_SR
Randomization visit
Range
20-03-2016
21-03-2016
Alk.Fosf.
20-Mar-2016 13:27
Value: 111.1 (U/L)
Code: K_AF_HP
ALAT
20-Mar-2016 13:27
Value: 98.5 (U/L)
Code: K_ALAT_HP
Alb.Chem
20-Mar-2016 13:27
Value: 31.6 (g/L)
Code: K_ALBC_HP
ASAT
20-Mar-2016 13:27
Value: {Code: K_ASAT_HP
Bilirubine
20-Mar-2016 13:27
Value: 11 (umol/L)
Code: K_BILT_HP
Calcium totaal
20-Mar-2016 13:27
Value: 2.26 (mmol/L)
Code: K_CA_HP
eGFR (MDRD)
20-Mar-2016 13:27
Value: 69 (mL/min/1.73m2)
Code: K_EGFRBer_HP
Follow Up
Range
22-11-2018
23-11-2018
Test-Castor
Range
24-11-2018

EDC integration in the EHR

- Structured Data Capture (SDC) IG
  - Infrastructure to standardize and automate data capture within the EHR
  - See Lloyd McKenzie's presentation from this morning

- Profiles for
  - Form definitions (SDC Questionnaire)
  - Form data (SDC Questionnaire Response)
  - Values sets (SDC Value Set)
  - Code Systems (SDC Code System)
  - Data Elements (SDC Data Element)



Source: https://wiki.ihe.net/index.php/Structured_Data_Capture

Improve FAIRness of data

- FAIR: Findable, Accessible, Interoperable, Reusable
  - Regarding data, metadata and infrastructure
- Defining metadata is hard for (medical) researchers
- FHIR CodeSystems at the source can greatly help
- Efforts required to harmonize used CodeSystems between hospitals/countries

FHIR in Clinical Research

- Ample opportunities for FHIR to improve research
  - Data exchange, patient recruitment, consent, device integration, etc.
- Uptake in (Dutch) hospitals steadily increasing
- Metadata annotation core priority
  - Focus on international standards (LOINC, SNOMED, ICD, etc.)
  - Collaborate on (national) FHIR profiles

What are your experiences?

Questions?

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