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Piloting the European Unified Patient Identity Management (EUPID) Concept to Facilitate Secondary Use of Neuroblastoma Data from Clinical Trials and Biobanking

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Introduction

- Neuroblastoma most common cancer in infancy
- Rare disease – about 650 Incidents p.a. USA [1]
- Data collection during clinical trials needs to be done over large networks and many institutions

Secondary Use

- Re-Use of existing datasets from clinical trials
- Combine datasets from different sources

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Aims

- Provide new findings
- Improve future treatment

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- Improve future treatment

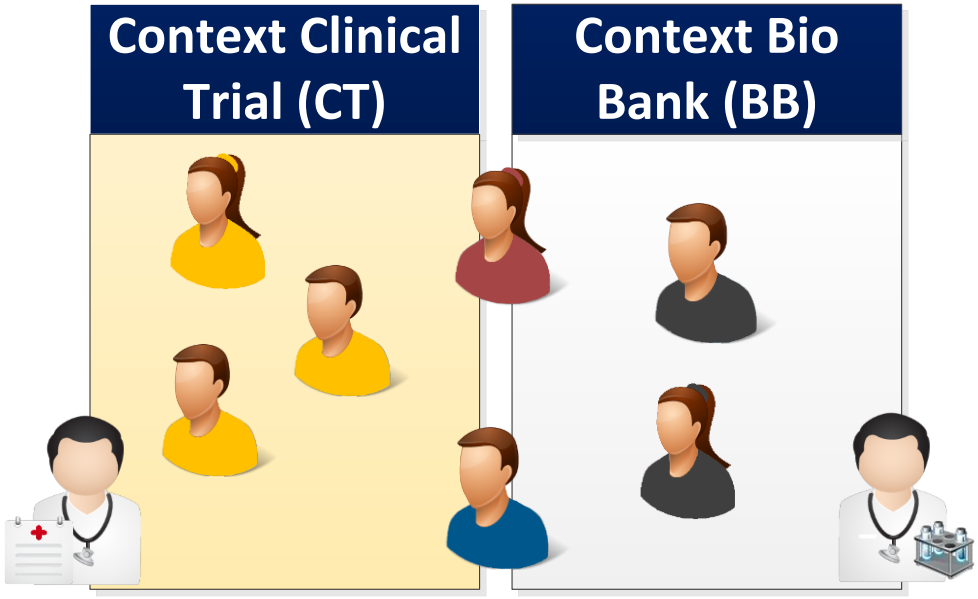
Hurdles

- Regulatory barriers
- Patient consent

Preparations for Secondary Use

- Pseudonymisation of Patients - Removing of patient identifiers from datasets
- Provide linkage patients over different trials
- Provide linkage of the accompanying datasets

Pilot Test Setting



European Unresectable Neuroblastoma (EUNB) trial

160 Patients

Results from array comparative genomic hybridisation (CGH) analyses from corresponding tumour samples

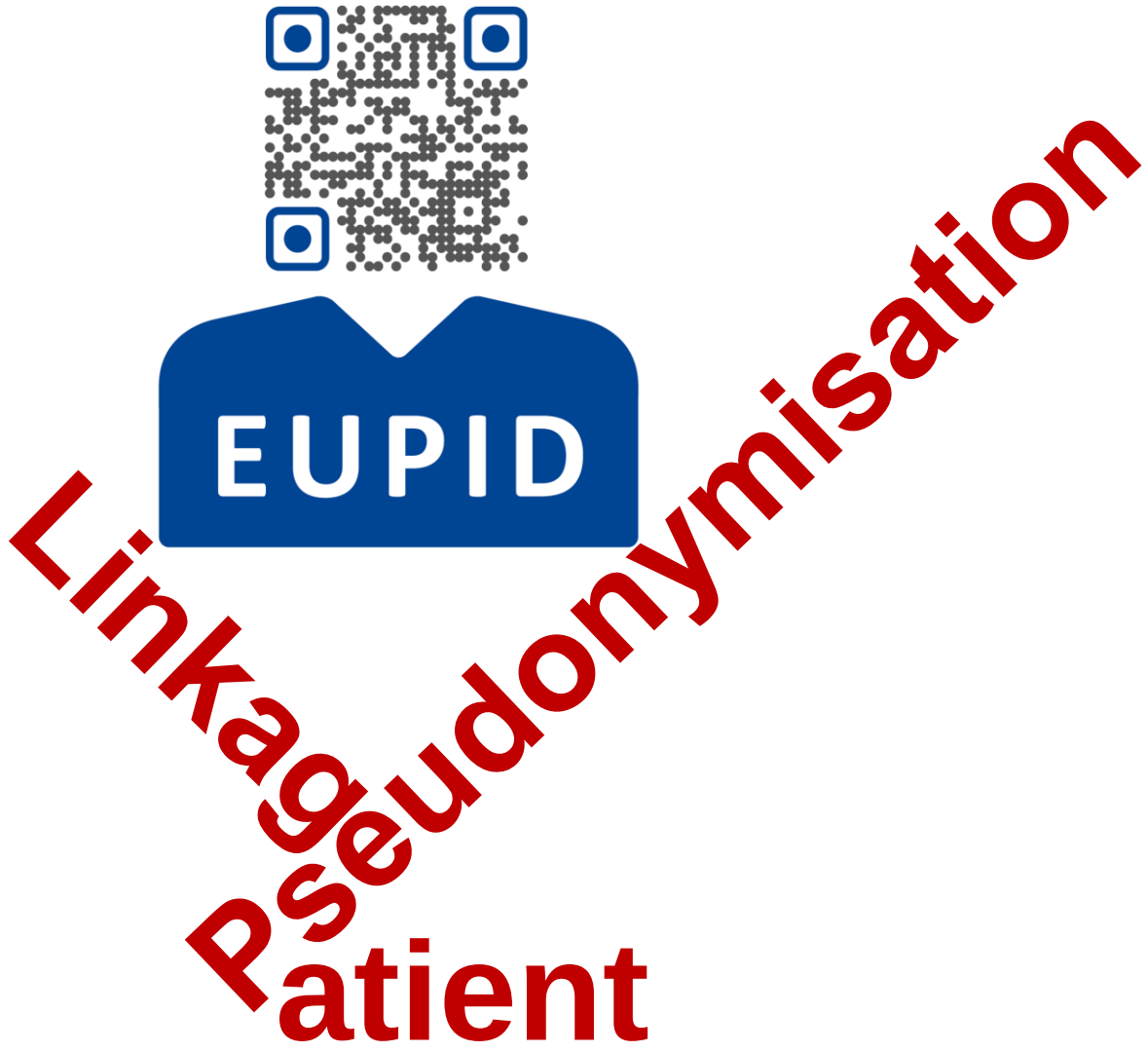
48 Patients

Needs for Secondary Use in the Pilot Test

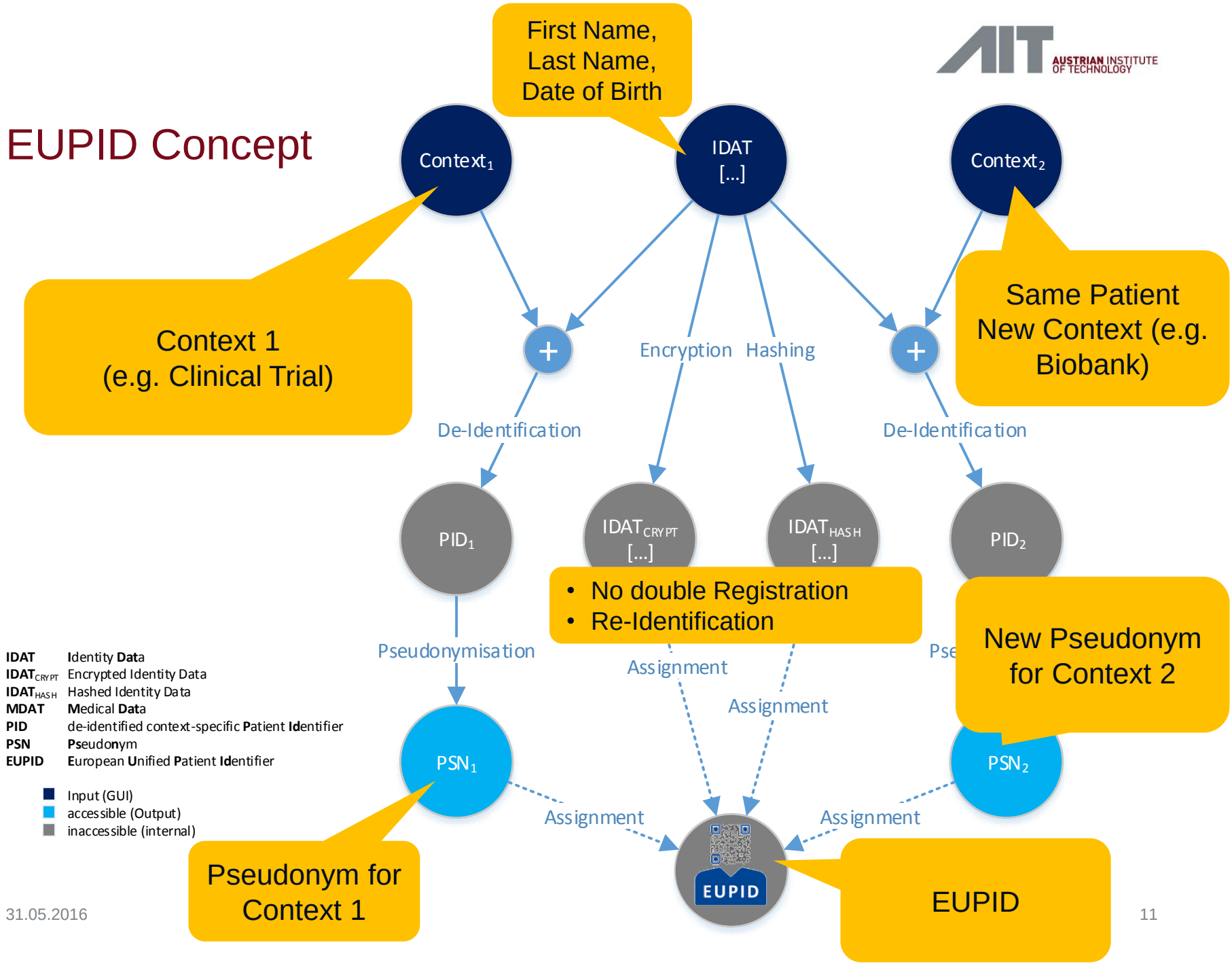
- Creation of Pseudonyms
  - Pseudonymisation of patients in Clinical Trial (CT)
  - Pseudonymisation of patients in Bio Banking (BB)

- Linkage of patients
- Linkage of accompanying datasets

European Unified Patient Identity Management



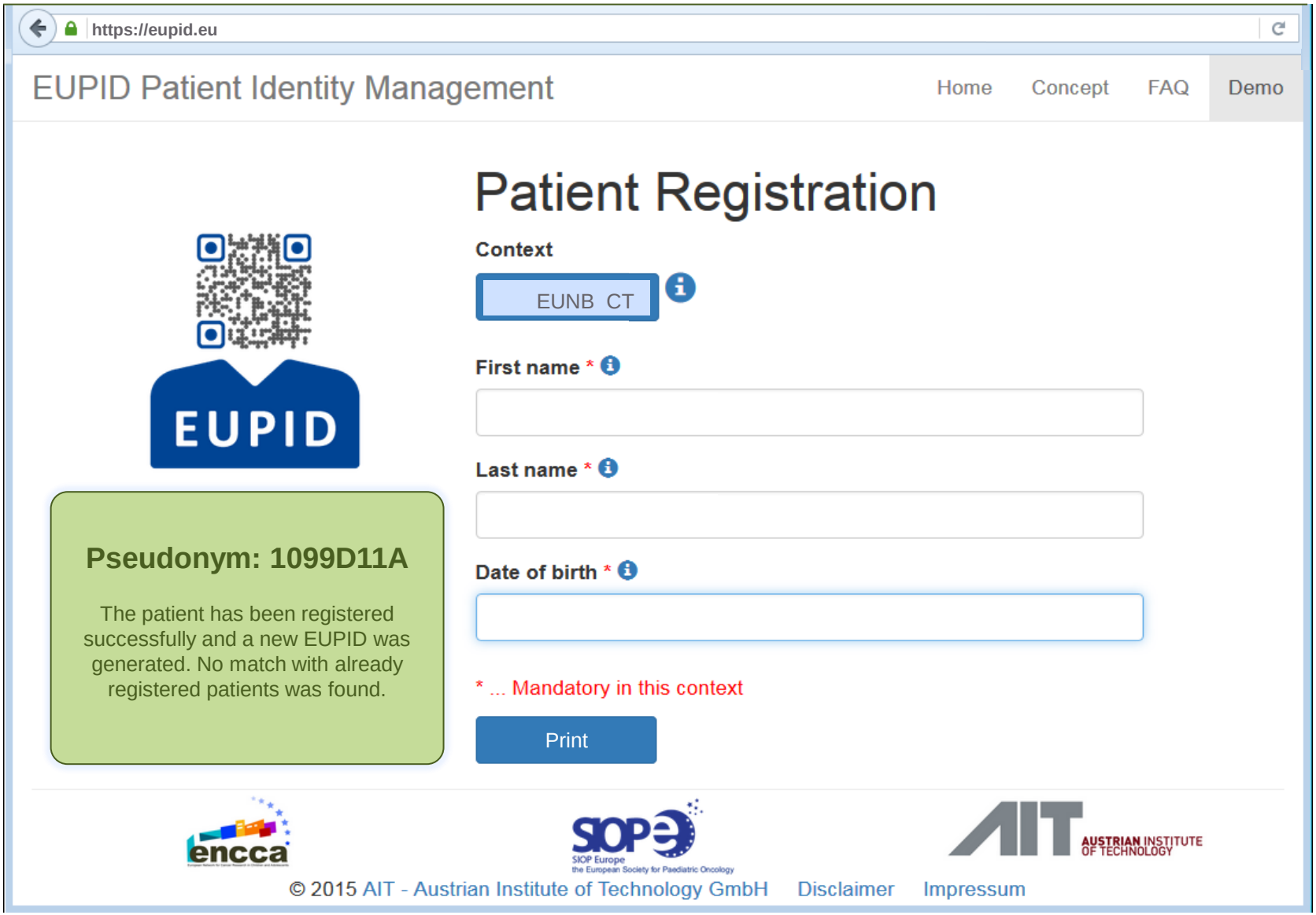
EUPID Concept



IDAT	**I**dentity **Dat**a
IDAT$_{CRYPT}$	Encrypted Identity Data
IDAT$_{HASH}$	Hashed Identity Data
MDAT	**M**edical **Dat**a
PID	de-identified context-specific **P**atient **Id**entifier
PSN	**Ps**eudo**n**ym
EUPID	**E**uropean **U**nified **P**atient **Id**entifier

Input (GUI)
accessible (Output)
inaccessible (internal)

EUPID - Client

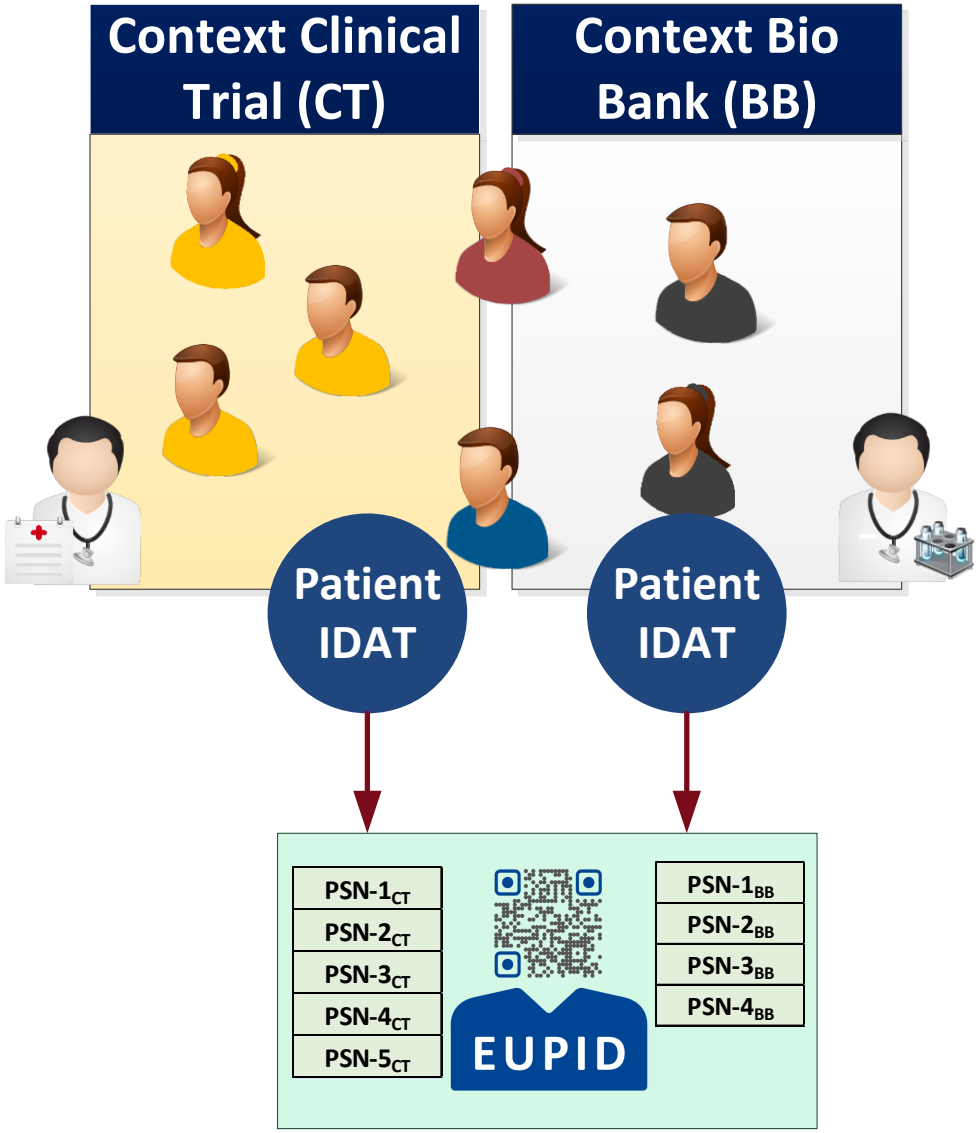


EUPID - Client

- Webapp on local client
- Plain text IDAT never leaves client
- Encrypting and phonetic hashing of IDAT done locally

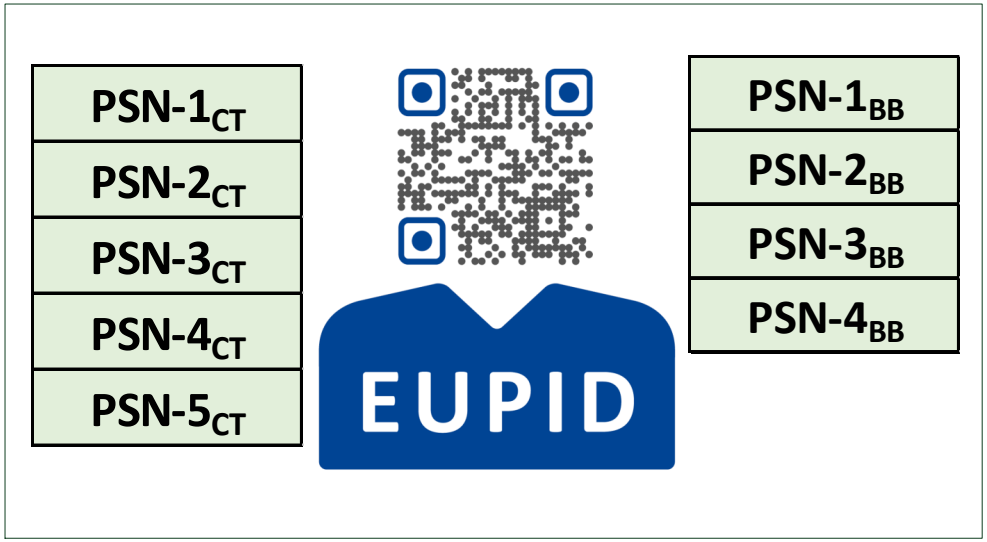
- Only Encrypted and Hashed Values are transferred

EUPID - Pseudonymisation



IDAT…Identification Data
PSN… Pseudonyms

EUPID – Linkage



Reference Table	
PSN_{CT}	PSN_{BB}
$PSN\text{-}1_{CT}$	$PSN\text{-}2_{BB}$
$PSN\text{-}2_{CT}$	
$PSN\text{-}3_{CT}$	$PSN\text{-}3_{BB}$
$PSN\text{-}4_{CT}$	

PSN… Pseudonyms

Needs for Secondary Use in the Pilot

- Creation of Pseudonyms
  - Pseudonymisation of patients in Clinical Trial (CT) ✓
  - Pseudonymisation of patients in Bio Banking (BB) ✓
- Linkage of Patients (if there is a link) ✓
- Linkage of accompanying data

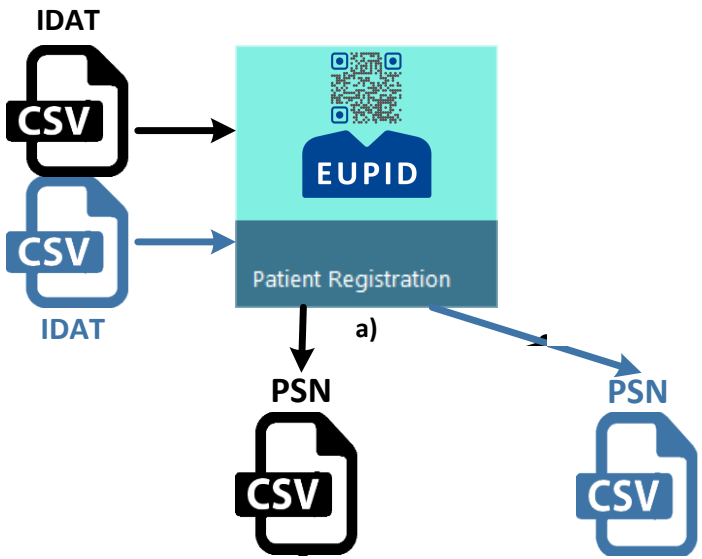
ABCD-4-E pipeline for data production

- EUPID Patient Registration
- Standardization of Data
  (Operational Data Model [14], XML-based)
- PSN-Exchange
- Data upload to Repository

ABCD-4-E … Advanced Biomedical Collaboration Domain for ENCCA [4]
ENCCA … European Network for Cancer Research in Children and Adolescents [5]

EUPID - Patient Registration

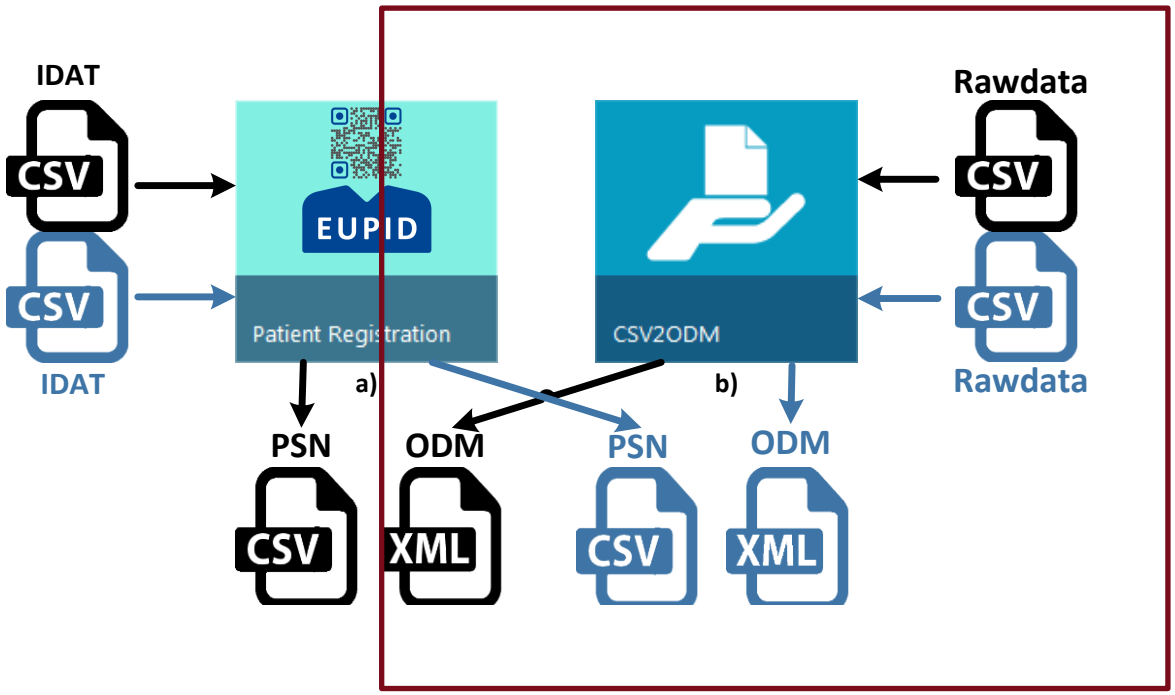
- **CLINICAL TRIAL (160 patients)**
- **BIOBANK (48 patients)**



IDAT … Identification Data
PSN … Pseudonym

CSV2ODM – Standardization of Data

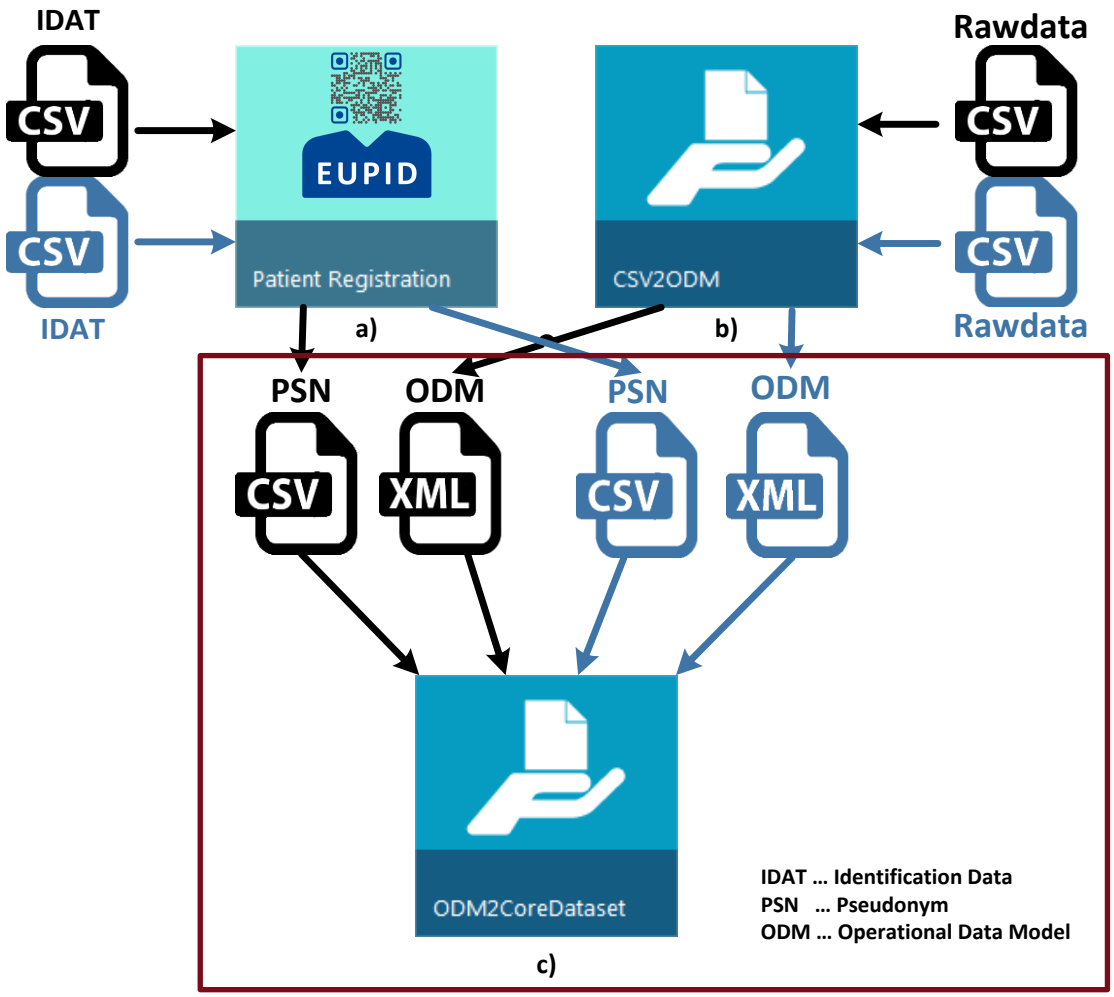
- **CLINICAL TRIAL (160 patients)**
- **BIOBANK (48 patients)**



IDAT … Identification Data
PSN … Pseudonym
ODM … Operational Data Model

ODM2CoreDataset - PSN-Exchange and Data upload

- **CLINICAL TRIAL (160 patients)**
- **BIOBANK (48 patients)**



Results

- EUPID was able to link each of the 48 patients from the biobank (BB) to their corresponding pseudonym from the clinical trial (CT).
- Joined dataset containing linked pseudonyms for 48 patients
- AIT took over the role of the trusted third party to access the *Reference Table*.

Discussion

- EUPID overcomes barriers of regulatory framework and patient consent
- Re-identification possible by Trusted Third Party
- Strategies to avoid Re-identification by comparing datasets
  - Randomizing order of datasets rows
  - Coarsening of typical individual information
  - k-anonymity
  - l-diversity

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Thank you

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