Using real world data for clinical trials.

Where are we and where are we going …

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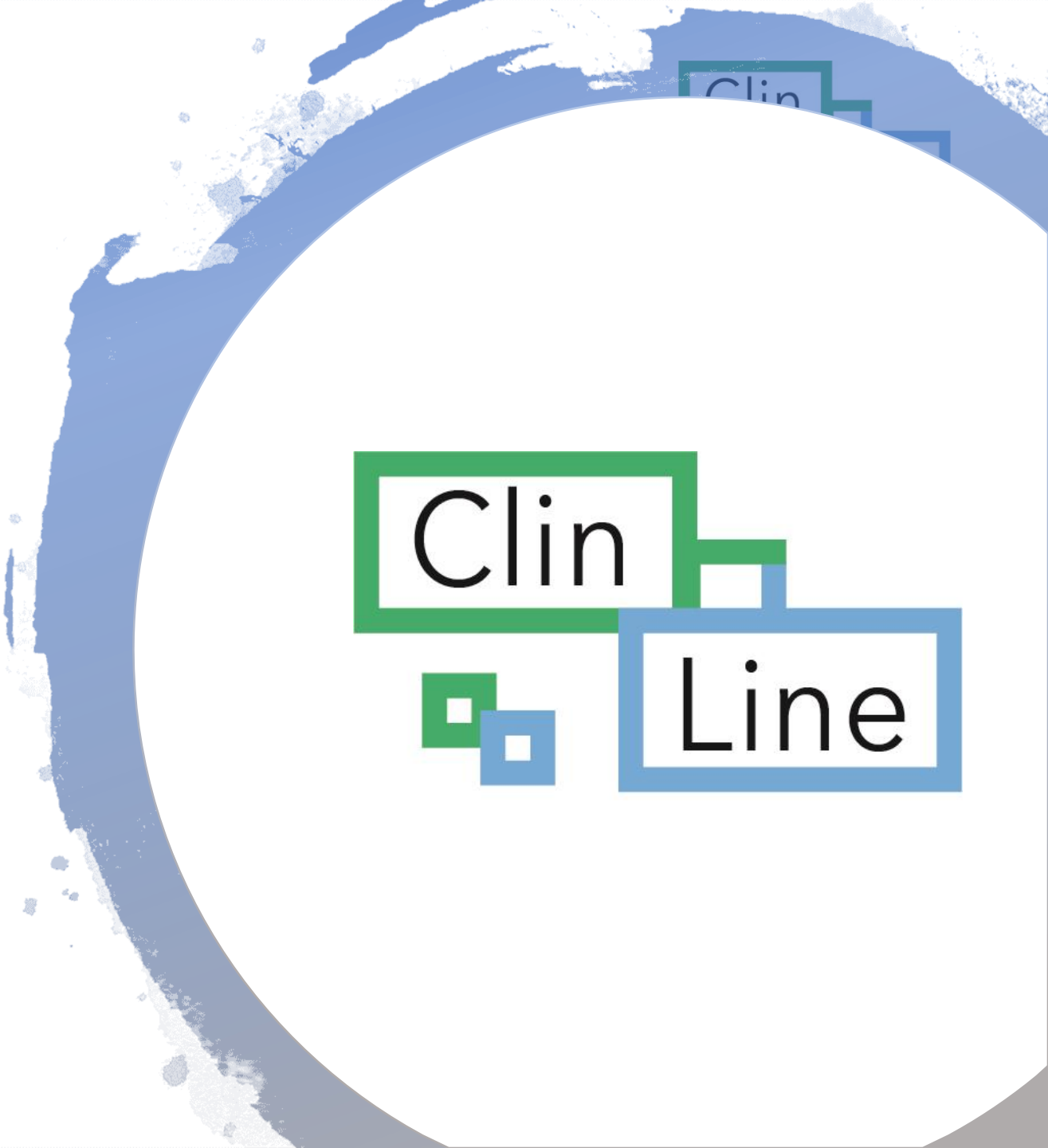


Content

- Where are we now?
- The future..
- Challenges
- Summary & conclusions

Where are we now?

- PRO
  - App, Web, IVRS, (EHR)
  - Primary or secondary outcomes
    - Pain (VAS)
    - Quality of life
    - Disease specific scales
  - Safety
    - Any AEs?

Where are we now?

- EHR, claims databases, lab data and registries
  - Study set-up
  - Selection and recruitment of patients
  - Safety reporting
  - Outcomes

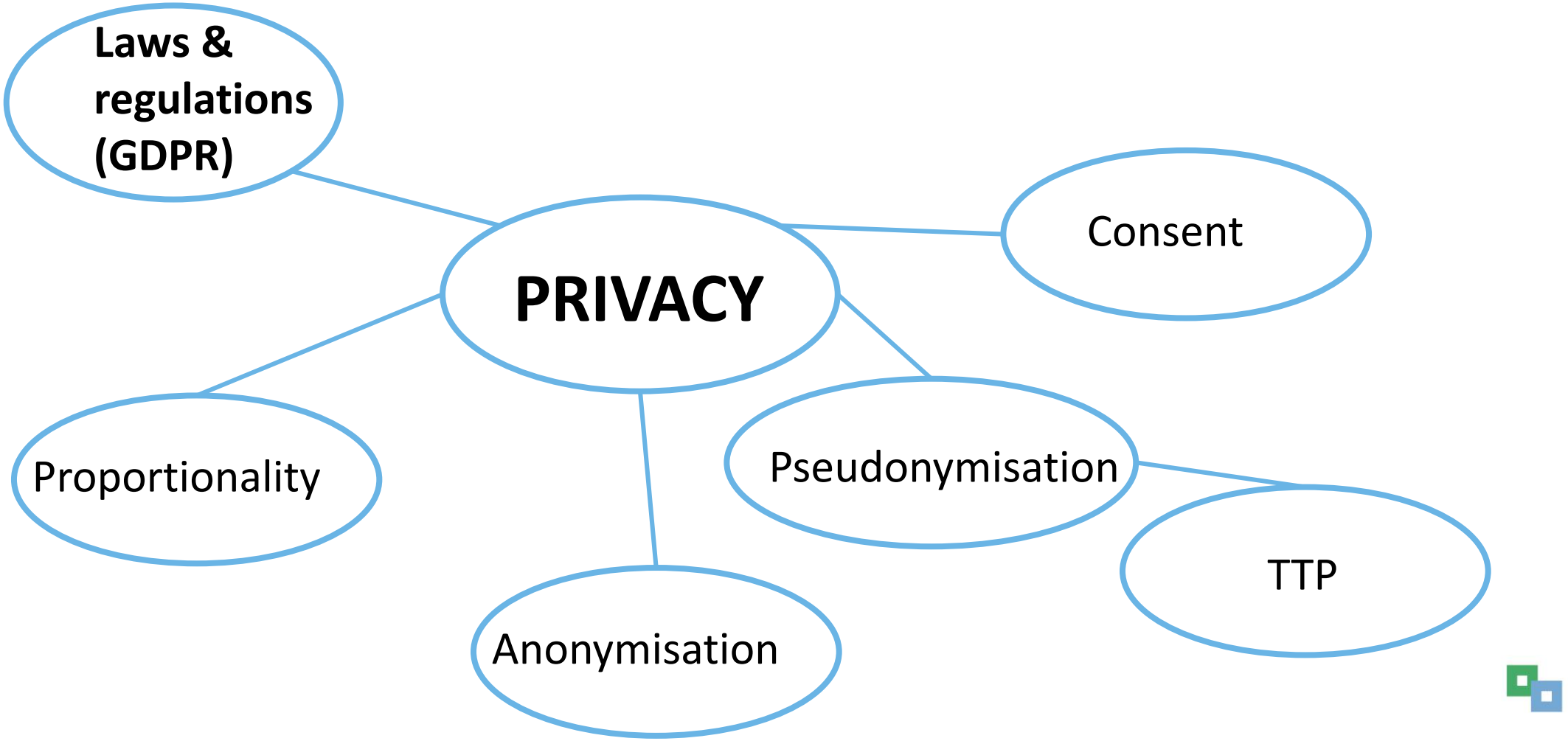
Where are we now?

- Patient generated data
  - Medical devices
  - Consumer devices
  - Social media
  - IoT

Future…

- RWD analysis for best study design
- Recruitment via pseudonymised data lakes
- PROs directly via devices and apps linked to clinical study database or from EHR
- Safety data from EHR
- Outcomes from EHR
- Follow up from EHR
- Other clinical study data returned to EHR
- More……..?

FAIR


Laws & regulations (GDPR)
PRIVACY
Consent
Proportionality
Pseudonymisation
TTP
Anonymisation

Data sources

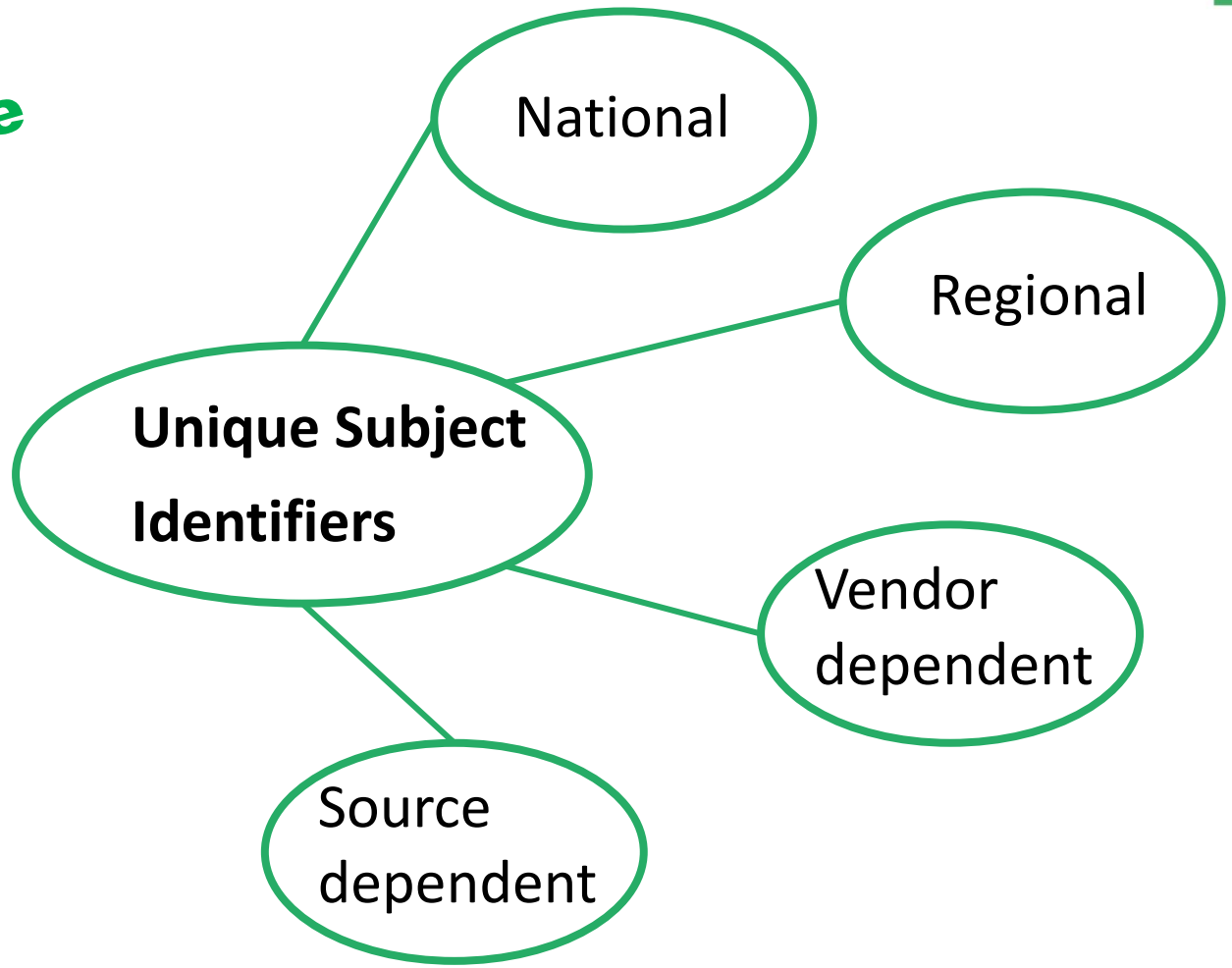
- Directly via health Care Professionals
- Health Care Software Providers – Centralized database
- Registries
- National Electronic Health Records
  - Patients can see and add their own information
- Other clinical health databases

Data Linkage

Exact Linkage

Deterministic Linkage

Probabilistic linkage



Data linkage

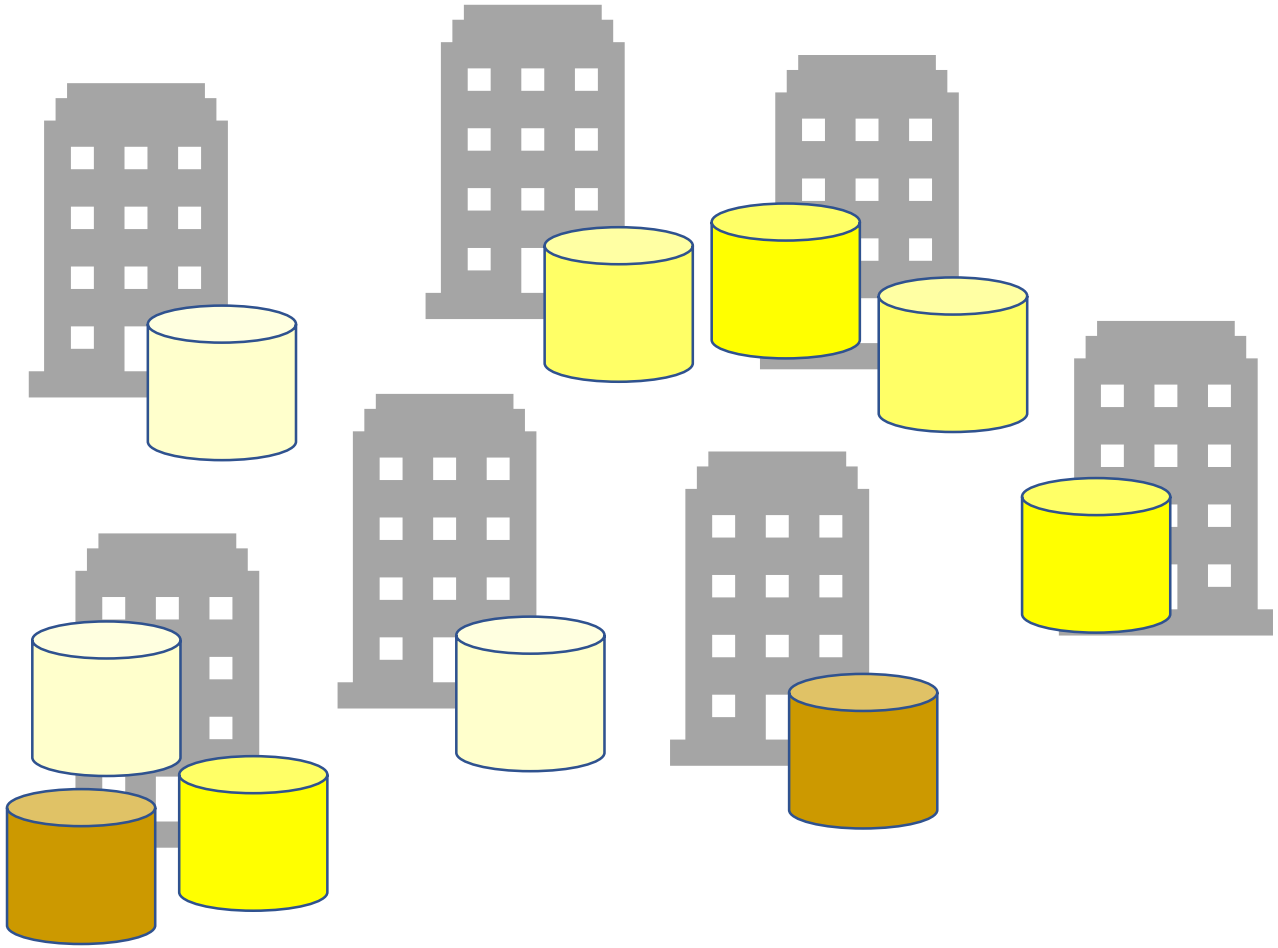
- Risks
  - Mismatches of patients
  - Duplication of patients
  - Unmatched data
  - Privacy issues increased
- Keep risks under control
- Describe risks and accuracy

Data linkage

- Improves
  (better registrations)
- Legacy data
- Independent data sources
  - Social media
  - Consumer data

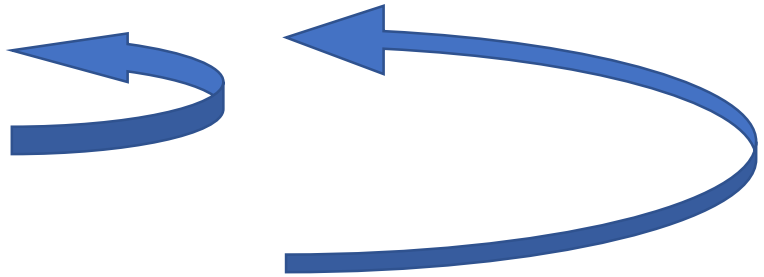
Using the clinical data sources

- Have a copy
  - Anonimized
  - Analyze whatever you want
  - Internal data lake
- Outsource the analysis
  - No copies of data
  - Outsourcing risks
- External access to the data
  - No outsourcing risk
  - No data, only results



Different standards

- CDISC
- FHIR
- OMOP
- GRDR / EUCERD
- PCORnet
- …



- Different goals
- Different levels of maturity
- Different controlled terminology lists

Dirty RWD

- Different systems
- Not intended for research
- Registration quality
- Duplications
- Missings
- Text mining

Uncertainty

Validation

Statistical methods

Technology challenges

- FAIR
- Privacy and Access control
- Data linkage
- Data validation and risk analyses
- New data structures
- Data availability and API’s
- Visualisation

The future proces

- Decrease in
  - Recruitment process
  - Collection time and errors
  - Investigator efforts
- Increase in
  - Validation and analysis techniques
  - Technology
  - Representativeness and scalability to real population

Conclusions

- A lot of posibilities and potential usages
- First steps and initiatives are taken to use EHR records in clinical studies
- Creating and finding the best standards in the future will need focus
- Adaption of mindset of data analysts from exact clean clinical study data to dirty RWD
- Privacy and security are top priority

Thank you

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