Medicines & Healthcare products Regulatory Agency

CPRD More Dimensions to Data

Optimising the drug development pathway and life cycle management through the integration of observational and interventional data and expertise

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Drug development pathway & life cycle management

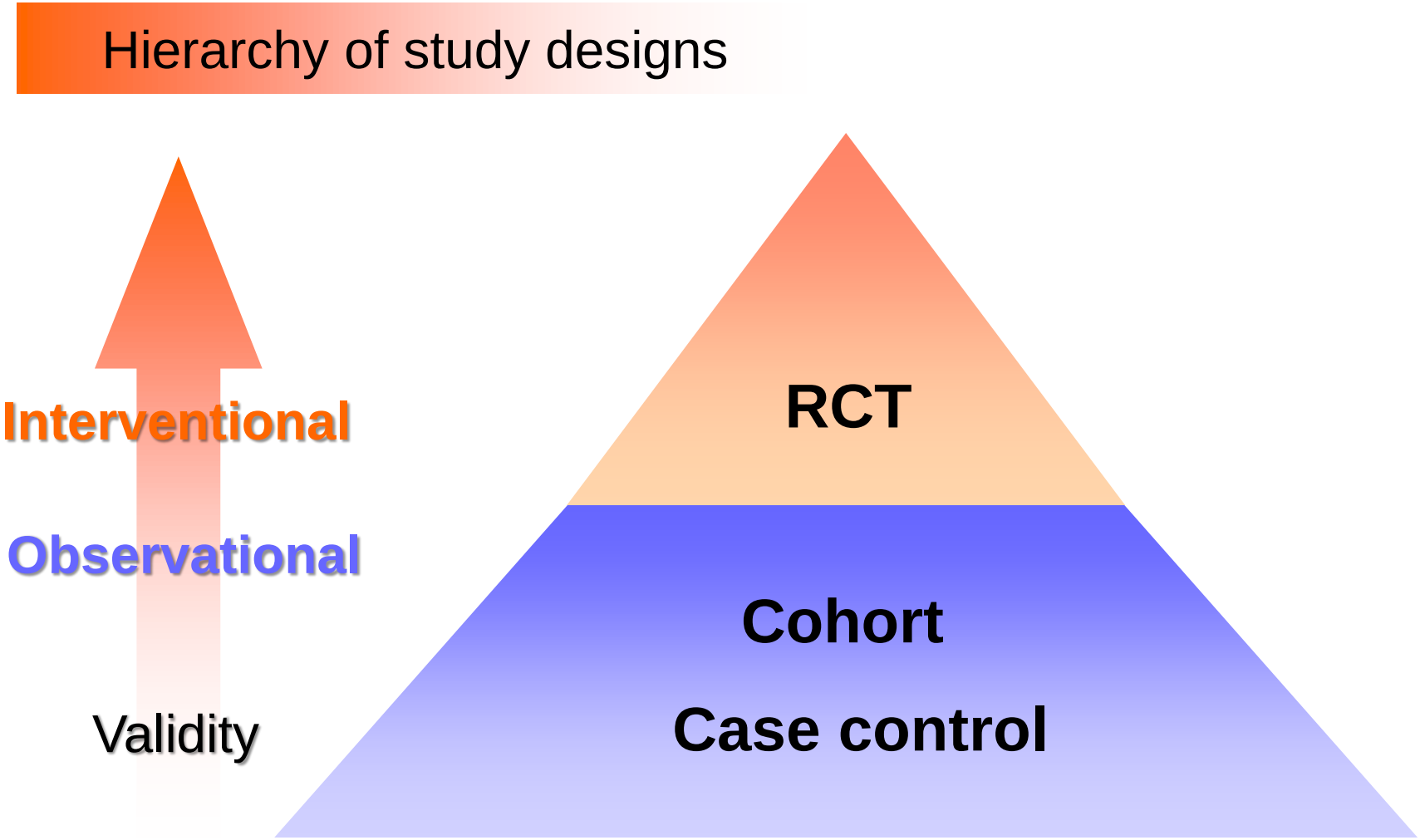
Are largely based upon Randomised Controlled Trials (RCTs) which have gold standard benefits.

BUT can RCTs reflect the real world?

Do Observational studies provide convincing evidence?

Real World data lacking randomisation makes it difficult to establish causality AND the complex nature of the data requires expert understanding based on objective validation of study variable definitions

RCTs vs OS: a spurious debate?



INTEGRATE!

Interventional & Observational Research are considered separate

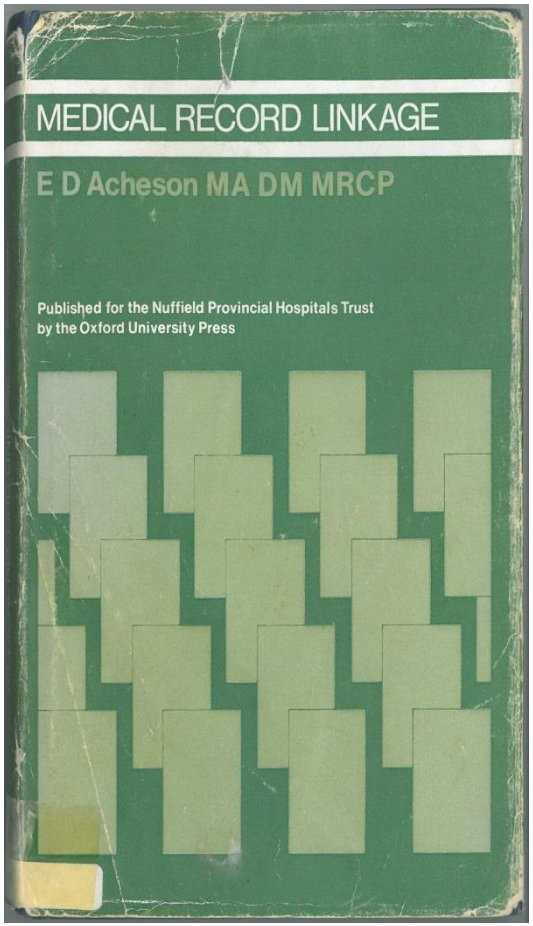
BUT what can we achieve by working together?

- Optimise match between proposed trial environment and trial objectives and design
- Maximise clinical relevance, data completeness and quality
- Contextualise study outcomes and adverse events

Use of EHR in Research

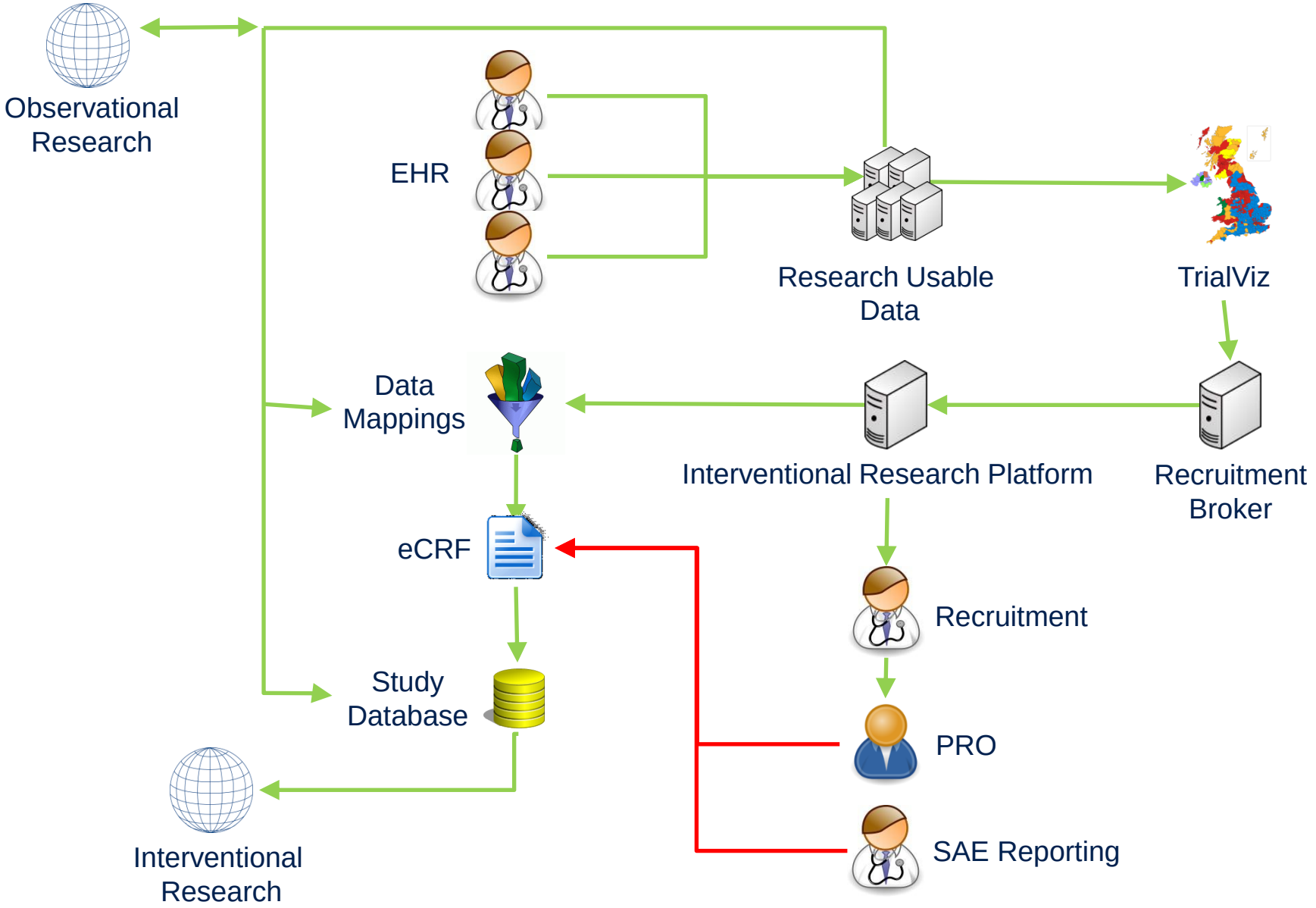
NHS ‘cradle to grave’ records of UK population

- Retrospective and prospective
- Real World setting
- Long term follow up
- Enables research at scale not otherwise possible
- Linkage across health records and other datasets
- Answer questions needing large datasets (e.g. rare conditions)
- Cost effective



Leveraging EHR for RWE

Integration of interventional and observational research expertise requires leveraging of EHR by amalgamation with Electronic Data Capture (EDC) using a component driven system using consistent data sources and methodologies to learn from and inform each stage of drug development.


Observational Research
EHR
Research Usable Data
TrialViz
Data Mappings
Interventional Research Platform
Recruitment Broker
eCRF
Recruitment
Study Database
PRO
Interventional Research
SAE Reporting

CPRD Real World Evidence for the drug development pipeline & life cycle management

Epidemiology, incidence / prevalence

Drug utilisation & prescribing

Standard of care delivery

Pharmacovigilance, Pharmacoepidemiology

Patient referral for intervention studies and clinical trials

Post authorisation pragmatic studies

Clinical trials feasibility – patient eligibility

Observational research

Interventional research

Any Questions?

CPRD's mission is to provide anonymised healthcare records for data services, interventional and observational research to

- *Improve public health*
- *Facilitate interventional studies to increase efficiency*
- *Enable academic and industry research in the UK and globally*
- *Support UK growth*

Back-up

Content of primary care data

- Consultations: 1.8 billion
- Exposures to drugs
  - Prescriptions: 1.7 billion
- Diagnoses and symptom recording
  - Referrals: 55 million
- Laboratory test results
  - Tests: 950 million
- Vaccination history
  - Immunisations: 150 million
- Demographic data