Definitions

Electronic health records (EHR)
Electronic medical records (EMR)
Electronic patient records (EPR)

Real-world data
Real-world evidence

Routinely-collected healthcare data (RCHD)
Routinely-collected data (RCD)
Administrative data

Healthcare systems data

Data-enabled trials
Digitally-enabled trials

Note: Some data only generated because someone is in a clinical trial
→ Prefer “HSD”
Healthcare Systems Data & Trials

Randomised controlled trials trial (RCTs) are gold standard for assessing the effects of healthcare interventions.

Timely & appropriate use of reliable, high-quality healthcare systems data could transform how many late-phase clinical trials are done.
Healthcare Systems Data & Trials

• Randomised controlled trials trial (RCTs) are gold standard for assessing the effects of healthcare interventions

• Considerable overlap between:
  → Data already collected in healthcare systems
  → Data needed for clinical trials

Timely & appropriate use of reliable, high-quality healthcare systems data could transform how many late-phase clinical trials are done
Healthcare systems data for clinical trials

• Rationale for using healthcare systems data include:
  - Reduce duplication of effort
  - Reduce transcription errors
  - Improve other aspects of quality (particularly completeness)
  - Allow focus on trial data & systems that need attention
  - Reduce trials costs (allowing more research)
  - Reduce burden on patients

• Risks of not using healthcare systems data include:
  - Missed events (eg admission to other hospitals)
  - Trials too small to give accurate answers (random error)
Are Trials Accessing HSD?

• 22 / 81 registries provided data to 160 trials (2013-2018)
• Small proportion: Estimate 3% UK trials (vs 2015)
• Trials = v small proportion of data releases (2%)


https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42019123088
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Contrast with 50% NIHR protocols *intending* to access EHR

Challenges for HSD in clinical trials

- Knowledge about data & costs
- Access timelines & timeliness
- Integrity & provenance
- Utility (good to replace CRFs?)
- Retention & archiving
- Onward data sharing

Example papers

- HDR UK, NIHR, CPRD Data Enabled Trials Day
doi: 10.1136/bmjopen-2020-043906

- BHF Data Science Centre Scoping Report
  MacArthur 2021 Zenodo
doi: 10.5281/zenodo.5079178

- BHF Data Science Centre Surgical Workshops
  BHF DSC 2022 Zenodo
doi: 10.5281/zenodo.6384889

- Challenges case study
  Macnair. 2021. Trials

- Challenges case study
  Mintz. 2023. BMJ Oncol
doi: 10.1136/bmjonc-2023-000038

- COMORANT: Methodology challenge consensus
  Williams. 2023. Trials
doi: 10.1186/s13063-023-07251-x
Trials Stakeholder Prioritisation Forum (TSPF)

- Despite challenges specific to using HSD within, & to support, clinical trials, there has been no forum that brings together in UK-wide, 4-nations approach key stakeholders:
  - Data collators
  - Users of data in trials community
  - Users and interpreters of trial findings

- Hence new group!
Trials Stakeholder Prioritisation Forum (TSPF)

- Forum to facilitate exchange of ideas between stakeholders
- Discuss barriers & how to address them
- Includes prioritising, providing, endorsing or commissioning research and/or practical guidance on obtaining and using HSD efficiently, with internationally reliable interpretability.
  - Specifying research needed
  - Specifying guidelines or clarity needed
More about you: Over to Menti…

What broad area do you most represent?

- Academia
- Consumer of Research Findings
- Data Collector / Provider
- Industry
- Research Funders
- Research Oversight