ICH E6(R3) Good Clinical Practice workshop with PCWP and HCPWP

ICH Guideline renovation

Clinical researchers perspectives : ECRIN

Presented by Jacques Demotes on 3 June 2020
Director, ECRIN www.ecrin.org

Supporting multinational trials in Europe

Registration trials

Repurposing trials

Comparative effectiveness trials

Personalised medicine

Challenges for clinical researchers

Personalised medicine research

Secondary use of data

Complex trials

Risk-based approach

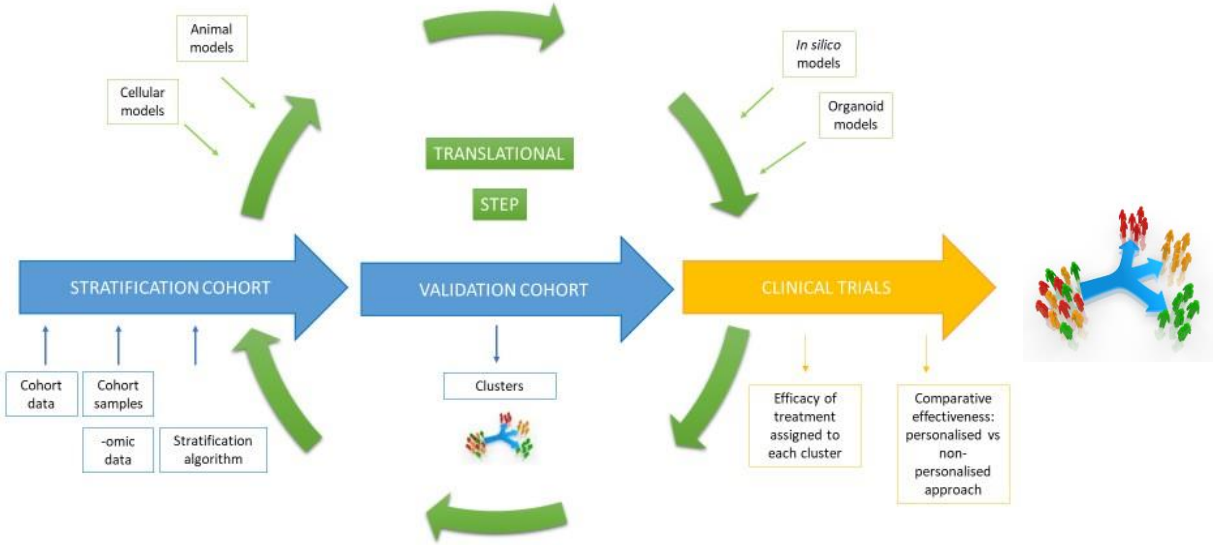
Personalised medicine research

PERMIT
PERsonalised MedicIne Trials

Data quality in stratification / validation cohorts ?

- C€ label for -omics ?
- traceability ?
- Quality control ?

Validity of machine learning stratification ?



Secondary use of data and data sharing

Harmonization of data standards ?

- EHR, registries, cohorts
- Clinical trial data (CDISC ?)

Quality / traceability requirements ?

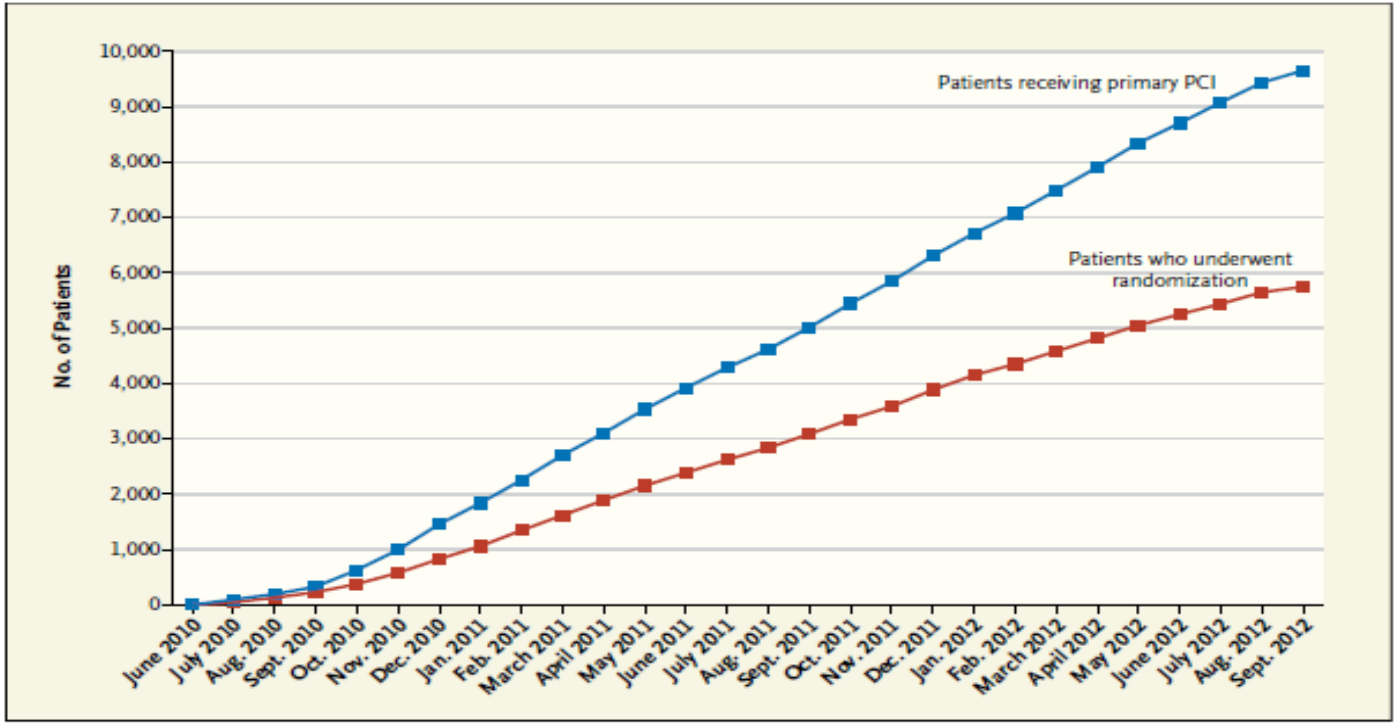
Harmonisation of data protection regulations ?

- HIPAA vs. GDPR
- Broad consent for secondary use / data sharing : objectives ? procedure ?

The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?

N ENGL J MED 369;17 NEJM.ORG OCTOBER 24, 2013

Michael S. Lauer, M.D., and Ralph B. D'Agostino, Sr., Ph.D.



Rapid Randomization in the TASTE Trial, with Enrollment of Most Patients Receiving Primary Percutaneous Coronary Intervention (PCI).

Adapted from the Institute of Medicine (www.iom.edu/~/media/Files/Activity%20Files/Quality/VSRT/LST%20Workshop/Presentations/Granger.pdf). The incremental cost of the Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia (TASTE) trial was $300,000, or $50 for each participant who underwent randomization.

Complex trials (adaptive platform trials)

For marketing authorization, or for comparative effectiveness ?

Data management

Statistical methods

Sponsor / co-sponsor ?

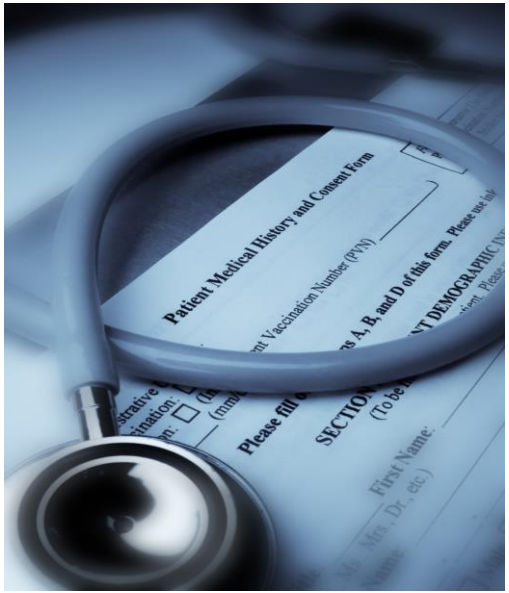
Data sharing

Risk-based trial management and oversight

OECD recommendation :

- Risk based provisions
- Harmonisation ?
  - IND / non-IND
  - Low-intervention trials

OECD Recommendation on the Governance of Clinical Trials



OECD

Any questions?

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