EORTC
European Organisation for Research and Treatment of Cancer

An academic organisation perspective on complex clinical trials: the EORTC experience

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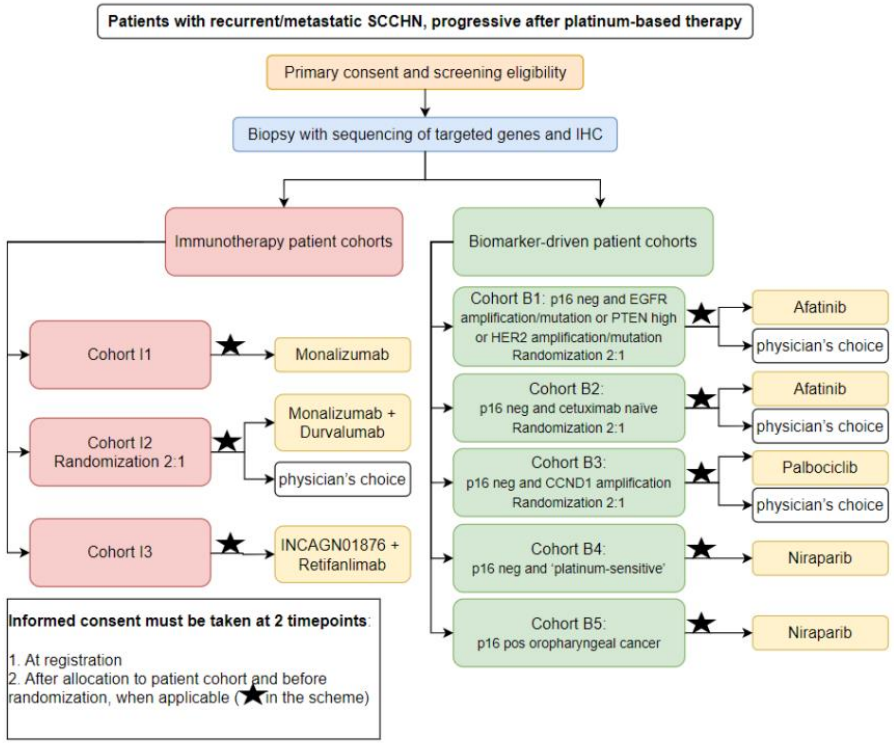
ACT EU Multi-Stakeholder Workshop on Methodology Guidance: A patient-centred approach to methodology

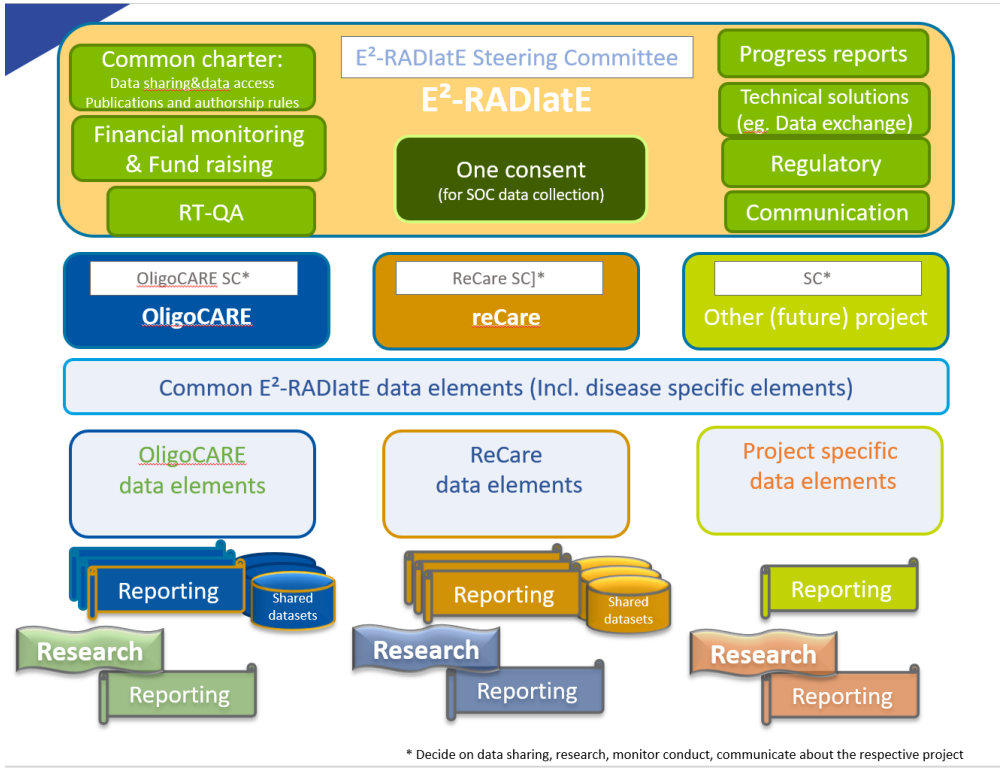
Examples

UPSTREAM
One platform, one disease, multiple cohorts



EUDRACT 2017-000086-74, NCT03088059

Oligocare
Observational study, randomized cohort (TWICS)



https://project.eortc.org/e2-radiate/

Some observations

Upstream

- No adjustment for multiple testing
  - Separate trials …
- Practically:
  - One study number
  - One (big) protocol
  - One database
    - similar structure for programming and analysis
    - becomes quite complex (~amendments)
    - well understood by sites?
- Separate parts submitted as one clinical trial with sub-protocols

  = amendment nightmare

Would be done differently if we had to restart today

Oligocare

- Observational study so slightly different approach (<> CTIS “needs”)
- Practically:
  - Several study numbers
  - Several protocols
  - One database
- *So far seems to work quite well*
- To embed a randomized question (XXX vs SOC) -> TWICs
  - https://www.twics.global/
  - Staged consent -> not generally accepted (yet?) by ECs
  - Could need to be written as CTR protocol (~XXX)
    - Separate protocol linked to a master protocol in CTIS?