Views of networks: trial preparedness

Obstacle 1

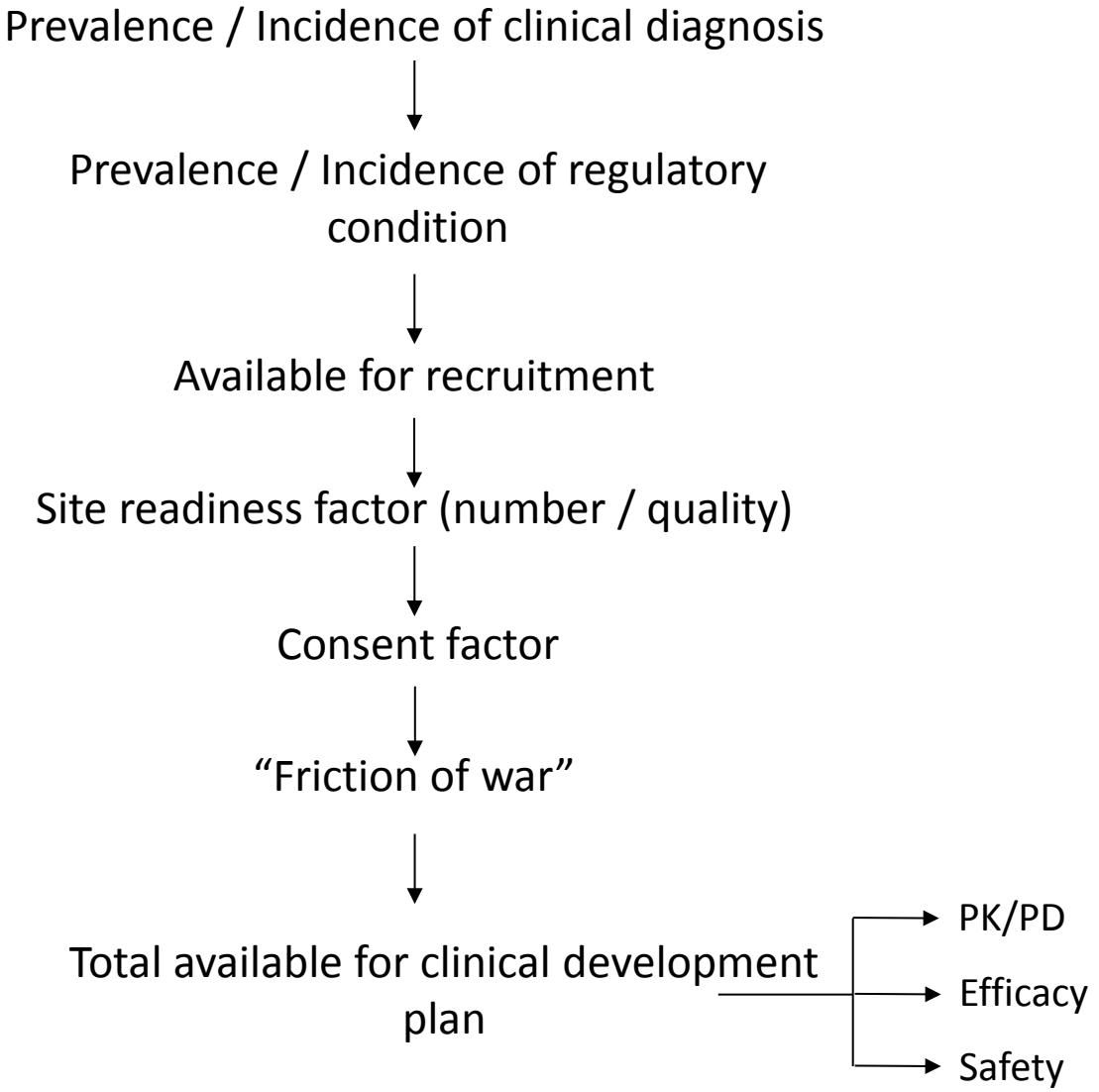
- PIPs and trials that are not based around validated data about patient availability, or realistic estimates of availability

Solution

- Trial preparedness
- Enpr-EMA Working Group
  - Gather best practice
  - Seek opinions
  - Write points to consider document

Preparedness: preliminary suggestions

1) Scope the clinical and regulatory context of the plan / study
2) Identify therapeutic need through comprehensive assessments including experts and sources such as sites, networks and registries
3) Consult sites and other sources
4) Consult participants about proposed trial procedures
5) Identify key influences on preparedness, e.g.
6) Construct flow diagram from epidemiology to eligibility (see Figure 2).
7) Construct flow diagrams from eligibility to contents of locked database
8) Conduct clinical trial simulations: in silico and in clinical simulation facilities
9) Consolidate this information into structured justification that the trial has been prepared adequately.



Views of networks: site readiness

Obstacle 2

- Sites are not ready for trials
- Each trial “reinvents the wheel”
- Sites do not have the drivers or incentives to maintain readiness

Solution

- Network to share best practice
  - Site standards
- National coordination to adapt to legal framework
- Education and training
- Consolidate requests to sites to develop economies of scale

Topic 4: Creation of a pan-European paediatric clinical trials network

Topic details

Topic code	IMI2-2016-10-04
Action type	Research and Innovation Action (RIA)
Submission & evaluation process	2 Stages

- Setup network
- Explore sustainability
- Expert groups
- Data management
- Education and training
- Implement network
- Dissemination and ethics