

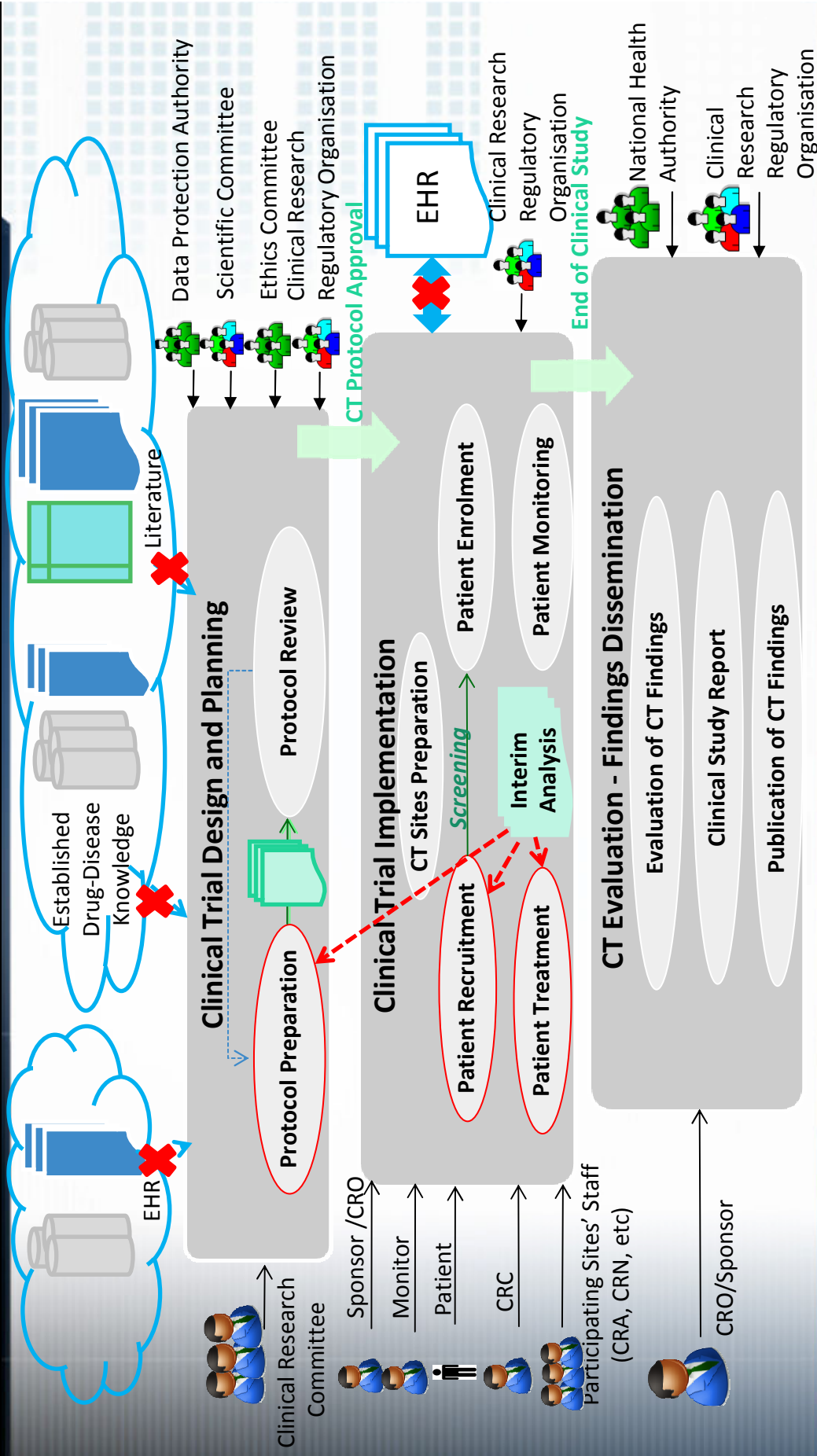


## Clinical trials - Why so much trouble?

- Average Drug Development **cost** is € 500-700 million per drug candidate and **timeline** more than 10 years.
- Tremendous reduction in **new active ingredients** reaching the market yearly:
  - ~ 60/year (late 1980s), 52 (1991), 31 (2001), 20-25 (currently)
- Clinical trials :
  - ~ 1/3 of the costs of drug development half of which depends on duration
  - Low recruitment rates – Long recruitment periods
  - Subjects recruited represent only partially the target patient population
  - Mortality rates in clinical study findings vs real life
  - 1 out of 5000 new drug candidates reach the market
- **Drug repositioning trend** and **Complex tests of hypothesis**: testing new treatment combinations of existing drugs on patients suffering from one or more disorders
- Humans' high variability in response to a drug treatment requires **large-scale clinical trial conduction** for ensuring that the investigational treatment is safe and effective



# The Clinical Trials Landscape



# Future Internet Platform



- *Semantic Interoperability* for bridging the gap between clinical research and clinical care
- Data in dispersed, unlinked, yet highly related, data sources (Electronic Health Records, published clinical findings, etc) – Need for linking and exploiting the information already available
- Novel data models allowing for efficient retrieval, indexing and management
- Advanced trust establishment management for enabling the collaboration between the clinical research centers, the pharmaceutical companies and the clinical care providers
- Data confidentiality, rapid and reliable data pseudonymisation mechanisms, elegant access control, highly effective encryption techniques, given the sensitivity of the data involved
- Secure composability of real and virtualised resources, including computational resources, knowledge bases, data sources, networks, servers
- High computational capacity for the processing, indexing, storage and management of the constantly evolving knowledge within the health domain
- Different, complicated workflows - Advanced, dynamic service composition and mash-up