The Escher Project

Research Areas

- Tool Development
  - Regulatory

At a Glance

- Status: Completed Consortium
- Year Launched: 2007
- Initiating Organization: Top Industry Pharma
- Initiator Type: Nonprofit foundation
- Location: Europe

Abstract

Mission

Various analyses (Rawlins Nat Drug Discovery 2004, U.S. Food and Drug Administration Critical Path, European Medicines Agency Roadmap, European Union Innovative Medicines Initiative, World Health Organization Priority Medicines) have provided evidence that the current system of pharmaceutical innovation is no longer sustainable, both from an economic point of view and from the perspective of unmet medical needs, therapeutic gaps, and access to medicines. At the same time, lack of efficacy (25 percent) and clinical safety (12 percent) are still major reasons for drug development projects to be stopped prematurely. Insufficient predictive capability, complexities in essay sensitivity, and lack of validated and accepted biomarkers are important hampering factors across virtually all the discovery, preclinical, and clinical phases of drug development.

Key objectives of the Escher Project are to identify, evaluate, and remove regulatory bottlenecks hampering the efficiency in pharmaceutical innovation and to stimulate factors helping innovation. The project encompasses three synergistic areas of research directed at regulatory barriers and opportunities in drug innovation, innovative models of testing, and monitoring efficacy and safety of...
new drugs and knowledge management, learning, and education. A major achievement has been the agenda-setting function of the project toward stakeholders and politicians.

Structure & Governance

July 2007: Start date
July 2012: End date

Impact/Accomplishment

Ph.D. theses from this project:
Frederieke van der Baan (project T6-202)
Personalized medicine: pharmacogenetic testing in drug development and clinical practice

Yan Miao (project T6-202)
Off-target effects of RAAS-inhibition: importance on renal outcomes in patients with diabetes

Grace Wangge (project T6-202)
Non-inferiority trials: methodological and regulatory challenges

Gert van Valkenhoef (project T6-202)
Making better use of clinical trials

Jacoline Bouvy (project T6-202)
The evaluation of drug regulation — Economic approaches into the valuation and evaluation of the drug regulatory framework

Guðrún Stefánsdóttir (project T6-202)
Innovations in post-marketing safety research

Arna Hrund Arnardottir (project T6-202)
Regulatory benefit-risk assessment
Ruud Boessen (project T6-202)  
Methods to improve the efficiency of confirmatory clinical trials

Rosemarie Bernabe (project T6-202)  
Ethical issues in postauthorization drug trials

Hans Ebbers (project T6-202)  
Biopharmaceuticals as challenges to the regulatory system

Michelle Putzeist (project T6-202)  
Marketing authorisation of new medicines in the EU: towards evidence-based improvement

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