Overview of the EHR4CR project

Electronic Health Record for Clinical Research

Pierre-Yves Lastic, PhD
Senior Director, Data Privacy & Healthcare Interoperability Standards
Sanofi R&D
Overview

• Drug Development & Clinical Research
• Innovative Medicine Initiative (IMI)
• Project Description
Pharmaceutical Research & Development

Discovery Research

is responsible for identifying the most promising research targets for therapeutic innovation and capitalizing on its biological and chemical skills to discover and propose new candidate compounds for development.

Development

takes the compounds proposed by Discovery Research and turns them into medications. As soon as a compound enters development, a dedicated project team is formed, with members drawn from a variety of functions including researchers, clinicians, pharmacists, toxicologists and representatives from regulatory affairs and marketing. The team's task is to develop the compound all the way to marketing.

R&D teams are international and team members located all over the world.
Clinical Trials: Definitions

A clinical trial (also called clinical study)

is designed to verify the efficacy and safety of a compound for use by human beings. It takes place after in vitro and animal studies (preclinical testing) have proved satisfactory.

The compound, also called investigational product,

is compared either to a placebo (a substance with no pharmacological activity) or to existing treatments, to determine whether it is more or less effective.

The clinical trial determines the effective dose regimen, possible toxicity and the nature and frequency of adverse events it may cause.
Clinical Trials: Objectives

Clinical trials are a mandatory part of the procedure leading to approval of a drug for marketing

– Before new treatments can be made available to all potential patients, they must be deemed effective and well tolerated.

– Clinical trials are used to validate new treatments but also to define the patient categories for which they are most effective.

– Finally, clinical trials help to gain a better understanding of the characteristics of a disease.
Clinical Trials: Phase I

Before the marketing of the drug is authorized, clinical studies are conducted by physicians or hospital teams and proceed along 3 successive phases:

– Phase I:
  • At this point, the compound is tested mainly on a limited number of healthy subjects*, who may receive compensation and are under strict medical supervision. The compound is tested over a short period of time. The purpose is to evaluate the product’s safety, how it evolves within the body, the tolerance threshold and adverse events.

(* Patients are recruited to phase I studies especially in cases such as cancer therapies.)
Clinical Trials: Phase II & III

– Phase II:
  • Testing involves larger groups of patients. The purpose is to test the product’s efficacy and determine optimal dosage regimen. These studies are usually comparative: one of two groups of patients is administered the product whereas the other group is given a placebo.

– Phase III:
  • Testing involves large number of patients, with the purpose of comparing the therapeutic efficacy of the compound to a reference treatment (if there is one) or to a placebo (when there is no alternative therapy). Such studies involve generally many study centers in several countries. In most cases, neither the patient, nor the medical profession are aware of what each patient is being treated with (double blind trial): this is to avoid any bias or prejudiced opinion on either side regarding efficacy or adverse events.
Clinical Trials: Post-Marketing

- Once these 3 phases have been successfully completed, the resulting data, together with the results of preclinical testing, are collected to compose a registration file that will be submitted to public Health Authorities for license to market.
- Trials do not cease once the Pharmaceutical has been put on sale; they continue throughout its marketing life.
- Trials called Phase IV, are carried out after approval in conditions close to those of usual medical care.
Patient Data from Clinical Trials

• Collected according to standards set by international rules based on the Helsinki Declaration on patients rights, known as Good Clinical Practice (GCP), defined by the International Conference on Harmonization (ICH) composed of members of Regulatory Authorities (FDA, EMEA, MHLW) and industry (PhRMA, EFPIA, JPMA)

• Patient medical data are pseudonymised (=key-coded)

• Patient sign an *Informed Consent* that describes the clinical trial and the use of their data, as well as their rights
Challenges in Clinical Development

• The development of a drug necessitates the recruitment of thousands of patients:
  – finding these patients and recruiting them in clinical trials is extremely difficult
  – Most trials are delayed and many fail to recruit enough patients to achieve statistically significant results
• The collection, analysis and reporting of clinical trial data is a cumbersome and lengthy process, with data being entered redundantly in many different, mutually incompatible computer systems in healthcare, research and regulatory organizations.
• These facts contribute to make the development of new medications an extremely expensive and lengthy process
About IMI

- A Public-Private Partnership between EU and EFPIA focused in research on needs common to the Pharmaceutical Industry and Patients at European level (2007-2017)
- Aims to removing major bottlenecks in drug development, where pre-competitive research is the key, and to re-invigorate the European bio-pharmaceutical sector
- IMI projects offers industry an opportunity to build new business models based on collaboration and transparency
- Coordinated research efforts with shared funding (EFPIA contributes with in-kind resources). Research focuses on fields of high industrial and policy relevance
- The IMI 2009 Call for proposal has 9 topics proceeding to stage 2 (final stage to become a project) addressing the two strategic pillars:
  - Predictivity of Efficacy Evaluation and
  - Knowledge Management (call topics 7,8 and 9).
Overall Structure of Research Projects

**IMI Call topics for proposals are conducted through a 2-stage process**

The first stage of the call process is addressing 'Applicant Consortia' (e.g. collaborations between academia, SMEs, patient organisations, non EFPIA industry, etc), to submit to the IMI JU an Expression of Interest in response to a call

- The second stage, following the first stage peer review, the 'Applicant Consortium' of the best Expression of Interest, and the 'EFPIA consortium' that already are associated to the topic, will be invited to form a full 'Project Consortium'

- The full project proposals will be evaluated based on consistency with the original Expression of Interest, on scientific excellence, the quality of the implementation plan and the potential impact

- Only full project proposals that have been favorably reviewed in the evaluation process can be selected for funding and will be invited to conclude a Grant Agreement governing the relationship between the selected project consortium and the IMI JU.

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The IMI project principles are to ensure shared leadership roles (research) but to be coordinated by EFPIA
EHR4CR Project: Concept

• Patient medical information is increasingly stored in Electronic Health Records (EHRs)
  Comparing these records with the inclusion criteria of clinical trials would help:
  – Improve the quality of trial protocols and
  – Find patients to recruit them into clinical trials

• Patient data is entered in hospital EHR systems as well as research databases, a duplication of work leading to errors and therefore a lot of quality control
  – If data could be only entered once then transferred between the systems, it would increase the speed and quality of the process
The EHR4CR project will develop a platform and business model for re-using EHR data for supporting medical research.

**Output:**

- Requirements Specification and Business Model
- Technical Platform (a set of tools and services)
- Different Pilots for validating the solutions:
  - for different scenarios (e.g. patient recruitment);
  - across different therapeutic areas (e.g. oncology);
  - across several countries (under different legal frameworks).
Vision: Scalable Organisational Model for EHR re-use

Regional interoperability

National interoperability

Cross EU States interoperability

Connect different sources and services of EHR for support clinical research

Federation of service providers – TTPs using the EHR4CR Business model
The partners

- 11* Pharmaceutical Companies (members of EFPIA)
- 22 Public Partners (Academia, Hospitals and SMEs)
- 5 Subcontractors (Advisory Board)

* (Amgen, AZ, Bayer, Eli Lilly, Merck KgA, MSD, Janssen/J&J, Novartis, Roche, Sanofi and MSD Europe)
The partners
Governance structure

Steering Committee - All Consortium participants
For annual project review, approval/removal of participants, approval of resource shift across work packages/project participants

Executive Committee - 11 Participants
Coordinator (AZ), Deputy Coordinator (Roche)
IMI JU Managing Entity (EuroRec) + All WP leaders
for operational project-leadership, continuous project review, issue resolution, proposal of changes within projects

Advisory Board

Ethics Board

Work Package Group 1
“Engagement & Business Model”
Leaders:
Public: UCL
EFPIA: Roche

Work Package Group 2
“Informatics Tools & Services”
Leaders:
Public: Custodix
EFPIA: Sanofi Aventis

Work Package Group 3
“Pilots”
Leaders:
Public: Univ. Münster
EFPIA: Amgen

Work Package Group 4: Project Management & Administration
EFPIA (AZ, Lilly) & Public partners (EuroRec, UCL)

All participants - Contributions to Work Package tasks
EHR4CR Technical Platform

• Support the feasibility, exploration, design and execution of clinical studies;

• Enable trial eligibility and recruitment criteria to be expressed in ways that permit searching for relevant patients across distributed EHR systems, and initiate confidentially participation requests via the patients’ authorised clinicians;

• Provide harmonised access to multiple heterogeneous and distributed clinical (EHR) systems and integration with existing clinical trials infrastructure products;

• Facilitate improvements of data quality to enable routine clinical data to contribute to clinical trials, and importantly vice versa, thereby reducing redundant data capture.
EHR4CR Platform Concept
Hospital “Endpoint” Architecture
EHR4CR project

More Info?

pierre-yves.lastic@sanofi.com