EU-PEARL
EU PATIENT-CENTRIC CLINICAL TRIAL PLATFORMS

SHAPING THE FUTURE OF CLINICAL TRIALS

Strategic alliance between the public and private sectors to create an innovative framework to conduct more collaborative platform trials which incorporate patients' perspectives to:

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Make clinical trials more efficient so that new drugs can be developed faster with proportionally fewer patients receiving placebo or the standard care.

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Create a forum of debate and knowledge sharing to advance science.

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BRING NEW TREATMENTS TO PATIENTS, FASTER

STANDARD CLINICAL TRIALS

ONE DRUG **SINGLE DISEASE**

In a standard clinical trial, **one drug** to treat a **single disease** is investigated to see whether **it works** and is **safe** to use.

TREATMENT GROUP **CONTROL GROUP**

One group receives the **new treatment** and another group receives a **placebo** or the normal standard care. This is called the control group. The differences between both groups are then compared.

STANDARD CLINICAL TRIALS FACE CHALLENGES

TIME

The process to develop and launch a **new drug** takes an average of **14 years***. 6.5 years correspond to the clinical study stage.

COST

Developing just one drug costs an **estimated $2.6bn**** with clinical trials taking a big part of the budget.

COMPETITION

Similar trials are often done **in parallel** by different companies without close collaboration and sharing of resources.

PATIENT RECRUITMENT

A clinical trial only gives significant results if a **certain number of patients** participate in the investigation. This puts a strain in **patient recruitment** as each trial requires its own treatment and control group.

*Source: Average time from pre-clinical testing to approval for a new drug'. Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs, Gail A.Van Norman MD, April 2016
**Source:Tufts Center for the Study of Drug Development.

There is a social need to develop an innovative efficient model for clinical trials to increase timely access to drugs, which complements classical clinical trials.

INNOVATIVE MASTER PROTOCOLS

Allow **simultaneous testing** of one or more investigational drugs, in one or more disease subtypes, all within the same overall trial structure (FDA).

MASTER PROTOCOLS CAN BE USED FOR DIFFERENT TYPES OF TRIALS:

Platform

To test multiple drugs for a single disease in a continuous manner, with drugs allowed to enter and leave the platform on the basis of a decision algorithm.

EU-PEARL focuses on PLATFORM TRIALS

Basket

To test one drug for multiple diseases or disease subtypes.

Umbrella

To test multiple drugs for a single disease.

BENEFITS OF PLATFORM TRIALS

Relevant for complex and/or rare diseases with high unmet needs.

Drugs are tested in parallel so treatments can be developed faster.

Shared infrastructure can result in trials becoming more efficient.

"Plug and play" system allows for potential drugs to enter and exit the trial according to the results observed.

Less strain in patient recruitment as only one control group is needed to test several drugs.

Outcomes and learnings are shared amongst different companies, researchers, etc, thus advancing science faster.

PLATFORM TRIALS REQUIRE NEW FRAMEWORKS TO ADDRESS:

Operational and scientific challenges.

Legal, regulatory and ethical challenges.

Data management, sharing and protection challenges.

INTEGRATED RESEARCH PLATFORMS (IRPs)

A framework to carry out a patient-centric platform trial which includes:

Shared master protocol and methodology.

Scientific, legal, regulatory and ethical requirements.

Network of hospitals, clinicians and researchers.

Data governance policies and procedures.

Regulated access to patient electronic health records and patient cohorts.

Pathway for patients' participation in trials design.

EU-PEARL is developing a generic patient centric IRP framework to bring more efficiency to clinical trials.

Follow us to learn more:

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This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 853966. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and CHILDREN'S TUMOR FOUNDATION, GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT NON PROFIT ORGANISATION, SPRINGWORKS THERAPEUTICS INC.