

Press Release – 18/12/19

The EU-PEARL project aims to shape future drug development through a systematic approach that enables patient focused, cross company collaborative platform trials

- **The EU Patient-cEntric clinicAl tRial pLatforms (EU-PEARL) is a unique public-private strategic partnership focused on creating a framework to set up adaptive clinical trial platforms of the future**
- **EU-PEARL hopes to transform clinical trials into a cross-company collaborative, multi-compound platform focused on patients**
- **EU-PEARL aims to define a novel enabling infrastructure where pharmaceutical companies and healthcare providers can work together and integrated research platforms will become an obtainable alternative**

For the first time, 36 world-leading institutions among European university hospitals, research centers, patient groups, non-profit product developers and pharmaceutical companies are coming together to shape the adaptive clinical trial platform of the future. The project, called **EU Patient-cEntric clinicAl tRial pLatforms (EU-PEARL)**, is a unique public-private strategic partnership funded by the Innovative Medicines Initiative (IMI) to conceptualize and lead the design of an integrated research platform, enabling patient-centric drug development in Europe.

Participants in EU-PEARL have the ambition of transforming the current approach of conducting single-compound clinical trials into the use of cross-company Integrated Research Platforms (IRPs), specifically for early development and focused on patients' interests, while seeking opportunities to address medical needs through the advancement of novel molecules.

The EU-PEARL initiative intends to develop new methods, tools and frameworks to create a novel enabling infrastructure for conducting patient-centric platform trials through an integrated system where pharmaceutical companies, non-profit product developers and healthcare providers work together. The intent is to shape future clinical trials that will be more patient friendly by design and patient focused by outcome in four diseases areas: Major Depressive Disorder, Tuberculosis, Non-Alcoholic Steatohepatitis and Neurofibromatosis; and provide the framework for designing and executing IRPs in other disease areas.

Traditional clinical trials versus platform trials

The current model of evaluating one drug at a time in one trial often results in a long, sequential cycle of drug development, substantial investment and delays in getting the most effective treatments to patients. Competing trials challenge patient recruitment and patients often struggle to navigate the complex trial landscape to find the optimum clinical study.

A platform trial is a clinical trial with a single master protocol in which multiple treatments are evaluated simultaneously. Adaptive platform designs offer flexible features such as removing a treatment group for futility or adding new groups and treatments to be tested during the course of the trial.

The challenge of EU-PEARL

Dr. Joan Genescà, Head of the Hepatology Clinical Department of Vall d'Hebron Barcelona Hospital Campus and coordinator of the project, said: **“We are facing an exciting near-term prospect: to be able to deliver medicines with a high molecular precision in a broad range of disease areas, within responsive and dynamic healthcare systems, and to facilitate a clinical decision-making process based on individual biological profiles and their response to therapies”**.

“I am excited that together with pharmaceutical industry peers and public partners, we have a unique opportunity to collaborate in shaping clinical trials of the future”, said Ann Van Dessel, Senior Vice President, Head Global Clinical Operations, Janssen Pharmaceutica NV. **“Through this unique effort, we aim to establish and implement a patient-centric, future-focused framework to bring the most innovative medicines to people who need them as quickly as possible”**.

The five pillars of EU-PEARL

EU-PEARL is based on these pillars:

The hospital hubs: The clinical network of hospitals will provide experienced environment for clinical trials and an ideal space to foster interaction of all stakeholders.

The patients: EU-PEARL will foster an environment for patient engagement to play an important role in approaches to change the way clinical trials are conducted.

Methods and Tools: EU-PEARL will develop an integrated set of methods and tools for the planning, implementation and analysis of adaptive platform trials.

Regulatory framework: To provide the necessary standards to ensure that the collection and inclusion, processing and use of health and wellbeing data complies with European and national data protection and ethical regulations, regulatory requirements and legislation.



Data governance: This project will also create the associated data governance ecosystem focusing on interoperability and quality of investigator/patient data; robust policies for access to global data and the creation of a governance structure for transparency, engagement and utilization.

Supported by a grant from the IMI

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EU-PEARL partners

The 36 world-leading institutions that are part of EU-PEARL are: Vall d'Hebron Research Institute (VHIR) and Janssen Pharmaceutica NV, **as coordinator and project leader respectively**; EATRIS ERIC **as co-coordinator** and Novartis Pharma AG **as co-project leader**; and Synapse Research Management Partners **as Executive Committee members**.

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