



# Pharmaceutical Education And Research with Regulatory Links

# **Background**

The European Pharmaceutical and Biopharmaceutical industries are a major contributor to EU well-being, both in public health and economic terms. To maintain global leadership, it must respond to challenges of declining product pipelines, and increasing R&D costs by bringing new drug molecules to the market in a streamlined, cost-effective manner.

Authorities in the EU have introduced a regulatory framework to bring important new drugs to patients as quickly as possible, with the aim of facilitating earlier patient access to breakthrough therapies. To fully realise the potential of this initiative, the pharmaceutical industry must respond to challenges by developing novel, bio-enabling formulations that unleash the full potential of new drug candidates and at the same time compact their development into the tightest of time-lines.

To realise these goals, scientists from academic, industry and regulatory agencies, with an integral understanding of drug development and regulatory approval processes, are urgently needed.

# **Objectives**

PEARRL combines an innovative research programme with an excellent training programme for Early Stage Researchers (ESR).

The main objectives of this research programme are to deliver novel bio-enabling formulations and new biopharmaceutics tools to predict their in vivo performance as means to improve efficiency and cost-competitiveness in drug development, facilitating earlier access of patients to "breakthrough therapies". Without a bio-enabling formulation, most drugs would be ineffective if given orally, simply because not enough of the dose would be absorbed to achieve a therapeutic response.

PEARRL will create innovation in all these areas to ensure streamlined molecule-to-market time-lines for poorly soluble drugs and thus ensure the future competitiveness of Europe's Pharma industry.

Simultaneously, PEARRL will train 15 ESRs who can develop such new bio-enabling formulations ("better drugs"), biorelevant and in silico methods to predict formulation performance in vivo ("streamlined development") and serve as communication bridgers between research and regulatory science ("accelerated approval"), thus bringing Pharma and regulatory objectives to fruition.

#### **Funding Programme:**

Horizon 2020 Framework Programme of the European Union



## Project Coordinator:

Dr Brendan Griffin, University College Cork, IE

## **Project Duration:**

01/05/2016-30/04/2020

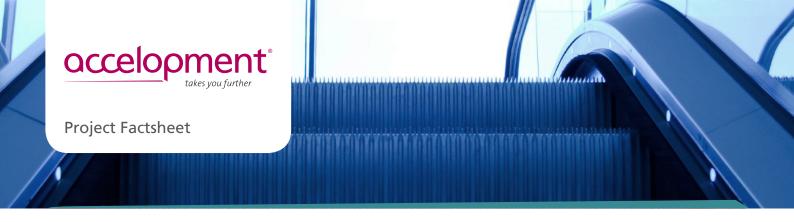
# Project Budget:

3.9 million euro

### **Project Website:**

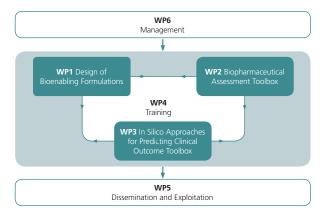
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## **Activities**

As PEARRL is an integrated work programme, the ESRs contribute to the different research WPs while working on their own individual projects.



Key PEARRL elements are individual research projects with synergistic output, exposure of all ESR to academia, industry and regulatory in secondments and ongoing innovative learning via Online Portals, Science Slams and Boot Camps.

## **Impact**

With its unique multi-sectorial approach, PEARRL will have a significant impact on two distinct sectors.

Firstly, PEARRL will enhance innovation-related human resources for the pharmaceutical industry and improve the individuals' skills and their working conditions in order to assure the realization of their full potential. This will manifest itself in the following ways:

- The newly trained ESRs will belong to a new calibre of pharmaceutical development scientists, with a state-of-the-art knowledge base, making them the natural future leaders in industry, regulatory agencies and academia.
- The research training with PEARRL will provide the ESRs with new career perspectives by transmitting a new skill set for challenging working conditions.
- Each ESR will have had direct experience in all three sectors (academia, industry and regulatory institutions), they will be in a position to become the communication bridgers of the future between the partners.

Secondly, PEARRL will contribute to the EU's objectives in Horizon 2020 with its emphasis on excellent science, industrial leadership and tackling societal challenges. Long-term collaborations between partners in research and training will be pursued to increase Europe's innovation capacity.

PEARRL will drive innovation, economic growth and create job opportunities for highly qualified researchers as well as help achieve the EU's objectives in Horizon 2020 with its emphasis on excellent science, industrial leadership and tackling societal challenges.

### Our Services:

- Proposal Writing
- Contract Negotiations
- Project Management
- Project Dissemination

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