Eliminating animals from the development of new oral drug formulations: EU funds MSCA-H2020 EID InPharma

The EU-funded **InPharma** project is working towards making drug development more predictable and reducing **animal testing in drug development by using a fully integrated, animal-free, end-to-end modelling approach to the formulation of drugs for oral administration.**

Society is becoming increasingly focused on eliminating animals from testing of new medicines. At the same time, the pharmaceutical industry is obliged to ensure that the safety and efficacy of new drugs meet regulatory requirements. However, in certain areas of drug development, such as oral drug product formulation, there is no regulatory requirement for the use of animals and yet, largely for historical reasons, animals continue to be used.

The challenges involved in developing an emerging drug substance into a licensed medicine have increased tremendously over the last few decades, mainly because most drugs coming through the Pharma pipeline have poor 'developability' properties. While a range of drug formulation technologies are available for improving drug performance, a new approach is needed to replace the trial and error methods currently used to identify the right formulation to progress to human clinical trials and essentially take the guesswork out of choosing the drug product development strategy.

InPharma is the first European Industrial Doctorate (EID) that aims at eliminating animals from the development of oral drug formulations by substituting them with computational and bio-predictive *in vitro* tools. InPharma will apply an 'end-to-end' model-based drug development approach, by linking data emerging from drug discovery into computational models that predict the optimal formulation design, which is then integrated into models that predict drug levels in simulated human clinical trials. This end-to-end model-based approach is essential to advance innovation and competitiveness of Pharmaceutical R&D in Europe, and at the same time support the European Commission's goal of animal-free testing.

The pharmaceutical industry is still lacking personnel trained in novel computational and laboratory-based technologies for oral drug formulation. InPharma will bridge this qualification gap by training doctoral students (early-stage researchers, ESRs) in computational pharmaceutics, innovative lab-based predictive tools and physiologically based pharmacokinetic (PBPK) modelling. In total, 13 ESRs will be recruited to work on individual projects as part of the InPharma network supported by experts in the field of oral drug development.

The InPharma project, which officially starts on January 1st, 2020, will bring together the complementary expertise of six multi-national pharmaceutical companies, five world-class academic research institutions and eight partner organisations to ensure the best research and training conditions for each individual to reach the overall project goals. The ESRs will have the opportunity to start their research careers in a truly intersectoral environment. Each ESR will experience life as a researcher at an innovative pharmaceutical company and at one of the leading research institutions in Europe. The local PhD programmes will be complemented by network-wide training events designed to prepare the ESRs to become highly successful researchers in the pharmaceutical industry. Recruitment for the 13 ESR positions will start in January 2020.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 955756.

InPharma Facts and Figures

- InPharma is a research project funded by the European Union
- 11 beneficiaries and 8 partner organisations are involved
  (7 academic, 10 industry, 1 regulatory agency, 1 management and dissemination service provider)
- The project starts on January 1st, 2020 and will end on December 31st, 2023
- Budget: € 3.47 Million
- Website: www.inpharma-network.eu
- Email: inpharma.network@gmail.com
- Twitter: @InPharma_EU
- Goal: A pan-European training network that develops innovative drug development strategies and regulatory tools tailored to facilitate earlier access to medicines
- Contact: Dr. Brendan Griffin, InPharma Project Coordinator, brendan.griffin@ucc.ie

InPharma network

Beneficiaries

- University College Cork, IE
- Fraunhofer Gesellschaft zur Förderung der angewandten Forschung e.V., DE
- National and Kapodistrian University of Athens, GR
- University of Southern Denmark, DK
- University of Applied Sciences & Arts Northwestern Switzerland, CH
- AstraZeneca AB, SE
- Bayer AG, DE
- Janssen Pharmaceutica NV, BE
- F. Hoffmann-La Roche AG, CH
- Solvias AG, CH
- Zentiva KS, CZ

Partner Organisations

- accelopment AG, CH
- Certara UK Ltd, UK
- Hafnium Labs ApS, CH
- Merck KgaA, DE
- Pion Inc (UK) Ltd, UK
- Johann Wolfgang Goethe University, DE
- University of Basel, CH
- Health Product Regulatory Authority, IR

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