

IMI-projects related to Pharmaceuticals in the Environment

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Potential interest to discussions on Oct 24 EFPIA/HCWH joint workshop

The Innovative Medicines Initiative (IMI) is working to improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need. IMI is a partnership between the European Union and the European pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

During its first phase (2008-2013), IMI had a budget of €2 billion, half of which came from the EU's Seventh Framework Program for research (FP7), and half of which came from in kind contributions by EFPIA companies. With a €3.3 billion budget for the period 2014-2024, IMI is the world's biggest public-private partnership (PPP) in the life sciences. Half of IMI's budget (€1.638 billion) comes from Horizon 2020, the EU's framework program for research and innovation. This will match €1.425 billion committed to the program by EFPIA companies, plus up to €213 million that could be committed by other life science industries or organisations that decide to contribute to IMI2 as members or associated partners in individual projects.

IMI Ongoing Projects (<http://www.imi.europa.eu/content/ongoing-projects>)

The Innovative Medicines Initiative (IMI) now has 47 projects that are up and running as a result of the successful launches of its first eight calls for proposals. Of those 47 projects, 8 projects, with a total budget of 455 Mio €, are shortly described below. The projects are closely or more remotely connected to areas of potential interest for the discussions regarding Pharmaceuticals in the Environment.

Risk assessments and toxicity predictions:

- **iPiE 10 Mio €:** Intelligence-led Assessment of Pharmaceuticals in the Environment: To develop predictive frameworks that utilizes information from existing datasets on environmental fate and effects from APIs, toxicological studies, pharmacological mode of action and in silico models to support more intelligent environmental testing of pharmaceuticals in development and to prioritize legacy pharmaceuticals for full environmental risk assessment and/or environmental (bio) monitoring.
- **eTOX 13.9 Mio €:** Integrating bioinformatics and chemoinformatics allowing the in silico prediction of toxicities: To develop innovative strategies and novel software tools to better predict the safety and the side-effects of new candidate medicines for patients. Reliable prediction of side-effects in the initial phases of drug development lowers the failure rate in later phases, significantly reduces the number of animal tests needed and accelerates the development of new drugs.

Green Chemistry:

- **CHEM21 26.4 Mio €:** Chemical manufacturing methods for the 21st century pharmaceutical industries: To generate a range of methods to make the drug development process more environmentally friendly. What's more, as well as being good for the planet, the methods developed by CHEM21 will also help the pharmaceutical industry to cut costs, resulting in cheaper medicines for patients.

Anti-microbial resistance

- **ND4BB:** New Drugs for Bad Bugs (umbrella project of COMBACTE, ENABLE, TRANSLOCATION): Antibiotic-resistant bacteria kill 25 000 people in the EU every year, and cost the economy €1.5 billion. IMI's New Drugs 4 Bad Bugs (ND4BB) program represents an unprecedented partnership between industry, academia and biotech organisations to combat antibiotic resistance in Europe by tackling the scientific, regulatory, and business challenges that are hampering the development of new antibiotics. The program currently comprises three projects.
 - **COMBACTE 250 Mio €:** Creating a pan-European network of clinical sites
 - **ENABLE 101 Mio €:** A drug-discovery platform for antibiotics
 - **TRANSLOCATION 29.3 Mio €:** Getting drugs into bugs (and keeping them there)

Additional example of a project with indirect relation to potential discussion on Oct 24

- **ORBITO 24.5 Mio €:** Oral biopharmaceuticals tools: Most drugs are taken orally, as tablets or capsules for example. However, designing these pharmaceutical products in such a way that the active ingredient is absorbed at an appropriate rate and extent by the gut is far from easy. The ORBITO project aims to enhance our understanding of how orally-administered drugs are taken up from the gastrointestinal tract into the body, and apply this knowledge to create new laboratory tests and computer models that will better predict the performance of these drugs in patients.