



SMEs in IMI2 Calls for Proposals

Why should an SME participate in an IMI project?

- IMI projects are focused on **translating excellent research** into real world outcomes – an opportunity for SMEs
- Unique **collaborative partnerships** in pharmaceutical research and development
- Collaboration with large pharmaceutical companies allows **access to whole value chain** of drug discovery
- Build research and business networks
- Funding: **100%** of costs **reimbursed**

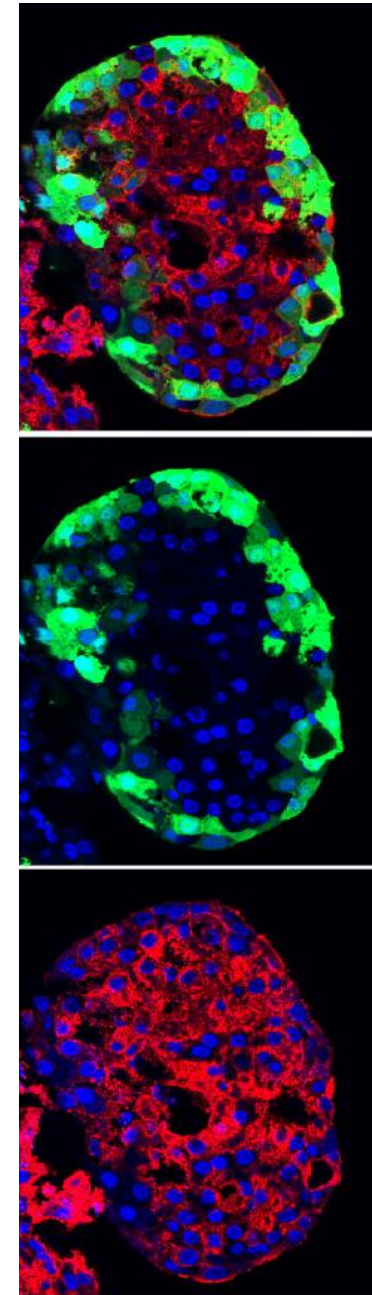
Some examples of the leading role of SMEs in IMI projects

IMIDIA delivers a world first – driven by SME involvement

- IMIDIA generated the first human pancreatic beta cell line
- A French SME was at the heart of the research

‘Thanks to this collaboration, the robustness of our beta cells has been validated by large pharma companies – a major advantage for a biotechnology company like Endocells.’

– Anne-Fabienne Weitsch, CEO of Endocells



European Lead Factory



Total Budget:	EUR 197 million
IMI funding:	EUR 80 million
SME funding:	EUR 54 million

Advanced, ultra high throughput
screening facilities

500 000 screening compounds
from pharma & SMEs

‘The ELF provided the missing piece in the puzzle – a potent, selective compound that provides a strong starting point for further development towards the clinic’

– Dr. Margit Mahlapuu, ScandiCure

EBOMAN - Vaccine manufacture capability

Established a platform capable of rapidly producing sufficient quantities of the vaccine



‘A great opportunity because we were part of an excellent network of experts (drug makers, manufacturers, etc) that goes beyond the financial support we received.

Our advice to other SMEs interested in applying to IMI is: Do it.’

Vibalogics



IMI IP rules consider SME's needs

- Opportunity for further development & validation of assets
- Background and sideground assets protected
- New results owned by the generator
- Result owner decides:
 - Best protection modalities
 - Exploitation strategy
- Access to expertise from the other partners on equal basis
- Publication/dissemination subject to conditions, such as respect of the legitimate interests



SME participation in IMI2 Call 13

Opportunities for SMEs in IMI2 Call 13

SMEs are particularly welcome to participate in IMI2 Call 13 topics in the following areas:

Topic 1: Assessment of the Uniqueness of Diabetic Cardiomyopathy Relative To Other Forms of Heart Failure Using Unbiased Pheno-Mapping Approaches

- Machine-learning
- Data management
- Image analysis
- Imaging technologies
- Metabolomics & Lipidomics analyses
- Project management in the context of IMI/H2020 projects.

Opportunities for SMEs in IMI2 Call 13

Topic 2: Genome-Environment Interactions in Inflammatory Skin Disease

- Advanced analytical approaches
- Data management including experience in the legal and ethical challenges associated with integrating multi-centre patient-derived data

Topic 3: The Value of Diagnostics to Combat Antimicrobial Resistance by Optimising Antibiotic Use

- Diagnostic tests, regulatory registered or in the registration process, including novel validated biomarkers
- Services, information systems or software for data sharing, storage and analysis
- Infrastructures, logistics and services for bio-banking and deep characterisation of pathogens or samples
- Project management and dissemination tools including set-up of education programs and training modules on the value of diagnostics to combat AMR

Opportunities for SMEs in IMI2 Call 13

Topic 4: Mitochondrial Dysfunction in Neurodegeneration

- Relevant standardised technologies and assays (see in the topic for all technical details)
- Other relevant know-how

Topic 5: Support and Coordination Action for the Projects in the Neurodegeneration Area of the Innovative Medicines Initiative

- Project management;
- Medical/scientific writing
- Outreach and communication for the different stakeholders and public at large
- Development of communication tools including websites and social media, platforms to create awareness of the programme and disseminate findings
- Creation of training and communication materials based on results of the projects

Opportunities for SMEs in IMI2 Call 13

Topic 6: A Sustainable European Induced Pluripotent Stem Cell Platform

- Significant experience, knowledge and know-how in logistics and infrastructure to operate a European-wide cell line repository, including a mirror iPSC bank according to ISO 9001 standards are prerequisites.

Topic 7: Linking Digital Assessment of Mobility to Clinical Endpoints to Support Regulatory Acceptance and Clinical Practice

- Complex data management and analysis and specifically in validation of technology-related medical tools
- Expertise in wearable technologies for activity monitoring
- Experience with medical device registration

Opportunities for SMEs in IMI2 Call 13

Topic 8: Human Tumour Microenvironment Immunoprofiling

- 'Deep profiling' technologies such as
 - Single cell RNA seq on sorted immune cell population (important)
 - Multi-color flow cytometry, especially of surgical specimen, realised by participating partners that have appropriate capabilities using a standardised panel of markers
 - Multiplex-IF including a panel of functional immune-related markers
 - Selected advanced technologies, e. g. CyTOF
 - Microbiome analysis
 - ctDNA and ctRNA analysis
 - Proximity ligation assay-based approaches for detection of e. g. receptor-ligand interactions

Opportunities for SMEs in IMI2 Call 13

Topic 9: Conception – Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now

- Expertise in design and analysis of existing data sets, electronic health records, epidemiological design and analytics
- Experience in legal, ethics and privacy law across regions
- Financial experts for advising on sustainability
- Experience in use of different communication channels to reach different interest groups and professional associations, ability to communicate and translate complex medical information into lay language, expertise in handling and dissemination of information through internet and social media, expertise in qualitative analysis of social media feedback, web design & maintenance.
- Regulatory expertise, experience dealing with regulatory agencies, professional expertise managing complex multi-stakeholder projects, professional project management capability and experience

Opportunities for SMEs in IMI2 Call 13

Topic 10: Improving the Preclinical Prediction of Adverse Effects of Pharmaceuticals on the Nervous System

- Innovative assays/techniques for detection of neurotoxic effects: stem cells, organs-on-chip, subcellular systems (synaptosomes, mitochondria), micro-electrode array (MEA) technology, blood-brain barrier assays, continuous video monitoring in rodents and non-rodents, live-brain imaging of neuronal activity
- Run prospective assays/studies with reference drugs
- Data and samples management: data access and data cleaning expertise
- Biostatistics/programming: data analysis and programming expertise
- Coordination and communication:
 - Ensuring the implementation of the coordinating tasks and running the day-to-day operation, such as project tracking and reporting, meetings, internal communication, budget management, etc
 - Ensuring the communication and dissemination with and/or media expertise and in developing tools

Opportunities for SMEs in IMI2 Call 13

Topic 11: Translational Safety Biomarker Pipeline (Transbioline): Enabling Development and Implementation of Novel Safety Biomarkers in Clinical Trials and Diagnosis of Disease

- Bioanalytical expertise for diagnostic assay development
- Bioinformatic analysis, data mining
- Data and sample management

Opportunities for SMEs in IMI2 Call 13

Topic 12: Pilot Programme on a Clinical Compound Bank for Repurposing

- Experience and capability to conduct all aspects of a clinical trial using an investigational medicinal product (including data analysis and reporting) under good clinical practice (GCP) in the proposed indication
- Clinical and preclinical expertise as necessary for the scope of a given study
- Expertise in the science of drug development including aspects of clinical pharmacology, study design and conduct
- Experience and capability to submit an application for clinical trial authorisation with the European Medicines Agency (EMA)/ national regulatory authorities in all member countries of a given consortium
- Capacity to recruit sufficient number of patients within a few clinical study centres
- Strong project management and communication expertise



SME participation in ongoing IMI Projects

IMI Drug Discovery Platforms - ELF



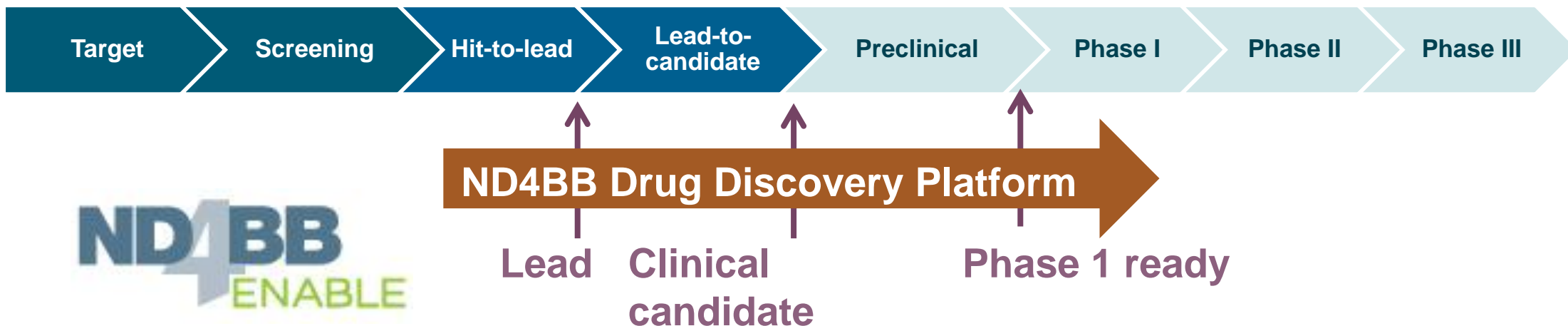
Screening deck of **500 000 compounds & ultra-HTS facilities** available **free** to anyone with an **innovative target to screen**.

Apply at <https://www.europeanleadfactory.eu>

Over **49 Hit Lists** already provided **free of charge** to European SMEs & academics

Innovative compound library ideas also welcome – rewards available

IMI Drug Discovery Platforms - ENABLE



Drug discovery expertise available to take your **AMR lead project** all the way to **Phase 1 clinical trials**

Apply at <http://nd4bb-enable.eu/>

Support available to submit your proposal

15 programmes already selected



Thank you

www.imi.europa.eu

 @IMI_JU