Webinar | IMI2 – Call 13
Opportunities for SMEs

7 December 2017 • 10:00 CET

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Opportunities for SMEs in IMI2 – Call 13 – Colm Carroll, IMI
- Questions & answers

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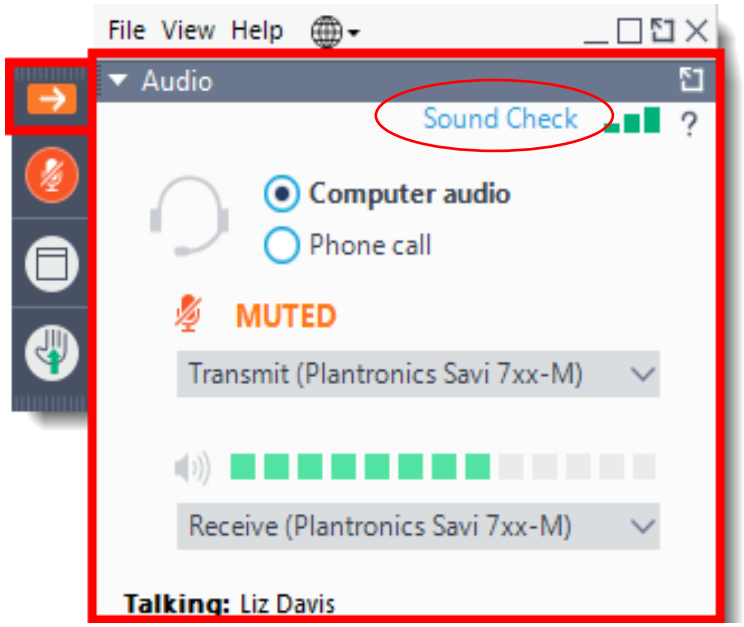

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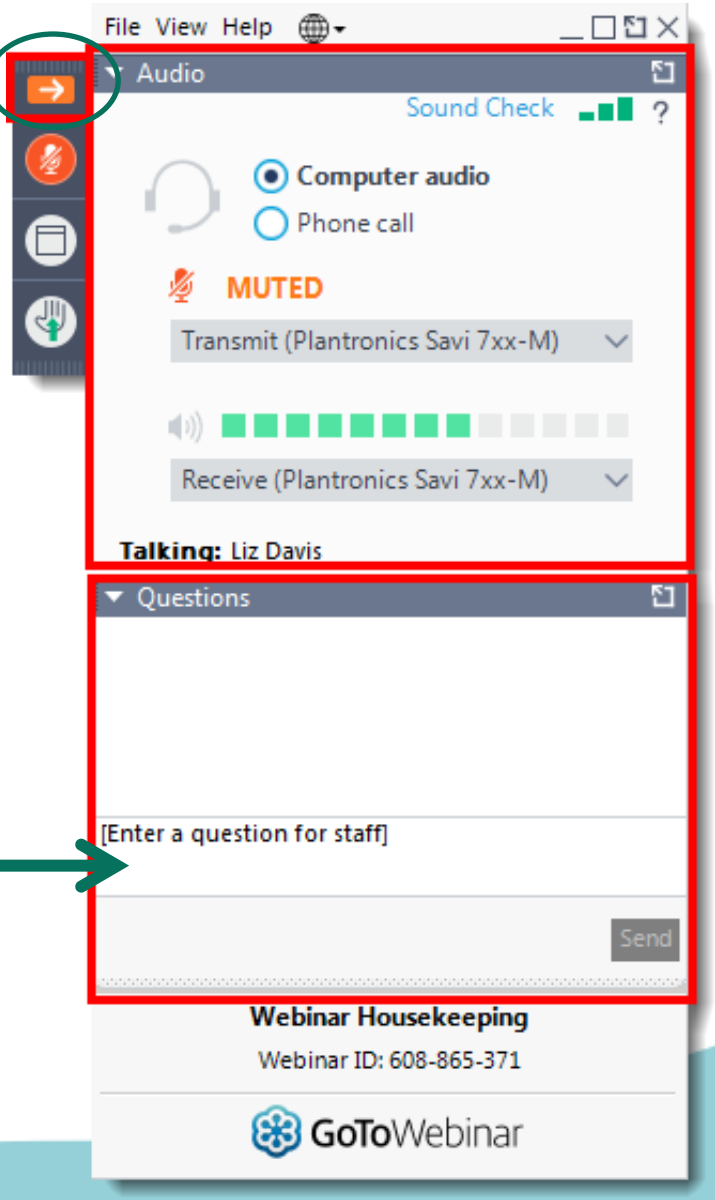

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Before we start…

- This webinar is being recorded and will be published on the IMI website and / or IMI YouTube channel
- Presentation slides will be published on the webinar web page
- A participant list will be circulated and published on the IMI website for networking purposes
- IMI2 – Call 13 has been launched and all Call documents & details of how to apply can be found on the IMI website
- Experiment time! (It's a poll)

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SMEs in IMI2 Calls for Proposals

Today's webinar

Will cover the following:

- Introduction to IMI
- Overview on why SMEs should join IMI projects
- Tips for joining applicant consortia
- SME opportunities in Call 13 topics
- Other SME opportunities

Will not cover rules and procedures

- The first webinar on rules and procedures will take place this afternoon, registration now closed.
- A second webinar will take place in early January, registration will open shortly

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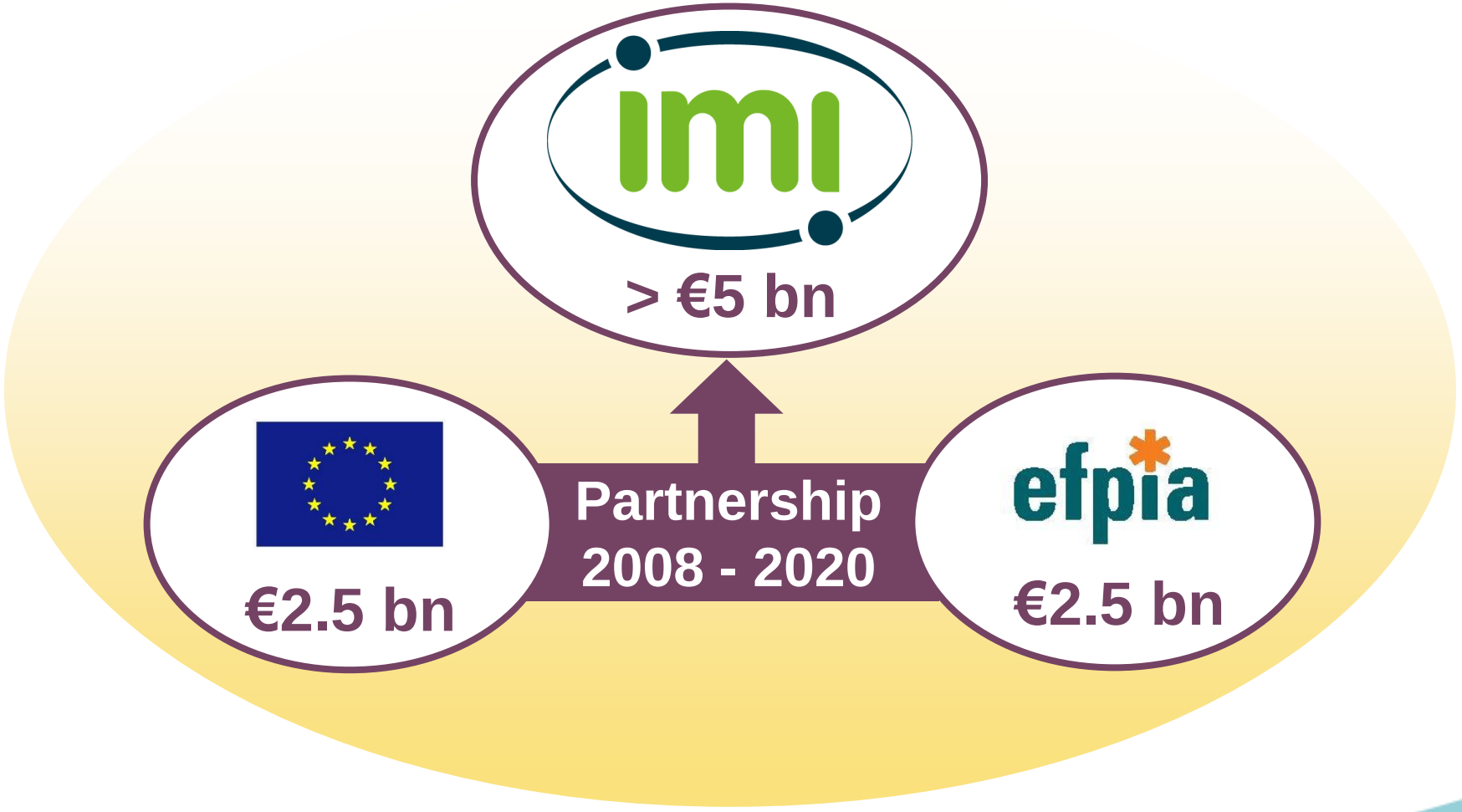
IMI – Europe's partnership for health



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How is IMI addressing the challenges in drug development?

By creating a **neutral platform** where **all involved** in drug development – academics, industry, SMEs, patients, regulators, others – can engage in **open collaboration** on **shared challenges**.

IMI's projects try to…

- **put patients at the centre**
- **share risk**
- **increase efficiency**
  - reduce duplication of effort
  - reduce timelines
- **integrate the latest science** into drug development
- **use data and knowledge management** to work more effectively

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An international, cross-sector community

Over 12 500 researchers working for:

- open collaboration
- improved R&D productivity
- innovative approaches to unmet medical needs

Why do we want SMEs in IMI projects?

- SMEs can act as a **key interface** between latest academic discoveries and implementation in industry
- SMEs can bring **industrial grade products/services** to IMI projects
- With a commercial focus, SMEs can **drive projects to achieve** high impact results
- By developing products & services, SMEs can ensure the results of IMI projects are **widely available after the funding ends**
- Help create a **favourable ecosystem for SME innovation and growth.**

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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
- SMEs can **fine-tune innovative services and products** with the actual end-user scientists
- Collaboration with large pharmaceutical companies and others allows **access to whole value chain** of drug discovery & **build research and business networks**
- **Building reputation and visibility**. IMI project achievements often get recognised and promoted on an international level
- Funding: **100%** of costs **reimbursed**

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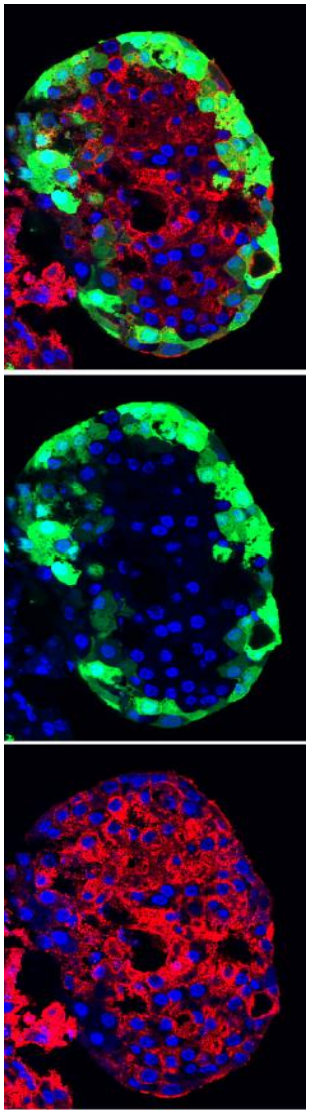
IMIDIA delivers a world first – driven by SME involvement

- 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



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EBOMAN - Vaccine manufacture capability

Established a platform capable of rapidly producing sufficient quantities of the vaccine candidate for the clinical trials

'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

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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

"We are a start-up company and our patents are the most valuable asset that we have. We jumped into the project and we are glad that we did, because our IP rights are protected – participating in this project didn't harm us at all."

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Joining an applicant consortium

- **Be proactive**
  - Develop your network
  - Reach out to potential coordinators, make their life easy
- **Be prepared**
  - Summarise your skills and proposed topic activities
  - Estimate the budget required
- **Be flexible**

Finding consortia / partners

- **Network with your contacts**
- Network with **SME & topic webinar participants**
- Use **Partner Search Tools**:
  - Horizon2020 participant portal
  - German NCP version: http://www.imi-partnering.eu
- Get in touch with your **local IMI contact point:** www.imi.europa.eu/content/states-representatives-groups
- Talk to your Health National Contact Point (NCP)
- **Network on social media** (e.g. IMI LinkedIn group)

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Tips for writing a successful proposal

- Read **all** the call-relevant material
- Begin **forming your consortium early**:
  - Partner search tools & networking events
- Provide reviewers with **all the information requested** to allow them to evaluate your proposal
- **Submit your proposal early**
- Contact the SME helpdesk: SME@imi.europa.eu

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Common Mistakes

- The proposal does not address **all the objectives of the topic**
- A proposal is scientifically excellent but will **have limited impact**
- Necessary expertise **not fully mobilised**
- **Admissibility/Eligibility** criteria not met:
  - submission deadline missed
  - minimum of 3 legal entities from 3 member states & H2020 associated countries not met

SME participation in IMI2 Call 13

Topic specific webinars

- We present a summary of all topics below
- If interested in a particular topic, please
  - Read the topic text

http://www.imi.europa.eu/apply-funding/open-calls/imi2-call-13

  - View the topic specific webinars at:

http://www.imi.europa.eu/news-events/events/webinars-imi2-call-13

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

Duration

- The indicative duration of the action is 60 months.

Indicative budget

- EFPIA in-kind contribution: EUR 6 000 000
- IMI2 JU contribution: up to EUR 6 700 000

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Goal & Key Deliverables

Goal

- Assess the uniqueness of diabetic cardiomyopathy
- Unveil the underlying mechanisms of cardiomyopathy in diabetic patients and the impact on cardio-vascular mortality

Key Deliverables

- Successful patient enrollment into the four groups (1000 patients each)
- Application of unsupervised machine learning algorithms
- Identification of causal mechanisms and pathways responsible for diabetic cardiomyopathy
- Better understanding of the disease biology of diabetic cardiomyopathy;
- Communicating value proposition to target audiences

Expected contributions from SMEs

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

Topic 2: Genome-Environment Interactions in Inflammatory Skin Disease

Duration

- The indicative duration of the action is 60 months.

Indicative budget

- EFPIA in-kind contribution: EUR 8 300 000
- IMI2 JU contribution: up to EUR 10 500 000

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Goal & Key Deliverables

Goal

- Elucidating the molecular pathways of these inflammatory skin conditions
- Identify biomarkers that will enable robust, efficient and meaningful patient management.

Key Deliverables

- Identify shared and distinct disease mechanisms of AD and Pso
- Establish a new disease ontology
- Identify molecular, immunological and microbial biomarkers that inform prognosis and response to therapy of patients

Expected contributions from SMEs

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

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

Duration

- The indicative duration of the action is 48 months.

Indicative budget

- EFPIA in-kind contribution: EUR 6 800 000
- IMI2 JU contribution: up to EUR 6 700 000
- Up to EUR 10 605 000 available for applicants

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Goals & Key Deliverables

Goals

- Understand, demonstrate, and quantify the value of diagnostics and the obstacles to their adoption and use in the framework of a Standardised Care Network

Key Deliverables

- Demonstrating how the use of diagnostics can help to achieve reductions in antibiotic use and the emergence of AMRs.
- Standardised Care Network comprising high-, medium- and low-antibiotic use countries in Europe,
- A multi-country and multi-centre clinical study
- A thorough exploration and analysis of the psychosocial obstacles preventing widespread adoption of diagnostics

Expected contributions from SMEs

- 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

Topic 4: Mitochondrial Dysfunction in Neurodegeneration

Duration

- The indicative duration of the action is 36 months.

Indicative budget

- EFPIA & IMI2 AP in-kind contribution: EUR 3 288 000
- IMI2 JU contribution: up to EUR 4 500 000

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Goals & Key Deliverables

Goals

- Identify and understand the impact of mitochondrial dysfunction in *in vitro* and *in vivo* models of neurodegenerative diseases

Key Deliverables

- Development of robust tools to study mitochondrial dysfunction
- Identification of mitochondrial dysfunction in established and well-characterised models (in vitro, in silico and in vivo)
- Develop a greater understanding of mitochondrial dysfunction
- Establishment of a European multidisciplinary research platform of excellence of mitochondrial dysfunction in neurodegeneration

Expected contributions from SMEs

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

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

Duration

- The indicative duration of the action is 36 months.

Indicative budget

- EFPIA & IMI2 AP in-kind contribution: EUR 1 200 000
- IMI2 JU contribution: up to EUR 1 200 000

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Goals & Key Deliverables

Goals

- Effective and efficient coordination and collaboration among the ongoing and future projects in the IMI area of neurodegeneration

Key Deliverables

- An operational platform to coordinate the neurodegeneration projects
- Enable effective interaction with regulatory authorities and HTAs.
- Good practices for sharing of data, biological tools and other materials
- An advisory boar , an up-to-date catalogue of project results.
- A series of workshops & a programme of outreach activities.
- Joint white papers.
- A map of the partnerships and collaborative efforts in AD.

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Expected contributions from SMEs

- 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

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Topic 6: A Sustainable European Induced Pluripotent Stem Cell Platform

Duration

- The indicative duration of the action is 36 months.

Indicative budget

- EFPIA in-kind contribution: EUR 4 000 000
- IMI2 JU contribution: up to EUR 4 000 000

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Goals & Key Deliverables

Goals

- A European iPSC repository that operates on a non-for-profit basis and allows researchers access to a continuously expanding number of well-characterised and fully quality controlled (QC) iPSC lines

Key Deliverables

- A standardised and at-scale human iPSC banking facility
- A cell line housing facility with the capacity to handle existing lines and be extendable to incorporate new ones
- Establish and maintain a mirror cell line bank at capacity
- Establish and maintain a European and worldwide distribution infrastructure

Expected contributions from SMEs

- 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

Duration

- The indicative duration of the action is 60 months.

Indicative budget

- EFPIA in-kind contribution: EUR 24 700 000
- IMI2 JU contribution: up to EUR 25 500 000

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Goals & Key Deliverables

Goals

- Measure in three chronically ill or frail populations:
  - Real world walking speed
  - Additional digital mobility assessments

Key Deliverables

- Development of the appropriate algorithm and one (or more) digital mobility assessment devices
- Digital mobility and clinical outcome assessment over 2-3 years in each of three populations
- Submission of data to health authorities and HTA bodies for consideration as a surrogate endpoint for clinical trials,

Expected contributions from SMEs

- 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

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Topic 8: Human Tumour Microenvironment Immunoprofiling

Duration

- The indicative duration of the action is 60 months.

Indicative budget

- EFPIA in-kind contribution: EUR 16 350 000
- IMI2 JU contribution: up to EUR 17 830 000
- Up to 27 880 000 available to the applicant consortium

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Goals & Key Deliverables

Goals

- Development of a fully integrated data set of defined immune cell subsets in samples from patients from specific cancer indications

Key Deliverables

- A data set on presence and spatial distribution of immune cell subtypes
- RNAseq analysis of all samples
- A ‘deep profiling’ data set for a subset of tumour samples

Expected contributions from SMEs

‘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

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

Duration

- The indicative duration of the action is 60 months.

Indicative budget

- EFPIA in-kind contribution: EUR 13 500 000
- IMI2 JU contribution: up to EUR 15 300 000

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Goals & Key Deliverables

Goals

- Provide improved tools and methods to generate more valuable, reliable and timely information to HCPs and pregnant and lactating women to enhance optimal care.

Key Deliverables

- Enhance our understanding of disease related pregnancy, birth/infant outcomes, medication use and safety in pregnancy
- Safety data collection in pregnancy and the analysis of case reports
- Enhance data generation about lactation during medicine use and standardise approaches to human lactation studies
- Establish a non-commercial, Europe-wide breast milk biobank building
- Dissemination to HCPs, pregnant/ breastfeeding patients and public

Expected contributions from SMEs

- 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

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

Duration

- The indicative duration of the action is 36 months.

Indicative budget

- EFPIA in-kind contribution: EUR 4 331 000
- IMI2 JU contribution: up to EUR 5 331 000

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Goals & Key Deliverables

Goals

- Improve the preclinical predictivity of adverse effects of pharmaceuticals on the central and peripheral nervous systems.

Key Deliverables

- New/improved in silico tools that allow establishment of QSAR
- Better understanding, modelling and simulation of the blood-brain barrier passage. Improved blood-brain barrier model.
- New/improved in vitro tool(s) for screening (pre-)candidate drugs
- Tool(s) for elucidating mechanism of toxicity (lab on a chip)
- New/ improved in vivo animal models, better characterisation of the most relevant animal species for each type of toxicity.
- Identification and validation of safety biomarkers
- Integration of the deliverables in a PK/PD/TD platform

Expected contributions from SMEs

- 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

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

Duration

- The indicative duration of the action is 60 months.

Indicative budget

- EFPIA in-kind contribution: EUR 14 000 000
- IMI2 JU contribution: up to EUR 14 000 000

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Goals & Key Deliverables

Goals

- Development of biomarkers of injury for liver, kidney, pancreas, vasculature, central nervous system (CNS) and the development of non-invasive liquid biopsies

Key Deliverables

- Biomarker qualification submissions to EMA, FDA and PMDA
- A new paradigm-changing non-invasive biomarker approach for interrogating mechanisms of toxicity
- Enable investigators to de-convolute observed miRs signatures to biological pathways in specific tissues;
- Robust biomarker assays compliant with regulatory requirements

Expected contributions from SMEs

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

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

Duration

- The indicative duration of the action is 48 months.

Indicative budget

- EFPIA in-kind contribution: EUR 4 160 000
- IMI2 JU contribution: up to EUR 1 040 000 per indication

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Goals & Key Deliverables

Goals

- Take one of the nine previously deprioritised clinical compounds and investigate their therapeutic potential in new clinical indications in areas of high unmet need.

Key Deliverables

- Initiation and completion of new Phase 2A clinical proof-of-concept studies
- Preclinical data to support a go/no-go decision for initiation of the clinical study in the new indication
- Dissemination of the results in high-impact publications.

Expected contributions from SMEs

- 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
- Capacity to recruit sufficient number of patients within a few clinical study centres
- Strong project management and communication expertise

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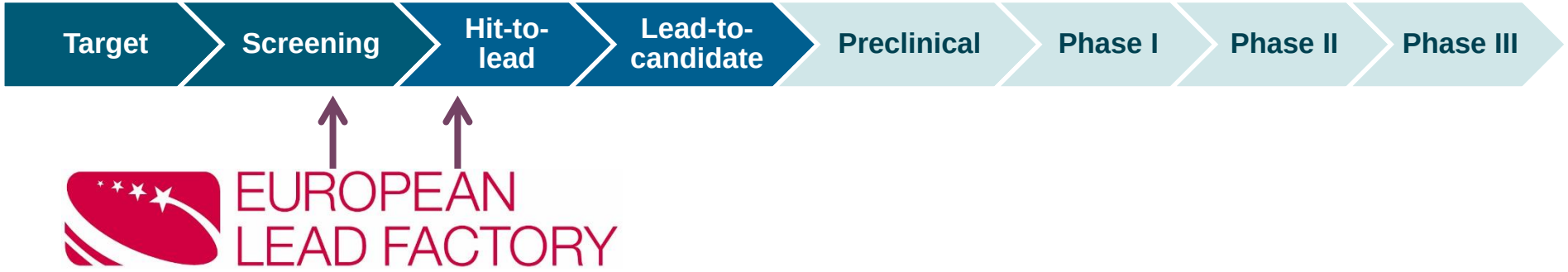
SME participation in ongoing IMI Projects

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

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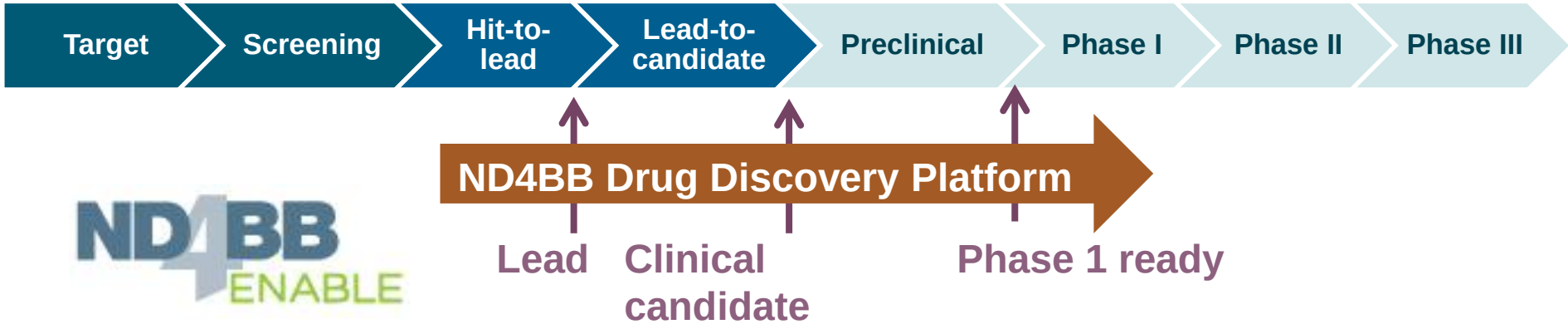
IMI Drug Discovery Platforms - ENABLE



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

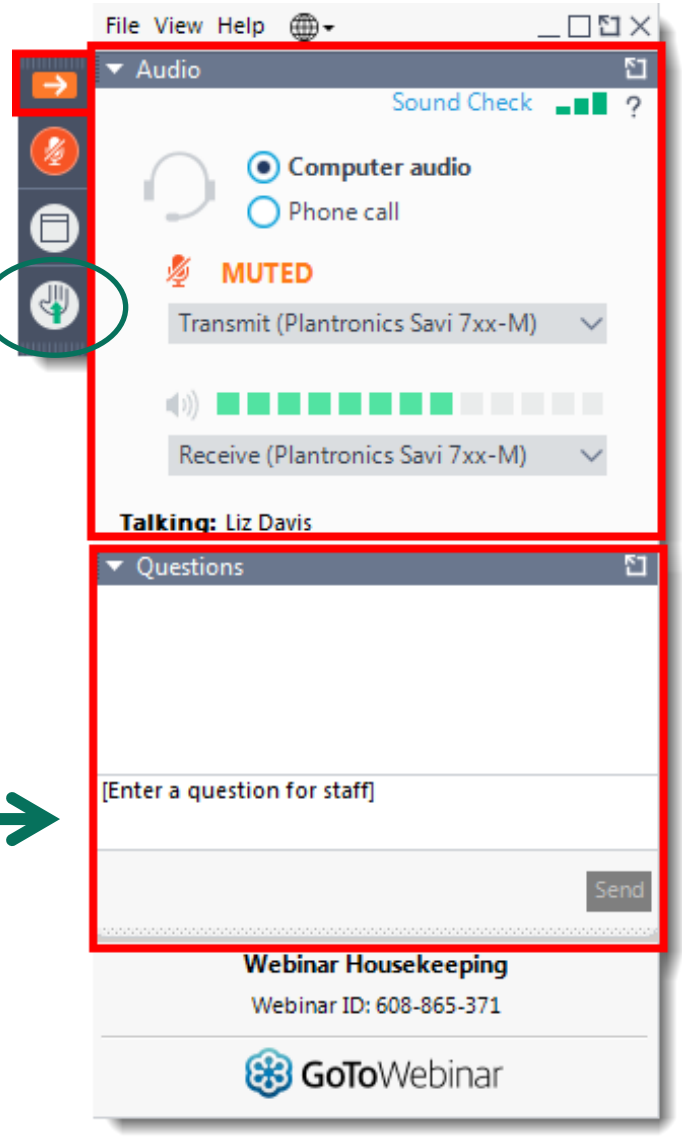
www.imi.europa.eu

@IMI_JU

Questions

Questions?

Raise your hand if you want to ask a question orally



Send a question in writing

After the webinar, send any questions to the **IMI Programme Office**

infodesk@imi.europa.eu

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