Opportunities for SMEs in IMI2 Call 13

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 pharmaceutical companies allows access to whole value chain of drug discovery
- Build research and business networks
- Funding: 100% of costs reimbursed

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 Phenomapping Approaches**

- 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**

- 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 to advocate on the value of diagnostic to combat AMR

**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 targeted for the different stakeholders and public at large
• Development of effective communication tools including websites and social media, platforms to create awareness of the programme and disseminate findings
• Expertise to create training and communication materials based on results of the programme.

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

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

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 and website maintenance experience
• Regulatory expertise, experience dealing with regulatory agencies, professional expertise managing complex multi-stakeholder projects, professional project management capability and experience

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 assay (optionally: combined with MEA, in order to correlate brain passage and neurotoxicity), 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 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**

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

**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