Potential future IMI Call topics for 2020

About this document

The following topics are under consideration for inclusion in future IMI Calls for proposals in the longer term. The discussions on these topics are still in their early stages. For this reason, the topics may change considerably and they will probably not be ready for inclusion in an IMI Call for proposals for several months. Furthermore, as the discussions advance, it is likely that some topics will be added to this list while others will be dropped. In any case, we hope that this list will give potential applicants a useful glimpse into what is under development in the longer term, and provide additional time to enhance their network. We will update this list whenever we have updates on the status of the topics.

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All information regarding future IMI Call topics is indicative and subject to change. Final information about future IMI Calls will be communicated after approval by the IMI Governing Board.

Neurodegeneration and other neuroscience priorities

Digital endpoints and placebo effect in chronic pain

The primary aim of this call is to progress digital endpoint(s) to Health Authority acceptance as primary / surrogate endpoints or key secondary endpoints for evaluation of chronic pain in pivotal clinical trials. The intention of this call is not to simply explore digital endpoint space in chronic pain, but to deliver endpoints ultimately via medical grade devices that can subsequently be used for regulatory approval. As the placebo effect in pain clinical trials is substantial, an additional aim is to assess new methods to better understand and control placebo effects to determine the real treatment advantage offered by analgesic agents.

Infection control including vaccines

Development of innovative personalized diagnostics and patient-guided therapies for the management of sepsis-induced immune suppression

The proposed topic is addressing Sepsis, a global health priority being targeted by many countries and the WHO. If not recognized early and managed promptly, sepsis can lead to septic shock, multiple organ failure and serious consequences including death. There are approximately 30 million sepsis patients per year worldwide. The primary aim of this call is to develop diagnostic tools for characterizing sepsis or injury-induced immunosuppression in order to target personalized management and therapeutic solutions for improving outcomes and decreasing the occurrence of secondary healthcare-associated infections (HAI). The main objectives will be to reduce mortality and decrease secondary HAI through diagnostic and therapeutic approaches including (i) implementation of an immune-based personalized diagnostic test to clearly identify sepsis patients in an immune-suppressed state and (ii) introduction of innovative immuno-modulators in order to restore immune homeostasis. The project also aims to demonstrate the medical and economic value and benefits of this approach to improve patient outcomes (organ dysfunction, disability, mortality, etc.), decrease infectious HAI complications, and reduce healthcare costs.

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Big data, digital health, clinical trials and regulatory research

Data lakes

Many pharma and life sciences companies are currently creating data lakes to bring together internal data to apply analytics and create insights. However, these data often need to be complemented with other data sources. Most health data are generated outside the life sciences, e.g. electronic health records, claims, biobanks etc. In addition, control over health data is starting to shift towards the patient; initiatives and healthcare technology companies already signal a future where the patient will be in control of data and can decide how and with who to share. To improve our ability to combine data from multiple sources and maximize insights generation from these data, we need a common approach to enable quick and efficient connectivity of data to use for diverse purposes. A fundamental requirement for this to work is to make data findable, accessible, interoperable and reusable (the underlying concepts are known as the FAIR principles). Therefore, we propose a project to create (1) a common set of tooling for managing and FAIRifying data lakes, i.e. the agreement or development of a common and potentially open source toolset, (2) agreement on the necessary key ontologies and standards and (3) to create a market place for datasets or individual-level data to further enhance data fluidity. With a successful implementation, users would be able to find, access and use data which data owner decides to share, and leverage them for different purposes. Data owners could do this at the individual level, e.g. a personal health record, the company level e.g. datasets from the company data lake, or an industry or even global level, e.g. data from an industry collaboration.

Oncology

Prospective real-world clinical implementation of liquid biopsies

Liquid Biopsy is a promising concept for patient selection and disease monitoring in drug development and in clinical practice. However, as of today, few clinical studies used Liquid Biopsies to systematically and prospectively identify eligible patients for clinical studies, therapy selection, therapy monitoring or detection of first signs of efficacy. Based on outputs from IMI CANCER-ID the project will use prospective clinical trials to investigate the efficacy and robustness of the method and its ability to guide recruitment to trials and therapeutic choices

Tumour plasticity

Drug resistance in cancer is one of the greatest causes of mortality and despite increasing success with targeted therapies in the clinic (including immunotherapy) the mechanisms by which cancer cells evade cell death are still not well understood. Drug combinations are likely to be critical to overcoming drug resistance but are dependent on identifying the cellular programs that cancer cells use to resist therapeutic agents. Recent technological advances in single cell RNA sequencing (scRNA-seq) has revolutionised the study of individual cells within cancer populations. Single cell sequencing provides information that is not confounded by genotypic or phenotypic heterogeneity of bulk samples. It has led to the identification of rare cancer cells ('persister cells') able to survive drug treatment and that are able to act as a reservoir for the emergence of drug resistant cancer populations. Characterising the transcriptionally altered pathways in persister cells, the biological processes they regulate and their druggability will be critical to future drug combination strategies, with the goal of preventing or significantly delaying the development of drug resistance. The transcriptional programs employed by persister cells in response to a therapy are likely to be lineage specific. Scientific advances in single cell sequencing, cancer organoid derivation, use of patient-derived xenografts (PDX) and tissue imaging have come together to create the perfect environment to address one of the most important challenges in cancer biology today, Drug resistance.

Facilitating the translation of advanced therapies to patients in Europe

Optimising patient access to new therapies for rare diseases

Payers and manufacturers recognise the challenges in delivering innovative medicines to Rare Disease patients and the need to address reimbursement hurdles which will demand new models of reimbursement based on value based agreements and performance guarantees. However determining the appropriate outcomes, data and standards required to make these decisions efficiently across the many healthcare systems requires transparency and alignment across all stakeholders, including patients, payers, regulators, industry and other experts. Additionally, there is a paucity of registries and databases that capture long term outcomes including patients' Quality of Life and functional data, coupled with general uncertainty regarding variability & durability of outcomes for new and novel treatment options including Advanced Therapy Medicinal Products (ATMPs). To facilitate the health economic evaluation of such new and novel treatments, the project will aim to build an ecosystem involving relevant stakeholders to identify and capture appropriate long term outcomes required by HTA bodies and assess how these may align with regulatory requirements (continued evidence generation). This project will aim to capture and demonstrate improved health outcomes important to patients and for payer reimbursement and regulatory decisions, providing patients more rapid access to new therapies.