

IMI Scientific Committee position on IMI-funded digital innovation and data integration in discovery of novel medicines

In the last two decades, OMICS technologies have evolved to indispensable instruments of drug discovery and essential components of biomarker discovery. This has led to a massive increase of data generation. These huge datasets offer an unprecedented potential to better understand human disease and to translate these findings into more targeted and individualized diagnosis and treatment options, often referred to as personalized medicine.

The general perception is that the benefits of the new learnings and innovations should be made available to patients as fast as possible. However, despite the increasingly high qualitative performance of technologies and bioinformatics tools, the translation into value-based health- and people-centered clinical applications continues to be a challenge for society. Rigorous statistical, bioinformatics, laboratory and clinical procedures are required to exploit, develop and validate the findings and evaluate their clinical utility.

Speeding up the translation further requires implementation of new concepts in regulation, clinical research and patient access to innovations, particularly in areas of unmet medical or social need. The Innovative Medicines Initiative (IMI) has identified this need and has, thus, from early on supported the scientific input and development of next generation methodologies to facilitate data integration and evidence generation for subsequent clinical translation.

Past and present IMI projects have contributed specific experience and novel scientific insights that have already moved the field forward. Many IMI projects have supported new resources for innovative approaches to drug discovery in this specific area. These range from online platforms that allow scientists to rapidly access diverse data sources to clinical networks facilitating clinical drug development. Approximately one third of the projects have created new businesses or improved the performance of existing businesses as a result of IMI project participation.

The IMI Scientific Committee gives strategic science-based recommendations to the IMI governing board. It advises on the current and emerging aspects and the relevance of the Strategic Research Agenda and the scientific priorities.

At present, digital health has superseded the implementation of OMICS technologies. It is more holistic because it comprises OMICS data and electronic patient data and it connects them with pharmacovigilance systems and modern devices that are necessary to apply or monitor drug administration, safety and efficacy. The integration of all of these technologies and the modeling and simulation exercises that can be based on all the collective information gathered is another big challenge. And, again, for this challenge to become an opportunity society needs scientific input.

The IMI Scientific Committee believes that the full transformatory potential of digital health sciences can be leveraged through public-private partnerships that not only support multidisciplinary and intersectional collaborations between industry, academia, patients, physicians and healthcare workers, payers and regulators, but also promote new concepts and platforms for interaction among these stakeholders. Notably, the value of an individual IMI project should be judged by its ability to generate substantial scientific achievements that have the potential to shape the landscape of innovative drug development. The overall goal of IMI and its projects should be to provide the EU with novel and sustainable resources and outputs that can drive the necessary change in drug development processes and facilitate patient access to innovation beyond the individual project. The IMI Scientific Committee, therefore, supports the objective of IMI to commit its research focus to the area of digital health and to building a new open innovation ecosystem for advancing medical research and drug development for the benefit of patients.

On behalf of the Scientific Committee

Beatriz Da Silva Lima, Chair
Isabelle Bekeredjian-Ding, Vice Chair

Brussels, January 19th, 2018

Relevant literature

1. *Evolution of Translational Omics: Lessons Learned and the Path Forward*. Editors Committee on the Review of Omics-Based Tests for Predicting Patient Outcomes in Clinical Trials; Board on Health Care Services; Board on Health Sciences Policy; Institute of Medicine; Micheel CM, Nass SJ, Omenn GS, editors. Source Washington (DC): National Academies Press (US); 2012 Mar.
2. *Integration of omics sciences to advance biology and medicine*. Boja et al. *Clinical Proteomics* 2014, 11:45.
3. *Scientific Panel for Health, vision on 'Better Research for Better Health', May 2016* (<https://ec.europa.eu/programmes/horizon2020/en/h2020-section/scientific-panel-health-sph>)
4. *IMI brochure 'Carrying the torch for medical innovation'* (http://www.imi.europa.eu/sites/default/files/news/Brochure_ResultsImpact.pdf)
5. *Rules of procedure of the Scientific Committee of the Innovative Medicines Initiative 2 Joint Undertaking* (https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/sc/IMI2_SC_RULES%20OF%20PROCEDURE.pdf)
6. *From genome to bedside: are we lost in translation?* Hayes DF. *Breast*. 2013 Aug; 22 Suppl 2:S22-6.