

Israel Precision Medicine Partnership Principles and Guidelines

Overview

The recent advances in our understanding of the molecular basis for human diseases, along with the rapid development of powerful and affordable approaches for large-scale genomic and gene products analysis, open an unprecedented opportunity for a novel type of Precision Medicine. With its extraordinary community of life science researchers, advanced and highly centralized medical system, and well-established entrepreneurial culture, Israel can play a central role in these developments.

The Israel Precision Medicine Partnership (IPMP) seeks to take advantage of these unique resources, by bringing together top researchers, clinicians and healthcare organisations, supported by government, private philanthropy, to advance basic scientific discovery and the development of new diagnostics and therapeutics. The Partnership is a grant making framework that aims to support the growth of Precision Medicine in Israel, by supporting cutting edge research on human health and disease, while at the same time helping to shape data infrastructures and build a culture of collaboration across research and clinical settings crucial for the long-term success of Precision Medicine in Israel. The Partnership is committed to advancing the public good through open sharing of data and science driven inquiry, operating within a transparent and responsible public framework.

The goals of the Partnership include:

- Advancing cutting edge research in Precision Medicine in Israel
- Promoting researcher access to clinical medical databases and 'multi-omics' data linking molecular and clinical information of Israeli patients for prospective and retrospective investigations.

- Establishing operational principles and guidelines that promote sustainable, long-term access to clinical and 'omics' data for Israeli researchers, while promoting a culture of collaboration between physicians and basic researchers, as well as between HMOs, Hospitals and academic institutions.

The Partnership will support 'bottom-up' Precision Medicine research in Israel, and will be operated by the Israel Science Foundation (ISF). It will require (subject to appropriate legal and ethical standards) broad researcher access to clinical and medical data, the sharing of data collected through research projects, and collaborative frameworks that bring together clinicians and basic researchers. Organisations that participate in these research projects must be committed to providing open and equitable access to their medical and clinical data, and to depositing data accumulated in research projects in accessible databases, in accordance with terms set out by the ISF, which reflect current best practices globally. It is expected that government efforts to establish appropriate data repositories for clinical-genomic data in Israel will be implemented within 12-18 months of the launch of the Precision Medicine Partnership, providing a reliable infrastructure to support data sharing among Israeli researchers.

The combination of advanced research projects, a robust data-sharing infrastructure and a culture of collaboration will enable Israel to become a leading international centre for Precision Medicine Research.

Governance

The system of governance will consist of three committees:

1. **Steering Committee:** Includes representatives from all participating organizations, including the Planning and Budgeting Committee of the Council of Higher Education (VATAT), Digital Israel, Yad Hanadiv, the Klarman Family Foundation (KFF), the Ministry of Health, The Forum for National Research and Development Infrastructure (TELEM) and

the ISF. The Chair of ISF's Academic Board will chair the Steering Committee. This committee is expected to meet at least once a year. It will review annual results, ensuring communication with relevant government programs, identify key issues, and provide strategic guidance for the IPMP.

2. **Executive Subcommittee:** To include a representative from VATAT, Digital Israel, ISF, Yad Hanadiv and the KFF. This subcommittee will serve as the main forum for ongoing operational and policy decisions required. It will meet as required but not less than three times per year.
3. **Scientific Advisory Committee:** Chaired by the head of the Biomedical field in the ISF. This committee will advise on scientific questions arising from the programme, including the desired scope of various grant tracks, identifying new scientific areas relevant to the programme, advising on scientific partnership opportunities, as well as ethical considerations arising from the work of the Precision Medicine Partnership. The committee will include senior scientists from Israel and abroad, and will be approved by the Executive Subcommittee. It will meet at least once a year in Israel.
4. All grant operations, including issuing calls for proposals, reviewing grants, and approval of funding for projects, will be fully managed by the ISF.

What type of research will be funded?

Projects supported under this framework will include:

- A broad range of research with direct relevance to human health and disease, including disease pathways, new approaches to diagnostics and therapeutics, and development of new medical technologies
- Emphasis on Precision Medicine and advanced approaches to studying the molecular and clinical variability in human disease
- A wide array of approaches, including study of germ-line genomics, somatic mutations, transcriptome, epigenomics, proteomics, microbiome, metabolomics and more.

Funding Guidelines

- The level of funding for projects will be significantly higher than currently available research grants in Israel and allow for large scale collection and analysis of omics data.
- Research programmes will generally be expected to make use of clinical samples and data, requiring extensive collaborations among university-based researchers and clinicians in hospitals and HMOs. All such collaborations will require obtaining appropriate Helsinki and IRB approvals, identifying suitable candidates for research projects and receipt of relevant clinical data and consent forms, according to existing rules and regulations.
- The data accumulated as part of research projects will be deposited based on criteria established by the ISF, in a national bio-medical database (or alternative databases). Data will be deposited in a manner that ensures patient anonymity/de-identification, while enabling future researchers to study links between the various molecular and clinical data obtained in past research projects. **Funding will only be made available to institutions that can ensure compliance with the data deposit requirements.**
- Clinical trials or research conducted at the initiative of commercial entities will not be supported. Research projects that work primarily on model organisms will also not be supported.
- Researchers must be eligible to receive funding from the ISF and research must be performed at an institution that meets the programme requirements as defined by the Steering Committee.
- This programme seeks to encourage collaborations between clinicians and basic researchers, and between researchers in clinical settings and in universities. Clinicians, experimental and theoretical researchers are all expected to take part in research projects.

Grant Tracks

At the outset, the Precision Medicine Partnership will provide grants in two research tracks:

- Projects involving extensive collection and analysis of data from participants, and collaborations across universities and medical institutions (average of \$400,000 per year for up to five years – total grants of up to \$2M)
- Technology Development Projects (\$50,000–\$100,000 per year for three years; up to \$300,000 per project)

Currently, four calls for applicants are anticipated, beginning in the 2018–19 academic year.

Changes to grant tracks or funding levels will be subject to review by the Scientific Advisory Committee and approval by the Steering Committee of the Partnership.