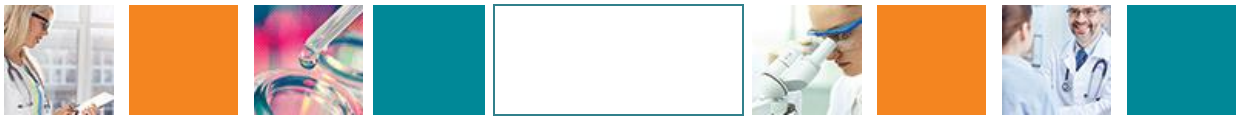
European Federation of Pharmaceutical Industries and Associations

Draft ☐ Final ✱

Partners in Research: implementing technology integration

Date: 16 November 2018 ✱ **Version:** final



EFPIA Partners in Research address the need for quality technology integration

The evolving societal and healthcare challenges as well as opportunities offered by new sciences and technologies, call for a much more integrated health research environment than in the past.

Beyond the "Associated partner" status provided in the IMI regulation, and responding to the need for integrated cross-sector collaboration in the R&D, EFPIA has created "Partners in Research" as a constituent entity open to companies operating in such associated sectors (imaging, MedTech, diagnostics, animal health, IT including e- and m-technologies, contract research organisations, etc.). This membership status makes it possible to jointly design and implement collaborative R&D initiatives in the framework of the Innovative Medicines Initiative (the largest public private partnership in health research worldwide), which will ultimately implement new R&D, operational and business models that will benefit all sectors involved (impact on R&D processes), patients (new treatment pathways), and society (incentives for reinvestment in areas where there is market failure).

What's the investment?

- Financial contribution: the annual fees are set as follows (for more details, please email science-policy@efpia.eu)
  - Group A Partners, i.e. micro, small and medium-sized enterprises and other companies with an annual turnover (i.e. sales on the European market) of € 500 million or less: € 5,000
  - Group B Partners, i.e. all other companies: € 10,000
- Appointment of a contact person that will liaise with EFPIA and facilitate access to relevant Partner in Research departments and their involvement in activities.
- In kind or cash contribution to IMI projects – the selection of projects and level of investment is up for decision of each company based on their interest and capabilities.

What's in it for you?

IMI projects offer a perfect safe harbour environment to develop and test new approaches to integration of pharma and non-pharma technologies and tools. Your contribution to IMI projects is matched by corresponding IMI funding for non-profit beneficiaries (academics, SMEs). In addition, the Partners in Research membership offers the possibility to jointly develop new integrated business models as well as:

- Platform for engaging with the pharmaceutical sector to develop new standards and methodologies for integrated life sciences and integrated care approaches (e.g. through IMI2 Strategic Governing Groups)
- Shaping the IMI strategies and projects to your company core activity and pipelines together with EFPIA members
- Guaranteed participation in IMI consortia, not subject to EU R&D funding competition, where your assets (tools, methodologies, etc.) can be improved and validated in real life R&D in several companies simultaneously
- Access to cohorts, data and know how not available in standard research collaborations
- Networking and access to the pharmaceutical ecosystem (large number of pharmaceutical companies)
- Support, advise and access to best practices in relation to participation in IMI projects through EFPIA team and other companies' experts

EFPIA Brussels Office
Leopold Plaza Building ✱ Rue du Trône 108
B-1050 Brussels ✱ Belgium
Tel: + 32 (0)2 626 25 55 ✱
www.efpia.eu ✱ info@efpia.eu

Annex 1: Integrated life sciences through the Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI), the largest public private partnership in health research worldwide, has piloted over the last few years a number of large scale programmes, which resulted in tangible outputs for companies (impact on R&D processes), patients (new treatment pathways), and society (incentives for reinvestment in areas where there is market failure).

Conceived as a "safe harbour" with an autonomous office, IMI involves all parties that can contribute to defining and running collaborative research, but also those that will ultimately implement the results of research in the regulatory framework, healthcare decision-making and clinical practice.

IMI projects:

- Develop a new area of knowledge (e.g. new classification of diseases)
- Develop and validate specific methods, or tools (biomarkers, diagnostics, cohorts, etc.) up to regulatory acceptance
- Contribute to regulatory, medical, regulatory and research practice (e.g. standards, outcomes measures, adaptive pathways, patient access models) (see examples below)

Non-exhaustive list of examples of areas where technology integration is of particular importance to address current and future healthcare challenges and which are in the scope of IMI:

- Stratification of patient populations to identify the potential responders (genetic sequences, existing healthcare data, patient registries, diagnostics, etc.)
- Generation of real world evidence through new technologies and use of real world data to prove efficacy, safety, outcomes and compliance
- Integration of new technologies (digital and others) in research, healthcare management, and new types of products (connected products and pill+)

Examples of structuring projects:

- **New models:**
  - The **Big Data for Better Outcomes (BD4BO)** programme aims at exploring the boundaries of outcomes based healthcare models. Projects in several therapeutic areas address outcome definition, outcomes measures, generation of outcomes data and outcomes based decision making. The anticipated impact is to remove inefficiencies from the value chain and to prioritize interventions which add most value, including combinations of products and technologies. See the BD4BO project factsheets and the BD4BO website.
  - **ADAPT-SMART** project looks into barriers and opportunities to adopt adaptive models (development, licensing and delivery) based on continued evaluation of value of products. Both adaptive models and outcomes based models rely on technologies able to reliably generate good quality real world data.
  - **DRIVE AB** aims at finding business models that help preserving antibiotics through rational use while incentivising continued investment where the expected return on investment will be extremely low. DRIVE AB delivered 5 potential models, which are now discussed with payers and healthcare decision-makers.

Standardisation: For a number of projects, generated data are the basis for new standards recognised by European and global regulators. A number of biomarkers obtained, or are just about to obtain, letters of support and/or positive qualification opinion from the European Medicines Agency (EMA), and the US Food and Drug Administration (FDA) is an observer of these initiatives: SAFE-T, U-BIOPRED, EU-AIMS. IMI is also very much involved in standardisation through a partnership with Clinical Data Interchange Standards Consortium (CDISC).

- **A broader reflection of digitalisation of medicines value chain -** EFPIA embarked on a reflection process on the digitalisation of the value chain from discovery to medicines life cycle management. There are two projects under way: WEB-RADR (social media mining to detect safety signals) and RADAR (remote patient monitoring through sensor and mobile, for now in CNS but diabetes and Alzheimer are planned). These are just two first steps, and by engaging with the holders of technologies we may better identify how different technologies complement and add value to each other.

-- end --


EFPIA Brussels Office
Leopold Plaza Building * Rue du Trône 108
B-1050 Brussels * Belgium
Tel: + 32 (0)2 626 25 55 *
www.efpia.eu * info@efpia.eu