



## PARADIGM International Liaison Group

### *Charter*

#### About PARADIGM

PARADIGM (Patients Active in Research and Dialogues for an Improved Generation of Medicines) is an IMI2 public private consortium aiming to enable and enhance meaningful and sustainable patient engagement in the medicines lifecycle with focus on three key decision points (R&D prioritisation, design of clinical trials, early dialogue between regulators and HTA bodies).

PARADIGM responds to the evolution of medicine development and new opportunities and expectations for more effective engagement, as well as to growing concerns on how to do it ethically and whether it delivers value. PARADIGM intends to contribute to increasing the understanding and appreciation of the added value of patient engagement in medicines lifecycle, by providing consensus-based recommendations and solutions on how to join up and 'mainstream' the currently dis-jointed engagement practices.

The PARADIGM consortium approach is to build on and join forces with existing European and international initiatives in the field of patient engagement in the medicine lifecycle continuum. Where needed, the consortium will identify and develop missing tools, new deployment approaches, and other resources.

#### PARADIGM INTERNATIONAL LIAISON GROUP (PILG)

The PARADIGM International Liaison Group is an information hub acting as an operational platform to connect PARADIGM with key IMI and other international engagement initiatives in co-development, and promote implementation of patient engagement practices.

The PILG will enable synergies -such as identification of existing practices- aligned with PARADIGM scope, reduce fragmentation and duplication, and the rollout of mechanisms where PARADIGM outputs are aligned with the mission and vision of the members to enhance their uptake and future implementation. Where appropriate, the PILG will also provide external guidance on relevance of PARADIGM strategic objectives and deliverables in different regions of the world.

Beyond the PARADIGM scope and timeframe, bringing together key international players into the PILG platform will offer an opportunity to defragment patient engagement activities and enhance efficiency of its constituent members.

#### Tasks of the PILG

- To support the members of the PARADIGM consortium to create a well-defined roadmap illustrating the strategical, operational and financial needs and resources between patient training and engagement
- To align the patient engagement initiatives across the entire PILG membership

- To create synergies to make patient engagement happen, to discuss its challenges and ways to overcome them.
- To share engagement practices from other initiatives across the entire PILG membership
- To support PARADIGM in elaborating and evolving existing guidance for patient engagement with the pharmaceutical industry and other stakeholders towards more operational documents and tools.
- To share PARADIGM outputs with other initiatives, to improve dissemination and implementation
- To provide advice to PARADIGM in developing relationships with key international players relevant to patient engagement, and establish an International Vision on patient engagement
- To provide advice on global relevance of PARADIGM results and on implementation of PARADIGM outcomes in an international setting
- To explore complementary activities, to design future collaborative projects, to generate mutual learning in an agreed framework, to bring patient engagement in specific sphere (maternal health, adaptive pathways, etc...), to collaborate and co-create new patient engagement tools by addressing commonly identified gaps

## Members of the PILG

Senior representatives of the following organisations are members of the PILG (additional initiatives may be invited as appropriate):

- International Children's Advisory Network (iCAN)
- Drug Information Association (DIA)
- European Patient Academy (EUPATI)
- National Health Council (NHC)
- International Society For Pharmacoeconomics and Outcomes Research (ISPOR)
- Patient Focused Medicines Development (PFMD)
- TransCelerate BioPharma Inc
- PREFER (IMI project)
- University of Bonn
- BD4BO PROGRAMME (IMI) – Through DO-IT (WP4)
- Clinical Trials Transformation Initiative (CTTI)
- FasterCures
- Children Tumor's Foundation (CTF)
- International Consortium for Health Outcomes (ICHOM)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- External expert:
  - Violeta Stoyanova from the Medicine Evaluation Board

### Pending confirmation

- *National Institute for Health and Care Excellence (NICE)*
- *Patient-Centred Outcomes Research Institute (PCORI)*

New members can be proposed by the PILG. Nominations will be validated by the Steering Committee.

Members may terminate their participation at any time in writing, by email or letter to the leaders of the PARADIGM Consortium.

## Mode of operations

The PARADIGM International Liaison Group:

- Interacts upon invitation with PARADIGM Steering Committee and relevant work packages to provide advice or share knowledge and to identify opportunities for synergies and nurturing each other's activities;
- Is consulted in writing on relevant key deliverables by the Steering Committee;
- Advises, at any time, the PARADIGM Steering Committee, on any topics that the members deem relevant in the relation to the overall mission of PARADIGM;
- Decisions are taken by consensus with the final arbitrage to the PARADIGM Steering Committee if needed;
- Meets face-to-face three times during the course of PARADIGM - the meetings will be organised to coincide with other PARADIGM activities or other relevant international meetings and fora – or via videoconference;
- Strategic and operational support is provided by the coordinator and management of PARADIGM

The PILG is coordinated by the PARADIGM coordinator. However, in the absence of a permanent chair, the PILG members will identify their representative(s) who will present PILG recommendations at the PARADIGM 2<sup>nd</sup> and 3<sup>rd</sup> forums, to act as a spokesperson.

## Rules of engagement

- Members of the PILG are instrumental in driving patient engagement overall, beyond individual or organizational interests
- Engagement and collaboration is based on mutual benefits and has a fully voluntary character
- Members of the PILG sign IMI confidentiality and conflict of interest forms
- bring value and expertise
- Members of the PILG do not receive IMI funding from PARADIGM