



PATIENT ENGAGEMENT OPEN FORUM - DAY 2 WORKSHOPS

It is now recognized that patient engagement is a major asset in clinical development, by making trials co-created with patients more acceptable, accessible and therefore more attractive to participate-in. This collaboration generates more consistent trials, improves trial recruitment rates, and speeds up the medicine development process which can lead to faster filings towards regulatory bodies and higher rates of approvals (a program co-created with patients has a 20% chance higher of obtaining Marketing Authorization¹). Despite this recently measured success, R&D global activity is still facing major increases in difficulty and costs, and too few programs of research succeed in reaching the clinical development stage or go on to fail early on. These wasted resources result in a heavier burden on the entire healthcare system, with an increase in the price of the few drugs reaching the market, and extremely long waiting times for patients with urgent medical needs.

This combined with the already measurable and reported benefits of involving and co-creating with patients during clinical trials should inspire stakeholders to collaborate earlier in the medicines lifecycle. Research papers and guidance on this topic often refer to patient involvement 'across the medicines development continuum', however, in practice there are only a few examples of meaningful partnership working between patients and those delivering research throughout discovery and early clinical phases of development.

WORKSHOP 1 - HOW TO ENGAGE PATIENTS IN EARLY DEVELOPMENT AND PRECLINICAL RESEARCH PHASES OF MEDICINES DEVELOPMENT

Together this Working Group from PFMD² has developed a model which encompasses elements that we feel are the key components in collaborating and co-creating with patients to develop a thorough understanding of all aspects of disease experience, patient preference, unmet need and benefit/risk that will ensure the development of a more relevant, robust and acceptable plan leading into the clinical development phase.

By joining this workshop, you will be able to

- participate in the discussion and co-creation of draft model developed for this how-to guide for patient engagement in the discovery and early phases of medicines development,
- give your input in areas that might be missing in the current draft model,
- participate in the collection of additional resources and case studies.

¹ The innovation imperative: the future of drug development, a study conducted by The Economist Intelligence Unit and commissioned by PAREXEL (<https://druginnovation.eiu.com/>)

² PFMD Working Groups consist of partners from pharmaceutical companies, patient organizations, researchers from academia and patients