

D2.2 Inventory of gaps in existing patient engagement practices and processes

777450 - PARADIGM

Patients Active in Research and Dialogues for an Improved Generation of Medicines

Lead contributors	Stuart Faulkner, Elin Haf Davies (UOXF) Carina Pittens, Nicole Goedhart (VU-ATHENA)
Other contributors	Matthias Gottwald, Malar Subramaniam (Bayer) Ana Diaz (AE) Mitch Herndon, Elizabeth Manning (UCB) Elisa Ferrer (EURORDIS) Mary Lynne Van Poelgeest-Pomfret (EFGCP)

Due date	31/12/2019
Delivery date	27/01/2020
Deliverable type	R
Dissemination level	CO

Description of Action	Version	Date
	V 0.3	24/01/2020

Executive Summary

One of the mechanisms to achieve a step-wise improvement in the implementation and sustainability of patient engagement (PE) in medicines development is to co-develop tools that can better enable the practice of PE and/or the various “start to finish” processes. For tools to be effective they need to fill a robustly defined gap where PE is currently poorly utilized or elements of PE are genuinely lacking.

The overall aim of D2.2 was to objectively assess the previously identified needs, expectations and preferences for effective, meaningful and ethical PE (from work package 1) against the practices and processes of PE within a large sample of PE initiatives in medicines development.

Development and analysis was undertaken in three key stages:

- Stage 1: A large sample of initiatives relevant, to the practice and process of PE (consisting of framework/guidance/process and individual case study) were sourced from large existing global databases with additional examples added directly from consortium partners. A final list of eighty-one initiatives were reviewed using a mix of publicly available and non-publicly available information and additional unstructured communications with initiative owners where possible.
- Stage 2: Previously defined minimum criteria for effective PE by work package one (WP1) were translated and transposed into a structured question and answer framework to create an online gap tool used to submit responses to the in-depth review.
- Stage 3: Combining qualitative and descriptive quantitative analysis of the submitted responses resulted in identifying both generalised gaps and a list of gaps ‘to action’ that are backed up by qualitative findings.

A total of sixteen gaps were identified along the whole PE activity timeline (see table below). Additionally, it was common to observe where process elements were attended to for a given criteria (i.e. training for [patient’s] roles and responsibilities) but a secondary contextual element was often lacking (i.e. making training material accessible to all participants and taking into consideration languages, literacy levels, and other relevance to potentially vulnerable populations).