

TOOL

Defining the Patient's Role

Although you may not have selected the expert patients or patient groups (EP/PGs) yet, outlining their roles and responsibilities at this stage helps to define your needs. Keep in mind that EP/PG roles may vary at different stages of the program or may evolve in response to new requirements. Once selected, discuss the roles with your EP/PGs to clarify what they can contribute based on their unique expertise and experience and avoid misunderstandings at the outset, e.g., if they're expecting to have a partnership role but you've designed reactor role (see Types of Patient Roles chart below).

Patient Role	Examples	Engagement Level
Partnership role	Patients provide a priori and continuous consultation on outcomes of importance, study design, etc. Patients are paid investigators or consultants Patients have a governance role - "a seat at the table"	High
Advisor role	Patients serve as advisory committee members or provide <i>a priori</i> consultation on outcomes of importance and study design, but have no leadership role or governance authority	Moderate
Reactor role	Patient input is collected distally through surveys, focus groups, or interviews, but patients are not consulted directly or a priori on such things as study design and outcomes of importance Patients are asked to react to what has been put before them rather than being the origin of the concepts of interest	Low
Trial or study participant	Patients are recruited or enrolled as study participant, but are not asked for input, consultation or reaction	None

Source: DIA (2017): Considerations Guide to Implementing Patient-Centric Initiatives in Health Care Product Development. (02/06/17)