

PFMD Creates Objective Quality Measure of Patient Engagement to Help Organizations Improve Research

PFMD Applies CTTI's Patient Group Engagement Recommendations

SUMMARY

Patient Focused Medicines Development (PFMD) is an independent global coalition of health stakeholders that aims to transform the way in which we understand, engage, and partner with patients globally in the design and development of research and medicines by focusing on unmet patient needs. The coalition used CTTI's Patient Group Engagement (PGE) recommendations to guide the development of its [PFMD Patient Engagement Quality Guidance](#) for planning and assessing the quality of engagement activities from early research through the clinical development lifecycle and beyond.

GOAL(S)

When PFMD was established in 2015, it did a landscape analysis of patient engagement implementation in clinical research, with a goal to map the landscape to understand the needs of different stakeholders. PFMD hoped to ultimately bring together and synergize disparate but complementary efforts that integrate the voice of the patient in drug development.

CHALLENGES

While conducting in-depth interviews and literature reviews, PFMD realized that there were a number of published guidance documents, but few addressed how and when to implement patient engagement concretely across the drug development continuum. From the interviews, PFMD gleaned that many stakeholders indicated they would like to start engaging patients, but were unsure how to begin a quality engagement effort. It became clear that to achieve its goal, PFMD needed to develop a practical guide to planning, developing and assessing the quality of patient engagement activities and projects throughout the development and lifecycle of medicines.

SOLUTION(S)

CTTI's [PGE recommendations](#) and resources were at the top of the list of 20 relevant frameworks PFMD used in the development of its Patient Engagement Quality Guidance. PFMD hoped to expand on CTTI's work with greater granularity, offering concrete actions to optimize patient engagement across the entire development lifecycle. CTTI's recommendations formed the baseline for how PFMD organized in two key ways. First, it helped PFMD get an understanding of existing knowledge around engagement. Second, it established a foundation across PFMD for conversations with stakeholders, such as industry, researchers, and patient advocates. With background knowledge from CTTI's recommendations and other relevant frameworks, PFMD launched workgroups to begin development of its Patient Engagement Quality Guidance.

TAKING ACTION

In the beginning, bringing multiple diverse stakeholders together was the biggest challenge PFMD faced. They needed to establish a culture of trust and partnership to ensure the principles of co-creation and non-competitiveness were fully rooted. There also had to be considerations for each stakeholder's personal experience. For example, someone from a background in pharmaceuticals has probably been instilled with principles of efficiency and cost. Implementing patient engagement in a meaningful way requires challenging those principles and considering other perspectives. In a diverse group of stakeholders, what works in one room may not work in another. PFMD needed to be flexible and considerate of the lens each stakeholder brings. PFMD ultimately formed seven working groups over the course of a year, growing the team and learning how to work with diverse stakeholders. Identifying preferences around how to work together became instrumental to the development of PFMD's guidance. For example, they learned that patients are often not comfortable speaking directly with pharma companies. In turn, pharma companies often perceived patients as emotional. These observations were made on multiple occasions through live workshops and anecdotes from the participants, who represented pharma, patients and other stakeholders like health care providers and patient organizations/advocates. To address this challenge, PFMD emphasized across all stakeholders the Seven Quality Criteria for good patient engagement that it had identified as part of its development process for its Patient Engagement Quality Guidance: 1. Shared purpose 2. Respect and accessibility 3. Representativeness of stakeholders 4. Roles and responsibilities 5. Capacity and capability for engagement 6. Transparency in communication and documentation 7. Continuity and sustainability This observation also changed the way PFMD conducted its meetings. For example, it began asking questions beforehand and setting clear guidelines and expectations on mutual respect and collaboration from all participants.

IMPACT

In 2018, PFMD released its [Patient Engagement Quality Guidance](#), a tool that contains seven quality measures to assess projects that involve patients. The guidance is a mechanism for capturing the quality of a patient engagement effort and the benefit it brings to stakeholders involved.


ADVICE

Not so long ago, "patient engagement" was widely considered a tokenistic "nice to have" with little published on concrete implementation and even fewer results showing its merit. Today, many organizations would consider the patient voice essential, and there is broad acceptance that patient engagement delivers high-quality results. Across the entire molecule to market lifecycle, patient engagement is critical and, according to PFMD, not difficult to implement. As the positive impact of engagement continues to gain broad acceptance, organizations that do not implement the patient voice risk being left behind.

ORGANIZATION

Patient Focused Medicines Development

CONTACT

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ORGANIZATION TYPE

Other

IMPLEMENTATION DATE

2016

TOPIC

Patient Engagement

RELATED CTTI PROJECT

[Patient Group Engagement](#)

CTTI RESOURCES

[CTTI Recommendations: Effective engagement with patient groups around clinical trials](#)

ADDITIONAL RESOURCES

[The Patient Engagement Quality Guidance](#)

[Discover Inspiring Patient Engagement Initiatives](#)

[PFMD Patient Engagement Quality Guidance](#)