

CONDUCTING EFFECTIVE PATIENT-FOCUSED DRUG DEVELOPMENT

Integrating crucial patient perspectives through a standing PFDD Council

People living with MS have a unique knowledge and understanding of how therapeutics can help with achieving their health objectives. Incorporating their perspectives into the clinical trial design process can result in trials that are more likely to meet recruitment and retention goals, and ensure that the outcomes are feasible and aligned with patient priorities.

In 2018, EMD Serono and iConquerMS launched a Patient Focused Drug Development (PFDD) collaboration to solicit and integrate perspectives of people with relapsing multiple sclerosis into a drug development program. The collaboration centered on the formation of a standing council which worked with EMD Serono over the course of a year.



Project phases included initial project definition and scoping; recruitment of 8 council members; council engagement; and, project review and debrief. Various channels were used including face-to-face workshops, teleconferences, structured surveys, and review of study plans and reports.

THE TOPICS ADDRESSED BY THE PFDD COUNCIL WERE:

Design & integration of endpoints in trials (i.e., Patient-Reported Outcomes)
Selection of domains most important to patients, assessment schedule

Development of MS PRO instruments
Input into research process & results interpretation

Establishing criteria for interpreting PRO endpoints
Meaningful within-patient score change criteria

Identification of disease-burden evidence gaps
Conceptualize/prioritize research questions important to patients

iConquerMS is ideally positioned to engage in PFDD because of our:

- **Access to a large and diverse cohort of people** highly motivated and interested in providing in-depth feedback
- **Ability to quickly assemble and engage** people affected by MS
- **Expertise** in patient-reported outcomes, harnessing patient insights and perspectives, and project design and execution

With our experience and the power of the iConquerMS research network, we can ensure that your effort to understand patient perspectives provides the insights you need.



THE VALUE OF ENGAGING A STANDING COUNCIL

Working with a group of participants over time creates the level of trust and mutual understanding necessary to elicit meaningful and actionable feedback. It also allows participants to build on past discussions creating depth and connection between topic areas.

RESULTS AND SUCCESS FACTORS

Successful PFDD collaborations require beginning with the end in mind; by defining clear objectives and priorities as well as planning how insights will be integrated within development programs.

PFDD collaboration requires a paradigm shift in patient engagement during drug development from a transactional engagement model towards a more transformative patient partnership approach.

To discuss opportunities for future collaboration, please reach out to **Sara Loud**,
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To learn more about the iConquerMS people-powered research network, please
visit www.iconquerms.org