

CTTI RECOMMENDATIONS: PATIENT GROUPS AND CLINICAL TRIALS

With the increasing commitment to Patient-Focused Drug Development and patient engagement in translational research, a significant opportunity exists to improve the clinical trials enterprise and enhance participation by patient groups. After decades of emphasis on mechanisms to speed bench-to-bedside development, patient engagement in clinical research should be considered an effort to extend the benefits of incorporating patient insight, experiences, desires, and preferences from bench to bedside and back.

The following CTTI recommendations are best practices for effective engagement with patient groups (PGs)¹ around clinical trials. These were developed as a result of a qualitative survey and semi-structured interviews involving stakeholders from industry sponsors, academic investigators, and PGs. The recommendations also incorporate feedback and experience from participants at the 2015 Expert Meeting representing a diverse group of stakeholders including PGs, industry sponsors, academic investigators, and government and regulatory agencies.

I. Recommendations for All Stakeholders

- Engage the patients' "voice" by establishing partnerships from the beginning of the R&D program to improve trial design and execution.
- From the start, clearly define the expectations, roles, and responsibilities of all partners, including the resources being committed, data being shared, and objectives of the program.
- Build the trust required for successful partnerships by being transparent and trustworthy, following through on commitments, and honoring confidentiality.
- Involve the expertise of multiple partners for a broader perspective to mitigate risk and enrich pipeline development.
- Manage real or perceived conflicts of interest by establishing policies that require full disclosure, transparency, and accountability.

II. Recommendations for Research Sponsors—Industry and Academia

- Integrate into your ongoing research and portfolio planning an assessment of PG expertise, assets, and value to your program.
- Match PG expertise and assets to the specific needs and phases of your R&D program.
- Ensure that PGs are essential partners throughout the R&D process and not token voices.
- For consistency, establish guiding principles and clear lines of communication to facilitate a fit-for-purpose process for collaborating with PGs.
- Measure the impact of PG engagement.
- Establish ongoing relationships with PGs and communicate openly with them on a regular basis.

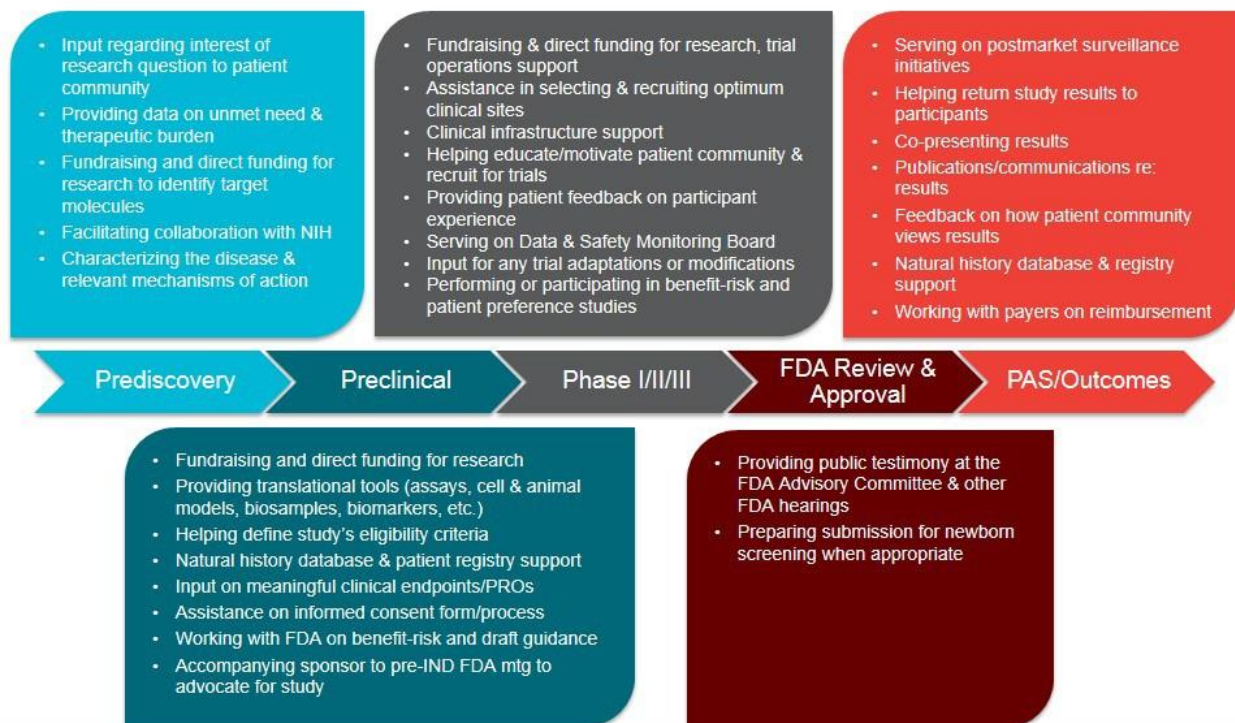
¹ Throughout this CTTI project, the term PG encompasses patient advocacy organizations, disease advocacy organizations, voluntary health agencies, nonprofit research foundations, and public health organizations. PG is not meant to refer to individual patients or advocates.

III. Recommendations for Patient Groups

- Proactively identify, engage, and bring the patients' voice to stakeholders relevant to your R&D interests.
- Promote your value as an essential partner by maximizing and articulating your expertise and assets.
- Deliver your expertise and assets to sponsors throughout the entire R&D process.
- Select sponsors who have a product or program with significant promise for your constituents and who are committed to engaging in a meaningful way.
- Manage real or perceived conflicts of interest by establishing policies that require full disclosure, transparency, and accountability.

PG Engagement Across the Research & Development Continuum

➤ From Bench to Bedside and Back



*Adapted from Parkinson's Disease Foundation materials for CTTI's Patient Groups & Clinical Trials Project

- These recommendations are based on results from CTTI's [Patient Groups & Clinical Trials Project](#).
- CTTI's [Executive Committee](#) approved the recommendations.
- Released in October 2015