Suggestions for Effective Collaboration Among Patient Advocacy Groups & Pharma

Value of Patient Advocacy Group/Pharma Collaboration throughout Development

Research

Pre-Discovery

- Learn about patients' lived experience, diagnostic journey & burden of disease
- Identify patient/care partner barriers & unmet needs
- Understand access and experience with current treatments
- Define research questions and outcomes relevant and important to patients
- Define meaningful outcomes to the patient and health care community
- Evaluate possibility of conducting a clinical trial in geographical region(s)
- Pharma Contacts: Medical Affairs & Clinical Operations Study Lead
- Patient Advocacy Group Contact: Leadership

Study Co-Design

- Create research objectives based on prioritized unmet needs
- Determine meaningful endpoints and patient-reported outcomes
- Design patient-friendly informed consent
- Define acceptable benefit-risk tradeoffs
- Identify and co-design recruitment, retention, and patient engagement strategies
- Incorporate what was learned in pre-discovery around pressing challenges (i.e., quality of life and access issues)
- Strategize efforts to disseminate study findings – focused both in scientific and community avenues
- Pharma Contacts: Medical Affairs & Clinical Operations Study Lead
- Patient Advocacy Group Contact: Leadership

Development

Pre-Clinical

- Provide spotlight on barriers to recruitment and participation
- Organize clinical research education and awareness-building campaigns
- Plan for drug administration and care delivery
- Pharma Contacts: Medical Affairs & Clinical Operations Study Lead
- Patient Advocacy Group Contact: Leadership

Clinical

- For each study phase, reference co-developed research strategy from Study Co-Design step when writing study concept and outline. Ensure study designs incorporate the meaningful endpoints that were discussed in earlier planning stages
- Walk through proposed study procedures and drug administration with patients and health care providers to determine feasibility and level of comfort
- Co-create patient-friendly educational materials
- Work with trusted channels to raise awareness about clinical trials and support diverse patient participation
- Select/recruit trial sites
- Ask for patient perspective and overall satisfaction with clinical trial experience
- Pharma Contacts: Medical Affairs & Clinical Operations Study Lead
- Patient Advocacy Group Contact: Leadership

Regulatory

- Pharma to ensure patient input has been included in race & ethnicity diversity plans and in overall development program
- Co-develop drug label language
- Collaborate on FDA Patient Listening Sessions
- Patient preference studies
- Pharma Contacts: Medical Affairs
- Patient Advocacy Group Contact: Leadership

Commercialization

Approval

- Co-design patient education
- Continue to break down barriers and misconceptions about research through multi-stakeholder awareness-building campaigns
- Translate scientific research into publications, manuscripts and co-develop plain language versions
- Pharma Contacts: Medical Affairs & Public Affairs/ Patient Advocacy
- Patient Advocacy Group Contact: Leadership

Post-Approval

- Co-create and disseminate study results/plain language summaries
- Collect real world evidence and identify unmet needs
- Create access strategies
- Continue to address unmet needs and challenges
- Collaborate on a long-term discovery and development strategy to improve treatment options and access
- Pharma Contacts: Medical Affairs, Public Affairs/Patient Advocacy, Commercial Marketing
- Patient Advocacy Group Contact: Leadership