



Suggestions for Effective Collaboration Among Patient Advocacy Groups and Biopharmaceutical Companies (Industry)

Value of Patient Advocacy Group/Industry Collaboration throughout Development

Research Development Commercialization

| Research | | Development | | | Commercialization | |
|--|---|--|--|--|---|--|
| Pre-Discovery | Study Co-Design | Pre-Clinical | Clinical | Regulatory | Approval | Post-Approval |
| <ul style="list-style-type: none"> 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) <p><i>Pharma Contacts: Medical Affairs & Clinical Operations Study Lead</i></p> <p><i>Patient Advocacy Group Contact: Leadership</i></p> | <ul style="list-style-type: none"> 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 <p><i>Pharma Contacts: Medical Affairs & Clinical Operations Study Lead</i></p> <p><i>Patient Advocacy Group Contact: Leadership</i></p> | <ul style="list-style-type: none"> Provide spotlight on barriers to recruitment and participation Organize clinical research education and awareness-building campaigns Plan for drug administration and care delivery <p><i>Pharma Contacts: Medical Affairs & Clinical Operations Study Lead</i></p> <p><i>Patient Advocacy Group Contact: Leadership</i></p> | <ul style="list-style-type: none"> 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 <p><i>Pharma Contacts: Medical Affairs & Clinical Operations Study Lead</i></p> <p><i>Patient Advocacy Group Contact: Leadership</i></p> | <ul style="list-style-type: none"> 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 <p><i>Pharma Contacts: Medical Affairs</i></p> <p><i>Patient Advocacy Group Contact: Leadership</i></p> | <ul style="list-style-type: none"> 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 <p><i>Pharma Contacts: Medical Affairs & Public Affairs/ Patient Advocacy</i></p> <p><i>Patient Advocacy Group Contact: Leadership</i></p> | <ul style="list-style-type: none"> 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 <p><i>Pharma Contacts: Medical Affairs, Public Affairs/Patient Advocacy, Commercial Marketing</i></p> <p><i>Patient Advocacy Group Contact: Leadership</i></p> |