

TOOL

Considerations for Implementing Expert Patient or Patient Group Input

Recommended Contributors :

- Program leaders
- Patient liaisons
- Sponsor representatives
- Clinical investigators
- Research team
- Trial site staff
- IRB
- Expert patient(s)/Patient Group representatives

Communicating with Patients throughout the Program

- How does the phase of drug/biologic/device development process covered by this program impact communication with patients?
- What translation and/or cultural adaptations are necessary?
- What language will be used to communicate with and about the patients?
 - Are research questions and procedures culturally sensitive and appropriate?
 - How will patients be referred to (e.g. “subject” vs. “patient” vs. “participant”)?
- What is the communication plan for patients throughout the program?
 - Message Content
 - Audience
 - Messenger
 - Delivery mechanisms
 - Timing
 - Feedback mechanisms
- What feedback mechanisms and processes are in place for the patients to comment on sites, investigators, and the study participant experience?
- What role will social media play in the communications?
 - How is social media defined?
 - How can social media be utilized (e.g. for trial recruitment, to educate patients)?
 - What restrictions should there be, if any? Why?
 - How will those limits be communicated and enforced?

- What methods will be used to interact with patients and other stakeholders?
 - Focus groups
 - Interviews
 - Surveys
 - Inclusion in advisory councils
 - Inclusion in meetings with researchers
- What data/information can and will be shared with the patients and when?
 - Aggregate (de-identified)
 - Patient-specific
- What are the restrictions (proprietary and regulatory) constraining the release of data?
- How do we ensure that this information is shared in patient-friendly language?
How will that be determined/monitored?

Additional resources

Communication Handbook for Clinical Trials.

Guidance for Biomedical HIV Prevention Trials, p 37-38: “Stakeholder education plan.”

Source: DIA (2017): Considerations Guide to Implementing Patient-Centric Initiatives in Health Care Product Development.