Sponsor-Patient Interactions During Drug Development: Good Practice Insights on Patient Engagement

Introduction

Patient-focused drug development (PFDD) recognizes the value of engaging patients throughout drug development. Life-science companies, known commonly as sponsors, aim to engage patients so that they can develop medicines that align with patient needs, resulting in better patient outcomes. However, many sponsors struggle with engaging patients in all but the most basic ways because of regulatory and legal uncertainty and lack of clear guard rails on non-promotional interactions with patients. To discuss issues associated with sponsor-patient interactions in drug development and identify good practices for those interactions, the National Health Council (NHC), Genetic Alliance (GA), and the Food and Drug Law Institute (FDLI) brought together 90 drug-development stakeholders from patient advocacy groups, life-science companies, professional associations, industry trade associations, academic institutions, nonprofit organizations and institutes, and government agencies for a one-day public meeting on June 15, 2017.

The meeting had three main objectives:
1. Explore multi-stakeholder views on how sponsors and patients can interact as part of patient engagement during drug development.
2. Begin to establish consensus on good practices for sponsor-patient interactions during drug development.
3. Offer examples of good practices to stimulate sponsor implementation and innovation, and begin a dialogue on what might become best practices in the future.

The meeting opened with a multi-stakeholder panel discussing why furthering the dialogue on sponsor-patient interactions was timely and needed. The remainder of the day was divided into breakout sessions with 10 groups of approximately nine participants each. Each breakout group was balanced as evenly as possible across the different stakeholders in attendance with the proportion of patient advocates in the majority. During each breakout session, half of the groups addressed one topic, while the other half addressed a second topic. Sessions focused on the following topics:

Breakout Session #1:
- WHY: Defining the Purpose of Interaction
- WHEN: Timing of Interaction

Breakout Session #2
- WHO: Establishing Who Interacts
- WHAT: Defining Data on Interactions To Be Collected

Breakout Session #3
- HOW: Structure of the Interaction
- WHERE: Where Interaction Takes Place

Summary of Findings

The consensus good practices and examples of good and poor practices learned from the day can:
- help sponsors structure meaningful sponsor-patient interactions as part of patient engagement in drug development while minimizing fears of regulatory uncertainty,
- assist sponsors and others in establishing benchmarks to be refined, and
- guide sponsors’ interactions with patients in order to advance patient engagement and innovations in patient engagement through the full drug-development lifecycle.

Outlook Moving Forward

Organizations need to have clear processes and protocols so their engagement actions will not be questioned or misinterpreted. While more work is needed to continue to advance this space, the good practices learned and outlined in “the table/infographic” are a start to helping drive this evolution and meet the good practices identified during the meeting.
<table>
<thead>
<tr>
<th>WHAT: The Relationship</th>
<th>WHY: Purpose/Objective</th>
<th>WHEN: The Timing</th>
<th>WHO: The Participants</th>
<th>HOW: The Structure</th>
<th>WHERE: The Location</th>
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<td>Establish observable, open, documented, transparent partnership(s) for the purposes of interaction. Interactions between sponsors and patients should reflect a win-win balance between partners.</td>
<td>Clearly define and share the specific purpose of any sponsor-patient interaction.</td>
<td>Interactions can and should take place prior to, in parallel with, and across all stages of a product's life cycle.</td>
<td>Choose appropriate participants from all partner organizations (patient community, sponsors, etc.), ideally through procedures co-created and standardized prior to the interaction.</td>
<td>Standardize protocols, forms, and procedures to guide sponsor-patient interactions.</td>
<td>The location chosen should be “neutral” so that patients do not feel unduly influenced or pressured.</td>
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**Examples of Good and Poor Practices**

**Good Practice:**
The sponsor has established long-term partnerships with individual patients and patient groups that include co-development of materials and other projects.

**Poor Practice:**
Interactions are ad hoc and created “on the fly” without continuity.

**Good Practice:**
The sponsor defines the purpose as: “Learn patient opinions on a draft clinical trial protocol to minimize trial burden on patients.”

**Poor Practice:**
The sponsor offers the purpose only when asked, but otherwise does not make the purpose transparent.

**Good Practice:**
The sponsor holds focus groups for the specific purpose of gathering patient input on how exiting therapies can be improved, which includes information on one of its approved products five years after its approval. The discussion is not focused on questions about that product, the discussion guide has been co-developed with a patient-group partner and clinical experts, and the focus groups are run by a third-party facilitator.

**Poor Practice:**
The sponsor makes product-specific outreach to patients at a time close to approval, but with no specific objective for the interaction.

**Good Practice:**
The sponsor includes a ratio of patient-to-staff participation that ensures parity and balance.

**Poor Practice:**
The sponsor invites patients with early-stage disease to talk about the preferences of the entire patient community (including those with late-stage disease).

**Great Practice:**
The sponsor routinely uses policies and procedures co-created with patients and updates them as new information and experiences become available.

**Poor Practice:**
The sponsor creates policies, procedures, forms, and materials without patient input on an as-needed basis with lack of consistency.

**Good Practice:**
The sponsor consistently follows co-created procedures and policies to choose a venue and mechanism to engage (e.g., in person, by phone, etc.).

**Poor Practice:**
The sponsor only hosts patient interactions at a company location that is not agreed-upon by the patient.

Sponsor does not take into account any access issues that may specific to the patient group (e.g., wheel chair accessibility, location of restrooms, etc.).