How Advocates Support the Clinical Trial Lifecycle

Clinical Trial Development Process

1. **Define**
   - Analyze portfolio
   - Create portfolio strategy
   - Propose concept

2. **Review**
   - Shape and refine concept
   - Prioritize concept
   - Evaluate proposal

3. **Design**
   - Refine protocol
   - Refine informed consent
   - Plan accrual & operations

4. **Implement**
   - Activate trial & execute accrual plan
   - Execute protocol operations
   - Conduct data & safety monitoring
   - Modify protocol as needed

5. **Share**
   - Analyze data
   - Publish results
   - Develop outreach plan
   - Disseminate findings

Advocate’s Role

- Provide feedback that frames trial questions important to patients
- Provide support for balanced trial portfolios across treatment, prevention, and control, where science supports research
- Review trial inclusion and exclusion criteria for maximal patient participation where safe and possible
- Collaborate on protocol development
- Provide feedback on communications and patient-friendly materials
- Create awareness around need for patient accrual
- Provide input on trial accrual strategies and offer support
- Share study results with appropriate patient and advocacy groups through interviews, presentation, publication, and social media channels
### Calibration Assessment for Patient Advocate Engagement

**Advocate:**

**Committee/Trial:**

**Committee/Study Chair:**

**Date:**

**Calibration Date:**

<table>
<thead>
<tr>
<th>Level Of Patient Advocate Engagement</th>
<th>Study/Committee Chair Assessment</th>
<th>Patient Advocate Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td><img src="none.png" alt="Empty" /></td>
<td><img src="none.png" alt="Empty" /></td>
</tr>
<tr>
<td>Some</td>
<td><img src="some.png" alt="Empty" /></td>
<td><img src="some.png" alt="Empty" /></td>
</tr>
<tr>
<td>Fully</td>
<td><img src="fully.png" alt="Empty" /></td>
<td><img src="fully.png" alt="Empty" /></td>
</tr>
</tbody>
</table>

#### Define
- Feedback on trial questions and importance, shape concept
- Support balance of trial portfolio

#### Review
- Assess accrual feasibility
- Evaluate competing treatments and trials
- Review inclusion and exclusion criteria
- Assess benefits and risks, including burden
- Develop and present formal reviews (Committee, Sponsor, Executive Review)

#### Design
- Collaborate on protocol
- Collaborate on consent form
- Collaborate and suggest patient collateral
- Support accrual planning

#### Implement
- Guide and support accrual and accrual strategies

#### Share
- Prepare and share study results

#### Other

---

**Study/Committee Chair Assessment**

**Patient Advocate Assessment**