Patient Involvement in the Design of Clinical Trials

Center for Devices and Radiological Health
PEAC Meeting
12 October 2017

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Global Medicines Development
“Patient-Centered” definition

Putting the patient first is an open and sustained engagement of the patient to respectfully and compassionately achieve the best possible experience and outcome for that person and their family.
Patient-Centered Research

Why
Recruitment, Retention and Compliance

When
Prior, During and Post Study

How
Partnering with Patients
Patient-Centered Research Framework at AstraZeneca

I. STUDY PLANNING

- Keep patients informed on access & future research opportunity

II. STUDY DELIVERY

- Patient Insight into Protocol Development
  - Study Visit Simulation
  - Advisory Board
  - Patient Expert Input
  - Online patient community research

III. POST STUDY

- Patient Engagement Within the Study

- Patient Engagement in Clinical Trial score

- TRACE

- Thank You's
- Clinical Trial Summaries
- Early Access Programs
- Pooling into online patient research communities

- Exit interviews
- Thank You’s
- Clinical Trial Summaries
- Early Access Programs
- Pooling into online patient research communities
Study Planning: Online Patient Community Research Feedback
Insight from online health communities shapes clinical studies

Through AZ’s collaboration with PatientsLikeMe we can ...

See patient-generated health data …
- Impact of symptoms
- Outcomes that matter to patients
- How patients describe their disease experience and goals

Survey patient views on study design …
- Biggest barriers to participation?
- What might impact retention?
- What would make a difference?

… patients have shared their views in …

2000
12

… studies in Phases II to IV

Resulting in …
- Optimised study designs
- Clearer study materials
- Improved study experience for patients
Study Planning:
Study Visit Simulation
“Subjects no more”

Our simulation explored the contribution patients can make to study design*

We wanted high-quality patient feedback before finalizing the protocol

Our hypothesis: engaged patients will improve recruitment, retention & compliance

“Subjects no more”

<table>
<thead>
<tr>
<th>Site Characteristic</th>
<th>Atlanta Study</th>
<th>Altoona Study</th>
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<tbody>
<tr>
<td>Practice type</td>
<td>Grady Hospital Emory Investigator</td>
<td>Private Practice Rheumatology</td>
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<tr>
<td>Lupus Clinical trials completed</td>
<td>&gt;25</td>
<td>&gt;34</td>
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<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>N=6</th>
<th>N=12</th>
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<tbody>
<tr>
<td>N (%)</td>
<td>N (%)</td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>6 (100)</td>
<td>-</td>
</tr>
<tr>
<td>White</td>
<td>-</td>
<td>12 (100)</td>
</tr>
<tr>
<td>Female</td>
<td>5 (83)</td>
<td>12 (100)</td>
</tr>
<tr>
<td>Age range, years</td>
<td>27–60</td>
<td>32–75</td>
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* Simulating clinical trial visits yields patient insights into study design and recruitment, Lim SS, Kivitz AJ, McKinnell D, Pierson ME, O’Brien FS *Patient Preference and Adherence* 2017, 11:1295-1307
Clinical Trial Simulation Approach

Mock clinical trial environment created at a clinical site familiar with lupus clinical trial process

Patients representative of lupus clinical trial population recruited for simulation participation

Patients signed a participation agreement form and consented to interviews with simulation team

Simulation “playbooks” describing procedures and activities provided to site

Informed consent process simulated

Screening visit and Visit-1 study procedures simulated
Clinical Trial Simulation: Analytical Methodology

Analytical approach for simulation based on patient-centric frameworks developed by the Picker Institute and The Institute of Medicine.

8 Dimensions of Patient-Centered Care
- Physical comfort
- Information, communication, and education
- Emotional support
- Continuity and transition

4 Domains of Clinical Trial Patient-Centricity
- Coordination of care
- Access to care
- Responsiveness to needs, values, and preferences
- Family and friends

1. Information, Communication, and Education

Patients can be overwhelmed by the amount and complexity of information provided during the conduct of the clinical study.

Patients value help and support to discuss their conditions and options with family and friends.

Study booklet/website (TRACE) was received positively.

Study sponsors should engage the lupus community through lupus community leaders.
2. Responsiveness to Needs

- Strong online and community support is important to patients
- Extent of disruption to patient lives due to study participation is a major factor for potential study withdrawal
- Limited work schedule and limited child care flexibility, which lead to financial burden, are significant concerns
- Increased heat and humidity during summer months are issues for retention and compliance
Maintaining patient comfort during study visits is important to the patients’ experience of study participation.

Staff members recommended condensed and/or electronic versions of informed consent form in text or audio format.

Infusion visits require coordination between relevant parties, consider shortening post-infusion observation times.

Duration of study visits (2+ hours) is a patient concern and makes them sensitive to wait time between procedures.
Elements Important to Patients in the Four Dimensions of Patient-Centric Care

4. Continuity and Transition

Not all patients understood commitment degree, despite completing consent form.

Patients want feedback on the assessments they undergo in the course of the study and how they relate to their general health status and progression of their disease status.

Patients are motivated by being part of developing a possible cure.

Patients see the possibility of an open-label extension as a potential benefit.
Study Delivery:
Utilizing the Patient Booklet/Website (TRACE)
TRACE is an online system that transforms study materials into patient-friendly content.

**Value of TRACE**
- Improve clinical trial experience
- Speed up recruitment
- Increase retention

**Study teams**
- Informed Consent Form
- Study Protocol
- Supporting Documents

**Generic Content**

**Content Creation Platform**

**Personalised Content**
- Patient Website
- Patient Booklet
- Patient Retention App

**Patients**

**Science Speak**

**Everyday Language**

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Start with Patient Insights

There are many ways of generating patient insight including patient advisory boards, patient community forums and patient interviews.

Use Insights to Co-Create Solutions with Patients

Clinical study performance can be improved by co-creating study protocols with patients, making studies more attractive to patients and their families. As a result, trials are likely to accelerate recruitment and improve patient retention and protocol compliance.

Measure Meaningful Impact

Measuring the impact of our work with patients will help us to quickly identify what solutions work, scale up those solutions that demonstrate positive impact, and disinvest in programs that fail to demonstrate value to patients.

… Putting patients first means delivering for patients with patients