Patient-Centered Clinical Trials

Perfecting the Clinical Trial Optimization (CTO) framework

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Consistent Patient-Centered Research Framework in Clinical Ops

**STUDY PLANNING**

- **Patient Insight into Protocol Development**
  - On-site Study Visit Simulation
  - Patient Preference and Adherence 2017, 11:1295-1307
  - Advisory Boards
  - Patient Partnership Program
  - Online patient community

**OPEN & SUSTAINED**

- **RESPECT & COMPASSION**
- **EXPERIENCE & OUTCOME**

**STUDY DELIVERY**

- **Patient Engagement Within Study**
  - Engagement apps (retention or adherence)
  - TRACE trial guide
  - Trial Experience Surveys

**POST STUDY**

- **Inform patients on access & future research opportunities**
- Exit interviews
- Trial Result Summaries
- Thank you notes
- Early Access Programs

**Ultimate goals of CTOs**

- Meet protocol approval and study initiation targets
- No amendment to protocol post-approval
- Accelerate recruitment
- Improve patient retention and protocol compliance

On-site Study Simulations: lupus Ph2 and Ph3

Methodology
- 18 patients (6 African American, 12 Caucasian) with dx SLE or LN
- Two study sites (Atlanta, GA and Altoona, PA)
- Simulate informed consent procedure, a mock screening visit, a mock dosing visit, and a debriefing period for patients and staff.
- Patients and staff interviewed to obtain sentiments and perceptions related to the simulated visits.

Findings
- Patients desired:
  - Simple background material (hard copy and online)
  - Knowledgeable and trusted staff
  - Personal results available after study
  - Comfortable settings
  - Value patient’s time and greater scheduling flexibility
  - Transportation and child care help during the visits
  - Confidentiality of patient data

Value and challenges
- Using these results, improvements study procedures to increase retention, recruitment, and compliance for clinical trials
- **However**, the on-site simulation was very expensive and time consuming for professional staff, patients, and AZ … with few recommendations requiring an “on-site” study simulation.
<table>
<thead>
<tr>
<th><strong>ONLINE PATIENT COMMUNITY</strong></th>
<th><strong>PATIENT PARTNERS or ADVISORS</strong></th>
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<tbody>
<tr>
<td><strong>Phase3 study for Patients with severe Nasal Polyposis</strong></td>
<td><strong>Phase 2b Type-2 Diabetes Mellitus</strong></td>
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<tr>
<td><strong>Simplify protocol design:</strong></td>
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<tr>
<td>-Simplify the visit procedures and PROs</td>
<td>-Home delivery of medication for the subjects</td>
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<td>-Source medication centrally so patients receive it at the site</td>
<td>❖-Remove certain PRO’s and reduce frequency of admin</td>
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<td><strong>Enhance site conduct of study procedures:</strong></td>
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<td>-Study portal for sharing study documents and information</td>
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<td>-Difficult procedures only in experienced sites and read centrally</td>
<td>-Develop a visit guide, visit calculator</td>
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<td>-All ePRO questionnaires to be done at home by patient</td>
<td><strong>Enhance clarity of study documents for patients:</strong></td>
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<tr>
<td>-Simplification of Informed Consent Form</td>
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<td>-Implement information booklet and website</td>
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<td>-Capture correct symptoms and use laymen terms in diary</td>
<td>-Provide patients with a simple study app</td>
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<td><strong>Improve study experience for patients:</strong></td>
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<td>-Patient support in travel arrangements and costs</td>
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<td>-Minimize number of site visits</td>
<td>-Provide trial experience survey pre-, during and post-trial</td>
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<td>-Lay Language summary at the end of the study</td>
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Measuring patient sentiment
Patient experience in a clinical trial impacts four generalized dimensions

**Empowerment through information**
Patients feel better when they have access to understandable, meaningful and relevant information;
• Understand the study
• Exploit the opportunity to learn about disease status
• Disease management
• Social empowerment

**Quality of care, medical and extra-medical**
How are the vulnerabilities of patients being addressed?
• Transportation / physical access
• Scheduling / availability
• Access to physician
• Waiting times
• Visit efficiency

**Patients as individuals**
Are the needs, values and preferences of the patient taken into account?
• Physical comfort
• Emotional support
• Logistics
• Responsiveness

**Entering and leaving a study**
Knowing what will be different during the study and afterwards;
• Follow-up and aftercare
• Transparency on outcomes
• Personal progress during study

**Information, communication, and education**

**Responsiveness to needs**

**Access to care and coordination of care**

**Continuity and transition**

Based on Picker and the IoM frameworks for measuring patient centered care