Meaningful Approaches to Patient Engagement:

Adding the Right Tools to Your Toolbox

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Jill McNair, Senior Director, Patient Engagement
Welcome!

- Introduction
- Trends in patient engagement
- Importance of engaging patients as partners
- Maintaining patient engagement long term
- Driving culture change

**Patient Engagement Tools:**

- Patient Advisory Boards
- Patient Clinical Trial Journey Workshops
- Communicating Trial Results Program

- Q&A
About CISCRP

• 15 year-old Boston-based independent nonprofit organization

MISSION:

• To educate, inform and engage patients and the public

• Promote greater awareness, understanding of and trust in clinical research participation and its role in public health

• Provide resources and services for the research community to better partner with study volunteers, patients and the public
Trends in Patient Engagement
### Increasing Protocol Complexity

**Typical Phase III Pivotal Trial (means)**

<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Total Number of <strong>Endpoints</strong></td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td>Total Primary and Key Secondary Endpoints</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Total Number of <strong>Eligibility Criteria</strong></td>
<td>31</td>
<td>50</td>
</tr>
<tr>
<td>Total Number of <strong>Procedures</strong></td>
<td>110</td>
<td>187</td>
</tr>
<tr>
<td>Total Number of Planned Volunteer <strong>Visits</strong></td>
<td>12</td>
<td>15</td>
</tr>
<tr>
<td><strong>Number of Investigative Sites</strong></td>
<td>40</td>
<td>65</td>
</tr>
<tr>
<td><strong>Number of Countries</strong></td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td><strong>Number of Patients</strong> Randomized</td>
<td>729</td>
<td>597</td>
</tr>
<tr>
<td><strong>Total Data Points Collected</strong></td>
<td>494,236</td>
<td>929,203</td>
</tr>
<tr>
<td>Proportion of Data ‘Non-Core’</td>
<td>18%</td>
<td>32%</td>
</tr>
</tbody>
</table>

*Source: Tufts CSDD; *DRI; **Medidata Solutions*
Enrollment and Retention Challenges

50% fail to enroll a single patient or under enroll

average drop-out rate of 30% across clinical trials

Source: Forte Research, 2016
Source: Tufts CSDD 2017
# The Burden of Participation

## Top Dislikes After Reviewing ICF

<table>
<thead>
<tr>
<th>Reason</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too many visits to study center</td>
<td>20%</td>
</tr>
<tr>
<td>Medical procedures too invasive</td>
<td>19%</td>
</tr>
<tr>
<td>Too many medical procedures</td>
<td>14%</td>
</tr>
<tr>
<td>It was too much of a burden on my family/caregiver</td>
<td>9%</td>
</tr>
</tbody>
</table>

Source: 2017 CISCRP P&I Study, n=337 those chose not to participate after reviewing ICF
## The Burden of Participation

### Top Dislikes During Participation

<table>
<thead>
<tr>
<th>Top Dislikes during Participation</th>
<th>% of Total **</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possibility of getting placebo</td>
<td>24%</td>
</tr>
<tr>
<td>Location of study center</td>
<td>23%</td>
</tr>
<tr>
<td>Study visits too time-consuming</td>
<td>11%</td>
</tr>
<tr>
<td>Side effects of study drug</td>
<td>11%</td>
</tr>
<tr>
<td>Compensation was not enough</td>
<td>9%</td>
</tr>
<tr>
<td>Overall time commitment was too much</td>
<td>8%</td>
</tr>
</tbody>
</table>

*Source: 2017 CISCRP P&I Study, n=2,194 those that participated in a clinical research study*
Adoption & Barriers

Plans to Implement Patient-Centric Initiatives

- No Plans
- Planning
- Piloting
- Broad Implementation

2009 - 2012 - 2015

Source: CenterWatch N= 95 companies
Rationale for Patient Engagement

For engagement activities resulting in avoiding an amendment and/or an improved patient trial experience, the benefits in cost and ENPV vastly outweigh the resources spent on engagement.

Source: CTTI, 2017
And Patients **Want to be Involved!**

<table>
<thead>
<tr>
<th>Activities Interested In (% mentioning)</th>
<th>TOTAL (n=12,427)</th>
<th>Participated (n=2,194)</th>
<th>Never Participated (n=10,233)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Being involved in the design and planning of a clinical research study</td>
<td>30%</td>
<td>35%</td>
<td>28%</td>
</tr>
<tr>
<td>Being part of an advisory committee helping companies plan clinical research activity</td>
<td>30%</td>
<td>37%</td>
<td>28%</td>
</tr>
<tr>
<td>Speaking with other patients considering participation in a clinical research study</td>
<td>37%</td>
<td>41%</td>
<td>36%</td>
</tr>
</tbody>
</table>

*Source: 2017 CISCRP P&I Study*
The Patient Engagement Toolbox
Partnering Opportunities: The Toolbox

- **Study Planning**
  - Unmet patient needs
  - Relevant outcomes
  - Study design
  - Eligibility criteria

- **Study Start Up/Recruitment**
  - Easing participation burden
  - Recruitment & other patient materials
  - Study medication administration
  - Study updates/communication
  - Assessing ongoing study experiences

- **Ongoing Study Conduct**

- **Post-Study**
  - Communicating trial results
  - Assessing study experiences
  - Study volunteer appreciation

- Patient Advisory Boards
- Patient Clinical Trial Journey Workshops
- Study updates

- Communicating trial results
- Thank you cards
- ...and many other tools!
**Tools for Patient Engagement**

**Patient Advisory Boards**

**IDEAL FOR:**
- Understanding challenges of condition and current treatments.
- Assessing perceptions of clinical trials and motivations to participate.
- Determining receptivity to clinical trial designs & related study materials.
- Identifying ways to enhance future study volunteer experiences.

**Patient Journey Workshops**

**IDEAL FOR:**
- Gaining a better understanding of patient clinical trial journeys from start to finish.
- Identifying TA-specific challenges and barriers during the journey.
- Building the ideal journey together with patients and optimizing future study volunteer experiences.
Patient Advisory Boards: Structure and Format

<table>
<thead>
<tr>
<th>FORMAT:</th>
<th>Structured, facilitated in-person meeting <em>(single meeting or ongoing series)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>COMPOSITION:</td>
<td>6 to 8+ Patients / Caregivers</td>
</tr>
<tr>
<td>TIMING/LOCATION:</td>
<td>Half-day meeting in convenient metropolitan location</td>
</tr>
</tbody>
</table>

**DISCUSSION TOPICS:**

- Study design elements
- Informed Consent Form
- Branding and study positioning communication
- Patient recruitment promotional messages; other patient facing study materials
- Clinical trial medicine kit design and administration
- New technology solutions
Clinical Trial Journey Workshops provide deep insights into the patient clinical trial experience and highlight opportunities for improved patient engagement.
Patient Journey Workshops: Structure and Format

**FORMAT:**  Structured, facilitated in-person meeting *(add-on to Patient Advisory Board or stand-alone)*

**COMPOSITION:**  6 to 8+ Patients / Caregivers

**TIMING/LOCATION:**  Half-day meeting in convenient metropolitan location

**DISCUSSION TOPICS:**
- Learning about clinical trial
- Informed Consent process
- Screening Visit
- Treatment Period
- Study follow-up
PATIENT PROFILE

Custom patient profile to help team connect with patient and better understand needs

ACTUAL vs. IDEAL

Patient’s ‘actual’ clinical trial experience vs. desired ‘ideal’ experience to identify challenges and build solutions
**KEY INSIGHTS, CONSIDERATIONS**

*Key insights highlight opportunity areas:*

- Motivators for participation
- Enrollment barriers
- Common communication channels
- Trusted sources of information
- Desired clinical trial information
- *And more....*
## Sampling of Patient Recommendations

### Protocols
- Frequency of Testing
  - Increase in monitoring assessments for aggressive condition
  - Decrease in painful diagnostic exams
- Schedule Burden
  - Home Visits
- Critical study-specific information to provide prospective study volunteers

### Patient Materials
- Culturally appropriate wording & color schemes
- Relatable images for condition
- Addition of tables and search features
- Clarification of patient instructions
- Preference of styles and formats
- Preference for distribution of information
Maintaining Patient Engagement
Patient Engagement – After Participation

Information Most Interested In Receiving After Participating in a Clinical Trial

- My individual study results (i.e. procedures and test results): 73%
- A summary of the study results: 72%
- Whether I received the study drug or placebo (sugar pill/inactive substance): 59%
- Drug approval status by the regulatory agency in your country: 49%
- The brand name for the study drug: 46%
- Information about upcoming clinical research studies: 35%
- Information about scientific publications: 25%
- Other: 2%

Source: 2017 CISCRP P&I Study, n=12,427
Patient Engagement – After Participation

Importance of Receiving Trial Results Summaries

- Very important: 62%
- Somewhat important: 29%
- Not very important: 6%
- Not at all important: 3%

91% report somewhat or very important

Source: 2017 CISCRP P&I Study, n=12,427
Did you receive any reports or updates on the results of the study once you finished the clinical research study?

I don't remember

17%

Yes

30%

No

53%

<table>
<thead>
<tr>
<th></th>
<th>EU</th>
<th>NA</th>
<th>SA</th>
<th>APAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>% reporting ‘no’</td>
<td>51%</td>
<td>59%</td>
<td>25%</td>
<td>42%</td>
</tr>
</tbody>
</table>

Compares to:

2011: 53%
2015: 51%

Source: CISCRP P&I 2017; n= 2,194 Participated
Unmet Need

72% want a Summary

91% think it’s really important

53% haven’t received one

Missed Patient Engagement Opportunity

Source: 2017 CISCRP P&I Study, n=12,427
Lay Summaries: 5 Main Goals

1. Meet participant expectations
2. Demonstrate appreciation
3. Reinforce meaningful experience
4. Build trust and research literacy
5. Improve recruitment and retention
Four Point Communication Process

**Informed Consent**

- **Set Expectations**
  - Inform volunteers — they will receive Trial Results Summary (TRS) in plain language

**Last Visit**

- **Thank Volunteers**
  - “Thank You” communication at last visit — explains timing of receipt of TRS

**Post-Trial Outreach**

- **Maintain Connection**
  - Continue engaging patients until the TRS is complete — periodic ongoing communications on expected trial end date

**Trial Results Summary**

- **Report Trial Results**
  - Delivered by investigative sites to study volunteers — print, posted online or both
Frequent Engagement is Key

Thank you cards, frequent communications and Lay Language Summaries **signal** to patients they are valued contributors to the process.

Thank you!
Key Program Attributes

Credible, Trustworthy & Independent

- Independent established, recognized non-profit
- Extensive development & implementation experience with pilot, single-study and portfolio-wide programs
- Ongoing interaction with regulatory & guidance-influencing consortia

Proven & Integrated

- User tested & continuously refined
- Leverage priced to reflect non-profit positioning
- Integrated process minimizing burden for sponsors, CROs, & investigative sites
- Distribution & translation in over 40 countries
Minimizing Operational Burden

The Role of the Sponsor

- Prepares/posts trial results and notifies CISCRP
- Reviews TRS to ensure scientific accuracy
- Fields investigative site follow-up questions
- Posts to EU Portal when available
Every TRS is reviewed by an editorial panel as part of our standard process

- Long standing health literacy best practice
- Ensures TRS is non-promotional & understandable
- NHS/HRA EU Lay Summary Guidance

“Sponsors should consider testing the readability of an initial version of the study results summary with a small number of people who represent the target population. Depending on the nature of the study, this could be patients with a particular disease or it could be members of the public.”
What’s Next?
Driving Culture Change

• Secure senior management support & adopt a patient-centric culture

• Create a function to manage patient engagement (centralized/de-centralized)

• Dedicate a budget to patient engagement activities

• Measure impact of patient engagement activities and disseminate best practices across organization
How to Get Started

1. Schedule informational meeting with CISCRP and your team:
   • Overview of process
   • Review study team objectives and potential timeline
   • Answer questions

2. CISCRP develops and submits proposal to you

3. You review/accept proposal

4. Contracting process

5. Schedule project Kick Off Meeting with CISCRP and your team
Any Questions?

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THANK YOU!