Recruiting and Retention (R&R) for Human Subjects Research: Part 1 – Inventory and Open Discussion

Ariana Winder, CCRP
Penn State CTSI
Bench to Bedside and Beyond (B3) Seminar Series
October 19, 2017
Objectives

- Industry current conditions
- New recruitment & retention specialist role
- PennState R&R methods inventory
- NCAT accrual & evidence-based metrics
- Challenges/barriers inventory
## Clinical Trial Awareness

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>85%</td>
<td>85% of clinical trials fail to retain enough patients.</td>
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<tr>
<td>80%</td>
<td>80% of clinical trials fail to finish on time.</td>
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<tr>
<td>50%</td>
<td>50% of sites enroll one or no patients in their studies.</td>
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<tr>
<td>40%</td>
<td>40% of the total US pharmaceutical clinical trial budget goes toward recruitment ($1.89B).</td>
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<tr>
<td>30%</td>
<td>30% of patients drop out of a clinical trial.</td>
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</table>


Source: Medrio eClinical Solutions
Why Aren’t Studies Accruing?

- Protocol too complex
- Lack of preparation
- Recruitment materials ≠ patient motivations
- Lack of recruitment innovation
- Lack of R&R tracking

Source: Kristina Lopienski, Forte Research
Why Aren’t Studies Accruing?

Survey Results: Key Findings
Perceived Barriers to Recruitment

- Finding patients who meet eligibility criteria: 81.1%
- Insufficient staff time for recruitment: 67.4%
- Consent forms (e.g., length and complexity): 65.6%
- Protocol requirements (other than recruitment criteria): 60.3%

Rated very/somewhat significant (by more than 50% of respondents)

Elizabeth Mahon et al. Applied Clinical Trials (2015)
How should we plan for dropouts?

100
Patients identified or available

The “Leaky Pipe” Analysis

The “typical” funnel shows the process of patient participation and is used to identify gaps and find where to “fill the funnel” or “manage the leaks.”

Industry benchmark data suggests that on average across all protocol phases and therapeutic areas, you need to identify ~10 patients to randomize 1.

The Leaky Pipe Analysis was contributed by Beth Harper of Clinical Performance Partners, Inc.

7 of 100
Known patients from the top of the funnel complete the trial

18%
Of patients randomized end up dropping out

Source: Forte Research
PennState’s CTSI

Promotes and supports clinical and translational science:

- Connecting PSU to emerging NIH initiatives
- Building connections across PSU for interdisciplinary, translational biomedical/behavioral health research
- Providing consultation, education, funding and infrastructure resources for research

Funded by NIH beginning in 2010
R&R Specialist

**Penn State Study Staff**
- Consult on recruitment strategies, budgeting, regulatory and best practices
- Create and disseminate practical recruitment tools for study staff
- Hold workshops and other recruitment related events

**CTSI and PSCI**
- Benchmark & monitor institutional research portfolio progress
  - NCATS accrual metrics
- Assist with related institutional efforts
- Liaise with Recruitment Innovation Center (RIC) & other industry recruitment stakeholders
- Serve as Trial Innovation Network Team hub liaison & ResearchMatch institutional liaison

**Scientific Community**
CTSA Common Metrics Initiative: Accrual Metrics

% of Participants Accrued =
\[
\frac{\text{# of participants accrued}}{\text{# of participants targeted}} \times 100
\]

% of Recruitment Period to Date =
\[
\frac{\text{# of days elapsed since open to recruitment}}{\text{# of days trial will be open to recruitment}} \times 100
\]

Accrual Ratio =
\[
\frac{\% \text{ of Participant Accrued}}{\% \text{ of Recruitment Period to Date}}
\]

PennState
Clinical and Translational Science Institute
CTSA Common Metrics Initiative: Accrual Metrics

# of participants targeted = 100
# days trial will be open to recruitment = 364
At the halfway point of the recruitment period, the trial has accrued 25 participants

\[
\text{Accrual Ratio} = \frac{25 \ \text{participants}}{100 \ \text{participants}} \times \frac{180 \ \text{days}}{365 \ \text{days}}
\]

Accrual Ratio = 0.51
CTSA Common Metrics Initiative: Accrual Metrics

Accrual Metrics

# accrued
# targeted
# days open
# total days

PennState Recruitment Efforts

Recruitment Specialist Position
R&R Working Group
Literature Review
1:1 Investigator Consultations
Results Dissemination
Stakeholder Liaising
Recruitment Database(s)
PSU Recruitment & Retention Working Group

**Mission**
To enable and facilitate information exchange for the advancement of PSU core values (respect, integrity, teamwork, excellence) for ourselves, our institution, and our community.

These topics may relate to:
- R&R regulatory, methods, or other innovative techniques for study enrollment
- R&R related events hosted internally or externally
- R&R best practices, updates, scientific knowledge and evidence-based strategies
- R&R diversity, engagement, and special considerations for minority populations
- R&R efforts or initiatives in industry, other Recruitment Innovation Centers (RIC)s to watch

**Charter**
The working group will be comprised of Penn State investigators, leadership, staff and other R&R stakeholders (internally or externally) to accomplish our mission through open discussion and interaction at regularly scheduled monthly meetings. The working group will also provide a key resource for interacting with other recruitment groups such as the Trial Innovation Network (TIN) or external Recruitment Innovation Centers.
CTSA Trials Innovation Network provided website that allows users to search PSU studies for opportunities to participate.

8,727 users in 2016
2:1 female: male
ResearchMatch.org: You may be a good match for this study!

A research team with The Ohio State University in Columbus, OH, believes you might be a good match for the following study:

Are you currently trying to get pregnant? Researchers at The Ohio State University are investigating whether a lifestyle change program may help couples get pregnant faster.

You may be eligible for this study if:
• You are a woman between 18-34 who is currently trying to get pregnant.

If you are eligible and enroll in this study, you will:
• Complete a baseline questionnaire online (will take about 20 minutes);
• Agree to be randomly selected (like the flip of a coin) to participate in the lifestyle intervention for 3 months, or to continue the lifestyle that you currently live;
• Provide two saliva samples for measurement of a biomarker. You will be sent the collection materials and a prepaid mailer to return them to investigators;
• Complete a short (5-minute) questionnaire online each week during the 3-month long study; and
• Complete a brief questionnaire at the end of the study about your thoughts and experiences related to the project.

Participants who complete the study will receive a $40 Amazon gift card. All who participate in the study will also be entered into a drawing for a $100 Amazon gift card.

If you are interested in this study and having the research team contact you directly, please select the “Yes, I’m interested” link below. By clicking the “Yes, I’m interested” link, your contact information will be released to the research team. If you select the “No, thanks.” link or do not respond to this study message, your contact information will not be released to the research team.

Yes, I’m Interested!  
No, thanks.
Recruitment Literature Review

• **Background:** CTSI / PSCI

• **Goal:** evidence-based recruitment in a central PA rural population

• **Methods:** rapid scoping review
  - n=830
  - Database searches
  - Covidence data management
  - Manuscript preparation

• **Results dissemination**

Source: Society for Clinical Research Sites (SCRS)
A PennState Front-Door Consent & “Healthy” Volunteers Database

- CLINICAL TRIALS: Inpatient/Outpatient or both?
- IPM: Patients or Patients & Families?

Informed Consent Process
- Where?
- When?
- By Whom?
- How?
- eConsent?

Consent Tracking
- Cerner tracking capabilities?
- Yes/No/Never/Ask Later?

Ariana Winder, CCRP
Research Recruitment, Retention & Optimization Manager
Nurturing Translational Research

Learn more about the CTSI's investment in translational research at Penn State.

More »

Accelerating discoveries to benefit human health

Upcoming Events

- Recruiting and Retention for Human Subjects Research: Part 1 – Inventory and Open Discussion

Recent CTSI News

- Penn State to host annual Appalachian Translational Research Network summit
- 9/28/2017

ENGAGE NEWSLETTER

Get the latest news, events and funding announcements from Penn State University's Clinical and Translational Science Institute.

First Name

Last Name

Email Address

SUBSCRIBE

FOLLOW ON TWITTER

Tweets by @PennStateCTSI

Don't forget to submit your applications for the KL2 Scholars Program - deadline is 9/1
REDCap & REDCap Cloud

- Advanced data management and analytics solutions
- 116 countries
- 469,000+ projects
- 616,000+ users
PSU Survey Research Center

Survey Design
Successful research projects rely on appropriate designs. Whether you are just starting out or getting ready to submit, our staff can help in the design phase of your project.

Telephone Surveys
The SRC Telephone Center uses Computer Assisted Telephone Interviewing (CATI) software and a trained team of interviewers to perform high-quality telephone surveys.

Mail Surveys
The SRC designs, prints, and scans self-administered surveys where the data are collected by the client or where our center administers the entire data collection.

Internet Surveys
Internet surveys are cost effective, and the SRC provides consultation on research strategies, questionnaire design, programming, and data management.

Field Surveys
Successful face-to-face data collection relies on interview and protocol design, staff selection and training, management of scheduling, interviewer accountability, and interview quality.

Focus Groups
The SRC provides a full range of focus group services, including question route development, moderator guidelines, recruiting participants, obtaining the site, moderating the session, note-taking, and transcription.

Multi-Mode Projects
The SRC has experience managing multi-mode projects which include telephone, self-administered and mail, face-to-face, and internet surveys, as well as focus groups.

Dynamic Real-Time Ecological Ambulatory Methodologies
The DREAM program includes a range of methods to assess ongoing behavior, experiences, physiology, and environmental factors in individual’s natural settings.

PennState Clinical and Translational Science Institute
# Enrollment Modeling

Enrollment = 22.3% of clinical development timeline

Table 1. Calculations Summary

<table>
<thead>
<tr>
<th>Calculation</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease Prevalence Rate × City (community) Population = Prevalence per City</td>
<td>71,315</td>
</tr>
<tr>
<td>Prevalence per City × Randomization:Screen Ratio = Potential Candidates per</td>
<td>23,533</td>
</tr>
<tr>
<td>Community</td>
<td></td>
</tr>
<tr>
<td>Potential Candidates per Community ÷ Enrollment Period (months) = Potential</td>
<td>2,615 patients/month</td>
</tr>
<tr>
<td>Number of Potential Subjects/Month × Percentage Likely to Consent = Number</td>
<td></td>
</tr>
<tr>
<td>of Suitable and Willing Subjects/Month</td>
<td>261</td>
</tr>
</tbody>
</table>

Remote Trials

• Place-shifting → Compliance
• Time-shifting* → Monitoring
• Hybrid***

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• E-patient recruitment
• Patient training
• Consent

"telemedicine, clinical trials, enterprise healthcare software, and digital media"
Manual Reviews

- High screen failure rate
- Time and labor intensive
- Costs typically not reimbursed
- Prone to human error
- 80% in free form text
R&R Informatics

• i2b2 is an NIH-funded National Center for Biomedical Computing focused on developing a scalable informatics network that enables use of existing clinical data for research ranging from discovery to targeted therapy/intervention studies that require identifiable cohorts.

• PSU provides training and data access for researchers such as for:
  – Database query
  – With permissions, to obtain contact information for participant recruitment
R&R Informatics

Effect of Diabetes Education

Cohort
Mar 16, 2017 14:36 933,240 / 23

Demographics

933,240 Patients

Criteria Analysis

Arrival Rate

Gender
- Female: 53%
- Male: 47%
- Unknown Gender: 0%

Race
- White: 42%
- Unknown Race: 41%
- Black or African American: 15%
- Asian: 1%
- American Indian or Alaska Native: 0%
- Native Hawaiian or Other Pacific Islander: 0%

Ethnicity
- Unknown Ethnicity: 72%
- Not Hispanic or Latino: 23%
- Hispanic or Latino: 5%
E-Recruitment

- Search Engine Marketing (PPC)
- Search Engine Marketing (SEO)
- Contextual
- Display
- Social
- Video
- Health Networks
- Patient Portals

Source: CISCRP
• “Crowdsourcing”
• “HITs” – Human Intelligence Tasks
• >500,000 registered users
• Online Consent Template
## Cost of E-Recruitment

<table>
<thead>
<tr>
<th></th>
<th>Example 1</th>
<th>Example 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration</strong></td>
<td>3 Months</td>
<td>6 Months</td>
</tr>
<tr>
<td><strong>Condition</strong></td>
<td>Emphysema</td>
<td>Acne</td>
</tr>
<tr>
<td><strong>Platform</strong></td>
<td>Google</td>
<td>Facebook</td>
</tr>
<tr>
<td><strong>Total Spend</strong></td>
<td>$11,018</td>
<td>$6,400</td>
</tr>
<tr>
<td><strong># of Visitors</strong></td>
<td>1,238</td>
<td>4,855</td>
</tr>
<tr>
<td><strong>Avg. Cost Per Click</strong></td>
<td>$8.90</td>
<td>$1.32</td>
</tr>
<tr>
<td><strong># of Referrals</strong></td>
<td>43</td>
<td>28</td>
</tr>
<tr>
<td><strong>Avg. Cost Per Referral</strong></td>
<td>$337</td>
<td>$229</td>
</tr>
<tr>
<td><strong>Avg. Cost Per Enrollment</strong></td>
<td>$5,687</td>
<td></td>
</tr>
</tbody>
</table>
R&R Tracking

Example Output: Not Actual Study Data

Source: MD Connect
Recruitment & Advertising Policies

- **Office for Research Protections**
- **Contact:**
  The 330 Building, Suite 205, University Park, PA 16802
  Phone: 814-865-1775 • Fax: 814-863-8699
  Email: orp@psu.edu
- https://www.research.psu.edu/irb/policies/guideline3
facilitating connections to resources + services that accelerate your research discoveries
Reach out any time!

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