Opportunities for Recruitment & Retention in Clinical Research: The Clinical Research Coordinator Perspective

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Health of Women (HoW) Public Workshop
June 24, 2013
Purpose

- To summarize the barriers to and opportunities for identified by CRCs related recruiting and retaining participants in clinical trials
Clinical Research Coordinator

- “Hands on” research experience
- Responsible for the day to day activities
- Success of the research study
- Duties include
  - Identifying and screening potential participants
  - Participant recruitment
  - Administering informed consent
  - Adverse event reporting
  - Completion of the case report form
  - Obtaining participant follow-up
Methods - Online Questionnaire

- August 17, 2009 - email invitation outlining the project
- August 28, 2009 - follow-up email reminder
- Included link to the questionnaire (28 questions)
- Sent to 8,963 ACRP members
- Survey was open for a two week period, from August 17 – August 31, 2009
Results - Respondents

- 1,024 recipients completed the survey

Role
- 75% - Coordinator
- 9% - Project Management

Work Environment
- 57% - Clinical Study Site
- 19% - Academia
- 9% - Healthcare Associations/Organizations
Results - Respondents

Location

- Midwest: 26%
- Northeast: 21%
- Southeast: 26%
- Southwest: 11%
- West: 13%
- OUS: 4%
Results - Respondents

Experience
- 29% - 13 or more years
- 32% - 8 - 12 years
- 26% - 4 - 7 years
- 13% - 3 years or less

Types of Studies
- 89% - Drug Studies
- 36% - Medical Device Studies
- 23% - Biologic Studies
Results - Respondents

Clinical Area
- 13% - Cardiology
- 11% - Oncology or Hematology
- 7% - Neurology
- 4% - Gastroenterology
- 4% - Endocrinology
- 4% - Psychiatry
- 4% - Pulmonology
- 4% - Pediatrics
Results – Respondents

Study Phase

- 35% - Phase 1
- 86% - Phase 2
- 95% - Phase 3
- 78% - Phase 4
- 43% - Disease, procedure or treatment registries
Recruitment
# Barriers to Recruitment of Subjects

<table>
<thead>
<tr>
<th>Barrier to Recruitment</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finding eligible patients</td>
<td>780 (77%)</td>
</tr>
<tr>
<td>Refusal - time commitment</td>
<td>54 (54%)</td>
</tr>
<tr>
<td>Refusal – concern about risk</td>
<td>475 (47%)</td>
</tr>
<tr>
<td>Refusal – distance/transportation</td>
<td>344 (34%)</td>
</tr>
<tr>
<td>Refusal – want standard care</td>
<td>343 (34%)</td>
</tr>
<tr>
<td>Competing protocols</td>
<td>294 (29%)</td>
</tr>
<tr>
<td>Refusal – protocol concern/consent</td>
<td>158 (16%)</td>
</tr>
<tr>
<td>Refusal – low payment</td>
<td>147 (15%)</td>
</tr>
</tbody>
</table>
## Factors That Ease Recruitment

<table>
<thead>
<tr>
<th>Ease Recruitment</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician mention</td>
<td>772 (76%)</td>
</tr>
<tr>
<td>Benefit to self</td>
<td>770 (76%)</td>
</tr>
<tr>
<td>Monetary incentive</td>
<td>540 (53%)</td>
</tr>
<tr>
<td>Answering questions</td>
<td>460 (45%)</td>
</tr>
<tr>
<td>Benefit to others</td>
<td>425 (42%)</td>
</tr>
<tr>
<td>Detailed consent</td>
<td>219 (21%)</td>
</tr>
</tbody>
</table>
### Demographics that Impact Recruitment

<table>
<thead>
<tr>
<th>Barrier to Recruitment</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comorbidities</td>
<td>596 (59%)</td>
</tr>
<tr>
<td>Distance/transportation</td>
<td>553 (55%)</td>
</tr>
<tr>
<td>Older age</td>
<td>386 (38%)</td>
</tr>
<tr>
<td>Hx of non-compliance</td>
<td>359 (36%)</td>
</tr>
<tr>
<td>Language barriers</td>
<td>313 (31%)</td>
</tr>
<tr>
<td>Lack of social support</td>
<td>206 (20%)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td>199 (20%)</td>
</tr>
<tr>
<td>Younger age</td>
<td>194 (19%)</td>
</tr>
<tr>
<td>Insurance coverage</td>
<td>169 (17%)</td>
</tr>
</tbody>
</table>
Recruitment of 3 Subgroups

- Recruiting Women Easier
- Recruiting Minorities Easier
- Recruiting Pediatrics Easier

Legend:
- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly Disagree**
Retention
# Barriers to Retention of Subjects

<table>
<thead>
<tr>
<th>Barrier to Retention</th>
<th>Number (%)</th>
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</thead>
<tbody>
<tr>
<td>Too much time</td>
<td>614 (60%)</td>
</tr>
<tr>
<td>Don’t see benefit</td>
<td>434 (43%)</td>
</tr>
<tr>
<td>Lose interest</td>
<td>385 (38%)</td>
</tr>
<tr>
<td>Move out of area</td>
<td>303 (30%)</td>
</tr>
<tr>
<td>Health difficulties</td>
<td>262 (26%)</td>
</tr>
<tr>
<td>Lack of social support</td>
<td>151 (15%)</td>
</tr>
</tbody>
</table>
Methods to Ease Retention of Subjects

<table>
<thead>
<tr>
<th>Strategy to Ease Retention</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexible schedule</td>
<td>899 (88%)</td>
</tr>
<tr>
<td>Monetary incentive</td>
<td>663 (65%)</td>
</tr>
<tr>
<td>Both phone and in-person</td>
<td>525 (51%)</td>
</tr>
<tr>
<td>Reminder</td>
<td>495 (49%)</td>
</tr>
<tr>
<td>Exclusive phone follow-up</td>
<td>489 (48%)</td>
</tr>
<tr>
<td>Answering questions</td>
<td>264 (36%)</td>
</tr>
<tr>
<td>Birthday card, newsletter, etc</td>
<td>242 (24%)</td>
</tr>
</tbody>
</table>
## Demographics that Impact Retention

<table>
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<th>Demographic</th>
<th>Number (%)</th>
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<tr>
<td>Distance/transportation</td>
<td>598 (59%)</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>486 (48%)</td>
</tr>
<tr>
<td>Hx of non-compliance</td>
<td>390 (38%)</td>
</tr>
<tr>
<td>Older age</td>
<td>361 (35%)</td>
</tr>
<tr>
<td>Lack of social support</td>
<td>256 (25%)</td>
</tr>
<tr>
<td>Younger age</td>
<td>182 (18%)</td>
</tr>
<tr>
<td>Language barriers</td>
<td>148 (15%)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td>123 (12%)</td>
</tr>
</tbody>
</table>
Retention of 3 Subgroups

- Retaining Women Easier
- Retaining Minorities Easier
- Retaining Pediatrics Easier

Percentages:
- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly Disagree
Additional Analyses

- Years of experience
  - Most frequent recruitment & retention barrier same
  - Higher frequency report for those with more experience

- Region of the country
  - Monetary incentive - highest in SE
  - Social support & language barrier - highest in SW
  - “Time” barrier to retention – highest in NE
Additional Analyses

- Clinical area
  - Evaluated 4 largest clinical areas
  - Refusal due to risk - lowest in Oncology/Hematology and Neurology
  - Monetary incentive on recruitment and retention – lowest in Oncology
  - Retention impacted due to loss of interest - highest in Oncology/Hematology and Neurology
  - Older age impact on recruitment and retention – highest in Cardiology
Focus Group
Focus Group - How Conducted

- Guided Discussion
  - Experience with types of studies coordinated (pre/post-market, research area, etc)
  - Experience with recruitment
  - Experience with retention
  - Perception of patient compliance
Findings – Participants

- September 22, 2009
- 7 participants
- Cardiovascular, Dermatologic, multiple areas
- Drug and Device experience represented
- 5-30+ years experience
Findings - Recruitment

- Finding potentially eligible subjects
- Role of principal investigator
- Role of site location / logistics
- Financial and other incentives
- Motivation vs. coercion
- Challenge to recruit patients who are compliant / follow protocol
Findings - Retention

- Rapport with Clinical Research Coordinator
- Financial and other incentives
- Visit and other contact schedule
- Retention difficult for extended timeframe
Findings – Patient Compliance

- Indicators at recruitment
- Suggested strategies to improve compliance
  - Only recruit compliant patients
  - Collect multiple contacts
  - Highlight additional medical attention with study involvement
Analysis of Focus Group Findings

- Similarities to survey
- Use of incentives
- Potential pitfalls to data analysis
- Potential pitfalls to generalizability
Relevance

- Importance recruitment and retention
- Critical role of CRC
- Identified perceived barriers and opportunities
- Identified potential places for improvement
Future Directions

- FDA needs to continue to gather knowledge from CRC
  - What works/What does not
  - Identify study phase specific strategies
  - Identify strategies unique to product types (device, drug, biologic)
  - Identify demographic specific strategies
Recruitment and Retention Strategies by Years of Experience
Percent of CRC Reporting Selected Recruitment Barriers by Years of Experience

- Finding eligible patients
- Refusal - time
- Refusal - risk
- Refusal - standard of care
- Refusal - protocol/consent

Categories:
- 3 or fewer years
- 4-7 years
- 8-12 years
- 13+ years
Percent of CRC Reporting Selected Recruitment Strategies by Years of Experience

- **Physician mentioned**
- **Benefit to self**
- **Benefit to others***
- **Monetary incentive**

Legend:
- 3 or fewer years
- 4-7 years
- 8-12 years
- 13+ years
Percent of CRC Reporting Effects of Selected Demographics for Recruitment by Experience

- Comorbidities*
- Distance/transportation
- Older age
- Social support*

Legend:
- 3 or fewer years
- 4-7 years
- 8-12 years
- 13+ years
Percent of CRC Reporting Selected Retention Barriers by Years of Experience

- **Too much time**: 4-7 years leads with a percentage slightly above 60%, followed by 3 or fewer years with around 55%, then 13+ years with about 45%, and 8-12 years with around 35%.
- **Don't see benefit**: 4-7 years has a high percentage, around 45%, followed by 8-12 years with about 35%, 3 or fewer years with around 30%, and 13+ years with around 25%.
- **Lose interest**: 4-7 years leads with a percentage slightly above 50%, followed by 8-12 years with around 45%, 3 or fewer years with about 35%, and 13+ years with around 30%.
- **Move out of area**: 4-7 years leads with a percentage slightly above 40%, followed by 8-12 years with around 35%, 3 or fewer years with about 30%, and 13+ years with around 25%.

*Note: The percentages for 'Move out of area' are approximate due to the nature of the data visualization.
Percent of CRC Reporting Selected Retention Strategies by Years of Experience

- Flexible scheduling *
- Montary incentive
- Phone and in-person

[Bar chart showing percentages for different retention strategies by years of experience.]
Percent of CRC Reporting Effects of Selected Demographics for Retention by Years of Experience
Recruitment and Retention Strategies by Region
Percent of CRC Reporting Selected Recruitment Barriers by Location

Percent of CRC Reporting

Barriers

Finding eligible patients
Refusal - time
Refusal - risk
Competing protocols*

Location
Midwest
Northeast
South-east
South-west
West
OUS

Percent

0 10 20 30 40 50 60 70 80 90

Finding eligible patients
Refusal - time
Refusal - risk
Competing protocols*

Midwest
Northeast
South-east
South-west
West
OUS

Legend
Percent of CRC Reporting Selected Recruitment Strategies by Location

- Physician mentioned*
- Benefit to self
- Benefit to others
- Monetary incentive*

Regions:
- Midwest
- Northeast
- South-east
- South-west
- West
- OUS

* indicates monitory incentive or personal benefit.
Percent of CRC Reporting Effects of Selected Demographics for Recruitment by Location

- Comorbidities
- Distance/transportation
- Lack of social support*
- Language barrier*

Percent

- Midwest
- Northeast
- South-east
- South-west
- West
- OUS
Percent of CRC Reporting Selected Retention Barriers by Location
Percent of CRC Reporting Selected Retention Strategies by Location

- **Flexible schedule**
- **Monetary incentive***
- **Phone and in-person**
- **Birthday card, newsletter, etc**

Legend:
- Yellow: Midwest
- Green: Northeast
- Brown: Southeast
- Orange: Southwest
- Pink: West
- Yellow: Outside US
Percent of CRC Reporting Effects of Selected Demographics for Retention by Location

- Distance
- Comorbidities
- Hx of non-compliance
- Older age

**Percent**

- Midwest
- Northeast
- Southeast
- Southwest
- West
- Outside US
Recruitment and Retention Strategies by Clinical Area
Percent of CRC Reporting Selected Recruitment Barriers by Research Area

- Finding eligible
- Refusal - time*
- Refusal - risk*
- Refusal - standard of care

Legend:
- Green: Cardiology
- Gray: Gastroenterology
- Brown: Neurology
- Orange: Oncology or hematology
Percent of CRC Reporting Selected Recruitment Strategies by Research Area

Physician mention*
Benefit self*
Answer questions*
Monetary incentive*

Cardiology
Gastroenterology
Neurology
Oncology or hematology
Percent of CRC Reporting Effects of Selected Demographics for Recruitment by Research Area

<table>
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<th>Comorbidities</th>
<th>Distance/transport*</th>
<th>Older age*</th>
<th>Hx of non-compliance*</th>
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<tbody>
<tr>
<td>Cardiology</td>
<td>Gastroenterology</td>
<td>Neurology</td>
<td>Oncology or hematology</td>
</tr>
</tbody>
</table>

- Cardiology
- Gastroenterology
- Neurology
- Oncology or hematology
Percent of CRC Reporting Selected Retention Barriers by Research Area

- Too much time*
- No benefit
- Lose interest*
- Lack of health*

Percent

Cardiology
Gastroenterology
Neurology
Oncology and Hematology
Percent of CRC Reporting Selected Retention Strategies by Research Area

- **Flexible scheduling**
  - Cardiology: 90%
  - Gastroenterology: 80%
  - Neurology: 80%
  - Oncology and Hematology: 70%

- **Monetary incentive**
  - Cardiology: 60%
  - Gastroenterology: 50%
  - Neurology: 40%
  - Oncology and Hematology: 30%

- **Phone and in-person**
  - Cardiology: 60%
  - Gastroenterology: 70%
  - Neurology: 80%
  - Oncology and Hematology: 90%
Percent of CRC Reporting Effects of Selected Demographics for Retention by Research Area

- Distance
- Comorbidities
- Hx of non-compliance
- Older age*

**Research Areas:**
- Cardiology
- Gastroenterology
- Neurology
- Oncology and hematology