The Importance of Participation – Rethinking Clinical Trials

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The Importance of Participation: Rethinking Clinical Trials - The Role of the Investigator:

ACRO Survey Findings

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Between 2004 and 2007 the number of FDA-regulated investigators...
Investigator Profile

Investigator Status
- 85% currently investigators
- 15% investigators within past 12 months

Practice Setting
- ~1/3 each from AMCs, Private Practice, and Hospitals / Other settings

Experience
- ~13 years experience as an investigator
- ~13 studies in past 24 months

Training
- 70% GCP

Investigator Income
- Average of $3,950 per patient

68% have 1 or more full-time research staff

Research Focus
- ~1/3 consider research an adjunct to their practice
- ~2/3 consider research significant or primary in their roles

85% use EDC
Importance of Specific Factors

- **Interest in participating in the advancement of medical science**
  - Very important: 91%
  - Somewhat important: 5%
  - Not important: 4%

- **Providing my patients with an avenue to novel treatments**
  - Very important: 81%
  - Somewhat important: 10%
  - Not important: 9%

- **Providing an additional source of income for my practice**
  - Very important: 44%
  - Somewhat important: 17%
  - Not important: 39%
Challenges for Investigators

- Patient recruitment/compliance/retention: 20%
- Time constraints: 14%
- Regulatory challenges: 9%
- Finance issues - reimbursements, etc.: 7%
- Instituting processes/organization: 6%
- Paperwork: 5%
- Access to trials: 4%
- Finding experienced research staff: 4%
- Training issues: 4%
Importance of Specific Factors

- 7-10 Very important
- 5-6 Somewhat important
- 1-4 Not important

Interest in participating in the advancement of medical science
- 91% Very important
- 5% Somewhat important
- 4% Not important

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- 81% Very important
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Challenges for Investigators

- Patient recruitment/compliance/retention: 20%
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- Paperwork: 5%
- Access to trials: 4%
- Finding experienced research staff: 4%
- Training issues: 4%
Interest in Being an Investigator

- Very interested: 59%
- Somewhat interested: 22%
- Slightly interested: 14%
- Not at all interested: 4%
Primary reason for non-participation

- Lack of time: 43%
- Have not been invited, lack of opportunity: 31%
- Staff related: 6%
- Finance related-reimbursement, etc.: 3%
- Don't know: 3%
- Other: 14%
More likely to participate

- Increased compensation: 23%
- More time: 14%
- More staff: 11%
- Collaboration with other investigators: 9%
- Training: 6%
- Less paperwork, documentation: 6%
- Simplified process: 3%
- Personal interest: 3%
- Don't know: 6%
- Other: 20%
“Regulations Make Trials Difficult to Manage”

- All Investigators (N=210):
  - 70% agree
  - 16% neutral
  - 14% disagree

- U.S. Investigators (N=93):
  - 66% agree
  - 19% neutral
  - 15% disagree

- W. European Investigators (N=117):
  - 74% agree
  - 15% neutral
  - 11% disagree
“Liability Concerns Deter Participation”

- All Investigators (N=210):
  - 7-10 Agree: 29%
  - 5-6 Neutral: 32%
  - 1-4 Disagree: 39%

- U.S. Investigators (N=93):
  - 7-10 Agree: 42%
  - 5-6 Neutral: 27%
  - 1-4 Disagree: 31%

- W. European Investigators (N=117):
  - 7-10 Agree: 20%
  - 5-6 Neutral: 37%
  - 1-4 Disagree: 43%
Impact of Income Disclosure

- **All Investigators (N=210)**
  - More likely to participate: 3%
  - Just as likely to participate: 83%
  - Less likely to participate: 11%
  - I Would not participate: 2%

- **U.S. Investigators (N=93)**
  - More likely to participate: 1%
  - Just as likely to participate: 75%
  - Less likely to participate: 22%
  - I Would not participate: 2%

- **W. European Investigators (N=117)**
  - More likely to participate: 4%
  - Just as likely to participate: 90%
  - Less likely to participate: 3%
  - I Would not participate: 3%
“Keeping Up To Date is Easy”

- All Investigators (N=210)
  - I strongly agree: 20%
  - I somewhat agree: 42%
  - Neither agree nor disagree: 20%
  - I somewhat disagree: 14%
  - I strongly disagree: 4%

- U.S. Investigators (N=93)
  - I strongly agree: 18%
  - I somewhat agree: 32%
  - Neither agree nor disagree: 26%
  - I somewhat disagree: 20%
  - I strongly disagree: 3%

- W. European Investigators (N=117)
  - I strongly agree: 21%
  - I somewhat agree: 50%
  - Neither agree nor disagree: 15%
  - I somewhat disagree: 9%
  - I strongly disagree: 5%
How to Improve Access to Information

- More comprehensive online marketplace/clearing house: 49% (Total Investigators), 56% (U.S. Investigators), 38% (European Investigators)
- Increased publicity: 9% (Total Investigators), 4% (U.S. Investigators), 19% (European Investigators)
- Increased interaction with research professionals: 9% (Total Investigators), 7% (U.S. Investigators), 13% (European Investigators)
- Other: 33% (Total Investigators), 34% (U.S. Investigators), 31% (European Investigators)
ACRO Policy Recommendations

• Harmonize regulations and apply industry standards
• Address liability issues for researchers
• Balanced approach to COI/disclosures
• Guarantee insurance for participants
• Expand and improve online access to information
Thank you!

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