

Patient and Investigator Recruitment Success



362 interviews with influential stakeholder audiences, including:

- ✓ **119 Patients**
 - 44 with clinical trial experience
 - 75 trial naïve patients
- ✓ **130 Principal Investigators**
- ✓ **113 Drug Development Professionals**
 - 92 from Pharma, Biotech, and Device companies
 - 21 from service providers (CROs, specialized patient recruitment companies)

What you will learn:

- ✓ Patients' motivations for participating in clinical trials
- ✓ Patients' participation concerns
- ✓ Investigators' perspectives on more and less successful recruitment practices
- ✓ Investigator, Sponsor, and CRO ideas for addressing feasibility shortcomings
- ✓ Desirability of new engagement models for sponsors and CROs

And much more...

Report Overview

Another complex drug development topic addressed by Industry Standard Research with rigor and insight.

**Finding patients - Finding Principal Investigators –
Retaining patients - Motivating Principal Investigators
- Accurately assessing study feasibility**

If you manage clinical trials – whether as a sponsor or a service provider – you understand the rocky road that is investigator and patient recruitment. More often than not, it is what dictates whether or not your product reaches the market on time.

The Patient and Investigator Recruitment Study untangles and examines from end to end the many interwoven pieces of the recruitment process, including Feasibility Studies, Site Selection and Retention, Patient Recruitment Advertising and Recruitment Practices, Investigator and Participant Satisfaction, and much more.

Completing such a comprehensive analysis meant that speaking to just a few industry stakeholders would not be good enough. Our analyses and insights are gained from 362 interviews with patients, investigators, and representatives from pharma, biotech, medical device, CRO, and specialist recruitment companies.

The report provides an unfiltered look at data from every question in the survey. The appendix includes more than 250 individual charts and graphs but the report is much more than a simple recitation of numbers. Many of the most striking findings come from probing, open-ended questions that elicited rich responses. And every verbatim response is included in the report.

Finally, as we are determined to raise your expectations of syndicated research in the drug development industry, the report delivers relevant, value-add analysis that is unlike any you’ve experienced in the past.

Respondent Demographics:

113 Drug Development Professionals

- ~60% North America
- ~25% are from Western Europe
- ~15% from Asia/ Eastern Europe/ Latin America

130 Principal Investigators

- ~60% North America
- ~30% Western Europe
- ~10% Eastern Europe

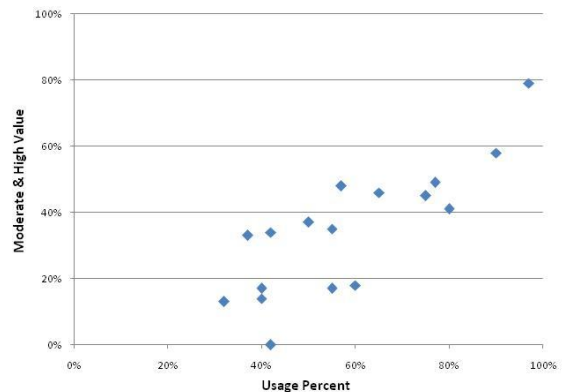
119 Patients, primarily from the United States

Below are just a few examples of some of the tables and charts that are included in the report.

Recruitment Methodology Effectiveness Summary

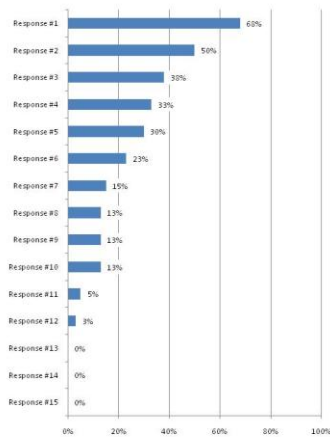
Survey Question: “Regardless of the cost-effectiveness, in your experience, how successful are each of the following patient recruitment methodologies or mediums in generating patients?”

“Now, thinking of the overall value (cost vs. benefit) of each methodology or medium below, how do they rate in terms of patient recruitment?”



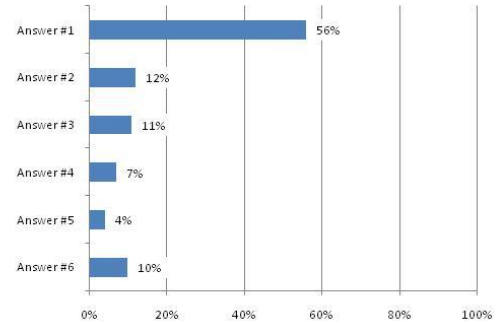
Most Important Attributes for Recruitment Success

Survey Question: "In your opinion, what are the top three (3) attributes of a study/project that have the most impact on patient recruitment success?"



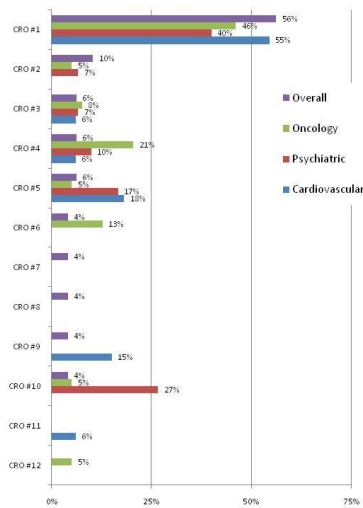
Biggest Issues with Investigators

Survey Question: "Which one of the following is the biggest issue when dealing with investigators?"



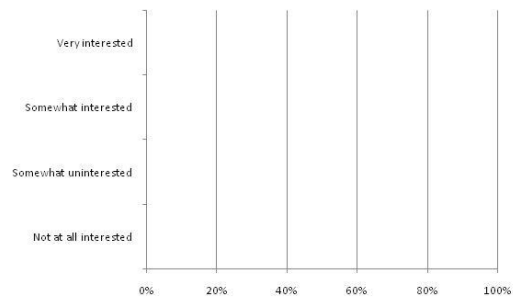
Best Investigator Databases

Survey Question: "Which CRO do you believe has the most productive investigator database...?"



Interest in Service Provider Guaranteeing Recruitment in Exchange for More Control

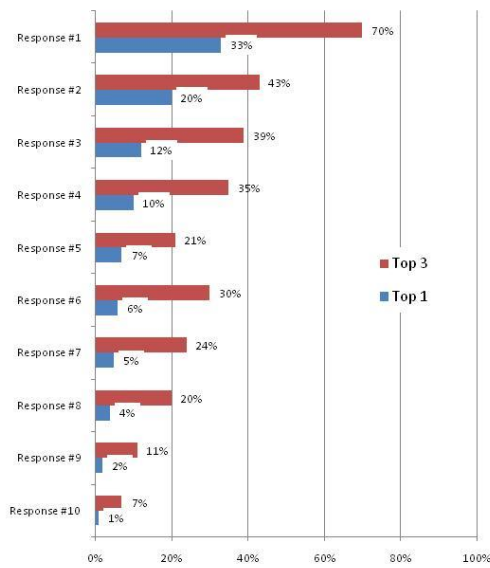
Survey Question: "How interested would your company be in an arrangement with an outside service provider (ARO, CRO, SMO, specialized site/patient access company) whereby they would "guarantee" by way of penalties and bonuses that they would complete patient recruitment on time, but they need complete control of site selection and patient recruitment?"



Top Activities to Shorten a Clinical Trial

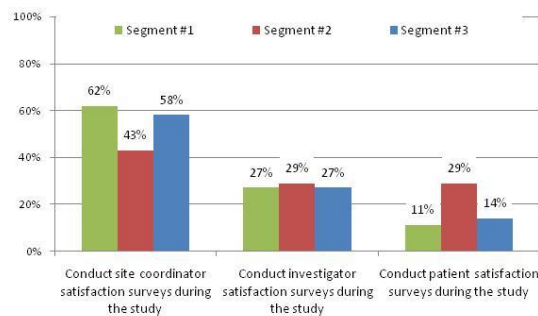
Survey Question: “If you were tasked with shortening the time needed to conduct a clinical trial, which three (3) of the activities below would you invest in to generate the greatest benefit?”

Survey Question: “If you were tasked with shortening the time needed to conduct a clinical trial, which one (1) activity below would you invest in to generate the greatest benefit?”



Trade-off Analysis: Satisfaction Survey Preference: Crosstabs

Survey Question: “If you had 10% extra money in your budget for your next clinical trial, would you rather...”



Pharma respondents – Individual Service Provider Site Selection Performance

Survey Question: “For those CROs with which you have direct experience, please rate their performance regarding the effectiveness of their site selection process.”

Pharma Section – CRO Patient Recruitment Performance

Survey Question: “For those CROs with which you have direct experience, please rate their performance on reaching patient recruitment milestones on time.”

Pharma respondents – Individual Service Provider Feasibility Performance

Survey Question: “For those CROs with which you have direct experience, please rate their performance regarding the accuracy of their feasibility studies.”

Responses for those only with experience	Greatly misses expectations	Somewhat misses expectations	Meets expectations	Somewhat exceeds expectations	Greatly exceeds expectations
AAI Pharma (N=2)					
CEDRA (N=3)					
Covance (N=20)					
i3 Pharma Services (N=9)					
ICON (N=19)					
Inc Research (N=12)					
Kendle (N=15)					
MDS (N=15)					
Omnicare (N=12)					
PPD (N=22)					
PRA (N=16)					
PAREXEL (N=23)					
PharmaNet (N=9)					
Premier Research (N=5)					
Quintiles (N=36)					
RPS (N=5)					

Appendix of Charts and Graphs

Biopharmaceutical Companies & Service Providers

Company Type
 Internal Development Capabilities
 Company Size (Revenue)
 Company & Respondent Location
 Respondent Demographics – Ever worked for Pharma?
 Respondent Demographics – Department
 Respondent Demographics – Functional Area
 Respondent Demographics – Role & Responsibility
 Respondent Demographics – Clinical Development Responsibility
 Respondent Demographics – Interactions with CROs
 Respondent Demographics – Interactions with SMOs
 Respondent Demographics – Interactions with Patient Recruitment Organizations
 Respondent Demographics – Interactions with Midsize or Large Pharma/ Biotech
 Respondent Demographics – Interactions with Small Pharma/ Biotech
 Respondent Demographics – Subject Matter Familiarity
 Specific Service Provider Experience
 Current Outsourcing Penetration
 Future Outsourcing Penetration

Biggest Issues with Investigators
 Biggest Issues with Investigators: Crosstabs - Functional Area
 Biggest Issues with Investigators: Crosstabs - Company Size
 Finding New Investigators
 Advice to Sponsors

Patient Recruitment and Retention Section

Frequency of Meeting Patient Recruitment Targets
 Most Important Attributes for Recruitment Success
 Most Important Attributes for Recruitment Success: Crosstabs – Company Type
 Most Important Attributes for Recruitment Success: Crosstabs – Company Size
 Most Important Attribute for Recruitment Success: Crosstabs
 Frequency of Market Research Efforts
 Market Research Value
 Frequency of Patient Satisfaction Surveys
 Patient Satisfaction Survey Value
 Drivers for Successfully Meeting Patient Recruitment Goals
 Obstacles for Successfully Meeting Patient Recruitment Goals
 Budget for Patient Recruitment (per patient)
 Budget for Patient Recruitment (per patient): Crosstabs – Company type & Company size
 Investigator Incentive Program Success
 Investigator Incentive Program Success
 Leading Edge Patient Recruitment & Retention Strategies
 Most Important Factor in Meeting Recruitment Timelines
 Largest Bottlenecks to Recruitment Success
 Largest Bottlenecks to Recruitment Success: Crosstabs – Company Type
 Use of Advanced Statistical Simulation & Modeling
 Magazine Advertising – Usage and Success
 Magazine Advertising – Overall Value
 Doctor Referral – Usage and Success
 Doctor Referral – Overall Value
 Online advertising (Google, Yahoo) – Usage and Success
 Online advertising (Google, Yahoo) – Overall Value
 Local Newspaper – Usage and Success
 Local Newspaper – Overall Value
 National Newspaper – Usage and Success
 National Newspaper – Overall Value
 Radio – Usage and Success
 Radio – Overall Value
 Affinity groups – Usage and Success
 Affinity groups – Overall Value
 Email blasts (rented lists) – Usage and Success
 Email blasts (rented lists) – Overall Value
 Direct mail advertisements – Usage and Success
 Direct mail advertisements – Overall Value
 Outbound call centers – Usage and Success
 Outbound call centers – Overall Value
 Print/posters at doctor’s offices – Usage and Success
 Print/posters at doctor’s offices – Overall Value
 Pharmacist education, referral programs – Usage and Success
 Pharmacist education, referral programs – Overall Value
 Direct mail letter from doctor – Usage and Success
 Direct mail letter from doctor – Overall Value
 Custom, study-specific websites – Usage and Success

Site and Investigator Section

Pharma respondents – Complete CRO site selection usage
 Pharma respondents – CRO site selection usage
 Pharma respondents – Source of Sites/ Investigators
 Pharma respondents – Site Performance
 Pharma respondents – Individual Service Provider Site Selection Performance
 Pharma respondents – Service Provider Site Selection Service Variability Index (SVI™)
 Pharma respondents – Covance Site Selection SVI™
 Pharma respondents – i3 Pharma Services Site Selection SVI™
 Pharma respondents – Inc Research Site Selection SVI™
 Pharma respondents – ICON Site Selection SVI™
 Pharma respondents – Kendle Site Selection SVI™
 Pharma respondents – MDS Site Selection SVI™
 Pharma respondents – Omnicare Site Selection SVI™
 Pharma respondents – PPD Site Selection SVI™
 Pharma respondents – PRA Site Selection SVI™
 Pharma respondents – PAREXEL Site Selection SVI™
 Pharma respondents – Quintiles Site Selection SVI™
 Pharma respondents – Summary of Site Selection SVI™
 Pharma respondents – Best CRO for Site Selection
 Pharma respondents – Best Choice for Site Selection
 Service Provider respondents – Site selection control
 Service Provider respondents – Site Performance
 Service Provider respondents – Source of Sites/ Investigators
 Service Provider respondents – Investigator Satisfaction Survey Prevalence
 Service Provider respondents – Investigator Satisfaction Survey Value
 Service Provider respondents – Adding Sites
 Best Investigator Databases – All Responses
 Best Investigator Databases – Those with Experience
 Drivers for Finding Highly Productive Investigators
 Obstacles for Finding Highly Productive Investigators
 Leading Edge Methods for Finding Productive Investigators

Custom, study-specific websites – Overall Value
 Television, cable – Usage and Success
 Television, cable – Overall Value
 Television, local – Usage and Success
 Television, local – Overall Value
 Television, national – Usage and Success
 Television, national – Overall Value
 Recruitment Methodology Effectiveness Summary
 Recruitment Methodology Usage Summary: Crosstabs – Company Type
 Current and 2012 Web Recruitment Expectations
 Pharma Section – Frequency of CRO Developing Recruitment Strategy
 Pharma Section – CRO Patient Recruitment Performance
 Pharma respondents – Best CRO for Patient Recruitment
 Pharma respondents – Best Choice for Patient Recruitment
 SMO Patient Recruitment Strategy Responsibility
 ARO Patient Recruitment Strategy Responsibility
 Specialized Patient Recruitment Company Usage
 Specialized Patient Recruitment Company Strategy Development
 Specialized Patient Retention Company Usage
 Future Specialized Patient Recruitment Company Usage

Feasibility Section

Current Feasibility Processes
 Current Feasibility Data/ Information Sources
 Use of Practicing Investigators
 Use of Practicing Investigators: Crosstabs – Company Type
 Current State of Feasibility Analysis
 Medical Claims Data Usage
 Electronic Medical Records Data Usage
 Prescription Data Usage
 Future Use of Medical Claims Data
 Future Use of Electric Medical Record Data
 Future Use of Prescription Data (Feasibility, Investigator Recruitment, Patient Recruitment)
 Use of “Alternative Data” Sources: Crosstabs – Company Size
 Pharma respondents – Individual Service Provider Feasibility Performance
 Pharma respondents – Individual Service Provider Feasibility Service Variability Index (SVI™)
 Pharma respondents – Covance Feasibility SVI™
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 Pharma respondents – PPD Feasibility SVI™
 Pharma respondents – PRA Feasibility SVI™
 Pharma respondents – PAREXEL Feasibility SVI™
 Pharma respondents – Quintiles Feasibility SVI™
 Pharma respondents – Summary of Feasibility SVI™
 Pharma respondents – Best CRO for Feasibility
 Pharma respondents – Best Choice for Feasibility
 Pharma respondents – Best Choice for Feasibility – Why Them?
 Pharma respondents – Feasibility Requests When Outsourcing
 Pharma respondents – In-house Feasibility Analysis When Outsourcing
 Pharma respondents – Frequency of CROs Not Bidding Based on Feasibility/ Timelines
 Pharma respondents – Trends of CROs Not Bidding Based on Feasibility/ Timelines

Pharma respondents – Experience of CROs Not Bidding
 Pharma respondents – Retrospective Assessment of CROs Not Bidding
 Pharma respondents – CRO Assessment Correct?
 CRO respondents – Frequency of Declining to Bid
 CRO respondents – Frequency of Altering Timelines
 CRO respondents – Frequency of Recommending Additional Sites

Business Model Assessment

Interest in Service Provider Guaranteeing Recruitment in Exchange for More Control
 Interest in Service Provider Guaranteeing Recruitment in Exchange for More Control: Crosstabs – Company size
 Interest in Service Provider Using Fixed Price Model for Patient Recruitment
 Use of Loyalty Programs with Investigators
 Use of AROs
 % of Patients from Outside US & W. Europe
 Top Activities to Shorten a Clinical Trial
 Top Activities to Shorten a Clinical Trial: Crosstabs – Functional Area
 Impact of IRBs
 Impact of IRBs: Crosstabs – Company Type
 Confidence in IRBs
 Trade-off Analysis: Extra Sites vs. Top Notch Retention Program
 Trade-off Analysis: Extra Sites vs. Top Notch Retention Program: Crosstabs – Company Type
 Trade-off Analysis: Satisfaction Survey Preference
 Trade-off Analysis: Satisfaction Survey Preference: Crosstabs – Company Type
 Trade-off Analysis: Feasibility vs. Payments vs. Market Research
 Trade-off Analysis: Feasibility vs. Payments vs. Market Research: Crosstabs – Company Type
 Trade-off Analysis: Feasibility vs. Payments vs. Market Research: Crosstabs – Company Size
 More Impact: Competing Drugs vs. Unmotivated PIs vs. Patient Awareness
 More Impact: Competing Drugs vs. Unmotivated PIs vs. Patient Awareness: Crosstabs – Company Type
 Service Provider Trade-Off: More Site Selection Control vs. Higher Patient Recruitment Budget
 CRO Service Offering Interest
 Pharma Outsourcing More Complex Studies?
 Pharma Outsourcing More Complex Studies?: Crosstabs – Company Size
 Pharma Outsourcing More Global Studies?

Clinical Trials Experienced Patients

Motivations for Participation
 Pre-existing Concerns
 Enrollment Retention
 Retention Motivations
 Rationale for Discontinued Participation
 Preference for Learning about Trials
 Source for Medical Research
 Familiarity with Clinical Trials
 Overall Trial Experience Perception
 Likelihood to Participate Again
 Likelihood of Participation for Free Medicine + Travel
 Likelihood to Recommend a Friend
 Medication Effectiveness vs. Placebo
 Regular vs. Different Physician

- Post-trial Communications with Physicians
- Travel Length Preference
- Home Nurse Visits & Clinical Trial Participation
- Importance of Clinical Trials
- How to Make Trial Participation More Compelling
- Patient Satisfaction Survey Prevalence

Clinical Trials Naive Patients

- Potential Motivating Factors for Trial Participation
- Rational for Trial Nonparticipation
- Clinical Trial Familiarity
- Importance of Clinical Trials
- Interest in Participating in Clinical Trials
- Preference for How to Learn About Trials
- Specific On-line Research Tool Usage
- Satisfaction with Current Treatment
- Medication Side Effects
- How to Make Trial Participation More Compelling

Principle Investigators

- Experience with Clinical Trials
- ARO Affiliation
- Office Location
- Number of Clinical Trials Conducted

- Recent Experience with Pharmaceutical Companies
- Recent Experience with CROs
- Site Management Performance
- Preferred "Customer"
- Site Coordinator Resources
- Investigator Satisfaction Research Frequency
- EDC Adoption
- Effects of EDC on Trials
- Feasibility Perspectives
- Impact of IRBs
- Hardest Part of Patient Recruitment
- Most Significant Impact on Clinical Trial Success
- Helpful / Innovative Activities
- Physician Recommended Recruitment Approaches
- Special ARO Analysis

Cross-Survey Analysis

- Satisfaction Survey Preference
- Hardest Part of Patient Recruitment
- Impact of IRBs
- Current State of Feasibility Analysis

Ordering Information

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