ISR reports

Smarter questions ∴ Smarter answers

**BEST PRACTICES IN**

Study Feasibility

PREVIEW OF

BEST PRACTICES IN STUDY FEASIBILITY

AUGUST, 2016

REPORT OVERVIEW

One of the primary challenges to successfully completing a clinical study is estimating the medical, clinical, logistical, and regulatory feasibility of the trial. Within the clinical trial feasibility process, sponsors, CROs and sites evaluate the possibility of conducting a clinical trial within a specific geographic region with the overall objective of completing the project with targeted patients and within defined timelines and costs. Thorough feasibility analyses that implement best practices will assist sponsors in delivering successful site start-ups and trials with data from the right patients while finishing on-time and on-budget. ISR gathered opinions from key stakeholders—sponsors, CROs and sites—to identify the best practices within the feasibility analysis process.

106 PAGES

94 CHARTS AND GRAPHS

17
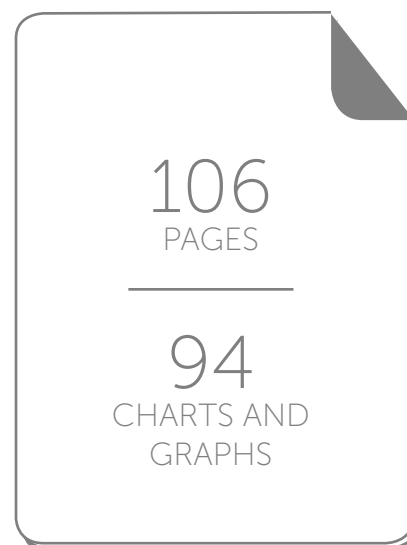
DATA COLLECTION IN Q1, 2016

20-MINUTE WEB-BASED SURVEY
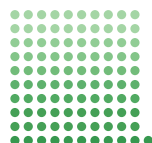
101 RESPONDENTS FROM SPONSORS, CROS AND SITES

VALUABLE FOR

CLINICAL DEVELOPMENT
CLINICAL OPERATIONS
EXECUTIVE MANAGEMENT
FEASIBILITY OR SITE SELECTION
INVESTIGATORS & SITE MANAGERS
THERAPEUTIC AREA HEADS
SITE RESEARCH COORDINATORS
SITE PRINCIPAL INVESTIGATORS

WHAT YOU WILL LEARN

- The percentage of trials that require a feasibility analysis and whether the analysis is conducted in-house or outsourced
- Objectives for conducting a feasibility analysis, the data sources utilized and site selection strategies
- Awareness of feasibility analysis service providers, frequency of use and how well providers performed with respect to client expectations

How you can use this report

- Implement the top techniques and innovations identified by sponsors and CROs for conducting a feasibility analysis
- Improve the accuracy of your own feasibility analyses by learning which characteristics and activities contribute to a predictive feasibility estimate
- Understand the potential value to be gained by engaging a specialized feasibility analysis firm under specific circumstances

FOR PHARMA

Compare feasibility analysis practices with industry peers to identify areas to improve the accuracy of internal and/or outsourced estimations as well as satisfaction with service providers

FOR SERVICE PROVIDERS

Refine your company's approach to conducting feasibility analyses by implementing the top techniques, innovations and best practices identified by the industry

MAJOR SECTIONS:

1. Facilitators & Barriers to Feasibility Analysis Success

2. Specialized Feasibility Analysis Firms Market Overview

3. Feasibility Analysis Service Provider Performance

4. Study Data

Full Table of Contents on next page.

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TABLE OF CONTENTS

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CHARTS AND GRAPHS

SAMPLE PAGES

SAMPLE PAGE:

FEASIBILITY ANALYSIS OBJECTIVES

Sponsors and CROs differ on what they see as the primary objective underlying feasibility analysis.

Objectives when conducting a feasibility analysis

Every component of the analysis has an underlying objective designed to answer the question, "What decisions will sponsors, CROs, or sites be able to make once the analysis is complete?"

Sponsors and CROs differ on what they see as the primary objective underlying a feasibility analysis.

"What are your objective(s) when conducting a feasibility analysis, by which we mean the process by which a clinical study sponsor or clinical research organization can forecast and manage the number of patients per site per month for a specific protocol and determine realistic parameters for site enrollment months? Please select all that apply." (Sponsors n=60, CROs n=20)

"What is your primary objective when conducting a feasibility analysis? Please select one." (Sponsors n=60, CROs n=20)
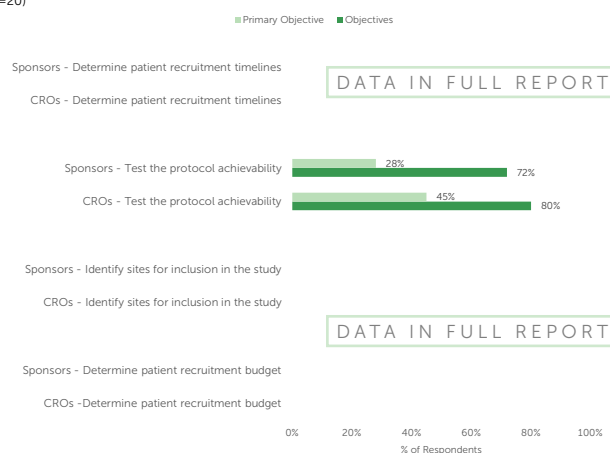
■ Primary Objective ■ Objectives

Sponsors – Determine patient recruitment timelines

CROs – Determine patient recruitment timelines

DATA IN FULL REPORT

Sponsors – Test the protocol achievability   28%   72%

CROs – Test the protocol achievability   45%   80%

Sponsors – Identify sites for inclusion in the study

CROs – Identify sites for inclusion in the study

DATA IN FULL REPORT

Sponsors – Determine patient recruitment budget

CROs – Determine patient recruitment budget

0%   20%   40%   60%   80%   100%
% of Respondents

■ Primary Objective ■ Objectives

Sponsors – Determine patient recruitment timelines

CROs – Determine patient recruitment timelines

DATA IN FULL REPORT

Sponsors – Test the protocol achievability   28%   72%

CROs – Test the protocol achievability   45%   80%
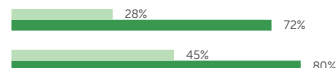
Sponsors – Identify sites for inclusion in the study

CROs – Identify sites for inclusion in the study

DATA IN FULL REPORT

Sponsors – Determine patient recruitment budget

CROs – Determine patient recruitment budget

0%   20%   40%   60%   80%   100%
% of Respondents

CLOSER LOOK

≪ CROs are more likely than sponsors to state the primary objective of a feasibility study is to Test the protocol achievability.

Data available in the full report, which can be found at:

www.ISRreports.com

SAMPLE PAGE:

CHARACTERISTICS OF A PREDICTIVE OR ACCURATE FEASIBILITY ESTIMATE — UNPROMPTED

This page shows which attributes and activities contribute to an accurate feasibility estimate from the perspective of sponsors, CROs and sites.

The full data is available in the report, which can be downloaded from www.ISRreports.com.

FACILITATORS & BARRIERS TO FEASIBILITY ANALYSIS SUCCESS

ISR reports

Characteristics of a predictive or accurate feasibility estimate – unprompted

Sponsors report the most predictive and accurate feasibility estimates are driven by *Prior results* in similar clinical studies (45%).

"In your experience, what makes for a predictive or accurate feasibility estimate? This is one of the key questions of the study. Please be as specific as possible in your answer. Thank you."

■ Sponsors (n=60) ■ CROs (n=20) ■ Sites (n=21)

Prior results (with similar patient population, protocol, therapy area) — 45% / 25% / 17%

© Industry Standard Research

Quality of responses to feasibilty questionnaire (evidence of serious interest, expertise, resources)

Clear and achievable inclusion and exclusion criteria

Clear and detailed protocol

Quality of investigator(s) and staff (experienced, interested)

Discussions with KOLs, thought leaders

Discounting stated feasibility estimate

DATA IN FULL REPORT

Local market knowledge

Reasonable time/budget estimates

Planning for retention

Readily available patients/patient database

Viable network of clinical sites

0%   20%   40%   60%   80%

% of Respondents

SAMPLE PAGE:

BEST TECHNIQUES AND INNOVATIONS FOR FEASIBILITY ANALYSIS — UNPROMPTED

This page shows unprompted responses from sponsors on the best techniques and innovations utilized in their experience with feasibility analysis.

The full data is available in the report, which can be downloaded from www.ISRreports.com.

STUDY DATA

Best techniques and innovations for feasibility analysis – unprompted

Sponsors

"In terms of a feasibility analysis, what are some of the best techniques or innovations you have experienced? Please be as specific as possible. Thank you." (n=60)

Category	% of Respondents
Applying technology/software to improving feasibility studies	
Build time in schedule for administrative/legal/recruiting delays	
Conducting patient chart reviews	
Establishing a preferred investigator network	DATA IN FULL REPORT
Greater use of EMR and other patient databases	
Improving feasibility survey (online, more specific information) and reporting	
Increased collaboration with investigators on protocol	
Integrate statistical modeling/knowledge of past performance into feasibility analyses	22%
Making direct, personal contact with investigators, sites to build better relationships	
More attention to detail/accuracy when developing estimates	
No innovations experienced	
Planning for patient retention	DATA IN FULL REPORT
Seek out input experienced investigators and sites coordinators	
Tailoring feasibility analysis to the patient population	
Using real-time data monitoring	
Using social media to measure interest	

0%   10%   20%   30%

% of Respondents

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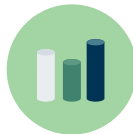
Our research categories include:

Biosimilars & Biologics

Clinical Trial Recruitment & Retention

Commercialization

Department Models & Structures

Trends & Technologies

Manufacturing

Service Provider Quality Benchmarking

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CUSTOM RESEARCH

UNDERSTAND YOUR MARKETS

Leverage ISR's experience and institutional knowledge to create a fit-for-purpose market research project that addresses the business decisions you need to make.

Are you:
- Developing a new product or service?
- Evaluating a new market?
- Targeting a new customer segment?
- Entering a new geography?
- Needing a deeper understanding of your customer or potential customer base?

UNDERSTAND YOUR CUSTOMERS

Who makes the decisions and in what contexts? ISR can help you gain a deeper understanding of your customers' decision-making units (DMUs) and decision-making processes (DMPs).

Key Questions Addressed:
- What motivates the purchase decision?
- How are companies, products, solutions, and/or brands evaluated?
- What factors drive the final buying decision?
- Where are your customers won or lost in the purchasing process?
- Why were specific opportunities won or lost?
- How do you keep customers engaged and manage their loyalty over time?

CUSTOM RESEARCH SERVICES

- Investigator Forum
- Brand, Advertising, and Message Testing
- Loyalty Management
- New Product and Service Development
- Competitive Intelligence
- Strategy War Games
- MORE

THE ISR DIFFERENCE

ISR'S REPORTS VS. THE COMMON SYNDICATED REPORT

ISR'S HEALTH PANEL

The industry's fastest growing panel of health care and pharmaceutical professionals, with nearly 1,500 members worldwide.

RESEARCH METHODS

Mostly primary research; always appropriate for the topic

One size fits all; usually publically available data

DATA COLLECTION

ISR's proprietary data tools and channels support fast, high quality data collection

Struggle to recruit the right targets and enough of them

RESPONDENTS

Sophisticated screening ensures genuine decision-makers make up respondents

Undisclosed methodologies and respondent demographics

SAMPLE SIZE

Robust sample sizes that instill confidence

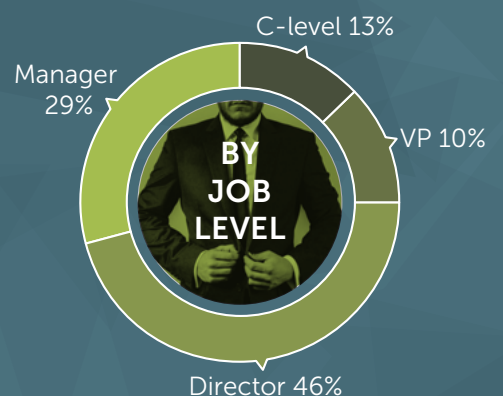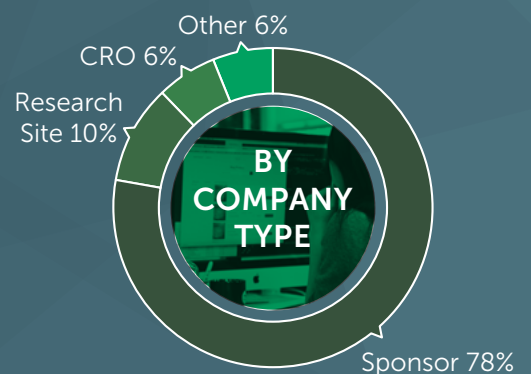Often insufficient industry representation that leaves you defending results

ANALYSTS

Decades of experience means more insights that are immediately usable

Junior analysts capable of reporting numbers

BY COMPANY TYPE

- Other 6%
- CRO 6%
- Research Site 10%
- Sponsor 78%

BY JOB LEVEL

- C-level 13%
- VP 10%
- Director 46%
- Manager 29%

BY EXPERIENCE IN YEARS

- 3-5 years 5%
- 6-10 years 11%
- 11-15 years 24%
- 16-20 years 23%
- 20+ years 37%

To learn more, visit www.ISRreports.com