INVESTIGATOR FORUM

Improve feasibility, site and patient recruitment

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DID YOU KNOW?

Protocol amendments have a significant impact on the time and money needed to complete a clinical trial.

69%
of all protocols have at least one amendment*

$450,000
cost to implement a single amendment to a trial*

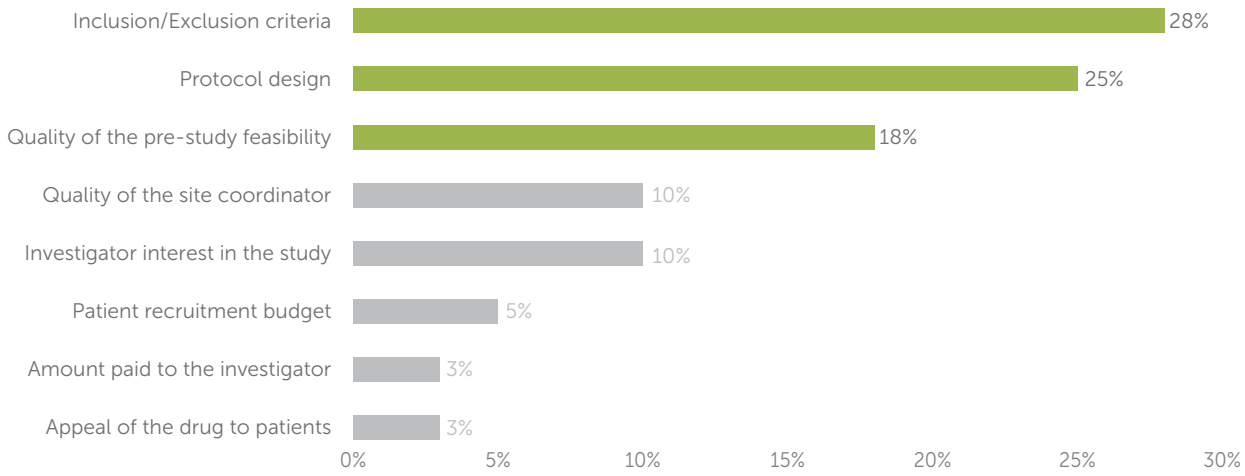
61
days added to a trial for each amendment*

According to Tufts CSDD, to save time and money, quality should be built into the protocol design process, finding opportunities to balance scientific and operating objectives.

WHAT IMPACTS RECRUITMENT SUCCESS?

From ISR's report *"Patient and Investigator Recruitment Success"*

"In your opinion, what is the single most important attribute of a study/project that has the most impact on patient recruitment success?"



You don't have to guess whether your study's inclusion/exclusion, con meds, or patient visit schedule will help or hinder patient recruitment.

* Tufts Center for the Safety of Drug Development

ISR's Investigator Forum

WHAT IS IT?

ISR's Investigator Forum is a non-real time, web-based focus group that occurs over 2-3 days and brings together 10-30 Investigators to answer questions, give opinions, and interact with peers on topics related to your protocol development, patient recruitment, and feasibility.

Inclusion/exclusion criteria:	Are they appropriate, complete? How will they impact patient recruitment?
Competing studies:	Which ones will cause recruiting issues?
Standard of care:	What are the implications in their facility/geography?
Informed consent:	Is it appropriate? How will patients react?
Endpoints:	Are they appropriate? What are other alternatives?
Visit schedule:	How will patients react? Is it burdensome for the site?

WHAT ARE THE BENEFITS?

- Facilitate the development of a protocol that maximizes the potential to recruit patients in a timely manner by gathering feedback on specific I/E criteria, standard of care, competitive trials, etc.
- Gather on-the-ground approaches to maximize the chance of recruitment success and provide realistic feasibility estimates
- Establish an interactive, creative environment that builds creative solutions and a sense of community and ownership

WHEN TO USE IT?

- Anytime you need to de-risk study operations and timelines
- When patient recruitment timelines are unusually aggressive or already behind schedule
- When the treatment is complex or novel
- With difficult-to-recruit indications and patient populations
- When the therapeutic area or indication is new to the organization
- On fixed-price or pay-for-performance contracts

PRACTICAL OUTCOMES:

- A protocol that is optimized for patient recruitment
- Scientific input and recommendations from practitioners
- Feasibility estimates that actually predict recruitment
- Creative solutions to challenges you may not have anticipated
- A sense of community and ownership among Investigators and project team members

ISR'S SERVICES

- Discussion guide development
- Analysis and reporting outputs (sortable Excel verbatim file + PowerPoint presentation)
- Competitive trial research
- Participant recruitment
- Technology

START — 4-6 weeks from start to finish, enabling fast decision-making. → FINISH

TECHNOLOGY/METHODOLOGY BENEFITS

UTILIZE SMART, DIGITAL TECHNOLOGIES

Convenience:	Investigators participate when it is convenient for them
Geographic reach:	Accommodates Investigators from different locations
Peer-based forum:	Investigators can view other responses and comment on them
Flexibility:	Topics and questions can be adjusted as necessary throughout the process
Probing:	Moderators can ask follow-up questions
Speed:	Responses can be captured and analyzed quickly
Interactive environment:	Facilitates structured and unstructured data collection
Transparency:	Observers from your company can watch the group in real-time
Cost effective:	No travel costs
Output:	PowerPoint report with recommendations and sortable Excel file of verbatim responses

INVESTIGATOR LISTS

Use your list or ours

- ISR can use a sponsor's Investigator database, a CRO's Investigator database, a list of pre-recruited Investigators, and/or supplement from ISR's database

COST

Volume and Development Program-based discounts available.

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For an online demonstration or for more information, please email us at Info@ISRreports.com or call (919)-301-0106

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