Assessing the Quality of {Company's} Relationship with its Investigative Sites After Conducting a Study

{Date}

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Project Background

- {Sponsor Company} conducted a clinical study (ies) {domestic and/or international} {Protocol Title}, lasting X weeks.
- The study(ies) were completed in {Year} and involved X number of patients.
- Some of the challenges associated with the study included:
  - An extremely complex protocol
  - The requirement of a high level of patient care
  - The use of new EDC technology

Business Objectives

- Given the complexity of the protocol and the various study challenges, {Sponsor Company} was interested in:
  - Assessing how investigative sites perceive their overall relationship with {Sponsor Company}.
  - Determining how {Sponsor Company} performed as a clinical trial sponsor:
    - Specifically, determine areas of strength and areas where improvement is necessary.
- {Sponsor Company} intends to apply the learning from this research to future clinical studies.

Survey Methodology

- Base survey instrument initially developed by CenterWatch for its global sponsor/ contract research organization and site relationship surveys. This base survey instrument was then customized with {Sponsor Company's} input to produce the final questionnaire.
- Survey conducted online in {DATE}.
- Survey emailed to X number of investigators and study coordinators worldwide.
- Final sample size was n=X, indicating a X% response rate.
- Respondents had an average of 10 years clinical research experience
- The final sample was composed of:
    - 39% Investigators
    - 60% Study Coordinators

Executive Summary

- Overall, investigative sites rate the quality of their relationship with {Sponsor Company} highly and enjoy working with the company as a clinical trial sponsor:
  - The supportive, knowledgeable and professional staff, as well as the creation of a team environment primarily drove positive perceptions of the company.
  - When compared to previous CenterWatch investigative site surveys conducted in the US and Europe, {Sponsor Company} overall relationship quality rating surpasses the average sponsor ratings.
  - Study coordinators and investigators share the same positive perceptions of {Sponsor Company}.

What Worked Well

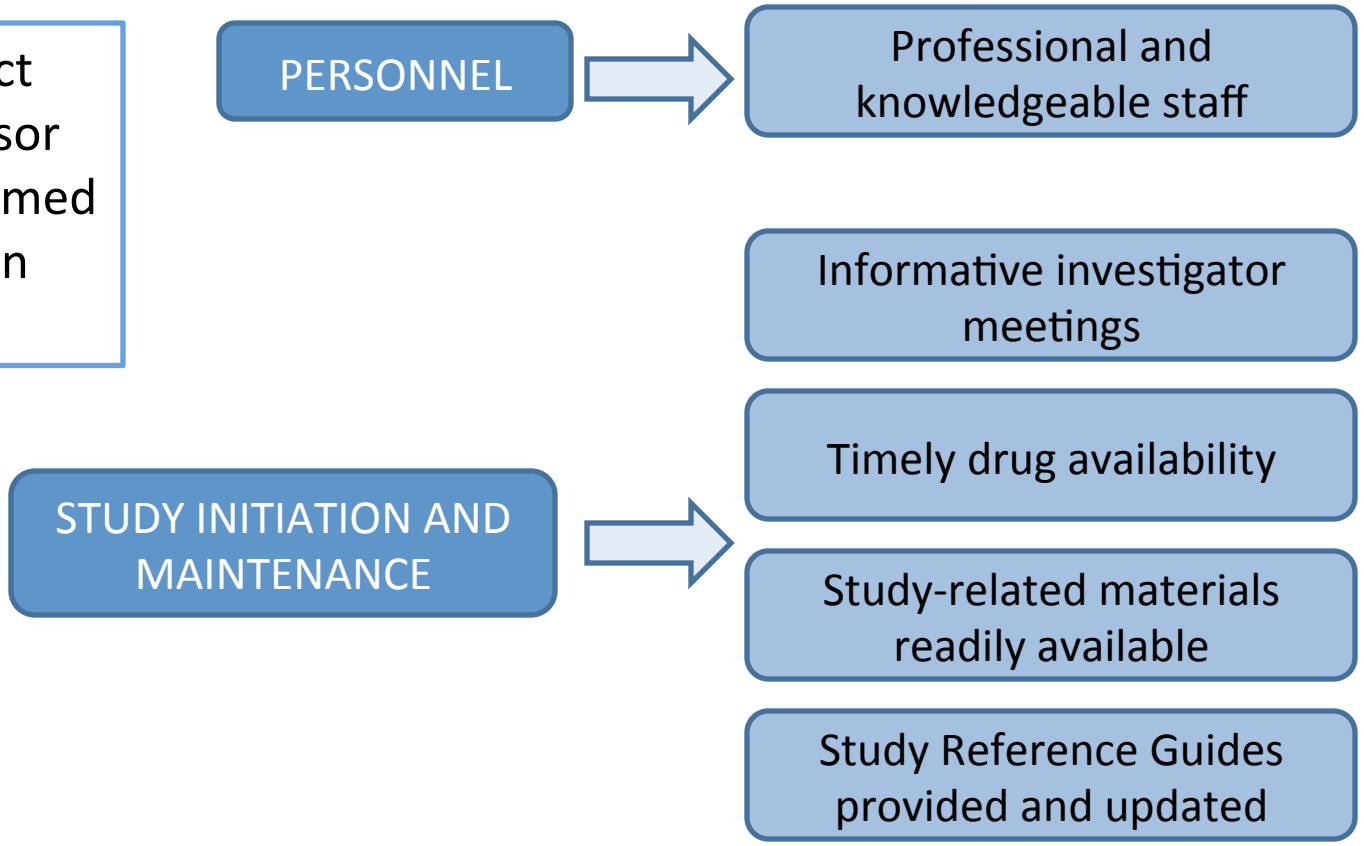
- Training programs achieved strong ratings. The investigator meeting and the Workshop were rated particularly highly.

- Sites also perceived {Sponsor Company} to communicate effectively - responding to inquiries in a timely manner and generally being satisfied with the responses to their inquiries.

- The Electronic Data Capture technology was perceived to be very user-friendly, regardless of one's experience level with EDC.

What Worked Well (cont'd)

On specific project attributes, {Sponsor Company} performed particularly well in these areas…

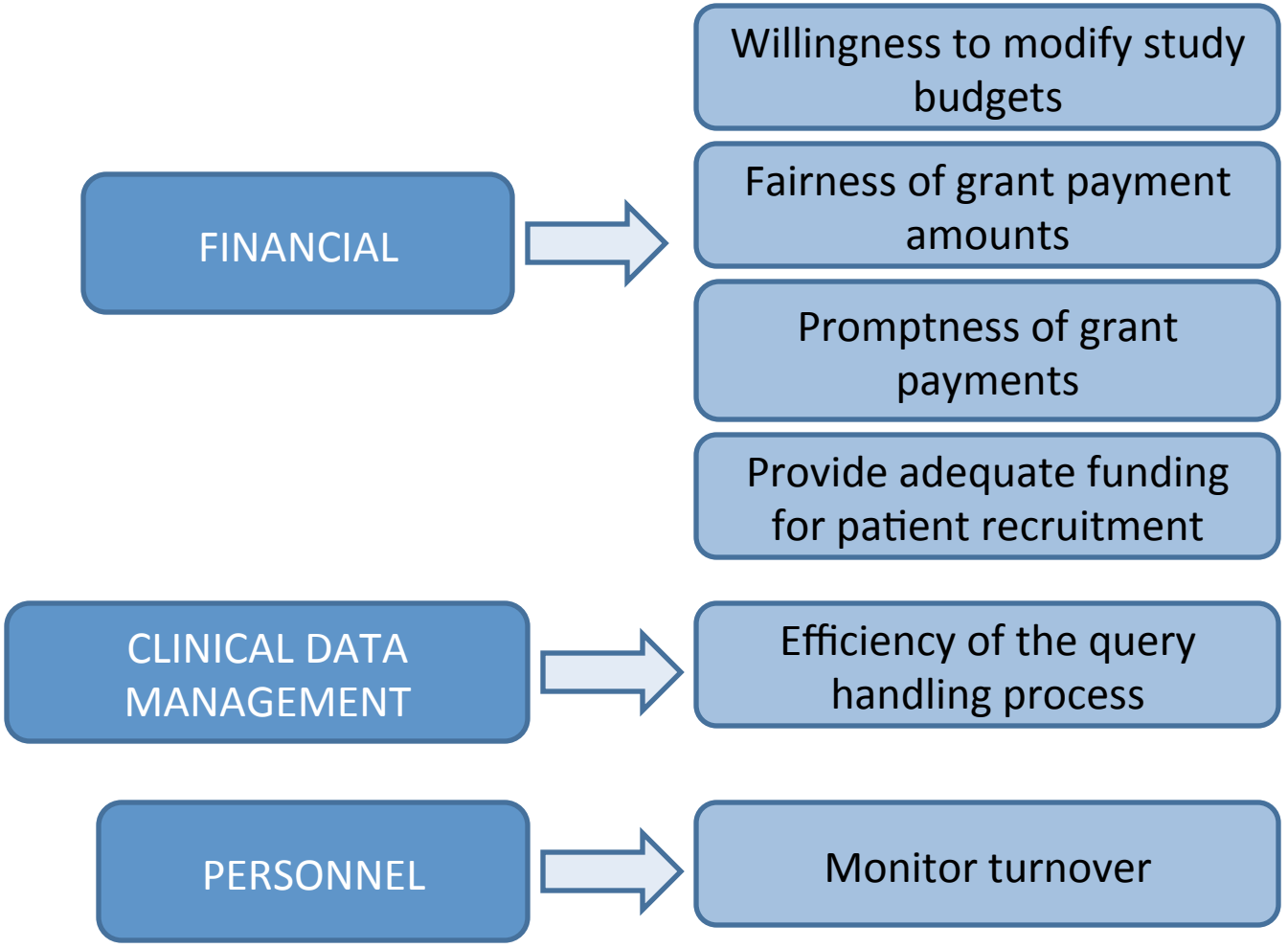


Improvement Areas

- While most were generally very satisfied with their experience with {Sponsor Company}, it is worth noting that issues were expressed in the following areas:
  - High monitor turnover
  - Infrequent monitoring visits
  - Quality issues with third parties:
    - {X Company} (delayed lab results and poor responsiveness to inquiries)
    - {X Company} (high monitor turnover)
  - Lack of flexibility with the budget, especially in cases where the study is extended
  - EDC: A few mentioned some difficulty entering corrections in the system and some experienced issues with the speed of the system (i.e. opening the program).

Improvement Areas

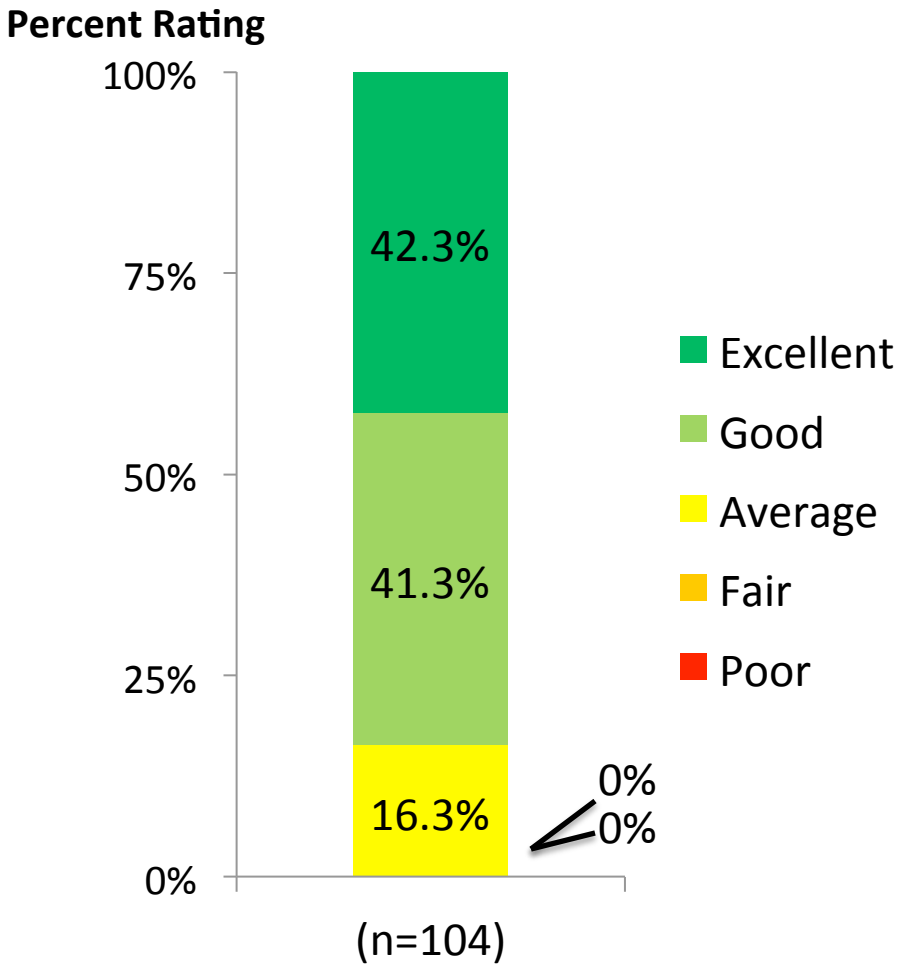
On specific project attributes, there is room for improvement in these areas…



{Sponsor Company}

OVERALL RELATIONSHIP QUALITY RATING

Overall Rating of Relationship



Respondents rate their overall relationship with {Sponsor Company} as Good to Excellent.

*May not add up to 100% due to rounding

General Relationship Quality Drivers

LIKES	
SUPPORTIVE, PROFESSIONAL AND KNOWLEDGEABLE STAFF/READILY AVAILABLE/FELT LIKE PART OF TEAM	73.0%
REALISTIC, WELL-DESIGNED PROTOCOL	9.5%
GREAT COMMUNICATION/ INFORMATION SHARING	7.9%
AVAILABILITY AND QUALITY OF TRAINING PROVIDED	6.3%
OTHER	3.2%

DISLIKES	
NONE	64.7%
MONITOR TURNOVER/INFREQUENT MONITOR VISITS/LACK OF IMMEDIATE ASSISTANCE	11.8%
QUALITY ISSUES WITH THIRD PARTIES	7.8%
LACK OF RESPECT FOR SITES/OPINIONS OF INVESTIGATOR	5.9%
OTHER	9.8%

The professionalism, friendliness and responsiveness of the staff, as well as the creation of a team environment, primarily drove positive perceptions of {Sponsor Company}. While most respondents did not mention any dislikes, some expressed issues with monitor turnover/lack of monitoring visits, quality issues with third parties involved and the occasional lack of respect for the judgment of investigators.

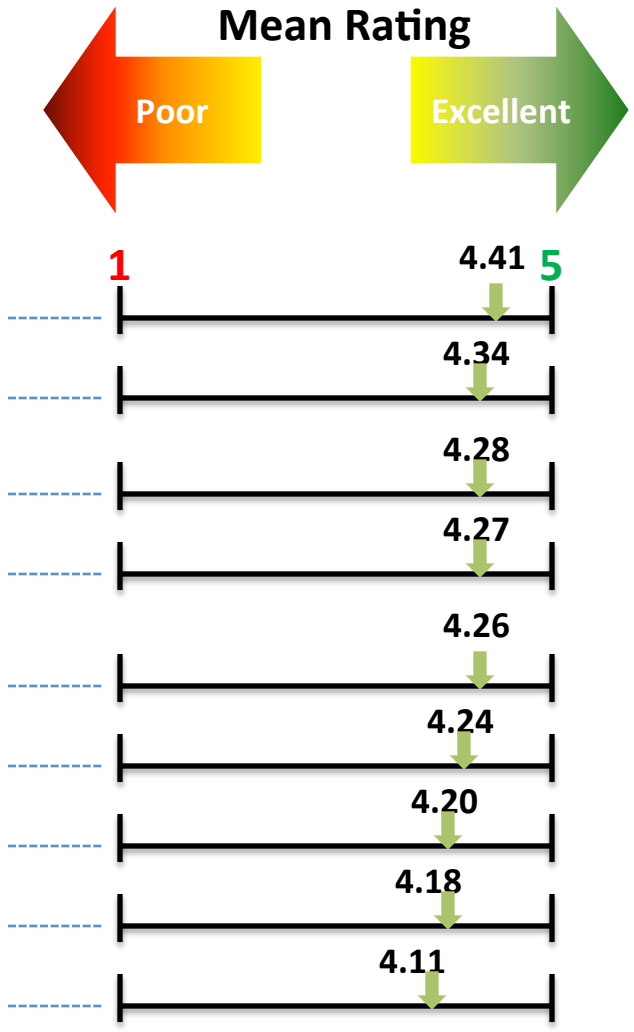
{Sponsor Company}

TRAINING EVALUATION

Training Evaluation

Respondents rate all training programs favorably, with the investigator meeting and the Workshop ranked highest.

TRAINING TYPE
Investigator meeting
Workshop
Training on study specific procedures
Initiation visits
Training on worksheet completion (SAE, weight & dose calculation worksheet)
Training on EDC technology
Source document verification (SDV) data review process
Disease activity proficiency test
On-site GCP training

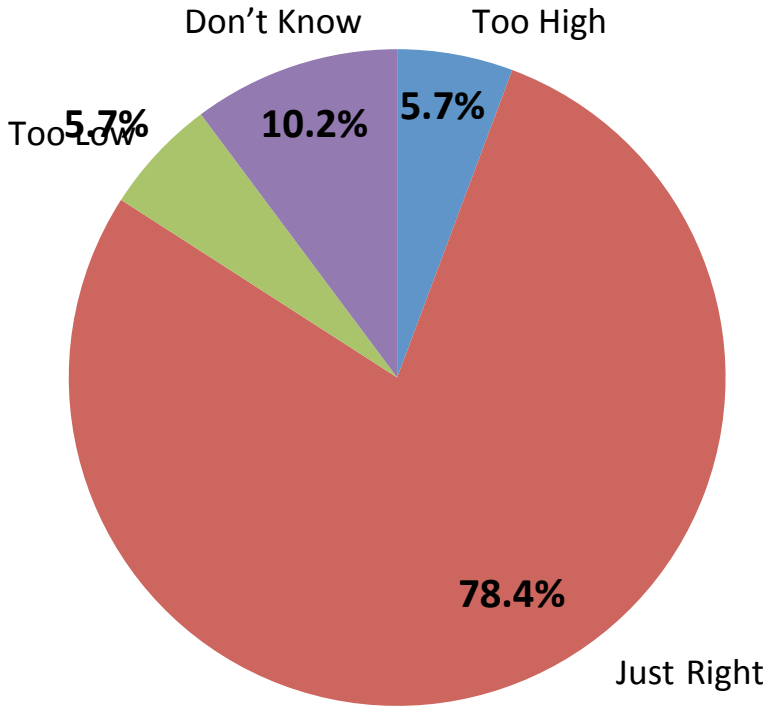


{Sponsor Company}

SPONSOR CONTACT

Sponsor Contact During Studies

Was the number of different personnel who contacted you during studies…



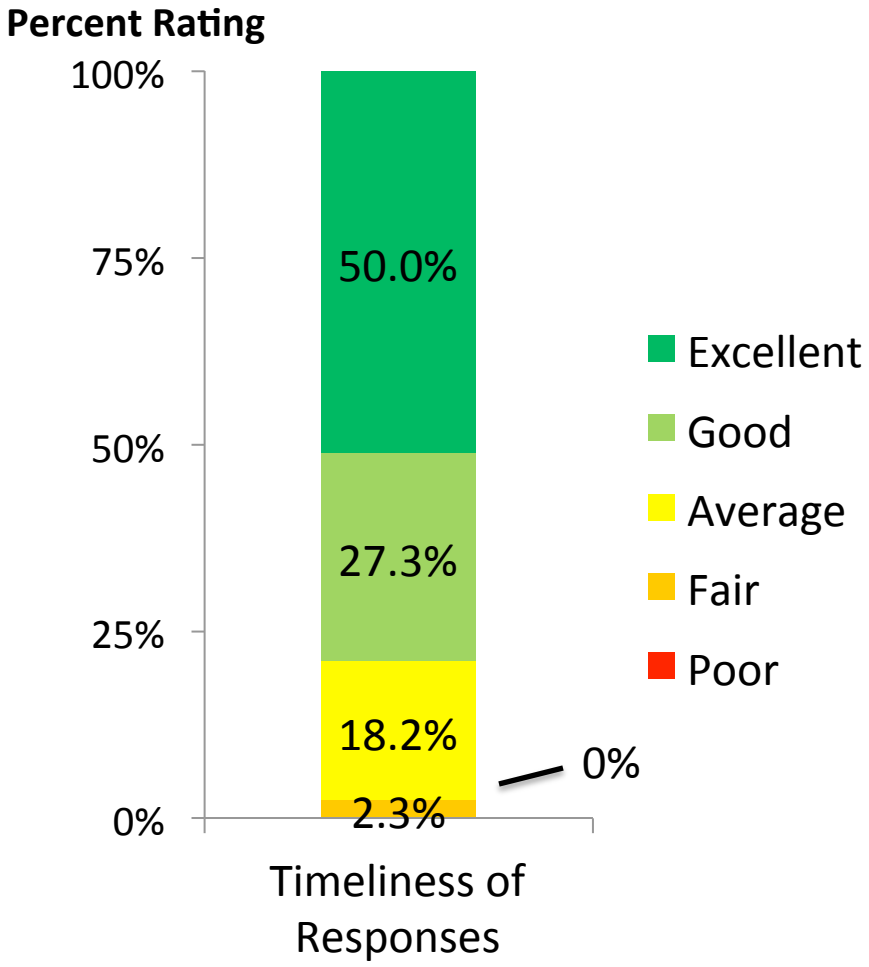
On average, how many times a month were you in contact with {Sponsor} or designee in a typical month?

	Times per Month
Mean	3
High	30
Low	0

Most respondents perceive the number of personnel who contact them during studies appropriate. The frequency of contact varies, averaging 3 times a month.

Measuring Communication Effectiveness:

Timeliness of Responses to Communication from Site



Most respondents perceive {Sponsor Company} to respond to inquiries in a timely manner.

{Sponsor Company}

DIAGNOSTICS – PROJECT ATTRIBUTES

Project Attribute Summary

- ✓Flexibility – willingness to modify study budgets
- ✓Providing fair overall grant payment amounts
- ✓Monitor turnover
- ✓Query handling process
- ✓Providing prompt payment of grants
- ✓Providing adequate funding for patient recruitment

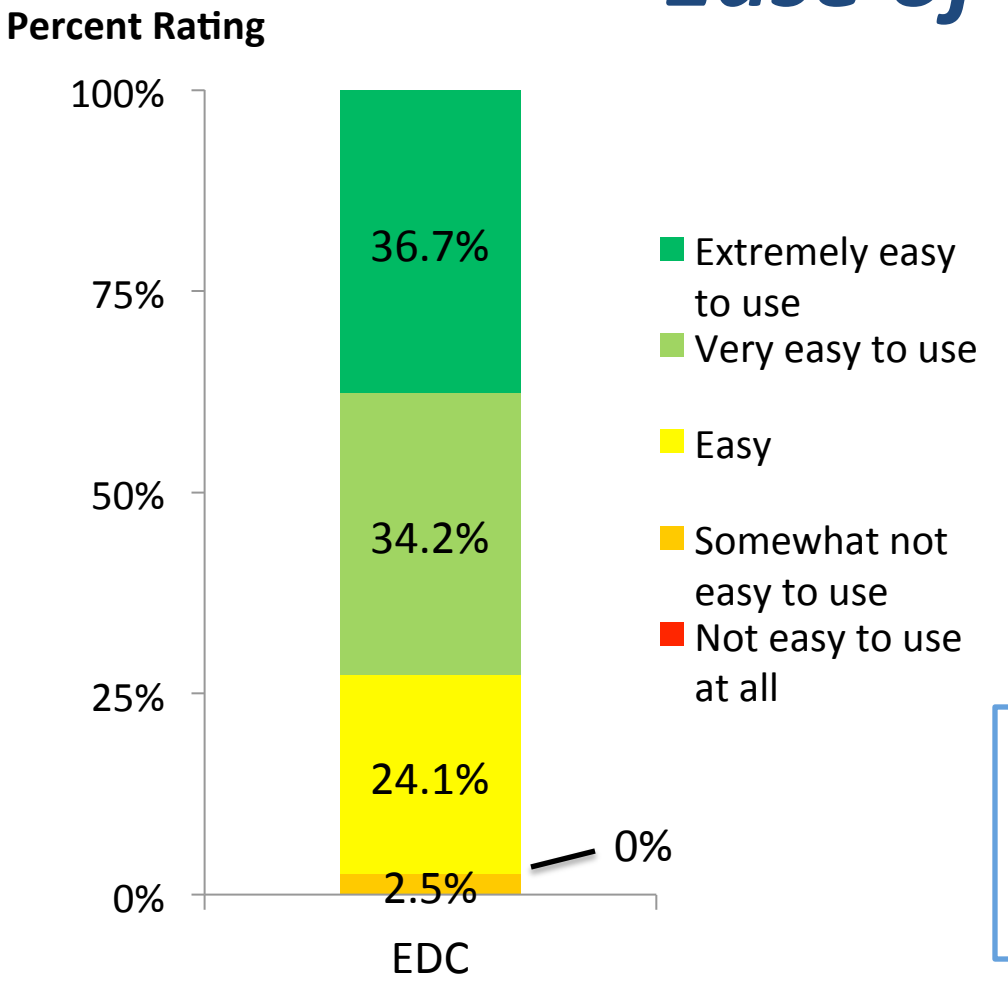
- ✓Professional and knowledgeable staff
- ✓Providing appropriate inclusions/ exclusions for disease under study
- ✓Timely drug availability
- ✓Study-related materials readily available
- ✓Study reference guides provided and updated as necessary
- ✓Informative investigator meetings

No significant differences were found between the investigators and study coordinators across all project attributes.

{Sponsor Company}

CLINICAL RESEARCH PROCESS

Electronic Data Capture Technology: *Ease of Use*



While most respondents perceive the electronic data capture technology to be user-friendly, some indicated issues with entering corrections/revising data.

Looking Ahead:
Improvements for Future Studies

Half of respondents had a great experience overall with {Sponsor Company} and did not have any recommendations for the future . 15% recommended reviewing/updating the budget when a study extension occurs. Finally, some expressed dissatisfaction with {Company} for high monitor turnover and (Company} for delayed laboratory results.

OVERALL GREAT EXPERIENCE – NO RECOMMENDATIONS	51.9%
SHOW FLEXIBILITY WITH REGARDS TO BUDGET - ESPECIALLY IF STUDY IS EXTENDED	14.8%
LESS MONITOR TURNOVER/ISSUES WITH INTERMEDIARIES	11.1%
OTHER:	22.2%
Early feedback in protocol process reduces amendments later	
Design a simpler protocol and CRF	
Training for new coordinators (site may not provide adequate training)	
Involve investigators more in data analysis and presentation	

Participating Countries

Country	
United States	39.4%
Argentina	8.5%
Brazil	8.5%
Taiwan	5.6%
Korea	4.2%
Germany	2.8%
India	2.8%
Israel	2.8%
Italy	2.8%
Mexico	2.8%
Philippines	2.8%
Canada	1.4%

Country	
Australia	1.4%
Chile	1.4%
Colombia	1.4%
Czech Republic	1.4%
France	1.4%
Peru	1.4%
Poland	1.4%
Puerto Rico	1.4%
Romania	1.4%
Spain	1.4%
Sweden	1.4%