Practical Strategies for Taking on New Studies Post COVID-19

SiteTalks

Table of Contents

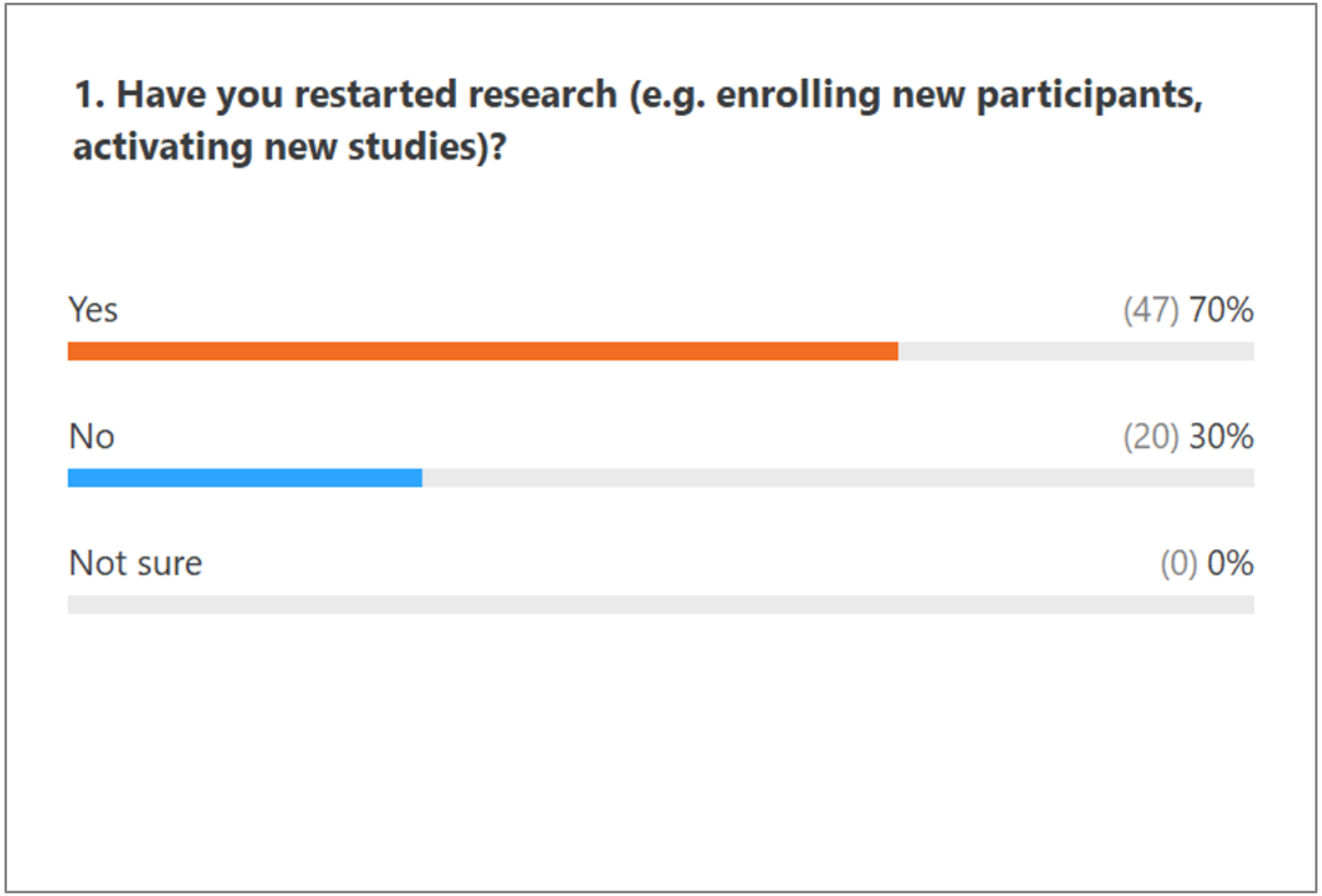
Speakers

Melissa Holbrook MSN, NP
Vice President, Operations
Velocity Clinical Research

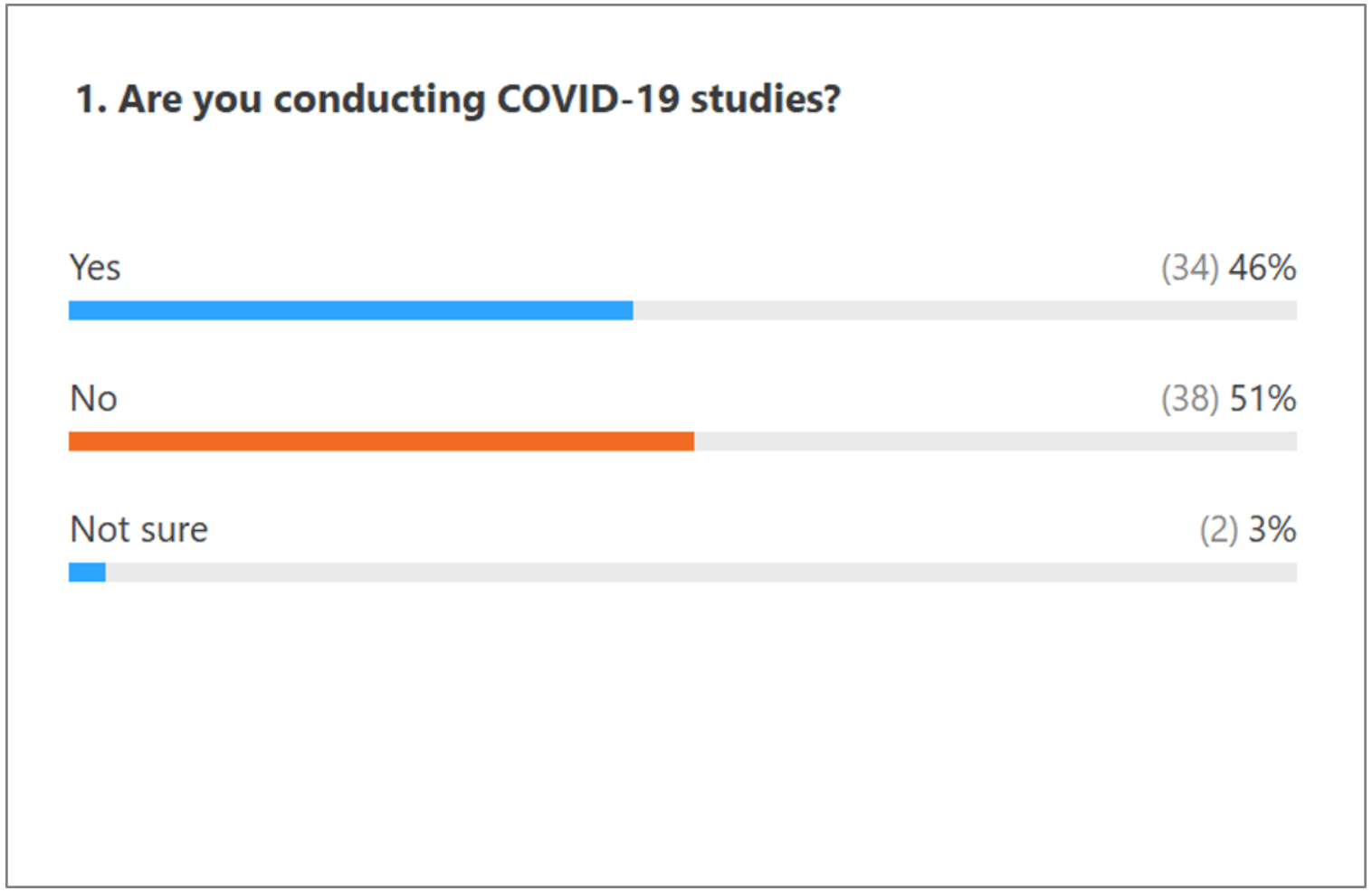
Mindy Muenich
Senior Director
Huron Consulting Group

Bree Burks, MSN, RN
VP Strategy, Site Solutions
Veeva Systems

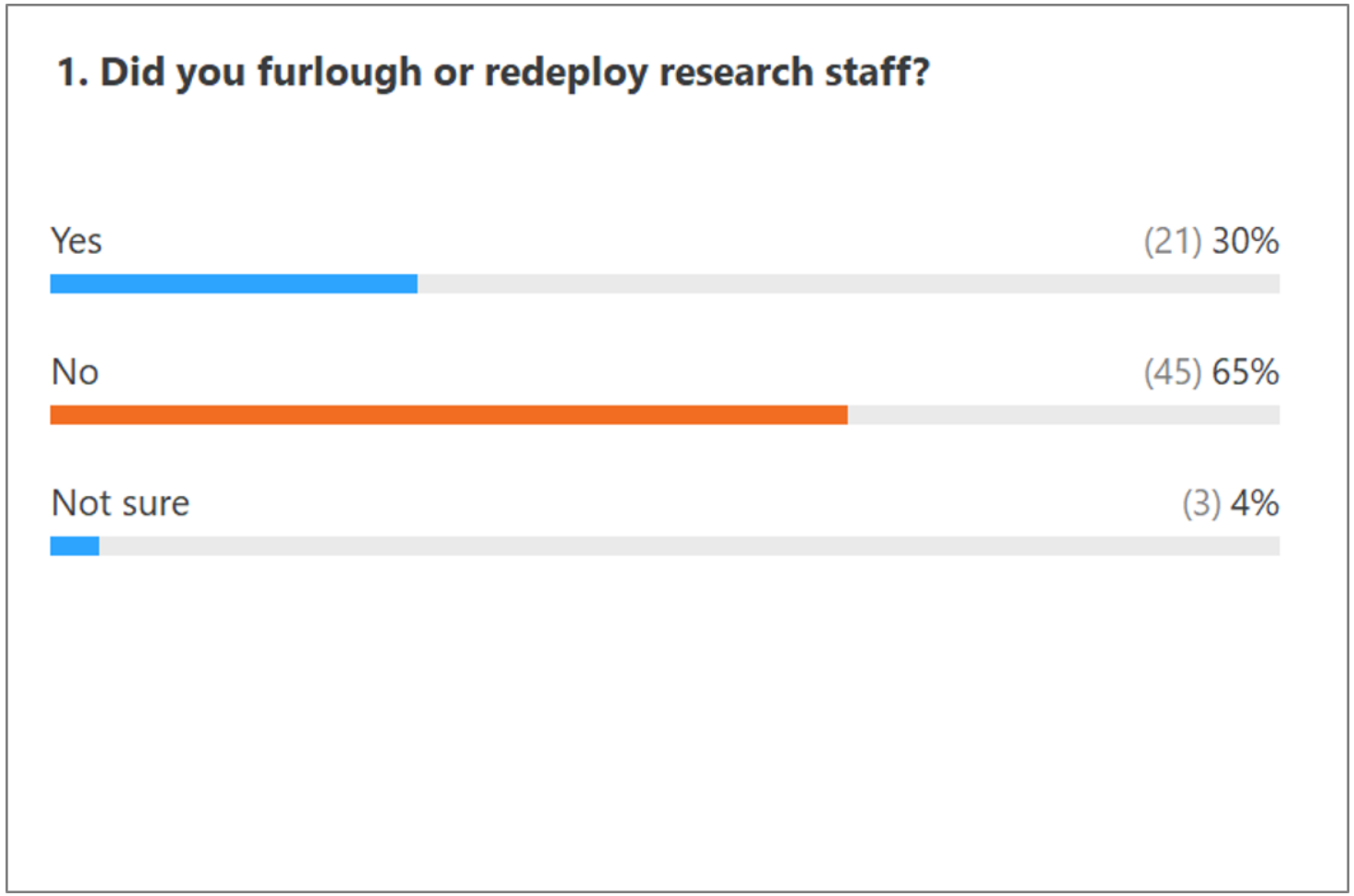
Polling Question 1 of 3



Polling Question 2 of 3



Polling Question 3 of 3



What should sites consider to ensure readiness when opening their doors?

What should sites consider to ensure readiness when opening their doors?

Consider the safety for staff, participants and monitors:

- Staff:
  - Some sites had to reduce staff: do you have the staff to restart?
  - Do you have PPE in order to protect the staff from potential exposure?
  - Are you screening staff prior to coming into the clinic? (symptom and temp checks)
  - Do you have the right processes in place? (PPE in patient care areas and anywhere that social distancing can't be maintained, hand washing stations, sanitizing processes for frequent touch areas? enough supplies to sustain these practices?
- Patients:
  - Are you prescreening patients prior to visits? Reschedule if has symptoms.
  - Are you allowing visitors to accompany patients to their visits?
  - Are you allowing them to wait in the waiting room? Are there other patients in the same waiting room (well versus sick visits)
  - How are you cleaning in between patient visits?
  - How are you managing potential COVID patients?
  - Are there designated entry points?
  - Provide clear instructions so patients know what to expect.

What should sites consider to ensure readiness when opening their doors?

- Communicate and share with your sponsors and CROs how you are preparing for their safety:
  - Do you have monitoring space that is outside of a patient care area?
  - Are you able to manage remote monitoring visits?
  - Have you been seeing/treating COVID+ pts in your clinic?
  - Should you screen your CRAs before entry into the clinic?
  - Should the CRAs be required to wear PPE? Should you provide PPE if needed to your CRAs?
  - How are you sanitizing the monitoring areas?
  - What measures have you put into place that will reassure the CRAs that it's a safe environment for them to work?
  - For device trials, are you allowing vendors/proctors onsite? If so, are there restricted areas?
  - Develop restart guidelines and provide them in writing to sponsor reps, monitors and vendors

How can sites establish their competitive advantage?

Establishing your competitive advantage

1. Establish your credibility
2. Gather information from sponsor/CRO
3. Confirm your resources and ability to run study
4. Bring your own data to the table

Establishing your competitive advantage

1 Establish your credibility

Establish a baseline understanding of what is needed from the feasibility process:

- What feasibility means to sites vs. sponsors/CROs?
- What do sponsors/CROs care about?
- What is your history with this particular? Sponsor/CRO? Is it good, bad or indifferent?
- Make sure you understand the TA and indication.
- Show your professionalism and business acumen.
- What data do you have on the sponsor/CRO?

2 Gather information from sponsor/CRO

- Project nuances, timelines, key objectives and important milestones
- The monitoring plan
- Information about how much data will be collected or special data requirements
- Systems / tech/vendors involved and training requirements
- Communication cadence
- References from open sites (challenges they're facing)

3 Confirm your resources and ability

- PI availability, and commitment
- Research team expertise
- Access to the patient population
- Facilities and equipment
- Access to PPE and other supporting materials and ancillary services
- Access to additional or alternative facilities if needed.

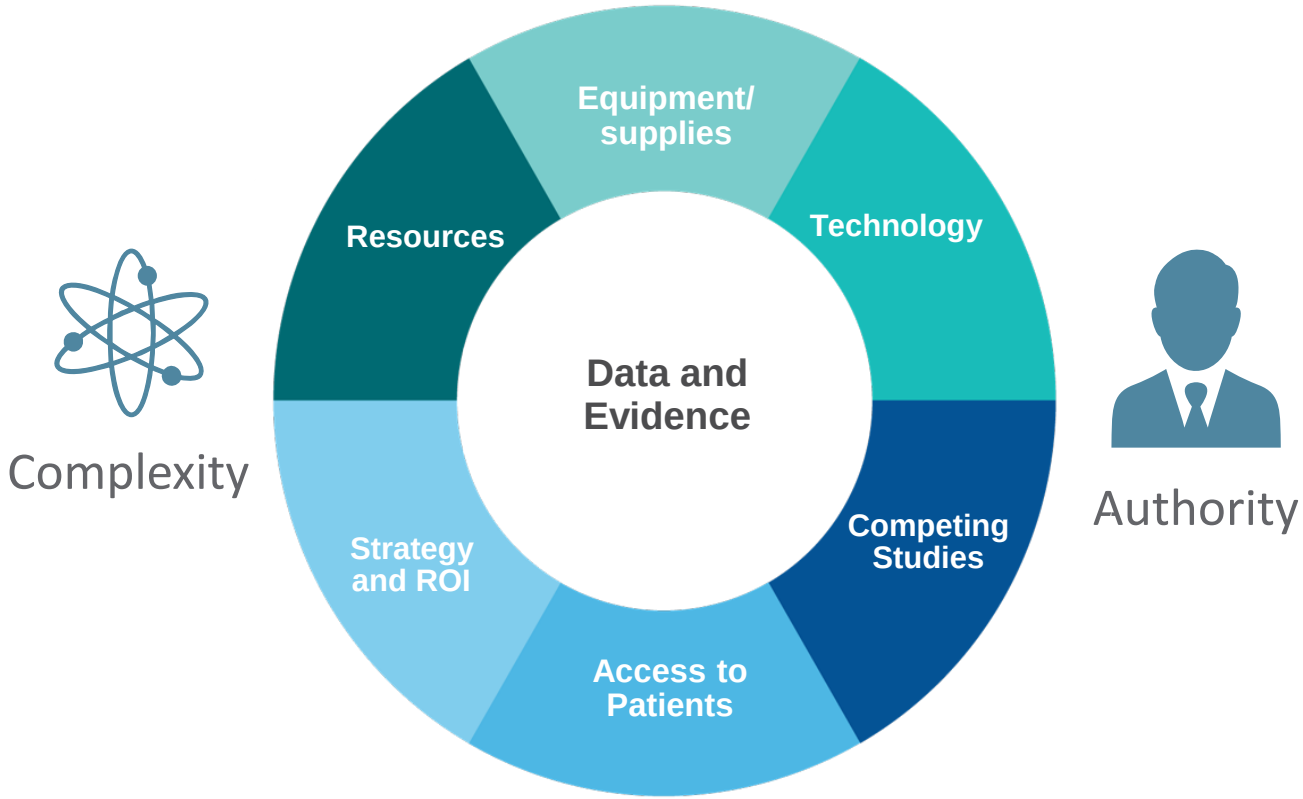
4 Bring your own data to the table

- What does the sponsor/CRO already know about you? Historical metrics:
  - Study history
  - Startup timelines
  - Recruitment
- Provide information above and beyond what they have/know
- Motivation to run the study
- Ways you're evolving to be more patient centric and leveraging technology

What are some best practices for determining which studies to accept?

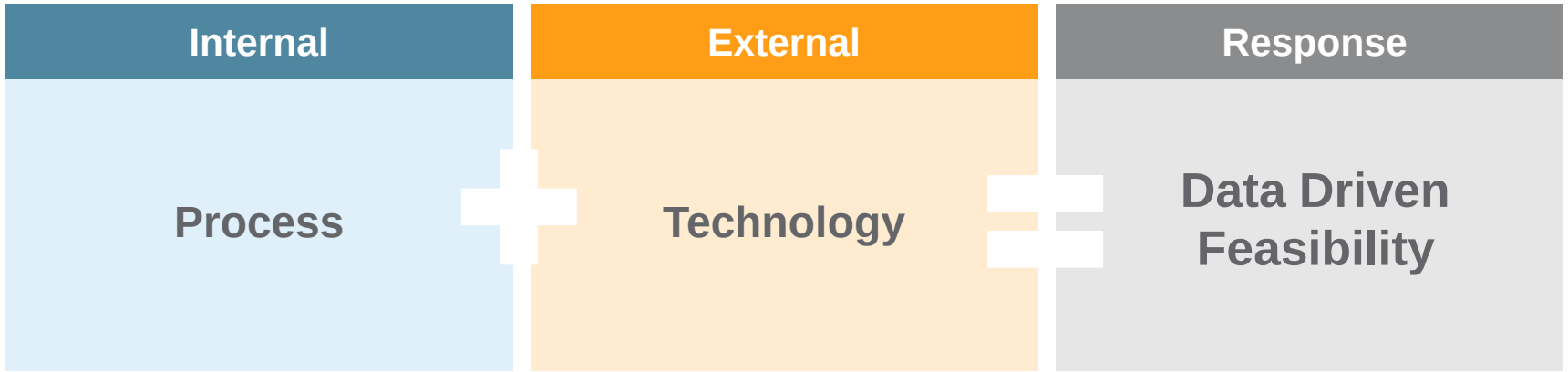
What are some best practices for determining which studies to accept?

Feasibility is a two-way street



What does the future of study feasibility look like and how can we expedite the process?

What does the future of study feasibility look like and how can we expedite the process?



- Protocol Specific Requirements
- Collect data to inform decisions
- Site Profiles
- Restart guidelines
- Feasibility Committee

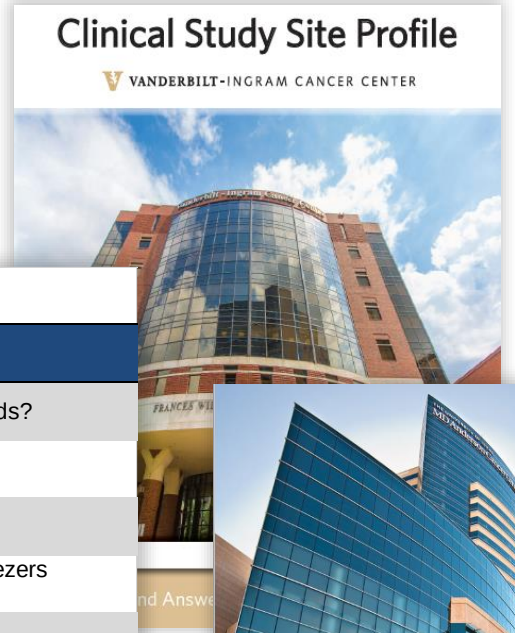
- Data on CROs and sponsors including key metrics
- Site profile databases
- Automate the process, reduce manual effort

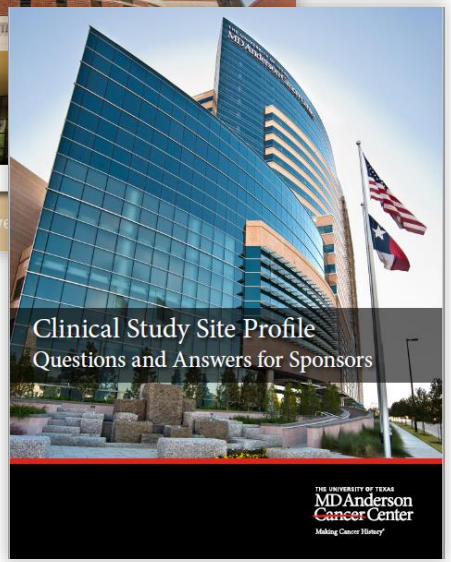
- Expedited timelines
- Less labor intensive
- Faster decision making

The Future of Feasibility: What can sites do to expedite the process?

Develop a Site Profile

- Eliminates the need to answer the same sponsor questions over and over
- Only complete study specific questions for sponsor questionnaires
- Create professional market collateral to gain credibility
- Use a data collection tool to track capabilities and provide valuable information to inform sponsors and internal team members

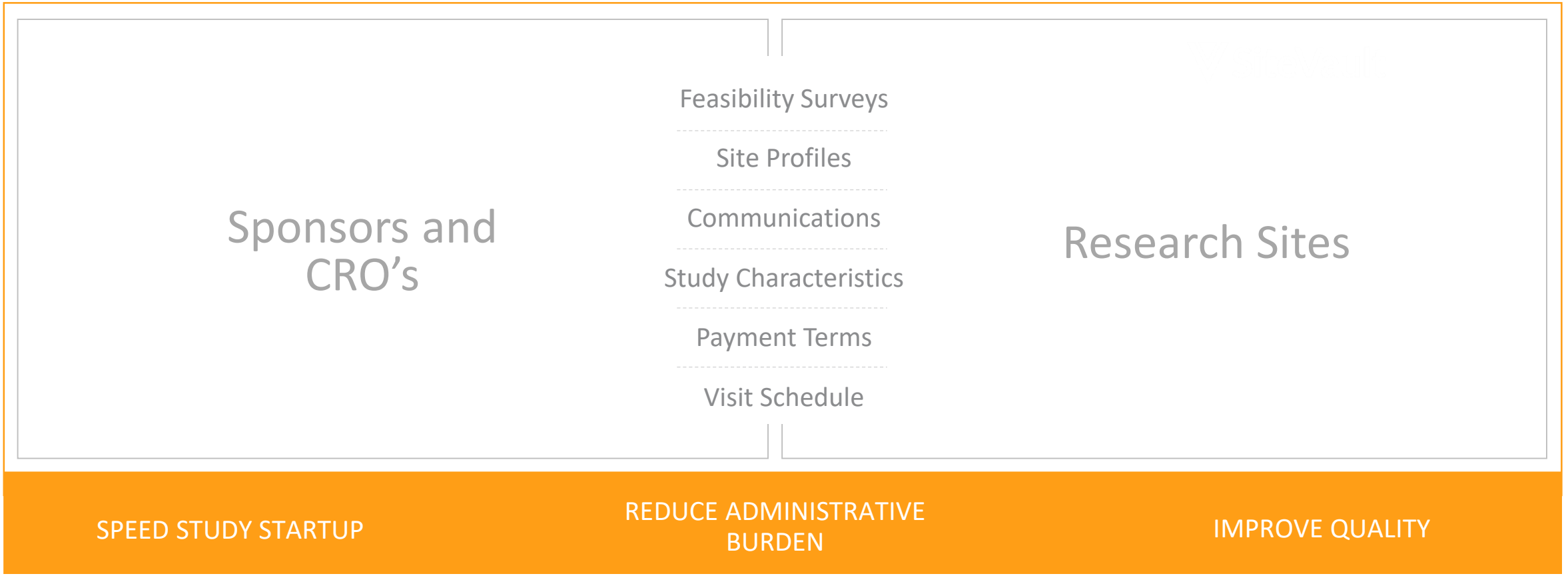




HURON	Site Profile Data Collection Tool
Category	**Question**
Computer and Internet	Are there written procedures for protection of the electronic records?
Contracts and Budgets	Do you have standard institutional administrative fees?
Department Specific	Is there prior site experience with use of an EDC system?
Facilities	Is a -70/-20 specimen storage freezer available? If so, are the freezers alarmed and monitored?
IRB/ Regulatory	Is the use of a central IRB permitted?
Participant Population	Do you have patients whose first language is not English?
Statistical Highlights	Total Active Clinical Protocols
Study Teams	Do your research study team members complete GCP training?

The Future of Feasibility

Connect sites and sponsor operations



Learn more during a webinar (https://bit.ly/Site-Sponsor) on June 23 at 12:00 p.m. EST

Additional Resources

Click to access each resource

On-demand recording

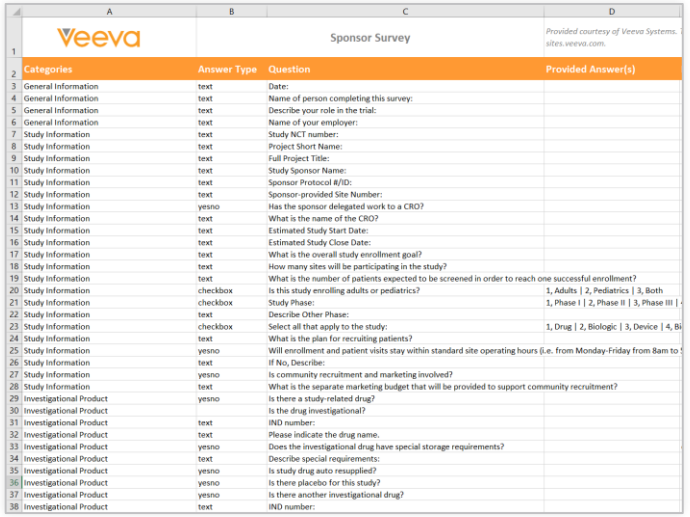
Site profile template

HURON — Site Profile Data Collection Tool

Provided courtesy of Huron Consulting Group. For more information on Site Profile development contact mruenich@huronconsultinggroup.com

Category	Question	Response	Resource / Contact	Status
Computer and Internet	Is there documentation that system users have been trained?			
Computer and Internet	Are there written procedures for protection of the electronic records?			
Computer and Internet	Does the system employ unique IDs and passwords for each user?			
Computer and Internet	Is there a historical electronic log that captures all users' actions?			
Computer and Internet	Are the computer's electronic records available for inspection and/or review?			
Computer and Internet	Are electronic signatures used in the system?			
Computer and Internet	If so, do system users who electronically sign records understand that they are essentially replacing their handwritten signature with the legally binding equivalent?			
Computer and Internet	Are sponsors or its designees allowed direct access to the electronic systems that contain source data?			
Computer and Internet	Are there multiple access ports for internet use?			
Computer and Internet	What Windows Operating System (OS) and Service Pack (SP) is used?			
Computer and Internet	What is the computer's processor speed?			
Computer and Internet	What is the computer's memory (RAM)?			
Computer and Internet	What is the monitor's display resolution?			
Computer and Internet	What is the Internet Explorer (IE) version?			
Computer and Internet	Are there CD-ROM drives?			
Computer and Internet	How do the computers connect to the internet?			
Computer and Internet	Are there monthly usage limitations for access to the internet?			
Computer and Internet	Is there internet security software installed on the computer?			
Computer and Internet	How are data back-ups handled?			
Computer and Internet	When changes are made to the system, is there repeat testing and documentation of this testing?			
Computer and Internet	Is a computer available for EDC data entry at all times throughout the whole term of the study?			

Sponsor Survey



Veeva — Sponsor Survey

Provided courtesy of Veeva Systems. sites.veeva.com

Categories	Answer Type	Question	Provided Answer(s)
General Information	text	Date:	
General Information	text	Name of person completing this survey:	
General Information	text	Describe your role in the trial:	
General Information	text	Name of your employer:	
Study Information	text	Study NCT number:	
Study Information	text	Project Short Name:	
Study Information	text	Full Project Title:	
Study Information	text	Study Sponsor Name:	
Study Information	text	Sponsor Protocol #/ID:	
Study Information	text	Sponsor-provided Site Number:	
Study Information	yesno	Has the sponsor delegated work to a CRO?	
Study Information	text	What is the name of the CRO?	
Study Information	text	Estimated Study Start Date:	
Study Information	text	Estimated Study Close Date:	
Study Information	text	What is the overall study enrollment goal?	
Study Information	text	How many sites will be participating in the study?	
Study Information	text	What is the number of patients expected to be screened in order to reach one successful enrollment?	
Study Information	checkbox	Is this study enrolling adults or pediatrics?	1, Adults | 2, Pediatrics | 3, Both
Study Information	checkbox	Study Phase:	1, Phase I | 2, Phase II | 3, Phase III |
Study Information	text	Describe Other Phase:	
Study Information	checkbox	Select all that apply to the study:	1, Drug | 2, Biologic | 3, Device | 4, Bi
Study Information	text	What is the plan for recruiting patients?	
Study Information	yesno	Will enrollment and patient visits stay within standard site operating hours (i.e. from Monday-Friday from 8am to	
Study Information	text	If No, Describe:	
Study Information	yesno	Is community recruitment and marketing involved?	
Study Information	text	What is the separate marketing budget that will be provided to support community recruitment?	
Investigational Product	yesno	Is there a study-related drug?	
Investigational Product		Is the drug investigational?	
Investigational Product	text	IND number:	
Investigational Product	text	Please indicate the drug name.	
Investigational Product	yesno	Does the investigational drug have special storage requirements?	
Investigational Product	text	Describe special requirements:	
Investigational Product	yesno	Is study drug auto resupplied?	
Investigational Product	yesno	Is there placebo for this study?	
Investigational Product	yesno	Is there another investigational drug?	
Investigational Product	text	IND number:	

List of questions to ask your sponsor

Questions?

Melissa Holbrook MSN, NP
Vice President, Operations
Velocity Clinical Research
Ph: 919-417-8384
mholbrook@velocityclinical.com
velocityclinical.com

Mindy Muenich
Senior Director
Huron Consulting Group
Ph: 513-207-0626
mmuenich@huronconsultinggroup.com
huronconsultinggroup.com

Bree Burks, MSN, RN
VP Strategy, Site Solutions
Veeva Systems
Bree.burks@Veeva.com
sites.veeva.com

Thank you