FRAMEWORK OF CHARACTERISTICS OF A QUALIFIED SITE TEAM: How Does Yours Measure Up?

The following framework of characteristics focuses on attributes that are within the control of investigators and their delegates,[1] and specifically those that they could modify through learning. Site infrastructure and resources, as well as protocol elements, are out of scope.[2]

This framework is not intended to serve as an all-inclusive checklist—it is designed to guide your gap analysis for a specific trial.

> **WHAT IS "QUALITY CONDUCT"?**
> The absence of errors that matter that is, errors that impact the safety of trial participants or the integrity of data (and consequently the care of future patients).

For sponsors and CROs: During protocol development and site evaluation, you should carefully evaluate how the characteristics are integrated and whether there are additional characteristics that arise from the trial's scientific and operational design or site and study participant requirements. We encourage you to freely adapt this framework to meet the unique needs of the site team and the protocol under consideration.

For site teams: You can use this tool to evaluate your general preparedness for any trial and identify any learning and training needs your investigators and delegates may have.

ABOUT THIS FRAMEWORK	
Who?	Site teams, sponsors, and contract research organizations (CROs)
What?	Gap analysis tool
When?	When assessing whether investigators and their delegates are qualified to conduct a particular trial
Where?	▶ At the site, by the site team; ▶ At the sponsor/CRO; and/or ▶ At the site, collaboratively, by the investigator in partnership with the clinical research associate (CRA)
Why?	▶ To assess a site team's current level of preparedness to conduct a particular protocol; and ▶ To identify • Knowledge and skills gaps
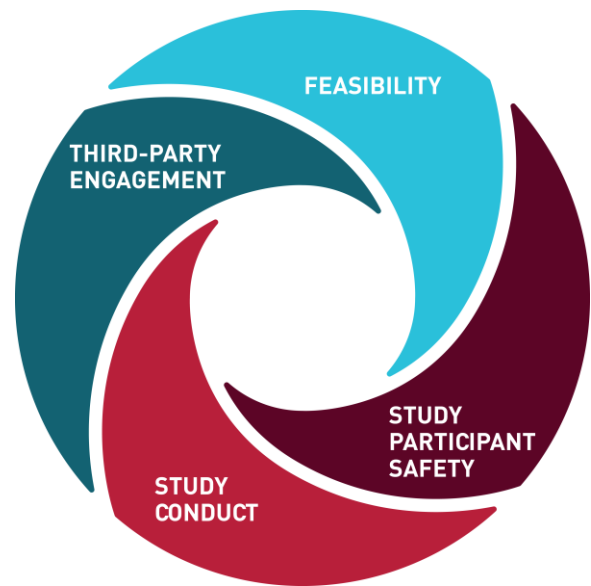
This framework is organized using the relevant categories of "critical to quality factors" as defined in CTTI's Quality by Design Principles Document.

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[1] For the purposes of this document, "delegates" are defined as both those individuals listed on the delegation of authority log and any additional individuals making material decisions about trial conduct.

[2] For recommendations on site infrastructure and resources, see CTTI's Investigator Community recommendations. For recommendations on developing high-quality protocols, see CTTI's Quality by Design resources.

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	• Learning/training needs

FEASIBILITY:

Is it possible for your site team to carry out the clinical trial operations?

Does your site team have the skills and experience to:

▶ Assess the learning requirements for the protocol?
▶ Assess the clinical relevance of a study protocol for your specific study participant population?
▶ Review case report form (CRF) design to assess requirements for data recording?
▶ Evaluate the likelihood of the recruitment commitment in the available study participant population?
▶ Develop a recruitment plan with achievable and measurable targets?
▶ Identify recruitment barriers and recommend and implement solutions?
▶ Assess whether there is sufficient staffing to manage the workload?
▶ Apply corrective and preventive actions (CAPA) from findings and observations?
▶ Obtain and maintain regulatory approval?

Does your site team have the knowledge and understanding to:

▶ Apply scientific research principles (e.g., identifying the primary endpoint) to study conduct?
▶ Provide expertise for the therapeutic area and study phase?
▶ Understand and uphold principles of research integrity?
▶ Integrate the objectives of Good Clinical Practice into the study procedures?
▶ Conduct a dry run of the protocol (i.e., walk through study procedures)?

Does your site team have the capacity and resources to:

▶ Evaluate and secure the staffing mix needed for a given protocol?
▶ Define clear roles and responsibilities for all positions?
▶ Manage potential conflicts of interest, bias, unblinding, etc.?
▶ Allocate dedicated time for team members to complete their assigned duties?
▶ Provide orientation and training for new staff?

Are the following part of your site team's culture?

▶ A strong belief in the value and importance of the research endeavor?
▶ Evaluate activities that put the study participant first?
▶ Physician-investigators committed to engaging with site teams and participants?
▶ Open, transparent communication and a cooperative environment that fosters knowledge sharing between team members?

- ▶ To learn from mistakes and to value and support process improvement?
- ▶ To encourage and support the continuous learning and growth of site personnel?
- ▶ Ethical conduct with a focus on study participant safety, quality data, and excellence?

STUDY PARTICIPANT SAFETY:
Is your site team prepared to ensure the safety of clinical trial participants?

Does your site team have the skills and experience to:

- ▶ Effectively and consistently communicate in advance of and throughout the consent process?
- ▶ Maintain communication with participants before, during, and after the study?
- ▶ Disseminate new information to participants in a timely manner?
- ▶ Prioritize engagement with participants to minimize and prevent participants who are "lost to follow-up"?
- ▶ Continually educate participants on protocol compliance and safety measures?
- ▶ Facilitate contact with participants for reporting of adverse events (AEs) / serious adverse events (SAEs)?
- ▶ Keep clear and effective communication with the sponsor, CRO, vendors, IRB, and participants?

Does your site team have the knowledge and understanding to:

- ▶ Detect safety issues and emerging concerns?
- ▶ Submit safety reports in accordance with regulatory requirements?
- ▶ Understand the safety profile of the investigational medical product (IMP) and how to implement the required safety measures?

Does your site team have the knowledge and understanding to:

- ▶ A standard operating procedure (SOP) to outline your site's consent process?
- ▶ Continuous physician oversight to recognize the criteria for stopping the investigational product?
- ▶ A program for ongoing safety reviews?
- ▶ Continuous AE / SAE reconciliation?
- ▶ Timely physician review, evaluation, and oversight for safety events?
- ▶ Dedicated time for staff education on safety events and their impact?
- ▶ An established process for working with a data monitoring committee?

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STUDY CONDUCT:

Is your site team qualified by training and experience for the quality conduct of a clinical trial?

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Does your site team have the skills and experience to:

▶ Implement the protocol, record the outcomes, and conduct the procedures?
▶ Adhere to the protocol with minimal deviations?
▶ Identify critical data for study outcomes and establish priorities?
▶ Conduct data monitoring and management?
▶ Establish and measure site team performance against key performance indicators (KPIs) and key quality indicators (KQIs) aligned with the trial objectives?
▶ Optimize consent processes and enrollment, time to enrollment, and absence of selection bias?
▶ Institute rapid corrective and preventive action for continuous improvement throughout trial conduct?
▶ Create an accurate and useable study process map?

Does your site team have the capacity and resources to:

▶ Enact escalation and corrective and preventive action (CAPA) processes?
▶ Complete and maintain the investigator site file (ISF)?
▶ Complete CRFs in a timely and accurate manner?
▶ Provide timely resolution of monitoring visit findings and queries?
▶ Complete process improvement?
▶ Assess the need for staff training to minimize errors and data queries?

Does your site team have the organization and infrastructure to:

▶ Optimize screening with timely and accurate identification of eligible study participants?
▶ Handle laboratory specimens for collection, preparation, and shipment?
▶ Improve participant retention and recover participants who are "lost to follow-up"?
▶ Maintain an organized system for visit scheduling and follow-up?
▶ Provide timely and quality data recording?

THIRD PARTY ENGAGEMENT:

Is your site team qualified to engage third parties as necessary for the quality

Does your study team have skills and experience in place to:

- ► Evaluate available data on prior performance by the third party or its business that might inform decision-making about whether to use a particular vendor?
- ► Define the nature of the contractual relationship with the sponsor regarding critical to quality activities when working to engage a third-party?
- ► Identify how roles will be clearly defined, such that clinical investigators and site staff know with whom they need to interact and when?
- ► Complete timely resolution of monitoring findings (immediate resolution for urgent safety findings)?
- ► Review and resolve data queries to maximize data quality between monitoring visits?

Does your study team have organization and infrastructure in place to:

- ► Maintain clear and effective lines of communication with the sponsor, CRO, IRB, and study-specific vendors?
- ► Create SOPs for interacting with / engaging third parties, including CROs, academic research organizations (AROs), and other study-specific vendors?
- ► Maintain a state of site readiness for onsite / remote monitoring visits?
- ► Address audit findings?
- ► Clearly define and accept the roles and responsibilities for allied personnel, departments, and third parties?