CTTI Questionnaire >> Welcome >> Introduction

The **Clinical Trials Transformation Initiative (CTTI)** is a public–private partnership with a mission to identify practices that through broad adoption will increase the quality and efficiency of clinical trials. To this end, we are conducting collaborative projects to generate empirical information about how clinical research is currently conducted and to identify ways to improve quality and efficiency. CTTI members represent a range of stakeholders from government, industry, patient and consumer organizations, investigator groups, academia, and other interested parties. More detailed information about CTTI may be found at www.trialstransformation.org/.

This survey is part of a project designed to identify best practices for monitoring clinical trials and to provide sensible criteria to help sponsors select the most appropriate monitoring methods over a range of clinical trial settings. The results of this project may significantly influence the field of clinical research both by improving trial quality and by optimizing the use of resources.

Your organization's feedback will be very helpful in providing insights regarding current monitoring practices and/or key quality objectives of clinical research monitoring. If your organization performs clinical research, the person completing the survey will be asked questions about your organization's selection of monitoring strategies and the rationale for such choices for the 'typical' type of clinical trial conducted by your organization. Regardless of whether your organization performs clinical research, questions will be posed concerning your organization's view of the high-level quality objectives of monitoring in clinical research. The survey may take between 10 and 30 minutes to complete.

The feedback you provide will be kept confidential. Once you complete the survey, your user-id will be stripped from the survey and all further use will be anonymous. We thank you in advance for your consideration, your time, and your valuable input.

Note: For questions that have response options of:

Always / Frequently / Occasionally / Never / Not Applicable (NA) / Not Sure

The following definitions apply: Frequently = 50+% of the time; Occasionally = <50% of the time.

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CTTI Questionnaire >> Confidentiality

There will be no identifying information accompanying your organization's response and the feedback your organization provides will be aggregated with that from others for analysis. If additional questions remain after the responses have been analyzed, we may issue a second questionnaire to obtain clarity on specific subjects. The collective results of the questionnaire(s) will be made public after all responses have been collected and analyzed.

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CTTI Questionnaire >> General Questions >> Organization Demographics

1. **Which of the following best describes your organization (select one)?**

   a. ◉ Industry:

   - Select -

   b. ○ Contract Research Organization (CRO):

   - Select -

   c. ○ Government:

      i. National Institutes of Health

      - Select -

         I. Specify Institute/Center

         - Select -

         Specify division/branch:

      ii. Veterans Administration

      Specify program:

      iii. Department of Defense

      Specify program:

      iv. US Food and Drug Administration

      Specify Division/Center/Office:

      v. International Regulatory Agency

      Specify program:

      vi. Other

      Specify program:

   d. ○ Academic

☐ Study or Data Coordinating Center for Clinical Research

☐ Clinical Research Site

e. ○ Non-Profit

☐ Professional Society

☐ Foundation

☐ Patient/Advocacy Group

☐ Other

f. ○ Cooperative Group / Consortium

Specify (optional): [ ]

g. ○ Investigational Site

Specify (optional): [ ]

h. ○ Institutional Review Board

Specify (optional): [ ]

i. ○ Patient / study participant advocate

Specify (optional): [ ]

j. ○ Other

Specify (optional): [ ]

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CTTI Questionnaire >> General Questions >> Clinical Trial Types

1. **Does your organization perform clinical trials?**

   - (•) Yes
   - ( ) No

2. ---

   1. **Types of clinical trials that your organization is/has been involved with (check all that apply):**

      a. What is the most common type of clinical trial that your organization conducts? *
      (Please answer only one question and provide all future responses with this type of trial as a point of reference).

      - ( ) Phase I / Feasibility
      - ( ) Phase II
      - ( ) Phase III / Pivotal
      - ( ) Phase IV/ Post Marketing
      - ( ) non-IND/IDE Studies
      - ( ) Other

      If other: Specify _____

      b. Does your organization perform device clinical trials (check all that apply):

      - [ ] No
      - [ ] Investigational Device Exemption Significant Risk
      - [ ] Investigational Device Exemption Non-Significant Risk
      - [ ] Post Market Surveillance
      - [ ] Exempt
      - [ ] Other

      c. If other: Specify _____

      d. Does your organization perform special types of studies (check all that apply):

☐ No

☐ Surgical approaches and techniques

☐ Psychological and behavioral interventions

☐ Other

☐ Dietary and lifestyle interventions

e. If other: Specify

2. **What size trials does your organization typically conduct?**
Number of sites *

☐ < 15

☐ 50 - 99

☐ > 200

☐ 15 - 49

☐ 100 - 199

3. Size of trials (number of subjects) *

☐ < 100

☐ 500 - 1499

☐ 5000 - 9999

☐ 100 - 499

☐ 1500 - 4999

☐ > 10,000

4. **Does your organization conduct clinical trials internationally?**

○ Yes

○ No

5. **Is the rationale for your organization's site monitoring program for clinical trials based on (check all that apply):**

☐ Regulatory requirements

☐ Standard Operating Procedures (SOPs)

☐ Validated processes/metrics

☐ Other

6. If other: Specify

7. **Does your organization have a staffed Quality Assurance (QA) department overseeing your organization’s clinical trial program?**

○ Yes

○ No

8. **Survey responder – organization level:** - Select -

If other: Specify group/association

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CTTI Questionnaire >> Trial Oversight & Governance

Does your organization put in place the following trial oversight and governance committees:	Always	Frequently	Occasionally	Never	NA	Not Sure
Independent data and safety monitoring board (DSMB or DMC)?	○	○	○	○	○	○
If always / frequently / occasionally,						
• Are the Chairpersons independent of both the funder and the organizations responsible for all other aspects of the conduct of the trial?	○	○	○	○	○	○
• Are the committee members independent of both the funder and the organizations responsible for all other aspects of the conduct of the trial?	○	○	○	○	○	○
Trial Steering Committee?	○	○	○	○	○	○
If always / frequently / occasionally,						
• Are the Chairpersons independent of both the funder and the organizations responsible for all other aspects of the conduct of the trial?	○	○	○	○	○	○
• Are the committee members independent of both the funder and the organizations responsible for all other aspects of the conduct of the trial?	○	○	○	○	○	○
Outcome / Endpoint Adjudication Committee?	○	○	○	○	○	○
Writing Committee?	○	○	○	○	○	○
Trial Management Committee?	○	○	○	○	○	○
If other type of committee: specify						

Please describe the rationale for your organization's decision to establish the oversight committee(s) noted and describe how this decision affects your organization's monitoring plan:

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CTTI Questionnaire >> Monitoring Plans >> Risk Assessment

1. **Does your organization**
   - Conduct an assessment of risk prior to developing a monitoring plan for each protocol?
     - (•) Yes
     - ( ) No
     - ( ) Sometimes
   - If yes or sometimes, does your organization consider the following to be important determinants of risk?
   - Factors that might affect the rights, safety and wellbeing of trial participants:

	Always	Frequently	Occasionally	Never	NA	Not Sure
Ability to obtain informed, written consent	( )	( )	( )	( )	( )	( )
Ability to maintain ongoing communication with participants	( )	( )	( )	( )	( )	( )
Nature and knowledge of the investigational product	( )	( )	( )	( )	( )	( )
Nature of assessment methods	( )	( )	( )	( )	( )	( )

   - Factors that might affect the reliability of the trial results:

	Always	Frequently	Occasionally	Never	NA	Not Sure
Target number of participants	( )	( )	( )	( )	( )	( )
Number of sites involved	( )	( )	( )	( )	( )	( )
Geographic location of sites	( )	( )	( )	( )	( )	( )
Protocol complexity	( )	( )	( )	( )	( )	( )
Assessment of inclusion criteria	( )	( )	( )	( )	( )	( )

Assessment of exclusion criteria						
Robustness of randomization process						
Compliance with trial intervention						
Completeness of follow-up						
Nature and assessment of key efficacy outcomes						
Completeness & accuracy of data						
Potential for, and likely impact of, fraud						

-
- Factors that relate to the type of trial:

	Always	**Frequently**	**Occasionally**	**Never**	**NA**	**Not Sure**
Type of submission to regulatory agency						
Phase of study						
Pivotal study						

- What particular risks does your organization feel are most important to mitigate or eliminate via a monitoring plan? (optional)

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CTTI Questionnaire >> Monitoring Plans >> Monitoring Plan Development

1. **Does your organization**	**Always**	**Frequently**	**Occasionally**	**Never**	**NA**	**Not Sure**
Create a unique Site Monitoring Plan for each protocol?	○	○	○	○	○	○
Have a required template for all Site Monitoring Plans?	○	○	○	○	○	○
Involve the site investigator(s) in developing the Site Monitoring Plan?	○	○	○	○	○	○
Have an established definition for protocol deviation and/or violation?	○	○	○	○	○	○
Create a unique Safety Monitoring Plan for each protocol?	○	○	○	○	○	○
Have a required template for the Safety Monitoring Plan?	○	○	○	○	○	○
Create a Quality Assurance Plan per protocol?	○	○	○	○	○	○

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CTTI Questionnaire >> Remote Monitoring >> Remote Monitoring Methods

1. **Does your organization perform periodic site contacts via teleconference?**
   - Yes
   - No
2. **Is there a tracking/reminder system for expected CRFs?**
   - Yes
   - No
3. **Does your organization perform data review and evaluate site performance using centrally available data?**
   - Yes
   - No

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CTTI Questionnaire >> Remote Monitoring >> Centralized Monitoring of Data

1. **Does your organization use a centralized data monitoring process**	**Always**	**Frequently**	**Occasionally**	**Never**	**NA**	**Not Sure**
To guide, target or supplement site visits? or	○	○	○	○	○	○
To completely replace onsite visits?	○	○	○	○	○	○

	Always	**Frequently**	**Occasionally**	**Never**	**NA**	**Not Sure**
2. **Does your organization conduct periodic audits of a sample of sites?**	○	○	○	○	○	○

3. **Which of the following factors would be likely to trigger a site monitoring visit?**

Select all that apply: ☐ None

☐ Number of protocol deviations
☐ Number of data queries
☐ Screen failure rate
☐ Incidence of adverse events
☐ Number of unanswered queries
☐ Laboratory data signals
☐ Suspected fraud
☐ Rate of enrollment
☐ Lack of experience with the site
☐ Missing CRFs
☐ Subject dropout rate
☐ Geographic location of site
☐ Other

Other, specify:

Please describe your organization's rationale for conducting centralized data monitoring:

4. **What analyses of centralized data does your organization use to trigger a site monitoring visit?:**

Select all that apply:

☐ Missing data (e.g. data points, case report forms, laboratory samples, investigations)
☐ Plausibility checks (e.g. range checks)

- [ ] Simple descriptive statistics (e.g. mean, frequency)
- [ ] More complex statistics (e.g. sd, skewness, kurtosis, correlations)
- [ ] Multivariate risk assessment (e.g. risk score)

5. **What types of data does your organization use to trigger a site monitoring visit?:**
Select all that apply:

- [ ] Case report form data
- [ ] Laboratory data
- [ ] Data relating to performance (e.g. time of day, duration, sequencing of study activities)
- [ ] External datasets (e.g. national death register, prescribing data, episode or claims data)

6. **How does your organization use centrally available data to assess:**

- Protocol compliance:
- Safety reporting:
- Investigational agent accountability:
- Sampling and material logistics (e.g. specimen collection. storage, and shipment):

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CTTI Questionnaire >> Site Monitoring Visits >> Onsite Monitoring Visits

	Always	Frequently	Occasionally	Never	NA	Not Sure
1. **Does your organization perform onsite monitoring visits?**	○	○	○	○	○	○

- The frequency of your organization's onsite monitoring visits is most commonly determined by: (Select all that apply)

☐ Budget
☐ Usual practice of your organization
☐ Critical study requirement/procedure
☐ Study design
☐ Pre-defined analyses of potential risks
☐ Study population
☐ Monitoring plan specified in protocol
☐ SOPs
☐ Other

- If other, specify: _____

	Always	Frequently	Occasionally	Never	NA	Not Sure
2. **Is there a minimum frequency of site monitoring visits for a study?**	○	○	○	○	○	○

- What is the minimum frequency?

○ Anually
○ 2-3 times annually
○ 4-6 times annually (every 8-12 weeks)
○ 7-11 times annually (every 4-6 weeks)
○ Once per month
○ Once per week
○ Other

If other, Specify: _____

3. **What is the typical frequency of site monitoring visits for a study?**

○ Anually
○ 2-3 times annually
○ 4-6 times annually (every 8-12 weeks)

- 7-11 times annually (every 4-6 weeks)
- Once per month
- Once per week
- Other

If other, specify:

	Always	Frequently	Occasionally	Never	NA	Not Sure
4. **Does your organization perform onsite monitoring visits for only a subset of sites involved in a study?**						

- What percentage?
  - 1-25%
  - 26-50%
  - 51-75%
  - > 75%
- Please describe the criteria used to select sites for an onsite monitoring visit

	Always	Frequently	Occasionally	Never	NA	Not Sure
5. **Does your organization require a site monitoring visit within 28 days of the first subject being enrolled at a site?**						

- How soon after enrollment?
  - 1-3 days;
  - 4-7 days;
  - 8-14 days;
  - > 14 days

6. **Please describe the rationale for your organization's on-site monitoring visit strategy:**

7. **Please describe any other monitoring technique or combination of monitoring techniques that your organization's have found to be particularly effective and efficient:**

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CTTI Questionnaire >> Site Monitoring Visits >> Consent and Information

1. **Does your organization assess**	**Always**	**Frequently**	**Occasionally**	**Never**	**NA**	**Not Sure**
Study staff's understanding of the trial protocol and procedures?	○	○	○	○	○	○
The ability of study staff to adequately explain the trial to participants?	○	○	○	○	○	○
The subjects' understanding of the trial?	○	○	○	○	○	○
• If always / frequently / occasionally, does your organization require documented confirmation (in addition to the subject's signature) of a subject's understanding of a protocol informed consent form?	○	○	○	○	○	○
• If always / frequently / occasionally, is formal testing of subjects by sites required?	○	○	○	○	○	○
The adequacy and timeliness of additional information provided to participants during the course of the trial (e.g. updates to knowledge about the disease or intervention that might alter the risk-benefit profile)?	○	○	○	○	○	○

2. **Please describe the rationale for your organization's assessment of consent and provision of information to participants (optional):**

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CTTI Questionnaire >> Site Monitoring Visits >> Source Data Verification

	Always	Frequently	Occasionally	Never	NA	Not Sure
Does your organization verify CRF data vs. source data (Source data are contained in source documents, e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, x-rays).	○	○	○	○	○	○

- **If Always/Frequently/Occasionally:**

What proportion of each of the following does your organization verify? For each of the following record (None / 1-25%, 26-75%, 75-99%, All)	**None**	**1-25%**	**26-75%**	**76-99%**	**100%**
Consent Form	○	○	○	○	○
Eligibility criteria	○	○	○	○	○
Primary endpoint reports	○	○	○	○	○
Secondary endpoint reports	○	○	○	○	○
Serious adverse event reports	○	○	○	○	○
Non-serious adverse event reports	○	○	○	○	○

- **If Always/Frequently/Occasionally:**
  How does your organization select the subjects for whom CRF data must be verified? (Check all that apply)
  - ☐ All participants
  - ☐ A pre-defined set (e.g., first 2 subjects)
    - Please describe:
  - ☐ A random sample of subjects
    - What percentage of subjects are targeted?

- 1-10%
- 11-25%
- 26-50%
- 51-75%
- > 75%

Please describe the rationale for the determination of your organization's source data verification strategy:

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CTTI Questionnaire >> Site Monitoring Visits >> Identity and Privacy

1. **Does your organization**	**Always**	**Frequently**	**Occasionally**	**Never**	**NA**	**Not Sure**
Require that the investigational sites maintain evidence of subjects' identification verification (e.g. photo ID)?	○	○	○	○	○	○
Assess the security of the study data and documentation?	○	○	○	○	○	○
Assess the security of data that might identify the subjects?	○	○	○	○	○	○

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CTTI Questionnaire >> Site Monitoring Visits >> Site Facilities

1. **Does your organization verify, in an ongoing manner, the adequacy of**	**Always**	**Frequently**	**Occasionally**	**Never**	**NA**	**Not Sure**
Protocol-required facilities and equipment?	○	○	○	○	○	○
Site staff (resources and training)?	○	○	○	○	○	○
Investigational product storage and control?	○	○	○	○	○	○

2. **Please describe the rationale for conducting your organization's evaluation of site facilities:**

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CTTI Questionnaire >> Site Monitoring Visits >> Procedures

1. **Does your organization verify**	**Always**	**Frequently**	**Occasionally**	**Never**	**NA**	**Not Sure**
Compliance with randomization procedures?	○	○	○	○	○	○
Maintenance of investigational product blinding (if applicable)?	○	○	○	○	○	○
Compliance with the study intervention?	○	○	○	○	○	○
Investigational product reconciliation?	○	○	○	○	○	○

2. **Please describe the rationale for conducting your organization's evaluation of procedures:**

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CTTI Questionnaire >> Site Monitoring Visits >> Regulatory Documentation

1. **Does your organization**	**Always**	**Frequently**	**Occasionally**	**Never**	**NA**	**Not Sure**
Confirm site informed consent forms are updated/modified when necessary (e.g. protocol changes, new approved treatments for trial indication, etc.)?	○	○	○	○	○	○
Back-translate translated site informed consent forms (ICF) to confirm translated ICFs are complete and adequate?	○	○	○	○	○	○
Perform onsite verification of required regulatory documents and communications?	○	○	○	○	○	○

2. **Please describe the rationale for your organization's oversight of consenting procedures:**

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CTTI Questionnaire >> Site Monitoring Visits >> Investigator responsibilities

	Always	Frequently	Occasionally	Never	NA	Not Sure
1. **Does your organization verify evidence of investigator oversight/involvement in trial-related procedures**	○	○	○	○	○	○

- **If always / frequently / occasionally, by what means (check all that apply):**

  - ☐ Note on patient chart
  - ☐ Signature on CRFs
  - ☐ Site Staff Meeting Minutes
  - ☐ Other

- Other, specify:

	Always	Frequently	Occasionally	Never	NA	Not Sure
2. **Does your organization confirm documentation of appropriate delegation of trial-related responsibilities to site staff?**	○	○	○	○	○	○

- **If always / frequently / occasionally, by what means and is this done before the trial has been initiated: (specify)**

	Always	Frequently	Occasionally	Never	NA	Not Sure
3. **Does your organization confirm the trial-related responsibilities were delegated to**	○	○	○	○	○	○

appropriately credentialed staff?	

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CTTI Questionnaire >> Trial Monitors >> Monitor Selection and Training

1. **What is the minimum level of education that your organization's monitors are required to have achieved?**

- Select -

If other, specify:

	Always	Frequently	Occasionally	Never	NA	Not Sure
2. **Does your organization require that your monitors have a minimum amount of experience?**	○	○	○	○	○	○

If always / frequently / occasionally, specify the minimum:

- Select -

If other, specify:

3. **Does your organization require that your monitors have:**	Always	Frequently	Occasionally	Never	NA	Not Sure
Experience in the disease area under investigation?	○	○	○	○	○	○
Continuing education in clinical research/monitoring?	○	○	○	○	○	○

4. **Does your organization provide training for monitors in the following areas?**

- ☐ monitoring process
- ☐ protocol procedure training
- ☐ GCP/Regulatory
- ☐ disease under investigation

	Always	Frequently	Occasionally	Never	NA	Not Sure
5. **Does your organization assess the skills and performance of monitors via periodic onsite evaluation by a third party (e.g. manager) during the monitoring visit(s)?**	○	○	○	○	○	○

	Always	Frequently	Occasionally	Never	NA	Not Sure
6. **Does your organization have quality indicators to assess the quality of monitoring being performed?**	○	○	○	○	○	○

If always / frequently / occasionally, specify:

7. **Please describe the rationale for conducting your organization's monitor selection/training:**

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	Always	Frequently	Occasionally	Never	NA	Not Sure
1. **Does your organization perform independent audits of trial sites using auditors from outside of your monitoring department?**	○	○	○	○	○	○

If Always / Frequently / Occasionally	**Always**	**Frequently**	**Occasionally**	**Never**	**NA**	**Not Sure**
Is there an audit plan?	○	○	○	○	○	○
Are audits performed during the trial?	○	○	○	○	○	○
Are audits performed at the end of the trial?	○	○	○	○	○	○
Are audits performed at random?	○	○	○	○	○	○
Are audits performed for cause?	○	○	○	○	○	○

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1. **What has your organization stated are the most important factors impacting site quality?**
   Specify:

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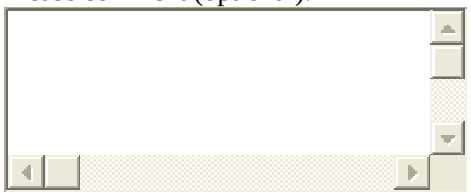
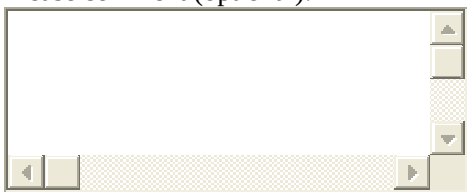
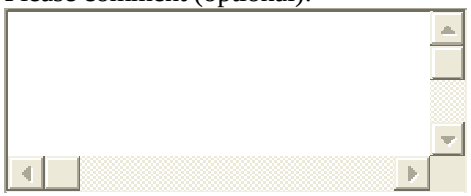
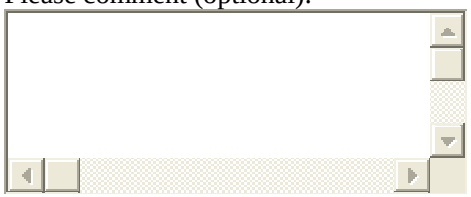
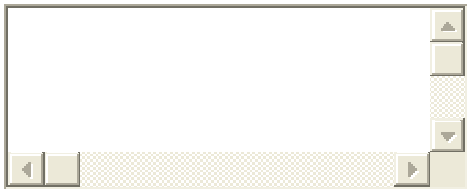
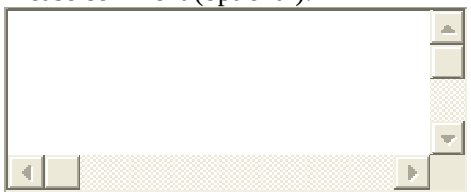
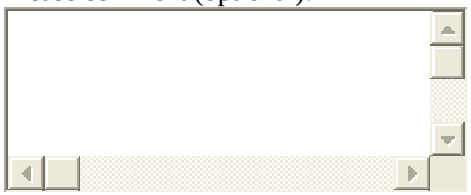
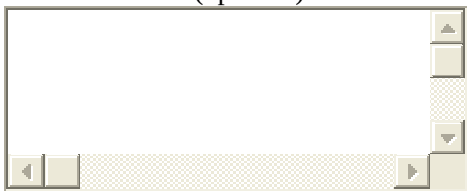
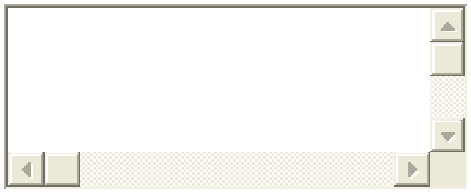
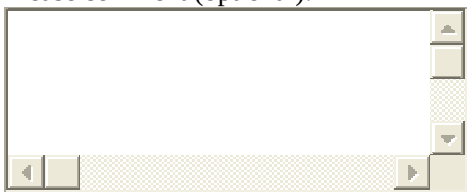
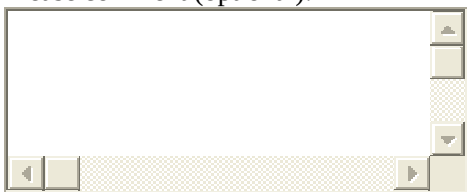
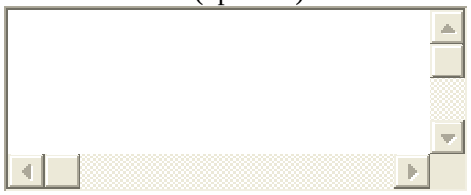
CTTI Questionnaire >> Monitoring Objectives

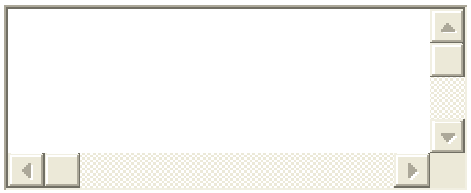
Please indicate what your organization has stated about the importance of the following quality objectives with respect to monitoring clinical trials.
Please provide additional comments as appropriate

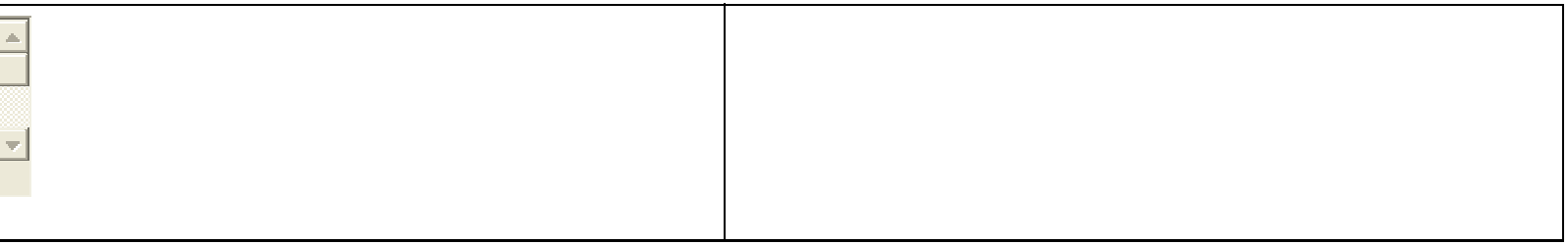
Adequate protection of the rights of human subjects Please comment (optional):	○ Very Important	○ Important	○ Moderately Important	○ Of Little Importance	○ Unimportant
Subjects adequately informed about the trial Please comment (optional):	○ Very Important	○ Important	○ Moderately Important	○ Of Little Importance	○ Unimportant
Written consent obtained from subjects Please comment (optional):	○ Very Important	○ Important	○ Moderately Important	○ Of Little Importance	○ Unimportant
Assuring the protection of subject safety Please comment (optional):	○ Very Important	○ Important	○ Moderately Important	○ Of Little Importance	○ Unimportant

Maintenance of confidentiality and privacy of human subjects Please comment (optional): 	○ Very Important	○ Important	○ Moderately Important	○ Of Little Importance	○ Unimportant
Few or no protocol violations (adherence to the protocol) Please comment (optional): 	○ Very Important	○ Important	○ Moderately Important	○ Of Little Importance	○ Unimportant
Identification and documentation of deviations from protocol or investigational plan Please comment (optional): 	○ Very Important	○ Important	○ Moderately Important	○ Of Little Importance	○ Unimportant
Selection of qualified clinical investigators who have experience with the intervention or condition Please comment (optional): 	○ Very Important	○ Important	○ Moderately Important	○ Of Little Importance	○ Unimportant
Assurance that required documentation is obtained from participating investigators (e.g. CV, financial disclosure, regulatory documentation) Please comment (optional):	○ Very Important	○ Important	○ Moderately Important	○ Of Little Importance	○ Unimportant

	
Assurance that the clinical investigator and staff are appropriately trained on protocol or investigational plan Please comment (optional): 	○ Very Important ○ Important ○ Moderately Important ○ Of Little Importance ○ Unimportant
Few or no data errors on key efficacy data? Please comment (optional): 	○ Very Important ○ Important ○ Moderately Important ○ Of Little Importance ○ Unimportant
Few or no data errors on safety data? Please comment (optional): 	○ Very Important ○ Important ○ Moderately Important ○ Of Little Importance ○ Unimportant
Few or no data errors on non-key data? Please comment (optional):	○ Very Important ○ Important ○ Moderately Important ○ Of Little Importance ○ Unimportant

	
Appropriate documentation of adverse events where there is a reasonable possibility that the event may have been caused by the medical product? Please comment (optional): 	○ Very Important ○ Important ○ Moderately Important ○ Of Little Importance ○ Unimportant
Investigational product accountability Please comment (optional): 	○ Very Important ○ Important ○ Moderately Important ○ Of Little Importance ○ Unimportant
Identification of fraud or misconduct Please comment (optional): 	○ Very Important ○ Important ○ Moderately Important ○ Of Little Importance ○ Unimportant
Accurate, complete, and timely maintenance of study records Please comment (optional):	○ Very Important ○ Important ○ Moderately Important ○ Of Little Importance ○ Unimportant





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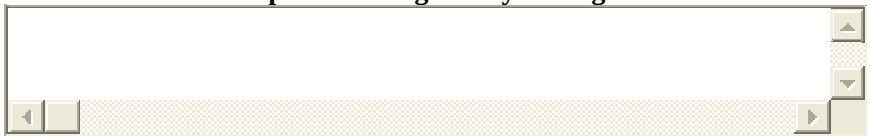
CTTI Questionnaire >> Key Quality Objectives for Monitoring

1. **Please list the most important things that your organization strives to accomplish by monitoring clinical trials.**



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CTTI Questionnaire >> Survey Completion >> Thank You For Completing This Survey

If your organization would like to learn more about the CTTI program, please contact: **ctti_monitoring-practices@ctsu.ox.ac.uk**

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