

UKCRC Registered Clinical Trial Units Questionnaire

Clinical Trial Monitoring

Introduction

We are finding out how clinical trial monitoring is carried out in the UKCRC registered Clinical Trials Units. Please could you fill in the questionnaire thinking of the phase III randomised CTIMP trials led from your CTU. To avoid duplication we have asked for your CTU name but we will not be using this for any analysis. The data will be stored in alignment with our CTU policy for trial data, it will only be accessible by those working on the project and will be analysed using STATA. We would like to publish the results of the questionnaire but will not be using the CTU name. For further information contact s.love@ucl.ac.uk For this questionnaire, monitoring is defined in the ICH way as

"The act of overseeing the progress of a clinical trial, and ensuring that it is conducted, recorded and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirements"

"The purposes of trial monitoring are to verify that:

- (a) The rights and well-being of human subjects are protected.
- (b) The reported trial data are accurate, complete, and verifiable from source documents.
- (c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s)."

https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step4_2016_1109.pdf (accessed 9Oct2018)

Thank you for your help.



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Trials at your CTU

1. Please enter your CTU name or registration number

2. What is the most common number of sites in your randomised phase III CTIMP trials ?

≤10 11-49 ≥50

3. What size randomised phase III CTIMP trials does your CTU usually conduct?

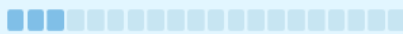
≤100 101-1000 1001-2499 ≥2500

4. Does your CTU conduct international trials?

Yes No

5. Does your CTU conduct an assessment of risk to inform your monitoring approach?

Yes Sometimes No

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6. Space for any comments on the questions above about randomised phase III CTIMP trials in your CTU

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Central monitoring

Central monitoring is defined here as any monitoring of the data or the sites that you do centrally. It does not include the automatic queries programmed in the database that occur during data entry.

7. Does your CTU use centrally available data to formally evaluate site/trial performance?

Yes No

8. Does your CTU use a centralised monitoring process to guide, target or supplement on-site visits?

Always
 Frequently
 Sometimes
 Never

9. Does your CTU use a centralised monitoring process to replace on-site visits?

Always
 Frequently
 Sometimes
 Never

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10. How do you program central monitoring for each trial?

- Bespoke software is written for each trial
- The same software is used for every trial in the CTU
- Pre-written modules are chosen for each trial with some bespoke programming
- Central monitoring is not programmed

11. How often do you run central monitoring reports or software? If different processes run at different times, tick more than one answer. If you run regular and linked to events central monitoring, then tick more than one answer.

- Daily
- Weekly, fortnightly or every 3 weeks
- Monthly
- Every 2-4 months
- Every 5-9 months
- Annually
- Linked to an event e.g. DSMC, final analysis
- Ad Hoc

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12. If you use triggered on-site monitoring, ie if you decide to visit sites based on information you have centrally at the trials unit, is the trigger

- Software generated
- Partially software generated (e.g. software generated guide which is then assessed by trial team/monitors)
- Human assessed (may be assisted by tables/graphs)
- Not Applicable - triggered monitoring not used. Please go to question 15

13. Which of the following factors would be likely to trigger a site monitoring visit? (tick all that apply)

- | | |
|--|---|
| <input type="checkbox"/> Consent issues | <input type="checkbox"/> Number of protocol deviations/violations |
| <input type="checkbox"/> Incidence of adverse events / SAEs | <input type="checkbox"/> Suspected fraud |
| <input type="checkbox"/> Missing CRF | <input type="checkbox"/> Number of data queries |
| <input type="checkbox"/> Number of unanswered queries | <input type="checkbox"/> Rate of enrolment (either quicker or slower than expected) |
| <input type="checkbox"/> Participant dropout rate | <input type="checkbox"/> Screen failure rate |
| <input type="checkbox"/> Laboratory data signals | <input type="checkbox"/> Lack of experience with site |
| <input type="checkbox"/> Number of eligible individuals who consented | <input type="checkbox"/> Number of patients with complete data for primary and important secondary outcomes |
| <input type="checkbox"/> Number of participants who started allocated intervention | <input type="checkbox"/> Not applicable |
| <input type="checkbox"/> Other <input type="text"/> | |

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14. However you agree a final trigger for an on-site visit, do you always action an on-site visit? ie when you have agreed that you need to visit a site, does the site visit always happen

Yes No Not applicable

15. Do you use information from routine electronic health records to compare against data captured in the trial database?

Yes No

16. Please provide any further comments, clarification or elaboration on your answers or anything you wish to add about Central Monitoring

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On-site monitoring

17. Does your CTU perform on-site monitoring visits?

- Always
- Frequently
- Sometimes
- Never

18. Who visits the site to monitor? Please tick all that apply

- Trial coordinator/manager
- Trial assistant
- Data manager
- Monitor
- Quality Assurance Lead
- Quality assurance team member
- Programmer
- Chief Investigator
- Pharmacist
- CRO
- Other

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19. How long is your average site visit?

- Up to 4 hours
- One day
- More than 1 day

20. How many people are generally sent on a site visit?

- 1
- 2
- 3
- ≥ 4

21. How do you decide when to visit a site? Please tick all that apply

- When triggered
- Fixed time period (e.g. annually, every 6 months)
- Number of patients (e.g. every 10 patients recruited)
- Linked to a trial event (e.g. site initiation, SAE)

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22. The frequency of your CTUs on-site monitoring visits is most commonly determined by (select all that apply)

- Study design
- Critical study requirements/procedure
- Monitoring plan in protocol
- SOPs
- Usual practice
- Pre-defined analysis of risks
- Study population
- Budget
- Other

23. How often do you visit each site? (If, for example, triggered and at least annually, then please tick both options)

- Only when triggered
- At least every 3 years
- At least every 2 years
- At least annually
- At least 6 monthly
- At least monthly

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24. What percentage of each of the following do you source data verify?

	%
All data	<input type="text"/>
Consent	<input type="text"/>
Eligibility criteria	<input type="text"/>
Primary endpoint reports	<input type="text"/>
Secondary endpoint reports	<input type="text"/>
Serious adverse events	<input type="text"/>
Non-serious adverse events	<input type="text"/>
Selected priority data	<input type="text"/>

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25. During on-site monitoring visits, does your CTU

	always	frequently	occasionally	never	not applicable	not sure
Assess staff's understanding of study procedures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Assess the ability of staff to explain the study to the participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Assess the adequacy and timelines of additional information provided to participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Assess informed consent updates/modifications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Verify CRF data versus source documents	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Assess regulatory documents and communications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Assess the security of study data and documentation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Check the site file is complete	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Check adherence to GDPR	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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26. Please provide any further comments, clarification or elaboration on your answers or anything you wish to add about on-site Monitoring

27. What aspect of monitoring would you most like to change ?

- Stop or reduce the number of on-site visits
- Stop or reduce SDV
- Optimise central monitoring
- Other

28. If you would like to be contacted with the result of the questionnaire, please give your email address here

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Finish

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Thank you for completing our questionnaire.