National survey

Exploring data quality monitoring in Australian clinical studies survey

Consent

I have been provided with the participant information sheet (attached below) about the project 'Exploring data quality monitoring within Australian clinical studies survey'. I have been advised of the potential risks and burdens associated with this research, which include completing a 20 to 30 minute online survey.

I understand that my participation in this research is voluntary, I am free to refuse to participate and I am free to withdraw from the research at any time. If I choose not to participate or withdraw consent it will not affect my treatment in anyway and/or my relationship with the University of Wollongong. I acknowledge that any responses given by me as part of this survey form my opinions and practices not necessarily those of the organisation with whom I am employed. I understand that my identifiable responses will not be shared with my organisation or anyone outside of the research team.

If I have any enquiries about the research, I can contact Ms Lauren Houston (Ph. XXXX or Email: lah993@uowmail.edu.au) who is conducting this research as part of her PhD thesis at the University of Wollongong. If I have any concerns or complaints regarding the way the research is or has been conducted, I can contact the Ethics Officer, Human Research Ethics Committee, Office of Research, University of Wollongong on Ph. (02) 42213386 or Email: rso-ethics@uow.edu.au.

By agreeing to the below I am indicating my consent (please tick):

- ○ Participate in this online survey

Participant demographics

Please follow instructions and select the most appropriate response(s) from the range of options or type free text in the box provided for the following questions.

1. Gender
    - ○ Female
    - ○ Male
    - ○ Prefer not to disclose
    - ○ Prefer to self-describe
        - Please specify:

          _____

2. Highest level of completed education
    - ○ Did not complete high school
    - ○ High school
    - ○ College/TAFE course (e.g. apprenticeship)
    - ○ Bachelor degree (including Honours)
    - ○ Masters/Postgraduate degree
    - ○ Doctoral degree

3. Current job title:

   _____

4. Duration of employment with current employer: _____

(Please provide numeric value to the nearest completed half year, for example, 6 months = 0.5 years)

5. Appointment (Current job or position)

For definitions hover mouse/cursor directly over words for popup window to display additional information. (May take a few seconds to appear)

- ○ Casual Student
- ○ Continuing
- ○ Visiting / Honorary fellow
- ○ Fixed-term contract
    - Current contract duration:

      _____

      (Please provide numeric value to the nearest half year, for example, 6 months = 0.5)

Clinical research demographics

The following questions relate to the specified clinical study outlined in the survey email.

For the purpose of this research a clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies.

6. What health professionals are part of the clinical study team? (Select all that apply)
   - ☐ Aboriginal and Torres Strait Islander health practitioner
   - ☐ Audiology
   - ☐ Chinese Medicine
   - ☐ Chiropractic
   - ☐ Dentistry
   - ☐ Dietetics
   - ☐ Exercise physiology
   - ☐ Genetic counselling
   - ☐ General practice/Physician
   - ☐ Medical radiation
   - ☐ Nursing
   - ☐ Nutrition
   - ☐ Occupational therapy
   - ☐ Optometry
   - ☐ Osteopathy
   - ☐ Orthotics
   - ☐ Paramedics
   - ☐ Pharmacy
   - ☐ Physiotherapy
   - ☐ Podiatry
   - ☐ Prosthetics
   - ☐ Psychology
   - ☐ Social work
   - ☐ Speech pathology
   - ☐ Other
     - Please specify:

       _____

       (If more than one please place a comma between list)

7. Which of the following best describes the organisation(s) that administers the clinical study? (Select all that apply)
   - ☐ Academic (University)
   - ☐ Cooperative group/consortium
   - ☐ Government
   - ☐ Hospital
   - ☐ Independent research institute
   - ☐ Industry
   - ☐ Non-governmental organisation
   - ☐ Not applicable
   - ☐ Don't know
   - ☐ Other
     - Please specify:
       _____

8. What is the clinical study type?
   - ○ Interventional (clinical trial)
   - ○ Observational

9. If 'Intervention trial' in question 8. What type of intervention is the clinical trial? (Select one)
   For definitions hover mouse/cursor directly over words for popup window to display additional information. (May take a few seconds to appear)
   - ○ Diagnostic
   - ○ Epidemiological
   - ○ Genetic
   - ○ Prevention
   - ○ Quality of Life
   - ○ Screening
   - ○ Treatment

10. What phase is the clinical study? (Select one)

For definitions hover mouse/cursor over words for popup window to display additional information. (This may take a few seconds)

- ○ Phase 0 (Exploratory)
- ○ Phase I
- ○ Phase II
- ○ Phase III
- ○ Phase IV
- ○ Don't know
- ○ Not applicable

11. Which of the following represents the clinical study?
    - ○ Single-site
    - ○ Multi-site

12. If ‘Multi-site’ in question 11. Number of sites:
    - ○ 2-4
    - ○ 5-9
    - ○ 10-19
    - ○ 20-49
    - ○ 50-99
    - ○ >100

13. If ‘Single-site’ in question 11. In what setting is the data collected? (Select one)
    - ○ Health centre
    - ○ Hospital
    - ○ Independent research institute
    - ○ In-home care
    - ○ Private practice
    - ○ University
    - ○ Other
        - Please specify:
          _____

14. If ‘Multi-site’ in question 11. In what setting(s) are the data collected? (Select all that apply)
    - ☐ Health centre
    - ☐ Hospital
    - ☐ Independent research institute
    - ☐ In-home care
    - ☐ Private practice
    - ☐ University
    - ☐ Other
        - Please specify:_____

15. If ‘Multi-site’ in question 11, Is the clinical study part of an international study? (Select one)
    - ○ Yes
    - ○ No

16. Number of participants targeted for baseline enrolment in the clinical study? (Select one)
    - ○ < 20
    - ○ 20-99
    - ○ 100-499
    - ○ 500-999
    - ○ 1,000-4,999
    - ○ 5,000-9,999
    - ○ >10,000

17. Does the clinical study/organisation employ a person as a data monitor and/or data manager?

Yes	No	Don’t know	Not applicable
○	○	○	○

The following questions are related to data management and are conducted prior to the study commencing. Such procedures include identifying data to be collected, defining data elements, designing case report forms (CRFs) and research protocols.

Does the clinical study... (Select one for each row)

	Yes	No	Don't know	Not applicable
18. have a data dictionary?	○	○	○	○
19. involve staff in develeoping case report forms (CRFs)?	○	○	○	○
20. have a defintion for protocol deviation and/or violation?	○	○	○	○
21. Have a data quality monitoring plan or standard operating procedure (SOP) for quality assurance and quality control?	○	○	○	○
22. outsource data monitoring to another company?	○	○	○	○
23. follow national and international regulations, guidelines and/or standards for data monitoring?	○	○	○	○

24. If 'Yes' or 'Don't know' to question 23. Please select which of the following regulations, guidelines and/or standards are followed. (Select all that apply)
    - ☐ National Statement on Ethical Conduct and Research
    - ☐ The Australian Clinical Trial Handbook - Therapeutic Goods Administration (TGA)
    - ☐ Good Clinical Practice Guidelines (GCP) - International Conference for Harmonisation
    - ☐ International Standards Organisation (ISO) quality systems standard
    - ☐ Food and Drug Authority (FDA)
    - ☐ 21 CRF part 11
    - ☐ Food and Drug Authority (FDA) Monitoring of Clinical Investigations
    - ☐ Health Level 7 (HL7)
    - ☐ Analysis Data Model (ADaM)
    - ☐ Operational Data Model (ODM)
    - ☐ Logical Observation Identifiers names and Codes (LOINC)
    - ☐ Clinical data acquisition standards harmonization (CDASH)
    - ☐ International classification of diseases (ICD): ICD-9 / IDC-10 / ICD-0-3 Systematized Nomenclature of Medicine -- Clinical Terms (SNOMED-CT)
    - ☐ Study data tabulation model implementation guide for human clinical trials (SDTM)
    - ☐ Don't know
    - ☐ Other
        - Please specify:_____

The following questions relate to the process by which data elements are accumulated known as data collection.

Does the clinical study... (Select one for each row)

	Yes	No	Don't know	Not applicable
25. have a standard operating procedure (SOP) specifically for data collection?	◯	◯	◯	◯
26. implement procedures to overcome missing values in the process of data collection?	◯	◯	◯	◯

- If yes to question 26. Please explain:

_____

_____

27. Which data capture instrument(s) are used to record source data? (Select all that apply)

Source data refers to the FIRST time a data value is recorded. Source data is contained in source documents, e.g. hospital records, clinical and office charts, laboratory notes and recorded data from automated instruments.

- ☐ Paper
- ☐ Mobile or tablet application
- ☐ Electronic case report form (eCRF)
- ☐ Database management software/tool
- ☐ Microsoft Excel spreadsheet/workbook
- ☐ Automated instruments (e.g. pathology, ultrasound, x-ray etc.)
- ☐ Don't know
- ☐ Other
  - Please specify:

    _____

28. Are any of the following clinical data management tools used to store data? (Select all that apply)
    - ☐ RAVE
    - ☐ MACRO
    - ☐ REDCap
    - ☐ TRialDB
    - ☐ PhOSCo
    - ☐ CLINTRIAL
    - ☐ openCDMS
    - ☐ OpenClinica
    - ☐ eClinical Suite
    - ☐ ORACLE CLINICAL
    - ☐ None
    - ☐ Not applicable
    - ☐ Don't know
    - ☐ Other
      - Please specify:

        _____

The following questions relate to the processes and systems applied to audit and monitor data within the clinical study.
For definitions hover mouse/cursor directly over words for popup window to display additional information. (May take a few seconds to appear)

Does the research team of the clinical study complete any of the following data monitoring procedures? (Select one for each row)

	Yes	No	Don't know	Not applicable
29. Logic, range and consistency checks	○	○	○	○
30. Double data entry	○	○	○	○
31. Statistical techniques	○	○	○	○
32. Risk-based taregted monitoring	○	○	○	○
33. Risk-based triggered monitoring	○	○	○	○
34. Remote monitoring	○	○	○	○
35. Centrlised monitoring	○	○	○	○
36. Onsite monitoring	○	○	○	○
37. Source data verification	○	○	○	○
38. Other	○	○	○	○

- If yes to question 38. Please explain:
  _____
  _____

Risk-based targeted monitoring - Focus on certain data points that have been identified to have the most risk.

Does the clinical study use a risk-based targeted monitoring procedure to... (Select one for each row)

	Yes	No	Don't know	Not applicable
32a. guide centralised monitoring visits?	○	○	○	○
32b. guide onsite visits?	○	○	○	○
32c. completely replace onsite visists?	○	○	○	○
32d. other	○	○	○	○

- If yes to question 32d. Please explain:

  _____

  _____

32e. What types of data does the risk-based monitoring target? (Select all)

- ☐ Safety data
- ☐ Patient visits
- ☐ Clinical data (key data/primary outcome)
- ☐ Not applicable
- ☐ Don't know
- ☐ Other
  - Please specify:

    _____

Risk-based triggered monitoring - After certain events like a large number of adverse events or deviations occur this leads to more detailed monitoring

Does the clinical study use a risk-based triggered monitoring procedure to... (Select on for each row)

	Yes	No	Don't know	Not applicable
33a. guide centralised monitoring visits?	○	○	○	○
33b. guide onsite visits?	○	○	○	○
33c. completely replace onsite visists?	○	○	○	○
33d. other	○	○	○	○

- If yes to question 33d. Please explain:

  _____

  _____

33e. Which of the following factors are likely to trigger a non-scheduled site monitoring visit? (Select all that apply)

- ☐ Suspected fraud
- ☐ Rate of enrolment
- ☐ Screen failure rate
- ☐ Laboratory data signals
- ☐ Number of data queries
- ☐ Subject dropout/withdrawal
- ☐ Incidence of adverse events
- ☐ Geographical location of site
- ☐ Number of protocol deviations
- ☐ Lack of experience with the site
- ☐ Missing case report forms (CRFs)
- ☐ None
- ☐ Not applicable
- ☐ Other
  - Please specify:

    _____

33f. What kinds of data are used to trigger a non-scheduled site monitoring visit? (Select all that apply)

- ☐ Laboratory data
- ☐ Case report form (CRF) data
- ☐ Data related to performance, e.g. time of day, duration, sequencing of study activities
- ☐ External data sets, e.g. national death registry, prescribing data, episode or claims data
- ☐ Not applicable
- ☐ Don't know
- ☐ Other

33g. Which type of data analyses are likely to trigger a non-scheduled site monitoring visit? (Select all that apply)
For examples hover mouse/cursor over words for popup window to display additional information. (This may take a few seconds)

- ☐ Missing data
- ☐ Plausibility checks
- ☐ More complex statistics
- ☐ Simple descriptive statistics
- ☐ Multivariate risk assessment
- ☐ None
- ☐ Not applicable
- ☐ Don't know
- ☐ Other
    - Please specify: - _____

Remote monitoring - Data monitored off-site, includes delivering documents via email, fax or snail mail to monitoring personnel to conduct source data verification.

Does the clinical study use a remote monitoring procedure to... (Select one for each row)

	Yes	No	Don't know	Not applicable
34a. perform periodic site audits via tele/video conference?	○	○	○	○
34b. perform data reveiew and site performance evaluations using centrally available data?	○	○	○	○
34c. other?	○	○	○	○

- If yes to question 34c. Please explain:
  _____
  _____

	Yes	No	Don't know	Not applicable
34d. Is there a tracking/reminder system for expected case report forms (CRFs)?	○	○	○	○

	Yes	No	Don't know	Not applicable
34e. Is there a set amount of time between data capture and sending files/reports?	○	○	○	○

- If yes to question 34e. Please enter the amount of time between data capture and when files/reports must be sent (weeks):
  _____

Centralised monitoring - Data collected through an electronic data capture and queries identified by monitor that may need further attention to alleviate problems.

Does the clinical study use a centralised monitoring procedure to... (Select one for each row)

	Yes	No	Don't know	Not applicable
35a. guide onsite visits?	○	○	○	○
35b. completely replace onsite visists?	○	○	○	○
35c. other	○	○	○	○

- If yes to question 35c. Please explain:

  _____

  _____

	Yes	No	Don't know	Not applicable
35d. Does the clinical study conduct periodic audits of a subset of data, sites, centres or participants?	○	○	○	○

35e. If 'Yes' to question 35d. Sample of: (Select one)

- ○ Data
- ○ Sites
- ○ Centres
- ○ Participants
- ○ Don't know
- ○ Other
  - Please specify:

    _____

35f. If 'Yes' to question 35d. What percentage? (Select one)

- ○ 1-25%
- ○ 26-50%
- ○ 51-75%
- ○ 76-99%
- ○ 100%
- ○ Depends on the data point/outcome measured. (E.g. 10% data monitoring from outcome A and 50% data monitored from outcome B).
  - Please explain:

    _____

    _____
- ○ Don't know

35g. Which of the following factors are likely to trigger a non-scheduled site monitoring visit? (Select all that apply)

- ☐ Suspected fraud
- ☐ Rate of enrolment
- ☐ Screen failure rate
- ☐ Laboratory data signals
- ☐ Number of data queries
- ☐ Subject dropout/withdrawal
- ☐ Incidence of adverse events
- ☐ Geographical location of site
- ☐ Number of protocol deviations
- ☐ Lack of experience with the site
- ☐ Missing case report forms (CRFs)
- ☐ None
- ☐ Not applicable
- ☐ Other
    - Please specify:

      _____

35h. What kinds of data are used to trigger a non-scheduled site monitoring visit? (Select all that apply)

- ☐ Laboratory data
- ☐ Case report form (CRF) data
- ☐ Data related to performance, e.g. time of day, duration, sequencing of study activities
- ☐ External data sets, e.g. national death registry, prescribing data, episode or claims data
- ☐ Not applicable
- ☐ Don't know
- ☐ Other
    - Please explain:

      _____

35i. What analyses of centralised data does the clinical study use to trigger a site monitoring visit? (Select all that apply)
For examples hover mouse/cursor over words for popup window to display additional information.

- ☐ Missing data
- ☐ Plausibility checks
- ☐ More complex statistics
- ☐ Simple descriptive statistics
- ☐ Multivariate risk assessment
- ☐ Not applicable
- ☐ Don't know
- ☐ Other
    - Please specify:

      _____

Onsite Monitoring - All monitoring activities undertaken at the clinical trial site.

36a. What data variables are included in onsite monitoring? (Select one)

- ○ All data points (100%)
- ○ Critical and non-critical data
- ○ Critical data points (key/primary data)
- ○ Non-critical (non-key/secondary data)
- ○ Not applicable
- ○ Don't know
- ○ Other
  - Please specify:
    _____

	Yes	No	Don't know	Not applicable
36b. Does the clinical study perform onsite monitoring vistsis for only a subset of data, sites, centres or participants?	○	○	○	○

36c. If 'Yes' to question 36b. Sample of: (Select one)

- ○ Data
- ○ Sites
- ○ Centres
- ○ Participants
- ○ Don't know
- ○ Other
  - Please specify:
    _____

36d. If 'Yes' to question 36b. What percentage? (Select one)

- ○ 1-25%
- ○ 26-50%
- ○ 51-75%
- ○ 76-99%
- ○ Depends on the data point/outcome measured. (E.g. 10% data monitoring from outcome A and 50% data monitored from outcome B).
  - Please explain:
    _____
    _____
- ○ Don't know

36e. If 'Yes' to question 36b. How does data monitor select the sample of data, sites, centres or participants for onsite monitoring? (Select one)

- ○ A sampling method
- ○ A pre-defined set (e.g. first 2 participants)
  - Please explain:
    _____
- ○ Not applicable
- ○ Don't know
- ○ Other
  - Please specify:
    _____

36f. If 'A sampling method' to question 36e. Which of the following sampling methods are used? (Select all that apply)
For definitions hover mouse/cursor over words for popup window to display additional information.

- ☐ Cluster sampling
- ☐ Stratified sampling
- ☐ Systematic sampling
- ☐ Multi-stage sampling
- ☐ Simple random sampling
- ☐ Other
  - Please specify: -
    _____

	Yes	No	Don't know	Not applicable
36g. Is there a minimum frequency of onsite monitoring visits for the clinical study?	○	○	○	○

36h. If 'Yes' to question 36g. What is the frequency? (Select one)

- ○ Annually
- ○ 2-3 times annually (every 4-6 months)
- ○ 4-6 times annually (8-12 weeks)
- ○ 7-11 times annually (every 4-6 weeks)
- ○ Once per month
- ○ Once per week
- ○ Other
  - Please specify: -
    _____

36i. If 'Yes' to question 36g. The frequency of onsite monitoring visits is most commonly determined by: (Select all that apply)

- ☐ Budget
- ☐ Study design
- ☐ Study population
- ☐ Usual practice of your organisation
- ☐ Monitoring plan specified in protocol
- ☐ Critical study requirement/procedure
- ☐ Pre-defined analyses of potential risks
- ☐ Standard operating procedures (SOPs)
- ☐ Not applicable
- ☐ Other
    - Please specify: -
      _____

Source data verification - Comparing source data (original or certified copy) documents to data recorded or entered to a case report form or electronic record or database.

Does the clinical study verify... (Select one for each row)

	Yes	No	Don't know	Not applicable
37a. source data to electronic database	○	○	○	○
37b. source data to electronic case report form (eCRF)				

	Yes	No	Don't know	Not applicable
37c. Does the clinical study complete source data verification on all data (100%) points?	○	○	○	○

If 'Yes' to question 37c.

	Yes	No	Don't know	Not applicable
37d. Is there a minimum frequency of source data verification visitis for the clinical study?	○	○	○	○

37e. If 'Yes' to question 37d. What is the frequency? (Select one)

- ○ Annually
- ○ 2-3 times annually (every 4-6 months)
- ○ 4-6 times annually (8-12 weeks)
- ○ 7-11 times annually (every 4-6 weeks)
- ○ Once per month
- ○ Once per week
- ○ Other
    - Please specify:

_____

If ‘No, Don’t know or Not applicable’ to question 37c.

For each of the following records, what proportion are verified? (Select one for each row)

	None	1-25%	26-50%	51-75%	76-99%	100%
37f. Consent form	○	○	○	○	○	○
37g. Eligibility criteria	○	○	○	○	○	○
37h. Critical data points (key data/primary outcomes)	○	○	○	○	○	○
37i. Non-critical data points (non-key data/secondary outcomes)	○	○	○	○	○	○
37j. Serious adverse events reports	○	○	○	○	○	○
37k. Non-serious adverse event reports	○	○	○	○	○	○

If ‘No, Don’t know or Not applicable’ to question 37c.

	Yes	No	Don’t know	Not applicable
37l. Does the clinical study perform source data verification for only a subset of data, sites, centres or participants involved in the study?	○	○	○	○

37m. If ‘Yes’ to question 37l. Sample of: (Select one)

- ○ Data
- ○ Sites
- ○ Centres
- ○ Participants
- ○ Don't know
- ○ Other
  - Please specify:

    _____

37n. If ‘Yes’ to question 37l. What percentage? (Select one)

- ○ 1-25%
- ○ 26-50%
- ○ 51-75%
- ○ 76-99%
- ○ Depends on the data point/outcome measured. (E.g. 10% data monitoring from outcome A and 50% data monitored from outcome B).
  - Please explain:

    _____

    _____
- ○ Don't know

37o. If 'Yes' to question 37l. How does data monitor select the sample of data, sites, centres or participants for onsite monitoring? (Select one)

- ○ A sampling method
- ○ A pre-defined set (e.g. first 2 participants)
  - Please explain:
    _____
- ○ Not applicable
- ○ Don't know
- ○ Other
  - Please specify:
    _____

37p. If 'Yes' to question 37l. Which of the following sampling methods are used? (Select all that apply)
For definitions hover mouse/cursor over words for popup window to display additional information.

- ☐ Cluster sampling
- ☐ Stratified sampling
- ☐ Systematic sampling
- ☐ Multi-stage sampling
- ☐ Simple random sampling
- ☐ Other
  - Please specify: -
    _____

If 'No, Don't know or Not applicable' to question 37c.

	Yes	No	Don't know	Not applicable
37q. Is there a minimum frequency of source data verification visitis for the clinical study?	○	○	○	○

37r. If 'Yes' to question 37d. What is the frequency? (Select one)

- ○ Annually
- ○ 2-3 times annually (every 4-6 months)
- ○ 4-6 times annually (8-12 weeks)
- ○ 7-11 times annually (every 4-6 weeks)
- ○ Once per month
- ○ Once per week
- ○ Other
  - Please specify:
    _____

The following questions relate to data analysis and the process of translating data into meaningful information.

Does the clinical study have... (Select one for each row)

	Yes	No	Don't know	Not applicable
38. a clear definition of 'poor data quality' or 'dirty data'?	○	○	○	○

- If 'Yes' to question 38. Please explain:

_____
_____

	Yes	No	Don't know	Not applicable
39. an error acceptance level?	○	○	○	○

- If 'Yes' to question 39. Please explain:

_____
_____

If 'Yes' to question 39.

	Yes	No	Don't know	Not applicable
40. If yes, and the error rate is found to be higher than the approved acceptance level, does your organisation implement further follow-up monitoring?	○	○	○	○

- If 'Yes' to question 40. Please explain:

_____
_____

	Yes	No	Don't know	Not applicable
41. a standard equation and/or method used to calculate error?	○	○	○	○

- If 'Yes' to question 41. Please explain:

_____
_____

	Yes	No	Don't know	Not applicable
42. data quality and consistency reports generated?	◯	◯	◯	◯

- If 'Yes' to question 42. Please specify how often they are generated and/or what triggers them:

  _____

  _____

43. If 'Yes' to question 42. Who reviews the reports of data quality and consistency? (Select all that apply)

- ☐ Sponsor
- ☐ Auditor/Monitor
- ☐ Data entry staff
- ☐ Chief investigator
- ☐ Senior staff management
- ☐ No one
- ☐ Don't know
- ☐ Other
  - Please specify:_____

	Yes	No	Don't know	Not applicable
44. a feedback mechanism in place to ensure continuous quality improvement? For example, a plan, do, check, act cycle.	◯	◯	◯	◯

- If 'Yes' to question 44. Please specify how often they are generated and/or what triggers them:

  _____

  _____

Education and training

Is it required that the primary person(s) responsible for data entry have...

	Yes	No	Don't know	Not applicable
45. achieved a minimum level of education?	○	○	○	○

- If 'Yes' to question 45. Please outline:

_____
_____

	Yes	No	Don't know	Not applicable
46. a minimum level of experience?	○	○	○	○

- If 'Yes' to question 46. Please outline:

_____
_____

	Yes	No	Don't know	Not applicable
47. training/development devoted to data quality?	○	○	○	○

48. If 'Yes' to question 47. Which of the following areas are data entry staff provided training in: (Select all that apply)

- ☐ Monitoring process
- ☐ Protocol procedure
- ☐ Skills development
- ☐ Specific research area investigation
- ☐ Standard Operating Procedure (SOP)
- ☐ International Conference on Harmonisation and Good Clinical Practice (ICH-GCP)
- ☐ Don't know
- ☐ Other
  - Please specify:

    _____

49. If 'Yes' to question 47. Please specify how education and training is delivered: (Select all that apply)

- ☐ Group
- ☐ One-on-one
- ☐ Online/computer module(s)
- ☐ Other
  - Please specify:

    _____

50. If ‘Yes’ to question 47. Please specify when education and training is delivered: (Select all that apply)

- ☐ Prior to research
- ☐ Throughout
- ☐ Triggered due to a reoccuring event (e.g. incomplete CRFs)
- ☐ Other
  - Please specify:

    _____

Is it required that the primary person(s) responsible for monitoring the data have...

	Yes	No	Don’t know	Not applicable
51. achieved a minimum level of education?	○	○	○	○

- If ‘Yes’ to question 51. Please outline:

_____

_____

	Yes	No	Don’t know	Not applicable
52. a minimum level of experience?	○	○	○	○

- If ‘Yes’ to question 52. Please outline:

_____

_____

	Yes	No	Don’t know	Not applicable
53. training/development devoted to data quality?	○	○	○	○

54. If ‘Yes’ to question 53. Which of the following areas is this person provided training in: (Select all that apply)

- ☐ Monitoring process
- ☐ Protocol procedure
- ☐ Skills development
- ☐ Specific research area investigation
- ☐ Standard Operating Procedure (SOP)
- ☐ International Conference on Harmonisation and Good Clinical Practice (ICH-GCP)
- ☐ Don't know
- ☐ Other
  - Please specify:

    _____

55. If ‘Yes’ to question 53. Please specify how education and training is delivered: (Select all that apply)

- ☐ Group
- ☐ One-on-one
- ☐ Online/computer module(s)
- ☐ Other
    - Please specify:
      _____

56. If ‘Yes’ to question 53. Please specify when education and training is delivered: (Select all that apply)

- ☐ Prior to research
- ☐ Throughout
- ☐ Triggered due to a reoccuring event (e.g. incomplete CRFs)
- ☐ Other
    - Please specify:
      _____

	Yes	No	Don’t know	Not applicable
57. Are the skills and performance of the person(s) in charge of data monitoring assessed via periodic onsite evaluations by a third party (e.g. manager) during monitoring visit(s)?	◯	◯	◯	◯

- If ‘Yes’ to question 57. Please explain:
  _____
  _____