Clinical Trials Operations (ClinOps)
Course Survey Questionnaires

Clinical trial site coordination course

Pre course survey

Name[1]:_____

Email address:

Professional address:

Country:

Tel including country code:

This survey is completely confidential. Your name will not be used in any analysis documents. Trainers will use the information to measure the level of each participant´s knowledge before and after the course as part of our commitment to deliver a quality course. The analysis will be of aggregated trends and any stored answers to the survey will be anonymous

1. Have you participated in a clinical trial site coordination course in the past?

☐ **YES** ☐ **NO**

If yes:

1.1. When (mm/YYYY)?.....

1.2. Who organised the course?.....

2. Have you ever worked as a site clinical coordinator?

☐ **YES** ☐ **NO** (If no, skip to Q4)

If yes:

2.1 Describe your most recent study:.....

2.2 In which year?.....

2.3 For how long (in months)?.....

3. Related to the clinical trial where you are currently involved (or have been involved) as site coordinator:

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3.1	On average, how many Corrective and Preventive Action (CAPAS's) findings were there per monitoring visit?	
3.2	On average, how many protocol deviations were there per monitoring visit?	
3.3	On average, how many non-complaints safety reports were identified per monitoring visit?	
3.4	On average, how many months were required for data entry?	Month/s
3.5	On average, how many protocol violation findings were there per monitoring visit?	
3.6	How many major audit findings were there (Mark NA, if no audit was done)?	
3.7	How many SOPs have you developed?	
3.8	How many SOPs have you updated?	

4. How confident are you to effectively coordinate the conduct of a clinical trial?

1 Not confident	2	3	4	5 Extremely confident

5. How confident are you about your understanding of the process of clinical trial data management?

1 Not confident	2	3	4	5 Extremely confident

6. How confident are you in your ability to conduct trials abiding by ethical principles and protecting participants?

1 Not confident	2	3	4	5 Extremely confident

7. How confident are you in your ability to secure approval and maintain these approvals from ethics committees and/or regulatory authorities?

1 Not confident	2	3	4	5 Extremely confident

8. How confident are you in your knowledge about research regulations such as:

8.1. international/local regulations? (*Regulations means GCP and requirements by regulatory authorities*)

1 Not confident	2	3	4	5 Extremely confident

8.2. phases of clinical trials

1 Not confident	2	3	4	5 Extremely confident

9. How confident are you about your understanding the informed consent process during conduct of a clinical trial?

1 Not confident	2	3	4	5 Extremely confident

10. How confident are you about your understanding of patient recruitment and retention approaches?

10.1. Patient recruitment approaches?

1 Not confident	2	3	4	5 Extremely confident

10.2. Patient retention approaches ?

1 Not confident	2	3	4	5 Extremely confident

11. **How confident are you about your understanding of the process of managing investigational products at a clinical trial site?**

1 Not confident	2	3	4	5 Extremely confident

12. How confident are you about your understanding of the patient safety reporting process (Adverse Event and Serious Adverse Event) to stakeholder such as the sponsor, ethics committee and/or regulatory authority)?

1 Not confident	2	3	4	5 Extremely confident

13. At your site, do you use indicators to improve clinical trial site operations?

☐ **YES** ☐ **NO**

11.1 If yes, please list the available indicators:

.....

.....

.....

14. List some key challenges in managing your clinical trial site (if not currently involved in a clinical trial, list key challenges that you know of).

Start with the highest priority key challenge
1.
2.
3.
4.
5.

15. Have you ever designed a quality system for a clinical trial?

☐ **YES** ☐ **NO**

13.1 If yes, which one/s? (give a brief description)?

.....

.....

.....

16. Have you ever maintained/implemented a quality system for a clinical trial?

☐ **YES** ☐ **NO**

17. How confident are you about designing and maintaining a quality system for a clinical trial?

	1 Low	**2 Some**	**3 Average**	**4 Good**	**5 High**
Designing SOPs					
Implementing SOPs					
Protocol development					
Protocol implementation					
Handling monitoring findings					

Managing documentations including site investigational files					
Randomization process					
Blinding procedures					

18. How confident are you in your ability to effectively manage Investigator Site Files? (Investigator Site Files are folders where all essential documents for the trial are filed)

1 Not confident	2	3	4	5 Extremely confident

19. How confident are you in your ability to effectively coordinate close-out of a clinical trial?

1 Not confident	2	3	4	5 Extremely confident

20. How confident are you about your understanding of financial management of a clinical trial site?

1 Not confident	2	3	4	5 Extremely confident

21. How confident are you about your understanding of project management of a clinical trial site?

1 Not confident	2	3	4	5 Extremely confident

22. How confident are you about your understanding of internal team management of a clinical trial site?

1 Not confident	2	3	4	5 Extremely confident

23. How confident are you about your understanding of managing external partners, including trial sponsors?

1 Not confident	2	3	4	5 Extremely confident

24. Does the site that you are currently coordinating have risk management documentation?

☐ **YES** ☐ **NO**

If yes, have you developed the risk management document?

☐ **YES** ☐ **NO**

If yes, have you implemented the risk management process?

☐ **YES** ☐ **NO**

Please provide evidence such as a delegation log, job description performance appraisal, etc.

25. What is the average time (in weeks) taken to prepare a site for clinical trial start up in your institution?

.....

26. Have you communicated/presented scientific findings of any studies that you have been involved in the past?

☐ **YES** ☐ **NO**

27.1. If yes, when and where? .....

27.2. If no, how confident are you about communicating/presenting scientific findings at national or international forums?

1 Not confident	2	3	4	5 Extremely confident

Clinical trial site coordination course

Post-course survey

Name[2]:_____

Email address:

Professional address:

Country:

Tel including country code:

This survey is completely confidential. Your name will not be used in any analysis documents. Trainers will use the information to measure the level of each participant´s knowledge before and after the course as part of our commitment to deliver a quality course. The analysis will be of aggregated trends and any stored answers to the survey will be anonymous.

PART I. Course content:

After completion of this course, please respond to the following:

1. **How confident are you to effectively coordinate the conduct of a clinical trial?**

1 Not confident	2	3	4	5 Extremely confident

2. **How confident are you about your understanding of the process of clinical trial data management?**

1 Not confident	2	3	4	5 Extremely confident

3. **How confident are you in your ability to conduct trials abiding by ethical principles and protecting participants?**

1 Not confident	2	3	4	5 Extremely confident

4. **How confident are you in your ability to secure approval and maintain these approvals from ethics committees and/or regulatory authorities?**

1 Not confident	2	3	4	5 Extremely confident

[2] *Your name will not be used in any analysis documents. Trainers will use the information to measure the level of each participant´s knowledge before and after the course.*

5. **How confident are you in your knowledge about research regulations such as:**

5.1. **international/local regulations? (*Regulations means GCP and requirements by regulatory authorities*)**

1 Not confident	2	3	4	5 Extremely confident

5.2. **phases of clinical trials**

1 Not confident	2	3	4	5 Extremely confident

6. **How confident are you about your understanding of the informed consent process during conduct of a clinical trial?**

1 Not confident	2	3	4	5 Extremely confident

7. **How confident are you about your understanding of patient recruitment and retention approaches?**

7.1. **Patient recruitment approaches?**

1 Not confident	2	3	4	5 Extremely confident

7.2. **Patient retention approaches?**

1 Not confident	2	3	4	5 Extremely confident

8. **How confident are you about your understanding of the process of managing investigational products at a clinical trial site?**

1 Not confident	2	3	4	5 Extremely confident

9. **How confident are you about your understanding of the patient safety reporting process (Adverse Event and Serious Adverse Event) to stakeholder such as the sponsor, ethics committee and/or regulatory authority)?**

1 Not confident	2	3	4	5 Extremely confident

10. How confident are you in your ability to effectively manage Investigator Site Files?

1 Not confident	2	3	4	5 Extremely confident

11. How confident are you in your ability to effectively coordinate close-out of a clinical trial?

1 Not confident	2	3	4	5 Extremely confident

12. At your site, do you use Key Performance Indicators to improve clinical trial site operations?

☐ **YES** ☐ **NO**

8.1 If yes, please list the available indicators:

.....

.....

.....

13. After completion of this course, list i) at least two key challenges, and ii) possible approaches to address them in managing clinical trial sites.

Start with high priority Key challenge	Approach to address each key challenges

14. How confident are you about your understanding of designing and maintaining a quality system for a clinical trial?

	1 **Low**	**2** **Some**	**3** **Average**	**4** **Good**	**5** **High**
Designing SOPs					
Implementing SOPs					
Protocol development					
Protocol implementation					

Handling monitoring findings					
Managing documentations including site investigational files					
Randomization process					
Blinding procedures					

15. How confident are you about your understanding of the financial management of a clinical trial site?

1 Not confident	2	3	4	5 Extremely confident

16. How confident are you about your understanding of project management of a clinical trial site?

1 Not confident	2	3	4	5 Extremely confident

17. How confident are you about your understanding of internal team management of a clinical trial site?

1 Not confident	2	3	4	5 Extremely confident

18. How confident are you about your understanding of managing external partners, including trial sponsors?

1 Not confident	2	3	4	5 Extremely confident

19. Has this course been useful in allowing you to better present scientific findings of your future studies at national or international forums?

☐ **YES** ☐ **NO**

If yes, how confident are you to present your scientific findings at national or international forums?

1 Not confident	2	3	4	5 Extremely confident

Part II. Course satisfaction:

20. Please indicate your level of agreement with the statements below by adding an X in the relevant box:

Statement	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
1.The objectives of the online course were clearly defined					
2. The content was well organized and easy to follow					
3. The case studies used helped to clearly understand the content					
4. The trainer/instructor was readily available via email or online discussion					
5. There was an opportunity to interact with other online students in the group					
6. The amount of time to complete the online course was appropriate					
7. The modules assessment/s were adequate					
8. The learning approach worked well for me					

21. Please indicate your level of satisfaction on below aspects of the course.

	1 **Not satisfied at all**	**2** **some**	**3** **Average**	**4** **Good**	**5** **High**
8. Quality of multimedia used in the course					
9. Quality of audio used in the course					
10. The accessibility of the online course					
11. Coordination of the group Discussion at: a) Voice Threads b) Discussion Forums c) Live tutorials d) Teamwork					
12. Overall technical quality of the online course					

22. Based on your experience, would you take another online course?

☐ **YES** ☐ **NO**

18.1 Why or why not?

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Part III. Overall course evaluation

23. Please rate the following on a scale of 1 – 5, where 5 is the most positive answer

	1 Least positive	**2**	**3**	**4**	**5 Most positive**
1. How would you rate this course overall?					
2. I have developed valuable expertise/skills during the course					
3. I was highly motivated to learn the content of this course					
4. I have actively participated in the course					
5. Course structure					
6. Clarity of Content					
7. Access to Content					
8. Timing of assessment					
9. Tutors performance during tutorials					
10. Tutors subject matter expertise					
11. Interaction with tutors during the course					
12. Interaction with classmates during the course					
13. Relevance of the course to your current job					

24. What was the best thing about this course?

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……..

……..

25. Give one example of how this course helped you in your current job.

……

……..

……..

26. Give one example of how you can use the content of this course to support others in your organization.

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27. Give one example of how the course could be changed to better meet your needs.

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