Survey about clinical trial protocols

1. What was your most recent primary role in clinical research?
   - Sponsor-Investigator
   - Principle Investigator
   - Investigator
   - Clinician
   - Position in quality assurance
   - Study coordinator
   - Pharmacist
   - Lab coordinator
   - Clinical trial nurse

2. For how many years have you been working in clinical trials?
   - 0-1 year
   - 2 - 4 years
   - 5 - 7 years
   - more than 7 years

3. In which diseases area are you working? (Please choose all that apply)
   - Malaria
   - Tuberculosis
   - HIV
   - Other neglected tropical diseases
   - Non communicable diseases
   - Other: enter here

4. In which kind of clinical trials are you involved in? (Please choose all that apply)
   - Vaccine trials
   - Drug trials
   - Other: enter here

5. The protocols you have worked with are
   - understandable (for all staff levels involved)
   - easy to implement
   - clear (no uncertainties)
   - well structured
   - complex

   not at all   partially   completely   no opinion
consistent (e.g. no ambiguities or contradictions)
well translated (only for not english-speaking countries)

6. The protocols you have worked with are

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<th>detailed</th>
<th>not at all</th>
<th>more or less</th>
<th>sufficiently</th>
<th>too much</th>
<th>no opinion</th>
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7. Optional field to comment on previous two questions:

8. How many amendments do you have in average per protocol?

- 0
- 1 - 2
- 3 - 5
- > 5
- I do not know
- Other: - enter here -

9. How well are the study procedures described in the protocol adapted to your specific setting? (1=poorly adapted, 5=well adapted)

- Informed consent procedure including documentation
- Inclusion and exclusion criteria
- Participants incentives to participate in the trial
- Recruitment procedure
- Data and information to be collected
- Medical interventions (e.g. ECG)
- Medical procedures and decisions (e.g. administration of drugs, treatment of concomitant diseases and emergencies)
- Safety reporting and management
- Follow-up procedure

10. How well are the protocols adapted to...? (1=poorly adapted, 5=well adapted)

- Amount of workforce available
- Infrastructure available
- Availability and needs of trial participants
- Daily clinical practice
- Ethics Committe system
- Drug Regulatory Authority system

11. Optional field to comment on previous two questions:
12. Are you involved in the study planning of the clinical trials you are working in? (Please choose all that apply)
- Stimulating the topic as an expert
- Major involvement in protocol writing
- Minor involvement in protocol writing
- Reviewing the protocol
- Participating in prediscussion of protocol
- As a sponsor-investigator
- Not involved
- Other: [Enter Here]

13. In which role would your involvement be most helpful within the study planning of the clinical trials you are working in? (Please choose all that apply)
- Stimulating the topic as an expert
- Major involvement in protocol writing
- Minor involvement in protocol writing
- Reviewing the protocol
- Participating in prediscussion of protocol
- Not involved
- Other: [Enter Here]

14. Have you ever heard about open source protocol development?
- Yes, I have heard about it
- Yes, I have heard about it and was participating in an open source protocol development
- No, I have never heard of it
- Other: [Enter Here]

15. Please tick the top three options you think help or would help to increase the suitability of trial protocols? (Please tick three options)
- Sponsor to solicit feedback from site on what went wrong in previous trials
- More careful assessment of local context, capacity and culture by sponsor
- Include participant perspective in study planning
- Involvement of local staff in the study planning/protocol development
- Use open source protocol development technique
- Single center trials: Adapt the protocol to site and health care specific systems
- Multi center trials: Having committees which consist of investigators from all involved research centres
- Making sure that everybody understands the protocol and knows his role and responsibility in the trial
- Having a kick-off meeting before the study start where issues can be discussed and detected
- Having a dry run before the enrolment of the first patient
- Having a checklist for all the practical steps of the trial
16. Optional field to comment on previous question:


17. In which country do you work most of the time? ☐

18. In what kind of institution are you working in? ☐
   ○ Clinical research centre
   ○ Hospital
   ○ Field site
   ○ Other: - enter here -

19. What percentage of your working time is spent for work on clinical trials? ☐
   ○ 0 - 25%
   ○ 26 - 50%
   ○ 51 - 75%
   ○ 76 - 100%
   ○ Other: - enter here -

20. For which percentage of clinical trials have you had a dry run (definition: a practice of the trial activities with dummy participants before the enrolment of the first participant)?
   ○ 0 %
   ○ 25 %
   ○ 50 %
   ○ 75 %
   ○ 100 %
   ○ Other: - enter here -

21. For which percentage of clinical trials have you had a kick off meeting where issues were detected and discussed before the start of the study?
   ○ 0 %
   ○ 25 %
   ○ 50 %
   ○ 75 %
   ○ 100 %
   ○ Other: - enter here -

22. For which percentage of clinical trials have you had a lessons learnt meeting after the trial has ended?
   ○ 0 %
   ○ 25 %
   ○ 50 %
   ○ 75 %
   ○ 100 %
23. Who was the sponsor of your study?
- Mostly pharmaceutical companies
- Mostly other than pharmaceutical companies
- Mixed
- I do not know
- Other: 

24. What percentage of your trials are multicenter trials?
- 0 %
- 25 %
- 50 %
- 100 %
- Other: 

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