
# CTF1 Completion

Avoiding category 3, 4, 5 and 6


- What is the CTF1….
- Its your sales pitch… your chance to explain to the reviewer exactly what you/ your sponsor wants to do


"I've got an elevator pitch, an escalator pitch, and, just to be safe, a stairway pitch."


- We need to add in explanation where necessary

- Keep in mind the reviewer is not in your head


- Make a list of all the documents you need (use the checklist as a guide)

- Go through the form and check what information you need from other people (labs, sites, sponsor, head office, medical advisor etc)

- And try to weasel final documents out of everyone… working with draft versions usually results in rework just before submission…

- Section 1 Part 2
- The reviewer wants to know that the sites chosen are suitable and able to conduct the trial
- Keep in mind they want 25% public sites. If you don't have this there needs to be a strong reason for it
- Don't forget the emergency trolley requirement


| PART 2: DETAILS OF TRIALISTS AND SITES | |
|---|---|
| 2.1 | Details of Site(s) (Name of site, physical address, contact details, contact person) |
| 2.2 | Details of how sites were selected |
| 2.3 | Details of investigators and staff (Investigators, staff, number of staff, names, qualifications, experience) |
| 2.4 | Details of capacity of site(s):<br>(site facilities, equipment, emergency facilities, other relevant infrastructure and investigator work load documents) |
| 2.5 | Details and evidence of competence of the laboratories:<br>• Collection and processing of samples for shipping to centralised testing facilities (include conditions of shipping)<br>• Bedside/point-of-contact testing and details of training of staff<br>• Screening and safety testing of clinical samples during the trial<br>• Specialised end-point testing (virology, immunology, cytokine analysis) |


- Workloads…..
- 168 hours is 24 a day 7 days a week….
- They cannot work 24/7
- Make sure they put sleep/leisure in the bottom section

| ESTIMATED TIME PER WEEK [168 hours denominator] | | Hours | % |
|---|---|---|---|
| Clinical trials | Clinical work (patient contact) | | |
| | Administrative work | | |
| Organisation (Practice / university / employer) | Clinical work | | |
| | Administrative work | | |
| Teaching | Preparation / evaluation | | |
| | Lectures / tutorials | | |
| Writing up work for publication / presentation | | | |
| Reading / sourcing information (e.g. internet searches) | | | |
| Other (specify) | | | |


- The level of detail required in this section has increased with the new form
- Most of this information can be found in the lab manuals or from the local lab (for a smaller trial)
- This section is still new so we are still trying to ascertain from SAHPRA exactly what aspects they would like us to focus on

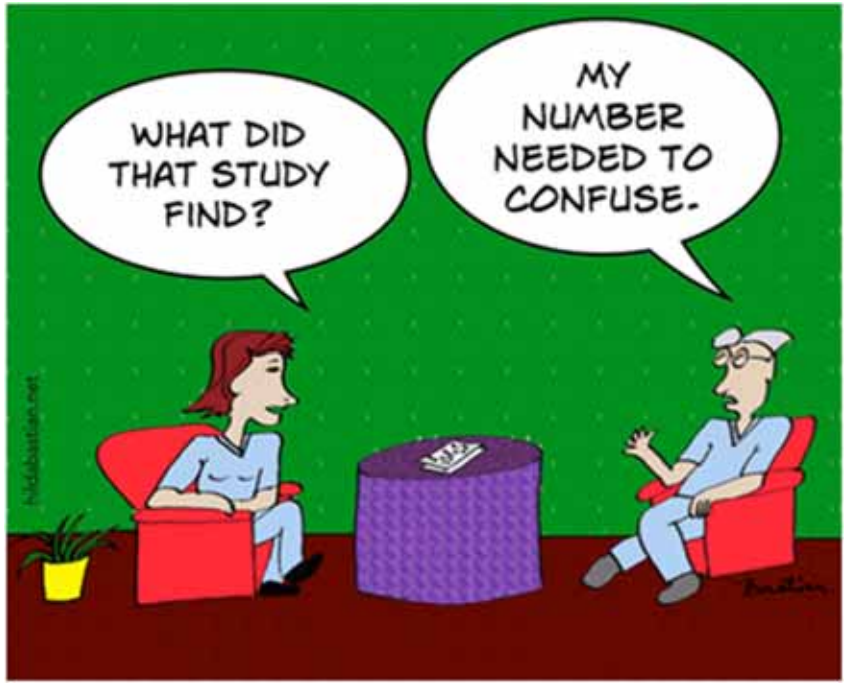
2.5 Details and evidence of competence of the laboratories:

- Collection and processing of samples for shipping to centralised testing facilities (include conditions of shipping)
- Bedside/point-of-contact testing and details of training of staff
- Screening and safety testing of clinical samples during the trial
- Specialised end-point testing (virology, immunology, cytokine analysis)


- Part 3
- 3.2 - If the trial is to be conducted in SA and not in the host country of the applicant / sponsor, provide an explanation

- They want to avoid exploitation of populations in less developed country than the sponsor's


- Section 2 – Part 4 - The IP
- Thankfully this is all in one place now
- Often NNT and NNH aren't in the IB or protocol… you may have to ask for this.




## 4.8 Estimated Quantity of Trial Material (each drug detailed separately) for which exemption will be required (including overage and justification for overage if above 20 %)


- Keep in mind that the approval letter uses this section… and the approval letter is your import licence.

- Customs seems to be getting stricter… so list everything coming in


- 4.9 If any of the above medicines are available in South Africa, give an explanation why they need to be imported from elsewhere

They are wanting us to use local medicines to stimulate the economy.


- 4.10 Details of drugs supply management and accountability (receipt of drugs from supplier, storage, dispensing, packaging and labelling of Investigational Product)

- Some of this is in the IB

- For labelling, it may not be included because its country specific.

- They want to know that there are processes in place and the IP will be handles and stored appropriately, and by qualified people (e.g pharmacist for dispensing)


- Part 5

- Don’t rush this bit its a chance to sell it as how it could help South Africa

What evidence is there for doing this trial in SA

- Global information compared to incidence / importance in SA
- Useful websites: WHO; SA DOH

| Background |
| --- |
| 5.1Disease / problem in South African context (e.g. local epidemiology) |
| 5.2Overall rationale for the study summarised |
| 5.3Rationale for the study in the South African context |


- Part 6 – Objectives endpoints and justifications

- Justify the objectives of the study – if the study is being conducted according to specific guidelines – why is this appropriate for the study population / relevance in SA?

- Alternatively look for the scientific justifications for why those end points are being used

- Don't just use "appropriate to study population or disease" as justification for every criteria… the reviewer will comment


# Part 7 - Design and Methodology

Provide information indicating potential of each site to recruit required number of patients within envisaged duration of trial

•They want to know if the sites you chose can actually recruit. So this is the opportunity to show the work that goes into site selection


- Part 9

- The reviewer wants to know what the trial will be run safely and if SAEs and SUSARs begin to form a pattern that the trial will be stopped.


Part 10 – Stats

- Statistics – why is the stats plan appropriate for proving the study hypothesis?
- What parameters are being measured that will enable a decision to be made regarding if the endpoints have been met or not
- Don't get confused between Quantitative and Qualitative… you will confuse the reviewer and they will comment on this


- Data processing
- This may seem inane but data is becoming more and more important
- POPI act
- Big data


- Capacity building…… part 11

- They want new sites and new researchers… especially in governemnt sites where there is viable capacity to train new clinical trial investigators


"Correct. And in the case of a cardiac arrest, every second counts. Who can tell me why? Anyone? Clock's ticking."


Silly but important tips

•Read it as though you've never seen it before and check that it makes sense

•Get someone else to check it for silly errors

•Get the national PI to check for scientific errors


Silly but important tips

•Don't say "refer to protocol" or IB or any other document or expect them to look up a hyperlink

•Try to make it as clear as possible, well explained, don't fall into the trap of being afraid to explain, it could be the difference between and rejection and an approval


"Until the virus has been identified and removed, IT has issued an immediate ban on any use of e-mail attachments. For more details, please refer to the attached document."


PREPARING FOR CHANGE
SACRA
8th
Clinical Research Conference
26-28 SEPT
Reading and adapting to industry trends

- Questions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"I don't have any answers. I'm a non-prophet."