



COMMUNICATION CHANNELS - Clinical Trials Unit STAKEHOLDER MEETING

01 July 2021

Background

- Procedure for consultation and following up on Application
- Guideline:

[10 Procedure-for-Consultation-Meetings-Clinical-Trial-Applicants Nov19-1.pdf \(sahpra.org.za\)](#)

- It is recognised that meetings between potential applicant for a clinical trial and Clinical Trials Committee (CTC)/Clinical Trials Unit (CTU) are useful but expensive and time consuming for both parties and any invited experts
- Procedures need to be established to optimize the benefits to both parties in such meetings
- No direct communication with the member of CTC is allowed. All communication should go via the Office of the CEO

Request - Consideration

- Meetings may be requested by an applicant/ sponsor, or SAHPRA
- The SAHPRA recognizes the benefits of engagement with potential applicants in the following cases:
 - Pre-investigational meetings, for guidance and clarification purposes before a potential applicant designs non-clinical or clinical studies for a new health product, indication or combination.
 - For clarification of exceptional queries following CTC review feedback to the applicant/ sponsor or any other issues that cannot be resolved through normal channels
- All correspondence requesting a consultative meeting with SAHPRA / CTC should be directed to the Office of the CEO to be considered on merit. This should be accompanied by a full justification for such a meeting

Procedure (1)

- When the applicant/sponsor decides that a meeting with SAHPRA/ CTC may be of value, the following procedure should be followed:
 - Communication with the CEO requesting a meeting with SAHPRA/ CTC
 - Setting out the reasons why such a meeting should be considered
 - Including list of the representatives of the applicant/sponsor that will attend and explaining the role and qualifications of each representative (SAHPRA reserves the right to immediately cancel the meeting if the designated applicant/sponsor are not present)
 - Including a list of queries to SAHPRA/ CTC for which responses are expected

Procedure (2)

- The CEO will consult with the CTU and chair of the CTC and decide if such a meeting is justified
- A suitable date, venue, relevant format and allowable number of representatives (with relevant expertise) of the applicant/sponsor that may attend (for scientific meetings, usually held during CTC meetings)
- The decision will be communicated to the applicant by the Office of the CEO.
- The CEO and Chair of the CTC may co-opt additional expertise from non-CTC members if necessary.
- Full documentation supporting the applicant's request must be made available to members of the CTC /CTU or other SAHPRA representatives at least five working days before the scheduled meeting date

Conduct of the meeting

- The duration of the meeting will be 30 minutes, ten minutes of which must be the applicant's presentation and the remainder for discussion. The time allocation must be adhered to strictly.
- The applicant's presentation should focus on the issues under discussion or in dispute, and avoid lengthy introduction and discussions. Any deviations from the agreed agenda will not be accepted.
- The chairperson or designated member of the CTC /CTU may lead the discussion, but may not necessarily be the reviewer of the study under discussion. The collective views of the committee will prevail in the decision.
- The applicant/sponsor will receive a formal written response from the CTC within 15 working days of the meeting.
- Requests related to specific applications should be done via the Unit or the Office of the CEO and not the Board.

Applications Follow up

- All queries to applications should be done via central CTC emails . Applicable email address
- Only the contact per authorised to communicate with CTU can make follow on applications
- Follow up on:
 - Checklist for new clinical trials (Non COVID): two - three weeks after submission
 - New clinical trials - three weeks after the CTC meeting is held
 - Amendments- one month after the electronic submission is made.
 - Investigators and sites- one month after the electronic submission is made.
 - COVID Applications - 12 working days after submission
 - COVID Amendments and Investigators – 15 working works after submission

Central Mailbox

Summary:

E-mail address for Responses to new Clinical Trial applications and related queries: **ctcresponses@sahpra.org.za**

E-mail address for Protocol amendments, responses to amendments and related queries: **ctcamendments@sahpra.org.za**

E-mail address for Additional Investigators & Sites, responses to additional and related queries: **ctcinvestigators@sahpra.org.za**

E-mail address for Bioequivalence studies, BE amendments, responses to BE studies and related queries: **ctcbeprotocols@sahpra.org.za**

E-mail address for Notifications and related queries: **ctcnotifications@sahpra.org.za**

E-mail address for Individual Patient Serious Adverse Events and related queries: **ctcsaes@sahpra.org.za**

Clinical Trials Unit Contacts

- Ms Kedibone Malatji: Clinical Trials
 - ❖ Kedibone.malatji@sahpra.org.za , Manager Clinical Trials Tel : 012 501 0330
- **New Clinical Trial Applications**
 - ❖ Ms Dominicah Thosago (Technical): Dominicah.Thosago@sahpra.org.za, Tel: 012 501 0331
 - ❖ Ms Maropeng Rapetsoa (Technical): Maropeng.Rapetsoa@sahpra.org.za, Tel: 012 0155 5499
- **Protocol Amendments**
 - ❖ Ms Boitumelo Mogajane (Technical): Boitumelo.@sahpra.org.za, Tel: 012 501 0438
 - ❖ Mr Katlego Mantsi (Admin): Katlego.mantsi@sahpra.org.za, Tel: 012 501 0335
- **Additional site(s)and Investigators**
 - ❖ Mr Philip Mabile (Technical): Philip.Mabile@sahpra.org.za, Tel: 012 501 0332
 - ❖ Ms Chene Labuschagne (Admin): Chene.Labuschagne@sahpra.org.za, Tel: 012 501 0334
- **Bioequivalence Studies**
 - ❖ Ms Dominicah Thosago (Technical): Dominicah.Thosago@sahpra.org.za, Tel: 012 501 0331
 - ❖ Ms Lillian Mokgobu (Admin): Lillian.Mokgobu@sahpra.org.za, Tel: 012 501 0488
- **Notification Studies**
 - ❖ Dr Tsakani Mathye (Technical): Tsakani.Mathye@sahpra.org.za
 - ❖ Ms Lillian Mokgobu (Admin): Lillian.Mokgobu@sahpra.org.za, Tel: 012 501 0488
- **Other Notifications (Progress Reports, SAEs, etc)**
 - ❖ Mr Philip Mabile (Technical): Philip.Mabile@sahpra.org.za, Tel: 012 501 0332
 - ❖ Ms Boitumelo Mogajane (Technical): Boitumelo.Mogajane@sahpra.org.za, Tel: 012 501 0438
 - ❖ Dr Tsakani Mathye (Technical): Tsakani.Mathye@sahpra.org.za
 - ❖ Ms Ntombizodwa Mnisi (Admin): Ntombizodwa.Mnisi@sahpra.org.za, 012 0155 452