



**Karolinska  
Institutet**



## **PREGART Clinical trial (RIA2017MC-2009)**

### **Investigators Meeting**

**Date: September 14-15, 2019**

**Place: Elilly international hotel, Addis Ababa, Ethiopia**

**Participants: All investigators of consortium institutions**

**Meeting chair: Dr. Abel Gedefaw**

**Meeting secretariat: Dr. Wondosen Tekelesilase**

#### **Day one ( September 14, 2019)**

<b>Time</b>	<b>Agenda</b>	<b>Responsible institutions /investigators</b>
<b>8:30-9:00 am</b>	<b>Registration</b>	<b>Mr. Sintayehu Tadesse Project manager,  HU</b>
<b>9:00 -9:10 am</b>	<b>Introduction of meeting program and welcoming Speech</b>	<b>Dr. Abel Gedefaw  Principal investigator,  HU</b>
<b>9:10-10:00 am</b>	<b>Over all planning of PREGART study implementation  <i>Deliverables:</i> - Present the status of the activities so far.</b>	<b>HU  Dr. Birkneh Tilahun</b>

	<ul style="list-style-type: none"> <li>- Present the activities which were done with regards to administration and coordination from HU</li> <li>- Discussion on the status and decision on interventions that improve the implementation further.</li> </ul>	Project Coordinator
10: 00 -10 :30 am	Team break	Elilly international hotel
10:30- 11:30	<p>Progress update on specific issues (SOPs, CRF, Data management)</p> <p><i>Deliverables:</i></p> <ul style="list-style-type: none"> <li>- Enlist the SOPs that are under development by the Ugandan and Ethiopian teams</li> <li>- Decide on the facilitation of completion of each SOP in line with the implementation plan laid out in the protocol</li> </ul>	<p><b>HU &amp; MU</b></p> <p>Dr.Birkneh</p> <p>Dr. Abel</p> <p>Dr. Jackson</p>
11:30 am -12:00 pm	<p>Study Drugs and Insurance for the Trial</p> <p><i>Deliverables:</i></p> <ul style="list-style-type: none"> <li>- Decide on the communication with the study drug supplier</li> <li>- CFA for submission to EFDA and NDA</li> <li>- Decide on insurance for the trial</li> </ul>	<b>HU, KI, MU,ISS</b>
12: 00 -12: 30 pm	<p>DSMB Establishment and SAC charter</p> <p><i>Deliverables:</i></p> <ul style="list-style-type: none"> <li>- Decide on the members of the DSMB – already have a list</li> <li>- Decide on the plan for the communication of members</li> <li>- Decide on finalization of the DSMB charter – there is a draft already</li> <li>- Review and decide on the finalization of the SAC charter</li> </ul>	<b>HU, KI, MU,ISS</b>
12:30- 2:00 pm	Lunch	Elilly international hotel

2:00 pm -5:00 pm	<p><b>Continue discussion on DSMB and SAC charter</b></p> <p><b>Consent, Contraception and DTG updates</b></p> <p><i>Deliverables:</i></p> <ul style="list-style-type: none"> <li>- Decide on the ICF and languages</li> <li>- Decide on issue of contraception in relation to the DTG issue</li> <li>- Discuss on the DTG updates and implications on the trial</li> </ul>	HU, KI, MU, ISS ( all participants )
------------------	---	---

**Day two (September 15, 2019)**

**Participants: all investigators**

<b>Time</b>	<b>Agendas</b>	<b>Responsible institutions /investigators</b>
9:00-10:00 am	<p><b>Review CRFs and SOPs (for which drafts are available) and Ethical application and documents in general.</b></p> <p><i>Deliverables:</i></p> <ul style="list-style-type: none"> <li>- Review the available SOPs from Uganda and Ethiopia</li> <li>- Decide on timelines for completion of the SOPs and circulating for review.</li> <li>- Discuss on the status of ethical applications and regulatory approval applications</li> <li>- Decide on revised timelines for submission of the ethics documents.</li> </ul>	<p><b>Dr. Birkneh</b></p> <p><b>Project Coordinator</b></p> <p><b>HU</b></p>
10: 00 -10 :30 am	<b>Team break</b>	<b>Elilly international hotel</b>
10: 30-11:00 am	<p><b>Discussion on the agenda for the KOM</b></p> <p><i>Deliverables:</i></p> <ul style="list-style-type: none"> <li>- Revised and final agenda for KOM</li> <li>- Review power point slides for the</li> </ul>	<b>HU, KI, MU,ISS</b>

	<p>presentation.</p> <ul style="list-style-type: none"> <li>- Final decision on who will present on what.</li> </ul>	
11:00- 11:30	<p>Discussion on Data management and Statistical analysis plan.</p> <p><i>Deliverables:</i></p> <ul style="list-style-type: none"> <li>- What analysis plan to use?</li> <li>- When and who to develop?</li> <li>- What data management tools to use (OpenClinica was discussed last time)?</li> <li>- Decision on double data entry.</li> </ul>	<p><b>HU , MU ,KI</b></p> <p>Dr. Birkneh</p> <p>Dr. Abel</p> <p>Dr. Jackson</p> <p>Prof. Eleni</p>
11:30 -12:00 am	<p>Administrative Discussion</p> <p><i>Deliverables:</i></p> <ul style="list-style-type: none"> <li>- Discuss and decide on reporting guidelines from EDCTP?</li> <li>- Decide on who to report what and when</li> <li>- Decision on expenses related to travels and other issues.</li> </ul>	<p><b>HU, KI, MU,ISS</b></p>
12: 00 -12: 30 pm	<p>Discussion on subsequent trainings</p> <p><i>Deliverables</i></p> <ul style="list-style-type: none"> <li>- Decide on what trainings to give – list of trainings</li> <li>- Decide on the timelines for each training</li> <li>- Decide on the required document preparation for the trainings and the training of trainer (ToT) for that.</li> </ul>	<p><b>HU, KI, MU,ISS</b></p>
12:30- 2:00 pm	<p>Lunch</p>	<p>Elilly international hotel</p>

<p>2:00 pm -5:00 pm</p>	<p>Discussion and planning on a year activities of the study</p> <p><i>Deliverables:</i></p> <ul style="list-style-type: none"> <li>- Decide on a list of activities and the responsible actors for each set of activities in year 1</li> <li>- Decide on the status of each activity so far.</li> </ul>	<p>HU, KI, MU,ISS</p>
<p>6:30-8:30 PM</p>	<p>Dinner together</p>	<p>2000 HABESHA RESTAURANT</p> <p>Addis Ababa</p> <p>HU</p>

This project is part of the EDCTP2 programme supported by the European Union



**E D C T P**