**CREDO Workshop 2 - Guidelines for Clinical Trial Scenario**

Prior to the workshop an abridged protocol is sent to the participants. They have 2 weeks to fill in the missing elements of the protocol template, based on what they have learned in the modules, and then bring this with them to the workshop.

At the workshop, they will be required to present their protocol to various stakeholders. Local community representatives, WHO country office, Ministry of health representatives, NGO partners in the field, Outbreak Clinical trial expert, Statisticians, and a representative of the European Medicines Agency. These roles will be played by the facilitators/Faculty.

The purpose of this scenario is for the participants to develop skills in implementing a written protocol in a challenging context.

There are two components to this

1. Partnership building with stakeholders who may have different agendas,
2. Adapting the protocol to improve its practicality and suitability once more is known about the circumstances of the outbreak.

With the aim of addressing the overall learning objectives of CREDO.

Based on their discussions with these stakeholders the participants will adapt their protocol in preparation for implementation in the fictitious outbreak.

Each group will then present their protocols to a group of funders (The other participants) who will peer review the protocol presented. The points on the form are added. To normalise the results between groups, the total score is divided by the number of people in the group.

The group with the highest score is declared the funded group and receives a prize.

**Scenario plan**

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| **Time** | **Plan** |
| 1pm – 1.10pm | Introduction and move into groups |
| 1.10pm – 2.15pm | Group rotations. 3 x 20 minute rotations (+ time to move)   * 2 x local community representatives (chief, elder, and or traditional healer) * 2 x NGO representative   National WHO representative and Minister of Health   * European Medicines Agency |
| 2.15pm – 3pm | Afternoon tea, and groups finalise presentation |
| 3pm – 4pm | Each group presents for 10 minutes (including questions)   * Slide 1: overview of PICO * Slide 2: overview of statistical design * Slide 3: one change made to protocol in response to practical issue during afternoon.   Individuals will vote for their favourite protocol (that is not their own). |

**Guide to facilitators**

Aim: The purpose of this scenario is for the participants to develop skills in implementing a written protocol in a challenging context. There are two components to this a) partnership building with stakeholders who may have different agendas, b) adapting the protocol to improve its practicality and suitability in an outbreak setting.

The facilitator roles are not designed with correct answers in mind - the aim is to provoke discussion irrespective of the choice the team has made (i.e. it is possible to challenge either the inclusion, or non-inclusion, of pregnant women, depending on what the group has chosen). This will work best if you’re able to get into character!

If there is a dominant member of your group, there’s provision for one team member to go into ‘isolation’ for a suspected fever - this means they can listen in, but not actively participate in the remainder of the session.

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| **Role: Local representative.**  Objective: this is an opportunity for the group to practice public engagement.  Your major concerns are   1. You’ve heard that there is a miracle treatment being given to medically evacuated international workers. Where is it and why isn’t your community getting access to it? 2. Why do researchers need to take patient’s blood and what happens to it? There have been community concerns about stealing of blood. 3. Will all of your community who are infected get access to the treatment? How will the researchers choose? 4. How can you be sure that the researchers are working in your community’s interest? 5. Will participants from your community be compensated fairly for their involvement? What will that mean? |
| **Role: WHO country office**  Objective: this is an opportunity for the group to discuss their ethics related decisions.  Your major concerns are:   1. Whether there will be enrolment of pregnant women and children. 2. The appropriateness the proxy consent process 3. How participants will be allocated (RCT vs SGA etc). 4. What provisions there may be for post-trial accessibility.   **Role: National Minister of Health**  Your major concerns are   1. Reputational cost to the country if the trial fails. 2. Who will be funding the trial. 3. How potential sites were selected. 4. Whether there is equitable post trial accessibility. |
| **Role: NGO partner**  Objective: to focus on practicalities and rationality of the assessment schedule.  Your major concerns are   1. The risk the research may detract from your immediate clinical priorities. How is this being prevented? 2. Whether patients can differentiate researchers from clinicians and what this means for consent. 3. Whether there will be duplication in assessments undertaken (i.e. two blood draws). 4. Whether the protocol is feasible for a laboratory with limited capacity. |
| **Role: European Medicines Agency**  Objectives: to focus on scientific merit of trial design and safety and regulatory procedures.  Your major discussion points are   1. Explanation of the trial design and statistical analysis plan 2. Understanding of independent data safety monitoring 3. Understanding of interim analysis if used |