This is a half-day workshop covering the various challenges that the presenters have encountered and how they dealt with them in setting up phase 2/3 MDR-TB clinical trials. They will also highlight the opportunities that should not be missed when setting up such trials. This workshop is designed to give the participants an overview of setting up a phase 3 MDR-TB clinical trial based on recent experience.

**Target audience**
1. Researchers and academics
2. Ministry of health officials
3. Public health specialists

**Objectives**
1. Provide an overview of the work involved in setting up phase 2/3 MDR-TB clinical trials
2. Explore the choices and decisions taken during phase 3 MDR-TB clinical trials protocol development
3. Provide insight into operational challenges that need to be anticipated and potential solutions
4. Highlight the opportunities that should not be missed in designing MDR-TB trials
5. Discuss ways of gaining the right to use drugs for the trial and to secure post-trial access

The workshop will trigger enthusiasm for involvement in MDR-TB clinical trials, based on the collaborative nature of such projects and the space for different experts to get involved. A lessons learnt document will be generated.

**Expected outcome**

**Keywords**
MDR-TB; clinical trial; phase 3

**Coordinator(s)**
Bern-thomas Nyang'wa (UK), Corinne Merle (Switzerland)

**Chair(s)**
Christian Lienhardt (Switzerland), Philipp Du Cros (UK)

**Presentations**
1. Accessing drugs for clinical trials - the before, during and after
   Grania Brigden (France)
2. Methodological challenges in designing phase 2/3 MDR-TB clinical trials
   Bern-Thomas Nyang'wa (UK), Corinne Merle (Switzerland)
3. Statistical considerations in phase 2/3 adaptive designs for MDR-TB trials
   Katherine Fielding (UK)
4. Engaging the community adequately in the design and set up of MDR-TB clinical trials: practice or rhetoric?
   Mirzagaleb Tillyashaykhov (Uzbekistan), NARGIZA Parpieva (Uzbekistan)
5. Pharmacokinetic aspects in MDR-TB clinical trials
   Geraint Rhys Davies (UK)
6. Integrating economic assessments in phase 3 MDR-TB clinical trials
   S. Bertel Squire (UK)
7. How could results from MDR-TB trials inform policy development? Suggested WHO requirements
   Gavin Churchyard (South Africa), Christian Lienhardt (Switzerland)
8. When should children be enrolled in new drug trials: presenting a consensus statement
   Sharon Nachman (USA)
9. So your treatment programme wants to be included in an MDR-TB clinical trial - what next?
   Philipp Du Cros (UK)