Session N.00406

05. Challenges in setting up phase 2/3 MDR-TB clinical trials

Wednesday, 02 December 2015, 13:00 - 16:00

Room Roof Terrace

Type of session	Workshop
Track	Drug-resistant TB care and treatment, including trials
Organised by	Médecins Sans Frontières
Duration	Half-day
Max attendees	60
Meeting type	Open meeting
Description	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
Expected outcome	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.
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)