

Tuberculosis Meningitis Platform Trial PROGRAMME

TUESDAY 23 MAY

18:00 - 19:30 **Pre-Conference Welcome Cocktail**

Venue: Cellars Hohenort Hotel, Conservatory Lawns

WEDNESDAY 24 MAY

DAY 1

Time	Topic	Speaker
9:00 - 9:45	SESSION 1 Venue: Spilhaus	Chair: Robert J Wilkinson
	<p>Welcome and introductions [10 min]</p> <p>Meeting objectives and structure [10 min]</p> <p>Overview of the field:</p> <ul style="list-style-type: none"> TBM: the past and what we know now [10 min] Current and planned clinical trials in tuberculous meningitis [10 min] Why do we need to change our approach: need for platform trial [10 min] <p>Discussion [10 min]</p>	<p>Robert J Wilkinson</p> <p>Sean Wasserman Joseph Donovan</p> <p>Reinout van Crevel</p> <p>Nina Ruslami</p> <p>Guy E Thwaites</p>
9:45 - 10:15	TEA [30 min]	
10:15 - 11:45	SESSION 2 Venue: Spilhaus	Chair: Joseph Donovan
	<p>Group 1: Presentations summarising the possibilities and key considerations [45 min]</p> <p>What are the key clinical questions, populations, and outcomes?</p> <ul style="list-style-type: none"> Clinical priorities: bacterial killing, inflammation control, secondary complications, duration of therapy, safety of new interventions Outcomes: death, disability, cognition, safety; ranking; composite Population: adults, children (can there be a single trial?), PLWHIV; eligibility criteria (TBM diagnosis and severity) 	<p><u>Joseph Donovan</u>, Julie Huynh, David Meya, Kant Misra</p>
11:45 - 12:45	LUNCH [1 hr]	
12:45 - 14:15	SESSION 3 Venue: Spilhaus	Chair: Evelyne Kestelyn
	<p>Group 3: Presentations summarising what is needed to execute and deliver a multi-country trial [45 min]</p> <p>How might an international multi-centre trial be organised and delivered</p> <ul style="list-style-type: none"> Sites: minimum requirements (case numbers, existing/potential capacity, locations, infrastructure, etc) Trial governance: CTUs, oversight, coordination, work packages/ domains, TSC, communication, Sponsor Ethical and regulatory considerations Data management and sharing and sample repository Policy translation (early engagement with WHO) 	<p><u>Evelyne Kestelyn</u>, Cari Stek, Angharad Grace Davis, Manish Modi</p>

14:15 - 14:45	TEA [30 min]	
14:45 - 16:15	SESSION 4 Venue: Spilhaus	Chair: James Watson
	<p>Group 2: Background on methodological and statistical considerations: understanding implications of different approaches [45 min]</p> <p>What are the possible trial methodologies?</p> <ul style="list-style-type: none"> • Trial designs • Analytical approach: Bayesian vs frequentist • Interim analyses and go/no go decision thresholds • Randomisation strategy (stratification factors) • Powering and sample size considerations • Application to a TBM trial (what are the specific considerations) • Using accumulating information from the trial to inform adaptation and selection of interventions/sub-groups 	James Watson, David Boulware, Diana Gibb, Kelley Dooley, Robert J Wilkinson
16:15 - 17:30	SESSION 5 Venue: Spilhaus	Chair: Sean Wasserman
	<p>Group 4: Presentations summarising the possibilities and key considerations [30 min]</p> <p>What therapeutic interventions should be selected for initial evaluation</p> <ul style="list-style-type: none"> • Anti-TB drugs and regimen, anti-inflammatory agents, secondary complications • New drugs/regimen possibilities • Framework for selection of interventions • Allocating sub-groups to specific interventions (at baseline or delayed) • Regulatory barriers, cost, availability of interventions (site-specific) 	Sean Wasserman, Reinout Van Crevel, Robert Aarnoutse, Fiona V Cresswell, Darma Imran
19:00	Conference Dinner	
	Venue: Cellars Hohenort Hotel, Conservatory Restaurant	

THURSDAY 25 MAY

DAY 2

Time	Topic	Speaker
8:30 - 8:45	SESSION 6 Venue: Spilhaus	
	Objectives for Day 2 [15 min]	Sean Wasserman & Joseph Donovan
8:45 - 10:00	SESSION 7	
	<p>BREAKOUT SESSIONS [1hr 15 min]</p> <p>Split into two groups for more detailed discussions, chaired by relevant group lead</p> <p>Deliverables:</p> <ul style="list-style-type: none"> • Refine discussions from the previous day; • Converge on consensus; and • Generate recommendations for each identified question <p>GROUPS</p> <p>1. Clinical questions, populations and outcomes Venue: Spilhaus</p> <p>2. Methodologies Venue: Camphor</p>	<p>Chair: Joseph Donovan</p> <p>Chair: James Watson</p>
10:00 - 10:30	TEA [30 min]	

10:30 - 11:00	SESSION 8	
	<p>BREAKOUT SESSIONS [30 min] Split into two groups for more detailed discussions, chaired by relevant group lead Deliverables:</p> <ul style="list-style-type: none"> • Refine discussions from the previous day; • Converge on consensus; and • Generate recommendations for each identified question <p>GROUPS 1. Organisation and delivery Venue: Spilhaus 2. Interventions Venue: Camphor</p>	<p>Chair: Evelyne Kestelyn Chair: Sean Wasserman</p>
11:00 - 11:40	SESSION 9 Venue: Spilhaus	Chair: Guy E Thwaites
	<p>Peter Horby: RECOVERY trial experiences [20 min presentation; 20 min discussion]</p>	
11:45 - 12:30	SESSION 10	
	<p>BREAKOUT SESSIONS cont. [45 min] Split into two groups for more detailed discussions, chaired by relevant group lead Deliverables:</p> <ul style="list-style-type: none"> • Refine discussions from the previous day; • Converge on consensus; and • Generate recommendations for each identified question <p>GROUPS 1. Organisation and delivery Venue: Spilhaus 2. Interventions Venue: Camphor</p>	<p>Chair: Evelyne Kestelyn Chair: Sean Wasserman</p>
12:30 - 13:30	LUNCH [1 hr]	
13:00 - 14:00	SESSION 11	
(Overlap with lunch)	<p>WORKING GROUP SESSION [1 hr] Split into the four working groups; chaired by respective group leads (an informal working meeting, attended by at least core members of each group, attendance by other delegates optional). Deliverables:</p> <ul style="list-style-type: none"> • Synthesise and document prior discussions; • Propose working draft for protocol development; and • Start to populate relevant section in protocol framework document. <p>GROUPS 1. Clinical questions populations and outcomes Venue: Spilhaus 2. Methodologies Venue: Camphor 3. Organisation and delivery Venue: Klaasenbosch 4. Interventions Greenhouse Restaurant</p>	
14:00 - 15:00	SESSION 12 Venue: Spilhaus	Chair: Fiona V Cresswell
	<p>WORKING GROUP Presentations & Recommendations [30 min each: 15 min presentation, 15 min discussion] 1. Clinical questions populations and outcomes 2. Methodologies</p>	

15:00 - 16:00	SESSION 13 Venue: Spilhaus	Chair: David Boulware
	WORKING GROUP Presentations & Recommendations [30 min each: 15 min presentation, 15 min discussion] 3. Organisation and delivery 4. Interventions	
16:00 - 16:30	TEA [30 min]	
16:30 - 17:00	SESSION 14 Venue: Spilhaus	Chairs: Guy E Thwaites & Robert J Wilkinson
	Funding - options and strategy [30 min]	
17:00 - 17:30	SESSION 15 Venue: Spilhaus	Chair: Guy E Thwaites
	Define and plan next steps [30 min] <ul style="list-style-type: none"> • Writing group • Timelines for trial protocol • Funding applications • Follow up meeting • Close and way forward 	

NOTES:

- **Alex Pym** (Wellcome) may attend and provide some guidance during the funding session.
- **Thomas Nyirenda** (EDCTP) may attend on day 1 and provide inputs on funding opportunities.
- For those checking into the hotel on 23 May, the check in time is 14h00.
- For those checking out of the hotel on 26 May, the check out time is 11h00.