**India-UK Networking Partnership Workshop on**

**“Meeting the Challenges of TB Research Priorities in India”**

**Venue: ICMR, New Delhi, Feb2019**

**Day 1 Agenda**

**Co-Chairs for the Day: CTU representative and ICMR representative**

**09.30 – 09.40 Registration**

**09.40 - 12.30**

**Setting the scene – view from India**

09.40 – 09.55 Inauguration and introductions:

09.55 – 10.30 An overview of what paediatric/adult TB research is being done in India and research priorities

10.30 – 11.05 TB research networks in India

11.05 - 11.20 Tea break

11.20 – 11.55 Key challenges to conducting clinical trials in India

11.55 – 12.30 Academic Clinical Research Unit (A-CRU) network – a possible solution

Each presentation **includes** 5 minutes for Q & A

**12.30** – **13.30 Lunch**

**13.30 – 16.15**

**TB trials in practice – view from MRC CTU**

13.30 – 14.05 Clinical Trial designs

14.05 – 14.40 Trial designs developed by the MRC CTU in TB

14.40 – 15.15 Review of TB Trials at the MRC CTU – highlighting methodology and design used

15.15 - 15.25 Tea break

15.25 – 16.00 Operational overview – SOPS and trial toolkits (Led by MRC CTU, interactive discussion with the site representatives)

Each presentation **includes** 5 minutes for Q & A

**16.00** – **16.15** Panel discussion

**16.15** – **17.05**

**Unanswered questions in TB – adults and paediatrics**

Adults (CTU expert)

Paediatrics (CTU expert)

Each presentation **includes** 5 minutes for Q & A

**17.05** – **17.35 Overview of Day 2 (Co-Chair)**

- Workshop attendees will form **4** groups

- Each group will be expected to design an imaginary trial based on one of these areas of importance in TB research, within one of the topics listed below, and be expected to populate the grant template provided. i.e. drug-resistant or –sensitive TB; TB prevention; diagnostics in TB; adjunctive therapies in TB; complications of TB (e.g. TB meningitis)

**Each group will plan for Day 2 Grant proposal writing**

**17.35** – **17.45** **wrap up and close of Day 1 (NIRT representative)**

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**Day 2 Agenda**

**Co-Chairs for the day: CTU representative and NIRT representative**

**09.00** – **09.30** Trial governance – role and importance of oversight committees (CTU)

**09.30** – **10.00** Team science in clinical trials (CTU)

**10.00** – **10.15** Q and A

**10.15 – 13.00 Grant proposal writing (4 groups with 9 convenors)**

**10.15** – **10.30** Introduction and purpose of this session (Co-Chair)

**10.30** – **12.30**

Each group populates the grant template provided

**12.30** – **13.00**

Each group briefly (10 mins per group) presents their Grant proposal – as bullet point summary, including some of the challenges they see

**13.00** – **13.45 Lunch**

**13.45** – **15.00 Research journey (Chair – CTU)**

**An interactive discussion (people still in their 3 groups), and thinking how this relates to the Grant you have put together, and will include other examples of challenges in STREAM, SURE, SHINE – and how they have been overcome**

Each group will need to think about how each of the below, and how these operational challenges impact their trial in the Grant application.

**1) Start up** – e.g. regulatory hurdles, recruitment, lab issues, establishing oversight committees, CRF design and database; drug procurement and logistics including labelling, importation, shipments etc

**2) During the trial** – e.g. recruitment, trial adherence, minimising loss to follow-up, protocol amendments, changing global guidelines, ongoing review by oversight committees, monitoring

**3) At the end of the trial** – e.g. close out, datalock, presentation and publication, informing participants, informing regulators and guideline panels, messages to key stakeholders, dissemination

Each group will provide a 10 minute summary of one of the above – groups will be randomly selected on the day to feedback on either 1) start-up, 2) during the trial, 3) at the end of the trial, challenges and solutions

**15.00** – **15.15 tea break**

**15.15** – **16.15**

**Research opportunities and future collaborations (CTU)**

**16.15** – **17.00**

**Summary of the 2-day workshop, wrap up, next steps** (CTU and NIRT representative)