

ATLS® vs standard care trial

Trial Management Group meeting, 11th March 2024

Agenda

1. Decide to go ahead with the attached protocol for ethics submissions
2. Decide to use the attached Trial Management Charter
3. Decide to join Trial Steering Committee and Data Monitoring Committee into a Joint Trial Steering and Data Monitoring Committee
4. Identify external members for the joint committee
5. Present cluster screening progress
6. Present timeline

Protocol

Consent

- Opt out consent for in-hospital data collection;
- Opt in consent for follow-up data collection;
- Opt in assent for follow-up data collection for participants who are minors; and
- Waiver of informed consent for patients who are unconscious or otherwise unable to provide consent and do not have a legally authorized representative.

Trial Management Group

Members

- Girish D Bakhshi
- Debojit Basak
- Abhinav Bassi
- Johanna Berg
- Shamita Chatterjee
- Kapil Dev Soni
- Martin Gerdin Wärnberg
- Karla Hemming
- Vivekanand Jha
- Monty Khajanchi
- Anurag Mishra
- Samriddhi Ranjan
- Nobhojit Roy
- Rajdeep Singh
- Lovisa Strömmer
- Li Felländer-Tsai

Joint Trial Steering and Data Monitoring Committee

Rationale

- Reduced complexity – meet once per year/every batch
- No blinding – no closed meetings
- Low safety risks

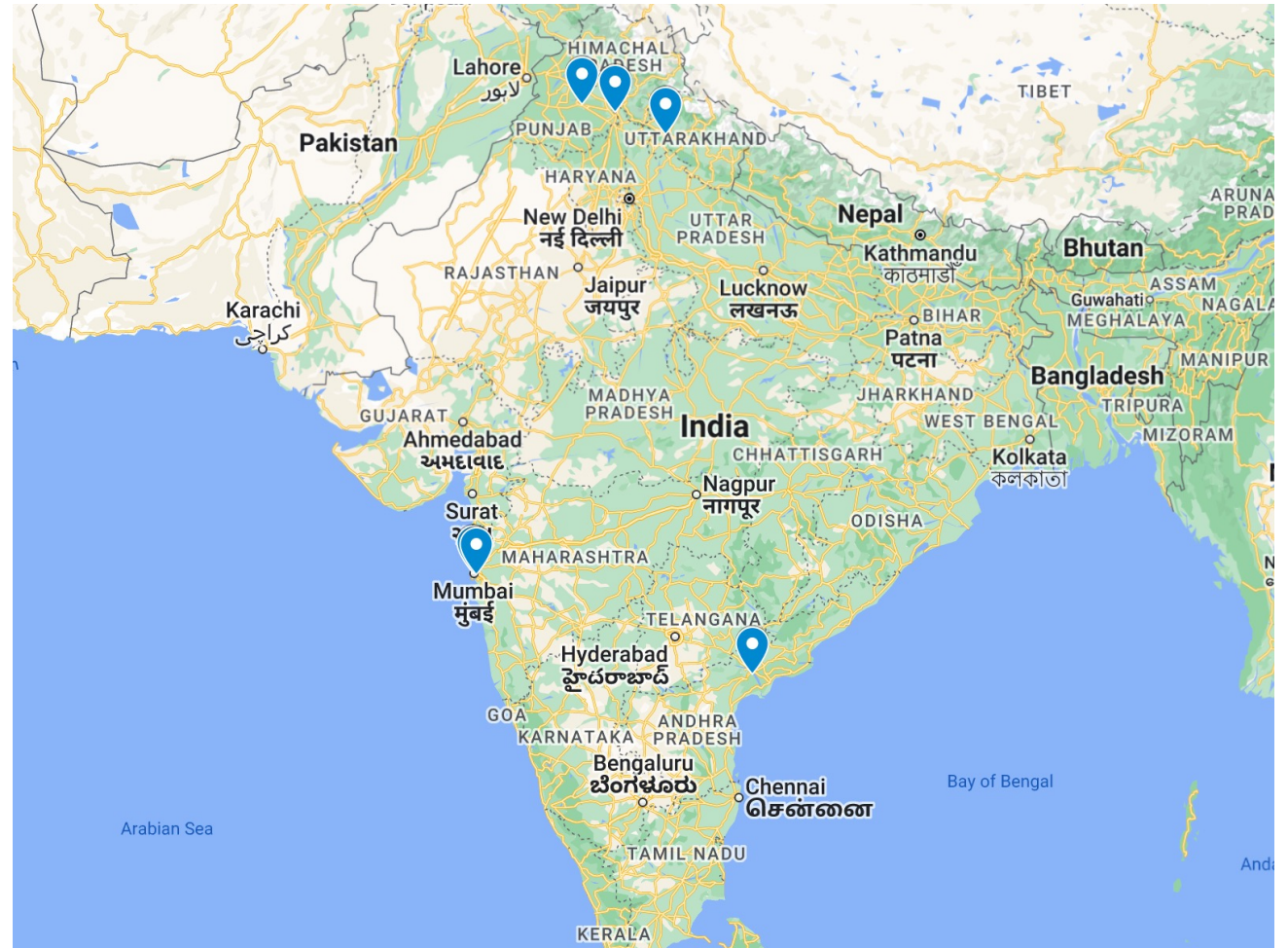
Composition

- Chair with previous experience
- Subject matter
- Statistician
- Patient/community representative

Cluster screening

In-depth interviews

- H.B.T. Medical College & Dr. R.N. Cooper Municipal General Hospital, Mumbai
- All India Institute of Medical Sciences, Mangalagiri
- Christian Medical College and Hospital Ludhiana
- Rajawadi Hospital, Mumbai
- Government Medical College & Hospital, Chandigarh
- Himalayan Institute of Medical Sciences, Uttarakhand



Timeline

Activity	Deadline
Trial registrations (CTRI and ClinicalTrials.gov)	March
Site ethics submission	April-June
HMSC submission	April-June
Start Batch 1	October

Next steps

- Screen additional sites
- Identify committee members – send suggestions to Martin
- Next meeting May 15