CTT Collaboration Independent Oversight Panel
Minutes of teleconference held on Monday 25 March 2019

Attendees
Oversight Panel: Emily Banks, Michael Blastland, Stephen Evans, Peter Weissberg, Janet Wittes
CTT, (CTSU, NDPH) University of Oxford: Jane Armitage, Colin Baigent, Lisa Blackwell, Rory Collins, Kelly Davies, Heather Halls, Lisa Holland, Christina Reith, Enti Spata, Anne Whitehouse

Apologies
Oversight Panel: Robert Temple
CTT, Oxford: Kate Bird, Charlie Harper, Boby Mihaylova, David Preiss

Agenda
1. Review and approval of minutes from last TC
2. Update on project progress/ plans for next CTT Collaborator Meeting
3. Public engagement
4. AOB

1. Review and approval of last minutes from last TC

The minutes from the last Oversight Panel TC (which took place on 17 September 2018) have been agreed, and are publically available via the CTT website:
https://www.cttcollaboration.org/independent-oversight.

2. Update on project progress/ Plans for next CTT Collaborator Meeting

The project remains highly complex, but major progress has been made since the last TC in September 2018 including receipt of individual participant data (IPD) for 28 trials, with HOPE-3 being the most recently received data.

Current main challenges include:

- >20M data items: very labour intensive even with streamlined approaches
- Use of pharmaceutical company data sharing platforms:
    1. Not necessarily designed with meta-analyses across multiple data sources in mind
    2. Timelines and processes involved in approval systems for data export requests
    3. Multiple re-anonymization of certain datasets

Current main focus:

- 3 main tasks re. AE data running in tandem to achieve this:
    1. Converting AE data into CDISC SDTM (+ associated resolution of data queries)
        - Extensive mapping of trial data to CDISC SDTM format already complete
    2. MedDRA mapping of AE terms (part automated, part manual)
        - CTT MedDRA-based coding system already been applied to multiple trials
        - More complex where extensive free text or multiple terms
        - Use of MedDRA Standardised Medical Queries (SMQs) will also be explored
        - Previous endeavours to map free text into MedDRA by natural language processing also noted
    3. Writing of analysis code/specification of tables and figures

Explained cleaning of laboratory, co-medication and reasons for stopping/compliance data will follow and supplement AE data. This will be especially relevant in relation to:

- Muscle outcomes (CK and reasons for stopping likely to be informative)
- New onset diabetes (glucose, HbA1c and co-meds may detect some additional events)

In tandem with this work, extensive efforts are being made to document CTT processes, and there are plans to disseminate the project's methodological approaches in the future so that others may learn from the CTT experience.

The Oversight Panel felt that good progress had been made. All agreed that involvement of regulators such as those in the UK MHRA, EU EMA, US FDA and Australian TGA would be important as results become available, as well as other relevant guideline and policy makers in due course.

3. Public engagement

Patient and public engagement remains a key focus of the project. Plans are underway to create a series of easily understandable short videos/animations in this respect. The CTT team has also been involved in 2 public engagement exercises (Oxford Open Doors and a primary school outreach activity) within the past few months.

4. AOB

Agreed that the next meeting should take place in August 2019; a Doodle poll to this effect will be sent to Panel members.