**RGIT CTIMP Decision Committee Charter:**

This document outlines the charter of the RGIT CTIMP Decision Committee.

1. The Committee’s remit is to replace the MHRA Scope service, and therefore as Sponsor to confirm if a study does or does not fall under the clinical trial regulations and therefore require an MHRA letter of no objection.
2. The Committee is formed of research governance experts in the Research Governance and Integrity Team.
3. As per SOP\_008 the Committee will be referred a study when during s review of a project if after review of the clinical trial of a medicinal product algorithm it is still uncertain if the study is a CTIMP. This process may also be followed if an amendment to the study is submitted that could then make the study a CTIMP.
4. The Chief Investigator (CI) will submit the Borderline CTIMP Decision Document and study protocol to the sponsor reviewer who will then forward to the Committee.
5. The Committee are not required to meet to make a decision, but the members involved in the review will email the sponsor reviewer their decision or request additional information if necessary.
6. The Committee will confirm if the study is a CTIMP or a non-CTIMP when the majority of the Committee finds as such.
7. A minimum of 3 Committee members are required in order for the Committee to be considered quorate.
8. In the event of a difference of opinion between the Committee members then further review or discussion will be conducted in order for the Committee to reach consensus.
9. The CI may appeal the decision but only if there is new information for the Committee to consider (i.e. an update to the study protocol, objectives or outcome measures). The Committee will then re-review the study.
10. Once confirmed the study will be reviewed as per the standard sponsorship review routes for CTIMP or non-CTIMP studies as per SOP\_009 or as per the Worktribe ethics process (for non-UK/EU studies only)
11. The Borderline CTIMP decision document and appropriate correspondence should be uploaded onto EDGE or Worktribe as part of the sponsorship pack once sponsorship or ethical has been issued.
12. Decisions made will be held on the RGIT CTIMP Decision Committee tracker, so that a record can be kept of all decisions and as a resource for future reviewers.