



Authorship and Publication Policy

Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia (REMAP-CAP)

REMAP-CAP Authorship and Publication Policy - Version 1, dated 16th February, 2024

Publication Policy

Introduction

This policy provides the overview and the relevant criteria for authorship of manuscripts arising from the REMAP-CAP platform trial. As a global Platform with multiple regions, defining the roles and responsibilities of authors for manuscripts arising from the Platform is important. To be named as an author on a REMAP-CAP manuscript implies, per ICMJE criteria, that the individual has made a significant contribution to the work and is accountable, to a certain degree, for the integrity of the data.

The REMAP-CAP Authorship and Publication Policy works under the following guiding principles:

- REMAP-CAP aims to be inclusive and equitable with regard to authorship
- Authorship will be fairly and consistently assigned across investigators

Relevant committees

The following committees and working groups are relevant to this Policy (see Figure 1):

- The **International Trial Steering Committee (ITSC)** is the global steering committee that takes overall responsibility for the decision-making related to REMAP-CAP. The role and responsibilities of the ITSC are defined in relevant Core Protocol documents and in the ITSC Terms of Reference.
- **Regional Management Committees (RMCs)** are responsible for regional-level decision making related to REMAP-CAP implementation in the relevant region. The role and responsibility of each RMC is outlined in Region Specific Appendices (RSAs)
- **Domain Specific Working Groups (DSWG)** are responsible for the design and implementation of specific domains. The role of DSWGs is outlined in relevant Core Protocol documents, and membership of each DSWG is specified in the relevant Domain-Specific Appendix (DSA)
- The **Statistical Analysis Committee (SAC)** are unblinded statisticians who takes responsibility for the conduct of the pre-planned adaptations in the trial. This task generally consists of running predetermined statistical models at each adaptive analysis and providing this output to the DSMB.
- The **Data Safety and Monitoring Board (DSMB)** are responsible for unblinded evaluations of data for safety and efficacy. They review received frequent updates of the trial's adaptive analyses from the SAC and monitor for safety. The role and composition of the DSMB is specified in the DSMB Charter.
- The **Report and Analysis Group (R&A)** are responsible for providing oversight of the publishing of results from the platform and ensuring clear, accurate and consistent representation of the methods, results and conclusions from the platform.
- The **Design Team** are responsible for designing the overall platform and the methodological aspects of individual domains. They also carry-out the unblinded analyses secondary and sensitivity analyses for publications.

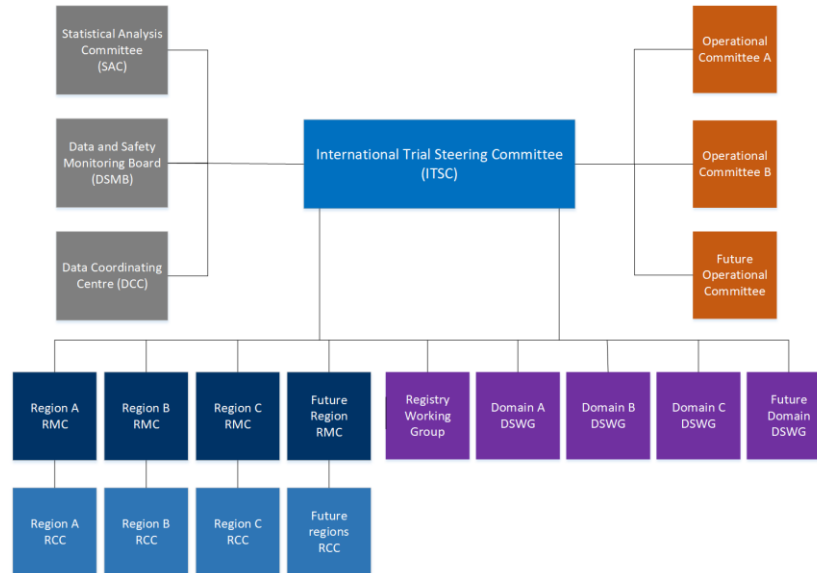


Figure 1. Organisational Structure of the REMAP-CAP Platform.

Manuscripts

Primary manuscripts present the primary results of domains within the REMAP-CAP Platform. To date, primary manuscripts have reported results from the Corticosteroid, COVID-19 Immune Modulation, Anticoagulation, Antiplatelet, Immunoglobulin, COVID-19 Antiviral, ACE2 RAS, Simvastatin and Vitamin C domains.

Secondary manuscripts present the results of analyses that are outside the primary reports of the DSAs and the Core Protocol. These may include analyses of subpopulations, reports of specific secondary outcomes, or alternate analytic strategies. An example is the [Long-term \(180-Day\) Outcomes in Critically Ill Patients With COVID-19 in the REMAP-CAP Randomized Clinical Trial](#).

Sub-study manuscripts present the results of sub-studies within the REMAP-CAP Platform that utilise data from the Platform but operate under a separate protocol and analytic plan from the main core protocol and domain specific appendix. An example of a sub-study manuscript is [Coronavirus disease 2019 subphenotypes and differential treatment response to convalescent plasma in critically ill adults: secondary analyses of a randomized clinical trial](#).

Meta-analyses, for the purpose of this policy, use REMAP-CAP data that are not routinely available from the primary manuscript. An example of a meta-analysis that included data from REMAP-CAP is the [Association between convalescent plasma treatment and mortality in COVID-19: a collaborative systematic review and meta-analysis of randomized clinical trials](#).

Trial Integrity

The primary role of REMAP-CAP is to produce high-quality evidence to inform clinical practice, which is achieved primarily by presenting major trial results from the platform, i.e., primary manuscripts. Hence, any secondary manuscripts, sub-study manuscripts, or meta-analyses can only be disseminated after any related primary results have been publicly disseminated.

Authorship

REMAP-CAP uses [the JAMA guide to Authorship and Team Science](#), and endorses the ICMJE guidance for [definitions of authorship](#), and employs the CRediT taxonomy for role assignment.

Criteria for authorship

As per ICMJE guidance definitions, there are authors and collaborators. Authors satisfy all of the following criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or reviewing it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Collaborators are those who have made a significant contribution but do not satisfy ICMJE criteria. Collaborators are indexed on PubMed.

Authorship of Primary Manuscripts

All primary manuscripts will have a Group Authorship as the byline, named 'The REMAP-CAP investigators' or "The REMAP-CAP Writing Committee" depending on the journal options.

When initially planning the manuscript, the DSWG chair(s) should discuss with the chairs of the R&A group and the ITSC who will form the writing committee and they should determine the order of first and senior authors for primary manuscripts arising from the domain. If they decide to appoint joint first and / or senior authors, a footnote will be included in the manuscript stating, "these authors contributed equally to this work". All other authors will be listed alphabetically or in random order, as agreed by the DSWG, R&A and ITSC chairs. If specific journals do not allow Group Authorship as the byline, then the same principles of authorship order will be applied if individual names appear in the byline. Group Authorship should always be requested and hopefully will be acceptable by all journals with time.

A writing committee should consist of a smaller number of the above individuals, who are tasked with the primary writing of the manuscript. This should include members of the DSWG, as well as any other individuals who have made a significant contribution to the design, management, or analysis of the domain or overall platform. If there is an ordered list for all authors, the Writing Committee may be among the front- and back-end of the author list, with other authors listed in the middle.

All individuals who were members of the SAC, design team, data coordination centre, safety committee and the ITSC during the period in which the domain was active will be offered opportunity to be listed as authors. It would be usual for all members of the DSWG to be authors but if circumstances have changed this will be guided by the DSWG chair. Other key operational or regional management staff should be offered opportunity to be listed as authors, at the discretion of the DSWG, ITSC and R&A chair.

Site investigators may be invited to be authors for primary manuscripts if it is deemed that they have contributed substantially to recruitment of participants contributing to the dataset that was the basis of the manuscript (e.g., for sites at which more than 5-10% of participants in a given dataset were enrolled, depending on size of the domain). Decisions about inclusion of site investigators as authors on a primary manuscript is at the discretion of the DSWG, R&A, & ITSC Chairs.

Any disagreements relating to authorship should be brought to the attention of the R&A and ITSC Chairs for discussion at an ITSC meeting, if needed.

Authorship of Secondary or sub-study manuscripts

Secondary and sub-study manuscripts may choose to be published under 'The REMAP-CAP investigators' for secondary analyses, or Individual Authors 'for the REMAP-CAP Investigators' if it represents a sub-study where only some investigators were involved in its creation.

Manuscripts generated from data where external investigators have access to REMAP-CAP data that have been approved by the Data Sharing Committee and ITSC must have pre-approved authorship arrangements to ensure that relevant REMAP-CAP investigators are appropriately recognized, including the first and senior authors of the relevant primary manuscripts.

Authorship of meta-analyses

Authorship will be determined by the relevant research team, and agreed to in advance with the REMAP-CAP ITSC. In general, authorship should be requested for the Chair(s) of relevant DSWGs, the Chair of the ITSC, and a member of the statistics (SAC or design team) or the Data Coordination Centre at a minimum. Where possible, 'the REMAP-CAP investigators' should be acknowledged as a collaborator.

Collaborators

Collaborators include other site investigators or operational staff who do not meet criteria for authorship. Each participating site may nominate individuals involved in the delivery of the trial at their site to be listed as collaborators.

The following can also be listed as collaborators for primary manuscripts:

- Current members of operational DSWGs within the REMAP-CAP Platform,
- Current project management staff,
- Current RMC members,

Review of manuscripts

All manuscripts involving data arising from REMAP-CAP (including sub-studies) must be reviewed and approved by the REMAP-CAP ITSC prior to submission.

All authors must be given the opportunity to review the manuscript prior to submission. As much time as possible should be given for this review and the aim should always be at least 7 days. It is appreciated that sometimes very rapid review may be required but this should never be less than 48 hours.

Chairs of the various committees, DSWGs and RMCs are responsible for checking that the authorship list is accurate and complete at this time.

All primary manuscripts must be approved the Chairs of the ITSC, SAC, R&A team and the senior statistician of the Design team before submission.

During the peer-review stage, any revised manuscripts should be circulated to all authors for comment using the timelines described above. It is recognised that editorial deadlines can be short and if a minimum of 48 hours cannot be met this should be discussed with the R&A and ITSC chairs.

The ITSC should be notified of any manuscripts describing results from studies that are not part of the REMAP-CAP trial but make use of REMAP-CAP logistics or include data derived from REMAP-CAP trial data, or any studies relating to the operationalisation of the REMAP-CAP trial. The ITSC should ensure that proposed analyses and subsequent manuscripts do not compromise the integrity of REMAP-CAP, but otherwise no additional approval from the ITSC is required.

Database of authors and collaborators

A central database of members within the REMAP-CAP Investigators will be maintained by the Reporting and Analysis team, with collaboration from the RMCs, DSWGs and central

coordination team. This central record will be circulated by the Reporting and Analysis team for update upon confirmation of a new manuscript for publication.

The Reporting and Analysis team is responsible for ensuring all authors and collaborators are followed up for any outstanding details prior to manuscript submission. Each RMC, DSWG and other REMAP-CAP committee chair is responsible for ensuring all authors and collaborators within their region are followed up for any outstanding details prior to manuscript submission. All authors will be asked to confirm in writing that they have met all the ICJME criteria.