

Standard Operating Procedure (SOP) for allocation of co-authorships in the primary publications of the INCEPT and EMPRESS trials

Purpose

This SOP outlines the principles and process for allocating co-authorships in the primary publications of the EMPRESS clinical trial and all domains on the INCEPT platform trial. The aim is to ensure fair and transparent distribution of authorship in accordance with international standards.

Scope

This SOP applies to all investigators and contributors involved in the INCEPT and EMPRESS trials who meet the criteria for authorship as defined by the International Committee of Medical Journal Editors (ICMJE).

Authorship Criteria

All authors must fulfill the **ICMJE criteria for co-authorship**, which require:

1. **Substantial contributions** to the conception or design of the work; or the acquisition, analysis, or interpretation of data.
2. **Drafting or critically revising** the manuscript for important intellectual content.
3. **Final approval** of the version to be published.
4. **Accountability** for all aspects of the work.

Allocation Principles

1. Management Committee Authorship

Members of the EMPRESS **Management Committee** and the relevant INCEPT Domain Management Committee, respectively, who meet the ICMJE criteria will be offered co-authorship.

2. Site Investigator Authorship

Site investigators with **one or more enrolled patients** who meet the ICMJE criteria will be offered co-authorship.

3. Additional Authorships Based on Recruitment

For every **50 patients enrolled** at a site, one additional co-authorship will be allocated, provided the individual(s) proposed for these positions also meet the ICMJE criteria.

4. Additional Authorships

Additional co-authorships can be granted following **substantial contribution** to the trials, e.g., to trial coordinators, data managers, statisticians etc., provided the individual(s) proposed for these positions meet the ICMJE criteria.

Conditions

- Meeting the ICMJE criteria is **mandatory** for all authorships.
- Authorship allocation is **subject to review and revision** if necessary to ensure compliance with journal requirements and fairness.

Review and Revision

The allocation may be revised by the **EMPRESS Management Committee and the INCEPT Platform Management Committee**, respectively, if:

- There are disputes regarding eligibility.
- Journal guidelines impose limitations on the number of authors or require group authorship.
- Additional contributors meet authorship criteria and need to be accommodated.

Documentation

Each proposed author must submit:

- A signed statement confirming compliance with ICMJE criteria alongside the submitted manuscript(s).
- A description of their contributions in the manuscript(s) according to the CRediT statement.

Approval

Final authorship lists will be approved by the EMPRESS Management Committee and the relevant INCEPT Domain Management Committee, respectively prior to manuscript submission.

Acknowledgement

All trial personnel who do not meet the criteria for co-authorship will be acknowledged.