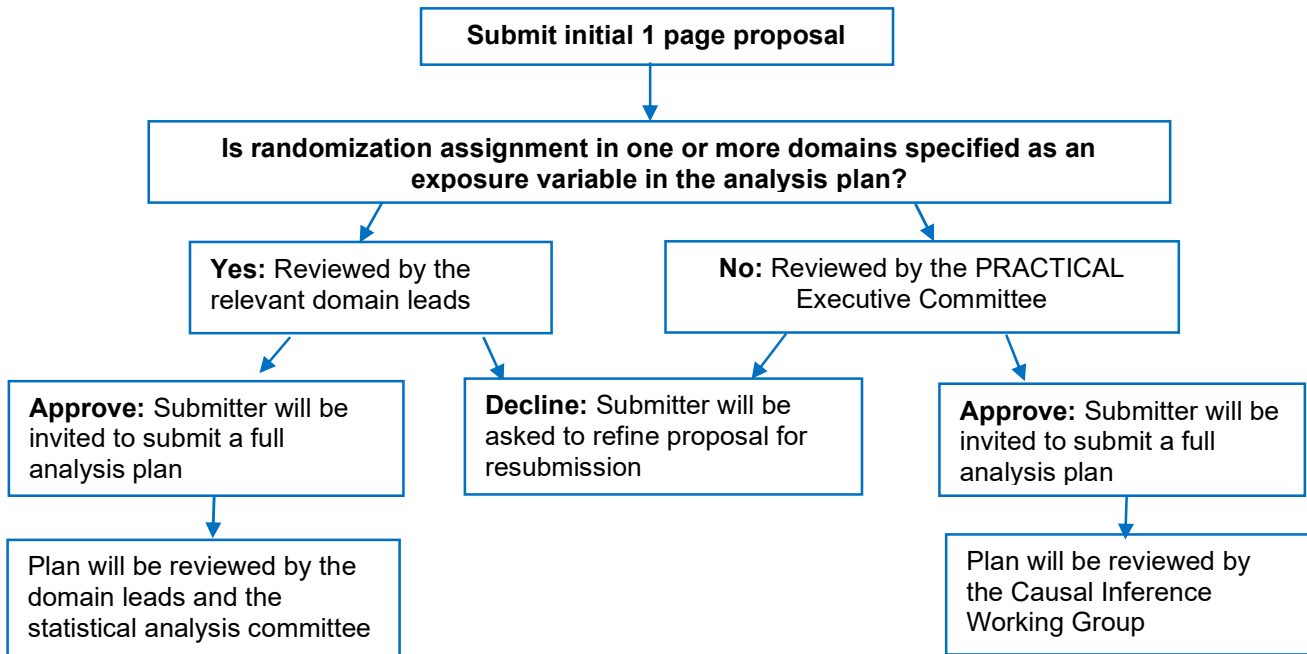


## Standard Operating Procedure (SOP): Process for Proposed Ancillary Analyses of Platform Data

The PRACTICAL platform welcomes investigators to submit proposals for ancillary analyses of PRACTICAL data. The review pathway depends on the nature of the proposed analysis:



### Submission Instructions:

- To propose a new scientific or observational data proposal, please complete the attached application form and include any relevant supplementary materials.
- Proposals need a sponsor (a domain or intervention lead in the platform); the support of this individual should be indicated on the application. The platform chairs can identify a platform sponsor for the analysis if needed. Sponsorship does not guarantee approval of the proposal.
- Submit all documents to [info@practicalplatform.org](mailto:info@practicalplatform.org).

### Note re PRACTICAL platform publication policies:

- For secondary analyses of randomized trials in PRACTICAL (where randomized assignment is an exposure variable), PRACTICAL investigators have exclusive access to the data for a specific trial for one year following the primary publication of the trial, and data will be made publicly available thereafter
- For secondary analyses of observational data in PRACTICAL (where randomized assignment is not an exposure variable), such analyses are potentially permissible prior to the publication of the primary trial(s) result, but will likely only be permitted if there is a pressing rationale for the analysis

### Evaluation Criteria: Proposals will be assessed based on:

- Scientific rationale
- Methodological rigor
- Feasibility and data use (who will perform the analysis, where will it be performed)
- Relevance to PRACTICAL goals
- Ethical and data governance considerations
- Potential impact on clinical practice, research, and the Platform
- Proposed authorship is deemed acceptable



## Application for Ancillary Analyses

### SECTION 1: GENERAL INFORMATION

**Name of Applicant:** Click or tap here to enter text.

**Proposal Title:** Click or tap here to enter text.

**Prior Engagement:** Has this proposal been discussed with any members of the PRACTICAL Executive Committee or domain or intervention leads?  Yes  No  
If yes, please specify: Click or tap here to enter text.

### SECTION 2: PROPOSAL DETAILS

#### SUMMARY INSTRUCTIONS:

Please provide a 1-2 page summary of your proposed scientific or observational data analysis, addressing the following key areas:

1. **Background & Rationale**

Briefly describe the clinical context, the knowledge gap your proposal addresses, and how it aligns with PRACTICAL's objectives (e.g., improving outcomes in acute hypoxemic respiratory failure).

2. **Methodological Approach**

Outline the study design, analytical framework, exposure variables, inclusion/exclusion criteria, and outcome measures.

3. **Implementation Plan**

Describe how the analysis will be initiated upon approval, including any planned sequential analyses and the overall timeline.

4. **Feasibility & Data Use**

Address ethical considerations, data governance, and the suitability of PRACTICAL platform data for your analysis.

Specify who will perform the analysis, and where will it be performed. Options include:

- a) In-house analysis at sponsor institution – please describe funding available to support statistician time
- b) Virtual platform environment hosted by sponsor institution, analysis conducted by applicant's team
- c) Data transfer to another institution for analysis by investigator, analysis conducted by applicant's team

5. **Potential Impact**

Highlight the anticipated clinical, scientific, and platform-level contributions of your proposal.