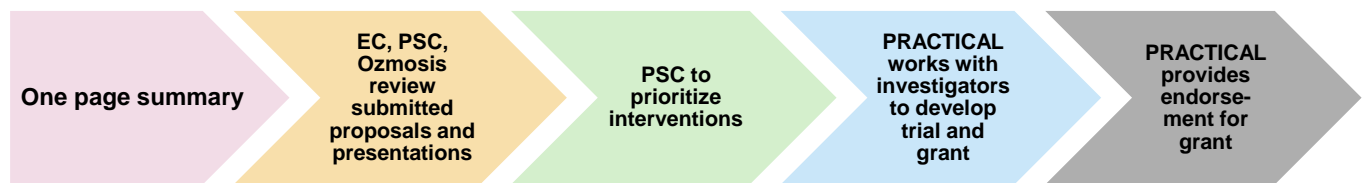


Process to apply for a new clinical trial in PRACTICAL

The PRACTICAL platform welcomes proposals for clinical trials on novel interventions intended for patients with acute hypoxemic respiratory failure (AHRF). Investigators from around the world are encouraged to submit their clinical trial proposals to the PRACTICAL. The evaluation of proposals will follow the outlined process below.

Note:

EC = Executive Committee, PSC = Platform Steering Committee



- Please complete the appended application and include supplementary materials if you wish to propose adding a new domain or intervention in an existing domain. Once complete, please send relevant attachments to info@practicalplatform.org.
- Applicant(s) will be scheduled to give a 15-min presentation to the PRACTICAL Executive Committee (EC), Platform Steering Committee (PSC), and the Ozmosis. If the proposal involves a new intervention in an existing domain, the relevant domain lead(s) will also participate in this preliminary review.
- Proposals will be evaluated according to the following criteria:
 - Alignment with PRACTICAL platform objective of improving outcomes for patients with AHRF
 - Investigator-initiated trial
 - Fit with existing domains and interventions currently active or in development
 - Bandwidth for development in clinical trial management and statistical design teams
- Platform Steering Committee (PSC) will be involved to help prioritize interventions
 - In the case of proposals that are highly ranked but the investigators face challenges access sufficient peer-reviewed funding for their proposal, including investigators from low- and middle-income countries, the platform team will work with the investigators to develop a funding strategy for the proposed trial.
- PRACTICAL will support investigators to develop their trial concept and grant applications, providing information on platform structure and function and how their trial would be implemented
 - Adaptive trial design support and advice
 - Standard language for grant sections on trial operations and biobanking

Other important information:

- New domain intervention applications will be grouped and presented twice yearly (April and October).



Application for a new clinical trial in PRACTICAL

- Please complete the appended application and include supplementary materials if you wish to propose adding a new domain or intervention in an existing domain. Once complete, please send relevant attachments to info@practicalplatform.org.
- You will be scheduled to give a 15-min presentation to the PRACTICAL Executive Committee (EC), Platform Steering Committee (PSC), and the Ozmosis.

APPLICANT(S) INFORMATION

Applicants:

	Name(s)	Institution	Department	Academic Status (Early / Mid / Senior)
1				
2				
3				
4				

PROPOSED PROJECT:

1) Please briefly describe the research question and intervention you wish to study.

2) (A) Has the proposal been discussed with any of the current PRACTICAL domain leads?

(B) Which state does the intervention apply to?

- State 1: Not intubated but require non-invasive oxygen/respiratory support for hypoxemia
- State 2: Intubated and have low respiratory system elastance (≤ 2.5 cm H₂O/(ml/kg PBW))
- State 3: Intubated and have high respiratory system elastance (> 2.5 cm H₂O/(ml/kg PBW))
- State 4: Receiving extracorporeal life support

(C) What is the name of the new intervention you're proposing?

1 PAGE SUMMARY:

Please describe the proposed clinical trial by addressing the following points in the following page.

- 1) Background and rationale for the trial and how the question aligns with PRACTICAL objectives of improving outcomes for patients with acute hypoxemic respiratory failure.
- 2) Whether the proposal is for a new domain or new intervention within an existing domain (if the latter, investigators are strongly encouraged to have discussed with relevant domain lead(s))
- 3) Patient, Intervention, Comparison, Outcome, and Time (PICOT) question
- 4) Importance
- 5) Funding plan and status

Please use space below for the 1-page summary.