

Appendix 1:

Presentation template provided to researchers.

Template presentation to CCTR COVID-19 clinical trials committee

High Quality Studies

- Strong rationale – specific to COVID-19 (targeting the viral mechanism or the cytokine release mediated injury to lungs or other organs)
- Multi-center trials with coordination by a Clinical Research Organization
- Phase III clinical trials
- Drugs that are FDA approved and/or have a known safety/risk profile

Low Quality Studies

- Incomplete developed rationale (i.e. vague anti-inflammatory mechanisms)
- Single-center studies exploring a small number of patients
- Lack of coordination by a Clinical Research Organization
- Phase I-II clinical trials
- Drugs without unknown safety risk profile

Study Title

Site PIs: NAME / Sponsor: NAME / Study PI: NAME /

Background and Rationale

- 1 or more slides
- Text and/or figure(s)

Protocol Summary

- Study Design
- Endpoints
- Schedule of Events

Selection criteria

- Inclusion Criteria
- Exclusion Criteria
- Highlight key differences with other trials (if applicable)

Research team

- Staff/resources available
- Additional resources required

Funding

- Available
- Requested
- Sufficient

Regulatory

- FDA IND status
- IRB review status

Target presentation: 10-15 slides; 10-12 minutes

Appendix 2:

The screenshots below provide a view of the scoring process (i.e., Impact and Complexity) for each protocol that the committee reviewed.

Conflict of Interest

Phase 3 multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of [redacted] on cytokine release syndrome in patients with COVID-19-induced pneumonia ([redacted])

Do you have any potential conflict of interest related to this study?

* must provide value

I declare that I have NO potential conflict of interest related to this study.

I recuse myself as I DO have a conflict of interest related to this study (NOTE: scoring form will automatically close).

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Impact Score

Scorer 1 ([redacted])

* must provide value

High Impact

Moderate Impact

Minor Impact

No Impact

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Impact Score	Description
High Impact	Should be strongly supported and made immediately available to patients. This would result in allocation of resources possible.
Moderate Impact	Should be support, it should be made available to patients as a back-up option. This would result in allocation in some resources but also some restrictions
Minor Impact	Can be supported, it can be made available to patients, but only if certain criteria are met. This would result in limited resources being allocated
No Impact	Should not be supported, should not be made available to our patients unless no other options exist. No support.

Resource Complexity Score

Scorer 1 ()

* must provide value

Low Complexity

Medium Complexity

High Complexity

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Complexity Score	Description
Low Complexity	Can be supported as required resources are readily available and commonly used.
Medium Complexity	Multiple resources and specialized expertise may be required but both are relatively common and/or readily available.
High Complexity	Requires resources from multiple sources, specialized resources, acquisition of new resources, and/or requires specialized expertise.

Comment ()

Expand