

Overview of Study Documents

**A Multicenter, Adaptive, Randomized,
Blinded Controlled Trial of the Safety and
Efficacy of Investigational Therapeutics for
Hospitalized Patients with Acute
Respiratory Distress Syndrome Associated
with COVID-19**

05 August 2025

NCT04843761

ACTIV-3b: Therapeutics for Severely Ill Inpatients With COVID-19 (TESICO) trial.

Overview of Trial Documents

Master protocol: NCT04843761

Aviptadil Substudy (H1): NCT06729606

Remdesivir Substudy (H2): NCT06729593

Document	Document Date	Description
Study Protocol: Master	March 8, 2022	<p>The master protocol document for TESICO/ACTIV-3b.</p> <p>This document should be used together with the agent specific appendices (H1 and H2) to understand the data collection for the Aviptadil and Remdesivir substudies.</p>
Study Protocol: Aviptadil (H1)	March 8, 2022	Appendix H1 to the TESICO master protocol document. Provides additional agent-specific information for the Aviptadil component of the trial.
Study Protocol: Remdesivir (H2)	April 1, 2021	Appendix H2 to the TESICO master protocol document. Provides additional agent-specific information for the Remdesivir component of the trial.
Statistical Analysis Plan: Main	August 5, 2021	This document applies for both the Aviptadil and Remdesivir substudies.
Statistical Analysis Plan: Addendum	May 1, 2022	This document applies to the Aviptadil substudy.
Informed Consent	March 8, 2022	This document applies for both the Aviptadil and Remdesivir substudies.