

Summary of Changes to the EU Appendix

Sponsor: University of Oxford

EU Trial number: CT-2023-507441-29-00

Application number: SM-9

Protocol Number: NA

Protocol Title: Randomised evaluation of COVID-19 therapy (RECOVERY)

The EU Appendix has undergone a substantial revision, resulting in a new version of this document (Version 2.0 – 30 June 2025). The changes compared to EU Appendix V1.0 dated from 24 January 2024 are summarized below.

Section	Description of changes	Reason
Version history	V2.0, 30 June 2025 was added	Updated version
EU Context	References to COVID-19 were removed Baloxavir was added to table 1 “alone” was replaced by “without relevant drug”	Updates to treatment arm Clarification
Governance in the EU	Reference to GCP “R2” was removed	Issuance of GCP R3 guideline in July 2025
3.1 EU Core protocol clarifications, Table 2	Baloxavir was added “28-day” was replaced with “initial” “call to participant” was removed Footnotes added	Update to treatment arm Simplification/practical change Practical update (not necessary) Added for clarification. Procedures have not changed from previous version.
3.2 Core protocol section 2.1: Eligibility	Reference to COVID-19 was removed Bullet points reformatted	Updates to treatment arms
3.3 Core protocol Section 2.2: Consent	Country specific details added for Belgium, Estonia, Portugal, Romania, Spain, Sweden	MSCs added
3.6 Core protocol section 2.4: Randomised allocation of treatment for COVID-19	COVID-19 treatment removed	Treatment arm has been removed from core protocol
New section 3.7 Core protocol section 2.4: Randomised	Moved to 3.6 Statement added that baloxavir arm is not open for pregnant/lactating women	Textual update New treatment arm

allocation of treatment for Influenza		
Through 3.18	Numbering updated	Textual update
3.10 Core protocol Section 3: Statistical Analysis	Rate ratio for mortality rates in table 3 was corrected	Correction
3.12 Core protocol section 4.4: Role of the Data Monitoring Committee	Added a sentence on where to find the DMC charter on the website	Additional information
3.15 Core protocol Section 6.5: Supply of study treatments	Supply information added for baloxavir	New treatment arm
4 Justification of low intervention status	Text added on the trial supply of baloxavir	New treatment arm
5.2 Baloxavir marboxil	Structured risk analysis for baloxavir marboxil added	New treatment arm
5.3 Corticosteroids	Dosing adjusted for pregnant and lactating women	Updated to match core protocol & training materials. 160mg daily is the total dose of hydrocortisone, which should be given as 80mg twice daily.
References	Formatting corrected	Correction