



# Protocol Amendment to Influenza Antiviral Domain-Specific Appendix Summary of Changes

## **REMAP-CAP: Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia**

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REMAP-CAP Influenza Antiviral Domain-Specific Appendix Amendment Summary of Changes

Dated 16 October 2021

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## **1. BACKGROUND TO AMENDMENT**

The Influenza Antiviral Domain-Specific Appendix Protocol document underwent an amendment in October 2023. The primary objective of this amendment is to make minor changes to provide clarification and context to the recruitment of pediatric patients to this domain of REMAP-CAP.

## 2. SUMMARY OF CHANGES

Section	Original text	New Text	Reason
Front page and whole document header	REMAP-CAP Influenza Antiviral Domain-Specific Appendix Version 2.1 dated 14 February 2022	REMAP-CAP Corticosteroid Domain-Specific Appendix Version 2.2 dated 16 October 2023	Administrative change
Whole document	Version 2.1  14 <sup>th</sup> February 2023	Version 2.2  16 <sup>th</sup> October 2023	Minor administrative corrections to align new sections referenced in the text and with nomenclature across protocol documents. Updated appendix approval date by Chair
Section 8.2	...moderate or severe state patients, and children down to 28 days of age).	...moderate or severe state patients, and children down to 28 days of age), <b>corrected gestational age</b> ).	The eligibility criteria were updated to incorporate corrected gestational age
Section 8.3.2	Dosing for children is 4mg/kg/day, divided into two doses. Dose adjustment for renal dysfunction in children will be per local guidelines.	Dosing for children is <b>4as per local guidelines. A standard dose for oseltamivir in children is 6 mg/kg/day</b> , divided into two doses, <b>up to children of 40 kg</b> . Dose adjustment for renal dysfunction in children will be per local guidelines.	The dosing recommendations for children were updated to incorporate variable dose practices.

	The shock strata will not contribute to unit-of-analysis for this domain. If applied in a future amendment of the Core Protocol, a COVID-19 strata will not contribute to unit-of-analysis for this domain.	The age strata will contribute to the unit-of-analysis for this domain. The shock strata will not contribute to unit-of-analysis for this domain. If applied in a future amendment of the Core Protocol, a COVID-19 strata will not contribute to unit-of-analysis for this domain.	The unit-of-analysis was updated to incorporate age-strata.
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