

REMAP-CAP Current Document Version Tracker

1. Contact Information		
Sponsor contact list	V2.0	10-Nov-2025
UK Trial Management contact list	V2.0	10-Nov-2025
Site mailing list form (supersedes site contact list)	V1.0	10-Nov-2025
2. Regulatory and Ethics		
Initial application and approvals (Ethics, HRA and MHRA)	Various	
COVID: Substantial amendments 1 to 36	Various	
COVID: Non substantial amendments 1 to 5	Various	
FLU: Substantial amendments 37 to 43	Various	
FLU: Non substantial amendments 6 to 14	Various	
REMAP-CAP Amendment Tracker	V24, 06-Jan-2026	
3. Contracts & Finances		
Statement of Activities	V1.0	19-Mar-2018
SoECAT	V2.0	01-Nov-2022
REMAP-CAP Retention of Records Statement	V3.0	05-Aug-2020
Site Agreement and Amendments	Site specific	
Flu Funding Agreement and Amendments	Site specific	
4a. Protocols / DSAs and other Appendices		Version
		Date
REMAP-CAP Core Protocol (SA43) + Summary of Changes (SoC)	V4.0	05-Nov-2024
REMAP-CAP COVID-19 Immunoglobulin domain specific appendix (SA43) + SoC	V4.0	05-Nov-2024
REMAP-CAP Antibiotic domain specific appendix + SoC (SA43)	V4.0	05-Nov-2024
REMAP-CAP Macrolide domain specific appendix + SoC (SA43)	V4.0	05-Nov-2024
REMAP-CAP Corticosteroid domain specific appendix + SoC (SA43)	V6.0	05-Nov-2024
REMAP-CAP Antiviral domain specific appendix + SoC (SA43)	V3.0	05-Nov-2024
REMAP-CAP Immune Modulation Influenza domain specific appendix, Adult + Paediatric patients (SA43)	V2.1	09-May-2025
REMAP-CAP European region specific appendix (SA43)	V4.0	06-Nov-2024
REMAP-CAP EU RSA Country Annex (UK)	V1.0	07-Aug-2025
REMAP-CAP Statistical analysis appendix + SoC (SA43)	V4.0	05-Nov-2024
REMAP-CAP Registry domain specific appendix (SA43)	V2.0	05-Nov-2024
REMAP-CAP PANDA	V1.0	05-Nov-2024
4b. Domain Choice pages		
REMAP-CAP COVID-19 Immunoglobulin choice page	V3.0	29-Nov-2021
REMAP-CAP Immune Modulation choice page	V1.1	6-Feb-2024
REMAP-CAP Antiviral choice page	V2.2	16-Jan-2024
REMAP-CAP Corticosteroid choice page	V5.1	17-Feb-2024
REMAP-CAP Macrolide choice page	V3.0	10-Jul-2019
REMAP-CAP Antibiotic choice page	V3.0	10-Jul-2019
REMAP- CAP Protocol signature page	V2.2	15-Nov-2024
5a. (P)IS/ICFs and posters etc. NOTE: not including site specific versioning		
REMAP-CAP Patient IS/ICF (SA43)	V3.0	01-Jul-2025
REMAP-CAP Patient Summary IS/ICF (SA43)	V3.0	01-Jul-2025
REMAP-CAP Patient Video CF (SA43)	V3.0	01-Jul-2025

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REMAP-CAP Personal Legal Rep IS/ICF (SA43)	V3.0	01-Jul-2025
REMAP-CAP Personal Legal Rep Summary PIS/ICF (SA43)	V3.0	01-Jul-2025
REMAP-CAP Personal Legal Rep Video CF (SA43)	V3.0	01-Jul-2025
REMAP-CAP Professional Legal Rep Summary ICF (SA43)	V3.0	01-Jul-2025
REMAP-CAP Telephone CF (SA43)	V4.0	01-Jul-2025
REMAP-CAP Young Children 0-9 yrs IS/ICF (SA43)	V3.0	01-Jul-2025
REMAP-CAP Children 10-15 yrs IS/ICF (SA43)	V3.0	01-Jul-2025
REMAP-CAP Young People 16-17 yrs IS/ICF (SA43)	V3.0	01-Jul-2025
REMAP-CAP Children 0-15 yrs Video Consent (SA43)	V3.0	01-Jul-2025
REMAP-CAP Young People 16-17 yrs Video Consent (SA43)	V3.0	01-Jul-2025
REMAP-CAP Children 0-17 yrs Professional Legal Rep Summary ICF (SA43)	V3.0	01-Jul-2025
REMAP-CAP Children 0-17 yrs Telephone CF (SA43)	V3.0	01-Jul-2025
REMAP-CAP Privacy Notice (SA43)	V2.0	27-Aug-2025
REMAP-CAP UK Leaflet for patients (NSA14)	V3.0	19-Dec-2025
REMAP-CAP UK Poster for Staff	V2.0	02-Feb-2024
REMAP-CAP UK Poster for Adult patients	V2.1	18-Mar-2024
REMAP-CAP UK Poster for Child patients	V2.0	18-Apr-2024
5b. Subject Logs / Questionnaires		
Subject Screening and/or Enrolment Log (or NTF if e-log)	V2.0	21-Oct-2020
Subject Identification Log (or NTF if e-log)	n/a	June 2015
D180 follow up questionnaire	V1.0	03-Dec-2020
D180 patient telephone script	V1.5	05-Jun-2023
D180 proxy telephone script	V1.5	07-Jun-2023
D180 telephone contact log	V1.0	20-Mar-2020
EQ-5D-5L interviewer administration	V1.4	2019
EQ-5D-5L Proxy 1 (Note: Proxy 2 is discontinued as of 1Aug25)	V1.4	2013
EQ-5D-5L telephone script	V1.3	2012
PedsQL 2-4 yrs parent (SA43)	V4.0	13-Oct-2015
PedsQL 5-7 yrs young child (SA43)	V4.0	13-Oct-2015
PedsQL 5-7 yrs parent (SA43)	V4.0	13-Oct-2015
PedsQL 8-12 yrs child (SA43)	V4.0	13-Oct-2015
PedsQL 8-12 yrs parent (SA43)	V4.0	13-Oct-2015
PedsQL 13-18 yrs teenager (SA43)	V4.0	13-Oct-2015
PedsQL 13-18 yrs parent (SA43)	V4.0	13-Oct-2015
6. Insurance		
Subject insurance policy May20 to Jun26 (SA41)	n/a	10-Jan-2023
Subject insurance policy - Endorsement No.3 (increased patients)	n/a	10-Jan-2020
Subject insurance policy - Endorsement No.4 (N domain) (SA41)	n/a	02-May-2024
Subject insurance policy - Endorsement No.5 (N domain) (SA43)	n/a	16-May-2025
7. Site Personnel		
REMAP-CAP Delegation Log	V3.0	13-Feb-2024
REMAP-CAP Paper Training Log (Adults & Paeds) Or e-log confirmation email from REMAP-CAP website	V1.0	10-Nov-2025
CVs (for all staff on delegation log except eligibility assessors)	Site specific	

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GCPs (for all staff on delegaton log except eligibility assessors)	Site specific	
8. Monitoring		
REMAP-CAP Initiation Visit Attendance log	V1.0	May 2015
Initiation Visit Report	Site specific	
REMAP-CAP Site Visit Log	V2.0	25-Oct-2022
Monitoring confirmation letters/emails	Site specific	
Monitoring follow up letters/emails	Site specific	
9a. Procedures: IMP Administration Guides		
Antibiotic Domain Administration Guide	V2.0	5-Dec-2019
Macrolide Duration Domain Administration Guide	V1.0	5-Dec-2019
COVID-19 immunoglobulin Administration Guide	V3.1	25-May-2022
Corticosteroid Domain Administration Guide	V2.0	10-Dec-2022
Antiviral Domain Administration Guide	V2.2	17-Jan-2024
Immune Modulation Domain Administration Guide	V1.0	26-Oct-2023
9b. Procedures: Score calculators, FAQs		
REMAP-CAP APACHE II Calculation Instruction V2	V2.0	n/a
REMAP-CAP Sofa score calculation	V1.0	n/a
REMAP-CAP FAQs	Ongoing	See REMAP-CAP website
9c. Procedures: Eligibility & Consent Statements		
REMAP-CAP Eligibility checklist and statement	V2.0	25-Jun-2025
REMAP-CAP Consent statement	V1.0	24-Jun-2025
9d. Procedures: Co-enrolment		
REMAP-CAP Co-enrolment Policy	V1.0	26-Nov-2018
REMAP-CAP Co-enrolment Table	V9.0	14-Oct-2025
10a. Pharmacy IMP Logs/Forms and Manuals		
IRAS 237150 Pharmacy Technical Review Form REMAP CAP complete REISSUED	N/A	18-Jun-2020
REMAP-CAP Pharmacy Guide (to be superseded soon)	V4.0	26-Oct-2023
REMAP-CAP Baloxavir Pharmacy Manual (to be superseded soon)	V2.1	2-May-2024
REMAP-CAP Temperature Deviation Form	V1.0	27-Oct-2025
REMAP-CAP IMP Resupply Request Form	V3.0	7-Nov-2025
REMAP-CAP IMP AoR Tocilizumab and Baloxavir	V1.0	21-Oct-2025
REMAP-CAP IMP Destruction Log Tocilizumab and Baloxavir	V1.0	22-Oct-2025
REMAP-CAP IMP Inventory Log Tocilizumab	V1.0	22-Oct-2025
REMAP-CAP IMP Inventory Log Baloxavir (tablets)	V1.0	22-Oct-2025
REMAP-CAP IMP Inventory Log Baloxavir (granules)	V1.0	22-Oct-2025
Baloxavir Sample Labels (tablets) - primary/secondary (SA41)	08-Mar-2024	
Baloxavir Sample Labels (granules) - primary/secondary (SA42)	01-Oct-2024	
Tocilizumab Sample Labels - primary/secondary (SA42)	08-Mar-2024	
10b. SmPCs, CoAs, QPs etc		
SmPCs (SA43)		
RSI Changes 2025:		
- Azithromycin tablets + Summary of Changes (SoC)	13-Feb-2025	
- Erythromycin powder + SoC	09-Apr-2025	

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<ul style="list-style-type: none"> - Erythromycin tablets + SoC - Hydrocortisone + SoC - Dexamethasone injection + SoC - Baricitinib + SoC - Tocilizumab + SoC 		<p>10-Oct-2024</p> <p>01-Feb-2025</p> <p>09-Apr-2025</p> <p>16-Jul-2024</p> <p>02-Oct-2024</p>
<p>RSI Changes 2024:</p> <ul style="list-style-type: none"> - Erythromycin tablets + SoC - Clarithromycin tablets + SoC - Clarithromycin powder + SoC - Baloxavir tablets + SoC - Baricitinib + SoC 		<p>20-Feb-2024</p> <p>15-Mar-2024</p> <p>07-Mar-2024</p> <p>08-Sep-2023</p> <p>27-Mar-2024</p>
<p>SmPCs (SA42):</p> <ul style="list-style-type: none"> - Baloxavir granules - Amoxicillin Clavulanate - Ceftriaxone - Levofloxacin - Moxifloxacin - Piperacillin Tazobactam - Roxithromycin - Oseltamivir - Dexamethasone tablets 		<p>07-Jan-2021</p> <p>03-Mar-2020</p> <p>21-Feb-2023</p> <p>02-Nov-2022</p> <p>09-Nov-2020</p> <p>29-Dec-2022</p> <p>May 2020</p> <p>25-May-2021</p> <p>07-Jun-2023</p>
<p>QP:</p> <ul style="list-style-type: none"> - QP declaration Tocilizumab (SA42) - QP declaration Baloxavir granules (SA42) - Roche regulatory compliance letter - Baloxavir switch to CT supply (SA42) - QP declaration Baloxavir tablets (SA41) - Roche regulatory compliance letter – Baloxavir commercial clinical supply (SA40) 		<p>31-Oct-2023</p> <p>22-Jul-2024</p> <p>22-Aug-2024</p> <p>31-Oct-2023</p> <p>29-Nov-2023</p>
11. Local labs & Nasal Swabs		
REMAP-CAP Antiviral Influenza Swab Guide	V1.2	27-Jan-2025
Influenza Nasal Swab Tracker	V1.0	30-Jan-2024
12. Safety		
Safety Reporting Flowchart	V1.0	04-Apr-2018
Paper SAE Form (back up)	V2.0	Nov 2020
SAE Log (download from study database)		Site specific
DSURs v4.1 to v8.0		Various
13. eCRF / Study Database		
REMAP-CAP Site Database Form	V16.0	19-Jan-2024
UK REMAP-CAP eCRF Data Completion Guidelines	V14.0	17-Jul-2024
REMAP-CAP Spiral Database User Guide	V13.0	6-Sep-2023
REMAP-CAP 2FA Guide	n/a	n/a
14. PDs and NTFs		
REMAP-CAP Note to File	V1.0	March 2017
REMAP-CAP Note to File Log	V1.0	March 2017
REMAP-CAP Protocol Deviation Log (Or download from study database)	V1.0	18-Jan-2022

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Study wide NTFs	Various	
15. Meetings		
REMAP-CAP Refresher slides Nov 2025	n/a	Nov 2025
Q&A sessions - see REMAP-CAP website for Q&As	Various	
Correspondence / Other		
ITSC letter - Closure of C2 domain intervention	n/a	06-Dec-2023
ITSC letter- Closure of Antibiotics and Macrolides for Covid-19 strata	n/a	25-Mar-2024
CMO Letter	n/a	03-Jan-2023
CSA Letter	n/a	12-Jan-2024
DSMB Letter (SA42)	n/a	07-Nov-2024
UKTIS Letter re Tocilizumab in pregnancy	n/a	12-May-2023
Newsletters (quarterly)	Various	