

PRINCIPLE Document Version Log

CURRENT version

Section	Document	Version	Date	Approval
A4		Protocol		
	Protocol	14.0	08.08.2022	SA22
	Protocol	13.0	24.01.2022	SA21
	Protocol	12.0	04.11.2021	SA20
	Protocol	11.0	19.10.2021	SA19
	<i>Protocol</i>	<i>10.0</i>	<i>19.09.2021</i>	<i>SA18 (non-acceptance from MHRA)</i>
	Protocol	9.1	24.07.2021	SA17
	Protocol	9.0	12.07.2021	SA16
	Protocol	8.1	12.04.21	SA15
	<i>Protocol</i>	<i>8.0</i>	<i>15.03.21</i>	<i>SA14 (non-acceptance from MHRA)</i>
	Protocol	7.1	22.02.21	SA13
	Protocol	7.0	14.02.21	SA12
	Protocol	6.3	30.12.20	SA11 (v6.2 submitted and updated to v6.3)
	Protocol	6.1	23.11.20	NS4
	Protocol	6.0	02.11.20	SA10
	Protocol	5.0	11.09.20	SA7
	Protocol	4.0	02.07.20	SA6
	Protocol	3.0	19.05.20	SA5
	Protocol	2.1	21.04.20	SA3
	Protocol	2.0	07.04.20	SA2
	Protocol	1.0	27.03.20	SA1
	Protocol	0.12	23.03.20	REC favourable opinion 26.03.20, MHRA CTA
A5.1		ICF		
	Participant Consent Form	6.0	08.08.2022	SA22
	Participant Consent Form	5.0	04.11.2021	SA20
	Participant Consent Form	4.0	19.10.2021	SA19
	<i>Participant Consent Form</i>	<i>3.0</i>	<i>24.09.2021</i>	<i>SA18 (non-acceptance from MHRA)</i>
	Participant Consent Form	2.3	27.01.21	SA13
	Participant Consent Form	2.2	26.11.20	SA11
	Participant Consent Form	2.1	07.11.20	SA10
	Participant Consent Form	2.0	11.09.20	SA7
	Participant Consent Form	1.3	18.05.20	SA5
	Participant Consent Form	1.2	21.04.20	SA3
	Participant Consent Form	1.1	07.04.20	SA2
	Participant Consent Form	1.0	27.03.20	SA1
	Participant Consent Form	0.5	22.03.20	REC favourable opinion 26.03.2020
A5.2		PIS		
	Participant Information Sheet	9.0	08.08.2022	SA22
	Participant Information Sheet	8.0	17.01.2022	SA21
	Participant Information Sheet	7.0	04.11.2021	SA20

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	Participant Information Sheet	6.0	19.10.2021	SA19
	Participant Information Sheet	5.0	20.09.2021	SA18 (non-acceptance from MHRA)
	Participant Information Sheet	4.2	24.07.2021	SA17
	Participant Information Sheet	4.1	12.07.2021	SA16
	Participant Information Sheet	4.0	22.02.21	SA13
	Participant Information Sheet	3.5	14.02.21	SA12
	Participant Information Sheet	3.4	26.11.2020	SA11
	Participant Information Sheet	3.3	07.11.20	SA10
	Participant Information Sheet	3.2	11.09.20	SA7
	Participant Information Sheet	3.1	02.07.20	SA6
	Participant Information Sheet	3.0	19.05.20	SA5
	Participant Information Sheet	2.1	21.04.20	SA3
	Participant Information Sheet	2.0	08.04.20	SA2
	Participant Information Sheet	1.1	27.03.20	SA1
	Participant Information Sheet	1.0	24.03.20	REC favourable opinion 26.03.2020
	Pictorial PIS	4.0	08.08.2022	SA22
	Pictorial PIS	3.0	19.10.2021	SA19
	Pictorial PIS	2.6	12.07.2021	SA16
	Pictorial PIS	2.5	13.03.21	SA13
	Pictorial PIS	2.4	12.02.21	SA12
	Pictorial PIS	2.3	09.11.20	SA10
	Pictorial PIS	2.2	11.09.20	SA7
	Pictorial PIS	2.1	02.07.20	SA6
	Pictorial PIS	2.0	19.05.20	SA5
	Pictorial PIS	1.0	20.04.20	SA3
	PIS Appendices	4.0	17.01.2022	SA21
	PIS Appendices	3.0	12.10.2021	SA19
	PIS Appendices	2.3	12.07.2021	SA16
	PIS Appendices	2.2	16.03.21	SA15
	PIS Appendices	2.1	22.02.21	SA13
	PIS Appendices	2.0	19.02.21	SA12
	PIS Appendices	1.4	02.12.20	SA11
	PIS Appendices	1.3	07.11.20	SA10
	PIS Appendices	1.2	02.07.20	SA6
	PIS Appendices	1.0	07.04.20	SA2
	Privacy Notice	2.0	03.02.2022	SA21
	Privacy Notice	1.3	05.08.21	SA17
	Privacy Notice	1.2	03.02.21	SA13
	Privacy Notice	1.1	07.11.20	SA10
	Privacy Notice	1.0	11.09.20	SA7
A5.3 Text Message Templates				
	Text Message Invite	4.2	12.07.2021	SA16
	Text Message Invite	4.1	12.10.20	SA8
	Text Message Invite	4.0	11.09.20	SA7

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	Text Message Invite	3.2	02.07.20	SA6
	Text Message Invite	3.1	04.06.20	NS1
	Text Message Invite	3.0	19.05.20	SA5
	Text Message Invite	2.0	01.05.20	SA4
	Text Message Invite	1.2	20.04.20	SA3
	Text Message Invite	1.1	07.04.20	SA2
	Text Message Invite	1.0	24.03.20	REC favourable opinion 26.03.20
	Text Message Invite (National 111)	1.2	01.05.20	SA4
	Text Message Invite (111)	1.1	20.04.20	SA3
	Text Message Invite (111)	1.0	27.03.20	SA1
	PRINCIPLE_Email_London Ambulance 111_	1.0	01.05.20	SA4
	SCAS Text Invite	1.2	03.11.20	NS3
	SCAS Text Invite	1.0	21.10.20	NS2
	Text Message New study invite	1.1	02.07.20	SA6
	Text Message New study invite	1.0	07.04.20	SA2
	Text Message Qualitative study invite (process evaluation invite)	1.0	07.04.20	SA2
	PRINCIPLE Text Message IMP	2.0	09.09.2021	SA20
	PRINCIPLE Text Message IMP	1.0	14.07.2021	SA16
	PRINCIPLE_Text Message Daily Diaries	3.0	01.05.20	SA4
	PRINCIPLE text messages_daily diaries	2.0	31.03.20	SA3
	PRINCIPLE text messages_daily diaries	1.0	27.03.20	SA1
	PRINCIPLE text messages_daily diaries	0.3	23.03.20	Not on list
A5.3	Other Patient Facing Information			
	Patient Recruitment Letter	2.5	12.07.2021	SA16
	Patient Recruitment Letter	2.4	29.03.21	NS5
	<i>Patient Recruitment Letter (redundant)</i>	2.3	07.01.21	SA13
	Patient Recruitment Letter	2.3	12.02.21	SA12
	Patient Recruitment Letter	2.2	09.11.20	SA10
	Patient Recruitment Letter	2.1	02.07.20	SA6
	Patient Recruitment Letter	2.0	19.05.20	SA5
	Patient Recruitment Letter	1.0	22.04.20	SA3
	Participant Introductory Letter	1.3	12.07.2021	SA16
	Participant Introductory Letter	1.2	12.02.21	SA12
	Participant Introductory Letter	1.1	02.07.20	SA6
	Participant Introductory Letter	1.0	19.05.20	SA5
	PRINCIPLE_End_of_Follow_Up_Letter	1.1	12.10.20	SA8

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	PRINCIPLE_End_of_Follow_Up_Letter	1.0	27.03.20	SA1
	PRINCIPLE_End_of_Follow_Up_Letter	0.2	23.03.20	REC favourable opinion 26.03.2020
	Study Partner Letter	1.4	12.07.2021	SA16
	Study Partner Letter	1.3	29.03.21	NS5
redundant	Study Partner Letter	1.2	07.01.21	SA13
	Study Partner Letter	1.2	12.02.21	SA12
	Study Partner Letter	1.1	09.11.20	SA10
	Study Partner Letter	1.0	19.05.20	SA5
	PRINCIPLE_Participant_Contact_Card	1.0	27.03.20	SA1
	PRINCIPLE_Participant_Contact_Card	0.2	19.03.20	REC favourable opinion 26.03.2020
	PRINCIPLE Information for participants	2.0	11.10.2021	SA19
	PRINCIPLE Information for participants	1.1	09.11.20	SA10
	PRINCIPLE Information for participants (Swab)	1.0	18.05.20	SA5
	PRINCIPLE Information for participants	1.3	18.05.20	SA5
	PRINCIPLE Information for participants (without swab info)	1.2	16.04.20	SA3
	PRINCIPLE Information for participants	1.1	08.04.20	SA2
	PRINCIPLE Information for participants	1.0	27.03.2020	SA1
	PRINCIPLE Information for participants	0.8	23.03.2020	Not on list
	IMP Returns Slip	1.0	19.09.2021	SA20
A5.3	Qualitative documents			
	PRINCIPLE_Interviews_HCP_Invitation	1.0	08.04.20	SA2
	PRINCIPLE_Interviews_HCP_PIS	1.0	08.04.20	SA2
	PRINCIPLE_Interviews_HCP_Topic	1.0	08.04.20	SA2
	PRINCIPLE_Interviews_HCP_Verbal Consent	1.0	08.04.20	SA2
	PRINCIPLE_Interviews_Patient_PIS	1.0	08.04.20	SA2
	PRINCIPLE_Interviews_Patient_Topic Guide	1.0	08.04.20	SA2
	PRINCIPLE_Interviews_Patient_Verbal Consent	1.0	08.04.20	SA2
A5.3	IMP Patient Facing Documents			
	IMP Return Letter	1.0	16.12.2021	SA21
	Ivermectin Wallet Emergency Card	1.0	15.03.21	SA15
	Participant Medication Card (Ivermectin)	1.0	15.03.21	SA15
	Favipiravir Wallet Emergency Card	1.0	03.02.21	SA13
	Participant Medication Card (Favipiravir)	2.0	24.02.2022	SA21
	Participant Medication Card (Favipiravir)	1.0	03.02.21	SA13

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	Participant Medication Card (Colchicine)	1.0	19.02.21	SA12
	Participant Medication Card (Budesonide)	1.0	07.11.20	SA10
	Participant Medication Card (Doxycycline)	1.0	02.07.20	SA6
	Participant Medication Card (Azithromycin)	1.2	17.05.20	SA5
	Participant Medication Card (Azithromycin)	1.0	07.04.20	SA2
	Participant Medication Card (Hydroxy)	1.1	02.07.2020	SA6
	Participant Medication Card (Hydroxy)	1.0	27.03.2020	SA1
	Participant Medication Receipt	1.0	07.04.20	SA2
A5.4	GP Letter			
	GP_Letter_Participant Follow-up	1.0	03.02.21	SA13
	PRINCIPLE GP letter	1.1	07.04.20	SA2
	PRINCIPLE GP letter	1.0	23.03.2020	REC favourable opinion 26.03.2020
	PRINCIPLE GP letter Scotland	2.1	12.02.21	SA12
	PRINCIPLE GP letter Scotland	2.0	11.09.20	SA7
	PRINCIPLE GP letter Scotland	1.0	01.05.20	SA4
	Medication Letter	1.1	07.01.21	SA13
	Medication Letter	1.0	19.05.20	SA5
A5.5	Patient Recruitment advertisements			
<i>redundant</i>	Patient Recruitment Pharmacy Poster	1.1	12.02.21	SA12
	Patient Recruitment Pharmacy Poster	1.0	12.10.20	SA8
	Participant Recruitment Poster	1.6	12.07.2021	SA16
	Participant Recruitment Poster	1.5	12.02.21	SA12
	Participant Recruitment Poster	1.4	25.08.20	SA7
	Participant Recruitment Poster	1.3	02.07.20	SA6
	Participant Recruitment Poster (including editable version)	1.2	19.05.20	SA5
	Participant Recruitment Poster (including editable version)	1.0	22.04.20	SA3
	Care Home Staff Poster	1.0	19.05.20	SA5
	NHS Testing Site Wording	1.1	12.02.21	SA12
	NHS Testing Site Wording	1.0	19.05.20	SA5

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	Website Advert	1.4	12.07.2021	SA16
	Website Advert	1.3	12.02.21	SA12
	Website Advert	1.2	02.07.20	SA6
	Website Advert	1.1	12.05.20	SA5
	Website Advert	1.0	01.05.20	SA4
	Social Media Post	1.4	12.07.2021	SA16
	Social Media Post	1.3	04.06.21	NS6
	Social Media Post	1.2	12.02.21	SA12
	Social Media Post	1.1	02.07.20	SA6
	Social Media Post	1.0	19.05.20	SA5
	Advert	1.2	12.07.2021	SA16
	Advert	1.1	12.02.21	SA12
	Advert	1.0	02.07.20	SA6
	Radio Advert	1.2	12.07.2021	SA16
	Radio Advert	1.1	12.02.21	SA12
	Radio Advert	1.0	02.07.20	SA6
	Video Infographic Script	1.4	12.07.2021	SA16
	Video Infographic Script	1.3	09.06.21	NS6
	Video Infographic Script	1.2	12.02.21	SA12
	Video Infographic Script	1.1	09.11.20	SA10
	Video Infographic Script	1.0	12.10.20	SA8
	Translated Video Script	1.1	12.02.21	SA12
	Translated Video Script	1.0	12.10.20	SA8
A10	CRFs and Data Collection (see DM folder for current CRFs)			
	PRINCIPLE_Baseline CRF	13.0	25.03.2022	
	PRINCIPLE_Baseline CRF	12.0	10.03.2022	
	PRINCIPLE_Baseline CRF	11.0	20.07.2021	
	PRINCIPLE_Baseline CRF	10.0	03.06.2021	
	PRINCIPLE_Baseline CRF	9.0	22.03.2021	
	PRINCIPLE_Baseline CRF	8.0	26.02.2021	
	PRINCIPLE_Baseline CRF	7.0	08.01.2021	
	PRINCIPLE_Baseline CRF	6.0	23.09.2020	
	PRINCIPLE_Baseline CRF	5.0	17.07.2020	
	PRINCIPLE_Baseline CRF	4.0	11.06.2020	
	PRINCIPLE_Baseline CRF	3.0	01.06.2020	
	PRINCIPLE_Baseline CRF	2.0	14.04.2020	
	PRINCIPLE_Baseline CRF	1.0	27.03.2020	
	PRINCIPLE_Baseline CRF	0.3	22.03.20	REC favourable opinion 26.03.20
	Day 2 Call	2.0	25.01.2022	
	Day 2 Call	1.0	14.10.2021	

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	PRINCIPLE_Day 7 14 and 28 Call CRF	16.0	27.04.2022	
	PRINCIPLE_Day 7 14 and 28 Call CRF	15.0	10.03.2022	
	PRINCIPLE_Day 7 14 and 28 Call CRF	14.0	25.01.2022	
	PRINCIPLE_Day 7 14 and 28 Call CRF	13.0	02.09.2021	
	PRINCIPLE_Day 7 14 and 28 Call CRF	12.0	06.08.2021	
	PRINCIPLE_Day 7 14 and 28 Call CRF	11.0	03.06.2021	
	PRINCIPLE_Day 7 14 and 28 Call CRF	10.0	19.04.2021	
	PRINCIPLE_Day 7 14 and 28 Call CRF	9.0	22.03.2021	
	PRINCIPLE_Day 7 14 and 28 Call CRF	8.0	26.02.2021	
	PRINCIPLE_Day 7 14 and 28 Call CRF	7.0	08.01.2021	
	PRINCIPLE_Day 7 14 and 28 Call CRF	6.0	01.12.2020	
	PRINCIPLE_Call CRF	5.0	17.07.2020	
	PRINCIPLE_Call CRF	4.0	28.05.2020	
	PRINCIPLE_Call CRF	3.0	21.04.2020	
	PRINCIPLE_Call CRF	2.0	14.04.2020	
	PRINCIPLE_Call CRF	1.0	27.03.2020	
	PRINCIPLE_Call CRF	0.3	22.03.20	REC favourable opinion 26.03.20
	PRINCIPLE_Eligibility CRF	19.0	22.10.2021	
	PRINCIPLE_Eligibility CRF	18.0	06.09.2021	
	PRINCIPLE_Eligibility CRF	17.0	20.07.2021	
	PRINCIPLE_Eligibility CRF	16.0	03.06.2021	
	PRINCIPLE_Eligibility CRF	15.0	27.05.2021	
	PRINCIPLE_Eligibility CRF	14.0	06.04.2021	
	PRINCIPLE_Eligibility CRF	13.0	22.03.2021	
	PRINCIPLE_Eligibility CRF	12.0	26.02.2021	
	PRINCIPLE_Eligibility CRF	11.0	13.01.2021	
	PRINCIPLE_Eligibility CRF	10.0	15.12.2020	
	PRINCIPLE_Eligibility CRF	8.0	23.11.2020	
	PRINCIPLE_Eligibility CRF	6.0	22.09.2020	
	PRINCIPLE_Eligibility CRF	5.0	17.07.2020	
	PRINCIPLE_Eligibility CRF	4.0	11.06.2020	
	PRINCIPLE_Eligibility CRF	3.0	21.04.2020	
	PRINCIPLE_Eligibility CRF	2.0	14.04.2020	
	PRINCIPLE_Eligibility CRF	1.0	27.03.2020	
	PRINCIPLE_Eligibility CRF	0.4	22.03.20	REC favourable opinion 26.03.20
	PRINCIPLE_Screening CRF	19.0	25.01.2022	
	PRINCIPLE_Screening CRF	18.0	20.07.2021	
	PRINCIPLE_Screening CRF	17.0	03.06.2021	
	PRINCIPLE_Screening CRF	16.0	27.05.2021	
	PRINCIPLE_Screening CRF	15.0	06.04.2021	
	PRINCIPLE_Screening CRF	14.0	22.03.2021	
	PRINCIPLE_Screening CRF	13.0	26.02.2021	
	PRINCIPLE_Screening CRF	12.0	13.01.2021	
	PRINCIPLE_Screening CRF	11.0	15.12.2020	
	PRINCIPLE_Screening CRF	9.0	23.11.2020	
	PRINCIPLE_Screening CRF	8.0	26.10.2020	

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	PRINCIPLE_Screening CRF	7.0	03.09.2020	
	PRINCIPLE_Screening CRF	6.0	17.07.2020	
	PRINCIPLE_Screening CRF	5.0	11.06.2020	
	PRINCIPLE_Screening CRF	4.0	29.04.2020	
	PRINCIPLE_Screening CRF	3.0	22.04.2020	
	PRINCIPLE_Screening CRF	2.0	14.04.2020	
	PRINCIPLE_Screening CRF	1.0	27.03.2020	
	PRINCIPLE_Screening CRF	0.4	20.03.20	REC favourable opinion 26.03.20
	PRINCIPLE_Daily Diary	15.0	10.03.2022	
	PRINCIPLE_Daily Diary	14.0	10.02.2022	
	PRINCIPLE_Daily Diary	13.0	25.10.2022	
	PRINCIPLE_Daily Diary	12.0	02.09.2021	
	PRINCIPLE_Daily Diary	11.0	06.08.2021	
	PRINCIPLE_Daily Diary	10.0	03.06.2021	
	PRINCIPLE_Daily Diary	9.0	19.04.2021	
	PRINCIPLE_Daily Diary	8.0	22.03.2021	
	PRINCIPLE_Daily Diary	7.0	26.02.2021	
	PRINCIPLE_Daily Diary	6.0	08.01.2021	
	PRINCIPLE_Daily Diary	5.0	20.10.2020	
	PRINCIPLE_Daily Diary	4.0	17.07.2020	
	PRINCIPLE_Daily Diary	3.0	28.05.2020	
	PRINCIPLE_Daily Diary	2.0	14.04.2020	
	PRINCIPLE_Daily Diary	1.0	27.03.2020	
	Notes Review CRF	5.0	03.06.2021	
	Notes Review CRF	4.0	19.04.2021	
	Notes Review CRF	3.0	26.02.2021	
	Notes Review CRF	2.0	30.07.2020	
	Notes Review CRF	1.0	24.04.2020	
	Notes Review Source Data	2.0	14.10.2021	
	Notes Review Source Data	1.0	06.09.2021	
	Death and Hospitalisation CRF	4.0	17.03.2022	
	Death and Hospitalisation CRF	3.0	03.06.2021	
	Death and Hospitalisation CRF	2.0	19.04.2021	
	Death and Hospitalisation CRF	1.0	12.05.2020	
	Discontinuation	7.0	14.10.2021	
	Discontinuation	6.0	06.09.2021	
	Discontinuation	5.0	10.08.2021	
	Discontinuation	4.0	26.02.2021	
	Discontinuation	3.0	20.10.2021	
	Discontinuation	2.0	08.09.2020	
	Discontinuation	1.0	27.03.2020	
	Lab Results	2.0	14.04.2020	

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	Lab Results	1.0	31.03.2020	
	Long Term Follow Up	2.0	01.06.2021	
	Long Term Follow Up	1.0	13.05.2021	
	Long Term Follow Up Telephone CRF	2.0	27.04.2022	
	Long Term Follow Up Telephone CRF	1.0	0.1.06.2021	
	SAE Report Form	1.0	27.03.2020	
	Safety Call	3.0	14.10.2021	
	Safety Call	2.0	03.06.2021	
	Safety Call	1.0	22.03.2021	
	Safety Monitoring	1.0	14.10.2021	
	Pregnancy Notification	1.0	22.10.2021	

A17.4		IMP		
	Ivermectin IB	3.0	04.05.2021	SA16
	Ivermectin IB	2.0	21.04.21	SA15
	Ivermectin IB	1.0	27.01.21	SA14 (MHRA Rejected)
	Favipiravir IB (400mg)	3.0	03.02.2022	SA21
	Favipiravir IB (200mg)	13.0	07.2021	SA16
	Favipiravir IB (200mg)	12.0	20.03.21	SA13
	Colchicine 500mcg SmPC	N/A	05.08.2019	SA12
	Budesonide Pulmicort Inhaler 400 SmPC	N/A	15.06.2017	SA10
	Doxycycline 100mg SmPC	N/A	19.12.2019	SA6
	Plaquenil-Hydroxychloroquine sulfate 200mg SmPC	N/A	10.03.2020	REC favourable opinion 26.03.2020, MHRA CTA
	Azithromycin 250mg SmPC	9.0		SA5
	Azithromycin 250mg SmPC		25.09.2019	SA2
	PRINCIPLE_IMP_Label form_Ivermectin	1.0	15.03.21	SA15
	PRINCIPLE_IMP_Label form_Favipiravir (400mg)	2.0	03.02.2022	SA21
	PRINCIPLE_IMP_Label form_Favipiravir (200mg)	1.0	03.02.21	SA13
	PRINCIPLE_IMP_Label form_Colchicine	1.0	19.10.21	SA12
	PRINCIPLE_IMP_Label form_Budesonide	1.0	07.11.20	SA10
	PRINCIPLE_IMP_Label form_Doxycycline	1.0	02.07.20	SA6
	PRINCIPLE_IMP_Label form_Azithromycin 250mg	1.3	17.05.20	SA5
	PRINCIPLE_IMP_Label form_Azithromycin 250mg	1.1	22.04.20	SA3
	PRINCIPLE_IMP_Label form_Azithromycin 500mg	1.1	22.04.20	SA3
	PRINCIPLE_IMP_Label form_Azithromycin 250mg	1.0	07.04.20	SA2
	PRINCIPLE_IMP_Label form_Azithromycin 500mg	1.0	07.04.20	SA2

	PRINCIPLE_IMP_Label form_Hydroxy (additional content for Fisher)	1.1	22.04.20	SA3
	PRINCIPLE_IMP_Label form_Hydroxy	1.0	23.03.20	REC favourable opinion 26.03.20, MHRA CTA