

Type	Document Title	File Name	File Size	Submission Version	Submission Date	Document Version	Document Date
Research protocol or project proposal	Trial Protocol	Protocol Draft 0.9 Final v1.0 27-Apr-2021.docx	357 Kb	1	28.04.2021 11:01	Draft 0.9/Final 1.0	27.04.2021
Summary CV for Chief Investigator (CI)	Chief Investigator CV	PROTECT-CH CI CV 03 Feb 2021.pdf	144 Kb	1	28.04.2021 11:01		
Participant information sheet (PIS)	Participant Information Sheet	Participant IS Draft 0.11 Final v1.0_27 Apr 2021.docx	682 Kb	1	28.04.2021 11:01	Draft 0.11/Final 1.0	27.04.2021
Participant information sheet (PIS)	Legal Representative Information Sheet	Legal Rep IS Draft 0.6 Final v1.0_27 Apr 2021.docx	685 Kb	1	28.04.2021 11:01	Draft 0.6/Final 1.0	27.04.2021
Participant consent form	Participant Informed Consent Form	Participant ICF Draft 0.6 Final v1.0_27 Apr 2021.docx	117 Kb	1	28.04.2021 11:01	Draft 0.6/Final 1.0	27.04.2021
Participant consent form	Legal Represent Consent Form	Legal Rep ICF Draft 0.6 Final v1.0_27 Apr 2021.docx	117 Kb	1	28.04.2021 11:01	Draft 0.6/Final 1.0	27.04.2021
GP/consultant information sheets or letters	GP eligibility check letter	PROTECT-CH_GP_eligibility_check_letter_draft_21Apr2021.docx	29 Kb	1	28.04.2021 11:01	Draft 0.1/Final 1.0	21.04.2021
GP/consultant information sheets or letters	GP IMP letter	PROTECT-CH_GP_IMP_letter_draft_21Apr2021.docx	32 Kb	1	28.04.2021 11:01	Draft 0.1/Final 1.0	21.04.2021
GP/consultant information sheets or letters	GP standard care letter	PROTECT-CH_GP_std_care_letter_draft_21Apr2021.docx	28 Kb	1	28.04.2021 11:01	Draft 0.1/Final 1.0	21.04.2021
Validated questionnaire	QoL (EQ5D5L)	PROTECT-CH_EQ5D5L_Final_Version_1.0_07_Apr_2021.pdf	79 Kb	1	28.04.2021 11:01	1.0	07.04.2021
Validated questionnaire	QoL (EQ5D5L) proxy	PROTECT-CH_EQ5D5L_Proxy_Final_Version_1.0_07_Apr_2021.pdf	68 Kb	1	28.04.2021 11:01	1.0	07.04.2021
Investigator's brochure / IMP Dossier	Ciclesonide IMPD stability data	Ciclesonide IMPD section 2.3.7.P stability data April 2021.docx	218 Kb	1	28.04.2021 11:01	April 2021	01.04.2021
Investigator's brochure / IMP Dossier	Ciclesonide IMPD	IMPD-CIC-nopb_Draft 0.1 Final V1.0 26 Apr 2021.docx	3 Mb	1	28.04.2021 11:01	1.0	26.04.2021
Investigator's brochure / IMP Dossier	Niclosamide IMPD 2.2 Nonclinical data	Niclosamide IMPD_2.2_Nonclinical_Data_version 1.0 26 Aug 2020.pdf	818 Kb	1	28.04.2021 11:01	1.0	26.08.2020
Investigator's brochure / IMP Dossier	Niclosamide IMPD 2.7.2.5	Niclosamide IMPD_2.7.2.5_Benefit_Risk_Assessment_V2.0 03 Mar 2021.pdf	117 Kb	1	28.04.2021 11:01	2.0	03.03.2021
Investigator's brochure / IMP Dossier	Niclosamide IMPD 2.7.2.4	Niclosamide IMPD_2.7.2.4_Previousclinical_experience_V1.0 26 Aug 2020.pdf	183 Kb	1	28.04.2021 11:01	1.0	26.08.2020
Investigator's brochure / IMP Dossier	Niclosamide IMPD 2.1P	Niclosamide IMPD_2.1P_DrugProduct_Version 4.0 03 Mar 2021.pdf	510 Kb	1	28.04.2021 11:01	4.0	03.03.2021
Investigator's brochure / IMP Dossier	Niclosamide IB	Niclosamide IB V1.0 26 Aug 2020.pdf	2 Mb	1	28.04.2021 11:01	1.0	26.08.2020
Summary of product characteristics (SmPC)	SmPC ciclesonide	Alvesco ciclesonide SmpC COVIS.pdf	135 Kb	1	28.04.2021 11:01		29.06.2020
Copies of materials calling attention of potential participants to the research	Participant poster	Participant Poster Draft v0.2 Final v1.0 01 Apr 2021.docx	259 Kb	1	28.04.2021 11:01	Draft 0.2/Final 1.0	01.04.2021
Copies of materials calling attention of potential participants to the research	Participant video	PROTECT-CH Participant Video V1.0 27 Apr 2021.pdf	3 Mb	1	28.04.2021 11:01	1.0	27.04.2021
Covering letter on headed paper	HRA REC Cover Letter	HRA REC letter 21001 signed.pdf	2 Mb	1	28.04.2021 11:01		28.04.2021

Type	Document Title	File Name	File Size	Submission Version	Submission Date	Document Version	Document Dat
Organisation Information Document	OID - care homes	OID_CH_21Apr21.pdf	459 Kb	1	28.04.2021 11:01	N/A	21.04.2021
Organisation Information Document	OID - GPs	OID_GPs_21Apr21.pdf	529 Kb	1	28.04.2021 11:01	N/A	21.04.2021
Organisation Information Document	OID - PIs and research nurses	OID_PI & RN_21Apr21.pdf	461 Kb	1	28.04.2021 11:01	N/A	21.04.2021
Schedule of Events or SoECAT (non-commercial projects). Please see green "i" button for current guidance	SoECAT	SoECAT PROTECT-CH v4 CRN Final Approved.xlsx	472 Kb	1	28.04.2021 11:01	4.0	27.04.2021
Contract/Study Agreement template - with any modifications highlighted (add template for each UK nation in which the project is taking place)	Care home contract template	CARE HOME CONTRACT_draft 0.1_version1.0_27Apr21.docx	66 Kb	1	28.04.2021 11:01		27.04.2021
Contract/Study Agreement template - with any modifications highlighted (add template for each UK nation in which the project is taking place)	GP contract template	GP contract letter_Draft 0.1_Final Version 1.0_27Apr21.docx	34 Kb	1	28.04.2021 11:01		27.04.2021
Contract/Study Agreement template - with any modifications highlighted (add template for each UK nation in which the project is taking place)	PI contract template	PROTEC~1.DOC	168 Kb	1	28.04.2021 11:01		27.04.2021
Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only)	Sponsor Clinical Trials Insurance	2020 Insurance Clinical Trials.pdf	260 Kb	1	28.04.2021 11:01		20.07.2020
	IMP Appendix A (ciclesonide)	IMP Appendix A Ciclesonide Draft 0.6 Final V1.0 27-Apr-2021.docx	78 Kb	1	28.04.2021 11:01	Draft 0.6/Final 1.0	27.04.2021
	IMP Appendix B (niclosamide)	IMP Appendix B Niclosamide Draft 0.5 Final V1.0 27-Apr-2021.docx	64 Kb	1	28.04.2021 11:01	Draft 0.5/Final 1.0	27.04.2021
	Sponsor professional indemnity letter	Professional Indemnity cover letter 2020-21.pdf	201 Kb	1	28.04.2021 11:01	N/A	20.07.2020
	Legal Representative Consent Letter 1	PLR Consent Letter 1 Draft 0.5 Final v1.0 23 Apr 2021.docx	113 Kb	1	28.04.2021 11:01	Draft 0.5/Final 1.0	23.04.2021
	Legal Representative Participation Update Letter 2	PLR Participation Update Letter 2 Draft 0.1 22 Apr 2021.docx	115 Kb	1	28.04.2021 11:01	Draft 0.1/Final 1.0	22.04.2021
	Legal Representative Consent Letter 3	PLR Consent Letter 3 Draft 0.4 Final v1.0 23 Apr 2021.docx	112 Kb	1	28.04.2021 11:01	Draft 0.4/Final 1.0	23.04.2021
	Legal Representative Eligibility & Randomisation Confirmation Letter 4	PLR Eligibility and Allocation Letter 4 Draft 0.1 Final v1.0 23 Apr 2021.docx	113 Kb	1	28.04.2021 11:01	Draft 0.1/Final 1.0	23.04.2021
	Legal Representative E-mails	PLR Email communications Draft 0.8 Final v1.0 23-Apr-2021.docx	29 Kb	1	28.04.2021 11:01	Draft 0.8/Final 1.0	23.04.2021

Type	Document Title	File Name	File Size	Submission Version	Submission Date	Document Version	Document Dat
	Ciclesonide dosing instructions	PROTECT-CH Ciclesonide dosing instructions V1.0 27Apr2021.docx	441 Kb	1	28.04.2021 11:01	Draft 0.2/Final 1.0	27.04.2021
	Niclosamide dosing instructions	PROTECT-CH Niclosamide dosing instructions V1.0 27 Apr 2021.docx	701 Kb	1	28.04.2021 11:01	Draft 0.2/Final 1.0	27.04.2021
	Consent and eligibility overview	PROTECT-CH Consent and Eligibility Overview Draft 0.2 Final v1.0 23-Apr-2021.pdf	51 Kb	1	28.04.2021 11:01	Draft 0.2/Final 1.0	23.04.2021
	Flowchart from point of outbreak (PEP)	Outbreak and eligibilty flow Draft 0.3 Final v1.0 21 Apr 2021.pdf	144 Kb	1	28.04.2021 11:01	Draft 0.3/Final 1.0	21.04.2021
	Safety reporting flowchart	Safety reporting flowchart Draft 0.2 Final v1.0 16 Apr 2021.pdf	202 Kb	1	28.04.2021 11:01	Draft 0.2/Final 1.0	16.04.2021