

Annex A

Application Documents	Version	Status
MHRA COVERING LETTER	23-Feb-2024	Redacted (Section 40 and 43)
MHRA-response-covering-letter	23-Apr-2024	Redacted (Section 40)
PPD Responses for Sanofi response cover letter	26-Mar-2024	Provided in full
Ethics Question set	23-Apr-2024	Redacted (Sections 22A, 40 and 43)
Protocol	V 3.0 7-Dec-2023	Redacted (Sections 22A, 40 and 43)
Study Overview Brochure	V2.0 9-Aug-2023	Provided in full
Poster	V1.0 9-Aug-2023	Provided in full
Parent Letter	V2.0 9-Aug-2023	Provided in full
HCP Letter	V2.0 9-Aug-2023	Provided in full
Flipchart	V2.0 9-Aug-2023	Provided in full
Study Website	v1.0 13-Sep-2023	Provided in full
Invitation Letter	V1.0 26-Oct-2023	Provided in full
PIS/ICF	V4.2 26-Mar-2024 (Tracked)	Redacted (Section 22A and 43)
PIS/ICF	V4.2 26-Mar-2024 (Clean)	Redacted (Section 22A and 43)
Patient Diary - App Subject Facing Screen Report	24-Nov-2023	Redacted (Section 22A and 43)
Patient Diary – Own Device	27-Nov-2023	Redacted (Section 22A and 43)
Country Specific Patient Card Text Form	23-Mar-2023	Redacted (Section 40)
Multi-fold Welcome Card	V2.1 10-Apr-2024	Provided in full
GP Letter	V1.0 24-Jan-2024	Provided in full
Letter of Authorisation	03-Jan-2024	Redacted (Section 40)
Thermo Scientific entity memo (Fisher Clinical Services Inc.)	02-Feb-2024	Redacted (Section 40)

Investigator Brochure	V7.0 19-Oct-2023	Redacted (Section 22A and 43)
Insurance Certificate	01-Nov-2023	Redacted (Section 40)
Thank You Card	V1.0 8-Jun-2023	Provided in full
Study Resource Review request (NIHR CRN – CPMS)	06-Mar-2024	Redacted (Section 40)
Medicines Information	23-Apr-2024	Redacted (Section 40)
Amendment Documents	Version	Status
AM01		
Amendment tool	04-Jun-2024	Redacted (Section 40)
AM02		
Amendment tool	27-Jun-2024	Redacted (Section 40)
PIS/ICF	V4.3 18-Jun-2024	Redacted (Section 22A and 43)
AM03		
Amendment tool	02-Jul-2024	Redacted (Section 40)
AM04		
Amendment tool	03-Jul-2024	Redacted (Section 40)
Bulletins	V1.0 03-Jul-2024	Provided in full
AM05		
Amendment tool	04-Jul-2024	Redacted (Section 40)
PIS/ICF	V4.3 18-Jun-2024 (Clean and Tracked versions)	Redacted (Section 22A and 43)
AM06		
Amendment tool	22-Aug-2024	Redacted (Section 40)
AM07		

Amendment tool	17-Oct-2024	Redacted (Section 40)
Protocol	V5.0 14-Jun-2024	Redacted (Sections 22A, 40 and 43)
Summary of Protocol Changes	14-Jun-2024	Redacted (Sections 22A and 43)
Investigator Brochure	V8.0 11-Jun-2024	Redacted (Sections 22A and 43)
Summary of IB Changes	11-Jun-2024	Provided in full
Investigator Brochure (RSVt vaccine)	V9.0 16-Sep-2024	Redacted (Sections 22A and 43)
Summary of IB Changes (RSVt vaccine)	16-Sep-2024	Provided in full
Flipchart	V2.1 20-Mar-2024	Provided in full
Multifold	V2.1 10-Apr-2024	Provided in full
Video Illustration Boards (Understand Your Study)	V1.0 24-Jan-2024	Provided in full
Video Illustration Boards (Understanding RSV Vaccines)	V1.0 04-Jan-2024	Provided in full
Video Illustration Boards (Understanding Vaccine Trials Parent/Guardian)	V1.0 04-Jan-2024	Provided in full
Social & Banner Ads	V1.0 21-feb-2024	Provided in full
Appointment Card	V1.0 06-Feb-2024	Provided in full
Postcard	V1.0 05-Feb-2024	Provided in full
UYS Book	V1.0 20-Mar-2024	Provided in full
Newsletter 1	V1.0 27-Feb-2024	Provided in full
Newsletter 2	V1.0 27-Feb-2024	Provided in full
Newsletter 3	V1.0 27-Feb-2024	Provided in full
AM08		
Amendment tool	13-Dec-2024	Withheld (Sections 22A and 43)
Dear Investigator Letter (Program Pause Fatal SAE)	13-Dec-2024	Withheld (Sections 22A and 43)

Temporary Halt Letter to Health Authorities	13-Dec-2024	Withheld (Sections 22A and 43)
AM09		
Amendment tool	28-May-2025	Withheld (Sections 22A and 43)
AM10		
Amendment tool	27-Jun-2025	Withheld (Sections 22A and 43)
Response Document (Response to Agency Request)	23-Jun-2025	Withheld (Sections 22A and 43)