Reference for Amendment Application to Application for Clinical Trial Authorisation, Clinical Trial Notification or Clinical Trial Certificate

This document serves as a reference guide to the editable fields for each Amendment Type in PRISM amendment application for Application for Clinical Trial Authorisation, Clinical Trial Notification or Clinical Trial Certificate.

The available Amendment Types are:

1. Protocol and/or Patient Information Sheet & Informed Consent Form Amendments
2. Change of Principal Investigator / Addition of Trial Site
3. Add Sponsor (for multi-sponsor investigator-initiated trials)
4. Change of Manufacturer / Chemistry, Manufacturing and Controls (CMC) information
5. Update of Investigator Brochure or New Safety Information
6. Change in Clinical Research Material Notification
7. Other Administrative / Trial Register Information Changes

Legend:

Yes = opened for editing

No = not opened for editing

S/N	Fields	Amendment Types								
		Protocol and/or Patient Information Sheet & Informed Consent Form Amendments	Change of Principal Investigator / Addition of Trial Site		Add Sponsor (for multi-sponsor investigator-initiated trials)	Change of Manufacturer / CMC Information		Update of Investigator Brochure / New Safety Info	Change in Clinical Research Material Notification	Other Administrative / Trial Register Information Changes
	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
1	**Introduction**									
1.1	Please select application type	No	No	No	No	No	No	No	No	No
2	**Trial Information**	**Not editable for ICF Amendment**								
2.1	Title of Clinical Trial (as stated in Protocol document)^*	Yes	No	No	No	No	No	No	No	Yes
2.2	Brief Title of Clinical Trial for the Public (in easily understood, non-technical language)^*	Yes	No	No	No	No	No	No	No	Yes
2.3	Protocol Number^*	Yes	No	No	No	No	No	No	No	Yes
2.4	Protocol Acronym, if any^	Yes	No	No	No	No	No	No	No	Yes
2.5	Secondary ID(s), if any^*	Yes	No	No	No	No	No	No	No	Yes
2.5.1	ID Type (e.g. ClinicalTrials.gov Identifier, EudraCT Number, name of organization that issued ID, etc)^*	Yes	No	No	No	No	No	No	No	Yes
2.5.2	ID^*	Yes	No	No	No	No	No	No	No	Yes

S/N	Fields	Amendment Types								
		Protocol and/or Patient Information Sheet & Informed Consent Form Amendments	Change of Principal Investigator / Addition of Trial Site		Add Sponsor (for multi-sponsor investigator-initiated trials)	Change of Manufacturer / CMC Information		Update of Investigator Brochure / New Safety Info	Change in Clinical Research Material Notification	Other Administrative / Trial Register Information Changes
	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
	(Summary Table for 2.5.1 to 2.5.2)	Yes	No	No	No	No	No	No	No	Yes
2.6	Phase of Clinical Trial^*	Yes	No	No	No	No	No	No	No	Yes
	If others, please specify^	Yes	No	No	No	No	No	No	No	Yes
2.7	Type of Sponsorship*	No	No	No	Yes	No	No	No	No	No
2.8	Source of Monetary or Material Support for the clinical trial (e.g. name of funding company, agency, organisation etc)^*	Yes	No	No	No	No	No	No	No	Yes
2.9	Therapeutic Area^*	Yes	No	No	No	No	No	No	No	Yes
	If others, please describe^	Yes	No	No	No	No	No	No	No	Yes
2.10	Health Condition(s) Studied^*	Yes	No	No	No	No	No	No	No	Yes
2.11	List the PRISM application number(s) of any previous application(s) for trials involving the same investigational product(s)*	Yes	No	No	No	No	No	No	No	Yes
	(Summary Table for 2.11)	Yes	No	No	No	No	No	No	No	Yes
	Trial Summary									
2.12	Involves*	Yes	No	No	No	No	No	No	No	No
2.13	Involves subjects who (please select where applicable)*	Yes	No	No	No	No	No	No	No	No
2.14	Clinical Trial in Emergency Situation*	Yes	No	No	No	No	No	No	No	No

S/N	Fields	Amendment Types								
		Protocol and/or Patient Information Sheet & Informed Consent Form Amendments	Change of Principal Investigator / Addition of Trial Site		Add Sponsor (for multi-sponsor investigator-initiated trials)	Change of Manufacturer / CMC Information		Update of Investigator Brochure / New Safety Info	Change in Clinical Research Material Notification	Other Administrative / Trial Register Information Changes
	Selected options		Change of PI	Addition of Trial Site		Change of Manf.	Change of CMC			
2.15	Study Type^*	Yes	No	No	No	No	No	No	No	No
2.16	Purpose of Trial^*	Yes	No	No	No	No	No	No	No	No
	If others, please describe^*	Yes	No	No	No	No	No	No	No	No
2.17	Primary Trial Objective(s)*	Yes	No	No	No	No	No	No	No	No
2.18	Primary Outcome Measure(s) (please include outcome measure and timepoint of interest, e.g. all-cause mortality at 1 year, cognition as measured by ADAS-Cog at week 24, dose-limiting toxicities, maximum tolerated dose, recommended phase 2 dose, etc)^*	Yes	No	No	No	No	No	No	No	No
2.19	Key Secondary Outcome Measure(s) (please include name of outcome, method of measurement and timepoint(s) of interest)^*	Yes	No	No	No	No	No	No	No	No
2.20	Allocation^*	Yes	No	No	No	No	No	No	No	No
2.21	Blinding^*	Yes	No	No	No	No	No	No	No	No
	If others, please describe^	Yes	No	No	No	No	No	No	No	No
2.22	Intervention model^*	Yes	No	No	No	No	No	No	No	No
	If others, please describe^*	Yes	No	No	No	No	No	No	No	No

S/N	Fields	Amendment Types								
		Protocol and/or Patient Information Sheet & Informed Consent Form Amendments	Change of Principal Investigator / Addition of Trial Site		Add Sponsor (for multi-sponsor investigator-initiated trials)	Change of Manufacturer / CMC Information		Update of Investigator Brochure / New Safety Info	Change in Clinical Research Material Notification	Other Administrative / Trial Register Information Changes
	Selected options		Change of PI	Addition of Trial Site		Change of Manf.	Change of CMC			
2.23	Number of study arms/groups*	Yes	No	No	No	No	No	No	No	No
2.23.1	Study Arm/Group Type^*	Yes	No	No	No	No	No	No	No	No
	If others, please describe^	Yes	No	No	No	No	No	No	No	No
2.23.2	Arm label (short name to identify arm, e.g. metformin, placebo, or lifestyle counselling)^*	Yes	No	No	No	No	No	No	No	No
2.23.3	Brief description of study arm (for drugs, use generic name and include route of administration, dose and dosing regimen/administration schedule; for other interventions provide brief description of study arm)^*	Yes	No	No	No	No	No	No	No	No
2.23.4	Duration of drug dosing/intervention^*	Yes	No	No	No	No	No	No	No	No
	(Summary Table for 2.23.1 to 2.23.4)	Yes	No	No	No	No	No	No	No	No
2.24	Involves the use of (please select where applicable)*	Yes	No	No	No	No	No	No	No	No
2.25	Number of Therapeutic / Medicinal Product (excluding CTT Products) to be Investigated*	Yes	No	No	No	No	No	No	No	No

S/N	Fields	Amendment Types								
		Protocol and/or Patient Information Sheet & Informed Consent Form Amendments	Change of Principal Investigator / Addition of Trial Site		Add Sponsor (for multi-sponsor investigator-initiated trials)	Change of Manufacturer / CMC Information		Update of Investigator Brochure / New Safety Info	Change in Clinical Research Material Notification	Other Administrative / Trial Register Information Changes
	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
2.26	Number of Cell- and Tissue-based Therapeutic (CTT) Product to be Investigated	Yes	No	No	No	No	No	No	No	No
2.27	Number of Comparator Therapeutic Product used*	Yes	No	No	No	No	No	No	No	No
2.28	Number of Auxiliary Therapeutic Product used*	Yes	No	No	No	No	No	No	No	No
2.29	Key Inclusion and Exclusion Criteria^*	Yes	No	No	No	No	No	No	No	No
2.30	Describe the design of the trial if necessary to supplement information provided above	Yes	No	No	No	No	No	No	No	No
2.31	Please provide the benefit-risk assessment for the clinical trial*	Yes	No	No	No	No	No	No	No	No
2.32	Is there a Data Safety Monitoring Committee for this study?*	Yes	No	No	No	No	No	No	No	No
2.33	Website URL link to the study record in ClinicalTrials.gov, if applicable^	Yes	No	No	No	No	No	No	No	Yes
	Trial Site(s)									
2.34	Location of Trial Site(s)*	Yes	No	No	No	No	No	No	No	Yes
2.35	List of Countries participating in the trial^	Yes	No	No	No	No	No	No	No	Yes
2.36	Number of Trial Site(s) in Singapore*	No	No	Yes	No	No	No	No	No	No

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2.37	Planned Number of Trial Subjects in Singapore^*	Yes	No	No	No	No	No	No	No	Yes
2.38	Total Planned Number of Trial Subjects per Protocol^*	Yes	No	No	No	No	No	No	No	No
2.39	Overseas Sponsor	Yes	No	No	No	No	No	No	No	No
	Regulatory Status of Study									
2.40	Is this a US IND/IDE study?*	Yes	No	No	No	No	No	No	No	Yes
2.41	Is this a EUDRACT study?*	Yes	No	No	No	No	No	No	No	Yes
2.42	Is there a negative opinion (including clinical hold) for this study elsewhere by a Regulatory Agency or Ethics Committee?*	Yes	No	No	No	No	No	No	No	Yes
	If yes, please provide reasons for negative opinion*	Yes	No	No	No	No	No	No	No	Yes
	Duration of Study									
2.43	Planned Study Start Date^*	Yes	No	No	No	No	No	No	No	Yes
2.44	Planned Study Start Date in Singapore^*	Yes	No	No	No	No	No	No	No	Yes
2.45	Planned Study End Date^*	Yes	No	No	No	No	No	No	No	Yes

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	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
	Contacts for Public and Scientific Queries									
	Contact for Public Queries									
2.46	Salutation^	Yes	No	No	No	No	No	No	No	Yes
2.47	Name^*	Yes	No	No	No	No	No	No	No	Yes
2.48	Company/Organisation/Institution	Yes	No	No	No	No	No	No	No	Yes
2.49	Email^*	Yes	No	No	No	No	No	No	No	Yes
2.50	Telephone number^*	Yes	No	No	No	No	No	No	No	Yes
2.51	Fax number	Yes	No	No	No	No	No	No	No	Yes
2.52	Address	Yes	No	No	No	No	No	No	No	Yes
	Contact for Scientific Queries									
2.53	Salutation^	Yes	No	No	No	No	No	No	No	Yes
2.54	Name^*	Yes	No	No	No	No	No	No	No	Yes
2.55	Affiliation/Designation (e.g. principal investigator, medical director employed by the sponsor)^*	Yes	No	No	No	No	No	No	No	Yes
2.56	Company/Organisation/Institution:	Yes	No	No	No	No	No	No	No	Yes
2.57	Email address^*	Yes	No	No	No	No	No	No	No	Yes
2.58	Telephone number^*	Yes	No	No	No	No	No	No	No	Yes

S/N	Fields	Amendment Types								
		Protocol and/or Patient Information Sheet & Informed Consent Form Amendments	Change of Principal Investigator / Addition of Trial Site		Add Sponsor (for multi-sponsor investigator-initiated trials)	Change of Manufacturer / CMC Information		Update of Investigator Brochure / New Safety Info	Change in Clinical Research Material Notification	Other Administrative / Trial Register Information Changes
	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
2.59	Fax number	Yes	No	No	No	No	No	No	No	Yes
2.60	Address	Yes	No	No	No	No	No	No	No	Yes
3	**Investigational Therapeutic Product / Medicinal Product**	**Not editable for ICF Amendment**								
3.1	Investigational Therapeutic Product (test) / Medicinal Product	Yes	No	No	No	No	No	No	No	No
3.2	Active Ingredient / Generic Name / Any code designation^* (please use the active ingredient/generic name stated in the Investigator Brochure)	Yes	No	No	No	No	No	No	No	No
3.2.1	Standardised IP Name	Yes	No	No	No	No	No	No	No	No
3.3	Other Product Identifier(s), if any^	Yes	No	No	No	No	No	No	No	No
3.4	Brand/Trade Name, if any^	Yes	No	No	No	No	No	No	No	No
3.5	Pharmacological Class*	Yes	No	No	No	No	No	No	No	No
3.6	Is there any re-packaging and/or re-labelling done for the investigational product at local trial sites?*	Yes	No	No	No	No	Yes	No	No	No
3.7	Does this product contain a psychotropic substance or a controlled drug?*	Yes	No	No	No	No	No	No	No	No

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	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
	Dosage Form, Route of Administration, Strength									
3.8	Dosage Form^*	Yes	No	No	No	No	No	No	No	No
3.9	Route of Administration^*	Yes	No	No	No	No	No	No	No	No
3.10	Strength^*	Yes	No	No	No	No	No	No	No	No
3.11	Category of Investigational Therapeutic Product*	Yes	No	No	No	No	No	No	No	No
3.12	For Category IIB products, state countries in which marketing authorisation has been granted*	Yes	No	No	No	No	No	No	No	No
3.13	For Category III or IV products, provide the Product Registration No.	Yes	No	No	No	No	No	No	No	No
	(Summary Table for 3.8 to 3.13)	Yes	No	No	No	No	No	No	No	No
	Product Owner									
3.14	Company Name	Yes	No	No	No	No	No	No	No	No
3.15	Address	Yes	No	No	No	No	No	No	No	No
3.16	Telephone no.	Yes	No	No	No	No	No	No	No	No
3.17	Fax no.	Yes	No	No	No	No	No	No	No	No
	(Summary Table for 3.1 to 3.17)	Yes	No	No	No	No	No	No	No	No

S/N	Fields	Amendment Types								
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	Selected options		Change of PI	Addition of Trial Site		Change of Manf.	Change of CMC			
4	Investigational Product (Cell- and Tissue-based Product)	Not editable for ICF Amendment								
4.1	Investigational CTT Product	Yes	No	No	No	No	No	No	No	No
4.2	Active Ingredient / Generic Name / Any code designation^*	Yes	No	No	No	No	No	No	No	No
4.2.1	Standardised IP Name	Yes	No	No	No	No	No	No	No	No
4.3	Brand/Trade Name, if any^	Yes	No	No	No	No	No	No	No	No
4.4	Pharmacological Class	Yes	No	No	No	No	No	No	No	No
4.5	Product Description	Yes	No	No	No	No	No	No	No	No
4.6	Origin of Cells/Tissue*	Yes	No	No	No	No	No	No	No	No
	Please describe, if necessary	Yes	No	No	No	No	No	No	No	No
4.7	Cell/Tissue Type*	Yes	No	No	No	No	No	No	No	No
4.7.1	If stem cells, please select*	Yes	No	No	No	No	No	No	No	No
	If others, please describe*	Yes	No	No	No	No	No	No	No	No
4.7.2	If differentiated cells, please describe type of cells (e.g. Keratinocytes, fibroblasts, chondrocytes etc)*	Yes	No	No	No	No	No	No	No	No
4.8	Please describe degree of cell/tissue processing/manipulation (e.g. In vitro/ex	Yes	No	No	No	No	No	No	No	No

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	Selected options		Change of PI	Addition of Trial Site		Change of Manf.	Change of CMC			
	vivo expansion/ activation/ differentiation/ genetic manipulation/ cryo-conservation, etc)*									
4.9	Proposed Use*	Yes	No	No	No	No	No	No	No	No
	Please describe, if necessary	Yes	No	No	No	No	No	No	No	No
4.10	Combined with Drug/Biologic/Device?*	Yes	No	No	No	No	No	No	No	No
	Please describe, if necessary	Yes	No	No	No	No	No	No	No	No
4.11	Primary Intended Action*	Yes	No	No	No	No	No	No	No	No
4.12	Regulatory Classification in the US (for product manufactured in US)	Yes	No	No	No	No	No	No	No	No
4.13	Regulatory Classification in the EU (for product manufactured in EU)	Yes	No	No	No	No	No	No	No	No
4.13.1	If advanced therapy medicinal product, please select	Yes	No	No	No	No	No	No	No	No
4.13.2	If others, please specify	Yes	No	No	No	No	No	No	No	No
4.14	Route of administration*	Yes	No	No	No	No	No	No	No	No
4.15	Category of Investigational CTT Product*	Yes	No	No	No	No	No	No	No	No

S/N	Fields	Amendment Types								
		Protocol and/or Patient Information Sheet & Informed Consent Form Amendments	Change of Principal Investigator / Addition of Trial Site		Add Sponsor (for multi-sponsor investigator-initiated trials)	Change of Manufacturer / CMC Information		Update of Investigator Brochure / New Safety Info	Change in Clinical Research Material Notification	Other Administrative / Trial Register Information Changes
	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
4.16	For Category IIB products, state countries in which marketing authorisation has been granted*	Yes	No	No	No	No	No	No	No	No
4.17	For Category III or IV products, provide the Product Registration No.	Yes	No	No	No	No	No	No	No	No
	Product Owner									
4.18	Company Name*	Yes	No	No	No	No	No	No	No	No
4.19	Address	Yes	No	No	No	No	No	No	No	No
4.20	Telephone no.	Yes	No	No	No	No	No	No	No	No
4.21	Fax no.	Yes	No	No	No	No	No	No	No	No
	(Summary Table for 4.1 to 4.21)	Yes	No	No	No	No	No	No	No	No
5	**Manufacturer Particulars**									
5.1	Investigational Therapeutic Product / Medicinal Product / Cell- and Tissue-based Product*	Yes	No	No	No	Yes	Yes	No	No	No
5.2	Manufacturer Name*	Yes	No	No	No	Yes	Yes	No	No	No
5.3	Type*	Yes	No	No	No	Yes	Yes	No	No	No
5.4	Address	Yes	No	No	No	Yes	Yes	No	No	No
5.5	Telephone no.	Yes	No	No	No	Yes	Yes	No	No	No

S/N	Fields	Amendment Types								
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	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
5.6	Fax no.	Yes	No	No	No	Yes	Yes	No	No	No
	(Summary Table for 5.1 to 5.6)	Yes	No	No	No	Yes	Yes	No	No	No
6	**Comparator Therapeutic Product**	**Not editable for ICF Amendment**								
6.1	Comparator Therapeutic Product	Yes	No	No	No	No	No	No	No	No
6.1.1	Active Ingredient / Generic Name / Any code designation* (please use the active ingredient/generic name stated in the Investigator Brochure)	Yes	No	No	No	No	No	No	No	No
6.1.2	Brand/Trade Name, if any	Yes	No	No	No	No	No	No	No	No
6.1.3	Pharmacological Class*	Yes	No	No	No	No	No	No	No	No
	Dosage Form, Route of Administration, Strength									
6.2.1	Dosage Form^*	Yes	No	No	No	No	No	No	No	No
6.2.2	Route of Administration^*	Yes	No	No	No	No	No	No	No	No
6.2.3	Strength^*	Yes	No	No	No	No	No	No	No	No
6.2.4	Category of Investigational Therapeutic Product*	Yes	No	No	No	No	No	No	No	No

S/N	Fields	Amendment Types								
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	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
6.2.5	For Category IIB products, state countries in which marketing authorisation has been granted*	Yes	No	No	No	No	No	No	No	No
6.2.6	For Category III or IV products, provide the Product Registration No.	Yes	No	No	No	No	No	No	No	No
	(Summary Table for 6.2.1 to 6.2.6)	Yes	No	No	No	No	No	No	No	No
	(Summary Table for 6.1 to 6.2.6)	Yes	No	No	No	No	No	No	No	No
7	**Auxiliary Therapeutic Product**	**Not editable for ICF Amendment**								
7.1	Auxiliary Therapeutic Product	Yes	No	No	No	No	No	No	No	No
7.1.1	Active Ingredient / Generic Name / Any code designation* (please use the active ingredient/generic name stated in the Investigator Brochure)	Yes	No	No	No	No	No	No	No	No
7.1.2	Brand/Trade Name, if any	Yes	No	No	No	No	No	No	No	No
7.1.3	Pharmacological Class*	Yes	No	No	No	No	No	No	No	No
	Dosage Form, Route of Administration, Strength									
7.2.1	Dosage Form^*	Yes	No	No	No	No	No	No	No	No
7.2.2	Route of Administration^*	Yes	No	No	No	No	No	No	No	No

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	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
7.2.3	Strength^*	Yes	No	No	No	No	No	No	No	No
7.2.4	Category of Investigational Therapeutic Product*	Yes	No	No	No	No	No	No	No	No
7.2.5	For Category IIB products, state countries in which marketing authorisation has been granted*	Yes	No	No	No	No	No	No	No	No
7.2.6	For Category III or IV products, provide the Product Registration No.	Yes	No	No	No	No	No	No	No	No
	(Summary Table for 7.2.1 to 7.2.6)	Yes	No	No	No	No	No	No	No	No
	(Summary Table for 7.1 to 7.2.6)	Yes	No	No	No	No	No	No	No	No
8	**Local Trial Site(s), PI(s) and IRB(s)**	**Not editable for ICF Amendment**	**Existing trial sites**	**New trial sites**						
8.1	Trial Site No.	No	No	Yes	No	No	No	No	No	No
8.2	Name of Trial Site^*	No	No	Yes	No	No	No	No	No	No
	If others, please specify^	No	No	Yes	No	No	No	No	No	No
8.3	Planned No. of Trial Subjects*	Yes	No	Yes	No	No	No	No	No	Yes
	Principal Investigator Details									
8.4	Salutation	No	Yes	Yes	No	No	No	No	No	Yes
8.5	Name of Principal Investigator^*	No	Yes	Yes	No	No	No	No	No	No

S/N	Fields	Amendment Types								
		Protocol and/or Patient Information Sheet & Informed Consent Form Amendments	Change of Principal Investigator / Addition of Trial Site		Add Sponsor (for multi-sponsor investigator-initiated trials)	Change of Manufacturer / CMC Information		Update of Investigator Brochure / New Safety Info	Change in Clinical Research Material Notification	Other Administrative / Trial Register Information Changes
	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
8.6	NRIC / FIN of PI*	No	No	No	No	No	No	No	No	No
8.7	Designation*	No	Yes	Yes	No	No	No	No	No	Yes
8.8	Qualified Area(s) of Specialty*	No	Yes	Yes	No	No	No	No	No	Yes
	If others, please specify	No	Yes	Yes	No	No	No	No	No	Yes
8.9	Name of Place of Practice*	No	Yes	Yes	No	No	No	No	No	Yes
	If others, please specify	No	Yes	Yes	No	No	No	No	No	Yes
8.10	Department	No	Yes	Yes	No	No	No	No	No	Yes
8.11	Trial Site Address*	No	No	Yes	No	No	No	No	No	No
8.12	Telephone no.*	No	Yes	Yes	No	No	No	No	No	Yes
8.13	Fax no.*	No	Yes	Yes	No	No	No	No	No	Yes
8.14	Primary Email*	No	Yes	Yes	No	No	No	No	No	Yes
8.15	Alternative Email	No	Yes	Yes	No	No	No	No	No	Yes
	Study Coordinator Details									
8.16	Salutation	No	Yes	Yes	No	No	No	No	No	Yes
8.17	Name of Study Coordinator	No	Yes	Yes	No	No	No	No	No	Yes
8.18	Telephone no.	No	Yes	Yes	No	No	No	No	No	Yes
8.19	Fax no.	No	Yes	Yes	No	No	No	No	No	Yes

S/N	Fields	Amendment Types								
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	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
8.20	Email	No	Yes	Yes	No	No	No	No	No	Yes
	Satellite Site(s) Details									
8.21	Is there any satellite site(s) for this trial site?*	No	Yes	Yes	No	No	No	No	No	No
8.22	Name of Satellite Site*	No	Yes	Yes	No	No	No	No	No	No
	If others, please specify	No	Yes	Yes	No	No	No	No	No	No
8.23	Trial activities to be carried out*	Yes	Yes	Yes	No	No	No	No	No	No
8.24	Satellite Site Address*	No	Yes	Yes	No	No	No	No	No	No
8.25	Telephone no.*	No	Yes	Yes	No	No	No	No	No	Yes
8.26	Fax no.*	No	Yes	Yes	No	No	No	No	No	Yes
	IRB Details									
8.27	Name of responsible IRB*	No	No	Yes	No	No	No	No	No	Yes
8.27.1	If others, please specify	No	No	Yes	No	No	No	No	No	Yes
8.28	IRB Address*	No	No	Yes	No	No	No	No	No	Yes
8.29	Telephone no.*	No	No	Yes	No	No	No	No	No	Yes
8.30	Fax no.*	No	No	Yes	No	No	No	No	No	Yes

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	Selected options		Change of PI	Addition of Trial Site		Change of Manf.	Change of CMC			
	IRB Representative									
8.31	Name of IRB Representative*	No	No	Yes	No	No	No	No	No	Yes
8.32	Email Address of IRB Representative*	No	No	Yes	No	No	No	No	No	Yes
8.33	NRIC / FIN of IRB Representative*	No	No	Yes	No	No	No	No	No	Yes
	(Summary Table for 8.1 to 8.33)	No	Yes	Yes	No	No	No	No	No	Yes
9	**Local Sponsor(s)**									
9.1.1	UEN*	No	No	No	No	No	No	No	No	No
9.1.2	Company Name^*	No	No	No	No	No	No	No	No	No
9.1.3	Company Address*	No	No	No	No	No	No	No	No	No
9.1.3.8	Telephone number*	No	No	No	No	No	No	No	No	No
9.1.3.9	Fax number*	No	No	No	No	No	No	No	No	No
	Sponsor Contact Person									
9.2.1	Salutation	No	No	No	No	No	No	No	No	Yes
9.2.2	Name of Contact Person*	No	No	No	No	No	No	No	No	Yes
9.2.3	NRIC/FIN*	No	No	No	No	No	No	No	No	No
9.2.4	Designation*	No	No	No	No	No	No	No	No	Yes

S/N	Fields	Amendment Types								
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	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
9.2.5	Telephone no.*	No	No	No	No	No	No	No	No	Yes
9.2.6	Fax no.*	No	No	No	No	No	No	No	No	Yes
9.2.7	Mobile Number	No	No	No	No	No	No	No	No	Yes
9.2.8	Primary Email (please ensure that the email address is correct, otherwise you will NOT receive the system notifications)*	No	No	No	No	No	No	No	No	Yes
9.2.9	Alternative Email	No	No	No	No	No	No	No	No	Yes
9.3	**Other Sponsor(s)**				**For new sponsor(s)**					
9.3.1	Company Name^*	No	No	No	Yes	No	No	No	No	No
9.3.2	UEN *	No	No	No	Yes	No	No	No	No	No
9.3.3	Company Address*	No	No	No	Yes	No	No	No	No	No
9.3.10	Telephone no.*	No	No	No	Yes	No	No	No	No	No
9.3.11	Fax no.*	No	No	No	Yes	No	No	No	No	No
	Other Sponsor Contact Person									
9.4.1	Name of Contact Person*	No	No	No	Yes	No	No	No	No	Yes
9.4.2	Primary Email	No	No	No	Yes	No	No	No	No	Yes

S/N	Fields	Amendment Types								
		Protocol and/or Patient Information Sheet & Informed Consent Form Amendments	Change of Principal Investigator / Addition of Trial Site		Add Sponsor (for multi-sponsor investigator-initiated trials)	Change of Manufacturer / CMC Information		Update of Investigator Brochure / New Safety Info	Change in Clinical Research Material Notification	Other Administrative / Trial Register Information Changes
	Selected options		Change of PI	Addition of Trial Site		Change of Manf.	Change of CMC			
	Other Sponsor Contact Details (To Be Filled By Endorser)									
9.5.1	Salutation	No	No	No	No	No	No	No	No	Yes
9.5.2	Name of Contact Person*	No	No	No	No	No	No	No	No	Yes
9.5.3	NRIC/FIN*	No	No	No	No	No	No	No	No	Yes
9.5.4	Designation*	No	No	No	No	No	No	No	No	Yes
9.5.5	Telephone no.*	No	No	No	No	No	No	No	No	Yes
9.5.6	Fax no.	No	No	No	No	No	No	No	No	Yes
9.5.7	Mobile Number	No	No	No	No	No	No	No	No	Yes
9.5.8	Primary Email* (please ensure that the email address is correct, otherwise the relevant party will NOT be able to login)	No	No	No	No	No	No	No	No	Yes
9.5.9	Alternative Email	No	No	No	No	No	No	No	No	Yes
	(Summary Table for 9.3.1 to 9.5.9)	No	No	No	Yes	No	No	No	No	Yes

S/N	Fields	Amendment Types								
		Protocol and/or Patient Information Sheet & Informed Consent Form Amendments	Change of Principal Investigator / Addition of Trial Site		Add Sponsor (for multi-sponsor investigator-initiated trials)	Change of Manufacturer / CMC Information		Update of Investigator Brochure / New Safety Info	Change in Clinical Research Material Notification	Other Administrative / Trial Register Information Changes
	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
10	**Clinical Research Material Notification**								**Existing records cannot be deleted**	
10.1	Is import of therapeutic products / medical devices / medicinal products, or the supply of therapeutic products / medical devices / medicinal products by a local manufacturer required for this trial?*	No	No	No	No	No	No	No	Yes	No
10.2	Please select all that applies*	No	No	No	No	No	No	No	Yes	No
10.3	Please select the type of CRM to be imported or supplied*	No	No	No	No	No	No	No	Yes	No
	Company Particulars									
10.4	Please select*	No	No	No	No	No	No	No	Yes	No
10.5	Is the importer / manufacturer the local sponsor for the trial?*	No	No	No	No	No	No	No	Yes	No
10.6	UEN *	No	No	No	No	No	No	No	Yes	No
10.7	Company Name^*	No	No	No	No	No	No	No	Yes	No
10.8	Address*	No	No	No	No	No	No	No	Yes	No
10.9	**Contact Particulars**									

S/N	Fields	Amendment Types								
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	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
10.9.1	Salutation	No	No	No	No	No	No	No	Yes	No
10.9.2	Company Representative*	No	No	No	No	No	No	No	Yes	No
10.9.3	NRIC*	No	No	No	No	No	No	No	Yes	No
10.9.4	Designation*	No	No	No	No	No	No	No	Yes	No
10.9.5	Telephone no.*	No	No	No	No	No	No	No	Yes	No
10.9.6	Fax no.	No	No	No	No	No	No	No	Yes	No
10.9.7	Mobile Number	No	No	No	No	No	No	No	Yes	No
10.9.8	Email (please ensure that the email address is correct, otherwise the relevant parties will NOT receive the endorsement notification)*	No	No	No	No	No	No	No	Yes	No
	Particulars of Clinical Research Materials (CRM)									
10.10	**Medicinal / Therapeutic Product**									
10.10.1	Active Ingredient / Generic Name / Any code designation*	No	No	No	No	No	No	No	Yes	No
	If Others, please specify	No	No	No	No	No	No	No	Yes	No
10.10.2	Brand/Trade Name, if any	No	No	No	No	No	No	No	Yes	No

S/N	Fields	Amendment Types								
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	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
10.10.3	Does this product contain a psychotropic substance or a controlled drug?*	No	No	No	No	No	No	No	Yes	No
10.10.4	Dosage Form*	No	No	No	No	No	No	No	Yes	No
10.10.5	Route of Administration*	No	No	No	No	No	No	No	Yes	No
10.10.6	Strength*	No	No	No	No	No	No	No	Yes	No
10.10.7	Estimated Total Quantity*	No	No	No	No	No	No	No	Yes	No
10.10.8	Remarks	No	No	No	No	No	No	No	Yes	No
	(Summary Table for 10.10.1 to 10.10.8)	No	No	No	No	No	No	No	Yes	No
10.11	**Medical Device for Investigational Purpose**									
10.11.1	Device Name*	No	No	No	No	No	No	No	Yes	No
10.11.2	Type of Medical Device*	No	No	No	No	No	No	No	Yes	No
10.11.3	Identifier (e.g. Model No)*	No	No	No	No	No	No	No	Yes	No
10.11.4	Description & Intended Purpose*	No	No	No	No	No	No	No	Yes	No
10.11.5	Risk Class	No	No	No	No	No	No	No	Yes	No
10.11.6	Product Owner*	No	No	No	No	No	No	No	Yes	No
10.11.7	Address of Product Owner*	No	No	No	No	No	No	No	Yes	No
10.10.8	Registration/Marketing Status*	No	No	No	No	No	No	No	Yes	No

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	Selected options		**Change of PI**	**Addition of Trial Site**		**Change of Manf.**	**Change of CMC**			
10.11.9	Estimated Total Quantity*	No	No	No	No	No	No	No	Yes	No
10.11.10	Remarks	No	No	No	No	No	No	No	Yes	No
10.11.11	Upload via Excel	No	No	No	No	No	No	No	Yes	No
	(Summary Table for 10.11.1 to 10.11.10)	No	No	No	No	No	No	No	Yes	No
10.12	**Medical Device for Non-Investigational Purpose**									
10.12.1	Device Name*	No	No	No	No	No	No	No	Yes	No
10.12.2	Identifier (e.g. Model No)*	No	No	No	No	No	No	No	Yes	No
10.12.3	Product Owner*	No	No	No	No	No	No	No	Yes	No
10.12.4	Address of Product Owner*	No	No	No	No	No	No	No	Yes	No
10.12.5	Estimated Total Quantity*	No	No	No	No	No	No	No	Yes	No
10.12.6	Remarks	No	No	No	No	No	No	No	Yes	No
10.12.7	Upload via Excel	No	No	No	No	No	No	No	Yes	No
	(Summary Table for 10.12.1 to 10.12.6)	No	No	No	No	No	No	No	Yes	No