

Session Number	Processes Covered
1	Sponsorship and Approvals
2	Creating Documents, version control & Trial Master File (TMF) – Creation and managing*
3	CRF design; completion and correction*
4	IT System Validation and Management, Software Development*
5	Risk Assessment and Risk Management* Part 1
6	Risk Assessment and Risk Management* Part 2
7	Training; Working Instructions
8	Sample size
9	Randomisation Setup and Validation (Sortition, emergency Rx); Randomisation and CDB; Change Management
10	Clinical Database Build and Validation
11	Statistical Analysis Plan*
12	DMECs/TSCs
13	Vendor selection
14	Site Selection and Initiation*
15	Managing coordinating centres and Acting as a coordinating centre

16	Audits and inspections
17	Informed Consent*
18	Confidentiality, Security of Personal Data and Participant complaint procedure
19	Safety reporting – CTIMPs and non-CTIMPs
20	Incident Reporting and Serious Breaches; urgent safety measures*
21	IMP and Investigator Brochures
22	Trial Equipment; Lab arrangements
23	Data entry, Data Queries
24	Data Cleaning, Data coding
25	Closure of Coordinating Centre and a Research Site
26	Trial Closure, Archiving and CSR*
27	Final and interim database lock, Data transfer
28	Stats Analysis and report and QC*

Related SOPs	Tutor	Date	Room Booked
PC-CTU_SOP_TM108 PC-CTU_SOP_TM131	Julie Allen	30/01/2020	Gibson room 3
PC-CTU_SOP_TM101 PC- CTU_SOP_TM106 PC- CTU_SOP_TM112	Mina Davoudianfar	06/02/2020	RPC Room 1
PC-CTU_SOP_DM109 PC CTU_SOP_DM102	Sadie Kelly	13/02/2020	Gibson room 3
PC-CTU_SOP_DM104 PC-CTU_SOP_DM105	David Judge	27/02/2020	Gibson room 3
PC-CTU_SOP_TM115	Pati Faria-Shayler	05/03/2020	Gibson room 3
PC-CTU_SOP_TM115	Pati Faria-Shayler	12/03/2020	Gibson room 3
PC-CTU_SOP_TM116 PC- CTU_SOP_TM130	Louise Jones	19/03/2020	Gibson room 3
PC-CTU_SOP_ST103	Ly-Mee Yu	26/03/2020	Gibson room 3
PC-CTU_SOP_ST105	David Judge	02/04/2020	Gibson room 3
PC-CTU_SOP_DM104	DM	23/04/2020	Gibson room 3
PC-CTU_SOP_ST101	Ly-Mee Yu	30/04/2020	Gibson room 3
PC-CTU_SOP_TM133	Jill Mollison	07/05/2020	Gibson room 3
PC-CTU_SOP_GN104	Greig Dougall	14/05/2020	Gibson room 3
PC-CTU_SOP_TM110	Hannah Swayze	21/05/2020	Gibson room 3
PC-CTU_SOP_TM134 PC- CTU_SOP_TM136	Mina Davoudianfar	04/06/2020	Gibson room 3

PC-CTU_SOP_QA102 PC-CTU_SOP_QA103	Pati Faria-Shayler	18/06/2020	Gibson room 2
PC-CTU_SOP_TM107	Heather Rutter	25/06/2020	Gibson room 3
PC-CTU_SOP_GN106 PC- CTU_SOP_GN102	Hannah Swayze	02/07/2020	Gibson room 3
PC-CTU_SOP_TM119 PC- CTU_SOP_TM122	Emma Ogburn	09/07/2020	Gibson room 3
PC-CTU_SOP_TM125 PC- CTU_SOP_TM128	Pati Faria-Shayler	16/07/2020	Gibson room 3
PC-CTU_SOP_TM118 PC- CTU_SOP_TM135	Emily Bongard	23/07/2020	Gibson room 3
PC-CTU_SOP_TM132 PC- CTU_SOP_TM121	Sharon Tonner	30/07/2020	Gibson room 3
PC-CTU_SOP_DM106	Jenna Grabey	17/09/2020	Gibson room 3
PC-CTU_SOP_DM110	Ly-Mee Yu, DM	24/09/2020	Gibson room 3
PC-CTU_SOP_TM129	Julie Allen	01/10/2020	Gibson room 2
PC-CTU_SOP_TM123 PC- CTU_SOP_TM124 PC- CTU_SOP_TM117	Sharon Tonner	15/10/2020	Gibson room 3
PC-CTU_SOP_DM107 PC- CTU_SOP_DM108	DM	22/10/2020	Gibson room 3
PC-CTU_SOP_ST104	Ly-Mee Yu	29/10/2020	Gibson room 3