

Sub Proc ess Title	SOP/ WI	SOP/WI No. and Title and Other Trainings	Timeframe for Completion	Mode of Training	Applicable Roles (check footnote for abbreviation)							
					SP	SSP	LSP	PSP	S	SS	LS	PS
TCS Generic Trainings												
BSP	TCS	Introduction to Clinical Research	Prior to deployment	Instructor-led/ Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		ICH GCP	Prior to deployment	Instructor-led/ Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		21 CFR Part 11 awareness	Prior to deployment	Instructor-led/ Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Good Documentation Practice	Prior to deployment	Instructor-led/ Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Business Continuity Plan	As per requirement	Instructor-led/ Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Induction And Training manual - TCS Janssen	As per requirement	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		ICH GCP Refresher Updates	Annually	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TCS Generic SOP's - Knowmax												
BSP	TCS	TCS-LSP-CQA-001 (SOP on Inspection Readiness)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LS-CQA-002 (Handling Internal and Client Audits)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

		TCS-LSP-CQA-003 (Training and Evaluation of Employees)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-CQA-004 (SOP Management)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-CQA-005 (Archival of Records)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-CQA-006 (Fraud and Misconduct)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BSP	TCS	TCS-LSP-CQA-007 (Change Control)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-CQA-008 (Recording of Data Reporting of Results and Correcting Mistake in Documents)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-CQA-009 (Supplier Management)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-CQA-010 (Handling Deviations)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-CQA-011 (Organization Chart Management)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-CQA-012 (Work Instruction Management)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TCS Process SOP's - Knowmax												
BSP	TCS	TCS-LS-CDM-012 (Annotation Of CRF/eCRF)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	No	No	Yes	Yes
		TCS-LS-CDM-014 (Database Lock)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

		TCS-LS-CDM-023 (Study Data Tabulation Model Data Conversion)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	No	No	Yes	Yes
		TCS-LSP-COP-002 (CDMS Operations)	As per requirement	Self-directed	Yes	Yes	Yes	Yes	No	No	Yes	Yes
		TCS-LSP-COP-004 (Application Login Process for Clinical Operations Platform)	As per requirement	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-COP-006 (Incident and Problem Management)	As per requirement	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BSP	TCS	TCS-LSP-COP-009 (Change Release Configuration Management)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	No	No	Yes	Yes
		TCS-LSP-BSP-001 (Randomization And Blinding)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-BSP-002 (Statistical Analysis Plan)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-BSP-004 (Programming and Validation of SAS Programs)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-BSP-005 (Statistical Analysis Report)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-BSP-006 (Documenting Changes to Requirements And Specifications)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TCS J&J Specific WI's (CDM, BSP, MW and PK Office) - Knowmax												

BSP	TCS	WI-JNJ-BSP-001 (Working Instructions for Biostatistics and Programming)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LSP-WI-BSP-002 (Working Instruction for Data Anonymization)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	No	No	Yes
		WI-JNJ-CDM-005: SDTM Activities performed in TCS Janssen	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LS-WI-CDM-010: Database Lock-Unlock for Janssen CDM Process	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		WI-JNJ-CDM-018: External Data Handling activities in TCS Janssen	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS-LS-WI-MWR -001 (Preparation Of Clinical Study Protocol And Protocol Amendment)	As per requirement	Self-directed	No	No	No	No	Yes	Yes	Yes	Yes
BSP	TCS	TCS-LS-WI-MWR -003 (Preparation Of Clinical Study Report And Narrative)	As per requirement	Self-directed	No	No	No	No	Yes	Yes	Yes	No
TCS BSP Process Training - TCS Sharedrive												
BSP	Client	Overview of Biostatistics and Programming (Systems, Standards, Macros)	Prior to deployment	Instructor-led	Yes	Yes	Yes	Yes	No	No	No	No
BSP	Client	Overview of Janssen system (S: Drive, LSAF)	As per requirement	Instructor-led	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

BSP	Client	Janssen Training on Standards (Protocol, SAP, Metadata)	Prior to deployment	Instructor-led	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BSP	Client	Janssen Global Macro Training	Prior to deployment	Instructor-led	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TCS MW Process Training - TCS Sharedrive												
BSP	Client	Clinical Pharmacology (Pharmacokinetics and Pharmacodynamics) (By MW Team)	As per requirement	Instructor-led/ Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Data Transparency Training (Including Transcelerate Guidelines) (By MW Team)	As per requirement	Instructor-led/ Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BSP	Client	Basics of Clinical Pharmacology (PK and PD) (By PK Team)	As per requirement	Instructor-led/ Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Introductions to PK/PD Parameters	As per requirement	Instructor-led/ Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		In vitro-In vivo correlation	As per requirement	Instructor-led/ Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BSP	Client	Approach in Different study types: - First in Human Studies - Steady state PK studies - Mass Balance studies - BA/BE Studies - Dose finding and dose ranging	As per requirement	Instructor-led/ Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

		studies - Intrinsic and Extrinsic Factor studies											
		Pharmacokinetics in special population	As per requirement	Instructor- led/ Self- directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
J&J Mandatory Training - SUMMT /Sharepoint													
BSP	Client	Johnson & Johnson Policy on Business Conduct	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Records Management Training	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		POL-06825 (Policy on External Service Provider)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes
		IAPP - Information Asset protection Policy	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
J&J SOPs/WI/Guidelines - SUMMT /SharePoint													
BSP	Client	STA1007 (Qualification and Training)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		SOP10924 (Trial Set Up Activities)	As per requirement	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		SOP13108 (PK/PD Data File generation, submission and storage)	As per requirement	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		SOP-14993 (Database Lock/Unlock for outsourced DM activities)	As per requirement	Self-directed	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes
BSP	Client	Hermes SAS Drug Development (SDD) Platform - Introduction to SDD Release 1	As per requirement	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

		Hermes SAS Drug Development (SDD) Platform - Workflows (Light version) - Release 2	As per requirement	Self-directed								
		Hermes SAS Drug Development (SDD) Platform - upload files in SDD e-learning	As per requirement	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<p><i>Note: Applicable TCS and Client SOPs/WIs/Guidance Documents for all domains to be referred from respective Training Plans</i></p> <p>SP-Statistical Programming, SSP - Sr. Statistical Prog., LSP - Lead Statistical Prog., PSP - Principal Statistical Prog., S - Statistician, SS -Senior Statistician, LS - Lead Statistician, PS - Principal Statistician</p>												