					Applicable Roles (check footn abbreviation)							
Sub Proc	605/	CODMANA	Timeframe	Agada af	SP	SSP	LSP	PSP	S	SS	LS	PS
ess	SOP/	SOP/WI No. and Title and	for	Mode of								
Title	WI	Other Trainings	Completion	Training								
			ics Gen	eric Trainings								
		Introduction to Clinical Research	Prior to deployment	Instructor- led/ Self- directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	TCS	ICH GCP	Prior to deployment	Instructor- led/ Self- directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BSP		21 CFR Part 11 awareness	Prior to deployment	Instructor- led/ Self- directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BSP		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 - Knowm	ах							
BSP	TCS	TCS-LSP-CQA-001 (SOP on Inspection Readiness)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
RSb	ICS	TCS-LS-CQA-002 (Handling Internal and Client Audits)	Prior to deployment	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

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		TCS-LSP-CQA-003 (Training	Prior to	Self-directed								
		and Evaluation of	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Employees)										
		TCS-LSP-CQA-004 (SOP	Prior to	Self-directed	Yes	Yes	Yes	Yes	Yes	Voc	Yes	Voc
		Management)	deployment		res	res	res	res	res	Yes	res	Yes
		TCS-LSP-CQA-005 (Archival	Prior to	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		of Records)	deployment		163	163	163	163	163	163	163	163
		TCS-LSP-CQA-006 (Fraud	Prior to	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		and Misconduct)	deployment		163	163	163	163	163	163	163	163
		TCS-LSP-CQA-007 (Change	Prior to	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Control)	deployment		163	163	163	163	163	163	163	163
		TCS-LSP-CQA-008 (Recording	Prior to	Self-directed								
		of Data Reporting of Results	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		and Correcting Mistake in			103	103	103	103	103	103	103	103
		Documents)										
		TCS-LSP-CQA-009 (Supplier	Prior to	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BSP	TCS	Management)	deployment		103	103	103	103	103	103	103	103
		TCS-LSP-CQA-010 (Handling	Prior to	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Deviations)	deployment		103	163	23 103	103	163	163	163	103
		TCS-LSP-CQA-011	Prior to	Self-directed								
		(Organization Chart	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Management)										
		TCS-LSP-CQA-012 (Work	Prior to	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Instruction Management)	deployment		103	103	103	103	103	103	103	103
			TCS Process	SOP's - Knowm	ax							
		TCS-LS-CDM-012	Prior to	Self-directed	Voc	Voc	Yes Yes	Vos	No	No	Yes	Yes
BSP	TCC	(Annotation Of CRF/eCRF)	deployment		Yes	Yes		Yes				
R2h	TCS	TCS-LS-CDM-014 (Database	Prior to	Self-directed	Voc	Vos	V V	Vaa	Vac	V	V	Voc
		Lock)	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

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		TCS-LS-CDM-023 (Study	Prior to	Self-directed								
		Data Tabulation Model Data	deployment		Yes	Yes	Yes	Yes	No	No	Yes	Yes
		Conversion)										
		TCS-LSP-COP-002 (CDMS	As per	Self-directed	Yes	Yes	Yes	Yes	No	No	Yes	Yes
		Operations)	requirement		163	163	163	163	INO	INO	163	163
		TCS-LSP-COP-004	As per	Self-directed								
		(Application Login Process	requirement		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		for Clinical Operations			103	103	103	103	103	103	103	103
		Platform)										
		TCS-LSP-COP-006 (Incident	As per	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		and Problem Management)	requirement		165	165	165	res	165	165	165	162
		TCS-LSP-COP-009 (Change	Prior to	Self-directed								
		Release Configuration	deployment		Yes	Yes	Yes	Yes	No	No	Yes	Yes
		Management)										
		TCS-LSP-BSP-001	Prior to	Self-directed								
		(Randomization And	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Blinding)										
		TCS-LSP-BSP-002 (Statistical	Prior to	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Analysis Plan)	deployment		103	103	103	103	103	103	103	103
BSP	TCS	TCS-LSP-BSP-004	Prior to	Self-directed								
		(Programming and	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Validation of SAS Programs)										
		TCS-LSP-BSP-005 (Statistical	Prior to	Self-directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Analysis Report)	deployment		103	103	103	103	103	103	103	103
		TCS-LSP-BSP-006	Prior to	Self-directed								
		(Documenting Changes to	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Requirements And			103	103	103	103	103	103	103	103
		Specifications)										
		TCS J&J Speci	fic WI's (CDM, B	SP, MW and PK	Office) - Kno	wmax					

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		WI-JNJ-BSP-001 (Working	Prior to	Self-directed								
		Instructions for Biostatistics	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		and Programming)										
		TCS-LSP-WI-BSP-002	Prior to	Self-directed								
		(Working Instruction for	deployment		Yes	Yes	Yes	Yes	Yes	No	No	Yes
		Data Anonymization)										
		WI-JNJ-CDM-005: SDTM	Prior to	Self-directed								
ı		Activities performed in TCS	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Janssen										
BSP	TCS	TCS-LS-WI-CDM-010:	Prior to	Self-directed				Yes				
		Database Lock-Unlock for	deployment		Yes	Yes	Yes		Yes	Yes	Yes	Yes
1		Janssen CDM Process										
		WI-JNJ-CDM-018: External	Prior to	Self-directed								
		Data Handling activities in	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		TCS Janssen										
		TCS-LS-WI-MWR -001	As per	Self-directed								
		(Preparation Of Clinical	requirement		No	No	No	No	Yes	Yes	Yes	Yes
		Study Protocol And Protocol				J NO	NO NO	INO	163	165		163
		Amendment)										
		TCS-LS-WI-MWR -003	As per	Self-directed								
	TCS	(Preparation Of Clinical	requirement		No	No	No	No	Yes	Yes	Yes	No
BSP		Study Report And Narrative)										
		TC	S BSP Process T	raining - TCS Sh	aredriv	⁄e						
		Overview of Biostatistics	Prior to	Instructor-led								
BSP	Client	and Programming (Systems,	deployment		Yes	Yes	Yes	Yes	No	No	No	No
		Standards, Macros)										
		Overview of Janssen system	As per	Instructor-led								
BSP	Client	(S: Drive, LSAF)	requirement		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

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		Janssen Training on	Prior to	Instructor-led								
BSP	Client	Standards (Protocol, SAP,	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Metadata)	Details	1								
BSP	Client	Janssen Global Macro	Prior to	Instructor-led	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
БЭР	Client	Training	deployment		163	163	163	163	163	163	163	163
		тс	S MW Process T	raining - TCS Sh	aredriv	ve			•			
		Clinical Pharmacology	As per	Instructor-								
		(Pharmacokinetics and	requirement	led/ Self-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Pharmacodynamics) (By MW		directed	103						162	103
BSP	Client	Team)										
		Data Transparency Training	As per	Instructor-								
		(Including Transcelerate	requirement	led/ Self-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Guidelines) (By MW Team)		directed								
	Client	Basics of Clinical	As per	Instructor-								
		Pharmacology (PK and PD)	requirement	led/ Self-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		(By PK Team)		directed								
		Introductions to PK/PD Parameters	As per	Instructor-	Yes						Yes	
BSP			requirement	led/ Self-		Yes	es Yes	Yes	Yes	Yes		Yes
			•	directed								
		In the last to the completion	As per	Instructor-	\/	V	V	V	V	V	V	V
		In vitro-In vivo correlation	requirement	led/ Self- directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Approach in Different study	As per	Instructor-								
		types:	requirement	led/ Self-								
		- First in Human Studies		directed								
		- Steady state PK studies		d 2022d								
BSP	Client	- Mass Balance studies			Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		- BA/BE Studies										
		- Dose finding and dose										
		ranging										

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		studies - Intrinsic and Extrinsic										
		Pharmacokinetics in special population	As per requirement	Instructor- led/ Self- directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	J&J Mandatory Training - SUMMT /Sharepoint											
		Johnson & Johnson Policy on	Prior to	Self-directed	 							
		Business Conduct	deployment	Jen directed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Client	Records Management	Prior to	Self-directed					100			
DCD		Training	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BSP		POL-06825 (Policy on	Prior to	Self-directed								
		External Service Provider)	deployment		Yes	Yes	Yes	Yes	No	No	Yes	Yes
		IAPP - Information Asset	Prior to	Self-directed								
		protection Policy	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		J&J S	OPs/WI/Guideli	nes - SUMMT /	ShareF	Point						
		STA1007 (Qualification and	Prior to	Self-directed								
		Training)	deployment		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		SOP10924 (Trial Set Up	As per	Self-directed								
		Activities)	requirement		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BSP	Client	SOP13108 (PK/PD Data File	As per	Self-directed								
551	Circiic	generation, submission and	requirement									
		storage)			Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		SOP-14993 (Database	As per	Self-directed								
		Lock/Unlock for outsourced	requirement									
		DM activities)			Yes	Yes	Yes	Yes	No	No	Yes	Yes
		Hermes SAS Drug	As per	Self-directed								
BSP	Client	Development (SDD)	requirement									
	Girerre	Platform - Introduction to						V	.,	.,		l
		SDD Release 1			Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

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Hermes SAS Drug	As per	Self-directed								
Development (SDD)	requirement									
Platform - Workflows (Light										
version) - Release 2			Yes							
Hermes SAS Drug	As per	Self-directed								
Development (SDD)	requirement									
Platform - upload files in										
SDD e-learning			Yes							

Note: Applicable TCS and Client SOPs/WIs/Guidance Documents for all domains to be referred from respective Training Plans 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

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