

COD.	PROCEDURE	VERSION	DATE
GENERAL SOPs			
SOP-PCF04	Training management and creating a training plan	1	13/10/16
REGULATORY AND MONITORING PROGRAMME SOPs			
SOP-PRM02	Creating, approving and modifying a clinical trial's monitoring plan and manual	1	15/09/16
SOP-PRM04	Monitoring clinical trials	1	18/05/15
SOP-PRM05	Initiation (visit) of a clinical trial	1	15/10/15
SOP-PRM06	Close out (visit) of a clinical trial	1	01/02/16
SOP-PRM07	Clinical trial master file	1	03/05/16
SOP-PRM09	Informed consent in clinical trials	1	05/09/16
SOP-PRM10	Centers and researchers capacities assessment to conduct a clinical trial	1	29/03/18
PHARMACOVIGILANCE PROGRAMME SOPs			
SOP-PFV01	Obtaining basic project information	1	21/05/15
SOP-PFV02	Receiving serious adverse event notifications	1	21/05/15
SOP-PFV03	Data registration and entry in the information system and generation of CIOMS form	1	21/05/15
SOP-PFV04	Assessment of the causal relationship and the expectedness	1	21/05/15
SOP-PFV05	Notification to the sponsor/coordinating investigator and confirmation of the assessment of serious adverse events	1	21/05/15
SOP-PFV06	Assessing the need for additional information and follow-up of serious adverse events	1	21/05/15
SOP-PFV07	Expedited reporting of suspected unexpected serious adverse reactions	1	21/05/15
SOP-PFV08	Unblinding and unmasking in the case of a suspected unexpected serious adverse reaction	1	21/05/15
SOP-PFV09	Management of pregnancy notifications	1	17/07/15
SOP-PFV10	Assessment of the safety section of the clinical trial protocol	1	21/03/16
SOP-PFV11	Management of periodic safety reports	1	23/07/15
DATA MANAGEMENT SOPs			
SOP-PMBGD01	CRF Design (Hospital 12 Octubre node)	2	02/02/17
SOP-PMBGD02	Data Management Plan (Hospital 12 Octubre node)	1	20/03/17
SOP-PMBGD03	CRF Training (Hospital 12 Octubre node)	2	20/03/17
SOP-PMBGD04	Data Entry (Hospital 12 Octubre node)	2	02/02/17
SOP-PMBGD05	Data Coding(Hospital 12 Octubre node)	2	02/02/17
SOP-PMBGD06	SAE Reconciliation (Hospital 12 Octubre node)	2	02/02/17
SOP-PMBGD07	Randomización, blinding and code break procedures (Hospital 12 Octubre node)	1	24/02/17
SOP-PMBGD08	Database Design (Hospital 12 Octubre node)	2	02/02/17
SOP-PMBGD09	Database Validation (Hospital 12 Octubre node)	2	02/02/17
SOP-PMBGD10	Data Validation (Hospital 12 Octubre node)	2	02/02/17
SOP-PMBGD11	Data Quality (Hospital 12 Octubre node)	2	02/02/17
SOP-PMBGD12	Data Transfer (Hospital 12 Octubre node)	2	24/02/17

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SOP-PMBGD13	Database Locking and unlocking (Hospital 12 Octubre node)	1	02/02/17
SOP-PMBGD14	Data Archiving (Hospital 12 Octubre node)	1	24/02/17
SOP-PMBGD15	Laboratory data management (Hospital 12 Octubre node)	1	24/02/17
SOP-PMBGD16	Server Configuration	1	18/07/16
SOP-PMBGD17	Server Maintenance	1	18/07/16
SOP-PMBGD18	System Security Assessment	1	26/01/17
SOP-PMBGD19	User's account management	1	29/09/17
SOP-PMBGD20	System Validation	1	24/03/17
SOP-PMBGD40	Data management plan start meeting 8 (H. Clinic node)	1	09/05/18
SOP-PMBGD41	Data Management Plan Development and fulfillment report (H. Clinic node)	1	24/03/17
SOP-PMBGD42	Quality Control (H. Clinic node)	1	17/03/17
SOP-PMBGD43	eCRF Design(H. Clinic node)	1	17/03/17
SOP-PMBGD44	eCRF Design Meeting (H. Clinic node)	1	17/03/17
SOP-PMBGD45	eCRF Backup and Restoration (H. Clinic node)	1	24/03/17
SOP-PMBGD48	eCRF Status Change Approvals (H. Clinic node)	1	17/03/17
SOP-PMBGD49	Data export (H. Clinic node)	1	15/05/18
SOP-PMBGD52	eCRF User Acceptance Testing (H. Clinic node)	1	24/03/17
SOP-PMBGD53	eCRF Status Management (H. Clinic node)	1	24/03/17
SOP-PMBGD54	Data Entry (H. Clinic node)	1	24/03/17
SOP-PMBGD63	MedDRA Coding (H. Clinic node)	1	24/03/17
WIn-PMBGD01	User Access control management of Hospital 12 de Octubre's data center (H. Clinic node)	1	24/03/17
WIn-PMBGD02	User Access control management to CDMA for DM (H. Clinic node)	1	24/03/17
WIn-PMBGD03	User Access control management of Corporation Sanitaria Clinic data center (H. Clinic node)	1	24/03/17