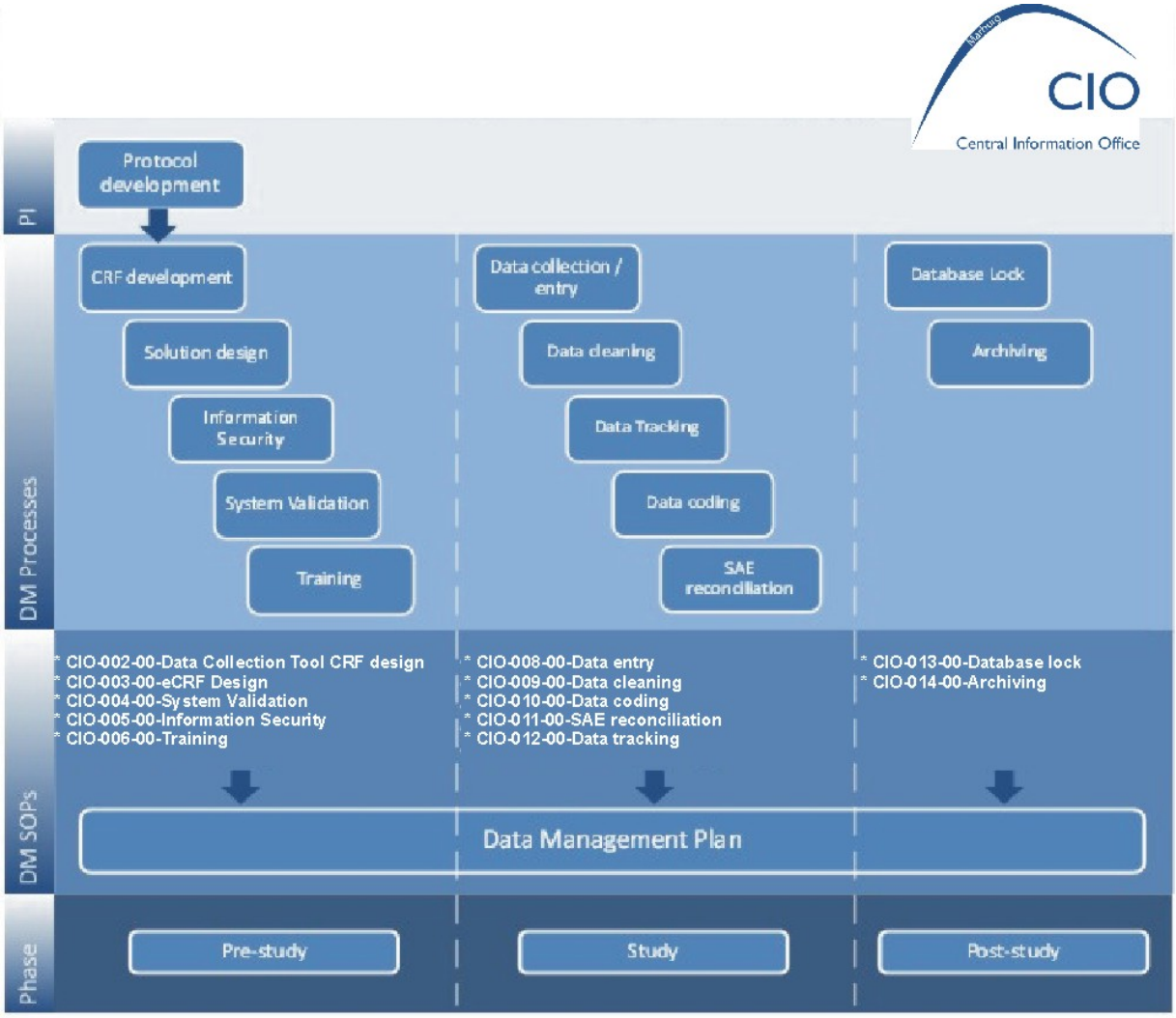
Data Management Plan				
Project Title				
Document No.				
	Role	**Name**	**Date**	**Signature**
Author				
Approved	**Project Leader**			
Approved	**QA**			

Study / Project Overview

Process Overview

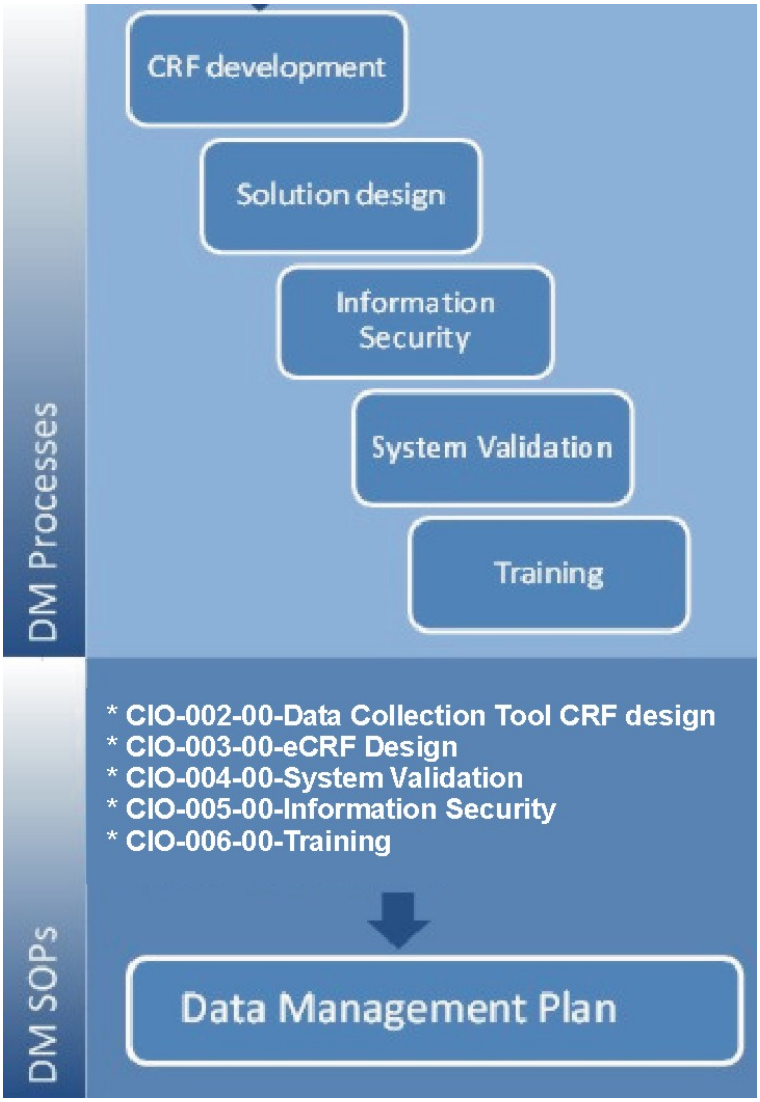
Figure 1 shows the overall flow of data management (DM) activities within a research project. The use of the listed DM specific processes are decided on a study by study basis, depending on the type of project (epidemiological study, qualitative research, phase III clinical trial, phase IV clinical trial, pharmacovigilance project, diagnostic study etc.) and on the extent of support that is required for DM.

Figure 1: Flow of Data Management activities and related SOP's



This document should be used to aggregate all of the DM SOPs being used in the study / project, according to the phase they take place in.

Section 1 – Pre-Study / Project phase

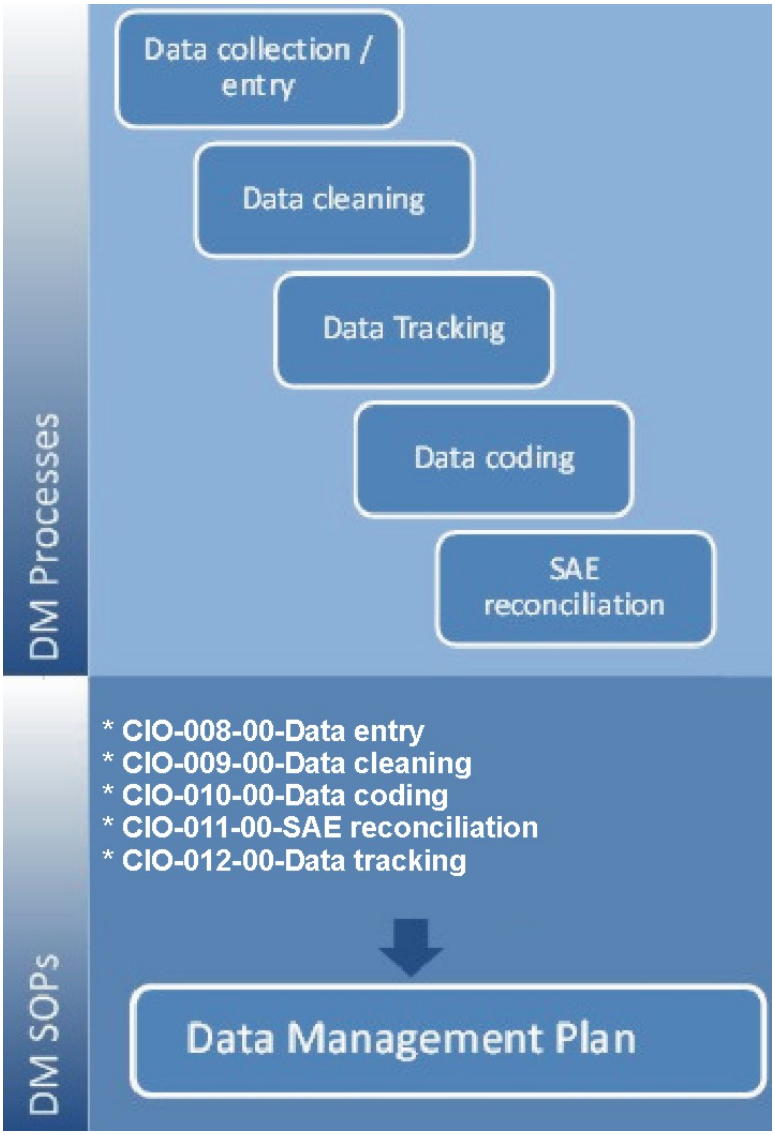


This phase focus' on the design of the data collection tool, whether it is a paper based case record form (pCRF) or an electronic case record form (eCRF).
During this phase the information security policies will be drafted along with the system validation plan. Detailed documentation of each phase has to be created with the tools of the CIO Marburg, especially the tools inside the secuTrial® system, additions can be stored in the activeCollab projekt management system and/or the CIO projects database of the CIO Marburg.

Outputs

- CIO-002-00-Data Collection Tool CRF design
- CIO-003-00-eCRF Design
- CIO-004-00-System Validation
- CIO-005-00-Information Security
- CIO-006-00-Training

Section 2 – Study / Project phase

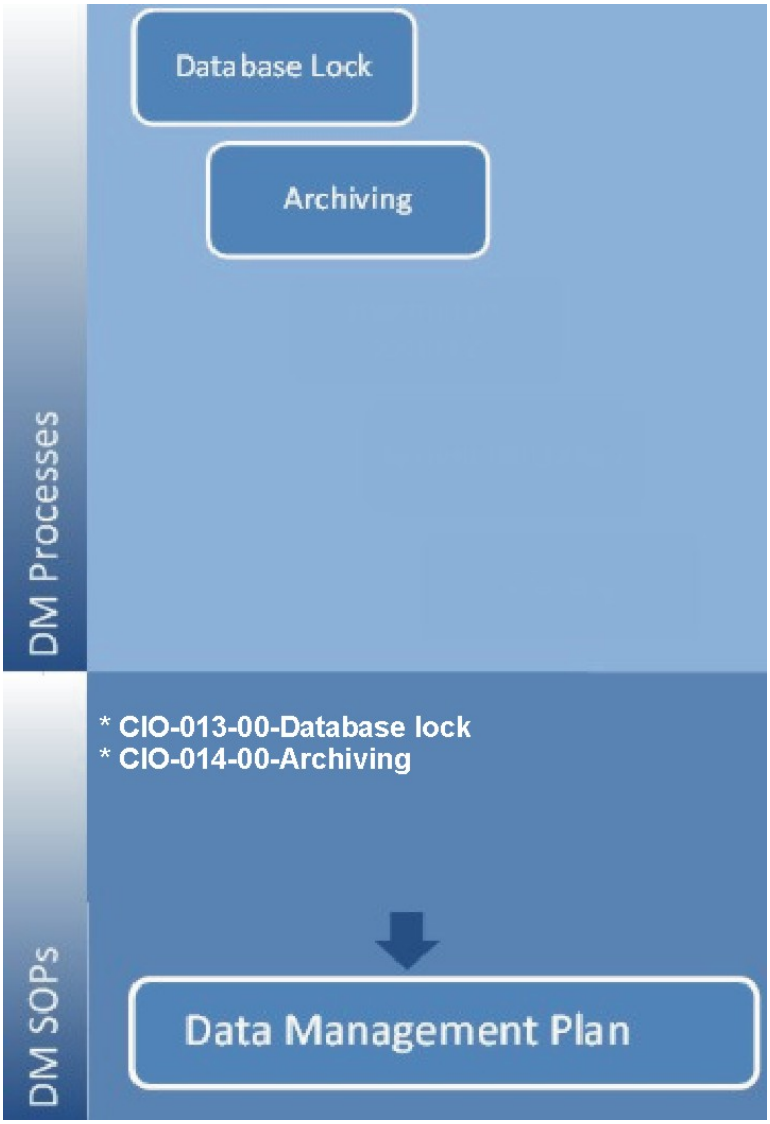


This phase focus' on the data handling, particularly how the data is to be collected and entered into the electronic data capture system (EDC). The process of cleaning data will be detailed along with the requirements for coding of the database. A map highlighting the flow of data within the study will also be created to aid with data tracking. In case of a clinical trial (according to AMG) SAE reconciliation will also be undertaken to ensure that all cases are reported correctly in the database.

Outputs

- CIO-008-00-Data entry
- CIO-009-00-Data cleaning
- CIO-010-00-Data coding
- CIO-011-00-SAE reconciliation
- CIO-012-00-Data tracking

Section 3 – Post study / project phase



This phase focus' the concept of database lock and the criteria for this process. Once the study / project is deemed complete, an Archiving process should be followed to ensure that all electronic research data remains accessible. In case of the project's final aim is a research database for anonymised external access the step of transferring the data into a new research database can be added.

Outputs

- CIO-013-00-Database lock
- CIO-014-00-Archiving