

A. IT Infrastructure

IT01. Procurement and Installation (Servers)

IT02. Physical Security and Management

IT03. Logical Security and Management

IT04. Logical Access Control

IT05. Business Continuity

B. IT culture

IT06. General System Validation

IT07. Local Software Development

D. Specific Clinical DM application

DM 01: Clinical DM Application - Design and Development

DM 02: Clinical DM Application - Validation

DM 03: Clinical DM Application - Change management

E. Trial Data Management

IT09. Treatment Allocation Systems ----- DM 04: Treatment Allocation and (Un)Blinding Management

IT10. Reporting DM 05: Site Management, Training & Support

IT11. Data Export DM 06: Data Entry and Processing

IT12. Importing & Uploading Data DM 07: Data Quality Checks

IT13. Directly Amending Data DM 08: Query Management

DM 09: Data Coding and Standards

DM 10: Pharmacovigilance Data Management

IT14. Delivery of Data for Analysis ----- DM 11: Pre-Analysis Data Management

IT15. Long Term (electronic) Data Curation ----- DM 12: Managing (physical) Archives

F. General

IN01: International Aspects

SC01: Trials Unit staff competence

C. Trial IT Support

IT08. Clinical DBMS Systems