acdm

association for **clinical data management**

Functional Integration Map

ACDM eDigital DMEG

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Introduction:

- The aim of this functional integration map is to highlight potential digital integrations that exist within the clinical trial life cycle to uncover potential areas where there may be opportunities to improve operational efficiency and data access and security.

- Each box relates to a software function, however, it is possible and potentially preferable for a single software product to contain enough features which enable the software product to claim multiple functions. In this instance you should group the boxes into one. A description of a subset of features that should be used to define each function can be found in the Functional Definitions.

- Over the following 6 diagrams, groups of systems will be added to form the total clinical system or eClinical Platform. These groups are
    1. Clinical Data Collection Systems
    2. Trial Management Systems
    3. Clinical Data Storage, Reporting and Analysis
    4. Study Close Out
    5. Quality Management and Training
    6. Functional Integration Map

- The colour coding is to highlight the new systems that have been added in and does not highlight that these are the only systems that form part of the group. For example, many systems are involved in “quality management and training” and it is not limited to the eQMS, learning management system and HRMS.

- In the final diagram, each arrow represents a possible integration that can be explored, to determine if the benefit of integration outweighs the cost.

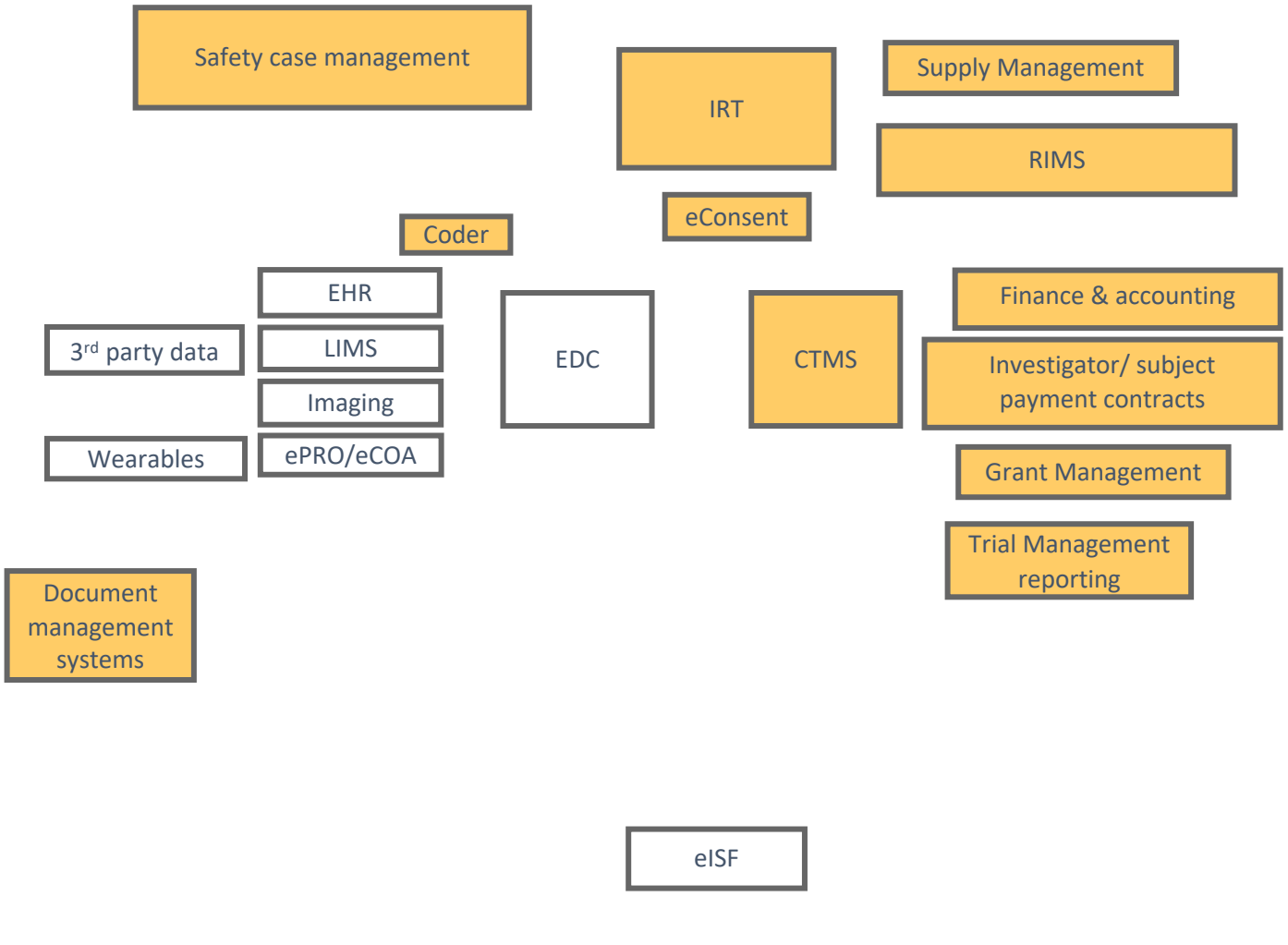
Clinical Data Collection Systems:

Key:

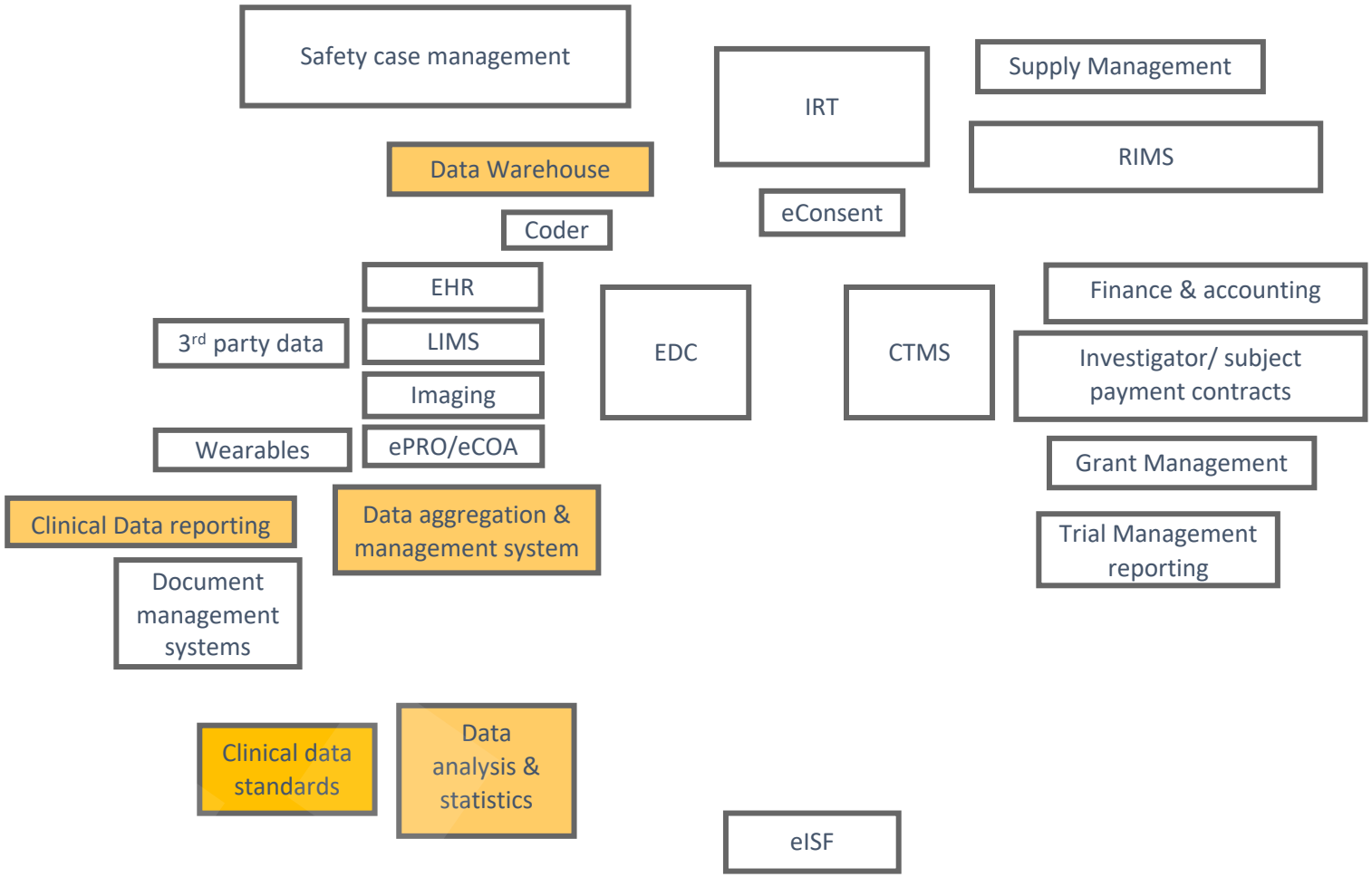
: New Function

eISF

Trial Management Systems:



Clinical Data Storage, Reporting and Analysis:

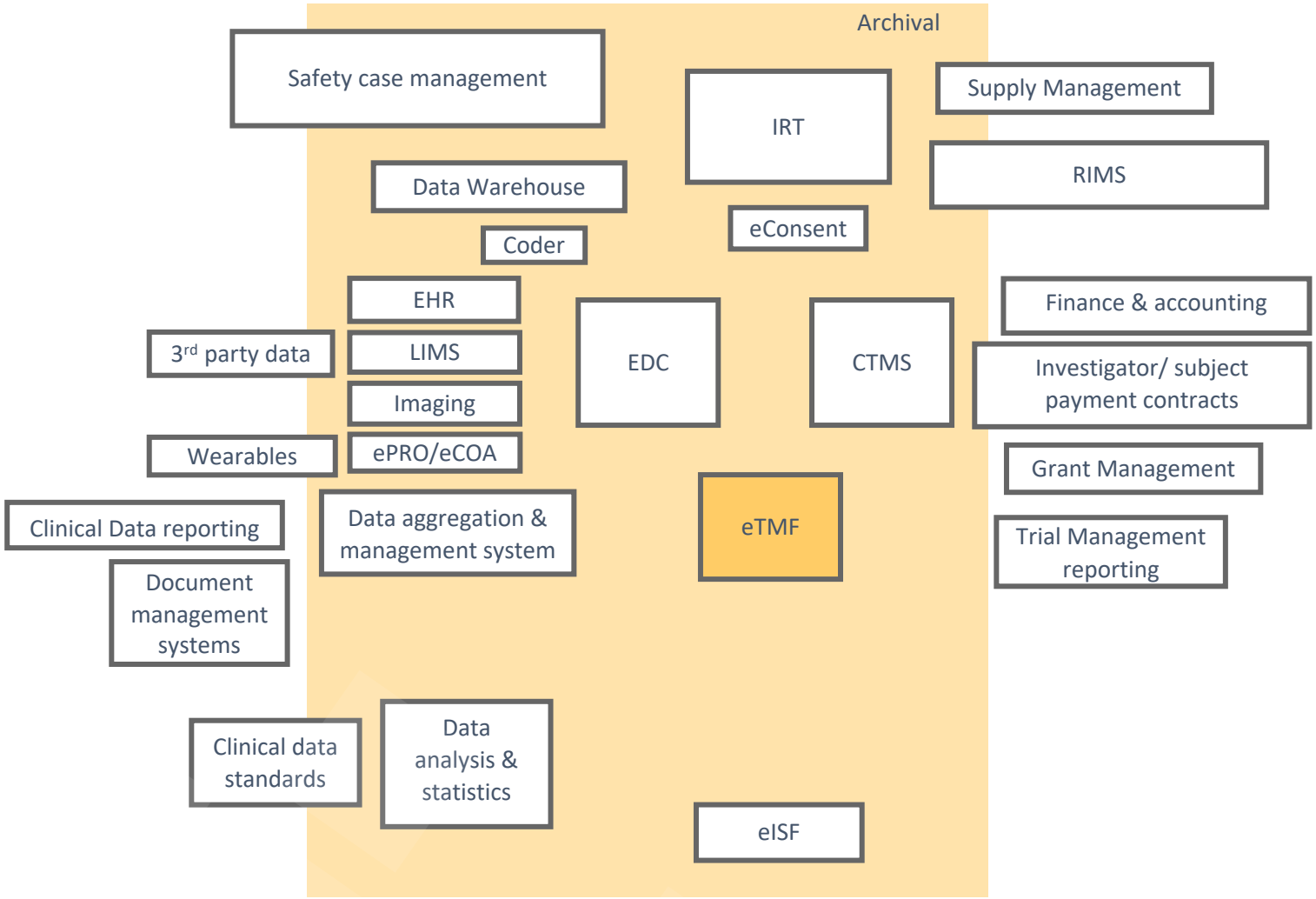


Key:

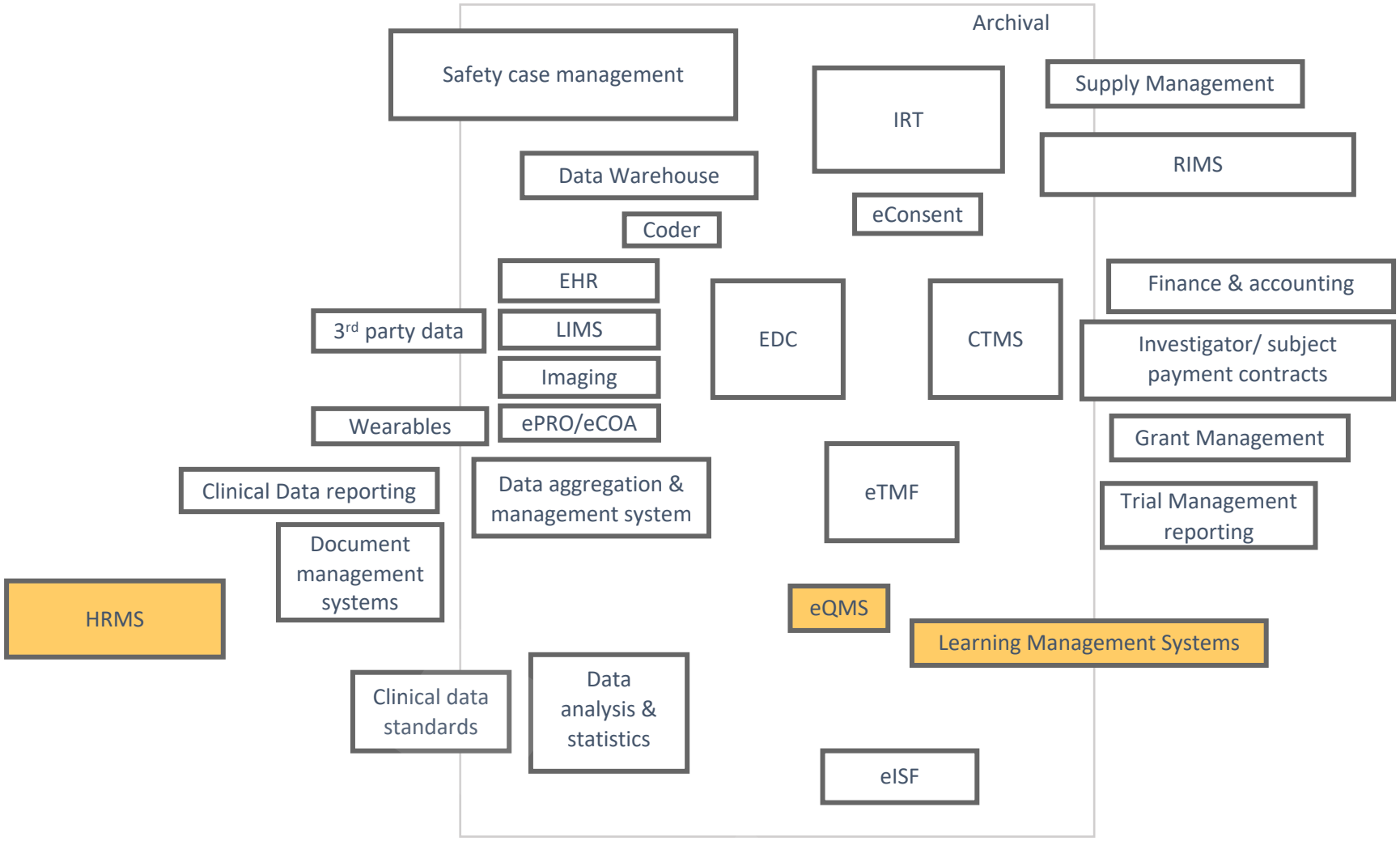
: New Function

: Function that was included in an earlier group

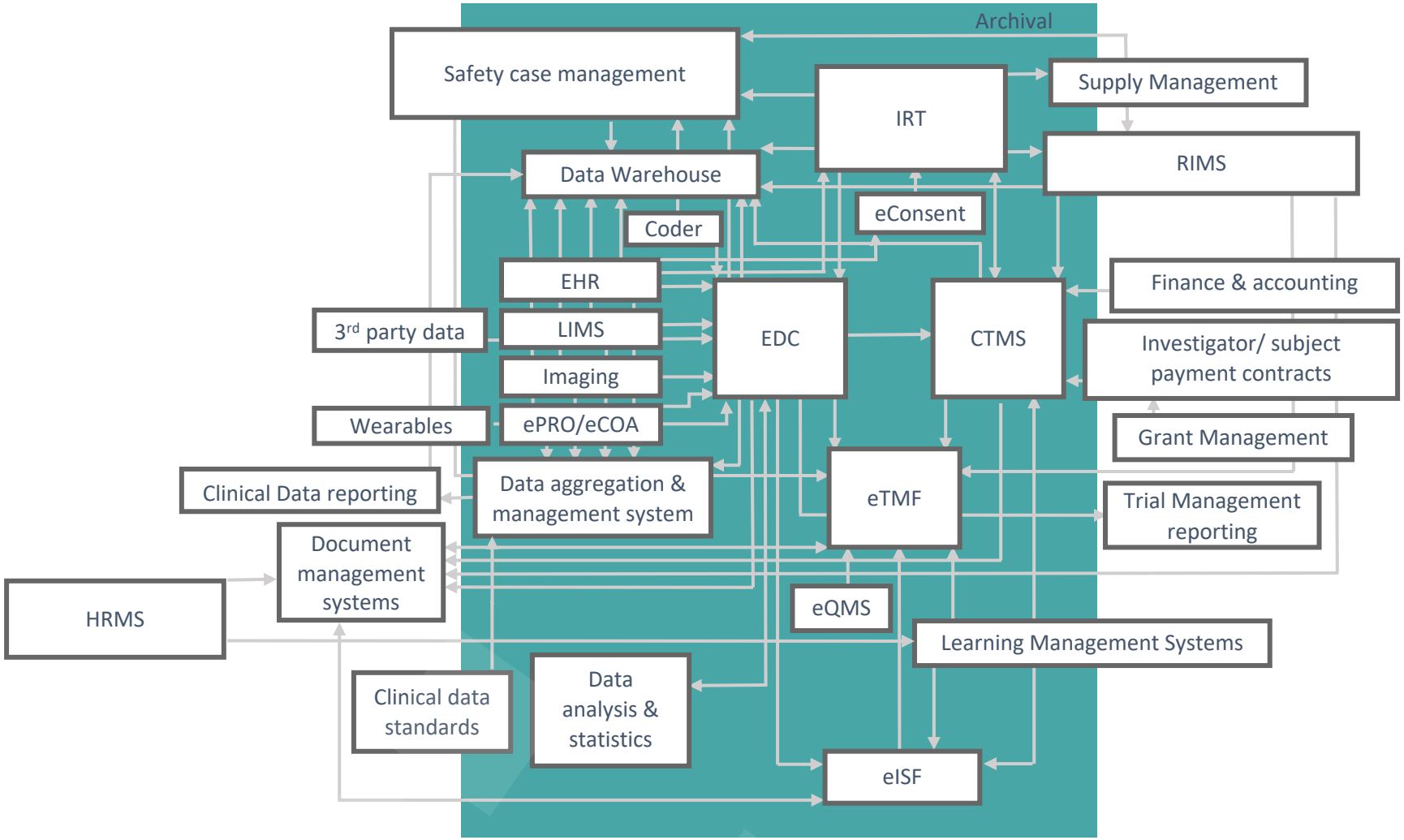
Study Close Out:



Quality Management and Training:



Functional Integration Map:



Functional Definitions Overview:

- The following table lists some of the core features which exist within each function.
- Teams should discuss and align on required features that each function is required to have and any preferences in consideration for the clinical trial and operational and data management team. After aligning on this, teams can assess the ability different providers have to meet the identified needs.
- Note that available features may extend beyond the core features listed here and the requirement for different features may be influenced by the complexity or specific needs of the clinical trial.

Functional Definitions:

Function	Features
3rd Party Data	• Data: inclusion of CRO/vendor data, which is usually laboratory data
Archival	• Document storage and organization: Robust data storage system that is secure and supports long-term retention of the trial-related documents.
Clinical dashboard	• Study overview: a summary of key metrics pertaining to the clinical trial, including the number of enrolled participants, active sites, completed visits and overall Study progress
Clinical Data Standards	• Data Standardization: Supports the use of standardized data formats
Coder	• Medical Coding Dictionaries: facilitates the translation of medical terms and drug names into a standardized code • Auto-Code Suggestions: provides suggestions or automates code input for matching criteria • Coding review and approval: supports a workflow to review, amend and accept codes
CTMS (Clinical Trial Management System)	• Study Planning and Setup: enables planning, design and setup of clinical trials, e.g., capturing study protocol, study sites, inclusion/exclusion criteria and milestones • Recruitment and Enrolment: tracks participant enrolment, e.g., screening, status updates and consent • Visit Scheduling: tracks the study monitoring visits, procedures and activities
Data aggregation and management system	• Data hub for clinical trial data • Review and cleaning of clinical trial data • Roles: Used by data managers and medical monitors

Functional Definitions:

Software product	Features
Data warehouse	• Centralized repository: consolidates and stores large volumes of data • Archival: stores and safeguards data for the required retention period, where consent allows, supports data reuse
Document management systems	• Document repository: to store study-related documents, e.g., protocol, informed consent forms, regulatory submissions, etc
eConsent	• Electronic / Digital Signature: Allows participants to electronically sign the consent form • Consent Withdrawal: Enables participants to request to withdraw their electronic consent • Delivers Trial Information: Supports participants understanding of the trial, the purpose of the trial, what is required from them and how their data will be used
EDC (Electronic Data Capture)	• eCRFs (electronic Case Report Forms): create and manage eCRFs • Data Management: ability to query data and to maintain data accuracy and completeness • Data Monitoring: enables the review and monitoring of clinical data
EHR (Electronic Health Record)	• Patient Demographic and Medical History: captures patient information, including contact details, demographic data and their medical history • Medication Management: enables the prescribing of medical products and retains a record • Clinical notes: allows healthcare providers to enter clinical notes • Lab and test results: stores laboratory and diagnostic results

Functional Definitions:

Software product	Features
eISF (electronic Investigative Site Files)	• Document repository: secure storage for site document information, e.g., protocol, informed consent forms, ethics committee correspondence, regulatory approvals • Version Control: Ability to maintain multiple versions with a clear audit trail for users to ensure they are using the most up-to-date version but retain the ability to track changes and review previous versions • Document collaboration: facilitates real-time and simultaneous editing and commenting
ePRO/eCOA (electronic Patient Recorded Outcome/electronic Clinician Outcome Assessment)	• Data capture: patient or clinical entered data • Interface: intuitive and user-friendly interface • Multilingual: ability to support different languages • Device variation: supports either bring-your-own device or provisions devices and has broad compatibility (e.g., iOS, Android) • Offline data entry: Ability to capture data while offline
eQMS (electronic Quality Management System)	• Document management: storage and version control for quality related documents, e.g., policies, standard operating procedures (SOPs), etc • Change control: workflow enabling change management to documents and processes • Corrective and Preventative Action (CAPA): tracking and managing CAPA processes • Incident management: reporting and investigating incidents, deviations and adverse events through to corrective action taken

Functional Definitions:

Software product	Features
eTMF (electronic Trial Master File)	• Document management and archival: centralized storage of essential trial documents, e.g., protocol, investigator brochures, regulatory submissions, site-specific documents
Finance & accounting	• Financial management: managing the financial aspects related to the clinical trial, e.g., budgeting, cost tracking, invoicing, financial reporting and vendor management • Expense Approvals: establishing workflows to maintain control and compliance with company policy • Electronic Invoicing and Billing: enabling efficient financial transactions
Grant Management	• Budgeting and Financial Tracking: Allows for the creation and management of study budgets, to track expenses and ensure compliance with grant requirements • Contract Management: Stores previous contracts and may support benchmarking.
HRMS (Human Resources Management Systems)	• Personnel Information Management: Storing and managing employee information, e.g., contact details, qualifications, certifications, CV • Recruitment and On/offboarding: facilitating the recruitment and on/offboarding process • Absence, Time and Attendance: tracking absence, time and attendance as required during a clinical trial
Imaging	• Image Management: storing, retrieving, processing and supporting the analysis of medical images from a variety of sources, e.g., X-ray, MRI scans, CT scans, ultrasound • DICOM: compatibility with the Digital Imaging and Communications in Medicine (DICOM) standard • Image Review: provisions tools for viewing, reviewing and annotating • Image Processing and Enhancement: improves image quality and visibility

Functional Definitions:

Software product	Features
Investigator/ subject payment systems	• Data Security and Privacy: robust security measures to protect participant payment information • Payment Tracking: monitoring and tracking payments based on clinical trial participation • Tax Reporting: provisioning tools for tax reporting and to ensure compliance with tax regulations in each country
IRT (Interactive Response Technology) or RTSM (Randomization and Trial Supply Management)	• Randomization and Drug Allocation: randomly assigns participants to different treatment arms or control group, facilitating blinded or unblinded treatments as required • Subject Screening and Enrolment: facilitates the screening of participants based on the eligibility criteria • Drug Dispensation: tracks the dispensation of study drugs to the sites and subjects
Learning management systems	• Training management: tracks and manages training progress, completion and certification • Role-Based Training: facilitates training requirements by the user job role and responsibility • Document Repository: stores training materials and resources • Audit Trail: maintains a record of training activities
LIMS (Laboratory Information Management System)	• Sample management: to track and manage samples (from receipt to disposal) • Workflow automation: automates tasks such as sample processing, data entry and result reporting • Data management: stores and organizes data generated through testing and analysis • Quality control and compliance: ensures adherence to regulatory standards • Result reporting: generates and delivers reports after the sample testing is complete • Inventory management: manages laboratory supplies, reagents and other consumables • Audit trail: maintains a detailed record of all actions and changes made in the system

Functional Definitions:

Software product	Features
RIMS (Regulatory Information Management System)	• Document management: storage and management of regulatory documents • Submission management: allows for the preparation and tracking of regulatory submissions and tracking of the approval process
Safety Case Management	• Adverse Event Reporting: allows the capture, documentation and reporting of adverse events for management by the pharmacovigilance functions • Safety Signal Detection: identifies potential safety concerns • Reporting and analytics: generates safety reports, trend analysis and performance metrics • Audit trail: tracks activities
Statistical analysis system	• Data management: provides tools for data import, cleaning and analysis • Statistical tools: supports common statistical analysis requirements e.g., mean, median, standard deviation, percentiles • Analysis and Hypothesis Testing: supports a variety of statistical methods e.g., regression analysis, survival analysis, power and sample size calculations • Data Visualization: provides tools to support data exploration and interpretation • Export and Reporting: supports a variety of export formats and enables customizable reports

Functional Definitions:

Software product	Features
Supply management	• Inventory management: tracks and manages clinical trial supplies e.g., investigational drugs, medical devices, other study materials • Batch and Lot Tracking: maintains traceability of items • Forecasting and Demand Planning: predicts future supply requirements • Order Management: supports ease of ordering • Data Analytics and Reporting: for efficiency improvements, identifying bottlenecks and optimizing inventory management • Temperature monitoring: monitors storage and transportation of temperature-sensitive products
Trial Management reporting	• Data visualization: Provides an overview of the trial management data which may include patient recruitment and enrolment, site performance, timelines and milestones, etc.
Wearables	• Data Collection and Transmission: enables the collection and transmission of relevant patient data • Real-Time Monitoring: allows for the ability to monitor patients in real-time, improving patient safety and provisioning more data

Conclusion:

- Integrating different functions used in the eClinical Platform has many benefits, including the reduction of transcription errors and time required to manually transcribe data, the improvement of data reporting and enabling centralized monitoring by enabling real-time or near real-time data access and improved data quality, improved auditability and ability to build in workflows.

- Many possible data integrations exist within the eClinical Platform and while it has the potential to make operations more efficient it can also increase complexity. Some of the common issues include the identification of who is responsible for maintaining the integration, which can be affected by software updates, for example, and, where middleware is required, who is responsible for building and quality checking that integration?

- A detailed review will need to take place to highlight where it is most cost-effective to implement potential integrations and to assess the level of integration that exists or is being developed.

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