Draft

CONFORM eClinical

eClinical is a comprehensive, unified system, which is a part of the *CONFORM* platform. eClinical comprises Admin, Coding, Clinical Trial Management System (CTMS), Electronic Data Capture (EDC), electronic Trial Master File (eTMF), Interactive Web Response System (IWRS), Pharmacovigilance (PV), Study Designer (SD), and eDiary/eCOA.

eClinical provides a complete solution for study design and conduct, subject randomization, clinical supply, data collection, drug safety monitoring, electronic data capture, clinical data and documentation management, operational management, compliance monitoring, and much more.

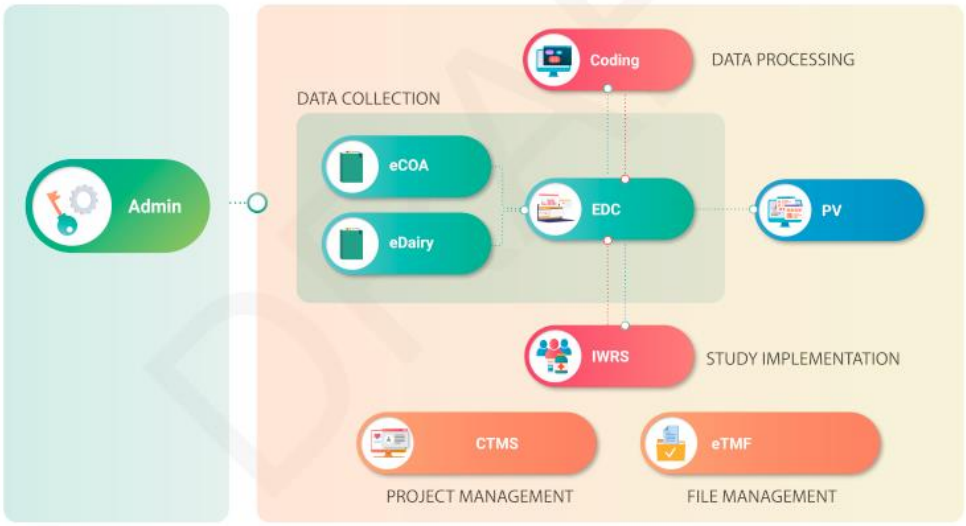

Figure 1. eClinical ecosystem

Let us go into more detail about each eClinical component.

- **Admin**: it represents an administrative system used to manage users, authorities, and sponsors at the company level. It provides studies, sites, and sponsors with high-granularity role-based access management across all eClinical applications.

- **Coding**: it is intended for managing elements of data collected during clinical trials to organize large amounts of information in a standardized way, facilitating data analysis, and ensuring accuracy and consistency in reporting.
- **Clinical Trial Management System (CTMS)**: it primarily manages and controls the personnel, communication, budget, progress, expenses, documents, and declaration involved in the entire clinical trial. It provides study and site management, study quality control, study progress tracking, project management, risk management, reports, and a visualized dashboard.
- **Electronic Data Capture (EDC)**: it is mainly used to collect and manage subject data during clinical trials. It integrates with the Study Designer (SD) application and relies on CRF to complete data collection and management. It also provides an audit trail, data alert, source data verification (SDV), payment management, adjudication, and other functions as well as supports data export according to the CDISC ODM standard.
- **Electronic Trial Master File (eTMF)**: it represents a storage repository and management center for clinical trial files.
- **Interactive Web Response System (IWRS)**: it represents a unified and configurable subject randomization and trial supply management tool for subject grouping, drug inventories, shipments, and dispensations, as well as other vital processes during a clinical trial.
- **Pharmacovigilance (PV)**: it provides instruments for the collection of *AE* data from clinical trials, post-marketing, and literature. It carries out centralized management and scientific data evaluation through analysis, reporting, signal detection, and other methods building a comprehensive pharmacovigilance informatization management and data integration system. The module is fully integrated with the EDC system and third-party systems through *Safety Gateway*. Also, the module supports a global regulatory submission of *ICSR* through *E2B R3* electronic transmission.
- **Study Designer (SD)**: it supports the design of the *CDSIC* ODM-compliant electronic CRF forms to support EDC and eDiary data collection and management.
- **Electronic Clinical Outcome Assessments (eCOA)**: it is a mobile application designed for the collection of such outcome assessments as