# Viedoc

## EDC & ePRO

## Product Specification

# Our commitment as an EDC vendor – here's what you get

The Viedoc EDC system is designed to come with all the required and requested features of the clinical trials industry. Evaluating everything that Viedoc is capable of as well as its regulatory compliance can take a lot of time and work – time we'd rather see our clients spend on their clinical trials instead.

So, to streamline and simplify the evaluation and auditing process for both our current and future clients, we have created the Viedoc Product Specification. In this document, all the features that we commit to deliver are outlined, detailed, and explained.

# Features 1/2

- An online intuitive web-based interface without client installation or client data storage
- Audit-trail and electronic signatures compliant with FDA 21 CFR part 11, and a contemporaneous and independent investigator copy being created each time a CRF is saved
- Country, site group and site scoping of study subjects and personnel
- Extensive support for configurable automated data management (optionality, missing values, range- and edit-checks)
- Support for configurable responsive/interactive visibility conditions on both role-, study schedule- or data dependency-level
- A metrics interface to overlook the study
- A data export feature that allows output of all or subsets of data to Excel, CSV, SAS, PDF/A (compliant to FDA submission format as laid out by eCTD) and CDISC ODM formats, as well as online chart visualization, and blank/annotated CRF output
- A randomization and study drug allocation feature that offers the choice to assign values from a pre-computed static list or a dynamically generated/randomized list
- An electronic data capture feature to collect, view and review CRF data in an ICH GCP compliant manner, including capture of binary data (images/documents)
- A configurable role-based permission system
- Data review, lock and query features, as well as selective SDV, that support common industry SOP:s
- Support for configurable calculated values (close to unlimited in algorithm complexity level)
- Multi-lingual support
- A feature for entering and applying laboratory reference values with both time, location and factor scope
- An API that allows for both import and export of data in CDISC ODM format to allow for integration with other systems, as well as a stand-alone command-line application that takes CSV files and a define.xml compliant mapping (feature to create this mapping is available) to for import to the API to cover the basic cases of data import
- A medical coding feature that supports MedDRA, WHODrug (with major version 4 being certified by UMC), ATC and Iyakuhinmei Data File (IDF)

# Features 2/2

- A sophisticated email alert feature to make key personnel aware of important data events
- A configuration interface that allows for complete independence in terms of study configuration and enables reuse of study building blocks (and for major version 4 and up; WYSIWYG editor, comprehensive version management, transportability/import/export and off-line examination/revision of the configuration in CDISC ODM XML format)
- An administrative interface to facilitate study maintenance and helpdesk tasks, as well as manual data import and possibility of study-recreation from a previous snapshot
- User authentication and data security measures that, at any point-in-time, is up-to-date with industry standards
- Multi-tenant hosting in one of the regions Europe, Japan or China with strict data isolation, encryption-in-transit and encryption-at-rest
- Maintenance and operation of the major version in which an individual study is set up throughout the study license term
- Respect to applicable industry standards in terms of development practices, system validation and IT operations
- An integrated and configurable electronic Patient Reported Outcomes feature (ePRO) according to the BYOD model, including email and SMS reminders
- Support for simultaneously running unlimited versions of a study configuration
- A study-level database-lock feature, and a unique and fully self-service studydecommissioning feature, including status reports and archiving recommendations
- Online documentation/eLearning for both end-users, managers and administrators
- A service level agreement (SLA) that details service availability, data continuity and security
- Continuous updates and improvements but with backwards compatibility with all versions within the same major version
- Regulatory compliance with clinical trial regulations according to EMA, FDA, JPMA and CFDA
- Regulatory compliance with the Personal Data Protection laws including GDPR (EU), APPI (Japan), HIPAA (US) and the Personal Information Security Specification (China)


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