Software Specification

1 oomnia Core

A detailed specification of all software modules, features and their purpose within the complete portfolio of the oomnia system.

Workflows	System Module	Contained Features	Feature Purpose
System and Study Setup Management and Work Administration	***Administration Module***	*User Management*	*Clients can create and manage users and export user data efficiently within the system.*
		Roles and Permission Management	*Clients can create and manage roles, control module access, and set document type permissions based on role*
		Document Type Management	*Clients can create and manage document types used in the system, including EDC documents and read-only document types.*
		Organization Management	*Clients can create and manage organizations involved in the study, such as Sponsors, CROs, Vendors, and other.*
		Language Management	*Clients can create and manage system interface language.*
		System Settings Management	*Clients can configure user security settings and manage email notifications for system events and activities.*
	Trials Module	*In-system Study (Trial) Creation and Management*	*Clients can manage trial protocols, input and organize trial data, oversee trial organization and documents, handle trial environments, manage trial countries, configure randomization and supply settings, receive notifications on key trial events, manage trial laboratories, handle trial queries, generate real-time graphical reports, and perform medical coding.*
EDC Document Creation and Management	***Document Management Module***	*Document Management*	*Clients can manage all trial documents, handle test and production environments, create and manage document types, customize document controls, control document status and settings, set signatures, and export document data dictionaries.*
		Document Designer	*Clients can create EDC documents, design forms, manage chapter, page, field, and group properties, select field types, set field dependencies, perform date/time checks, configure triggers, handle date imputation, apply formulas,*

Workflows	System Module	Contained Features	Feature Purpose
			perform data calculations, evaluate currency, manage partial dates, and maintain running records.
Data Entry	***Data Capture Module***	*Data Capture Document Overview*	*Clients can manage all trial documents and handle both test and production environments.*
		Data Entry	*Clients can perform data entry on created EDC documents, as well as manage field properties, page user controls, field menus, and access field audit trails.*
		Source Data Verification (SDV)	*Clients can perform SDV on EDC documents in the SDV environment.*
		Queries	*Clients can generate and resolve queries on specific fields, interact with queries through a dedicated interface, and manage query menu controls.*
		MedDRA Coding	*Clients can perform MedDRA coding through a dedicated interface.*
		WHODrug Coding	*Clients can perform WHODrug coding through a dedicated interface.*
	Data Comparison Module	*Double Data Entry Mode and Document Merging*	*Clients can create double document instances, perform double data entry, compare documents, and perform document merge.*
Performance Enhancing Tool	***Study Calendar Module***	*Study Calendar, with task, event, and reminder functions*	*Clients can manage calendar functionalities, set reminders, organize tasks and events, filter calendars, and use a planner for efficient scheduling.*
Data Analysis	***Clinical Table Module***	*Clinical Database Overview and Export*	*Clients can view and filter clinical databases, access clinical database overviews, and export clinical database data.*
Progress Report and Metrics	***Query Management Module***	*Query Management Table*	*Clients can access and manage condensed query information for overview and referral, and filter queries effectively.*
	Study Metrics Module	*Custom Reports*	*Clients can manage reports, filter real-time data reports, access real-time data report overviews, and export real-time data reports.*
		Patient Dashboard	*Clients can oversee study subject-related data entry metrics, such as data completion and specific field related metrics, and export patient dashboard data.*
		Audit Logs	*Clients can view a detailed presentation of all user activities, complete with time and date stamps for accurate tracking and auditing.*

Workflows	System Module	Contained Features	Feature Purpose
Randomization and Trial Supply Management	***RTSM Module***	*Send Shipment*	*Clients can create shipments with built-in temperature controls, customize shipment controls, and export sent shipment data.*
		Receive Shipment	*Clients can receive IMP shipments, control shipment receipt with automatic quarantine features, customize shipment receipt controls, and export shipment data.*
		Unblind Subject Menu	*Clients can access an emergency unblinding interface to quickly and securely unblind trial data when necessary.*
		Randomization list upload	*Clients can manage randomization list tables, upload randomization lists, and export randomization lists efficiently.*
		Randomization	*Clients can view real-time randomization status and export randomization status data.*
		Unblinded Randomization	*Clients can view real-time unblinded randomization status and export unblinded randomization status data.*
		Manage IMP Kits	*Clients can manage IMP kit tables and allocations, upload kit lists, and export kit lists efficiently.*
Laboratory Management	***Laboratory Management Module***	*Laboratory Addition and Management*	*Clients can manage centralized laboratory overview tables, customize laboratory table controls, and create local laboratories with defined reference ranges.*
eTMF Management	***eTMF Module***	*eTMF Management*	*Clients can manage multiple trial eTMFs and handle both test and production environments efficiently.*
		eTMF Creation	*Clients can design trial-specific eTMF hierarchies, manage root, zone, section, artifact, sub-artifact, and ad hoc sub-artifact controls, and handle templates, blueprints, and placeholders effectively.*
		eTMF Document Management	*Clients can manage document uploads and downloads, control document versioning, handle document approvals, and lock documents to ensure security and integrity.*
		eTMF Export	*Clients can manage and export eTMF structures and documents, as well as control document history.*
		eTMF Query Process Management	*Clients can raise, update, and resolve queries at various levels, including artifacts, templates, blueprints, placeholders, sub-artifacts, and ad hoc sub-artifacts.*
Clinical Trial Management	***CTMS Module***	*General Information Overview*	*Clients can track key milestone and enrolment dates, monitor recruitment information, oversee essential documentation progress, and identify risk indicators.*

Workflows	System Module	Contained Features	Feature Purpose
		Study Team Management	*Clients can manage and track both active and inactive members.*
		Milestone and Enrollment Tracking	*Clients can track key milestone and enrolment dates, as well as monitor recruitment information.*
		Start Up Documentation	*Clients can oversee essential documentation, manage the training matrix and log, and maintain the delegation log.*
		Monitoring	*Clients can review monitoring visit reports and manage action item logs.*
		Subjects	*Clients can manage the list of participants, track recruitment sources, and maintain the participant tracking log.*
		Management of AEs and PDs	*Clients can manage lists of adverse events and serious adverse events, track protocol deviations, and conduct protocol deviations analysis.*
Electronic Informed Consent Management	***eConsent Application****	*Admin Application*	*Clients can manage eConsent setup, including trials, organizations, users, roles, participants, quizzes (Q&A), and view audit logs.*
		Participant Application	*eConsent users can view document information, sign eConsent, access Q&A sections, and perform document downloads.*
Electronic Patient Reported Outcomes Management	***ePRO Application****	*Questionnaire Representation - Participant App*	*ePRO users can view questionnaires collect data through ePRO interface.*

**eConsent and ePRO are considered as a part of the Oomnia ecosystem of software. Considering that these systems process non-anonymized participant data, they are available as separate applications, seamlessly connected to the Oomnia CRIS platform.*

2 oomnia EDC and ePRO/eCOA

A detailed specification of all software modules, features and their purpose within the oomnia EDC/ePRO/eCOA solution

Workflows	System Module	Contained Features	Feature Purpose
System and Study Setup Management and Work Administration	***Administration Module***	*User Management*	*Clients can create and manage users and export user data efficiently within the system.*
		Roles and Permission Management	*Clients can create and manage roles, control module access, and set document type permissions based on role*
		Document Type Management	*Clients can create and manage document types used in the system, including EDC documents and read-only document types.*
		Organization Management	*Clients can create and manage organizations involved in the study, such as Sponsors, CROs, Vendors, and other.*
		Language Management	*Clients can create and manage system interface language.*
		System Settings Management	*Clients can configure user security settings and manage email notifications for system events and activities.*
	Trials Module	*In-system Study (Trial) Creation and Management*	*Clients can manage trial protocols, input and organize trial data, oversee trial organization and documents, handle trial environments, manage trial countries, configure randomization and supply settings, receive notifications on key trial events, manage trial laboratories, handle trial queries, generate real-time graphical reports, and perform medical coding.*
EDC Document Creation and Management	***Document Management Module***	*Document Management*	*Clients can manage all trial documents, handle test and production environments, create and manage document types, customize document controls, control document status and settings, set signatures, and export document data dictionaries.*
		Document Designer	*Clients can create EDC documents, design forms, manage chapter, page, field, and group properties, select field types, set field dependencies, perform date/time checks, configure triggers, handle date imputation, apply formulas, perform data calculations, evaluate currency, manage partial dates, and maintain running records.*

Workflows	System Module	Contained Features	Feature Purpose
Data Entry	***Data Capture Module***	*Data Capture Document Overview*	*Clients can manage all trial documents and handle both test and production environments.*
		Data Entry	*Clients can perform data entry on created EDC documents, as well as manage field properties, page user controls, field menus, and access field audit trails.*
		Source Data Verification (SDV)	*Clients can perform SDV on EDC documents in the SDV environment.*
		Queries	*Clients can generate and resolve queries on specific fields, interact with queries through a dedicated interface, and manage query menu controls.*
		MedDRA Coding	*Clients can perform MedDRA coding through a dedicated interface.*
		WHODrug Coding	*Clients can perform WHODrug coding through a dedicated interface.*
	Data Comparison Module	*Double Data Entry Mode and Document Merging*	*Clients can create double document instances, perform double data entry, compare documents, and perform document merge.*
Performance Enhancing Tool	***Study Calendar Module***	*Study Calendar, with task, event, and reminder functions*	*Clients can manage calendar functionalities, set reminders, organize tasks and events, filter calendars, and use a planner for efficient scheduling.*
Data Analysis	***Clinical Table Module***	*Clinical Database Overview and Export*	*Clients can view and filter clinical databases, access clinical database overviews, and export clinical database data.*
Progress Report and Metrics	***Query Management Module***	*Query Management Table*	*Clients can access and manage condensed query information for overview and referral, and filter queries effectively.*
	Study Metrics Module	*Custom Reports*	*Clients can manage reports, filter real-time data reports, access real-time data report overviews, and export real-time data reports.*
		Patient Dashboard	*Clients can oversee study subject-related data entry metrics, such as data completion and specific field related metrics, and export patient dashboard data.*
		Audit Logs	*Clients can view a detailed presentation of all user activities, complete with time and date stamps for accurate tracking and auditing.*
Laboratory Management	***Laboratory Management Module***	*Laboratory Addition and Management*	*Clients can manage centralized laboratory overview tables, customize laboratory table controls, and create local laboratories with defined reference ranges.*

Workflows	System Module	Contained Features	Feature Purpose
Electronic Informed Consent Management	***eConsent Application****	*Admin Application*	*Clients can manage eConsent setup, including trials, organizations, users, roles, participants, quizzes (Q&A), and view audit logs.*
		Participant Application	*eConsent users can view document information, sign eConsent, access Q&A sections, and perform document downloads.*
Electronic Patient Reported Outcomes Management	***ePRO Application****	*Questionnaire Representation - Participant App*	*ePRO users can view questionnaires collect data through ePRO interface.*

**eConsent and ePRO are considered as a part of the Oomnia ecosystem of software. Considering that these systems process non-anonymized participant data, they are available as separate applications, seamlessly connected to the Oomnia CRIS platform.*

3 oomnia EDC and RTSM

A detailed specification of all software modules, features and their purpose within the Oomnia EDC/RTSM solution.

Workflows	System Module	Contained Features	Feature Purpose
System and Study Setup Management and Work Administration	***Administration Module***	*User Management*	*Clients can create and manage users and export user data efficiently within the system.*
		Roles and Permission Management	*Clients can create and manage roles, control module access, and set document type permissions based on role*
		Document Type Management	*Clients can create and manage document types used in the system, including EDC documents and read-only document types.*
		Organization Management	*Clients can create and manage organizations involved in the study, such as Sponsors, CROs, Vendors, and other.*
		Language Management	*Clients can create and manage system interface language.*
		System Settings Management	*Clients can configure user security settings and manage email notifications for system events and activities.*
	Trials Module	*In-system Study (Trial) Creation and Management*	*Clients can manage trial protocols, input and organize trial data, oversee trial organization and documents, handle trial environments, manage trial countries, configure randomization and supply settings, receive notifications on key trial events, manage trial laboratories, handle trial queries, generate real-time graphical reports, and perform medical coding.*
EDC Document Creation and Management	***Document Management Module***	*Document Management*	*Clients can manage all trial documents, handle test and production environments, create and manage document types, customize document controls, control document status and settings, set signatures, and export document data dictionaries.*
		Document Designer	*Clients can create EDC documents, design forms, manage chapter, page, field, and group properties, select field types, set field dependencies, perform date/time checks, configure triggers, handle date imputation, apply formulas, perform data calculations, evaluate currency, manage partial dates, and maintain running records.*

Workflows	System Module	Contained Features	Feature Purpose
Data Entry	***Data Capture Module***	*Data Capture Document Overview*	*Clients can manage all trial documents and handle both test and production environments.*
		Data Entry	*Clients can perform data entry on created EDC documents, as well as manage field properties, page user controls, field menus, and access field audit trails.*
		Source Data Verification (SDV)	*Clients can perform SDV on EDC documents in the SDV environment.*
		Queries	*Clients can generate and resolve queries on specific fields, interact with queries through a dedicated interface, and manage query menu controls.*
		MedDRA Coding	*Clients can perform MedDRA coding through a dedicated interface.*
		WHODrug Coding	*Clients can perform WHODrug coding through a dedicated interface.*
	Data Comparison Module	*Double Data Entry Mode and Document Merging*	*Clients can create double document instances, perform double data entry, compare documents, and perform document merge.*
Performance Enhancing Tool	***Study Calendar Module***	*Study Calendar, with task, event, and reminder functions*	*Clients can manage calendar functionalities, set reminders, organize tasks and events, filter calendars, and use a planner for efficient scheduling.*
Data Analysis	***Clinical Table Module***	*Clinical Database Overview and Export*	*Clients can view and filter clinical databases, access clinical database overviews, and export clinical database data.*
Progress Report and Metrics	***Query Management Module***	*Query Management Table*	*Clients can access and manage condensed query information for overview and referral, and filter queries effectively.*
	Study Metrics Module	*Custom Reports*	*Clients can manage reports, filter real-time data reports, access real-time data report overviews, and export real-time data reports.*
		Patient Dashboard	*Clients can oversee study subject-related data entry metrics, such as data completion and specific field related metrics, and export patient dashboard data.*
		Audit Logs	*Clients can view a detailed presentation of all user activities, complete with time and date stamps for accurate tracking and auditing.*
Randomization and Trial Supply Management	***RTSM Module***	*Send Shipment*	*Clients can create shipments with built-in temperature controls, customize shipment controls, and export sent shipment data.*

Workflows	System Module	Contained Features	Feature Purpose
		Receive Shipment	*Clients can receive IMP shipments, control shipment receipt with automatic quarantine features, customize shipment receipt controls, and export shipment data.*
		Unblind Subject Menu	*Clients can access an emergency unblinding interface to quickly and securely unblind trial data when necessary.*
		Randomization list upload	*Clients can manage randomization list tables, upload randomization lists, and export randomization lists efficiently.*
		Randomization	*Clients can view real-time randomization status and export randomization status data.*
		Unblinded Randomization	*Clients can view real-time unblinded randomization status and export unblinded randomization status data.*
		Manage IMP Kits	*Clients can manage IMP kit tables and allocations, upload kit lists, and export kit lists efficiently.*
Laboratory Management	***Laboratory Management Module***	*Laboratory Addition and Management*	*Clients can manage centralized laboratory overview tables, customize laboratory table controls, and create local laboratories with defined reference ranges.*

4 eTMF oomnia

A detailed specification of all software modules, features and their purpose within the oomnia eTMF solution.

Workflows	System Module	Contained Features	Feature Purpose
System and Study Setup Management and Work Administration	***Administration Module***	*User Management*	*Clients can create and manage users and export user data efficiently within the system.*
		Roles and Permission Management	*Clients can create and manage roles, control module access, and set document type permissions based on role*
		Document Type Management	*Clients can create and manage document types used in the system, including EDC documents and read-only document types.*
		Organization Management	*Clients can create and manage organizations involved in the study, such as Sponsors, CROs, Vendors, and other.*
		Language Management	*Clients can create and manage system interface language.*
		System Settings Management	*Clients can configure user security settings and manage email notifications for system events and activities.*
	Trials Module	*In-system Study (Trial) Creation and Management*	*Clients can manage trial protocols, input and organize trial data, oversee trial organization and documents, handle trial environments, manage trial countries, configure randomization and supply settings, receive notifications on key trial events, manage trial laboratories, handle trial queries, generate real-time graphical reports, and perform medical coding.*
Performance Enhancing Tool	***Study Calendar Module***	*Study Calendar, with task, event, and reminder functions*	*Clients can manage calendar functionalities, set reminders, organize tasks and events, filter calendars, and use a planner for efficient scheduling.*
Progress Report and Metrics	***Study Metrics Module***	*Custom Reports*	*Clients can manage reports, filter real-time data reports, access real-time data report overviews, and export real-time data reports.*
		Audit Logs	*Clients can view a detailed presentation of all user activities, complete with time and date stamps for accurate tracking and auditing.*
eTMF Management	***eTMF Module***	*eTMF Management*	*Clients can manage multiple trial eTMFs and handle both test and production environments efficiently.*
		eTMF Creation	*Clients can design trial-specific eTMF hierarchies, manage root, zone, section, artifact, sub-artifact, and ad hoc sub-*

Workflows	System Module	Contained Features	Feature Purpose
			artifact controls, and handle templates, blueprints, and placeholders effectively.
		eTMF Document Management	*Clients can manage document uploads and downloads, control document versioning, handle document approvals, and lock documents to ensure security and integrity.*
		eTMF Export	*Clients can manage and export eTMF structures and documents, as well as control document history.*
		eTMF Query Process Management	*Clients can raise, update, and resolve queries at various levels, including artifacts, templates, blueprints, placeholders, sub-artifacts, and ad hoc sub-artifacts.*

5 oomnia EDC and CTMS

A detailed specification of all software modules required for deployment of Oomnia EDC/CTMS solution

Workflows	System Module	Contained Features	Feature Purpose
System and Study Setup Management and Work Administration	***Administration Module***	*User Management*	*Clients can create and manage users and export user data efficiently within the system.*
		Roles and Permission Management	*Clients can create and manage roles, control module access, and set document type permissions based on role*
		Document Type Management	*Clients can create and manage document types used in the system, including EDC documents and read-only document types.*
		Organization Management	*Clients can create and manage organizations involved in the study, such as Sponsors, CROs, Vendors, and other.*
		Language Management	*Clients can create and manage system interface language.*
		System Settings Management	*Clients can configure user security settings and manage email notifications for system events and activities.*
	Trials Module	*In-system Study (Trial) Creation and Management*	*Clients can manage trial protocols, input and organize trial data, oversee trial organization and documents, handle trial environments, manage trial countries, configure randomization and supply settings, receive notifications on key trial events, manage trial laboratories, handle trial queries, generate real-time graphical reports, and perform medical coding.*
EDC Document Creation and Management	***Document Management Module***	*Document Management*	*Clients can manage all trial documents, handle test and production environments, create and manage document types, customize document controls, control document status and settings, set signatures, and export document data dictionaries.*
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Workflows	System Module	Contained Features	Feature Purpose
Data Entry	***Data Capture Module***	*Data Capture Document Overview*	*Clients can manage all trial documents and handle both test and production environments.*
		Data Entry	*Clients can perform data entry on created EDC documents, as well as manage field properties, page user controls, field menus, and access field audit trails.*
		Source Data Verification (SDV)	*Clients can perform SDV on EDC documents in the SDV environment.*
		Queries	*Clients can generate and resolve queries on specific fields, interact with queries through a dedicated interface, and manage query menu controls.*
		MedDRA Coding	*Clients can perform MedDRA coding through a dedicated interface.*
		WHODrug Coding	*Clients can perform WHODrug coding through a dedicated interface.*
	Data Comparison Module	*Double Data Entry Mode and Document Merging*	*Clients can create double document instances, perform double data entry, compare documents, and perform document merge.*
Performance Enhancing Tool	***Study Calendar Module***	*Study Calendar, with task, event, and reminder functions*	*Clients can manage calendar functionalities, set reminders, organize tasks and events, filter calendars, and use a planner for efficient scheduling.*
Data Analysis	***Clinical Table Module***	*Clinical Database Overview and Export*	*Clients can view and filter clinical databases, access clinical database overviews, and export clinical database data.*
Progress Report and Metrics	***Query Management Module***	*Query Management Table*	*Clients can access and manage condensed query information for overview and referral, and filter queries effectively.*
	Study Metrics Module	*Custom Reports*	*Clients can manage reports, filter real-time data reports, access real-time data report overviews, and export real-time data reports.*
		Patient Dashboard	*Clients can oversee study subject-related data entry metrics, such as data completion and specific field related metrics, and export patient dashboard data.*
		Audit Logs	*Clients can view a detailed presentation of all user activities, complete with time and date stamps for accurate tracking and auditing.*
Laboratory Management	***Laboratory Management Module***	*Laboratory Addition and Management*	*Clients can manage centralized laboratory overview tables, customize laboratory table controls, and create local laboratories with defined reference ranges.*

Workflows	System Module	Contained Features	Feature Purpose
Clinical Trial Management	***CTMS Module***	*General Information Overview*	*Clients can track key milestone and enrolment dates, monitor recruitment information, oversee essential documentation progress, and identify risk indicators.*
		Study Team Management	*Clients can manage and track both active and inactive members.*
		Milestone and Enrollment Tracking	*Clients can track key milestone and enrolment dates, as well as monitor recruitment information.*
		Start Up Documentation	*Clients can oversee essential documentation, manage the training matrix and log, and maintain the delegation log.*
		Monitoring	*Clients can review monitoring visit reports and manage action item logs.*
		Subjects	*Clients can manage the list of participants, track recruitment sources, and maintain the participant tracking log.*
		Management of AEs and PDs	*Clients can manage lists of adverse events and serious adverse events, track protocol deviations, and conduct protocol deviations analysis.*

Software System Requirements

Technical Requirements

The successful use of oomnia EDC/CTMS does not require intensive investment in technology resources.

The oomnia use framework allows the user to use the system in relatively “light” and “adaptive” software and hardware infrastructure.

Hardware Requirements

Hardware	Minimum Requirements
CPU (processor speed)	Intel or AMD processor with 2.8 GHz or faster
System memory (RAM)	4 GB of RAM
Internet connectivity	Minimal speed 1 Mbps (125 KB/s)

Other hardware features, such as minimum GPU or video memory, computer monitor, available ports (USB, Ethernet, etc), audio hardware (sound card, speakers, etc), and HDD storage space are not considered as a prerequisite for 0omnia operations and shall be regarded as optional.

Software Requirements

oomnia works in any operating system and the user computer or operating device needs to have installed web browser versions that are GDPR-compliant, and support data security and privacy.

Software	Software Name	Version
Operating System (laptop or desktop)	Microsoft Windows©	Windows 10 or newer version. Supports the functions of the recommended browser, or the later browser version.
	Linux ©	Supports the functions of the recommended browser, or the later browser version.

Operating System (smartphone)	Mac OS©	Supports the functions of the recommended browser, or the later browser version.
	Android OS©	Supports the functions of the recommended browser, or the later browser version.
	IOS©	Supports the functions of the recommended browser, or the later browser version.
Internet Browser*	Google Chrome©	Version 115, released on July 18, 2023, or a later version
	Firefox Browser©	Version 115, released on July 04, 2023, or a later version
	Microsoft Edge ©	Version 115, released on July 21, 2023, or a later version
	Safari©	Safari version 16, released on September 12, 2022, or later version
	Other Browsers	The latest stable version for optimal security and performance