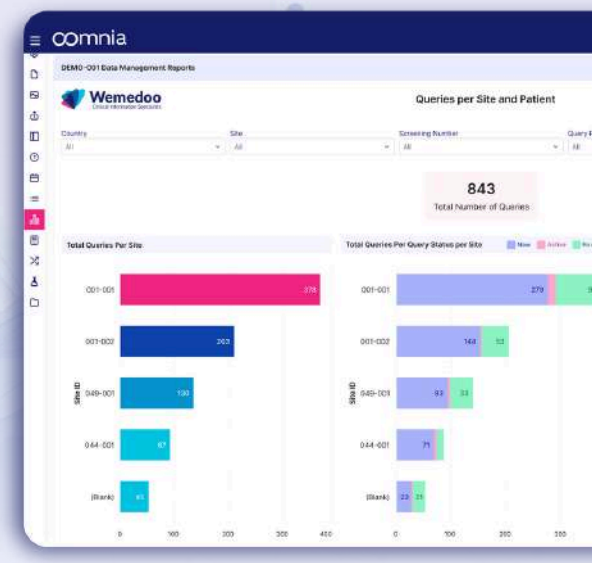
Unified clinical trial software for rare and orphan disease studies

One platform. Trusted data. Designed for rare complexity.



oomnia supports rare and orphan disease research within a unified Clinical Research Information System (CRIS), allowing teams to coordinate globally dispersed studies, manage evolving protocols, and generate reliable, traceable evidence from limited patient populations

The operational reality of rare and orphan disease trials

Small, dispersed patient populations

Rare disease studies rely on very limited patient cohorts, often spread across countries and specialized centers

Limited clinical knowledge and evolving evidence

Many rare conditions lack established histories or validated endpoints, so studies often need to adapt protocols, cohorts, and measures

Diverse and longitudinal data requirements

Trials frequently combine clinical outcomes, patient reported data, registries, biomarkers, and long-term follow-up

High dependency on precision and coordination

With each patient representing a significant portion of the data, errors, inconsistencies, or delays can have a disproportionate impact

Regulatory and ethical complexity

Strict requirements and ethical constraints can complicate study design and execution

One connected system for rare disease trial execution

Brings clinical, operational, and patient level data into a single structured environment

Adapts quickly to protocol changes driven by emerging evidence or regulatory input

Provides continuous visibility into patient progression and study status across long timelines

Replaces disconnected systems with a single workflow spanning sites, vendors, and sponsors

One platform for rare and orphan disease trial execution

Rare disease workflows, unified from day one

oomnia consolidates clinical and operational processes into one cohesive system, ensuring that all study data, from initial enrollment to long-term follow-up, remains consistent, accessible, and traceable across stakeholders

EDC

Captures precise patient level data across clinical outcomes, biomarkers, and long-term follow-up, with validation controls to maintain accuracy in small cohorts

CTMS

Tracks study progress, site activity, and operational status across globally distributed rare disease programs

RTSM

Supports flexible allocation strategies suitable for small populations and evolving cohort structures

eConsent

Facilitates remote and on-site consent, including updates when protocols change or new patient groups are introduced

eCOA / ePRO

Collects disease specific symptoms, functional outcomes, and quality of life data directly from patients over extended follow-up periods

eTMF

Ensures all documentation remains complete, organized, and inspection ready throughout adaptive and long-running studies

Patient engagement tools

Supports sustained participation through reminders and communication tailored to long study durations and dispersed populations

Analytics and reporting

Combines clinical, safety, and patient reported data into real-time views, enabling ongoing evaluation and evidence generation

EDC: Electronic Data Capture; CTMS: Clinical Trial Management System; RTSM: Randomization and Trial Supply Management; eConsent: Electronic Informed Consent; eCOA/ePRO: Electronic Clinical Outcome Assessment / Electronic Patient-Reported Outcome; eTMF: Electronic Trial Master File.

How oomnia fits into the rare disease study ecosystem

oomnia provides a unified foundation that links specialist sites, laboratories, diagnostic providers, and sponsor systems, enabling structured collaboration across every stage of a rare or orphan disease trial

Built for regulatory and operational confidence

- 21 CFR Part 11–compliant data records with full traceability and secure electronic signatures
- Risk based quality management aligned with ICH E6(R3) practices
- Standardized data structures supporting CDISC-aligned reporting
- Designed for global studies and regulatory interactions, including orphan submissions and post approval evidence collection

Measurable impact for rare and orphan disease teams

Maximized value from limited patient data

Every data point is captured, validated, and connected, supporting robust analysis despite small sample sizes

Clear visibility across long-term studies

Unified dashboards provide a complete view of patient progression, safety, and study performance over time

Reduced operational complexity

A single platform simplifies coordination across dispersed sites, vendors, and stakeholders

Improved data integrity and traceability

Consistent data capture and validation ensure reliability across extended timelines and evolving study designs

ICH E6(R3): International Council for Harmonisation Guideline for Good Clinical Practice (Revision 3); CDISC: Clinical Data Interchange Standards Consortium; 21 CFR Part 11: Title 21 Code of Federal Regulations Part 11 (Electronic Records and Electronic Signatures).

Explore how oomnia supports rare and orphan disease trials

Request a demo

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