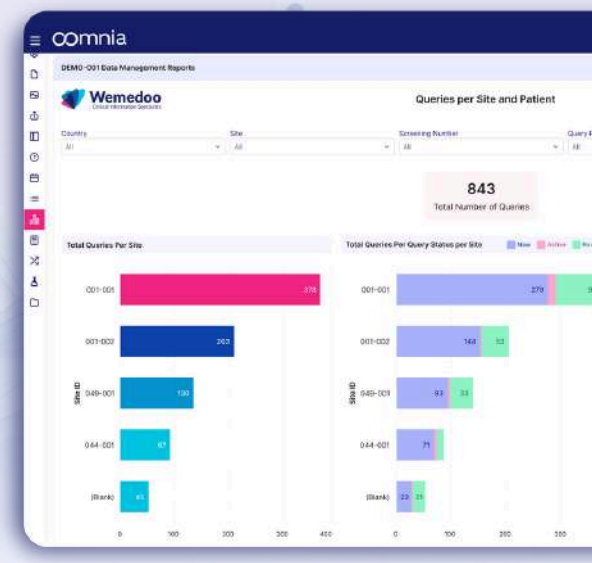
Unified clinical trial software for CVRM studies

One platform. Connected data. Built for long-term outcomes.



oomnia brings Cardiovascular, Renal, and Metabolic (CVRM) trials into a single Clinical Research Information System (CRIS), helping teams run large, data intensive studies with greater coordination, cleaner data, and clearer oversight across the full study lifecycle

The operational reality of CVRM trials

Chronic disease timelines and outcome driven designs

CVRM studies often span multiple years and depend on event based endpoints

Broad, heterogeneous patient populations

Participants frequently present with overlapping cardiovascular, renal, and metabolic conditions, creating complex eligibility criteria

Data volume from multiple clinical domains

CVRM trials rely on a continuous flow of clinical measurements, laboratory results, imaging, and device generated data

Distributed sites and sustained site workload

Large enrollment numbers and geographically dispersed sites place heavy demands on coordinators, particularly when workflows are fragmented

Endpoint adjudication and consistency

Event validation across sites requires rigorous adjudication to ensure consistent and reliable outcome assessment

One connected system for CVRM trial execution

Unifies clinical visits, lab results, imaging, safety data, and real-world inputs into a single dataset

Enables configuration driven updates to adapt to protocol changes, endpoint refinements, or regulatory requirements

Tracks complex endpoints such as MACE, hospitalizations, renal decline, and metabolic progression

Replaces fragmented systems, labs, imaging vendors, and digital health providers with one coordinated environment

CVRM: Cardiovascular, Renal, and Metabolic; MACE: Major Adverse Cardiovascular Events

One platform for CVRM trial execution

CVRM trial workflows, unified from day one

oomnia replaces layered integrations with a single unified infrastructure. Once data is captured, it is immediately available across the study, without duplication or downstream reconciliation

EDC

Supports high-volume CVRM data capture across repeated visits, lab results, imaging, and outcomes, designed for long-term studies and chronic disease follow-up

CTMS

Provides real-time visibility into enrollment, visit adherence, site performance, and milestones across large, distributed CVRM programs

RTSM

Enables stratified randomization by risk factors or biomarkers and supports supply planning for variable visits, extended treatments, and changing patient needs

eConsent

Manages consent and re-consent workflows for protocol changes, imaging, lab tests, and biomarker or genetic analysis

eCOA / ePRO

Captures symptoms, quality of life, and functional outcomes, integrating patient reported and device generated data

eTMF

Maintains inspection ready documentation across long CVRM trials, including safety, monitoring, endpoints, and amendments

Patient engagement tools

Support long-term retention via reminders, remote data capture, and structured communication

Analytics and reporting

Combines clinical events, lab trends, imaging, and real-world data to support analysis, safety monitoring, and endpoint evaluation

CVRM: Cardiovascular, Renal, and Metabolic; 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 CVRM study ecosystem

oomnia acts as the central hub connecting CVRM trial stakeholders and systems, including clinical sites, laboratories, imaging providers, digital health tools, safety platforms, and sponsor analytics. This connected environment enables continuous oversight of CVRM outcomes while supporting timely, data-driven decisions

Built for regulatory and operational confidence

- 21 CFR Part 11–compliant records with secure signatures and full audit trails
- Risk based quality management aligned with ICH E6(R3)
- CDISC-aligned data structures with submission ready outputs
- Designed for multinational CVRM studies and global regulatory review

Measurable impact for CVRM teams

Clearer oversight across long duration studies

Unified dashboards improve visibility into patient outcomes, safety events, and site execution over time

Stronger data quality across endpoints

Integrated capture and validation reduce discrepancies between clinical, lab, imaging, and real-world data

Reduced site burden

A single system replaces multiple tools, simplifying workflows for sites managing high enrollment and frequent follow-up

Ready for change

Protocol updates, endpoint refinements, and evolving guidelines are handled through configuration, without disrupting ongoing trials

CVRM: Cardiovascular, Renal, and Metabolic; 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 CVRM trials

Request a demo

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