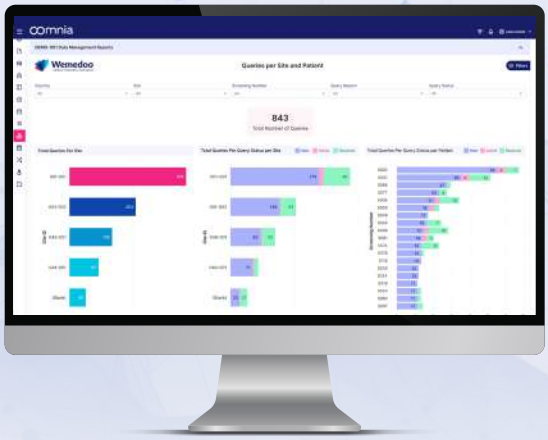
oomnia

# Unified clinical operations for complex oncology trials

One system. One database. Eight unified modules.



oomnia is Wemedoo's unified clinical research information system designed to support adaptive, data-intensive oncology protocols for biotech and mid-market pharma sponsors, improving execution speed and data quality across global studies.

## The oncology trial complexity challenge

### Frequent protocol changes driven by complex study designs

Multi-arm, adaptive, and biomarker-driven oncology protocols result in amendments in more than 90% of studies, each adding significant cost and time to execution[1]

### Heavy and fragmented data burden

Phase II oncology trials generate substantially more data than non-oncology studies, often forcing sites into manual data reconciliation and re-entry across disconnected systems[2]

### Tight timelines in competitive indications

Delays from protocol changes, reconciliation, and data cleaning directly impact timelines to FPI and database lock

### Global, multi-center operational complexity

Oncology studies span regions with varying site maturity and technology readiness, increasing execution risk

### Balancing site burden with data quality and compliance

High query volumes and duplicate workflows strain sites while sponsors remain accountable for inspection-ready data

## Why oncology teams choose oomnia

- Designed specifically for adaptive, biomarker-driven oncology research
- Configuration replaces redevelopment when protocols evolve
- Built on a single relational architecture rather than layered integrations
- Reduces operational friction for sites, sponsors, and CROs

FPI: First Patient In; CROs: Contract Research Organizations

# One solution for oncology execution

## All trial activities, aligned from the start

**oomnia unifies eight traditionally separate systems into one clinical trial infrastructure.** Information entered once becomes immediately available across the entire environment without interface reconciliation or duplicated workflows.

### EDC

Supports complex oncology schemas, multi-arm designs, and protocol amendments with minimal disruption during study execution

### CTMS

Provides real-time visibility into enrollment, milestones, and site performance across global, multi-center oncology studies

### RTSM

Enables adaptive and biomarker-driven randomization while supporting predictive drug supply planning for oncology programs

### eConsent

Handles complex consent scenarios, including re-consent for new cohorts, protocol changes, and genetic or biomarker testing

### eCOA / ePRO

Captures symptoms of burden, adverse events, and quality-of-life data in oncology patients with flexible visit windows and remote entry

### eTMF

Maintains inspection-ready documentation aligned with oncology protocols, amendments, and evolving regulatory requirement

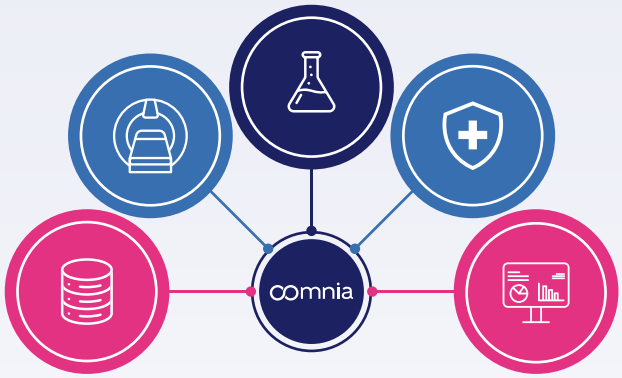
### Patient portals / Engagement tools

Supports long-term follow-up and remote patient interaction, reducing site burden in extended oncology trials

### Analytics & reporting

Aggregates clinical, imaging, laboratory, and biomarker data to support interim analyses, safety review, and sponsor decision-making

## How oomnia fits in the oncology sponsor ecosystem




oomnia acts as a central clinical data hub between site EHRs, laboratories, imaging vendors, safety systems, and sponsor analytics. In oncology trials, imaging data flows from central reading centers through oomnia into analytics, while laboratory and biomarker data feed safety oversight and clinical decision-making.

**This unified data flow enables real-time monitoring and faster, insight-driven decisions.**

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

# Measurable operational outcomes

| Challenge area | Legacy performance | oomnia result |
|---|---|---|
| Protocol amendment costs | Up to $535K[3] | Configuration changes in hours |
| Drug supply overage | 200–300% typical[4] | Reduced to 30–50% |
| Database lock delays | 50% from non-CRF data reconciliation[5] | Removed by design |
| Query management | ~96,980 per Phase III[4] | Real-time edit checks prevent errors at entry |
| Site workload | 98 %Manual re-entry across systems[6] | Single interface, single sign-on |

# Regulatory & data ecosystem readiness

- 21 CFR Part 11 compliant, including audit trails and electronic signatures
- ICH E6(R3) Risk-Based Quality Management embedded into workflows
- CDISC-aligned data structure (CDASH during collection, SDTM-ready outputs)
- Supports submissions to FDA, EMA, and global regulatory authorities

# Measurable operational outcomes

**Faster study execution**

Accelerates start-up, supports faster FPI, and reduces delays to database lock

**Higher data quality by design**

Structured capture and built-in validation reduce errors, queries, and rework

**Lower site burden**

A single interface replaces multiple systems, minimizing duplicate entry

**Built for oncology complexity and change**

Supports multi-arm, adaptive, biomarker-driven protocols, with mid-study updates managed through configuration, not rebuilds

CRF: Case Report Form; CFR: Code of Federal Regulations; CDISC: Clinical Data Interchange Standards Consortium; CDASH: Clinical Data Acquisition Standards Harmonization; SDTM: Study Data Tabulation Model; ICH E6(R3): International Council for Harmonisation Good Clinical Practice guideline; RBQM: Risk-Based Quality Management; FDA: Food and Drug Administration; EMA: European Medicines Agency; FPI: First Patient In


**References:**

[1] Botto, E., Smith, Z., & Getz, K. (2024). New Benchmarks on Protocol Amendment Experience in Oncology Clinical Trials. Therapeutic Innovation & Regulatory Science, 58, 645–654.
[2] CenterWatch. (2025). Emerging challenges in oncology trials (Updated October 29, 2025; originally published June 22, 2021). CenterWatch Insights.
[3] Industry benchmarking based on aggregated sponsor-reported data.
[4] Customer-reported operational benchmark
[5] Indani, A., Sharma, S., Bote, S., et al. (2021, July 20). Establishing metrics and standardization for non-CRF data in EDC. Applied Clinical Trials.
[6] Stokman, P. G., Ensign, L., Langeneckhardt, D., Mörsch, M., Nuyens, K., Herrera, D., Hochgräber, G., Cassan, V., Beineke, P., Kwock, R., Voortman, A., Vogelgesang, S., Boussetta, S., & Bitzer, B. (2021). Risk-based Quality Management in CDM: An inquiry into the value of generalized query-based data cleaning. Journal of the Society for Clinical Data Management, 1(1).


Explore how **oomnia** supports modern oncology research

**Request a demo**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