



Unified clinical trial software for immunology and inflammatory disease studies

One platform. Unified data. Built for complexity.

omnia brings immunology and inflammatory disease trials into a unified Clinical Research Information System (CRIS), enabling teams to manage variable immune responses, complex biomarkers, and multi-endpoint designs with coordinated execution and continuous visibility across the full study lifecycle



The operational reality of immunology and inflammatory disease trials

Variable disease activity and unpredictable patient response

Immune-mediated conditions often follow fluctuating patterns, including flare cycles and remission periods.

Complex biomarker and diagnostic landscapes

Immunology trials rely on diverse datasets including immune biomarkers, serology, imaging, and functional assessments.

Multi-endpoint and longitudinal study designs

Studies frequently assess multiple endpoints across extended periods, requiring precise coordination of visits, assessments, and follow-ups

High operational and coordination burden

Diverse patient phenotypes, specialized testing, and global site networks increase the complexity of study execution

Recruitment, retention, and adherence challenges

Strict eligibility, variable disease activity, and long study durations make it difficult to enroll and retain patients

One connected system for immunology and inflammatory disease trial execution



Brings together clinical data, biomarker results, imaging outputs, and operational workflows into a single, synchronized dataset



Enables real-time tracking of immune response, disease activity, and treatment outcomes across patient populations



Supports rapid protocol adjustments driven by flare patterns, biomarker findings, or evolving study designs



Eliminates fragmentation between sites, laboratories, and vendors by replacing multiple tools with one coordinated environment

One platform for immunology trial execution

Immunology workflows, streamlined from the outset

oomnia replaces fragmented system landscapes with a unified infrastructure where clinical, biomarker, imaging, and operational data are continuously aligned and accessible across study teams

EDC

Captures high-volume immunology data including biomarkers, symptoms, disease activity scores, imaging inputs, and safety events, with real-time validation across diverse datasets

CTMS

Provides real-time visibility into study progress, site performance, and operational readiness across global immunology programs

RTSM

Supports adaptive randomization based on biomarkers, immune-response subgroups, or disease severity, with flexibility for evolving study designs

eConsent

Enables flexible consent processes, including remote onboarding and re-consent as protocols evolve or new cohorts are introduced

eCOA / ePRO

Captures patient-reported symptoms, flare activity, and quality-of-life data to monitor disease progression in real time

eTMF

Maintains inspection-ready documentation across complex, adaptive studies, including biomarker-driven amendments and evolving trial protocols

Patient engagement tools

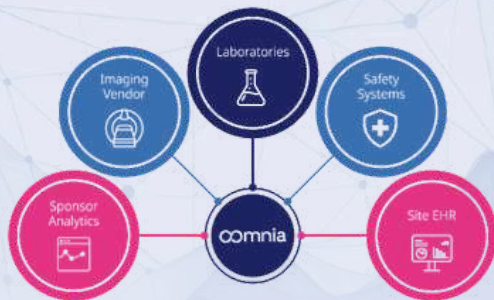
Supports ongoing monitoring, adherence, and long-term follow-up through automated communication and reminders tailored to variable disease activity

Analytics and reporting

Integrates clinical, biomarker, imaging, and real-world data into real-time dashboards for informed decision-making, safety monitoring, and interim analysis

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 immunology study ecosystem



oomnia serves as a central coordination layer connecting clinical sites, specialty laboratories, imaging vendors, and digital health tools. It creates a unified environment for managing complex, biomarker-driven and globally distributed immunology trials.

Built for regulatory and operational confidence



21 CFR Part 11-compliant records with complete audit trails and secure electronic signatures



Risk-based quality management aligned with ICH E6(R3) principles



CDISC-aligned datasets supporting standardized reporting across immunology studies



Designed for global deployment and regulatory submissions to international health authorities

Measurable impact for immunology and inflammatory disease teams

Improved management of disease variability

Centralized data and configurable workflows enable consistent tracking of flare cycles, immune response, and long-term disease progression

Greater visibility across complex datasets

Unified dashboards combine biomarker, clinical, and imaging data for a complete view of patient status and study performance

Reduced operational complexity

A single platform replaces fragmented tools, simplifying coordination across sites, labs, and vendors

Stronger data quality across multi-source inputs

Real-time validation and unified data models reduce discrepancies and ensure consistency across biomarker-rich studies

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 immunology trials

[Request a demo](#)

