

Corsano CardioWatch 287 System

Continuous Vital Signs Monitoring for Pharmaceutical Clinical Trials

Phase 1 · Phase 2 · Phase 3 · Phase 4 / Post-Market

Why Corsano for Pharmaceutical Clinical Trials

Drug development demands continuous, objective, and reliable physiological data throughout the trial lifecycle. Traditional approaches rely on episodic, site-based measurements that capture only snapshots of a patient's condition, missing critical inter-visit events and limiting the resolution of safety and efficacy assessments. As regulatory agencies increasingly endorse digital endpoints and wearable-derived biomarkers, pharmaceutical sponsors need a monitoring platform that is medically certified, clinically validated, and practical for real-world, multi-site deployment.

Corsano's CardioWatch 287 System addresses this need directly. It is a wrist-worn, medical-grade, multi-parameter monitoring system — CE-MDR certified (Class IIa) and FDA 510(k) cleared — that enables continuous, 24/7 collection of vital signs and raw sensor data in ambulatory, in-clinic, and home-based settings. The system has been deployed in over 200 clinical studies across cardiovascular, oncology, immunology, and stress-related therapeutic areas, making it one of the most extensively validated wearable platforms in pharmaceutical research.

Monitored Parameters

The CardioWatch 287 captures a comprehensive set of clinically relevant parameters from a single, lightweight (~15g) wrist-worn device, eliminating the need for multiple sensors, patches, or body-worn devices that increase participant burden and reduce compliance.

Continuously monitored parameters:

Heart rate (PPG and ECG derived), heart rate variability (RR intervals), respiratory rate (breaths per minute), peripheral oxygen saturation (SpO₂), cuffless non-invasive blood pressure (cNIBP), core body temperature (CBT), activity levels (steps, cadence, motion classification), sleep staging and duration, and galvanic skin response (GSR/EDA) for stress and autonomic assessment.

On-demand and supplementary parameters:

Single-lead ECG for arrhythmia confirmation, atrial fibrillation detection with AFib burden quantification, and non-invasive cuffless blood pressure. The system captures up to 19 vital parameters, configurable per study protocol.

Raw sensor data: Accelerometer (XYZ), PPG (Green, Red, Infrared channels), and ECG waveforms are available at sampling rates up to 128 Hz, enabling sponsors and research partners to develop proprietary algorithms and novel digital biomarkers from IP-free raw data.

Value Across Clinical Trial Phases

Phase 1: First-in-Human and Early Safety

Phase 1 trials require intensive safety monitoring of healthy volunteers or small patient cohorts during first-in-human dosing, dose escalation, and pharmacokinetic/pharmacodynamic studies. Conventional monitoring relies on periodic vital sign checks and scheduled ECGs, leaving gaps where drug-induced cardiac, respiratory, or autonomic effects may go undetected.



Corsano enables:

Continuous cardiac safety surveillance. Real-time heart rate, heart rate variability, and on-demand ECG monitoring capture transient arrhythmias, QT-related signals, and heart rate changes associated with drug exposure, including nocturnal events missed by daytime site visits.

Autonomic and physiological profiling. Continuous respiratory rate, SpO₂, cNIBP, temperature, and GSR data provide a comprehensive autonomic profile around dosing events, enabling researchers to characterize drug effects on the cardiovascular and respiratory systems with greater temporal resolution than episodic measurements.

Dose response signal detection. High-frequency, multi-parameter data during dose escalation supports early identification of physiological thresholds and dose-limiting signals, contributing to more informed go/no-go decisions.

Objective sleep and activity assessment. Continuous sleep staging and activity monitoring reveal drug effects on circadian rhythm, sedation, and physical function, parameters increasingly valued by regulators as digital endpoints.

Phase 2: Efficacy Signals and Dose Optimization

Phase 2 trials expand to larger patient populations to evaluate preliminary efficacy, refine dosing, and further characterize safety. This phase is where digital endpoints and wearable-derived biomarkers offer the greatest opportunity to differentiate a drug's profile and inform Phase 3 design.

Corsano enables:

Digital biomarker development. Access to IP-free raw data (PPG, accelerometer, ECG at up to 128 Hz) enables sponsors to develop proprietary digital biomarkers and novel endpoints specific to their therapeutic area. Examples are immune oncology response signatures, frailty indices, or stress-related autonomic markers.

Continuous efficacy measurement. For cardiovascular drugs (antiarrhythmics, anticoagulants, antihypertensives), Corsano enables continuous measurement of treatment effect: AFib burden reduction, heart rate control, blood pressure trends, and respiratory improvement. Corsano provides richer efficacy data than periodic site measurements.

Patient stratification. Continuous multi-parameter data can identify responders versus non-responders earlier in the trial, supporting adaptive trial designs and optimized patient population selection for Phase 3.

Decentralized and hybrid trial support. The wrist-worn form factor, long battery life (7 days), and remote data transmission via smartphone or gateway enable participants to be monitored at home, reducing site visit frequency, expanding recruiting geography, and supporting diversity and inclusion objectives.

Phase 3: Pivotal Trials at Scale

Phase 3 pivotal trials require monitoring at scale across multiple sites and geographies, with regulatory-grade data quality and consistent patient compliance over extended periods. The operational burden of wearable deployment, device logistics, participant onboarding, data quality assurance, and technical support becomes a critical success factor.



Corsano enables:

Scalable pharmacovigilance. Continuous vital sign monitoring across large cohorts enables a shift from retrospective adverse event reporting to proactive, real-time safety surveillance. Drug-induced cardiac effects, respiratory depression, or autonomic disturbances are captured as they occur, supporting faster signal detection and more complete safety databases.

Superior participant compliance. The CardioWatch’s wrist-worn design, lightweight build, IP66 water resistance, and extended battery life are specifically engineered for multi-week continuous wear in real-world conditions. This addresses a well-documented limitation of chest-patch and adhesive-sensor alternatives, which frequently cause skin irritation, discomfort, and declining adherence in longer trials. Corsano’s system has been proven with over 21,000 patients including senior and paediatric populations.

Automated data quality assurance. Incoming data is automatically assessed for quality and plausibility in real time. The Research Portal provides study nurses with workflows to onboard patients, manage the device fleet, and monitor device status, data streams, and compliance metrics reducing manual data processing time and improving data integrity.

Multi-site fleet management. Corsano’s Device Hub enables remote management of circulating devices across sites and geographies. It provides real-time visibility into device assignment, connectivity, firmware status, and data completeness, addressing a key operational gap in multi-centre wearable deployments.

Regulatory-grade data trail. All data is reliably stored with metadata including participant ID, sensor hardware version, sensor settings, and firmware version, supporting audit readiness and regulatory submission requirements. The platform is GDPR and HIPAA compliant with end-to-end encryption.

Phase 4 / Post-Market Surveillance

Post-approval, Corsano supports long-term real-world evidence generation and post-market safety monitoring. The same platform used in registration trials can be deployed for Phase 4 studies, enabling continuity of digital endpoints and longitudinal tracking of treatment effects in broader patient populations under real-world conditions.

Clinical Trial Platform and Integration

Corsano Research Portal

The Corsano Research Portal is purpose-built for clinical trial operations. It connects researchers with participants and provides a centralised interface across web, mobile, and desktop. Key capabilities include: study configuration with flexible parameter settings (vital parameters, sampling frequency, and raw data capture can be configured per study protocol); blinded study support where the clinical trials app allows researchers to retrieve live vital sign data while conducting a blinded study, with participants unable to see their own data; compliance monitoring with real-time dashboards showing device status, data completeness, wearing time, and participant adherence; and automated data quality assessment with plausibility checks on incoming data streams.



Data Integration and API Access

Corsano provides REST API and cloud-to-cloud integration, enabling pharmaceutical sponsors and CROs to connect CardioWatch data directly to their proprietary data platforms, EDC systems, and analytics environments. This supports complex analyses including machine learning, predictive modelling, and digital biomarker development. Raw data exports are available in standard formats for independent analysis.

Branded Applications

Corsano offers development of branded applications for pharmaceutical sponsors, enabling trials to run under the sponsor's own identity. This supports participant engagement features such as reminders, medication tracking, and symptom monitoring, while providing the sponsor with greater control and ownership of the data collected during the study.

Summary: Corsano Value by Trial Phase

Trial Phase	Primary Application	Key Corsano Capabilities
Phase 1	First-in-human safety, dose escalation, PK/PD profiling	Continuous cardiac monitoring, autonomic profiling, sleep/activity assessment, dose response signal detection
Phase 2	Efficacy signals, dose optimization, digital biomarker development	IP-free raw data for biomarker discovery, continuous efficacy measurement (AFib burden, HR control), patient stratification, hybrid/DCT support
Phase 3	Pivotal trials at scale, regulatory submission	Scalable pharmacovigilance, superior long-term compliance, automated data QA, multi-site fleet management, audit-ready data trail
Phase 4	Post-market surveillance, real-world evidence	Longitudinal monitoring, treatment effect tracking, continuity of digital endpoints from registration trials



Why Corsano: Key Differentiators for Pharma

Medical-grade, regulatory-cleared platform. CE-MDR Class IIa certified and FDA 510(k) cleared, with ISO 13485 manufacturing, meeting the regulatory expectations for digital endpoints in submissions to EMA and FDA.

Proven at scale. Validated in over 200 clinical studies, with more than 15,000 devices produced and over 21,000 patients monitored, including senior and paediatric populations.

Wrist-worn compliance advantage. The ~15g, IP66-rated wrist device delivers superior long-term adherence compared to adhesive chest patches, critical for multi-week and multi-month trial protocols.

IP-free raw data access. Sponsors retain full access to high-resolution raw sensor data for proprietary algorithm development and novel digital biomarker discovery, with no IP encumbrance.

Broadest parameter set in a single wearable. Up to 19 vital parameters from one device, reducing participant burden, eliminating multi-device logistics, and providing a unified, time-synchronised dataset.

Configurable per protocol. Vital parameters, sampling frequency, and raw data capture are fully configurable per study through the Research Portal, enabling protocol-specific optimisation.

Blinded study support. Patient-facing app can be configured to display no clinical data, ensuring study blinding while researchers access live data through the Research Portal.

End-to-end data security. GDPR and HIPAA compliant, with end-to-end encryption, best-practice security architecture, and full metadata trail for regulatory audit readiness.

Therapeutic Areas of Current Deployment

Corsano is actively deployed in pharmaceutical and academic clinical trials across the following therapeutic areas: cardiovascular (arrhythmia management, hypertension, heart failure, cardiac arrest detection), immune oncology (treatment response monitoring, toxicity surveillance, CRS, frailty assessment), respiratory and pulmonary medicine, neurology and stress-related disorders, infectious disease, post-surgical recovery, and sepsis detection. The system's multi-parameter capability makes it suitable for any therapeutic area where continuous physiological monitoring adds clinical or regulatory value.

Engagement Model

Corsano works directly with pharmaceutical sponsors and CROs to configure and deploy the CardioWatch 287 System within trial protocols. Engagement options include device supply and fleet management, branded application development, custom parameter and sampling configuration, API integration with sponsor data platforms, data science support for digital biomarker development, and co-development of novel algorithms and features to support specific therapeutic objectives. For research consortia and grant-funded programmes, Corsano participates as a technology partner and co-developer, contributing to successful consortium applications across European and international research frameworks.

