



InoRx Rescue Studies: Frequently Asked Questions

Answers for sponsors and clients evaluating a clinical trial rescue or CRO transition with InoRx. This FAQ is designed to address the most common questions sponsors, clinical operations, regulatory, and quality stakeholders ask when considering whether to switch to InoRx for a rescue engagement.

Section 1: Rescue model and CRO transition

Q. How is InoRx's Rescue Studies service different from simply switching to another CRO?

A. InoRx begins every rescue with a structured, seven-domain diagnostic, the InoRx Rescue Score, rather than a proposal-first transition. The Rescue Score assesses enrollment, site performance, data integrity, regulatory standing, vendor oversight, monitoring, and governance, and returns a 0–100 recoverability read with a Preserve, Fix, or Replace verdict for each domain before any commitment is made. This diagnostic-first approach allows sponsors to protect the value already invested in a study, targeting only the failing components instead of defaulting to a full restart.

Q. Does switching to InoRx mean starting the entire study over?

A. No. InoRx's rescue model is explicitly designed to fix the broken parts of a study rather than forcing a complete restart. The domain-level Preserve, Fix, or Replace verdicts from the Rescue Score identify which sites, data pipelines, vendor relationships, and regulatory filings are sound and should continue, and isolate only the failing components for intervention. For example, in a recent medical device study, InoRx retrained existing site staff and restored data integrity through the sites' existing REDCap system instead of replacing sites outright, enabling the program to reach its 2,000-participant enrollment target without disrupting cohorts already underway.

Q. What happens if InoRx's diagnostic concludes that a study is not recoverable?

A. If the Rescue Score and diagnostic conclude that a study is not recoverable or only partially recoverable, InoRx states this directly in the Recovery Blueprint. Sponsors receive a transparent domain-by-domain view showing where Preserve, Fix, or Replace verdicts apply, along with the evidence behind each recommendation. This fixed-scope, independent diagnostic ensures sponsors receive an honest recoverability assessment rather than a sales-driven push to proceed, so they can choose whether to narrow the rescue scope, re-structure the program, or decide not to transition.



Section 2: Site network and patient access

Q. What clinical site network does InoRx bring to a rescue engagement?

A. InoRx's clinical trial rescue services are anchored in a vetted site network with direct access to the SRM hospital system across India. This network includes more than 3,600 hospital beds, over 500 vetted clinical sites, and approximately 800 clinicians and Principal Investigators, with experience across at least 55 Phase I–IV studies and more than 50 oncology sites. Because this capacity is already established, InoRx can activate sites and patient access quickly to support distressed enrollment curves.

Q. How quickly can InoRx activate sites and start enrolling patients in a rescue study?

A. Activation timelines in an InoRx rescue are measured in days, not months. In a recent BA/BE study where the incumbent CRO had failed to open eight planned sites one month before clinical trial material expiry, InoRx activated four high-performing sites and achieved first patient dosing within two days of activation, ultimately randomizing 80 participants in about 25 days with zero missed pharmacokinetic timepoints. In a separate Phase I rescue driven by a late CDSCO mandate, an ICMR-recognized government site was activated and Ethics Committee approved within two weeks, with 75 volunteers pre-screened during the review period itself so recruitment could begin immediately upon approval.

Q. Can InoRx absorb additional enrollment if other sites continue to underperform mid-rescue?

A. Yes. InoRx's flexible capacity model allows its own network sites to absorb incremental enrollment when other sites underperform or face delays. In the same BA/BE rescue, Ethics Committee delays at three of the four prioritized sites led the sponsor to increase the InoRx–SRM site's enrollment target from 20 to 30 participants. The team absorbed the additional 10 participants without missing a single pharmacokinetic sampling timepoint, protecting the sponsor's overall timeline and demonstrating that rescue commitments remain resilient even when new issues emerge mid-recovery.

Section 3: Quality, regulatory, and compliance

Q. What regulatory and quality credentials does InoRx hold, and how do they protect a sponsor during a rescue?

A. InoRx operates as a CDSCO-registered Contract Research Organization under India's New Drugs and Clinical Trials Rules (NDCTR 2019), and anchors its rescue services in a strong compliance foundation. The SRM network includes an ICMR-recognized Phase I Centre, a NABH-accredited Clinical Trial Research Centre, and a NABL-accredited Biosafety Level 3 (BSL-3) laboratory supporting infectious disease and vaccine trials, including prior COVAXIN early-phase experience. Senior regulatory leadership manages filings and inspection readiness across CDSCO, EMA, and USFDA. Together, these credentials help ensure that



enrollment recovery and operational fixes can withstand regulatory scrutiny rather than creating deferred compliance issues.

Q. How does InoRx handle late or changing regulatory mandates mid-study?

A. Late regulatory mandates, such as CDSCO requirements that a defined percentage of subjects be enrolled at a government-recognized site, are among the most disruptive triggers for a rescue. InoRx mitigates this risk through its connection to an ICMR-recognized Phase I unit within the SRM hospital network, which provides a ready, compliant site option. In one Phase I rescue, InoRx activated and obtained Ethics Committee approval for a government Phase I site within two weeks of a new CDSCO mandate, pre-screening 75 volunteers during review and enabling immediate recruitment upon approval, so the mandate was met and the sponsor's audit cleared with repeat business awarded.

Q. How does InoRx remediate Good Clinical Practice (GCP) and data integrity gaps left by a previous CRO?

A. InoRx begins every rescue involving data or compliance concerns with a comprehensive, documented site inspection led by senior clinical research associates, followed by a structured corrective and preventive action plan. In a recent medical device study rescue, the incumbent CRO had provided no site oversight, staff were off GCP, electronic case report forms contained inaccurate data, and laboratory set-up did not meet Clinical Investigation Plan requirements. InoRx delivered protocol-specific and GCP retraining, restored data integrity through active monitoring and REDCap support, coordinated reliable vendor supply and timely payments, and reset communication between sponsor, site, and CRO, bringing enrollment back to the full 2,000-participant target with accurate, on-time data capture.

Section 4: Therapeutic area expertise

Q. What therapeutic area expertise can InoRx bring to a rescue study?

A. InoRx's therapeutic expertise spans oncology, virology and infectious disease (including vaccines), respiratory and pulmonary disease, cardiovascular indications, and endocrinology, metabolic, and nephrology conditions. Oncology is the most extensively documented, with more than 50 oncology sites in the network and high coverage across major indications such as breast, lung, head and neck, gynecological, gastrointestinal, and hematological cancers. This breadth helps sponsors struggling with oncology enrollment curves access diverse patient populations rapidly during a rescue.



Section 5: Data integrity, monitoring, and operations

Q. How does InoRx maintain continuity of data and oversight throughout a rescue engagement?

A. InoRx maintains continuous oversight across enrollment, data, and monitoring rather than relying on a single handover milestone. During a rescue, the Rescue Score and Recovery Blueprint are tracked live, critical path and enrollment forecasts are re-baselined as the study stabilizes, and governance and escalation are integrated so issues surface directly to the named executive sponsor. This model allows InoRx to add sites, adjust enrollment targets, and remediate data issues mid-recovery without losing control of the overall study trajectory.

Section 6: Engagement process, timelines, and proof

Q. Who leads and stays accountable for a rescue engagement with InoRx?

A. Every InoRx rescue engagement is led by a named senior executive sponsor who remains accountable from diagnosis through delivery, supported by a dedicated Rescue Project Manager and functional leads across clinical operations, regulatory, data, and quality. Decision rights sit at the top: executive leadership makes the recoverability call based on functional experts' assessments and then hands delivery to the Rescue PM. This single-owner model directly addresses a common pain point in distressed studies where accountability is fragmented between the CRO's project manager, the sponsor's clinical operations lead, and site investigators.

Q. How long does it take to get a recoverability decision, and what does the Rescue Score measure?

A. Sponsors typically receive a recoverability decision in under a week from sharing the protocol, enrollment curve, and open issues under a confidentiality agreement. The Rescue Score evaluates the study across seven domains, including regulatory standing, enrollment, site performance, data integrity, monitoring, vendor management, and governance, with each domain assessed by the relevant functional expert. It returns a 0–100 recoverability score and domain-level Preserve, Fix, or Replace verdicts. Once a GO decision is made, InoRx runs contracting, incumbent handover, resourcing, and planning in parallel, enabling a Go/No-Go decision within roughly 48 hours of diagnostic completion and mobilizing the rescue team within about 72 hours.

Q. Is the initial diagnostic confidential, and does it require a long-term commitment?

A. The initial Rescue Score diagnostic is a fixed-scope engagement conducted under a confidentiality agreement, specifically to allow sponsors to evaluate recoverability before committing to a CRO switch. Sponsors share their protocol, enrollment data, and open issues with the InoRx Rescue Studies team, receive a Recovery Blueprint and Rescue Score, and can then decide whether to proceed with a full rescue engagement.



Q. What proof does InoRx have that its rescue approach actually works?

A. InoRx measures rescue engagements against hard delivery outcomes rather than process activity. Three representative examples illustrate the approach: a Phase I rheumatoid arthritis study facing a late CDSCO mandate requiring 50% government-site enrollment, where InoRx activated and obtained Ethics Committee approval for a government site within two weeks and met the mandate on time; a 2,000-participant medical device study with no CRO site oversight and inaccurate eCRF data, where InoRx restored GCP compliance, corrected data, and returned enrollment to the full target; and a BA/BE study in an anemic population where eight planned sites remained unopened close to CTM expiry, in which InoRx dosed the first patient within two days of activation, randomized 80 participants in about 25 days, and completed the study within CTM shelf life with zero missed pharmacokinetic sampling timepoints. These outcomes demonstrate that the rescue model delivers tangible, sponsor-relevant results.

When your study stalls, come home to InoRx. If you have a question not covered here, visit the **InoRx Rescue Studies page** or write to hello@inorx.com to schedule a confidential Rescue Consultation.