



Rescuing a live Phase 2a study through flexible outsourcing

A US clinical-stage biotech returned to ExperTrials when operational and data-transition risks emerged in a live APAC study. ExperTrials responded with rapid assessment, senior fractional leadership and hands-on data-management delivery.

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THE SITUATION

A live study under pressure

The sponsor needed a rapid path to continuity after its delivery model created growing operational and data risks.

- Active Phase 2a study in APAC
- Continuity and data transition at risk
- Budget limited full-service options

2

SPONSOR RETURN

Restore control before change

ExperTrials structured a 3–4 week mobilization around study continuity, data control and quality oversight.

- Protect study and vendor continuity
- Assess EDC and migration feasibility
- Establish governance and escalation

3

EXPERTRIALS MODEL

A targeted team for critical gaps

Fractional leaders and a full data-management team work as one sponsor extension, with scope that scales only when needed.

- Fractional ClinOps and QA leadership
- Full data-management team
- Optional MM, CTMS and eTMF support

THE CASE IN ONE LINE

Rapid assessment, senior oversight and hands-on data-management delivery are combined in one sponsor-led model, avoiding the cost and complexity of a full CRO transfer.



The rescue starts with control over continuity, data and quality

The immediate objective was not to replace every provider. It was to identify where continuity could fail, secure the live data environment and create an accountable structure for rapid decisions.

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STUDY CONTINUITY

Keep the live trial moving

Mobilization had to protect ongoing study conduct while roles, systems and vendor dependencies were being reassessed.

- 3–4 week mobilization window
- Site and vendor continuity
- Minimal uncontrolled downtime

2

DATA CONTROL

Secure the transition pathway

A formal assessment would determine database ownership, EDC options and the safest approach to data migration.

- Transition and due diligence
- EDC and migration feasibility
- UAT, reconciliation and traceability

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QUALITY OVERSIGHT

Rebuild inspection readiness

Quality oversight would connect sponsor decisions, procedures and escalation routes across the changing delivery model.

- Governance and escalation
- SOP adaptation and bridging
- CAPA and inspection readiness

RECOVERY PRIORITY

Continuity comes first: every decision is sequenced to protect participants, data integrity and the sponsor's next clinical milestone.



A modular senior team closes only the critical gaps

ExperTrials combined fractional leadership with hands-on delivery. Each capability can be activated at the level required by the study rather than bundled into a fixed full-service package.

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CLINICAL OPERATIONS

Fractional leadership and oversight

A Fractional Head of Clinical Operations provides senior control without adding a full-time executive role.

- Governance, priorities and escalation
- CRO and vendor oversight
- Timeline, budget and risk control

2

QUALITY & DATA

QA leadership plus a full DM team

Fractional QA oversight is paired with a complete data-management capability for the live transition.

- Transition assessment and SOPs
- Database migration and UAT
- Data cleaning and reconciliation

3

OPTIONAL SCALE-UP

Scale support as the study evolves

The sponsor can add support without redesigning the operating model or committing to unnecessary scope.

- Fractional Medical Monitor
- CTMS and eTMF support
- Additional operational capacity

ONE INTEGRATED MODEL

Senior specialists work as an extension of the sponsor team, within one governance framework and with scope that scales to the actual need.



A 3–4 week mobilization plan turns urgency into control

The planned transition follows three overlapping stages. Sequencing assessment, mobilization and stabilization reduces disruption while preserving sponsor decision-making.

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WEEK 1 | ASSESS

Establish the facts and risks

Begin with focused due diligence across study status, responsibilities, systems, data and vendor dependencies.

- Confirm ownership and sign-offs
- Map gaps, risks and dependencies
- Prioritize immediate decisions

2

WEEKS 1–2 | MOBILIZE

Stand up the rescue model

Define governance, onboard the fractional team and agree the procedural and technical transition pathway.

- Approve RACI and escalation
- Bridge SOPs and reporting
- Select EDC and migration approach

3

WEEKS 2–4 | STABILIZE

Execute under active oversight

Implement the transition with structured testing, reconciliation, reporting and quality review.

- Run UAT and data checks
- Track risks, issues and CAPAs
- Prepare steady-state governance

STATUS: IN PROGRESS

This case study presents the designed rescue approach and recovery objectives. Final outcomes will be added once the transition is complete.