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Clinical Operations

Trial delivery for biotech sponsors, from study set-up to close-out, without the overhead of a full-service CRO.



niche.org.uk

The challenge

Running a trial with a lean team

Early-phase programmes move fast and change often. Sponsors need experienced people on the ground and clear oversight of every vendor, but few biotechs can justify building a full clinical operations department for one or two studies.

01 Tight timelines from final protocol to first patient

02 Limited in-house clinical operations resource

03 Several sites and vendors to coordinate and oversee

04 Inspection readiness and a complete trial master file

Our approach

Experienced people who stay with your study

Our clinical operations team works directly on your programme, from planning to close-out. You deal with the specialists doing the work, not an account manager overseeing a junior team.

- Direct access to senior specialists
- Fast quote turnaround and rapid contracting
- Budget awareness and continuity of support
- Transparent resource utilisation
- Open communication and regulatory compliance

25+
years of experience

~8yr
average client relationship

1998
founded

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What we deliver

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Clinical Project Management

End-to-end project leadership: plans, timelines, budgets and day-to-day coordination of your study.

Study Monitoring and Site Management

Site selection, set-up and monitoring to keep sites performing and data reliable.

Trial Master File and Document Management

An inspection-ready TMF, set up and maintained with every document tracked.

Study Documents

Protocols, consent forms and study plans, written with your regulatory team.

Quality Management Systems

SOPs and quality systems that keep your study inspection ready.

Vendor Oversight

Vendor selection, assessment and oversight, so every partner meets the standard.

How we work

Four clear stages, led by the same senior specialists from start to finish.

01

Plan

Protocol input, budget, timelines and vendor selection agreed with your team.

02

Set up

Sites, approvals, systems and the trial master file ready before first patient.

03

Deliver

Monitoring, site management and regular reporting while the study runs.

04

Close

Close-out, TMF reconciliation and support for the clinical study report.

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One team, not three silos

BioStack™ integrates our three service pillars to deploy Niche resources efficiently and effectively. Your projects can seamlessly access our closely knit team to deliver what your programme needs.

Clinical Operations — This pillar

Regulatory Affairs

Medical Communications

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BioStack™

A smarter way to structure CRO support.

- Modular by design
- Integrated expertise
- Faster execution
- Cost efficiency

Work that speaks for itself

+30 See more case studies →

Clinical Operations · Phase I/II

Pulmocide

Study monitoring, CTA applications, protocols, IBs and study reports for an early-stage company expediting its path to acquisition.

> *Niche work flexibly, are responsive and always aim to deliver within agreed timelines and specified budget*

View more →

Clinical Operations · EU Trials

Surface Logix

Legal representative and on-the-ground CRO for a US biotech, delivering four EU trials alongside regulatory and writing support.

> *We have relied on Niche for regulatory, clinical ops and medical writing functions*

View more →

Clinical Operations · Genetic Medicines

ReCode Therapeutics

ReCode's first patient study in a leading London hospital: IMPD, IB and protocol, the MHRA application, site management, monitoring and study reporting.

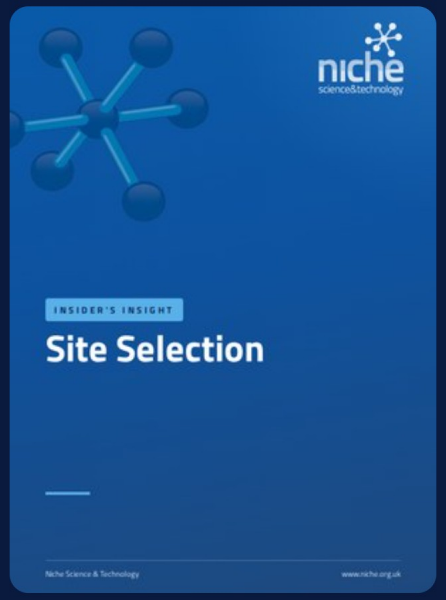
> *I am pleased to endorse and recommend Niche to any prospective sponsor requiring regulatory advice, clinical operations or medical writing support*

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Insider's Insights

Free practical guides drawn from over 25 years of hands-on experience, already downloaded more than 20,000 times.

See all 34 guides →



Site Selection

How to identify high-performing clinical sites.

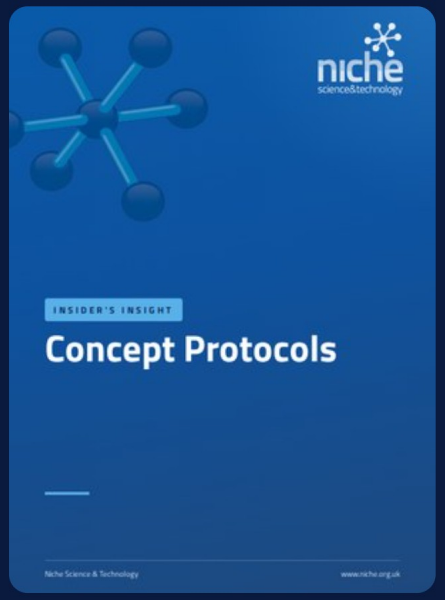
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Investigator Initiated Trials

The benefits and risks for investigators, patients and sponsors.

View guide →



Concept Protocols

Short, flexible protocols that can be reviewed and edited quickly.

View guide →



Training Records

What GCP training records should contain and how to keep them current.

View guide →

Free tool

Concept Protocol tool

Turn a study idea into a structured concept protocol. Answer a few questions about your study and receive a first draft to discuss with our team.

01 **Describe your study**

02 **Receive a draft concept protocol**

03 **Refine it with a Niche specialist**

Launching soon on niche.org.uk

Start with a concept protocol

Concept protocols are short, flexible documents that can be reviewed quickly and edited easily, the ideal first step before a full protocol.

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Let's build the future, together

Your next milestone starts with the right partner

Behind every breakthrough therapy is a team committed to making a difference. We provide senior-led clinical operations support to take your study from plan to close-out.

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