ALTASCIENCES

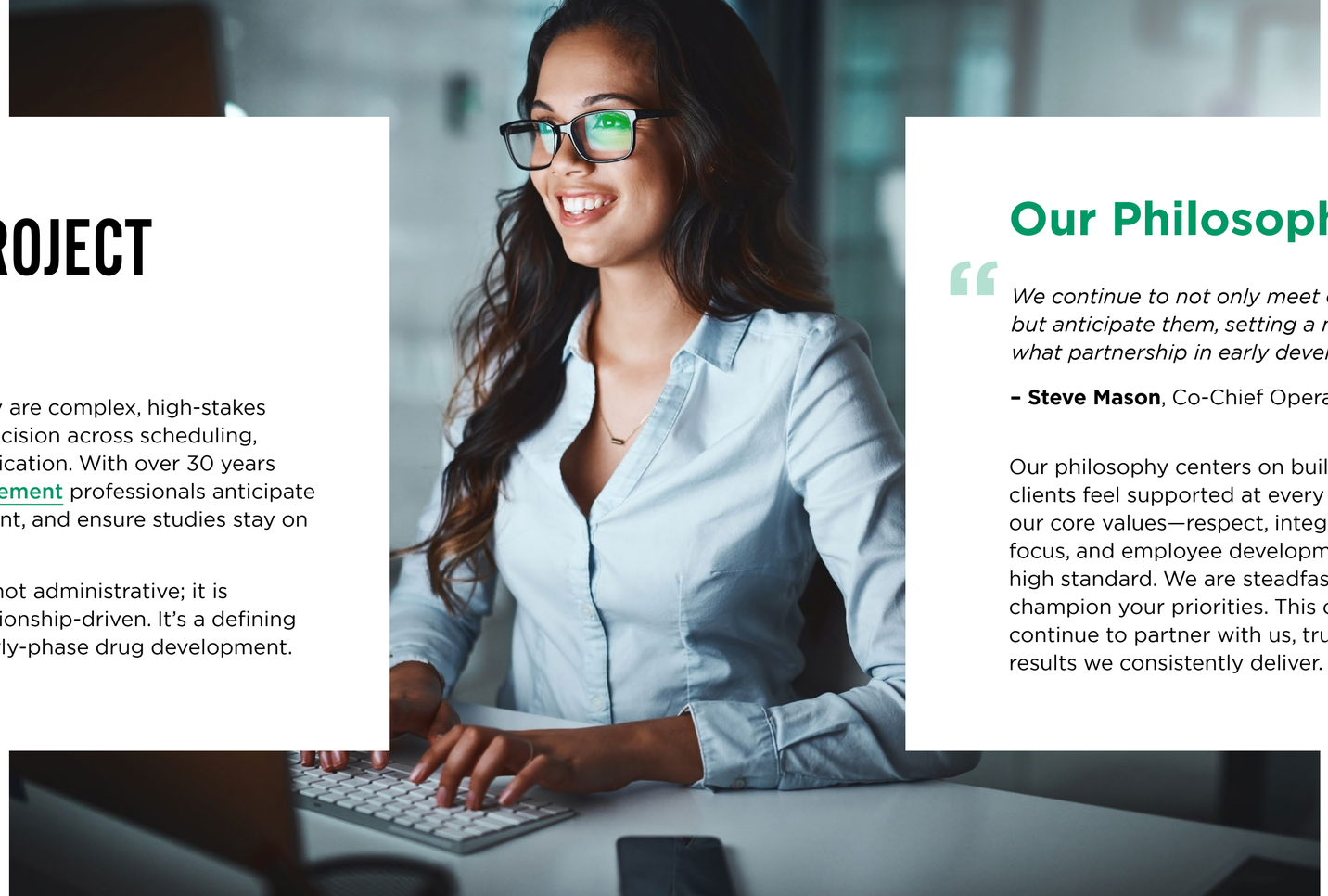
PROJECT MANAGEMENT

Where Science, Strategy, and Operations Converge

THE POWER OF PROJECT MANAGEMENT

Early-phase clinical trials move fast. They are complex, high-stakes and deeply interdependent, requiring precision across scheduling, science, operations, quality, and communication. With over 30 years of experience, our clinical project management professionals anticipate risk, orchestrate cross-functional alignment, and ensure studies stay on track, on budget, and inspection-ready.

At Altasciences, project management is not administrative; it is strategic, scientific, operational, and relationship-driven. It's a defining advantage of our unified approach to early-phase drug development.



Our Philosophy

> *We continue to not only meet our clients' needs but anticipate them, setting a new benchmark for what partnership in early development can be.*

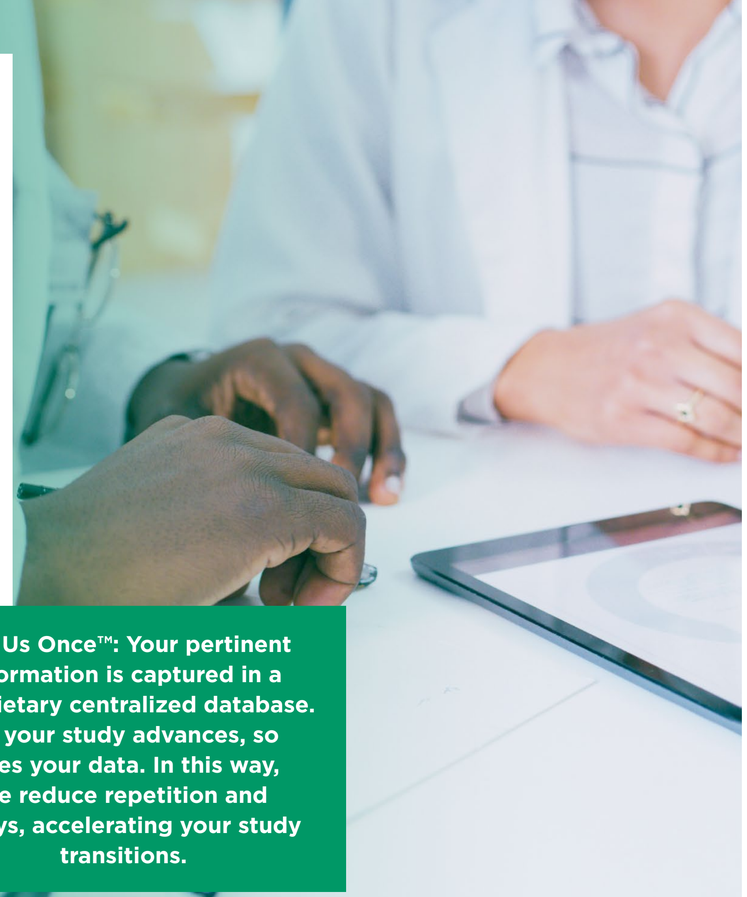
– Steve Mason, Co-Chief Operating Officer

Our philosophy centers on building trusted partnerships in which clients feel supported at every moment of their journey. By honoring our core values—respect, integrity, quality and excellence, customer focus, and employee development—we deliver projects on time to a high standard. We are steadfast collaborators who understand and champion your priorities. This client-first approach is why sponsors continue to partner with us, trusting our expertise and the reliable results we consistently deliver.

WHAT IS CLINICAL PROJECT MANAGEMENT?

Clinical project management at Altasciences is built on proven experience and established processes to effectively address the complexities of early-phase drug development. From project initiation through study completion and final delivery, our active approach to transparent and continual collaboration, and integrated oversight, supports a seamless early-phase experience throughout the clinical development process.

Project managers lead studies from project award through trial master file (TMF) delivery, acting as the operational and communication hub. With our **Tell Us Once™** commitment, we proactively share your preferences, requirements, drug information, and study results across all internal teams, regardless of study phase, for a seamless and effortless journey.



Tell Us Once™: Your pertinent information is captured in a proprietary centralized database. As your study advances, so does your data. In this way, we reduce repetition and delays, accelerating your study transitions.

Core Project Manager Responsibilities

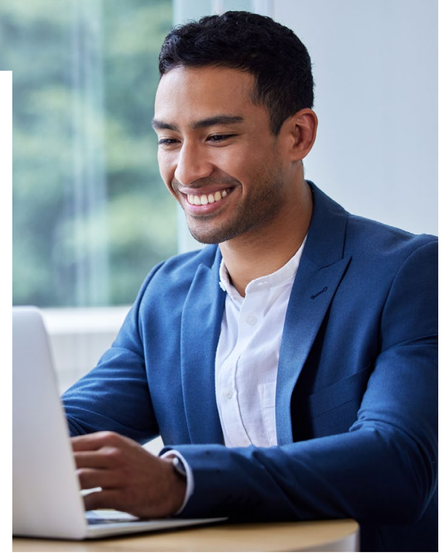
- Managing timelines, milestones, and deliverables
- Leading and aligning cross-functional teams
- Facilitating compliance with GCP and regulatory standards
- Overseeing clinical sites and external vendors
- Developing and maintaining risk management plans
- Managing budgets, forecasts, and financial accuracy
- Executing escalation pathways, issue resolution, and corrective and preventive actions (CAPAs)
- Providing full oversight and delivery of an inspection-ready TMF

We enable timely decision-making, reduce ambiguity, and keep communication moving smoothly across the full process to help teams stay aligned, and issues are addressed early.

THE ALTASCIENCES APPROACH

How Our Project Managers Support Your Studies

Each study our project managers oversee is guided by four key principles that provide a strong foundation for the progress of your program.



A Trusted Partner That Has Your Back

Our project managers act as a single point of contact, delivering seamless, transparent, and timely communication to provide customized support that keeps you informed, confident, and fully aligned with the project's direction.

No silos. No chasing updates. No surprises.

On-Budget and On-Time. Every Time.

Through proven project management processes, proactive risk oversight, and close collaboration across every stage of early-phase development, we keep milestones on track, budgets transparent, and timelines protected.

We expedite contracting and maintain momentum by providing site budget comparisons, smooth clinical trial agreement negotiations, and pre-established master clinical trial agreements with our site partners.

Uniting Scientific Expertise With Operational Excellence

Equipped with decades of operational and clinical knowledge, our project managers guide studies with strategic, regulatory-aware decision-making. All deliverables are designed to meet GCP standards and adhere to established protocols.

Proactive Risk Assessment for Fast, Effective Responses

Project managers protect trial integrity by identifying risks early, planning mitigation strategies, and monitoring progress. They escalate issues promptly to enable cross-functional alignment and implement CAPAs that address problems at their source, prevent recurrence, and support high-quality outcomes.

TOOLS AND SYSTEMS THAT POWER YOUR SUCCESS

Our project managers are equipped with purpose-built tools and standardized systems that streamline planning, improve visibility, and ensure every study is executed with precision. These platforms support proactive decision-making, real-time oversight, and uniform processes across all projects.

We use a suite of tools designed to enhance transparency, consistency, and efficiency:

- **Project Management Manual:** training, standards, guidance
- **Microsoft Project:** project timeline development
- **Smartsheet:** client dashboards and collaboration
- **Compass:** scheduling, milestone and KPI tracking
- **Montrium:** TMF build, quality control, and document management
- **SOPs and Job Aids:** foundational guidance for compliance and harmonization

Budget Transparency and Financial Stewardship

We provide clear, detailed budget visibility—including change order oversight, monthly accruals, and financial forecasting—allowing resources to be used efficiently, responsibly, and transparently.

Scientific Expertise That Advances Your Program

Project managers utilize extensive scientific, operational, and regulatory insights to improve project planning and drive efficient execution. Receiving invaluable support from expert scientists, our teams maintain unparalleled precision, compliance, and a strong commitment to safety and quality.

- **Risk management plans** are integrated early, enabling us to flag operational, regulatory, and vendor-related risks before they escalate.
- **Mitigation strategies** are conducted and aligned with risk assessments and identification, to reduce their likelihood and lessen impact.
- **Risk registers** are maintained to provide real-time tracking of active risks and continuously monitor mitigation strategies.
- **Proactive oversight** means we stay ahead of the curve—ensuring accountability across the project team, driving early identification of emerging risks and timely escalation when required.

IT'S A TEAM EFFORT

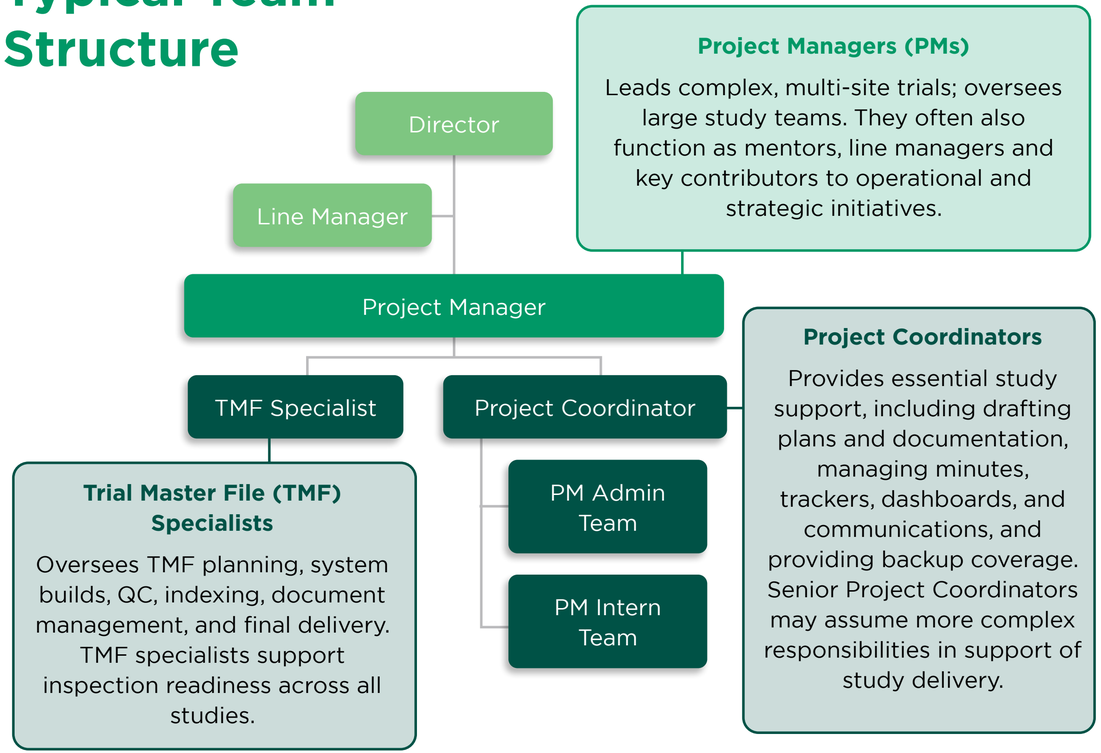
The Foundation of Project Management Excellence

Altasciences' clinical project management team brings experienced leadership and structured coordination to every project, working in close partnership with our scientific and operational teams—driving clear communication, disciplined execution, and accountability across timelines, quality expectations, and client priorities.

In complex, fast-moving environments, we provide consistent follow-through, thoughtful collaboration, and the adaptability to support reliable delivery and strong outcomes.

ALTASCIENCES

Typical Team Structure



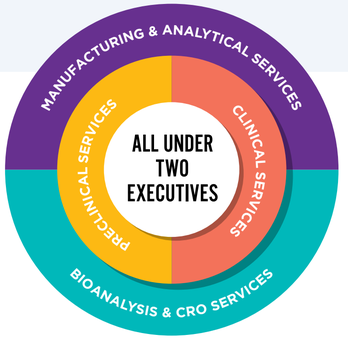
CROSS-FUNCTIONAL COLLABORATION

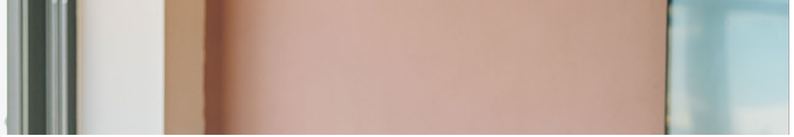
By connecting business development, regulatory expertise, clinical operations, bioanalytical, data science, medical writing, quality assurance, and finance, our project managers turn a complex, cross-functional effort into a unified, efficient process.

Our Project Managers Work Seamlessly With:

- ✓ **Business Development:** handovers, feasibility, alignment
- ✓ **Regulatory Affairs and IRB:** submissions, approvals
- ✓ **Clinical Operations:** clinic execution
- ✓ **Medical Monitoring:** safety oversight
- ✓ **Bioanalytical:** method development, validation, sample delivery
- ✓ **Data Management and Biostatistics:** database planning, TFL generation
- ✓ **Medical Writing:** protocols, amendments, clinical study reports
- ✓ **Report Production:** final report delivery
- ✓ **Monitoring Services:** site oversight and issue resolution
- ✓ **Quality Assurance:** audit readiness and compliance
- ✓ **Proposals, Contracts and Finance:** budgets, change orders, accruals

This tight integration ensures study success is a shared endeavor, supported by coordinated cross-functional execution. Every team contributes expertise, guided by project management to maintain alignment, clarity, and progress.





COORDINATION WITHOUT COMPLEXITY

Project Management for Multi-Center Trials

Running a multi-center study shouldn't mean managing multiple timelines, expectations, and communication streams. We eliminate that burden by placing a project manager at the center of your multi-center study—meaning every site, vendor, and internal function operates as one coordinated unit.

With one project manager serving as the single point of contact for your entire study, regardless of the number of sites or cohorts, you benefit from one unified plan and full accountability.

This streamlined structure creates clarity and reduces operational noise for faster, data-driven decision-making. Through integrated oversight across all sites, the project manager aligns Phase Ib to IIa startup sequencing and activation, coordinates key vendors—including laboratories, ECG and imaging providers, and recruitment partners—and proactively forecasts and tracks enrollment to prevent delays. They also manage data flow and queries to ensure consistency, enabling every site to operate uniformly while maintaining high operational and quality standards.

The Altasciences Advantage

Built for Speed and Risk Reduction

Multi-site studies can accelerate development timelines, if managed properly. Our project managers do this by:

- Identifying enrollment risks early and redistributing focus across sites
- Standardizing workflows so that each site follows a unified operational model
- Ensuring clean, synchronized data across all locations
- Resolving site issues before they impact your critical milestones

The goal is not just on-time delivery; it's reducing preventable delays at every stage.

Visibility and Control for Sponsors

Sponsors stay informed without being overwhelmed. Our project management provides:

- Dashboards with site-level performance metrics
- Timely status reports covering enrollment, data, safety, and risks
- Transparent budget tracking and accrual forecasting
- Clear escalation pathways when decisions are needed

You get complete visibility as the project management team handles day-to-day operational complexity.

Seamless Integration Between Internal and External Teams

Our project managers work closely with internal functional groups (clinical operations, bioanalysis, data management, biostatistics, regulatory, medical writing) and external patient sites, for:

- Faster resolution of issues
- Immediate access to scientific or operational expertise
- Consistent communication across all partners
- Alignment of timelines, deliverables, and expectations

The result: a multi-site study that operates as a single, cohesive project.

Designed for the Realities of Phase Ib to IIa Development

Early patient studies require agility, protocol amendments, adaptive cohorts, dose escalations, and evolving data. Our project managers are trained specifically for these environments, allowing them to:

- Coordinate adaptive changes quickly
- Manage complex sample logistics
- Support PK/PD-driven decisions
- Align safety reviews across dispersed clinical teams

Your multi-site trial remains flexible and tightly controlled. Multi-site studies don't have to be complicated.

IN A NUTSHELL

Exceptional project management is the backbone of successful clinical conduct. At Altasciences, our project managers bring scientific depth, operational discipline, and clear, partnership-driven communication to your studies.

Our approach to clinical project management delivers tangible advantages:

- ✓ Reduced operational burden on your internal teams
- ✓ Faster enrollment and milestone completion
- ✓ Aligned communication across sites and vendors
- ✓ Cleaner, more consistent data
- ✓ Lower risk of site-related delays
- ✓ Greater transparency and control for sponsors

ALTASCIENCES

ABOUT ALTASCIENCES

Altasciences is a forward-thinking, drug development solution company offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services. For over 30 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, clinical monitoring, and data management, all customizable to specific sponsor requirements.

Altasciences helps sponsors get better drugs to the people who need them, faster.

ALTASCIENCES

contact@altasciences.com