White paper

Coordinated development as an execution framework

The strategic advantage of structural alignment across clinical research, development, manufacturing, and supply

Executive summary

Drug development and clinical research have long relied on distributed execution. Clinical research, CMC development, manufacturing scale-up, and clinical supply are often managed by different organizations under separate contracts, oversight structures, and data environments.

Each transition between those stages requires documentation to be reconciled, technical assumptions to be revalidated, and accountability to shift. Alignment is rebuilt repeatedly over the life of a program. That repetition introduces timing variability and incremental cost, particularly when technical knowledge and project context must be re-established at each transition.

In this context, development performance is shaped less by individual activities and more by how those activities are aligned across the lifecycle.

When clinical research, development, manufacturing, and supply are coordinated within a shared execution framework, transitions are more predictable, decisions carry forward with greater continuity, and programs are better positioned to progress without disruption.

This report examines how coordinated governance and integrated execution influence development performance across three core themes:

1. Connectivity across the development lifecycle
2. Speed enabled by structural integration
3. Scalable execution supported by standardized oversight

These elements shape how alignment across clinical research, development, manufacturing, and supply influences development speed, milestone predictability, and execution risk.

Structural fragmentation and lifecycle transitions

Drug development progresses through defined stages, from discovery and preclinical research into clinical development across phases. Throughout this progression, CMC strategy, process development, manufacturing scale-up, and global supply planning evolve in parallel to support successful advancement and approval.

In distributed models, each of these key activities operates within its own contractual and operational boundary. Clinical decisions inform development. Development informs manufacturing. Manufacturing informs supply. At each boundary, context must be translated and validated.

That structural fragmentation carries consequences: misalignment between clinical research and CMC strategy, communication gaps across functions, technology transfer complexity, duplicated documentation, increased potential for re-work and limited cross-phase visibility.

Those consequences become most visible during transitions—when programs move from development into manufacturing scale-up or from production into global supply. Responsibility shifts. Assumptions are revisited. Project knowledge is lost. Documentation must be reconciled across organizations. Continuity depends on how those transitions are governed.

As modality and therapeutic indication diversity expands and programs span more geographies, transition management has become central to execution performance, with alignment at these boundaries directly affecting release timing and trial start-up. For example, in a **global Phase III vaccine trial** across more than 20 countries, early reconciliation of quality agreement parameters unlocked five weeks of time savings on investigational medicinal product release and ensured on-time delivery to support first-patient-in (FPI) milestones.

Connectivity across the development and clinical research lifecycle

Connectivity across the lifecycle is established when oversight extends from clinical research through commercialization.

In coordinated structures, clinical strategy, CMC planning, manufacturing readiness, and supply forecasting operate within a shared planning and decision framework. Technical context is preserved across phases. Decisions made early in development incorporate downstream implications.

This continuity supports:

- Earlier alignment on commercial requirements
- Fewer corrective adjustments during scale-up
- Consistent regulatory context across documentation cycles
- Greater visibility across program milestones

Lifecycle connectivity reduces the need to reconstruct alignment at each phase boundary.

This effect becomes visible in portfolio-scale execution. For example, In a **global clinical research program** spanning more than 450 sites and 800 patients, centralized governance and shared KPIs reduced program kickoff meeting timelines by 35%, enabled first site activation 13 days ahead of schedule, and supported enrollment completion up to 98 days earlier than milestone targets.

Structural enablers of integrated execution

Maintaining alignment across clinical research, development, manufacturing, and supply requires shared systems designed to operate consistently across phases and regions. Core structural considerations include:

- Program governance spanning clinical research through global supply
- Portfolio-level CMC oversight and milestone visibility across programs
- Integrated modeling and forecasting capabilities supporting early decision-making
- Standardized regulatory documentation and submission workflows
- Digitally enabled supply planning and real-time logistics visibility
- Harmonized quality agreement frameworks across regions

Speed enabled by structural integration

Once lifecycle connectivity is established, integrated execution changes how programs are planned and sequenced across functions.

When clinical research, development, manufacturing, and supply operate within integrated execution structures, planning assumptions are shared earlier across functions. Milestone sequencing reflects those cross-functional dependencies, and resource planning incorporates downstream constraints before they surface operationally.

Integrated execution is reinforced by shared infrastructure, including modeling platforms, supply forecasting systems, documentation workflows, and portfolio-level governance mechanisms. These tools support earlier visibility across functions and reduce downstream corrections.

Shorter feedback loops between stages improve milestone stability. This is most evident when early technical decisions are aligned before clinical entry.

For example, in one **program** facing a potential 18-month delay to start Phase I, early API specification alignment and integrated study design accelerated the path to first-in-human by 12 months and avoided $1 million in unnecessary manufacturing expense.

The same execution discipline must hold as programs expand across geographies, regulatory environments, and production volumes.

Scalable execution supported by standardized oversight

As programs expand across regions, regulators, and production environments, oversight cannot be reconstructed at each stage. Governance must operate consistently across geographies and modalities while preserving clear accountability as development activities progress toward commercial-scale manufacturing.

Defined decision authority, standardized documentation workflows, and consistent risk management processes reduce variability introduced by ad hoc coordination or phase resets. These practices allow programs to expand without restructuring governance at each phase boundary.

Global supply networks introduce additional coordination demands across regions, depots, and regulatory jurisdictions. Effective execution requires centralized visibility into inventory, documentation, and release status, while maintaining clear accountability at the local level. Without that alignment, expansion in volume or geography can fragment oversight and introduce timing variability. Scalability is not simply a function of capacity. It reflects whether governance, infrastructure, and execution practices remain stable as complexity increases. That stability supports predictability in timing, cost, and regulatory progression across the life of a program.

Coordinated execution in practice

At Thermo Fisher Scientific, these structural principles are embodied in **Accelerator™ Drug Development**.

The framework aligns clinical research, development, manufacturing, and clinical supply under coordinated governance designed to extend oversight across lifecycle stages. Execution operates within a shared structure rather than through sequential handoffs.

In practice, coordination is supported by integrated program teams that align clinical strategy, CMC planning, manufacturing readiness, and supply execution within a shared governance framework. Cross-functional teams maintain continuity of technical context and decision-making across phases, enabling earlier alignment on development assumptions and more consistent milestone progression as programs advance.

Sustaining this level of coordination requires systems that provide shared visibility across development, manufacturing, and supply as programs scale and geographic complexity increases.

These include platforms such as **MySupply** for cross-regional logistics visibility, **OSDPredict™** for modeling and predictive development insights, and the DigitalSME decision-support tool for preserving technical development context and decision history across stages.

Additionally, AI-enabled documentation and workflow systems reduce reconciliation burden during regulatory cycles while supporting coordinated oversight across programs.

Together, these systems maintain visibility across development, manufacturing, and supply, helping programs advance across phases without repeated operational resets.

Quantifying the impact

In addition to the operational stability and cross-phase visibility described above, the Accelerator™ Drug Development model translates into quantifiable economic outcomes.

Independent analysis conducted with the Tufts Center for the Study of Drug Development evaluated the financial impact of programs operating within this single-partner, coordinated structure and found measurable improvements in risk-adjusted value compared with traditional distributed execution approaches. **The findings** reflect reduced transition inefficiencies, improved milestone predictability, and lower duplication of effort across development stages.

In capital-constrained environments, execution structure influences both time and capital efficiency. Economic validation reinforces the operational case for lifecycle continuity

A coordinated development model as the structural solution

In modern drug development, execution architecture influences not only predictability and cost, but the trajectory of a program's progress and its likelihood of success.

As pipelines diversify and complexity increases across modalities and geographies, development programs must operate across more functions, regions, and regulatory frameworks than ever before. Sustaining forward momentum requires preserving technical context and minimizing execution resets as programs advance from early research through commercialization.

In this environment, development strategies require embedded coordination across phases, supported by governance, infrastructure, and integrated execution practices that extend beyond individual transition points.

Enterprise foundations that support coordinated development

Coordinated execution across clinical research, development, manufacturing, and supply depends on enterprise-level systems that operate consistently across the organization. Structural alignment is sustained when governance, regional execution, and infrastructure investment function within a unified framework rather than as parallel capabilities.

The essential enterprise foundations include:

Quality discipline. Established quality systems, harmonized documentation standards, and consistent regulatory oversight practices that extend from development through commercial supply. Examples include standardized quality agreements across regions, shared inspection readiness frameworks, and cross-phase compliance continuity that limits rework during regulatory transitions. *[Read: Quality as a strategic differentiator]*

Global flexibility. Regional development and manufacturing infrastructure, integrated supply networks, and adaptable execution pathways that support geographic shifts, modality expansion, and evolving clinical strategies. Coordinated tech transfer across sites, distributed manufacturing capacity, and supply plan adjustments preserve continuity as programs encounter regulatory, market, or regional change. *[Read: Flexibility in drug development]*

Sustained investment and innovation. Ongoing capital expansion, digital infrastructure, and technical platform development that strengthen readiness across modalities. Investments in sterile capacity, process modeling environments, supply forecasting systems, and portfolio-level CMC oversight reinforce execution stability as programs scale. *[Read: Building the advantage]*

When these enterprise capabilities operate within a single coordinated structure, alignment is preserved across clinical research, development, manufacturing, and supply, enabling coordinated execution to function consistently as complexity increases.

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