

What's Changing in How You Run Your Programmes

Biotech Research

You have seen this on your development engine

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01

Why is our trial budget drifting on programmes our model says should hold?

02

What happens to our first-cycle acceptance when our senior regulatory and CMC leads step back?

03

Why have our milestone cycles not moved in a decade?



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Every Chief Operating Officer or Head of Development Operations at a mid-sized European biotech has had the same Monday morning. Three meetings on the calendar. The first is a CRO steering committee on your Phase IIb programme, and site activation has drifted to week twelve against a plan of week eight. The second is a CDMO quality review on the comparator batch, with an out-of-spec your senior CMC lead is the only person in the company who can fully interpret. The third is a thirty-minute slot Thursday with your senior regulatory affairs director. The subject line says transition.

You have run this function for fifteen years. The pattern used to be simple. Hire the best clinical operations, regulatory, and CMC people you could find. Write the SOPs. Follow them. Keep the cash burn honest for the CFO. Keep the board reporting clean. The business was understandable.

Something changed. Your monthly cash-burn conversations with the CFO are tighter every quarter. Your senior regulatory and CMC leads are the scarcest resource in the firm, and they are spending most of their billable week on coordination and preparation work an infrastructure you have not built could carry. Your milestone cycles have not meaningfully shortened in fifteen years, despite the tooling that exists now. And you can name the three or four senior people whose retirement inside five years will cost you more than any operations-cost programme has ever gained you.

This is not a you problem. It is an industry problem and a development-engine problem, happening at the same time. Most biotech COOs are treating them as two. The ones who see them as one are going to own the next decade of European mid-market biotech operations.

This briefing covers what is happening in your sector, what it means inside your development engine, and the three questions your operations team should answer before the next pipeline review.

Biotech development just lost the equation that ran it for a generation

Every technology wave your sector absorbed in the last thirty years gave your firm a reason to hire more senior operations people. ICH E6 revisions widened the monitoring and quality workload. EudraCT and CTIS pulled more regulatory operations into every submission. Risk-based monitoring shifted CRO oversight back onto the sponsor. Adaptive trial designs stretched the protocol-amendment cycle. Each new layer gave the senior headcount plan a new reason to grow. Development operations has run on senior specialists plus SOPs for a generation, and it never once broke.

AI does not behave the same way. Your programmes still need the same IND, the same CTA, the same quality agreement, the same CMC dossier. The scope of the work is unchanged. But the coordination, preparation, cross-reference, and documentation layer that used to absorb most of your senior people's week can now be done in a fraction of the time by infrastructure the firm has not deployed. Under a senior-heavy operations model, that shift means the same cash-burn run rate for the same pipeline, while competitors who rebuilt the architecture are hitting milestones four to eight months faster on the same capital. Your sector is starting to call this milestone compression, and for the first time in a generation, the senior operations cost structure is actually moving.

Your partners' and acquirers' due-diligence teams are showing up with explicit questions about programme continuity. By the time your team walks into the data room, the risk premium has already been set.

The competitors in your segment are not waiting. A handful of Nordic and continental biotechs have committed serious budget to development-operations infrastructure in the last eighteen months. The ones moving first are submitting INDs in twelve to fourteen months that used to take eighteen, activating sites in eight to ten weeks that used to take twenty, and closing partnership conversations on programme-continuity terms that competitors cannot credibly offer. The other half of the story sits on the partnership side. Licensors and acquirers who used to pay a heavy key-person-risk premium against mid-market biotech are now paying a materially smaller one to firms whose development history lives in infrastructure. The firm that builds that infrastructure first captures a valuation asymmetry the incumbents will not close quickly.

Your engine, your submissions, and your CMC are feeling it every day

Your clinical operations. Programme managers are working harder to hold sites, amendments, and data lock on the same timelines. Handoffs between CRO project manager, internal operations, and monitoring carry friction built when the function was organised around a 2008 ICH workflow and never redesigned. The firm activates a site and locks a database the same way it did in 2015. The tooling, the CROs, and the agency expectations have all changed. The operations engine has not.

Your regulatory and quality. First-cycle acceptance has not moved in ten years, and is now at risk. The senior regulatory director who catches the protocol finding a junior would miss, who reads the agency's meeting minutes before others see them, who walks your team through a regulator's unwritten preference, carries that judgment as biography. When one steps back, the firm runs two submissions with a visible quality gap before anyone names the cause. Three before a reviewer questions the precedent cited. Five before an inspection finds something that loses a partnership.

Your CMC and supply. Your senior CMC lead carries tech-transfer history, batch-record pattern reading, yield-trend judgment, and CDMO relationship memory for the two or three CDMOs you depend on most. Most of that knowledge has never left the monthly review call. The reasoning behind the specification choices your CDMOs now take as given sits in one person's head. The next time you add a CDMO, or a project manager rotates, that knowledge is the asset that either transfers or does not.

Your programme and partnership team. Your programme managers run dashboards, pipeline reviews, data rooms, and investor briefings on substrate the firm has accumulated over a decade. Most of that substrate lives in a hundred thousand emails, a hundred PowerPoints, and a programme history nobody has written down. When a partner asks why the Phase II design branched the way it did in 2023, the person who knows the answer schedules a call and reconstructs it from memory. That call is the valuation exposure.

Your senior experts. Your three to six most senior development-operations people cost the firm between €220 and €380 thousand fully loaded. On a standard week they deliver twelve to sixteen hours of the judgment only they can provide. The remaining twenty-four hours go into agency correspondence, CDMO coordination, CRO oversight, precedent cross-reference, and documentation assembly. The scarcest resource in the firm is spending most of its week on the work it is least suited for.

The firms pulling ahead are building one piece of infrastructure

Your sector is compressing from above because AI compresses discovery, sending more programmes into the clinical bridge and loading more work onto your development operations. Your engine is compressing from below because your senior regulatory and CMC leads are spending most of their week on coordination work the firm has not built infrastructure to hold. Same force, two altitudes. But there is a third thing happening that most biotech COOs have not named yet, and it is the one that matters most.

You do not have three problems. You have one. The senior judgment that makes your programmes credible, to agencies, to CDMOs, to partners, to acquirers, has never been separated from the senior who carries it. Every milestone slip, every quality finding, every protocol amendment cycle, every stuck negotiation is a symptom of that single unsolved thing. Pay a senior regulatory director to prepare a pre-IND briefing book from scratch, and velocity drifts. Let a senior CMC lead step back with their CDMO judgment still in their head, and your next tech transfer costs you two quarters. Keep the development engine designed around a bottleneck that cannot be unblocked, and the milestone cycle cannot shorten.

Look at the firms pulling ahead. Clinical operations, regulatory, CMC, and partnership history are not four separate programmes. They are one piece of infrastructure. Every submission enriches the infrastructure. The senior who retires adds to it on the way out. The mid-level programme manager learns by using it. The partnership conversation holds because the answers live in it. The same infrastructure that protects first-cycle acceptance protects tech-transfer continuity and shortens the milestone cycle.

You can tell which camp a firm is in from a single question. Can you point to one thing in your development engine that is measurably smarter this quarter than last quarter? Most biotechs cannot. The ones that can have already made the shift, and they are already running the programmes you thought were uniquely yours.

You have eighteen to twenty-four months. The AI adoption debate is over. Your question now is whether you build the infrastructure your firm will run on for the next decade, or wait until the CFO brings in a vendor who will build one that belongs to someone else.

What most firms are doing. What the winners are doing instead.

Every biotech COO has had the AI conversation. Most are making the same four decisions. A smaller group is making different ones. The difference is architecture, not tooling.

THE DEFAULT PATH

Hold CRO unit rates, push senior oversight up

Same CRO mechanic, harder sponsor oversight. Senior coordination drifts as scope widens.

Treat senior departures as an HR problem

Mentor, hire replacements at premium, and watch a submission or partnership exposure open up every time.

Deploy copilots on top of the existing development engine

Every programme manager gets a chatbot. Individual productivity rises. Milestone cycle does not move because the engine is still 2008.

Defend the mid-level programme team by avoiding the conversation

Pretend roles do not change. Lose the best programme managers to firms that moved first. Bench thins at the worst moment.

THE WINNERS' PATH

Rebuild sponsor scope around the coordination an infrastructure carries

CRO pricing renegotiated. Senior hours redirected to judgment work. Milestone velocity rises.

Extract senior judgment as a side-effect of daily work

Capture from the artefacts they already produce. Seniors stay the escalation layer. Programme judgment stops walking out.

Rebuild the development engine around the new unit

Programme manager plus agent plus extracted precedent delivers senior-tier output. Cycle compresses from eighteen months to twelve.

Redesign the junior pathway around judgment from day one

New programme managers pair with agents and the firm's extracted corpus. The five-year curve compresses to eighteen months.

Same development engine. Same twelve months. Opposite outcomes. The difference is the architecture, not the agents.

Trial Economics. Submission Reliability. Programme Velocity.

Three questions every biotech COO is tracking. None of them used to be the same question. They are now.

01 · TRIAL ECONOMICS

Why is our trial budget drifting on programmes our model says should hold?

The protocol has not changed. The CRO has not changed. But cash burn is running three to five per cent above plan each quarter, and your CFO is asking why. The work that justified the senior coordination layer has compressed. Most firms are still paying the old bill for the old architecture. The CRO unit rate is fine. The architecture around it is the question.

02 · SUBMISSION RELIABILITY

What happens to our first-cycle acceptance when our senior regulatory and CMC leads step back?

Three to six of your most senior development-operations people are within five years of retirement or career transition. Each carries agency-specific and CDMO-specific judgment that took twenty-five years to build and has never been written down. Your first-cycle rate holds because they are in the room. When they leave, the floor drops before the inspection, and the partnership risk premium rises the quarter after the announcement.

03 · PROGRAMME VELOCITY

Why have our milestone cycles not moved in a decade?

A standard pre-IND to IND cycle takes sixteen to eighteen months. Roughly half of that elapsed time is literature review, precedent cross-reference, briefing-book assembly, and internal coordination that now compresses to hours, not weeks. The firms that rebuild development operations around this close the same cycle in eleven to fourteen. Same pipeline. Same regulatory quality. Four to six months earlier on every milestone. Not a productivity story. A pipeline-velocity story.

What the firms winning this play are actually doing

Four concrete moves any biotech COO can start this quarter. Each touches one part of the development engine. Pulled together, they become one architecture the firm runs on.

1 **Clinical operations: decompose every trial phase to the task level, then rebuild CRO scope around the tasks that still deliver value**

Most COOs are redesigning trial phases. The right unit is the deliverable task. List the task bundles inside each phase. Mark each: agent-owned with human audit, composite, senior-only, retired. What remains is a different phase at a different cost base. The COO who walks into the next CRO renewal with the task-level map owns the conversation. The ones with phase-level budgets are running the 2019 playbook.

2 **Regulatory and quality: extract senior judgment now, as a side-effect of daily work, not as a separate documentation project**

Documentation sprints have failed in every biotech for twenty years. The judgment is not articulable in prose. Extract from the artefacts the specialist already produces: agency meeting minutes, response letters, batch investigation reports, redlined submissions. The firm captures reasoning patterns as a side-effect of paid work. Senior consent is straightforward because no-one is asked to explain themselves. Their role elevates from preparation to escalation. The judgment stops being biographical.

3 **CMC and supply: institutionalise the CDMO relationship so batch knowledge and tech-transfer history transfer on architecture**

Every biotech CEO has lost a tech-transfer month once, the quarter after the CMC lead who carried the CDMO relationship stepped back. Treat every major CDMO relationship as a small intelligence asset under active construction. Five years of batch records. Yield-trend judgment. Deviation patterns. Quality-agreement history. When the CMC lead rotates, the next senior inherits the asset. The relationship holds on architecture, not biography.

4 **Programme and partnership: rebuild programme history as a continuous artefact, not a pitch the team recreates**

Every time a partner or acquirer opens due diligence, your team rebuilds a ten-year history from memory. The work burns two to four weeks of senior time each cycle, and the story lands differently each time. Build the history once. Keep it current as a side-effect of every board pack and investor update. Open the data room with an artefact the partner reads before the first call. The risk premium falls. The negotiation moves faster.

The only firm that joins senior advisory to working infrastructure

The biotech COO has four places to go for help. None of them can do what we do.

The big consulting firms' life-sciences practices sell €500K to €2M operating-model diagnostics delivered by partners and analysts billing hours. They produce decks. They cannot put working infrastructure into a regulatory director's workflow in three months. Their own revenue model is part of your problem.

The biotech-specialist CROs and advisory firms sell seconded regulatory or CMC specialists on retainer. They carry domain expertise. They do not deliver infrastructure that outlives the engagement. Senior judgment stays biographical, rented instead of owned.

The biotech-operations software vendors sell a platform and leave you to fill it. They cannot tell you which precedent is worth extracting or how to structure it. Every biotech has watched this purchase underdeliver once.

Your internal IT and the process-mining platforms will build a chatbot on your document system. IT optimises for standardisation. It does not sit close enough to how your seniors reason about agency precedent to codify it.

The market offers four things you have already said no to. GRAIL is the fifth option.

WHAT YOU GET

Senior advisory that speaks development-floor, not diagnostic-deck

Working infrastructure your team uses the same week

Custom agents built on your programmes, your CDMOs, your submissions

The start of a programme-history infrastructure your seniors feed

No vendor lock-in at any phase of the engagement

WHY IT MATTERS

Founded by operators who have run professional-services delivery

Business first, technology second

Three weeks from first meeting to working infrastructure

Your team keeps the infrastructure, you own the IP

Every next step earned by what just shipped, never assumed

Three sessions with your development leaders. Working infrastructure from week one.

We start with your leadership team because the change cannot outrun their personal understanding of what is possible. Three workshops. Each delivers standalone value.

WORKSHOP 01

How to think

Walk through what is happening in your sector and inside your development engine. Build the first piece of infrastructure in the room: a programme-specific agent for one of your live submissions, extracted from the archive you already have. Your operations team leaves with a shared view of what to do next and the first piece of working infrastructure already in their hands.

WORKSHOP 02

Your development infrastructure

A half-day build. Your Head of Clinical Operations, Head of Regulatory Affairs, Head of CMC, and Head of Programme Management each leave with five to ten pieces of working infrastructure tuned to their function. Agency precedent retrieval. CDMO batch pattern reading. Protocol amendment drafting. Programme history assembly. Pipeline briefing prep. Infrastructure your teams use the same week, not decks about infrastructure.

WORKSHOP 03

Ready to run

Refined infrastructure based on real use. The rollout plan to your wider development organisation. The knowledge-extraction plan for your senior experts. The pathway plan for your mid-level programme managers. And the CEO and CFO conversation with numbers they can check: cash-burn per milestone, first-cycle acceptance trend, programme velocity by phase.

Three weeks. No IT project. No board approval needed to start. The infrastructure your development engine is already running on when we finish.

For your next pipeline review

The questions where your operations team cannot agree on an answer are the ones worth an hour on the agenda. Ask these honestly.

Of the last five programmes where milestone dates drifted, how many drifted because senior coordination hours were the bottleneck rather than scientific or clinical reasons? If you do not know, how would you find out?

What percentage of your senior regulatory, CMC, and programme leads' week is spent on coordination, preparation, and cross-reference, and what would it take to cut that in half?

If your top three senior development-operations people stepped back next year, what would happen to the programmes they carry? What have you actually transferred to the rest of the team in the last twelve months?

Can you point to one thing in your development engine that is measurably smarter this quarter than last quarter? If not, what are the next four quarters going to add up to?

Which of your mid-level programme managers is already working the way the rest of the team will need to work by 2027? What would it take for that to be the default across your development organisation?

If any of these produces a disagreement in your operations team, that is the conversation worth having before the board asks.

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