

What's Changing in Your Specialist Operations

Life Sciences

You have seen this on your specialist bench

“More programmes reaching the regulatory stage simultaneously. The same number of specialists. The same preparation-heavy model. The queue builds on the most expensive resources in the firm.”

01

Why does each submission cost the same when half the preparation work has changed?

02

What is our quality exposure when two seniors are at capacity and a third programme lands?

03

Why does our time from CHMP opinion to first HTA filing take twice as long as it should?



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Every COO or Head of Operations at a mid-sized European pharma affiliate has had the same Tuesday. Three active programmes on the senior regulatory director's desk. The Day 120 EMA response is due today. The PSUR review for the cardiometabolic programme is due Thursday. The Germany HTA package ships next week. The market access manager who joined in January is covering the fourth programme. The regulatory director has been in the firm for twenty-seven years. She knows the reviewers at three HTA bodies by name. She is the bottleneck, and the CEO asked about programme timelines in the last GMT.

You have managed this function long enough to know the pattern. The specialist bench that kept programmes moving has not grown at the same rate the programme load has. Your senior regulatory and market access professionals are spending roughly half their week on compilation, cross-referencing, and monitoring work that does not require their judgment. And you can name the two or three people whose departure would put a programme in jeopardy.

This is not a staffing problem. It is a capacity architecture problem. The preparation layer that consumes half your specialists' time has always been separable from the judgment layer. The firms redesigning that preparation layer now are running more programmes with the same bench, at the same quality, reaching market access timelines their peers cannot match.

This is an industry problem and a specialist-operations problem, arriving at the same time. The COOs who treat them as one are building a different kind of firm.

This briefing covers what is changing in life sciences operations, what it means inside your specialist bench, and the three questions your operations team should answer before the next programme review.

Life sciences operations just inherited a coordination problem it was not designed for

The EU HTA Regulation went live in January 2025 for oncology drugs and advanced therapy medicinal products. For the first time, a single clinical assessment covers all member states simultaneously. The evidence package that used to move through country-by-country filings in sequence now must be prepared for parallel review across regulatory affairs, market access, medical affairs, and commercial operations at the same time.

AI is compressing the early part of the value chain. Target identification timelines are down thirty to forty percent. Clinical phases remain biology-bound. The result is more programmes reaching the regulatory and market access phase simultaneously, putting capacity pressure on exactly the specialists who are hardest to replace. Discovery runs faster. The commercial and regulatory bottleneck deepens.

More programmes reaching the regulatory stage simultaneously. The same number of specialists. The same preparation-heavy model. The queue builds on the most expensive resources in the firm.

The firms moving ahead are not hiring faster. They have redesigned the preparation layer inside their specialist bench. Country-specific HTA package assembly, regulatory guideline monitoring, PSUR narrative compilation, and Day 120 response drafting run on structured infrastructure. Specialists own the judgment, the agency relationship, and the final output. The firms that made this shift are filing first-market HTA submissions three to four months faster than peers on the same clinical package. Three months of market access advantage in a reference-pricing environment is a commercial gap that compounds.

Your specialist bench is feeling the load on every programme

Your regulatory affairs function. Your regulatory directors and managers spend a significant share of each week on preparation work: monitoring guideline updates, compiling cross-reference tables, formatting submission packages, and drafting first-pass agency responses. That work is necessary. It is not where their judgment adds distinctive value. The director who spent four hours compiling a Day 120 response could have spent those hours on the argumentation and the agency relationship that actually determines the outcome.

Your market access function. Each national HTA submission requires a country-specific evidence package from the global clinical dossier. For Germany, France, England, Sweden, and three more markets simultaneously, that assembly is substantial. Your market access managers know the argumentation and the payer landscape. The assembly, formatting, and consistency-checking runs in parallel with the argumentation. Right now it runs on the same people.

Your medical affairs and pharmacovigilance function. Your MSLs carry scientific conversations that open doors no sales contact can. Your pharmacovigilance specialists own signal assessment and the regulatory narrative. Both have preparation layers: literature monitoring, case narrative compilation, PSUR database synthesis. This preparation occupies thirty to fifty percent of specialist time. The specialists doing it are the ones you cannot replace.

Your specialist bench. The regulatory directors, market access managers, and MSLs who carry programme knowledge took eight to fifteen years to develop. Specialist searches in regulatory affairs take nine to twelve months. When a programme needs cover because one specialist is at capacity, the solution is usually to overload another. The bench has no slack designed into it.

Your programme operations. Cross-functional coordination runs on shared calendars, email threads, and the judgment of whoever last read the latest agency guidance. The firms that have built structured programme infrastructure run four programmes in parallel at the team size that used to run two.

The firms pulling ahead are building one piece of infrastructure

Your sector is adding programme volume because AI has accelerated discovery. Your specialist bench is not keeping pace because the preparation layer has never been separated from the judgment layer. Your regulatory director is brilliant. She is also compiling. Your market access team knows every HTA body's preferences. They are also assembling packages. Your pharmacovigilance lead can spot a safety signal at first reading. He is also mining databases.

You do not have three problems. You have one. The specialist judgment that makes your programmes succeed has never been separated from the person who carries it. Every cycle-time problem, every quality risk, every programme queue is a symptom of that single unsolved thing. Build the infrastructure to carry the preparation and the judgment becomes available for what it is actually worth.

The firms that made this shift are running more programmes with the same bench. Their seniors review rather than compile. Their juniors learn by working alongside structured precedent infrastructure from week one, not by spending two years in preparation tasks before they reach anything that builds judgment. The knowledge the 27-year regulatory director accumulated stops being biographical when it lives in the firm's infrastructure.

The preparation that consumes half your specialist bench's time is not the work that makes your firm valuable to regulators or payers. The judgment that takes the other half is. Building the infrastructure to carry the preparation is what frees that judgment to matter.

You have twelve to eighteen months before the HTA coordination pressure is fully visible in your programme timelines. The firms that redesigned the preparation layer in early 2026 will be filing earlier, reaching market access faster, and compounding capacity through the same period you are still deciding.

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

Every life sciences COO is thinking about capacity. Most are reaching the same four conclusions. A smaller group is reaching different ones. The difference is architecture, not headcount.

THE DEFAULT PATH

Hire more specialists when the queue builds

Nine to twelve months per experienced RA hire. Programmes wait. The queue re-forms around the next bottleneck.

Accept that senior knowledge walks out at retirement

Succession planning means a replacement who takes two years to reach the same programme fluency.

Deploy AI tools on individual specialists

Each specialist uses a chatbot for their own preparation. Programme coordination stays on shared inboxes. Cycle time does not move.

Sequence programmes due to bench capacity limits

Market access timelines extend. The competitor who filed first sets the reference price.

THE LEADERS' PATH

Extract the preparation layer from the existing bench

Same specialists cover more programmes. The queue clears because the bottleneck was preparation, not headcount.

Build precedent infrastructure as a side-effect of daily work

Agency negotiation patterns, submission history, HTA body preferences captured and accessible to the next specialist from day one.

Rebuild the programme infrastructure around the new unit

Country package assembly, regulatory monitoring, PSUR drafting run on structured agents. Specialists own the judgment calls and the regulatory relationship.

Run programmes in parallel by freeing specialist capacity

Same bench. Same quality. Timelines compress. The pricing window stays open.

Same bench. Same twelve months. Opposite programme timelines. The difference is whether the preparation layer is still running on your specialists or running on the infrastructure you built around them.

THREE QUESTIONS

Knowledge Delivery Cost. Specialist Output Quality. Programme Cycle Time.

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

01 · KNOWLEDGE DELIVERY COST

Why does each submission cost the same when half the preparation work has changed?

Your specialists are fully loaded. Your cost per submission is high and has not moved. The regulatory and market access preparation that used to justify that cost structure is increasingly doable by well-structured agents at a fraction of the time. The specialist cost is appropriate for the judgment calls and the agency relationship. It is overqualified for compilation, formatting, and first-draft synthesis. The question is not whether your specialists are worth it. It is whether the preparation architecture is worth rebuilding.

02 · SPECIALIST OUTPUT QUALITY

What is our quality exposure when two seniors are at capacity and a third programme lands?

Your quality floor holds because your senior regulatory directors are in the room. The quality risk is not the specialists you have. It is the programmes they cannot cover simultaneously. A Day 120 response prepared by a specialist under competing deadlines is not the same as one prepared by a specialist who had time to think. The quality ceiling does not rise when the bottleneck is preparation. It rises when specialists can be fully present for the judgment calls that matter.

03 · PROGRAMME CYCLE TIME

Why does our time from CHMP opinion to first HTA filing take twice as long as it should?

A six to nine month timeline from CHMP opinion to first national HTA filing is standard in firms where the market access team assembles every country package from scratch. The firms that have built structured assembly infrastructure are reaching first filings in three to four months. Same team. Same quality. The cycle time that had not moved in a decade moved when the preparation layer stopped sitting on the specialists. First-mover position in market access is worth the investment in any therapeutic area where reference pricing applies.

What the firms leading this transition are actually doing

Four concrete moves any life sciences COO can start this quarter. Each touches one part of the specialist bench. Pulled together, they become one architecture the firm runs on.

1**Regulatory affairs: extract the preparation layer from your submission specialists**

Your regulatory team spends significant time each week monitoring guidelines, compiling cross-references, and drafting first-pass agency responses. Agent infrastructure handles these. Your directors review, validate, and own the judgment call. The Day 120 response the director reviews is better than the one she compiled under deadline pressure because she had time to think about what it needs to say.

2**Market access: rebuild dossier assembly so specialists own the argument, not the package**

Country-specific HTA package assembly is preparation work. Your market access managers know the argumentation and each HTA body's preferences. Agent infrastructure handles assembly, cross-referencing, and formatting for each national submission. Your specialists focus on the country-specific argument and the payer negotiation. Cycle time compresses when assembly is not the bottleneck.

3**Medical affairs and pharmacovigilance: free senior professionals from monitoring and first-draft work**

Literature monitoring, PSUR database synthesis, and case narrative compilation occupy thirty to fifty percent of your safety and medical affairs specialists' time. Agent infrastructure handles literature synthesis and first-draft PSUR narratives. Your safety specialists own signal assessment, causality judgment, and the regulatory narrative. The PSUR reviewed is more complete because the agent ran every database and the specialist had time to think about the signal.

4**Specialist bench: solve knowledge continuity before the retirement conversation starts**

The 27-year regulatory director's EMA negotiation patterns, her knowledge of three HTA bodies' unwritten preferences, her memory of every precedent: none of that is in a system. Extract it as a side-effect of daily work. Submission files, agency correspondence, annotated precedents. The market access manager who joined in January operates inside accumulated precedent from week one. The knowledge stops being biographical when it lives in the firm's infrastructure.

The only firm that joins judgment to working specialist tools

The life sciences COO has four places to go for help. None can do what we do, and each for a specific reason.

The big consulting firms' life sciences operations practices produce a diagnostic billed on the same specialist-hour model your firm runs on. They write the strategy. They cannot put working infrastructure into your regulatory team's submission workflow in eight weeks at a fixed fee.

The regulatory technology and knowledge management vendors sell a document repository with metadata tagging and version control. Document management is not knowledge extraction. Every life sciences COO has watched a Vault implementation solve traceability without solving what your regulatory director does with Tuesday morning.

The life sciences commercial analytics consultancies answer which market to enter and at what price. They do not answer how your market access team prepares the dossier for six HTA bodies while two specialists are already at capacity.

The hyperscaler life sciences consulting practices are platform-optimised. The agency precedents your regulatory team accumulates become a cloud asset, not a firm asset. That is lock-in with an expiry date.

The market offers four options you have already considered. GRAIL is the fifth.

WHAT YOU GET

Advisory that speaks submission-floor, not strategy deck

Working infrastructure your specialists use the same week

Custom agents built on your programmes, submissions, precedents

Knowledge infrastructure fed through daily work

No vendor lock-in at any phase

WHY IT MATTERS

Business first, technology second

Three weeks from first meeting to working infrastructure

IP is yours from day one

Every next step earned by what just shipped

Fixed fee throughout. You buy outcomes, not hours.

Three sessions with your specialist leadership. Working infrastructure from week one.

We start with your operations leadership because the change cannot outrun the team's personal understanding of what is possible. Three workshops. Each delivers standalone value. Each earns the right to the next.

WORKSHOP 01

How to think

Walk through what is changing in life sciences operations and what it means inside your specialist bench. Build the first piece of infrastructure in the room from your actual submission archive. Your regulatory, market access, and medical affairs leads leave with a shared view of what changes and the first working piece already in their hands.

WORKSHOP 02

Your specialist infrastructure

A half-day build. Your Heads of Regulatory Affairs, Market Access, Medical Affairs, and Pharmacovigilance each leave with five to ten working tools tuned to their function. Submission preparation agents. HTA package assembly. PSUR drafting. Guideline monitoring. Knowledge capture from your senior specialists' daily work. In use the same week.

WORKSHOP 03

Ready to run

Refined infrastructure based on real programme use. The rollout plan for your wider specialist organisation. The knowledge-extraction plan for your senior directors. And the CEO and CFO conversation with numbers they can check: cost per submission, programme throughput per specialist, cycle time from CHMP opinion to first HTA filing.

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

For your next operations review

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

Of your regulatory and market access specialists, what percentage of their week is currently spent on preparation and compilation work versus judgment and agency relationship work? If you do not know, how would you find out before the next programme comes off the HTA queue?

If your most experienced regulatory director were to leave the firm next year, what would happen to the three programmes she is currently covering? How much of her agency negotiation history and HTA body knowledge is currently accessible to anyone else?

What is your current time from CHMP opinion to first national HTA submission? What would a thirty percent reduction in that timeline be worth in market access position and first-mover pricing in your lead therapeutic area?

How many programmes are currently queued or sequenced because your specialist bench cannot run them in parallel? What is the cost of that sequencing in delayed market access per programme?

Which member of your specialist team is already working the way the rest of the bench will need to work by 2028? What would it take for that to be the default across your regulatory, market access, and medical affairs operations?

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

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