

Twelve People, No Labs

The virtual model can carry a compound to an Investigational New Drug application, provided you never outsource the four functions that cannot be bought.

DAVID CRAIG | D. CRAIG CONSULTING LLC | JULY 2026

The call has a recognizable shape. A project manager at a contract research organization phones on a Wednesday afternoon to say a study start has moved by three weeks, and the reason offered is scheduling. Two further calls surface the actual reason. The test article arrived with a certificate of analysis that did not match the specification written into the protocol, and the receiving group quarantined the material rather than escalate it.

Nobody did anything wrong. The analytical group issued the certificate it was contracted to issue. The shipper shipped. The receiving group followed its quarantine procedure exactly as written, and the project manager reported the schedule impact once it was confirmed rather than when it was suspected. Four parties each behaved correctly inside their own scope and the program lost a month.

That is the characteristic failure of the virtual development model, and it is not a vendor failure. It is an interface failure. Interfaces are the one thing no vendor is contracted to own.

THE SHORT VERSION

The argument in full

A development organization of roughly 12 people, owning no laboratories and no animal facilities, can take a small molecule from lead selection to an Investigational New Drug application. I have watched that model work and I have watched it stall. The difference has almost never been the science, and it has almost never been the quality of the vendors.

The model rests on a single distinction. Outsource capacity and instrumentation, which the contract market supplies better and cheaper than an early sponsor can build them. Never outsource judgment, of which there are four kinds: the integrated development plan, the regulatory argument, the quality decision, and the interfaces between vendors. Every failure I have seen traces back to one of those four having drifted outside the sponsor.

The management problem is therefore not vendor performance. Vendors in this market are audited, qualified, and generally competent. The problem is that a fully outsourced

program contains more interfaces than an integrated one, that no contract covers an interface, and that the default information architecture of an outsourced program delays bad news for entirely rational reasons.

What follows is the disposition of functions, the four that never move, and the specific mechanics by which an uncomfortable fact reaches the sponsor in days rather than at the next quarterly review. The uncomfortable part, stated up front: the model trades fixed cost for coordination load, and the coordination load lands on one person. Where that person's attention is divided across other obligations, the model has a failure mode built into it that no amount of vendor quality will offset.

PART ONE

What the model actually is

Virtual is not a synonym for small. A small integrated company owns benches, instruments, and the people who run them, and its constraint is headcount. A virtual company owns contracts, and its constraint is attention. The two look similar on an organization chart and behave nothing alike in practice.

Three consequences follow from that difference, and each of them is felt within the first year.

Capacity is elastic upward and rigid downward. A virtual sponsor can add a study faster than an integrated group can, because adding a study is a purchasing decision rather than a hiring decision. The reverse does not hold. Once a study is booked into a vendor's calendar and the slot is paid for, no amount of urgency compresses it. Speed is bought before the work starts, never during it.

Fixed cost is low and switching cost is high. The absence of facilities is the advertised benefit. The unadvertised cost is that changing vendors mid-program requires a technology transfer, which is measured in months and paid for twice. A sponsor that selects badly at the start is not free to correct cheaply, which makes vendor selection a higher-stakes decision in the virtual model than in the integrated one.

Institutional memory lives in documents or it does not exist. An integrated group carries knowledge in the people who did the work and can be asked a question in a corridor. A virtual sponsor has no corridor. Every assumption, every rejected alternative, and every reason a specification reads the way it does has to be written down at the time, because the person who knew it works for a company that is no longer under contract.

A virtual company owns contracts, and its constraint is attention.

PART TWO

What moves out

Nearly all execution moves out, and it should. The contract market for preclinical development is deep, mature, and audited, and buying into it is not a compromise made for want of capital. A contract research organization runs a given bioanalytical method continuously across many programs. An in-house group at an early sponsor would run it four or five times. Repetition is what produces reliability, and repetition is precisely what a small sponsor cannot generate on its own.

The table below sets out the usual disposition for a small-molecule program.

Function	Disposition	Reason
Synthesis and scale-up of active pharmaceutical ingredient	Moves out	Deep vendor market, capital intensive to build, and the sponsor gains nothing by owning reactors.
Analytical method development and qualification	Moves out	Instrumentation and repetition. The vendor runs the method continuously and the sponsor would not.
Formulation and drug product manufacture	Moves out	Requires Good Manufacturing Practice facilities that no preclinical sponsor should own.
Toxicology and safety pharmacology execution	Moves out	Good Laboratory Practice accreditation, animal facilities, and qualified study directors.
Bioanalysis and pharmacokinetic sample handling	Moves out	Volume driven, heavily instrumented, and audited as a matter of course.
Regulatory publishing and submission assembly	Moves out	Specialized software and format expertise with low judgment content.
The integrated development plan and critical path	Stays in	No vendor has line of sight across every workstream, and each optimizes its own.
The regulatory argument	Stays in	The agency asks the sponsor, and the sponsor answers in its own name.
Quality decisions on deviations	Stays in	Cannot be delegated to the party whose study is in question.
Vendor-to-vendor interfaces	Stays in	Nobody is contracted to own them, so they are owned by the sponsor or by no one.

Table 1. Disposition of development functions in a fully outsourced small-molecule program. A biologic redistributes several of these rows, particularly manufacture and analytical comparability.

The case against the model deserves to be stated fairly, because it is real. An integrated group iterates faster on an unexpected result, for the ordinary reason that the chemist and the biologist share a building and can revise an experiment the same afternoon. A virtual sponsor pays for its flexibility in latency. Every clarification is a scheduled call, every change is a contract amendment, and the accumulated delay across a program is not trivial. Anyone choosing the model should choose it knowing that latency is the tax, and that the tax is levied on exactly the moments when speed matters most.

PART THREE

What never moves out

Four functions stay with the sponsor under all circumstances. Each of them can be advised on, drafted for, and supported by consultants. None of them can be transferred.

The integrated development plan stays with the sponsor. Chemistry, manufacturing, and controls has a plan. Toxicology has a plan. Regulatory has a plan and clinical has a plan, and each is internally coherent and optimized for its own scope. The critical path across all of them exists in exactly one file, and that file belongs to the sponsor. A vendor asked to comment on the plan will comment on its own segment, correctly and helpfully, and will have no view at all on the dependency that actually governs the timeline.

The regulatory argument stays with the sponsor. A regulatory consultant drafts. A publisher assembles. The argument for why a particular molecule should be administered to a human being, at a particular starting dose, with a particular monitoring plan, is the sponsor's argument. An agency directs its questions to the sponsor and expects the sponsor to answer without a relay. A principal who cannot defend the safety rationale unaided has outsourced something that was never available for purchase.

The quality decision stays with the sponsor. Deviations happen in every study. Someone then decides whether the study remains fit for its purpose, whether the affected data can support the submission, and whether the work has to be repeated. That decision cannot sit with the party whose study is in question. The conflict there is structural rather than personal, and it does not resolve because the relationship is a good one.

The interfaces stay with the sponsor. This is the one that surprises people, and it is the source of the failure described at the opening of this piece. Test article transfer, specification alignment, data format handoffs, assumption inheritance from one study into the design of the next: all of it lives in the space between vendors. No statement of work covers the space between vendors. A statement of work by construction describes one party's obligations. The space is owned by the sponsor or it is owned by nobody, and programs lose more time there than anywhere else.

No statement of work covers the space between vendors.

PART FOUR

How you hear bad news early

The default information architecture of an outsourced program is designed to delay bad news, and not for cynical reasons. A project manager is trained to report confirmed facts, because reporting an unconfirmed one that later dissolves damages the vendor's credibility. Confirmation takes time. While the fact is being confirmed it is also aging, and the sponsor's options narrow with every day it ages. The problem is structural and the fix is mechanical.

Contract for the escalation, not only for the deliverable. Write into the statement of work an obligation to notify the sponsor within one business day of any event that could affect a study start or a report date, on observation rather than on confirmation. This costs nothing to negotiate before signature. It is very close to impossible to add afterward, and the moment you want it is the moment you cannot have it.

Know the person doing the work, not only the person managing the work. Ask for the study director, the analytical lead, and the process chemist by name on the kickoff call, and speak to them directly at least occasionally thereafter. Project managers exist to protect scientists from sponsors, which is a legitimate function and also a filter. Once the working level knows the sponsor as a person rather than as an account, the working level calls.

Hold a short weekly call and never cancel it. The value is not in the agenda, which will often be thin. The value is that a weekly cadence gives an uncomfortable fact a scheduled place to surface within five days. A monthly call gives that same fact 30 days to sit, and by then the decision it required has usually been made by default. Canceling the call when there is nothing to discuss is the specific mistake, because the weeks with nothing to discuss are what make the call safe to use.

Ask the question that has no comfortable answer. Asking whether a program is on track invites the answer yes. A yes-or-no question invites a yes. Asking what would have to be true for this date to slip produces an entirely different conversation, because it gives a careful person permission to describe a risk without asserting a failure. The best information I have ever received from a vendor came from that question or a close variant of it.

Read the raw data, not only the report. Look at the chromatograms, the individual animal records, and the batch documentation. You will not catch what the study director catches, and that is not the purpose. The purpose is to catch the thing nobody flagged because each party assumed another party had already flagged it, and that failure mode is invisible in a summary report by design.

Instrument every handoff. Each transfer between vendors gets a named owner on the sponsor side, a written specification agreed by both the sending and the receiving party before anything ships, and a confirmation of receipt checked against that specification. Most interface failures are not negligence. They are a specification that two competent parties read differently, and a five-minute confirmation step catches nearly all of them.

None of this is sophisticated and all of it is expensive in the only currency the model is short of. Running a program this way costs roughly a day a week of the principal's time, spread across short conversations that cannot be batched and cannot be delegated to someone without the authority to make a decision on the call. That day is the least compressible obligation in a virtual sponsor's week, and it is the first thing to be sacrificed when other demands arrive.

A yes-or-no question invites a yes.

CLOSING

What the model is actually buying

The virtual model is usually sold as a cost structure, and the cost structure is the least interesting thing about it. What the model actually buys is the ability to stop.

An integrated organization that owns benches and employs the people at them has a structural reason to keep a marginal program alive, because terminating it means terminating employment for scientists whose work was competent and whose data were simply not good enough. That pressure is rarely acknowledged and it is always present. A virtual sponsor can close out a statement of work, absorb a cancellation fee, and redirect within a quarter, with no one's livelihood attached to the decision. That is a governance advantage rather than a financial one, and over the life of a program it is worth more than the savings on facilities.

The corollary is less comfortable. If stopping is structurally cheap, then the discipline of actually stopping becomes the substance of the job, and the principal is the only party to the arrangement with any incentive to exercise it. Every vendor in the chain is paid to continue. Every consultant is paid to continue. The one person holding the integrated view is also the one person whose conviction created the program, which is not an ideal arrangement and is the arrangement the model produces.

So the model does not make development easier, and anyone selecting it on that basis has misread it. It relocates the difficulty: from the bench to the interfaces, from headcount management to attention management, and from the question of whether the organization can execute to the question of whether one person can hold four kinds of judgment at once without dropping any of them. That is the trade being made. It is a good trade for a small number of programs and I have no evidence that it remains one at scale.

ABOUT THE AUTHOR

David Craig advises rare disease and specialty therapeutics companies on development strategy and capital formation through D. Craig Consulting LLC. He is the author of *The New Rules of Biotech*. He also serves as chief executive of a preclinical therapeutics company, and readers should weigh that operating role when assessing the arguments made here. He holds a Bachelor of Science in Pharmacy and a Master of Business Administration.

NOTE ON SOURCES

Claims in this piece are graded below. Where a figure could not be verified to a standard the reader could check, no figure is given.

HIGH CONFIDENCE

The content and format requirements for an Investigational New Drug application are set out in Title 21 of the Code of Federal Regulations, Part 312. The framework governing which nonclinical studies are expected to support human trials, and in what sequence, is set out in International Council for Harmonisation guideline M3(R2). Both are published primary regulatory documents and are traceable.

HIGH CONFIDENCE

Good Laboratory Practice requirements for the conduct of nonclinical safety studies, including the role and responsibilities of the study director and the handling of protocol deviations referenced in Part Three, are set out in Title 21 of the Code of Federal Regulations, Part 58.

DIRECTIONAL ONLY

Published estimates of the duration and total cost of a package of studies enabling an Investigational New Drug application vary materially by modality, indication, and scope, and different databases produce different figures for the same period. No such figure appears in this piece for that reason.

INDICATIVE, NOT VERIFIED

The claim in Part Two that a vendor running a method continuously achieves greater reliability than a sponsor running it a handful of times is corroborated in direction by method qualification practice and by routine audit findings. The magnitude of that difference is not verifiable from published sources and no magnitude is asserted.

DELIBERATELY EXCLUDED

Cost and speed multiples comparing virtual to integrated development models circulate widely and are excluded here. The published figures do not disclose methodology, sample construction, or the development stage at which the comparison was drawn, and several appear to trace to a single unsourced original.

THE OPEN QUESTION

Whether the advantages described here survive past a small number of programs and past first-in-human dosing. Everything in this piece is observed on the near side of the clinic and at low program count. A second and third program consume the same principal's attention, and attention rather than capital or vendor capacity is the binding constraint in this model. I cannot establish from this vantage where that ceiling sits, and I have not found a published account that establishes it either.