



R&D analytics organization: Getting the structure right

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There is an open secret circulating in the C-suite corridors of life sciences R&D organizations. Even as increasing amounts of dollars have gone into R&D, the productivity of these dollars has consistently been on the decline. Ten years ago, it was about a 7% decline, and the past decade has only seen that number grow. The picture only gets more dismal the further into it we look: 90% of drug candidates fail in clinical trials; when assets reach trials, more than 80% fail to enroll; and 85% of trials are delayed or fail post-enrollment. These issues are particularly prevalent in big pharma companies—in fact, a disproportionate number of new breakthrough assets are now discovered by emerging pharma companies.

What's behind this dire productivity picture? Lack of analytically driven decision-making is one of the biggest reasons for R&D's productivity decline. It's common for clinical trial sites to be chosen based on the "gut feel" of clinical operations leads and for data to exist in silos between the different parts of the R&D organization. It's also common for protocols to be designed with undue patient burden, leading to patient drop-off and trial failure.

Of course, R&D executives are keenly aware of this situation, and many have correctly identified that data and analytics should drive decisions. A ZS study found 60% of top pharma companies have started analytics transformation programs in either the drug development or research arms. Some have started both. Still, many C-level executives struggle with the fundamental question of how to set up their new or improved analytics organization. Should it be independent, or should it be housed within the clinical or research subfunctions? Both have their merits and drawbacks.

This paper will focus on describing the analytics structures and recommendations for R&D analytics organizations as a single entity. However, most of the research revealed possibilities on the development side of R&D. This focus is in sync with how organizations spend on R&D operations and analytics, where three quarters of the spending happens on the development side.

R&D analytics organizations: The structural archetypes and the pros and cons of each

ZS researched top pharma companies and found R&D analytics organizations across the industry can be broadly classified into three archetypes: centralized, decentralized and hybrid. In a centralized model, companies consolidate their analytics activities and resources in a central group catering to the needs of all business line functions (e.g., global drug development organizations). In a decentralized model, companies embed analytics in each business function (e.g., with global clinical operation group running their own analytics). A hybrid model is somewhere between the centralized and decentralized.

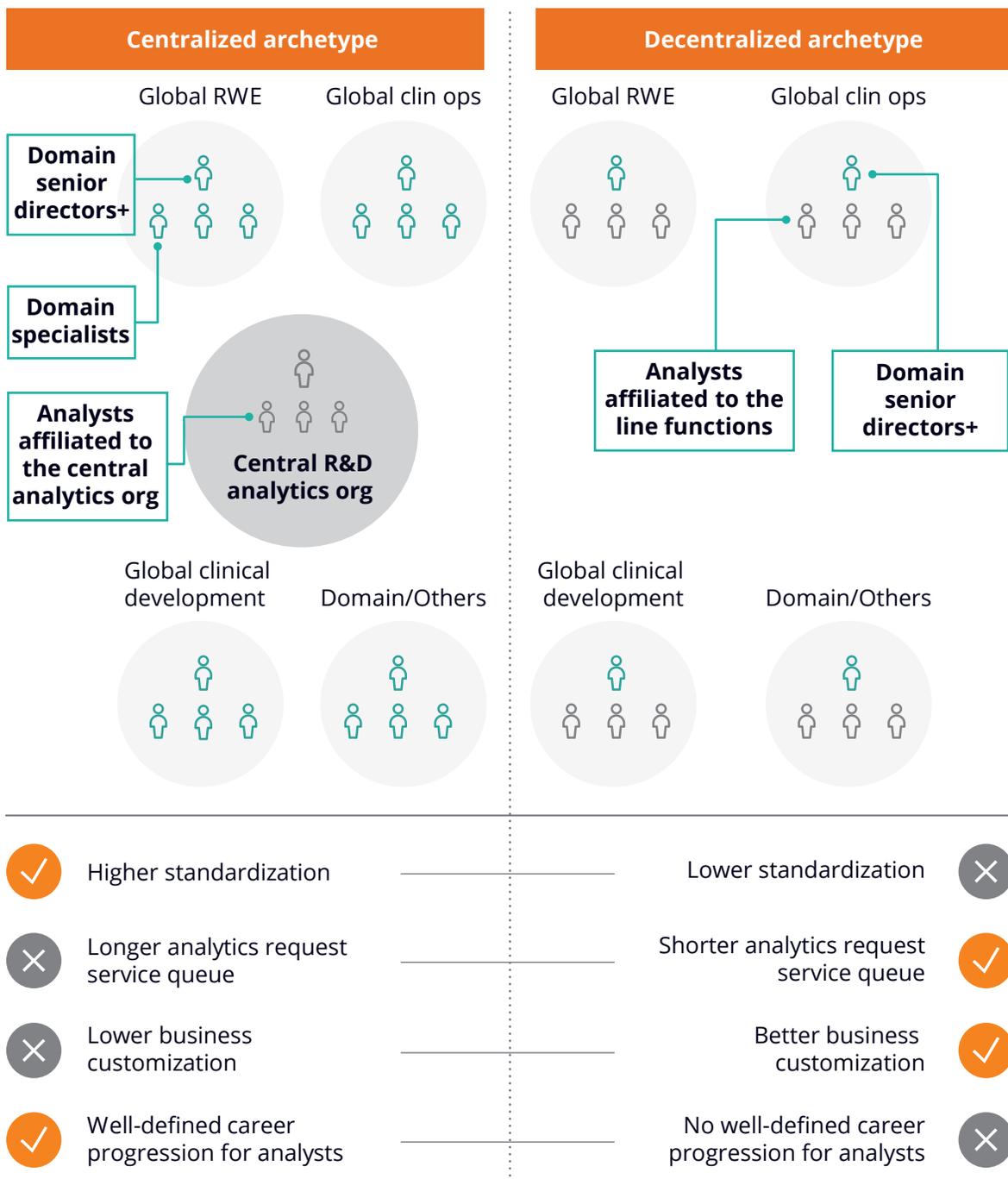


Recently, a mid-sized U.S. pharma company experienced a high volume of protocol amendments in the trial startup stage. The clinical operations (clin ops) team wanted to diagnose the reasons for this. The initial strategy was to classify protocol amendments based on their nature and reason. This company had a centralized R&D analytics organization with a C-suite directive to centralize analytics under this group. The clin ops team approached them for quick insights. The central analytics organization had central data architecture, innovative tools, highly standardized algorithms and well-trained analysts at their disposal. They employed advanced algorithms to identify reasons for the protocol amendments. This model had lots of merits, like use of a consistent data source and highly advanced techniques. But it also had some downsides. For example, the central analytics team missed the basic tagging of amendments as “avoidable” versus “unavoidable,” resulting in overstating results around unavoidable amendments—something that would have been one of the critical variables the clin ops team would have analyzed had they executed this. Also, the central analytics team took a while to work on this analysis due to having other priorities and the clin ops team lost a significant amount of time as a result.

Now, let’s see how things would have played out had the analytics request originated at a company with a decentralized analytics model. The clin ops team would have had their own analytics resources, data and tools to work with. They would have been able to kickstart the work right away and include required nuances such as classifying amendments as “avoidable” versus “unavoidable.” However, that solution would have lacked the highly advanced techniques, statistical robustness and intuitive visualizations implemented by the central organization above. Sourcing the right data would have been a potential issue as well.

FIGURE 1

Centralized and decentralized archetypes





How top pharma organizations are structured, and how they're making an impact with analytics

We researched ten of the top pharma companies and found a wide variety of analytical structures at play, with three to four companies landing in each category.

FIGURE 2

Companies span a wide range on the spectrum, between highly centralized and decentralized



FIGURE 3

Range of R&D customers served by the analytics organization

Company	Discovery	Early Dev	Asset Evaluation Pipeline Strategy	Portfolio Management	Clinical Trial Design and Operations	Resource Management	Digital Enablement	Real World Data, Evidence	Medical Affairs	Performance Reporting
Company J										
Company I										
Company F										
Company H										
Company G										
Company C										
Company E										
Company D										
Company B										
Company A										

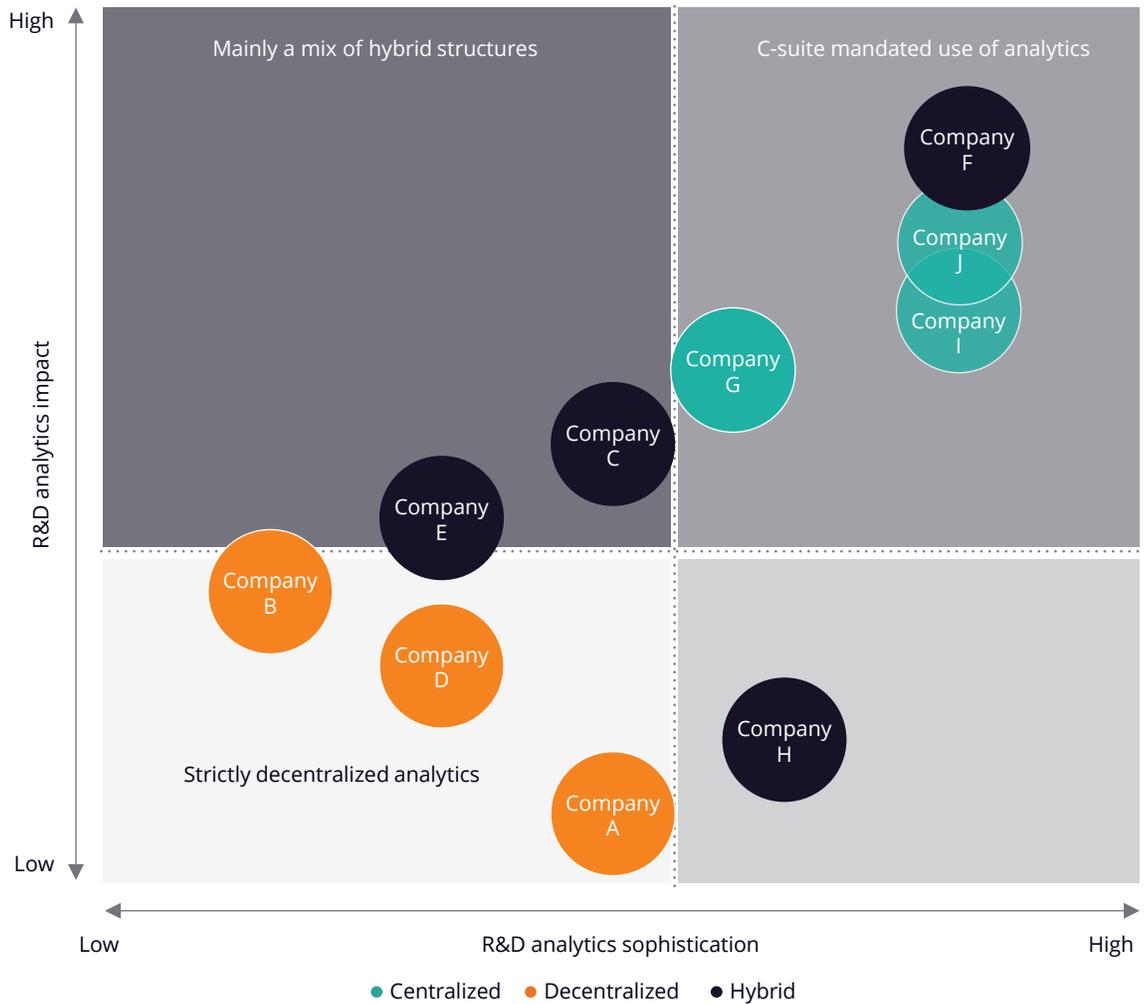
The study also reveals how the scope of analytics across R&D can vary, but it’s typical for centralized analytics to cover clinical development, with more variability in ownership of real-world evidence (RWE), digital and medical. It’s less common for centralized analytics to cover discovery.

To validate the research, ZS also leveraged secondary analytics using multiple productivity metrics to measure R&D sophistication and impact, such as:

- Average cycle time across phases
- Average cost of trials across phases
- Average enrollment rate across phases
- Number of assets entering phase I and number of assets launched

FIGURE 4

How companies are faring on analytics sophistication and maturity vs. impact on R&D organizations



Three quadrants are particularly interesting:

Quadrant 1 (top right) - Companies in this quadrant are majorly controlled by C-suite mandated analytics use.

For these companies, artificial intelligence (AI) and machine learning (ML) continue to be key priorities, which companies are continuing to build and scale. Some other noteworthy details:

- Across companies, R&D analytics leadership are at the VP and SVP level, and they are given a seat at the table with other R&D leaders to drive key decisions.
- Even with a centralized R&D analytics organization, it's common for some analytics capabilities to remain with the business—true centralization is very hard to achieve.
- Most of these companies have descriptive reporting managed by IT. Disruptive innovation typically is an organizationwide cross-functional initiative, typically powered through digital, digitization and platforms.
- Few of these companies are actively publishing and presenting analytics cases and impact in industry forums.

Quadrant 2 (top left) - This quadrant sees a mix of companies with a hybrid way of conducting analytics, with divided responsibilities between center and functional lines and those with a decentralized R&D analytics structure. Some other noteworthy details:

- Across hybrid and decentralized analytics archetypes, analytics VPs lead the line functions rather than central hubs to help to bring in agility, speed of decision-making and reduced turnaround times.
- There's good collaboration and engagement with the central team. The central team is also responsible for maintaining data integrity and data management.
- Some analytical teams are focusing on building their next-generation analytical capabilities and are empowered with the right funding and an appetite for experiments.
- The use of AI and ML is usually sporadic, lacking vision.

Quadrant 3 (bottom left) - All companies in this quadrant showcase a high degree of decentralization, where analytics is almost always happening in a fragmented way.

- Across these companies there's usually ambiguity around what leverage advanced analytics or AI can provide to support R&D goals. There's a lack of trust on how analytics can drive value, leading to line functions doing ad hoc analytics in response to operational needs. Adoption of any enterprise tool or accelerator to fire analytics is slow, and, IT is tasked to elevate analytics maturity.
- Data and information continue to be siloed, dispersed, incomplete and unreliable in this type of set up. There's limited use of technology infrastructure to support analytics.

Key considerations to ensure alignment with broader R&D goals

Our research shows the drivers for centralized analytics structure originate top down, where there's an intent to push a central mandate or a C-suite vision to embed analytics across the drug development continuum in a consistent way. Drivers for decentralized models include having domain-richness in analytics insights and a quick throughput for analytics services.

As organizations think about their analytics structure, they'll want to consider some fundamental questions to align with broader R&D goals:

- **Executive mandate:** Is there an executive mandate with a vision to embed analytics across the R&D life cycle in a consistent way?
- **Control:** To what degree does the organization want to control enterprise analytics and tech investments, data fabric and capability enablers so users get a singular experience?
- **Speed of insights:** Can the organization wait for an analytics answer (throughput)? And what's its appetite to process massive volumes of analytics requests?
- **Domain-richness:** What's the domain flavor intensity the organization wants its analytics to be? And to what degree is vanilla R&D analytics acceptable?

4 trends that will transform R&D analytics in the coming decade

For those stakeholders with an eye toward the future, there are four trends we believe will transform R&D analytics in the coming years:

1. **Leveraging AI and ML to drive action:** Descriptive analytics will be supplemented and replaced by AI and ML predictive analytics to, for example, create "one-click" protocol authoring.
2. **Digitization and digitalization of trials:** Virtual clinical trials leveraging wearables, remote sample collection and patient monitoring will usher in a new age of digitally enabled trials.
3. **Novel real-world data (RWD) sources to improve trial outcomes:** RWD and novel data sources across the drug development cycle will improve trial design and quality and cut trial times.



4. Increased speed of insights: R&D functions will demand ever quicker answers as seen during COVID-19 when organizations had to create site feasibility alternatives quickly.

Many of these trends will benefit from a centralized analytics organization with the investment muscle and talent upgrade to excel in these new areas. Understanding which R&D to purchase, how to stand up new AI models and how to create an ML operations environment all require a significant talent upgrade and investment. However, if analytics organizations are too centralized, they move too far from business realities. Without significant closeness to R&D stakeholders, those AI models may be rejected as irrelevant, regardless of sophistication.

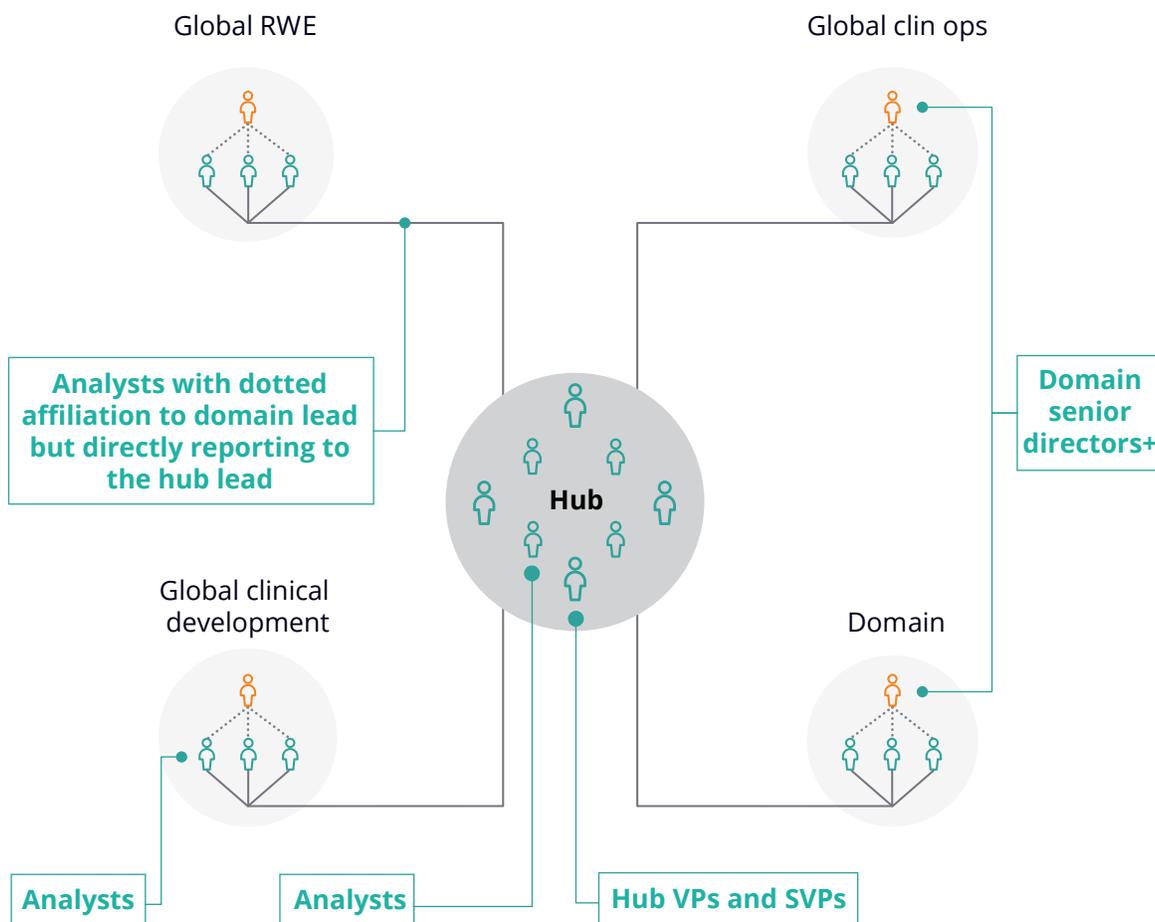
On the other end, decentralized organizations struggle to implement C-suite mandates consistently and lack control over key enterprise investments, including data. The answer has to lie in between these two poles. There has to be a central function to elevate key skills and focus investment in new areas close enough to the business to remain agile and relevant.

The hub-and-domain model

The hub-and-domain model captures both the need for investment in new skills, technology and data (favoring a centralized structure) with the need for speed and domain-richness to the R&D stakeholders (favoring a decentralized structure).

FIGURES 5

Hub-and-domain model representation, indicating the role of analysts



As the figure below shows, the hub drives the data strategy, supports data governance and ensures consistent use of tools, methods, standards and resources across the organization. The hub drives new AI and self-serve capabilities and can take on advisory work (for example, deciding how to create a digital clinical strategy). The hub is also responsible for training, developing and rotating analysts across the domains. The “spokes,” or domains, are embedded into the R&D functions. They tackle custom analytics to address the most pressing and immediate problems, enable data-driven decisions and allow for a “seat at the table” with the key R&D decision-makers.

FIGURE 6

Hub vs. domain responsibilities

Item	Hub responsibility	Domain responsibility
Analytics governance (which analysis will be delivered by the hub vs. the domain)	✓	
Advisory services (consulting, thought leadership and research)	✓	
Information management (monolithic data governance and data fabric)	✓	
AI and ML, digital tools and technology (enterprise scaling enablers)	✓	
Reporting (regular reporting, publishing and maintenance)	✓	
Analytics knowledge management (analytics framework and methodology for reusability)	✓	
Analytics delivery (ad hoc analysis and stakeholder key business questions analysis)		✓
Custom projects (report and dashboard development and advanced analytics development)		✓

Robust people strategy

In this revolutionary hub-and-domain model, we think the analyst can be hired, trained, paid and managed by the hub. This will ensure the hub harmonizes the analyst onboarding experience and offers supporting career trajectories in the organization for analysts to grow and evolve.

However, analysts in this model will be working closely with the domain, reporting to the day-to-day project manager affiliated with the projects run by the domain. The hub will still retain some ownership on the analyst's project or program placement from a medium- or long-term lens.



A model to withstand future headwinds

Analytics will be a key driver of R&D excellence over the next decade, even as analytics itself evolves. The analytics of the future will drive more predictions, use more data and enable new models (e.g., fully digital trials)—shrinking timelines and speeding up the pace of the industry. It's imperative C-suite R&D leaders decide how to structure their analytics organization in order to take full advantage of this future.

Our recommended structure is the hub-and-domain model. This model captures the need for new capabilities in AI, data, technology and digital, which can be focused and harnessed in the hub while also deploying analysts close to R&D stakeholders in the domains. This allows analytics transformation while also keeping the overall analytics organization relevant and agile—both important considerations for companies intending to lead a rapidly evolving industry where technology is only getting more complex. Those companies not planning to leverage a structure that creates possibility instead of limiting it, may find themselves in the unenviable situation in the future of having to restructure and do the work their competition has already taken care of long ago.

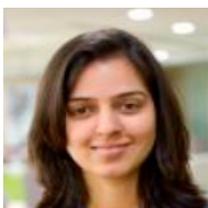
About the authors



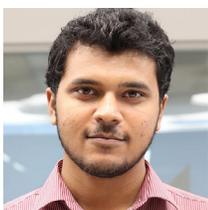
Rohan Fernando is the managing principal for East Americas. Rohan is also on ZS's Shareholders Council (Board) and is the chair of the Client Services Council. He has collaborated with over 50 pharmaceutical, medical technology and biotech companies. Rohan has worked across several topics, from drug discovery to pharma commercialization. He has helped clients grow into new areas as well as co-creating innovations across drug development, the evolution of pharmaceutical business models and commercialization strategies. Rohan is an invited speaker at numerous conferences.



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