WHITE PAPER

Pharma's GCP Analytics maturity evolution

Best practices and quick wins for the R&D organizations to improve overall effectiveness

By Jonathan Rowe, Arup Das, Ankita Praharaj, Ektaa Sharma and Deepak Nandan

Effective quality risk management is fundamental to ensuring the protection of human subjects and the reliability of clinical trial results. Good clinical practice (GCP) quality risk management supports the effective delivery of clinical development programs and, ultimately, the delivery of treatments to patients. Analyzing, diagnosing and predicting risk are core to effective quality management. In addition, the landscape of quality risk management in clinical development continues to evolve as regulatory authorities adopt elements of risk management to promote proactive quality management.

Our white paper explores the maturity of the top pharma companies in their use of GCP quality analytics to drive scientific decisions. Through detailed desk research and industry interviews, we answer three questions:

1. What is the framework used to analyze the maturity of top pharma companies, and how do they fare on the maturity scale?
2. What are some of the frontier practices in organizations with high GCP analytics maturity?
3. How can companies leapfrog their GCP quality analytics maturity?

Why is good clinical practice (GCP) quality important?

In the life sciences R&D industry, the cost, timeliness and quality of clinical trials are three important factors that help companies judge the productivity of their R&D organizations. Quality in clinical development has been described as the absence of errors that matter. In good clinical practice (GCP), quality is focused on ensuring that human subjects are protected and that clinical trial results are reliable, with minimal or no significant errors.

Yet quality analytics are often overshadowed by the more demanding asks of optimizing costs and getting drugs to the market faster. This rush can have serious repercussions, such as misleading outcomes and safety issues. There is a definitive need to oversee the performance of GCP quality to ensure quality oversight and quality risk management. Today, GCP quality analytics maturity is far from uniform across the industry. While some organizations have well-developed frameworks for effective quality and quality risk management, others have only disjointed systems, fragmented data and ad hoc analytics.

Understanding the GCP maturity spectrum across pharma companies

We developed a framework consisting of six dimensions to evaluate the maturity of GCP quality analytics across the industry (Figure 1). Based on our framework, we interviewed key GCP quality analytics personnel from some of the top-10 pharma companies. We saw GCP quality analytics maturity across a spectrum, ranging from disjointed analytics to a vision to empower with "first in industry" disruptions in each of the six dimensions.

FIGURE 1:

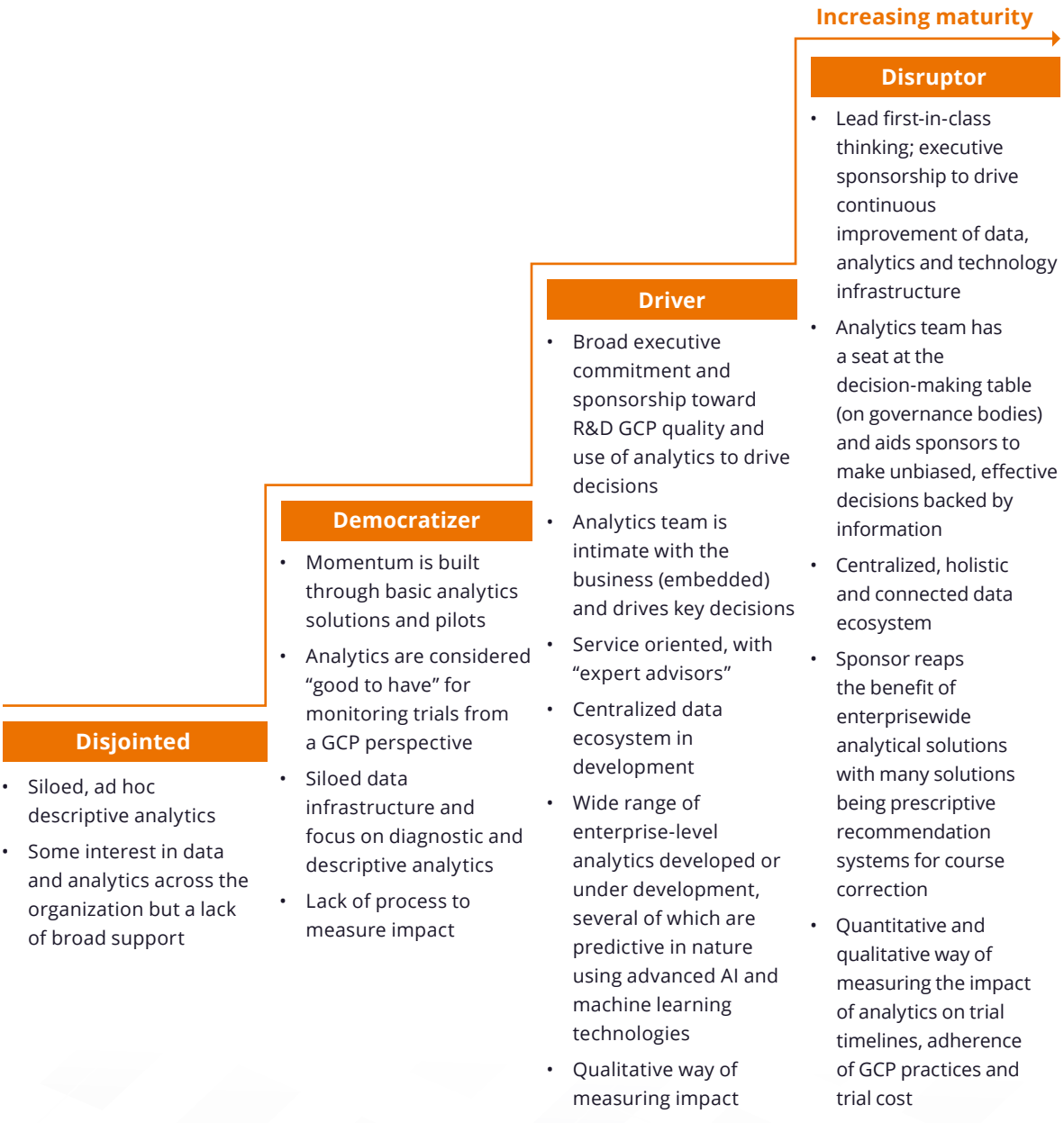
ZS's 6-dimension framework for evaluating GCP quality analytics

Vision and culture	• How does GCP quality fit into the R&D vision of the company? • Does the organization understand the value of using analytics to drive data-led scientific decisions? • Do we have executive sponsorship and support to drive adoption of analytical solutions and insights?
Organizational design and skill	• Where does the GCP quality analytics organization reside within the company? – Is it within a centralized analytics organization or is it embedded within a business function? • How many dedicated resources are working on GCP quality analytics • What are the different mix of skills within the team?
Operating model	• How are analytics problem statements defined? • Are these problem statements defined by business stakeholders, the people who are focused on GCP analytics within the organization or by co-creation? • Do the analytics team members or the analytics organization have a seat at the table? • Are there set governance mechanisms and escalation pathways?
Data strategy and infrastructure	• Is there a clear data strategy to procure, create, enrich, integrate and share the data? • Are the key data sources and metrics housed within an enterprise-level data lake? • Does the team have access to data for both in-house and outsourced trials?
Analytics infrastructure	• What is the range of analytics being implemented and used (diagnostic, descriptive, predictive, prescriptive)? • Does the team have the ability to extract insights from both structured and unstructured data sets? • How easily does the team adopt new technology and tools available in the market (for example, use of AI and machine learning to predict audit or inspection findings)?
Organizational impact	• How do you measure the impact of the analytics solutions that are built and deployed? • How are the solutions adopted by the broader organization? • Is there a clear value of measure (quantifiable impact) delivered by analytics (for example, risk mitigation, trial timeline delay avoidance, business satisfaction)?

Once we were able to evaluate these companies, we developed a four-step analytics maturity scale to classify the pharma companies in each of the six dimensions. The four steps in the scale correlate with the strategic choices the companies made for their GCP analytics organizations and the maturity level as an outcome (Figure 2).

FIGURE 2:

The ZS 4-step analytics maturity scale classifies each level pharma organizations can achieve

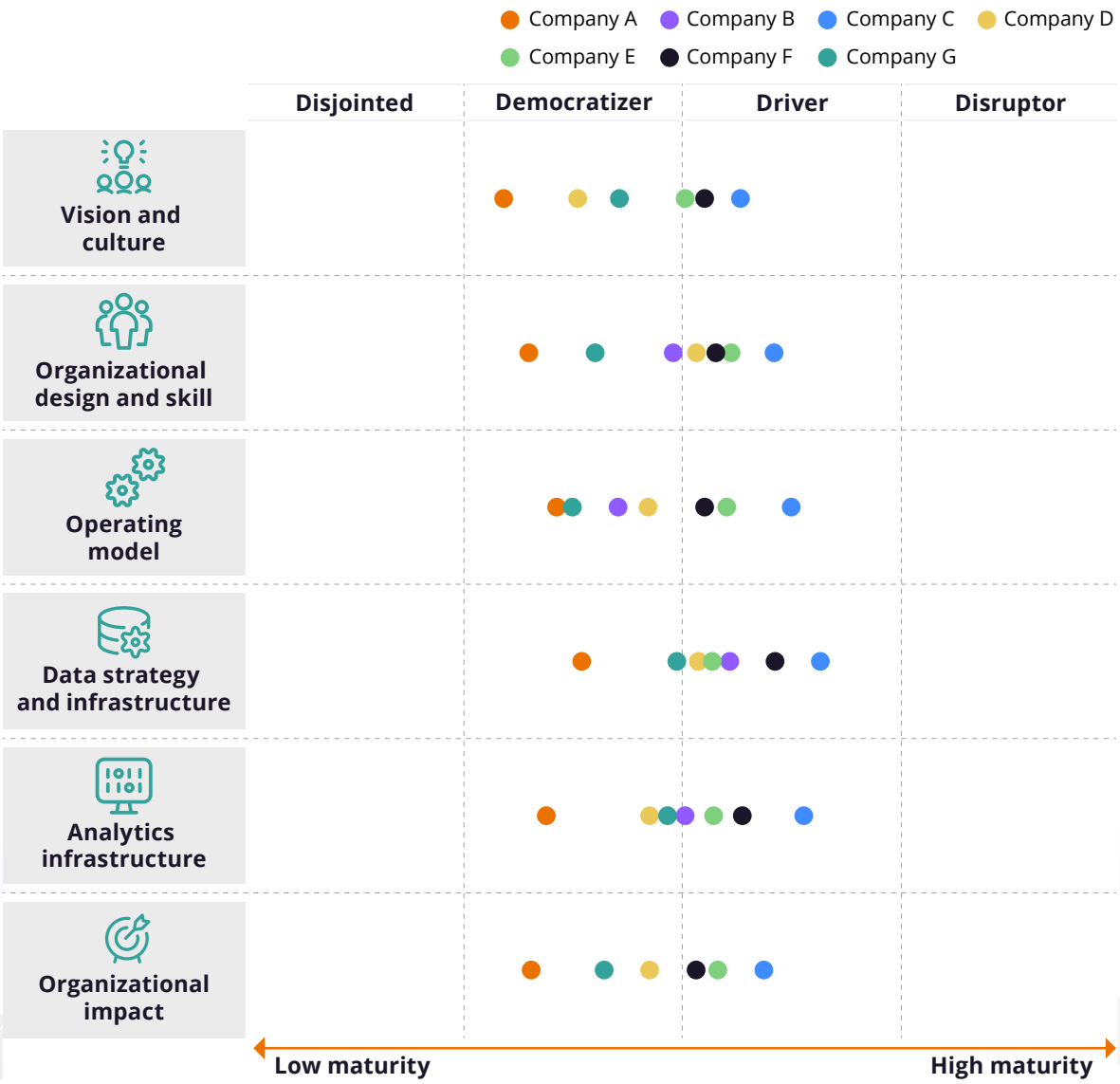


GCP analytics maturity benchmarking results: Our assessment

Through our interviews of key GCP quality analytics personnel from select top-10 pharma companies, we developed assessments of the industry maturity on each of the six dimensions in Figure 3. We found that GCP quality analytics maturity for most sponsors lies in a band between level 2 and 3 of the maturity scale. In most sponsors, we observed that trial performance analytics (such as timelines and enrollment rate) had a higher maturity as compared to the GCP quality analytics.

FIGURE 3:

Our assessment of the companies across the dimensions of the ZS GCP analytics maturity framework



Our assessment found:

No centralized analytics teams exist. In almost all the companies we interviewed, we found that there is no centralized group focused on analytics. The GCP analytics usually sit within the R&D quality group, with some dotted-line reporting structure to the development group.

Outsourcing reduced analytics maturity. Data strategy and infrastructure maturity was lower for sponsors that outsourced most of their trials, resulting in lower analytics maturity. Some sponsors highlighted that the focus on GCP quality analytics was a function of the importance given by global development leads. They have seen analytics maturity regress when there are leadership and organizational changes (especially in terms of vision and culture, organizational design and skills, operating model and impact).

There is no consistency in roles. The role of the individuals in the analytics group varies significantly. Sometimes the people focused on GCP quality analytics become translators between the business and IT (such as can be seen in Company A in the figure above). In other cases, these folks are more involved with the business and enable change management (such as Company C and F).

Generative AI adoption is happening. Almost all the sponsors have adopted generative AI in some form, but mainly for productivity gains (summarizing inspection findings, SOP authoring, etc.) rather than critical decision-making like the grading of findings.

Leading practices that GCP-mature sponsors follow

Our research found several key practices that more-mature GCP sponsors followed.

Executive sponsorship. The most successful organizations have a mandate to use analytics for decision enablement from senior leadership. Apart from this, their leadership also enables forums and collaboration mechanisms where people from different groups can come together and share ideas. For example, one sponsor had an AI center of excellence that partnered with the GCP quality analytics organization to develop advanced analytics capabilities.

Another sponsor had a network of analytics professionals (even though not specifically focused on GCP quality) who frequently connected to share ideas related to analytics problem-solving, change management and stakeholder adoption. In many cases, the sponsors have helped their team members learn from the industry by sponsoring participation in one or more quality analytics industry consortiums or forums. Many sponsors are in touch with one or more external scientific communities (like the IMPALA Consortium and Tufts) to learn and share best practices.

Joint ownership and accountability. The sponsors on the higher end of the maturity scale have established a governance model that empowers different groups and stakeholders to collaborate effectively. Some best practices of these sponsors are:

- **A formalized process to develop potential analytical use cases.** Both analytics and IT teams have a seat at the table for developing and suggesting use cases.
- **Adoption and stakeholder change management support.** This is considered right at the beginning of the project, and the analytics professionals also help embed this into the process (for example, embedding amendment occurrence prediction analysis into the protocol review process spearheaded by the therapeutic area lead).
- **There is a growth path for the individuals involved in the GCP clinical quality analytics.** Many of them get integrated within the business or move to enterprise digital functions.

Centralized and harmonized data ecosystems. Analytics maturity seems to follow the maturity of data infrastructure at the sponsor. Currently, no sponsor has a perfect data and technology infrastructure solution, but a few sponsors are investing significant effort or budget in these areas. The sponsors who are investing in building a centralized connected data ecosystem are likely to reap benefits in the longer term, as any advanced data science solution (like generative AI) will also need a strong technology infrastructure.

Use of advanced analytics techniques. Analytics maturity varied significantly between sponsors. With generative AI entering the scene, the most advanced sponsors already have proof of concepts underway for extracting insights from free text, for example audit and inspection finding content tagging and classification. Stakeholders are much more excited about this use case versus dashboard automation. But the focus on predictive and prescriptive insights is still on the lower end for most sponsors. The most advanced sponsors have use cases focused on site audit and inspection finding prediction, but the maturity of such models is also limited.

A focus on value articulation for prioritization of analytics use cases as well as impact measurement. Typically, sponsors look at three kinds of metrics:

- **Base—consumption metrics:** These metrics track the utilization of existing reports or dashboards. Most sponsors are focused on this now.
- **Intermediate—value metrics:** At this level, the team focuses on metrics like ROI, quantified in terms of reduction in FTE resources or dollars. For example, we can look at this metric across 1,000 sites and compare and contrast situations.
- **Mature—trial outcomes:** The team tries to correlate the trial outcomes (such as a reduction in critical findings) to an analytical capability that has been set up. Another way of looking at this is trial delay avoidance, where a lack of the analytics capability would have most likely resulted in a quality issue—resulting in a trial delay (which is derived from historical benchmark trials).

Only limited teams are using value metrics or trial outcomes to articulate value today, but the more mature sponsors have started thinking about these. Many sponsors are also estimating some of these metrics upfront (prior to project start) to prioritize the use cases coming from the business.

4 quick wins sponsors for sponsors looking to increase their GCP analytics maturity

It was clear from our research that the companies at the forefront of GCP quality analytics are not only investing in establishing the right infrastructure to support the data, technology and analytics needs of the organization but are also focused significantly on enabling the right organization support ecosystem for GCP analytics professionals. They may be addressing this in terms of executive sponsorship or in terms of providing access to the right forums and resources to enhance their analytics maturity. This is a path all sponsors must follow. It's not a question of "if" but "how soon." Because of health authorities' increasing scrutiny on clinical trial execution, analytics will be the most powerful tool for sponsors to have at their disposal for quality control and monitoring.

With this in mind, here are four recommendations sponsors can implement to make quick wins:

1. **Establish a quality analytics center of excellence (COE) that houses business, analytics and technology experts.** This will help enable objective, data-driven, unbiased quality analytics. These COEs will help the organization with quality analytics standards, best practices and driving innovation.
2. **Ensure the availability of external and internal data sources in an all-encompassing quality data lake**. Set up a holistic and complete data infrastructure capturing data from both insourced and outsourced trials. This data will be the foundation of all future analytics.
3. **Recruit and retain the right talent.** Given the nuanced nature of GCP quality analytics, it is critical to hire, retain and grow the right people who are technologically advanced, understand the data landscape and have a robust backbone in GCP quality analytics.
4. **Pivot toward early signal detection and proactive risk identification.** Focus on developing predictive models that will analyze data and enable signal detection and quality risk identification instead of analyzing the situation in the aftermath.

About the authors

Jonathan Rowe is a principal at ZS who leads ZS's Clinical Development Quality, Operations and Risk Management practice. He has over 25 years of industry experience and has held leadership roles in both large and startup pharma organizations across clinical development, medical affairs, intellectual property strategy, portfolio management, business development and pharmaceutical sciences. From 2014 through 2019, Jonathan was the global head of clinical development, quality performance and risk management at Pfizer, where his responsibilities included developing, monitoring, modeling and predicting the Pfizer GCP quality management system, leading the analysis of Pfizer's clinical trial quality performance and ensuring clinical trial quality risk management was built into all trials.

Arup Das is a principal in ZS's Pune office with over 14 years of management consulting experience assisting life sciences clients with a variety of clinical analytics, clinical operations, RWD and drug development issues aimed at improving R&D productivity. He leads multiple global R&D analytics teams with deep focus on the application of data, analytics and AI to improve clinical drug development and operations, making these simpler for patients and sponsors.

Ankita Praharaj is an associate principal in the Princeton office with 12 years of management consulting experience. She has worked extensively with clients and has led several analytics engagements in the clinical and RWD domains. She is a part of the ZS global R&D analytics team and has partnered with clients to solve complex problems through the development of innovative analytical capabilities. These include FTE resource forecasting, clinical risk-based quality assessments and RWD strategy and analytics.

Ektaa Sharma is a manager in the Pune office with 11 years of management consulting experience. She has worked extensively across U.S., EU and APAC markets on life-sciences-related business problems ranging from risk-based quality analytics to asset evaluation, real-world data strategy, innovation and digital health, clinical operations and commercialization. As a member of the ZS global R&D analytics team she has partnered with clients to solve problems and implement innovative solutions.

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About ZS

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