PISTOIA ALLIANCE

FAIR BUSINESS SURVEY REPORT

Beyond Research: Realizing the Value of FAIR Initiatives

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FAIR 2024 Business Survey Report:
Insights and Recommendations

Date: 2025-04

Report shared with: General Public

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INTRODUCTION

The adoption of FAIR (Findable, Accessible, Interoperable, and Reusable) Data Principles, originally published in 2016, has gained traction within pharmaceutical and life science companies, yet the business value of such initiatives remains an area requiring further exploration. While many organizations internally assess the benefits of FAIR, an industry-wide methodology for evaluating its impact is still lacking. In response, the Pistoia Alliance FAIR Community of Experts launched a study in 2024 to bridge this gap, leveraging secondary research, survey data, and expert interviews. Key findings from the analysis of 36 questionnaire responses and 12 follow-up interviews indicate that pharmaceutical companies are applying FAIR principles beyond research, extending into development, clinical, and operational functions (Figure 1). Notably, organizations that initiated FAIR initiatives five or more years ago (see: FAIR toolkit) are now realizing tangible benefits, often backed by high-level executive support, including improvements in data management processes and enhanced operational efficiency.

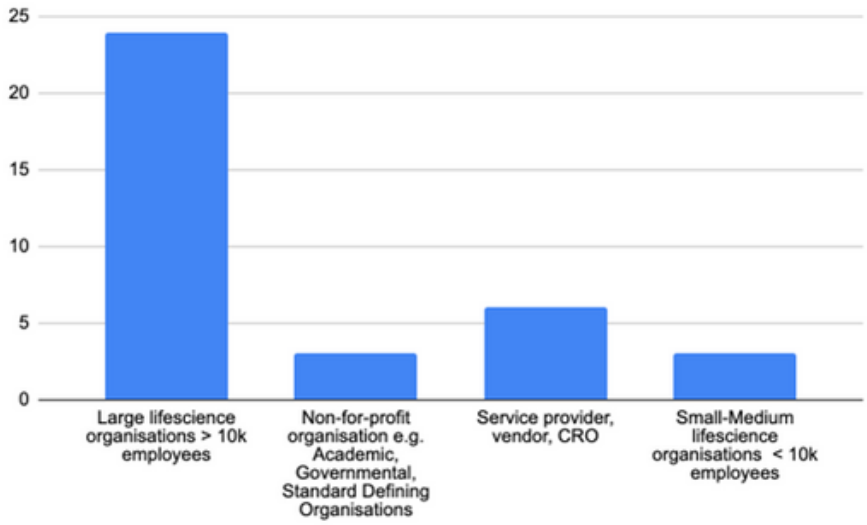

Figure 1: Types of organization's represented in the survey

The survey indicates several key business drivers for FAIR Data Principles implementation:

- Trusted data: Improved data quality, integrity, compliance, and enabled AI capabilities.
- Cost savings: Resource productivity, automation, avoiding data duplication, minimizing investment waste.
- Speed: Faster time to market, decision-making efficiency, pipeline cycle time, pipeline throughput.
- Effectiveness: New insights, ideas, innovations that would otherwise not have been possible, increased probability of technical success.

However, as FAIR becomes operationalized, there is a growing demand for well-defined business cases that incorporate both qualitative and quantitative Return on Investment (ROI) projections, coupled with initiatives to enhance data literacy at all organizational levels. The initial excitement surrounding FAIR has given way to a need for demonstrable outcomes. Additionally, FAIR is now seen as a critical enabler of AI and machine learning, reinforcing its long-term strategic importance. Nevertheless, cultural and mindset challenges persist, particularly in gaining business buy-in and overcoming entrenched data and process silos.

The analysis of secondary sources aligns with the survey data. Time and cost savings emerge as significant business drivers for FAIR. Importantly, the survey highlights the value of data quality, trust in data, and AI enablement as the main motivating factors for FAIR, which warrants further quantification efforts.
The survey reveals additional nuances of FAIR as a value driver, highlighting the emphasis on execution speed not only as a time-saving measure that could lead to cost savings, but also as a broader factor in driving effectiveness in new activities. This aspect is essential in recognizing insight generation as a value driver, which is likely challenging to quantify from an investment standpoint.

Figure 2 illustrates the distribution of responses to the question, "How do you measure success, and what metrics are used to assess FAIR implementation initiatives?" These responses are then clustered into broader value drivers.

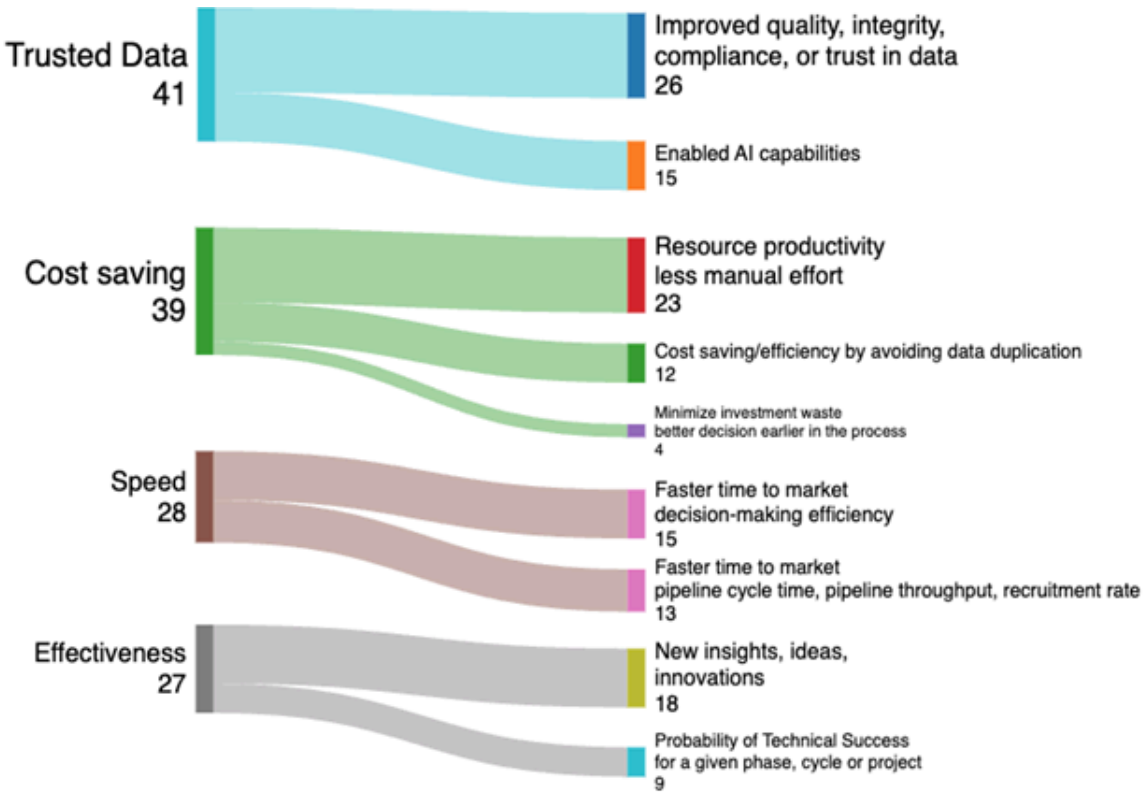

Figure 2: Reported Business drivers of FAIR initiatives "

Observed business outcomes included:

- Improved data governance
- Enablement of generative AI
- Value achieved is through helping build data-as-a-product or data products
- Improved metadata and compliance
- Data quality, consistency, and error reduction from the lab to production
- Improving data accessibility, and efficiency with continued progress

The perception of FAIR is shifting; once seen as a cutting-edge initiative, it is now often overshadowed by emerging machine learning solutions. Despite this shift, a recurring theme in leadership responses was the recognition that FAIR data remains a foundational enabler - not only for effective data reuse but also for the success of AI applications and other novel approaches.

Finally, the most persistent challenge identified is not technical but cultural: a fundamental mindset change within the business is required to realize the full value of data-driven transformation, irrespective of technological advances in infrastructure.

Recommendations:

- Develop Value Narratives to Secure Leadership Support: Success stories from users and stakeholders should be collected and shared to demonstrate FAIR's impact. The cost of business-as-usual and of not having FAIR data is implicit and may lead to a strategic disadvantage. Mandates from top leadership are essential for breaking down data and process silos and driving integration efforts. Intermediate management support is a must and requires additional value-add argumentation, including Return on Investment (ROI).
- Engage All Key Stakeholders Early – FAIR data is not an end by itself, but a means to an end. Business functions especially must collaborate from the outset with IT and enabling functions. Ensuring all stakeholders recognize and embrace the value FAIR brings to their processes is key to long-term sustainability and success.
- Clearly Define Business Value: Once business leaders understand the benefits of FAIR, they can become strong advocates. There is a need for a shared FAIR business value framework and shared practices to evaluate the business impact of FAIR, including shared ROI calculations methods. This report provides some materials to further design such frameworks.

This work was realized by the FAIR-for-Pharma community of experts / Working Group FAIR for business, coordinated by Giovanni Nisato, Pistoia Alliance. Special thanks to: Chris Day, Perdl Limited; Birgit Meldal, Pfizer; Genta Spahiu Pina, Pfizer; Valerie Morel, Ontoforce; John Apathy, XponentL Data; Despoina Sousoni, Elixir; Nick Juty, Manchester University; Ted Slater, EPAM Systems; Nalini Mehta, GSK.

More comprehensive versions of this report are available for Pistoia Alliance members and the FAIR-for-pharma community of experts.

For more information:

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Benefits of FAIR initiatives emerging from the interviews: themes and examples

Theme	**Examples paraphrased from the interviews**
Speed increase	Metadata increases the speed of digesting data. The project accelerated pipeline progression and key handovers in the organization. It also reduced time-to-insight and partner identification (e.g., CRO), and increased the speed of clinical trial setup.
Time savings	Reduce the time to find the correct data from 3 days to hours or less. Shortened the duration of clinical trials.
Findability, Accessibility, Reusability.	*Findability*: Increased data discovery (findability) and availability. Improved ability to search multiple data sets, including statistics, on a more extensive data set. Enhanced capability to use a larger set of criteria. *Accessibility*: Provided access to enormous data sets unsuitable for management via Excel, for example. *Reusability*: Facilitated data reuse across teams or through shared data products (e.g., from research to development, manufacturing, CMC processes, and regulatory submissions). Enabled cross-project data analysis and rapid showcasing of data aggregation.

Theme	Examples paraphrased from the interviews
Trust in data: quality, integrity, compliance	Metadata enhances data quality and enables quality assessment; good metadata ensures high-quality data. Lack of metadata indicates data quality issues. Eliminates manual and automated work needed for data curation.
Employee productivity and satisfaction	Optimized allocation and reallocation of human resources and talent, allowing the same team to manage a larger pipeline. Increased work satisfaction: 'I love this.' Improved processes, including experiment design in research.
Data sharing across functional groups	More effective predictions for downstream outcomes, including feedback from downstream activities and RWE, providing early visibility into decisions and their implications for downstream systems or processes.
Generate new insights	For example, insights generated from in vivo pharmacology and clinical studies, such as mechanics of pathways and endpoints.
AI capabilities	AI-driven analytics is facilitated or improved with increasingly curated data sets. Machine readability simplifies Gen AI projects, and metadata enables faster and more accurate Gen AI insight extraction.
Better visibility of information	For example, senior management can delve into data through dashboards. Ability to query data in sophisticated ways without programming skills at all levels.
Cost reduction	Reduction in storage costs by avoiding multiple versions of the same data, saving human resources and time.
Data Ownership	Improve accountability in managing data ownership. Clearly identify and clarify product data owners and ownership.

Benefits of FAIR initiatives emerging from the interviews: themes and examples

Experts in at least 4 cases indicated that it is too early to observe the full benefits of FAIR principles. It is estimated that it may take 2 to 5 years for these benefits to become apparent, depending on the duration of processes such as clinical trials and the adoption of regulatory standards. The time frame is linked to the time when such processes, for example, clinical trials or regulatory body adoption of standards are implemented. We should also consider the possibility that future users of the FAIR data might not directly recognize the connection of the benefits with FAIR due to unawareness of the invested efforts. For this reason, it is important to build value-add argumentation cases to follow the full journey of FAIR data.

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