



Expert Insights

Converging IT and OT to transform biopharma manufacturing

Unleash the power
of cross-enterprise data

IBM Institute for
Business Value



Experts on this topic



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Empowering intelligent workflows through optimized use of cross-enterprise data requires bringing out the best in both IT and OT.

Key takeaways

To move faster and work smarter, biopharma businesses face growing pressure to unleash the full power of cross-enterprise data. While emerging Industry 4.0 technologies offer enormous potential for biopharma, siloed data and a lack of tight integration between IT and OT are roadblocks to success. Creating a synchronized IT/OT framework lets business information flow freely across the enterprise, driving manufacturing performance and data-led innovations.

A disconnected IT/OT environment exposes biopharma organizations to significant cybersecurity risks and regulatory compliance concerns. Rigorously identifying and protecting against cyberthreats and regulatory risks such as data integrity should happen *before* connecting manufacturing processes, plants, networks, and applications. IT and OT need to join forces to mount the most effective defense and build trust.

Biopharma organizations must act quickly to embrace IT/OT integration. The industry is beginning to rally around this concept. One example: 77% of pharmaceutical manufacturers plan to manage IT and OT cyber risk together within three years.¹ Transforming to an integrated digital business requires developing an action plan that delivers swift results and competitive advantage.

Connecting IT and OT for biopharma transformation

The business of biopharma is rapidly changing. Digitization is reshaping product development, operating models, manufacturing processes, and requirements from both healthcare providers and patients. The ongoing repercussions of COVID-19 only add to the need for agility. To keep pace, enterprises are evolving to the next generation of Industry 4.0 by designing intelligent workflows using artificial intelligence (AI), data, analytics, cloud, and the Industrial Internet of Things (IIoT).

But to realize the full benefits of these technologies, information technology (IT) and operational technology (OT) functions must modernize and synchronize. Typically, IT collects, manipulates, analyzes, and generates insights from information. OT monitors and controls physical operations.

This scenario raises big questions: How can two vastly different technology systems work together? What value will be gained by merging and integrating the two environments holistically? What is the cost impact? Could this affect manufacturing production and to what extent? How do two separate organizations cooperate to identify and prioritize the most impactful changes?

Historical disconnects between IT and OT management, particularly for biopharma organizations with large-scale, asset-intensive manufacturing operations, can stand in the way. Yet empowering agile operations and intelligent workflows through optimized use of cross-enterprise data requires bringing out the best in both IT and OT, emphasizing the expertise, capabilities, and skillsets of each.

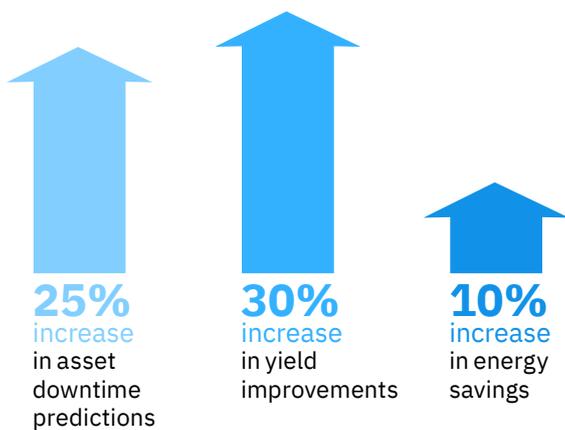
When IT and OT work together, information flows seamlessly across the enterprise and can facilitate faster decision making and real-time visibility into global manufacturing and quality. Exploiting data and technologies such as AI can also improve market responsiveness, among other advantages (see Figure 1).

Figure 1

Putting data to work

AI can help businesses become agile and resilient at a time when nothing is more important²

Enhancing operational effectiveness with AI- and data-driven insights could potentially result in:



Source: Internal IBM client information.

The case for change

Manufacturing, with its IIoT-connected machines and devices, generates more data than virtually any other business function. When run through AI-driven analytics, this data can create valuable real-time information and insights. Recent advances in AI, machine learning, and edge computing reveal new opportunities for manufacturers to evolve past cost-cutting initiatives and into process optimization, using data to optimize supply chains, inventory balancing, distribution management, and more. Yet companies that fully leverage their data are the exception, not the rule—and the IT/OT divide can often be the culprit. *For biopharma companies to derive the full power from cross-organizational data, IT and OT must align.*

Because the two organizations were developed to be largely independent of each other, IT and OT bring disparate processes, infrastructure, key performance indicators (KPIs), and regulatory guidelines to the table. They're often two separate departments, each with full autonomy to accomplish discrete missions, embodying different priorities, approaches, and skillsets.

But this is not a simple divide of IT being digital and OT being operational. OT operators at the manufacturing plant level are highly skilled technicians. But their expertise lies in a different type of technology, one that includes robotics, connectivity, and specialized edge devices with custom software. As well, OT operators tend to prize—and fiercely guard—their autonomy within the manufacturing site, whereas IT has traditionally been applied to centralized corporate functions.

These differing perspectives can contribute to a relationship that at times seems less than cooperative, with conflicting views stemming from a desire for ownership and control. Inevitably, disconnects arise. Building alignment, finding common ground, and calibrating cultures and expectations are essential to OT and IT convergence success.

That common ground between IT and OT—a mutuality of interests—is becoming increasingly clear.

That common ground—a mutuality of interests—is becoming increasingly clear. As OT portfolios advance, they're often based on IT architecture, with the central governance that warrants. Cross-organization teamwork is also required to effectively counter cybersecurity risks and manage regulatory compliance issues, especially in complex, IIoT-connected environments. Overall, to drive true transformational change and competitive advantage, organizations need to better use data sources from across both the business and the shop floor—and convert that data into meaningful business insights.

Compelled to converge: The benefits of integrating IT and OT

While biopharma manufacturers generate an immense volume of data, quantity does not always mean quality. How can that data best be interpreted and used to benefit the business? Information needs to be shared and analyzed effectively, bridging longstanding divides and addressing organizational issues holistically.

The convergence of IT and OT provides a common structure for that exchange of information, helping manufacturing data coalesce productively with the business domain. That convergence connects smart systems into networks and lets information flow freely across the organization. It empowers intelligent workflows, predictive analytics, and data-driven decisions that enhance performance—while also helping to alleviate cybersecurity and compliance concerns.

Forward-thinking biopharma leaders understand that by bringing the business and production functions closer together, they can create their own singular version of an Industry 4.0 manufacturing enterprise. Yes, the concept of connecting “shop floor to top floor” has been around for decades in the biopharma industry. At times, it's seen success at plant scale or for specific operations or use cases. But our vision, supported by converged IT and OT organizations, is much more ambitious. The benefits can be considerable, including real-time visibility into global manufacturing and supply chain data, and product launch advantages.

Intelligent workflows

The good news: autonomous machines can run entire production processes. The challenge: in disconnected environments, valuable data remains siloed and inaccessible. The rise of exponential technology such as robotics, blockchain, augmented reality/virtual reality (AR/VR), AI, and IIoT can connect those diverse operations with the data they generate, creating information that can drive decisions.

Aligning OT and IT can collect, aggregate, and analyze data from disparate systems that were not initially designed to work together. Ultimately, operational insights are bridged to the business domain. The result: enhanced smart, autonomous workflows, fueled by data and machine learning, that transform operations and can lead to decreased cycle times, increased yields, and improved quality control.

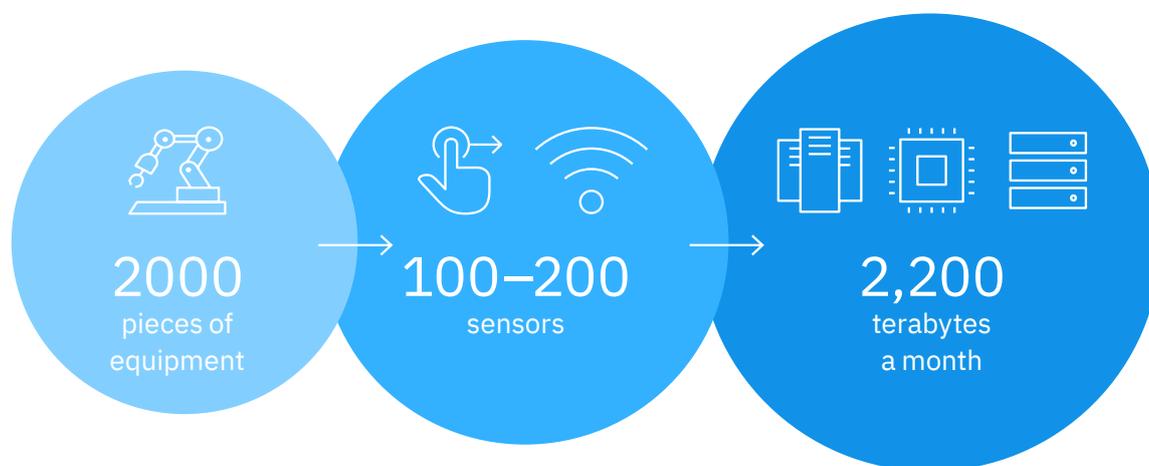
For example, a connected shop floor can leverage data from machines and devices to identify patterns and insights more quickly, identifying process chokepoints and constraints. The amount of data generated can be considerable—sometimes 2,200 terabytes per month (see Figure 2). And while our figure reflects metrics for manufacturing overall, biopharma facilities tend to generate even greater volumes of data.³ AI-driven predictive technologies and preventative maintenance can reduce disruptions and manage on-time repair—improving product quality and consistency, production line performance, and overall efficiencies. Extended equipment life and lower maintenance costs are other potential benefits.

Getting specific doses of therapeutics to patients when and where they need them—or not—can have significant consequences.

Figure 2

AI is the key

AI is needed to unlock insights from exponential data volume⁴



Source: “3 Must-Haves For Intelligent Manufacturing.”
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Smarter workflows can also translate into smarter employees. Overall, these employees, now armed with greater insights and actionable information, can resolve problems faster, decrease production delays, and better manage market responsiveness. For biopharma, this transcends mere customer satisfaction metrics. Getting specific doses of therapeutics to specific patients when and where they need them—or not—can have significant consequences.

Real-time visibility into global manufacturing data

Too often, global manufacturing data languishes unused or locked away. Meeting the challenges of the biopharma industry means playing to the strengths of both IT and OT (see “Perspective: IT and OT” on page 5).

For example, biopharma companies face particularly steep concerns in the manufacturing and distribution of personalized medicines. These therapeutics require a completely new process and technology platform that encompasses related activities—including initial planning and scheduling, manufacturing, distributing to clinics, and driving patient engagement. And pharmaceutical products need to comply with extensive regulations related to formulations, data protection, standard operating procedures, equipment, and more.

To facilitate this end-to-end cycle, manufacturing shop floor systems must capture and share intricate data throughout. To achieve seamless integration, and implement, deploy, and maintain these capabilities, IT and OT functions need to fully align and access data on both sides of the equation. The result: intelligent new workflows and integrated technology platforms that can support the complex processes required by personalized medicine, as well as help organizations navigate regulatory requirements.

The availability and visibility of manufacturing data can also help drive successful implementations of global Manufacturing Operation Management (MOM) or Manufacturing Execution Systems (MES). These systems offer significant value but are often hampered by long deployment timelines and excessive costs to integrate existing plants and processes. IT and OT need to align at the enterprise level and partner on program standards, approaches, and timelines. Otherwise, these initiatives can derail after significant investments in time and money.

General technology lifecycle management is also a common challenge for shop floor automation systems. Often, the usage period of equipment, such as a new coating machine or tablet press, far exceeds the lifespan of related IT systems. Upgrades can be challenging and costly, and equipment vendors can implement technical solutions with outdated operating systems or patches, creating cyberthreat exposures. Helping to ensure that technology and security measures are up to date requires intense collaboration between IT and OT.

Perspective: IT and OT—A collaboration, not a competition

IT, with its emphasis on centralized data, and OT, with its location-specific, hardware-centric focus, can seem at competitive odds. In reality, they make ideal collaborators. For example, an IIoT-connected shop floor can bring the physical world online—but also create a multitude of possibilities for cyberthreats. Enter the IT department, with its systems and networks designed to protect proprietary information across organizational layers. IT also provides the data storage and governance measures that smart operations require. And, as OT begins to explore and deploy exponential technologies, IT again steps in with a role that's behind the scenes but pivotal: helping to address security, compliance, regulatory, and governance concerns.

At a high level, the benefits of IT and OT convergence can include:

- Creating flexibility, scalability, and opportunities to innovate
- Providing a more holistic view of production and processes
- Unlocking OT data for broader organizational use, predictive analytics, and machine learning
- Protecting industrial controls, automation, data, intellectual property, and physical security
- Reducing overall total cost of ownership
- Increasing speed to value through expedited delivery of projects

A world of connected “things,” for all its advantages, can expose potential cyber vulnerabilities, particularly for biopharma manufacturing.

Managing cybersecurity and regulatory compliance challenges

Without due diligence, a world of connected “things,” for all its advantages, can expose potential cyber vulnerabilities, particularly for biopharma manufacturing. At risk are operational disruptions, plant downtime, costly physical damage, intellectual property loss, employee safety—and ultimately patient safety and trust. Regulatory compliance is another weighty concern.

The resilient response: Converging to enhance cybersecurity

Penetration points via the OT network infrastructure—not IT—have escalated security concerns for many manufacturers. In fact, more than half of manufacturing organizations say OT is vulnerable to cyberattacks.⁵ And one IBM study reported a 2,000% increase in cyber incidents that focused on OT environments between 2018 and 2019.⁶

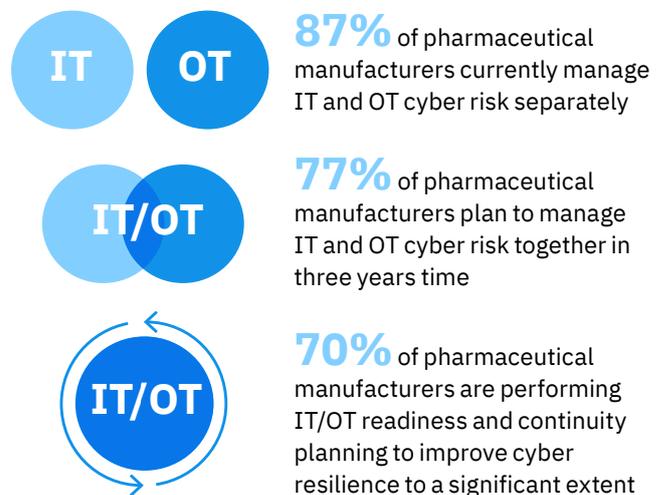
Looking ahead, it’s estimated that the IoT will include 83 billion connections by 2024.⁷ Rigorously identifying and protecting against cyberthreats is a step that should be executed *before* connecting manufacturing processes, plants, networks, and applications. With supply chains, factories, customers, and operations all interwoven, cyberthreats can impact corporate systems and beyond. This is especially valid when biopharma manufacturing systems are targeted.

Some OT groups may view a multi-tiered architecture as ample protection from cyberthreats. This could hold true for an externally introduced incident, but, as we’ve noted, malware can just as easily attack directly on the shop floor. In this scenario, IT and OT must come together, acting as one to quickly restore operations. If they’re already converged, that’s a huge advantage. Of concern: right now, 87% of pharmaceutical manufacturers manage IT and OT cyber risk separately. But there’s reason for optimism: 77% of pharmaceutical manufacturers plan to manage IT and OT cyber risk together within three years (see Figure 3).⁸

Figure 3

Convergence is coming

Start planning now to keep up with agile competitors



Source: “IT and OT cyber risk security and resilience benchmarking data.” IBM Institute for Business Value benchmarking database. Unpublished information. 2020. n count=30.

OT managers shouldn’t go it alone. They need to draw upon the extensive experience that IT personnel have in information security, data protection, and privacy procedures. IT staff can serve as a critical collaborative resource to help troubleshoot security, data storage, and governance issues.

A fundamental point to consider: as automation networks are integrated with enterprise business networks, a single owner is required. After all, when two distinct organizations assume ownership, no one owns it in the end. For essential issues such as cybersecurity and regulatory compliance, the gap is perilous.

Teamwork: Presenting a united front to regulatory agencies

The topic of data integrity is an area of particular focus and scrutiny. Data integrity gaps in existing shop floor systems can have significant impact to operations, leading to fines or even cessation of manufacturing indefinitely through regulatory actions. Additionally, computer system validation and data integrity processes sometimes differ between IT and OT groups. An advantage to converging the two: one common framework for adhering to regulations from agencies such as the Food and Drug Administration (FDA) in the US, the European Medicines Agency, and the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. This engagement can occur both within sites and across the global network.

When IT and OT join forces, they can better evaluate and protect industrial controls, automation, data, intellectual property, and physical security. Familiar technologies already honed across the enterprise, such as authentication, authorization, auditing, encryption, and data integrity, can be even more potent in a converged IT/OT environment. These technologies are all essential to regulatory compliance.

How to get there from here: Three paths to convergence

Inevitably, separate organizational silos for OT and IT create disparate perspectives across people, technology, and cultures. Bringing the two sides together is challenging, but perseverance can pay off.

We've identified three distinct approaches to IT/OT convergence. They all require a thorough analysis of IT and OT values, priorities, and skillsets within that particular organization, and trends for the industry at large—as well as processes for reconciling differences. And, these approaches offer varying degrees of integration, requiring an assessment of areas to assimilate, or not, depending on organizational direction and requirements.

1. Organizational realignment—OT aligning to IT, or vice versa

To accurately determine priorities for direct manufacturing operations, OT organizations often express the need to report into a site. However, we've seen many operating models in which OT is merged into a corporate IT function succeed—in both biopharma as well as other industries.⁹ Reporting to an IT function does not mean an OT group loses its connection to—or control of—the shop floor. A simple change in reporting structure can suffice, such as hard-lined versus dotted-lined. The reality: everyone at a manufacturing plant understands that keeping operations running is the top priority. If an issue arises, the clear mission is to resolve it quickly, regardless of where an employee falls on an organizational chart.

One case in point: a large biopharma company initiated the process to align their site OT function under corporate IT after a cyber event shut down operations at a key plant. Combining the groups across the plant network led to numerous benefits, including operational efficiency and improved employee engagement (see case study, "Global biopharma organization" on page 8).

An alternate model is aligning IT to OT. Depending on an organization's skills and capabilities, this can be a viable option. This solution is less common, however, because OT groups do tend to be site-centric. And they don't engage as frequently with enterprise standard processes and tools such as a global Configuration Management Database, or ticket management and validation programs that can more easily extend from IT to the OT function. However, it does happen, with a benefit being that IT offers a perspective that spans the entire enterprise.

2. Starting fresh—a new, separate organization

Another option is to create an entirely new entity that combines a subset of IT and OT personnel, with a focus on digital transformation and innovation. It can ultimately report into various top-level organizations, but a common approach is to link the new entity to global engineering. In order to be successful, however, a number of factors must be addressed. For example, decisions can no longer be site dependent, but rather driven top-down with an enterprise-centric approach—and an entirely new governance model. Although this approach may require heavy lifting initially, it provides a clean organizational slate. IT and OT tightly align as one from the start and are unencumbered by allegiances to either of the legacy units.

3. Step by step—a hybrid model/ transitional approach

A hybrid model can be an iterative process, serving as a steppingstone to a fully merged IT and OT organization. This model starts with delineating clear roles and responsibilities across separate groups, in effect constructing guardrails to facilitate alignment and collaboration.

The next step could create a subset of the two organizations that initially focuses on one particular process. For example, one company created a small group of IT and OT personnel to concentrate on lifecycle management, working with site engineering as new equipment and capital projects were launched. This collaboration helped ensure technology requirements were fulfilled, managing the equipment throughout its lifespan for upgrades and cybersecurity.¹⁰

Another possible step toward moving to a fully integrated organizational model is to combine IT and OT groups at the beginning of a digital project. Ideally, participants should use Design Thinking methodology—or any approach that iterates, aggregates, and refines best practices—to bring together end users and line operators. This enables the two groups to effectively collaborate and co-create solutions, helping them to pursue joint goals and objectives.

This approach of combining IT and OT was used by a multinational personal care company to quickly enable their manufacturing digital transformation. Their first step was to collectively design a model IIoT reference architecture. Once this was established, the two teams were able to quickly enable a number of digital capabilities that helped to significantly improve Overall Equipment Effectiveness (OEE), reduce changeover times, and enable predictive analytics capabilities.¹¹

Global biopharma organization: Enhancing speed-to-value and employee engagement¹²

Like many of its peers, this company had maintained separate IT and OT organizations, with IT reporting into the CIO and OT reporting into site engineering groups across the network of plants. Meanwhile, automated equipment began to utilize more IT functions, and the need for data analysis increased. At one point, a major cyber event impacted manufacturing operations for an extended period—an episode that led to a reassessment and restructuring.

To better prepare for such events in the future and to optimize current operations, this company integrated site automation and OT functions across eight plant locations. It established a joint IT/OT governance structure for asset lifecycle management, cybersecurity, and capital projects. As well, it implemented cross-training programs and developed job aids for IT and OT support, providing additional career development opportunities for each discipline.

As a result, this organization was able to increase speed-to-value by 25% to 50% through aligned resources and priorities. Employee engagement scores increased by 10% to 15% through enhanced career opportunities. Support and maintenance contracts were reduced by 10% to 15%. And the company discovered that collaboration led to increased innovation, for example, the development of machine learning algorithms for common support issues experienced with manufacturing shop floor systems. Overall, lifecycle management capabilities for manufacturing-related IT assets improved. And cybersecurity, especially in support of automation equipment, was enhanced.

Action guide

Our approach to IT/OT convergence

As we've discussed, many biopharma companies maintain separate organizations for IT and OT.

Whatever the current-state structure, evolving toward Industry 4.0 calls for aligned IT/OT organizations working in concert toward manufacturing- and data-driven innovations. Addressing this challenge sooner rather than later is critical to enabling true transformation, both in individual biopharma companies and in the industry overall.

The time to act is now, and we've outlined steps to consider as you build your roadmap.

Assess: Evaluate the current landscape, new and future needs, and gap analysis.

- Determine how to bridge silos between IT and OT, effectively integrating and developing structures and technologies that support collaborative, agile, entrepreneurial teams.
- Investigate how the broad business adoption of intelligent operations, underpinned by data and seamless information flow, can deliver capabilities across the enterprise.
- Address change management requirements. What will it take to assimilate the collective skillsets, backgrounds, experiences, and priorities that IT and OT bring to the table?
- Establish a budget to truly plan a comprehensive IT/OT assessment that not only focuses on business needs but also establishes a well-defined data foundation with astute oversight.

Define: Build a value case for convergence, gain consensus on priorities, and motivate stakeholders.

- Investigate where your organization can be more responsive to a rapidly changing industry. How can converging IT and OT move you toward those goals?

- Identify new business models required to respond to a rapidly evolving industry—for example, by facilitating the exploration of more curative, personalized therapies.
- Determine where new, emerging technologies are needed to effectively collect and analyze data and share actionable insights across the organization—accelerating faster innovation and impact.
- Examine how a converged, more agile IT/OT organization can improve manufacturing execution, process automation, and quality management.

Design: Develop plans for people, process, technology, and guiding change.

- Build effective governance strategies to handle evolving technical systems and organizational change.
- Build your talent engine. Determine how to obtain needed skills now and in the future for both IT and OT. Do you nurture these skills internally, acquire externally, or a combination of both?
- Redesign organizational culture, structures, and processes to help employees navigate a shifting work landscape.
- Develop intelligent workflows that integrate data-led processes, facilitate AI-human collaboration, increase productivity, and lower costs.

Implement: Orchestrate a phased rollout to rapidly innovate, optimize, and scale.

- Select a site or particular process area and execute an initial pilot for converged functions.
- Implement a minimum viable product (MVP) to deliver value quickly and magnify benefits at scale.
- Use IT skills and improved IT/OT asset management to promote the critical importance of data integrity and cybersecurity in a data-led enterprise.
- Provide leaders with holistic views across the enterprise, creating data-driven insights into research and development, production, product lifecycle management, supply chain, marketing, and sales.

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The IBM Institute for Business Value thanks Carrie Worley for her contributions in developing this Expert Insights report.

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Expert Insights represent the opinions of thought leaders on newsworthy business and related technology topics. They are based upon conversations with leading subject-matter experts from around the globe. For more information, contact the IBM Institute for Business Value at iibv@us.ibm.com.

Notes and sources

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