Regulatory COVID-19 Research Paper

COVID-19 Pushes Regulatory Toward the Cloud and Outsourcing

IQVIA

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Introduction

It took only a few months for COVID-19 to effect sometimes irreversible changes on regulatory and compliance activities in the life sciences industry. The impact on regulatory workflows, clinical data management, and trial monitoring has been wildly disruptive, triggering an evolution in the way regulatory professionals do their work. It has also shined a new spotlight on the benefits that cloud technology and outsourcing can bring to regulatory compliance – particularly in times of crisis.

Cloud eases pandemic transition

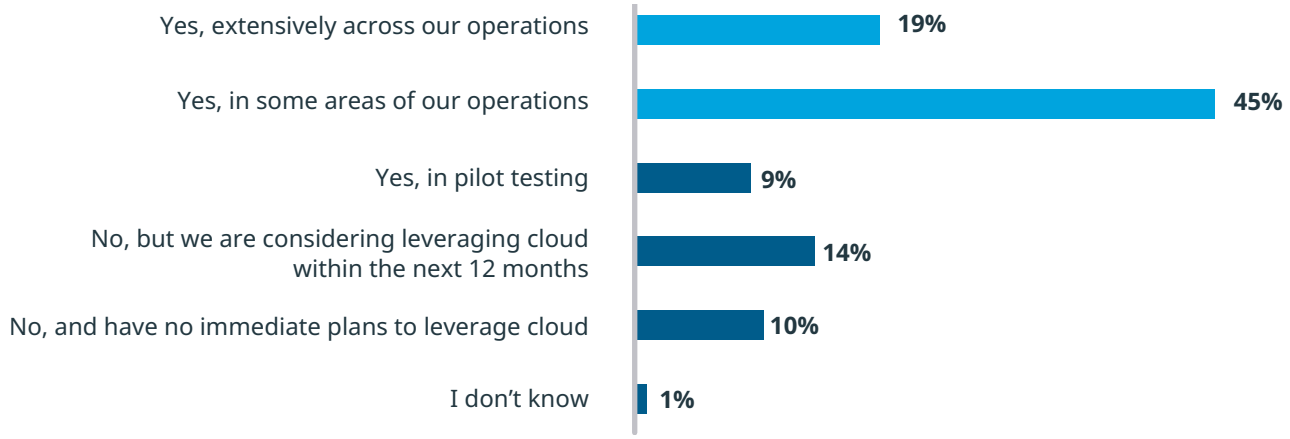
In a recent survey conducted by Informa Pharma Intelligence in partnership with IQVIA, 74% of life sciences regulatory professionals who currently use cloud technology said it has been extremely/very important to the smooth running of their operations during the pandemic.

This is not surprising given the need to rapidly adapt to remote monitoring and remote sharing of large data sets in order to maintain regulatory compliance. "I'm actually surprised it is not near 100%," commented one executive at a medical device company who was interviewed for this report.

The survey also found that cloud technology usage in regulatory is rapidly increasing. Fully 64% of respondents report leveraging the cloud in some or all of their regulatory activities (see Figure 1A). That figure rose to 80% for large biopharmaceutical companies (1,000+ employees), where globalization, the volume/complexity of regulatory activities, and potential economies of scale often encourage cloud migration sooner rather than later.

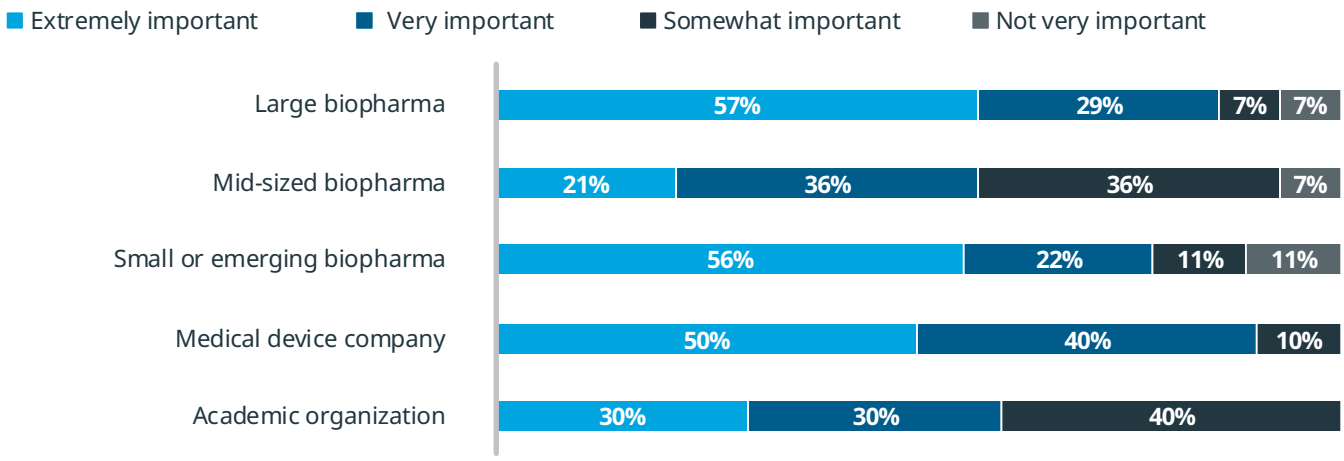
Figure 1A: Leveraging Cloud for Regulatory

Does your organization leverage cloud technology for regulatory?



Question: Does your company currently utilize cloud technology for regulatory?
Base: All respondents (n=77).

Figure 1B: Leveraging Cloud for Regulatory



Question: How important has cloud technology been for your ability to operate smoothly during the pandemic?
Base: All respondents (n=57).

Even in small/emerging companies, where only half of respondents reported current cloud utilization for regulatory, 78% felt that it has been extremely or very important for their ability to operate smoothly since the advent of COVID-19 (see Figure 1B). "I would 100% agree that cloud technology is necessary," noted one Regulatory Affairs executive in an emerging biopharma company interviewed for the report. "(It is) even more important in the face of a pandemic. If people can't work in the same room, can't really talk, it is the only way to create shared understanding of how data gets generated, stored and retrieved."

Among those regulatory professionals who didn't benefit from having cloud solutions in place before the pandemic began, 53% intend to implement the technology within the next 18 months, and more than a third (37%) said the pandemic has accelerated their cloud deployment plans.

This doesn't surprise Ronan Brown, IQVIA's SVP & Head of Integrated Technology & Compliance. He noted that traditional regulatory and compliance technology was not designed for the cloud, and on-premise solutions have seen little innovation in the past decade. That is causing many regulatory professionals to embrace cloud technology to achieve greater speed, flexibility, and freedom from manual data management tasks. "We are getting a lot more requests from regulatory teams, safety and core compliance areas in R&D looking for cloud-based systems because they see the value it can bring to their workflow," Brown said.

"Regulatory professionals are innately conservative, but once they evaluate the lessons learned, I think we will start to see a greater reliance on the cloud and outsourcing."

— Ronan Brown

Non-cloud users face data overload

With 96% of regulatory staff working remotely during the pandemic, cloud-based systems helped address one of the biggest challenges regulatory teams faced: having easy access to large amounts of data and documentation and the ability to easily transfer it.

This is a critical component of regulatory affairs, particularly in a global market characterized by significant regulatory variations.

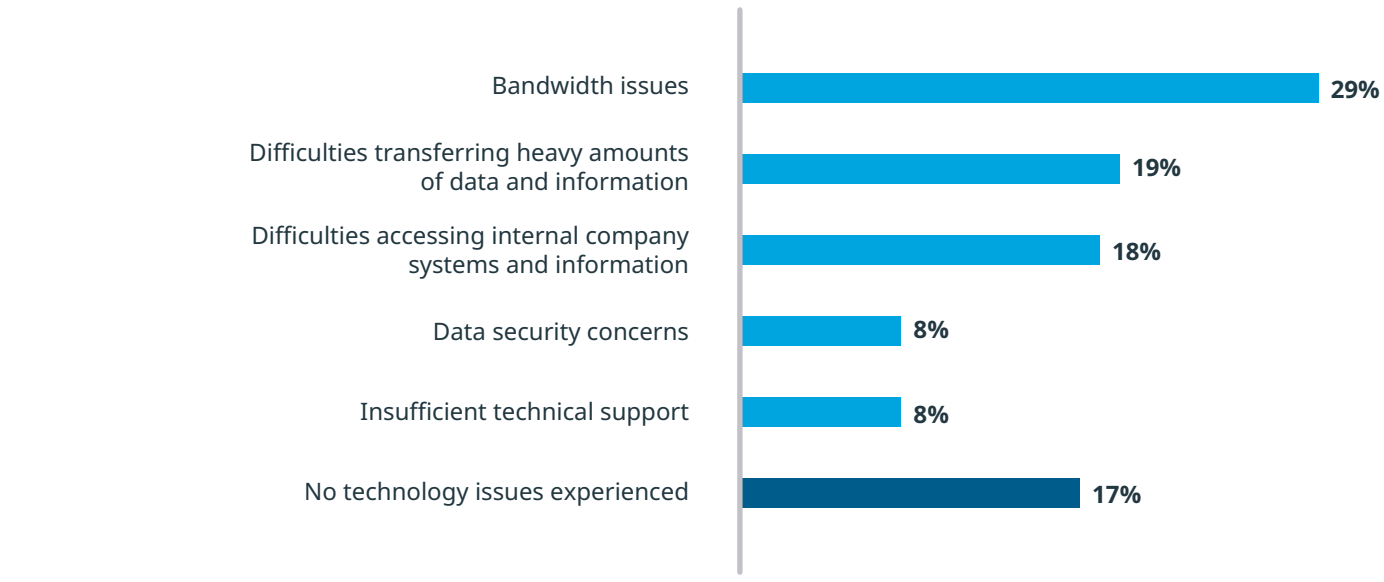
It is also where access to cloud technology really comes into its own.

"Having access to high-speed networks was also a major problem for remote regulatory workers, more so for those in mid-sized biopharmas (41%) than for large biopharmas (33%), which are likely to have an established global infrastructure for data-sharing.

Conversely, small biopharmas (27%) tend not to make large on-premise investments early-on, which gives them the freedom to adopt newer, modular cloud-based technology, allowing more flexible, agile approaches.

Bandwidth issues (29%) was another significant technology-related obstacle, experienced by regulatory organizations of all sizes during the pandemic, followed by problems transferring large volumes of data, and difficulties accessing internal company systems (see Figure 2). This was borne out in interviews with survey participants.

Figure 2: Biggest Technology Issue Encountered During the Pandemic



Question: What is the biggest technology issue you have encountered while working during the COVID-19 pandemic?
Base: All respondents; multiple responses permitted (n=77).

More than 53% of respondents were already outsourcing some or all of their regulatory processes, especially submissions planning and/or publishing.

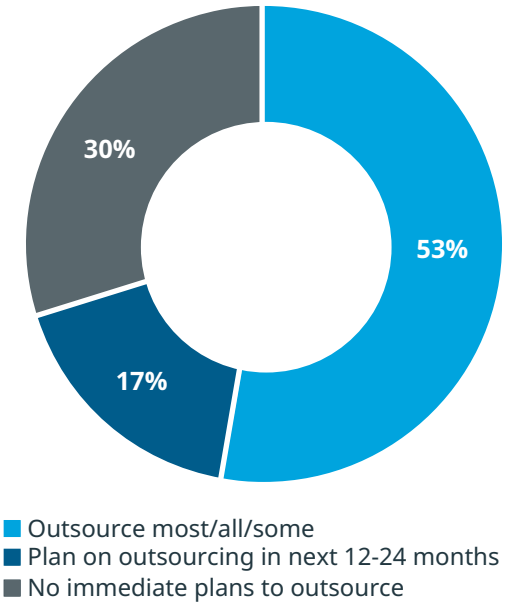
"Being able to share documents back and forth without having to save them, just some shared services would have made a huge difference," commented one respondent from a small company still working with paper-based systems. "Working remotely, I don't have access to some of the document databases."

Another respondent pointed out that inadequate bandwidth can add substantially to data-processing times. "Where we had to upload all of these documents in our internal storage, and even trying to access them, we had lower [response] times. So, we spend lots of time trying to upload and download and share different files."

In contrast, regulatory teams that had cloud solutions in place faced fewer disruptions. "We were using a cloud platform prior to the pandemic, and everyone knows what we mean by 'make sure you share and save your data at this particular location in the database hierarchy'," said one respondent, whose team had been using cloud for more than two years. "So, we didn't really have a problem transferring massive sets of data to facilitate remote working for some personnel."

Figure 3: Outsourcing Regulatory Processes

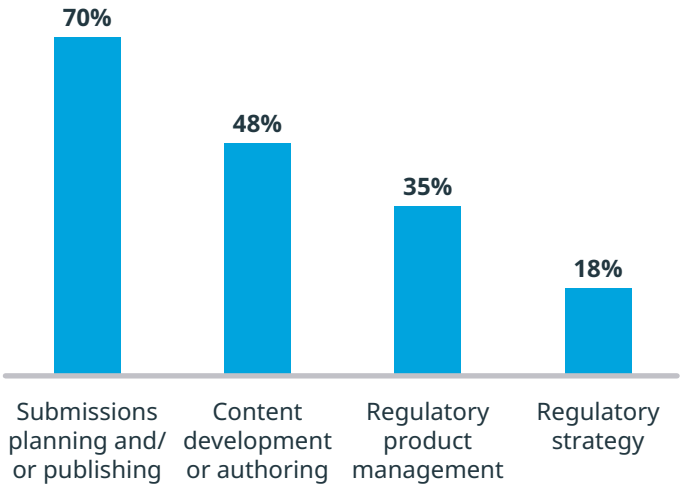
Does your organization outsource any regulatory processes?



Question: Does your company currently outsource any of your regulatory processes?

Base: All respondents (n=77).

Top Regulatory Tasks Currently Outsourced

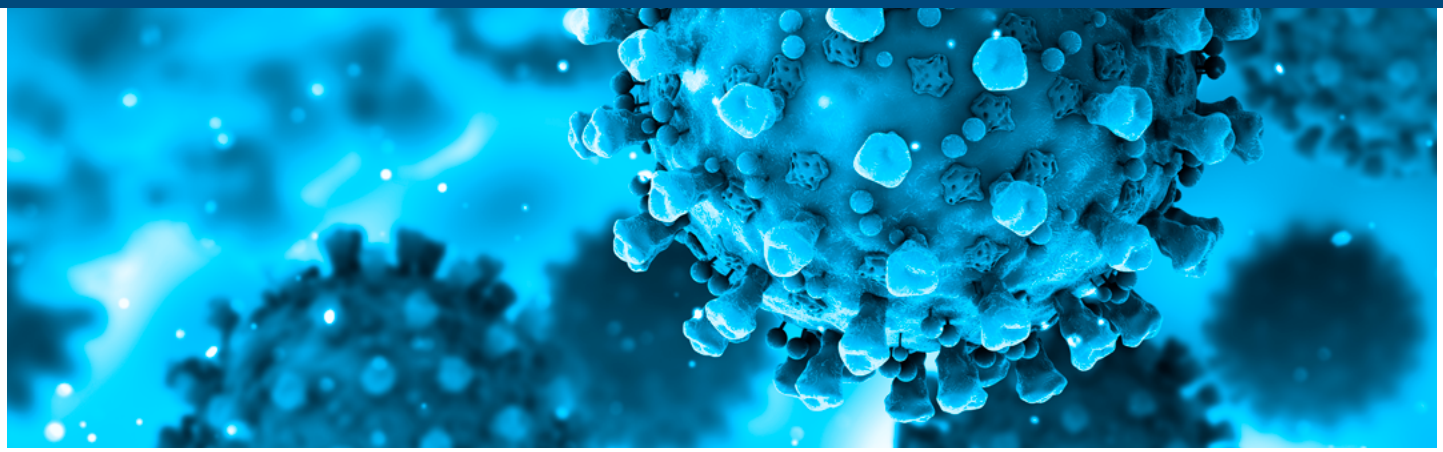


Question: Which regulatory tasks do you currently outsource? (Select all that apply)

Base: Respondents outsourcing regulatory; multiple answers permitted (n=40).

Time to outsource

Navigating the pharmaceutical landscape during COVID-19 also pushed many regulatory professionals to further embrace or consider outsourcing more repetitive, process-based tasks.



In the survey, more than half (53%) of respondents were already outsourcing some or all of their regulatory processes, especially submissions planning and/or publishing (see Figure 3). They cited the added time and resources to focus on core competencies (41%), access to expertise unavailable in-house (40%), cost-efficiencies (31%) and improved flexibility/operational agility (24%) as the leading benefits of this operating model.

They also benefitted from added adaptability during the pandemic, according to Brown. “When you have outsourcing programs in place it’s easy to shift the workload,” he said. “That’s the entire purpose of an outsourcing model.”

He noted that several IQVIA customers have reported facing less disruption than peers who faced huge backlogs when employees couldn’t access their data. “We’ve had feedback from several large clients who were relieved that they were able to handle safety reporting so easily as they were working at companies that had actively planned for remote systems access by their staff.”

Migration to electronic submissions at regulatory agencies was also cited as one reason to step up outsourcing, as was data-gathering for products sourced outside the EU, and the need to embrace more advanced document-control and exchange systems.

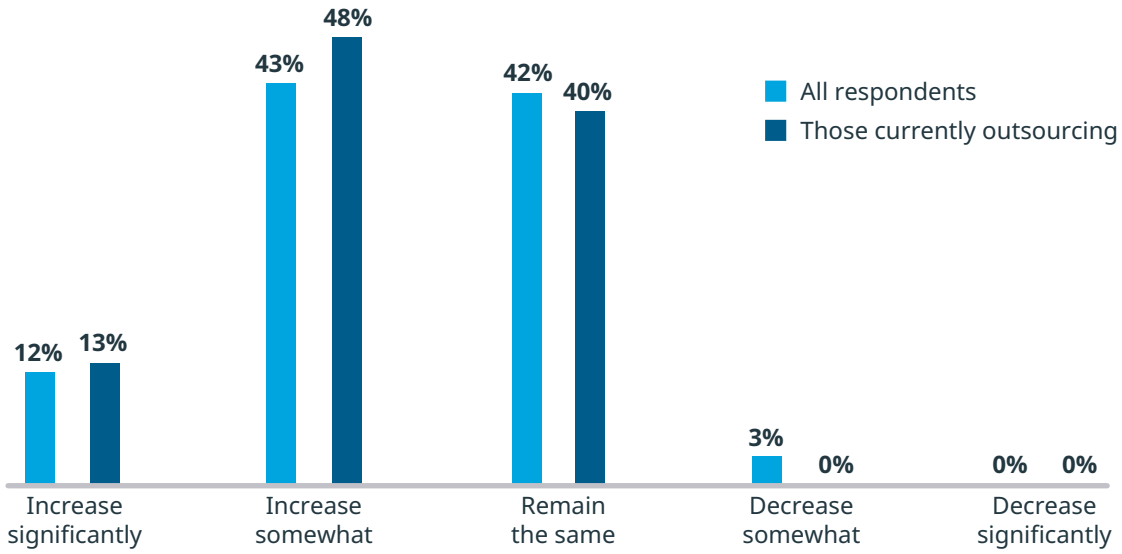
Brown believes the experience of adapting to COVID-19 will only increase interest in outsourcing for regulatory and compliance operations. “Regulatory professionals are innately conservative, but once they evaluate the lessons learned, I think we will start to see a greater reliance on the cloud and outsourcing.”

He noted that outsourcing frees regulatory professionals to focus more on higher value tasks, and to leave more repetitive, manual work to their outsourcing partner. “They can spend more time working with development teams, liaising with the FDA and other authorities, and developing regulatory strategies.”

The survey results reinforce this prediction. A majority (55%) of survey respondents said they expect their regulatory outsourcing will increase either significantly or somewhat over the next two years w Figure 4). Large biopharmas scored notably higher in this respect (67%) compared with other industry groups (mid-sized biopharmas, 53%; small biopharmas 50%; device companies, 40%). Only about one-fifth of participants felt the pandemic had delayed rather than accelerated their outsourcing plans (see Figure 4).

> *"There has been an acceleration of interest in digital solution, driven primarily the FDA's approach to digital health."*
>
> *— VP, MedTech Company*

Figure 4: Expected Change in Outsourcing – Next Two Years



Question: How do you anticipate the use of outsourcing will change at your organization over the next two years?
Base: All respondents (n=77).

Risk mitigation post-COVID-19

Along with choosing new technologies and partners, regulatory professionals are using the pandemic as a catalyst to improve efficiencies across their operations.

Despite the fact that 80% said they are extremely/very confident in their company's ability to respond to future crises based on how they are dealing with COVID-19, most report plans to make changes to their crisis management strategies and/or workflows.

Fully 71% felt the pandemic had influenced future crisis-management planning, with 24% describing the impact as significant. And nearly a third (32%) saying they were already implementing new regulatory processes or systems due to COVID-19 (40% in large biopharmas), while another 35% planned to do so within the next year.

The effects were felt most keenly at mid-sized biopharmaceutical companies, where 74% of respondents said COVID-19 had affected crisis-management planning. That compared with 67%

at large biopharmaceutical companies, which may be more accustomed to working in global, high-risk, volatile regulatory environments. Only 34% of respondents at small biopharmas saw an impact on future crisis-management planning, perhaps because they are less involved in global, large portfolio-oriented regulatory challenges than their larger peers.

Brown believes the desire to make changes has been spurred by the profound ways that regulators, pharma companies, and trial sites have responded to this crisis. He points to regulators' willingness to adapt trials for remote environments and rapid decision-making for COVID-19 treatments and vaccines, as well as the industry's efforts to accelerate remote recruiting, and to adopt patient-centric strategies to maintain safety and compliance goals.

Remote work: Here to stay

These changes may include adopting a permanent remote work option for regulatory personnel. Not surprisingly, fully 96% of respondents either expanded on pre-existing remote-working policies/allowances (32%) or started implementing working from home for some or all employees (64%).

As with their support of cloud technology, one respondent pointed out that having remote work options pre-COVID-19 would have prevented a lot of wasted ramp-up time and costs. "We started using Zoom conference-calling two-and-a-half months ago, so that was a learning curve," he said. "If we'd had those sorts of remote video-conferencing capabilities in place prior to the pandemic, we wouldn't have had to waste… our time just trying to figure it out."

Similarly, when survey participants were asked how COVID-19 might affect their organization's regulatory operations in the future, the most frequently cited impact was increased use of remote or flexible work arrangements (56%), followed by more virtual communications with health authorities (51%) and more flexible business operations and processes (39%) (see Figure 5).

"It proves the industry can be incredibly innovative in the face of a common threat, our biggest hope is that we can take that and apply it in the future across any study"

— Ronan Brown

Figure 5: Most Likely Changes to Future Company Regulatory Operations

Question: In your opinion, how might the COVID-19 pandemic affect your company's regulatory operations in the future?
Base: All respondents (n=77).

Learning from the crisis

The survey findings also illustrate how much COVID-19 has moved crisis management up the agenda as a function of regulatory operations. As one respondent put it: "Like everyone else, I guess we had to adapt fast and respond quickly on the avalanche of requests. So, from a management point of view, I would say we have adjusted our processes, just in terms of speeding them up."

From the survey and the accompanying interviews, it was evident that the COVID-19 pandemic will have far-reaching effects on regulatory procedures and practices in the life sciences sector. That carries clear implications for future reliance on regulatory outsourcing, and especially on cloud technologies that facilitate remote working and seamless data exchange.

More routine remote working over the long term, or at least better provision to switch seamlessly from office-based to remote working, could well be part of that process. If more proactive and comprehensive usage of cloud technology and outsourcing are added to the mix, life sciences organizations may really start to embrace regulatory infrastructures and processes fit for the digital age and for a new era of post-COVID uncertainty.

The environment is changing, and regulatory professionals are being handed more work with no more added resources, so they need to work with partners who can help leverage a combination of technology and process changes to meet those requirements moving forward.

These adjustments will prove invaluable not only in dealing with the unavoidable outcomes of COVID-19, such as more extensive remote working and communications, but in delivering regulatory strategies and operations more efficiently and cost-effectively at any time. Notwithstanding its many disastrous consequences, COVID-19 has served as a much-needed wake-up call for the life sciences sector to address more dynamically the demands of regulatory compliance.

In the survey conducted by Informa Pharma Intelligence and Informa Engage between 13 May and 8 June 2020, 77 respondents from a range of positions in regulatory affairs, operations, management and consulting assessed the impact of COVID-19 on regulatory processes in life-science organizations. Among those respondents, 58% were at director/associate director level or higher. Geographically, 52% of respondents were based primarily in the US/Canada and 48% in Europe. The breakdown by organizational type was 19% large biopharmas, 25% mid-sized biopharmas, 16% small biopharmas, 21% device companies and 19% academic organizations.

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