

Unlock pharma's value through cloud technology

How companies can use new-generation cloud platforms to defragment data and enable value through digital technology



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Executive summary

Pharma has never had more opportunities to realize value from data, yet it is struggling to do so.

These opportunities exist across precision medicine; real world evidence; patient-centred healthcare; genomics; digitized therapeutics; digitized and virtual clinical trials; and collaborative, multi-stakeholder R&D.

All require the ability to link, share, synthesize and analyze data often in new ways, both from within the organization and increasingly also from outside it.

Cloud platforms can be instrumental in creating infrastructure that allows for data to be freed from traditional data silos, making the data scalable, available and accessible. Cloud can be one of the ways pharmaceutical companies can overcome the limitations of silo-inducing legacy data arrangements that lack a common data architecture. This is especially the case within large companies that operate disparate data systems across geographies, markets and functions.

Further, Cloud can offer pharma access to new tools and expertise in fields outside of the core competencies of traditional life science organizations. This includes areas such as machine learning (ML) and artificial intelligence (AI), to more tailored search and database innovations

developed specifically for the life science and healthcare sectors.

These new cloud capabilities are already enabling pioneering life science companies to confront many of the data challenges that seemed insurmountable just a few years ago.

Beyond simply enhancing analytics, Cloud computing can be a key ingredient into larger digital-transformation efforts. These type of transformations are not easy, but are often built on a foundation of Cloud computing. In addition, true transformations must be supported by strong leadership and a culture that supports a new approach to data within the organization.

This paper will explore what cloud can offer the life sciences sector and will speculate on the imminent innovations that it might enable. It will then explore what breakthroughs cloud is enabling pioneers to achieve today.

Finally it will summarize the factors that are holding many other pharma organizations from making the most of their data and will suggest approaches to cloud adoption that can help overcome these challenges.

Life sciences organizations are facing challenges in all areas of the value chain, and cloud can help transform each area

Pharmaceutical organizations have struggled to optimally manage their data, particularly so that it flows to where its value can be best realized.

Companies that are seeking new data management solutions are designing new processes for

conducting faster R&D, speeding clinical trials of novel treatments, innovating with more personalized and digitized medicines, and gaining deeper insights into patient and customer needs.



Research & development

Siloed and legacy infrastructure

Discover previously undetected drug patterns using data management, analytics, A/ML and collaboration solutions



Clinical trials

Stringent regulatory requirements

Efficiently store, de-identify, and aggregate complex data sets across clinical trial sites



Manufacturing & distribution

Track-and-trace compliance through supply chain

Predict supply and demand and reduce time-to-clinical-site and time-to-patients using inventory management



Sales & marketing

Changing competitive landscape

Target provider and patient groups effectively and optimize drug pricing using market segmentation and analytics



Patient value

Data security risks

Integrate data from multiple sources to personalize medical treatment

Cloud transformation opportunities

Scale and access: the potential of cloud data

The benefits of cloud

There are five key areas that Life Science companies should consider when planning for their digital transformation via the cloud:

Successes achieved by companies such as Recursion Pharma (see case study) demonstrate what is already possible, potentially cutting the time to discover new medicines by a factor of 10.

Additionally, Cloud-driven insights offer new opportunities in early intervention (even potentially the prevention) of a disease.



Security

Cloud enhances overall data security by removing data from outdated servers that may not have the latest security updates and enables strong security controls to be implemented.



Analytics

Regardless of the volume, velocity, and variety of data that might be distributed via a cloud service, its scalability unlocks a number of new opportunities. Cloud helps unlock insights from disparate types of data such as electronic medical records, patient portals, biomedical data, mobile apps and IoT devices.



Data integration

Cloud can offer a way to free siloed data within large pharma organizations where it is 'trapped' inside the varied operating affiliates and sub-organizations around the globe.



Collaboration

By allowing for instant collaboration, easy sharing, and a variety of seamless communication methods, organizations can use Cloud as a productivity tool. Cloud based tools can revolutionize knowledge sharing and integrative decision-making, especially in areas such as clinical trial management and pharmacovigilance.



Data externalization

Bringing disparate data sets together faster also means being able to share data externally with less friction. This is important in an era when large multinational research projects pursue breakthroughs between pharma, clinical research organizations, academic institutes, hospitals and trial centres. A data management

infrastructure that enables all stakeholders to share data easily with strict security and access controls is a vital prerequisite for participation in this projects.

Sanofi's new destination

Sanofi drives digital transformation with Google Cloud.

“We’ve got a hypothesis that we can create new revenue streams through this approach,” says Ameet Nathwani, Chief Medical Officer and Chief Digital Officer. The company is pursuing an ambitious data transformation with a new business model in mind.

Sanofi is looking to create value from data in new ways. This could involve selling analytics; creating new therapeutics built on data insights; offering new recommendations and solutions for healthcare systems based on its data; enabling virtual healthcare and even managing population health.

These type of innovations will also likely challenge the traditional pharmaceutical business model. Perhaps these services will be offered on a subscription recurring-revenue model, globally, at scale and across many diseases, says Nathwani. “In order to enable [these innovations] we needed this digital engine, which means that you connect all the data in the right place with the right specification, right technology, the right oversight and have the right analytics capabilities built in.”

“I believe that with this technology, we can do far more than we do today for society in healthcare.”

The idea of data as ‘medicine’ in the era of digital therapeutics driven by new platforms and software tools doesn’t sound as far-fetched as it once did, according to Sara Kuethe, Head of Life Science and Medical Device Marketing at Google Cloud.

“There is a desire and a new possibility to move beyond therapeutics by using data. It isn’t always about a new molecule. Equally important is how do we help build and create new health care apps, understand data and connections about existing products while keeping patient data secure.”



I believe that with this technology, we can do far more than we do today for society in healthcare.”

Ameet Nathwani,
Chief Medical Officer and Chief Digital Officer,
Sanofi

Transformation partnership & accelerators



Evolving business models

Phillipe Barillion, Head of Insights and Analytics at Takeda, can see a path to such a future.

“A traditional ‘pharma company’ should become a patient’s last resort,” he says. “In essence by the time a person comes to us, we are too late when you consider conditions such as oncology, diabetes, cardiovascular disease.”

Companies like Takeda and Roche are already starting to offer digital health services and platform technologies that facilitate health interventions, help doctors make better diagnosis and expand what constitutes a treatment choice, says Barillion. “Core pharma business models will change in the era when everyone is connected to devices and will be able to access their own data and take charge of their own wellness and healthcare.”

Becoming data-led organizations will better equip pharma businesses to cope with the change from its core pharmacotherapeutic businesses, says Barillion. “We are just starting to enlist the power of the human genome; we can only begin to imagine lots of great findings and insights here including data on risk profiles, likely treatments and preventative measures.”

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Phillipe Barillion,
Head of Insights and Analytics, Takeda

Digital continues to transform life sciences

Life sciences CEO's top priorities

01

Drive **innovation and business** value across the organization

02

Develop a robust **product pipeline** to drive long-term growth

03

Maximize **patient value** - from R&D to commercialization

Digital shifts

Adoption of digital tools in clinical trials

Open Source innovation models driven by technology

Utilization of AI for achieving clinical outcomes

○ Cloud as a game changer:

○

○

What the pioneers are doing now

Cloud platforms are already enabling some breakthrough innovations among health companies that have relevant implications for pharma. These organizations have transformed their ability to process huge volumes of data and drive new insights from it.

The four use cases below show what some of the pioneers are doing with the capabilities of the cloud.



The Broad Institute

The Broad Institute has increased the speed at which it analyzes human genomes by 400% after moving its inhouse genome sequence and analysis onto the cloud.

Founded in 2004, the Institute studies the human genome to discover the origins of diseases and help fund new cures or therapies.

During its first decade, it used onsite servers and storage to sequence genomes. But with more scientists conducting research on more samples, the Institute found itself having to store and process data volumes far beyond what its on-premises infrastructure could handle. Not only was the institute referring to existing data on an ongoing basis, its rate of new data generation was doubling every year.

Generating one human genome's worth of sequenced data every 12 minutes – approximately 12 terabytes per day – is a storage challenge, as is the need to dynamically adjust to data sequencing operations running 24/7. So the institute built 'Genomes in the Cloud', a secure, cloud-based infrastructure for processing and analyzing genomic data to quickly scale computing and storage capabilities.

Sequencing studies consist of extracting DNA separating and photographing samples before storing them on Google Cloud Platform. The fragments are then reassembled using the Genome Analysis Toolkit (GATK) pipeline developed by the

Broad Institute. Cloud products such as Google Cloud's Life Sciences API make it easier to run this pipeline at scale.

"We can do important research faster than ever," says Geraldine Van der Auwera, Associate Director of Outreach and Communications at Broad's Data Sciences Platform. "This will lead to a greater understanding of the human genome and the links between genetics and human disease."

Working on the cloud has also enabled the Institute to:

- 01** Increase computing speed to sequence a complete human genome, fourfold
- 02** Protect genomic data by controlling privacy, daily use, data access, sharing and permissions
- 03** Quickly scale computing power to meet spikes in demand for data processing and storage.



Recursion Pharmaceuticals

Despite advances in scientific research and medical technology, the process of drug discovery has become slower and more expensive over the last decade.

Recursion, headquartered in Salt Lake City, is looking to overhaul R&D in terms of speed and productivity, by combining rich biological datasets with the latest in machine learning to reinvent the discovery and development process.

Recursion's two-year-old drug discovery platform combines chemistry, automated biology, and cloud computing to reinvent the drug discovery and development process, revealing new therapeutic candidates and potentially cutting the time to discover and develop a new medicine by a factor of 10.

The data pipeline it has developed incorporates image processing, inference engines and deep learning modules that use computational power that can run to bursts of computation amounting to trillions of calculations per second.

Starting with wet biology—glass plates containing thousands of healthy and diseased human cells—biologists run experiments on the cells, applying stains that help characterize and quantify the features of the cellular samples: their roundness, the thickness of their membrane, the shape of their mitochondria, and other characteristics. Automated microscopes capture this data by snapping high-resolution photos of the cells at several different light wavelengths.

Cloud-based tools extract and analyze cellular features from the images. Deep neural networks then process this information to find patterns, including those humans might not recognize. The neural nets are trained to compare healthy and diseased cell signatures with those of cells before and after a variety of drug treatments. This process yields promising new potential therapeutics.

To train its deep learning models, Recursion uses on-premises GPUs, then Google Cloud's CPUs to perform inference on new images in the pipeline using these models. Recursion is now evaluating cloud-based alternatives including using Cloud TPU technology to further accelerate and automate image processing.

As a result, Recursion has:

- 01 Created hundreds of disease models
- 02 Generated a shortlist of drug candidates across several diseases
- 03 Advanced drug candidates within the human testing phase for two diseases



American Cancer Society



Tools on the cloud are helping the American Cancer Society in its mission to better understand hard-to-treat molecular subtypes of cancer that offer a poor prognosis.

The society had been looking at the medical records and surgical tissue samples for approximately 1,700 women diagnosed with breast cancer. The aim was to find out more about how lifestyle, medical, and genetic factors are related to subtypes of breast cancer and whether different features in the breast cancer tissue translate to a better survival rate.

Doing this was a heavy undertaking in terms of data and analysis. The technical challenges in analyzing high-resolution tissue images in uncompressed, proprietary formats were significant, not to mention the fact that typically a team of highly trained pathologists would be required to then spot novel patterns in the data.

Even if such a team could have been assembled, it would have involved years of human endeavour to analyze all the images, and the results would inevitably be subject to human fatigue and bias. Some patterns might not even be detectable by humans, potentially decreasing the value of the study.

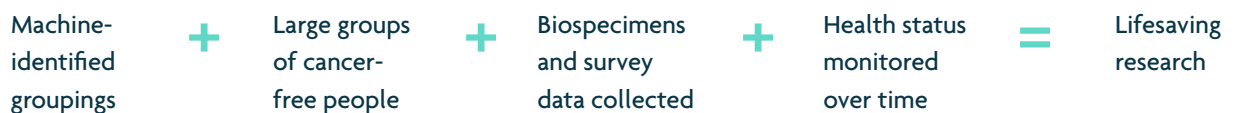
Data analytics specialist Slalom recommended running machine learning models on Google Cloud Platform (GCP) to facilitate an unsupervised type of deep learning. Its algorithms would determine the accuracy of their predictions and make adjustments without an engineer stepping in.

Slalom built a machine learning pipeline, and was able to complete the entire project on GCP in just three months, first applying deep learning on a sample set and then scaling and distributing models across the full set of images.

It was a task that might not have even been possible with local infrastructure. Image conversion alone would have been exceedingly difficult and time consuming for 1,700 images with file sizes up to 10GB, not to mention deep learning at scale.

The analysis found potentially impactful patterns in the cancer tissue images which should help relate the data to breast cancer survival and risk factors associated with the tissue patterns.

The American Cancer Society is now equipped with processes and a cloud infrastructure it can reuse on similar future projects. “Image analysis via deep learning opens a new frontier of research,” says Mia Gaudet, PhD, Scientific Director of Epidemiology Research at the American Cancer Society. “Applying digital image analysis to human pathology may reveal new insights into the biology of breast cancer. We’re excited about what we’ll find.”





Color Genomics

Any doctor can now assess a patient’s risk for common hereditary cancers and hereditary heart conditions – and offer insights into how genes may influence your ability to process certain medications – by sending for a \$249 analysis of their saliva, offering potentially lifesaving insights.

Achieving such insights from raw genomic data requires marrying huge computing power with sophisticated algorithms and genetic analysis.

Color Genomics, which developed the test, had been using an open-source database for customer phenotype, health history, and other reports to gain insights from the de-identified data. Initially its engineers didn’t have a satisfactory solution for heavy data mining of genetic variants, which was crucial for expanding its tests, understanding clients’ DNA better, and delivering new insights.

Now Color uses a cloud-based query engine able to import billions of rows of data and then analyze the data in seconds. It can now load, store and analyze massive amounts of de-identified genomic data directly into Google Cloud.

Google’s BigQuery cloud data warehouse and analytics engine scales to accommodate the growing volume of genomic data Color uses to provide insights to its customers.

Cloud capabilities have also enabled Color to develop its new product, called Color Data, the largest public database of de-identified, aggregated clinical and genetic information, culled from 50,000 Color test users who have consented to be included.

Color’s scientists can now do real-time data exploration, ask questions, hunt for patterns, and explore potential outcomes within seconds or minutes, tasks that would otherwise have taken up to 12 hours per query. “When you have to wait for results, it’s easy to lose your focus and get distracted by emails or other activities,” says Ryan Barrett, Software Engineer for Color. “Real-time exploration keeps scientists in a continual flow state, focused on achieving insights — a powerful shift in how we work.”



What's holding life science companies back from cloud adoption?

Healthcare, including pharmaceuticals, has been slow to embrace cloud compared to other sectors such as retail or banking.

Until quite recently, early adoption by life sciences companies was often delayed or disrupted by concerns they had around security.

But there has been a significant shift in the last two to three years. Pharmaceutical companies no longer need convincing of the importance of developing data strategies fit for the new commercial and technological possibilities, says Kuethe.

“As the amount of data is growing at an exponential rate, we are seeing pharma’s internal capability and cultures transforming, with a new willingness to change. What we now discuss when helping with systems purchase is value-based: how to work towards personalized medicine models, how to store critical information for specialised products.”

Changing minds

Despite this new openness to change, there can still be a tendency for some parts of an organization to retain a territorial approach to data.

“Whatever data you buy doesn’t actually matter; the only criteria is that it all needs to

be connected,” according to the CEO of a large pharma company that didn’t want to be named. “There needs to be linked attribution and application. A company needs to accept they can’t do everything and can’t do all the data connecting themselves, but they need to be determined to find ways to connect the data.”

Data sharing sensitivities remain

Compliance concerns present further barriers to the sharing of data. Different parts of the organisation may resist granting other divisions or functions routine access to data, says Takeda’s Barillion.

The largest companies with multiple affiliates each operating with three dimensions to their data management – country, function, franchise - face the most complex challenges here, according to Barillion.

“Ethics and compliance groups are highly sensitive to data access and a legal framework for health data in R&D is just not there yet... despite a lot of people with genuine scientific and medical interest in accessing data to deliver value.”

The lack of an overarching data strategy

To capture the full potential of truly shared data, a more coherent organization-wide data strategy and direction is essential, says Barillion. “Pharma big data experts need to have a single, central team to drive improvements across the entire business.”

Without establishing such a team to drive progress, the truly transformative benefits from data will not be realized, Barillion adds. “If data management and using the cloud is not seen as core to our business, with no strategic understanding or centralized mandate to reap the financial benefits of data acquisition, then the insights and analytics of big data and cloud computing will never be properly implemented.”

Innovate, don’t renovate

The Chief Digital Officer of one major company, fears the industry will make the mistake of taking an incremental ‘renovate rather than innovate’ approach, and so will be slow to adapt. “A more ambitious vision across the pharma business is sorely lacking. It starts when I start seeing some big partnerships” he says.

“

We are re-architecting what a biotech (organization) should look like... It’s about insights that are data-driven and about being the first biotech born in AI, rather than where IT solutions are a mere afterthought in R&D.”

Milind Kamkolkar,
Chief Data Officer, Cellarity

Life sciences continues to advance digitally:

The amount of data generated per day by genomics research **doubles** every 7 months¹

Healthcare AI to reach **\$13 billion** by 2025²

1 NCBI, Big Data: Astronomical or Geonomical? 2015.

2 Global Market Insights, Healthcare Artificial Intelligence Market to Hit \$13 Billion by 2025, 2019.

Getting cloud adoption right

For organizations beginning to embark on their data transformation journey involving cloud, it can pay to smooth the way with the following steps:

01

Look at your existing data hygiene

One valuable exercise to carry out prior to embarking on significant (or multiple) cloud implementations is to look at the efficiency of the organization's existing file management setup.

Cleaning up your file management can be transformational. It can cut storage costs by 30% and make the CIO look like a hero," says Sheffi.

02

Define the scope for, and limits to, cloud as a solution

Being clear where cloud will help realise value from data, and where it won't, is an obvious but often overlooked starting point, says Sheffi. "Cloud is a powerful tool, but it's not right for every single problem. You need to ask the right questions, define the problem and what the right aspects of solution would be."

Organizations that aspire to be truly 'digital enterprises' will take a first-principles approach to every workflow and process, says Cellarity's Kamkolkar. Each of these

should be looked at in terms of how technology can be brought to bear to help extract value from data.

"Include everything as you create a digital and data factory for your salesforce, your supply chain, your inventory management, your forecasting, your procurement. Ask: how do you use data to transform how you do research, how you do development and how you do real world evidence? Bring big data to bear," says Kamkolkar.

03

Establish data projects oversight

An independent committee reviewing the outputs from data innovation projects should provide the means to formally assess the partnerships involved, consider and oversee the

scale-up process and understand the level of investment needed, says Sanofi's Nathwani.

04

A 'crawl-walk-run' approach

Working with the organization's implementation partners to lay out and develop a portfolio of cloud projects and to develop the business case for these projects will help lay the groundwork to build support and buy-in for projects internally.

It may pay to start with small datasets and workloads that have lower compliance requirements, perhaps pre-clinical rather than clinical, for example, says Sheffi. "Focusing on relatively quick wins to demonstrate success before

moving onto the next will help maintain momentum towards a longer-term transformation."

Building the business case for taking projects into the cloud that will enable the organization to do things it does not have the internal capacity for can be a powerful persuader, says Sheffi. "Large-scale analytics are difficult to do in on-premise data centers, for example, and being able to bring in different products and partners is really valuable."

05

Draw up a checklist for prospective cloud partners

Ask your prospective cloud providers what other healthcare and life sciences organizations they already work with. Which of the providers on your shortlist can provide differentiated, industry-specific products and solutions or provide engineers able to do coding that is bespoke to pharma workloads? Finding providers who have experience in life sciences, who understand the problems and opportunities specific to it, who have a commitment to building long-term products meant to solve to address them with increasing efficacy over time, is important. A lack of commitment to the specific needs

of the industry can be costly further down the line.

It will also be instructive to see what healthcare and life sciences software products a cloud partner has in development. Google Cloud is an example of a cloud organization devoted to building healthcare and life science specific products. For example, the Life Science API, now in Beta leverages Google Cloud's built-in ML and AI to import, process, analyze, and annotate biomedical and genomic data at scale. Another is the Cloud Healthcare API, also in Beta that bridges the gap between care systems and applications built on Google Cloud.

Questions CIOs and CMOs should ask of their data infrastructure

- Does it enable evidence generation throughout the life of our products so we can adapt them?
- Can it enable you to perform remote or digital clinical trials?
- Can it manage people at home?
- Is it able to collect relevant wearables data in a precise enough manner?
- What about data interoperability with GDPR, HIPAA and EHRs?
- Can it streamline the CRO process?
- Will it enable us to build the insilico models for real world evidence or synthetic arms?



Key requirements

As a highly regulated sector that handles extremely sensitive data, the key health IT management requirements of any cloud service provider should include:

01

Reliable, intuitive data deployment: capacity with robust backup and disaster recovery with minimal transfer and setup Recovery target objective (RTO) - if the system went down, how long would it take to recover? Recovery point objective (RPO) if the system went down, how much data would be lost?

02

Effective data security: features to safeguard against breaches and unauthorised access are the minimal requirement

03

Compliance alignment: broad national and international regulatory frameworks must be met including the EU's General Data Protection Regulation (GDPR) for the protection of personal data and the US Health Insurance Portability and Accountability Act (HIPAA) for secure data portability. Additional medical certifications should be considered if necessary, to benefit confidence in use.

Obtaining organizational buy-in

Maintaining the data transformation process – strategic issues to address

Getting the organization ready, conducting pilots and engaging with cloud providers is only the start for those organizations seeking far-reaching improvements in the value they can realise from data.

The governance of data innovation projects, the level of investment, as well as the state of digital literacy of the organization should all be addressed.

Culture and senior sponsorship

As with any disruptive organization wide change, having senior leadership sponsorship is essential if you want to truly digitally transform your organization says Shweta Maniar, Google Client Lead for Life Science Organizations.

“In my experience, senior sponsorship is crucial to ensure organization wide change and to communicate that this is a strategy that everyone will need to take an active role to adopt. From there the onwess is on the business leaders and the cloud provider to educate, train, and reiterate to ensure this transformation that takes the organization to the next level.”

A fit-for-purpose data architecture

If the organization’s data infrastructure is piecemeal, fragmented and iteratively constructed it may need a data architect to create a coherent

approach. Value only comes when we strategically connect and link data, but that’s often lacking right now. True value comes from a strategy and an IT infrastructure that is purchased, retained and connected for maximum benefit.

Cloud facilitation should be looked at and driven from the center of the organization not from its business units, says Barillion. “Data acquisition is expensive to a local affiliate; large parts of the organization have P&L budgets to purchase beneficial systems, but most affiliates do not. Global should leverage their global power to purchase systems en-masse and implement a strategy that serves the whole business.”



In my experience, senior sponsorship is crucial to ensure organization wide change and to communicate that this is a strategy that everyone will need to take an active role to adopt.”

Shweta Maniar,
Global Client Lead, Cloud Healthcare & Life Sciences, Google Cloud

Sanofi's new partnership model

Old ways of working and old partnership approaches need rethinking in data-led organizations.

The traditional CRO client-vendor service model [in which pharma outsourced some key capabilities] is not a good fit in the era of cloud and Big Data management, says Sanofi's Nathwani. "I've always hated the 'vendor at arms' length' CRO model because I think it has held us back as an industry and we've never been creative in how we can do things differently."

Nathwani doesn't intend to replicate the CRO models of the past, which outsourced control critical processes. Many of the valuable insights gained through analytics will be realized through a combination of expert strengths from inside and outside of the organization.

Sanofi is focusing on partnerships with a limited number of technology providers who are likely to enable the creation of more value. "This is the new model we're developing," says Nathwani. "Sanofi invites its partners to work more collaboratively. I'm telling them they can take our data; we will organize and we will give you our Big Data, you'll use your AI and will help us create new algorithms.

"Those algorithms are going to be proprietary to us, you'll then give us a set of recommendations and we will then take our internal expertise to make a judgement, and we'll use other data sources that are

not part of that health dataset to actually come up with a clear business decision."

This model means that partner technology organizations are not competing, although the ownership of IP is a challenge that must be addressed upfront, says Nathwani.

"It's complicated [but] we have to own it. At the end of the day, it's going to be our responsibility even within a hybrid model. There needs to be sensible and natural conversations about who brings what to the game, but we do that for each partner in a very specific way."



Sanofi invites its partners to work more collaboratively."

Ameet Nathwani,

Chief Medical Officer, Chief Digital Officer,
Sanofi



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