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Seeing patterns in the cloud: Charting a digital strategy with Life Sciences solutions

For Life Sciences companies, selecting a cloud deployment model to support operations requires careful and well-informed consideration. Every enterprise takes a different path to digital transformation and each is at a different stage in the journey. This white paper explores the pros and cons of different delivery models to help organizations chart the right course.

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Executive summary

Life Sciences organizations are actively looking for ways to balance regulatory and security requirements, as well as existing investments, with the agility, speed of innovation and cost savings of the cloud. However, there are as many different approaches to cloud adoption as there are Life Sciences companies. How can an organization map out the right strategy? Determine the right balance between maintaining control and enabling external partner collaboration or the cost advantages of the cloud and intellectual property protection? And, while cloud adoption is widely cited as an intrinsic element of digital transformation, where does a cloud deployment fit with legacy infrastructure?

OpenText helps customers answer these questions every day. To look at the cloud from all sides, OpenText has distilled the options into five patterns, ranging from traditional on-premises infrastructure to a "cloud-native" approach, with various combinations in between. While there is overlap from one pattern to the next, presenting the options in this way facilitates a better understanding of each general approach.

No matter which direction an organization chooses, OpenText offers a flexible path to the cloud, ensuring the right Enterprise Information Management (EIM) solutions and deployment strategy for any organization.

The path to the cloud

One of the key challenges for Life Sciences companies deciding on the best use of computing and IT staff resources is what to deploy in the cloud and what to retain on-premises. For many, a combination of both legacy and cloud infrastructure will be the best solution, for both the short- and long-term. Forrester reports that 22 percent of global software decision makers primarily deploy ECM on-premises, unchanged from 2017 but down from 30 percent in 2016. 21 percent use a hosted model, while 22 percent describe their deployments as hybrid—a mixture of cloud and on-premises models.[1]

Today, many companies are no longer willing to house their entire infrastructure in their own data centers, although the path to cloud for ECM applications remains varied: Hosted and hybrid still dominate over SaaS models.[2]

There are many good reasons why cloud adoption is considered a key element of digital transformation and overall modernization initiatives for Life Sciences companies. Given the tremendous pressure to increase efficiency, speed time to market and reduce costs, along with the added demand of keeping up with regulatory changes and compliance, Life Sciences companies are prime candidates for moving EIM solutions to the cloud. And, while cost reduction might be the most widely-cited benefit, the strongest drivers are improved business agility and speed of adoption.

Regardless of the deployment model, cloud computing allows more flexibility than traditional on-premises deployments. Hardware and operating environments are easier and faster to deploy and ready to begin application work immediately, while running EIM solutions in the cloud improves the ability to keep applications current.

Cost considerations are also a factor. Moving applications to the cloud can reduce operating costs by 15 to 30 percent or more, and enterprises that have a large support and operational staff may see savings of 30 to 40 percent. Shifting the expenditure of infrastructure from capital to operational expense (CAPEX vs. OPEX) can free capital for spending in other areas.

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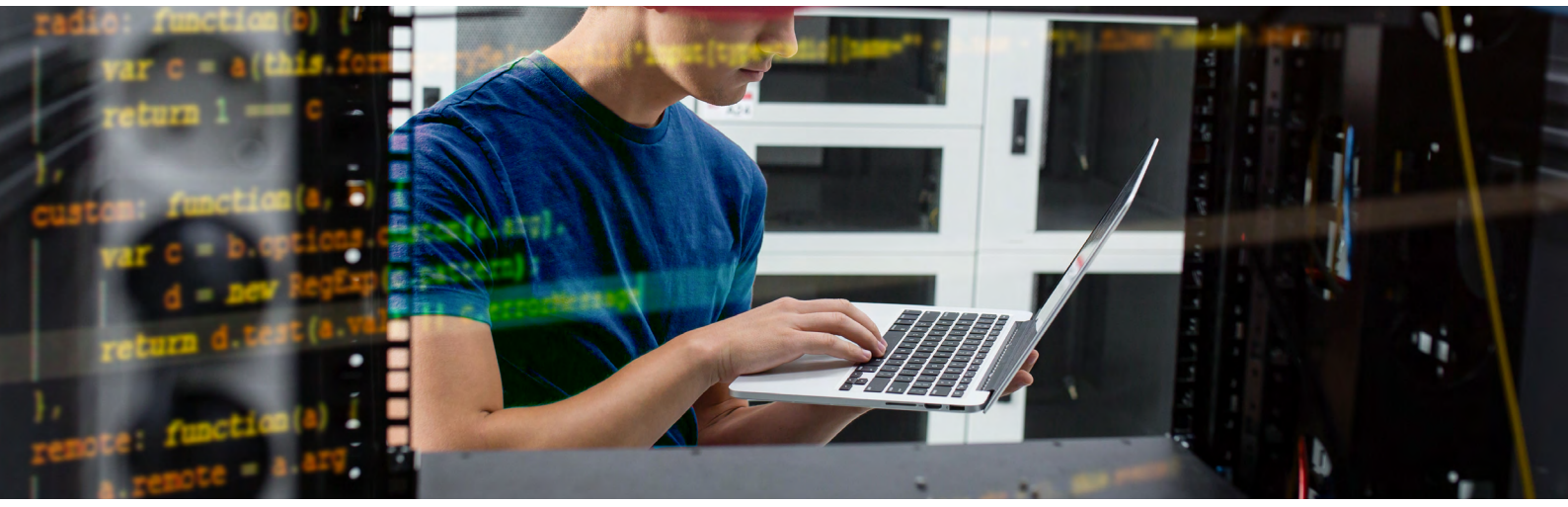
To summarize, the top drivers for cloud adoption for EIM platforms include:

- Pace of adoption compared to the lengthy process of approving, procuring, installing and validating hardware and software.
- More flexible and agile operations.
- The ability to keep applications current.
- Offloaded burden of infrastructure investment and administration.
- Easier content sharing and collaboration across the extended enterprise, comprising customers, partners, suppliers and regulators.
- Cost savings.

Below are the five different patterns that OpenText has identified to help organizations evaluate the right cloud deployment model.

Cloud destination patterns

1 Off-cloud	2 DIY public cloud	3 Managed Service on private cloud	4 Managed service on public cloud	5 SaaS cloud
• Behind the firewall • You manage, update and upgrade software	• Customer managed • Complex set of relationships and SLAs	• Managed service • Single vendor relationship	• Managed service • Single vendor relationship	• Cloud-native multi-tenant applications • Self-service configuration
Run VM or cloud-native inside the firewall with regular and simplified updates	**Move existing EIM workloads to the cloud to lower costs, improve agility and drive innovation**	**Software run by the experts. A single SLA that covers infrastructure and application**	**Deploy on public cloud to accelerate growth and address data sovereignty, elasticity and compliance requirements**	**Integrate SaaS applications to offer efficiency and flexibility to meet specific use cases**



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1 Off-cloud

- Behind the firewall
- You manage, update and upgrade software

Run VM or cloud-native inside the firewall with regular and simplified updates

Pattern 1: Off-cloud

The traditional approach, where hardware and software are run on-premises, or "off-cloud." Running on-premises infrastructures allows organizations to manage and properly utilize its IT team and gives complete control over the IT landscape, including upgrade and maintenance schedules. A large enterprise can realize economies of scale by running on-premises and amortizing the cost across multiple lines of business.

As Life Sciences companies can experience complications exiting a vendor relationship, concerns about migrating data from one provider to another, or back in-house, are legitimate. This model avoids the risk of "vendor lock-in."

Finally, some companies are making a strategic decision to retain the status quo, largely because they want to be 100 percent confident they are protecting intellectual property, primarily drug formulas and device designs.

2 DIY public cloud

- Customer managed
- Complex set of relationships and SLAs

Move existing EIM workloads to the cloud to lower costs, improve agility and drive innovation

Pattern 2: DIY public cloud

In this model, a third-party "hyper-scaler," such as AWS, Microsoft® Azure or the Google Cloud Platform™ delivers managed services for an organization's OpenText EIM solutions. Also called "public cloud," this approach offers massive scale that can result in significant cost savings. Upgrades are delivered automatically within specific time windows and isolated from the infrastructure for faster and more predictable maintenance without disruption.

Managing costs while delivering on business demands is key. Managed services with a predictable cost structure keep organizations current on the latest technology, reduces burden on IT staff and ensures optimal application management by EIM experts. However, organizations now have not one contract but three, OpenText, the cloud provider and a systems integrator. This added layer of complexity might outweigh the advantages.

This model works well for a mid-sized pharma that acquires a new division and needs to strengthen quality and manufacturing procedures. The company may want to connect a cloud-based quality management system for nonconformance and corrective and preventive action (CAPA) management. The quality management system would connect to the existing document management system to ensure that standard operating procedures and other documentation are updated.

3 Managed Service on private cloud

- Managed service
- Single vendor relationship

Software run by the experts. A single SLA that covers infrastructure and application

Pattern 3: OpenText Enterprise Managed Services on private cloud

This pattern describes a managed service deployment as a single tenant in a private cloud. OpenText delivers the EIM solution in the OpenText Cloud as a fully managed cloud service in OpenText data centers, with enterprise-grade, best-in-class security, back-up and recovery options, as well as a service-level agreement (SLA) and unified support model. In short, OpenText takes responsibility for the delivery, support and service, which enables the organization's IT team to focus on higher-value efforts.

With OpenText Managed Cloud and OpenText Enterprise Managed Services, organizations realize the operational efficiencies of the cloud with the flexibility and configurability expected of an on-premises deployment. Organizations benefit from fast time to deployment, predictable costs and minimized investment in infrastructure and in-house management.

A typical use-case is a mid-sized pharma with a modest IT department that wants to keep IT costs under control and remain agile for future growth. By moving infrastructure to cloud computing, costs shift from CAPEX to OPEX and capital is freed for spending in other areas. By selecting OpenText Enterprise Managed Services, the company avoids the burden of managing complex software upgrades and can take advantage of customizations needed to run the business.

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4 Managed service on public cloud

- Managed service
- Single vendor relationship

Deploy on public cloud to accelerate growth and address data sovereignty, elasticity and compliance requirements

Pattern 4: OpenText Enterprise Managed Services on public cloud

OpenText EIM solutions reside in a third-party public cloud, yet the cloud environment is "containerized" for an organization's operations and, as such, pre-validated. Users have complete flexibility without restrictions on customization, with control over software versions for upgrades, certifications and timing.

This approach offers all the benefits of speed, economies of scale and an SLA from OpenText, without the complexity of managing multiple relationships, licenses and contracts. OpenText's recently announced agreement with Google Cloud Platform provides another attractive option to support individual needs.

A pharma that orchestrates global submissions will appreciate the flexibility, security and control of this model. It provides the needed flexibility to integrate authoring systems with regulatory publishing, product registration information and other components of a regulatory information management (RIM) solution.

5 SaaS cloud

- Cloud-native multi-tenant applications
- Self-service configuration

Integrate SaaS applications to offer efficiency and flexibility to meet specific use cases

Pattern 5: Native SAAS cloud on OpenText OT2

In a native SAAS cloud environment, solutions are built from the ground up on modern architecture and applications and services are self-provisioning and dynamically scaling. Organizations can benefit from low maintenance and predictable payments but with all the security and robust features typically found in on-premises systems, as well as support from the OpenText™ OT2 family of products.

This model could be ideal for a new start-up that wants all infrastructure to be cloud-native to support cutting-edge innovation, with a team of developers building their own apps. In addition, pharmas will also find this approach strategically beneficial when upgrading content-based processes to be cloud-native.

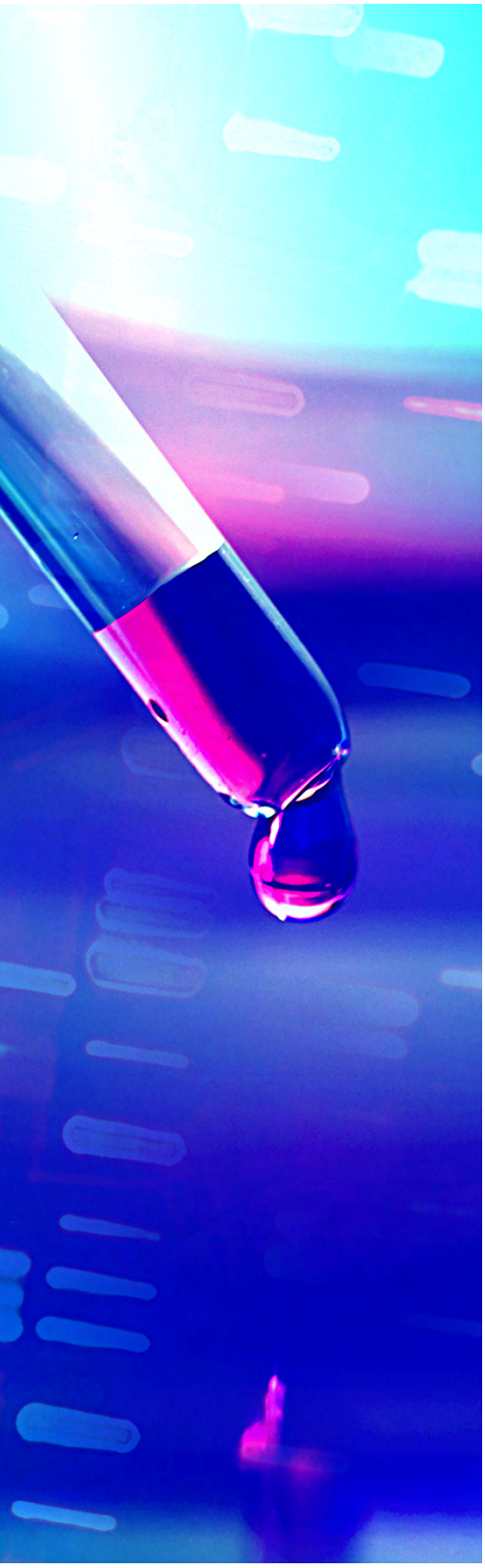
Choosing the right model—or a combination

It is important to recognize that most companies do not "rip and replace" when implementing or upgrading EIM solutions. Organizations take a measured, strategic approach, often integrating operating environments in the cloud with core on-premises infrastructure and data and sometimes combining the different patterns as it suits their objectives.

A typical pattern combination, for example, is a large pharma organization that wants to keep infrastructure on-premises for full in-house control. In appropriate situations, the company permits access to on-premises systems for external users, such as partners, contract research organizations (CROs) and regulators via a modern, cloud-based SAAS application, combining patterns one and five.

Thanks to the flexibility of the cloud, enabling external access does not require extensive IT involvement. With a secure connection and authenticated credentials, external users have access to only the systems and data relevant to their roles. The modern UI makes it easy to accomplish everyday tasks, with the same streamlined interface that internal users have on their desktops or with their tablets or phones when working remotely.

OpenText is uniquely able to combine a flexible range of cloud deployment options with EIM managed services expertise to unlock the value of an organization's information assets.



OpenText Documentum for Life Sciences solutions

OpenText offers solutions purpose-built to support every step of the digital transformation journey, regardless of the chosen approach. OpenText™ Documentum™ for Life Sciences breaks down information silos to transform how organizations access, manage and share regulated content to create a single, authoritative source.

Clinical trials

Improve inspection readiness and compliance for clinical trials.

With OpenText™ Documentum™ for eTMF, organizations can effectively plan, collect and maintain essential clinical trial documentation. Both sponsors and CROs can reduce complexity and risk by controlling and synchronizing study artifacts, tracking progress in clinical trial documentation collection and ensuring fast, secure access to documentation, both during and after trials. Users will realize gains in efficiency, manage clinical trial documents according to Good Clinical Practice and ensure inspection-readiness.

With easy access for CROs and investigators paramount, choosing a cloud deployment provides ubiquitous access in a single tenant application. Organizations can also opt for a traditional on-premises deployment that offers full control.

Regulatory submissions

Streamline creation, review and approval of regulatory submission documentation.

OpenText™ Documentum™ for Research and Development accelerates the regulatory submission process with secure information sharing across the extended enterprise, while still adhering to regulatory rules and requirements that vary by region and country. Predefined taxonomies and templates reduce deployment time and ensure compliance with industry standards, while automated workflows improve productivity and streamline review and approval processes. With the ability to link and share content across various Documentum for Life Sciences solutions, users can quickly search for, identify and retrieve submission-ready content.

Available on-premises and in the cloud, the solution supports collaborative authoring among internal stakeholders, external CROs and regulators, with complete security and role-based access control.

Obtain a 360-degree view of regulatory activity and improve compliance of archived submissions with OpenText™ Documentum™ Submission Store and View. It simplifies the search and retrieval of archived submissions and associated correspondence by linking files, enabling a full view of regulatory activity and transparent tracking of open and closed queries. Users can move submission files off uncontrolled file shares into a secure, compliant OpenText™ Documentum™ repository.

This solution can be deployed either on-premises or in the cloud for a central, secure repository to ensure effective alignment with an organization for both locally-focused and highly-dispersed functional teams operating in today's increasingly complex and global regulatory environment.

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OpenText Life Sciences solutions

OpenText Documentum for Life Sciences

Blog: Seeing patterns in the clouds

Quality and manufacturing

Control critical quality documentation and streamline and automate processes while ensuring compliance.

OpenText™ Documentum™ for Quality and Manufacturing enables organizations to control quality and manufacturing documents and automate workflows across the extended enterprise. It ensures compliance with good manufacturing practices (GMP) standards and 21 CFR Part 11 and Annex 11, providing audit trails, e-approvals and e-signatures.

With cloud, Enterprise Managed Services and on-premises deployment options, the solution enables realtime collaborative authoring with internal users and external partners. Users can automatically distribute documentation to employees and partners, and the solution harmonizes data and procedures across distributed sites.

A flexible path to the cloud

OpenText offers deployment options, consulting and integrations for on-premises, hybrid, cloud and Enterprise Managed Services solutions, easing an organization's transition and guiding it in a way that leverages existing technology investments.

About OpenText

OpenText, The Information Company, enables organizations to gain insight through market leading information management solutions, on-premises or in the cloud. For more information about OpenText (NASDAQ: OTEX, TSX: OTEX) visit: opentext.com.

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