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The Future of Life Sciences Technology

Why Strategic Technology Partnerships will Outperform Point Solutions in the Digital Transformation Race

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EXECUTIVE SUMMARY

Life science organizations are under pressure to bring safe, effective products to market quickly while satisfying compliance requirements. With the regulatory environment evolving rapidly, this proposition is becoming more difficult by the year.

Up to now, life science organizations have been forced to rely on a patchwork of disconnected technologies to address specific challenges and pain points. While this approach has been successful to some degree, it fails to address the underlying problems faced by the life sciences industry.

Patient data is the industry's #1 asset in addressing these challenges. However, at present industry players are unable to effectively manage and derive insights from patient data. This is because current technologies, processes, and partner ecosystems simply cannot cope with the huge volume of (largely unstructured) data being collected.

Over the next 2-5 years, the life sciences industry will look to embrace disruptive technologies as a means of understanding and leveraging patient data. To achieve this, organizations must identify a technology partner that truly understands the industry, and can provide the tools they need to manage the massive quantities of data and regulatory content they collect.

This report covers everything life science leaders need to know about how disruptive technology will help industry players take back control of their data and use it to address the challenges they face.

KEY TAKEAWAYS

- The life sciences industry faces a myriad of challenges, from increased regulation and consumer expectations to the aging population, growth of chronic disease, and outdated business models.
- 2. 'Big data' including patient data and regulated content holds the key to solving these challenges. However, current technologies and processes are not fit for purpose, leaving life science organizations unable to take advantage of their #1 asset.
- In the future, all healthcare will be patient centered, and life science ecosystems will be geared to make patient data available in real-time to all stakeholders including the patients themselves.
- The 'radical data interoperability' needed to facilitate this future will demand more than just technology it will require a strategic technology partner that understands life sciences and is committed to building and maintaining genuine solutions to the industry's challenges.
- Ultimately, failing to keep up with this trend will put life science organizations at a competitive disadvantage. Organizations are aware of the importance of digital transformation, but many are yet to fully commit to transformation initiatives.

SIX CHALLENGES FACING THE LIFE SCIENCES INDUSTRY

The life sciences industry landscape is evolving rapidly, and organizations find themselves faced with a host of challenges.

1. The aging population and chronic disease

At the turn of the 20th century, life expectancy in the U.S. was 47. Today, it has risen to 78. This drastic improvement in lifespans is a testimony to the huge medical advances made over the last century, but it also presents a problem.

These extra years largely fall within the middle of life.² While life expectancy is now 78 in the U.S., the average 'health span' is just 62, with later years often spent managing chronic or acute health conditions. This 17 year health gap places a huge strain on the life sciences industry and is a major factor in rising health care costs.³

And it isn't just older people who suffer from chronic conditions. According to one study, chronic diseases account for 7/10 deaths in the U.S., and 45% of Americans have at least one chronic disease. This is partly due to advancements in healthcare, which saves the lives of patients suffering from previously fatal diseases, but also correlates with poor diet and lifestyle choices. The explosion in chronic disease over the last three decades has substantially damaged quality of life and forced healthcare costs ever-upward.

Unmet medical needs add an additional load to the industry as, in lieu of effective treatment, patients receive ongoing care to extend life and increase comfort. The Belgian Federal Agency of Medicines and Health Products defines unmet medical need as:

"Chronically or seriously debilitating diseases or diseases considered to be life threatening and that cannot be treated satisfactorily by an authorized medicinal product"

Combined, these three factors are placing a strain on the life sciences industry to contain costs without affecting health outcomes.

2. Consumer expectations

Over the last two decades, consumers have come to expect outstanding user experience in a broad range of industries. In particular, online products and services — even in traditional industries like finance — have trained consumers to demand a highly personalized service. In the near future, consumers will demand the same level of personalization from healthcare providers, and will "vote with their feet and their wallets." ⁵

Delivering this heightened level of service will require the life sciences industry to embrace the same technology trends as other digitized industries: harnessing data-driven insights through big data architecting, AI, and machine learning (ML).

At the moment, while life science organizations understand the need to adopt these technologies, the exact path forward remains unclear. Most organizations have a multitude of legacy technology solutions in place, but will need to fully embrace digital transformation and integration to deal with the huge volume of patient data effectively.

3. The expanding healthcare ecosystem

Presently, the life sciences industry operates in discrete silos. For privacy, legislative, security, and competitive reasons, there is minimal data sharing between organizations. However, to deliver the patient-centered future of healthcare, far more cooperation will be required — even between competitors.

This new industry model is often referred to as radical interoperability, and the process has already begun. The topic will be covered in more detail later in this report.

In 2020, there is already far more cooperation between life science organizations than ever before. Deloitte identifies value-based care and regulatory pressures as the key motivators for broader interoperability. Major benefits are expected to be found in cost of care, consumer experience, and care coordination and patient outcomes.

However, cooperation between life science organizations — and data sharing in particular — presents tremendous logistical and security challenges. Breaking down silos and building the future of healthcare will require organizations across the industry to embrace disruptive technologies wholeheartedly.

Based on interviews with 100 life science executives conducted by Deloitte, 80% have hired data architects to define their interoperability strategies, while 73% have a dedicated team to oversee interoperability.⁷

4. The changing geopolitical climate

Increased regulation and need for transparency is placing many new requirements and restrictions on the industry, particularly in first world nations like the U.S. and EU. As regulators try to keep pace with the rate of advancement, incumbent players are in turn struggling to interpret and conform to regulatory changes.

According to Deloitte:

"Interpreting the growing volume of regulatory legislation accurately and implementing any necessary changes in a co-ordinated, cost-efficient and timely manner, across a number of business functions, is testing the capabilities of the industry." 7

Until available technology solutions catch up with industry needs, this will continue to be a major challenge for life science organizations.

And that's not the only challenge presented by the rate of regulatory change. Increasing regulation is in large part responsible for the fact that pipeline development is delivering lower yields than in previous years. Since 2010, the cost of bringing assets to market has risen from under \$1.2 billion to almost \$2 billion. During the same period, R&D returns have declined dramatically to just 1.8%.8

5. Outdated business models

Historically, the life sciences industry placed a huge emphasis on 'blockbuster' drugs and treatments. However, with costs rising and returns falling, this business model is not outdated. Once again, the future of healthcare lies in putting patient experience at the center of business strategy — and that requires embracing disruptive technology.

KPMG argues that:

"Life sciences companies need to develop a digital data strategy comprising all business units and stakeholders. All of the technological advancements in the different steps of the supply chain that generate data [...] should be considered in a holistic concept." 9

While many life science organizations understand this need, few are wholeheartedly embracing digital transformation at the present time. Technology investments are ongoing, but major business model overhauls are yet to happen.

6. Digital disruption

Digital disruption in the industry has arguably been going on for decades. However, one of the major challenges faced by life science organizations is determining which vendors and solutions will add value — not just today, but as the industry moves toward a patient-centric business model.

Presently, most vendors sell 'point solutions' designed to solve a single problem without regard for other business needs or functions. Many vendors lack a detailed understanding of life sciences and have simply adapted a generic solution in an attempt to break into a new market. The future of healthcare will require more integrated solutions designed to address the specific challenges faced by the life sciences industry.

The problem with most solutions currently available to life science organizations is simple: they lack a focus on outcomes. Point solutions focus on solving specific pain points (e.g., data storage) rather than bringing organizations closer to the outcomes they need to achieve. This only deepens the issue of information silos and ultimately leaves organizations with a myriad of uncoordinated technologies.

According to a Gartner report:

"Lack of alignment of digital initiatives to business objectives threatens to be a barrier to delivering on the digital promise to customers and to the growth ambitions executives have for digital." 10

BIG DATA AND THE FUTURE OF HEALTHCARE

For several years now, big data and its related technologies have promised to solve the challenges facing the life sciences industry.

The promise is simple: If organizations can harness the mass of patient data they hold to produce meaningful insights, they'll have the power to improve everything from patient experiences to R&D returns.

However, producing usable insights is far from trivial. Life science organizations collect massive quantities of data, up to 175 exabytes a year industry-wide by some estimates. This volume far exceeds most organizations' ability to process and interrogate data, especially in real-time — something that will be essential to deliver the patient experiences, health outcomes, and business benefits big data has promised to enable.

Of course, addressing these challenges requires the use of technology. But as alluded earlier, current point solution offerings are not sufficient to enable organizations to benefit from the wealth of data they possess. Even achieving data visibility throughout the patient journey is something the industry is currently unable to achieve using legacy technologies.

These problems have arisen because the process for selecting and implementing technology is backward.

A NEW MODEL FOR LIFE SCIENCES TECHNOLOGY

So far, the industry has used technology to solve specific, discrete pain points. As a result, many organizations have expended time and resources to adopt technology solutions that can barely keep pace with the rate of change.

To harness the benefits of big data, the industry must start by identifying the outcomes needed, and only then look to technology. Simply, the process for identifying and adopting transformative technology should follow three steps:

- 1. Start with the desired outcomes for all stakeholders and work backwards to determine exactly what is needed.
- ldentify and analyze available data to derive insights. This requires full visibility of all data, including so-called 'dark data' an organization may not be aware of, e.g., data acquired through M&A.
- Use data insights to design and automate new business models and processes that will serve the industry now and in the future.

These three steps are only possible by leveraging transformative technologies. However, starting with technology solutions is still a mistake. Instead, life science organizations should look for a technology <u>partner.</u>

MOVING BEYOND TECHNOLOGY SOLUTIONS

To leverage big data in a meaningful way, organizations need more than technology. They need a strategic technology partner that understands the life sciences industry and can build genuine solutions to the problems the industry faces.

Life sciences is a rapidly evolving industry, with a constantly changing regulatory landscape. Not only that, the industry faces huge pressure to control costs, provide personalized patient experiences, and improve health outcomes. Organizations need a technology partner that can adapt to changing demands in a manner that ensures consistency of outcomes and regulatory compliance.

If such a partner can be found, and big data can be harnessed effectively, there is little doubt that major strides can be made to combat the challenges laid out earlier in this report.

Organizations at the forefront of this digital transformation will be prepared for a future where personalized medicine, telehealth, and the Internet of Medical things (IoMT) are a reality built on interoperable data platforms.

WHAT DOES THE FUTURE LOOK LIKE?

Today, too much of healthcare is reactive. Poor diets, lifestyle choices, and environmental factors cause many people to become ill or injured unnecessarily. This forces the healthcare cost curve ever-upward and leads to poor health outcomes.

The future of healthcare will solve these problems by harnessing the industry's #1 asset — patient data — in real time. Patients will benefit from personalized healthcare, where negative health indicators are identified early, and preventative treatments applied.

Likely scenarios include:

- Use of sensors and wearables to identify early indicators of chronic disease or mental health conditions.
- Individuals will receive personalized recommendations related to diet, exercise, treatment options, and proper management of chronic conditions.
- Healthcare providers will have a full picture of patient health, enabling safer and more effective treatment.

For these scenarios to be possible, there must be a radical shift in the way patient data is stored, interrogated, and shared.

RADICAL DATA INTEROPERABILITY

The future of the healthcare ecosystem lies in radical data interoperability. That means all relevant consumer data will be available for research and action, no matter where the individual seeks treatment or advice.

Deloitte envisages a future where the focus of healthcare shifts altogether onto health and wellness. Through a web of interconnected devices and sensors, consumers will receive a personalized experience of health care, including preventative advice and treatment designed to maximize wellness.

This future will depend on technology at every stage of the patient journey. It will require:

- Internal integration of data, platforms, roles, and processes to ensure captured data is actionable.
- Real-time production of data insights to inform better healthcare products and services and improved health outcomes.
- Seamless data transmission and exchange between organizations to enable patient-centered care, e.g., early detection of conditions and preventative care.
- Instant access to data insights for all healthcare stakeholders including patients to reduce costs and improve health outcomes, consumer experience, and scientific discovery.

To achieve this, life science organizations must:

"Focus on interoperability in current and future partnerships. Be active, open, and curious, as there might be opportunities to collaborate differently with traditional competitors, regulators, large technology companies and startups, and community and nonprofit organizations than has been possible in the past."

WHY IS DATA INTEROPERABILITY NEEDED?

The case has been made for radical data interoperability on the basis of lowered costs, improved health outcomes, and greater consumer experience. However, the true need boils down to two factors:

1. Better management of diseases that are expensive and crippling to quality of life

A massive proportion of global healthcare spending is for people with chronic and mental health conditions. In the U.S., these two groups alone account for 90% of healthcare expenditure. ^{12 13} To make matters worse, the prevalence of multiple chronic conditions and poorly managed health conditions is rising year-on-year. ^{14 15} This contributes a huge cost and resource burden to the healthcare and life sciences industries and also robs the global economy of countless hours in lost productivity. ¹⁶

Radical data interoperability is essential for the effective management of chronic and mental health diseases. Without it, the future vision of identifying conditions early and providing patients with personalized healthcare and guidance is simply not possible.

2. The need for greater transparency

The regulatory landscape for life sciences has evolved at an unprecedented rate over the last decade and shows no signs of slowing down. In recent years, there has been a huge push globally for increased transparency reporting throughout the life sciences industry. As more countries around the world adopt transparency reporting regulations, and the scope of existing regulations is broadened, life science organizations will continue to come under pressure in this area.¹⁷

At the same time, consumers are increasingly demanding transparency, particularly in pricing and value. In the future, consumers will 'vote with their feet' by choosing organizations that can demonstrate high value while controlling costs. For this reason, KPMG describes transparency as "table stakes in a consumer-centric healthcare system," even if it is not mandated by regulators. 18

HOW CAN LIFE SCIENCE ORGANIZATIONS PREPARE?

For life science organizations to provide higher levels of transparency, making effective use of captured patient data will be essential. However, once again, life science organizations must avoid the temptation to settle for non-ideal technology solutions. Instead, they must start with a focus on the outcomes needed, and then identify a technology partner that will enable those outcomes. Deloitte notes that:

"The most common mistake when getting started with transparency analytics is focusing on technology solutions first, and then working backwards to make the business process or analysis needs fit the selected/implemented technology. Another approach is to start by carefully considering the information needs of your business. [...] Once you understand the business issues or requirements, it is much easier to determine which tools and algorithms are the best fit." 19

At the same time, life science organizations must actively collaborate with regulators to develop new standards for transparency. These standards will include — even assume — the presence of technology to capture, interrogate, and report on real-world data in near real time.²⁰ This is simply because without such technology, continuing to meet evolving regulatory and compliance requirements will be impossible.

THE CURRENT STATE OF LIFE SCIENCES TECHNOLOGY

To determine the current state of technology use in the life sciences industry, OpenText and Informa Connect conducted a survey of industry professionals. Of the 84 respondents, the majority were line of **business managers/directors (48%)** and **C-suite executives (33%)**. Respondents were from organizations spread evenly across a range of life science functions including biotech, pharmaceuticals, medical devices, research, and consultancy.

How are Life Science Organizations Currently Using Technology?

Respondents were asked to identify all technologies currently in use by their organization. Out of 20 possible options, the top five currently in use by life science organizations are:

- Business process management (50%)
- Content management (50%)
- Cyber security (42%)
- Big data analytics (38%)
- Master data management (27%)

Other notable technologies in current use include AI, Identity and Access Management (IAM), Internet of Things (IoT), and interoperable data platforms, all of which are in use by approximately 20% of respondent organizations.

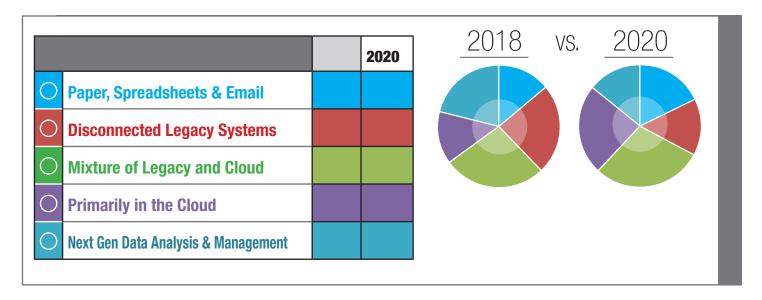
How Well Do Life Science Organizations Manage, Control, and Utilize Digital Information?

Respondents identified how successful they believe their organization is (on a scale of 1-10) at managing, controlling, and utilizing digital information. Responses were spread evenly across the scale, with 4% rating their organization at 10/10, while 2% rated their organization at zero.

Over a quarter (27%) of respondents rated their organization at 5/10, while two-thirds chose scores of 6/10 or less. Overall, while it's difficult to draw any firm conclusions from subjective ratings, these responses suggest that most life science professionals believe their organizations have some distance to go in this area.

Current Use of Technology for Efficiency and Automating Business Processes

Survey respondents were asked to gauge their organization's current use of technology to gain efficiencies and automate business processes. The table compares the results to those of a similar survey of life science professionals from 2018. The 2018 survey was of a similar size and demographic split.



There is a 10% swing between 'disconnected legacy systems' and 'primarily in the cloud'. The move to the cloud has been a major business trend in recent years, so this is unsurprising. However, what's notable is that the overall split remains similar in 2020 to what we saw in 2018. That suggests many life science organizations have not yet made major decisions about the future of their digital strategy.

Are Life Science Organizations Considering Enterprise Information Management (EIM) technologies, and How Will They Help?

Currently, 35% of respondent organizations are considering the use of EIM technology. Respondents identified the top five business functions that might benefit from EIM — either through increased efficiency or the ability to produce greater insights — as:

- Document management (60%)
- Quality systems and validation (45%)
- Quality management (37%)
- Regulatory submissions (31%)
- Regulatory Review Promotional content (30%)

How Well Defined are IT Processes in Life Sciences?

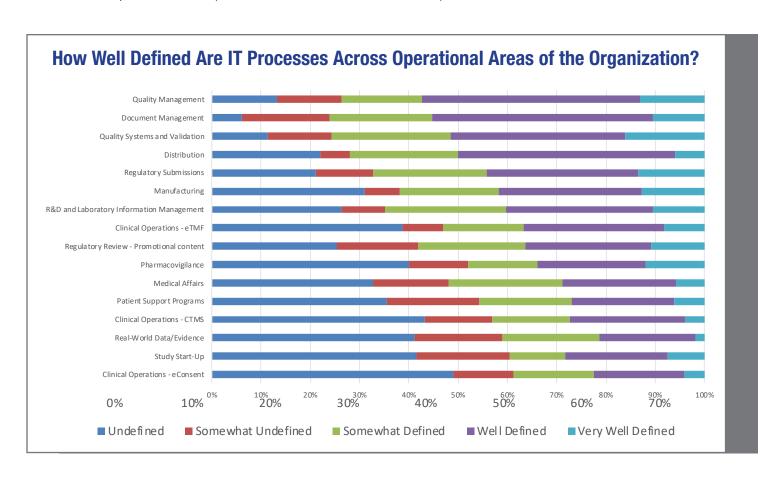
Respondents were asked to gauge how well defined IT processes are at their organization across a variety of business functions. Predictably, business functions that are closely linked with regulatory requirements had more well defined IT processes. More recent and less regulated functions were consistently rated as having less well defined IT processes.

Most defined areas:

- Quality management (57% well defined or very well defined)
- Document management (55% well defined or very well defined)
- Quality systems & validation (52% well defined or very well defined)
- Distribution (50% well defined or very well defined)

Least defined areas:

- Clinical operations eConsent (61% undefined or somewhat undefined)
- Study start-up (60% undefined or somewhat undefined)
- Real world data/evidence (59% undefined or somewhat undefined)
- Clinical operations CTMS (57% undefined or somewhat undefined)



Will Life Science Business Models be Seriously Disrupted in the Next Two Years?

This question highlighted a clear divide in the industry. 42% of respondents somewhat or completely agreed that their organization's business model could be seriously disrupted within two years, while 41% somewhat or completely disagreed. The remaining 17% shared no opinion.

How Important is Digital Transformation?

Whether or not they believe disruption is imminent, respondents overwhelmingly confirmed that digital transformation is important to their organization. 69% see digital transformation as either very important or important, while 29% see it as somewhat important, and just 3% believe it is unimportant.

Given the rapidly evolving regulatory landscape and the position of all major industry analysts on the importance of disruptive technology, these results are in line with expectations.

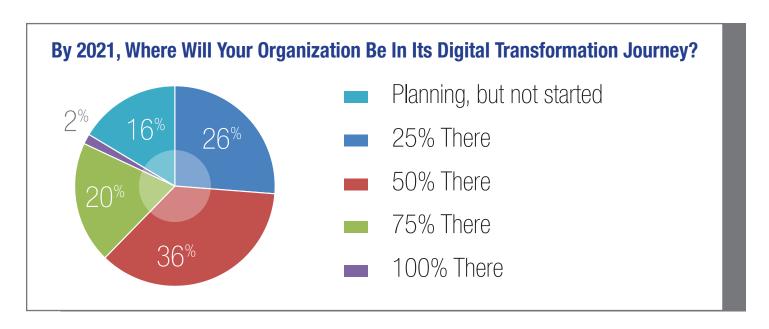
Are Organizations On Track to Meet the Trends & Challenges of Life Sciences 4.0?

Almost half (48%) of respondents believe their organization's information management strategy is not on track to address the trends and challenges of life sciences 4.0. Just under a third of respondents (31%) are at least somewhat sure that their organization is on track.

Digital Transformation by 2021?

Survey respondents were asked: By 2021, where is your company in the overall Digital Transformation Journey, leveraging EIM to 'understand, anticipate, and redefine your patient's healthcare experiences?'

78% of respondents believe their organization will be halfway or less through their digital transformation journey by 2021. Comparatively, just 2% believe their organization will have completed its journey.



WHAT CONCLUSIONS CAN BE DRAWN?

The results of the survey make two things immediately apparent:

- 1. Life science organizations overwhelmingly believe digital transformation is essential; but,
- 2. Many are yet to 'pull the trigger' and invest heavily in disruptive technology.

Why might that be? While it's impossible to tell for certain, it seems likely that hesitance results from a lack of faith that technology providers can support the evolving needs of life science organizations. If life science CIOs and other executives can be convinced that a technology partner genuinely understands — and can support — the needs of the industry, substantial investment in disruptive technologies becomes more likely.

It's worth noting that all of the assessments made by survey respondents are subjective. When it comes to each organization's technological current 'readiness', the accuracy of assessments depends on whether the anticipated timeline for industry disruption is accurate.

However, it's hard not to notice discrepancies in the survey data. 42% of respondents are concerned their organization's business model could be seriously disrupted within two years — but only 2% believe their organization will have completed its digital transformation journey within that period. This suggests that the 31% of respondents who believe their organization is on track to meet the challenges of Life Sciences 4.0 — using technology to take full advantage of patient data — may be over-optimistic. Given the slow rate of technological advance within the industry between 2018-2020, it remains to be seen whether external factors will force life science organizations into more rapid adoption of new technologies.

THE IMPACT OF COVID-19 AND OTHER DISASTERS

This report has alluded to the major challenge of life sciences: bringing safe, effective products to market quickly while staying compliant. Achieving this balance is often difficult, and the case has been made for disruptive technology as a means for life science organizations to re-balance the equation in their favor.

However, 2020 has served as a reminder that no matter how good business continuity processes are, they can always be tested. COVID-19 has placed the life sciences industry under extreme pressure as it aims to develop, produce, and supply all manner of medical products on an unprecedented scale and an extremely short timeline.

It should be noted, also, that COVID-19 is not an isolated case — although it has affected the industry and the world on an unprecedented scale. Individual regions have been heavily affected within recent memory by epidemics like SARS and Avian Flu and even natural disasters like earthquakes and tsunamis. Being prepared for highly disruptive events like epidemics and natural disasters requires a myriad of emergency and disaster recovery procedures. However, one clear way to prepare for these events in future is to invest in disruptive technologies — specifically, technologies that improve the storage, management, interrogation, and flow of patient, R&D, and compliance data.

By working with a strategic technology partner that understands the industry's challenges, life science organizations can begin to implement the data interoperability capabilities that will fuel the future of healthcare. At the same time, this technology will provide increased control over industry data, helping organizations function effectively during the most challenging times.

EMBRACE DIGITAL TRANSFORMATION WITH OPENTEXT

The life sciences industry is under huge pressure to bring safe, effective products to market quickly at a lower cost while satisfying rapidly evolving regulatory requirements. Technology will play a crucial role in helping life science organizations unlock the value of patient data. However, current legacy systems and ad hoc processes can no longer cope with the sheer volume of patient data. As yet, most life science organizations have not identified a suitable technology partner to enable their digital transformation.

A DIGITAL TRANSFORMATION PARTNER

This report has identified the need for more than new technology solutions. Life sciences have long been sustained by a myriad of disconnected solutions that solve individual problems without understanding the industry's wider needs. Worse, most of these solutions were never designed for life science organizations, and have simply been repurposed.

As organizations look to embrace digital transformation, they need a genuine technology partner that understands life sciences — and can build and maintain technology solutions that address the industry's genuine needs and pain points.

OpenText is that partner. OpenText for Life Sciences is a set of purpose-built solutions that enable organizations to take full control of data, information, and content from all sources. These solutions help speed study startups, minimize compliance risk, boost productivity, simplify integration, and much more.

WHY CHOOSE OPENTEXT FOR LIFE SCIENCES?

OpenText for Life Sciences is a complete technology solution — an end-to-end portfolio of technologies designed specifically to address the industry's needs and challenges. Operational benefits include:

- **Take control of patient data.** Easily manage, interrogate, and transfer information from electronic medical records, clinical trials, implants, wearables, and patient generated sources.
- **Streamline regulatory compliance.** Simplify and enhance compliance and reporting processes with a single authoritative source of regulated and non-regulated content.
- **Robust managed services.** Unlike point solutions, OpenText's team of subject matter experts ensures customers receive full support in delivering greater health outcomes and results.
- **No more silos.** Break down divisional and departmental silos, enabling information sharing and collaboration across the ecosystem of suppliers and partners.
- **Source and technology agnostic.** Integrate natively with anything systems, applications, data sources, and even connected IoT devices via API.
- A flexible path to the cloud. OpenText for Life Sciences is cloud native software that can run anywhere, giving your organization freedom of choice.

To find out more about how OpenText for Life Sciences can help your organization achieve its digital transformation objectives, visit the website.

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ABOUT OPENTEXT

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OpenText Information Management solutions help Life Sciences organizations leverage the full potential of their information assets, from research and development (R&D) through to commercialization.

Life Sciences solutions from OpenText, combined with OpenText's information management expertise in the Life Sciences industry, help organizations transform and automate processes related to asset management, information governance, clinical trials, drug development, and real-world evidence. With its extensive end-to-end portfolio of technologies, OpenText delivers Life Science solutions focused on health outcomes and results.

Pharmaceutical, Biotech, and Medical Devices companies trust OpenText to help them meet information management challenges by:

- Enabling Any-to-Any Integrations
 Integrate, manage, and securely exchange data across people, systems, and things
- Providing a Broad Solution Portfolio
 Single, authoritative source of regulated content
- Delivering Flexible Paths to Cloud
 Freedom of choice with cloud-native software that can run anywhere

All of the top 20 Life Sciences organizations rely on OpenText's Information Management solutions and team of industry experts.



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OpenText, The Information CompanyTM, enables organizations to gain insight through market leading information management solutions, on-premises or in the cloud.

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Contact us to **learn more** about how OpenText for Life Sciences can help you transform your organizational needs and opportunities.