

NTT DATA

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**LIFE SCIENCES
WHITE PAPER**



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AN INDUSTRY BASED ON CONSTANT INNOVATION IS REINVENTING ITSELF...

And is facing a future which contains both challenges and opportunities

The industry has moved on from a past “golden age” dominated by blockbuster drugs. The pharmaceutical industry has reinvented itself with biological medicines and has reduced healthcare costs for society with generics and biosimilars, but at the same time it has taken giant steps in personalized medicine and genomics. COVID-19 has driven the development in record time of new platforms (T-Cells) and technologies such as mRNA anticipating 10-15 year of innovation in the sector.

The challenge for this industry is to complete digitization, pervasively use advanced data analysis tools and collaborate on a holistic approach to the provision of health care. NTT DATA has the business insights, technological expertise and industry knowledge to help companies on their journey to a very different future.



KEY TRENDS

NTT DATA has identified a number of trends that are of long-term strategic significance for almost every player in this field.

Regulatory pressure

Consensus on global market rules is breaking down, which throws established rules for governing international trade into question. Although there are positive interventions (the move from CSV to CSA as a way to reduce documentation requirements), some national regulators are intervening more aggressively to ask for action in specific areas and set rules on everything from pricing at point of sale to local content. Governments and trading blocs, such as the EU, are also effective in negotiating favorable prices, matched by quality advances. This type of process will continue and will connect to:

- **Security and pedigree.** An international market is sensitive to everything from trade disputes to fraud. Both cybersecurity and physical ePedigree systems are now major issues for large companies, and the more they disaggregate their R&D and/or manufacturing, so the pressure on systems of record grows. Serialization (related to each individual unit of a batch) adds to the pressure on systems, bringing further granularity to ePedigree requirements.
- **Cyber-security.** The Life Sciences market is as open to the rapidly increasing number of cyber threats. The WannaCry attack, for example, led to disruption of major systems across the healthcare sector, as well as in other parts of the global economy. For Life Sciences companies there is another level of complexity, as well. As they diversify into medical devices (a topic we will explore later), so their duties related to cyber security will grow dramatically. Home-based medical devices must be accessible online, which potentially makes them hackable. ePedigree/Serialization is the key to drug security, and cyber is the key to device security. Both are critical for regulatory compliance.
- **Patient data.** No information is or can be more sensitive than DNA, and as the industry moves towards targeted or patient-specific medicines, so pharma companies need to develop capabilities that enable GDPR compliance, complete anonymization, patient access to their own data, all alongside the need to develop truly effective medicines that operate on a very different basis, compared with classic “mass market” drugs.

Time and cost for development

The value of a pharmaceutical company is the same as the value of its pipeline. Developing new molecules that may turn into tomorrow's blockbusters is increasingly costly, time-consuming and expensive.

- **The Patent Cliff.** This has been a problem for decades, as the cost of developing new formulations grows and the time allowed for monetization shrinks (due to the length of time for clinical trials). Global Pharma players, in particular, have seen growth driven by a limited number of "blockbuster" drugs, and when these come out of patent, that element of their revenues will decline very suddenly.
- **Generics.** The rise of generics and biosimilar products means there is usually a lower-cost rival to take their market share with identical (or very similar) products, retailed at a fraction of the cost. There is also a political side to this whole issue, with the "Global South" hosting major generics players (notably in India), governments and trading blocs taking an active role in price negotiations, and even in copying patented medicines with the encouragement and facilitation of government.
- **Buy-in vs in-house development.** Major pharma companies are motivated to buy-in new formulations because, by scanning the entire market rather than relying only on in-house teams, they reduce risk and increase the potential for growth. Large companies are prepared to pay a premium for promising new molecules, and that is leading to different strategies and ways of managing risk.
- **Specialization vs M&A.** Different options are available for improving the hit rate for new formulations. Very large pharma companies may set up highly specialized in-house units to focus on very specific areas, while others may opt for Merger and Acquisition (M&A) as their chosen strategy. Others use a lean business model in which their focus is on research and patent management, with other functions outsourced. All these models can work, but both require skills that go beyond traditional R&D, together with plenty of risk capital.
- **Computer Aided Drug Design (CADD).** To improve the chances of discovering a winning formula, Data is becoming increasingly important. Algorithmically-based drug discovery systems, using quantum computing are now in use for carrying out theoretical work on precise suitability of specific chemicals for addressing specific concerns, potentially speeding up the discovery process. Data mining is also used to marry new insights with historical data, often taken from past projects (that appeared to have led to no useful results). This marriage of classic IT, emerging data analytics and chemical research is gradually changing the rules of this particular game.

Technology innovation

The Covid-19 crisis has shown the importance of new approaches to solution development, with mRNA-based biotech treatments happening due to new technology options and development of new manufacturing models (such as continuous production for biopharma).

- **Business models.** There is an inherent challenge here to existing business models. New options, such as “Cure as a Service”, or combinations of medical devices with specific drugs for targeted treatments are in development. Yet we need to remember that the industry is (necessarily) risk averse, so developing new models will never be fast or easy, although government and regulator pressure can accelerate such changes.
- **Targeted medicines.** Within this category there are two distinct segments: precision medicines (such as the mRNA vaccines developed for Covid-19), and personalized medicines, such as CAR-T, which uses a specific individual’s own stem cells. The use of CRISPR (for gene editing) is enabling development of more effective (with fewer side effects) targeted cancer treatments, and can also be used for diagnostics and many other purposes.
- **New alliances.** These are just samples of innovations that have the potential to radically transform at least some parts of the industry. The combination of a small, innovation bio-tech company (BioNTech) and a traditional pharma giant (Pfizer) for development of a completely new treatment for a previously unknown pathogen at unprecedented speed is an illustration of what might become the norm in the future.

New operational scope

This emerging new world of targeted treatment presents a major challenge to traditional manufacturing techniques.

- **Quality management.** Regulators will increasingly seek enhanced (in-line) monitoring, driven by 2020 ICH update, and we are likely to see a rise in predictive quality management, based on identifying critical parameters that affect quality, and managing these more strictly to improve quality of output without needing intensive sampling. This enables companies to move from post-production (traditional) quality control techniques to in-process quality management.
- **Horizontal integration.** It is starting to make sense for Life Sciences companies to integrate horizontally (drugs, medical devices, care provision, dispensing, even insurance...) rather than vertically in the same silo. The growing correlation between devices and drugs, treatment regimes and Cure as a Service, requires different types of capability, vision, expertise and areas of innovation.
- **Industry 4.0.** Almost every Life Sciences manufacturer is moving to an industry 4.0 vision, and this may lead to a future that looks very different from today's reality. One likely development is the increased willingness of Market Authorization Holders (MAH) to work alongside Contract Manufacturing Organizations (CMO) to produce medicines or devices for go to market value propositions.

Strategic direction setting

Given the major forces impacting the industry today, what should each individual business seek to become in the future?

The historical advantages gained by collating multiple capabilities inside a single, massive corporation are starting to unwind, and at high speed. The Covid-19 crisis has already highlighted resilience issues in supply chains, which large pharma companies are racing to address, often by developing modular supply chains. Third party capabilities are now more visible, and it has become more acceptable to create ecosystems, rather than seeking to "own" everything.

Does it make sense to be a vertically integrated business? Is there a case for disaggregating at business, as well as technology level? With dispersed production facilities, outsourcing of sales, Contract Research Organizations (CROs) and even quality management?



STRATEGIC ASSESSMENT AND VISION

The problem for major Life Sciences companies is not so much a shortage of opportunity but rather an excess of choices. Different avenues into the future are available, and we are setting out our view of the three main options for large players in the market today.

Focus on holistic, individually-customized treatments

We expect some companies to extend their business scope to cover the total care landscape.

- **Device and drugs in combination.** This could involve strategic partnerships with, or acquisitions of specialized medical device design and manufacturing businesses, so that an holistic treatment will include both bio-tech derived individualized drug therapy with monitoring devices and other forms of medical hardware. It can also extend to such innovations and the Otsuka Abilify Mycite 2, which embeds a microscopic sensor in a pill to measure speed and efficiency of drug uptake.
- **The rise of drug platforms.** Manufacturers making this strategic choice will focus less on developing a traditional pipeline of treatments and instead focus on “platforms”: base level technologies that enable extensive customization and targeting, using group or even individual DNA for targeted treatments.
- **The importance of feedback loops.** In such cases, data forms a feedback loop in which real information about reception and efficacy of individualized treatments is used as the basis for continuous development and improvement. Ownership of this Real World Data is critically important.



- **New structures, new capabilities.** Many large pharmaceutical companies are discovering the need to acquire new capabilities to address a changing market. These can be focused, covering only those capabilities that directly relate to drug-based treatment (for example, gaining an interest in a specific range of medical devices). In some markets, however, we can imagine a recalibration of scope to go much further. Moving into personalized medicines, for example, requires reorganization of production plants into modular structures, with near-the-patient facilities and services around the drug, itself.

Cure as a Service models means a move away from high volume sales strategies and also demands a new range of environmental measures, in particular dealing with spoilage and recycling. It is also possible, for example, to work with insurance specialists to deliver complete packages of treatment, covering costs, human support, general medical services and treatments that maximize mobile communication and data technologies to enable home-based treatment, even for very complex conditions.

Innovation first, last and always

We need to remember that all pharmaceutical companies began with the same vision: to create excellent and innovative products that contribute to quality of life.

- **Changing patent landscape.** The nature of innovation in the market is sure to change simply because of the rapid rise in personalized technologies. It is not clear as yet whether it is even legally possible to patent highly targeted or incremental innovation, especially when some treatments will include DNA that is (by definition) the property of the patient. Complete treatments may also require patents that cover property of multiple corporations in different field devices AND drugs AND service support formulae.

- **Choosing the right roles.** The lesson of the past two decades is that it is becoming harder both to create potentially game-changing innovations and play all the other roles, as well. A factor in this growing complexity is that diseases, themselves, are now also more complex and less frequent, while people's life expectancy has increased to the point where many develop multiply morbidities (several diseases at the same time), so they will be taking several drugs in parallel.

All trends suggest that fast-moving, often very specialized groups of research scientists, data scientists and engineers, often working in informal, extended ecosystems, are now better placed to make the conceptual breakthroughs that drive value today and into the future, than very large, centrally managed corporate departments. It is quite possible that large Life Sciences companies may conclude that they should either innovate or manufacture, but that it is increasingly hard to do both.

- **Ecosystem approach.** To bring a radical innovation to market, such as recently-announced potential MS treatments from newly-established bio-technology firms, may be best managed through non-traditional alliances, rather than centralized manufacturing. Covid-19 vaccines requires a global marketing/development partnership, but with multiple local contractors producing for individual markets or groups of markets. Some innovations (such as the Pfizer/BioNTech Covid-19 vaccine) will go to market through mass produced treatments, while in others it may be delivered as a customized solution, wrapped with other capabilities, including services, hardware and financing.

Focus on Industry 4.0

In every industry sector, manufacturing is being transformed through a combination of data analytics, enabling sensor-based asset management, digital twins and enhanced controls for predictive management, use of data as product pedigree information, asset fleets managed from single points of control...

- **Enhanced data management.** Data is not simply about managing assets. Production line sensors also deliver improved insights, providing control over parameters that impact quality anywhere in the value chain, while permitting early intervention, based on production-generated insights. This can include internal cold chain issues, use of machine vision to generate quality data (for example, for incoming goods), serialization and global tracking (including external cold chain), while providing insights to a complex ecosystem of Contract Manufacturing Organizations for enhanced decision-making.
- **Seeking competitive advantage.** Manufacturing in most sectors is now subject to radical change, and businesses that want to stay profitable as manufacturers need to be leaders in this process, not reluctant converts. For branded pharmaceuticals companies, the key requirement in the future may be to stop complaining about low-cost generics specialists and start trying to beat them by being better as pure-play manufacturers.
- **Agile compliance.** We can see two major options that are likely to prove very important in the future, yet which both present management and technical challenges.

Continuous manufacturing removes the overhead associated with preparation, cleaning and changing production systems connected to different batches, while requiring predictive quality management and intervention to meet regulatory standards.

Modular manufacturing enables production lines to be assembled on the fly, validating modules rather than the entire process. It may then be possible to assemble an ad hoc production line, pre-validated, for each order. This could also reduce costs and accelerate roll-out to less developed countries, as it would eliminate real estate and many investment costs.

SETTING PRIORITIES

As any business contemplates its possible futures, choosing priorities becomes the most important management requirement. Our view is simple: the most urgent first step is to make sure the ERP/core systems of record are optimized, along with the business processes associated with the core. This is the essential foundation for everything that follows and is the most basic necessity.

Rethinking use of data

Every industry believes in digitization and the accompanying need to unlock the full value of all the data they produce or process, as far as regulations allow.

The pharmaceuticals industry has been slow to move in this area, and for a good reason. This is a very cautious industry, still with highly paper-based processes, making products that impact people's lives and subject to intense scrutiny and regulation.

- **Data journey.** Many businesses have therefore begun their data journeys by digitizing their more peripheral processes (sales and marketing, HR, communications)... To make rapid progress, they will need to focus on how to transform mission-critical processes, such as R&D, production, distribution and quality. For this journey to be successful, the business core of the company must also be digitized.
- **Data gathering and analysis.** A range of data-focused enablers will support this journey towards complete digitization. Here is a (non-exhaustive) list:
 - Data analytics, enabled by AI and Machine Learning, supports product innovation by re-analyzing in a more granular way the existing data from previous medical trials and from discarded research projects.
 - Public data can also be collected through RPA or integration platforms, and held within datalakes, which can ingest both structured and unstructured data, in all formats. Data can then be analyzed to provide improved pharmacovigilance, giving early warning of adverse effects from medication, and adding depth to the understanding corporate teams have of how their treatments are received in markets around the world.
 - Sensor data enhances machine learning to improve predictive maintenance, while product data acts as a pedigree, not only for formulations in general but for every part of every individual batch, enabling end-to-end batch genealogy.
 - This leads to effective ePedigree management, including serialization, to counter the threat of counterfeiting, while protecting corporate reputation.

- **Breaking down siloes.** We have discussed the need to connect and then break-down operational siloes within production, enabling end-to-end, fully integrated manufacture, driving quality up and costs down. Yet this general requirement does not only apply to production.
 - Removing siloes in different subsystems (such as LIMS, QMS, ERP and MES) enables sharing of data across departments, closer collaborative working and holistic insights for use by data scientists and product specialists.
 - Data also provides insights and actionable intelligence for decision-makers. It will also become easier to transform data into the reporting formats required by different regulators.

Data needs to be standardized before it can enter a datalake, to ensure harmonization, consistent naming conventions and suitability for analysis. Finally, we need understand that all these existing systems will evolve into data loops, where outcomes are constantly refined and continuously fed back into research, leading to accelerated development.

Of course, data has always been the key in this knowledge-based industry, but the growth in use of sensors, cloud platforms and connectivity is offering new tools and capabilities to management teams. Perhaps the most important change is the move from reactive to predictive and even to prescriptive management. This is the equivalent of moving from fast response to a component failure (reactive), to early intervention (predictive) to continuous analysis of data as a driver for targeted strategies aimed at optimizing performance across a complex system (prescriptive).



Changing and evolving your systems of record

All major IT-based systems are on a journey from specialist oversight of siloed applications through to open platforms designed to enable agile, integrated, scalable operations.

- **From OT and IT to IoT.** The divide between Operational technology (OT) and Information Technology (IT) is finally disappearing, and IoT is becoming the key concept for the future. Integrated OT and IT is becoming the norm, so systems of record must also be capable of open interfacing or can be replicated into a datalake, with role-based views end-to-end to provide a relevant and accurate version of the truth for all authorized personnel.
- **Cloudification.** Boundaries are becoming permeable, with Edge devices used to integrate very low latency apps (response to alarms, for example), with planning apps and business management, which are increasingly managed in secure corporate locations hosted on hyperscale cloud platforms. This has transformed costs and enabled faster introduction of specialized services.
- **Disaggregation.** The core of an enterprise is no longer so much a customized fortress, with the rest of the world locked out, as a disaggregated and intelligent ecosystem, with security embedded at the point of each individual interaction. This is a different concept of how an enterprise should be structured, managed and secured. The right decisions at this stage will make future evolution simpler and more profitable.
- **Hyperautomation.** Right across manufacturing industry, there is a rapid move through use of augmented intelligence in production processes towards what is increasingly known as hyperautonomy or hyperautomation. This combines use of distributed AI (located within Edge devices, connected to sensors and IoT systems), supported by multi-agent systems to make key processes fully autonomous. In this model, the role of people is to set strategies and measurement criteria but to remove humans from all minute-by-minute active roles, which are fully automated, right across a complex production environment.

The Life Sciences industry is of its nature designed for a central role in the lives of citizens and societies of every shape and size. It is about the health of nations, after all, and the growing interconnect between core systems, innovation partnerships and flexible deployment of collaborative work environments is likely to drive faster evolution.

BUILDING A ROADMAP TO THE FUTURE

Every business is at a different level of maturity, capability and strategic positioning right now. Every business has decisions to make about what they want to be in the future.

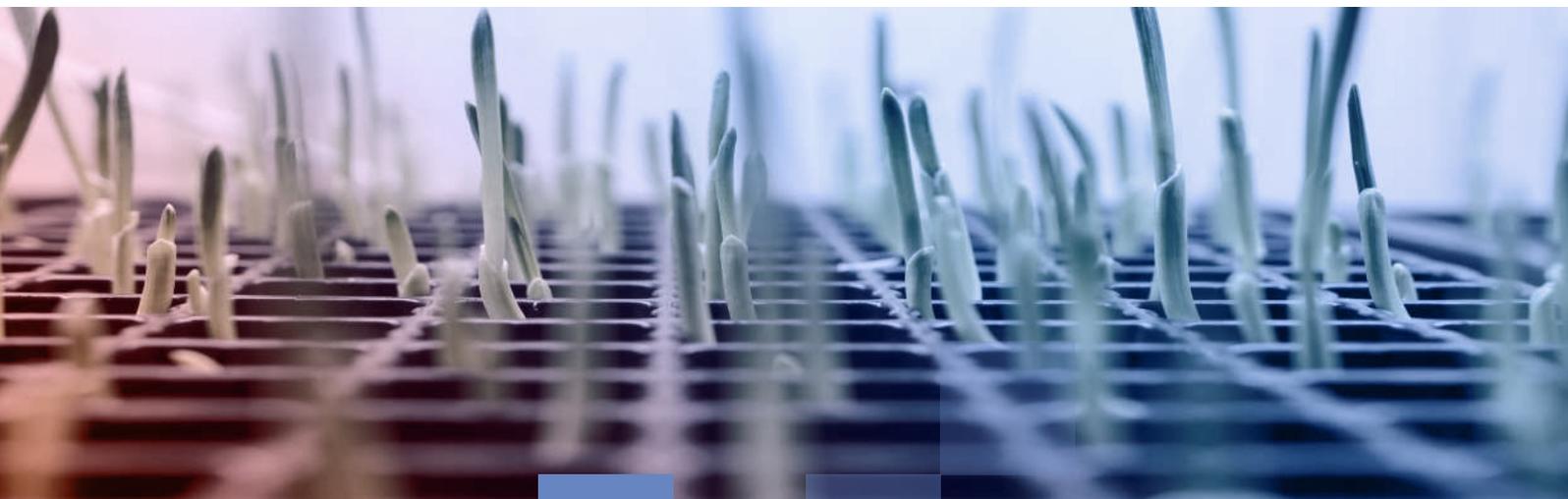
Enterprises start from different places

We do not believe the current future marketplaces will be forgiving to companies which lack strategic clarity or are unable to make up their minds. This process of route-planning will be difficult and important. The foundations need to be solid and data quality is perhaps the highest priority of all. Without quality data, backed by lean and standardized business processes across siloes and other boundaries, everything built by that enterprise will be at best unreliable and uncompetitive, and at worst, useless.

Whatever your strategy, you need to focus on the core

Every Life Sciences company needs as a minimum to become more agile and fast-moving.

Strategic directions may vary but long-term success is unthinkable unless enterprises start to apply Industry 4.0 principles to every interaction and transaction across what are becoming more complex and extended value chains.



- **Real-time data.** If we can define one key difference between Industry 4.0 as a concept and everything that has gone before, it is the application of real-time data analytics to turn reactive enterprise planning and management into predictive and even prescriptive management for even more granular control.

We have seen some examples of how predictive management can operate, ranging from:

- The basic approach (how to make production machines more reliable, reducing downtime and improving operational efficiency, driving Predictive Quality Management).
- Through to the more visionary (using advanced analytics in very large data lakes to eliminate adverse reactions, identify potential candidate molecules, micro-manage individual care packages for millions of individuals).
- And the futuristic (progressively introducing AI as a management and operational tool, with agency and authority to act autonomously across the organization).

These many different applications are not separate from each other but rather operate on a continuum that ultimately depends on an agile and integrated operational core. Manufacturing, innovation, logistics, ecosystem management, regulatory compliance, security and pedigree assurance: everything is driven by the integrated set of enterprise applications forming the true heart of the enterprise.

- **Renewing ERP.** The roadmap to the future begins with a clear-sighted assessment of core applications as they are today and a program to ensure these reach a status in which they can support any potential future. The logical starting point is to ensure that SAP S/4HANA is fully implemented across the business, because this acts as the necessary foundation for virtually every other development, and especially for what is being seen as Intelligent ERP. In this essential concept, conventional SAP is supplemented by AI, real-time data, sensor information from IoT and Edge devices, with Blockchain providing distributed management across the value chain.

This is a dramatic change, and will inevitably lead to implications for organizational structures and empowerment.



PARTNERING FOR LONG-TERM SUCCESS

No company, not even the largest and most capable, is going to navigate the tricky path to the future alone. They need the right partners and they need to choose carefully. External partners can add value in specific areas, especially in reducing risk and accelerating change by providing access to capabilities and knowledge that are time-consuming and costly to develop in-house. We believe the most useful partner will not just be a good IT generalist but will possess specialist capabilities in at least three areas:

Industry knowledge, including deep experience of SAP across the Life Sciences value chain, backed by the ability to cross-fertilize by bringing innovations from other industries.

Data management, supplementing Pharma research through a range of techniques that accelerate and enhance outcomes, including AI and data analytics.

Ability to integrate, developing agility for the future by building strong foundations now, enabling more flexible business models and driving integration across technology siloes.

About NTT DATA

- **Industry track record.** NTT DATA has deep Life Sciences industry experience. We work with pharmaceutical and biotech companies of every shape and size, and in most geographies. This includes 15 years' experience for SAP implementation in Life Sciences and a strong point of view in hyperautomation and wider process automation across the marketplace.
- **SAP experience.** NTT DATA has developed ERP-for-Pharma expertise, able to combine core ERP with AI, analytics, IoT, packaged solutions, Blockchain and other requirements. We also recognize that moving to S/4HANA can be challenging, and we address this through proven consulting and change management capabilities.
- **Pharma specific.** NTT DATA has deep experience in specialized capabilities that are now essential to industry development, such as Serialization and advanced track & trace; Predictive and Prescriptive quality management; highly demanding global cold chain and innovation support.

■ **Innovations.** NTT DATA has a dedicated innovation team for Life Sciences and is developing a range of new concepts with the potential to drive growth and operational efficiency. These include:

- Solutions for predictive quality management, using a growing range of tools to build an integrated approach to quality, that enables real-time visibility and dynamic intervention to prevent wastage and avoid supply issues.
- Internal and external cold chain solution, automating key stages in the freeze-thaw processes, based on real-world conditions and specific batch handling.
- CMO cockpit, creating a model, virtual CMO structure in SAP, acting as a form of digital twin, that allows for faster onboarding and better performance in key supply chain components.
- Attribute Based Encryption (ABE), a new approach to value chain security, developed by NTT Research in association with Johns Hopkins University. This provides a cryptographic “last line of defense” that is essential for fields in which information sharing about specific individuals (such as targeted medicines) is required.
- Analytics framework to measure operational excellence, calibrated with a wide range of pharma-specific indicators, and optimized for use with SAP.

■ **Recognition.** We are seen as a leader in the field by international consultancies, with IDC rating us as a top performer in project management, work quality and proven ability to contribute best practice insights into client ecosystems.





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