astrix

Emerging Technologies Impacting a Digital Transformation of Life Sciences

(Part 2)

Executive Summary

Underlying successful digital transformations, is the critical need for R&D organizations to leverage information assets to enable enhanced insights, decision making, and process automation. While companies are at different starting points, there are several in common approaches to a digital transformation.

- First is the increased emphasis on understanding and employing innovative technologies and data sciences, not just in one function but across larger segments of R&D.
- Second is the emphasis on leveraging information assets, or data assets to better enable the business.
- Third, is consideration of emerging technologies, not standalone, but in concert with existing and planned infrastructure to optimize what technology can deliver to the business.

By considering emerging technologies in concert with existing infrastructure, the organization can not only optimize technology, but increase operational effectiveness, and encourage data findability and reuse. This facilitates an agile, harmonized, and optimized workflows to advance the pipeline, increase collaboration, enable rapid decision making, and accelerate time to market.

In our Emerging Technologies Impacting a Digital Transformation of Life Sciences (Part 1), we discussed Enterprise Data Fabric, Hyperautomation, Big Data, Structured Content Authoring, and Advanced Analytics and Simulation. In this white paper, we discuss 5 additional important emerging technologies including:

1. **Voice Command and NLP**
2. **Security and Block Chain**
3. **Digital Patient Engagement**
4. **Composable Architecture**
5. **Non-Classical Computing**

Voice Command and NLP/NLG's Impact on a Digital Transformation of Life Sciences

What is this Technology?

Voice Command and Natural Language Processing is the computer's understanding of spoken and written language. The ability of voice assistants like Google, Siri, and Alexa to detect human speech, react to it, and carry out voice-based requests is made possible through a process called natural language processing (NLP). NLP is the technology that makes it possible for machines to comprehend and communicate with human speech, however it is not just used for voice interactions.[1]

Natural Language Generation (NLG) is another important term. While NLP parses information, NLG brings data together to create language (e.g., content for submission to health authorities).

Industry Trends for This Technology in Life Sciences

More organizations are moving towards the implementation of technology supporting key capabilities such as part-of-speech tagging, parsing, text conversion, pattern matching, etc. These technologies are providing major efficiencies in R&D. Some of the bigger use cases for voice command and Natural Language Processing (NLP) are in the R&D efficiency area with the potential to assist with improving research, lab notebooks, development and regulatory documentation, and the processing of unstructured repositories and text as we standardize, analyze, translate, and/or predict outcomes.

For example:

- **Smart speakers/apps, sensors, chatbots, etc.,** enhance the patient experience
- **IoT speech recognition and voice commands** dynamically capture lab observations into Electronic Lab Notebooks
- **Machine-reading for large amounts of unstructured content** helps to support regulatory intelligence and publication search
- **Automated document generation, translation, and redaction** through neural machine language technologies (NLG) can support regulatory authoring and submissions.
- **In the lab, the implementation of a digital lab assistant** is eliminating the need for paper/typing notetaking and NLP combined with machine learning capabilities is creating narratives from unstructured content.

Establishing archetypes for these technologies will streamline strategies and accelerate outcomes.

Some Considerations with this Technology for Relevant Technology Selection and NLP Training

- Toolkits to support the implementation of NLP are available from a variety of open source or commercial locations
- Neural networks and AI are required to work in conjunction with NLP capabilities to train recognition of speech patterns and common phrases enabling analytics and predictions.
- Leveraging AI trained vernacular when asking and answering questions enables end users to sort, filter, and build on previously asked questions utilizing simple, common commands.
- A plethora of options are currently available for cloud-enabled listening devices, requiring decisions to be made on which devices best fit your organization’s needs for voice command capabilities.
- Consideration should be given to devices based on features like security, privacy, mobility, underlying architecture, NLP capabilities, and connectivity.

Security and Blockchain's Impact on a Digital Transformation of Life Sciences

It is critical that Life Sciences organizations protect patient information. The pharmaceutical industry is a popular target for hackers because of the access to sensitive information like R&D data, patents, and patient information. This unauthorized access to sensitive information leads to loss of public confidence, stolen intellectual property, and large income losses. The pharmaceuticals sector reported the third highest average cost of a data breach among all industries in 2021. This was after healthcare and financial services.

Cybersecurity breaches inflict huge costs on pharmaceutical companies. Estimates from 2020 place the average cost of an attack at US $5.06 million, which is 1.3 times the global average.[2]

Security and Blockchain

Security relative to Information technology (IT) refers to the procedures, apparatus, and personnel employed to safeguard a company's digital assets. IT security aims to prevent unauthorized users, also known as threat actors, from stealing, exploiting, or disrupting these assets, devices, and services.[3]

Enhanced metadata collection and tagging for security purposes is one technique being employed to strengthen security. Machine-readable tagging of data enables dynamic security models within and across enterprises. This tagging enables attribute-based security models and access enforcement.

Blockchain is another technology that can be used to enhance security. A blockchain is simply a digital ledger of transactions that is replicated and disseminated across the entire network of computer systems on the blockchain. Each block on the chain consists of several transactions, and each participant's ledger receives a copy of each new transaction that takes place on the blockchain.[4]

The digitization and dynamic real-time enforcement of security policies in trusted, secure environments, like blockchain, ensures data integrity and privacy compliance. Blockchain's use of hashing proof of work mechanism, and distributed nature provides a mechanism to capture data securely, verifiably, and immutably within and outside of the sponsors' environment of control.

Unfortunately, Life Sciences has been very slow to adopt blockchain compared to other industries as models are complex, difficult to scale, and a lack of blockchain SMEs with life science domain expertise.

Emerging and Deployed use Cases for Block chain

The following are ways in which blockchain is currently being used in the industry.

- **Commercial platforms f**or secure exchange of genomic information, allowing different labs to contribute to an individual's genomic blockchain record and for the individual to own and control access to the use of such data.
- **Commercial drug serialization** which allows a complete record of the chain of custody/condition and repackaging of drugs and supports supply chain management.
- **Partnership collaboration platforms** facilitate data sharing across organizations while still allowing each company to protect its intellectual property rights.
- Used as a **Storage Architecture** where block chain ensures the immutability and integrity of data.

Considerations with Security and Blockchain

Life Science organizations need to determine their strategy for accessing and protecting patient data in this evolving environment. We see this happening across the industry, including:

- GDPR legislation.
- The decision of 23andMe to block access to their genomic databases.
- Aggressive moves by Amgen, AZ, and Regeneron to launch genetic sequencing projects to build IP.
- Nebula Genomics' plans for a blockchain-enabled genomics data sharing/analysis platform highlight the urgency to move now or risk being locked out of desirable options.

External pressures are driving the need for Pharma to lead the way in developing responsible security and privacy strategies to build public trust. The following are some considerations relative to securing data in the organization:

Trusted Execution Environments

- Complex collaborations will require dynamically formed, trusted execution environments to perform secure data exploration and analysis (e.g., genomics analysis). These environments will leverage technologies such as secure data enclaves (e.g., Intel's Software Guard Extensions) and working through object fingerprints (e.g., chemical properties, signatures) to provide in memory protection of data, computations, and results.

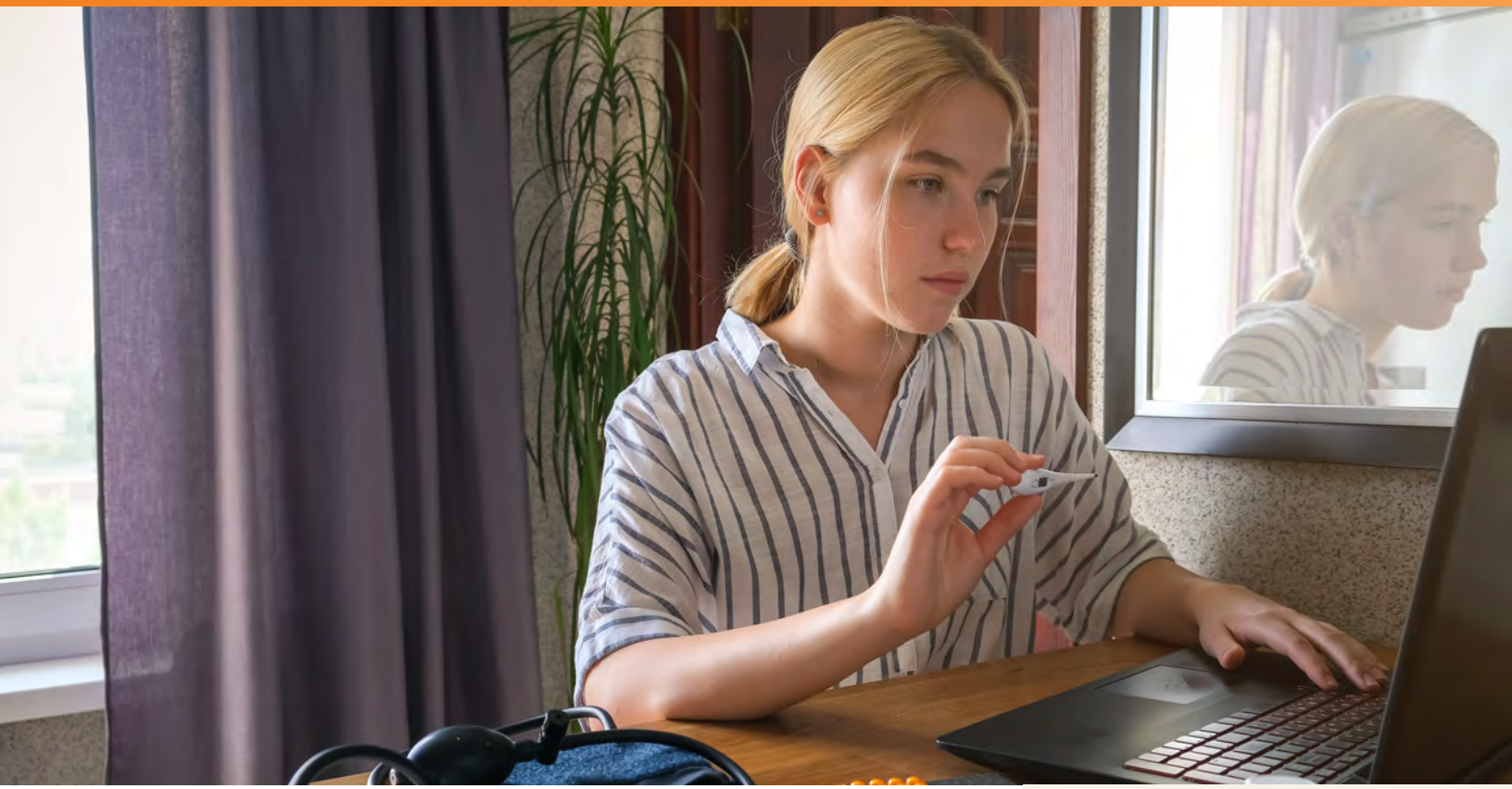
- Use case-appropriate tooling will be automatically provisioned within each trusted environment, such as the dynamic provisioning of bioinformatics platforms for collaborative research and development.

Secure Data Sharing

- Permissioned (not public) distributed ledgers (e.g., blockchain) will be required to allow data generators (patients, collaborators) to share data in a trusted environment, releasing only that which has been appropriately permissioned for use by verified network participants.

Dynamic Policy Enforcement

- Rapidly evolving data protection regulations and cultural shifts require R&D to instantiate mechanisms to centrally enforce data access policies automatically. Data resources must be dynamically tagged upon creation/ingestion with sufficient metadata to describe their allowable uses. Central enforcement points combine this metadata with machine-readable policies and roles to determine who gets access to data resources.



Digital Patient Engagement and Its Impact on a Digital Transformation of Life Sciences

With greater emphasis on patient centricity, it's increasingly important to engage with them in the digital landscape. Finding ways to meet patients where they are to better engage with and educate them through their entire care journey.

What is Digital Patient Engagement (DPE)

Is digital data capture tied to patient-centric approaches for the design and execution of clinical trials. A DPE platform is an intuitive digital application that can be utilized by healthcare organizations and patients as a means to monitor pre- and post-operative care. This platform should be incorporated into the patient engagement strategy.[5]

> *Digital patient engagement brings together multiple technologies (remote data capture via devices, use of eSource, etc.). This supports the emphasis on patient-centric trial approaches to enroll, educate, and to analyze and use results in trials across the ecosystem more quickly.*

Benefits of DPE

There are several benefits of leveraging DPE.

- For the patient, this patient-centric approach to clinical trial design and conduct addresses patient needs that go unmet in traditional trial methods. Technology approaches using telehealth, total experience (TX), digital communications and engagement help to support the entire patient experience. These technologies are being used to support patient reported outcomes, digital biomarkers and endpoints, remote patient monitoring and testing, patient education, and electronic informed consent

- For the Sponsor the benefits include:
    - Accelerating clinical development
    - Enabling more representative patient access, gathering data directly from patients that would not otherwise be captured
    - Developing a more robust evidence package than traditional trials

Industry Trends

- Decentralized Trial (DCT) approaches are rapidly gaining traction. This is partially driven by COVID, making patient-centric and site-centric approaches, including direct to patient supplies, remote assessments, telemedicine, at-home sample collection, point of care assays and other means of collecting patient data faster.

- Digital patient engagement is increasing. This is happening through linking to social media and patient communities for improved demographics and enrollment, to the use of telehealth to connect with and educate patients and physicians, to supporting tracking, monitoring, to receiving data sooner and more reliable data collection and ingestion

- Move towards rapid collection of more granular and rich data. Leveraging digital biomarker and endpoints for faster medical and safety assessments, adaptive trial design, and exploratory and translational research

Considerations with DPE

The ability to collect patient information and results more rapidly, and with richer datasets, enables better inputs for clinical, translational and exploratory research using data that extends from “bench to bedside”. There are however several factors to consider with DPE.

Requirement for a Technical Framework to collect patient data

- The need to establish technical capabilities (e.g., devices, apps, data transfer, etc.) keeping user experience in mind to enable patient research to collect patient data and endpoints. This in support of data driven innovation (in clinical, translational and exploratory) while assuring secure interactions, including identifying confirmation and protection.

- Establishment of a core common product platform and the continual assessment of changes in the marketplace to ensure cutting edge technologies are being leveraged.

- Introduction of core product integrations where relevant including advanced technologies.

- Different technologies may be used separately or combined to deliver capabilities in the Digital patient experience space such as:
    - Semantic and context sensitive graphical interfaces for patient facing systems
    - Touch interfaces on devices, wearables, data collection applications, etc.
    - Voice interfaces, chatbots and personal AI-assistants

Data Governance and Regulation

- The need to enable Dynamic Data Masking (DDM)1 to mask any patient sensitive data based on HIPAA and other regulations.

- Incorporation of verification method for the availability of patient consent and expiration date if required.

- Deepen understanding of mechanisms of action through digital twins for the design of precision medicine.

- The need to utilize social media and mHealth technologies to improve recruiting, screening, enrollment and retention of patients in clinical trials.

- Enablement of clinical and translational to rapidly access and use relevant clinical data in work.

Composable Architecture's Impact on a Digital Transformation of Life Sciences

What is Composable Architecture

Composable Architecture shifts the focus from monolithic application suites and hosting to use of best of breed solutions as part of a unified platform-ecosystem. By leveraging business architecture, technologies, and agile thinking, organizations can speed discovery, gain greater agility, and enable flexibility to handle future changes. Many organizations find that the fundamental components to enable Composable Architecture are already in place.

Benefit to Life Sciences

The value of composable architecture is that Life Sciences R&D needs to deliver innovation and adapt quickly to industry needs. This requires scalable technologies which can be implemented efficiently, agilely and in less time. Composable architecture fits the bill and makes it feasible to deliver technologies which can be assembled quickly, reassembled if needed and extended in the future.

> *Composable architecture offers a fresh perspective on how to align the business with technology by utilizing components that work together, thus improving the way organizations can use existing competencies and making it easier to build complex fit for function solutions without traditional point to point integrations and coding. By breaking down traditional organizational silos and introducing API-centric models, developers are able to more efficiently access data and drive workflows cross-functionally and drive digital disruption.*[6]

Developing a platform centric composable architecture approach for capabilities across R&D:

- Reduces redundant capabilities
- Facilitates and accelerates AI adaptation
- Enables faster digital transformation efforts
- Unifies the user experience
- Supports workflow orchestration

Considerations when implementing Composable Architecture

Here are several key considerations for organizations moving towards Composable Architecture:

Composable Architecture and Organization Readiness

- Establish powerful integration platform (API management) strategy to enable democratized, self-service integration and reduce point to point integrations

- Enable business-user focused applications and modernize existing solutions (monolithic applications). to adapt support and expand a modular architecture ecosystem, expand modular architecture around the same,

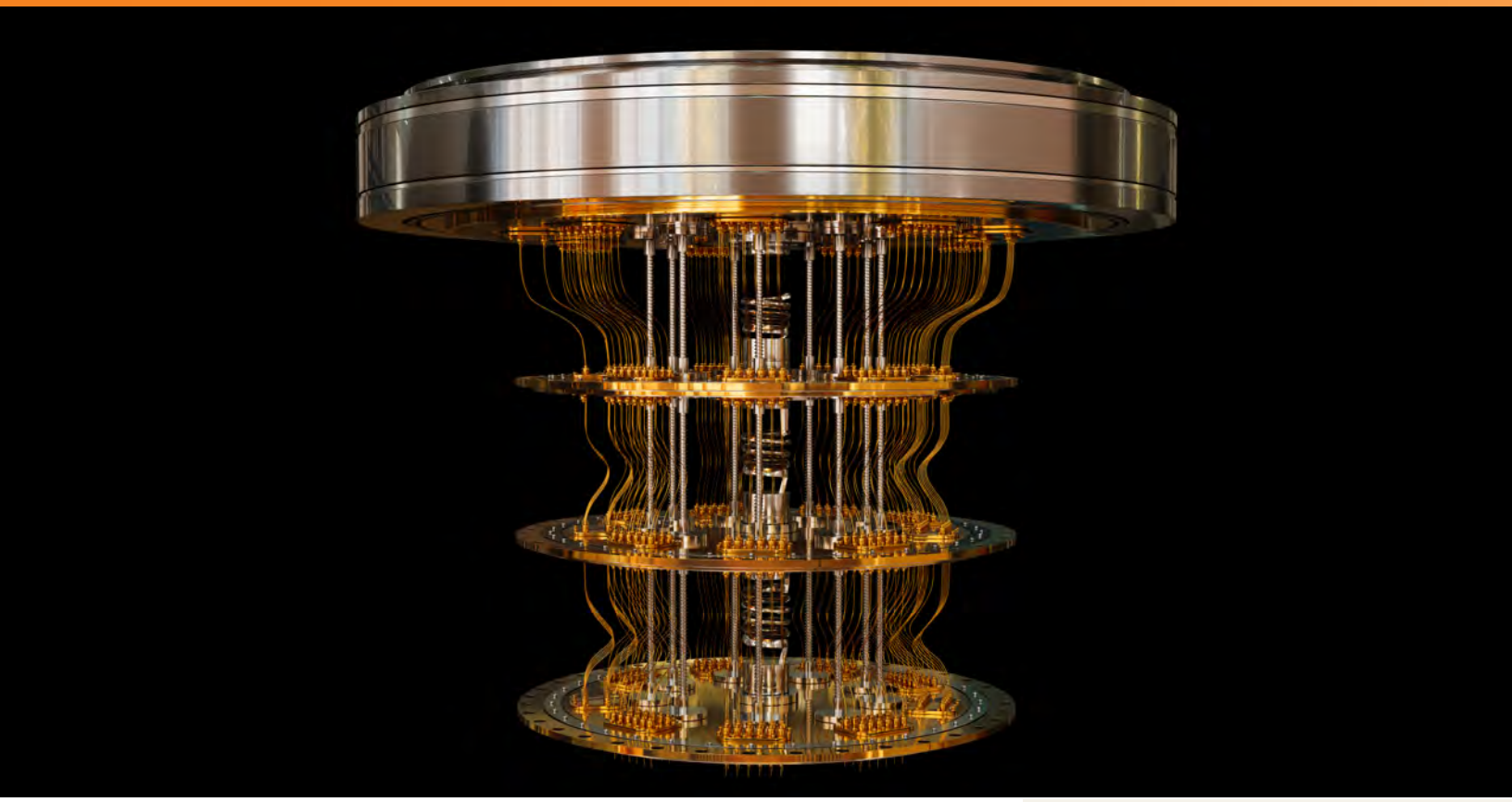
- Maintain traditional or SaaS solutions when they fulfill needs easily, but combine with other solutions to more fully meet the needs of the business and support other capabilities more seamlessly.

Partnerships and Vendor Management

- Support deeper collaboration between internal stakeholders (IT and business) as well external partners

- Establish a sourcing strategy around technology partners/vendors who have capabilities around modular components

- Investigate vendors offering packaged business capabilities, which can fulfill current and future needs



Non-Classical Computing is Impacting the Digital Transformation of Life Sciences

Non-Classical Computing

High-performance computing is a fundamental enabler for Big Data, AI, and Advanced Simulations and non-classical computing architectures use parallelism, in-memory processing, and other mechanisms to dramatically increase computing throughput potential.

The development of processes and architectures for highly specialized purposes, use of Graphical Processing Units or GPUs (formerly limited to video programming), and Grid-based cloud computing to enable scalable computing through elasticity enable businesses to run algorithms currently not solvable on digital computers today. As interest and investment continue to grow and these technologies mature, the potential for dramatic increases and scalability in processing power opens new modeling, simulation, and permutation calculations that can help inform Life Sciences R&D.

> *Non-Classical computing platforms, such as quantum computing or large-scale (i.e., exascale) computing platforms, are making it possible to run previously impossible algorithms to compute in a reasonable time.*

A Few Industry Trends Associated with Non-classical Computing

- Enabling on-demand compute environments, fully configured for analytics and data sciences use cases including ready access to the data required

- Establishment of statistical and/or data sciences compute environments that support model and code sharing, auto-code technology, and “electronic notebook” capabilities linking code versions to data set versions, enabling sharing, and offering the ability to revisit algorithms with new data sets and verify results on decision data sets with new algorithms

- Drug research and development areas are prime candidates for use of Quantum Computing; potential use cases include hit generation and identification, lead generation and optimization, predictive analyses, and simulations for protein folding, ADME, dosing and solubility prediction, among others

- Similar to the pharmaceutical industry, the chemical industry is also benefiting from development of chemical molecules

Implications for Life Sciences Organizations

High performance computing requires specialized computing platforms, environments, and services to bring them to scale, including collaboration conditions. Life Sciences companies can facilitate the orchestration and elasticity for rapid access to need-specific computing power on demand, coupled with new integrated in silico working environments and services. A strategy based on archetypes will accelerate value in the short term, enabling maximized attention to ensure mid- and long-term solutions.

The following are considerations when looking to leverage non-classical computing:

Data Sciences Ecosystem

- Algorithmically driven science, clinical and operations will require new collaborative environments that marry algorithm code, data, and results. Companies must conceive integrated fabrics using technologies that overcome cumbersome silos associated with today’s systems

Computing Infrastructure

- There is a need to enable an evolutionary ecosystem of different computing resources suitable to the breadth needed in life sciences. There are clear compute strategies needed for each of the advanced technologies such as big data, AI, advanced simulation and blockchain.

- Preferred partnerships are also needed to cover the breadth of R&D needs, from contract service providers to academic and start up participants who will lead the run up to exascale and quantum computing

Intelligent Orchestration

- In order to understand patterns and workflows in scientific, exploratory, translational, and statistical computing, you need to provide an ecosystem of intelligent automated solutions leveraging virtualized services (marketplace) and distributed computing architectures to optimize computational resources wherever data may exist. These solutions need to be on-demand and effectively delivered to end user communities to maximize their usage.

Incorporating Emerging Technologies, The Importance of Strategy, Processes, and Technology

It is critically important, when looking to incorporate new emerging technologies into the business, that you ensure you have the right external organizations involved who can assist you. Formulating the appropriate strategy along with the proper processes, and technology is imperative. Astrix's team of professionals have worked with many of the top life science organizations to assist them with respect to their business needs in these areas. As a partner without a preconceived preference for a specific technology, we work closely with your team to ensure solutions are reviewed and incorporated into your business that will help you succeed.

About Astrix

Astrix is the unrivaled market-leader in creating & delivering innovative strategies, solutions, and people to the life science community. Through world class people, process, and technology, Astrix works with clients to fundamentally improve business & scientific outcomes and the quality of life everywhere. Founded by scientists to solve the unique challenges of the life science community, Astrix offers a growing array of strategic, technical, and staffing services designed to deliver value to clients across their organizations

References

1. Arm Glossary, "What is Natural Language Processing"
2. Mint, "Safeguarding Patient Data is Crucial for Pharmaceutical Companies, March 2022
3. TechTarget, "What is Security"
4. EUROMONEY Learning, "What is Blockchain",
5. Force,"What is a Digital Patient Engagement Platform"
6. Architecture & Governance Magazine,"Composable Architecture: The Latest Trend in EA Helping Companies Adapt and Grow", Aug 2022

astrix

Corporate Headquarters
125 Half Mile Rd Suite 200
Red Bank, NJ 07701 USA

732-661-0400
info@astrixinc.com

For more information, visit:
www.astrixinc.com/pharmacovigilance-services