Everest Group®

Artificial Intelligence (AI) in the Pharmaceutical Industry

Transitioning from Pilots to Enterprise-wide Scale

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Introduction

The life sciences industry found itself at the epicenter of innovation and digital transformation as the COVID-19 outbreak struck and pharmaceutical firms took immediate action to maintain business continuity. As the pandemic intensified, consumer demand for new and existing drugs and the search for new vaccines constantly pushed pharmaceuticals to expedite the drug discovery and development process. These events acted as a catalyst for the deployment of AI solutions across the pharma industry, from drug discovery to supply chain and distribution. Pharma companies partnered with product providers and IT service providers to augment their in-house talent, reduce time-to-insights, replace obsolete models, and understand fast-evolving customer behavior.

While AI offers significant benefits to the pharma industry, it also has unique challenges: availability and quality of training data sets from multiple sources; a demand-supply mismatch for talent that has thorough understanding of the industry and technology; and infrastructure and complex integration issues. As a result, pharma companies will want to prioritize use cases based on specific market requirements and business needs.

In this report, we discuss how to prioritize use cases as well as the importance of creating blueprint for success that can enable you to maximize the value or your AI-enabled solutions.

The current state of Artificial Intelligence (AI) in the pharmaceutical industry

The amount of data generated in the life sciences industry has increased exponentially with the rise in use of connected devices, the adoption of (Internet of Things) IoT, and industry-wide digitization. This increased activity is driving pharma enterprises to invest in areas such as next-generation sequencing, digital therapeutics, Internet of Medical Things (IoMT), pharmacovigilance, and Real-World Evidence (RWE), to turn massive amounts of data into actionable insights to improve returns. Exacerbating the challenge: data-generating sources in life sciences commercial teams tend to be siloed, and pharma companies face difficulties in integrating newer AI/ML solutions into their legacy systems, which – in turn – suboptimizes brand strategy decisions. As a result, the life sciences industry is shifting data ingestion from unreliable descriptive models to high-precision prescriptive models, driving investments in cognitive AI and advanced analytics.

> Data analytics, fueled by machine learning and other forms of AI, are accelerating drug discovery and development, and enhancing prevention, early detection, personalized treatment, and digital therapies. Quantum computing capabilities will help us bring medicines more quickly to patients. Distribution is being reshaped by online and retail pharmacies and new intermediaries. We believe that COVID-19 has advanced these trends by as much as five years. It's not so much that these are new technologies, more that we are applying them at scale.
>
> – Lidia Fonseca, Chief Digital and Technology Officer, Pfizer

The current global macroeconomic and socio-political uncertainty, coupled with the increasing R&D IT expenditure, have created enormous pressure for the pharma industry to expedite the drug development process while also reducing resource consumption. Pharmaceuticals are prioritizing investments with the potential for quicker RoI over moonshot investments. Legacy technologies in the commercial space lack the real-time or data integration capabilities that AI and analytics solutions offer; as a result, pharma enterprises lack visibility into the interplay among stakeholders in the life sciences technology landscape and fail to realize the full value from their technology initiatives.

Trends driving the adoption of AI across the value chain

We have identified and highlighted the following benefits of AI adoption for pharma enterprises at every step of the biopharma value chain:

- **Discovery and research**
  - Mine social media to help improve understanding of complex disease biology to identify new potential drug targets
  - Predict drug-target affinity, de novo design, next-generation sequencing (NGS)
  - Repurpose and reposition drugs

- **Drug and product development**
  - Support clinical trial study design and site selection with text mining and AI-based patient trial matching
  - Create a digital platform to enable precision diagnosis and to assist in clinical decision making
  - Enable the adoption of decentralized clinical trials and enhance remote patient monitoring through sensors
- **Manufacturing**
  - Enhance manufacturing efficiency and reduce deviations by analyzing large data sets and finding correlations
  - Facilitate predictive asset maintenance and workflow leveling and optimization
  - Empower manufacturing process control; simplify quality control and compliance
- **Supply chain and distribution**
  - Reduce counterfeiting and validate the authenticity of physical objects by linking them to unique identifiers
  - Increase fleet efficiency to improve safety and save money
  - Support data-driven demand and supply planning and streamlined product provider selection and management
- **Sales and marketing services**
  - Develop personalized care platforms to improve patient experience
  - Improve the quality of sales conversation with clinicians through virtual assistants
  - Facilitate Healthcare Provider (HCP) segmentation and targeting, Salesforce segmentation, and real-time sales intelligence

Below we explore the key emerging trends that are compelling pharma enterprises to adopt AI-enabled solutions.

- **Increasing data volumes:** The life sciences industry maintains enormous amounts of Real-World Data (RWD) from diverse sources, including Electronic Health Records (EHR), clinical trials, multi-omics biobanks, medical imaging, published literature, wearables, and health apps, which pharma companies want to use to generate Real-World Evidence (RWE). However, they face multiple challenges, including legacy systems, disparate data sources, and regulatory complications. AI systems can help them to address these challenges. AI creates opportunities for companies to quickly gain unique patient segmentation insights to deliver patient-specific drug dosages, cell and gene therapies, immunotherapies. It also helps them to speed the development of specialized therapies and drugs, reducing the number of potential drug candidates and expediting the drug development process. Pharma companies are actively collaborating with RWD providers, especially for the genomic data to support development of precision medicine
- **Challenging clinical trials:** Pharmaceutical companies have always found clinical trials to be costly and time-intensive, slowing time to market. Delays in clinical trials can largely be attributed to poor patient selection techniques and the inability to effectively monitor patients. AI has proven to be an effective way to improve these processes and increase clinical trial success rates. Machine Learning (ML) and natural language processing (NLP) play a vital role in improving patient selection by reducing population heterogeneity and identifying populations more likely to respond to treatment. AI improves success rates by applying predictive analysis on patients' genetic information to identify the patient group and determine the optimal sample size

- **Rising consumerism in healthcare:** With consumerism on the rise across industries, patients are demanding increased engagement, control, convenience, and quality. The pandemic has further fueled consumers' demands for AI-powered voice assistants and personalized web portals with AI-driven diagnostics. Pharma enterprises are increasingly leveraging AI to improve stakeholder experience – including HCPs and patients – through platform modernization to improve visualization and monitoring, enabling remote operations to enhance patient experiences and drive personalization in marketing campaigns

Adoption of AI across the pharma value chain

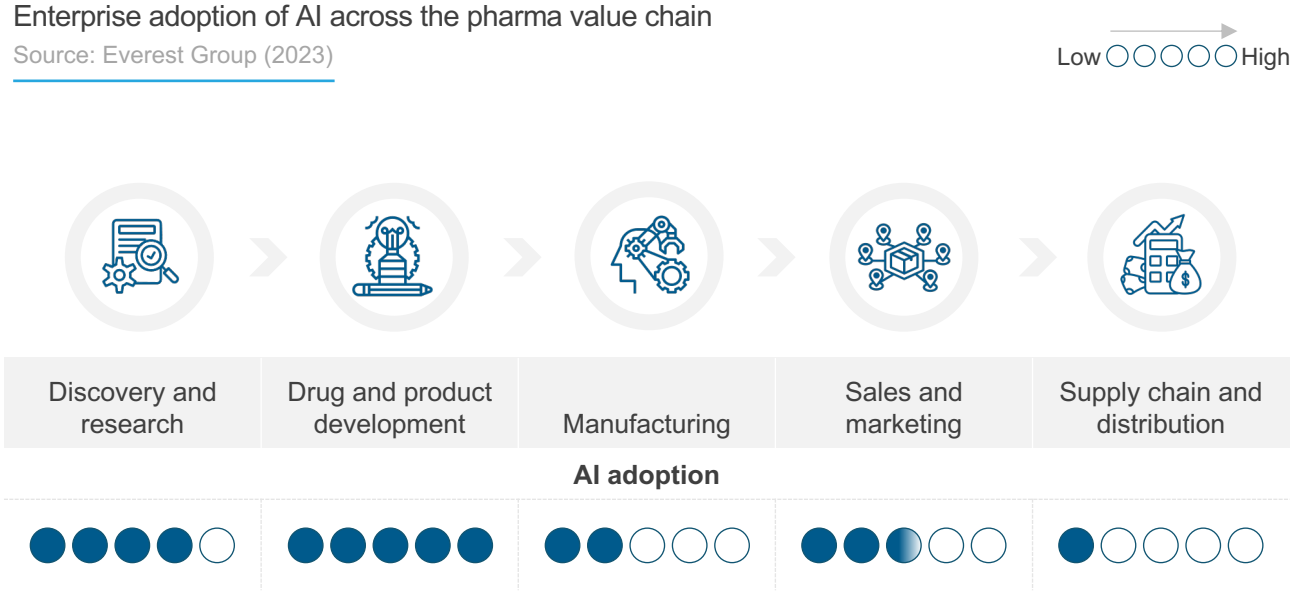
Pharma companies are focusing their digital investments on expanding AI capabilities through start-up investments and innovation labs with the primary goal of customer engagement. As Exhibit 1 shows, adoption of AI solutions is highest in research and development, a situation that was advanced by the need to accelerate the clinical trial process for more precise diagnosis and accelerated vaccine development during the COVID-19 pandemic.

The pandemic also saw pharma enterprises making major investments in discovery and research to uncover novel and promising drug targets and improve understanding of disease pathogenesis. Adoption of AI in the sales and marketing value chain, though lower than the R&D value chain, has been rising steadily, especially because of the unique challenges/opportunities the pandemic presented, such as rise of omnichannel marketing and HCP engagement. Manufacturing and supply chain have the lowest AI solution adoption given legacy infrastructure and high capital investment required; however, advances in manufacturing 4.0 and a shifting focus toward tracking, tracing, and end-to-end supply chain visibility are driving use cases such as predictive maintenance and control towers.

EXHIBIT 1

Enterprise adoption of AI across the pharma value chain

Source: Everest Group (2023)



Key stakeholders involved in AI deployment in pharma

We can broadly categorize the main stakeholders in the AI landscape into pharmaceutical companies, IT service providers, Independent Software Vendors (ISVs), and hyperscalers (AWS, Azure, Google Cloud) as Exhibit 2 shows. The AI solution landscape largely centers around building custom solutions for pharma requirements and is dominated by IT service providers, ISVs, and hyperscalers collaborating for implementation of AI solutions accompanied by multi-cloud functionality.

Exhibit 2 shows the four stakeholders' roles and functions in the AI technology ecosystem related to development and delivery of AI-enabled solutions.

EXHIBIT 2

AI technology solution landscape

Source: Everest Group (2023)

Pharma enterprises

These companies are looking to optimize their existing AI investments and initiatives while increasing adoption across the value chain for increased efficiency, cost optimization, faster drug discovery, and better patient care along with regulatory and compliance adherence

Independent Software Vendors (ISVs)

These firms offer highly specialized (pharma value chain element and/or technology-specific) productized AI-enabled tools and enterprise platform technologies have high domain expertise (cheminformatics, bioinformatics, genomics, etc.), and have started offering related enabling solutions and services

Hyperscalers

These are cloud vendors that have built AI/ML-specific modules, including highly specialized modules such as omics-analysis, HPC workload optimization, knowledge graphs, and have a comprehensive suite of connectors and services to enable pharma to work with complex datasets

IT service providers

These providers leverage their rich technical expertise and project management, digital solution engineering, delivery capabilities, cloud credentials as well as infrastructure and support experience for pharma enterprises. They are now focusing on building a full spectrum of AI-based offerings, customized to pharma requirements

Roadblocks and controversies around AI in pharma

Although AI solutions have proven valuable across the pharma value chain, there are challenges that restrict full adoption.

- **Data Security:** 51%[1] of enterprises consider data security to be a primary concern when adopting AI. There is a significant amount of data in the life sciences industry; given its highly sensitive nature, it is

1 Based on feedback collected from 34 enterprise buyers. The percentage figures indicate the frequency distribution of challenges as a percentage of all responses. The cumulative percentage scores may cross 100%, as the buyer may have indicated multiple challenges in many instances

Source: Everest Group (2022)

vulnerable to privacy breaches and cyber-attacks. Pharmaceuticals struggle to maintain the balance between leveraging AI to optimize functions and drive innovation with the need to limit data sharing to maintain data security

- **Training data challenges:** Small data sets – especially for rare medical conditions – pose a challenge as they do not provide enough data to train ML models to work efficiently and accurately. Small data sets can result in inaccurate diagnoses due to data bias introduced when training data sets are not representative of the entire population given a lack of genetic, racial, and gender diversity among clinical trial participants
- **Talent demand-supply mismatch:** 42%[2] of enterprises consider a shortage of relevant and sufficient AI talent to be a key challenge. Adding to this challenge is the fact that AI solutioning is becoming more complex as AI is paired with technologies such as computer vision, IoT, and digital twins, and domain requirements such as informatics and genomics, which require deeper domain and technical expertise. To make matters worse, pharma companies are competing with IT service providers for the same talent. As a result, it is crucial for pharmas to upskill and reskill their talent
- **Infrastructure and integration challenges:** The life sciences industry lacks suitable IT infrastructure to support AI initiatives, primarily because most of the applications and infrastructure currently in use were not developed or designed with AI in mind. Another major roadblock is the high complexity of integrating analytics and AI solutions into legacy systems that have disparate data sources. Lack of coordination between data science and IT teams, productivity challenges involved with model development and advanced applications, and limited immediate meaningful RoI are some of the other hurdles to scaling and adoption of AI

Targeting the AI gold mines in pharma

Prominent AI use cases across the pharma value chain

As pharmaceutical companies faced challenges brought on by the pandemic (and post-pandemic), most have come to realize that AI is no longer good-to-have but a necessary core business function. While there are multiple AI use cases across each value chain, we have described those use cases with the most potential below, by value chain.

USE CASES IN DRUG DISCOVERY

Predicting drug-target affinity

Many of the current computational methods predict drug-target affinity using binary classification, which determines if a drug-target pair interacts or not. If the binding affinity is not strong, the drug might not be useful. Advanced ML models can predict the interaction's strength, thereby reducing time and resource consumption and accelerating the drug development process.

Computer vision for target validation and hit identification

Pharma is increasingly turning to robotic automation and computer vision (ML models trained to identify changes in cells at a micro level). Target tracking helps researchers infer subsequent unknown target information on the basis of known target state information in video sequences. Target tracking methods based on deep learning are crucial for image classification, target detection, target tracking, and

2 Ibid

semantic segmentation. Researchers are also using computer vision to train ML models on 2D structures to better understand the detailed spatial 3D structures of proteins and molecular models.

Multi-omics analysis
Knowledge graphs are used for ingestion and integration of various omics data sets (genomics, proteomics, transcriptomics, and metabolomics) from multiple sources, in a standardized and normalized format enabling contextualization of the relationships such as molecular interactions, gene-functional associations, and drug-target interactions. ML and deep learning models can then use these knowledge graphs to identify and prioritize genes and biological functions for a specific disease type.

De novo drug design
Drug researchers are leveraging deep learning methods for de novo drug design to extract the desired chemical and physical properties of a drug. Deep learning solutions provide an effective method to automate this task-related feature extraction. For example, the pharma industry demonstrated the utility of de novo design to generate potential new drug targets to target the main protease of the novel coronavirus.

USE CASES IN CLINICAL TRIALS

Clinical trial matching
By incorporating AI solutions into clinical trial models, pharma companies have been able to identify patients for specific clinical trial opportunities in near-real time, which accelerates enrollment for hard-to-enroll trials related to oncology, complex autoimmune conditions, and progressive diseases and facilitates greater diversity in clinical trial populations while also making patient engagement more efficient and effective. For example, a clinical trial model developed under the Lung Cancer Master Protocol public-private partnership is helping patients with advanced-stage non-small-cell lung cancer participate in clinical studies that match their tumor profiles. The pilot was successful enough that the studies expanded to all types of advanced non-small-cell lung cancers.

Remote patient monitoring
Sensors and Software as a Medical Device (SaMD) enable remote patient data collection, track patients' health statuses, and provide HCPs with a live RWD stream. These devices ingest large volumes of data from various types of devices, providing real-time insights. Remote monitoring systems with analytics engines can deploy ML algorithms to ascertain medication adherence, assess risk factors for adverse events, ensure compliance and adherence to regulatory standards pertaining to personal health indicators, and enable timely and effective intervention.

AI for safety signal management
Data for signal management can come from multiple sources such as spontaneous reporting, interventional studies, systematic reviews, and non-clinical studies. AI techniques on this data are enabling early detection for potentially serious threats while enhancing pharmacovigilance as these techniques are well-suited to improving identification and classification of safety alert security levels.

AI/ML-enabled case and complaint processing
A surge in case volumes and rising costs associated with them is forcing sponsors to look for solutions to drive costs out of case processing. Customer complaint management solutions are increasingly turning to AI to automate data entry and minimize decision bias through the automation of complaint categorization and priority classification, and to accelerate regulatory reporting.

USE CASES IN MANUFACTURING

AI-powered predictive asset maintenance

AI-based predictive maintenance solutions for pharma manufacturing can take asset maintenance from preventive to predictive. These models use historical maintenance data analysis, real-time monitoring of critical assets, and identification of potential issues and relevant actionable recommendations to enable pharmas to plan effective maintenance schedules with minimum downtime, lower maintenance costs, and increased product throughput. When integrated with digital twins, these models can aid pharmaceuticals in unlocking the full potential of smart manufacturing in pharma (orchestration of digital and physical processes by means of smart technologies within factories and across the supply chain to optimize cost and effort and improve demand-supply forecasting).

AI-enabled production planning

Pharma manufacturers are putting AI to use in planning production based on Purchase Orders (POs) and customer requirements. The predictive algorithms run on past production data, current inventory levels, available resources, and changeover timings. These AI platforms closely monitor raw material inventory levels in real time to keep delivery on track.

AI-assisted quality control and compliance

AI is particularly powerful in improving process development through defect spotting in raw materials prior to them entering production, which enables manufacturers to meet stringent regulatory requirements such as Identification of Medicinal Products (IDMP) and Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC), identify quality issues, and predict new and emerging risks. Pharma manufacturers are also deploying IoT technologies coupled with AI-based computer vision for real-time fault detection on the production line.

Moving toward continuous manufacturing

The shift from batch manufacturing to continuous manufacturing is boosting adoption of AI-based systems to automate process management. Companies are using deep learning algorithms to identify exceptions for real-time feedback and alerts. They are using AI/ML-based solutions for their contextualization capabilities to mitigate data standardization and integration challenges to enable Continuous Process Verification (CPV).

USE CASES IN SUPPLY CHAIN

Enabling end-to-end supply chain visibility

Supply chain models are transforming globally, given demands for better visibility, compliance, and serialization practices. Analytics tools and software facilitate the use of historical data and scenario simulation for accurate demand forecast and supply planning. Beyond forecasting and planning, data and analytics initiatives ensure end-to-end visibility for all supply chain stakeholders, alert organizations to supply disruptions, and help them prepare contingency and risk-mitigation plans.

Digital twins and AI for warehouse automation optimization

Pharma manufacturing is using AI and computer vision-empowered solutions to generate digital twins of the drug to be manufactured in real-time. Integrating AI with warehouse automation solutions enables manufacturers to predict and position high-volume items efficiently to reduce congestion.

USE CASES IN SALES AND MARKETING

AI for Competitive Intelligence (CI)

Pharma companies are using AI-powered tools to harvest data from millions of web pages to gain valuable business insights. For example, companies are scraping web pages to track competitors' digital footprints and to monitor and provide real-time alerts on competitor price trend data. NLP-enabled solutions empower marketers to monitor social networks to understand how a brand or a product is perceived or performing.

Hyper personalization

HCPs have become more digitally savvy, with many using digital options for personal learning and development. Developing precise, targeting strategies and curating personalized content require life sciences enterprises to extract insights from sizable data volumes from diverse sources. ML algorithms facilitate segmentation and precise targeting based on parameters such as market and patient potential, brand loyalty, and referral patterns by mining user data across touchpoints such as social media and wearables.

Omnichannel marketing

AI is catalyzing transformation of multi-channel marketing to omnichannel marketing, enabling pharma marketers to deliver impactful next-best action recommendations and predictive insights within and across channels for both HCPs and field reps. They are using AI- and ML-powered solutions to create a better understanding of the multi-indication drugs that they distribute through multiple channels and personalizing their messaging depending on the situation, needs, and recommendations for related follow-up research.

AI/ML-led enablement of field representatives

Pharma enterprises have enabled field representatives with ML-based virtual assistant models that automate paperwork and administrative tasks and provide personalized predictive analytical insights, allowing them to spend more time building relationships in the field. They are using AI-based chatbots to boost productivity and generate insights from analysis of physicians' prescribing histories, demographics, care impact of the drugs being prescribed, and other competitors in use within the same specialty.

Adoption patterns and the prevalence of AI-based solutions across the pharmaceutical value chain demonstrate that AI is often used in conjunction with another technology depending on the particular use case. The exponential growth in adoption of AI solutions can also be attributed to the emergence of other technologies such as rise in adoption of high-performance computing and quantum computing, cloud modernization, the shift from batch manufacturing to continuous manufacturing, and the implementation of end-to-end supply chain visibility. With pharma companies' technology investments increasing year-over-year, AI will increasingly be used to unlock the potential of IoT, ML, deep learning, IoMT, SaMD, AR/VR, computer vision, and blockchain solutions across the value chain.

Prioritizing AI use cases for success

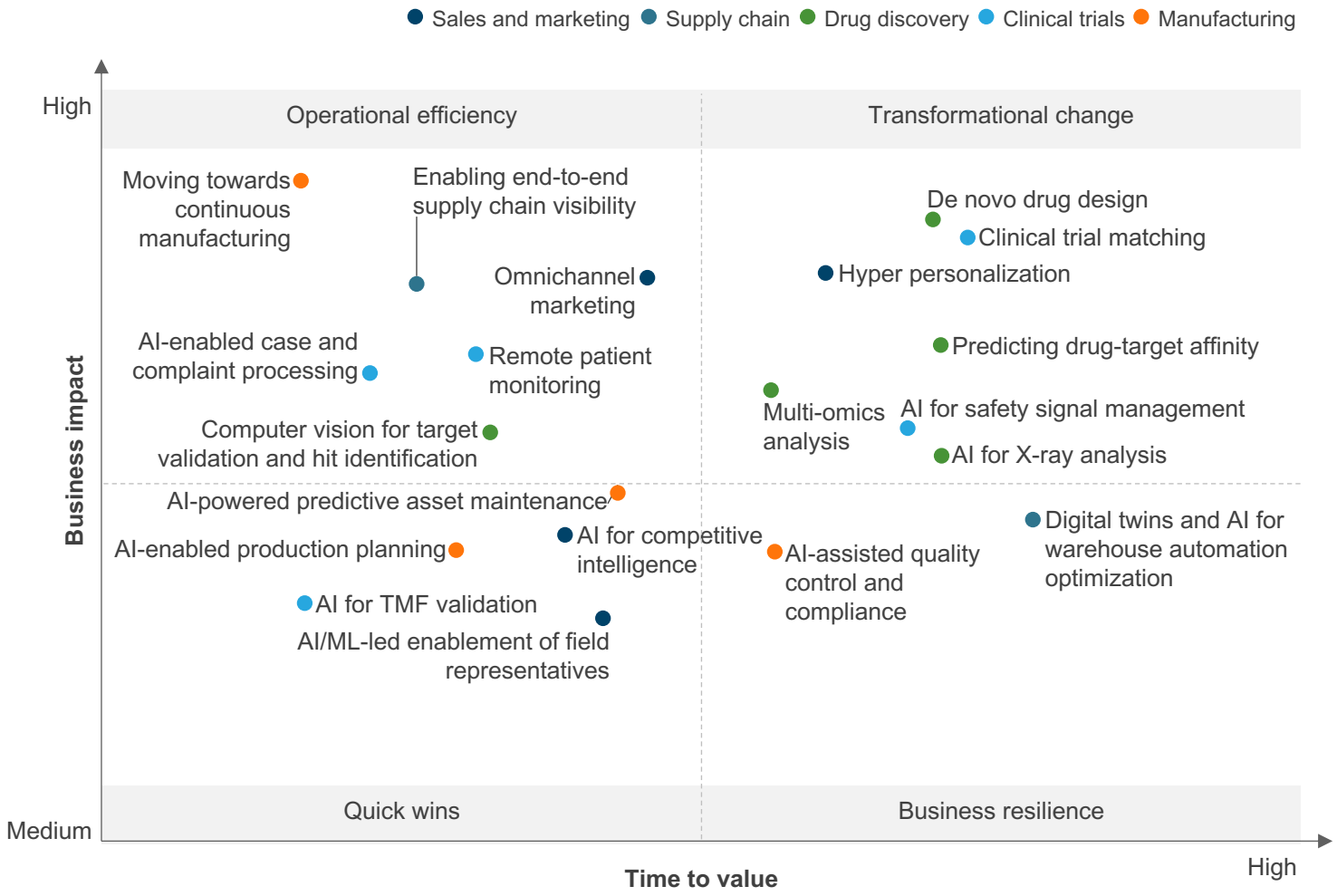
Pharma companies that are successfully adopting AI need to prioritize from among a wide variety of potential use cases to formulate their short- and long-term investment strategies. Exhibit 3 is a framework that maps the most relevant AI use cases along two axes: time to value and business impact. Time to value is measured as the time taken to realize tangible benefits such as reduced drug development and trial timelines, efficient demand forecasting and planning, understanding patient and HCP preferences, increased transparency across the supply chain, and next-best action recommendations. As the complexity of the use cases increases, pharma companies also need to invest in peripheral and connected technologies, which, in turn, increases both the investment in absolute terms and the RoI realization period. Business impact is measured by the value unlocked through data and analytics interventions including patient/physician benefits and process standardization.

EXHIBIT 3

Prioritization of AI use cases to develop an investment strategy

Source: Everest Group (2023)

NOT EXHAUSTIVE



We have grouped the use cases into four quadrants:

- **Quick wins:** These are tested use cases that present pharma companies with the potential for quickest RoI realization
- **Business resilience:** Every enterprise is trying to build business resilience in the wake of the pandemic. Although these use cases will not generate disproportionate or organization-wide impact, they are worthwhile investment opportunities to create robust business units and departments. Prioritizing technology investment for AI-based use cases in this quadrant will enable pharmas to become more resilient and prepare to deal with unprecedented disruptions
- **Operational efficiency:** Creating patient-centric trials and treatments is the goal for every life sciences company and investing in initiatives related to remote patient care, patient screening and recruitment, protocol design, and social media mining will give them a competitive advantage. These options are low-hanging fruit, generating high business impact and improving operational performance within a short time
- **Transformational change:** If pharma companies are looking to achieve a sustainable competitive advantage for the future, they should invest in bold initiatives. These use cases require continual investment over time, and they will not likely result in quick wins, but they have the potential to bring about a revolutionary change (such as faster drug development timelines or significant cost savings)

CASE EXAMPLE 1: AI for trial master file (TMF) validation

TMF is the repository that contains all the documentation generated throughout a clinical trial, which is crucial to demonstrate that the investigators, sponsors, and monitors complied with Good Clinical Practices (GCP) standards and that the trial was conducted as per the study protocol. Given heightened TMF scrutiny by regulatory agencies, pharma companies have begun to see the potential of AI and ML models to transform clinical trials through better document management, risk management, and process optimization. TMF is a key performance metric for GCP compliance, serving as the reference for standards of data exchange across multiple touchpoints among trial Contract Research Organizations (CROs), sites, committees, and sponsors. Pharma companies are required to ensure the completeness of clinical trial data and the consistency in compliant document filing and minimal duplication. An eTMF provides a formalized means of storing and organizing digital content, images, and other documents, which helps pharma companies to meet regulatory requirements related to digital content archiving, security, and access control, change controls, audit trails, and system validation.

Managing numerous TMF-related documents generated from multiple clinical trials is a herculean task that requires highly skilled and experienced professionals for time-consuming, repetitive, and mundane processes. Clinical trial sponsors and pharma companies face a number of challenges related to both paper based and electronic TMF validation:

- **Inspection readiness:** The sponsor is responsible for ensuring that the TMF is always up to date and accessible to inspectors during a trial. Sponsors are challenged to meet all guidelines, including completing the TMF by end of the trial, having it always ready for on-demand access by member states, and periodic quality assurance checks. The need for multiple reviews of these documents during the trial adds dependencies, making management even more challenging. It is common for documents in TMF/eTMF to be inaccessible to investigators during audits because of data inconsistency, a lack of defined standards, and poor integration among the different systems used for data capture

- **Metrics for monitoring:** Monitoring measures are imperative for both TMFs and eTMFs, not only from a compliance standpoint but also from a project-specific adherence standpoint as well. In the absence of automated monitoring, these trial-specific artifacts are validated by Subject Matter Experts (SMEs) manually using random sampling methods, which poses a serious risk as random sampling hampers extensive document coverage. A lack of relevant metrics adds to the complexity of monitoring thousands of documents across various systems
- **Challenges with centralized systems:** Inaccessibility of third-party legacy systems for inspections is a common cause of trial failure. Even sponsor companies that have transitioned to a centralized system to manage TMF documents generated by various legacy systems (in-house and third-party) face challenges: They are plagued by the additional workload and traceability complications that come from double filing and monitoring artifacts if they continue to use both the legacy systems and copy the artifacts into the TMF
- **Lack of sponsor oversight:** The European Medical Agency's 2019 guidance on TMF and Medicines and Healthcare products Regulatory Agency (MHRA)'s GCP guide both stress the oversight of critical third-party trial documents and accountability for an outsourced TMF. CROs' involvement adds to the complexity, as they might maintain documents in a different format. Lack of effective oversight of a TMF by a sponsor increases the chances of errors, including missing, misfiled, misnamed, or duplicated documents. A lot of time, money, effort, and domain expertise goes into manual enrichment, classification, extraction, and mapping of the thousands of documents generated across clinical trials, based on the TMF reference model. These challenges with TMFs and eTMFs adversely impact drug development pipelines in the form of delays, delaying time to market. The pandemic-induced demand patterns are inspiring the adoption of AI- and NLP-based automation tools for TMF validation. This kind of automated solution can help pharmaceutical companies to identify links among data points in the TMF documents by classifying and performing complex extractions from documents and reconciling and validating with minimal human intervention.

  Below we describe the key features pharma companies should look for in an AI-powered automation solution for TMF validation.

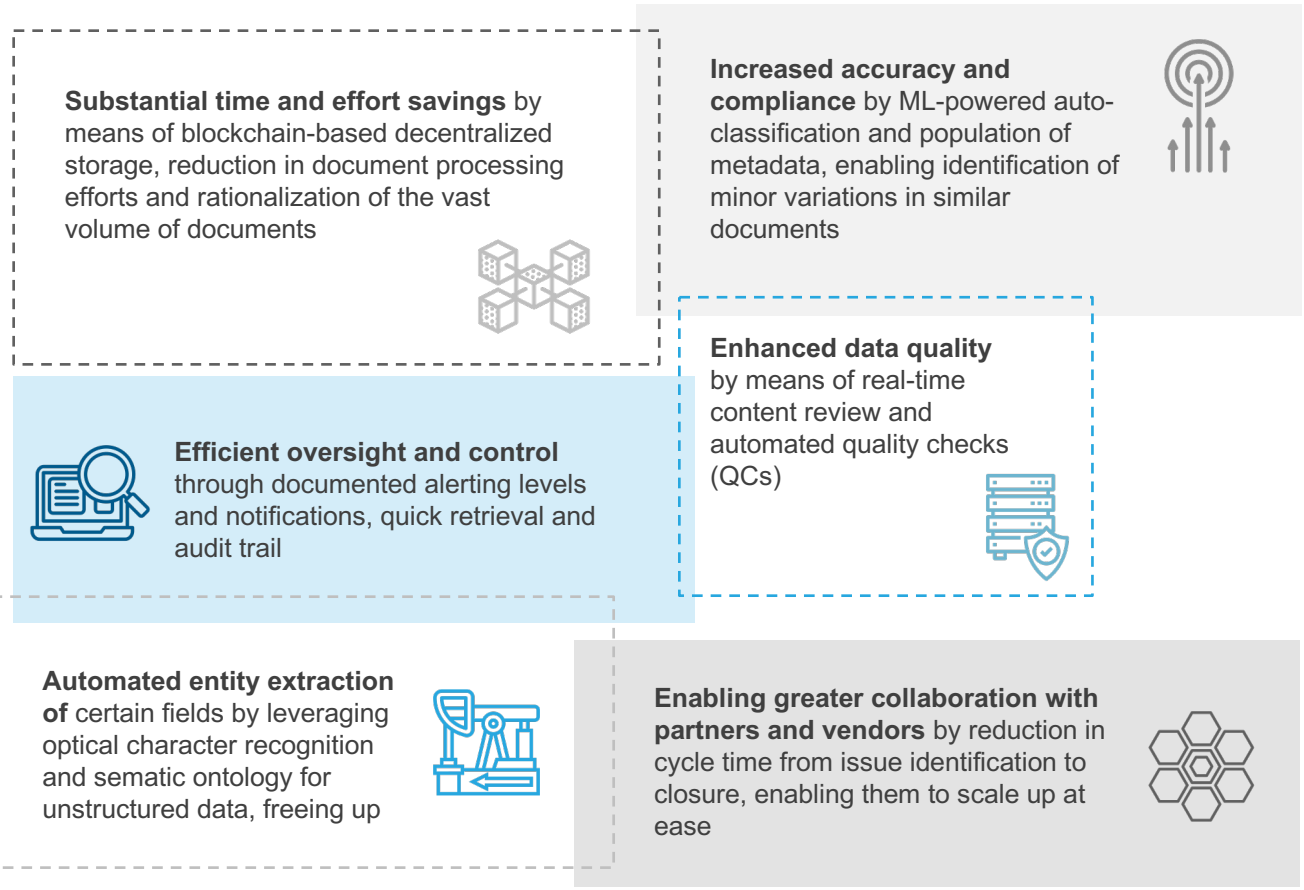
- **Auto-classification and efficient indexing:** ML technologies have the potential to uncover critical metadata embedded in unstructured data to improve and accelerate the process of classification and automate identification and classification of different types of source data based on pattern recognition. Neural networks can be trained using optical character recognition to link an extracted attribute to the relevant clinical study. Protected Health Information (PHI) and Personally Identifiable Information (PII) can be automatically redacted permanently prior to storage for trials in Phase III
- **Robust document exchange mechanism:** ML applications can effectively enable a TMF exchange mechanism by reducing the number of content exchanges and eliminating the need for mapping metadata. AI can further enhance document exchange by identifying minor variations in similar artifacts and checking for document orientation. Sponsors can use ML models to compare extracted values from a trial artifact with the existing metadata to identify inaccurate entries in the target database

- **Language detection:** Sponsors require AI-enabled multilingual validation solutions for multi-country clinical trials using translation workflows for better linguistic consistency and quality while reducing overheads arising from localization. ML-based techniques also have the potential to assist translators in ensuring that keywords and phrases of clinical significance are accurately translated so that the essential documents[3] are made available to local inspectors as is required by GCP mandates. AI-enabled solutions can further boost the efficiency of linguistic validation by enabling more accurate reviews and alterations to translations and automating some manual human touch points within the clinical translation lifecycle

EXHIBIT 4

Benefits of AI-enabled TMF management

Source: Everest Group (2023)



3 FDA regulated research is required to conform to standards of Good Clinical Practice (GCP). Section 8 of the GCP guidelines outlines the "Essential Documents" that investigators are responsible for creating and maintaining. These documents individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements

CASE EXAMPLE 2: AI for X-Ray analysis

One area of pre-clinical testing that AI can truly revolutionize is pre-clinical imaging. The early 2020s have seen an emergence in AI-based algorithms that can perform preliminary interpretations, though the current FDA-approved algorithms assist with a limited number of findings. In April 2022, the European Union paved the way for the use of AI for analysis of chest X-rays; this analysis automatically identifies and sends patients reports in which X-rays showed no abnormalities. In March 2023, a provider of AI software for medical imaging received clearance from the European Union Medical Device Regulation for software that assists radiologists with interpretation and analysis of radiological scans.

Advances in high-resolution scanning and a growth in imaging orders coupled with the need for rapid diagnosis have increased radiologists' workloads.

Furthermore, analysis of pre-clinical images is burdened by three key set of challenges that are preventing pharma companies from realizing the true potential of AI for X-ray analysis.

EXHIBIT 5

Challenges associated with use of AI for X-ray analysis

Source: Everest Group (2023)

Data challenges

- Data privacy laws around patient data along with regulatory barriers for software as a medical device affecting availability of X-rays
- Lack of standardized image acquisition and inconsistency in radiological images owing to the variety of scanning machinery, optical settings, and mechanisms
- Inaccurate labeling of radiological images used for training, (which leads to creation of inaccurate image description), and viewing limitations for radiologists arising from patient positions, poor image quality, and tissue overlays

Limitations of current AI solutions

- Limited applicability of the currently deployed AI-enabled X-ray analysis arising from training on single hospital data set
- Absence of systematic cataloging for findings from chest radiographs inhibits analysis of finer granularities beyond core findings
- Inaccurate performance metrics and a need to transition from label-based evaluations to metrics such as image-based sensitivity, Positive Predictive Value (PPV), and specificity

Challenges around animal testing

- Ethical concerns related to the use of animals for pre-clinical testing and ineffectiveness of animal studies to reliably predict human behavior
- Delays in drug discovery and the inability to extract meaningful insights from current pre-clinical animal testing data repositories because of reliance on animal experimentation

Pharma companies are increasingly turning to AI to solve challenges with legacy X-ray analysis techniques and improve the efficiency and accuracy of currently employed AI-enabled medical image analysis. The current need is a solution that automates algorithms for extraction of significant findings from X-ray analysis such that the findings are comprehensive enough for a full-fledged report. Eventually, this kind of tool can then help to reduce radiologists' workloads and time pressures. AI can also improve outcomes by enabling quicker and more efficient anomaly detection, given that manual analysis is subject to decision fatigue and incorrect diagnosis.

AI-powered X-ray analysis will open new avenues of research for pharmas and bolster their efforts related to precision medicine, cardiology, and neurology by helping them unlock the underlying mechanisms of specific diseases. Medical imaging data collected by healthcare provider networks across various touchpoints can provide unique insights for development of novel chemical entities and candidate drugs. The pharma industry is increasingly considering multimodality devices that are designed to help uncover insights on pathophysiological processes under study.

The FDA Modernization Act 2.0, which was signed into law in January 2023, approves the use of New Approach / Alternative Methodologies (NAMs), enabling the pharma industry to transition to an alternative to animal testing wherever appropriate. AI, ML, and deep learning are already seeing some success, as drugs are being designed entirely with the help of simulated organs trained by AI for rare diseases. AI also is applicable in toxicity prediction models, and companies can use quantum computing to analyze historical pre-clinical medical image data and conduct bio simulation to reduce drug development costs and time. These solutions also provide alternatives to remote pre-clinical testing sites, where radiology talent with pharma expertise can be hard to come by.

Maximizing returns from AI-specific investments

The combination of evolving computing hardware and software advances is enabling the shift of many prioritized AI use cases from proofs-of-concept or pilot stages to enterprise-wide adoption; the pandemic served as a further accelerator. Enterprise-wide adoption of AI-powered solutions will empower a pharma company to enhance the value of its current portfolio, strengthen core competencies and intellectual property (IP), and truly leverage its network of partners and collaborators (including research consortia and academic bodies) to stay ahead of the curve. Current adoption represents the tip of iceberg in terms of AI's full transformational potential, particularly in conjunction with other technologies.

Sourcing considerations for AI solutions and suppliers

Enterprise-scale adoption of AI solutions has the potential to create significant competitive advantage, realizing its full potential requires more than capital investment in cutting-edge technology, algorithms and enabling infrastructure. To truly capitalize on the incredible power of AI-enabled solutions enabled by other technologies (cloud, IoMT, SaMD, AR/VR, HPC, computer vision, and blockchain), life sciences companies need to take an end-to-end approach and commit to becoming data-driven enterprises. The implementation of any AI solution will be primarily driven by successful data and analytics initiatives across the value chain. Enterprises need to move quickly beyond pilots, starting with a select few use cases to build momentum. Quick wins will fuel further innovation and move them up the learning curve, enabling them to implement transformative use cases using powerful tools and models. Pharma companies need to consider five major factors when adopting and scaling AI solutions, as depicted in Exhibit 6.

EXHIBIT 6

Considerations for pharma companies adopting and scaling AI solutions

Source: Everest Group (2023)

Industrialization and reusable assets

- Harmonize coding approaches and implement standards in development for solution robustness
- Make the right technology infrastructure and methodology enablers are in place that can support scaling up of solutions across the value chain

Talent management

- Develop strategies to retain, recruit, develop, reskill, and upskill current AI talent
- Define new roles that will bring together technical and scientific expertise
- Ensure availability of talent for implementing AI solutions and evaluate existing partnerships

Vision and strategy

- Develop an overarching vision of the AI-enabled transformation by means of use case prioritization across the value chain and pipeline
- Envision an elaborate cross-functional roadmap with quantifiable objectives

Building blocks

- Create a scalable unified data repository of high-quality internally- and externally-sourced datasets which are cleansed, aggregated and normalized
- Implement efficient and appropriate algorithms, ensuring the tech-stack, data warehousing and management, and data governance models are in place

Partnerships

- Evaluate current partners on domain expertise, technical knowledge, synergies in vision
- Identification of new partners in accordance with requirements of targeted use cases and the strategic roadmap

- **Vision and strategy:** The first step is to define the problem statement or the business objectives that you want to achieve using AI. It is imperative to formulate a plan to integrate AI into the broader business operations and corporate strategy and then build a vision around it. Business leadership needs to ensure visibility around technology- and domain-specific investments over time. These objectives should be tied back to the use cases to help you prioritize initiatives based on current capabilities, financial strength, and corporate goals. At this stage, you must be clear on both the present and desired state of systems and have a clear definition of performance requirements. All this needs to be aligned to a sound and simple change management structure that ensures necessary upskilling and realignment from a technology, business, and leadership perspective.

- **Building blocks:** Any AI-empowered solution will effectively work as a module to the existing solution, not as a standalone component, so it will need to work cohesively with digital technologies already in place. The efficacy and accuracy of AI-enabled solutions are crucially dependent on the quality, diversity, and sample size of the training data sets. Hence, you should gather data (structured, unstructured, real-time, and batch-mode) from the disparate and distributed sources relevant to a particular use case into a unified data repository. This incrementally built, scalable platform will serve as a foundation to establish data standards and implement advanced analytics and AI solutions for metadata.
- **Partnerships:** The sheer magnitude of talent, capital, and data necessary to realize the benefits of an AI-empowered solution is significantly greater than what one enterprise can muster. Strategic alliances, partnerships, and development of an AI ecosystem to enable synergies with AI-startups, specialized product providers and product owners (business, clinical, scientific, technology and systems architecture expertise) will be necessary to advance toward your goals. Additionally, you will need to consider the following issues in developing your partnership strategy for AI initiatives:
  - Strike a balance between developing talent in-house and being selective and specific about the capabilities your partners can bring to the table.
  - Evaluate opportunities to acquire AI partners across the solution spectrum keeping in mind your future therapeutics focus areas.
  - Consistently work collaboratively with organizations around the globe (academia and research institutions) to help build a unified data lake to ensure expansive training data sets for your AI-based solutions.
- **Industrialization and reusable assets:** For pharma enterprises to make the best of their existing AI investments to increase operational efficiency, transformational change, and business resiliency, it is vital to have the enabling infrastructure, data architecture and methodologies such as ML Operations (MLOps) and data operations (DataOps). While DataOps enables you to accelerate the identification of insights from your data by, MLOps ensures reliability and delivery at scale for AI by providing the right platform, tools, services, operating model, and standards. It is imperative to focus efforts on the creation of inter-related components such as data connectors and pipelines, and visual interfaces to address productivity challenges that could arise from poor integration or fragmented components. For robustness and scalability of solutions, uniform standards for coding and harmonization in development will pave the way to the creation of reusable assets and facilitate sharing of these assets across projects.

This step-based approach is an iterative process rather than a linear journey. The models and methods applied in any initiative will be different from others, and every initiative will be a learning opportunity for your organization to get better at unlocking value from data. A continuous feedback loop will enable you to improve at prioritizing initiatives and implementing transformative use cases. By taking an iterative approach, you will be able to embed AI into the DNA of your organization, making it truly data-driven.

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