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HOW AI & BLOCKCHAIN ARE CHANGING DRUG DEVELOPMENT

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INTRODUCTION/DEFINITIONS

In 2021, SCORR published "How Artificial Intelligence & Blockchain Are Changing Drug Discovery."[1] This primer — "How Artificial Intelligence & Blockchain Are Changing Drug Development" — is intended to build off of as well as complement the previous primer.

As stated in the previous primer, the biopharmaceutical industry faces ongoing challenges in drug development with cost, time, and efficiency. A recent Deloitte report states the average cost of developing a new drug among the top 20 global biopharmas increased from about $2 billion to $2.3 billion.[2] The Pharmaceutical Research and Manufacturers of America (PhRMA) has long stated that it takes on average 10-15 years to develop one new medicine.[3]
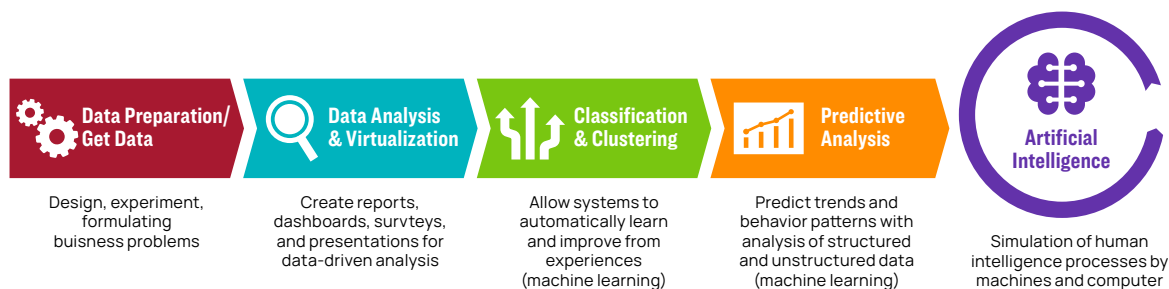
Artificial intelligence (AI) has been increasingly used in drug discovery; in fact, the first drug ever generated by AI just entered Phase II clinical trials.[4] The hope and promise of AI is that the relative efficiency in which it can complete data-driven tasks can also be applied to other stages of drug discovery.[5]

Before discussing how AI and blockchain have been and can be applied to aiding in drug development, we will first define some terms that will be used throughout this guide. Note: some of the definitions presented below are from the 2021 primer.

Machine learning is an algorithmic technique modeled on the human brain.[6] Through a process of trial and error, the accuracy of the algorithm gradually improves. The same technology can be adapted to any high data output system.
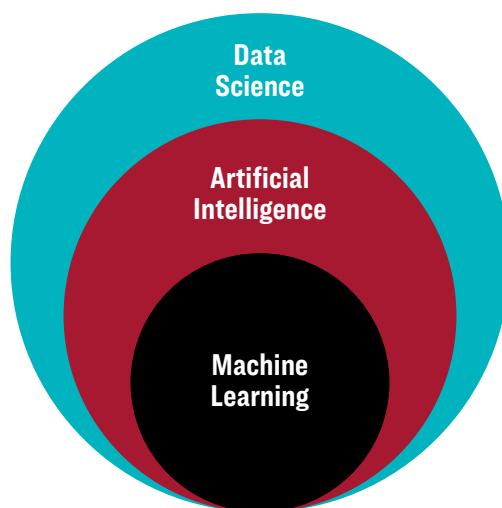
Artificial intelligence (AI) is a field of data science that uses large data sets to enable problem-solving.[7] Within the field of AI are multiple disciplines, including machine learning, deep learning, and other forms of probabilistic analysis for huge data sets.
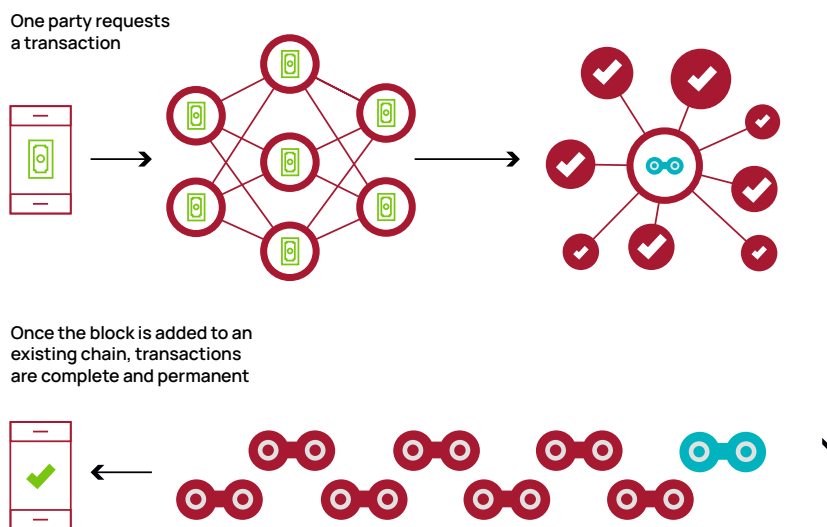
How Artificial Intelligence Works

Data Preparation/ Get Data	Data Analysis & Virtualization	Classification & Clustering	Predictive Analysis	Artificial Intelligence
Design, experiment, formulating buisness problems	Create reports, dashboards, survteys, and presentations for data-driven analysis	Allow systems to automatically learn and improve from experiences (machine learning)	Predict trends and behavior patterns with analysis of structured and unstructured data (machine learning)	Simulation of human intelligence processes by machines and computer

Source: Wintech, "Artificial Intelligence" (undated: viewed on 6/20/23): link[8]

Data science — IBM defines data science as the "[combination of] math and statistics, specialized programming, advanced analytics, artificial intelligence (AI), and machine learning with specific subject matter expertise to uncover actionable insights hidden in an organization's data."[9] The goal of data science is to improve organizational decision making and strategic planning.

In other words, machine learning is considered a type of artificial intelligence, and artificial intelligence is a subset of data science.

How Does Blockchain Work?

One party requests a transaction

Once the block is added to an existing chain, transactions are complete and permanent

Source: SCORR, "How Artificial Intelligence & Blockchain Are Changing Drug Discovery" (December 2021) — graphic based on client's "Blockchain Explained: It Builds Trust When You Need It Most," (February 12, 2018)[1]

Blockchain technology is a system of public databases that cross-reference each other continuously.[10] Each block can hold a certain amount of data. Once filled, it connects to the next block that is generated, creating an unbroken chain of blocks throughout the system. Data cannot be changed once incorporated into the system, creating a method to enforce both security and reliability.

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MARKET OVERVIEW

Artificial intelligence and blockchain markets are booming. The AI market is projected to grow at a compound annual growth rate (CAGR) of 37% through 2030.[11] The blockchain market is expected to grow at a whopping CAGR of 60% through 2030.[12]

As the pharma industry can be slow to adapt to new technologies, AI and blockchain growth has not been as robust in the life sciences as it has been generally. Still, AI and blockchain utilization has markedly increased in the past few years.[13] The projected compound annual growth rate (CAGR) for both the AI and the blockchain clinical trial markets, while lower than overall growth rates, are expected to be around 20% from now until 2030.[14,15]

Projected CAGR thru 2030
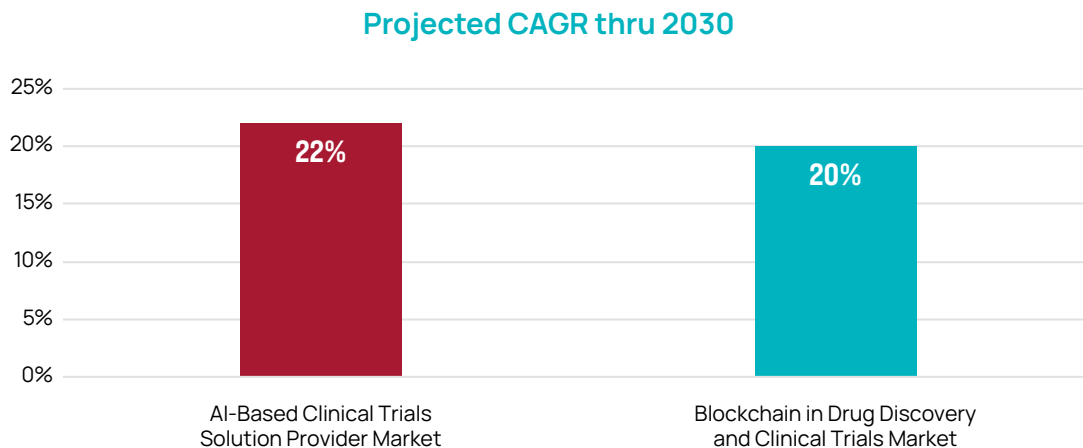
Sources: Grand View Research, "AI-Based Clinical Trials Solution Provider Market Size, Share & Trends Report: Forecasts, 2023-2030" (June 2022) and Roots Analysis, "Blockchain Technology in Healthcare Industry Market" (February 2023)

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AI PIPELINE STATUS REPORT

Much of AI or blockchain drug development investment has gone into drug discovery. Over time, however, more drug projects have graduated from drug discovery to later stages in the pipeline.

According to the GlobalData Drugs Database, as of August 8, 2023, there were 1,274 pipeline projects with the "AI" drug descriptor.[16] The highest stage of development for 1,045 of them are between discovery and Phase III (see chart below).

> Therapy area: 437 of them are in oncology; 155 of them are for CNS

> Molecule type: 522 of them are small molecule drugs

> The four sponsors with the most projects are Exscientia (26), InSilico (25), Chengdu WestGene (18), and Recursion (also 18).

Highest Stages of Projects with AI Descriptor

| Stage	Count
Discovery	652
Preclinical	312
Phase I	48
Phase II	28
Phase III	5
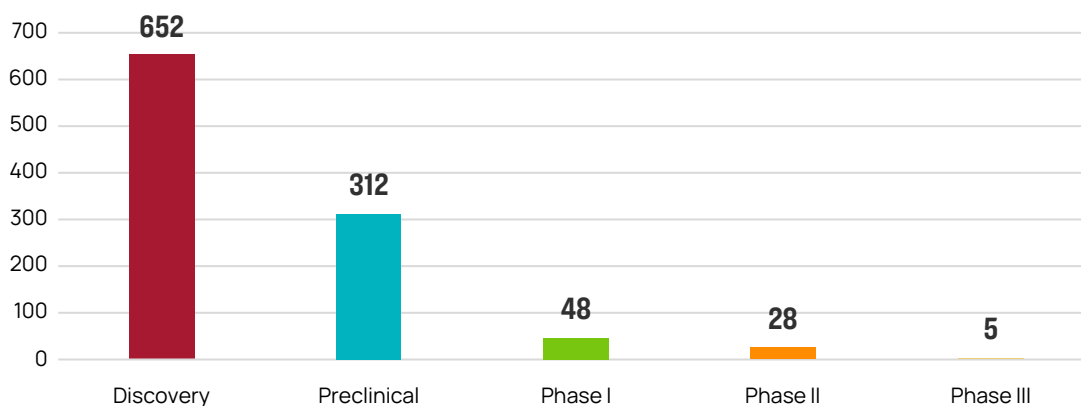
Source: GlobalData Drugs Database search on 8/8/23

As can be seen in the chart, the volume of AI-related pipeline projects currently in the discovery and preclinical phases will likely eventually result in more AI-developed drugs.

# HOW AI & BLOCKCHAIN BENEFIT THE CLINICAL TRIAL PROCESS

While there are applications for both AI and blockchain throughout the clinical trial process, blockchain can be especially utilized in stages where data are being created or collected. Artificial intelligence is notably useful for processing huge batches of data as it can do so much more effectively and efficiently than humans.
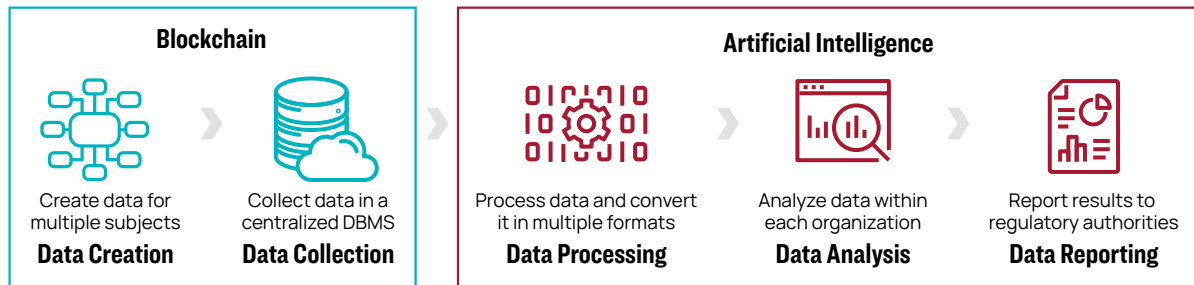
Source: The Institution of Engineering and Technology "Blockchain for Applications of Clinical Trials" (8/27/22)

Data Creation, Date Collection

> Accessibility: Blockchains allow for decentralized access. For example, clinical trials could be run in a patient's home or at a traditional brick-and-mortar research site.[17]

> Data collection: AI can be used to create structured and standardized data collection to improve clinical trial data collection and promotion of digital data flow.[18]

> Data sharing and interoperability: Blockchain structure results in one single source of data that can be shared in multiple locations.[19]

> Data security: Blockchain makes it easier to aggregate health data in a secure, trusted, automated, and error-free way.[20]

> Digital twin: Digital twins are made by combining data from sensors and other sources with computer models to create a virtual model. This virtual model can then be used in simulations to test new ideas or designs or make predictions to further understanding of the entity being represented by the digital twin.[21]

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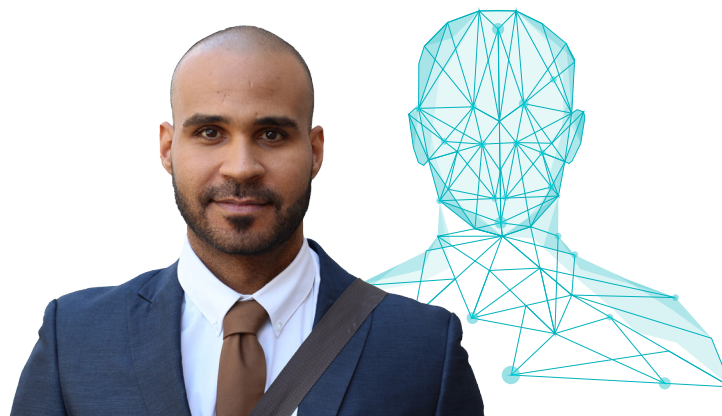
Data Processing, Data Analysis, Data Reporting

❯ Clinical trial design: AI can be used to find patterns in data to better predict patient behavior and drug efficacy to optimize trial design.[22]

❯ Patient experience: Artificial intelligence can be used to drive self-service patient portals to improve patient experience.[23]

❯ Patient recruitment: AI trial matching platforms help overcome some obstacles associated with clinical trial recruitment by processing patient information more efficiently.[24]

❯ Patient diversity: Wearable devices powered by AI can reduce patient burden, which in turn can result in increased ability to recruit from diverse population.[18]

❯ Site feasibility: AI software reduces time spent administering, processing, and reviewing feasibility surveys. This allows for quicker decisions and more time for staff to interact with patients.[25]

❯ Supply chain optimization: AI can review large amounts of supply chain data to optimize the process and to improve efficiency, improve safety, and reduce costs.[26]

Each of the items noted above potentially helps one or more of the following: improves process, makes things better for patients, reduces cost, or saves time.

AI/Blockchain

BETTER

Data Creation

Data Collection

Data Processing

Data Analysis

Data Reporting

Improved Process

Improved Patient Experience

Reduced Cost
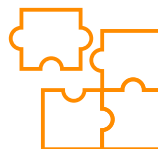
Time Saved

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CHALLENGES

Though utilization of artificial intelligence and blockchain technology can benefit clinical research in many ways, human oversight is still necessary.[24] AI and blockchain are only as good as the people who initiate or structure them.
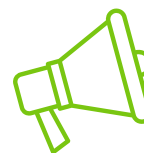
LACK OF DATA   **RISK AVERSION**   **RESISTANT COMPANY CULTURE**   **LACK OF AWARENESS AND EXPERIENCE**

Source: SCORR, "How Artificial Intelligence & Blockchain Are Changing Drug Discovery," (December 2021)

> Lack of data: To maximize benefits associated with artificial intelligence, there needs to be sufficient, clean data. "Management and inherent bias in datasets need to be addressed first."[27]

> Risk aversion: Change — even positive change — can be difficult and often requires an adjustment period time. For example, when asked about AI, study coordinators and clinical research associates (CRAs) expressed mixed feelings about it.[28]

> Resistant company culture: Fortune 1000 companies reported a decline in the leading metrics which are used for measuring the success of their data and AI investments. … 92.2% of mainstream companies report that they continue to struggle with cultural challenges relating to organizational alignment. … As management guru Peter Drucker once said, "Culture eats strategy for breakfast."[29]

> Lack of awareness and experience: Even though utilization and familiarity with AI and blockchain technologies has increased over time, a gap in familiarity and experience continues to exist.[30] From a survey of physicians and medical students:

> A minority — 10-30% [of survey respondents] — had used AI previously

> The awareness rate was just 38%

> The utility rate of clinical AI was just 20%

> More than one-half — 53% — lacked basic knowledge of clinical AI

"Despite the hype and potential, there has been little AI adoption in health care."
— Brookings Institution, "Why Is AI Adoption in Health Care Lagging?"[31]

EXAMPLES

Sponsors and health care organizations have attempted to incorporate AI/blockchain technology to improve clinical research process or patient care.

Sponsor Examples

Sponsor	Purpose/Goal
Pfizer	Evaluation of sensors and wearables
abbvie	Precision medicine — multi-omics analysis
MERCK	Integration of Saama's LSAC tech into clinical development systems
Bristol Myers Squibb	Optimization of clinical trials — making them more efficient
AstraZeneca	Improvement of patient ID, selection, trial conduct, data capture
sanofi	Enhancement of trial design and improvement of manufacturing
Lilly	Optimization of contract production or rote administrative work
GSK	Entered collaboration agreement with Tempus and its AI-enabled platform to improve clinical trial design

"The application of artificial intelligence in clinical trials allows for a broad array of opportunities to create efficiencies that reduce time and cost. One area of particular interest for AI application is patient enrollment. Through AI predictive modeling techniques researchers gain knowledge about patient outcomes and drug efficacy. With this knowledge, researchers can design more efficient clinical trial protocols while potentially identifying the most suitable patient populations and treatment regimens."

— Bill Hirschman, Chief Commercial Officer, Bullfrog AI[32]

Health Care Organization Examples

Organization	Purpose/Goal
MAYO CLINIC	Onboarding Triall's blockchain-integrated eClinical platform to embed verifiable data integrity
(logo)	Developing a virtual hospital where storage of medical records will use blockchain technology
UNC HEALTH	Development of chatbot for staff using AI technology
BAPTIST HEALTH	Used IBM Watson's AI platform to extract relevant data from electronic health records
Metro Health	Teamed with Case Western Reserve University researchers to use AI to improve access to clinics for minorities
VA U.S. Department of Veterans Affairs	Partnered with DeepMind to develop a machine learning system to predict life-threatening kidney disease

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CRO MESSAGING

Contract research organizations employ messaging on their websites to promote their utilization of artificial intelligence, blockchain, and/or technological innovation.

CRO	Messaging
ICON	AI and clinical trials
IQVIA	AI & Machine Learning with a Healthcare IQ
labcorp Drug Development	Artificial Intelligence (AI)
MEDPACE	Artificial Intelligence Can Boost Reliability and Speed of Medical Imaging Analysis in Clinical Trials
parexel	Putting AI to work in your safety program
PPD	Our Technology Informs, Analyzes, Automates, Simplifies and Accelerates Your Clinical Trials
Syneos Health	Syneos Health Collaborates with Microsoft to Accelerate AI Across the Clinical to Commercial Continuum
WORLDWIDE CLINICAL TRIALS	Worldwide Clinical Trials and Deep Lens Enter Strategic Alliance to Accelerate Recruitment and Development Timelines for Oncology Trials

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SUMMARY

01 Artificial intelligence and blockchain technology are increasingly being incorporated into clinical research tasks.

02 The market is booming.
- The expected compound annual growth rate (CAGR) for both AI and blockchain in clinical research from 2023 to 2030 is at or above 20%.
- GlobalData's Drugs Database shows more than 1,000 pipeline projects with a drug descriptor of "AI." These are drugs that incorporate AI into at least part of the drug development process.

03 While both AI and blockchain can be applied throughout the different stages of the clinical trial process, they are most notably used for different types of tasks.

Technology	Primary Task(s)
Blockchain	Data creation, data collection
Artificial intelligence	Data processing, data analysis, data reporting

04 Challenges remain. Lack of data, incompatibility with company culture, and a general lack of awareness and experience each limit AI's and blockchain's potential utility.

05 The finish line: improved clinical trial processes brought on by AI/blockchain will lead to improved patient experience, lower costs, and time saved.

06 Both sponsors and CROs utilize AI/blockchain-specific messaging to promote themselves and/or services (e.g., "integration," "optimization," "technology").

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