

PreScouter

What are the applications of artificial intelligence in drug discovery & development?

Research Support Service

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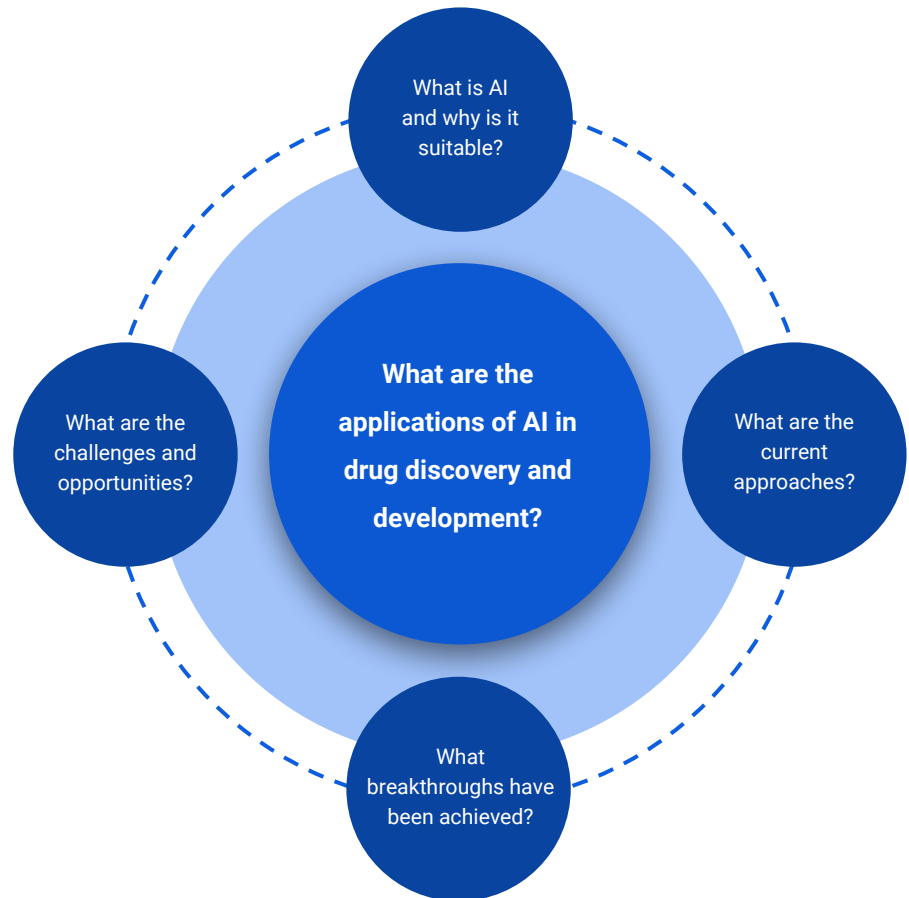
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Question

The overarching question that PreScouter addresses in this intelligence brief is: what are the applications of artificial intelligence (AI) in drug discovery and development, and can we make this process more efficient using AI?

This is tackled by answering a number of smaller questions:

- *What is AI and why is it suitable for application in drug discovery?*
- *What are the current approaches for utilizing AI in drug discovery?*
- *What breakthroughs have already been achieved using AI in the pharmaceutical industry?*
- *What are the challenges and potential roadblocks facing these uses of AI?*



Why did PreScouter choose this topic?

Pharmaceutical companies are routinely faced with drug development timelines of about 15 years, costs in excess of \$1 billion, and a minute rate of success.

It's estimated that 1 in 10 small molecule projects become candidates for clinical trials and only about 1 in 10 of those compounds will then pass successfully through clinical trials.



Many disease conditions cannot be successfully addressed through the traditional drug development process.

Barriers include inability to devise a molecule that selectively drugs the desired target or absence of sufficient financial incentives based on size of addressable market.

AI has the potential to transform the drug development process

making it both **more efficient** and **more effective**, thus benefiting all parties involved—from the companies developing new drugs to the patients in desperate need of viable treatments.

Executive Summary

The use of AI in the pharmaceutical industry is projected to bring in billions of dollars in funding in the near future, underlying the huge potential for growth in this specific sector.

In this report, we first provide an **introduction to potential uses of AI** within the drug discovery and development process, in particular comparing to conventional methods for carrying out these tasks and highlighting the pros and cons of AI. We limited our focus to the early stages of discovery of new drug compounds and preclinical drug development (stopping short of uses of AI for clinical trials).

Currently, several startups are using AI to improve the process of drug discovery and development. A number of detailed **case studies** are provided to illustrate the current state-of-the-art for applying AI within the pharmaceutical industry. **Six startups** providing an AI solution applicable during a particular research phase of the drug discovery & development process are highlighted as follows:

1. **Generating novel drug candidates:** Atomwise, TwoXar, ReviveMed
2. **Understanding disease mechanisms:** Phenomics AI, Structura Biotechnology
3. **Aggregating and synthesizing information:** Arpeggio Biosciences

Executive Summary

The present report also details the key **challenges** that AI will need to address and overcome in order to realize its full potential within the pharmaceutical industry. Challenges include ethical concerns, regulatory hurdles, and technical obstacles.

Finally, we conclude with the **opportunities** AI holds for the biopharmaceutical industry.

This report was driven by questions PreScouter receives from clients in every industry about specific ways in which AI could improve upon the current way of doing things. We chose to focus on the pharmaceutical industry because we are at the point where early use cases are becoming available that highlight the potential for AI to improve the process of discovering and developing a new drug, which is currently an incredibly difficult task.

--- Charles Wright, PhD, PreScouter Project Architect

AI in drug discovery & development

Aggregating and synthesizing information



- Combines new RNA sequencing technologies with proprietary machine learning
- Mine data to help quickly identify the direct targets of a novel drug

TRL 5

Understanding disease mechanisms



- Analysis of genome-wide screens
- Identify proteins involved in regulating the cell cycle
- Discovery of the next generation of therapies against cancer.

TRL 3



- Training computer vision and machine learning models on cryo-EM data
- Provide detailed spatial 3D structure of proteins and molecular complexes
- CryoSPARC System™ software enables reconstructions of research and drug targets.

TRL 8

Generating novel drug candidates



- Structure-based deep CNN
- Predict bioactivity of small molecules
- Predict new active molecules for targets with no previously known modulators
- Development of agricultural pesticides (partnered with Monsanto)

TRL 5



- Screen compound libraries for efficacy against a disease
- Identify biologic targets
- Uncover novel disease biology hypotheses supported by real world data.

TRL 4



- Network-based machine learning approach
- Measure metabolite masses fast and inexpensively
- Predict the identity of each metabolite mass
- Integrate data with other large-scale molecular datasets

TRL 3

Introduction to Potential Uses of AI-Based Drug Discovery & Development

How is AI used in drug discovery?

Traditional drug discovery methods are *target-driven*, i.e., a known target is used to screen for small molecules that either interact with it or affect its function in cells.

- These approaches work well for easily druggable targets that have a well-defined structure and whose interactions inside the cell are understood in detail.
- However, these methods are extremely limited due to the complex nature of cellular interactions as well as limited knowledge of intricate cellular pathways.

AI can overcome these challenges by identifying novel interactions and inferring functional importance of different components of a cellular pathway.

- AI utilizes complex algorithms and machine learning to extract meaningful information from a large dataset, e.g., a dataset of RNA sequencing can be used to identify genes whose expression correlates with a given cellular condition.
- AI can also be used to identify compounds that could bind to 'undruggable targets', i.e., proteins whose structures are not defined. Through iterative simulations of interactions of different compounds with small pieces of a protein, a predictive set of compounds can be easily identified in a relatively small amount of time.

Traditional VS AI-based drug discovery methods

TRADITIONAL

- Target-driven
- Work well for easily druggable targets that have a well-defined structure and whose interactions inside the cell are understood in detail
- Extremely limited due to the complex nature of cellular interactions & limited knowledge of intricate cellular pathways

AI-BASED

- Data-driven
- Complex algorithms and machine learning can extract meaningful information from a large dataset
- Identify compounds that could bind to 'undruggable targets', i.e., proteins whose structures are not defined

A predictive set of compounds can be easily identified with AI in a relatively small amount of time and at a quarter of the cost of traditional methods.

Benefits of applying AI to drug discovery

The application of AI to drug discovery has the potential to revolutionize the current time scale and scope of drug discovery.

- ✓ AI does not rely on predetermined targets for drug discovery. Therefore, subjective bias and existing knowledge is not a factor in this drug development process.
- ✓ AI utilizes the latest advances in biology and computing to develop state-of-the-art algorithms for drug discovery. With the rapid increase in processing power and reduction in processing cost, AI has the potential to level the playing field in drug development.
- ✓ AI has a higher predictive power to define meaningful interactions in a drug screen. Therefore, the potential for false positives can be reduced by carefully designing the parameters of the assay in question.
- ✓ Most importantly, AI has the potential to move drug screening from the bench to a virtual lab, where results of a screen can be obtained with greater speed and promising targets can be shortlisted without the need for extensive experimental input and manpower hours.

Drawbacks of applying AI to drug discovery

As is the case with any advance that brings a paradigm shift in our understanding of an existing technology, AI still cannot replace a human scientist entirely in the process of drug discovery.

- ✗ AI predictions are as good as the algorithms used to investigate a dataset. The algorithm should clearly lay out the criteria that should be used to parse out meaningful information when the results are in the 'gray zone' of interpretation.
- ✗ AI can suffer from *algorithm bias*, where the creators' own bias manifests itself in the way information is processed to generate predictions. Therefore, the process is not entirely objective.
- ✗ While the cost of supercomputing and high-throughput screening has decreased appreciably over the past decade, establishing these pipelines still requires significant investment.
- ✗ Ultimately, predictions made by a computer have to be verified by a scientist to make sure they are valid.

Case Studies

TRL Rating Scale

The following case studies have been assigned a Technology Readiness Level (TRL).

The TRL Scale is an industry standardized metric by which PreScouter evaluates technologies for each client. Based on the constraints on the innovation challenge, PreScouter assigns a TRL number to each identified academic, company or patent. This process allows each solution to be easily identified for commercialization potential. Higher number TRLs do not always equate to the best technology – for example, most late stage academic technology is best suited for optimization and integration, but would have a TRL between 2-4.

TRL 9	Systems Operation - Actual system operated over full range of expected conditions
TRL 8	System Commissioning - Actual system completed and qualified through demonstrate tests
TRL 7	System Commissioning - Full-scale, similar prototype demonstration in relevant environment
TRL 6	Technology demonstration - Engineering / pilot scale prototype testing in relevant environment
TRL 5	Technology development - Lab-scale validation in relevant environment
TRL 4	Technology development - Component or system validation in lab environment
TRL 3	Research to prove feasibility - Analytical / experimental test of critical function - proof of concept
TRL 2	Basic technology research - Technology concept and/or application formulated
TRL 1	Basic technology research - Basic principles observed and reported

Applications: Reduce the amount of money and time researchers spend on finding compounds for medications. Atomwise's AI technology is also used to develop safer, more effective agricultural pesticides.

AI Drug Discovery: Atomwise Introduced the first structure-based deep CNN, called AtomNet, designed to predict the bioactivity of small molecules for drug discovery applications. It shows how AI exploits feature locality and hierarchical composition to the modeling of bioactivity and chemical interactions.

- AtomNet shows how to predict new active molecules for targets with no previously known modulators.
- ➔ **Led to the discovery of two drugs that significantly reduce Ebola infectivity. These drugs were intended for unrelated illnesses and their potential to treat Ebola was previously unknown.**
- The CNN outperforms previous docking approaches on a diverse set of benchmarks by a large margin, achieving an area under the curve (AUC) greater than 0.9 on 57.8% of the targets. The AUC metric represents the total drug exposure over time and is proportional to the total amount of drug absorbed by the body.

AI Research Directions:

Expend molecular discovery programs and focus on compounds against crop protection targets that are important areas of focus for agrochemical R&D in partnership with Monsanto.

Level of Development:

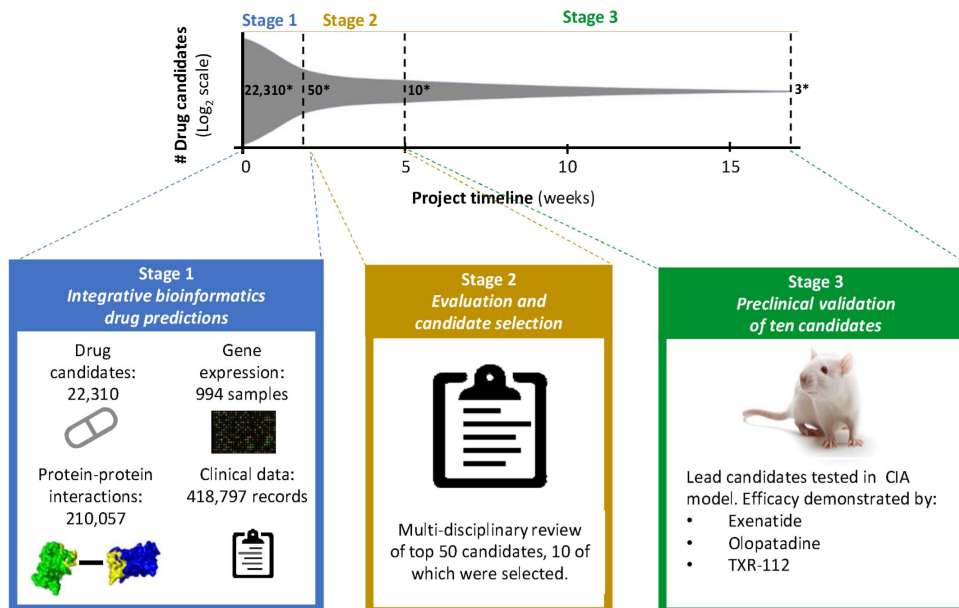
TRL 5. Many discoveries are being validated in the academic setting. Other discoveries have been licensed to pharmaceutical companies in confidential deals.

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2. <https://www.atomwise.com/news/>
3. <https://techcrunch.com/2018/03/07/atomwise-which-uses-ai-to-improve-drug-discovery-raises-45m-series-a/>

Applications: Identify drug candidates by uncovering novel disease biology hypotheses supported by real world data.

AI Drug Discovery: TwoXAR uses AI to screen compound libraries for efficacy against a disease to discover new drug candidates from a public library, and identify biologic targets (use cases follow).



Researchers analyzed DrugBank and the Therapeutic Targets Database and based on predicted therapeutic potential identified 50 high-probability candidates, followed by algorithm evaluation and candidate due diligence to select 10 optimal and novel candidates, and finally testing in an *in vivo* model of RA to identify 3 lead candidates, all within a 4-month period.

- Developed a computational model of rheumatoid arthritis (RA) that significantly enriched FDA-approved treatments for RA among the top-ranked candidates.
- Collaboration with the Asian Liver Center at Stanford to discover TXR-311, an experimental drug for liver cancer. This drug showed a positive results in cell-based assays.
- Identification of variables and interacting drug pairs associated with reduced 5-year mortality using electronic health records (EHR) of breast cancer patients.
- Identification of differentially expressed genes from 14 human breast cancer gene expression datasets.

AI Research Directions:

Focus on new treatments in a particular disease area, like diabetes.

Level of Development:

TRL 4. Currently developed in academic setting, with results verified in animal models.

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2. <https://academic.oup.com/jamia/article/24/3/565/2664593>
3. <https://www.biorxiv.org/content/early/2018/01/07/243998>

Applications: Integrative analysis of untargeted metabolomic data with other large-scale molecular information such as data from genes, proteins, drugs and diseases.

AI Drug Discovery: AI is applied to measure metabolite masses fast and inexpensively using network-based machine learning algorithms. These algorithms predict the identity of each metabolite mass, and integrate the data with other large-scale molecular datasets such as genomics and proteomics. Use cases are as follows:

- Development of a network-based approach, prize-collecting Steiner forest algorithm for integrative analysis of untargeted metabolomics (PIUMet), that infers molecular pathways and components via integrative analysis of metabolite features, without requiring their identification.
- Establishment of the ability for integrative analysis of untargeted metabolomics data with proteomics data, demonstrating that this approach elicits disease-associated metabolites and proteins that cannot be inferred by individual analysis of these data.

AI Research Directions:

Discover detailed molecular pathways associated with a specific disease and build more accurate AI models to find new mechanistic-based biomarker signature associated with a disease or a drug treatment from biofluid metabolomic data.

Level of Development:

TRL 3. Currently being developed in academic setting.

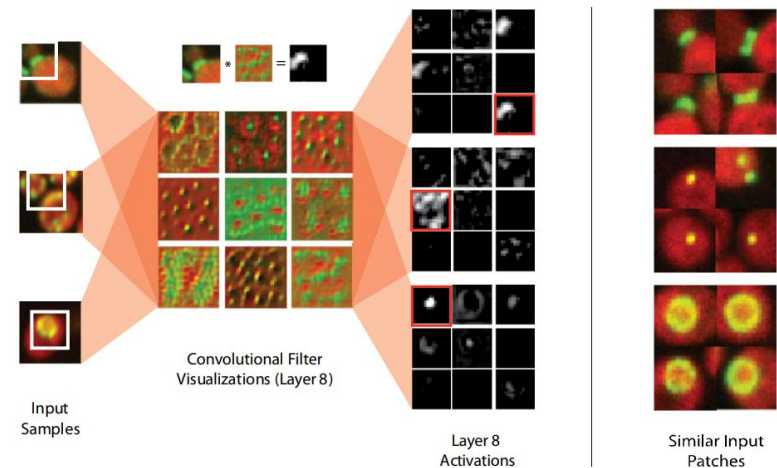
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Applications: Analyzing genome-wide screens, mechanism of action profiling, and metastases detection in histopathology.

AI Drug Discovery: Phenomic AI relies on training computer vision models, typically CNN based on millions of individual cells from genome wide microscopy screens, to identify proteins involved in regulating the cell cycle. The cell cycle is an essential process for all living organisms and mutations leading to misregulation of the cell cycle are often associated with human disease, particularly cancer. Use cases include:

- Introduction of the steps required to create high-quality image-based (i.e., morphological) profiles from a collection of microscopy images.



Features in the CNN are activated when a learned pattern matches an input image.

- Use of a deep CNN to analyze yeast cell images to show improved performance over traditional approaches in the automated classification of protein subcellular localization.
- Recommendation of techniques proven useful in each stage of the data analysis process on the basis of the experience of 20 laboratories worldwide that are refining their image-based cell-profiling methodologies in pursuit of biological discovery.

AI Research Directions:

Using computer vision and reinforcement learning to enable discovery of the next generation of therapies against cancer.

Level of Development:

TRL 3. Currently being developed in academic setting.

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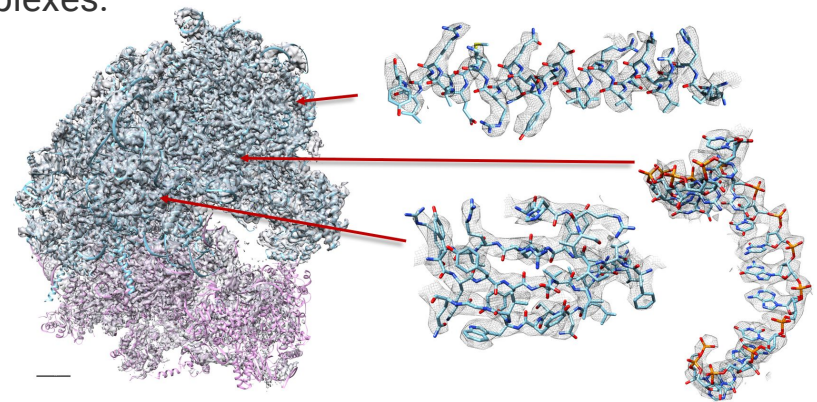


Applications: Enhancing the success of structural biology research and drug discovery projects by discovering protein molecules, complexes, and drug targets.

AI Drug Discovery: Structura Biotechnology's AI platform relies on training computer vision and machine learning models on cryo-EM microscope data (2D structure) to understand the detailed spatial 3D structure of proteins and molecular complexes.

Structura built a software, called the cryoSPARC System™, that enables both *ab initio* 3D heterogeneous reconstruction and rapid high-resolution refinement of cryo-EM density maps, in minutes on a single GPU.

➔ Previously unknown conformation of a AAA+ unfoldase was discovered using cryoSPARC.



An example of a high-resolution 3D atomic structure of a protein molecule (left) with insets (right) showing the level of detail that Structura's advanced algorithms can attain. This protein is a ribosome from the parasite that causes malaria. The 3D structure, solved by algorithms, is the critical ingredient in structure-based drug design, where a drug molecule can be designed to precisely bind to this 3D protein, inhibiting its function and thereby killing the parasite and curing the disease.



AI Research Directions:

Support 2D classification, heterogeneous refinement for 3D classification and the full processing pipeline starting with movies and ending with 3D structures.

Level of Development:

TRL 8. The software cryoSPARC has an initial version for commercial use, which rapidly generates high-resolution 3D reconstructions of research and drug targets from cryo-EM data; applications are so far mostly within an academic setting.

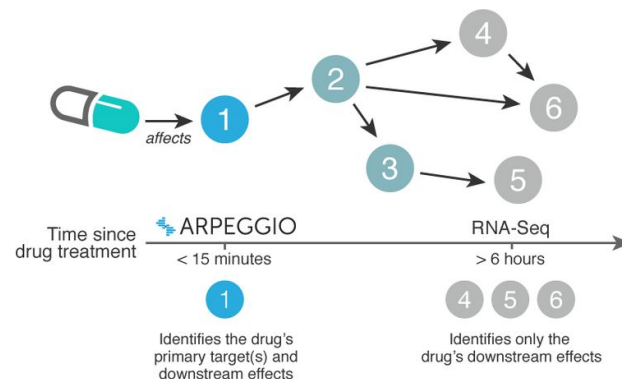
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1. <https://www.nature.com/articles/nmeth.4169>
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3. <https://elifesciences.org/articles/25754>
4. <https://cryosparc.com/>

Applications: Mining data to help quickly identify the direct targets of a novel drug, which can then be used to continuously improve the sensitivity of its experiments to differentiate responses due to primary modulation of the therapeutic target, from secondary and tertiary effects, as well as understand transcription factor (TF) activity and various drugs' mechanism of action.

AI Drug Discovery: Arpeggio combines new RNA sequencing technologies with proprietary machine learning to shorten the time needed to capture significant quantities of biological information. Use cases include:

- Enhancing RNA profiling to predict TF activity and uncover dozens of previously unexplored links between diverse stimuli and the TFs they affect.
- Show that RNA being produced from the “dark regions” of the genome (RNA that never becomes protein) could reveal a lot more about the activity of the cell than previously suspected.



Arpeggio's technology quickly identifies the direct targets (both genes and proteins) affected by a drug, allowing to measure the changes in biological systems within minutes of drug exposure.

AI Research Directions:

Understanding how a drug works (i.e. what is the drug's mechanism of action in a complex biological system), understanding what delineates sensitive biological systems from insensitive systems in order to predict responsive patient populations.

Level of Development:

TRL 5. Arpeggio Biosciences has created a pilot-scale prototype testing, called Clarion™ Technology.

References

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3. <https://www.fiercebiotech.com/cro/celgene-partnered-forma-teams-arpeggio-to-understand-drug-target-interactions>

Challenges

Ethical Issues & Regulations

AI algorithms being used today have not been optimized for the definition of **fairness**. They have been optimized to do a task. A supervised learning algorithm is designed to identify statistical patterns in a training dataset. If this **training** dataset reflects existing **biases against a minority class** when the dataset is unbalanced, the algorithm is likely to incorporate these biases. This can lead to less advantageous decisions for classes of these minority groups.

Since 2017, FDA has approved AI algorithms in cardiac imaging. However, few formal regulations around AI are available—when they exist at all. Applications of AI raise many ethical questions, particularly in the event of an **error in the AI diagnosis** and the role of each stakeholder in the construction of safe AI devices.

The implementation of AI will have to balance rapid technical advances with ethical and regulatory concerns, in order to leave time to map the potential risks and drawbacks with greater clarity. Bioethical discussions led by biologists during the design step and doctors during the validation step should be placed in the front line to monitor these processes closely and to establish long-term **research standards** on how to use AI in drug discovery.

Ethical Issues & Regulations

While leaving a complicated drug development pipeline to a sophisticated computer algorithm sounds like a brilliant idea to circumvent human error, there are critical ethical issues that are still to be addressed:

- Does AI have the capability to identify drug targets for rare conditions that the computer cannot feasibly be trained to predict?
- Drug discovery approaches rely on a degree of confidence that a drug is specific to a target of interest. How can AI-based drug discovery approaches meet that FDA's criteria for approval?
- **Virtual clinical trials** are just that - *virtual*. What degree of oversight is required to eventually replace early clinical trials with AI-based virtual clinical trials?
- Who should be held responsible for a **misdiagnosis** or **wrong treatment** to a patient when the treatment is administered based on AI-based predictions?

Ethical issues and regulations



fairness?

treatment error?

misdiagnosis?

research standards?

bias against minority classes?

FDA approval?

training biases?

virtual clinical trials?

Technical Obstacles

The biggest hindrance in using AI to predict drug targets remains translating traditional basic research conducted in labs around the world into a language that a computer can understand. Machine learning programs rely on data presented in a format where patterns can be identified and the machine can be trained. This often requires a sophisticated experimental design where human error is kept at a minimum and multiple different iterations of an experiment can be performed in nearly identical condition.

Machine learning algorithms convert data into pathways detection, 3D protein structure, metabolite mass measure, etc. These AI transformations can occur with unprecedented speed. However, in many cases, the data being used are not of optimal quality (e.g., resolution of images) or are not balanced (i.e., samples from rare diseases are under-represented in the dataset).

While data augmentation techniques have been extensively used to balance data, and thus reduce prediction bias, defining quantitative metrics is still an open problem. Improving image quality and variation have been largely studied in the last few years and the current state-of-the-art method uses generative adversarial networks (GAN).

Technical Obstacles

Additionally, in order to boost performance on the minority classes, we can assign different importance degrees to different classes to represent the relative number of samples of each class. This technique called weighted classification can be applied by adding a penalty for misclassifying minority class examples.

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Opportunities

Combining Target Identification with Lead Discovery

Current drug discovery approaches suffer from two common issues:

1. The huge amount of funding required to take a drug candidate from pre-clinical development to clinical trials, thereby crippling further funding for optimization or re-discovery.
2. The lack of efficacy of the drug due to the unique needs of each patient as well as their specific genetic background.

AI has the potential to overcome these issues by employing state-of-the-art machine learning algorithms to combine target identification with lead discovery. AI can mine publicly available databases to identify promising cellular targets and lead compounds that could reduce the time spent in pre-clinical development and channel resources more efficiently. Moreover, AI can make predictions on the efficacy of a drug treatment based on a patient's genetic information, which can be especially useful in cases where a patient has unique needs because of predisposition to other health conditions.

Future Prospects

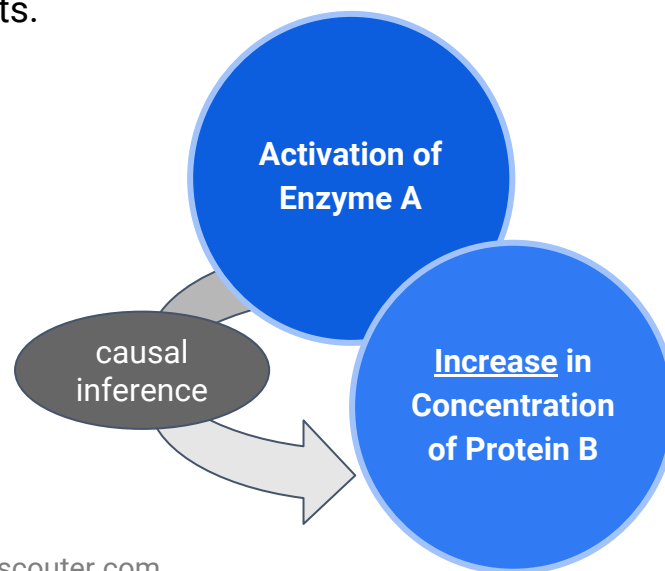
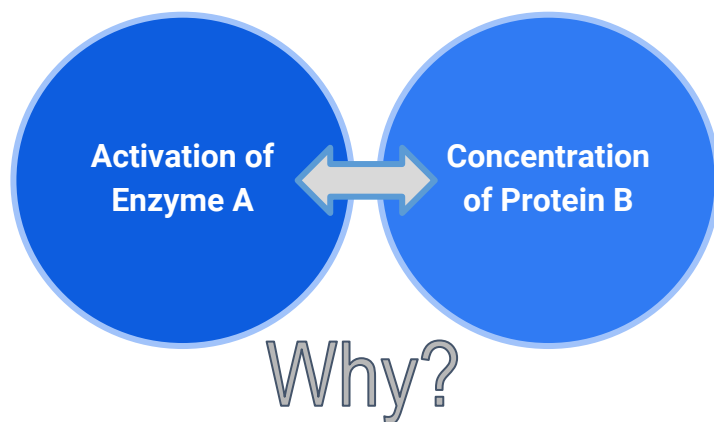
One of the most recent developments of adopting AI to accelerate drug discovery is the recent [acceptance](#) of the pediatric investigation plan of Pharnext for their product PXT3003 by the European Medicines Agency for the treatment of Charcot-Marie-Tooth disease. Pharnext is a French biopharmaceutical company pioneering the use of AI in drug discovery based on big genomic data. We should expect an increasing number of such examples of AI-aided drug discovery, both from established pharmaceutical companies as well as smaller newcomers in coming years.

Looking further into the future, one of the next steps for improving use of AI within the pharmaceutical industry will be through the ability for AI algorithms to understand causation. [Judea Pearl](#), the 2011 winner of the [Turing Award](#) and the AI godfather who introduced the probabilistic approach to AI, has emphasized that the design of the next generation of AI algorithms should include a causal framework. A causal inference framework can replace reasoning based on *association* with reasoning based on *causation*, by identifying relationships established between a cause and its effects.

Future Prospects

For example, it is impossible to comprehensively test a new lead compound in combination with all available drug molecules; this would require thousands of studies to analyze known side effects and investigate unknown interactions. However, an AI algorithm that can reason from **causal inference** could allow for successful prediction of unintended effects.

Instead of the ability to merely correlate between the activation of enzyme A and the concentration of protein B (left), such a machine would have the capacity to reason that enzyme A causes the increase of protein B's concentration (right). Once available, such an approach would prove invaluable in further accelerating drug development efforts.



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5. [Artificial intelligence is infiltrating medicine-- but is it ethical?](#)
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7. [Is artificial intelligence the future of drug discovery?](#)
8. [To build truly intelligent machines, teach them cause and effect](#)

Next Steps

Next Steps

Topic	Question	Report
How to leverage pharmacological and genomic data to complement image datasets	How can pharmacological and genomic datasets improve AI models' drug discovery rate?	Landscape of open-source pharmacological and genomic datasets
		Deeper dive into AI analysis of such datasets in academic research
		Best practices gleaned from analysis of image datasets
Integration of AI models to existing infrastructure	How to ensure the compatibility of AI with legacy infrastructure?	Best practices applied in other industries, with example use cases
		Commercial platforms and software that connect AI with legacy infrastructure
		Case studies of real-world uses of AI for EHRs and other medical data
		Interviews with Key Opinion Leaders to understand specific challenges
Uses of AI during clinical development	How can AI be used to improve clinical trials management?	Products currently available or under development that use AI for clinical trials
		Emerging technologies that could be ready in the next 5–10 years

About the Authors



Charles Wright, PhD

PreScouter

Charles Wright is one of PreScouter's Project Architects. He works with PreScouter's clients to achieve successful project outcomes by coordinating between clients and research teams. He is responsible for ensuring that clients' innovation needs are being addressed and for managing the timeline of project deliverables. As the industry lead for the Medical Vertical, Charles focuses on the healthcare and life sciences space. He has managed projects covering all stages of the development pipeline from emerging academic research through development of medical devices and therapeutics to implementations of products in clinical settings.

As an academic, Charles developed high-throughput, integrated microscopy and computational systems for studying the growth statistics of single bacterial cells as well as the connection between neuronal function and behavior in worms. Charles graduated with a BA in Physics, Molecular and Cellular Biology, and Spanish from Vanderbilt University, then earned his PhD in Biophysical Sciences from the University of Chicago before working as a Postdoctoral Scholar at Purdue University.

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Mohamed Akrou

University of Toronto (Canada)

Professional Summary:

Mohamed earned a B.S. in Computer Science and Statistics from University of Montreal and an M.S. in Artificial Intelligence from University of Toronto. His master's topic is about applying reinforcement learning algorithms to perform skin disease symptoms checking that outperform the dermatologist-level accuracy. His research interests lie between artificial intelligence and healthcare applications. He is interested in translating several learning mechanisms from the brain to mathematical techniques in order to build the next generation of AI algorithms.

Research Background:

Computer Science, Machine Learning, Reinforcement Learning, Neuroscience, Artificial Intelligence, Sequential Modeling, Bayesian Inference and High Performance System (GPUs) analysis.

About the Authors



Navneeta Kaul, PhD

University of Denver (USA)

Professional Summary:

Navneeta Kaul recently completed her PhD in Biology at the University of Denver in Colorado. After earning an engineering degree in Biotechnology, her passion for cutting-edge biological research motivated her to pursue her Master's at the University of Arizona in Tucson. At the University of Denver, she is studying the biological mechanism behind Fragile X syndrome, an autism spectrum disorder affecting nearly 1.3 million adults in the United States.

Research Background:

Navneeta graduated with a PhD in Biology from the University of Denver in August 2018. The focus of her research was to understand the mechanism of local protein synthesis at the synapse which is important for memory formation in vertebrates. She has experience in using biochemical and molecular biology techniques like cloning, PCR, real-time PCR, western blotting, immunoprecipitation, live cell and fixed cell imaging.

Scientific Interests:

Molecular biology, Biotechnology, Biochemistry, Microscopy, Life sciences, Scientific consulting

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