

AI Impact on Drug Development

Our Expert :

Tomasz Zastawny

Chief Drug Development Officer at Parexel International Corporation (February 2023 – present)

- Senior Vice President, Development - Rakuten Medical, Inc. (June 2021 – December 2022)
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Dr. Tomasz H. Zastawny is a seasoned life science executive and scientist with over 25 years of experience in the pharmaceutical, biotechnology, and medical device industries. He has excelled in creating and executing global product development strategies, resulting in the successful launch of several pharmaceutical products and medical devices, as well as numerous FDA, PMDA, and EMA breakthrough and orphan drug designation approvals. He additionally was a strategic advisor to Clara Health which was one of the first AI technologies used for drug development. In his current role at Parexel, he is responsible for AI/ML used in drug development.

Moderator:

Max Le Sieur

Founder & Managing Partner at Rosemont Legacy

- MBA, Harvard Business School
- Investment Banking Associate at BMO Capital Markets (July 2016 - August 2020)

Expert Insights On:

- How can AI help the drug development process? Which areas benefit most from AI?
- What are the most expensive and difficult parts of drug development?
- What exactly does AI do to improve the drug discovery process?
- What is AI's use within clinical trial optimization? In what ways is it helpful in the clinical trial phase?
- Can the models used in drug discovery be trained on what is generally available or do they have to be trained on a specific type of data? Where does that data typically come from?
- Is it possible to be successful using AI and drug discovery with just publicly available data?
- What are the key ethical considerations emerging with regards to the use of AI in the drug development process?
- What is emerging as the posture of regulators, the things they're pretty focused on, and any predictions you have with the frameworks they have put in?
- What are the biggest challenges related to leveraging AI in the drug development process?
- Will value be captured by pharmaceutical companies the same way in a drug development world with AI versus without AI? Will it be the same players?
- Is collaboration between companies expected to increase, given the importance of data and how that data can be used by a variety of different participants?
- What is the expected impact of quantum computing on drug discovery?



Introduction -

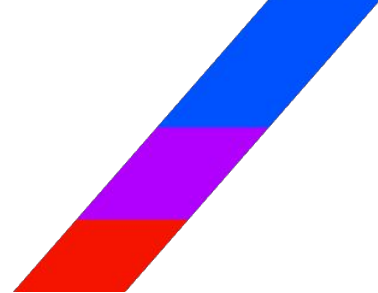
Max: Okay, Tomasz, thank you so much for taking the time to be with us today. My name is Max, and I'll be leading this call on behalf of Coleman Research. As you know, the purpose of the discussion is to learn about the impact of AI on pharmaceutical drug development, including key players and trends in the industry. Before we begin, I would like to remind you that we are in no way soliciting any non-public information or information that is confidential and related to any organization you are currently or have ever been affiliated with. And if you believe the answers to any of these questions involve non-public information, please just tell me right away, and I'll take us in a different direction.

Tomasz: Okay. It's a pleasure to be here and I'm happy to help you guys.

Overview of AI and Drug Development Process -

Max: Okay, great. I think we're ready to hop right in. First section and what I want to start with is what is drug development and how can AI help? And I don't want to spend too much time on drug development, but just very brief. The first question is what are the most expensive and difficult parts of the drug development process? Let's start there. What are the areas that are difficult so that we help frame how AI can potentially help?

Tomasz: Let's think about the drug development asset, a few stages and divide it in stages on the terms of a development conduct from one side from the other side, who is doing it because those elements are important to connect it with the next part of this question about the cost of this development. So the first, basically we usually divide the drug development in four stages. First one is a discovery stage. Second one is a discovery stage is a part where we are finding the molecule and we are connecting the molecule with potential target, and we are defining an opportunity to develop new treatment. That's the discovery. The second stage is preclinical research. In preclinical research, basically we are trying to find the preclinical proof of concept. Is it working or not? And the next stage after we find the preclinical proof of concept, and we collect enough data to move to the clinical stage. We go to the clinic. The clinical stage, it is a shortly speaking scientific experiment that involves a human being as a part of this experiment.



Tomasz:

And the last stage of drug development of the medicinal development is post-approval development. And this stage is maybe not that exciting but also extremely important from the perspective of an entire life cycle of a product on the market. That's the first stage. Now let us look where, which one is the most complicated? If I look from my personal perspective, I would say that the discovery stage seems to be the most complicated part of a development because we have so many options, we have so many targets and we have so many potential solutions. Connecting them together, that is a challenge. They required tons of data to analyze, and that is where the artificial intelligence will find and is already finding the application. And the most expensive part of a development is clinical research.

While we go to the stage of a clinical development of a new drug, we have to multiply the cost and time by factor of 10. And that's why it is extremely important to design the initial clinical development path in a way that you don't need to go back and redesign the process and rerun it again because for some type of companies going back means the case of a debt for the company that has a time only to try once because investors will not take a risk to reinvest into the product that already failed. And we have several reasons for failing. One of them is human error. One of them is a design that does not fit that was prepared in a not necessarily good way. That's the four stages, the most expensive clinical discovery, in my opinion the most complicated one. Does that answer your question, Max?

Max:

Got it. That makes sense. So just to make sure I understood correctly, drug discovery is pretty difficult and expensive and clinical trials are pretty expensive, especially when you have to go back to the trial because of some finding or some change that needs to happen. Is that correct?

Tomasz:

I would say that the discovery is maybe not as expensive as clinical stage of the development.

Max:

Okay.

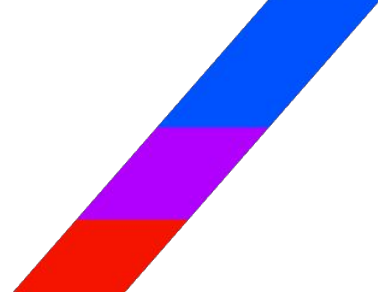
Tomasz:

But it is much more complicated on the terms of amount of data you need to analyze.

Max:

Got it, got it.

Overview of AI and Drug Development Process -



Tomasz: Clinical research is complicated. Yes, true but also extremely expensive. A reason for the high cost of a clinical stage of a development is that we are conducting a scientific experiment with human beings as a subject of this experiment.

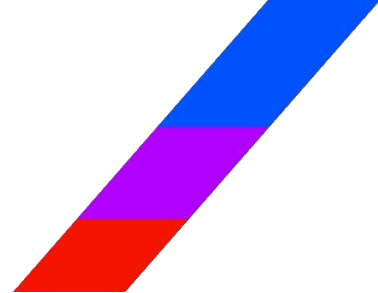
Max: Yeah.

Tomasz: Therefore, this is a heavily regulated area as far as the discovery process is practically not regulated by agencies. Clinical research, the clinical development stage is heavily regulated by the regulatory agencies, especially in the context of safety of the participants taking a part of this study. So that's what is increasing the price, that's what is slowing down the process and up to now there is no way to do it in a different way.

Max: Got it. That's helpful. And so in what areas do you think can AI be most helpful?

Tomasz: In the discovery area, this is something that is already working with AI very well. I mean, I believe you are already aware that some drugs were already designed based on the artificial intelligence a few years ago. For example, Paxlovid developed by Pfizer and commercialized by Pfizer last year it was actually the entire process involved the artificial intelligence for the target selection and for the molecule design. That's what already happened.

Max: Got it. And how exactly is that work? AI is a little bit of a buzzword. Drug discovery is this super complicated process. Can you explain what exactly AI does to improve the drug discovery process?

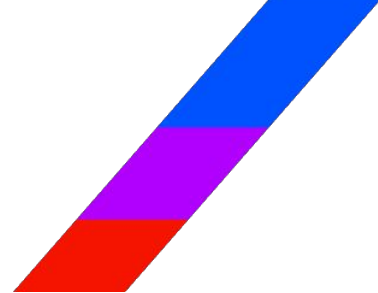


Tomasz: Imagine that we have two elements. We have a therapeutic molecule, and we have a biological target, and those two elements need to fit one to each other. And the molecular structure of a target is very complicated. It's usually a protein that is regulated, some processing and if we want to affect the function of this protein, we need to find the molecule that will be able to attach to the target and modulate the activity of the target to find this molecule. We are dealing with a tremendous amount of data before we can preselect the one that have potential, and we'll be able to prove it in a preclinical experiment. While we are capable today using the artificial intelligence to conduct this preselection process based on our knowledge of the structure of two elements, target and the molecule, it saves tremendous amount of time and increase the significantly probability of a preclinical proof of concept with a significantly lower number of preclinical experiments versus what we were doing eight years ago. Just go and try in a lab.

Max: Yeah. It's kind of like we went from trial and error to basically targeted drug discovery. Is that the right way to summarize it? I know that's a little bit crude but...

Tomasz: That's a very good summary from trial and error to planning, fitting in a computerized analysis and then trying how it works. And of course we are not going straight forward to a one molecule, we are running a preselection process, but the amount of empirical experiments is dropping down significantly at this stage thanks to the artificial intelligence and this is already happening. We have a number of technologies, for example, benevolent artificial intelligence that aggregates and analyze literature data to identify and refine drug leads and related target patients. Atomwise, that's another technology that specialize in scientific data, primary chemical and biological information that can be applied for the drugs that's for discovery. So yes, we have already tools designed specifically for this stage of a process.

Max: Got it. That's super helpful. And you mentioned one example of a drug that was developed using artificial intelligence. Are there specific drug types or specific molecules that lend themselves better to this kind of work? Or are we talking like this is a change that applies to every single drug discovery process possible?



Tomasz: If we look at this from the strategical perspective, it can apply for every type of development. Either it's a small molecule or it's biologicals, it applies, the rules applies. The difference here is in the area of amount of information you need to analyze because obviously while you have a small molecule, the amount of information will be required to analyze and find the best fit is lower while you are dealing with biological type of molecules, that's a completely different part of a story and the amount of information you need to analyze prior the decision, it's significantly higher.

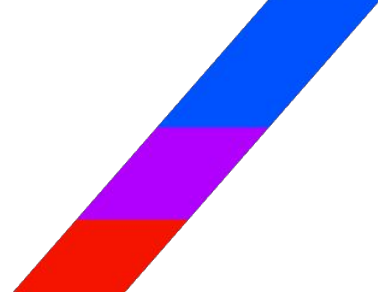
Max: Got it. Super helpful. And just a final question on this topic. AI is not used in other areas of the drug development process. So is it not used at all in from a clinical trial optimization perspective?

Tomasz: AI is used across entire development pathways these days. In a discovery that's a one-off application. In a discovery stage, this is one off applications that we are benefiting from this application in the way that we are reducing the amount of a workload in a lab for the discovery purpose. We are screening the large number of the potential drug candidates faster and in a less expensive way. But about the pricing, that's a different kind of a story and I think we will go back to the cost of involvement of artificial intelligence in a drug development budget. That's something that we will speak a little bit later.

AI's use within clinical trial optimization -

Max: Got it. Super helpful. That's great. Well actually just one follow up to that then. Can you specify in what ways is it helpful in the clinical trial phase? Because you emphasized that that was the most expensive stage. I'm curious what aspects of the clinical trial phase are facilitated with AI?

Tomasz: I think I will be pretty accurate if I will say that practically most of the aspects of a clinical trial can benefit from involvement of artificial intelligence in a process. That's what I strongly believe, and I will try to go through some examples. My first example is my own story. A time ago I supported in a setup and development of a company named Clara Health. This is a public information that I'm not disclosing and a proprietary information, and I serve as a strategy advisor to the company. And it was back in 2014, 2015, while the entrepreneurs setting up this company were planning to do application of artificial intelligence in streamlining the patient enrollment process for the purpose of a clinical trial. We know that and probably you had a chance to hear it a lot that one of the biggest problems is to find the right patients to my study.



Tomasz:

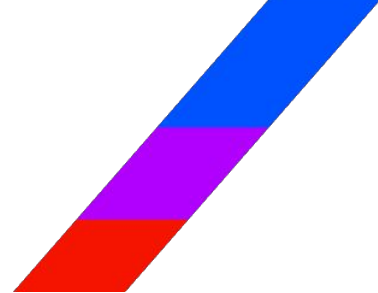
And a number of the companies are not able to finish the clinical development stage on time because limited number of patients available for the trial or maybe not the right fit of a patient to the trial. Clare Health started thinking more than 10 years ago about how we can potentially streamline the enrollment process. The idea was very simple and straightforward. They developed the mobile application for prospective patients who are looking for the clinical trial solution for themselves. And from the other side they connected with a publicly available source of data like clinicaltrial.gov information and they were facilitating the match process between the patient who was looking for a participation in a particular clinical trial and the sponsor, the biotech or biopharma company that was conducting the clinical trial and they were "sending" these patients in a direction to the right clinic to the right hospital where the clinical study was conducted.

It was 10 years ago already. So that's one example facilitating the patient enrollment process using artificial intelligence and publicly available information. But there are many other examples. Imagine the design of a clinical protocol. If you look at the biotech companies' market in the US, we have thousands on them on the market right now. And there is one very specific characteristic of most of them, especially during the beginning of the development of a new biotech company. These companies don't have experience because these companies often are set up by academia teams who did the discovery at the academia stage and want to commercialize the idea of a new drug on their own. And they are setting up a new company with no past experience of how to do it.

If you are in this kind of a situation, and you learn that you are entering an enchanted area of a heavily regulated industry, artificial intelligence applications gold mine to design a simple clinical protocol or to design the entire pathway of how this drug can be developed based on the historical knowledge, as long as you have an access to the historical knowledge of hundreds or thousands of previous clinical trials, you can offer an outstanding services using the artificial intelligence.

And this what I'm speaking right now about is something that contract reserve organizations, especially the large ones, are already utilizing for the purpose of supporting the customers. They are using their own historical knowledge. They are using the publicly available data sources to help to design the development pathway. And the development pathway means here a single document required for the clinical trial.

AI's use within clinical trial optimization -



Max: Got it.

Tomasz: Or entire process design in a context of a future market that will change.

Max: Got it.

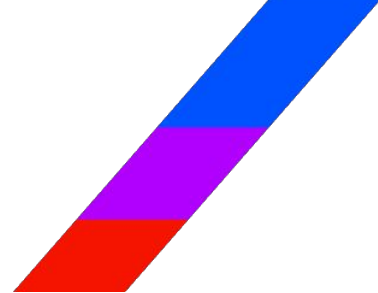
Tomasz: That's a tremendous opportunity for the artificial intelligence. Some companies are already offering here the solutions.

What I'm seeing right now on the area of different solutions from different companies, they are rights now addressing a little bit narrow areas of the needs. But I can predict from this point that it will tend to the consolidations of different tools and the entire development process will be covered with artificial intelligence.

But one restriction here is extremely important. The quality and the outcome of the artificial intelligence application or the purpose of a clinical development stage is as good as ethical as they have a right access to the right source of the data. So the validation of data used for this purpose is a critical element, and this is something that regulatory agencies are already working on over the last few years. And while I'm going to several conferences in the US and abroad related to the application of artificial drug development purpose, the presence of regulatory agencies is already very strong and there is very proactive also approach from the regulatory agency helping and supporting the companies to design it in the right way to ensure the ethical and the regulatory aspect as well.

Models used in Drug Discovery -

Max: Perfect. I'm going to pause you there. That's exactly where I want to go next into this next section on key considerations and challenges. The first thing I want to ask about is data. And so can models used in drug discovery, let's stick to drug discovery for example for now because you said that was like as of today the area where AI can have the most impact. Can the models used in drug discovery be trained on what is generally available or do they have to be trained on a specific type of data? And is that private data, is that public data? Where does that data typically come from? Let's bookend this question with regards to an AI model used for drug discovery. Where does the data come from?



Tomasz:

We have two source of data here. The first source of course generally in a drug development we have two sources type of a source of data. The first one is coming out from the public sources. We know that regulatory agencies require sponsors of new medical technologies to disclose that design of a clinical stage of development and disclose a location where the clinical development is going. And also, they require the publication of all the data from the human trials in scientific literature. That's a public source of data. However, this is not everything because at the same time we know that we have a large number of scientific journals that are publishing the data, publishing the entire articles and the data from clinical trials and not necessarily only from clinical trials, although also from the scientific research from academia as well. And this data is often combined in databases which are not publicly available and AI technology owners need to license the access to this and not publicly available data.

And based on my personal experience, this access to scientific research data is absolutely critical in the design of a process, data interpretation and any other kind of application in a clinical stage of development.

Max:

Yes.

Tomasz:

This is critical.

Max:

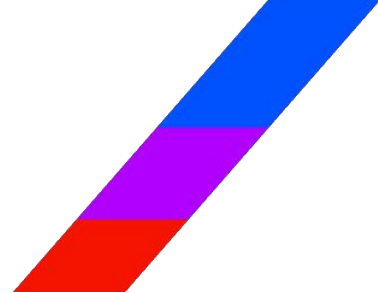
That was source number one, right? You said there was a second source?

Tomasz:

Yeah, the source number one was public data sources, like for example .gov or FDA data sources. The second one I described was non publicly available source of data where the organizations are combining the access to the scientific publications. Those are commercially available, but access needs to be purchased.

Max:

Okay, got it. That makes sense. That makes sense. There is value in the data set and what I mean by that is it's not as if all of the data, well I guess let me ask the question this way. Is it possible to be successful using AI and drug discovery with just publicly available data? In which case by extension there would not be a lot of value in having your own data. The cost of drug discovery would get very low, would become very competitive and people would just push data into their models and then come up with all this drug discovery or is the proprietary data especially valuable and increases in value over time, in which case you'll see a lot of value accrue to the players that are able to grow and keep and maintain and use a database in the AI model?



Tomasz:

Going to the beginning of this question, I would say that involvement of artificial intelligence for the drug development based exclusively on the publicly available data will be helpful. However, it will be still quite complicated to base exclusively on the publicly available data for the detailed planning process for the projection of the outcome of a drug development.

This would be complicated. And as I said at the beginning, your AI is as good as the source of data you have and an extremely important part of a source of the data in especially clinical stage of a development is the validation of data used for this purpose.

I based our decision on analytical information. We know that the study conduct done on the 10 patients` population will not have the same value, not the same statistical value as a medical experiment conducted on 20,000 patients. That's a different kind of... So being able to distinguish the value of data and being certain through the validation of a data source and for the purpose of our planning is a critical success factor for successful application of artificial intelligence drug development process plan.

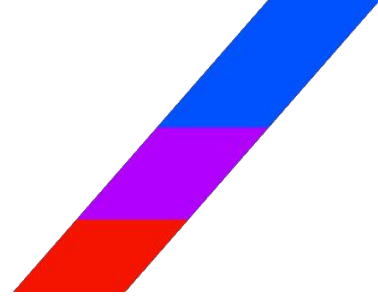
Ethical considerations to the use of AI -

Max:

Got it, that's super helpful. In terms of data, I want to talk about regulation, but I think we should start with ethics because that probably helps drive the regulation conversation. What are the key ethical considerations emerging with regards to the use of AI in the drug development process? Briefly.

Tomasz:

You are challenging me here, Max. It's hard to speak briefly about the ethics in the clinical stage of a development. That's really hard but ethical elements are absolutely critical element in the application of artificial intelligence in drug development. What kind of challenges do we have? Let's go through accountability. That's one of the elements. As a sponsor of a clinical trial, you cannot go and say to the agency, "Oh, artificial intelligence tool told me to design this study this way." No, you are accountable for all the decisions as a sponsor. You are accountable for all the decisions related to the study design, to your study conduct, outcome of the study and the risk that is involved for the patients as a participant in the studies. Accountability stays where it was before while we were doing the clinical development in an old-fashioned way, error handling. So, procedures must be in place to identify and address and learn from errors or advanced outcomes results of artificial intelligence use.



Tomasz:

This way or another we use the artificial intelligence to project this kind of conduct, but we have to still handle the outcome of a study and be able to react in the right way, the way that the regulatory agencies regulate clearly if the outcome is not necessarily the same like we projected using the artificial intelligence. That's something that is a challenge. Another element of ethical consideration using artificial intelligence is data privacy and security. Data anonymization is a critical field and either we are using the publicly available sources or not publicly available sources. The data anonymization is still in place, we cannot modify it or change. Also I think that the purpose and intent is very important while we are applying the artificial intelligence in their development and the purpose and intent of a research with the AI should clearly align to vertical standards used for the purpose of clinical trials. That's what I can share shortly about the ethical aspect of using artificial intelligence in the development process.

Max:

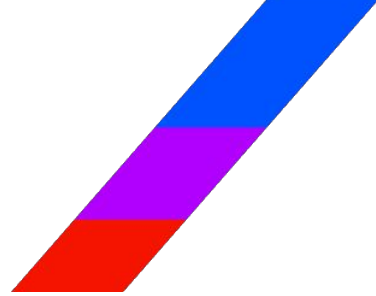
Got it. Those are super helpful points. Those all make sense. And then what about regulators? Again, what is emerging as the posture of regulators, the things they're pretty focused on, and any predictions you have with the frameworks they have put in? Well, they're going to put in place.

Tomasz:

Regulators, as I mentioned earlier today, are already working closely with the industry and regulators are observing how the industry is applying artificial intelligence for drug development purposes. Regulators are already doing what they are designed to do. They are overseeing the process. They are working closely with the industry to develop the standards that will ensure that ethical requirements and regulatory requirements status quo in a drug development with artificial intelligence used for the drug development process purpose. Regulators are open. They're really open-minded. I was in several panels in a discussion with a regulatory agency from Europe and from US about this topic and we have already some guidelines from FDA related to the way of using artificial intelligence and securing some areas how and when it can be used and when it should be considered.

But again, the basic position of regulatory is that as long as there is an element of a validation of a data source first, second oversight of a sponsor of a development and third accountability of the sponsor. They're very open to support it. That's what I learned on my own over the last couple of years from the regulatory agencies' communication.

Ethical considerations to the use of AI -



Max: The other players in this are the insurance companies, are they not? How do the insurance... Is that intuition correct that insurance companies will eventually need to adapt or change something or not so much because insurance companies play in the downstream and market area, which is less likely to change? What's your view on the involvement of insurance companies?

Tomasz: Look, I have to be very transparent here that I'm not an expert in actually in the insurance aspect of healthcare industry. But I think that artificial intelligence provides the tools to project future markets and project the risks related to the particular treatment. And I believe insurance might have a strong interest to elaborate about this kind of potential application. And they might be also in the future or maybe they're already starting, I am not sure because I was not following on this aspect of artificial intelligence, but they might have a strong interest to also be a part of this process and they might be able to assess their financial potential benefits from the involvement of artificial intelligence across the new drug development process to build the cost projection for themselves and the risk projection for themselves.

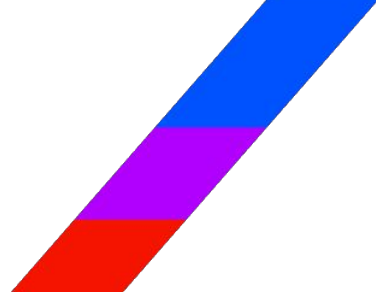
This area is one of those areas that would require a strong impact from the regulatory agencies and from the ethical authorities as well. Lost what we have from the insurance. Insurance as a purpose is related to a certain risk, and if we can project this risk, are we in a position to increase the premium following the customers based on the artificial intelligence data? That's an ethical consideration that I don't have an answer right now and I'm not an expert to elaborate too much about this.

Biggest challenges related to leveraging AI -

Max: Got it. No, that's helpful. Okay, great. And taking a step back, Tomasz, what are the biggest challenges, in your opinion, related to leveraging AI in the drug development process?

Tomasz: In my opinion, I see two elements that are the biggest trend. The first one is data source validation. If we have validated data, the outcome of our product will bring much more value versus we have data that are not confirmed that we don't know how the data we received and we are using it for our decision purpose. Data validation, that's one of the biggest, in my opinion, challenges in involvement of artificial intelligence in drug development process. The second part, in my opinion, what we are currently missing here in the industry is a holistic approach with artificial intelligence across entire design and projection of a product life cycle.

Biggest challenges related to leveraging AI -



Tomasz:

That's something that I believe is missing, but if I can use some analogy here, I remember about 25 years ago we were working on involvement of electronic solutions for the NS aspect of a clinical trial, and we're switching from the paper base to the electronic version and projection of some people were catastrophic in that were going to use the control on everything, that there would be a lot of problems related to the access to the data, data confidentiality thing like this happened actually we developed the processes and right now what I'm seeing as a challenge here is that we are applying it to narrow aspects of drug development, and we don't have a holistic approach.

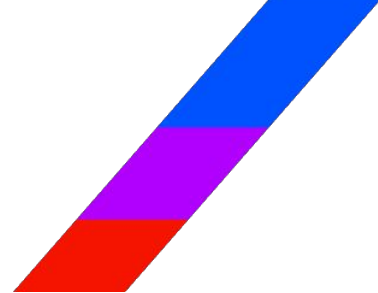
Ideally, I could project the future of artificial intelligence from early identification of target, early identification of a product, and at the same time being able to project the structure of a future drug market, let's say five, six, seven years from now. And the design of a process using the initial discovery elements applied across entire clinical and pre-clinical stage of a development. This is something that is missing right now in my opinion in the industry, but I strongly believe that this is coming, that this consolidation will come within the next few years.

Will value be captured by pharmaceutical companies the same way in a drug development world with AI versus without AI? -

Max:

That's super helpful. Okay, moving on to the next section. What I want to ask you is do you think value will be captured by pharmaceutical companies the same way in a drug development world with AI versus without AI? Will it be the same players? Will it be the existing players in each stage that continue to accrue the most value or will there be major disruption to the types of companies, number of companies and identity of the companies that are successful in these processes?

Will value be captured by pharmaceutical companies the same way in a drug development world with AI versus without AI? -



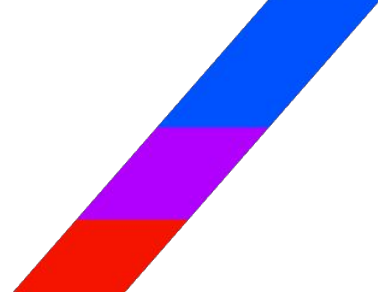
Tomasz:

In my opinion, I think that we are drifting in a direction that there is no place for the companies that will not use artificial intelligence in a drug development purpose for a simple reason, because the time of a development today without artificial intelligence application, the time will be not acceptable for investors. That's obvious and this competition will dictate what will happen in a market. I will give you a one live example here. When I was a part of several successful drug developments in the past, while I was going to plan the development pathway, I usually spend approximately three, four months to collect all the data I needed to put the draft plan of this draft development in a clinic. Today I can collect the same data in 25 seconds. That's a factor. And in a past, it took about at least one month to design and develop the clinical protocol based on the knowledge of particular people who are involved in this process.

Today, we can do the same design based on similar designs using artificial intelligence in a half an hour and then run it through the review process. That's examples of how big the difference is between the world of using artificial intelligence versus not using artificial intelligence for several aspects of the clinical trials. There is no way or around, and what I'm seeing with great satisfaction right now I'm seeing a number of AI types of companies offering several services already. I believe this element of the market like setting up artificial intelligence services companies will open the door not only for the large pharma organization or large biopharma organization who can develop it on their own. I think rather the direction will be in a large number of artificial intelligence applications on a server aspect of a drug development available for customers. And they will design the pricing strategy in a way that it will be affordable for both aspects, large organization and the small startup biotech companies.

And later in the time, I think it will be element of a consolidation of these companies that, so at the end of the day, in a few years from now probably a few main players of AI in drug development will stay and they will offer comprehensive services in a server aspect of drug development. That's how I can project from my perspective. And this is I think a similarity to what happened in the past while we were switching from paper-based to the electronic version of a drug development of oversight processes. I hope it answers your question, Max.

Will value be captured by pharmaceutical companies the same way in a drug development world with AI versus without AI? -

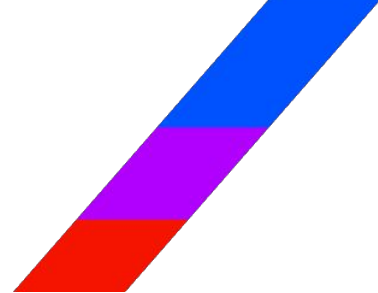


Max: Yep, yep, that answers my question. Thank you, that's super helpful. You mentioned one example of a drug that was developed at the drug discovery stage using AI. I'm curious if there are other marquee case studies of artificial intelligence being applied to the process, to the drug development process generally not just drug discovery? Marquee examples or case studies of AI playing a pivotal role in the drug development process and any insights on how that's expected to continue.

Tomasz: We have right now a number of tools of your label in drug development. Like for example, if you review the services of several CRO companies, you will find the same process named either protocol optimization or protocol design. And this is another example of how artificial intelligence is right now utilized for the purpose of a single study strategy purpose. And we have a number of ongoing developments right now where some aspects of artificial intelligence are involved. The drug that I mentioned was Paxlovid, and it was a drug developed during the COVID-19, and it was a drug with COVID-19 antiviral potential. And that's why I think it's the best example of utilization of artificial intelligence because based on what I know on this from some conversation with industry experts, the artificial intelligence in Paxlovid, it was utilized in a stage of a discovery but also in a stage of a preclinical planning and path design as well.

Max: Got it. Super helpful. Are there examples of failed attempts at using AI in the process and anything we can learn from those or any key mistakes that have happened in the industry so far?

Tomasz: Max, you are challenging me with this question. Why is that? Because people usually don't have a tendency to publicize the failures, especially the companies, especially the public companies will not make the failure public. I don't know personally if the development failed in a development stage while using artificial intelligence, but I can imagine that yes, the failure might happen using artificial intelligence for a simple reason. We are building our algorithm that operates based on the existing data, and we still don't have all the data we need for drug development. That's why we're developing a new drug. The question is chicken or egg first, and I can imagine that algorithm will design the development process. However, we'll not have sufficient data and after a few years this design will not be relevant anymore because then new data arrived.



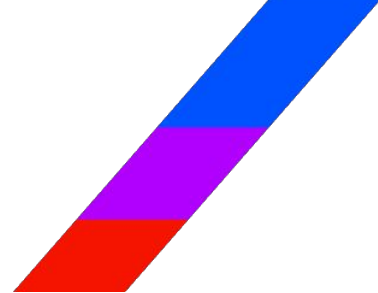
Collaboration between Companies -

Max: Got it. Super helpful. Super helpful. Do you expect collaboration between companies to increase, given the importance of data and how that data can be used by a variety of different participants?

Tomasz: I think, Max, I can dream about the collaboration between the companies. I can dream about this and I'm dreaming about this always while I'm involved in the drug development process. Unfortunately, over the 25 plus years, the collaboration is still not at this stage. I would like to see it on my own from my own personal perspective, but what we discovered recently, the collaboration between the organization is significantly influencing the development process, sharing the information with the organization, become more and more critical. And I think it might not necessarily go directly from insight in other organizations. However, it can be potentially motivated by the investors who are actually looking for the end game outcome of a particular development. For them, the outcome is a product for a market exclusive product on the market for them as long time as the patent expired and investor can actually influence the collaboration process, selecting the companies that they will invest in the way that they can actually set up the collaboration in place prior the investment and enforce it somehow. That's my perspective, observing the market for a number of times.

Expected impact of Quantum Computing on Drug Discovery -

Max: Super helpful. What about quantum computing? Is that likely to have an impact? Just as an inexperienced person on this topic, it seems to me like going from trial and error and drug discovery to targeted makes a ton of sense and AI can help a lot, but then you layer on quantum computing. Does that take that to an entirely new level, or do you expect that impact to be subdued? Is that not really applicable?



Tomasz: Look, again, the key element here is access to the data and the way we build the algorithms. That's a key element. I think all the quantum computing potential will be strong value here. A question here is that we still don't know much about the potential of quantum computing. The quantum computing itself is in a relatively early stage of a development and therefore we don't know much about the potential for the biotech purpose, but I can visualize it like adding steroids to the training purpose. Yes, the muscle can grow quickly.

And I would see a huge potential adding value with quantum computing, especially in terms of time of a processing ability to analyze the data. But I don't have a good idea how we fulfill this gap of data sources, the data sources that still do not include enough data. That's how I'm seeing, but I can project the large potential of quantum computing for sure.

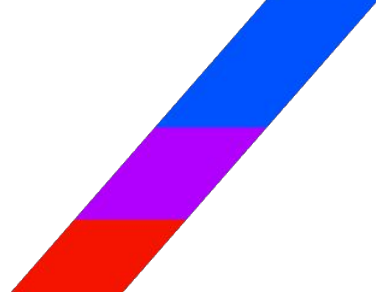
Max: Right. Got it. Okay. Well, Tomasz, this has been fantastic. I want to ask one more question before we wrap here, and I know we've gone over already. Is there anything we haven't talked about today that you think is particularly important with regards to applying AI to the drug development process?

Tomasz: I think probably we should also speak a little bit more about the patient's perspective in-

Max: Oh sure, that's a great one.

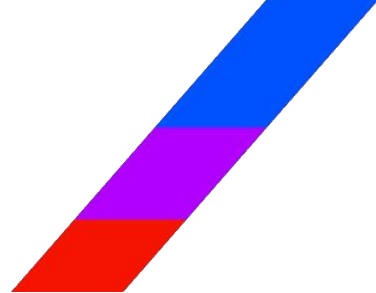
Tomasz: That's a critical one. And try to think from the benefits of a patient, how the individual patients can benefit from the application of artificial intelligence in a drug development? This is something that I think also required a lot of attention, and I think it would be a great subject for another discussion.

Max: Just briefly, what is it about the patient perspective? What changes for them and what are the considerations?



- Tomasz:** Look, the drug development process, at the end of the day, it's an end user of a product of this process. The patients today, they do have a number of options, but these options are different in different countries and these options are different in the context of different insurance circumstances involved. And patients at the end of the day is offered several options, and they maybe would like to learn a little bit more what the advantage, what's the disadvantage of a particular option? So, that kind of aspect is really very interesting to discuss as well. And also elements of a projection of a future patient, how the future patient looks like on the terms of ability to go through the therapy that is designed and several options for the patients who might specifically have different conditions that are also applicable. This is something that is extremely interesting, but it's a large area for a conversation and it will be difficult to speak about this in a few minutes.
- Max:** Yeah, fair enough. Well, Tomasz, thank you so much for your time. This was a fantastic conversation. It's exactly the perspective we were looking for. We really, really appreciate you taking the time.
- Tomasz:** Thank you, Max, and thank you, Alex. I really appreciate for inviting me to this discussion. I'd be happy to be a part of other type of a conversation related to the drug development process and artificial intelligence. This is my passion over the last few years, and I'm glad that some of my knowledge might have a potential for other people as well.
- Alex:** Perfect. Thank you both so much. I especially enjoyed the piece around admitting any kind of failures from public companies. It's probably not going to happen too much on AI application.
- Tomasz:** I do want to go here and let's be honest. Today, the failure rate of drug development in clinics are approximately 86%. And this is not only because of specific medical, or clinical conditions related to this. Sometimes it's related to human error. Sometimes it's related to the strategy design, sometimes to the technical aspect, sometimes to the aspect of development elements like a formulation, like a dosage, like other elements. But again, it's hard to make a company to commit. All right, that's my mistake.
- Alex:** Certainly. Certainly, yeah, not something they want to admit to.

Collaboration between Companies -



Tomasz: 86% of the developments are failing. If we can reduce it by 50%, that's a huge value added to the investors and to the patients as well.

Max: Thank you. Have a great day, guys.

Tomasz: Thank you.

Max: Thank you.

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