

## The Biopharma Confidence Index The BCI Brought to You by Kineticos Life Sciences and Worldwide Clinical Trial

The Biopharma Confidence Index, or BCI, is intended to be a forward-looking index designed to measure C-Suite and Executive Leadership sentiment in the biopharma industry asking questions about their confidence levels concerning key issues. We look for the BCI to become a valuable and highly sought-after resource for its unique insights across both key industry-related issues and critical business functions.

### Moderator

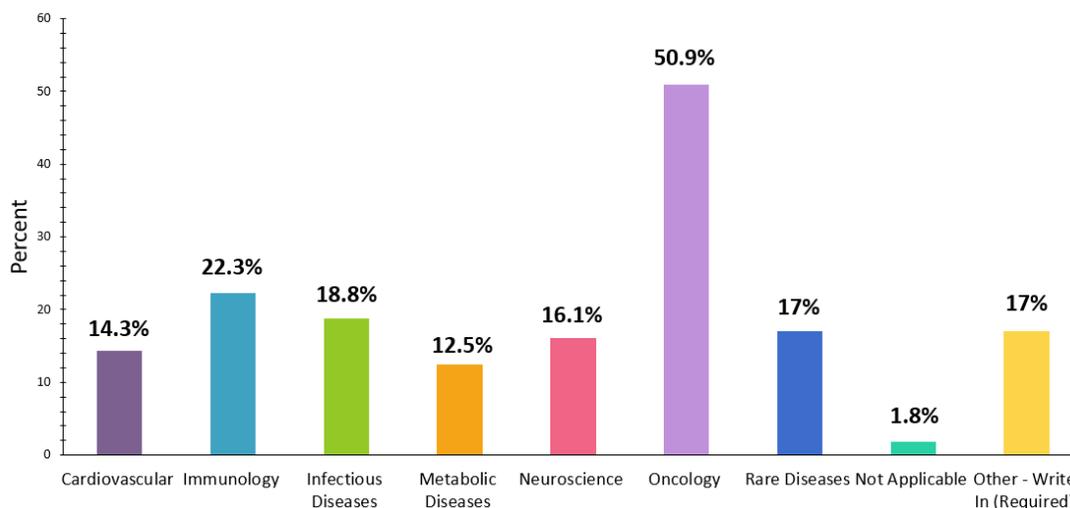
- **Philip Gialenios**, Chief Commercial Officer, Kineticos

### Panel Members

- **Aman Khera**, Global Head of Regulatory Strategy, Worldwide Clinical Trials
- **Kevin Hampton**, Senior Vice President, Kineticos Life Sciences
- **Tom Zietlow**, Operating Executive, Kineticos Life Sciences
- **Dan McCormick**, Senior Vice President, Kineticos Life Sciences

**Moderator:** We want to start by thanking our four panelists for joining us today. We have Aman Khera, Global Head of Regulatory Strategies for Worldwide Clinical Trials, Kevin Hampton, Senior Vice President of Biopharma at Kineticos Life Sciences, Tom Zietlow, Operating Executive for Kineticos, and Dan McCormick, Senior Vice President of Biopharma at Kineticos.

Over this quarter, we will deliver five panel discussions covering five specific sections of the Biopharma Confidence Index, or BCI. The data we are sharing today is based on 112 respondents. We are sharing those responses who acknowledged a confidence level of eight (8) or above in relation to a scoring scale of one (1 = no confidence or no importance) to ten (10 = high confidence and high importance). Our respondents are C-Suite and Executive Level Leaders working for private, startup or mid- to large-sized pharma companies. In our first panel, we covered the [Fundamental Elements of Running a Biopharmaceutical](#). Today, we will cover the Impact of AI, Machine Learning, and New Technologies.

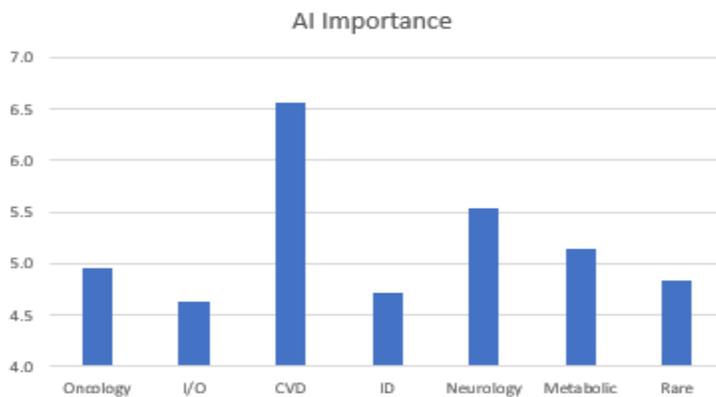


**Moderator:** Our first set of charted data and questions are about the application of AI (artificial intelligence) and Machine Learning by our respondents related to their top therapeutic areas. This includes oncology, immuno-oncology, cardiovascular disease, infectious disease, neurology, metabolic conditions and rare diseases. Looking at the responses, companies that engaged in cardiovascular disease research clearly value AI and Machine Learning more than other therapeutic indications. There is also a higher expectation of positive ROI from AI investments. Is this due to cardiovascular patients generating more data, such as blood pressure, EKGs, echocardiograms, MRI's, which leads to higher expectations of companion information and AI and Machine Learning for cardiovascular drugs?

## Applications of Artificial Intelligence (AI)/Machine Learning

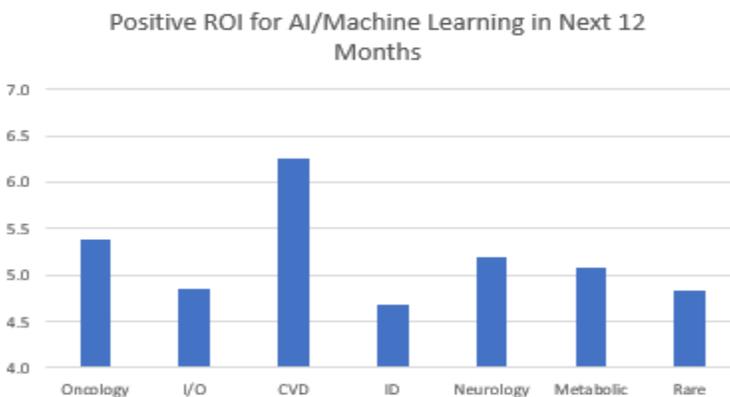
Graph (Top): Average response for companies on Importance of AI/Machine Learning (10-Highest)

Graph (Bottom): Average response for companies on Positive ROI for AI/Machine Learning in the next 12 Months (10-Highest)



Insights:

Companies engaged in cardiovascular disease research clearly value AI/Machine Learning more than other indications. There is even an expectation of positive ROI in AI investments in next year in CVD, much less in other indications



**Aman:** Absolutely. I'm going to take a step back and say that AI and Machine Learning are considered "buzz words" in the healthcare space right now. This survey has indicated how cardiovascular disease patients are generating far more data and that is due to the increased usage of this "wearable" technology that has become more acceptable. We are now looking at the software as a medical device which has come out in more regulatory agencies reacting to this new, relevant form of data. It is a companion to the products in development. This is a growing space. It's not surprising to see cardiovascular indications in the index. Oncology has been rising, too, but early adaptors have been in the cardiovascular space.

**Kevin:** It's interesting. I would have expected oncology to be higher in the index ahead of neurology and metabolic areas. There is so much activity surrounding precision medicine, precision oncology and companion diagnostics. At Kineticos, we have spoken to a lot of AI and Machine Learning companies and many are chasing after oncology targets. This could be indicative of some of the challenges that we have experienced in oncology over the past few decades. We have come a long way in our battle to cure cancer, but looking to overall response rates, we haven't cracked the nut.

**Dan:** I agree. Given the increase in genomics data over time in those aforementioned areas, I was surprised, too, that oncology did not rate higher.

**Moderator:** Aman, as you stated, when you look at something like cardiovascular disease, you begin to think about the "wearables" and some of the data that comes out of constant monitoring. You can see this in other areas like diabetes, too. Do you see that playing a large role in where the larger part of AI and Machine Learning will have the biggest impact in these therapeutic areas? How will this change over time?

**Aman:** Looking at the index, we see that cardiovascular disease is substantially higher than all other spaces. I pivot cautiously in saying that this is due to early adoption that has occurred. There's more buzz and talk in this space. In oncology and other areas, they are not early adopters. There's an entire paradigm involved with oncology drug development. Cardiovascular is one-and-done; there is more variation in other areas. It's a growing space and we should pay attention to how this is developing. The use of AI and Machine Learning is only going to increase as the flow, availability, and accessibility of more data occurs in our industry.

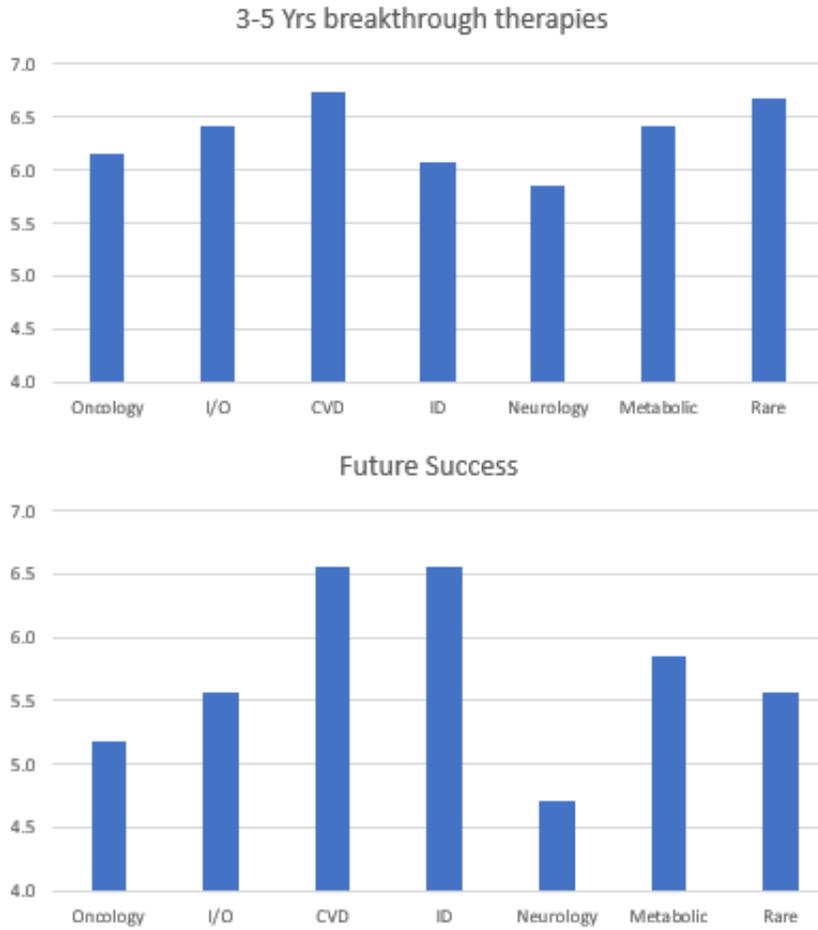
**Tom:** Oncology may have suffered a bit from intense data mining in the last ten years. There might be somewhat of a "fatigue effect" within oncology, too.

**Moderator:** Our second set of data is showing us the expectations of our respondents for AI and Machine Learning providing breakthroughs in these same therapeutic areas. Would they see this happening in the next three to five years? Also, will this be part of their future success? We can see that all companies are expecting AI and Machine Learning will support breakthroughs in these therapies in the future. However, cardiovascular and infectious disease clearly expect that AI and Machine Learning will be significant and essential to their future success. Where are we in terms of CROs preparing to support AI use to develop a sponsor's drugs? What do we see as the expectations for support with biopharma from CROs and consultants in this area? Most important, how can we help our clients leverage associated AI and Machine Learning?

## Applications of Artificial Intelligence (AI)/Machine Learning

Graph (Top): Average response for companies on Confidence AI/Machine Learning will provide breakthroughs delivering new therapies and drugs in the next 3 to 5 years (10-Highest)

Graph (Bottom): Average response for companies on Importance of AI/Machine Learning capability to support future success of their company (10-Highest)



### Insights:

All companies are expecting AI/Machine Learning to support breakthrough therapies in the near future, although CVD and ID expect AI to be important to their particular company's success

**Aman:** CROs are already helping sponsor companies as AI is being used in drug development. There is discovery of potential assets using AI and Machine Learning being undertaken. This is due to the pull to access of data. I would pay close attention to the early winds of disruption we see in the current landscape. Even though you may have discovered a potential asset via AI, in order to start its development journey, you need to fall within the parameters of the development of such a product in the standard, regulated environment we are in. When biopharma engages with CRO's, they are engaging for the expertise, as well. Companies are looking for CROs that are monitoring the landscape, understanding what the nuances are and how regulatory agencies are responding. They understand not only how to operationalize the development of a product, but to help the company think strategically. AI is going to break through and into all of these indications that we are talking about. It is interesting to note how Rare diseases is up there as well in the confidence; due in part to the smaller subpopulations available and the need to gain all the help you can get.

**Kevin:** From our perspective and how Kinetics tries to help, a lot of it comes down to building awareness and getting these technologies out there. We are firm believers that there is a place for AI and Machine Learning. The potential benefit is significant when using such predictive systems. We worked with an AI company that was conducting predictive modeling to help pharma companies recruit patients most likely to respond to their given therapy. On this company's behalf, we went out and talked to KOL's and leading researchers in this space. We asked the KOL's and researchers where the potential blind spots were for this technology. After gathering this information, we went out and started engaging with potential pharma customers. We discovered that these companies weren't ready to invest; this was about 2-3 years ago. The companies were looking for the prospective data to see if the technology could truly predict how a drug would affect a patient. The AI company did have a lot of retrospective data sets, but that was not what the pharma companies were looking for. I believe as the data sets evolve, we'll see a "fast follower" approach as the trail blazers of AI and Machine Learning begin to eliminate some of the speed bumps along the way.

**Dan:** In response to the question around biopharma's expectations of CRO's and consultants, top biopharma priorities are increased efficiency, speed, and effectiveness. From a CRO and consulting perspective, we can best help by finding and translating relevant evidence indicative of how AI and Machine Learning might strengthen and align with the biopharma's value proposition. The clearer the value proposition the greater the adoption AI and Machine Learning.

**Aman:** You are right Dan, and we're talking about early adoption versus fast followers. I think that the fast followers are key, because many people are waiting to see other companies' mistakes. This is a rapidly expanding space and with a significant amount of data coming in and there is a race to develop products faster and more efficiently. I follow this space closely to see who is going to be the early adopters and who will be the fast followers because those are the ones that are really paving the way forward about how products can be developed accordingly.

**Moderator:** Aman, I think that's absolute with both fronts from Worldwide Clinical Trials and also with Kineticos. When you engage these clients, they are trying to find the best way to apply AI and Machine Learning and quickly discern where it fits between that early adopter characteristic versus that fast follower. It is important for us to understand if they are a part of the early adopter group, or the fast followers. Additionally, there are those that wait and see.

**Aman:** Absolutely, we haven't even talked about that. The fast followers versus early adopters that maybe somewhat more cautious, but at the same time they might get ahead in the race versus the larger population of "wait-and-sees." This will be an interesting space to watch.

**Dan:** The more apparent the successes, the broader the adoption. As we have increased evidence of AI and Machine Learning helping reduce the number of failed drugs and improve target identification, safety and efficacy etc., we'll have increased adoption and multiple stakeholders will begin to win; then we are off to the races.

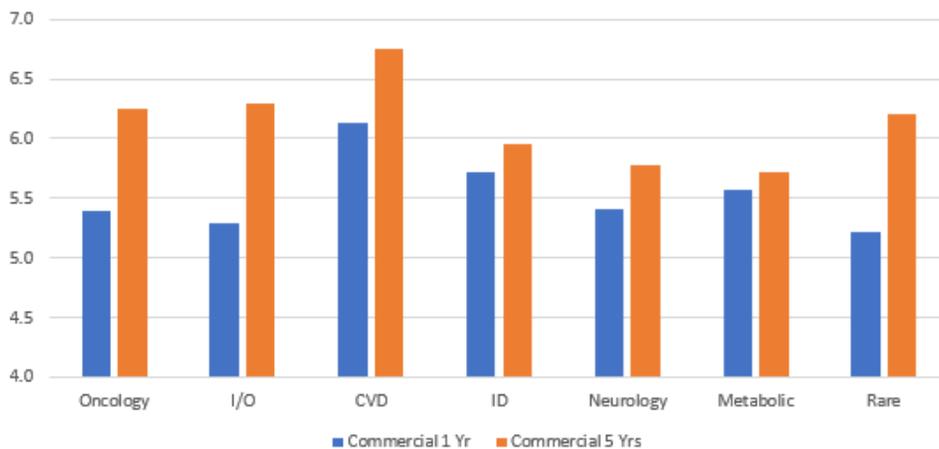
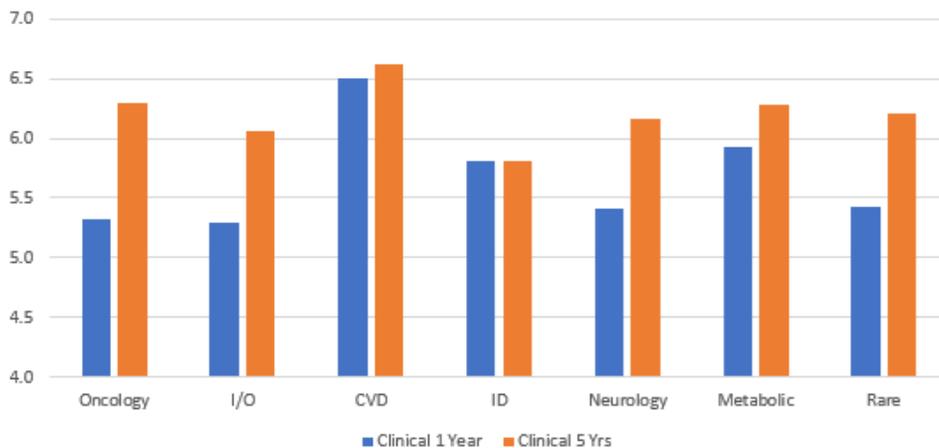
**Moderator:** We are going to move on to our third set of data, where we charted our participants expectations on how they will apply AI and Machine Learning and how it will

become a useful tool for them in areas such as preclinical, clinical work, and all the way out to commercial planning development and execution. We asked for responses based on the next 12 months and also out to 5 years. What we found was responses suggest application for AI and Machine Learning are expected to become more prevalent in the next five years in preclinical and clinical as well as commercial spheres. Dan and Kevin, with your backgrounds in commercial and back to preclinical, is it surprising that AI and Machine Learning are perceived as useful tools in all of these spheres, with some stronger expectations on the commercial side?

## Applications of Artificial Intelligence (AI)/Machine Learning

Graph (Top): Average response for companies on AI/Machine Learning will become useful tools in pre-clinical and clinical development in 12 months and 5 years (10-Highest)

Graph (Bottom): Average response for companies on AI/Machine Learning will become key tools used for commercial planning and execution in 12 months and 5 years (10-Highest)



### Insights:

Applications of AI/Machine Learning are expected to become more prevalent in the next five years, in both clinical development and commercial spheres

**Dan:** Across the value chain from R&D through manufacturing to commercial launch and patient engagement, we all understand that AI can be quite beneficial. It is not surprising to me from a commercial perspective that the interest in AI remains strong. While our discussion has been focused on R&D, we would be remiss if we didn't comment biopharma's efforts to leverage AI and ML in support of its promotional strategies. A top priority is bringing the right content (e.g. brand messages) to the right stakeholder at the right time via the right

promotional channel (e.g. digital/online, field sales or inside sales). Biopharma has entire departments devoted to building and executing multi-channel strategies, the foundation of which is leveraging machine learning to make “actionable” sense of the enormous volumes of available data pertaining to the customer universe that can benefit the prescriber and patient.

**Moderator:** Kevin, now let’s step back to the clinical side of AI and Machine Learning.

**Kevin:** Before Dan came onboard, I had been living in the pre-commercial world for the past 6 years with non-revenue generating, early Phase 1 and Phase 2 companies. Dan understands how these tools can be used on the commercial side. If you asked me 6 months ago, I would have also expected AI to be much more relevant to the clinical development, but that’s clearly not the case now. If you just look at the data on the clinical side, it tells me that there is still upside and the 5-year outlook is much better than today. Oncology strikes me as a little low here, but I think we have talked about some of the reasons why this might be the case. Another thing to potentially take away if you look at cardiovascular and infectious disease, one could make an argument that what we have seen in AI to-date is significant, but there will be many more advancements down the road. It’s hard for me to believe that it would play out that way. I think that those two therapeutic areas have seen advancements early on and are closer to achieving significant breakthroughs.

**Moderator:** Thank you Kevin. Does anyone want to add to that.

**Aman:** I think everyone has covered the key points. Oncology does surprise me as a space for early adopters, but I want to touch on Rare. With the increasing concentration from regulatory agencies for example and patient advocacy groups as well. They want faster treatments and maybe if you ask these questions again in another year or so cardiovascular might wane because the data is quick and fast with the wearable technology. The really cool stuff will occur when you have to truly look at the data sources and pull out the right story that goes back to the regulators for development of such a product in Rare diseases. I am patiently waiting to see how this is going to develop for sure.

**Moderator:** Aman, I wanted to ask one follow-up question. It almost seems like to some point that AI and Machine Learning have this feedback loop where the commercial side feeds back into the clinical side. People will no longer look at these business divisions as separate, they will look at it as a continuous loop going back and forth between clinical and commercial. Does that seem like the possible future?

**Aman:** Absolutely, before there has been development activity that has been a bit siloed where clinical is doing their part and then they pass the ball onto commercial; but they haven’t strategized. This technology and future advancements will help break down those siloes so that when you are developing a treatment you are thinking more about commercialization now that you have access to the data. How you read and apply that data for future clinical development is another story.

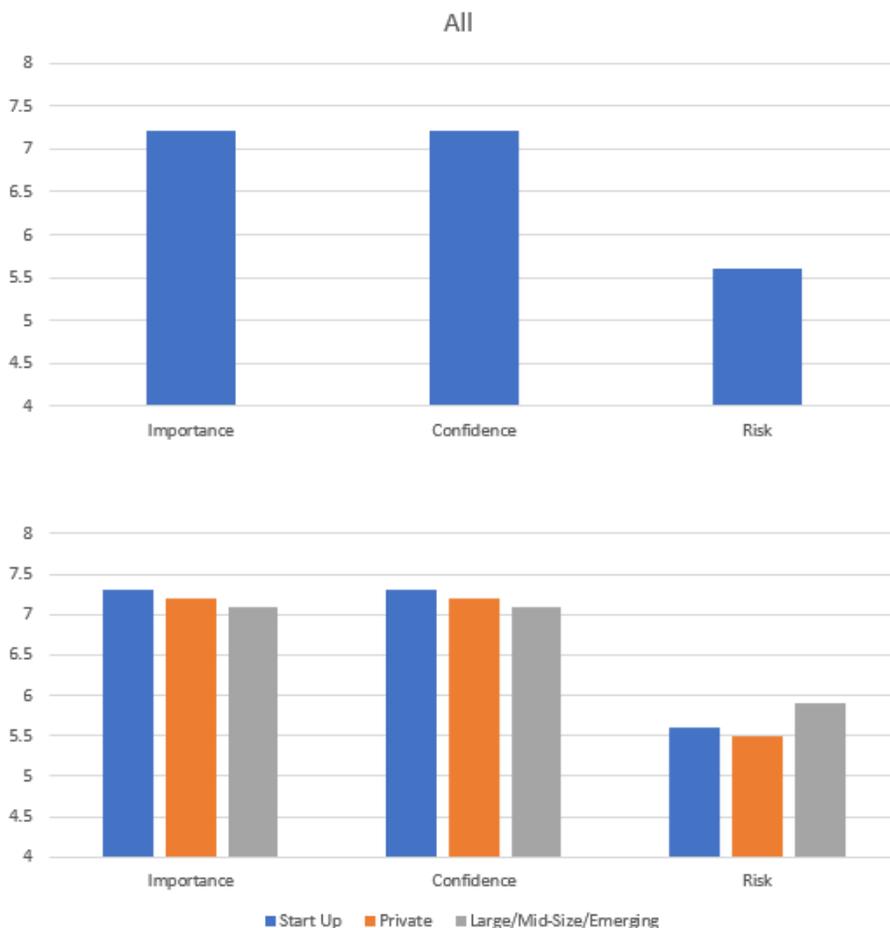
**Moderator:** We will move onto our fourth set of data. We charted out data and asked questions about our respondent’s views on the importance versus their confidence, and their view on risk, when they are considering R&D innovation. We first looked at the overall

importance, confidence, and risk for all companies. We then segmented that data into the three groups that I spoke of in the beginning: startups, private, and large to mid-sized companies. If you look into the data we know that R&D innovation has been the bedrock of the pharmaceutical industry for decades and the respondents seem to be very positive about importance and confidence with R&D Innovation and execution in the future, but interesting that there are limited concerns regarding Risk. The questions I have, starting with Aman and Kevin, are looking at the importance, confidence, then what you see with risk. Are there any surprises based on current attitudes you are seeing with our customer base? With any innovation, there must be risks to consider. So why is there a lower response to risk? How can we help our clients prepare for that risk?

## R&D Innovation

Graph (Top): Average response for companies R&D Innovation: Importance/Confidence/Risk (10-Highest)

Graph (Bottom): Average response for and by company type for R&D Innovation: Importance/Confidence/Risk (10-Highest)



### Insights:

R&D Innovation has been a bedrock of the pharmaceutical industry for decades and the respondents appear to be very confident in both importance and execution in the future.

**Aman:** When looking at the data I was surprised to see risk not as high as the importance and confidence. You are right that R&D has been the bedrock with innovator companies. With innovator technologies, there is emerging biopharma and sometimes existing biopharma that

have pivoted to a directional concentration. They are doing this with their eyes wide open, which gives me a sense that they understand the importance and their confident. What concerns me is that the industry should also be looking at ways to de-risk. Now maybe that is what biopharma is doing as well. If they have an asset in development, should they be exploring not just one disease or indication, should you be branching out early in the process so that you aren't going down the wrong road? The journey down the development road is very long and early engagement and dialogue to de-risk your program or asset is essential. Should you be having early engagement with agencies globally? Should you and can you use expedited pathways? You have to balance this out with the potential return in investment when it comes to commercialization. You need to also look at the reimbursement potential and the payer perspective.

**Kevin:** There are a couple of ways you can look at risk. Just looking at the data, it is just over 7 for importance and confidence. Then it's at 5.5 or so for risk. While it is lower, to me it is not that significant of a variance and Aman made a good point to the extent that you can de-risk from a CRO perspective or Kineticos perspective. A component of every strategy project that we do here at Kineticos is to help our client quantify and eliminate risk. The second part of the equation is finding strategies to mitigate risk. Nearly all the work we do at Kineticos is helping our clients identify where the risks are and helping them navigate around them. I think even though we have been working in oncology, cardiovascular and infectious disease for decades, you would think we would know what the risks are. This is just not true. We are constantly uncovering new risks every day as we develop new drugs.

The bias associated with company size is not being reflected here. I think we can all agree that innovation in larger pharma has not decreased, it has just been outsourced by buying up smaller companies. I think true innovation in the large pharmaceutical sector has diminished; I'm surprise to see that it is only marginally below startups. This could be due to the possibility of bias since it was a self-assessment. I know there is data out there on how many of the recently approved drugs are internal programs for big pharma versus ones that have been discovered through smaller companies; or even academia.

**Moderator:** Dan I know through your background and experience you have a lot of history with large pharma and I thought it was interesting that the importance and confidence is slightly lower with large pharma, but the risk is higher. When you think about big pharma, they tend to be more risk adverse then the smaller companies.

**Dan:** I agree with you. From an established biopharma perspective, the level of willingness to take on higher levels of risk seems to be less as some leaders shy away from potentially costly and career limiting failures. To create a safer environment for adopting new technologies and piloting new approaches, some organizations have carved out centralized resources including dedicated "innovation budgets" to both drive and identify sources of innovation.

**Aman:** I thought those were all very good points. Working with virtual biotech's versus large pharma, knowing how each are set up, there is more nimbleness in smaller companies and sometimes they are a bit braver. Larger companies have more functions, more people involved, more layers and more approvals needed. I do think there may be some bias in this data and I

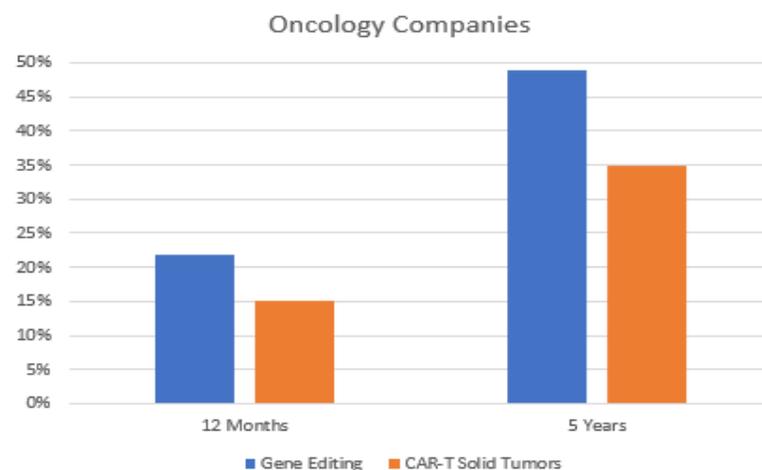
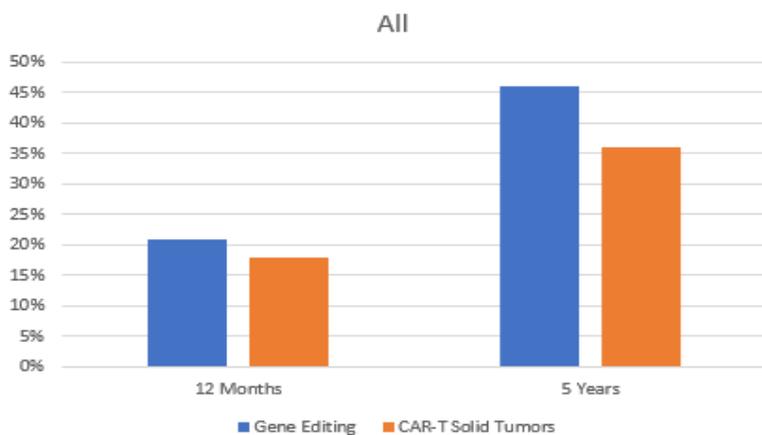
would love to look again in another year or so because R&D Innovation is fast moving and ever changing.

**Moderator:** Let's move on to our fifth and final set of data. We charted the data looking at our respondent's views regarding innovation very specific to whether "Gene editing will be a powerful new approach in multiple therapeutic areas over the next 12 months and out to 5 years". Then we asked the same question regarding whether or not CAR-T will allow targeting of solid tumors in the same time frames. We first asked these questions of all respondents, then we decided to look at responses from only our specific oncology companies. What we see from the data is that all companies expect that these new technologies will be successful within the next 5 years versus 12 months. However, looking at the data, we would have expected to see the oncology companies more confident; this data shows that they were slightly less confident. Is this somewhat of a surprise that the oncology companies seem to be less confident of solid tumor CAR-T breakthroughs when compared to the overall industry?

## Confidence in Gene Editing and CAR-T

Graph (Top): %Highly Confident: Gene editing will be a powerful new approach in multiple therapeutic areas: 12 months and 5 years; New technologies will allow CAR-T to target solid tumors – All companies

Graph (Bottom): %Highly Confident: Gene editing will be a powerful new approach in multiple therapeutic areas: 12 months and 5 years; New technologies will allow CAR-T to target solid tumors – Oncology companies



### Insights:

All companies reasonably expect that new technologies in gene editing and solid-tumor effective CAR-T therapies will be successful within 5 years.

**Aman:** There's a lot of talk in the industry around CAR-T cell therapy and gene editing. In comparison to where we were 5 years ago to now, this space is exploding. But those directly involved in the space can understand the complexities involved. You only have to look at the public domain to see there are many trials and many assets in development in this space. Maybe other companies are watching very carefully to what the oncology sector is doing. This could be why oncology is adopting these technologies at a slower pace. Oncology companies are more cautious and risk adverse because they are directly involved in the space and they understand these complexities; that trials are expensive, that materials are expensive, and the logistical needs that can be somewhat complex must be carefully considered. They are truly being experimental with the therapy as well. This confidence is a true snapshot. Other companies are well aware of what is occurring in the oncology space.

**Kevin:** I think what we have here is counter forces. In theory, oncology companies should be thinking more about CAR-T and more confident in potential breakthroughs because it's relevant to what they are working on and investing in. You also must keep in mind that these people know that for every single minor success you have, there are 10, 20, 30, even 40 failures. I think if you are not an oncology company, you could look at this question not knowing what oncology companies are doing daily in this space and you're only seeing the more positive versus the negative results; especially what is seen in the news. If you're the one experiencing all of the challenges daily, that confidence could start morphing into indifference or even skepticism. I think that's why it's great to see so many new biotech's being funded. In an area that's as difficult as oncology, it just comes down to more shots on goal. The more shots on goal we get with these new and emerging start-up companies, the more likely we will achieve the positive results expected by all the other companies.

**Moderator:** That's a good point Kevin. Anything to add here Dan?

**Dan:** I'm not surprised by the data and the respondents' feedback. We've got great evidence from companies who have worked very hard to pave the way for the industry in this space. In recent years, two of the trailblazers went on to big-time acquisitions. One company had very unfortunate challenges with patients in its trials, which led to major setbacks and adversely impacting the market's confidence in its ability to recover. With an exceptionally strong leadership team, the company overcame the setback to go on and be a part of two subsequent major acquisitions. The industry's leaders in this space are quite committed and resilient, and we should all be encouraged. Another trailblazer recently shared news around market uptake with resulting revenues and a forecast being much less than the acquirer had expected. Examples like this should lead to extra diligence and effort around solving to make the right investment decisions at the right time (i.e. how to mitigate the risk of being nearly a billion dollars below expected revenues while only a couple of years post-acquisition). Just last week, we had another trailblazer encounter a tough challenge. On the heels of regulatory success in the EU, the global company encountered unexpected US regulatory hurdles. No doubt the Oncology community and patients around the world are grateful for these trailblazers who have taken on this hard work. With some of the setback, it's rational to expect some prudent risk aversion, but in the end, my sense is we can count on great strides forward with these innovative therapies.

**Moderator:** I want to thank our panel today for their participation. It was a lively conversation, a lot of great ideas and insights. I want to thank everyone for joining us today for our second BCI panel discussion covering the Impact of AI, Machine Learning, and New Technologies. These BCI panel discussions are brought to you by Kineticos Life Sciences and Worldwide Clinical Trials. Please join us next week for our third installment when we will be discussing Raising Capital and Mergers and Acquisitions.