Oncology Diagnostics Series:
Part 1 - Can Diagnostics Keep Up with Pharma?

Panel Members
Eric Mayer, CEO, EDP Biotech
Brian Kelly, Global Director, Diagnostic Partnering, Thermo Fisher
Sandra Dunn, CEO, Phoenix Molecular

Kineticos: As the diagnostic and cancer landscape continue to involve, new technologies are bound to follow. We're witnessing a shift from diagnosing based on tissue of origin to new discoveries and methodologies that are able to diagnose cancer regardless of tissue of origin. These new technologies are destined to play a tremendous role in cancer treatment and we've got a panel of experts ready to discuss this very topic.

Brian, I want to start off with you because, being with Thermo Fisher, you see a lot of different technologies when looking at partnering. Can you talk about some of the newer, emerging technologies that really excite you and why you find them exciting?

Brian: As you alluded to, there are many technologies that are looking to cross from the traditional research applications into diagnostics. Many efforts in that space have been stymied not by the lack of applicable technologies, but in many cases, it's simply the rate of discovery. When talking about specific technologies, the classic Immunohistochemistry (IHC) and other basic molecular testing modalities such as real-time PCR and traditional sanger sequencing started a trend of advancing diagnostic by leveraging technology innovation. Now in the last 5 years, next generation sequencing (NGS) has hit its stride. Continued investment by Thermo Fisher, not only in NGS, but in other areas such as mass spectrometry, can hopefully broaden the menu of the available solutions. In particular, multi-omics has always been a strong research attempt for discovery, and now we're starting to see biomarker programs that will combine multi-dimensional data from different diagnostic test platforms. Whether it be through genetics, genomics, or proteomics, how the data from these different dimensions might be used together is certainly an opportunity for advancement in this space.

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Sandra: The cancer agnostic approach to treatment is exciting. The first example was the FDA accelerated approval of Keytruda based on high microsatellite instability in 20171. Loxo Oncology is following suit in a small, niche market with an uncommon cancer. They have centered their business efforts around developing a companion diagnostic and then applying the drug to patients while applying the learnings to help guide drug delivery.

Kineticos: What Loxo did was very interesting to the market. We no longer think of tissue origin – we think about the molecular basis of cancer. Eric, I know that at EDP is really focused on early detection of disease and that your new tests are blood based. Same question for you – can you talk about some of the emerging technologies that really excite you?

Eric: As I prepared for this panel session, I had similar thoughts to those of Brian. Specifically, NGS came to mind looking at genes and protein expression with the multi-omics approach. One new area of research that's exciting is how exosomes are packaging together so much

information on what's happening inside of the body. It's interesting to think about how to digest and take advantage of that information.

Some of these new, deep learning and machine learning mathematical algorithms are exciting as well. They are advancing mathematics to tie disparate biological information together to discover higher order relationships between these genes and their proteins. The most exciting part about these advancements is the fact that they are enabling companies to reduce costs and timelines. Clinical research incorporating block-chain technology is a great example. It is time stamped, it's legered, you can't edit it. These are some of the ways that I see diagnostics evolving in the future.

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Kineticos: Eric, what you said is very interesting to me. When I started my career off in the laboratory, we used to talk all the time about rate limiting steps. When you're working in a production laboratory, it's actually not the sample handling or analysis that's holding you back, rather the data management and data review. We had relatively sophisticated equipment back then, but now I wonder something else – do you think we've gotten to the point where the analytical methodology and our ability to sample parts of the human body have become so sophisticated that we need AI and machine learning in order to be able to process this information? Furthermore, could it be beyond our human comprehension to even understand what it means?

Eric: That's a great question, but I see it as 2 parts. I would say that we're not as sophisticated as we think we are yet. We're throwing a lot of data at the problem and some of it is creating noise, so we've got to really improve that signal-to-noise ratio to ensure we're feeding AI the most important data. Is AI going to win out the day or will machine learning prevail? With machine learning, you have to train mathematical models then see how well it predicts unknowns. These models are becoming more accurate in my experience. Regarding AI, I don't believe it is anywhere near where it needs to be to make diagnostic decisions, and I don't think we are sophisticated enough yet to get AI involved at this point. I see this as emerging and exciting but there's just so much noise out there.

Kineticos: Brian, given you are with Thermo Fisher, I suspect this is an area that you and your organization will be highly focused on. Can you comment?

Brian: You both make great points. Eric, what you're speaking about definitely resonates strongly with what I think everyone in the space is trying to grapple with today. It's one thing to have the innovation on the technology side to allow for massive amounts of data generation. It becomes a limitation when the data set is too large to be interpreted by humans. So, leveraging not only more advanced analysis but rather interpretation algorithms will be critical to take it from real world data to real world evidence. I personally find the evidence component to be a bigger challenge. Whether it's a potentially cutting-edge diagnostics attempting to detect cancer earlier, or whether it's a classic diagnostic that is actually having a significant impact in clinical care, the evidence needs to be present and accepted by the clinical community. In summary, it's a combination of technology with sophisticated analysis and interpretation that is critical for advancement.

Kineticos: Brian, you bring up a good point because we've done analysis on this for some clients, and ultimately, one of the things that we've concluded is what really mattered in adoption of new diagnostic technology was something very simple - clinical utility.

Brian: It may be intuitively obvious to many of us; it's still a challenge for most in grasp what we really mean here. In many cases, such as the focus Thermo Fisher has in the NGS space for companion diagnostics, the utility itself is a given as a result of co-development effort with a therapeutic. That said, the evidence to a healthcare system or to a payer that this is actually going to have significant impact to healthcare outcomes is yet another bar that I think is critical to have for long term success.