

# Oncology Diagnostics Series: Part 2 - Making Up for Unfavorable Reimbursement

## Panel Members

Eric Mayer, CEO, EDP Biotech

Brian Kelly, Global Director, Diagnostic Partnering, Thermo Fisher

Sandra Dunn, CEO, Phoenix Molecular Designs

**Kineticos:** Diagnostics are responsible and involved in driving clinical decisions in about 80% of all patients, but yet it's only 3% of the overall healthcare spend. So, there is tremendous disparity between the current utility compared to what is reimbursed. A lot of people understand that dynamic and still want to get into diagnostics for many reasons. Eric, I'd like to start with you given the likelihood you live this more than Brian and Sandi right now, but what are some other ways, besides reimbursement, that diagnostic companies can monetize their assets? I'm thinking about things like working on research with pharma, developing a specific box, consumer supplies, and managing data. I would like to get your understanding about what other business models diagnostic companies could use to help offset some of the development costs so that we can provide these lifesaving procedures and treatment options based on a diagnostic test.

**EM:** That's a question we, almost a 15-year-old start-up, wrestle with all the time. Some obvious ways, as you mentioned, are out-licensing assets or markers that we may discover for companion use or for some type of targeted therapeutic use. We've also entertained the idea of giving some IP to academic researchers to see what they can come up with using their own time and grant money. In that scenario, we would arrange some type of future milestone

or royalty payment for any new discoveries or commercialization.

There are also revenue sharing agreements that can go back and forth between small diagnostic companies. For example, if I have a specimen bank and another company wants to use it, we may just give them access and take the royalties off of what gets commercialized. One of the other things that is really important, since a lot of us are in this together, is incubating together or co-working and providing different contract research or contract manufacturing models for diagnostic companies. We can each leverage our own unique competencies but take advantage of a large community because as you said, the diagnostics themselves, while we recognize the importance of them and I think physicians absolutely understand the importance, the payers don't always see the value. That goes back to Brian's point from Part 1 about needing more data and more health economic arguments to justify higher reimbursement.

**Kineticos:** Eric, I'm not particularly convinced more data would really do anything. I say that more as commentary than a question because there are some of these things that have tremendous amounts of data, yet it seems like the reimbursement is low because people say, "Well, healthcare is expensive; we cannot really pay for a diagnostic procedure." That's not really the case here – diagnostic procedures are relatively inexpensive compared to the utility. I appreciate your comment and I'm always hopeful but I'm not counting on agencies to all of the sudden start making it easier on us to get paid for the research.

*"...I think physicians absolutely understand the importance [of diagnostics], the payers don't always see the value"*

**EM:** I think some of that is going to come from Capitol Hill. We have to speak up and talk to the legislators and say “Look, a pound of prevention is definitely worth more than spending billions trying to find a cure someday”. They must begin to prioritize preventative medicine, they have to prioritize diagnostics, and it’s a conversation that may be happening in the background but not in the forefront. Everybody talks about drug pricing even though drug cost is only 8-10% of healthcare spending. I feel that we’re focusing

analysis that can provide further information on the topic.

The challenge is, whether you’re a payer, provider, drug manufacturer, diagnostic developer, or even a patient, everyone has different incentives. When these incentives are not aligned with the presumed ultimate goal of providing better healthcare, perhaps they are better described as what’s commonly referred to as “perverse” incentives. If we provide better diagnostics and better drugs that are costlier than current practice, and we keep people alive longer, but they still die of their disease, is that a real benefit? It certainly might be to the patient, but not to the payer. Unfortunately, it is a very real challenge and it becomes a moral dilemma of having alignment of different stakeholders with different incentives to enable personalized medicine. Perhaps that’s overly simplistic and too impossible to solve, but the reality is that’s why you’re hearing the call to value-based healthcare instead of service-based healthcare.

*“The challenge is, whether you’re a payer, provider, drug manufacturer, diagnostic developer, or even a patient, everyone has different incentives.”*

the conversation on the wrong things and I think that myself, Brian, Sandi, you guys at Kineticos, we all in industry need to make our voices heard a little louder.

**Kineticos:** The advocacy point is not on our agenda, but it’s an important one and I’m going to try to come back to it later. Brian – the same question about reimbursement for you. We recognize the problem and I suspect you work with a lot of different diagnostic players and innovators. What are some of the other ways they are monetizing their assets?

**BK:** To follow up on where Eric was heading – this is not a new challenge. Unfortunately, this is something we’ve been facing for a long time. It has now become heightened as we have many more technologies and unique tests that have been developed over the last 10-15 years, which are highlighting some of the faults in the system. As far as the cause of reimbursement challenges, I’ll point to the Personalized Medicine Coalition, as they did a study over 10 years ago looking at the return on investment in personalized medicine. They looked at value from all the different stakeholders’ perspectives. It’s an older study but it’s still a very relevant

Relatedly, we’re starting to see that the era of blockbuster oncology drugs has ended. People have since pivoted to the targeted molecular therapy space which could drive much better efficacy but in a very small segmented patient population. When the industry realized that biomarkers were going to be required as a companion to show the efficacy of a drug, certainly pharma was not on board with this approach at first. This segmented their patient population that would presumably be prescribed to take their drug. The development costs didn’t go down correspondingly, and you now have an increased cost for the patient/provider and ultimately the payer on a per patient basis. It’s a challenge that’s risen, but now with quality diagnostics in place, we’re starting to see the movement by some of these groups to create value-based payment structures where pharma is compensated only if we see the efficacy in patients.

One notable poster-child for this type of model is Loxo Oncology, whose drug is priced around \$400,000. Their clinical trial data demonstrates

an approximately 80% response rate; however, they have structured payment terms so if the drug doesn't demonstrate efficacy, they're not going to receive payment for that patient. There are novel ways in which the pharma developers are pivoting, and we have to think about that similarly from the diagnostic developer side.

Now what does that mean? Well it's not about whether a test works or not, it's about having enough people being tested to make the business models viable while ensuring we don't lose sight of patient benefit. One of the biggest challenges for diagnostics is that most people that should be tested so they can have access to better solutions are not being tested. There is an opportunity to work with providers and payers to demand more testing. Patients already are demanding it but only if they're knowledgeable enough. If a network is incentivized to do this by the way in which they pay for performance, this is one novel opportunity.

**Kineticos:** There's another thing interesting to me here. Unlike other therapeutic areas, and it's probably because of prognosis, cancer patients are much less likely to enroll in clinical trials. Only 5% or so of cancer patients actually enroll in clinical trials and with almost 40% of all drugs being in the oncology space so access to patients is a really big issue. I don't hear anybody talking about.

**EM:** That is interesting. Since most of our work at EDP is not focused on US or FDA approval, that's not an area that I'm as familiar with. Piggybacking off of the topic in general, we have to generate cost effectiveness data and one way to do that, and to get more patients involved to boost that 5% number up, is to push the payers and providers towards valuing organized screening models. We see these models in other countries and they are effective. They're reducing cancer incidence, promoting the "average Joe" off the street to come in and quickly and cheaply get screened for common cancers. The more people aware of the program and the associated benefits, the more they will get involved, which will increase

enrollment. I think it is part education, part reimbursement, and part health economics cost effectiveness.

**Kineticos:** Sandi, I've been trying to get to you but can you close us out on this topic?

**SD:** Branching into other indications could help further monetize. We are focused in triple negative breast cancer, but our companion diagnostic is applicable across a broad platform. As long as you have a broad platform, you can expand. Expectations of making a lot of money on a diagnostic need to be managed and realistic. People need to be realistic about how much money they can make and what their reimbursement will be.

Monetization should be a simple accurate approach – A user-friendly approach that has rapid market uptake is the way to go. That said, it has to be precise and accurate. The companion diagnostics space is competitive, and the forerunners are those that recognize this first.



*Kineticos is a specialized management consulting firm serving the life sciences industry. The firm is focused on identifying opportunities to drive strategic growth for its clients. Through its three practice areas -- Biopharmaceutical, Biopharmaceutical Services, and Diagnostics -- Kineticos has experience working with companies across the life science industry ecosystem*

*For more information, please visit  
[www.kineticos.com](http://www.kineticos.com)*