In My View

In this opinion section, experts from across the world share a single strongly held view or key idea.

Submissions are welcome. Articles should be short, focused, personal and passionate, and may deal with any aspect of laboratory medicine. They can be up to 600 words in length and written in the first person.

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Intelligent Pharma Partners

Pathology AI needs a new business model – and partnering with the pharmaceutical industry is an attractive opportunity

By Holger Lange, Chief Technology Officer, and Cris Luengo, Director of Image Analysis at Flagship Biosciences, Westminster, USA

The true barrier to artificial intelligence (AI) in pathology is not the technology; it's the business model. To get pathology AI into clinical laboratories, payers need to provide a value-based model that creates a viable business case.

We estimate the US anatomic pathology market for tissue image analysis, based on the current reimbursement model, to be about US$550 million (about $7–8 per test), even though it is unlikely that the Centers for Medicare and Medicaid Services is going to just add $550 million to their reimbursements. The problem is that the anatomic pathology market is segmented into subspecialties, which correspond to different tissue types, each with a list of different tests that typically correspond to different stains. Indeed, myriad "tissue–stain–clinical outcome"-specific tests each have their own little market segment that we estimate to be on average about $11 million, shared by multiple manufacturers.

Pathology AI is dependent on the adoption of digital pathology, which by itself does not have a tangible business case. Depending on whether or not a laboratory has a scanner, any additional reimbursement for computer assistance may need to fund the purchase of the digital pathology equipment as well. And when you consider the costs associated with building and commercializing a pathology AI system as a medical device, its business case becomes a challenge. Ultimately, though, we believe that pathology AI will drive the adoption of digital pathology, providing it with a return on investment!

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Applications that provide the same results as pathologists using a microscope, but with better consistency or requiring less time, make almost no difference in the market to the end user. We have seen this very clearly with the tissue image analysis immunohistochemical (IHC) HER2 test for breast cancer – the poster child for these kinds of applications. Its adoption was very strong between 1998 and 2002, when the additional reimbursement was very high (about an additional $170 per test); by 2002, about 450 ACIS systems (the first commercial product) were placed. The reimbursement dropped to under $60 in 2003, and in 2007 only 250 ACIS systems were still in the market. Today, the additional reimbursement is less than $10 per test.

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Interestingly, several additional tissue image analysis IHC medical devices have been developed over the years, all by digital pathology manufacturers who have a completely different business case in mind: to introduce their digital pathology equipment into the clinical market. The predicate device, the ACIS system, smoothed their way. But not even devices aimed at rare event detections (such as acid-fast bacilli or mitotic figures), which could save pathologists a lot of time, were able to break into that market. So why would the diagnosis of cancer, the latest application everybody is talking about, be any different? After all, the gold standard is a pathologist using a microscope. Why change – and potentially lose money?

The adoption of pathology AI under the current reimbursement model will only be driven by "microscope-impossible" tests that require the use of AI. Today, immuno-oncology is the "killer app," with a massive business case behind it. There is an extensive need for tissue context data that other modalities, such as next generation sequencing, cannot provide. Analysis of the tissue is far too complex for a pathologist using only a microscope.

Pharmacogenomics allow us to identify the patients who are more likely to respond to particular therapies or who require dose modifications. Stratification of clinical trials, even retrospectively, boosts efficacy and eliminates toxicity. How much is that worth?

Prescribed cancer treatments are effective in only about 25 percent of cancer patients, making them inefficient, expensive and detrimental to patient health. In the US alone, adverse drug reactions account for 100,000 patient deaths and $100 billion in healthcare costs each year. Between 1997 and 2004, 19 drugs were removed from the market because of adverse events.

We believe that the true opportunity for pathology AI lies in personalized medicine with big data. We could run a single test in a clinical laboratory – a standardized panel with multiple markers that provide rich information data for tissue – and use it as a basis for treatment decisions that include the full spectrum of all available and future drugs. New diagnostics, prognostics, and companion diagnostics could be created by clinicians in the field; as the test generates the underlying data, diagnostics, prognostics, and companion diagnostics become just a scoring scheme – a formula that any laboratory professional can develop by correlating existing or emerging health conditions with this database of information. Better characterization of the patient population using rich information data from the test could make drug development faster and cheaper through smarter patient selection. Diagnostics, prognostics, and companion diagnostics based on the test could significantly simplify regulatory pathways. With the generation of rich information data for tissue using a single standardized test, the regulatory pathway can be divided into two steps: first, an easy FDA clearance of the test to provide data (measurements not related to clinical outcome) only; and second, diagnostics, prognostics, and companion diagnostics that are now just simple scoring schemes with much simpler regulatory pathways. For pathologists who want to improve patient care, pharmaceutical companies who want to bring their drugs to market, and payers who want to lower healthcare costs, the combination of AI-assisted pathology, pharmacogenomics, and big data could yield a viable business model – and a bright future for everyone involved.

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