Companion Diagnostics – a Burgeoning Market

by Jessica P. Johnson, MS

Since the first drug requiring a companion diagnostic test was approved by the U.S. Food and Drug Administration (FDA) in 1998, the global market for companion tests has exploded to $1.8 billion in 2012 and is projected to triple to $5.6 billion by 2019, according to a report by Transparency Market Research.

“Companion diagnostics are an indispensable part of personalized medicine and will likely continue to rapidly increase in number and application to disease areas,” says Amit Agarwal and colleagues in a study of the future of companion diagnostics, published in the Journal of Pharmacogenomics and Personalized Medicine last year.

The concept of developing tests to predict a patient’s response to a particular drug treatment is not new. It has been pursued since at least the 1970s, but got off to a slow start because of the scepticism of drug manufacturers who worried that linking a drug with a diagnostic test would hinder marketing.

But then along came trastuzumab (brand name Herceptin), and its success changed a lot of minds. Herceptin is a highly effective inhibitor of cell proliferation in aggressive breast cancer tumors that overexpress a certain growth-stimulating protein. However, the drug only works in approximately one quarter to one third of breast cancers that overexpress the protein. Hence the need for tests that identify patients who have the types of tumors that respond to Herceptin.

Companion diagnostic tests have enabled trastuzumab and other drugs used to treat patients with diseases linked to less common genetic abnormalities to hold their own in the market even though they don’t treat a large section of the population – so-called “niche-busters.” For example, imatinib (brand name Gleevec), used to treat patients with chronic myeloid leukemia who account for only 14% of patients with leukemia worldwide, won its developers the Lasker-DeBakey Clinical Medical Research Award for “converting a fatal cancer into a manageable chronic condition.” The drug may not have been pursued without the marketability provided by the development of companion diagnostic tests.

By 2006, the FDA had approved five companion diagnostic tests, all designed to accompany cancer drugs. Today, that number has risen to 19. If one takes into account the fact that many of these tests can be used alongside more than one drug, there are now at least 63 drug-companion diagnostic tests combinations available to help tailor treatment to an individual, according to the FDA.

More recently designed tests now serve a much broader group of patients than those with cancer. Nearly a quarter of approved companion diagnostics accompany drugs that treat cardiovascular disease. And a growing group of tests have been paired with drugs including those used to treat mental illness, HIV, and cystic fibrosis.

In response to the rapidly expanding companion diagnostics market, the FDA issued guidance to industry and FDA personnel in July 2014, which was designed to encourage simultaneous development of drugs and the appropriate accompanying diagnostic tests, to speed delivery of drug treatments to patients whose genetics predict their response to treatments, and to ensure that drug labeling includes instructions when the use of a companion diagnostic is indicated.
The FDA now requires companion diagnostic tests to be developed for drugs that have a specific genetic or biological target that is not present in all patients with a disease. “The companion diagnostic is essential to the safe and effective use of the drug,” the FDA says in its guidance statement. The FDA also evaluates both the drug and the test simultaneously to determine whether they should be approved together. Further, it recommends that a determination of genetic suitability be performed before clinical trials begin in order to optimize trial results.

The guidance “…will give health care providers more confidence in these tests to direct the therapies because the tests and therapies have been developed and evaluated together,” says Elizabeth Mansfield, director of Personalized Medicine Staff in the FDA Center for Devices, in a statement.

There’s a lot of work to be done in terms of developing new companion diagnostic tests, but the field is still wide open, so the opportunities for enhanced patient care appear endless. And some existing diagnostic platforms need only to be fine-tuned. Eli Lilly and Company utilizes Qiagen’s Modaplex diagnostic platform which simultaneously analyzes DNA and RNA biomarkers in order to identify the potential success or failure of different therapies in a single test.

“We are relentlessly focused on delivering diagnostic solutions that can be applied in a clinical laboratory setting,” says Andrew Schade, senior director of Diagnostics and Experimental Pathology at Eli Lilly. Schade says that Modaplex has gotten lost in the shuffle of excitement over next generation sequencing, which can produce similar results, but is much more time consuming and less cost effective in a clinical setting. NGS is currently more suited to academic research, he says. “What [the Modaplex] platform allows is to consolidate disparate types of testing onto a single platform. For a clinical lab with limited resources and personnel, this is a really impactful capability,” Schade says.

The companion diagnostics market is unlikely to falter anytime soon. As of 2012, companion diagnostics accounted for 8% of Qiagen’s fiscal year revenues, and others report similar returns – Utah-based Myriad Genetics, for example, reported that companion diagnostics comprised 5% of FY 2012 revenues. And presently, there are roughly 100 drugs in phase II, III, and IV clinical trials with companion diagnostic tests listed as potentially integral to their prescription and labeling. There’s no guarantee that all of these drugs will ultimately be paired with companion diagnostics, but the sheer number currently under consideration is a good indicator of what the future holds.

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