DEVELOPING YOUR COMPANION DIAGNOSTIC STRATEGY

By: Mark J. Roberts, PhD, Director of Diagnostic Development, Covance

As the pace of companion diagnostic innovation continues to accelerate, Covance has enhanced its development solutions to help our biopharmaceutical and diagnostic partners fill a void in the drug/companion diagnostic co-development process.

The drug development industry faces several headwinds. Numerous patent ‘cliffs’ are affecting the sales of blockbuster drugs; competition is increasing for a limited clinical trial population in increasingly global trials; and health outcomes pressures from patients, payors and healthcare providers are transforming the drug development process.

Over the past 10 years, advances in analytical technologies have provided new tools to identify patients who are more likely to positively respond to a certain drug or, conversely, experience a negative reaction to the particular therapy. These tools, known as companion diagnostics, are laboratory tests for biomarkers that, once commercialized, are designed to be an accompaniment to the safe and effective use of a particular therapy.

The Role of Biomarker Testing

Biomarker tests are enormously valuable in predicting response, lack of response or adverse responses to treatments. Genome sequencing can identify specific mutations and individual triggers, while expression levels can help individualize a treatment. One or more of these analytical tests can allow physicians to predict the response to therapy before treatment commences.

As for any therapy, these tests must go through clinical validation and regulatory approval before they can accompany their drug as a companion diagnostic.

Historically, companion diagnostics were introduced either late in the development process or even after the therapy is on the market when broader usage revealed sub-populations of patients with varied response to therapy. This rearview-mirror approach often required additional clinical trials, adding complexity, cost and time to the overall drug development process.

Early Design Considerations

Recognizing the need to develop these tools well before the compound’s pivotal trials, the industry is now shifting to consider a companion diagnostic strategy much earlier in the development process where it can be utilized to influence the design of the clinical trials.
If a known patient population expresses a biomarker indicating a varied response to therapy, this information is very powerful for stratifying the patient population to balance treatment arms. The risk of skewing an analysis with a weakly randomized population is therefore reduced. The same biomarker assay may then be used in later studies to exclude non-responders and amplify clinical outcomes.

**Blockbuster Potential with Companion Diagnostics**

In the early days of personalized medicine, there was reluctance to use a patient stratification tool for fear of reducing the patient population with downstream economic consequences. In practice, the opposite has been the case with the market welcoming the advent of targeted therapies with more clearly identified patient population. Indeed the term “nichebuster” has been attached to such drugs that, while indicated for only a subset of patients, still achieve annual sales in excess of $0.5 billion.

**Focusing on the Commercialization Approach**

The commercialization approach to a companion diagnostic strategy bears many similarities to that of a drug; a companion diagnostic is of little use if it doesn’t provide a result within a clinically relevant time frame, is too costly or is not widely available.

Most biopharmaceutical companies don’t have internal diagnostic expertise. For those that haven’t acquired or built their own internal capabilities, it’s crucial to select the correct diagnostic commercialization partner, as mistakes can be costly.

In doing so, sponsors must consider the partner’s size, global reach (instrument installed base) and diversity of technology as part of the decision process. While the early days of companion diagnostics saw a wide variety of partnerships springing up, most announcements these days reference diagnostic companies with a proven track record of delivering on companion diagnostic development projects – a factor that is a significant risk reducer for the drug developer.

**The Co-Development Process**

Covance has worked diligently to form partnerships with the top diagnostic providers across multiple technology areas. Working in a three-way partnership with our sponsors and their diagnostic commercialization partner, we can streamline the development process and illuminate decision points for both the drug and the assay.

Referred to as companion diagnostic co-development, this type of partnership leverages our ability to enroll patients globally, as well as offer development and validation of candidate biomarkers through the Covance Translational Biomarker Services group. With Covance acting as the collaborator, our sponsors learn how the diagnostic works in a true clinical setting, obtaining strong data for regulatory approval of both the drug and the diagnostic.

With the increasingly global nature of clinical trials, as well as the turnaround time (TAT) required by the drug sponsor, it is important to have central laboratory resources situated not only within North...
America and Europe but within Asia Pacific and in particular China and Japan. In addition to reducing TAT, these laboratories are able to address the challenges of importation of reagents and exportation of patient samples as well as execute any country-specific trials required to meet local device registration requirements.

Recently, Covance partnered with one of our sponsors and their diagnostic partner to support a global clinical trial evaluating a novel companion diagnostic. As the assay transitioned from the research labs to the clinics, we collaborated with the sponsor to provide feedback that allowed them to reduce site-to-site data variability through standardized procedures and training. As a result, our sponsor received reliable, consistent results when processing data from multiple global studies.

New Areas of Interest

Historically, companion diagnostic strategies were focused on oncology. More recently, we are seeing developments in other therapeutic areas such as inflammation, neurodegeneration and infectious disease. Companies are now considering all their options in personalized medicine to better tailor their compounds to targeted populations. In fact, many drug developers indicate that over half of their future compounds will be accompanied by a companion diagnostic.

Implementing companion diagnostic strategies into clinical trial drug design is revolutionizing drug development. At Covance, we are excited to be a part of the personalized medicine revolution.

Getting in touch to learn more about our drug/companion diagnostic co-development process can move you forward.

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Mark J. Roberts, received his PhD in Pharmaceutical Sciences from the University of Nottingham (UK) and has worked in the clinical diagnostics arena for over 20 years, holding senior positions in both the in vitro diagnostic and reference laboratory industries. He joined Covance in 2012 to spearhead our Companion Diagnostics initiative, designed to assist pharmaceutical and diagnostic companies in drug/companion diagnostic co-development.

Learn more about our drug development solutions at www.covance.com

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