

The Contract Diagnostics Organization: Revolutionizing Management for Co-Development of Companion Diagnostics

Specialty Pharma Interview with Mathew W. Moore PhD and Philip D. Cotter PhD, ResearchDx

The use of companion diagnostics in conjunction with custom pharmaceuticals is expected to expand as the promise of personalized medicine continues to be realized. However, a concurrent development cycle of both diagnostic and therapeutic components requires a complex synergy of both diagnostic and drug development, and represents a significant deviation from the current pharmaceutical model. In response, ResearchDx, LLC of Irvine, CA, launched the first-ever Contract Diagnostics Organization (CDO) in February 2011. This new business model facilitates simple, straightforward options to initiate the parallel development of companion diagnostic tests in synergy with drug development.

Specialty Pharma recently interviewed Mathew W. Moore, PhD, and Philip D. Cotter, PhD, Principals and Co-Founders of ResearchDx, to discuss the concept of a CDO and how this new business model stands to impact personalized medicine and revolutionize management of the co-development of companion diagnostics.

Q: ResearchDx is the first-ever Contract Diagnostics Organization (CDO)— what is a CDO?

A: With a shared passion for, and experience in, the field of personalized medicine, ResearchDx created the concept of the Contract Diagnostics Organization in response to the numerous pitfalls we have personally experienced in the companion diagnostics development process. With our team's extensive experience in managing clinical laboratories, designing and managing clinical research, and navigating the complex regulatory environment specific to diagnostics, we saw the opportunity to fill an unmet need for partnership with the biopharmaceutical and diagnostics industries. As a result, ResearchDx provides all of the services necessary to develop a companion diagnostic in an integrated, technology-independent manner that stays focused on our customers' business objectives. As a CDO, ResearchDx offers clinical research, a clinical laboratory, manufacturing, and consulting all in one organization - eliminating the need for outsourcing to multiple partners. This also builds in flexibility as well as the ability to implement an efficient, nimble strategy that may naturally shift as development continues.

Q: Can you speak to the uses of companion diagnostics in today's healthcare environment?

A: Broadly speaking, companion diagnostics can be used in one of three categories: (1) Patient Stratification; (2) Drug Dose Determination; or (3) Monitoring Treatment. In the case of Patient

Stratification, companion diagnostics can assist in identifying patients who will - and perhaps equally as important, who will not - benefit from a particular therapeutic treatment. With regard to Drug Dose Determination, biomarker information derived from companion diagnostics can be used to calculate appropriate drug dosage. In the area of Monitoring Treatment, companion diagnostic assays are used to monitor the effectiveness of a given therapeutic treatment. All of these applications - patient stratification, drug dose determination, and monitoring treatment - are integral to the overall concept and emerging era of "personalized medicine."

Q: The regulatory environment regarding diagnostic development seems to be rapidly changing; can you tell us more about this and how a CDO can help companies navigate this changing regulatory landscape?

A: The US FDA's guidance document The Drug-Diagnostic Co- Development Concept was drafted in 2005 to help outline a process to prospectively co-develop a therapeutic product and diagnostic test in a scientifically robust and efficient way. This document identified and outlined the recommended multi-step path from basic research to, ultimately, FDA filing and/or approval and product launch.

Following this, the FDA's Guidance on Pharmacogenetic Tests and Genetic Tests for Heritable Markers document was released in 2007 and intended to recommend a basic framework for the types of data and regulatory issues that should be addressed in a genetic test submission and provide a common baseline from which both manufacturers and scientific reviewers can operate. In June 2011, the FDA issued Draft Guidance regarding *In Vitro* Companion Diagnostic Devices. This document further emphasizes the importance of companion diagnostics and speaks to the co-development of drugs and companion diagnostics.

As evidenced above, the regulatory initiatives and guidance documents are numerous. As such, the need for specific expertise in the diagnostic industry throughout the companion diagnostic co-development process is paramount. Use of a CDO fills this need by bringing expertise in the area of diagnostics and diagnostic assay development to the companion diagnostic co-development process. To navigate the changing regulatory environment requires a depth of knowledge with regard to diagnostic assay development, and a CDO brings that level of knowledge and expertise.

Q: You mentioned experiencing pitfalls, or challenges, in your own experiences in the companion diagnostics development process; what are some of these issues and how can ResearchDx help companies combat these challenges?

A: The challenges faced are numerous, and may include any or all of the following:

- Knowledge-base, need for in-depth diagnostics knowledge
- Strategic, consideration regarding restriction of assay platform options
- Need for an accredited clinical laboratory partner
- Timeline management, coordination of parallel timelines for therapeutic and diagnostic development
- Management of multiple partnerships

In short, ResearchDx offers all of these services - all within one organization, and there is no need to manage multiple R&D partners because we do it all. As a CDO, ResearchDx can build, validate, and perform any assay that a business demands, or alternatively work with competing technology vendors to ensure the best fit for the application. Clients can trust that the focus and motivation from ResearchDx as a CDO are solely on the diagnostic development, with no competing interests. Our partnerships are based on flexibility, allowing us to build and validate any assay without bias toward existing product platforms, or to work with emerging technology to ensure the best solution. As a CDO, ResearchDx takes contract R&D for diagnostics to the next level. Our partners trust ResearchDx to provide everything they need to develop a diagnostic product, and that we will make their business objectives our priority.

Q: Your description of a CDO sounds similar to that of a Contract Research Organization (CRO); how do you distinguish between the two?

A: CROs have been traditional choices for outsourcing partnerships with pharma in the management of clinical trials for pharmaceuticals. However, CROs cannot provide the in-depth diagnostics knowledge, and many CROs do not have an accredited clinical laboratory solution for clients. A CDO provides all of the services and expertise needed from biomarker identification to submission for regulatory approval to manufacturing all from one partner.

Q: You describe ResearchDx as a non-competitor provider to pharmaceutical & diagnostics companies; what do you mean by that?

A: Because ResearchDx does not own a proprietary testing platform, we are able to ensure our clients' needs are met using the platforms and methodologies that best meet the commercialization strategy and needs of the client. ResearchDx provides all the necessary components of the companion diagnostics development process in an integrated, technology-independent manner that keeps the focus on the clients' business needs and objectives. ResearchDx can build, validate, and perform any assay that a business demands, or work with competing technology vendors to ensure the best fit for the application. Because ResearchDx has no competing interests, clients can trust that the focus and motivation is on the companion diagnostic development process.

Q: Describe the services offered by ResearchDx?

A: ResearchDx offers services in three key areas of focus: (1) Companion Diagnostics Services, (2) Clinical Laboratory Services, and (3) Manufacturing Services. Within our Companion Diagnostics Services, we offer independent and unbiased guidance, as well as expert and seamless integration of all the services pharma needs to develop a companion diagnostic assay. ResearchDx can design, manage, and coordinate all aspects of clinical trials for the development of a diagnostic product from assay concept to assay development, through to regulatory submission and commercialization.

Our Clinical Laboratory is CLIA-certified and CAP-accredited in which we perform high-complexity, esoteric laboratory testing. We are an ideal laboratory partner for companies looking to outsource high-complexity laboratory testing. We allow our clients to confidently offer a broad range of genetic testing and provide outstanding service to their ordering physician clients. Through our Clinical Laboratory Services, we offer seamless integration into our clients' lab operations and industry-leading turnaround times. As part of our Manufacturing Services, we offer clients a GMP manufacturing partner that will meet the unique specifications of a project, stay on target with the development timelines, and put our clients' business first. Services include manufacture of a range of products including reagent kit components and IVD kits for clinical trials or product commercialization. Our Manufacturing Services division offers clients unparalleled flexibility, focus, and experience.

While offering services in these seemingly distinct areas, we are able to deliver these services in a seamless manner to the client, in such a way that the client experiences an integrated services approach, with integration of all the services needed to develop a diagnostic product. We also pride ourselves on operating in a flexible manner that allows us the ability to adapt in order to meet clients' complex and constantly evolving needs during the diagnostic development process. We focus on our clients' business needs - our sole focus is our clients' diagnostic development needs.

Q: In closing, what do you see as the future of personalized medicine?

A: The basic science behind personalized medicine will continue to offer a myriad of choices for pharmaceutical companies to create companion diagnostics in healthcare, further driving the demand for companion diagnostic assays. In addition, there is already more attention being given to the field of personalized medicine due to the changing regulatory environment. The downstream market for custom therapeutics has significant untapped potential. Yet, the traditional bench-to-bedside development of such therapeutics can be arduous and inefficient. Opportunities to advance the practice of healthcare via personalized medicine may be lost in the development process due to the obstacles and challenges we have discussed. Yet, there is a solution. ResearchDx, as the first-ever CDO, can seamlessly provide everything a company needs, from start to finish, to develop a successful diagnostic product and impact the future of how medicine is practiced.

Reference

Specialty Pharma Interview: The Contract Diagnostics Organization: Revolutionizing Management for Co-Development of Companion Diagnostics. Drug Development and Delivery. 2012.
<http://specialtypharma.com/Main/Back-Issues/The-Contract-Diagnostics-Organization-Revolutioniz-434.aspx#sthash.rnltZuP.dpuf>