Company Profile

Labceutics

Laboratories are often the forgotten partners in the delivery of personalized therapies to physicians worldwide, yet the research and quality of their service in delivering seamless test results to physicians can either enhance the value proposition of a targeted therapy or destroy it. The need for integrated highest quality laboratory networks in fragmented markets such as Europe and Asia are needed to truly leverage the power of companion diagnostics.

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Labceutics was founded in 2010 to address the global personalized medicine (PM) industry's need for superior laboratory services aligned with physicians' delivery of therapy and treatment for patients. Labceutics has partnered with leading laboratories across the EU, Asia and other markets to address the increasing need for a comprehensive laboratory network on a global scale; a network that provides pharmaceutical and diagnostic companies with a 'one-stop' PM laboratory partner. Labceutics' specific focus is on the development and implementation of companion and diagnostic laboratory testing and related services that enable a high return on investment for personalized therapies.

PM is a term that means different things to different people. Over the past 10 years, its meaning has evolved and its importance has grown significantly. The most common stakeholders across the PM landscape include pharmaceutical companies identifying and developing new therapies and treatments for stratified patient populations, diagnostic companies that are developing and validating the targeted biomarkers associated with disease, the provider community comprised of physicians and medical professionals delivering 'individualized' care to patients, and finally, the payors that are making reimbursement decisions for the delivery of care in each region. Invariably, there is one key stakeholder that is conspicuously left out of these discussions, a group that in many ways is closer to care delivery than those mentioned above and significantly impacts and informs life-critical decisions: laboratories.

Effective healthcare delivery relies on quality laboratories to provide quality services to their prescribing communities, in fact, an estimated 60–70% of all decisions regarding a patient's diagnosis and treatment, hospital admission and discharge are based on laboratory test results [101]. However, with the global demand for molecular diagnostic and genetic testing the fastest growing area of clinical pathology laboratory testing [102], laboratories are often the forgotten voice in an area that has the potential to transform medicine.

Fragmented market

Unlike the diagnostic market, in which the top ten companies control 80% of the market, there are no dominant laboratory companies globally. Instead, each region is served by a combination of private, hospital and small specialty laboratories (an exception is the USA, where two major laboratory companies, LabCorp [NC, USA] and Quest [NJ, USA], are used by the majority of physician offices).The picture in the rest of the world shows an extremely fragmented market with different regional reimbursement dynamics, commercialization strategies and business goals. Labceutics addresses this fragmentation by enabling pharmaceutical and diagnostic companies to leverage the capabilities of leading laboratories in the EU, Asia and other markets. Labceutics' extensive experience working within the PM space has uncovered significant gaps in the companion diagnostic industry and laboratory space and our objective is to ensure that the right test is available to physicians when considering a personalized therapy. The network creates seamless availability of

Future Medicine part of fsg

testing to physicians and provides superior levels of service, including faster adoption and turnaround time, higher accuracy and better reporting, ultimately leading to better clinical outcomes.

Key areas in any successful companion diagnostic launch include ensuring pharmaceutical and diagnostic companies have established the optimal regional laboratory footprint and strategy (centralized or decentralized) based on specific therapy and indication; implementing proficiency and external quality assurance programs to ensure quality standards; and deploying a laboratory outreach program to the physician population that addresses education, test adoption and the delivery of seamless test results, all or which can either enhance the value proposition of a targeted therapy or destroy it. Labceutics' programs provide these services in an environment where clinicians routinely order and interpret large numbers of laboratory tests and testing profiles to diagnose, treat and monitor their patients, but have trouble keeping up with the changes in tests that they use in day-to-day clinical practice, to say nothing of the more specialized and complex tests they may encounter less frequently. Labceutics helps facilitate these 'high touch' clinical laboratory consultations, which is one of the most promising means of diminishing inappropriate test utilization and poor interpretation of results. In fact, a growing body of literature supports the need for better test ordering and interpretation through laboratory consultation services that supplement provider knowledge.

All of Labceutics' partners are certified laboratories: they have International Organization for Standardization (ISO), European accreditations or country-specific accreditations for external quality assurance. Providing novel technologies and a robust testing menu are significant drivers of their business models. Many of Labceutics' partners are participating in rapid multisite validation trials and evaluations, others develop high-quality laboratory-developed tests (LDTs) to improve choices in quality testing and provide development teams with key reference laboratories and experts to plan and conduct validation trials. The Labceutics network provides a ready infrastructure of clinical services including:

- Identifying, verifying, validating a biomarker or rescuing a drug through biomarker identification;
- Understanding signature of response;
- Conducting market research;
- Developing a test, array or kit;
- Validating the biomarker or signature and test (LDT or kit) or platform analytically and clinically for regulatory purposes;
- Performing retrospective analysis on samples from clinical trials or biorepositories;
- Validating the test and demonstrating clinical utility for the biomarker.

Monitoring progress via Labceutics CONNECT™

Proactive patients are compounding the demand for clinical information as testing becomes more complex and results more difficult to interpret. More and more, patients and family members are asking physicians questions about the value PM can bring to their specific case. This puts a significant burden on providers to provide answers given that there are more than 2500 genetic tests today, a figure that continues to grow at a significant rate [103]. Laboratories within the Labceutics network have access to the latest testing and technology being implemented and adopted through a secure information technology platform called Labceutics CONNECT™. The Labceutics CONNECT™ information technology platform provides a secure and ready communication channel amongst all laboratory partners, providing the latest information in PM and allowing immediate evaluation of testing issues to improve the mechanics of sample flows and key testing metrics. Labceutics CONNECT™ enables all network partners to securely share information, learn from each other in a peer-to-peer environment and collaborate on best practices to enable high-quality testing to support targeted therapies. Within the network, Labceutics conducts periodic surveys and studies to gauge network trends, collective thinking and opportunities for improvement. Survey results are shared to

help guide strategic planning and tactical execution, which enables our network to stay at the forefront of PM services.

Learning from laboratories

In fall 2011, Labceutics conducted a survey among its network to better understand the dynamics and pain points they are facing with respect to PM adoption [1]. The Labceutics study asked a number of questions of the participating laboratories relevant to their approach towards integrating and embracing the use of companion diagnostics. Key survey findings included:

- Laboratories as PM stakeholders have been largely forgotten by pharmaceutical companies, yet hold the key for successful companion drug/test combinations;
- Unlike the USA, Europe has a fragmented laboratory market with strong country personalities, therefore centralized approaches may not be effective;
- A decentralized laboratory strategy in Europe will enable a 'high touch' service among laboratory managers or pathologists and physicians;
- One-size-fits-all laboratory testing plans or 'kit' approaches will encounter slow uptake in Europe given the preference for LDTs in this region;
- Successful introduction of PM therapeutics and companion diagnostics must include early preplanning with laboratories.

The survey indicated that 40% of laboratories take between 7 and 12 months to fully implement a new test and a further 25% indicated that they could make a new test available in 3–6 months. These lag times required to prepare for the introduction of these novel tests are rarely understood by the pharmaceutical industry today, which opens up the very real risk that the demand for a therapy will be held back by the lack of ready availability of a test to a physician, either through lack of oversight of such minor details like the presence of the test on the physician's laboratory order form or, more likely, through long delays in turnaround time during the launch period that will undercut physician confidence in using the test and, therefore, the therapy.

Laboratories also revealed through the survey that there are four key 'very important' areas of concern for early focus in test adoption as they require long lead times to adequately address:

- Optimization and validation of the new test method
- Availability of quality control
- Protocols standardization
- Training in the interpretation and notification of results

Superior service translates into return on investment

The research and experience Labceutics has in the marketplace clearly demonstrates that therapy teams seeking to improve the doctor–laboratory dynamic and facilitate use and interpretation of a particular targeted therapeutic should be engaging with laboratories that specialize in providing 'gold-plated' services to doctors. The Labceutics network provides a higher level of service to the point that it actually adds value to the treatment creating a halo effect for both the laboratory and the therapy. The quality and value of laboratory information depends on an array of factors, including selecting the right test at the right time for the right patient. There can be a significant difference in laboratory use among physicians investigating patients with the same diagnosis and also a significant number of tests that are ordered unnecessarily. Even if doctors believe a test is relevant, they may hesitate to requisition it if the order process is unwieldy or the form is confusing. Conversely, reports that are difficult to read or interpret, or that present ambiguous results, may deter physicians from reordering a test. Physicians may choose to order a test from a different laboratory, or not to order it at all. As guidelines do not necessarily specify the preferred testing method (kit or LDT), pathologists are typically responsible and trusted by physicians to determine the right method of testing, which can cause a level of confusion.

Grouped together, these challenges conspire to negatively impact appropriate test adoption. Labceutics allows pharmaceutical companies to communicate

directly with laboratories that are working directly with the prescribing doctors. The quality and access of available testing is optimized for the specific PM drug launch and fully integrates into the drug brand. Labceutics 'PM-ready footprint' enables rapid market access, transparency and clinical services that result in significantly improved test turnaround time, resource savings and improved outcomes. Whether an LDT or *in vitro* diagnostic, Labceutics covers all the bases to ensure the highest testing quality, standards and delivery.

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