BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Cutting Clinical Costs with Companion Diagnostics

01 September 2024 | Analysis | By Ayesha Siddiqui

Advancing personalised medicine has become a key goal for many pharma firms, evident from the rising number of such therapies under clinical development. In 2022 alone, 12 new personalised medicines were approved, marking these treatments as accounting for at least a quarter of new drug approvals over the past eight years. This contrasts sharply with a decade ago when personalised medicines constituted less than 10 per cent of new approvals annually, according to The Personalised Medicine Coalition report. As the trend towards precision medicine and targeted therapies continues, companion diagnostics (CDx) are becoming increasingly vital, particularly in oncology. Let's explore the opportunities that CDx presents and the hurdles in their development and implementation.

Companion diagnostics (CDx) are the cornerstone of precision medicine and play a critical role in optimising patient outcomes and reducing healthcare costs by ensuring that therapies are tailored to individual patient profiles. Currently, there are 51 CDx tests approved by the US Food and Drug Administration (FDA). The majority of these are for haematological malignancies and solid tumours. In fact, of the 170 approved indications listed on the FDA website for companion diagnostics, only three are for non-oncology drugs.

In addition to their role in personalised medicines, CDx can also enhance clinical trials and expedite drug development by pinpointing appropriate patient populations. Research and Markets indicates that CDx-guided drug development has the potential to cut clinical trial costs by up to 60 per cent. This allows pharmaceutical companies to bring proven drugs to market more quickly and at a lower cost through clinical trials. That's why there has been a rise in partnerships between pharmaceutical companies and diagnostics firms. Notable examples include Incyte's collaboration with Agilent on CDx development, Foundation Medicine's partnership with Repare Therapeutics to provide genomic profiling services and develop CDx., Additionally, there's Roche and Janssen's strengthened collaboration to develop CDx tests for targeted therapies.

Challenges in CDx development

There are several key stages involved in developing a CDx test all of which must be synchronised with drug development. “CDx development and commercialisation processes are rigorous and involve close alignment across multiple stakeholders, which can make meeting clinical timelines a big challenge. Navigating the complex and evolving regulatory landscape across different regions can also delay approval and implementation,” said **Karina Kulangara, Associate Vice President, R&D, Companion Diagnostics at Agilent Technologies.**

Currently, approval of a CDx test is mandatory in four major markets—the US, EU, Japan, and China—where it is linked to the market approval (and sometimes reimbursement) of the therapeutic product. This landscape is evolving, with additional countries such as Australia, Canada, and South Korea planning to gradually implement mandatory CDx test approvals for therapeutic products in the coming years.

“In the intricate and dynamic landscape of global regulations, an increasing number of countries are adopting advanced regulatory frameworks. This shift necessitates that companies specialising in diagnostics and therapeutics engage in early-stage coordination during their development processes. Such proactive collaboration is essential to achieve strategic harmony among industry players and to align with the mandates of external regulatory authorities. Ensuring this alignment is crucial for navigating the complexities of the global market and for the successful deployment of medical innovations,” said **Randy Evans, Vice President, Medical Affairs at BD Biosciences.**

Molecular diagnostics is a fast-paced and ever-changing field, with new markers and technologies advancing at a significant rate. Keeping up with these changes can be both a challenge and an opportunity.

“The main challenge I see is that their development and implementation are fragmented, even within the same tumour subtypes driven by the same genetic alteration and therapeutically addressed with molecules with comparable mechanisms of action. This increases the complexity in their implementation and the associated development costs,” said **Dr Francesco Hofmann, Head of R&D at Pierre Fabre Laboratories.**

And of course, another major challenge in CDx development is clinical uptake, especially without a clear path to test commercialisation. Research from Diaceutics indicates that, on average, there is a 4.5-year gap between the launch of a new test and its clinical adoption among the biomarker-positive patient population it targets. As a result of this delay, up to 50 per cent of oncology patients may not have access to the testing needed to identify the most suitable biomarker-guided treatment for their condition.

“Without effective strategies for distribution, provider awareness and education, CDx may face delays in reaching both healthcare providers and patients. However, collaborating with a company that excels in commercialisation can help overcome these barriers. It helps to ensure that the CDx are not only ordered efficiently but also that providers are well-informed and educated about their use. This leads to quicker access to targeted and more effective therapies for patients and improves overall adoption and integration into clinical practice. It’s best to work in parallel with drug development to create a test tailored to a novel therapeutic, which helps make the most of the opportunity to reach the right patients at the right time,” said **William Finger, Vice President and General Manager, Pharma Services, Quest Diagnostics.**

Road ahead

Currently, approximately 50 per cent of drug approvals in oncology include a CDx or biomarker on the label. Moving on to the future, the use of CDx is anticipated to grow beyond oncology, potentially covering other areas such as metabolic, cardiovascular, and neurological disorders.

“While CDx have historically focused on oncology applications, we anticipate significant expansion into other therapeutic areas as more clinically relevant markers are discovered for different disease states. We're already seeing CDx moving beyond oncology into hereditary and chronic diseases,” said **Victoria Fox, Senior Director, Global Marketing Excellence MDx & Head of APEC Regional Marketing, QIAGEN.**

QIAGEN has partnered with pharmaceutical firms on QIAstat Dx for Metabolic Dysfunction-Associated Steatohepatitis (MASH), a liver disease that can progress to fibrosis and cirrhosis if untreated. In 2022, Neuron23 and QIAGEN announced their collaboration to develop a CDx – the first to be developed for Parkinson’s.

Genomic data serve as the core of CDx, and advancements in genomic technologies are driving the development of more effective diagnostics. Moving forward though, beyond genomics, multi-omics approaches—including proteomics, metabolomics, and more—will enable a more comprehensive understanding of disease pathways, thereby increasing the accuracy of personalised treatment through integrated multi-omics data.

“As precision medicine becomes more widely adopted, we expect the use of CDx to grow. Over the next five years, we anticipate CDx will continue to evolve along two simultaneous paths. One path involves leveraging multi-omics approaches, integrating genomics, transcriptomics, proteomics and metabolomics to offer a comprehensive view for patient stratification and treatment personalisation. With multi-omics providing broader insights and focused tests ensuring the right patients receive the most effective targeted treatments,” said William.

Randy agrees, “As the number of therapeutic options increases, there will inherently be more solutions and CDx can provide a competitive advantage for biopharma. From a technology perspective, using a multimodal approach (e.g. genomic and proteomic) could lead to even better outcomes by enabling an even more personalised approach.”

As with everything these days, AI is expected to enhance the accuracy, turnaround and efficiency of CDx tests.

“With advancements in genomic technologies, the integration of big data and AI will become increasingly important. AI will play a pivotal role in efficiently interpreting genetic information, discovering new biomarkers, and predicting potential treatment options, thereby significantly enhancing the precision and effectiveness of CDx,” said a spokesperson from Macrogen.

“Advances in biomarker discovery and next-generation sequencing technologies will likely drive the development of new and more sophisticated CDx tools, such as AI-enabled CDx,” said **Adrianna Shen, International Business Leader for Personalised Healthcare Solutions, Roche.**

Companies like Agilent and Roche are incorporating AI into CDx development through strategic partnerships and technological advancements. Roche entered into an agreement with PathAI, a provider of artificial intelligence (AI)-powered technology for pathology. Under the terms of this agreement, PathAI will exclusively work with Roche Tissue Diagnostics (RTD) to develop AI-enabled digital pathology algorithms in CDx space. Agilent has also partnered with several digital pathology providers to combine their assay development expertise to create integrated solutions that enhance the accuracy and efficiency of CDx tests by leveraging AI for better data interpretation and analysis.

Next-generation sequencing (NGS)-based in vitro diagnostic (IVD) testing has been expanding rapidly over the last five years to become the preferred CDx for many drugs and experts believe this trend will continue in the future as well.

“In the next five years, CDx will play an increasingly important role in ensuring patients receive the best treatment possible for their disease based on their unique genomic profile. Specifically, NGS-based CDx tests are the future of CDx as they can simultaneously evaluate multiple biomarkers at an accelerated rate compared to single biomarker testing,” said **Kathy Davy, President of Clinical Next-Generation Sequencing at Thermo Fisher Scientific.**

As healthcare systems continue to embrace precision medicine, CDx will play a critical role in optimising patient outcomes and reducing healthcare costs by ensuring that therapies are tailored to individual patient profiles.

“The ultimate goal is to make therapies available sooner to the correct cohort of patients, closing the gap between diagnosis and treatment. As CDx technologies continue to improve in speed, accuracy, and cost-efficiency, we expect to see more personalised treatment approaches across a broader range of diseases,” said Victoria.

“Evolving regulatory frameworks and increased collaboration between pharmaceutical companies and diagnostic developers is expected to facilitate smoother integration of CDx into clinical practice. Overall, while there are hurdles to overcome, the benefits of CDx in enhancing precision medicine are immense and transformative for patient care,” said Adrianna.

With a shift towards precision medicine and targeted therapies becoming more prominent, it’s only natural that a shift towards CDx, and tests that can qualify patients for gene therapy, will follow. Enhanced collaboration between diagnostic and pharmaceutical companies will help to drive innovation, ensuring that companion diagnostics are seamlessly integrated into personalised treatment regimens.

Ayesha Siddiqui