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Trends and Innovations in Companion Diagnostics

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Abstracts

Are companion diagnostics becoming a “must have” for market access?

Companion Diagnostics (CDx) are playing an increasingly vital role in market access by supporting product value claims and improving patient outcomes. What are the upsides for developers, pharma, payers and physicians and how can the challenges around new technology adoption, reimbursement and clinician uptake be overcome?

To really understand the issues and trends that are shaping the CDx market, senior managers in diagnostic development companies and the pharma industry should turn to this report.

“Pharma companies around the world are scouring tumour cells to find something different. It’s logical that detecting those differences would in fact then be down to a companion diagnostic.” Rob Steitz, Insight Genetics Inc.

Answering key questions:

Pharma’s benefit: Are CDx becoming essential for regulatory approval and clinical diagnosis?

New therapy areas: Beyond oncology, what therapy areas are being targeted by CDx?

All in the timing: At what stage should CDx be included in a drug’s development?

New technologies: How revolutionary will next generation sequencing, liquid tumour testing, biopsies and bioinformatics be in driving future uptake of CDx?

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Engaging Physicians: Many physicians do not use approved CDx, or choose alternatives. Should the use of approved CDx be mandatory and enforced?

Where's the money? Reimbursement models do not reflect the wider value of advanced CDx – what are the options for change and how is this influencing developers thinking and investment?

Point of Care: What are the future prospects for the development of PoC CDx?

With this report you will be able to:

Identify the new CDx approaches and evaluate their benefits.

Understand how and where they will impact the market and review the challenges they must overcome.

Assess the activities, policies and partnerships of CDx-progressive pharma companies.

Understand how financial and reimbursement models need to change to reflect the real value of CDx.

Learn how advanced CDx can radically improve clinical trial research and outcomes.

Formulate strategies that encourage physicians to use approved CDx.

Identify the therapy areas and conditions where next generation CDx will make an impact.

Grasp the growing importance of research consortia in the identification of biomarkers.

Key Topics Explored:

Pharma is sometimes compelled to identify a CDx as part of securing regulatory

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approval, but physicians are not obligated to use it. Is it time to make their use mandatory?

Reimbursement models do not allow for premium pricing of advanced CDx. Taking potential cost savings and improved patient outcomes into account, isn't it time that a fair price was paid?

Some pharma companies may see CDx as unnecessary revenue capping, while others take a more progressive view. Will the benefits of CDx mean they become key in supporting value claims and securing market access?

Pharmaceutical companies, diagnostic companies, patients, physicians, payers, testing laboratories and regulators are all stakeholders. They should be engaged as early as possible.

Payers have most to benefit by using CDx to ensure that expensive drugs are prescribed optimally, so why are some payers concerned?

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All respondents met FirstWord's stringent screening criteria, and were compensated for participating. To encourage frank and forthright responses, their names have been withheld.

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