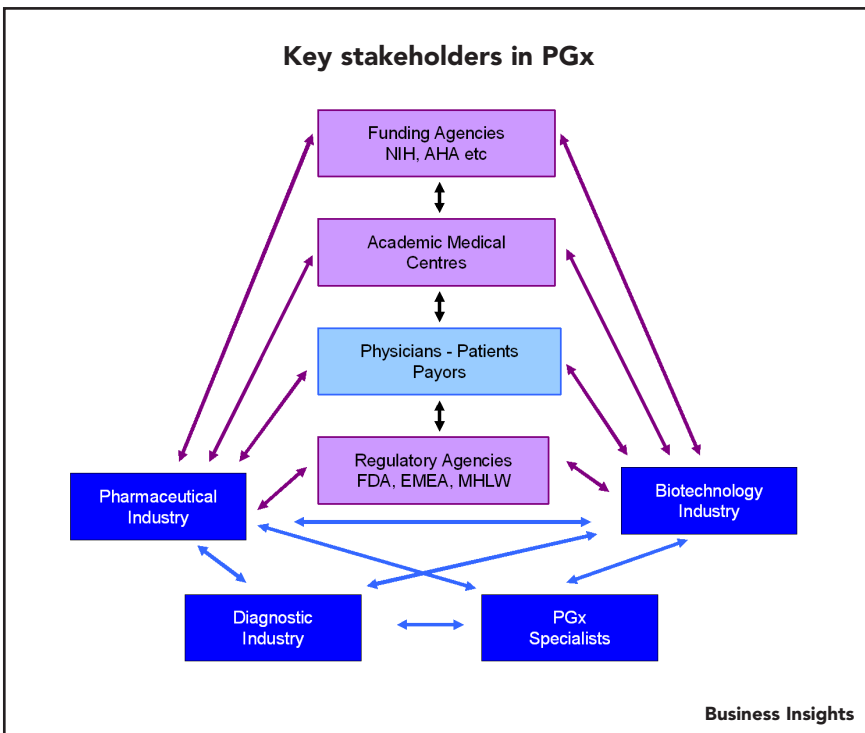


BUSINESS INSIGHTS

Impact of Pharmacogenomics on Public Healthcare Policy

Educating patients, payors and regulators

For more information,
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“Companies such as **Abbott, Johnson & Johnson** and **Roche** are in a unique position to maximize their PGx potential both in their diagnostic and product development programs. However, large pharma are increasingly forming strategic alliances with specialists and diagnostic companies in order to strengthen their position within this field...”

Examine the rapidly advancing fields of pharmacogenomics and pharmacogenetics, and measure the impact of pharmacogenomic techniques on reimbursement and health economics with this new report....

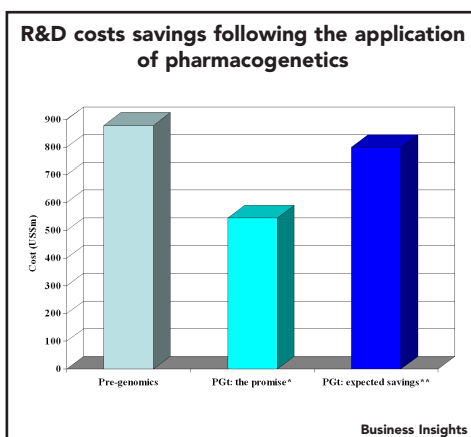
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Some key findings from this report...



"The application of genomic technologies could reduce drug development costs by up to US\$335 million if PGx was successfully applied in each project. However, given that PGx may not always be applicable the group anticipate that PGx has the potential to result in average cost savings of US\$80 million where it's application is successful..."

- **Pharmacogenomics (PGx) can improve drug safety and efficiency to increase success rates in pharma R&D.** Although the biotech and diagnostic industries have been quick to adopt this technology, the pharma industry has been the slowest to realize the potential benefits.
- **Regulators in the US, Europe and Japan are beginning to engage in the collection, submission and analysis of PGx data** through a newly established regulatory framework. However, there are concerns that regulations that may stifle innovation in this rapidly evolving field.
- **Pharma, biotech and diagnostics companies have adopted a variety of PGx strategies** in their R&D programs, and in some cases have active companion diagnostic programs that run in parallel.
- **The pharma industry continues to fight for cost-effectiveness and fair reimbursement in PGx tests and products.** PGx testing is generally not mandatory prior to drug prescription and approval does not currently guarantee reimbursement.
- **The patent landscape will become more complex as companies seek to develop personalized medicines** in an effort to improve the proprietary status of approved and novel drugs.

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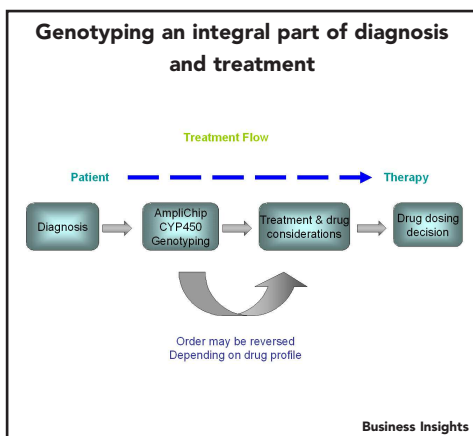
Impact of Pharmacogenomics on Public Healthcare Policy

Immense advances in genetic code decipherment over the last decade have recently led to personalised medicine, or 'the right drug for the right person', becoming an achievable concept. Pharmacogenomics (PGx) embodies the principles of personalised medicine by combining pharmacology with genetic information to improve drug safety and efficiency. The pharma industry is currently applying PGx throughout its R&D processes to enhance decision-making, streamline clinical trial design and reduce drug failures and product withdrawals. Companies are also attempting to increase the impact of PGx by engaging in strategic alliances and collaborations. However, it is crucial that governments and regulators provide sufficient rewards for developers if innovation in this field to continue. This can be achieved by establishing suitable incentives, regulatory frameworks and reimbursement environments.

Impact of Pharmacogenomics on Public Healthcare Policy: Educating patients, payors and regulators is a new report published by Business Insights that examines how PGx implementations can help to improve efficiency and productivity within the industry, across the fields of pharma, biotech and diagnostics. The PGx strategies of major companies are profiled and recent alliances and licensing opportunities are highlighted. This report discusses how reimbursement issues may influence the uptake of PGx and assesses major regulatory issues in Europe, Japan and the US. The current market trends, future challenges and opportunities facing PGx are also investigated.

Discover the potential value of pharmacogenomic tests and products to your R&D program, identify the latest regulatory and reimbursement issues and benchmark PGx implementation strategies with this report...

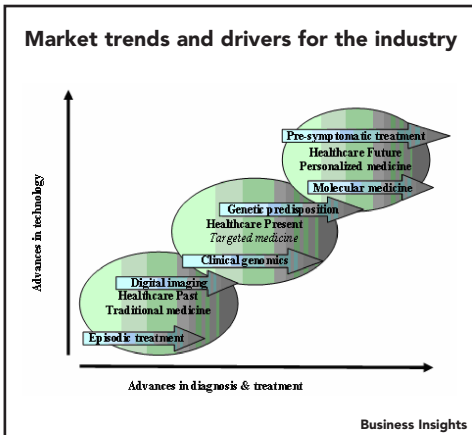
Top five reasons to order your copy today



- **Identify how companies are implementing PGx technologies** with this report's analysis of **key strategies, alliances and licensing opportunities** for major pharma, biotech and diagnostics companies.
- **Discover how PGx can create cost-savings through improved decision-making and reduced development times** by examining the challenges and opportunities facing this technology and assessing the realistically attainable benefits.
- **Understand the latest reimbursement issues influencing coverage, coding and payment in the PGx field** by using this report's profile of key reimbursement drivers and analysis of the cost-effectiveness and commercial viability of PGx tests and technologies.
- **Assess the extent to which changes in the regulatory landscape may influence future applications of PGx** with this report's analysis of influential white papers currently under review and major developments in the regulatory environments of **Europe, Japan and the US**.
- **Evaluate stakeholder importance in the uptake of PGx products and tests** and understand how education and patient consent will affect PGx utilization in the drive towards personalized medicine.

"Roche is in the process of developing microarray-based PGx diagnostic tools for HIV-1 resistance genotyping, p53 cancer resequencing, colorectal cancer risk prediction, cystic fibrosis, leukemia sub-typing (AML and AMML) and human papilloma virus genotyping (a the leading cause of cervical cancer) due to its commitment in PGx and its belief that genotyping will become an integral part of diagnosis and treatment..."

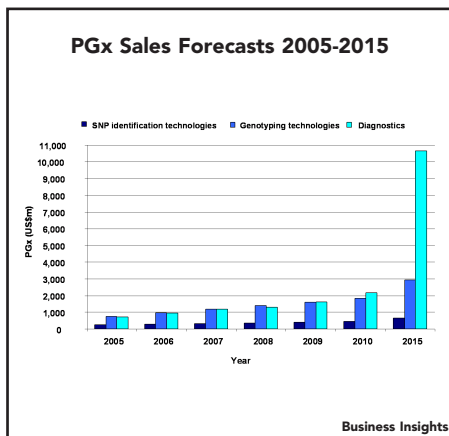
Key issues examined in this report...



"Many of these drivers provide stakeholders with significant challenges and opportunities now and in the future, including the uptake of other new technologies, the migration towards automated systems, the transition towards personalized medicine and the evolution of clinical practice..."

- **Productivity improvements.** PGx technologies aim to alleviate the current productivity crisis in the biopharma industry, specifically in terms of regulatory approvals, reimbursement, containment of R&D costs and accurate stratification of patient populations.
- **Industrial consolidation.** Reductions in productivity have been one of the key factors driving consolidation within the pharma industry. The application of new technologies such as PGX testing and patient stratification is helping to address this issue.
- **Go/no-go decision-making.** The additional information and resources associated with PGx applications can be used to make go/no-go decisions earlier in the drug development process, reducing the financial liability of potential drug failures.
- **Toxicology and safety.** Effective PGx implementations can result in the earlier identification of toxicology and safety issues in late-stage R&D. Clinical trials can then be adapted to reposition the drug candidate, significantly reducing the prospect of negative publicity.

Your questions answered...



"By 2007, it is estimated that the PGx market generated nearly US\$2.7 billion of sales. This figure is forecast to increase to US\$4.4 billion by 2010 and over US\$14.0 billion by 2015, as a plethora of PGx tests reach the market to diagnose and aid the treatment of neuropsychiatric disorders, cancer, immune disorders and infectious diseases ..."

- What is PGx and how is it being applied in the industry?
- Which of the leading companies adopting PGx and how are they applying it to their development programs?
- What are the opportunities and challenges facing PGx?
- Which strategies are diagnostic companies using to develop PGx tests?
- What reimbursement hurdles do PGx tests and products have to overcome in order to reach the market?
- How is the evolution of PGx changing the reimbursement environment?
- How will regulatory frameworks provide incentives for the adoption of PGx technologies in the future?
- What is the current IP landscape within the PGx field?

Sample Information: 'Impact of Pharmacogenomics on Public Healthcare Policy'

Chapter 2: Implementation of PGx by the industry

Efficacy studies

According to industry experts the response rate to current medicines is unacceptably low (Figure 2.8). For many therapy areas, less than 50% of the addressable patient population responds to therapy, raising the question of whether or not the right drug is being prescribed to the wrong patient. Therefore, the industry needs to identify predictive markers that can help in the development of more efficacious medicines.

PGx screening has the potential to identify patients that may respond to therapy provided there is a high genetic component to the drug response. However, there are many genetic and non-genetic factors that influence the efficacy and outcome of drug treatment. For example, enrichment of studies based on patient characteristics – demographics, pathophysiology, history, genetics, gender, age – can enable the industry to select patients for study in order to make the detection of a drug effect more likely. Enrichment does not stratify patients and raise questions of generalization. Trials are designed to assess group effects and not individual responses; however an increase in our understanding of the underlying cause of a disease or mechanism of action of a product can help in enrichment strategies.

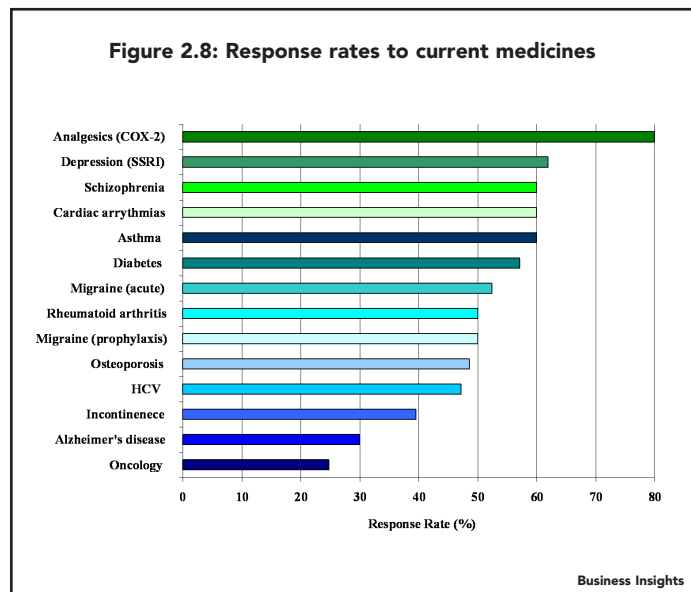


Table 2.4: Patient stratification for Herceptin trials

Trial Design	With Her-2neu	Without Her-2 neu
No. of patients	470	2200
Response Rate	50%	10%
Years of follow-up	1.6	10

Business Insights

Enrichment strategies were adopted in the development of Roche/Genentech's Herceptin (trastuzumab) for the treatment of breast cancer. Herceptin is an antibody that blocks cell surface Her-2 receptors that are over-expressed in approximately 20% to 25% of breast cancers which contribute to cancerous cell growth. During the development of Herceptin a Her-2/Neu-2 clinical trial assay (CTA) was developed to help identify over-expressing patients.

The stratification of patients resulted in smaller trial sizes leading to cost-savings of around US\$35 million. This resulted in the acceleration of the development program by eight years which led to revenues of US\$2.5 billion, and has enabled 120,000 patients to gain access to the drug.

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