Industry perspectives on personalized medicine

Although the potential of personalized medicine based on genomic knowledge has been widely discussed for more than a decade, the pace of implementation has been less rapid than initially hoped. To better understand the current role of personalized medicine and pharmacogenomics in drug development, the Tufts Center for the Study of Drug Development conducted interviews and a follow-up survey of a group of companies about the current role of personalized medicine and pharmacogenomics in their company. Overall, information was collected from 21 companies (9 major biotechnology companies and 12 large pharmaceutical companies) between 2009 and 2010; see [Supplementary information S1](#) (box) for details).

When asked what percentage of their company's current clinical development pipeline comprised personalized medicines, responses ranged from 12% to 50%. Up to half of a company's pipeline projects could have associated biomarkers, but substantially fewer projects (10% or less) had identified specific target populations or companion diagnostics. All companies noted that biomarker research is done for compounds before they enter clinical development. However, having a biomarker was not a requirement to move into clinical development for 70% of the companies; in addition, the follow-up survey indicated that across the companies about half of the compounds in early stages of development and a third in late stages use biomarker data in the development process (FIG. 1a). All of the companies explained that the primary intent of biomarker development was to provide more

information about products internally, not for prescribing or monitoring a marketed product. For this reason, the few companies that require associated biomarkers for compounds in development also require personalized medicine end points for all trials, and use these end points for decision making.

These measures of usage across company pipelines varied considerably between therapeutic areas. As indicated in FIG. 1b, oncology was the most cited area in which the companies that were investigated were focusing their personalized medicine research and development (R&D) efforts. The responses indicated that R&D activity was also robust in immunology and neurology, as well as rapidly advancing in other therapeutic areas such as anti-infectives and metabolic/endocrine disorders.

Beyond the scientific problems, respondents considered that utilizing pharmacogenomic data was challenging because of a lack of

regulatory guidance. Although progress has been made — such as the release of [draft guidance](#) from the US Food and Drug Administration on pharmacogenomics in early-phase clinical studies — many companies felt that they were unable to use pharmacogenomic data in an approval package until pathways are better defined.

Overall, the respondents were generally optimistic about personalized medicine as a more promising path forward for the industry than the blockbuster model. This approach may enable the industry to overcome its productivity shortfall, so they believe, because targeted medicines are more likely to tip the scales of regulators' benefit–risk decisions in favour of approval, as well as influence payers' product value assessment more favourably towards reimbursement. Thus, respondents believed that the impact of personalized medicines on R&D generally, on company portfolios and in the marketplace will be strongly felt for the foreseeable future.

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Figure 1 | Role of personalized medicine approaches in industry: survey responses.

a | Percentage of company pipeline relying on biomarker data. **b** | Number of times respondents mentioned personalized medicines for particular therapeutic areas (see [Supplementary information S1](#) (box) for details). CNS, central nervous system.