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**Aspects, Prospects and Visions. Personalised Medicine: the Role of Predictive Biomarkers**

The zeitgeist of 21st century medicine can be summed up with two words: personalised medicine. Indeed, this tiny phrase encapsulates the spectrum of components that comprise the modern healthcare ethos: improved drug safety and efficacy, faster/smaller clinical trials, cutting edge science (based on genomics and proteomics) that includes biomarkers, new diagnostics and reduced drug spending, to name but a few.

One of the key aspects personalised medicine, and the expected benefits, is the idea that with modern bio-technologies we can identify specific patient characteristics that will enable physicians to prescribe the most effective treatment for the disease or condition; or conversely, avoid prescribing a treatment that will not be of benefit.

Accordingly, a key aspect of personalised medicine is the identification of a marker that can correctly and consistently predict the efficacy of a particular therapeutic agent in any given patient. These markers are known as predictive biomarkers.

The identification of predictive biomarkers is most advanced in oncology, probably driven by substantial breakthroughs in basic scientific research that have identified many genes and proteins involved in the genesis, progression and spread of cancer. Coupled with this is the deep desire to: improve efficacy (many patients do not respond to currently available therapies, and there are still many cancers without effective therapies); minimise unnecessary toxicity (many therapies are often associated with unpleasant and even life threatening side effects), and reduce overall costs (administering agents to individuals who do not respond is not cost effective).

The power of predictive biomarkers in oncology is clearly exemplified in metastatic colorectal cancer (mCRC). Here, epidermal growth factors receptor (EGFR) inhibiting antibodies (such as panitumumab) are approved for use in combination with various chemotherapy regimens or as monotherapy for the treatment of mCRC. In 2008, data from an Amgen trial were published showing that patients with tumours that had a mutation in a single gene called *KRAS* do not benefit from EGFRIs, but if *KRAS* is unmutated (wild type) patients could potentially benefit. Following confirmatory studies, it is now a requirement for physicians to routinely test patients’ tumours for *KRAS* mutations prior to administration of an EGFRI. Recognizing the importance of predictive biomarkers, we at Amgen have embarked on ambitious biomarker discovery programmes, integrating biomarker-based analyses both retrospectively and prospectively into our clinical trials.

So what are the prospects for ensuring a sustainable future for personalised medicine?

Ultimately, it is necessary to: continue driving basic scientific research to identify potential new biomarkers; construct intelligent clinical trial designs that prospectively include analyses for potential predictive biomarkers and develop regulatory protocols that allow rapid and safe integration of new scientific information into trials and clinical practice. Furthermore, it is essential that European policy makers, the pharmaceutical industry, and country healthcare systems consider how to optimally integrate biomarker technologies and testing programmes into future clinical practice.

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