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Use of Biomarkers – The Regulatory Perspective

The external environment requires change from the way we used to develop drugs. At a time when basic science is making radical progress the development costs of pharmaceuticals continue to increase and the output from R&D does not keep up with the pace of evolving science.

It is acknowledged by the key stakeholders - academia, pharmaceutical industry, regulatory authorities and patient advocacy - that significant collaborative initiatives are required to utilise the opportunities being offered by scientific progress and new technologies.

Biomarkers and surrogate endpoints will be key in developing more efficacious and/or safer drugs and will help to create the best medicine for the right patient at the right dose and the right time.

This presentation reviews opportunities and challenges for using biomarkers from a regulatory perspective. Key EMEA and FDA initiatives are being discussed. These are aiming at the creation of a regulatory framework that will enable stakeholders to realise the potential of the biomedical and technological developments of the last few years.

The holding of initial workshops, creation of cross-functional working parties and setting up of informal meetings to discuss strategies or data surrounding biomarkers have helped to identify and prioritise issues and provided a forum for mutual learning.

Future drug development will have to be accompanied by even earlier dialogue among the stakeholders than today and all parties need clarity when investigating a novel target, a new technology platform or a promising compound/compound class.

Many questions have to be addressed as to what will be required by regulatory authorities, how this can be achieved at a reasonable cost, what might be acceptable for earlier access to the market and how this information will be assessed during the review of a new drug application. Furthermore the question of how biomarker information will be reflected in product information is of paramount interest to all parties involved.

Several examples of recently approved oncology drugs are discussed where data involving biomarkers or surrogate endpoints were part of the review and subsequently reflected in the product information and the European Public Assessment Report (EPAR).

While the stakeholders are aware that we are just at the beginning of a promising and exciting journey significant first steps in the right direction have already been taken.