NEWS IN BRIEF

Database of cancer uncertainties launched

The UK's National Institute for Health and Clinical Excellence (NICE) has launched a new database that aims to identify and prioritize future cancer research across Europe.
The lowdown: In conjunction with the CoCanCPG (Coordination of Cancer Clinical Practice Guidelines in Europe) consortium, NICE has developed the database of cancer uncertainties, which is in a pilot phase until the end of January 2010 (http://www.nice.org.uk/aboutnice/howwework/researchanddevelopment/cocancpg.jsp). The database has been developed because evidence gaps or uncertainties in cancer management are often highlighted during guideline development (including systematic reviews and economic modelling) or post-production of guidelines (exploring the research recommendations and other stand alone uncertainties in cancer management). Examples include uncertainty about clinical effectiveness, cost effectiveness, diagnosis, prognosis, appropriate outcome measures and identification of adverse effects. Guidance published with the database also discusses the reasons why uncertainty may arise. These include research that was not methodologically robust, inconclusive results, or the enrolment of too few patients to achieve statistical significance.

The CoCanCPG consortium aims to identify all uncertainties in cancer guidance and prioritize recommendations for future research. In addition, the consortium will promote the research recommendations to potential funders. CoCanCPG consists of 16 institutions from 11 countries that are involved in the funding and management of clinical practice guidelines for cancer. It was established in 2006 and is partly funded by the European Commission. Overall, CoCanCPG aims to reduce duplication of efforts between institutions that are developing guidelines across Europe and, in the long term, to have consistent policies and patient-oriented strategies for cancer care at the regional and national levels.

Regulatory review goals must be met

John Jenkins, Director of the Office of New Drugs (OND) at the Center for Drug Evaluation and Research (CDER) at the US FDA, has withdrawn permission for reviewers to extend timelines for evaluating regulatory applications that are required under the Prescription Drug User Fee Act (PDUFA).
The lowdown: As part of PDUFA (currently PDUFA IV, which was re-enacted as part of the FDA Amendments Act (FDAAA) 2007), the FDA is required to respond to 90% of standard submissions in a review time of 10 months, and 90% of priority reviews within 6 months. In November 2007, John Jenkins granted permission to managers of the OND to "exercise greater flexibility regarding PDUFA goals due to workload/resource constraints". On 3 December 2009, during his "New Drug Review: 2009 Update" presentation to the FDA–CMS (Centers for Medicare and Medicaid Services) summit, Jenkins withdrew permission to miss PDUFA goals, stating that they should be met wherever possible. This may in part be because the staff numbers at the OND have increased by 26% since FDAAA 2007 was enacted in September 2008. However, Jenkins also stated that 38% of current CDER and OND staff have less than 2 years of experience. To address this, at the end of November 2009, the FDA announced that it has awarded the National Institute for Pharmaceutical Technology and Education a US$652,000 2-year contract to develop and deliver a training programme for FDA reviewers by September 2011.

One of the reasons that may have contributed to the FDA missing PDUFA goals is the introduction of risk and evaluation mitigation strategies (REMS) through FDAAA 2007 (*Nature Rev. Drug Discov.* **8**, 10–11; 2009). During his presentation, Jenkins stated that "Incorporating development and approval of complex REMS during the first review cycle is almost impossible," and added that developers must plan well in advance (at the end of Phase II or before submitting a new drug application or biologic licence application) for complex REMS to allow the possibility for a first-cycle approval. It is also thought that the number of required REMS will increase through the Safe Use Initiative that aims to reduce preventable harm from medications, which was launched in November 2009 (http://www.fda.gov/downloads/Drugs/DrugSafety/UCM188961.pdf).

Biotechs lose out in Roche group's portfolio review

The Roche group has terminated development agreements with Actelion, Genmab and Seattle Genetics.
The lowdown: Since the integration of Roche and Genentech, the two companies have been reviewing their R&D portfolios. In December, Actelion announced that Roche has decided not to continue with their 2006 collaboration to develop and commercialize ACT-128800, a selective sphingosine-1-phosphate receptor 1 agonist. However, Actelion will proceed with the clinical development of ACT-12880, which is currently in Phase II trials for the treatment of multiple sclerosis and psoriasis. Also in December, Genmab announced that Roche will discontinue development of RG1507, a monoclonal antibody specific for the insulin-like growth factor 1 receptor, which Roche had been developing for the treatment of breast cancer, sarcoma and non-small-cell lung cancer. Genmab did not announce whether they plan to proceed with development of RG1507. In addition, Seattle Genetics announced that Genentech has ended a collaboration agreement to develop dacetuzumab, a monoclonal antibody targeting CD40 that has been in early clinical trials for the treatment of various haematological malignancies. Seattle Genetics plans to review the clinical data for dacetuzumab to consider its possible future development.