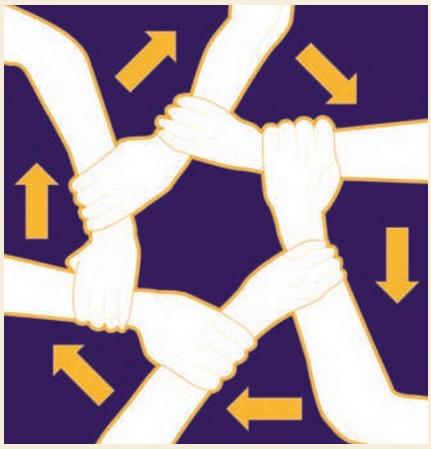
NEWS IN BRIEF

More pharma–academia R&D collaborations



Sanofi–Aventis, Genentech, Pfizer and Biogen Idec have all recently announced R&D collaborations with academic institutions.

The lowdown: In February and March this year, several pharma–academia partnerships were announced that all aim to progress drug R&D, primarily by creating collaborative research teams that work alongside one another.

On 17 February, Sanofi–Aventis outlined a 5-year research partnership with the French Life Sciences and Healthcare Alliance (AVIESAN). Up to 50 million euros will be invested into research areas such as ageing, immuno-inflammatory diseases, infectious diseases and regenerative medicine. Joint research teams, laboratories, technological platforms and possibly research centres will be considered between Sanofi–Aventis and AVIESAN, which include institutions such as the National Centre for Scientific Research, the National Institute of Health and Medical Research, and the Institut Pasteur.

Later in February the University of California, San Francisco (UCSF), USA, announced a partnership with Genentech to support the research of several investigators at the UCSF Small Molecule Discovery Center. A research team at Genentech will work with the UCSF research scientists to discover and develop drug candidates for neurodegenerative diseases.

Tackling another challenging disease area, King's College London (KCL), UK, announced on 10 March that it has partnered with Pfizer to create an open innovation laboratory for pain research. The Pfizer scientists will have joint academic appointments at KCL and will collaborate with established teams at KCL to understand the fundamental mechanisms underlying chronic and neuropathic pain.

Finally, on 12 March, the Brain Science Institute (BSI) at Johns Hopkins University, USA, announced that it has entered into a licensing agreement with Eisai to discover and develop small-molecule glutamate carboxypeptidase II (GCPII) inhibitors. Researchers at the BSI's NeuroTranslational Program will use Eisai's GCPII technology to generate inhibitors for the treatment of diseases including peripheral neuropathy, Alzheimer's disease and stroke, as well as non-central nervous system diseases. The NeuroTranslational Program team includes experts in medicinal chemistry, assay development, animal pharmacology and the conduct of preclinical studies. So, rather than Eisai and BSI researchers directly working together, the NeuroTranslational Program team will be responsible for all early clinical work, which Eisai will have an exclusive option to develop and commercialize. However, the research will be led by a joint steering committee of representatives from both entities.

Joint initiative aims to speed access to new therapies

The US FDA and the National Institutes of Health (NIH) unveiled an initiative that aims to accelerate the process of translating scientific discoveries into new therapies by focusing on regulatory science.

The lowdown: Both agencies have identified that successful translation of basic research into innovative therapies requires improved alignment of translational and regulatory science. The FDA and NIH will therefore establish a joint leadership council that will "spearhead collaborative work on important public health issues," paying close attention to ensure that the needs of regulators are included in biomedical research planning, as well as ensuring that "the latest science is integrated into the regulatory review process." Through the initiative, US$6.75 million will be made available over 3 years to provide research into methods, models or technologies that will inform regulatory science and may lead to better approaches to evaluate the safety and efficacy of new therapies. This collaboration comes at a time when the NIH is funding ~$483 million annually on clinical and translational science awards that aim to enhance the efficiency and quality of clinical and translational research by transforming the research and training environment. No specific details have been released about how the new FDA–NIH initiative will proceed, but at the time of going to press, the FDA and NIH said that they would hold "a public meeting in the spring to solicit input on how the agencies can work better together."

European agencies discuss relative effectiveness

The European Medicines Agency (EMA) is collaborating with the European network for Health Technology Assessment (EUnetHTA) to determine how it can contribute to assessments of relative effectiveness.

The lowdown: The EMA and EUnetHTA will collaborate to determine how European Public Assessment Reports (EPARs) can contribute to the assessments of relative effectiveness conducted by health technology assessment (HTA) agencies in Europe. The EPAR is a summary of the evaluation process that the EMA's Committee for Medicinal Products for Human Use completes when it assesses a marketing authorization application for a new product. It includes all clinical trial data in support of a product's efficacy and safety, and is published at the end of the evaluation process. This is the first time that the EMA has been given a political mandate to interact with HTA agencies.

In the European Union, the growing influence of HTA agencies — such as the UK's National Institute for Health and Clinical Excellence — means that meeting their requirements for relative effectiveness, in addition to those of regulatory agencies for safety and efficacy, is becoming increasingly important in achieving market access (*Nature Rev. Drug Discov.* **9**, 277–291; 2010). In turn, this is having a greater impact on drug development strategies (*Nature Rev. Drug Discov.* **7**, 876–878; 2008). Debate around the importance of assessing relative efficacy of investigational drugs compared with existing therapies is also becoming more prominent in the United States. However, given the relatively small patient exposure during the clinical trials process, and the variability in drug response, concerns have been raised that misuse of comparative effectiveness studies prior to drug approval could limit the number of therapies available in a real-world clinical setting, and impede the advance of more personalized medicine (*Nature Rev. Drug Discov.* **8**, 261–263; 2009).