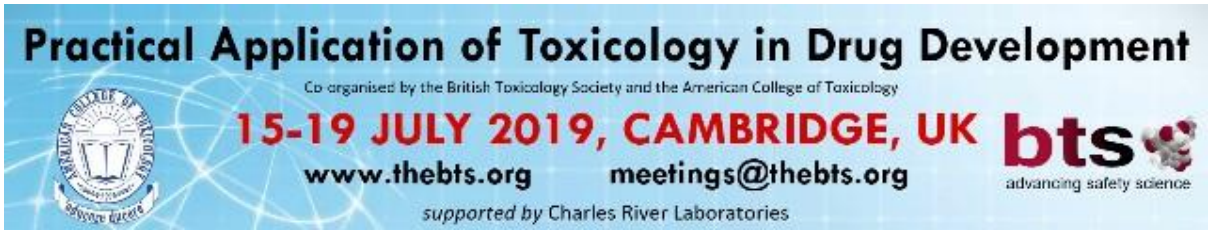

Feedback from BTS members on the Practical Application of Toxicology in Drug Development course, 2019

Sarah Hocquigny with input from Bryony Labram and Osahon Osalodor

The sixth iteration of the UK course in Practical Application of Toxicology in Drug Development (PATDD), jointly organised by the BTS and ACT, was held at the Møller Centre in Cambridge in July 2019.

The aim of the course was to provide participants with an understanding of the principles of non-clinical toxicology data and interpretation, and their application in the drug development process.

There were 28 attendees who came from as far away as Israel, Saudi Arabia, Korea, and China, and from a variety of backgrounds/roles, including staff from regulatory agencies, CROs, pharmaceutical companies, and government bodies. All attendees found the course to be very well organised and agreed that it provided an excellent overview of a diverse range of topics, beginning with an overview of the drug development process, then delving into individual aspects including pharmacology/safety pharmacology, pathology and organ systems, DMPK/ADME, biologic drugs, genetic toxicology, carcinogenicity, immunotoxicology, clinical pharmacology, and developmental/reproductive toxicology. In addition to these topics there was also a focus on regulatory aspects including risk assessment and the Common Technical Document/Standard for Exchange of Nonclinical Data. The speakers were all extremely knowledgeable and encouraged discussion/questions, and several of the presentations included real-life case studies which were helpful in demonstrating how the concepts discussed apply to the interpretation of data.

In addition to the lectures, workshops were held in which participants were split into breakout groups to review regulatory data and documents from real drugs and answer questions, which really helped to cement what we had learned in terms of how the data we were provided supports and informs the development of a drug. Towards the end of the week we also had a unique opportunity to engage with regulators from the FDA and MHRA and hear about how they review the non-clinical data they are provided, and we were also encouraged to ask questions regarding our own lines of work.

The Møller Centre itself was an excellent choice of venue with great facilities, and the catering, in particular, was superb (I'm sure lunch was a highlight for many!). The course was very intensive so it was nice to have a space for relaxing in between lectures, particularly on the days when the weather was nice enough for us to spend a bit of time outdoors.

The breakout groups and the drinks reception held on Monday evening provided a great chance for participants to meet each other and build networks with industry colleagues in a relaxed and informal setting. The evenings were left as free time so many participants ventured into Cambridge to explore the city. Participants visited some of the local pubs and restaurants, tried punting on the Cam, or even caught a Shakespeare play at one of the various colleges as part of the Cambridge Shakespeare festival.

This course is a superb learning opportunity for toxicologists, providing a truly comprehensive overview of non-clinical safety data and how it fits into the drug development picture. The course slides (made available to all participants) will certainly be a useful resource in the years ahead and there is no doubt that the knowledge gained will be of benefit not only now but as we continue in our careers in toxicology.

With thanks to Ernie Harpur for the photos of the lecture/breakout groups and Norman Kim for the class photo.