



In the words of Denis Lacombe, co-Chair of the Innovation and Biomarkers in Cancer Drug Development (IBCD) meeting, “we need to adapt quickly to the rapidly evolving field of precision medicine.” These opening remarks set the agenda for this meeting, a joint project from the European Organisation for Research and Treatment of Cancer (EORTC), the US National Cancer Institute (NCI), the European Medicines Agency (EMA) and the American Association for Cancer Research (AACR), which was held in Brussels, Belgium.

The meeting was preceded by a workshop, in which the challenges associated with conducting clinical research in the EU were examined. Currently, different aspects (such as health care, research or the commercialization of products) are regulated by separate European legislative frameworks. Speakers from different specialties from members of regulatory bodies to clinicians) discussed how these gaps in regulation primarily affect data protection. Participants agreed that measures need to be implemented to define the threshold between privacy and transparency. Importantly, patients should have a central role in setting these boundaries.

At IBCD 2016, delegates from Europe, North America and Japan discussed topics ranging from quality assurance assessment to future uses of biomarker-based approaches. Several initiatives conducted in these regions were presented to illustrate how clinical trial design is evolving in the era of precision medicine.

A special focus was placed on ‘big data’ analysis and translational genomics, with presentations from

Moritz Gerstung and Philip Beer. The currently available technologies enable the collection of information in large datasets. The challenge now, in Beer’s words, “is how to unlock the clinical utility of this information. Barriers exist but they are not insurmountable.”

Perhaps the session that best summarized the take-home messages of IBCD 2016 was the debate moderated by Jeffrey Moscow. The notion that precision medicine can be delivered in a sustainable and affordable manner was defended by Richard Schilsky and Nils Wilking, and argued against by Tito Fojo and Daniel Hochhauser. As Moscow clarified, “in the vision of cancer precision medicine, advances in diagnostics and targeted agents could result in hundreds of different individualized therapeutic combinations where now there might be only one. The questions are how do we determine the efficacy, safety and value of each combination, and who will pay for it?” Different examples were presented from both sides to support their position. The diversity in outcomes illustrates the need to explore new strategies to measure therapeutic benefit and cost–benefit relationships. All participants agreed on the importance of informing patients about specific risks at each stage of treatment. The debate ended with no winner, but raised more questions.

A unifying conclusion from both events is the need for ongoing international dialogue between all stakeholders. As Schilsky commented after the debate session, “in the end, we are all committed to improving cancer therapies.”

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