A progress report on the 3rd International Symposium on Scientific and Regulatory Advances in Biological and Non-Biological Complex Drugs: A to Z in Bioequivalence

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Abstract

The 3rd International Symposium on Scientific and Regulatory Advances in Biological and Non-Biological Complex Drugs: A to Z in Bioequivalence (3rd SRACD) was organized in Budapest, Hungary on 12–14 November 2018. This symposium discussed the science base for the assessment of equivalence of biosimilars and follow-on versions of non-biological complex drug (NBCD) products, nanosimilars. More in particular, the debate centred around the following questions: What is equivalence for these products and why does it need our attention? Will recent technology developments solve the challenges in determining Critical Quality Attributes of complex drug products? Can the successful biosimilar development approach inspire the development of nanosimilars? Is there a possibility for global harmonization of regulatory policies for NBCD products and other complex drug products? The discussions led to a clear call to action to take the international discussions around regulatory alignment and harmonization for complex drug products to the next level.

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