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Advances in bioequivalence and biowaivers in Latin American Countries

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In Latin America, the implementation of bioequivalence (BE) studies is still unequal. There are remarkable advances, as well as there are some countries without regulations in this field. Despite of this heterogeneity it is possible to recognize efforts from the National Regulatory Agencies (NRA) in discussing bioequivalence criteria, biowaivers based on the concept of the Biopharmaceutical Classification System (BCS), therapeutical equivalence, and interchangeability issues. With this background, regulations have emerged based on *in vitro* and *in vivo* assays, but there are differences in terms of the assessment criteria and time elapsed from the application to final approval. However, since the emergence of the BCS there has been an interesting discussion regarding the possibility of including biowaivers in some cases. There is a consensus to apply a biowaiver study for solid oral dosage forms containing an active principle ingredient belonging to Class 1 of BCS (high solubility and high permeability), excluding drugs with narrow therapeutic index, but the interpretation of how to apply biowaivers based on other BCS classes differs between regulatory authorities. Considering that, the pharmaceutical market can reach USD 1,200 billion by 2016, it seems that is necessary to conciliate innovation and implementation of generic drugs. Furthermore, this implementation should be based on the best BE and biowaiver practices and criteria to improve access to safe and effective medicines at reasonable costs.

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Cellular and molecular basis for dysregulation associated with immunomodulatory biologics

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Immunomodulatory biologics are a major focus of drug development with a variety of clinical indications including cancers and autoimmunity. However, these biopharmaceuticals are associated a risk of serious adverse effects such as cytokine release syndromes (cytokine storm), infection, immunogenicity and autoimmunity. This is dramatically exemplified by the near-fatal cytokine storm induced in human volunteers in a Phase I clinical trial with the immunomodulatory biologic, TGN1412. Detailed understanding of the target biology followed by identification and screening of target specific biomarkers for risk assessment is essential for the development of safe immunomodulatory biologics. Recent work in our laboratory has focussed on defining the cellular and molecular basis for T cell dysregulation induced by TGN1412. Our results reveal that critical elements of T cell co-inhibitory pathways are dysregulated in TGN1412-activated T cells. We have also identified central changes in T cell metabolism and bioenergetics that underlie and drive the dysregulation. The background to this area and our findings will be discussed in the talk.

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