PRI Safety Task Group

A task group dedicated to addressing the regulatory challenges in regards to safety and toxicity assessment of Live Biotherapeutic Products (LBPs).

An important issue in the microbiome and health industry is the assessment of safety and toxicity in the development of microbiome-based drug products as it represents a paradigm shift for the authorities due to the absence of absorption of the products, their complex mode of action as living microorganism(s), and the very challenging, sometimes impossible, translation from animals to humans.

Over the last year (mid-2018 to mid-2019) the PRI Safety Task Group has held discussions around the important key safety aspects which have to be addressed in regards to Live Biotherapeutic Products (LBPs). The work of the Task Group initially addressed the key issues relating to the importance of the intrinsic characteristics of such microorganism(s) in the development of safety and toxicity pre-clinical studies.
During its second meeting the Group addressed the specific difficulty when developing pre-clinical safety and toxicity programs in an environment where translation from animals to humans is often very challenging but still required by authorities before first-in-man studies.

Finally, in its third meeting, the Group will also address the safety aspects when it comes to clinical trials and the safety assessment in the human host. Early clinical developments of medicinal products always have an intrinsic element of uncertainty in relation to both the efficacy and the safety of the drug candidate. In the case of LBPs, the difficult translation from animals to humans potentially increases the level of uncertainty before first-in-man trials. Consequently, during the third meeting, the Group will discuss how safety can be addressed before first-in-man trials based on the two previous meeting recommendations (regarding the intrinsic characteristics of the LBPs as well as the pre-clinical safety assessment program) and how this should be put into perspective for the actual design of first-in-man trials as well as the safety assessment along clinical development in order to make both a robust demonstration of safety to patients as well as product efficacy.

For more information about this or any other project coordinated by the PRI, please contact:

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