

# 11<sup>th</sup> EUROPEAN BIOSIMILARS CONGRESS

April 26-27, 2018 Rome, Italy

## Bioanalytical methods for biosimilars: An approach

**R Helena Bustos-Cruz**

Universidad de La Sabana, Colombia

The success of biosimilar development involves demonstrating biosimilarity in terms of quality, security, and efficiency. It is important to establish the bioanalytical principles and methods to allow detailed characterization and to be able to undertake the clinical and non-clinical studies that can verify the security and clinical efficiency and to be granted marketing authorization for biopharmaceuticals. Moreover, to minimize the risk related to biosimilars, immunogenicity studies must be carried out in patients with biopharmaceutical treatment. Thus, the detection and detailed characterization of Antidrug Antibodies (ADAs) will allow for further understanding in relation to the potential impact in terms of the efficiency and safety of the molecule object of study. There is currently no test that provides all the necessary information to be able to define a specific immunogenicity profile. Therefore, the conception of a bioanalytical strategy is necessary: One that sequentially includes the accomplishment of a test panel. Firstly, the most widely accepted methodology includes the accomplishment of a screening test that can assess the capacity of the Ab to bind biotherapeutic proteins. There is then a test to determine the neutralizing (Nab) capacity, the data which will be analyzed in light of the pharmacokinetic/pharmacodynamic parameters, and the magnitude of the biological effect in patients. This test also identifies the risk profile that will allow the rigor in the time parameters for the sampling to be established. These types of immunogenicity studies, which are mostly predictive, require a rigorous validation process to establish an adequate correlation level with clinical results; they also determine feasibility, which allows for the findings to be extrapolated.

### Biography

R Helena Bustos-Cruz studied at the University of Tübingen in Germany and carried out her Postdoctoral studies at the Universidad Nacional in Colombia. She is Group Leader of the Therapeutic Evidence Group at the Universidad de La Sabana. She works in Nanobiosensors development for the evaluation and characterization of molecular interaction in biological drugs. She introduced nanobiosensors (surface plasmon resonance and quartz crystal microbalance) as a new research technology in Colombia. Her group works in the field of safety and efficacy for drugs, clinical pharmacology, and pharmacovigilance. Additionally, she participated in elaborating the evaluation guidelines for biosimilars according to the National Institute for the Monitoring of Medicine and Food (INVIMA).

rosa.bustos@unisabana.edu.co

### Notes: