Meetings International
SciTechnol

J Nephrol Ren Dis 2018, Volume: 2
DOI: 10.4172/2576-3962-C1-006

WORLD BIOSIMILARS CONFERENCE
&
Annual Conference on
NEPHROLOGY AND UROLOGY

August 20-21, 2018
Chicago, USA

Optimizing clinical trials as part of the totality of data to support the marketing approval of biosimilars

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Doubt exists as to whether a potential biosimilar possesses the same risk benefit profile as the original biologic. The need for PK equivalence trials to address this is indisputable but usually equivalence of efficacy is also required. Equivalence trials present a number of challenges including the need to conduct the study under the same conditions as the original placebo controlled trials that proved the efficacy of the original product. This can present challenges as practices change. Thus it is important to critically evaluate the contribution of the therapeutic trial in adding to the totality of data. Improvements in analytical testing, mean other than immunogenicity driven, clinical differences are improbable, and as many biologics are dosed on the flat part of the dose response curve (Chatzidionysiou et. al, 2016; Maini R et. Al, 1999) efficacy differences are unlikely to be observed. The potential of the biosimilar to elicit an immune response remains an area of uncertainty; there have been a number of cases of immunogenicity associated with changes in production and formulation (Casadevall, N et. al, 1996; Boven, et. al, 2005 Raut S. et. al, 1988). Clinical development of a biosimilar should be risk based starting with known and potential differences and risks. Such an approach could reduce or eliminate the need for a therapeutic equivalence trial, allowing for more flexibility in trial design so making the development of biosimilars simpler and faster, and this should be in all our interests.

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