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## TITLE

### ARE BIOAVAILABILITY STUDIES WARRANTED IN SPECIFIC DISEASE STATES?

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Over the last century with rapid strides in fields of drug development & formulation technologies have resulted in continually evolving regulatory guidance on BA / BE requirements. These requirements have been factoring in increasing intricacies, so as to reflect more completely - rate and extent to which active ingredient or active moiety is absorbed from a drug product becomes available at the site of action; remains within therapeutic window; so as to achieve maximum clinical benefit with minimal harm to patient. "The Patient" rightly remains the central foci around whom the sciences of medicine & therapeutics have developed. However, the increased understanding of etiopathogenesis of various disease conditions, especially chronic diseases with multi-organ involvement like for example, HIV disease & AIDS which, in addition to altering GI enterocyte patho-physiology, with its concomitant incidence of opportunistic illnesses requiring multi-drug therapies, many at the same time, including the need for use of biopharmaceutical class IV drugs, have raised apprehensions about adequacy & applicability of the current healthy volunteers BA data, of many drug formulations used in these specific disease conditions in treating patients in "real-life on field situations" where TDM facilities are non-existent. In the instant case with tuberculosis being the most common co-infection / opportunistic infection in HIV disease in Indian settings, and rifampicin, a biopharmaceutical class IV drug, forming the backbone of currently available anti-TB regimens, BA studies of rifampicin in advanced HIV disease would be vital in determining an adequate and safe dose of rifampicin in this disease condition.