

## TITLE

### ENDEAVORING BIOWAIVERS USING IVIVC: SHIFTING PARADIGMS

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Customarily, all oral dosage forms have to be evaluated for their *in vivo* bioavailability as per the federal requirements and otherwise. Manufacturers seeking regulatory approval of generic products, therefore, must provide detailed bioequivalence evidence showing head-to-head comparative performance of their product against the innovator's Herculean task involving myriad technical, economical and ethical hiccups. Accordingly, every pharma house would endeavor its best to circumnavigate these hitches by seeking. Today, when the pharma industry is eyeing the drug molecules going off-patent, such biostudies gain far more corporate relevance. Nevertheless, establishment of oral bioequivalence through *in vivo* human bioavailability studies is usually a requisite biowaivers invariably via *in vitro/in vivo* correlations (IVIVC). The major objective of establishing IVIVC is to facilitate *in vitro* dissolution studies to serve as surrogate for *in vivo* bioequivalence testing, especially during scale-up and post approval changes (SUPAC). Besides, a predictive IVIVC may be used to learn about the relative contribution of *in vitro* dissolution to product's overall absorption kinetics, minimize the number of human studies required during product development, and assist in setting meaningful dissolution specifications. The immense significance of IVIVC is usually harvested in the background of Biopharmaceutics Classification System (BCS), a scientific framework for classifying drug substances based on their aqueous solubility and permeability. Of late, newer paradigms like *in vitro/in vivo* relations (IVIVR) and *in vitro/ in vivo* matching (IVIVM) have also been postulated to facilitate prognosis of *in vivo* behavior of formulations by examining their *in vitro* release profiles. Citing apt instances from our work experience, the current presentation will tend to provide a structured insight on various updated trends of IVIVC, IVIVR and IVIVM not only for grant of biowaivers, but as excellent product development tools too.