ALTASCIENCES
CLINICAL SERVICES

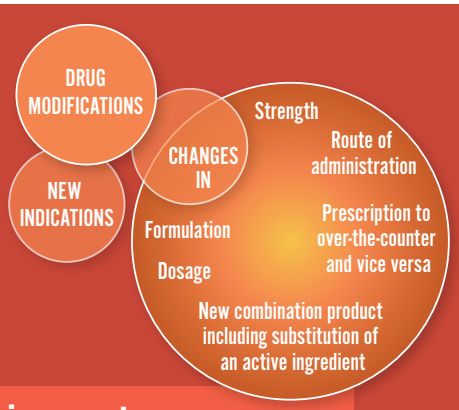
The 505(b)(2) NDA/Hybrid Market Authorization Pathway

The 505(b)(2) New Drug Application (U.S.) or Hybrid market authorization (E.U.) pathway provides an accelerated timeline for approval of a wide range of new drug applications involving already approved molecules. Altasciences offers expert scientific guidance in clinical study design to address critical endpoints such as safety, pharmacokinetics, and pharmacodynamics, in accordance with all relevant regulatory criteria.

The key to a viable development strategy for an accelerated pathway is early identification of existing submission gaps, and planning for studies to effectively bridge those gaps. The most likely obstacle to a successful application is a lack of appropriate data to support the proposed modifications of the Reference Listed Drug (RLD).

In order to fully address the requirements for each individual submission, it is essential to meet with the regulatory bodies prior to initiating studies to discuss both the scientific rationale and strategic planning behind the application.

Altasciences has conducted numerous clinical trials for successful 505(b)(2) and Hybrid targeted filings. With high quality trial conduct and individualized clinical program guidance, we support sponsors in optimally navigating this development pathway.



Hybrid or 505(b)(2) vs Generic Submission Requirements

Hybrid or 505(b)(2)	Generic
Bioavailability (BA) studies versus approved RLD: • If the new formulation is bioequivalent to the RLD, and the indication is the same, subsequent studies are greatly reduced. • If they are not bioequivalent, safety and efficacy will need to be established and submission requirements may include preclinical and clinical efficacy studies. Whenever possible, submitted data can be previous regulatory decisions or published research.	Bioequivalence (BE) studies versus approved RLD: • Once bioequivalence is established, assessment relies on the agency's previous safety and efficacy findings reported for the RLD. • Only applies when the new product and the RLD are bioequivalent, and possess identical characteristics e.g., – Active ingredient, – Dosage form, – Strength, – Route of administration, – Uses, etc.
Most common study requirements Formulations that are not locally acting: • Single dose comparative BA fasted • Single dose comparative BA fed state Other studies that may be required based on case-by-case evaluation: • Preclinical toxicology studies • PK-PD, DDI, TQT • Multiple dose comparative BA steady-state • Clinical endpoint studies	**Most common study requirements** Formulations that are not locally acting: • Single dose BE fasted • Single dose BE fed state – if food effect is noted in label • Steady-state BE – for EMA when there is accumulation for extended release products. Other formulations will be evaluated case-by-case: • Other study designs may be required based on the drug product or by different regulatory agencies

contact@altasciences.com
altasciences.com