VEEDA EDGE

First to File

The main advantage for a generic company of having first to file Abbreviated New Drug Application (ANDA) with a Paragraph IV certification without the subsequent lawsuit is that the generic company is granted a period of market exclusivity of 180 days.

The 180-day exclusivity incentive can be significant for a generic company as it would be the only generic version on the market. So, it can price its product slightly below the branded version for six months, take market share from the branded product, and maintain its price point before other generics enter the market and erode the price and segment margins. The additional profit for a generic firm can be enormous if the product it challenges is a so-called blockbuster or megabrand.

Main Challenges for first to file bio study

- Lack of availability of Literature
  - Handling of BENOC application
  - Designing the study
- Analytical method development
- Delivery of reports with strict timeline

Our achievements :

1. Completion of more than 35 pivotal bio studies to support more than 14 first to file including NCE-1 ANDA applications
2. Completion of first to file ANDA submission projects like Antipsoriatic, Anti retroviral, Antipsychotic, urinary disorders, Anti hypertensive, Immunomodulatory class, Anti arrhythmic, Anti depressant, Anti coagulants, Anti Alzheimer's class of drugs

Veeda Advantage :

- **Thorough data review by Quality Monitor and Quality Assurance**
- More than 450 experience manpower
- **Total clinical bed capacity :** 418 beds
- **Total Bioanalytical Instruments :** 36+
- **Privately owned Clinical Research Organization** without association with any Pharma Company

Our Capabilities :

- Flexibility in on floor study schedule with respect to Clinical, Bioanalytical and report delivery Example: Delivery of one FTF Bioanalytical study within 3 days after enrolling all instruments in one study
- State of the art Bio-analytical Unit with more than 400 validated assays in its library of compounds, 35 NCE methods & 20 more under development.
- Team having experience in understanding the challenges of study design and logistics of study execution
- Proven regulatory track record with 11 USFDA, 5 European, 4 WHO & 7 ANVISA audits
- Trusted CRO partner to 10 of the world's top 15 Global Pharmaceutical Companies

Veeda has proven track record and we are best equipped to handle FTF projects to support your drug development.

VEEDA CLINICAL RESEARCH PVT. LTD.

Vedant Complex, Beside YMCA club S.G.Highway, Vejalpur,Ahmedabad-380051,Gujarat India

+91 79 3001 3000 | +91 79 3001 3010 | info@veedacr.com | www.veedacr.com