veeda clinical research®

# BRING YOUR GENERIC PRODUCT TO MARKET QUICKLY & EFFECTIVELY WITH OUR BA/BE EXPERTISE

## We are now supporting you through all the stages in a drug development continuum

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## What are generic drugs?

A generic drug is an equal substitute or alternative for its brand-name counterpart as it **has the same strength and provides the same clinical benefit as the branded drug.** The USFDA defines a generic drug as medication developed and produced to have the API, dosage form, strength, therapeutic use, route of administration, and quality performance characteristics, same as an already marketed branded drug.


## What is an ANDA?

ANDA stands for Abbreviated New Drug Application. Pharmaceutical companies need to submit an ANDA to the regulatory authority for review & approval to market a generic drug. The ANDA contains information that proves that the generic medicine is safe and effective as the brand drug.

## What is 505 (b) (2) application?

FDA defines **505 (b) (2)** application as a New Drug Application (NDA) containing complete reports of investigations of safety and effectiveness in which some of the required information for regulatory approval comes from studies that the applicant has not conducted or for which the sponsor/applicant has not obtained a right of reference or use. 505 (b) (2) candidates include an NME, New active ingredient, New dosage form, New combination, New indication, New formulation, previously marketed but without an approval & Rx to OTC (Previously approved drug changed to OTC or changes to existing OTC product ).

## Types of Generic Drugs

- Super Generics
- Speciality Generics
- Complex Generics
- Authorized Generics
- Branded Generics
- Unbranded Generics

# Leveraging the Veeda Edge to handle your BA/BE Studies

## Our services include

- Study Design & Study Conduction
- Project Management
- Medical Affairs
- Bio Analytical Services
- Data management & Biostatistics
- Regulatory Guidance

# Tackle the Complexity of your Generic Drug Development with Veeda

Our experience of conducting BA/BE studies in healthy volunteers across different dosage forms

Vaccine

Injectable Emulsion

Injection

Rectal/ Vaginal Suppository/ Foam

Nasal Spray

Inhalation

Transdermal System/ Transdermal Patch

Topical Product

Syrup

Oral

Capusle

Tablet

| Type of Study | Total Numbers |
|---|---|
| Generic (BA/BE) | 3900+ |
| Pilot | 1200+ |
| Pivotal | 1900+ |
| Standalone Bioanalytical | 730+ |

## End-to-End support with robust clinical strategy for your next trial on Complex Generics

Demonstrating the bioequivalence, safety, and efficacy of a Complex generic drug can be challenging. Veeda Clinical Research has the experience and expertise to expedite your reach to the Market.

| TOTAL NO. OF BA/BE STUDIES ON COMPLEX GENERICS | |
|---|---|
| Inhalational Bioequivalence Studies (Experience in pMDI, dry powder inhalation, and nasal spray studies) | 28 |
| Long-Acting Injectables (LAI) Bioequivalence studies | 12 |
| Transdermal Patch Studies | 11 |
| Suppositories/Rectal Products(Rectal Foam) Studies | 6 |
| Glucose Clamp Studies | 13 |
| TOTAL | 70 |

# Proven Expertise to handle your Complex Generics Studies

## 1 Experience in handling Complex Dosage Forms

- **Inhalational Bioequivalence Studies-** Successfully completed 28 inhalational bioequivalence studies with approximate volunteer dosed till date to be 1100+

- **Bioequivalence Studies on Topical Drugs-** Veeda has experience in conducting Transdermal patch studies Bioequivalence (BE) with pharmacokinetic (PK) endpoints and adhesion study, Skin irritation and sensitization study (Proof of Procedure). We have successfully completed 11 Transdermal Patch Clinical Studies (4 Pivotal study, 1 Pilot study, and 6 PK endpoint and Adhesion trials).

- **Bioequivalence studies on Suppositories/Rectal Products-** Veeda has an experience of successfully completing 6 studies (2 Pilot & 4 Pivotal)

## 2 Experience in handling Bioequivalence studies involving Complex Route of Drug Administration and Complex Devices

- **Bioequivalence Studies on Long Acting Injectables (LAIs)**

  • Till date Veeda CR has completed 12 BA/BE studies involving Long Acting Injectables (LAIs)
  • Experience in understanding the challenges, clinical development, study design, and exexecution of LAI antipsychotic drugs like

  - Aripiprazole depot injection
  - Olanzapine modified release injection
  - Paliperidone palmitate modified release injection
  - Risperidone modified release injection
  - Leuprolide acetate injection

- **Glucose Clamp Studies**

  • Extensive experience and professional expertise in conducting complex Glucose Clamp Studies
  • Till date we have used 810 Glucose Clamps in 13 different studies
  • We have experience of clamp ranging from 8 hours to 36 hours duration

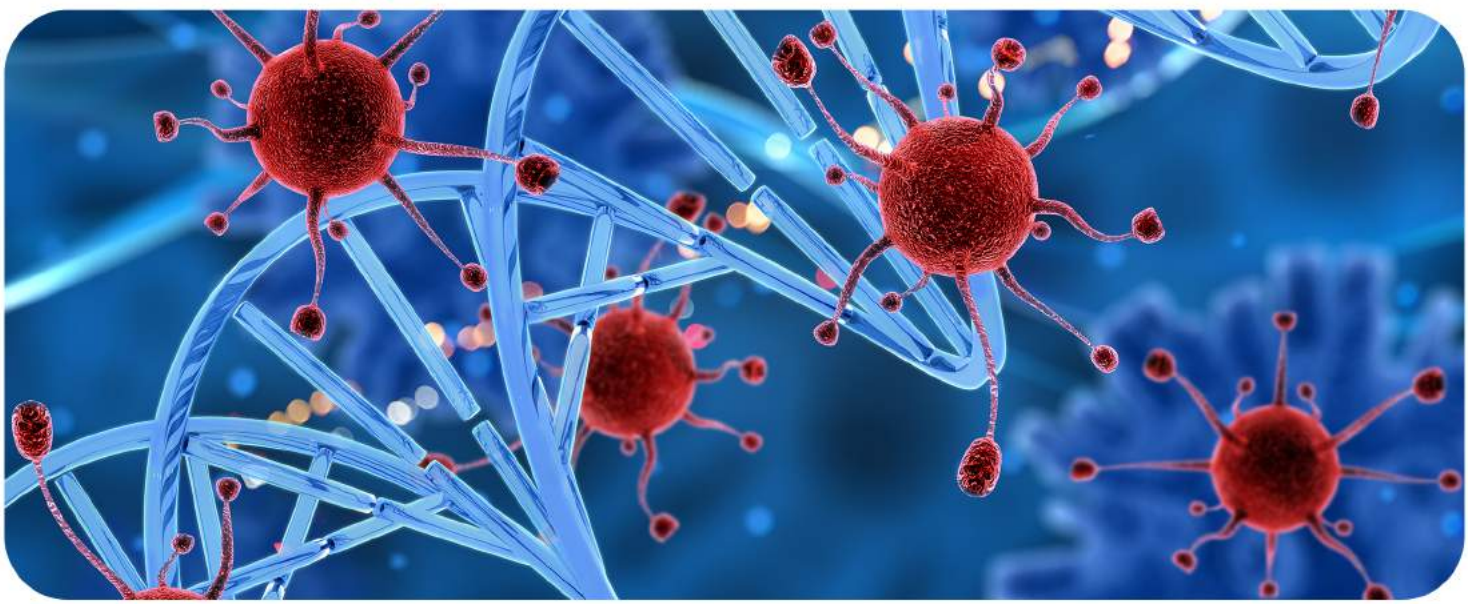
## 3 Bioanalytical capabilities of Veeda CR for Complex Drug Molecules

- Amino Acid Analysis
- Peptides (small molecules) analysis by LC/MS (Experience in handling molecules like Desmopressin, Leuprolide, and Octreotide)
- Bioanalysis of Endogenous Compounds (Experience in handling molecules like Estrone (Unconjugated) +Estradiol (Unconjugated), Isotretinoin, and Levothyroxine)
- Bioanalysis of Enantiomers (Chiral Methods) (Experience in handling molecules like R-trans & S-trans Tranylcypromine; R & S Lercanidipine; R-SSS & S-RRR Nebivolol)
- Biomarker Analysis and Analysis of Protein Bound Formulation

## 4 Veeda's Experience in handling 505(b)(2) studies

Veeda provides best-in-class services with a combination of expertise and experience to conduct patient-based bioequivalence studies for various 505 B2 and complex generic products

**Veeda CR has been a partner in supporting 505 (b) (2) applications with ~45 studies experience with various clients.**



# BA/BE studies in Patients

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## Our experience of handling Patient PK trials across diverse therapy areas

| Therapeutic Areas and Indications | No. of Studies | No. of Patients | Type of Study |
|---|---|---|---|
| **Antiviral** | | | |
| HIV | 1 | 48 | PK Endpoint Study |
| **Oncology (22 studies)** | | | |
| Chronic Myeloid Leukemia (CML) | 6 | 160 | PK Endpoint Study |
| CML & Gastrointestinal stomal tumor (GIST) | 1 | 40 | PK Endpoint Study |
| Metastatic Breast Cancer (MBC) | 3 | 203 | PK Endpoint Study |
| Metastatic Breast Cancer (MBC) and Colo Rectal Cancer (CRC) | 2 | 99 | PK Endpoint Study |
| Multiple Myeloma (MM) | 1 | 54 | PK Endpoint Study |
| Orthopaedic Cancer | 1 | 58 | PK Endpoint Study |
| Ovarian Cancer | 2 | 120 | PK Endpoint Study |
| Ovarian and MBC | 3 | 202 | PK Endpoint Study |
| Renal Cell Carcinoma (RCC) | 3 | 86 | PK Endpoint Study |
| **Psychiatry** | | | |
| Schizophrenia | 7 | 463 | PK Endpoint Study |
| **Rheumatology** | | | |
| Rheumatoid Arthritis (RA) and Psoriasis | 1 | 42 | PK Endpoint Study |

**Veeda's expertise in handling clinical method development, site selection, trial execution, regulatory documents submission and on time regulatory approval for generic oncology drugs**

- Highly trained and well experienced personnel for conducting diverse oncology studies
- Our study sites have experienced nurses and other housing staff to conduct patient based bioequivalence studies
- Experience in enrolling and retaining more than 250 ovarian cancer patients and breast cancer patients
- We have 140 experienced investigators that have the expertise to develop robust clinical methods and execute oncology BA/BE studies
- Site for oncology studies are highly regulated with systematic approaches and strategies
- Successfully completed multiple regulatory audits without any major observations and most of them being for oncology studies.

# What makes Veeda Clinical Research a perfect choice for your next Generic Drug Trial?

- Extensive Scientific Competence to service a Diverse client base
- High Customer Centricity and Satisfaction
- Skilled personnel with focus on Continuous Professional Development
- Robust Quality & Regulatory Compliance
- State of the Art Infrastructure for complex studies
- Diverse pool of volunteers including males, females, elderly population & post-menopausal females
- Completed 3900+ BA/BE studies
- Completed largest healthy volunteer study: 120 in single group and 300 in multiple groups
- Experience of conducting long duration healthy volunteer study: eight months in multiple visit and 27 days in single stay
- We are continually validating new bioanalytical methods and have developed over 1040 bio analytical methods till date
- Providing full service as well as functional services in all the stages of drug discovery and development to support critical drug development programs of global (Bio) Pharmaceutical companies

To know more about
our expertise in BA/BE Studies, mail us at
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Partners in creating a healthier tomorrow

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