₹ VEEDA EDGE

Better planning of your BE studies for **Long-acting Antipsychotic Injections**

Long-acting injections (LAIs) of antipsychotic medication (depots) are being developed specifically to promote treatment adherence and are a valuable option for maintenance medication in psychotic illnesses. With a competent team of 300 experienced scientists and a focused approach towards providing quality solutions, Veeda is well equipped to meet the special clinical trial execution requirements for generic drug development of Antipsychotic Long-acting Injectables (LAIs).



Main challenges for LAI antipsychotics

- **Designing the studies** in line with various regulatory requirements.
 - Getting the **stabilized schizophrenic patients** with tolerability assessment.
 - Handling of **BENOC requirements** for executing the
 - Patient retention due to long duration of the trial.

Few LAI antipsychotics requiring BE studies are

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

Our Capabilities

- Team having experience in understanding the challenges of study design and logistics of study execution.
- Consultant Psychiatrist as a key opinion leader, with over 10 years of clinical trial experience and having successfully faced 3 US FDA inspections.
- Investigators database of more than 40 investigators having prior experience in handling schizophrenic patients.
- Investigators' sites inspected by USFDA.
- Excellent regulatory liaison with proven track record.

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Veeda Advantage

Road Map for more than 45 molecules for Patient based Pharmacokinetic Studies and more than 30 molecules for Clinical **End Point Studies**

Proven regulatory track record with 26 USFDA, 5 European, 4 WHO & 5 ANVISA audits

Two BE studies of LAI antipsychotics are currently in start-up phase

Trusted CRO partner to 10 of the world's top 15 Global Pharmaceutical Companies

State of the art Bio-analytical Unit with more than 550 validated assays in its library of compounds, 50 NCE methods , 45 complex molecules and 10 more under development.