

# 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 250 experienced scientists and a stern focus on providing quality solutions, Veeda is well equipped to meet the special clinical trial execution requirements for generic drug development of Long-acting injections (LAIs) of antipsychotics.

# 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** for executing the trial.

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
- Leuprolide acetate 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** having prior experience in handling schizophrenic patients.
- Investigators' sites inspected by USFDA.
- Excellent regulatory liaison with proven track record.



### Veeda Advantage

100% data review by Quality Assurance

Privately owned Clinical Research Organization without association with any Pharma Company

Road Map for more than 25 molecules for Patient based Pharmacokinetic Studies and more than 15 molecules for Clinical End Point Studies

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Proven regulatory track record with 8 USFDA, 4 European, 4 WHO & 7 ANVISA audits

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

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State of the art Bio-analytical Unit with more than 340 validated assays in its library of compounds, 35 NCE methods and 20 more under development.

