veeda clinical research®

Veeda's experience with NMPA studies

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Veeda's provides end-to-end integrated clinical packages tailor made to suit client requirements. Veeda's pillar of technical and scientific expertise lies in working with a clinical team that comprises of meticulous and disciplined professionals with thorough knowledge in varied therapeutic domains and different phases of clinical trials.

Veeda's experience in NMPA studies

- Veeda has conducted **8 pivotal** and **80 pilot studies** designed specifically as per **NMPA guidelines**
- Additionally, Veeda has supported **NMPA dossier submissions of 22 studies** submitted to other international regulatory bodies after necessary documentary supplementation to meet NMPA requirements.

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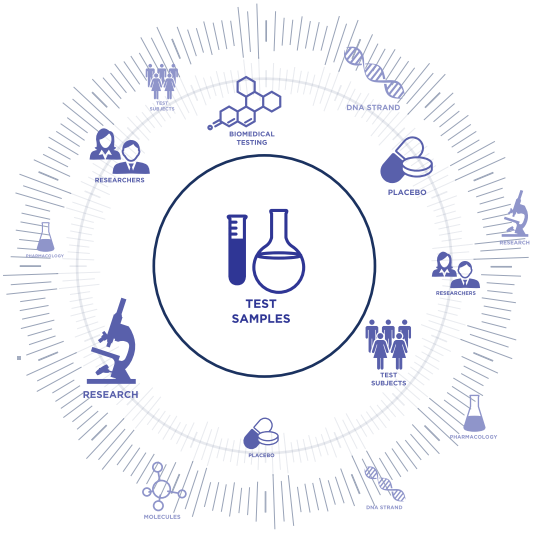
Veeda credentials to support your NMPA studies

- Veeda has demonstrated expertise in conducting studies and preparing dossiers as per **NMPA requirements**

- This is further backed by Veeda's extensive experience in **conducting diverse clinical studies** in compliance with global regulatory requirements

- Veeda is the leading independent, full service capability **CRO in India** with a very strong regulatory track record across key regulatory agencies including **USFDA, MHRA, ANSM, AGES, WHO, Anvisa, NPRA, MCC and DCGI** backed by a robust Quality Management System

Additional requirement for NMPA in addition to USFDA & EU



- Clinical trial information summary form
- Data management and statistical analysis report
- Data management and statistical analysis plan
- Original database (.xpt format)
- Excel format of raw data for calculation using WinNonlin software
- Details of delegation of study personnel
- Attendance sheet of Ethics Committee (EC) meeting
- Master list of standard operating procedures (SOP)
- Good Clinic Practice (GCP) statement
- GCP inspection reports and approval letters
- Subject information such as screening number, inclusion code, check-in and check-out time of each subject, and subject screening log
- 100% Chromatograms of method validation and 100% chromatograms of subjects sample analysis (Note : Chromatograms shall be presented as two chromatograms per page)
- Injection sequences of all subject samples
- Details of the inter-laboratory standardization methods
- Biological sample transport information
- Dataset mapping specifications and data model (ADaM) results (Not applicable to EU/MHRA dossier)
- Pharmacokinetic analysis of data of subjects who have completed at least one period of study and have at least one evaluable pharmacokinetic parameter

Veeda is known in the clinical research domain for its unwavering commitment to regulatory compliance and ethics, uncompromised high quality deliverables even in stringent deadlines, and its deep passion for continued scientific and technological excellence.

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