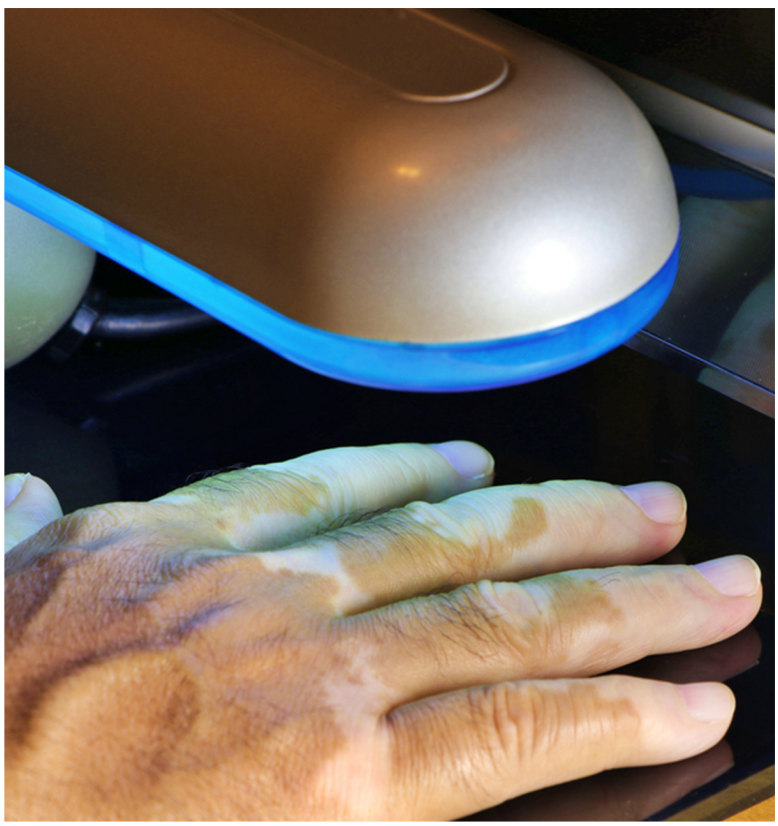
Case Study

veeda clinical research®



Dermatology Phase I Trial

Veeda's successfully execution of a Phase I, double blinded SAD and MAD study in healthy volunteers treating Vitiligo

Situational Analysis

An Indian multinational pharmaceutical company was preparing to apply for Vitiligo treatment approval in the United States. Veeda was bestowed with the responsibility of providing full services to the client.

Our services for the study included:

- Project Management
- Investigational Product Management
- Assigning the Principal and Clinical Investigator for the study
- Designing the study which included conducting the study in two parts (SAD and MAD), evaluating the Inclusion and Exclusion Criteria, and determining the sample size
- Development of Clinical Study Protocol, ICF, and CRF
- Ethics committee submission
- Volunteer Recruitment
- Screening of the volunteers
- Study Conduct (dosing and sampling)
- Clinical Data Management
- Lab Logistics
- Follow-up with the volunteers who participated in the study

Study Title

A Phase I, double-blind, randomized, placebo-controlled study to assess the safety, tolerability and pharmacokinetics of single and multiple doses of AS012 administered orally in healthy subjects.

Safety / tolerability parameters assessed throughout the study included

- Clinical Examination
- Clinical Laboratory Assessments
- Adverse Events
- Vital Signs
- ECG

Highlights of Results Delivered

- Completed the study in only **09 months**
- **46 subjects** were randomized
- Achievement of all study objective including exploratory objectives for **SAD and MAD**
- **Zero SAEs**

Addressing some of the Major Challenges faced during the study

Challenges	Action Plan/Management Strategy
To prevent: ◉ Cross-contamination of samples during plasma separation ◉ Deviation in PK time-points ◉ Missing of PK samples due to vein collapse/ thrombosis ◉ Inadequate amount of blood withdrawal before blood sampling	◉ To avoid cross contamination, separate disposable syringe and pipette were used for every sample ◉ Medical monitor has trained the site staff on PK time points as part of protocol training ◉ Clinical Research coordinator was trained to monitor to withdraw sufficient volume of heparinize solution i.e. ~0.3 ml prior to blood sample collection as per study protocol
How to tackle Accidental un-blinding?	Though there were no accidental un-blinding during the study course, However, Veeda had planned the mitigation strategy if such situation had occurred during the trial. ◉ The unblinded subject will not be allowed to perform any other activity that can affect the study outcome ◉ After due analysis, study impact will be assessed. Unblinding will be documented with due analysis
Proper volunteer recruitment and lower volunteer drop-out count	◉ All the possible efforts were made to recruit the required volunteers for the study ◉ Delay in patient recruitments were identified and necessary steps were taken to address those issues ◉ Screening of volunteers was carried out through proper documentation ◉ Volunteers those who were fit and met the inclusion criteria, only those were allowed to participate in the study ◉ If due to any unknown circumstances, the site was unable to recruit, then recruitment was carried out in the next possible day
Recruitment difficulties for volunteers (Specifically for female)	Proper planning of screening started on time. More number of volunteer screened. Drop out volunteers for second screening contacted telephonically if required and their arrival was confirmed for check in purpose.

Infrastructural capabilities of Veeda Clinical Research that helped in smooth execution of the study

- An MD Physician/ Intensivist was available from pre-dose till completion of housing of subject in each period/cohort
- Veeda's Clinical facility is well equipped with ICU for management of medical emergencies. All lifesaving equipment's like defibrillator, suction apparatus, laryngoscope and emergency medicines are available in our clinical facilities
- Experienced Study Physicians were appointed round the clock in clinical facility for subjects' monitoring
- Mobile ICU with all lifesaving equipment's and medications are kept round the clock in clinical facility for subject monitoring
- Veeda has contacts with multi-specialty hospitals for emergency management of subject during the study
- At the time of end of study, iron supplements were provided to subject sufficient for one month
- 24*7 availability of continuous cardiac monitoring facility was available with Veeda-CRO
- In case subject was dropped or withdrawn from study after dosing, safety assessment of the subject was done as mentioned in the protocol

Result

Veeda successfully completed Dermatology Phase I (SAD and MAD) studies under the COVID-19 situation by creating a controlled environment for study volunteers and study staff.