National, 4-cohort Female Health Study

100% Digital and Decentralized for Investigators and Participants

Participant Statistics

2,160 Contacted

950 Screened

175 Enrolled

137 Completed

Study Details

- **Study Length:** 5 months per participant, Study completed in 8 months vs the budgeted 9 months from recruitment to DBL
- **Staffing Required:** No CRAs, .15 FTE Project Manager, .15 Data Manager
- **Sponsor Fees:** Fixed price contract, zero change fees
- **Study Product & Materials:** Validcare provided full logistic support for all aspects of the study
- **Patient Surveys:** Medical History and Updates, Concomitant Medication, Vaginal Health, Quality of Life, Sexual Health, GI Health, Vaginal pH, Daily Product Journal, AE/SAE
- **Interim Analysis:** Time from Last Reported measure to data available for analysis = 1 day
- **Time to Database Lock (DBL):** Achieved in 2 days after last participant reported survey. Data readied for reporting within 5 days

FOCUS

Sponsor contacted Validcare to run a post-market, double-blind placebo controlled RWE clinical trial of its product to better understand any impact on female health, quality of life, and a number of secondary measures (GI, Skin, and Sexual Health).

SOLUTION

Validcare wrote a protocol for a sponsor's consideration. Sponsor agreed to protocol and its endpoints and contracted with Validcare to submit for IRB approval, list study on clinicaltrials.gov, provide end-to-end CRO services and prepare final write up of study results.

The study protocol was approved by the IRB, to include four separate cohorts to receive study product or placebo. The study was initiated with three of four cohorts fully enrolled in less than one week. The final cohort was successfully enrolled within two weeks after an approved change was made to the inclusion criteria and informed consent. Study execution was completely digital for participants and investigators.

All activities including recruitment, screening, enrollment, study product receipt and validation, testing materials and participant engagement were completed without involvement of CRAs or other staff. Enrollment reached significance within three months and included adults from age 18-70 across 41 states.

Participants completed a training and wash-out period, followed by active involvement including a Daily Product Use Journal, QOL surveys, and testing for vaginal pH results.Data were collected and reported by participants remotely, and results were monitored in near real-time by the principal investigator and staff in Florida.

RESULTS

An interim assessment was conducted and blinded data were shared with sponsor within two business days to determine whether to end enrollment early. Based on the data, the sponsor terminated enrollment as statistically significant data trends were apparent.

The decision to terminate enrollment resulted in reaching DBL 30 days early. Results for primary and secondary endpoints were statistically significant and readied for reporting within five (5) days of receipt of the pH and participant reported survey results by the final participant.

The data were delivered to sponsor within thirty (30) days of study close.

Validcare
Digital 1st CRO Experience
info@validcare.com
www.validcare.com
+1 844 825 4322