100% Digitally Executed Study Answers FDA's Call for Safety Data

100% Digital and Decentralized for Investigators and Participants

Participant Statistics

32,490 Contacted

2,730 Screened

1639 Enrolled

1061 Completed

Study Details

- Participant Access and Direct Data Capture: 48 states in the US
- Separate Cohorts: 17
- Study Length: 20 months
- Staffing Required: No CRAs, .25 FTE Project Manager, .25 FTE Data Manager
- Sponsor Fees: Fixed Priced contract
- Lab Tests: Liver panel (primary endpoint), free and total testosterone (secondary endpoint) collected remotely via pre-certified, national laboratory chains
- Patient Surveys: Stanford Sleep Scale (secondary endpoint), PROMIS (Quality of Life)
- Time from Last IA visit to data available = 2 days
- Time from Last Patient Last Visit to database lock = 5 days

FOCUS

The passage of the US Farm Bill in 2019 descheduled hemp from the Controlled Substances list. Congress then ordered the FDA to regulate hemp and its derivatives. FDA expressed concerns about long term use of ingestible hemp-derived products including liver toxicity, gonadotropic issues and unwanted drowsiness and quickly called for submission of science-based safety data. None existed.

SOLUTION

Congressional leadership asked Validcare to work with FDA and industry sponsors to design and execute a clinical study(s) to investigate and address FDA's safety concerns. Validcare designed a protocol based on FDA's feedback and received IRB approval in July 2020. The study was approved by IRB to be conducted via the 21 CFR Part 11 compliant Validcare Study™ Clinical Trial Platform.

The study was initiated in August 2020, at the height of COVID. Study execution was completely digital for participants and investigators. All activities including recruitment, screening, enrollment, and participant engagement were completed without involvement of CRAs or other staff. Enrollment reached 100% of goal and participants included adults from age 18-78 across all 48 states. Data and blood samples were collected remotely and results were monitored in near real time by the two co-investigators and staff in New York and Florida.

RESULTS

An interim assessment was conducted in February 2021 and data were shared with FDA in mid-March 2021. Based on the data, FDA requested enrollment continue to include another 200 participants and a second blood draw. This required IRB approval of updates to the protocol and Informed Consent (ICF). Study participation for affected participants was paused for five days to allow for IRB approvals. Upon approval, participants received and electronically re-consented via Validcare StudyTM platform within 48 hours.

The study concluded after twenty (20) months. Results for primary and secondary endpoints were statistically significant and readied for reporting within five (5) days of receipt of the final serum results from the final participant.

The data were delivered to FDA, Congress and sponsors within thirty (30) days of study close. Subsequently, UK Food Safety Authority requested and received access to the data. Peer reviewed journal articles were also published and are available upon request.

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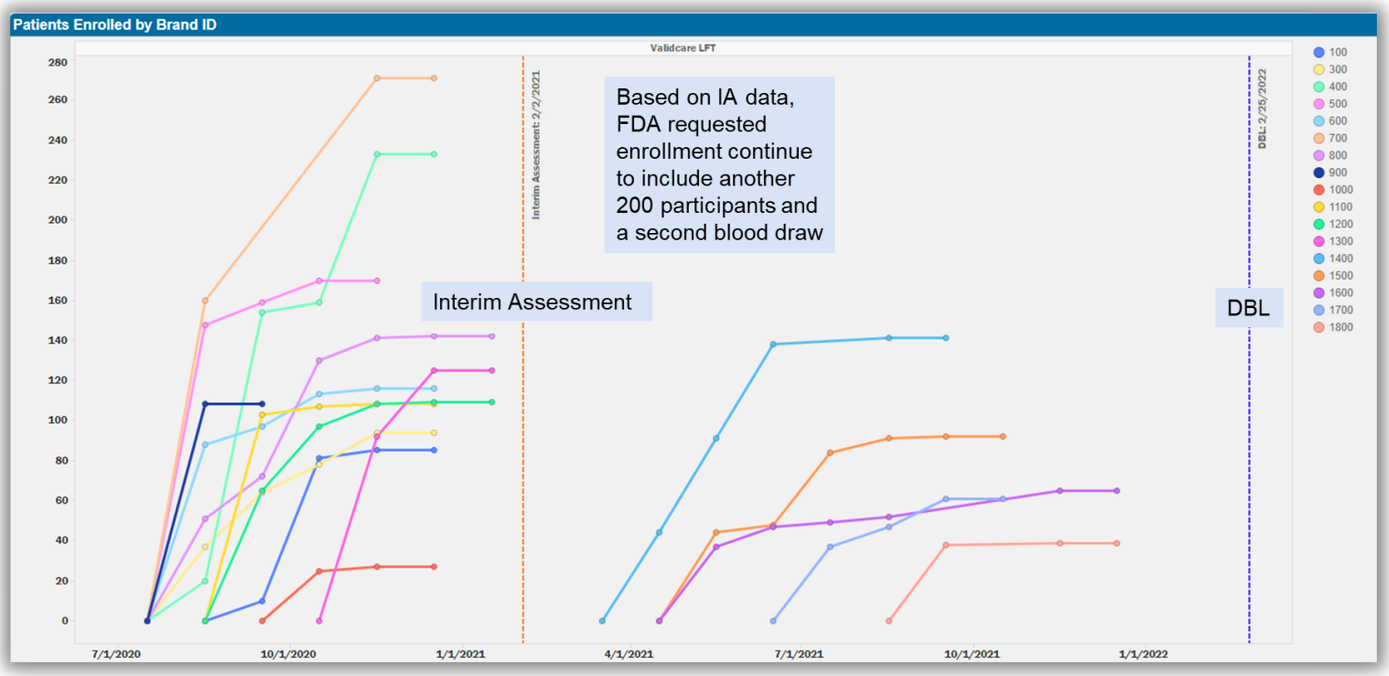
ALL BRAND COHORTS ENROLLMENT: PRE- AND POST-IA



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