

Use of Digital Health Technology Tool to Assess Medication Adherence in Schizophrenia: The INTERACT Study Experience

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Methodological Issue Being Addressed Use of Digital Health Technology Tool to Assess Medication Adherence in Schizophrenia

Introduction A significant issue facing schizophrenia clinical trials is subject non-adherence to study medication. In an effort to address this issue, digital technology tools have been developed to provide reminders to patients and monitor their medication intake.

Methods A smartphone-based application (henceforth described as “the platform”), that utilizes computer vision technology to verify study medication intake, was used in the study of TAK-831/NBI-844 (luvadaxistat) as an adjunctive treatment for negative symptoms of schizophrenia (the INTERACT Study). This study was a phase 2, 12-week, randomized, double-blind, placebo-controlled, efficacy, safety, and pharmacokinetic (PK) study of 3 doses (50, 125 and 500 mg) of luvadaxistat. In order to assess the platform performance, we correlated the platform usage against pill counts and detectable plasma levels of luvadaxistat.

Results Of 256 subjects randomized, 169 subjects were assigned to take luvadaxistat. We first focused on a subset of 165 subjects with PK data and adherence to the platform use data. Of the 165 subjects, we observed 160 subjects with $\geq 75\%$ overall adherence to the platform use of which 144 subjects (144/160 or 90%) also had quantifiable level of luvadaxistat in plasma sample collected whereas the remaining 16 of 160 subjects (10%) had plasma concentrations of luvadaxistat below quantifiable levels. The remaining 5 subjects assigned to take luvadaxistat had quantifiable plasma concentrations of luvadaxistat but $< 75\%$ overall adherence to the platform. There were no subjects with both below quantifiable plasma concentrations of luvadaxistat and $< 75\%$ overall adherence to platform.

We also looked at a subset of 154 subjects with pill count data and platform use data. Similar to the observed relationship between platform use and quantifiable plasma concentration, there were 151 subjects (151/154 or 98.1%) that showed $> 75\%$ adherence to platform use and high ($> 90\%$) pill count compliance level. Pill count compliance is defined as percentage of the number of prescribed pills corrected for the number of returned pills divided by the period (in days) multiplied by 100%. Of the remaining 3 subjects with $< 75\%$ adherence to the platform use, one subject showed $< 75\%$ pill count compliance. The other two subjects had high pill count percentages; one subject close to $\sim 100\%$, and the other with $> 140\%$ reported on pill count.

Conclusion These preliminary findings demonstrate high drug adherence in the INTERACT Study across multiple methods. When assessing adherence to study drug intake, there seemed to be a

90% or higher concordance with overall adherence to platform use when paired with either detectable PK level or pill count compliance. There is ongoing effort to determine the correlation between detectable luvadaxistat in plasma, pill count, and platform usage for the two weeks before week 12 (end of double blind) plasma PK sample collection, as well as the impact of timing between dosing and PK draws that may influence interpretation. Further analysis and findings to be presented.

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