Case Study: Shortened Trial Duration & Enhanced Endpoint

CHALLENGE

- Registration trials for acute schizophrenia are a set duration and use a lengthy symptom scoring tool (PANSS) as the primary endpoint.
- Can data science methodology be used to evaluate the feasibility of a shortened scoring tool and reduced trial duration

SOLUTION

- Efficacy information from 8 new drug applications between 2001 and 2015 was integrated (14,219 subjects)
- Analysis of baseline PANSS items, estimation of change from baseline and concordance of the full scoring tool for implication on sample size

OUTCOME

- Only 2/3 of PANSS items are sensitive to schizophrenia symptom severity
- Use of modified PANSS (mPANSS) at 4 weeks is similar to full PANSS at 6 weeks
- mPANSS at 4 weeks is a feasible alternative endpoint for acute schizophrenia registration trials

Reference: J Pharmacokinet Pharmacodyn (2018) 45(Suppl 1): 3. https://doi.org/10.1007/s10928-018-9606-9