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Industry Collaborations, a Cost-effective Method to Advance the State-of-the-Art

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DESCRIPTION

The publication, Cecchi, et al., validation of a suite of ERP and QEEG biomarkers in a pre-competitive, industry led study in subjects with schizophrenia and healthy volunteers, demonstrates that industry collaborations can cost effectively advance the state of the art for all stakeholders while limiting competitive risks.

This study was sponsored by the ERP biomarker qualification consortium to meet objectives specifically identified by the industry members to optimize the use of ERP/EEG biomarkers in therapeutic trials. This included standardizing ERP/EEG testing methods and determining the variability of these biomarkers in real-world trials.

The published results document the standardized methods and variance statistics which are critical to operationalizing these biomarkers in studies of compounds to treat patients with schizophrenia. The large number of biomarkers investigated will give the pharma industry a wide selection of validated measures of drug effects. The reported within subject, within group, and between group variances will enable drug companies to accurately power studies in these populations. And finally, the study was performed at commercial trial sites with academic oversight, demonstrating that cutting-edge science could be conducted in operationally practical study environments.

The fact that a consortium of ten, highly competitive pharma companies, plus academic and NIH advisors, were able to work collaboratively to design, execute, and publish this study is a testament to the teamwork and commitment to answering critical questions encountered in many CNS drug development programs.

This unique industry-focused consortium should serve as a model for additional collaborative work intended as a “rising tide” for the pharmaceutical industry.

The publication by Cecchi, et al., in schizophrenia research demonstrates how industry collaborations can advance the use of ERP/EEG biomarkers in therapeutic trials for patients with schizophrenia. The study was sponsored by the ERP biomarker qualification consortium, which aimed to optimize the use of these biomarkers in drug development. The study standardized ERP/EEG testing methods and determined the variability of these biomarkers in real world trials.

The results of the study provide critical information for drug companies, including standardized methods and variance statistics, which are necessary for operationalizing these biomarkers in drug development. The study investigated a large number of biomarkers, giving the pharma industry a wide selection of validated measures of drug effects. The reported within-subject, within-group, and between group variances will enable drug companies to accurately power studies in these populations.

The study was performed at commercial trial sites, with academic oversight, ensuring that cutting-edge science could be conducted in operationally practical study environments. The fact that a consortium of ten highly competitive pharma companies, academic and NIH advisors were able to work collaboratively to design, execute, and publish this study is a testament to the teamwork and commitment to answering critical questions encountered in many CNS drug development programs.

This unique industry-focused consortium is a model for additional collaborative work intended to benefit the pharmaceutical industry as a whole.

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