Utilizing Experienced Research Networks to Conduct Global Clinical Trials in Difficult to Access Populations for Drug Development in Psychiatry

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SUBMISSION DETAILS

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Methodological Issue Being Addressed Can site networks established for publicly funded research be utilized to conduct industry-sponsored clinical trials in a difficult to access population; early in illness schizophrenia and bipolar disorder?

Introduction Increasingly there is interest from the public, scientist, and patients to evaluate early treatments for people at risks of, or in early-stages of severe mental illness. Additionally, through research done by the FDA and updates to guidance documents, there may be opportunities to expedite pediatric labeling for newly developed antipsychotics by including pediatric patients in registration studies when criteria for extrapolation are possible. Early in illness patients, including pediatric patients, have traditionally been difficult to recruit into industry-funded fund trials as private research sites with the infrastructures to meet the increasing burdens of clinical research are not where patients are treated and diagnosed clinically. By contrast, most multicenter studies done in similar populations have been investigator-initiated or publicly funded and conducted largely in academic medical centers The additional burden of conducting industry-funded clinical trials has been sited as a common reason clinically based researchers do not participate in these clinical trials. The aim of this study methodology was to determine if two academic medical center-based site networks established to study early in illness schizophrenia populations could collaborate with a global CRO experienced in conducting registration studies for an industry-funded trial of an investigational drug.

Methods The UMC Utrecht, Clinical Trial Center (CTC) was initially established to coordinate a large multicenter trial in first episode schizophrenia patients . Similarly, the Vanguard Research Group (VRG) was established out of Northwell Health to conduct a NIMH funded study in patients following an initial episode of schizophrenia . A global CRO, in collaboration with the CTC and VRG network project leadership was utilized to ensure overall quality and adherence to GCP-standards (ie; medical monitoring, safety reporting, regulatory filings, etc). The CTC and VRG sites were selected based on previous successful collaborations where they demonstrated to be able to recruit sufficient numbers of participants and delivered high quality data – building on past experience with dedicated study coordinators and researchers at academic sites and community mental health centers. They are also aware of the channels to utilize to access the patient population, e.g. existing working relationships with patient/family associations, having an established reputation as a research center, etc. These researchers had demonstrated successful patient retention through engagement during their studies.

Results 31 of the 73 activated global sites were from VRG (15) and CTC (16) research networks.

Activated VRG/CTC sites were composed of academic medical centers, private healthcare clinics and community mental health practices. Additional global sites were selected from the CRO/sponsor. Site identification, contracting, start-up activities and site/CRO communications were facilitated by VRG/CTC for sites they managed to reduce site burden and expedite start-up. Within the US 34.1% of enrollment came from VRG sites (71/208 subjects). All enrollment in Central and Western Europe and Israel came from CTC sites (59 subjects). Additional global enrollment regions included Korea, Ukraine and Russia (161 subjects). Full details on site activation timelines, overall enrollment and retention by VRG/CTC vs other sites will be presented.

Conclusion This model may allow for expansion of drug development to be conducted in hard to access populations by reducing investigator burden while still enabling GCP-level quality required for industry-funded research.

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Guidelines I have read and understand the Poster Guidelines

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