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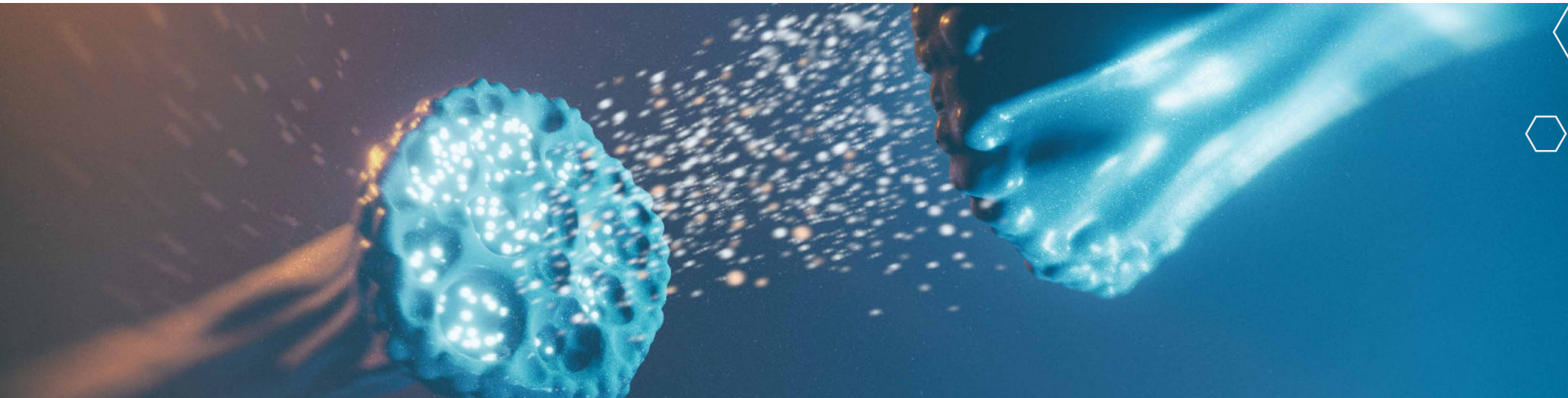
PSYCHIATRY

Leveraging Experienced Research Networks for Global Psychiatry Studies in Difficult-to-Access Populations

Introduction

When approached for an early-in-illness schizophrenia trial, Premier Research knew that patient recruitment would be challenging and require creative approaches for success. Based on our experience in mental illness studies and with this indication, we recognized the importance of identifying sites where patients were already being diagnosed and treated. To achieve this, the Premier team implemented a site network model, in addition to standalone sites, that could reach this difficult-to-access patient population through community mental health practices, academic centers, and private healthcare clinics. The model proved to be successful, with 30% of the patients enrolled via the site networks, leading to accelerated enrollment and increased diversity in the study.



Background

There is increasing interest among the public, scientists, and patients to evaluate early treatments for individuals at risk of—or in the early stages of—severe mental illness. However, it can be challenging to recruit early-in-illness patients[1], including pediatric patients, into industry-sponsored trials because the private sites with the necessary infrastructure for clinical research are not the locations where patients are diagnosed and treated. Instead, most multi-center studies in these populations have been investigator-initiated or publicly-funded and have been conducted largely in academic medical centers.[2]

Objective

Our objective was to determine whether site networks established for publicly-funded research could be utilized to conduct industry-sponsored clinical trials in early-in-illness schizophrenia, a population that has traditionally been difficult to recruit.

Approach

We identified two academic medical center-based site networks that were established to study early-in-illness schizophrenia populations—the Vanguard Research Group (VRG) and the UMC Utrecht, Clinical Trial Center (CTC). Both site networks were established to conduct clinical trials in patients with first-episode schizophrenia. Premier collaborated with these site networks to conduct a registration study for an industry-sponsored trial of an investigational drug.[3]

Execution

VRG and CTC sites were selected based on previous successful collaborations demonstrating their ability to meet recruitment targets and deliver high-quality data. The selected sites also had established channels for accessing the target patient population and proven track records of successful patient retention.

Of the 73 global sites activated for the registration study, 31 were from the VRG and CTC networks, comprising academic medical centers, private healthcare clinics, and community mental health practices. VRG/CTC facilitated site identification, contracting, start-up activities, and site/CRO communications for their respective sites to reduce site burden and expedite start-up.

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[1]Accelerating Medicines Partnership Schizophrenia. Available at https://www.ampscz.org/.

[2]Correll CU, et al. Weight gain and metabolic changes in patients with first-episode psychosis or early-phase schizophrenia treated with olanzapine: A meta-analysis. Int J Neuropsychopharmacol. 2023;26(7):451-464.

[3]Kahn RS, et al. Olanzapine/samidorphan in young adults with schizophrenia, schizophreniform disorder, or bipolar I disorder who are early in their illness: Results of the randomized, controlled ENLIGHTEN-Early Study. J Clin Psychiatry. 2023;84(3):22m14674.

Results

Within the US, 34.1 percent of enrollment came from VRG sites (71/207 subjects). All enrollment in Central and Western Europe and Israel came from CTC sites (59 subjects).

Site Affiliation	Sites	Screen Fail Rate (%)	Enrolled Subjects	Sites Enrolling ≥3 Subjects (%)
VRG/CTC	31	45%	130	13 (41.9)
US non-VRG	19	38%	137	9 (47.4)
Other Regions	23	10%	161	18(78.3)
Total	**73**	**33%**	**428**	**40 (54.8)**

Figure 1. Enrollment by site/region in an industry-sponsored trial of an investigational drug for early-in-illness schizophrenia

Takeaway

Collaborating with established, experienced research networks may allow for expansion of drug development to include difficult-to-access populations by reducing investigator burden, while still enabling the Good Clinical Practice (GCP)-level quality required for industry-sponsored research. Working with a CRO that has relationships with site networks can help to accelerate enrollment and even increase clinical trial diversity by reaching patients where they already receive care. To learn more about how Premier can help sponsors access hard-to-reach populations, contact us.

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Summary

Project Description

To demonstrate that established site networks can be used to conduct industry-sponsored clinical trials in difficult-to-access populations.

Therapeutic Area

Psychiatry

Outcome

Established site networks represented 42% of all activated sites and accounted for 30% of overall enrollment.

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