

FOR IMMEDIATE RELEASE

European Group for Research in Schizophrenia Selects OmniComm Systems® TrialMaster® Risk-Based & Centralized Monitoring with Auto-Redaction to Reduce Monitoring Costs

Fort Lauderdale, FL, February 24, 2015 - OmniComm Systems, Inc. (OmniComm) (OTCQB: OMCM), a global leading provider of clinical data management technology, announces that the European Group for Research in Schizophrenia (EGRIS) has selected TrialMaster electronic data capture (EDC) technology with risk-based and centralized monitoring for its European Long-acting Antipsychotics in Schizophrenia Trial (EULAST). The EULAST trial will span 16 countries, involve 45 investigator sites, enroll up to 720 patients and is expected to run for 7 years. EULAST is a Late Phase (Phase IV) interventional study aimed at investigating possible advantages of depot medication over oral antipsychotics in an independently designed and conducted, randomized, pragmatic trial.

“Non-adherence to effective medications is a source of relapse and unnecessary hospitalization in individuals suffering from schizophrenia,” says Dr. Michael Davidson, professor and head of the department of psychiatry at the Sheba Medical Center and professor of psychiatry at the Sackler School of Medicine. “Despite the common sense notion that depot medication administered once a month should increase adherence and thereby reduce relapse risk (in comparison with oral medication that has to be administered daily) it has been difficult to demonstrate this in traditional blinded clinical trials. Because of its size and design the EULAST will provide a definitive answer whether long acting medication indeed increases successful treatment continuation. For this, data quality is of the highest importance. We feel reassured that data quality and protocol adherence is supported by the innovative solutions offered by TrialMaster.”

TrialMaster’s risk-based and centralized monitoring capabilities with auto-redaction were significant factors for the selection of TrialMaster. TrialMaster is the only EDC application available with built-in auto-redaction capability. This first of its kind, patent pending technology enables site investigators to protect patient privacy and remove patient identifiable information by irreversibly masking these fields. TrialMaster’s centralized monitoring auto-redaction capability allows site monitors to view and inspect documents remotely, significantly reducing the high costs associated with on-site visits. This is an important consideration when taking into account the scope of the EULAST.

“With a trial of this magnitude, centralized monitoring capabilities and elaborate reporting options of the system are very useful in identifying any issues in the conduct of the trial early on and achieving the quality of the data we require,” says Dr. René Kahn, professor and chair of the department of psychiatry and head of the division of neuroscience at the University Medical Center, Utrecht, Netherlands. “This way, we will be able to focus our attention more effectively on data quality as well as the protection of study participants.”

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Physician and site personnel turnover is not unusual in a study of this magnitude and length making compliance and training an ongoing challenge. TrialMaster’s intuitive user interface and eLearning functionality minimizes the training effort typically associated with new site personnel and ensures data quality and integrity is maintained throughout the study.

“We are proud to be selected by EGRIS as their strategic technology partner,” said Wolf Ondracek, senior vice president of Academic and Asian Markets and managing director at OmniComm Systems. “Using TrialMaster’s risk-based and central monitoring with auto redaction will lower their total monitoring costs while ensuring data quality and facilitating better and faster decision making. As the leading innovators in EDC technology, OmniComm provides the most efficient, effective and modern EDC technology needed for their clinical program.”

The trial is overseen by three internationally renowned principal investigators, Dr. René Kahn, professor and chair of the department of psychiatry and head of the division of neuroscience at the University Medical Center, Utrecht, Netherlands; Dr. Wolfgang Fleischhacker, professor in the department of psychiatry and psychotherapy at Innsbruck University Clinics, Innsbruck, Austria; and Dr. Michael Davidson, professor and head of the department of psychiatry at the Sheba Medical Center and professor of psychiatry at the Sackler School of Medicine, Tel Aviv, Israel.

Supporting Information

- [TrialMaster](#)
- [Risk-Based and Centralized Remote Monitoring](#)

About OmniComm Systems, Inc.

OmniComm Systems, Inc. is a leading strategic software solutions provider to the life sciences industry. OmniComm is dedicated to helping the world’s pharmaceutical, biotechnology, contract research organizations, diagnostic and device firms, and academic medical centers maximize the value of their clinical research investments. Through the use of innovative and progressive technologies these organizations drive efficiency in clinical development, better manage their risks, ensure regulatory compliance and manage their clinical operations performance. OmniComm provides comprehensive solutions for clinical research with an extensive global experience from over 4,000 clinical trials. For more information, visit www.omnicomm.com.

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OmniComm Systems, Inc.
2101 West Commercial Blvd.
Suite 3500
Fort Lauderdale, FL 33309 USA
Phone: +1.954.473.1254
Fax: +1.954.473.1256
www.omnicomm.com

Contact Info

Dennis Constantinou
OmniComm Systems, Inc.
+1.954.473.1254
dconstantinou@omnicomm.com

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