

## OmniComm Systems Experiencing Rapid Adoption of TrialOne® in China

### *Three New Clients to Implement OmniComm’s Phase I Clinic Automation Solution*

Fort Lauderdale, FL, January 16, 2017 OmniComm Systems, Inc. (OTCQX: OMCM), a leading provider of clinical data management technology, has just signed landmark contracts to provide OmniComm’s proprietary TrialOne clinic automation solution to several major clinical research organizations in China. OmniComm has signed agreements for TrialOne with Xiyuan Hospital, the Chinese Anti-Cancer Association (CACA) and eStart Medical Technology Co., Ltd. The contracts represent TrialOne’s debut in China and were sparked by a strategic partnership with Tri-I Biotech (Shanghai) Inc., a market-leading China-based solutions provider to the life sciences sector.

“We sought an early-phase, cost-effective, market-leading clinical trial system that is widely used in the world,” said Dr. Lu Fang, associate director, General Office of National Institution of Clinical Trials, Xiyuan Hospital. “With TrialOne, we expect to see significant improvement in the quality and productivity of our early-phase studies, allowing us to pass on cost savings to our clients. Using TrialOne, we will run clients’ studies in a top-quality and 21 CFR Part 11 compliant system that is easy to learn and accessible via the web to our staff and sponsors. This will allow us to improve our operation by ensuring we have timely, reliable, quality data.”

TrialOne was selected for several reasons, including its status as a market-leading EDC and site automation system for early-phase clinical trials. Additionally, TrialOne supports the Chinese language and provides the opportunity for research organizations to greatly improve productivity and efficiency during clinical trials. As a system compliant with global industry standards and best practices for clinical trials, TrialOne allows user organizations to secure the quality and integrity of the data collected and managed during clinical trials. TrialOne’s ability to enable users to comply with Chinese FDA regulations aimed at harmonizing local practices to global standards was also a key factor influencing the adoption of TrialOne.

“We are in the process of standardizing the oncology bioequivalence studies for our 12-member hospitals,” says Dr. Zhao Yan, general secretary at CACA. “With OmniComm’s TrialOne, we can streamline our early-phase study process and reduce the study build time. TrialOne provides a CDASH library that will support us as we submit study data in CDISC standards.”

Regulatory changes in China have increased the importance of clinic automation systems during clinical trials. Currently, early-phase research centers lack the systems needed to manage clinical trials, while addressing the regulatory requirements for data quality and integrity.

Fort Lauderdale, FL United States	Somerset, NJ United States	Bonn Germany	Southampton United Kingdom	Leiden Netherlands	Tokyo Japan
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“We have been in the process of evaluating early phase clinic systems for the last five years. We came to the conclusion that TrialOne represents top quality and provides an FDA regulation compliant system that meets our needs,” said Dr. Jennifer Hou, chief medical officer of eStartMed. “We will use TrialOne in our three sites in China. TrialOne has a rich library for interfacing with bedside devices. We have purchased devices that can easily connect with TrialOne for direct data capture. This automation step will significantly improve the data quality and productivity in our studies. I am confident using TrialOne will greatly increase throughput from our sites.”

TrialOne is a comprehensive set of modules that drive efficiencies, reduce timelines and costs through faster and more directed volunteer recruitment, easy-to-build schedule-based workflows, real-time bedside data collection, direct data capture from devices, sample processing automation and modern data processing. The browser-based, tablet-compatible system provides an advanced platform for automating clinic operations, complies with FDA 21 CFR part 11, and supports data standards such as CDISC for faster and easier exporting and reporting of data.

“The last 12 months have turned out to be a pivotal year for the penetration of TrialOne into APAC — the Asia and Pacific region,” said Wolf Ondracek, managing director and senior vice president at OmniComm. “After welcoming Sydney-based Scientia Clinical Research, our first customer in Australia, we now have a leading position in the early-phase site automation and EDC systems market in China with these three new customers. Both CACA and eStart Medical cover multiple hospitals that collaborate in clinical research, thereby giving TrialOne exponential exposure and tremendous growth potential for the coming years.”

### Supporting References

[TrialOne](#)

[OmniComm Systems® Announces Reseller Agreement with Tri-I Biotech Shanghai Inc.](#)

### About Xiyuan Hospital

Xiyuan Hospital is a large AAA-grade TCM hospital that integrates scientific research, education and healthcare. It is also the Online International Emergency-Aid Center of the Ministry of Public Health of China, the TCM training site for western doctors authorized by the Ministry of Public Health of China, the clinical teaching and practice base for Beijing University of Chinese Medicine, and the teaching site for International Acupuncture and TCM Education. For more information, visit [www.xyhospital.com](http://www.xyhospital.com).

### About The Chinese Anti-Cancer Association

The Chinese Anti-Cancer Association, established in 1984, seeks to be the leading non-governmental organization devoted to increasing the survival rate of cancer patients, decreasing the incidence and

mortality rate of cancer, and improving cancer control in China and the world. CACA’s mission is to help prevent and treat cancer via organizing, mobilizing and supporting clinical, scientific and technological professionals in the field of oncology. CACA is affiliated with the Chinese Association of Science & Technology and registered in the Ministry of Civil Affairs of the People’s Republic of China. For information visit, [www.caca.org.cn/english](http://www.caca.org.cn/english).

**About eStart Medical Technology Co., Ltd**

eStart Medical Technology Co., Ltd. (eStartMed) is a contract research organization (CRO) offering one-stop services of early phase clinical trial for global and domestic pharmaceutical, biotech and medical device companies. eStartMed offers seamless services, including registration and strategical consulting, project management, monitoring and auditing services, protocol design, data management, biostatistics, sites operation, especially in FIH and phase I clinical trials of innovative drugs, bioequivalence studies, and clinical evaluation of cardiac toxicity, etc. For more information visit, [www.estimate.net/en](http://www.estimate.net/en).

**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 risks, ensure regulatory compliance and manage clinical operations performance. With extensive global experience from more than 5,000 clinical trials, OmniComm provides comprehensive solutions for clinical research. For more information, visit [www.omnicomm.com](http://www.omnicomm.com).

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