

## PRESS RELEASE

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# TFS research unit successfully inspected by the Swedish Medical Products Agency (MPA)

TFS Trial Form Support International's (TFS) research unit integrated with Karolinska Trial Alliance (KTA) at the Karolinska University Hospital, Stockholm, Sweden was successfully inspected by the Swedish Medical Products Agency (MPA) in March 2008.

Since the First-in-Man (FIM) clinical trial of TGN1412 there has been increased activity on the part of the EMEA and regulatory authorities to regulate and control the way in which FIM studies are conducted in Europe. The EMEA produced a draft guideline for the conduct of FIM studies in March 2007 followed by procedures for Phase I unit inspections in September 2007. The Medicines and Healthcare Products Regulatory Agency (MHRA) introduced a local accreditation program for FIM centers in the UK in November 2007. The Swedish MPA inspections of FIM units in Sweden should be seen as part of the increased activity by European agencies to ensure that FIM studies are conducted in a manner which protects the rights and welfare of participants in first in man studies.

The inspection was conducted by inspectors from the Swedish MPA as part of their First-in-Man (FIM) inspection program. The inspection program will include inspections of all research units in Sweden conducting FIM studies. The TFS research unit at Karolinska was selected as the first unit to be inspected in Sweden.

The purpose of inspecting these clinical trial sites is to verify that participants' safety can be assured during the study. The main focus of the inspection was thus on the competence of the staff, the structure of the organization, the unit's processes and the functionality of the facilities used.

The inspection was a routine inspection for the purpose of verifying whether or not the organization, personnel, processes and facilities at Karolinska Trial Alliance are suitable for performing First-in-Man studies in accordance with the applicable regulations, CPMP/ICH/135/95 and LVFS 2003:6.

*"TFS and KTA have ever since the initiation of the research unit made every effort to ensure that the unit should fulfil the highest quality standards and we are of course very pleased to receive official verification from the Swedish inspectors that the unit is approved for the conduct of First-in-Man studies", says Mr. Alistair Bone, Director Global Quality Assurance at TFS.*



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The Swedish Medical Products Agency's Inspections unit is responsible for the inspection of clinical trials conducted in Sweden. As part of this responsibility, special focus has been placed on assuring patients' safety when participating in clinical trials. This applies particularly to the units, clinics and institutions that perform studies where drugs are given to people for the first time, termed First-in-Man studies.

The inspectors wished to stress that the TFS research unit at Karolinska seemed to be of good quality both with respect to the competence of the trial personnel and the facilities in which the studies were being performed. The trial participants thus appeared to be well taken care of, and the data collected to have been documented in accordance with the regulations.

No major or critical findings were observed. The TFS research unit was deemed to fulfill the Swedish Medical Products Agency GCP requirements.

*"This means that the KTA phase 1 unit is approved with a green light by the Medical Products Agency. They are satisfied with their findings. This is obviously not another "Holiday Inn phase one unit", but rather a highly sophisticated and complex centre for exploring translational biology and clinical medicine. Thanks to the competence and training of the staff we perform top of the line first in man and proof of concept studies. I am so grateful to our dedicated staff and our partner Trial Form Support for this achievement",* says Professor Pierre Lafolie, Head of Karolinska Trial Alliance at the Karolinska University Hospital.

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To review the abbreviated Inspection Report visit:

<http://www.trialformsupport.com/business/trials.htm>

### Information about TFS Trial Form Support International (TFS)

TFS is a full-service clinical CRO, providing the pharmaceutical, biotechnological, medical device, diagnostic and functional food industries with a wide range of clinical trial services. TFS services cover the whole clinical development programme from early explorative Phase I trials to registration trials in Phases II-III and post marketing surveillance trials in Phase IV. Over 420 highly competent employees dedicated to accuracy and service are working from multiple offices spread throughout 15 countries in Europe, India, Japan and the USA.

### Information about Karolinska Trial Alliance (KTA)

Karolinska Trial Alliance (KTA) within Karolinska University Hospital is a unit that supports research around pharmaceuticals, diagnostics and medical devices. KTA's unit conducts early clinical trials together with TFS Trial Form Support International AB as their partner.



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