



TENALEA – Trans European Network for Clinical Trials Services

Background

The main objective of TENALEA is to reduce administrative overhead in clinical trials data management to the investigator, data centers and stakeholders. The key instrument to achieve this objective is harmonisation of the Clinical Trials Data Management tools which are being pushed towards the investigators and study sites. TENALEA is an initiative by 6 major European Clinical Trial Coordination Centres to provide best-of-breed solutions for a cost price to those who are now faced with major development costs, operational and support costs, and costs for QA and compliance.

The TENALEA Initial Deployment project is conducted in a 50 months term starting October 2006 and ending 31 December 2010. This project is carried out by a consortium of Academic Clinical Trials Coordination Centres, a regional healthcare network and a software firm. The Initial Deployment phase is the follow up to a Market Validation phase which was completed in December 2005, and in which a business plan was developed for a roadmap towards full deployment. The business plan concluded that TENALEA should provide a service deployment framework which defines the management of the service portfolio offered by TENALEA.

Current services: randomisation and eCRF

Two services are currently provided: TENALEA Randomisation and TENALEA eCRF.

The TENALEA Randomisation service has gone through several cycles of development over the past 20 years. It has been validated by 20 data centres throughout EU member states, tested by the pharmaceutical industry, and has been localised to meet their functional and operational requirements. 37 Clinical Trial Coordination centers throughout the world are currently using TENALEA Randomisation for well over 300 trials.

TENALEA eCRF provides a comprehensive, rich electronic Case Report Forms system allowing Clinical Trial Coordination Centers to switch from paper CRF to electronic CRF. The service is based on an industry grade enterprise electronic forms system: Microsoft Infopath 2007 for form design and Microsoft Forms Server 2007 for data entry. The TENALEA eCRF service is being operated in production since January 2008. TENALEA eCRF is currently operated for 12 trials from France, the Netherlands, UK, Belgium, Poland and Indonesia.

QA and Compliance

The TENALEA Services are hosted in a commercial datacenter in Den Bosch, the Netherlands with failover to co-location facilities at the NKI premises. A comprehensive QA system for the operational



management of the service is in place. The TENALEA service environment has been officially certified by external auditors in November 2010.

The main task in the Initial Deployment phase is the roll out of TENALEA Services to clinical trials coordination centres throughout Europe including training and education, QA and validation, compliance, localisation, local activation and migration from current systems to TENALEA for those data centers which have a legacy system in place. In addition, facilities for SLA (Service Level Agreement) based contracts have been established for service the pharmaceutical industry and Contract Research Organisations.

Current status

November 2009 marks milestone 3 of the project, at which the system validation has been completed, the localization of the ALEA software has been released as TENALEA Randomisation and TENALEA eCRF, and a new server farm has been taken into use.

As off 1 January 2010, customers will be charged a fee for TENALEA Randomisation and TENALEA eCRF. In Q1 of 2010, a marketing campaign will be launched to attract additional customers, including a new website and updated handout materials.

The TENALEA Initial Deployment consortium

The consortium of the TENALEA Initial Deployment project is:

- Coordinator: Nederlands Kanker Instituut/Antoni van Leeuwenhoek ziekenhuis, NL
- Contractor: Institut Gustave Roussy, FR
- Contractor: Universitäts Klinikum Köln, DE
- Contractor: Oxford Radcliffe Hospitals Trust, UK
- Contractor: Medical University of Gdansk, PL
- Contractor: Réseau de Cancérologie d'Aquitaine, FR
- Member: InferMed Ltd, UK
- Member: Academisch Medisch Centrum, NL
- Member: Clinical Trial Centre Maastricht, NL
- Member: Centre George François Leclerc, FR
- Member: The Chancellor, Master and Scholars of Oxford, UK
- Member: University of Southampton, UK

More information

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