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EXECUTIVE SUMMARY OF PRE-CONTRACT AUDIT OF SUBCONTRACTOR: ETHICAL GmbH

Location/Areas audited:	GM Servizi S.r.l.
ADDRESS:	Via 4 Novembre 71 - 18100 Imperia ITALY
TELEPHONE:	+39 0183 660023
EMAIL:	Mimmo.garibbo@ethical.ch
DATE OF AUDIT:	13-15JAN2014
AUDITOR :	Catherine Pham, Quality Specialist
CONTACT NAME:	Mimmo Garibbo, Director; Mauro Favero, QA Manager

Objective and Scope of the Audit:

The audit was conducted to assess the suitability of Ethical GmbH to provide a service regarding an e-CEC adjudication system for UCR with an acceptable and consistent level according to UCR procedures. Other objectives of the assessment were to ensure that:

- eAdjudication system includes the basic functions for CEC process at UCR and easy customized/configured to adapt UCR CEC process
- Ethical GmbH has a documented validation of the system according to ISO 27001: 2005 and requirements for computer system validation used for clinical trials.

Compliance Standards:

ISO 27001: 2005, CFR21 part 11 compliant, EudraLex Volume 4 Annex 11, ICH GCP

Audit Approach:

The assessment was performed in accordance with SOP UCR-014, Risk-based Vendor Management and Investigational Site Evaluation.

The in-house assessment consisted of review the responses to and documents attached to the UCR vendor assessment questionnaires.

The on-site assessment consisted of:

- A short introductory meeting with relevant staff at GM Servizi office, for introduction and to agree upon the assessment agenda, and to ensure that all those involved clearly had understood the objective and scope of the assessment
- A review on-line of CEC adjudication standalone system, demo version
- A review of validation documents
- A tour of server facility at GM Servizi
- Interviews/Discussion with Ethical GmbH director, QA Manager, Project Managers, and IT& Security Manager
- Visit data center Level iP, at Milano and interview/discussion with Engagement Manager
- An exit meeting to report preliminary the outcomes of the assessment.



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Audit Areas:

- Demo version of eAdjudication
- Quality systems: risk analysis, request tickets system, CAPA system, monitoring systems
- Validation documentation of eAdjudication demo version
- Server facility at GM Servizi
- Data center Level iP located in Milano, is Ethical GmbH subcontractor

Audit Conclusion:

There were good quality systems/ validation procedures in place at Ethical GmbH. Staff showed good awareness of quality, expertise in developing the electronic clinical databases, well understanding in e-CEC (Clinical Endpoint Classification) adjudication process for clinical trial studies and were very helpful and enthusiastic.

The system which was an electronic integrated system for whole CEC process including collection, handling of clinical event documents, and adjudication of clinical events, was shown to be a user friendly system and the process built in the system closely reflected CEC process at UCR.

ETHICAL GmbH is qualified for use as an electronic CEC adjudication system for a multi-site study at UCR

Catherine Pham, QA Specialist

14 Feb 2014

Date