

Curriculum Vitae

Personal Information

Name **EMILIANO STENDARDO**

Education

2013 November, 11th Postgraduate course, 1st level Master degree in **Data Management in Clinical Research** 1st edition (working student), University of Milano-Bicocca.

2010 December, 21st Doctor of Philosophy (PhD.) in **Chemical Sciences**, University of Naples "Federico II".

2006 June, 20th Professional practice exam for **Italian Chemists Register**, University of Naples "Federico II".

2005 December, 19th Laurea Magistrale (M.Sc equivalent) in **Pharmaceutical Chemistry and Technology**, University of Naples "Federico II". Laurea degree grade 109/110.

1998 Italian upper secondary school diploma (HSD equivalent) in **Chemical Consultant** expert in industrial chemistry, I.T.I.S. "Francesco Giordani", Naples.

Experience

2014 May – Present

Ethics Committee (EC) Coordinator at Ethics Committee technical and scientific secretariat - fixed term collaboration contract, IRCCS Istituto Nazionale dei Tumori Foundation, Milan (INT). Oncology filed.

Management and check of regulatory documentations of clinical studies submitted to Ethics Committee by means of "modalità transitoria" (paper-submission) and "nuovo sistema informativo dell' OsSC" (electronic-submission). Development of customized informatics tools and drafting of SOPs for the optimization of the Ethics Committee office activities.

- Main Duties**
- Management, check and archive of electronic and paper regulatory documentation related to clinical studies activity such as essential study documents, DSUR and SUSAR listing and site specific documentation.
 - Support to submission and approval of clinical studies and amendments (about 15-20 studies and 20-40 amendments per month) and validation of submitted documentation.
 - Filling of "Appendici DM 21 dicembre 2007 (Comitati etici)" and further upgrade, in the case of paper or electronic submission.
 - Implementation of the electronic archive.
 - Support to data entry, maintenance and analysis activity of electronic clinical

study Data Base (DB) by means of DBMS "Pratiche Web".

- Support to management of administrative documents by means of document management system VT Docs.
- Planning and development of customize informatics tools (based on Microsoft Office suite), for fast analysis and reporting, and daily office activities optimization.
- Planning of EC monthly session.
- Communication with Sponsor, EC Members, Competent Authority and third parties.

2014 March – September

Clinical Study Coordinator - fixed term collaboration contract, IRCCS Istituto Nazionale dei Tumori Foundation, Milan.

Data Management and coordination activities for Phase I to IV and Non-Interventional studies in oncology field.

- Main Duties
- eCRF (different EDC systems)/pCRF data entry.
 - Support for clinical study activities (SAE report, IVRS system, drug request).
 - Trial Master File management upgrade and maintenance.
 - Support for monitoring, audit, site initiation and close-out visits.
 - Support for new clinical trial applications in compliance with GCP and regulatory requirements.

2011 March – 2014 March

CNR Researcher - fixed term collaboration contract, CNR Institute of Biostructures and Bioimaging (IBB), Naples.

Basic research in theoretical/computational studies of systems and processes of interest in materials science and biotechnology.

- Main Duties
- Study of electronic excited states in gas and condensed phases and design of organic photovoltaic materials.
 - Communication and presentation of results.

2013 May – October

Junior Clinical Data Manager - 1st level Master training course, Pierrel Research Italy Spa, Sesto San Giovanni (MI), Italy.

Data Management activities for Phase I to IV and Non-Interventional studies with the support of Hypersuite web-based platform to collect, access, exchange and archive data and documents. Oncology and autoimmune diseases.

- Main Duties
- Support for design the paper or electronic CRF in co-operation with the project managers, medical writers and statisticians.
 - Support to prepare the data management and the data validation plans.
 - Preparation and validation of the eCRF/clinical databases.
 - Preparation and validation of the off- and on-line edit checks.
 - Data management of all data relevant for a clinical trial as well as database

- cleaning according to relevant SOPs (e.g. CRF data, diary data).
- Perform eQuery, data clarification form and obvious correction management.
- Preparation, maintenance, and checking of data management documentations and files according to relevant SOPs.
- Support to perform SAE reconciliation.
- Participate to blinded data review meetings.
- Communication with sponsor and third parties.

2011 January – March

Information Technology Manager and Researcher - Consultancy contract, Dep. of Chemistry of the Natural Substances, University of Naples "Federico II".

Optimization of computational procedures for scientific research:

- Main Duties
- Development and implementation of tools for scientific software.
 - Drafting and review of internal laboratory's SOPs.
 - Staff training about new hardware, software and networking resources.
 - Planning of network, hardware and software implementations and upgrade.

2007 October - 2010 December

PhD student in Chemical Sciences - PhD Fellowships, Dep. of Chemistry "Paolo Corradini", University of Naples "Federico II". Faculty of Sciences, Scuola Normale Superiore, Pisa (visiting student).

- Main Duties
- Study of antimalarials mechanism of action with generation of free radicals.
 - Development of theoretical and computational methods in chemistry.
 - Development and implementation of scientific software.
 - Communication and presentation of results.

2007 June – September

Information Technology Manager and Researcher - Consultancy contract, Dep. of Chemistry of the Natural Substances, University of Naples "Federico II".

- Main Duties
- Development and implementation of tools for scientific software.
 - Drafting and review of internal laboratory's SOPs and staff training.

2006 May - 2007 May

Researcher - Research fellowship, BioTekNet, an Italian network of research focused on biotechnologies, Naples.

- Main Duties
- Development of quantum mechanical methods for radical species.
 - Communication and presentation of results.

Languages **Italian:** native.

English: proficiency in writing reading and verbal skills.

Certificates and Publications **2015 May, 6th** Re-training on **Clinical Trial Application** procedure and introduction to **Regulation (EU) No 536/2014**. "Aggiornamento dei nuovi orizzonti nella ricerca clinica" (8h). FormaFutura Health Manager, Milano

2014 October, 15th Validated user at OsSC platform (Ethics Committee user):
<https://www.agenziafarmaco.gov.it/aifaossc/>

2014 July, 2nd Training on document management system VT Docs adopted by INT, in compliance with Regione Lombardia regulations. (7h).

2013 July, 22th Training on **IMP-GMP** (4 h).

2013 August, 1st Training on **ICH-GCP** (4 h).

Both at Pierrel Research Italy spa, Sesto San Giovanni (MI), Italy.

Author of **eight scientific publications** (two as first author) in high impact factor international journals, poster presentations and short seminars since 2006 .
Documentation available on request.

Computer Skills

- Excellent knowledge of major Linux and Windows operating systems.
- Advanced knowledge of the applications Word, Excel, PowerPoint of Microsoft Office package, versions from 2003 to present
- Excellent - Good knowledge of the applications Access, Outlook, SharePoint of Microsoft Office package, versions from 2003 to present.
- Excellent knowledge of software and web applications for research and management bibliography; browsing the web, remote access, transfer and exchange of data; instant messaging, video calls and online meetings.
- Good knowledge of Web-based EDC (eCRF) and CDM systems.
- Good knowledge of SQL for querying databases in the variants used in the Oracle RDBMS (PL / SQL), MySQL and Access 2010.
- Basic knowledge of SAS software system for statistical analysis.
- Excellent - Good knowledge of software and procedures for recovery of operating systems, data recovery, security audit of the network.

Further Information

Driving license type B (own car). I practice non-competitive sporting activities such as cycling, hiking and fitness. I participate to workshop related to clinical trials and specific workshop focused on EC activities and coordination (List on request). I work constantly to improve my language, scientific and computer skills by combining practical experience with books and reference guides.

References and Privacy

References available on request.

Allow to process my personal data pursuant to Italian Legislative Decree 196/2003.

In witness whereof

Emiliano Stendardo

Emiliano Stendardo MILANO 06/08/2015