

PERSONAL INFORMATION

Marco Poggiu

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Sex Male | Date of birth 26/10/1989 | Nationality Italian

WORK EXPERIENCE

Jan 2025 - today **Quality Assurance GCP Consultant – I FAIR Program**

Sardegna Ricerche

- Data Collection & Analysis: Gathered and analyzed comprehensive information regarding the "I FAIR" Program and the regional clinical research landscape.
- SOP Development: Assisted in defining and structuring Standard Operating Procedures (SOPs) for the FAIRification of independent clinical trials
- Dissemination of Results: Supported communication and dissemination activities to effectively promote project achievements and research outcomes.

May 2024 - today **Regional Representative of the Oncology Network**

Società Italiana di Farmacia Clinica e Terapia (Sifact), Sardinia

- Coordinating oncology initiatives across the region, ensuring alignment with clinical pharmacy and therapeutic guidelines.
- Promoting collaboration among healthcare professionals and institutions within the Oncology Network to enhance patient care and treatment protocols.

Nov 2023 - today **Hospital Pharmacist, Hospital Pharmacy Department**

ASL 3 Nuoro – San Francesco Hospital

Clinical Hospital Pharmacist activities:

- UFA Coordination: organizing the work schedule for support staff, managing relationships with prescribing clinicians, and ensuring the achievement of specific quality objectives; responsible for the quality of the prepared products, ensuring compliance with Good Preparation Practices (NBP) and GMP (where applicable), as well as for the safety of the operators through the implementation of written procedures; contributing to the development of technological innovations within the unit.
- Oncology Drug Management: Handle the inventory and administration of oncology and oncohematology drugs, including intravenous, oral, and topical forms. The role also includes managing therapeutic plans and MEAS agreements.
- Quality Assurance Responsible (RAQ): Developing procedures to manage early access drugs, such as off-label use, L. 648 drugs, compassionate use, and those funded by the AIFA 5% fund.

Jan 2020 - today **Clinical Quality Assurance GCP Phase I Specialist in compliance with Ministerial Decree 15/11/2011 and AIFA Determination 809/2015**

Hematological Phase I Unit, Hematology Department - A.O.U. Città della Salute e della Scienza di Torino.

Quality Management Phase I Unit activities:

- Management and coordination activities for AIFA GCP Inspection according to AIFA Determination n.809/2015 of Phase I Unit (26-28 March 2018) and subsequent follow-up (CAPA plan);
- Management of the Phase I Unit quality system;
- Management and coordination of internal and external audits;
- Assurance of the correct management of SOPs in compliance with GxP (resources and processes);
- Roles, responsibilities and operational methods definition for the Phase I Unit.

May 2018-today **Clinical Trial Quality Team (CTQT) Member in compliance with Doc. AIFA April 2008**

A.O.U. Città della Salute e della Scienza di Torino.

Activities for non profit clinical trials:

- Verification of the activities planned before the beginning of the study;
- Verification of the conduction of the activities planned according to Monitoring Plan;
- Verification of the activities foreseen at the end of the study.
- Support in the evaluation process of clinical protocols and related documentation before the submission to the ethics committee.

Oct 2017-Dec 2019 **Quality Manager Phase I Unit and Clinical Study Coordinator**

European Myeloma Network (EMN) Research Italy, Hematology Department - Prof. Boccadoro – A.O.U. Città della Salute e della Scienza di Torino.

☐ Data Management activities for profit and non profit clinical trials:

- Taking care of national and international phase I/II/III onco-hematology clinical studies;
- Conduction of clinical trials (regulatory, quality and clinical practices);
- eCRF guidelines writing: EMN18 clinical trial (DaraVCd);
- Insertion of clinical data in eCRF;
- Review of data collecting from source data;
- Analysis of information from patient's hospital records;
- Data collection in MM clinical trials;
- Data analysis in eCRF and clinical results evaluation with physicians;
- Management of SAE forms and notification to Authorities;

☐ Management of monitoring visits;

- ☐ i2TEAMM collaboration with Mayo Clinic (USA): evaluation and validation of Minimal Residual Disease (MRD) as a surrogate endpoint of progression-free survival in multiple myeloma clinical trials through prospectively planned meta-analytic surrogacy analysis based on individual patient in order to obtain the approval by the FDA.

☐ Quality Management Phase I Unit activities:

- Management and coordination activities for AIFA GCP Inspection according to Determination n.809/2015 of Phase I Unit (26-28 March 2018) and subsequent follow-up (CAPA plan);
- Management of the Phase I Unit quality system;
- Management and coordination of internal and external audits;
- Assurance of the correct management of SOPs in compliance with GxP (resources and processes);
- Roles, responsibilities and operational methods definition for the Phase I Unit.

Mar-Sept 2016 **University Internship Program**

Farmacia Monari (Turin, Italy).

- Interactions analysis between drugs according to the case;
- Organization of tasks all over the day in order to respect deadlines;
- Reports of the ordinary and extraordinary Inspections.

EDUCATION AND TRAINING

March – May 2022 Clinical Quality Assurance: A Key Role in Clinical Research

Advanced Training Course for the development of peculiar competences of Clinical Quality Assurance (DM 15/11/11)

- Comprehensive understanding of the drug development process, from in vitro testing to clinical trials.
- In-depth knowledge of clinical trial regulations and quality system frameworks, including the creation and management of quality documentation.
- Expertise in delegation and contract management, as well as the training of clinical research personnel and the organization of study archives.
- Skills in auditing document quality, conducting inspections, and validating computerized systems in line with Quality Assurance (QA) standards.

Jan 2020 – Oct 2023 School of Specialization in Hospital Pharmacy

Università degli Studi di Torino - A.O.U. Città della Salute e della Scienza di Torino (70/70 cum laude).

Final thesis: "The economic impact of clinical trials on the National Health Service (SSN)", with Prof. M.Collino and Dr. F. Cattel.

Jan - Dec 2019 Clinical Quality Assurance Trainee

Yghea - Health and Safety - Ecol Studio S.p.A.

▪ One-year training course on-the-job in order to reach the requirements to become Clinical Quality Assurance in compliance with Ministerial Decree 15/11/2011: practical activity related to quality management of clinical trials; training activity on quality assurance related to clinical research and Contract Research Organization (CRO) activities, particularly:

- GCP E6 (R2);
- Monitoring Plan;
- Pharmacovigilance on clinical trials;
- Risk Assessment on clinical trials;
- MedDRA: Adverse Events coding;
- EudraLex: Annex 13;
- Clinical trials Legislation;
- Clinical Patient Folder;
- Regulation UE536/2014;
- Clinical Monitoring;
- SOPs;
- AIFA Legislation 809/2015.

Mar 2018 co-Quality Assurance activity during AIFA GCP pre-inspection, certificated by Doctor Sforza Federica QA Consultant from Quality Management Associates s.a.s March 19-21, Turin.

Mar 2018 AIFA GCP Inspection according to Determina AIFA n.809/2015 of Unità di Fase I ALF and Unità Operativa Fase I - Ematologica, conducted by Doctor Salvatore Caruso Senior Inspector GCP and Lead Inspector with Doctor Angela Pollicino Senior Inspector GCP, March 26-30, Turin.

Jul-Aug 2017 Course "Missione CRA" (CRAsecrets.com, Yghea CRO, Isbem SCpA)

50 hours clinical research training course as per the Ministerial Decree 15.11.2011. Mesagne (BR).

- Methodology and regulation of clinical trials;
- Good Clinical Practice (ICH-GCP);
- Standards for Good Manufacturing Practice (GMP);
- Quality systems and quality assurance.

Tasks of monitors referred to in paragraph 5.18 of Annex 1 to the Ministerial Decree July 15, 1997.

Jul 2017 State examination for professional practice.

2009 – 2017 Pharmacy Master Degree at UNIVERSITA' DEGLI STUDI DI TORINO (106/110).

Final thesis: “Inorganic nanomaterials protein-corona composition in a solution simulating plasma”, with Prof. Ivana Fenoglio and Marco P. Monopoli, PhD.

Mar – Sep 2015

Erasmus Program, Centre for Bio-Nano Interactions and Conway Institute Mass Spectrometry Resource University College Dublin.

-Research and development activities in an international environment with 40 researchers specialized in Nanomedicine and Nanotoxicology;

-Managing priorities with the objective to collect the higher number of data, organizing and analysing them;

-Staff training activities according to protocols.

PERSONAL SKILLS

Mother tongue(s) Other language(s)	Italian				WRITING
	UNDERSTANDING		SPEAKING		
	Listening	Reading	Spoken interaction	Spoken production	
English	Fluent	Fluent	Fluent	Fluent	Fluent

Communication skills ▪ Good communication skills gained through my experience as quality assurance

Organisational / managerial skills / Job-related skills ▪ Leadership and good command of quality assurance processes (currently responsible for quality management system of Phase I Unit)

Computer skills ▪ Good command of Microsoft Office™ tools

Driving licence ▪ B

ADDITIONAL INFORMATION

Publications Presentations Projects Conferences

- Abstract: C. Frairia, G. Arrigo, M. Scaldaferri, M. Poggiu, [...], S. D'Ardia. "Arsenic Trioxide Neurotoxicity In Acute Promyelocytic Leukemia Patients: Single Center Experience With Literature Review". 50°Congresso Nazionale Sie -Società Italiana di Ematologia (Roma) 23-25 Ottobre 2023.
- Abstract: C. Frairia, F. Catania, F. Di Biase, J. L. M. Poggiu, M. Scaldaferri, I. Urbino, E. Becciaro, F. Audisio. "Luspatercept in Patients with Myelodysplastic Syndrome With Ring Sideroblasts: Real-Life Experience In Turin". 50°Congresso Nazionale Sie -Società Italiana di Ematologia (Roma) 23-25 Ottobre 2023
- Abstract: M. Scaldaferri, R. Aldieri, M. Poggiu, D. I. Toma, E. Castellana, F. Cattel. "Core binding factor acute myeloid leukaemia following immune checkpoint inhibition for solid tumours: two case reports and literature state of the art". European Journal of Hospital Pharmacy (2023) 30(Suppl 1), March 2023.
- Abstract: M. Poggiu, D. I. Toma, M. Scaldaferri, M. R. Chiappetta, F. Cattel. "Bevacizumab single- agent come trattamento off-label del glioma recidivante o refrattario". Giornale italiano di Farmacia clinica 2022, 36, Suppl. 1 al n. 3, August 2022.
- Manuscript: S. Aydin, R. Passera, M. Scaldaferri, [...], M. Poggiu and A. Busca. "Sorafenib maintenance after hematopoietic stem cell transplantation improves outcome of FLT3ITDmutated acute myeloid leukemia". International Journal of Hematology (2022), July 20, 2022.
- Abstract: D. Fiorentino, I. Colasanto, A. Varese, S. Traina, S.M.A. Gioradno, C. Bertiond, M. Poggiu, D.I. Toma, F. Cattel. Il ruolo del farmacista ospedaliero durante la campagna vaccinale contro il Covid-19. Bollettino SIFO_1_2_2021, 12 September 2021.
- Abstract: S. Aydin , M. Scaldaferri , C. Dellacasa , [...], M. Poggiu, [...] and A. Busca. Sorafenib maintenance after hematopoietic stem cell transplantation improves outcome of flt3-itd positive acute myeloid leukemia. 47° Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT), virtual, 14-17 March 2021.
- Abstract: A. Larocca, P. Corradini, R. Mina, [...], M. Poggiu, [...] and S. Bringhen. "Efficacy and Safety of Ixazomib-Dexamethasone, Ixazomib- Cyclophosphamide-Dexamethasone, Ixazomib-Thalidomide-Dexamethasone and Ixazomib-Bendamustine-Dexamethasone for Elderly Newly Diagnosed Multiple Myeloma (NDMM) Patients: Analysis of the Phase II Randomized Unito-EMN10 Study". 61° Annual Meeting American Society of Hematology (ASH), Orlando, 7-10 December 2019.
- Abstract: M. D'Agostino, G.M. Zaccaria, B. Ziccheddu, [...], M. Poggiu, [...] and F. Gay. "Maintenance Therapy vs Re-treatment at Biochemical Relapse vs Observation in Relapsed/Refractory Multiple Myeloma Patients: Results of a Phase II, Randomized Study.". XVII International Myeloma Workshop (IMW), Boston 12-15 September 2019.
- Abstract: R. Mina, A. Larocca, A. Belotti, [...], M. Poggiu, [...] and M. Boccadoro. "Maintenance Therapy vs Re-treatment at Biochemical Relapse vs Observation in Relapsed/Refractory Multiple Myeloma Patients: Results of a Phase II, Randomized Study." XVII International Myeloma Workshop (IMW), Boston 12-15 September 2019.
- Manuscript: S. Bringhen, M. D'Agostino, L. Paris, [...], M. Poggiu, [...] and A. Larocca. "Lenalidomide-based induction and maintenance in elderly newly diagnosed multiple myeloma patients: updated results of the EMN01 randomized trial." «Haematologica» 2019.
- Abstract: A. Marucco, M. Poggiu, L. Soddu [...] and I. Fenoglio. "The role of surface chemistry and particle size on the protein corona composition of silica and carbon aggregated or monodisperse nanomaterials in plasma." Abstract # P 13.23 presentato come poster, NanoTox 2018 - 9th International Conference on Nanotoxicology, Dusseldorf, 18-21 settembre 2018.
- Abstract: A. Marucco, M. Poggiu, M. Monopoli and I. Fenoglio. "The role of fibrinogen in the prediction of nanoparticles toxicity." School of Nanomedicine, CNR-IC, Bari, Italy, 2-4 December 2015.

ICH-GCP TRAININGS
Seminars

- Instructor Of “Comitati Etici Ed Autorità Competente - Buone Pratiche Nella Sperimentazione Clinica Good Clinical Practice For Investigator And Trial Sites Based On Ich E6(R2)”. Aou Città' Della Salute E Della Scienza Di Torino - S.S. Formazione Permanente E Aggiornamento. August 30, 2022
- Instructor Of “Safety Del Paziente - Buone Pratiche Nella Sperimentazione Clinica Good Clinical Practice For Investigator And Trial Sites Based On Ich E6(R2)”. Aou Città' Della Salute E Della Scienza Di Torino - S.S. Formazione Permanente E Aggiornamento. August 30, 2022
- Instructor of “I Risultati Delle Ispezioni Gcp - Buone Pratiche Nella Sperimentazione Clinica Good Clinical Practice For Investigator And Trial Sites Based On Ich E6(R2)”. Aou Città' Della Salute E Della Scienza Di Torino - S.S. Formazione Permanente E Aggiornamento. August 30, 2022.
- advanced clinical research training: CLINICAL QUALITY ASSURANCE: UN RUOLO CHIAVE NELLA RICERCA CLINICA - LIFE SCIENCE ACADEMY, March 11 – May 7, 2022;
- e-Seminary: La ricerca clinica in Italia e il Regolamento Europeo: Partiamo!, SIMEF, January 31, 2022;
- e-Seminary: La regolamentazione delle sperimentazioni cliniche: l'entrata in vigore del Reg. UE 536/2014, ALMA MASTER STUDIUM Università di Bologna Centro studi di diritto sanitario SPISA, January 21, 2022;
- e-Seminary: La qualità negli studi clinici di Fase I no-profit. Il ruolo del CTQT, PHASE1.IT, January 25, 2022;
- e-Seminary: Regulatory Science Needs (RSRN), EMA, January 18, 2022;
- XLII Congresso Nazionale SIFO, SIFO, Roma, October 14-17, 2021;
- e-Seminary: MSL – Quali regole per una RWE etica, di qualità e a passo con l'innovazione scientifica? SIMEF, September 24, 2021;
- e-Seminary: MONITORAGGIO DA REMOTO: VALIDA ALTERNATIVA AL MONITORAGGIO ON-SITE? – GIMEMA. September 15, 2021
- e-Seminary: MSL – Perché e come fare ricerca osservazionale? SIMEF, September 10, 2021;
- e-Seminary: MSL- Il Valore della Ricerca Clinica, SIMEF, June 25, 2021;

- e-Seminary: PILLOLE DI FARMACOVIGILANZA - AOU CITTA' DELLA SALUTE E DELLA SCIENZA DI TORINO, July 5, 2021;
- e-Seminary: Come mappare un processo e redigere una SOP, aspetti di medical writing applicati alla ricerca clinica, AOU Città della Salute e della Scienza di Torino, July 1, 2021;
- e-Seminary: La Farmacovigilanza: La Best Practices del sistema, GIMEMA, June 6, 2021;
- e-Seminary: MSL – L'iter autorizzativo: Autorità regolatoria e Comitati Etici, SIMEF, June 11, 2021;
- e-Seminary: MSL - LA STORIA DI UNO STUDIO CLINICO: DALLA FATTIBILITA' AL CLINICAL TRIAL REPORT – SIMEF, June 4, 2021;
- e-Seminary: Il consenso informato: Aspetti Tecnico-Scientifici, Regolatori ed Etici, GIMEMA, June 3, 2021;
- e-Seminary: La Ricerca Clinica in Italia e il Regolamento Europeo: ai blocchi di partenza, SIMEF, May 28, 2021;
- e-Seminary: La Gestione dei documenti accessori, GIMEMA, May 5, 2021;
- e-Seminary: Determina AIFA 809/2015 sulle sperimentazioni cliniche di Fase I: Aspetti normativi, Operativi e Ispettivi, SIMEF, May 17, 2021;
- e-Seminary: MSL- Il cuore della Ricerca Clinica: Dal protocollo alla pubblicazione, SIMEF, May 15, 2021
- e-Seminary: Il Valore della Ricerca Clinica, GIMEMA, April 22, 2021;
- e-Seminary: Sfide, Esigenze e opportunità per la ricerca clinica: cosa fare? UNITELMA SAPIENZA, April 16, 2021
- e-Seminary: L'impatto del Regolamento Europeo UE 2016/679 sulle sperimentazioni cliniche, GIMEMA, March 31, 2021;
- e-Seminary: Uso Terapeutico di medicinale sottoposto a sperimentazione clinica, SIMEF, March 29, 2021
- e-Seminary: Sistemi informatici nei Clinical Trials, AFI, March 25, 2021;
- e-Seminary: Le Unità di Fase I in Italia, requisiti minimi e principali sfide. Il progetto Phase I Site Support , February 24, 2021;
- e-Seminary: Medicines: Regulatory Tools "Gli studi di Fase I" SIARV e SIMEF, February 24, 2021;
- e-Seminary: Consenso Informato e trattamento dei dati, Corrado Iacono, February 10, 2021;
- e-Seminary: Aspetti generali della regolamentazione della Sperimentazione Clinica SIARV e SIMEF, January 27, 2021.
- e-Seminary: Sperimentazioni cliniche in oncologia tra scienza, etica e regolatorio studi clinici di Fase I e l'impatto della pandemia AIOM, LILT e GIDM, December 11, 2020;
- e-Seminary: Qualità nelle sperimentazioni cliniche: il punto di vista del centro sperimentale GIDM, December 10, 2020;

- e-Seminary: Gestione dei dati di Farmacovigilanza negli organized data collection programs SIMeF, December 02, 2020;
- e-Seminary: Sessione Farmacovigilanza e Qualità processi e integrazioni AFI, November 27, 2020;
- e-Seminary: Covid-19 Risk Analysis For Clinical Trials/Investiagtions Personale Data Management During the Remote Source Data Verification GIQAR e SIMeF, November 20, 2020.
- e-Seminary: Il management della ricerca clinica in oncologia AIOM, October 09, 2020;
- e-Seminary: La gestione dello studio clinico e la valorizzazione dei risultati AFI e SSFO, October 06, 2020.
- e-Seminary: Il protocollo clinico e la gestione del materiale sperimentale AFI e SSFO, September 29, 2020;
- e-Seminary: La sperimentazione clinica: passato presente e futuro, dal farmaco di sintesi alle terapie avanzate AFI, September 24, 2020.
- e-Seminary: GCP training on-line, AOU Città della Salute e della Scienza di Torino July 27, 2020;
- e-Seminary: Visite di monitoraggio da remoto e relativi strumenti digitali AFI e SIMeF, July 09, 2020;
- e-Seminary: Presentazione del documento programmatico sul miglioramento della sperimentazione clinica AFI e SIMeF, July 01, 2020.
- e-Seminary: Sperimentazione Clinica ed esperienza COVID come organizzarsi per le emergenze? Quale futuro per la ricerca clinica post-covid? AFI, June 19, 2020;
- e-Seminary: L'esperienza di un CE Unico Nazionale durante l'emergenza Covid-19 SIMeF, June 12, 2020;
- e-Seminary: Laboratori & Sperimentazione Clinica GIQAR e SIMeF June 10, 2020.
- e-Seminary: Sperimentazione Clinica e emergenza coronavirus: giusto equilibrio tra privacy, ricerca e salute SIMeF e AFI, May 21, 2020;
- Seminary: Fundamentals and methodology of clinical research: design and types of clinical studies, Dipartimento di Scienza e Tecnologia del Farmaco Torino, May 4-8-11, 2020, Turin.
- Seminary: Sperimentazione clinica, come lavorare in qualità: il punto di vista degli Stakeholders IRCCS IRST Meldola, December 18, 2018, Meldola
- Investigator Meeting (Aquila study), Janssen Pharmaceutical, April 18, 2018, Rome.
- European Myeloma Network Meeting (EMN), April 19-21, 2018, Turin.
- Seminary: L'evoluzione della ricerca clinica: quale impatto per i giovani, Society for Applied Pharmacological Sciences, May 18, 2018, Milan.
- Training course: "ICH-GCP E6(R2)" e normativa sulla sperimentazione clinica, lecturer Doctor Carla Turriziani QA Consultant and GCP Auditor, Society for Applied Pharmacological Sciences and Assomonitor, July 5, 2018, Rome.
- GCP certification (E6 - R2) validated by TransCelerate.
- Gli Attori della Ricerca Clinica on-line course by FormazioneNelFarmaceutico.com", May 2017.

References • Available upon request.

I authorize the use of my personal data in compliance with Legislative Decree 196/03 and Regulation (EU) 2016/679.

DATA

25/05/2026

FIRMA

Marco Poggiu