Curriculum Vitae

Personal information

Diego Alejandro Dri

Work experience

1. Employer: Agenzia Italiana del Farmaco (AIFA)
   - Start date: 07/2015
   - End date: current
   - Position: MANAGER, Level I _ CHEMISTRY
   - From 05/03/2024 to 15/04/2024 Coordinator of the Clinical Trials Office Activities including People Management (33 Px)
   - Activities: Clinical Trials Scientific Assessor (Regulatory/Quality/Clinical) at the Clinical Trials Office, supporting the Head of the Clinical Trials Office in the management of all scientific and regulatory activities related to Clinical Trials assessment and authorization. Tutoring of new assessors. Product Owner supporting EMA with the Clinical Trials Information System (CTIS) project.
   - Country: Italy
2. Employer: MSD Italia S.r.l.
   - Start date: 05/2014
   - End date: 06/2015
   - Position: ASSOCIATE DIRECTOR, REGIONAL CLINICAL PROJECT MANAGER
   - Activities: As part of the company Global Clinical Trial Operations, Regional Operating Center in Europe, I was responsible for achieving the objectives of projects (clinical trials) at regional level in the EU, focusing on the safety of subjects participating to the studies, the achievement of the enrollment targets and data quality; I managed the study teams to the highest performance, supporting and interacting directly with the Clinical Research Associates to manage site level activities, communicating closely with the Clinical Research and Clinical Operations Managers of all the EU countries in order to streamline the timelines at country level, and dialoguing with the Country Clinical Research Directors to lead the efficiency in the start_up, execution and close_out phases of clinical studies across the region.
   - Country: Italy
3. Employer: MSD Italia S.r.l.
   - Start date: 07/2010
   - End date: 04/2014
   - Position: SENIOR SPECIALIST, CLINICAL PROJECT MANAGER
   - Activities: According to ICH, GCP, company SOPs and clinical development plans, in agreement with all applicable national and international laws and regulations, I managed the site selection, implementation, execution and follow_up phases of clinical trial projects in Italy, in several therapeutic areas with focus on oncology, diabetes, pediatrics; Interacting with country key opinion leaders and international cross_functional company departments (e.g. daily contacts with headquarter colleagues) I managed the submission to Ethic Committees and Competent Authority, developed and managed the study budget and contracts for Phase I_IV studies, ensuring the safety of subjects participating to the studies, the achievement of the enrollment targets and data quality; I participated to company Quality Control programs executing Quality Control Visits at several study sites across the country.
   - Country: Italy
4. Employer: MSD Italia S.r.l.
   - Start date: 12/2009
   - End date: 06/2010
   - Position: REGULATORY ADMINISTRATION MANAGER & OUTSOURCING POINT OF CONTACT
   - Activities: Outsourcing Point of Contact at the Clinical Research Department, managing at country level all clinical trials outsourced to Clinical Research Organizations (CROs), establishing and increasing the relationship with CROs according to the company global outsourcing strategy and model.
   - Country: Italy
5. Employer: MSD Italia S.r.l.
   - Start date: 03/2002
   - End date: 11/2009
   - Position: CLINICAL RESEARCH ASSOCIATE/CLINICAL MONITOR
   - Activities: According to ICH, GCP, company SOPs and clinical development plans, I have been monitoring more than 30 clinical studies in several therapeutic areas in Italy, acting also as Unblinded CRA, and supporting the company management with site selection and validation of clinical study sites.
   - Country: Italy
6. Employer: I.B.H.I. s.a.s./ NORPHARMA S.p.A.
   - Start date: 06/2001
   - End date: 02/2002
   - Position: RESEARCHER
   - Activities: Research on composition and formulation of disinfectants and detergents; Management of a Team of researchers working on the development of drug products and organic synthesis processes.
   - Country: Italy

Education and training

1. Subject: University of Rome “La Sapienza”

- Start date: 112019
- End date: 122022
- Qualification: Doctor of Philosophy degree (PhD)
- Organisation: PhD Programme in MOLECULAR DESIGN AND CHARACTERIZATION FOR THE PROMOTION OF HEALTH AND WELL_BEING: FROM DRUG TO FOOD [DOTT] (35° cycle)
- Country: Italy

2. Subject: University of Rome "La Sapienza"
   - Start date:
   - End date: 022001
   - Qualification: Chemistry MSc Degree
   - Organisation: Organic Chemistry; Development of drug products; Synthetic processes;
   - Country: Italy
3. Subject: University of Rome "La Sapienza"
   - Start date: 112016
   - End date: 102017
   - Qualification: University Master II Level _ 1 Year _ 60 university credits
   - Organisation: Natural Compounds
   - Country: Italy

Additional information

Publications

1) "Design and Synthesis of a new Furanosic Sialylmimetic as a Potential Neuraminidase Viral Inhibitor" _ Letters in Organic Chemistry, Volume 2, N°1, 2005 _ D.A. Dri , A. Bianco, M. Brufani, C. Melchioni and L. Filocamo.

2) "The preparation of quaternary ammonium_based ionic liquid containing a cyano group and its properties in a lithium battery electrolyte" _ Journal of Power Sources,Volume 138, Issues 1_2, 15 November 2004, Pages 240_244, 2004 _ Minato Egashira, Shigeto Okada, Jun_ichi Yamaki, Diego Alejandro Dri, Francesco Bonadies, Bruno Scrosati.

3) "Functionalized tetraalkylammonium ionic liquid electrolyte for use in lithium batteries" – Presentation at International 203rd Spring Meeting of the Electrochemical Society, Paris, France, 2003 _ M. Egashira, S. Okada, J. Yamaki, D.A. Dri, F. Bonadies, B. Scrosati.

4) Dri DA, Marianecci C, Carafa M, Gaucci E, Gramaglia D. Surfactants, Nanomedicines and Nanocarriers: A Critical Evaluation on Clinical Trials. Pharmaceutics. 2021 Mar 13;13(3):381. doi: 10.3390/pharmaceutics13030381. PMID: 33805639; PMCID: PMC7999832.

5) Dri DA, Gaucci E, Torrieri I, Carafa M, Marianecci C, Gramaglia D. Critical Analysis and Quality Assessment of Nanomedicines and Nanocarriers in Clinical Trials: Three Years of Activity at the Clinical Trials Office. Pharmaceutics. 2022;14(7):1438. doi:10.3390/pharmaceutics14071438.

6) Dri DA, Praticò G, Gaucci E, Marianecci C, Gramaglia D. Quality Assessment of Investigational Medicinal Products in COVID_19 Clinical Trials: One Year of Activity at the Clinical Trials Office. Pharmaceuticals (Basel). 2021;14(12):1321. doi:10.3390/ph14121321.

7) Dri, DA, Rinaldi, F, Carafa, M. et al. Nanomedicines and nanocarriers in clinical trials: surfing through regulatory requirements and physico_chemical critical quality attributes. Drug Deliv. and Transl. Res. (2022). https://doi.org/10.1007/s13346_022_01262_y.

8) Gramaglia D, Dri DA, Massella M, Verrelli NM, Praticò G, Petraglia S, Foggi P, Di Marzo M, Agricola E. Guide to the submission of a request for authorisation of a Clinical Trial involving the use of Artificial Intelligence (AI) or Machine Learning (ML) systems. AIFA, May 24th 2021. Available online: https://www.aifa.gov.it/documents/20142/871583/Guide_CT_AI_ML_v_1.0_date_24.05.2021_EN.pdf.

9) Dri DA, Massella M, Gramaglia D, Marianecci C, Petraglia S. Clinical Trials and Machine Learning: regulatory approach review. Reviews on Recent Clinical Trial. 2021, 16, 341_350. doi: 10.2174/1574887116666210715114203.

10) Trogu P, Cagnazzo C, Collamati S, Corrao G, Daniele D, Dri DA, Galliccia F, Primiero P, Serafini E. Implementing Decentralized Clinical Trials in Italy: why and how? Multistakeholder expert opinion on priorities for methodology, regulatory affairs, ethics and training. Book Chapter: Management of digital (and other) data. Tendenze nuove Rivista semestrale online. Issn: 2239_2378. Special Issue 2/2022.

11) Massella M, Dri DA, Gramaglia D. Regulatory Considerations on the use of Machine Learning based tools in Clinical Trials. Health Technol (Berl). 2022;12(6):1085_1096. doi:10.1007/s12553_022_00708_0.

12) Decentralised elements in clinical trials: recommendations from the European Medicines Regulatory Network Al Monique et al. The Lancet, Volume 401, Issue 10385, 1339
Dri Diego Alejandro, Member of DCT Task Force drafting the 'Recommendation paper on decentralized elements in clinical trials'.

13) Book Chapter: The role of artificial intelligence and machine learning in clinical trials
Artificial Intelligence for Drug Product Lifecycle Applications - ELSEVIER - Chapter 8: D.A. Dri, M. Massella, M. Carafa, C. Marianecci
- ISBN 978-0-323-91819-0, DOI: 10.1016/B978-0-323-91819-0.00008-7

14) Critical Analysis of Non-Profit Clinical Trials: Three Years of Activity at the Clinical Trials Office
Reviews on Recent Clinical Trial. 2024, Diego Alejandro Dri, Marta De Cata, Maria Carafa, Eleonora De Paola, Raffaella Maione,
Paola Aita and Donatella Gramaglia;

Projects

_ Clinical Trials Assessor; _ CTIS Portal & Database as per Regulation (EU) No 536/2014; _ EU Clinical Project Manager for Clinical Trials in the following therapeutic areas: oncology, endocrinology, gastroenterology, pediatrics; _ Monitoring more than 30 clinical studies in several therapeutic areas;

Memberships

EMA Expert Group "EU CTIS meeting with Experts" and alternate for "EU CTIS meeting with Stakeholders"; CTIS Product Owner; Italian National Competent Authority Point of Contact for User Acceptance Testing of EU CT Portal and Union database systems; Product Owner as of July 2019 according to the new Delivery Process of the Clinical Trial Information System (CTIS)

Other Relevant Information

Tutoring of new Clinical Trials Scientific Assessor (Clinical/Quality); Tutoring of new Clinical Project Managers; Training junior CRAs on Site Selection, Study Monitoring, GCP; Organization and speaker at national/International Investigators' Meetings; SOPs Revision; User for more than 13 years of clinical study management systems, such as Clinical Trial Management System (CTMS) in Oracle environment, Electronic Data Capture (EDC) web based, Interactive Voice Response Systems (IVRS); Superuser and country implementation Leader for the following applications: CTMS (2009_2010); CPAC (Clinical Portal Administration and Collaboration, 2007_2009); GLS (Global Learning System, 2008); TMF (Trial Master File, performing the User Acceptance Testing and managing users,

2004_2008);