

## CV\_Elda Caccia

Year and place of birth: 1977, Milan

*Freelance consultant of Clinical Study and expert of GCP*

### **Working experience:**

- **05/2020 -onwards CDPharma Group srl, Milan, Italy**

Senior Data Manager consultant and designer for the implementation of Trials, data capture forms (eCRF), implemented in OpenClinica Cloud and REDcap.

Collaboration in the definition of data management procedures. Review of SOPs. Definition and coordination of the times for the activities related to the trials.

- **11/2010 -onwards Oncology Department, IRCCS Istituto di Ricerche Farmacologiche Mario Negri, Milan, Italy**

Senior Data Manager and designer of User Interface for the implementation of Clinical Trials and Biobanks electronic data capture forms (eCRF), implemented in the open-source Peer-to-Peer Clinical Trial.

Management Application HeavyBase, for all the research projects carried out by the Department. Team member of Clinical Software Validation against International data management standards including: FDA Cfr21 part 11, ICH-GCP, and data protection laws including the 2016 EU GDPR

*since 2019 - REDcap Study Administration for Oncology Studies.*

I follow the study on REDcap in every phase: adaptation of the paper version of the CRF to the best electronic version, eCRF design, development DVP and planning of the related controls, data management activities, creation and activation of all user profiles, closure of the trials. Development and reviewing SOPs regarding data management, IT activities on clinical trials and documentation of the validation of the eCRF (PQ). Thirteen-year experience in randomized trials (phase I, II and III) and national and international registries.

### **Education and training:**

7/2004 Milan Polytechnic, Milan, Italy. Degree in Industrial Design (95/100)

### **Skills and competences:**

*Languages* - Italian (mother-tongue), English (B2 level)

*Informatics* - Expert knowledge of the following softwares: 3D, Autocad, Adobe, MS Office.

Excellent knowledge of softwares specialized in clinical trials (REDcap, OpenClinica). Programming base: Python, SQL. Operating systems used: Linux and Windows.

30/01/2024

