Andrea Cassa

ELECTRONIC CLINICAL TRIALS EXPERT AND CLINICAL DATA MANAGER

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A "*versatile technician*" (me, in short)

I work in the clinical trial sector since 1998. During this period, I've played several roles, but in particular two roles: **clinical data manager** (from junior to Head of DM Department) and **eDC/eCRF/eTMF/ePro/eCTMS expert** (from developer to Head of the Development Unit).

"Summing" all the experiences, I've been involved in more than 200 clinical trials!

Moreover, for some years I also worked in "pure IT" companies, as database expert or IT project manager or IT Operations manager. These experiences gave me robust and wide IT skills.

Despite these roles have always been technical, a thing that is in common between all these experiences is that I've been always involved in interactions with customers and stakeholders, constantly building "lexical bridges" between the different stakeholders.

This is due to my ability to "translate the business needs into activities for the tech team" and vice versa to re-transform their "technical outputs" into "usable deliverables".

For this reason, I consider myself a "***versatile technician***", a definition that should suggest professional knowledge/competence in synergy with appropriate relational soft skills.

Working Experiences

<u>2024-now</u> **Senior clinical data manager** *(c/o Cd Pharma CRO)*

Leading data management activities, relationship with customers. Preparation of SAS programs for data cleaning and listings. Use/configuration of Openclinica as main company eDC system.

<u>2024-now</u> **Consultant** *(Nubilaria)*

Clinical data manager, Actide eDC expert, business analyst.

<u>2018-2024</u> **Technology advisor**, **Scientific director, electronic trials expert and Head of data management** *(c/o Nubilaria as freelance)*

I joined Nubilaria again in 2018, initially assuming the role of clinical data manager, and rapidly upgrading to the higher position of Head of the data management department and – in 2019 – of Scientific Director (btw: the head of data management was still me, for the entire period; as data manager I "reported" to myself as SD).

In this role I had the opportunity to expand the business of Nubilaria among the Italian CROs, with more than 150 trials conducted through our solutions, to develop their electronic trials platform and to directly be the clinical data manager of about 20 trials (for which Nubilaria was outsourced as the data management CRO).

In March 2024 I left the Scientific Director position and assumed the role of Technology Advisor, still helping the company in designing solutions, but now with more time to interact directly with customers and prospects (meetings, travels, demos, and so on)

<u>2014-2017</u> **IT operations manager and database expert** *(c/o PwC Italy)*

This role has been mainly technical, focused on my database experience and my management experience (I leaded the IT operations team).

2008-2013 **Clinical data manager, part-time** *(c/o Nubilaria as part-time freelance)*

Nubilaria is another Italian CRO, for which I worked 5 years from 2008 to 2013 and again from 2018 to now.

They are specialized in creating software for clinical trials. In the years 2008 – 2013 I played for them role of Head of Clinical data management. In practice I helped them to set-up the department, prepare the SOPs and manage about 20 clinical trials, hosted in Nubilaria's eCRF platform.

This role was- again – both technical (at the beginning there was just 1 clinical data manager: me) and of a management kind (discussing requirements, reading protocols, designing the CRF, preparing the database, dealing with new customers and so on)

2012-2013 **SENIOR IT CONSULTANT** *(c/o ENI working with IT third parties)*

Senior consultant in an ENI's "IT operations group".

2010-2011 **PROJECT MANAGER** *(c/o ENI working with IT third parties)*

Project manager for an "important infrastructure migration".

2010-2011 **SERVICE MANAGER** *(c/o ENI working with IT third parties)*

Service manager (leading an IT infrastructure team).

2008-2010 **ORACLE DATABASE EXPERT AND ARCHITECT** *(c/o ENI working with IT third parties)*

Oracle senior consultant, PL/SQL developer, data architect, ETL team leader.

2000-2007 **eCRF development manager and clinical data manager** *(c/o Pierrel group, formerly Hyperphar)*

Hyperphar was an emerging Italian CRO based in Milan. For Hyperphar I played the role of Head of the eCRF development and of Clinical data manager (for the studies for which we offered the eCRF platform).

During the relevant experience in Hyperphar I had the opportunity to personally design the clinical database of more than 50 trials electronically conducted through our software "Hypernet".

I laid also the basis of my clinical data management experience, both as an employee following the company Sops (cleaning, dictionary coding, emitting and following clarifications, db locking and so on) and as a software designer, studying all the processes and needs of the Biometrics department and transforming them in functions of the platform!

1998-1999 **eCRF developer** *(c/o Consorzio Interuniversitario Cineca)*

In Cineca I worked as eCRF developer in their healthcare department. In this role I was scouted by an Italian entrepreneur that offered me the above position in Hyperphar

Skills & abilities

- Clinical trials (reading protocols, speak with stakeholders, design crfs, preparing edit checks, supporting cras and investigators, using CTMS and/or eTMFs)
- Data driven business intelligence (preparing reports, listings, charts, creating or calculating study metrics and kpis)
- Clinical data management (design database and/or eCRF, prepare data management plans and strategies, edit checks, clean and lock databases, Sas listings&programming)
- Use of dictionaries (I daily work with Meddra and with WHO ATC; I worked in past with WHO Drugs, ICD IX and ICD X) and terminologies (Cdash, cdisc standards, SDTM)

- Therapeutic areas of experience (since 1998 I've been involved in more than 200 clinical trials from the perspective of the eCRF, and in more than 50 clinical trials as a clinical data manager; as a data manager I covered many therapeutic areas, including some huge oncology trials)
- Art of database (sql language, oracle, mysql, sql server, database modelling, database development, stored procedures, triggers, functions, indexes, performance)
- Web development (php, javascript, ajax, css, user interface, html)
- Problem solving (committed to the result and help other people to stay committed too)
- Leadership when needed (mentoring experience, team leading experience)

Objective

Open to collaborate full-time, or part-time, in a flexible way, as employee or freelance.

Education

University of Trieste "Sissa"   **1998-1999**

Two years of Master in Scientific Journalism *(unfortunately uncompleted, due to the start of my first full time job)*

University of Firenze (Florence)   **in the '90**

Degree in physics (110 cum laude)

Teaching experiences

2021-now

Since 2021, twice a year, I attend, as a teacher of clinical data management, the Mycroscope school (https://www.mycroscope.it/)

Languages

English

Advanced (written, oral), certified C1

Relevant trainings during my career

TRAINING: *30 hours/year required*

• Date (from – to)	2018 to now
• Duration	30 hours/year, required (by regulations) training
• Scope	Clinical trials, clinical data management, IT security
• Certificate	Sometimes

TRAINING: *Agile methodology*

• Date (from – to)	2016
• Duration	40 hours Agile methodology
• Scope	Project management
• Certificate	Yes

TRAINING: *PMP methodology*

• Date (from – to)	2015
• Duration	60 hours PMP methodology
• Scope	Project management
• Certificate	No

TRAINING: *iOS development*

• Date (from – to)	Oct 2012
• Duration	iOS 20 hours
• Scope	iOS
• Certificate	Frequency certificate

TRAINING: *ADVANCED ORACLE*

• Date (from – to)	Oct 2010 to June 2011
• Duration	120 hours
• Scope	Oracle
• Certificate	Frequency certificate

TRAINING: UML

• Date (from – to)	Feb 2010 to June 2010
• Duration	UML 60 hours
• Scope	UML
• Certificate	Frequency certificate

TRAINING: PHP & MYSQL

• Date (from – to)	Nov 2007 to June 2008
• Duration	Php&MySQL (400 house)
• Scope	Php e MySQL
• Certificate	Frequency certificate with final grade (100 on 100)

Keywords&products

- eCRF, eDC, eTMF, ePRO, clinical trials, eSAE, IWRS, eCTMS,
- business intelligence, BI, reports, listings, charts, metrics, kpi, Qlik, Excel, apache superset
- Clinical data management, design database, data management plan, edit checks, clean and lock databases, Sas listings & programming
- Meddra, WHO ATC, WHO Drugs, ICD IX, ICD X, Cdash, cdisc standards, SDTM
- Sql, Oracle, mysql, sql server, database modelling, database development, stored procedures, triggers, functions, indexes, performance, tuning, dba, relational models
- Web development, php, javascript, ajax, css, user interface, html, dom, json, jquery, xml, perl, phyton, client side, server side, full stack, apache, nginx, regular expressions.
- Problem solving, Leadership, mentoring, team leading
- Migrations (data, software, infrastructure, complex projects, platforms)
- Agile, project management, PMP, Scrum
- ETL, Extract Transform Load, IBM DataStage, Data Warehouse, DWH

- Infrastructure management, hosts, virtual machines, Vmware, monitoring, nagios, icinga, metrics, performance

- Unix, linux, shell, bash, scripting, cron, crontab, C, C++

- Excel, Word, Powerpoint, Office, Access, Visio, Gsuite, Google docs, Google spreadsheet, Google presentations, Photoshop, Notepad++