CURRICULUM VITAE -RAFFAELLA PASQUALI

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VITAL STATISTIC & CONTACTS

- First & Last Names**:** ***RAFFAELLA PASQUALI***
- Citizenship/Nationality: ***ITALIAN***
- Location: ***ITALY-ROME***

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MOBILE: +39 340 8239638

ADDRESS Under smart working contract-mainly home-based in Rome

SUMMARY

Over 27-year expert in Clinical Research Field both inside Pharma industry and CRO.

Since Feb 2021 covering **Regional EMEA Line Manager** role **at IQVIA** managing in solid line about 15 Coordinating-CRAs (junior Global Study Managers) engaged for a specific FSP model from 4 different countries.

Committed as resource hiring manager to build and stabilize the staff engaged on multiple global trials for the same client. Working to comply with the internal and external stakeholders.

From Jun 2016 to Feb 2021 **CRA Line Manager at IQVIA FSP** in a model running since 2015. Responsible for Italy and till Feb 2017 for Romania as well. Engaged as resource hiring manager to build, motivate and develop the CRA staff needed for multiple study sites, fully responsible for CRA individual development, direct reviewer of trial visit reports for finalization, direct responsible for country KPIs and productivity metrics. In direct interactions and negotiation with client counterparts and co-workers in EMEA, owner of quality issues at site and country levels, owner of audit finding, FDA inspection and CAPAs. Required to set creative solutions and contributor to various task forces, at client and IQVIA side.

From June 2010 to June 2016 as **Sr Clinical Global Trainer at IQVIA serving FSP** Department. Great Worldwide experience across 29 countries. Working as Primary Global Learning & Development contact for internal and external team members in the main FSP models. (2 years on a model started in March 2010, 4 years on another started in 2008, 1 year also supporting for another). Delivering remote and F2F events to CRAs and DLMs from any Country. Working on close connections with IQVIA and clients' Quality Management functions.

Over 14 years from 1996 to 2010 spent covering various positions in Clinical Research at Pfizer Global Research and Development (PGRD) and at Pfizer Italy (**CRA, srCRA, CPM in Ophta/CNS and CPM in Onco**).

Since 2020 Delivering ad-Hoc lessons to Italian University Master classes of Clinical Research courses. as expert IQVIA representative from Research & Development Department

Best skills in leadership and teamwork. Highest retention rates showed as DLM. Mentor for junior DLMs. Well known for resilience, reliability, hardworking and excellence orientation. Highly and constantly people oriented.

CURRENT POSITION

Date of Employment:	Feb/2021 - Present
Company	IQVIA-FSP
Job Title:	**Regional EMEA C-CRA Dedicated Line Manager**
Key Responsibilities:	In a Specific FSP model in partnership with a big pharma, responsible for the allocation, development and management of not less than 14 junior Global trial Managers called Coordinating-CRA who work supporting the senior GTM in partnership with mirrored roles in the pharma client. Operating as sourcing and hiring manager in 4 elective EMEA countries. Working in alignment with the individual FSP Country Operational Leads and also with the top level IQVIA management for the FSP Model.

Keeping the oversight of the CCRA resources and performance in terms of operations, productivity, and quality at any time.
Working in conjunction with other 4 C-CRA DLMs placed in other regions.
Contribution to model specific task forces and consultant for the revision of model processes and procedures.

PAST PROFESSIONAL EXPERIENCES

Date of Employment: Jun/2016 - Feb/2021
Company IQVIA-FSP
Job Title: **CRA Dedicated Line Manager**
Key Responsibilities: In a specific FSP model in partnership with a big pharma responsible for correct delivery of trials at the selected sites in the country in accordance to SOPs, GCP, and applicable regulatory requirements. Tasks included (not limited to):performance management and professional development of CRAs, Point of contact for site quality escalation; check on compliance to SOPs, regulations, laws, etc.; Assignment and oversight of CRA activities on and off site; Review and approval of site visit reports with central reviewers support; Check that staff adhere and comply with training plan at model, country and trial levels; Performance management; Professional development of individual reporting CRA.
Since role can be Cross-Country. initial responsibility was for Italy and Romania. Since end Feb 2017it was just for Italy due to Italian team increasing.
Worked in close touch with the Client counterparts at country levels. Since Oct 2018 Developed and mentored other CRA LMs for the country in the same model coordinating the various activities and DLMs responsibilities.

Date of Employment: Jun/2010 - Jun/2016
Company IQVIA-HR- Global Learning & Development Dept
Job Title: **Senior Clinical Trainer**
Key Responsibilities: Sr Clinical Trainer serving exclusively FSP.
About 3 years on a global FSP model as unique primary Trainer for internal and external IQVIA team members (CRA, CTA and DLM)
Responsible for: Development and maintenance of model specific role based training curricula (RBCs) and on-boarding activities, negotiating with internal and external customers.; support to Dedicated Line Managers in the process of monitoring staff compliance to RBCs; Support Quality Management function in the development of remedial plans; Identification and application of IQVIA training tools and systems to the model;- Coordination, facilitation and delivery of training events (e.g. process cascades, customer CRA certification Workshop, Fundamentals of Oncology Workshop, etc); Close Work with global top senior model management, DLMs, and sponsor referral people to identify training needs; Coordination and mentoring one assigned Trainer Administrator.

About other 3.5 years for another global FSP model in place since 2008. Certified as trainer according to the Client procedures to deliver various training courses (CRA onboarding program, CTMS for CRA role, EDC process, eSAE system basic and advanced courses, CRA oversight program for LM etc.).
Responsible for: Training delivery to CRAs, CRA Mentors and CRA Line Managers engaged by IQVIA in such World Wide FSP model in multiple Non US countries (Russia, Germany, France, the Baltic's, the Netherland, South Africa, Israel, Ukraine, Switzerland China, India, S. Korea, Thailand, Singapore, Malaysia, Taiwan, Philippines); Intensive and continuous team work with the other Trainers engaged on the same model US and Non Us; Back trainer for US countries by delivery training both remotely and in presence; Planning, delivery and follow up of training events remote and in presence; diligence to attend promptly Train The Trainer sessions delivered by the client in order to keep personal certifications always valid and current; responsible to build ad hoc Solution provisions to team individuals when required by LM and customer; Management of the dedicated SharePoint's and mailboxes; Mentoring of jr trainers.

About 6 months for a third Global FSP Model. Delivery of specific CTMS training sessions for the CRA role.

Date of Employment: Feb/2006 - May/2010
Company **Pfizer Global Research & Development**
Job Title: Clinical Country Project Manager in the Oncology
Key Responsibilities: Working as member of Pfizer Rome Office Oncology Clinical Research team.

Management up to 7 global trials simultaneously most in set up and ongoing stage **phase 2 and 3. Mainly in Kidney Cancer and Advanced Breast Cancer .**
Functional coordination up to 23 different Italian CRA's and 4 CTAs working as per a regional model on about 100 Italian sites. CRA's and CTA's as both internal and outsourced from FSPs. Regular contact with their LMs to discuss/improve individual performance.
Daily contact with Pfizer Global Study teams, in order to comply with Study and Pfizer metrics in the deliveries.
Oversight and collaboration with local Set Up team to ensure appropriate approach with Ethics Committee and Regulatory Authorities.
Regular touch with local administrative people and local Clinical Supplies Chain Coordinator in order to negotiate, manage and oversight global project budgets assigned to Italy and also reviewing finances accountabilities and payments with the institutions and FSP.
Close connection with other company departments (i.e. Italian Oncology Business Unit, Legal Dept etc).
Responsible of any final site selection in Italy.
Responsible of study training local delivery to all CRA staff also including information on the pathology.
Personal management of any site issue escalation communicated by CRAs or caused by CRAs low performance.
In touch with internal Quality management function to discuss issues and to stay updated on general information (lessons, learned, internal processes updating etc)
Personal involvement in any Audit and inspection impacting sites, also travelling to the location.
Other frequent travels done to meet key opinion leaders, to personally solve in place any escalated study issue, to oversight trial activities on site, to attend project meeting, investigator meeting and medical congresses in Italy and abroad.
Active involvement also with Regional Medical Liaisons and sells on field to update on the studies status and upcoming projects.

Date of Employment:	Sep/2003 - Jan/2006
Company	**Pfizer Italy-Medical Department**
Job Title:	Clinical Country Project Manager in Central Nervous System/ Ophthalmology
Key Responsibilities:	In Pfizer Rome Office as belonging to a team with other 3 CPMs. Working on international projects for **phase 3 sleep disorders, and phase 3 trials on glaucoma and age-related macular degeneration** Cross functional activities as per typical CPM role at country level.

Date of Employment:	Mar/1996 – Aug 2003
Company	**Pfizer Global Research & Development**
Job Title:	Clinical Monitor, CRA and Sr CRA
Key Responsibilities:	1 year in jr CRA role, 4 years as CRA and 3 years as srCRA in Rome office. Always working in international trials FDA covered trials with competitive recruitment to register new drugs or new indications (pre marketed IP trials). Great and prolonged experience in **neurovascular (Migraine, Acute Cerebral stroke), antinfective (Acute Tonsillitis, Invasive Mycosis), and cardiovascular /metabolic (Hypercholesterolemia, Dyslipidaemia)** Travelling for at least 3 days a week in Italy and abroad to cover any site management activity including feasibility, selection, set up, invoicing and finance, active monitoring, filing and close out. Attendance in presence at the investigator meeting, medical congresses, global company meeting and department procedure training events.

Date of Employment:	1990 – 1997
Company	"La Sapienza" -first University of Rome -Science Department-
Job Title:	**Volunteer in Biological Research**
Key Responsibilities:	working in the Chemistry Laboratory of Institute of Zoology. Active collaborations in a Base Research Group using crustaceans to fix genetic models as applicable to the Evolution Biology. Personal work published in biological congresses in 1997

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REMARKABLE PROFESSIONAL EXPERIENCES

Feb 2022	Supporting the responses to the **AIFA inspection** report on a COVID trial site inspected in Nov 2021

May-Sep 2020	Involved on the **set up of a Covid trial** to be rolled out also in Italy while there was no contingency procedure yet to manage the COVID pandemic matters. Close collaboration with the client counterpart to create procedures fitting the need and the changes month by month.
Apr 2019	Involved in an Onsite **FDA inspection** as CRA DLM in Italy
Jun 2016-Feb 2017	Conducting **multiple on site Assessment Site Visits in Romania**.
Aug 2012 and Mar 2014	Arranging and delivering in F2F modalities entire week onboarding **training events for multiple CRAs in Beijing China and in US-Durham NC.**
Feb 2011	Attending in person in UK the **model kick-off meeting** for transition of operational Research activities from the Client to the CRO. Attending as Quintiles delegated for Training function.
May 2006	**Personal F2F contacts with Italian oncology KOLs** during the year congress to test the interest in upcoming Onco trials. Immediate net working with the Pfizer Oncology Business Unit.
Apr 2006	Directly involved in **2 regulatory inspections held by Italian Ministry of Health (AIFA)** at 2 oncology sites for which responsible as country study manager. Worked in all the follow up activities under consultation of local and international Quality/Legal team members at Pfizer
Jan 2005	**Attending a Regulatory Authority meeting as hosted sponsor** in order to support the rationale of a relevant phase 2 study. Medical Project Leader come from US headquarter just for the event. He attended and presented in English with me translating into Italian. Finally, the action led to the study regulatory approval in Italy in **2003.**
Dec 2002	Last and decisive 1:1 and **Face to face meeting with the Director of the Clinical Trials Observatory for Italian Ministry of Health** to interpret the related and just released low and also to apply it at the best. Outcome led to the kick-off of the very first multi-country trial involving Italian General Practitioners
Sep 2002-Sep 2003	Delegated by Director of Pfizer Global Research & Development Rome Office to work on **feasibility, implementation, set up and management at country level of the very first trial in Italy involving General Practitioners**. Trial finally gone with 6 selected GPs who worked internationally with competitive recruitment and EDC system. Finally, in Italy the trial completed on target and other sponsors re-stepped in the pathway stated.

EDUCATION

- **State Professional Examination For Biologists**
  Date: 1998- Institution: "La Sapienza" first University of Rome – Italy
- **Master's Degree in Biological Sciences**
  Date: 1995- Institution: "La Sapienza" first University of Rome – Italy-Vote: 110/110
- **General Certificate of Education-High school diploma**
  Date: 1986- Institution: National Lyceum for Classical Humanistic Studies "E.Q. Visconti" in Rome- Vote 54/60
- **English courses** released by British Institutes in 1998 and 2008/9.
- **GCP certified every 2 years (last in 2022)**

BEST SKILLS & REMARKS

- English fluently Written and Spoken. Italian native with known speaking ability and elegant written style.
- Good laptop user applying the main Microsoft programs (word, excel, PowerPoint, acrobat etc).
- Familiarity with WebEx, TEAM and other apps to meet remotely. Able to manage meeting room presenter's facilities (projectors etc.).
- Great public speaker both in English and in Italian while presenting slides too.
- Great attitude to the teamwork and collaboration.
- Extremely people oriented with showed high retention rates as DLM.
- Excellent communication and negotiation skills with internal and external customers and even with ethic and regulatory authorities.
- homebased contract preferred but flexible to get hybrid Home/office based.
- No problem to travel up to 30% of the work time.
- Driving licence since 1988.

PRIVATE INTERESTS AND COMMITMENTS

- About 10-year belonging to a volunteer association to feed and support homeless in Rome city centre. Weekly commitments to collect donated food items, prepare meals and dispense everything by working in team with other volunteers from the same association.
- Supporter and protector of human and animals' rights.

- Passioned attendant of Theatre shows, Cinema, Art exhibitions.
- Loving travel in Italy and abroad to appreciate the Nature, the seacoasts and cultural itineraries.
- Married since 1999. Mother of two over major age boys.

NOTES

- Please keep present CV as Confidential
- I authorise the use of my personal data according to the current Italian law governing Personal data protection.

SIGNATURE

Raffaella Pasquali

Digitally signed by Raffaella Pasquali
Date: 2023.10.04 19:34:08 +02'00'

Raffaella Pasquali