CURRICULUM VITAE

Name	Gabriella Laurora
Foreign languages	Fluent in English Mother tongue: Italian
Education	University degree in Pharmaceutical Chemistry and Technology, Università degli Studi di Milano, Italy (magna cum laude)

Professional Experience

Jul 2020- ongoing **Senior Director, Clinical Delivery, Hub Lead Italy & Nordics, PRA Health Science Italy, Milan, Italy (acquired by ICON plc as of July 2021)**

Responsible for the oversight of the full Clinical Delivery Team (Associate Directors, Managers of Clinical operations, Clinical Team Managers, Clinical Research Associates and Site management Associates) in the HUB (Italy, Denmark, Iceland, Norway, Sweden and Finland). As such, Gabriella has full oversight on hiring, development, resourcing, training of the full team. In addition, she is accountable for quality, finance and projects milestone for any project managed in the abovementioned countries.

Jul 2018- Jun 2020 **Senior Director, Clinical Trial Management Group, PRA Health Science Italy, Milan, Italy (acquired by ICON plc as of July 2021)**

Responsible for the oversight of teams of Clinical Team Managers in Scandinavia, UK, France, Belgium, Netherlands, Spain, Italy and Portugal, through the management of Directors and Associate Directors in charge of the direct management of the CTMs. Oversight includes both line and project management.
Determination of the training, resourcing , hiring needs of the EU-APAC CTM teams in collaboration with executive management of the group, in charge of the development and oversight of goals and objectives for the full group, across EU and APAC.
Representative of the group for the Adaptive Trial Management & Monitoring (Risk Based Monitoring) initiative, she supported development of the model at global level and implemented it within the business unit.

Sep 2013- Jun 2018 **Director, Clinical Trial Management Group, PRA Health Science Italy, Milan, Italy (acquired by ICON plc as of July 2021)**

Responsible for Management of teams Clinical Team Managers in Portugal, Spain, France, Italy, UK, Sweden and South Africa, including Recruitment, Retention (motivation and engagement), training and project oversight (operations, Finance and quality).

Aug 2012- Sep 2013 **Director, Clinical Operations, INC Research , Milan, Italy**

Responsible for Management of a team of approximately 100 European Clinical Research Associates (CRAs, in-house CRAs, Clinical Team Leads and Managers, Clinical Operations) in a Functional Service Provider model. As such, Gabriella contributed to the implementation of the European team, phased according to the creation of the FSP and increasing of the business volume. She has been responsible for the alignment of the business model between the two companies, with specific focus on monitoring activities, metrics management and project oversight.

Jan 2010- Sep 2012 **Associate Director, Clinical Operations, Kendle International SrL, Milan, Italy (acquired by INC Research as of 12 July 2011)**

Responsible for Management of a team of European Clinical Team Leaders (span of control of 15 people). As such, accountable for the management of the performance, growth and professional development of the team. Assurance of the quality, consistency and timeliness of monitoring service across all projects through direct management , evaluation and development of the staff is key for day-to-day activities.

As Associate Director, Gabriella, in collaboration with the international team, has developed the job description of the Clinical Team Leader (CTL), a plan for the development and training of this professional figure as far as financial tasks and responsibilities are concerned, tools and templates for the CTL team, has collaborated in the development of budget and text for proposals, has been appointed as supervisor for Clinical Operations activities in projects in a crucial phase, has developed work instruction for compliance with the Italian legislation. Participation to the monthly Project Review Meetings for the projects managed by the CTL team is part of the tasks of the AD Clinical Operations.

January 2009- September 2009 **Ad interim Associate Director, Global Clinical Development, Kendle International SrL, Milan, Italy**

Responsible for Management of a team composed of Project Leaders, LeadCRAs and CRAs based in the Milano office. As Associate Director, Gabriella has been responsible for allocation of resources for Italian based projects (CRAs) and for international projects (both LeadCRAs and Project Leaders) in collaboration with the Director Clinical Development, and for the line management of Italian Project Leaders. Oversee of the projects managed by Italian Project Leaders, including international reporting responsibilities, together with support to the Italian business development activities had been among the major tasks.

January 2008- December 2009 **Project Leader, Global Clinical Development, Kendle International SrL, Milan, Italy**

Responsible for Management of international Clinical Projects (Phase I-III), as far as operations, resources, budget and timelines are concerned. In particular management of an European Project on solid tumors (Renal Cell Carcinoma) in Phase I (Italy and Germany) and of the European part (15 countries, 60 sites involved) of an IND phase III pivotal trial in sarcoma patients (oncology).

Development of budget and text proposals for Clients and participation to Bid Defense Meetings with Clients together with Kendle international team.

Line management of internal resources (Clinical Research Associates and Project Assistants) working on different projects (training, carrier development, definition of year objectives, interviews).

February. 2004- December 2007 Senior Manager, Corporate Clinical Research, Bracco Imaging SpA, Milan, Italy

Reporting to: Head, Corporate Clinical Research, located in Princeton, New Jersey, USA

Working in compliance with Global SOP (EU and US legislation compliant).

Responsible for:

- Corporate clinical research activities related to the worldwide development of a new radiopharmaceutical compound (therapeutic area: combination of oncology and nuclear medicine/radiotherapy) in compliance with global SOP (compliant with both European and US clinical trial regulations); specifically:
    - Protocol writing
    - CRF development
    - Qualification of phase I sites in Italy
    - Submission to Ethics Committees
    - Review of the documentation to be submitted to Istituto Superiore di Sanità
    - Coordination of pre-study activities at the site: validation of transfer of specific procedures (labelling of the compound, HPLC method validation);
    - Organization of Investigators' meetings (Recruitment and review meetings), including preparation and presentation of the documentation at the meetings;
    - Study start-up and monitoring of this phase I trial
    - Contact person between internal International Medical Working Group and the site
    - Maintain routine communications with US based counterpart involved in the project
    - Provide and maintain timelines and budget of the project
    - Coordinate activities with Biometrics and Medical Writing

- Multicenter multinational clinical trial in Magnetic Resonance Imaging:
    - Development of the clinical documents necessary for the study including (but not limited to): protocol, CRF, CRF Completion Manual, Drug Log Book, Monitoring Plan;
    - CRO selection and management;
    - Vendor selection and management (Centralized ECG management vendor)

    - Sites selection (in Italy, Germany, UK, The Netherlands),
    - Start-up activities (including budget negotiation, EC submissions and Competent Authorities submissions)
    - Management of Chinese counterpart
    - Trial management (including reporting activities)
    - Timelines and budget management

- Case-Control study (therapeutic area: follow-up of Serious Adverse Events in post-marketing subjects) in European countries ; specifically:
    - Organization of the trial
    - Contact with Competent Authorities to check which kind of documentation should be submitted in case of trial without administration of Investigational Medicinal Product
    - Selection and management of vendor for the submissions to Ethics Committees in different European countries (Italy, Switzerland, UK, Germany, France)
    - Review of statistical and Data Management documentation prepared by vendors

- Protocol development for and IND phaseII/III protocol for a new indication for a magnetic resonance imaging contrast agent

- Management of internal resources on specific projects, located in different countries (Italy and US), such as Medical Writing, Biometrics, Pre-clinical development, Pharmaceutical Development, taking into account timelines and budget
- Management of external vendors in phase I and phase III international (US and EU based) projects

- Training Corporate Clinical research personnel on the following:
    - Clinical Trial Directive, including related guidelines
    - Implementation of Clinical Trial Directive in different European countries
- Review corporate international business processes, taking into account both European (Clinical trial Directive) and US legislation
- Managing internal resources for Trial Master Files archiving for the whole Department
- Management of internal resources for the development of business processes for the for optimization of inter-functional activities (Clinical Research and Drug safety) related to implementation of Clinical Trial Directive
- Management of internal resources (Clinical Research Manager), including interview, selection and training
- Writing and reviewing SOPs for Corporate Clinical Research (SOP on reporting SUSAR to Ethics Committees and Investigators, SOP on pre-study documentation necessary to start a site, SOP on Clinical Supplies and Qualified Person, SOP on documentation to be archived in the Trial Master File at Sponsor's and at Investigator's site)
- Providing input to the Head, CCR when projecting the Clinical Research budget.

June 2002-January 2004 Senior Manager, Corporate Clinical Research, Bracco Imaging SpA, Milan, Italy

Reporting to: Medical Leader, Corporate Medical Planning and Management, Princeton, New Jersey, US

Working in compliance with Global SOP (EU and US legislation compliant)

Responsible for:

- Management of all clinical research activities in Europe in the ultrasound area (therapeutic area: diagnostic imaging, ultrasound)
- Management of European clinical research activities in phaseII/III development of an ultrasound contrast agent, including management of vendors (submissions, monitoring, centralized laboratories, centralized ECG reading, centralized imaging laboratory)
- Selection and management of vendors for European based clinical trials (including budget and contract negotiation)
- Giving input and review both Data Management and Biometrics activities related to each Clinical Trial
- Review and input to Medical Writing for 10 Clinical Trial Reports writing and finalization
- Guiding and supervising Corporate Clinical Research (CCR) tasks performed by direct reports, including training activities (in house and on-site)
- Interview CRAs for recruitment purposes
- Interview CRAs/monitors from CROs to evaluate their assignment to specific projects
- Developing Team Approach in assigned projects (with both internal and external resources)
- Training internal and external resources on specific topics (protocol and projects requirements)
- Determining together with the CCR managers, the assignment of tasks to be accomplished by vendors.
- Determining global research resource allocation
- Representing ultrasound area as Corporate Clinical Research representative to the International Ultrasound Medical Working Groups (IMWG)
- Conducting meetings with CCR managers on a routine basis
- Providing the Corporate Clinical Research monthly status report for Ultrasound Group to the Head of CCR routinely or when requested

Jan. 2000-May 2002 Clinical Study Manager, Medical Affairs Europe, Bracco Imaging SpA, Milan, Italy

Reporting to: Medical Director, Medical Affairs Europe, Milano , Italy

Working in compliance with International SOP (EU legislation compliant).

Responsible for:

- Protocols development of phase IIIb international (European) studies in ultrasound imaging area (therapeutic area: diagnostic imaging, ultrasound)
- Management of CROs concerning centres' selection, prospective monitoring phase IIIb studies.
- Reviewing of clinical data for the finalisation of the Clinical Trial Reports.
- Management of study budgets including negotiating vendor and investigators contracts.

Jan. 1998-Dec. 1999 Clinical Group Leader, Medical Regulatory Affairs-Pharmacoepidemiology, Bracco SpA, Milan, Italy

Reporting to: Medical Director, Medical Affairs, Milano , Italy

Working in compliance with International SOP (EU legislation compliant).

Responsible for:

- Protocols development of phase II-III clinical trials of an ultrasound contrast agent (therapeutic area: diagnostic imaging, ultrasound).
- Management of CROs concerning centres' selection, prospective monitoring phase II-III studies.
- Management of internal resources (1 Medical Doctor) and external resources (CROs and employees of other affiliate companies)

May 1995 – December 1997 Clinical Monitor, Pharmacoepidemiology Unit, Direzione Medica Mezzi di Contrasto, Bracco SpA, Milan, Italy

Reporting to: Medical Director, Medical Affairs, Milano , Italy

Working in compliance with International SOP (EU legislation compliant).

Responsible for:

- Managing two ongoing observational studies in Italy (nearly 40 centers involved) (therapeutic area: diagnostic imaging, X-ray).
- Managing internal and external resources: monitoring CRO, CRO dedicated to the development and management of the specific software used in the studies, Biometrics, Consultants, Investigators, Investigators' Meetings
- Final Reports writing on 25 different subjects, all related to the two observational studies.

January 1994-April 1995 Clinical Monitor, Direzione Medica Mezzi di Contrasto, Bracco SpA, Milan, Italy

Reporting to: Medical Director, Medical Affairs, Milano , Italy

Working in compliance with International SOP (EU legislation compliant).

Responsible for:

- Running a complete Phase IIIb program for an X-ray Contrast Medium (10 studies) (therapeutic area: diagnostic imaging, X-ray), coordinating protocol writing activities of 2 Medical Doctors, CRF design, site selection and qualification.
- Selection and Management a Contract Research Organisation for Submission of Ethics Committee and Regulatory Opinions and Monitoring Activities for the overall program.

- Team Member of the dedicated company Project Team.

January 1992 – December 1993 Clinical Research Associate, Direzione Medica Mezzi di Contrasto, Bracco SpA, Milan, Italy

Reporting to: Medical Vice-Director, Medical Affairs, Milano , Italy

Working in compliance with International SOP (EU legislation compliant).

Responsible for:

- Prospective monitoring of phase II clinical trials in magnetic resonance area (therapeutic area: diagnostic imaging. MRI).
- Retrospective monitoring and Quality Control of the documentation (on-site and at the Sponsor) of European phase II and III studies of an X-ray contrast medium for an NDA.
- Coordination of activities with Data Management for query solution fro 22 clinical trials conducted in 1988-1990 period.

I authorize the treatment of my personal data, according to Italian law (art. 13, D. Lgs.196/2003)