europass

# Donatella Albanesi

**Nationality**: Italian

- Wide experience and knowledge of clinical drug development, regulatory requirements and medical interactions
- Strong capability of working in complex matrix environment at Country and Global level
- Effective communication and networking skills with proven negotiation and conflict management capabilities
- Strategical thinking and effective decision making in managing operational challenges with agility and resilience, risk assessment and contingency plans
- Wide experience of large teams' and people management with strong and inclusive leadership
- Team player with flexible, dynamic and innovative profile

## EDUCATION AND TRAINING

1990–Milan, Italy

**PROFESSIONAL QUALIFICATION as BIOLOGIST –** University of Milan. 1990

1988–Milan, Italy

**MASTER DEGREE in BIOLOGICAL SCIENCES –** University of Milan. 1988

1983–Milan, Italy

**SCIENTIFIC HIGH SCHOOL DIPLOMA –** XIII Liceo Scientifico", Milan. 1983

## WORK

2024 currently–Milan,Italy

**Ethical Committee Office, Scientific Coordinator –** Fondazione IRCCS Istituto Nazionale dei Tumori

- Responsible for the scientific and operational coordination of the Ethical Commitee Office team (5 associates) , including the management of validation, evaluation and monitoring activities for all the EC submitted clinical trials (pharmacological, interventional, observational, medical devices studies, expanded access and compassionate use programs) in accordance with the EU CTR and local requirements
- Coordinating the Etichal Commitee Office on a Regional level as « Comitato Etico Territoriale Lombardia 4 »), including the afferents offfices, armonizing processes and procedures in order to guarantee the respect of timelines and quality for the evaluation of clinical trials
- Managing the organizaton of EC meeting and supporting the EC President and Members by preparing and supervising all the relevant documentation to be evaluated (on a shared area)
- Provìding Scientific and Regulatory support to Research Physicians and Study Coordinators for the planning , start-up and conduction of clinical trials, with special focus on indipendent research

## 2015- 2023 Novartis

2017–2023 Milan, Italy

### Head of Oncology Development Unit -Trial Monitoring Operations – Novartis Farma

- Reporting to Country Head of Trial Monitoring Operations, accountable for planning, management and delivering of clinical trial activities at Country level
- Ensure the execution and delivery of the full oncology portfolio (Solid and Rare tumours & disease, Haematology, Immune Oncology, CAR-T, Radioligand Therapy) from phase I to IIIb, with over 120 trials managed yearly with a wide involvement in early phase/FIH studies
- Responsibility of the overall Development Unit staff (>30 headcount with 4 Line managers), ensuring hiring, assignment, and performance of CSMs / CRAs, CRA Managers / CSM Managers, supporting development plans and talents retention
- Responsibility for oversight and support of CRO external resources (>20 CRAs/CSMs)
- Responsible for the formulation of clinical trial strategy in collaboration with Country CSO and global stakeholders to ensure effective trial execution and completion with high quality
- Identification and implementation of innovative practices of Country feasibility and Patient engagement strategies, to create competitive advantages for the country footprint
- Full responsibility and accountability for the Dev. Unit budget
- Country Champion for Decentralized Clinical Trials (DCT)
- As an example of high performance, in a key phase IIIb breast cancer study, obtained an excellent cross functional cooperation with the other departments resulting in a stronger participation of Italy vs EU, enrolling over 600 patients in 100 centres, achieving site activation and target delivery in record time, contributing to 50% of the overall objectives.

2015–2017 Milan, Italy

### Country Head Global Monitoring Operations – Novartis Oncology

- Solid line to Country Oncology Medical Director and dotted line to Regional Head of Global Monitoring Operations
- Responsible for all the activities related to the initiation, delivery and completion of the Global and Regional clinical trials within the Country
- Full responsibility for Global Monitoring Operations budget at a Country level
- Responsibility of the overall staff management (33 headcount)
- Responsibility for oversight and support of CROs activities (>30 resources), ensuring performance, high quality data and timelines
- Compliance with applicable policies, procedures, and regulations
- Support the preparation and conduct of audits and inspections
- Work closely with Global clinical operations as well as Global and Local clinical teams to ensure a smooth launch, execution, and close-out of clinical trials
- Responsibility for the implementation of the Oncology BU strategy, working closely with Country Oncology Medical Director concerning study allocation and sites' selection
- Communication and strong collaboration with local Medical Scientific functions on trial sites and enrolment status
- Relationship with external customers including Regulatory agencies
- Direct impact on Novartis decision making timelines and Health Authority submissions
- Influence in defining Novartis procedures and policies for trial execution

## 1999 to 2015 GlaxoSmithKline SpA, Verona

2011-2015 Verona, Italy

### Clinical Development Manager Oncology – Global Clinical Operations - GlaxoSmithKline

- Direct reporting to the Clinical Operations Director, functional reporting at EU level
- Line management of the oncology Study Management team, functional coordination of Monitoring team and Start-up oncology teams
- Local and central accountability for the management and delivery of all the phase I/II to IV studies of the oncology and haematology R&D therapeutic assets

2008-2011 Verona, Italy

### Clinical Development & Monitoring Manager – GSK Oncology

- Direct reporting to the Medical Director of the Oncology BU management, with functional reporting to the EU Head of Clin Ops Oncology R&D
- Creation and management of the Onco Clin Ops team (8 Project/Study Managers + 6 Monitors Manager/Monitors), functional coordination o the Start-up oncology team
- Full responsibility and accountability for the management and delivery of all the phase I/II to IV studies for all the oncology therapeutic assets (oncology and haematology R&D and Biological immunotherapy). Wide involvement and Country contribution to the development and filing of several new drugs (Tykerb/Tyverb, Promacta/Revolade, Arzerra, Votrient, Mekinist and Tafinlar) in US and EU markets
- Strong collaboration and partnership with Medical Affairs (i.e. KOLs networking, sites' engagement activities, congresses and events)

2006-2008 Verona, Italy

### Clinical Development Manager Oncology – Global Clinical Operations - GlaxoSmithKline

- Direct reporting to the Head of Clinical Operations
- Line management of a team of 4 Clinical Research Scientists
- Local accountability for the management and delivery of all the phase I/II to IV studies of the oncology area

2001-2006 Verona, Italy

### Senior Clinical Research Scientist Oncology - Global Clinical Operations - GlaxoSmithKline

- Functional responsibility and coordination of junior CRSs on phase II to IV studies in the oncology and urology areas
- Management and handover of SmithKline oncology portfolio studies' acquisition

1999-2001 Verona, Italy

### Senior Clinical Research Manager - GlaxoWellcome

- Management of R&D and local studies, phase II to III, in oncology, urology and hepatitis areas (full project management activities and responsibilities including clinical study reports and abstracts writing)
- Relationships with Investigators and Opinion Leaders

**1990 - 1999 Roche S.p.A., Milan**

1993–1999 Milan,Italy

**CRA / Senior Clinical Research Associate –** Roche S.p.A.

- Monitoring activity in several projects in the cardiovascular and other areas
- Local Manager of the computerized CRFs' data flow system
- Experience in several pharmacokinetics and bioavailability pilot studies

1990–1993 Milan,Italy

**Headquarter Clinical Research Associate –** Roche S.p.A.

- Secondment to Roche HQ (Basel, Switzerland), to US HQ (Nutley, NY), to a CRO in Munich (Germany), in a cardiovascular international project (contributing to development and filing of Inhibace in congestive heart failure)

## OTHER EXPERIENCES

1988–1990: Conference and editorial activities at Gruppo Scientifico Italiano Studi e Ricerche, Milan
1989–1990: Researcher, Ecology Dept. of the University of Milan

A continuative training and update in specific therapeutic areas and professional /personal learning has been pursued through courses and congresses (including Project Management SDA-Bocconi, SSFA; ASCO/ESMO/AIOM attendance)

## LANGUAGE SKILLS

Mother tongue(s): **ITALIAN**

Otherlanguage(s) : **ENGLISH**|(advanced)

## DIGITAL SKILLS

MicrosoftWord|MicrosoftExcel|PowerPoint|SocialMedia|Outlook|MicrosoftPowerpoint

## DRIVING LICENCE

Driving Licence : B

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