

## PERSONAL INFORMATION

## Paola Baiardi

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C.F.: [REDACTED]

Sex F [REDACTED] Nationality Italian

## WORK EXPERIENCE

March 2020- Present

### Scientific Director Pavia Institute IRCCS and Head of Operations of Scientific Direction

Clinical and Scientific Institutes Maugeri, IRCCS, Scientific Direction, Pavia, Italy

Since March 2020, while continuing to act as coordinator of the Scientific Direction of ICS Maugeri acquiring the role of Head of Operations, she is specifically in charge of managing the research activities of the Pavia Institute, one of the nine IRCCS hospitals of the Maugeri network among the eighteen hospitals throughout Italy

Business or sector Healthcare

January 2013–February 2020

### Coordinator Scientific Direction

Clinical and Scientific Institutes Maugeri, IRCCS, Scientific Direction, Pavia, Italy

Planning, monitoring and supervising scientific and staff activities within the Scientific Direction. Staff management. Contribution to scientific strategies and discussion with top positions of the organization. Interaction with researchers to promote scientific activities. Evaluation, monitor and supervision of research projects and protocols including reporting and accountability. Scientific and methodological support for drafting research proposals and papers.

Business or sector Healthcare

January 2001–December 2012

### Coordinator of cooperative research projects

Salvatore Maugeri Foundation, IRCCS and Consorzio per Valutazioni Biologiche e Farmacologiche, Pavia, Italy

Workpackage leader and coordinator of European and National projects. Planning and management of clinical trials with focus on paediatrics and rare diseases. Drafting of statistical analysis plans. Statistician in charge for paediatric trials. Realization and management of disease and drug registries (rare diseases), post marketing surveillance and pharmacoepidemiological studies. Focus on regulatory issues.

In the period January 2010–December 2012 she acted as Director of Consorzio per Valutazioni Biologiche e Farmacologiche.

Business or sector Healthcare

January 1992–December 2000

### Biostatistician

Salvatore Maugeri Foundation, IRCCS, Information System Department, Pavia, Italy

Planning and management of clinical studies. Survival analysis, Meta-analysis, Psychometric Techniques. Preclinical research (toxicology and pharmacology). Decision support systems (neural networks).

Business or sector Healthcare

April 1987–December 1991

### Research Assistant

Salvatore Maugeri Foundation, Medical Informatics Unit, Pavia, Italy

Experience in DBMS (DataBase Management System), planning and carrying out of clinical managerial procedures (particularly in oncology). Design and modelisation (object-oriented approach) of an clinical information system.

Business or sector Healthcare

## EDUCATION AND TRAINING

- July 1994 **Specialist in Biostatistics and Epidemiology**  
University of Milan, Italy  
Biostatistics - planning and management of clinical studies - data analysis  
Epidemiology - design of clinical and drug utilisation studies - data analysis
- April 1987 **Degree in Mathematics**  
University of Pavia, Italy  
Principles of mathematics - Applied mathematics - Probability Theory - Informatics

## PERSONAL SKILLS

Mother tongue Italian

Other language(s)

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
English	C1	C1	C1	C1	C1

Levels: A1/A2: Basic user - B1/B2: Independent user - C1/C2 Proficient user  
[Common European Framework of Reference for Languages](#)

## Expertise and job-related skills

As biostatistician with wide experience in healthcare, she focused on methodological aspects related to the conduction of clinical trials in small populations (rare diseases, paediatrics, population subgroups), including the implementation of innovative study designs as well as new approaches to achieve scientific evidence in these niche contexts (modelling and simulation techniques, extrapolation of efficacy data from adults to children). Her remarkable experience is also related to the planning, management and evaluation of clinical trials in her fields of interest. She has also extensive experience in regulatory issues at the National and European level acquired during her participation in the Paediatric Committee at the EMA and in the Paediatric Working Group at the Italian Medicines Agency (AIFA).

Main research areas are:

- 1) Methodology for clinical trials in small populations, with special attention to trial designs aimed at increasing acceptability while limiting sample size. Applications in case of paediatrics and rare diseases: she has been in charge of the planning and management of early phase trials based on Bayesian sequential designs and of phase III trials in chronic diseases based on innovative designs (randomized-withdrawal design).
- 2) Planning and management of clinical trials and observational (cohort) studies. Main area of interest: oncology, nephrology, allergology, cancer rehabilitation and rheumatology. Her experience is mainly in the planning and reporting of phase II and phase III trials.
- 3) Pharmacoepidemiological evaluations aimed at assessing drug usage and safety. She has performed studies of drug utilization in children (respiratory drugs) and methodological studies aimed at collecting adverse drug reaction in the paediatric population.
- 4) Drug post marketing surveillance, mainly oriented to the realization of nationwide disease registers with focus on small populations (children and rare diseases). Thanks to her collaboration with patient associations, she has to his credit extensive knowledge and experience in thalassemia and children affected by rare diseases.

As for the Scientific Direction of a Research Hospital she has developed skills in management of clinical research, covering all the aspects related to the identification and management of personnel and resources needed to carry out the researches as well as the supervision and monitoring of the scientific activities.

## Digital competence

SELF-ASSESSMENT				
Information processing	Communication	Content creation	Safety	Problem solving
Proficient	Proficient	Independent	Independent	Independent

Levels: Basic user - Independent user - Proficient user  
[Digital competences - Self-assessment grid](#)

- Good command of office suite (word processor, spread sheet, presentation software)
- Good command of statistical packages (SPSS, SAS)

## Driving licence

B

## ADDITIONAL INFORMATION

## Research Projects

She has been involved in several research projects within the European Community and the Italian Ministry of Health. In details:

- 1) Coordinator of the EU project "EuOrphan - Service for the support of the European Orphan medicine market", an e-TEN project granted by DG Information Society (2005-2006) aimed at realising a web-based database of designated and commercialised orphan drugs worldwide.
- 2) Participation (WP leader) in the TEDDY (Task-Force in Europe for Drug Development for the Young) project, a FP6 Network of Excellence (2005-2010) aimed at better structuring European research in paediatrics by supporting the rational use of drugs in children and developing collaborations among the different stakeholders. She coordinated the activities of the following workpackages: a) "Paediatric Clinical Studies", dealing with methodological issues in paediatric research ; b) "European Paediatric Medicines Database" for the collection of studies (registrative and spontaneous) supporting the use of drugs in children
- 3) Participation (WP leader) in the GRIP (Global Research In Paediatrics) project, FP7 Network of Excellence (2011-2016). GRIP is a methodological research network that encompasses researchers, regulatory agencies (EMA, FDA, Japan) and WHO whose aim is to optimize all scientific and regulatory processes for paediatric drug development. GRIP has also a strong educational mission on paediatric matter. She has been in charge of the workpackage "Methodology for Clinical Trials in Paediatrics" including 5 working groups (Modelling & Simulation, Extrapolation, Innovative Design, Sample Size, Comparator). She is also a teacher of the Module "Experimental Drug Evaluation in Paediatrics" for the aspects related to paediatric research methodology.
- 4) Participation (WP leader) in the FP7 DEEP (DEferiprone Evaluation in Paediatrics) project (2011-2015), aimed at completing the development of deferiprone chelator for its use in children in accordance with the 2009 PDCO Priority List for off-patent drugs. She is the leader of the workpackage for the planning and management of the efficacy and safety study of deferiprone in children affected by hereditary haemoglobinopathies.

At the national level she has been WP leader (2007-2011) within the project "Safety of psychotropic drugs in the Italian paediatric population", granted by the Italian Medicines Agency (AIFA) where she coordinated an observational prospective cohort study aimed at assessing the safety of psychotropic drugs in Italy based on prescription databases.

Moreover, she participated (2007-2011) into the project "HTA-Thal: HTA evaluations of iron overloaded patients" granted by the Italian Ministry of Health, ex art.12., where she was in charge of the planning and realization of the Italian Registry of thalassemic patients.

Finally, she is currently exploiting her expertise in the supervision of the research projects, clinical trials and other scientific activities of her Institute.

## Membership

She has been a member of the Paediatric Committee at the EMA (2015-2020) as representative of patient associations (Leonardo Giambone Foundation) where she actively contributed to the activities of the Committee. Main involvement concerned the assessment of Paediatric Investigation Plans in the areas of thalassemia and other anemias, rare diseases, allergy and oncology and participation into working groups and discussion on statistical issues (modelling and simulation, extrapolation, estimands).

She has been (2008-2012) a member of the Paediatric Working Group at the Italian Medicines Agency (AIFA) where she provided her contribution both at the scientific and regulatory level. In details she acted as: 1) Assessor named by AIFA for CMDh Worksharing Procedures in compliance with Art. 45/46 of the Paediatric Regulation (EC) No 1901/2006 and amendments; 2) Internal reference expert for evaluation of paediatric drugs used off-label in Italy finalized to their inclusion in the Italian list of special use of drugs under the Act 648/96.

Other current memberships are:

- 1) Member of the Institutional Review Board of Maugeri Institute
- 2) Member of the Management Board of Gianni Benzi Foundation

#### Other relevant information

Teaching experience:

- 1) Contract Professor at Postgraduate School in Regulatory Disciplines, University of Pavia, Italy (years 2001 - present)
- 2) Contract Professor at Master I level in Pharmaceutical Management and Health Policy, University of Bologna, Italy (years 2003-2007)
- 3) Contract Professor at Postgraduate School in Health Psychology, University of Torino, Italy (course: Methodology for Psychosocial Research) (years 1998 - 2002)
- 4) Contract Professor at Postgraduate School in Medical Pharmacology, University of Pavia, Italy (course: Pharmacological Experimental Design) (year 1999)

Publications Author/co-author of more than 120 publications at national and international level (H-Index: 36).

Pavia, 20/12/2023

Paolo Barbieri

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