

PERSONAL INFORMATION **Francesca Rocchi**

WORK EXPERIENCE

February 2017- Present

Head of Regulatory Affairs Service

Bambino Gesù Paediatric Hospital (OPBG) (Italy)

Regulatory Affairs Service within the "Center of Excellence for the development of medicine, vaccine and medical device for paediatric Use". Coordinating and providing support in defining the appropriate and applicable regulatory strategies for the implementation of not-for-profit/investigator driven clinical studies/clinical research projects conducted within the OPBG Hospital; coordinating the preparation/review of the necessary ethical/regulatory documentation

Coordinator of Clinical Trial Quality Team

Senior scientific Coordinator of INCIPIT (Italian Network for Paediatric Clinical Trials) - the Italian National Hub in c4c Network

Clinical project management of EU funded projects

PDCO Member Representing Healthcare Professionals (since 2017)

October 2014-February 2017

Senior Regulatory Affairs Manager (on secondment)

Fondazione PENTA ONLUS (Italy)

- Clinical assessor and expert in regulatory aspects
- Italian Delegate Alternate at Paediatric Committee European Medicine Agency (since 2007).
- Research activities within the EU-funded project GRIP (Global Research in Paediatrics Network of Excellence): development of Master of Science Programme in Paediatric Medicines Development and Evaluation

October 2012-October 2014

Clinical Assessor

Agenzia Italiana del Farmaco - European Assessment Unit (Italy)

- Italian Delegate Alternate at Paediatric Committee, European Medicine Agency (EMA) since 2007
- Clinical assessor (efficacy and Safety) for Paediatric Investigational Plans
- Product Team Leader and clinical assessor for Committee for Medicinal Products for Human Use (CHMP) procedures and Scientific Advice procedures
- Coordinator of the activities related to Paediatric Medicine within AIFA (interaction with other Units and Department, interaction with the network of external Experts)

October 2011-October 2012

Regulatory affairs manager (on secondment)

Bambino Gesù Paediatric Hospital - Clinical Trials Centre (Italy)

- Italian Delegate Alternate at Paediatric Committee, European Medicine Agency (EMA) - Clinical assessor for Paediatric Investigational Plans and Scientific Advice Procedures
- Advisor on regulatory issues in clinical research and strategy for implementing clinical research Networks
- Research activities in EU funded projects
- Training and education activity

May 2005-October 2011

Clinical Assessor

Agenzia Italiana del Farmaco (AIFA) (Italy)

- Italian Delegate Alternate at Paediatric Committee, European Medicine Agency (EMA)

nomination in January 2007

- Clinical assessor for Paediatric Investigational Plans
- Product Team Leader and clinical assessor for CHMP procedures and Scientific Advice procedures
- Drug prescriptions and drug use analysis
- Drug prescribing information activities, pharmaceutical expenditure, drug use monitoring, analysis of rational drugs prescribing
- National Formulary periodic review

April 2003-April 2005 **Regulatory affairs manager**

Ministry of Health, General Directorate of Drugs, Pharmaceuticals and Medical Devices (Italy)

- Medical writing activity (ISDB Bulletin, newsletter , contents for website)
- Drug information for health professionals and public
- Drug prescriptions and drug use analysis
- Drug prescribing information activities, pharmaceutical expenditure and drug use monitoring, analysis of rational drugs prescribing
- National Formulary periodic review
- Scientific secretariat for Italian Drug Reimbursement Committee

2002- 2003 **Research fellow**

Servizio Farmaceutico Territoriale ULSS 20 (Italy)

- Medical writing activity
- Drug information activity for health professionals and public
- Drug prescriptions analysis in sub-population (paediatrics and childbearing women)
- Phase IV pharmacological research (with General Practitioners)

1998- 2002 **Research fellow**

Istituto di Ricerche Farmacologiche Mario Negri - Laboratory for Mother and Child Health (Italy)

- Drug information for health professionals and public in relation to drugs use in paediatric population and childbearing women
- Drug prescriptions analysis in sub-population (paediatrics and childbearing women)
- Research activities in clinical pharmacology and pharmaco-epidemiology
- Data entry and data management

EDUCATION AND TRAINING

June 2016-September 2016 **Diploma Tr@inforPed HIV 2016**

PENTA in collaboration with European Society for Paediatric Infectious Diseases ()

September 2004-November 2005 **Second level University Master Degree**

Centro Interuniversitario "Thomas C Chalmers" Università degli Studi di Modena e Reggio Emilia (Italy)

2001- 2004 **Specialist in Hospital Pharmacy**

Faculty of Pharmacy, Università degli Studi di Modena e Reggio Emilia (Italy)

- 1998- 2001 (Specialist in Pharmacology Research degree) PhD equivalent
Institute for Pharmacological Research Mario Negri (Italy)
- 1991- 1997 Degree Magna cum Laude in Pharmaceutical Chemistry and Technology
Faculty of Pharmacy Università degli Studi di Bologna (Italy)
- 1987- 1991 Diploma Liceo Scientifico (Scientific high school)
Liceo Scientifico Luigi Valeriani (Italy)

ADDITIONAL INFORMATION

- Expertise** Paediatric drug development
Clinical trials in paediatric population (methodology - ethics)
Education and Training
- Publications** Pontrelli G, Cimini G, Roversi M, Gabrielli A, Salina G, Bernardi S, Rocchi F, Simonetti A, Giaquinto C, Rossi P, Sylos Labini F. Prioritizing the First Doses of SARS-CoV-2 Vaccine to Save the Elderly: The Case Study of Italy. *Front Public Health*.2021 Jul 14;9:684760.
- Turner MA, Hildebrand H, Fernandes RM, de Wildt SN, Mahler F, Hankard R, Leary R, Bonifazi F, Nobels P, Cheng K, Attar S, Rossi P, Rocchi F, Claverol J, Nafria B, Giaquinto C. The conect4children (c4c) Consortium: Potential for Improving European Clinical Research into Medicines for Children. *Pharmaceut Med*. 2021 Mar;35(2):71-79
- Pontrelli G, Ciabattini M, De Crescenzo F, Biondi I, Cocchiola R, Copponi G, Frillici C, Molinari F, Rocchi F, Simonetti A, Rossi P, Livadiotti S. The Investigational Clinical Center: a clinical-supportive and patient-centered trial unit model. Ten years of experience through normal and pandemic times of a large pediatric trial center in Italy. *Ital J Pediatr*. 2021 Jul 13;47(1):156.
- Ruggieri L, Bonifazi D, Landi A, Bonifazi F, Bartoloni F, Costello M, Felisi MG, Gasthuys E, Godo A, Martinon Torres F, Nadal D, Nuytinck L, Rocchi F, Turner M, Ceci A. Survey by TEDDY European Network of Excellence for Paediatric Clinical Research demonstrates potential for Europe-wide trials. *Acta Paediatr*. 2019 Sep 18. doi: 10.1111/apa.15020
 - [Penazzato M](#), [Gnanashanmugam D](#), [Rojo P](#), [Lallemant M](#), [Lewis LL](#), [Rocchi F](#), [Saint Raymond A](#), [Ford N](#), [Hazra R](#), [Giaquinto C](#), [Belew Y](#), [Gibb DM](#), [Abrams EJ](#); [Paediatric Antiretroviral Working Group \(PAWG\)](#). Optimizing Research to Speed Up Availability of Pediatric Antiretroviral Drugs and Formulations. *Clin Infect Dis*. 2017 Jun 1;64(11):1597-1603
 - Chiurciu S, Calo Carducci F, Rocchi F, Simonetti A, Bonatti G, Salmaso S, Melchiorri D, Pani L and Rossi P. Is HCMV vaccine an unmet need? The state of art of vaccine development. *Int J Immunopathol Pharmacol*. 26:15-26, 2013.
 - Rocchi F, Tomasi P; The development of medicines for children. *Pharmacol Research Pharmacol Res*. 2011 Mar 3. [Epub ahead of print]
 - Rocchi F, Paolucci P, Ceci A, Rossi P. The European Paediatric Legislation: benefits and perspectives. *Ital J Pediatr*. 36:56; 2010
 - Rocchi F, Addis A, Martini N. Current national initiatives about drug policies and cost control in Europe. *J Ambulatory Care Manage*. 27:127-131;2004
 - Reggi V, Balocco-Mattavelli R, Bonati M, Breton I, Figueras A, Jambert E, Kopp C, Montane E, Rago L, Rocchi F; The International Comparative study on Drug Information. Prescribing information in 26 countries: a comparative study. *Eur J Clin Pharmacol*. 59 :263-70;2003
 - Rocchi F, Clavenna A, Ferrara T, Campi R, Calati MG, Bonati M. Information and education in sanitary setting. *Paed Perinatal Drug Ther* 2003;5:149.
 - Pandolfini C, Impicciatore P, Provasi D, Rocchi F, Campi R, Bonati M, Italian Paediatric Off-label Collaborative Group. The off-label use of drugs in Italy: a prospective, observational, multicentre study. *Acta Paediatrica* 91:339-347;2002

- Ricci E, Parazzini F, Motta T, Ferrari CI, Colao A, Clavenna A, Rocchi F, Gangi E, Paracchi S, Gasperi M, Lavezzari M, Nicolosi AE, Ferrero S, Landi ML, Beck-Peccoz P, Bonati M. Pregnancy outcome after cabergoline treatment in early weeks of gestation. *Reprod Toxicol* 16:791-3;2002.

- Bonati M, Rocchi F, Pirola M. Electrocardiography first for reducing cot death. *Lancet* 357:889; 2001.

- Rocchi F, Raffaelli MP, Marelli G, Taddei GC, Bonati M. Prospective surveillance of extemporaneous dispensing of medicines for children. *Pediatr Perinatal Drug Ther* 4(4):152-155; 2001.

- Bonati M, Rocchi F, Pirola M. Electrocardiography first for reducing cot death. (Author's replay). *Lancet* 358:673; 2001.

- Conroy S., Choonara I., Mohn A., Impicciatore P., Arnell H., Rane A., Knoepfel C., Seyberth H., Pandolfini C., Raffaelli M.P., Rocchi F., Bonati M., Jong G., de Hoog M., Anker J. Survey of unlicensed and off label drug use in paediatric wards in European countries. *BMJ* 320:79-82; 2000

BOOKS AND CHAPTERS

- Carlo Giaquinto and Francesca Rocchi. Registration of Vaccines, Safety Follow-Up, and Pediatric Investigation Plan. In *Pediatric Vaccines and Vaccinations. A European Textbook*. pp251-258. Editor Timo Vesikari and Pierre Van Damme

- Rocchi F (co-autore): Guida all'uso dei farmaci; sulla base del British National Formulary. Elsevier Masson srl, Milano 2007.

- Gruppo di lavoro OsMed: L'uso dei farmaci in Italia. Rapporto nazionale anno 2006. Pensiero Scientifico Ed. Roma 2007.

- Gruppo di lavoro OsMed: L'uso dei farmaci in Italia. Rapporto nazionale anno 2005. Pensiero Scientifico Ed. Roma 2006.

- Rocchi F (membro del comitato editoriale): Prontuario Farmaceutico Nazionale 2005. Agenzia Italiana del farmaco. Istituto Poligrafico e Zecca dello Stato. Roma 2005.

- Rocchi F (membro del comitato editoriale): Farmaci e Gravidanza. Agenzia Italiana del Farmaco. Pensiero Scientifico ed. Roma 2004.

- Gruppo di lavoro OsMed: L'uso dei farmaci in Italia. Rapporto nazionale anno 2004. Pensiero Scientifico Ed. Roma 2005.

- Rocchi F (co-autore): Guida all'uso dei farmaci per i bambini. Istituto Poligrafico e Zecca dello Stato, Roma 2003.

- Traversa G, Magrini N, Addis A e gruppo di lavoro OsMed. Il consumo e la spesa farmaceutica: una valutazione comparata tra regioni. In: I servizi sanitari in Italia 2003. Fiorenti G. Il Mulino, Bologna 2003.

- Gruppo di lavoro OsMed: L'uso dei farmaci in Italia. Rapporto nazionale anno 2003. Pensiero Scientifico Ed. Roma 2004.

- Gruppo di lavoro OsMed: L'uso dei farmaci in Italia. Rapporto nazionale anno 2002. Pensiero Scientifico Ed. Roma 2003

Projects - Early treated Perinatally HIV Infected individuals: Improving Children's Actual Life (EPICAL 2020-2024).

- conect4children (COllaborative Network for European Clinical Trials For Children) - c4c - IMI2-2016-10-04 Creation of a pan-European Paediatric Clinical Trials Network (Innovative Medicines Initiative 2 (Grant agreement N.777389). Training and Education Work Package Leader

- Pharmaledger - Blockchain Enabled Healthcare (Innovative Medicines Initiative 2 (Grant agreement N. 853992)

- PROMISE Preparing for RSV Immunisation and Surveillance in Europe (Innovative Medicines Initiative 2 Joint Undertaking under grant agreement 101034339)

Memberships Member of PENTA-ID Network

Other Relevant Information Member of the Ethic Advisory Board of VERDI project 101045989) (<https://verdiproject.org>)