

PERSONAL INFORMATION **Francesca Rocchi**

WORK EXPERIENCE

February 2017–Present

Senior reasearch and regulator affairs manager

Bambino Gesù Children Hospital -University Department of Paediatrics (Italy)

Scientific secretary of INCiPiT -Italian Network for Paediatric Clinical Trials

October 2014–September 2016

Senior Regulatory Affairs Manager

PENTA Foundation Onlus (Italy)

Activities within the EU-funded project GRIP (Global Research in Paediatrics – Network of Excellence) in the following workpackages (WP):

- WP1 (Joint paediatric clinical pharmacology international educational program Master of Science): development of Master of Science Programme in “Paediatric Medicines Development and Evaluation”;
- WP3 - Research tools to facilitate interoperability in paediatric research;
- WP4 - New methods for clinical studies in paediatrics;
- WP7 - Work Package 7 - Dissemination and Networking;

October 2012–September 2014

Clinical assessor

Agenzia Italiana del Farmaco AIFA (Italy)

Clinical Assessor at European Assessment Unit

Italian Delegate Alternate at Paediatric Committee, European Medicine Agency (EMA) since 2007

Clinical assessor for Paediatric Investigational Plans

Product Team Leader and 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, participation in Communication Campaign on medicine for Children)

Research activity in European Project funded by European FPVII funds (GRIP)

October 2011–October 2012

Regulatory Affair Manager

Bambino Gesù Paediatric Hospital (Italy)

- Pharmaologist at Clinical Trial Center
- 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 activity in European Project funded by European FPVII funds (GRIP and Neomero)
- Training activity

May 2005–October 2011

Clinical assessor

Agezia Italiana del Farmaco - AIFA (Italy)

- Pharmacist and Clinical Assessor at European Assessment Unit

- 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 utilization analysis (Osservatorio Nazionale sull'Uso dei Medicinali)

- Drug prescribing information activities, pharmaceutical expenditure and drug utilization monitoring (national and regional level)

- Analysis of rational drugs prescribing

- National Formulary periodic review

April 2003–April 2005

Clinical Assessor

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

- Pharmacist at Information and Communication Unit
- Medical writing activity (ISDB Bulletin, newsletter, contents for website)
- Activity of copyediting and editing
- Drug information activity for health professionals and public
- Drug prescriptions and drug utilization analysis (Osservatorio Nazionale sull'Uso dei Medicinali)
- Drug prescribing information activities, pharmaceutical expenditure and drug utilization monitoring (national and regional level)
- Analysis of rational drugs prescribing
- National Formulary periodic review
- Scientific secretariat for Italian Drug Reimbursement Committee

October 2002–March 2003

Research fellow

Servizio Farmaceutico Territoriale ULSS 20 (Italy)

- Fellowship Centro Regionale del Farmaco
- Medical writing activity (ISDB Bulletin, newsletter, contents for website)
- Drug information activity for health professionals and public
- Drug prescriptions analysis in sub-population (paediatric and childbearing women)
- Phase IV pharmacological research activity (with General Practitioners)

October 1998–October 2002

Research Fellow

Mario Negri Pharmacological Research Institute (Italy)

- Fellowship (pharmacist) at Regional Drug Information Center - Laboratory for Mother and Child Health
- Drug information for health professionals and public in relation to drugs to be used in pediatric population and childbearing women
- Drug prescriptions analysis in sub-population (pediatrics and childbearing women)
- Research activities in clinical pharmacology
- Research activities in pharmaco-epidemiology
- Data entry and data management

EDUCATION AND TRAINING

September 2004–November 2005

Second Level University Degree Master

Centro Interuniversitario

Evidence based medicine
Methodology in pharmacological research
Systematic review
Public health

September 2001–July 2004

Specialist in Hospital and Clinical Pharmacy

Faculty of Pharmacy, University of Modena and Reggio Emilia (Italy)

Specialist in Hospital Pharmacy
Hospital pharmacy
clinical pharmacy

November 1998–June 2001

Pharmacological Research Specialists

Mario Negri Pharmacological Research Institute (Italy)

Pharmacology
Pharmacoepidemiology
Epidemiology
Drug information

November 1991–June 1997

Degree in Pharmaceutical Chemistry and Tecnology

Faculty of Pharmacy, Ubiversità degli studi di Bologna (Italy)

 Chemical pharmacy
 Pharmacology
 Toxicology

ADDITIONAL INFORMATION

Expertise

Paediatric medicine development
 Clinical trials
 Methodology in clinical research
 Regulatory

Publications

Penazzato M, Gnanashanmugam D, Rojo P, Lallemand M, Lewis LL, Rocchi F, Saint Raymond A, Ford N, Hazra R, Giaquinto C, Belew Y1, 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

Chiurchiù S, Calò 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*. 2013. 26:15-26. Review.

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.
Peadiatr 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., Knoeppel 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

Publications(Chapters and Books):

Pediatric Vaccines and Vaccinations - A European Textbook. Editors Timo Vesikari and Pierre Van Damme. Rocchi F (Co-autor) in New Vaccines in Pipeline Development. Registration of Vaccines, Safety Follow-up and Pediatric Investigation Plan. Springer International Publishing AG 2017.

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

Global Research in Paediatrics – Network of Excellence (GRiP)

Involvement in WP1 (training and education). Scientific tutor of the International Master Programme in "Paediatric Medicines Development and Evaluation" led by the University of Rome Tor Vergata (Italy)

RESCEU - Respiratory Syncytial Virus Consortium in Europe

Funded by Innovative Medicines Initiative 2 (Grant agreement N.116019)

connect4children (COLlaborative Network for European Clinical Trials For Children) c4c - (Grant agreement N.777389) IMI2-2016-10-04 Creation of a pan-European Paediatric Clinical Trials Network. Scientific Administrator of the Italian National Hub

Memberships

PENTA-ID Network

PEDIANET

Other Relevant Information