



Curriculum Vitae

Personal information **Francesca Rocchi**

Work experience

1. Employer: Bambino Gesù Paediatric Hospital (OPBG)
 - Start date: 022017
 - End date:
 - Position: Head of Regulatory Affairs Service
 - Activities: Regulatory Affairs Service within the "Clinical Studies Center for the paediatric medicine" - Scientific Department. 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 PDCO Member Representing Healthcare Professionals (since 2017)
 - Country: Italy
2. Employer: Fondazione PENTA ONLUS
 - Start date: 102014
 - End date: 022017
 - Position: Senior Regulatory Affairs Manager (on secondment)
 - Activities:
 - 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"
 - Country: Italy
3. Employer: Agenzia Italiana del Farmaco _ European Assessment Unit
 - Start date: 102012
 - End date: 102014
 - Position: Clinical Assessor
 - Activities:
 - 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)
 - Country: Italy
4. Employer: Bambino Gesù Paediatric Hospital _ Clinical Trials Centre
 - Start date: 102011
 - End date: 102012
 - Position: Regulatory affairs manager (on secondment)
 - Activities:
 - 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
 - Country: Italy
5. Employer: Agenzia Italiana del Farmaco (AIFA)
 - Start date: 052005
 - End date: 102011
 - Position: Clinical Assessor
 - Activities:
 - 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
 - Country: Italy
6. Employer: Ministry of Health, General Directorate of Drugs, Pharmaceuticals and Medical Devices
 - Start date: 042003
 - End date: 042005
 - Position: Regulatory affairs manager
 - Activities:
 - 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
 - Country: Italy
7. Employer: Servizio Farmaceutico Territoriale ULSS 20
- Start date: 2002
 - End date: 2003
 - Position: Research fellow
 - Activities:
 - 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)
 - Country: Italy
8. Employer: Istituto di Ricerche Farmacologiche "Mario Negri" _ Laboratory for Mother and Child Health
- Start date: 1998
 - End date: 2002
 - Position: Research fellow
 - Activities:
 - 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
 - Country: Italy

Education and training

1. Subject: PENTA in collaboration with European Society for Paediatric Infectious Diseases
 - Start date: 062016
 - End date: 092016
 - Qualification: Diploma Tr@inforPed HIV 2016
 - Organisation:
 - Country:
2. Subject: Centro Interuniversitario "Thomas C Chalmers" Università degli Studi di Modena e Reggio Emilia
 - Start date: 092004
 - End date: 112005
 - Qualification: Second level University Master Degree
 - Organisation:
 - Country: Italy
3. Subject: Faculty of Pharmacy, Università degli Studi di Modena e Reggio Emilia
 - Start date: 2001
 - End date: 2004
 - Qualification: Specialist in Hospital Pharmacy
 - Organisation:
 - Country: Italy
4. Subject: Institute for Pharmacological Research Mario Negri
 - Start date: 1998
 - End date: 2001
 - Qualification: (Specialist in Pharmacology Research degree) PhD equivalent
 - Organisation:
 - Country: Italy
5. Subject: Faculty of Pharmacy Università degli Studi di Bologna
 - Start date: 1991
 - End date: 1997
 - Qualification: Degree Magna cum Laude in Pharmaceutical Chemistry and Technology
 - Organisation:
 - Country: Italy
6. Subject: Liceo Scientifico Luigi Valeriani
 - Start date: 1987
 - End date: 1991
 - Qualification: Diploma Liceo Scientifico (Scientific high school)
 - Organisation:
 - Country: Italy

Additional information

Publications

- Landi A, D'Ambrosio F, Faggion S, **Rocchi F**, Paganin C, Lain MG, Ceci A, Giannuzzi V; EPIICAL Consortium. Sharing Data and Transferring Samples Within Pediatric Clinical Studies: How to overcome challenges and Make them a science opportunity. *Healthcare*. 2024 Dec 6;12(23):2473
- Chesshyre ELD, Bradbury JD, Cook H, **Rocchi F**, Roes K, Turner MA, Brüggemann R, Warris A. The impact of COVID-19 pandemic and the changing landscape of CF in the cASPerCF trial: a real-world experience. *Trials*. 2024 Oct 2;25(1):645
- Pinon M, Giugliano L, **Rocchi F**, Cananzi M, Auriti C, Wade B, Calvo PL, Giaquinto C, Indolfi G. Inadequate Hospital Practices to Prevent Mother-to-Child Transmission of hepatitis B Virus Infection: A European Survey. *J Pediatr Gastroenterol Nutr*. 2023 Jun 1;76(6):716-722.
- 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
- 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.* 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. *Paediatr 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

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 (EPIICAL 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 _ Pharmedger _ 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)_ VERDI - SARS-CoV2 variants Evaluation in pRegnancy and paediatrics cohorts (101045989 funded by the European Union).

Memberships

Member of PENTA_ID Network
 President of INCIPIIT (Italian Network for Paediatric Clinical Trials) since January 2024

Other Relevant Information

President of INCIPIIT (Italian Network for Paediatric Clinical Trials) _ the Italian National Hub in c4c Network Clinical project management of EU funded projects From 31 January 2024 to 30 September 2025
 Member of the Ethic Advisory Board of VERDI project 101045989) (<https://verdiproject.org>)