

BUONA PRATICA CLINICA: LE REGOLE PER UNA RICERCA CLINICA DI QUALITÀ IN PEDIATRIA

Roma, lunedì 5 e martedì 6 ottobre 2026 – Aula Salviati 1 e 2

Razionale: La ricerca clinica è essenziale per un IRCCS. Le norme di Good Clinical Practice (GCP), alla base di ogni attività legata alla gestione degli studi clinici, sono in continua revisione per far sì che le responsabilità dei diversi attori coinvolti in uno studio clinico siano sempre più aderenti alle esigenze normative e operative, al fine di garantire una raccolta dati di alta qualità mantenendo standard di assoluta tutela della sicurezza. Questa giornata si propone come aggiornamento sulle GCP per fornire la certificazione necessaria ai ricercatori, da rinnovare ogni 2 anni.

Obiettivo Formativo: accreditamento strutture sanitarie e dei professionisti. La cultura della qualità, procedure e certificazioni, con acquisizione di nozioni di processo **(14)**

Figure Professionali: Tutte

Crediti: 6,3

Responsabili Scientifici:

Marina Vivarelli – *Ospedale Pediatrico Bambino Gesù*

Giuseppe Pontrelli – *Ospedale Pediatrico Bambino Gesù*

Relatori e Moderatori:

Sara Abbate – *Ospedale Pediatrico Bambino Gesù*

Isabella Biondi – *Ospedale Pediatrico Bambino Gesù*

Marta Ciofi Degli Atti – *Ospedale Pediatrico Bambino Gesù*

Giorgia Copponi – *Ospedale Pediatrico Bambino Gesù*

Tiziana Corsetti – *Ospedale Pediatrico Bambino Gesù*

Lucia Di Maggio – *Ospedale Pediatrico Bambino Gesù*

Cinzia Filice – *Ospedale Pediatrico Bambino Gesù*

Chiara Mennini – *Ospedale Pediatrico Bambino Gesù*

Francesca Molinari – *Ospedale Pediatrico Bambino Gesù*

Alessandro Nanni Costa – *Ospedale Pediatrico Bambino Gesù*

Carla Paganin – *Ospedale Pediatrico Bambino Gesù*

Giuseppe Pontrelli – *Ospedale Pediatrico Bambino Gesù*

Francesca Rocchi – *Ospedale Pediatrico Bambino Gesù*

Federica Sforza – *Ospedale Pediatrico Bambino Gesù*

Alessandra Simonetti – *Ospedale Pediatrico Bambino Gesù*

Marina Vivarelli – *Ospedale Pediatrico Bambino Gesù*

Don Luigi Zucaro – *Ospedale Pediatrico Bambino Gesù*

PROGRAMMA SCIENTIFICO

Lunedì 5 ottobre (ore 13.30 – 18.00)

13:30 – 14:00 Registrazione partecipanti

14:00 – 14:15 Saluti di apertura – *M. Raponi, A. Onetti Muda, A. Nanni Costa*

14:15 – 14:30 Benvenuto e scopo del corso – *P. Rossi*

Moderatori: *C. Mennini, Don L. Zucaro*

14:30 – 15:00 **Introduzione alle ICH-GCP nella ricerca clinica in pediatria e Autorizzazione etico-regolatoria degli studi clinici, aggiornamento R3** – *F. Rocchi*

15:00 – 15:20 **I comitati etici** – *A. Nanni Costa*

15:20 – 15:40 **Lo studio clinico dall'inizio alla fine** – *S. Abbate*

15:40 – 16:00 pausa

16:00 – 16:20 **Il percorso interno di Start Up** – *L. Di Maggio*

16:20 – 17:00 **Il ruolo degli Sperimentatori** – *M. Vivarelli*

17:00 – 17:30 **Il processo del consenso informato e assenso** – *A. Simonetti*

17:30 – 18:00 Discussione finale e chiusura prima giornata

Martedì 6 ottobre (ore 14.00 – 18.00)

Moderatori: *C. Paganin, M.L. Ciofi Degli Atti*

14:00 – 14:30 **Documenti essenziali e ALCOA+** - *G. Copponi*

14:30 – 15:00 **Campioni e risultati di laboratorio** – *F. Molinari*

15:00 – 15:20 **Safety reporting** – *G. Pontrelli*

15:20 – 15:40 **Monitoraggio** – *I. Biondi*

15:40 – 16:00 Pausa

16:00 – 16:20 **Audit e ispezioni** – *F. Sforza*

16:20 – 16:40 **Gestione del farmaco e farmacovigilanza** – *T. Corsetti*

16:40 – 17:00 **I flussi in OPBG** – *C. Filice, M. Vivarelli*

17:00 – 17:30 Discussione e Conclusioni

17:30 – 18:00 Test di valutazione finale e chiusura corso

**FORMATO EUROPEO
PER IL CURRICULUM
VITAE**



INFORMAZIONI PERSONALI

Nome*

VIVARELLI MARINA

Indirizzo

VIA DELLA PENITENZA 10 - 00165 ROMA

Telefono*

3294128353

Fax

E-mail*

marina.vivarelli@opbg.net

Nazionalità

Italiana / statunitense

Data di nascita

18 DICEMBRE 1972

ESPERIENZA LAVORATIVA*

Da Novembre 2023

Nome e indirizzo del datore di lavoro

RESPONSABILE U.O.C. CLINICAL TRIAL CENTER

Tipo di azienda o settore

Ospedale Pediatrico Bambino Gesù, Piazza Sant'Onofrio n° 4, 00165, Roma

Tipo di impiego

Sanità

Principali mansioni e responsabilità

Medico Chirurgo

Dirigente Medico di II livello

ISTRUZIONE E FORMAZIONE*

1992 - 1998

Nome e tipo di istituto di istruzione o
formazione

Laurea in Medicina e Chirurgia

Università degli Studi di Pavia

Qualifica conseguita

Medico Chirurgo

1999 - 2004

Nome e tipo di istituto di istruzione o
formazione

Specializzazione in Pediatria

Università degli Studi di Pavia e Università degli Studi di Roma La Sapienza

Conoscenza lingue

Italiano - Inglese - Francese

ALTRE POSIZIONI

2026: Co-Chair, KDIGO Controversies meeting on Complement in Kidney Disease

2025-date: Member, Consiglio Superiore di Sanità – Italian Ministry of Health

2025-date: Member, National Pediatric Ethics Committee – AIFA (Comitato Etico Nazionale Pediatrico – Agenzia Italiana del Farmaco)

2025: Co-Chair, KDIGO Controversy on Therapies targeting B cells in Immune-mediated kidney diseases, group on Podocytopathies

2025-date: Chair, Scientific Committee for International Pediatric Nephrology Association Meeting 2027

2024-date: Editorial Board Member, Journal American Society of Nephrology

2024-date: Co-Chair, Thrombotic Microangiopathies Working Group and Member, Executive Committee, European Rare diseases Kidney NETWORK (ERKNET)

2023-date: Council member, Italian Society of Pediatric Nephrology (SINePe)

2023-date: Member Scientific Advisory Board, European Renal Association (ERA)

2022-date: Member, Expert Group Task Force on Clinical Studies for the development of pediatric treatments and vaccines, Bambino Gesù Pediatric Hospital and Research

Center, Rome, Italy

2022: Co-Chair, KDIGO Controversies meeting on Complement in Kidney Disease

2021-date: Member, European Rare Kidney disease registry (ERKReg) Executive Board

2021-date: Associate Editor, Frontiers in Pediatrics – Pediatric Nephrology

2021-date: Chair, Scientific Committee European Society of Pediatric Nephrology meeting 2022

2020-date: Editorial Board Member, Kidney International

2020-2022: Chair, Immune-mediated glomerulopathies Working Group

2019-date: Editorial Board member, Pediatric Nephrology

2018-date: Core Group Member, KDIGO Committee on guidelines for Glomerulonephritis

2017-2020: Council member, European Society of Pediatric Nephrology (ESPN)

2016-2022: Chair, Glomerular Disease Working Group, European Society of Pediatric Nephrology

MEMBERSHIPS

International Pediatric Nephrology Association

European Society Pediatric Nephrology

American Society of Nephrology

International Society of Nephrology

Italian Society of Pediatric Nephrology (SINePe)

Italian Society of Pediatrics (SIP)

SELECTED PUBLICATIONS

Benigni A, Daina E, Löffler-Wirth H, Piras R, Rigoldi M, Schmidt M, Carrara C, Donadelli R, Imanifard Z, Mele C, Alberti M, Marasà M, Martinatto C, Bresin E, Gamba S, Quadri L, Nanchen G, **Vivarelli M**, Emma F, La Manna G, Vidal E, Pasini A, Raghino A, Donati G, Verrina E, Angeletti A, Brunori G, Giordano M, Alberici F, Maggiore U, Malgieri G, Remuzzi G, Breno M, Noris M; Italian Registry of MPGN. Hierarchical clustering uncovered disease patterns and further untangled complexities in immune complex-mediated idiopathic MPGN and C3 glomerulopathy. *Kidney Int.* 2026 Jan;109(1):178-195

Colucci M, Riganati M, Zotta F, Gargiulo A, Massella L, Ruggiero B, Cotugno N, Ricci G, Palma P, Emma F, **Vivarelli M**. Prolonged impairment of immunological memory after anti-CD20 treatment in pediatric idiopathic nephrotic syndrome: an extended follow-up. *Front Immunol.* 2025 Dec 18;16:1736921

Nanchen G, Marasà M, Breno M, Martinatto C, Rigoldi M, Noris M, Bresin E, Gamba S, Bottanelli L, Imanifard Z, Piras R, Donadelli R, Trillini M, Emma F, **Vivarelli M**, Antonucci L, Carrara C, Ruggenenti P, La Manna G, Comai G, Vidal E, Silecchia V, Pasini A, Raghino A, Cingolani A, Donati G, Giovanella S, Biancone L, Valenza L, Verrina E, Angeletti A, Brunori G, Sottini L, Giordano M, Torres DD, Alberici F, Mescia F, Maggiore U, Gentile M, Benigni A, Remuzzi G, Daina E; Italian Registry of MPGN. Natural History and Clinical Associations with Long-Term Outcomes in Primary C3 Glomerulopathy and Immune Complex-Mediated Membranoproliferative GN. *Clin J Am Soc Nephrol.* 2025 Dec 23

Fakhouri F, Bomback AS, Ariceta G, Delmas Y, Dixon BP, Gale DP, Greenbaum LA, Han SH, Isabel N, Le Quintrec M, Licht C, Mastrangelo A, Mizuno M, Neves de Holanda MI, Pickering MC, Remuzzi G, Van De Kar N, **Vivarelli M**, Walker PD, Wallace D, Zecher D, Francois C, Deschatelets P, Li L, Wang Z, Abad-Franch L, Kinnman N, López-Lázaro L, Szamosi J, Nester CM; VALIANT Trial Investigators Group. Trial of Pegcetacoplan in C3 Glomerulopathy and Immune-Complex MPGN. *N Engl J Med.* 2025 Dec 4;393(22):2210-2220

Kavanagh D, Bomback AS, **Vivarelli M**, Nester CM, Remuzzi G, Zhao MH, Wong EKS, Wang Y, Krishnan I, Schuhmann I, Trapani AJ, Webb NJA, Meier M, Israni RK, Smith RJH; APPEAR-C3G investigators. Oral iptacopan therapy in patients with C3 glomerulopathy: a randomised, double-blind, parallel group, multicentre, placebo-controlled, phase 3 study. *Lancet.* 2025 Oct 11;406(10512):1587-1598

Riganati M, Conversano E, Zotta F, Gargiulo A, Antonucci L, Giannini C, Ricci G, Diomedi-Camassei F, Debiec H, Ronco P, Emma F, **Vivarelli M**, Colucci M. Comparison of B lymphocyte profile between membranous nephropathy and idiopathic nephrotic syndrome pediatric patients. *Pediatr Nephrol.* 2025 Aug;40(8):2551-2559

Kidney Disease: Improving Global Outcomes (KDIGO) Nephrotic Syndrome In Children Work Group; Floege J, Gibson KL, **Vivarelli M**, Liew A, Radhakrishnan J, Rovin BH. KDIGO 2025 Clinical Practice Guideline for the Management of Nephrotic Syndrome in Children. *Kidney Int.* 2025 May;107(5S):S241-S289

Floege J, Gibson KL, **Vivarelli M**, Liew A, Radhakrishnan J, Balk EM, Gordon CE, Adam G, Tonelli M, Earley A, Rovin BH. Executive summary of the KDIGO 2025 Clinical Practice Guideline for the Management of Nephrotic Syndrome in Children. *Kidney Int.* 2025 May;107(5):806-808

Vujović A, Sellier-Leclerc AL, Mancuso MC, Boyer O, Awan A, Gargiulo A, Loos S, Fila M, Jankauskiene A, Ariceta G, Kanzelmeyer N, Vidal E, Van Dyck M, Levart TK, Šimánková N, Decramer S, Hofstetter J, **Vivarelli M**, Sciascia S, van de Kar NCAJ, Schaefer F; ERKNet TMA Working Group. Real-world use of complement inhibitors for haemolytic uraemic syndrome: an analysis of the European Rare Kidney Disease Registry cohort. *EClinicalMedicine.* 2025 Mar 27;82:103159

Riganati M, Conversano E, Zotta F, Gargiulo A, Antonucci L, Giannini C, Ricci G, Diomedi-Camassei F, Debiec H, Ronco P, Emma F, **Vivarelli M**, Colucci M. Comparison of B lymphocyte profile between membranous nephropathy and idiopathic nephrotic syndrome pediatric patients. *Pediatr Nephrol.* 2025 Aug;40(8):2551-2559

Cappoli A, Kersnik-Levart T, Silecchia V, Ariceta G, Gjerstad AC, Ghiggeri G, Haffner D, Kanzelmeyer N, Levtchenko E, Pasini A, Waters A, Aguilera JCL, Peruzzi L, Noris M, Bresin E, Gargiulo A, Emma F, **Vivarelli M**. C3 glomerulopathy in children: a European longitudinal study evaluating outcome. *Pediatr Nephrol.* 2025 Apr;40(4):979-986

Hari P, Khandelwal P, Boyer O, Bhimma R, Cano F, Christian M, Duzova A, Iijima K, Kang HG, Qian S, Safouh H, Samuels S, Smoyer WE, **Vivarelli M**, Bagga A, Schaefer F; IPNA Best Practices and Standards Committee and c4c Pediatric Nephrology Expert Working Group. IPNA consensus definitions for clinical trial outcomes in steroid-resistant nephrotic syndrome. *Pediatr Nephrol.* 2025 Mar;40(3):865-872

Vivarelli M, Samuel S, Coppo R, Barratt J, Bonilla-Felix M, Haffner D, Gibson K, Haas M, Abdel-Hafez MA, Adragna M, Brogan P, Kim S, Liu I, Liu ZH, Mantan M, Shima Y, Shimuzu M, Shen Q, Trimarchi H, Hahn D, Hodson E, Pfister K, Alladin A, Boyer O, Nakanishi K; International Pediatric Nephrology Association. IPNA clinical practice recommendations for the diagnosis and management of children with IgA nephropathy and IgA vasculitis nephritis. *Pediatr Nephrol.* 2025 Feb;40(2):533-569

Roma, data 17 GIU 2026

FIRMA



Autorizzo il trattamento dei dati personali ai sensi dell'art. 13 GDPR (UE 2016/679)

Roma, data 17 GIU 2026

FIRMA



PERSONAL INFORMATION

Francesca Rocchi

Head of Regulatory Affairs Service

*Clinical Studies Center for paediatric medicine
Scientific Department*

**Paediatric Committee (PDCO) Member at European Medicine Agency (EMA)
Representing Healthcare Professional (nomination by European Commission)****IRCCS Bambino Gesù Children Hospital (OPBG)**

Clinical Studies Area for the development and implementation of medicines, vaccines, and medical devices for paediatric use

Pza Sant Onofrio 4, 00152 Rome (Italy)

<http://www.ospedalebambinogesu.it/home>

POSITION

1 FEB 2017 - PRESENT

- Strategic Advisor on regulatory issues in OPBG clinical research projects and clinical studies within the activities of Clinical Studies Center for paediatric medicine
- Responsible for the preparation and review of ethical/regulatory documentation for obtaining specific approvals to conduct and maintain no-for-profit clinical studies conducted in OPBG in the framework of Clinical Studies Center for paediatric medicine
- Coordinator of the Clinical Trial Quality Team, (CTQT) providing support, before, during and after a Clinical Trial is running, to Principal Investigator for their No-Profit Paediatric Clinical Studies on drugs, vaccines, medical devices.
- Regulatory Senior Manager of the CTQT
- As PDCO Member: Assessment of Paediatric Investigational Plans (Therapeutic area: infectious diseases and immunology) and all activities related to the Committee.

WORK EXPERIENCE

1 Feb 2024 – 30 Sep 2025

President Italian Network for Paediatric Clinical Trials (INCIPIT)

Italian Network for Paediatric Clinical Trials (INCIPIT)

Passeggiata del Gianicolo snc – Edificio Villino “SION”, 00165, Rome Italy

<https://www.incipit-pediatric.net/>

- Legal and institutional representative of the Consortium.
- Chair of the General Assembly and the Board of Director
- Activities: defining and overseeing strategic objectives and operational implementation; coordinating the organization, conduct, and oversight of INCIPIT studies; ensuring quality standards, harmonization of procedures, and efficient collaboration across participating centers; promoting national and international partnerships, including participation in European research programs and networks.
- Representative of INCIPIT consortium in c4cS

1 Oct 2014–1 Feb 2017

Senior Regulatory Affairs Manager (on secondment)

Fondazione PENTA ONLUS

Istituto di Ricerca Pediatrica Corso Stati Uniti 4, 35127 Padova (Italy)

<https://penta-id.org>

- Strategic Advisor on regulatory issues in PENTA clinical research projects
- 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”
- Italian Delegate Alternate at Paediatric Committee European Medicine Agency (since 2007).

17/10/2012 to 01/10/2014

Clinical AssessorEuropean Assessment Unit - Agenzia Italiana del Farmaco, AIFA via del Tritone 181, Rome - Italy www.agenziafarmaco.it

- Italian Delegate Alternate at Paediatric Committee, European Medicine Agency (EMA) from January 2007 till July 2016
- Clinical assessor 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, participation in Communication Campaign on medicine for Children)
- AIFA contact point for the Agreement with IRCCS Bambino Gesù Children Hospital
- Research activity in European Project funded by European FPVII funds (GRIP)

15/10/2011 o 16/10/2012

Regulatory Affair ManagerAcademic Department of Paediatric - IRCCS Bambino Gesù Children Hospital (Agreement with AIFA for a position on secondment) – pza S.Onofrio 4 Rome Italy <http://www.ospedalebambinogesu.it>

- 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

01/05/2005 to 14/10/2011

Clinical AssessorAgenzia Italiana del Farmaco, AIFA – via del Tritone 181, Rome Italy www.agenziafarmaco.it

- 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

01/04/2003 to 30/04/2005

Pharmacist at Information and Communication Unit

Ministry of Health, General Directorate of Drugs, Pharmaceuticals and Medical Devices,
Rome Italy www.ministerosalute.it

- 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

EDUCATION AND TRAINING

16/01/2016 to 01/09/2016

Diploma Tr@inforPed HIV 2016 (part of the Oxford Paediatric Infectious Diseases Diploma)

PENTA Foundation Onlus in collaboration with the European Society for Paediatric Infectious Diseases

01/09/2004 to 01/11/2005

Second level University Master Degree in "Metodologia della Ricerca e Evidence Based Medicine"

Centro Interuniversitario "Thomas C Chalmers" Università degli Studi di Modena e Reggio Emilia, Italy
Evidence based medicine, methodology in pharmacological research, systematic review, public health

03/09/2001 to 19/07/2004

Specialist in Hospital Pharmacy

Faculty of Pharmacy, Università degli Studi di Modena e Reggio Emilia, Italy
Hospital pharmacy, clinical pharmacy

01/11/1998 to 22/06/2001

(Specialist in Pharmacology Research degree) PhD equivalent

Institute for Pharmacological Research Mario Negri Milano, Italy

- Pharmacology, pharmacoepidemiology, epidemiology, drug information

04/11/1991 to 17/06/1997

Degree in Pharmaceutical Chemistry and Technology, Faculty of Pharmacy

Faculty of Pharmacy, Università degli Studi di Bologna Italy

- Chemical pharmacy, pharmacology, toxicology (110/110 cum laude)

01/09/1987 to 30/06/1991

Secondary Degree

Liceo Scientifico "Luigi Valeriani" Imola (BO) Italy



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Date: 5 Nov 2025

Francesca Rocchi



NOME COGNOME	Professione	Disciplina	ENTE DI APPARTENENZA / LIBERA PROFESSIONE
Francesca Rocchi	Farmacista	Farmacista pubblico del SSN	Ospedale Pediatrico Bambino Gesù - Roma
Marina Vivarelli	Medico chirurgo	Nefrologia	Ospedale Pediatrico Bambino Gesù - Roma
Sara Abbate	Farmacista	Farmacista di altro settore	Ospedale Pediatrico Bambino Gesù - Roma
Isabella Biondi	Biologo	Biologo	Ospedale Pediatrico Bambino Gesù - Roma
Marta Ciofi Degli Atti	Medico chirurgo	Igiene, epidemiologia e sanità pubblica - Pediatria	Ospedale Pediatrico Bambino Gesù - Roma
Giorgia Copponi	Biologo	Biologo	Ospedale Pediatrico Bambino Gesù - Roma
Tiziana Corsetti	Farmacista	Farmacista pubblico del SSN	Ospedale Pediatrico Bambino Gesù - Roma
Lucia Di Maggio	Farmacista	Farmacista territoriale	Ospedale Pediatrico Bambino Gesù - Roma
Cinzia Filice	Biologo	Biologo	Ospedale Pediatrico Bambino Gesù - Roma
Chiara Mennini	Farmacista	Farmacista pubblico del SSN	Ospedale Pediatrico Bambino Gesù - Roma
Francesca Molinari	Infermiere	Infermiere	Ospedale Pediatrico Bambino Gesù - Roma
Alessandro Nanni Costa	Medico chirurgo	Chirurgia generale	Ospedale Pediatrico Bambino Gesù - Roma
Carla Paganin	Biologo	Biologo	Ospedale Pediatrico Bambino Gesù - Roma
Giuseppe Pontrelli	Medico Chirurgo	Igiene, epidemiologia e sanità pubblica, Pediatria	Ospedale Pediatrico Bambino Gesù - Roma
Federica Sforza	Psicologo	Psicologo	Ospedale Pediatrico Bambino Gesù - Roma
Alessandra Simonetti	Medico Chirurgo	Allergologia ed immunologia clinica, Pediatria	Ospedale Pediatrico Bambino Gesù - Roma
Luigi Zucaro	Medico chirurgo	Privo di specializzazione	Ospedale Pediatrico Bambino Gesù - Roma