

BIOGRAPHICAL SKETCH

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NAME: Nicolino Ruperto

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Prof. of Paediatrics at the University of Milan Bicocca, Director of the Paediatric Rheumatology Research Unit at Fondazione IRCCS San Gerardo dei Tintori in Monza, Italy, and Senior Scientist of the Paediatric Rheumatology International Trials Organisation (PRINTO)

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Pavia, Italy	Degree	1990	Medicine, magna cum laude
University of Pavia, Italy	Specialisation	1994	Pediatrics
Children's Hospital Medical Center, Cincinnati, OH, USA	Specialisation	1995-97	Pediatric Rheumatology
Harvard School of Public Health, Boston, MA, USA	MPH	1996-97	Public Health
Bocconi University School of Management (Scuola di Direzione Aziendale – SDA, Milan, Italy)	Exec. Master	2013-15	Mgmt of Health and Social Care Orgs.

A. Personal Statement

Prof. Ruperto has been involved in the pediatric rheumatology field since Medical Degree in 1990 under the supervision of Prof. Martini at the University of Pavia, Italy. He spent 2 years in Cincinnati, OH, USA under the supervision of Prof. Giannini learning clinical trials and consensus methodologies. While in the USA he took a "Master in Public Health" at the Harvard School of Public Health in Boston, MA and won the Senior Rheumatology Scholars Award in 1996. He is the founder with Prof. Martini (in 1996) of the Paediatric Rheumatology International Trials Organisation (PRINTO, www.fondazione-printo.it) where he currently holds the position of PRINTO Senior Scientist. He took active part in the management of the multi-national consensus efforts that lead to the development and prospective validation of the core set of response variables and preliminary definition of improvement for use in juvenile idiopathic arthritis (JIA), juvenile dermatomyositis (JDM), and juvenile systemic lupus erythematosus (JSLE) future clinical trials. He has been the PI and project manager for several PRINTO grants from the public and private bodies for 50 million Euros. Prof. Ruperto has published more than 430 peer reviewed papers.

B. Positions and Honors**Positions and Employment**

1990-1993: Paediatric Fellowship, Clinica Pediatrica, University of Pavia, Italy.

1994: Medical Assistant, San Giovanni Bianco, Bergamo, Italy
1995-June 1996: Paediatric Rheumatology Research Fellowship, Children's Hospital Medical Centre, Cincinnati, Ohio, USA under the supervision of Edward H. Giannini, MSc, DrPH
1996 today: Scientific Director of the Paediatric Rheumatology International Trials Organisation (PRINTO, www.fondazione-printo.it)
September 1996-2001: Medical Assistant at Department of Medical Informatics, IRCCS, Policlinico S. Matteo, University of Pavia, Italy.
2001-2018: Medical Assistant at the Medical Assistant at the Clinical Pediatrica e Reumatologia, PRINTO of the IRCCS G. Gaslini, Genova, Italy
2014- Patent 14709900.6 - 1952 of 28/2/2014 Autoinflammatory Disease Activity Index (AIDA)
2017-2024: Medical Director of the Phase I clinical trial unit of the IRCCS G. Gaslini
2018-2022: Medical Director UOSID "Centro Trial" IRCCS Istituto G. Gaslini, Genova
2023-2024-09: Director Gaslini Trial Centre IRCCS Istituto G. Gaslini, Genova
2024-10 Today: Full Professor of Paediatrics at the University of Milan Bicocca and Director of the Pediatric Rheumatology Unit of the IRCCS Fondazione San Gerardo Monza, Italy

Membership

European League Against Rheumatism (EULAR)
American College Rheumatology (ACR)
Pediatrics Rheumatology European Society (PRES)
Italian Pediatrics Rheumatology European Society (ReumaPed)

Honours and Awards

1994-1996: IRCCS Policlinico S. Matteo, Pavia, Italy, Research Scholarship at the Paediatric Clinic of the University.
1994-1995: IRCCS Policlinico S. Matteo, Pavia, Italy, Research Scholarship at Division of Rheumatology, Children's Hospital Medical Center, Cincinnati, Ohio, USA.
1995-1996: Children's Hospital Medical Centre, Cincinnati, Ohio, USA, Research Scholarship
1996: Senior Rheumatology Scholars Award at the 60th National Meeting of the American College of Rheumatology, Orlando, Florida, USA.
2002: Kourir award at the annual PRES meeting (Stockholm, Sweden)
2005: "2005 Gerolamo Gaslini Prizes for Excellence in Research" Gerolamo Gaslini Foundation
2008 Italian Society of Pediatrics (Società Italiana di Pediatria-SIP) prize for clinical research.
2008-2018: three times recognition as European League Against Rheumatism (EULAR) Centre of Excellence in Rheumatology 2008-2023
2013: professional qualification for the position of full professor in Pediatrics
2016: professional qualification as Scientific Director (IRCCS Burlo Garofalo, Trieste)
2020: professional qualification as Scientific Director (IRCCS Istituto G. Gaslini, Genova)
2021: Kourir award at the annual PRES meeting (Virtual meeting)
2022: Distinguished International Rheumatology Professional Award the American College of Rheumatology

Patents

2007. Uses and Compositions for Treatment of Juvenile Rheumatoid Arthritis. Brevetto USA 11/811,873
2013. Method for assessing activity of an autoinflammatory disease. Brevetto EU EP113305231.6

C. Contribution to Science

PRINTO brief overview

One of the main research activities of the group Paediatric Rheumatology International Trials Organisation (PRINTO, www.fondazione-printo.it or www.pediatric-rheumatology.printo.it), based in Monza (Italy) at the Fondazione IRCCS San Gerardo dei Tintori, is to find new treatments for rheumatic

diseases in children. A vast majority of the new drugs approved or marketed for juvenile idiopathic arthritis have been registered thanks to trials managed and directed by PRINTO.

PRINTO's history began in the early Nineties, when Prof Nicolino Ruperto went to Cincinnati Children's Hospital (US), where the coordinating centre of a similar research network for the United States (Pediatric Rheumatology Collaborative Study Group or PRCSG, www.prcsg.org), devoted to the study of new therapies for children with rheumatic diseases, is based.

After two years in Cincinnati and a Master's Degree in Public Health obtained at Harvard University, Prof Ruperto came back to Pavia (Italy) to work as a full time Physician at the IRCCS Policlinico San Matteo (now Fondazione San Matteo).

In order to perform controlled clinical trials in rare diseases, such as paediatric rheumatic diseases, it was essential to create a network of many specialised centres in various countries and, in this way, to be able to put together a fair amount of data within reasonable timelines. Therefore, in Pavia in 1996, Prof Ruperto and Professor Alberto Martini founded PRINTO, a scientific network as an informal association of researchers/clinicians, whose coordinating centre was in Pavia.

Prof. Martini and Prof. Ruperto moved in 2001 to Genoa, Italy, to the Istituto di Ricovero e Cura a Carattere Scientifico (IRCCS) G. Gaslini, where PRINTO was based until October 2024.

Beginning with paediatric rheumatology centres of 14 European countries, PRINTO has grown a lot, and it now includes almost all pediatric rheumatic diseases-specialised centres in the world (more than 90 countries) with the exception of North America that, as mentioned earlier, is coordinated by PRCSG. Since PRINTO's creation, PRINTO and PRCSG have worked in strong and very close cooperation.

PRINTO is an informal association made of no-profit clinical researchers, and it has the goal to foster, facilitate and coordinate the development, management and analysis of controlled clinical trials, to standardise the evaluation of treatment response and to analyse the quality of life and long-term outcome of children with paediatric rheumatic diseases.

Due to the introduction of the Best Pharmaceuticals for Children Act in the US, and of specific legislation for paediatric medicines development (Paediatric Regulation) in the European Union (EU), after 2000 PRINTO activities have grown dramatically. PRINTO was the only network who could assist the pharmaceutical companies in performing controlled clinical trials in children, as per the new FDA and EMA legislation. Any company intending to register a new drug for adult use, in fact, should also present data on its safety and efficacy also in children if an analogous paediatric disease exists.

Besides a great increase in amount of work and services provided, this new phase also required a remarkable ability in problem solving and prompt response.

The results obtained by PRINTO can be summarised as follows:

1. Extension of the network to 95 countries, with 700 academic centres and more than 2000 members;
2. More than 400 articles on international reviews and journals such as New England Journal of Medicine, Lancet, Journal of the American Medical Association, Arthritis and Rheumatism, Annals of the Rheumatic Diseases (for detailed list, see www.fondazione-printo.it);
3. Data collection from about **45,000 patients** from over 300 centres in 67 countries for no-profit studies and from **5,000** from about 250 centres in 39 countries for pharmaceutical companies clinical trials;
4. Funding received from its creation from public and private entities for a total of 50 million €;
5. Training provided to more than 250 physicians from 34 different countries.

As founder, Senior Scientist and project coordinator of the international activities for PRINTO, Prof Ruperto has taken care of the scientific and coordination management of all the network projects. The main research projects that PRINTO have managed can be briefly summarised as follows:

1. Standardisation of treatment response criteria for:
 - a. Juvenile idiopathic arthritis (American College of Rheumatology Paediatric 30 criteria, recognized by Food and Drug Administration and European Medicine Agency for all trials regarding biologic agents) ,
 - b. Juvenile systemic lupus erythematosus (American College of Rheumatology/Paediatric Rheumatology International Trials Organisation criteria),

- c. Juvenile Dermatomyositis (American College of Rheumatology/Paediatric Rheumatology International Trials Organisation/European League Against Rheumatism criteria),
2. No-profit trials in JIA (two clinical trials for methotrexate and a phase IV study for cyclosporine-A) and in juvenile dermatomyositis;
3. Creation of a dedicated website (www.fondazione-printo.it) and creation of a website for families (www.pediatric-rheumatology.printo.it) with information on paediatric rheumatic diseases (frequently answered questions), the list of specialised centres and the list of family associations. The family website is accessible in more than 50 languages and is visited daily by more than 10,000 people from more than 130 countries,
4. Cultural adaptation and validation of three questionnaires in more than 40 languages for the assessment of disability and of quality of life: Childhood Health Assessment Questionnaire (CHAQ), Child Health Questionnaire (CHQ) and Juvenile Arthritis Multidimensional Assessment Report (JAMAR) with more than 10,000 patient's collected,
5. PRINTO supports and cooperates in no-profit research for protocol drafting and writing, creation of Case Report Forms, data collection, data analysis and publications for:
 - a. Remission criteria for Juvenile Idiopathic Arthritis and juvenile dermatomyositis;
 - b. DNA sampling in families with at least 2 children affected by JIA;
 - c. New EULAR/PRINTO/Pediatric Rheumatology European Society (PRES) classification criteria for juvenile vasculitis;
 - d. Auto-inflammatory diseases registry (Eurofever project)
 - e. Pharmacovigilance registry in JIA (Pharmachild project)
 - f. Epidemiology and outcome of Childhood Arthritis (EPOCA project)
 - g. Anti-drug antibody formation in the treatment with biopharmaceuticals Registry (Abirisk project).
 - h. Registry to evaluate long-term adverse events in JIA patients treated with abatacept (abatacept Registry) or etanercept (etanercept Registry).
 - i. New classification criteria for Juvenile Idiopathic arthritis
6. PRINTO supports and cooperates in pharmaceutical companies' research for protocol drafting and writing, creation of Case Report Forms, data collection, data analysis and publications. A vast majority of the new drugs approved or marketed for juvenile idiopathic arthritis have been registered thanks to trials managed and directed by PRINTO. PRINTO has worked essentially with all companies interested in developing and testing biologic agents for pediatric rheumatic diseases.

The European Medicines Agency (EMA) "Report from the Commission to the European parliament and the council State of Paediatric Medicines in the EU - 10 years of the EU Paediatric Regulation (26/10/2017)" in section 4 states:

"The last 10 years have seen some considerable progress in the availability of medicines for children in certain therapeutic fields because of the Regulation. Rheumatology (i.e. PRINTO/PRCSG) or infectious diseases are often referred to as prime examples. The significant surge of new treatments for children with rheumatologic diseases following the completion of PIPs has transformed a sector, which was previously neglected." The reference rheumatology is PRINTO.

D. Additional Information: Research Support and/or Scholastic Performance

Publications' metrics

Over 430 manuscripts peer reviews on prestigious international journal: h-index January 2026 (Scopus 89; ISI Web of Science 74; google scholar 101), citations (Scopus 29837; ISI 20174; GS 43400). Impact factor >1500.

Selected top 20 manuscript 1997-2025 (first, second, last author)

1. Giannini EH, Ruperto N, et al. Preliminary definition of improvement in juvenile arthritis. *Arthritis Rheum* 1997; 40: 1202-1209.
2. Ruperto N, et al for PRINTO. A randomized trial of parenteral methotrexate comparing an intermediate with a higher dose in children with juvenile idiopathic arthritis who failed to respond to standard doses of methotrexate. *Arthritis Rheum* 2004; 50(7):2191-2201.

3. Ruperto N, et al for PRINTO/PRCSG. A randomized, placebo-controlled trial of infliximab plus methotrexate for the treatment of polyarticular course juvenile rheumatoid arthritis. *Arthritis Rheum* 2007;56:3096-3106.
4. Lovell DJ*, Ruperto N*, et al for PRINTO/PRCSG. Adalimumab with or without methotrexate in juvenile rheumatoid arthritis. *N Engl J Med* 2008;359:810-820.
5. Ruperto N*, Lovell DJ*, et al for PRINTO/PRCSG. Abatacept in children with juvenile idiopathic arthritis: a randomised, double-blind, placebo-controlled withdrawal trial. *Lancet* 2008;372(9636):383-391.
6. Consolaro A*, Ruperto N*, et al for PRINTO/PRCSG. Development and validation of a composite disease activity score for juvenile idiopathic arthritis. *Arthritis Rheum* 2009; 61(5):658-66.
7. Ruperto N, et al for PRINTO. EULAR/PRINTO/PRES criteria for Henoch-Schönlein purpura, childhood polyarteritis nodosa, childhood Wegener granulomatosis, and childhood Takayasu arteritis: Ankara 2008. Part I: overall methodology and clinical characterisation. *Ann Rheum Dis* 2010;69:790-797.
8. Ozen S, et al, Ruperto N, for PRINTO. EULAR/PRINTO/PRES criteria for Henoch-Schönlein purpura, childhood polyarteritis nodosa, childhood Wegener granulomatosis, and childhood Takayasu arteritis: Ankara 2008. Part II: final classification criteria. *Ann Rheum Dis* 2010;69:798-806.
9. De Benedetti F, Brunner HI, Ruperto N, et al for PRINTO/PRCSG. Randomized Trial of Tocilizumab in Systemic Juvenile Idiopathic Arthritis. *N Engl J Med* 2012;367:2385-2395.
10. Ruperto N, et al for PRINTO/PRCSG. Two Randomized Trials of Canakinumab in Systemic Juvenile Idiopathic Arthritis. *N Engl J Med* 2012;367:2396-2406.
11. Pirmam M, et al, Ruperto N, for EUROFEVER, EUROTRAPS and PRINTO. Validation of the auto-inflammatory disease activity index (AIDAI) for hereditary recurrent fever syndromes. *Ann Rheum Dis* 2014;73:2168-2173.
12. Brunner HI*, Ruperto N*, et al for PRINTO/PRCSG. Efficacy and safety of tocilizumab in patients with polyarticular-course juvenile idiopathic arthritis: results from a phase 3, randomised, double-blind withdrawal trial. *Ann Rheum Dis* 2015;74:1110-1117.
 1. *HIB and NR contributed equally
13. Ruperto N, et al for PRINTO. Prednisone versus prednisone plus ciclosporin versus prednisone plus methotrexate in new-onset juvenile dermatomyositis: a randomised trial. *Lancet* 2016;387:671-678.
14. Rider LG, et al, Ruperto N PRINTO. 2016 American College of Rheumatology/European League Against Rheumatism Criteria for Minimal, Moderate, and Major Clinical Response in Juvenile Dermatomyositis: An IMACS/PRINTO Collaborative Initiative. *Ann Rheum Dis* 2017;76(5):782-791
15. Gattorno M, et al Ruperto N for Eurofever PRINTO. Classification criteria for autoinflammatory recurrent fevers. *Ann Rheum Dis* 2019;78:1025-1032.
16. Brunner HI, et al, Ruperto N PRINTO/PRCSG. Safety and efficacy of intravenous belimumab in children with systemic lupus erythematosus: results from a randomised, placebo-controlled trial. *Ann Rheum Dis* 2020;79:1340-1348.
17. Ruperto N, et al for PRINTO/PRCSG. Tofacitinib in juvenile idiopathic arthritis: a double-blind, placebo-controlled, withdrawal phase 3 randomised trial. *Lancet* 2021;398(10315):1984-1996.
18. Martini A, et al Ruperto N. Juvenile idiopathic arthritis. *Nat Rev Dis Primers* 2022;27;8(1):5. PMID: 35087087
19. Brunner HI, et al, Ruperto N for PRINTO/PRCSG. Secukinumab in enthesitis-related arthritis and juvenile psoriatic arthritis: a randomised, double-blind, placebo-controlled, treatment withdrawal, phase 3 trial. *Ann Rheum Dis* 2023;82(1):154-160.
20. Ramanan AV, et al, Ruperto N for the JUVE-BASIS/PRINTO. Baricitinib in juvenile idiopathic arthritis: an international, phase 3, randomised, double-blind, placebo-controlled, withdrawal, efficacy, and safety trial. *Lancet*. 2023 Aug 12;402(10401):555-570. PMID: 37423231.