



Paediatric Rheumatology  
International Trials Organisation

## 34th Newsletter | September 24

[ PRINTO General Assembly at the PReS Congress ]

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?Dear Friends,

We are happy to invite all of you to the upcoming Annual PRINTO General Assembly at the PReS 2024 Congress, that will be held this year on **Thursday, September 12, from 8:00 to 9:30 CET (Room H1+H2).**

Here is a preliminary **agenda of the assembly**:

1. *Introduction (Nicolino Ruperto)*
2. *The PRINTO/PReS research Grant (Alexandre Belot)*
3. *Cross-cultural adaptation and validation of LoSQI in JLS (Clare Pain)*
4. *Comparison of Kobayashi and Kawanet IVIg resistance scores - the KIWI study (Maria Vincenza Mastrolia)*
5. *Optimizing Treatment in sJIA and MAS/Secondary HLH - the METAPHOR project (Francesca Minoia)*
6. *The PhGA consensus meeting (Veronika Rypdal)*
7. *Macrophage Activation Syndrome in Kawasaki disease: features, treatment, outcome, predicting factors, and diagnostic criteria – the MASKd study (Teresa Giani)*
8. *The EuroFever Registry (Marco Gattorno)*
9. *The HyperPED-COVID Registry (Roberta Caorsi)*
10. *The DAISY study (Dragana Lazarevic)*
11. *The STARS trial (Alessandro Consolaro)*
12. *The CEST-JIA trial (Giovanni Filocamo)*
13. *The JIA classification study (Nicola Ruperto)*
14. *General update on the PRINTO research activity (Nicola Ruperto)*

Elisa, Veronica and Marco from the staff of the PRINTO Coordinating centre will be available at the **PRINTO booth** during the Congress and will be more than happy to meet you and discuss the network's projects and initiatives!

Thank you in advance for your participation, and see you in Gothenburg!

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### Meet the PIs!

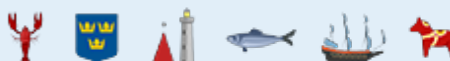
The PIs of the ongoing studies will be also available at the PRINTO booth for further clarifications on their projects and to meet already participating or potentially interested colleagues.

Detailed schedule of their presences will be available at the PRINTO booth, so do not miss your chance to meet the PIs!

Add the PRINTO GA to my calendar!



31<sup>st</sup> European Paediatric Rheumatology Congress



11-14 SEPTEMBER 2024  
Gothenburg • Sweden

## [ PRINTO on going projects ] ?



PIs: Nicolino Ruperto, Nico Wulffraat

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PharmaChild is a **pharmacovigilance project** which aims at observing children with JIA for 3-10 years undergoing treatment with MTX or biologic agents in order to collect **moderate, severe or serious adverse events** occurred. Pharmachild started in 2011 thanks to a European Union (EU) grant within the FP7 framework and has obtained the ENCePP Study Seal (ENCEPP).

As of today, **almost 9,300 patients have been enrolled from 86 centres in 31 countries.**

The PharmaChild project has also a sub-study on abatacept, in collaboration with Bristol Myers and Squibb.

**Enrolment is still open**, although no reimbursement for data entry is provided.



**PI: Nicolino Ruperto**

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The JIA Classification study is a translational study that aims to validate, in a **prospective collection of at least 1,000 patients at disease onset**, the proposed PRINTO consensus classification criteria for JIA. This entails also the collection of biologic samples for ANA, anti CCP, RF, HLA B27 determinations and DNA analysis.

**Enrollment is now closed** and we have collected a total of **1520 patients** from **97 enrolling centres**.

**Import of biological samples to PRINTO is also completed** and samples analysis is in its final phase



**PI: Alessandro Consolaro**

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? The comparison of S**T**ep-up and step-down therapeutic strategies in childhood AR**th**riti**S** trial (STARS) is a new

interventional trial aiming to investigate whether an early aggressive therapeutic intervention in children with JIA , based on the initial start of synthetic and biologic DMARDs (Step-down strategy), is superior to an approach based on treatment escalation conducted following the treat-to-target principle (Step-up strategy).

At the moment we have 20 active centres and a total of 239 patients enrolled in Italy.



PI: Marco Gattorno

The Eurofever registry was promoted in 2008 by the work group of autoinflammatory diseases of the Paediatric Rheumatology European Society (PRES) and was supported by the Executive Agency for Health and Consumers (EAHC).

The **main objective of the project** has been the **creation of a registry of autoinflammatory diseases**.

The registry collects information about the clinical picture, the onset of **complications** , the **treatment** , the current findings (laboratory and instrumental), **safety** , compliance to the therapy and the **quality of life** .

From 2009 to date, **the information of**

more than 5800 patients have been collected from 135 centers distributed in 44 countries around the world.

**Enrolment is still open**, a reimbursement is being provided.

**Seza Ozen** is now coordinating a new project in order to analyze longitudinally the data on FMF patients and a new study on DADA2 is ongoing.

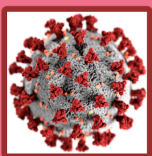


**PI: Dragana Lazarevic**

The DAISY study (Applicability of standardized ultrasound examination to estimate disease activity in combination with JADAS and inflammation markers in JIA patients) **aims to investigate sensitivity and predictive value of the multi-biomarker panel** and to evaluate if it could be applied in limited number of joints in patients with oligo and polyarticular JIA course as a new disease activity tool and outcome measure.

This **multicenter international study** in JIA patients involves selected pediatric rheumatology centers with expertise in the ultrasound examination of joints. The coordinating centers are Nis (Serbia) and Genoa (Italy).

**Enrollment is now closed and we** have collected 103 patients from **10 enrolling centres**.



**HyperPED  
COVID**

**PI: Marco Gattorno**

HyperPED-COVID is a retrospective observational study.

Its principal aim is to capture the burden of this spectrum of hyperinflammatory conditions related to COVID-19 in children and young adults.

For this reason, a **joined PReS, ISSAID, ESID, ERN-RITA and PRINTO network's effort** was started aimed to collect **standardized clinical** data of these patients in a **common registry**.

Primary endpoint of the project is to collect information on clinical presentation, laboratory parameters, clinical outcome and response to treatment of **patients with COVID-19 related hyperinflammation**.

As of today we have more than **1400 subjects enrolled in 60 sites** worldwide.

**It is still possible to join, to include your patients and to propose related analysis!**

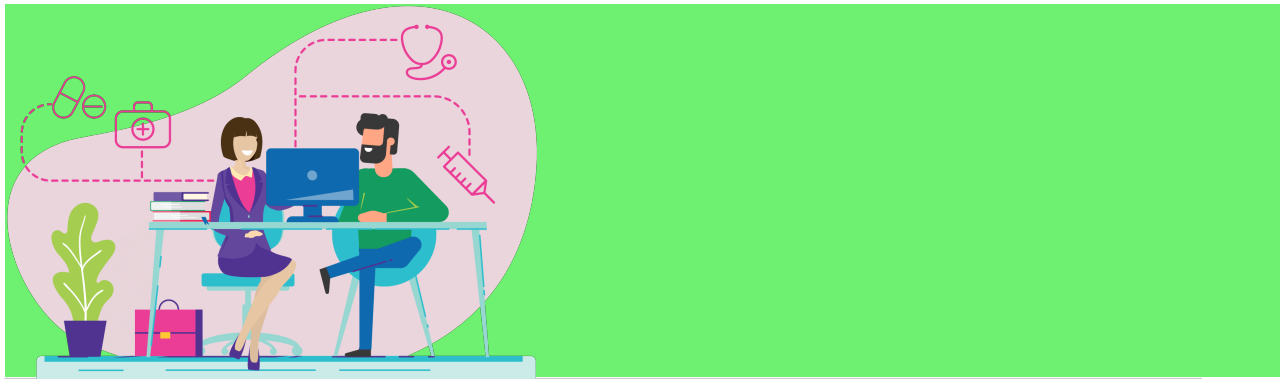
## CEST - JIA

**PI: Giovanni Filocamo**

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The **CEST-JIA** study is an interventional trial aiming to compare the **safety and efficacy of adalimumab and etanercept originator molecules vs biosimilars** in the treatment of **polyarticular course JIA** as well as to evaluate **safety and efficacy of switching from originator biological molecules to bsDMARDs and vice-versa** in current clinical practice as per the local standard of care and according to international recommendation. As of today we have 5 active centres and a total of 29 subjects enrolled, but we are currently opening more sites in Italy.

**Enrollments in PRINTO studies**



## [ PRINTO publications ]

**10 peer-reviewed manuscripts accepted and published** in scientific journals with IF in the last year! **A special thanks to all co-authors!**

**Here are the titles...**

**Paediatric rheumatologists do not score the physician's global assessment of juvenile idiopathic arthritis disease activity in the same way.**

Backström M, Tarkiainen M, Gottlieb BS, Trincianti C, Qiu T, Morgan E, Lovell DJ, Bovis F, Löyttyniemi E, Ruperto N, Vähäsalo P, Consolaro; for the Paediatric Rheumatology International Trials Organisation (PRINTO).

*Rheumatology (Oxford)*. 2023 Oct 3;62(10):3421-3426.

**TNFRSF1A-pR92Q variant identifies a subset of patients more similar to systemic undifferentiated recurrent fever than TNF receptor-associated periodic syndrome.**

Gerritsma AM, Sutera D, Cantarini L, Cattalini M, Lachmann HJ, Minden K, Jansson AF, Touitou I, Bustaffa M, Antón J, Insalaco A, Moreno E, Sanchez-Manubens J, Ruperto N, Frenkel J, Gattorno M; for the Eurofever/Eurotraps projects and Paediatric Rheumatology International Trials Organisation (PRINTO).

*Clin Exp Rheumatol*. 2023 Oct;41(10):1998-2007

**Performance of the 2016 ACR-EULAR myositis response criteria in juvenile dermatomyositis therapeutic trials and consensus profiles.**

Kim H, Saygin D, Douglas C, Wilkerson J, Erman B, Pistorio A, McGrath JA, Reed AM, Oddis CV, Bracaglia C, van Royen-Kerkhof A, Bica B, Dolezalova P, Ferriani VPL, Flato B, Bernard-Medina AG, Herlin T, Miller FW, Vencovsky J, Ruperto N, Aggarwal R, Rider LG; for the International Myositis Assessment and Clinical Studies Group (IMACS) and the Paediatric Rheumatology International Trials Organization (PRINTO).

*Rheumatology (Oxford)*. 2023 Nov 2;62(11):3680-3689.

**Long-Term Maintenance of Clinical Responses by Individual Patients with Polyarticular-Course Juvenile Idiopathic Arthritis Treated with Abatacept.**

Brunner HI, Tzaribachev N, Louw I, Calvo Penades I, Avila-Zapata F, Horneff G, Foeldvari I,

Kingsbury DJ, Paz Gastanaga ME, Wouters C, Breedt J, Wong R, Askelson M, Zhuo J, Martini A, Lovell DJ, Ruperto N; Paediatric Rheumatology International Trials Organisation (PRINTO) and the Pediatric Rheumatology Collaborative Study Group (PRCSG) investigators.

*Arthritis Care Res (Hoboken)*. 2023 Nov;75(11):2259-2266.

### **Abatacept as Monotherapy and in Combination with Methotrexate in Patients With Juvenile Idiopathic Arthritis: Analysis of 2 Phase III Trials.**

Ruperto N, Lovell DJ, Berman A, Anton J, Viola DO, Lauwerys B, Rama ME, Bohnsack J, Breedt J, Fischbach M, Lutz T, Minden K, Ally M, Rubio-Pérez N, Gervais E, Van Zyl R, Wong R, Askelson M, Martini A, Brunner HI; for the Pediatric Rheumatology Collaborative Study Group (PRCSG) and the Paediatric Rheumatology International Trials Organisation (PRINTO).

*J Rheumatol*. 2023 Nov;50(11):1471-1480.

### **Ten-year safety and clinical benefit from open-label etanercept treatment in children and young adults with juvenile idiopathic arthritis.**

Vojinović J, Foeldvari I, Dehoorne J, Panaviene V, Susić G, Horneff G, Stanevich V, Kobusinska K, Zuber Z, Dobrzyniecka B, Akikusa J, Avčin T, Borlenghi C, Arthur E, Tatulych SY, Zang C, Tsekouras V, Vlahos B, Martini A, Ruperto N. for the Paediatric Rheumatology International Trials Organisation (PRINTO).

*Rheumatology (Oxford)*. 2024 Jan 4;63(1):140-148.

### **Long-term efficacy and safety of subcutaneous tocilizumab in clinical trials of polyarticular or systemic juvenile idiopathic arthritis.**

Brunner HI, Ruperto N, Ramanan AV, Horneff G, Minden K, Calvo Penades I, Alexeeva E, Cleary G, Stern SM, Kone-Paut I, Maldonado Velázquez MDR, Rabinovich CE, Remesal A, Silva CA, Nikishina I, Zucchetto M, Brockwell L, Gordon O, Nagel S, De Benedetti F; on the behalf of the PRINTO and PRCSG Investigators.

*Rheumatology (Oxford)*. 2024 Sep 1;63(9):2535-2546.

### **Clinical features, treatment and outcomes of Italian children with enthesitis-related arthritis and juvenile psoriatic arthritis: a cross-sectional cohort study.**

Rebollo-Giménez AI, Rosina S, Natoli V, Burrone M, Barone P, Campus S, Civino A, Consolini R, Filocamo G, Gallizzi R, Gattinara M, La Torre F, Maggio MC, Magni-Manzoni S, Magnolia MG, Miniaci A, Montin D, Pastore S, Petaccia A, Pieropan S, Rigante D, Simonini G, Ridella F, Orsi SM, Angioloni S, Carlini L, Ruperto N, Consolaro A; for the Paediatric Rheumatology International Trials Organisation (PRINTO).

*Clin Exp Rheumatol*. 2024 Mar;42(3):757-763.

### **Defining criteria for disease activity states in juvenile dermatomyositis based on the Juvenile Dermatomyositis Activity Index.**

Rosina S, Consolaro A, Pistorio A, Rebollo-Giménez A, Bracaglia C, Dolezalova P, Guilaisne Bernard-Medina A, Herlin T, Trachana M, Vargová V, Wouters C, Carenini L, Ruperto N, Ravelli A; for the Paediatric Rheumatology International Trials Organisation (PRINTO).

*RMD Open*. 2024 Feb 2;10(1)



## Thrombotic manifestations in pediatric Behcet syndrome: A multicenter comparative study from the EUROFEVER registry

Mastrolia MV, Matucci-Cerinic C, Ozen S, Kasapcopur O, Gaggiano C, Koné-Paut I, Cantarini L, Dusser P, Kaya-Akça Ü, Yildiz M, Brunner J, Filocamo G, Gallizzi R, Insalaco A, Pastore S, Rigante D, Sanchez-Manubens J, Tsitsami E, Ruperto N, Gattorno M, Simonini G; for the EUROFEVER Registry and the Pediatric Rheumatology International trial organization (PRINTO).

*Semin Arthritis Rheum.* 2024 Jun;66:152454

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## [ PRINTO Membership ]

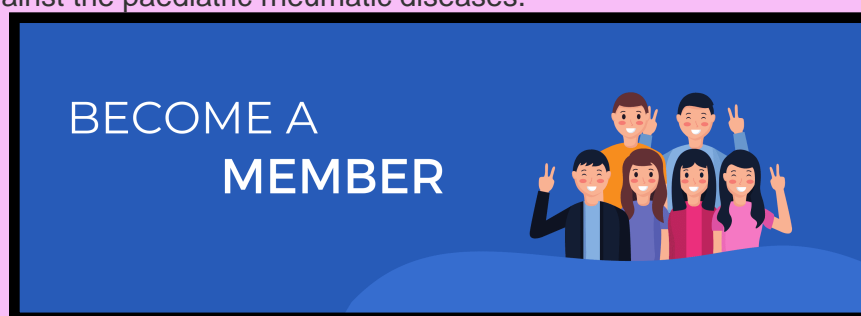
PRINTO has now reached **2075 effective members in 729 centres from 95 countries** worldwide.

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If you wish to become a PRINTO member and receive regular updates and invitations to our research projects, click on the banner below or feel free to contact PRINTO.

### Join the network!

Your cooperation will be more than welcome and your effort will be essential for the research against the paediatric rheumatic diseases.



### Chairman

**Alberto Martini** , MD, Prof - Genoa, Italy

### Counsellors

**Tadej Avcin** , MD, PhD - Ljubljana, Slovenia

**Michael Hofer** , MD, Prof - Lausanne, Switzerland

**Seza Ozen** , MD, Prof - Ankara, Turkey

**Pierre Quartier** , MD - Paris, France

**Claudia Saad Magalhães** , MD, Prof - Botucatu, Brazil

**Joos Swart** , MD - Utrecht, The Netherlands

**Senior Scientist**

**Nicolino Ruperto** , MD, MPH - Genoa, Italy

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