

## PRINTO PROJECTS

	Pharmachild	Eurofever	JIA MAS
Albania		1	
Argentina		25	39
Armenia		101	1
Australia		10	
Belgium		13	2
Bosnia			33
Brazil		8	19
Canada			
Chile		5	20
China			13
Croatia	111	8	
Czech		46	6
Denmark		118	29
France		257	6
Georgia		9	15
Germany		255	37
Greece	127	31	
Hungary		7	55
India		3	10
Israel		152	343
Italy	134	530	2
Japan			
Kuwait			47
Latvia	210	4	42
Libya			
Lithuania		1	
Netherlands		88	8
Norway			
Oman	22	4	
Poland	52	3	
Romania	6	16	
Russia		24	15
Saudi Arabia		39	2
Serbia		3	6
Slovakia		1	
Slovenia		9	14
Spain		82	37
Sweden		1	
Switzerland		68	1
Turkey		165	131
Un. Kingdom		263	2
USA			90
Venezuela			8
<b>Total</b>	<b>662</b>	<b>2350</b>	<b>1033</b>

Paediatric Rheumatology International  
Trials Organisation (PRINTO)  
IRCCS G. Gaslini Pediatrica II  
Via Gaslini, 5  
16147 Genova - ITALY



May 2012

## Paediatric Rheumatology International Trials Organisation (PRINTO)



### ADVISORY COUNCIL

#### Chairman

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

#### Counsellors

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

*Michael Beresford, MD - Liverpool, UK*

*Susan Nielsen, MD - København, Denmark*

*Pierre Quartier, MD - Paris, France*

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

*Nico Wulfraat, MD, PhD - Utrecht, The Netherlands*

#### Senior Scientist

*Nicola Ruperto, MD, MPH - Genova, Italy*

IRCCS G. Gaslini

Pediatria II - PRINTO

Via Gaslini, 5

16147 Genova, ITALY

Tel: +39-010-38-28-54 or +39-010-39-34-25

Fax +39-010-39-33-24 or +39-010-39-36-19

E-mail: [printo@ospedale-gaslini.ge.it](mailto:printo@ospedale-gaslini.ge.it)

[www.printo.it](http://www.printo.it)

[www.pediatric-rheumatology.printo.it](http://www.pediatric-rheumatology.printo.it)

**PReS Congress 2012 Berlin, Germany**  
Friday, June 8th, 2012 at **12.00-13.00**  
Room 5.1 - PRINTO workshop

Agenda for the annual PRINTO workshop

- Introduction (A. Martini)
- Update on PRINTO Projects (N. Ruperto)
- Pharmachild website (N. Wulfraat, N. Ruperto)
- The PRES EuroFever project (M. Gattorno)
- The EPOCA and MAS study (A. Ravelli)

**The PharmaChild Project:** This project is a retrospective and prospective registry with the aim to collect moderate-severe serious adverse events and related efficacy in JIA patients treated with biologics and/or MTX on a long-term period.

During the PRINTO workshop the web database will be presented. The web data base has been created with the aim to be an international electronic resource for all PRINTO centres in order to collect safety and efficacy information on JIA patients. It will allow the immediate **quantification** of the disease activity (JADAS, ACR, flare, inactive disease etc) status as well as the possibility to autonomously **download electronic data** for local research or other related purposes. The web system is supposed to be friendly enough to be used in **daily clinical practice**.

As of May 2012, 117 PRINTO centres have expressed their interest in participating. Out of the 117, 46 ethics committee approvals have been obtained, 17 have been submitted and 26 centres do not need the approval. A total of 662 patients have been entered into the census. Data collection is already in progress in 30 PRINTO centres.

The project is financed by the European Union (PI Dr N. Wulfraat 2011-2014).

**The JAMAR/EPOCA study (EPidemiology, treatment and Outcome of Childhood Arthritis).** The study is aimed at photographing the current status of children with JIA across continents and countries. PRINTO national coordinators (NCC list at [www.printo.it](http://www.printo.it)) were asked firstly to translate and cross-culturally validate the parent and child versions of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR) and secondly to assess 100 consecutive JIA patients and 100 healthy children. Additional centres may participate by collecting each 100 consecutive JIA patients. The national language translations of the JAMAR will be published in a dedicated supplement in *Clinical and Experimental Rheumatology*.

The aim of this study is therefore twofold:

- 1) to foster regular use of parent/patient-reported outcomes in paediatric rheumatology practice;
- 2) to obtain information about the frequency of ILAR categories, treatment modalities, and current outcome of JIA around the world.

As of today 34 translations have been completed and other 14 are in progress (see [www.printo.it/jamar.asp](http://www.printo.it/jamar.asp)). The data collection phase has started last fall through a dedicated web database on the PRINTO member area and > 1000 patients have been already entered.

**The PRES Eurofever project.** The Eurofever Registry (PI Dr M. Gattorno) is fully enrolling. A total of 2350 patients (see table) have been enrolled. Two additional papers have been recently published (see list next page). Other publications on CAPS, TRAPS, FMF and CRMO are ongoing.

**The MAS criteria study:** The second phase of the project, which is aimed to collect data from patients with MAS and control patients, in ongoing. Data collection refers to the following 3 groups of patients:

- 1) Patients with systemic JIA who had an episode of MAS, diagnosed and treated as such by the attending physician, and were seen from January 2002 to date;
- 2) An approximately equal number of instances of active disease (in the absence of MAS) in children with systemic JIA seen in the same period;
- 3) An approximately equal number of children with an acute febrile infection, admitted to the hospital (inclusion of these patients is optional).

A total of 309 patients from group 1, 407 from group 2 and 347 from group 3 have been enrolled via the PRINTO database system.

We foresee to close the enrollment at the end of May.

#### **New onset JDM trial:**

The enrollment of the trial is now closed with 139 patients recruited from 55 centres in 23 countries. No major safety concern identified since last year. The analysis of the data is on going.

**Membership:** 896 effective members (20% increase) in 402 centres from 81 countries.

### Recent PRINTO publications

For reprints go to [www.printo.it](http://www.printo.it) and click on papers.

- Consolaro A, Ruperto N, Pistorio A, Lattanzi B, Solari N, Galasso R, Pederzoli S, Varnier GC, Dolezalova P, Alessio M, Burgos-Vargas R, Vesely R, Martini A, Ravelli A, for the Paediatric Rheumatology International Trials Organisation (PRINTO). Development and initial validation of composite parent and child-centered disease assessment indices for juvenile idiopathic arthritis. **Arthritis Care Res** 2011;63(9):1262-1270.
- Hasija R, Pistorio A, Ravelli A, Demirkaya E, Khubchandani R, Guseinova D, Malattia C, Canhao H, Harel L, Foell D, Wouters C, De Cunto C, Huemer C, Kimura Y, Mangge H, Minetti C, Nordal EB, Philippet P, Garozzo R, Martini A, Ruperto N, for the Paediatric Rheumatology International Trials Organisation (PRINTO). Therapeutic approaches in the treatment of juvenile dermatomyositis in patients with recent-onset disease and in those experiencing disease flare. An international multicenter PRINTO study. **Arthritis Rheum** 2011;63(10):3142-3152.

- Rygg M, Pistorio A, Ravelli A, Maghnie M, Di Iorgi N, Bader-Meunier B, Da Silva C, Roldan-Molina R, Barash J, Dracou C, Gandom Laloum S, Jarosova K, Job Deslandre C, Kone-Paut I, Garofalo F, Press J, Sengler C, Tauber T, Martini A, Ruperto N for the Paediatric Rheumatology International Trials Organisation (PRINTO). A longitudinal printo study on growth and puberty in juvenile systemic lupus erythematosus. **Ann Rheum Dis** 2012;71:511-517.

- Toplak N, Frenkel J, Ozen S, Lachmann HJ, Woo P, Koné-Paut I, De Benedetti F, Neven B, Hofer M, Dolezalova P, Kümmerle-Deschner J, Touitou I, Hentgen V, Simon A, Girschick H, Rose C, Wouters C, Vesely R, Arostegui J, Stojanov S, Ozgodan H, Martini A, Ruperto N, Gattorno M. for the Paediatric Rheumatology International Trials Organisation (PRINTO). An International registry on Autoinflammatory diseases: the Eurofever experience. **Ann Rheum Dis** 2012;Feb 29. [Epub ahead of print]

- Lazarevic D, Pistorio A, Palmisani E, Miettunen P, Ravelli A, Pilkington C, Wulffraat N, Malattia C, Garay S, Hofer M, Quartier P, Dolezalova P, Calvo I, Ferriani V, Ganser G, Kasapcopur O, Melo-Gomes JA, Reed AM, Wierzbowska M, Rider LG, Martini A, Ruperto N for the Paediatric Rheumatology International Trials Organisation (PRINTO). The PRINTO criteria for clinically inactive disease in juvenile dermatomyositis. **Ann Rheum Dis** 2012; in press.

- ter Haar NM, Lachmann HJ, Ozen S, Woo P, Uziel Y, Modesto C, Koné-Paut I, Cantarini L, Insalaco A, Neven B, Hofer M, Rigante D, Al-Mayouf SM, Touitou I, Gallizzi R, Papadopoulou-Alataki E, Martino S, Kümmerle-Deschner JB, Obici L, Iagaru N, Simon A, Nielsen S, Martini A, Ruperto N, Gattorno M, Frenkel J, for the Paediatric Rheumatology International Trials Organisation (PRINTO) and the Eurofever/Eurotraps Projects Treatment of autoinflammatory diseases: results from the Eurofever registry and a literature review. **Ann Rheum Dis** 2012; in press.