PRINTO PROJECTS

COUNTRIES	PRINTO member/ centres	No of pts enrolled MTX trial	No. of pts enrolled Quality of life in JCA project CHAQ/CHQ
Argentina			134
Austria	2/2	2	144
Belgium	4/3	9	155
Brazil	8/6	24	482
Bulgaria	1/1		
Chile	1/1		128
Croatia	1/1		21
Czech Republic	7/5	11	157
Denmark	3/2		143
Finland	5/2	7	151
France	9/8		273
Germany	8/7	8	117
Greece	6/4		145
Hungary	2/1		134
Georgia			
Israel	7/6	4	158
Italy	25/13	126	1187
Korea (South)	1/1	2	221
Latvia	2/2		20
Luxembourg	1/1		
Mexico	3/1	14	210
Netherlands	6/4	31	177
Norway	7/3	14	25
Portugal	1/1		140
Russia	2/1		151
Slovakia	4/4	11	124
Spain	8/6	16	168
Sweden	3/3	5	25
Switzerland	3/3	8	136
Turkey	1/1	10	160
Un. Kingdom	12/10	107	437
Yugoslavia	1/1		140
USA		8	
Totals	**146/106**	**417**	**5671**

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AUGUST 2000

Paediatric Rheumatology International Trials Organisation - **PRINTO**

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V NEWSLETTER

VII European Paediatric Rheumatology Congress (Geneva, September 23-27, 2000)

a PRINTO workshop will be held on

Tuesday September 26, 2000 11.00-12.30 am

All the PRINTO members, and interested people, are invited to participate.

The agenda will be as follows:

- Introduction (Alberto Martini)
- PRINTO projects update (Nicola Ruperto)
- Meeting of the PRINTO national co-ordinators

Membership: We have now 146 effective members in 106 centres in 32 countries.

Methotrexate (MTX) trial (medium vs high dose) in the idiopathic arthritides of childhood (IAC): the goal of the trial is to assess the efficacy and safety of a 6 months course of parenteral MTX in **MEDIUM** (15 mg/m^2/once a week max dose 20 mg/once a week) versus **HIGH** dose (30 mg/m^2/once a week; max dose 30 mg/once a week) in children who failed a standard dose MTX (8-12.5 mg/m^2/once a week for 4-6 months). **62 centres** in **20** countries have now obtained Ethics Committee approval. A total of **417 patients** have been enrolled in the screening phase with **51** patients randomised to higher dose of MTX. The trial is proceeding extremely well!!

ENDING DATE FOR PATIENTS ENROLLMENT IN SCREENING PHASE:

MARCH 31, 2001

Quality of life project in the IAC - the Childhood Health Assessment Questionnaire (CHAQ) and the Child Health Questionnaire (CHQ): goal of the project is to cross-cultural adapt and validate the CHAQ and CHQ in all languages of the PRINTO members. This will constitute the starting point for standardised functional, physical and psychosocial assessment in future clinical trials in the pediatric rheumatic diseases. Data collection is now over in **32** countries with **5671** patients collected. Results will be published in a supplement on Clin Exp Rheumatol in year 2001.

Core sets of outcome measures and definition of improvement for juvenile systemic lupus erythematosus (JSLE) and juvenile dermatomyositis (JDM). It is with great pleasure we announce that PRINTO has been recently awarded with its second 3 years grant (2000-2003) from the European Union (EU QLG1-CT-2000-00514).

Aim of this new project is to establish:

1. a JSLE and JDM core sets of outcome measure
2. a JSLE and JDM definitions of improvement to be used in future clinical trials.

AIM 1 will be reached through a set of questionnaire surveys among PRINTO members and "Pediatric Rheumatology Collaborative Study Group – PRCSG" members. An international consensus conference will be held at the end of this phase (March 2001).

AIM 2 will be reached through a large data collection (details to follow) and a second consensus conference to be held in 2003.

IMPORTANT this time PRINTO has obtained funds from the European Union to pay approximately **400 EURO** for each of the 500 patients you will send to Pavia, Italy.

The process is similar to that has been used for the juvenile arthritis definition of improvement (Giannini EH, Ruperto N, Ravelli A, Lovell DJ, Felson DT, Martini A: Preliminary definition of improvement in juvenile arthritis. Arthritis Rheum 1997; 40:1202-9).

A single definition of improvement for JSLE and JDM, will facilitate the standardisation, conduct, interpretation and efficiency of future clinical trials and meta-analyses. It is anticipated that these definitions of improvement might also be useful to physicians to decide if a child has responded adequately to therapy in routine clinical practice. The successful accomplishment of this project will therefore set the basis for planning future clinical trials for new therapeutic options for JSLE and for JDM patients.

It is the basic premise of this project that without a wide involvement of the paediatric rheumatologist community these studies will never be conducted.