



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 February 2012  
EMA/94295/2012  
Human Medicines Development and Evaluation

## European network of paediatric research (EnprEMA)

### Recognition criteria for self assessment

The European Medicines Agency is tasked with developing a European paediatric network of existing national and European networks, investigators and centers with specific expertise in the performance of studies in the paediatric population.

Following a test pilot phase, public consultation and the outcome of the second workshop with participants of 28 networks and/or clinical trial centres in March 2010, recognition criteria have been finalised which will have to be fulfilled by existing networks to become a member of the European paediatric network. All networks wishing to become a member of EnprEMA are invited to perform self-assessment and to send the filled-in document to the European Medicines Agency.

|                                                                                                                     |
|---------------------------------------------------------------------------------------------------------------------|
| The document should be sent to <a href="mailto:Merja.Heikkurinen@ema.europa.eu">Merja.Heikkurinen@ema.europa.eu</a> |
|---------------------------------------------------------------------------------------------------------------------|

|                                      |              |
|--------------------------------------|--------------|
| <b>END OF SELF-ASSESSMENT PERIOD</b> | 31 July 2010 |
|--------------------------------------|--------------|



# EnprEMA

## European network of paediatric research at the European Medicines Agency

### ***Recognition criteria for self-assessment***

The European Paediatric Regulation (EC) No 1901/2006, as amended, calls for the fostering of high-quality ethical research on medicinal products for use in children. This should be achieved through efficient inter-network and stakeholder collaboration. To meet this objective, a European paediatric research network is to be formed of national and European networks, investigators and centres with specific expertise in performing drug trials in the paediatric population. General information can be found at:

<http://www.emea.europa.eu/htms/human/paediatrics/network.htm>

### ***Minimum criteria that have to be fulfilled to be recognised as a member of the EnprEMA***

This document defines 6 criteria with several subcategories (items) for self-assessment. The criteria and their items have been set up in a public process. Minimum criteria were defined that networks should fulfil to be recognised as a member of the EnprEMA. The defined minimum criteria are flagged with a superscript "M".

Irrespective of whether or not only minimum criteria / items are fulfilled, the full list of the criteria and items as well as the network identification should be completed to the extent possible.

### ***Use of the document and application of the recognition criteria***

The criteria should be reported for the highest level that the network currently attains. Networks should report on the status of the network, not on individual investigators or sites. For the purpose of this document, the highest level is called the reporting party.

The document should be filled in by the reporting party (once only per network), taking into account the guidance text provided for the various items within the respective criterion. For transparency in general and to permit public scrutiny of the self-assessment, the completed document should be made public by the reporting party, for example, on their website.

For the same purpose, the reporting party should also make publicly accessible the actual data on which the statements are based. For example, if numbers of paediatric trials are provided, references to clinical trial registration numbers could be made publicly accessible.

The self-assessment should be updated annually.

This document should be sent to the European Medicines Agency; it will be published on the EMA webpage.

## **Criteria for the recognition of an investigator\*, site\* or network as a member of the EnprEMA**

\* only when the investigator or the site is not part of a network

### **Identification <sup>M</sup>**

|                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                            |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| Name                          | Pediatric Rheumatology International Trials Organisation (PRINTO)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Include legal address, define acronyms                                                                     |
| Type                          | Pediatric Rheumatology specialty network<br>The Paediatric Rheumatology International Trials Organisation (PRINTO) is a not for profit, non governmental, international research network founded by Alberto Martini and Nicolino Ruperto in 1996, and initially included 14 European countries (now more than 50 and 396 centres worldwide), with the goal to foster, facilitate and co-ordinate the development, conduct, analysis, and reporting of multi-centres, international clinical trials and/or outcome standardisation studies in children with paediatric rheumatic diseases (PRD). | Indicate type of reporting party, e.g. national or speciality network. May include short mission statement |
| Street                        | c/o IRCCS Istituto G. Gaslini<br>Pediatria II, PRINTO<br>Largo Gaslini, 5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                            |
| Postal code                   | 16147                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                            |
| Town                          | Genoa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                            |
| Country                       | Italy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                            |
| Telephone 1                   | +39-010-38-28-54                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                            |
| Telephone 2                   | +39-010-39-34-25                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                            |
| Mobile phone                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                            |
| Fax                           | +390104211018 or +39-010-393324<br>or +39-010-393619                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                            |
| Web site                      | <a href="http://www.printo.it">http://www.printo.it</a> or <a href="http://www.pediatric-rheumatology.printo.it">www.pediatric-rheumatology.printo.it</a>                                                                                                                                                                                                                                                                                                                                                                                                                                       | If available (see criterion 4)                                                                             |
| Email for general enquiries   | <a href="mailto:printo@ospedale-gaslini.ge.it">printo@ospedale-gaslini.ge.it</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | If available (see criterion 4)                                                                             |
| Representative (main) contact | ---                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Include first and second name, email, telephone, address, as far as available                              |
| First name                    | Nicolino                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                            |
| Second name                   | Ruperto                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                            |
| Telephone                     | +39-010-38-28-54                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                            |
| Mobile phone                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                            |

|                                                       |                                                                                                                                                           |                                                                                             |
|-------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| Email                                                 | nicolaruperto@ospedale-gaslini.ge.it                                                                                                                      |                                                                                             |
| Further contact(s)                                    | ---                                                                                                                                                       | Include first and second name, email, telephone, address, as far as available               |
| First name                                            | Alberto                                                                                                                                                   |                                                                                             |
| Second name                                           | Martini                                                                                                                                                   |                                                                                             |
| Telephone                                             | +39-010-5636386                                                                                                                                           |                                                                                             |
| Mobile phone                                          |                                                                                                                                                           |                                                                                             |
| Email                                                 | albertomartini@ospedale-gaslini.ge.it                                                                                                                     |                                                                                             |
| The data in this document are 'current' as of         | 08/03/2012                                                                                                                                                | Provide the date when the criteria were last updated                                        |
| State how this document can be accessed by the public | <a href="http://www.printo.it">http://www.printo.it</a> or <a href="http://www.pediatric-rheumatology.printo.it">www.pediatric-rheumatology.printo.it</a> | This should be a link to a webpage, but other means and formats to make public are possible |

## Description <sup>M</sup>

|                                                                    |                                                                     |                                                                                                                                                                                                  |
|--------------------------------------------------------------------|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Year of foundation                                                 | 1996                                                                | Of the network, or of the investigator's or site's specific paediatric research activities                                                                                                       |
| Paediatric age ranges of study participants covered by the network |                                                                     |                                                                                                                                                                                                  |
| Preterm and / or term newborn                                      | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Newborn: from birth to less than 28 days of age                                                                                                                                                  |
| Infants from 1 month to less than 24 months of age                 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |                                                                                                                                                                                                  |
| Children from 2 years to less than 12 years of age                 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |                                                                                                                                                                                                  |
| Adolescents from 12 years to less than 18 years                    | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |                                                                                                                                                                                                  |
| Specialities / Conditions covered                                  | Pediatric Rheumatology                                              | ENPREMA will cover a range of different networks, from single speciality trials groups to those covering all paediatrics. If not all areas within one speciality are covered, specify conditions |
| Multispeciality? Specify                                           |                                                                     | For example, oncology or infectious diseases                                                                                                                                                     |
| Speciality or disease specific? Specify                            | Pediatric Rheumatology                                              | For example, cardiology only                                                                                                                                                                     |

|                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                               |
|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| Conditions covered? Specify                | <p>JUVENILE IDIOPATHIC ARTHRITIS</p> <p>SYSTEMIC LUPUS ERYTHEMATOSUS</p> <p>JUVENILE DERMATOMYOSITIS</p> <p>SCLERODERMA</p> <p>JUVENILE SPONDYLOARTHROPATHIES</p> <p>KAWASAKI DISEASE</p> <p>HENOCH- SCHOENLEIN PURPURA</p> <p>RARE JUVENILE PRIMARY SYSTEMIC VASCULITIS</p> <p>Polyarteritis nodosa, Takayasu, Wegener's granulomatosis, Other vasculitides</p> <p>RHEUMATIC FEVER AND POST-STREPTOCOCCAL REACTIVE ARTHRITIS</p> <p>AUTOINFLAMMATORY DISEASES</p> <p>Blau's disease/Juvenile Sarcoidosis</p> <p>Cryopyrin associated periodic syndromes (CAPS)(CINCA/ Muckle Wells/ FCAS)</p> <p>Chronic non bacterial osteomyelitis/osteitis (or CRMO)</p> <p>Deficiency of IL-1 receptor antagonist (DIRA)</p> <p>Familial Mediterranean Fever (FMF)</p> <p>Mevalonate kinase Deficiency (MKD) (or Hyper IgD syndrome)</p> <p>NALP12-related disease</p> <p>PAPA syndrome (pyoderma gangrenosum, acne, pyogenic arthritis)</p> <p>PFAPA (Marshall's syndrome)</p> <p>TNF receptor associated periodic syndrome (TRAPS)</p> <p>BEHCET'S DISEASE</p> <p>LYME ARTHRITIS</p> <p>PAIN SYNDROMES</p> | E.g. hypertension (within cardiology) or asthma (within respiratory diseases) |
| Procedure / intervention specific? Specify |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | For example, surgery, organ or stem cell transplantation                      |

|                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                            |
|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Number of collaborating countries | <p>53</p> <p>List all collaborating countries:<br/> Argentina, Armenia, Australia, Austria, Belgium, Brazil, Bulgaria, Chile, China, Colombia, Costa Rica, Croatia, Cuba, Czech Republic, Denmark, Egypt, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, India, Iran, Israel, Italy, Japan, Korea (South), Latvia, Lithuania, Mexico, Netherlands, New Zealand, Norway, Oman, Peru, Portugal, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Tunisia, Turkey, United Kingdom, Venezuela</p> | <p>State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other..... (describe)</p> |
| Number of collaborating centres   | <p>396</p> <p>List all collaborating centres: see attachment</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>State the number of collaborating centres and provide a list of all collaborating centres (attachment or link possible)</p>             |
| Type of activity/studies          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                            |
| Clinical studies                  | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                            |
| Experimental research             | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                            |
| Other activity                    | Educational activity for foreign doctors attending our Unit for academic purposes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Describe type of activities other than clinical and/or non-clinical studies                                                                |

## ***Evidence for each criterion***

|                                                                                         |           |
|-----------------------------------------------------------------------------------------|-----------|
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## ***How to provide evidence***

1. The evidence for this self-assessment document should be based only on the activity of the network during in the last 5 years.
2. Evidence used in this document should have a reference (e.g., publication, annual or periodic report or internal network document).
3. The self-assessment document is to cover a range of different network types. It is recognised that some networks may not be able to accurately respond to every item. In such circumstances, state why it is not possible to respond.
4. The network is referred to as the “reporting party”.

## Criterion 1: Research experience and ability

Do not include planned trials, but only ongoing and completed trials.

|                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.1<br>Number of completed trials <sup>M</sup><br>Number of ongoing trials <sup>M</sup>                                                                                                               | 6<br><br>5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ( <sup>M</sup> ): one ongoing or one completed trial.                                                                                |
| 1.2<br>Total number of participants actually recruited each year<br><br>Proportion of eligible participants actually recruited each year<br><br>Describe way of screening and participant recruitment | 896<br><br>1000<br><br>The number above refers to the total number of patients recruited for the trials from 2006 to 2010 (academic and industry sponsored). PRINTO performs a feasibility survey asking PRINTO centres to indicate the potential number of patients that might be eligible based on the inclusion/exclusion criteria. Once the trial is implemented a log of patients eligible and patient recruited is kept by PRINTO (for academic studies) or by the pharmaceutical industry. | Relevant to speciality specific networks. State total recruitment capacity for any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Which strategies or pathways are used to screen and recruit participants? |
| 1.3<br>Total number of collaborating centres                                                                                                                                                          | 396 (total number of centers affiliated to the network, although not all of them actively enroll patients)                                                                                                                                                                                                                                                                                                                                                                                        | For completed and ongoing (open) paediatric trials. Do not include sites in set-up.                                                                                                                                                                                                                                            |
| Academic (investigator) initiated studies                                                                                                                                                             | ---                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Studies conducted independently from pharmaceutical companies (no sponsorship and no funding). There is a separate category (below) for industry-funded studies.                                                                                                                                                               |

|                                                                       |                                                                                   |                                                                                                                                                                                                                                                                                                |
|-----------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.4<br>Number of ongoing and completed clinical trials                | Absolute number:<br>2<br><br>Proportion of all studies:<br>20% (2/10)             | Paediatric interventional trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation by regulatory authority) (for other Paediatric trials unrelated to drug development see below)                                  |
| 1.5<br>Number of paediatric specialities covered by paediatric trials | 1                                                                                 | Count specialities, without repetition, across all ongoing or completed paediatric trials                                                                                                                                                                                                      |
| 1.6<br>Number of paediatric conditions covered by paediatric trials   | 2                                                                                 | If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials                                                                                                                                                         |
| 1.7<br>Number of other ongoing research studies / programs            | 2                                                                                 | For example, epidemiological studies, outcome studies, translational research in which the reporting party is participating Include cohort studies but not audits. Research is defined as a project with a specific research question in which the participant/family provides formal consent. |
| 1.8<br>Indicate the proportion of public funding                      | Proportion of academic initiated studies:<br>20%<br>Proportion of budget:<br>100% | Indicate the proportion of the budget handled for completed and ongoing paediatric trials that is derived from public funding sources such as governmental programs, competitive public grants, university contributions                                                                       |
| 1.9<br>Number of registered study participants (all studies)          | 100                                                                               |                                                                                                                                                                                                                                                                                                |
| Industry-sponsored trials                                             | ---                                                                               |                                                                                                                                                                                                                                                                                                |
| 1.10<br>Number of ongoing and                                         | 8                                                                                 | Paediatric interventional trials of any phase of the                                                                                                                                                                                                                                           |

|                                                                        |    |                                                                                                                                        |
|------------------------------------------------------------------------|----|----------------------------------------------------------------------------------------------------------------------------------------|
| completed trials                                                       |    | pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation)                             |
| 1.11<br>Number of paediatric specialities covered by paediatric trials | 1  | Count specialities, without repetition, across all ongoing or completed paediatric trials                                              |
| 1.12<br>Number of paediatric conditions covered by paediatric trials   | 1  | If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials |
| 1.13<br>Number of registered study participants (all studies)          | 50 |                                                                                                                                        |

## Criterion 2: Network organisation and processes

|                                                                                                                                            |                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.1<br>Existence of an identified contact person for external enquiries <sup>M</sup>                                                       | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br><br>Comments:<br><br>PRINTO international coordinating centre in Genoa (Italy) with PRINTO Senior Scientist plus 8 research assistants working full-time                                                          | Enquiries from patients, parents, organisations, researchers, pharmaceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above. |
| 2.2<br>Existence of an internal steering committee <sup>M</sup>                                                                            | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br><br>Comments:                                                                                                                                                                                                     | Minimum requirement ( <sup>M</sup> ): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).                                                                                                   |
| 2.3<br>Existence of an external advisory / steering committee directing the reporting party <sup>M</sup>                                   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br><br>Comments:<br>Committee are formed ad-hoc based on the specific study needs                                                                                                                                    | Minimum requirement ( <sup>M</sup> ): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).                                                                                                   |
| 2.4<br>Existence of a website                                                                                                              | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br><br>Comments:<br>www.printo.it or www.pediatric-rheumatology.printo.it                                                                                                                                            | If available, mention in "identification" above                                                                                                                                                                                         |
| 2.5<br>Existence of newsletter                                                                                                             | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br><br>Comments:<br>Usually one per year general newsletter plus several per year specific to each study                                                                                                             | Newsletter of any format (electronic, surface mail), distributed actively to selected recipients.                                                                                                                                       |
| 2.6<br>Existence of an internal database(s) for disease, condition, treatment and / or outcome <sup>M</sup><br><br>If yes, please describe | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br><br>Comments / description:<br>Ad-hoc web-based databases are created for the purposes of data collection of the specific trial                                                                                   | For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data)                                                                                          |
| 2.7<br>Provisions to ascertain data protection and data security <sup>M</sup>                                                              | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br><br>Comments:<br>For the online data collection databases are put on an https platform with access restricted with username and password only to registered centres (e.g. centres with ethics committee approval) | Are provisions in place to ascertain patients' /study participants' data protection and data safety within network                                                                                                                      |

|                                                                                      |                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                         |
|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.1<br>Existence of an identified contact person for external enquiries <sup>M</sup> | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br><br>Comments:<br><br>PRINTO international coordinating centre in Genoa (Italy) with PRINTO Senior Scientist plus 8 research assistants working full-time | Enquiries from patients, parents, organisations, researchers, pharmaceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above. |
| 2.8<br>Procedure(s) to access the database by third parties                          | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>A request has to be done to the PRINTO Chairman and the request is then discussed for approval by the PRINTO Advisory Council               | Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)?                                                                                                                                       |
| 2.9<br>Access to external databases /registries                                      | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>Comments:                                                                                                                                                | For example, national databases that are not publicly accessible but to which the reporting party has open or privileged access; database(s) immediately relevant to area and / or scope                                                |
| 2.10<br>Standardised process to access an external database(s)                       | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>Comments:                                                                                                                                                | Is a standardised process in place to access external/ national databases?                                                                                                                                                              |

### Criterion 3: Scientific competencies and capacity to provide expert advice

|                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>3.1</p> <p>Number of peer-reviewed publications in the last 5 years</p> <p>Provide exact reference(s)</p> <p>Describe the network's contribution to publication(s)</p> | <p>40</p> <p>see list attached</p> <p>For most of the publications (either academic or industry-sponsored) the paper is written by the PRINTO international coordinating centres. For academic studies also the analysis is done centrally for most of the studies</p>                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>The publications should indicate that they are related to and reference the reporting party.</p>                                                                 |
| <p>3.2</p> <p>Number of competitive grants obtained in the last 5 years</p>                                                                                               | <p>3</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <p>Grants obtained by reporting party (exclusively or not).</p>                                                                                                     |
| <p>3.3</p> <p>Access to expert groups <sup>M</sup></p>                                                                                                                    | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>The PRINTO Chairman is permanently in the Council of the Pediatric Rheumatology European Society (PRES)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>Indicate if the reporting party has specific access to established expert groups, such as learned societies</p>                                                  |
| <p>3.4</p> <p>Capacity to answer external scientific questions <sup>M</sup></p>                                                                                           | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>The entire PRINTO staff (9 people) is working full-time to answer daily scientific questions. In particular, for 6 trials industry sponsored the PRINTO staff is evaluating, independently from company, the primary outcome of the trial. PRINTO staff receive via fax the case report forms related to the primary outcome and provide the assessment directly to the centre (see Ruperto et al Efficacy and safety of abatacept in children with juvenile idiopathic arthritis: A randomized, double-blind, placebo-controlled withdrawal trial. Lancet 2008;372(9636):383-391.)</p> | <p>Indicate if coordinated capacity (staff, process) is available to answer external scientific questions in relation to clinical trials during daily business.</p> |
| <p>Standardized procedures for assessment of:</p>                                                                                                                         | <p>---</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                     |

|                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                           |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| <p>3.5<br/>Site feasibility</p>               | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br/>Comments:<br/>Feasibility is done for every specific study to evaluate the enrollment potential in relation to the inclusion/exclusion criteria. Feasibility is done both for academic studies or after request from a pharmaceutical company</p>                                                                                                                                                                                                                      | <p>This concerns the suitability of a site for conducting a given trial</p>               |
| <p>3.6<br/>Participant recruitment</p>        | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br/>Comments:<br/>Data collection is done entirely by PRINTO online via PRINTO website for academic studies; monitoring for academic studies is done through the use of standardised and validated questionnaires (no local monitoring available). For pharma companies, we monitor the quality of the primary outcome data by receiving the related case report forms via fax; in addition we perform the evaluation of response to therapy on behalf of the company.</p> | <p>This concerns provisions to regularly monitor recruitment progress for a trial.</p>    |
| <p>3.7<br/>Budget calculation for studies</p> | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br/>Comments:<br/>For company sponsored studies PRINTO request centrally to all companies 2 provisions:<br/>1) that the drug is provided for free to all children enrolled until the drug is labelled for the disease in the participating country or is beneficial to the child;<br/>2) a minimum per patient fee, equal for all, is required to be given to all participating centres irrespective of the country of origin</p>                                          | <p>This concerns, for example, quotes and prospective financial planning for a trial.</p> |

## Criterion 4: Quality management

|                                                                                                        |                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.1<br>Documented adherence to Good Clinical Practice (GCP) guideline <sup>M</sup>                     | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>This is valid for studies with pharma industry while for academic studies funding are not sufficient for a proper local monitoring                                                                                                       | Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.                                                                                                                                                                                                                            |
| 4.2<br>Documented adherence to the ethical considerations for clinical trials in children <sup>M</sup> | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>all studies are approved by the local ethics committees according to the law of the participating country                                                                                                                                | Indicate if documented data / information are publicly available on implementation of / provisions for special ethical requirements for the paediatric trial(s) according to the document " <a href="#">Ethical considerations for clinical trials on medicinal products conducted with the paediatric population</a> ". |
| 4.3<br>Documented adherence to ethical considerations                                                  | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>Not all ethics committees have a declared pediatric expertise                                                                                                                                                                            | Declare whether reporting party requests approval by an independent ethics committee with paediatric expertise for all studies conducted.                                                                                                                                                                                |
| 4.4<br>Availability of Standard Operation Procedures (SOP)                                             | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>If yes, provide reference to available SOPs<br>PRINTO is in the process to obtain certification by ISO 9001. SOP are available in-house and they mainly relate to the assessment of response to therapy in JIA on behalf of pharmaceutical industries | Indicate existence of SOP e.g. for study management, adverse events reporting etc.                                                                                                                                                                                                                                       |
| 4.5<br>Capacity to monitor studies (academic trials, industry sponsored trials) <sup>M</sup>           | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>For academic studies monitoring is done through standardised questionnaires (no local monitoring available for funding issues).<br>For pharma sponsored studies GCP monitoring is done by the companies                                  | Indicate if the reporting party implements the monitoring of paediatric trials according to ICH 6 Good Clinical Practice Guideline.                                                                                                                                                                                      |
| 4.6<br>Capacity to monitor performance of collaborating centres                                        | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>Performance is evaluated by the rate of recruitment in collaborative studies                                                                                                                                                             | Indicate if the reporting party implements the monitoring of performance of collaborating centres.                                                                                                                                                                                                                       |

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| <p>4.7</p> <p>Quality control and quality assurance, traceability and data safety <sup>M</sup></p> | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>Quality control for primary outcome assessment for pharma companies is done via fax by receiving related data.</p> <p>For academic studies monitoring for efficacy and safety is done entirely by PRINTO centrally with electronic methods (no local monitoring)</p> | <p>Indicate if this is implemented in the reporting party's remit.</p> |
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## Criterion 5: Training and educational capacity to build competences

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| 5.1<br>Evidence of collaboration with regulatory authorities <sup>M</sup>                     | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>EMA GUIDELINE ON CLINICAL INVESTIGATION OF MEDICINAL PRODUCTS FOR THE TREATMENT OF JUVENILE IDIOPATHIC ARTHRITIS                                                                                            | Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.                                                                                               |
| 5.2<br>Capacity to provide competent consultation to regulatory authorities                   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>EMA required our assistance for some trials                                                                                                                                                                 | Indicate the capacity of the reporting party to provide expert advice to regulatory authorities. For example, nominations into standing scientific committees to regulatory authorities, registration(s) as authorities' external expert(s). |
| 5.3<br>Formal meetings for clinical trials<br>If yes, provide number                          | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>For each pharma company-sponsored trial there is at least one dedicated investigators meeting. For academic studies meeting are done annually at the PRES conference where a PRINTO workshop is always held | For example, investigator meetings, trainings specific to a given ongoing or planned trial.                                                                                                                                                  |
| 5.4<br>Training courses given over the last 2 years <sup>M</sup><br>If yes, provide number    | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>At each investigator meeting PRINTO provides some training (e.g. joint assessment procedures, evaluation of response to therapy)                                                                            | For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party. Minimum requirement (M): training courses either given (5.4) or received (5.5).                                |
| 5.5<br>Training courses received over the last 2 years <sup>M</sup><br>If yes, provide number | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>participation to investigator's meeting and scientific meetings                                                                                                                                             | For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party. Minimum requirement (M): training courses either given (5.4) or received (5.5).                                |

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| <p>5.6</p> <p>Promotion of participation in clinical trials in countries with limited resources</p> <p>Provide list of countries</p> | <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>Latin and Central America, Eastern Europe, India</p> | <p>Indicate if support for such trials is provided by the reporting party.</p> |
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## Criterion 6: Public involvement <sup>M</sup>

Minimum requirement (M): involvement in at least one of the below items.

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| 6.1<br>Involvement of patients, parents or their organisations in the protocol design                                         | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>Comments:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Indicate if public stakeholders are /have been involved |
| 6.2<br>Involvement of patients, parents or their organisations in creating the protocol information package                   | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>Comments:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Indicate if public stakeholders are /have been involved |
| 6.3<br>Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>Comments:<br>Patient's and parent's organisations have been identified through a specific project funded by the European Union that allowed the creation of a website for families available on more than 50 languages ( <a href="http://www.pediatric-rheumatology.printo.it">www.pediatric-rheumatology.printo.it</a> ). The website provides information on pediatric rheumatic diseases, the list of pediatric rheumatology centres and the list of family help association.<br>In addition, organisations are invited to attend the annual PRINTO workshop held each year at the PRES scientific meeting | Indicate if public stakeholders are /have been involved |