



Mail - In: 147544

Date of receipt: 27/05/2011

B: _____

L: _____



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

Declaration on compliance with the ENCePP Code of Conduct for ENCePP Studies¹

The (primary) lead investigator and a person authorised to sign on behalf of the coordinating study entity hereby declare for the purpose of conducting the study "Long-term PHARMacovigilance for Adverse effects in Childhood arthritis focusing on Immune modulatory drugs" (project number 260353).

- to follow the rules and principles for the independent and transparent conduct of pharmacoepidemiological and pharmacovigilance studies of the ENCePP Code of Conduct adopted on 19 / 3 / 2010;
- to inform the ENCePP Secretariat, without delay, of any change or decision to change that constitutes a deviation from the provisions of this Code.

It is of note that the (primary) lead investigator and the person authorised to sign on behalf of the coordinating study entity may be identical.

Name of (primary) lead investigator:

Nico Wulfraat, MD, PhD, Nicolino Ruperto, MD, MPH

Date: 10 / 5 / 2011 (xx/yy/zzzz)

Stamp (if applicable) and signature:



Name of the coordinating study entity: Pediatric Rheumatology International Trials Organisation (PRINTO) at IRCCS G. Gaslini, Genoa, Italy

Address:

Pediatria II, Reumatologia, PRINTO

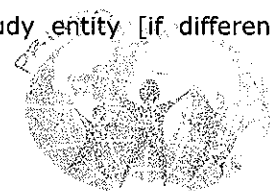
Via Gaslini, 5, 16147 Genoa (Italy)

Pediatric Rheumatology International Trials Organisation
IRCCS G. Gaslini
Pediatria II
Largo Gaslini 5
16147 - Genova - ITALY

Name of person authorised to sign on behalf of the coordinating study entity [if different from (primary) lead investigator]:

Date: 10 / 5 / 2011 (xx/yy/zzzz)

Stamp (if applicable) and signature:



Pediatric Rheumatology International Trials Organisation
IRCCS G. Gaslini
Pediatria II
Largo Gaslini 5
16147 - Genova - ITALY

The (primary) lead investigator should also mark the date the Checklist of the ENCePP Code of Conduct for ENCePP Studies.

Universitair Medisch Centrum Utrecht
Wilhelmina Kinderziekenhuis
Divisie Kinderen
Huispostnr. KB.03 023.3
Postbus 85090
3508 AB Utrecht



¹ Complete the declaration on screen, then print, stamp (if applicable) and sign.