ITALY[i]

a) Laws governing clinical trials

- Law n. 189 of November 8th 2012 on urgent actions to safeguard health
- Ministerial Decree 21st December 2007 - Directions for submitting the request for authorisation of a clinical trial on a medicinal product for human use to the Competent Authority, for communicating substantial amendments, for declaring the end of the trial and for the request of an opinion to the Ethics Committee
- Ministerial Decree of November 6 2007: "Transposition of Directive 2005/28/EC relating to principles and guidelines for good clinical practice for medicines in experimental phase for human use, and requirements for the authorization to produce and to import these medicines"
- Ministerial Decree of May 12, 2006 "Minimum requirements for the institution, organization and functioning of Ethical Committee for clinical trials with medicines"
- Ministerial Decree of December 17, 2004 "Prescriptions and conditions of a general nature referring to the conduct of clinical trials of medicines with special reference to those designed to enhance clinical practice as an integral part of health and medical care"
- Legislative Decree no. 211 of June 24, 2003 "Transposition of Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for clinical use"
- Decree of the President of the Republic of September 21, 2001 "Regulations to simplify the Procedures and to Verify and Check New Systems and Experimental Therapeutic Protocols"
- Ministerial Decree of May 10, 2001 "Controlled clinical trials conducted by General Practitioners and Paediatricians".

b) Ad hoc provisions for paediatric trials

- Article 4 Directive 2001/20/EC implemented
- Usually both parents must give the consent. Assent is usually required.
- The Ministerial Decree 14/07/2009 establishes that for clinical trials involving children, the minimum period of tail coverage for the risk is at least 10 years from completion of the clinical trial; this being the minimum time required to ascertain their regular psychophysical development.

c) Ethics Committees / National Competent Authority

- Local or Regional Ethics Committees
- Italian Medicine Agency (AIFA) - Competent Authority

d) Paper or electronic application / existence of a national website Electronic application on the (new) national website (as soon as available). The sponsor has to be subscribed in the national database by filling in the form here.
e) Procedures for compiling the EU CTA form (e.g. from EudraCT or from the national database) The EU CTA form to be completed from the national website (and then transferred to EudraCT directly by the Italian Agency) only if the new national database will be available.
f) Requested documents to be submitted Documents to be submitted to the Coordinator Ethics Committee (list 1a) and to the satellite Ethics Committees (list 1B) are detailed at the end of the format of the Italian CTA form, as required by the Ministerial Decree 21/12/2007. For no profit trials, special requirements from Ministerial Decree 17/12/2004 are needed to be complied with.

SOURCES:

- Italian Medicines Agency website (www.agenziafarmaco.gov.it)
- Portal of Clinical Research with Medicines in Italy (https://www.agenziafarmaco.gov.it/ricclin/en/RegistrazionePromotore_eng)

[i] *This document has been prepared by TEDDY Network as part of its research activity. Information have been derived by questionnaires filled in by researchers and from official national databases where available. It does not replace the official data that can be accessed directly or are provided at the experimental site.*
The material cannot be distributed nor re-utilised without acquiring a specific preliminary consent from the Network.