THE NETHERLANDS[i]

a) Laws governing clinical trials

- Dutch Medicines Act (Geneesmiddelenwet)
- Medical Research Involving Human Subjects Act (WMO)
- Code of conduct relating to expressions of objection by minors participating in medical research
- GCP-NL

b) Ad hoc provisions for paediatric trials

- Article 4 Directive 2001/20/EC implemented
- Both parents must give the consent. Children 12 years older should sign as well.

c) Ethics Committees / National Competent Authority

- Twenty-seven Medical Research Ethics Committees (METCs)
- Central Committee on Research Involving Human Subjects (CCMO) - Competent Authority

d) Paper or electronic application / existence of a national website

Both paper and electronic format accepted[1].
No national databases.

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 EudraCT.

f) Requested documents to be submitted

Documents to be submitted available on CCMO website at the following page http://www.ccmo.nl/en/standard-research-file.

SOURCES: CCMO website (www.ccmo.nl).

[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.*

[1] It is required to submit the cover letter in hard copy http://www.ccmo.nl/en/digital-or-hard-copy. For CCMO application, digital files are preferred http://www.ccmo.nl/en/primary-submission?51d2da24-13e8-4f4c-937e-4096525ed690