CZECH REPUBLICH[i]

a)	**Laws governing clinical trials** - Act on Pharmaceuticals (Act No 378/2007 Coll.) - Decree on good clinical practice and detailed conditions of clinical trials on medicinal products (Decree No 226/2008 Coll.)
b)	**Ad hoc provisions for paediatric trials** - No regulatory specifics for paediatric trials.
c)	**Ethics Committees / National Competent Authority** - Local Ethics Committees - SÚKL (State Institute of Drug Control)
d)	**Paper or electronic application / existence of a national website** Paper and electronic submission.
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 are available at http://www.sukl.eu/medicines/klh-20-version-5

SOURCES: National Agency website (http://www.sukl.eu/medicines/klh-20-version-5?lang=2).

[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.*