

# **D1\_\_Protocol Synopsis Placeholder 2023-543210-11-00\_\_v1.00**

## **About this document**

This document is not required as part of the transfer from the regulatory framework of the Clinical Trials Directive 2001/20/EC to the Clinical Trials Regulation No. 536/2014, following the instructions in Section 11 Transitional arrangements of the CTR (EU) No. 536/2014 Questions and Answers document latest version.

Specifically, this aspect was assessed by National Competent Authority and/or Research Ethics Committee and is therefore covered by the conclusion of the original assessment under the Clinical Trials Directive.