

Medical Research Agency

<https://www.abm.gov.pl/en/polish-clinical-trials-network/clinical-trials-support-centre/ctsc-model-standard/237,CTSC-Model-Standard.html>
29.04.2024, 12:57

CTSC Model Standard

The CTSC Model Standard is intended for Applicants and Beneficiaries of competitions for the establishment and development of CTSCs announced by the Medical Research Agency and for entities wishing to become members of the Polish Clinical Trials Network (PCTN). Applicants and Beneficiaries are primarily required to comply with detailed legal regulations, ICH GCP and the Declaration of Helsinki. These guidelines address minimum requirements, with the Applicant and Beneficiary required to provide resources appropriate to the level of complexity, risk and characteristics of the research appropriate to its operations.

CTSCs are required to implement uniform systemic quality and process solutions to standardize the conduct of clinical trials. The purpose of the document is to indicate the minimum requirements, optimal criteria and guidelines for the use of funds in the implementation of projects for the establishment and development of MRA-funded CTSC..

In 2023 the standard was updated to version 2.0 and adapted to the changes that have taken place in recent years in the Polish market due to the COVID-19 pandemic and the economic situation.

Downloads

[Modelowy Standard CWBK 2.0 pdf, 609.65 KB, 20.10.2023](#)

[Załącznik nr 1 do Standardu_CWBK ABM-2020-3 pdf, 143.96 KB, 20.10.2023](#)

[Załącznik nr 1 do Standardu_CWBK ABM-2021-4 pdf, 144.68 KB, 20.10.2023](#)

[Załącznik nr 1 do Standardu_OnkoCWBK ABM-2021-6 pdf, 227.23 KB, 20.10.2023](#)