Supreme Bioethics Committee

Please specify in the title of the transfer the indications given in the following tables - last column "Transfer title required" (instead of trial number please enter EU CT number)

Clinical trial (CT)		Fee amount to the Medical Research Agency account*	Required transfer title
phase I–III commercial clinical trail	1 The Republic of Poland acts as rapporteur	15 000,00 PLN	CT_1_EU trial number
	2 The Republic of Poland does not act as rapporteur		CT_2_EU trial number
	3 based on Art. 14 of Regulation 536/2014		CT_3_EU trial number
phase IV clinical trail	4 The Republic of Poland acts as rapporteur		CT_4_EU trial number
	5 The Republic of Poland does not act as rapporteur		CT_5_EU trial number
	6 based on Art. 14 of Regulation 536/2014		CT_6_EU trial number
non-commercial clinical trail	7 The Republic of Poland acts as rapporteur	4 000,00 PLN	CT_7_EU trial number
	8 The Republic of Poland does not act as rapporteur		CT_8_EU trial number
	9 based on Art. 14 of Regulation 536/2014		CT_9_EU trial number

Substantial modification (SM)		Fee amount to the Medical Research Agency account*	Required transfer title**
substantial modification to the clinical trial in the aspect covered by Part I of the clinical trial ethical assessment report	1 The Republic of Poland acts as rapporteur	5 000,00 PLN	SM_1_EU trial number
	2 The Republic of Poland does not act as rapporteur		SM_2_EU trial number
substantial modification to the clinical trial in the aspect covered by Part II of the clinical trial ethical assessment report	3		SM_3_EU trial number
substantial modification to the clinical trial in the aspect covered by Part I of the clinical trial ethical assessment report and the substantial modification to the clinical trial in the aspect covered by Part II of the clinical trial ethical	4 The Republic of Poland acts as rapporteur		SM_4_EU trial number
	5 The Republic of Poland does not act as rapporteur		SM_5_EU trial number
the same substantial modification to more than one clinical trial protocol in the aspect covered by Part I of the clinical trial evaluation report (in accordance with Article 17 of Regulation 536/2014)	6 modification in the first clinical trail	100% amendment fee	SM_6_EU trial number
	7 modification in each subsequent study	50% of the amount of the fee for the modification in the first clinical trial	SM_7_EU trial number

**The amount of the fees referred to in paragraph. 1 Art. 58 of the ACT of March 9, 2023 on clinical trials on medicinal products for human use, is subject to indexation every 5 years to the extent corresponding to the consumer goods and services price index total for the previous 5 years, calculated on the basis of average annual consumer goods and services price index, announced by the President of Statistics Poland on the basis of the regulations on retirement and disability pensions from the Social Insurance Fund, rounded up to whole zlotys.*

** In accordance with Art. 58 of the ACT of March 9, 2023 on clinical trials on medicinal products for human use Fees due for submission of different applications are paid separately.