Medicinal Products for Human use	Poland
Competent Authority	
Submission Fees	
Fees for trial submission mandatory	Yes
Fees	Phase I-III, commercial clinical trials • The Republic of Poland acts as a repporteur: 15 000 PLN (approx. 3 750 EUR) • The Republic of Poland does not act as a repporteur: 10 000 PLN (approx. 2 500 EUR) • based on Article. 14 of Regulation 536/2014: 10 000 PLN (approx. 2 500 EUR) Phase IV • The Republic of Poland acts as a repporteur: 10 000 PLN (approx. 2 500 EUR) • The Republic of Poland does not act as a repporteur: 6 000 PLN (approx. 2 500 EUR) • based on Article. 14 of Regulation 536/2014: 6 000 PLN (approx. 1 500 EUR) Non-commercial clinical trials • The Republic of Poland acts as a repporteur: 4 000 PLN (approx. 1 000 EUR) • The Republic of Poland does not act as a repporteur: 2 000 PLN (approx. 500 EUR) • based on Article. 14 of Regulation 536/2014: 2 000 PLN (approx. 500 EUR)
Waiver for academic (non-commercial) studies possible	Reduced fees are charged
Payment requirements (timelines)	Prior to submission of application
Official guidance on required fees available	Yes
Official guidance on required fees	Current fees are provided in English on the URPL website in section: Fees. (https://www.urpl.gov.pl/pl/op%C5%82aty)
National legal framework in place	Yes
Applicable national legal framework/reference	Act of 9 March 2023 on clinical trials of medicinal products for human use (Dz.U. 2023 poz. 605 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20230000605/O/D20230605.pdf)
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	President of the Office is a government administrative authority, competent for matters concerning marketing authorization of medicinal products and clinical trials – within the scope determined by the Act on Pharmaceutical Law of 6 September 2001 (Dz.U. 2001 nr 126 poz. 1381 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20011261381/U/D20011381Lj.pdf) The Office is a public administration body supporting the President of the Office in realization of the above matters. The rules and the scope of responsibilities is determined by the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Dz.U. 2011 nr 82 poz. 451 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20110820451/U/D20110451Lj.pdf)
Ethics Committee	
Submission Fees	

Medicinal Products for Human use	Poland
Fees for ethical review mandatory	Yes
Waiver for academic (non-commercial) studies possible	Reduced fees are charged
Fees for ethical review	Phase I-III, commercial clinical trials • The Republic of Poland acts as a repporteur: 15 000 PLN (approx. 3 750 EUR) • The Republic of Poland does not act as a repporteur: 15 000 PLN (approx. 3 750 EUR) • based on Article. 14 of Regulation 536/2014: 15 000 PLN (approx. 3 750 EUR) Phase IV • The Republic of Poland acts as a repporteur: 15 000 PLN (approx. 3 750 EUR) • The Republic of Poland does not act as a repporteur: 15 000 PLN (approx. 3 750 EUR) • based on Article. 14 of Regulation 536/2014: 15 000 PLN (approx. 3 750 EUR) Non-commercial clinical trials • The Republic of Poland acts as a repporteur: 4 000 PLN (approx. 1 000 EUR) • The Republic of Poland does not act as a repporteur: 4 000 PLN (approx. 1 000 EUR) • based on Article. 14 of Regulation 536/2014: 4 000 PLN (approx. 1 000 EUR)
Official guidance on required fees available	Yes
Official guidance on required fees	Current fees are provided in English on the Supreme Bioethics Committee website in section: For sponsors. (https://nkb.gov.pl/?serwis=sbc&dzial=for-sponsors/application-fees&id=233)
National legal framework in place	Yes
Applicable national legal framework/reference	Act of 9 March 2023 on clinical trials of medicinal products for human use (Dz.U. 2023 poz. 605 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20230000605/O/D20230605.pdf)
Additional information	
Additional Information & Specifics	
Additional Information & Specifics	

Study Specific Requirements

Study participants - informed consent	
Standard IC form (ICF) available	Not specified
Standard IC form (ICF)	
Standard ICF - Additional Information	
IC is regulated by law	Yes
Informed Consent - Definition/ Requirements	Definition in accordance with Regulation 526/2013. Prior to the commencement of a clinical trial, informed consent must be obtained from study subjects. Informed consent means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial.

Medicinal Products for Human use	Poland
National legal framework in place	Yes
Applicable national legal framework/ Reference	Act of 9 March 2023 on clinical trials of medicinal products for human use (Dz.U. 2023 poz. 605 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20230000605/O/D20230605.pdf) Act of 5 December 1996 on proffesion's of physician and dentis, Article 25 (Dz.U. 1997 nr 28 poz. 152 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU19970280152/U/D19970152Lj.pdf)
Additional Information	
Study participants - vulnerable population	
Minors / Children - Studies allowed	Yes Special provisions apply
Specific provision	Legal Act (for editing - no possibility of entering longer text)
Legal framework/Reference (Minors/Children)	Act of 5 December 1996 on proffesion's of physician and dentis, Article 25 (Dz.U. 1997 nr 28 poz. 152 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU19970280152/U/D19970152Lj.pdf)
Incapacitated persons - Studies allowed	Yes Special provisions apply
Specific provisions	It is prohibited to conduct a research experiment on an incapacitated person. The consent of a person who is completely incapacitated to participate in a therapeutic experiment shall be given by his or her legal guardian. If the totally incapacitated person has sufficient understanding, his or her consent shall also be required.
Legal framework / Reference (Incapacitated persons)	Act of 5 December 1996 on proffesion's of physician and dentis, Article 25 (Dz.U. 1997 nr 28 poz. 152 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU19970280152/U/D19970152Lj.pdf)
Emergency situations - Studies allowed	No national legal framework available
Specific provisions	
Emergency situation without prior consent of patient or proxy - Studies allowed	Yes Special provisions apply
Conditions allowing trial participation in emergency setting without prior consent	In the case of a participant who is a person with full legal capacity but lacking the ability of mental judgement to give consent, authorisation to conduct the therapeutic experiment shall be given by the guardianship court with territorial jurisdiction in the area where the experiment is to be conducted.
Legal framework / Reference (Emergency Situation)	Act of 5 December 1996 on proffesion's of physician and dentis, Article 25 (Dz.U. 1997 nr 28 poz. 152)
Pregnant or breastfeeding women - Studies allowed	No national legal framework available
Specific provisions	
Legal framework / Reference (Pregnant or breastfeeding women)	
Study participants - compensation & reimbursement	

Medicinal Products for Human use	Poland
Reimbursement for study participants	Optional
Compensation is limited to/provided for	Expenses arising from study participation (e.g. Travel)
Additional Information	No specific provisions in national legislation
Data protection	
Notification to DP Authority/ Ombudsmann is mandatory	No
Approval/authorisation required	No
Specific notification timelines before operations start	Not applicable
Laguage of notification	Not applicable
Notification format	Not applicable
Notification fee required	No
Fee	
Guidance on notification requirements available	No
Guidance on notification requirements	
Data protection authority/agency - contact details	The President of the Personal Data Protection Office
Contact name 2	Robert Miętkowski - the Data Protection Officer (iod@uodo.gov.pl)
Contact name 3	
Phone	+48 22 532 82 50
Fax	
E-mail	kancelaria@uodo.gov.pl
Web address	https://uodo.gov.pl/pl
Address	ul. Stawki 2, 00-193 Warszawa
ZIP/City	00-193 Warszawa
Country	Poland
Additional information	
Insurance	

Medicinal Products for Human use	Poland
Liability insurance or alternative arrangements for damages mandatory for	Investigator(s) Sponsor
Responsible for covering insurance	Sponsor
Isurance fee: a minimum coverage sum is defined	Yes
Minimim coverage sum	The minimum guarantee sum of civil liability insurance, depends on the number of participants in the clinical trial and is the equivalent in PLN of: • up to 50 participants - EUR 2,000,000; • over 50 persons - 5,000,000 euros.
National legal framework/reference	Yes
Applicable national legal framework/reference	Act of 9 March 2023 on clinical trials of medicinal products for human use (Dz.U. 2023 poz. 605 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20230000605/O/D20230605.pdf)
Additional information	
National legislations	
General Information	
Official governmental legal database available	Yes
Official governmental legal database	ISAP (Internetowy System Aktów Prawnych, ang. The Internet System of Legal Acts), Online Database system of legal acts containing bibliographic and legal texts published in official publications (the Journal of Laws and the Polish Monitor) issued by the Prime Minister - https://isap.sejm.gov.pl/
Additional information	
Clinical trials on IMPs in Humans	
Applicable national regulations	General Act(s) on Medical/Clinical Research in Humans
Radiation & Radiotherapy	
Specific framework available	Yes
Applicable legal framework	Regulation of the Minister of Health of 11 January 2023 on the conditions for the safe use of ionising radiation for all types of medical exposure (Dz.U. 2023 poz. 195 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20230000195/O/D20230195.pdf) Act of 29 November 2000 on Nuclear Law (Dz.U. 2001 nr 3 poz. 18 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20010030018/U/D20010018Lj.pdf) Act of 6 September 2001 on Pharmaceutical Law (Dz.U. 2001 nr 126 poz. 1381 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20011261381/U/D20011381Lj.pdf)
Additional information	
Biobanking	

Medicinal Products for Human use	Poland
Specific framework available	No
Applicable legal framework	
Additional information	
Additional Information & Specifics	
Additional Information & Specifics	
Definitions	
Observational study	
Observational study - Definition available in national law	No
Observational study - Definition	
Academic sponsors	
Academic Sponsors - Definition available in national law	Yes
Academic Sponsors - Definition	Based on the Act of 9 March 2023 on clinical trials of medicinal products for human use (Dz.U. 2023 poz. 605 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20230000605/O/D20230605.pdf), the Sponsor or co-sponsor of clinical trials is: • an entity reffered to in Article 7 of the Act of 20 July 2018 - Law on Hihger education and Science (Dz.U. 2022 poz. 574 -https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20180001668/U/D20181668Lj.pdf), or • an therapeutic entity reffered to in Article 4(1) of the Act of 15 April 2011 on therapeutic activity (Dz.U. 2022 poz. 633 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20111120654/U/D20110654Lj.pdf), or • Investigator, or • an association whose statutory objective is to protect patients' rights, or • an association which is, in accordance with the provisions of its statutes, a scientific society of national scope, associating specialists in the relevant field of medicine, the field of nursing or the field of obstetrics, or • a legal person or an organisational entity other than those referred to in points (a) to (e) whose purpose is not to make a profit by conducting and organising clinical trials or by manufacturing or marketing medicinal products.