Medicinal Products for Human use	Greece
Competent Authority	
Submission Fees	
Fees for trial submission mandatory	Yes
Fees	Initial submission of Interventional Commercial Study: 3.000€ Amendment of Interventional Commercial Study: 1.500€ Initial submission of Interventional Non-Commercial Study: 1.500€ Amendment of Interventional Non-Commercial Study: 750€ All the above fees are subject to an additional fee of 2,4%
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	https://www.eof.gr/web/guest/clinical/interventional
National legal framework in place	Yes
Applicable national legal framework/reference	https://www.eof.gr/web/guest/newya
Additional information	Regarding the submission to the Competent Authority (EOF) the following items may be provided in the English language only on the first day (D0) of each CTIS submission: 1. Cover letter 2. Protocol (incl. Patient facing documents as part of the protocol) 3. Application form. However, Greek translations will be requested during Validation/Assessment.
Additional Information & Specifics	
Additional Information & Specifics	N/A
Ethics Committee	
Submission Fees	
Fees for ethical review mandatory	No
Waiver for academic (non-commercial) studies possible	Not applicable
Fees for ethical review	N/A
Official guidance on required fees available	Yes
Official guidance on required fees	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	https://www.eof.gr/web/guest/eed? p_p_id=62_INSTANCE_PpP6&p_p_lifecycle=0&p_p_state=maximized&p_p_mode=view&_62_INSTANCE_PpP6_struts_action=%2Fjournal_articles%2Fview&_62_INSTANC
Additional information	Guidance on submission folders: https://www.eof.gr/web/guest/eed;jsessionid=96aee495b389cc8f45d2cbf2fe49? p_p_id=62_INSTANCE_PpP6&p_p_lifecycle=0&p_p_state=maximized&p_p_mode=view&_62_INSTANCE_PpP6_struts_action=%2Fjournal_articles%2Fview&_62_INSTANC
Additional Information & Specifics	
Additional Information & Specifics	https://www.eof.gr/web/guest/eed
Study Specific Requirements	
Study participants - informed consent	
Standard IC form (ICF) available	Not specified
Standard IC form (ICF)	N/A
Standard ICF - Additional Information	N/A
IC is regulated by law	Yes
Informed Consent - Definition/ Requirements	The informed consent of the participant, or of the legal representative of the participant, should be in writing, dated and signed by them. Prior to the signature of the informed c inform the future participant orally and in simple and understandable language about 1. the nature of the study, its targets, the benefits, the consequences, the possible dange and their right to withdraw from the clinical trial, 3. all the conditions under which the trial is taking place. The participant should be in position to make any questions they wish.
National legal framework in place	Yes

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Applicable national legal framework/ Reference	FEK B' 4131/22.12.2016 article 9
Additional Information	N/A
Study participants - vulnerable population	
Minors / Children - Studies allowed	Yes Special provisions apply
Specific provision	Minors(above 10 years old) must give their written consent. Both their legal guardians must give written and signed consent.
Legal framework/Reference (Minors/Children)	FEK B' 4131/22.12.2016 article 10 (a)
Incapacitated persons - Studies allowed	
Specific provisions	**Incapacitated persons must be fully informed about the study and understand all the dangers and benefits of participating. Both incapacitated persons and their l**
Legal framework / Reference (Incapacitated persons)	FEK B' 4131/22.12.2016 article 10 (b)
Emergency situations - Studies allowed	
Specific provisions	Studies are allowed only when the husband, partner or the closest ascendant or descendant relative of the patient give their consent.
Emergency situation without prior consent of patient or proxy - Studies allowed	No
Conditions allowing trial participation in emergency setting without prior consent	N/A
Legal framework / Reference (Emergency Situation)	FEK B' 4131/22.12.2016 article 12
Pregnant or breastfeeding women - Studies allowed	Yes Special provisions apply
Specific provisions	According to article 33 of Regulation (EU) No 536/2014
Legal framework / Reference (Pregnant or breastfeeding women)	No national legal framework
Study participants - compensation & reimbursement	
Reimbursement for study participants	Mandatory
Compensation is limited to/provided for	Expenses arising from study participation (e.g. Travel) Expenses (e.g. transportation, meals, and others such as salary lost)
Additional Information	The Sponsor compensates: -the emergency transportation expenses from and to the sites -the travel expenses of the participants for the conduct of special medical examinations to medical centers, which are chosen by the Sponsor -in case of adverse event during the study. All the above are valid even if they not written in the informed consent, which are signed by the participants, and even if they are not questioned and/or commented by the Cor
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	N/A
Guidance on notification requirements available	N/A
Guidance on notification requirements	N/A
Data protection authority/agency - contact details	Hellenic Data Protection Authority

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Contact name 2	
Contact name 3	N/A
Phone	+30 210 6475 600
Fax	+30 210 6475 628
E-mail	contact@dpa.gr
Web address	http://www.dpa.gr/
Address	Kifisias Av. 1-3 Ampelokipi Athens
ZIP/City	11523
Country	Greece
Additional information	According to the applicable law the sponsor should have implemented document(s), such as a data transfer agreement or other agreement, which ensure that the personal da such agreement, the applicant shall state the reason and may predict for a specific patient consent for the transfer of the data, under the condition that the ICF will include exp (which must be named). The use of the document “Statement of compliance with Regulation (EU) 2016/679 (GDPR)", which has been uploaded at Eudralex Vol. 10, Chapter Additionally, as per the clinical trial contract template which is regulated in FEK 2015/3-6-2019, the contracted members of the clinical investigation acknowledge the EE regul and 3471/2006.
Insurance	
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	300.000€ per participant
National legal framework/reference	Yes
Applicable national legal framework/reference	FEK B' 4131/22.12.2016 article 15
Additional information	The sponsor has to contract insurance for the liability coverage of the sponsor, the PI and the study team members. The coverage sum for all clinical studies taking place in th work which will result from the participation in the clinical study. Additionally, all expenses for the below cases are covered bythe Sponsor: 1. urgent transfers of the participants to the study sites for security reasons 2. transfers of the participants for the conduct of special medical examinations which are needed for the study 3. all medical examinations in case of adverse events.
National legislations	
General Information	
Official governmental legal database available	Yes
Official governmental legal database	1. www.et.gr 2. www.eof.gr
Additional information	1. The National Printing House is the public service for the dissemination of Greek law and all national regulations can be found in the website in digital format. 2. The National Organisation for Medicines (EOF) is a public entity of the Ministry of Health and its objective is to ensure public health and safety. All national regulations abou
Clinical trials on IMPs in Humans	
Applicable national regulations	National Act on Medicinal Products
Radiation & Radiotherapy	
Specific framework available	No
Applicable legal framework	N/A
Additional information	ACCORDING TO 536: The sponsor should include information on exposure to ionising radiation in the protocol in order to allow assessment of the benefits and risks of the clinical trial. Exposure to r - Radiodiagnostic procedures: the risks and inconveniences for the trial subjects regarding interventions involving radiation exposure should be justified in comparison to the e clarified in the protocol: maximum effective dose per procedure , number of procedures per trial participant per year, and estimated number of additional radiodiagnostic proce - Radiotherapeutic procedures: systemic radiation therapies with radiopharmaceuticals. The sponsor should include in the protocol 1. a benefit/risk section and 2. a descriptior the best available evidence.
Biobanking	
Specific framework available	No
Applicable legal framework	No national legal framework available on Biobanking.
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	N/A

Medicinal Products for Human use	Greece
Definitions	
Observational study	
Observational study - Definition available in national law	Yes
Observational study - Definition	FEK B' 4131/22.12.2016 article 23 **The observational studies must meet the following conditions:** **-the drug or drugs are prescribed as usual, according to the conditions provided in the marketing authorization** **-the inclusion in the specific treatment strategy is not decided a priori by a study protocol, but it is determined by the current medical practice** **-the decision to administrate the medicinal product is clearly separated from the decision to enroll the patient in the study** **-no additional procedures (diagnostic or follow up) are applied to the patients** **-epidemiological methods are applied for the analysis of the collected data**
Academic sponsors	
Academic Sponsors - Definition available in national law	Yes
Academic Sponsors - Definition	The clinical study which is conducted by investigators without the participation of a pharmaceutical company and it has all the following characteristics: -The sponsor is a university, hospital, public scientific body, non-profit organization, patient organization or individual investigator, who does not act,**directly or indirectly,** on b -The ownership of data of the research belongs to the Sponsor from the beginning of the trial. -The planning, the conduct, the collection, the recording of data and the results of the clinical study as well as the communication is under the exclusive responsibility and the -These clinical studies cannot be part of the development program for the issuance of marketing authorization of one pharmaceutical product (original approval, amendment or -Any third party provision or agreement between sponsor/ investigator and third party regarding the investigational medical product administration, the cover of medical examir future assignment of the study results, or license of use or exploitation of the ethical and intellectual property rights of the sponsor.