



PREPARE

Platform for European Preparedness Against (Re-) Emerging Epidemics

EARL: Ethical, Administrative, Regulatory and Logistical solutions

REPORT PART B: APPENDIX

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June 2014

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AUSTRIA

Total Population: 8.43 Million

Languages: German

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 73.6%, Protestant 4.7%, Muslim 4.2%, other 3.5%, unspecified 2%, none 12% (2001 census)

Urban population: 68% of total population (2010)

Life expectancy at birth: 80.17 years (male: 77.25 years, female: 83.24 years)

Health expenditures: 10.6% of GDP (2011)

Physicians density: 4.86 physicians/1,000 population (2010)

Hospital bed density: 7.6 beds/1,000 population (2010)



Health System

Primary care system

A fundamental characteristic of the Austrian health-care system is that all members of the population have relatively unrestricted access to all levels of care (GPs, specialists and hospitals). Patients can choose between single-person practices, hospital outpatient clinics, free-standing outpatient clinics and, group practices. An exact division between primary care and secondary care is not possible, as hospital outpatient clinics also play an important role in primary care provision. Treatment by specialist physicians is available at individual practices as well as at free-standing and hospital-based outpatient clinics.

Social insurance is the most important source of health care funding. Out-patient care is almost entirely financed by social health insurance funds. Expenditure for in-patient care is shared between the public sector and social insurance. Long-term care services are mostly funded through taxes.

Source: Health system in Transition 2013

http://www.euro.who.int/_data/assets/pdf_file/0017/233414/HiT-Austria.pdf

Acute hospital system

For inpatient care standard (basic secondary care services) and specialist (eg. orthopaedic surgery) hospitals as well as highly developed “central” (full secondary and tertiary services, eg. university) hospitals are available.

Source: Health system in Transition 2013

http://www.euro.who.int/_data/assets/pdf_file/0017/233414/HiT-Austria.pdf

Public health agency

Name of public health agency

Ministry of Health, Family and Youth (BMGFJ) (Need to confirm)

Website of public health agency

<http://bmg.gv.at/>

Contact details of public health agency

Federal Ministry of Health - Radetzky Straße 2 - 1030 Wien - Phone: +43-1/711 00-0

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

Austrian Federal Office for Safety in Health Care (BASG)/ Austrian Medicines and Medical Devices Agency (AGES Medizinmarkaufsicht) is the competent authority in Austria.

Website of competent authority

<http://www.basg.gv.at/>

Contact Address of competent authority

Federal Office for the Safety in Health Care (BASG)

Traisengasse 5 | 1200 Vienna

Tel. international: +43 (0)50 555-36111

Email: clinicaltrials@ages.at

Application process of clinical trial approval

The clinical trial application has to be submitted in proper (“valid”) form by the sponsor. The assessment of formal completeness of the application is the first action taken by the CA. The subsequent date of the “clock start” for the 35 (calendar-) day scientific assessment period is noted in the confirmation of formal completeness, which is sent to the sponsor (or named representative) by FAX or e-mail. Should the dossier be incomplete, additionally required information will be requested by phone or e-mail. The dossier is only considered complete (“validated”) upon receipt of the lacking information or the required formal corrections (xml).

Further details on application for the submission and conduct of a Clinical Trial according to § 40 AMG (Arzneimittelgesetz = Austrian Medicinal Product Act, as amended) is available here

<http://www.basg.gv.at/en/medicines/before-authorisation/clinical-trials/>

Time line for approval process

The clinical trial application can be considered as approved if the BASG has not communicated an objection within 35 days after this date (silent approval) or if the decision on the procedure has been published earlier than 35 days on the BASG website

Process for fast track approvals during epidemics/pandemics

No available process for fast track approvals

Ethics Committees

Structure and configuration of Ethics committees

There are three Medical Universities, and an estimated 26 (research) ethics committees in Austria. Under a Federal Act on University Organizations ethics committees are required to review all applied medical research on humans including those that do not specifically include drugs, medical devices, or the application of new medical methods. Ethics committee are usually set up by the local institution (such as the hospital) that normally recruits for research. Additionally the province authorities have to establish (research) ethics committees for clinical trials in institutions outside of hospitals. This applies to clinical trials with drugs as well as to clinical trials with medical devices and methods. The Austrian Drug Regulatory Authority (Bundesamt für Sicherheit im Gesundheitswesen) is the supervising authority.

Ethics Application/Approval process

The initiation of a clinical trial requires a positive vote of the ethics committee (EC) concerned. Opinion of a single Austrian lead-ethics committee is sufficient for multicentre trials (§ 41b AMG). Opinion of a local ethics committee is sufficient for monocentric trials (monocentric worldwide).

The application to the ethics committee can be submitted prior to or simultaneously with the application to the BASG, but not following thereafter. The date of submission needs to be stated in the cover letter as well as in the application form (section H). If already available at the time of submission to the BASG, the vote of the ethics committee (EC) should be included in the clinical trial dossier. Should the EC not come to a positive conclusion on the trial (i.e. a negative vote) the clinical trial application will be refused by BASG.

Further information is available at the website of the Forum of Austrian Ethics committees:

<http://www.ethikkommissionen.at>

Ethics: Fast-track approval available?

No

Ethics: Pre-approval of study protocol available?

No

Ethics: Waived consent?

No

Fast-track application process for ethical approval

Not available

Contact Details of Ethics committees

Contact details of ethics committees in Austria is available here

<http://www.medunigraz.at/ethikkommission/Forum/Mitglieder/index.htm>

Local ethics committees: www.ethikkommissionen.at

Website addresses of ethics committees

Website addresses of ethics committees in Austria is available here

<http://www.medunigraz.at/ethikkommission/Forum/Mitglieder/index.htm>

Website links to ethics application forms

See the link <http://www.medunigraz.at/ethikkommission/Forum/Mitglieder/index.htm>

Website links to meeting time tables

See the link <http://www.medunigraz.at/ethikkommission/Forum/Mitglieder/index.htm>

Ethical approval timeline

For multi-site research the Committee must normally decide within 35 days, with only one “clock stop” permitted. Clinical trials regarding gene therapy, somatic cell therapy including xenogene cell therapy as well as including all drugs with genetically altered organisms, is 90 days. The timelines for clinical trials including medical devices are 60 days.

Ethical approval application Fees

Fees may apply, but are normally be waived, for academic research applications.

For single site clinical trials, as well as for multi-site clinical trials with only one center in Austria: €1.500.

For multi-site clinical trials (“one single national opinion”): €4.000.

For the administration of a multi-site clinical trial at each “local” Ethics Committee: €500.

For current rates see (Bundesamt für Sicherheit im Gesundheitswesen] at <http://www.ages.at>

Special requirements for studies involving children/vulnerable people

For vulnerable patients unable to consent due to an emergency the Drug Act and Medical Devices Act allow for a waiver where there is no legal representative; or where no information is available to indicate that the patient would refuse to participate;

where such research is deemed important to validate data; where the drug (or medical device) is meant for emergency situations; where the trial is for the benefit for the patient (or there is no risk at all); where the trial has EC approval; The EC has expertise in emergency medicine; The public has to be informed (e.g. a poster with the information about the clinical trial at the department where the study is conducted and/or information on the website of the hospital); The patient has to be asked immediately after regaining consciousness for further participation otherwise his participation in the trial has to be stopped.

For all other patients who are not able to consent such as children or mentally compromised patients, parents or a legal representative has to give assent. The child and the patient have to be informed according to their ability to understand, and where possible, asked for consent.

Special requirements if studies include collection and use of human tissues

No special requirements in this instance

Helpful notes for obtaining ethical approvals

Hospital approval necessary before start of trial; contracts need to be in place (eg with university)

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

Austrian Medicines and Medical Devices Agency (AGES Medizinmarkaufsicht) is the competent authority in Austria.

Bundesamt für Sicherheit im Gesundheitswesen (BASG); operating arm: AGES (Austrian Federal Office for Safety in Health Care) -

<http://www.basg.gv.at/arsneimittel/formulare/klinische-pruefungen/>

Application process for IMP

Submission of documents in parallel or after EC. Confirmation of completeness, implicit approval

Details are available here <http://www.basg.gv.at/en/medicines/before-authorisation/clinical-trials/>

Timeline for IMP trial approval

The clinical trial application can be considered as approved if the BASG has not communicated an objection within 35 days after this date (silent approval) or if the decision on the procedure has been published earlier than 35 days on the BASG website

Fees for IMP approval

2,500 € for clinical trials Phase I-III, 1,500 € for clinical trials Phase IV and 400 € for substantial amendments. Academic clinical trials are exempted from fees.

Pre-approval of protocols

Not available.

IMP: Fast-track approval available?

No

IMP: Pre-approval available?

No

Biological samples

Registration and bio-banking requirements

Not available/To be updated

Regulations around transport and sample sharing

Not available/To be updated

Data protection

Data protection regulations

Section 46 of the Data Protection Act details on data use for Scientific Research and Statistics. German version of the data protection act available here <http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10001597>

Unofficial English translation available at

http://www.ris.bka.gv.at/Dokumente/Erv/ERV_1999_1_165/ERV_1999_1_165.pdf

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

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Medical University of Vienna

Allgemeines Krankenhaus

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1090 Vienna

Austria

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Contact details of National Network leads

To be updated

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

BELGIUM

Total Population: 11.14 Million

Languages: Dutch, French , German

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religion: Roman Catholic 75%, other (includes Protestant) 25%

Ethnic groups: Fleming 58%, Walloon 31%, mixed or other 11%

Health Expenditure: 10.6% of GDP (2011)

Physician density: 3.78 physicians/1,000 population (2010)

Hospital density: 6.5 beds/1,000 population (2011)

Urban population: 97% of total population (2010)



Health System

Primary care system

In the Belgian health system, there is no clearly defined gatekeeper function. Belgian patients have free choice of the first physician to contact, can change physician at any time, and get a second opinion or even consult several physicians at a time. Furthermore, they can directly access specialists or enter a hospital. Delivery of ambulatory care in Belgium is mainly private and based on the principles of independent medical practice, i.e. independent medical practitioners and paramedics are reimbursed via fee-for-service payment and there is free choice of physician by the patient. The vast majority of physicians work as independent self-employed health professionals. Patients in Belgium can visit GPs or specialists in their surgeries; they can also visit a specialist in the hospital or in an outpatient department, usually situated in a hospital.

Source: Belgium Health System Review 2010

http://www.euro.who.int/__data/assets/pdf_file/0014/120425/E94245.PDF

Acute hospital system

Secondary care in Belgium refers to inpatient care in hospitals as well as in day care. In Belgium, hospitals are private or public non-profit-making organizations that are classified into acute, psychiatric, geriatric and specialized hospitals. People are free to choose which hospital they visit and public hospitals have to accept all patients. Thus, there is no formal referral system between primary and secondary/tertiary care, but, in

practice, it is usually the GP or the private specialist who decides to send the patient to a hospital.

Source: Belgium Health System Review 2010

http://www.euro.who.int/_data/assets/pdf_file/0014/120425/E94245.PDF

Public health agency

Name of public health agency

Federal Public Service Health (Need to confirm)

Website of public health agency

<http://health.belgium.be/eportal/index.htm>

Contact details of public health agency

Federal Public Service (FPS) Health, Food Chain Safety and Environment

Eurostation II

Place Victor Horta, 40 box 10

1060 Brussels

Belgium

Contact Center: +32 (0)2 524.97.97

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The Federal Agency for Medicines and Health Products (FAMHP)

Website of competent authority

<http://www.fagg-afmps.be/en/>

Contact Address of competent authority

Federal Agency for Medicines and Health Products

EUROSTATION building, block 2

Place Victor Horta, 40/ 40

1060 Brussels

Phone number: 00 32 2 524 80 00

Fax number : 00 32 2 524 80 01

e-mail: welcome@fagg-afmps.be

Application process of clinical trial approval

The sponsor submits the application to the competent authority (the Federal Agency for Medicines and Health Products: FAMHP). The authority has in principle 28 days (with the possibility of one clock-stop of maximum one month for questions), 15 (fifteen) days

for phase 1 trials. The approval by the competent authority is a silent one: if there is no answer within the 28 days, the experiment can start.

Further details are available in this circular http://www.fagg-afmps.be/en/binaries/circular-575-2010-12-22_tcm292-114021.pdf

Also see this page http://www.fagg-afmps.be/en/human_use/medicines/herbal_medicinal_products/research_development/clinical_trials/

Time line for approval process

The maximum time taken by FAMHP to give an opinion is 15 days for monocentric phase I clinical trials and 28 days for all other clinical trials with a possible clock-stop of maximum one month.

Process for fast track approvals during epidemics/pandemics

No information

Ethics Committees

Structure and configuration of Ethics committees

There are currently about 215 committees. The majority are associated with hospitals and some are associated with non-hospital institutions. Until the 31st of March 2012, 38 of these research ethics committees have the full recognition, ie, give a single opinion in multicentre studies and in single centre studies. The other hospital committees (approximately 170 committees) can give local advice for multicentre studies, in which they evaluate the competence of the local investigator, the infrastructure of the research site and the informed consent documents. In addition, there is a central Consultative Committee for Bioethics, (officially formed in 1996), which formulates opinion & informs the public, acting only on a consultative basis. It is not involved in the evaluation of clinical trial protocols. There no single organisation to which to apply for ethical review of a clinical trial for an investigational medicinal product, regardless of whether this is for a single site or multiple sites.

Source: EFGCP Report Belgium

<http://www.efgcp.eu/downloads/efgcpreportfiles/belgium%20definitive.pdf>

Further details are available: http://www.fagg-afmps.be/en/human_use/medicines/medicines/research_development/ethic_committee/

Ethics Application/Approval process

A clinical trial can only start after receiving a favourable opinion from the Ethics Committee. The principal / coordinating investigator for the trial submits the single

application for ethical review. Information regarding the application procedure and required documents can be found in Chapter VIII (regarding Ethics Committees) and Chapter IX (regarding the competent authority) of Law 7/2004.

French version of the law is available here http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2004050732&table_name=loi

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

No information

Contact Details of Ethics committees

A list of recognised ethics committees is available on Federal Agency for Medicines and Health Products' website. http://www.fagg-afmps.be/en/binaries/Lijst%20EC%27s%20-%20Liste%20CE-2014-05-08-OK_tcm292-27289.pdf

Website addresses of ethics committees

A list of recognised ethics committees is available here http://www.fagg-afmps.be/en/binaries/Lijst%20EC%27s%20-%20Liste%20CE-2014-05-08-OK_tcm292-27289.pdf

Website links to ethics application forms

To be updated

Website links to meeting time tables

To be updated

Ethical approval timeline

15 calendar days for phase 1 studies, 28 days for other studies.

Ethical approval application Fees

RECs charge fees for trials with a commercial sponsor as follows:

For interventional studies: Initial evaluation: single opinion committee €1000; other committees €300 (local advice only).

Amendments: €250 to the ethics committee that gave the single advice.

For non-interventional studies: Initial evaluation: single opinion committee €400; other committees €100 (local advice only).

Amendments: €100 to the ethics committee that gave the single advice. The fees are fixed by the Royal Decree of July 15, 2004, but they are subject to an indexation each year. Correct fees can be found on the Agency's website.

Special requirements for studies involving children/vulnerable people

Consent may be given by the legal representative in trials with children, with vulnerable adults and in emergency situations. This permitted only when strict conditions are met.

Special requirements if studies include collection and use of human tissues

Not available/to be updated

Helpful notes for obtaining ethical approvals

To be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The Federal Agency for Medicines and Health Products (FAMHP)

Application process for IMP

Details are available in this circular http://www.fagg-afmps.be/en/binaries/circular-575-2010-12-22_tcm292-114021.pdf

Timeline for IMP trial approval

15 calendar days for mono center phase 1 studies, 28 days for other studies.

Fees for IMP approval

Each submitted file must be accompanied by payment of a fee. Each complete file requires payment of € 3676.45 and each modification requires payment of € 605,33.

Details are available here (in French) http://www.fagg-afmps.be/en/binaries/omzendbrief%20606%20FR_tcm292-239695.pdf

Pre-approval of protocols

Not available/to be updated

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available/to be updated

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

Clinical trials must comply with Data Protection act of December 8, 1992.

French version of the act is available at http://www.privacycommission.be/sites/privacycommission/files/documents/CONS_ar_execution_loi_vie_privée_13_02_2001.pdf

Unofficial English version is available here http://www.privacycommission.be/sites/privacycommission/files/documents/Royal_Decree_2001.pdf

Further details are available with Belgian Data Protection Authority <http://www.privacycommission.be/>

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

Nancy DE BREMAEKER

Clinical and Epidemiological Investigation Center (CIEC)

Public Research Centre for Health - Centre de Recherche Public de la Santé (CRP-Santé)

1A-B, rue Thomas Edison, L-1445

STRASSEN / LUXEMBOURG

Phone: +352 26 970 804

Email: nancy.debremaeker@crp-sante.lu

Contact details of National Network leads

To be updated

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

BULGARIA

Total Population: 7.30 Million

Languages: Bulgarian

Time Zone: UTC + 02:00

Further demographic info (cultural/religious etc.)

Religion: Eastern Orthodox 59.4%, Muslim 7.8%, other 1.7%, none 3.7%, unspecified 27.4% (2011 est.)

Urban population: 73.1% of total population (2011)

Health expenditures: 7.6% of GDP (2010)

Physicians density: 3.76 physicians/1,000 population (2010)

Hospital bed density: 6.5 beds/1,000 population (2010)



Health System

Primary care system

The legislations of 1998–1999 (the Health Insurance Act, the Professional Organizations Act and the Health Establishments Act) regulate provision of all levels of care in Bulgaria. Public health services are organized by the Ministry of Health and its 28 regional health centres and are financed centrally. Every Bulgarian citizen should be covered by the compulsory health insurance scheme to receive a basic benefits package of health services. Primary health care is provided by GPs in private practice, group practice and/or in an outpatient department. Each Bulgarian citizen has a free choice of GP and inpatient facility. All types of GP are gatekeepers by law, making referrals to inpatient and outpatient specialists. GPs carry out basic examinations, diagnostics, treatment (including minor ambulatory operations), provide consultations, and are responsible for prescription of drugs

Acute hospital system

Hospital care in Bulgaria is provided by public and private health establishments. According to the Law on Therapeutic Establishments, the hospitals are divided into multidisciplinary (with at least four specialized wards) and specialized hospitals (providing services for certain health conditions or diseases with the same or similar diagnosis: gynaecological, paediatric, psychiatric, respiratory, etc.). Hospitals can also be classified, depending on treatment duration, as an active treatment hospital (for short lengths of stay), a recovery, post-treatment and rehabilitation hospital and/or a rehabilitation hospital. Another way to categorize hospitals is based on their ability to provide specialized care. The hospitals that are able to provide specialized care include:

the training hospitals affiliated with the five universities of medicine in the country, the national hospitals, the interregional hospitals, the regional hospitals and the local area multidisciplinary hospitals.

Public health agency

Name of public health agency

National Centre for Public Health Protection

Website of public health agency

<http://ncphp.government.bg/>

Contact details of public health agency

cad. Ivan Evst. Geshov 15 blvd,

Sofia 1431 Bulgaria

E-mail: ncpha@ncpha.government.bg

Phone: 359 2 8056444

Fax: 359 2 9541211

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

Bulgarian Drug Agency

Website of competent authority

<http://www.bda.bg/>

Contact Address of competent authority

8 Damyan Gruev Str.

Sofia 1303

BULGARIA

Phone: +359 2 8903555

E-mail: bda@bda.bg

Application process of clinical trial approval

The application accompanied by the required documentation is submitted to the Bulgarian Drug Agency of initial validation. Once the validation is over the documentation is transferred to the Specialized Committee for Authorization of Performance of Clinical Trials (SCAPCT). The SCAPCT assesses the protocol and accompanying documentation and issues a decision.

Further details are available on Section 1 of the Medicinal Products in Human Medicine Acts

http://pop3.bda.bg/regulations/zakoni/Medicinal_Products_in_Human_Medicine_Act.pdf

For more information visit Bulgarian Drug Agency's website (in Bulgarian).

http://www.bda.bg/index.php?option=com_content&view=category&layout=blog&id=62&Itemid=120&lang=bg

Time line for approval process

Within 60 days of the date of submission of the application. A clinical trial may begin, if within 60 days the Bulgarian Drugs Agency has not issued a notification refusing to approve the clinical trial.

See Article 118. of the Medicinal Products in Human Medicine Acts

Process for fast track approvals during epidemics/pandemics

No information available

Ethics Committees

Structure and configuration of Ethics committees

The Bulgarian Drug Agency is the responsible body for accreditation and oversight of ethics committees in Bulgaria. Ethics committees shall be set up with treatment establishments in which clinical trials are conducted, whose composition shall be specified by the head of the respective treatment establishment. An Ethics Committee for Multi-Centre Trials shall be set up with the Minister of Health and its composition shall be specified by an order of the Minister and shall include regular and alternate members. All trials are approved by the local ethics committee at the trial site, regardless of the specificity of the trial. Currently there are 103 approved ethics committees that can give opinion on trials to be performed at the specific site.

Ethics committees in Bulgaria

1. Central Ethics Committee to the Council of Ministers
2. Ethics Committee for multicentre clinical trials to the Minister of Health
3. Five RECs at the Medical Universities
4. Twenty RECs at the University Hospitals
5. Twenty seven RECs at the Regional Hospitals

Further details are available on Bulgarian Drug Agency's website

http://www.bda.bg/index.php?option=com_content&view=category&layout=blog&id=66&Itemid=149&lang=bg

Ethics Application/Approval process

In order to obtain an opinion, the chief or coordinating researcher and the sponsor shall submit to the respective ethics committee under Article 103 of Medicinal Products in Human Medicine Acts . Where the trial is to take place in more than one centre on the

territory of the Republic of Bulgaria, an application shall be filed with the Ethics Committee on Multi-Centre Trials under Article 103, Paragraph 1. Where the trial is to take place in only one centre on the territory of the Republic of Bulgaria, an application may be filed with the respective ethics committee under Article 103, Paragraphs 1 or 2 at the choice of the applicant. The opinion of the ethics committee under Article 103, Paragraph 1 shall be valid for all centres on the territory of the Republic of Bulgaria.

Medicinal Products in Human Medicine Acts is available at http://pop3.bda.bg/regulations/zakoni/Medicinal_Products_in_Human_Medicine_Act.pdf

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

No information

Contact Details of Ethics committees

Not available/to be updated

Website addresses of ethics committees

Not available/to be updated

Website links to ethics application forms

Not available

Website links to meeting time tables

Not available

Ethical approval timeline

Within a period of 60 days of filing an application, the ethics committee concerned shall rule, issuing an opinion, which it shall send to the applicant and to the Bulgarian Drug Agency.

Ethical approval application Fees

Fees range around 500-1.200 BNG (€250-600).

Special requirements for studies involving children/vulnerable people

Article 97. (1) of Medicinal Products in Human Medicine Acts says "Clinical trial on a minor shall be carried out after obtaining written informed consent from both parents or from the legal guardians of the individual, subject to Article 96, Paragraphs 1 and 3."

Section II of Medicinal Products in Human Medicine Acts describes the details of Clinical trials with vulnerable groups of patients.

Medicinal Products in Human Medicine Acts

http://pop3.bda.bg/regulations/zakoni/Medicinal_Products_in_Human_Medicine_Act.pdf

Special requirements if studies include collection and use of human tissues

Not available/to be updated

Helpful notes for obtaining ethical approvals

To be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

Bulgarian Drug Agency

Application process for IMP

To be updated

Timeline for IMP trial approval

To be updated

Fees for IMP approval

To be updated

Pre-approval of protocols

To be updated

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available/to be updated

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

When gathering of data from patients is planned in the study, their prior consent shall be obtained. The patients' personal data shall be processed in compliance with the requirements under the Personal Data Protection Act

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

Not available/to be updated

Contact details of National Network leads

Not available/to be updated

Potential risk

Potential risk of implanting WP 3.4.5 in this country

Not available/to be updated

CYPRUS

Total Population: 1.13 Million

Languages: Greek, Turkish

Time Zone: UTC + 02:00

Further demographic info (cultural/religious etc.)

Religions: Greek Orthodox 78%, Muslim 18%, other (includes Maronite and Armenian Apostolic) 4%

Urban population: 70.5% of total population (2011)

Life expectancy at birth: male: 75.54 years, female: 81.27 years

Health expenditures: 7.4% of GDP (2011)

Physicians density: 2.75 physicians/1,000 population (2010)

Hospital bed density: 3.5 beds/1,000 population (2010)

Health System

Primary care system

The health system consists of two parallel delivery systems: a public one and a separate private one. It is exclusively financed by the state budget, with services provided through a network of hospitals and health centres directly controlled by the Ministry of Health. The private system is financed mostly by out-of-pocket payments and to some degree by voluntary health insurance (VHI).

Primary/ambulatory care services are delivered by a mix of public and private providers. Public sector services are delivered by a network of 38 health centres. Additionally, primary/ambulatory care services are delivered by the outpatient departments of five district and two specialized hospitals. There is no strict gate-keeping or referral system. A significant portion of primary/ambulatory services is provided by the private sector.

Source: Health System Review Cyprus 2012.

http://www.euro.who.int/_data/assets/pdf_file/0017/174041/Health-Systems-in-Transition_Cyprus_Health-system-review.pdf

Acute hospital system

Inpatient care is provided by public and private hospitals, with around 3000 beds roughly allocated equally between the public and private sectors. Citizens generally prefer public hospitals, not only because they are free of charge but also because many feel that the public facilities offer better specialized care. The relationship between

primary and secondary care is minimal since there is no referral system or statutory procedure for managing patients between different levels of care or health facilities.

Source: Health System Review Cyprus 2012.

http://www.euro.who.int/_data/assets/pdf_file/0017/174041/Health-Systems-in-Transition_Cyprus_Health-system-review.pdf

Public health agency

Name of public health agency

Medical and Public Health Services (MPHS)

Website of public health agency

www.moh.gov.cy/mphs/

Contact details of public health agency

MINISTRY OF HEALTH ADMINISTRATION

1 Prodromou & Chilonos Street 17

1448 Nicosia, Cyprus

Call Center: 00357 22 605 300/301

Email Address: perm.sec@moh.gov.cy

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The Drugs' Council

Website of competent authority

<http://www.moh.gov.cy/phs>

Contact Address of competent authority

PHARMACEUTICAL SERVICES

MINISTRY OF HEALTH

1475

NICOSIA

CYPRUS

Phone Number: + 357 22608607

Fax Number: +357 22 608649

E-mail: phscentral@phs.moh.gov.cy

Application process of clinical trial approval

Application forms are available here:

<http://www.moh.gov.cy/Moh/phs/phs.nsf/All/8957C0F4F7D97915C225730800376730?OpenDocument>

Clinical trials are regulated by [P.I. 452/ 2004] Laws regarding Human Use Drugs (Best Clinical Practices) of 2004 (in Greek only)

[http://www.moh.gov.cy/MOH/phs/phs.nsf/All/9C064264122B82BEC22572FA003433A5/\\$file/%CE%9A.%CE%94.%CE%A0.%20452%20%CF%84%CE%BF%CF%85%202004.pdf?](http://www.moh.gov.cy/MOH/phs/phs.nsf/All/9C064264122B82BEC22572FA003433A5/$file/%CE%9A.%CE%94.%CE%A0.%20452%20%CF%84%CE%BF%CF%85%202004.pdf?OpenElement)

[OpenElement](#)

Time line for approval process

No information available

Process for fast track approvals during epidemics/pandemics

No information available

Ethics Committees

Structure and configuration of Ethics committees

According to the national legislation, Cyprus National Bioethics Committee (CNBC) is the body responsible for the bioethical review of all research protocols involving human subjects in Cyprus. CNBC was established by Law providing for the Establishing and Function of the National Bioethics Committee (N. 150 (I) /2001). It consists of thirteen (13) members appointed by the Council of Ministers of the Republic of Cyprus for a term of office of four (4) years. The Cyprus National Bioethics Committee, with very few changes, adopted the “Operational Guidelines for Ethics Committees that Review Biomedical Research” formulated by the World Health Organization, to form the basis of the guidelines issued to the Cyprus Ethics Committees.

Sources:

<http://www.efgcp.eu/Downloads/EFGCPReportFiles/Cyprus%20definitive%20Updated.pdf>

<http://www.eurecnet.org/information/cyprus.html>

Relevant laws are available here;

<http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/538006E398361B89C22571C9002B25A1?OpenDocument>

Ethics Application/Approval process

All the clinical trials involving medicinal products for human use must be submitted to the CNBC for bioethical review and approval as per the provisions of the relevant legislation. It should be specified that for all local centres in the Republic of Cyprus only one combined application is submitted to CNBC for bioethical review and approval (Regulation 15 (i) of the Legislation on Medicinal Products for Human Use (Good Clinical Practice - K.Δ.Π. 452/2004). The principal investigator is responsible for submitting the request for ethical review in all cases.

Further

details:

http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/DMLrec_en/DMLrec_en?OpenDocument

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

Not available/to be updated

Contact Details of Ethics committees

Corner of Nicos Kranidiotis & Makedonias, 2411 Engomi, Nicosia

Telephone numbers: (+357) 22-809038 / 22-809039

Fax number: (+357) 22-353878

E-Mail: cnbc@bioethics.gov.cy

Website addresses of ethics committees

<http://www.bioethics.gov.cy/>

Website links to ethics application forms

Not available/to be updated

Website links to meeting time tables

Not available/to be updated

Ethical approval timeline

An ethics committee must announce its decision on the application within a period of 40 days after the submission of a complete study review application

Ethical approval application Fees

For bioethical assessment a fee of €600 for each protocol is charged by CNBC. This fee is collected by the Ministry of Health.

Special requirements for studies involving children/vulnerable people

According to the provisions of the national legislation (Regulations Concerning Medicinal Products of Human Use (Good Clinical Practice) of 2004 (K.Δ.Π 452/2004) in the case of vulnerable subjects who are potentially to be involved in a clinical trial informed consent is obtained via their legal representative. In case of minors, the informed consent of the parents or the legal representative is obtained, but consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor.

Special requirements if studies include collection and use of human tissues

Not available/to be updated

Helpful notes for obtaining ethical approvals

To be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The Drugs' Council

Application process for IMP

Not available/to be updated

Timeline for IMP trial approval

60 days

Fees for IMP approval

€600 payable at the accounts department of the Ministry of Health.

Pre-approval of protocols

Not available/to be updated

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available/to be updated

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

The Processing of Personal Data (Protection of Individuals) Law 2011

<http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/9C592B821FE281B6C22571C9002B2A5F?OpenDocument>

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

Not available

Contact details of National Network leads

Not available

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

CZECH REPUBLIC

Total Population: 10.51 Million

Languages: Czech

Time Zone: UTC + 01:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 10.4%, Protestant (includes Czech Brethren and Hussite) 1.1%, other and unspecified 54%, none 34.5% (2011 est.)

Urban population: 73.4% of total population (2011)

Life expectancy at birth: 78.31 years. male: 75.34 years, female: 81.45 years (2014 est.)

Health expenditures: 7.4% of GDP (2011)

Physicians density: 3.71 physicians/1,000 population (2010)

Hospital bed density: 7 beds/1,000 population (2010)



Health System

Primary care system

Since the early 1990s, the Czech Republic has had a system of social health insurance (SHI) based on compulsory membership in one of a number of health insurance funds, which are quasi-public, self-governing bodies that act as payers and purchasers of care. SHI contributions are mandatory and take the form of a payroll tax split between employers and employees; self employed individuals must contribute a fixed percentage of their profits.

Approximately 95% of primary care services are provided by physicians working in private practice, usually as sole practitioners. Patients register with a primary care physician of their choice, but can switch to a new one every three months without restriction. Primary care physicians do not play a true gate-keeping role; patients are free to obtain care directly from a specialist and do so frequently.

Source: Czech Republic Health System Review

http://www.euro.who.int/_data/assets/pdf_file/0010/97633/E92968.pdf

Acute hospital system

Secondary care services in the Czech Republic are offered mainly by private practice specialists, health centres, polyclinics, hospitals and specialized inpatient facilities. After a variety of reforms in the 1990s, hospitals that formerly belonged to the State are now owned and managed by a range of actors, including government ministries, regions, private entities and churches.

http://www.euro.who.int/_data/assets/pdf_file/0010/97633/E92968.pdf

Public health agency

Name of public health agency

The National Institute of Public Health (NIPH).

Website of public health agency

<http://www.szu.cz/home-original-en>

Contact details of public health agency

The National Institute of Public Health

Šrobárova 48

100 42, Praha 10

Phone: 00420 26708 1111

E-mail: zdravust@szu.cz

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

State Institute for Drug Control (SÚKL)

Website of competent authority

<http://www.sukl.eu/index.php?lang=2>

Contact Address of competent authority

SÚKL, Šrobárova 48,

100 41 Praha 10,

Phone: +420 272 185 111

E-mail: posta@sukl.cz

Application process of clinical trial approval

An application for clinical trial authorisation shall be submitted for each clinical trial which uses investigational medicinal products and is required even for non-investigational medicinal products provided by the sponsor. The clinical application form (CTA) is available from the European Medicines Agency (EMA) website <https://eudract.ema.europa.eu> under “Access to EudraCT” The completed CTA shall be submitted in hard copy (signed) and electronically in the XML format on a CD ROM or DVD. Each application for authorisation/notification of a clinical trial must contain the EudraCT identification number, which may be obtained from <https://eudract.ema.europa.eu/>.

Further details on application procedure and documents required are available at

<http://www.sukl.eu/medicines/klh-20-version-5>

Time line for approval process

SÚKL shall provide its opinion on the application within 60 days. For advanced therapy IMPs the period shall be extended by further 30 days.

Process for fast track approvals during epidemics/pandemics

No information about whether these are available or possible.

Ethics Committees

Structure and configuration of Ethics committees

There are two types of ethics committees in the Czech Republic: 1) Local ethics committees established by the director of the relevant health care institution or research institution. They review all research projects.

2) Ethics committees for multi-centre (MEC) studies are also established by the director of the relevant health care institution or research institution, but recommended by SÚKL and approved by the Ministry of Health. There are 11 Multicentre RECs and nearly 100 Local RECs present in Czech Republic.

Ethics Application/Approval process

The opinion of an ethics committee (EC) should be sought for any CT or biomedical research project to be conducted in the Czech Republic. Documents and source materials shall be submitted to the ethics committee in the Czech language; the ethics committee may allow for the submission of documents and source materials also in another language. Single-site trial ethical review is done by the relevant local ethics committee; multi-site clinical trial ethical review is done by an ethics committee for multi-site studies (MEC) (and also by each of the local ECs). Requests to Local RECs may be submitted by the sponsor or the investigator. Requests to MRECs should be submitted by the sponsor or the sponsor's authorised (power of attorney) person.

Source: Decree of June 23, 2008 on "Good Clinical Practice and Detailed Conditions of Clinical Trials on Medicinal Products."

http://www.sukl.cz/uploads/Legislativa/226_2008_clinical_trials.pdf

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

No information.

Contact Details of Ethics committees

Ethics Committees for Multicentric Clinical Trials

<http://www.sukl.eu/sukl/ethics-committees-for-multicentric-clinical-trials?highlightWords=ethics>

List of Ethics Committee established at healthcare facilities

<http://www.sukl.eu/sukl/ethics-committee-established-at-healthcare-facilities?highlightWords=ethics>

Website addresses of ethics committees

Ethics Committees for Multicentric Clinical Trials

<http://www.sukl.eu/sukl/ethics-committees-for-multicentric-clinical-trials?highlightWords=ethics>

List of Ethics Committee established at healthcare facilities

<http://www.sukl.eu/sukl/ethics-committee-established-at-healthcare-facilities?highlightWords=ethics>

Website links to ethics application forms

See the link

<http://www.sukl.eu/sukl/ethics-committees-for-multicentric-clinical-trials?highlightWords=ethics>

Website links to meeting time tables

See the link

<http://www.sukl.eu/sukl/ethics-committees-for-multicentric-clinical-trials?highlightWords=ethics>

Ethical approval timeline

Within 60 days of the delivery date of the application ethics committee must give its reasoned opinion on the relevant clinical trial to the sponsor.

Ethical approval application Fees

Fees are paid to the institution where the REC is located, and are not paid directly to the REC. The MREC fee is charged in the range of 40000- 100000 - CZK (1600 – 4000 Euros) depending on the number of sites. Local RECs usually charge around 10000 - CZK. The fee for Amendment negotiation is usually 5000 - CZK.

Special requirements for studies involving children/vulnerable people

In acute cases when it is impossible to obtain the trial subject's informed consent prior to the inclusion in the clinical trial, the consent shall be requested from the subject's

guardian. Where such guardian has not been assigned or is unavailable, the trial subject may only be included in the clinical trial if the inclusion procedure is specified in the protocol and the investigator has obtained a written favourable opinion from the trial's ethics committee which contains an explicit position on the procedure of including trial subjects. The opinion of the ethics committee may include a condition according to which the inclusion of each single trial subject must be approved by the ethics committee. The investigator shall obtain the consent of the trial subject or, where applicable, his or her guardian, with the trial subject's continued participation in the clinical trial as soon as practicable with respect to the condition of the trial subject or the availability of the guardian.

Special requirements if studies include collection and use of human tissues

Not available/to be updated

Helpful notes for obtaining ethical approvals

To be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

State Institute for Drug Control (SÚKL)

Srobarova 48, 100 41 Praha 10, Czech Rep. posta@sukl.cz

Phone: 00420 272 185 111

Application process for IMP

The clinical application form (CTA) is available from the European Medicines Agency (EMA) website <https://eudract.ema.europa.eu> under “Access to EudraCT” The completed CTA shall be submitted in hard copy (signed) and electronically in the XML format on a CD ROM or DVD. Each application for authorisation/ notification of a clinical trial must contain the EudraCT identification number, which may be obtained from <https://eudract.ema.europa.eu/> .

Timeline for IMP trial approval

SÚKL shall provide its opinion on the application within 60 days. For advanced therapy IMPs the period shall be extended by further 30 days.

Fees for IMP approval

Details of fees are available on the website of State Institute for Drug Control at <http://www.sukl.eu/sukl/fees?highlightWords=fees>

Pre-approval of protocols

No information

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available/to be updated

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

The main provisions are contained in the Act no. 101/2000 Coll., on the Protection of Personal Data.

English version is available here

http://www.uoou.cz/en/vismo/zobraz_dok.asp?id_ktg=1107&p1=1107

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

Marianna Brabencova

Masaryk University

Department of Pharmacology Faculty of Medicine Masaryk University Kamenice 5

Brno CZECH REPUBLIC

Phone: +420 549 495 595

Email: brabencova@med.muni.cz

Contact details of National Network leads

GRACE

Prof. Bohumil Seifert

Email: seifert@terminal.cz

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

DENMARK

Total Population: 5.59 Million

Languages: Danish, Faroese, Greenlandic

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Evangelical Lutheran 80%, Muslim 4%, other 16%

Life expectancy at birth: 79.09 years; male: 76.68 years, female: 81.64 years (2014 est.)

Health expenditures: 11.2% of GDP (2011)

Physicians density: 3.42 physicians/1,000 population (2007)

Hospital bed density: 3.5 beds/1,000 population (2010)



Health System

Primary care system

Primary health care deals with general health problems and is usually the first point of contact. The primary sector consists of private (self-employed) practitioners and municipal health services, such as nursing homes, home nurses, health visitors and municipal dentists. GPs are the first point of contact for patients and act as the gatekeepers to hospitals, specialists, physiotherapists and others. GPs run private practices, either on their own as solo practitioners or in collaboration with other GPs. The municipalities are responsible for nursing homes, home nurses, health visitors, municipal dentists (children's dentists and home dental services for the physically and/or mentally disabled), school health services, people carrying out home help services, and the treatment of alcohol and drug users. Professionals involved in delivering these services are paid a fixed salary.

Source: Denmark Health System Review

http://www.euro.who.int/_data/assets/pdf_file/0004/160519/e96442.pdf

Acute hospital system

Most secondary and tertiary care takes place in general hospitals owned and operated by the regions. Doctors and other health professionals are employed at hospitals on a salaried basis. Hospitals have both inpatient and outpatient clinics, as well as 24-hour emergency wards. Most public hospitals are general hospitals with different specialization levels. There is no official classification of hospitals according to the level of specialization.

Source: :Denmark Health System Review

http://www.euro.who.int/_data/assets/pdf_file/0004/160519/e96442.pdf

Public health agency

Name of public health agency

The Danish National Institute of Public Health (NIPH)

Website of public health agency

<http://www.si-folkesundhed.dk/>

Contact details of public health agency

National Institute of Public Health

University of Southern Denmark

Øster Farimagsgade 5 A

DK-1353 Copenhagen K

Denmark

Telephone +45 6550 7777

Fax: +45 3920 8010

E-mail: niph@niph.dk

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

Danish Health and Medicines Authority

Website of competent authority

<http://sundhedsstyrelsen.dk/en>

Contact Address of competent authority

Axel Heides Gade 1

2300 Copenhagen S, Denmark

Tel. +45 7222 7400

Email: sst@sst.dk

Application process of clinical trial approval

Pursuant to the Danish Medicines Act, the sponsor is the person, company or institution which undertakes the responsibility for the initiation, management and possibly the financing of a clinical trial. The sponsor may delegate the task of applying for authorisation for a clinical trial. Before applying to the Danish Health and Medicines Authority, the applicant must order a EudraCT number. The EudraCT number is an identification number for the clinical trial, which applies throughout the EU. This number can be ordered via <https://eudract.ema.europa.eu/eudract-web/index.faces>.

The review of the application by the regional research ethics committee will take place when a complete and valid application has been submitted. A valid application must include: Application form, The clinical trial protocol, Subject information and the informed consent procedure, and A protocol resumé.

Details of procedure is available here:

<https://sundhedsstyrelsen.dk/en/medicines/regulation/clinical-trials/trials-in-humans/guideline-for-applications-for-authorisation-of-clinical-trials-of-medicinal-products-in-humans>

Time line for approval process

The Danish Health and Medicines Authority has 60 calendar days to handle a duly completed application. The Danish Health and Medicines Authority aims to give grounds for non-acceptance or grant authorisation within 30 working days.

Process for fast track approvals during epidemics/pandemics

No information available

Ethics Committees

Structure and configuration of Ethics committees

According to the Act on Research Ethics Review of Health Research Projects of 2003, the regional scientific ethical committees are set up by the regions on a geographical basis. The Danish National Committee on Biomedical research Ethics is set up by the Minister for Interior and Health.

The Act on Research Ethics Review of Health Research Projects is available here;

<http://www.cvk.sum.dk/English/actonabiomedicalresearch.aspx>

Ethics Application/Approval process

No biomedical research project shall be initiated until a research ethical evaluation has been made and approval has been granted by the regional committee. The investigator must submit an application to the appropriate regional scientific ethical committee, depending on the location of the principal site for the clinical trial. The co-ordinating chief investigator submits an application for a multi-site study to the regional scientific ethical committee for the area in which he/she is operating. This regional committee must make its decision, which forms the basis for an opinion, and then inform the other regional committees and the Danish National Committee for Biomedical Research Ethics for the investigators at the other sites involved. However non-intervention trials involving medicinal products shall not be notified to the committee system as the

patient is not exposed to any special harm or risk, and the primary aim of prescribing the medicinal product is treatment.

Detailed guidance on the ethical review process is available in English on the website of the Danish National Committee on Biomedical Research Ethics at <http://www.cvk.sum.dk/English/guidelinesaboutnotification.aspx>.

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

No information available

Contact Details of Ethics committees

Den Nationale Videnskabetiske Komité

Finsensvej 15

DK-2000 Frederiksberg

Tlf: +45 72 26 93 70

E-mail: dnvk@dnvk.dk

Links and contact information for the regional ethical committees are available here

<http://www.cvk.sum.dk/forskere/hvordansoegerjeg/ansoegningregionalkomite.aspx>

Website addresses of ethics committees

The website for the Danish National Committee on Biomedical Research Ethics is:

<http://www.cvk.sum.dk/CVK/Home/English.aspx>

Links and contact information for the regional ethical committees are available here

<http://www.cvk.sum.dk/forskere/hvordansoegerjeg/ansoegningregionalkomite.aspx>

Website links to ethics application forms

Links and contact information for the regional ethical committees are available here

<http://www.cvk.sum.dk/forskere/hvordansoegerjeg/ansoegningregionalkomite.aspx>

Website links to meeting time tables

Links and contact information for the regional ethical committees are available here

<http://www.cvk.sum.dk/forskere/hvordansoegerjeg/ansoegningregionalkomite.aspx>

Ethical approval timeline

The committee shall decide on the approval of the project within 60 days of receiving the duly formulated application.

Ethical approval application Fees

The fee for notifying a project shall be DKK 4000 and for a supplementary protocol, DKK 1500.

Special requirements for studies involving children/vulnerable people

Surrogate consent is needed when the trial involves subjects who because of age or reduced physical or mental abilities due to depression, age, mental deficiencies or similar conditions are incapable of giving informed consent to participation in a trial.

Surrogate consent shall mean a decision in writing, dated and signed, or in electronic form along with an electronic signature, cf. the Act on Electronic Signatures, to take part in a biomedical research project, such decision being made by the closest relatives and the general practitioner, alternatively the medical officer of health or the holder of custody or the guardian following satisfactory information about the nature, significance, implications and risk of the project and receipt of suitable documentation.

Special requirements if studies include collection and use of human tissues

A biomedical research project which involves trials on human biological material such as blood, cells, tissue and body fluids, but also hair, saliva, specimens of urine, must be notified to the Committee on Biomedical Research Ethics whether the material is identifiable with a person or it is "anonymous". Data are identifiable with individual subjects if it is possible to identify such subjects either by name or by code. If just one subject has the "key", the material is identifiable with a subject and is not "anonymous".

See <http://www.cvk.sum.dk/English/guidelinesaboutnotification.aspx>

Helpful notes for obtaining ethical approvals

To be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

Danish Health and Medicine Authority

Application process for IMP

Clinical trials with medicinal products in humans must be conducted in accordance with good clinical practice (GCP) cf. the Danish Medicines Act section 88(2). An application is made by the sponsor to the Danish Medicines Agency on the EudraCT application form. For trials concerning more than one site in Denmark, one full application must be

submitted by the sponsor. All the additional participating trial sites must be listed on the application form.

Further details available here;

<https://sundhedsstyrelsen.dk/en/medicines/regulation/clinical-trials/trials-in-humans/guideline-for-applications-for-authorisation-of-clinical-trials-of-medicinal-products-in-humans>

Timeline for IMP trial approval

60 days

Fees for IMP approval

The application fee for notification of clinical trials is DKK 7,545.

The fee for substantial protocol amendments is DKK 1,711.

Pre-approval of protocols

No information

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Information shall be given to the ethics committees if biological material is removed from the trial subject for the purpose of storage in a research biobank, cf. Section 2.6

See Guidelines about Notification

<http://www.cvk.sum.dk/English/guidelinesaboutnotification.aspx>

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

According to the Danish Act on Processing of Personal Data, medicinal product trials must also be notified to the Danish Data Protection Agency. This may take place at the same time as the application to the Danish Health and Medicines Authority. However, several areas of the private sector are exempt from this notification duty.

More information in Danish can be found via this link:

<http://www.datatilsynet.dk/nyheder/seneste-nyheder/artikel/nye-fritagelser-fra-anmeldelsespligten-i-den-private-sektor/>

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

Berit GREVSTAD

Copenhagen Trial Unit

Rigshospitalet, Dept. 78.12

Tagensvej 22

DK-2100 Copenhagen Ø

Denmark

Ph. +45 3545 7170

Email- bg@ctu.dk

Contact details of National Network leads

GRACE

Prof Lars Bjerrum

Department of Public Health, Section of General Practice

Øster Farimagsgade 5 opg. Q, Postboks 2099, Room 24-0-43

1014 1014 København K

Email- lbjerrum@sund.ku.dk

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

ESTONIA

Total Population: 1.34 Million

Languages: Estonian, Russian

Time Zone: UTC+02:00

Further demographic info (cultural/religious etc.)

Religions: Lutheran 9.9%, Orthodox 16.2%, other Christian 2.2%, other 0.9%, none 54.1%, unspecified 16.7% (2011 est.)

Urban population: 69.5% of total population (2011)

Life expectancy at birth: 74.07 years; male: 68.85 years, female: 79.61 years (2014 est.)

Health expenditures: 6% of GDP (2011)

Physicians density: 3.34 physicians/1,000 population (2010)

Hospital bed density: 5.3 beds/1,000 population (2010)



Health System

Primary care system

Reform of primary care began in 1991 with the aim of developing a family medicine-centred primary health care system and establishing family medicine as a medical specialty. The 2001 Health Services Organization Act established primary care as the first level of contact with the health system, provided by independent family doctors. Every family doctor has a service area (an area of a local government) determined by the Health Board and maintains a practice list. Family doctors are private owners and may practice as private entrepreneurs or companies. Patients have the right to change their family doctor at any time after submitting a written application to a new family doctor. Family doctors are paid a combination of a basic monthly allowance, an age-weighted capitation fee per registered insured per month, and some fees for services provided.

Source: Estonia Health System Review http://ee.euro.who.int/HiT-Estonia_2013.pdf

Acute hospital system

The hospital sector is dominated by public hospitals, and most hospitals are owned by the state, local governments or public legal bodies. In many instances, hospitals have multiple owners, or the state and municipalities jointly own one hospital. Hospitals in Estonia are divided into regional, central, general, local, special, rehabilitation care and nursing care hospitals depending on the catchment area, services provided and/or the

location of the hospital. Regional hospitals provide a full range of health care services. Central

hospitals deliver most services; however, some services, such as cardiosurgery, neurosurgery and certain oncological services, are excluded. General hospitals provide 24/7 emergency care as well as intensive care and some surgical and medical specialties. Local hospitals deliver 24-hour doctor-based emergency care but no surgeries.

Source: Estonia Health System Review http://ee.euro.who.int/HiT-Estonia_2013.pdf

Public health agency

Name of public health agency

Health Board

Website of public health agency

<http://www.terviseamet.ee/info/uudised.html>

Contact details of public health agency

Paldiski mnt 81, 10617 Tallinn,

Tel 6943500,

E-mail: kesk@terviseamet.ee

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

State Agency of Medicine

Website of competent authority

<http://www.sam.ee/>

Contact Address of competent authority

State Agency of Medicines

Nooruse 1, 50411 Tartu, Estonia

Phone: +372 737 4140

Fax: +372 737 4142

Email: info@ravimiamet.ee

Application process of clinical trial approval

The clinical trials are regulated by the Medicinal Products Act . Notification of the clinical trial needs to be submitted to the State Agency using the EudraCT format 60 days before the planned commencement of the trial at latest.

Full details are available here <http://www.sam.ee/en/clinical-trials-medicinal-products-estonia>

Time line for approval process

A formal letter of 'no objection' will be given within 30 days for phase II – IV studies (for phase I studies within 60 days and for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms within 90 days after receipt of the application and required documentation).

Process for fast track approvals during epidemics/pandemics

No information

Ethics Committees

Structure and configuration of Ethics committees

There are two independent research ethics committees that consider medical research and clinical trials in Estonia – one in Tartu and another in Tallinn. The ethics committees of hospitals are not responsible for clinical trials and medical research. The Research Ethics Committee of the University of Tartu operates also as ethics Committee of the Estonian Genome Center University of Tartu. The Estonian Council of Bioethics, established by the Ministry of Social Affairs, is the national co-ordinating centre.

Ethics Application/Approval process

The application for a clinical trial must be submitted to the secretary of the (research) ethics committee (EC) at least 10 days before the EC meeting, held in every month. The relevant parts of the application are sent to all EC committee members and the research project will be discussed at the next meeting of EC. If there are questions or problems they will be presented to the principal investigator (study coordinator), the answers will be revised and if there are relevant changes they will be discussed on the next meeting.

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

No information

Contact Details of Ethics committees

Tallinn Medical Research Ethics Committee

National Institute for Health Development

42 Hiiu Str

11619 Tallinn

Tel +372 659 3924

Fax +372 659 3901

e-mail: marje.liibek@tai.ee

Ethics Review Committee on Human Research of the University of Tartu

Office of Research and Development

University of Tartu

Ülikooli 18-304

50090 Tartu, Estonia

Tel: +372 737 5514

Fax: +372 737 5508

E-post: eeetikakomitee@ut.ee

Website addresses of ethics committees

<http://www.tai.ee/en/about-us/tallinn-medical-research-ethics-committee>

<http://www.ut.ee/en/research-ethics-committee-university-tartu>

Website links to ethics application forms

<http://www.tai.ee/en/about-us/tallinn-medical-research-ethics-committee>

<http://www.ut.ee/en/research-ethics-committee-university-tartu>

Website links to meeting time tables

<http://www.tai.ee/en/about-us/tallinn-medical-research-ethics-committee>

<http://www.ut.ee/en/research-ethics-committee-university-tartu>

Ethical approval timeline

The committee has to give a decision within 60 days after the submission of all documents. Upon application for the clinical trial of a medicinal product, gene therapy, cell therapy or an immunological medicinal product as well as using a genetically modified organism, the Committee shall make a resolution within 90 days.

Ethical approval application Fees

The fee charged for assessing the protocol for a clinical trial is 383 euros. For protocol variations there is no fee.

Special requirements for studies involving children/vulnerable people

Same process followed for ethics approvals

Special requirements if studies include collection and use of human tissues

Same process followed for ethics approvals

Helpful notes for obtaining ethical approvals

Anticipate delays if drug not registered in Estonia, or elsewhere in the EU, also delays during summer holiday period in July.

All timelines given are provisional and vary from study to study Separate IC is needed for genetic studies Agreement from hospital is needed as well

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The State Agency of Medicines

<http://www.ravimiamet.ee/en/clinical-trials-medicinal-products-estonia> All information is in this web-page

Application process for IMP

The State Agency of Medicines must be informed of the trial. In order to obtain approval, an applicant must submit a written application to this effect to a committee together with data specified under subsection

92 (8) of the Medicinal Products Act. The application is to be submitted in the EU format, acceptable in English. All documents required are in accordance with Detailed Guidance for the Request for Authorisation of a Clinical Trial on a Medicinal Product for Human Use (http://ec.europa.eu/health/files/eudralex/vol-10/2010_c82_01/2010_c82_01_en.pdf). The signed declaration by the head of the health-care institution (study centre).

Details area available in the Medicinal Products Act. <http://www.sam.ee/en/medicinal-products-act>

Timeline for IMP trial approval

A formal letter of ‘no objection’ will be given within 30 days for phase II – IV studies (for phase I studies within 60 days and for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms within 90 days after receipt of the application and required documentation).

Fees for IMP approval

Clinical trial application (includes one research centre) €383,46

For each additional research centre €15,97

Details of fees are available here <http://www.sam.ee/en/state-fees-and-assessment-fees>

Pre-approval of protocols

Not available

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Cells, tissues and organs can only be handled by special medical care providers who hold an activity licence for the handling of cells, tissues and organs.

Further details are available <http://www.sam.ee/en/handling-cells-tissues-and-organs>

Regulations around transport and sample sharing

According to the Ministry of Social Affairs Regulation No.31, 18 February 2005 (available in Estonian), blood and blood components are considered to be medicines, requiring special authorisation for transport and export/import to/from the European Economic Area (EEA) and third countries. (<http://www.sam.ee/en/special-authorisation-import-and-export-and-notification-import-and-export-blood-components>)

On the basis of the Medicinal Products Act §18 p 41 the import and export of cells, tissues and organs of human or animal origin that are intended for human application can be carried out by the holder of a cells, tissues and organs activity licence. (<http://www.sam.ee/en/special-authorisation-import-and-export-and-notification-import-and-export-cells-tissues-and-organs>)

Data protection

Data protection regulations

Personal Data Protection Act (RT I 2003, 26, 158) available at <http://www.dataprotection.eu/pmwiki/pmwiki.php?n=Main.EE>

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

To be updated

Contact details of National Network leads

To be updated

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

FINLAND

Total Population: 5.41 Million

Languages: Finnish, Swedish

Time Zone: UTC+02:00

Further demographic info (cultural/religious etc.)

Religions: Lutheran 78.4%, Orthodox 1.1%, other Christian 1.1%, other 0.2%, none 19.2% (2010 est.)

Urban population: 85% of total population (2010)

Life expectancy at birth: 79.69 years; male- 76.24 years; female- 83.29 years (2014 est.)

Health expenditures: 8.9% of GDP (2011)

Physicians density: 2.9 physicians/1,000 population (2010)

Hospital bed density: 5.9 beds/1,000 population (2010)

Health System

Primary care system

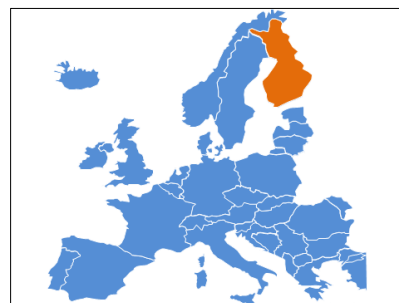
Finland's social welfare and health care system is founded on government-subsidised municipal social welfare and health care services. In addition to the public sector, many private enterprises and non-governmental organisations also provide services. The current system of delivering municipal primary health services originated with the enactment of the Primary Health Care Act in 1972. It obliged municipalities to provide primary care services to their inhabitants in what was a completely novel provider organization at that time, a "health centre". A municipal health centre can be defined as a functional unit or an organization that provides primary curative, preventive and public health services to its population. Health centres offer a wide variety of services: outpatient medical care, inpatient care in inpatient wards (in larger cities these can be classified more as a GP-run hospitals), preventive services, dental care, maternity care, child health care, school health care, care for older people, family planning, physiotherapy and occupational health care. As a rule, patients must use the health centre of their own municipality of residence, except in emergency situations.

Source: Finland Health System Review

http://www.euro.who.int/_data/assets/pdf_file/0007/80692/E91937.pdf

Acute hospital system

Secondary care is mainly provided by the municipality-owned hospital districts. There are 20 hospital districts in Finland. In addition, there are private specialized



ambulatory services and 41 private hospitals. About 10% of specialist level outpatient visits are provided by health centres. Each hospital district has a central hospital and other hospitals as needed, depending on the size of the hospital district. Five of the central hospitals are university teaching hospitals offering more demanding forms of specialized medical care and tertiary care. Hospital districts are funded by the member municipalities mainly based on fee-for service. Physicians and other personnel in public hospitals are salaried employees of hospital districts. Hospital districts provide specialized outpatient care, inpatient care and day surgery, usually in the same facilities. Patients need a referral from their health centre physician or any other licensed physician in order to access the outpatient or inpatient department in a specialized care hospital, except in emergencies.

Source: Finland Health System Review

http://www.euro.who.int/_data/assets/pdf_file/0007/80692/E91937.pdf

Public health agency

Name of public health agency

National Institute for Health and Welfare

Website of public health agency

<http://www.thl.fi/web/thlfi-en>

Contact details of public health agency

National Institute for Health and Welfare (THL)

Postal address: P.O. Box 30, FI-00271 Helsinki, Finland

Street address: Mannerheimintie 166, Helsinki

Tel. +358 29 524 6000

E-mail addresses: firstname.lastname@thl.fi

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

National Agency for Medicines

Website of competent authority

<http://www.fimea.fi/>

Contact Address of competent authority

Visiting: Mannerheimintie 103b, 00280 Helsinki

Postal: P.O. Box 55, FI-00034

Tel: +358 29 522 3341

Fax: +358 29 522 3001

Email: communications@fimea.fi

Application process of clinical trial approval

The Finnish Medicines Agency Fimea must be notified of interventional clinical trials on medicinal products, regardless of whether the investigational medicinal product has marketing authorisation or not.

Fimea need not be notified of investigations other than interventional trials. These non-interventional trials must meet the following criteria: Medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data

In the case of any uncertainty, Fimea will decide whether a notification for a clinical trial on medicinal products should be submitted.

Further details are available here http://www.fimea.fi/supervision/clinical_drug_trials

The Medicines Act 395/1987 is available here http://www.fimea.fi/download/18580_Laakelaki_englanniksi_paivitetty_5_2011.pdf

Time line for approval process

Within 90 days of having received an appropriate application. The Agency may extend the period by 90 days if

giving an opinion calls for extensive further documentation. There is no fixed time limit for decisions on xenogenic cell research.

Process for fast track approvals during epidemics/pandemics

No information

Ethics Committees

Structure and configuration of Ethics committees

According to the Finnish Medical Research Act, all medical research plans must first be approved by an independent ethics committee. An ethical assessment must be carried out for all medical trials. The assessments are principally based on the relevant regulations and other generally accepted ethical principles.

Independent ethics committees must evaluate whether trials have been planned in an ethically acceptable manner so as to not cause unnecessary harm or risks to potential research subjects. Particular emphasis is given to the safety, legal status, and rights of the subjects. An assessment of the scientific rationale, the appropriateness of the

information presented to subjects, and the procedure used to seek consent is of particular importance.

Ethics committees are not, however, responsible for granting licences to carry out trials. The committees only issue opinions which the licensing authorities must take into account.

In Finland, statutory ethics committees include the National Committee on Medical Research Ethics (TUKIJA) and regional ethics committees. Each of the hospital districts operating a university hospital must have at least one ethics committee. The Hospital District of Helsinki and Uusimaa, the largest of the Finnish hospital districts, has currently four ethics committees.

Source: http://www.tukija.fi/en/general_information/ethics_committees

The Medical Research Act is available here

<http://www.finlex.fi/en/laki/kaannokset/1999/en19990488.pdf>

Ethics Application/Approval process

The first step in all clinical trials is for the sponsor to apply for a ruling from TUKIJA on whether the ethical admissibility of the proposal is to be reviewed by TUKIJA or by one of the regional ethics committees. Sponsors can apply for a ruling on jurisdiction as soon as it becomes likely that the trial in question will be run in Finland, even if the actual application is not yet complete. Depending on the ruling, the sponsor then applies for an ethics review to be carried out either by TUKIJA or by the relevant regional ethics committee.

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

No information

Contact Details of Ethics committees

National Committee on Medical Research Ethics TUKIJA

Postal Address: Valvira, P.O. Box 210, FI-00531 Helsinki, Finland

Visiting address: Lintulahdenkuja 4, 00530 Helsinki, Finland

Tel. +358 295 209 111

e-mail: tukija@valvira.fi

Website addresses of ethics committees

National Committee on Medical Research Ethics

<http://www.tukija.fi/en>

List of regional ethics committees

http://www.tukija.fi/fi/linkit/eettiset_toimikunnat

Website links to ethics application forms

Meeting time table is available on the websites of regional ethics committees.

Links to regional ethics committees websites are available here

http://www.tukija.fi/fi/linkit/eettiset_toimikunnat

Website links to meeting time tables

Meeting time table is available on the websites of regional ethics committees.

Links to regional ethics committees websites are available here

http://www.tukija.fi/fi/linkit/eettiset_toimikunnat

Ethical approval timeline

The ethics committee shall give its opinion to the body asking it within 60 days of having received an appropriate request for opinion as well as communicate it to the Finnish Medicines Agency for information.

Ethical approval application Fees

Fees details are available here (in Finnish)

http://www.ppsHP.fi/instancedata/prime_product_julkaisu/npp/embeds/31048_STM_mak-suasetus_No_650-2013.pdf

Special requirements for studies involving children/vulnerable people

Extensive guidelines on research involving adults unable to consent for themselves (Section 7) and research on minors (Section 8) is given in the Medical Research Act.

If minors less than 15 years are studied, the consent is given by the guardian. Minors older than 15 years of age can give an individual consent, if the research is supposed to give direct benefit for research participants. In this case guardians are informed about the trial. If direct benefit is not expected, the consent from guardians is required. If the minor understands the purpose, risks and benefits of the trial, the consent/assent of the minor is also required.

The Medical Research Act is available here

<http://www.finlex.fi/en/laki/kaannokset/1999/en19990488.pdf>

Special requirements if studies include collection and use of human tissues

Not available/to be updated

Helpful notes for obtaining ethical approvals

To be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The Finnish Medicines Agency

Application process for IMP

The Finnish Medicines Agency Fimea must be notified of interventional clinical trials on medicinal products, regardless of whether the investigational medicinal product has marketing authorisation or not. Application procedure include: Apply for a EudraCT number; Fill in, save and print the notification form; Submit the CD-ROM and the signed printout to the Finnish Medicines Agency, Fimea.

Timeline for IMP trial approval

Within 90 days of having received an appropriate application. The Agency may extend the period by 90 days if giving an opinion calls for extensive further documentation. There is no fixed time limit for decisions on xenogenic cell research.

Fees for IMP approval

The amount of payment for a clinical trial notification is 2200 €. In the case of trials involving medicinal products for gene therapy, somatic or xenogenic cell therapy or medicinal products containing genetically modified organisms the amount of payment for an application is 2500 € according to the Ministry of Social Affairs and Health.

Pre-approval of protocols

Not available

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available/to be updated

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

Processing of personal data in connection with a clinical trial subject to the Personal Data Act (523/1999). Details on Personal Data Act in relation to Clinical Trials are available on Data Protection Ombudsman's website

<http://www.tietosuoja.fi/fi/index/ratkaisut/tietosuojavaltuutetunohjaussuostumuksenp.html>

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

Heli PEHRMAN

Finn-Medi Oy

Biokatu 12

33520 Tampere

Finland

Phone: +358 (0) 40 821 6944

Email: Heli.Pehrman@finnmedi.com

Contact details of National Network leads

To be updated

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

FRANCE

Total Population: 65.7 Million

Languages: French

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 83%-88%, Protestant 2%, Jewish 1%, Muslim 5%-10%, unaffiliated 4%

Urban population: 85% of total population (2010)

Life expectancy at birth: 81.66 years; Male- 78.55 years; Female- 84.91 years (2014 est.)

Health expenditures: 11.6% of GDP (2011)

Physicians density: 3.38 physicians/1,000 population (2011)

Hospital bed density: 6.6 beds/1,000 population (2010)

Health System

Primary care system

The French health care system is one of universal health care largely financed by government national health insurance. The French government generally refunds patients 70% of most health care costs, and 100% in case of costly or long-term ailments. The entire population must pay compulsory health insurance. The insurers are non-profit agencies that annually participate in negotiations with the state regarding the overall funding of health care in France.

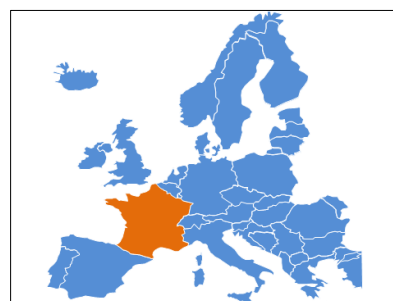
Primary care in France is mostly delivered in the ambulatory care sector by self-employed professionals. From the late 1990s, GPs have gained a major role in the coordination of care, with the implementation of a partial gate-keeping system that provides patients with an incentive to visit their GP prior to consulting a specialist. Primary and secondary health care that does not require hospitalization is delivered by self-employed doctors, dentists and medical auxiliaries (including nurses and physiotherapists) working in their own practices, and, to a lesser extent, by salaried staff in hospitals and health centres.

Source: Health System Review France

http://www.euro.who.int/_data/assets/pdf_file/0008/135809/E94856.pdf

Acute hospital system

Hospital care is delivered by public, private non-profit-making and private profit-making hospitals, and long-term care for the elderly and disabled is provided through



both residential care and home care. Acute medical, surgical and obstetric care is provided by public as well as private hospitals, with different areas of specialization. Acute medical care is mainly provided by public hospitals, which account for three-quarters of acute medical care capacity and performs 75% of full-time episodes and 55% of day-care. episodes. Private profit-making hospitals account for 10% of full-time beds and 20% of day-care beds, and they provide 15% of full-time episodes and 40% of day-care episodes.

Source: Health System Review France

http://www.euro.who.int/__data/assets/pdf_file/0008/135809/E94856.pdf

Public health agency

Name of public health agency

French Institute for Public Health Surveillance

Website of public health agency

<http://www.invs.sante.fr/en>

Contact details of public health agency

Institut de veille sanitaire

12, rue du Val d'Osne

94415 Saint-Maurice cedex

France

Tel : 33 (0) 1 41 79 67 00

Fax : 33 (0) 1 41 79 67 67

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

Agence Nationale de Sécurité du Médicament et des Produits de Santé ANSM (National Security Agency of Medicines and Health Products)

Website of competent authority

<http://ansm.sante.fr/>

Contact Address of competent authority

ANSM - site de Saint Denis

143/147, boulevard Anatole France

93285 SAINT-DENIS CEDEX

Tél : +33 (0)1 55 87 30 00

Email: listes@ansm.sante.fr

Application process of clinical trial approval

The authorisation to conduct a trial requires both the ethics committee approval and the competent authority authorization. For any research on medicinal products for human use, it is essential to obtain a registration number from the European database of clinical trials on medicinal products for human use "EudraCT" before starting the process of authorization application.

Forms are available here http://www.bfarm.de/EN/Service/Formulare/_node.html

Time line for approval process

Not available/to be updated

Process for fast track approvals during epidemics/pandemics

Fast track approvals are facilitated.

Ethics Committees

Structure and configuration of Ethics committees

Clinical trials on medicinal products for human use are reviewed by the an ethics committee/Comité de Protection des Personnes-CPP. France has been divided in seven regional areas. The protocol can be reviewed by any CPP in the area where the principal investigator (or coordinating investigator in the case of multi centre studies) is located (L.1123-6 Chapter 3 CSP).

CPP (Committee for Patients Protection)

CPP du SUD-OUEST et OUTRE-MER IV Centre Hospitalier ESQUIROL Cabanis Haut
15 rue du Docteur Marcland 87025 LIMOGES CEDEX Tél : 05.55.43.11.19 Fax :
05.55.43.10.27 E.mail : cppsoom4@ch-esquirol-limoges.fr

Ethics Application/Approval process

The sponsor is responsible for the submission to the competent authority. The sponsor also submits the request to a CPP responsible for the principal investigator. Both mono and multi-centre trials require only one approval from an Ethics Committee (CPP). No ethical requirements for observational/qualitative studies for the time being but additional legislation may be implemented in the future. However authorization must be requested from the national data protection authority (Comité National Informatique et libertés (CNIL)

Details can be found on chapter 3 of Code de la santé publique (code of Public Health)
<http://legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665>

Ethics: Fast-track approval available?

Yes

Ethics: Pre-approval of study protocol available?

No

Ethics: Waived consent?

No

Fast-track application process for ethical approval

This is obtained by the Ministry of Health for the benefit of an institution (eg hospital).

Contact Details of Ethics committees

A list of all CPP can be found on the Recherche biomédicale website

<http://www.recherche-biomedicale.sante.gouv.fr/pro/comites/coordonnees.htm>

Website addresses of ethics committees

A list of all CPP can be found on the Recherche biomédicale website

<http://www.recherche-biomedicale.sante.gouv.fr/pro/comites/coordonnees.htm>

Website links to ethics application forms

Not available/to be updated

Website links to meeting time tables

Not available/to be updated

Ethical approval timeline

The CPP sends its written advice within 35 days.

Ethical approval application Fees

No fees

Special requirements for studies involving children/vulnerable people

For children, consent should be obtained from both parents or guardians. For persons lacking capacity to consent, this should be obtained from a trusted person. A second application to the ethical committee is very often required.

Special requirements if studies include collection and use of human tissues

Approvals processes no different in these cases.

Helpful notes for obtaining ethical approvals

Positive ethical approval is nationally universal, meaning that a unique approval is enough and valid for the whole country wherever it has been given.

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

Agence Nationale de Sécurité du Médicament et des Produits de Santé ANSM (National Security Agency of Medicines and Health Products)

ANSM - site de Saint Denis 143/147, boulevard Anatole France 93285 SAINT-DENIS CEDEX Tél : +33 (0)1 55 87 30 00 <http://ansm.sante.fr/>

Application process for IMP

The authorisation to conduct a trial requires both the ethics committee approval and the competent authority authorization. For any research on medicinal products for human use, it is essential to obtain a registration number from the European database of clinical trials on medicinal products for human use "EudraCT" before starting the process of authorization application.

Timeline for IMP trial approval

2-3 months

Fees for IMP approval

No fee

Pre-approval of protocols

Pre-approval is allowed - exact process unclear

IMP: Fast-track approval available?

Yes

IMP: Pre-approval available?

Yes

Biological samples

Registration and bio-banking requirements

When a collection of human biological samples is formed for the sole purpose biomedical research, it is declared to the competent authority for this search.

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

In France, the privacy of participants is protected by Law 2004-801 relating to the protection of individuals with regard to the processing of personal data that modifies Act 78-17 of 6 January 1978 on Data Processing, Data Files and Individual Liberties. This law includes provision concerning health data collecting within clinical research.

The trial must be submitted to the committee for data protection (<http://www.cnil.fr/english/>) assessing the storage and to the Comité Consultatif sur le Traitement de l'Information en Matière de Recherche dans le Domaine de la Santé (CCTIRS, <http://www.enseignementsup-recherche.gouv.fr/cid20537/cctirs.html>) assessing the content of information collected.

English version of data protection law: <http://www.cnil.fr/fileadmin/documents/en/Act78-17VA.pdf>

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

Amélie MICHON

F-CRIN, French Clinical Research Infrastructure Network

AROPA

35 Rue Bernard de Ventadour

31300 Toulouse Cedex

France

Phone: +33 (0)5 34 55 75 92

Email: amelie.michon@inserm.fr

Contact details of National Network leads

GRACE

Pia Touboul, Brigitte Dunais

University of Nice-Sophia Antipolis

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

GERMANY

Total Population: 80.5 Million

Languages: German

Time Zone: UTC + 1

Further demographic info (cultural/religious etc.)

Religions: Protestant 34%, Roman Catholic 34%, Muslim 3.7%, unaffiliated or other 28.3%

Urban population: 74% of total population (2010)

Life expectancy at birth: 80.44 years (male: 78.15 years, female: 82.86 years)

Health expenditures: 11.1% of GDP (2011)

Physicians density: 3.69 physicians/1,000 population (2010)

Hospital bed density: 8.3 beds/1,000 population (2010)

Health System

Primary care system

Germany operates a two tiered health care system. The Länder (states) and the Federal Government and civil society organisations, share the responsibility for health care in Germany. It is compulsory for all citizens and long-term residents to have health insurance, via a public Statutory Health Insurance (SHI) scheme (Gesetzliche Krankenversicherung, GKV). The German health care system has traditionally no gatekeeping system; instead patients are free to select a sickness-fund-affiliated doctor of their choice. General practice medicine and specialist care is the responsibility of physicians who are legally mandatory members of regional Associations.

Source: HIT 2004,

http://www.euro.who.int/_data/assets/pdf_file/0018/80703/E85472.pdf

Acute hospital system

Acute care and long-term care are commonly provided by non-profit or for-profit providers employing nurses,

assistant nurses, elderly caretakers, social workers and administrative staff.

Source: HIT 2004,

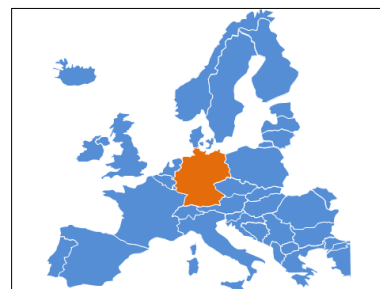
http://www.euro.who.int/_data/assets/pdf_file/0018/80703/E85472.pdf

Public health agency

Name of public health agency

Robert Koch Institute

Website of public health agency



http://www.rki.de/EN/Home/homepage_node.html

Contact details of public health agency

Robert Koch Institute

Postfach 65 02 61

D-13302 Berlin

Germany

Phone: +49 (0)30 - 18754-0

Fax: +49 (0)30 - 18754-2328

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

There are two different competent authorities regulating clinical trials in Germany; Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM - Federal Institute for Drugs and Medical Devices) and Paul Ehrlich Institut (PEI)

Website of competent authority

The Federal Institute for Drugs and Medical Devices-

http://www.bfarm.de/EN/Home/home_node.html

Paul Ehrlich Institut (PEI)- <http://www.pei.de/DE/home/de-node.html>

Contact Address of competent authority

Federal Institute for Drugs and Medical Devices

Kurt-Georg Kiesinger-Allee 3,

53175 Bonn, Germany

Phone:+49 228 9930730

Paul-Ehrlich-Institut,

Paul-Ehrlich-Str. 51-59

63225 Langen

Phone: +49 6103 77 0

Application process of clinical trial approval

Section 7 (1) of the Ordinance on GCP lays down that applications for the authorisation of a clinical trial must be submitted in a paper version and the application form as well as the documents to be attached must in addition, also be submitted to the federal competent authority on an electronic data carrier.

Details of application process can be available here

http://www.bfarm.de/EN/Drugs/licensing/clinicalTrials/_node.html

or (in German)

<http://www.pei.de/DE/infos/pu/genehmigung-klinische-pruefung/genehmigung-klinische-pruefung-node.html>

Time line for approval process

30 - 90 days depends on the type of study.

Process for fast track approvals during epidemics/pandemics

No information

Ethics Committees

Structure and configuration of Ethics committees

There are no central ethics committee in Germany. Germany has a total of 53 research ethics committees, 33 attached to Faculties of Medicine/Universities, 17 attached to Medical Associations ("Ärzttekammern") in the States and 3 attached to States governments.

Ethical consent needs to be obtained from the Ethics Commission (EC)/ Independent Review Board (IRB) responsible for the respective investigator's institution. In multicenter clinical trials according to the German Drug Law (AMG) or the Medical Devices Act (MPG) the EC/ IRB of the coordinating physician acts as leading EC/ IRB, giving mutual approval with all participating ECs/ IRBs. In multicenter trials that are not subject to the German Drug Law (AMG) or the Medicinal Product Law (MPG) separate approval from each participating EC/ IRB has to be obtained.

Ethics Application/Approval process

The sponsor must submit a request for a favourable opinion to the competent REC. For a multicentre trial, the sponsor nominates one investigator as the lead investigator (Leiter der klinischen Prüfung, LKP). Then the REC of this LKP becomes the master REC which combines the opinions of the local RECs into a single opinion. For the submission of requests for trials with pharmaceutical drugs, medical devices or radiation research the sponsor is responsible. For other research projects the investigator himself is responsible, but in general he can delegate this also to the sponsor. The competence of RECs is determined by the fixed affiliation of the principal investigator (single centre trial) or the co-ordinating investigator (multi-centre trial) to their REC.

Source: EFGCP Report

<http://www.efgcp.eu/Downloads/EFGCPReportFiles/Germany%20definitive%20Updated.pdf>

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

Yes

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

For more specific questions (and all questions regarding fast-track approval or waivers) please contact the "Arbeitskreis Medizinischer Ethikkommissionen in der Bundesrepublik Deutschland e.V." <http://www.ak-med-ethik-komm.de/aktuelles.html>
[med.ethik.komm](http://www.med.ethik.komm)

Contact Details of Ethics committees

A list of Public service ethics committees of the state medical board, and Public-sector medical ethics

committees of the University Hospitals are available here

<http://www.ak-med-ethik-komm.de/>

Website addresses of ethics committees

The National Council for Ethics is at <http://www.ethikrat.org/>

Bio-ethics Commission of the Bavarian State Government

<http://www.bioethik-kommission.bayern.de/>

Bio-ethics Commission Rhineland-Palatinate

<http://www.mjv.rlp.de/Ministerium/Bioethik/>

Central Ethics Commission for stem cell research

http://www.rki.de/DE/Content/Kommissionen/ZES/zes_node.html

Central Ethics Commission of the German Medical Association

<http://www.zentrale-ethikkommission.de/>

Website links to ethics application forms

See this link to access the websites of ethics committees <http://www.ak-med-ethik-komm.de/>

Website links to meeting time tables

See this link to access the websites of ethics committees <http://www.ak-med-ethik-komm.de/>

Ethical approval timeline

For mono-site trials it is 30 days for pharmaceutical drug trials and 60 days for medical device trials. For multi-site trials (with pharmaceutical drugs or medical devices) it is 60 days after receipt of complete application documents. For radiation research it is also 60 days. Other biomedical research projects do not have timelines for assessment. For

substantial amendments the timelines are 20 days for pharmaceutical drug trials, 30 days for medical device trials and 35 days for trials on somatic cell or gene therapy.

Source: EFGCP Report

<http://www.efgcp.eu/Downloads/EFGCPReportFiles/Germany%20definitive%20Updated.pdf>

Ethical approval application Fees

RECs charge fees for their work in the range € 1000 – 6000 for clinical trial assessments and €200–1000 for substantial amendments.

Special requirements for studies involving children/vulnerable people

For minors; consent must be given by the legal representative(s), usually both parents. Assent of the minor has to be sought if possible. Refusal must be accepted. For vulnerable adults: the consent has to be provided by the legal representative. Assent of the vulnerable adult has to be sought if possible, refusal must be accepted.

Process for obtaining ethical approvals is the same.

Special requirements if studies include collection and use of human tissues

Processes for obtaining ethics approvals are much the same, but a specific description should be included when obtaining informed consent.

Helpful notes for obtaining ethical approvals

With respect to an adaptive trial the ethics committees have no experiences. It has to be discussed with the leading ethics

The following factors can create delays: Faults - changes - GCP certificates are not available

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

Paul-Ehrlich-Institut (PEI)

Federal Institute for Drugs and Medical Devices (BfArM)

Application process for IMP

Details of application process can be available here

http://www.bfarm.de/EN/Drugs/licensing/clinicalTrials/_node.html

or (in German)

<http://www.pei.de/DE/infos/pu/genehmigung-klinische-pruefung/genehmigung-klinische-pruefung-node.html>

Timeline for IMP trial approval

30 - 90 days depends on the type of study.

Fees for IMP approval

Details are available

http://www.bfarm.de/EN/Service/gebuehren/_node.html

<http://www.pei.de/EN/information/license-applicants/fees/fees-node.html>

Pre-approval of protocols

Not available/To be updated

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available/To be updated

Regulations around transport and sample sharing

Not available/To be updated

Data protection

Data protection regulations

Details concerning data protection is listed in section 40 subsection 2a AMG and the Bundesdatenschutzgesetz (BDSG) - German Data Protection Act. (In German

http://www.gesetze-im-internet.de/bundesrecht/bdsg_1990/gesamt.pdf)

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

Anke STRENGE-HESSE

KKS-Netzwerk

Network Coordinating Centres for Clinical Trials/Central office

Kerpener Str. 62

D-50937 Cologne

Germany

Phone: +49 (0) 221 478 89331

Fax: +49 (0) 221 478 96510

anke.strenge-hesse@uk-koeln.de

Contact details of National Network leads

To be updated

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

GREECE

Total Population: 11.28 million

Languages: Greek

Time Zone: UTC+02:00

Further demographic info (cultural/religious etc.)

Religions: Greek Orthodox (official) 98%, Muslim 1.3%, other 0.7%

Urban population: 61% of total population (2010)

Life expectancy at birth: 80.3 years; male: 77.71 years; female: 83.06 years (2014 est.)

Health expenditures: 9% of GDP (2011)

Physicians density: 6.04 physicians/1,000 population (2008)

Hospital bed density: 4.9 beds/1,000 population (2009)

Health System

Primary care system

A gatekeeping mechanism and a referral system have not been developed in Greece. Patients can choose to visit the emergency department of any public or private contracted hospital, bypassing primary health contact points. As the user charges for emergency visits are low, a large proportion of patients go directly to emergency departments.

Primary health care in Greece is delivered by a mix of public and private health service providers such as local authorities, private sector, social insurance funds and ESY (National health system). Primary health care in rural and semi-urban areas is mostly delivered free of charge by a network of 201 health centres staffed by GPs and specialists. Although one of the principal functions of the health centres should be that of gatekeeping, implementation of this function is severely inhibited by the lack of GPs. The 114 outpatient departments of public hospitals provide primary health care within the ESY. They cover all specialties and are the major providers of primary care services in urban areas.

Social insurance funds play a significant role in the provision and funding of primary health care services. IKA, the largest social insurance fund, is responsible for primary health care provision to its 5.5 million beneficiaries. OGA is the second largest social insurance fund (covering 20% of the total population). It is financed mainly through the state budget and, to a lesser extent, through health contributions. During the last decade some large municipalities have established small health centres offering a



limited range of services to be provided by GPs, cardiologists, paediatricians, gynaecologists, dentists and oculists. In addition to public primary care services, there are more than 25 000 private practices and laboratories and approximately 400 private diagnostics centres.

Source: Greece Health System Review

http://www.euro.who.int/__data/assets/pdf_file/0004/130729/e94660.pdf

Acute hospital system

Secondary and tertiary health care is provided by ESY (National health system) hospitals, other non-ESY public hospitals and private clinics. Greek hospitals are categorized as either general or specialized according to the type of services they offer. Specialized hospitals are referral centres for a single specialty such as obstetrics, paediatric care, cardiology, psychiatry and so on. The most complex and technologically sophisticated services are offered by hospitals linked to the country's medical schools. There are also some rural health centres called "health centre-hospitals", which provide basic diagnostic services, minor surgery and care for patients who need nursing care; they operate in distant and isolated areas such as islands, remote areas or mountainous locations.

Source: Greece Health System Review

http://www.euro.who.int/__data/assets/pdf_file/0004/130729/e94660.pdf

Public health agency

Name of public health agency

General Director of Public Health of Ministry of Health and Social Solidarity

Website of public health agency

<http://www.ermis.gov.gr/>

Contact details of public health agency

Address: Veranzeroy 50

Postal code : 10437

Municipality/area : Athinaion

Phone No. : 2105222393

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The National Organization for Medicines (Εθνικός Οργανισμός Φαρμάκων EOF)

Website of competent authority

<http://www.eof.gr/>

Contact Address of competent authority

National Agency for Medicines

Mesogion 284.15562 Cholargos

Call center: 2040 213 000

Fax: 210 65 45 535

E-mail: relation@eof.gr

Application process of clinical trial approval

Applications for approval of clinical studies submitted for the Department of Clinical Trials, Division of Pharmaceutical Studies and Research, together with the necessary supporting documents.

Non-Commercial Clinical Studies (Invasive and Non-Invasive) The Ministerial Decision DYG3/89292 Gazette V1973/31-12-2003 and Directive 2005/28/EC on Good Clinical Practice provides specific rules will apply to "non-commercial clinical trials" conducted by researchers without the participation of pharmaceutical industry.

Further details are available here (in Greek) <http://www.eof.gr/web/guest/clinical>

Time line for approval process

Not available - survey respondent also said she didn't know

Process for fast track approvals during epidemics/pandemics

Yes - If the investigator pay a fee of 500 euro

Ethics Committees

Structure and configuration of Ethics committees

There is one central (National Ethics Committee) and one in each hospital (Local Ethics Committee/Institutional Review Board). The National Ethics Committee (E.E.D.) for clinical studies consist of nine (9) leading scientists, who are defined by the Ministerial Decisions by AP DY1d/G.P. 127482/25-11-2010 and AP DY1d/G.P. 142742/11/2-3-2012.

Ethics Application/Approval process

In order to conduct a clinical trial in Greece the application must be submitted to the Competent Authority (EOF) and a separate application must also be submitted to the National Ethics Committee (NEC). EOF issues an authorisation for the conduct of the clinical trial, provided that NEC has given a positive opinion.

Ethics: Fast-track approval available?

Yes

Ethics: Pre-approval of study protocol available?

Yes

Ethics: Waived consent?

Yes

Fast-track application process for ethical approval

Fast-track approval requires a fee of 500 euro paid at the local institutional boards of the hospitals

Contact Details of Ethics committees

Mesogion 284, 155 62 Cholargos

Secretary: Dr. Luminous Tzavellas

E-mail: ftzavella@eof.gr

Website addresses of ethics committees

<http://www.eof.gr/web/guest/eed> (in Greek)

Website links to ethics application forms

<http://www.eof.gr/web/guest/eed>

Website links to meeting time tables

<http://www.eof.gr/web/guest/eed>

Ethical approval timeline

Not available

Ethical approval application Fees

500 Euro

Special requirements for studies involving children/vulnerable people

Ethical approval processes are no different

Special requirements if studies include collection and use of human tissues

Ethical approval processes no different

Helpful notes for obtaining ethical approvals

To be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The National Organization for Medicines (Εθνικός Οργανισμός Φαρμάκων EOF)

Application process for IMP

Applications for approval of clinical studies submitted for the Department of Clinical Trials, Division of Pharmaceutical Studies and Research, together with the necessary supporting documents.

Timeline for IMP trial approval

no information

Fees for IMP approval

Approval for (intervention) clinical trial, per study: 3.000,00 euro.

For the amendment (intervention) clinical trial, per modification: 1.500,00 euro.

For approved non-invasive clinical study per study, 2,000.00 euros.

To amend non-interventional clinical study, per amendment: EUR 1,000.00.

Fast - track approval requires a fee of 500 euro paid at the local institutional boards of the hospitals

Pre-approval of protocols

Not available

IMP: Fast-track approval available?

Yes

IMP: Pre-approval available?

Yes

Biological samples

Registration and bio-banking requirements

Not available

Regulations around transport and sample sharing

Not available

Data protection

Data protection regulations

Law 2472/1997, Protection of Individuals with regard to the Processing of Personal Data

English version is available here

http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ENGLISH_INDEX/LEGAL%20FRAMEWORK/LAW%202472-97-APRIL010-EN%20_2_.PDF

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

GRACE

Christos Lionis

University of Crete Medical School

Contact details of National Network leads

GRACE

Christos Lionis

University of Crete Medical School

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

HUNGARY

Total Population: 9.94 million

Languages: Hungarian

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 37.2%, Calvinist 11.6%, Lutheran 2.2%, Greek Catholic 1.8%, other 1.9%, none 18.2%, unspecified 27.2% (2011 est.)

Urban population: 69.5% of total population (2011)

Life expectancy at birth: 75.46 years (male: 71.73 years, female: 79.41 years) (2014 est.)

Health expenditures: 7.7% of GDP (2011)

Physicians density: 3.41 physicians/1,000 population (2010)

Hospital bed density: 7.2 beds/1,000 population (2010)

Health System

Primary care system

Participation in the health insurance scheme is compulsory for all citizens living in Hungary, and opting out is not permitted. The contributions themselves are pooled in the Health Insurance Fund (HIF), which is administered by the National Health Insurance Fund Administration (NHIFA).

In Hungary, municipalities are responsible for ensuring the provision of primary care to the local population including family doctor services (through family physicians and family paediatricians), dental care, out-of-hours services, MCH nurse services and school health services. Family doctor services are provided to adults by family physicians and to children by family paediatricians. Local governments are responsible for ensuring that family doctor services are available to their population. Family doctors are meant to act as gatekeepers in the Hungarian health care system. With the exception of certain specialist services, physician referrals are mandatory for obtaining higher-level care, and patients are generally obliged to pay user charges if they bypass the referral system.

Source: Hungary Health System Review 2011

http://www.euro.who.int/_data/assets/pdf_file/0019/155044/e96034.pdf

Acute hospital system

The provision of secondary and tertiary care is shared among municipalities, counties, central government and, to a minor extent, private providers. County governments



usually own large multi-specialty county hospitals, which provide secondary and tertiary inpatient and outpatient care to people with acute and chronic illnesses, whereas municipalities own polyclinics (multi-specialty institutions providing exclusively outpatient specialist care), dispensaries (single-specialty institutions providing only outpatient care, typically to the chronically ill) and multi-specialty municipal hospitals (providing secondary inpatient and outpatient services for acute and chronic illnesses). The central government also owns hospitals, which provide acute and chronic inpatient and outpatient care. A small private sector is also involved in the provision of specialist care, but users have to pay out-of-pocket.

Source: Hungary Health System Review 2011

http://www.euro.who.int/_data/assets/pdf_file/0019/155044/e96034.pdf

Public health agency

Name of public health agency

National Public Health and Medical Officer Service (NPHMOS)

Website of public health agency

<https://www.antsz.hu/>

Contact details of public health agency

H-1097 Budapest, Florian Albert Road 2-6.

Email: biocid.helpdesk@oth.antsz.hu

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The National Institute of Pharmacy

Website of competent authority

http://www.ogyi.hu/main_page/

Contact Address of competent authority

Address: H-1051 Budapest, Zrínyi u. 3.

Post: 1372 P.O. Box 450.

Tel.: +36 1 8869-300

Fax: +36 1 8869-460

E-mail: ogyi@ogyi.hu

Application process of clinical trial approval

Applications should be submitted to the National Institute of Pharmacy (NIP). NIP validate the document within 5 days and the validation letter (with the list of deficiencies if applicable) is sent to the applicant. Deadline for submission of missing

documents is specified in the validation letter. NIP usually provides 15 working days for the applicant to submit the requested supplementary documentation (clock-stop). If the applicant does not reply within the given time-frame, the application will be rejected by the NIP. As soon as the supplementary documentation is submitted, the clock will be restarted. One copy of the documentation will be sent to the CEC for ethical review and opinion. If the documentation is appropriate, questions have been answered properly, and the opinion of CEC is favourable, NIP provides its approval. If the documentation is not appropriate, or CEC opinion is not favourable NIP rejects the application.

Full details are available here;

http://www.ogyi.hu/clinical_trial_submission_procedure/

Time line for approval process

45 work days

Process for fast track approvals during epidemics/pandemics

Ministry can handover and shorten approval process in case of epidemic or pandemic, pre-approvals of protocols and waived consent allowed.

Ethics Committees

Structure and configuration of Ethics committees

There are three Central Ethics Committees in Hungary which are all part of the Medical Research Council (ETT): The Clinical Pharmacology and Ethics Committee (KFEB) evaluates clinical trials on medicinal products. The Committee on Human Reproduction (HRB) gives permission to trials with human embryos and stem cells and to genetic studies concerning human reproduction. The Scientific Research Ethics Committee (TUKÉB) deals with all other interventional studies including medical devices and multicentre non-interventional studies. Regional Ethics Committees give only advice on the feasibility of a medicinal products trial.

Ethics Application/Approval process

The competent authority, the National Institute of Pharmacy (NIP), will forward a copy of the complete application to the ethics committee. No need to submit a separate application to the EC.

Ethics: Fast-track approval available?

Yes

Ethics: Pre-approval of study protocol available?

Yes

Ethics: Waived consent?

Yes

Fast-track application process for ethical approval

Ministry can handover and shorten approval process in case of epidemic pandemic urgency.

Contact Details of Ethics committees

Not available

Website addresses of ethics committees

Not available

Website links to ethics application forms

Not available

Website links to meeting time tables

Not available

Ethical approval timeline

35 working days

Ethical approval application Fees

The amount of the fee on the authorization of a new clinical trial HF 580,000 (including authorization and ethical approval). Assessment for non-commercial trials are free.

Further details are available here http://www.ogyi.hu/klin_vizsg_igszolg_dij/

Special requirements for studies involving children/vulnerable people

It is described in the Health Care Act . Professional/legal representatives give the consent on behalf of the vulnerable patient. The latter may be involved into the trial only if there is a direct benefit for them. This is the same for trials both with investigational medicinal products and other biomedical ones.

Relevant acts are available in Hungarian here

http://www.ogyi.hu/laws_and_regulations/

Approval processes are the same.

Special requirements if studies include collection and use of human tissues

Approval processes are the same.

Helpful notes for obtaining ethical approvals

To be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

Application for authorization is to be submitted to the National Institute of Pharmacy (NIP). Ethical approval is granted by the Clinical Pharmacology and Ethics Committee (KFEB).

Application process for IMP

Details on application procedure is described here (in Hungarian)

http://www.ogyi.hu/uj_klinikai_vizsgalat/

Application process is the same as CEC - two approvals are applied for in one process.

Timeline for IMP trial approval

45 working days

Fees for IMP approval

Details available here (in Hungarian) http://www.ogyi.hu/klin_vizsg_igszolg_dij/

Pre-approval of protocols

Pre-approvals are allowed.

IMP: Fast-track approval available?

Yes

IMP: Pre-approval available?

Yes

Biological samples

Registration and bio-banking requirements

Not available/to be updated

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

Data protection is regulated by Act CXII of 2011. A copy of the act (in Hungarian) is available here <http://www.magyarokozlony.hu/pdf/9906>

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

Erika BALOGH

University of Szeged

Albert Szent Györgyi Clinical Centre

Clinical Research Coordination Centre

6720 Szeged, Dugonics square 13., office 33-34.

HUNGARY

Phone: +36 62 546 895

Email: clin.trial@mail.u-szeged.hu

Contact details of National Network leads

To be updated

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

IRELAND

Total Population: 4.5 Million

Languages: English, Irish

Time Zone: UTC + 0

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 84.7%, Church of Ireland 2.7%, other Christian 2.7%, Muslim 1.1%, other 8.8%

Urban population: 62% of total population (2010)

Life expectancy at birth: 80.56 years (male: 78.28 years, female: 82.97 years)

Health expenditures: 9.4% of GDP (2011)

Physicians density: 3.19 physicians/1,000 population (2008)

Hospital bed density: 3.2 beds/1,000 population (2010)

Health System

Primary care system

Primary care in Ireland include access to GPs as well as other community-based services including nursing, social work, chiropodists, midwives, physiotherapists, occupational therapists, speech and language therapists, child health care, dental care and ophthalmic care services. GPs are the first point of contact for health care, and if necessary, followed by referral to specialist physicians. GPs charge typically €60–80 for a consultation, however those with GP Visit Card or Medical Card can avail GP services free of cost.

Ref: Ireland Health system review 2009

http://www.euro.who.int/_data/assets/pdf_file/0004/85306/E92928.pdf

Acute hospital system

Access to the publicly funded acute hospital sector generally requires an initial letter of referral from a GP unless an emergency admission is required. The public hospital sector incorporates both “voluntary” and HSE hospitals which may be further subdivided into regional, county and district hospitals

Public health agency

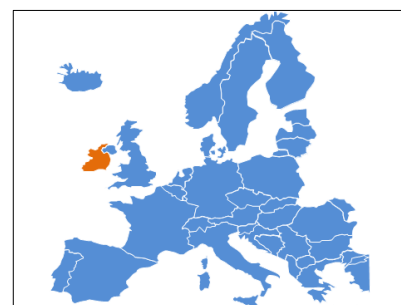
Name of public health agency

Health Service Executive (HSE)

Website of public health agency

<http://www.hse.ie/eng/>

Contact details of public health agency



Oak House, Millennium Park, Naas, Co. Kildare

Phone: +353 (0)45 880400

Fax: 1890 200 857

Dr. Steevens' Hospital, Dublin 8

Phone: +353 (0)1 635 2000

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

Irish Medicines Board (IMB)

Website of competent authority

<http://www.imb.ie/>

Contact Address of competent authority

Irish Medicines Board,

Kevin O'Malley House,

Earlsfort Centre,

Earlsfort Terrace,

Dublin 2,

Ireland.

Telephone number: +353-1-6764971

Fax number: +353-1-6767836

E-mail: customerservice@imb.ie

Application process of clinical trial approval

The Irish Medicines Board (IMB) is the competent authority in Ireland. Clinical Trial Application (CTAs) must be submitted to the IMB by the sponsor of the trial. Before an application can be submitted to the Board, a EudraCT number (EudraCT - European Clinical Trials Database) must be obtained from the website of the European Agency for the Evaluation of Medicinal Products (EMA).

Details of application process is described in IMB's "Guide to Clinical Trial Application" available at

http://www.imb.ie/images/uploaded/documents/AUT-G0001%20Guide%20to%20clinical%20trial%20applications%20v6_web%202.pdf

Time line for approval process

An application is assessed within 30 days of receipt of a valid application. Written notice is sent to the applicant setting out either acceptance of the request for authorisation, with conditions if necessary, or grounds for non-acceptance of the request.

Process for fast track approvals during epidemics/pandemics

Fast track approval possible via chairman's action i.e. through direct written request to Chair of Ethics Committee

Ethics Committees

Structure and configuration of Ethics committees

There are 12 recognized ethics committees under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004.

A list of recognized ethics committees are available here. http://www.dohc.ie/other_health_issues/Clinical_Trials_for_Medicinal_Products/ethics_committees.html

Operational procedures of bioethics committees are described in this document. http://www.dohc.ie/working_groups/Current/nacb/Operational_Procedures.pdf?direct=1

Ethics Application/Approval process

An application for ethics committee review in respect of proposed research must be made in writing and signed by a qualified researcher responsible for the conduct of the study. All properly submitted and valid applications shall be reviewed in a timely fashion and according to an established review procedure described in the REC's standard operating procedures.

Details of application procedure is discussed in section 4 of the "Operational Procedures for Research Ethics Committees: Guidance 2004" available at

http://www.dohc.ie/working_groups/Current/nacb/Operational_Procedures.pdf?direct=1

Ethics: Fast-track approval available?

Yes

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

Through direct written request to Chair of Ethics Committee

Contact Details of Ethics committees

Website of National Advisory Committee on Bioethics

http://www.dohc.ie/working_groups/Current/nacb/?lang=en

A list of recognized ethics committees are available at http://www.dohc.ie/other_health_issues/Clinical_Trials_for_Medicinal_Products/ethics_committees.html

Website addresses of ethics committees

A list of recognized ethics committees

http://www.dohc.ie/other_health_issues/Clinical_Trials_for_Medicinal_Products/ethics_committees.html

Website links to ethics application forms

NA

Website links to meeting time tables

NA

Ethical approval timeline

Under the Clinical Trials on Medicinal Products for Human Use Regulations 2004 RECs are required to give an opinion on research protocols involving standard products, no more than 60 days after acknowledgement of receipt of a “valid” application has been received.

Ethical approval application Fees

For industry-sponsored trials a fee of €1000.00 in connection with each application and a fee of €150.00 in respect of each trial site to which the application relates.

For non-industry-sponsored trials, the application fee is reduced to €150.00.

Notification of amendments attracts a fee of €200 (industry) or €50 (non- industry).

Special requirements for studies involving children/vulnerable people

"Parental or guardian's consent must be sought, but such consent can only be accepted where the research in question is clearly in the best interests of the subject concerned, or where the research concerned carries minimal risk or impact on the subject concerned." (section 1.1, Operational Procedures for Research Ethics Committees: Guidance 2004)

The Ethics committee will review the research to ensure that it firstly needs to be carried out in vulnerable populations and that the same objectives could not be met with non vulnerable populations and then will check thoroughly the procedures and documentation (patient information leaflets and informed consent documents) to ensure that they adequately protect the patient, and that the vulnerable patients/minors are able to assent to the research to the best of their ability.

Special requirements if studies include collection and use of human tissues

No special requirements with regard to submission for ethical approval.

Helpful notes for obtaining ethical approvals

To be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

Irish Medicines Board (IMB)

Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland. Tel: 353-1-676 4971 Tel: 353-1-676 4976 Fax: 353-1-676 7836 Email: imb@imb.ie

Application process for IMP

Applications for clinical trial authorisation should be made by the trial sponsor or a legal representative acting on behalf of the sponsor. Applications should comply with the European Commission's guideline, 'Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1)' in Chapter 1 of Volume 10 of Eudralex.

Details of application procedure are available in Irish Medicines Board's Guide to Clinical Trial Applications <http://www.imb.ie/images/uploaded/documents/AUT-G0001%20Guide%20to%20clinical%20trial%20applications%20v3.pdf>

Timeline for IMP trial approval

An application is assessed within 30 days of receipt of a valid application.

Fees for IMP approval

Details on fees are available in the "IMB Guide to Fees for Human Products".

2014 fees details are available here

<http://www.imb.ie/images/uploaded/documents/FIN-G0002%20Guide%20to%20fees%20for%20human%20products%202014%20v17.pdf>

Pre-approval of protocols

No information

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Molecular Medicine Ireland has published "Guidelines for standardized bio-banking" and "Guidelines for standardized tissue bio-banking".

These documents are available at: <http://www.molecularmedicineireland.ie/page/g/t/103>

Regulations around transport and sample sharing

Not available

Data protection

Data protection regulations

The Data Protection Act, 1988 (Ireland) and the Data Protection (Amendment) Act, 2003 (Ireland) transposed into Irish law, Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of Such Data.

The acts are available here:
<http://www.dataprotection.ie/ViewDoc.asp?fn=%2Fdocuments%2Flegal%2FLawOnDP.htm&CatID=7&m=1>

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

Susan LENNON

Molecular Medicine Ireland (MMI),

Irish Clinical Infrastructure Network (ICRIN) Newman House

85a St Stephen's Green

Dublin 2

Ireland

Email: susan.lennon@ molecularmedicineireland.ie

Contact details of National Network leads

GRACE

Tom Fahey

Dublin

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

ITALY

Total Population: 60.92 million

Languages: Italian

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Christian 80%, Muslims 2%, others 18%

Urban population: 68% of total population (2010)

Life expectancy at birth: 82.03 years (male: 79.4 years, female: 84.82 years)

Health expenditures: 9.5% of GDP (2011)

Physicians density: 3.8 physicians/1,000 population (2009)

Hospital bed density: 3.5 beds/1,000 population (2010)

Health System

Primary care system

Primary care is provided by GPs, pediatricians and self-employed and independent physicians working alone under a government contract who are paid a capitation fee based on the number of people (adults or children) belonging to their own list. GPs and pediatricians initially assess the patient and are expected to provide most primary care. They act as gatekeepers for access to secondary services. People may choose any physician they prefer at any time, provided that the physician's list has not reached the maximum number of patients allowed.

Source: Italy Health system review 2009;
http://www.euro.who.int/_data/assets/pdf_file/0006/87225/E93666.pdf?ua=1

Acute hospital system

Specialist ambulatory services, including visits and diagnostic and curative activities, are provided either by Azienda sanitaria locale (ASL - local health enterprise) or by accredited public and private facilities with which ASLs have agreements and contracts. Services are listed in specific formularies that vary among regions. Since waiting lists are very long and the quality of services is not always satisfactory, especially in central and southern regions, many people seek care in private clinics, particularly if they have VHI covering the associated costs. Since 1994, major hospitals (highly specialized hospitals with national relevance) have been given financial and technical autonomy, and granted the status of independent hospital enterprises (aziende ospedaliere, 'hospital enterprises' (AO)).

Source: Italy Health system review 2009;



http://www.euro.who.int/_data/assets/pdf_file/0006/87225/E93666.pdf?ua=1

Public health agency

Name of public health agency

Servizio Sanitario Nazionale (The National Health Service)

Website of public health agency

<http://www.salute.gov.it/portale/home.html>

Contact details of public health agency

Contact details available here

http://www.salute.gov.it/portale/p5_0.jsp?lingua=italiano&id=58

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The Italian Medicines Agency is the Competent Authority for clinical trials using: gene therapy, somatic cells therapy, and IMPs containing GMO.

The National Institute of Health (Istituto Superiore di Sanità - ISS) is the Competent Authority for phase I

Website of competent authority

The Italian Medicines Agency <http://www.agenziafarmaco.gov.it/en>

The National Institute of Health <http://www.iss.it/>

Contact Address of competent authority

Agenzia Italiana del Farmaco

Via del Tritone, 181

00187 Roma

Tel. 06 5978401

Istituto Superiore di Sanità

Dipartimento del farmaco

V.le Regina Elena, 299

00161 Roma - Italy

E-mail: segreteria.commac@iss.it

Application process of clinical trial approval

The Italian Medicines Agency is the Competent Authority for clinical trials using: gene therapy, somatic cells therapy, and IMPs containing GMO. The National Institute of Health (Istituto Superiore di Sanità - ISS) is the Competent Authority for phase I clinical trials.

The submission of the clinical trial application data and supporting documents must be done through the National Clinical Trials Monitoring Centre Database (Osservatorio – OsSC). The sponsor must submit these data mainly in Italian except for free text core data set, where English language is required. Information required are compliant with the Ministerial decree 21st December 2007. To access the OsSC, the sponsor/C.R.O. should obtain a user ID/password. To request the user ID/password, it is necessary to connect with the web-site of OsSC and follow the instructions. The registration of the trial data and documents within the OsSC complies with the Italian and European requirements (EudraCT DB) for Clinical Trial electronic data transmission to the Competent Authority. Blank copies of the CTA form to apply for authorisation and Ethics Committee opinion are available in the OsSC.

For all the other clinical trials, and namely, for those that are neither phase I trials nor trials testing gene/somatic cells/GMO therapies, authorisation has to be requested from the local Competent Authority of each clinical site (that is the legal Officer: i.e. director general of the Hospital). The legal Officer can authorise the trial within 60 days. If the legal Officer has not informed the applicant of any grounds for non-acceptance within 60 days, the trial is considered authorised, provided that the opinion of the Ethics Committee is favourable. Timeframe is reduced to 35 days for the authorisation/no grounds for non acceptance of any substantial amendment.

For further details are available here

<http://www.agenziafarmaco.gov.it/frontend/cortesia.html>

National Clinical Trials Monitoring Centre Database (Osservatorio – OsSC)

<http://www.agenziafarmaco.gov.it/frontend/>

Time line for approval process

60 days

Process for fast track approvals during epidemics/pandemics

Not available

Ethics Committees

Structure and configuration of Ethics committees

According to the Legislative Decree no. 211, section 6 and 7, the Ethics Committee shall give its opinion, before a clinical trial commences, on any issue requested. In Italy, according to the Ministerial Decree of May 12, 2006: “Minimum requirements for the institution, organization and functioning of Ethical Committee for clinical trials with medicines”, local Ethics Committees are established by the organ of administration of the public health facilities in which clinical trials are conducted. The Regional

Authorities are responsible for the accreditation of the Ethics Committees working within their regions and for the transmission of the list of them to the Italian Medicines Agency. Regional bioethics committees may act as co-ordinators for local ethics committees and also as a link between them and the National Bioethics Committee. In some regions where there is only a Regional bioethics committee, it will act as a local ethics committee and review research proposals. The National Bioethics Committee acts as a consultative body of the Council of Ministers. Parliament, research centres, local ethics committees and individuals can approach it for advice. It may present proposals of laws.

Ethics Application/Approval process

The sponsor an applicant appointed by the sponsor must apply to the local competent Authority. For multi-centre trials the “Single opinion” (on ethical, scientific and legal aspects) from the coordinating centre REC applies. The RECs of the other participating centres may then accept/reject and modify the Informed Consent only.

Ethics: Fast-track approval available?

No

Ethics: Pre-approval of study protocol available?

Yes

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

Not available/to be updated

Contact Details of Ethics committees

Direzione Scientifica - Comitato Etico Milano Area B Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico Via Francesco Sforza n. 28 - 20122 MILANO Tel. (diretto): 02/5503.5420 Fax: 02/5503.8264 Cell.: 392/9870.580 E-mail: giuliana.fusetti@policlinico.mi.it

Website addresses of ethics committees

Not available/to be updated

Website links to ethics application forms

Not available/to be updated

Website links to meeting time tables

Not available/to be updated

Ethical approval timeline

In the case of single site trials - 60 days

In the case of multi-sites trials - 30 days

Ethical approval application Fees

The Ethics Committees usually charge fees to the sponsors for the performance of their tasks according to the directives of the Regional Authorities with a range between €1,500 and €4,000 per trial.

Special requirements for studies involving children/vulnerable people

No special requirements

Special requirements if studies include collection and use of human tissues

Yes - a specific informed consent form is required

Helpful notes for obtaining ethical approvals

To be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The Italian Medicines Agency

<http://www.agenziafarmaco.gov.it>

Research and Clinical Trials Head of Office: Carlo Tomino

Phone: +39 06 5978 4474

Fax: +39 06 5978 4110

E-mail: Sperimentazione.clinica@aifa.gov.it

Application process for IMP

The Italian Medicines Agency is the Competent Authority for clinical trials of IMPs containing GMO. For all the other clinical trials authorisation has to be requested from the local Competent Authority of each clinical site.

<http://www.agenziafarmaco.gov.it/en/content/clinical-trials>

The submission of the clinical trial application data and supporting documents must be done through the National Clinical Trials Monitoring Centre Database (Osservatorio – OsSC). The sponsor must submit these data mainly in Italian except for free text core data set, where English language is required. Information required are compliant with the Ministerial decree 21st December 2007 “Modalità di inoltro della richiesta di autorizzazione all’Autorità competente, per la comunicazione di emendamenti sostanziali e la dichiarazione di conclusione della sperimentazione clinica e per la richiesta di parere al comitato etico”. To access the OsSC, the sponsor/C.R.O. should obtain a user ID/password. To request the user ID/password, it is necessary to connect with the web-site of OsSC and follow the instructions. The registration of the trial data and documents within the OsSC complies with the Italian and European requirements

(EudraCT DB) for Clinical Trial electronic data transmission to the Competent Authority. Blank copies of the CTA form to apply for authorisation and Ethics Committee opinion are available in the OsSC.

Timeline for IMP trial approval

60 days

Fees for IMP approval

Not available/to be updated

Pre-approval of protocols

Not available/to be updated

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available/to be updated

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

Data Protection Code - Legislative Decree no. 196/2003 available here
http://www.garanteprivacy.it/web/guest/home_en/italian-legislation#1

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

Rita BANZI

Mario Negri Institute for Pharmacological Research

Via La Masa 19

20156 Milan

Italy

Phone: +39 02 39 01 46 71

Email: rita.banzi@marionegri.it

Contact details of National Network leads

GRACE

Francesco Blasi

Respiratory Medicine Section

University of Milan

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

LATVIA

Total Population: 2.02 million

Languages: Latvian, Russian

Time Zone: UTC+02:00

Further demographic info (cultural/religious etc.)

Religions: Lutheran 19.6%, Orthodox 15.3%, other Christian 1%, others 64.1% (2006)

Urban population: 68% of total population (2010)

Life expectancy at birth: 73.44 years (male: 68.41 years, female: 78.75 years)

Health expenditures: 6.7% of GDP (2010)

Physicians density: 2.9 physicians/1,000 population (2010)

Hospital bed density: 5.3 beds/1,000 population (2010)

Health System

Primary care system

The central Government is responsible for financing the statutory health care system through tax revenue. In addition, financing for health services comes directly from household payments as well as VHI.

The bulk of services at the primary care level are provided by primary care practitioners (mainly GPs) who work independently, either as self-employed individuals or as private sector agents. Health centres are former polyclinics and occupational health service facilities that were converted for use in primary care provision. Ownership may be either entirely public (local governments consisting of districts and municipalities), mixed between local governments and physicians themselves (i.e. a public–private arrangement), or they may be wholly private. Health centres employ GPs for primary care provision. In all cases, statutory care is provided through contracts with the State Compulsory Health Insurance Agency (SCHIA), which are carried out either directly (in the case of self-employed doctors) or through the health care institution at which the doctor is employed.

Family doctors provide general health care for children, adults and elderly people (care of acute and chronic diseases), including outpatient surgical procedures, rehabilitation, pregnancy care, prenatal care, and emergency care; they prescribe medications, carry out diagnostic tests and engage in preventive work (immunization) and health promotion.

Source: Latvia Health system review 2008,
http://www.euro.who.int/_data/assets/pdf_file/0003/95124/E91375.pdf



Acute hospital system

Patients with a referral from the family doctor can freely choose ambulatory care services at medical institutions. Secondary ambulatory care can be received from; specialist physician practices, hospitals, state agencies (such as the State Centre for Mental Health, Tuberculosis and Lung Diseases Centre, Centre for Infectious Diseases, etc.), Diagnostic services fall under the ownership of the central Government or local governments, or Health centres. These institutions have contracts with the SCHIA in order to be able to provide statutorily funded services. Tertiary health care is not contracted by the SCHIA but receives budget transfers from the Ministry of Health.

Source: Latvia Health system review 2008,
http://www.euro.who.int/_data/assets/pdf_file/0003/95124/E91375.pdf

Public health agency

Name of public health agency

Disease Prevention and Control

Website of public health agency

<http://www.spkc.gov.lv/>

Contact details of public health agency

Head Office: Dunte Street 22, Riga, Latvia, LV-1005

Phone: 67501590

Fax: 67501591

E-mail: info@spkc.gov.lv

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

State Agency of Medicines

Website of competent authority

<http://www.zva.gov.lv/>

Contact Address of competent authority

Jersikas 15, Riga, LV - 1003

Phone 67078424, Fax 67078428

E-mail: zva@zva.gov.lv , info@zva.gov.lv

Application process of clinical trial approval

A clinical trial cannot be started without a positive decision from an ethics committee and without authorization from the State Agency of Medicines.. The State Agency of Medicines accepts the receipt of clinical trial application in electronic version, ie, by CD-

ROM with a signed cover letter or via e-mail ct@zva.gov.lv . In order to receive authorisation from the State Agency of Medicines, the sponsor or the authorised person of the sponsor shall submit the following documents and information to the State Agency of Medicines: a) confirmation of the receipt of European Clinical Trial Database (EudraCT) number; b) application form developed by the European Commission (link available on the web site of European Commission http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/eudralex/vol-10/11_an1_14-2005_en.pdf), signed by the sponsor or the authorised person of the sponsor

(XML file shall also be provided);

Clinical trials in Latvia is regulated by the Cabinet Regulation No 289. See section V "Authorisation of the State Agency of Medicines" for further details <http://www.zva.gov.lv/index.php?id=381&sa=381&top=333&lang=>

Time line for approval process

The State Agency of Medicines shall have a maximum of 60 days from the date of receipt of a valid application to review the application.

Process for fast track approvals during epidemics/pandemics

No information

Ethics Committees

Structure and configuration of Ethics committees

There are 5 independent Ethics Committees, one central and four other independent committees, for Clinical Trials in Latvia. The Ethics Committee shall give its opinion, before a clinical trial commences, on any issue requested in order to protect the rights, safety and well-being of the trial subjects, and in order to provide public assurance of this protection. The Ethics Committee is an independent body working within a medical establishment or independently from a medical establishment. The Ethics Committee shall consist of qualified and experienced professionals who are able to review the ethical and scientific aspects of the proposed clinical trial. The Minister of Health approves the composition of the Ethics Committee indefinitely.

Ethics Application/Approval process

The sponsor should submit an application both to the ethics committee and to competent authority (State Agency of Medicines). Responsibility for issuing guidelines on all aspects of clinical research involving investigational medicinal products rests with the State Agency of Medicines.

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

No information

Contact Details of Ethics committees

Contact details are available here

http://www.zva.gov.lv/doc_upl/etikas_komiteju_saraksts-en-20120224.doc.pdf

Ethical committee of Pauls Stradins University Hospital Development Society Peteris Stradinš (Head of the committee), address: Pilsonu Str 13, Riga, LV-1002, Tel: +371 67069669, fax: +371 67069946, e-mail: etikas-komiteja@stradini.lv

Website addresses of ethics committees

Not available/to be updated

Website links to ethics application forms

Not available/to be updated

Website links to meeting time tables

Not available/to be updated

Ethical approval timeline

No later than 30 days after the registration of an application. If the clinical trial involves medicinal products intended for gene therapy or somatic cell therapy or contain genetically modified organisms, the Ethics Committee may extend the time period.

Ethical approval application Fees

Ethics committees charge 500-1000 EUR for review of application; 200 EUR for review of amendments.

Special requirements for studies involving children/vulnerable people

Paragraph 32 and 33 Cabinet Regulation No. 289 provides details of requirements for studies involving children/vulnerable people. English version of the act is available here

http://www.zva.gov.lv/doc_upl/MK_not_289_English_02062010.pdf

Approvals usually go through the Central Ethics Committee

Special requirements if studies include collection and use of human tissues

No special requirements

Helpful notes for obtaining ethical approvals

Studies involving human genetics, stem cells or children tend to be more complex and obtaining ethical approvals is more challenging. Also, the more commercial a proposal looks, the more difficult it is to obtain approvals.

Additional body: www.stradini.lv

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

State Agency of Medicines

State Drug Agency Details here <http://www.zva.gov.lv/?id=396&sa=396&top=386>

Jersikas street 15, Riga, LV-1003, Latvija Talr.: +371 67078424 Mob. talrunis: +371 29447659 Fakss: +371 67078428 e-pasts: info@zva.gov.lv

Application process for IMP

See section V of Cabinet Regulation No. 289

http://www.zva.gov.lv/doc_upl/MK_not_289_English_02062010.pdf

Timeline for IMP trial approval

60 days

Fees for IMP approval

Not available

Pre-approval of protocols

Not available

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available

Regulations around transport and sample sharing

Not available

Data protection

Data protection regulations

Latvia's general law on data protection, the Personal Data Protection Law, was passed in 2000. It implements Directive 95/46/EC into national legislation. Details are available on the website of State Data Inspectorate of Latvia <http://www.dvi.gov.lv/en/>

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

To be updated

Contact details of National Network leads

To be updated

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

LITHUANIA

Total Population: 2.98 million

Languages: Lithuanian (official), Russian, Polish

Time Zone: UTC+02:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 77.2%, Russian Orthodox 4.1%, others 18.7%

Urban population: 67% of total population (2010)

Life expectancy at birth: 75.98 years (male: 71.2 years, female: 81.02 years)

Health expenditures: 7% of GDP (2010)

Physicians density: 3.64 physicians/1,000 population (2010)

Hospital bed density: 6.8 beds/1,000 population (2010)

Health System

Primary care system

Primary care is delivered by a GP or a primary care team. The municipalities administer the entire network of primary health-care institutions through one of two models. In the centralized model, one primary health-care centre manages a pyramid of smaller institutions. In the decentralized model, GP practices or primary care teams are legal entities holding contracts with the NHIF. Specialist outpatient care in Lithuania is delivered through outpatient departments of hospitals or polyclinics as separate legal entities, as well as through private providers. For free access to specialist care, patients require a signed referral from their GP or primary care physician.

Source: Lithuania Health system review 2013,
http://www.euro.who.int/_data/assets/pdf_file/0016/192130/HiT-Lithuania.pdf

Acute hospital system

Patients are admitted to hospital either through the emergency department or through a referral from a doctor or specialist.

Public health agency

Name of public health agency

Health Emergency Center

Website of public health agency

<http://www.essc.sam.lt/lt/naujienos.html>

Contact details of public health agency

Birutės g. 56,

Vilnius LT-08110



Tel.: (8 5) 261 9888

Fax: (8 5) 231 4436

Email: essc@sam.lt

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The State Medicines Control Agency (SMCA)

Website of competent authority

<http://www.vvkt.lt/>

Contact Address of competent authority

Žirmūnų str. 139A, Vilnius, Lithuania

E-mail: vvkt@vvkt.lt,

Phone: +370 5 263 92 64

Fax: +370 5 263 92 65

Application process of clinical trial approval

The sponsor must apply for clinical trial authorization to the State Medicines Control Agency (SMCA) in accordance to the procedure laid down by European Commission.

Details are available here (in Lithuanian)

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=277308&p_query=&p_tr2=

Time line for approval process

Within 60 days

Process for fast track approvals during epidemics/pandemics

Not available

Ethics Committees

Structure and configuration of Ethics committees

The Lithuanian Bioethics Committee (LBEC) is the main institution responsible for bioethics policy in Lithuania and it is also responsible (among other functions) for the ethical review of multi-site biomedical research projects (including clinical trials on IMP), issuing the single opinion for the country. The LBEC is established by and is accountable to the Ministry of Health. According to the Law on Ethics of Biomedical Research, Regional Biomedical Research Ethics Committees are established at the universities where medical studies of three levels take place. Currently there are two Regional Biomedical Research Ethics committees in Lithuania: in Kaunas region (based at Kaunas Medical University) and in Vilnius region (based at Medical faculty of Vilnius

University). The activities of the Regional Biomedical Research Ethics committees are monitored by the LBEC.

Source: <http://bioetika.sam.lt/>

Ethics Application/Approval process

The sponsor of biomedical research, its authorised representative and/or the principal investigator wishing to obtain an authorisation shall submit a list of documents approved by the Minister of Health to the Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee. The documents must be considered and an authorisation must be granted or a reasoned refusal to grant the authorisation must be given not later than within 45 calendar days from the receipt of all the properly executed documents.

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No

Fast-track application process for ethical approval

No information about whether this is possible.

Contact Details of Ethics committees

Didžioji str. 22, LT-01128 Vilnius

Tel.: (+370 5) 212 45 65,

Fax: (+370 5) 260 86 40

E-mail: lbek@sam.lt

Website addresses of ethics committees

<http://bioetika.sam.lt/>

Website links to ethics application forms

Not available/to be updated

Website links to meeting time tables

Not available/to be updated

Ethical approval timeline

45 days

Ethical approval application Fees

According to the Decree of the Government of the Republic of Lithuania, the state fee ranges from approximately 2000 to 3000 LTL depending on the number of research ethics committees involved.

Special requirements for studies involving children/vulnerable people

According to the Article 7 of the Law on Ethics of Biomedical Research (“Protection of Vulnerable Persons”) if the subject is a minor, consent to undertake a biomedical research shall be given by both parents or by the legally acceptable representatives of the minor and the children’s rights protection agency of a district or a city. If the parents of a minor are separated, consent of one of the parents or of the legally acceptable representative and of the district or city children’s rights protection agency must be obtained. The consent of a person who has a mental disorder but may give his free and informed consent to take part in a biomedical research must be attested by two witnesses and the head of a health care establishment where a biomedical research is being conducted. Approval of the Medical Ethics Commission must also be obtained. The procedure of forming the Medical Ethics Commission and conducting its activities are laid down in the model regulations of the Medical Ethics Commission of a health care establishment approved by the Ministry of Health.

Special requirements if studies include collection and use of human tissues

Ethics approval processes the same.

Helpful notes for obtaining ethical approvals

Trial sponsors usually obtain permissions

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The State Medicines Control Agency (SMCA).

Application process for IMP

The sponsor must apply for clinical trial authorization to the State Medicines Control Agency (SMCA) in accordance to the procedure laid down by European Commission.

Details are available here (in Lithuanian)

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=277308&p_query=&p_tr2=

Timeline for IMP trial approval

60 days

Fees for IMP approval

Not available/to be updated

Pre-approval of protocols

Approval of protocols not allowed.

IMP: Fast-track approval available?

No

IMP: Pre-approval available?

No

Biological samples

Registration and bio-banking requirements

Not available/to be updated

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

Law on Legal Protection of Personal Data (2008) Available at

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=315633

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

GRACE

Ruta Radzeviciene-Jurgute

Klaipeda

Contact details of National Network leads

GRACE

Ruta Radzeviciene-Jurgute

Klaipeda

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

LUXEMBOURG

Total Population: 0.53 million

Languages: Luxembourgish, French, German

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 87%, other (includes Protestant, Jewish, and Muslim) 13% (2000)

Urban population: 85% of total population (2010)

Life expectancy at birth: 80.01 years (male: 76.77 years, female: 83.46 years)

Health expenditures: 7.7% of GDP (2011)

Physicians density: 2.78 physicians/1,000 population (2011)

Hospital bed density: 5.4 beds/1,000 population (2010)

Health System

Primary care system

Luxembourg's healthcare system is mainly publicly financed through social health insurance. General practitioners provide basic care. All citizens have the right to choose their doctor, specialist and hospital.

Acute hospital system

There are no private hospitals in Luxembourg as all hospitals are state run by the Caisse de Maladie and need a referral from GP for an admission to hospital, unless it is an emergency. The patient initially has to pay for the medical fees, which are decided on and revised annually by the Caisse de Maladie, and then submit the receipts for a reimbursement, which varies from 80 to 100 percent.

Public health agency

Name of public health agency

The Department of Public Health

Website of public health agency

<http://www.crp-sante.lu/Research-Departments/Public-Health>

Contact details of public health agency

Not available

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

Division de la Pharmacie et des Médicaments



Website of competent authority

<http://www.ms.public.lu/fr/direction/divisions-services/pharmacie-medicaments/>

Contact Address of competent authority

Division of Pharmacy and Medicines

Allée Marconi - Villa Louvigny

L-2120 - Luxembourg

Luxembourg

Application process of clinical trial approval

Submission of a file containing:

- Confirmation of EudraCT number.
- Clinical Trial Application form.
- List of competent authorities in the EU to which an authorisation request has already been submitted for the study.
- Copy of the CNER opinion if it is already available when the file is submitted to the CA.
- Study protocol with all the previous amendments (and their dates) if applicable. ²
Peer review of the trial if available.
- Patient information sheet and informed consent form in French and German.
- Investigator brochure with all information regarding the safety and pharmaceutical quality of the product.
- IMPD or simplified IMPD for the known products.
- SmPC for the products which have already received a market authorization within the EU.
- A list of all ongoing clinical trials with the same experimental product.
- A copy of the manufacturing authorisation following the article 13 of the 2001 EU Directive.
- A recent curriculum vitae of the principal investigator.
- Other documents specifically demanded for a study by the Division de la Pharmacie et des Médicaments

Practical information on the dossier to be submitted can be found on the website EudraCT

Time line for approval process

60 days (silent approval)

Process for fast track approvals during epidemics/pandemics

Not available

Ethics Committees

Structure and configuration of Ethics committees

In Luxemburg, there is only one national research ethics committee, called Comité National d'Ethique de Recherche (CNER).

Ethics Application/Approval process

After the requested documents have been received at the CNER secretariat, the principal investigator is invited to orally present his study to the CNER at its next meeting. If the study is a medical study, it is imperative that one of the responsible physicians be present.

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

No information

Contact Details of Ethics committees

Comité National d'Ethique de Recherche (CNER)

1a-b rue Thomas Edison

L-1445 Strassen

Luxembourg

Tel +352 26 970/879

Fax +352 26 970/870

Email: contact@cner.lu

Website addresses of ethics committees

<http://www.cner.lu/>

Website links to ethics application forms

Not available

Website links to meeting time tables

Not available

Ethical approval timeline

60 days. 90 days for trials involving medicinal products for gene therapy and somatic cell and all medicinal products containing genetically modified organisms therapy

Ethical approval application Fees

Study proposed by a commercial sponsor: 1000 euros (+ VAT 15%)

Academic Study: 500 euros (+ VAT 15%)

Compassionate Use program (CUP): 250 euros (+ VAT 15%)

Substantial amendment: 250 euros + VAT 15% (free of charge for amendments to MNPs and CUPs)

Special requirements for studies involving children/vulnerable people

Article 4 and 5 of "Grand-Ducal Regulation of 30 May 2005 on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use" describes the requirements for studies involving children/vulnerable people.

French version is available here <http://eli.legilux.public.lu/eli/etat/leg/rgd/2005/05/30/n5>

Ethics approval process the same.

Special requirements if studies include collection and use of human tissues

Ethics approval process the same

Helpful notes for obtaining ethical approvals

Meetings of the committee only take place at fixed dates every 2 months.

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

Division de la Pharmacie et des Médicaments

Ministry of Health - Direction de la Santé Villa Louvigny Allée Marconi L-2120

Luxembourg Tél. : (+352) 247 - 85500 info@ms.public.lu

Application process for IMP

Practical information on the dossier to be submitted can be found on the website EudraCT

Timeline for IMP trial approval

60 days

Fees for IMP approval

No information

Pre-approval of protocols

No information

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available/to be updated

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

Generally, research projects involving human subjects also have to be notified to or authorized by the National Data Protection Commission. see the website

<http://www.cnpd.public.lu/fr/index.html>

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

To be updated

Contact details of National Network leads

To be updated

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

MALTA

Total Population: 0.41 million

Languages: Maltese, English

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic (official) 98%

Urban population: 95% of total population (2010)

Life expectancy at birth: 80.11 years (male: 77.8 years, female: 82.56 years)

Health expenditures: 8.5% of GDP (2010)

Physicians density: 3.23 physicians/1,000 population (2011)

Hospital bed density: 4.4 beds/1,000 population (2011)

Health System

Primary care system

The state primary health-care system includes general practice, community care, immunization, child guidance clinic, child development and assessment unit, national screening unit, occupational health unit and the school health service. These are offered mainly through eight public health centres in Malta and one in Gozo. There are also local health clinics which are staffed by their respective district health centre. All publicly financed health services are free of charge at the point of use and primary care is readily accessible. The private sector accounts for about two-thirds of the workload in primary care and is remunerated on a fee-for-service basis. Many people choose to access primary care services in the private sector because it offers better continuity of care.

Source: Malta Health system review 2014

http://www.euro.who.int/_data/assets/pdf_file/0010/241849/HiT-Malta.pdf

Acute hospital system

Secondary and tertiary care are provided through public and private general hospitals. The main acute general hospital (Mater Dei) provides the bulk of day and emergency care and most of its services are provided free of charge. In the public sector, medicines on the Government Formulary List (GFL) are provided free of charge to patients who are entitled to them. In the private sector, patients must pay the full cost of pharmaceuticals.

Source: Malta Health system review 2014

http://www.euro.who.int/_data/assets/pdf_file/0010/241849/HiT-Malta.pdf

Public health agency

Name of public health agency

The Infectious Disease Prevention and Control Unit

Website of public health agency

https://ehealth.gov.mt/healthportal/public_health/idcu/introduction.aspx

Contact details of public health agency

The Director

Health Promotion and Disease Prevention Directorate,

5B, The Emporium,

Triq C. De Brocktorff,

Msida MSD 1421,

Malta

Mail to: disease.surveillance@gov.mt

Regulatory Authority/Competent Authority**Name of Regulatory Authority/Competent Authority**

Medicine Authority

Website of competent authority

<http://www.medicinesauthority.gov.mt/>

Contact Address of competent authority

Medicines Authority

203, Level 3,

Rue D'Argens,

Gzira GZR 1368

Malta

Email: info.medicinesauthority@gov.mt

Telephone: 356 2343 9000

Fax: 356 2343 9161

Application process of clinical trial approval

The legal framework for Clinical Trials with medicinal products for human use is set out in the Clinical Trials Regulations (Subsidiary legislation 458.43) implementing the European Clinical Trials Directive 2001/20/EC. In Malta, clinical trials must be notified to the Maltese Licensing Authority (through the Medicines Authority) by the person, individual or group that takes overall responsibility for the trial (the sponsor), but a doctor or a dentist (the investigator) must always participate in the conduct of the trial. The Medicines Authority evaluates both the quality of the investigation and the patient safety of clinical trials. Clinical trials must also be notified to the health ethics

committee established under the Clinical Trials Regulations (Subsidiary legislation 458.43), which performs an overall assessment of the trial's ethical aspects. Before a clinical trial can be started, approvals must be obtained from both the health ethics committee and the Licensing Authority.

Further details are available here;

<http://www.medicinesauthority.gov.mt/clinicaltrialsa?l=1>

Time line for approval process

60 days

Process for fast track approvals during epidemics/pandemics

Not available/to be updated

Ethics Committees

Structure and configuration of Ethics committees

In Malta there is only one ethics committee that has the power of approval (the HEC), but other advisory ethics committees are also established at the University of Malta, at the Medical School of Malta and at the Institute of Health Care. The establishment of the Health Ethics Committee (HEC) is under the remit of the Ministry of Health. The Ministry also appoints a Bioethics Consultative Committee, which is an advisory committee but which is not involved in the assessment of clinical trials.

Ethics Application/Approval process

Clinical trials must be notified to the health ethics committee established under the Clinical Trials Regulations (Subsidiary legislation 458.43), which performs an overall assessment of the trial's ethical aspects. Before a clinical trial can be started, approvals must be obtained from both the health ethics committee and the Licensing Authority

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

Not available/to be updated

Contact Details of Ethics committees

Health Ethics Committee

Department of Health Information & Research

95, Guardamangia Hill,

Guardamangia PTA 1313

Malta

Phone: (+356) 25599000

Fax: (+356) 25599385

Email: hec@gov.mt

Website addresses of ethics committees

https://ehealth.gov.mt/HealthPortal/others/regulatory_councils/health_ethics_committee/health_ethics_committee.aspx

Website links to ethics application forms

See

https://ehealth.gov.mt/HealthPortal/others/regulatory_councils/health_ethics_committee/health_ethics_committee.asp

Website links to meeting time tables

See

https://ehealth.gov.mt/HealthPortal/others/regulatory_councils/health_ethics_committee/health_ethics_committee.asp

Ethical approval timeline

60 days

Ethical approval application Fees

Investigational medicinal products € 1,000

Medical devices € 1,000

Combination products € 1,200

Other € 1,000

Non-interventional studies € 500

Academic research without financial support from industry and clinical trials on orphan drugs may apply for reduced fees.

Source:

https://ehealth.gov.mt/HealthPortal/others/regulatory_councils/health_ethics_committee/health_ethics_committee.aspx

Special requirements for studies involving children/vulnerable people

The HEC follows Directive 2001/20/EC, ICH Guideline on Good Clinical Practice and any other relevant guidance documents published by the European Commission.

Special requirements if studies include collection and use of human tissues

Not available/to be updated

Helpful notes for obtaining ethical approvals

Not available/to be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

Medicine Authority

Application process for IMP

In Malta, clinical trials must be notified to the Maltese Licensing Authority (through the Medicines Authority) by the person, individual or group that takes overall responsibility for the trial (the sponsor), but a doctor or a dentist (the investigator) must always participate in the conduct of the trial.

Timeline for IMP trial approval

60 days

Fees for IMP approval

Phase 1, 2 or 3 patient trial with a known product € 1,164.69 (€ 349.41)

Phase 1, 2 or 3 patient trial with a new product € 1,747.03 (€ 698.81)

Phase 4 patient trial € 1,397.62 (€ 232.94)

Amendment/s € 93.17

(Fees in brackets are for applications for academic research without financial support from industry)

Pre-approval of protocols

Not available/to be updated

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available/to be updated

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

Data protection act is available here

http://idpc.gov.mt/dbfile.aspx/DPA_amended2012.pdf

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

To be updated

Contact details of National Network leads

To be updated

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

NETHERLANDS

Total Population: 16.4 million

Languages: Dutch

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 28%, Protestant 19% , others 53%

Urban population: 83% of total population (2010)

Life expectancy at birth: 81.12 years (male: 79.02 years, female: 83.34 years)

Health expenditures: 12% of GDP (2011)

Physicians density: 3.92 physicians/1,000 population (2007)

Hospital bed density: 4.7 beds/1,000 population (2009)

Health System

Primary care system

Primary care in the Netherlands has a wide variety of providers, such as GPs, physiotherapists, pharmacists, psychologists and midwives. Every Dutch person is required to register with a GP, mainly in their own neighbourhood. Patients register with a GP of their choice and can switch to a new one without restriction. A patient must obtain a GP referral prior to a specialist visit. Many GP practices are solo practices, but support each other through 'cooperatives' to provide out-of-hours care. A GP consultation usually costs €9, which patients can claim back from their insurer.

Source: The Netherlands Health system review 2010

http://www.euro.who.int/_data/assets/pdf_file/0008/85391/E93667.pdf

Acute hospital system

Secondary care encompasses those forms of care that are only accessible upon referral from a primary care health provider, such as a GP, dentist or midwife. More than 90% of Dutch hospitals are owned and managed on a private not-for-profit basis, with specialists working on a self-employed basis. There are six types of institutions that provide hospital or medical specialist care: general hospitals, academic (university) hospitals, categorical hospitals, independent treatment centres, top clinical centres (specialized in e.g. cancer, organ transplantation, IVF), and trauma centres. Except in cases of emergency, patients only consult a specialist upon referral from a GP. Most hospitals also have 24-hour emergency wards.

Source: The Netherlands Health system review 2010



http://www.euro.who.int/_data/assets/pdf_file/0008/85391/E93667.pdf

Public health agency

Name of public health agency

National Institute for Public Health and the Environment

Website of public health agency

<http://www.rivm.nl/English>

Contact details of public health agency

RIVM

P.O. Box 1

3720 BA Bilthoven

The Netherlands

Tel.: +31 (0)30 274 9111

Fax: +31 (0)30 274 2971

Email: info@rivm.nl

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The Central Committee on Research Involving Human Subjects (CCMO)

Website of competent authority

<http://www.ccmo.nl/>

Contact Address of competent authority

Central Committee on Research Involving Human Subjects (CCMO)

Postal address: PO Box 16302, 2500 BH The Hague

Visiting address: Rijnstraat 50, 2515 XP The Hague

Telephone: + 31 (0) 70 340 6700

Email: ccmo@ccmo.nl

Application process of clinical trial approval

Before a research with human subjects which falls under the scope of the Medical Research Involving Human Subjects Act (WMO) can commence it must first be reviewed by an accredited MREC or the CCMO. This requires you submit a complete research file. Do not forget to check the meeting dates and the submission deadlines for the committee carrying out the review for a faster review (MREC or CCMO). To prevent any misunderstandings, and when in doubt over the review timelines, contact the accredited MREC or the CCMO.

Investigators can use the ToetsingOnline portal to submit their research to be reviewed to a Medical Research Ethics Committee (MREC) and competent authority (CA). These committees and authorities then use the Toetsingonline portal to register the reviewing process and monitor the review time periods.

Details: https://www.toetsingonline.nl/to/ccmo_web.nsf/CCMO.xsp?page=home

Medical Research (Human Subjects) Act <http://www.ccmo.nl/attachments/files/wmo-engelse-vertaling-29-7-2013-afkomstig-van-vws.pdf>

Time line for approval process

Within 60 days of receiving the application

Process for fast track approvals during epidemics/pandemics

No information available

Ethics Committees

Structure and configuration of Ethics committees

There are 24 accredited MRECs in the Netherlands that review medical/scientific research proposals. The majority are linked to an institution such as an academic medical centre or a hospital. An accredited MREC determines the region it covers with regards to reviewing research. This is known as the working environment. In practice, the majority of MRECs review for the whole of the Netherlands.

Further details are available here <http://www.ccmo.nl/en/accredited-mreecs?527d2d37-aded-445d-9f43-6ffdc35ff8ba>

Ethics Application/Approval process

All research involving human subjects that fall under the WMO must be assessed in advance by a committee. This is usually undertaken by an accredited Medical Research Ethics Committees (METC) or occasionally by the CCMO, depending on the type of research. METCs consider all clinical trials on investigational medicinal products as well as non-therapeutic observational studies, and the CCMO considers medical research in the field of gene therapy, iRNA, anti-sense oligonucleotides, (stem) cell therapy, xenotransplantation, vaccines, and non-therapeutic interventional studies with minors and incapacitated subjects. Only accredited research ethics committees (METCs or the CCMO) can review biomedical research with human subjects.

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

No information

Contact Details of Ethics committees

List of accredited ethics committees is available here

<http://www.ccmo.nl/en/accredited-mrecs?527d2d37-adec-445d-9f43-6ffdc35ff8ba>

Website addresses of ethics committees

List of accredited ethics committees is available here

<http://www.ccmo.nl/en/accredited-mrecs?527d2d37-adec-445d-9f43-6ffdc35ff8ba>

Website links to ethics application forms

<http://www.ccmo.nl/en/meeting-dates>

Website links to meeting time tables

<http://www.ccmo.nl/en/meeting-dates>

Ethical approval timeline

The ethical review of research with medicinal products, whether single- or multi-site, must be completed within 60 days of receipt of a valid application. For specific studies (e.g., gene therapy) the time line is 90 days. The clock may stop once to request further information or clarification from the applicant.

Ethical approval application Fees

Not available/to be updated

Special requirements for studies involving children/vulnerable people

In the case of children, both parents have to sign the informed consent form. If the child is 12 or older, he/she should sign as well. In the case of incapacitated subjects (e.g., Alzheimer patients) their partner, children (> 18 years old) or their legal representatives should sign.

Ethics approval process is the same.

Special requirements if studies include collection and use of human tissues

Contradictory information received about whether different approval processes required. Possible that there are different processes, and that obtaining permissions is more difficult because informed consent is needed.

Helpful notes for obtaining ethical approvals

Approval of clinical trials is more difficult to obtain than for an observational study. Also cluster randomised designs where a waiver of informed consent is needed, are more difficult to obtain consent for.

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The Central Committee on Research Involving Human Subjects (CCMO)

<http://www.ccmo.nl/>

Application process for IMP

A research with a medicinal product must undergo a prior registration in the EudraCT database. Research with a medicinal product must undergo an extra review alongside the medical ethical review. This review is carried out by the competent authority. If the research is with a medicinal product then it must be submitted to two different authorities: a reviewing committee (MREC or CCMO); the competent authority (CCMO or Ministry of Health, Welfare and Sport).

Further details; <http://www.ccmo.nl/en/research-with-a-medicinal-product?52179209-f9ec-4664-8f83-394dc35ff8ba>

Timeline for IMP trial approval

Not available/to be updated

Fees for IMP approval

Not available/to be updated

Pre-approval of protocols

No information

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available/to be updated

Regulations around transport and sample sharing

Not available/to be updated

Data protection

Data protection regulations

Wet Bescherming Persoonsgegevens (WBP; Dutch Data Protection Act)

http://www.dutchdpa.nl/Pages/en_ind_wetten_wbp.aspx

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

Ron F.J. De Winter

Julius Center for Health Sciences and Primary Care

UMC Utrecht

Huispostnummer Str 6.131

P.O. Box 85500, 3508 GA Utrecht

THE NETHERLANDS

Phone: +31 88 75 551 53

Email: R.F.J.deWinter-4@umcutrecht.nl

Contact details of National Network leads

GRACE

Theo Verheij

Alike van der Velden

Utrecht

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

POLAND

Total Population: 38.54 million

Languages: Polish

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Catholic 87.2%, Orthodox 1.3%, others 11.5%

Urban population: 60.9% of total population (2011)

Life expectancy at birth: 76.65 years (male: 72.74 years, female: 80.8 years)

Health expenditures: 6.7% of GDP (2011)

Physicians density: 2.07 physicians/1,000 population (2010)

Hospital bed density: 6.6 beds/1,000 population (2010)

Health System

Primary care system

In Poland the state healthcare system is funded in two ways; through government budgets to healthcare and through compulsory individual contributions to the state healthcare insurance scheme. A primary care physician is usually the entry point to the health care system, steering patients to more complex care. Primary care physicians are gatekeepers in the system, steering patients to more complex care, and may be freely chosen by way of registration. Primary health care comprises preventive health care services and diagnostic therapeutic and rehabilitative care in the area of ambulatory general, family and paediatric care. Services are provided by primary care physicians, nurses and midwives.

Source: Poland Health system review 2011

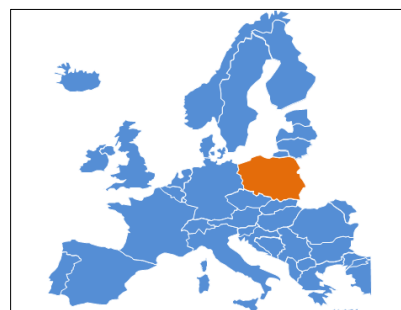
http://www.euro.who.int/_data/assets/pdf_file/0018/163053/e96443.pdf

Acute hospital system

Hospitals in Poland are classified in several ways: according to their territorial coverage (gmina, powiat, voivodeship or over-voivodeship), their scope of services (general or specialist), the type of condition or population they serve or their founding body. Most hospitals provide health care services in several types of specialization. Patients are admitted to hospital either through the emergency department or through a referral by their doctor. Once a patient is admitted treatment is controlled by one of the hospital doctors. There are usually waiting lists for non-emergency treatments and services.

Source: Poland Health system review 2011

http://www.euro.who.int/_data/assets/pdf_file/0018/163053/e96443.pdf



Public health agency

Name of public health agency

National Institute of Public Health

Website of public health agency

<http://www.pzh.gov.pl/page/>

Contact details of public health agency

National Institute of Public Health - National Institute of Hygiene

24 Chocimska str.

00-791 Warsaw

Poland

Tel.: +48 22 54 21 354

e-mail: sek-zhk@pzh.gov.pl

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Website of competent authority

<http://en.urpl.gov.pl/>

Contact Address of competent authority

Al. Jerozolimskie 181C

02-222 Warszawa

Telephone: +48 22 492 11 00

Fax : +48 22 492 11 09

Email: incydenty@urpl.gov.pl

Application process of clinical trial approval

Clinical trials in Poland is regulated by The Act on Pharmaceutical Law of 6 September 2001, Dz.U. 2008, No 45, item 271 (Polish version available here <http://isap.sejm.gov.pl/DetailsServlet?id=WDU20080450271>).

The sponsor must apply for an authorisation to conduct a clinical trial to the competent authority in Poland, which is the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Documents need to be submitted include; study protocol, patient information leaflet and informed consent form. There is also a need to provide information about insurance and about the study sites. In multicenter clinical trials of medicinal products Polish regulations are in accordance with art. 7 DIRECTIVE 2001/20/EC. Similar regulations are for multicenter clinical trials of medical devices.

Forms are available here <http://www.urpl.gov.pl/wm-kliniczne-formularze>

Further details are available here (in Polish) <http://www.urpl.gov.pl/pozwolenia-na-badania-kliniczne>

Time line for approval process

60 days

Process for fast track approvals during epidemics/pandemics

No information

Ethics Committees

Structure and configuration of Ethics committees

There are three groups of Bioethics Committees in Poland;

- The Bioethics Committees of the Medical Universities.
- The Bioethics Committees of the (non-university) Medical or Scientific Institutes.
- The Bioethics Committees of the Regional Chambers of Physicians and Dentists

There are 52 Regional Bioethics Committees and one Appeal Bioethics Committee in the Ministry of Health.

The 52 Regional Committees comprise:

- 12 appointed by the Medical Universities.
- 17 appointed by the Medical or Scientific Institutes.
- 23 appointed by the Regional Chambers of Physicians and Dentists.

Bioethics committees evaluate all kind of medical research including all types of clinical trials.

Source: EFGCP Report Poland

<http://www.efgcp.eu/Downloads/EFGCPReportFiles/Poland%20definitive.pdf>

Ethics Application/Approval process

The Chief Investigator, or the Co-ordinating Investigator, must apply for a Bioethics Committee opinion to the appropriate committee depending on his or her place of work and the site at which the trial is to be conducted.

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

Not available/to be updated

Contact Details of Ethics committees

A list of polish ethics committees is available on the website of "European Network of Research Ethics Committees"

<http://www.eurecnet.org/information/poland.html>

Website addresses of ethics committees

Website address can be found here

<http://www.eurecnet.org/information/poland.html>

Website links to ethics application forms

Not available

Website links to meeting time tables

Not available

Ethical approval timeline

35 days

Ethical approval application Fees

The fees are not uniform. They are determined by the Bioethics Committee founding bodies. The fee is on average about 2000 euros. Research Doctors pursuing their own unsponsored medical experiments are usually exempted from fees.

Source: <http://www.eurecnet.org/information/poland.html>

Special requirements for studies involving children/vulnerable people

Clinical trials involving children are covered by Minister of Health Regulations of April 2004, mentally ill patients unable to give consent may be legally represented, and research on the unconscious patient is covered by submitting a protocol for such a study in advance to the Local Guardianship Court: this Court can then give permission for such a study to take place on condition that it is notified when an unconscious patient is actually recruited.

Special requirements if studies include collection and use of human tissues

Same processes for submission for ethical review.

Helpful notes for obtaining ethical approvals

To be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Urząd Rejestracji Produktów leczniczych wyrobów medycznych i Produktów Biobojczych

Aleje Jerozolimskie 181 c 02-222 Warszawa 004822 4821100

Application process for IMP

The sponsor must apply for an authorisation to conduct a clinical trial to the competent authority in Poland, which is the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

Further details are available here (in Polish) <http://www.urpl.gov.pl/pozwolenia-na-badania-kliniczne>

Timeline for IMP trial approval

60 days

Fees for IMP approval

Application fee for a license to conduct the clinical trial is 5000 PLN

Pre-approval of protocols

No informations

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available

Regulations around transport and sample sharing

Not available

Data protection

Data protection regulations

ACT of August 29, 1997 on the Protection of Personal Data, available here http://www.giodo.gov.pl/144/id_art/171/j/en/

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

Cezary SZMIGIELSKI

Department of Internal Medicine, Hypertension and Vascular Diseases,

The Medical University of Warsaw,

CP CSK, Banacha Street 1A, 02-097, Warsaw

Poland

Phone: +48 22 599 28 28

Email: cszmigielski@wum.edu.pl

Contact details of National Network leads

GRACE

Maciek Godycki-Cwirko, Lodz

Slawomir Chlabicz, Szczecin

Slawomir Chlabicz, Bialystok

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

PORTUGAL

Total Population: 10.53 million

Languages: Portuguese

Time Zone: UTC+00:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 81%, other Christian 3.3%, others 15.7%

Urban population: 61% of total population (2010)

Life expectancy at birth: 79.01 years (male: 75.76 years, female: 82.47 years)

Health expenditures: 10.4% of GDP (2011)

Physicians density: 3.76 physicians/1,000 population (2009)

Hospital bed density: 3.4 beds/1,000 population (2010)

Health System

Primary care system

All residents in Portugal have access to health care provided by the National Health Service (NHS), financed mainly through taxation. Health care delivery is based on both public and private providers. Public provision is predominant in primary care and hospital care, with a gatekeeping system in place for the former.

A mix of public and private health service providers delivers Portuguese primary health care. This network incorporates primary care centres integrated in the National Health Service, private sector primary care providers and professionals or groups of professionals with which the NHS contracts or develops cooperation agreements. In 2008, the creation of the Groups of primary care centres (ACES) restructured the organization of Portuguese primary health care. Primary health care in the public sector is mostly delivered through publicly funded ACES. Each ACES has organizational and financial independence, and is composed of several units. The primary care network promotes health and disease prevention, as well as management of acute or serious health problems.

Source: Portugal Health system review 2011

http://www.euro.who.int/_data/assets/pdf_file/0019/150463/e95712.pdf

Acute hospital system

Secondary and tertiary care is mainly provided in hospitals, although, some primary care centres still employ specialists who provide specialist ambulatory services. The first point of contact within the public system is the GP/family doctor in a primary care centre. However many patients prefer to go directly to emergency care services in



hospitals or the private sector where the full range of diagnostic tests can be obtained in a few hours. Hospitals are classified according to the services they offer. Most hospital services are provided according to the integrated model directly run by the NHS. Also, diagnostic and therapeutic services in the ambulatory sector are mainly provided by the private sector through “any willing provider” contracts.

Source: Portugal Health system review 2011

http://www.euro.who.int/__data/assets/pdf_file/0019/150463/e95712.pdf

Public health agency

Name of public health agency

Directorate-General of Health

Website of public health agency

<http://www.dgs.pt/>

Contact details of public health agency

Alameda D. Afonso Henriques,

45 - 1049-005 Lisbon - Portugal

Tel: 21 843 05 00

Fax: 21 843 05 30

E-mail: geral@dgs.pt

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The Medicines Evaluation Agency (INFARMED)

Website of competent authority

<http://www.infarmed.pt/>

Contact Address of competent authority

Parque de Saúde de Lisboa - Avenida do Brasil, 53

1749-004 Lisboa - Portugal

Phone: 21 7987283

Fax: 21 7987248

Email: cimi@infarmed.pt

Application process of clinical trial approval

Follow the European Commission's, "Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1)" accessible at:

<http://eur->

lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:082:0001:0019:EN:PDF

Further details are available here (in Portuguese)

http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/ENSAIOS_CLINICOS

Law 46/2004 of August 19 is available here

http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/036-C_Lei_46_2004_1.%AAAlt.pdf

Time line for approval process

Within 60 days

Process for fast track approvals during epidemics/pandemics

No information

Ethics Committees

Structure and configuration of Ethics committees

By law all health care institutions must have an institutional ethics committee that have also the responsibility for the evaluation of all clinical research with human beings except in what concerns clinical trials with human medicines. The review of Clinical Trials on Medicinal Products for Human Use is responsibility of the Ethical Committee for Clinical Research (CEIC), which is a national ethics committee and the competent one as defined in the law 46/2004 of 19 August 2004.

Ethics Application/Approval process

The sponsor or his legal representative in the European Union must present an application (cover letter) addressed to the President of the CEIC, written in Portuguese, signed and on whose header should appear EudraCT number, protocol number assigned by the clinical trial sponsor and the title of it. For an application to be valid must be accompanied by all the information indicated in Annex I to this Guideline (see the link below)

More details are available in the Guidelience (in Portuguese)

http://www.ceic.pt/portal/page/portal/CEIC/UTILIDADES_INFORMACAO/SUBMISSAO_PEDIDO_PARECER/INSTRUCOES/ceic_instrucoes_0.pdf

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No

Fast-track application process for ethical approval

No information available

Contact Details of Ethics committees

National Ethics Committee for Clinical Research

Av. do Brasil, 53 - Pav. 17-A

1749-004 Lisboa

Tel: +351 21 798 53 40

Fax: +351 21 798 72 09

ceic@ceic.pt

Website addresses of ethics committees

<http://www.ceic.pt>

Website links to ethics application forms

Not available

Website links to meeting time tables

Not available

Ethical approval timeline

60 days

Ethical approval application Fees

Not available

Special requirements for studies involving children/vulnerable people

Described on the Guideliience (in Portuguese)

http://www.ceic.pt/portal/page/portal/CEIC/UTILIDADES_INFORMACAO/SUBMISSAO_PEDIDO_PARECER/INSTRUCOES/ceic_instrucoes_0.pdf

Different processes for applications involving children - Lei n.º 21/2014 is very discriminative. Please see corresponding articles: Article 7: Children participants
Article 8: Largest participants unable to do informed consent

Special requirements if studies include collection and use of human tissues

Not available

Helpful notes for obtaining ethical approvals

Not available

Investigational Medicinal Products (IMP) Requirements**Agency responsible for approving IMP studies**

The Medicines Evaluation Agency (INFARMED)

Application process for IMP

Follow the European Commission's, "Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1)" accessible at:

<http://eur->

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:082:0001:0019:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:082:0001:0019:EN:PDF)

Timeline for IMP trial approval

Within 60 days

Fees for IMP approval

Stages I to III € 1,000;

Stage IV € 450;

To amend the Protocol - € 100;

More information (in Portuguese) available here

https://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/portaria_396-2005.pdf

Pre-approval of protocols

no information available

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available

Regulations around transport and sample sharing

Not available

Data protection

Data protection regulations

Act on the Protection of Personal Data available at <http://www.cnpd.pt/english/bin/legislation/Law6798EN.HTM>

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

Ana Pais

Faculdade de Ciencias Medicas da Universidade Nova de Lisboa

Campo Mártires da Pátria, 130

Lisboa PORTUGAL

Phone: + 351 21 88 03 035

Email: ana.pais@fcm.unl.pt

Contact details of National Network leads

GRACE

Alexandre Gouveia

Braga

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

ROMANIA

Total Population: 21.33 million

Languages: Romanian

Time Zone: UTC+02:00

Further demographic info (cultural/religious etc.)

Religions: Eastern Orthodox 81.9%, Protestant 6.4%, Roman Catholic 4.3%, others 7.4%

Urban population: 52.8% of total population (2011)

Life expectancy at birth: 74.69 years (male: 71.23 years, female: 78.36 years)

Health expenditures: 5.9% of GDP (2010)

Physicians density: 2.39 physicians/1,000 population (2010)

Hospital bed density: 6.3 beds/1,000 population (2010)

Health System

Primary care system

According to law, public health services in Romania are guaranteed by the state and financed by the state budget, local budgets, the health insurance fund and direct contributions. Following reforms in 1998, patients in Romania are allowed to choose their primary/ambulatory care doctor, with the possibility of changing to another doctor after a minimum period of six months' registration with the previous doctor. General practitioners were renamed "family doctors" and ceased to be state employees, functioning instead as independent practitioners, contracted by the (public) health insurance fund but privately operating their medical offices. Family doctors provide preventive and curative care as well as antenatal and postnatal care and some health promotion and health education. Specialized ambulatory health care is delivered by a network of hospital outpatient departments, centres for diagnosis and treatment, and office-based specialists.

Source: Romania Health systemreview 2008

http://www.euro.who.int/_data/assets/pdf_file/0008/95165/E91689.pdf

Acute hospital system

In Romania secondary care hospitals are organized on the basis of geographical criteria into regional hospitals, district hospitals, and local hospitals. Tertiary care is provided in specialized units (specialized hospitals, institutes and clinical centres) and a number of cardiovascular and other surgery departments in teaching hospitals. Except a few tertiary units all hospitals are owned by local councils. Hospitals are authorized by the



Ministry of Public Health and accredited by the National Hospital Accreditation Commission.

Source: Romania Health systemreview 2008

http://www.euro.who.int/_data/assets/pdf_file/0008/95165/E91689.pdf

Public health agency

Name of public health agency

The Ministry of Public Health

Website of public health agency

<http://www.ms.ro/>

Contact details of public health agency

Ent. Cristian Popișteanu, no. 1-3, sector 1,

cod 010024, Bucharest

Phone: +4 021 3072 500

Email: dirrp@ms.ro

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The National Medicines Agency

Website of competent authority

<http://www.anm.ro/>

Contact Address of competent authority

National Medicines Agency

Str. Aviator Sanatescu,

Nr. 48, Sector 1, 011478,

Bucuresti, ROMANIA

Phone: +4021 317.11.00

Fax: +4021 316.34.97

Application process of clinical trial approval

European guidelines on application for authorisation of a clinical trial on a medicinal product for human use

to the competent authorities has been transposed into National legislation NMA SCD No. 22/2010. (No details on application procedure is available on The National Medicines Agency's website)

Time line for approval process

2-3months (from survey participant)

Process for fast track approvals during epidemics/pandemics

Not available

Ethics Committees

Structure and configuration of Ethics committees

The National Ethics Committee for Clinical Trials is an independent body and it is under the direct authority of the Minister of Health. There are a few other ethics committees organized in hospitals with accreditation for clinical trials, but these are used only in consultative matters.

Source: EFGCP Report Romania,
<http://www.efgcp.eu/Downloads/EFGCPRportFiles/Romania%20definitive.pdf>

Ethics Application/Approval process

EU guidance on the application format and documentation to be submitted in an application for an ethics committee opinion on the clinical trial on medicinal products for human use has been transposed into national legislation- NMA SCD No. 50/2006

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

No information

Contact Details of Ethics committees

Not available

Website addresses of ethics committees

National Ethics Committee for Clinical Trials (NECCT) has no website

Website links to ethics application forms

Not available

Website links to meeting time tables

Not available

Ethical approval timeline

Not available

Ethical approval application Fees

The fees is between € 170 and 670.

Source: EFGCP Report,

<http://www.efgcp.eu/Downloads/EFGCPReportFiles/Romania%20definitive.pdf>

Special requirements for studies involving children/vulnerable people

The informed consent of vulnerable subjects to participate in a clinical trial may be obtained from the legal representative and must be the presumed expression of the will of the subject, provided that the subject has received information adequate to his/her capacity of comprehension; furthermore it may be withdrawn at any time.

Special requirements if studies include collection and use of human tissues

Not available

Helpful notes for obtaining ethical approvals

No information

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The National Medicines Agency

Application process for IMP

European guidelines on application for authorisation of a clinical trial on a medicinal product for human use to the competent authorities has been transposed into National legislation NMA SCD No. 22/2010. (No details on application procedure is available on The National Medicines Agency's website)

Timeline for IMP trial approval

more than 4 months (from survey participant)

Fees for IMP approval

Phases I–III €1250

Phase IV €410

Approval of changes to protocol/investigational medicinal product €200

Pre-approval of protocols

Not available

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available

Regulations around transport and sample sharing

Not available

Data protection

Data protection regulations

Details are available on the website of "The National Supervisory Authority for Personal Data Processing " <http://www.dataprotection.ro/>

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

Not available

Contact details of National Network leads

Not available

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

SLOVAKIA

Total Population: 5.41 million

Languages: Slovak, Hungarian, Roma

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 62%, Protestant 8.2%, Greek Catholic 3.8%, other or unspecified 12.5%, none 13.4%

Urban population: 54.7% of total population (2011)

Life expectancy at birth: 76.69 years (male: 73.09 years, female: 80.52 years)

Health expenditures: 9% of GDP (2010)

Physicians density: 3 physicians/1,000 population (2007)

Hospital bed density: 6.4 beds/1,000 population (2010)

Health System

Primary care system

The health care system in Slovakia is based on universal coverage, compulsory health insurance, a basic benefit package and a competitive insurance model with selective contracting and flexible pricing. The state, represented by the Ministry of Health, is the owner of the largest health insurance company. Furthermore, the state owns the largest health care providers, including university hospitals, large regional hospitals, highly specialized institutions, and almost all psychiatric hospitals and sanatoria.

Ambulatory care consists of general care and specialized care. Since 1993, many services in ambulatory care have been privatized. All GPs have their own private practices. Most specialized outpatient departments have been privatized as well, either as independent practices or associated with polyclinics. Patients register with GPs through a written agreement for a period of at least six months, which can only be terminated in writing.

Source: Slovakia Health system review 2011

http://www.euro.who.int/_data/assets/pdf_file/0004/140593/e94972.pdf?ua=1

Acute hospital system

Admission of a patient to a hospital requires a referral from a physician or a specialist. Inpatient care is provided in general hospitals (including university hospitals) and specialized hospitals, owned publicly or privately. Hospitals usually provide specialized ambulatory care as well. The Ministry of Health issues permits for specialized hospitals



and biomedical research institutes to operate. Self-governing regions issue permits for all other health care facilities.

Source: Slovakia Health system review 2011

http://www.euro.who.int/_data/assets/pdf_file/0004/140593/e94972.pdf?ua=1

Public health agency

Name of public health agency

Public Health Authority of the Slovak Republic (SIDC)

Website of public health agency

<http://www.uvzsr.sk/en/>

Contact details of public health agency

Public Health Authority of the Slovak Republic

Trnavská 52, 826 45 Bratislava

Tel: 02/49 284 111

Email: uvzsr@uvzsr.sk / podatelna@uvzsr.sk

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

State Institute for Drug Control

Website of competent authority

<http://www.sukl.sk/en>

Contact Address of competent authority

ŠUKL

Kvetná 11

825 08 Bratislava 26

Tel: +421 903 251 979

Fax: +421 2 5556 0022

E-mail: sukl@sukl.sk

Application process of clinical trial approval

Slovak republic has adopted Commission directives 2001/20/EC and 2005/28/EC into Act No. 362/2011 Col. There are some differences in the procedures between Slovak Acts and these directives, which is available here; http://www.sukl.sk/en/clinical-trials/instructions/main-changes-in-slovak-drug-law-clinical-trials-human?page_id=2822

Request for a clinical trial authorization should contain at least: Covering Letter, Application form, Investigator's Brochure, Protocol, Subject information leaflet (in Slovak language), Informed consent form (in Slovak language), Investigational

Medicinal Product Dossier (IMPD), a copy of authorisation (licence) of health care provider(s) acting as trial site(s), and copy of ethics committee opinion.

Detailed information is available here; http://www.sukl.sk/en/clinical-trials/news?page_id=990

Time line for approval process

In 2010 it ranges from 131 days to 146 days

Source:

http://www.sukl.sk/buxus/docs/AnglickaVerzia/ClinicalTrials/Duration_of_approval_processes_2010.pdf

Process for fast track approvals during epidemics/pandemics

No information

Ethics Committees

Structure and configuration of Ethics committees

There are 8 regional ethics committees, and about 60 “local” ethics committees. According to the law each inpatient health care facility in Slovakia should have an ethics committee, which is expected to assess applications for the ethical review of clinical trial protocols to be conducted at that facility. If chosen by the sponsor, that committee may give “the single opinion” for a multi-site clinical trial. Regional ethics committees are appointed by the regional state authority. Local ethics committees are appointed by directors of health care facilities or research institutions. No centralized authority currently supervises or audits ethics committees.

Source: EFGCP Report Slovakia;

<http://www.efgcp.eu/Downloads/EFGCPRReportFiles/Slovakia%20interim.pdf>

Ethics Application/Approval process

An opinion of the ethics committee (EC) should be sought for any CT or biomedical research project, to be conducted in Slovakia, and the necessary authorization is granted only after positive opinion from EC has been obtained. It should be asked for and the necessary documents sent by the sponsor to:

a) For a single-site clinical trial: the EC of the health care facility or research institution, where the trial is to be conducted.

b) For a multi-site trial:

ba) Conducted solely in the inpatient institutions: the EC of one of the involved institutions, chosen and specifically asked by the sponsor to issue “a single opinion” as required by Dir. 2001/20/EC (usually this is the EC of the institution of the country coordinator of the trial).

bb) Conducted in the outpatient facilities: the regional EC, chosen and specifically asked by the sponsor to issue “a single opinion” as required by Dir. 2001/20/EC (as described in 12).

bc) Conducted both in the inpatient and outpatient facilities: the regional EC, chosen and specifically asked by the sponsor to issue “a single opinion” as required by Dir. 2001/20/EC (as described in 12).

Source: EFGCP Report Slovakia;
<http://www.efgcp.eu/Downloads/EFGCPReportFiles/Slovakia%20interim.pdf>

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

No information available

Contact Details of Ethics committees

Contact details of ethics committees is available here

http://www.sukl.sk/sk/klinicke-skusanie-liekov/pokyny/zoznam-etickych-komisi-v-a0slovenskej-republike?page_id=1947

The Ethics Commission of the autonomous counties

http://www.sukl.sk/sk/klinicke-skusanie-liekov/pokyny/zoznam-etickych-komisi-samospravnych-krajov?page_id=1851

Website addresses of ethics committees

The Ethics Commission of the autonomous counties

http://www.sukl.sk/sk/klinicke-skusanie-liekov/pokyny/zoznam-etickych-komisi-samospravnych-krajov?page_id=1851

Contact details of ethics committees is available here (no website address)

http://www.sukl.sk/sk/klinicke-skusanie-liekov/pokyny/zoznam-etickych-komisi-v-a0slovenskej-republike?page_id=1947

Website links to ethics application forms

Time tables are available on the websites of the Ethics Commission of the autonomous counties

http://www.sukl.sk/sk/klinicke-skusanie-liekov/pokyny/zoznam-etickych-komisi-samospravnych-krajov?page_id=1851

Website links to meeting time tables

Time tables are available on the websites of the Ethics Commission of the autonomous counties

http://www.sukl.sk/sk/klinicke-skusanie-liekov/pokyny/zoznam-etickyh-komisii-samospravnych-krajov?page_id=1851

Ethical approval timeline

Not available

Ethical approval application Fees

There is no official regulation for ECs' fees (it is pending, however), the range is about €300 – €900. For non-commercial studies, the fees are usually waived.

Source: EFGCP Report Slovakia;

<http://www.efgcp.eu/Downloads/EFGCPReportFiles/Slovakia%20interim.pdf>

Special requirements for studies involving children/vulnerable people

Not available

Special requirements if studies include collection and use of human tissues

Not available

Helpful notes for obtaining ethical approvals

Not available

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

State Institute for Drug Control

Application process for IMP

MP 107/2011-the procedure for making the application for the authorisation of clinical trials of medicinal products;

<http://www.vucbb.sk/portal/sites/default/files/bbsk/stranky/2011/nezavisla-eticka-komisija-bbsk/mp-107-2011-postup-pri-podavani-ziadosti-o-povolenie-klinickeho-skusania-liekov.pdf>

Timeline for IMP trial approval

In 2010 it ranges from 131 days to 146 days

Fees for IMP approval

Clinical trial of medicinal product for human use - 331,50 €

Pre-approval of protocols

No information available

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available

Regulations around transport and sample sharing

Not available

Data protection

Data protection regulations

Act no. 122/2013 Coll. on the protection of personal data and on amendments to certain laws.

More details are available on the website of "Office for Personal Data Protection"

<http://www.dataprotection.gov.sk/uouu/sk>

Presence of PREPARE networks

PREPARE Networks present in the country

Contact details of ECRIN representative

Not available

Contact details of National Network leads

Not available

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

SLOVENIA

Total Population: 2.06 million

Languages: Slovenian

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Catholic 57.8%, Muslim 2.4%, Orthodox 2.3%, others 37.5%

Urban population: 50% of total population (2010)

Life expectancy at birth: 77.83 years (male: 74.21 years, female: 81.69 years)

Health expenditures: 9% of GDP (2010)

Physicians density: 2.54 physicians/1,000 population (2010)

Hospital bed density: 4.6 beds/1,000 population (2010)

Health System

Primary care system

Most of the health care delivery in Slovenia is carried out by state-owned (hospitals, most of outpatient specialist care and tertiary care) and municipality-owned providers (primary health care centres), who collectively employ more than 75% of the total health workforce. Both public and private providers of care are involved in primary health care. Among public providers there are health care centres and health stations. Health care centres are established and owned by one or more local communities, which are responsible for management of the day-to-day functioning of the centre, as well as for administration and provision of adequate funds for the maintenance of premises. Apart from public provision of health care there is also private provision, which is carried out by either individual health professionals acting as providers, or by group practices with various combinations of services and specialties. Health care personnel involved in delivering primary health care include: GPs/family physicians, dentists, nurses, pharmacists, physical therapists, speech therapists, occupational therapists, psychologists or psychiatrists, midwives and other health professionals necessary to carry out the work of the health centre.

Source: Slovenia Health system review 2009

http://www.euro.who.int/_data/assets/pdf_file/0004/96367/E92607.pdf

Acute hospital system

Specialist outpatient activities at the secondary care level are performed in hospitals, spas or in private health facilities. Approximately 75% of secondary care is provided by hospitals, either as inpatient or outpatient care. Clinics and specialized institutes



provide more complex health services at the tertiary care level. The overwhelming majority of hospitals are state owned, but three smaller private hospitals exist and there are further initiatives under consideration for private provision of hospital care.

Source: Slovenia Health system review 2009

http://www.euro.who.int/_data/assets/pdf_file/0004/96367/E92607.pdf

Public health agency

Name of public health agency

Institute of Public Health of the Republic of Slovenia

Website of public health agency

<http://www.ivz.si/>

Contact details of public health agency

National Institute of Public Health

Trubarjeva 2, 1000 Ljubljana

Phone: +386 1 2441 400

Fax: +386 1 2441 447

E-mail: info@nijz.si

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The Agency for Medicinal Products and Medical Devices (JAZMP)

Website of competent authority

<http://www.jazmp.si/en/>

Contact Address of competent authority

Javna agencija RS za zdravila in medicinske pripomočke,

Ptujska ulica 21, 1000 Ljubljana,

Phone: +386 (0)8 2000 500,

Fax: +386 (0)8 2000 510,

Email: info@jazmp.si

Application process of clinical trial approval

The application is made by the applicant to the competent authority, the JAZMP. The authorisation is required for clinical trials involving advanced therapy medicinal products; for all other clinical trials notification is required. Either a sponsor or sponsor's representative (written authorisation by sponsor) may apply for a clinical trial. The sponsor or sponsor's representative must be established in the EU. The application must be submitted to the address of JAZMP, Einspielerjeva 6, 1000 Ljubljana. At the

same time, the application should also be submitted to the National Medical Ethics Committee. In the case of clinical trials with genetically modified organisms (GMO) it is necessary to obtain a special permit from the Ministry of Environment and Spatial Planning. The application should be prepared in accordance with Article 20 of the Rules on clinical trials of medicinal products (Uradni list RS, No. 54/06, <http://www.uradni-list.si/1/content?id=73527>). Decisions on applications for approval/notification of clinical trials are made by JAZMP. Clinical trials may begin when the conditions from Article 59 of the Medicinal Products Act (ZZdr-1) are met and a favourable opinion of the National Medical Ethics Committee of the Republic of Slovenia is obtained.

The application for notification/approval of a non-commercial clinical trial should be prepared in accordance with Article 20 of the Rules on clinical trials of medicinal products (Uradni list RS, No. 54/06). Relief is provided in payment of the fee.

Prior to the beginning of a non-interventional clinical trial, the applicant must notify JAZMP of this in accordance with Article 29 of the Rules on clinical trials of medicinal products (Uradni list RS, No. 54/06).

For more details on application procedure (in Slovenian)

<http://www.jazmp.si/fileadmin/datoteke/dokumenti/SEK/NA-ectd.pdf>

General information

http://www.jazmp.si/en/human_medicines/clinical_trials/notificationapproval_of_clinical_trials/

Time line for approval process

Not available

Process for fast track approvals during epidemics/pandemics

Not available

Ethics Committees

Structure and configuration of Ethics committees

At the national level there is only one research ethics committee, i.e. the National Medical Ethics Committee (NMEC). Local ethics committees have recently been set up at university and regional hospitals. The NMEC reviews all biomedical research funded by the State agencies or institutions, all multi-centre and multinational clinical trials. The local/regional ethics committees are only authorised to review local studies that do not present any serious risk to the participants. They are also invited to preliminarily review the protocols of all studies to be carried out at the local level, and to monitor their progress after they had been approved by the NMEC. Research involving gene

technology or medically assisted procreation must also be passed by relevant special advisory committees before going to the NMEC for approval.

Source: EFGCP Report Slovenia,
<http://www.efgcp.eu/Downloads/EFGCPReportFiles/Slovenia%20incomplete.pdf>

Ethics Application/Approval process

The project proposal should be submitted to the NMEC. Guidelines for preparation of the application are available at <http://www.kme-nmec.si/>. The proposal is reviewed by at least one rapporteur. Decisions are taken at monthly meetings.

Ethics: Fast-track approval available?

Yes

Ethics: Pre-approval of study protocol available?

Yes

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

Process is the same and you have to provide the same information as regularly. As an exception, preliminary opinion may be issued 'by chairman's action' in order to gain time for other official procedures.

Contact Details of Ethics committees
Božidar Voljč, M.D., D.Sc. Chairman
Institute of Clinical Neurophysiology,
University Medical Centre Ljubljana,
Zaloška cesta 7,
SI-1525 Ljubljana,
Slovenia

Phone: +386 1 522 1517,

Email: tone.zakelj@kclj.si

Website addresses of ethics committees

<http://www.kme-nmec.si>

Website links to ethics application forms

The NMEC holds meetings once every month. To be put on the agenda, applications must be received by regular mail (only original, no copies needed; e-submission unavailable) at least one week prior to the session.

Website links to meeting time tables

The NMEC holds meetings once every month. To be put on the agenda, applications must be received by regular mail (only original, no copies needed; e-submission unavailable) at least one week prior to the session.

Ethical approval timeline

Within 60 days (A typical response time is less than 4 weeks.)

Ethical approval application Fees

No fees are charged for review of any type of application.

Special requirements for studies involving children/vulnerable people

Article 16 and 17 of "RULES of clinical trials of medicinal products" describes the requirements for studies involving children/vulnerable people. <http://www.uradni-list.si/1/content?id=73527>

Process for obtaining ethical approvals is the same.

Special requirements if studies include collection and use of human tissues

Process for obtaining ethical approvals is the same.

Helpful notes for obtaining ethical approvals

No additional information.

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The Agency for Medicinal Products and Medical Devices (JAZMP)

Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)
Ptujška ulica 21 1000 Ljubljana, Slovenia P: +386 (0)8 2000 500, fax: +386 (0)8 2000 510, e-mail: info@jazmp.si www.jazmp.si

Application process for IMP

The application is made by the applicant to the competent authority, the JAZMP. The application should be prepared in accordance with Article 20 of the Rules on clinical trials of medicinal products (Uradni list RS, No. 54/06, <http://www.uradni-list.si/1/content?id=73527>).

Timeline for IMP trial approval

1-3 months (information from survey participants)

Fees for IMP approval

Details on fees are available here http://www.jazmp.si/en/human_medicines/fees/

Pre-approval of protocols

Not possible

IMP: Fast-track approval available?

No

IMP: Pre-approval available?

No

Biological samples

Registration and bio-banking requirements

Not available

Regulations around transport and sample sharing

Not available

Data protection

Data protection regulations

The Personal Data Protection Act (Zakon o varstvu osebnih podatkov, ZVOP, Ur.l. RS No. 59/99).

English version is available here <http://www.ics.uci.edu/~kobsa/privacy/SLOVENIA.htm>

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

GRACE

Janko Kersnik

Ljubljana (Jesenice)

Contact details of National Network leads

GRACE

Janko Kersnik

Ljubljana (Jesenice)

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

SPAIN

Total Population: 47.27 million

Languages: Spanish

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 94%, other 6%

Urban population: 77% of total population (2010)

Life expectancy at birth: 81.47 years (male: 78.47 years, female: 84.67 years)

Health expenditures: 9.6% of GDP (2010)

Physicians density: 3.96 physicians/1,000 population (2011)

Hospital bed density: 3.2 beds/1,000 population (2010)

Health System

Primary care system

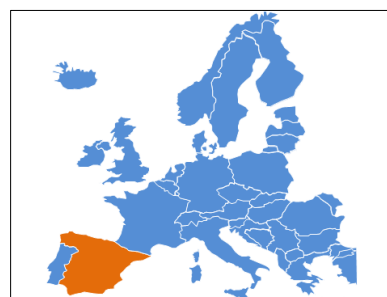
Primary health care in Spain is an integrated system composed of primary health care centres and multidisciplinary teams, and provides personal and public health services. Care for the most common conditions, either acute or chronic, follows well-defined protocols, often locally tailored to match health needs. GPs, being the first point of contact with the system, play the gatekeeper role. Upon the onset of symptoms, individuals will visit the family doctor they are registered with. GPs in Spain are trained and equipped to deal with a wide range of conditions; thus patients will mostly have their problem solved at this care level. When this is not the case and referral is necessary, the patient will be provided with an appointment for the corresponding specialist, normally based in the area ambulatory polyclinics. Based on the GP's referral report and their clinical assessment, the specialists will decide on the need for further testing or inpatient procedures, or will prescribe the treatment and either send the patient back to the GP or arrange for follow-up visits. Once the specialist discharges the ambulatory patients, a report will be sent to the referring GP.

Source: Spain Health System Review 2010

http://www.euro.who.int/__data/assets/pdf_file/0004/128830/e94549.pdf

Acute hospital system

Hospital-based emergency care is provided to patients referred by their primary care or specialist care doctor, or by primary care emergency centres. The specialized health care services common package in the SNS is defined to cover the following activities: specialized care in outpatient clinics, medical and surgical day hospitals, hospitalization



on an inpatient basis, support to primary care in cases of early hospital discharge and home care, palliative care for terminally ill patients, mental health care and rehabilitation for patients with functional deficiencies. It also includes intensive care, anaesthesia and resuscitation, haemotherapy, rehabilitation, nutrition and diet, pregnancy follow-up, surgical family planning and assisted human reproduction.

Source: Spain Health System Review 2010

http://www.euro.who.int/__data/assets/pdf_file/0004/128830/e94549.pdf

Public health agency

Name of public health agency

The National Institute of Health Management

Website of public health agency

<http://www.ingesa.msssi.gob.es/>

Contact details of public health agency

Email: informacioningesa@ingesa.msssi.es

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The Spanish Agency for Medicines and Medical Devices

Website of competent authority

<http://www.aemps.gob.es/>

Contact Address of competent authority

C / Campezo No.1, Building 8

28022 Madrid

Phone: +34 91 822 59 97

Application process of clinical trial approval

The sponsor submits the application to the competent authority. The application procedure is described in the Section 3 of the Royal Decree 223/2004, of 6 February.

Available here (in Spanish)

http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rc1_2004_325.pdf

Time line for approval process

60 days

Process for fast track approvals during epidemics/pandemics

No fast track process is available

Ethics Committees

Structure and configuration of Ethics committees

In Spain, the Clinical Research Ethics Committees (Comités de Ética en Investigación Clínica, CEIC) are the oversight bodies of methodological adequacy, ethical goodness and regulatory compliance regarding research on human subjects. There are institutional or local committees and others of regional level, without implying a hierarchy between them. The Royal Decree 223/2004 transposing the European Directive (20/2001/CE) implemented an option for "Single Opinion" for multicentre clinical drug trials whereby it is only necessary the approval of one CEIC (CEIC of reference) for each EU Member State.

Source: <http://www.eurecnet.org/information/spain.html>

From survey response:

From a political and geographical point of view, Spain is divided into 17 regions. Some have their own Ethics Committee; others regions have an Ethics Committee in each hospital. However, for the PREPARE study, the reference Ethics Committee for the whole Spanish territory is the Autonomic Research Ethics Committee of Galicia (CAIEG).

Website: http://www.sergas.es/MostrarContidos_N2_T01.aspx?IdPaxina=60018 Phone number:+ 34 881.546.425 Fax number:+34 881.541.804 E-mail: ceic@sergas.es Address: CAEI Galicia Secretaria Xeral Consellería de Sanidade Edificio Administrativo San Lázaro s/n 15781 Santiago de Compostela (A Coruña) Spain

Ethics Application/Approval process

Not clear (information available only in Spanish)

Some details are available here

<http://www.msssi.gob.es/profesionales/farmacia/ceic/documentacionEnsayoCli.htm>

From survey:

Clinical Trials: Application to the referral Ethics Committee must be done via handwritten form and delivered by post mail. Clinical trials should be evaluated in each center involved in the study but the referral Ethics Committee submits the last inform. It is also necessary to notify the existence of the clinical trial to the "Office of Children" (Spanish Government) • Observational Studies: Application to the referral Ethics Committee must be done electronically (via e-mail). It is important to consider that documentation, except informed consent, can be written in English. Informed consent should be translated into Spanish and Galician. The submission should be done before the day 5 of each month to be evaluated in that month. There is not any meeting during August. After the evaluation the committee issues an inform and there is the possibility of submitting the answer to the clarifications proposed.

Ethics: Fast-track approval available?

No

Ethics: Pre-approval of study protocol available?

No

Ethics: Waived consent?

No

Fast-track application process for ethical approval

No process for fast track applications is available.

Contact Details of Ethics committees

A list of accredited ethics committees is available here

<http://www.msssi.gob.es/profesionales/ceicsca.do>

Website addresses of ethics committees

<http://www.msssi.gob.es/profesionales/farmacia/ceic/home.htm>

Website links to ethics application forms

Not available

Website links to meeting time tables

Not available

Ethical approval timeline

Within 60 days

Survey responses indicate between 1 and 3 months.

Ethical approval application Fees

Fees vary, ranging from 300 € to 1200€ per protocol.

Source:

EFGCP

Report;

<http://www.efgcp.eu/Downloads/EFGCPReportFiles/Spain%20definitive%20Updated.pdf>

From survey:

For clinical trials: 1087,74€. For observational studies: 111€. However, it is possible to ask for exemption from payment of administrative fees.

Special requirements for studies involving children/vulnerable people

Article 4 and Article 5 of the Royal Decree 223/2004, of 6 February describes the requirements for studies involving children/vulnerable people. Available here (in Spanish)

http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rcl_2004_325.pdf

Survey responses suggest the same processes are followed for ethics approvals.

Special requirements if studies include collection and use of human tissues

Unclear - survey responses are contradictory.

Helpful notes for obtaining ethical approvals

Not available

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The Spanish Agency for Medicines and Medical Devices

Website: <http://www.aemps.gob.es/home.htm> Email: There is not a direct email. Phone number: - National calls: 902 101 322 - International calls: +34 91 822 59 97 Address: Agencia Española de Medicamentos y Productos Sanitarios (Área de Ensayos Clínicos) Parque empresarial Las Mercedes, edificio 8, 2ª Planta A. C/ Campezo nº 1, Edificio 8 28022 Madrid Spain

Application process for IMP

Clinical drug trials have been subject to regulation under Title III of Law 25/1990 of 20 December. The sponsor submits the application to the competent authority.

From survey:

Only for clinical trials: After making the payment of administrative fees (no fee exemption), the application is done through a web portal for which you need a digital certificate to sign the application. To obtain approval of the Spanish Agency of Medicines and Medical Devices Competent Authority is necessary to send (through a web portal) the approval of reference Ethics Committee and the approval of one participating center in the clinical trial. It is important to consider that if the protocol is sent in English, a protocol resume must be sent in Spanish. However, there is a Voluntary Harmonization Procedure, which is an efficient tool to achieve harmonized and quick approvals of clinical trials in 2 or more Members States of the EU in one procedure.

Timeline for IMP trial approval

60 days (90 days for those clinical trials referring to cell or gene therapy and GMO medicinal products)

Fees for IMP approval

Fees information is available here

<http://www.aemps.gob.es/en/investigacionClinica/medicamentos/ensayosClinicos.htm#tasas>

From survey: Depending on whether the clinical trial drug is approved by the EMEA and/or the AEMPS (The Spanish Agency of Medicines and Medical Devices), the fee can be from 111€ to 4200€

Pre-approval of protocols

Pre-approval of protocols not allowed.

IMP: Fast-track approval available?

No

IMP: Pre-approval available?

No

Biological samples

Registration and bio-banking requirements

Not available

Regulations around transport and sample sharing

Not available

Data protection

Data protection regulations

Details are available on the website of Agencia de Protección de Datos (Spanish Data Protection Agency)

<https://www.agpd.es/portalwebAGPD/index-ides-idphp.php>

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

Nuria SANZ

UASP- Farmacologia Clínica

Hospital Clínic de Barcelona

c/Villarroel, 170

08036 Barcelona

SPAIN

Phone: +34 932279328

Email: NSANZ@clinic.ub.es

Contact details of National Network leads

GRACE

Antoni torres

(Via: Patricia Fdez-Vandellos)

Barcelona

Jordi Almirall

Mataro

SERGAS

Federico Martinon-Torres

E-mail: federico.martinon.torres@sergas.es

Tel. +34 981955093

Carmen Rodriguez-Tenreiro

E-mail: carmentenreiro@hotmail.es

Tel. +34 981955093 / +34 981950123

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

SWEDEN

Total Population: 9.52 million

Languages: Swedish

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Lutheran 87%, other 13%

Urban population: 85% of total population (2010)

Life expectancy at birth: 81.89 years (male: 80.03 years, female: 83.87 years)

Health expenditures: 9.4% of GDP (2011)

Physicians density: 3.8 physicians/1,000 population (2010)

Hospital bed density: 2.7 beds/1,000 population (2010)

Health System

Primary care system

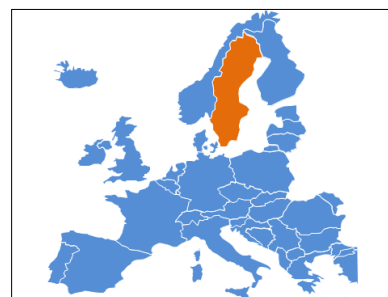
In Sweden primary health care involves services that do not require advanced medical equipment and is responsible for guiding the patient to the right level within the health system. Choice of primary care provider for the population and freedom of establishment for primary care providers accredited by the local county councils is mandatory in Sweden. Patients can register with any public or private provider accredited by the local county council. Primary care has no formal gate-keeping role in most county councils and patients are free to contact specialists directly. There are more than 1100 primary care units throughout the country, with about one-third being privately owned.

Source: Sweden Health System Review 2012

http://www.euro.who.int/_data/assets/pdf_file/0008/164096/e96455.pdf

Acute hospital system

Specialized somatic care involves health and medical services requiring medical equipment or other technologies that cannot be provided in the primary care setting but requires treatment at the hospital level. In Sweden, a relatively large proportion of the resources available for medical services have been allocated to the provision of care and treatment at hospital level. Public hospitals are grouped into county council hospitals and regional/university hospitals. There are 7 regional/university hospitals and about 70 hospitals at the county council level, offering specialized inpatient and outpatient somatic and psychiatric care. County council hospitals can be divided into acute care hospitals and local hospitals. About two-thirds of the county council hospitals are acute care hospitals. In acute care hospitals, care is offered 24 hours a day and a larger



number of clinical expert competences are represented than in local hospitals. There are six private hospitals in Sweden, of which three are non-profit-making and three are profit-making. Highly specialized care is provided at regional/university hospitals. Swedish counties are grouped into six medical care regions with seven regional/university hospitals to facilitate cooperation regarding tertiary medical care and to maintain a high level of advanced medical care.

Source: Sweden Health System Review 2012

http://www.euro.who.int/_data/assets/pdf_file/0008/164096/e96455.pdf

Public health agency

Name of public health agency

Public Health Agency of Sweden

Website of public health agency

<http://www.folkhalsomyndigheten.se/>

Contact details of public health agency

Public Health Agency

171 82 Solna

Telephone: +46 10 205 20 00

Email: info@folkhalsomyndigheten.se

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

The Medical Products Agency (Lakemedelsverket)

Website of competent authority

<http://www.lakemedelsverket.se/english/>

Contact Address of competent authority

Medical Products Agency

P.O. Box 26

SE-751 03 Uppsala

SWEDEN

Phone: +46 18 174600

Fax: +46 18 548566

Email: registrator@mpa.se

Application process of clinical trial approval

Obtaining EudraCT number and fill in the application form. Applications can be submitted either as an attachment to email (limited size, 20MB), CD, USB or Eudralink.

Application packages are suitably placed in different folders as separate PDF files according to the following structure: General Information, Study protocol, Investigator's brochure, IMPD, Additional info Sc advice or PIP. Initially, the MPA a review of the documents attached to verify that the submitted application is valid. If MPA finds that the application is not valid this will be notified to the sponsor within 10 days.

Time line for approval process

60 days (For trials with gene therapy or somatic cell therapy, as well as any therapy in which genetically modified organisms (GMOs) 90 days)

Process for fast track approvals during epidemics/pandemics

No information available

Ethics Committees

Structure and configuration of Ethics committees

From January 1, 2004 there is a law on the ethical review of research involving humans (Ethical Code). The most important change since the beginning of 2004 is the establishment as independent authorities of one central ethical vetting board and six local ones. The regional boards' offices located at the universities of Gothenburg, Linköping, Lund, Umeå and Uppsala and the Karolinska Institute in Stockholm.

Act (2003:460) concerning the Ethical Review of Research Involving Humans is available [here;](http://www.riksdagen.se/sv/Dokument-Lagar/Lagar/Svenskforfattningssamling/Lag-2003460-om-etikprovning_sfs-2003-460/)

http://www.riksdagen.se/sv/Dokument-Lagar/Lagar/Svenskforfattningssamling/Lag-2003460-om-etikprovning_sfs-2003-460/

In the 2008 amendment scope of the Act has been extended to all research involving the handling of sensitive personal data, whether research subjects give their consent or not. A further extension of the scope of the Act is that research carried out by a method that involves obvious risk of injury be ethically inadmissible.

Ethics Application/Approval process

Application is made to the relevant EC (Board for Ethics Review) using a form that is available on the website <http://www.epn.se>.

Ethics: Fast-track approval available?

No Info

Ethics: Pre-approval of study protocol available?

No Info

Ethics: Waived consent?

No Info

Fast-track application process for ethical approval

Not available

Contact Details of Ethics committees

Central Ethical Review Board

c / o Research Council

Box 1035

101 38 Stockholm

Phone: 08-546 77 610

Fax: 08-546 44 180

Email: kansli@cepn.se

Addresses of regional ethics committees are available on the website of Central Ethics Committee <http://www.epn.se>

Website addresses of ethics committees

<http://www.epn.se>

Website links to ethics application forms

Available on the website of Central Ethics Committee <http://www.epn.se>

Website links to meeting time tables

Available on the website of Central Ethics Committee <http://www.epn.se>

Ethical approval timeline

60 days from the acknowledgement of the application

Ethical approval application Fees

Ranging from 2,000 SEK to 16,000 SEK

Special requirements for studies involving children/vulnerable people

Not available

Special requirements if studies include collection and use of human tissues

Not available

Helpful notes for obtaining ethical approvals

to be updated

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

The Medical Products Agency (Lakemedelsverket)

Application process for IMP

Obtaining EudraCT number and fill in the application form. Applications can be submitted either as an attachment to email (limited size, 20MB), CD, USB or Eudralink. Application packages are suitably placed in different folders as separate PDF files according to the following structure: General Information, Study protocol, Investigator's brochure, IMPD, Additional info Sc advice or PIP. Initially, the MPA a review of the

documents attached to verify that the submitted application is valid. If MPA finds that the application is not valid this will be notified to the sponsor within 10 days.

Timeline for IMP trial approval

60 days

Fees for IMP approval

Application for permission to carry out clinical trials: 45 000 SEK. Fee waiver may be granted for a clinical trial if the trial can be classified as non-commercial.

Pre-approval of protocols

Not available

IMP: Fast-track approval available?

No Info

IMP: Pre-approval available?

No Info

Biological samples

Registration and bio-banking requirements

Not available

Regulations around transport and sample sharing

Not available

Data protection

Data protection regulations

The 1998 Personal Data Act. The Act is based on and implements an EC Directive (95/46/EC) on data protection. The Act is applicable to automatic processing of personal data in both the public and private sector. An English version is available here <http://www.government.se/content/1/c6/01/55/42/b451922d.pdf>

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE

Contact details of ECRIN representative

Pierre LAFOLIE

Clinical Pharmacology - Solna, L2:03

Dep of Medicine, Karolinska Institutet

SE-171 76 Stockholm, Sweden

Phone: +46 870 484 67 11

Email: pierre.lafolie@ki.se

Contact details of National Network leads

GRACE

Sigvard Molstad

Lund Jönköping

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

UNITED KINGDOM

Total Population: 63.7 million

Languages: English

Time Zone: UTC + 0

Further demographic info (cultural/religious etc.)

Religions: Christian 59.5%, Muslim 4.4%, Hindu 1.3%, other 2%, none 25.7%, unspecified 7.2% (2011 est.)

Urban population: 80% of total population (2010)

Life expectancy at birth: 80.42 years (male: 78.26 years, female: 82.69 years)

Health expenditures: 9.3% of GDP (2011)

Physicians density: 2.77 physicians/1,000 population (2011)

Hospital bed density: 3 beds/1,000 population (2010)

Health System

Primary care system

England, Northern Ireland, Scotland and Wales each have their own systems of private and publicly funded healthcare. Most healthcare in England is provided by the National Health Service (NHS). In Scotland it is NHS Scotland and Wales it is NHS Wales. In Northern Ireland health care is provided by Health and Social Care in Northern Ireland. Each NHS system uses General Practitioners (GPs) to provide primary healthcare and to make referrals to further services as necessary. Hospitals then provide more specialist services, including care for patients with psychiatric illnesses.

Source: Wikipedia http://en.wikipedia.org/wiki/Healthcare_in_the_United_Kingdom

Acute hospital system

Secondary and tertiary care are provided mainly in hospital settings by specialist doctors working with a range of other health professionals. Most of this care is provided and paid for by the public sector although there is also a sizeable private sector. The NHS also provides some private care. To access NHS specialist care, patients require a referral for a consultation from a GP, although they may also be admitted as an emergency.

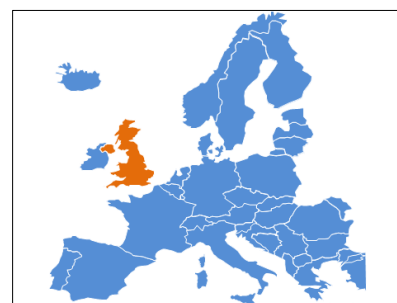
Copied from; United Kingdom (England) Health system review 2011.

http://www.euro.who.int/_data/assets/pdf_file/0004/135148/e94836.pdf

Public health agency

Name of public health agency

England – Public Health England



Website: <https://www.gov.uk/government/organisations/public-health-england>

Contact: 020 8200 4400 or 020 8200 6868

N Ireland – Public Health Agency (N Ireland)

Website: <http://www.publichealth.hscni.net/>

Contact: 028 903

Website of public health agency

See above

Contact details of public health agency

See above

Regulatory Authority/Competent Authority

Name of Regulatory Authority/Competent Authority

Medicines and Healthcare Products Regulatory Agency (MHRA)

Website of competent authority

<http://www.mhra.gov.uk/>

Contact Address of competent authority

151 Buckingham Palace Road

Victoria

London, SW1W 9SZ

Telephone: 020 3080 6000

Fax: 0203 118 9803

Email: info@mhra.gsi.gov.uk

Application process of clinical trial approval

Clinical trials in the UK are regulated by The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031) as amended. These regulations implement Directive 2001/20/EC ('The Clinical Trials Directive').

<http://www.legislation.gov.uk/ukxi/2004/1031/contents/made>

The sponsor must apply for the CTA (Clinical Trial Authorisation) at the Medicines and Healthcare products Regulatory Agency - MHRA, which is the competent authority for all counties in the UK. All clinical trials also require a favourable opinion from an Ethics Committee.

Applicants should submit electronic documents on disk, with one PDF file for each document.

Further details are available at

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Applyingforaclinicaltrialauthorisation/index.htm>

Fees

Applications with an IMP Dossier is £3,400

Applications without an IMP Dossier is £250

Clinical Trial Variation/Amendment is £250

Phase IV Notification is £0

Time line for approval process

The initial assessment will be performed within 30 days. For the purposes of this calculation, the day of receipt of the valid application by the Clinical Trials Unit is day 0. Applications for Healthy Volunteer Trials and sponsor-determined Phase I trials in non-oncology patients will be assessed and processed within 30 days, with an average of 14 days or less. Applicants are advised to state in the Covering Letter that the submission is for a Phase I trial eligible for the shortened assessment time, when applicable.

Process for fast track approvals during epidemics/pandemics

During the last pandemic a special initiative was administered to make the approvals faster. The same process was followed but it was expedited.

Ethics Committees

Structure and configuration of Ethics committees

The National Research Ethics Service (NRES) works to maintain a UK-wide system of ethical review that protects the safety, dignity and well being of research participants, whilst facilitating and promoting ethical research within the NHS. Detailed information on the types of study that require ethical approval are available on the NRES Website.

<http://www.hra.nhs.uk/research-community/before-you-apply/determine-which-review-body-approvals-are-required/>

Ethics Application/Approval process

All applications to Research Ethics Committees (RECs) in the UK are made using the NHS REC form in the Integrated Research Application System (IRAS). All applications must be accompanied by the research protocol and relevant documents as per the applicant's checklist (which must also be submitted).

Detailed guidance on using the IRAS system is available on the IRAS website.

<https://www.myresearchproject.org.uk/help/hlpusingiras.aspx>

Ethics: Fast-track approval available?

Yes

Ethics: Pre-approval of study protocol available?

Yes

Ethics: Waived consent?

No information

Fast-track application process for ethical approval

Section 8 of the "Standard Operating Procedures for Research Ethics Committees"

(<http://www.hra.nhs.uk/documents/2013/08/standard-operating-procedures-for-research-ethics-committees-sops.pdf>)

"There is no statutory provision for the expedited review of a

Contact Details of Ethics committees

Health Research Authority

Skipton House

80 London Road

London SE1 6LH

Tel: 020 797 22545

General enquiries: contact.hra@nhs.net

NRES/research queries: HRA.Queries@nhs.net

Website addresses of ethics committees

Health Research Authority

<http://www.hra.nhs.uk/>

Directory of NRES Research Ethics Committees

<http://www.nres.nhs.uk/contacts/nres-committee-directory/>

Website links to ethics application forms

Not available

Website links to meeting time tables

Not available

Ethical approval timeline

(a) In the case of a clinical trial involving a medicinal product for gene therapy or somatic cell therapy or a medicinal product containing a genetically modified organism—

(i) where a specialist group or committee is consulted, 180 days, or

(ii) where there is no such consultation, 90 days; or

(b) in any other case, 60 days;

Section 15.10 of The Medicines for Human Use (Clinical Trials) Regulations 2004

<http://www.legislation.gov.uk/uksi/2004/1031/contents/made>

Ethical approval application Fees

No fees are charged

Special requirements for studies involving children/vulnerable people

Care is needed when seeking consent from children and from vulnerable adults, such as those with mental health problems or learning difficulties. Arrangements must be made to ensure that relevant information is provided in appropriate written or pictorial form, and that the role and responsibilities of parents, carers or supporters are clearly explained and understood. (section 2.2.3 Research Governance Framework for Health and Social Care Second edition, 2005

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf)

Special requirements if studies include collection and use of human tissues

Care is also needed when research involves tissue or organs. The Human Tissue Act 2004 is to come into effect in 2006. Current good practice should ensure that research complies with the Act before it takes effect. For the use of tissue from patients, the consent of the patient is required except in the circumstances specified in the Act, such as when a research ethics committee has agreed to the study and the samples are anonymised. For the use of tissue taken postmortem, the consent of the person concerned before they died, or of the relatives of the deceased, must always be obtained. Agreeing to such research involves relatives in difficult choices. Arrangements must be described for the respectful disposal of material once the research is completed, and for the reporting of the findings of the research to relatives, if they wish it. The new Human Tissue Authority is responsible for regulating and giving guidance on the storage and use of human tissue and organs. (section 2.2.4 Research Governance Framework for Health and Social Care Second edition, 2005

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf)

The Human Tissue Act 2004 is available (<http://www.legislation.gov.uk/ukpga/2004/30/contents>)

Helpful notes for obtaining ethical approvals

No information

Investigational Medicinal Products (IMP) Requirements

Agency responsible for approving IMP studies

Clinical trials of investigational medicinal products (CTIMPs) conducted in the UK requires both clinical trial authorisation (CTA) from the Medicines and Healthcare products Regulatory Agency (MHRA) and a favourable opinion from an ethics committee.

Application process for IMP

Information about applying to conduct a clinical trial is available here.

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Applyingforaclinicaltrialauthorisation/index.htm>

Timeline for IMP trial approval

The initial assessment will be performed within 30 days. For the purposes of this calculation, the day of receipt of the valid application by the Clinical Trials Unit is day 0. Applications for Healthy Volunteer Trials and sponsor-determined Phase I trials in non-oncology patients will be assessed and processed within 30 days, with an average of 14 days or less. Applicants are advised to state in the Covering Letter that the submission is for a Phase I trial eligible for the shortened assessment time, when applicable.

Fees for IMP approval

Fees for Applications with an IMP Dossier is £3,400.

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Applyingforaclinicaltrialauthorisation/Howmuchdoesitcost/index.htm>

Pre-approval of protocols

Same procedures followed but these are expedited.

IMP: Fast-track approval available?

Yes

IMP: Pre-approval available?

Yes

Biological samples

Registration and bio-banking requirements

Not available

Regulations around transport and sample sharing

A Material Transfer Agreement (MTA) should be in place to ensure that human tissue to be exported from England, Wales and Northern Ireland is used in accordance with the consent that has been obtained.

a. HTA Code of Practice 1: Consent, September 2009:

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm>

b. HTA Code of Practice 9: Research, September 2009:

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm>

c. MHRA Recommendations on the control and monitoring of storage and transportation temperatures of medicinal products:

<http://www.mhra.gov.uk/home/groups/commsic/documents/publication/con007569.pdf>

d. World Health Organization (WHO) guidance on regulations for the Transport of Infectious Substances 2011-2012:

http://www.who.int/ihr/publications/who_hse_ihr_20100801/en/

Data protection

Data protection regulations

The Data Protection Act 1998 will apply whenever research is conducted using data from lining identifiable individuals.

Further information: <http://www.hra.nhs.uk/resources/data-legislation-and-information-governance/>

Presence of PREPARE networks

PREPARE Networks present in the country

GRACE, COMBACTE, Paediatric

Contact details of ECRIN representative

a. PRIMARY CARE: Cardiff University (GRACE, TRACE); Southampton Universities (GRACE, TRACE); Imperial College, University of Oxford (TRACE)

b. HOSPITAL CARE: Brighton Collaboration Foundation (PENTA-ID); North Bristol National Health Service Trust (COMB

Contact details of National Network leads

a. PRIMARY CARE: Cardiff University (GRACE, TRACE); Southampton Universities (GRACE, TRACE); Imperial College, University of Oxford (TRACE)

b. HOSPITAL CARE: Brighton Collaboration Foundation (PENTA-ID); North Bristol National Health Service Trust (COMB

Potential risk

Potential risk of implanting WP 3.4.5 in this country

To be updated

APPENDIX 2

Survey cover letter to network leads

07 April 2014

Dear (add in relevant national co-ordinator),

I am writing to you as PI for WP1 EARL ('Ethical, Administrative, Regulatory and Logistical' solutions) which is part of PREPARE ('Platform for European Preparedness against (Re) emerging Epidemics' an EU-funded project. (PREPARE, <http://www.prepare-europe.eu/>.)

EARL aims to identify barriers to setting up and conducting research during a pandemic/epidemic and includes consideration of any social and cultural values. Our first goal is to do this via a report to the other Work Package co-ordinators and due at the end of May 2014 to better inform them of current practices and problems arising in different countries when conducting clinical trials in Europe. As part of this exercise we are conducting primary and secondary research. The primary research data will be collected via qualitative interviews and via a survey. The timeline is short and we wish to involve people with relevant experience at this early stage of the project to tap into their experience.

We have written to your Network Lead and asked them to contact their national co-ordinators in relation to this. We would, therefore, greatly appreciate your co-operation and assistance in completing this online survey in a timely manner.

Survey link:

www.juliuscenter.com/evaluatie/en-gb/startup?projecthost=evaluation&key=36EA73AD-7A9C-4b69-89D2-755F2FB87C61&id=auto&surveytype=prepare_wp1

The survey takes approximately twenty to twenty five minutes to complete.

Many thanks in anticipation of your very valuable help with this, which is much appreciated and it will be immensely useful to our member networks.

With best regards,

Prof. Alistair Nichol

07 April 2014

Dear (add in relevant network lead),

I am writing to you as PI for WP1 EARL ('Ethical, Administrative, Regulatory and Logistical' solutions) which is part of PREPARE ('Platform for European Preparedness against (Re) emerging Epidemics' an EU-funded project. (PREPARE, <http://www.prepare-europe.eu/>.)

EARL aims to identify barriers to setting up and conducting research during a pandemic/epidemic and includes consideration of any social and cultural values. Our first goal is to do this via a report to the other Work Package co-ordinators and due at the end of May 2014 to better inform them of current practices and problems arising in different countries when conducting clinical trials in Europe. As part of this exercise we are conducting primary and secondary research. The primary research data will be collected via qualitative interviews and via a survey. The timeline is short and we wish to involve people with relevant experience at this early stage of the project to tap into their experience.

After some thought, the agreed most efficient way to do this is online via the PREPARE platform when we are asking relevant network leaders to contact their national co-ordinators as appropriate.

We would, therefore, greatly appreciate your co-operation and assistance in distributing this online survey to your national co-ordinators requesting that they complete the online survey in a timely manner.

Survey link:

www.juliuscenter.com/evaluatie/en-gb/startup?projecthost=evaluation&key=36EA73AD-7A9C-4b69-89D2-755F2FB87C61&id=auto&surveytype=prepare_wp1

The survey takes approximately twenty to twenty five minutes to complete. In order to better facilitate your contact with the national coordinators please find a pre-pared letter of explanation and a direct link to the online survey.

Many thanks in anticipation of your valuable help with this which is much appreciate by the team and will be immensely useful.

With best regards,

Prof. Alistair Nichol

APPENDIX 3

Survey questionnaire

WELCOME

We are delighted and grateful to you for considering giving up some of your valuable time to this important research project. This questionnaire is part of an EU-funded project called 'Platform for European Preparedness Against (Re)emerging Epidemics' (PREPARE, <http://www.prepare-europe.eu/>).

Your Network is involved in this project.

Further information about the project can be found at <http://www.prepare-europe.eu/>

The aim of PREPARE work package 1 (WP1 EARL) is to identify the Ethical, Administrative, Regulatory and Logistical (EARL) barriers to setting up and conducting research during a pandemic / epidemic, and how to negotiate these. The purpose of this survey is to gather some practical information about EARL requirements of setting up and conducting a pandemic/epidemic research projects across Europe.

WP1 EARL is being led by Prof. Alistair Nichol from the University College Dublin.

The EARL study manager is Dr. Jill Turner who can be contacted if you have any queries.

Email: jill.turner@ucd.ie

Click "Next" to continue

CONSENT TO PARTICIPATE

Participation in the survey typically takes approximately 30 minutes. The survey will ask about your knowledge of conducting research in your country. Your answers will help researchers to conduct future epidemic/pandemic in your country.

The survey has four sections:

1. Your demographics
2. Ethical requirements
3. Administrative / regulatory requirements
4. Other research governance, logistical requirements /information.

Any information you provide within this survey will be anonymised in any reports or publications resulting from this survey. You do not have to give your name unless you agree to be contacted by us for further information should we need this. If you agree to be contacted you will be invited to provide a contact e-mail address.

You must complete the survey in one session, if you log out without completing and finalizing it, it will be empty when you log in again and you will have to start all over.

If you have further questions about this study or your rights, or if you wish to lodge a complaint or concern, please contact the EARL manager via email: Email: jill.turner@ucd.ie

IF YOU FREELY CONSENT to participate in the study, click the "I accept" bullit and click "NEXT" to begin the survey.

IN CASE YOU DO NOT FREELY CONSENT to participate in the study, click the "I do not accept" bullit and click "NEXT" to skip the survey and close.

I accept

I do not accept

Section 1: DEMOGRAPHICS

1. Please state the country in which you have experience of research and for which you are completing this survey.

2. What is the organisation in which you do most of your work?

3. Can we contact you if we have any questions?

Yes No

3a. Please provide your name and contact details

.....

4. Do you have knowledge of the ethical and regulatory requirements for conducting research in your country?

Yes No

6. Please provide the contact details of the body / organisation (website, phone number, email address).

.....

7. Is there a fee for applying for ethics approval?

- Yes
- No
- Don't know

7a. How much is the fee approximate for applying for ethics approval?

.....

Section 2: ETHICAL REQUIREMENTS

8. Please briefly describe the process for obtaining ethical permissions (online form / paper form / opportunity to respond to comments or questions / attendance at meeting).

.....

9. How long does it normally take to obtain ethical approval for a clinical trial involving an investigational medical product (e.g. medicine or medical device)?

- Less than 1 month
- 1 - 2 months
- 2 - 3 months
- 3 - 4 months
- 4 months or over; how long?
- Don't know

10. Is the procedure for obtaining ethical approval the same for observational / qualitative studies

(which involve the recruitment of patients)?

- Yes
- No
- Don't know

10a. What are the differences?

.....
11. Are there additional / different approval processes for use with children or vulnerable participants (e.g. those lacking capacity to consent) are included in a clinical trial or observational research study?

- Yes
- No
- Don't know

11a. Please describe additional / different approval processes of children or vulnerable participants:

.....

12. Are there additional / different approval processes if collection of human tissue such as blood samples or nasal swabs are included in a study?

- Yes
- No
- Don't know

12a. Please describe additional / different approval processes if collection of human tissue:

.....

13. Are you aware of any factors (such as study design factors) that are likely to make obtaining ethical approval more difficult / challenging in your country?

- Yes
- No
- Don't know

13a. Please describe factors that are likely to make obtaining ethical approval more difficult / challenging:

.....

14. Is there a process for obtaining fast-track ethical approval in a pandemic / epidemic situation in your country?

- Yes
- No
- Don't know

14a. Please describe process for obtaining fast-track ethical approval:

.....

15. Does your ethics committee allow 'pre-approval' of study protocols that can then be implemented more quickly in the event of an epidemic/pandemic?

- Yes
- No
- Don't know

16. Does your ethics committee allow waived consent in the event of an epidemic/pandemic?

- Yes
- No
- Don't know

17. What are the essential documents that are required in order to obtain ethical approval in your country (e.g. patient information, consent form, protocol, sponsorship confirmation).

Select all that apply

- Patient information
- Consent form
- Protocol
- Sponsorship confirmation
- Other (please explain below)

17a. Please describe "other" essential documents:

.....

18. Are there additional factors which create delays in obtaining ethical approval in your country?

- Yes

- No
- Don't know

18a. Please describe additional factors which create delays:

.....

19. Is there anything else that you can tell us about obtaining ethical permissions in your country, that you think will be of use / interest?

.....

20. What is the name of the body / organisation that is responsible for regulating clinical trials of investigational medicinal products (CTIMPs) in your country?

.....

21. Please provide contact details for the body / organisation (website, phone number, email address).

.....

22. Briefly describe the process for obtaining permission (if required) from your medicines regulator to conduct a CTIMP.

.....

23. Is there a fee?

- Yes
- No
- Don't know

23a. How much is the approximate fee?

.....

24. How long does it normally take to obtain approval from your medicines regulator?

- Less than 1 month
- 1 - 2 months

- 2 - 3 months
- 4 months or over; how long?
- Don't know

25. What study design factors make obtaining approval from medicines regulators more difficult?

(For example, in randomised double blind studies.)

.....

26. In your country's medicines agency, is there a process for obtaining fast-track approval in a pandemic/epidemic situation?

- Yes
- No
- Don't know

26a. Please describe it and type the main contact for obtaining fast-track approval.

.....

27. Does your medicines regulator allow 'pre-approval' of protocols that can then be implemented in the event of a pandemic or epidemic?

- Yes
- No
- Don't know

Section 4: OTHER RESEARCH GOVERNANCE, LOGISTICAL REQUIREMENTS /INFORMATION

28. Are there any other organisations who need to provide approval for research in your country? (e.g. national health service, insurance companies, regional, local, hospital)?

- Yes
- No
- Don't know

28a. Please provide details:

Name(s) of organisation(s):

Details of process

Timelines

Please provide details of other organisations if relevant.

29. What are the legal or sponsorship (insurance) requirements for conducting a trial in your country?

.....

30. Are you aware of any problems with the time frame regarding contracts between the research sponsor and institutions, for example, hospitals?

Yes No

31. Have you had experience of setting up or conducting a study during a pandemic/epidemic?

Yes No

32. Have you had experience of setting up or conducting a study involving more than one European country?

Yes No

33. Please rank the factors below with 1 being the most challenging, and 11 being the least challenging to rapidly setting up a study during a pandemic/ epidemic:

Challenge factors

Priority Index

Clinical staff too busy

Consent

Contracting

Recruiting research sites

Supply of Investigational Medicinal Product /Placebo

Timely identification of participants

Training sites

Participant recruitment

- Storage of samples
- Sponsor's research services department if required to approve the protocol prior to ethics submission

Transport of samples

Other challenging factor(s)? (please specify):

Yes

34. Other than getting protocols pre-approved by ethics and / or other regulatory bodies, can you think of any steps that would help to allow for the rapid set-up of research studies during a pandemic/epidemic in your country?

.....

35. In your opinion is public reaction to an epidemic/pandemic likely to be an important consideration when progressing clinical trials?

- Yes
- No
- Don't know

35a. Please describe influence of public reaction

.....

35b. Do you have any suggestions that might improve public willingness to participate in research during an epidemic / pandemic?

.....

36. Are you aware of any social factors, such as religious, ethnic, economic or other cultural issues which may impact on the participant's willingness to offer consent during an epidemic/pandemic?

- Yes
- No
- Don't know

36a. Please describe social, economic or cultural issues

37. Is there any other information that you feel would be of help?

.....

38. Is there anyone else who you think we should also contact for information?

.....

38a. Please provide contact details (name and e-mail) if you feel this is appropriate, or forward them the survey link.

.....

Thank you for completing the survey and assisting the PREPARE project!
Please click "FINALIZE"

APPENDIX 4

Participant Information Sheet for Telephone Interviews

Platform for European Preparedness Against Re-Emerging Epidemics (PREPARE) Ethical, Administrative, Regulatory and Logistical issues (EARL)

Why is the research needed?

EARL aims to identify barriers to setting up and conducting research during a pandemic/epidemic and includes consideration of any social and cultural values. Our first goal is to do this via a report to the other Work Package co-ordinators and due at the end of May 2014 to better inform them of current practices and problems arising in different countries when conducting clinical trials in Europe. As part of this exercise we are conducting primary and secondary research. The primary research data will be collected via qualitative interviews and via a survey. The timeline is short and we wish to involve people with relevant experience at this early stage of the project to tap into your experience.

Who is undertaking the research?

EARL Work Package 1 is part of the PREPARE project funded by the EC Seventh Framework Programme. We are based in UCD Dublin and Cardiff University. The project began in February 2014.

About the fieldwork. A small number of face to face interviews have been completed and the survey is currently underway. We now wish to undertake a small number of telephone interviews. This will enable us to gather more supplementary information and to add rigour to our analysis.

Why have I been approached to take part?

Your name was suggested to us by a colleague who supports our research aims as someone with relevant experience to ensure that our data represents an accurate understanding of the main issues arising.

What will I be asked to do if I take part?

You will be asked to consent to a telephone interview y approximately 30 to 35 minutes. A date will be set at your convenience in the very near future. The

interview will ask a range of questions about your experiences in relation to clinical trials in your area of expertise.

Do I have to take part?

Participation is completely voluntary and there is no pressure on you to take part. You are welcome to change your mind at any time before the interview even if you have already said that you want to take part in this study. You can also change your mind and pull out during the interview at any time.

If you decide that you want to withdraw the information you have provided after the interview then we can do this if you contact us before we have started analysing it. This will be 2-3 weeks after the date of the interview.

Can I be identified by taking part?

The information you provide and any published data will be anonymous. The data collected for this study will be coded and recorded with your name removed. All recordings will be destroyed following transcription and stored securely and only the researchers conducting this study will have access to this data. Interview data will be kept in a locked cabinet or will be stored securely (e.g. on a secure drive on password protected computers).

With your consent, the results of your interview may be archived by University College Dublin for potential use by other researchers in the future but this will only take place if all the features that could identify you, other individuals and/or your local areas can be removed so that the transcript is completely anonymous. Anonymous direct quotations from your interview may be used in the reports or publications from the study but your name will not be attached to them.

What will happen to the research findings?

The results will be analysed and reported to other researchers involved with PREPARE to inform their research work packages and may form part of work to be submitted for publication in an academic or professional journal. If you would like to stay informed about the project please see <http://www.prepare-europe.eu/>

Who has reviewed the project?

This study has been reviewed by the UCD Research Ethics and approved to proceed.

What should I do next?

You will be contacted by a member of the EARL research team, when with your approval, we will arrange a convenient time for the telephone interview to take place. At that time, following an opportunity to ask any questions you may have about the research, you will also be invited to give your consent to taking part by offering verbal consent. Participating in the interview will evidence your continued consent at the time of interview.

Where can I find out more if I need to?

If you have any questions about the study in the first instance please contact:

Dr. Jill Turner email: jill.turner@ucd.ie

Tel: 00353 (1) 716 4646

Making complaints: If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researchers, you can contact the project lead:

Professor Alistair Nichol

Email: alistair.nichol@ucd.ie

APPENDIX 5

Consent Form for Telephone Interviews

Platform for European Preparedness Against Re-Emerging Epidemics
(PREPARE)

Ethical, Administrative, Regulatory and Logistical issues (EARL)

Please read the participant information sheet and tick each box below if you agree. If you have any questions then please contact the researcher.

1. I confirm that I have read the information sheet and fully understand what is expected of me within this study.
2. I confirm that I have had the opportunity to ask any questions and to have them answered.
3. I understand that I am not obliged to take part in this study and that I can withdraw my agreement before or during the interview. I also understand that I can ask for any information I provide during an interview to be withdrawn provided I do this before data analysis begins to be written up (approximately 2-3 weeks after the date of the interview).
4. I understand that the information from my interview will be combined with other participants' responses, anonymised and may be used in reports, conferences and journal publications.
5. I agree for the information that I provide in my interview to be archived by University College Dublin for potential use by other researchers in the future but that this will only take place if all the features that could identify individuals and local areas can be removed.
6. I consent to the research team keeping my contact details so they may, with my consent, contact me again in the future but that this information will not be passed onto anyone else.
7. I consent to take part in the above study.

Name of Participant

Date

Name of Researcher

Date

APPENDIX 6

Aide Memoire: Telephone Interviews

Platform for European Preparedness Against Re-Emerging Epidemics
(PREPARE)

Ethical, Administrative, Regulatory and Logistical issues (EARL)

1: EARL Interviewer preamble

Conducting the ‘conversation’

Suggested Preamble text guide

‘Good day. ‘Thank you for agreeing for me to talk to you today.’

‘This normally takes from around 30 minutes once we get started.’

‘I will be asking you about a number of areas concerned with your experiences of the procedures and barriers in your particular country / countries in relation to applying to conduct clinical trials; what can be done to overcome them and what questions need to be addressed as we progress in WP1.’

I’m interested in your own experience and your opinions of the issues and processes involved’.

‘The information sheet should have covered most of the areas concerned with the interview but do you have any questions?’

‘Have taken you taken a look at the consent form? Are you happy to go ahead? OK let’s begin’.

On tape ‘This is interview ‘X’, on X date, professional status, of e.g.; virologist, clinician Interviewee and name of interviewer.’ (But *not the name of the interviewee as this may/should be de-identified at this stage. An agreed code will be assigned – I suggest*

T-EARL RM1

Or

T-EARL JT2 etc.)

2: General remarks;

We need to cover the EARL areas of ethics, administration, regulation and logistics in broad terms. We also need to use a 3 tiered approach beginning with observational studies up to interventional studies as appropriate to the

participant's own experience. We, therefore, need to allow the participant to select what is relevant for them and their priorities to some extent and to be sensitive to their context both clinically and culturally. The 'talk' should result in the interviewer responding and reflecting upon the participant's area of discussion so the below is only a guide.

We should be asking 'why' questions as well as 'what, when, how and who questions.

Questions might include;

'Could you briefly tell me of your experience in conducting research across European countries?

'Have you any experience of setting up or conducting a research study during an epidemic or pandemic?'

'What are your experiences of applying for ethical approval?'

'How do you seek approval?'

'How do you approach ethics? Why?'

'When do you seek approval? Why?'

'What challenges do you have with multiple country applications? Why?'

'Have any applications been straight forward/difficult? Why?'

When appropriate – 'What is your experience of issues in terms of; Medicinal products; biological samples; data storage; participant consent?'

'What are the timelines?'

'Where are the blockages?'

'What might improve the situation?'

At the end of the 'conversation' we should ask;

'Is there anyone else we should be talking to?'

'If, after considering this session we think it would be useful to follow up for clarification or more information, would you be willing for a member of the WP 1 team to contact you please?'

3: Cultural and Behavioural questions

'We want to understand what it is like in your world when negotiating the systems, what it is really like? How do the regulations and rules of the ideal model translate in reality, pragmatically?'

'What's it really like? *A follow up if the first question doesn't result in success.*

'Who are the key people or key institutions?'

‘Are there any gaps?’

‘Are there any cultural, religious, local belief systems relevant to conducting the research?’

‘If so, how do they impact at the local (micro), (middle) meso and structural (cross cultural and political) levels? *Will need unpacking in context of each interview.*

‘Are language barriers or issues with conducting trials across multi –sites, for example, meanings of structural definitions, and any hidden or unspoken issues?’

‘How important is the role of the public in all this?’

‘If you have any experience of epidemics, are there any lessons we should note? What worked and what didn’t and why?’

‘What role does being known and knowing key people in the system have?’

4: The areas below offer further areas to be explored in the time allowed.

Ethics

Standard *national, regional or institutional* approval?

What is the normal approval process for, **observational studies?** Adults, Children. (Not/competent? Proxy). (Note: Child age issues).

What is the normal approval process for **interventional studies?**

What is the normal approval process for, all of above but **to include bio-samples?**

Are you aware of different approval processes for conducting trials/research during a pandemic or epidemic?

Administration

Who to go to for ethical approval.

Who to go to for ethical approval for medicinal products. (e.g. Irish Medicines Board or equivalent)

Timelines to prepare for ethical submission (plus any other approvals needed) and from submission to all approvals.

Is there a cost involved? If so, how much?

National, regional or individual site Contracts. Timelines.

Are other approvals needed?

Rules and Regulations of the processes.

Local, national, international rules and regulations.

Sharing personal data.

Data protection. Anonymised or Pseudo anonymised data.

Who owns IP?

Data protection course.

Logistical barriers? Especially during a pandemic/epidemic/ also include a question in relation to logistics i.e. Placebo manufacture and distribution.

Transport of research bio-samples across borders, bio-banking, possibilities for conducting research on routinely collected diagnostic samples.

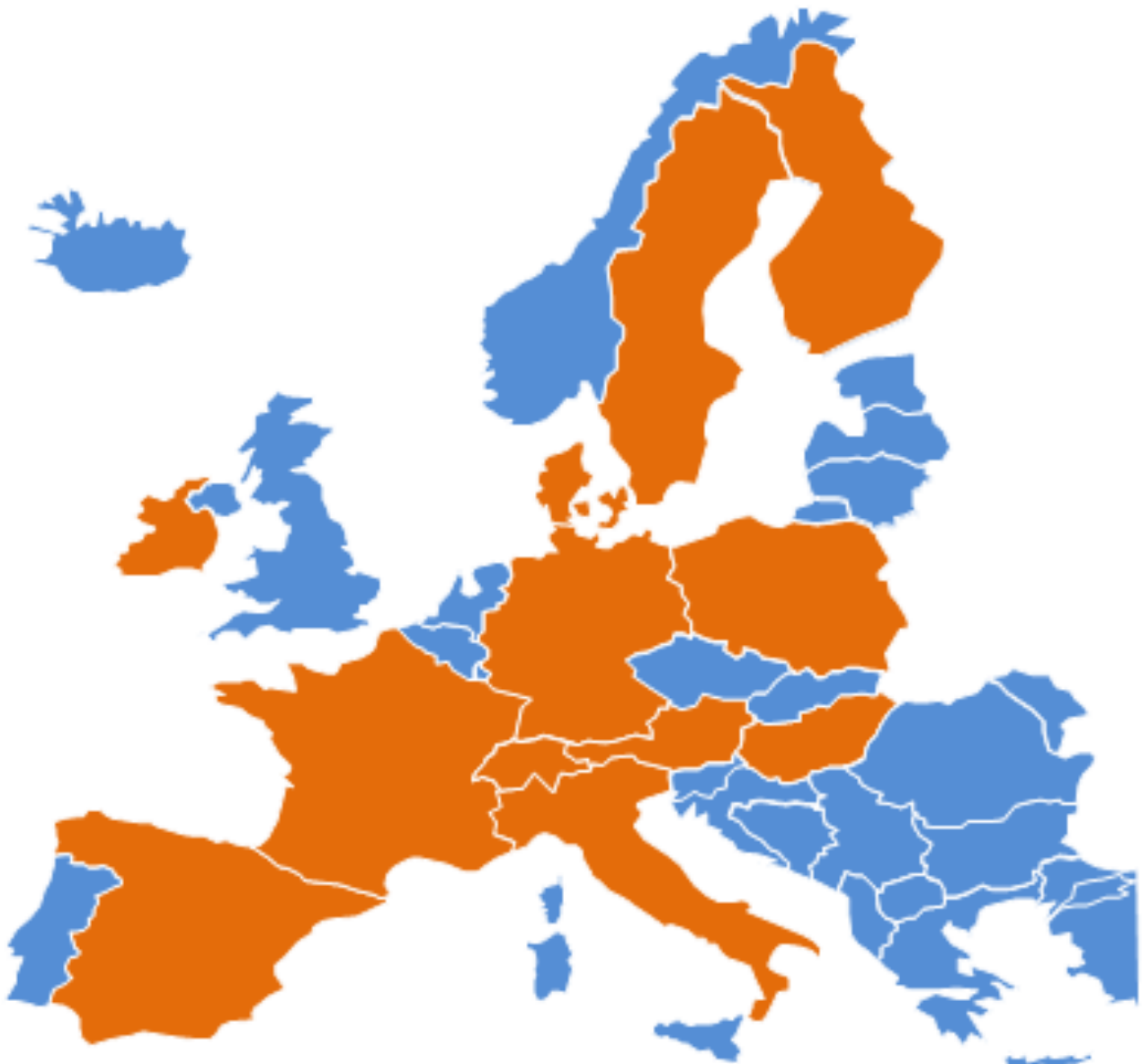
Consent issues and regulations? Are these different for epidemic/pandemic research?

APPENDIX 7 Network Maps

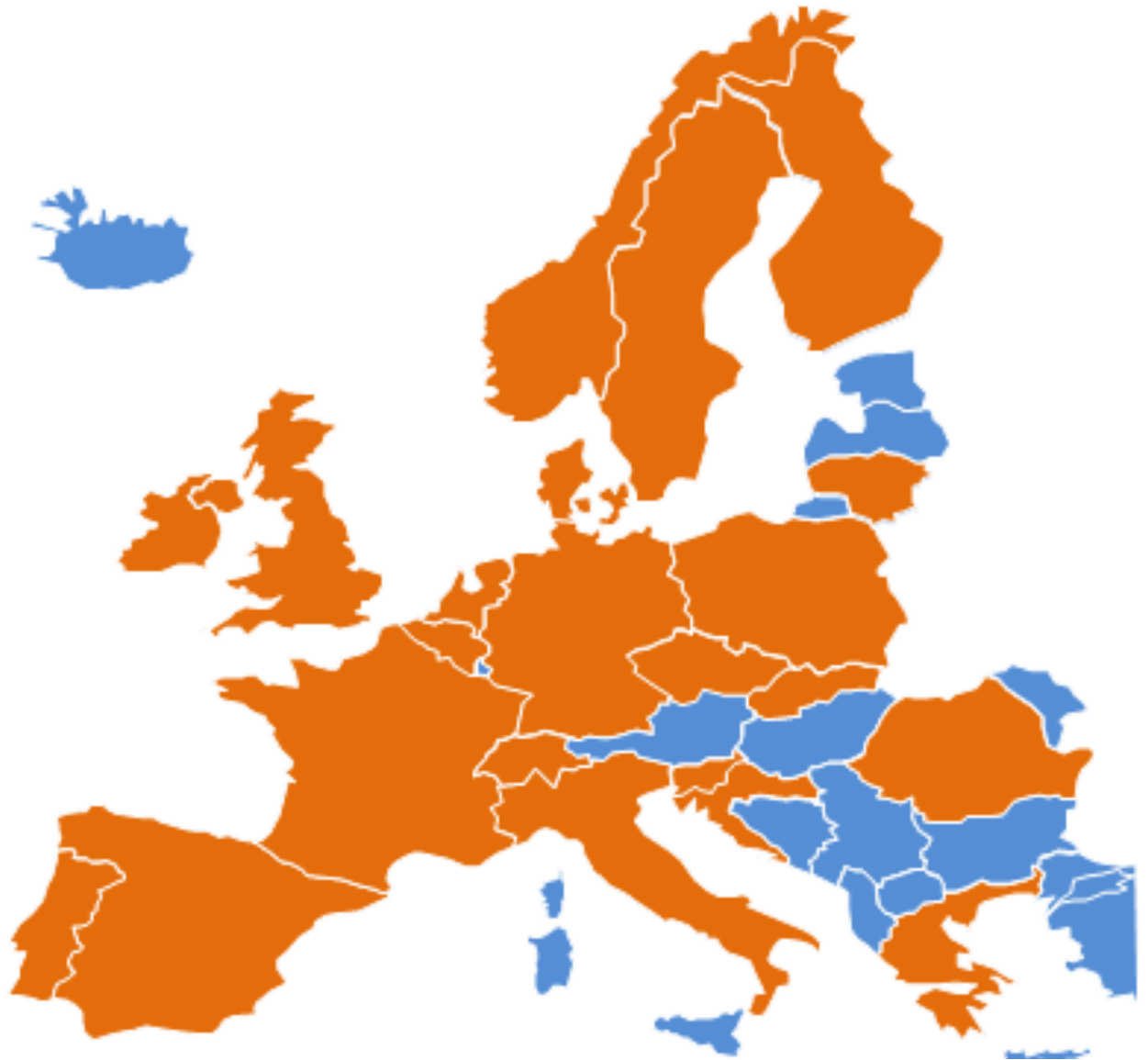
COMBACTE Network



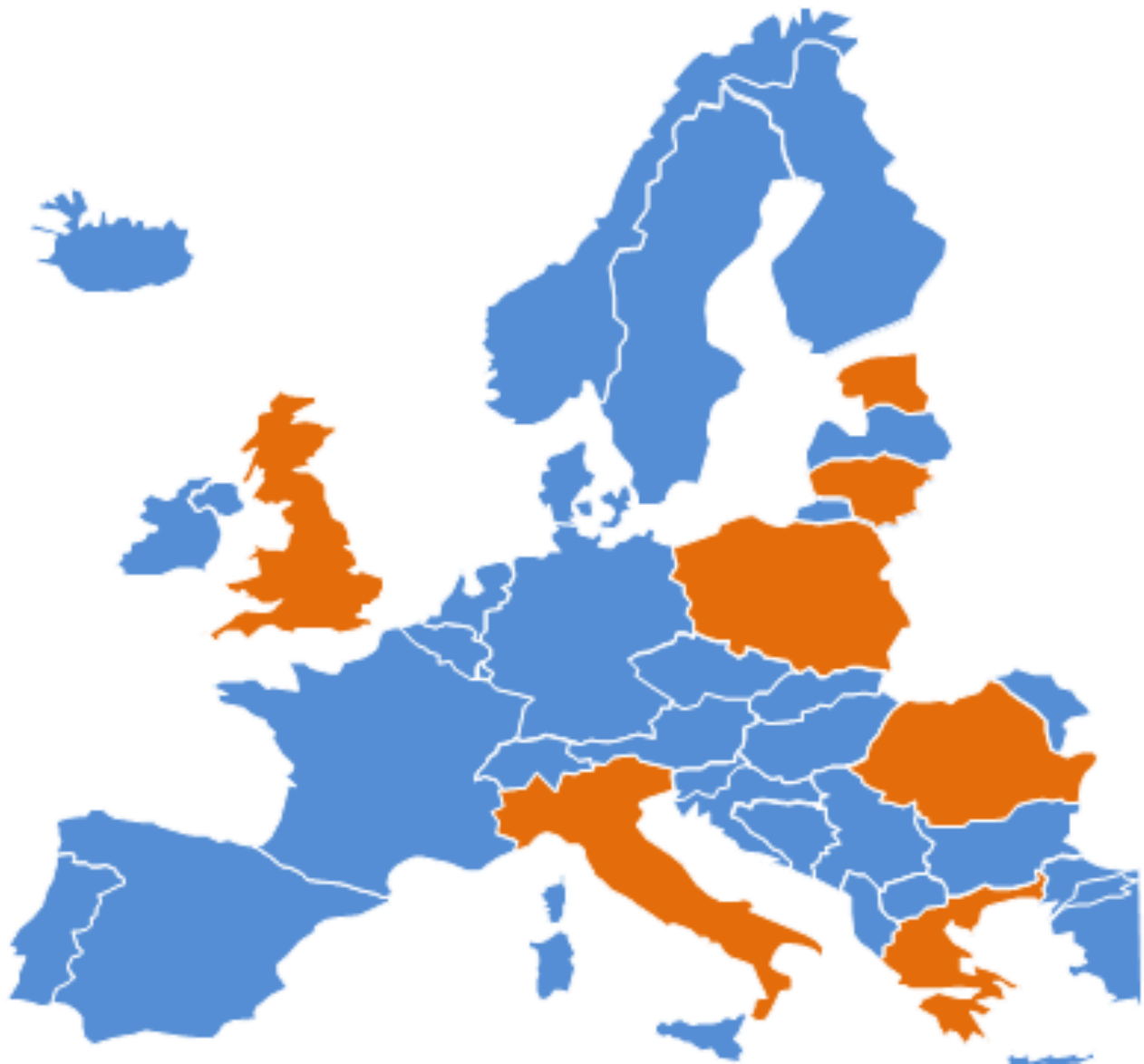
ECRIN Network



GRACE Network



PENTA-ID Network



SERGAS Network

