Medical Devices - POLAND

**Competent authority**

<table>
<thead>
<tr>
<th>Contact Details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contact Name 1</strong></td>
<td>The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products- URPL („The Office“)</td>
</tr>
<tr>
<td><strong>Phone</strong></td>
<td>+48 22 492 11 00</td>
</tr>
<tr>
<td><strong>Fax</strong></td>
<td>+48 22 492 11 09</td>
</tr>
<tr>
<td><strong>Email Department</strong></td>
<td><a href="mailto:wm@urpl.gov.pl">wm@urpl.gov.pl</a></td>
</tr>
<tr>
<td><strong>Address</strong></td>
<td>Al. Jerozolimskie 181C</td>
</tr>
<tr>
<td><strong>ZIP/City</strong></td>
<td>02-222 Warszawa</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>Poland (PL)</td>
</tr>
<tr>
<td><strong>Web address</strong></td>
<td><a href="http://www.urpl.gov.pl">http://www.urpl.gov.pl</a></td>
</tr>
<tr>
<td><strong>Additional Information</strong></td>
<td>Medical Devices vigilance, surveillance and clinical trials Department</td>
</tr>
<tr>
<td></td>
<td>Fax +48 22 492 11 29</td>
</tr>
<tr>
<td></td>
<td>Incidents related to Medical Devices: <a href="mailto:incydenty@urpl.gov.pl">incydenty@urpl.gov.pl</a></td>
</tr>
<tr>
<td></td>
<td>Medical Devices AE reporting: <a href="mailto:wm@urpl.gov.pl">wm@urpl.gov.pl</a></td>
</tr>
<tr>
<td></td>
<td>No other local CA.</td>
</tr>
</tbody>
</table>

**Trial Authorisation / Registration / Notification**

**Regulatory and ethics bodies involved in approval process**

Competent Authority/-ies (CA)/ For certain types of MDs
Ethics committee(s)

**CA - Submission for authorisation mandatory for**

- MD CE-marked, use outside label
- MD CE-marked, use outside label + IMP
- MD without label
- MD without label + IMP

**CA - Registration/ notification without approval required for**

-  

**CA - Submission required to**

-  

**CE-marked MD used within label are exempted from any notification obligation to CA**

Yes
<table>
<thead>
<tr>
<th>National trial registry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Register of Clinical Research (CEBK), but not available for the public.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Submission of Application</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Responsible for study submission</strong></td>
</tr>
<tr>
<td>Sponsor</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Entitled to study submission</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Prerequisites for submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive opinion by relevant EC(s)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guidance on submission of application</th>
</tr>
</thead>
<tbody>
<tr>
<td>The application documentation is specified in Art 44(3) Medical Device Act of 2010 (en).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Applicable national legal framework/ Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Art 44 of the Act on Medical Devices of 20 May 2010 (en)/ Dz.U. 2010, No 107, Item 679 (pl)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>NB! A positive opinion of the competent EC is a prerequisite for application to the CA, as this is an integral part of the submission</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Submission Format</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Format option(s)</strong></td>
</tr>
<tr>
<td>Paper hardcopy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preferred format</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Standard application form</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Standard Application Form for submission to the CA and the EC: &quot;Wzór wniosku o wydanie pozwolenia na prowadzenie badania klinicznego&quot;; available on the CA website (in Polish). The application form is also provided in Annex 1 (Załącznik Nr.1) of the Order of the Minister of Health of 15 Nov 2010/ Dz.U. 2010 nr 222 poz. 1453 (pl).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Language of Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Language(s) of application</strong></td>
</tr>
<tr>
<td>Spanish</td>
</tr>
<tr>
<td>English</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preferred language of application</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>English accepted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partly, not for all documents</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Documents mandatory to be in official national language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information material, Documents and Forms intended for study participants and patient information</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Documents mandatory to be in local language of study site</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Documents mandatory to be in language of the study participant</th>
</tr>
</thead>
</table>
**Submission Fees**

**Fees for trial submission mandatory**

Yes

**Fees**

Fees for authorization:
1) Clinical investigation: 5000 PLN (approx. € 1200.-)
   (In general terms described as up to seven minimum remuneration for work for the fee for starting a study according to Art 44 (2.1) Medical Device Act 2010)
2) Amendments: 1500 PLN (approx. € 350.-)
   (In general terms described as up to half of the amount charged for authorization of a clinical investigation according to Art 44 (2.2) Medical Device Act 2010)

Non-commercial trials: No waiver or reduced fee are granted (as opposed to IMP trials - there is no analogy between medicinal products' law and medical device in that matter in Poland)

**Waiver for academic (non-commercial) studies possible**

No

**Official guidance on required fees**

Fees are specified in the Order of the Minister of Health 15 Nov 2010/ Dz.U. 2010 nr 222 poz. 1453

**Applicable national legal framework/ Reference**

Order of the Minister of Health 15 Nov 2010/ Dz.U. 2010 nr 222 poz. 1453
Medical Device Act 2010 (en)/ Dz.U. 2010 nr 107 poz. 679 (pl)

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**Timelines Authorisation**

**General timespan (max nr days)**

60

**Mode of approval (General)**

Tacit (Silent)

**Clock-stop possible if complementary information requested**

Yes

**Timespan counted from**

—

**Applicable national legal framework/ Reference**

Art 45 & 46 Medical Device Act 2010 (en) / Dz.U. 2010 nr 107 poz. 679 (pl)

---

**Amendments/ Substantial Amendments (SA)**

**Notification mandatory for**

—

**Authorisation mandatory for**

All clinical investigations requiring authorisation by CA

**Responsible for submission of SA**

Sponsor

**Standard notification form available**

Yes
Standard notification form

A Standard Application Form for the Submission of Amendments (Wzór wniosku o wydanie pozwolenia na wprowadzenie zmian w badaniu klinicznym) to the CA and the EC is provided on the CA website.
The application form is also provided in Annex 2 (Załącznik Nr.2) of Health Minister Order 15 Nov 2010.

Timeline for approval of SA (max nr days)

Guidance on submission of SA available

Yes

Guidance on submission of SA

The application documentation for submission of amendments is specified in Art 44(3) Medical Device Act 2010 (en)/ Dz.U. 2010 nr 107 poz. 679 (pl).

Applicable national legal framework/ Reference

Art 44 Medical Device Act 2010 (en)/ Dz.U. 2010 nr 107 poz. 679 (pl)
Annex 2 (Załącznik Nr.2) of Health Minister Order 15 Nov 2010

Additional Information

NB! A positive opinion of the competent EC is a prerequisite for application to the CA.

Safety Reporting

Responsible for AE reporting to CA

Sponsor must declare reportable events to

National CA
Relevant EC(s)

Reportable AEs

SAE (Serious Adverse Event)
SADE (Serious Adverse Device Effect)
Any events with the potential to influence safety of a subject

SUSAR being life-thereatening or leading to death must be reported

All other SUSARs

SAE /SADE must be reported

Within a max of 7d from the day when the event occurred

National standard reporting form available

Yes

Standard Reporting Form

"Form for medical incident notification"/ "Formularz zgłoszenia incydentu medycznego" (in en/pl).
Form available on the URPL website.

Reporting format - Options

Preferred format
Provision of Annual safety report mandatory
Yes

Annual safety report shall be provided by sponsor to National CA

Applicable national legal framework/ Reference
Art 51 Medical Device Act 2010 (en) / Dz.U. 2010 nr 107 poz. 679 (pl)

Additional Information
An annual safety report shall be submitted to the CA clinical investigations on MD (interventional and observational) and registries (MD CE-marked used within label are exempted from this obligation).

Investigator shall report SAE to
—

Reporting timeline
—

End of trial declaration mandatory for
All clinical investigations requiring authorisation by CA

Responsible for End of trial declaration
Sponsor

Regular Termination - Declaration timespan (max nr days)
90

Timespan counted from
—

Early/premature Termination - Declaration timespan (max nr days)
15

Reasons for early termination shall be clearly stated
Yes

Applicable national legal framework/ Reference
Art 54 Medical Device Act 2010 (en)/ Health Minister Order 15 Nov 2010 (related details on the final report)

Additional Information
In case of a multinational investigation, the relevant bodies of the Member States shall be notified of completing the clinical investigation. Premature termination: The sponsor shall also notify the relevant bodies of the Member State and the European Commission if the investigation has been early terminated due to safety considerations.
**Additional Information**

Summary of the description of the URPL Office related to medical devices:

President of the Office is a government administrative authority, competent for matters concerning marketing and use of medical devices – within the meaning and on the basis of the Act on Medical Devices of 20 May 2010 (O.J. No 107, item 679) and clinical trials within the scope determined by the Medical Devices Act of 20 May 2010.

The Office is a public administration body supporting the President of the Office in realization of the above matters.

The rules and the scope of responsibilities is determined by the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

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**Ethics committee**

<table>
<thead>
<tr>
<th>Contact Details</th>
<th>Contact Name 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local independent Research Ethics Committees (in Poland named „Bioethics Committees”)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact Name 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 local RECs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Web address</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.oil.org.pl/xml/oil/oil68/tematy/komisje/stale/bioetyki/komisje">http://www.oil.org.pl/xml/oil/oil68/tematy/komisje/stale/bioetyki/komisje</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local RECs are established at academic institutions (e.g. medical universities), non-university medical research centres and health institutes or at the Regional Chambers of Physicians and Dentists. List of ECs is provided on the website of the Regional Chamber of Physicians and Dentists in Warsaw (Okręgowa Izba Lekarska).</td>
</tr>
</tbody>
</table>

No central Ethics Committee.

<table>
<thead>
<tr>
<th>Ethical Review - General</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission for Ethical review mandatory for</td>
</tr>
<tr>
<td>All clinical investigations of MD</td>
</tr>
</tbody>
</table>

| Submission to CA and EC to be performed in the following order |
| Not specified |

| Regulatory and ethics bodies involved in approval process |
| — |

| Ethical approval (favourable opinion) to be obtained from |
| Local EC |

<table>
<thead>
<tr>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>The competent local Research Ethics Committee (“Bioethics Committee”) issues its reasonable opinion on the application of the clinical investigation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Multi-Centre Studies - Ethical Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethical approval (favourable opinion) required from</td>
</tr>
<tr>
<td>Lead EC + All concerned local ECs for site-specific assessment</td>
</tr>
</tbody>
</table>

| Submission of application required to |
| Lead EC (authorised to issue a single opinion) |
### Additional Information

The sponsor shall appoint a coordinator of clinical investigation from among all the clinical investigators involved in a multi-centre clinical investigation (Art 42 Medical Device Act 2010).

The sponsor or the designated coordinator shall submit the application to the EC ("Bioethics Committee") where the coordinating investigator has his/her registered office. This EC, acting as “lead” EC, shall inform all other ECs of the involved trial sites on the envisaged participation. They have 14 days to perform a site-specific assessment and submit reservations concerning the participation of the investigator or site in the clinical investigation. The designated “lead” EC is authorized to issue a binding “single opinion” on the clinical investigation on behalf of the other involved ECs. (Art 49 Medical Device Act 2010)

### Submission of Application

<table>
<thead>
<tr>
<th>Responsible for study submission</th>
<th>Sponsor</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Entitled to study submission</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Prerequisites for submission / approval</th>
</tr>
</thead>
</table>

Positive opinion by relevant EC(s)

### Applicable national legal framework/ Reference

Art 49 Medical Device Act 2010 (en) / Dz.U. 2010 nr 107 poz. 679 (pl)

### Additional Information

The sponsor shall submit the request for approval of the clinical investigation to the local REC of the trial site. In case of a multi-centre investigation it shall be submitted to the EC where the coordinating clinical investigator has its registered office.

### Submission Format

<table>
<thead>
<tr>
<th>Format option(s)</th>
</tr>
</thead>
</table>

Paper hardcopy

<table>
<thead>
<tr>
<th>Preferred format</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Standard application form available</th>
</tr>
</thead>
</table>

Yes

<table>
<thead>
<tr>
<th>Standard application form</th>
</tr>
</thead>
</table>

Form for submission of the clinical investigation to the CA and the EC (Wzór wniosku o wydanie pozwolenia na prowadzenie badania klinicznego) is available on the CA website (in Polish). The application form is also provided in Annex 1 (Załącznik Nr.1) of Health Minister Order 15 Nov 2010.

### Guidance on submission format

The application documentation is specified in Art 44(3) (1-10) Medical Device Act 2010 (en)/ Dz.U. 2010 nr 107 poz. 679 (pl).

### Applicable national legal framework/ Reference

Art 44(3) (1-10) Medical Device Act 2010 (en)/ Dz.U. 2010 nr 107 poz. 679 (pl)
Annex 1 (Załącznik Nr.1) of Health Minister Order 15 Nov 2010

### Language of Submission

<table>
<thead>
<tr>
<th>Language(s) of application</th>
</tr>
</thead>
</table>

Polish

English
Preferred language of application

- English accepted
  Partly, not for all documents

Documents mandatory to be in official national language

Information material, Documents and Forms intended for study participants and patient information

Documents mandatory to be in local language of study site

Documents mandatory to be in language of study participant

Submission Fees

Fees for Ethical review mandatory

Yes

Fees for Ethical review

Depending on EC concerned: each regional Ethics Committee has its own payment criteria; eg Bioethics Commission Jagiellonian University:
Single center trial 1500 Euro
Multi-centre trial: 1500 Euro + 250 Euros for each subsequent examination center

Timelines Ethical Review

General timespan for single-centre studies (max nr days)

60

General timespan for multi-centre studies (max nr days)

60

External expert advice required: Timespan (max nr days)

Clock-stop possible if complementary information requested

Yes

Timespan counted from

Date of submission of valid application

Amendments/ Substantial Amendments (SA)

Ethical review mandatory for

Any substantial amendments

Responsible for notification of SA

Sponsor

Standard notification form available

Yes

Standard notification form

Standard Form for Submission of Amendments ("Wzór wniosku o wydanie pozwolenia na wprowadzenie zmian w badaniu klinicznym") to CA and EC is provided on the URPL website.
The application form is also provided in Annex 2 (Załącznik Nr.2) of Health Minister Order 15 Nov 2010.

Timeline Ethical review of SA (max nr days)

60
Safety Reporting

Additional Information

NB! A positive opinion of the competent EC is a prerequisite for application to the CA.

Adverse Events (AE) - Definitions (pursuant to national law)

Definition of SAE according to Art 2 (9) Medical Device Act 2010 (en)/ Dz.U. 2010 nr 107 poz. 679 (pl):
A medical event due to which a subject
a) Died
b) Suffered serious deterioration of health (suffered a life-threatening disease or trauma, suffered permanent disability of bodily structure or function, required hospitalisation or extension of hospitalisation, required medical intervention to prevent permanent disability of bodily structure) or function
c) Suffered the death of foetus, threat to the life of the foetus, a congenital defect of labour-related damage.

Reportable AEs

SAE (Serious Adverse Event)
SADE (Serious Adverse Device Effect)
Any events with the potential to influence safety of a subject

Investigator shall report SAE to
Sponsor

Reporting timeline
Immediately (without delay)

Responsible for AE reporting to relevant EC(s)
Sponsor

SUSAR being life-threatening or leading to death must be reported
—
All other SUSAR must be reported
—
SAE/SADE must be reported
Immediately (without delay)
Within a max of 7d from the day when the event occurred

National Standard Reporting form available
Yes

Standard Reporting Form
"Form for medical incident notification"/ "Formularz zgłoszenia incydentu medycznego" (in en/pl).
Available on URPL website in section: Wyroby Medyczne » Nadzór Rynku » Formularze.

Reporting format - Options
—

Preferred reporting format
—

Applicable national legal framework/ Reference
Art 51 Medical Device Act 2010 (en) / Dz.U. 2010 nr 107 poz. 679 (pl)
End of Trial

End of trial Declaration mandatory
Yes

Responsible for End of trial Declaration
—

Regular Termination - Declaration timespan (max nr days)
Not specified

Timespan counted from
—

Early/premature Termination - Declaration timespan (max nr days)
15

Reasons for early termination shall be clearly stated
Yes

Applicable national legal framework/ Reference
Art 54 (2) Medical Device Act 2010 (en)/ Dz.U. 2010 nr 107 poz. 679 (pl)

Additional Information
Premature termination of the clinical investigation: The sponsor shall also notify the relevant bodies of the Member State and the European Commission if the investigation has been early terminated due to safety considerations.

Study specific Requirements

Sponsor

Sponsor - Definition available in national law
Yes

Sponsor - Definition (pursuant to national law)
Definition of sponsor pursuant to Art 2 (28) Medical Device Act 2010: “Any entity responsible for initiating and conducting a clinical investigation having the place of residence or the registered office in a Member State or acting solely through the agency of its legal representative having the place of residence or the registered office in a Member State”. Definition of Authorised representative: see Art 2 (2) Medical Device Act 2010.

Sponsorship mandatory
Yes

Co-Sponsor - Definition available in national law
No

Co-sponsorship allowed
No

Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:
Yes

Investigator

Entitled to be principal investigator
—
**Additional Information**

The investigator may be a doctor or another person with professional qualifications necessary to perform a clinical investigation of a MD (pursuant to Art 40 Medical Device Act 2010).

In the case of clinical investigation of Active implantable MD, the clinical investigator may only be a doctor.

In terms of qualification, the clinical trials directive and guidelines (Volume 10), ICH E6 apply (qualified by training and experience).

<table>
<thead>
<tr>
<th>Study Participants - Informed Consent (IC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Additional Information</strong></td>
</tr>
<tr>
<td>The investigator may be a doctor or another person with professional qualifications necessary to perform a clinical investigation of a MD (pursuant to Art 40 Medical Device Act 2010). In the case of clinical investigation of Active implantable MD, the clinical investigator may only be a doctor. In terms of qualification, the clinical trials directive and guidelines (Volume 10), ICH E6 apply (qualified by training and experience).</td>
</tr>
</tbody>
</table>

| **Standard IC form (ICF) available**      |
| Not specified                             |

| **IC is regulated by law**                 |
| Yes                                        |

| **Informed Consent - Definition/ Requirements** |
| Prior to the commencement of a clinical investigation with MD, informed consent must be obtained from study subjects according to the provisions specified in the national law. |

| **Applicable national legal framework/ Reference** |
| • Art 40 (4) and 56 Medical Device Act 2010 (en) |
| • Art 37b (2) and Art. 37f Pharmaceutical Law 2001 (en) |
| • Art 25 (1) Physician’s Profession Act 1996 (Dz.U. 1997 nr 28 poz.152) |

<table>
<thead>
<tr>
<th>Study Participants - Vulnerable Population</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minors / Children - Studies allowed</strong></td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Special provisions apply</td>
</tr>
</tbody>
</table>

| **Specific provision**                     |
| Clinical investigations with MD on minors are possible under special provisions. Clinical trials on minors include trials on: preterm newborns, full-term newborns (0-27 days), infants and small children (28 days-23 months), children (24 months-11 years) and teenagers (12-18 years). A specific regulation issued by the Minister of Health covers in detail the provisions for the conduct of clinical trials on minors: Order of the Minister of Health 30 April 2004 (Dz.U. 2004 nr 104 poz. 1108). |

| **Legal framework/Reference (Minors/Children)** |
| Art 40 (10) Medical Device Act 2010 (en)       |
| Order of the Minister of Health 30 April 2004 (Dz.U. 2004 nr 104 poz. 1108) |

| **Incapacitated persons - Studies allowed**   |
| Yes                                        |
| Special provisions apply                  |

| **Legal framework / Reference (Incapacitated persons)** |
| Art 40 (11-13) Medical Device Act 2010 (en) |
| Art 26 (2&3) of Act of 5 December 1996 on the professions of a physician and a dentist |

| **Emergency situations - Studies allowed**    |
| Yes                                        |
| Special provisions apply                  |
Emergency situation without prior consent of patient or proxy - Studies allowed

Legal framework / Reference (Emergency Situation)
Art 40 (11-13) Medical Device Act 2010 (en)

Pregnant or breastfeeding women - Studies allowed
Yes
Special provisions apply

Legal framework / Reference (Pregnant or breastfeeding women)
Art 26(1&2) Physician’s Profession Act 1996 (DzU. 1997 nr 28 poz. 152)
Not explicitly mentioned in Medical Device Act 2010.

Reimbursement for study participants
Depends on study

Compensation is limited to/provided for

Additional Information
No incentives or financial inducements shall be given to study subjects, except compensation for any expenses incurred (pursuant to Art 40 (9) Medical Device Act 2010). Payment may be made to healthy volunteers of age taking part in bioavailability studies, or Phase I studies conducted in Poland.

Notification to DP Authority/ Ombudsmann is mandatory
Yes

Specific notification timelines before operations start

Language of notification

Notification format

Notification fee required
No

Data Protection Authority/ Agency - Contact Details
The Inspector General for Personal Data Protection - GIODO

Phone
+48 22 860 70 86

Fax
+48 22 860 70 86

E-Mail
kancelaria@giodo.gov.pl

Web address
http://www.giodo.gov.pl/
Address
ul. Stawki 2

ZIP/City
00-193 Warszawa

Country
Poland (PL)

Additional Information
Notification of clinical investigations to GIODO is required for all clinical investigations of MD.

The right for the subject to personal data protection shall be safeguarded according to Art 40 (4.3) and 55 Medical Device Act 2010 and the Act on Patients’ Rights and the Spokesman for the Patients’ Rights 6 November 2008 (Dz.U. 2009 nr 52 poz. 417):
Before obtaining consent, the investigator shall inform the participant, that source documents will be available for monitoring purposes, internal and external audits. The sponsor must archive the documentation of a study for 5 years starting from the beginning of the year after the study was completed unless a contract between the sponsor and the investigator defines a different time period (Art. 37ra. par. 1).

Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)

Insurance

Liability insurance or alternative arrangements for damages mandatory for
Investigator(s)
Sponsor
Study participants

Responsible for covering insurance
Sponsor

Insurance fee: A minimum coverage sum is defined
Yes

Minimum coverage sum
The guaranteed insurance sums depend on the number of persons (pers) in the trial: up to 10 pers : 500 000 €/ 11-25 pers: 1 000 000 € / 26-50 pers: 2 000 000 €/ 51-100 pers: 4 000 000 €/ above 100 pers: 5 000 000€

National legal framework in place
Yes

Applicable national legal framework/ Reference
• Order of the Minister of Finance 30 Apr 2004 (Dz.U. 2004 nr 101 poz. 1034) regulating mandatory civil liability insurance of investigators and sponsors
• Order of the Minister of Finance 6 Oct 2010 (Dz.U. 2010 nr 194 poz. 1290) concerning the mandatory civil liability insurance of investigators and sponsors in clinical trials of medicinal products
• Order of the Minister of Health 10 Feb 2012 (Dz.U. 2012 poz. 207) for detailed Conditions for Determining Level of Compensation in Case of Medical Adverse Event

Quality Assurance/ Quality Control (QA/QC)

Monitoring
Compulsory
### Audit by sponsor
Compulsory

### Standard Operating Procedures (SOPs)
Compulsory

### Additional Information
The quality control related to the Good Clinical Practice can be performed by the Clinical Trials Inspectorate according to the Art. 37ae of the Pharmaceutical Law (en).

The President of URPL informs EMA about the results of the control of a clinical trial. The report from the control can be available to EMA, EU or EFTA countries and the local EC, if officially requested.

### Archiving & Data Management

<table>
<thead>
<tr>
<th>Study documents must be kept at least (in years)</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>National legal framework in place</td>
<td>Yes</td>
</tr>
<tr>
<td>Applicable national legal framework/ Reference</td>
<td>Art 55 (4) Medical Device Act 2010</td>
</tr>
</tbody>
</table>

### National legislation

#### General Information: Applicable Legislation & Conventions

**Official website providing relevant national legislation available**
Yes

**Official website providing relevant national legislation**
All relevant and binding legal provisions are available (in Polish) on the URPL website.

**Official governmental legal database available**
Yes

**Official governmental legal database**
ISAP (Internetowy System Aktów Prawnych): Online Database system of legal acts containing bibliographic and legal texts published in official publications (the Journal of Laws and the Polish Monitor) issued by the Prime Minister.

#### Clinical Trials on IMPs in Humans

**Applicable national regulations**
- Transposition of (GCP) Directive 2005/28/EC

#### Investigations on Medical Devices

**Applicable national regulations**
National Act on Medical Devices
Transposition of EU Directives on MD
Other

**Act on Medical Devices (or comparable national legal framework)**
Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)


The acts are specified by several ordinances and regulations issued by the Minister of Health (or Finance). Some of the most relevant regulations published in the Journal of Laws (Dziennik Ustaw, Dz.U):

(1) Medical Devices: Classification, Application, AE reporting
- Order of the Minister of Health 10 March 2011 (Dz. U. 2011, No 63, issue 331) for detailed requirements for clinical evaluations of Medical Devices or Active implantable Medical Devices
- Order of the Minister of Health 15 Nov 2010 (Dz.U. 2010 nr 222 poz. 1453) on clinical trial application, the submission fees for authorization and the final report on the conduct of a clinical trial
- Order of the Minister of Health 2 Feb 2011 (Dz. U. 2011, No 33, issue 167) for Reporting Adverse Events related to Medical Devices and Actions related to Safety of the Devices
- Order of the Minister of Health 5 November 2010. (Dz. U. 2010, No 215, issue 1416) for classification of Medical Devices
- Order of the Minister of Health 18 October 2010 (Dz. U. 2010, No 202, issue 1341) for applications and notifications of Medical Devices

(2) Clinical investigations on Minors
- Order of the Minister of Health 30 April 2004 (Dz.U. 2004 nr 104 poz. 1108) on the conduct of clinical trials in minors

(3) Insurance
- Order of the Minister of Finance 30 Apr 2004 (Dz.U. 2004 nr 101 poz. 1034) regulating mandatory civil liability insurance of investigators and sponsors
- Order of the Minister of Finance 6 Oct 2010 (Dz.U. 2010 nr 194 poz. 1290) concerning the mandatory civil liability insurance of investigators and sponsors in clinical trials of medicinal products
- Order of the Minister of Health 10 Feb 2012 (Dz.U. 2012 poz. 207) for detailed Conditions for Determining Level of Compensation in Case of Medical Adverse Event

Additional Information

Current regulation of clinical investigations with MDs (and IMPs for combined studies) is dispersed among many legal acts, the most important ones are provided here.

Use of radiation or radioactive compounds - Specific requirements

Yes

Applicable legal framework

Special requirement apply for the use of MD emitting radiation, as specified in:
- Regulation of the Minister of Health of 25 August 2005 on the conditions for the safe use of ionizing radiation exposure for all types of medical research
- Act of 29 November 2000 on Nuclear Law

Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)

National Data Protection Act
Other legislation covering DP related issues
### Definition

**MD/MD Investigation**

<table>
<thead>
<tr>
<th>Definition available in national law</th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
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</tbody>
</table>

**MD - Definition**

Definitions and classification of MDs are provided in Art 2 and Art 20-32 (Chapter 4) Medical Device Act 2010 and Order of the Minister of Health 5 November 2010. (Dz. U. 2010, No 215, issue 1416) for classification of Medical Devices.

The definitions used in Poland for investigations on MD are the same as in Directive 2007/47/EC.