Medical Devices - POLAND

Competent authority

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

	National trial registry Central Register of Clinical Research (CEBK), but not available for the public. **Submission to CA and EC to be performed in the following order** –
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission** Positive opinion by relevant EC(s) **Guidance on submission of application** The application documentation is specified in Art 44(3) Medical Device Act of 2010 (en). **Applicable national legal framework/ Reference** Art 44 of the Act on Medical Devices of 20 May 2010 (en)/ Dz.U. 2010, No 107, Item 679 (pl) **Additional Information** 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
Submission Format	**Format option(s)** Paper hardcopy **Preferred format** – **Standard application form** A Standard Application From for submission to the CA and the EC: "Wzór wniosku o wydanie pozwolenia na prowadzenie badania klinicznego"; 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).
Language of Submission	**Language(s) of application** Spanish 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 the study participant** –

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)
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 From 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

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 & Specifics	**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

Ethics committee

Contact Details	**Contact Name 1** Local independent Research Ethics Committees (in Poland named „Bioethics Committees“) **Contact Name 2** 50 local RECs **Web address** http://www.oil.org.pl/xml/oil/oil68/tematy/komisje/stale/bioetyki/komisje **Additional Information** 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). No central Ethics Committee.
Ethical Review – General	**Submission for Ethical review mandatory for** All clinical investigations of MD **Submission to CA and EC to be performed in the following order** Not specified **Regulatory and ethics bodies involved in approval process** –
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Local EC **Additional Information** The competent local Research Ethics Committee (“Bioethics Committee”) issues its reasonable opinion on the application of the clinical investigation.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC + All concerned local ECs for site-specific assessment **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	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission / approval** 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	**Format option(s)** Paper hardcopy **Preferred format** – **Standard application form available** Yes **Standard application form** 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	**Language(s) of application** 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

Additional Information

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

Safety Reporting

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-thereatening 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 » Nadzor 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 guidlines (Volume 10), ICH E6 apply (qualified by training and experience).

Study Participants - Informed Consent (IC)

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)

Additional Information

Special provisions apply to vulnerable populations such as minors, incapacitated adults and subjects in emergency situations (Art 40 (4,10,11,13) Medical Device Act 2010).

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Yes
Special provisions apply

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

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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 (Dz.U. 1997 nr 28 poz. 152)
Not explicitly mentioned in Medical Device Act 2010.

Study Participants - Compensation & Reimbursement

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.

Data Protection

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)

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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

Study documents must be kept at least (in years)

5

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 55 (4) Medical Device Act 2010

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

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Transposition of (GCP) Directive 2005/28/EC

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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)

Act of 20 May on Medical Devices (en) (hereinafter referred to as "Medical Device Act 2010")/ Dz.U. 2010 nr 107 poz. 679 (covering regulations about medical devices and implementing European Directives such as 90/385/EEC, 93/42EEC, 98/79/EC, 2007/47/EC)

Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)

• Act of 5 December 1996 on the professions of a physician and a dentist, hereinafter referred to as „The Physician's Profession Act 1996" (Dz.U. 1997 nr 28 poz. 152) covers medical experiments on humans and basic regulations concerning Bioethics Committees.

• Act of 6 September 2001 Pharmaceutical Law (en), published in Journal of Laws from 2008, No. 45, item 271 (hereinafter referred to as Pharmaceutical Law 2001). It adopts the principles of the clinical trials Directive 2001/20/EC.

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.

Radiation & Radiotherapy

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:
• Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
• 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

Data Protection

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

	National DP act Act on Patients' Rights and the Spokesman for the Patients' Rights 6 November 2008 (Dz.U. 2009 nr 52 poz. 417) Act on Personal Data Protection 1997 (en)
Additional Information & Specifics	**Additional Information** Article 45 (2) of the Physician's Profession Act 1996 (Dz.U. 1997 nr 28 poz. 152) introduces a ban on conducting experiments and research on embryos.

Definition

MD/MD Investigation	**MD - Definition available in national law** Yes **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.