Regulatory and ethical requirements in medical devices studies

Serbia
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
SECTION

A. Type of research
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I. Healthy volunteers/Patients
J. Specific requirements
A. Type of research

We have differentiated 8 types of research:

- Medical device alone with CE mark use within label
- Medical device alone with CE mark use outside label
- Medical device alone without CE mark
- Medical device combined with medicinal product with CE mark use within label
- Medical device combined with medicinal product with CE mark use outside label
- Medical device combined with medicinal product without CE mark
- Observational studies with medical device
- Registries
A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
## B. Definitions/Legal basis

<table>
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<td>J. Specific requirements</td>
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</table>

### Definitions in Serbian law

- The 8 types of research with medical device are define in Serbia.

- The definitions can be found at the following adress:
  
Conventions/guideline/laws to apply

• Declaration of Helsinki
• ICH Guideline of EMA
• European Directive 2001/20/EC
A. Type of research
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J. Specific requirements

 Acts to apply

• Hospital act
• Data protection act
• Genetical engineering act
• Medical device act
• Drug Act
SECTIONS

A. Type of research
B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements
C. Insurance

• For all the type of studies an insurance must be contracted. It has to cover:
  - Patients *(Except for observational studies)*
  - Healthy volunteers
  - Investigators *(Except for observational studies)*

The sum covered by the Insurance depends on the contract

There is no compensation sums per participant and/or per trial covered by the insurance
SECTIONS

A. Type of research
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<table>
<thead>
<tr>
<th><strong>D. Sponsor</strong></th>
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</tbody>
</table>

It is mandatory to have a sponsor or legal representative in Serbia for any of the 8 types of studies.

Co-sponsorship is allowed for all the study types.
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor

E. Investigators

F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
• In Serbia, to participate in a trial investigator are required to have a certificate from the Section for Clinical pharmacology Serbian Medical Society (SCPSMS) accredited by Serbian Medical Chamber for Continuous Medical Education: Good Clinical Practice in clinical investigation

• The Investigator have to be a doctor of medicine or doctor of dentistry and have to be directly involved and responsible for the treatment and care for patients or participants in the trial
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
Serbian Competent Authority:

Medicines and Medical Devices Agency of Serbia
Zorica Vucinic, MD and Aleksandra Vujacic,pharm
458, Vojvode Stepe Street
Belgrade 11221
Republic of Serbia
Tel.: +381 11 3951-158; +381 11 3951-199
Fax +381 11 3951-158
hygia@alims.gov.rs
## F. Competent Authority

<table>
<thead>
<tr>
<th></th>
<th>Approval</th>
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<tbody>
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<tr>
<td><strong>Medical device combined with medicinal product with CE mark use outside label</strong></td>
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<tr>
<td><strong>Medical device combined with medicinal product without CE mark</strong></td>
<td>x</td>
</tr>
<tr>
<td><strong>Observational studies with medical device</strong></td>
<td>x</td>
</tr>
<tr>
<td><strong>Registries</strong></td>
<td>x</td>
</tr>
</tbody>
</table>
F. Competent Authority – Initial submission

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

• When a submission is required, the sponsor, the PI or the academic institution is responsible of it
• The submission to the Serbian Competent Authority is national: you only have to submit one dossier to the national competent authority
• The submission have to be by paper
• English documents are accepted
• A submission fee have to be paid
  • 200 € for phase I to III study
  • 60 € for phase IV study
F. Competent Authority – Initial submission

- In general, it take 60 days after the submission to obtain approval
- No deadlines for submission, you can submit anytime
- You need to have some kind of representative or a legal entity in Serbia to submit an application to the Competent Authority. It can be:
  - CRO
  - Sponsor
  - PI
  - Academia (for ECRIN it is SMS)
### F. Competent Authority – Initial submission

| A. Type of research | Main documents required for submission (1/2):
| B. Definitions/Legal basis |
| C. Insurance |
| D. Sponsor |
| E. Investigators |
| **F. Competent Authority** |
| G. Ethics Committee |
| H. Data Protection |
| I. Healthy volunteers/Patients |
| J. Specific requirements |
| |

- Submission letter
- Clinical Trial application form
- Clinical Investigation Plan/Protocol signed
- Clinical Investigation Plan/Protocol summary
- CRF draft
- Inform consent form and subject information leaflet
- General practitioner information letter
- Copies of advertisement materials for research participants
- Investigator’s brochure or CE certificate
- Instruction for use/Technical manual
- Performance evaluation
<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>Main documents required for submission (2/2):</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td>• Insurance Certificate</td>
</tr>
<tr>
<td>C. Insurance</td>
<td>• Signed and dated CV of investigators</td>
</tr>
<tr>
<td>D. Sponsor</td>
<td>• Investigator agreement</td>
</tr>
<tr>
<td>E. Investigators</td>
<td>• GCP training certificate of investigators</td>
</tr>
<tr>
<td>F. Competent Authority</td>
<td>• Product training of investigators</td>
</tr>
<tr>
<td>G. Ethics Committee</td>
<td>• Qualification certificate of investigators</td>
</tr>
<tr>
<td>H. Data Protection</td>
<td>• Conflict of interest statement from the investigator</td>
</tr>
<tr>
<td>I. Healthy volunteers/Patients</td>
<td>• Financial disclosure</td>
</tr>
<tr>
<td>J. Specific requirements</td>
<td>• Study approval from administration department</td>
</tr>
<tr>
<td></td>
<td>• Agreement between sponsor and CRO specifying responsibilities</td>
</tr>
<tr>
<td></td>
<td>• Proof of payment of submission fees</td>
</tr>
</tbody>
</table>
F. Competent Authority – Initial submission

- Standard application form available on the Serbian Competent authority website:

![Application Form Image]
| A. Type of research | • SAE definition: Serious adverse event is every adverse event having a consequence:  
| B. Definitions/Legal basis |   • Death  
| C. Insurance |   • Life vulnerability  
| D. Sponsor |   • Permanently or serious damage/disability,  
| E. Investigators |   • Hospital treatment or prolonged present hospital treatment  
| F. Competent Authority |   • Congenital anomalies or baby defect detected after birth  
| G. Ethics Committee |   • Other medical significant state  
| H. Data Protection | • SADE (Serious adverse Device Effect) declaration by the sponsor:  
| I. Healthy volunteers/Patients |   - If life in danger: 7 days  
| J. Specific requirements |   - Other case: 15 days  
| | • The sponsor has to declare events to the Competent Authorities in the specific countries  
| | • The sponsor needs to provide to the Competent Authority an annual safety report |
### F. Competent Authority - Vigilance

**Events mandatory to declare to the Competent Authority:**

<table>
<thead>
<tr>
<th>Event Description</th>
<th>AE</th>
<th>ADE</th>
<th>SADE</th>
<th>SAE</th>
</tr>
</thead>
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<td>Medical device alone with CE mark use within label</td>
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<td>x</td>
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<tr>
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<td>x</td>
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<tr>
<td>Observational studies with medical device</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Registries</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

**Abbreviations:**
- **AE:** Adverse Event (Non device related)
- **ADE:** Adverse Device Effect (Device or procedure related)
- **SADE:** Serious adverse Device Effect (Device or procedure related)
- **SAE:** Serious Adverse Event (Non device related)
<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>• The sponsor, PI or Academic institution are responsible for the declaration to the Competent Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td>• Special form for the declaration of AE available at the following address</td>
</tr>
<tr>
<td>D. Sponsor</td>
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<tr>
<td>E. Investigators</td>
<td></td>
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<tr>
<td>F. Competent Authority</td>
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<tr>
<td>H. Data Protection</td>
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<tr>
<td>I. Healthy volunteers/Patients</td>
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<tr>
<td>J. Specific requirements</td>
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<tr>
<td>Section</td>
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<tr>
<td>A. Type of research</td>
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<td>B. Definitions/Legal basis</td>
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<tr>
<td>F. Competent Authority</td>
<td>• No specific requirement to notify the first patient enrolled to the Competent Authority</td>
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<td>H. Data Protection</td>
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<td>J. Specific requirements</td>
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</tbody>
</table>
**F. Competent Authority – Substantial amendment**

- There is a specific procedure for submitting a substantial amendment to the Competent Authority (Submission is done by the Ethic Committee)
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
In Serbia, Each Hospital have an Ethic Committee
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<thead>
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<tr>
<td>Observational studies with medical device</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Registries</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
• When a submission is required, the sponsor, PI or Academic Institution are responsible of it
• The submission to the Ethics Committee is local (submission to the EC of each site involved)
• The submission have to be by paper or electronic format (depending on the EC)
• English documents are accepted
• There is a submission fee (depend on the EC)
| A. Type of research | • In general, 60 days maximum to obtain approval |
| B. Definitions/Legal basis | • No deadlines for submission, you can submit anytime |
| C. Insurance | • When both Competent Authority approval and Ethics Committee positive opinion are required, it is not possible to request the 2 (authorization and approval) in parallel |
| D. Sponsor | • You need to have some kind of representative or a legal entity in Serbia to submit an application to the Competent Authority. It can be: |
| E. Investigators | • CRO |
| F. Competent Authority | • Sponsor |
| G. Ethics Committee | • PI |
| H. Data Protection | • Academia (for ECRIN it is SMS) |
| I. Healthy volunteers/Patients |  |
| J. Specific requirements |  |
Main documents required for submission (1/2):
- Submission letter
- Clinical Trial application form
- Clinical Investigation Plan/Protocol signed
- Clinical Investigation Plan/Protocol summary
- CRF draft
- Inform consent form and subject information leaflet
- General practitioner information letter
- Copies of advertisement materials for research participants
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- Product training of investigators
- Qualification certificate of investigators
- Conflict of interest statement from the investigator
- Financial disclosure
- Study approval from administration department
- Agreement between sponsor and CRO specifying responsibilities
- Proof of payment of submission fees
G. Ethics committee – Initial submission

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority

G. Ethics Committee

H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

- Use the same standard application form that for the Competent Authority
- Standard application form available on:
  
G. Ethics Committee - Vigilance

• SAE declaration by the sponsor:
  - If life in danger: 7 days
  - Other case: 15 days

• The sponsor also has to declare events to the Ethics Committee in the specific countries

• The sponsor don’t needs to provide to the Ethics Committee an annual safety report
<table>
<thead>
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<th>Event Description</th>
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AE: Adverse Event (Non device related)
ADE: Adverse Device Effect (Device or procedure related)
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G. Ethics Committee - Vigilance

A. Type of research
B. Definitions/Legal basis
C. Insurance
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E. Investigators
F. Competent Authority

G. Ethics Committee

H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

- The sponsor, PI or Academic institution are responsible for the declaration to the Ethics Committee
- Special form for the declaration of AE available at the following address

http://www.alims.gov.rs/ciril/prijava-nezeljene-reakcije-na-medicinsko-sredstvo/
| A. Type of research                          | • There is no specific requirement to notify the first patient enrolled to the Ethics Committee |
| B. Definitions/Legal basis                  |                                                |
| C. Insurance                               |                                                |
| D. Sponsor                                 |                                                |
| E. Investigators                           |                                                |
| F. Competent Authority                     |                                                |
| **G. Ethics Committee**                    |                                                |
| H. Data Protection                         |                                                |
| I. Healthy volunteers/Patients             |                                                |
| J. Specific requirements                   |                                                |
• There is a specific procedure for submitting a substantial amendment to the Ethics Committee
SECTIONS

A. Type of research
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C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
Serbian Data Protection:

Commissioner for Information of Public Importance and Personal Data Protection
(in serbian: Poverenik za informacije od javnog značaja i zaštitu podataka o ličnosti)

15, Bulevar kralja Aleksandra str, Belgrade 11000
Tel: +381 11 3408 900
Fax: +381 11 3343 379
office@poverenik.rs
### H. Data Protection

<table>
<thead>
<tr>
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<th>Notification required</th>
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</tr>
<tr>
<td>Observational studies with medical device</td>
<td>x</td>
</tr>
<tr>
<td>Registries</td>
<td>x</td>
</tr>
</tbody>
</table>

- A confidentiality agreement have to be signed between Sponsor and Investigators
H. Data Protection

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients
J. Specific requirements

- English accepted for submission
- Submission fee
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
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I. Healthy volunteers/Patients
J. Specific requirements
## I. Healthy volunteers/Patients

### A. Type of research

### B. Definitions/Legal basis

### C. Insurance

### D. Sponsor

### E. Investigators

### F. Competent Authority

### G. Ethics Committee

### H. Data Protection

### I. Healthy volunteers/Patients

### J. Specific requirements

- In Serbia, there are specific requirements/regulations for specific population:
  - Children
  - Elderly
  - Pregnant women
  - Lactating women
  - Prisoners and psychiatric patients
I. Healthy volunteers/Patients

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

• No specific requirements regarding compensation fees for subjects (patients or healthy volunteers) participating in a clinical research

• No national healthy volunteer registry

• Obligation to inform the healthy volunteers/patients on the outcomes of the study
SECTIONS

A. Type of research
B. Definitions/Legal basis
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G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
### J. Specific requirements

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>• For sponsored studies it is mandatory to have sponsor permission to publish study results in scientific journal.</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td>• Specific requirements/regulations regarding devices emitting radiation: <strong>medical device class III are regulated by Serbian Law for drugs and medical devices</strong></td>
</tr>
<tr>
<td>C. Insurance</td>
<td>• Specific requirements/regulations regarding the ICF: <strong>needs to be written in Serbian</strong></td>
</tr>
<tr>
<td>D. Sponsor</td>
<td>• Specific requirements/regulations regarding archiving of documentation: <strong>5 years</strong></td>
</tr>
<tr>
<td>E. Investigators</td>
<td>• Specific requirements regarding blood/tissue samples (circulation and storage): <strong>regulated by ministry of science.</strong></td>
</tr>
<tr>
<td>F. Competent Authority</td>
<td></td>
</tr>
<tr>
<td>G. Ethics Committee</td>
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<tr>
<td>J. Specific requirements</td>
<td></td>
</tr>
</tbody>
</table>
## J. Specific requirements

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>• Specific requirements for data management: have to be done in accordance to GCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td>• Specific strategies for monitoring</td>
</tr>
<tr>
<td>C. Insurance</td>
<td>• Mandatory to register clinical studies in a registry managed by the Competent Authority</td>
</tr>
<tr>
<td>D. Sponsor</td>
<td>• Accreditation process for research centres by Ministry of science</td>
</tr>
<tr>
<td>E. Investigators</td>
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<td>F. Competent Authority</td>
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