MDR
Risk and Clinical Requirements

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Introduction

Risk Management under the MDR

• Risk-Benefit analysis

Clinical Requirements under the MDR

• Clinical Investigations under the MDR

• When is a Clinical Investigation Required

• Expectations above and beyond MEDDEV 2.7.1, Rev 4
  • Definitions
  • Equivalence
  • SSCP & PSUR

• Changes to Conformity Assessment Procedures
Risk Management under the MDR
References to Risk Management

The MDR is in alignment with EN ISO 14971:2012 and EN ISO 13485:2016

Risk, Risk Management or Benefit-Risk is cited over 250 times within the Regulation

Risk is defined in Article 2, Definitions as:

\[ \text{the combination of the probability of occurrence of harm and the severity of that harm} \]

Benefit-Risk Determination is defined in Article 2 as:

\[ \text{the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer} \]

Article 10, General Obligations:

\[ \text{Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I} \]

The Quality Management Systems shall address:

\[ \text{risk management as set out in in Section 3 of Annex I} \]
Devices shall be safe and effective and shall not compromise ... the health or the safety of patients, users or other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits ... and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

The requirement ... to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.

EN ISO 14971: 2012
Content Deviation #1

EN ISO 14971: 2012
Content Deviation #3

Annex “Z” compliance to MDD requirements
Manufacturers shall:
(a) establish and document a risk management plan for each device;
(b) identify and analyse the known and foreseeable hazards associated with each device;
(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;
(d) eliminate or control the risks referred to in point (c);
(e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and
(f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.

Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating.

a) EN ISO 14971:2012 Clause 3.4
b) EN ISO 14971:2012 Clause 4.3
c) EN ISO 14971:2012 Clause 5
d) EN ISO 14971:2012 Clause 6
e) EN ISO 14971:2012 Clause 9
f) EN ISO 14971:2012 Clause 6
Annex I

SPR#4

Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable.

In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:

(a) eliminate or reduce risks as far as possible through safe design and manufacture;

(b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and

(c) provide information for safety (warnings/precautions/contraindications) and, where appropriate, training to users.

Manufacturers shall inform users of any residual risks.

EN ISO 14971: 2012 Content Deviation #5

EN ISO 14971: 2012 Content Deviation #6

EN ISO 14971: 2012 Content Deviation #7
In eliminating or reducing risks related to use error, the manufacturer shall:

(a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

(b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.
For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.
MedDev 2.7.1 – A7.2 Requirement for acceptable benefit/risk

a) Evaluation of the description of the intended purpose of the device

b) Evaluation of the device’s benefits to the patient

c) Quantification of benefit(s) to the patients
   - Probability of the patient experiencing one or more benefit(s)
   - Duration of effect(s)

d) Evaluation of the clinical risks of devices (extent of risk(s) / harm(s), the following should be addressed individually and in aggregate):
   - Severity, number and rates of harmful events
   - Probability of a harmful event
   - Duration of harmful events
   - Risk from false-positive or false-negative results (diagnostic medical devices)

e) Evaluation of acceptability of the benefit/risk profile
Clinical Requirements under the MDR
MDR
Clinical Investigations
Clinical Investigations (MDR Article 62)

Clinical Investigations... where carried out as part of the clinical evaluation for the conformity assessment purposes for one or more of the following purposes:

• To establish/verify that, under normal conditions of use a device is design, manufactured and packaged in such a way that it suitable for one or more of the specific purposes (as defined in Article 2, point 1) and achieves the **performances** intended as specified by the manufacturer (MDD, Annex X 2.1 & MDR, Annex I, SPR 1)

• To establish/verify the clinical benefits of the device as specified by the manufacturer

• To establish/verify the **clinical safety** of the device and to determine any undesirable side-effects, under normal conditions of use of the device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the devices (MDD, Annex X 2.1 & MDR Annex I, SPR 1)
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**MDR**

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ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Search for studies:
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209 studies found for: knee joint prosthesis
Modify this search | How to Use Search Results

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Include only open studies | Exclude studies with Unknown status

| Rank | Status | Study | Condition | Intervention | Outcome | Change in Knee Society Knee Score | State
|------|-------|-------|-----------|-------------|---------|-----------------------------------|------
| 1    | Recruiting | Correlation Between Alignment of Lower Limb and Clinical Outcome After Total Knee Prosthesis | Osteoarthritis of the Knee Joint | Procedure: patients who undergo a total knee prosthesis | 54 | 93.9 (4.66) |
| 2    | Unknown | Active Knee Prosthesis Study for Improvement of Locomotion for Above Knee Amputees | Amputation | Device: Active Knee Prosthesis | 54 | 93.7 (4.53) |
| 3    | Completed | Range of Motion of Standard and High-Extension Posterior Cruciate Retaining Total Knee Prostheses | Osteoarthritis | Device: Total knee replacement with NexGen CR knee prosthesis; Device: Total knee replacement(TKR) with NexGen CR-flex | 54 | 93.9 (4.66) |

No statistical analysis provided for Change in Knee Society Knee Score

Measured Values

<table>
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<tr>
<th>Number of Participants Analyzed</th>
<th>High-Extension Posterior Cruciate Retaining TKA</th>
<th>High-Extension Posterior Cruciate Scoring TKA</th>
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<tbody>
<tr>
<td>Units: participants</td>
<td>54</td>
<td>54</td>
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<tr>
<td>Change in Knee Society Knee Score</td>
<td>93.9 (4.66)</td>
<td>93.7 (4.53)</td>
</tr>
<tr>
<td>Units: scores on a scale</td>
<td>54</td>
<td>54</td>
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<tr>
<td>Mean (Standard Deviation)</td>
<td>54</td>
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Serious Adverse Events

NexGen CR and CR-flex Knee Prosthesis

<table>
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<tr>
<th>Total, serious adverse events</th>
<th>NexGen CR and CR-flex Knee Prosthesis</th>
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<tr>
<td># participants affected / at risk</td>
<td>0/54 (0.00%)</td>
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*Performance
*Safety
*Sponsor
When is a clinical investigation required?

New and Existing Devices
The MDR is essentially silent on what are the triggers for conducting a new Clinical Investigation when a device is changed or modified.

BSI would expect a new clinical investigation would be required when the change/modification calls into question one of requirements of Article 62, Section 1:

- suitability of its intended use (medical purpose) and achievement of the intended performance
- to verify that the clinical benefits as specified have not been altered
- that the device is still clinically safe
- the undesirable side effects continue to constitute acceptable risks when weighed against the benefits of the device
How should manufacturers and evaluators decide if there is sufficient clinical evidence?

- When clinical data are required in order to draw conclusions as to the conformity of a device to the Essential Requirements, the data need to be in line with current knowledge / the state of the art, be scientifically sound, cover all aspects of the intended purpose and all products / models / sizes / settings foreseen by the manufacturer.

- If gaps are present that cannot be addressed by other means, clinical investigations should be planned and carried out.
MedDev 2.7.1 – A2 When should clinical investigations be carried out?

**Devices likely to require clinical investigation data:**

- Implants / High-risk devices
- Devices based on technologies where there is little or no experience
- Devices that extend the intended purpose of an existing technology

**Annex X MDD / Annex 7 AIMDD:**

- Clinical investigations are required for implantable and class III devices unless it can be duly justified to rely on existing clinical data alone.
- The need for clinical investigations depends on the ability of the existing data to adequately address the safety, performance, benefit/risk profile, claims and side-effects in order to comply with the applicable Essential Requirements.
- Clinical investigations may also be required for other devices, including class I, class IIa and class IIb devices that are not implantable.
When should clinical investigations be carried out?

Special attention should be given to:

• new design features, new materials,
• new intended purposes, new medical indications,
• new target populations (age, gender),
• new claims,
• new types of users (lay persons),
• seriousness of direct and/or indirect risks,
• contact with mucosal membranes or invasiveness,
• increasing duration of use or numbers of re-applications,
• incorporation of medicinal substances,
• use of animal tissues,
• medical alternatives with lower risks greater benefits are / become available,
• new risks are recognised (due to progress in medicine, science, technology),
• whether the data are amenable to evaluation through a clinical investigation
Article 61, Clause 6 states that a clinical investigation may not be required for implantable devices and class III devices:

- If the clinical evaluation of the CE marked device is based on sufficient clinical data and is in compliance with the relevant product-specific Common Specification (CS) (where available) or

- Devices are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such a CS is available. Note: Devices may be added/removed to the CS via Delegated Acts.
Article 61, Clause 10 (which is essentially MDD’s Annex X 1.1 d) states that other than for class III and implantable devices, a clinical investigation may not be required where demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate.

- Adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performances intended and the claims of the manufacturer.

- In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, to be adequate.
Expectations above and beyond MEDDEV 2.7.1, R4
Clinical Evidence

- the **clinical data** and **clinical evaluation report** pertaining to a device
- **sufficient amount** and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s) when used as intended by the manufacturer

Clinical Evaluation

- a methodologically sound / **systematic and planned** process to continuously generate, collect, analyse and assess the **clinical data** pertaining to a device
- to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer

Clinical Data

- clinical investigation on the device concerned
- clinical investigation reported in the scientific literature, of a device for which equivalence to the device in question can be demonstrated
- **peer reviewed** scientific literature on other clinical experience of either the device in question or a device for which equivalence can be demonstrated
- clinically relevant information from the manufacturer’s post-market surveillance system, in particular post-market clinical follow-up
Equivalence
Technical
- be of similar design
- used under similar conditions of use
- have similar specifications and properties (e.g. physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, software algorithms, porosity, particle size, nanotechnology, specific mass, atomic inclusions – nitrocarburising, oxidability)
- use similar deployment methods (if relevant)
- have similar principles of operation and critical performance requirements

Biological
- use same materials or substances in contact with the same human tissues or body fluids
- for a similar kind and duration of contact and similar release characteristics of substances
- including degradation products and leachables
- Exceptions can be foreseen for devices in contact with intact skin and minor components; in these cases risk analysis results may allow the use of similar materials taking into account the role and nature of the similar material. Evaluators should consider biological safety (e.g. ISO 10993) as well as other aspects necessary for a comprehensive demonstration of equivalence. A justification explaining the situation should be provided for any difference.

Clinical
- used for the same clinical condition or intended purpose (including similar severity and stage of disease, medical indication)
- at the same site in the body
- in a similar population (including age, gender, anatomy, physiology)
- have same kind of user
- not foreseen to deliver significantly different performances
- have similar relevant critical performance according to the expected clinical effect for a specific intended purpose

Each device with which equivalence is claimed must fulfil all clinical, technical, biological characteristics
Equivalence: MedDev 2.7.1 Rev 4 & MDR (Annex XIV)

MedDev 2.7.1 Rev 4 recommends the following:

• Differences between the subject device and the equivalent device needs to be identified, fully disclosed, and evaluated; explanations should be given why the differences are not expected to significantly affect the clinical safety and performance

• Potential impact of differences in manufacturing processes on technical & biological characteristics to be considered

• where possible, clinically relevant specifications and properties should be measured both in the subject device and the equivalent device, and presented in comparative tabulations

• comparative drawings or pictures to be included to compare shapes and sizes of elements in contact with the body

• material characterisation & comparative testing in accordance with ISO 10993 series towards demonstrating biological equivalence

• data required to demonstrate equivalence should be summarised in the CER, and the location of supporting information in the technical file cited.

MDR requires the following:

For implants and Class III devices, equivalence can only be claimed with

• The manufacturer’s own device

• Other manufacturer’s devices if contract is in place allowing full access to data on on-going basis
Equivalence, Clinical Investigation and Recertification under the MDR

• A clinical investigation may not be required for implantable devices and class III devices if the device is a modification of a CE marked device by the same manufacturer, the equivalence for which has been endorsed by the NB and the clinical evaluation is sufficient to demonstrate conformity with the relevant safety and performance requirements (Article 61, Clause 4).
  • Adequacy of the PMCF plan and PMS studies to demonstrate the safety and performance of the device shall be verified.

• A clinical investigation may not be required for a device demonstrated to be equivalent to another manufacturer’s CE marked device, may rely on the aforementioned, in case the two manufacturers have a contract allowing full access to the technical documentation on an ongoing basis, the original clinical evaluation complies with the MDR and the subject manufacturer provides clear evidence thereof to the NB (Article 61, Clause 5).
SSCP & PSUR

Reporting Requirements
**Article 32 - Summary of Safety and Clinical Performance (SSCP)**

- In the case of devices classified as **class III and implantable devices**, the manufacturer shall draw up a summary of safety and clinical performance.

- It shall be written in a way that is clear to the intended user and, if relevant, to the patient and **shall be available to the public via EUDAMED**.

- The draft of this summary shall be submitted to the notified body and **shall be validated** by that body. After validation the notified body shall upload this summary report to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary report is available.

**Article 49 – Clinical Evaluation**

For devices classified as **class III and implantable devices**, the PMCF report and, if indicated, the summary of safety and clinical performance shall be **updated at least annually** with these data.

- Manufacturer + SRN
- Device + UDI
- Intended Purpose, Indications, Contra-indications
- Description, previous variant(s), differences, accessories, other products intended to be used in combination
- Possible diagnostic or therapeutic alternatives
- Harmonised Standards / Common Specifications
- Summary of the Clinical Evaluation Report + PMCF
- Suggested profile and training for users
- Information on residual risks, undesirable effects, warnings & precautions
Article 86 – Periodic Safety Update Report

- Manufacturers of class IIa, class IIb and class III devices shall prepare a PSUR for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the PMS data gathered ...

- Throughout the lifetime of the device concerned that PSUR shall set out:

  - Conclusions of the benefit risk determination
  - Main findings of PMCF
  - Volume of Sales
  - Estimate of the Population that use the device
  - Where practicable usage frequency of the device

- Manufacturers of class IIb and III devices shall update the report at least annually.
- Manufacturers of class IIa devices shall update the report at least every two years.
- For custom-made devices the PSUR shall be part of the documentation referred to Annex XIII.
- Manufacturers of devices in class III or implantable devices shall submit reports by means of the electronic system to the notified body.
- The notified body shall review and add its evaluation to that electronic system with details of any action taken. Such PSURs and the notified body evaluation shall be made available to competent authorities through that electronic system.
- For devices other than class III or implantable, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.
Changes to Conformity Assessment Procedures

Clinical Evaluation
Consultation with “Expert Panel” and Scrunity
Changes to Conformity Assessment Procedures

CECP (Chapter V, Article 54)

- Applies to Class III implants and Class IIb active device intended to administer or remove a medicinal product
- Does not apply to:
  - Certificate renewals
  - Design modifications where manufacturer satisfactorily demonstrates to NB that risk-benefit ratio is unaffected
  - Clinical evaluation CS exists for that device type, and NB confirms that the CER meets CS requirements

Article 54(3):
- NBs must notify CAs and Commission through Eudamed of decision of whether or not this consultation is to be applied
- Notification shall be accompanied by CEAR
CECP for Class III implants and Class IIb devices (Article 54; Annex IX, Section 5.1, Article 55)

- **Notified Body Review**
  - 21 days
  - Manufacturer’s Clinical Evaluation
  - NB Clinical Evaluation Assessment Report
  - PMCF Plan

- **EU Commission**
  - Benefit:Risk Determination
  - Consistency with indications
  - PMCF Plan

- **No ‘scientific opinion’**
  - Restrict indications
  - Limit duration of certificate
  - Undertake specific PMCF studies
  - Adapt IFU or Summary of Safety and Clinical Performance
  - Impose other restrictions

- **Notified Body Review**
  - 39 days
  - NB must justify if expert panel advice not followed

- **Complete Conformity Assessment**

- **Notified Body Certificate**

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- **Class III Implant or IIb active drug delivery**
Some good news!!!

Clinical Evaluation (Article 61, Section 2):

Manufacturers of Class III implants and Class IIb active devices intended to administer or remove medicines (Rule 12) the Mfg. may prior to its clinical evaluation and/or investigation, consult an “expert panel”:

• to review the intended clinical development strategy and proposals for clinical investigations
• Manufacturer shall give due consideration to the reviews expressed by the “expert panel”

Manufacturer must include conclusions in clinical evaluation report submitted to NB
Conclusion

Risk Management under the MDR

- Risk-Benefit analysis  
  \textit{Alignment with EN ISO 14971:2012}

Clinical Requirements under the MDR

- Clinical Investigations under the MDR  
  \textit{Alignment with EN ISO 14155:2011}

- When is a Clinical Investigation Required  
  \textit{New Class III Implants}

- Expectations above and beyond MEDDEV 2.7.1, Rev 4
  
  Definitions  
  \textit{Clinical Evidence defined}

  Equivalence  
  \textit{Stringent equivalence requirements}

  SSCP & PSUR  
  \textit{Increased oversight of PMS data}

- Changes to Conformity Assessment Procedures  
  \textit{CECP for Class III implants & certain Class IIb active devices}
Questions

Thank You!