Finding the right Medical Device information in Scientific Literature

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Agenda

In this presentation, we will discuss:

- **New Medical Device Regulations (MDR 2017/745) and Medical Device Guidelines (MEDDEV 2.7/1 rev 4) and their implications**
- **How Embase addresses these requirements**
- **(Case study) How to design effective literature searches for Clinical Evaluation Reports to identify:**
  - Device performance
  - Comparison of device with existing device(s)
  - Adverse device effects
- **How to set a scheduled search for Post-Market Surveillance (PMS)**
European Medical Device Regulations (MDR 2017/745) and a revised CER guidance (MEDDEV 2.7/1 rev 4) reflect more stringent requirements for clinical data.

New European Medical Device Regulations (MDR 2017/745) and a revised CER guidance (MEDDEV 2.7/1 rev 4) have been released. Both documents reflect more stringent requirements for clinical data.

The relevant guidelines should be applied to all medical devices sold in European Union, including those manufactured elsewhere. If a company plans to sell a medical devices in Europe, it must produce and maintain a Clinical Evaluation Report (CER).

Post-market surveillance (PMS) is an integral part of the European Medical Device Regulation (MDR), nicely aligned with the requirement to evaluate medical device thorough the life-cycle of the product.
EU Medical Devices Regulation timelines: three-year transition period ending in 2020

On April 5, 2017 the EU adopted the new Medical Device Regulations (MDR 2017/745), replacing the two existing directives, the Medical Devices Directive (MDD) and the Active Implantable Medical Devices (AIMD) Directive.

The new regulation will enter into force after a three-year transition period ending in spring 2020. This means that the market access framework for all member countries of the European single market (EU member states including the UK, the members of the EEA – Iceland, Lichtenstein and Norway, and through bilateral treaties Switzerland) will change significantly.

Timelines

• April 5, 2017: The EU Medical Device Regulation was adopted.
• May 5, 2017: The Regulation was published in the Official Journal of the European Union.
• May 26, 2017: The Regulation entered into force and will apply in parallel with the current medical devices directive MDD 93/42/EEC for a transition period of three years.
• December, 2017: The process of re-designating Europe’s Notified Bodies under the new regulation begins. The first designations are expected to be finalized 12 to 18 months from the date of publication of the legislation.
• May 25, 2020: The transition period ends and Medical Devices Regulation becomes mandatory.
MDR will address inherent weaknesses in old directives and rapid evolution of science and technology in the field of medical devices

Compared to the MDD, MDR 2017/745 introduces:

- **Life-cycle approach to ongoing CE Marking compliance.** Conformity assessment procedures are more complex, and equivalence will be more rigorously interpreted.
- Clinical data and **Clinical Evaluation Report** (CER) will face heavy scrutiny and require recurring updates.
- Reinforcement of the criteria for designation and processes for **oversight of Notified Bodies**.
- Improved transparency through the establishment of a comprehensive **EU database on medical devices** and of a **device traceability system** based on Unique Device Identification.
- Inclusion of certain **aesthetic devices** which present the same characteristics and risk profile as analogous medical devices.
- Introduction of an “**implant card**” containing information about implanted medical devices for a patient.
- Manufacturers must fulfill **increased post-market surveillance requirements**, perform more **Post-Market Clinical Follow-up** (PMCF) studies, and deliver **Periodic Safety Update Reports** (PSUR) for class IIa devices and above.
For each medical device, whether it is a high risk active implant or a low risk walking aid, post-marketing data shall be collected.

MDR outlines that the PMS system shall be proportionate to the risk class of the device. Previously, a reactive approach for lower risk devices, e.g. in the form of vigilance registries, would be acceptable, as long as strong clinical evidence for safety and performance was expected based on pre-market data.

Currently, it is more likely that your Notified Body requires you to proactively collect data on the clinical safety and clinical performance of your device, regardless of its classification.

‘for any device, proportionate to the risk class and appropriate for the type of device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system which shall be an integral part of the manufacturer’s quality management system.’ MDR
Clinical Evaluation Reports lifecycle

Clinical evaluation involves the assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device.

Companies are required to prepare and submit a clinical evaluation report with the technical file as part of the CE Marking. The initial report is just the beginning of the CER’s lifecycle.

When to update CER?
CER has to be regularly updated based on ongoing clinical evaluations, or as part of the post-market surveillance and vigilance operations. Updates to the CER are required:
• Every year (class IIb and implantable devices)
• When new information from post-market surveillance are received that could change the current evaluation
• Every 2-5 years if the device is not expected to carry significant risks and is well established (IIa)
CER must be based on clinical data

The CER must be based on clinical data, which may include clinical data from:

- literature
- clinical experience
- clinical trials

or any combination of the three.

Search strategies, full search results, appraisal strategy and results, analysis of the data and a clear and functional list of references must be included in the CER.

MEDDEV 2.7.1 rev 4 includes detailed information on:

- Where to search for literature
- How to search for literature
- How to record the process of collecting, appraising and analyzing the items found.
Appendix A4 of MEDDEV 2.7/1 rev 4, highlights the important literature databases to be used as sources, specifically stating:

- “MEDLINE® or PubMed® can provide a good starting point for a search. However, with potentially incomplete coverage of European journals and reduced search features, comprehensiveness is not necessarily guaranteed.”

- “databases may need to be used to ensure adequate coverage of devices and therapies in use in Europe, to identify relevant clinical trials and publications of user experience, and to facilitate searches by device name and manufacturer. Listed additional databases include Embase® and the Cochrane Central Trials Register.”
**MEDDEV 2.7.1 rev 4 Guidelines – How to Search for Literature**

**Types of search (MEDDEV 2.7/1 rev 4)**

“Objective, non-biased, systematic search and review methods should be used:

- **PICO** (patient characteristics, type of intervention, control and outcome queries)
- **Cochrane Handbook for Systematic Reviews of Interventions**

The **Cochrane Handbook** outlines eight general steps for preparing a systematic review:

1. Defining the review question(s) and developing criteria for including studies
2. **Searching for studies** (*Embase,..*)
3. Selecting studies and collecting data
4. Assessing risk of bias in included studies
5. Analyzing data and undertaking meta-analyses
6. Addressing reporting biases
7. Presenting results and "summary of findings" tables
8. Interpreting results and drawing conclusions
HOW EMBASE ADDRESSES MEDDEV 2.7.1_4 REQUIREMENTS
How Embase addresses MEDDEV 2.7/1_4 requirements

Embase is the most comprehensive biomedical literature database (over 8,300 journals and 32 million records). It contains over 2,900 journals that are not in MEDLINE.

- Embase has unmatched coverage of devices and therapies in use in Europe
- Powerful search capabilities to find results based on Booleans, proximity, wildcards and dozens of filters, limits
- **PICO** search framework
- Ability to create, save, share and schedule complex search strategies
- Facilitate searches by device name and manufacturer based on in-depth indexing
- Unique coverage of over 2.7m conference abstracts from >8,100 conferences
- Much more coverage of non-English content and randomized controlled trials
- 2.3 Million records about medical devices are indexed in Embase

Recommended by (regulatory) authorities:

- EMA for Pharmacovigilance
- European Commission for Clinical Evaluation Reporting of medical devices
- NICE and Cochrane for Evidence Based Medicine
Using the PICO Framework to Structure a Question and Search for Evidence

P = Patient
I = Intervention
C = Comparison/control
O = Outcome

PICO is a method to structure the elements (concepts) of the review question into a search strategy.

On the next few slides, we’ll look at PICO to answer a diagnostic question: What is the value of chest radiography in diagnosis of asthma?
P (Patient, Problem or Population)

A generic formula for this search strategy is:

1. **Disease Emtree preferred term**
   ‘name of the disease’/exp

2. **Disease term as free text search (in title, abstracts, keywords)**
   ‘name of the disease’ OR ‘synonyms for the disease’

3. #1 OR #2

e.g.

'**asthma**'/exp OR (‘asthma' OR 'asthma bronchiale' OR 'asthma pulmonale' OR 'asthmatic' OR 'asthmatic subject' OR 'bronchial asthma' OR 'bronchus asthma' OR 'childhood asthma' OR 'chronic asthma' OR 'lung allergy‘):ab,ti,kw

I (Intervention)

A generic formula for this search strategy is:

1. **Emtree preferred term**
   ‘name of the intervention’/exp

2. **Intervention (e.g. drug) as free text search**
   ‘name of intervention’ OR ‘synonyms for the intervention’

3. #1 OR #2

   e.g.
   'thorax radiography'/exp OR ('x chest' OR 'chest radiogram' OR 'chest radiograph' OR 'chest radiography' OR 'chest radiology' OR 'chest roentgenogram' OR 'chest roentgenography' OR 'chest roentgenology' OR 'chest x ray' OR 'chest xray' OR 'mass chest x-ray' OR 'thoracic radiography' OR 'thoracic roentgenology' OR 'thoracic x ray' OR 'thoracic radiogram' OR 'thoracic radiograph' OR 'thoracic radiography' OR 'thorax radiography' OR 'thorax radiology' OR 'thorax roentgenogram' OR 'thorax roentgenography' OR 'thorax roentgenology' OR 'thorax x ray' OR 'thoraxradiography’):ab,ti,kw

Logical Operators

The Boolean **OR operator** is used to search the terms **within** each individual concept. PICO is using **AND** Boolean logical operators to search **between** the concepts:

P-elements
    AND
I-elements
    AND
C-elements
    AND
O-elements

How Embase addresses MEDDEV 2.7/1_4 requirements

Ability to build searches in Embase.com using a structured PICO framework, which also allows easy incorporation of Emtree terms and synonyms, supports the creation of comprehensive CERs.
CASE STUDY
Case study

Scenario: Manufacturer needs to create a CER for coronary stent (everolimus eluting coronary stent)

Goal: Find critical information needed for successful regulatory submissions that includes:

- Device clinical performance
- Comparison of device with an existing device
- Device safety – finding adverse device effects
DEVICE CLINICAL PERFORMANCE
Clinical performance information

Sensitive search created using PICO search form

('everolimus eluting coronary stent'/exp OR 'promus element' OR 'xience xpedition' OR 'xience-v' OR 'everolimus eluting coronary stent') **AND** ('randomized controlled trial'/exp OR 'systematic review'/exp OR 'meta analysis'/exp)
Example of a result

Safety and Efficacy of Resolute Zotarolimus-Eluting Stents Compared with Everolimus-Eluting Stents

Piccolo P., Stefani N.G., Frangoni A., Spitzer E., Blochinger S., Heg D., Juni P., Windischer S.

Circulation: Cardiovascular Interventions 2015 8:4 Article Number e002223

Go to publisher for the full text

Abstract

Background - Although new-generation drug-eluting stents represent the standard of care among patients undergoing percutaneous coronary intervention, there remains debate about differences in efficacy and the risk of stent thrombosis between the Resolute Zotarolimus-eluting stent (R-ZES) and the everolimus-eluting stent (EES). The aim of this study was to evaluate the safety and efficacy of the R-ZES compared with EES in patients undergoing percutaneous coronary intervention. Methods and Results - A systematic literature search of electronic resources was performed using specific search terms until September 2014. Random-effects meta-analysis was performed comparing clinical outcomes between patients treated with R-ZES and EES up to maximum available follow-up. The primary efficacy end point was target-vessel revascularization. The primary safety end point was definite or probable stent thrombosis. Secondary safety end points were cardiac death and target-vessel myocardial infarction. Five trials were identified, including a total of 3899 patients. Compared with EES, R-ZES had similar risks of target-vessel revascularization (risk ratio [RR], 1.06; 95% confidence interval [CI], 0.90–1.22; P=0.50), definite or probable stent thrombosis (RR, 1.25; 95% CI, 0.86–1.85; P=0.24), cardiac death (RR, 1.01; 95% CI, 0.79–1.30; P=0.91), and target-vessel myocardial infarction (RR, 1.10; 95% CI, 0.89–1.36; P=0.39). Moreover, R-ZES and EES had similar risks of late definite or probable very late stent thrombosis (RR, 1.06; 95% CI, 0.52–2.11; P=0.87). No evidence of significant heterogeneity was observed across trials. Conclusions - R-ZES and EES provide similar safety and efficacy among patients undergoing percutaneous coronary intervention.

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DEVICE COMPARISON

1. Sensitive (broad), specific search using PICO search form
2. Focused, non-specific search
3. More focused, specific search
Device Comparison (with a specific device)

1. Sensitive (broad), specific search using PICO search form

Search based on co-location of terms in records:

('everolimus eluting coronary stent'/exp OR 'promus element' OR 'xience xpedition' OR 'xience-v' OR 'everolimus eluting coronary stent') AND ('biolimus eluting coronary stent'/exp OR 'biolimus a9 (device)' OR 'biolimus eluting coronary stent' OR 'umirolimus eluting coronary stent')
Device Comparison (with any device)

2. Focused (narrow), search using subheadings

'everolimus eluting coronary stent'/'device comparison' (276 hits)
Device Comparison (with a specific device)

3. More focused (narrower), specific search based on triple-linking (indexed semantic relationships between the two devices):

'everolimus eluting coronary stent'/'device comparison'/'sirolimus eluting coronary stent'
Example of a result

Outcome: increased precision i.e. only truly relevant records are retrieved significantly improving your efficiency
DEVICE SAFETY

1. Focused, non-specific search
2. Sensitive (broad) search using Emtree and free text (Search Strategy for PMS)
Device Safety

1. Focused search using subheadings:
'everolimus eluting coronary stent'/'adverse device effect'
Example of a result

Impact of Preexisting Vascular Disease on the Outcome of Patients with Acute Coronary Syndrome: Insights from the Comparison of Bioactive Stent to the Everolimus-Eluting Stent in Acute Coronary Syndrome Trial
Nammas W., Airaksinen J.K.E., Romppanen H., Sia J., De Belder A., Karjalainen P.P.
Angiology 2017 88:6 (513-518)

Drug Terms
acetylsalicylic acid, clopidogrel, heparin

Disease Terms
acute coronary syndrome, bioactive stent, heart death, heart disease, ST segment elevation myocardial infarction, stent thrombosis, target lesion revascularization, vascular disease

Device Terms
everolimus eluting coronary stent, coronary stent, everolimus eluting coronary stent

Key Subheadings
everolimus eluting coronary stent (major focus)
device comparison, coronary stent
adverse device effect, heart death, major adverse cardiac event, stent thrombosis, ST segment elevation myocardial infarction

Long-Term (6-Year) Outcomes of Atrial Fibrillation Among Patients Receiving Drug-Eluting

J. 10:11 (1075-1085)

View Full Text
Search Strategy for Post-Market Surveillance (PMS)

2. Sensitive search using Emtree and free text:

('everolimus eluting coronary stent'/exp OR 'promus element' OR 'xience xpedition' OR 'xience-v' OR 'everolimus eluting coronary stent')
AND
('adverse device effect'/exp OR 'adverse device effect'/lnk OR 'device safety'/exp OR 'device failure'/exp OR 'equipment safety' OR device-induced OR 'device infection'/exp OR 'misplacement' OR 'complication'/exp OR comp* OR 'risk'/exp OR risk* OR 'side effect'/exp OR complaint* OR 'injury'/exp OR injur* OR 'death'/exp OR death* OR died OR mortality OR fatalit* OR obstruction* OR failure* OR perforat* OR rupture* OR breakag* OR malfunction* OR impair* OR hazardous OR irritant* OR irritat* OR (patient* NEAR/2 discomfort*):de,ab,ti,kw OR ((device OR equipment OR mechanical or technical) NEAR/2 (safety OR failure* OR malfunction* OR withdrawal OR ineff* OR problem*)):de,ab,ti,kw OR ((adverse OR side OR undesirable OR unwanted OR lack OR allergic OR fatal OR unexplained OR loss OR unexpected) NEXT/2 (effect* OR reaction* OR event* OR outcome*)):de,ab,ti,kw)

2,357 hits
MEDDEV 2.7.1 REV 4 GUIDELINES

HOW TO RECORD THE PROCESS OF COLLECTING RECORDS
Search strategies, full search results and a clear and functional list of references must be included in the CER.
AUTOMATIZE SEARCHING FOR POST-MARKET SURVEILLANCE
Automatize Searching for Post-Market Surveillance

(‘everolimus eluting coronary stent’/exp OR ‘promus element’ OR ‘xience xpedition’ OR ‘xience-v’ OR ‘everolimus eluting coronary stent’) 
AND
(‘adverse device effect’/exp OR ‘adverse device effect’/lnk OR ‘device safety’/exp OR ‘device failure’/exp OR ‘equipment safety’ OR device-induced OR ‘device infection’/exp OR misplacement* OR ‘complication’/exp OR complicat* OR ‘risk’/exp OR risk* OR ‘side effect’/exp OR complaint* OR ‘injury’/exp OR injur* OR ‘death’/exp OR death* OR died OR mortality OR fatalit* OR obstruction* OR failure* OR perforat* OR rupture* OR breakag* OR malfunction* OR impair* OR hazardous OR irritant* OR irritat* OR (patient* NEAR/2 discomfort*):de,ab,ti,kw OR ((device OR equipment OR mechanical or technical) NEAR/2 (safety OR failure* OR malfunction* OR withdrawal OR ineff* OR problem*)):de,ab,ti,kw OR ((adverse OR side OR undesirable OR unwanted OR lack OR allergic OR fatal OR unexplained OR loss OR unexpected) NEXT/2 (effect* OR reaction* OR event* OR outcome*)):de,ab,ti,kw)

Set up an email alert
Email Alert - Automatized Search for PMS

Embase®

Publication years
Authors
Conference Abstracts
Drug Trade Names
Drug Manufacturers
Device Trade Names
Device Manufacturers

33,975 results for search #2

Prenatal paracetamol use and asthma

Effect of tramadol/acetaminophen on maternal pain in patients with chronic non-cancer pain
Tetsunaga T., Tetsunaga T., Tanaka M., Nishida K., Takei Y., Ozaki T. Pain Research and Management 2016 Article Number 7458534

Granulomatous lobular mastitis in pregnancy: A case report
Ilhan B., Klik B., Bademlier S., Ozgur I., Turkay R., Karailik H.

Set Email Alert

Email alerts will produce an email with a maximum of 1000 records.

Alert name
Type the name of your search here

Comments (optional)

Email addresses(s)
lkrstic@elsevier.com

Email addresses should be separated by a semicolon (;)

Email format
- HTML
- Text
- RIS (as an attachment)

Content selection

Frequency
Every week on Monday

Alert sent
Send an alert only when there are results

Articles in Press and in Process
Include

Cancel | Set email alert
Email Alert history is auditable

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Summary

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- How Embase addresses these requirements
- (Case study) How to design effective literature searches to identify:
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- How to set an automatized search for PMS
Thank you!

Any questions?

Dr. Ivan Krstić
Senior Product Development Manager Embase
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Embase content flow

Articles (pre-pub) -> 2,500 journals

Articles in Press (AiPs)

Journal issue (published) -> <1 week

In process records (IPs)

Fully indexed records -> <1 week

900K records

6,250 journals (3,000 unique)

Articles (pre-pub)

Journal issue (published)

Fully indexed records

Embase

- MESH to Emtree conversion
- PMID addition
- Deduplication

MEDLINE articles

5,300 journals

Conference abstracts

350K records