

# Finding the right Medical Device information in Scientific Literature

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# Agenda

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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

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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.

<b>MEDDEV 2.7/1 rev 4</b>	<b>MDR 2017/745</b>
June 2016	May 2017

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

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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

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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

## Post-market surveillance (PMS) shall be proportionate to the risk class

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**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

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**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

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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.



## MEDDEV 2.7.1 rev 4 Guidelines - Where to Search for Literature

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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

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### 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:

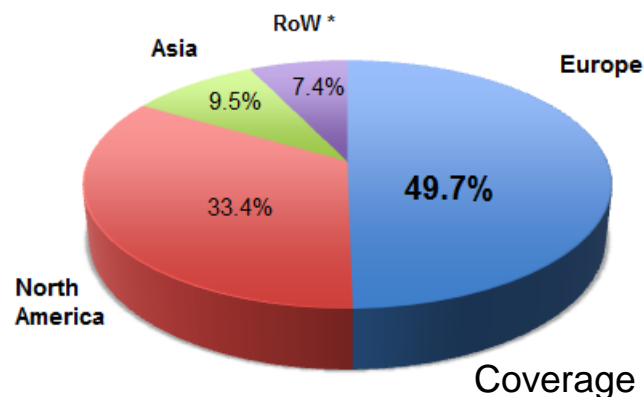
1. Defining the review question(s) and developing criteria for including studies
2. **Searching for studies (Embase,..)**
3. Selecting studies and collecting data
4. Assessing risk of bias in included studies
5. Analyzing data and undertaking meta-analyses
6. Addressing reporting biases
7. Presenting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

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# 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**.



### Recommended by (regulatory) authorities:

- **EMA** for Pharmacovigilance
- **European Commission** for Clinical Evaluation Reporting of medical devices
- **NICE** and **Cochrane** for Evidence Based Medicine

- **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

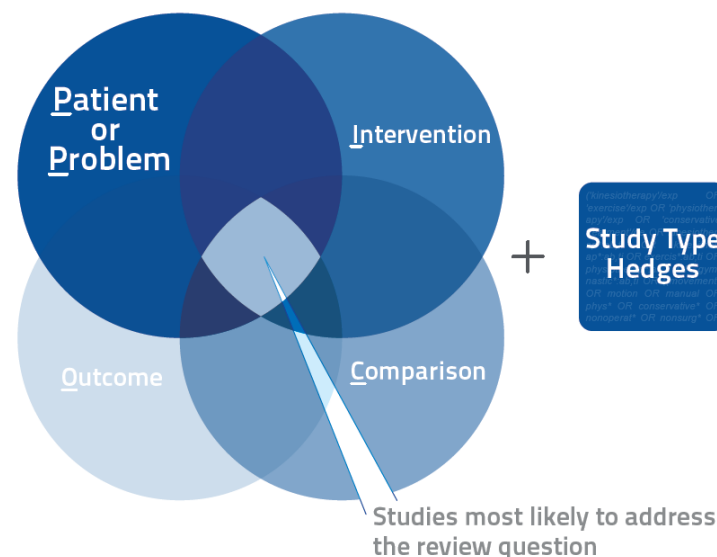
# Using the PICO Framework to Structure a Question and Search for Evidence

**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)**

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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)

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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 'thorax radiogram' OR 'thorax radiograph' 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

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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**.

### PICO Search

Note: Filling any search line is optional

Default search strategy

☐ /mj ☐ /de ☒ /exp ☐ /br

Intervention

everolimus eluting coronary stent /exp ▼ + 4 synonyms:all ▼

Clear field

Comparison

biolimus eluting coronary stent /exp ▼ + 3 synonyms:all ▼

Clear field

Study design (or miscellaneous)

randomized controlled trial /exp ▼ + 8 synonyms:all ▼ or ▼ systematic review /exp ▼ + 2 synonyms:all ▼

or ▼ meta analysis /exp ▼ + 4 synonyms:all ▼

Reset query ▶ Info

Show 53 results >

# CASE STUDY

## Case study

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**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**

Embase®

# 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)

### PICO Search

Note: Filling any search line is optional

Default search strategy

☐ /mj ☐ /de ☒ /exp ☐ /br

Intervention

everolimus eluting coronary stent /exp ▼ + 4 synonyms:all ▼

Clear field

Study design (or miscellaneous)

randomized controlled trial /exp ▼ or ▼ systematic review /exp ▼ or ▼

meta analysis /exp ▼

Reset query ▶ Info

Show 377 results >

# Example of a result

Embase®

Search ▾ Browse ▾ Results My tools ▾ Ivan Krstic □ Logout ⚙️ 🔔(1)

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

Piccolo R., Stefanini G.G., Franzone A., Spitzer E., Blöchliger S., Heg D., Jüni P., Windecker 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 9899 patients. Compared with EES, R-ZES had similar risks of target-vessel revascularization (risk ratio [RR], 1.06; 95% confidence interval [CI], 0.90-1.24; P=0.50), definite or probable stent thrombosis (RR, 1.26; 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, 0.53-2.11; 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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### Disease Terms

[open all disease terms](#)

heart death ☹️, heart infarction ☹️, in-stent restenosis ☹️, stent thrombosis ☹️

### Device Terms

[open all device terms](#)

everolimus eluting coronary stent ☹️, zotarolimus eluting coronary stent ☹️

### Other Terms

article ☹️, comparative study ☹️, coronary artery recanalization ☹️, device safety ☹️, follow up ☹️, human ☹️, meta analysis ☹️, outcome assessment ☹️, percutaneous coronary intervention ☹️, priority journal ☹️, randomized controlled trial (topic) ☹️, systematic review ☹️

# 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

Intervention


everolimus eluting coronary stent /exp ▼ + 7 synonyms:all ▼


Clear field

Comparison

biolimus eluting coronary stent /exp ▼ + 5 synonyms:all ▼

Clear field

 Reset query

 Info

Show 192 results >

### Search based on co-location of terms in records:

('everolimus eluting coronary stent'/exp OR 'promus element' OR 'xience xpediton' 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)

Embase® Search ▾ Browse ▾ Results My tools ▾ Ivan ▾

### Device Search

'everolimus eluting coronary stent'

Search > Mapping ▾ Date ▾ Sources ▾ Device fields ▾ Device subheadings ^ Quick limit

Device subheadings

☐ Adverse device effect

☒ Device comparison

☐ Device economics

☐ Clinical trial

☐ OR ☐ AND

<input type="checkbox"/> sirolimus eluting coronary stent	61
<input type="checkbox"/> bioresorbable scaffold	51
<input type="checkbox"/> bare metal stent	41
<input type="checkbox"/> paclitaxel eluting coronary stent	41
<input type="checkbox"/> zotarolimus eluting coronary stent	34
<input type="checkbox"/> biolimus eluting coronary stent	20
<input type="checkbox"/> drug eluting coronary stent	19
<input type="checkbox"/> bioresorbable vascular stent	14
<input type="checkbox"/> everolimus eluting coronary stent	12
<input type="checkbox"/> metal stent	11
<input type="checkbox"/> coronary stent	10
<input type="checkbox"/> drug eluting stent	10
<input type="checkbox"/> balloon catheter	6
<input type="checkbox"/> drug eluting balloon	6
<input type="checkbox"/> percutaneous transluminal angioplasty balloon	6
<input type="checkbox"/> everolimus eluting metallic stent	5
<input type="checkbox"/> balloon	4
<input type="checkbox"/> bioresorbable vascular scaffold	3
<input type="checkbox"/> drug coated balloon	3
<input type="checkbox"/> everolimus eluting bioresorbable vascular scaffold	3
<input type="checkbox"/> paclitaxel eluting balloon	3
<input type="checkbox"/> PTCA catheter	3

## 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'

The screenshot displays a web application interface for device comparison. It consists of three main panels:

- Devices Panel (Left):** A list of medical devices with checkboxes and details links. The first device, 'everolimus eluting coronary stent', is highlighted in orange. Other devices include 'sirolimus eluting coronary stent', 'bare metal stent', 'zotarolimus eluting coronary stent', 'paclitaxel eluting coronary stent', 'bioresorbable scaffold', and 'drug eluting stent'.
- Key subheadings Panel (Center):** A list of subheadings with checkboxes and counts. The first subheading, 'adverse device effect', has a count of 152. The second subheading, 'device comparison', is highlighted in orange and has a count of 276.
- Device comparison Panel (Right):** A search interface for device comparison. It includes a search bar with the placeholder text 'type any device comparison (autocomplete)'. Below the search bar is a list of devices with checkboxes and counts. The first device, 'sirolimus eluting coronary stent', is highlighted in orange and has a count of 61. Other devices include 'bioresorbable scaffold', 'bare metal stent', 'paclitaxel eluting coronary stent', 'zotarolimus eluting coronary stent', 'biolimus eluting coronary stent', 'drug eluting coronary stent', and 'bioresorbable vascular stent'.

# Example of a result

Embase®

Search ▾ Browse ▾ Results My tools ▾ Ivan Krstic ☒ Logout ⚙️ 🔔(1)

## Comparative effectiveness and safety of new-generation versus early-generation drug-eluting stents according to complexity of coronary artery disease: A patient-level pooled analysis of 6,081 patients

Piccolo R., Pilgrim T., Heg D., Franzone A., Rat-Wirtzler J., Räber L., Silber S., Serruys P.W., Jüni P., Windecker S.

JACC: Cardiovascular Interventions 2015 8:13 (1657-1666)

Go to publisher for the [full text](#)

### Abstract

**Objectives** The purpose of this study was to compare the 2-year safety and effectiveness of new- versus early-generation drug-eluting stents (DES) according to the severity of coronary artery disease (CAD) as assessed by the SYNTAX (Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) score. **Background** New-generation DES are considered the standard-of-care in patients with CAD undergoing percutaneous coronary intervention. However, there are few data investigating the effects of new- over early-generation DES according to the anatomic complexity of CAD. **Methods** Patient-level data from 4 contemporary, all-comers trials were pooled. The primary device-oriented clinical endpoint was the composite of cardiac death, myocardial infarction, or ischemia-driven target-lesion revascularization (TLR). The principal effectiveness and safety endpoints were TLR and definite stent thrombosis (ST), respectively. Adjusted hazard ratios (HRs) with 95% confidence intervals (CIs) were calculated at 2 years for overall comparisons, as well as stratified for patients with lower (SYNTAX score ≤11) and higher complexity (SYNTAX score >11). **Results** A total of 6,081 patients were included in the study. New-generation DES (n = 4,554) compared with early-generation DES (n = 1,527) reduced the primary endpoint (HR: 0.75 [95% CI: 0.63 to 0.89]; p = 0.001) without interaction (p = 0.219) between patients with lower (HR: 0.86 [95% CI: 0.64 to 1.16]; p = 0.322) versus higher CAD complexity (HR: 0.68 [95% CI: 0.54 to 0.85]; p = 0.001). In patients with SYNTAX score >11, new-generation DES significantly reduced TLR (HR: 0.36 [95% CI: 0.26 to 0.51]; p < 0.001) and definite ST (HR: 0.28 [95% CI: 0.15 to 0.55]; p < 0.001) to a greater extent than in the low-complexity group (TLR Pint = 0.059; ST Pint = 0.013). New-generation DES decreased the risk of cardiac mortality in patients with SYNTAX score >11 (HR: 0.45 [95% CI: 0.27 to 0.76]; p = 0.003) but not in patients with SYNTAX score ≤11 (pint = 0.042). **Conclusions** New-generation DES improve clinical outcomes compared with early-generation DES, with a greater safety and effectiveness in patients with SYNTAX score >11.

© 2015 American College of Cardiology Foundation.

### Device Terms

[open all device terms](#)

**biolimus eluting coronary stent** <sup>Ⓢ</sup>, **everolimus eluting coronary stent** <sup>Ⓢ</sup>, **paclitaxel eluting coronary stent** <sup>Ⓢ</sup>, revascularization <sup>Ⓢ</sup>, **sirolimus eluting coronary stent** <sup>Ⓢ</sup>, **zotarolimus eluting coronary stent** <sup>Ⓢ</sup>.

### everolimus eluting coronary stent

#### Key Subheadings

**adverse device effect** heart death, heart infarction, heart muscle ischemia, stent thrombosis

**device comparison** **biolimus eluting coronary stent**, **paclitaxel eluting coronary stent**, **sirolimus eluting coronary stent**, **zotarolimus eluting coronary stent**

**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'

### Device Search

Search >

Mapping ▾

Date ▾

Sources ▾

Device fields ▾

Device subheadings ▲

#### Device subheadings

☒ Adverse device effect

☐ Device comparison

☐ Device economics

☐ Clinical trial

☐ OR

☐ AND

1 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  
 Namas W., Airaksinen J.K.E., Romppanen H., Sia J., De Belder A., Karjalainen P.P.  
*Angiology* 2017 68:6 (513-518)  
 Embase [Abstract](#) [Index Terms](#) [View Full Text](#)

**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](#)

[everolimus eluting coronary stent \(major focus\)](#)

**Key Subheadings**

<b>device comparison</b>	coronary stent
<b>adverse device effect</b>	heart death, major adverse cardiac event, stent thrombosis, ST segment elevation myocardial infarction

# 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 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)**

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

## Embase Session Results (15 Nov 2016)

No.	Query	Results
#30	'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 'complication'/exp OR 'postoperative complication'/exp OR postoperative NEXT/2 complication* OR complicat* OR 'risk'/exp OR risk* OR 'side effect'/exp OR (adverse OR side OR undesirable OR unwanted OR lack) NEXT/2 (effect* OR reaction* OR event* OR outcome*))	1612

1,612 results for search #30 [Set email alert](#) [Set RSS feed](#) [Search details](#)

☐ Results View | Print

1612 Select

☐ 1 Review: The ou  
Tsai M.-L., Chen C.-C.  
*International Journal of*  
Embase [Abstr](#)

☐ 2 Safety of 6-mor  
design of the S  
with acute coro  
Lee J.M., Cho D.-K., I  
*American Heart Jour*  
Embase [Abstr](#)

☐ 3 Symptomatic in-stent restenosis due to complete stent fracture treated with drug coated balloon  
Richter D., Sluka M., Vindis D., Ostransky J., Taborsky M.  
*Minerva Cardioangiologica* 2016 64:6 (707-709)

### Export Data

Export format:

Output:

Include search ☐  
query in export

Citations only export includes the following:

- Title
- Author names
- Source

[Cancel >](#) [Export >](#)

# **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

1,612 results for search #30 [Set email alert](#) [Set RSS feed](#) [Search details](#)

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<input type="checkbox"/> 1	<p>Review: The outcomes of different vessel diameter in patients receiving coronary artery stenting</p> <p>Tsai M.-L., Chen C.-C., Chen D.-Y., Yang C.-H., Hsieh M.-J., Lee C.-H., Wang C.-Y., Chang S.-H., Hsieh I.-C.</p> <p><i>International Journal of Cardiology</i> 2016 224 (317-322)</p> <p>Embase <a href="#">Abstract</a> <a href="#">Index Terms</a> <a href="#">View Full Text</a></p>
<input type="checkbox"/> 2	<p>Safety of 6-month duration of dual antiplatelet therapy after percutaneous coronary intervention in patients with a design of the Smart Angioplasty Research Team—safety of 6-month duration of Dual Antiplatelet Therapy after percutaneous coronary intervention with acute coronary syndromes (SMART-DATE) prospective multicenter randomized trial</p> <p>Lee J.M., Cho D.-K., Hahn J.-Y., Song Y.B., Park T.K., Oh J.-H., Lee J.B., Doh J.-H., Kim S.-H., Yang J.H., Choi J.-H., Choi S.-H., Lee S.H., Gwon H.-C.</p> <p><i>American Heart Journal</i> 2016 182 (1-8)</p> <p>Embase <a href="#">Abstract</a> <a href="#">Index Terms</a> <a href="#">View Full Text</a></p>

The screenshot displays the Embase database interface. On the left, a sidebar contains filters for 'Publication years', 'Authors', 'Conference Abstracts', 'Drug Trade Names', 'Drug Manufacturers', 'Device Trade Names', and 'Device Manufacturers', each with a dropdown arrow. Below these filters is an 'Apply' button. The main search results area shows '33,975 results for search #2'. A 'Set email alert' button is highlighted with a red box. The 'Results' section lists three items, each with a checkbox, a title, authors, and publication details. The first result is 'Prenatal paracetamol use and asthma in...' by Fan G., Wang B., Liu C., Li D. The second is 'Effect of tramadol/acetaminophen on medication in patients with chronic low back pain...' by Tetsunaga T., Tanaka M., Nishida K., Takei Y., Ozaki T. The third is 'Granulomatous lobular mastitis in pregnancy: A case report' by Ilhan B., Kilic B., Bademler S., Ozgur I., Turkey R., Karanlik H. A 'Set Email Alert' dialog box is open in the foreground, allowing the user to configure email alerts for the selected search. The dialog includes fields for 'Alert name', 'Comments (optional)', 'Email address(es)', 'Email format' (HTML, Text, RIS), 'Content selection' (Citations only), 'Frequency' (Every week on Monday), 'Alert sent' (Send an alert only when there are results), and 'Articles in Press and in Process' (Include). Buttons for 'Cancel' and 'Set email alert' are at the bottom right of the dialog.

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☐ 1 Prenatal paracetamol use and asthma in  
Fan G., Wang B., Liu C., Li D.  
[Article in Press] *Allergologia et Immunopathologia* 2016  
Embase [Abstract](#) [Index Terms](#) [View Full Text](#)

☐ 2 Effect of tramadol/acetaminophen on medication in patients with chronic low back pain  
Tetsunaga T., Tetsunaga T., Tanaka M., Nishida K., Takei Y., Ozaki T.  
*Pain Research and Management* 2016 2016 Article Number 7458534  
Embase [Abstract](#) [Index Terms](#) [View Full Text](#)

☐ 3 Granulomatous lobular mastitis in pregnancy: A case report  
Ilhan B., Kilic B., Bademler S., Ozgur I., Turkey R., Karanlik H.

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Email addresses should be separated by a semi-colon (;)

Email format ☒ HTML ☐ Text ☐ RIS (as an attachment)

Content selection

Frequency  on

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

This is the history of alert "PV alert" as exported on 01 May 2016 19:38 GMT. This alert was originally set up on 22 Dec 2015 10:11 GMT.							
Alert name	Event	Search que	Date & time (GMT)	Records in	Frequency	Recipients	Status
PV alert	Automatic run	'adverse d	25.04.2016 03:10	2353	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	18.04.2016 03:10	3446	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	11.04.2016 03:10	1913	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	04.04.2016 03:10	2178	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	28 Mar 2016 03:10	2923	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	21 Mar 2016 03:10	2192	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	14 Mar 2016 03:10	2131	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Send now alert	'adverse d	08 Mar 2016 15:25	315	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Edited (content sele	'adverse d	08 Mar 2016 15:25	n/a	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	07 Mar 2016 03:10	3215	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	29.02.2016 03:10	1716	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Edited (enabled)	'adverse d	22.02.2016 18:46	n/a	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Edited (disabled)	'adverse d	22.02.2016 18:46	n/a	Every week on Monday	i.krstic@elsevier.com	Off
PV alert	Send now alert	'adverse d	22.02.2016 18:43	0	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	22.02.2016 03:10	2383	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	15.02.2016 03:10	3209	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	08.02.2016 03:10	1906	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	01.02.2016 03:10	2871	Every week on Monday	i.krstic@elsevier.com	On
PV alert	Automatic run	'adverse d	25.01.2016 03:10	1820	Every week on Monday	i.krstic@elsevier.com	On

# Summary

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In this presentation, we've 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 to identify:**
  - **Device performance**
  - **Comparison of device with existing device(s)**
  - **Device safety – finding adverse device effects**
- **How to set an automatized search for PMS**



# Thank you!

Any questions?

Dr. Ivan Krstić  
Senior Product Development  
Manager Embase  
[i.krstic@elsevier.com](mailto:i.krstic@elsevier.com)

# Embase content flow

