



ELSEVIER

# What's new in Embase<sup>®</sup>?

The details of our July 2019 release



# New! Medical device search framework

To ensure that your post market surveillance literature monitoring is as comprehensive as possible, we're adding a new Medical device search to Embase.

From July 2019, Embase users can run a post market surveillance search for medical devices in just a few steps:

- Select the device term
- Add synonyms to the device
- Add general device adverse effects
- Add specific device adverse effects
- Limit to clinical or pre-clinical studies
- Limit to a specific time frame

# European Medical Device Regulations (MDR 2017/745) reflect more stringent requirements for Clinical Data and a continuous process of Clinical Evaluation



The new MDR Article 2 defines:

**Clinical evaluation** means a systematic and planned process to continuously **generate, collect, analyse and assess the clinical data** pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.

# A stepwise framework for building complex medical device post-market surveillance (PMS) queries

The screenshot displays the Embase 'Device wizard' interface. At the top, the Embase logo and navigation links (Search, Entree, Journals, Results, My Tools, My Account, Logout) are visible. Below the navigation bar, the 'Device wizard' title and a 'Select language' dropdown are present. The main content area is titled 'Medical device search form' and is divided into three sections, each highlighted with an orange border:

- Device name:** This section contains a search input field with the text 'Name: Medical thermometer' and a '4 name variants' button. An 'OR' operator is positioned between the input field and the variants button.
- Adverse reactions:** This section contains a search input field with the text 'General device adverse reaction snippet' and an '+ Add device specific adverse reactions' button. An 'AND' operator is positioned to the left of this section.
- Query details:** This section contains several sub-sections:
  - Subheadings:** A list of checkboxes for 'Adverse device effect', 'Clinical trial', 'Device comparison', and 'Device economics'. 'Adverse device effect' and 'Device economics' are checked.
  - Search in:** A dropdown menu labeled 'Choose field'.
  - Limit to:** A list of checkboxes for 'Human studies' and 'Animal studies'. 'Human studies' is checked.
  - Publication years:** A range slider with '1996' on the left and '2014' on the right. The slider is currently set to '2000' to '2010'.
  - Records added to Embase (including end date):** A checkbox that is currently unchecked.
  - Choose dates:** A dropdown menu.

At the bottom of the interface, a blue button displays 'Show 64,719 results'.

# Post market surveillance for medical devices on one page

- Sensitive search using syntax and **specific** suggestions

## INPUT

Medical device search form

Device name

Name:  OR

Include subheading

Adverse device effect  Clinical trial

Device comparison  Device economics

AND

Adverse effects

OR

AND

Query details

Limit to

Human studies  Animal studies

Publication years  >1988

Records added to Embase

Select date


01-01-2019 to 31-12-2019

Show 6,571 results

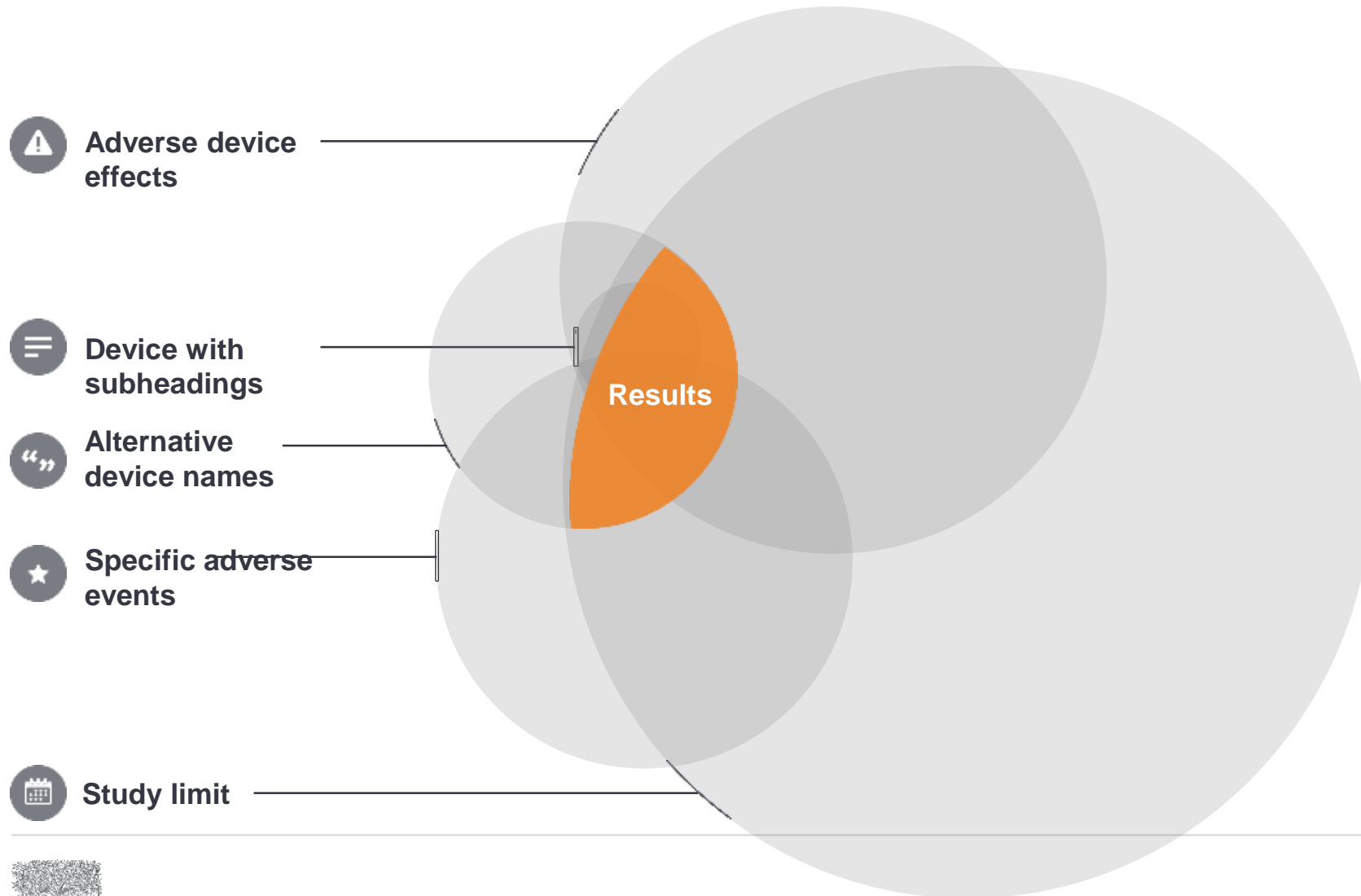
## QUERY

(stent:de,ab,ti OR 'stent/exp/adverse device effect' OR 'corinthian (device)':tn,ti,ab OR 'e-luminexx':tn,ti,ab OR 'hanarostent':tn,ti,ab OR 'hanaro stent':tn,ti,ab OR 'herculink elite':tn,ti,ab OR 'lifestent':tn,ti,ab OR 'parodi (device)':tn,ti,ab OR 'stent':tn,ti,ab OR 'stenting':tn,ti,ab OR 'stents':tn,ti,ab) AND ('adverse device effect'/exp OR 'adverse device effect'/lnk OR 'device safety'/exp OR 'device failure'/exp OR 'complication'/exp OR 'risk'/exp OR 'side effect'/exp OR 'injury'/exp OR 'death'/exp OR 'device induced':de,ab,ti,kw OR 'misplacement':de,ab,ti,kw OR 'complicat':de,ab,ti,kw OR 'risk':de,ab,ti,kw OR 'safe':de,ab,ti,kw OR 'complaint':de,ab,ti,kw OR 'injur':de,ab,ti,kw OR 'death':de,ab,ti,kw OR 'died':de,ab,ti,kw OR 'mortality':de,ab,ti,kw OR 'fatalit':de,ab,ti,kw OR 'obstruction':de,ab,ti,kw OR 'failure':de,ab,ti,kw OR 'perforat':de,ab,ti,kw OR 'rupture':de,ab,ti,kw OR 'breakag':de,ab,ti,kw OR 'malfunction':de,ab,ti,kw OR 'impair':de,ab,ti,kw OR 'hazardous':de,ab,ti,kw OR 'irritant':de,ab,ti,kw OR 'irritat':de,ab,ti,kw OR '((device OR equipment) OR mechanical OR technical) NEAR/2 (safety OR fail' OR withdrawal OR ineff' OR problem' OR removal' OR loosen' OR migrat')):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) OR 'in-stent restenosis'/exp OR 'stent thrombosis'/exp OR 'medical device complication'/exp OR 'stent migration'/exp OR 'stent complication'/exp OR 'stent fracture'/exp OR 'endoleak'/exp OR 'stent dislodgement'/exp OR 'bleeding'/exp OR 'stenosis'/exp OR 'stent malapposition'/exp OR 'stent deformation'/exp OR 'cerebrovascular accident'/exp OR 'brain hemorrhage'/exp OR 'stent collapse'/exp OR 'thromboembolism'/exp OR 'thrombosis'/exp OR 'aortic dissection'/exp OR 'blood vessel injury'/exp OR 'brain ischemia'/exp OR 'device infection'/exp OR 'heart infarction'/exp OR 'hepatic encephalopathy'/exp OR 'hyphema'/exp OR 'perforation'/exp OR 'recurrent disease'/exp OR 'aortic rupture'/exp OR 'arteriovenous fistula'/exp OR 'artery dissection'/exp OR 'bile leakage'/exp OR 'blood vessel occlusion'/exp OR 'brain artery aneurysm rupture'/exp OR 'embolism'/exp OR 'false aneurysm'/exp OR 'fistula'/exp OR 'graft infection'/exp OR 'granuloma'/exp OR 'heart disease'/exp OR 'hematoma'/exp OR 'hemoptysis'/exp OR 'hyperplasia'/exp OR 'in stent stenosis' OR 'intraocular hypotension'/exp OR 'metallic implant corrosion'/exp OR 'postoperative complication'/exp OR 'stent dislocation' OR 'stent edge dissection' OR 'thorax pain'/exp OR 'ulcer'/exp OR 'vasospasm'/exp OR 'abdominal pain'/exp OR 'absence of side effects'/exp OR 'acute diseases'/exp OR 'acute kidney failure'/exp OR 'acute liver failure'/exp OR 'acute otitis media'/exp OR 'acute pancreatitis'/exp OR 'airway obstruction'/exp OR 'alar injury' OR 'anastomosis leakage'/exp OR 'aneurysm'/exp OR 'aneurysm rupture'/exp OR 'anterior chamber inflammation' OR 'anterior eye chamber disease'/exp OR 'aortobronchial fistula' OR 'aortointestinal fistula'/exp OR 'artery occlusion'/exp OR 'artery perforation'/exp OR 'artery rupture'/exp OR 'bacterial infection'/exp OR 'bile duct fistula'/exp OR 'biliary stent dysfunction' OR 'biliary tract disease'/exp OR 'billowing' OR 'blood vessel perforation'/exp OR 'blood vessel rupture'/exp OR 'bradycardia'/exp OR 'brain embolism'/exp OR 'bronchus laceration' OR 'bronchus perforation'/exp OR 'cardiovascular disease'/exp OR 'cataract'/exp OR 'cholestasis'/exp OR 'choroid disease'/exp OR 'choroidal effusion' OR 'chronic disease'/exp OR 'columellar tear' OR 'cornea edema'/exp OR 'coronary artery aneurysm'/exp OR 'coronary artery occlusion'/exp OR 'coughing'/exp OR 'dacryocystitis'/exp OR 'delayed in-stent stenosis' OR 'device migration'/exp OR 'digestive system perforation'/exp OR 'duodenal stent dysfunction' OR 'duodenum disease'/exp OR 'dysphagia'/exp OR 'encephalitis'/exp OR 'endothelial dysfunction'/exp OR 'epithelium hyperplasia'/exp OR 'erosion'/exp OR 'external auditory canal stenosis' OR 'external ear disease'/exp OR 'extravasation'/exp OR 'eye discomfort'/exp OR 'fever'/exp OR 'foreign body reaction'/exp OR 'foreign body sensation' OR 'graft dysfunction'/exp OR 'graft migration' OR 'graft occlusion'/exp OR 'granulation tissue formation' OR 'groin hematoma'/exp OR 'headache'/exp OR 'heart arrhythmia'/exp OR 'heart death'/exp OR 'heart ventricle arrhythmia'/exp OR 'hematothorax'/exp OR 'hematuria'/exp OR 'hypotension'/exp OR 'ileus'/exp OR 'inadvertent extraction' OR 'infection'/exp OR 'inferior mesenteric arterial type ii endoleak' OR 'inflammation'/exp OR 'intestine perforation'/exp OR 'intracranial aneurysm'/exp OR 'intraocular hemorrhage'/exp OR 'intrathoracic anastomotic leak' OR 'laceration'/exp OR 'lacrimocutaneous fistula' OR 'late stent thrombosis' OR 'leg ischemia'/exp OR 'limb pain'/exp OR 'limb swelling'/exp OR 'liver abscess'/exp OR 'longitudinal stent compression' OR 'lung edema'/exp OR 'macular edema'/exp OR 'major adverse cardiac event'/exp OR 'malapposition' OR 'microstent exposure' OR 'mucosa inflammation'/exp OR 'mucosal disease'/exp OR 'mucostasis' OR 'nasal floor dehiscence' OR 'neurological complication'/exp OR 'obstructive ilio caval lesion' OR 'occlusive cerebrovascular disease'/exp OR 'ophthalmoplegia'/exp OR 'osteomyelitis'/exp OR 'otalgia'/exp OR 'pac man sign' OR 'pain'/exp OR 'pancreatitis'/exp OR 'perforator vessel stroke' OR 'peroperative complication'/exp OR 'phrenic nerve paralysis'/exp OR 'postthrombosis syndrome'/exp OR 'prolapse'/exp OR 'prosthesis dislocation'/exp OR 'prosthesis loosening'/exp OR 'pulmonary artery dissection' OR 'pulmonary aspiration'/exp OR 'puncture point bleeding' OR 'rare disease'/exp OR 'recurrent dacryocystitis' OR 'recurrent microhyphema' OR 'retina disease'/exp OR 'retinal epithelial defect' OR 'retroperitoneal hemorrhage'/exp OR 'sepsis'/exp OR 'shunt disconnection' OR 'shunt infection'/exp OR 'shunt malposition' OR 'side branch complication' OR 'skin necrosis'/exp OR 'skin ulcer'/exp OR 'stent displacement' OR 'stent distal migration' OR 'stent embolization' OR 'stent erosion' OR 'stent extraction' OR 'stent failure' OR 'stent graft induced new entry' OR 'stent loss' OR 'stent prolapse' OR 'stent recoil' OR 'stent underexpansion'/exp OR 'stomach paresis'/exp OR 'subarachnoid hemorrhage'/exp OR 'sudden cardiac death'/exp OR 'suprachoroidal bleeding' OR 'thrombophilia'/exp OR 'thrombotic thrombocytopenic purpura'/exp OR 'vascular erosion' OR 'vein occlusion'/exp OR 'vein thrombosis'/exp OR 'venous sinus stenosis' OR 'vestibular disorder'/exp OR 'vestibular stenosis' OR 'wound infection'/exp OR 'xerostomia'/exp) AND [humans]/lim AND [1-1-2019]/sd NOT [1-1-2020]/sd



 Set email alert

# The fundamentals of the device search form



## Search Summary

Start [Device] / [Subheading]  
OR ([Device name]  
AND ([Adverse device effects]  
OR [Special adverse effects]))  
AND [Study limit]

# Finding adverse device effects: all possible mentions

## INPUT

## OUTPUT QUERY

• 3,923 hits

The screenshot shows the Embase 'Device wizard' search interface. It includes a search bar with 'Medical thermometer' entered, an 'AND' button, a section for 'Adverse reactions' with a 'General device adverse reaction snippet' and an 'OR' button, and a 'Query details' section with checkboxes for 'Adverse device effect', 'Clinical trial', 'Device comparison', and 'Device economics'. There is also a 'Limit to' section with checkboxes for 'Human studies' and 'Animal studies', and a 'Publication years' range from 1996 to 2014. A 'Show 64,719 results' button is at the bottom.

1. Type in a device term

2. Specify the adverse effects

3. Limit to: patients; time frame

'everolimus eluting coronary stent'/exp OR 'promus element' OR 'promus element plus' OR 'xience alpine' OR 'xience prime' OR 'xience prime II' OR 'xience xpedition' OR 'xience nano' OR 'xience-v' OR 'everolimus eluting coronary stent' OR 'xience' OR 'xience v  
AND ('adverse device effect'/exp OR 'adverse device effect'/lnk OR 'device safety'/exp OR 'device failure'/exp OR 'device infection'/exp OR 'complication'/exp OR 'risk'/exp OR 'side effect'/exp OR 'injury'/exp OR 'death'/exp OR 'device induced':de,ab,ti,kw OR misplacement\*:de,ab,ti,kw OR complicat\*:de,ab,ti,kw OR risk\*:de,ab,ti,kw OR safe\*:de,ab,ti,kw OR complaint\*:de,ab,ti,kw OR injur\*:de,ab,ti,kw OR death\*:de,ab,ti,kw OR died:de,ab,ti,kw OR mortality:de,ab,ti,kw OR fatalit\*:de,ab,ti,kw OR obstruction\*:de,ab,ti,kw OR failure\*:de,ab,ti,kw OR perforat\*:de,ab,ti,kw OR rupture\*:de,ab,ti,kw OR breakag\*:de,ab,ti,kw OR malfunction\*:de,ab,ti,kw OR impair\*:de,ab,ti,kw OR hazardous:de,ab,ti,kw OR irritant\*:de,ab,ti,kw OR irritat\*:de,ab,ti,kw OR ((device OR equipment OR mechanical OR technical) NEAR/2 (safety OR fail\* OR withdrawal OR ineff\* OR problem\* OR removal\* OR loosen\* OR migrat\*)):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 OR (patient\* NEAR/2 (discomfort\* OR risk\*)):de,ab,ti,kw)

# Thank you

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