Increased support for medical device research: the new Emtree® release

Why are Emtree releases important?
Emtree is Elsevier’s life sciences thesaurus, used to index the records in Embase® and ensure accurate retrieval and consistent description. Terminologies used by MHRA, Emmet, FDA and WHO are the essential sources for choosing the relevant concepts and terms for Emtree.

As of May 2018, Emtree contained:
- 81,000+ preferred terms, of which 32,000+ are for drugs and chemicals
- 355,000+ synonyms, of which 204,000+ are for drugs and chemicals
- 82 subheadings and 52 check tags
- All the terms from the MEDLINE® thesaurus MeSH® terms
- 24,000+ CAS registry numbers

With each Emtree release, terms for the latest drugs, diseases, devices and procedures are added and used for indexing, with back-posting of older records. This ensures that Embase users can search extensively with more synonyms (including trade names) mapping to each drug and device term. This makes finding answers easier and faster.

**Our second Emtree release for 2018** focuses on medical devices, adding 615 new medical device concepts and 3,763 device trade names.

The following areas are the focus of this release:
- The ‘diagnostic kit’ branch: 50 new concepts added
- The ‘prosthesis and orthosis’ branch: 54 new concepts added
- The ‘catheters and tubes’ branch: 32 new concepts added
- The ‘bandages and dressings’ branch: 24 new concepts added
- The ‘dental device’ branch: 47 new concepts added
- The ‘nerve stimulator’ branch: 14 new concepts added
- The ‘ostomy device’ branch: 13 new concepts added
- The ‘forceps’ branch: 10 new concepts added
- The ‘endoscope’ branch: 20 new concepts added
- The ‘lens implant’ branch: 10 new concepts added
- 3,673 device trade names added
- Review and restructure of the ‘orthopedic prosthesis and orthosis’ and ‘orthopedic implant’ branches

As of May 2018, Emtree contained:
- 4,300+ preferred terms for medical devices
- 15,400+ synonyms, including device trade names
Medical device literature searches on the rise

Peer-reviewed and grey literature containing technical information and safety issues, case reports, and clinical trial registries are all considered important as sources for both pre- and post-market medical device research activities.

1. Pre-market research

In June 2016, the European Commission released Revision 4 of MEDDEV 2.7/1: Clinical Evaluation: Guide for Manufacturers and Notified Bodies. This provides regulatory guidance for a robust and systematic clinical evaluation process supporting scientifically valid clinical evaluation reports. These guidelines should be applied to all medical devices sold in the European Union, including those manufactured elsewhere.

For instance, a manufacture that plans to implement design changes to a Class III device is required to submit a clinical evaluation report to the Notified Body with clear clinical evidence to support the design changes and the benefits and risks of the device. Evidence from the biomedical literature is considered important alongside clinical experience and clinical trials.

2. Post-market surveillance

In May 2017, the European Medical Device Regulation and In Vitro Diagnostics Regulations came into effect, introducing more incisive and prescriptive measures for post-market surveillance. The information to be collated includes:

- Details of serious incidents
- Records referring to non-serious incidents
- Data on any undesirable side effects
- Trend reports
- Relevant content from specialist and/or technical literature, databases and/or registers
- Feedback, including complaints, provided by users, distributors and importers
- Publicly available information about similar medical devices

Finding the right literature for clinical evaluation reports and post-market surveillance

Embase is recommend by MEDDEV 2.7/1 rev 4 as an important source of evidence.

“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.”
Embase offers:

- Unmatched coverage of drugs, devices and therapies in use in Europe and the rest of world
- Unique coverage of 2,900+ journals not available in MEDLINE
- Grey literature, including over 2.9 million conference abstracts since 2009
- Extensive coverage of non-English content and randomized controlled trials
- Powerful search capabilities with dedicated frameworks for systematic reviews and device searches
- Strategy management functionalities for creating, saving, sharing and scheduling complex searches

Crucially for clinical evaluation reports and post-market surveillance, Embase has in-depth indexing of medical device items, which supports:

- Consistent and precise search and retrieval of published clinical evidence
- Discovery of links between device subheadings and concepts, making it easier to identify adverse device effects, make comparisons, research economics and identify clinical evidence
- Discovery of device trade names and manufacturer names

Learn more about Embase support for medical device clinical evaluation and post-market surveillance in this recent webinar presented by our expert Dr. Ivan Krstic.

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