

Embase Indexing Guide 2020

A comprehensive guide to Embase indexing policy

Contents

| | | |
|-------|---------------------------------------------|----|
| 1. | Introduction | 3 |
| 2. | The Embase database | 3 |
| 3. | Scope of Embase | 3 |
| 4. | How Embase articles are indexed | 4 |
| 4.1 | Indexing principles | 4 |
| 4.2 | Indexing process | 4 |
| 4.3 | Emtree thesaurus | 4 |
| 4.4 | Major/minor terms | 4 |
| 4.5 | Quality control | 5 |
| 5. | Embase indexing in detail | 6 |
| 5.1 | Original versus non-original articles | 6 |
| 5.2 | Item types | 6 |
| 5.3 | Index terms | 7 |
| 5.3.1 | General terms | 7 |
| 5.3.2 | Check tags | 7 |
| 5.3.3 | Drug terms | 7 |
| 5.3.4 | Subheadings | 7 |
| 5.3.5 | Drug trade names and manufacturers | 10 |
| 5.3.6 | Device trade names and manufacturers | 10 |
| 5.3.7 | Clinical trial numbers | 10 |
| 5.3.8 | Molecular sequence numbers | 10 |
| 5.3.9 | CAS Registry Numbers | 11 |
| 5.4 | Candidate terms | 11 |
| 5.5 | Automatic indexing | 11 |
| 5.6 | Embase section headings | 11 |
| 6. | Coverage of MEDLINE in Embase | 12 |

Appendices

1. Embase check tags (with scope notes)
2. Embase subheadings
3. Embase section headings

1. Introduction

This indexing guide describes the indexing policy for journals covered by Embase. Although not intended to be a practical search guide, it will help you formulate search queries and will give you some insight as to what results you can expect. In other words, this guide focuses not on *How to search* but on *What to search*.

2. The Embase database

Embase, produced by Elsevier B.V., is the largest and arguably most comprehensive Abstract and Indexing (A&I) database for peer-reviewed biomedical information available today - both as a stand-alone database (www.embase.com) and via traditional vendor platforms.

Embase provides reliable access to the content of millions of articles using extensive and authoritative indexing. Together with its sister product Embase Classic, Embase covers nearly 38 million¹ articles back to 1947, and is growing at over 1.7 million records a year.

Indexing is based upon the Elsevier Life Science Thesaurus, Emtree. Each article is indexed with as many terms as required to describe its content, with a special focus on drugs, devices and diseases.

3. Scope of Embase

As a biomedical database covering around 8,100 journal titles¹, Embase covers all disciplines of medicine and biomedical science, and includes substantial coverage of Allied Health subjects.

How articles are indexed depends both on the origin of the source journals and the stage in the production process:

- Almost 6,300 Embase titles are indexed by Elsevier using the guidelines described in this Guide. This includes about 3,300 journals which represent the core titles of biomedical science and are also covered by MEDLINE.
- A further 1,800 MEDLINE titles that are considered relatively less important for the core content of Embase (drugs and clinical science) are licensed from NLM. Indexing for these titles is derived from the MeSH terms assigned by NLM by mapping to Emtree in order to maximize consistency of access and retrieval (see Section 6).
- Since 2009, Embase has covered conference abstracts published primarily in journal supplements. These abstracts, which represent the entire record (i.e. there is no full-length article with additional content), are indexed using automated procedures based upon the manual guidelines described here (see Section 5.5).
- Automated procedures are also used to provide a provisional index for articles-in-press and “in-process” records which have not yet been fully manually indexed.

¹ Status November 2019

4. How Embase articles are indexed

4.1 Indexing principles

Indexing facilitates consistent and comprehensive retrieval of information from Embase, significantly enhancing search options which would otherwise be limited to citation and abstract only. Embase embodies three core principles of indexing:

- In assigning index terms, indexers check the full article (not just title and abstract).
- Index terms are controlled by the Emtree thesaurus (see below), resulting in consistent coverage of concepts that may be expressed in many ways in the literature.
- Indexing is carried out according to well-defined guidelines (summarized in this Guide), which further enhances the consistency of the database.

4.2 Indexing process

With the exception of articles designated for automatic indexing (see Section 5.5), indexing for Embase is a manual process performed by trained indexers with a biomedical background.

Indexers read and analyze the full text of articles in order to identify relevant concepts, and index them with the most specific Emtree terms. At the same time, they index other terms in fields not validated by Emtree, such as drug and device trade names and manufacturer names, clinical trial numbers and molecular sequence numbers.

The English title and abstract (if present) are used to index articles which are not in English.

4.3 Emtree thesaurus

Emtree, also known as the Elsevier Life Science Thesaurus, contains almost 84,000 biomedical preferred terms and 380,000 synonyms ordered within 14 facets (topic-specific taxonomies) including anatomy, diseases, organisms, biochemical functions, biomedical procedures, health care concepts, study types and geographical areas among others².

The largest facet, “chemicals and drugs”, includes both *drugs* (see Section 5.3.3) and chemical entities of every kind, from endogenous compounds to environmental toxins. This facet accounts for almost half of all Emtree preferred terms and over 60% of its synonyms.

As well as being an essential search tool, the Emtree thesaurus functions as a key indexing aid. Using Emtree, indexers can identify the correct preferred term for any concept they find in the full text of the articles they read. Users can therefore be confident in their use of Emtree preferred terms for searching.

Example: *Navelbine* and *vinorelbine* are alternative names for the same drug. Without indexing, both names would have to be searched to maximize retrieval. However, with the help of Emtree all records are indexed with the preferred term *navelbine*, so that comprehensive retrieval is assured using this term alone. If users instead search using the synonym *vinorelbine*, Emtree maps this term to *navelbine*, thus ensuring identical results.

4.4 Major/minor terms

When reading and analyzing articles, indexers ensure that each relevant concept is identified by an index term. In addition, they designate selected terms representing the focus of the article as *major* terms. All other terms are (by extension) *minor* terms.

Articles are indexed with an average of 3-4 major terms, and up to 50 minor terms are possible, though there is much variation. Since the major status of a searched index term identifies the most relevant records in a search, it is a useful tool to limit retrieval.

² Status November 2019

4.5 Quality control

An important aspect of indexing for Embase is quality control. Quality control is carried out at two stages of the indexing process:

- Validation during indexing: indexers are warned if they attempt to index terms in the wrong field, or if terms cannot be found in Emtree.
- Overall indexing quality: this is monitored in monthly checks using representative samples. Feedback is given to the indexers to improve the quality of their work.

5. Embase indexing in detail

The Embase indexing guidelines described in this Guide are applied to the core content of Embase (see Section 3), 6,300 journals which are indexed by Elsevier, including all major drug and clinical journals. Approximately two thirds of articles are indexed with at least one drug or chemical term.

For articles derived from the 1,800 additional MEDLINE journals included in Embase, MeSH terms are mapped to Emtree to provide indexing that is compatible with Elsevier indexing (see Section 6).

5.1 Original versus non-original articles

Embase covers both original literature (e.g. research articles) and non-original literature (e.g. reviews). Original articles are typically identified using the Item types *article* and *conference paper*. The most important non-original Item types are *review* and *short survey*.

Original articles. Only original (new) information is indexed. Information originating from other publications (e.g. background information in the Introduction or results from other studies mentioned in the Discussion) is not indexed.

Non-original articles. Only topics that are substantially discussed are indexed. Although the check tags *human*, *nonhuman*, and *systematic review* are indexed whenever the definition applies, other check tags are only indexed if they are the main topic of the article. Similarly, subheadings for disease, drug, and device terms are only indexed if they are the main topic of the article.

5.2 Item types

Every record in Embase is identified by a single item type (also known as a publication type). Item types are defined with scope notes as follows:

| | |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Article | Original research or opinion |
| Conference abstract | Abstract or poster item presented at a conference or symposium |
| Conference paper | Original article reporting data presented at a conference or symposium |
| Conference review | Review item summarizing conference abstracts presented at a single conference or symposium |
| Data paper | Used for searchable metadata documents describing a particular on-line accessible dataset, or a group of datasets, published in accordance to the standard academic practices. |
| Editorial | Item summarizing several articles or providing editorial news |
| Erratum | Item reporting an error, correction or retraction of a previously published paper |
| Letter | Letter to or correspondence with the editor |
| Note | Note, discussion or commentary |
| Review | Significant review of original research |
| Short survey | Short or minireview of original research |

5.3 Index terms

The following categories of index term may be assigned in Embase:

- general terms (controlled by Emtree)
- drug terms (controlled by Emtree)
- check tags (controlled by Emtree)
- candidate terms (not controlled)
- drug, disease and device subheadings
- drug trade names and manufacturers
- device trade names and manufacturers
- clinical trial numbers
- molecular sequence numbers
- CAS registry numbers

Each of these categories is discussed below. All articles³ are indexed with general terms and check tags, and over two thirds of articles with drug terms. Other categories are assigned or generated when applicable.

5.3.1 General terms

General terms are defined as all Emtree terms that are not drugs or chemicals, and include terms from all 13 Emtree facets other than “chemicals and drugs” (see Section 4.3). They are distinguished from drug terms in that the latter are indexed in greater depth (Section 5.3.3).

5.3.2 Check tags

Check tags comprise 58 terms including most item types (see Section 5.2), study types and age groups (see Appendix 1) whose definitions are described by scope notes. Check tags are assigned using a [check list](#) to ensure the highest possible consistency of indexing.

5.3.3 Drug terms

Drug terms are index terms used for all drugs and chemicals: not only therapeutic drugs, but also endogenous compounds, laboratory chemicals and environmental chemicals or toxins. It is important to realize that “drug terms” as defined in Embase may refer to any chemical entity.

Clinical drugs. Clinical drugs are defined as compounds, factors or preparations that are in clinical use, or have a potential clinical use, as therapeutic, palliative, prophylactic or diagnostic agents. They are indexed in greater depth than other drug terms, by which is meant both that they are indexed even when they are not the primary focus of the article, provided at least some significant information is available, and that they are generally modified using drug subheadings as described in Section 5.3.4.2.

Drug group names. Drug group names (e.g. *antineoplastic agent*) are indexed if the group as a whole is discussed, or when they are required as “umbrella terms” for candidate drug terms (see Section 5.4).

Other drug terms. Drug terms that do not fall under the above definition of clinical drugs (for example endogenous compounds) follow the same indexing policy as general terms: they are indexed when relevant to the article.

5.3.4 Subheadings

Subheadings are Emtree terms that are also used as concept modifiers for drugs, diseases and devices. When used as *drug subheadings*, *disease subheadings* and *device subheadings*, these terms are defined by scope notes (see Appendix 2).

Nine subheadings (5 for drugs, 2 for diseases and 2 for devices) are denoted *key subheadings*. For these concepts, the following sections describe how they are indexed in greater depth.

³ In this guide “article” is used as a shorthand to refer to any item type

Disease subheadings

Disease subheadings may be used to modify any disease term, e.g. *infection* or *myocardial infarction*. They are assigned whenever applicable, as defined in their scope notes. Among the 14 disease subheadings, two are designated as *key* subheadings:

- *drug therapy*: when this subheading is indexed, the drugs used to treat the indexed disease are also indexed with drug subheading *drug therapy*.
- *side effect*: when this subheading is indexed, the drugs reporting the indexed side effect are also indexed with drug subheading *adverse drug reaction*.

Drug subheadings

There are 64 drug subheadings, including 47 routes of drug administration. Among the 17 other subheadings, five are designated as *key* subheadings:

- *drug therapy*: when this subheading is indexed, the diseases treated are also indexed with the disease subheading *drug therapy*.
- *adverse drug reaction*: when this subheading is indexed, all reported adverse reactions are also indexed with the disease subheading *side effect*. See also Section 5.3.5.
- *drug comparison*: all drugs compared to the indexed drug are also indexed with the same drug subheading, *drug comparison*.
- *drug combination*: all drugs given concomitantly with the indexed drug are also indexed with the same drug subheading, *drug combination*.
- *drug interaction*: all drugs that show an interaction with the indexed drug are also indexed with the same drug subheading, *drug interaction*.

In general, assignment of any drug subheading requires a certain emphasis in the article on that concept. Exceptions are *drug therapy*, *adverse drug reaction*, *endogenous compound* and *routes of drug administration*, which are used whenever they can be applied.

In addition, these drug subheadings warrant special attention:

- *drug toxicity* and *endogenous compound*: these subheadings can be used to modify all drug terms. All other drug subheadings, including *routes of drug administration*, can only be used to modify *clinical drugs* (as defined in section 5.3.3).
- *clinical trial*: this subheading is used only for prospective clinical trials on drugs. In contrast, the check tag *clinical trial* can also be used for other medical interventions.
- *drug administration*: although specific *routes of drug administration* are indexed whenever applicable, the subheading *drug administration* is only used when the route of drug administration is a significant aspect.

Device subheadings

Four device subheadings were introduced in March 2014 and may be used to modify any general or medical device. Two are defined as *key* subheadings:

- *adverse device effect*: when this subheading is indexed, the adverse effects are also indexed when possible with the disease subheading *complication*
- *device comparison*: all devices compared to the indexed device are also indexed with the device subheading *device comparison*

Adverse drug reactions

Adverse effects are a key aspect of Embase indexing. This section describes how they are indexed in Embase.

When an adverse effect is reported for a drug, this is indexed as follows:

- The drug is modified by the drug subheading *adverse drug reaction*
- The specific disease adverse effect(s) are modified by the disease subheading *side effect*
- In Embase.com, this indexing is displayed as a triplet:

```
cimetidine * adverse drug reaction * constipation
constipation * side effect * cimetidine
```

The following rules apply for the indexing of adverse effects:

- The adverse effect is always indexed from original data items, whether reported as severe or not. Indexing of an adverse effect as a major descriptor means that it is a main topic of the article. It does not imply that the effect is reported as severe.
- All adverse effects in Embase are disease terms⁴. If an adverse drug effect is reported that cannot be designated by a disease term, it is still indexed - but since Embase requires that a disease term is indexed as a side effect for every reported adverse drug reaction, in this case the disease term *side effect* is additionally indexed and modified by the disease subheading *side effect*, leading to a format as shown in this example, where risperidone causes weight gain (which is not a disease term):

```
risperidone * adverse drug reaction *side effect
weight gain
side effect * side effect
```

- If an article only reports adverse effects in general for a specific drug (without mentioning any specific adverse effect), the disease term *unspecified side effect* is indexed (modified by the subheading *side effect*)

PV subheadings **[NEW]**

We introduced two new categories of subheadings for pharmacovigilance reporting:

- Special situation for pharmacovigilance: the special situation subheading links a drug to a special situation term, indicating if the drug was used under special circumstances or in a particular population.
- Unexpected outcomes of drug treatment: the unexpected outcome subheading links a drug to an unexpected outcome term, it captures specific information about the efficacy of the drug.

⁴ There is an exception in the case of articles originating from MEDLINE: see Section 6

5.3.5 Drug trade names and manufacturers

For all drug index terms, any trade names mentioned in the article are indexed in a separate drug trade names field. Both ‘true’ trade names (registered trademarks) and laboratory codes can be indexed in this way.

Similarly, drug manufacturers mentioned in the article in relation to the drug index terms (either in combination with the trade name or alone) are indexed in a separate drug manufacturers field. Designations of legal entities (e.g. Co., Comp., GmbH, Inc.) as part of the manufacturer name are omitted.

Search tip: to find articles with a specific drug trade name (e.g. *aspirin*), search for this name in the drug trade names field. A similar search in the indexing field (where many trade names are mapped to the corresponding generic name as preferred term) will retrieve articles indexed with the *generic name*, and may not be about the specific trade name.

5.3.6 Device trade names and manufacturers

General and medical devices are broadly defined as equipment, reagents or systems intended for use in healthcare and, more specifically, in the diagnosis, prevention, treatment, cure or mitigation of disease in humans, animals or animal models. These include:

- Patient-related equipment such as prostheses, infusion systems, contraceptive devices
- Laboratory-related equipment such as analyzers and centrifuges
- Diagnostic test systems such as kits and culture media
- In-vitro reagents used in healthcare applications
- Computer software used in healthcare

Excluded are contrast media and substances defined in Embase as drugs.

Devices are indexed when relevant device-related information is given in the article, and device trade names and/or manufacturer names (if mentioned in the article) are indexed in designated fields by analogy with drug trade names and manufacturer names.

5.3.7 Clinical trial numbers

Clinical trial numbers are the numbers under which a clinical trial is registered at one of the registries, registered at the World Health Organization. They have been indexed for Embase since 2007.

Search tip: to find articles with registration details for a drug clinical trial, search the drug name with the subheading *clinical trial* and limit your results to records for which clinical trial numbers have been indexed.

5.3.8 Molecular sequence numbers

Molecular sequence numbers are the accession numbers under which nucleic acid or amino acid sequences can be found in their respective repositories (Genbank, PIR & SWISSPROT). The repository name and accession number for all molecular sequence numbers mentioned in Embase articles are indexed.

Only newly submitted sequences are indexed. However, these designations are not visible and searchable on all platforms.

Search tip: to find articles discussing a protein’s amino acid sequence, search the protein name and limit your results to records containing molecular sequence numbers. If there are many results, consider in addition limiting the protein name to “major terms”.

5.3.9 CAS Registry Numbers

Chemical Abstracts Service (CAS) Registry Numbers are generated (when available) for all drug terms and are displayed together with the corresponding drug name.

Since some drug derivatives (such as the hydrate or hydrochloride) are defined as synonyms of a single (more generic) Emtree preferred term, more than one CAS number may be generated for each preferred term. For instance, *amantadine* has two CAS numbers: one for “amantadine” (768-94-5) and one for amantadine hydrochloride (665-66-7).

5.4 Candidate terms

Indexers may find that terms discussed in articles are valuable additions for enrichment of Emtree. In such cases a *candidate term* may be indexed, together with a broader Emtree term covering the new term at a higher level (an “umbrella” term). For example, when a new antiviral agent is designated as a candidate term, indexers also assign the broader term *antiviral agent*. For candidate *drug* terms, the term *unclassified drug* is also indexed.

Search tip: to find articles in which new antiviral agents have been indexed as candidate terms, search using the terms *antiviral agent* and *unclassified drug*.

More than 100,000 candidate terms – drugs, diseases, devices and other terms - are proposed each year, including many which are never indexed more than a handful of times. Frequently indexed candidate terms are evaluated regularly for possible inclusion in Emtree, including synonyms which may have been separately indexed as candidate terms. For new drug terms, a CAS Registry Number is also assigned if possible.

In the case of drugs, new entities may initially be designated as laboratory codes and only later using chemical names, trade names or generic names. In Emtree, the preferred term is always the generic name, if it is available. When older terms are replaced in Emtree by newer terms, articles with the older index terms can be *backposted* so that the old terms are replaced by the new index terms. This procedure is used on Embase.com but is not available on all platforms.

5.5 Automatic indexing

Automatic indexing for selected articles was introduced into Embase in 2009. Three types of article are indexed in this way:

- conference abstracts
- articles in press
- in-process records

Automatically indexed articles are indexed with Emtree terms, selected by an algorithm which is applied to the text of titles, abstracts and author keywords.

The algorithm can differentiate major and minor index terms; however, candidate terms and subheadings are not indexed. Non-Emtree indexing such as trade names, manufacturer names, clinical trial numbers and molecular sequence numbers is also not indexed.

5.6 Embase section headings

In addition to assigning index terms, indexers also classify articles to Embase *section headings* (e.g. *Cancer* or *Surgery*). These headings correspond to the printed Abstract Journal titles in which Embase abstracts have traditionally been published: see Appendix 3 for a complete list.

Each article is assigned at least one such section heading. Normally, articles are assigned no more than five or six section headings.

6. Coverage of MEDLINE in Embase

More than 3,300 of the 5,260 journal titles currently indexed for MEDLINE are independently indexed for Embase by Elsevier, using the guidelines described in this Indexing Guide⁵.

For articles from another 1,800 MEDLINE titles (with a focus on basic biomedicine, Allied Health and other topics that are peripheral to the core topics of Embase), MeSH index terms are mapped to Emtree to provide an index that is compatible with the Elsevier indexing.

- MeSH terms and check tags (all MeSH terms are included in Emtree)
- MeSH subheadings (many are also found in Emtree; where this is not the case, or when the definition is slightly different, an appropriate translation is made)
- Publication types
- Numerical codes (molecular sequence numbers, clinical trial numbers): these are used to generate the corresponding Embase code

Records licensed from MEDLINE are not indexed with Embase-specific indexing such as trade names and manufacturer names, or with Embase classifications.

⁵ Status November 2019

Appendix 1: Embase check tags⁶ (with scope notes)

Human study types

| | |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| human | Used for all items where humans are a feature, including studies on human tissue, cells or cell components |
| normal human | Used for original studies on normal humans or normal (non- diseased) human tissue |
| major clinical study | Used for original items reporting clinical work on greater than 50 patients |
| clinical article | Used for original studies reporting clinical work on 1–50 patients |
| case report | Used for original studies reporting clinical work which details the symptoms, signs, diagnosis, treatment, and follow-up of one or more individual patients (cases) that are indicated by information such as initials, patient identification number, date of birth, age, age group or gender. Also used when identified as such by the author/s |
| human experiment | Used for original items reporting experiments on humans (e.g. psychological tests and pharmacokinetic studies) which are not clinical (the study subjects are not studied as patients) |
| human tissue | Used for original studies on normal or diseased human tissue |
| human cell | Used for original studies on normal or diseased human cells |

Animal study types

| | |
|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| nonhuman | Used for all items on non-human organisms (animals, bacteria, viruses, plants etc.) or on tissue, cells or cell components from such organisms |
| animal experiment | Used for original studies using whole animals |
| animal tissue | Used for original studies on normal or diseased animal tissue |
| animal cell | Used for original studies on normal or diseased animal cells |
| animal model | Used for original studies using animal models of disease |

⁶ Item types are also defined as check tags (see section 5.2) but are not included in this Appendix

Sex and age

| | |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| male | Used for items reporting either clinical or experimental studies mentioning male humans or animals, including studies on tissue, cells or cell components |
| female | Used for items reporting either clinical or experimental studies mentioning female humans or animals, including studies on tissue, cells or cell components |
| embryo | Used as an age indicator in human or animal studies; in humans, the first trimester after conception |
| fetus | Used as an age indicator in human or animal studies; in humans, the second and third trimesters after conception |
| newborn | Used as an age indicator in human or animal studies; in humans up to 1 month of age |
| infant | Used as an age indicator in human or animal studies; in humans, between 1 month and 1 year of age |
| child | Used as an age indicator in human studies identifying children between 1–12 years of age (or unspecified) |
| preschool child | Used as an age indicator in human studies identifying children between 1–6 years of age |
| school child | Used as an age indicator in human studies identifying children between 7–12 years of age |
| adolescent | Used as an age indicator in human or animal studies; in humans, 13–17 years of age |
| adult | Used as an age indicator in human or animal studies; in humans, 18–64 years of age |
| young adult | Used as an age indicator in human or animal studies; in humans, 18–24 years of age |
| middle aged | Used as an age indicator in human or animal studies; in humans, 45–64 years of age |
| aged | Used as an age indicator in human or animal studies; in humans, greater than 64 years of age |
| very elderly | Used as an age indicator in human or animal studies; in humans, 80 years of age and older |

Clinical trials

| | |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| clinical trial | Used for original reports of prospective clinical studies in which the (comparative) efficacy of one or more medical interventions in humans is evaluated; also used for prospective clinical veterinary trials in which the (comparative) efficacy of one or more medical interventions in animals is evaluated |
| controlled clinical trial | Used for original reports of clinical trials using a control group (e.g. placebo, sham or no treatment, standard intervention) for comparison with the experimental intervention |
| phase 1 clinical trial | Used for original items in which the reported studies are defined as phase 1 clinical trials (limited to drug trials) |
| phase 2 clinical trial | Used for original items in which the reported studies are defined as phase 2 clinical trials (limited to drug trials) |
| phase 3 clinical trial | Used for original items in which the reported studies are defined as phase 3 clinical trials (limited to drug trials) |
| phase 4 clinical trial | Used for original items in which the reported studies are defined as phase 4 clinical trials (limited to drug trials) |
| meta analysis | Used for original reports evaluating medical interventions by the statistical analysis of a large collection of analysis results from individual studies, for the purpose of integrating the findings; not limited to clinical trials |
| randomized controlled trial | Used for original reports of clinical trials using a control group (e.g. placebo, sham or no treatment, standard intervention) for comparison with the experimental intervention, with random allocation of subjects to experimental and control groups |
| double blind procedure | Used for original items reporting clinical trials that utilize a double blind procedure. Also used for non-original studies, but only if the concept is a main topic |
| single blind procedure | Used for original items reporting clinical trials that utilize a single blind procedure. Also used for non-original studies, but only if the concept is a main topic |
| crossover procedure | Used for original items reporting clinical trials that utilize a crossover procedure. Also used for non-original studies, but only if the concept is a main topic |
| multicenter study | Used for original reports of clinical trials performed at two or more medical centers |

Other study types

| | |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| observational study | Used for an original study that is a report on a clinical study in which the subjects may receive diagnostic, therapeutic, or other types of interventions, but the subjects are not assigned to specific interventions (as in an interventional study); usually identified as such by the author/s |
| pilot study | Used for an original study that is a report of a small-scale test of a method or procedure to be used on a larger scale if the pilot study demonstrates that the method or procedure can work; usually identified as such by the author/s |
| longitudinal study | Used for an original study that is a report of an assessment of variables relating to an individual or group of individuals over a period of time; usually identified as such by the author/s |
| retrospective study | Used for an original study that is a report on tests of etiological hypotheses about exposure to causal factors relating to characteristics of the patients in the study or to events/experiences in the past; patients with the disease or outcome are compared to unaffected subjects; usually identified as such by the author/s |
| case control study | Used for an original study that starts with the identification of patients with a disease of interest and a control (comparison, referent) group and reports on the relationship of an attribute to the disease by comparing patients identified as having the disease to healthy subjects with regard to the frequency or levels of the attribute in each group; usually identified as such by the author/s |
| cohort analysis | Used for an original study identifying subsets of a defined population in which exposure to factors could influence the likelihood of the disease or other outcome; cohorts are defined populations which are followed to determine distinguishing subgroup characteristics; usually identified as such by the author/s |
| cross-sectional study | Used for an original study in which the presence or absence of disease or other health-related variables are determined in each member of the study population or in a representative sample at one particular (moment in) time; this is in contrast to a longitudinal study which follows patients over a period of time; usually identified as such by the author/s |
| systematic review | Used for studies that systematically summarize all relevant evidence pertaining to a defined health question, and including items identified as such by the author/s |
| controlled study | Used for original studies with a control group, i.e. in which previously defined groups are compared with each other. Also used for studies with control material or control procedures. Retrospective studies may also be included |
| diagnostic test accuracy study | Used for original studies or systematic reviews which assess how accurately a test distinguishes humans or animals having a condition or disease from those who do not. Typically, the test under evaluation is called the index test and its results are compared to the results of the best available standard test (reference standard), which defines the condition or disease |

Appendix 2: Embase subheadings

Subheadings in Embase may be linked with disease terms (disease subheadings), device terms (device subheadings), or drug terms (drug subheadings). Key subheadings are underlined.

Disease subheadings

| | |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| complication | Used as a disease subheading for a disorder or symptom which arises as a complication of a pre-existing disease or medical procedure other than drug treatment |
| congenital disorder | Used as a disease subheading when attention is drawn to the congenital nature of a disease or malformation, including hereditary disorders present at birth |
| diagnosis | Used as a disease subheading when information is published on the diagnosis of disease or the application of diagnostic tests |
| disease management | Used as a disease subheading to identify a disease for which information is published on the evaluation of health care, including cost aspects, treatment outcome or quality of life studies |
| drug resistance | Used as a disease subheading to identify a disease for which resistance to drug treatment (other than drug tolerance) is a significant aspect |
| <u>drug therapy</u> | Used as a disease subheading to identify a disease or condition treated with a drug |
| epidemiology | Used as a disease subheading for the epidemiology of a disease, including its morbidity and mortality |
| etiology | Used as a disease subheading for both the etiology (causative factors) and pathogenesis (pathological mechanisms) of a disease |
| prevention | Used as a disease subheading to identify a disease for which information is published on its prevention and control, including prophylactic treatment with drugs or vaccines |
| radiotherapy | Used as a disease subheading for the treatment of a disease using radiotherapy |
| rehabilitation | Used as a disease subheading when information is published on procedures to rehabilitate patients recovering from a disease |
| <u>side effect</u> | Used as a disease subheading for a condition which arises as an undesired effect of a drug used at therapeutic dose ranges in humans, including drug-induced disease |
| surgery | Used as a disease subheading when information is published on the application of surgical procedures or techniques to treat a disease |
| therapy | Used as a disease subheading when information is published on any treatment of a disease other than by drug therapy, radiotherapy or surgery |

Device subheadings

| | |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <u>adverse device effect</u> | Used as a device subheading to identify a device that is used for diagnostic, therapeutic or procedural purposes in humans or animals, and for which an undesired effect is reported |
| clinical trial | Used as a device subheading when the clinical trial of a device is reported |
| <u>device comparison</u> | Used as a device subheading when two or more devices are compared within the same study |
| device economics | Used as a device subheading for the economic evaluation of a device, including cost analysis, treatment outcome and quality of life studies |

Drug subheadings

| | |
|-------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <u>adverse drug reaction</u> | Used for any untoward (adverse) medical occurrence in a patient/subject administered a medicinal product (drug) not necessarily having a causal relationship with the treatment. This subheading applies to humans or animals. For animal studies it is limited to veterinary clinical studies |
| clinical trial | Used for a drug in an original item that is the report of a prospective clinical study, in which the (comparative) efficacy of the drug in humans is evaluated; use also for prospective clinical veterinary trials in which the (comparative) efficacy of the drug in animals is evaluated; contrast with drug development, limited to those drugs that are the subject of the study |
| drug administration | Used as a drug subheading when the route of drug administration is emphasized |
| drug analysis | Used as a drug subheading for the identification, determination or structural analysis of a drug or potential drug |
| <u>drug combination</u> | Used as a drug subheading for drugs given in combination or concomitantly |
| <u>drug comparison</u> | Used as a drug subheading when two or more drugs are compared within the same study |
| drug concentration | Used as a drug subheading when information is published on the concentration of a drug in body fluids or tissues |
| drug development | Used as a drug subheading for the stages of drug development from screening, isolation and synthesis up to testing in animals, but excluding trials in humans |
| drug dose | Used as a drug subheading when drug dosage, including the relation between dosage and effects over time, is a significant factor |
| <u>drug interaction</u> | Used as a drug subheading for interactions between drugs, or between a drug and food, alcohol or other chemicals in humans or animals |
| <u>drug therapy</u> | Used as a drug subheading to identify a drug used to treat disease (including curative, palliative, symptomatic or prophylactic treatment) |
| drug toxicity | Used for toxicity of drugs or other chemicals in animals (including LD50 tests), in animal or human cells & tissues, and in other toxicity studies. Indexed for substances for which toxicity is reported or investigated (including chemical toxicity) |
| endogenous compound | Used as a drug subheading for a substance that is endogenous to the organism, tissue, cells or body fluids being studied |
| pharmaceutics | Used as a drug subheading for the formulation of a drug or drug mixture, including the physical and chemical properties of drugs relevant to drug pharmacy |
| pharmacoeconomics | Used as a drug subheading for the economic evaluation of drug therapy, including cost analysis, treatment outcome and quality of life studies |
| pharmacokinetics | Used as a drug subheading for the kinetics of absorption, distribution, biotransformation or elimination of a drug in humans and animals |
| pharmacology | Used as a drug subheading for the mechanism of action of a drug, including drug binding to receptors and drug sensitivity/resistance studies (other than for microorganisms) |
| <u>special situation for pharmacovigilance</u> [NEW] | Used for any drug administered in one of the special situations |
| <u>unexpected outcome of drug treatment</u> [NEW] | Used for any drug which treatment resulted in one of the unexpected outcomes |

Special situation for pharmacovigilance [NEW]

| | |
|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| compassionate use | Used in the case of compassionate use of a drug or an expanded access program/trial for a drug. Used when indicated as such by the author/s |
| counterfeit drug | Used when the authors suspect or confirm a falsified drug. Used when indicated as such by the author/s |
| disease transmission via medicinal product | Used when the authors suspect or confirm the transmission of an infectious agent via a drug or a medicinal product. Used when indicated as such by the author/s |
| drug abuse | Used in the case of drug abuse. Drug abuse is the intentional excessive use of a drug accompanied by harmful physical or psychological effects. Used when indicated as such by the author/s |
| drug exposure during lactation | Used when a nursing infant is exposed to a drug through breast feeding. Used when indicated as such by the author/s |
| drug misuse | Used in the case of drug misuse. Drug misuse is the intentional and inappropriate use of a drug not in accordance with the authorized product information. Used when indicated as such by the author/s |
| drug overdose | Used in the case of a drug overdose. Used when indicated as such by the author/s |
| drug quality defect | Used when the authors suspect or confirm a quality defect of a drug. Used when indicated as such by the author/s |
| aged | Used when a drug is used for elderly patients (for humans age 65 years and over) |
| kidney failure | Used when the drug is used by patients with kidney failure. Used when indicated as such by the author/s |
| liver failure | Used when the drug is used by patients with liver failure. Used when indicated as such by the author/s |
| medication error | Used in the case of a medication error, including medication errors through device malfunction. Used when indicated as such by the author/s |
| named patient program | Used in the case of drugs used in a named-patient program. Used when indicated as such by the author/s |
| occupational drug exposure | Used in the case of exposure to a drug as a result of one's occupation. Used when indicated as such by the author/s |
| off label drug use | Used in the case of off-label drug use. Off-label use is the intentional use of a drug for a medical purpose not in accordance with the authorized product information. Used when indicated as such by the author/s |
| pediatric patient | Used when a drug is used for pediatric patients (for humans less than 18 years of age) |
| prenatal drug exposure | Used when the embryo or fetus is exposed to a drug through the parent. Used when indicated as such by the author/s |

Unexpected outcome of drug treatment [NEW]

| | |
|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| lack of drug effect | Used when the authors report a lack of therapeutic efficacy of the drug |
| partial drug response | Used when the authors report a partial response of the drug |
| unexpected therapeutic effect | Used when the authors report an unexpected therapeutic drug effect |
| disease worsening with drug treatment | Used when the authors report disease worsening after drug therapy. The authors must make a connection between drug and the disease worsening |

Routes of drug administration

Drug administration routes all have the scope note “Route of drug administration”. For a further explanation of the route, users are advised to consult a medical dictionary.

| | |
|---------------------------------------------|-------------------------------------|
| buccal drug administration | intraspinal drug administration |
| epidural drug administration | intrathecal drug administration |
| inhalational drug administration | intratracheal drug administration |
| intraarterial drug administration | intratumoral drug administration |
| intraarticular drug administration | intratympanic drug administration |
| intrabronchial drug administration | intraurethral drug administration |
| intrabursal drug administration | intrauterine drug administration |
| intracameral drug administration | intravaginal drug administration |
| intracardiac drug administration | intravenous drug administration |
| intracavernous drug administration | intravesical drug administration |
| intracerebral drug administration | intravitreal drug administration |
| intracerebroventricular drug administration | oral drug administration |
| intracisternal drug administration | parenteral drug administration |
| intradermal drug administration | periocular drug administration |
| intraduodenal drug administration | rectal drug administration |
| intra gastric drug administration | regional perfusion |
| intralesional drug administration | retrobulbar drug administration |
| intralymphatic drug administration | subconjunctival drug administration |
| intramuscular drug administration | subcutaneous drug administration |
| intranasal drug administration | sublabial drug administration |
| intraocular drug administration | sublingual drug administration |
| intraosseous drug administration | topical drug administration |
| intraperitoneal drug administration | transdermal drug administration |
| intrapleural drug administration | |

Appendix 3: Embase section headings

| | |
|---------|-----------------------------------------------------------------|
| 1 | Anatomy, anthropology, embryology and histology |
| 2 | Physiology |
| 3 | Endocrinology |
| 4 * | Microbiology: bacteriology, mycology, parasitology and virology |
| 5 | General pathology and pathological anatomy |
| 6 | Internal medicine |
| 7 | Pediatrics and pediatric surgery |
| 8 | Neurology and neurosurgery |
| 9 * | Surgery |
| 10 | Obstetrics and gynecology |
| 11 | Otorhinolaryngology |
| 12 | Ophthalmology |
| 13 | Dermatology and venereology |
| 14 | Radiology |
| 15 | Chest diseases, thoracic surgery and tuberculosis |
| 16 | Cancer |
| 17 | Public health, social medicine and epidemiology |
| 18 | Cardiovascular diseases and cardiovascular surgery |
| 19 | Rehabilitation and physical medicine |
| 20 | Gerontology and geriatrics |
| 21 | Developmental biology and teratology |
| 22 | Human genetics |
| 23 | Nuclear medicine |
| 24 | Anesthesiology |
| 25 | Hematology |
| 26 | Immunology, serology and transplantation |
| 27 | Biophysics, bioengineering and medical instrumentation |
| 28 | Urology and nephrology |
| 29 | Clinical and experimental biochemistry |
| 30 | Clinical and experimental pharmacology |
| 31 | Arthritis and rheumatism |
| 32 | Psychiatry |
| 33 | Orthopedic surgery |
| 34 * | Plastic surgery |
| 35 | Occupational health and industrial medicine |
| 36 | Health policy, economics and management |
| 37 | Drug literature |
| 38 | Adverse reaction titles |
| 39 ** | Pharmacy |
| 40 | Drug dependence, alcohol abuse and alcoholism |
| 46 | Environmental health and pollution control |
| 47 * | Virology |
| 48 | Gastroenterology |
| 49 | Forensic science abstracts |
| 50 | Epilepsy abstracts |
| 51 *** | Leprosy and other mycobacterial diseases |
| 52 **** | Toxicology |

* 1974-1991. Sections 47 and 34 were incorporated into sections 4 and 9 respectively in 1992

** Introduced in 1997

*** 1979-1988. Incorporated into section 4 (Microbiology: bacteriology, mycology, parasitology and virology) in 1989

**** Introduced in 1983