

# **Embase Indexing Guide 2024**

*A comprehensive guide to Embase indexing policy*

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## 1 Introduction

This indexing guide describes the indexing policy for journals covered by Embase. It shows what is indexed, how it is indexed and in how much detail. It is intended to give you some insight as to what can be used in a search to give the results you require.

## 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 ([embase.com](https://www.embase.com)) and via traditional vendor platforms.

Embase provides reliable access to the content of millions of articles<sup>1</sup> using extensive and authoritative indexing. Together with its sister product Embase Classic, Embase covers over 45 million<sup>2</sup> 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

Embase covers all disciplines of medicine and biomedical science and includes substantial coverage of Allied Health subjects. For the latest information on journal coverage visit <https://www.elsevier.com/products/embase/content>.

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

- Most of the journal articles are indexed by Elsevier using the guidelines described in this Guide. This includes the journals which represent the core titles of biomedical science and are also covered by MEDLINE.
- 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 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 4.2).
- Since November 2021, Embase covers preprints from several sources. The abstracts of these preprints are indexed using automated procedures.
- 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.

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<sup>1</sup> In this guide “article” is used as a shorthand to refer to any item (publication) type

<sup>2</sup> As of January 2024

## 4 How Embase articles are indexed

### 4.1 Indexing process

Each record is first indexed by automatic indexing where articles are indexed with Emtree terms, selected by an algorithm which is applied to the text of the title, the abstract (if present) and author keywords (if present).

An automated process selects records which have one or more Emtree disease, drug, or device terms, or are reviews or short surveys which are a case report, a meta-analysis or a systematic review<sup>3</sup> for manual indexing performed by trained indexers with a biomedical background.

Automatic indexing is retained until the status of the article changes to published (from in press) or to processed (from in process), then the article is sent for manual indexing.

Non -English articles with an English title and abstract (if present) will be indexed based upon the English title and abstract (if present) only.

### 4.2 Automatic indexing

With automatic indexing, articles are indexed with Emtree terms, selected by an algorithm which is applied to the text of the title, the abstract (if present) and author keywords (if present). Automatic indexing was introduced into Embase in 2009 and updated to a new technology in 2023. The algorithm can differentiate major and minor index terms; however, candidate terms and subheadings are not indexed. Trade names, manufacturer names, clinical trial numbers, and molecular sequence numbers are not indexed by automatic indexing<sup>4</sup>.

Automatic indexing is retained (no manual indexing is done) for records which are:

- not selected for manual indexing (do not have one or more Emtree disease, drug, or device terms in the automatic index)
- conference abstracts or preprints
- reviews or short surveys which are not a case report, a meta-analysis or a systematic review

### 4.3 Manual indexing

Manual indexing facilitates consistent and comprehensive retrieval of information from Embase, significantly enhancing search options which would otherwise be limited to citation and abstract only.

Records which have one or more Emtree disease, drug, or device terms, are reviews or short surveys which are a case report, a meta-analysis, or a systematic review, are selected by an automated process for manual indexing.

With manual indexing, driven by the indexing principles, 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, and other concepts such as clinical trial numbers and molecular sequence numbers.

#### 4.3.1 Indexing principles

Embase embodies three core principles of indexing:

- Assign index terms by checking the full article (not just title and abstract)
- Translate concepts, that may be expressed in many ways in the literature, to Emtree terms (the Embase controlled vocabulary) to ensure consistent coverage for optimal retrieval.
- Index concepts in accord with well-defined guidelines (summarized in this Guide) to ensure comprehensive and consistent coverage in the database.

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<sup>3</sup> From July 2024

<sup>4</sup> As of January 2024

#### 4.4 Emtree thesaurus

Emtree<sup>5</sup>, also known as the Elsevier Life Science Thesaurus, contains nearly 99,000 biomedical preferred terms and nearly 548,000 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 others.

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 more than one third of all Emtree preferred terms and about 50% 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 *vinorelbine tartrate*, so that comprehensive retrieval is assured using this term alone. If users instead search using the synonym *vinorelbine*, Emtree maps this term to *vinorelbine tartrate*, thus ensuring identical results.

#### 4.5 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.

#### 4.6 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) 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 in the additional MEDLINE journals included in Embase, MeSH terms are mapped to Emtree to provide indexing that is compatible with Elsevier indexing (see Section 6).

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<sup>5</sup> As of January 2024

## 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. Studies where the authors report, analyze and discuss their findings from original research work done by systematic investigation. The authors present a hypothesis or a research question, describe the purpose of the study, detail the research methods, report the results, analyze, and interpret the results and discuss possible implications. Includes meta-analyses and systematic reviews.

Concepts are indexed comprehensively to capture the essence of the study, guided by the context of item: objective of the study for the major concepts; details on the subjects, the type of study, the study set-up, the procedures, drugs, and medical devices (usually found in the materials and methods, methods, patients and methods, or similar); original findings and outcomes, especially adverse drug reactions and adverse device effects (primarily found in the results, sometimes parts of the discussion and the conclusion). Findings and related information taken from other publications (in the results and discussion) are not indexed.

Non-original articles. Studies where the authors report, analyze and discuss findings from previously published research work. The authors present the work as a narrative, there is a lack of details of the research methods, and the analysis and interpretation of results is based on a pooling or gathering of original results and findings from original published research.

Only the main topics are indexed. Although the check tags *human* and *nonhuman* 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 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	Searchable metadata document 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:

from controlled vocabulary (Emtree)	not from Emtree
general terms	candidate terms
drug terms	drug, disease and device subheadings
device terms	drug trade names and manufacturers
disease terms	device trade names and manufacturers
check tags	clinical trial numbers
(CAS registry numbers: generated from drug term)	molecular sequence numbers

All articles 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 diseases, drugs or chemicals, or medical devices and include terms from all Emtree facets other than “chemicals and drugs” (see Section 4.4), the subfacets “diseases” and “devices”. General terms are not indexed to the same depth.

### 5.3.2 Check tags

*Check tags* comprise 52 terms including 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, which means that they are indexed when they are used in an original study. Clinical drugs are generally modified using drug subheadings as described in Section 5.3.5.2.

*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 Medical device terms

Device terms are index terms used for all devices: not only therapeutic devices, but also for devices used in the laboratory.

*Medical devices.* Medical devices are equipment, instruments, apparatuses, implements, machines, prostheses, implants, in vitro 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—that do not normally enter metabolic pathways. They are indexed in greater depth than other device terms, which means that they are indexed when they are used in an original study. Medical devices are generally modified using device subheadings as described in Section 5.3.5.5.

These include but are not limited to:

- devices such as artificial organs, prostheses, implants, catheters, infusion systems, inhalers, contraceptive devices, inert materials (e.g., bone cement, silicone)
- diagnostic imaging equipment
- anesthetic equipment, cardiovascular equipment
- other healthcare technology such as computer software, including imaging software for radiography (CT, X-ray, MRI), health apps for cell phones, and workstations
- tests and test systems for diagnostic purposes, laboratory-related equipment such as analyzers, cell sorters and centrifuges, assays, kits and culture media
- in vitro reagents, when used in healthcare applications. These substances are indexed as drug terms, and their trade names (if mentioned) are indexed as drug trade names
- equipment such as hospital beds, wheelchairs, surgical gloves, bandages and dressings

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

*Other device terms.* Device terms that do not fall under the above definition of medical devices follow the same indexing policy as general terms: they are indexed when relevant to the article.

### 5.3.5 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.



### 5.3.5.1 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*.

### 5.3.5.2 Drug subheadings

There are 67 drug subheadings, including 47 routes of drug administration. 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 5.3.5.1.
- *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 or food that show an interaction with the indexed drug are also indexed with the same drug subheading, *drug interaction*.

For original studies, a drug subheading is assigned whenever it applies by definition to any drug used in the study. For non-original studies, a drug subheading is assigned if it is the main focus of the study.

The following 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.

### 5.3.5.3 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:  
for the drug: cimetidine \* adverse drug reaction \* constipation  
for the disease: 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 terms<sup>6</sup>. 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):  
weight gain  
risperidone \* adverse drug reaction \* side effect  
side effect \* side effect \* risperidone
- 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*)

#### 5.3.5.4 PV subheadings

There are two additional 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.

#### 5.3.5.5 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*

#### 5.3.6 Drug trade names and manufacturers

Any trade names mentioned for any of the drugs used in an original study 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.

#### 5.3.7 Device trade names and manufacturers

Any trade names mentioned for any of the medical devices used in an original study are indexed in a separate medical device trade names field. Both 'true' trade names (registered trademarks) and model numbers can be indexed in this way.

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

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<sup>6</sup> There is an exception in the case of articles originating from MEDLINE: see Section 6

### 5.3.8 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 and are indexed whenever they are mentioned in an article.

### 5.3.9 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 those molecular sequence numbers which are newly submitted to a repository mentioned in an original study are indexed. However, these designations are not visible and searchable on all platforms.

### 5.3.10 CAS Registry Numbers

Chemical Abstracts Service (CAS) Registry Numbers are generated (when available) for all indexed 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.

More than 100,000 candidate terms – drugs, diseases, devices and other terms – are proposed each month, 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 available.

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 was not available on all platforms until 2023. However, the new data delivery for platforms contains the backposting as well.

## 5.5 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

Most of the journal titles currently indexed for MEDLINE are independently indexed for Embase by Elsevier, using the guidelines described in this Indexing Guide.

For articles from other 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.

## Appendix 1: Embase check tags (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
mouse	Used for studies in which mice or mouse tissue/cells are used
rat	Used for studies in which rats or rat tissue/cells are used

## 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 compared 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 LD <sub>50</sub> 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)
special situation for pharmacovigilance	Used for any drug administered in one of the special situations
unexpected outcome of drug treatment	Used for any drug which treatment resulted in one of the unexpected outcomes

## Special situation for pharmacovigilance

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

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