ELSEVIER

Embase for Pharmacovigilance

Search Strategy Creation and Validation

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March 22th 2017

Agenda

In this webinar, we will discuss:

- Literature Screening for Pharmacovigilance – Intro
- Tips and Tricks – Embase Search Syntax
- How to Build a Search Strategy on Embase for PV Based on Industry Best Practices
- Demo – PV Wizard on embase.com

Pharmacovigilance

Pharmacovigilance is defined as the science and activities concerned with:

- **detection (Embase)**,
- assessment (**Quosa PV**),
- understanding and
- prevention

of **adverse reactions** to medicines.

The **ultimate goal of Pharmacovigilance** is to **improve the safe and rational use of medicines**, thereby:

- **improving patient care** and
- **improving public health**.

Regulatory Mandate for Literature Screening

- EMA's Good Vigilance Practice (GVP) Module VI
- Code of Federal Regulations, Title 21, parts 314.80.b
- Code of Federal Regulations, Title 21, parts 600.80.b

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA

EMA requirements (GVP Module VI)

VI.B.1.1.2. **Literature reports**

The scientific and medical literature is a significant source of information for the monitoring of the **safety profile and of the risk benefit balance of medicinal products**, particularly in relation to the detection of new safety signals or emerging safety issues. Marketing authorization holders are therefore expected to maintain awareness of possible publications through a **systematic literature review of widely used reference databases** (e.g. Medline, Excerpta Medica or **Embase**) no less frequently than once a week…

Reports of suspected adverse reactions from the scientific and medical literature, including relevant published **abstracts from meetings and draft manuscripts**, should be reviewed and assessed by marketing authorisation holders to identify and record ICSRs originating from spontaneous reports or non-interventional post-authorisation studies.

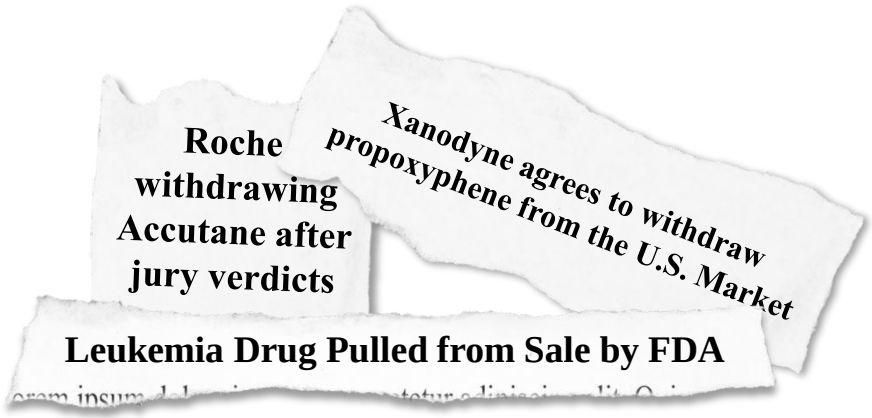
In addition, marketing authorisation holders should have procedures in place to **monitor scientific and medical publications** in **local journals** in countries where medicinal products have a marketing authorisation, and to bring them to the attention of the company safety department as appropriate.

Local literature project in pipeline. Interested?
Contact as at: embase@elsevier.com

Regulatory Compliance

Without Embase, critical ADR's might be missed, risking:

- Possible fines due to non-compliance
- Damage to company reputation
- Likelihood of review by gov't body

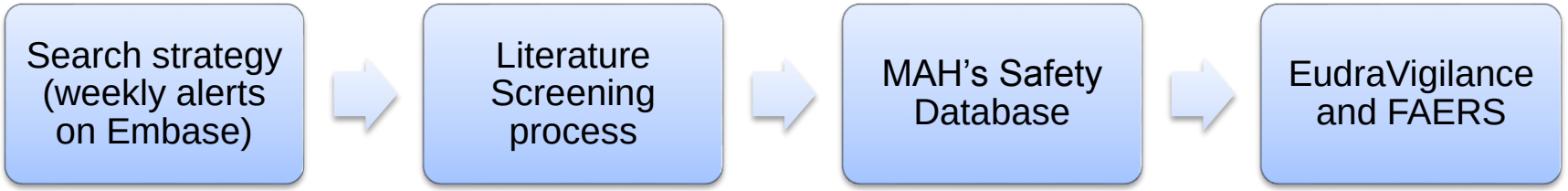


Why Embase?

- Comprehensive (8,600 journals, also AiP)
- Current (6,000 records/day)
- Deep indexing
- ADR subheadings
- Search for classes of drugs/ devices
- Weekly alerts
- Automate content delivery – API
- Lit. monitoring solution with QUOSA (PV)
- Includes grey literature (conference abstracts)
- 2,800 more journals than MEDLINE
- Recommended and used by EMA

Search Strategy for Literature Monitoring

Importance of Search Strategy in Literature Monitoring



Some consider that **search strategy creation and maintenance** should be handled as a **GxP** activity, needing **Verification and Validation**, as any other GxP process.

Although there is no specific regulatory mandate, the Literature Monitoring process can be (and in fact is) **inspected** and **audited**.

It is a field in which a QPPV must be ready to answer questions, and it must be described in the Pharmacovigilance System Master File (PSMF).

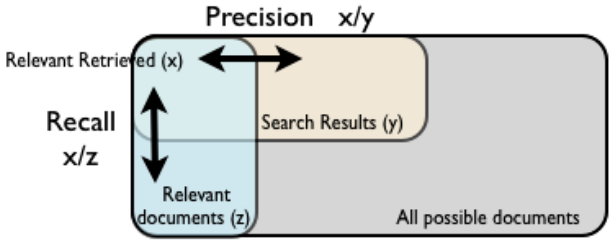
Search Strategy for Literature Monitoring

Validation of a search strategy consists of **documenting evidence** that a specific **search strategy** consistently produces a **set of records** meeting its pre-defined quality attributes.

Information science defines **Precision** and **Recall** as the two quality attributes of a search strategy.

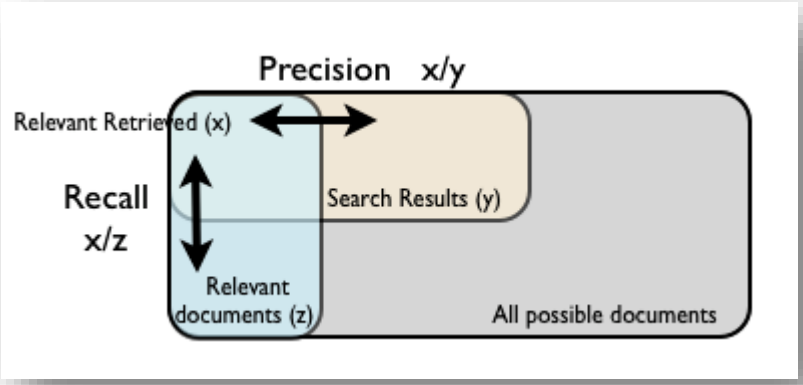
Precision: How many of the records in the result set are relevant to our need

Recall: From all records that are relevant to our need, how many are present in the search result



Precision and Recall

Precision and **Recall** are a balancing act. One has, usually, to sacrifice high Precision (let irrelevant records in) in order to get high Recall (not miss any relevant records).



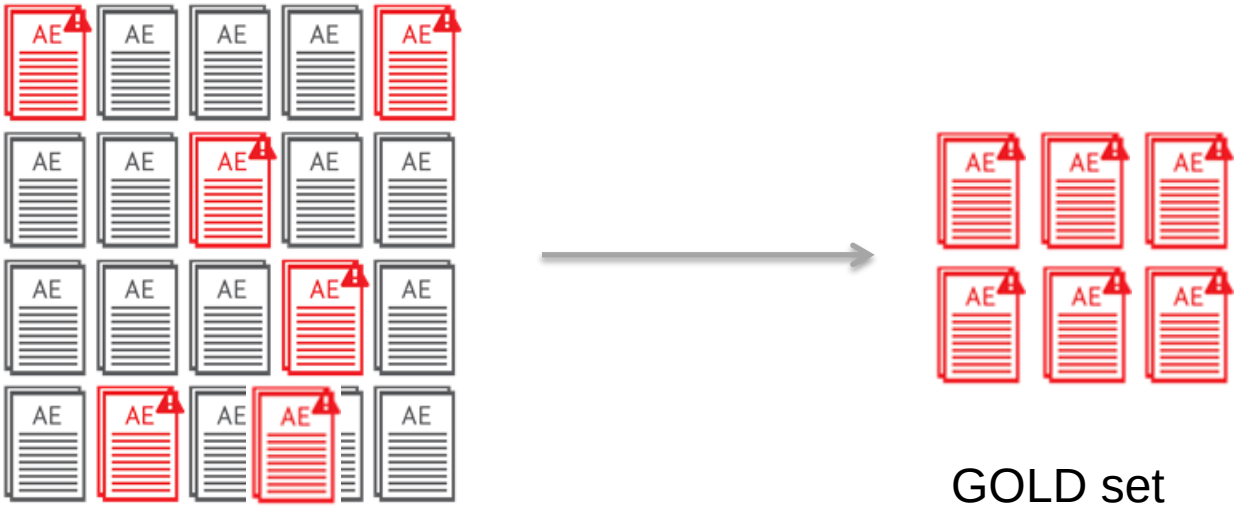
Precision impacts productivity: Low values mean too much noise (irrelevant records) is coming in, but **it can't be increased at the cost of Recall.**

Ideally the goal is to build a **search strategy with a recall close to 100% and as high as possible precision.**

Recall is the quality measurement of a literature monitoring search strategy.

Prerequisite

Presence of a **GOLD data set** from all known **relevant articles** for a limited time frame (no less than 150 articles)
e.g.: 2014-2017

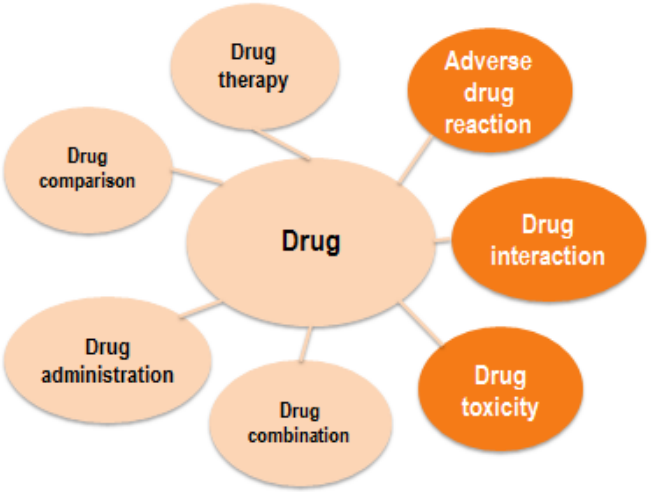


How to build search strategy – general tips

- Leverage **in-depth indexing** of drugs on Embase and use **Emtree terms** and **subheadings**.
- Text searching of the **title**, **abstract** required, as a supplementary measure.
- Great understanding of all the **fields** (meta data) available in the database (e.g.: **tradenames**)
- Good knowledge of the **search syntax** is required, e.g: **Boolean** and **proximity operators, wildcards**.
- Good understanding of the medicinal product properties and known interactions may also help.

Reminder: subheadings

Subheadings are Emtree terms that are also used as **concept qualifiers** for drugs to provide additional information about **context**.



Treatment of chronic non-malignant pain in the elderly: Safety considerations

Barber J.B., Gibson S.J.

Drug Safety 2009 **32:6** (457-474)

Go to publisher for the full text

Abstract

Non-malignant pain in the elderly is frequently under-treated, with physicians appearing to be uncertain concerning how best t aim of this review is to provide a brief overview and discuss the variety of interacting factors that contribute to the continuing u central objective is to encourage safer and more effective pain management in a population that is highly vulnerable to painful pain as experienced by the elderly is largely a consequence of uncertainties that arise within a complex environment that is un population. Uncertainties include the optimum management of pain in geriatric syndromes, frailty and dementia, and their imp an inadequate evidence base for pharmacological interventions in older persons with respect to pharmacokinetic and pharmac pain and the incidence of adverse drug reactions are identified as factors that encourage conservatism in prescribing, as are m of medications and polypharmacy.The major classes of analgesic drugs are summarized with reference to their mechanisms of have associated risks, the use of analgesics in managing persistent pain in elderly people is widely supported and guided on th pain management.It is concluded that the absence of trial data, specific to the elderly, is substantially offset by information bas analgesic and adjuvant treatments can and should be employed to relieve persistent pain in the expanding elderly population.

Drug Terms

acetylcysteine, acetylsalicylic acid, **analgesic agent**, anticoagulant agent, anticonvulsive agent, antidepressant agent, codeine, corticosteroid, cyclooxygenase 2 inhibitor, **dipeptidyl carboxypeptidase inhibitor**, diuretic ag oxidase inhibitor, morphine, **narcotic analgesic agent**, neuroleptic agent, **nonsteroid antiinflammatory agent** noradrenalin reuptake inhibitor, serotonin uptake inhibitor, tricyclic antidepressant agent, unindexed drug

paracetamol	
Key Subheadings	
adverse drug reaction	drug hypersensitivity, dyspepsia, gastrointestinal toxicity, hematologic disease, liver failure, nausea, nep
drug combination	acetylsalicylic acid, codeine, cyclooxygenase 2 inhibitor, narcotic analgesic agent, nonsteroid antiinflamm
drug interaction	anticoagulant agent, anticonvulsive agent, hypnotic sedative agent
drug therapy	chronic pain, musculoskeletal pain
Other Subheadings	
drug administration, drug concentration, drug dose, drug toxicity, oral drug administration, pharmacokinetics, pharmacology	

Reminder: Search syntax

Truncation / Wildcards		
* (replaces one or more letters)	sul*ur	retrieves sulfur, sulphur
	'heart attack*'	retrieves heart attack, heart attacks
? (single-letter truncation)	sulf?nyl	retrieves records that contain words like 'sulfonyl' and 'sulfinyl'
	catheter?	retrieves records that contain words like 'catheters', but not 'catheter' or 'catheterization'

Proximity operators		
NEAR/n	drug* NEAR/2 adverse	The words must be within n words inclusive of each other in the record
NEXT/n	adverse NEXT/2 reaction*	The words must be within n words inclusive of each other in the same order as they appear in the search form

Reminder: Search syntax

Field codes		
:ab,ti (in abstract or titles)	'heart attack':ab,ti	This option retrieves records where the phrase 'heart attack' is found in the title or abstract.
:de (Emtree term)	'heart attack':de	This option maps your search terms to the Emtree preferred indexing term.
/exp (term explosion)	'heart attack'/exp	This option maps your search terms to the Emtree preferred indexing term and then searches for the related narrower (children) terms.
/lnk (subheading)	'side effect'/lnk	Subheadings are concept qualifiers for drugs, diseases or devices used to refine context.

GVP Module VI

VI.B.1. Collection of reports
Competent authorities and marketing authorisation holders should take appropriate measures in order to **collect and collate all reports** of **suspected adverse reactions** associated with medicinal products for **human use** originating from unsolicited or solicited sources.

VI.B.6. Special situations
VI.B.6.1. Use of a medicinal product during **pregnancy** or **breastfeeding**
VI.B.6.2. Use of a medicinal product in a **paediatric** or **elderly** population
VI.B.6.3. Reports of **overdose**, **abuse**, **off-label use**, **misuse**, **medication error** or **occupational exposure**
VI.B.6.4. **Lack of therapeutic efficacy**

Building Search Strategy (Based on Industry Best Practices)

PV Search Strategy – full

'paracetamol'/'drug toxicity','drug interaction','adverse drug reaction'

OR ('paracetamol':de OR '4 acetamidophenol':tn,ab,ti OR '4 acetaminophenol':tn,ab,ti OR '4 acetylaminophenol':tn,ab,ti…

AND ('adverse drug reaction'/exp OR 'adverse drug reaction':lnk OR adverse:de,ab,ti OR ((side OR undesirable OR unwanted) NEXT/2 (effect* OR reaction* OR event* OR outcome*)):de,ab,ti OR 'side effect'/lnk OR 'side effect'/exp OR 'complication'/lnk OR 'complication'/exp OR complication*:de,ab,ti OR 'case report*':de,ab,ti …

OR 'pregnancy'/exp OR pregnant*:de,ab,ti OR pregnanc*:de,ab,ti OR 'pregnancy complication'/exp OR 'pregnancy disorder'/exp OR 'abortion'/exp OR 'abortion':de,ab,ti OR…))

AND ('human'/exp OR human OR m?n OR wom?n OR child OR boy OR girl)

Drug subheadings

Drug name and variants

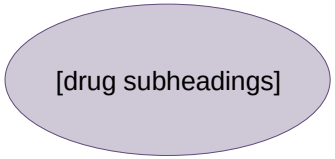
Adverse drug reaction concept

Special situations

Human limit

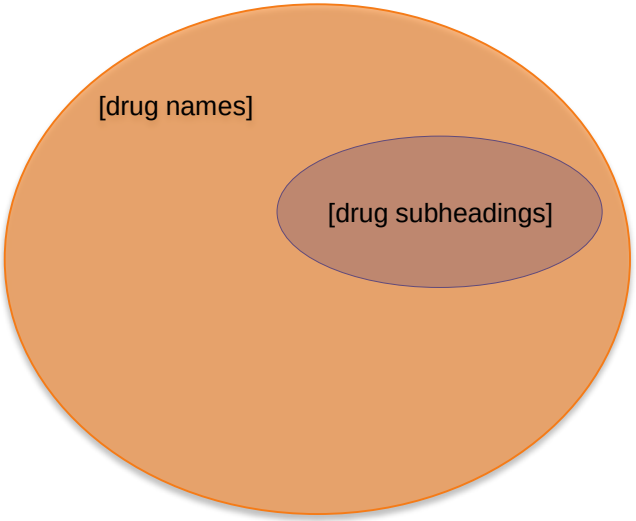
Recall 100%

PV Search Strategy – part 1



[drug]/[subheadings] **'paracetamol'/'drug toxicity','drug interaction','adverse drug reaction'**

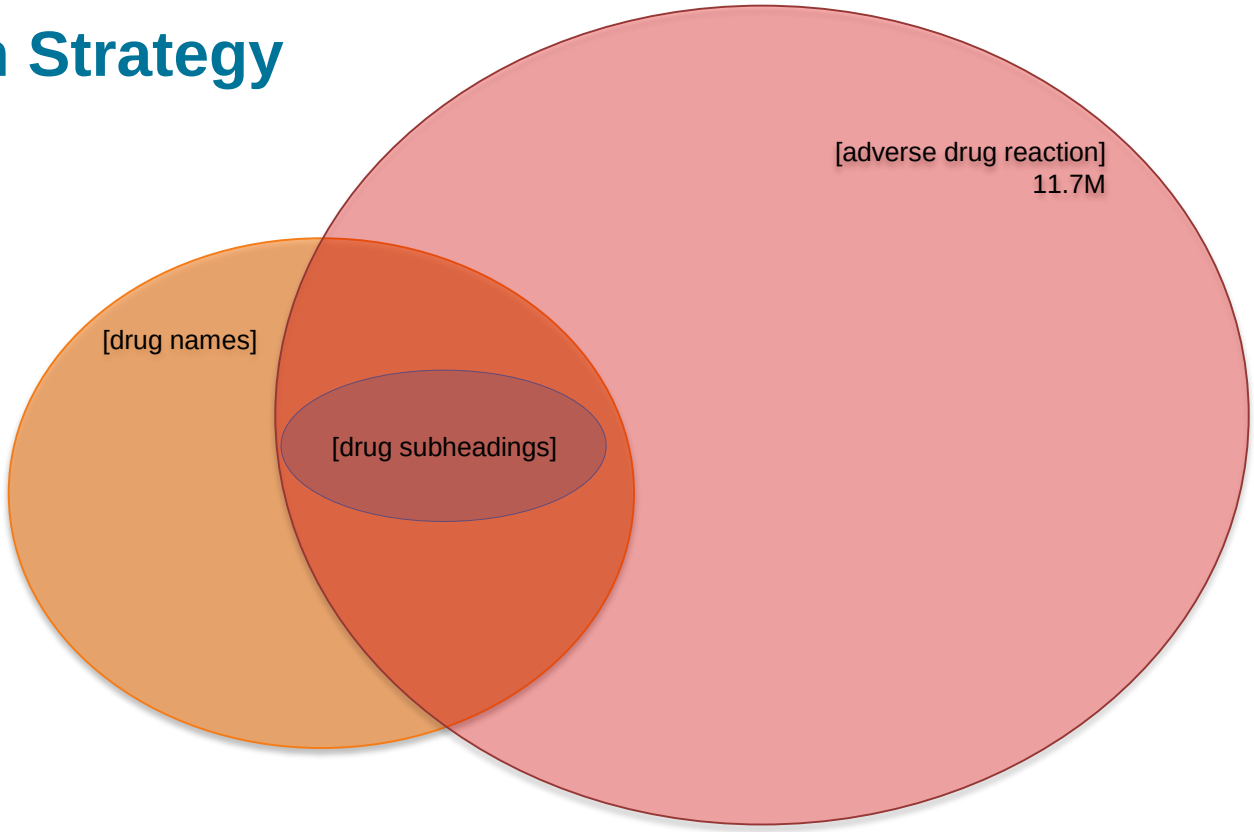
PV Search Strategy – part 2



[drug]/[subheadings] OR [drug names]

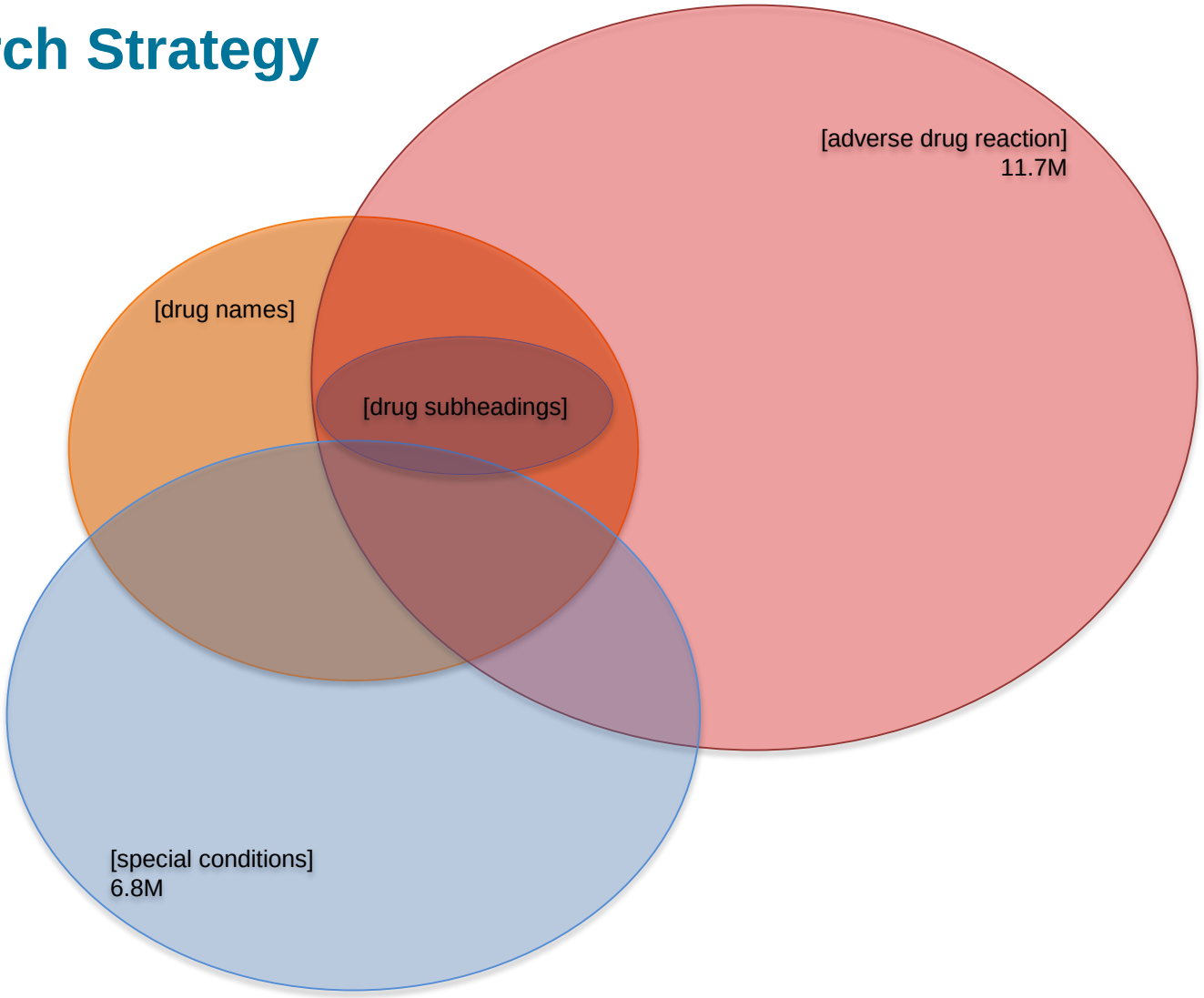
'paracetamol':de OR '4 acetamidophenol':tn,ab,ti OR '4 acetaminophenol':tn,ab,ti OR '4 acetylaminophenol':tn,ab,ti OR '4 hydroxyacetanilide':tn,ab,ti OR '4` hydroxyacetanilide':tn,ab,ti OR 'abenol':tn,ab,ti OR 'acamol':tn,ab,ti OR 'acamoli forte suppositories for kids':tn,ab,ti OR 'acenol':tn,ab,ti OR 'acephen':tn,ab,ti OR 'acet suppositories':tn,ab,ti OR 'acetalgin':tn,ab,ti OR 'acetamino phenol':tn,ab,ti OR 'acetaminophen':tn,ab,ti OR 'acetaminophene':tn,ab,ti OR 'acetaminophenol':tn,ab,ti OR 'acetamol':tn,ab,ti OR 'acetomenophen':tn,ab,ti OR 'acetylaminophenol':tn,ab,ti OR 'adorem':tn,ab,ti OR 'afebrin':tn,ab,ti OR 'algiafin':tn,ab,ti OR 'algotropyl':tn,ab,ti OR 'alphagesic':tn,ab,ti OR 'alvedon':tn,ab,ti OR 'amadil':tn,ab,ti OR 'anacin 3':tn,ab,ti OR 'anaflon':tn,ab,ti…

PV Search Strategy – part 3



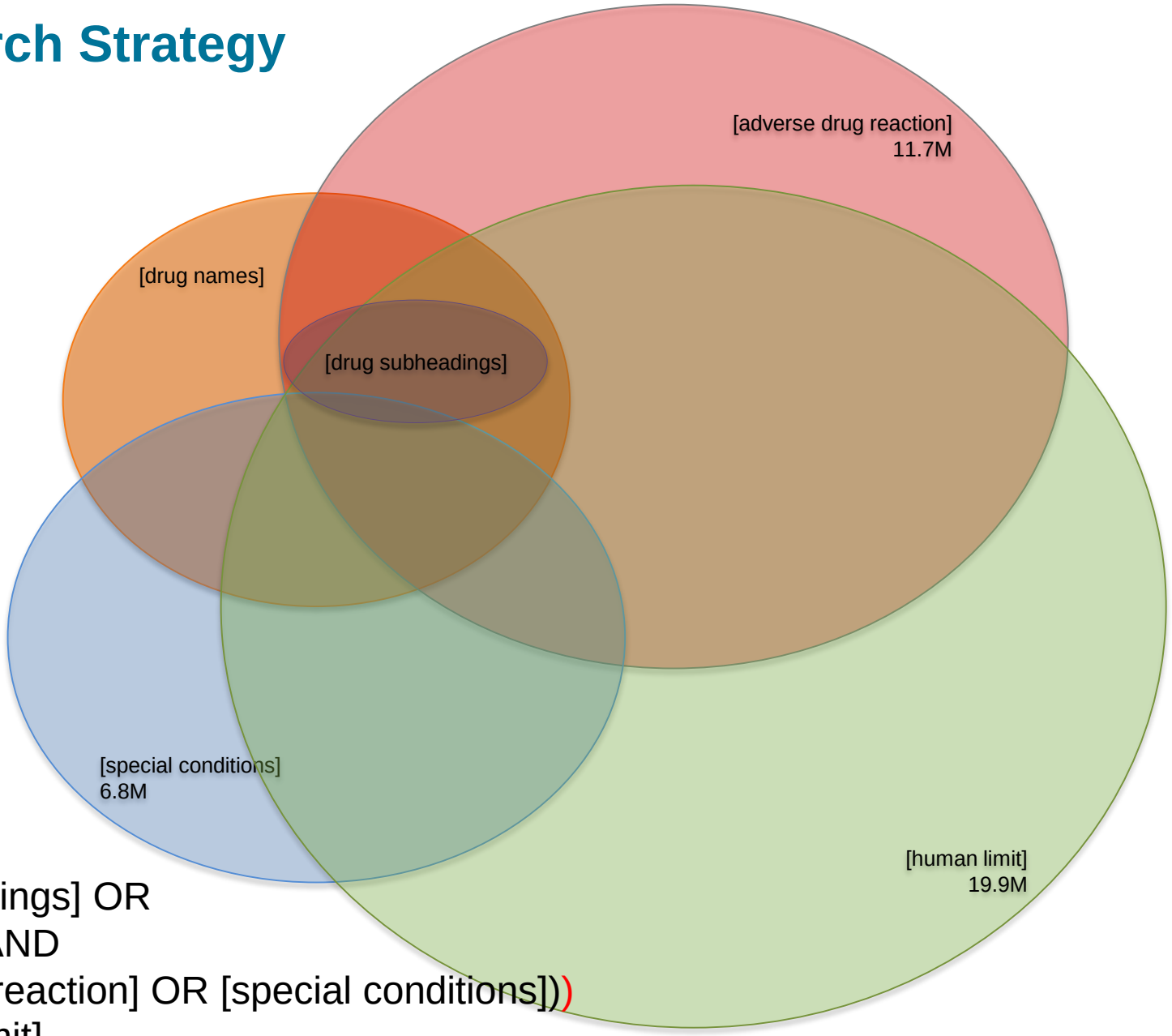
[drug]/[subheadings] OR
([drug names] AND [adverse drug reaction])

PV Search Strategy – part 4



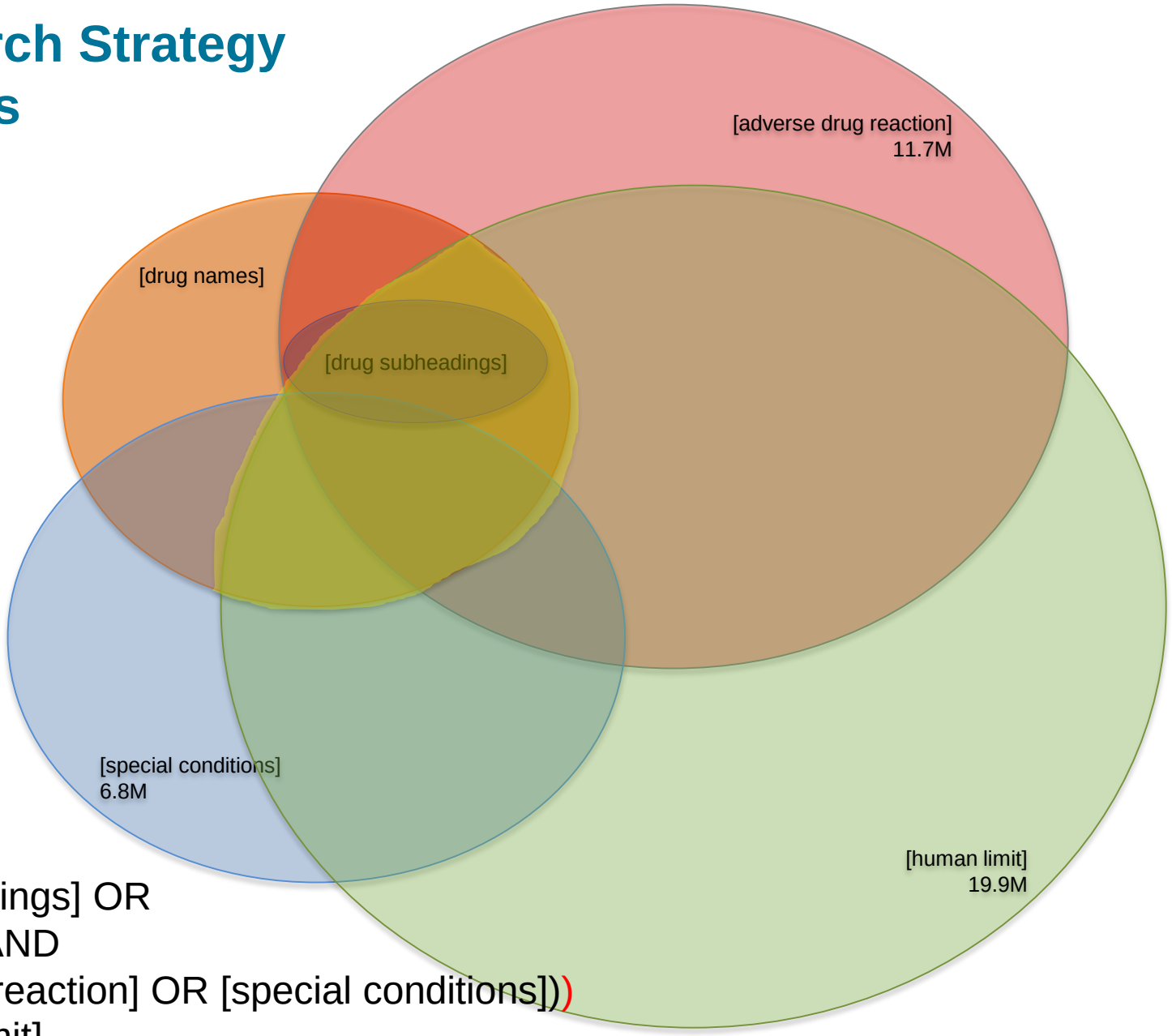
[drug]/[subheadings] OR
([drug names] AND ([adverse drug reaction] OR [special conditions]))

PV Search Strategy – part 5



[drug]/[subheadings] OR
([drug names] AND
([adverse drug reaction] OR [special conditions]))
AND [human limit]

PV Search Strategy – results



[drug]/[subheadings] OR
([drug names] AND
([adverse drug reaction] OR [special conditions]))
AND [human limit]

PV Search Strategy – Part 1: Subheadings

Drug subheadings

'paracetamol'/'drug toxicity','drug interaction','adverse drug reaction'

PV Search Strategy – Part 2: Drug Names

Drug name and variants

'paracetamol':de OR '4 acetamidophenol':tn,ab,ti OR '4 acetaminophenol':tn,ab,ti OR '4 acetylaminophenol':tn,ab,ti OR '4 hydroxyacetanilide':tn,ab,ti OR '4` hydroxyacetanilide':tn,ab,ti OR 'abenol':tn,ab,ti OR 'acamol':tn,ab,ti OR 'acamoli forte suppositories for kids':tn,ab,ti OR 'acenol':tn,ab,ti OR 'acephen':tn,ab,ti OR 'acet suppositories':tn,ab,ti OR 'acetalgin':tn,ab,ti OR 'acetamino phenol':tn,ab,ti OR 'acetaminophen':tn,ab,ti OR 'acetaminophene':tn,ab,ti OR 'acetaminophenol':tn,ab,ti OR 'acetamol':tn,ab,ti OR 'acetomenophen':tn,ab,ti OR 'acetylaminophenol':tn,ab,ti OR 'adorem':tn,ab,ti OR 'afebrin':tn,ab,ti OR …

Field codes:
:de – index term
:tn – tradename
:ti – title
:ab – abstract

PV Search Strategy – Part 3: Adverse Drug Reactions

'paracetamol-induced':ab,ti OR ('adverse drug reaction'/exp OR 'adverse drug reaction':lnk OR adverse:de,ab,ti OR ((side OR undesirable OR unwanted) NEXT/2 (effect* OR reaction* OR event* OR outcome*)):de,ab,ti OR 'side effect'/lnk OR 'side effect'/exp OR 'complication'/lnk OR 'complication'/exp OR complication*:de,ab,ti OR 'worsening':de,ab,ti OR 'case report*':de,ab,ti OR 'pharmacovigilance':de,ab,ti OR 'postmarketing surveillance'/exp OR 'drug interaction':lnk OR 'drug interaction'/exp OR 'toxicity'/exp OR 'drug toxicity':lnk OR toxic*:de,ab,ti OR intox*:de,ab,ti OR 'safety':de,ab,ti OR poison*:de,ab,ti OR pharmacotox*:de,ab,ti OR neurotox*:de,ab,ti OR cardiotox*:de,ab,ti OR nephrotox*:de,ab,ti OR hepatotox*:de,ab,ti OR immunotox*:de,ab,ti OR immunocytotox*:de,ab,ti OR cytotox*:de,ab,ti OR carcinogen*:de,ab,ti OR cancerogen*:de,ab,ti OR mutagen*:de,ab,ti OR terato*:de,ab,ti OR 'fatal outcome'/exp OR 'death'/exp OR death*:de,ab,ti OR 'suicide'/exp OR suicid*:de,ab,ti OR mortal*:de,ab,ti OR fatal*:de,ab,ti OR 'risk'/exp OR nocebo:de,ab,ti OR 'lethal concentration'/exp OR 'iatrogenic disease'/exp OR 'fertility'/exp OR 'substance-related disorders'/exp OR 'chemically induced':de,ab,ti OR 'morbidity':de,ab,ti OR 'congenital disorder':de,ab,ti OR infertility/exp OR injury/exp)

PV Search Strategy – part 4: Special Situations

'pregnancy'/exp OR pregnant*:de,ab,ti OR pregnanc*:de,ab,ti OR 'pregnancy complication'/exp OR 'pregnancy disorder'/exp OR 'abortion'/exp OR 'abortion':de,ab,ti OR 'lactation'/exp OR 'breast feeding':de,ab,ti OR 'breastfeeding':de,ab,ti OR 'breast milk':de,ab,ti OR 'reproduction'/de OR 'fetus'/de OR 'embryo'/de OR 'prenatal':de,ab,ti OR 'perinatal':de,ab,ti OR 'newborn':de,ab,ti OR ‘parameters concerning the fetus, newborn and pregnancy’/exp OR aged/exp OR elderly:de,ti,ab OR geriatric*:ti,ab OR ((environmental OR occupational) NEXT/1 exposure*):de,ab,ti OR 'compassionate use':de,ab,ti OR (named NEXT/1 (use OR patient*)):ab,ti OR 'inappropriate prescri*':de,ab,ti OR 'drug metabolism'/exp OR 'organ dysfunction':de,ab,ti OR 'organ failure':de,ab,ti OR 'hypersensitivit*':de,ab,ti OR allerg*:de,ab,ti OR counterfeit:de,ab,ti OR 'falsified drug':de,ab,ti OR ('unavailab*' NEAR/2 drug):de,ab,ti OR 'drug resistance'/exp OR 'drug resistance':de,ab,ti OR 'withdrawal syndrome'/de OR (drug* NEAR/3 (withdrawal OR toleran* OR interact* OR exposure* OR induc* OR resist* OR ineff* OR nonrespon* OR unrespon*)):de,ab,ti OR 'drug tolerance'/exp OR ((drug* OR treatment) NEXT/1 (failure* OR contraindication*)):de,ab,ti OR 'medication error'/exp OR (near NEXT/1 miss*):ab,ti OR ineff*:ti OR nonrespon*:ti OR unrespon*:ti OR ((lack OR no OR non OR 'not') NEXT/2 (eff* OR respon*)):ab,ti OR 'device failure':de,ab,ti OR manufacturing near/3 (error or fault or mistake or failure or contamination or impurity) OR ‘patient compliance’/exp OR overdos*:de,ab,ti OR 'drug abuse'/exp OR abus*:de,ab,ti OR misus*:de,ab,ti OR 'off label':de,ab,ti OR unlicensed:de,ab,ti

PV Search Strategy – Part 5: Human Limit*

…AND
('human'/exp OR human OR m?n OR wom?n OR child OR boy OR girl)

* for ICSR's

PV Search Strategy – full

'paracetamol'/'drug toxicity','drug interaction','adverse drug reaction'
OR 'paracetamol-induced':de,ab,ti
OR ('paracetamol':de OR '4 acetamidophenol':tn,ab,ti OR '4 acetaminophenol':tn,ab,ti OR '4 acetylaminophenol':tn,ab,ti OR '4 hydroxyacetanilide':tn,ab,ti OR '4` hydroxyacetanilide':tn,ab,ti OR 'abenol':tn,ab,ti OR 'acamol':tn,ab,ti OR 'acamoli forte suppositories for kids':tn,ab,ti OR 'acenol':tn,ab,ti OR 'acephen':tn,ab,ti OR 'acet suppositories':tn,ab,ti OR 'acetalgin':tn,ab,ti OR 'acetamino phenol':tn,ab,ti OR 'acetaminophen':tn,ab,ti OR 'acetaminophene':tn,ab,ti OR 'acetaminophenol':tn,ab,ti OR 'acetamol':tn,ab,ti OR 'acetomenophen':tn,ab,ti OR 'acetylaminophenol':tn,ab,ti OR 'adorem':tn,ab,ti OR 'afebrin':tn,ab,ti OR 'algiafin':tn,ab,ti OR 'algotropyl':tn,ab,ti OR 'alphagesic':tn,ab,ti OR 'alvedon':tn,ab,ti OR 'amadil':tn,ab,ti OR 'anacin 3':tn,ab,ti OR 'anaflon':tn,ab,ti OR 'analgiser':tn,ab,ti OR 'apamide':tn,ab,ti OR 'apap':tn,ab,ti OR 'apirex':tn,ab,ti OR 'apotel':tn,ab,ti OR 'arthralgen':tn,ab,ti OR 'atamel':tn,ab,ti OR 'ben-u-ron':tn,ab,ti OR 'benuron':tn,ab,ti OR 'biogesic':tn,ab,ti OR 'biogesic suspension':tn,ab,ti OR 'bodrex':tn,ab,ti OR 'calapol':tn,ab,ti OR 'calodol':tn,ab,ti OR 'calonal':tn,ab,ti OR 'calpol':tn,ab,ti OR 'causalon':tn,ab,ti OR 'cemol':tn,ab,ti OR 'christamol':tn,ab,ti OR 'claradol':tn,ab,ti OR 'clocephen':tn,ab,ti OR 'cp 500':tn,ab,ti OR 'cp500':tn,ab,ti OR 'dafalgan':tn,ab,ti OR 'daga':tn,ab,ti OR 'datril':tn,ab,ti OR 'depon':tn,ab,ti OR 'depyretin':tn,ab,ti OR 'dirox':tn,ab,ti OR 'dismifen':tn,ab,ti OR 'disprol':tn,ab,ti OR 'dolal':tn,ab,ti OR 'dolex':tn,ab,ti OR 'dolex 500':tn,ab,ti OR 'doliprane':tn,ab,ti OR 'dolitabs':tn,ab,ti OR 'dolofen':tn,ab,ti OR 'dolomol':tn,ab,ti OR 'dolorol':tn,ab,ti OR 'dolotemp':tn,ab,ti OR 'dolprone':tn,ab,ti OR 'doltem':tn,ab,ti OR 'drilan':tn,ab,ti OR 'dristan af':tn,ab,ti OR 'duorol':tn,ab,ti OR 'dymadon':tn,ab,ti OR 'efferalgan':tn,ab,ti OR 'efferalgan 500':tn,ab,ti OR 'efferalganodis':tn,ab,ti OR 'efferelgan':tn,ab,ti OR 'enelfa':tn,ab,ti OR 'eneril':tn,ab,ti OR 'eraldor':tn,ab,ti OR 'expandol':tn,ab,ti OR 'febrilix':tn,ab,ti OR 'fendon':tn,ab,ti OR 'fervex':tn,ab,ti OR 'fibrinol':tn,ab,ti OR 'fortolin':tn,ab,ti OR 'gelocatil':tn,ab,ti OR 'geluprane 500':tn,ab,ti OR 'gunaceta':tn,ab,ti OR 'headache strength allerest':tn,ab,ti OR 'hedex':tn,ab,ti OR 'infants` feverall':tn,ab,ti OR 'injectapap':tn,ab,ti OR 'janupap':tn,ab,ti OR 'kamolas':tn,ab,ti OR 'kyofen':tn,ab,ti OR 'lemgrip':tn,ab,ti OR 'letamol':tn,ab,ti OR 'liquiprin':tn,ab,ti OR 'lotemp':tn,ab,ti OR 'lyteca':tn,ab,ti OR 'malidens':tn,ab,ti OR 'medamol':tn,ab,ti OR 'meforagesic':tn,ab,ti OR 'metagesic':tn,ab,ti OR 'metalid':tn,ab,ti OR 'mexalen':tn,ab,ti OR 'milidon 500':tn,ab,ti OR 'minopan':tn,ab,ti OR 'mypara':tn,ab,ti OR 'n acetyl 4 aminophenol':tn,ab,ti OR 'n acetyl para aminophenol':tn,ab,ti OR 'n-acetyl-p-aminophenol':tn,ab,ti OR 'nalgesik':tn,ab,ti OR 'napamol':tn,ab,ti OR 'napap':tn,ab,ti OR 'naprex':tn,ab,ti OR 'nektol 500':tn,ab,ti OR 'neocitran':tn,ab,ti OR 'neodalmin':tn,ab,ti OR 'neopap':tn,ab,ti 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'tylenol forte':tn,ab,ti OR 'tylenol nr 1':tn,ab,ti OR 'tylex':tn,ab,ti OR 'valadol':tn,ab,ti OR 'winadol':tn,ab,ti OR 'winasorb':tn,ab,ti OR 'xebramol':tn,ab,ti OR 'zolben':tn,ab,ti OR 'zydinol':tn,ab,ti

AND ('adverse drug reaction'/exp OR 'adverse drug reaction':lnk OR adverse:de,ab,ti OR ((side OR undesirable OR unwanted) NEXT/2 (effect* OR reaction* OR event* OR outcome*)):de,ab,ti OR 'side effect'/lnk OR 'side effect'/exp OR 'complication'/lnk OR 'complication'/exp OR complication*:de,ab,ti OR 'worsening':de,ab,ti
OR 'case report*':de,ab,ti OR 'pharmacovigilance':de,ab,ti OR 'postmarketing surveillance'/exp OR 'drug interaction':lnk OR 'drug interaction'/exp OR 'toxicity'/exp OR 'drug toxicity':lnk OR toxic*:de,ab,ti OR intox*:de,ab,ti OR 'safety':de,ab,ti OR poison*:de,ab,ti OR pharmacotox*:de,ab,ti OR neurotox*:de,ab,ti OR cardiotox*:de,ab,ti OR nephrotox*:de,ab,ti OR hepatotox*:de,ab,ti OR immunotox*:de,ab,ti OR immunocytotox*:de,ab,ti OR cytotox*:de,ab,ti OR carcinogen*:de,ab,ti OR cancerogen*:de,ab,ti OR mutagen*:de,ab,ti OR terato*:de,ab,ti OR 'fatal outcome'/exp OR 'death'/exp OR death*:de,ab,ti OR 'suicide'/exp OR suicid*:de,ab,ti OR mortal*:de,ab,ti OR fatal*:de,ab,ti OR 'risk'/exp OR nocebo:de,ab,ti OR 'lethal concentration'/exp OR 'iatrogenic disease'/exp OR 'fertility'/exp OR 'substance-related disorders'/exp OR 'chemically induced':de,ab,ti OR 'morbidity':de,ab,ti OR 'congenital disorder':de,ab,ti OR infertility/exp OR injury/exp

OR 'pregnancy'/exp OR pregnant*:de,ab,ti OR pregnanc*:de,ab,ti OR 'pregnancy complication'/exp OR 'pregnancy disorder'/exp OR 'abortion'/exp OR 'abortion':de,ab,ti OR 'lactation'/exp OR 'breast feeding':de,ab,ti OR 'breastfeeding':de,ab,ti OR 'breast milk':de,ab,ti OR 'reproduction'/de OR 'fetus'/de OR 'embryo'/de OR 'prenatal':de,ab,ti OR 'perinatal':de,ab,ti OR 'newborn':de,ab,ti OR 'parameters concerning the fetus, newborn and pregnancy'/exp OR aged/exp or elderly:de,ti,ab or geriatric*:ti,ab
OR ((environmental OR occupational) NEXT/1 exposure*):de,ab,ti OR 'compassionate use':de,ab,ti OR (named NEXT/1 (use OR patient*)):ab,ti OR 'inappropriate prescri*':de,ab,ti
OR 'drug metabolism'/exp OR 'organ dysfunction':de,ab,ti OR 'organ failure':de,ab,ti OR 'hypersensitivit*':de,ab,ti OR allerg*:de,ab,ti OR counterfeit:de,ab,ti OR 'falsified drug':de,ab,ti OR ('unavailab*' NEAR/2 drug):de,ab,ti OR 'drug resistance'/exp OR 'drug resistance':de,ab,ti OR 'withdrawal syndrome'/de OR (drug* NEAR/3 (withdrawal OR toleran* OR interact* OR exposure* OR induc* OR resist* OR ineff* OR nonrespon* OR unrespon*)):de,ab,ti OR 'drug tolerance'/exp OR ((drug* OR treatment) NEXT/1 (failure* OR contraindication*)):de,ab,ti OR 'medication error'/exp OR (near NEXT/1 miss*):ab,ti OR ineff*:ti OR nonrespon*:ti OR unrespon*:ti OR ((lack OR no OR non OR 'not') NEXT/2 (eff* OR respon*)):ab,ti OR 'device failure':de,ab,ti OR manufacturing near/3 (error or fault or mistake or failure or contamination or impurity) OR 'patient compliance'/exp OR overdos*:de,ab,ti OR 'drug abuse'/exp OR abus*:de,ab,ti OR misus*:de,ab,ti OR 'off label':de,ab,ti OR unlicensed:de,ab,ti)

AND ('human'/exp OR human OR m?n OR wom?n OR child OR boy OR girl))

Designed to produce 100% recall against the gold set (in appendix).

Review Search Terms to Increase Recall

	intoxic*:de,ti,ab			
Products	# of records without	Additional Citations	Screened Citations	Relevant Citations
Product 1	11	0	0	0
Product 2	6325	58	58	6
Product 3	13	0	0	0
Product 4	78	2	2	0
Product 5	143	3	3	0
Product 6	4243	9	9	0
Product 7	177	0	0	0
Product 8	18343	317	100	1
Product 9	29	0	0	0
Product 10	764	5	5	0
Total	30126	394	177	7
period of 3 years				

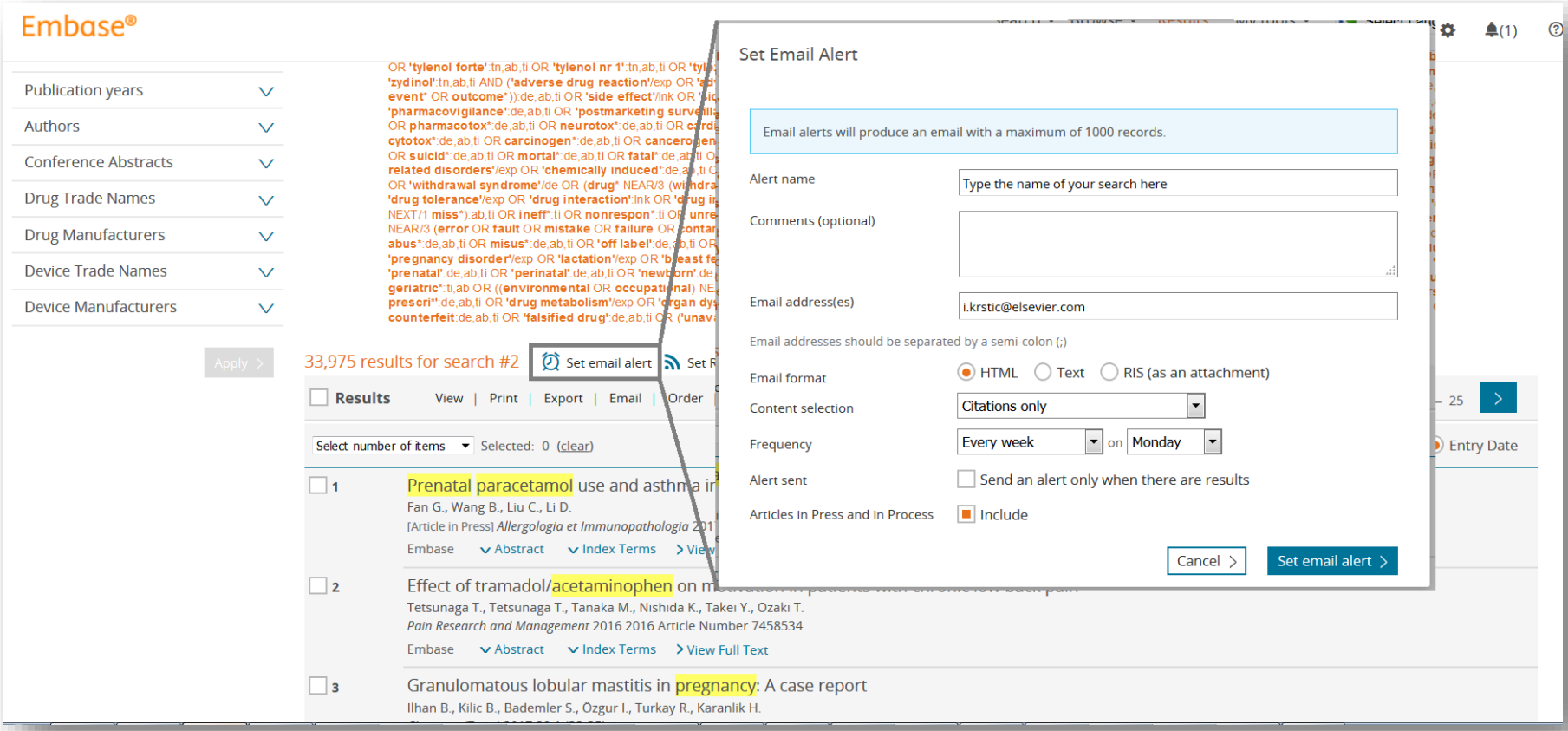
Please make sure all is documented!

Review Search Terms to Increase Precision

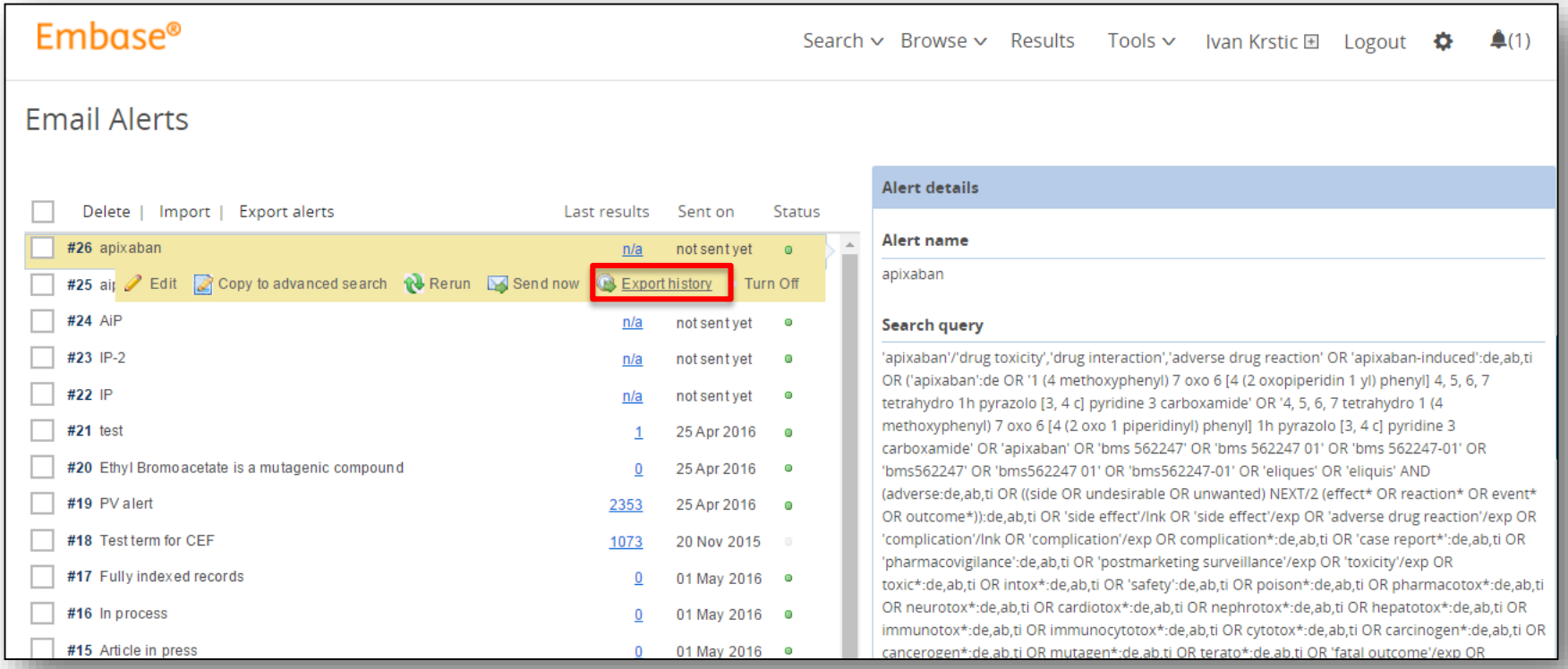
	intoxic*:de,ti,ab		poison*:de,ab,ti	
Products	# of Records WITH	Missed Citations WITHOUT	# of Records WITH	Missed Citations WITHOUT
Product 1	170	0	170	1
period of 3 years				

Please make sure all is documented!

Set up an Email Alert



Email Alert history can be exported

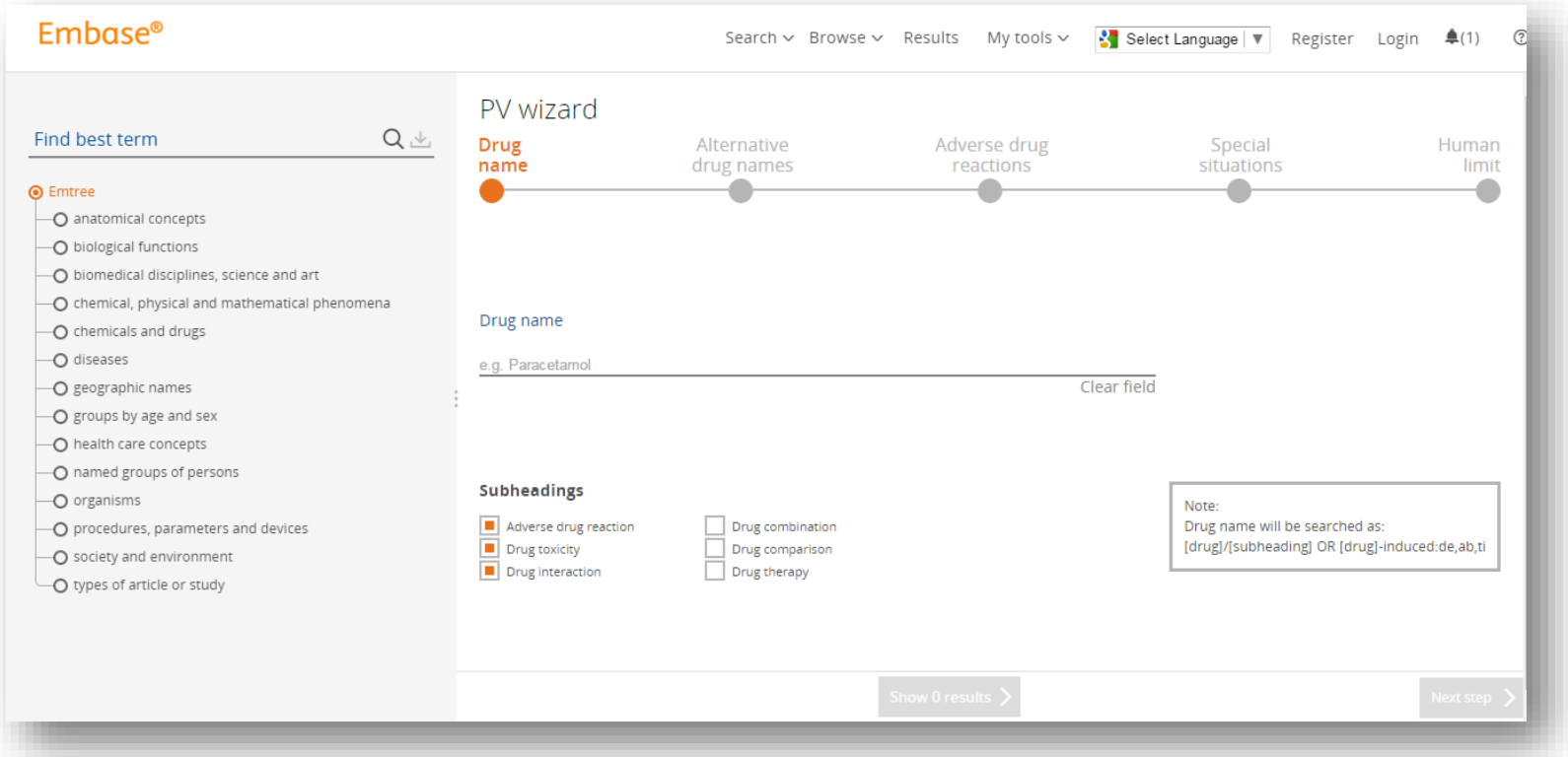


Email Alert history is auditable

This is the history of alert "PV alert" as exported on 01 May 2016 19:38 GMT. This alert was originally set up on 22 Dec 2015 10:11 GMT.

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

Demo



Please contact us at if you are interested in testing the PV wizard?

embase@elsevier.com

Regular Reviews of the PV Search Strategy

- Emtree updates three times per year
- New search artefacts can be introduced
- New indexing policies can be enforced
- Always perform the review maintaining **documented evidence** that a specific search strategy consistently produces a record set meeting its pre-determined quality attributes

Thank you!

Any questions?

Ivan Krstić, PhD
Senior Product Development Manager Embase

i.krstic@elsevier.com

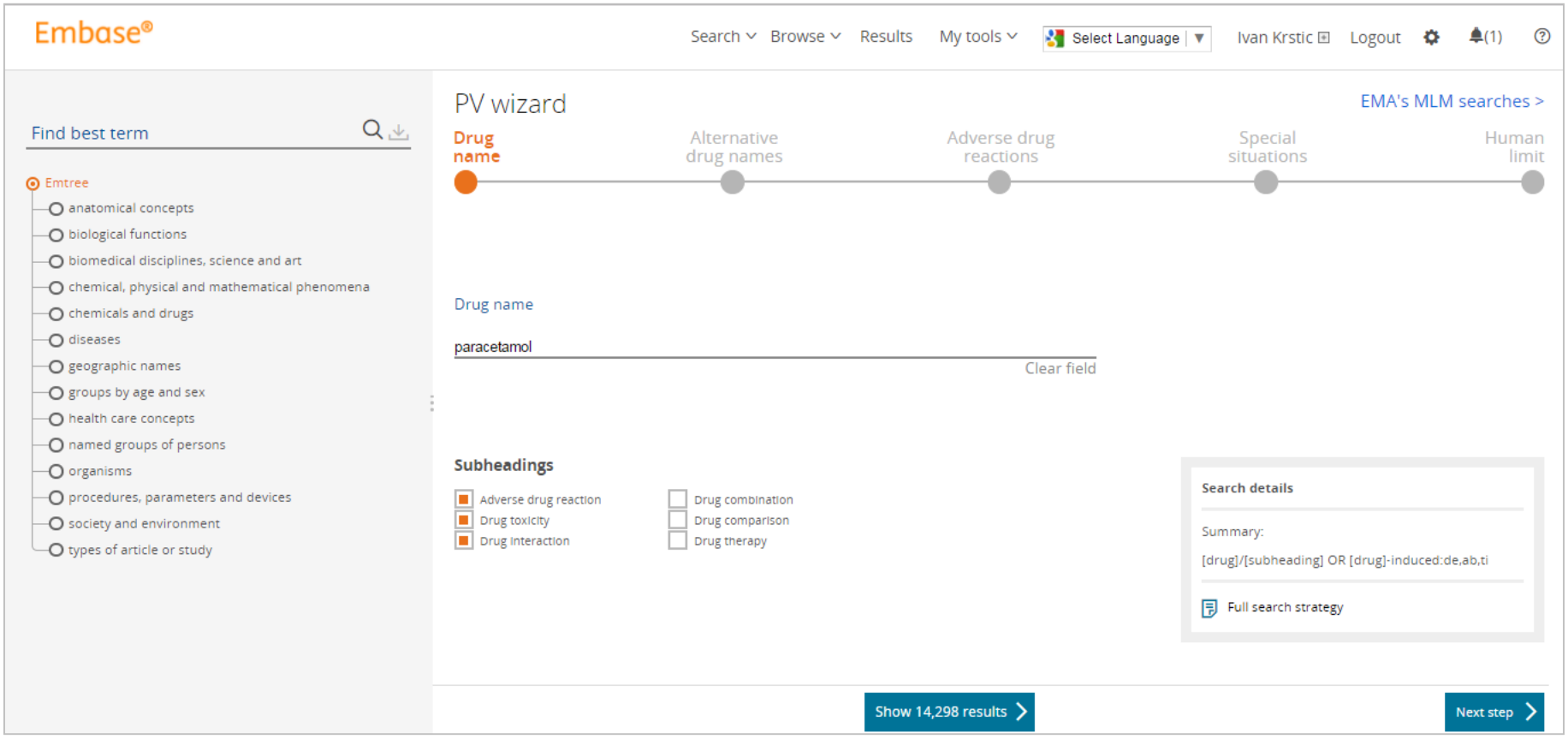
Appendix

Gold set – 170 records

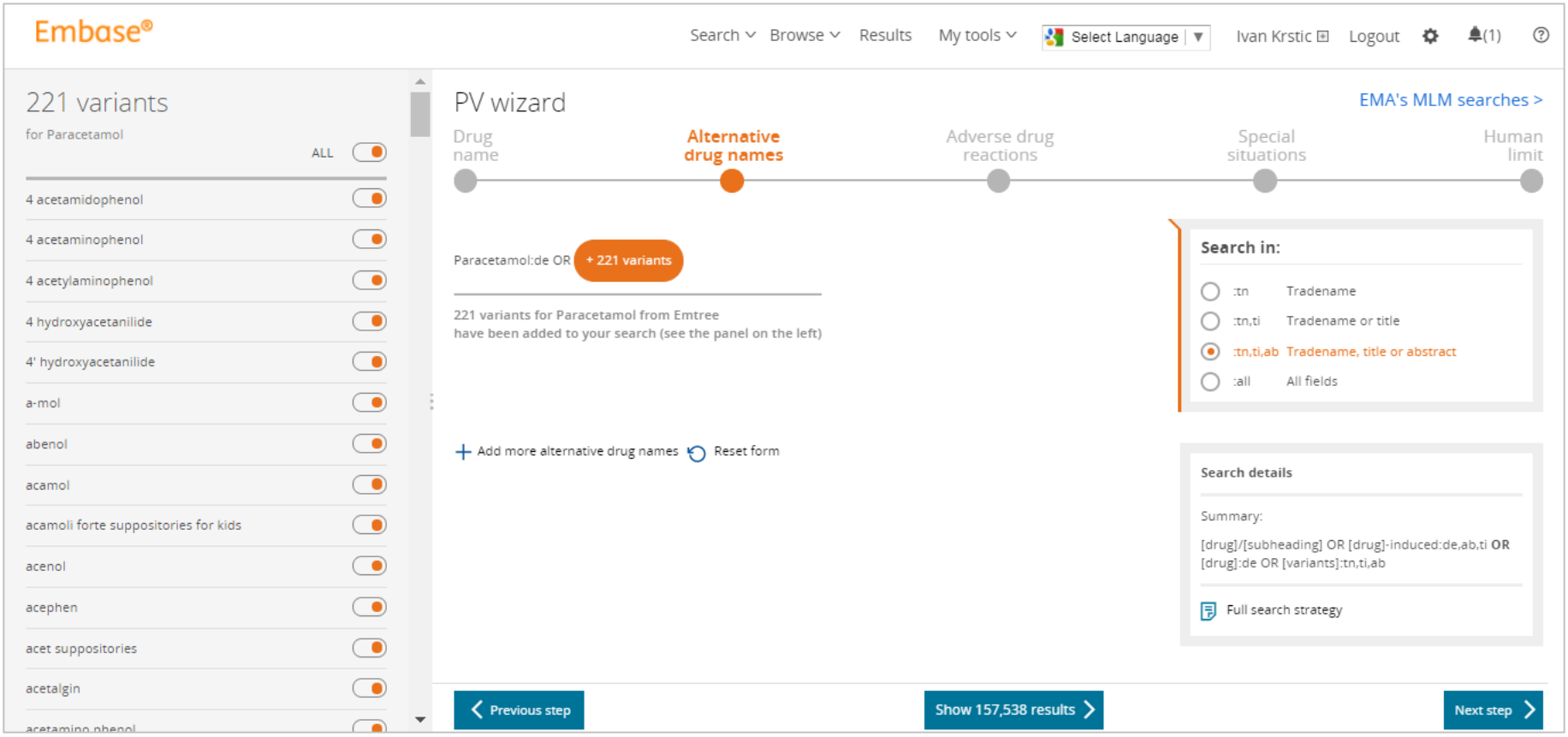
l604107918:id OR l603447181:id OR l72029418:id OR l72029417:id OR l603871480:id OR l71631169:id OR l71878151:id OR l72087309:id OR l71643543:id OR l605056337:id OR l72112544:id OR l72079751:id OR l606842637:id OR l602171104:id OR l71904136:id OR l600468438:id OR l602218885:id OR l72062194:id OR l607452692:id OR l72029407:id OR l602770165:id OR l72102753:id OR l72120217:id OR l604246500:id OR l603740721:id OR l71869391:id OR l71875149:id OR l604287782:id OR l71829014:id OR l606879227:id OR l72130806:id OR l604309892:id OR l604929800:id OR l600449934:id OR l603244919:id OR l71707962:id OR l604287214:id OR l604694975:id OR l71640938:id OR l71870093:id OR l72102807:id OR l71690844:id OR l71904350:id OR l72078560:id OR l604183495:id OR l606616380:id OR l71904078:id OR l72130954:id OR l71904076:id OR l606835591:id OR l604297073:id OR l607821733:id OR l71702288:id OR l71702442:id OR l607071680:id OR l71686509:id OR l601177982:id OR l71688096:id OR l72032915:id OR l72029187:id OR l72102778:id OR l600727195:id OR l71687677:id OR l71686587:id OR l52741354:id OR l600470051:id OR l71684043:id OR l71686581:id OR l71904363:id OR l72130946:id OR l603252934:id OR l53070431:id OR l373910994:id OR l607241877:id OR l72102149:id OR l606579898:id OR l600642429:id OR l373917384:id OR l607352538:id OR l71639410:id OR l72054098:id OR l71639402:id OR l71686596:id OR l607226353:id OR l71688135:id OR l72061877:id OR l71643744:id OR l606587689:id OR l604585112:id OR l605124146:id OR l563028253:id OR l71686638:id OR l71904336:id OR l72072640:id OR l72130858:id OR l600739898:id OR l71904339:id OR l600461323:id OR l600141655:id OR l604495667:id OR l71835452:id OR l603513544:id OR l601889353:id OR l600163062:id OR l604594461:id OR l53309170:id OR l604414049:id OR l603626191:id OR l72029442:id OR l72048422:id OR l71904060:id OR l604710896:id OR l603908417:id OR l71904180:id OR l607452814:id OR l71639416:id OR l606951609:id OR l607238853:id OR l71639418:id OR l71904066:id OR l71707944:id OR l607268041:id OR l71904347:id OR l71904104:id OR l600342491:id OR l607776590:id OR l72029959:id OR l604015278:id OR l72079739:id OR l600057502:id OR l603286559:id OR l607108983:id OR l606661918:id OR l71707645:id OR l71629947:id OR l72029433:id OR l72029430:id OR l603480784:id OR l72120422:id OR l72116286:id OR l606889625:id OR l600422149:id OR l604166996:id OR l603563730:id OR l600443960:id OR l603619072:id OR l606468505:id OR l606959548:id OR l72130862:id OR l72087296:id OR l72102732:id OR l72131150:id OR l604702450:id OR l600726582:id OR l71878046:id OR l72080793:id OR l53100860:id OR l604788478:id OR l53308375:id OR l607284852:id OR l605748088:id OR l606791581:id OR l71679185:id OR l71639759:id OR l71638706:id OR l71904285:id OR l604734144:id OR l604126124:id OR l600421443:id OR l604739155:id

PV Wizard

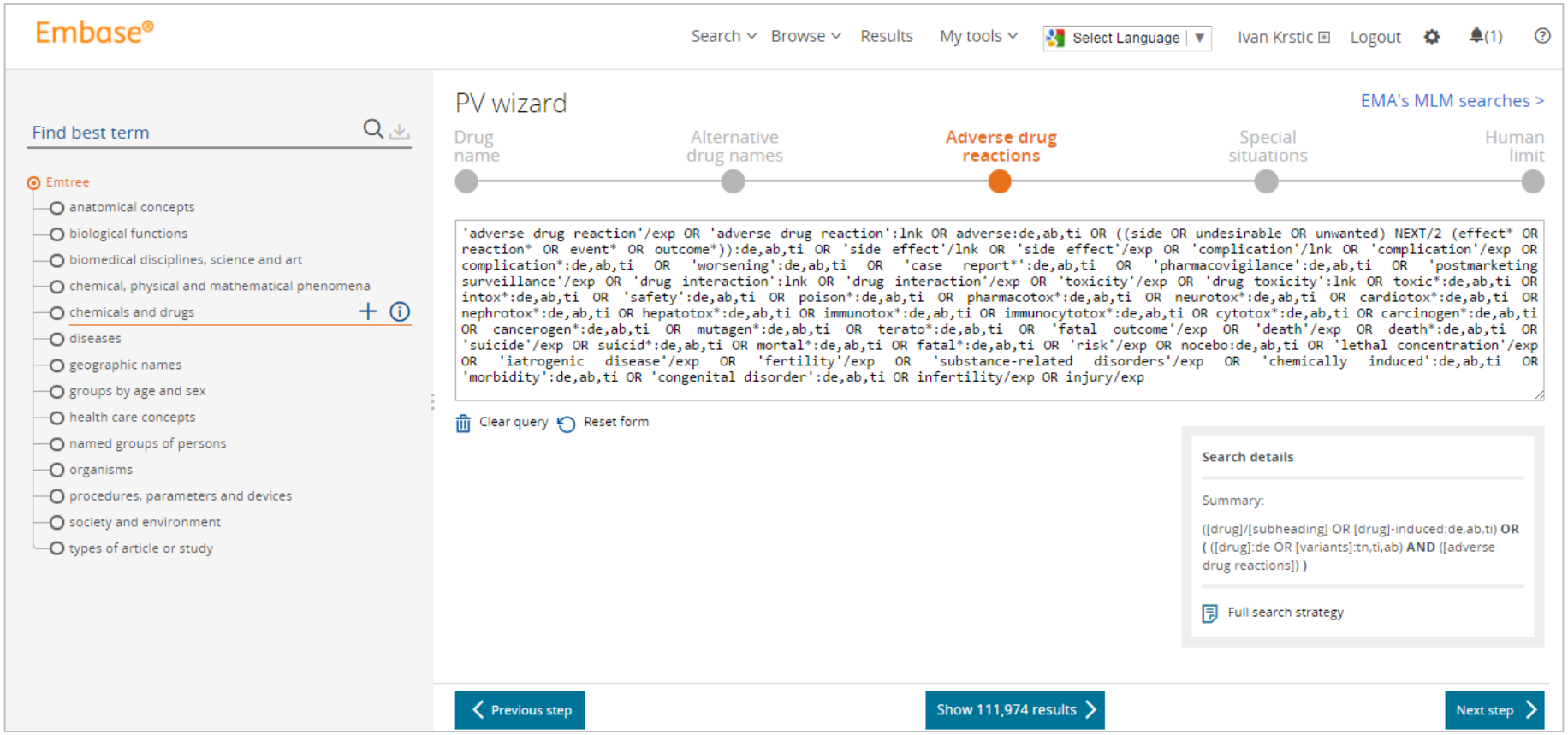
1/5


Embase®
Search
Browse
Results
My tools
Select Language
Ivan Krstic
Logout
(1)
Find best term
Emtree
anatomical concepts
biological functions
biomedical disciplines, science and art
chemical, physical and mathematical phenomena
chemicals and drugs
diseases
geographic names
groups by age and sex
health care concepts
named groups of persons
organisms
procedures, parameters and devices
society and environment
types of article or study
PV wizard
EMA's MLM searches >
Drug name
Alternative drug names
Adverse drug reactions
Special situations
Human limit
Drug name
paracetamol
Clear field
Subheadings
Adverse drug reaction
Drug toxicity
Drug interaction
Drug combination
Drug comparison
Drug therapy
Search details
Summary:
[drug]/[subheading] OR [drug]-induced:de,ab,ti
Full search strategy
Show 14,298 results
Next step

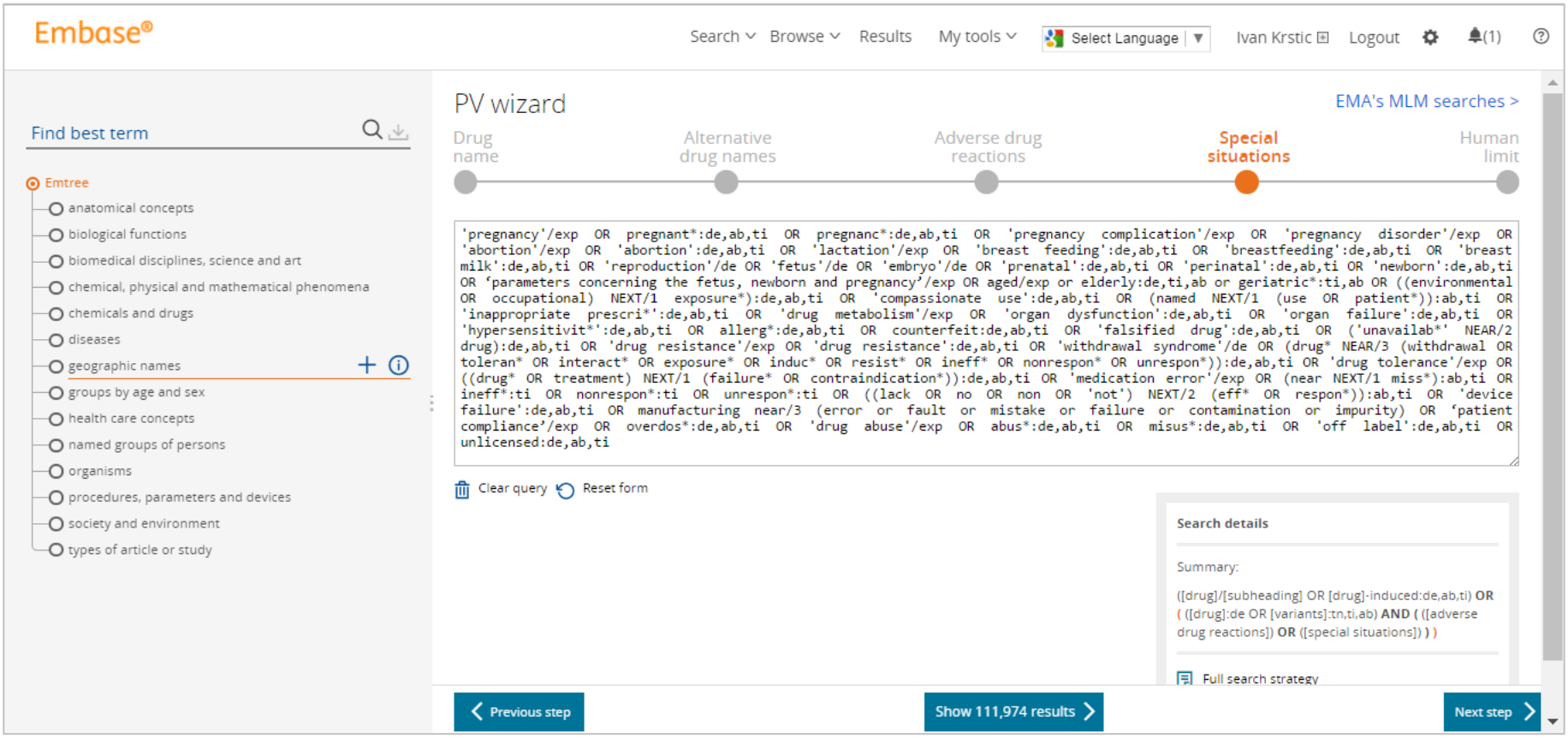
2/5


Embase®
Search
Browse
Results
My tools
Select Language
Ivan Krstic
Logout
(1)
221 variants
for Paracetamol
ALL
4 acetamidophenol
4 acetaminophenol
4 acetylaminophenol
4 hydroxyacetanilide
4' hydroxyacetanilide
a-mol
abenol
acamol
acamoli forte suppositories for kids
acenol
acephen
acet suppositories
acetalgin
acetamino phenol
PV wizard
EMA's MLM searches >
Drug name
Alternative drug names
Adverse drug reactions
Special situations
Human limit
Paracetamol:de OR + 221 variants
221 variants for Paracetamol from Emtree
have been added to your search (see the panel on the left)
Search in:
:tn Tradename
:tn,ti Tradename or title
:tn,ti,ab Tradename, title or abstract
:all All fields
Add more alternative drug names
Reset form
Search details
Summary:
[drug]/[subheading] OR [drug]-induced:de,ab,ti OR [drug]:de OR [variants]:tn,ti,ab
Full search strategy
Previous step
Show 157,538 results
Next step

3/5


Embase®
Search
Browse
Results
My tools
Select Language
Ivan Krstic
Logout
(1)
Find best term
Emtree
anatomical concepts
biological functions
biomedical disciplines, science and art
chemical, physical and mathematical phenomena
chemicals and drugs
diseases
geographic names
groups by age and sex
health care concepts
named groups of persons
organisms
procedures, parameters and devices
society and environment
types of article or study
PV wizard
EMA's MLM searches >
Drug name
Alternative drug names
Adverse drug reactions
Special situations
Human limit
'adverse drug reaction'/exp OR 'adverse drug reaction':lnk OR adverse:de,ab,ti OR ((side OR undesirable OR unwanted) NEXT/2 (effect* OR reaction* OR event* OR outcome*)):de,ab,ti OR 'side effect'/lnk OR 'side effect'/exp OR 'complication'/lnk OR 'complication'/exp OR complication*:de,ab,ti OR 'worsening':de,ab,ti OR 'case report*':de,ab,ti OR 'pharmacovigilance':de,ab,ti OR 'postmarketing surveillance'/exp OR 'drug interaction':lnk OR 'drug interaction'/exp OR 'toxicity'/exp OR 'drug toxicity':lnk OR toxic*:de,ab,ti OR intox*:de,ab,ti OR 'safety':de,ab,ti OR poison*:de,ab,ti OR pharmacotox*:de,ab,ti OR neurotox*:de,ab,ti OR cardiotox*:de,ab,ti OR nephrotox*:de,ab,ti OR hepatotox*:de,ab,ti OR immunotox*:de,ab,ti OR immunocytotox*:de,ab,ti OR cytotox*:de,ab,ti OR carcinogen*:de,ab,ti OR cancerogen*:de,ab,ti OR mutagen*:de,ab,ti OR terato*:de,ab,ti OR 'fatal outcome'/exp OR 'death'/exp OR death*:de,ab,ti OR 'suicide'/exp OR suicid*:de,ab,ti OR mortal*:de,ab,ti OR fatal*:de,ab,ti OR 'risk'/exp OR nocebo:de,ab,ti OR 'lethal concentration'/exp OR 'iatrogenic disease'/exp OR 'fertility'/exp OR 'substance-related disorders'/exp OR 'chemically induced':de,ab,ti OR 'morbidity':de,ab,ti OR 'congenital disorder':de,ab,ti OR infertility/exp OR injury/exp
Clear query
Reset form
Search details
Summary:
([drug]/[subheading] OR [drug]-induced:de,ab,ti) OR (([drug]:de OR [variants]:tn,ti,ab) AND ([adverse drug reactions]))
Full search strategy
Previous step
Show 111,974 results
Next step

4/5


Embase®
Search
Browse
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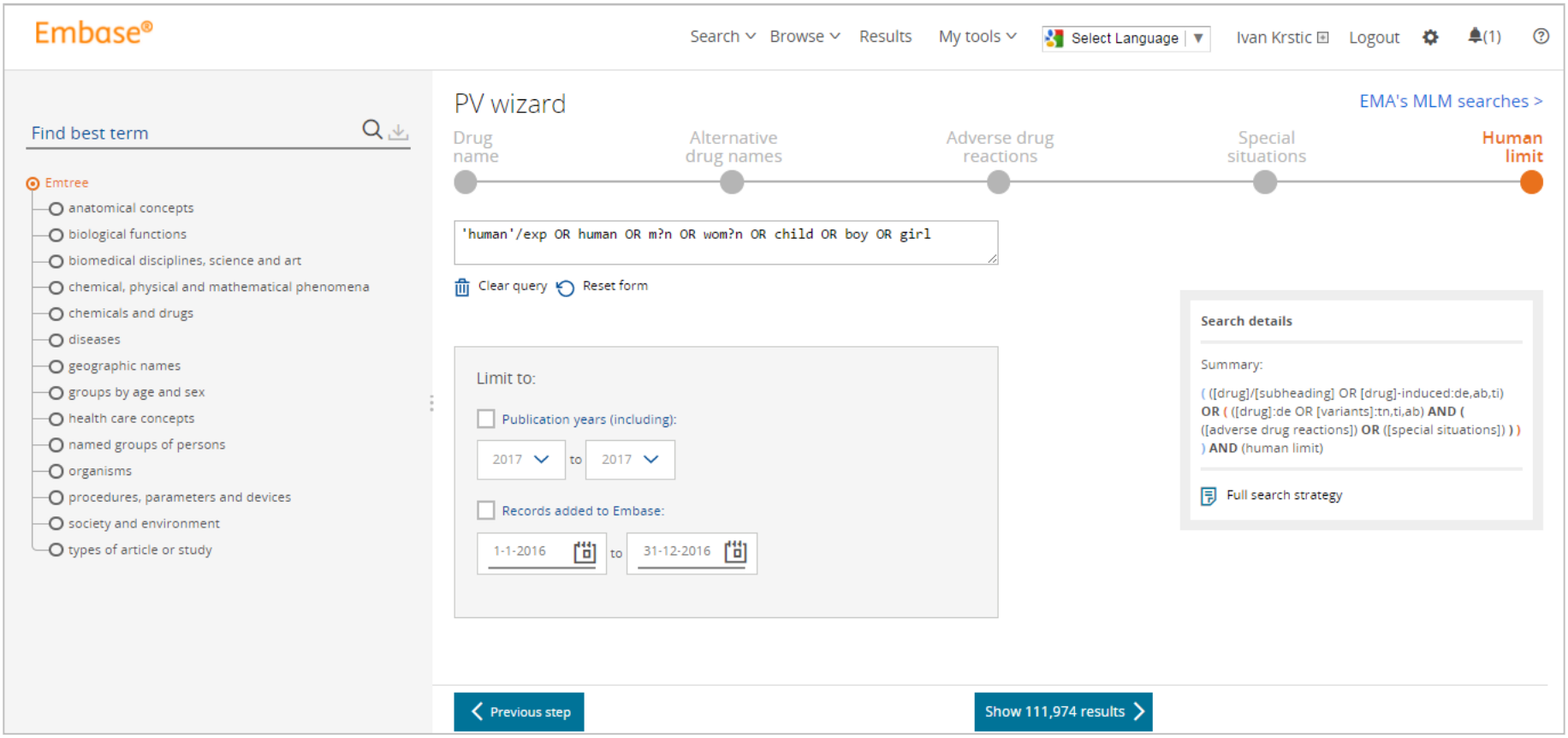
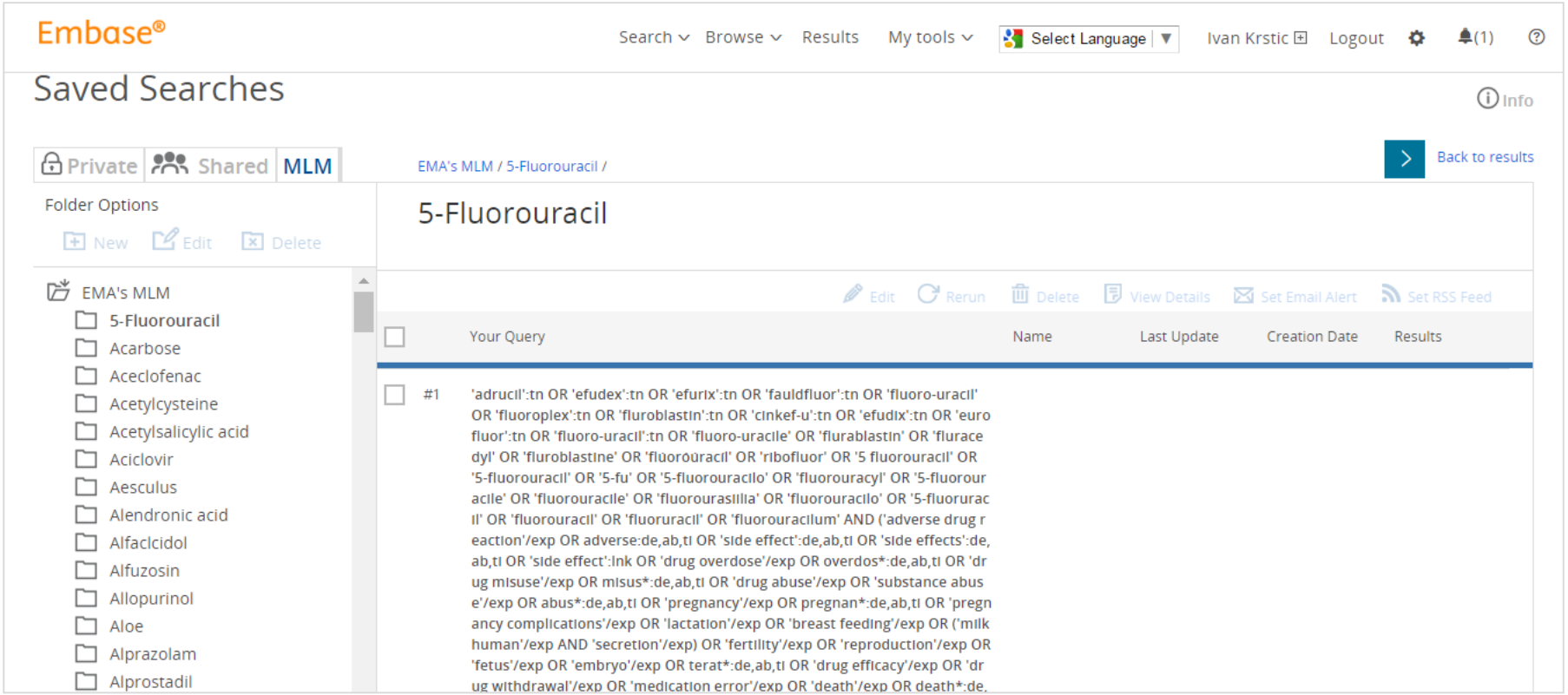
My tools
Select Language
Ivan Krstic
Logout
(1)
Find best term
Emtree
anatomical concepts
biological functions
biomedical disciplines, science and art
chemical, physical and mathematical phenomena
chemicals and drugs
diseases
geographic names
groups by age and sex
health care concepts
named groups of persons
organisms
procedures, parameters and devices
society and environment
types of article or study
PV wizard
EMA's MLM searches >
Drug name
Alternative drug names
Adverse drug reactions
Special situations
Human limit
'pregnancy'/exp OR pregnant*:de,ab,ti OR pregnanc*:de,ab,ti OR 'pregnancy complication'/exp OR 'pregnancy disorder'/exp OR 'abortion'/exp OR 'abortion':de,ab,ti OR 'lactation'/exp OR 'breast feeding':de,ab,ti OR 'breastfeeding':de,ab,ti OR 'breast milk':de,ab,ti OR 'reproduction'/de OR 'fetus'/de OR 'embryo'/de OR 'prenatal':de,ab,ti OR 'perinatal':de,ab,ti OR 'newborn':de,ab,ti OR 'parameters concerning the fetus, newborn and pregnancy'/exp OR aged/exp or elderly:de,ti,ab or geriatric*:ti,ab OR ((environmental OR occupational) NEXT/1 exposure*):de,ab,ti OR 'compassionate use':de,ab,ti OR (named NEXT/1 (use OR patient*)):ab,ti OR 'inappropriate prescri*':de,ab,ti OR 'drug metabolism'/exp OR 'organ dysfunction':de,ab,ti OR 'organ failure':de,ab,ti OR 'hypersensitivit*':de,ab,ti OR allerg*:de,ab,ti OR counterfeit:de,ab,ti OR 'falsified drug':de,ab,ti OR ('unavailab*' NEAR/2 drug):de,ab,ti OR 'drug resistance'/exp OR 'drug resistance':de,ab,ti OR 'withdrawal syndrome'/de OR (drug* NEAR/3 (withdrawal OR toleran* OR interact* OR exposure* OR induc* OR resist* OR ineff* OR nonrespon* OR unrespon*)):de,ab,ti OR 'drug tolerance'/exp OR ((drug* OR treatment) NEXT/1 (failure* OR contraindication*)):de,ab,ti OR 'medication error'/exp OR (near NEXT/1 miss*):ab,ti OR ineff*:ti OR nonrespon*:ti OR unrespon*:ti OR ((lack OR no OR non OR 'not') NEXT/2 (eff* OR respon*)):ab,ti OR 'device failure':de,ab,ti OR manufacturing near/3 (error or fault or mistake or failure or contamination or impurity) OR 'patient compliance'/exp OR overdos*:de,ab,ti OR 'drug abuse'/exp OR abus*:de,ab,ti OR misus*:de,ab,ti OR 'off label':de,ab,ti OR unlicensed:de,ab,ti
Clear query
Reset form
Search details
Summary:
([drug]/[subheading] OR [drug]-induced:de,ab,ti) OR (([drug]:de OR [variants]:tn,ti,ab) AND (([adverse drug reactions]) OR ([special situations])))
Full search strategy
Previous step
Show 111,974 results
Next step

5/5


Embase®
Search
Browse
Results
My tools
Select Language
Ivan Krstic
Logout
(1)
Find best term
Emtree
anatomical concepts
biological functions
biomedical disciplines, science and art
chemical, physical and mathematical phenomena
chemicals and drugs
diseases
geographic names
groups by age and sex
health care concepts
named groups of persons
organisms
procedures, parameters and devices
society and environment
types of article or study
PV wizard
EMA's MLM searches >
Drug name
Alternative drug names
Adverse drug reactions
Special situations
Human limit
'human'/exp OR human OR m?n OR wom?n OR child OR boy OR girl
Clear query
Reset form
Limit to:
Publication years (including):
2017
to
2017
Records added to Embase:
1-1-2016
to
31-12-2016
Search details
Summary:
(([drug]/[subheading] OR [drug]-induced:de,ab,ti) OR (([drug]:de OR [variants]:tn,ti,ab) AND (([adverse drug reactions]) OR ([special situations])))) AND (human limit)
Full search strategy
Previous step
Show 111,974 results

Import EMA's MLM search

Once a search is run from saved search space it gets displayed on results page as any other regular search.