MedDRA – What's New?

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Topics

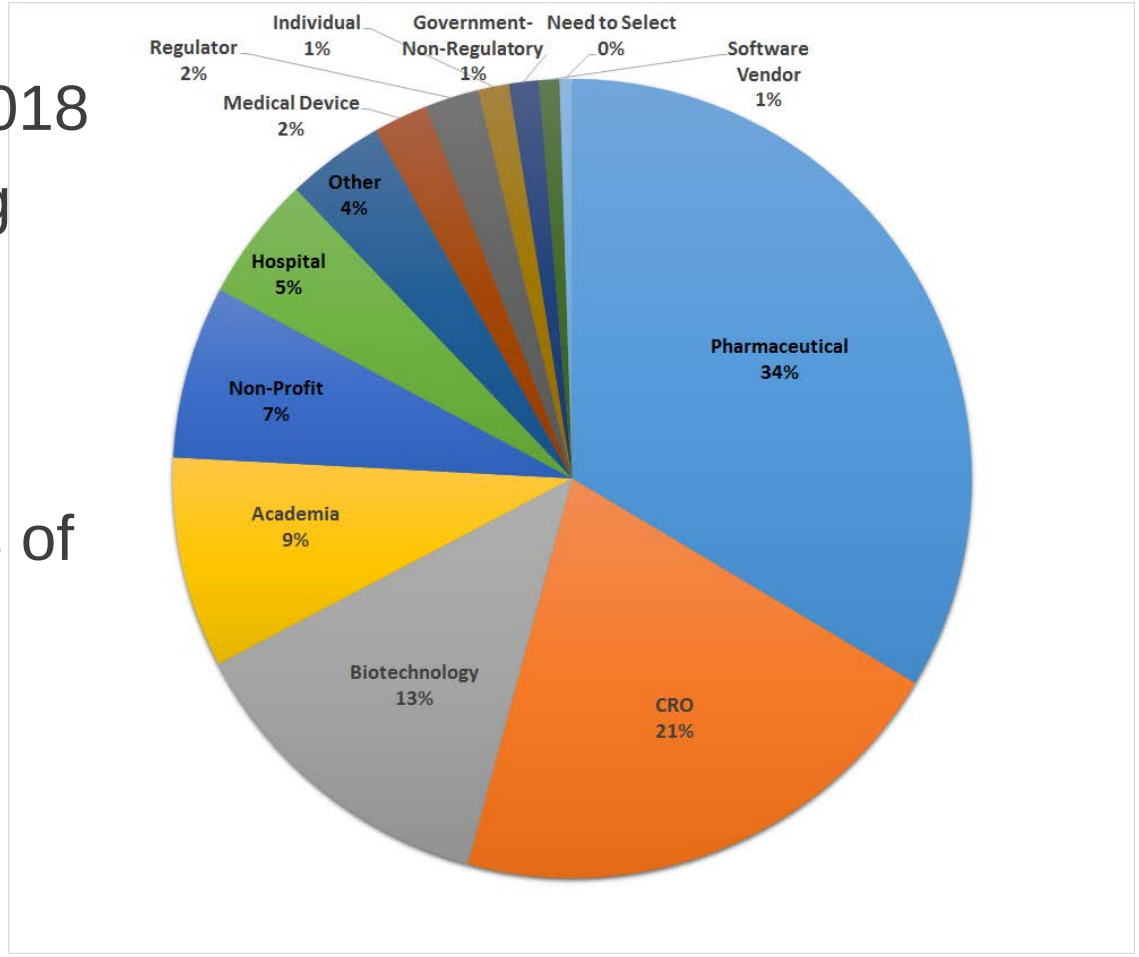
- 20 years of MedDRA
- Global uptake
- Points to Consider documents
- WEB-RADR project
- IMDRF and MedDRA
- Web-Based Browser update

20th Anniversary of MedDRA

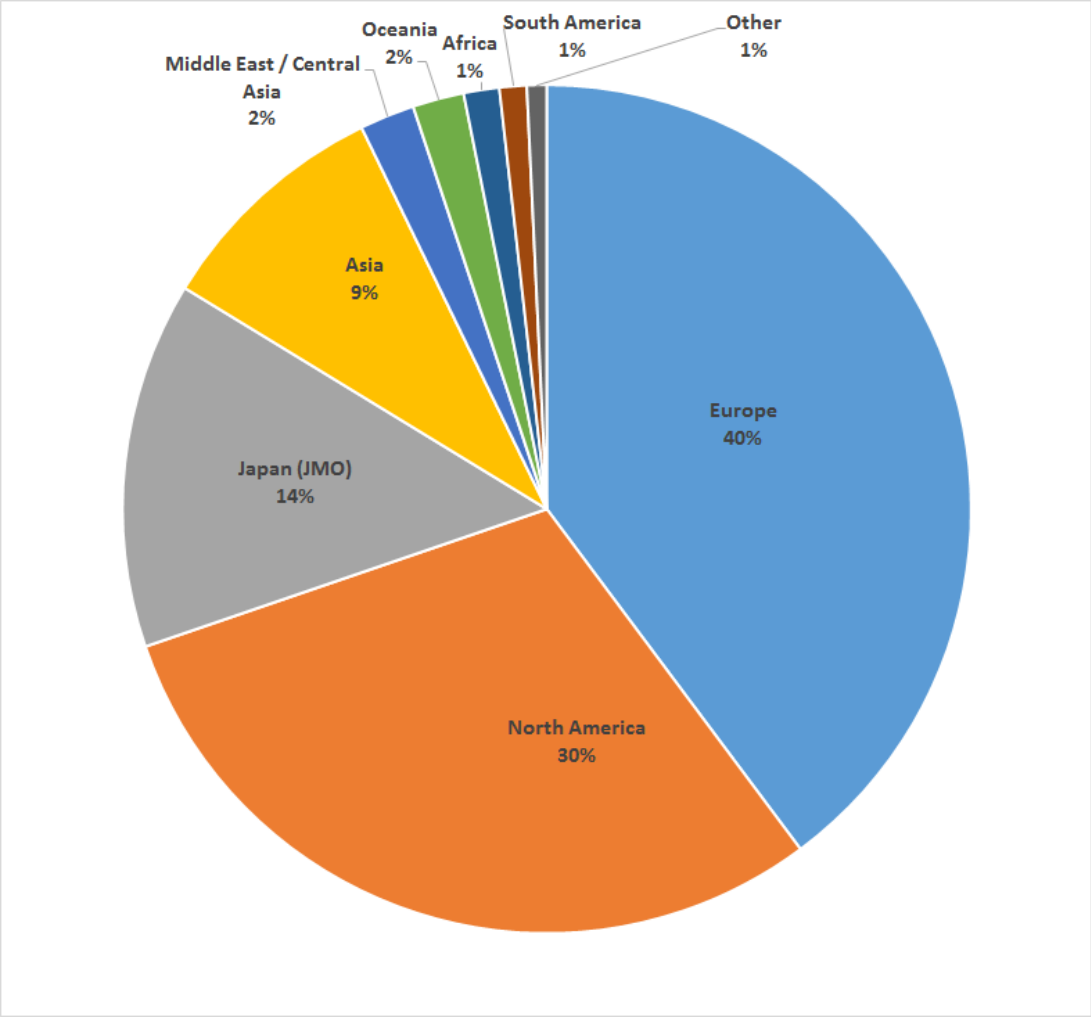
- In 2019 the MSSO will be celebrating twenty years of MedDRA
  - First release of MedDRA (version 2.1) on 1 March 1999
  - MedDRA was originally provided on diskettes; hardcopies were available for an additional charge

MedDRA Users Profile

- As of September 2018
  - 5,500 Subscribing organizations (MSSO+JMO)
  - 126 Countries
- Graph shows types of subscribing organizations



MedDRA Users by Region and Top 25 Countries



Country	Count
United States	1516
Germany	335
United Kingdom	332
France	248
China	234
Italy	209
Spain	145
Canada	129
South Korea	110
Australia	97
Sweden	94
Netherlands	88
India	82
Switzerland	81
Poland	74
Belgium	62
Chinese Taipei	60
Greece	54
Israel	52
Portugal	49
Denmark	47
Austria	45
Czech Republic	34
Russian Federation	34
Ireland	33

MedDRA Translations

- MedDRA is currently available in 11 languages
  - Chinese, Czech, Dutch, English, French, German, Hungarian, Italian, Japanese, Portuguese and Spanish
  - Translation includes all terms and documentation
- Working on Korean and Russian
  - Release dates for the new languages are to be determined

Local Support

- MSSO is in the process of hiring local support personnel
- China, India, Latin America, and the Republic of Korea
- To provide support for the use of MedDRA in the region
  - Training
  - Help Desk
  - Promotion of MedDRA
- Anticipate all will be engaged by early 2019

ICH M1 Points to Consider Working Group (PtC WG)

November 2017, Geneva, Switzerland

- Regulators and industry from EU, US, and Japan
- Health Canada
- MSSO
- JMO
- WHO (Observer)

New members 2017/2018

- MFDS, Republic of Korea
- ANVISA, Brazil
- NMPA, China

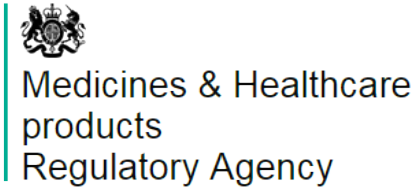
Points to Consider Documents

PtC Category	PtC Document	Purpose	Languages	Release Cycle
Term Selection	MedDRA Term Selection: Points to Consider	Promote accurate and consistent coding with MedDRA	English and Japanese	Updated with each MedDRA release
	MedDRA Term Selection: Points to Consider Condensed Version (NEW)	Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except English and Japanese)	Update as needed
Data Retrieval and Presentation	MedDRA Data Retrieval and Presentation: Points to Consider	Demonstrate how data retrieval options impact the accuracy and consistency of data output	English and Japanese	Updated with each MedDRA release
	MedDRA Data Retrieval and Presentation: Points to Consider Condensed Version (NEW)	Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except English and Japanese)	Update as needed
General	MedDRA Points to Consider Companion Document (NEW)	More detailed information, examples, and guidance on specific topics of regulatory importance. Intended as a “living” document with frequent updates based on users’ needs. First edition covers data quality and medication errors.	English and Japanese	Updated as needed

WEB-RADR 2 Project

- Supported by EU Innovative Medicines Initiative
- Build upon mobile application technology from original WEB-RADR project (WEB – Recognising Adverse Drug Reactions)
- Facilitate communication between regulatory and healthcare databases
- 18 month project: Sep 2018 – Feb 2020

Consortium Members



WEB-RADR 2 Project (cont)

- Work Package 4 “Terminology Mapping and Maintenance”
  - Develop a bi-directional pilot mapping between SNOMED CT and MedDRA
    - Starting point: ~7,000 frequently used MedDRA LLTs from EudraVigilance and MHRA databases
    - Reactions, indications, medical history, and limited set of test name terms
    - EMA Designated Medical Events (DMEs) also included
  - Develop licensing and distribution agreements
  - Develop ongoing maintenance processes

IMDRF and MedDRA

- International Medical Device Regulatory Forum (IMDRF)
  - Developing set of harmonized terminologies for reporting for medical devices
- Patient Problem Codes
  - IMDRF posted the draft Annex E: Health Effects – Clinical Signs, Symptoms and Conditions Terms and Codes for public comment (ended October 2018)
  - ~700 terms
  - Most of the terms are matches to existing MedDRA terms or are similar in concept

MSSO Feedback to IMDRF

- MSSO's interest is to narrow the differences between Annex E and MedDRA
  - It may not be possible to be exactly aligned
- IMDRF agreed to collaborate with the MSSO to map Annex E to MedDRA
  - Ideally, mapped MedDRA terms and codes would be included in IMDRF distribution format
- The use of MedDRA terms by IMDRF will help manufacturers that produce drugs, combination products, and devices since many are existing MedDRA users
- Discuss with IMDRF how to address ongoing maintenance of the list

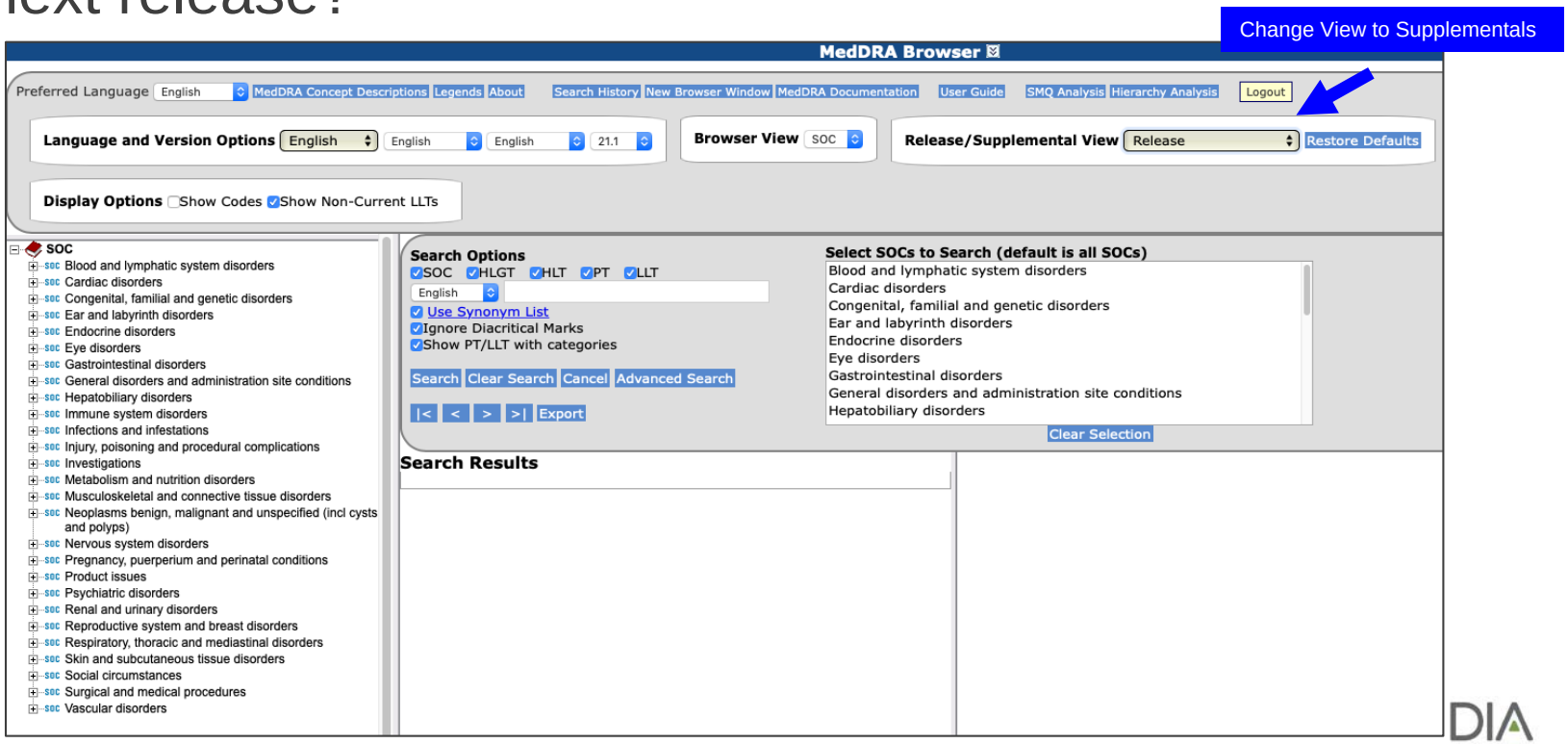
Web-Based Browser Update

- Web-Based Browser (WBB) 3.0
- New functionality for users
  - Preview upcoming (supplemental) changes in next release
  - View primary **and** secondary link information
  - Upload terms to run against SMQs
  - Advanced search options (e.g., NOT, OR)
- Deployed October 2018
- Corresponding MedDRA Desktop Browser update will follow in 2019*

*Supplemental view will not be available

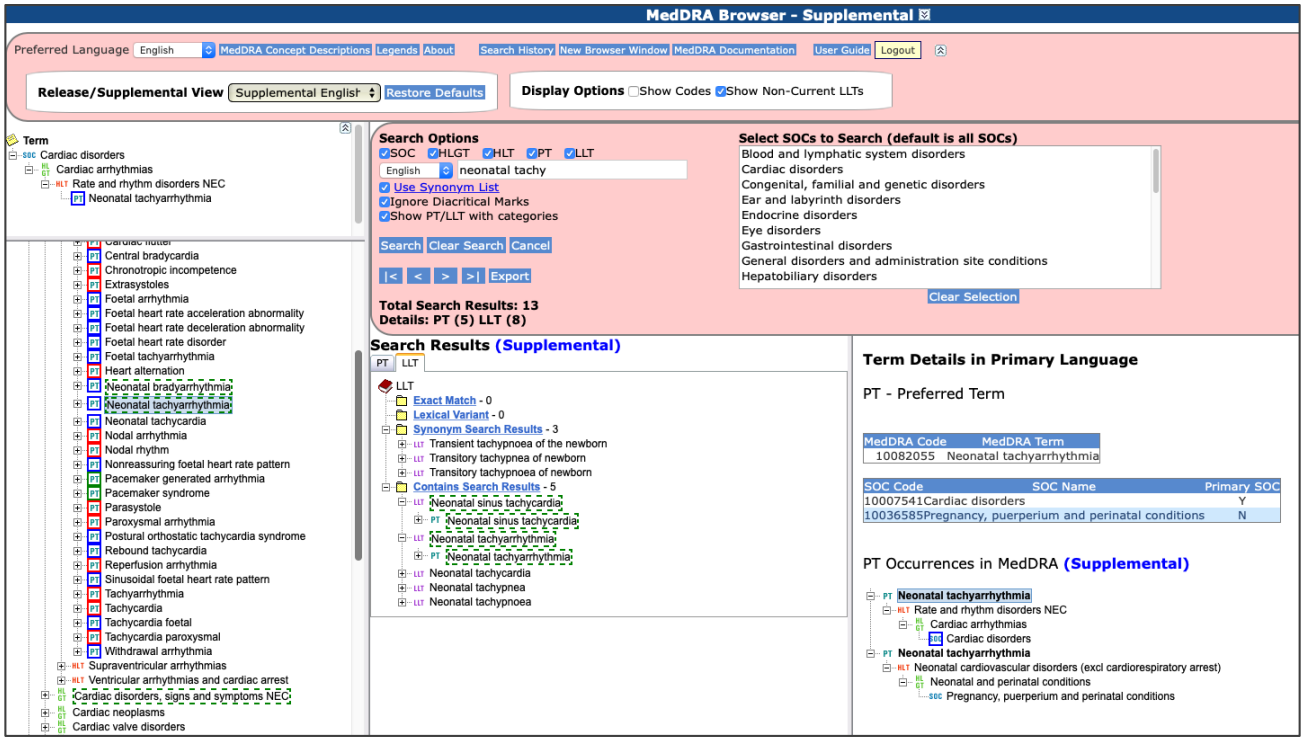
WBB Supplemental View

- Where will the Change Request that I submitted appear in the next release of MedDRA?
- What are the changes in a particular area of MedDRA in the next release?



WBB Supplemental View (cont)

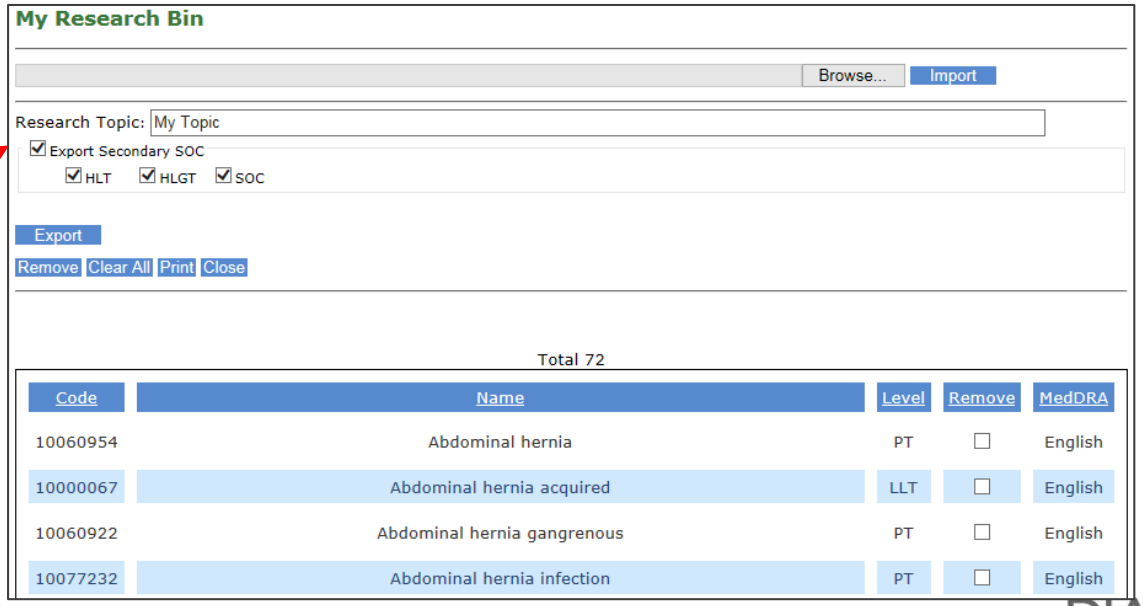
- Display changes color to pink
- Supplemental terms highlighted by broken green line
- Changes for the next release are displayed immediately after they are approved by the MSSO



Secondary SOC Information

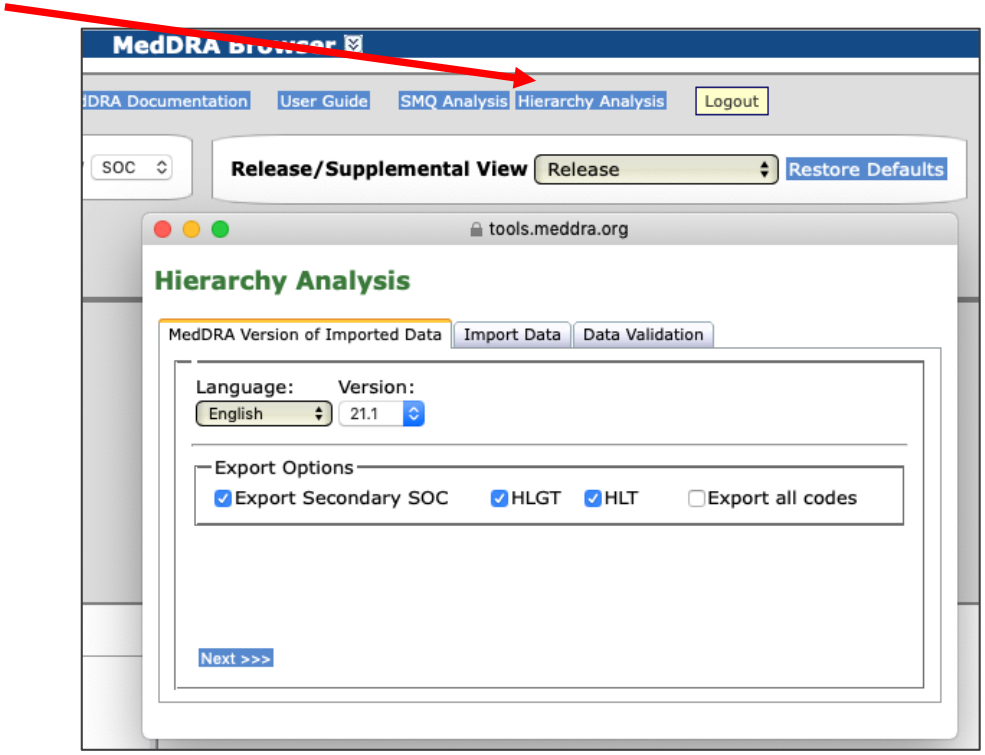
- My system shows only the primary SOC hierarchy. How do I view the secondary SOC links for a set of terms?
- Option 1: From the Research Bin
  - Add terms to Research Bin
  - Export with primary and secondary SOC hierarchies (default setting)

Optional Secondary SOC hierarchy



Secondary SOC Information (cont)

- Option 2: Hierarchy Analysis feature
  - Upload terms in spreadsheet
  - Export with primary and secondary SOC hierarchies
  - No need for programming



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Secondary SOC Analysis Example

- In my dataset, which are autoimmune disorders?

Row ID	Term	Primary SOC
1	Anaemia	Blood
2	Autoimmune neutropenia	
3	Evans syndrome	
4	Platelet anisocytosis	
5	Platelet toxicity	
6	Autoimmune myocarditis	Cardiac
7	Myocardial infarction	
8	Myocarditis	
9	Polyglandular autoimmune syndrome type I	Endocrine
10	Thyroid disorder	
11	Birdshot chorioretinopathy	Eye
12	Autoimmune uveitis	
13	Primary biliary cholangitis	Hepatobiliary
14	Hepatitis toxic	
15	Hepatocellular injury	
16	Autoimmune disorder	Immune
17	Arthritis	Musculoskeletal
18	Muscular weakness	
19	Polymyalgia rheumatica	
20	Rheumatoid arthritis	
21	Alopecia	Skin
22	Skin haemorrhage	
23	Vitiligo	

Input

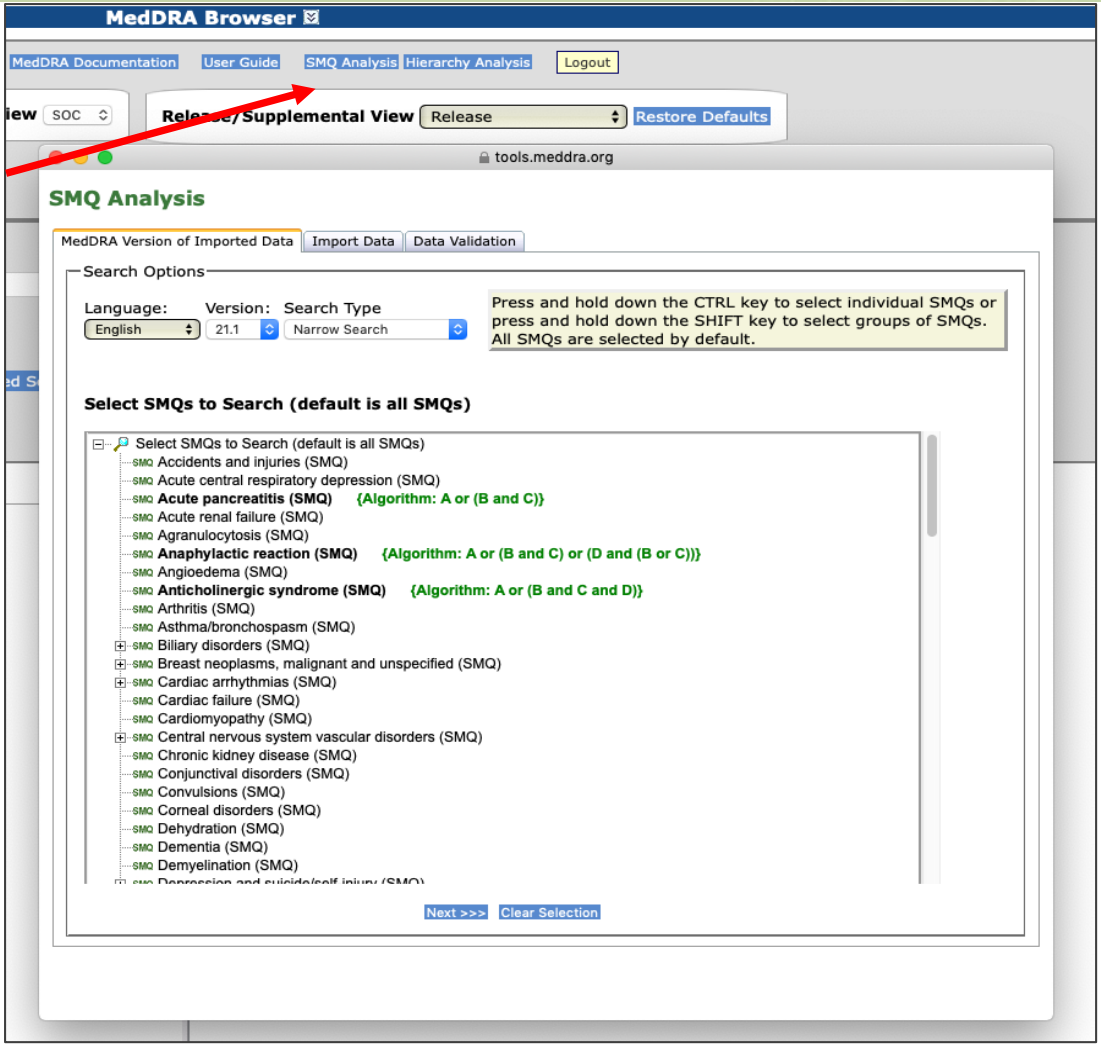
Secondary SOC Analysis Example (cont)

Row ID	Term	Code	Level	PT	HLT	HLGT	SOC	Primary SOC
6	Autoimmune myocarditis	10064539	PT	Autoimmune myocarditis	Autoimmune disorders NEC	Autoimmune disorders	Immune system disorders	N
12	Autoimmune uveitis	10075690	PT	Autoimmune uveitis	Autoimmune disorders NEC	Autoimmune disorders	Immune system disorders	N
11	Birdshot chorioretinopathy	10072959	PT	Birdshot chorioretinopathy	Autoimmune disorders NEC	Autoimmune disorders	Immune system disorders	N
2	Autoimmune neutropenia	10055128	PT	Autoimmune neutropenia	Blood autoimmune disorders	Autoimmune disorders	Immune system disorders	N
3	Evans syndrome	10053873	PT	Evans syndrome	Blood autoimmune disorders	Autoimmune disorders	Immune system disorders	N
9	Polyglandular autoimmune syndrome type I	10036072	PT	Polyglandular autoimmune syndrome type I	Endocrine autoimmune disorders	Autoimmune disorders	Immune system disorders	N
13	Primary biliary cholangitis	10080429	PT	Primary biliary cholangitis	Hepatic autoimmune disorders	Autoimmune disorders	Immune system disorders	N
19	Polymyalgia rheumatica	10036099	PT	Polymyalgia rheumatica	Muscular autoimmune disorders	Autoimmune disorders	Immune system disorders	N
20	Rheumatoid arthritis	10039073	PT	Rheumatoid arthritis	Rheumatoid arthritis and associated conditions	Autoimmune disorders	Immune system disorders	N
23	Vitiligo	10047642	PT	Vitiligo	Skin autoimmune disorders NEC	Autoimmune disorders	Immune system disorders	N
14	Hepatitis toxic	10019795	PT	Hepatitis toxic	Poisoning and toxicity	Exposures, chemical injuries and poisoning	Injury, poisoning and procedural complications	N
5	Platelet toxicity	10059440	PT	Platelet toxicity	Poisoning and toxicity	Exposures, chemical injuries and poisoning	Injury, poisoning and procedural complications	N
18	Muscular weakness	10028372	PT	Muscular weakness	Neuromuscular disorders NEC	Neuromuscular disorders	Nervous system disorders	N
22	Skin haemorrhage	10064265	PT	Skin haemorrhage	Bruising, ecchymosis and purpura	Vascular haemorrhagic disorders	Vascular disorders	N
7	Myocardial infarction	10028596	PT	Myocardial infarction	Coronary necrosis and vascular insufficiency	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Vascular disorders	N
3	Evans syndrome	10053873	PT	Evans syndrome	Anaemias haemolytic immune	Haemolyses and related conditions	Blood and lymphatic system disorders	Y
1	Anaemia	10002034	PT	Anaemia	Anaemias NEC	Anaemias nonhaemolytic and marrow depression	Blood and lymphatic system disorders	Y

Output sorted by secondary SOCs – 10 autoimmune disorders

SMQ Analysis

- SMQ Analysis feature
- Apply SMQs to user's MedDRA-coded data
  - Narrow/broad
  - Hierarchical
  - Algorithmic (separate search option to apply algorithm)



SMQ Analysis (cont)

- Run broad search on all SMQs
- In my dataset, which cases are “hits” for SMQs (potential cases of interest)?

A	B	C	D
Row ID	Term	Term Code	Case ID
1	Amylase abnormal	10072327	1
2	Abdominal distension	10000060	1
3	Acute kidney injury	10069339	2
4	Blood creatinine increased	10005483	2
5	Status asthmaticus	10041961	3
6	Gout	10018627	4
7	Joint effusion	10023215	4
8	Major depression	10057840	5
9	Suicidal ideation	10042458	5
10	Cataract operation	10063797	6
11	Abdominal pain	10000081	7
12	Diarrhoea	10012735	7
13	Palpitations	10033557	8
14	Atrial flutter	10003662	8
15	Pancreatitis acute	10033647	9
16	Dementia Alzheimer's type	10012271	10
17	Hypertension	10020772	10
18	Anaphylactic shock	10002199	11
19	Bronchospasm	10006482	12
20	Swelling face	10042682	12
21	Rash generalised	10037858	12
22	Hypotension	10021097	12
23	SLE arthritis	10040968	13
24	Haemolysis	10018910	14
25	Autoimmune nephritis	10077087	14
26	Double stranded DNA antibody positive	10069907	14
27	Photodermatosis	10051246	15
28	Pleural effusion	10035598	15
29	Epilepsy	10015037	15
30	Disease progression	10061818	16
31	Exercise tolerance decreased	10051301	16

Input

SMQ Analysis (cont)

- Results of broad search on all SMQs
  - Includes narrow search
  - Includes hierarchical SMQs
  - Algorithmic SMQ analysis not shown
- If term is not in an SMQ, shows as "No Match"

A	B	C	D	E	F	G	H	I	J	K
SMQ Analysis			(2_Upload_SMQ narrow broad W	8/17/2018 11:10:43 AM						
MedDRA English 21.0 (Search Type:: Broad Search			SMQs Selected: All)							
Row ID	LLT/PT Term	LLT/PT Code	PT	SMQ Matched	Scope	Category	Weight	Status	Case ID	SMQ Hierarchy
2	Abdominal distension	10000060	Abdominal distension	Gastrointestinal nonspecific symptoms and therapeutic procedures (SMQ)	Narrow	A	0	Active	1	Gastrointestinal nonspecific inflammation and dysfunctional conditions
2	Abdominal distension	10000060	Abdominal distension	Acute pancreatitis (SMQ)	Broad	C	0	Active	1	
11	Abdominal pain	10000081	Abdominal pain	Retroperitoneal fibrosis (SMQ)	Broad	A	0	Active	7	
11	Abdominal pain	10000081	Abdominal pain	Gastrointestinal nonspecific symptoms and therapeutic procedures (SMQ)	Narrow	A	0	Active	7	Gastrointestinal nonspecific inflammation and dysfunctional conditions
11	Abdominal pain	10000081	Abdominal pain	Acute pancreatitis (SMQ)	Broad	C	0	Active	7	
3	Acute kidney injury	10069339	Acute kidney injury	Tumour lysis syndrome (SMQ)	Broad	C	0	Active	2	
3	Acute kidney injury	10069339	Acute kidney injury	Toxic-septic shock conditions (SMQ)	Broad	A	0	Active	2	Shock (SMQ)
3	Acute kidney injury	10069339	Acute kidney injury	Torsade de pointes, shock-associated conditions (SMQ)	Broad	A	0	Active	2	Shock (SMQ)
3	Acute kidney injury	10069339	Acute kidney injury	Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (SMQ)	Broad	A	0	Active	2	Shock (SMQ)
3	Acute kidney injury	10069339	Acute kidney injury	Rhabdomyolysis/myopathy (SMQ)	Broad	A	0	Active	2	
3	Acute kidney injury	10069339	Acute kidney injury	Hypovolaemic shock conditions (SMQ)	Broad	A	0	Active	2	Shock (SMQ)
3	Acute kidney injury	10069339	Acute kidney injury	Hypoglycaemic and neurogenic shock conditions (SMQ)	Broad	A	0	Active	2	Shock (SMQ)
3	Acute kidney injury	10069339	Acute kidney injury	Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)	Broad	B	0	Active	2	
3	Acute kidney injury	10069339	Acute kidney injury	Dehydration (SMQ)	Broad	A	0	Active	2	
3	Acute kidney injury	10069339	Acute kidney injury	Anaphylactic/anaphylactoid shock conditions	Broad	A	0	Active	2	Shock (SMQ)
3	Acute kidney injury	10069339	Acute kidney injury	Acute renal failure (SMQ)	Narrow	A	0	Active	2	
1	Amylase abnormal	10072327	Amylase abnormal	Acute pancreatitis (SMQ)	Broad	B	0	Active	1	
18	Anaphylactic shock	10002199	Anaphylactic shock	Hypersensitivity (SMQ)	Narrow	A	0	Active	11	
18	Anaphylactic shock	10002199	Anaphylactic shock	Anaphylactic/anaphylactoid shock conditions	Narrow	A	0	Active	11	Shock (SMQ)
18	Anaphylactic shock	10002199	Anaphylactic shock	Anaphylactic reaction (SMQ)	Narrow	A	0	Active	11	

Summary

- MedDRA has come a long way in 20 years
- Established as a true international standard
- Will continue to evolve

Ask