What is proactive MedDRA Maintenance?

Proactivity relates to making more general changes to MedDRA – perhaps correcting a series of outdated terms or addressing an area of inconsistency to help resolve coding or analysis issues– based on user input outside the change request process.

Submitting your ideas for proactive maintenance

The MSSO is interested to hear any ideas you may have about "proactive" improvements to MedDRA. Please e-mail your ideas for "proactive" improvements to MedDRA to the MSSO Help Desk (mssohelp@meddra.org). Be as specific as possible in describing your issue. Suggestions must include a justification which indicates a specific organizational need or an issue that needs resolution.

Evaluating proactive maintenance proposals

The MSSO will evaluate all input received for potential implementation in a future version of MedDRA. Please keep the following in mind:

- Unlike the change request process – the MSSO will not be obligated to respond to users on the disposition of their submitted "proactivity" ideas in a specific time frame.
- The "proactivity" approach does not take the place of usual change requests for individual changes in MedDRA. The MSSO will not process individual change requests submitted as "proactivity" ideas.

Below are the current set of proactivity proposals and their status.

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
8	Adding bleeding LLTs to Haemorrhage PTs	"Bleeding" is a very commonly used synonym for "haemorrhage". Per MedDRA convention, "Haemorrhage" represents the PT concepts for bleeding. Not all "haemorrhage" PTs in MedDRA have "bleeding" LLTs. To facilitate coding of verbatim terms it will be helpful to add "bleeding" LLTs for all "haemorrhage" PTs that do not have already synonym LLTs with "bleed/bleeding". Example: add LLT Muscle bleeding to PT Muscle haemorrhage	Implemented	Per MedDRA convention, haemorrhage and bleeding are considered synonymous concepts. In MedDRA, haemorrhage is generally represented at the PT level and bleeding at the LLT level to facilitate coding. Based upon a proactivity request to improve MedDRA for coding and consistency, the MSSO is adding the missing bleeding LLTs under existing haemorrhage PT terms.	9/15/2011	15.0
9	MSSO created/authorized HLT abbreviations/truncated words of around 20 to 25 characters.	In our program we have started to make much more extensive use of HLTs in reports and analysis. Problem: While PT terms are relatively short and compact (we're talking string length here), many, many HLTs are wordy, lengthy and verbose. They are so long that it is really impossible to use them in a table listing on a standard 8.5 by 11 page. You can confirm this with a simple strength length check on HLTs. There is also one overly long PT that always wrecks tables: "Transmission of an infectious agent via a medicinal product" (10067591) We really need authorized HLT abbreviations of around 20 to 25 characters.	Declined to pursue	The MSSO has decided not to pursue a proposal to create standardized HLT/HLGT abbreviations of around 20 to 25 characters to represent lengthy HLTs and HLGTs (i.e., exceeding 25 characters). The MedDRA data schema defines the field length of term names to be 100 characters or less. HLTs and HLGTs represent grouping terms which are likely to have longer names to accurately describe their contents (i.e. their respective HLTs and PTs). The MSSO cannot always accommodate limitations of a MedDRA user's software or data analysis methods.	9/22/2011	N/A
10	Harmonize the use of hyphen in "Non-" terms.	Look up other "Non-" and "Non" terms to harmonize the use of hyphen and determine if there is any point in doing this harmonization. A subscriber made a comment in the justification section of their request - Would you consider using a consistent spelling of these hyphenated and non-hyphenated words in MedDRA? PT terms: Appendicitis noninfective Croup noninfectious Cystitis noninfective Endocarditis noninfective Hyperglycaemic hyperosmolar nonketotic syndrome Meningitis noninfective Nongerminomatous germ cell tumour of the CNS Noninfective bronchitis Nonspecific reaction Nontherapeutic agent urine negative Nontherapeutic agent urine positive Sinusitis noninfective Treatment noncompliance Urethritis noninfective.	Declined to pursue	The MSSO has decided not to pursue the proposal to harmonize the use of a hyphen in terms with a 'non' modifier. The use or the absence of a hyphen in MedDRA terms is generally based on the prevalent use of these terms in medical literature and consistency with existing terms. For example, terms that contain the words "Non-Hodgkin's lymphoma" have a hyphen. The MSSO reviewed all terms with a 'non' qualifier with and without hyphens and concludes that it would be very difficult to establish and implement rigid rules for the use of a hyphen for these terms without hampering data retrieval and analysis of other MedDRA users. However, the MSSO will consider individual changes to hyphenated terms with adequate justification of need via the usual change request process.	1/19/2012	N/A
11	Addition of death and injury resulting from terrorism	I was looking in the CDC website today and found a section on the "Classification of death and injury resulting from terrorism" (using ICD-9 coding). I was wondering if you had suggestions/guidelines on how to code these acts (if recorded as adverse events or medical history entries) in MedDRA or if there should be a section in the MedDRA points to consider guidelines addressing how these types of acts should be coded in MedDRA?	Declined to pursue	The proposal to add death and injury concepts resulting from terrorism will not be pursued. The MSSO acknowledges that it may be important to capture death and injury concepts resulting from terrorism as adverse events or to record medical history, however, such concepts would be considered combination terms. Combination terms are generally not added to MedDRA because it is not feasible to account for all possible combinations of death and injury resulting from terrorism. Therefore, please consider submitting change requests for addition of new terms such as "terrorism" or "victim of terrorism". "Terrorism" or "victim of terrorism" could be paired with the appropriate adverse event (e.g., LLT Injury radiation) to indicate that the condition resulted from terrorism. Please note section 3.5.4 of the Term Selection: Points to Consider Document provides the option for splitting and coding.	9/22/2011	N/A

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12	Reconciling SDTM/CDISC terms into MedDRA because of an increasing interest.	With the increasing interest in SDTM/ CDISC, I would like to suggest to the MSSO they review the CDISC Lab tests and routinely add these to MedDRA where these are found to be missing but appropriate. I realise that in some cases the LLT name would need to be modified from the CDISC submission values to fit MedDRA rules. In addition, the MSSO could also consider including the Microorganisms included in CDISC Microorganisms code lists. This would increase the value of the Investigations SOC in analysis and reporting.	Declined to pursue	The MSSO has decided not to pursue the proposal to add CDISC laboratory tests and microorganism code lists to MedDRA. At this time, the MSSO prefers to rely on individual user submitted requests to add laboratory tests and microorganism concepts to MedDRA based on a specific need rather than add the CDISC lists which could present long term maintenance issues. With respect to the CDISC Microorganisms code lists, a number of these organisms have already been renamed to a more updated microorganism classification; such reclassifications could present a significant maintenance challenge if the entire list of microorganism terms proposed were added. The MSSO will consider adding individual laboratory tests and microorganism terms with adequate justification of need via the usual change request process to reflect the specific needs of the user community.	1/19/2012	N/A
13	Add terms specific for indication that would differentiate the cause of medically-induced abortion.	In the circumstance when a medically-induced abortion is performed because of a non-lethal congenital anomaly, it is not appropriate to give the name of the anomaly or condition as the indication for the termination since it is by definition subjective rather than objective reasoning. Example: Pregnant woman undergoes medically-induced abortion at 23 weeks gestation because she finds on prenatal ultrasound that baby has spina bifida. Procedure: Medically-induced abortion Indication for procedure: ????? Spina bifida is a diagnostic term for a specific congenital anomaly, but not an indication for termination of a pregnancy. The indication is a maternal and/or paternal factor in this case. Contrast to anencephaly or another lethal anomaly for which extra-uterine survival is impossible; diagnostic term condition could potentially be used as indication. For consistency, specific terminology for indication for medically-induced abortion could be developed that differentiates indications. “Lethal congenital anomaly” could indicate impossibility of extra-uterine survival, while another term could indicate parental preference as the indication. Failure to distinguish between these two indications is both medically inaccurate as well as analytically false when the data are examined. Clarity also removes the coding process from “political correctness” or use of coding to further any particular social agenda. I reviewed most of the “points to consider” documents and did not find this topic addressed.	Declined to pursue	The proposal to add terms for specific indications that would differentiate the cause of medically-induced abortion will not be pursued. It is not feasible to add specific terms for every possible type of indication and medically-induced abortion. Such combination terms are generally not added to MedDRA to avoid overpopulation of the terminology. There are a number of existing abortion terms that can be paired with an appropriate indication. Please note that section 3.5.4 of the Term Selection Points to Consider Document recommends selecting more than one term to accurately capture clinical information.	9/22/2011	N/A
14	PTs representing ruptured aneurysms	For safety data retrieval, hemorrhages are of major relevance. PTs like Aortic aneurysm rupture are not represented under HLGT Vascular haemorrhagic disorders, although aneurysm rupture will definitely lead to bleeding. This PT even includes LLTs like Abdominal aortic aneurysm h(a)emorrhage or Aortic aneurysm h(a)emorrhage. Similarly, PT Ruptured cerebral aneurysm includes LLT Intracracranial h(a)emorrhage ruptured aneurysm but is not represented as haemorrhagic disorder. Deviating from this approach, ruptured varices of the GI tract are always represented as haemorrhagic conditions and respective LLTs are even linked to "haemorrhage" PTs (e.g. LLT Gastric varices ruptured is linked to PT Gastric varices haemorrhage, LLT (O)esophageal varices is linked to PT Oesophageal varices haemorrhage). In contrast, PT Varicose vein ruptured is not grouped as haemorrhagic condition, but under HLT Varicose veins non-site specific. We do not want to start a purely academic discussion and do recognize that similar conditions may be represented differently in MedDRA for pragmatic reasons. But in this instance, we feel that the current handling of these terms is inadequate and should be reconsidered.	Declined to pursue	The MSSO has reviewed your request to place ruptured aneurysm concepts (e.g., PT Aortic aneurysm rupture) under a MedDRA hierarchical grouping for “haemorrhage,” in addition to, or instead of, their current placement under site-specific or non-site-specific aneurysm HLTs in SOC Vascular disorders. The MSSO has decided not to pursue this request. Aneurysm terms – such as PT Aortic aneurysm rupture – are in SOC Vascular disorders because the anatomic “site” of this lesion is the vascular system. MedDRA rules do not allow a PT to be in more than one grouping (HLT or HLGT) within a single SOC. Linking PT Aortic aneurysm rupture to two HLTs in the same SOC as proposed in this proactivity request – one representing the disorder of the vessel (aneurysm) and another representing the consequence of rupture (hemorrhage) – would violate this rule. The same principles apply to other vascular rupture terms in SOC Vascular disorders, such as PT Varicose vein ruptured. SMQ Haemorrhage terms (excl laboratory terms) may also be used to identify reports of hemorrhage, including those related to ruptured aneurysms and other vascular ruptures.	10/15/2013	N/A

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
15	Terms referring to "bruises"	The MedDRA approach to handle "bruises/bruising" and "contusion" as synonyms is problematic. Often, "contusions" do not imply bleeding (e.g. in many cases of brain contusion) but "bruise/ bruising" always reflects bleeding. The LLTs with the string "bruise/ bruising" are sometimes represented under PT Contusion but sometimes linked to "haematoma" PTs. For safety signaling purposes, consistent representation of LLTs with the string "bruis" under suitable "haematoma" PTs seems to be more appropriate, because drug-induced bruising is not caused by contusion but due to bleeding tendency. An example out of daily coding practice: Based on the current MedDRA philosophy, a "Bruised liver" would be coded to LLT Liver contusion (PT Traumatic liver injury), completely losing the bleeding aspect. In our view, LLT Hepatic haematoma would be the better option, especially when the investigationsl/ suspect drug is an anticoagulant or antiplatelet agent. But when coding to the latter, we would deviate from MedDRA and start work-arounds which are not fully in line with ICH guidelines ("code as reported"). Also, Coders would get completely confused because they routinely take MedDRA as a guidance.	Implemented	The MSSO reviewed the placement of bruise, contusion, and ecchymosis concepts in MedDRA. The review focused on reviewing established medical definitions for bruise, contusion, and ecchymosis and then harmonizing the placement of these terms in a more consistent manner to facilitate coding and data analysis. A total of 64 changes were made. Please see the What's New MedDRA Version 16.0 document for more details on the general convention used to modify these terms.	12/4/2012	15.1
16	Missing UK/US spelling LLT pairings	A MedDRA user pointed out that there are missing US spelling LLT counterparts to British term LLT spellings containing the word "esophag". Examples of British spellings without a US counterpart include, but are not limited to, the following terms: Barrett's oesophagitis, Cytomegalovirus gastroesophagitis, Esophagitis, unspecified, Oesophagitis bacterial nos, Oesophagitis nos Other esophagitis, and Worsening of oesophagitis. Please identify and add the missing spellings. There may be additional missing UK/US pairings that need to be added.	Implemented	In MedDRA v15.1 the MSSO added a small set of missing American English or British English spelling counterparts to existing esophageal terms to improve MedDRA for coding and consistency. After implementing these missing counterparts, a more extensive review was conducted to identify additional missing American or British spellings of existing terms throughout MedDRA. This review was completed for MedDRA v16.1 and resulted in 216 new terms being added.	5/15/2013	16.1
17	bruises, hematomas and ecchymosis	Would you kindly help clarify the MSSO's perspective on the coding of (bruises, hematomas and ecchymosis) as the PT's differ based on specification and body location. By definition, ecchymosis and bruising are medical terms that have the same meaning. The MSSO changes the PT on "Contusion" based on the location from a "Genital Injury" and "Bruise" to "Contusion" and "Bruise" to "Hematoma". This changes the (SOC) System Organ Classing from Injury, Poisoning Procedural Complication to Reproductive System and Breast Disorder. Another topic that remains unclear would be "Ecchymosis". As if a subject or investigator reported simply "Ecchymosis" we would code the verbatim and the PT would be "Ecchymosis". However, if the patient or investigator reports "Penile Ecchymosis" the PT level is upgraded to a hemorrhage level . By medical definition a hemorrhage is not the same as a "bruise, contusion or ecchymosis". Your expertise and the MSSO's guidance would help our term selection methods and assure quality with coding as well as facilitate a common understanding of the term selection for business purposes and regulatory requirements.	Implemented	The MSSO reviewed the placement of bruise, contusion, and ecchymosis concepts in MedDRA. The review focused on reviewing established medical definitions for bruise, contusion, and ecchymosis and then harmonizing the placement of these terms in a more consistent manner to facilitate coding and data analysis. A total of 64 changes were made. Please see the What's New MedDRA Version 16.0 document for more details on the general convention used to modify these terms.	12/4/2012	16.0
18	Congenital, acquired and unqualified terms	The current convention for conditions and diseases that exist in both congenital and acquired forms is to represent the more common form at the PT level without a qualifier (e.g., PT Hypothyroidism) and to represent the less common form as a PT with a qualifier added (e.g., PT Congenital hypothyroidism). When reviewing data, it is not readily apparent whether an unqualified PT represents a congenital or acquired condition without looking further up the hierarchy to the SOC level. To facilitate analysis, would the MSSO consider representing both congenital and acquired forms with qualifiers at the PT level (e.g., PT Congenital hypothyroidism and PT Acquired hypothyroidism)? The existing unqualified PTs with unqualified LLTs should remain as placed according to the current convention to enable coding and retrieval of conditions/diseases where the congenital or acquired form is not specified in the reported verbatim.	Declined to pursue	An in-depth review of the current placement of congenital and acquired terms in MedDRA was performed. The MSSO recognizes that the current convention of representing the more common form of a disease or condition at the PT level without a qualifier and representing the less common form as a PT with a qualifier may not always be optimal as it is not always clear which concept is congenital or an acquired condition. However, adjusting MedDRA as proposed to have both congenital and acquired forms with qualifiers and an unqualified term at the PT level would create two very similar PT concepts which could lead to coding confusion and signal dilution. In addition, the proposal would necessitate a great number of changes and would likely impact the legacy data of MedDRA users. For these reasons, the MSSO will not pursue this proposal.	5/7/2013	N/A

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
19	Include more device terms in MedDRA	Reqeust to add more device terms in MedDRA with a focus on the ISO adverse event terms and usability terms.	Declined to pursue	Device related terms are an evolving area of interest to the MedDRA user community and therefore the MSSO took a conservative approach when evaluating this proposal. As part of our ongoing initiative to expand MedDRA terminology pertaining to medical devices, we are currently evaluating the general area of user-related device concepts. The MSSO has deferred action on a number of the proposed terms of this nature, and pending completion of our evaluation, we will inform the submitter of our decisions. Nonetheless, 5 new LLTs were added from the information provided by the submitter that could enhance coding. They are as follows: • LLT Device burst and LLT Device cracked were added to PT Device breakage • LLT Device material degradation was added to PT Device material issue • LLT Device colour faded and LLT Device color faded were added to PT Device colour issue These changes were implemented for MedDRA Version 16.1. The MSSO will consider additional device related terms on a case by case basis.	8/26/2013	N/A
20	Review reassigning the Primary SOC for Autoimmune disorders	This review and analysis is based on a MedDRA user request submitted for Version 15.0 (change request 2011328009; batch 10100938) to reassign the primary SOC of the PT Sjogren's syndrome from SOC Musculoskeletal and connective tissue disorders to SOC Immune system disorders. Justification provided;" Change primary SOC to Immune SOC. The primary concept of this syndrome is an autoimmune disorder, and site of manifestation varies depending on the patient. Therefore, it should be linked primarily to Immune SOC". Definition of Sjogren's syndrome; systemic autoimmune disease in which immune cells attack and destroy the exocrine glands[2] that produce tears and saliva. After review, the request was not approved with the rationale that the placement of PT Sjogren's syndrome is in accordance with the MedDRA rule for primary SOC allocation to the site of manifestation. Sjögren is classified as autoimmune system disorder affecting the collagen tissues mainly of lacrimal, salivary glands. Accordingly, the PT primarily links to HLT Connective tissue disorders (excl LE) in the SOC Musculoskeletal and connective tissue disorders and secondarily is represented in SOC Eye disorders, SOC Immune system disorders, and SOC Gastrointestinal disorders. However, the rationale provided by the submitter may be applicable to other autoimmune disorder concepts classified as "systemic" and the MSSO decided to review these autoimmune disorder concepts with respect to their primary SOC allocation.	Implemented	The MSSO reviewed the placement of autoimmune disorder concepts classified as "systemic" as part of a proactivity initiative. The review focused on providing additional links, or in some cases reassigning the primary SOC, of existing terms to SOC Immune system disorders. A total of 50 changes were made based on this review in MedDRA v16.0.	12/4/2012	16.0
21	Infectious and non-infectious inflammatory terms	MedDRA is inconsistent with the way it assumes inflammatory terms as infectious or not. We note sinusitis reports under the infections while pneumonitis maps to the respiratory SOC; diverticulitis codes to infections while colitis maps to the GI SOC, etc. When we receive terms that are specified as non-infectious, such as "non-infectious diverticulitis" or "non-infectious salpingitis", for example, proper coding becomes a challenge. Can the MSSO consider including non-infectious LLT and PTs for at least the common inflammatory terms that would map under the anatomic SOC instead of the infections SOC?	Implemented	The MSSO was asked to review inconsistencies in the representation of existing infectious and noninfectious concepts and to identify missing infectious and noninfectious counterpart terms that could be useful for coding and analysis. As a result of this initiative, 18 new valid medical concepts were added and 54 changes to existing terms were made in MedDRA v17.0. The preferred wording for the new terms is "infective" and "noninfective" (without a hyphen), in accordance with the format of most existing MedDRA terms. Primary SOC allocations for new PTs were made in accordance with section 6.11.2 of the MedDRA Introductory Guide.	1/24/2014	17.0
22	Catheter and stoma site terms	For clear presentation of data It is important to be able to capture the specifics of a "catheter or stoma site" reaction in order retrieve data for analysis. For signal identification it will be important to determine if the "site reactions" are common skin complication which usually fall into one of five categories: faecal/urine dermatitis, trauma, infection, pre-existing skin conditions, allergy or another reaction that requires additional investigation.	Implemented	The MSSO added a set of catheter site term in MedDRA Version 16.1 to improve coding and data analysis. The current MedDRA hierarchy does not have an appropriate grouping term to add "stoma site" terms in MedDRA. For this reason, the MSSO will propose a new HLT Stoma site reactions under HLGT Procedural related injuries and complications NEC for MedDRA Version 17.0. The proposed list of stoma site terms will be used as a basis to include terms under this new HLT.	7/9/2013	17.0

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
23	Misinterpretation of “intestinal” terms with the qualifiers	I would like to make you aware of an issue in MedDRA wording that can be misinterpreted. This has already caused some confusion in operational coding but also in the interpretation of coded safety data. There are numerous LLTs and PTs combining the information “intestinal” with the qualifiers “small” and “large”. In many instances, the combination of these terms is ambiguous - it is not fully clear whether e.g. LLT Large intestinal ulcer refers to a “large intestine ulcer ” or is describing a “large ulcer in the intestinal tract”. The wording “intestinal” in these terms should rather be replaced by “intestine”. This way, there would be no room for interpretation.	Declined to pursue	A MedDRA user asked the MSSO to modify terms with 'intestinal' to 'intestine' to avoid potential confusion between severity of concepts and the anatomical site. The MSSO did an in-depth review of this issue, and concludes that changing the qualifiers such as 'small intestinal' or 'large intestinal' to 'small intestine' or 'large intestine' respectively, results in the same potential confusion between a disease entity being localized to an anatomical site or an indication of the severity of the disease. For example a small intestine ulcer (versus small intestinal ulcer) could either represent an ulcer in the small intestine or a small ulcer in the intestine. To address this issue, the MSSO proposes to clarify in section 5.1 of the MedDRA Introductory Guide that terms with a combination of small /large and intestine/intestinal refers to the anatomical site, such as PT Small intestinal haemorrhage and PT Large intestinal obstruction, and does not represent severity of concepts.	4/23/2013	N/A
24	Neonatal LLTs not linked to "Neonatal" PTs	I would like to draw your attention to an additional issue in MedDRA that may be worth to look at. There are several “neonatal, “neonaturum”, “perinatal”, “newborn”, “due to birth trauma” LLTs that are not linked to a “neonatal” term (or similar wording) on the PT level. Some examples: · LLT: Polycythaemia neonatorum · LLT: Unspecified perinatal disorder of digestive system · LLT: Maternal anaesthesia and analgesia affecting fetus or newborn · LLT: Intestinal obstruction due to inspissated milk in newborn · LLT: Fracture of clavicle due to birth trauma I would like to make the proposal to systematically approach this problem in MedDRA via string searches in order to identify critical terms. The goal would be to map them to (new) PTs which allow groupin	Implemented	The MSSO identified neonatal terms that were subordinated to terms that were not specific to the neonatal period and also identified terms that could be better aligned in the hierarchy. As a result of this review, a total of 37 changes, including the addition of 4 new terms were implemented.	8/26/2013	16.1
25	Expansion of Product Quality Terms in MedDRA	This is a reqeust to add a new set of product quality terms to MedDRA. The addition of these terms will allow us to provide more consistent and accurate trending/data analysis that will ultimately help us determine current good manufacturing practices (CGMP) areas that need focused attention and/or correction.	Implemented	In MedDRA Version 20.0 revisions were made to the medication error and product use issues hierarchy. The new hierarchy groups the medication errors and unspecified product use issues terms together under new HLGT Medication errors and other product use errors and issues avoiding the forced classification between these sometimes overlapping concepts. These revisions also included the addition of new PT and LLT product quality concepts. Please see the MedDRA Version 20.0 What’s New document for more details on the hierarchical changes. For detailed information on the placement of PTs and LLTs in the revised hierarchy, please use the Web-Based Browser.	12/1/2016	20.0
26	Patient friendly terms	Please consider the addition of patient friendly terms to MedDRA for the purposes of patient reporting of adverse events.	Declined to pursue	In general, most of the proposed concepts are already represented by existing MedDRA terms. In the case of the more colloquial expressions in English, the MSSO refrains from adding colloquial terms unless the concept is internationally accepted and can be accurately translated into the other languages in MedDRA.	10/21/2013	N/A
27	Drug Utilization Terms	Please consider a set of drug utilization terms for inclusion into MedDRA.	Implemented	Based on our review most of the requested concepts are already represented in MedDRA – with either direct matches or close concepts (e.g. issue with device – LLT/PT Device issue, or patient not compliant with treatment – LLT/PT Treatment noncompliance). As a result, a total of three new terms were added (PT Clinical trial participant, PT Planning to become pregnant and LLT Drug supply chain interruption) and the status of LLT Out of medication was changed to non-current. Most of the “non-medical” concepts, (e.g. Drug too expensive, patient did not like the drug, doctor decision etc.) are out of scope at the moment and were not be implemented. However, the MSSO is considering how to best accommodate additional drug supply or availability concepts in the future.	10/30/2014	18.0

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
28	Pressure terms linked to either Pain or Discomfort	In reviewing our Philosophy document, our MedDRA team has noted that there is seemingly inconsistent mapping of LLTs containing “Pressure” to either PTs of Discomfort or PTs of Pain/Ache, e.g. LLTs of Pressure feet links to a PT of Limb discomfort, Chest pressure links to a PT of Chest discomfort, Vaginal pressure ls linked to Vulvovaginal discomfort, but Head pressure links to a PT of Headache and Sinus pressure links to a PT of Sinus pain. There may be other examples as well, but these are a few. Would the MSSO be able to review these types of terms and clarify the rationale for the variance in PT selection to Pain or to Discomfort, or make changes so that there is more consistency in these hierarchies?	Implemented	The MSSO reviewed the pressure terms linked to pain or discomfort. Based on this review, the MSSO made nine changes that will be implemented for MedDRA Version 17.1. Most of these changes were moves of LLTs for better alignment. Examples include moving LLT Head pressure from PT Headache to PT Head discomfort and moving LLT Infusion site pressure sensation from PT Infusion site pain to PT Infusion site discomfort.	4/18/2014	17.1
29	Consider adding additional ’administration site’ reaction terms	Please consider proactively adding more ’administration site’ reaction terms (Administration site xxxx) similar to the other types of administration site reactions (injection site reactions, application site reactions, etc), to allow for more detailed coding for reactions for other delivery systems (e.g. vaginal delivery, nasal sprays, suppositories).	Implemented	Based on this review, a total of 224 new concepts and 111 changes to existing concepts were made. The MSSO’s approach was to add a set of administration site terms similar to injection site terms and fill in gaps to mirror injection site terms as appropriate for vaccination site, infusion site, application site and medical device site terms. These concepts will be available for MedDRA Version 18.0 (released March 2015).	10/30/2014	18.0
30	Review placement of hernia concepts	In my group, we came across the following issue. In medicine, hernia incarceration, obstruction and strangulation are quite clearly distinguished: • Incarcerated hernia: a hernia that cannot be reduced and that may, but must not lead to bowel obstruction or strangulation • Obstructive hernia: hernia that causes an intestinal obstruction that may be mild or lead to a life-threatening condition • Strangulated hernia: a hernia that blocks blood supply and represents a medical emergency It seems that in MedDRA, strangulated and obstructive hernia are considered as quasi-synonyms. In our opinion, both concepts should be represented separately on the PT level for all manifestation sites as strangulated hernia always represents a life-threatening condition. Taking the worst case approach, incarcerated hernia may be classified as “obstructive” on PT level, but in some instances like e.g. Richter’s hernia, this would not be medically accurate.	Implemented	Based on a review of the placement of hernia concepts, 23 changes were implemented in MedDRA v17.1 for better alignment. Additionally, the for the MedDRA v18.0 complex change review, the MSSO medical team will propose adding a new HLT Abdominal hernias NEC and merging existing HLT Abdominal hernias, site unspecified under it to streamline existing concepts and broaden the scope of this new HLT. If this were implemented, certain PTs from HLT Abdominal cavity hernias NEC such as PT Diverticular hernia, PT Peritoneal hernia, etc. would be moved to the new HLT Abdominal hernias NEC.	4/18/2014	17.1
31	Mood disorders	The way mood disorders are currently captured leads to PTs containing insufficient information on the one hand, and redundant terms on the other. For example, Bipolar I Disorder is a chronic illness characterized by periodic exacerbations of a few different types. Currently, a person with known bipolar I disorder who is in remission and a person who experiences a severe exacerbation (e.g. a manic psychotic episode or, alternatively, a major depressive episode) will both be coded under the same PT. This obscures the clinical state of the patient and makes it much more difficult to analyze adverse events reported at the PT level. In addition, a person with known bipolar I disorder who becomes severely depressed might equally coded under the PT Bipolar I Disorder (LLT Bipolar affective disorder, depressed) or under the PT Depression or the PT Major depression. I suggest an alternative to the current way mood disorders are coded which is closely aligned with the DSM-V and allows for the coding of mood episodes within the PT with or without a diagnosis of a mental disorder.	Declined to pursue	The MSSO reviewed the placement of mood disorders in MedDRA and, after careful consideration, decided not to pursue this request. In general, MedDRA does not include or align itself with specific disease classifications, diagnostic criteria, or rating scales because such classifications may not conform to MedDRA's structure or purpose as an international medical and regulatory terminology. While information about the severity and clinical course of manic and depressive episodes in bipolar disorders, for example, is important in forming the basis of diagnostic criteria in DSM-V, MedDRA typically does not include these types of qualifying concepts. Furthermore, some of the proposed PTs, e.g., Bipolar I disorder, current or most recent episode manic, represent combinations of concepts whereas MedDRA PTs are defined as distinct descriptors representing single medical concepts. It is recognized that, because MedDRA does not accommodate the fine level of granularity of DSM V, coding and retrieval strategies need to take this into account. Depending on the reported information available and on an organization's coding conventions, a report of a depressive episode in a patient with bipolar disorder I may be coded with single terms, e.g., LLT Bipolar disorder I, LLT Depressive episode or a combination of terms (split coding). In order to retrieve all relevant cases of bipolar disorder, it may be necessary to include additional terms in the search strategy that relate to depression, psychosis, etc. and using SMQs such as SMQ Depression and suicide/self-injury and SMQ Psychosis and psychotic disorders may facilitate this search.	7/31/2014	N/A
32	Consider the adding terms related to partner pregnancy	We would suggest the MSSO consider the adding of a set of terms related to partner pregnancy as what was done in HLGT Maternal complications of pregnancy and HLGT Pregnancy, labour, delivery and postpartum conditions For example: a couple PT Complication of pregnancy (already in HLGT Maternal complications of pregnancy) and PT Complication of pregnancy of partner (to add)	Declined to pursue	The MSSO reviewed the request to consider adding terms related to partner pregnancy and, after careful consideration, decided not to pursue this request. The existing partner terms in MedDRA either focus on events directly relating to a subject and partner (e.g., PT Artificial insemination by partner and PT Exposure via partner) or to general social issues that may affect subjects and their partners from economic or psychological perspectives (see under HLT Family and partner issues for terms such as PT Pregnancy of partner, PT Infertile partner, and PT Miscarriage of partner.) However, the proposal to add terms such as PT Complication of pregnancy in partner is very open-ended as any pregnancy-related term could potentially have an "in partner" counterpart. Furthermore, in the context of pharmacovigilance, it is unclear how such terms relate to a subject, as opposed to the partner of a subject, or how they would constitute a reportable event or "case".	7/31/2014	N/A

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
33	Consider adding more "site" terms to MedDRA	Consider terms related to reaction. the PT as xxx site reaction is sometimes too vague. The addition of the set of more gruanular terms provides for better analysis.	Implemented	Based on this review, a total of 224 new concepts and 111 changes to existing concepts were made. The MSSO's approach was to add a set of administration site terms similar to injection site terms and fill in gaps to mirror injection site terms as appropriate for vaccination site, infusion site, application site and medical device site terms. These concepts will be available for MedDRA Version 18.0 (released March 2015).	10/30/2014	18.0
34	Consider adding sublingual application site terms, drug component and contraindicated treatment concepts to MedDRA	The proactivity proposal is a set of three separate topics the MSSO was asked to review.	Implemented	The MSSO supports the requester's current handling of sublingual site reactions by selection of two terms e.g. Mouth oedema in addition to Application site oedema, in order to distinguish between oedema at another site within the mouth. It was acknowledged that there was a need for the addition of terms to capture a wider range of reactions at an administration site. As a result, the MSSO added additional 'site' (e.g., administration site) concepts to MedDRA to provide more coding options for all MedDRA users. A total of 224 new concepts were added in MedDRA Version 18.0 mostly to SOC General disorders and administration site conditions. MedDRA is used to represent reactions to a range of products, not solely drugs, having multiple routes and sites of administration, therefore, it was decided not to add terms specific to anatomical application sites, such as sublingual. Because MedDRA cannot accommodate a term for a specific reaction or disorder for every possible anatomical administration/procedural site, the MSSO's approach was to add a set of administration site terms similar to existing injection site terms and fill in gaps to mirror injection site terms as appropriate for vaccination site, infusion site, application site, and medical device site terms. Appropriate secondary links were added for new terms based on MedDRA rules and conventions described in the MedDRA Introductory Guide. These new administration site concepts can then be used in addition to the appropriate site specific term (e.g. Selection of the LLT Application site dysaesthesia, in addition to the LLT Oral dysaesthesia). On the second topic of drug component concepts, Customized therapeutic preparations or named patient products are very specific and are not necessarily authorized or recognized in all regulatory regions in the same manner. Please review existing LLTs such as LLT Incorrect product formulation administered, LLT Product formulation issue, and LLT Drug administration error for your coding needs. For contraindicated drugs - it is important to capture situations where a contraindicated drug is administered to a patient, whether it be the result of a medication error, misuse or off label use; this concept is represented by PT Contraindicated drug administered (added in MedDRA Version 17.1) which was moved from HLT Maladministrations to the new HLT Product use issues NEC in MedDRA Version 18.0. Terms such as Contraindicated drug prescribed and Contraindicated drug dispensed have not been added as these are less specific because they do not indicate whether the drug was administered to the patient and do not specify the circumstances, i.e., medication error, misuse, off label use, etc., making placement difficult. Therefore, these specific concepts have not been added to MedDRA. Users should also consider selecting, in addition, existing terms such as LLT Drug prescribing error, LLT Drug dispensing error or LLT Off label use if specific information about the circumstances is known. LLT Labelled drug-disease interaction medication error and LLT Labelled drug-drug interaction medication error may also be selected to accompany LLT Contraindicated drug administered to represent relevant reported information.	7/9/2015	18.0
35	Classification of spinal terms versus conditions of vertebrae	When looking into MedDRA and considering definitions for "vertebra/ vertebral column" and "spine" in Dorlands, the attribute "spinal" can rather be considered as a broader term that may refer to neurological, connective tissue/ vertebral disc and vertebral body/ bone conditions of the spine. In contrast, "vertebral body/ vertebrae" rather refers to the bony structure of the spine. The differentiation between disorders of the bony structures and other structures of the spine is medically relevant. In my view, it would be helpful to have a clear distinction between bone spinal structures from unspecified spinal conditions, as already implemented for spinal cord, spinal disc/ connective tissue and spinal nerve disorders. A respective MedDRA concept description would give a better guidance to Coders and alignment of related terms with the concept description would improve coding consistency. In daily practice, we have many reports related to "back bone" disorders and had repetitive internal discussions on how to classify in MedDRA and the current MedDRA hierarchy for the corresponding terms. I do not want to initiate an "academic" discussion, but find that this area needs some clarification.	Implemented	A review of this proactivity proposal was conducted primarily with regard to the use of the following words in existing MedDRA terms: spine; spinal, vertebra; vertebral; and back. Emphasis was placed on current vs. non-current terms. Of the total 1,366 LLT, PT, HLT and HLGT applicable MedDRA terms reviewed, 12 Change Requests were implemented (Change Request Batch #20103247) relevant to the consistent use of terms containing spine; spinal, vertebra; vertebral; and back. Revisions pertained to consistency of term definition, term status, and hierarchical relationships. In section 5.1 GENERAL WORD USAGE of Introductory Guide to MedDRA, a statement will be included explaining that spine/spinal terms, for purpose of MedDRA, are considered synonymous to vertebral and spinal column concepts rather than to spinal cord, unless "spinal" clearly represents a neurological concept such as PT Spinal claudication.	10/23/2014	18.0
36	Consider adding more "low" and "high" laboratory terms	I have a request for a "proactive review" of terminology currently used in the MedDRA dictionary. It deals with the use of "low" and "high" terminology when dealing with lab terms. I understand why the such terms are included under their increased/decreased counterparts in MedDRA; however, I would like to request this to be reviewed. When dealing with lab terms such as Glucose low it may not always be appropriate to code to the PT of Blood glucose decreased, which is where it codes. The patient's glucose level may be low, but it may have increased from the baseline. The same is true for a high glucose value that may technically be high, but that also may have decreased from baseline. Because coding is typically done out of context and without that additional information, I feel it is important to add "low" and "high" PTs to the dictionary.	Declined to pursue	Per MedDRA convention, the qualifiers "low/decreased" and "high/increased are considered synonyms. Section 6.13.2 Conventions and Exceptions of the MedDRA Introductory Guide states "The qualifier 'increased' in MedDRA terms refers to changes from normal state to high, from low to normal, from low to high, and from low normal to high normal. Similar considerations apply to results that are 'decreased.' MedDRA investigation terms use the qualifiers of 'low' and 'high' at the LLT level only; these LLTs with 'low' and 'high' are linked to PTs with qualifiers of 'decreased' and 'increased' respectively. Additionally, qualifiers 'low/decreased' and 'high/increased' in SOC Investigations are considered synonyms." Therefore, based on this convention, the MSSO medical team decided not to pursue this request.	5/21/2014	N/A

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
37	Adopt a convention at the PT level for the use of noninfective	I would like the MSSO to review and adopt a convention at the PT level for the use of noninfective. Some examples of current PTs include: · Non-infectious endophthalmitis · Noninfective retinitis · Appendicitis noninfective · Noninfective oophoritis · Cystitis noninfective · Noninfective bronchitis · Croup noninfectious Could we agree on the spelling, word order and also whether it is noninfectious vs. noninfective ? I am happy for the varients to remain at LLT level, but it would really help if we had consistency at the PT level for searching and reporting	Declined to pursue	Going forward the MSSO will continue to add new terms in natural word order format, according to Section 4.6: Word Order, of the MedDRA Introductory Guide. However, the MSSO will refrain from adjusting existing PTs for consistency of word order or hyphenation, due to the potential impact on legacy data. With respect to “infectious” and “infective”, both terms are considered to be synonymous in MedDRA, as are “noninfectious” and “noninfective”. For the purpose of consistency, the MSSO has decided to represent such concepts in new terms using “infective” and “noninfective”, unless “infectious” is inherent in a recognized medical term (e.g., infectious hepatitis; infectious mononucleosis). The MSSO does not intend to modify existing “infectious/non-infectious” terms if the conceptual representation of MedDRA terms is not altered by the use of “infectious” versus “infective” or “noninfectious” versus “noninfective” adjectives.	5/21/2014	N/A
38	Pharmacogenomic biomarkers in Drug labeling	Please consider adding additional medically relevant pharmacogenomic terms to MedDRA. For reference, FDA has posted a table of Pharmacogenomic Biomarkers in Drug Labeling:http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm	Implemented	After reviewing the proposal, the MSSO added 74 new medically relevant pharmacogenomic terms to MedDRA and made changes to four existing terms. These changes will be implemented for MedDRA Version 18.0.	10/21/2014	18.0
39	non- traumatic LLTs under HLTs implying trauma	I have noticed that several terms at the LLT level which specify non- traumatic (or variations of that wording) are linked to a PT which loses the non traumatic aspect and in turn these are linked to a Primary SOC of Injury or to HLTs implying trauma Examples of these LLTS are: · Non-traumatic extradural hemorrhage · Rupture of muscle, non-traumatic · Non-traumatic rupture of patellar tendon	Implemented	There are terms at the LLT level which specify non- traumatic (or similar wording) under a PT concept which loses the non traumatic aspect with a primary link to SOC Injury, poisoning and procedural complications or to HLTs implying trauma. Examples include: • LLT Non-traumatic extradural haemorrhage under PT Epidural haemorrhage - Primary HLT Cerebral injuries NEC to SOC Injury, poisoning and procedural complications; Secondary HLT Traumatic central nervous system haemorrhages, Nervous system haemorrhagic disorders to SOC Nervous system disorders, Vascular disorders • LLT Non-traumatic rupture of patellar tendon in PT Tendon rupture - Primary HLT Muscle, tendon and ligament injuries in SOC Injury, poisoning and procedural complications; Secondary HLT Tendon disorders in SOC Musculoskeletal and connective tissue disorders The MSSO determined that it is appropriate to keep the primary SOC allocation of SOC Injury, poisoning and procedural complications even for non-traumatic concepts because, in the case of tendon and muscle tissues for example, the broad concept of “injury” can apply to other damaging factors in addition to trauma such as changes due to aging, inflammation, fibrosis, and drug effects. The MSSO noted that there were four non-traumatic LTTs under PT Epidural haemorrhage in HLT Traumatic central nervous system haemorrhages (see one example in the table above). This placement under a “trauma” HLT is not appropriate; however, to move them would require the creation of a new, qualified non-traumatic PT for epidural hemorrhage with the possibility of setting a precedent for the addition of unqualified and qualified (traumatic and non-traumatic) terms for multiple hemorrhage terms at various anatomical sites. It is not practical from a pharmacovigilance perspective to create combination hemorrhage terms reflecting both etiology and anatomical location therefore the best solution with a minimal impact on legacy data was to change the status of the LLT Non-traumatic extradural haemorrhage and LLT Non-traumatic extradural hemorrhage to non-current. The two other non-traumatic LLTs, LLT Nontraumatic extradural haemorrhage and LLT Nontraumatic extradural hemorrhage, were already non-current. See section 4.5 LLT Currency Status Changes.	11/17/2015	19.0

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
40	Primary SOC allocation Haemorrhage and Haematoma terms	We would like to propose a proactivity request for the MSSO to review the primary SOC Allocation for the Haemorrhage and Haematoma PTs. Please see the attached file of all terms. We would like the MSSO to : • Ensure consistency between the primary SOC allocation for the haemorrhage and corresponding Haematoma terms (In most cases these should be the same Primary SOC) • Review and determine the criteria for when the primary SOC is Injury, poisoning and procedural complications.	Implemented	The MSSO reviewed the placement of haemorrhage and haematoma terms in MedDRA and, after careful consideration, made 19 changes which will be available for MedDRA Version 18.1. Pairs of haemorrhage and haematoma terms that were not identically mapped in their primary SOC representation were changed so that their primary mappings are identical based on the site of manifestation or cause (I.e., Injury). Placement rules for the primary SOC of most PT concepts are dictated by the site of manifestation and as such it is not possible to consistently align corresponding haemorrhage and haematoma PTs throughout all of MedDRA. Therefore, in order to retrieve all relevant cases of haemorrhage/haematoma, it may be necessary to leverage other resources such as SMQ Haemorrhages. The second point the proactivity request asked the MSSO to review and determine the criteria for when the primary SOC is Injury, poisoning and procedural complications. The MedDRA Introductory Guide Version 18.0 in section 6.12.1 provides information on placement of concepts primary to SOC Injury, poisoning and procedural complications.	3/25/2015	18.1
41	Transportation Related Product Quality Terms	Pharmacovigilance and pharmaceu?cal quality are directly linked issues. As an example the heparin scandal shows us that a lack of quality could lead to crical side-effects. In addion to the risk associated with an API itself, external factors can impact the quality of a product and potenally lead to side effects. In order to enable all-encompassing data entry of quality-related issues into PV databases, the addion of new terms concerning quality issues is highly desirable.	Declined to pursue	Since the reorganization of product quality terms in SOC Product issues in MedDRA Version 19.0, the MSSO has participated in several discussions with the MedDRA Expert Panel about the level of granularity needed for product transportation issues. The Panel, which is comprised of regulatory and industry representatives, indicated that a high level of granularity for these concepts is not necessary at this time. PT Manufacturing product shipping issue, which has been added in MedDRA Version 20.0, can represent issues identified with products occurring during transportation. In addition, there are other broad concept PTs that can be used to capture issues associated with distribution and storage: namely; PT Inappropriate release of product for distribution, PT Manufacturing product storage issue, and PT Product distribution issue.	3/14/2017	To be determined
42	Terms relating to burning sensations at the LLT level	Terms relating to burning sensations at the LLT level appear to be linked inconsistently to PT terms reflecting either pain, discomfort, irritation or burning sensation. See attached PDF for examples. Similarly, while most 'irritation' LLTs link to an 'irritation' PT, a few have links to 'discomfort', 'pain' or '-itis' PT. See examples in the attached PDF. Please consider if the LLT-PT linking of these terms need to be harmonised.	Declined to pursue	The MSSO performed an extensive review and analysis of the placement of burning sensation / irritation terms. Based on this review, the MSSO has declined to make any changes. Burning and burning sensation at the LLT level are lay expressions that can be accommodated under different PT concepts depending on the context (e.g., discomfort, pain, irritation, burning etc.). Additionally, Irritation in the context of subjective description of 'feelings of irritation' at the LLT level links to some 'discomfort PTs' (e.g., Abdominal discomfort; Epigastric discomfort; Nasal discomfort). In some cases, irritation at the LLT level links to medical terms for which 'irritation' is a component of the definition for the medical term (e.g., PT Meningism/LLT Meningeal irritation; PT Chelitis/LLT Irritation lips; PT Glossitis/LLT Tongue irritation. Therefore it is not feasible to harmonize these concepts in a meaningful way.	3/31/2015	N/A
43	Skin mycosis concepts used synonymously with "dermatophytosis"	in the anglo-american language,"Tinea" or "ringworm" are used for any of a variety of skin mycosis and used synonymously with "dermatophytosis". But this approach is not necessarily adopted by other medical schools. Based on the anglo-american view, the classification of the "Tinea" PTs (and theirs underlying LLTs) under HLT Skin and subcutaneous tissue fungal infections is correct. But on the other hand, MedDRA has a separate HLT for Tinea infections, e.g. Tinea infections are not subsumed under HLT Fungal infections NEC. Also, there is a separate PT Fungal skin infection. This makes the handling of similar terms in MedDRA inconsistent. If Tinea infections are to be considered a separate medical entity, this approach should also be implemented elsewhere by e.g. separating unspecified fungal skin infections of the hands or feet from tinea infections with the same localisation.	Implemented	After reviewing this request, the MSSO made 10 changes to better align Tinea concepts. Many Tinea PTs link to HLT Tinea Infections but there were LLTs under these Tinea PTs which do not indicate "Tinea" but are more general in nature. For example, LLT Foot infection fungal NOS was under to PT Tinea pedis and was moved to PT Fungal skin infection for more accurate placement. Additionally, two PTs – PT Microsporum infection and PT Trichophytic granuloma were moved from HLT Fungal infections NEC to HLT Tinea infections to better align these concepts.	3/25/2015	18.1

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44	Consistency of coding of local reactions at device sites/ implant sites	Consistency of coding of local reactions at device sites/ implant sites is difficult based on existing MedDRA hierarchy (numerous PTs to capture implant or catheter site reactions under HLGT Administration site reactions and one separate PT Medical device site reaction under HLGT Complications associated with device). Should LLTs under PT Medical device site reaction only be used when the device is not implanted? But then LLT Adverse local tissue reaction around prosthesis is not appropriately grouped under this PT. It may be worthwhile to consider MedDRA concept descriptions for the terms “administration site “ (assuming that this term does include more than just drug adminitration sites), “implant” and “medical device” and when to use related PTs.	Declined to pursue	The MSSO considers that it is not practical to develop concept descriptions for administration site terms and other concepts such as “medical device” and “implant” because of the varying interpretations and usages of these terms in different regions. For example, “administration” is a broad concept that can apply to a range of products (not only drugs) and to a range of different administration routes. Some MedDRA users may choose to use a more specific route of administration term if it is available, e.g. Infusion site, or they may use the broader administration terms for routes such as sublingual, rectal, etc. Providing a concept description for “medical device” is particularly challenging because products can be regulated as a device in one region and another type of product, such as a drug, biologic, or a cosmetic, in other regions. Similarly, implants can be various entities; there are drug implants, device implants, and drug-device/biologic/device implants that may be regulated as drugs, biologics, or devices, depending on the region. MedDRA users are advised to develop and document their own conventions for when they use particular terms based upon their own products.	2/5/2015	N/A
45	Inconsistencies in the handling of “drug implant” terms versus “implanted drug” terms in MedDRA	There are inconsistencies in the handling of “drug implant” terms versus “implanted drug” terms in MedDRA. They are sometimes represented as devices in the hierarchy (e.g. LLT: Drug implant migration and LLT: Difficulty removing drug implant) or as separate PTs (e.g. LLT: Expulsion of implanted drug under PT Expulsion of medication or PT Migration of implanted drug). A consistent handling would better support safety data retrieval and analysis. A differentiation of "implanted drug" and "drug implants" is hard to make because both would need systems/ devices for delivery. http://www.sciencedirect.com/science/article/pii/S1056871998000276 There are three options to solve the issue: 1. Always represent drug implants/ implanted drugs under “device” PTs – would be consistent with previous MedDRA representation 2. Always represent drug implants/ implanted drugs under “drug” PTs – not optimal because the device component may be more relevant than the drug component when dislocation, migration or breakage is reported 3. Always represent drug implants as separate PTs based on their special status as already implemented for PT Migration of implanted drug – they are considered “drugs” based on regulatory requirements but clearly have a device component e.g. intra-uterine contraceptive devices with hormone release.	Declined to pursue	The MSSO reviewed the request to improve the consistency in the placement of “drug implant” terms versus “implanted drug” terms in MedDRA. Regulatory authorities are not consistent in the way they categorize “drug implants” and “implanted drugs”. Some classify them as drug products while others treat them as devices. Therefore, it is not feasible for the MSSO to develop a consistent approach to the hierarchical placement of “drug implant” and “implanted drug” terms. However, the MSSO did make the following changes as part of this review: • LLT Difficulty removing drug implant was promoted to a PT under HLT Non-site specific procedural complications because in MedDRA drug implants are not considered devices and therefore are not subordinated to device related terms (A drug implant may be a sustained release drug formulation which is ultimately completely absorbed, and does not necessarily consist of a device component). • LLT Difficulty removing drug rods moved from PT Device difficult to use as a sub-concept LLT to the newly promoted PT Difficulty removing drug implant (A drug rod may relate to an implantable drug formulation which is not necessarily comprised of a device). Also, in a separate request from another MedDRA user, LLT Drug implant migration was moved from PT Device dislocation to PT Migration of implanted drug as these concepts are synonyms. These changes will appear in the MedDRA Version 19.1 release.	1/21/2016	19.1

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
46	Review of ambiguous Medication error, intentional misuse and off label use LLT and PT names	With the introduction of the new PTs Product use issue and Intentional product use issue, more vague terms became available when the information provided does not allow to classify an event as an error, intentional misuse or off label use. Major hierarchical changes were implemented to make the MedDRA structure consistent and to clearly separate these concepts. Unfortunately, some MedDRA LLT and PT names remain ambiguous and are not appropriately grouped in the hierarchy bases on their wording. Some examples: • LLT Wrong drug selected is grouped under PT Drug dispensing error. Couldn't this term also apply to a patient who selected the wrong drug? • PT Drug administered at inappropriate site is considered an administration error but PT Drug administered to patient of inappropriate age a product use issue • PT Drug administered in wrong device is considered an administration error although the unintentional/ accidental aspect is not mentioned – could also relate to e.g. intentional misuse • LLTs Drug maladministration and Drug misadministration are very vague and should not be classified as administration error under PT Drug administration error • PT Drug dose omission could also relate to off label use when HCP advises to skip a dose/ doses due to medical reasons • PT Inappropriate schedule of drug administration is classified as administration error although not indicating accidental or intentional aspect • PT Incorrect dosage administered is classified as administration error although not indicating accidental or intentional aspect – could also relate to e.g. off label use • … As a general rule, all terms under HLGT Medication error should include the qualifier accidental/ unintentional/ error unless the term itself clearly indicates an error (like in the instance of PT Counterfeit drug administered or PT Expired drug administered or PT Wrong drug administered) or only factors that could lead to a medication error are described (like PT Product label confusion or PT Incorrect product storage).	Implemented	To address these issues, revisions were made to the medication error and product use issues hierarchy for MedDRA Version 20.0 with input from the MedDRA Expert Panel and the ICH M1 Points to Consider Working Group. The new hierarchy groups the medication errors and unspecified product use issues terms together under new HLGT Medication errors and other product use errors and issues avoiding the forced classification between these sometimes overlapping concepts. Please see the MedDRA Version 20.0 What's New document for more details on the hierarchical changes. For detailed information on the placement of PTs and LLTs in the revised hierarchy, please use the Web-Based Browser.	12/1/2016	20.0
47	Representation of organ/body site enlargement versus hypertrophy	Current representation of organ/body site enlargement versus hypertrophy of the same organ/site is inconsistent. E.g. for the liver and kidney, hypertrophy and enlargement/-megaly are clearly separated on PT level, wheras both concepts are grouped together for the breast, salivary gland (here also hyperplasia is included), parotid gland, clitoris, genital labia and uterus. According to Dorlands, hypertrophy is defined as the "enlargement or overgrowth of an organ or part due to an increase in size of its constituent cells". Enlargement can be caused by hypertrophy, but also by e.g. abscesses, neoplasms, hyperplasia. Therefore, the concepts of enlargement and hypertrophy (and hyperplasia) should be clearly separated in MedDRA on PT level.	Implemented	The MSSO reviewed the current representation of organ/body site enlargement versus hypertrophy of the same organ/site for inconsistencies in MedDRA. Both the correctness of PT/LLT subordination, and possible concept duplication (over-representation) at the PT level were reviewed. A total of 15 changes were made including 9 LLT promotions, 1 PT demotion, 4 LLT moves and 1 term rename.	6/14/2016	19.1
48	Surgical shunts versus spontaneous shunts	In many instances, unspecified "shunt" terms represented in MedDRA can relate to both a surgical procedure or to a pathological condition. Examples: • PT Portal shunt with LLTs Mesocaval shunt, LLT Portacaval shunt and LLT Portal systemic shunt • PT Splenorenal shunt • PT Vascular shunt with LLT Femoral-popliteal shunt, LLT Intra-abdominal venous shunt and LLT Peripheral vascular shunt The first two PTs and related LLTs are represented in SOC Surgical and medical procedures but represent findings that are typical for collateral circulation in liver cirrhosis or liver cancer. Therefore, they are ambiguous and should be replaced by separate PTs indicating "procedure" or "acquired" or similar in the PT and LLT names. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3389944/ http://radiopaedia.org/articles/portal-systemic-collateral-pathways The third PT is represented in SOC Vascular disorders, although the PT and its LLTs may also relate to surgical procedures - the term "shunt" is often used in the context of bypass surgery. Again, the current terms are ambiguous and should be replaced by separate PTs indicating "procedure" or "acquired" or similar in the PT and LLT names (PT Surgical vascular shunt is already available). http://www.ncbi.nlm.nih.gov/pubmed/11693420 http://www.ncbi.nlm.nih.gov/pubmed/1295910	Implemented	Shunt terms that can only refer to surgical procedures are placed in SOC Surgical and medical procedures; shunt terms that can only refer to anatomical/pathophysiologic conditions/disorders are placed in the appropriate "disorder" SOC. For other shunt concepts that could represent either a procedure or a condition/disorder, the unqualified shunt term is considered to represent the condition/disorder and a counterpart term qualified with the word "procedure" represents the surgical procedure concept. Based on this rationale 13 changes were made to existing "shunt" terms.	11/17/2015	19.0

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
49	Review placement existing influenza terms and consider adding new terms	I recently requested a new PT of H2N2 influenza which is a subtype of Influenza A. Influenza A is an LLT under the PT Influenza. There is another PT of H1N1 influenza with the LLT of Swine flu, added during the 2009 epidemic. Perhaps this needed to be a PT for clinical significance at that time. As Influenza A is the Species for both of these subtypes, it seems strange to see it as an LLT under the non-specific term Influenza. I propose that this area is reviewed for placement of the hierarchy of existing terms and consideration of adding new terms for completeness of subtypes and synonyms as this can be a confusing area for coders. There may also be review needed in the Investigations SOC for the test names and results relating to the subtypes etc.	Declined to pursue	The hierarchical organization of influenza terms in SOC Infections and infestation do no follow a taxonomical organization, as they do in SOC Investigations. Instead, the MSSO prefers subordinating terms such as influenza virus A or B as LLTs under the general PT Influenza, and representing only those serotypes that have been related to notable epidemic outbreaks at the PT level, such as those involving interspecies transmission from swine or birds to humans. Influenza virus infections in anatomical sites of significant clinical relevance (such as PT Encephalitis influenzal) are also represented at the PT level. The species of Influenza A virus is responsible for pandemics/outbreaks in humans and animals. Serotypes that have undergone the ability to infect new host species, e.g. from swine or avian species to humans, are of particular interest for epidemiologic reasons (such as the outbreak of Avian flu in 2013 with the serotype H7N9) and therefore are placed at the PT level. Regarding the proposal to add new serotypes of influenza A infection to the SOC Infections and infestations and corresponding laboratory terms to the HLT Virus identification and serology in the SOC Investigations, the MSSO prefers to be conservative and only add new terms if a new serotype is associated with pandemics. It is not feasible to add all possible serotypes combinations to the broad PTs for influenza A virus test terms.	1/20/2016	19.1
50	Review inconsistency in the mapping of site specific “Wound” terms	An inconsistency has been noted in the mapping of site specific “Wound” terms. The PT Wound maps to the HLT Non-site specific injuries NEC. However, of the 106 current LLTs that are currently mapped to PT Wound, 101 reference a site. (Examples: LLT Lower limb wound; LLT Open wound of back; LLT Open wound of ear.) In comparison, the HLT Site specific injuries NEC contains similar concepts, example: the LLT Open wound of ocular adnexa (PT Eye injury). Dorland’s equates wound with injury (definition: ‘an injury or damage, usually restricted to those caused by physical means with disruption of normal continuity of structures. Called also injury and trauma.’) The rationale for mapping site specific injuries and wounds differently between several HLTs is unclear. The loss of site specificity has an impact on reporting leading to less specific reporting at the PT and higher levels than is conveyed in the LLT. Would the MSSO undertake a proactive review of the mapping of LLTs under PT Wound?	Implemented	After performing a review, the MSSO Medical Team performed the following actions: 1. A total of 94 LLTs under PT Wound were changed to a status of non-current because these terms represent combinations of two or more concepts, and/or are vestiges of ICD terms that were incorporated into the initial versions of MedDRA. These terms were moved to site-specific PTs as appropriate. There were three situations where no appropriate PT was available, as a result, a new site specific PT was added. 2. There were an additional 63 LLTs that were under PT Wound which pertain to anatomically-specific wound sites (e.g., LLT Lower limb wound). These terms, many of which already had a non-current status, were moved from PT Wound to a respective PT that corresponds to a site of injury, or promoted to a site-specific injury PT concept as appropriate. There were three situations where no appropriate PT was available, as a result, a new site specific PTs was added or an LLT was promoted. 3. The remaining current LLTs under PT Wound were reviewed to ensure they are not site-specific, and are appropriately designated as current or non-current. See the graphic below, which shows how PT Wound and its revised group of subordinate LLTs will appear in MedDRA Version 19.1.	6/14/2016	19.1

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
51	Review of infusion related reactions and their MedDRA representation	We are facing problems in clinical studies with the handling of infusion related reactions and their MedDRA representation. These reaction may range from mild fever, chills, pain up to anaphylactic shock. Therefore, there is clear regulatory guidance e.g. from FDA (Guidance on Immunogenicity Assessment for Therapeutic Drug Products (2014): In the absence of an agreed-upon definition for infusion reaction, the categorization of certain adverse events as infusion reactions without further detail is problematic and is not recommended. Sponsors are encouraged to use more-descriptive terminology when possible, noting the timing, duration, and specific signs and symptoms observed upon administration of a therapeutic protein product . Unfortunately, LLTs like Infusion associated discomfort, Infusion associated sensation of cold, Infusion associated shivering, Infusion related pain and Infusion associated chills are grouped under PT Infusion related reaction, not under the specific related concepts. And the LLT Infusion associated symptoms may be used as "grouping term" for all kind of reactions. In order to overcome the problem, relationship to infusion should be captured by splitting or via a tick box in clinical studies. Specific signs/ symptoms should be documented and coded separately. To clearly separate both, the specific LLTs mentioned above should be moved under the PTs representing the concept, e.g. PT Pain.	Declined to pursue	The MSSO has decided not to pursue the proposal to move the infusion associated/related LLTs from PT *Infusion related reaction* to PTs representing the more general concept. The current placement under the specific infusion related PT is appropriate and facilitates coding and analysis of these concepts; moving the LLTs under non-specific PTs would make retrieval more difficult and could potentially dilute a safety signal. The MSSO notes that an SMQ for infusion related reactions is under development and it is unlikely that terms such as PT *Pain* or PT *Discomfort* would be included because they would create too much "noise". The broader terms LLT *Infusion associated symptoms* and LLT/PT *Infusion related reaction* do "group" various types of reactions but they are needed for reports where the specific symptoms are not specified, particularly in post-marketing reports. In clinical trials, where it is important to characterize the specific signs and symptoms of an infusion reaction, a possible approach could be to establish a coding convention to select a term for the general concept such as pain, chills, etc. and then have a check box to indicate relationship to the infusion. In this manner, all the signs and symptoms designated as related to the infusion could be summarized. In addition, since there is only a limited set of infusion related signs and symptom terms, e.g., LLT *Infusion associated discomfort* , this approach would allow the selection of a wide range of terms to describe the nature of the reaction such as LLT/PT *Dyspnoea* , LLT/PT *Anaphylactic* reaction, etc.	5/25/2016	N/A
52	Review "device type" and "device event/finding" terms in MedDRA.	There are inconsistencies with the handling of "device type" and "device event/finding" terms in MedDRA. Several years ago, both the specific devices (like contraceptive devices) AND the specific events/findings (like dislocation, leakage etc) were represented on PT level. When having a closer look into the device terminology, it soon became obvious that this approach would create too much granularity on PT level. Based on the recommendations of a working group initiated by the MedDRA Expert Panel that I participated in, it was then decided to represent the events/findings on PT level and have the devices causing these on LLT level. Now there are more and more exceptions from this rule, causing confusion in operational coding. Recent example is the new PT Mobile medical application issue. If a malfunction of such a device is reported, should it now be coded to the new PT or to PT Device malfunction? Why is this PT not grouped under the more general PT Device issue but made a separate PT? Other examples: why is LLT Device failure, alarm grouped under PT Device alarm issue and not under PT Device failure (keeping to the wording, although "device failure" rather refers to complete functional failure of a device) or PT Device malfunction (failure affecting a part of the device only)? Other examples. • Pump reservoir issue is represented on PT level • Lead dislodgement and Device lead damage are represented on PT level • PT Device battery issue groups specific events/ finding like leakage, failure etc. Same is true for PTs Needle issue and Syringe issue. The Introductory Guide generally mentions these exceptions on page 56: "Device terms are event based, not device type based. Therefore, the MedDRA term name will generally not include the specific type of device. However, exceptions may be made for generic types of devices and device components (in widespread use) such as stents, pumps, catheters, needles, and syringes. " Catheters are not represented on PT level but included as LLTs for coding of device findings. If it is considered necessary to represent certain devices/ device components on PT level (with or without related events/ findings underneath), it would be helpful to explain the underlying principles for decision making in the MedDRA Introductory Guide and to give more detailed guidance for this area in the PTC for MedDRA term selection (Prioritization of event/ finding over device type if both options exist on PT level? Splitting if a general PT for the specific device exists but event/ finding can only be captured with an additional PT?) Currently, it is difficult to come up with consistent and plausible internal Coding Conventions in this area. I expect more specific terms to be added in the next MedDRA versions, after MedDRA was amended with the new SOC Product issues. Therefore, your support would be highly appreciated.	Implemented	The general convention for representing device terms as event based rather than on the specific type of device still applies. However, MedDRA has evolved in response to users' requests to add certain device type terms when these devices are widely used or have a particular clinical relevance. The general convention has been to place device type terms as LLTs to device event PTs. The MSSO performed a careful review of the PTs and LLTs under HLGT Device issues and HLGT Complications associated with device and concluded that, in general, device type terms are subordinate LLTs under the appropriate device event term PTs. There are justifiable exceptions such as certain stent complications (e.g., endo-leaks, where the event and device type are linked), and the representation at the PT level of certain device components which are present in many devices, such as batteries, leads, syringes, or needles. However, two PTs were identified which do not warrant PT status and, to be consistent with similar device type terms, would be better placed as LLTs under a more general device term. The MSSO will perform the following changes: • Demote PT Pump reservoir issue under PT Device issue • Demote PT Feeding tube complication under PT Complications associated with device Other device type PTs (e.g., PT Implant subsidence, PT Allergy to surgical sutures, and PT Capsular contracture associated with breast implant) warrant PT status due to their frequency of use, their clinical relevance, or the specificity of the device type to the event. Likewise, the PT Mobile medical application issue was considered a special case, since it is referring to a specific tool (software application) to transmit information to or from a device, rather than to a device itself. The MSSO recognizes that there are some challenges when coding these concepts and organizations may have different focuses on the device type vs. event. Internal coding conventions can provide guidance and there is always the option to select terms for both the device type (if available) and the general device event if this provides more information. The MSSO will update section 6.8.2 and 6.19.2 of the MedDRA Introductory Guide to describe the general conventions for representing device events and types, and the relevant exceptions that are made reflecting the evolution of users' needs in device reporting.	6/6/2016	19.1

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
53	Blindness	Provide consistent options in MedDRA that convey a reduction in visual ability. The PT of Blindness (current option) implies a total and complete loss of vision and is not suitable.	Implemented	A MedDRA user requested that the MSSO provide consistent coding options that convey a reduction in visual ability, including a differentiation between reduction in visual acuity (sharpness of vision) and other reductions in vision. After performing a review, the MSSO has taken the following actions: • A total of 12 LLTs were moved from PT Visual acuity reduced to PT Visual impairment for better conceptual term alignment. Examples include LLT Vision decreased and LLT Poor vision. For similar reasons, LLT Transient partial visual loss was moved from PT Visual acuity reduced transiently to PT Blindness transient. • While MedDRA includes an extensive variety of LLTs subordinate to PTs such as PT Visual acuity reduced and PT Visual impairment which convey a reduction of visual ability, there may not always be clear categorical distinctions among terms pertaining to blindness, partial vision loss, and other concepts relating to visual impairment. To address this situation, the MSSO will propose new HLT Visual impairment and blindness (excl colour blindness) for the next MedDRA Version 21.0 Complex Change review to group such terms.	1/31/2017	20.0
55	Gradation of chemical burns	We sometimes receive reports of “chemical burns”, associated with some of our products (mostly dermally applied cosmetics, although reports associated with detergents too are also received). Frequently these “chemical burns” are accompanied by a form of gradation: mostly in the degree (first through fourth) system, occasionally in the more descriptive fashion (e.g. “partial thickness”). The majority of our reports come from consumers; confirmation from healthcare professionals are less frequent, however in most cases, HCPs seem to prefer the degree system of classification. I would like you to consider including the gradation of chemical burns in terms, in a similar fashion to the gradation of thermal burns in the Thermal burn HLT. I am unclear how best these terms should be reflected in MedDRA, thus I am submitting as a proactivity proposal rather than a change request: currently there are four PTs for chemical burns (GI tract, respiratory tract, skin and eye) – whether this system needs to be re-assessed if you agree to the above is where I become unstuck. Further, two chemical burn terms exist as LLTs under the Chemical injury PT: perhaps Chemical burn should be promoted to a PT, or moved to a new PT for chemical burn of unspecified location/degree. Finally, if it is felt that grading chemical burns by degree is acceptable, those terms in the Thermal burn HLT, which do not contain the word “thermal” (e.g. Burns first degree) could be made non-current/demoted in order to ensure clarity that these terms specifically relate to thermal burns and not burns due to another source.	Implemented	The MSSO reviewed the request to consider adding a set of terms for gradation of chemical burns to MedDRA. After careful review, the following PTs will be added to MedDRA for Version 20.0: • PT *First degree chemical burn of skin* • PT *Second degree chemical burn of skin* • PT *Third degree chemical burn of skin* • PT *Fourth degree chemical burn of skin* These terms will be added to primary HLT *Chemical injuries* in SOC *Injury, poisoning and procedural complications* with a secondary link to HLT *Dermatitis ascribed to specific agent* in SOC *Skin and subcutaneous tissue disorders* . Additionally, the MSSO will switch the positions of PT *Chemical injury* and LLT *Chemical burn* so that Chemical burn will be a PT and Chemical injury will be an LLT. Elevating Chemical burn to the PT level aligns this concept with the new PTs and could be used in situations where the stage of chemical burn is not known. The suggestion to demote PTs or change status of LLTs to non-current under HLT *Thermal burns* which do not contain the word “thermal” will not be implemented. By virtue of their placement under HLT *Thermal burns* , the underlying PTs and LLT represent thermal burns whether they bear the qualifier ‘thermal’ or not. Additionally, changing the status of LLTs without the word “thermal” to a status of non-current would likely have an adverse effect on legacy databases.	11/23/2016	20.0

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
56	Review of terms to capture descriptions of treatment/interaction between patients and healthcare professionals	Currently the Surgical and medical procedures SOC provides for Emergency care and Hospitalisation and Intensive care as well as Office visit (presumably to capture reports of patients visiting a doctor at their surgery for instance). However, these terms do not seem to capture the full gamut of interactions between a patient and HCPs, which could be key in capturing the severity, at least perhaps in the patients' eyes, of their reaction. Whilst the term Hospitalisation, captures admission to hospital, I do not feel it is appropriate to use this term to capture reports where either it is unclear if the consumer was hospitalised, or those where it was clear that the consumer was not hospitalised – for instance attending as an outpatient or receiving treatment in the hospital's emergency department (though the latter could be judged to fall under the term Emergency care, it is not clear and this concept could be considered broader and include emergency treatment outside of a hospital. Consideration should be given to those situations where it is known only that a visit or interaction occurred, as opposed to those where some sort of treatment was received: the former conveys some uncertainty to the level of severity, whilst the former is clearer. Given the multiple points open for consideration and whether these terms comply with MedDRA term conventions, along with the need for utilising a more global terminology, rather than one influenced by the British and American healthcare system setups, I felt is was more appropriate to submit this a Proactivity Proposal, rather than a large number of potentially inappropriate Change Requests. However for your benefit, here are some of my thoughts on potential terms: · Ambulatory care visit or Walk-in centre visit – the current Office visit implies a less immediate nature to the interaction; Emergency care implies that some sort of immediate interventional treatment was received, rather than something less severe. · Accident and emergency visit, Emergency room visit, Emergency department visit and Hospital visit – again, the current Office visit implies a less immediate nature to the interaction; Emergency care implies that some sort of immediate interventional treatment was received, rather than something less severe; visiting hospital does not imply admission to hospital, which the current term Hospitalisation does. · Inpatient treatment could also be added, as well as Hospital treatment, to capture treatment rather than hospitalisation for observation – although whether this is an unnecessary distinction is another question. · Outpatient treatment could be added as an LLT in the PT Therapeutic procedure, again allow the capture that some sort	Declined to pursue	The MSSO has decided not to pursue the proposal to add terms to capture descriptions of treatment/interaction between patients and healthcare professionals. MedDRA does contain a limited number of terms for hospitalization, office visit, etc. but it is not practical for MedDRA to contain a comprehensive list of all possible healthcare interactions. These patient/HCP interactions can be defined differently in various regions of the world and certain concepts may not translate universally (such as the concepts of "urgent care" centers, pharmacy "minute clinics" and outpatient surgical centers). Also, in some regions, the terms used to describe the location and type of healthcare interaction are based upon administrative and insurance-related nuances (e.g., hospital "admission" versus hospital "observation", ambulatory center surgery versus inpatient surgery). In addition, as the requester has noted, the location of a patient/HCP interaction does not always accurately reflect the severity or type of interaction which occurred; the focus should be on capturing the event and treatment received if this information is known, rather than capturing the location of the interaction. The MSSO has therefore concluded that it would be impractical to include multiple healthcare interaction terms, many of which would not be globally applicable.	7/16/2016	20.0
57	Review mapping of metastatic adenocarcinoma	MedDRA is inconsistent in mapping of metastatic adenocarcinoma plus locations. Some PTs keep metastatic part, others do not . e.g., LLT Adenocarcinoma endometrial metastatic, PT Endometrial adenocarcinoma vs. LLT Esophageal adenocarcinoma metastatic, PT Oesophageal adenocarcinoma metastatic Can the MSSO have a look on this issue and give us an explainable rationale for the different mapping?	Implemented	Adenocarcinomas may be classified according to a variety of characteristics, including the predominant pattern of cell arrangement, such as papillary, alveolar, etc.; a particular product of the cells, such as mucinous adenocarcinoma; the stage of progression for of a type of adenocarcinoma; and primary versus metastatic forms of the neoplasm. In MedDRA, metastatic adenocarcinomas are generally placed at the LLT level subordinated to the non-metastatic correspondent form of the neoplasm (e.g.; LLT Metastatic gastric adenocarcinoma under PT Adenocarcinoma gastric) or, in several cases, to the metastatic qualified PT of the histologically unspecified neoplasm of the same anatomical location (e.g.; LLT Breast adenocarcinoma metastatic under PT Breast cancer metastatic). Two PTs, PT Oesophageal adenocarcinoma metastatic and PT Lung adenocarcinoma metastatic are the only exceptions to this convention. For hierarchical consistency, the following changes will be made for MedDRA Version 20.0: 1) Demotion of PT Oesophageal adenocarcinoma metastatic to an LLT under PT Oesophageal adenocarcinoma, which is the corresponding unqualified PT of the same histological specificity. 2) For same reason, PT Lung adenocarcinoma metastatic will be demoted to an LLT under PT Lung adenocarcinoma	11/23/2016	20.0

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
58	Review placement of site ecchymosis terms	I am proposing that the terms of …….. site bruising terms be changed. This would be applicable for all site terms including Administration/application/catheter/implant/infusion/injection/instillation/medical device/vaccination/vessel puncture site terms. A bruise is considered to be a contusion caused by an injury. Ecchymosis is defined as a small hemorrhagic spot, larger than a petechia, in the skin or mucous membrane forming a nonelevated, rounded or irregular, blue or purplish patch in Dorlands dictionary. Since the bruising at the sites typically would not be due to an injury but would be more of a hemorrhage within the skin creating a bruise appearance (ecchymosis) I'm proposing that the LLT terms of …… site ecchymosis be promoted to PT terms and the LLT terms of ….. site bruising be linked to the PT of …..site ecchymosis. For example: the LLT of Injection site bruising would be linked to a PT term of Injection site ecchymosis. Currently the ….site bruising terms are coded to a PT of …..site bruising. You typically would not have a contusion (caused by an injury) at an injection site. The bruise appearance would be caused by hemorrhage in the skin which equates to ecchymosis. The terms of …..site ecchymosis are currently routed to a PT of ….site haemorrhage. This code implies active bleeding but the ecchymosis is more of a hemorrhage into the skin and not active bleeding.	Declined to pursue	The MSSO has reviewed the proposal to change the representation of site bruise terms and, after careful consideration, has decided not to pursue the request. For MedDRA Version 16.0, the MSSO reviewed the placement of bruise, contusion, and ecchymosis concepts in MedDRA in response to a proactivity proposal (No. 17). General conventions were established and changes were made to harmonize the placement of these terms in a more consistent manner (see What's New MedDRA Version 16.0 document for details). The convention for bruise terms is that they are generally placed at the LLT level, to an appropriate contusion PT, with the following exception: Considering that "bruise" and "contusion" are synonyms, a specific bruise term may be at the PT level if it represents the common clinical use of the respective concept (e.g., PT Increased tendency to bruise, and PT Application site bruising). Furthermore, the convention notes that bruises/contusions are primarily a result of injury, or procedural complications. The MSSO considers that the various administration site bruise concepts do represent injuries where the tissue is damaged as part of the procedure to administer drugs via infusion/injection or to implant devices, etc. The convention also states that because ecchymosis is a localized interstitial haemorrhage of usually a small quantity of blood, site-specific LLT ecchymosis terms will continue to be mapped to the appropriate site-specific or procedure-specific hemorrhage PT. (e.g., LLT Injection site ecchymosis under PT Injection site haemorrhage). The MSSO will therefore not be modifying the existing site bruise terms and will adhere to the established conventions for representation of these concepts.	8/19/2016	20.0
59	Consider adding "drain site" terms to MedDRA	Addition of drain site terms to match other site reactions e.g. inflammation, discharge, infection, redness, swelling, etc. When these are reported in clinical trials, we are unsure whether to select a catheter site term, or puncture site, or implant site, or another term as we don't know the type of drain. Sometimes we are told the type of drain so will select one of these, but then the terms are spread across several PTs.	Declined to pursue	To cover the immediate coding need, the MSSO added PT Drain site complication under HLT Non-site specific procedural complications for Version 20.1. The MSSO does not consider it practical to mirror all the possible site reactions such as in "catheter" and "puncture" site, etc. with "drain" site terms. If other specific drain site concepts are needed, they can be considered on a case by case basis via the established change request process.	1/10/2017	N/A
60	Review of foreign body terms in PT Foreign body	Related to Proactivity Proposal 50, inconsistency in mapping of wound terms, please could you consider taking a similar look at the placement of foreign body terms in the Foreign body PT. There are a number of site-specific foreign body LLTs in this PT, which is mapped to the Non-site specific injuries NEC HLT. The majorities of the 45 LLTs are site specific. Reviewing historical Change Requests shows that in 6.0, a number of site specific foreign body terms (such as Foreign body in eye and Foreign body in knee) were demoted to LLTs: it is decided that at the time that there would be no "additional terms to MedDRA based on anatomical differences unless the variation is a significant difference in the disorder or treatment". However Foreign body in eye was subsequently promoted to a PT (in 8.0). Given your recent review of the placement of site specific wound LLTs in an explicitly non-site specific HLT, it is not clear whether this decision needs to be revisited. It is also noted that there are some site specific foreign body removal PTs, such as Removal of foreign body from respiratory tract, in the Surgical SOC Some of the foreign body terms could be broadly grouped and moved to the relevant body site specific injury HLT, in the Injuries HLGT; for instance, rather than promote Foreign body in pharynx and Foreign body in trachea to separate PTs, a more general PT such as Foreign body in respiratory tract could be created and placed in the Site specific injuries NEC HLT. Even if a broader change were not considered necessary, in some cases it could be argued too that a foreign body in the respiratory tract is of significant difference, in terms of both potential severity and treatment, than a foreign body in the gastrointestinal tract or reproductive system and could be consistent with the decision to separate Foreign body in eye as a separate PT and thus warrant a limited promotion of significant LLTs from this PT.	Implemented	After performing a review, several modifications were made to accommodate this request. A total of 6 new PTs have been added for MedDRA Version 20.1 and one LLT has been promoted to the PT level with HLT links to the appropriate site specificity. The PTs are as follows: PT *Foreign body in gastrointestinal tract* PT *Foreign body in reproductive tract* PT *Foreign body in respiratory tract* PT *Foreign body in urogenital tract* PT *Foreign body in ear ** PT *Musculoskeletal foreign body* PT *Soft tissue foreign body* LLTs have been moved from PT Foreign body to more specific PTs accordingly.	6/7/2017	20.1

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
61	'Aggravated' LLTs	I'd like to request the MSSO review the existing LLTs that specify 'aggravated', 'exacerbation' and 'worsening' with a view to changing currency status. The majority of the existing LLTs with 'aggravated', etc., map to a single medical concept PT and are benign. But there's a significant number that are being used where MedDRA has multiple related concepts at the PT level, but the 'aggravated' term is selected over the more accurate condition PT. I'm specifically concerned about terms related to seizures/epilepsy, diabetes mellitus and dementia. Please see attached file with some examples where this could occur. A specific example our PV colleagues coded a reported event 'absence seizures worsening' to the LLT Convulsions aggravated, PT Seizures rather than the LLT Absence seizure, PT Petit mal epilepsy. The PV physician wanted the coding to capture the 'aggravation' but when I pulled in the Study Director/Medical Monitor, he felt (and I agreed) that the type of seizure was more clinically relevant. I've had frequent discussions over the years with enough medical reviewers/study directors to come to the conclusion that the use of these terms is decided by individual preferences. The demotion of 'aggravated' PT terms back in v6.0 was done for good reasons. The MSSO has generally refused to add new aggravated LLTs. I personally believe the time is long past to remove these terms, but I know it's not feasible. I've counted over 400 current LLTs and understand it would have too big an impact on legacy data.	Declined to pursue	As mentioned in the request, the MSSO conducted an extensive review of “aggravated” terms in MedDRA Version 6.0. A limited set of such terms are represented in MedDRA based on user feedback and the MSSO generally does not add additional “aggravated” concepts unless they are distinct medical entities such as PT/ LLT Infective pulmonary exacerbation of cystic fibrosis. The “aggravated” terms are valid medical concepts and do not meet the criteria for changing them to a non-current status. Furthermore, any change in currency status would have a large impact on legacy data. Please consider developing coding conventions for “aggravated” concepts based on the MedDRA Term Selection: Points to Consider document section 3.9 – Modification of Pre-existing Conditions.	3/13/2017	N/A
62	Differentiation between administration errors/issues and medication errors/product use issues on LLT and PT level	The new hierarchy for unauthorized product uses is helpful and has solved a lot of previous ambiguities. But one issue remains: the clear differentiation between administration errors/issues and medication errors/product use issues on LLT and PT level. Just some examples from v20.0: · LLT Drug use in unapproved age group (PT Drug administered to patient of inappropriate age) is grouped under HLT Product administration errors and issues, whereas LLT Drug use in unapproved population (PT Product use issue) is grouped under HLT Medication errors, product use errors and issues NEC · LLT Expired drug used (PT Expired product administered) is grouped under HLT Product administration errors and issues, whereas LLTs Discontinued product administered and Recalled drug administered (PT Product use issue) is grouped under HLT Medication errors, product use errors and issues NEC · LLT Wrong dose administered (PT Incorrect dose administered) is grouped under HLT Product administration errors and issues, whereas LLT Unapproved dose administered (Product use issue) is grouped under HLT Medication errors, product use errors and issues NEC · LLTs representing inappropriate administration techniques like e.g. Paravenous drug administration (same PT) or LLT Lack of injection site rotation (same PT) are grouped under HLT Product administration errors and issues, whereas LLT Inhalation not administered correctly (PT Wrong technique in product usage process) is grouped under HLT Medication errors, product use errors and issues NEC. Also, for several concepts only “use” terms exist, with no corresponding “administration” terms. A clear differentiation of the concepts “administration” and “use” is of special relevance, because Regulators want us to capture both the type of unauthorized product use (off label use, medication error, product use issue etc.) and whether this finally reached the patient (by assigning a LLT capturing the specific administration issue). It was also made very clear during our discussions in the MedDRA Expert Panel that “product use” is not to be considered a synonym for “product administration”. Due to the existing inconsistencies in the current MedDRA hierarchy, it is difficult to come up with consistent and	Implemented	Depending on the particular context, the concepts of “product administration” and “product use” may be synonymous or they may have distinctly different meanings. The MSSO performed a careful review of “administration” and “use” terms in HLGT Medication errors and other product use errors and issues and made four changes for better alignment and consistency of placement. These include placing “unapproved use” concepts under PT Product use issue because the main concept is the unapproved use, rather than an administration error/issue. In addition, the concepts of discontinued, expired, recalled, counterfeit products being administered are all to be represented at the PT level to facilitate retrieval and analysis because they are potentially important safety issues. The changes, which will be implemented in MedDRA version 21.1, are: - Move LLT Drug use in unapproved age group from PT Drug administered to patient of inappropriate age to PT Product use issue - Promote LLT Discontinued product administered from PT Product use issue to primary HLT Product administration errors and issues - Add new PT Recalled product administered to primary HLT Product administration errors and issues - Move LLT Recalled drug administered from PT Product use issue to new PT Recalled product administered	5/23/2018	21.1

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
63	PTs referring to drug effect or therapeutic response	Under HLT Therapeutic and nontherapeutic responses there are many PTs referring to drug effect or therapeutic response. The differentiation between these concepts is not at all intuitive, but no generally accepted definitions exist and there are no MedDRA concepts descriptions in this area. One example: I a patient takes a pain killer for chronic headache that is to be taken once daily but reports that the headache comes back after only 6 hours, is this · Therapeutic response shortened (PT) · Therapeutic response decreased (PT) · Drug effect decreased (PT) · Drug effect incomplete (PT) · Therapy partial responder (PT) "Drug effect" usually refers to the therapeutic effect of a drug and when no therapeutic response is reported, normally PT Drug ineffective is assigned. This is also reflected in the ICH PTC document, where "Patient took drug for a headache, and her headache didn't go away" is to be coded to LLT Drug ineffective (section 3.23.1). Or shall similar events be coded to PT Therapy partial responder because they definitely relate to the therapeutic effect? The difference between all these terms is small and it would be very helpful if the MSSO could add LLTs to make the PT names more explicit, provide concept descriptions to support the differentiation of these terms and potentially also trigger additional guidance in the ICH PTC document. Maybe even reduction of granularity on PT level could be an option. More guidance would definitely improve coding consistency across MedDRA users because otherwise, every company may come up with its own definitions and coding approaches.	Declined to pursue	The MSSO has reviewed the proposal to change the representation of drug effect and therapeutic response concepts in MedDRA and to create concept descriptions, and, after careful consideration, has decided not to pursue this request. There are no standard definitions in the literature for effectiveness or therapeutic response, and, therefore, it would be difficult to create concept descriptions for these terms in MedDRA. There may be different interpretations but, in general, a therapeutic response, which can represent expected and unexpected beneficial results of a therapy, is broad in nature, as it may relate to a variety of therapeutic products (e.g., biologics, vaccines, medical devices, blood products) and is thus not limited to drugs. The drug effect concepts may represent the therapeutic effect of the drug, however, they may also refer to the effect of a drug which is used not for the purpose of treatment, but for other uses such as diagnosis, prophylaxis, or supplementation, etc. The present level of granularity reflects the needs of MedDRA users to code a variety of different effect and therapeutic response scenarios. The MedDRA Term Selection: Points to Consider (MTS:PTC) document is not intended to provide specific guidance on individual MedDRA terms; it is recommended that organizations establish their own internal coding conventions for these concepts, consistent with the general principles in the MTS:PTC.	8/3/2017	N/A
64	Review classification of benign tumors with specific histology and localization	The classification of benign tumors with specific histology (adenoma, lipomas etc.) and localization is inconsistent in MedDRA. Sometimes they are represented on PT level (e.g. Thyroid adenoma, Urethral adenoma, Rectal adenoma, etc.), sometimes only on LLT level under general "Benign neoplasm" PTs (e.g. LLT Pituitary adenoma under PT Pituitary tumour benign, Parathyroid adenoma under PT Parathyroid tumour benign, LLT Pancreatic adenoma under PT Benign pancreatic neoplasm, etc). There is no general rule for the classification of benign neoplasm with specific histology and localization in the MedDRA Introductory Guide that would better guide MedDRA users. For Medical Coders and for the compilation of Coding Conventions, the current situation is quite confusing: Shall localization be prioritized for benign neoplasms with specific histology when no specific MedDRA term is available (e.g. "Lipoma of the parotid gland" to be coded to LLT Benign salivary gland neoplasm), even if the specific histology is lost? Or shall histology be prioritized, even though localization is lost, when no specific MedDRA term is available covering both (e.g. "Gastric lipoma" to be coded to LLT Lipoma of intra-abdominal organs instead of LLT Benign gastric neoplasm)? More guidance and a potential revision of LLT/ PT assignments would make the MedDRA philosophy in this area more transparent and improve coding consistency across MedDRA users, thereby better supporting safety data retrieval, presentation and analysis.	Declined to pursue	The MSSO has reviewed the proposal to review the classification of MedDRA terms pertaining to benign tumors with respect to specific histology and localization and, after careful consideration, has decided not to pursue this request. PTs for benign neoplasms intentionally represent either broad concepts, or those of a more specific histological description, to facilitate coding and retrieval of safety data on the basis of available reported information (e.g., PT Benign breast neoplasm and PT Breast adenoma). It would be problematic to categorically adopt a rule that requires that PTs terms represent only site specific histological, or only general neoplastic descriptions of benign tumors. The Seventh MedDRA Blue Ribbon Panel (BRP 7) recognized such a need for both specific and broad terms at the PT level to represent neoplastic lesions. The existing terms for benign neoplasms and their placements at the PT vs. LLT level generally reflect characteristics relevant to the clinical context and the frequency of use of the concepts. For example, Eccrine spiradenoma, the rare benign adnexal eccrine neoplasm is placed as a sub-concept LLT to PT Sweat gland tumour, a more general benign tumor concept without histological specificity. The placement of every histological type of benign neoplastic tumor at the PT level would result in a high degree of granularity which could compromise safety signal detection. In contrast, PT Colon adenoma is not an uncommon histological organ specific adenoma concept which is subordinated by several LLT sub-types of colonic adenomas (e.g., LLT Colonic serrated adenoma, LLT Colonic tubular adenoma, LLT Colonic villous adenoma, and LLT Colonic tubulovillous adenoma). It is recommended that organizations establish their own internal conventions for selection of terms that prioritize the location of the neoplasm vs. the specific histological type in the absence of terms that combine both concepts.	10/23/2017	N/A

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
65	Lesion and Lesion excision terms	There are instances where “lesion excision” terms in MedDRA do not have a corresponding term representing the lesion itself. For example, LLT Bronchial lesion excision does not have a counterpart term “Bronchial lesion”. This poses challenges in coding reports of lesion excisions when there is no matching term to capture the condition that was excised in a surgical procedure. Using the example above, the general term, LLT Bronchial disorder, would not be a suitable counterpart to the excision term because a disorder is not a physical entity and cannot be excised. Similarly, there are instances where “lesion” terms do not have a “lesion excision” counterpart, e.g., LLT Hepatic lesion does not have a counterpart term, “Hepatic lesion excision”. Please could the MSSO consider adding selected terms to facilitate coding of lesions and their excisions.	Declined to pursue	After careful consideration, the MSSO has decided not to pursue the proposed request to add “lesion” and “lesion excision” terms. The MedDRA Introductory Guide, Section 5.1 “PT and LLT Naming Conventions”, states: “Lesion terms may be considered for inclusion in MedDRA when the word “lesion” is part of a medical concept, e.g., PT Glomerulonephritis minimal lesion or a well-documented medical concept, e.g., LLT Brain lesion. However, the term will not be added when adding a broad “lesion” term only adds an additional imprecise term to existing “disorder” concepts, e.g., “renal lesion,” when one could use for coding the existing LLT Renal disorder under PT Renal disorder.” Although there are existing “lesion excision” terms within MedDRA which do not have a companion “lesion” term by itself, the MSSO does not believe that the terminology will be enhanced by adding further non-specific and broad “lesion” terms. Rather, users are encouraged to use appropriate existing MedDRA terms for pathologic processes (e.g., mass, abnormality, cyst, disorder, disease, etc.) if the desire is to code both the presence of a pathologic finding and its subsequent excision or removal. In addition, the MSSO notes that not all existing “lesion” terms within MedDRA warrant a corresponding “excision” term since some “lesion” terms do not describe a pathologic process treated by surgical excision (e.g., LLT Bankart lesion or LLT Janeway lesion). Users are encouraged to select more specific terms, already in MedDRA, for surgical excision, removal and “ectomy” concepts.	2/12/2018	N/A
66	Prophylaxis terms	There are many very specific terms for prophylaxis in MedDRA that fall under each body system category, e.g., LLT Arrhythmia prophylaxis, but if the reported term is not one of them we lose all information and can only code to the general prophylaxis terms, LLT Prophylaxis or LLT Prevention. Please could the MSSO consider adding prophylaxis terms based on SOCs such as “Cardiac disorder prophylaxis” so that we can capture broad anatomical/physiological information for prophylaxis concepts.	Implemented	The MSSO assessed the placement of existing prophylaxis/prevention terms in HLT Prophylactic procedures NEC and will move them to optimize their placement in MedDRA as part of a proactive review requested by a MedDRA User. As part of this proactive request, the addition of a new group of terms to represent general prophylaxis concepts was proposed. The MSSO generally refrains from adding a new prophylaxis term for every specific medical disorder represented in MedDRA, because an overwhelmingly large number such potential terms would likely result. However, on the basis of the review of the terms proposed in this proactivity request, new terms will be added that represent prophylaxis and prevention concepts pertaining to general disorder/disease categories. Please see batch # 20109014 for the new concepts.	5/11/2018	21.1
67	LLTs under PT Procedural complication	This request refers to a previous request to promote LLT Intraoperative neurological injury and move the PT to HLT Neurological and psychiatric procedural complications. Peripheral nerve injuries are a frequent and an acknowledged perioperative complication that can be very debilitating. They may be caused by the surgery itself, but also due to mechanisms like stretch, compression, ischemia, and metabolic/environmental abnormalities. Based on the relevance of the medical condition/ concept, this LLT should be promoted to PT level as current placing of the LLT prevent searching for procedural complications at specific body localisations which hinders safety data retrieval and analysis. In addition the current placement is inconsistent with other site specific procedural complications such as Lymphatic duct injury, Ovarian injury and Surgical skin tear that are represented on PT level under HLGT Procedural related injuries and complications NEC.	Implemented	The MSSO performed a proactivity review of all LLTs under PT Procedural complication and made changes to align some terms in a more anatomically appropriate placement or by the addition of a new term. These changes were based on a suspended request (Batch # 10107457; change request # 2017331022) to promote LLT Intraoperative neurological injury from PT Procedural complication. A total of 35 changes were made in batch # 20107887.	3/7/2018	21.1
68	Coding of dental prosthesis/restoration terms	The coding of differing dental prosthesis/restoration terms is causing us some difficulties with potential inconsistency and we would like your advice and clarification. For the purposes of placement in the MedDRA hierarchy does the MSSO consider the following dental restoration or prosthesis? Dental implants Artificial dental crowns Currently Artificial crowns are suffering some inconsistency in definition e.g. Failure coding to PT Dental restoration failure and breakage to LLT Dental prosthesis breakage. In the 21.0 hierarchy the PT Restoration failure contains specific LLTs relating to fillings and implants. Those MedDRA hierarchy terms for dental prostheses do not include any specificity as to type	Declined to pursue	The MSSO has reviewed the concepts of dental prosthesis and restoration in MedDRA and determined that the placement of existing terms is appropriate. Dental restoration is a broad concept covering restoring the integrity of individual teeth with fillings or implants and restoring intraoral defects such as missing teeth or parts of teeth with fixed or mobile prosthetics (e.g., artificial crowns, bridges, dentures, and implant prosthetics). Failure and breakage are different concepts for devices (although with dental devices, a breakage often leads to failure) so they are kept separate at the PT level. If terms are needed to specify a particular type of prosthesis, e.g., Dental crown breakage, which are not currently represented in MedDRA, please feel free to submit a change request via our WebCR application.	7/31/2018	22.0

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
69	Placement of anaesthesia terms	Below is a proactivity proposal to review the placement of anaesthesia terms, and also perhaps consider the naming of the Paraesthesias and dysaesthesias HLT. As described below, there are a few issues which I feel need addressing: given the number, and a lack of a strong opinion regarding "correct" approach, I've decided not to raise individual Change Requests. Anaesthesia terms in MedDRA are split between the Paraesthesias and dysaesthesias HLT and Sensory abnormalities NEC HLT. For instance: (see table in a PDF attached to this request) There should be consistency of mapping of anaesthesia terms to the same HLT, particularly "site" (e.g. injection) anaesthesia and Anaesthesia. Also, some anaesthesia terms are found at the PT level, whilst others exist only at the LLT level, e.g. Application site anaesthesia is a PT, but Oral mucosal anaesthesia is an LLT in the Hypoaesthesia oral PT. Anaesthesia could be considered on a continuum of hypoaesthesia, so justifying it sublimation as a sub-concept LLT; however a contrary opinion could be taken too. Finally, should all the anaesthesia terms be moved to the Paraesthesias and dysaesthesias HLT, you could consider renaming the HLT to include the phrase anaesthesia – this one depends on whether the term "dysaesthesia" is assumed to cover conditions such as hypoaesthesia and anaesthesia.	Implemented	For consistency of placement, the following PTs will be moved from HLT Sensory abnormalities NEC to HLT Paraesthesias and dysaesthesias: PT Anaesthesia dolorosa PT Anaesthesia, PT Hemianaesthesia and PT Thermoanaesthesia. The proposal to add a new HLT will not be implemented. Dysesthesias is a broad concept considered to cover hyperesthesia, hypoesthesia, and anesthesia.	10/10/2018	22.0
70	Review the placement of chemical burns vs. corrosive injuries	Please consider looking at the placement of Chemical burn and Corrosive injury terms with the aim of ensuring a consistent mapping of these terms at the LLT and PT level. Some corrosive injury terms appear as an LLT in chemical burn PTs and vice versa. See attached for examples. Our preference is to see Chemical burn represented at the PT, as this is the phrase most frequently used when reporting, both by Healthcare Professionals and non-Healthcare Professionals. Also for consideration should be the placement of Chemical injury terms – sometimes placed as LLTs under Chemical burn terms, e.g. Chemical injury in Chemical burn or sometimes as a separate PT, e.g. Chemical eye injury and Chemical burns of eye.	Implemented	The MSSO reviewed the proactive request to consider modifications to the placement of existing chemical burn and corrosive injury terms. Based in this review, the following changes were made for more consistent placement in MedDRA Version 22.0. 1. PT Chemical iritis and PT Chemical eye injury were demoted under existing PT Chemical burns of eye to reduce over-granulation of anatomically closely related concepts. 2. LLT Chemical phlebitis was promoted from under PT Phlebitis to the PT level and linked to primary HLT Chemical Injuries in SOC Injury, poisoning and procedural complications for consistent representation in MedDRA. The position of LLT Chemical burn of oral cavity was switched with PT Corrosive oropharyngeal injury because chimerical burn is broader than corrosive injury. Chemical burn of oral cavity is now a PT with Corrosive oropharyngeal injury as its underlying LLT. 3. A new link for PT Reactive gastropathy to HLT Chemical injuries in SOC Injury, poisoning and procedural complications was established. The primary SOC of PT Reactive gastropathy SOC was changed from SOC Gastrointestinal disorders to SOC Injury, poisoning and procedural complications with the rationale that reactive gastropathy, also called chemical gastropathy, is an abnormality in the stomach caused by chemicals, e.g. bile, alcohol, Nonsteroidal anti-inflammatory drugs (NSAIDs) and characteristically has minimal inflammation.	11/7/2018	22.0
71	Disseminated vs Systemic terms	I'm writing this to seek MSSO's advice as to how a disease entity has been determined to be 'disseminated' vs 'systemic'. It seems that there is an indiscernible difference between the two descriptive terms, yet it doesn't seem to be applied or captured consistently throughout the dictionary. We understand that the character of the spread also depends on the very nature of the disease entity itself, but perhaps you could share your rationale and shed light on the subtle difference? So if dissemination is widespread and is dispersed throughout an organ or body, then systemic is the same but with blood and lymphatic involvement? Below are just a few examples. Any help elucidating this subtle difference would be greatly appreciated. [See attached MS Word document]	Implemented	All existing MedDRA terms containing "disseminated" or "systemic" were reviewed in light of the nature of the concepts, and to the consistency of their respective placement in the terminology hierarchy. Based on this review, 27 changes were made to better align these concepts. These changes will be available in MedDRA Version 23.0.	9/17/2019	23.0

ID	Title	Description	Status	MSSO Comment	Date Complete	Version of Implementation
72	Efficacy term placement	The placement of product efficacy terms is inconsistent in MedDRA. There are nine Therapeutic product effect PTs, four Drug effect PTs, and six Device effect PTs. Some Drug effect and Device effect LLTs are found under Therapeutic product effect PTs. Consistency of term placement is desirable. Either the product's regulatory status is of sufficient importance to consistently justify a term as a PT or it is not.	Declined to pursue	After careful consideration, the MSSO has decided not to pursue the proposed request to change the placement of product efficacy terms in MedDRA. Per the MedDRA Introductory Guide, "product" can refer to various types of products intended for human use such as drugs, biologics, combination products, devices, etc. In some cases, particularly for new terms, drug and device terms may be placed as LLTs under broad product PTs to avoid excessive granularity at the PT level but there is no general rule for the placement level. Many drug and device concepts warrant representation at the PT level because they refer to a unique concept or are important from a pharmacovigilance perspective. This is particularly true for medication errors where drug concepts are largely at the PT level. Demoting these terms under broad product PTs would have a considerable effect on legacy data. Regarding the primary and secondary placement of the device lack of effect terms, the fact that these link to HLGT Device issues in SOC Product issues does not mean that the lack of efficacy is due to a product quality issue; the HLGT simply focuses on issues with devices. Note that product quality concepts are grouped separately in HLGT Product quality, supply, distribution, manufacturing and quality system issues in SOC Product issues. If a drug or device lack of effect is known to be the result of a product quality issue, a relevant product quality term could be selected in addition to the lack of effect term.	7/30/2019	N/A
73	Abrasion term placement	Please consider changes to address consistency of abrasion term placement in MedDRA.	Implemented	A MedDRA user requested a review of existing abrasion terms for consistency of placement in MedDRA. After reviewing the mapping of existing abrasion LLTs to injury PTs for appropriate representation of the underlying medical concept, the MSSO moved six existing abrasion LLTs from their erosion PTs to corresponding injury PTs. In addition, three new abrasion LLTs were added to corresponding injury PTs to improve coding options.	10/25/2019	23.0