



Blue Ribbon Panel on Proposed HLGT/HLT Changes to Improve MedDRA Data Analysis

**16 November 2006
Ingelheim, Germany**

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Agenda

- 0900** – Welcome and Introduction
- 0915** – Review “NEC” HLTs and HLGTS
- 1045** – Break
- 1100** – Multi-Axiality of SOC *Investigations*
- 1230** – Lunch
- 1330** – Multi-Axiality of SOC *Social circumstances*
- 1500** – Break
- 1515** – Eliminate Multi-Axial HLTs in Cumulative Data Output
- 1600** – Break
- 1615** – Review of Recommendations of BRP; Q&A
- 1700** – Meeting adjourned



Introduction

- Logistics
- Purpose/background of BRPs
- Roles and Responsibilities
 - Panelists
 - Observers
 - MSSO
- Introduction of Panel members



Participants

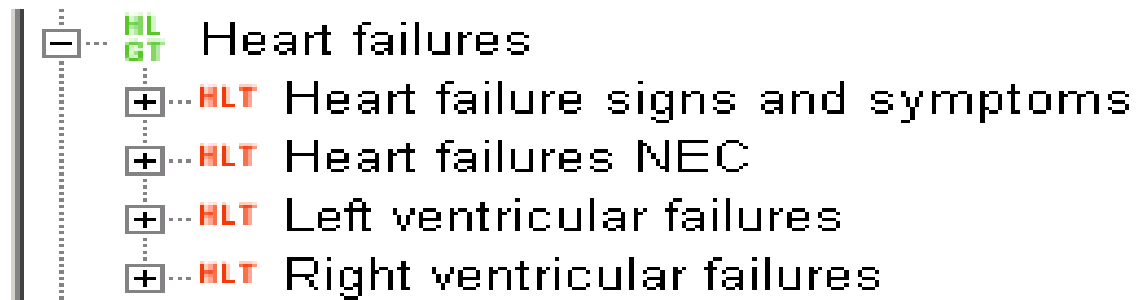
- Panelists:
 - Gottfried Kreutz (CIOMS)
 - Jürgen Kübler (EU Industry/Subject Expert)
 - Reiji Tezuka (Japan)
 - George Rochester (US regulator)
 - Greg Gribko (US Industry)
- Moderators:
 - Anna Zhao-Wong
 - Eva Rump



Review “NEC” HLTs and HLGTs

“NEC” Is Not Intuitive

- The acronym “NEC” is not intuitive, i.e., it does not reflect grouped subordinate concepts explicitly





Proposed Changes

- Explore alternative naming convention to convey content more clearly
 - Replace “NEC” with a more meaningful name if subordinate PTs are relatively “pure”
 - E.g., Rename HLT *Heart failures NEC* to HLT *Heart failures, laterality unspecified*
 - Only “where applicable”
 - HLT/HLGT groupings for “miscellaneous” PTs may always be needed



Oversized “NEC” HLTs

- Analyzing MedDRA coded data by HLTs with large numbers of subordinate PTs proves to be challenging at times
- Based on our analysis using 50 PTs as dividing line (arbitrary), there are 46 HLTs (3%) containing ≥ 50 PTs



Oversized “NEC” HLTs (cont)

- Among the 46 HLTs with ≥ 50 PTs:
 - 31 HLTs are in *SOC Investigation*
 - Among the 15 non-investigation HLTs:
 - Many of them (8) are “NEC” ones



Oversized “NEC” HLTs (cont)

Count of PTs	HLT	HLGT	SOC
172	Therapeutic procedures NEC	Therapeutic procedures and supportive care NEC	Surgical and medical procedures
123	Bacterial infections NEC	Bacterial infectious disorders	Infections and infestations
75	Infections NEC	Infections - pathogen class unspecified	Infections and infestations
74	Viral infections NEC	Viral infectious disorders	Infections and infestations
70	General signs and symptoms NEC	General system disorders NEC	General disorders and administration site conditions
69	Fungal infections NEC	Fungal infectious disorders	Infections and infestations
61	Prophylactic procedures NEC	Therapeutic procedures and supportive care NEC	Surgical and medical procedures
50	Non-site specific injuries NEC	Injuries NEC	Injury, poisoning and procedural complications



Proposed Changes

- Review oversized HLTs and possibly reduce the number of subordinate PTs by building new HLTs, for example
 - HLT *Therapeutic procedures NEC*
 - New HLT *Physiotherapeutic procedures*
 - New HLT *Drug therapies*
 - New HLT *Naturopathic procedures*



User Feedback

- Support the proposed concept or idea
- Large number of subordinate PTs is OK if the HLT group is specific and medically meaningful
- Rename NEC HLTs where possible but keep NEC if not possible
- Opinions are different on which HLTs should change and how to change them
- It is necessary to make implementation schedule



Panel Discussion

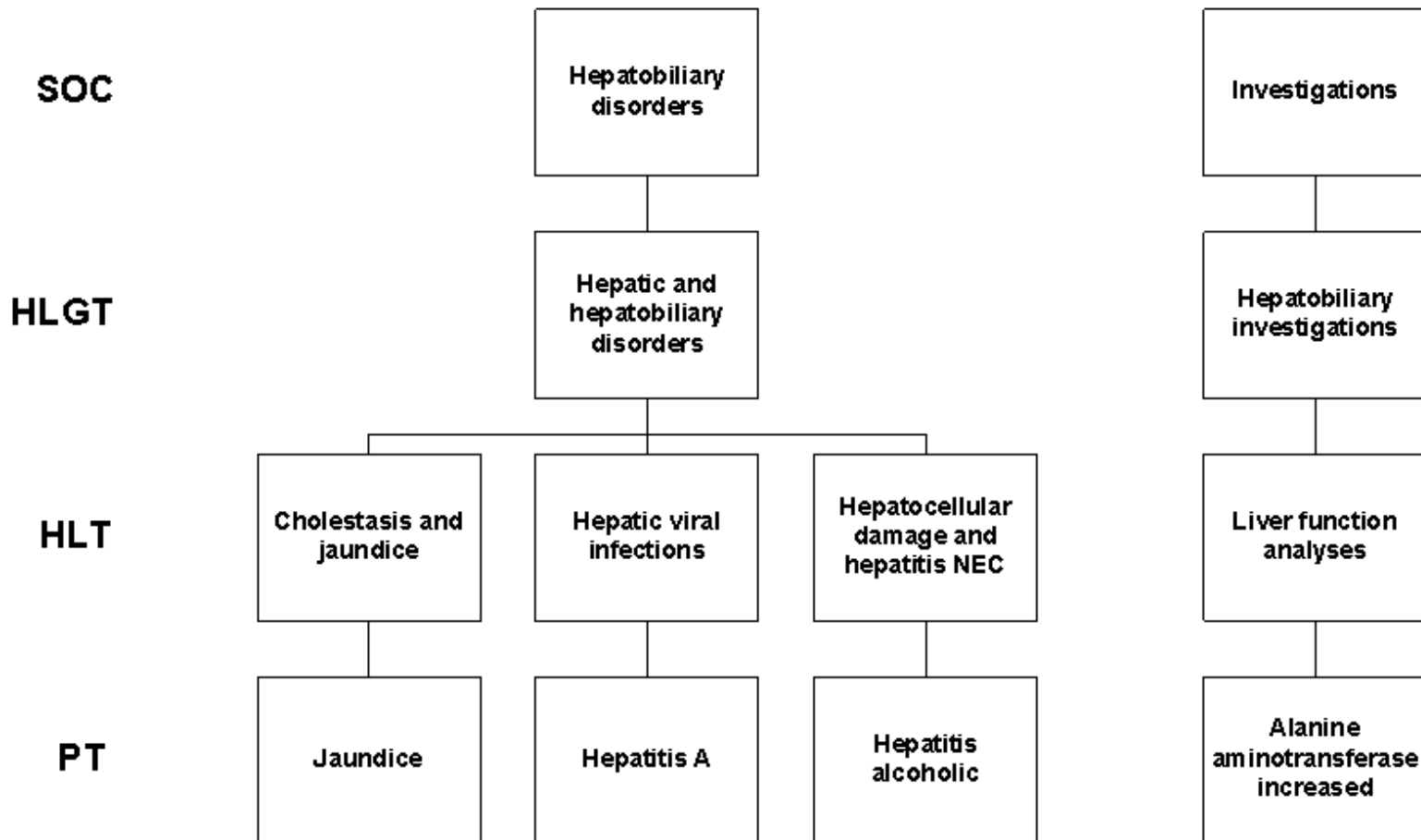
- Should MSSO review and implement these changes if and where applicable?
 - if yes; which SOC's should take priority?
- Is a maximum of 50 PTs to a single HLT appropriate?
 - if no, can the panel recommend an appropriate number of PTs?



Multi-Axiality for SOC *Investigations*

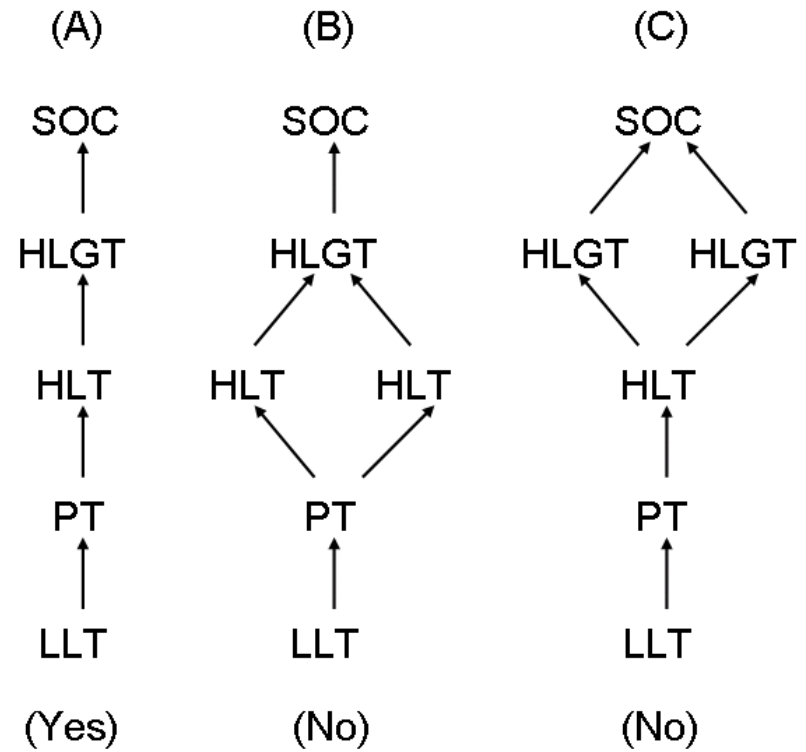
Single Axial SOC

- *SOC Investigations* is a single axial SOC



Proposed Change: Multi-Axiality of SOC Investigations

- MedDRA rules required:
 - Primary SOC allocation
 - One PT can only be linked to one SOC through one path





Proposed Change: Multi-Axiality of SOC *Investigations* (cont)

- Proposed conventions:
 - All investigation PTs would be primarily linked to SOC *Investigations*
 - Apply secondary links to investigation results that meet the following criterion:
 - Investigation results that could **only** represent the specific disease or diagnosis (pathognomonic)
 - Example:
 - PT *Hepatitis A antigen positive* – Yes. Multiaxial to SOC *Hepatobiliary disorders*
 - PT *Alanine aminotransferase increased* – No.



- HLT Hepatic viral infections
 - +PT Adenoviral hepatitis
 - +PT Asymptomatic viral hepatitis
 - +PT Congenital hepatitis B infection
 - +PT Cytomegalovirus hepatitis
 - +PT Gianotti-Crosti syndrome
 - +PT Hepatitis A
 - +PT Hepatitis B
 - +PT Hepatitis C
 - +PT Hepatitis D
 - +PT Hepatitis E
 - +PT Hepatitis F
 - +PT Hepatitis G
 - +PT Hepatitis H
 - +PT Hepatitis infectious
 - +PT Hepatitis infectious mononucleosis
 - +PT Hepatitis non-A non-B
 - +PT Hepatitis non-A non-B non-C
 - +PT Hepatitis post transfusion
 - +PT Hepatitis viral

- HLT Hepatic viral infections
 - +PT Adenoviral hepatitis
 - +PT Anti-HBc antibody positive
 - +PT Anti-HBc IgG antibody positive
 - +PT Anti-HBc IgM antibody positive
 - +PT Anti-HBe antibody positive
 - +PT Anti-HBs antibody positive
 - +PT Asymptomatic viral hepatitis
 - +PT Congenital hepatitis B infection
 - +PT Cytomegalovirus hepatitis
 - +PT Gianotti-Crosti syndrome
 - +PT Hepatitis A
 - +PT Hepatitis A antibody positive
 - +PT Hepatitis A antigen positive
 - +PT Hepatitis A positive
 - +PT Hepatitis B
 - +PT Hepatitis B antibody positive
 - +PT Hepatitis B antigen positive
 - +PT Hepatitis B core antigen positive
 - +PT Hepatitis B DNA assay positive
 - +PT Hepatitis B e antigen positive
 - +PT Hepatitis B positive
 - +PT Hepatitis B surface antigen positive
 - +PT Hepatitis C
 - +PT Hepatitis C antibody positive
 - +PT Hepatitis C positive
 - +PT Hepatitis C RNA positive
 - +PT Hepatitis D
 - +PT Hepatitis D antibody positive
 - +PT Hepatitis D antigen positive
 - +PT Hepatitis D RNA positive
 - +PT Hepatitis E
 - +PT Hepatitis E antibody positive
 - +PT Hepatitis E antigen positive
 - +PT Hepatitis F
 - +PT Hepatitis G
 - +PT Hepatitis H
 - +PT Hepatitis infectious
 - +PT Hepatitis infectious mononucleosis
 - +PT Hepatitis non-A non-B
 - +PT Hepatitis non-A non-B non-C
 - +PT Hepatitis post transfusion
 - +PT Hepatitis viral

Potential Consequence of Proposed Changes



User Feedback

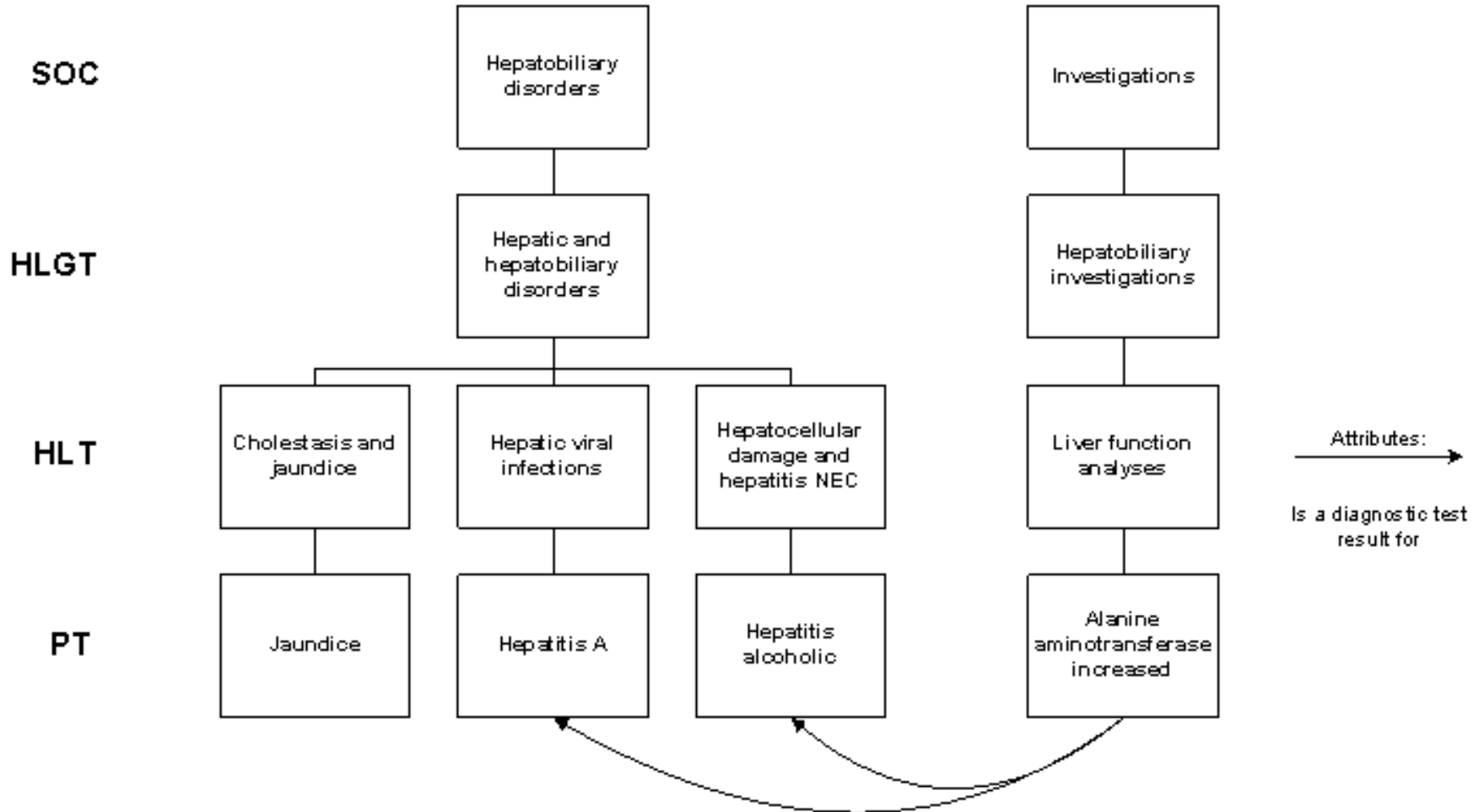
- Although the secondary links help, incompleteness would jeopardize the good intention of this proposal
- Not happy with some proposed secondary links, such as
 - Link PT *Blood pressure decreased* to HLT *Vascular hypotensive disorders*



Panel Discussion

- Should SOC *Investigations* be left as is or made multi-axial?
- If yes to the multi-axial question, does the Panel support the proposed criteria for creating secondary links for investigation results?

A Different Option





A Different Option (cont)

- The same result can be achieved by adding attributes to investigation terms
- Attributes provide medical information about a term
 - For example, investigation terms could include the attribute “Is a diagnostic test for”

Concept Attribute

- Concept attributes are handled by an additional file – “attrib.asc”

Name	Size	Type	Date Modified
attrib.asc	1 KB	ASC File	10/3/2006 2:10 PM
hgt.asc	18 KB	ASC File	7/31/2006 12:27 PM
hgt_hlt.asc	34 KB	ASC File	7/31/2006 12:27 PM
hlt.asc	83 KB	ASC File	7/31/2006 12:27 PM
hlt_pt.asc	470 KB	ASC File	7/31/2006 12:27 PM
intl_ord.asc	1 KB	ASC File	7/14/2006 3:30 PM
llt.asc	3,955 KB	ASC File	7/31/2006 12:27 PM
mdhier.asc	4,553 KB	ASC File	7/31/2006 12:27 PM
pt.asc	922 KB	ASC File	7/31/2006 12:27 PM
SMQ_Content.asc	478 KB	ASC File	8/3/2006 10:18 AM
SMQ_List.asc	69 KB	ASC File	8/2/2006 4:42 PM
soc.asc	2 KB	ASC File	7/31/2006 12:27 PM
soc_hlgt.asc	7 KB	ASC File	7/31/2006 12:27 PM
spec.asc	1 KB	ASC File	7/31/2006 12:27 PM
spec_pt.asc	26 KB	ASC File	7/31/2006 12:27 PM

```

10001551$Is a diagnostic test for$10019719$
10003481$Is a diagnostic test for$10019719$
10005287$Is a diagnostic test for$10019719$
10059570$Is a diagnostic test for$10019719$
10005364$Is a diagnostic test for$10019719$
10019725$Is a diagnostic test for$10019719$
10058751$Is a diagnostic test for$10019719$
10057398$Is a diagnostic test for$10019719$
10001551$Is a diagnostic test for$10009208$
10001565$Is a diagnostic test for$10009208$
10003481$Is a diagnostic test for$10009208$
10005287$Is a diagnostic test for$10009208$
10003481$Is a diagnostic test for$10028596$
10005474$Is a diagnostic test for$10028596$
10005630$Is a diagnostic test for$10028596$
10014391$Is a diagnostic test for$10028596$
10014392$Is a diagnostic test for$10028596$
10014395$Is a diagnostic test for$10028596$
10028625$Is a diagnostic test for$10028596$
10058268$Is a diagnostic test for$10028596$
10058267$Is a diagnostic test for$10028596$
10058269$Is a diagnostic test for$10028596$

```

Concept Attribute (cont)

- Concept attributes are handled by an additional file – “attrib.asc” (cont)

Test result	Relationship	Diagnosis
Alanine aminotransferase increased	Is a diagnostic test for	Hepatitis A
Aspartate aminotransferase increased	Is a diagnostic test for	Hepatitis A
Blood albumin decreased	Is a diagnostic test for	Hepatitis A
Blood alkaline phosphatase increased	Is a diagnostic test for	Hepatitis A
Blood bilirubin increased	Is a diagnostic test for	Hepatitis A
Hepatitis A antibody positive	Is a diagnostic test for	Hepatitis A
Hepatitis A antigen positive	Is a diagnostic test for	Hepatitis A
Hepatitis A positive	Is a diagnostic test for	Hepatitis A
Alanine aminotransferase increased	Is a diagnostic test for	Cirrhosis alcoholic
Albumin globulin ratio decreased	Is a diagnostic test for	Cirrhosis alcoholic
Aspartate aminotransferase increased	Is a diagnostic test for	Cirrhosis alcoholic
Blood albumin decreased	Is a diagnostic test for	Cirrhosis alcoholic
Aspartate aminotransferase increased	Is a diagnostic test for	Myocardial infarction
Blood creatine phosphokinase MB increased	Is a diagnostic test for	Myocardial infarction
Blood lactate dehydrogenase increased	Is a diagnostic test for	Myocardial infarction
Electrocardiogram ST segment depression	Is a diagnostic test for	Myocardial infarction
Electrocardiogram ST segment elevation	Is a diagnostic test for	Myocardial infarction
Electrocardiogram T wave inversion	Is a diagnostic test for	Myocardial infarction
Myoglobin blood increased	Is a diagnostic test for	Myocardial infarction
Troponin I increased	Is a diagnostic test for	Myocardial infarction
Troponin increased	Is a diagnostic test for	Myocardial infarction
Troponin T increased	Is a diagnostic test for	Myocardial infarction

Test result	Relationship	Diagnosis
Alanine aminotransferase increased	Is a diagnostic test for	Cirrhosis alcoholic
Alanine aminotransferase increased	Is a diagnostic test for	Hepatitis A
Aspartate aminotransferase increased	Is a diagnostic test for	Cirrhosis alcoholic
Aspartate aminotransferase increased	Is a diagnostic test for	Hepatitis A
Aspartate aminotransferase increased	Is a diagnostic test for	Myocardial infarction
Blood albumin decreased	Is a diagnostic test for	Cirrhosis alcoholic
Blood albumin decreased	Is a diagnostic test for	Hepatitis A



User Feedback

- Only received two comments
- Helpful to smaller users where there isn't instant access to a physician
- Not agree
 - Difficult to understand
 - Require significant amount of time and effort



Panel Discussion on Concept Attribute



Multi-Axiality for SOC *Social circumstances*



Issue with Terms in SOC *Social circumstances*

- The “lifestyle” terms, LLT *Drug addict*, LLT *Drug abuse* are in SOC *Social circumstances*
- The corresponding psychiatric conditions, e.g., LLT *Drug addiction*, are in SOC *Psychiatric disorders*

- 93C Social circumstances
 - 93C1 Lifestyle issues
 - 93C11 Drug and chemical abuse
 - 93C111 Drug abuser

- 93C111 Drug abuser
 - 93C1111 Addicted to amphetamine
 - 93C1112 Addicted to cocaine
 - 93C1113 Addicted to drugs
 - 93C1114 Addicted to heroin
 - 93C1115 Amphetamine or related acting sympathomimetic abuse
 - 93C1116 Amphetamine or related acting sympathomimetic abuse, continuous use
 - 93C1117 Amphetamine or related acting sympathomimetic abuse, episodic use
 - 93C1118 Amphetamine or related acting sympathomimetic abuse, in remission
 - 93C1119 Amphetamine or related acting sympathomimetic abuse, unspecified use
 - 93C1120 Analgesic abuse
 - 93C1121 Antidepressant type abuse
 - 93C1122 Antidepressant type abuse, continuous use
 - 93C1123 Antidepressant type abuse, episodic use
 - 93C1124 Antidepressant type abuse, in remission
 - 93C1125 Antidepressant type abuse, unspecified use
 - 93C1126 Barbiturate abuse
 - 93C1127 Barbiturate and similarly acting sedative or hypnotic abuse
 - 93C1128 Barbiturate and similarly acting sedative or hypnotic abuse, continuous use
 - 93C1129 Barbiturate and similarly acting sedative or hypnotic abuse, episodic use
 - 93C1130 Barbiturate and similarly acting sedative or hypnotic abuse, in remission
 - 93C1131 Barbiturate and similarly acting sedative or hypnotic abuse, unspecified use
 - 93C1132 Caffeine abuse
 - 93C1133 Cannabis abuse
 - 93C1134 Cannabis abuse, continuous use
 - 93C1135 Cannabis abuse, episodic use
 - 93C1136 Cannabis abuse, in remission
 - 93C1137 Cannabis abuse, unspecified use
 - 93C1138 Cocaine abuse
 - 93C1139 Cocaine abuse, continuous use
 - 93C1140 Cocaine abuse, episodic use
 - 93C1141 Cocaine abuse, in remission
 - 93C1142 Cocaine abuse, unspecified use
 - 93C1143 Drug abuse
 - 93C1144 Drug abuse in remission
 - 93C1145 Drug abuse NOS
 - 93C1146 Drug abuser
 - 93C1147 Drug abuser NOS
 - 93C1148 Drug addict
 - 93C1149 Glue sniffing
 - 93C1150 Hallucinogen abuse
 - 93C1151 Hallucinogen abuse, continuous use
 - 93C1152 Hallucinogen abuse, episodic use
 - 93C1153 Hallucinogen abuse, in remission
 - 93C1154 Hallucinogen abuse, unspecified use

- 93D Psychiatric disorders
 - 93D1 Psychiatric disorders NEC
 - 93D11 Substance-related disorders
 - 93D111 Drug dependence

- 93D111 Drug dependence
 - 93D1111 Addiction any drug
 - 93D1112 Addiction to drugs
 - 93D1113 Addiction to drugs (excl drug psychosis)
 - 93D1114 Amphetamine and other psychostimulant dependence
 - 93D1115 Amphetamine and other psychostimulant dependence, continuous use
 - 93D1116 Amphetamine and other psychostimulant dependence, episodic use
 - 93D1117 Amphetamine and other psychostimulant dependence, in remission
 - 93D1118 Amphetamine and other psychostimulant dependence, unspecified use
 - 93D1119 Amylobarbitone dependency
 - 93D1120 Barbiturate and similarly acting sedative or hypnotic
 - 93D1121 Barbiturate and similarly acting sedative or hypnotic dependence
 - 93D1122 Barbiturate and similarly acting sedative or hypnotic dependence, continuous use
 - 93D1123 Barbiturate and similarly acting sedative or hypnotic dependence, episodic use
 - 93D1124 Barbiturate and similarly acting sedative or hypnotic dependence, in remission
 - 93D1125 Barbiturate and similarly acting sedative or hypnotic dependence, unspecified use
 - 93D1126 Barbiturate dependency
 - 93D1127 Benzodiazepine dependent
 - 93D1128 Cannabis addiction
 - 93D1129 Cannabis dependence
 - 93D1130 Cannabis dependence, continuous use
 - 93D1131 Cannabis dependence, episodic use
 - 93D1132 Cannabis dependence, in remission
 - 93D1133 Cannabis dependence, unspecified use
 - 93D1134 Cocaine addiction
 - 93D1135 Cocaine dependence
 - 93D1136 Cocaine dependence, continuous use
 - 93D1137 Cocaine dependence, episodic use
 - 93D1138 Cocaine dependence, in remission
 - 93D1139 Cocaine dependence, unspecified use
 - 93D1140 Combinations of drug dependence excluding morphine type drug
 - 93D1141 Combinations of drug dependence excluding opioid type drug
 - 93D1142 Combinations of drug dependence excluding opioid type drug, continuous use
 - 93D1143 Combinations of drug dependence excluding opioid type drug, episodic use
 - 93D1144 Combinations of drug dependence excluding opioid type drug, in remission
 - 93D1145 Combinations of drug dependence excluding opioid type drug, unspecified use
 - 93D1146 Combinations of morphine type drug with any other drug dependence
 - 93D1147 Combinations of opioid type drug with any other drug dependence
 - 93D1148 Combinations of opioid type drug with any other drug dependence, continuous use
 - 93D1149 Combinations of opioid type drug with any other drug dependence, episodic use
 - 93D1150 Combinations of opioid type drug with any other drug dependence, in remission
 - 93D1151 Combinations of opioid type drug with any other drug dependence, unspecified use
 - 93D1152 Dependence addictive
 - 93D1153 Dependence drug (NOS)



User Feedback

- Some support moving “abuse” terms to SOC *Psychiatric disorders* instead of secondary links
- Some have great concern of potential massive implication of such change (secondary links to SOC *Social circumstances*)
- Additional guide on how to use terms in SOC *Social circumstances* would be necessary (e.g., PTC document)



Panel Discussion

- Should “abuse” terms, e.g., LLT *Drug abuse* be moved to SOC *Psychiatric disorders*?
- Should SOC *Social circumstances* be made multi-axial to allow other concepts to be grouped by second SOC linkages



Eliminate Multi-Axial HLTs in Cumulative Data Output



Multi-Axiality in MedDRA

- The representation of a medical concept in multiple SOCs
- Allows terms to be grouped by different classifications
- Allows retrieval and presentation via different data sets
- Each PT has only one primary SOC



Primary SOC Rule and Multi-Axial HLTs

- When PTs under the multi-axial HLT have different primary SOC allocations, the following display will occur in the primary SOC view

Primary SOC View

SOC Skin and subcutaneous tissue disorders

- ⊕ **HL** **GT** Angioedema and urticaria
- ⊕ **HL** **GT** Cornification and dystrophic skin disorders
- ⊖ **HL** **GT** Cutaneous neoplasms benign
- ⊖ **HLT** Skin neoplasms benign
 - ⊕ **PT** Dermal cyst

SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps)

- ⊕ **HL** **GT** Breast neoplasms benign (incl nipple)
- ⊕ **HL** **GT** Breast neoplasms malignant and unspecified (incl nipple)
- ⊕ **HL** **GT** Cancer-related morbidities
- ⊖ **HL** **GT** Cutaneous neoplasms benign
 - ⊖ **HLT** Skin neoplasms benign
 - ⊕ **PT** Acanthoma
 - ⊕ **PT** Acrochordon
 - ⊕ **PT** Becker's naevus
 - ⊕ **PT** Benign neoplasm of skin
 - ⊕ **PT** Bowenoid papulosis
 - ⊕ **PT** Epithelioma adenoides cysticum
 - ⊕ **PT** Fibrous histiocytoma
 - ⊕ **PT** Haemangioma of skin
 - ⊕ **PT** Hair follicle tumour benign
 - ⊕ **PT** Juvenile melanoma benign
 - ⊕ **PT** Keratoacanthoma
 - ⊕ **PT** Lentigo
 - ⊕ **PT** Leser-Trelat sign
 - ⊕ **PT** Melanocytic naevus
 - ⊕ **PT** Osteoma cutis
 - ⊕ **PT** Pyogenic granuloma
 - ⊕ **PT** Sebaceous adenoma
 - ⊕ **PT** Seborrhoeic keratosis
 - ⊕ **PT** Silicon granuloma
 - ⊕ **PT** Skin papilloma
 - ⊕ **PT** Sweat gland tumour
 - ⊕ **PT** Xanthoma
 - ⊕ **PT** Xanthoma multiplex

Proposed Changes

- Eliminate multi-axiality of involved HLTs by renaming:

Proposed New Hierarchy of Single-axial (Yellow highlight indicates new term)					
Skin SOC	HLGT Benign cutaneous neoplasms	HLT Benign skin neoplasms	Neoplasm SOC	HLGT Cutaneous neoplasms benign	HLT Skin neoplasms benign



Proposed Changes (cont)

- OR correct the root cause:
 - Different primary SOC allocations among PTs under the multi-axial HLT
 - Option 1: Change the primary SOC for cyst and polyps terms from site of manifestation to SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
 - Option 2: Remove the link of cyst and polyp terms from SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*



User Feedback

- Comments are supportive in principle
- Some suggest eliminating multi-axial HLTs completely
- Objection received for changing the primary SOC of cyst and polyp terms
- The lexical variant approach is potentially confusing and does not translate into other languages
 - JMO suggested to add SOC abbreviation at the end of multi-axial HLTs? E.g.,
 - HLT *Skin neoplasms benign(Skin)*
 - HLT *Skin neoplasms benign(Neopl)*



Panel Discussion

- Should this proposal (elimination of multi-axial HLTs by a renaming approach) be implemented?
- If so, should multi-axiality be eliminated from all HLTs and HLGTS because the same problem could occur again as long as there are still multi-axial HLTs?



Panel Recommendations



Panel Recommendations

- “NEC” HLTs
 - “NEC” naming should not be revised unless there is a more medically meaningful name within the hierarchy
 - Large-sized “NEC” groupings should be analyzed for possible new groupings with the following priority:
 - Oversized HLTs (≥ 50 PTs)
 - Medium or large HLTs with higher frequencies in a regulator’s database
 - Utilize regulatory risk assessment areas for prioritization



Panel Recommendations (cont)

- “NEC” HLTs (cont)
 - HLT re-grouping should be based on medicine, such as pathology or physiology:
 - Avoid force fitting of PTs for the purpose of reducing HLT size
 - Avoid over-granularity at the HLT level
 - Consider the use of age and gender criteria
 - Consider a schedule that completes the implementation in a short timeframe:
 - Consider the potential of consecutive complex releases



Panel Recommendations (cont)

- *SOC Investigations:*
 - Recommend a pilot study on concept attribute approach:
 - MSSO to develop a sample set of investigation terms with concept attributes
 - To be tested by regulators and industry volunteers



Panel Recommendations (cont)

- *SOC Social circumstances*
 - Request PTC Working Group to provide additional guidance on *SOC Social circumstances*, specifically, addict/dependence/abuse terms



Panel Recommendations (cont)

- *SOC Social circumstances* (cont)
 - No change to current SOC structure
 - Review “abuse” related LLTs:
 - Clarify the PT/LLT wordings to differentiate terms in *SOC Social circumstances* from those in *SOC Psychiatric disorders*
 - Move “abuse” terms to *SOC Psychiatric disorders* and keep them as independent PTs from “dependence” counterparts
 - Keep terms that refer to people, such as PT *Drug abuser*, in *SOC Social circumstances*



Panel Recommendations (cont)

- Multi-Axial HLTs in Cumulative Data Output:
 - Create separate HLTs for cyst and polyps terms
 - Consult expert pathologists and oncologists
 - Review all multi-axial HLTs to ensure primary SOCs are appropriate



Next Step

- BRP recommendations will be presented to MedDRA Management Board for approval