



MedDRA

Blue Ribbon Panel 8 – Scope of MedDRA

Recommendations

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Panel Members

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Question 1

What should be defined as the scope of MedDRA, taking into account its function as an international medical and regulatory terminology?





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Question 1

Recommendations

- Scope is medical/health-related and regulatory concepts
- Products covered in scope can include food, cosmetics, tobacco, etc. even if not subject to regulation in all regions
- Maintain MedDRA's current structure even if additional components are added (27th SOC, lists)
- Direct patient reporting and social media
 - Addition of colloquial terms not recommended because of difficulties in interpretation and translation
 - Users should perform coding based on context and using principles in MedDRA Term Selection: Points to Consider document



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Question 2

What are the general criteria to be applied when considering new topic areas for expansion in the future?

- **Examples for consideration:**
 - Manufacturing product quality terms
 - Additional device-related terms
 - Drug utilization terms
 - Labeling qualifiers





Question 2

Recommendations: Specific Topics

- Manufacturing product quality terms
 - Harmonization of quality and safety is a benefit
 - A single terminology or interoperability between terminologies is the goal
 - Separate these terms from the rest of MedDRA (27th SOC is favored option)
 - Terms need to be unambiguous at all levels
 - Focus on defects and processes, less on human factors



Question 2

Recommendations: Specific Topics (cont)

- Additional device-related terms
 - Task the MSSO to coordinate with other stakeholders on device-related projects to harmonize multiple device reporting requirements and terminologies
 - Terms need to be unambiguous at all levels
 - Consider human use factor terms to identify root causes and systems/process errors, not individual human errors



Question 2

Recommendations: Specific Topics (cont)

- Drug utilization terms
 - Identify use cases to learn how terms are used
 - Low priority
- Labeling qualifiers
 - Low priority. Identify use cases to learn how terms are used.
 - If added, the intended use should be clearly defined
 - The qualifier list should be a maintained list outside of MedDRA's current structure



Question 2

Recommendations: General Criteria

- New topics/areas to be developed based on collaborative efforts involving relevant experts
 - Working groups with industry and regulatory representatives
 - Coordination with ICH M1 Points to Consider Working Group
- Adequate lead times
- Addition of new topic areas to undergo usual MSSO change request process





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Question 3

What are the criteria for accepting terms that include human use factors or causality related concepts?





Question 3

Recommendations

- Focus on the event but not the individual at fault, e.g., Prescription error is an acceptable concept. Avoid “finger pointing”.
- Granularity of concepts should be at a general level, e.g., Instructions not followed. Don’t identify individual’s role.
- Terms to avoid from a liability perspective: “reckless use”



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Question 4

Where should new concepts/topics be placed in MedDRA?

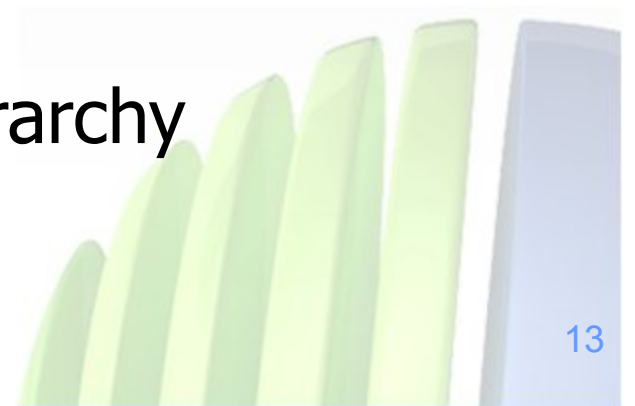
- For consideration:
 - Will depend on particular topic
 - Based on MedDRA principles
 - Availability of other terminologies
 - Best options/approaches for implementation
 - IT considerations
 - Impact on users' systems, processes, SOPs, coding and analysis conventions



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Question 4 (cont)

- Variety of possible options
 - Within existing MedDRA structure with 26 SOC's
 - A 27th SOC, e.g., for “Product related” topics such as product quality, device terms
 - 5 level hierarchy and multi-axial links
 - Maintained term lists, e.g., for labeling qualifiers
 - Separate from MedDRA hierarchy
 - Others





Question 4

Recommendations

- A 27th SOC is favored option for terms that are separate from patient safety and clinical information
- Proposed initial contents
 - New product manufacturing quality terms
 - Existing product quality terms (HLGT *Product quality issues*)
 - Existing device terms (HLGT *Device issues*)
 - Human use factors
- HLGT *Complications associated with device* to remain in General disorders SOC
- No change to HLGT *Medication errors*; to remain in Injury SOC



Question 4

Recommendations (cont)

- 27th SOC is to maintain the same 5-level hierarchy with multi-axial links as appropriate
- MSSO is to give an adequate lead time, e.g., 3 releases for users to implement
- MSSO is to form a working group with quality experts and safety experts from regulatory authorities and industry from ICH countries to conduct field testing of different hierarchy options for 27th SOC. Members to provide sample terms to MSSO for testing.