



MedDRA

Blue Ribbon Panel 8 – Scope of MedDRA

29 April 2014

Gaithersburg, Maryland, USA





MedDRA

Acknowledgments

The MSSO is grateful to



for providing the facilities for this
Blue Ribbon Panel meeting



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What is a Blue Ribbon Panel?

- Provides a forum for MedDRA experts to make recommendations on challenging MedDRA issues
- Panelists include experts from all ICH regions and parties
- Observers play an important role
- Panel produces recommendations for MedDRA Management Board consideration



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Panel Members

Mr. Barry Hammond (Terminologeze)

Dr. Norbert Paeschke (BfArM)

Dr. Stewart Geary (Eisai)

Mr. Daisuke Sato (PMDA)

Dr. Sonja Brajovic (FDA)

Ms. Lisa Lawrence-Miyasaki (Santen)





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Agenda

0900 – 0915 Welcome and Introduction
Patrick Revelle, Director, MSSO

0915 – 0945 Background

Judy Harrison, MD, Chief Medical Officer, MSSO

0945 – 1030 Scope of MedDRA as a medical
and regulatory terminology

Panel discussions and recommendations

Observer comments

[1030 – 1045 Break]





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Agenda (cont)

1045– 1115 Manufacturing product quality terms

1115 – 1145 Additional device-related terms

1145 – 1215 Drug utilization terms

Panel discussions and recommendations

Observer comments

[1215 – 1315 Lunch]





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Agenda (cont)

1315 – 1345 Labeling qualifiers

1345 – 1430 General criteria for expansion and causality-related concepts

1430 – 1515 Placement of new concepts/topics in MedDRA

Panel discussions and recommendations

Observer comments

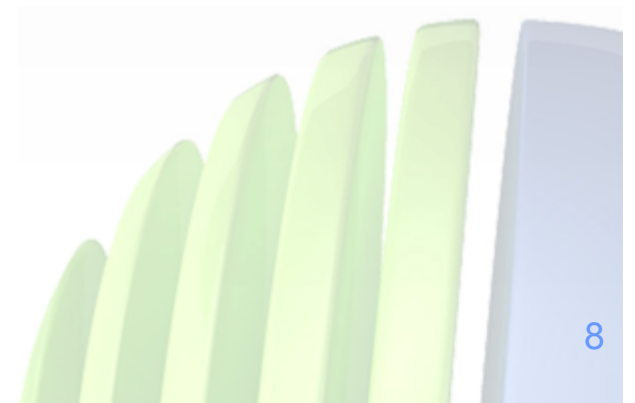
[1515-1530 Break]

1530 – 1600 Summary of Panel Recommendations.
Final comments by Observers.

1600 Meeting concludes



Background





BRP 1. Scope and Specificity of MedDRA

- May 2003 in Reston, Virginia
- Focus on specificity in *SOC Investigations*, then other SOCs
- Recommendations
 - Provided guidance on level of granularity
 - MedDRA can expand into new areas based on user input
- Outcomes
 - Recommendations endorsed by MB
 - Implemented by MSSO in MedDRA v7.0





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Need for a BRP

- Growing use by worldwide community has resulted in expansion of medically relevant terms, e.g., toxicology and pharmacogenetic terms
- More recently, MSSO has received requests that test the boundaries of MedDRA's scope
- Need to reexamine the scope of MedDRA as a global medical regulatory terminology and to provide a framework for its evolution





MedDRA

Scope of MedDRA

OUT
IN

Not a drug dictionary

Frequency qualifiers

Patient demographic terms

Medical conditions
Indications
Investigations (tests, results)
Medical and surgical procedures
Medical, social, family history
Medication errors
Product quality issues
Device-related issues
Pharmacogenetic terms
Toxicologic issues
Standardized queries

Numerical values for results

Clinical trial study design terms

Severity descriptors

Not an equipment, device, diagnostic product dictionary



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Questions for BRP

- BRP to discuss and provide recommendations to Management Board on:
 1. What should be the scope of MedDRA as a medical and regulatory terminology?
 2. What are the general criteria when considering new topic areas for expansion?
 3. What are the criteria for terms that include human use factors or causality related concepts?
 4. Where should new concepts/topics be placed in MedDRA?



Potential Topic Areas for Expansion

- New types of terms falling into “gray area” as defined by current scope
- Examples
 - Manufacturing product quality terms
 - Additional device-related terms
 - Drug utilization terms
 - Labeling qualifiers
- BRP to use examples to formulate general criteria for inclusion of new topics in future



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Placement of New Topics

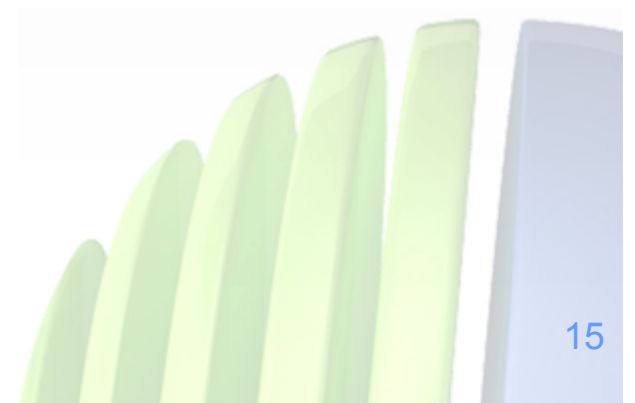
- Variety of possible options
 - Within existing MedDRA structure
 - A 27th SOC
 - Maintained term lists
 - Others





Panel Discussions and Recommendations

Observer Comments





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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?

- For consideration
 - Food, tobacco, cosmetics regulated in some regions
 - Increased direct patient reporting

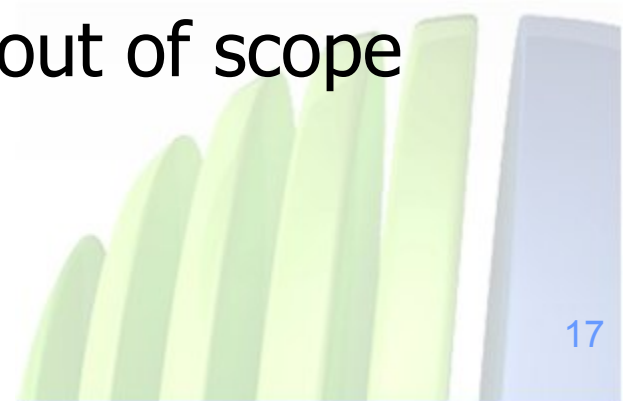


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Question 2

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

- For consideration:
 - Four potential topic areas as examples
 - What topics would be entirely out of scope





Manufacturing Product Quality Terms

- Terms relating to product manufacturing and quality control issues
 - Testing, out of specification, process control, shipping, and packaging
- Integration in MedDRA would enable single system to be used for adverse event and quality issues





Manufacturing Product Quality Terms (cont)

Term Example		
Existing MedDRA Term	Possible future terms if scope of MedDRA is expanded	Not suggested for scope expansion at the moment
PT Product raw material issue	a) Process controls incorrect temperature issue b) Testing stability performed incorrectly	HEPA filter

- a) Refers to manufacturing process quality control. Not directly related to patient but may impact patient safety
- b) Example of "Performed incorrectly" concept

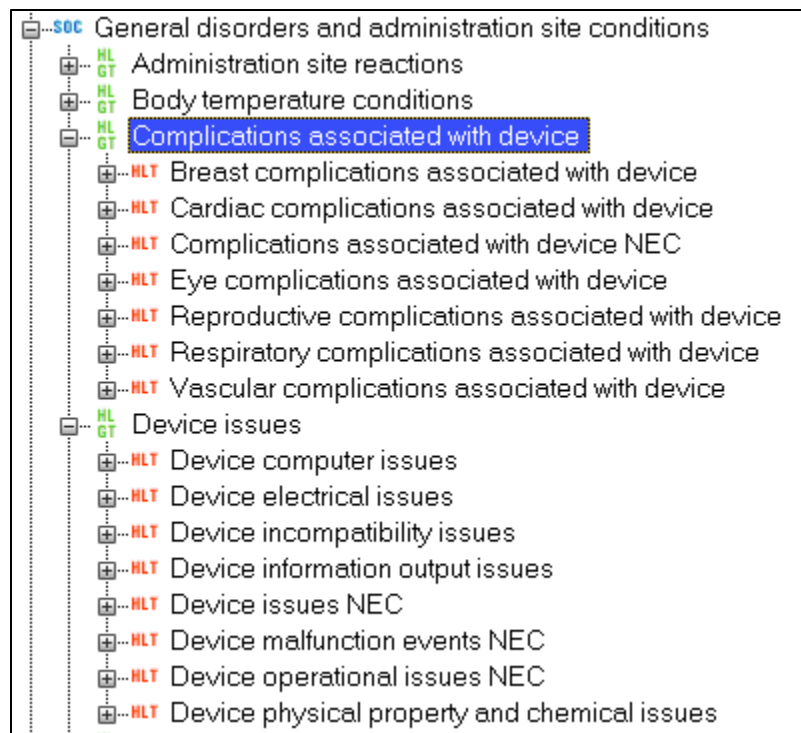
Out of scope: Equipment terminology



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Device-Related Terms

- Device related terms always part of MedDRA (~160 in v2.1)
- Expansion with improved hierarchical groupings in v13.0
- No current regulatory mandate for MedDRA in device reporting but widely used by companies in internal databases





Device-Related Terms (cont)

Term Example		
Existing MedDRA Term	Possible future terms if scope of MedDRA is expanded	Not suggested for scope expansion at the moment
PT Wrong device used	a) No check of device prior to use b) Reckless use	Femoral component

- a) Example of "Negative" or "Not done" concept
- b) "Human use/causality" term with potential legal implications

Out of scope: Device terminology



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Drug Utilization Terms

- Terms for issues such as stopping or changing medication and the reasons (compliance, adverse events, patient decision)
- Important concepts for EU Risk Management Plans, phase IV studies, pharmacoeconomic analyses





Drug Utilization Terms (cont)

Term Example		
Existing MedDRA Term	Possible future terms if scope of MedDRA is expanded	Not suggested for scope expansion at the moment
PT Refusal of treatment by patient	Drug withdrawn from market	Drug could not be prescribed on NHS

- Possible future term: “Product availability” concept
- Out of scope: Product availability concept specific to one particular country



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Labeling Qualifiers

- Review conducted on applicability of MedDRA for coding indications
- Many indications concepts already in MedDRA
 - Disease, symptoms, treatment, prophylaxis, etc.
- Other concepts not represented
 - Age groups, response to therapies, low vs. high risk, disease stage, first-, second-, third-line treatment, etc.
- Adding qualifier and attribute concepts would facilitate use of MedDRA in coding relevant indications information in labeling



Labeling Qualifiers (cont)

Term Example		
Existing MedDRA Term	Possible future terms if scope of MedDRA is expanded	Not suggested for scope expansion at the moment
PT Convulsion prophylaxis	Failed first-line treatment	15-17 years

- Possible future term: "Response to previous therapy" concept
- Out of scope: Numerical values



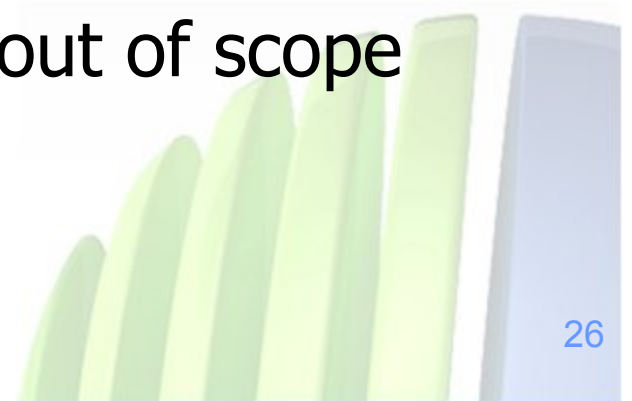


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Question 2

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

- For consideration:
 - Four potential topic areas as examples
 - What topics would be entirely out of scope





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Question 3

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

- For consideration:
 - Should liability issues be considered as an acceptance criterion?





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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





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Medical Dictionary
for Regulatory Activities

Thank you

