

“Innovative Uses of MedDRA”

Use of MedDRA beyond Coding and Signal Detection



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Agenda

- MedDRA Groupings
 - What they are
 - What they can be used for
- Examples
 - Coding Quality Review
 - Quality Checks
 - Autolistedness
 - Custom Important Medical Events
 - Reporting Rules
- How to create MedDRA Groupings
- How to maintain MedDRA Groupings
- Summary



MedDRA Groupings - What they are:

- Documented purposeful Assembly of MedDRA Terms
 - Provided Groups
 - Standardised MedDRA Query (SMQ)
 - MedDRA hierarchical Group (Higher Level Term (HLT) , ...)
 - Unqualified Test Name Term List
 - Important Medical Events List (IME - eudravigilance)
 - Custom Groups
 - Modified SMQs (Additions / Deletions / Combinations),
 - Modified MedDRA hierarchical Groups (Additions / Deletions / Combinations)
 - Groups of Preferred Terms (PTs) / Lowest Level Terms (LLTs)

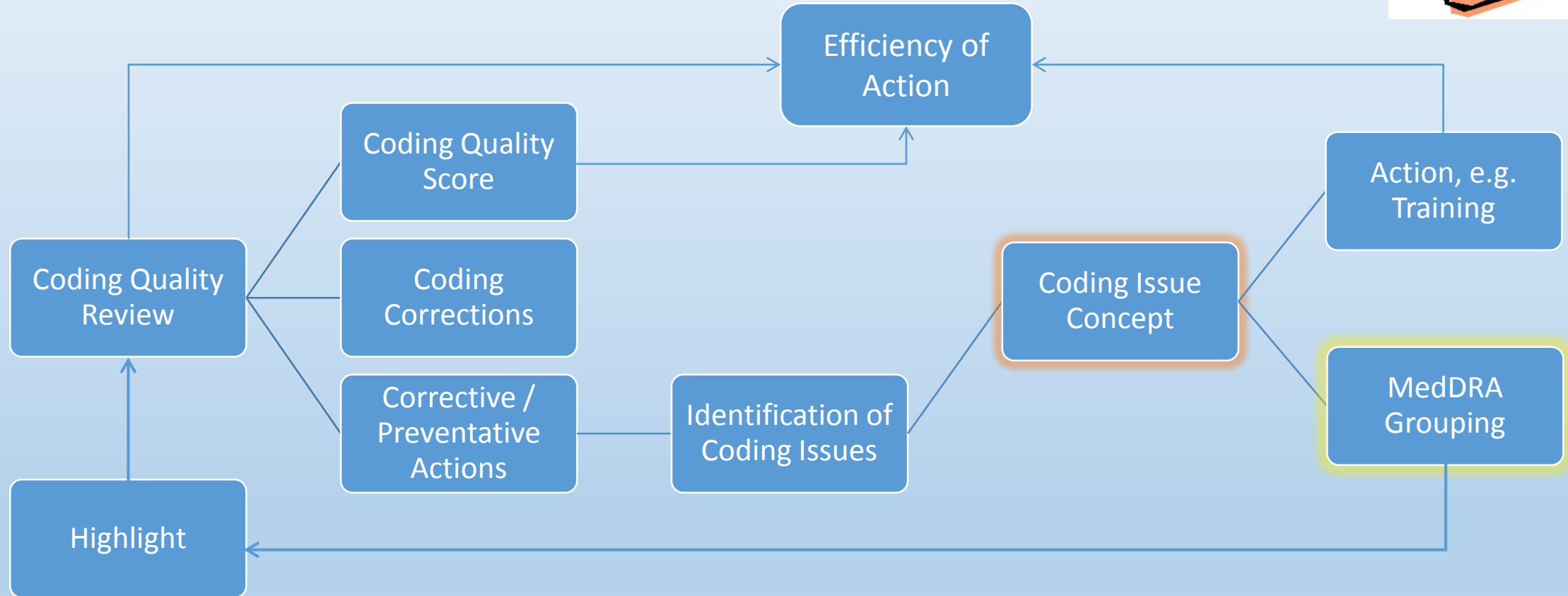


MedDRA Groupings - What they can be used for:

- Signal Detection (out of Scope)
- Quality Checks / Support
 - Assessment – Listedness / Seriousness
 - Coding Quality
 - Data Entry – MedDRA Data corresponds to other Data Elements
- Reporting Rules

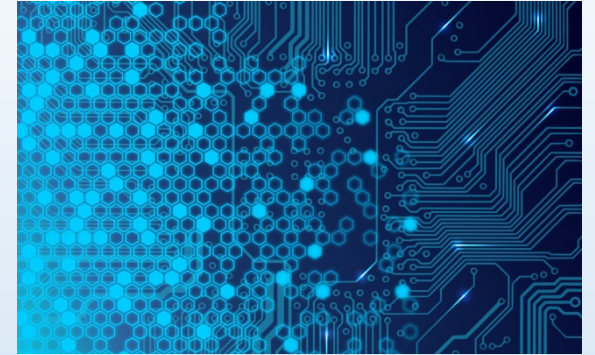


Coding Quality Review (1)



Coding Quality Review (2)

“Simple High-tech”



- Review on Excel Listings
- Macro highlighting defined Scenarios via “conditional formatting”
- All Levels of MedDRA Hierarchy available
- SMQs or other long Lists can be included as external Look-up
- Short Lists of PTs can be included separated by Semicolon
- Issues are weighted – highest Weight displayed, additional Column shows complete Issue Hit-list

Coding Quality Review (3)

Highlight	Ranking	Category	Value	Note
PT	6	Oxygen	Oxygen consumption; Oxygen consumption decreased; Oxygen consumption increased	Note: DD Dyspnoe / Oxygen saturation decreased
PT	5	Extrapyramidal	Extrapyramidal disorder	Note: Autocode issue
HLT	3	Application site reactions	Application and instillation site reactions	Note: Application vs Administration site reactions
SOC	4	Procedures	Surgical and medical procedures	Note: No true AE / Check coding of Condition / Splitting
SMQ	2	SMQ		Note: Medication errors - check all in source
PT	8	Malaise	Malaise	Note: Feeling sick vs Being sick
PT	7	Erythrocyte anti-bodies	Anti-erythrocyte antibody positive; Anti-erythrocyte antibody; Anti-erythrocyte antibody negative	Note: specific bloodgroup reported?
HLT	9	Interactions	Interactions	Note: Check precision
SOC	10	Product issues	Product issues	Note: Monitor for possible difficulties
LLT	11	Autocode issue	Recurrent respiratory tract infections	Note: Autocode issue
HLT	14	Unspecific codes	General signs and symptoms NEC	Note: Unspecific AE Codes (e.g. Condition aggravated)
SOC	12	Investigations	Investigations	Note: Investigation or Condition reported?
LAB TERMS	1	LAB		Note: LabTestName, not to be used for Coding.
PT	13	Malabsorption	Malabsorption	Note: Autocode issue

Quality Checks

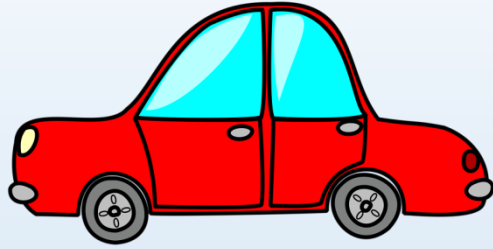


- **Quality Check:** Function in an Adverse Event Database to assist Data Entry by recognising erroneous Entries and alerting User accordingly.

- **Example:**

Unqualified Test Name Terms are supposed to be used for Database List Maintenance but not for active Coding Purposes

> May also be used for other important Coding Quality Issues.



Autolistedness

- Autolistedness: Set of Terms set up in Adverse Event Database to assist Listedness Assessment / Data Entry
- Transition of Terms from Reference Safety Information to MedDRA Term Lists need to follow the Rules of Listedness Assessment.
- Any Conditionality cannot be easily programmed into the System
- Maintenance including MedDRA Re-versioning may become a Challenge

Custom Important Medical Event List



- Important Medical Event (IME) List:
 - Within eudravigilance a set of Terms is maintained that should be considered when assessing Events for Seriousness.
- This List can be set-up in the Data Base as a Quality Check to assist Seriousness Assessment of Adverse Events.
- Due to Company / Product specifics it may be an Option to expand on this List or use a Company specific List.
- Maintenance including MedDRA Re-versioning may become a Challenge

Reporting Rules



- Reporting Rule:
 - Algorithm within a Data Base identifying specific Cases to schedule a certain Report.
- Reporting to Authorities and other Vigilance Partners is not necessarily limited to the classical Triade of Seriousness / Relatedness / Listedness.
- A Partner may wish to receive Reports based on a Medical Condition. This can be put to a MedDRA Grouping and be used as (a component of) a Reporting Rule.
- Examples:
 - Reports of Lack of Effect in certain Countries.
 - Post-Approval Commitment for a new Product
- Maintenance including MedDRA Re-versioning may become a Challenge

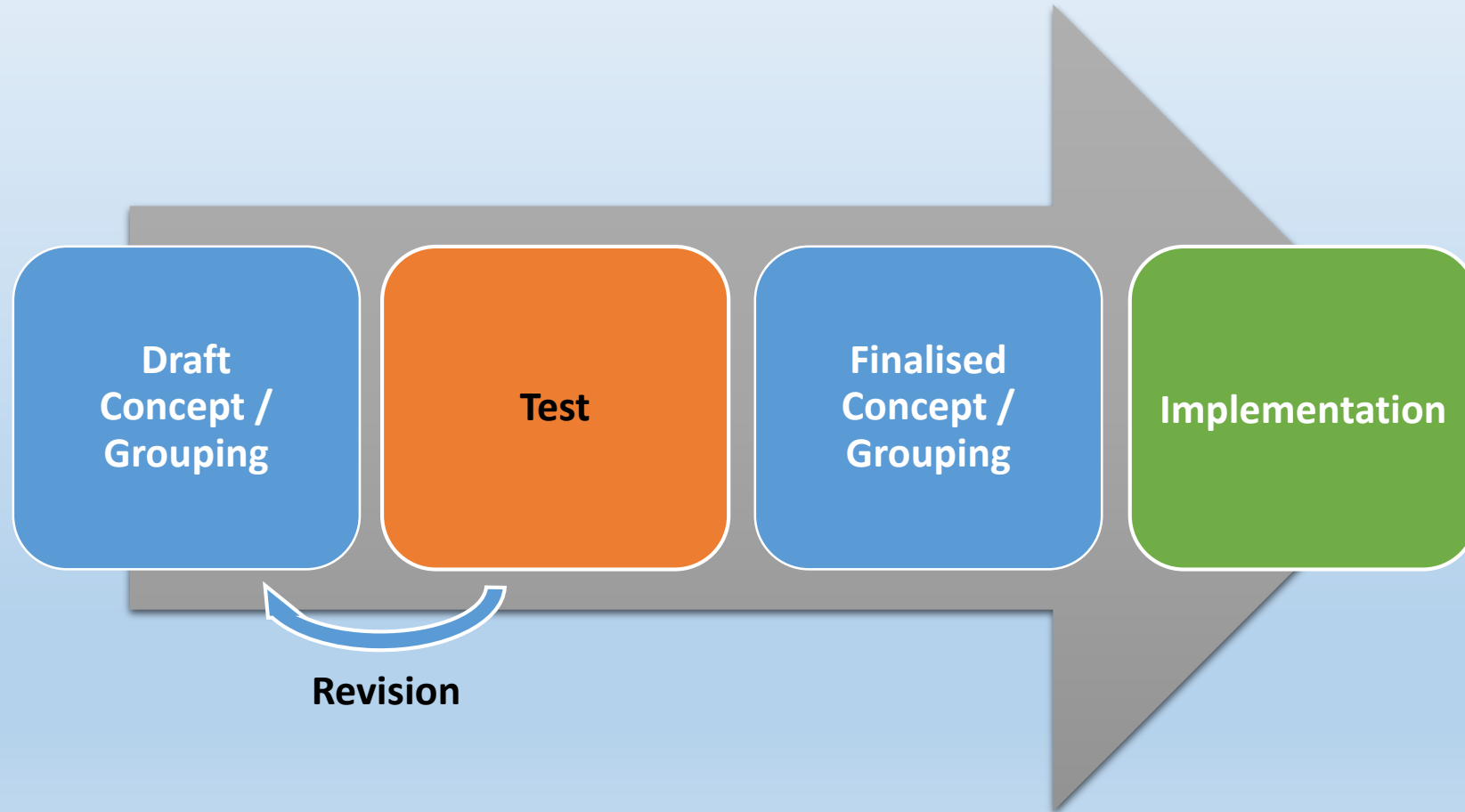
MedDRA Groupings – How to create: Documentation is Key!

- Purpose
- Medical Concept Definition
- (Signs and Symptoms)
- (Mono-axial SMQs)
- (Alternative reported Terms)
- MedDRA Term Search Strategy
- Inclusion / Exclusion Criteria
- (Detailed Term/Term Analysis)



- **MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER**

MedDRA Groupings – How to create:



MedDRA Groupings – Medical Concept Sheet:

CSL		
019-Infusion-site-reactions¶ Medical-Concept-Sheet¶		
Form¶	Date:-10-Aug-2016¶	Version:¶1.0¶
Step¶	Descriptions¶	Comments¶
Purpose-definition¶	Local reactions at infusion/injection sites are a known risk of subcutaneous immunoglobulins and theoretically may be a potential risk for all medications administered via infusion/injection.¶	Why do you need a MedDRA-Set of Terms?¶
Medical-condition-definition¶	Localised reaction at the site of the infusion/injection.¶	Describe the medical condition.¶
Case-description¶	See: Medical condition definition.¶	If applicable provide a case description.¶
Diagnosis¶	"Infusion site reaction" or "Injection site reaction"¶	Narrow scope terms: Provide the names of diagnoses covering the condition of interest, include synonyms and subtypes.¶
Signs-and-Symptoms¶	Not included as respective signs seen are in principle very unspecific and are usually not specified as a localised reaction (e.g. Rash vs. Infusion site rash).¶	Broad scope terms: Provide the signs and symptoms of the condition—provide information on how specific the symptom is concerning the condition of interest.¶
Investigations¶	none¶	Broad scope terms: Provide what lab-values /vital-parameters are found to be abnormal in the condition of interest. Please provide information on how (high vs. low) and specificity.¶
Procedures¶	none¶	Broad scope terms: Provide the procedures typically performed in conjunction with the condition of interest.¶

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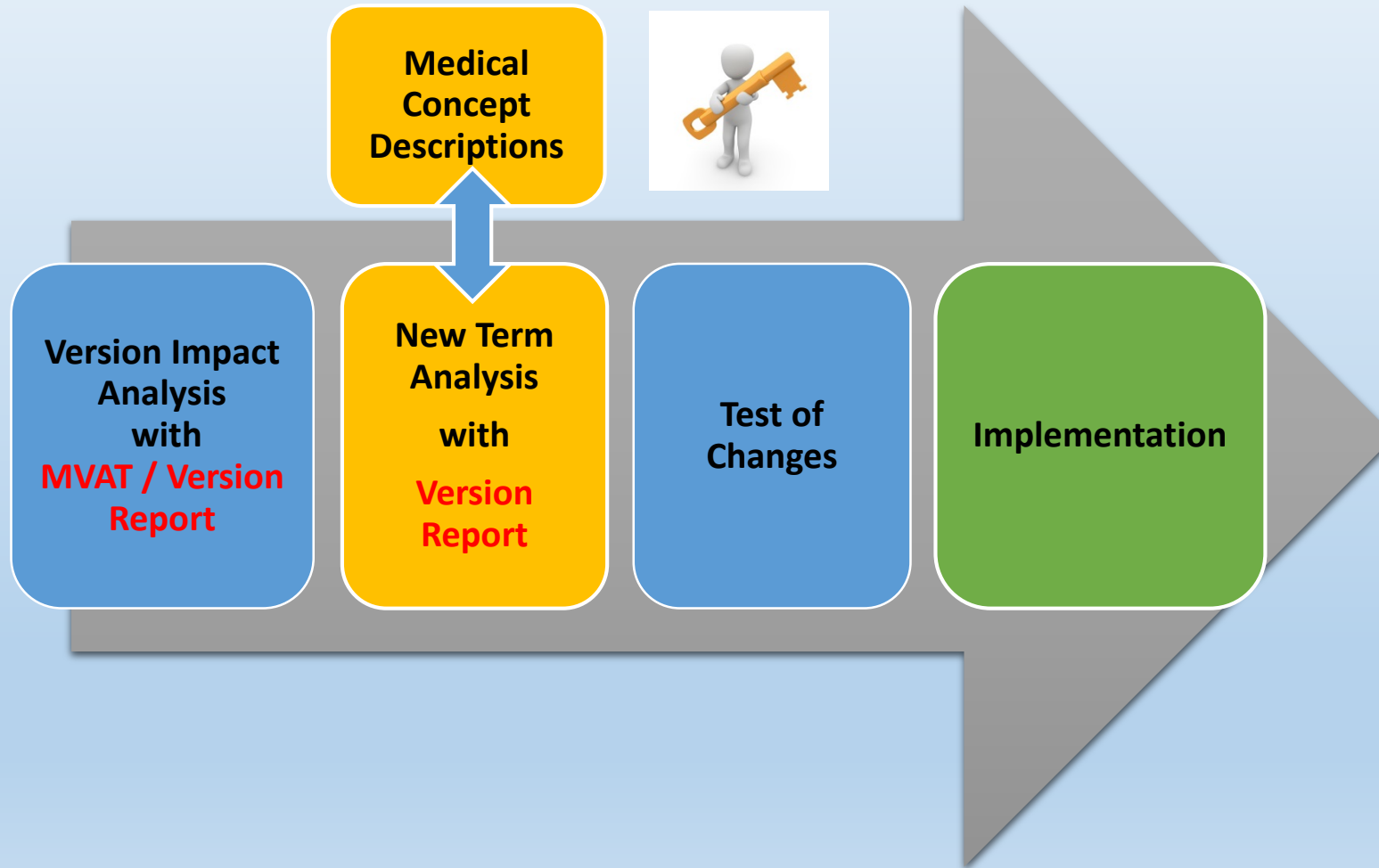
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CSL		
019-Infusion-site-reactions¶ Medical-Concept-Sheet¶		
Form¶	Date:-10-Aug-2016¶	Version:¶1.0¶
Step¶	Descriptions¶	Comments¶
Social-circumstances¶	none¶	Broad scope terms: Provide the Social-circumstances typically associated with the condition of interest.¶
Differential-Diagnosis-/Inclusion¶	none¶	Broad scope terms: Please describe which similar medical conditions you want to be included (providational).¶
Differential-Diagnosis-/Exclusion¶	none¶	Exclusions:¶ Please describe what other similar medical conditions you want to be excluded (providational).¶
References¶	n.a.¶	Provide references (e.g. Disease monographs).¶
Step¶	Descriptions¶	Comments¶
MedDRA-Search-Descriptions¶	Administration site reactions (HLGT) referring to reactions relevant to specific types of administration including infusion, injection, catheter, or an unspecified local administration.¶	Describe search approaches used to identify relevant Terms or Groupings.¶
MedDRA-Inclusion¶	Administration site reactions NEC (HLT)¶ Implant and catheter site reactions (HLT)¶ Infusion site reactions (HLT)¶ Injection site reactions (HLT)¶	Provide reasoning for inclusion of Terms / Groupings.¶
MedDRA-Exclusion¶	Administration site reactions referring to a topic application (Application and installation site reactions HLT) or to vaccines (Vaccination site reactions HLT)¶	Provide reasoning for exclusion of Terms / Groupings.¶
¶		
References¶		
Doc ID¶	Title	
SAF_WIN_018¶	How to Transfer a Medical Concept into MedDRA Terminology for Safety Risk Management Evaluations¶	

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MedDRA Groupings – How to maintain: Medical Concept Descriptions are Key!



Summary



- MedDRA can be used beyond Coding and Signal Detection to increase Quality and support Operations in Drug Safety and Pharmacovigilance in a Number of Ways
- Key Element is a stringent Medical Concept Management and Good Documentation
- Simple Low-tech Solutions may be easy at Hand
- Dependent on Volume Documentation and Re-versioning may become challenging, though



