

# Example for use of SMQs at BfArM

How to link hierarchical SMQs to the Database

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## Experience so far

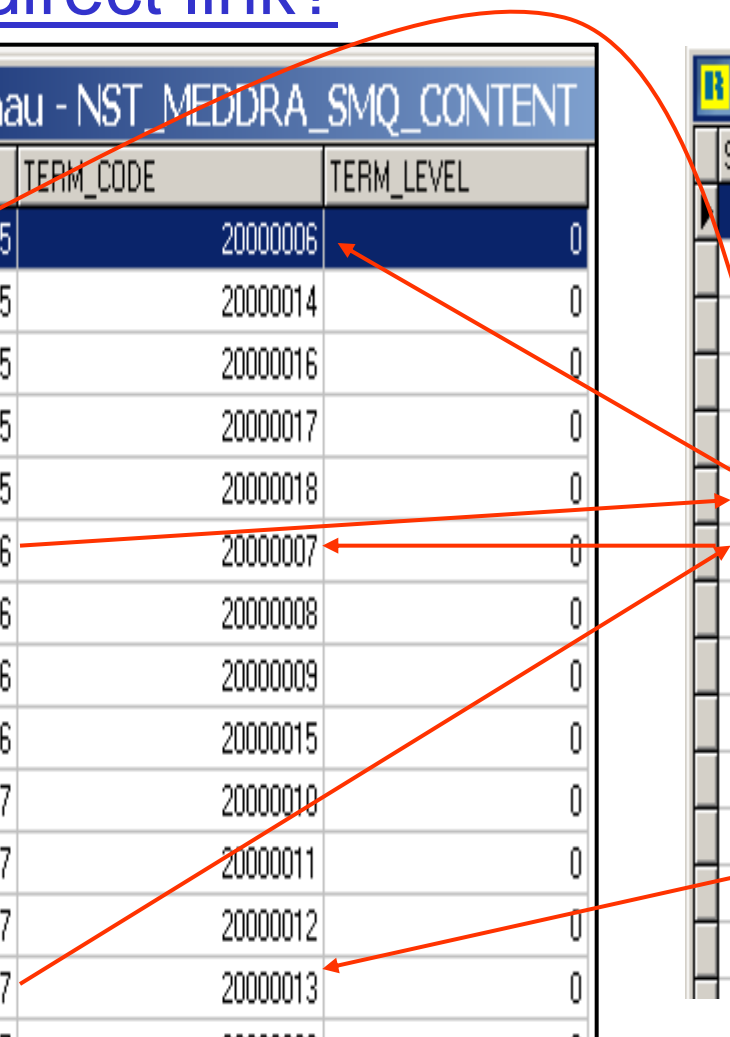
- Pharmacovigilance inspections
  - Task for inspected companies for database query and presentation
  - Date retrieval using SMQs
  - Data presentation according to SMQ structure
    - hierarchical SMQs preferred
  - Results (most) often disappointing:
    - explanation that SMQs not supported by the database
      - awareness is there
    - Or respective terms are retrieved
      - but presented alphabetically or according to SOC-structure
  - Requirement in Volume 9a to make use of SMQs in data analysis
  - Similar problems at BfArM
    - SMQs used for routine data base queries, preparation of answers to specific questions from the general public („Freedom of Information Act“)
    - SMQ with hierarchical structure cannot be linked directly to cases (LLT-codes) in a database due to file structure

# Why no direct link?

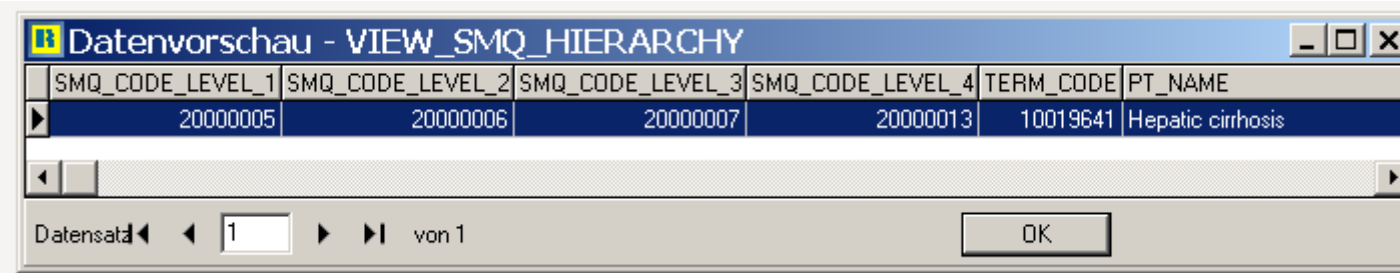
Datenvorschau - NST_MEDDRA_SMQ_CONTENT			
SMQ_CODE	TERM_CODE	TERM_LEVEL	
20000005	20000006	0	
20000005	20000014	0	
20000005	20000016	0	
20000005	20000017	0	
20000005	20000018	0	
20000006	20000007	0	
20000006	20000008	0	
20000006	20000009	0	
20000006	20000015	0	
20000007	20000010	0	
20000007	20000011	0	
20000007	20000012	0	
20000007	20000013	0	
20000027	20000028	0	
20000027	20000029	0	

Datenvorschau - NST_MEDDRA_SMQ		
SMQ_CODE	SMQ_LEVEL	SMQ_NAME
20000001	1	Torsade de pointes/QT prolongation (
20000002	1	Rhabdomyolysis/myopathy (SMQ)
20000003	1	Acute renal failure (SMQ)
20000004	1	Cardiac failure (SMQ)
20000005	1	Hepatic disorders (SMQ)
20000006	2	Drug related hepatic disorders - compr
20000007	3	Drug related hepatic disorders - severe
20000008	3	Liver related investigations, signs and
20000009	3	Cholestasis and jaundice of hepatic or
20000010	4	Hepatitis, non-infectious (SMQ)
20000011	4	Liver neoplasms, malignant and unspe
20000012	4	Liver neoplasms, benign (incl cysts an
20000013	4	Hepatic failure, fibrosis and cirrhosis ar
20000014	2	Congenital, familial, neonatal and gene


Datenvorschau - NST_MEDDRA_SMQ_C			
SMQ_CODE	TERM_CODE	TERM_LEVEL	PT_NAME
20000013	10019641	4	Hepatic cirrhosis



## Solution at BfArM



SMQ_CODE_LEVEL_1	SMQ_CODE_LEVEL_2	SMQ_CODE_LEVEL_3	SMQ_CODE_LEVEL_4	TERM_CODE	PT_NAME
20000005	20000006	20000007	20000013	10019641	Hepatic cirrhosis

- Hierarchical structure in one dataset
  - Similar to the MDhierarchy-file for SOCs
- Now easy to link to e.g. reaction section in E2B
- Hierarchy-levels not used are left empty
  - report generators may skip printout of empty sections
- example 

Thank you  
for your attention!

Questions?

# Spreadsheet of ADRs according to MedDRA-SMQ-Hierarchy

search criteria:



## SMQ: Hepatic disorders (SMQ)

**Description:** Disorders of the liver, including signs, symptoms, radiologic and laboratory findings. Sub-searches address cholestatic conditions, neoplasms, non-infectious hepatitis, alcohol-associated, and pregnancy associated conditions involving the liver. Possible drug-related events are also addressed in the sub-searches. Note that biliary disorders (e.g., cholelithiasis) are excluded from this SMQ

Algorithm: N

SMQ	narrow/broad	GER	other EU	third countries/not stated	total
<b>Hepatic disorders (SMQ)</b>					
<b>Drug related hepatic disorders - comprehensive search (SMQ)</b>					
<b>Drug related hepatic disorders - severe events only (SMQ)</b>					
<b>Hepatitis, non-infectious (SMQ)</b>					
Hepatitis	narrow	4	0	7	11
Hepatitis acute	narrow	1	0	0	1
Hepatitis cholestatic	narrow	1	1	0	2
Hepatitis fulminant	narrow	0	1	2	3
Hepatitis toxic	narrow	1	1	2	4
<b>Liver neoplasms, benign (incl cysts and polyps) (SMQ)</b>					
Hepatic adenoma	narrow	0	0	5	5
<b>Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)</b>					
Acute hepatic failure	narrow	4	7	7	18
Ascites	narrow	3	1	1	5
Asterixis	narrow	2	0	4	6
Chronic hepatic failure	narrow	0	0	1	1
Coma hepatic	narrow	0	0	1	1
Hepatic encephalopathy	narrow	2	0	2	4
Hepatic failure	narrow	22	4	4	30
Hepatic lesion	narrow	0	0	1	1
Hepatic necrosis	narrow	5	1	0	6
Hepatic steatosis	narrow	0	2	0	2

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<b>Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)</b>					
Hepatitis fulminant	narrow	0	1	2	3
Hepatocellular injury	narrow	6	0	3	9
Hepatotoxicity	narrow	5	7	10	22
Liver disorder	narrow	33	2	2	37
Liver injury	narrow	7	1	4	12
Liver transplant	narrow	2	0	2	4
Reye's syndrome	narrow	0	0	2	2
<b>Liver related investigations, signs and symptoms (SMQ)</b>					
Alanine aminotransferase increased	narrow	17	3	4	24
Ammonia increased	narrow	15	1	10	26
Ascites	narrow	3	1	1	5
Aspartate aminotransferase increased	narrow	22	1	4	27
Blood bilirubin increased	narrow	2	1	0	3
Foetor hepaticus	narrow	0	0	1	1
Gamma-glutamyltransferase increased	narrow	5	0	1	6
Hepatic enzyme abnormal	narrow	0	1	0	1
Hepatic enzyme increased	narrow	10	3	13	26
Hepatic function abnormal	narrow	1	3	8	12
Hepatic mass	narrow	0	0	1	1
Hepatomegaly	narrow	0	0	6	6
Hepatosplenomegaly	narrow	0	0	1	1
Hyperammonaemia	narrow	44	7	59	110
Hyperbilirubinaemia	narrow	1	0	1	2
Liver function test abnormal	narrow	3	5	6	14
Transaminases increased	narrow	6	4	4	14
Blood alkaline phosphatase abnormal	broad	0	0	1	1
Blood alkaline phosphatase increased	broad	4	0	1	5

SMQ	narrow/broad	GER	other EU	third countries/not stated	total
<b>Hepatic disorders (SMQ)</b>					
<b>Drug related hepatic disorders - comprehensive search (SMQ)</b>					
<b>Liver related investigations, signs and symptoms (SMQ)</b>					
Hypoalbuminaemia	broad	0	0	3	3
<b>Cholestasis and jaundice of hepatic origin (SMQ)</b>					
Cholestasis	narrow	1	0	3	4
Hepatitis cholestatic	narrow	1	1	0	2
Hyperbilirubinaemia	narrow	1	0	1	2
Jaundice	narrow	2	2	4	8
Ocular icterus	narrow	0	0	1	1
<b>Liver-related coagulation and bleeding disturbances (SMQ)</b>					
Blood fibrinogen decreased	narrow	2	0	0	2
Coagulation factor decreased	narrow	4	0	0	4
Coagulation factor VII level decreased	narrow	1	0	0	1
Coagulation factor X level decreased	narrow	1	0	0	1
International normalised ratio increased	narrow	0	0	2	2
Prothrombin level decreased	narrow	1	0	0	1
Prothrombin time prolonged	narrow	2	0	2	4
<b>Congenital, familial, neonatal and genetic disorders of the liver (SMQ)</b>					
Jaundice neonatal	broad	2	0	0	2
<b>Liver infections (SMQ)</b>					
Hepatitis A	narrow	2	0	1	3
Hepatitis B	narrow	0	0	1	1
Liver abscess	narrow	1	0	0	1

number of case-reports from Germany: 440, other EU-countries: 383, third countries: 881, not stated: 68, total: 1772

total no. of cases with terms from this SMQ: 336, no. of cases with narrow terms: 333