



Welcome and MSSO Update

Anna Zhao-Wong, MD, PhD
 Chinese MedDRA User Group Meeting
 Beijing, China
 16 April 2018



Meeting Agenda

Time	Topic	Speaker
09:00 – 09:45	Welcome and MSSO Update	Anna Zhao-Wong (MSSO)
09:45 – 10:00	ICH工作办公室的角色、实施MedDRA计划	周思源 ICH工作办公室主任
10:00 – 10:40	ICH药物警戒相关二级指导原则及其对CDE的影响及对未来的展望	王涛 药审中心化药临床二部部长
10:40 – 10:50	Break	
10:50 – 11:10	ICH药物警戒相关二级指导原则及其对CDR的影响及对未来的展望	董铎 评价中心化学和生物药品部部长
11:10 – 11:20	药品上市后监测中E2B实施规划	侯永芳 评价中心办公室副主任
11:20 – 11:30	中国实施M1面临的问题挑战	田春华 评价中心基本药物部部长
11:30 – 12:00	问答环节	所有讲者
12:00 – 13:00	Lunch	

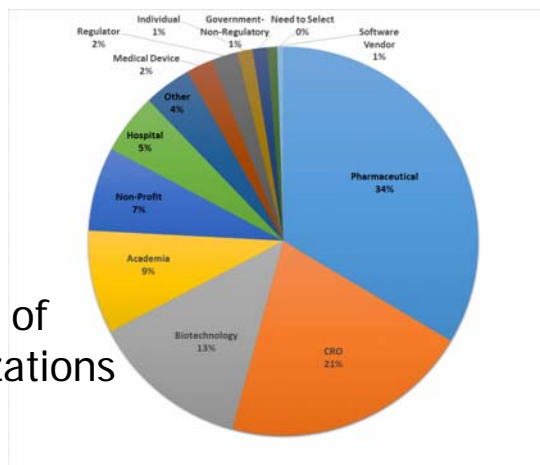


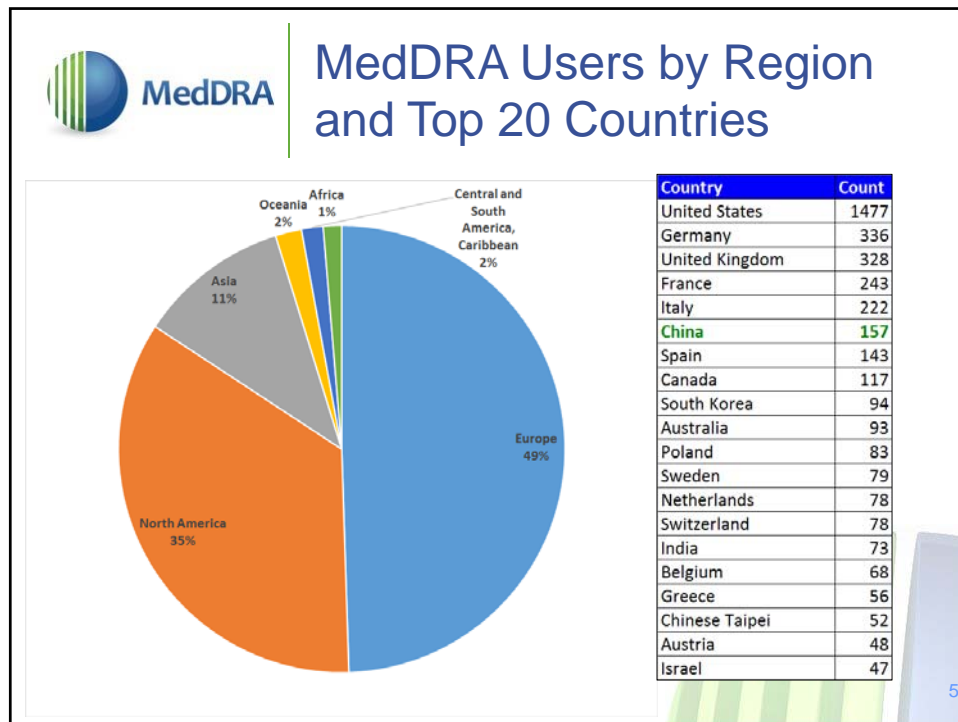
MedDRA Subscriber Profile and Subscription Rate Reduction in 2018



MedDRA Users Profile


- As of March 2018
 - 5,200 Subscribing organizations (MSSO+JMO)
 - 120 Countries
- Graph shows types of subscribing organizations





2018 MedDRA Subscription Rates


- Commercial 0-2 subscription rates reduced (5%) in 2018
- Reduction is a reflection of the continued success of MedDRA as a global standard in public health
- Costs of maintaining and developing MedDRA are distributed over a wider base
 - While still providing the same high standard of tools and services to MedDRA users
 - In fact, expanding services to include more translation and more software tools




2018 MedDRA Subscription Rate Table

MedDRA Subscription Types	2018 Annual Subscription Rates	Additional Rates for Japanese Translation
Regulatory Authority	\$0 USD	\$0 USD
Non-Commercial / Non-Profit	\$0 USD	\$850 USD
Commercial (Parent Company Annual Revenue or Turnover)		
Level 0 (Annual Revenue < \$1 Million)	\$162 USD	\$850 USD
Level 1 (Annual Revenue \$1-\$10 Million)	\$688 USD	\$850 USD
Level 2 (Annual Revenue \$10-\$20 Million)	\$2,627 USD	\$850 USD
Level 3 (Annual Revenue \$20-\$500 Million)	\$4,976 USD	\$850 USD
Level 4 (Annual Revenue \$500 Million-\$1 Billion)	\$10,440 USD	\$850 USD
Level 5 (Annual Revenue \$1-\$5 Billion)	\$43,316 USD	\$850 USD
Level 6 (Annual Revenue \$5-\$20 Billion)	\$57,194 USD	\$850 USD
Level 7 (Annual Revenue > \$20 Billion)	\$74,620 USD	\$850 USD
System Developer	\$2,661 USD	\$850 USD

76% of all MedDRA users pay no fee or \$688 (or less)




Patient Friendly Term List





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Patient-Friendly Term List

- MSSO and partner organizations developed a “patient-friendly” term list
 - Sub-set of MedDRA Lowest Level Terms in English
 - Derived from adverse events reported by patients and consumers in several pharmacovigilance databases

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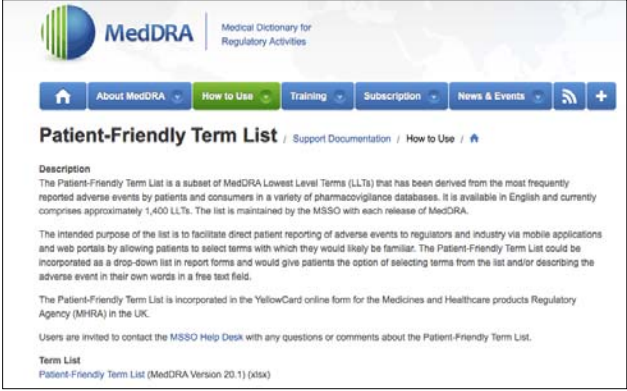
Use of Patient-Friendly Terms

- For adverse event reporting websites and mobile applications intended for patients and consumers
- Allows direct reporting using terms that are already in MedDRA
 - No need for additional coding into MedDRA
 - Immediately available for analysis
- List is used in YellowCard online form for the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK

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List Available for Download



- Link on Support Documentation page on MedDRA website
- Spreadsheet of LLT names and codes
 - 1,440 terms in v21.0
 - Maintained by MSSO with each MedDRA release

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List v21.0

1	LLT	LLT code
2	Abdomen enlarged	10000045
3	Abdominal bloating	10048746
4	Abdominal cramps	10000057
5	Abdominal crampy pains	10000058
6	Abdominal discomfort	10000059
7	Abdominal hernia	10060954
8	Abdominal infection	10056519
9	Abdominal mass	10000077
10	Abdominal pain	10000081
11	Abdominal tenderness	10000097

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Mapping Initiatives

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Mapping Initiatives

- Regulatory and industry users interested in getting access to more sources of data
- MSSO is part of a consortium of regulators, industry, and maintenance organizations
 - Funded by the Innovative Medicines Initiative (IMI)
 - Public-private partnership between the EU and EFPIA
 - IMI aims to boost biopharmaceutical innovation, speed up the development of better and safer medicines for patients

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 MedDRA | **IMI Partners**

 **MHRA**
Regulating Medicines and Medical Devices

 **Lareb**
Nederlands Bijwerkingen Centrum
Netherlands Pharmacovigilance Centre

 **m** agencia española de
medicamentos y
productos sanitarios

 **DANISH HEALTH
AUTHORITY**

 **NOVARTIS**
caring and curing

 **abbvie**

 **CSL Behring**

 **MedDRA**
Medical Dictionary
for Regulatory Activities

 **SNOMED
International**

 **WHO**

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 MedDRA | **Work Package Goals**

- **Work Package 3.1 Terminology Mapping and Maintenance**
 - Facilitate communication between regulatory and healthcare databases
 - Establish mapping protocols and distribution agreements
 - Delivering an initial mapping between a subset of key pharmacovigilance terms

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MSSO Goals for Mapping

- To be provided with MedDRA subscription at no additional charge
- Establish a process to propose additional terms to be mapped or changes to existing mappings
- Regular maintenance of the mappings

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MSSO Tool Update - WBB

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Supplemental files

- MSSO posts weekly interim changes to MedDRA
- Purpose:
 - Provide information on changes that will appear in the next MedDRA Version
- Posting includes:
 - Weekly changes
 - Comprehensive changes to date
 - A PDF file describing all changes considered
 - Sequential extended ASCII files that can be applied to non production environments

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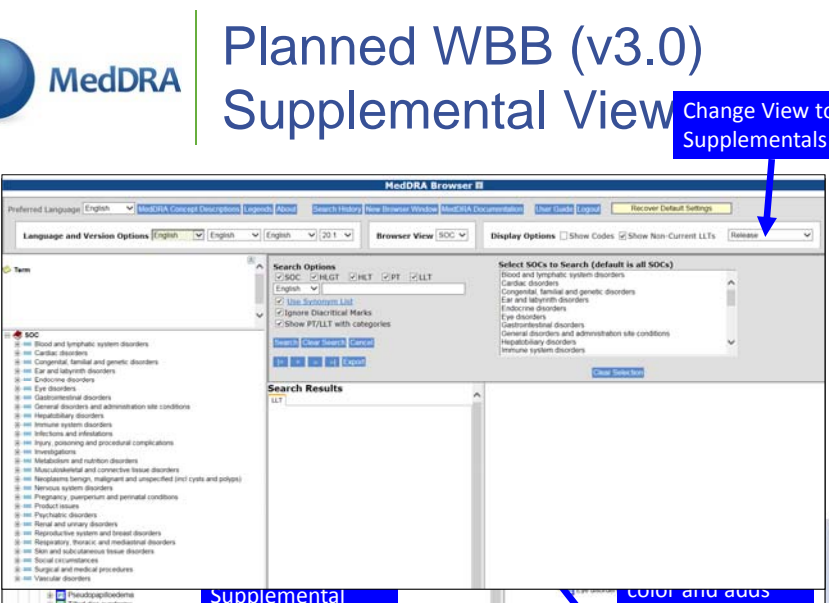
MedDRA

Supplemental files (cont)

MedDRA Version 20.0 Supplemental Changes / Downloads / [Home](#)

Comprehensive	PDF format	SEQ ASCII format	Date
Comprehensive changes for MedDRA 20.0			12 Aug 2016
Segmented	PDF format	SEQ ASCII format	Date
Supplemental changes for MedDRA 20.0			12 Aug 2016
Supplemental changes for MedDRA 20.0			5 Aug 2016
Supplemental changes for MedDRA 20.0			29 July 2016

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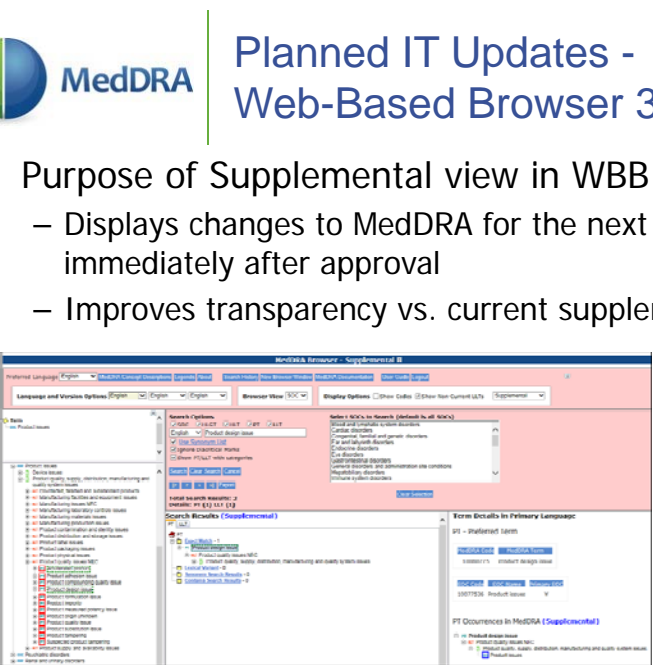
MedDRA | **Planned WBB (v3.0) Supplemental View**

Change View to Supplementals

Supplemental changes highlighted

Color and add labels for supplemental view

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MedDRA | **Planned IT Updates - Web-Based Browser 3.0**

- Purpose of Supplemental view in WBB 3.0:
 - Displays changes to MedDRA for the next release immediately after approval
 - Improves transparency vs. current supplemental posting

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MedDRA WBB 3.0 Boolean Search

Search Options
 SOC HLGHT HLT PT LLT
 English | back pain
 Use Synonym List
 Ignore Diacritical Marks
 Show PT/LLT with categories
 Search Clear Search Cancel Advanced Search
 Total Search Results: 15
 Details: PT (1) LLT (14)

Search Results
 PT | LLT
 LLT
 Exact Match - 1
 Back pain
 Lexical Variant - 1
 Pain back
 Synonym Search Results - 0
 Contains Search Results - 12
 Acute back pain
 Back pain (with radiation)
 Back pain (without radiation)
 Back pain aggravated
 Back pain psychogenic
 Chronic back pain
 Low back pain
 Low back pain (without radiation)
 Myofascial low back pain
 Other back pain with radiating symptoms
 Pain over the back
 Upper back pain

Basic – Logical “AND” search

Advanced – Boolean “AND”, “OR”, “NOT” search

Search Options
 SOC HLGHT HLT PT LLT
 English
 Use Synonym List
 Ignore Diacritical Marks
 contains liver NOT
 contains deliver AND
 contains
 Search Clear Search Cancel Basic Search
 Total Search Results: 1453
 Details: SOC (1) HLGHT (7) HLT (32) PT (351) LLT (1062)

Search Results
 SOC | HLGHT | HLT | PT | LLT
 LLT
 Abnormal liver function tests
 Abscess of liver
 Accessory liver lobe
 Acute alcoholic hepatitis
 Acute and subacute necrosis of liver
 Acute cholestatic hepatitis
 Acute cytolytic hepatitis
 Acute derangement of liver function
 Acute fatty liver
 Acute fatty liver of pregnancy
 Acute fulminant hepatitis
 Acute graft versus host disease in liver
 Acute hepatic congestion
 Acute hepatic failure

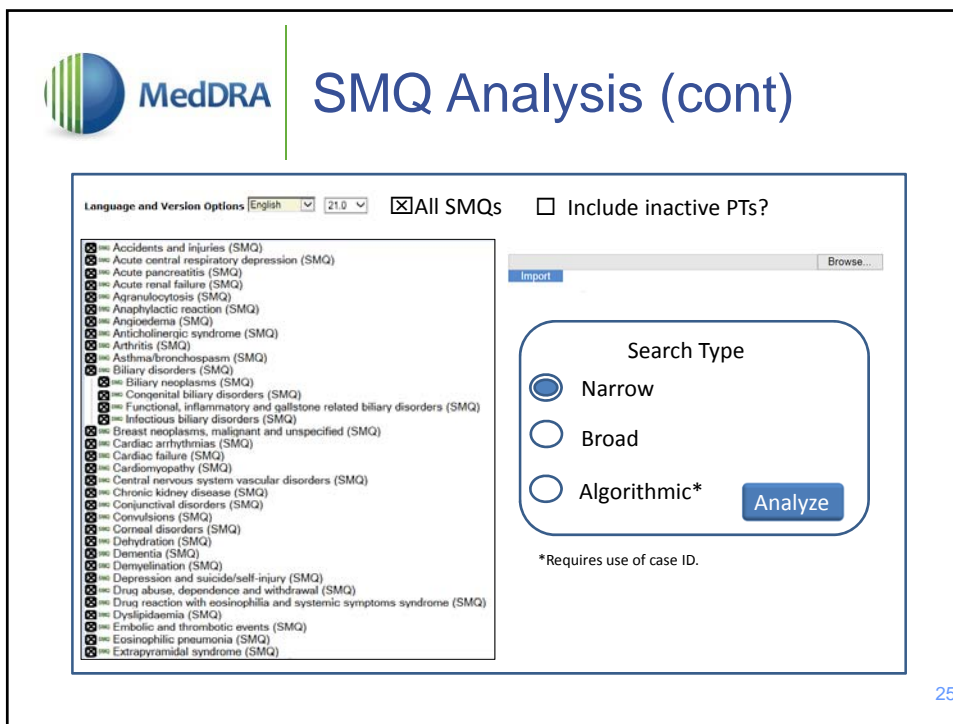
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MedDRA SMQ Analysis

- Purpose – assist MedDRA users in applying SMQs to their coded data
- Input:

Row ID	MedDRA Code	Term Name	Case ID
1	10051394	Allergic cystitis	A2346
2	10002240	Anaplastic thyroid cancer	A2347
3	10002456	Angioimmunoblastic T-cell lymphoma stage III	A2348
4	10077160	Central nervous system melanoma	A2345
5	10080355	Congenital nipple inversion	B4587
6	10010688	Conjoined twins	B4588
7	10076874	Dose calculation error	B4589
8	10052826	Erythroplasia of lip	B4590
9	10015816	Extragenital primary seminoma (pure) stage IV	B4591
10	10016862	Foetal malnutrition	B4592
11	10017865	Gastritis erosive	B4593
12	10020071	High grade B-cell lymphoma Burkitt-like lymphoma refractory	C2057

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MedDRA SMQ Analysis (cont)

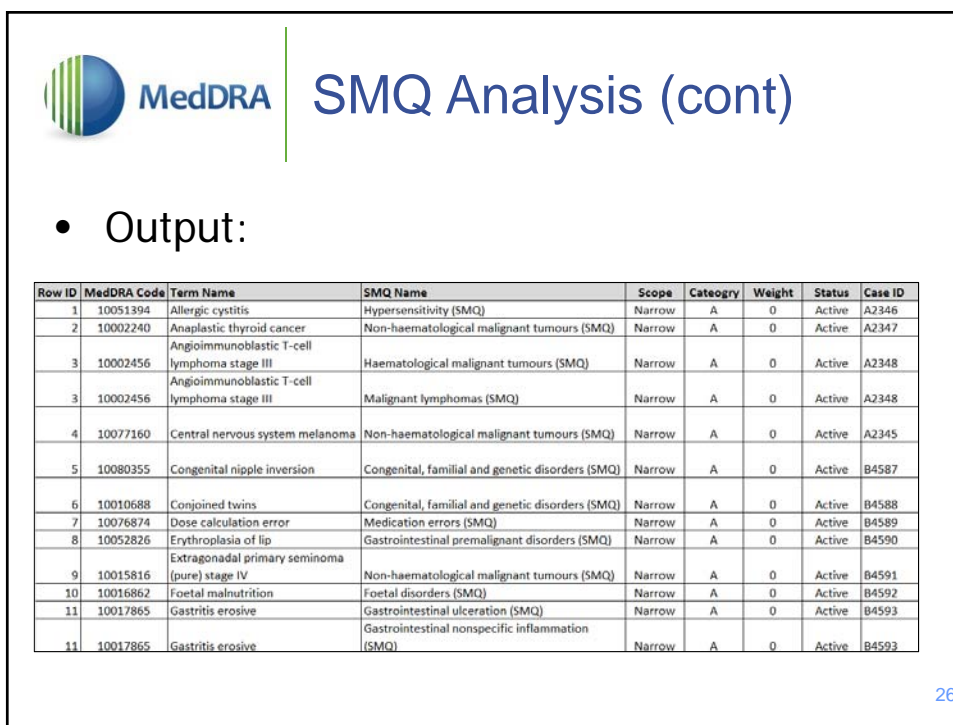
Language and Version Options: English | 21.0 | All SMQs | Include inactive PTs?

Accidents and injuries (SMQ)
 Acute central respiratory depression (SMQ)
 Acute pancreatitis (SMQ)
 Acute renal failure (SMQ)
 Agranulocytosis (SMQ)
 Anaphylactic reaction (SMQ)
 Angioedema (SMQ)
 Anticholinergic syndrome (SMQ)
 Arthritis (SMQ)
 Asthma/bronchospasm (SMQ)
 Biliary disorders (SMQ)
 Biliary neoplasms (SMQ)
 Congenital biliary disorders (SMQ)
 Functional, inflammatory and gallstone related biliary disorders (SMQ)
 Infectious biliary disorders (SMQ)
 Breast neoplasms, malignant and unspecified (SMQ)
 Cardiac arrhythmias (SMQ)
 Cardiac failure (SMQ)
 Cardiomyopathy (SMQ)
 Central nervous system vascular disorders (SMQ)
 Chronic kidney disease (SMQ)
 Conjunctival disorders (SMQ)
 Convulsions (SMQ)
 Corneal disorders (SMQ)
 Dehydration (SMQ)
 Dementia (SMQ)
 Demyelination (SMQ)
 Depression and suicide/self-injury (SMQ)
 Drug abuse, dependence and withdrawal (SMQ)
 Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)
 Dyslipidaemia (SMQ)
 Embolic and thrombotic events (SMQ)
 Eosinophilic pneumonia (SMQ)
 Extrapyrimal syndrome (SMQ)

Search Type: Narrow | Broad | Algorithmic* **Analyze**

*Requires use of case ID.

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MedDRA SMQ Analysis (cont)

- Output:

Row ID	MedDRA Code	Term Name	SMQ Name	Scope	Category	Weight	Status	Case ID
1	10051394	Allergic cystitis	Hypersensitivity (SMQ)	Narrow	A	0	Active	A2346
2	10002240	Anaplastic thyroid cancer	Non-haematological malignant tumours (SMQ)	Narrow	A	0	Active	A2347
3	10002456	Angioimmunoblastic T-cell lymphoma stage III	Haematological malignant tumours (SMQ)	Narrow	A	0	Active	A2348
3	10002456	Angioimmunoblastic T-cell lymphoma stage III	Malignant lymphomas (SMQ)	Narrow	A	0	Active	A2348
4	10077160	Central nervous system melanoma	Non-haematological malignant tumours (SMQ)	Narrow	A	0	Active	A2345
5	10080355	Congenital nipple inversion	Congenital, familial and genetic disorders (SMQ)	Narrow	A	0	Active	B4587
6	10010688	Conjoined twins	Congenital, familial and genetic disorders (SMQ)	Narrow	A	0	Active	B4588
7	10076874	Dose calculation error	Medication errors (SMQ)	Narrow	A	0	Active	B4589
8	10052826	Erythroplasia of lip	Gastrointestinal premalignant disorders (SMQ)	Narrow	A	0	Active	B4590
9	10015816	Extragenital primary seminoma (pure) stage IV	Non-haematological malignant tumours (SMQ)	Narrow	A	0	Active	B4591
10	10016862	Foetal malnutrition	Foetal disorders (SMQ)	Narrow	A	0	Active	B4592
11	10017865	Gastritis erosive	Gastrointestinal ulceration (SMQ)	Narrow	A	0	Active	B4593
11	10017865	Gastritis erosive	Gastrointestinal nonspecific inflammation (SMQ)	Narrow	A	0	Active	B4593

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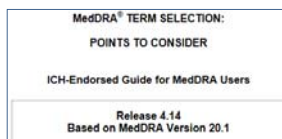


PTC Guidance Document Update

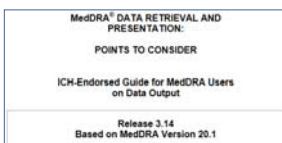


ICH MedDRA User Guides – PTC Documents (ICH考虑要点文档)

- PTC documents provide valuable guidance with Coding and analysis examples
- MedDRA Term Selection: Points to Consider (MedDRA术语选择: 考虑要点)



- MedDRA Data Retrieval and Presentation: Points to Consider (MedDRA数据检索和展示: 考虑要点)





Condensed (精要版) PTC Documents in Chinese

- Condensed (精要版) PTC documents contain all PTC principles with fewer examples
- Translated into all MedDRA languages
 - Except English and Japanese
- Will be available to users in late half of 2018



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Condensed (精要版) PTC Documents in Chinese

- Condensed (精要版) PTC documents were translated by MSSO translation vendor
- Reviewed by
 - Xiaoyi Dong, 董晓易 (Pfizer)
 - Wei Liu, 刘巍 (Pfizer)
 - Xiafang Chen, 陈夏芳 (Pfizer)
 - Joy Zhu, 朱丽琳 (IQVIA)
 - Siwei Ji, 季思伟 (Yidu Cloud Ltd.)
 - Pansie Zhang, 张芑 (Merck)
 - Anna Zhao-Wong (MSSO)
- MedDRA users provided valuable input based on their experience in MedDRA coding and analysis

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PTC Companion Document

- Companion document is intended to provide more information on specific topics
 - Detailed guidance
 - Examples
 - “Question and Answers”
- Focus on topics of global regulatory importance
- Intended as “living” document with frequent updates based on users’ needs

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PTC Companion Document (cont)

- Not tied to bi-annual PTC document releases
- Two topics in first edition
 - Data quality
 - Medication errors
- Planned for release in Q2 2018
- Available in English and Japanese

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Medical Dictionary
for Regulatory Activities

Thank You

Questions?

