

Bristol-Myers Squibb Co.

**Approach to
MedDRA Versioning**

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Driving Needs

- **Why**

- **Availability of meaningful data retrieval tools that leverage latest MedDRA terminology**

- **How**

- **Results oriented Data Management solution for timely, efficient, and reliable MedDRA upgrade process**

Business Needs

- **Retrieval of data using the latest release of MedDRA**
- **Ability to reproduce a Case that was previously reported**
- **Code at the LLT level**

Code at the LLT level

- **Linking to the lowest controlled level simplifies management of new releases of terminology**
- **Eliminates inconsistencies between MSSO LLTs and BMS Synonyms**
- **Support E2bM requirement for inclusion of LLT and PT**

Data Management Needs

- **Rapidly load new MedDRA release**
- **Manage changes to MedDRA at the dictionary level utilizing default approaches**
- **Minimize down time of “Mission Critical” corporate safety system**

BMS Case specifics

- Data retrieval tools revisited to use Hierarchy stored in Dictionary and not in Case data**
- Case data includes Verbatim term, Synonym code, complete MedDRA hierarchy , MedDRA version.**
- Primary tree is stored during Case validation**
- Latest release of MedDRA used for data entry and regulatory reporting**

BMS Dictionary specifics

- **Manage changes introduced by MedDRA with the introduction of a sixth level**
 - **Creation of a “new synonym” level below the LLT level**
 - **Golden rule - BMS synonyms will always be mapped to current LLT's**
- **MedDRA dictionary is not versioned or replaced, all codes are maintained by setting appropriately the “non current” flag to maintain older values for older Case versions**

Effect on data

- **Expedited Reporting**
 - » Latest MedDRA version
- **Aggregate (PSUR/USPR) Reporting**
 - » MedDRA version at time of data lock
 - » Effect on USPR index of 15-day reports
- **Data Retrieval**
 - » All legacy data retrieved using latest MedDRA version by mapping case synonyms to dictionary tree structure
- **Implication of MedDRA on Case versioning**
 - » Application changes made to enable previous versions of cases to be presented as they were coded

Types of changes affecting “loader”

- **Creation of LLT**

- Synonym created matching new LLT if none already exists

- **Retirement of LLT**

- Set to non-current in dictionary and synonym mapped to LLT that equals the PT of the disabled LLT

- **Promote LLT**

- Synonym - LLT mapping not affected since PT will always have an LLT that equals itself

Medical review should be performed

- **Verify default mappings and make adjustments if needed**
- **Review existing mappings for more appropriate mappings introduced by new version of terminology**
- **Tools can be used to facilitate review process**

Summary

- **When implementing new releases of MedDRA, legacy data needs to be mapped to new terminology to maintain consistency and facilitate data retrieval**
- **Organizations need to develop reasonable automated processes to implement new releases without disrupting day-to-day functionality**
- **Sound scientific oversight and review needed**

Q&A

