

Feasibility of Annual MedDRA Release

General

With each release of MedDRA, there are a series of actions taken by MedDRA users to implement the new version. The efforts involved in implementing MedDRA version updates vary by organization but can be significant for both medical and information technology resources. As a result, the question of the frequency of MedDRA releases is a topic for the Blue Ribbon Panel (BRP).

History and Current Process

Initially, MedDRA was released on a quarterly basis from March 1999 (MedDRA Version 2.1) until June 2001 (MedDRA v4.0) when the release frequency was changed to the current semiannual release (March 1 and September 1).

The number of implemented changes per MedDRA release (see Figure 2) has declined significantly since MedDRA v6.1. The average number of changes per MedDRA release from versions 7.0 through 12.0 is 1327. It should be understood that each release includes a combination of changes to existing terms (e.g., change of primary SOC assignment) and new terms added to MedDRA.

Between official releases of MedDRA, the MSSO receives change requests from MedDRA users. The approved change requests are published on the MSSO Web site as supplemental changes on a weekly basis. Supplemental terms include the MedDRA term, code, and hierarchy. All supplemental changes are guaranteed to be included in the next release of MedDRA.

Most organizations do not implement supplemental terms for a number of reasons:

- It is not clear what version number to associate with the term (i.e., it is not the current version and it is not the next version yet)
- Using a supplemental term in an electronic message may produce a rejection from the recipient (regulatory authority or industry partner) if they do not implement supplemental terms
- It is difficult to get the necessary resources available to review and implement small numbers of changes multiple times between official releases

Given the current approach to supplemental terms by most users of MedDRA, the longest wait for a MedDRA release to include an approved change request is 10 months (i.e., request received by the MSSO on day after the freeze date). In an annual release of MedDRA, that period could be extended to as much as 19 months (see Figure 1 below).

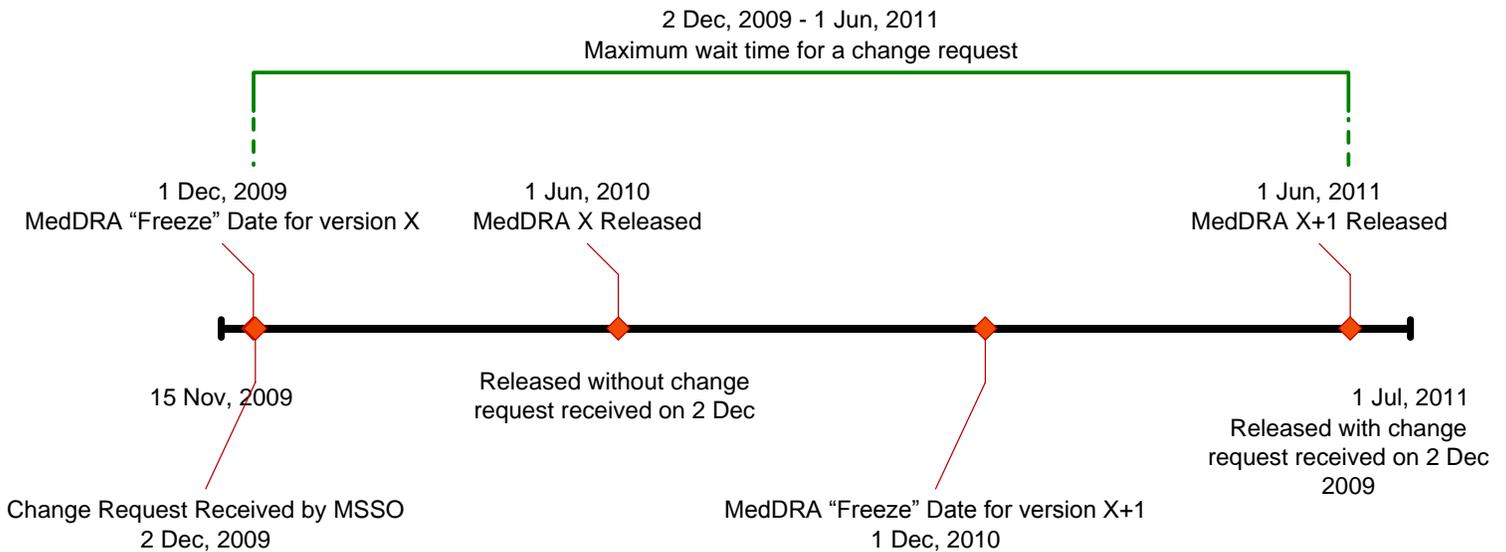


Figure 1 Maximum change request wait time for an annual release

In considering a single annual release of MedDRA, the dates associated with the release would be impacted. This includes:

- "Freeze date" (last date to submit changes for the next release)
- Release date for the English version
- Release date for the translations of MedDRA.

Currently, the MSSO and JMO have 4 months from the freeze date to the release of English and Japanese versions of MedDRA. The translations of MedDRA are released two weeks after the English and Japanese releases of MedDRA. These current timelines would likely be extended to handle all of the changes in a single release.

Questions to Panel

1. If MedDRA is released once a year, a MedDRA user will have to wait as much as 19 months before a change is officially released in MedDRA. Is that scenario acceptable?
2. If users cannot wait 19 months to implement new terms, can the MedDRA user community (industry and regulatory authorities) revise current practices to incorporate supplemental terms?
3. If a change is made to support supplemental terms, it will be necessary to define a version associated with supplemental changes? Could we simply use the next release number of MedDRA?
4. If a single annual release of MedDRA were recommended, what would be the most convenient release date in the calendar year?
5. If now is not the right time to go to an annual release, when should this question be revisited (i.e., if the number of changes in MedDRA falls below a certain threshold)?

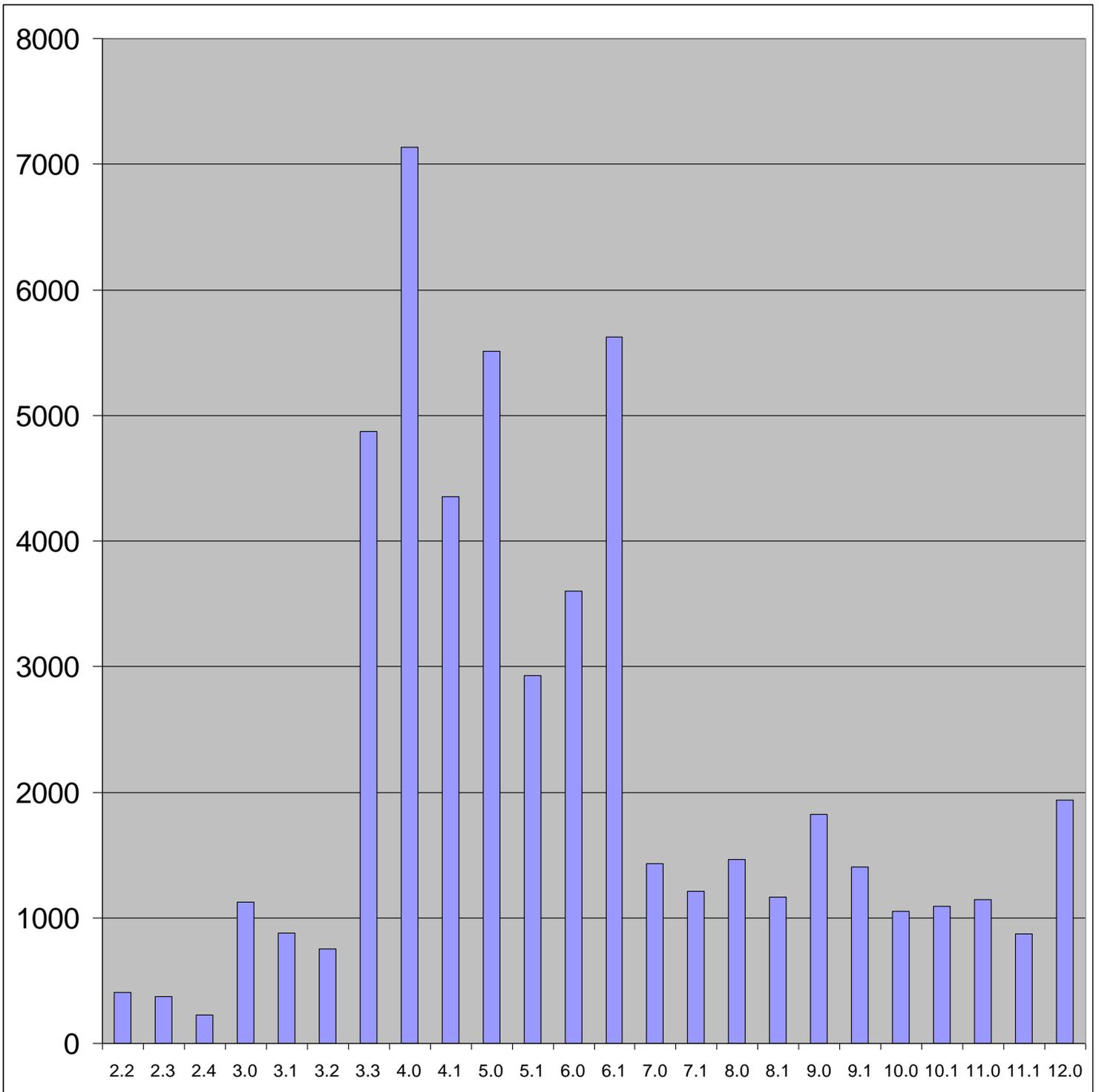


Figure 2 Implemented changes in MedDRA