Innovative Medicines Initiative
WEB-Recognising Adverse Drug Reactions 2
Webinar 2: WEB-RADR 2 terminology mappings
Question and Answer

Q: If users disagree with a mapping, will they have to provide a justification with a mapping change request?
A: Any requests for changes to either of the maps should be accompanied by a reason and suggested alternative map. This is part of process.

Q: When the map is released for use will any changes/additions to the map between versions be highlighted in the release notes?
A: The release notes will provide detail of changes to each of the maps. Obviously over time how this is represented will depend on the number of changes – for example, if there is a big batch of additional maps to cover a specific use case, how this is described in release notes will need to be considered.

Q: How can users submit proposed additions or changes to the existing mappings?
A: The existing maps are out for Alpha test/feedback, through to end September 2020. No additions are being made to the maps ahead of the Production releases in April 2021 but comments based on quality and accuracy can be provided by 30 September with supporting evidence/reasoning. Once the production release is available, licensed SNOMED CT and/or MedDRA users will have access to a single portal to submit their requests for adding to the maps or proposing a change to an existing map.

Q: What is the plan for future releases of the mapping?
A: First Production release is April 2021. After that, releases will be annual unless there is an international requirement for different scheduling.

Q: How will be the mapping of new MedDRA or SNOMED version handled?
A: Maintenance and updating process will identify any changes in the underlying terminologies which require changes to the maps. At the moment the plan is to base the annual releases on SNOMED CT January International Release and MedDRA September release of the previous year. These changes will be proactively applied to the mappings by the SNOMED-MedDRA maintenance team and included in the next release of the mappings.

Q: Are stakeholders allowed to see the Alpha test of the Map, and how do we get access? We would be keen to be involved.
A: Contact either MedDRA MSSO (mssohelp@meddra.org) or SNOMED International (info@snomed.org).

Q: With an increasing overlap between medicines and medical devices, including combination products, is there scope to work with IMDRF on mapping Health Effect terms from SNOMED? This might support automation of incident reporting, or at least give some key terms to search for when analysing health records for potential adverse incidents involving medical devices.
A: SNOMED International are happy to discuss this further with IMDRF.

Q: In what format is the mapping being released? Are multiple formats to be made available?
A: Format is SNOMED RF2 format and spreadsheet format from MedDRA MSSO. Other formats have to date not been suggested. Please let us know if there are formats that would be useful.

Q: This all seems practical and useful with significant ongoing commitment. to mapping. As WEB-RADR makes its first steps in medical device reporting and in line with the earlier question. Is there now a case for plans to develop SNOMED-CT to/from MedDRA mappings for the published medical device IMDRF adverse event codes?
A: As discussed before, SNOMED International is happy to discuss further with IMDRF as are MedDRA MSSO.

Q: Is there a possibility of automation in the mapping process?
A: This is something we have explored over a number of years with other maps. To date, we have not found an effective and efficient way to do this but this is something we continue to explore very actively because we see this as an evolving area. Mapping cannot be done purely on lexical matching, it has to be semantic and in the case of SNOMED CT and MedDRA the structures and editorial rules are very different which makes automation more difficult.