IMDRF International Medical Device Regulators Forum

“Development of common terminology and code related to adverse event of medical device”

NWI proposal sub committee report

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Development of common terminology and code related to adverse event of medical device

Purpose of the new work item proposal

•To improve, harmonize and where necessary expand the terminology and systems being used to code information relating to medical device adverse events.

•To establish IMDRF AE terminology composed of following three parts: terms for medical device malfunction, terms for patient/user outcome and terms for part/component of medical device.

(Note: Evaluation terms and code is not the scope of this WG)

Proposed project leader

•Current IMDRF Management Committee Member

Development of common terminology and code related to adverse event of medical device

Subcommittee discussion

- 3 teleconferences were held.
- Reviewed and clarified the scope of this new work item proposal and revised for discussion in the 7th IMDRF Management Committee meeting.
- Issue regarding the relationship with the current ISO standards on medical devices hierarchical coding structure for AE: ISO/TS19218-1 and -2 was raised.

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Conclusion

a) Added more clarification mainly to the scope of this proposal

b) The Work Plan is divided into two parts.

1st step: establishing the harmonized concept

2nd step: discussion toward implementation

c) Considered the current ISO standards with taking its working timeframe into consideration and proposed to seek collaboration with ISO/TC210 *after* finalizing document in the second step.

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General Work Plan and Timelines

•Revised new work item proposal to the IMDRF Management Committee for consideration in March 2015 in Tokyo.

•Workgroup established by the end of April 2015.

•Prepare draft paper on the discussion of the **First Step** by the end of Jul. 2015 for consideration of the IMDRF Management Committee at Sep. 2015 meeting.

•Move onto the **Second Step**.

•Draft the summary of the WG results and prepare the draft by the end of Feb. 2016 for consideration of the IMDRF Management Committee at 2016 meeting.

•Public comments to be received by May 2016.

•Resolve comments and prepare Final document by Sept 2016.

- Seek collaboration with ISO/TC210 to revise current ISO/TS 19218 based on the deliverable of this work item after finalizing the document in the second step.

Thank you