

# Comments template – for submitting comments on proposed IMDRF documents.

Once completed, please forward to [bakul.patel@fda.hhs.gov](file:///C%3A%5CUsers%5CCatherine.Bahr%5CDocuments%5CIMDRF%5CN23%5Cbakul.patel%40fda.hhs.gov)

Interested parties should respond **by close of business Tuesday 13 December 2016.**

Document number:  **SaMD WG (PD1)/N41R3** Title: [**Software as a Medical Device (SaMD): Clinical Evaluation**](http://www.imdrf.org/docs/imdrf/final/meetings/imdrf-meet-160308-brazil-presentation-samd-clinical-evaluation.pdf)

Submitted by (name): Affiliated to: On:\_\_\_\_\_\_\_\_\_\_

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| **High level feedback** | **Yes/No** | **Comment and rationale and proposed recommendations** |
| Does the document address the intention captured in the introduction/scope or vice-a versa? |  |  |
| Does the document appropriately translate and apply current clinical vocabulary for SaMD? |  |  |
| Are there other types of SaMD beyond those intended for non-diagnostic, diagnostic and therapeutic purposes that should be highlighted/considered in the document? |  |  |
| Does the document adequately address the relevant clinical evaluation methods and processes for SaMD to generate clinical evidence? |  |  |
| Are there other appropriate methods for generating clinical evaluation evidence that are relevant for SaMD beyond those described in the document? |  |  |
| Are the recommendation identified in section 7.2 related to the” importance of clinical evaluation evidence” appropriate as outlined for the different SaMD categories ? |  |  |
| Are the recommendation identified in section 7.3 related to the” importance of independent review ” appropriate as outlined for the different SaMD categories ? |  |  |
| Given the uniqueness of SaMD and the proposed framework -- is there any impact on currently regulated devices or any possible adverse consequences? |  |  |

**Detailed Feedback**

| **Comment Number** | **Page / Section / Line** | **Editorial or Technical** | **Comment and rationale** | **Proposed revised text** | **IMDRF Decision****(& date)** |
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