HBD WG 4 (Regulatory Convergence & Communication)
Summary Technical Documentation Proof of Concept Study Guidelines

May 3, 2010 - Version 1.4 (Final)

1. Purpose

With the involvement of the U.S. and Japan, GHTF (Global Harmonization Task Force) developed guidance on STED that recommended format and content for evidence of conformity with the harmonized essential requirements of safety and performance of medical devices. The STED is intended to harmonize the evidence requirements and improve the consistency and efficiency of the conformity assessment process.

The use of STED in regulatory submissions in the U.S. and Japan has not been adequately compared. Our retrospective study (presented during the 2008 HBD East Meeting) demonstrated differences warranting prospective evaluation. It was also limited by the small number of STED submitted to date. To address this need for additional evaluation, we propose to collect and analyze regulatory submission data from multiple applications incorporating STED in U.S. and Japan in order to further understand differences that may exist with format and content, to define best practices and improve processes.

The STED POC is a prospective study that will evaluate the format and content differences between the U.S. Class II and Class III submissions per the U.S. Food and Drug Administration (U.S. FDA) STED Pilot Program requirements and the Japan Class II, III and IV submissions in accordance with the Japanese Pharmaceutical Affairs Law (JPAL) STED requirements. It is hoped that resulting information will promote further convergence between Japan and U.S. requirements for pre-market submission evaluations and review practices.

2. Scope

The amount of detailed data in the STED submission is dependent on the risk classification of the device. To make the comparison useful, it's important to compare devices that are of a similar risk classification and are handled similarly by Japan and U.S. Therefore, this proposal applies to Japan and U.S. Medical Device STED submissions for products of similar risk classifications and handled using comparable regulatory processes.

U.S. / Japan STED:

- U.S. Class II Premarket Notification Application or 510(k): Traditional and Abbreviated (Not Special 510(k)s) vs. Japan Designated Class II Devices
- U.S. Class III Premarket Approval Application or PMA: Under STED Pilot Program vs. Japan Class III & IV

The scope includes all medical devices (except IVD's or in-vitro diagnostic devices) and is not limited to cardiovascular devices.

3. Operational Responsibilities

It is the responsibility of a firm participating in this study to submit the application(s) that comply with the requirements outlined in this proposal and the medical device regulatory requirements of both Japan and the U.S. It is the responsibility of the applicant to submit their STED directly to the U.S. FDA or Third Party (Accredited Persons) and Japan's MHLW/PMDA (Ministry of Health, Labour and Welfare/Pharmaceutical and Medical Devices Agency) or the Registered Certification Body in the customary processes. In order to be part of the HBD WG 4 POC the applicants must notify the WG 4 Co-Chairs of their involvement in the POC (See Annex A). Co-Chairs will acknowledge receipt of such notification.

4. Procedure

The notification letter to the WG 4 Co-Chairs should be in writing (See Annex A) and include name of firm, contact person, a distinguishing project identifier as specified by the applicant or reference that could be used to indicate the firm's POC notification and the firm's willingness to comply to the purpose (outlined in section 1 above) of the POC, i.e.,

1. Submit one STED POC Notification Letter per regulatory submission for Japan and U.S.,
2. Submitting parallel STED applications on the same device to both Japan and U.S.,
3. Collecting and analyzing the comparative data, and
4. Providing comparison data to HBD WG 4 in a summary form (with no confidential information).

In the U.S. the firm is responsible for following the FDA STED Pilot Program requirements which are located on the FDA Website[1]. In Japan, STED is already a requirement and the applicant will comply with Shonin requirements.

Applicants will submit similar information in the GHTF STED format while ensuring compliance to U.S. and Japan STED regulatory requirements (See Section 8: References)

5. Methods

STED POC Notification Letters can be submitted to HBD WG 4 Co-Chairs up to one year following the date this document (HBD WG 4 STED POC Study Guidelines) has been released and the regulatory dossier submitted within 3 months of notification (there is no limit on the number of submissions evaluated as part of this study). It will be posted on the FDA's HBD Website[2] and firms interested in participating may contact WG 4 Co-Chairs.

The studies will be conducted prospectively. The following data will be collected by firms participating in this study and provided to HBD WG 4 for analysis for both the U.S. and Japan submissions:

- List sections / format differences: evaluated upon approval / clearance (once all additional information has been incorporated as requested by regulatory reviewers during the review process).
- List content differences: evaluated upon approval / clearance (once all additional information has been incorporated as requested by regulatory reviewers during the review process).

6. Data Analysis

Data will be evaluated using descriptive / qualitative analysis. Results will be used to identify general trends and observations. Analysis will identify the types of data that are found valuable to each agency. In addition, the analysis will identify best practices leading to convergence of a single set of data needed to obtain approval / clearance. It is recognized that the laws of each country may require specific information that is unique to that country. The objective is regulatory convergence of format and content and not a decrease in regulatory requirements. The results of this study will be made public.

7. Terms and Definitions

Summary Technical Documentation (STED): A summary of technical documentation held or submitted for conformity assessment purposes.

Proof of Concept (POC) Study: Proof of concept is evidence which demonstrates that a model or innovative approach is viable, feasible and capable of solving or diminishing a particular problem.

Harmonization By Doing (HBD): An international effort to develop global clinical trials and address regulatory barriers that may be impediments to timely device approvals. This process is a cooperative effort to move both Japan and the U.S. toward international regulatory harmonization.

8. References

1. Japan STED Requirements PAL [3]
2. U.S. STED Requirements - STED Pilot Program[4]
3. GHTF STED Guidance Document - GHTF/SG1/N011:2008[5]

Annex A : HBD WG 4 STED POC Notification Letter Template

[Date]

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Dear Harmonization By Doing (HBD) WG 4 Co-Chairs,

This letter is being sent on behalf of **[Firm's Name]** as a notification to HBD regarding our firm's plan to participate in the HBD WG 4 Proof of Concept (POC) Summary Technical Documentation (STED) Study. This notification is identified with the following **[Project Identifier]**.

[Firm's Name] is committed to complying with the intent of the POC Study by submitting parallel STED applications on the same device to both Japan and the U.S., collecting and analyzing the comparative data and providing comparison data to HBD in a summary form that does not contain confidential information.

If you have any questions, or would like more details, please feel free to contact me as I will be the **[Firm's Name]** contact person for this STED POC Study. I may be reached at **[Telephone Number** or by e-mail at **[E-mail Address]**.

Sincerely,

[Name and Address of Firm's Contact Person]