MEDICAL DEVICE DEVELOPMENT CONSULTATION FORM

Version No.: 001
Effective Date: 20 May 2024

INSTRUCTIONS:

1. Please download the latest version of the form at the following url: http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Regulatory_Updates/md_initiatives.html

2. The form should be completed in English.

3. Please ensure that all fields are completed. Incomplete forms will not be accepted.

4. Please send the completed form and related documents to HSA_MD_Tech@hsa.gov.sg , with the subject of the email in the following format:
   "Medical Device Development Consultation <Appointment date> Ref: <Booking Reference>"

5. All documents shall be submitted at least **30 days** before the appointment date. Incomplete or insufficient information may result in cancellation of the appointment. Please note that all fees paid are non-refundable.

NOTE TO APPLICANT:

1. This consultation is not an endorsement of any validation plans, test protocols and results discussed. The consultation is not meant to be an iterative process and does not guarantee approval or clearance for pre - market registration.

2. Please note that our advice will be based on your questions or issues raised during the meeting in line with your proposed agenda. Any new information or data presented during the meeting and related issues may not be addressed in the meeting as the new data and its implication on device validation or development pathway will need to be assessed thoroughly.

3. Advice given in the meeting is based on the information presented prior to the meeting. Any changes made to the development plans or new data or information generated after the meeting may affect the advice given during the meeting.

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Clear Form

BOOKING REFERENCE NO.:		DATE OF APPOINTMENT:	

SECTION A: ATTENDEE PARTICULARS

	NAME OF ATTENDEE	DESIGNATION / COMPANY NAME
1.		
2.		
3.		

SECTION B: MEETING AGENDA
(please tick all applicable topics of concerns and provide a 'Brief Summary' of the overall questions & concerns below)

☐ General regulatory requirements in Singapore
☐ Regulatory Strategy
☐ Risk Classification
☐ Product Claims
☐ Design Validation
☐ Clinical Trials
☐ Others : _____

BRIEF SUMMARY

- *Please provide clear and concise questions, or areas of concerns you wish to discuss during the consultation session.*
- *Separately, please attach the supporting information/ documents in relation to the questions to be discussed. Information can be provided in any format, e.g. PowerPoint slides, summary copies etc. Please keep your supporting information targeted and focused on the questions at hand. Please note that submission of extraneous information can be counterproductive.*

Have you enquired on this medical device previously?	○ Yes ○ No If yes, please state the reference number of the previous enquiry: _____ *(You may attach the email communications of the previous enquiry, where necessary.)*
SECTON C: BASIC MEDICAL DEVICE INFORMATION *(please provide sufficient information for better understanding of the device to be discussed)*	
PRODUCT NAME	
PROPOSED INTENDED USE/ INDICATIONS FOR USE *This may include:* • *Disease/ condition the device is indicated to prevent, mitigate, screen, monitor, treat, or diagnose.* • *For IVDs, the analyte/condition to detect and the assay methodology* • *Targeted population* • *Part of the body or type of tissue to which applied or with which the device is interacting*	
DEVICE/ TECHNOLOGY DESCRIPTION *To include sufficient information to understand what the proposed device is and how it works, such as:* • *Brief device description in text, pictures and/or diagrams (as applicable)* • *Brief explanation of the mechanism of action, technology basis, and/or, if applicable, how the device output is used* • *An explanation of the scientific basis for the device and/or the expected clinical utility* • *Description of the materials used in the device (where necessary)* • *For an IVD, detailed technical description of the device including instruments, reagents, components, software, principles of operation, and accessories*	

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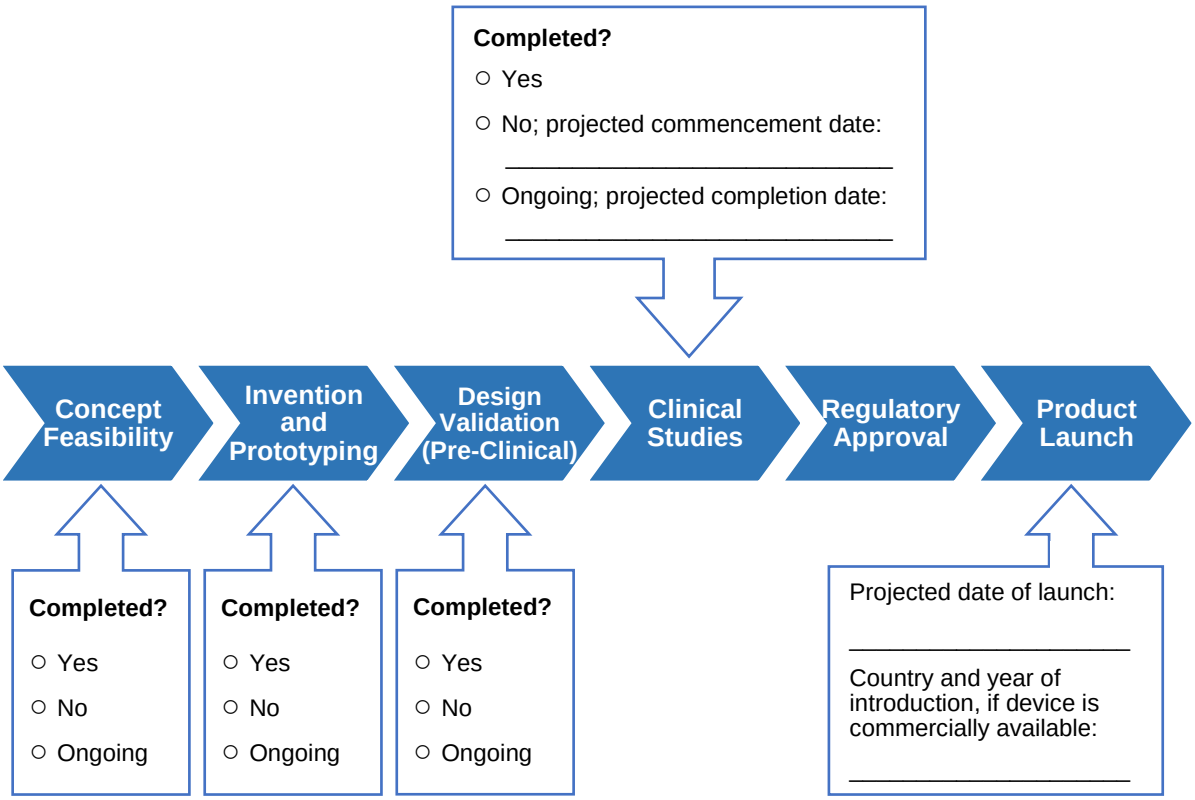
OVERVIEW OF DEVICE DEVELOPMENT

(please select accordingly based on current development progress of the device)



SECTION D: DECLARATION

☐ I hereby attest that the information provided is accurate, authentic and complete.