MDS – G002

Guidance on Innovative Medical Devices

Version Number: 3.0
Version Date: ../../2024

MDS-G-012-V3/24000

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Introduction

Innovative Medical Devices have an important role in improving and facilitating both patients' and healthcare practitioners' quality of life. The delays in access to Innovative Medical Devices could limit use of such technologies that provide superior effectiveness in diagnosis, treatment or monitor.

The SFDA has introduced a dedicated pathway for Innovative Medical Devices to accelerate the regulatory procedures and facilitate patients' and healthcare practitioners' access to novel technologies with significant benefits over available products while ensuring safety and effectiveness.

Purpose

The purpose of this guidance is to specify the designation criteria for Innovative Medical Devices, associated review processes, and the features of the pathway to outline the requirements for applying through the Innovative Medical Devices Pathway, and to explain the submission process.

Scope

This guidance applies to innovators, developers, manufacturers, and authorized representatives wishing to obtain Medical Devices Marketing Authorization for Innovative Medical Devices which is defined in Annex (D): Definitions and Abbreviations.

Background

SFDA has issued this guidance document in reference to Article 9 of the "Low of Medical Devices" issued by the Royal Decree No. (M/54) dated 6/7/1442 H indicating that "the SFDA may exclude an innovative medical device from some of the conditions and procedures to obtain a marketing authorization in a way that does not affect its safety and performance when used as intended, as determined by the Regulation.

Innovative Medical Devices Pathways

The innovative medical device journey begins with establishing an innovative concept that goes through multiple iterations and developments (see annex C, Part A) that shall account for pre-clinical considerations and may include the request of product classification by SFDA (see annex C, part B) to ensure that the innovative product is safe and effective. This pathway will continue to require providing evidence that the medical device meets the Essential Principles for Safety and Performance (EPSP). The pathway is comprised of two stages: Pre-Submission Assessment and Priority Assessment for Marketing Authorization. The process of Innovative Medical Devices Pathways is outlined in a flowchart.

Pre-MDMA Application Assessment

The first stage is intended to provide free of charge, continuous feedback and guidance based on SFDA expectations and regulatory requirements during medical device's technical file preparation and prior to applying for marketing authorization.

Priority MDMA Application review

The second stage is intended to provide a priority for the innovative medical device MDMA application to be reviewed in front of MDMA applications queue. Such priority does not mean that MDMA technical file assessment will be shortened or reduced in any way, it just means that the assessment, that would be comprhensive due to the novelty of the technology, will commence sooner after receipt of the technical file.

Innovative Medical Device Designation Criteria

This section outlines the criteria for eligibility for a medical device to be considered innovative. A medical device may be designated as an Innovative Medical Device if it meets the following conditions:

- The medical device is designed with innovative features in the technology, indications for use, or performance attributes that have no equivalence in the local/global market.
- The medical device provides a considerable clinical/medical advantage over existing alternative treatments.
- Any other criteria to be determined by the SFDA and published through the website.

Applicants must justify how the medical device meets these criteria to SFDA. SFDA may request additional information from applicants if needed to make a final determination about Innovative Medical Device Designation, and applicants will be notified of the status of their application, whether it is accepted for priority review or not.

SFDA Facilitation for Innovative Medical Devices

It is important to understand that Innovative technologies, by their very nature, are new and less well understood than established technologies. Therefore, they may present higher risks and must be subject to comprehensive and rigorous review.

In order to ensure that applicants are well prepared, provided optimum submissions, and the reviews proceed as smoothly as possible, SFDA has introduced the following facilitations which assist both parties to maintain a continuous dialogue and to prioritize the review of Innovative Medical Devices:

Facilitations for Pre-Submission Assessment Pathway

- **Preliminary Regulatory Feedbacks**

This service will be free of charge prior to submitting Medical Device Marketing Authorization (MDMA) request. Pre-submission assessment is the first stage of the pathway. It will provide the applicants with ongoing feedback and guidance regarding their applications and will explain SFDA requirements. Moreover, the developers/manufacturers will be notified in advance of the regulatory expectations of the proposed device.

Facilitations for Priority Assessment for Marketing Authorization Pathway

- **Prioritizing Evaluation**

Innovative Medical Devices will be placed at the front of the review queue of marketing authorization requests and evaluated in priority ahead of other submissions. Because of the novelty of the technology, reviews will need to be thorough. Priority treatment does not mean that reviews will be shortened or reduced in any way, but it does mean that the review will commence sooner after receipt of submission files.

- **Granting Conditional Marketing Authorization**

Conditional marketing authorization could be granted to some Innovative Medical Devices that comply with valid clinical evidence. Conditional marketing authorization allows the applicant to market the Innovative Medical Device under SFDA post-market requirements, such as limitation of distribution, and subjecting to post-market surveillance studies. Full marketing authorization could be obtained if the application fulfilled all SFDA MDMA requirements.

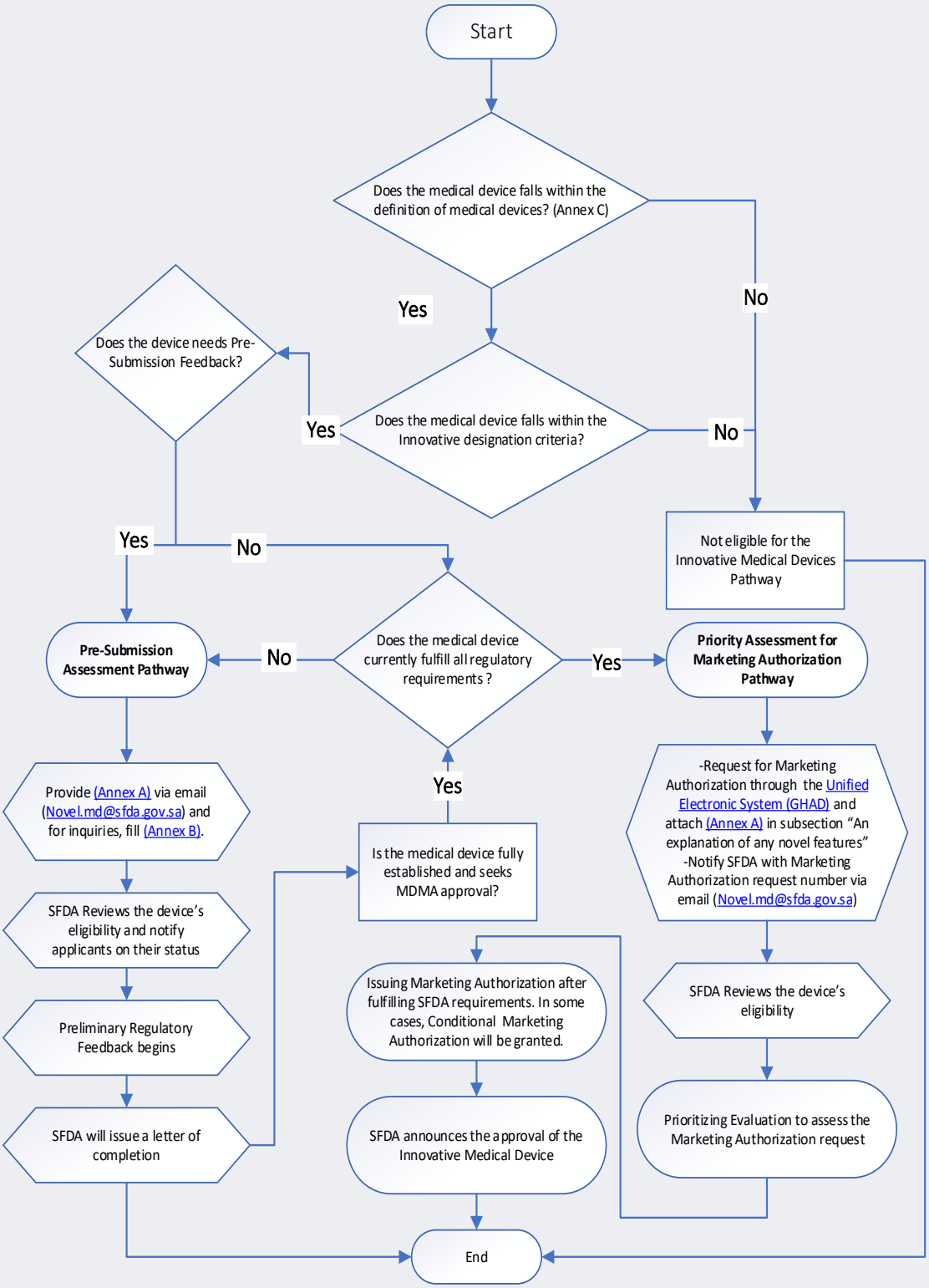
- **Release Announcement**

After granting MDMA to the Innovative Medical Device, SFDA may announce on its website and/or other channels that the Medical Device Marketing Authorization has been obtained for the Innovative Medical Device.

Requirements and Procedures

General	1	Applicants shall comply with the following: – Law of Medical Devices. – Implementing Regulation of the Law Medical Devices. – Requirements for Medical Device Marketing Authorization (MDS-REQ1). – Innovative Medical Device Designation Criteria. – Meeting the Essential Principles for Safety and Performance requirements.
Application Form for Innovative Medical Device	2	– Applicants shall submit "Application Form for Innovative Medical Device" via email (Novel.md@sfda.gov.sa).
Specific Requirements for Pre-Submission Assessment Pathway	3	– SFDA will review applications to determine the devices' eligibility, and may require additional supporting documentation or clarification. – SFDA will notify the applicants of the status of their applications. – When the Pre-Submission Assessment is complete, SFDA will issue a letter of completion.
Specific Requirements for Priority Assessment for Marketing Authorization Pathway	4	– Applicants shall submit a request for Priority MDMA Application Review through "GHAD" system and attach the required form (Annex A) in MDMA portal subsection "**An explanation of any novel features**". – Applicants notify SFDA via email (Novel.md@sfda.gov.sa) with the MDMA request number. – SFDA will review the applications to determine the devices' eligibility, and may require additional supporting documentation or clarification. – Once accepted, applicants will have all distinctive pathway facilitations.

Flowchart


Start
Does the medical device falls within the definition of medical devices? (Annex C)
Yes
No
Does the device needs Pre-Submission Feedback?
Yes
Does the medical device falls within the Innovative designation criteria?
No
Yes
No
Not eligible for the Innovative Medical Devices Pathway
Pre-Submission Assessment Pathway
No
Does the medical device currently fulfill all regulatory requirements ?
Yes
Priority Assessment for Marketing Authorization Pathway
Provide (Annex A) via email (Novel.md@sfda.gov.sa) and for inquiries, fill (Annex B).
Yes
-Request for Marketing Authorization through the Unified Electronic System (GHAD) and attach (Annex A) in subsection "An explanation of any novel features"
-Notify SFDA with Marketing Authorization request number via email (Novel.md@sfda.gov.sa)
SFDA Reviews the device's eligibility and notify applicants on their status
Is the medical device fully established and seeks MDMA approval?
SFDA Reviews the device's eligibility
Preliminary Regulatory Feedback begins
Issuing Marketing Authorization after fulfilling SFDA requirements. In some cases, Conditional Marketing Authorization will be granted.
SFDA will issue a letter of completion
SFDA announces the approval of the Innovative Medical Device
Prioritizing Evaluation to assess the Marketing Authorization request
End

Annexes

Annex (A): Application Form for Innovative Medical Device

1	Applicant Name	
2	Establishment Information (name, address and contact information for research center/university/manufacturer/authorized representative)	- If applicable
3	Medical Device Name	
	Type of Medical Device (Medical Device (MD) or In-Vitro Medical Device (IVD))	
5	Device History (If the device has been previously authorized, address previous history interaction with regulatory jurisdictions; such as, FDA, EU, TGA etc.)	
6	Risk Class (A, B, C or D) and Rationale	Refer to: - MDS-REQ 1 Annex (5) Risk Classification Rules for Medical Devices - MDS-G008 Guidance on Medical Devices Classification
7	Applicable Innovative Medical Device Designation Criteria	□ The medical device is designed with an innovative and unprecedented characteristics in technology, indications for use or performance, locally or internationally. □ The medical device provides a considerable clinical/medical advantage over existing alternative treatments. □ Other (explain in the below section)
8	Provide detailed rationale for considering the device as an Innovative Medical Device.	
9	Intended Use, *Which may include:* − Indications for use (treat/prevent/diagnose/monitor; when and how to use the device) − Patient population (age/gender/disease) − Body parts affected − Intended user	
10	Device Description, *Which may include:* − Brief description (written/diagram/picture) − Mechanism of action (how the device achieves its intended purpose)	

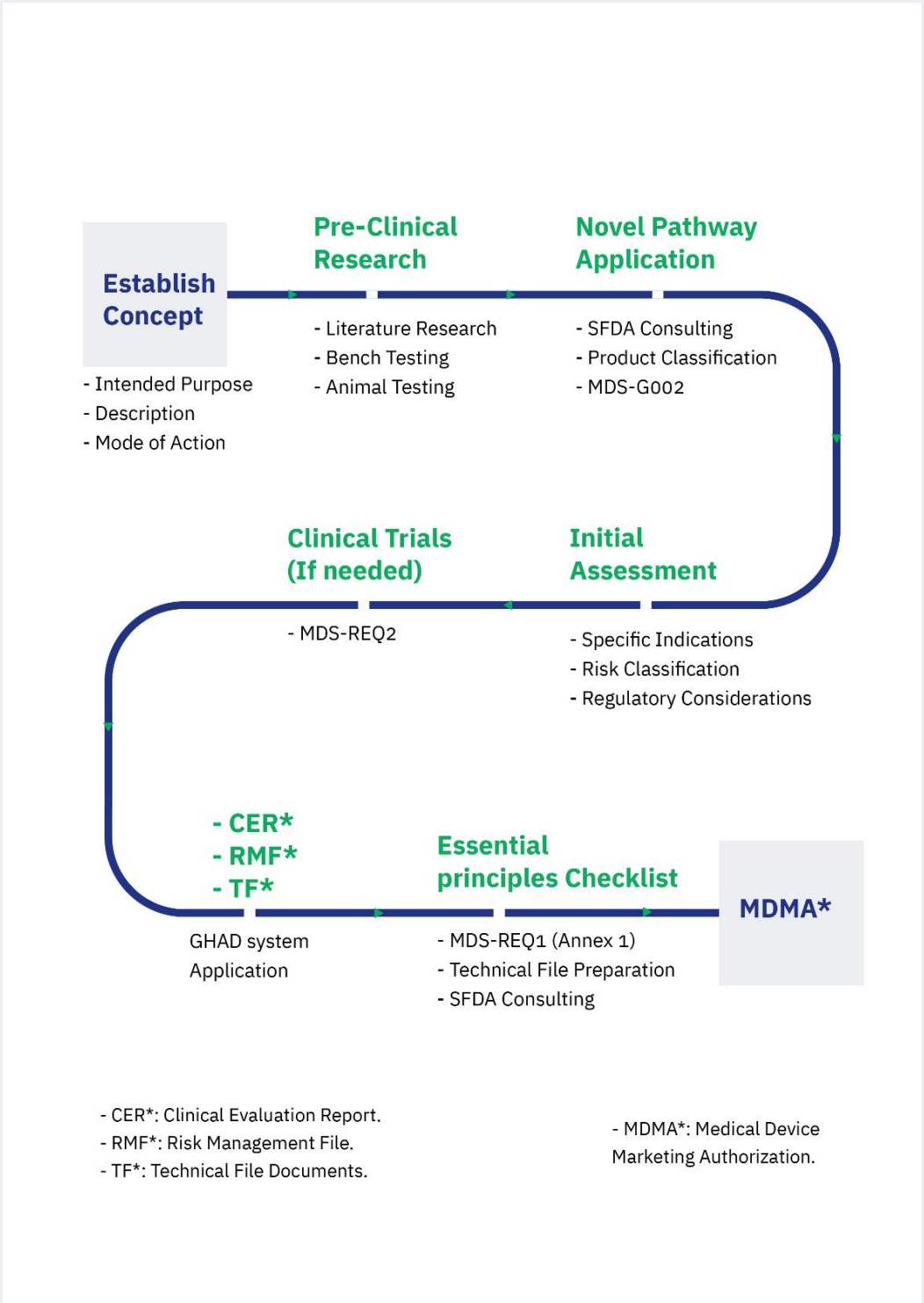
11	Device Characteristics: (address all that apply) - □ Software - □ Biological - □ Single use - □ Sterile (sterilization method) - □ Material used (Animal origin/human/tissue/medicinal substance) - □ Duration of body contact - □ Other characteristics (reagents/components/accessories)	
12	Level of Evidence (identify and discuss) Pre-clinical data: - □ Animal studies - □ Usability study - □ Software validation - □ Sterilization validation - □ Risk-benefit analysis - □ Any other lab test Clinical Trials Documentation and Investigator's Brochure: - □ Pilot Study (if applicable) - □ Pivotal Study (if applicable) - □ Primary safety endpoint identified: (if yes, describe) - □ Primary effectiveness endpoint identified: (if yes, describe) - □ Clinical Evaluation/Literature Review	
13	Attestations:	□ I confirm that the information given in this form is true, complete and accurate.

Annex (B): Innovative Medical Devices Requirements and Procedures Inquiries Form

1	Applicant Name:	
2	Device Name:	
3	Select the Primary Topics of Inquiries: □ General regulatory requirement □ Innovative Medical Device Designation Criteria □ Risk classification □ Essential Principles for Safety and Performance (EPSP) □ Design validation (pre-clinical data) □ Product claims □ Validity of clinical trials □ Conditional marketing authorization □ Release anouncement □ Others:	

Annex (C): Innovative Medical Device Roadmap

Part A: Roadmap



Part B: Pre-Clinical Considerations

The purpose of preclinical studies is to provide reasonable evidence of safety and performance prior to testing in humans in clinical trials to demonstrate that novel technologies are safe and effective. Preclinical evaluation of medical devices provides information to investigate and study the intended use of medical device in all stages of design and development.

Preclinical Studies

In the preclinical phase of development, the medical device prototype will undergo a cycle of preclinical testing and redesigning until the product or the prototype is ready for testing in humans.

Bench Testing, Technical Testing, Animal Testing, and Simulated Use are some examples of Preclinical Studies.

Bench Testing

Bench testing includes mechanical tests to determine properties such as fatigue lifecycle, tensile strength, compression strength, puncture resistance, and flexural strength. performed in a controlled environment to rule out performance-related mechanical or design flaws in the medical device. Bench testing of medical devices also evaluates their endurance and capability to perform with the same efficiency under different forms of load to test the safety and performance of the device.

Technical testing

This involves testing the materials and electronic elements for accuracy, reliability, electromagnetic, and specific performance testing.

Animal Testing

Experiments on animals or cells to estimate safety and potential efficacy of medical device either by in vitro or in vivo animal testing, such as biocompatibility testing.

Annex (D): Definitions and Abbreviations

SFDA	Saudi Food and Drug Authority
Authorized Representative (AR)	Individual or judicial or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.
Manufacturer	Any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.
MDMA	Medical Devices Marketing Authorization
Medical Device	Any instrument, apparatus, implement, implant, in vitro reagent or calibrator, software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
Innovative Medical Device	A medical device with an innovative idea in technology, use or performance , and which has not previously placed on the market, locally or internationally.

Annex (E): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
2.0 01/01/2020	• Update the following documents: ○ Guidance on Innovative Medical Devices (MDS-G43) to (MDS-G002).
3.0 16/10/2024	• Update the following documents: ○ Annex (C): Innovative Medical Device Roadmap has been added