MDS – REQ 2

Requirements for Clinical Trials of Medical Devices

Version Number: 5.0
Version Date: 11/06/2024

MDS-REQ-002-V5/240611
"Translated Copy"

Table of Content

Introduction

Purpose

The purpose of this document is to specify and clarify the requirements for conducting clinical trials of medical devices within KSA.

Scope

This document applies to organizations or researchers wishing to conduct clinical investigations of medical devices or clinical performance studies of in vitro diagnostics medical devices within KSA.

Backgorund

SFDA has issued this document in reference to the following:

- Articles (Seven) and (Twenty-Eight) of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 AH.
- Articles (7/1), (7/2), (7/3), (7/4), (7/5), (7/6), (7/7), (7/8) and (28/2) of the "Implementing Regulation of Medical Devices Law" issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443 AH.

Requirements

General	1	SFDA import permission shall be obtained for all medical devices intended to be imported for clinical trials in accordance with the Requirements for Importation, Exportation and Shipment Clearance of Medical Devices (MDS-REQ 5).
	2	The labelling or the instructions for use shall indicate that the medical device is exclusively for use in a clinical trial, and shall adhere to the requirements referred to in "Requirements for Medical Devices Marketing Authorization (MDS-REQ 1)"
	3	For clinical trials involving innovative medical devices, SFDA has developed a pathway to provide continuous regulatory assessment and feedback during all development phases of the innovative medical device, as specified in the Guidance on Innovative Medical Devices (MDS-G002).
Regulatory References and Standards	4	The clinical trial shall comply with the following: – Implementing Regulations of the Law of Ethics of Research on Living Creatures. – Declaration of Helsinki. – The standard of good clinical practice for clinical investigation of medical devices (ISO 14155) or any other similar standard. – The standard of good study practice for clinical performance studies of in vitro diagnostics medical devices (ISO 20916) or any other similar standard.

Procedures

Submitting the Application	1	Applicant can be a local sponsor, an authorised representative (in the case of sponsor located outside KSA), or a licensed Contract Research Organisation (CRO).
	2	All required documents shall be submitted by email to MDCI@sfda.gov.sa as follows: A. Prior to conducting the clinical trial, as specified in section (A) of "Required Documents". ▪ In case of missing documents, SFDA will notify the applicant within (5 days). ▪ The application will be considered "Void" in case the required documents is not completed within (60 days) from the date of submitting the application. ▪ After completion of the required documents, the SFDA will evaluate the application within (60 days) and take a decision as follow: o Once conditions and requirements are satisfied, SFDA will issue a "Approval Letter". o If conditions and requirements are not satisfied, SFDA will issue a "Rejection Letter" with justifications. In this case, the applicant is entitled to lodge an objection to the decision within (30 days). B. During the clinical trial, as specified in section (B) of "Required Documents". C. After completing the clinical trial, as specified in section (C) of "Required Documents".
Visit of the Study Site	3	SFDA may conduct a visit of the study site without any prior notice.
Deviations in a Clinical Trial	4	SFDA shall be notified within (5 days) of any occurrence of a major deviation from the approved clinical investigation plan (CIP) that could have a substantial impact on the safety and rights of subjects, details should be provided about the nature of the deviation and any proposed corrective actions.

Reporting and Investigating Serious Adverse Events or Device Deficiencies Related to Clinical Trial	5	• The National Center for Medical Devices Reporting (NCMDR) shall be provided with the "Form of Reporting Serious Adverse Events and Device Deficiency of Medical Devices Used in Conducting the Clinical Trial" regarding any serious adverse events (SAE) within the specified time period indicated below:
		  • (10) days for any serious adverse event that have led to any of the following:
		  a. Death.
		  b. Serious deterioration in the health of the subject, users, or other persons.
		  c. Fetal distress, fetal death, a congenital abnormality, or birth defect including physical or mental impairment.
		  • (10) days for any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
		  • (30) days for any adverse device effect that has a causal relationship with the investigational device or the comparator.
		  • The investigation shall be conducted and the investigation's final report shall be submitted to the National Center for Medical Devices Reporting (NCMDR) in accordance with what is mentioned in "Reporting and Investigating Medical Devices Incidents and Complaints" within the Requirements for Post-Market Surveillance for Medical Devices (MDS-REQ 11).

Suspension of a Clinical Trial	6	SFDA has the right to suspend a clinical trial due to noncompliance or serious breaches in the approved protocol that would lead to a substantial impact on the safety and rights of subjects. • If the EC/IRB terminates or suspends its approval of a trial, SFDA shall be notified within (5 days) of receiving the withdrawal notice and provide a detailed explanation of the termination or suspension

		• If the sponsor terminates or suspends a trial, SFDA shall be notified with an explanation and a description of any follow-up measures within:
		  • (5 days) in case of safety issues or significant concerns.
		  • (15 days) for other reasons.

Completion of a Clinical Trial	7	SFDA shall be notified about completion of the clinical trial within (10 days) of last patient follow-up. A copy of the final report shall be submitted within one year from the end of the clinical trial.

Required Documents

Documents should ideally be provided in PDF format and, where possible, be searchable. Please do not include compressed PDFs or scanned documents.

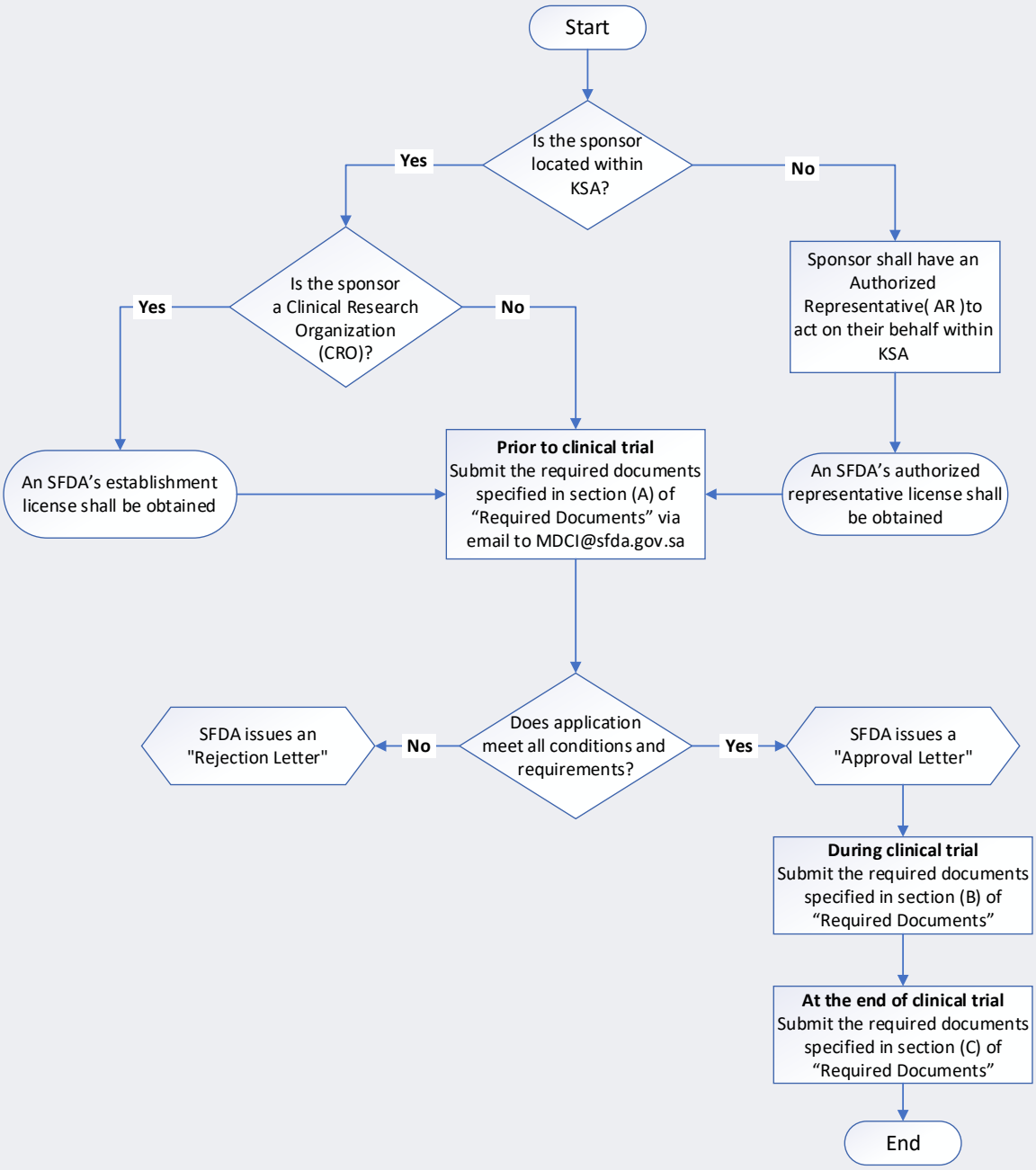
	Required Documents	Note
(A) Required documents prior to conducting the clinical trial		
1	Application Form for Clinical Trials of Medical Device	See Annex (1) and Annex (2) This form must be completed by(local sponsor / Authorized representative/ licenses CRO)
2	Labelling of the Medical Device	- Includes instruction for use (IFU) - For pre-market trials, It shall include a clear indication that the medical device is exclusively for use in a clinical trial.
3	Agreement between sponsor/authorized representative and study site/principal investigator	The agreement shall define the responsibilities of each party in the clinical investigation. All agreements shall be recorded in writing, signed, and dated by all parties involved.
4	Agreement between sponsor/authorized representative and Contract Research Organization (CRO)	In case a licensed CRO is contracted by the sponsor to perform one or more of the sponsor's clinical investigation-related duties and functions, an agreement shall be recorded in writing, signed, and dated by all parties involved.

5	Local Research Ethics Committee (REC) Approval Letter	- A signed/dated approval letter from a local EC/IRB registered at the National Committee of Bio Ethics (NCBE). - take into consideration the approval of the local research ethics committee regarding other requirements in this document
6	Clinical Investigation Plan (CIP) or Clinical Study Protocol (CSP)	A version-controlled CIP shall clearly outline the objectives of the clinical trial. The proposed design shall be adequately justified based on scientific and ethical principles. The objective(s) of the study determine(s) whether an exploratory or a confirmatory design is appropriate to ascertain that the objectives of the clinical trial can be reached. The CIP shall specify the version number and date of the document as approved by the local EC/IRB.
7	Case Report Form (CRF)	A version-controlled paper or electronic CRF to collect data from trial subjects and capture all the information required by the protocol. The CRFs shall include information on the condition of each subjects upon entering, and during the course of the clinical trial, exposure to the investigational device and any other therapies. The CRF shall specify the version number and date of the document as approved by the local EC/IRB.
8	Investigator's Brochure (IB)	For pre-market studies, a version-controlled IB consisting of a compilation of the current clinical and non-clinical information on the investigational medical device(s), relevant to the clinical trial. The IB shall specify the version number and date of the document as approved by the local EC/IRB.
9	Informed consent	A version-controlled ICF in Arabic and English that explains the purpose, risks,

		benefits, and procedures involved in the clinical trial to potential subjects. The ICF shall specify the version number and date of the document as approved by the local EC/IRB.
10	Medical insurance policy	It is only required for interventional studies.
11	CV and qualifications of Principal Investigator(s) and Investigator(s)	A CV or any other qualifications including certificates of education, training and experience.
12	Conflict of Interest Disclosure Form	- See Annex (3). It shall be completed by the principle investigator responsible for the study.
(B) Required documents during the clinical trial In addition to the above document, the following shall be submitted during the study as evidence of all relevant new information as it becomes available		
13	Progress report	A progress report should be submitted within (one year) from the date on which the No Objection Letter was issued. It shall include a summary of all deviations and adverse events whether related or not related to the investigational medical device or the procedure, including a discussion of the severity, resolution and relevant principal investigator's judgment concerning the causal relationship with the investigational devices or procedure.
14	Amendment form	- See Annex (4). - It shall be submitted within (10) days from the occurrence of amendment to any documents approved by SFDA. - All amendments shall be notified to, or approved by, the EC/IRB. The version number and date of amendments shall be documented.
15	Change of Principal Investigator (PI)	SFDA shall be notified with the following documents: o Change of PI Request Form (Annex 5) o CV for the new PI

		○ EC/IRB approval letter for PI change. ○ Document and agreements signed by the new PI.
16	Clinical trial deviations report	Promptly report any deviations that affect the rights, safety or well-being of subjects or the scientific integrity of the study, including those which occur under emergency circumstances. – It shall be reported within (5 days) from the occurrence of deviations.
(C) Required documents after completing the clinical trial		
17	Clinical trial completion notification	It shall be provided to SFDA within (10 days) of last subject follow-up.
18	Final Clinical Trial report	It shall be submitted to SFDA within (One year) from the clinical trial completion notification.

Flowchart


Start
Is the sponsor located within KSA?
Yes
No
Is the sponsor a Clinical Research Organization (CRO)?
Yes
No
Sponsor shall have an Authorized Representative(AR)to act on their behalf within KSA
An SFDA's establishment license shall be obtained
Prior to clinical trial
Submit the required documents specified in section (A) of "Required Documents" via email to MDCI@sfda.gov.sa
An SFDA's authorized representative license shall be obtained
Does application meet all conditions and requirements?
No
Yes
SFDA issues an "Rejection Letter"
SFDA issues a "Approval Letter"
During clinical trial
Submit the required documents specified in section (B) of "Required Documents"
At the end of clinical trial
Submit the required documents specified in section (C) of "Required Documents"
End

Annexes

Annex (1): Application Form for Clinical Trials of Medical Device

Saudi Food and Drug Authority **Medical Devices Application**	DATE RECEIVED: SFDA USE ONLY APPLICATION NUMBER: SFDA USE ONLY

STUDY INFORMATION

Aim of Study	Type of Study	Will the investigational device be imported to KSA?
☐ Pre-market approval for a new device ☐ Pre-market approval for new claims ☐ Post-market study ☐ Non-market study	☐ Observational study ☐ Interventional study	☐ Yes (SFDA importation license is required) ☐ No

Is this a first-in-human study?	Is there a Data and Safety Monitoring Committee (DSMC)?
☐ No ☐ Yes, Brief description:	☐ No ☐ Yes

SPONSOR INFORMATION

Type of sponsor		Type of sponsorship	Type of aid
☐ Manufacturer ☐ AR ☐ Hospital ☐ Independent individual	☐ Foundation ☐ University or Institution ☐ Other, please specify:	☐ Commercial ☐ Non-commercial, specify:	☐ Material support ☐ Funding support ☐ Other, please specify:

Name of sponsor:		
SFDA account:	Phone:	Email:
Address:		

Contact person name:	Contact person phone:	Contact person email:
AUTHORIZED REPRESENTATIVE INFORMATION		
Is the sponsor located outside KSA? ☐ No ☐ Yes, complete the following information:		
Name of AR:		
SFDA license:	Phone:	Email:
Address:		
Contact person name:	Contact person phone:	Contact person email:
CRO INFORMATION		
Is any part of the clinical study to be conducted by a Contract Research Organization (CRO)?	☐ No	☐ Yes, complete the following information:
Name of CRO:		
SFDA license:	Phone:	Email:
Address:		
Contact person name:	Contact person phone:	Contact person email:

INVESTIGATIONAL DEVICE INFORMATION			
Is the Investigational device authorized by SFDA?			Investigational Device Name
☐ Yes, Medical Device Marketing Authorization (MDMA) license No.:	☐ No, but registered in: ☐ Australia ☐ Canada	☐ Not registered anywhere.	

☐ Japan ☐ USA ☐ EU ☐ Other, specify:	Manufacturer Name:

The intended purpose of the investigational device

Device category

☐ Active implantable devices	☐ Single use devices
☐ Anesthetic and respiratory devices	☐ Assistive products for persons with disability
☐ Dental devices	☐ Diagnostic and therapeutic radiating devices
☐ Electro mechanical medical devices	☐ Complementary therapy devices
☐ Hospital hardware	☐ Biologically derived devices
☐ Non-active implantable devices	☐ Healthcare facility products and adaptations
☐ Ophthalmic and optical devices	☐ Laboratory equipment
☐ Reusable devices	☐ Other:

Is the device implantable?	Will the device be used for cosmetic rather than medical purposes?
☐ No ☐ Yes, brief description: ☐ Is the device intended to remain permanently in patient? ☐ No ☐ Yes	☐ No ☐ Yes, Select: ☐ A non-corrective contact lens ☐ An implant for augmentation, fixation, or sculpting of body parts ☐ A facial or other skin filler ☐ Equipment for liposuction ☐ Surgical laser equipment

Does the device contain or incorporate an ancillary medicinal substance?	Does the device incorporate tissues or cells, or their derivatives of animal origin?	Does the device incorporate tissue, cells, or their derivatives, of human origin?	Does the device incorporate cells or substances of microbial origin?

☐ No ☐ Yes, name of medicinal substance:	☐ No ☐ Yes, type of tissue, cell, or substance:	☐ No ☐ Yes, type of tissue, cell, or substance:	☐ No ☐ Yes, type of microbial cells or substances:

STUDY INFORMATION	
Clinical Investigation Plan (CIP)	Scientific title:
	Abbreviated title:

Clinical Investigation Plan information				
CIP number	CIP date	CIP version	Study start date	Study completion date

Study Design			
☐ Randomized ☐ Non-randomized	☐ Open-label ☐ Single-blind ☐ Double-blind	☐ Controlled study ☐ Parallel study ☐ Crossover study ☐ Uncontrolled study	☐ Experimental arm ☐ Active comparator arm ☐ Sham comparator arm ☐ No intervention arm
Other study design:			

Does this study include vulnerable subjects? ☐ No ☐ Yes

Number of subjects involved in the clinical study in KSA:	Total number of subjects involved in the clinical study:
Is the clinical study conducted in other countries? ☐ No ☐ Yes, specify:	Is the clinical study conducted in multiple sites in KSA? ☐ No ☐ Yes, a separate application shall be submitted for each study site.

Number of study sites in KSA:

STUDY SITE IN KSA
Name:

Address:		
Name of principal investigator:	Email:	Phone:
Name of Ethics committee (EC):		
EC Address:		
EC email:	EC phone:	EC registration number at National Committee of Bioethics:

DECLARATION

By signing below, I certify that:

I will i) accept responsibility for the scientific and ethical conduct of the study, ii) conduct the study in accordance with the regulation of the of Medical Devices Law, the standard of good clinical practice for Clinical Investigation of Medical Devices (ISO 14155:2020), and the Requirements for Clinical Trials of Medical Devices (MDS-REQ 2).

Name	**Position**
Signature	**Date**

Annex (2): Application Form for Clinical Trials of In Vitro Diagnostic Medical Devices

Saudi Food and Drug Authority **In Vitro Diagnostic Medical Devices Application**	DATE RECEIVED: SFDA USE ONLY APPLICATION NUMBER: SFDA USE ONLY

STUDY INFORMATION		
Aim of Study	Type of Study	Will the IVD device be imported to KSA?
☐ Pre-market approval for a new device ☐ Pre-market approval for new claims ☐ Post-market study ☐ Non-market study	☐ Observational study ☐ Interventional study	☐ Yes (SFDA importation license is required) ☐ No

SPONSOR INFORMATION			
Type of sponsor		Type of sponsorship	Type of aid
☐ Manufacturer ☐ AR ☐ Hospital ☐ Independent individuals	☐ Foundation ☐ University or Institution ☐ Other, please specify:	☐ Commercial ☐ Non-commercial, specify:	☐ Material support ☐ Funding support ☐ Other, please specify:

Name of sponsor:		
SFDA account:	Phone:	Email:
Address:		
Contact person name:	Contact person phone:	Contact person email:

AUTHORIZED REPRESENTATIVE INFORMATION		
Is the sponsor located outside KSA? ☐ No ☐ Yes, complete the following information:		
Name of AR:		
SFDA license:	Phone:	Email:
Address:		
Contact person name:	Contact person phone:	Contact person email:

CRO INFORMATION		
Is any part of the clinical study to be conducted by a Contract Research Organization (CRO)? ☐ No ☐ Yes, complete the following information:		
Name of CRO:		
SFDA license:	Phone:	Email:
Address:		
Contact person name:	Contact person phone:	Contact person email:

INVESTIGATIONAL DEVICE INFORMATION		
☐ Yes, Medical Device Marketing Authorization (MDMA) license No.:	Is the device registered at SFDA? ☐ No, but registered in: ☐ Australia ☐ Canada ☐ Not registered anywhere.	Investigational Device Name

	☐ Japan ☐ USA ☐ EU ☐ Other, specify:	Manufacturer Name:

The intended purpose of the investigational device

Device category	
☐ Clinical Chemistry ☐ Coagulation ☐ Hematology ☐ Histology & Cytology ☐ Human genetics ☐ Immunohematology (blood banking) ☐ Infectious disease	☐ Instrument/Analyzer ☐ Microbiological culture media ☐ Software IVDs ☐ Specimen receptacle ☐ Tissue typing ☐ Other:

Is the device used as a companion diagnostic device?	Is the device used as a home-use diagnostic device?	Is the device used as a near-patient diagnostic device?
☐ No ☐ Yes, name of corresponding drug or biological product:	☐ No ☐ Yes	☐ No ☐ Yes

STUDY INFORMATION	
Clinical Study Protocol	Scientific title:
	Abbreviated title:

Clinical Study Protocol information				
Protocol number	Protocol date	Protocol version	Study start date	Study completion date

Does this study include vulnerable subjects? ☐ No ☐ Yes	
Number of subjects involved in the clinical study in KSA	Total number of subjects involved in the clinical study
Is the clinical study conducted in other countries? ☐ No ☐ Yes, specify:	Is the clinical study conducted in multiple sites in KSA? ☐ No ☐ Yes, a separate application shall be submitted for each study site.
Number of study sites in KSA:	

STUDY SITE IN KSA		
Name:		
Address:		
Name of principal investigator:	Email:	Phone:
Name of Ethics committee (EC):		
EC Address:		
EC email:	EC phone:	EC registration number at National Committee of Bioethics::

DECLARATION
By signing below, I certify that: I will i) accept responsibility for the scientific and ethical conduct of the study, ii) conduct the study in accordance with the regulation of the of Medical Devices Law, the standard of good clinical practice for Clinical Investigation of Medical Devices (ISO 20916:2019), and the Requirements for Clinical Trials of Medical Devices (MDS-REQ 2).

Name	**Position**
Signature	**Date**

Annex (3): Conflict of Interest Disclosure Form

Saudi Food and Drug Authority

Conflict of Interest Disclosure Form

STUDY IDENTIFICATION	
Principal Investigator:	Email:
Study Title:	

CONFLICT OF INTEREST QUESTIONS		
Do you have any agreement to receive financial benefit from the research beyond what is described in the proposal budget?	☐ Yes	☐ No
Do you have an inventive or ownership interest in any intellectual property that will be utilized in this project?	☐ Yes	☐ No
Do you have a proprietary interest(s) or potential proprietary interest, in the product under study or the outcome of the research including, but not limited to, patents, trademarks, copyrights and licensing agreements?	☐ Yes	☐ No
If you answered **"YES" to ANY question above**, please describe:		

SIGNATURES/CERTIFICATIONS

By signing and submitting this form, I certify that:

All of the foregoing information in this form is true and complete to the best of my knowledge. I agree to promptly provide an update to this information if any relevant changes occurring during the course of the study.

I will i) accept responsibility as Principle Investigator for the scientific and ethical conduct of the study, ii) conduct the study in accordance with the regulation of the of Medical Devices Law, the standard of good clinical practice for Clinical Investigation of Medical Devices (ISO 14155:2020) or Clinical performance studies of in vitro diagnostic medical devices (ISO 20916:2019), and Requirements for Clinical Trials of Medical Devices (MDS-REQ 2).

PI Name	**Position**
PI Signature	**Date**

Annex (4): Amendment Form

Saudi Food and Drug Authority

Substantial Amendment Form

This form is to be used for a request to the SFDA for authorization of a substantial amendment

STUDY IDENTIFICATION	
Does the substantial amendment concern more than one study?	☐ No ☐ Yes, repeat this form as necessary.
Date of this submission:	Approval Letter ID:
Study title:	
PI name:	

DESCRIPTION OF EACH SUBSTANTIAL AMENDMENT	
Reasons for the substantial amendment:	
Changes in safety or integrity of study subjects:	☐ No ☐ Yes
Changes in interpretation of scientific documents/value of the study:	☐ No ☐ Yes
Other change:	☐ No ☐ Yes, specify:
Original statements:	
New statements:	
Comments/explanation/reasons for substantial amendment:	

CHECKLIST DOCUMENTS TO BE SUBMIITED WITH THIS FORM (TICK AS APPROPRIATE)	
Revised Protocol with a new version number and date, highlighting amended text in bold.	☐ COMPLETED
Revised Informed Consent Form with a new version number and date, highlighting amended text in bold.	☐ COMPLETED
Revised Investigator Brochure with a new version number and date, highlighting amended text in bold.	☐ COMPLETED
Revised Instruction For Use (IFU)/Labeling, highlighting amended text in bold.	☐ COMPLETED

SIGNATURES/CERTIFICATIONS

By signing below, I certify that:

I will i) accept responsibility for the scientific and ethical conduct of the study, ii) conduct the study in accordance with the regulation of the of Medical Devices Law, the standard of good clinical practice for Clinical Investigation of Medical Devices (ISO 14155:2020), and the Requirements for Clinical Trials of Medical Devices (MDS-REQ 2).

Name	**Position**
Signature	**Date**

Annex (5): Change of Principal Investigator Form

Saudi Food and Drug Authority

Change of Principal Investigator Form

Submit this completed and signed form along with supporting materials (as applicable)

STUDY IDENTIFICATION	
Date of this submission:	Approval Letter ID:
Study title:	
Current PI name:	

NEW PRINCIPAL INVESTIGATOR	
Reason for change of PI:	
New PI Name:	Phone: Email:
Has the EC/IRB been notified of this change?	☐ Yes ☐ No, please state the reason:
Has the study subjects been notified of this change?	☐ Yes ☐ No, please state the reason:
Has study-related documents/agreements been revised to reflect the name of the new PI?	☐ Yes ☐ No, please state the reason:

CHECKLIST ATTACHMENT TO BE COMPLETED BY NEW PI	
Curriculum vitae for the new PI.	☐ COMPLETED
EC/IRB approval letter, if applicable.	☐ COMPLETED
Signed Disclosure of Principal Investigator Conflict of Interests form.	☐ COMPLETED

Amended Informed Consent Form – reflecting the name of the new PI, if applicable.	☐ COMPLETED
Amended Protocol – reflecting the name of the new PI, if applicable.	☐ COMPLETED
Amended copies of all other study-related documents containing the name of the principle investigator.	☐ COMPLETED

SIGNATURES/CERTIFICATIONS

By signing below, I certify that:

I will i) accept responsibility as Principle Investigator for the scientific and ethical conduct of the study, ii) conduct the study in accordance with the regulation of the of Medical Devices Law, the standard of good clinical practice for Clinical Investigation of Medical Devices (ISO 14155:2020), and Requirements for Clinical Trials of Medical Devices (MDS-REQ 2).

Name	**Position**
Signature	**Date**

Annex (6): Definitions and Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
MDMA	Medical Devices Marketing Authorization
NCMDR	National Center for Medical Devices Reporting
NCBE	National Committee of Bio Ethics
Medical device	Any machine, instrument, application device, culture device, laboratory reagents, laboratory calibration materials, software or operating materials for medical devices, or any similar or related device manufactured alone or in combination with other devices. It is used in the diagnosis, prevention, monitor, control, treatment, mitigation, palliation, or compensation of injuries, as well as in an examination, replacement, modification, anatomical support, influence on the functions of body organs, support or enablement of life (vital functions for humans) to continue, organize or assist pregnancy, sterilize medical devices and supplies, and give information - for a medical or diagnostic purpose - extracted from laboratory tests of samples taken from the human body, as well as that cannot achieve the goal for which they were made in or on the human body. It is mediated by the drug or the immune factor or metabolic transformations but only helps achieve their interactions.
Medical Supply	A medical material or product used in diagnosis, treatment, prosthetics, or orthotics; or in disability cases or other medical uses for humans, including medical gases.
Adverse Device Effect (ADE)	Adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. NOTE 1 This definition includes any event resulting from use error or from intentional misuse of the investigational medical device. NOTE 2 This includes ‘comparator’ if the comparator is a medical device.
Adverse event (AE)	Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device or procedure.

Authorized Representative (AR)	A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of the "Medical Devices Law and its Regulations.
Clinical Trial	Applied research in which a medical device is used on one or more persons to assess its safety and sufficiency when used.
Clinical Investigation Plan (CIP)/Clinical Study Protocol	Document that state(s) the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation.
Contract Research Organization (CRO)	Person or organization contracted by the sponsor to perform one or more of the sponsor's clinical trial-related duties and functions.
Deviation	Instance(s) of failure to follow, intentionally or unintentionally, the requirements of the CIP.
Device Deficiency (DD) medical device	Inadequacy of investigational medical device with respect to its identity, quality, durability, reliability, safety or performance. NOTE Device deficiencies include malfunctions, use errors, and inadequate labelling.
Ethics Committee (EC)	Independent body whose responsibility is to review clinical trials in the study site in order to protect the rights, safety and well-being of subjects.
Final clinical trial report	Document describing the design, execution, statistical analysis and results of a clinical investigation.
Identifying Information	Any statement, information, or illustration printed on a medical device or supply, including name of the device, code/lot or serial number, technical description, method of use, and manner of storage and transportation.
Informed Consent Form (ICF)	Process by which an individual is provided information and is asked to voluntarily participate in a clinical trial. Note: Informed consent is documented by means of a written, signed and dated informed consent form.
Innovative medical device	A medical device designed with innovative features in the technology, indications for use, or performance attributes that have no equivalence in the local/global market.
Investigator	Individual member of the investigation site team designated and supervised by the principal investigator at a study site to perform critical clinical trial-related procedures or to make important clinical trial-related decisions. NOTE An individual member of the investigation site team can also be called "sub-investigator" or "co-investigator".
Investigator's Brochure (IB)	Compilation of the current clinical and non-clinical information on the investigational medical device(s), relevant to the clinical trial.

Investigational medical device	Medical device being assessed for safety or performance in a clinical trail. NOTE 1 This includes medical devices already on the market, that are being evaluated for new intended uses, new populations, new materials or design changes. NOTE 2 The terms “investigational medical device” and “investigational device” are used interchangeably.
Principal Investigator (PI)	Qualified person responsible for conducting the clinical trial at a study site Note If a clinical trial is conducted by a team of individuals at a study site, the principal investigator is responsible for leading the team.
Study Site	Institution(s) or location(s) where the clinical trial is carried out, under the supervision of a principal investigator.
Sponsor	Individual or organization taking responsibility and liability for the initiation or implementation of a clinical trial.
Subject	Individual who participates in a clinical trial. NOTE A subject can be either a healthy volunteer or a patient.
Serious Adverse Event (SAE)	Adverse event that may directly or indirectly lead to: A. death of a patient, user or other person, B. serious deterioration in the health of patient, user or other person, that either resulted in: • life-threatening illness or injury, or • permanent impairment of a body structure or a body function, or • in-patient or prolonged hospitalization, or • medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function. C. fetal distress, fetal death, congenital abnormality or birth defect

Annex (5): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
4.1 26/12/2022	• Amendment to the scope section. • Editorial changes to the “Procedures” section. • Editorial amendment to the “Required Documents” section. • Editorial amendment to the “Definition and Abbreviations” annex. • Adding (2) annex and updating (2) annex.