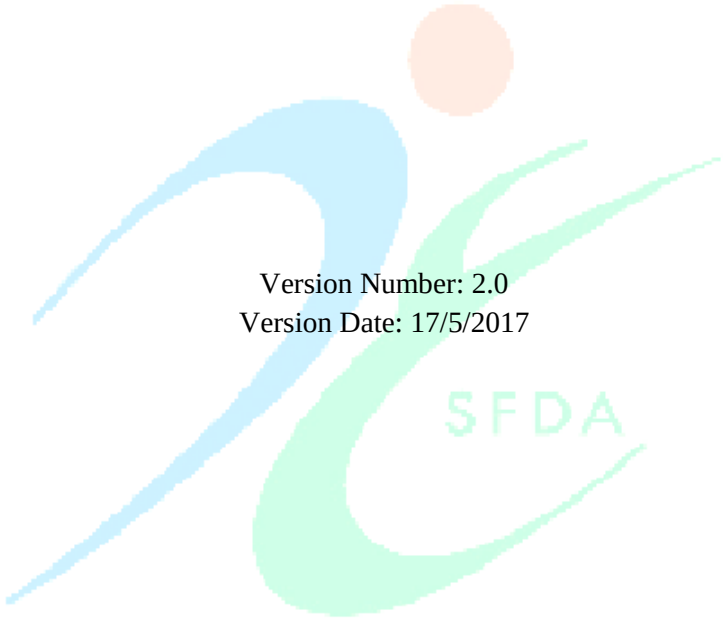
MDS – G20

GUIDANCE ON REQUIREMENTS FOR CLINICAL INVESTIGATIONS OF MEDICAL DEVICES



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DEFINITIONS & ABBREVIATIONS

Definitions

Adverse Events (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. Note 1: This definition includes events related to the investigational medical device or the comparator. Note 2: This definition includes events related to the procedures involved. Note 3: For users or other persons, this definition is restricted to events related to investigational medical devices.
Authorized Representative (AR)	means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks, including the obligation to represent the manufacturer in its dealings with the SFDA.
Clinical Investigations* (of Medical Devices) (CIMD)	systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device. Note: "Clinical trial" and "clinical study" are synonyms for "clinical investigation".
Clinical Investigation Plan (CIP)*	document that state(s) the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation. Note: The term "protocol" is synonym for "CIP". However, protocol has many different meanings, some not related to clinical investigation, and these can differ from country to country. Therefore, the term CIP is used in this International Standard.
Clinical Investigation Report*	document describing the design, execution, statistical analysis and results of a clinical investigation.
Contract Research Organization (CRO)*	person or organization contracted by the sponsor to perform one or more of the sponsor's clinical investigation-related duties and functions.
Data Monitoring Committee (DMC)*	independent committee that may be established by the sponsor to assess, at intervals, the progress of the clinical investigation, the safety data or the critical performance endpoints and to recommend the sponsor whether to continue, suspend, modify, or stop the clinical investigation. Note: Examples of DMCs are "Data Safety Monitoring Board (DSMB)" or "Data Safety Monitoring Committee (DSMC)".
Deviation*	instance(s) of failure to follow, intentionally or unintentionally, the requirements of the CIP.
Device Deficiency*	inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. NOTE: Device deficiencies include malfunctions, use errors, and inadequate labeling.
Endpoint(s)*	⟨primary⟩ principal indicator(s) used for assessing the primary hypothesis of a clinical investigation.

establishment National Registry Number	means the number issued to a person by the SFDA under the establishment registration provisions of the Medical Devices Interim Regulation.
Ethics Committee (EC)*	independent body whose responsibility it is to review clinical investigations in order to protect the rights, safety and well-being of human subjects participating in a clinical investigation. Note 1: For the purposes of this International Standard, "ethics committee" is synonymous with "research ethics committee", "independent ethics committee" or "institutional review board". The regulatory requirements pertaining to ethics committees or similar institutions vary by country or region. Note 2: In the KSA, all local ECs supervising a clinical study have to be listed in The List of Registered Local Committees at the National Committee of Bioethics (NCBE) in King Abdulaziz City for Science & Technology (KACST): http://bioethics.kacst.edu.sa/LocalCommittees/What_are-the-local-committees.aspx
Informed Consent Process*	process by which an individual is provided information and is asked to voluntarily participate in a clinical investigation. Note: Informed consent is documented by means of a written, signed and dated informed consent form.
Investigation Site*	institution or site where the clinical investigation is carried out. Note: For the purpose of this International Standard, "investigation site" is synonymous with "investigation centre".
Investigational Medical Device*	medical device being assessed for safety or performance in a clinical investigation. 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: In this International Standard, the terms "investigational medical device" and "investigational device" are used interchangeably.
Investigator*	individual member of the investigation site team designated and supervised by the principal investigator at an investigation site to perform critical clinical-investigation-related procedures or to make important clinical-investigation-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 investigation
Labelling	means written, printed or graphic matter A. Affixed to a medical device or any of its containers or wrappers. B. Information accompanying a medical device, related to identification, technical description. C. Information accompanying a medical device, related to its use, but excluding shipping documents.

Legally Authorized Representative*	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 investigation.
Medical Device	means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: o Diagnosis, prevention, monitoring, treatment or alleviation of disease, o Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, o Investigation, replacement, modification, or support of the anatomy or of a physiological process, o Supporting or sustaining life, o Control of conception, o Disinfection of medical devices, o Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; And B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
Medical Devices National Registry (MDNR)	is the database of registered establishments and the medical devices they manufacture or import or distribute.
National Centre for Medical Device Reporting (NCMDR)	means an organization managing a database of information on safety and/or performance related aspects of medical devices and employing staff capable of taking appropriate action on any confirmed problems.
Objective*	main purpose for conducting the clinical investigation
Point Of Enrolment*	time at which, following recruitment, a subject signs and dates the informed consent form.
Principal Investigator*	qualified person responsible for conducting the clinical investigation at an investigation site Note 1 If a clinical investigation is conducted by a team of individuals at an investigation site, the principal investigator is responsible for leading the team. Note 2 Whether this is the responsibility of an individual or an institution can depend on national regulations
Serious Adverse Event (SAE)*	adverse event that a) led to death, b) led to serious deterioration in the health of the subject, that either resulted in 1. a life-threatening illness or injury, or 2. a permanent impairment of a body structure or a body function, or

	3. in-patient or prolonged hospitalization, or 4. medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, c) led to foetal distress, foetal death or a congenital abnormality or birth defect Note: Planned hospitalization for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.
Sponsor*	individual or organization taking responsibility and liability for the initiation or implementation of a clinical investigation NOTE When an investigator initiates, implements and takes full responsibility for the clinical investigation, the investigator also assumes the role of the sponsor and is identified as the sponsor-investigator.
Subject*	individual who participates in a clinical investigation NOTE A subject can be either a healthy volunteer or a patient.
Vulnerable Subject*	individual whose willingness to volunteer in a clinical investigation could be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of retaliatory response from senior members of a hierarchy in case of refusal to participate example Individuals with lack of or loss of autonomy due to immaturity or through mental disability, persons in nursing homes, children, impoverished persons, subjects in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, and those incapable of giving informed consent. Other vulnerable subjects include, for example, members of a group with a hierarchical structure such as university students, subordinate hospital and laboratory personnel, employees of the sponsor, members of the armed forces, and persons kept in detention.
* Source: ISO 14155:2011	

Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
GHTF	Global Harmonization Task Force
MDNR	Medical Devices National Registry
MDMA	Medical Devices Marketing Authorization
NCMDR	National Center for Medical Devices Reporting
AR	Authorized Representative
CIMD	Clinical Investigations of Medical Devices
CRO	Contract Research Organization

CIP	Clinical Investigation Plan
EC	Ethics Committee/Institutional Review Board
IB	Investigator's Brochure
NCBE	National Committee of Bio Ethics
GCP	Good Clinical Practice
MDIL	Medical Devices Importation License

INTRODUCTION

Purpose

The purpose of this document is to clarify the requirements of conducting CIMD within the KSA.

Scope

This document is applicable to any party wishes to conduct CIMD within the KSA.

Background

In accordance with "Medical Devices Interim Regulation" issued by the SFDA Board of Directors decree No. (1-8-1429) and dated 29/12/1429 H, stipulating that medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of the Medical Devices Interim Regulation, as signified by the SFDA issuing the manufacturer with a written marketing authorization (MDMA). SFDA/MDS requires MDIL, instead of MDMA, for medical devices imported for clinical investigation. And in accordance with "Implementing Regulation of the Law of Ethics of Research on Living Creatures", SFDA requires approval for conducting CIMD within the KSA.

SFDA issues this guidance to specify the requirements to obtain MDIL and the approval for conducting CIMD in order to protect the rights, safety and well-being of participants during the clinical investigation, and to ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results.

REQUIREMENTS

General	1	Any CIMD within KSA shall be approved by SFDA before commencment.
	2	Investigational medical devices imported for clinical investigation may access KSA only if MDIL is obtained from SFDA/MDS.
Regulations and Standards	3	CIMD shall comply with the Law of Ethics of Research on Living Creatures.
	4	CIMD should be in accordance with: o Declaration of Helsinki o ISO 14155 (or any equivalent standard GCP)
Labeling Requirements	5	The labeling of the device shall comply with the requirements described in SFDA's guidance document entitled MDS – G10 Guidance on Labeling Requirements for Medical Devices.
Reporting of Serious Adverse Event and Device Deficiency	6	• The principal investigator shall report to the sponsor and the ECs about any serious adverse event without delay but not later than 48 hours of the investigator first knowing about the event. • Sponsor shall report to the SFDA's NCMDR and ECs about any serious adverse events of which it becomes aware, that involve the medical device. This shall be reported without delay but not later than five working days after the sponsor first knowing of the events. In case of multicenter studies, sponsor shall notify all principal investigators, at all investigational sites, in writing of all serious adverse events that have been reported, and ensure that all serious adverse events are reported to their ECs. • The principal investigator shall submit to the ECs and the sponsor a report about the device deficiency that leads to a medical occurrence (but not serious adverse event) without delay but not later than 10 working days of knowing about the deficiency.
Prerequisite	7	Before applying for CIMD: o the sponsor located within the KSA is required to have an Establishment National Registry Number that is issued through SFDA's MDNR. Independent individuals are exempt. o the sponsor located outside the KSA is required to assign an AR, the AR is required to have: - establishment National Registry Number that is issued through SFDA's MDNR

		- AR license (For more information, see SFDA's guidance document entitled MDS – G3 Guidance on for Authorized Representatives).
Submitting Documents to SFDA	8	Sponsor (either located within the KSA, or outside the KSA through his AR) shall submit the required documents by email to MDCI@sfda.gov.sa as follows: 1. prior to CIMD, the required documents are specified in section (A) of "REQUIRED DOCUMENTS". Once satisfied, SFDA will send a "No Objection Letter" to the applicant's email (together with MDIL if the device(s) is imported for clinical investigation). 2. during the CIMD, the required documents are specified in section (B) of "REQUIRED DOCUMENTS". 3. at the end of the CIMD, the required documents are specified in section (C) of "REQUIRED DOCUMENTS".
Inspection of the CIMD	9	SFDA has the right to inspect the CIMD without previous notification.
Reviewing Fees	10	No fees are required.

REQUIRED DOCUMENTS

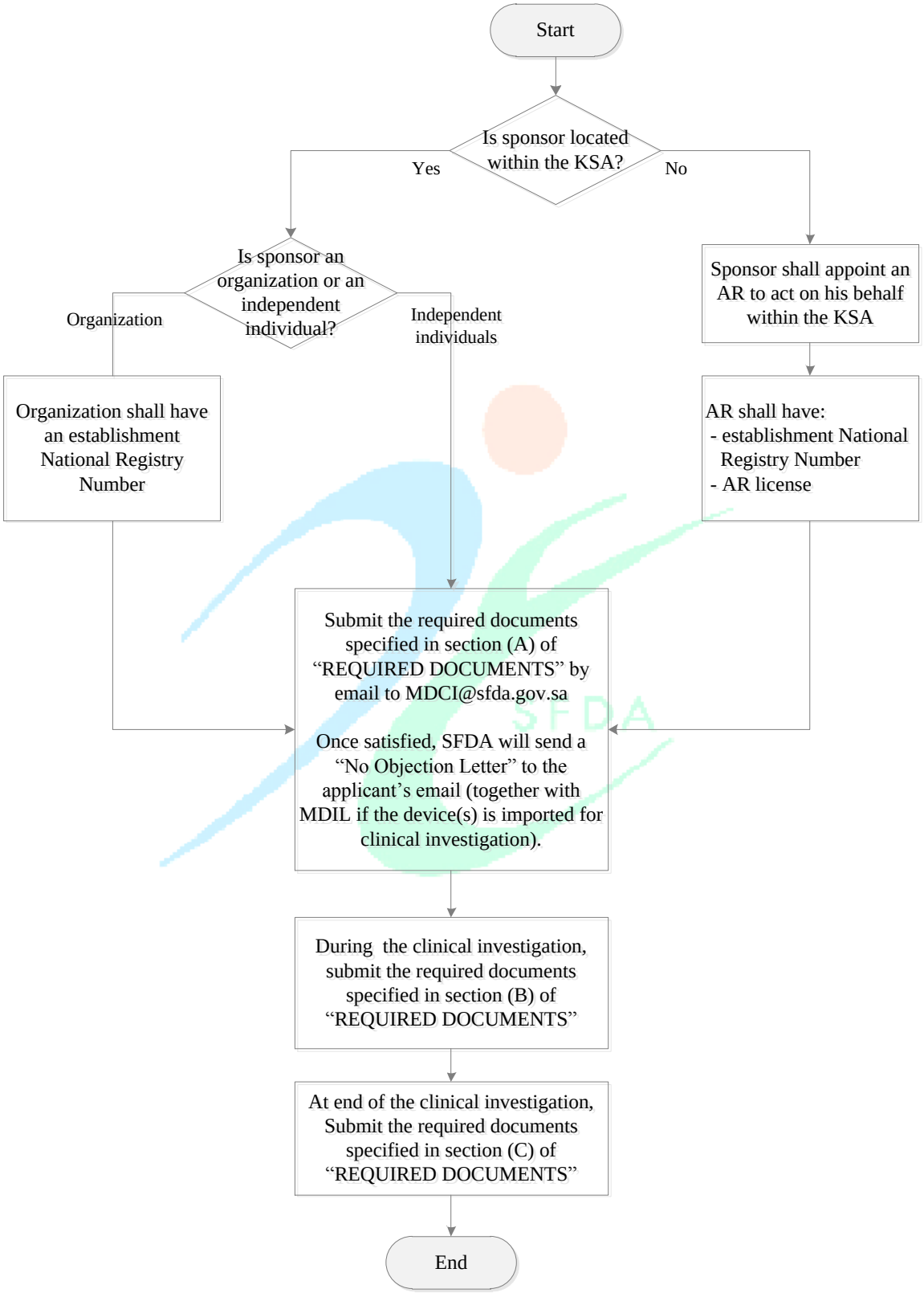
	Required Documents	Sample	Note
(A) Required documents prior to CIMD			
1	Application Form for CIMD	See Annex1	• See points (7) and (8) of "REQUIREMENTS" • SFDA responds within a week in case of missing documents. • Application reviewing time is 60 working days.
2	Labelling of device	-	• See point (5) of "REQUIREMENTS"
3	Clinical investigation agreement between sponsor and clinical investigation site(s)/principal investigator(s)	-	-
4	Clinical investigation agreement between sponsor and CRO	-	-
5	EC approval letter	-	• It is required for each site • The EC shall be registered at National Committee of Bio Ethics (NCBE)
6	Clinical Investigation Plan (CIP)	-	-
7	Investigator's Brochure (IB)	-	• It is required only for premarket studies.
8	Informed consent	-	• It shall be in Arabic and English
9	Clinical investigation insurance for subjects	-	• It shall cover the cost of treatment of subjects in the event of injuries related to clinical investigation
10	Any compensation and/or payments at any type made to the subjects (e.g. transportation expenses)		• If applicable
11	Selection report of investigation site	-	-
12	Curriculum Vitae of principal investigator(s) and investigator(s)	-	-
13	Disclosure of conflict of interest	See Annex 2	• Separate form shall be submitted for each investigator

14	Declaration of conflict of interest	See Annex 3	-
(B) Required documents during CIMD			
15	Progress Report	-	• It shall be submitted in yearly intervals
16	Change Form	See Annex 4	• Separate form shall be submitted for each change • It shall be submitted prior to major amendment(s) which includes the following: - amendment in the basic principles of device operation - amendment without supporting information collected during the investigation - amendment to informed consent - significant modification in design - changes to the CIP that affect the validity of the generated data, risk analysis, the scientific soundness of the investigation, or the rights, safety or welfare of subjects • In case of non-major amendments, it shall be submitted not later than five working days after change occurrence
17	Curriculum Vitae(s) of new principal investigator(s) and investigator(s)	-	-
18	Monitoring visit reports	-	-
19	Withdrawal of EC approval	-	• Sponsor shall notify SFDA and principal investigators in case of withdrawal of EC approval or part of it, within five working days of receiving the withdrawal notice

20	Notification on temporary halting the clinical investigation	-	• It shall be submitted to SFDA withoud dalay but not later than: - five working days in case of halting because of safety grounds - 15 working days in case of reasons other than safety grounds
21	Major deviations from the investigational plan that have a substantial impact on the safety or rights of subjects or on the robustness or reliability of the clinical data generated by the investigation	-	• It shall be submitted without delay but not later than five working days
22	Request for device recall and/or device disposition regarding return, repair, or dispose the device or a part of it	-	• It shall be submitted with justifications by sponsor to SFDA and EC within 30 working days after receiving the request from the principal investigator
23	Independent assessment from an uninvolved physician	-	• It is required only in case of emergency use of the investigational device • SFDA shall be notified about the emergency use of the device without delay but not later than five working days of the emergency use • It shall be submitted within five working days after SFDA notification
24	Evaluation report of the serious adverse events including device deficiencies that lead to serious adverse events	-	• It shall be provided to the SFDA without dealy but not later than 15 working days from the sponsor first knowing about the serious adverse event
25	Report about device deficiencies that lead to medical occurrence but not serious adverse event	-	• It shall be provided to the SFDA without dealy but not later than 30 working days from the sponsor knowing about the deficiency occurance
(C) Required documents at the end of the CIMD			
26	Notification of clinical investigation termination	-	• If applicable

27	Justifications for premature termination of a clinical investigation	-	• If applicable • It shall be submitted within 15 working days of the termination
28	Close-out notification of the investigation	-	• It shall be submitted without delay but not later than 15 working days of the termination
29	Close-out monitoring report of the investigation or Follow up letter containing a summary of key findings	-	• It shall be submitted to the SFDA and ECs without delay but not later than two months after the termination
30	Written procedure for investigational device accountability	-	-
31	Clinical investigation final report	-	• It shall be submitted to the SFDA and ECs without delay but not later than 12 months after the termination (after study database locked)

FLOWCHART


Start
Is sponsor located within the KSA?
Yes
No
Is sponsor an organization or an independent individual?
Organization
Independent individuals
Sponsor shall appoint an AR to act on his behalf within the KSA
Organization shall have an establishment National Registry Number
AR shall have:
- establishment National Registry Number
- AR license
Submit the required documents specified in section (A) of "REQUIRED DOCUMENTS" by email to MDCI@sfda.gov.sa
Once satisfied, SFDA will send a "No Objection Letter" to the applicant's email (together with MDIL if the device(s) is imported for clinical investigation).
During the clinical investigation, submit the required documents specified in section (B) of "REQUIRED DOCUMENTS"
At end of the clinical investigation, Submit the required documents specified in section (C) of "REQUIRED DOCUMENTS"
End

ANNEXES

Annex 1
Application Form for CIMD

	Date Received		(For SFDA use only)
	CIMD Application Number		(For SFDA use only)
1. Status			
1.1	Type of submission	☐ First submission ☐ Amendments to previous submission	
1.2	Aim of Study	☐ Pre-marketing approval for new device ☐ Pre-marketing approval for new claims ☐ Post-Marketing study ☐ Non Marketing study	
1.3	Type of Study	☐ Observational study ☐ Interventional study	
1.4	Does this clinical investigation involve first in human use?	☐ Yes ☐ No	
1.5	Will the investigational device be imported to KSA?	☐ Yes (MDIL is required) Please list device items in section (5.2), so they will be included in the MDIL ☐ No	
2. Sponsor Details			
2.1	Manufacturer	Name	
		establishment National Registry Number, that is issued through SFDA's MDNR (if applicable)	
		Address	
		Phone	
		Fax	
		E- mail	
		Contact person name	
		Contact person phone	
		Contact person e-mail	
2.1	AR, if applicable	Name	
		establishment National Registry Number, that is issued through SFDA's MDNR (if applicable)	
		AR license number	
		Address	
		Phone	
		Fax	
		E- mail	
		Contact person name	
		Contact person phone	

		Contact person e-mail	
2.3	Sponsor, if other than manufacturer	Name	
		establishment National Registry Number, that is issued through SFDA's MDNR (if applicable)	
		Address	
		Phone	
		Fax	
		E- mail	
		Contact person name	
		Contact person phone	
		Contact person e-mail	
2.5	Person responsible for completing the application.	Name	
		Position	
		Phone	
		E-mail	
3. CRO Details			
3.1	CRO, if applicable	Name	
		establishment National Registry Number, that is issued through SFDA's MDNR (if applicable)	
		Address	
		Phone	
		Fax	
		E- mail	
		Contact person name	
		Contact person phone	
		Contact person e-mail	
4. Sponsorship details			
4.1	Type of Sponsorship	☐ Commercial ☐ Non-commercial	
4.2	Type of sponsor	☐ local manufacturer ☐ AR ☐ Hospital ☐ Independent individuals ☐ Foundation ☐ University or Institution ☐ Other, please specify:	
4.3	Type of aid	☐ Material support ☐ Funding support ☐ Other, please specify:	
5. Investigational Device Information			
5.1	Is the device registered at SFDA?	☐ Yes, Medical Device National Listing Number issued through SFDA's	

		MDMA is: …… …… ☐ No, but registered in: ☐ Australia ☐ Canada ☐ Japan ☐ USA ☐ EU ☐ Other, please specify: …… ☐ Not registered anywhere	
5.2	Investigational Device Name		
5.3	Device Generic name (if not specified above)		
5.4	Alternative name for the device used elsewhere (if applicable)		
5.5	Is the device approved to be marketed elsewhere for other use than intended for this clinical investigation?	☐ No ☐ Yes, explain:…… …… ……	
5.6	Device Category	☐ active implantable devices ☐ anesthetic and respiratory devices ☐ dental devices ☐ electro mechanical medical devices ☐ hospital hardware ☐ non-active implantable devices; ophthalmic and optical devices ☐ reusable devices ☐ single use devices ☐ assistive products for persons with disability ☐ diagnostic and therapeutic radiating devices ☐ complementary therapy devices ☐ biologically derived devices ☐ healthcare e facility products and adaptations ☐ Laboratory equipment ☐ Other: ……	
5.7	Does the device is an implantable?	☐ No ☐ Yes, ➢ Brief description:…… …… …… ➢ Is the device intended to remain permanently in patient: ☐ No ☐ Yes	

58	Whether the device intended to be used for cosmetic rather than medical purposes	☐ 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	
5.10	Does the device incorporate, as an integral part or substance, a medicinal product in achieving its primary intended action?	☐ No ☐ Yes ➢ Brand name of drug:…… ➢ Active ingredient:…… ➢ Drug manufacturer:…… ➢ SFDA Drug Registration Number (if Applicable):……	
5.11	Does the device incorporate a substance of animal origin?	☐ No ☐ Yes ➢ Type of tissue, cell, or substance:……	
5.12	Does the device incorporate human tissue, cell, or substance?	☐ No ☐ Yes ➢ Type of tissue, cell, or substance:……	
5.13	Does the device incorporate cells or substance of microbial origin?	☐ No ☐ Yes ➢ Type of microorganism:……	
5.14	The intended purpose of the device		

5.15	Targeted patient population as intended by the manufacturer	☐ All patient ☐ Specific group of patients ➢ Clearly defined:…….……..	
5.16	Nomenclature code number (if any):	☐ GMDN:…… ☐ UMDNS:……..…….. ☐ Other:……	
5.17	Device classification based on GHTF guidance "Principles of Medical Devices Classification"	☐ A ☐ B ☐ C ☐ D	
5.18	Device Classification in other countries	☐ Country:…… ☐ Class:…… ☐ Country:…… ☐ Class:…… ☐ Country:…… ☐ Class:……	
6. Design of Clinical Investigation			
6.1	Clinical Investigational Plan title	Scientific title	
		Abbreviated title	
6.2	Clinical Investigational Plan (CIP) information	CIP number	
		CIP date	
		CIP version	
6.3	Clinical investigation objective(s)	Primary objective(s)	
		Secondary objective(s)	
6.4	Clinical investigation endpoint(s)	Primary endpoint(s)	
		Secondary endpoint(s)	
6.5	Type of Design	☐ Open-label non-randomized clinical investigation ☐ Randomization, Randomized controlled clinical investigation o Parallel group: …… o Cross over: …… ☐ Blinding ☐ Single blinded ☐ Double blinded ☐ Other ☐ Comparator used ☐ Placebo ☐ Comparator device, identify: ……	
6.6	Subject health status	☐ Healthy volunteers ☐ Patients ☐ Both	
6.7	Subjects Gender	☐ Male ☐ Female	

		☐ Both	
6.8	Does this study includes vulnerable subjects?	☐ No ☐ Yes	
6.9	Size of the sample population	Planned total number of subjects involved in the clinical investigation	
		Planned number of subjects involved in the KSA	
6.10	Number of study centers in the KSA		
6.11	Other countries where this clinical investigation is carried out		
6.12	Inclusion / Exclusion Criteria	Reference page in the CIP for inclusion criteria	
		Reference page in the CIP exclusion criteria	
6.13	Duration of the study	Planned start date	
		Planned completion date	
6.14	Is there a Data Safety Monitoring Committee for this study?	☐ Yes ☐ No	
7. Investigation Site(s) in the KSA			
7.1	Site 1	Name	
		Address	
		Phone	
		E-mail	
		Name of principal investigator	
		EC name	
		EC address	
		EC phone	
		EC e-mail	
		Protocol number approved by HREC/EC	
7.2	Site 2	Name	
		Address	
		Phone	
		E-mail	
		Name of principal investigator	
		EC name	
		EC address	
		EC phone	
		EC e-mail	
		Protocol number approved by HREC/EC	
Add			
8. Declaration			
8.1	I, the sponsor defined in this application,:		

	☐ undertake that I comply with the Law of Ethics of Research on Living Creatures. ☐ undertake that I will report to the SFDA's NCMDR, ECs, principal investigators and investigators any serious adverse event of which I become aware that involves the medical device; without delay but not later than 10 working days of occurrence. ☐ undertake that I will provide the documents specified in sections (B) and (C) of "REQUIRED DOCUMENTS" in SFDA's guidance document entitled MDS – G20 Guidance on Requirements for Clinical Investigations of Medical Devices. ☐ undertake to notify ECs, principal investigators and investigators in case of withdrawal of SFDA's approval, or part of it, within five working days of receiving the withdrawal notice. ☐ undertake, under any request from the ECs, and/or SFDA, to respond by providing accurate, current, and complete information about any aspects of the study. ☐ declare that SFDA has the right to inspect the study at any time without previous notification. ☐ declare that all information provided in this application is true and complete. Name: Position: Date: Signature:

Annex 2
Disclosure of Conflict of Interests

Title of Clinical Invstigation Plan	
Date received:	(For SFDA use only)
CIMD Application Number:	(For SFDA use only)

I disclose the following regarding the involvement in the investigation in the submitted application:

- ☐ any financial arrangement entered into between the sponsor and the clinical investigator, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;
- ☐ any significant payments of other type made from the sponsor, including but not limited to a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;
- ☐ any proprietary interest in the investigational product held by the clinical investigator;
- ☐ any considerable equity interest (including but not limited to any ownership interest, stock deal, or other financial interest) held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

Name of sponsor:
Position:
Date:
Signature:

Note: Separate form shall be submitted for each principal investigator and investigators investigator.

Annex 3
Declaration of Conflict of Interests

Title of Clinical Invstigation Plan	
Date received:	(For SFDA use only)
CIMD Application Number:	(For SFDA use only)

As the sponsor of the relevant clinical investigation(s) defined in the CIMD application in which this certificate is attached and submitted, I certify that:

- ☐ I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) by which the value of compensation to the investigator could be affected by the outcome of the study. The effects include but not limited to any payments and/or compensation in any form that could be greater meant for afavorable outcome than for an unfavorable outcome, such as a royalty interest.
- ☐ Each listed clinical investigator required to disclose to the sponsor whether the investigator has a proprietary interest (or other financial interest in the product including, but not limited to, a patent, trademark, copyright or licensing agreement) in the investigational product or a considerable equity (including but not limited to any ownership interest, stock deal, or other financial interest) in the sponsor did not disclose any such interests.
- ☐ No listed investigator was the recipient of payments of other type excluding the cost of conducting the study.

Name:
Position:
Date:
Signature:

Annex 4
Change Form for CIMD

Date:	
CIMD Application Number:	
1. The document type where the change occur	
2. The original statement	
3. The changed statement	
4. Reason of change	

Note: Separate form shall be submitted for each change.