

SFDA – Medical Device Sector
Clinical Investigations for Medical Device
(CIMD)

Version Number :1.0 Version Date: 27/05/2015

TABLE OF CONTENT

Part 1. DEFINITIONS	3
Part 2. INTRODUCTION	11
Subpart 2.1. Purpose.....	11
Subpart 2.2. Scope.....	11
Part 3. SFDA CIMD APPLICATION	13
Part 4. SFDA CIMD DECLARATION	23
Part 5. SFDA CIMD ATTACHMENTS	24
Part 6. SFDA CIMD REQUIREMENTS FOR LABELLING	27
Part 7. SFDA CIMD REQUIREMENTS FOR REPORTING PROGRESS	29
Subpart 7.1. Principal Investigator Reporting	29
Subpart 7.2. Sponsor Reporting	30
Part 8. SFDA CIMD CHANGE FORM	32
Part 9. NO USE DECLARATION FOR PORT OF ENTRY CLERANCE.....	33
Part 10. REVIEWING FEE	34

PART 1. Definitions

For the purpose of this guidance, the following definitions apply.

KSA means the Kingdom of Saudi Arabia.

Saudi Food and Drug Authority (SFDA) is the government entity with legal responsibility for regulating medical devices in KSA.

SFDA National Registry (MDNR) is an online database of registered organizations and the regulated devices the SFDA has authorized to be placed on the KSA market.

SFDA National Center for Medical Device Reporting (NCMDR) is an online submission portal within the SFDA that devoted to (i) receive adverse events reports and feedback information about any medical devices and (ii) manages a database of information on safety and/or performance related aspects of regulated devices, and (iii) has the capability of taking appropriate action on any confirmed problems.

SFDA Medical Devices Establishment Licensing System (MDEL) is an online submission licensing medical devices establishments involved in importation and/or distribution of medical devices in Saudi market including importer, local distributor, local manufacturer and authorized representative.

Adverse Device Effect ADE means adverse event related to the use of an investigational medical device. This includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. This definition also includes any event resulting from use error or from intentional misuse of the investigational medical device.

Adverse Event AE means any malfunction or deterioration in the characteristics and/or performances of a medical device, including any inadequacy in its labelling or the instructions for use, or use error, which may compromise the health or safety of patients, users or third parties.

Authorized Representative 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.

Audit means a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Blinding/Masking means a procedure in which one or more parties to the clinical investigation are kept unaware of the treatment assignment(s). Single blinding usually refers to the subject(s) being unaware of the treatment assignment(s). Double blinding usually refers to the subject(s), investigator(s), monitor and, in some cases, centralized assessors being unaware of the treatment assignment(s).

Case Report Forms CRFs means a set of printed, optical or electronic documents for each subject on which information to be reported to the sponsor is recorded, as required by the CIP.

Case Series means the investigational device has been used in a series of patients and the results reported, with no control group for comparison.

Clinical Data means safety and/or performance information that are generated from the clinical use of an investigational device.

Clinical Evaluation means the assessment and analysis of clinical data pertaining to an investigational device to verify the clinical safety and performance of the device when used as intended by the manufacturer.

Clinical Evidence means the clinical data and the clinical evaluation report pertaining to an investigational device.

Clinical Investigation is a systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device for marketing purpose. The term “**Clinical trial**” or “**clinical study**” are synonymous with “**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. The term “**protocol**” sometimes used as a synonymous with “**Plan**”. **Note:** In the CIP copy submitted to the Reviewing IRBs, an Arabic translation of the CIP summary must be provided.

Clinical Investigation Report is a written form document describing the identification of the device(s), the methodology, the design, any deviations from the CIP, execution, data analysis together with statistical analysis, a critical appraisal of the aims of the clinical investigation, and results of a clinical investigation.

Clinical Performance means the ability of an investigational device to achieve its intended purpose as claimed by the manufacturer.

Clinical Safety means the absence of unacceptable clinical risks, when using the Investigational device according to the manufacturer's Instructions for Use.

Ethics Committee (EC), Research EC (REC), Human REC (HREC), Independent EC (IRC), Institutional Review Board (IRB) an independent body whose responsibility is to review clinical investigations in order to protect the rights, safety and well-being of human subjects participating in a clinical investigation.

For the purposes of this guidance, "ethics committee" is synonymous with "Research Ethics Committee", "Human Research Ethics Committee", "Independent Ethics Committee" or "Institutional Review Board".

Such ECs must have a valid accreditation from the National Committee of Bioethics in King Abdulaziz City for Science and Technology.

Comparator is medical device, therapy (e.g. active control), placebo or no treatment, used in the reference group in a clinical investigation.

Completion Date means the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical investigation concluded according to the prespecified protocol or was terminated.

Contract Research Organization CRO means a person or organization contracted by the sponsor to perform one or more of the sponsor's clinical investigation-related duties and functions.

Coordinating Investigator is an investigator who is appointed by the sponsor to coordinate work in a multicenter clinical investigation.

Deviation instance(s) of failure to follow, intentionally or unintentionally, the requirements of the CIP.

Device Deficiency means inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Device deficiencies include malfunctions, use errors, and inadequate labelling.

Endpoint(s) means indicator(s) measured or determined to assess the objectives of a clinical investigation, prospectively specified in the clinical investigation plan.

- I. (primary) principal indicator(s) used for assessing the primary hypothesis of a clinical investigation.
- II. (secondary) indicator(s) used for assessing the secondary hypotheses of a clinical investigation.

Family of medical devices is a group of medical devices that are made by the same manufacturer, that differ in only shape and features, that have a similar design and that have the same common intended use.

Global Harmonization Task Force (GHTF) are countries working to achieve harmonization in medical device regulation among themselves. These countries are Australia, Canada, Japan, the USA and the EU/EFTA. The GHTF is no longer exist and now it is known as the he International Medical Device Regulators Forum (IMDRF).

GHTF Founding Member jurisdictions namely Australia, Canada, Japan, USA or the EU.

Home use medical device is a medical device intended to be used outside healthcare facility by non-healthcare professional.

Hypothesis is an attestable statement, resulting from the objective, regarding the investigational medical device safety or performance that is used to design the clinical investigation and that can be accepted or rejected based on results of the clinical investigation and statistical calculations. The primary hypothesis is the determinant of the investigational medical device safety or performance parameters and is usually used to calculate the sample size. Secondary hypotheses concerning other points of interest can also be evaluated.

Independent means a body not involved in the conduct of a clinical investigation, except for their specifically assigned responsibilities, in order to avoid bias or a conflict of interest.

Informed consent process refer to a process by which an individual is provided information and is asked to voluntary participate in a clinical investigation. Informed consent is documented by means of a written, signed and dated informed consent form.

Instructions for Use means information provided by the manufacturer to inform the device user of the medical devices intended purpose and proper use and of any precautions to be taken.

Intended Use / Purpose means the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions for use and information provided by the manufacturer.

Investigation Site is a site where the clinical investigation is carried out. For the purpose of this guidance, “investigation site” is synonymous with “investigation center”.

Investigational Medical Device is a medical device or in vitro diagnostic device being assessed for safety or performance in a clinical investigation. The definition cover other product including prescription eyeglasses, contact lenses and their solutions. This includes medical devices already on the market, that are being evaluated for new intended uses, new populations, new materials or design changes.

In this guidance, the terms “investigational medical device” and “investigational device” are used interchangeably.

Investigator is an 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.

An individual member of the investigation site team can also be called “sub-investigator” or “co-investigator”.

Investigator's Brochure (IB) is a compilation of the current clinical and non-clinical information on the investigational medical device(s), relevant to the clinical investigation.

In Vitro Diagnostic (IVD) medical device means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. IVD is a synonym of near patient IVD.

Label means the written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

Labelling means the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

Legally Authorized Representative: is an individual or judicial or other body authorized under applicable SFDA law to consent, on behalf of a prospective subject to the subject's participation in the clinical investigation.

Malfunction means a failure of an investigational medical device to perform in accordance with its intended purpose when used in accordance with the instructions for use or CIP.

Manufacturer refer to any natural or legal person with responsibility for design and/or manufacture of an investigational device with the intention of making the device available for use, under his name; whether or not such a device is designed and/or manufactured by that person himself or on his behalf by another person(s).

Medical Device means any instrument, apparatus, implement, machine, appliance, implant, 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:

- 1) Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- 2) Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- 3) Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- 4) Supporting or sustaining life,
- 5) control of conception,
- 6) Disinfection of medical devices, and
- 7) Providing information 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, in or on the human body, but which may be assisted in its intended function by such means.

Medical Device System refer to comprises of a number of constituent-components to complete a common intended purpose.

Monitoring is the act of overseeing the progress of a clinical investigation and to ensure that it is conducted, recorded, and reported in accordance with the CIP, written procedures, this International Standard, and the applicable regulatory requirements.

Multicenter Investigation refer to a clinical investigation that is conducted according to a single CIP and takes place at two or more investigation sites.

Objective means the main purpose for conducting the clinical investigation.

Point of Enrolment refer to the time at which, following recruitment, a subject signs and dates the informed consent form.

Principal Investigator is a qualified person responsible for conducting the clinical investigation at an investigation site.

If a clinical investigation is conducted by a team of individuals at an investigation site, the principal investigator is responsible for leading the team.

Randomization refer to the process of assigning subjects to the investigational medical device or comparator groups using an established recognized statistical methodology to determine the assignment in order to reduce bias.

Recruitment refer to the active efforts to identify subjects who may be suitable for enrolment into the clinical investigation.

Residual risk means the risk remaining after risk control measures have been taken.

Risk Management means the systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk.

Serious Adverse Device Effect SADE refer to the adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Serious Adverse Event SAE, are the 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
- 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.

Single Medical Device is a medical device from a manufacturer identified by a medical device proprietary name with a specific intended purpose. It is sold as a distinct packaged entity and it may be offered in a range of sizes, quantity and color.

Source Document refer to the printed, optical or electronic document containing source data.

Examples Hospital records, laboratory notes, device accountability records, photographic negatives, radiographs, records kept at the investigation site, at the laboratories and at the medico-technical departments involved in the clinical investigation.

Sponsor means an individual or organization taking responsibility and liability for the initiation or implementation of a clinical investigation.

Start Date is the date of the clinical investigation initiation when the enrollment to the protocol begins.

Subject is an individual who participates in a clinical investigation. A subject can be either a healthy volunteer or a patient.

Test Kit means an in vitro diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test.

Unanticipated Serious Adverse Device Effect (USADE) refer to the serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk analysis report.

Use Error means an act, or omission of an act relating to the use of a product within the scope of this Regulation, whereby the resulting outcome is different from that intended by the manufacturer or expected by the user.

User means the person, either professional, lay or patient, who uses an investigational device within the scope of this Regulation.

Vulnerable Subject refer to an 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.

PART 2.Introduction

Subpart 2.1. Purpose

Individuals, institutes, manufacturers, authorized representatives or distributors may choose to undertake one or more clinical investigations within the KSA either for marketing (to other regulator than SFDA) or scientific purposes. This document offers guidance to the parties concerned in such circumstances.

Clinical Investigation should be conducted in accordance with the Declaration of Helsinki, The National Committee of Medical & Bioethics, GCP/ISO 14155, and this guidance.

Subpart 2.1. Scope

All clinical investigations of medical device conducted within the Kingdom of Saudi Arabia must obtain the SFDA approval before their commencement. No investigational device will be cleared from any port entry before obtaining SFDA CIMD approval. The sponsor can also submit a port of entry clearance letter prior to SFDA completion of the reviewing process (**refer to Part 9: No Use Declaration for Port of Entry Clearance**). All investigational devices must comply with the labeling requirements (**refer to Part.6**) along with the reporting progress requirements (**refer toPart.7**)

This guidance applies the following products:

- a) Any product that meets the definition of the term ‘medical device’ and has to undergo clinical investigations.
- b) An accessory to an authorized medical device, shall be treated as if it is a medical device in its own right
- c) An authorized medical device incorporating substances of animal origin.
- d) An authorized medical device incorporating human tissues, cells and substances.

- e) An authorized medical device incorporating cells and substances of microbial origin.

And to the following parties if they choose to undertake a clinical investigation:

- f) Any party that meets the definition of the term ‘manufacturer’.
- g) Manufacturers’ authorized representatives.
- h) Clinical investigation sponsors, when different from manufacturer.
- i) Research institutes, universities, and healthcare facilities.
- j) Clinical Research Organization (CRO).

PART 3. Application

For SFDA use only

Date Received: day/month /year

Application Number:

1. STATUS

- **Type of submission**
 - First submission
 - Amendments to previous submission.
- **Aim of Study**
 - Pre-marketing approval for new device
 - Pre-marketing approval for new claims
 - Post-Marketing study
 - Non Marketing study
- **Does this clinical investigation involve first in human use:**
 - Yes
 - No

2. CONTACT DETAILS

Manufacturer:		Contact for this Clinical investigation
Name		name:
SFDA number, if applicable		
Street/road	Number/house/floor	Phone
Postal code	City	Fax

State/Region	Country	E- mail
Authorised Representative within the KSA if applicable:		Contact for this Clinical investigation
Name		name:
SFDA number		
Street/road	Number/house/floor	Phone
P.O.Box	City	Fax
Postal Code	Region	E- mail
Sponsor, if other than manufacturer:		Contact for this Clinical investigation
Name		name:
SFDA number, if applicable		
Street/road	Number/house/floor	Phone
Postal code	City	Fax
State/region	Country	E- mail
CRO, if applicable:		Contact for this Clinical investigation
Name		name:
SFDA number, if applicable		
Street/road	Number/house/floor	Phone
Postal code	City	Fax
State/region	Country	E- mail

- **Type of Sponsorship**

- Commercial
- Non-commercial

- **Type of sponsor**
 - Legal local manufacturer of the device
 - Authorized representative of the global legal manufacturer
 - CRO
 - Hospital
 - Investigator/physician
 - Foundation
 - University or Institution
 - Other, please specify

- Type of aid
 - Material support
 - Funding support
 - Other, please specify

- **Contact details of the individual responsible for completing the application**
 - 1..1. Name
 - 1..2. Role
 - 1..3. Phone number
 - 1..4. Email

3. INVESTIGATIONAL DEVICE INFORMATION

- **Is the device registered in SFDA**
 - Yes, Registration Number:
 - No, but registered in:
 - FDA
 - EMA
 - Health Canada
 - TGA
 - Other, please specify
 - Not registered anywhere**

- **Device Name:** _____

- **Generic name of the medical device (if name not specified above)**
- **Name used elsewhere to market same medical device (if applicable)**
- **Is the investigational medical device approved to be marketed elsewhere for other use than intended for this clinical investigation? explain**
- **Device Category, select for MD**
 - Anaesthesiology
 - Cardiovascular
 - Dental
 - Ear, Nose and Throat
 - Gastroenterology and Urology
 - General and Plastic Surgery
 - Neurology
 - Obstetrics & Gynaecology
 - Ophthalmology
 - Orthopaedics
 - Physical Medicine
 - Radiology/Imaging
 - General Hospital
 - Other (.....)
- **Device Category, select for IVD**
 - Chemistry
 - Hematology
 - Immunology
 - Microbiology
 - Pathology
 - Clinical Toxicology
 - Other (.....)
- **Device Category, for more description (.....)**

- **Device Type; select the appropriate**
 - Single medical device
 - Medical device family
 - Medical device system
 - Test kit
 - Near patient IVD
 - Home use device
 - Other (.....)

- **Does the investigational device is an implantable?**
 - No
 - Yes,
 - Brief description of the implantable investigational device (.....)
 - Is the implantable investigational device intended to remain permanently in patient:
 - No
 - Yes

- **Whether the investigational device intended to be used for cosmetic rather than medical purposes**
 - No
 - Yes, Select:
 - A non-corrective contact lens; or
 - An implant for augmentation, fixation, or sculpting of body parts; or
 - A facial or other skin filler; or
 - Equipment for liposuction; or
 - Surgical laser equipment.

- **Does the investigational 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 Identification Number (if Applicable):

- **Does the investigational device incorporate a substance of animal origin?**
 - No
 - Yes
 - Type of tissue, cell, or substance

- **Does the investigational device incorporate human tissue, cell, or substance**
 - No
 - Yes
 - Type of tissue, cell, or substance

- **Does the investigational device incorporate cells or substance of microbial origin:**
 - No
 - Yes
 - Type of microorganism

- **The intended purpose of the investigational device.**

- **Targeted patient population as intended by the manufacturer**
 - All patient
 - Specific group of patients
 - Clearly defined.....

- **The investigational device's GMDN code (if applicable).**

- **Other internationally recognized nomenclature if no GMDN code is available.**

- **IMDRF (former GHTF) Classification of the investigational device ([click her for classification guidance](#))**
 - A
 - B
 - C
 - D

- **Classification of the investigational device in other countries involved in the same clinical investigation or where the device is already on the market**
 - Country
 - Class

4. DESIGN OF CLINICAL INVESTIGATION

- **Clinical Investigational Plan title**
 - Scientific title:
 - Abbreviatedtitle:

- **Clinical Investigational Plan (CIP) information**
 - CIP number
 - CIP date
 - CIP version

- **Clinical investigation objective(s)**
 - Primary objective(s)
 - Secondary objective(s)

- **Clinical investigation endpoint(s)**
 - Primary endpoint(s)
 - Secondary endpoint(s)

- **Type of Design**
 - Open-label non-randomized clinical investigation
 - Randomization
 - Randomized controlled clinical investigation
 - Parallel group:
 - Cross over:
 - Blinding
 - Single blinded
 - Double blinded
 - Other
 - Comparator used
 - Placebo
 - Comparator device, if yes identify

- **Subject health status**

- Healthy volunteers
- Patients
- Both

- **Subjects Gender**

- Male
- Female
- Both

- **Does this study includes vulnerable subjects?**

- No
- Yes

- **Size of the sample population**

- Planned total number of subjects involved in the clinical investigation
- Planned number of subjects involved in the KSA

- Number of study centers in the KSA
- Other countries where this clinical investigation is carried out
- Inclusion / Exclusion Criteria

# Inclusion criteria	Reference page in the CIP	# Exclusion criteria	Reference page in the CIP

- **Duration of the study**
 - Planned start date
 - Planned completion date
- **Is there a Data Safety Monitoring Committee for this study**
 - Yes
 - No

5. INVESTIGATION SITE(S) IN THE KSA

	1	2	3
Name and address of the Site			
Site contact (phone + email)			
Name of principal investigator			
Name and address of the reviewing IRBs			
Reviewing IRBs contact (phone + email)			
Protocol number approved by HREC/IRB			

PART 4. Sponsor / Legal Manufacturer / Authorized Representative / CRO Declaration

I am the **sponsor** defined in **Part 3.2.SPONSOR DETAILS** -of this guidance declare that:

- I hereby certify that information provided in this notification is correct and is carried out in accordance with the Declaration of Helsinki, The National Committee of Medical & Bioethics, GCP/ISO 14155, the applicable regulatory requirement(s).and the attached clinical investigation plan.
- I declare that all information provided in the clinical investigation application is true and complete.
- I declare that I will maintain the labeling requirements as described in **Part.6** of this guidance.
- I declare that I will maintain the reporting progress as described in **Part.5** of this guidance.
- OTHER, under any request from the reviewing IRBs, and the SFDA, I have to response by providing accurate, current, and complete information about any aspects of the study.

Name:

Position:

Address:

Date:

Signature:

PART 5. Compulsory Attachment

The sponsor conducting the clinical investigation should maintain the progress of providing the compulsory attachment in accordance with SFDA requirements (refer to **Part.7 Requirements for Reporting Progress**) together with the ISO 14155:2011 requirements.

A. Prior to Clinical Investigation:

- The labeling of the device. (The investigational device, the instructions for use and the packaging shall indicate that the investigational device is exclusively for use in a clinical investigation in English and Arabic).
- Clinical investigation agreement between sponsor/principal investigator and clinical investigation site.
- The clinical investigation agreement between sponsor and CRO (if applicable).
- Reviewing IRBs official approval letter.
- Clinical investigation plan (CIP) in accordance to ISO 14155:2011.
- In the CIP copy submitted to the Reviewing IRBs, an Arabic translation of the CIP summary must be provided.
- Investigator Brochure in accordance to ISO 14155:2011.
- Informed consent in Arabic & English language in accordance with the ISO 14155:2011.
- A copy of the clinical investigation insurance policy with a local insurer covering subjects participation in the in the clinical investigation.
- Selection report of investigation site.
- Curriculum Vitae of investigator(s) and sub-investigators.

B. During Clinical Investigation:

The sponsor conducting the clinical investigation should maintain the progress of providing the compulsory attachment in accordance with SFDA requirements (refer to **Part.7 Requirements for Reporting Progress**) together with the ISO 14155:2011 requirements.

- Progress reports.
- Any change to the investigators brochure.
 - refer to **Part.8** “Changes Form”
- Any change to the investigation plan.
 - refer to **Part.8** “Changes Form”
- Any changes to Informed Consent, advertisement, patient information documents.
 - refer to **Part.8** “Changes Form”
- Dated approval of IRB of the amended documents.
- Curriculum vitae for new investigators.
- Suspension of the clinical investigation and notification of resuming the investigation after suspension.
- Monitoring visit reports.

C. After Clinical investigation:

The sponsor conducting the clinical investigation should maintain the progress of providing the compulsory attachment in accordance with SFDA requirements (refer to **Part.7 Requirements for Reporting Progress**) together with the ISO 14155:2011 requirements.

- Notification of clinical investigation termination (including early termination).
- Close-out monitoring report.

- Investigational device accountability.
- Clinical investigation report.

PART6. Labelling Requirements of **the Investigational Device**

The investigational device or its immediate packaging must show a label with the following information:

1. Labelling of the investigational devices shall identify the device and its manufacturer (the name and place of the manufacturer) communicate safety and performance related information to the user.
2. The quantity of content.
3. The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the investigational device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s).
4. If it is not practicable or appropriate, for the information required on the label to be provided on the device itself, some or all of that information shall appear on the packaging for each unit, and/or on the packaging of multiple devices.
5. The following statement must be clearly presented on each unit of the investigational device itself and on the packaging for each unit, and/or on the packaging of multiple devices “CAUTION: Investigational Device Restricted for Investigational Use”.
6. Instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.
7. Instructions for use shall be provided in a means appropriate for, and accessible to, the anticipated user population. This may be either in paper or non-paper format. Examples of non-paper formats are on a screen incorporated into the device, downloaded from the manufacturer’s web site using the internet, and machine-readable sources. Where instructions for use are provided on a medium other than paper, the manufacturer shall ensure the user has information on how to:
 - view the instructions for use;
 - access the correct version of the instructions for use; and
 - obtain a paper version of the instructions for use, if such is required.
8. Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contraindications, interfering substance or device, precautions, or warnings in the labelling.

9. Labels and instructions for use in the English language are acceptable where the user(s) of the product is likely to be qualified professionals.
10. The manufacturer's instructions to importers and distributors in order to ensure that investigational devices will be correctly handled, stored, and transported during the supply chain. Such instructions shall be in both the Arabic and English languages and in a format that makes them accessible to the importer or distributor without removing protective packaging from the product.

PART 7. Requirements for Reporting

Progress

These requirements apply on any clinical investigation of medical device involving human subjects. SFDA requires the following progress reporting:

7.1. Principal Investigator Reporting:

- **SERIOUS ADVERSE DEVICE EFFECTS AND UNANTICIPATED SERIOUS ADVERSE DEVICE EFFECTS**, an investigator should submit to the sponsor and to the reviewing IRBs a report of any unanticipated adverse device effect as soon as possible but maximally within 3 calendar days of the investigator first know of the effect.
- **PROGRESS REPORT**; the investigator is expected to submit reports on the investigation progress to the sponsor, and there viewing IRBs in a regular time base, not less of a yearly intervals.
- **MAJOR DEVIATIONS FROM THE INVESTIGATIONAL PLAN**. Any major deviation caused by the principal investigator, and that have a substantial impact on the safety or rights of the subjects, or on the robustness or reliability of the clinical data generated by the investigation must be reported to the sponsor, and there viewing IRBs as soon as possible but not later than 3 working days.
- **EMERGENCY DEVIATIONS FROM THE INVESTIGATIONAL PLAN**. An investigator shall notify the sponsor, reviewing IRBs, and SFDA of any emergency deviation from the investigational plan to protect a subject in an emergency situation. Such notice shall be given as soon as possible, but not later than 2calendar days after the emergency occurred. Refer to **ISO 14155:2011** for details on emergency use.
- **RECALL AND DEVICE DISPOSITION**, an investigator should notify the SFDA about any request from the investigator regarding return, repair, or dispose the

device or a part of it. A justification of such request should be attached. This should be made within 30 working days after receiving the request.

- **CLINICAL INVESTIGATION REPORT**, an investigator should send a clinical investigation report to the reviewing IRBs and SFDA within 6 months of the completion or termination of the full investigation in all centers, or the investigator's part of the investigation.

7.2. Sponsor Reporting:

- **SERIOUS ADVERSE DEVICE EFFECTS AND UNANTICIPATED SERIOUS ADVERSE DEVICE EFFECTS**, the sponsor whose responsibility to evaluate adverse device and unanticipated adverse device effects should submit the result of the evaluations to the SFDA National Center for Medical Devices Reporting (SFDA-NCMDR), reviewing IRBs, and involving investigators as soon as possible but maximally within 10 working days of first know of the effect. An additional report regarding the effects need to be submitted upon the SFDA request.

- **WITHDRAWAL OF IRBs APPROVAL**, the sponsor should notify to the SFDA, all reviewing IRBs, participating investigator when withdraw of approval of an investigation or a part of an investigation happen ,to the investigation or a part of it, within 5 working days since receive the withdraw notice.

- **WITHDRAWAL OF SFDA APPROVAL**, the sponsor should notify to the reviewing IRBs, participating investigator when withdraw of approval happen by the SFDA, to the investigation or a part of it, within 5 working days since receive the withdraw notice.

- **MAJOR DEVIATIONS FROM THE INVESTIGATIONAL PLAN**, any major deviation caused by the principal investigator(s), and 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 must be reported by the sponsor to SFDA within 5 working days.

- **PROGRESS REPORT**; the sponsor is expected to submit reports about the investigation progress to reviewing SFDA in a yearly intervals.
- **RECALL AND DEVICE DISPOSITION**, the sponsor should notify the SFDA about any return, repair, or disposal of the device or a part of it. A report justifying such action request should be attached. This should be made within 30 working days after receiving the request.
- **HALTING A CLINICAL INVESTIGATION**, if the sponsor has temporarily halted a clinical investigation on safety grounds, he shall inform the SFDA within 15 calendar days of the temporary halt.
- **HALTING A CLINICAL INVESTIGATION**, if the sponsor has temporarily stop a clinical investigation, he shall inform the SFDA within 15 calendar days of the halting and justify the reason for halting the investigation.
- **PREMATURE TERMINATION OF A CLINICAL INVESTIGATION**, if the sponsor terminates a clinical investigation prematurely, he shall inform the SFDA within 15 days of the termination and justify the reason for terminating the investigation.
- **CLOSE- OUT NOTIFICATION** of the investigation including close out progress report, should be sent by the sponsor to the SFDA as soon as possible but not later than 30 working days of terminations.
- **CLOSE-OUT REPORT** is reired to be sent by the sponsor to the SFDA, reviewing IRBs, as soon as possible but not later than 2 months after termination.
- **CLINICAL INVESTIGATIONREPORT** is required to be sent to the SFDA, reviewing IRBs, and principal investigator(s) as soon as possible but not later than 6 months after termination.

PART 8. Change Form

This form applied on each change may occur in the document of the relevant CIMD; including: investigators brochure, clinical investigation plan, informed consent, advertisement material, or patient information documents investigation. The sponsor is required to fill this form and submit it to SFDA immediately but not later than 5 working days after change occur. Each change require a separate change form.

Change Form Number: CIMD No/C
Date:
<ol style="list-style-type: none">1. The document type where the change occur2. The original statement3. The changed statement4. Reason of change

PART 9. No Use Declaration for Port of Entry Clearance

This declaration must be signed by the sponsor , who identified in **Part 3.2.SPONSOR DETAILS** in the relevant CIMD application, in order to declare the investigational device from the port of entry before the corresponding CIMD is approved by the SFDA.

<p><u>No Use Declaration for Port of Entry Clearance Corresponding to the CIMD number.....</u></p>
<p><input type="checkbox"/> I am the sponsor defined in Part 3.2.SPONSOR DETAILS declare that I will not use the investigational device defined in Part 3.3.INVESTIGATIONAL DEVICE INFORMATION until the corresponding CIMD application number Is approved.</p> <p><input type="checkbox"/> I also herby that I will maintain all the transport and storage standards.</p>
<p>Name: Position: Address: Date: Signature:</p>

PART 10. Reviewing Fee

For each CIMD approval request, the reviewing of the Investigation documents shall not begin until the fees is received by SFDA.

This fee is waived if the CIMD is for scientific or research purposes rather than a marketing purposes. In addition, if the sponsor is a research institute, university, researcher, or healthcare facility the fee is waived.