الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority (SFDA)

SFDA. MD. SFDA/MDS/TC 194 . DS. ISO 14155:2011

الدراسات السريرية للأجهزة الطبية في الانسان – الممارسة السريرية الجيدة

Clinical investigation of medical devices for human subjects — Good clinical practice

ICS: 11.100.20

تقديم

الهيئة جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والاجهزة والمنتجات الطبية والتشخيصية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والاجهزة والمنتجات الطبية والتشخيصية سواء كانت مستوردة او مصنعة محلياً بواسطة لجان فنية متخصصة، وقد قام قطاع الاجهزة والمنتجات الطبية بالهيئة ضمن عمل اللجنة الفنية رقم:

SFDA/MDS/TC 194

" التقييم السريري والحيوي للأجهزة الطبية"

بتبني المواصفة الدولية رقم **ISO 14155:2011**

"الدراسات السريرية للأجهزة الطبية في الانسان – الممارسة السريرية الجيدة"

والتي اصدرتها "المنظمة الدولية لتقييس - ISO"

وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بلغتها الاصلية وذلك في اجتماع مجلس الادارة بالهيئة رقم () والذي عقد بتاريخ (../../..14هـ) الموافق (../../..20م)

FOREWORD

Saudi Food and Drug Authority (SFDA) is a national Organization responsible for safety and effectiveness of foods, drugs and medical devices. One of SFDA main functions is to issue national Standards /Technical regulation through specialized technical committees (TCs).

SFDA through the technical committee TC No **SFDA/MDS/TC 194**

"Biological and clinical evaluation of medical devices"

has adopted the International Standard No. ISO 14155:2011

"Clinical investigation of medical devices for human subjects -- Good clinical practice"

Issued by "International Organization for Standardization - ISO".

This standard has been approved as National Standard in its original language by SFDA Board of Directors in its meeting No .../... Held on / / / AH, / / G.

SCOPE

This document is applicable to any parties wish to conduct clinical investigation of medical devices or its accessories for human subjects within KSA.

مرفق التعديلات

#	رقم الصفحة Page No.	رقم البند/البند الفرعي Clause/Subclause No.	فقرة/صورة/جدول Paragraph/Figure/Table	نوع الملاحظة Comments Type	الملاحظات Comm-ents	التعديل Modification
1	1	1 Scope		te		Include the note: NOTE 1 For *in vitro diagnostics* regulation refer to national regulation, under-preparation SFDA Guidance on Performance Evaluation Studies of In Vitro Diagnostic Medical Devices (PEIVD).
2	2	3.3 audit		te		Add: (i.e. the SFDA Guidance on Clinical Investigations of Medical Devices)
3	4	3.18 ethics committee EC		te		Include the note: NOTE 2 in the Kingdome of Saudi Arabia, 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/registered-IRB.aspx
4	7	4.1 General		te		Include the note: NOTE In the Kingdom of Saudi Arabia all clinical investigation must be conducted in accordance with the Law of Ethics of Research on Living Creatures. http://www.kacst.edu.sa/eng/Maarifah/Policies/Documents/Research%20Bioethics%20Regulations.pdf
5	8	4.3 Compensation and additional health care		te		Include the note: NOTE Any compensation and/or payments made to the subject must be clarified to the SFDA with the study application. Refer to the national regulation, SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / A. Required document prior to CIMD/ No.10.
6	8	4.3 Compensation and additional health care		te		Include the note: NOTE 2 Refer to the national regulation, SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / A. Required document prior to CIMD/ No.9.
7	9	4.5.4 Continuing communication with the EC		te		Include the note: NOTE For SFDA continuing submission requirements please refer to the national regulation, SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / A. Required document during CIMD/ No.1 to 10.
8	10	4.7.2 Process of obtaining informed consent	e)	te		Include the note: NOTE For SFDA requirement on informed consent process, please refer to: 1. SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / A. Required document prior to CIMD/ No. 8. 2. SFDA submission during the clinical investigation please refer to the SFDA Guidance on Clinical

						Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.2.
9	11	4.7.3.4 Emergency treatments	g)	te		Include the note: NOTE For SFDA requirements on emergency use of a clinical investigation please refer to the national regulation, SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.9.
10	15	5.10 Labelling		te		Include the note: NOTE 2 Refer to national law, 1. the SFDA Guidance on Clinical Investigations of Medical Devices / Requirements / Labelling Requirements / No.4 2. the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / A. Required document prior to CIMD/ No.2
11	16	6.1 General		te		Include the note: NOTE Obtaining SFDA approval is obligatory prior to the commencement of the clinical inestigation. For more information, refer to national regulations, SFDA Guidance on Clinical Investigations of Medical Devices / Introduction / Background.
12	17	6.5.1 Amendments		te		Include the note: NOTE SFDA approval or notification required before amendments. Filling and submitting the Change Form is obligatory. For more information on amendments on CIP refer to national regulation, SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.2.
13	19	6.9 Investigational device accountability	g)	te		Include the note: NOTE 2 Refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / C. Required document at the end of the CIMD/ No.6
14	20	7.1.1 Procedure for suspension or premature termination		te		Include the note: NOTE Refer to national law, 1. the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.6 2. the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / C. Required document at the end of the CIMD/ No.2
15	23	8.2.1 Selection of clinical personnel	d)	te		Include the note: NOTE for SFDA requirements on conflict of interest disclosure, please refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / A. Required document prior to CIMD/ No.13 and 14.
16	24	8.2.2 Preparation of documents and materials	d)	te		Include the note: NOTE refer to national regulation, the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / A. Required document prior to CIMD/ No.9
17	24	8.2.2 Preparation of documents and materials	f)	te		Include the note: NOTE Obtaining SFDA approval is obligatory prior to the commencement of the CI. For more information, refer to SFDA Guidance on Clinical Investigations of Medical Devices / Introduction / Background.
18	26	8.2.4.5 Routine on-site monitoring visits	j)	te		Include the note: NOTE refer to national regulation, the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.10
19	26	8.2.4.5 Routine on-site monitoring visits	k)	te		Include the note: NOTE refer to national regulation, the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.7 and 10

20	27	8.2.5 Safety evaluation and reporting	c)	te		Include the note: NOTE For information on SAE reporting to SFDA , refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.10
21	27	8.2.5 Safety evaluation and reporting	d)	te		Include the note: NOTE For information on SAE reporting to SFDA , refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.10
22	27	8.2.5 Safety evaluation and reporting	f)	te		Include the note: NOTE For information on SAE reporting to SFDA , refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.10
23	28	8.2.6 Clinical investigation close-out	d)	te		Include the note: NOTE refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / C. Required document at the end of the CIMD/ No.3 and 4..
24	28	8.4 Communication with regulatory authorities	a)	te		Include the note: NOTE Obtaining SFDA approval is obligatory prior to the commencement of the CI. For more information, refer to SFDA Guidance on Clinical Investigations of Medical Devices / Introduction / Background.
25	28	8.4 Communication with regulatory authorities	b)	te		Include the note: NOTE For information on progress reporting to SFDA , refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during the CIMD/ No.1
26	30	9.6 Compliance with the CIP	f)	te		Include the note: NOTE refer to national regulation, 1. SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.2 2. SFDA Guidance on Clinical Investigations of Medical Devices / Annex 4.
27	31	9.8 Safety reporting	b)	te		Include the note: NOTE For information on SAE reporting to sponsor , refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.10
28	31	9.8 Safety reporting	c)	Te		Include the note: NOTE For information on SAE reporting to sponsor , refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.10
29	31	9.8 Safety reporting	d)	te		Include the note: NOTE SAE reporting from the investigator to SFDA is not require by SFDA .
30	32	Annex A A.1.3 Sponsor		te		Include the note: NOTE 2 For international sponsors, SFDA required an authorized representative. For more information, refer to SFDA Guidance on Clinical Investigations of Medical Devices / Requirements / Pre-requisite.
31	36	Annex A A.9 Amendments to the CIP		te		Include the note: NOTE For SFDA requirements in case of amendments to the CIP, refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.2
32	36	Annex A A.10 Deviations from clinical investigation plan	d)	te		Include the note: NOTE For SFDA requirements in case of deviation from the CIP, refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required

						document during CIMD/ No.7.
33	37	Annex A A.12 Statements of compliance	e)	te		Include the note: NOTE For declarations required by SFDA refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Annex I. Application Form for CIMD / Section 8. Declaration/ No 8.1.
34	37	Annex A A.14 Adverse events, adverse device effects and device deficiencies	d)	te		Include the note: NOTE For information on SAE reporting to SFDA , refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Required Documents / B. Required document during CIMD/ No.10 and 11.
35	40	Annex B B.6 Regulatory and other references	b)	te		Include the note: NOTE: For declarations required by SFDA , refer to the SFDA Guidance on Clinical Investigations of Medical Devices / Annex I. Application Form for CIMD / Section 8. Declaration/ No 8.1.

Comment type: **ge** = general **te** = technical **ed** = editorial

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