Global Harmonization Working Party
Towards Medical Device Harmonization
GHWP

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority
SFDA

MEDICAL DEVICES REGULATION

(Saudi Arabia Updates)

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Saudi Food & Drug Authority

28th GHWP Annual Meeting and 28th GHWP TC Meeting, 9th - 12th Dec 2024
Kuala Lumpur, Malaysia

Content

- An overview about SFDA 4th Strategic Plan.
- SFDA Medical Devices Regulation Framework.
- Requirements for Obtaining a Medical Device Marketing Authorization (MDMA).
- 2024 Updates

SFDA 4th STRATEGIC PLAN (2023 - 2027)

VISION
To be a leading international science-based regulator to protect and Promote public health.

MISSION
Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed.

Themes → **Product Safety** | **Local and International Partnerships** | **Operational Excellence**

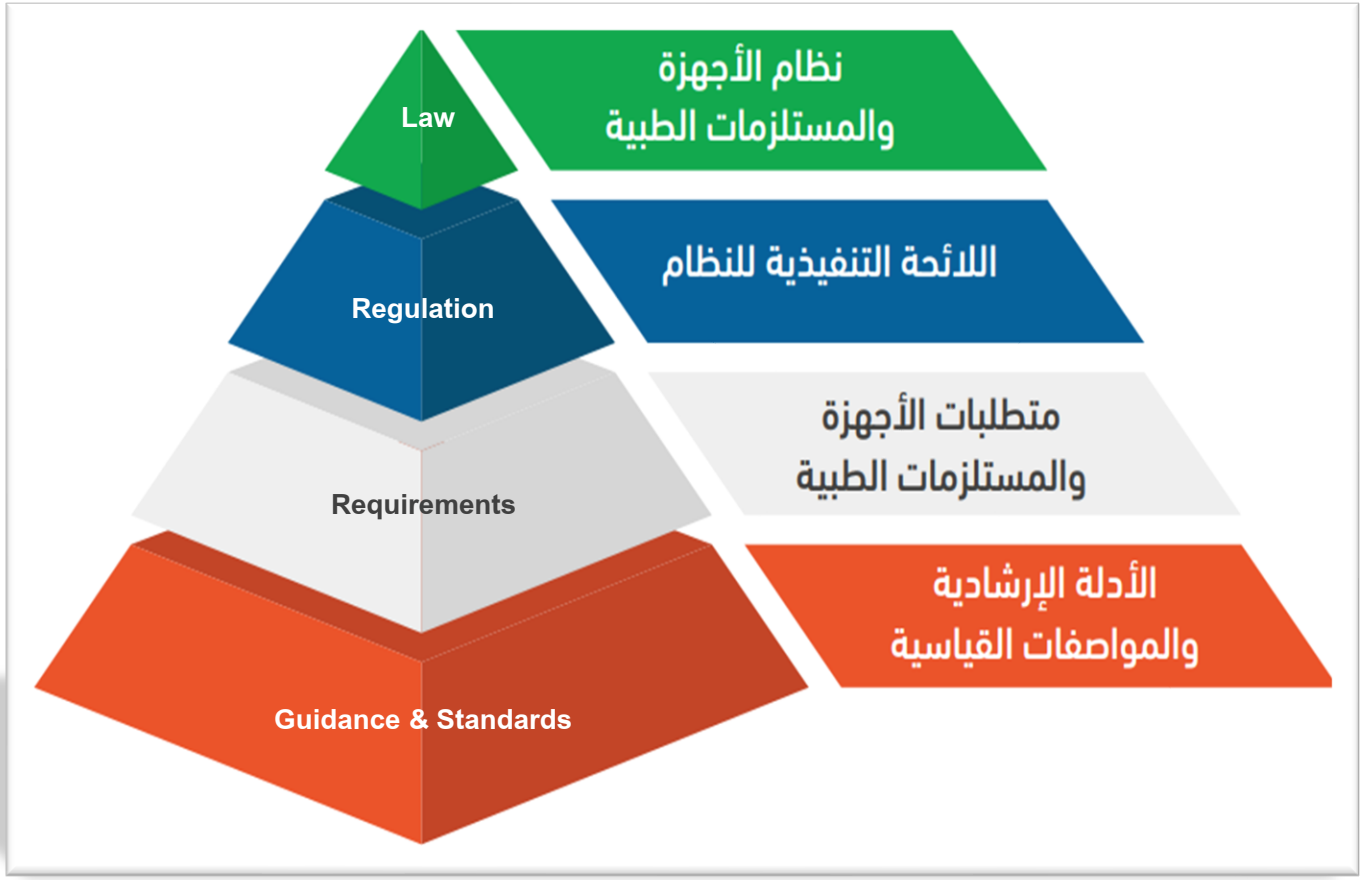
STRATEGIC OBJECTIVES

Beneficiaries	Developing the Regulatory System	Improving Communication and Awareness	Enhancing Products Availability	Enhancing International Leadership
Financial Sustainability	Diversification of Revenue Resources			
Internal Processes	Developing Regulations and controls of new technology and bio-tech products	Support Research and Innovation	Enable Investors	
SFDA Capabilities	Human capital Development	Increase The Use of Advanced Digital Technology		

Values

- Keep Learning and Developing
- Community Health is Top Priority
- Effective & Transparent Communication
- Sharing Responsibility
- Striving to Achieve Leadership & Excellence

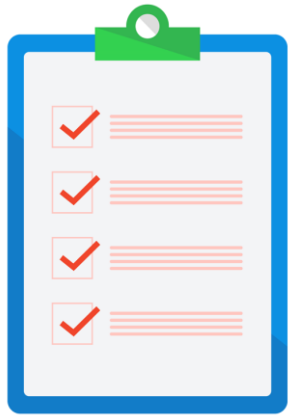
SFDA Medical Devices Regulation Framework



DESIGN & DEVELOPMENT → MANUFACTURE → PACKAGING & LABELING → STORAGE & TRANSPORT → ADVERTISING & MARKETING → USE → DISPOSAL

Medical Devices Marketing Authorization (MDMA) Requirements

- **Local and Overseas MD Manufacturers Shall establish**, document and maintain an effective Quality Management System (QMS).
- **Overseas Manufacturer shall** assign Authorized Representative (AR) established within the KSA (By a written mandate from the manufacturer to act on his behalf for specified tasks).
- **Local Manufacturer shall** obtain an Establishment License from SFDA.

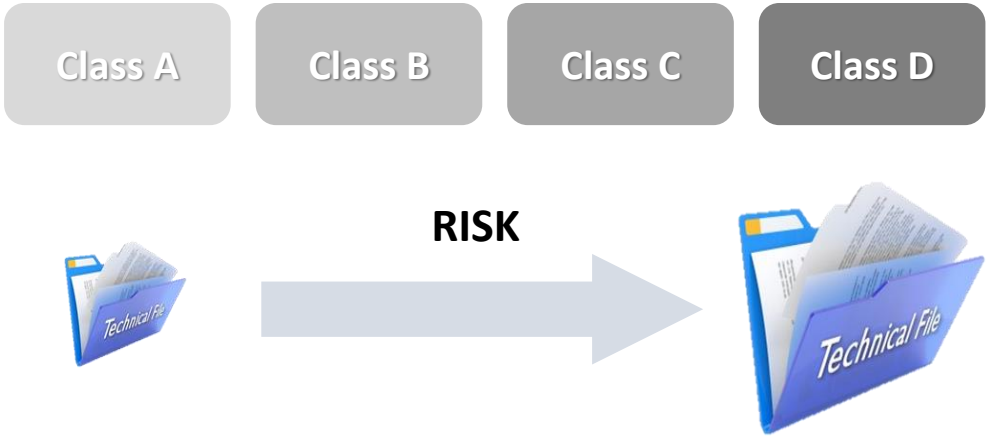


Reference: *SFDA MDS-REQ 10*

Medical Devices Marketing Authorization (MDMA) Requirements

Submit Technical File for Scientific Evaluation including the followings:

1. Device Description and Specification, Including Variants and Accessories
2. Information to be Supplied by the Manufacturer
3. Design and Manufacturing Information
4. Essential Principles of Safety and Performance
5. Benefit-risk Analysis and Risk Management
6. Product Verification and Validation
7. Post-market Surveillance Plan
8. Periodic Safety Update Report (PSUR) and Post-market Surveillance Report



Reference: *SFDA MDS-REQ 1*

2024 Updates:

- International Participations
- New Departments
- Announcements, Documents, General updates
- Statistics
- Timeline of SFDA-MD Regulations & Efforts

SFDA International Participations

SFDA International Participations

- Currently, SAUDI ARABIA participates in :

PROJECT: Development of IEC 60601-1, Edition 4

The technical committee (IEC/ TC62) for Medical equipment, software, and systems developing the main standard for electrical medical devices (IEC 60601-1, Edition 4 project) and all collateral standard. The development includes the requirements for maintaining basic safety and essential performance.

Therefore, 12 working groups were established to discuss specific tasks to achieve the project goals, including the need to reduce cross references; consolidation of the collaterals into the main standard; considering the Advancement of technologies; and simplify the structure and clarification of the scope.

2024 Updates: New Departments

1 Clinical Trails & Biological Products Department

Main Task

- **Prompting** the establishment of clinical trials of medical devices within the Kingdom of Saudi Arabia as global clinical trials hub.
- **Assessing** clinical trials of medical devices including IVDs
- **Developing** a legislative and regulatory framework that takes into account the developments and advancements in biotechnology for diagnosis, treatment, and health enhancement.
- **Evaluating** innovative biotechnology based medical devices (such as companion diagnostics CDx) and In-house IVDs within Saudi Arabia.

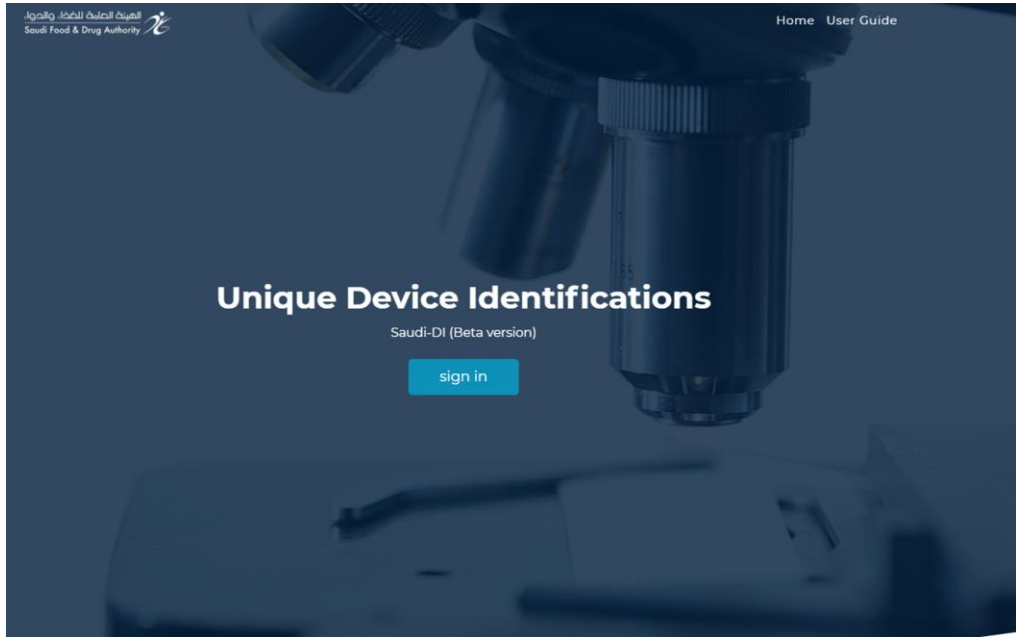
2 New Technology & Digital Health Department

Main Task

- **Developing** a legislative and regulatory framework for new technologies and digital health.
- **Ensure** the safety, security, and efficiency of new technologies and digital health.
- **Build** strategic partnerships with research centers, hospitals and relevant stakeholders in areas of common interest.
- **Facilitate** the registration procedures for innovative medical devices to enter the Saudi market.
- **Support** innovation and medical devices technology development.

2024 Updates: Announcements, Documents, General updates

SAUDI-DI



# of Devices	353178
# of Accessories	39496
# of Manufacturers	1494

Announcement (MDS-CIR-002-V2/
(following the Announcement (01) 8/2021)

SUBJECT: Updates on the compliance timeframe for the requirements of medical devices unique device identification (Saudi -DI).

ADDRESSES: Local and Overseas Medical Devices Manufacturers, Authorized Representatives.

Reference to the published requirements for medical devices unique device identification (Saudi-DI) by Saudi Food & Drug Authority. And after launching the UDI database (Saudi-DI), therefore, SFDA has approved the postponed timeframe for UDI compliance as follows:

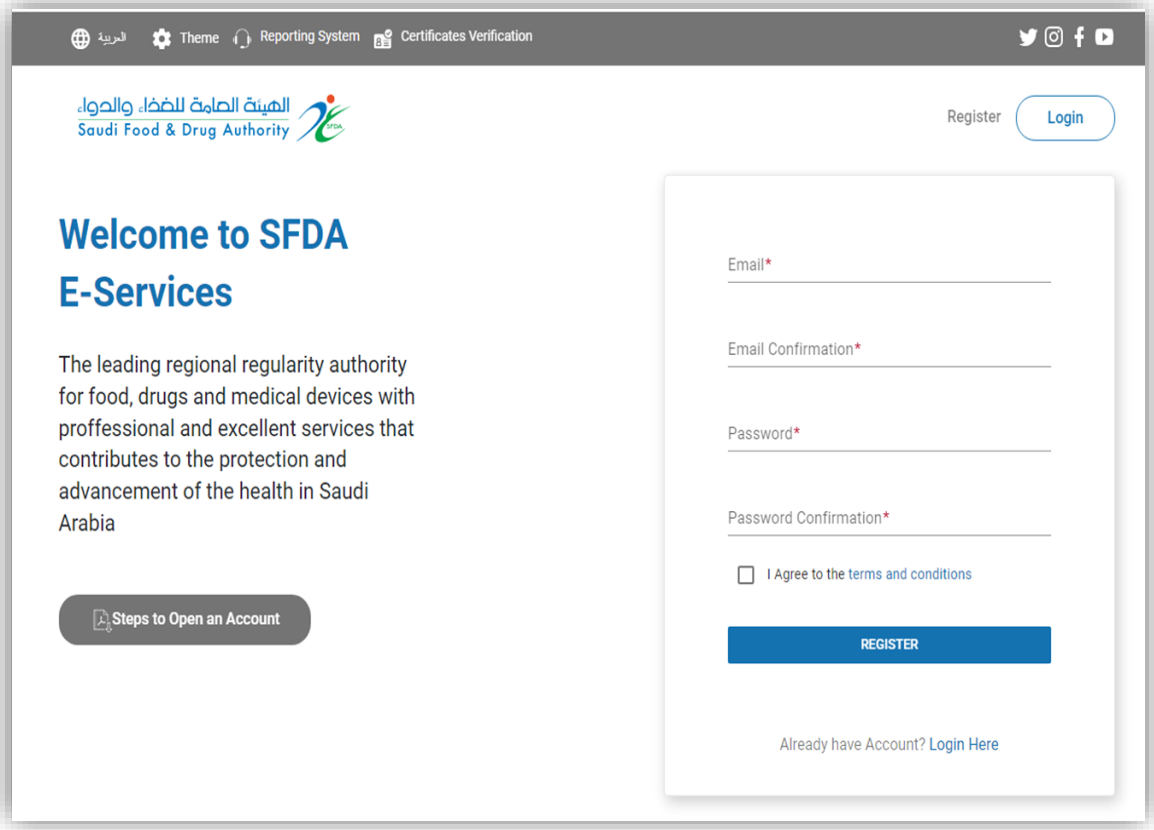
Compliance Timeframe	
Launching the UDI database and starting optional registration for all type of devices	1st October 2020
Risk Class	**Compliance date**
Class B & C (Medium risk) Class D (High risk)	1st September 2023
Class A (Low risk)	1st September 2024

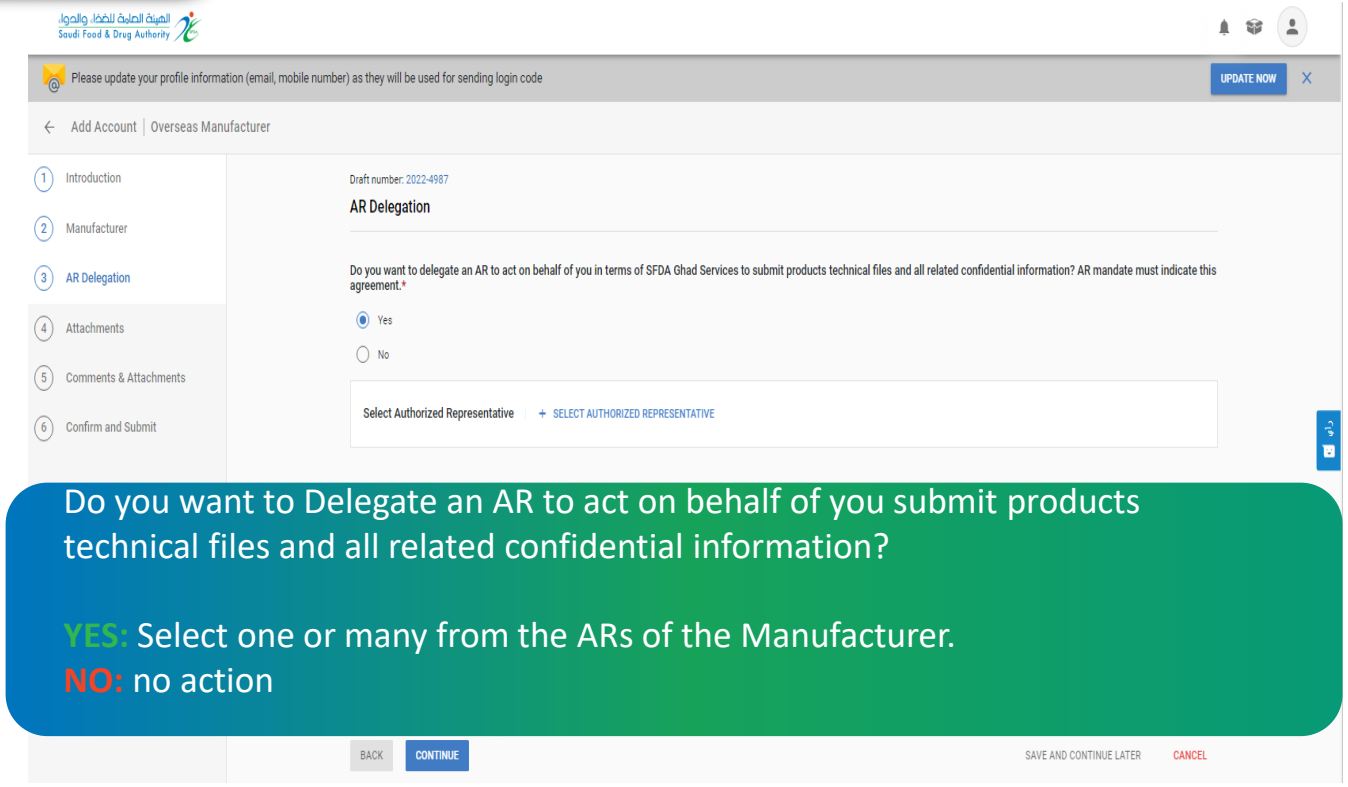
- Requirements for Unique Device Identification (UDI) for Medical Devices (MDS – REQ 7)
- UDI database (Saudi-DI): https://udi.sfda.gov.sa/

For further inquiries regarding this announcement, please contact md.rs@sfda.gov.sa or call 19999.

2024 Updates: Announcements, Documents, General updates

Overseas MD Manufacturer' Account

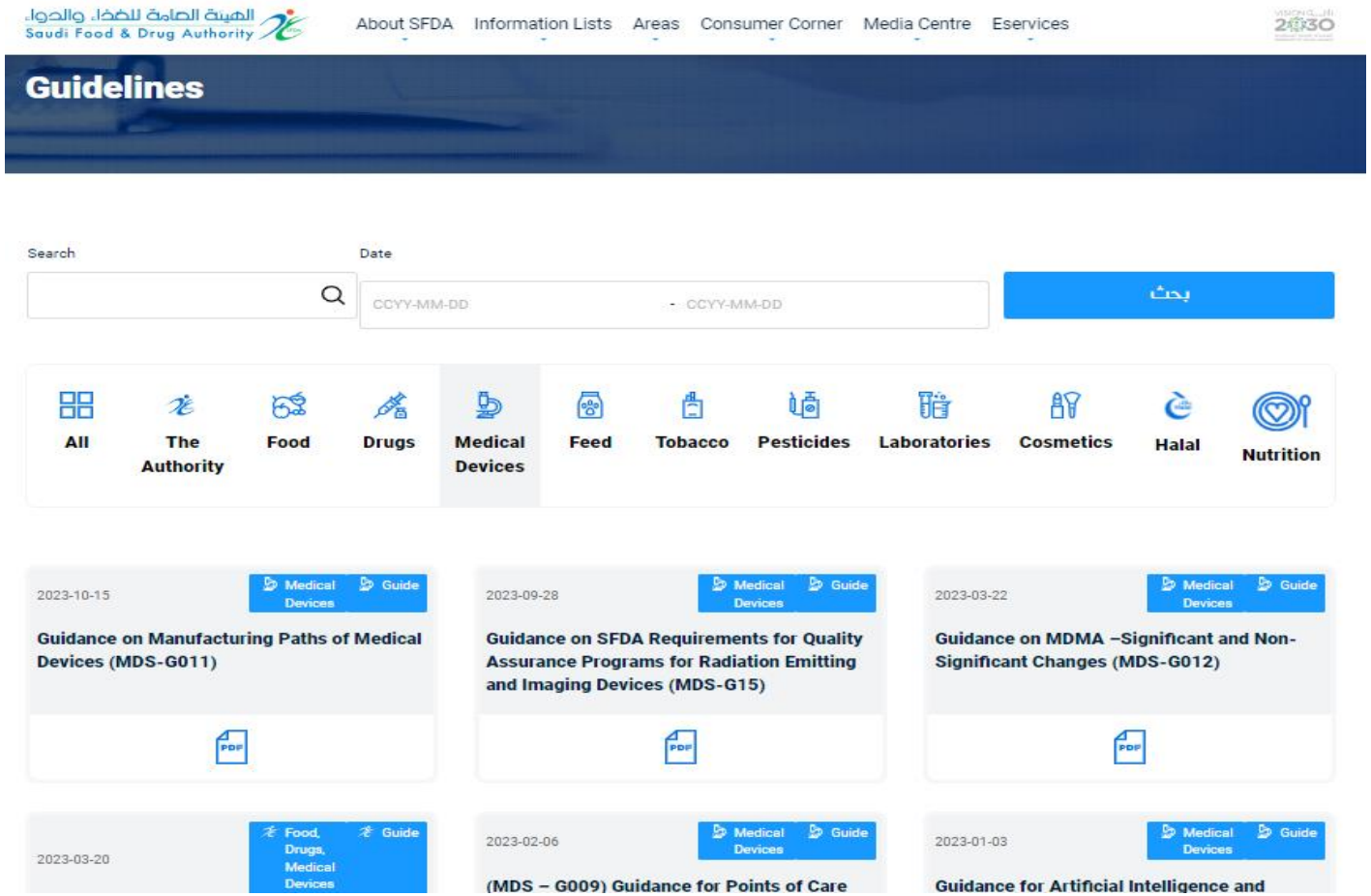




Do you want to Delegate an AR to act on behalf of you submit products technical files and all related confidential information?

YES: Select one or many from the ARs of the Manufacturer.
NO: no action

2024 Updates: Announcements, Documents, General updates



To access SFDA-MD Regulations and Requirements

2024 Updates: Postmarket Surveillance Statistics (Jan- Nov 2024)

Safety Alerts		
# Safety Alerts	**402 safety alerts** affected the Saudi market out of 2902 globally detected safety alerts	
Action Types	Correction	Removal
	296	106
# Medical Devices Affected	**29,052,213**	

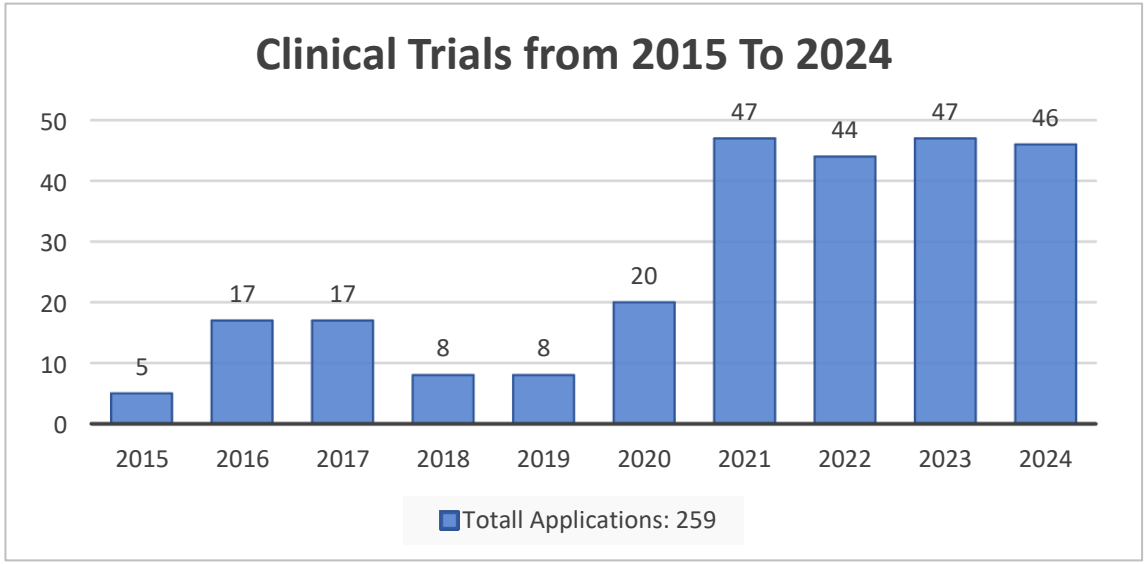
Adverse Events & Complaints			
Received AE & Complaints reports	**140,000**		
Type of Reports	Healthcare providers	Manufacturers and companies	Public
	36253	**103633**	**114**

Officers of Healthcare providers
1153 officers Registered

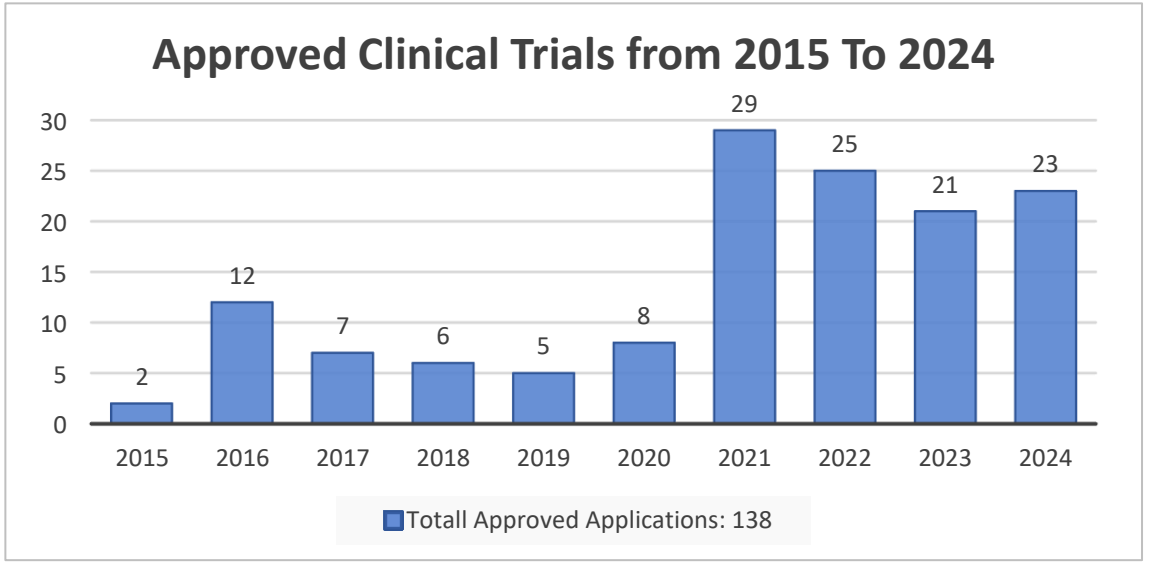
https://ade.sfda.gov.sa/Home/NcmdrReport#

2024 Updates: Clinical Trials Statistics (Jan- Nov 2024)

- Since 2015, the SFDA has evaluated 259 applications for MD Clinical trials (46 applications in 2024).



- A total of 138 approval letter has been issued to conduct clinical trials located within different cities around Saudi Arabia.



All the requirements are clearly specified in SFDA MDS-REQ 2.

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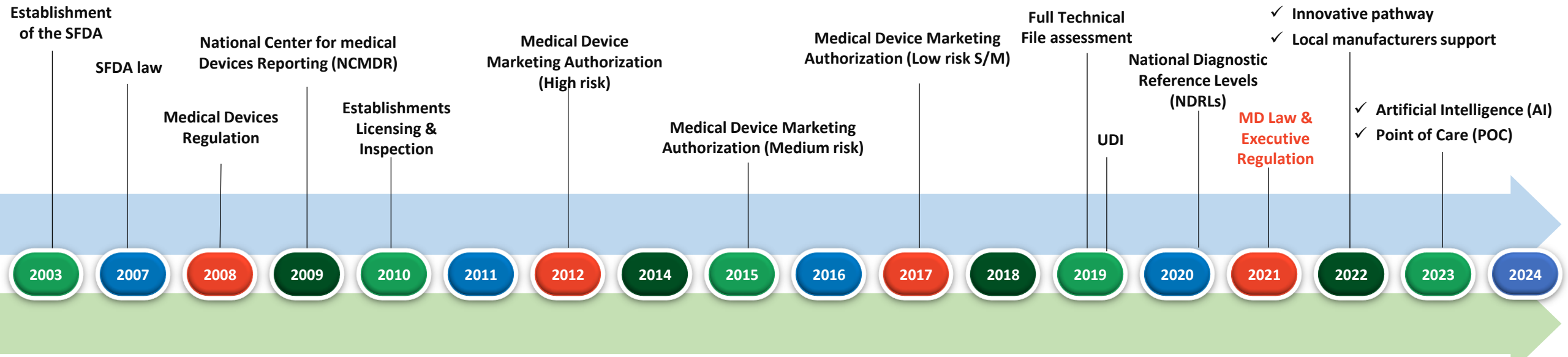
Timeline of SFDA-MD Regulations & International Particpations



AHWP TC Chair (2014-2018)

AHWP Chair (2011-2014)

AHWP TC Co-Chair (2011-2014)

GHTF Study Group 3 - QMS (2008-2011)

GHWP Chair (2018-2022)

IMDRF (2024-)

GHWP TC Chair (2023-)

IEC SNAIG (2022-)

ISO & IEC Technical Committees (2013-)

IMDRF Personalized Medical Devices (PMD) (2018-)

WHO Strategic and Technical Advisory Group (2022-)


Thank You