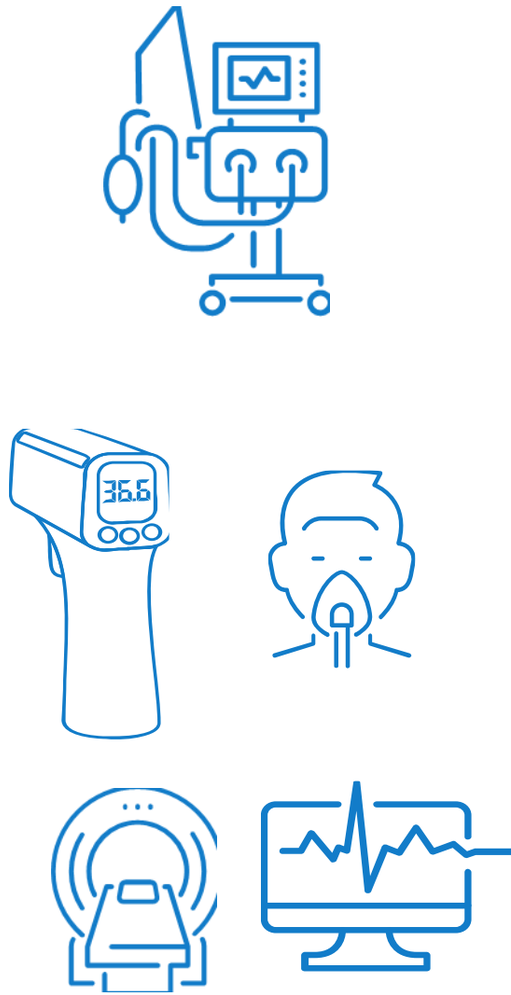
AHWP/GHWP Online Annual Meeting (2021)

Medical Devices Regulation Overview and Updates

Medical Devices Sector
SFDA

Eng. Abdullah Alghuraibi
MD Regulations & Registration Support
1/12/2021



Vision and Mission

Medical Device Sector

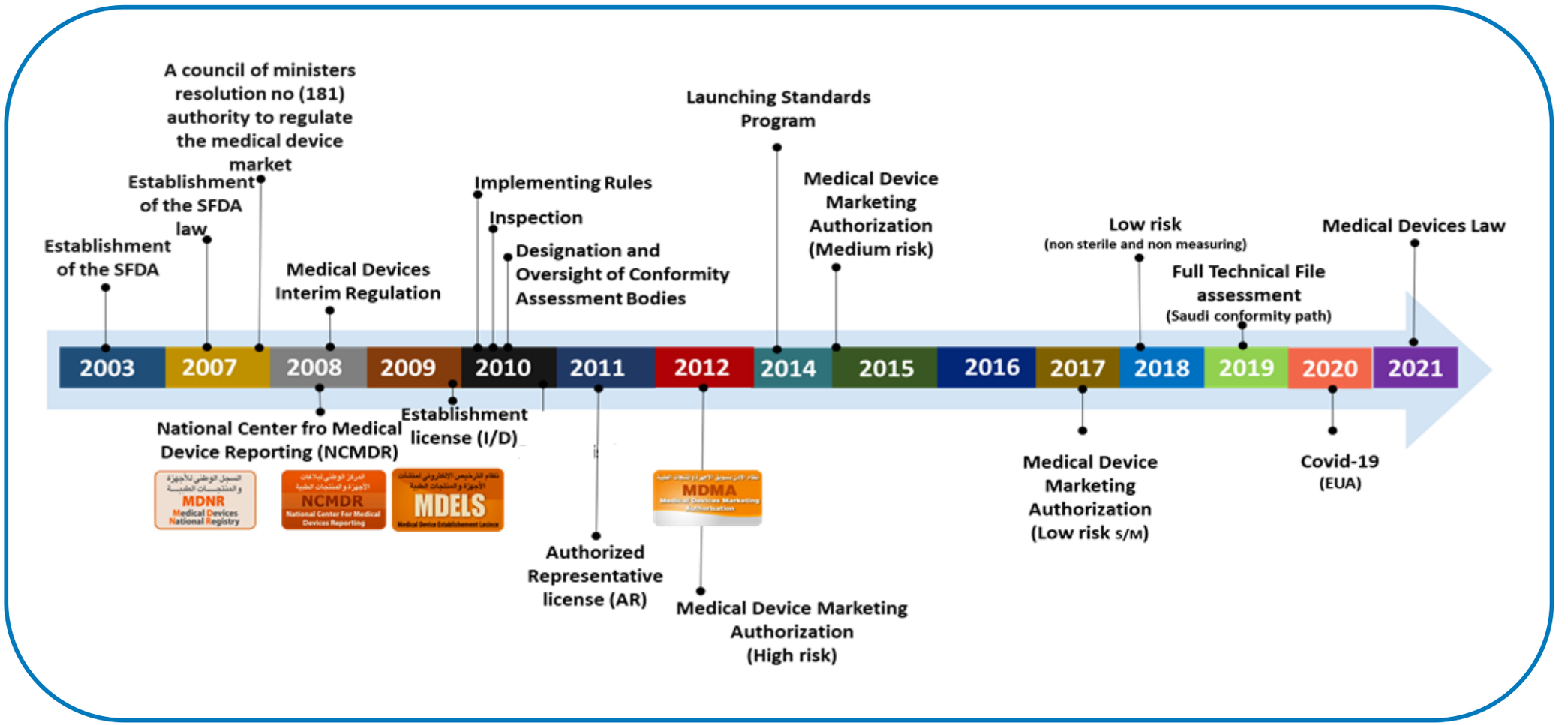
Vision

To be a regionally and internationally distinguished regulatory authority for medical devices and related electronic products, working toward safeguarding the public health of Saudi Arabia.

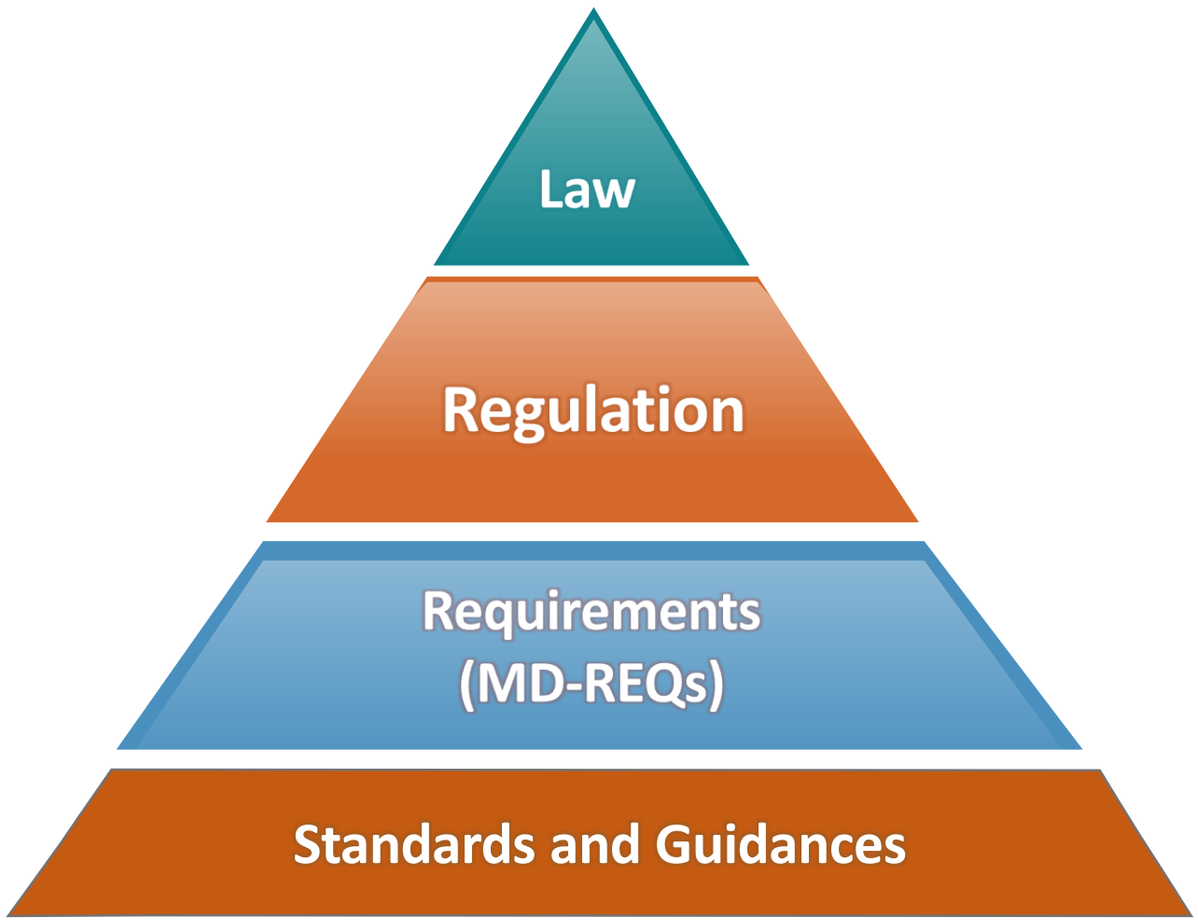
Mission

To ensure safety, effectiveness and quality of medical devices and their performance according to their intended purpose and to ensure the safety of related electronic products.

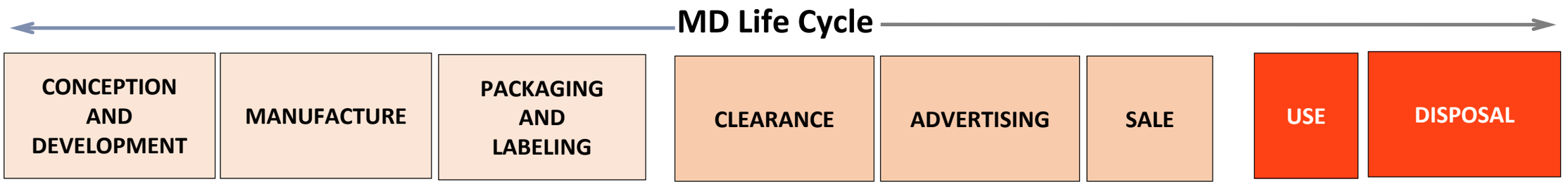
Medical Devices Regulation Key Millstones



SFDA Medical Devices Regulatory Scheme



Medical Devices Law

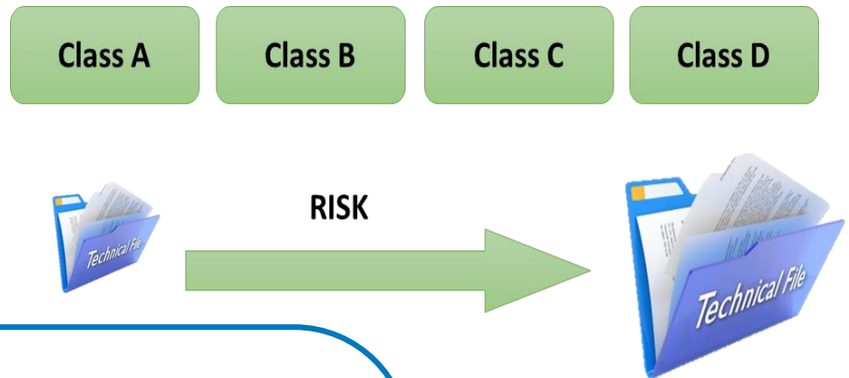


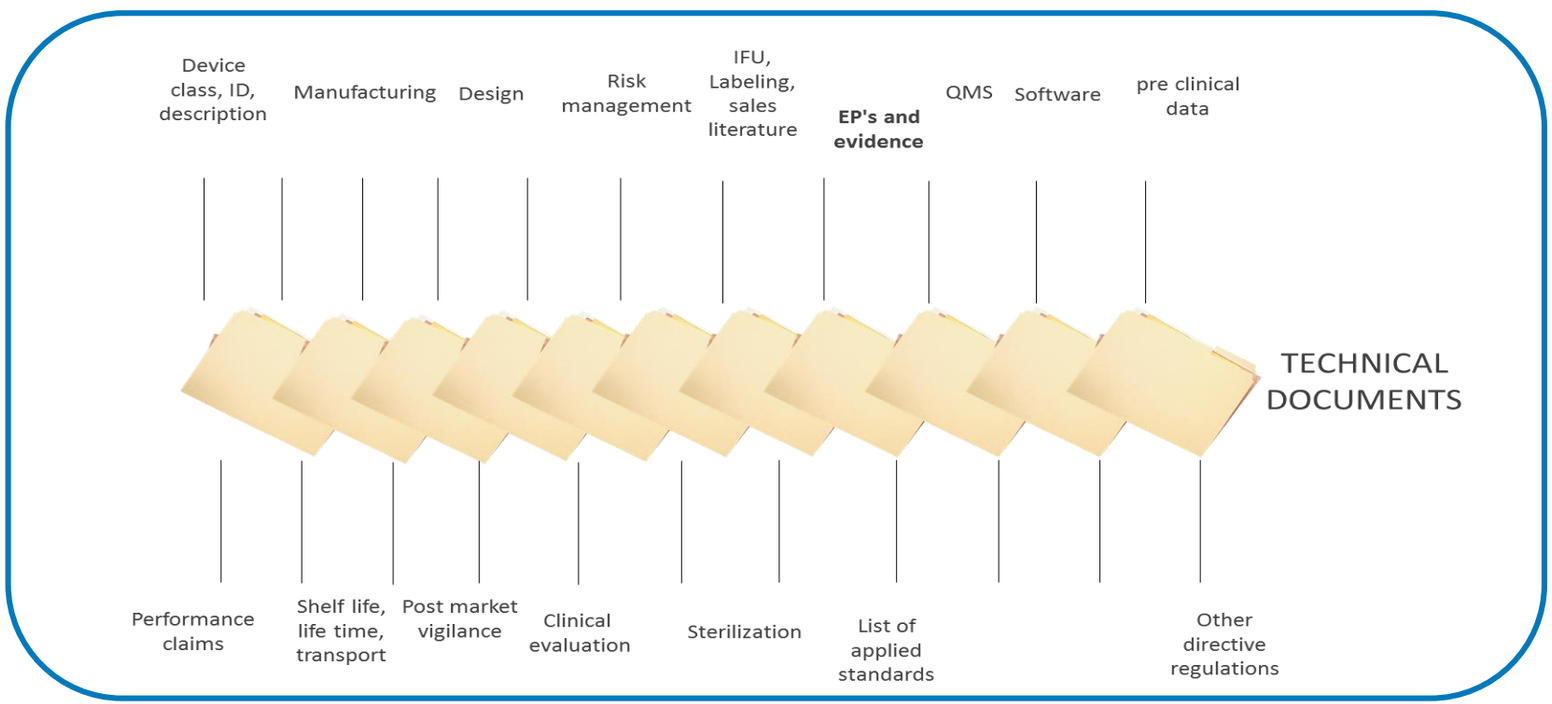
Aims to:

- ✓ **Protect the public health** in Saudi by applying the procedures and requirements that assures the patient's safety as well as end user.
- ✓ **Taking measures** and assign responsibilities to ensure conformity of law requirements.
- ✓ **Enhance the Kingdom's leading role** internationally in the medical devices field.
- ✓ **Support investments** by having harmonized law which encourages manufactures and big corporates to invest and launch branches in the Kingdom.
- ✓ **Effective economic impact** for the Saudi market.
- ✓ **Support innovation** and medical devices technology development.

Medical Device Technical File Assessment

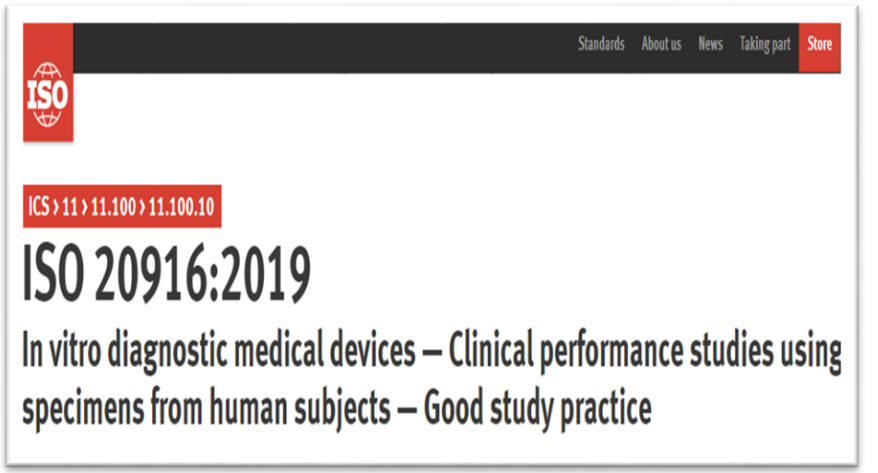
- Manufacturers of Medical Devices Shall submit the **Technical File** To SFDA.
- Approvals from Other Authorities are considered as **supporting documents**.
- **Technical File Contents** are specified clearly in MDS-REQ 1





Requirements for Clinical Trials of Medical Devices (MDS- REQ2)

- **Performance Evaluation** Studies of In Vitro Diagnostics Medical Devices (PESIVD) and
- **Clinical Investigations (Trials)** of Medical Devices within KSA Shall be approved by SFDA before commencement and comply with ISO 14155:2020

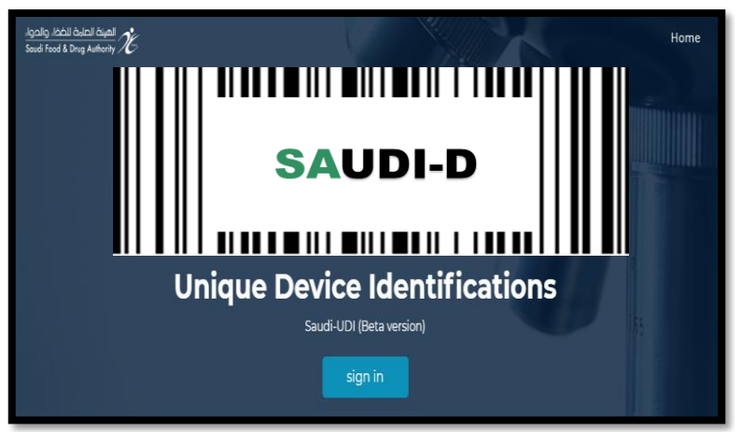


SFDA Requirements for advanced technology and applications

- ✓ Covering the followings:
  - ✓ Medical devices **Cybersecurity** (for healthcare providers and manufacturers).
  - ✓ **Software** as a Medical Device
  - ✓ **3D printing** in medical devices
  - ✓ **Innovative** Medical Devices
  - ✓ **E-IFU** Requirements
  - ✓ **Artificial intelligence** (AI)

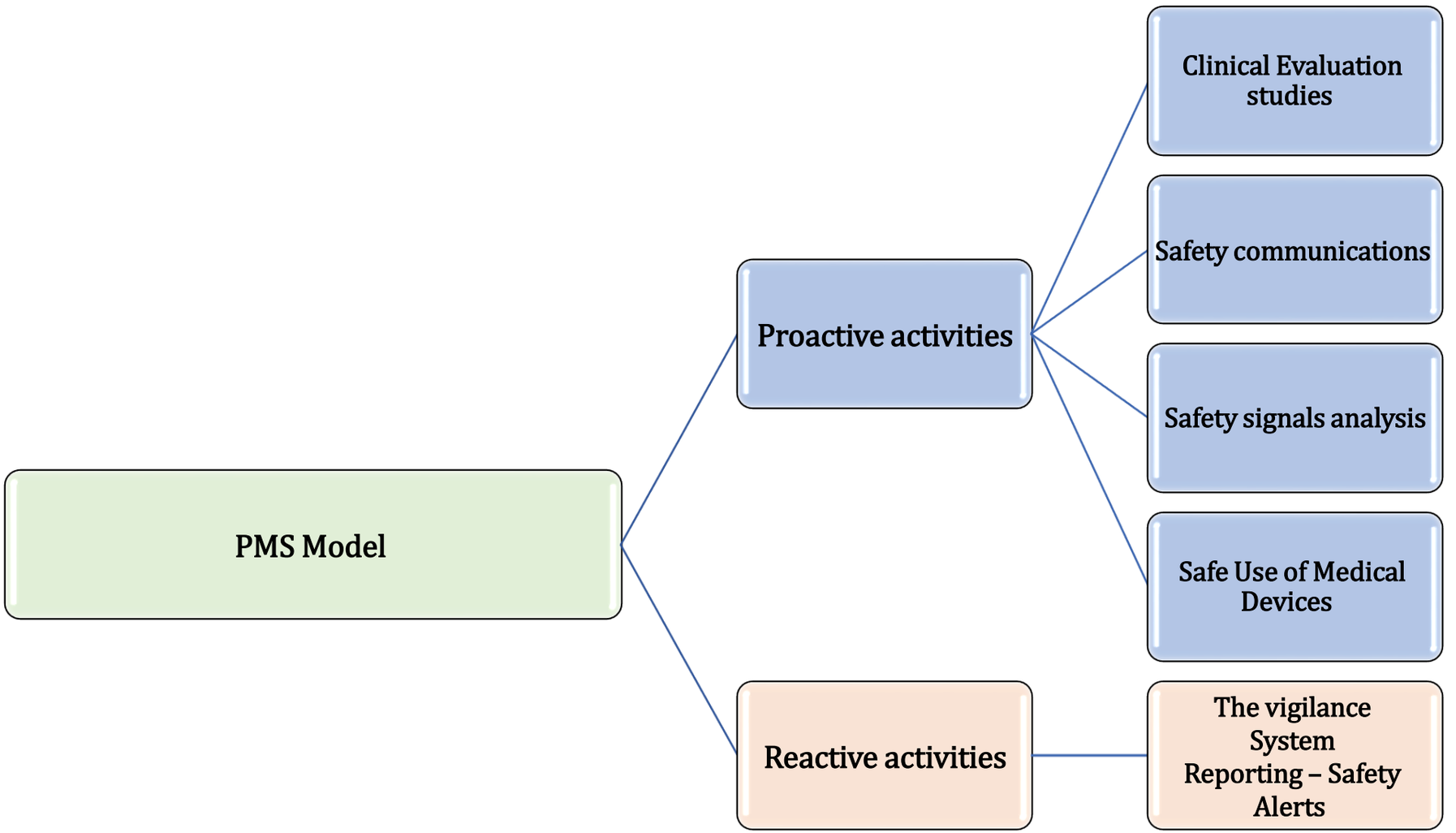
SFDA- Unique Device Identification UDI

- ✓ The manufacturer, or its authorized representative, shall submit and maintain the appropriate data to UDI database
- ✓ Shall be **checked and maintained** periodically be manufacturer
- ✓ The data for new UDI-DI shall be available in UDI database at the time the device is placed on the market.
- ✓ Ensure all data in GHAD System & Saudi-DI are accurate and valid such as models name, GMDN code , ...)



Go to https://udi.sfda.gov.sa/

SFDA-Post-market Surveillance Model



Safety Communication and Safety Alerts concepts- (National Centre for Medical Devices Reporting)

Based on the medical devices law, here are the new defined terms of disseminated reports from the NCMDR:

Safety Alert

A notification from the SFDA to relevant medical device users in relation to a Field Safety Corrective Action.

Safety Communication

A communication by NCMDR to health professional or public, and provides an information and recommendations about safety , efficacy and performance of medical devices.

SFDA monitors facilities with radiation-emitting devices to ensure proper compliance

Safe use of medical devices

SFDA Medical Devices Radiological Health Department

Radiological Health function	Radiological Health Role	Impact of Devices and SFDA Role
	Publish National Diagnostic Reference Level for radiation dosing	**High risk/ wide-spread impact:** Radiological products are used on many patients over the device lifespan and can impact millions of patients **Device performance over time:** Performance of radiological devices will evolve with use necessitating continuous maintenance and calibration
	Publish best practices for safe use of medical devices covering healthcare providers and cosmetic clinics	**Low level of external support:** There is a capability gap in other agencies to adequately assess and monitor radiological facilities within the Kingdom
	Monitor radiological products and their operating environments	**SFDA monitoring:** SFDA monitors facilities that use radiation-emitting devices within the Kingdom, including: • Hospitals • Polyclinics • Dental clinics • Cosmetic clinics **External support:** SFDA has option to outsource activities to consultation offices and CABs. SFDA is also working with CBAHI & MoH so they adopt requirements

SFDA medical devices efforts during COVID-19 pandemic

- ✓International collaboration, support , consultation and sharing knowledge and sharing experience .
- ✓Support the local medical devices manufacturing.
- ✓Communication with healthcare providers and monitoring of performance and safety in KSA.
- ✓Support local scientists and developers of In-house developed diagnostic tests for COVID-19 .
- ✓Creating SFDA special evaluation for Corona Virus (Covid-19) IVD Tests - Emergency Use Authorization (EUA)
- ✓Acceleration of approval to obtain marketing authorization of any devices needed during pandemic (PPE, ventilators)
- ✓Develop standards and guidance documents for: Protective **Medical Goggles, Face Shields , Ventilators, Medical Masks and Particulate Respirators**

SFDA- MD Sector Regional & International Participation and Activities

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

World Health Organization

IMDRF International Medical Device Regulators Forum

ISO

IEC

هيئة التقييس
لدول مجلس التعاون لدول الخليج العربية
GCC Standardization Organization

Thank You

شكراً لكم

To access SFDA-MD Regulations and Requirements,

kindly visit the below link:

https://www.sfda.gov.sa/en/regulations?tags=3