



**Global Harmonization Working Party**

GHWP Towards Medical Device Harmonization

## Egypt's Regulatory Updates

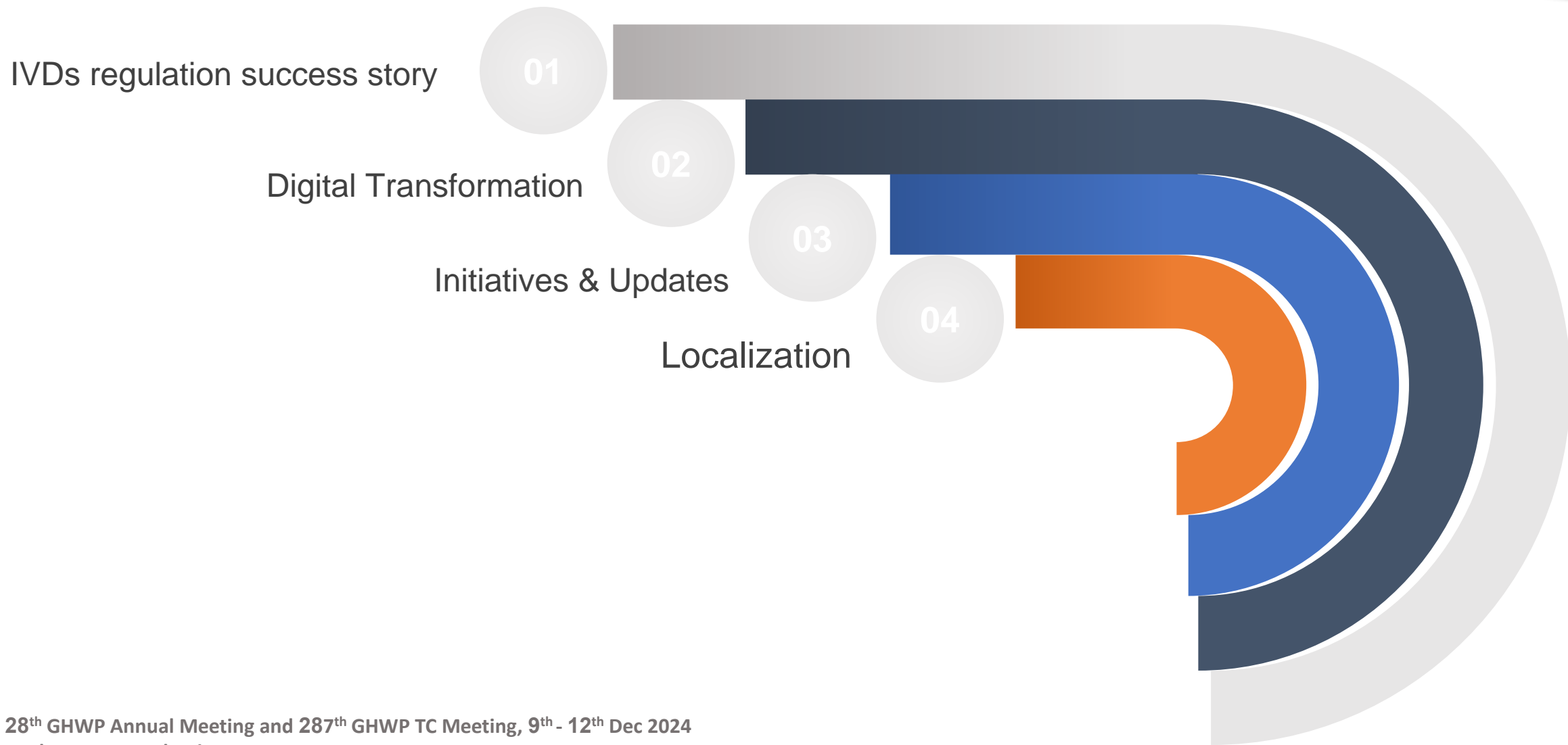
Dr. Rania Soliman,

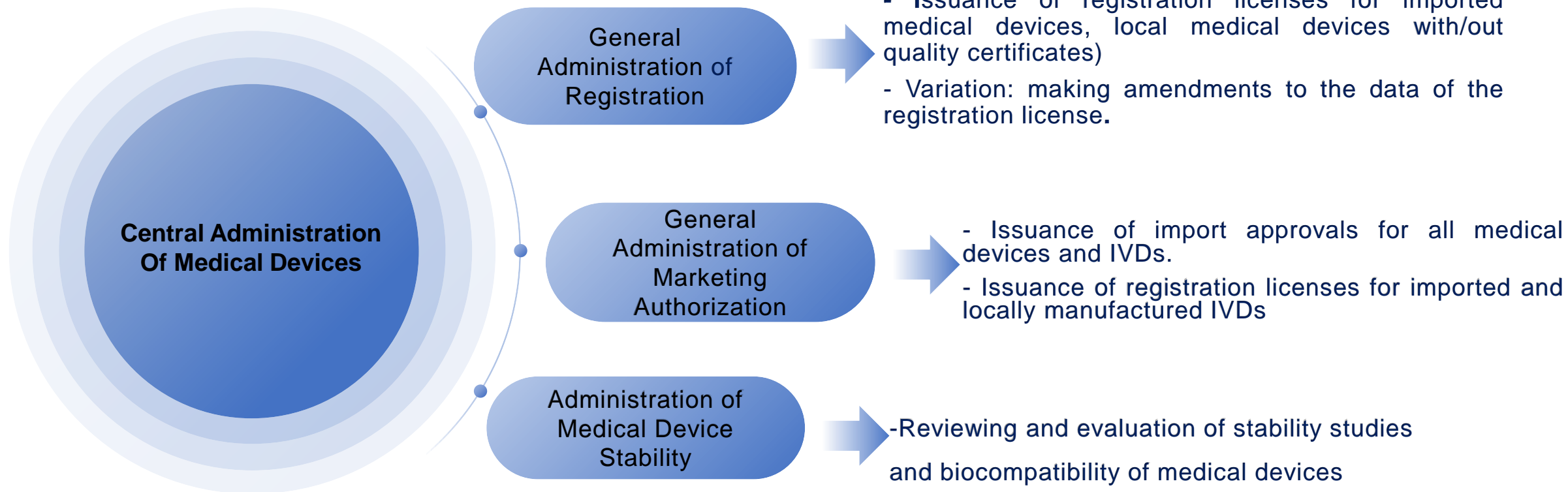
General Manager of General Administration of  
Medical Devices Marketing Authorization,

Central Administration of Medical Devices (CAMD)

**The Egyptian Drug Authority (EDA)**









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# IVDs Regulation success story

## IVD regulation success story in Egypt

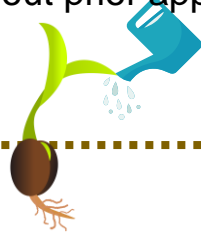
**30/06/2020**

The Central Administration for Medical Devices attempted to control and supervise the dissemination of IVDs. A working committee was organized to develop regulatory rules.



**13/01/2021**

The EDA chairman issued decree No. 2 of 2021 to regulate and manage the dissemination of IVDS, as well as banning imports without prior approval.



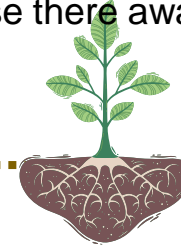
**01/04/2021**

The COVID-19 pandemic has contributed a great demand for approvals of IVDs correlated to the virus. Companies lack awareness of current regulatory procedures was a big challenge .

**By the end of 2021**

EDA was able to overcome the situation through:

- Working from home in addition to traditional working hours
- Issuing annual licenses for importation instead of per invoice.
- Providing several workshops to companies to raise there awareness



**By the end of 2022**

EDA managed to successfully regulate IVDs through:

- Registration of imported IVDs.
- Registration of locally manufactured IVDs.
- Dynamic regulations update in reliance with global updates.

## IVDS Regulatory Framework

### Issuance of IVDs Import Approvals

Import approvals issued by EDA to ensure the safety, quality, and efficacy of IVDs dissemination.

**Key Steps:**

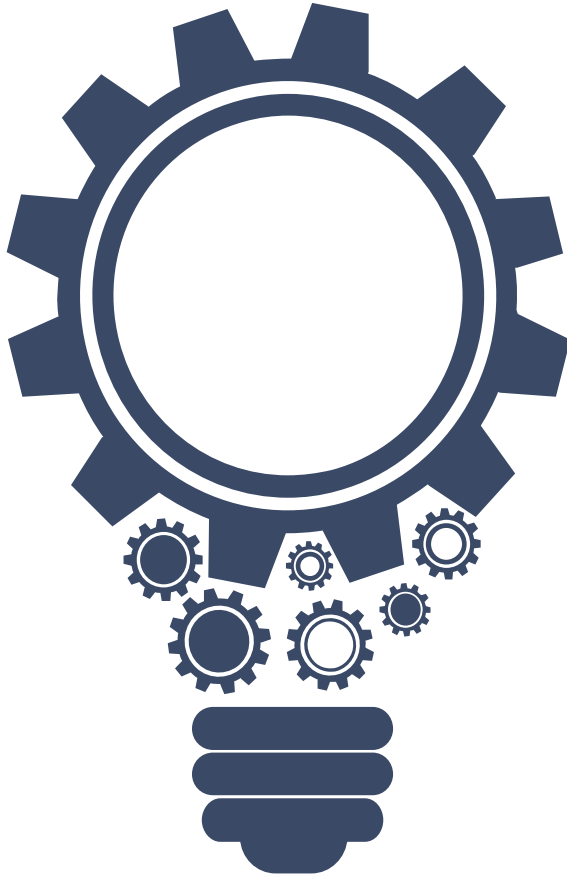
1. **Application Submission** Submission of application on MeDevice platform, including regulatory documents mentioned in application instructions.
2. **Documentation Review**: Review of submitted application.
3. **Issuance of Approval**: Once the documentation and product quality are verified, the EDA issues an Importation Approval, which allows the product to enter the Egyptian market.
4. **Customs Clearance**: Importers use the EDA-issued approval for customs clearance of the shipment.

### Marketing Authorization licenses

Marketing Authorization licenses issued by EDA to ensure the safety, quality, and efficacy of IVDs dissemination.

**Key Steps:**

1. **Submission**: Submission of application on MeDevice platform, including regulatory documents mentioned in application instructions.
2. **Technical Review**: Evaluation of the product's technical file to ensure compliance with Egyptian and international regulations.
3. **Performance and Safety Data**: Manufacturers must provide performance data (e.g., sensitivity, specificity) and safety profiles to ensure the IVD is effective for its intended use.
4. **Issuance of Marketing authorization licenses**: Once the documentation and product quality are verified, issuance of marketing authorization licence occurs, which allows the product to enter the Egyptian market.



## Challenges in regulatory process implementation

In the early stages of adopting legislation governing the dissemination of IVDs , among the primary pertains addressed were:

### 1-Alignment with International Standards

Several companies faced significant challenges in complying with the requirements including:

- Availability of Non-compliant Products
- Lack of Adherence to Quality Standards
- Limitations of Verifying Product Sources
- Limited Market Oversight

### 2-Registration Process Efficiency :

Several companies faced significant challenges in complying with the requirements including:

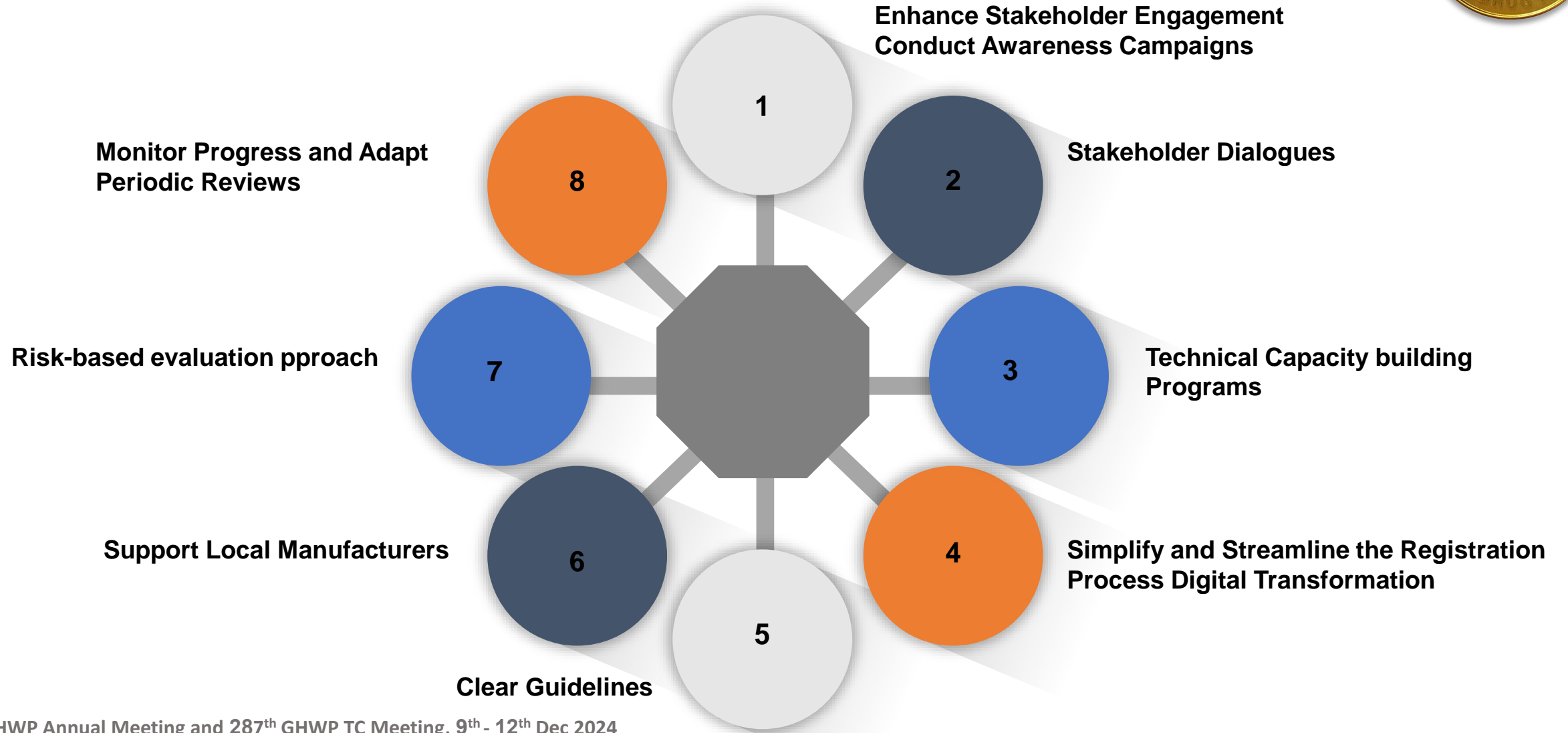
- Inability to Prepare Technical Files
- Reluctance to Register Imported Products

### 3-Capacity and Expertise:

Additional professional and technical skills must be inforced for all stakeholders for faciltiating the evaluation of advanced diagnostic technology.



# Overcoming the challenges regulatory process implementation







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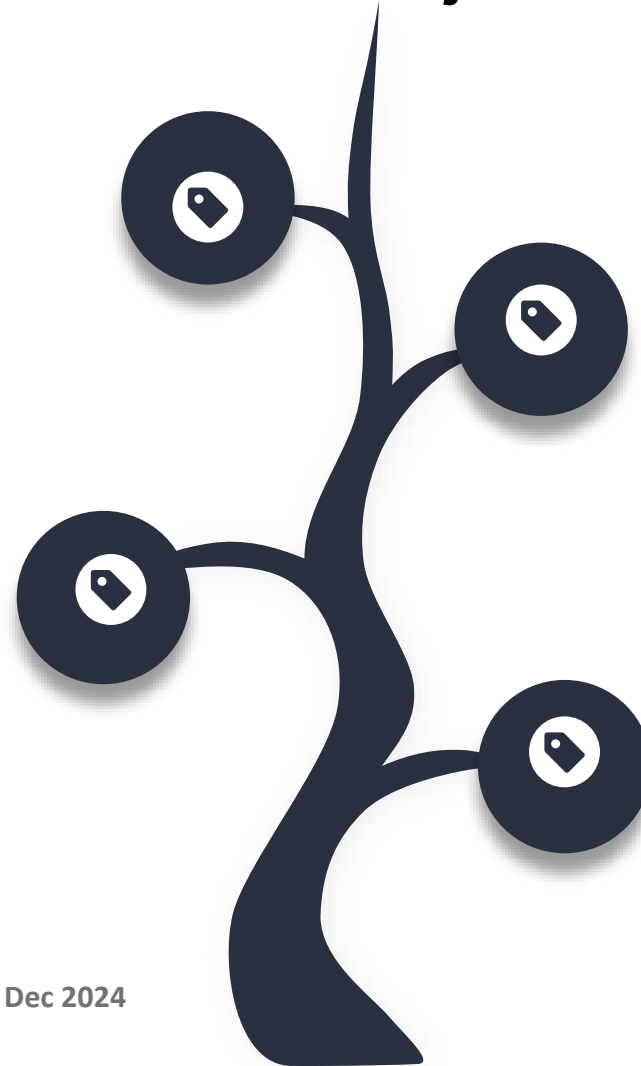
# Digital Transformation

28<sup>th</sup> GHWP Annual Meeting and 287<sup>th</sup> GHWP TC Meeting, 9<sup>th</sup> - 12<sup>th</sup> Dec 2024  
Kuala Lumpur, Malaysia

## How the digital transformation journey started

The COVID-19 outbreak prompted the EDA to transition from paper submissions to electronic submissions

EDA decided immediately to begin accepting submissions through Google Drive **in order to reduce individual communication and virus transmission**

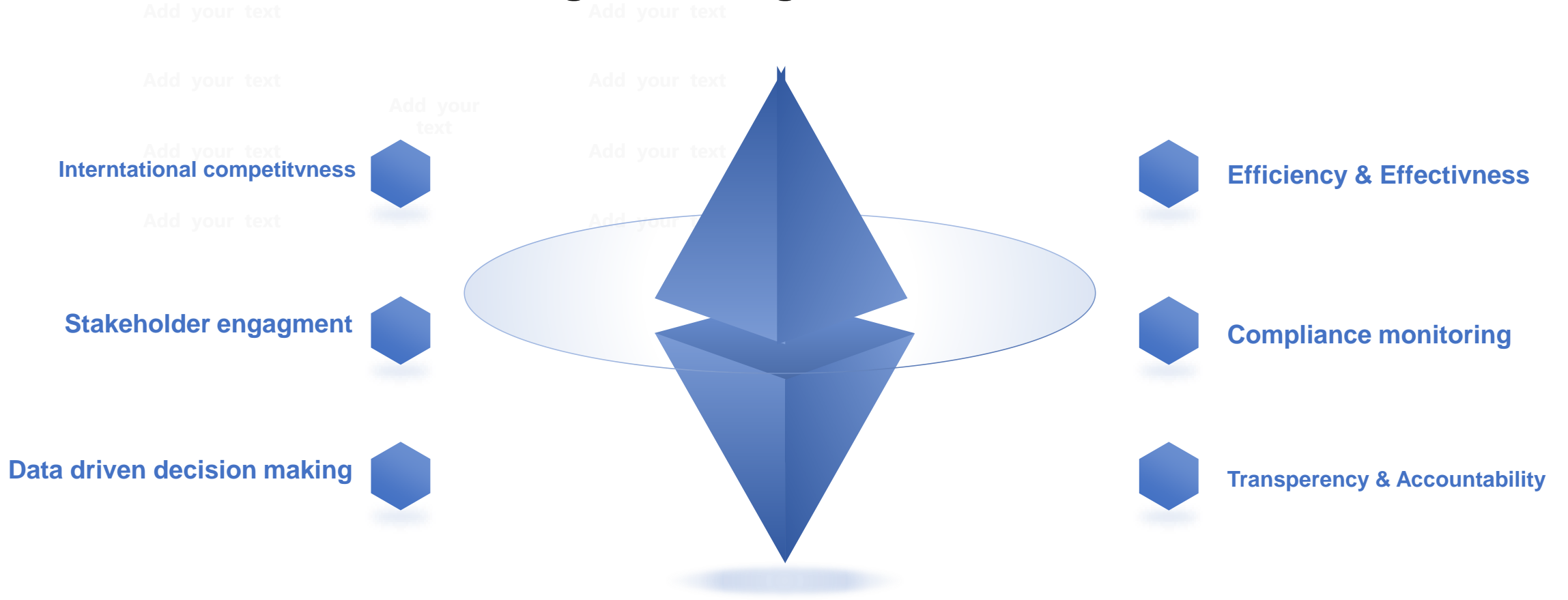


Regulatory bodies require rapid and secure communication to comprehend decision-making and expedite approvals, as this has been revealed

MeDevice platform allows applicants to submit their applications online, via a platform, The platform also enables the EDA employees to process applications faster and more efficiently

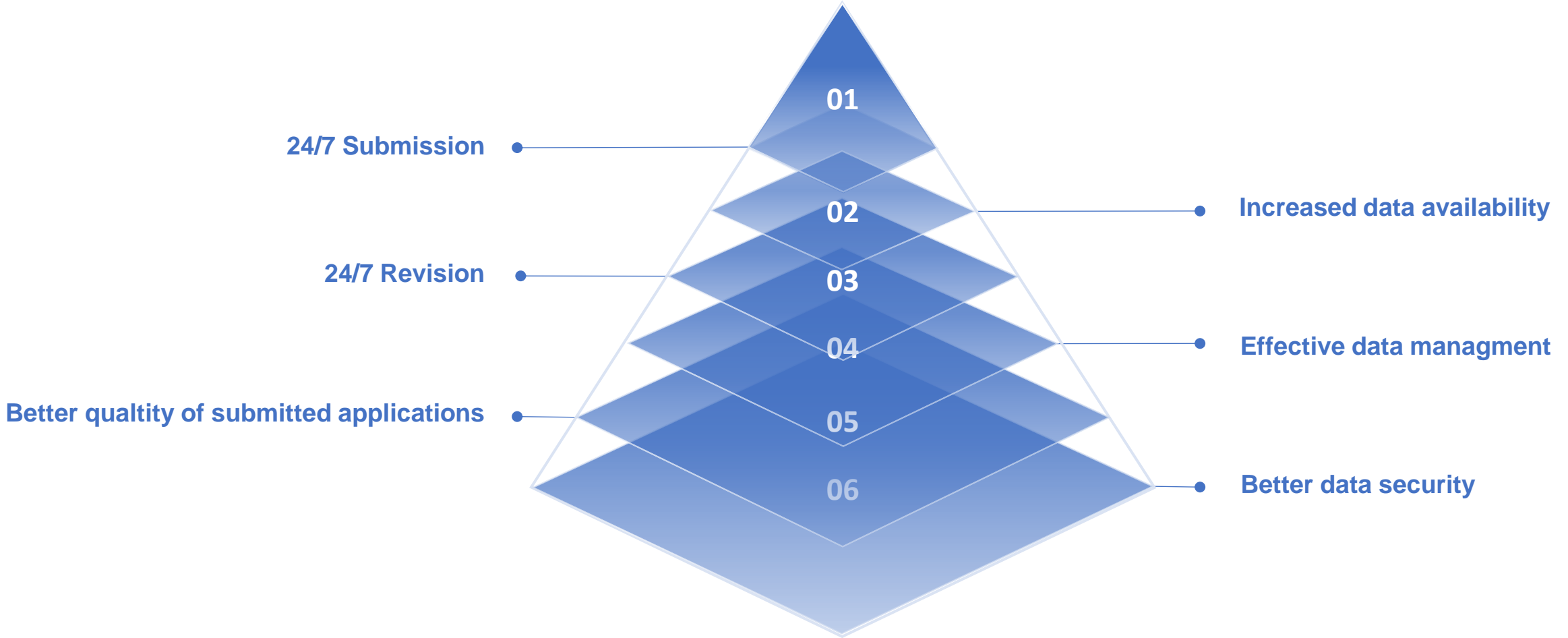


# Challenges Pre-digital transformation





## Benefits of applying digital transformation





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# Initiatives & Updates

# Initiatives undertaken to bring scientific or regulatory progress

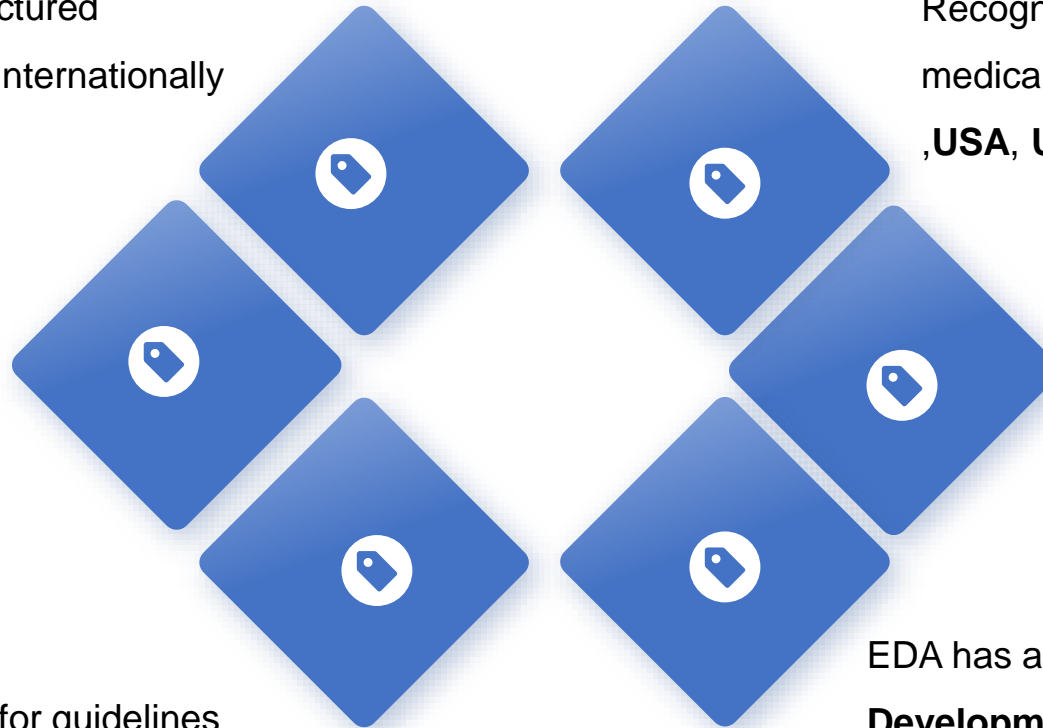
## Launched **MeDevice** platform

Registration of locally manufactured medical devices **not holding** internationally recognized certificates

Recognized certificates issued according to medical devices and IVDs regulations in **EU, USA, UK, Canada, Australia** and **Japan**

Registration and circulation of In Vitro Diagnostics including IVDs not holding internationally recognized certificates.

EDA has a **dedicated reference laboratory** that offers resources and expertise to encourage research and development to stakeholders



## UDI implementation

In process of issuing version two for guidelines concerning the regulation of **low-risk medical devices** and **listing of medical equipment**

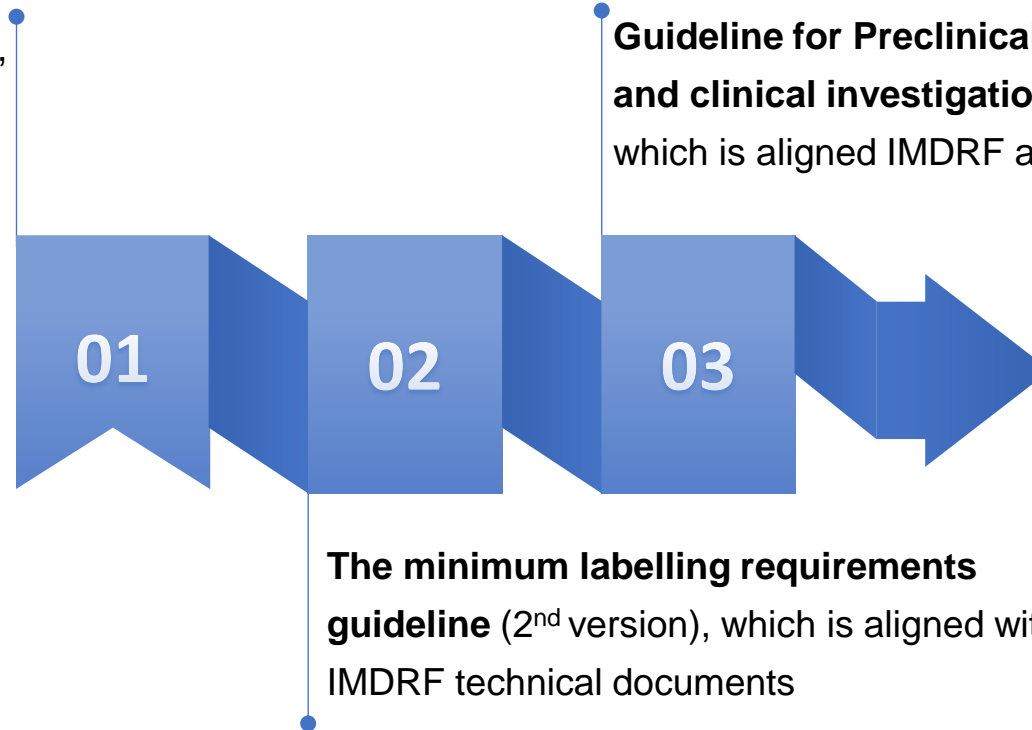
EDA has a **Center for Continuing Professional Development (CPD)** that develops consistent training programs for EDA stakeholders on a regular basis



## New/Revised EDA Guidelines in the process of finalizing

**IVD regulatory guideline (2<sup>nd</sup> version)**, which is closely aligned with IMDRF technical documents

**Guideline for Preclinical testing and clinical investigation for Medical devices** which is aligned IMDRF and GHTF documents



**The minimum labelling requirements guideline (2<sup>nd</sup> version)**, which is aligned with IMDRF technical documents



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# Localization





## Egyptian Medical Device Industry Growth Factors

01

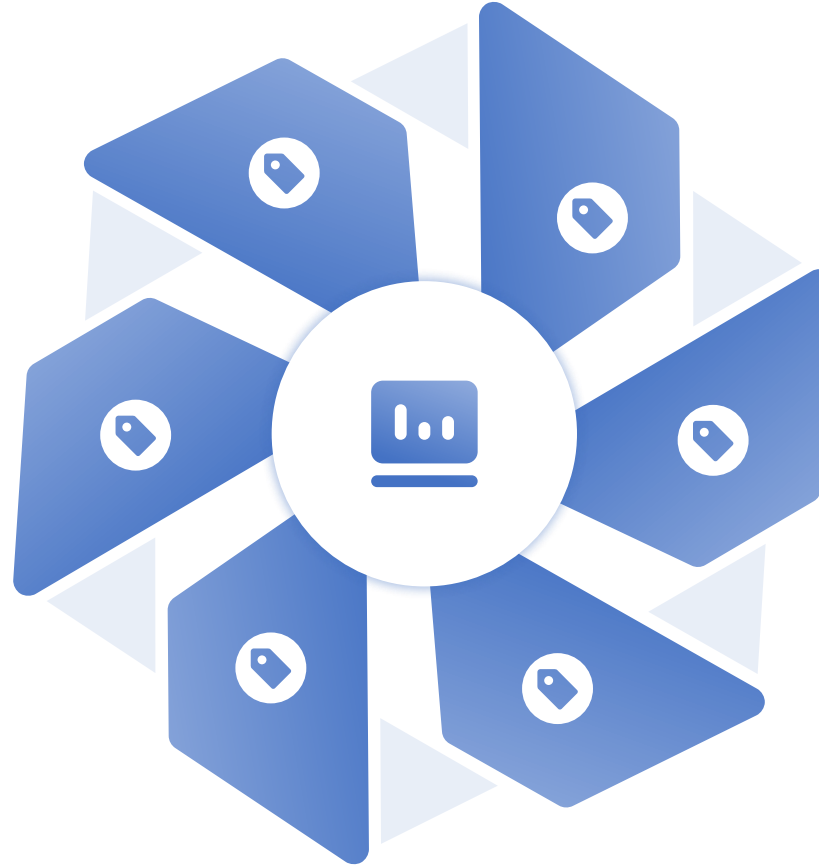
Increasing demand for healthcare services, government initiatives to promote medical device manufacturing, and foreign investment in the sector

06

EDA has paved the road for regulating of locally manufactured Medical devices & IVDs before placing in the market.

05

EDA offers all support to local industries to ensure that products meet EDA standards which are Safety and Effectiveness.



02

There are several local manufacturers that produce a variety of products ranging from basic diagnostic equipment to more complex medical devices

03

The Egyptian medical device industry has great potential for growth due its increasing demand from domestic markets as well as opportunities from foreign investment due to favorable government policies such as tax incentives

04

In line with the government's sustainable development strategy 2030, EDA aims to increasing the competitiveness of Egyptian local products



### Support to local manufacturers to:

- ✓ Ensure self-sufficiency
- ✓ Expand export horizons
- New adaptable strategies were established, including the substitution of internationally recognized certificates by EDA conformity assessment procedures.
- EDA has formulated a scientific committee for evaluating locally manufactured medical equipment including **innovative ones** intended to be circulated in the Egyptian market .





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*Thank You*