IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

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MINISTRY OF HEALTH

MTIIR
Medical Technology, Innovation, Health Information and Research Directorate

MTIIR Regulatory and Policy Updates

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Presentation Overview

- MTIIR involvement in IMDRF
- Enabling Regulation – Reliance
- Regulatory Sandbox for Breakthrough AI Technologies in Healthcare
- Key Principles for Evaluating AI-Driven Interventional Trials

Involvement in IMDRF

- MTIIR and IMoH experts participate in two working groups:
  - Artificial Intelligence/Machine Learning-enabled medical devices
  - Software as a Medical Device

- Adoption of N88 – Good machine learning practice (GMLP) for medical device development: Guiding principles:
  - The GMLP guidelines were adopted in Israel prior to their adoption by the IMDRF. MTIIR is currently examining whether it is necessary to update the local document.

Enabling Regulation – Reliance

Ongoing efforts to streamline and improve regulatory frameworks

- Self Declaration route for reliance-based Class I/Class A submissions.
- Fast Route for expedited reliance-based registration submissions.
- Updated, route specific guidelines and forms.

These measures and initiatives have enabled us to streamline our reliance workflow and enhance the transparency and clarity of the regulatory process.
The resulting improvements in efficiency have significantly shortened registration timelines and accelerate the processing of registration amendments and renewals, with turnaround time as short as 10 days in some cases.

Enabling Regulation – Reliance

Low Risk Class I Immediate	Medium Risk Class II, IIa 10, 45 Days	Medium-High Risk Class IIb 10,60 Days
Main Regulatory Requirements: • Local importer's Declaration • Assessment Documentation from another authority (if applicable)	Main Regulatory Requirements: • Local importer's Declaration • Assessment Documentation from another authority. • Technical Documentation review, evaluation of quality management systems etc.	Main Regulatory Requirements: • Local importer's Declaration • Assessment Documentation from 2 other, non dependent authorities. • Technical Documentation review, evaluation of quality management systems etc.

Timeline depends on:

- Type of submission: Registration, Significant/Insignificant Change, Renewal
- Product classification

Regulatory Sandbox for Breakthrough AI Technologies in Healthcare: Overview

Controlled Environment

A pioneering initiative led by the Ministry of Health (IMoH) and Israel Innovation Authority (IIA) providing a flexible framework to test high-autonomy AI in support of authority distribution/redefining professional roles and decision making authority, in real-world clinical settings.

Safety & Ethics | **Supervised Testing**

Core Objectives

- Designed to accelerate the validation of autonomous medical solutions while proactively addressing critical regulatory challenges surrounding liability, clinical oversight, and risk mitigation.
- Enable AI supported delegation of clinical authority
- Generate evidence for adaptive regulation and new models of professional responsibility

Clear Pathway | **Policy Co-Creation**

Strategic Scope

- **Task Redistribution:** Expanding clinical responsibilities to broader healthcare staff.
- **Autonomous AI:** Evaluating systems making independent diagnostic/treatment choices.
- **Clinical Decision Support:** Setting legal and regulatory boundaries for AI care.

Regulatory Sandbox
Eligibility Criteria & Support Pathways

ENTRY CRITERIA

Target Audience & Readiness

Geared toward MedTech innovators and healthcare institutions tackling regulatory barriers to bring high-impact AI solutions into the healthcare ecosystem.

Technology Readiness Level: TRL 6+ (core technology validated and ready for real-world pilot testing).

Implementation Horizon: Solutions capable of clinical adoption within ~2 years.

Local Operations: Pilot activities must be conducted at an operational healthcare site in Israel.

PROGRAM OPTIONS

Dual Support Architecture

Applicants can benefit from specialized regulatory advisory and combined financial support:

Joint IMoH & IIA Pilot Fund Track: Comprehensive support providing regulatory guidance alongside competitive government grant funding.

IMoH Regulatory Advisory Track: Tailored regulatory road mapping, assigned Single Point of Contact (SPOC), and direct consultation with regulatory experts.

Regulatory Sandbox
Initial Pilot Cohort: Selected Companies

HOME ULTRASOUND

Pulsenmore Ltd.

Developing an autonomous AI platform to analyze at-home ultrasound scans performed by pregnant women.

Regulatory Goal: Establish a pathway enabling autonomous clinical decisions without requiring physician review for every routine scan.

Beilinson Hospital (Rabin Medical Center)

CARDIAC CARE

Cordio Medical Ltd.

AI-driven home monitoring system for heart failure management, analyzing voice, sensor, smartwatch, and EMR data.

Regulatory Goal: Validate AI detection of early clinical deterioration to autonomously recommend medication protocol adjustments.

Tel Aviv Sourasky (Ichilov)

OBSTETRIC CARE

Simhawk Ltd.

Intelligent real-time AI guidance software enabling healthcare personnel to perform fetal weight estimations.

Regulatory Goal: Assess regulatory adaptations required to safely expand ultrasound execution beyond specialist doctors.

Hadassah Medical Center

Key Principles for Evaluating AI-Driven Interventional Trials

To address the unique considerations involved in evaluating AI-based clinical trials, the Israeli Ministry of health has published the Document: Key Principles for Evaluating AI-Driven Interventional Trials.

The document outlines guiding principles for examining submissions for interventional clinical trials using AI-based tools.
The document was developed through a multidisciplinary collaborative effort involving the Ministry of Health and external experts in medicine, technology, research, ethics, and more.

Purpose
The document is intended to support Institutional Review Boards (IRBs) and other relevant stakeholders in reviewing applications for clinical trials of AI-based Digital Health Technologies (DHTs).
It is important to emphasize, these are guiding principles, not binding regulatory requirements.

subjects_Digital_Medical_Technology_Key-Principles-for-Evaluating-AI-Driven-Interventional-Trials-en.pdf (www.gov.il)

Key Principles for Evaluating AI-Driven Interventional Trials

Objectives

- Presenting guiding principles for conducting and evaluating clinical trials involving AI-based DHTs.
- To assist IRBs in identifying key questions during the review of clinical trial applications.
- To encourage knowledge and experience sharing between industry, academia, and regulators
- To promote ongoing discussion regarding complex issues that have yet to be resolved.

The document is supported by relevant international work including IMDRF guidance on SaMD and risk characterization.

Examples of relevant international work supporting the document include:
SPIRIT AI, IMDRF N81 (Characterization Considerations for Medical Device Software and Software-Specific Risk), and IMDRF N88 (GMLP)

Key Principles for Evaluating AI-Driven Interventional Trials

Status:
The document was published following a public consultation period.

This document, along with other international policy materials, has been used to develop a training program (a university course). The program was attended by members of various national IRBs responsible for the approval of human clinical trials.

Future Objectives:
Similar document outlying guiding principles for clinical trial planning and submission, targeting companies and organizations planning to conduct clinical trials.

Thank You

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