MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

IN VITRO DIAGNOSTICS REAL WORLD EVIDENCE OPEN HAND (COVID REAL WORLD EVIDENCE)

Regulatory submission interactions are typically confidential. With the lens of a public health emergency, Open Hand used this opportunity to build a framework for utilizing real-world data and real-world evidence to support regulatory submissions and decision-making. In this collaborative pilot effort, medical device manufacturers shared high-level learnings to support the transition of SARS-CoV-2 diagnostic test that had Emergency Use Authorization to full market authorization with support from an interactive regulatory review supplied by the US Food and Drug Administration.

Initiative Goals

1. Provide a transparent process to evaluate new technology and methods.
2. Capture the 'how' to share with the broader community while staying in the precompetitive space and protecting proprietary technology and methods
3. Disseminate recommendations from this important exercise in the form of an instructional whitepaper and an article in a peer-reviewed journal.

Learn More

- MDIC Website – Open Hand
  www.mdic.org/project/covid-rwe/
- MDIC Framework: Real-World Clinical Evidence Generation: Advancing Regulatory Science and Patient Access for In Vitro Diagnostics (IVDs) -
  www.mdic.org/resource/ivd-rwe-framework/
- Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices
  www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices
- FDA Documents

ABOUT MDIC

The Medical Device Innovation Consortium (MDIC) is a public-private partnership that brings together representatives of the FDA, NIH, CMS, NIST, and other agencies, industry, non-profits, and patient advocacy organizations to improve the processes for development, assessment, and review of new medical technologies.

MDIC coordinates the development of methods, tools, and resources used in managing the total product life cycle of a medical device to improve patient access to cutting-edge medical technology.

We are driving faster, safer, and more cost-effective innovation for patient benefit.

MDIC'S CLINICAL DIAGNOSTICS INITIATIVE

The IVD Initiative falls under MDIC's Clinical Diagnostics Initiative. MDIC's Clinical Diagnostics Initiative addresses the biggest barriers to collecting adequate clinical evidence in support of new medical technology. Clinical Diagnostics stakeholders work together to create blueprints for innovative clinical trials techniques, develop standards and metrics for effective clinical trial designs, and encourage the collection of adequate and appropriate clinical and patient preference data.

CONTACT

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