MEDICAL DEVICE INNOVATION CONSORTIUM

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Clinical Diagnostics Program
Clinical Evidence Statement of Work

What is the issue?

Market entry for an IVD test requires evidence of analytical and clinical validity: how well the test predicts the presence, absence or risk of a specific condition in order to get the analyte cleared or approved by FDA. Payer coverage and provider adoption also require evidence of clinical utility: whether the information that a test provides is useful to improve the management and outcome of a condition. This project will create an evidence framework that test sponsors can use to make decisions on how to develop credible evidence of analytical and clinical validity and clinical utility. The scope of the statement of work is specific to the United States.

What is the goal of this project?

The goal is a framework that outlines:

a) Analytical validity: the ability of an in vitro diagnostic to identify, detect, measure, calculate, or analyze one or more measurands to support its intended use and the type of analytical data required to support the claims.

b) The elements of defining clinical validity; the ability of an in vitro diagnostic product to identify, measure, predict, monitor, screen, prevent, or otherwise diagnose, or assist in selecting treatment for, a disease or condition in humans through the identification, detection, measurement, calculation, or analysis of one or more measurands to support its intended use and the type of clinical data required to support the claims.

c) The elements of defining clinical utility; how the elements can be applied to specific clinical settings and the types of evidence required to support potential claims of clinical utility.

What will we produce (i.e., Deliverables)?

The deliverable is a 12 – 15 page concept paper that lays out an outline for a framework for developing an IVD. One section will focus on analytical validity, one section on clinical validity and the last on clinical utility. The framework will be further refined such that test sponsors can use it to make decisions on how to develop credible evidence of analytical and clinical validity and clinical utility. The timeline is to prepare documents that are final draft and available for comment at the annual MDIC meeting, September 21st, 2016.

The document will have three main sections, as follows:

a. Elements of analytical validity: a general scheme of how medical test claims are determined to obtain market entry.
    i. Definitions of components of analytical validity
    ii. Data sources

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iii. Data requirements

b. Elements of clinical validity: a general scheme of how medical test claims are determined along with potential alternate methods to obtain market entry
   i. Definitions of components of clinical validity (feasibility and intended use(s))
   ii. Data sources
   iii. Data requirements

c. Elements of clinical utility: a general scheme of how medical tests impact clinical care outcomes, including types of decisions and potential outcomes of such decisions.

   i. Application to specific clinical settings. Formulating PICO (patients, intervention, comparators, outcomes); analytic framework; decision model; specifying performance measures and clinically meaningful magnitudes of difference.

   ii. Types of evidence to support potential claims, including direct vs. indirect evidence

Who is working on this project?
MDIC has assembled a work group comprised of member organizations and other subject matter experts to guide work on this project.

Industry:
Vicki Anastasi, ICON
Amy Durtschi, PhD, Abbott
Maurice Exner, PhD, Abbott
Tremel Faison, BARDA
Jaime Houghton, Sysmex
Greg Payne, BD
Susan Piotrowski, Abbott
Michael Reiner, BD
Sandra Statz, Exact Sciences
Lee Termini, MediMedia Managed Markets
Songbai Wang, MD, Janssen Diagnostics

Program Manager:
Carolyn Hiller

FDA:
Marina Kondratovich, PhD, OIR
Rochelle Chodock Fink, MD, JD, CDRH

Expert Advisors:
Susan Alpert, MD, PhD
Naomi Aronson, PhD
Constantine Gatsonis, PhD
Louis B. Jacques, MD