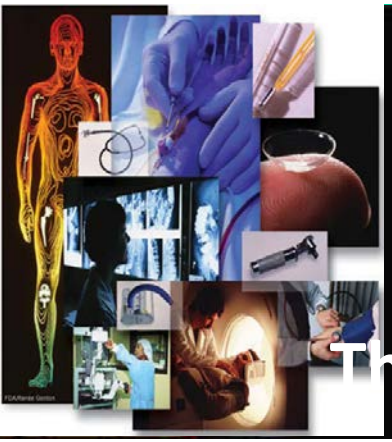

COI and the Center for Devices and Radiological Health: The Network of Experts and The Medical Device Innovation Consortium (MDIC)

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Center for Devices and Radiological Health,
U.S. Food and Drug Administration

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What we do…

- CDRH is responsible for regulating firms who manufacture, repackage, re-label, and/or import medical devices sold in the United States.

CDRH

RCA's- Includes Organizational CDA and COI

Organization 1
AIMBE

Organization 2
ACC

Organization 3
Intervent. Radio.

Specific Scientific Issue

No Relevant Experts

4 Experts

1 Expert

Screen Individuals for Topic-Specific COI and Use CDA (if needed)

Talk 1-on-1 **OR** **Convene N of E Call**

Network of Experts Question Categories- Stratified by Risk to CDRH

A. General questions about a field of engineering, science, medicine or public health

B. Questions about a product line or specific medical indication

C. Questions about a specific product or products, could include pending applications

A. <u>Limited risk to CDRH.</u>

Self cert COI with basic questions, general CDA at organizational level only

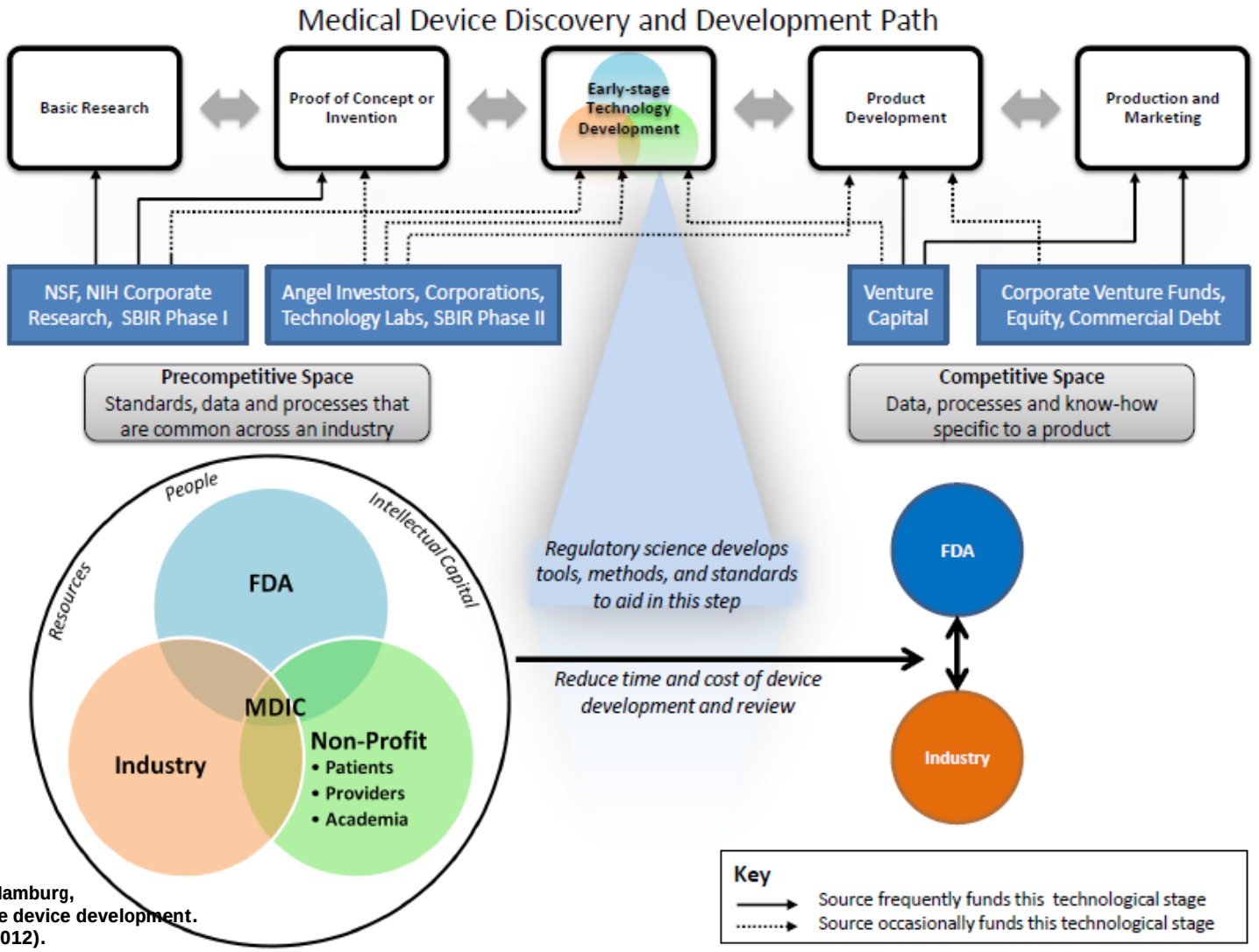
B. <u>Moderate risk to CDRH.</u>

Self cert COI with topic-specific questions, general CDA at organizational level only

C. <u>High risk to CDRH.</u>

Full COI with CDRH vetting, sponsor signed release to disclose info, individual and organizational CDA

THE MDIC Solution



M. McMurry-Heath and M. A. Hamburg,
Creating a space for innovative device development.
Sci. Transl. Med. 4,163fs43 (2012).

THE MDIC Solution: Structure

Executive Committee

- Oversee Steering Committees
- Members selected based upon recommendations from stakeholders
- Led by a Chair and Vice Chair

Steering Committees

- Identify and oversee individual projects
- Members represent academia, government, industry, and non-profit organization
- Led by two co-chairs

MDIC Staff

- Executive Director
- Program Managers
- Administrative Support

MDIC Foundational Members

BD

Boston Scientific
Defining tomorrow, today.™

ABIOMED

CVRx®

FDA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Cyberonics®

THE PEW CHARITABLE TRUSTS

NORD
National Organization for Rare Disorders

IMMUCOR GAMMA®

LifeScience Alley®

Medtronic

TERUMOBCT

Align • Achieve • Accelerate

Projects

1. Computational Modeling and Simulation, Randy Schiestl
   - **Development**
   - **Assessment**
   - **Review**
2. Clinical Trial Reform, Rick Kuntz, MD
   - **Large Simple Trials**
   - **Post Market Surveillance**
   - **Data Transparency**
   - **Clinical Trial Efficiency**
3. Patient Centeredness and Risk Management, Ross Jaffe, MD
   - **Validation strategies for measuring patient views on device benefits and risks**
   - **Provide suggestions on how to utilize this data in the regulatory setting**

THE MDIC Origins and History

Recruit industry leaders to join the MDIC

- Interest in the regulatory space
- Strong technical background
- Broad industry, cross sector, experience
- Willing to invest time and money

Develop business documents

- Charter and bylaws
- IP and Data Sharing Principles
- Financial plan
- Organizational plan
- Implementation phases

Engage stakeholders

- Develop effective communication tools
- Initiate educational programs
- Recruit broader membership
- Request project proposals

Initiate project work

- Select lead projects
- Allocate funding
- Engage teams