Introduction to MDIC & Update of the Initiative

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Chip Hance
MDIC EFS Initiative

Pamela Goldberg – MDIC President and CEO
Chip Hance – MDIC-EFS Initiative Board Champion

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MDIC WORKS TO HELP PATIENTS GAIN ACCESS TO INNOVATIVE MEDICAL TECHNOLOGIES

MDIC is a 501(c)3 and the first public-private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit.
**MDIC METHODOLOGY**

<table>
<thead>
<tr>
<th>Create a forum for collaboration</th>
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<tbody>
<tr>
<td>Flexible</td>
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**Identify strategic investments in regulatory science**

| Improve efficiency | Unmet needs | Innovation timeline |

**Provide tools and methods to drive innovation**

| Evidence generation | Patient engagement | Quality/Safety |

Coordinate the development of tools and methods used in managing the total product life cycle to improve patient access to novel medical technology.
OUR CORE INITIATIVES DRIVE OUR WORK TO IMPROVE HEALTH OUTCOMES

MDIC facilitates a number of programs and activities to advance the medical device regulatory process for patient benefit. These programs are housed within four core initiatives of MDIC.
EARLY FEASIBILITY STUDIES

Early Feasibility Studies (EFS) may provide patients early access to innovative devices and therapies.
# EFS Stakeholder Benefits

## Patients
- Access to novel, potentially life-saving technology
- Mitigation of risks inherent to clinical trials

## FDA
- Early exposure to novel technology
- Better definition of requirements for demonstrating safety & efficacy; reduces development risks.

## Sites
- High quality U.S. healthcare data & networks
- Innovative treatment options
- Expert Key Opinion Leaders stay involved in innovation

## Sponsors
- Earlier access to high-quality EFS data and outcomes
- Improved innovation and feedback opportunities
EFS PROGRAM GROWTH – FIRST 5 YEARS

EFS IDE Submittal and Approval Trends: CDRH Office of Device Evaluation

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Submitted</th>
<th>Approved</th>
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<tbody>
<tr>
<td>FY14</td>
<td>26</td>
<td>24</td>
</tr>
<tr>
<td>FY15</td>
<td>47</td>
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<td>FY16</td>
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<td>FY17</td>
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<td>45</td>
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<tr>
<td>FY18</td>
<td>73</td>
<td>53</td>
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MDIC: EFS THROUGH THE YEARS

2013 - FDA Published EFS Guidance

In 2013 FDA published the EFS/FIH Guidance document:
• This EFS Guidance successfully improved average EFS IDE approval times.

2015 – Blueprint for Early Feasibility Study (EFS) Success

• Commissioned the EFS/FIH Industry Perspectives survey
• Published the Blueprint for EFS Success, supplementing the 2013 FDA Guidance
• MDIC, Sponsors, and FDA: 1st ever collaboration to share de-identified EFS Administrative and Clinical metrics.
• Baseline represents approximately 25% of EFS trials started FY14 – FY17

2017 – Baseline EFS Performance Metrics

2018 – Tools & Processes

On MDIC’s website:
• Master Clinical Trial Agreement
• Patient Informed Consent template
• Education Tools: IRB, Research teams and Patients

2019 – EFS Network

• 18 sponsors – 31 sites
• Best Site Practices Workshop
• EFS workstream development
EFS Site Network Pilot

Chip Hance
MDIC-EFS Initiative Board Champion
EFS Site Network Pilot - Purpose

Develop a national EFS learning system

• Track and report EFS metrics
• Test the utility and effectiveness of EFS-specific tools and methods
• Serve as a launching point for a future network of high-performing EFS sites
  • Nation-wide coverage
  • Multiple therapeutic areas
EFS Initiative: Supporting Partners (18)
EFS Site Network Pilot: 60:60:60 GOAL

EFS Metrics: Administrative Baseline

<table>
<thead>
<tr>
<th>EFS Metric Category</th>
<th>Mean Time from EFS IDE Approval (Days)</th>
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<tbody>
<tr>
<td>IDE Approval</td>
<td>68</td>
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<tr>
<td>IRB Approval</td>
<td>72</td>
</tr>
<tr>
<td>Contract Approval</td>
<td>133</td>
</tr>
<tr>
<td>1st Subject Enrollment</td>
<td>187</td>
</tr>
</tbody>
</table>

IDE Approval: 60 Days
IRB Approval: 60 Days
Contract Approval: Next 60 Days
1st Subject Enrollment: 187 Days
EFS Site Best Practices Workshop

March 6-7, 2019, Arlington, VA.

- Over 65 attendees were present, including representatives from 20 sites, 14 sponsors, FDA, CMS and service providers
- Topics covered:
  - Managing Risk, SAEs & IRB Reporting
  - Timely & Effective Contracting
  - Budgeting between EFS Sites and Sponsors
  - EFS Staffing and Resources
  - Patient Identification, Enrollment & Retention
  - Coverage Determinations & Site Budgets
EFS Site Network Pilot

Completed Tools and Methods

• Development of a Master Clinical Trial Agreement
• Patient Informed Consent Form Template
• Tools for educating IRB, research staff and potential patients on EFS

http://mdic.org/cts/efs/
EFS Site Network Pilot: Plans for 2019

I. Communications
   • Continue with EFS Express Communications
   • Webinars on Best Practices

II. Workshops
   • TVT Symposium/Workshop on Site Best Practices for Patient Screening/Enrollment
   • Contracting Webinar
   • IRB/Informed Consent Workshop

III. Working Groups
   • Budgeting Working Group

IV. Metrics
   • Data on 2017/18 EFS Study Metrics
   • Site Survey
Questions?

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

MDIC has been formed to add value at the intersecting needs of the medical device industry, regulators, and the related organizations that are together responsible for a vibrant medical device industry that serves the public health needs of the United States.

Our Work
MDIC, through its public-private partnership, aims to advance the regulatory process in the medical device industry. MDIC coordinates the development of methods, tools, and resources used in managing the total product life cycle of a medical device in an effort to improve patient access to cutting-edge medical technology.

MDIC’s initiatives focus on four areas:

**Clinical Science** – Address the biggest barriers to collecting adequate clinical evidence in the support of new medical technology by creating blueprints for innovative clinical trials techniques, developing standards and metrics for effective clinical trial designs and encouraging the collection of adequate and appropriate clinical and patient preference data.

**Data Science & Technology** – Fulfill the promise of advances in data analysis by creating tools and methods to use advanced data analysis techniques and new technology to accelerate the collection of clinical data, remove barriers to patient access and monitor product safety, quality and effectiveness.

**Health Economics & Patient Access** – Create predictability and transparency of evidentiary requirements for coverage and improve pathways for coverage, coding and payment to speed patient access and amplify the patient voice in selection of treatment options.

**National Evaluation System for health Technology Coordinating Center (NESTcc)** – Work with stakeholders across the medical device ecosystem to catalyze the timely, reliable, and cost-effective development of Real-World Evidence to enhance regulatory and clinical decision-making.
Initiatives
Several MDIC Initiatives have one or more programs designed to meet a specific need:

Clinical Science
• Clinical Diagnostics
• Early Feasibility
• Science of Patient Input

Data Science & Technology
• Case for Quality
• Computational Modeling and Simulation
• Cybersecurity
• External Evidence Methods

Health Economics & Patient Access
• Coverage
• Reimbursement

National Evaluation System for Health Technology Coordinating Center (NESTcc)
• Governance
• Data-Network
• Test-Cases
• Data Quality and Methods

Membership
MDIC members are leaders in the medical technology industry. MDIC focuses on providing patients access to innovative medical technologies, so many of our members are companies that can help us serve this mission.

Member organizations are substantially involved in medical and/or medical device research, development, treatment, or education; the promotion of public health; or expertise in regulatory science.

LEARN MORE ABOUT MDIC
Learn more about MDIC by visiting www.mdic.org, sending a message to info@mdic.org, or calling (202) 828-1600

www.mdic.org