STATE OF THE UNION AND EFS UPDATE

Pamela Goldberg

MDIC President and CEO

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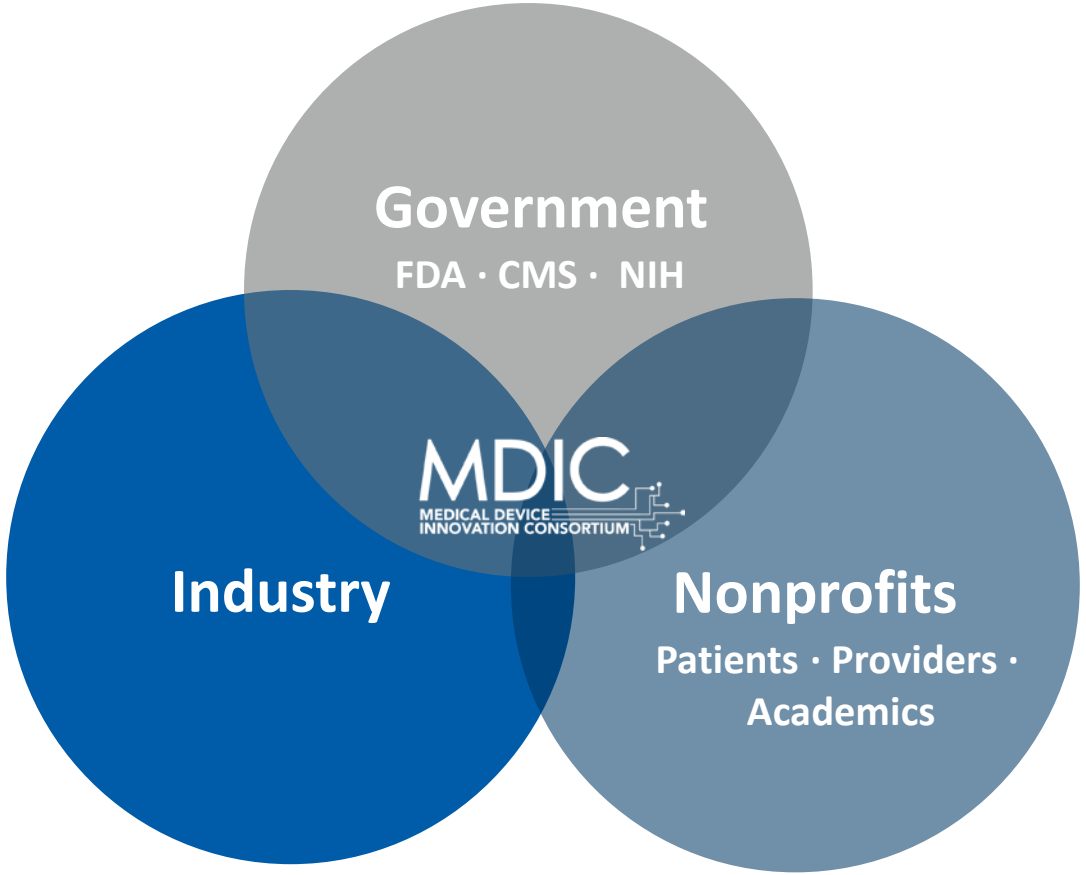
MEDICAL DEVICE INNOVATION CONSORTIUM

MDIC WORKS TO HELP PATIENTS GAIN ACCESS TO INNOVATIVE MEDICAL TECHNOLOGIES



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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.

EARLY FEASIBILITY STUDY

Early Feasibility Study (EFS) may provide patients early access to innovative devices and therapies.

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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.

INSTITUTIONS

- 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

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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

2017 – Baseline EFS Performance Metrics

- 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

2018 – Tools & Processes

On MDIC's website:

- Master Clinical Trial Agreement
- Patient Informed Consent template
- Education Tools: IRB, Research teams and Patients

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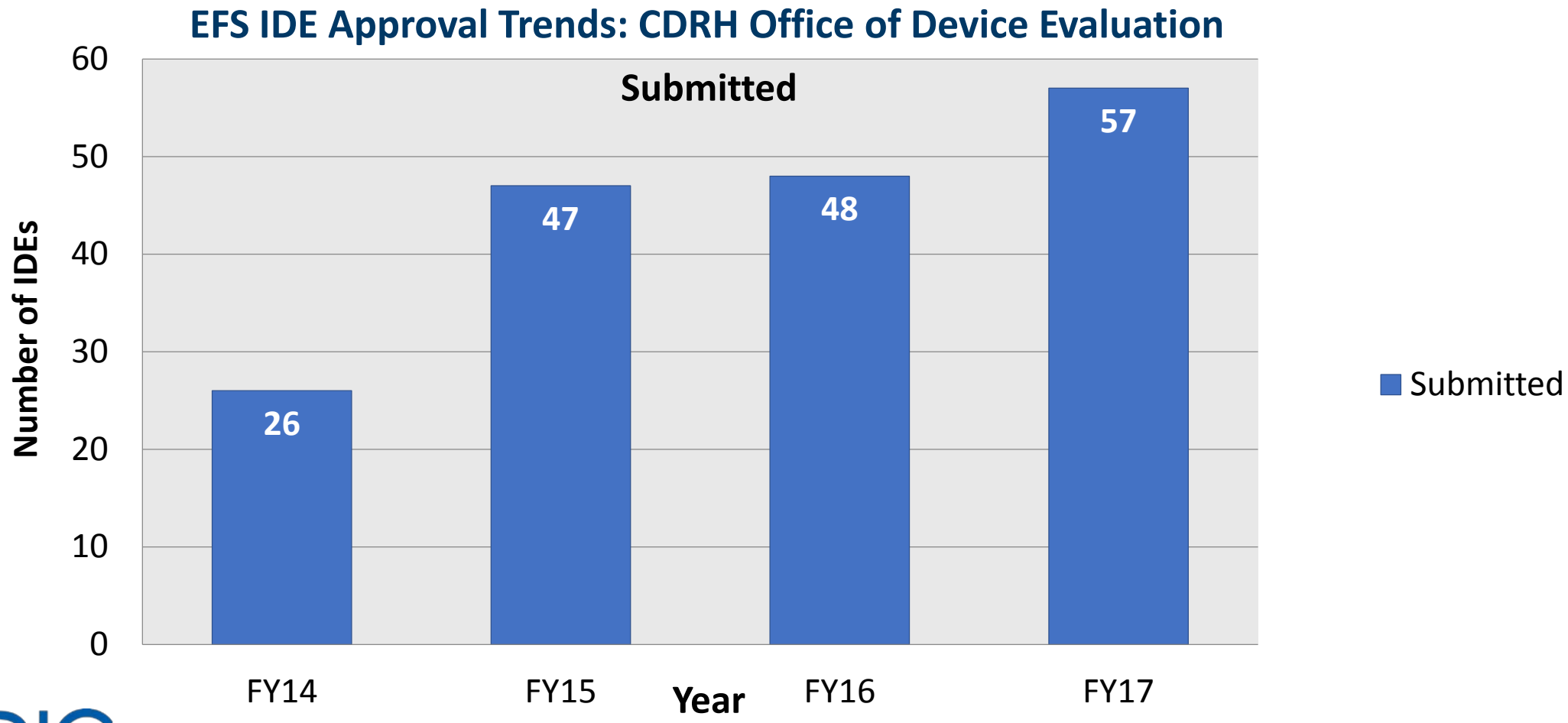
IDE SUBMISSION TRENDS: FIRST FOUR YEARS OF EFS



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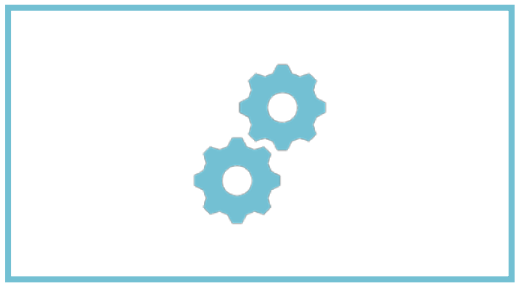
PURPOSE OF THE EFS INITIATIVE

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

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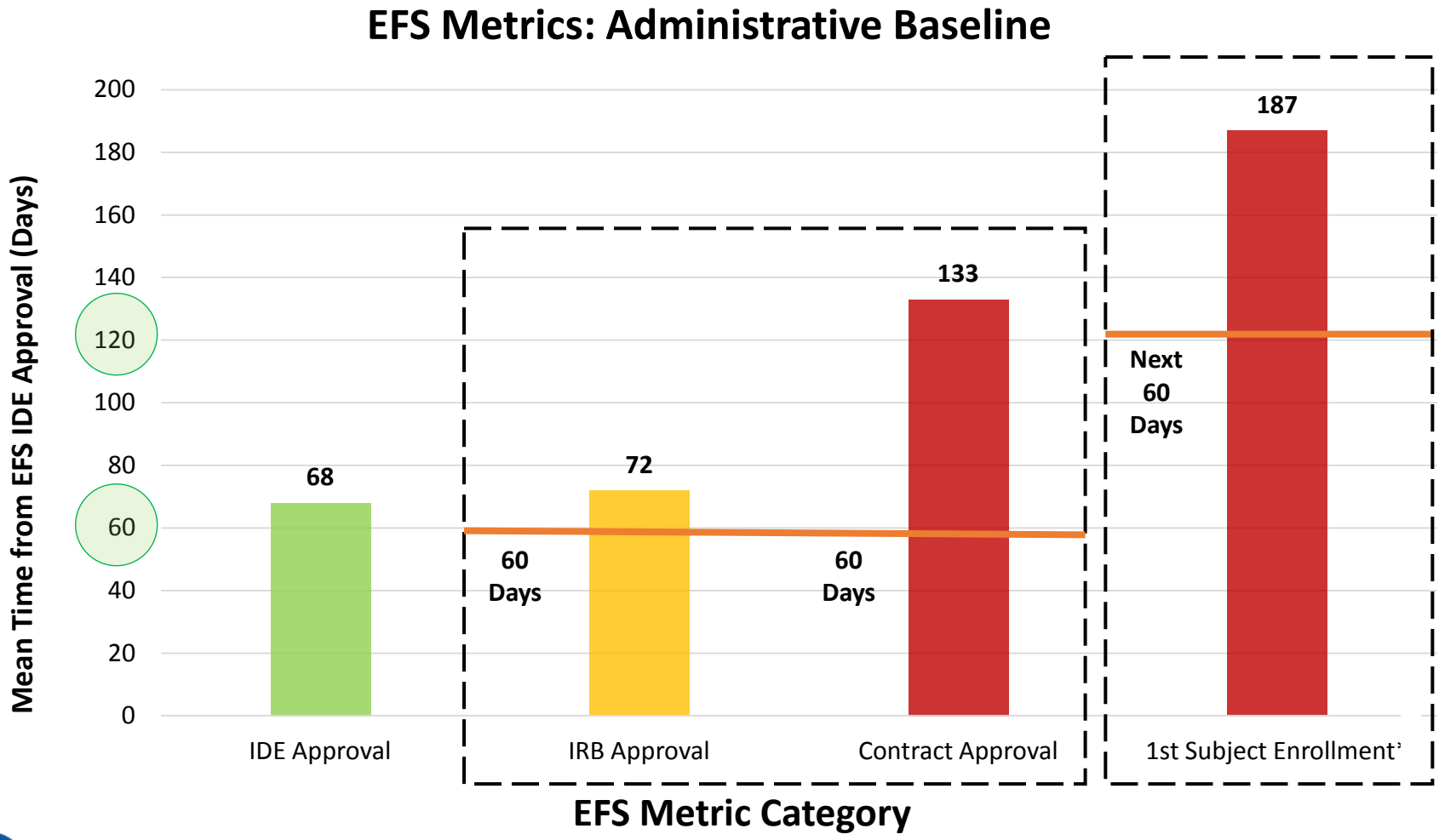
60:60:60 GOALS OF EFS INITIATIVE



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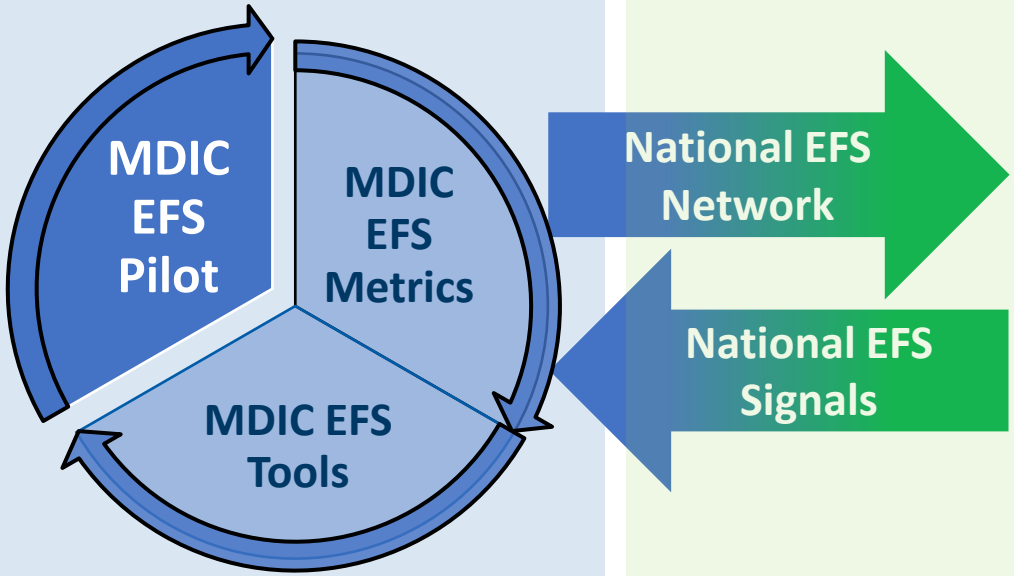
EFS INITIATIVE - COLLABORATIVE LEARNING

EFS Signals/Trends (2004 – 2012)

- OUS Migration of EFS
- US KOLs underutilized
- ↓ Med Tech investments
- ↓ US Patient access to novel technologies

EFS Ecosystem Actions (2013 – Current)

- 2013 FDA EFS Guidance
- \+
- 2016 MDIC EFS Initiative



National EFS Network (Future)

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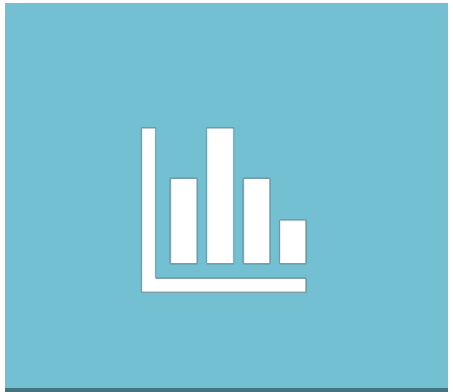
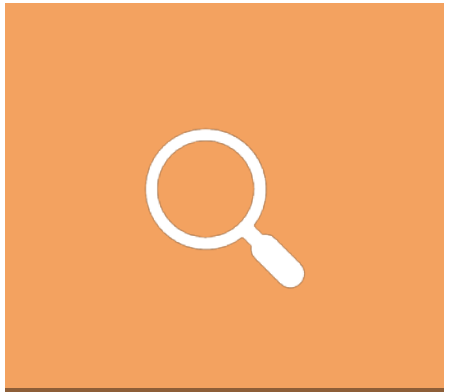
EFS INITIATIVE: SITE & SPONSOR EXPECTATIONS



Commitment to pursue target EFS performance metrics

EFS tool use & impact reporting



Identify and address institutional barriers and resources

Sponsors responsible for site selection, EFS management and trial operations

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EFS INITIATIVE: MDIC EXPECTATIONS

01

- Facilitate stakeholder collaboration between participating Sponsors and Sites

02

- Collect, deidentify and aggregate performance metrics
- Analyze and publicly report summary statistics

03

- Modify or create new tools based on metrics

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