



# Early Feasibility Studies (EFS) Working Group: Administrative & Clinical Practices



**2017 Program Summary**



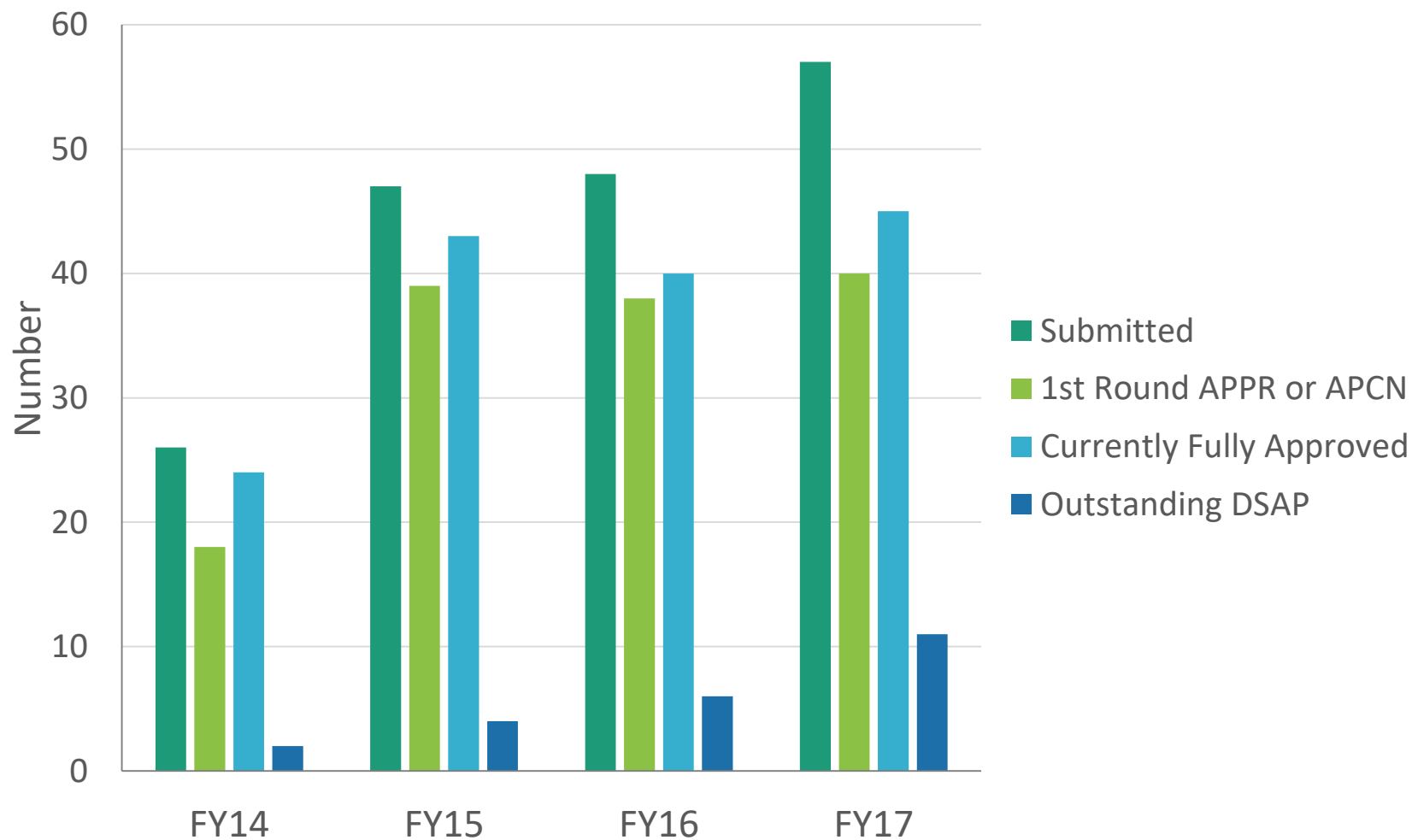
# EFS Program: 2017 MDIC Metrics Project

- Background: By 2009, the U.S. had seen a significant decrease in the percent of clinical trials being conducted for medical technologies<sup>1</sup>
- Agency Response:
  - FDA/CDRH recognizes that medical devices, in contrast to a pharmaceutical, may require modifications on a near constant basis
  - In 2013, FDA/CDRH release the guidance on Early Feasibility Studies (EFS)
- MDIC: EFS Analysis
  - In 2017, MDIC works with sponsors to analyze EFS performance metrics
  - MDIC Metrics analysis demonstrate
    - Administrative Challenges are now the largest barriers to clinical trial operations
    - Especially Contracting and Patient Recruitment

<sup>1</sup>Holmes DR, Califf R, Farb A, et al. Overcoming the challenges of conducting early feasibility studies of medical devices in the United States. *J Am Coll Cardiol.* 2016; 68(17): 1908–1915, doi: 10.1016/j.jacc.2016.07.769, indexed in Pubmed: 27765194.



# EFS IDE Submissions & Review Decision Trends

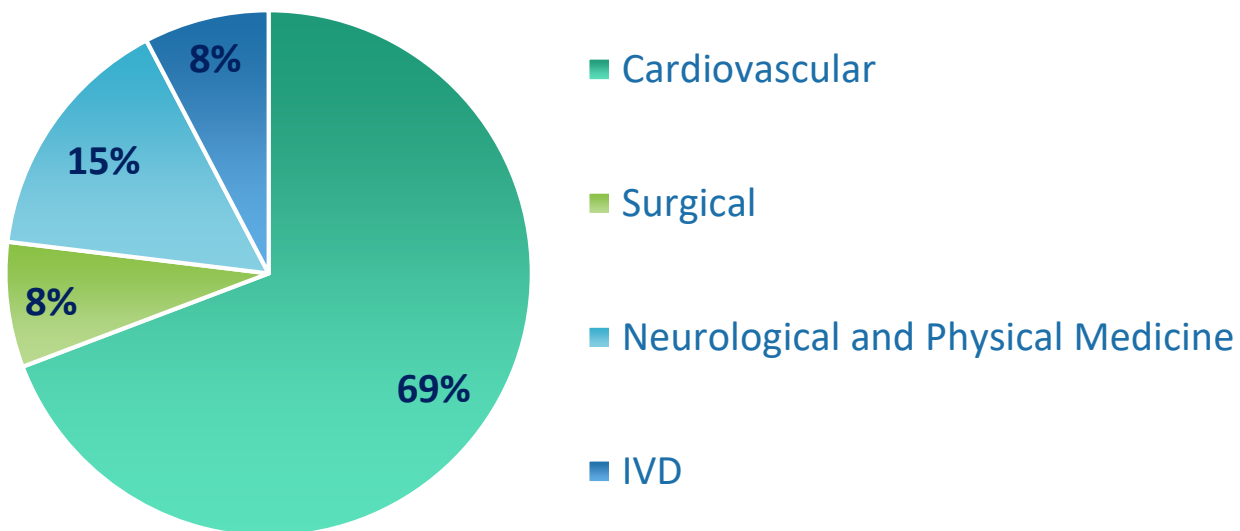




# EFS Performance Metrics: Respondents

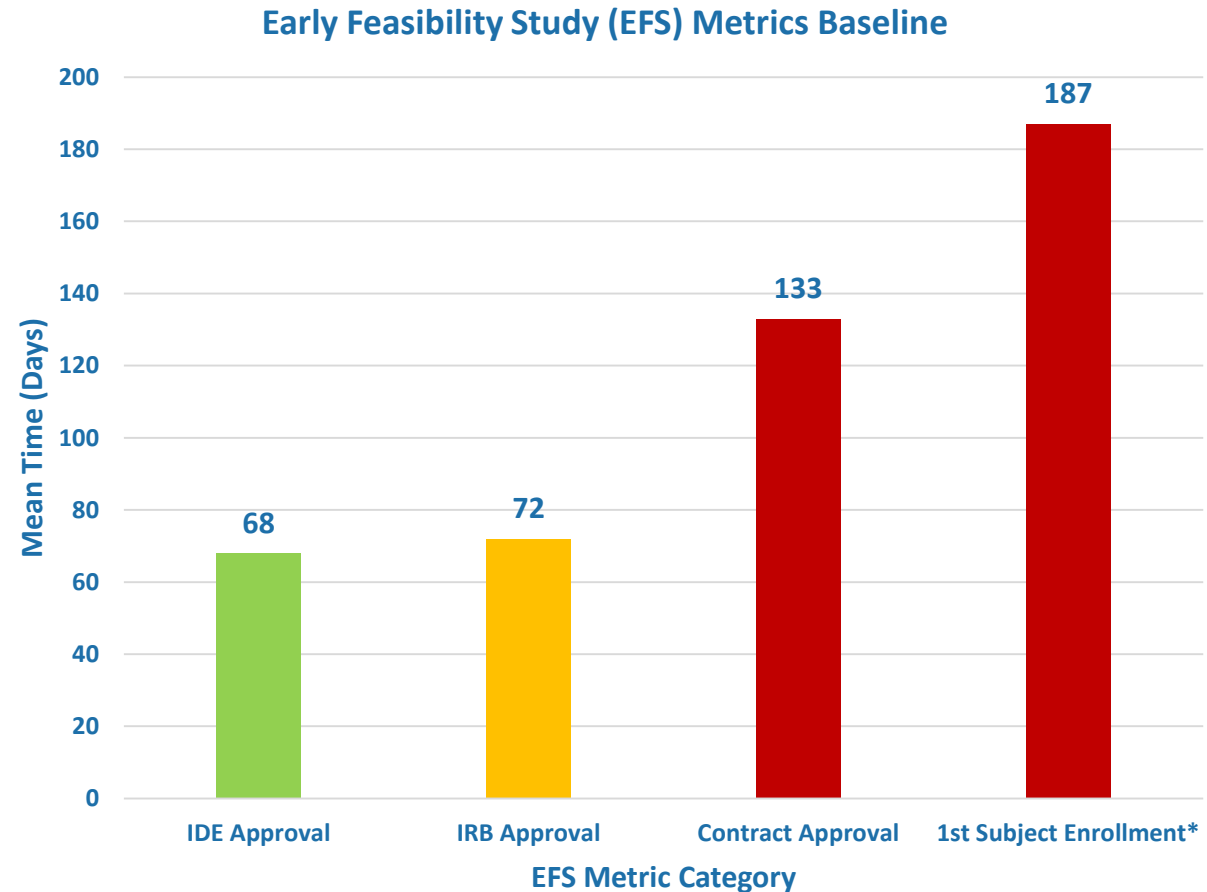
- First ever collaborative sharing of Sponsor administrative data
- 13 Study Sponsors provided data to MDIC to compile EFS Performance Metrics
- Individual data remains proprietary to Sponsors
- Consolidated output provides guidance for Process Improvement

EFS Metrics Respondents



# Early Feasibility Study (EFS) Metrics

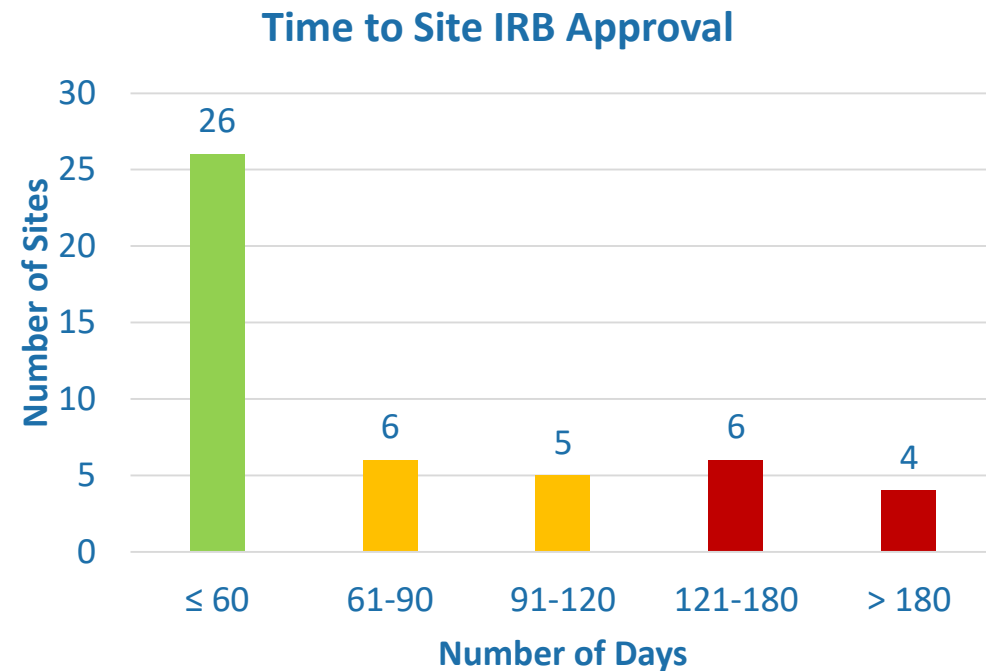
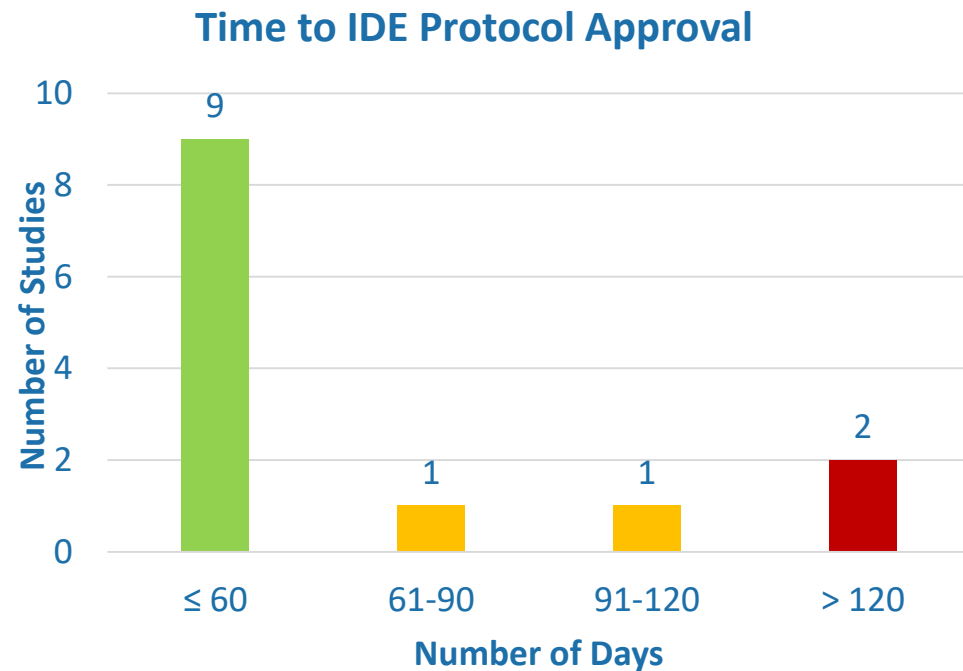
- MDIC collected metrics on 22.8% of all industry IDEs submitted through the EFS program between 2015 to 2017.
- These metrics reflect 12 industry sponsors and 50 clinical sites
- IDE Cycle Time Mode: One round
- IDE Cycle Time Mean: Two rounds
- \*First Subject Enrollment: Measured from last to occur among site IRB or Contract approval
- Suggested Goals of 60/60/60
  - 60 Days for IRB Approval
  - 60 Days for Contract Execution
  - 60 Days for first subject Enrollment





# What's Working Well...

## FDA Approvals and Site IRB Reviews

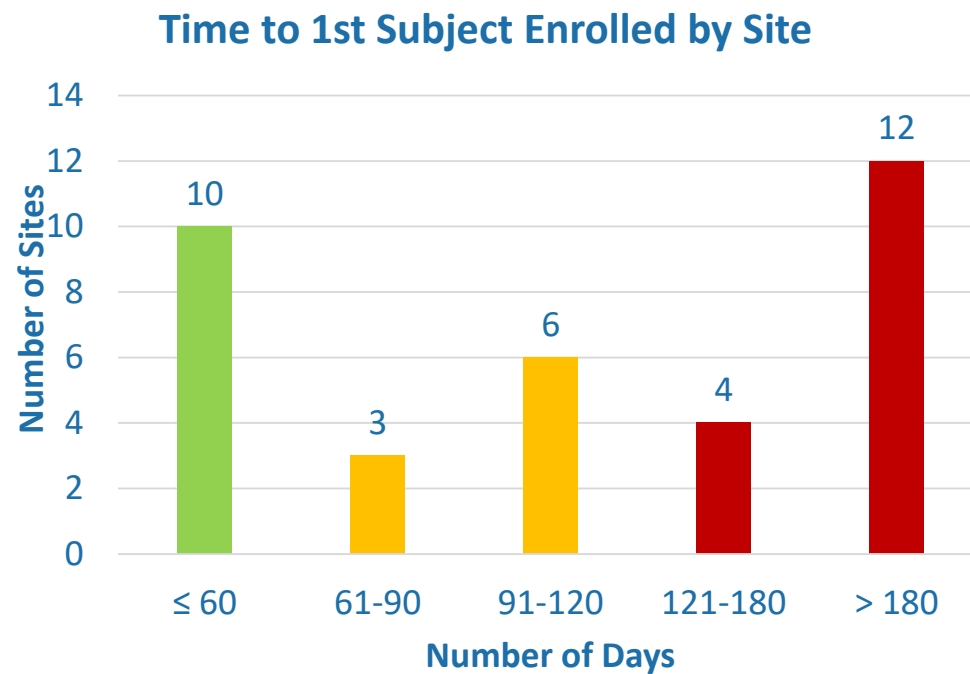
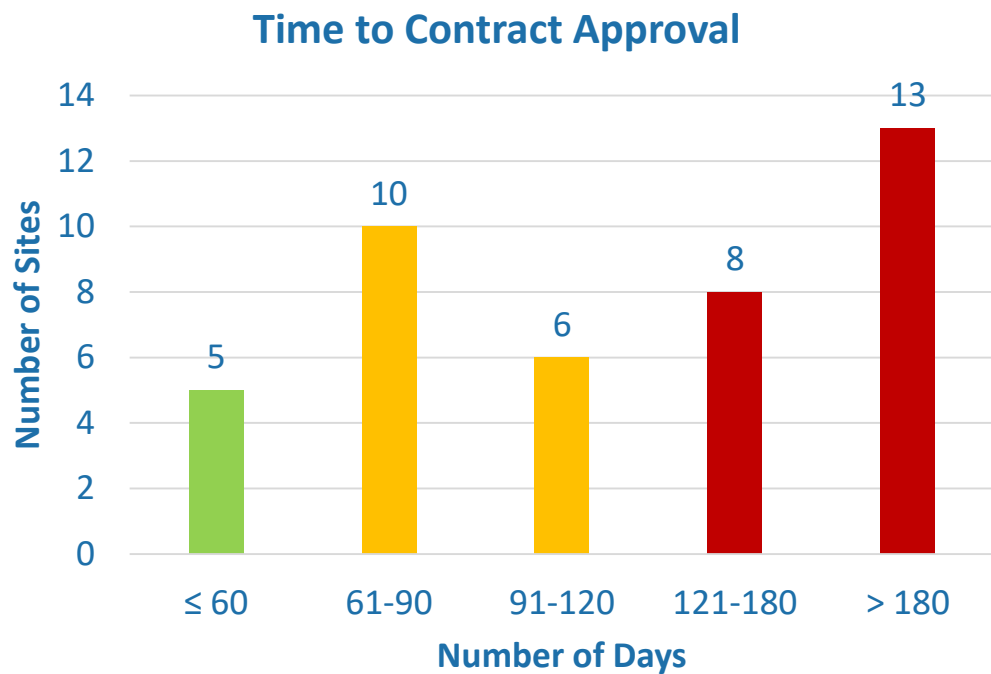


MDIC Collected data from 13 EFS Company Sponsors on study and site performance. Data collected April-Sept 2017 from Studies performed in 2015/16/17



# What's Not Working Well...

## Site Contracting and Patient Enrollment



MDIC Collected data from 13 EFS Company Sponsors on study and site performance. Data collected April-Sept 2017 from Studies performed in 2015/16/17



# EFS Metrics in the US: Summary

- FDA Changes Enable (IDE) Early Feasibility Studies in the U.S.
- Companies Have Embraced FDA's New Pathway
  - Studies in the U.S. Increasing
- MDIC-EFS Analysis
  - Administrative Challenges Now the Largest Barrier, Especially Contracting and Patient Recruitment
- Further Collective Efforts Required to Make U.S. Clinical Ecosystem Competitive
- A Clinical Site Demonstration project in Partnership with Industry Could Carry On Process Improvements





# EFS Program: Contact Information

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