Early Feasibility Studies: Metrics Update 2019

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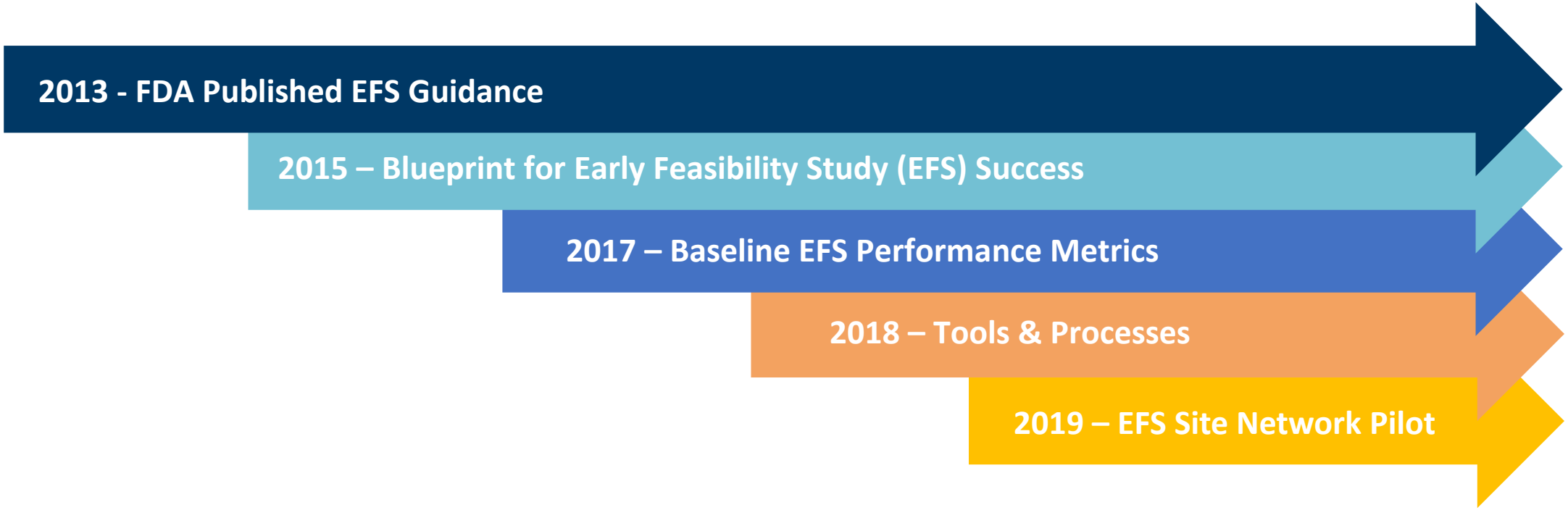
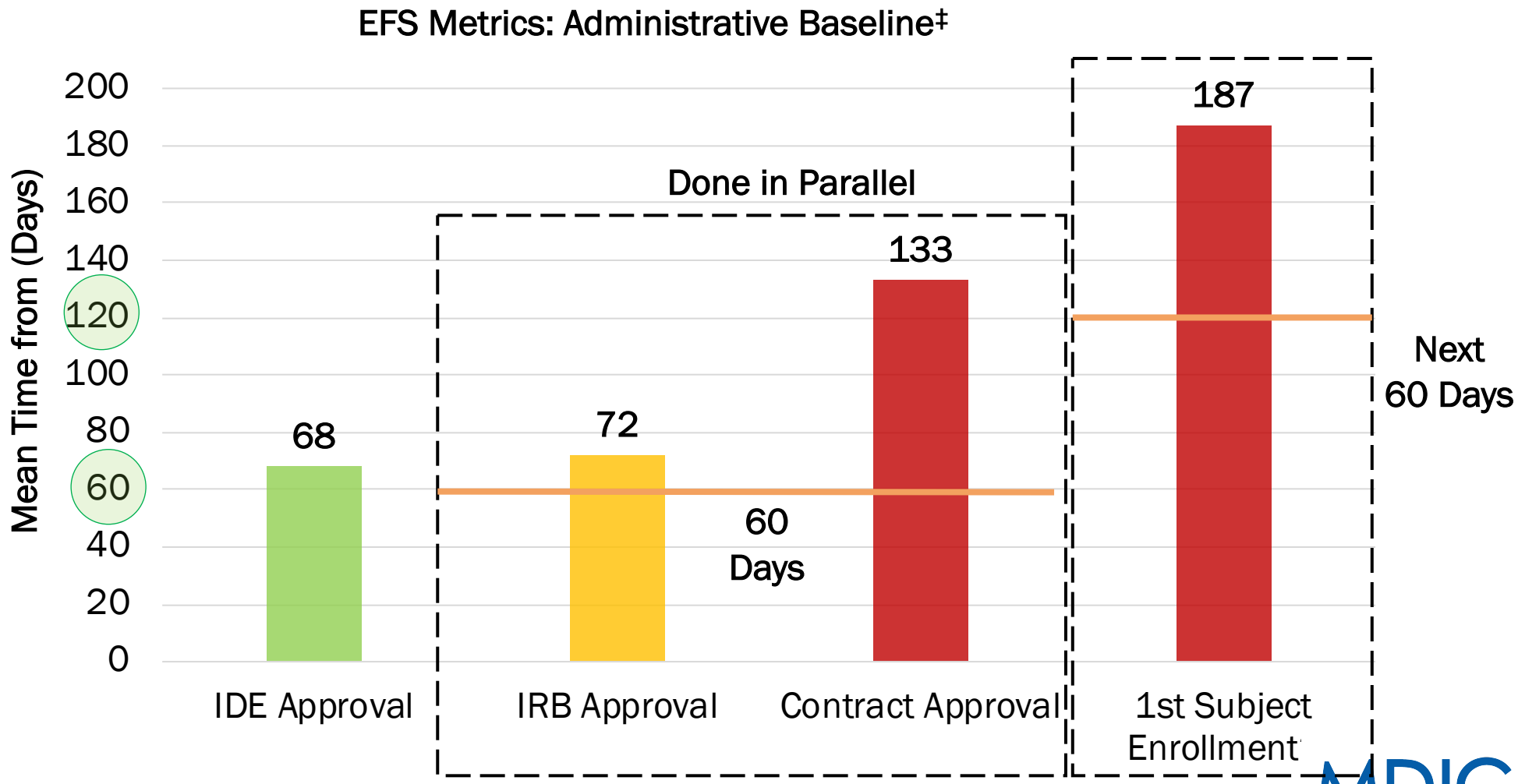
Early Feasibility Studies

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

MDIC: EFS Through The Years



2017: EFS Challenges – "60:60:60" Goal



@MDICAnnualForum

‡Baseline metrics collected from EFS trials conducted FY14 – FY17, compiled from 13 EFS trials and 48 sites.

MDIC ANNUAL PUBLIC FORUM

MDIC EFS Initiatives: 2018 – 2019

Site Network Pilot:

- 31 sites & 18 partners
- 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

Administrative Issues:

- Best Practices Workshop (March & June 2019)

Contracting Working Group:

- Updating Master Clinical Trial Agreement

Regulatory Working Group:

- IRB workshop (October 2019)
- Updating Informed Consent Template

Budgeting Working Group:

- Still figuring out what issues to address

2019 Sponsor Metrics

Sponsor Metrics: Basis for Comparison

Baseline FY14 - FY17

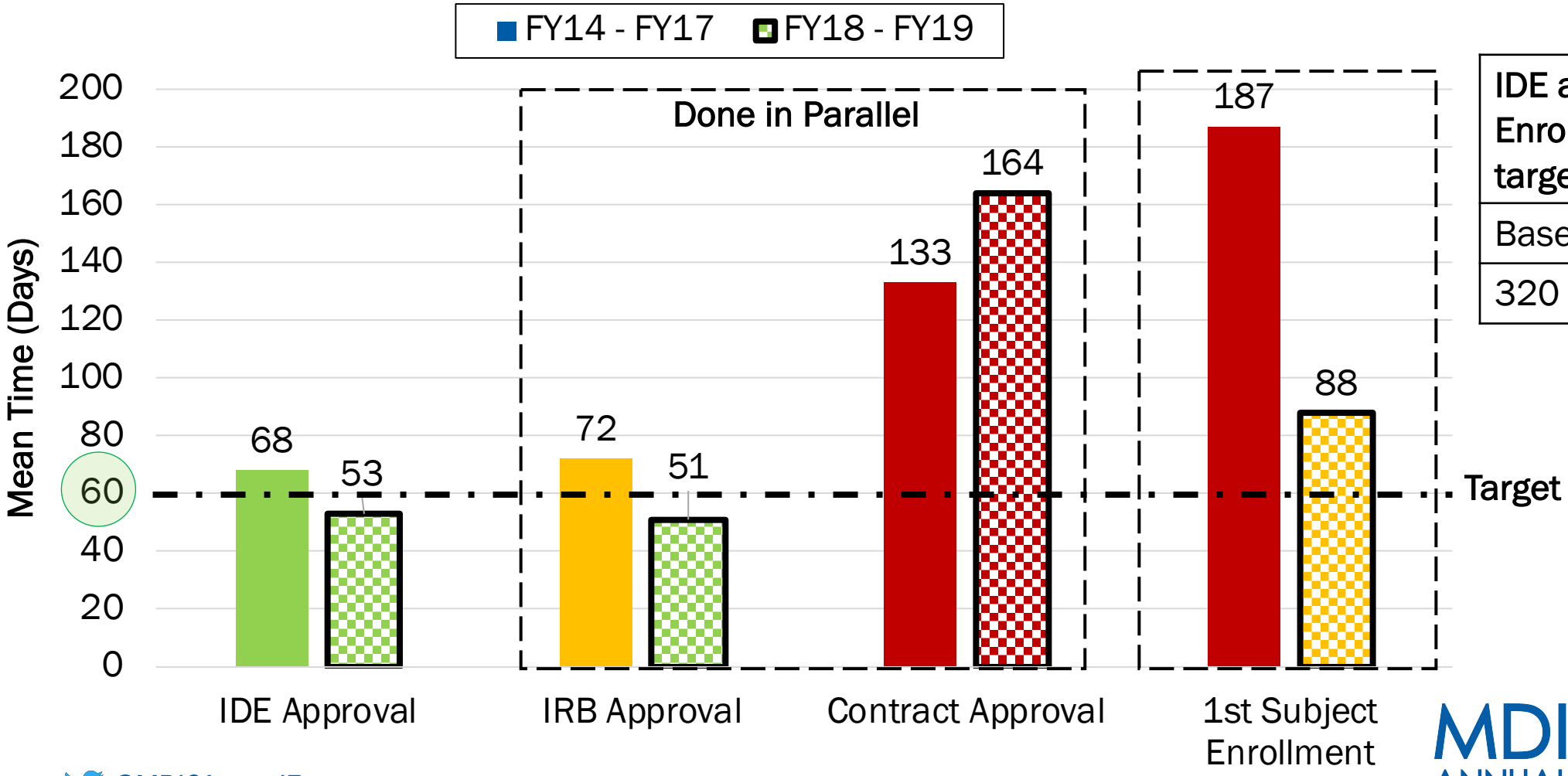
- 13 EFS trials
  - 9 Cardiovascular
- 48 sites

New FY18 - FY19

- 9 EFS trials
  - 9 Cardiovascular
  - 6 FIH
- 60 sites
  - 40 different sites
  - 21 from our network
- Coverage
  - FDA assigned Cat A to 6 trials and Cat B to 3 trials
  - All studies applied for CMS Coverage
  - 6 of 9 studies got approved
- MDIC Tools
  - 4 Sponsors used MDIC tools
  - 33 Sites used MDIC's MCTA

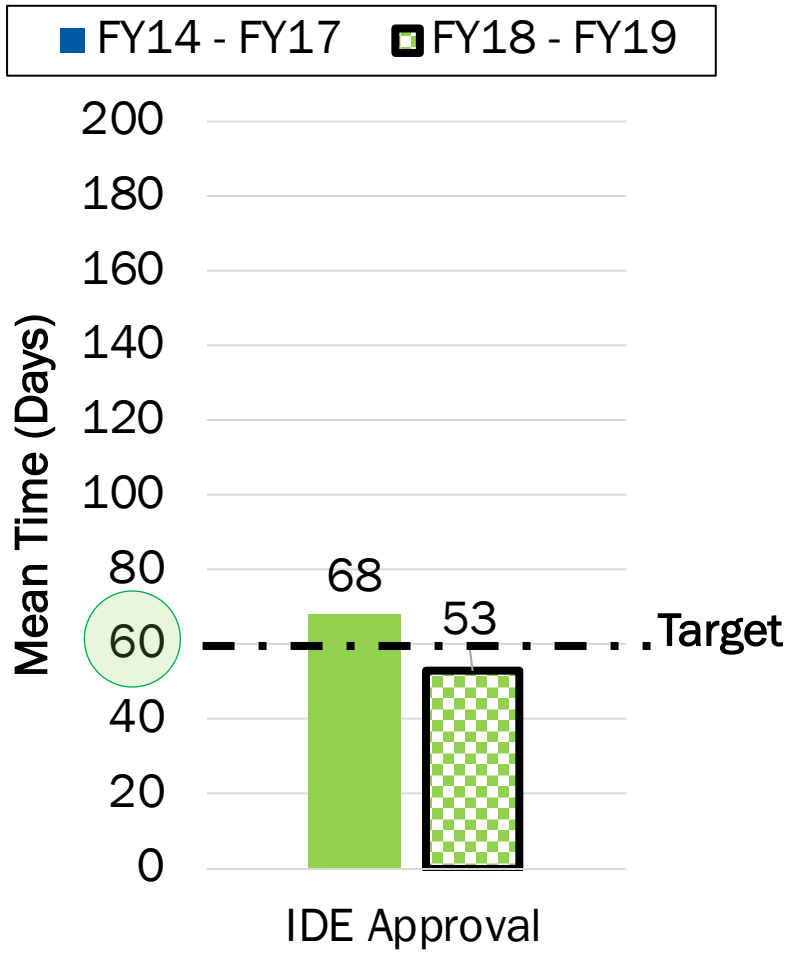
*FY refers to Federal Fiscal Year

IDE Approval to 1st Subject Enrollment Time Improved by 2 Months



IDE approval to 1st Enrollment: 120 day target	
Baseline	New
320 Days	252 Days

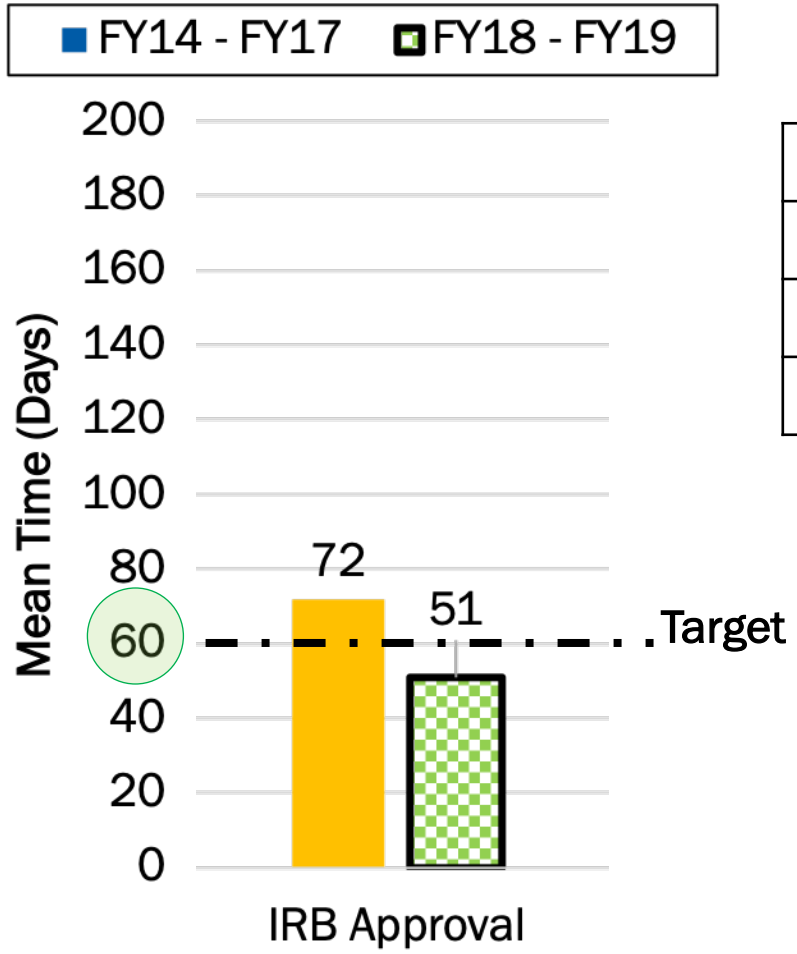
FDA Review Process Continues to Improve



	Baseline: FY14 - FY17	New: FY18 - FY19
Minimum (days)	25	13
Median (days)	30	32
Maximum (days)	238	148

- Time to IDE approval has decreased and it is now under 60 days
- CDRH doing a good job with turn around of IDEs

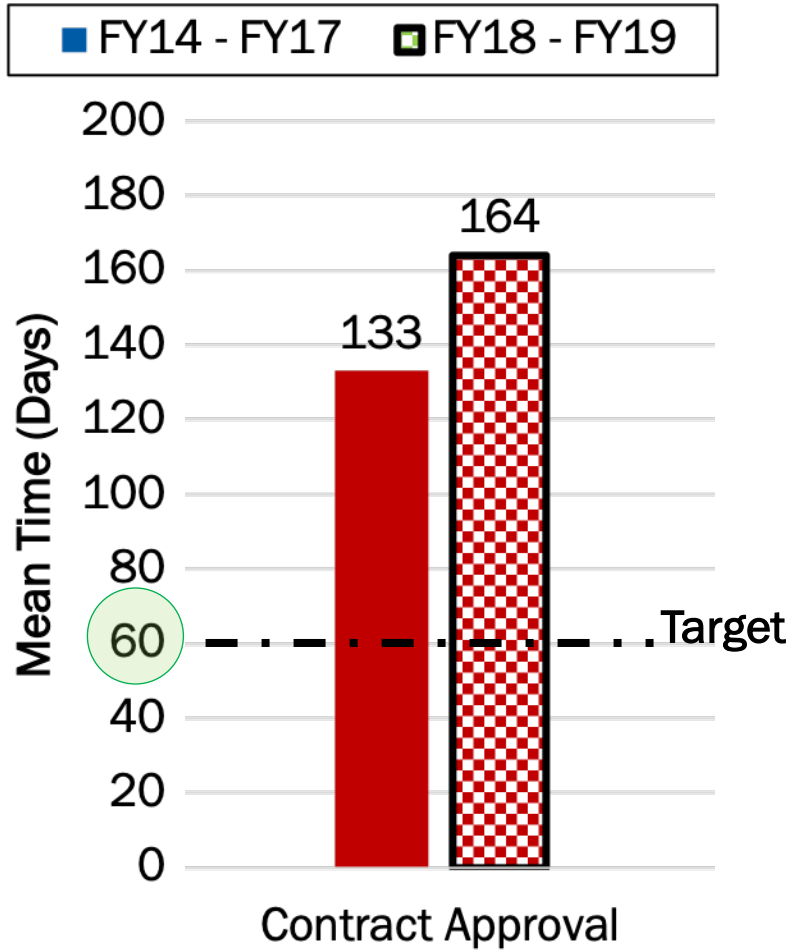
IRB Process Has Improved



	Baseline: FY14 - FY17	New: FY18 - FY19
Minimum (days)	5	3
Median (days)	56	38
Maximum (days)	246	372

- Time to IRB approval has decreased and is now meeting the 60-day goal

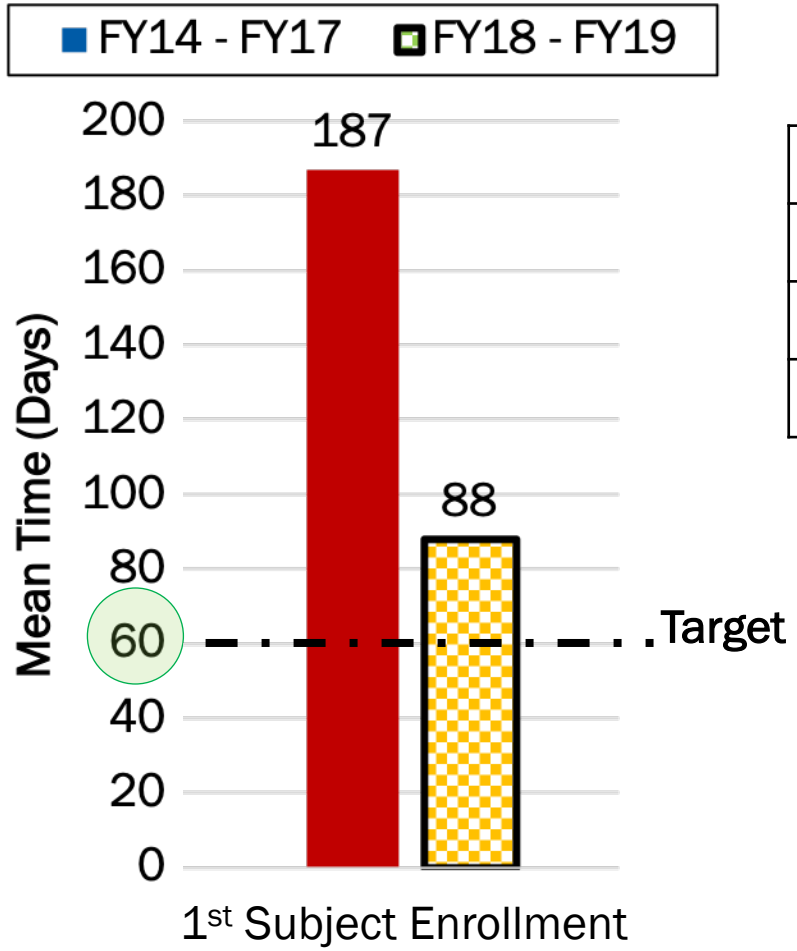
Contract Approval Remains Too Slow



	Baseline: FY14 - FY17	FY17 - FY19
Minimum (days)	24	35
Median (days)	120	149
Maximum (days)	329	469

- Time to Contract approval has increased
- Budget approval is taking 113 days in average
- Negotiating EFS contract and budget is still a big issue

Time to 1st Subject Enrollment is Improving



	Baseline: FY14 - FY17	New: FY18 - FY19
Minimum (days)	7	16
Median (days)	105	67
Maximum (days)	+600	264

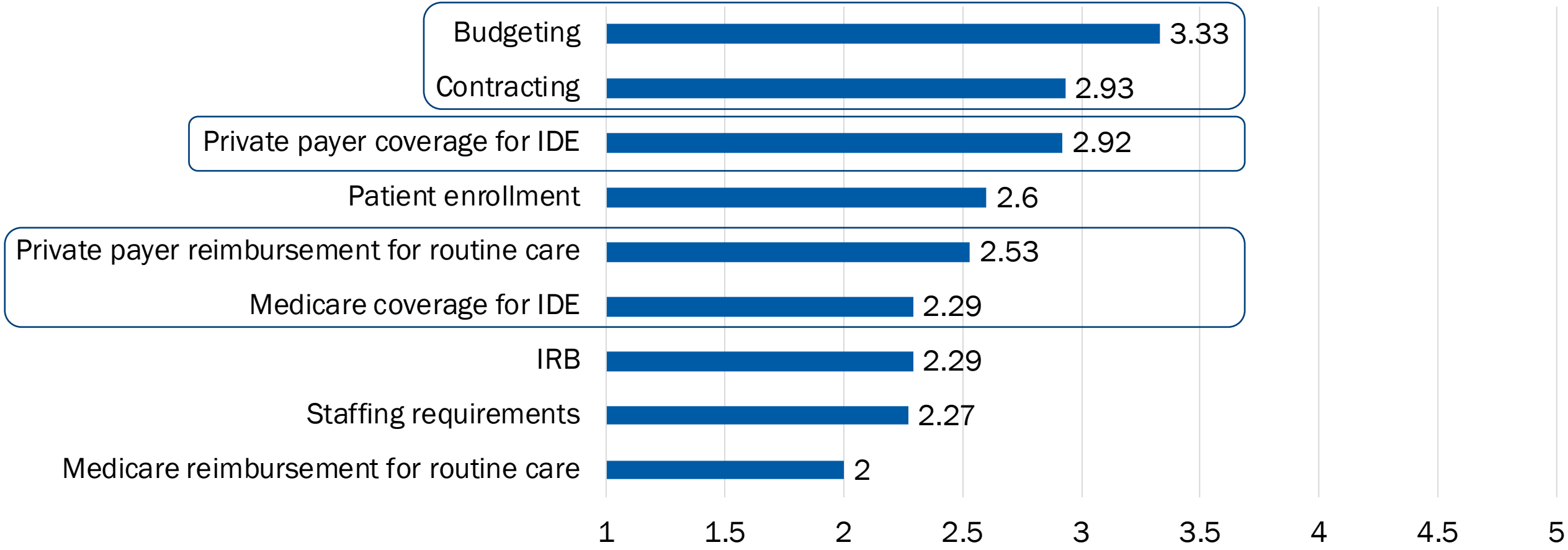
- 1st Subject Enrollment time has decreased
- Need more work to get to the 60-day goal

Summary

- FDA IDE review process continues to improve
- IRB process seems to go well
- Contract approval is still too slow
- Time to 1st subject enrollment is improving but remains significantly above target
  - 252 days vs. 120 day target
- The fastest sites easily achieve the 60 day targets, other sites have very lengthy internal processes

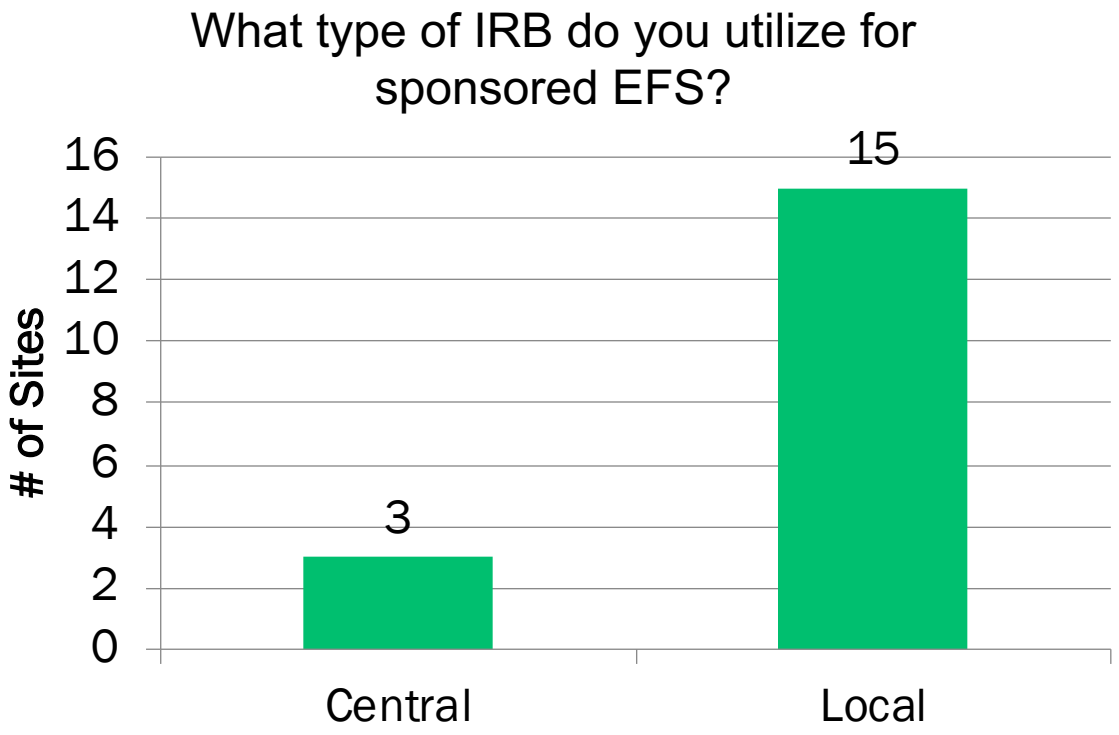
2019 Survey of Sites in the Pilot Network

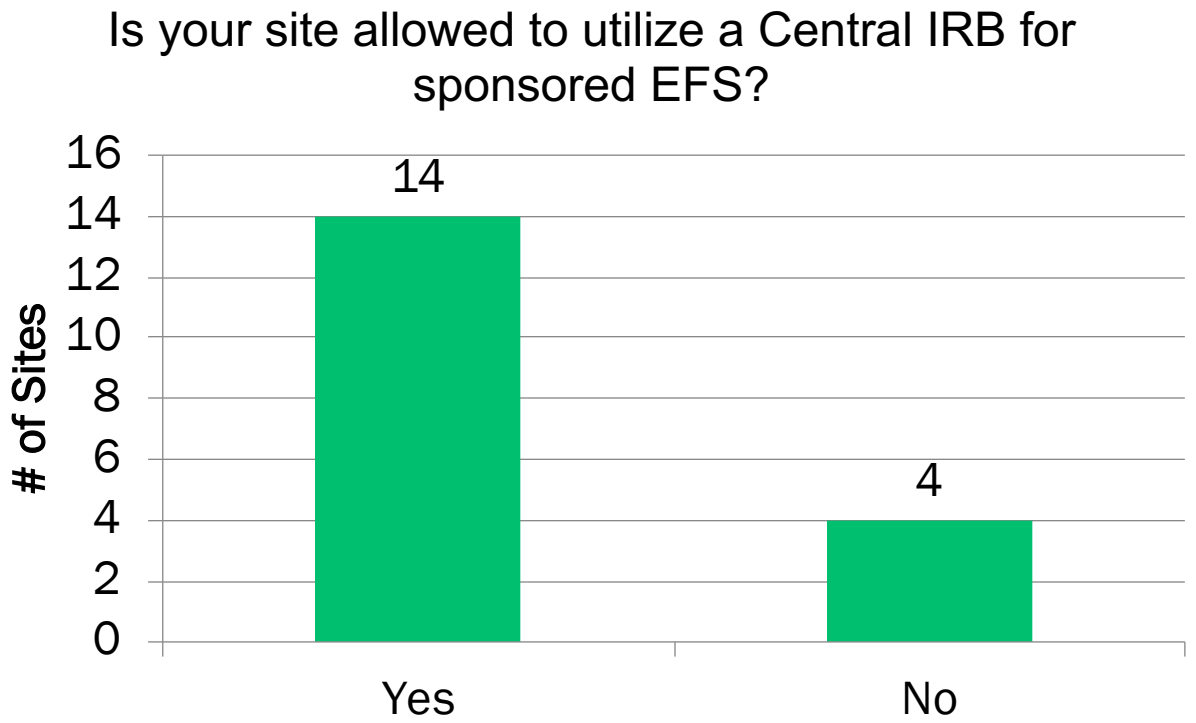
Sites ranked Budgeting and Contracting as the highest delaying factors when initiating an EFS



Sample Size = 17 sites

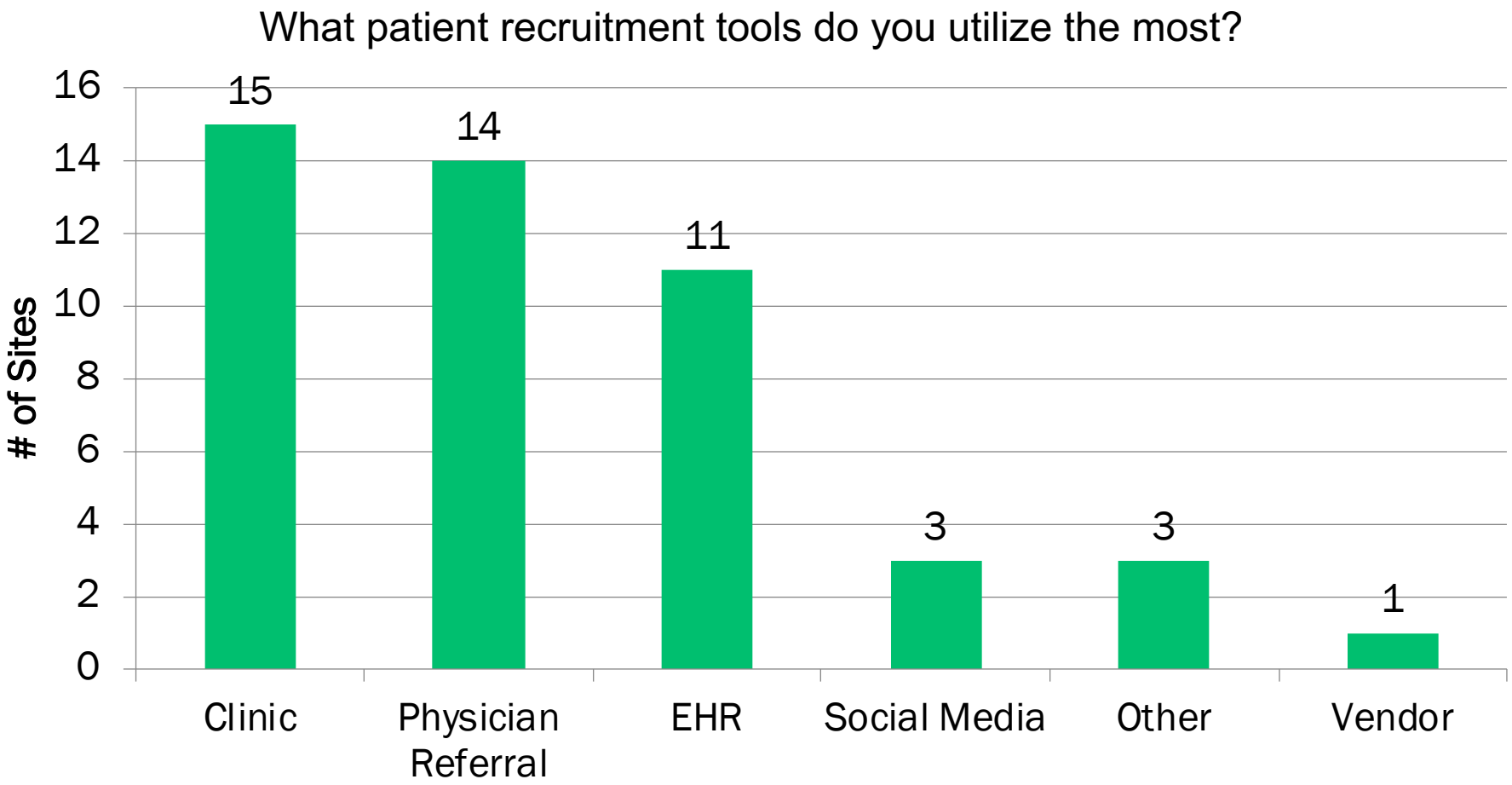
Most Sites Go With The Local IRB





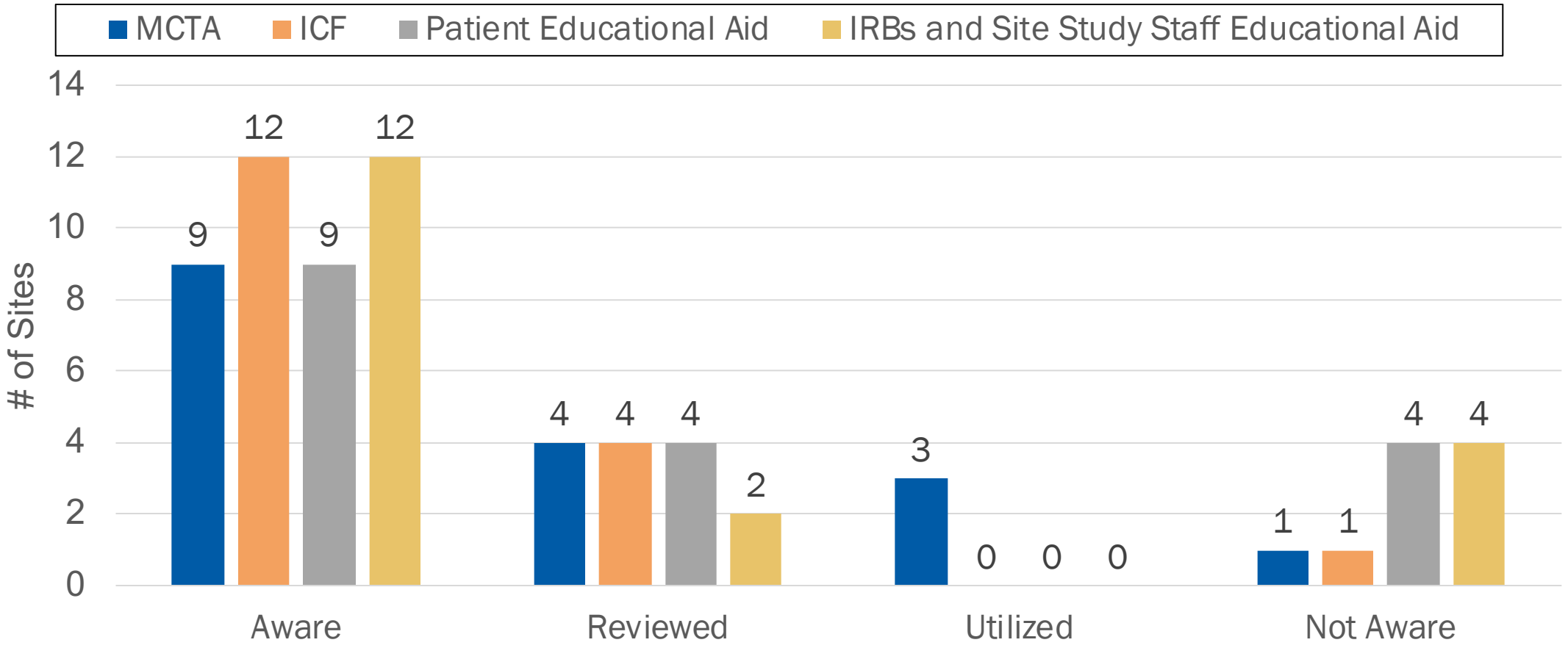
Sample Size = 18 sites

Patient Recruitment Tools



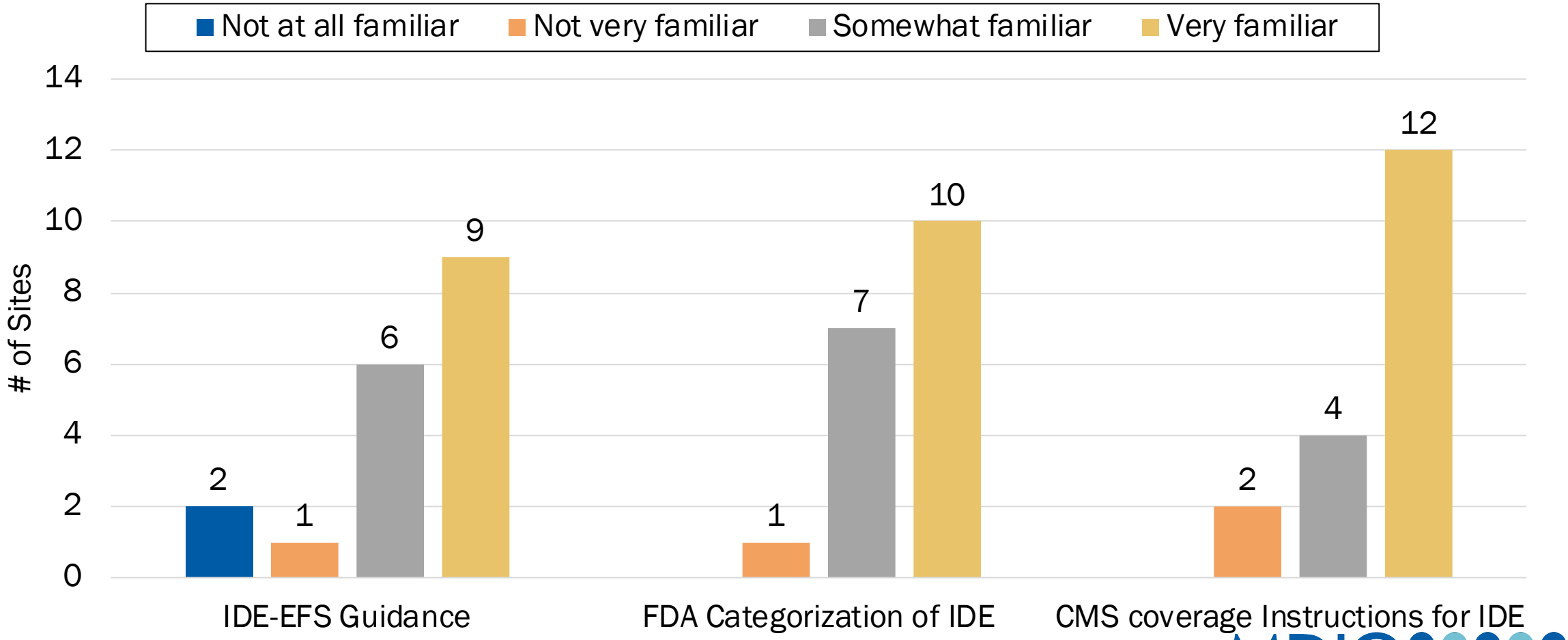
Sample Size = 18 sites

MDIC Tools:
Awareness Is Good But Usage Is Low



Sample Size = 18 sites

Sites are Familiar with FDA Guidance and CMS Instructions



Sample Size = 18 sites

Conclusions

1. Administrator processes reported by Sponsors have gotten better to yield faster time to 1st subject enrollment
   - Contract and Budgeting are very significant issues
   - Total average time of ~8 months greatly exceeds target of 4 months.
2. Sites report contracting and budgeting are the biggest issues followed by coverage and reimbursement
3. Very helpful to periodically assess administrative challenges to provide guidance on what is more helpful and to create tools that can have an impact

Upcoming Events

https://mdic.org/event/

Regulatory RoundTable

- MDIC and Baylor Scott & White Research Institute
- October 2nd & 3rd
- Dallas Texas
- Who:
  - Manager/Director IRB
  - Regulatory Affairs

Panel Discussion

Our Panelists

- Andrew Farb, MD, FACC
  - Chief Medical Officer, Office of Cardiovascular Devices, CDRH, FDA
- David R. Holmes, Jr., MD, MACC
  - Professor of Medicine, Mayo Clinic College of Medicine
- Mark Carlson, MD
  - Chief Medical Office, Abbott
- Tamara Syrek Jensen, JD
  - Director, Coverage and Analysis Group (CAG), CMS

- Moderator – Chip Hance
  - EFS Board Champion