FDA: 510(k) Pathway Study 2022

Over 250 Medical Technology Executives, Regulatory Affairs, and Industry Consultants responded.

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Goal of the Survey

To understand the Med Tech industry's perception of the FDA's administration of the 510(k) pathway

Key Themes and Observations

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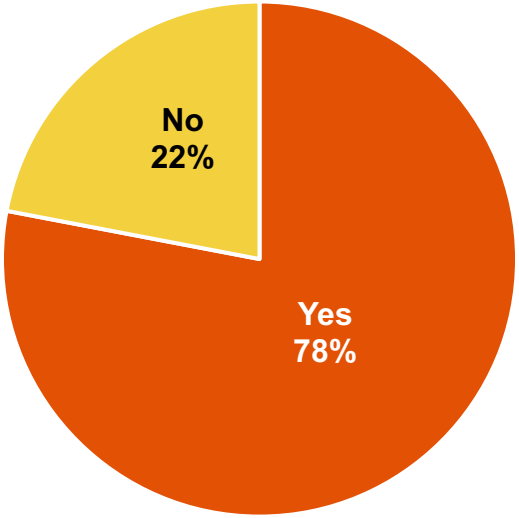
- **Modest improvements in overall 510(k) performance seen, with continued significant areas for additional improvement**
- **Largest improvement is related to FDA acknowledging that it applied Least Burdensome principles, but largely without transparency for how or if they were actually applied**
- **A root cause for poor performance on FDA side appears to be insufficient training of review staff on regulatory/legal issues surrounding 510(k) submissions**
- **The RTA data suggest there is room for improvement on both FDA and Industry's side in the quality of their submissions and reviews**

**Note: Although the total number of respondents is 263, due to a variety of factors such as qualifying questions, partial responses and survey branching based on individual responses, the total number of responses on any given question may vary.*

Participant Summary

Participant Summary

Has your company submitted one or more medical devices to the FDA using the 510(k) pathway between 2016 and 2021?



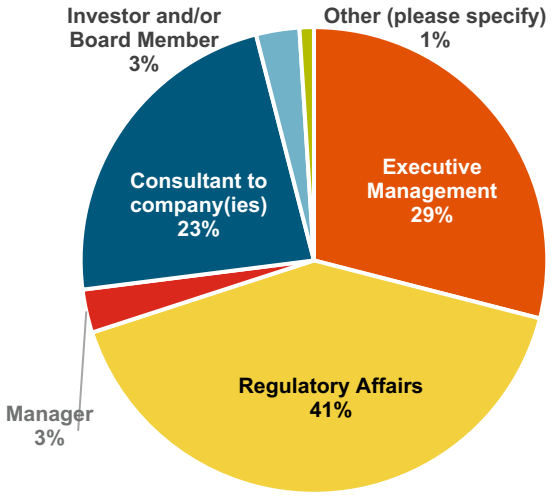
(n=263)

KEY TAKEAWAY

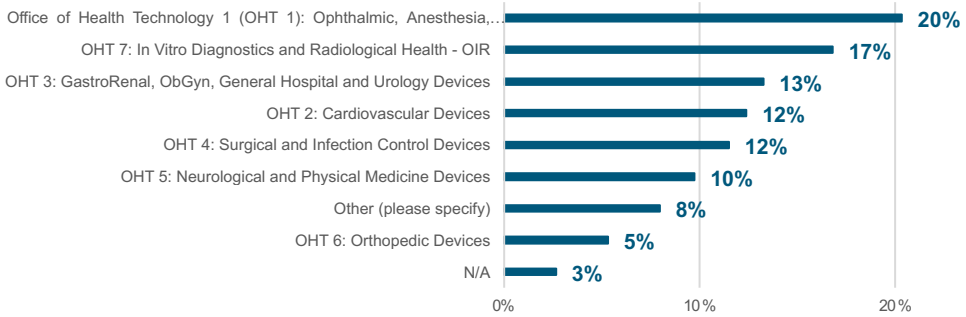
The study reached 263 online respondents and 205 used the 510(k) pathway between 2016 and 2021.

Participant Summary

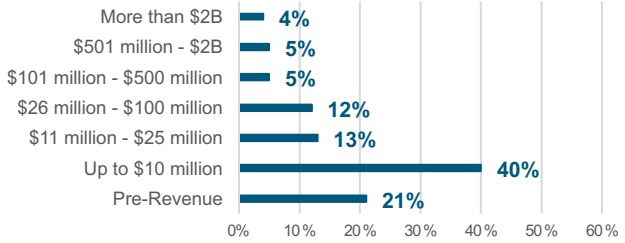
263 Overall Respondents*



Respondent Type (n=112)



FDA Office (n=113)



Company Size (n=112)

THE STUDY DETAILS

The goal is to understand the Med Tech industry's perception of the FDA's administration of the 510(k) pathway.

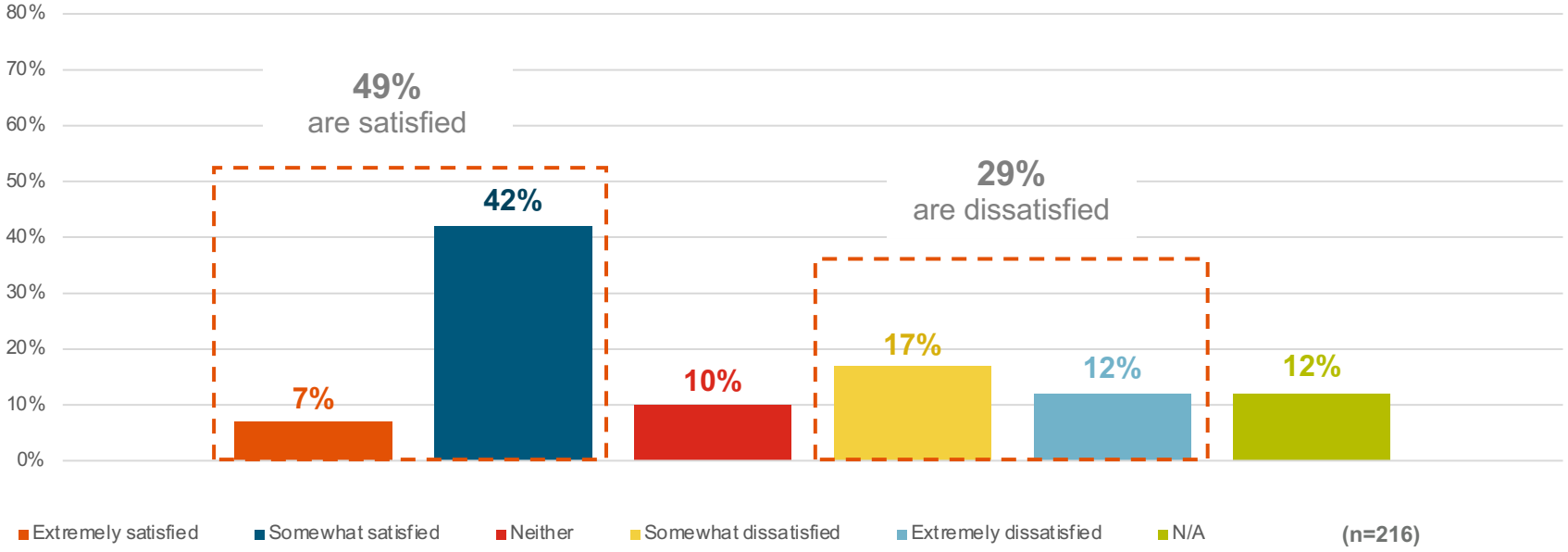
***Note: Although the total number of respondents is 263, due to a variety of factors such as qualifying questions, partial responses and survey branching based on individual responses, the total number of responses on any given question may vary.**

Overall Impression & Satisfaction with 510(k) Process

Overall Satisfaction – All Survey Participants

(Includes participants who have not submitted 510(k) in last 5 years)

How satisfied are you with the FDA's management of the 510(k) pathway?

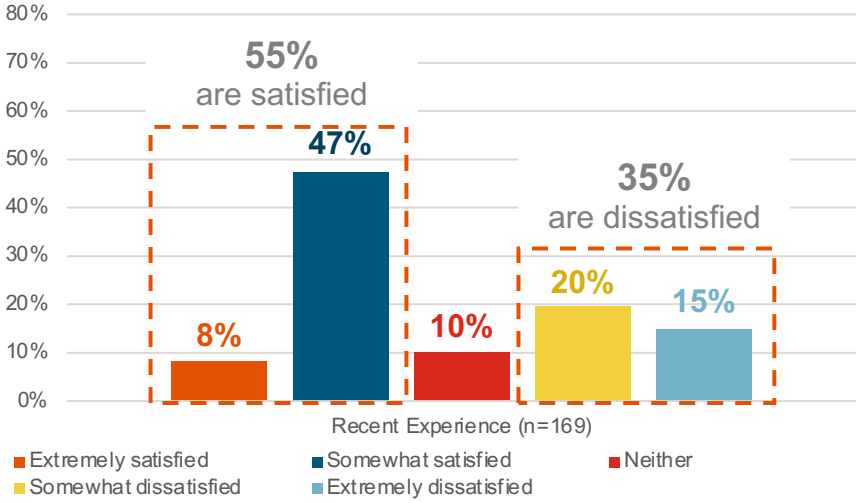


KEY TAKEAWAY

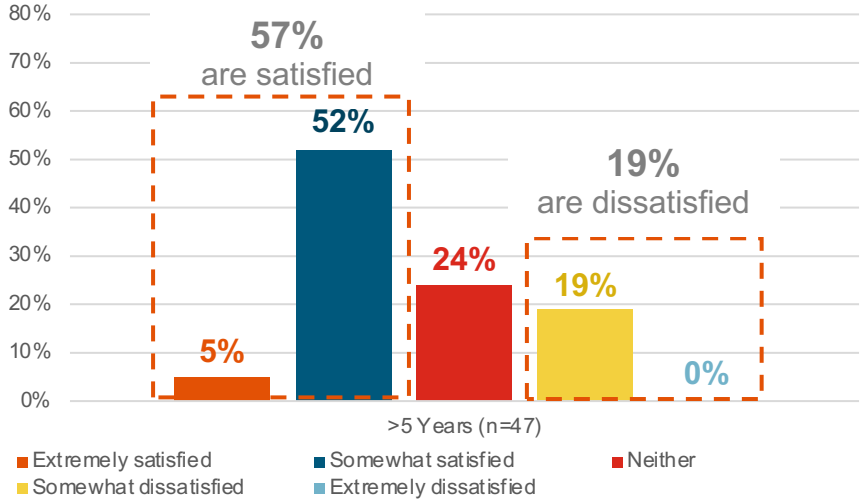
Almost half of respondents were satisfied with close to one-third dissatisfied.

Overall Satisfaction – Recent Experience vs. >5 Years

If your company submitted one or more medical devices to the FDA using the 510(k) pathway between 2016 and 2021, how satisfied are you with the FDA's management of the 510(k) pathway?



If your company has not submitted one or more medical devices to the FDA using the 510(k) pathway between 2016 and 2021, how satisfied are you with the FDA's management of the 510(k) pathway?

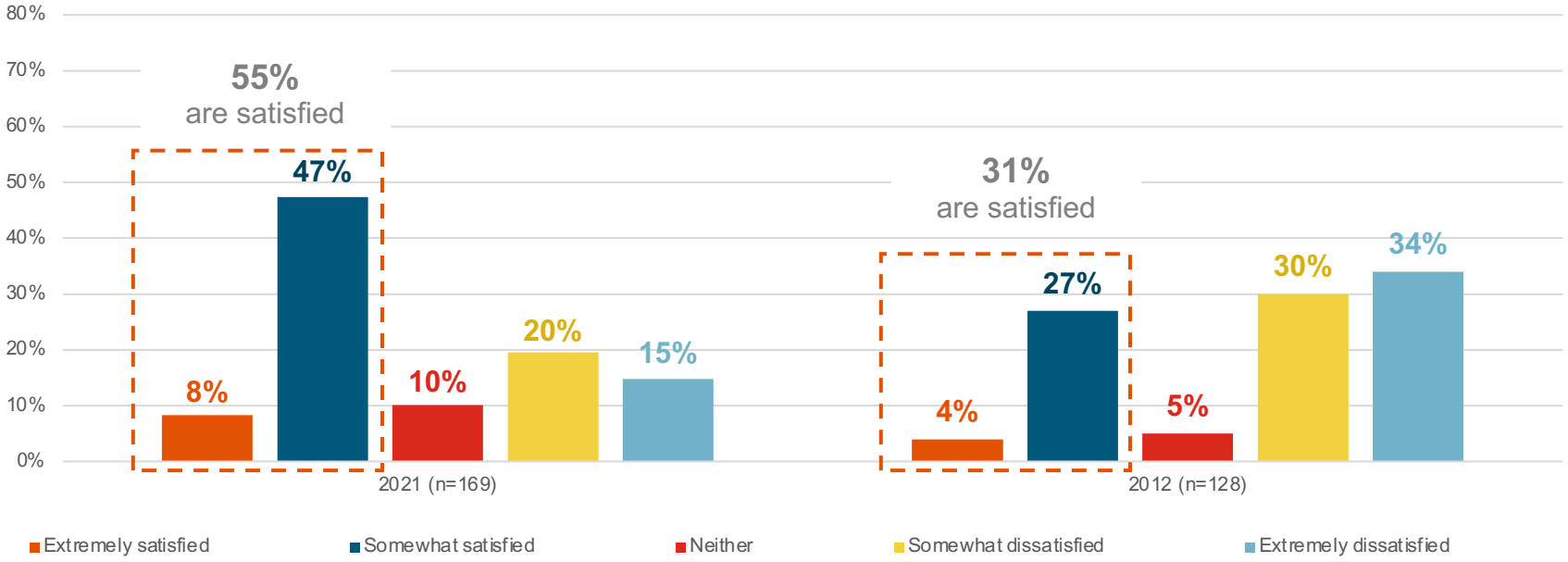


KEY TAKEAWAY

People with recent experience are more dissatisfied.

Overall Satisfaction – 2021 vs 2012

How satisfied are you with the FDA's management of the 510(k) pathway?



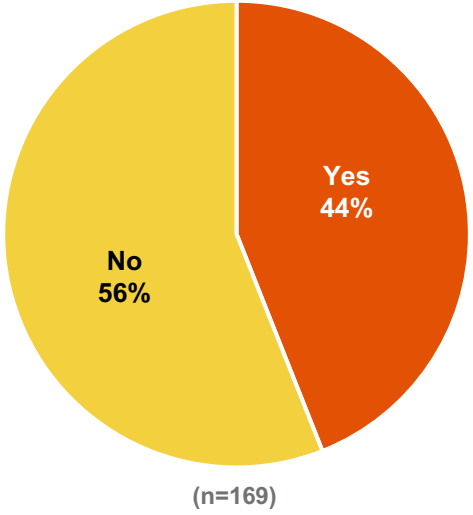
KEY TAKEAWAY

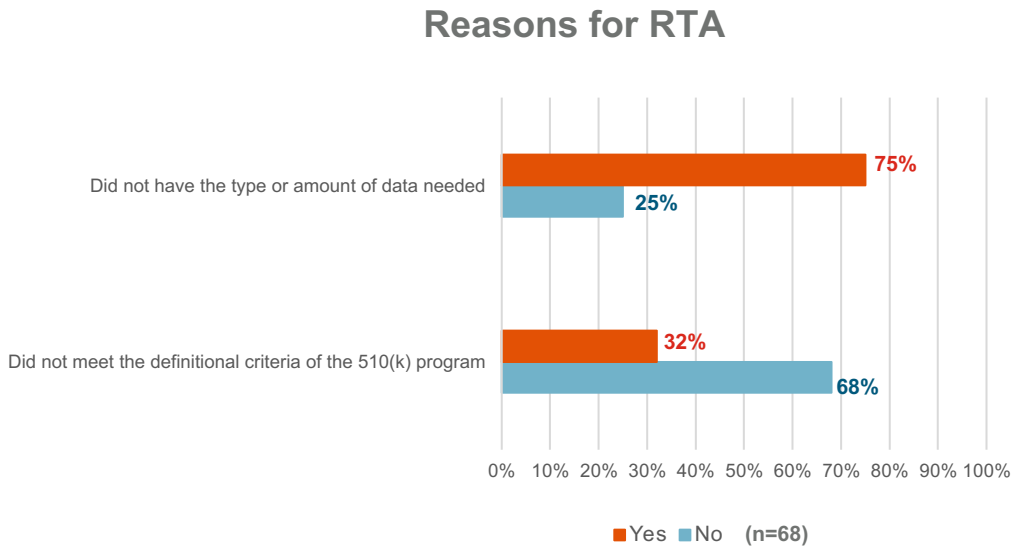
Industry's satisfaction with the performance of the FDA's management of the 510(k) pathway increased over the last 10 years.


Refuse
to Accept

Refuse to Accept (RTA) Policy Responses

Did FDA stop your review under the 510(k) Refuse To Accept (RTA) Policy checklist? (See "Refuse to Accept Policy for 510(k)s Guidance for Industry and Food and Drug Administration Staff," Document issued on September 13, 2019).





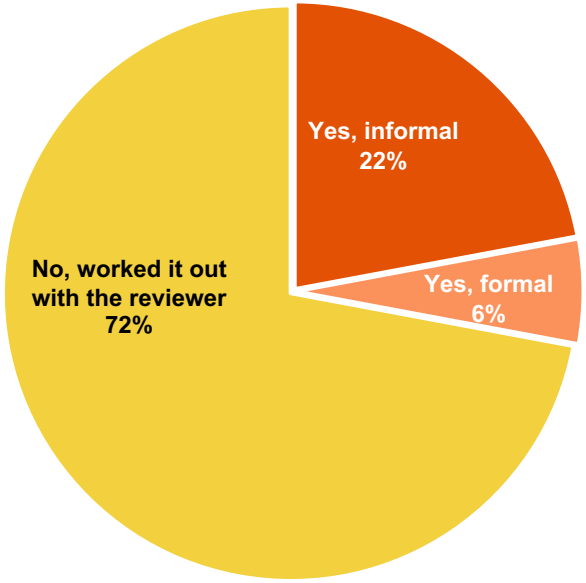
KEY TAKEAWAY

The most prevalent cause of an RTA decision is related to the type or amount of data provided.

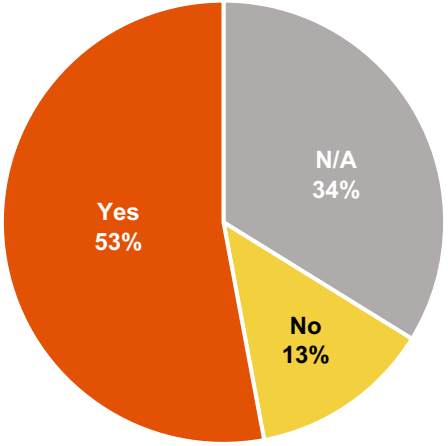
Despite issuance of FDA guidance for RTA, nearly half of 510(k) submissions were placed on RTA hold.

RTA Appeals

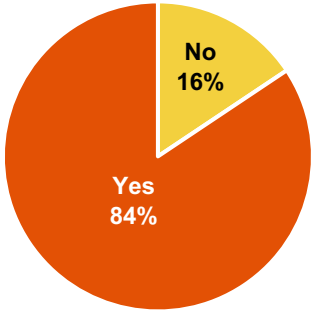
Did you have to informally appeal that decision above the reviewer to the next level of supervision to have your submission accepted or take a formal appeal (e.g., 21 C.F.R. §10.75)? (n=68)



(n=68)



In your formal or informal appeal of the RTA, did FDA management resolve the issue and put your device on the 510(k) path? (n=68)



After the FDA stopped your review under the 510(k) Refuse To Accept (RTA) Policy checklist, did you continue the 510(k) program? (n=32)

KEY TAKEAWAY

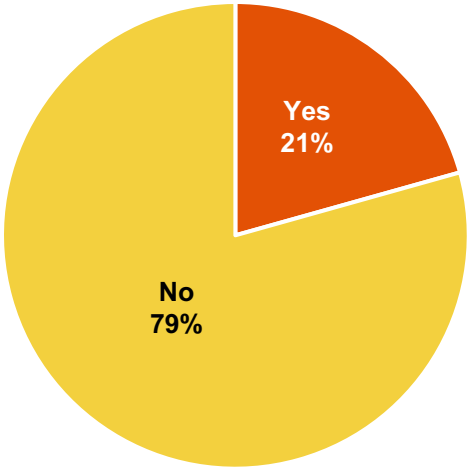
Many RTA decisions may be successfully appealed.

A negative RTA decision is not likely to impact continuation on the 510(k) pathway.

AINE and NSE Letters

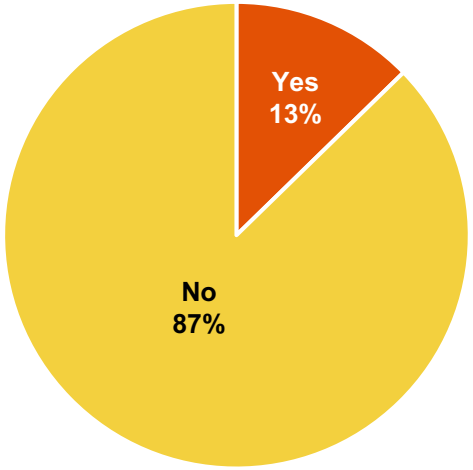
Receipt of AINE and NSE Letter

Did you receive an AINE letter stating you are not likely to receive a Substantially Equivalent (SE) determination from the FDA?



(n=155)

Did you receive an NSE determination from the FDA?



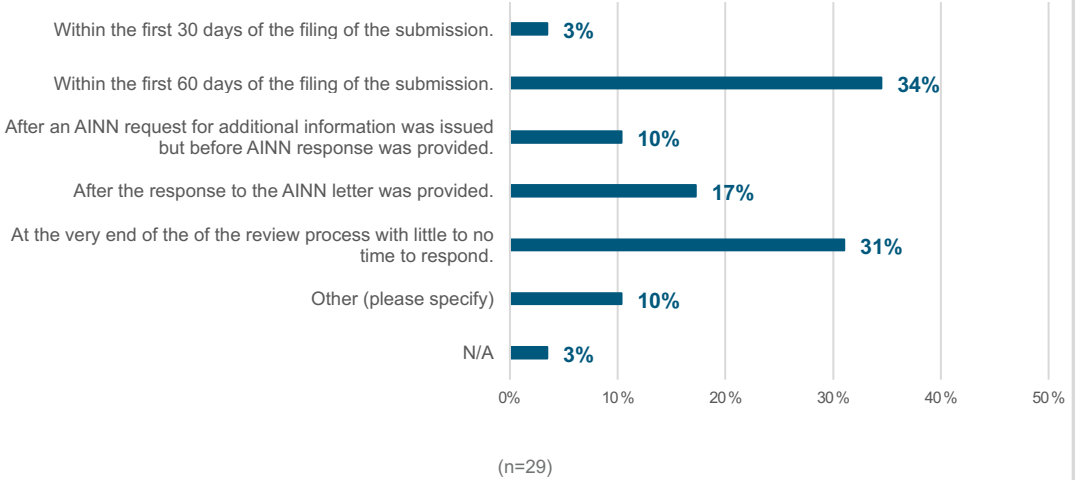
(n=118)

KEY TAKEAWAY

Most 510(k)s did not result in AINE letter or NSE decision.

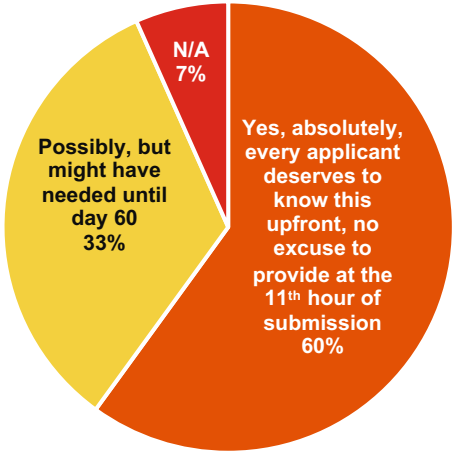
Receipt of AINE Letter

If FDA provided your company an AINE letter stating the reasons why your submission was not likely to receive an SE determination, when did FDA send you that letter?



(n=29)

If FDA provided your company an AINE letter stating the reasons why your submission was not likely to receive an SE determination, should those reasons have been known to FDA in the first 30 days of the review on the 90-day clock?



(n=30)

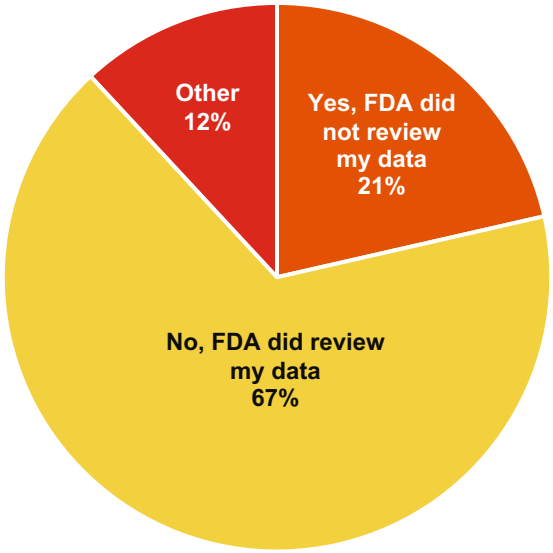
KEY TAKEAWAY

FDA implementation of AINE policy is not as intended (early indicator of concern with pathway).

Over 50% of AINE letters were issued late in the review process (after AINN response, at very end of process, over 6 months after review started) despite FDA visibility to reasons stated in AINE within the initial 510(k) documentation in the majority of submissions.

Notification that FDA Did Not Review Data

Did the FDA in the AINE or NSE letter notify your company that the FDA did not review your data because the device does not meet the definitional issues of same intended use, or different technological characteristics that do not raise different questions of safety and effectiveness?



(n=42)

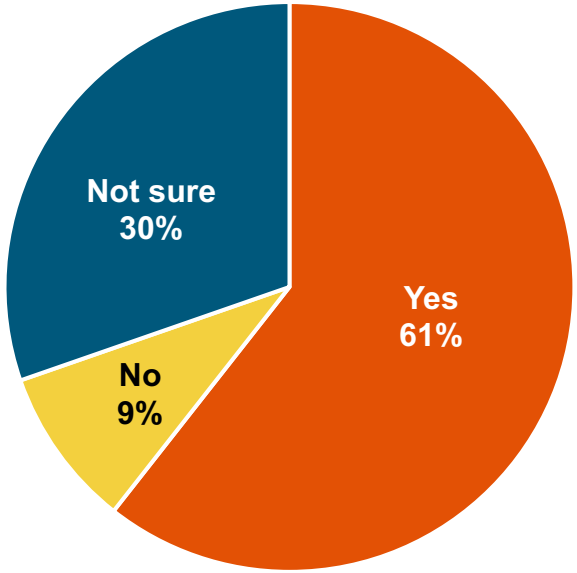
KEY TAKEAWAY

FDA review was conducted for most AINE letters – likely reflective of late issuance.

Data Review

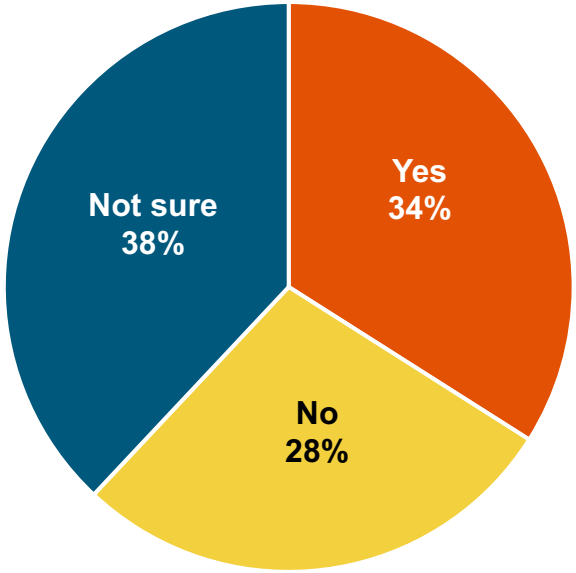
Did FDA review and consider your performance and/or clinical data before making a decision of NSE or possibly NSE?

2021



(n=19)

2012



(n=101)

KEY TAKEAWAY

Data suggest an increase consideration of performance and clinical data before making a NSE decision.

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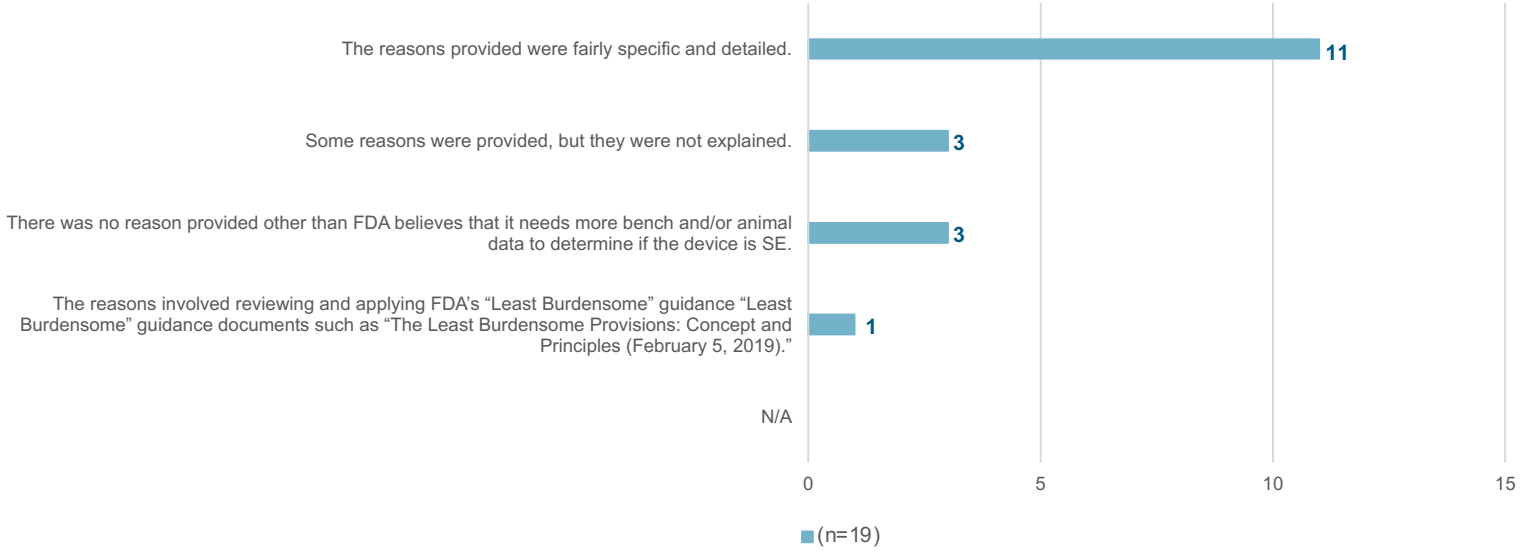
If the FDA considered non-clinical performance data before making NSE decision

If the reason used by the FDA is, there is not or may not be enough performance data (bench and/or animal data), what reason or justification did FDA use? (Select all that apply or N/A.)

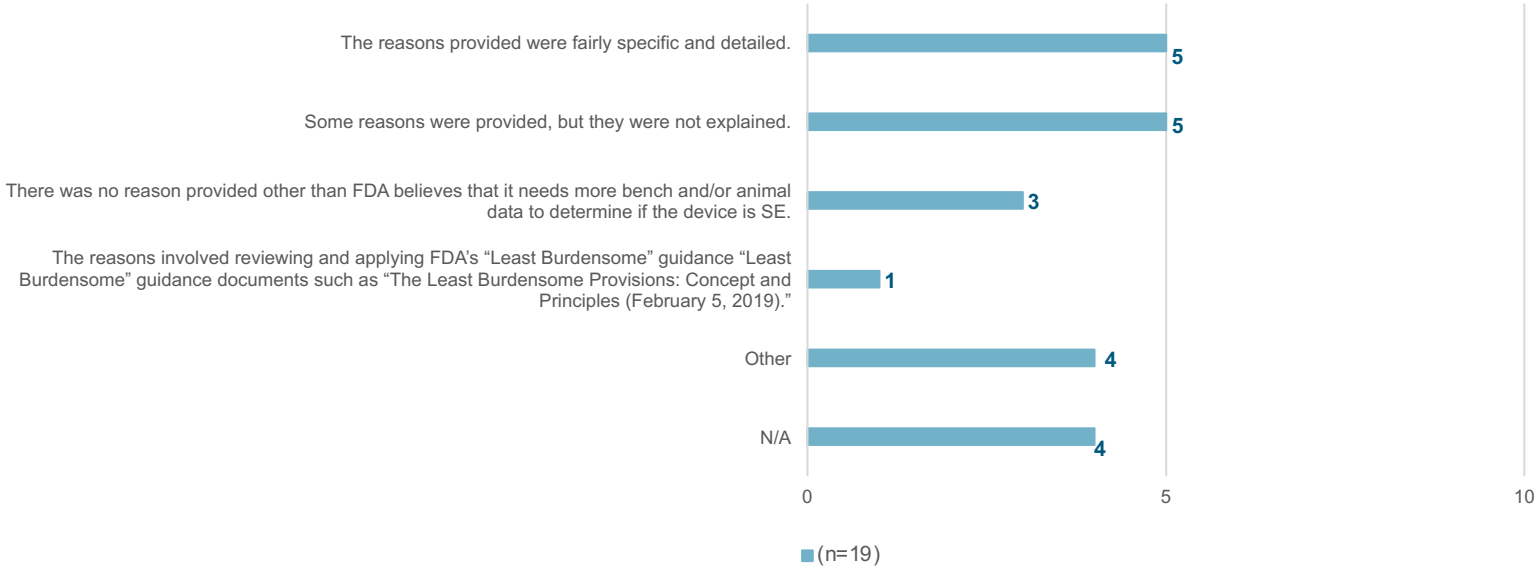


KEY TAKEAWAY

Data suggest most NSE decisions are accompanied by communication of specific reasons for decision.

If the FDA considered clinical data before making NSE decision

If the reason used by the Agency is, there is not or may not be enough clinical data, what reason/justification did FDA use? (Select all that apply or N/A.)



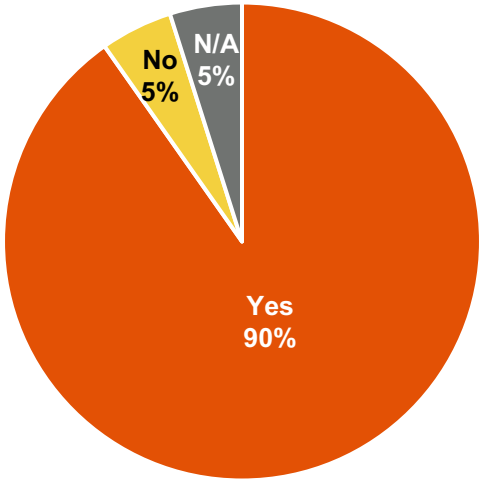
KEY TAKEAWAY

Data suggest most NSE decisions related to clinical data are accompanied by specific rationale.


Rejection
or Pause

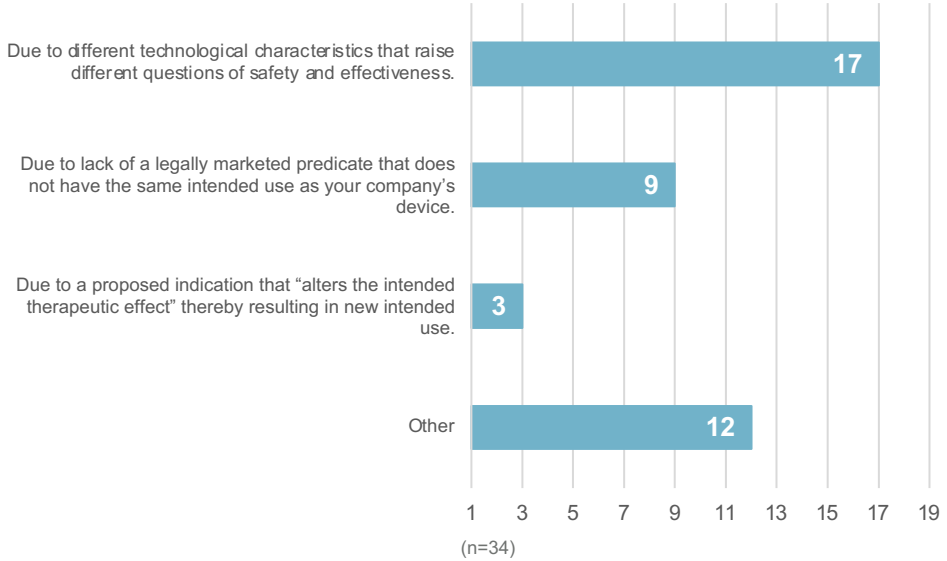
Reason for Rejection or Pause

Did the FDA provide a reason or justification for the basis of its decision to reject or pause your review?



(n=41)

What reason(s) or justification(s) did the FDA provide for the basis of its decision to reject or pause your review? (Select all that apply.)



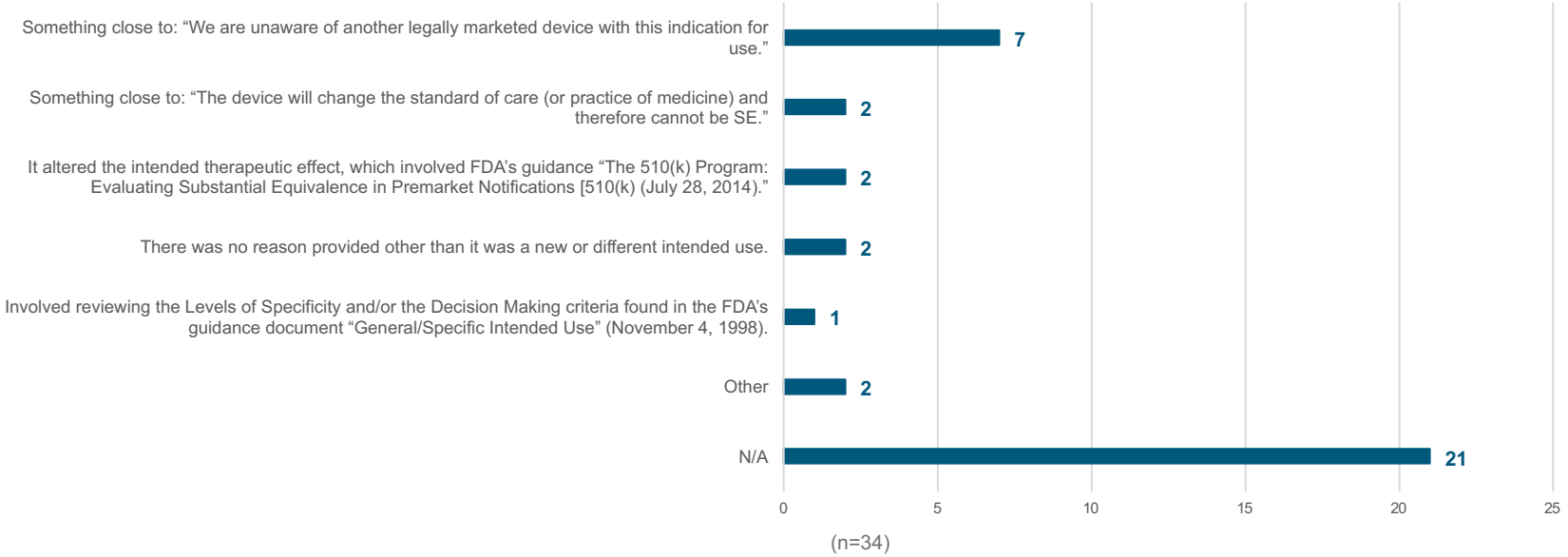
(n=34)

KEY TAKEAWAY

Most rejections/pauses in review appear to be associated with technological characteristics.

Reason: New Intended Use

If the reason used by the Agency is, there is or may be a new intended use, did the FDA use any of the following reasons? (Select all that apply or N/A.)

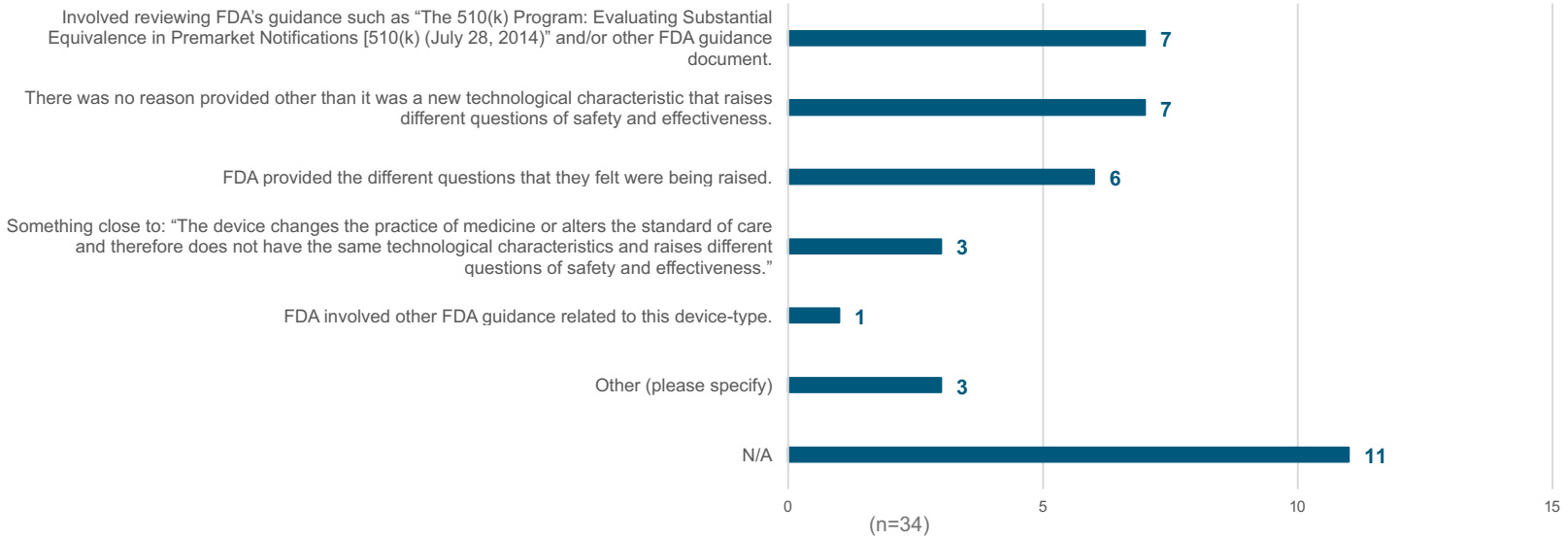


KEY TAKEAWAY

The data suggest the most common reason for rejection/pause based on a perceived new intended use is the lack of another device with the same Indication for Use.

Reason: New Technological Characteristics that Raised Different questions of Safety Effectiveness

If the reason used by the FDA was, there is or may be a new technological characteristic that raised different questions of safety and effectiveness, what reason or justification did FDA use? (Select all that apply or N/A.)

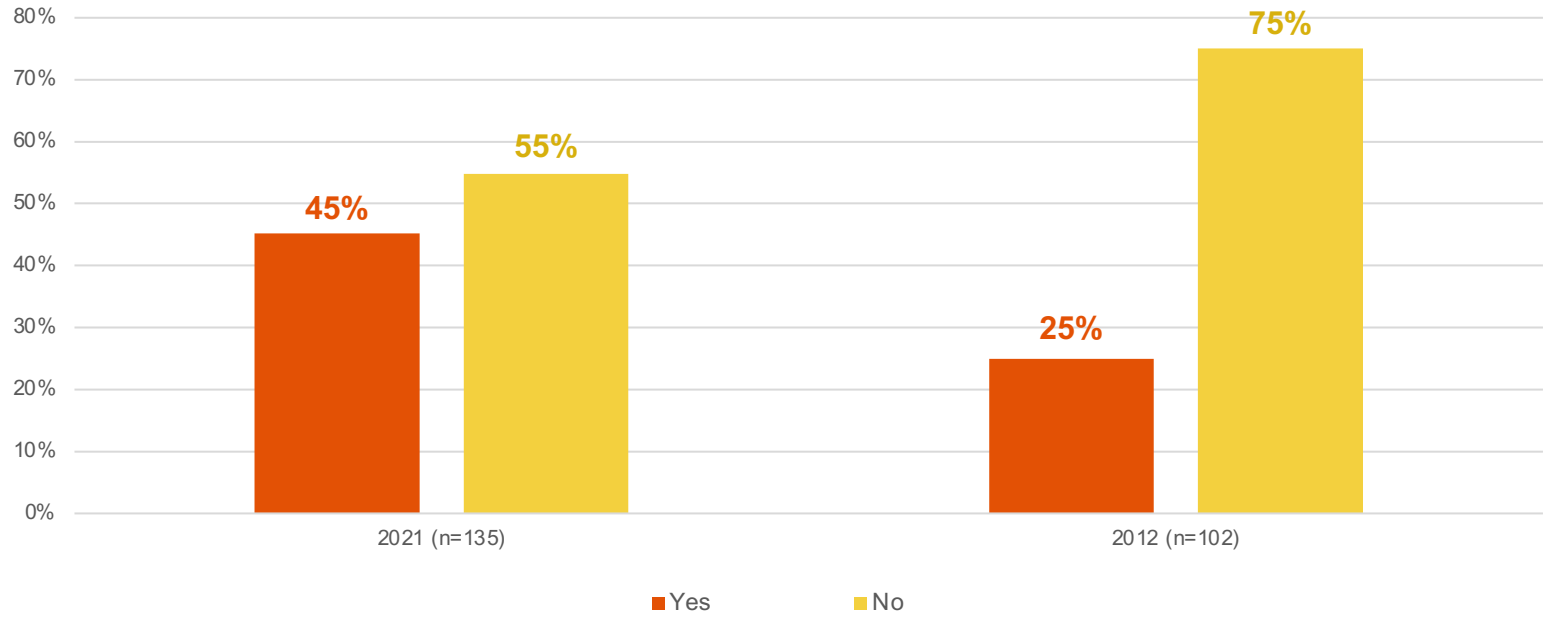


KEY TAKEAWAY

The data suggest rejection/pause based on perceived concern with technological characteristics is most likely to be associated with reference to FDA guidance documents or provide no specific reason.

“Least Burdensome”

Did FDA mention the use of "Least Burdensome" principles in making its decision?

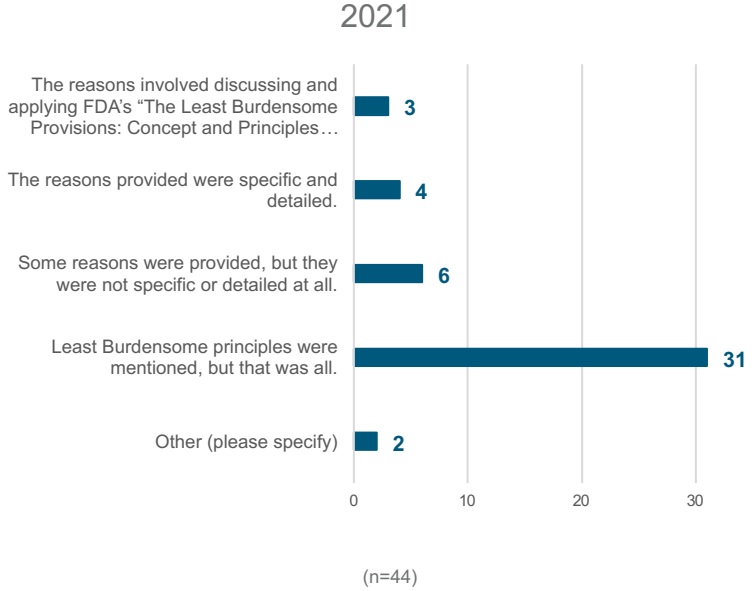


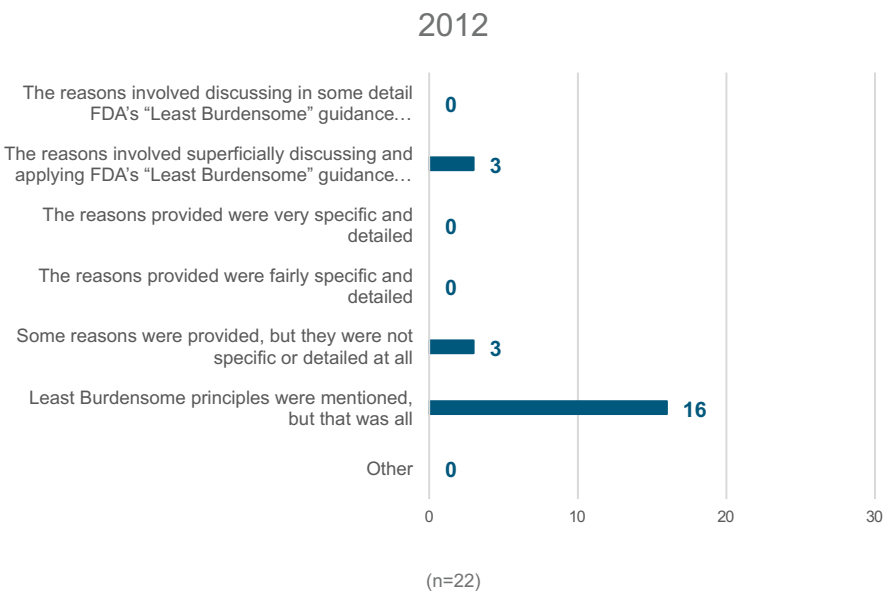
KEY TAKEAWAY

FDA is getting better at referencing least burdensome principles in their communications.

Specificity of “Least Burdensome”

How specific was FDA’s discussion of the use of “Least Burdensome” principles in making its decision? (Select all that apply.)



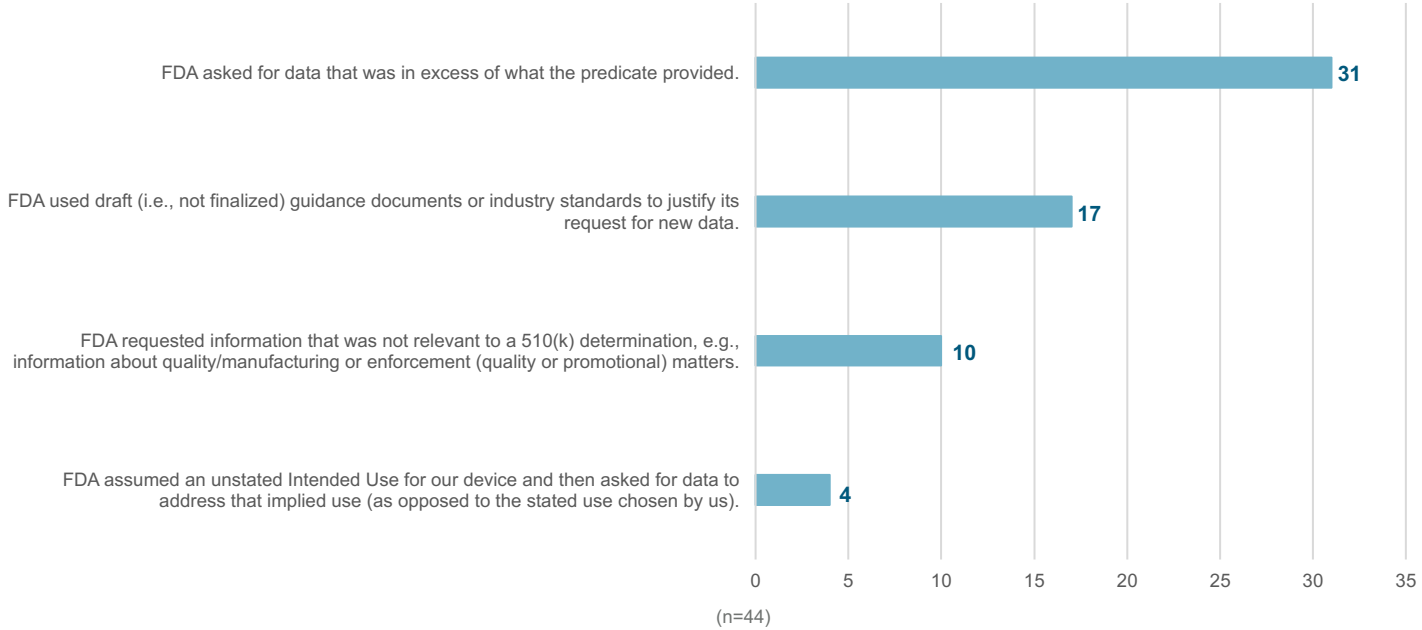


KEY TAKEAWAY

Most references to Least Burdensome principles are general references without specific details of application.

NSE Issued or Mentioned

If FDA suggested it may issue or actually issued an NSE determination, did any of the following occur? (Select all that apply)



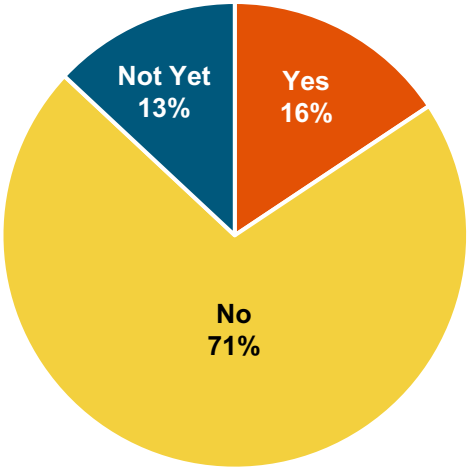
KEY TAKEAWAY

Most NSE letters stem from request for new data in excess of what the predicate provided often resulting from draft guidance or standards.

Appeal

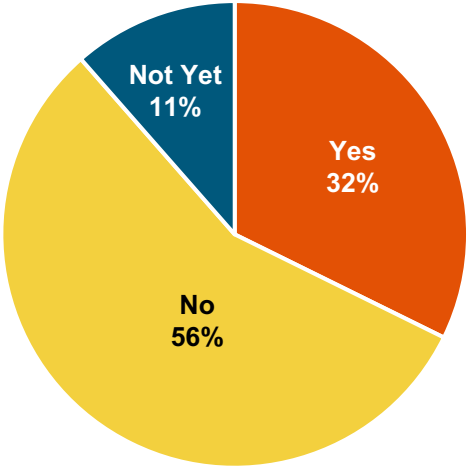
Did your company appeal FDA's NSE or "possibly NSE" decision?

2021



(n=115)

2012



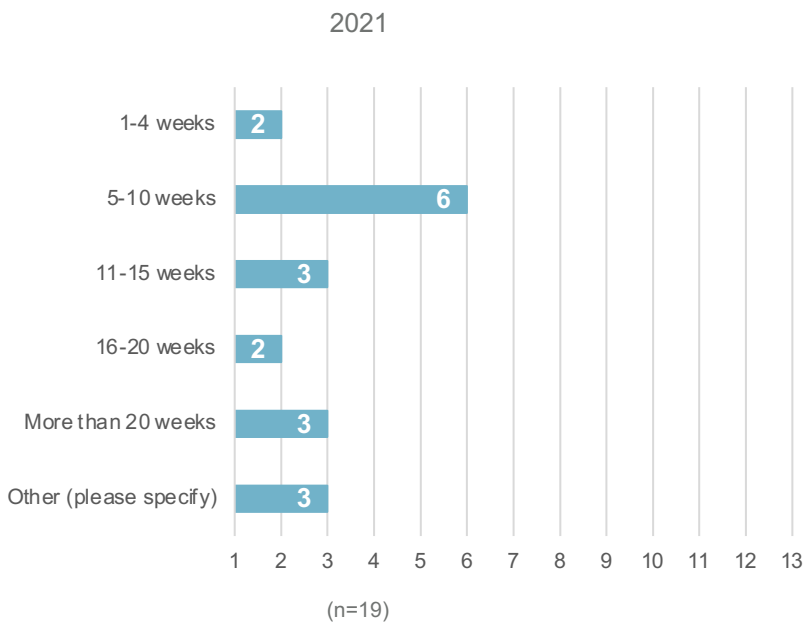
(n=96)

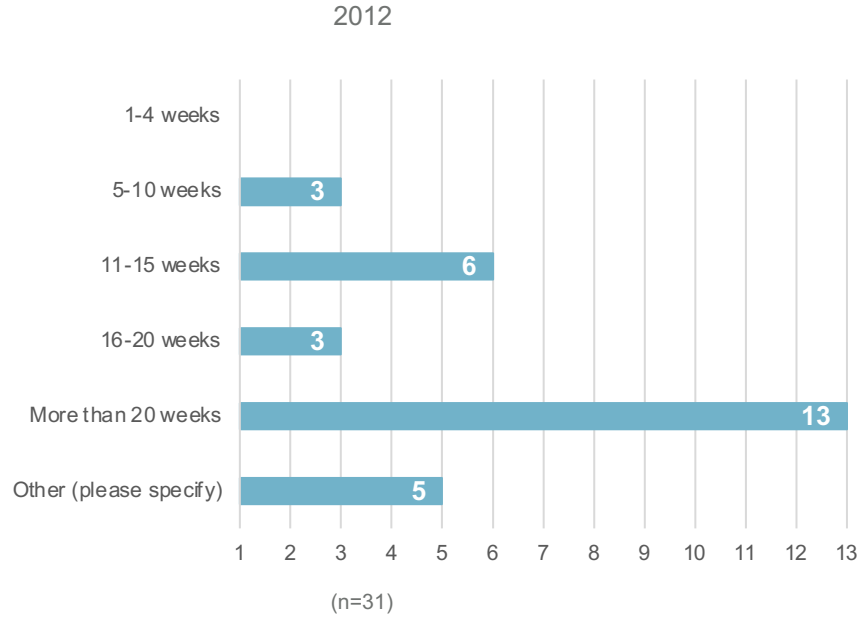
KEY TAKEAWAY

Most companies do not appeal NSE decisions.

Length of Appeal

If your company appealed FDA's NSE or "possibly NSE" decision, how long did the appeal take from the date of submission of the appeal (including meeting/hearing and final decision)?



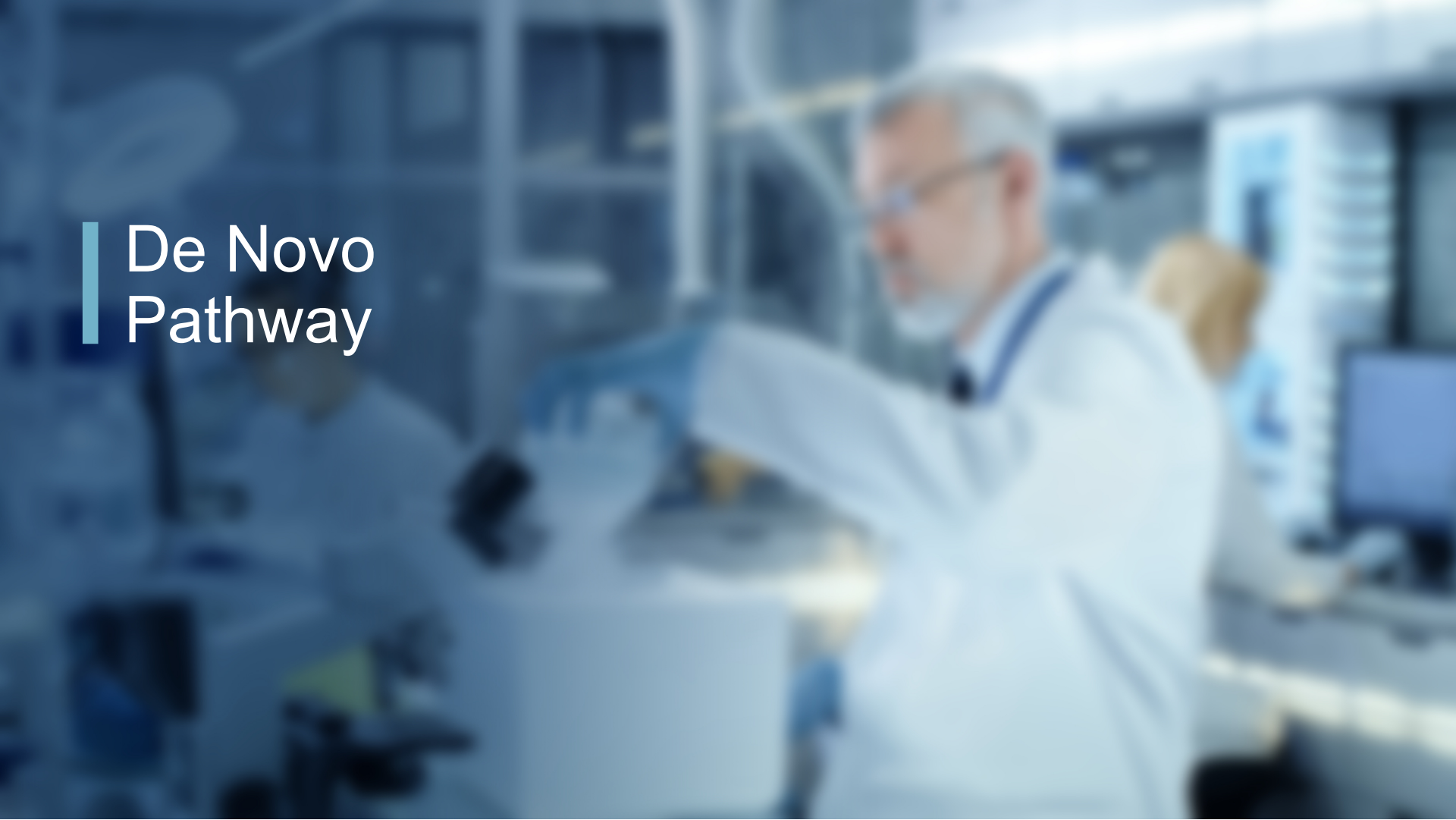


KEY TAKEAWAY

When the appeal process is used, the decision is typically rendered within 5-10 weeks from the appeal submission.

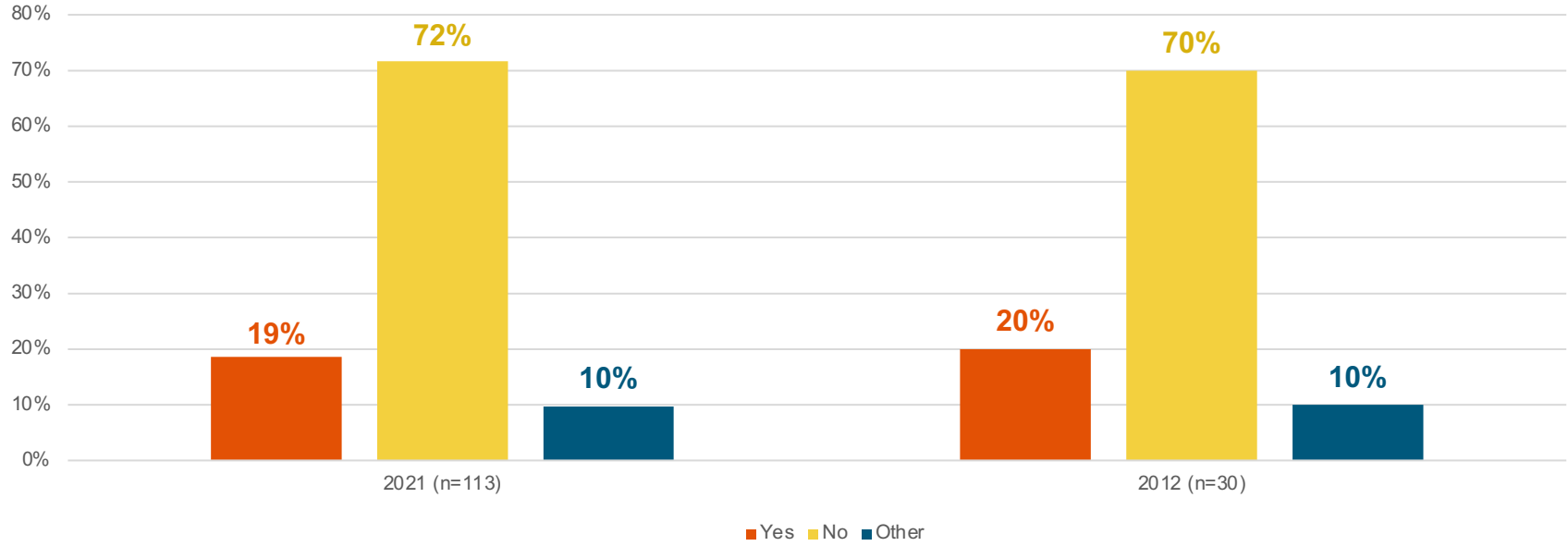
From 2012 to 2021 the appeal processing time has decreased.

De Novo Pathway



De Novo Pathway

Did FDA recommend the product for consideration via the De Novo pathway?



KEY TAKEAWAY

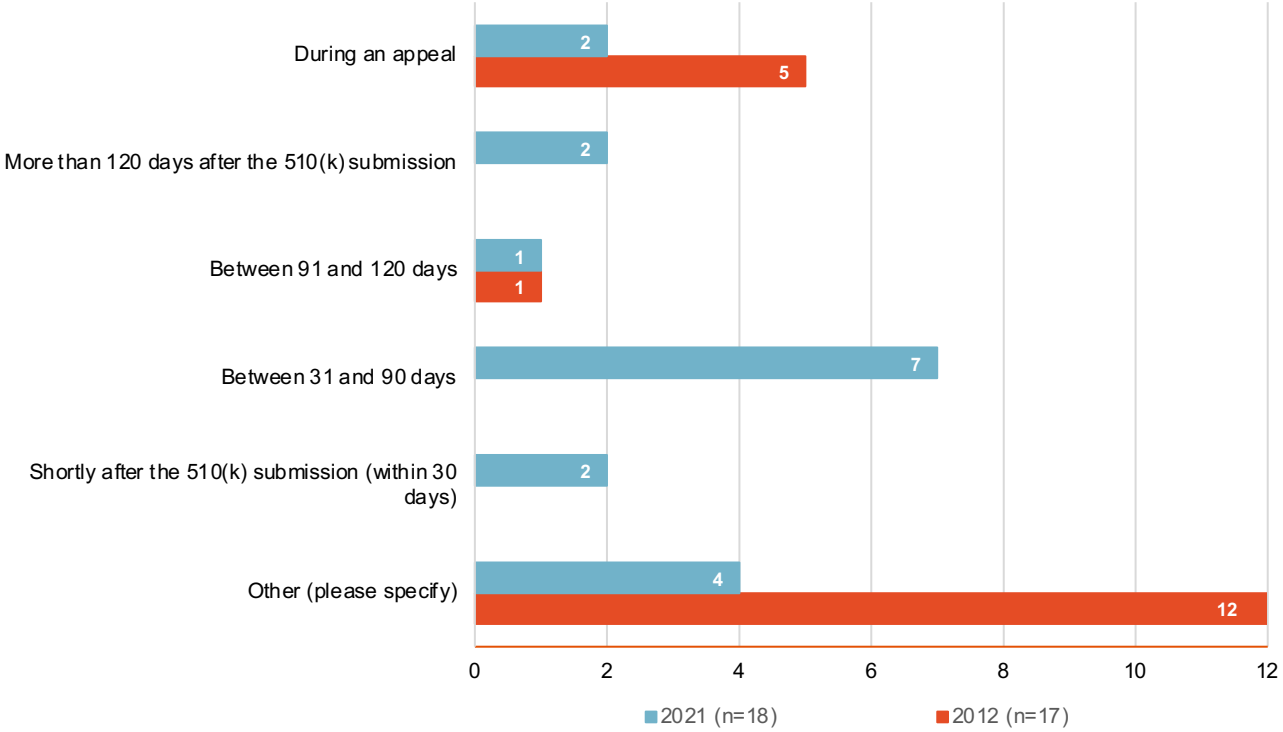
A comparable proportion (2012 vs. 2021) of recommendations for De Novo pathway was reported.

***Note 2012 had only 30 responses so less statistically relevant**

Timing

If the FDA recommended the De Novo pathway, how soon in the process did FDA recommend the De Novo pathway?

Note: In 2012 data, respondents could select more than one answer.



KEY TAKEAWAY

Time to the recommendation for use of De Novo decreased – most often coming during substantive review (between 31 and 90 days).

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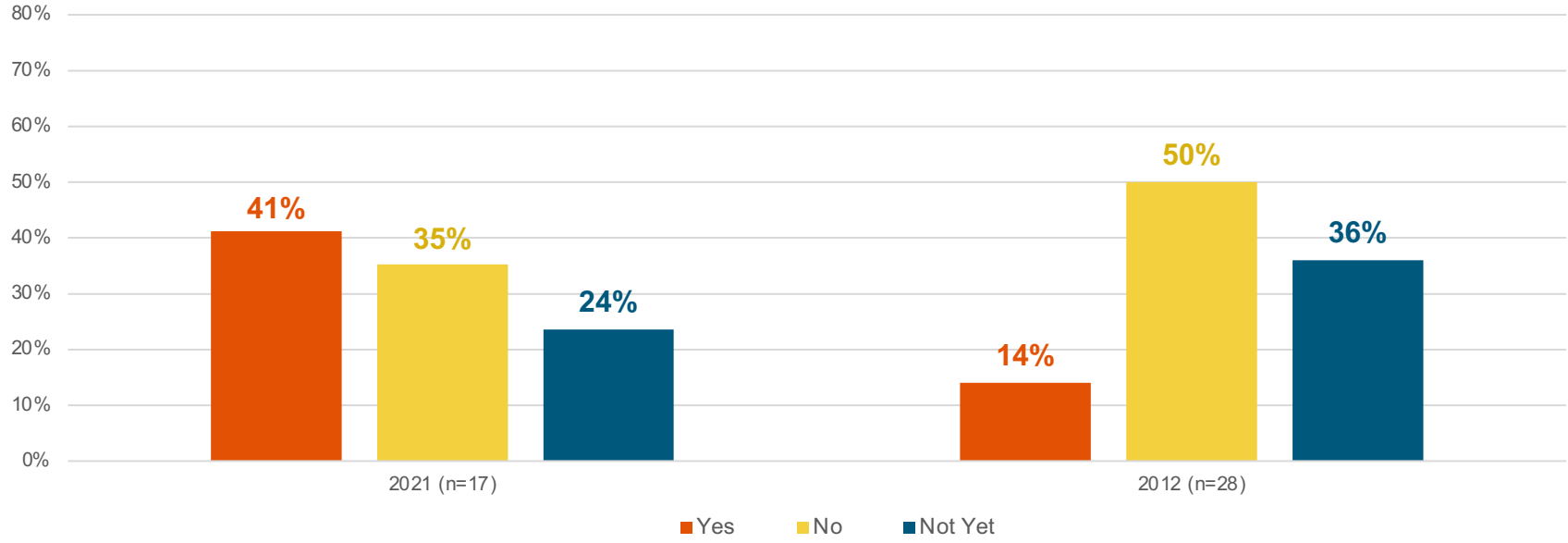
Pursuit of De Novo

Did you pursue the De Novo pathway?



KEY TAKEAWAY

Data suggest a significant increase in the number of De Novo submissions pursued.

Summary/Key Opportunities

Opportunities

- Data reflect a significant need for training of review staff on legal/regulatory issues related to 510(k) submissions – including:
  - criteria required for a substantially equivalent determination;
  - legitimate reasons for a NSE determination;
  - utilization of Least Burdensome principles; and
  - role of guidance documents (draft and final nonbinding)
- FDA should continue to build on the trend of acknowledging Least Burdensome principles by improving transparency of how they were applied
- FDA needs to improve on performance related to when an AINE letter is issued so that these are issued (when appropriate) early in the review process and not after many months and after rounds of AINN questions and responses

Thank You

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