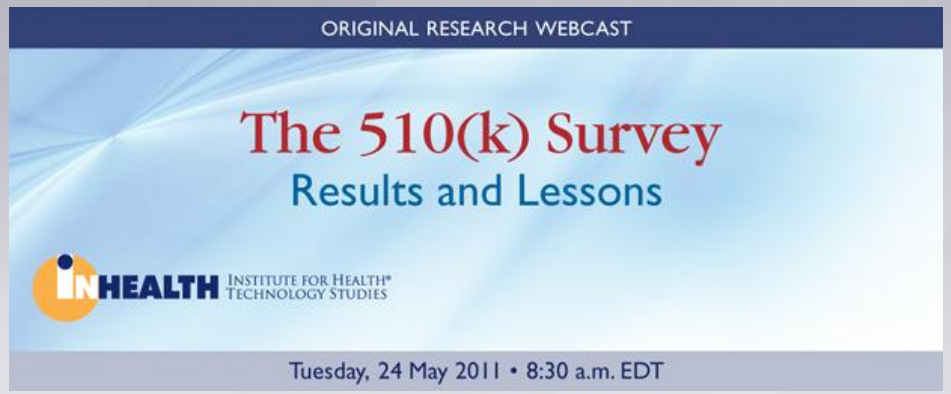
ORIGINAL RESEARCH WEBCAST

The 510(k) Survey

Results and Lessons

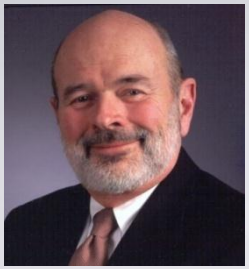
Tuesday, 24 May 2011 • 8:30 a.m. EDT



Moderator

Robert J. Rubin, MD
Clinical Professor of Medicine, Georgetown University
Member, InHealth Board of Directors
Chair, InHealth Research Council

Presenting Investigators



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INHEALTH INSTITUTE FOR HEALTH TECHNOLOGY STUDIES

A Comprehensive Analysis of the FDA 510(k) Process

Industry Practice and the Implications for Reform

John H. Linehan, Ph.D. *Northwestern University*

Jan B. Pietzsch, Ph.D. *Wing Tech Inc.; Stanford University*

National Press Club, Washington, D.C.

May 24, 2011

- Revised July 19, 2011 -

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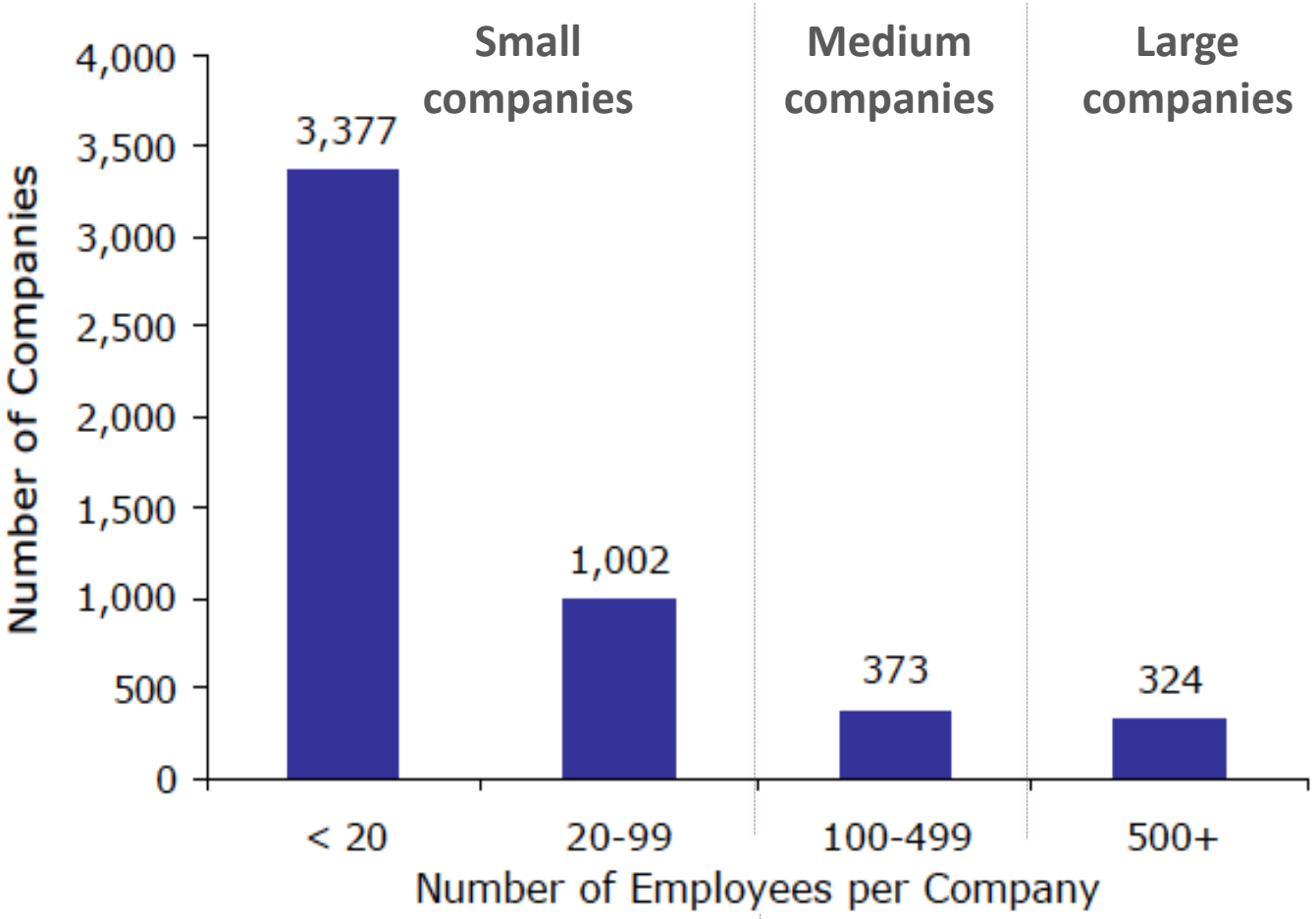
Outline

- The Medical Device Industry and Device Development
- Introduction to the Research Study
  - Objectives and Methodology
  - Respondent Characteristics
- Key Findings
  - Predictability and Interaction with FDA
  - Different Impact on Large and Small Companies
  - International Comparison
- Observations: Opportunities for Improvement
- Concluding Remarks

The Medical Device Industry and Medical Device Development

Medical Device Companies by Size



% of Total US Medical Device Employment	**28%**	**18%**	**54%**

Source: Number of companies: US Dept of Commerce, 2001. Employment: US Census, 2008.

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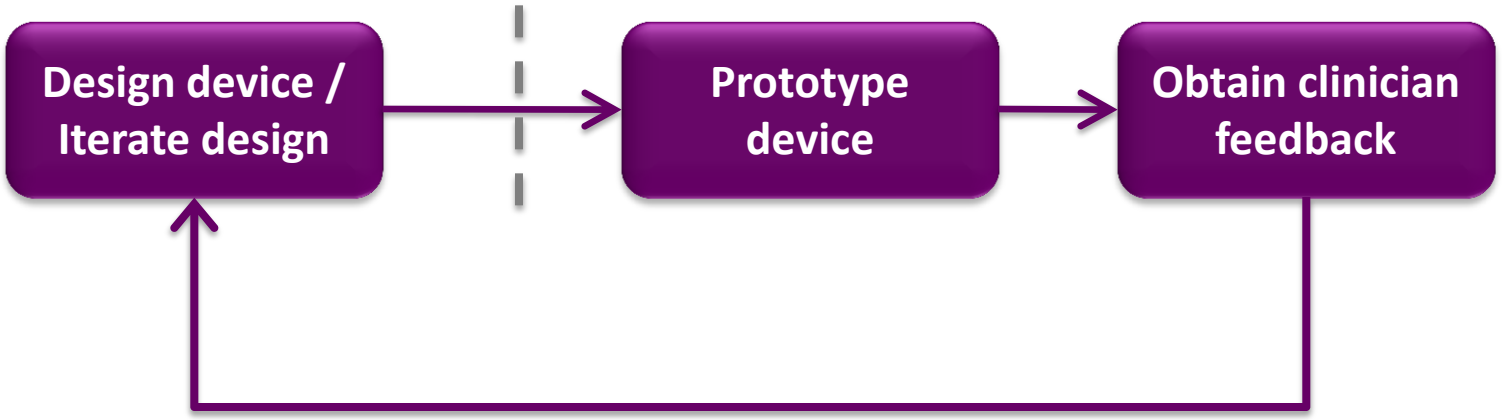
Device Development Is an Iterative Process



- Medical device development is a highly iterative process.
- Need to improve product continuously through frequent, positive iterations, while avoiding unnecessary iterations
- Efficient planning and execution requires predictable process.

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Medical Device Development Functions

- Cross-Functional Management
- Reimbursement
- Marketing
- Manufacturing & Operations
- Research & Development
- Quality
- Legal
- Clinical
- Regulatory
- Sales

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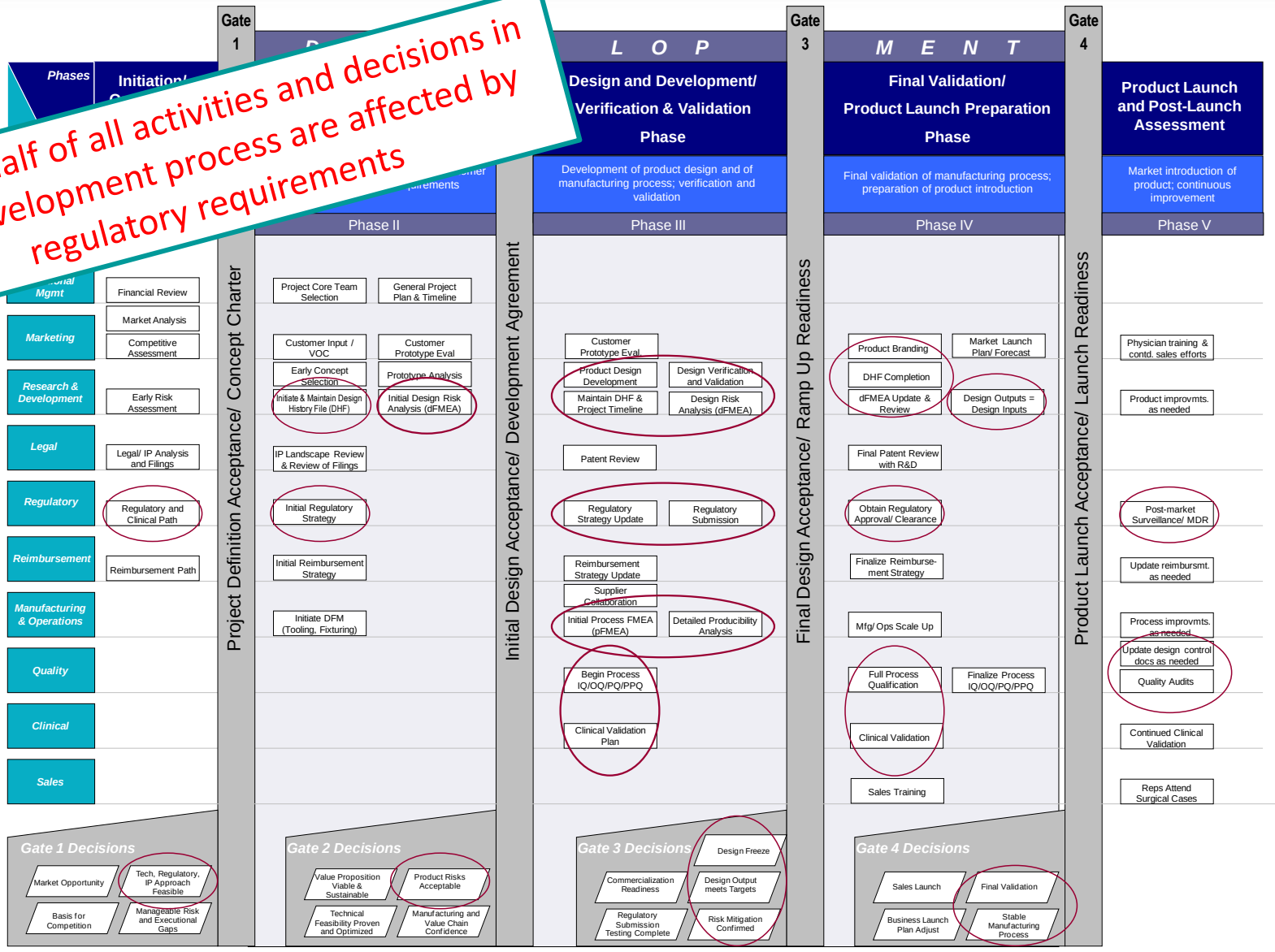
Impacts of Regulation on Device Development

Almost half of all activities and decisions in the development process are affected by regulatory requirements



Introduction to the Research Study

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Study Objective and Methodology

- Elicit from those engaged in medical device development, what seems to work well and how the 510(k) regulatory process could be further strengthened.

- Collect comprehensive data set to provide the basis for constructive input to strengthening the process:
  - Timelines
  - Interactions with the agency
  - Issues and challenges in current implementation
  - Comparison among international regulatory programs

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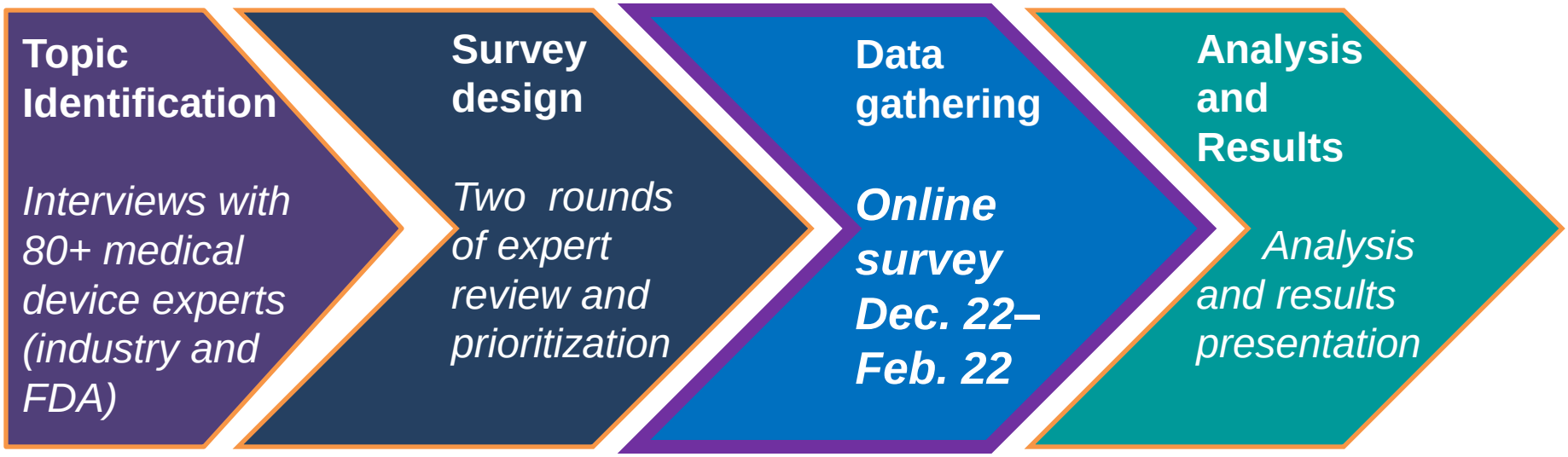
Approach and Study Methodology



8/2010

5/2011

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Approach and Study Methodology

- Target respondents:
  - Individuals closely involved with the 510(k) process
  - Broad outreach through professional societies, industry groups, and trade media
- Survey Structure:
  - General part and device-specific part
  - 86 questions total
- Responses:
  - N=356 respondents total
  - Number of respondents varied per question, as not all questions were answered by every respondent
  - N per question stated for each question in graphs and appendix

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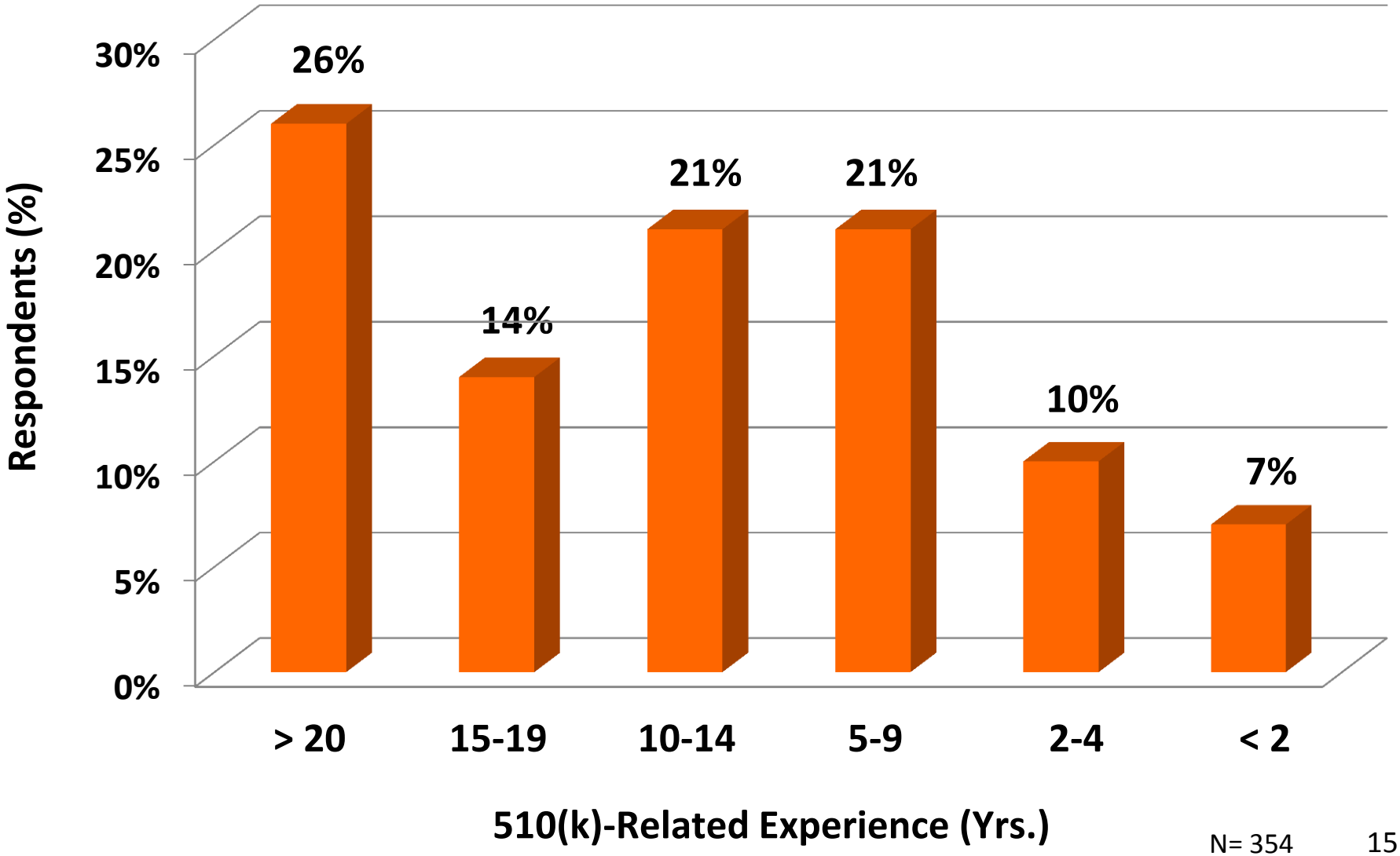
Respondents' 510(k)-Related Experience



N= 354

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Representativeness: Breakdown by Device Type

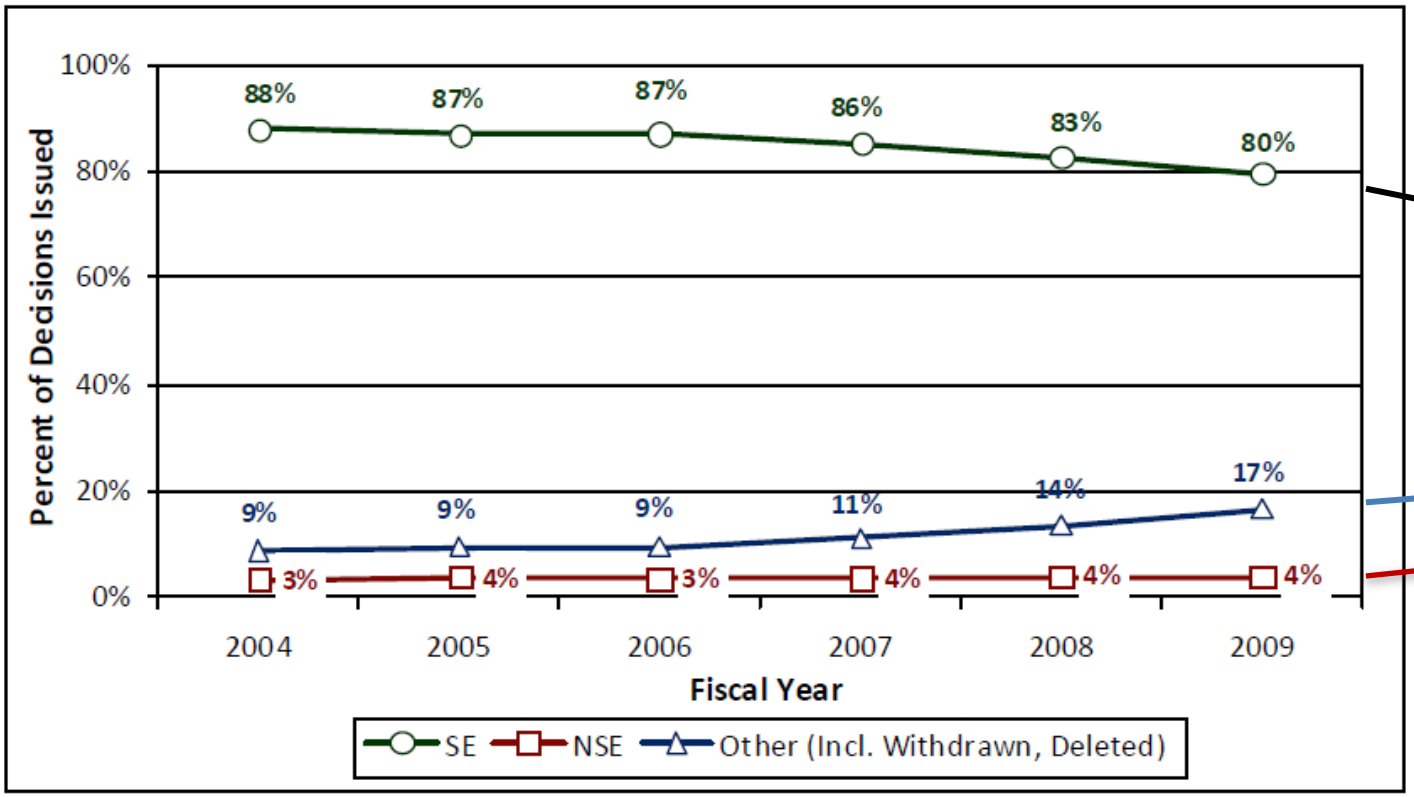
Type of Device	Actual % of FDA Applications	Survey Respondents %
Surgical, Orthopedic, and Restorative Devices	28%	37%
Cardiovascular Devices	13%	23%
Anesthesiology, General Hospital, Infection Control,and Dental Devices	23%	13%
Reproductive, Abdominal, and Radiological Devices	17%	7%
Ophthalmic, Neurological, and ENT Devices	6%	5%
Chemistry and Toxicology Devices	5%	3%
Immunology and Hematology Devices	3%	2%
Microbiology Devices	2%	1%
Other	3%	9%

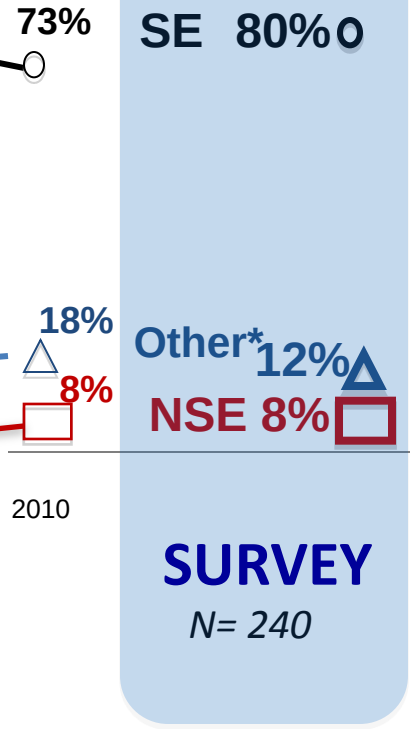
Actual % FDA applications: Based on all applications to FDA in 2008-2010 (See FDA database at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

Survey Respondents %: Based on respondent's statement about device field with most extensive 510(k) experience.

FDA's Internal Assessment compared to Survey Responses

Figure 4.9. 510(k) Decisions Issued: FY 2004-2009



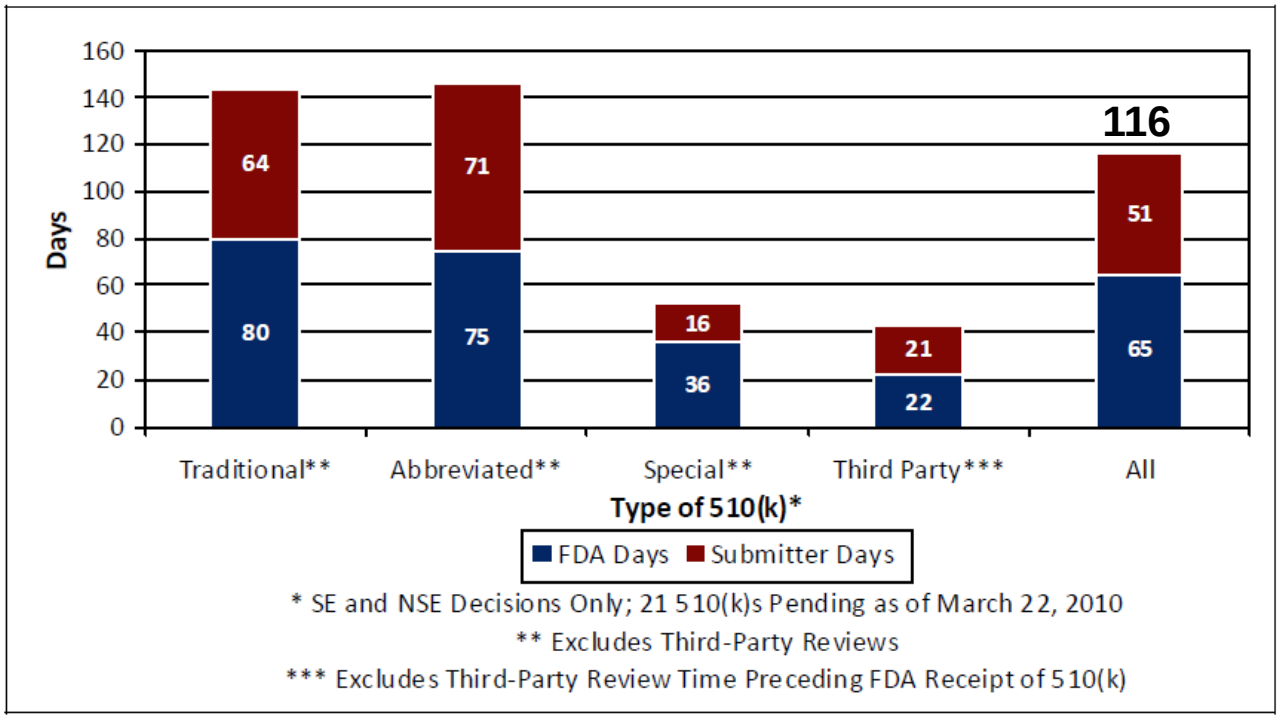


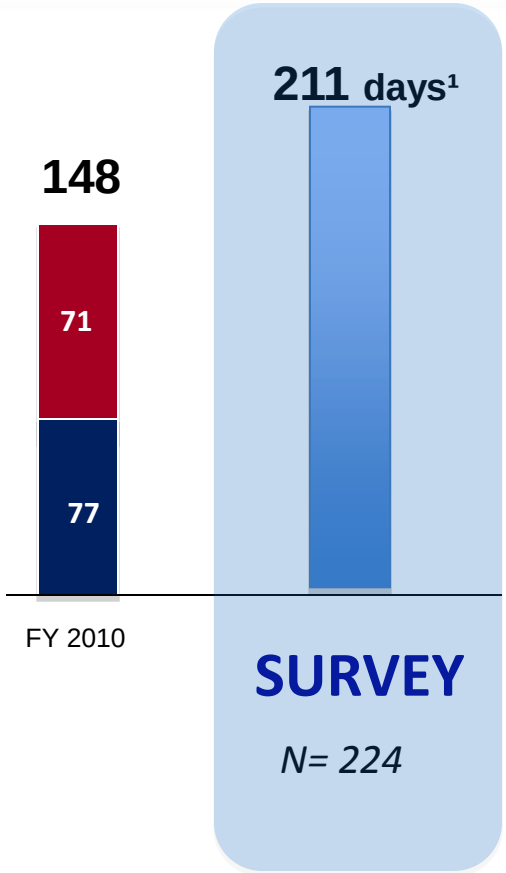
Source: - FDA CDRH, 510(k) Working Group - Preliminary Report and Recommendations, Vol. 1, August 2010.
- MDUFA Meeting Report, 2011.

* Includes the following responses: De-Novo, Converted to PMA, Other

FDA's Internal Assessment compared to Survey Responses

Figure 4.5. Average Time to 510(k) Decision by Type of 510(k): FY 2008 Receipt Cohort [80]

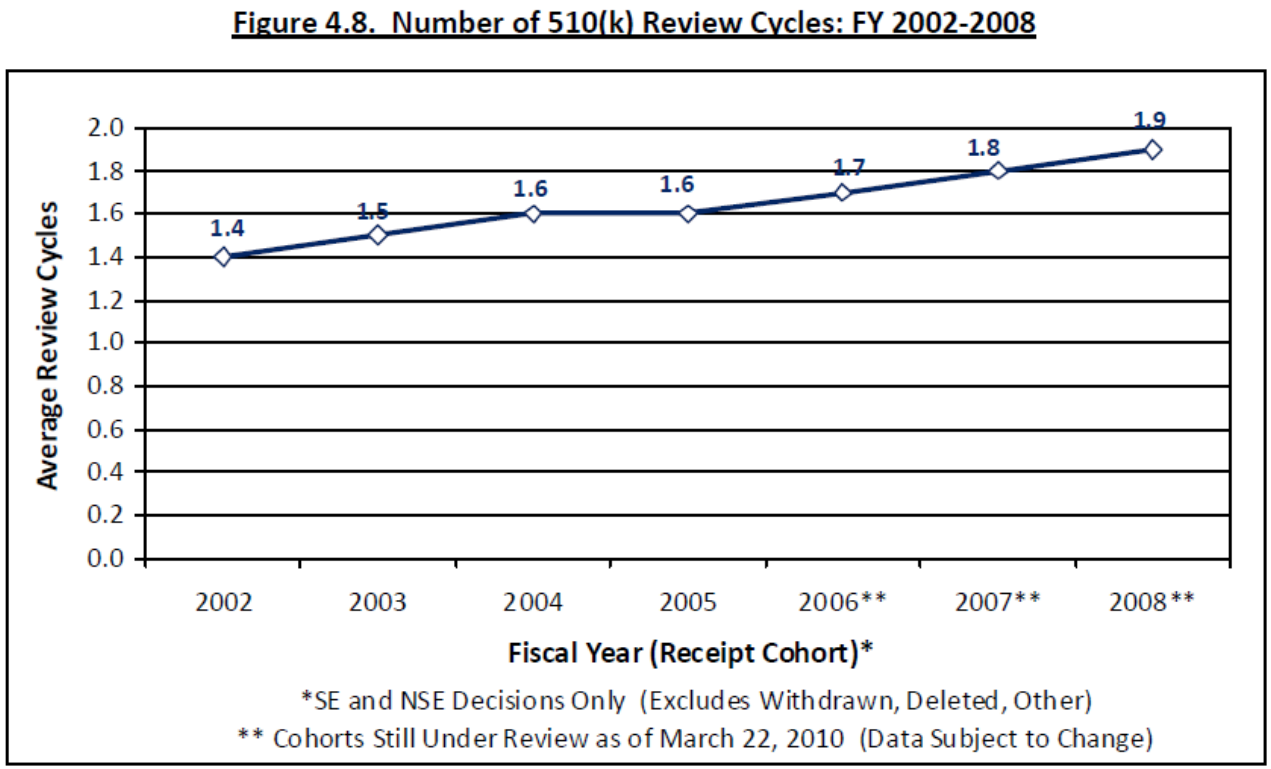


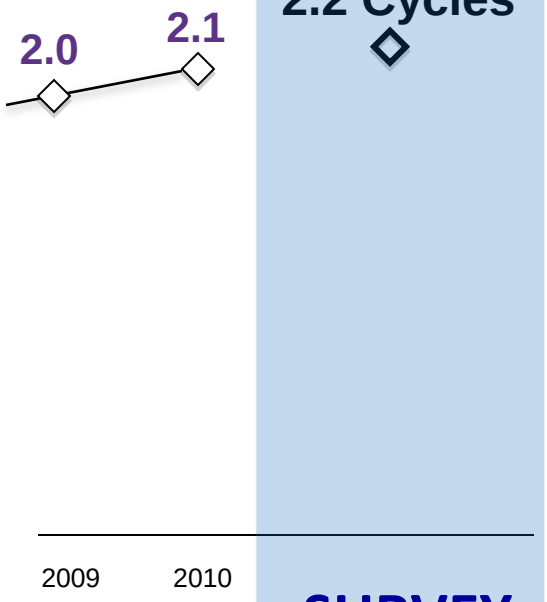


Source: - FDA CDRH, 510(k) Working Group - Preliminary Report and Recommendations, Vol. 1, August 2010.
- MDUFA Meeting Report, 2011 *(as amended/corrected by FDA 7/2011)*

[1] SE and NSE only.
Avg. duration for SE: 204 days (N=179); NSE: 279 days (N=18); Withdrawn: 330 days (N=13), with long tail.

FDA's Internal Assessment compared to Survey Responses





2.2 Cycles

SURVEY

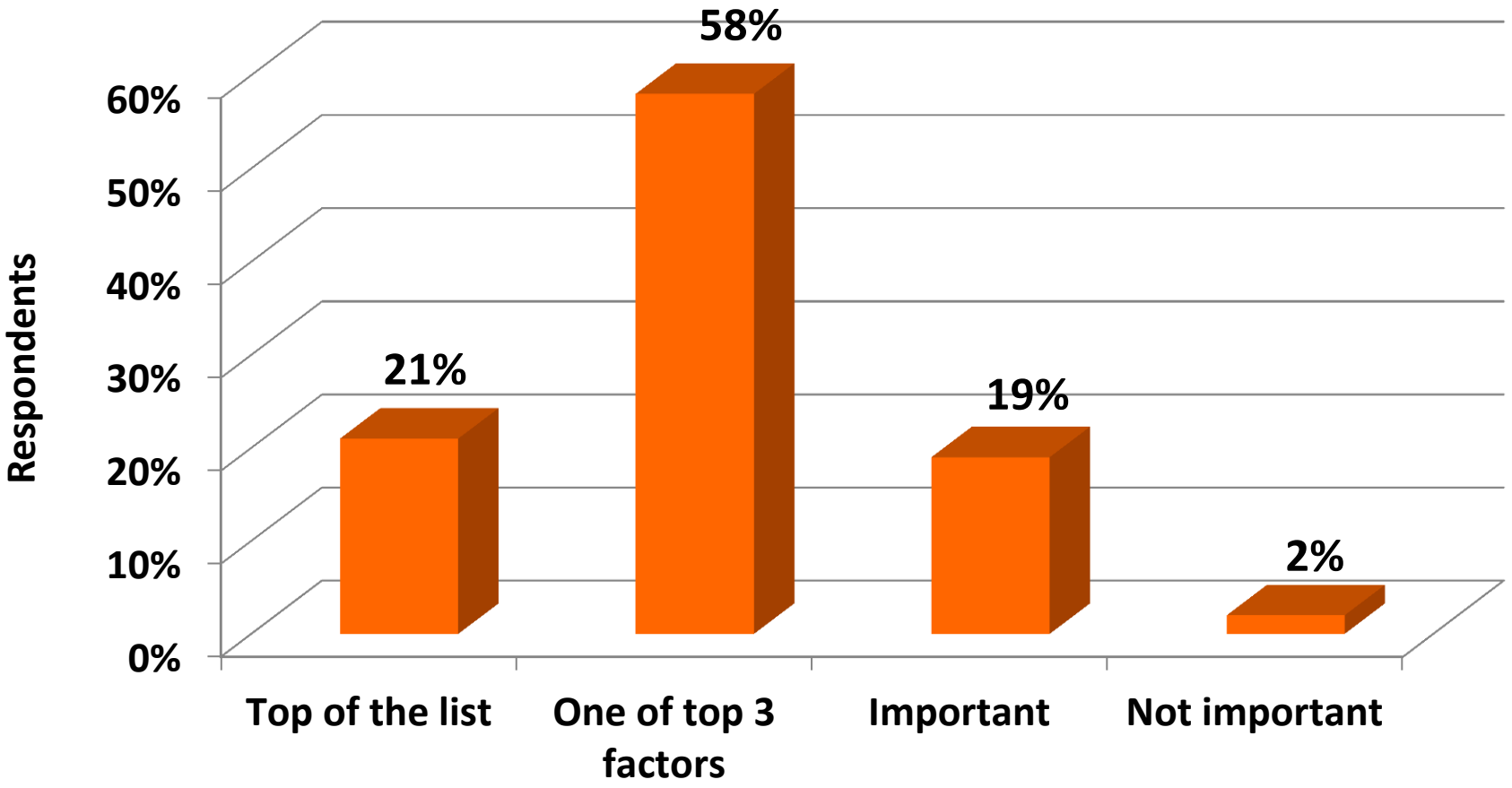
N= 211

Source:
- FDA CDRH, 510(k) Working Group - Preliminary Report and Recommendations, Vol. 1, August 2010.
- MDUFA Meeting Report, 2011.

N= 211; SE: 2.1 cycles (N=191); NSE: 2.8 cycles (N=20)
Withdrawals (not included in computation): 2.9 cycles (N=14)

Key Findings
Predictability and Interaction with FDA

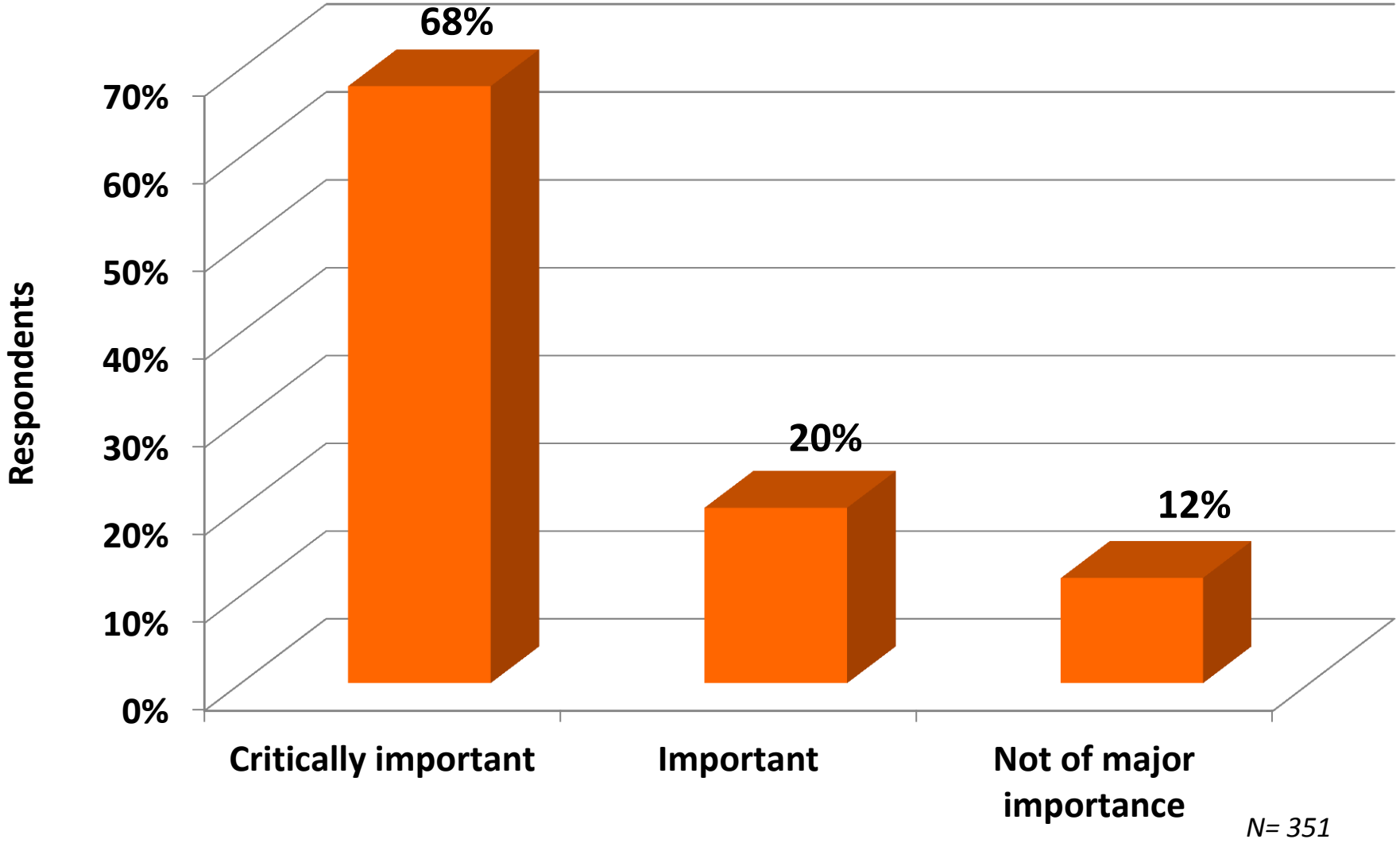
Importance of Regulatory Requirements in Decision to Invest in a New Product



N= 351

How important are regulatory requirements to your business decision to a major investment in a new product?

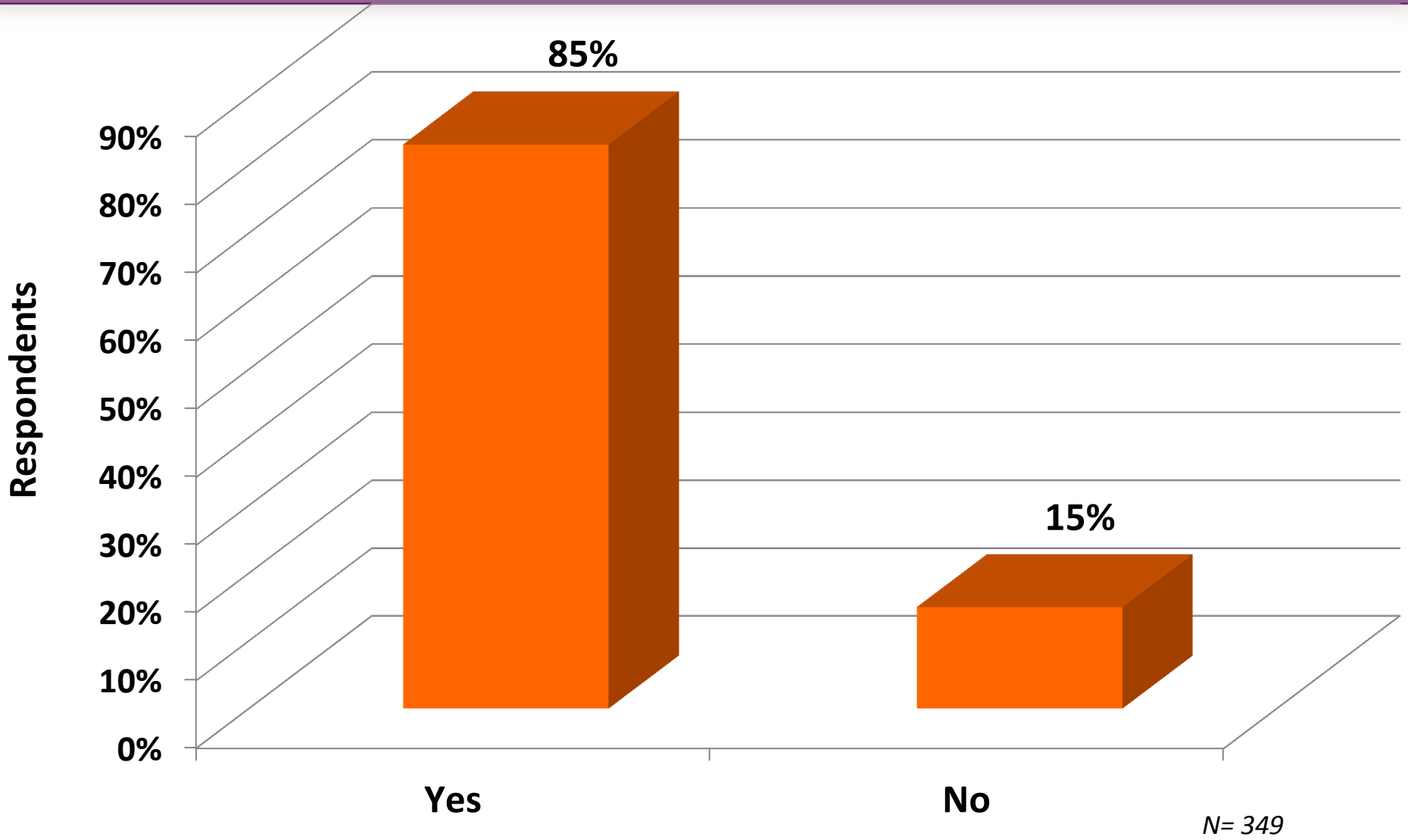
Importance of Regulatory Process Predictability for Decision about First Country for Market Launch



N= 351

For the technologies you have worked on, how important is predictability of the regulatory process in deciding first country for market launch?

Respondents Perceiving Substantive Changes in FDA Review Process



From your experience in the last 3 years, have you perceived any substantive changes in the FDA review process and/or clearance decision of a 510(k) submission?

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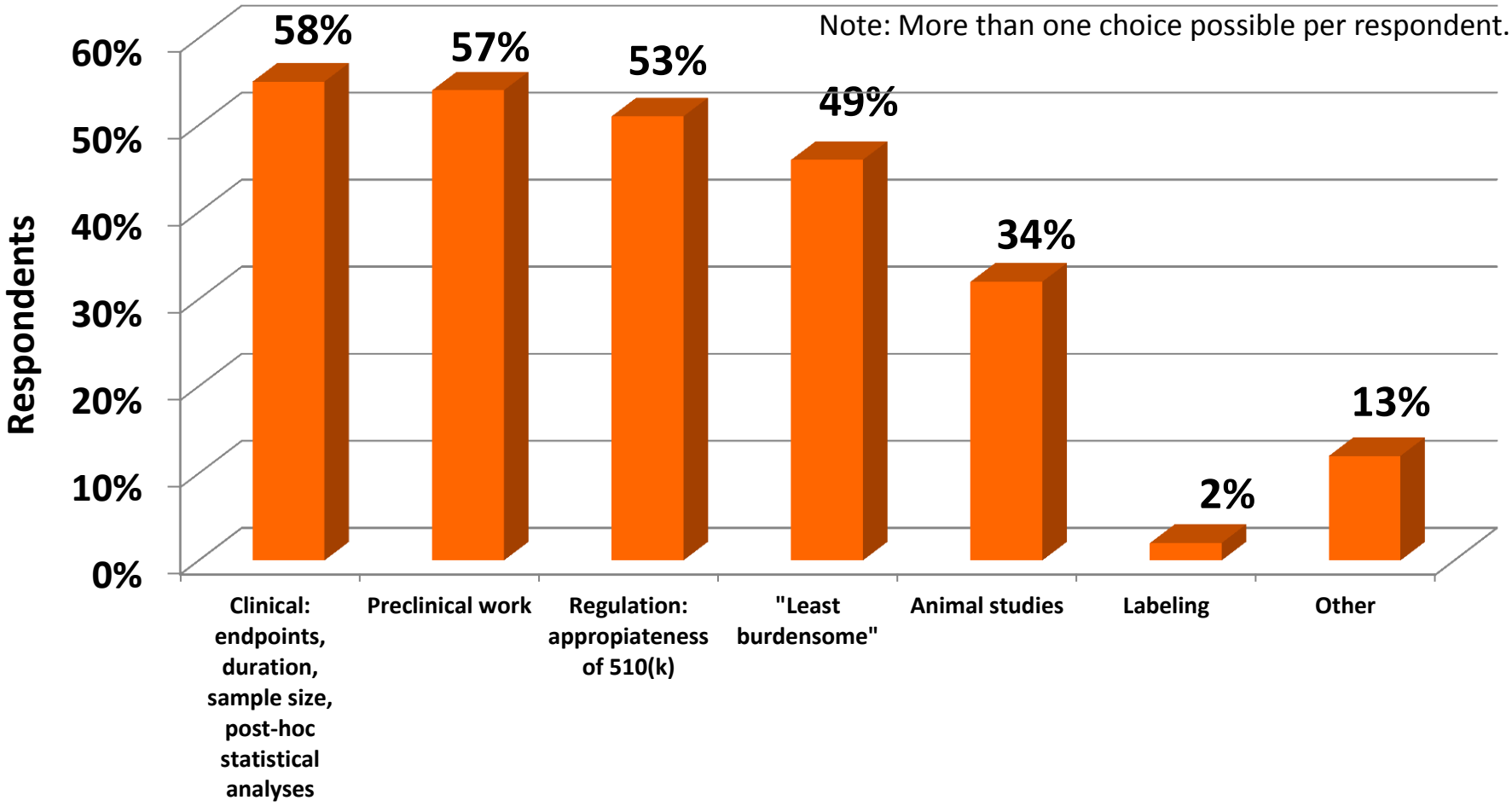
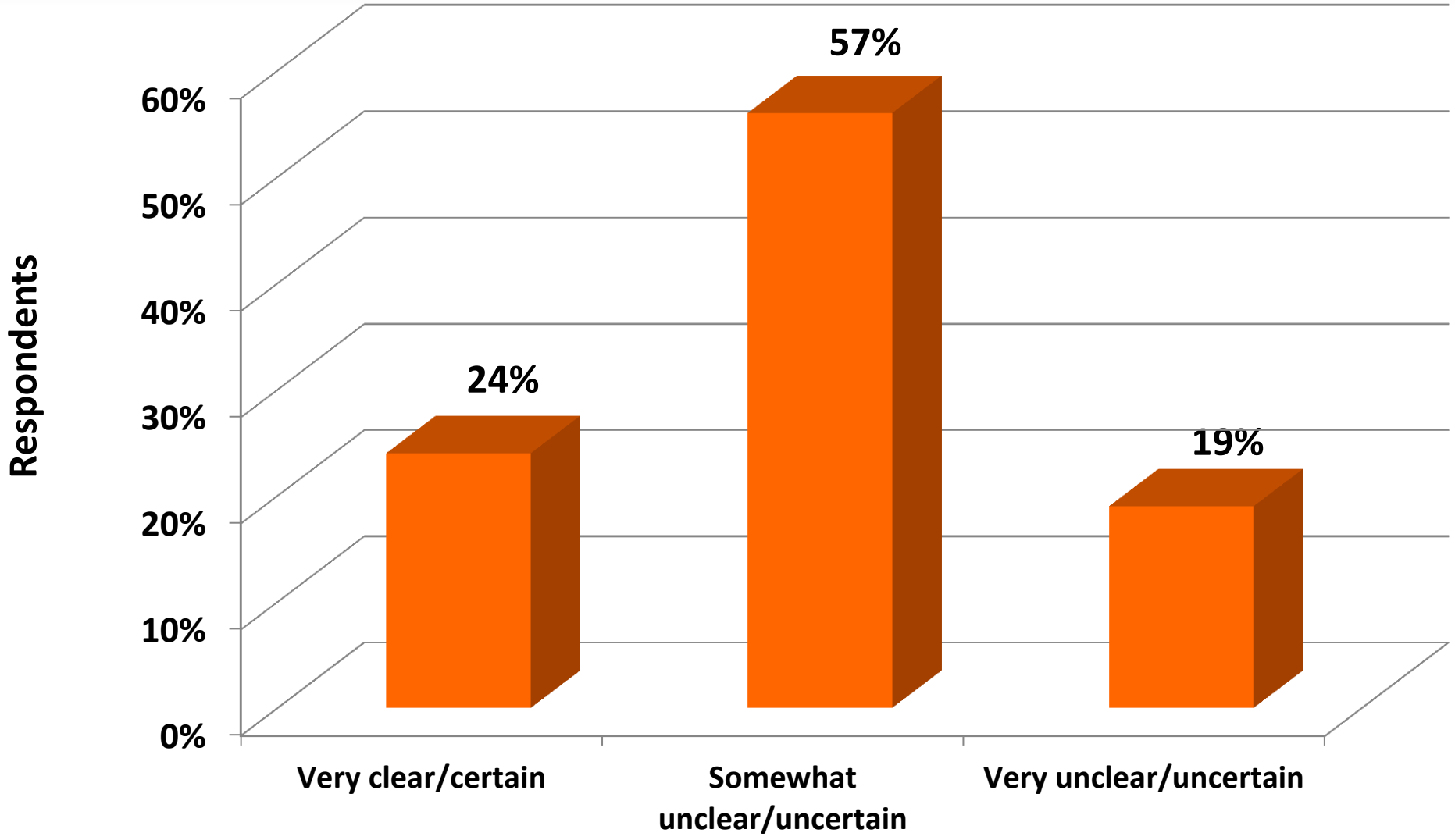
Perceived Changes in FDA's Requirements



N= 337

In the last 3 years, in what specific areas have you perceived changes in the FDA's requirements?

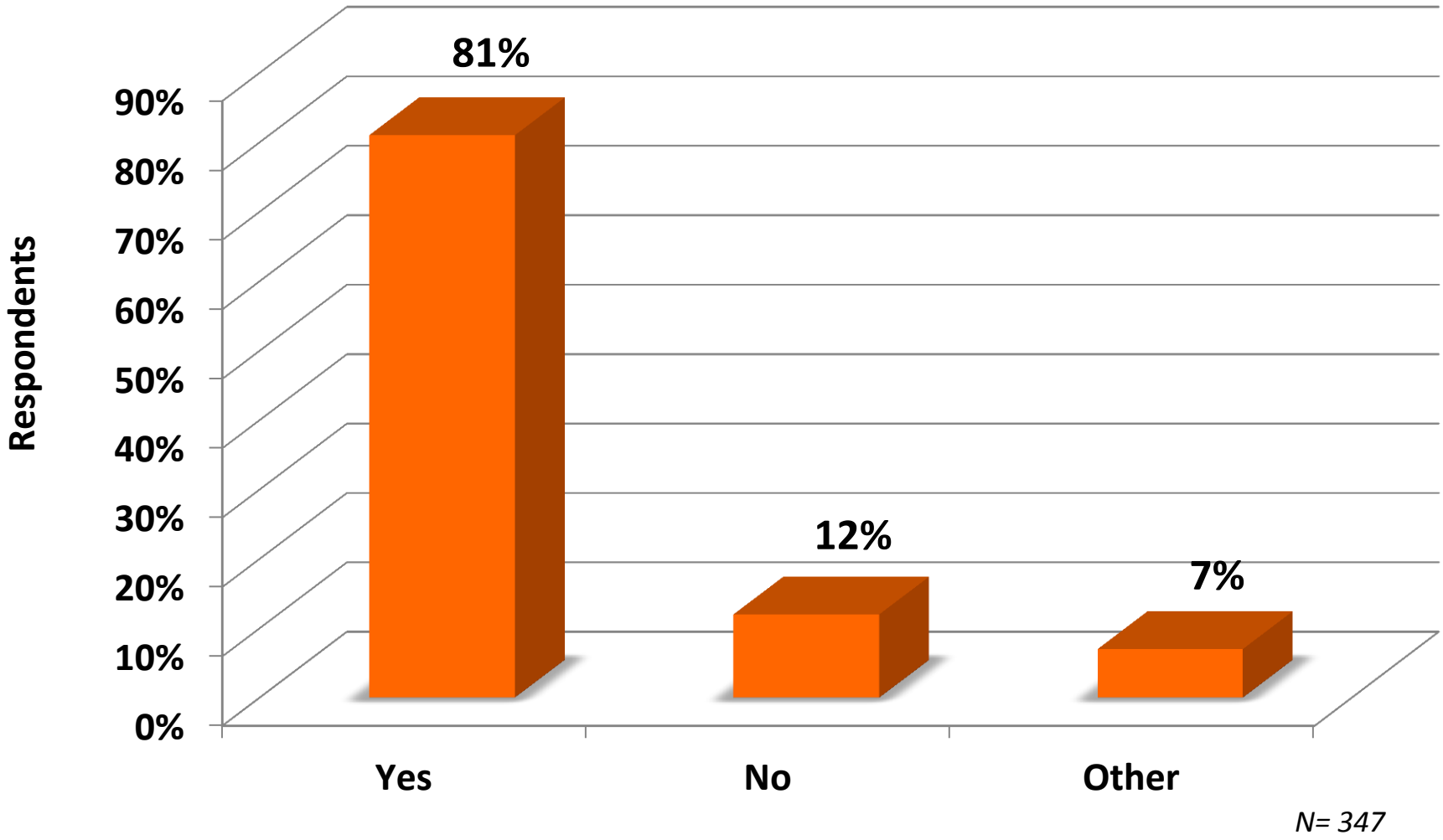
Clarity of Preparation Requirements for a 510(k) Submission



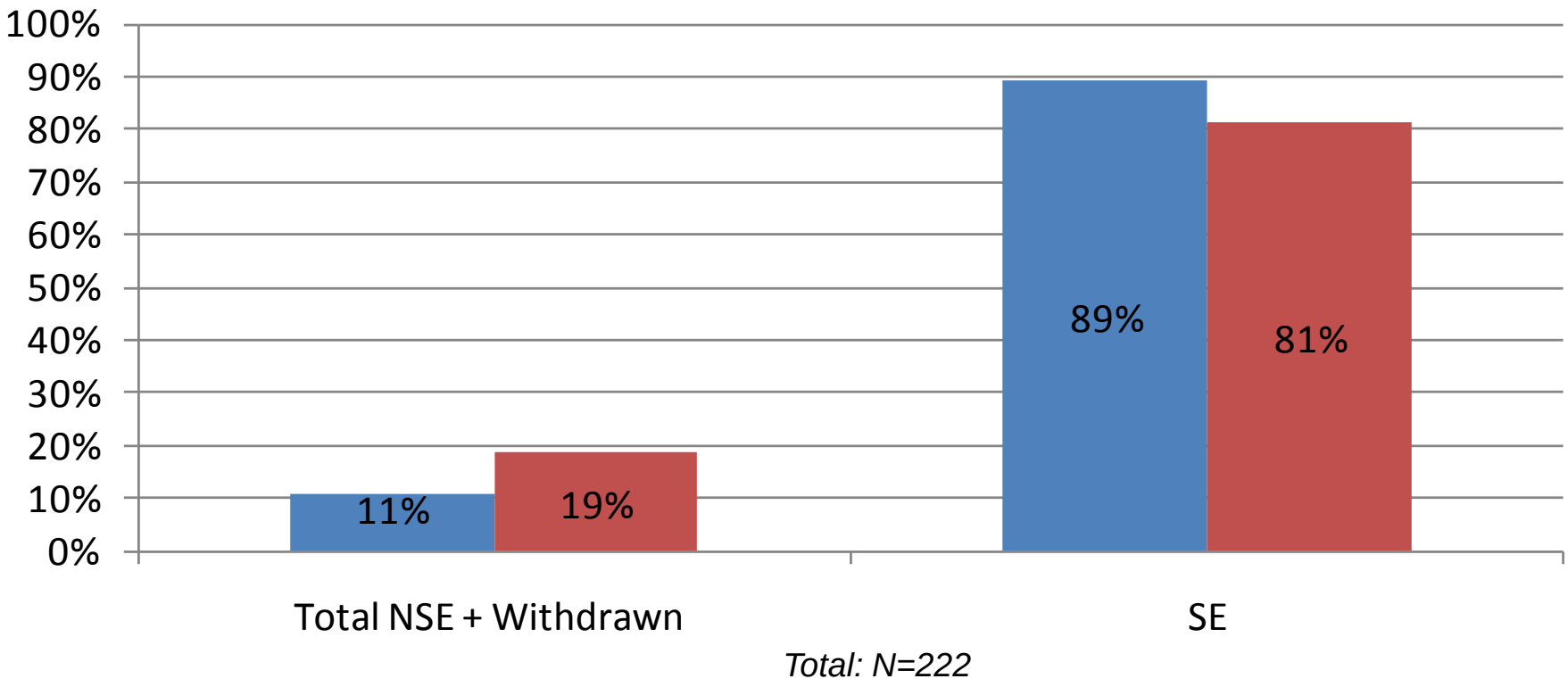
N= 354

Based on your understanding, what is the current level of clarity of the requirements for preparation and submission of a 510(k)?

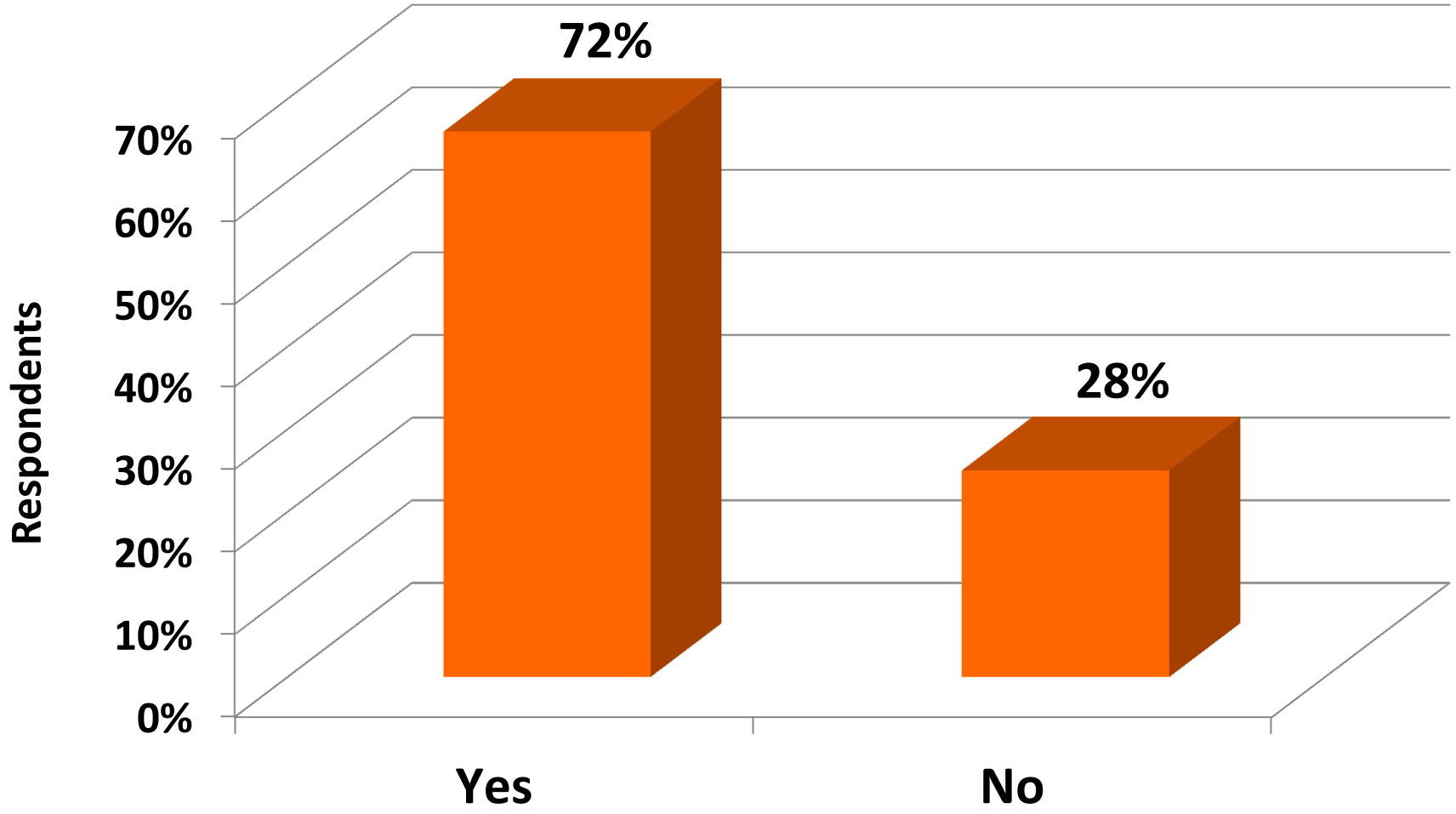
Have Guidance Documents been Critical to your Company in Preparing Successful Submissions?



Availability of Guidance Document has an Impact on the Ultimate Decision



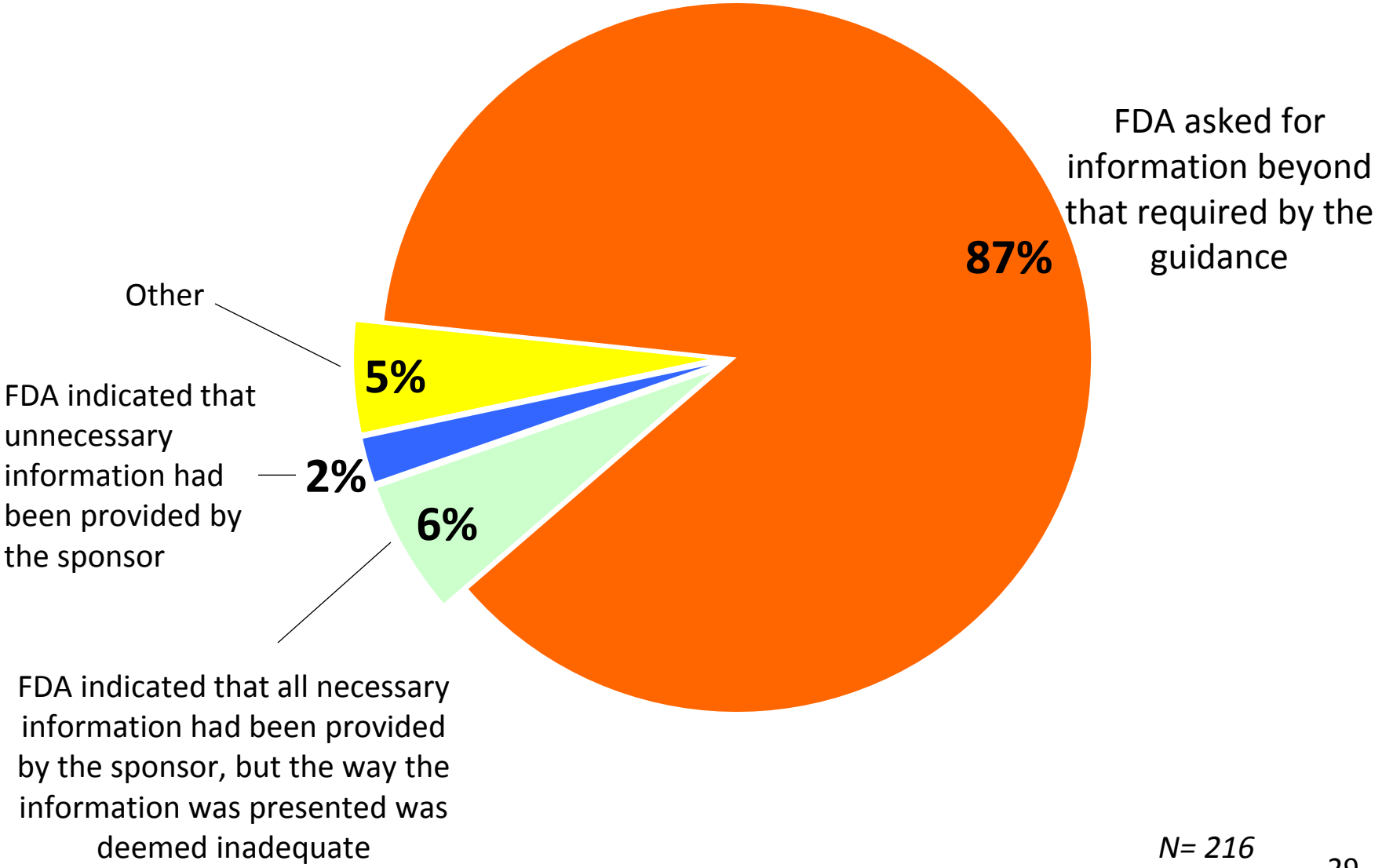
Respondents Perceiving Differences Between Guidance Document and FDA Review



N= 300

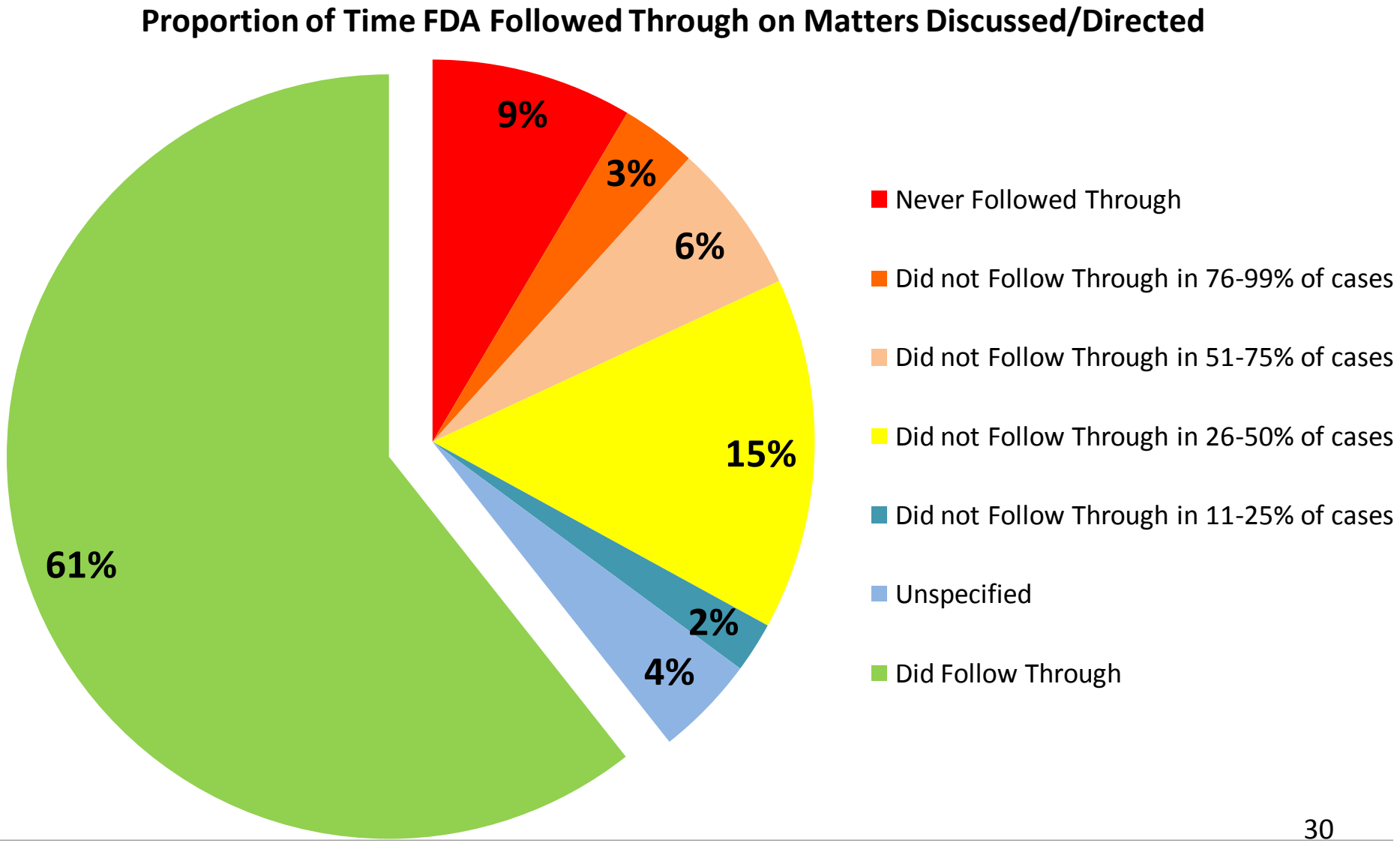
If an appropriate guidance existed and was used by your company during submission of a 510(k), did you perceive any difference between the guidance document and the way the FDA reviewed your submission?

Reason for Perceived Difference between Guidance Document and FDA Review

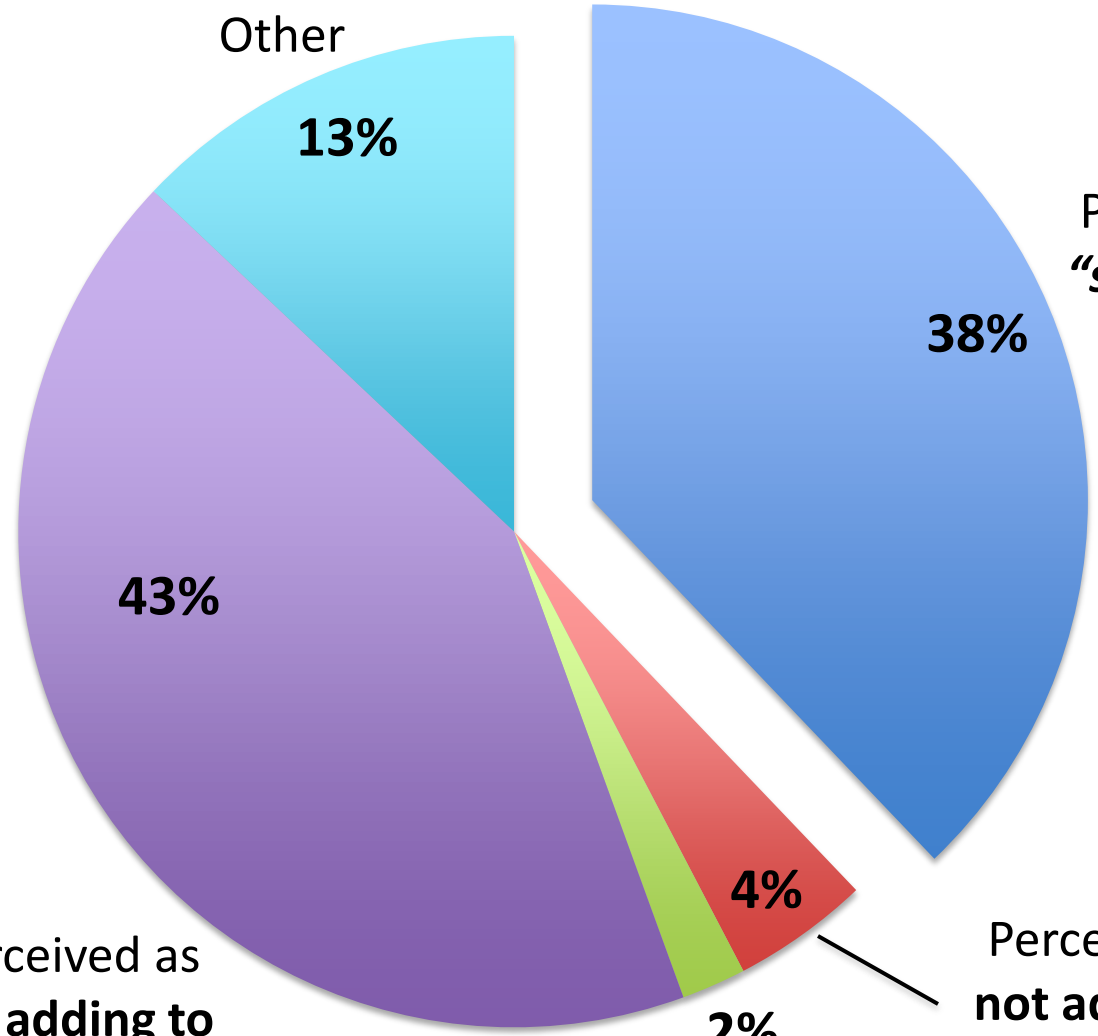


N= 216

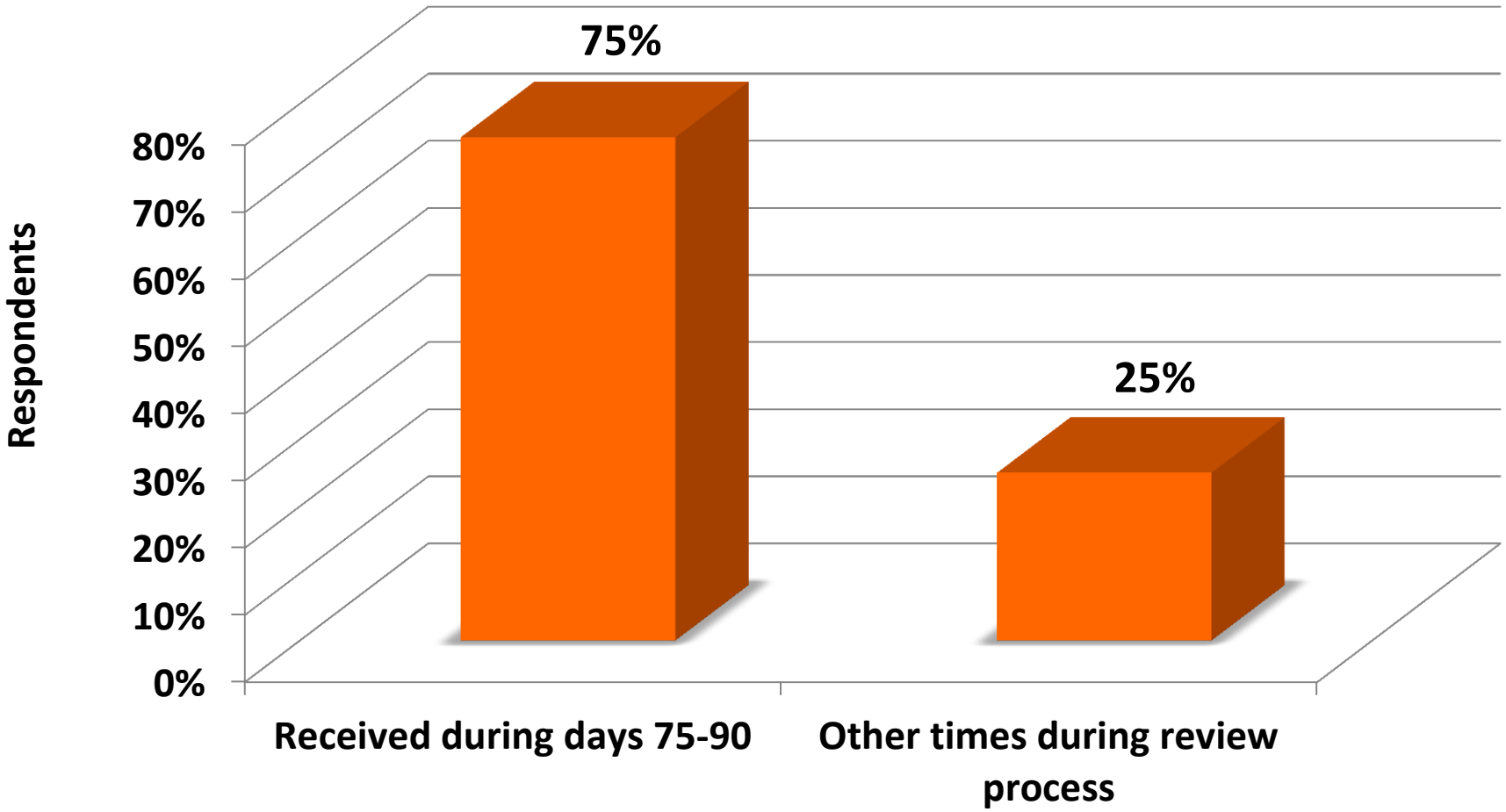
Perceived Difference between Pre-Submission Meeting Discussion and FDA Review



Interaction: Questions/Requests for Information

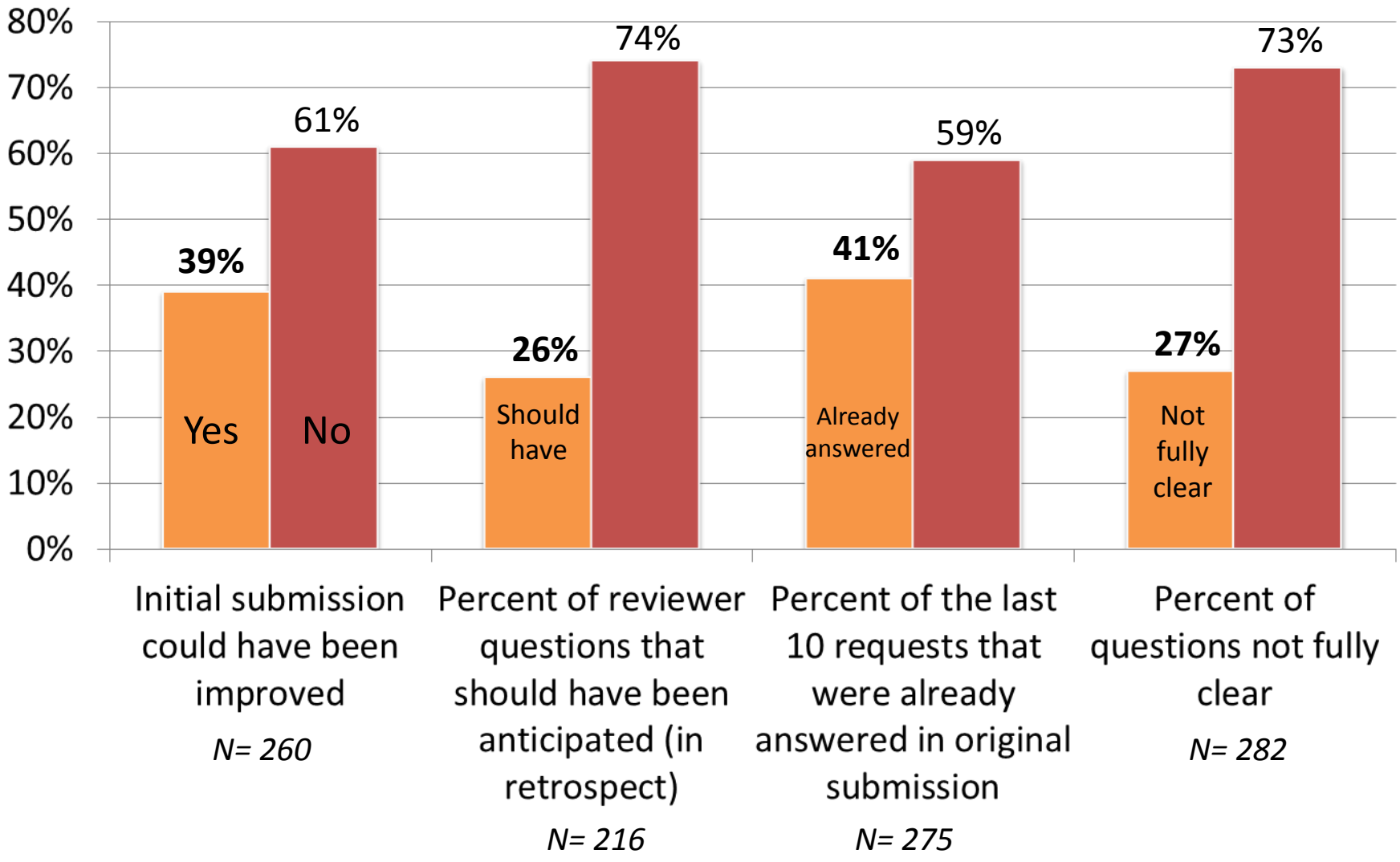


Percent of Requests for Information Obtained During Days 75-90 of FDA's 90-day Review Period



N= 293

Interaction: Respondent's Perspective



Key Findings
Different Impact on Large and Small Companies

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Key Differences between Large and Small Companies

	Small Companies	Large Companies
New product (vs. line extension) [%]	**72%**	**35%**
SE Decision [%]	**61%**	**88%**
NSE Decision [%]	**13%**	**6%**
Interaction with FDA during development process	**earlier**	**later**
Pre-submission meeting with FDA sought	**39%**	**17%**
Duration of pre-IDE process [months]	**10.8**	**7.4**
Change in lead reviewer [%]	**19%**	**10%**
Total avg. review time [days]	**330**	**177**

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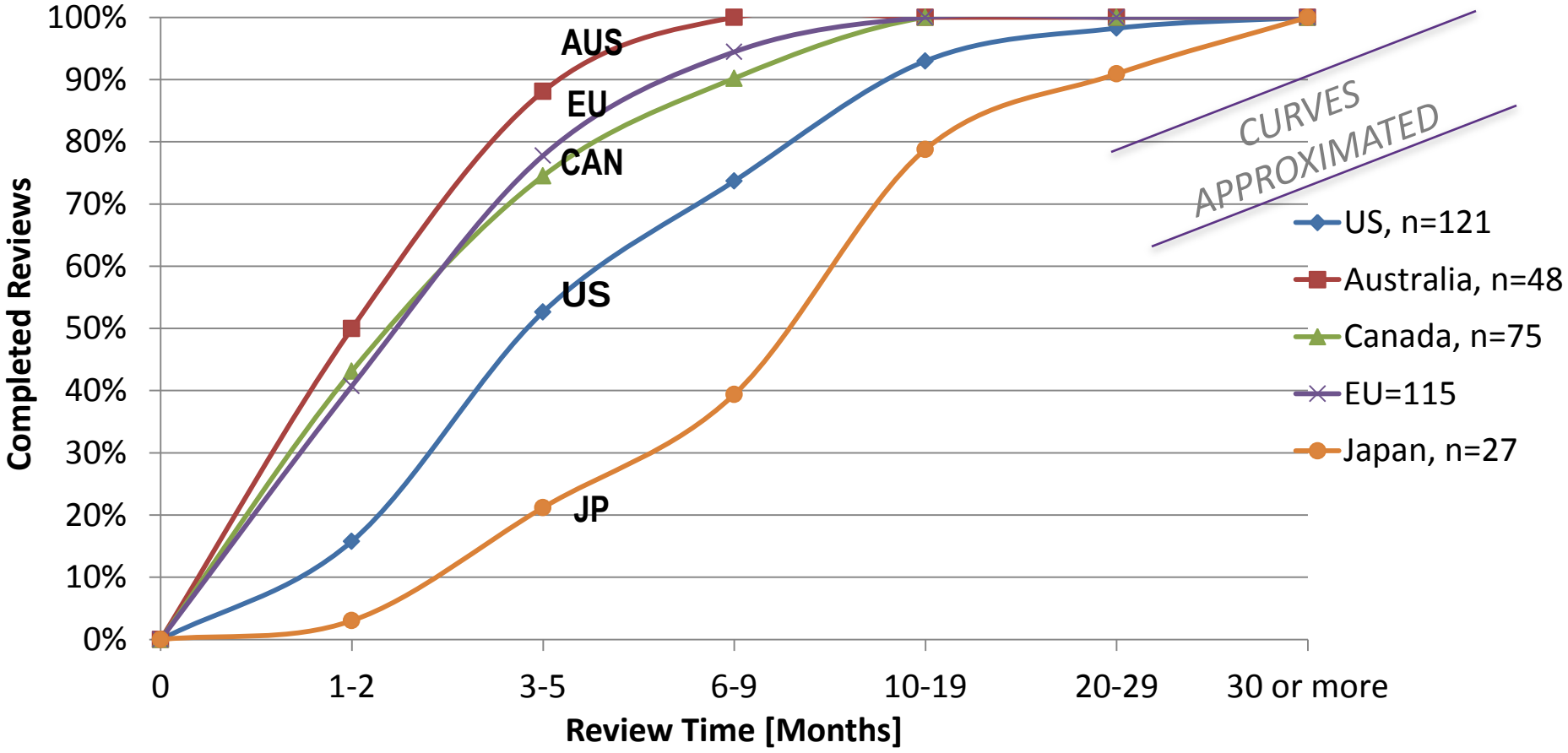
Key Differences between Large and Small companies

Respondents perceive:	Small Companies	Large Companies
Major difference with FDA's risk assessment [%]	**48%**	**23%**
% of FDA requests already answered in original submission	**53%**	**33%**
% of FDA requests "scientifically justified"	**30%**	**42%**
FDA requests having major effect on time [%]	**45%**	**36%**
FDA requests having major or medium effect on financial resources [%]	**76%**	**64%**

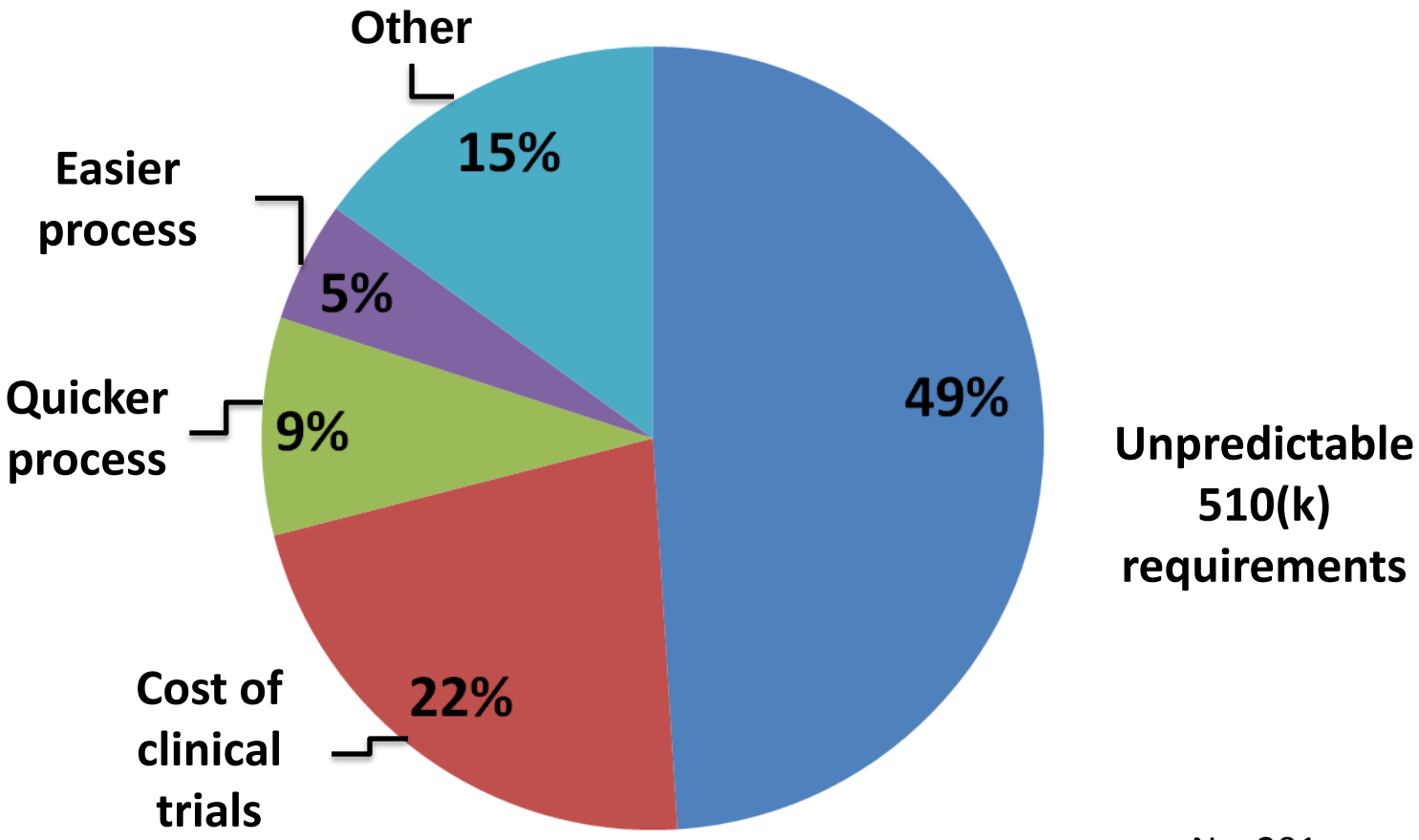
Key Findings
International Comparison

Comparison of International Review Time from Submission to Clearance/Registration



Length of review process in months (based on data points for "1-2", "3-5", "6-9", "10-19", "20-29", "30+ months" for the various regulatory systems. N per country: see above. Graph shows ultimately cleared/registered devices only.

Major Reason to Bring a Device OUS First



N = 201

Within the last 3 years, if your company chose to first bring to market a specific device OUS, what was the major reason?

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International Comparison between EU and US

	EU	US
Considered "most predictable regulatory system" [%]	**64%**	**8%**
First regulator/"body" approached to discuss and plan submission [%]	**80%**	**4%**
Review time (submission to decision) for products not requiring clinical data [months]	**2.7**	**5.9**
Review time (submission to decision) for products requiring clinical data [months]	**4.8**	**13.2**

Moving Forward to Foster Innovation and Timely Patient Access to Safe & Effective Technologies

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Opportunities

Enhance predictability

- Increase number of guidance documents
- Timely update of guidance documents
- Clear and timely communication of *new* FDA expectations before publication in guidance

Increase process consistency

- Increase training (particularly implementation of current regulations)
- Reduce perceived differences in agency follow-through (by enhanced communication)
- Reduce reviewer turnover

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Opportunities

Ensure efficient review process

- Preparation of clear and complete submissions
- Eliminate repeat requests of information already provided
- Timely access to meetings
- Increased use of interactive review concept

Close gap with international systems

- Continued harmonization efforts (GHTF)
- Sharing best practices (particularly on process side), while acknowledging differences in regulatory requirements

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Opportunities

Increase attention to specific needs of small companies (while maintaining a level playing field)

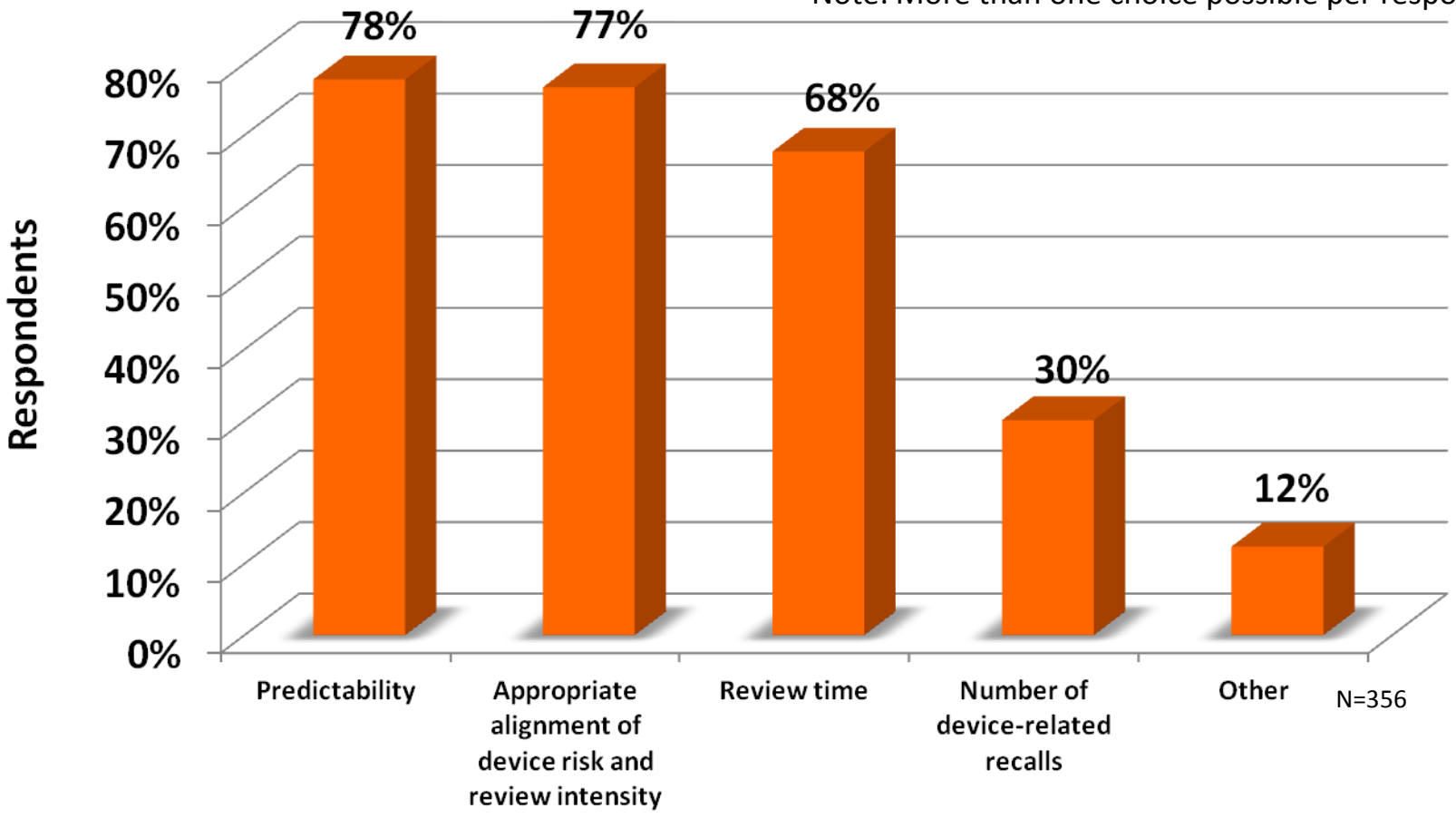
- Improve opportunities for interaction
- Provide training support in areas where small companies tend to face particular challenges

Monitor effect of process changes

- Evaluate impact of any process changes through appropriate performance metrics
- Work with industry to monitor process performance over time

Respondent-Suggested Metrics to Evaluate Future Changes in the 510(k) Process

Note: More than one choice possible per respondent.



Assuming that the FDA will make changes to the 510(k) clearance process, what primary metrics should be used to evaluate the overall performance of the revised 510(k) process?

Concluding Remarks

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Funding Source

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Outreach Partners

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Making better healthcare products possible[sm]

AdvaMed Advanced Medical Technology Association

American Institute for Medical and Biological Engineering

DeviceAlliance

MassMEDIC

MDMA Medical Device Manufacturers Association

Medical Device Summit

MICHBIO

MPO Medical Product Outsourcing

MD Medical Design.com

ODT Orthopedic Design & Technology

onemedplace

QSMA

STANFORD biodesign

eZASSI

Survey partner: ReadexResearch Experienced. Trusted. Insightful.

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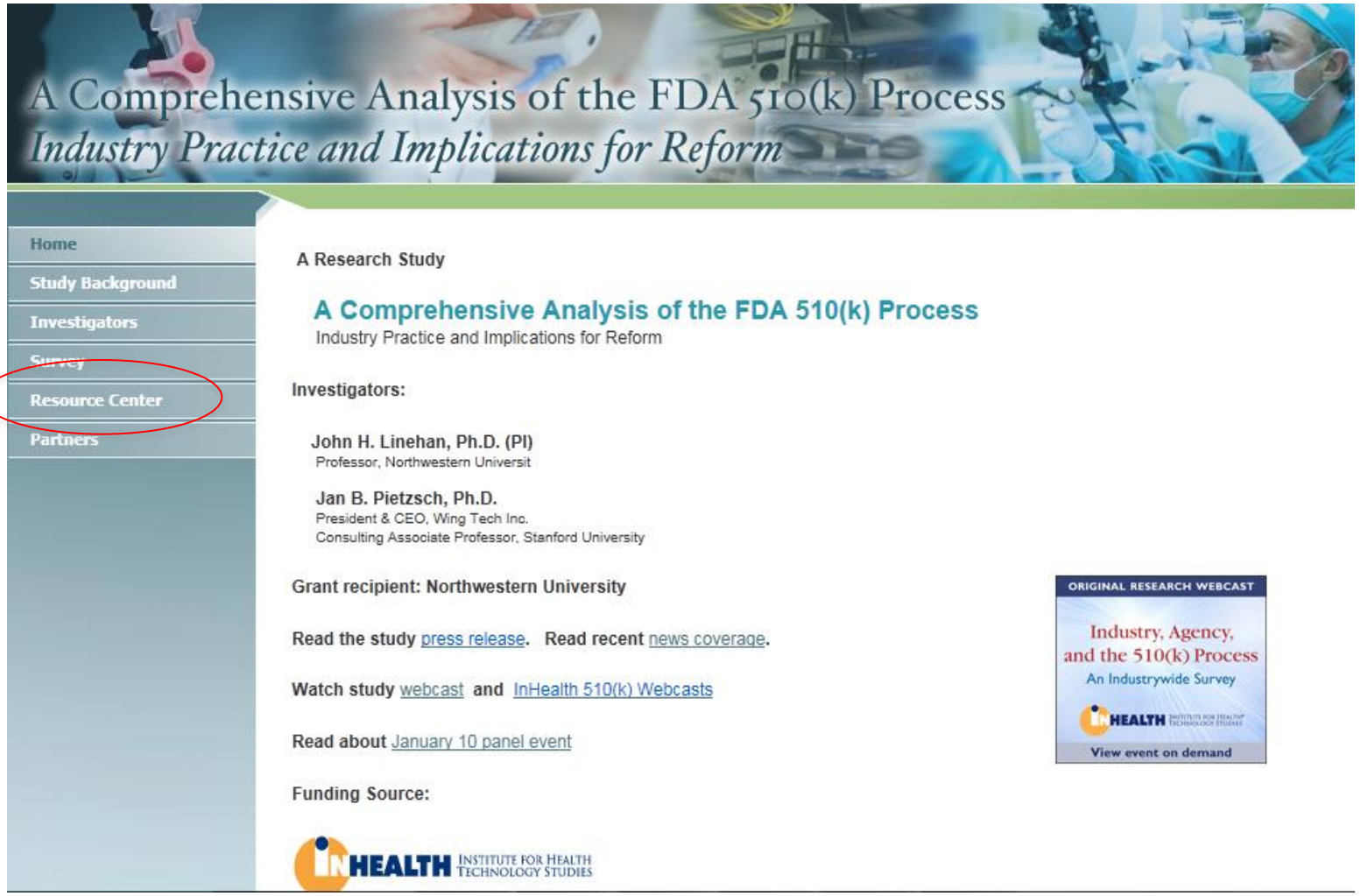
Study website @ www.510k.net



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Resource Center @ www.510k.net

- 510(k) Basics
- FDA, Government and Medical Devices
  CDRH, ODE and OIVD documents, Medical Device User Fee and Modernization Act (MDUFMA) and US House of Representatives: Committee on Energy and Commerce
- FDA Guidance Documents relating to 510(k) regulatory process
- Workshops & Conferences - Webinars, TownHall and Public mtgs
- Literature - published articles pertaining to 510(k) process
- FDA Training and Continuing Education Courses
- Institute of Medicine of the National Academies (IOM)
  Links to agendas, webcast, presentations and reports from Meetings 1, 2 and 3 relating to 510(k)
- International Regulations

Respondents' Panel

Susan Alpert, MD, PhD
Former Senior Vice President and Chief Regulatory Officer
Medtronic Inc.

Peter Barton Hutt
Senior Counsel
Covington & Burling LLP

Philip J. Phillips
President
Phillips Consulting Group LLC

Jeffrey E. Shuren, MD, JD
Director
FDA Center for Devices and Radiological Health

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