A joint session of:

LIFE SCIENCE tennessee

MEMPHIS BIO WORKS BUSINESS ASSOCIATION

Jeffrey Shuren, MD, JD

Director, Center for Devices and Radiological Health
U.S. Food and Drug Administration

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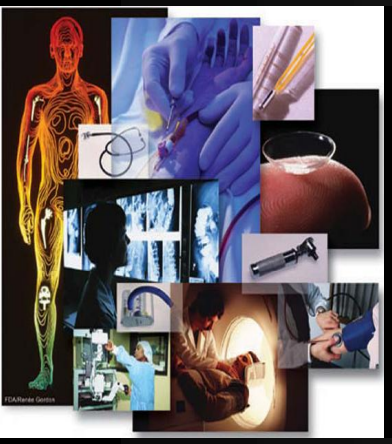
Jeffrey Shuren, MD, JD

Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration

- Previously served as Acting Center Director beginning in September 2009.
- Held various policy and planning positions within FDA including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner.
- Board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati.
- Served as Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services.
- Received B.S. and M.D. degrees from Northwestern University under its Honors Program in Medical Education and J.D. from the University of Michigan.



Tennessee Roundtable

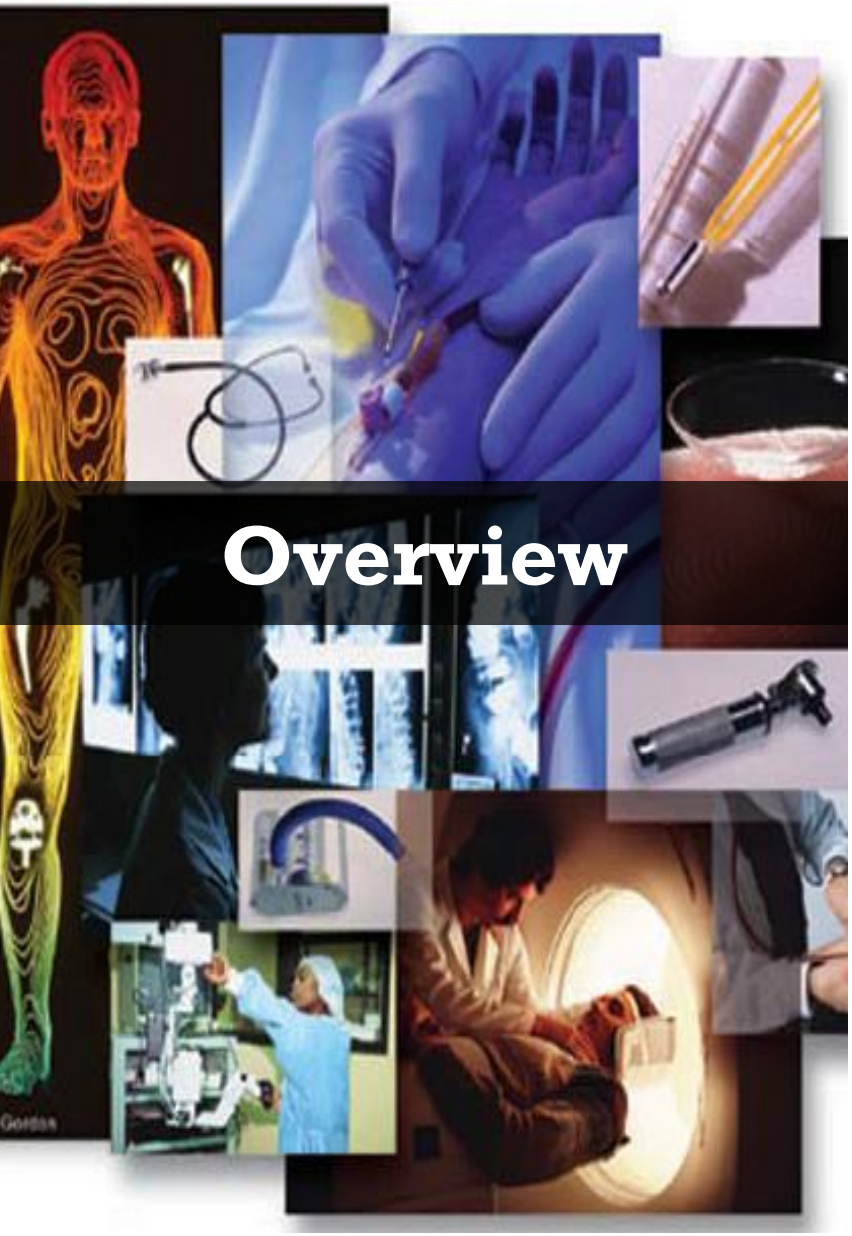
C·D·R·H
Center for Devices and Radiological Health

Jeffrey Shuren, MD, JD

Center for Devices and Radiological Health

U.S. Food and Drug Administration

June 11, 2012



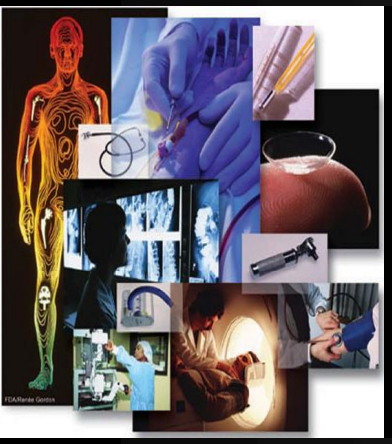
Overview

- CDRH's Vision
- Pre-Market Programs
- Innovation Pathway 2.0

Our Vision

- **Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.**
- **The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.**
- **U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance.**
- **Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.**
- **Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.**

FDA



Pre-Market Programs

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Past Actions

- **2010 510(k) and Use of Science Working Group Reports:**

  http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm220784.pdf

  http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm220783.pdf

- **2011 Plan of Action to Improve Pre-Market Programs:**

  http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm239450.pdf

Past Actions

- **Overview Report:**

  http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm276272.htm

- **Accomplishments:**

  http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm276286.htm

- **Innovation Initiative**

  http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm242067.htm

Recent Actions

- **Benefit-Risk Determination Final Guidance**
- **Appeals Draft Guidance**
- **Triage Program**
- **Experiential Learning Program**
- **On Deck:**
  - Pre-Submission Interactions Draft Guidance
  - Standards Draft Guidance
  - MDUFA III Implementation

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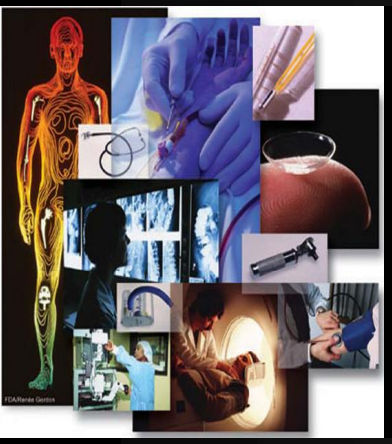

510(k)s

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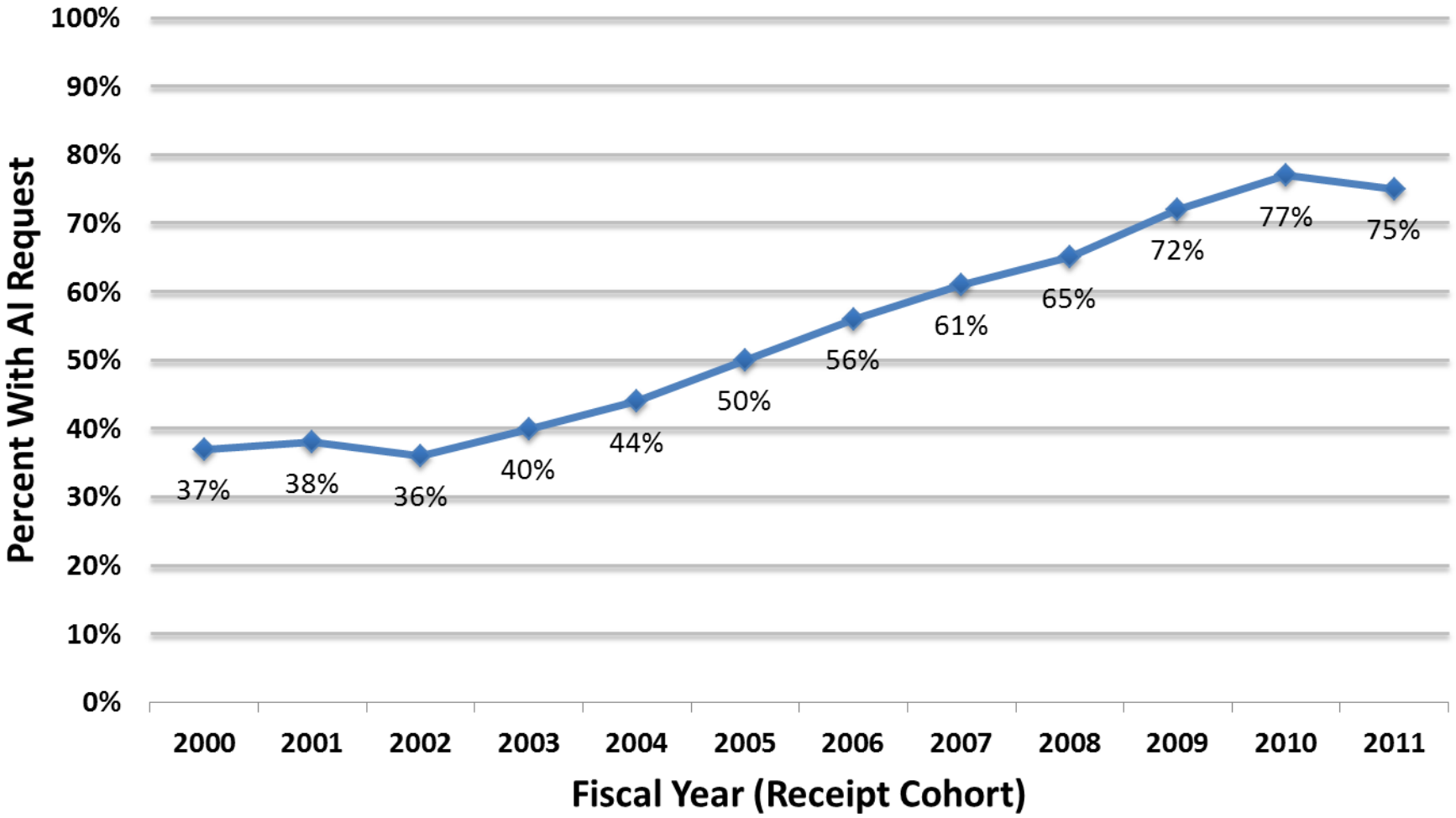
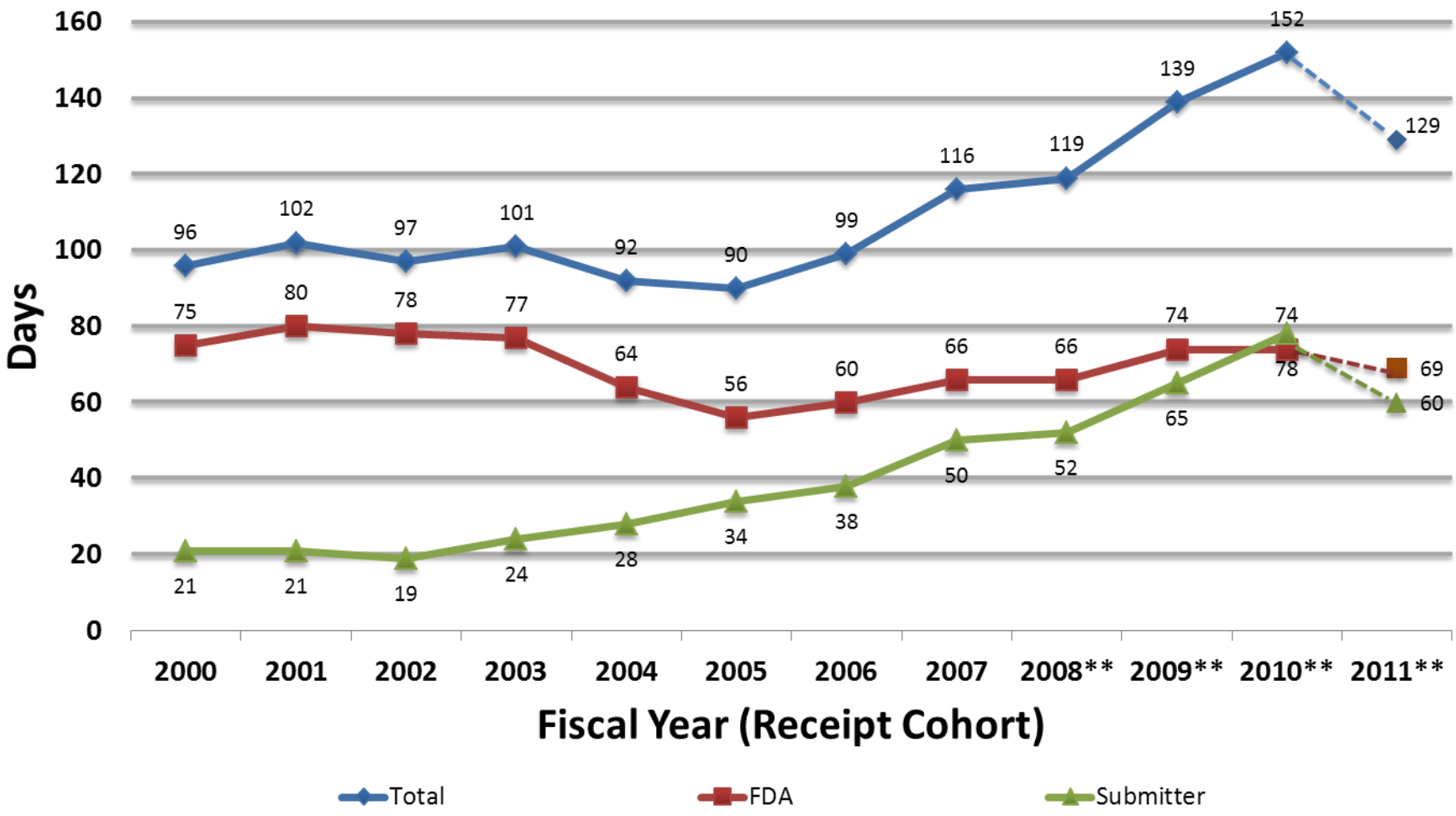
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



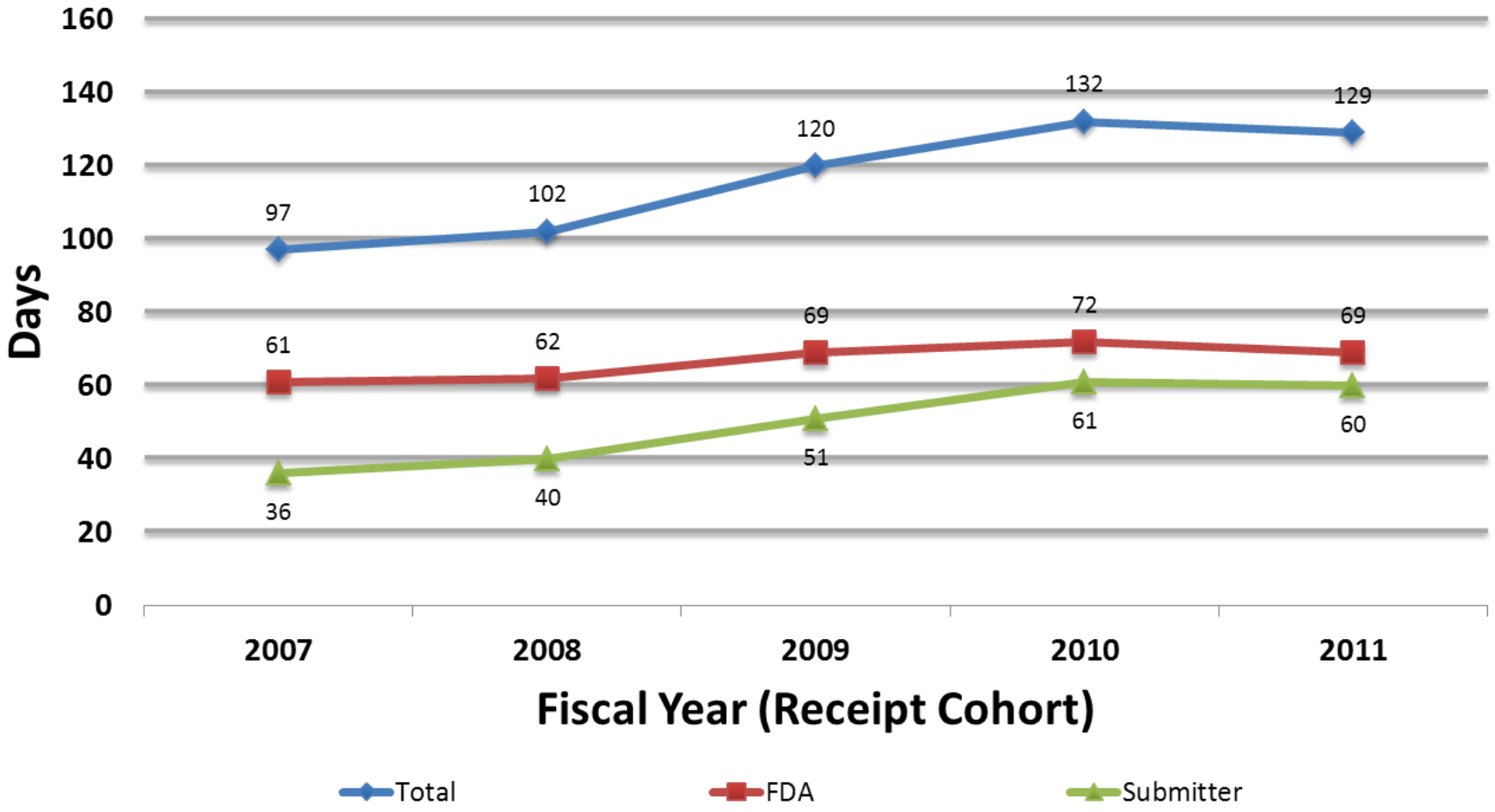
Average Time to Decision: 510(k)s*
(Receipt Cohorts as of April 30, 2012)



*SE and NSE decisions only; times may not add to total due to rounding

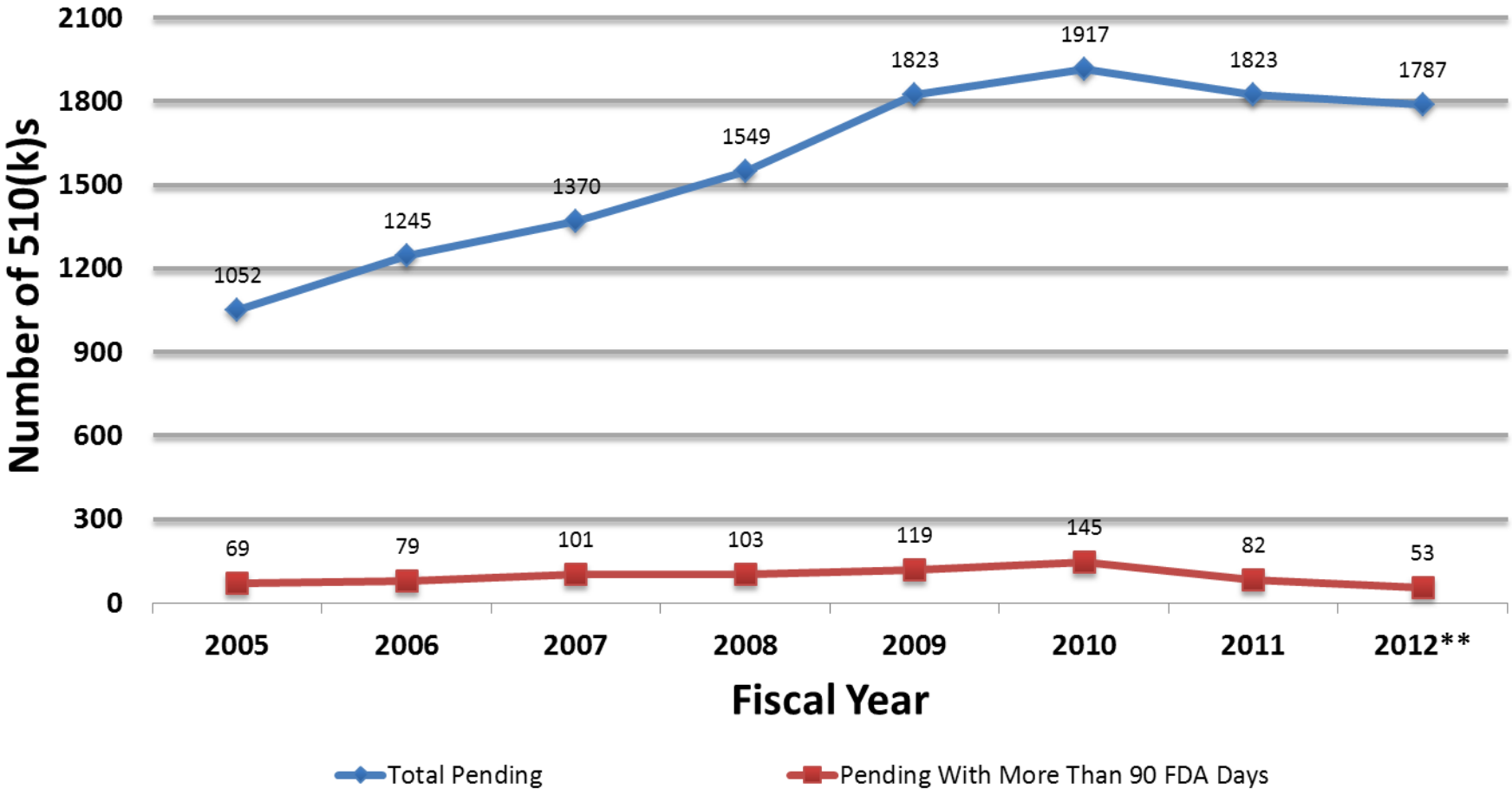
**Cohorts still open; FY 2011 cohort is only 91% closed and average times will increase

Average Time to Decision: 510(k)s*
- Comparison of Receipt Cohorts When 91% Closed -



*SE and NSE decisions only; times may not add to total due to rounding

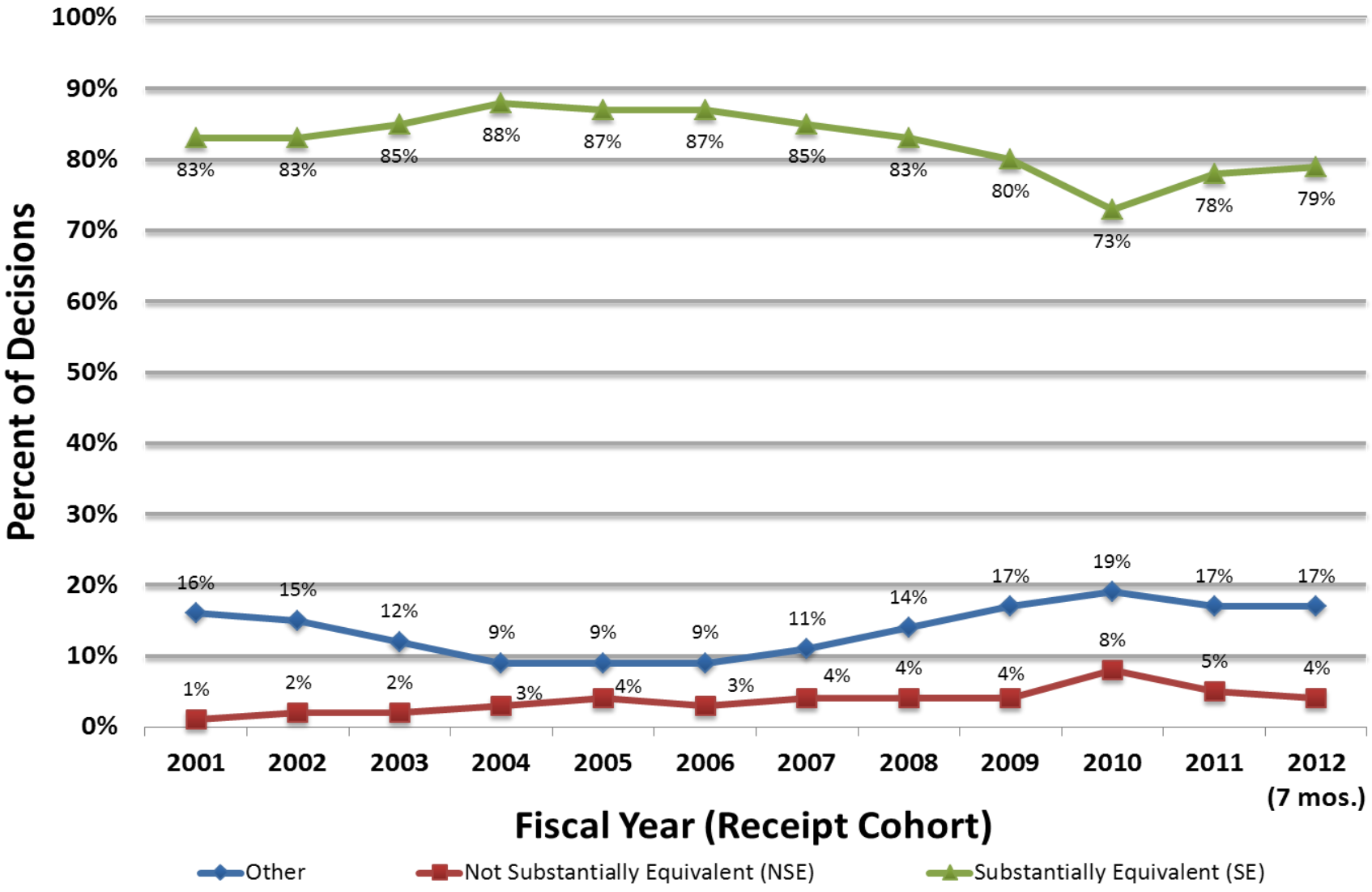
510(k)s Pending* at End of Year



*Under review or on hold

**FY 2012 is as of April 30, 2012

Percent of 510(k)s Determined to be Substantially Equivalent (SE)



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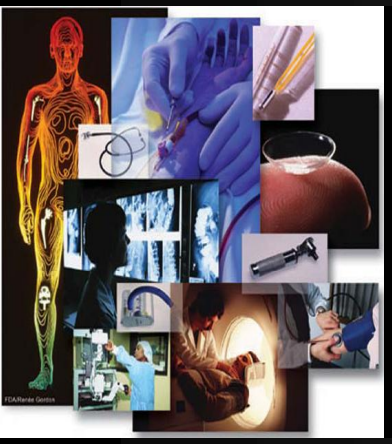

PMAs

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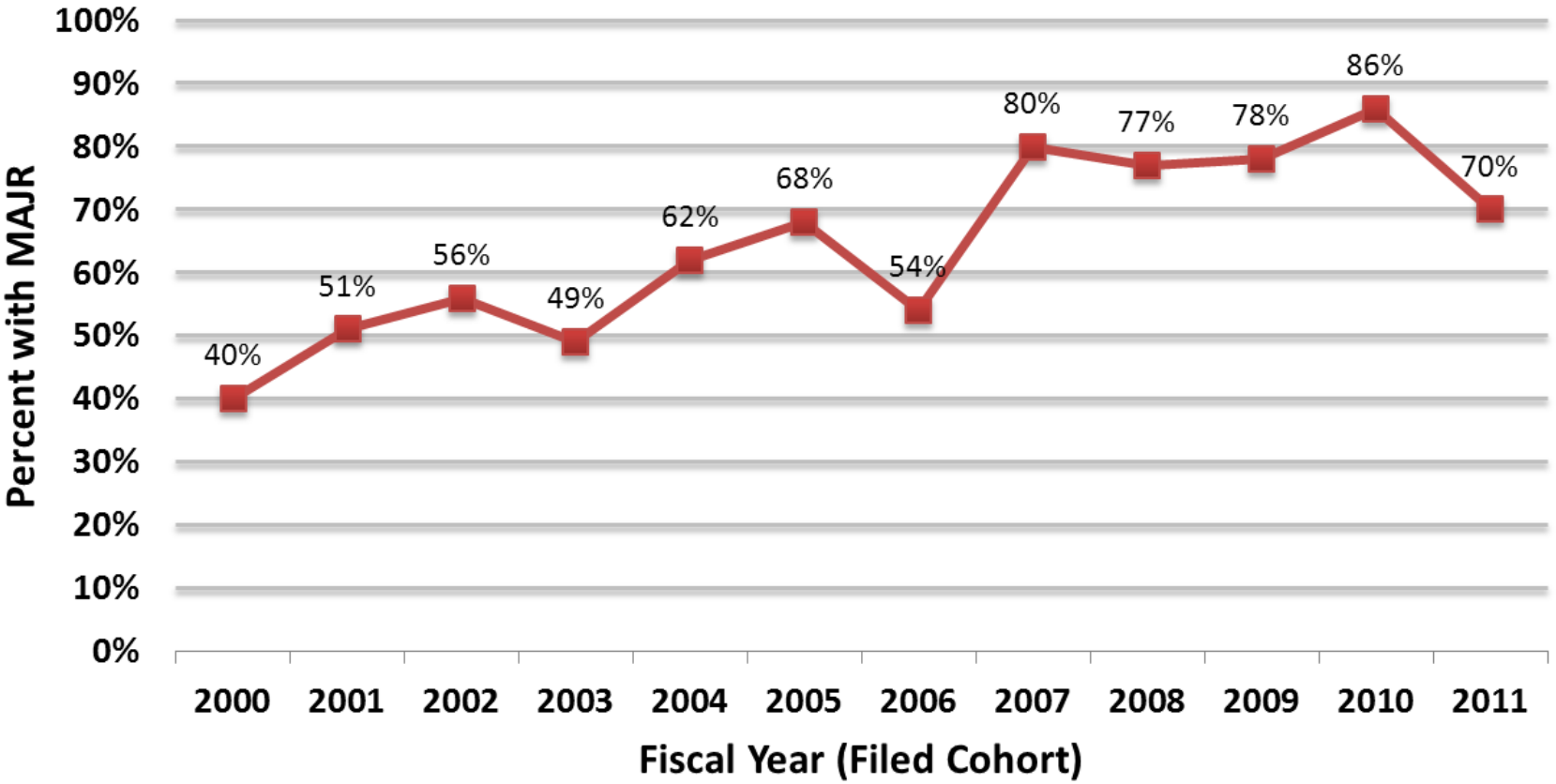
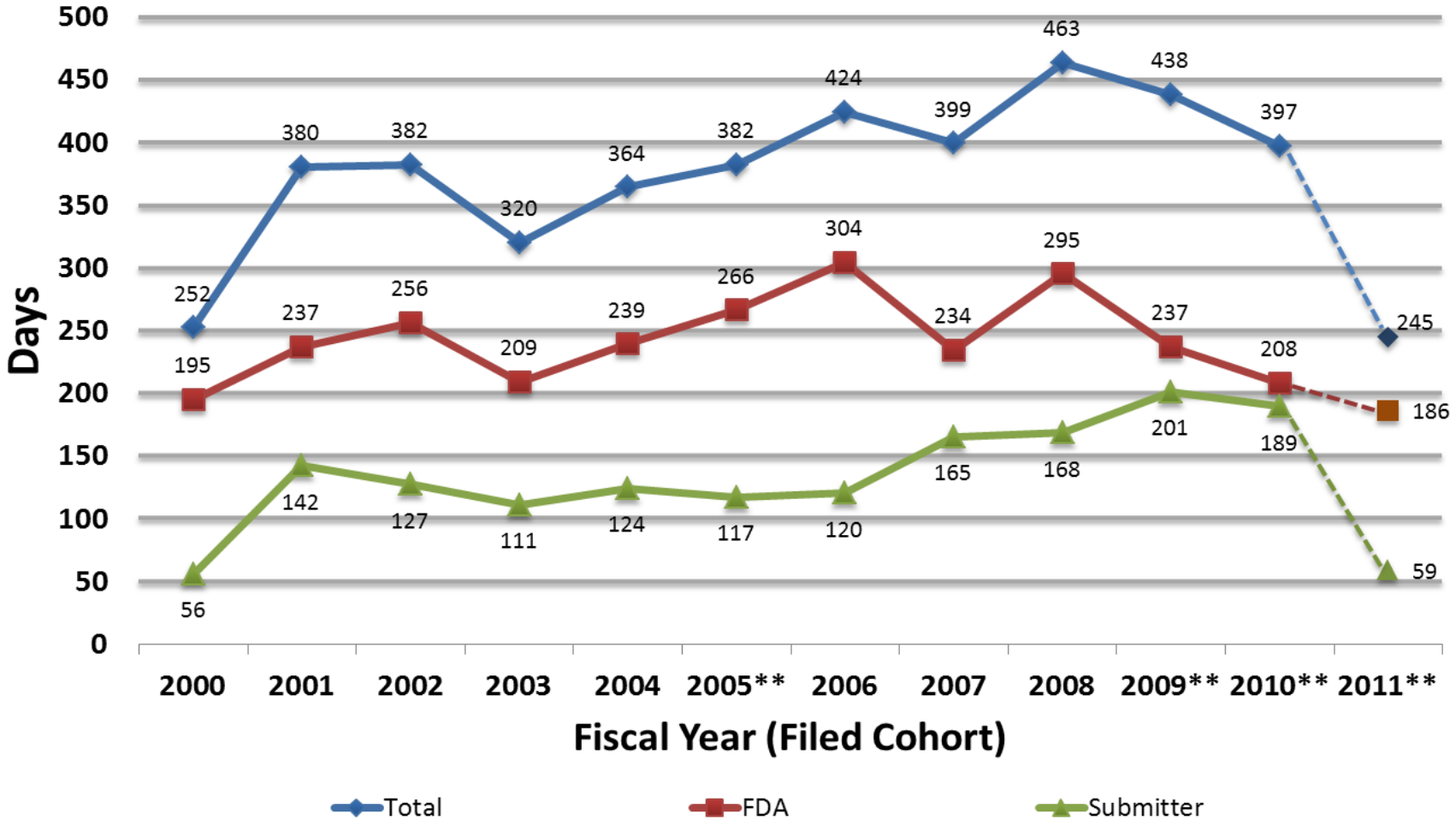
Percent of PMAs With Major Deficiency Letter (MAJR) on 1st FDA Review Cycle*



*Includes all filed original PMAs (1st cycle completed for all cohorts)

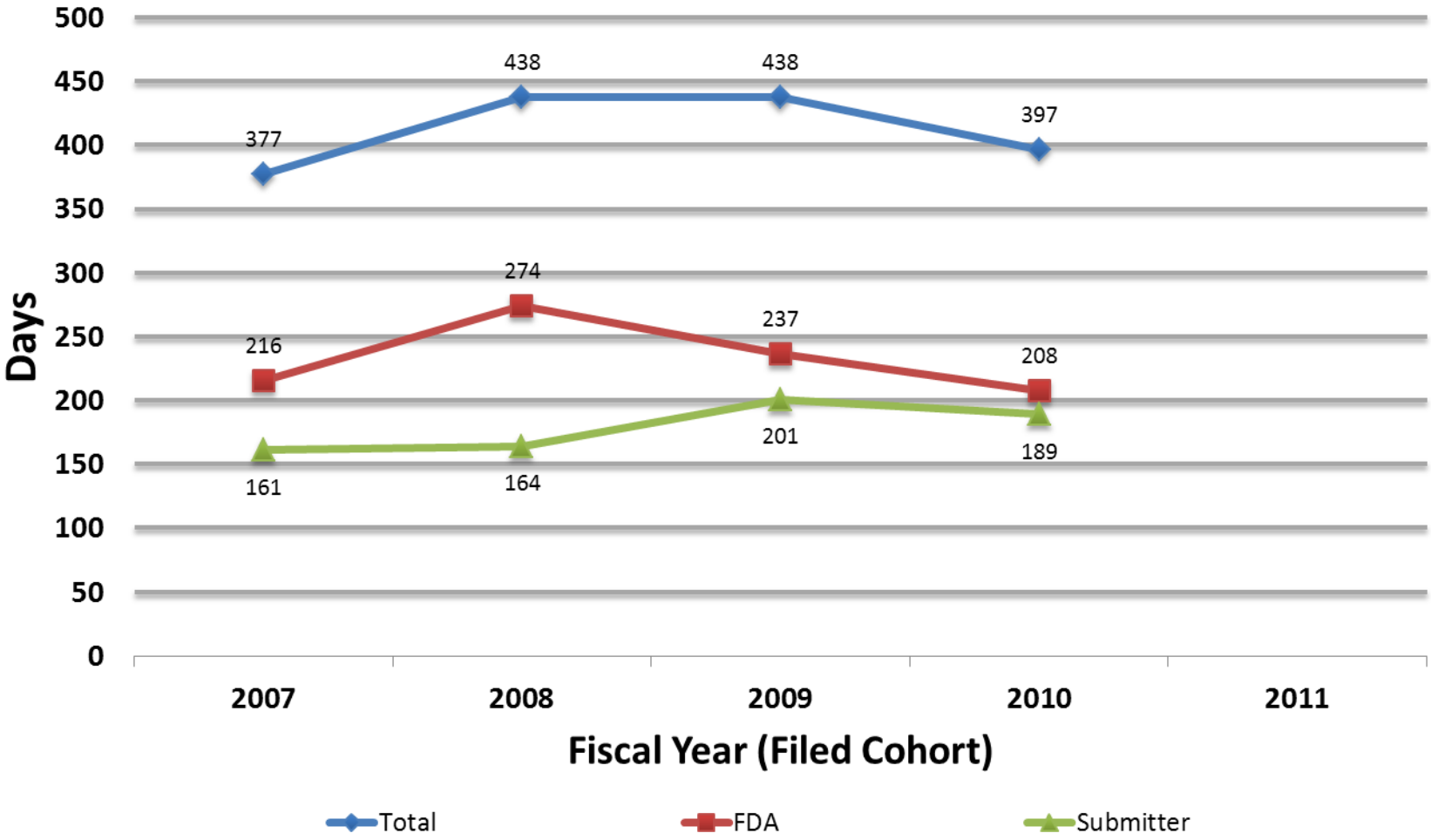
Average Time to MDUFA Decision: PMAs*
(Filed Cohorts as of May 21, 2012)



*Includes all filed original PMAs; times may not add to total due to rounding

**Cohorts still open, average times will increase; percent of cohort with MDUFA decision: FY05 = 98% (46/47); FY09 = 97% (31/32); FY10 = 98% (42/43); FY11 = 74% (32/43)

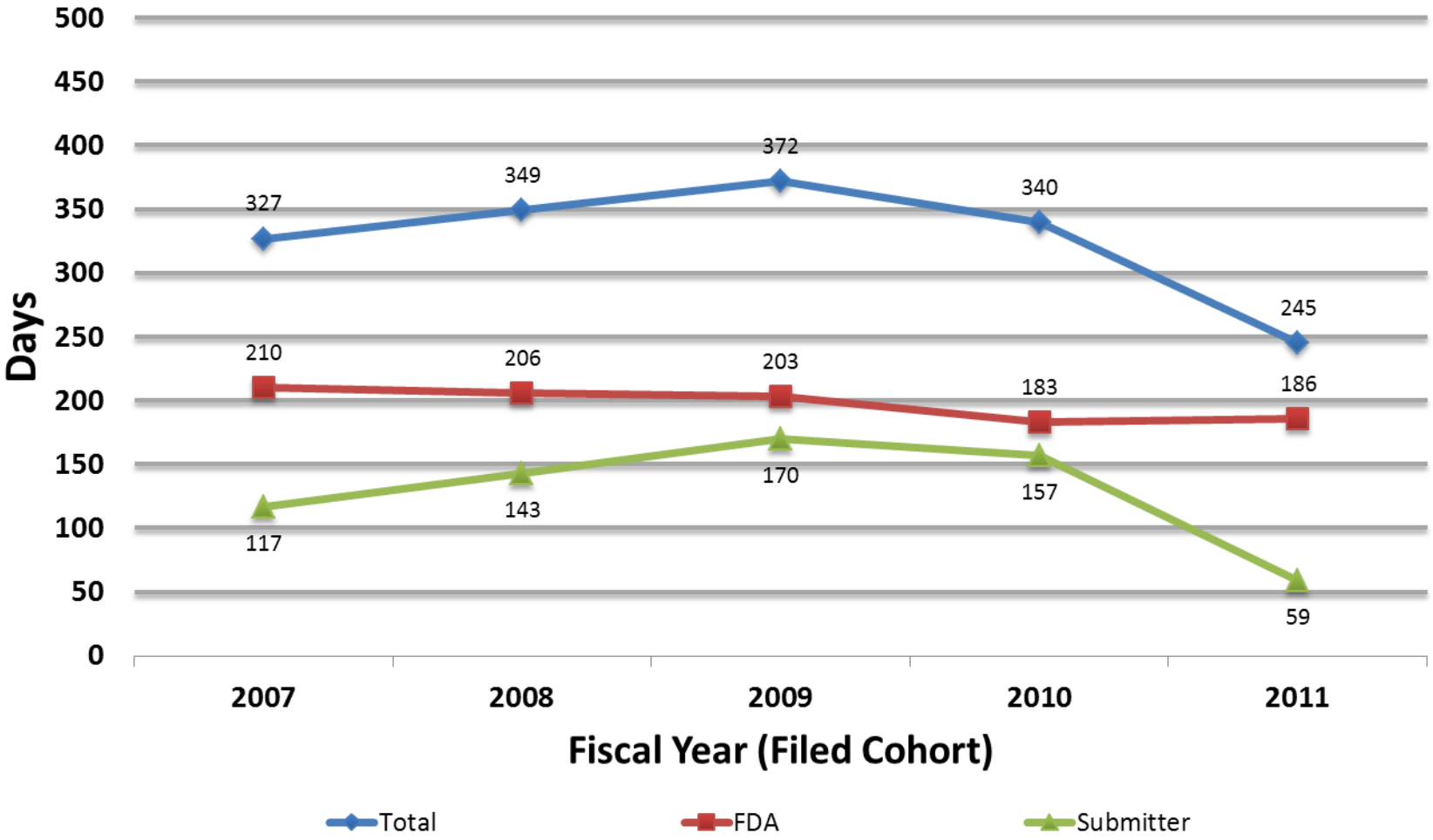
Average Time to MDUFA Decision: PMAs*
- Comparison of Filed Cohorts When Approx. 98% Closed** -



*Includes all filed original PMAs; times may not add to total due to rounding

**Proportion of cohort closed (MDUFA decision): FY07 = 34/35; FY08 = 29/30; FY09 = 31/32; FY10 = 42/43; FY11 = (not yet 98%)

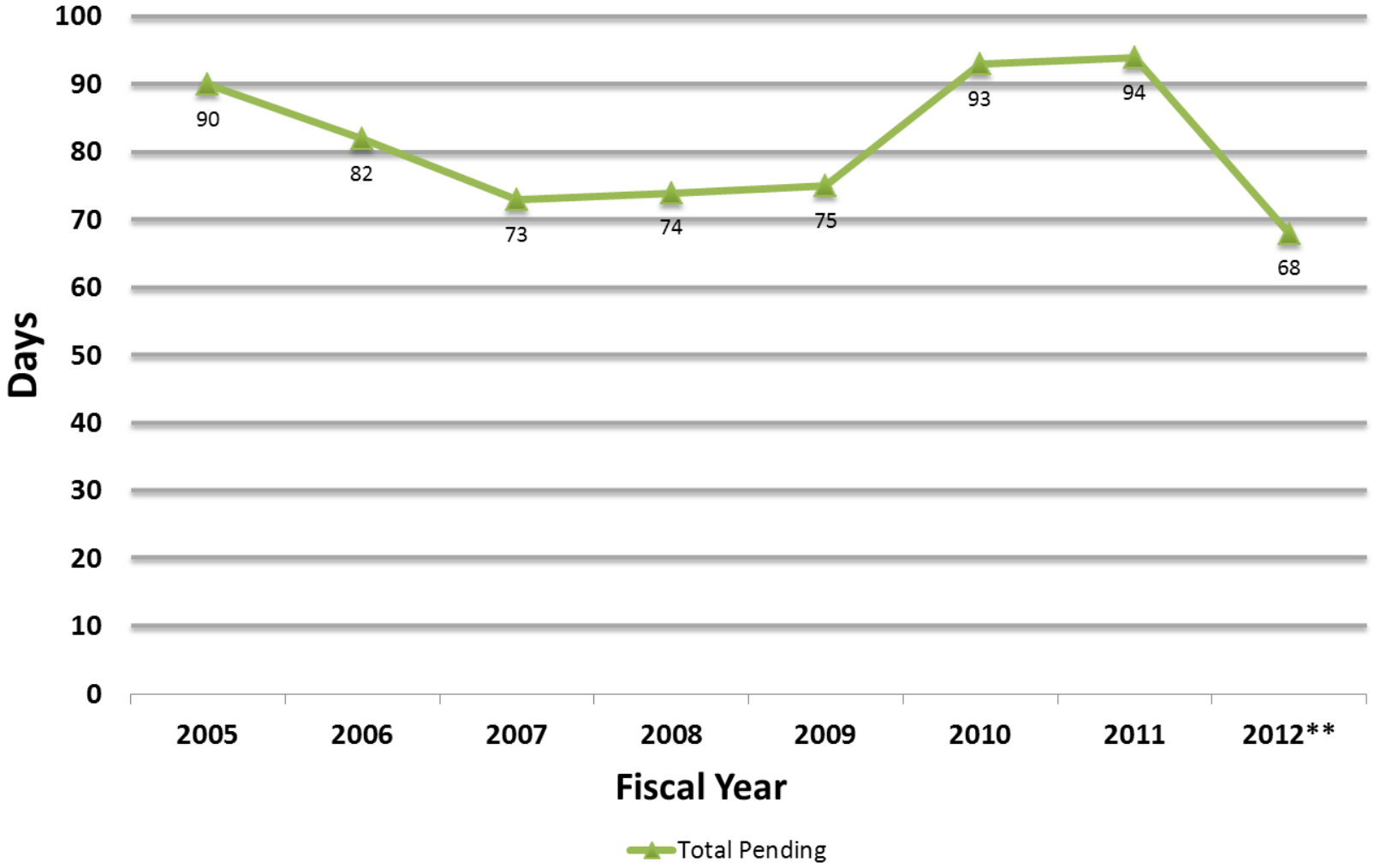
Average Time to MDUFA Decision: PMAs*
- Comparison of Filed Cohorts When Approx. 74% Closed** -



*Includes all filed original PMAs; times may not add to total due to rounding

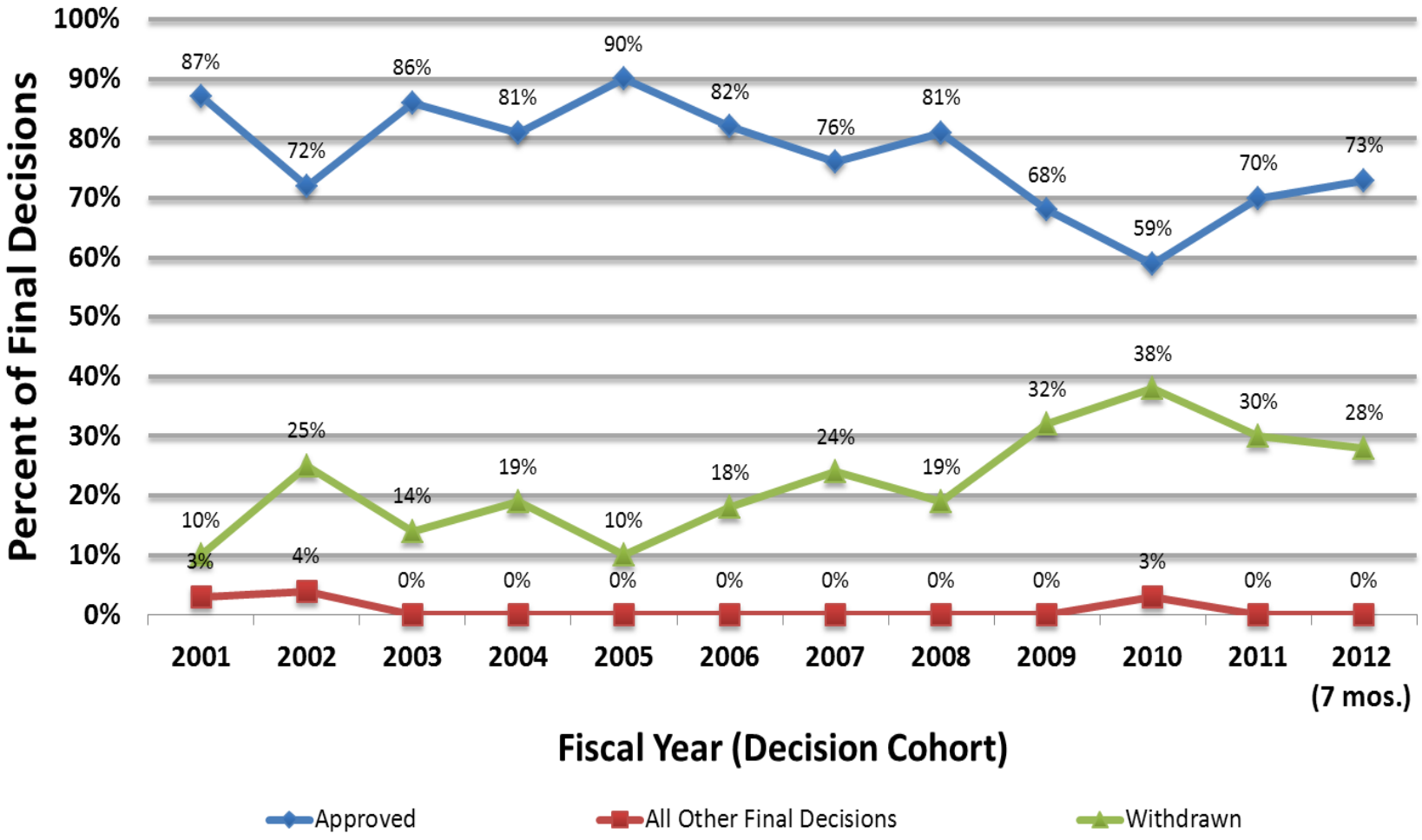
**Proportion of cohort closed (MDUFA decision):FY07 = 26/35; FY08 = 22/30; FY09 = 24/32; FY10 = 32/43; FY11 = 32/43

PMAs Pending* at End of Year



*All original PMAs under review or on hold
**FY 2012 is as of May 21, 2012

Percent of PMAs Approved*



*Based on original PMAs that were accepted for filing

Innovation Pathway 2.0

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/default.htm

Innovation Pathway 2.0

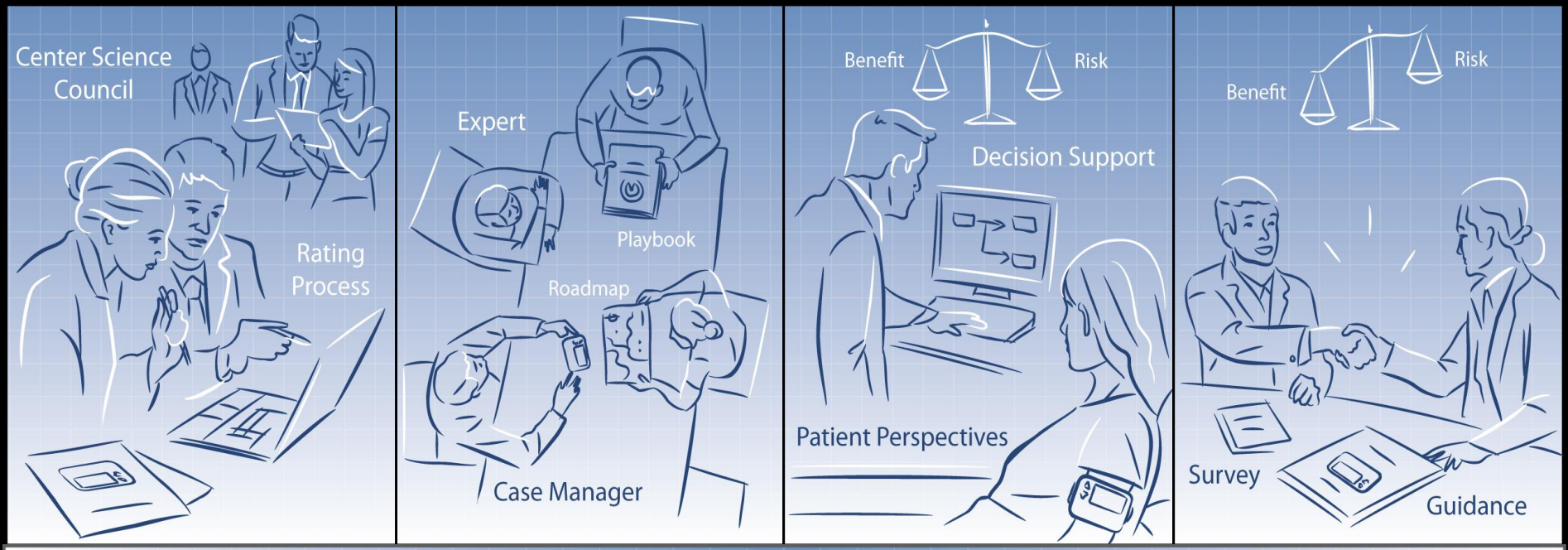
Shorten the time and cost to market for innovative (and other) medical devices

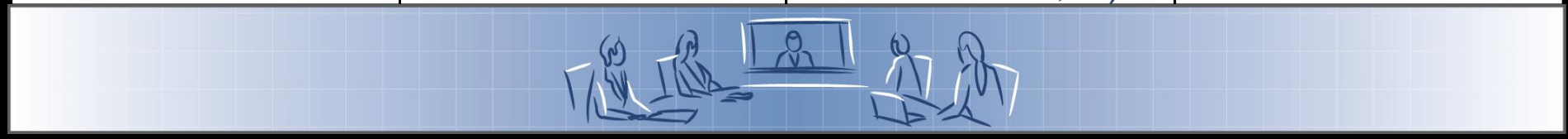
Transform how FDA and innovators work together

Innovation Pathway 2.0

Prototype
Pressure Test
Iterate

Application Process | Collaboration Phase | Clinical Trials Phase | Market Approval





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  - Over 50 Medical device and Radiological Health modules
  - Video and PowerPoint presentations available 24/7
  - Certificate of completion upon passing post-tests
  - Many modules are translated into Chinese and Spanish
  - http://www.fda.gov/Training/CDRHLearn/

- **Device Advice – Online Regulatory Information**
  - Searchable by topic
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/

- **Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) – Live Regulatory Assistance**
  - Technical Assistance for the Medical Device Industry
  - Available 8:00 am – 5:00 pm EST
  - 800-638-2041 or 301-796-7100
  - DSMICA@fda.hhs.gov


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