



# Office of Scientific Investigations



## Metrics

[Updated: January 2014 ]

## OSI Metrics Overview

- These slides provide annual inspection metrics for the compliance programs overseen by the Office of Scientific Investigations, or OSI (formerly the Division of Scientific Investigations, or DSI) in FDA's Center for Drug Evaluation and Research (CDER). The vast majority of these inspections are conducted by FDA's Office of Regulatory Affairs (ORA).
- As FDA's approval decisions are based on a review of the data submitted to the agency by an applicant, it is essential for the agency to ensure the integrity of the data submitted and to verify that the rights, health and welfare of those who participated in the studies were protected and that applicants continue to meet their obligations (e.g., for safety reporting) after approval.
- On-site inspection is one of many tools the FDA has for ensuring the integrity of data, the health and welfare of research participants, and the protection of public health.



## OSI Bioresearch Monitoring Metrics Overview

- Data source:
  - Information was extracted from OSI's databases and other sources as noted.
- Data conventions
  - OSI metrics are based on key events during the inspection process, including starting an inspection, issuing an inspection assignment, or issuing post-inspectional correspondence to the inspected party.
  - Differences in inspection counts when comparing data across varying sources (e.g. The Office of Regulatory Affairs' (ORA) FACTS database) may be the result of different tallying methods of inspection-related data.
- Changes from prior versions
  - Footnotes in individual slides indicate where significant changes from previous versions have occurred. These changes are due to improvements to OSI's database and associated processes.

For further information, please contact [cderr-osr@fda.hhs.gov](mailto:cderr-osr@fda.hhs.gov)  
or call 301-796-3150.



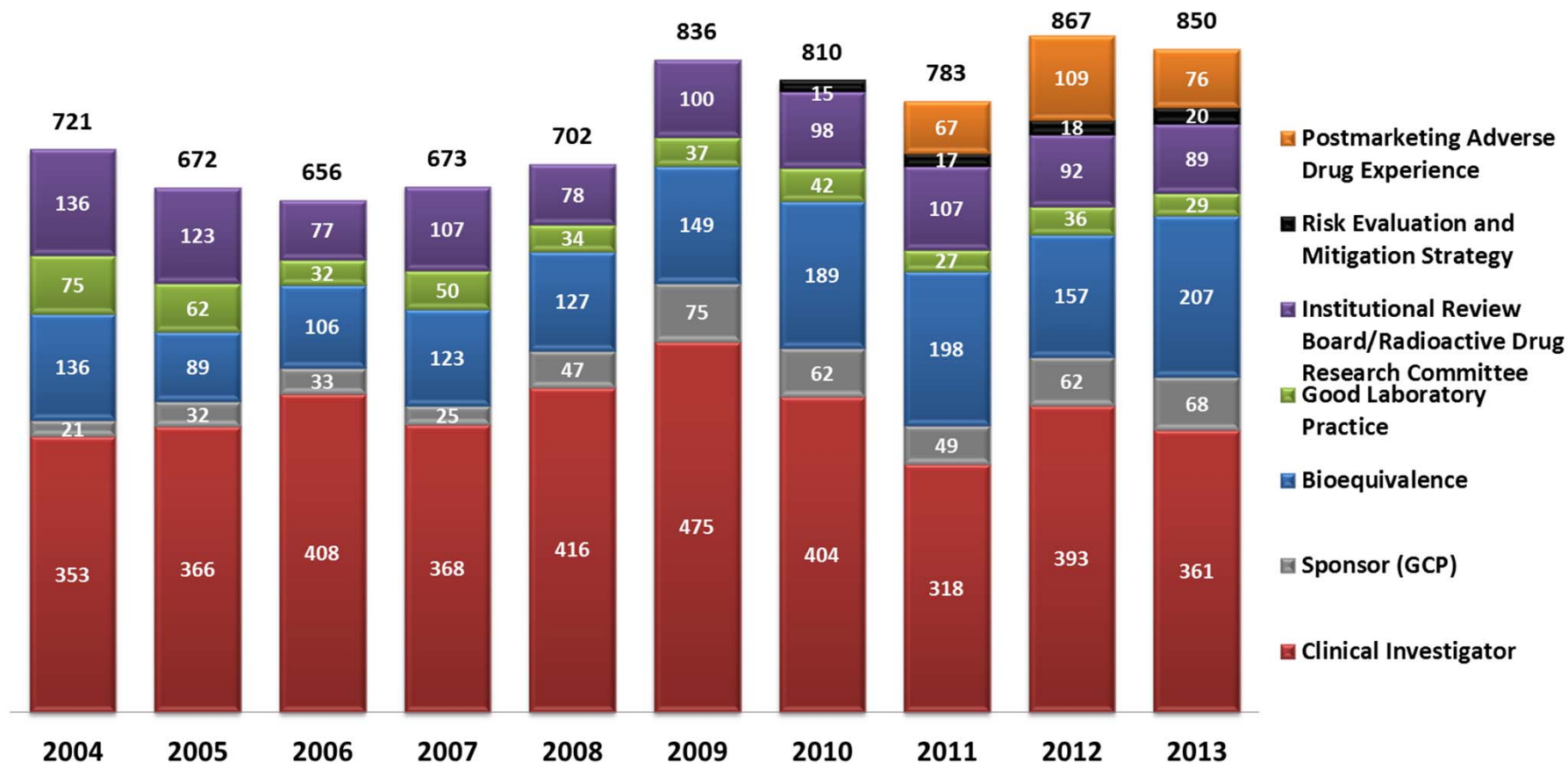
## OSI Metrics Terms

- BE or BEQ – Bioequivalence
- BIMO – Bioresearch Monitoring
- CI or Clin– Clinical Investigator
- CRO – Contract Research Organization
- GCP – Good Clinical Practice
- GLP – Good Laboratory Practice
- IRB – Institutional Review Board
- PADE – Postmarketing Adverse Drug Experience
- PMR – Postmarketing Requirements
- RDRC – Radioactive Drug Research Committee
- REMS – Risk Evaluation and Mitigation Strategy
- Sponsor – Sponsor or Sponsor-Investigator
- CDER – Center for Drug Evaluation and Research
- CBER – Center for Biologics Evaluation and Research
- CDRH – Center for Devices and Radiological Health



## Inspections Overseen by OSI\*

(CDER, FY 2004 - FY 2013)



\*Based on inspection start date – [OSI database as of January 31, 2014]

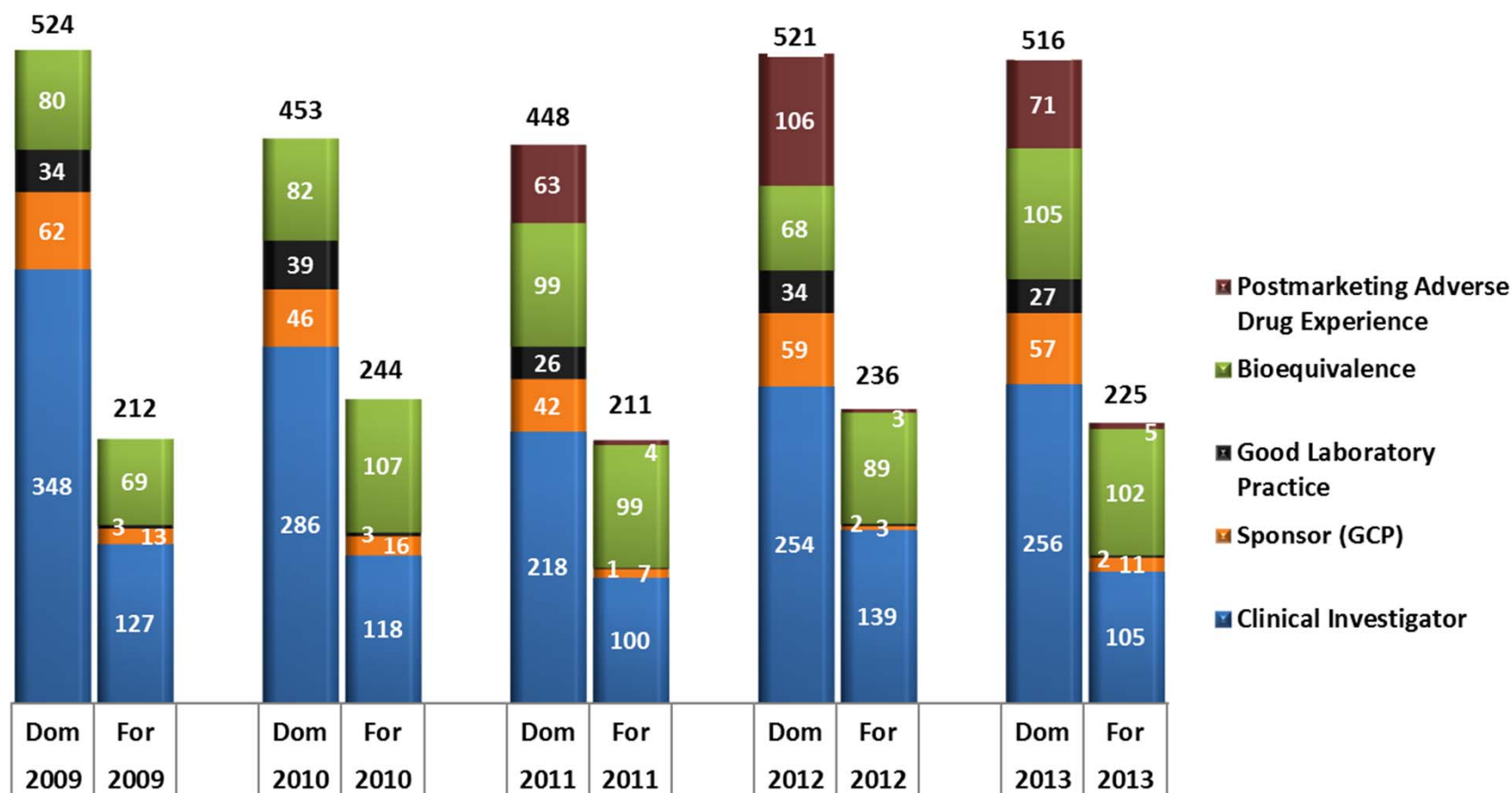
- IRB includes only CDER numbers – previously reported metrics may have used combined data across CDER, CBER and CDRH, Sponsor (GCP) includes Sponsor/CRO/Sponsor-Investigator
- Postmarketing Adverse Drug Event and Risk Evaluation and Mitigation Strategy inspection programs incorporated into OSI June 2011





## Domestic vs. Foreign Inspections Overseen by OSI\*

(CDER, FY 2009 - FY 2013)

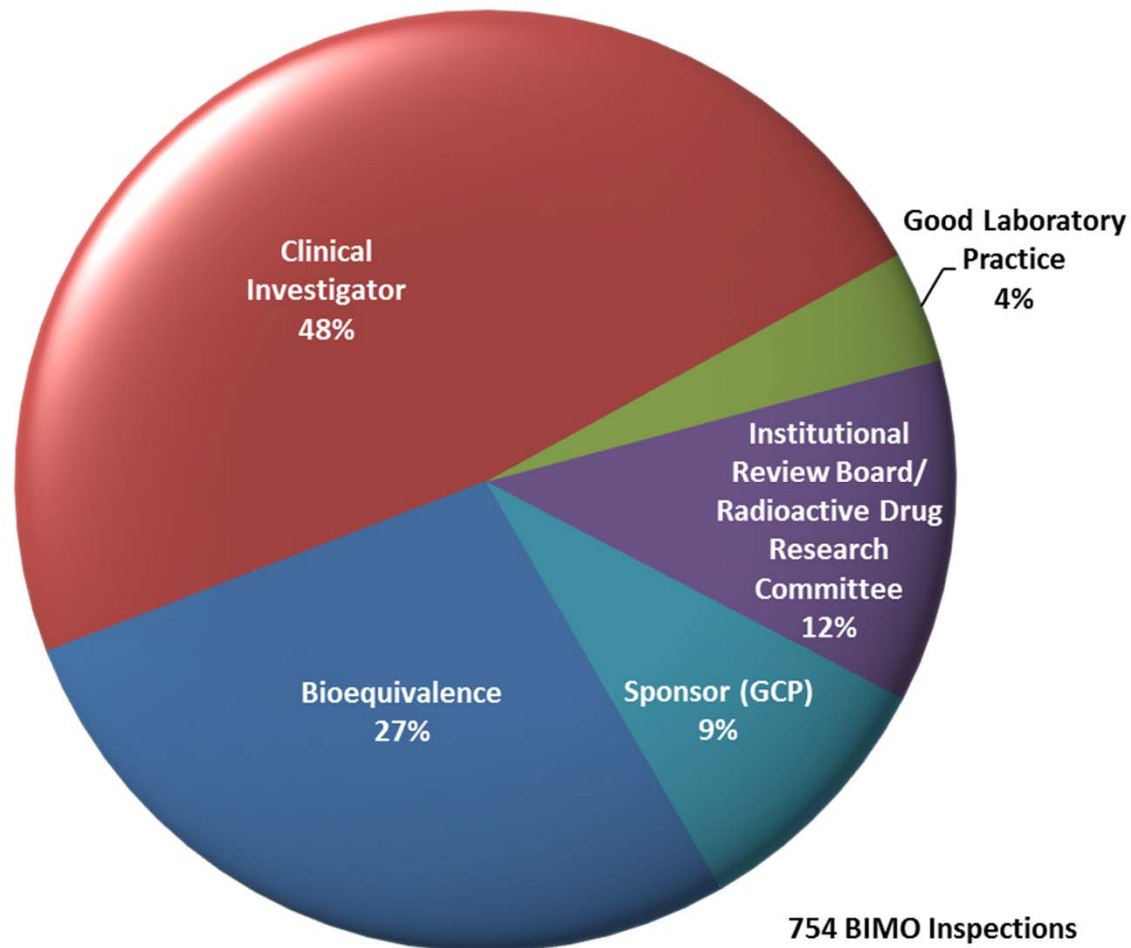


\*Based on inspection start date – [OSI database as of January 31, 2014]

- Sponsor (GCP) includes Sponsor/CRO/Sponsor-Investigator
- As of June 2011, Postmarketing Adverse Drug Event inspection programs were incorporated into OSI



## Bioresearch Monitoring Program Inspections\* (CDER, FY 2013)

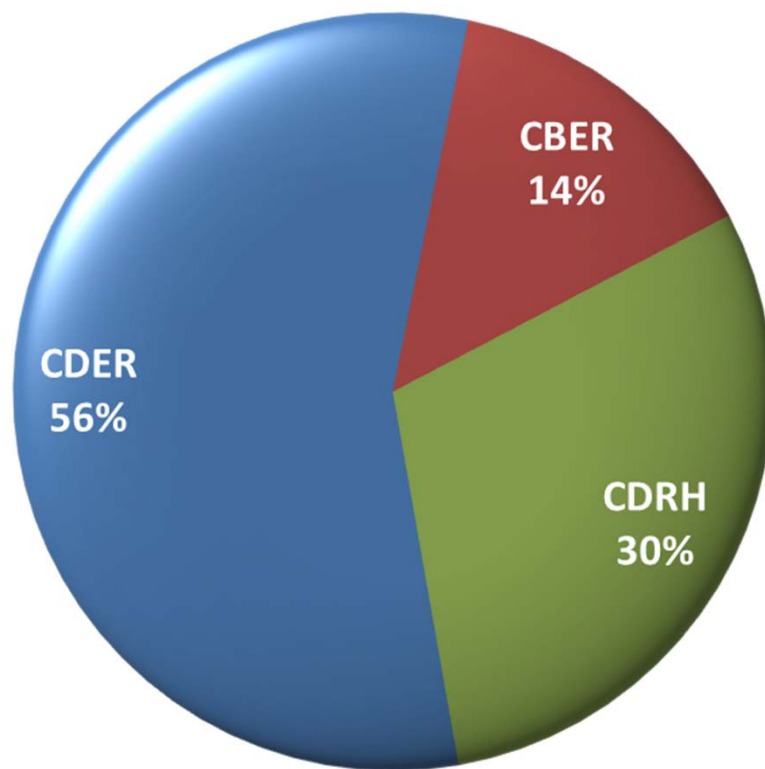


\*Based on inspection start date – [OSI database as of January 31, 2014]

- IRB includes only CDER numbers – previously reported metrics may have combined data across CDER, CBER and CDRH



## Clinical Investigator Inspections\* (All Centers, FY 2013)



CDER	361
CBER	91
<u>CDRH</u>	<u>193</u>
Total	645

\*CDER numbers based on inspection start date – [OSI database as of January 31, 2014]

• CDRH numbers based on inspection end date, CBER numbers based on end date of classified inspections

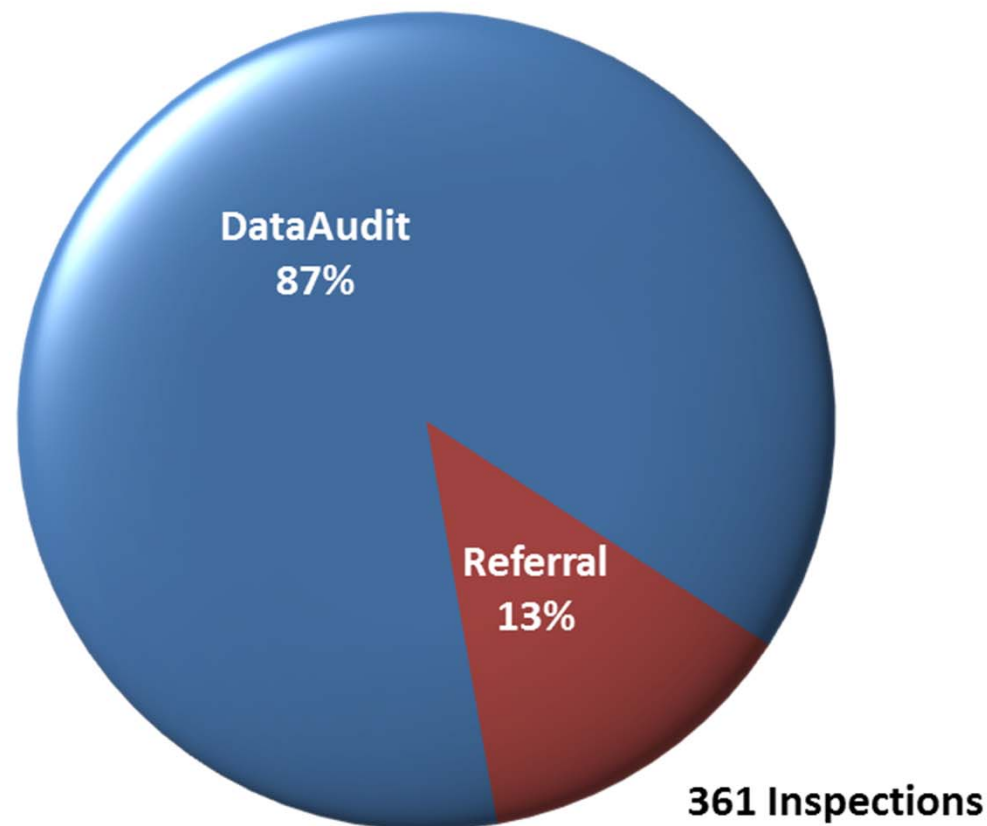
• CDER: Center for Drug Evaluation and Research. CBER: Center for Biologics Evaluation and Research. CDRH: Center for Devices and Radiological Health.





## Clinical Investigator Inspections: Data Audit versus Referral \*

(CDER, FY 2013)



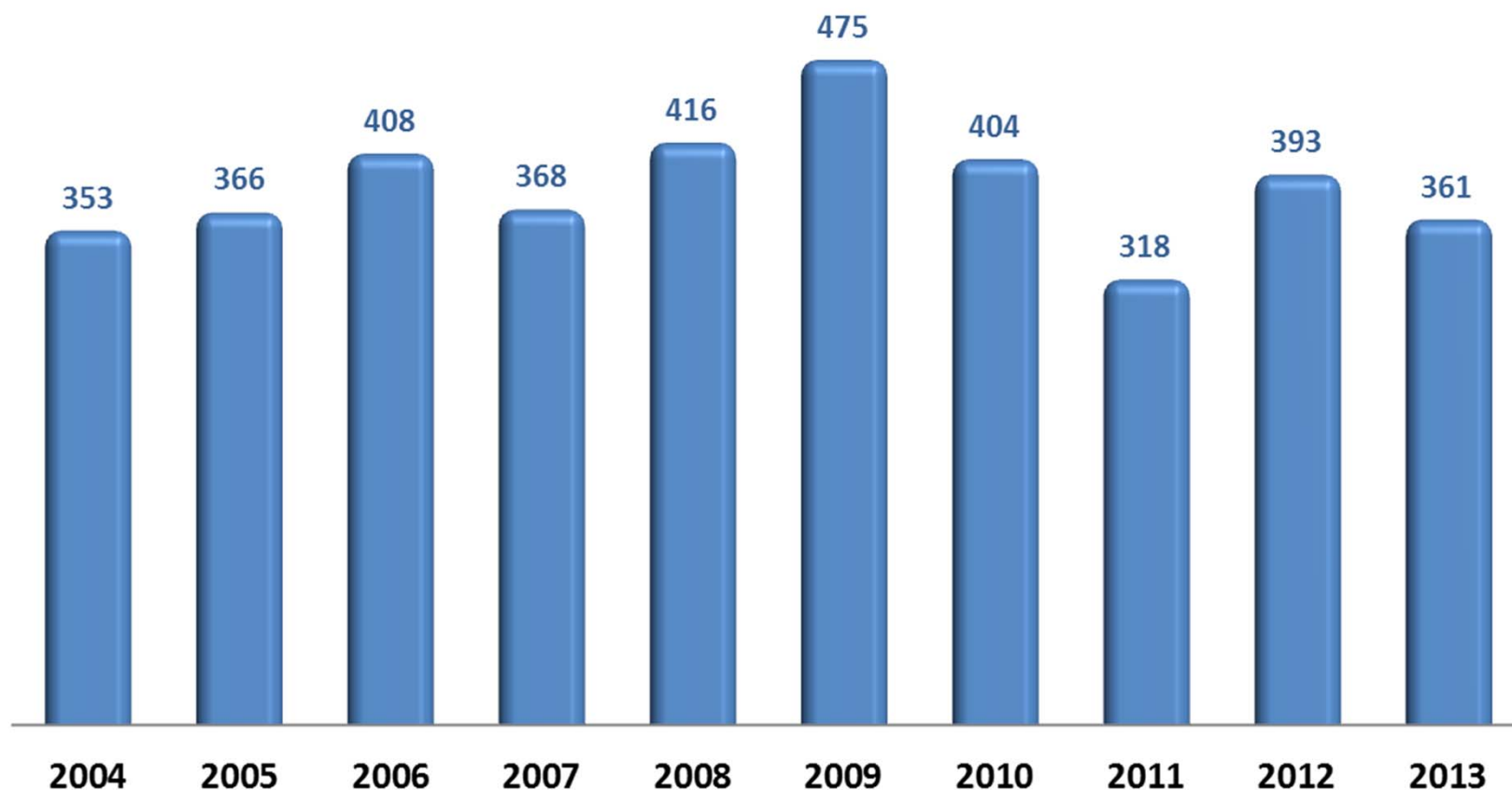
\*Based on inspection start date – [OSI database as of January 31, 2014]

- Referrals include Complaints, Required Reports, IRB/Sponsor Notifications, and other referrals-internal and external for All OSI Branches



## Clinical Investigator Inspections\*

(CDER, FY 2004 – FY 2013)

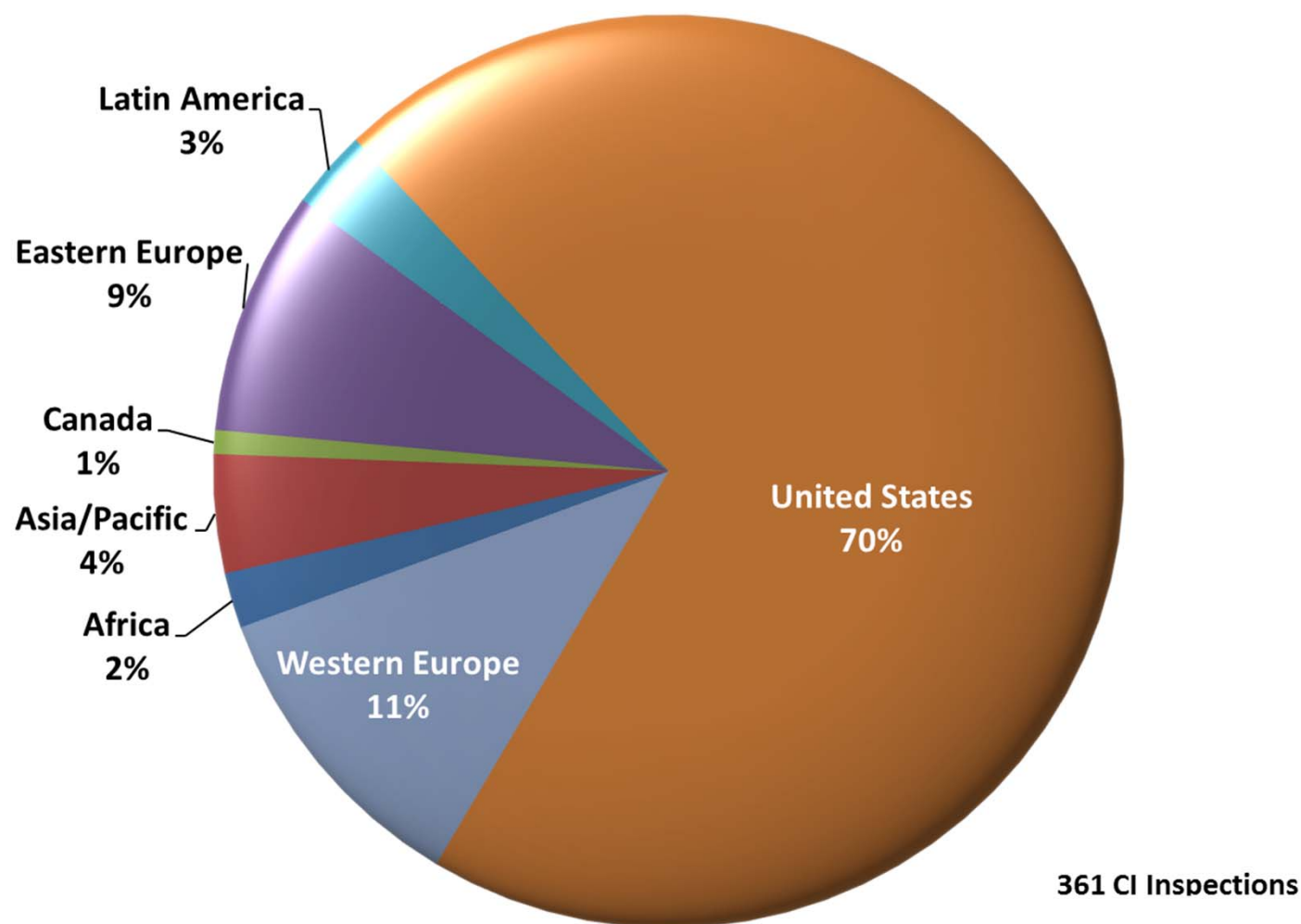


\*Based on inspection start date – [OSI database as of January 31, 2014]



## Clinical Investigator Inspections by Location\*

(CDER, FY 2013)

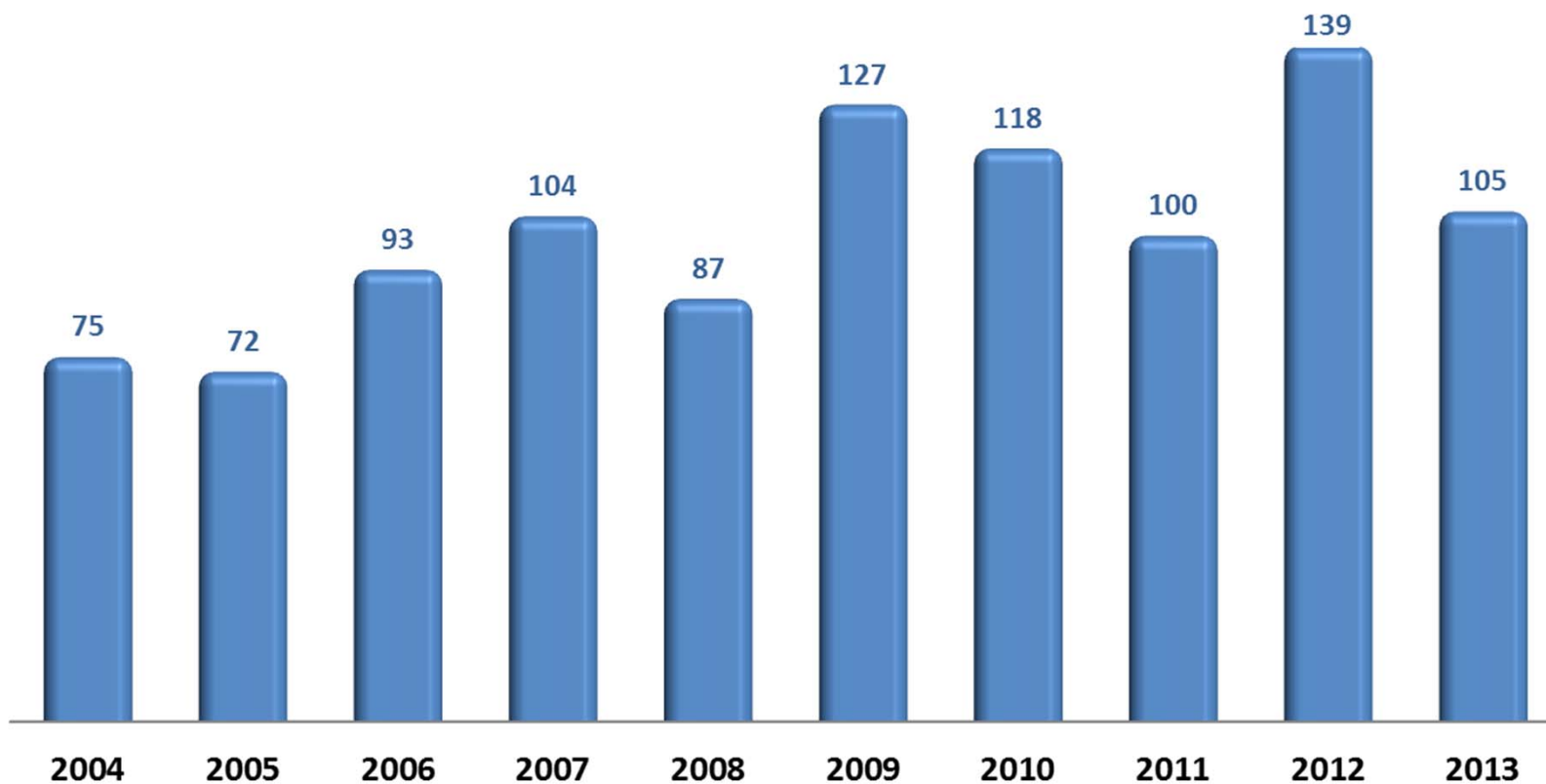


\*Based on inspection start date – [OSI database as of January 31, 2014]



## International Clinical Investigator Inspections\*

(CDER, FY 2004 - FY 2013)

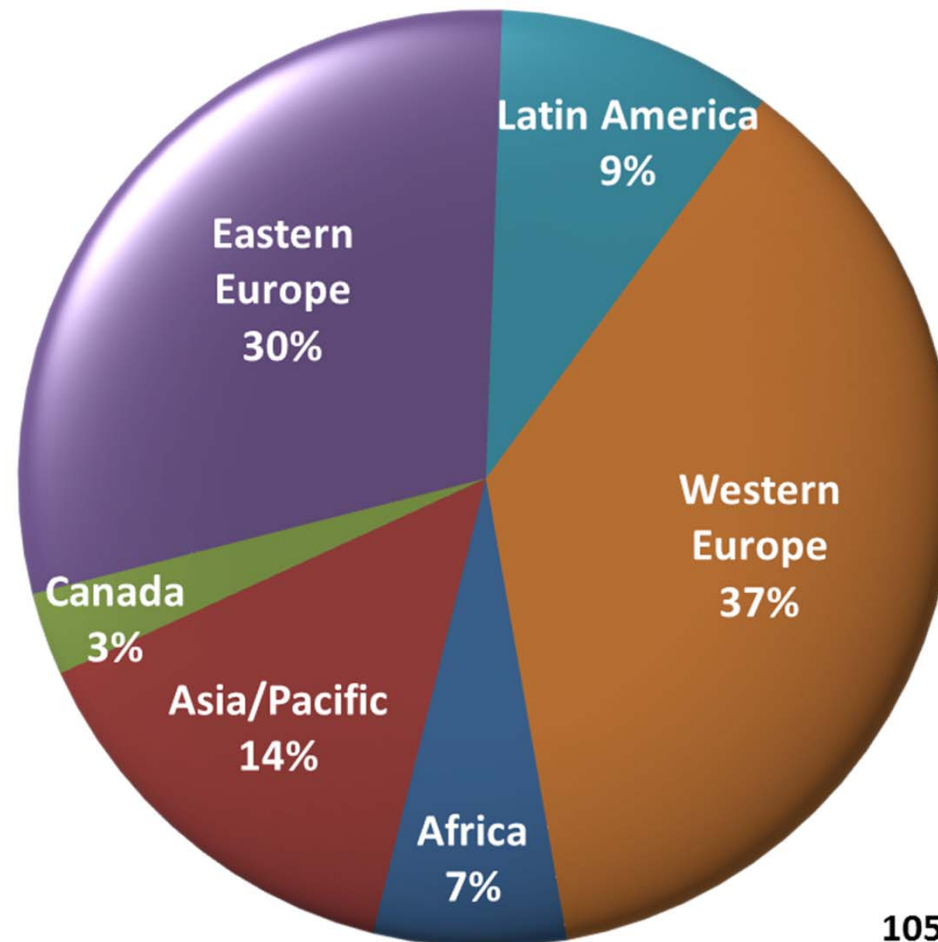


\*Based on inspection start date – [OSI database as of January 31, 2014]



## International Clinical Investigator Inspections by Location\*

(CDER, FY 2013)

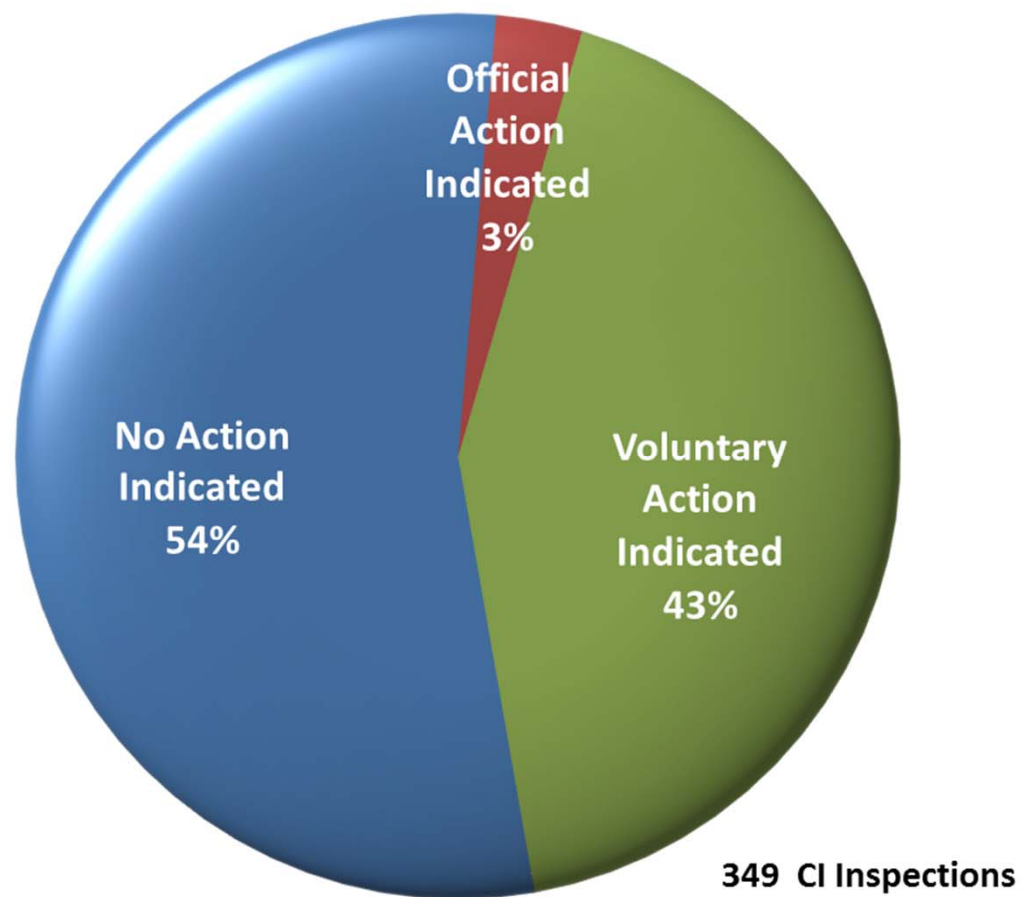


105 Inspections

\*Based on inspection start date – [OSI database as of January 31, 2014]



## Clinical Investigator Inspections Final Classification\* (FY 2013)

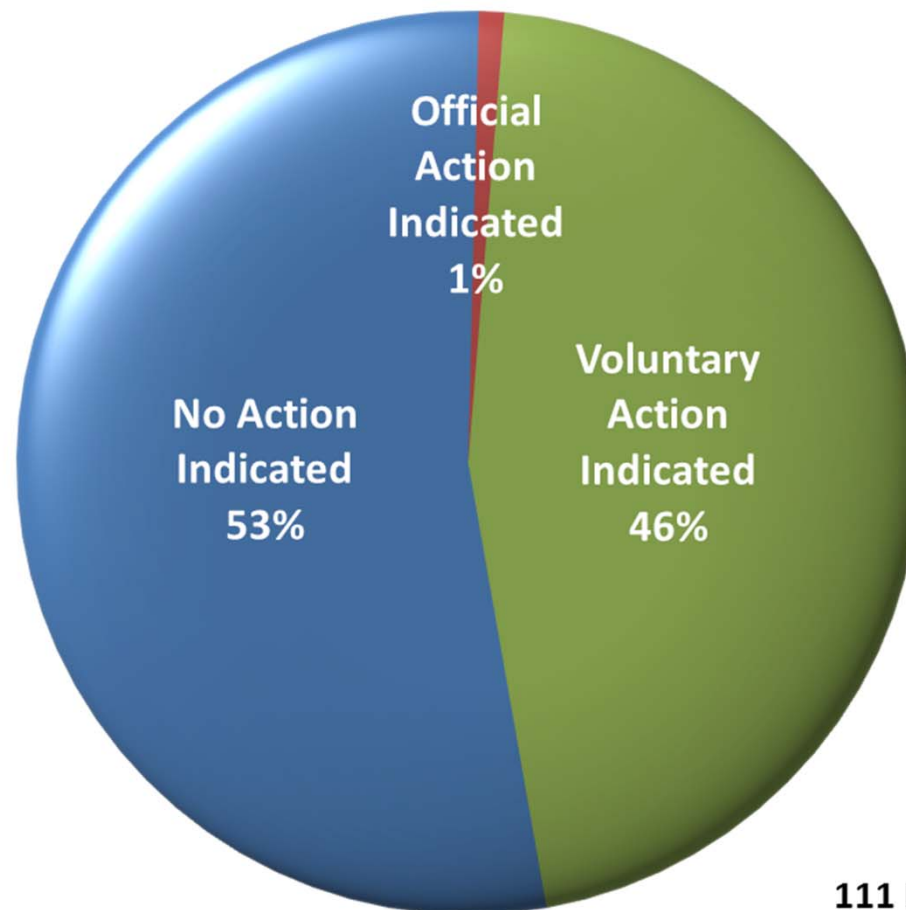


\*Based on Letter Issue date; Includes OAI Untitled Letters, [OSI database as of January 31, 2014]





## International Clinical Investigator Inspections Final Class\* (CDER, FY 2013)

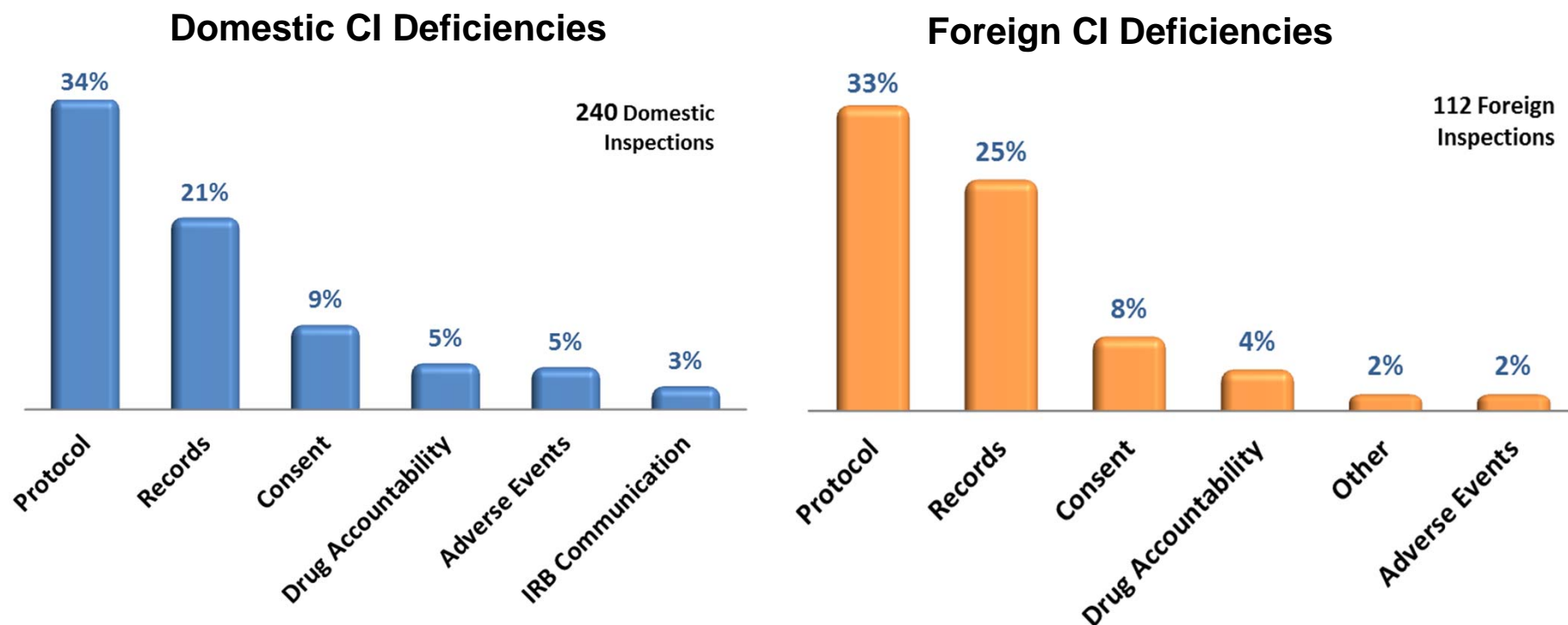


**111 Inspections**

\*Based on Letter Issue date; Includes OAI Untitled Letters, [OSI database as of January 31, 2014]



## Frequency of Clinical Investigator-Related Deficiencies Based on Post-Inspection Correspondence Issued\* (CDER, FY 2013)

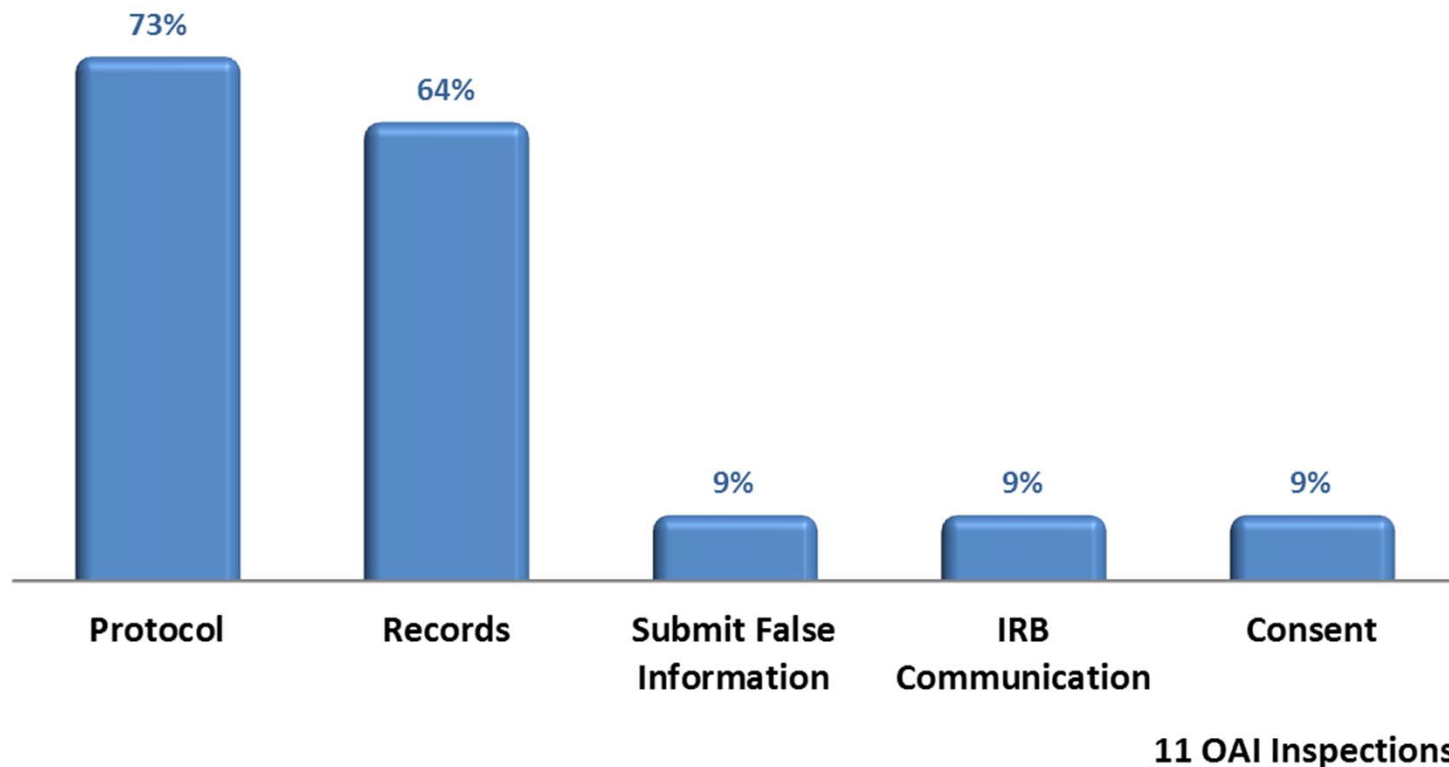


\*Based on letter issue date; Inspections may have multiple deficiencies, [OSI database as of January 31, 2014]

Note: this does not denote number of inspections completed, but rather number of inspection reports evaluated and closed in FY2013.



## Frequency of Clinical Investigator Related Deficiencies Based on Post-Inspectional Correspondence Issued: Official Action Indicated (OAI) Final classification\* (CDER, FY 2013)

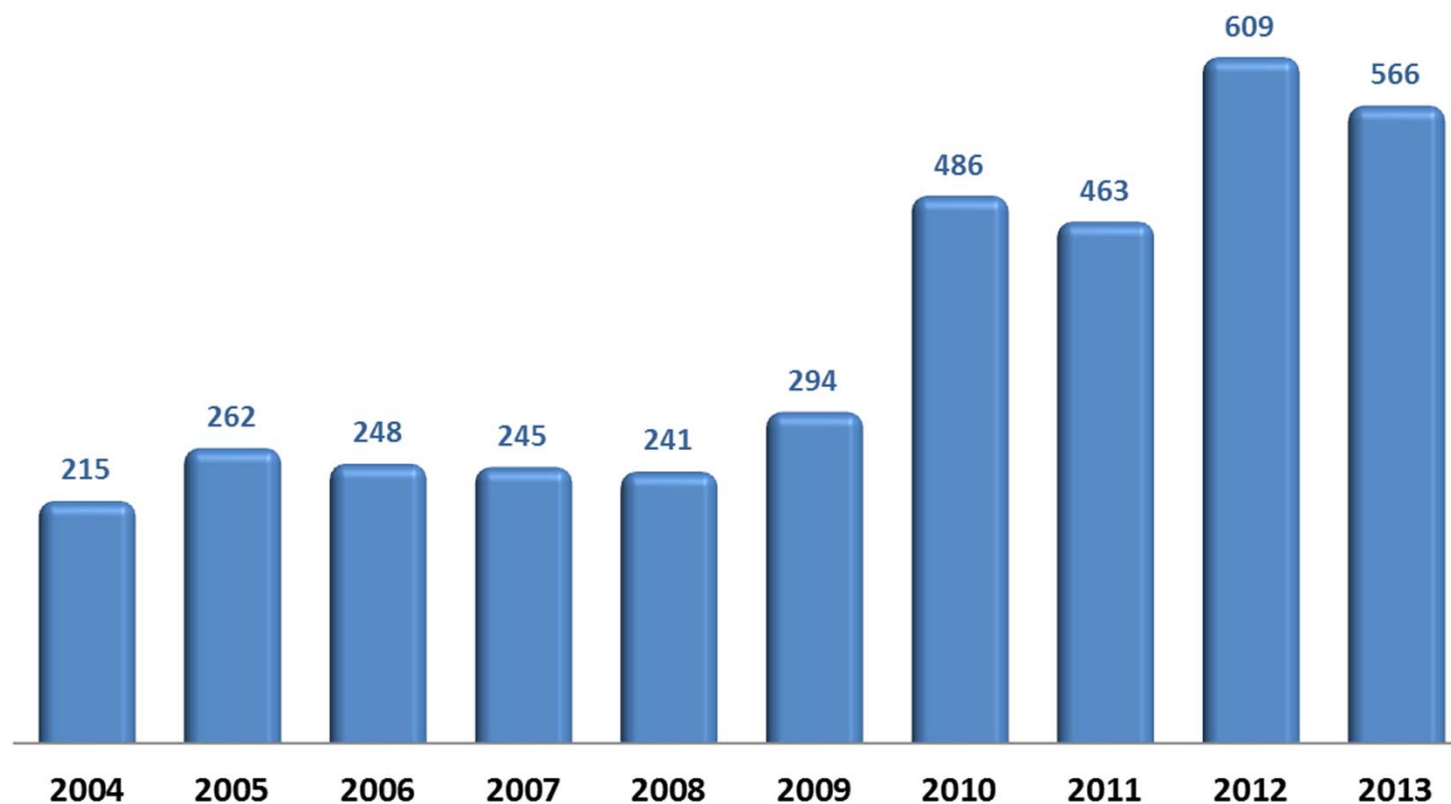


\*Based on letter issue date. Inspections may have multiple deficiencies. Includes OAI untitled letters. [OSI database as of January 31, 2014]  
Note that this does not denote number of inspections completed, but rather number of inspection reports evaluated and closed in FY2013.



## Referrals Received by OSI\*

(CDER, FY 2004 - FY 2013)

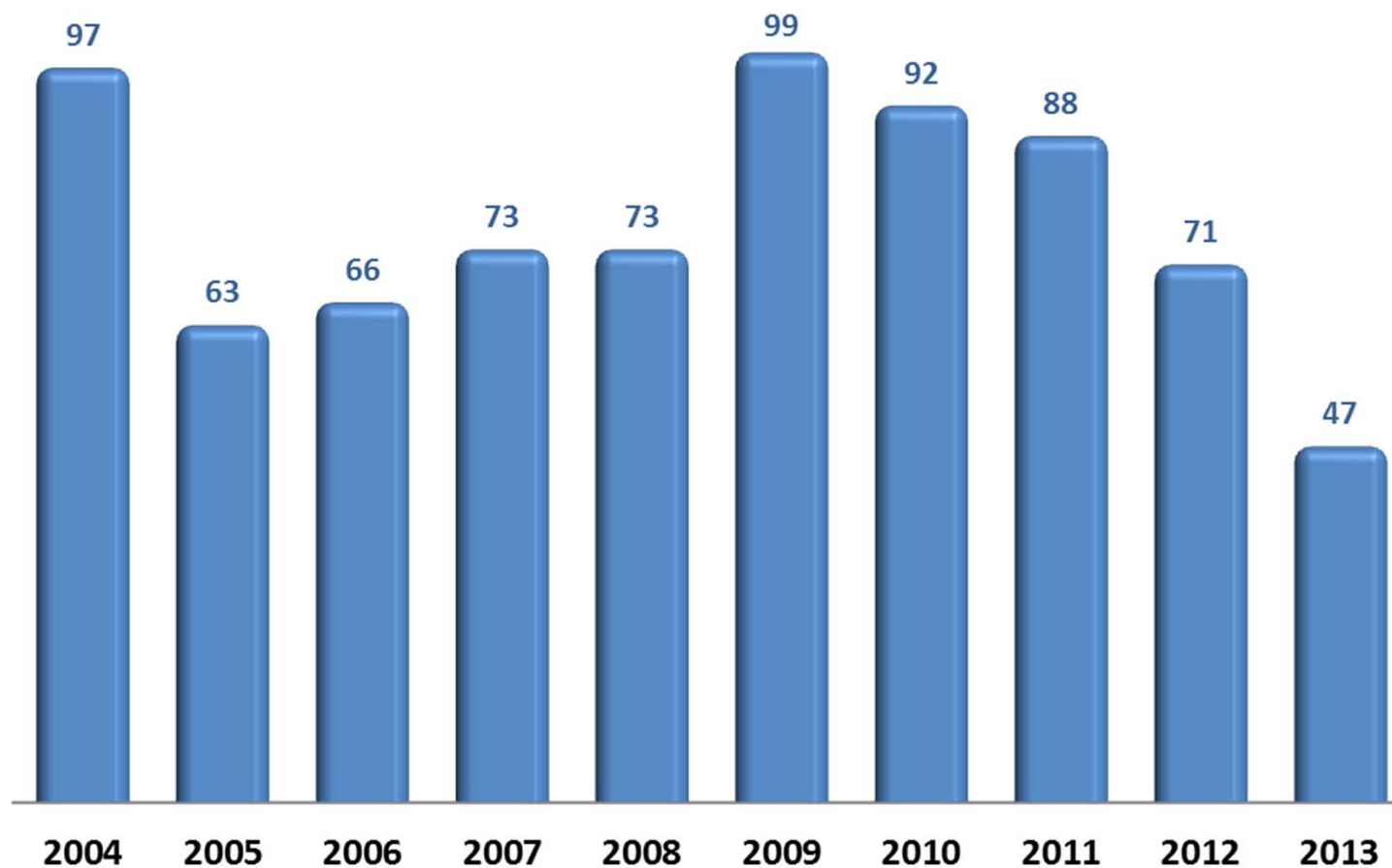


\*Includes Complaints, Required Reports, IRB/Sponsor Notifications, and other referrals-internal and external for All OSI Branches – Evaluation may result in inspection  
[OSI database as of January 31, 2014]



## Referral-Related Clinical Investigator Inspections\*

(CDER, FY 2004 - FY 2013)

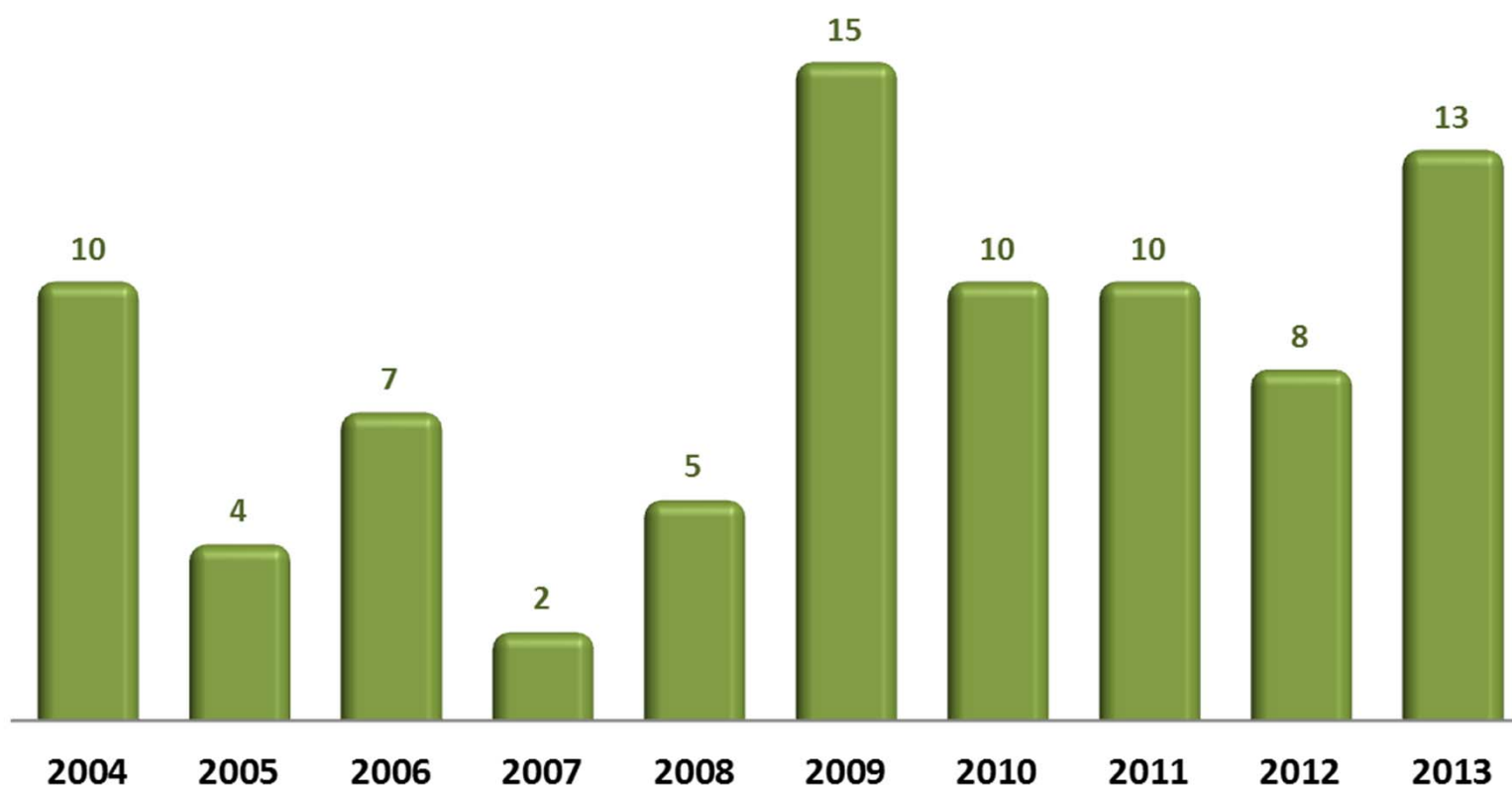


\*Based on inspection start date; Referrals include Complaints, Required Reports, IRB/Sponsor Notifications, and other referrals-internal and external for All OSI Branches  
[OSI database as of January 31, 2014]



## Referral-Related Sponsor Inspections\*

(CDER, FY 2004 - FY 2013)



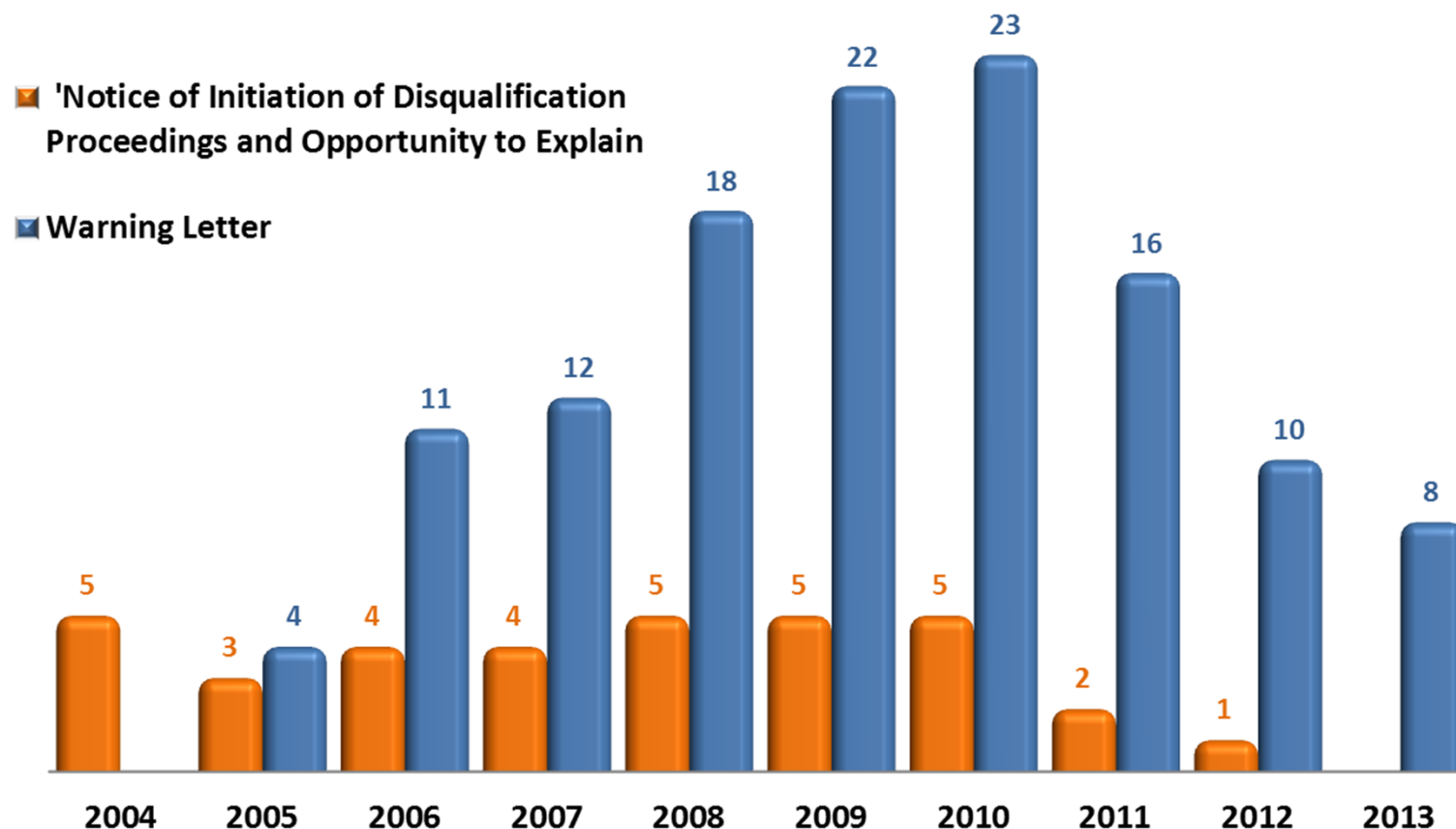
\*Based on inspection start date; Referrals include Complaints, Required Reports, IRB/Sponsor Notifications, and other referrals-internal and external for All OSI Branches  
[OSI database as of January 31, 2013]





## BIMO Warning/NIDPOE Letters\*

(CDER, FY 2004 - FY 2013)



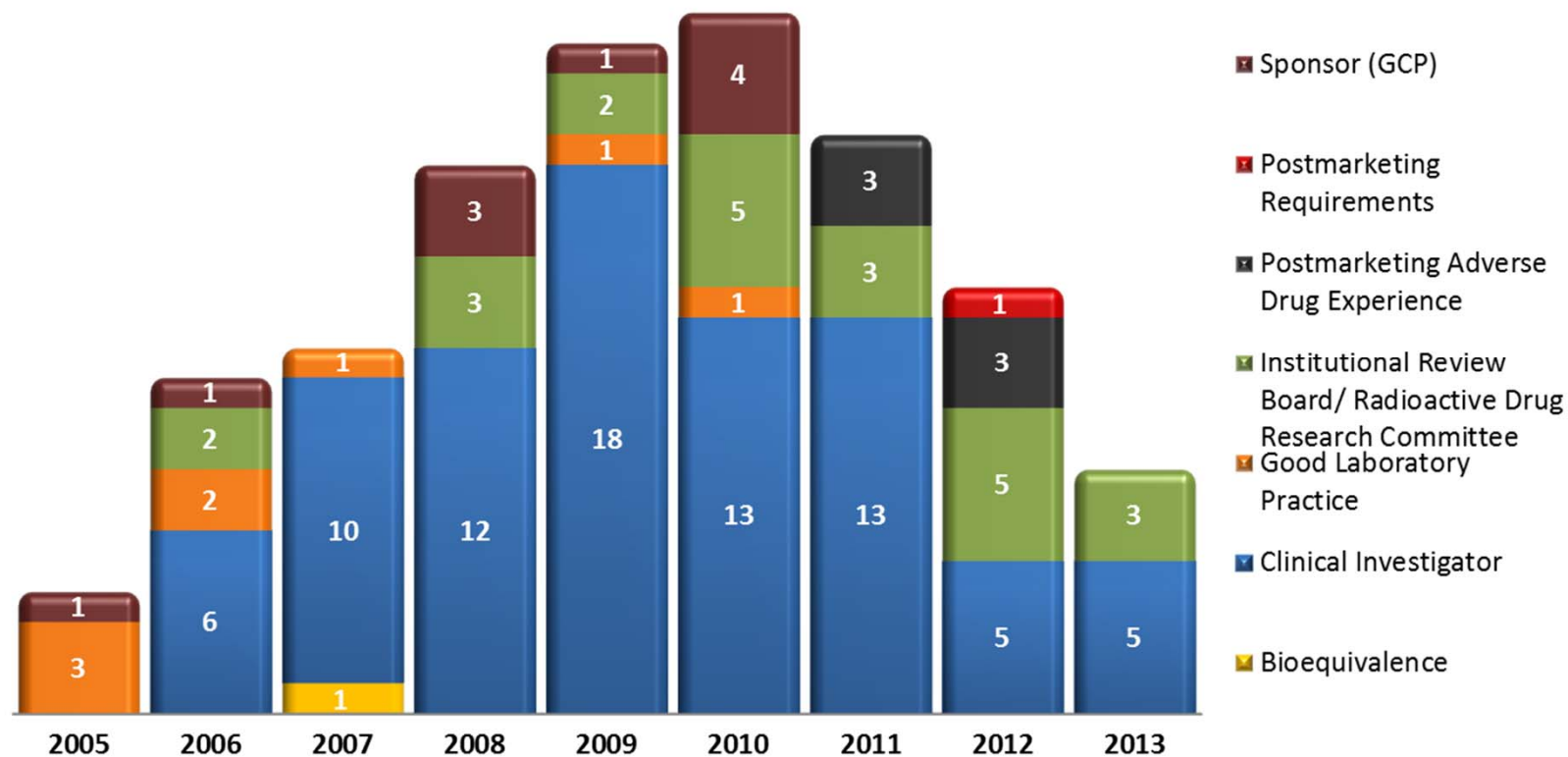
\*Based on letter issue date [OSI database as of January 31, 2014]

- BIMO = Bioresearch Monitoring (Clinical Investigators, Sponsor/CRO/Sponsor-Investigator (GCP), IRB, BEQ, GLP)
- NIDPOE = Notice of Initiation of Disqualification Proceedings and Opportunity to Explain



## OSI Warning Letters\*

(CDER, FY 2004 - FY 2013)

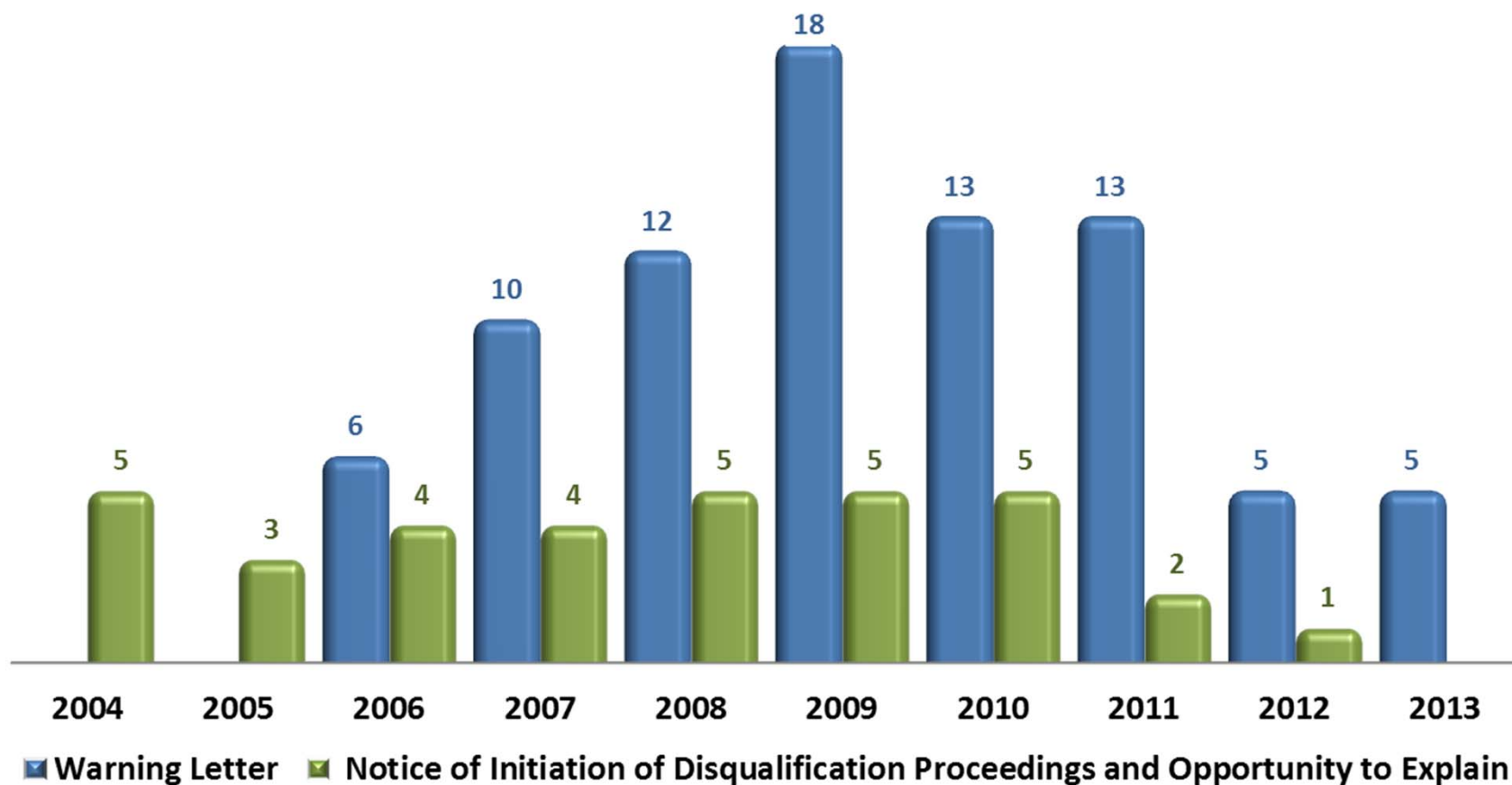


- \*Based on letter issue date [OSI database as of January 31, 2014]
- As of June 2011, the Postmarketing Adverse Drug Event inspection program was incorporated into OSI
- Includes Clinical Investigators, Sponsor/CRO/Sponsor-Investigator (GCP), IRB, BEQ, GLP, Adverse Drug Event (ADE) and Postmarketing Requirements (PMR) Warning Letters
- PMR includes all required studies and clinical trials that are mandated by statute (e.g., section 505(o)(3) of FDCA, PREA, Animal Rule and 21 CFR 314 and 601 Subparts H and E, respectively)



## Clinical Investigator Warning/NIDPOE Letters\*

(CDER, FY 2004 - FY 2013)



\*Based on letter issue date [OSI database as of January 31, 2014] NIDPOE = Notice of Initiation of Disqualification Proceedings and Opportunity to Explain



## Clinical Investigator Regulatory Actions\*

(CDER, FY 2004 - FY 2013)

Action	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13*
WL**	0	0	6	10	12	18	13	13	5	5
NIDPOE	5	3	4	4	5	5	5	2	2	0
NOOH	1	0	1	1	1	2	1	2	1	0
CA-Restricted	1	1	3	1	2	0	3	0	0	0
CA-Full DQ	1	2	0	2	6	3	3	2	0	0
DQ-Hearing/Commissioner	0	0	0	0	4	0	2	1	1	0

WL = Warning Letter

NIDPOE = Notice of Initiation of Disqualification Proceedings and Opportunity to Explain

NOOH = Notice of Opportunity for Hearing

CA = Consent Agreements (Restricted Agreements)

CA = Consent Agreements (Full Disqualification)

DQ = Disqualification by Hearing or Commissioner

\*Based on letter issue date [OSI database as of January 17, 2014]

\*\*WLs are informal and advisory in nature, not regulatory actions (FDA Regulatory Procedures Manual Chapter 4, Section 1-1)



## OSI Warning Letters\*

(CDER, FY 2004 - FY 2013)

Program Area	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13*
Bioequivalence**	1**	1**	1**	1	0	0	0	1**	0	0
Good Laboratory Practice	0	3	2	1	0	1	1	0	0	0
Clinical Investigator	0	0	6	10	12	18	13	13	5	5
Sponsor-Investigator (GCP)	0	1	0	0	0	0	2	0	0	0
Sponsor (GCP)	0	0	1	0	3	1	1	0	0	0
Contract Research Organization (GCP)	0	0	0	0	0	0	1	0	0	0
Institutional Review Board	0	0	2	0	3	2	5	2	5	3
Radioactive Drug Research Committee	0	0	0	0	0	0	0	1	0	0
Postmarketing Adverse Drug Event***	N/A	N/A	N/A	N/A	N/A	N/A	N/A	3	3	0
Risk Evaluation and Mitigation Strategy***	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0
Postmarketing Requirements^	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1	0

\*Based on letter issue date [OSI database as of January 17, 2014]

\*\*Posted Bioequivalence OAI untitled letters.

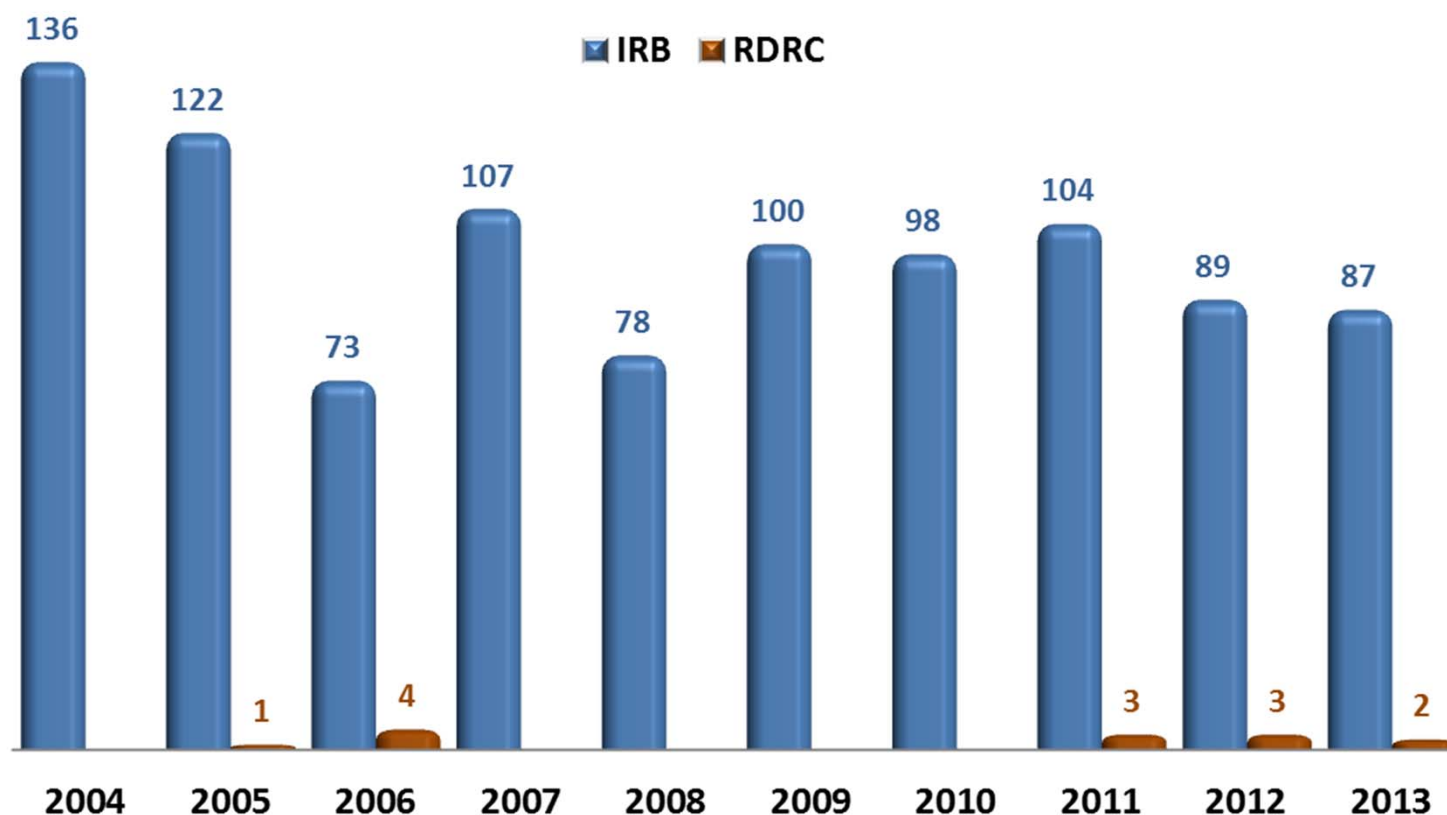
\*\*\*As of June 2011, Postmarketing Adverse Drug Event and Risk Evaluation and Mitigation Strategies inspection programs incorporated into OSI.

^Postmarketing Requirements (PMR) includes all required studies and clinical trials that are mandated by statute (e.g., section 505(o)(3) of FDCA, PREA, Animal Rule and 21 CFR 314 and 601 Subparts H and E, respectively.



## IRB/RDRC Inspections\*

(CDER, FY 2004 - FY 2013)



\*Based on inspection start date [OSI database as of January 31, 2014]

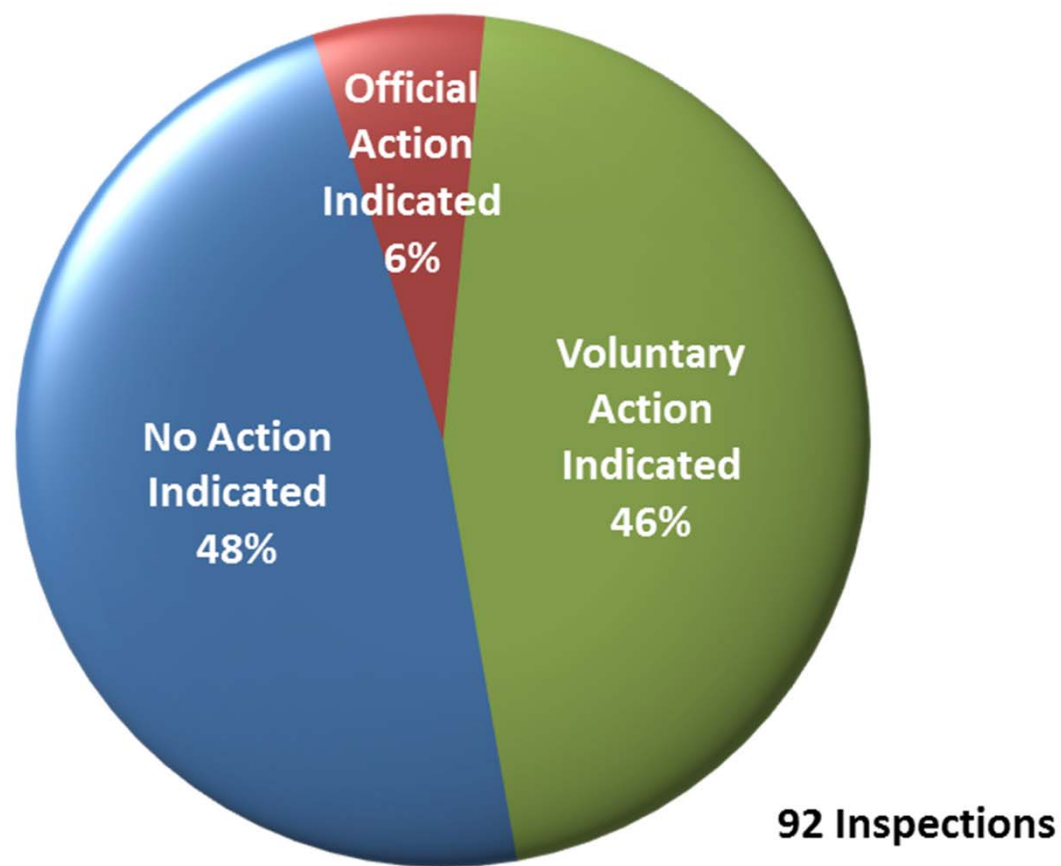
Includes only CDER numbers – previously reported metrics may have used combined data across CDER, CBER and CDRH





## IRB Inspection Final Classifications\*

(CDER, FY 2013)

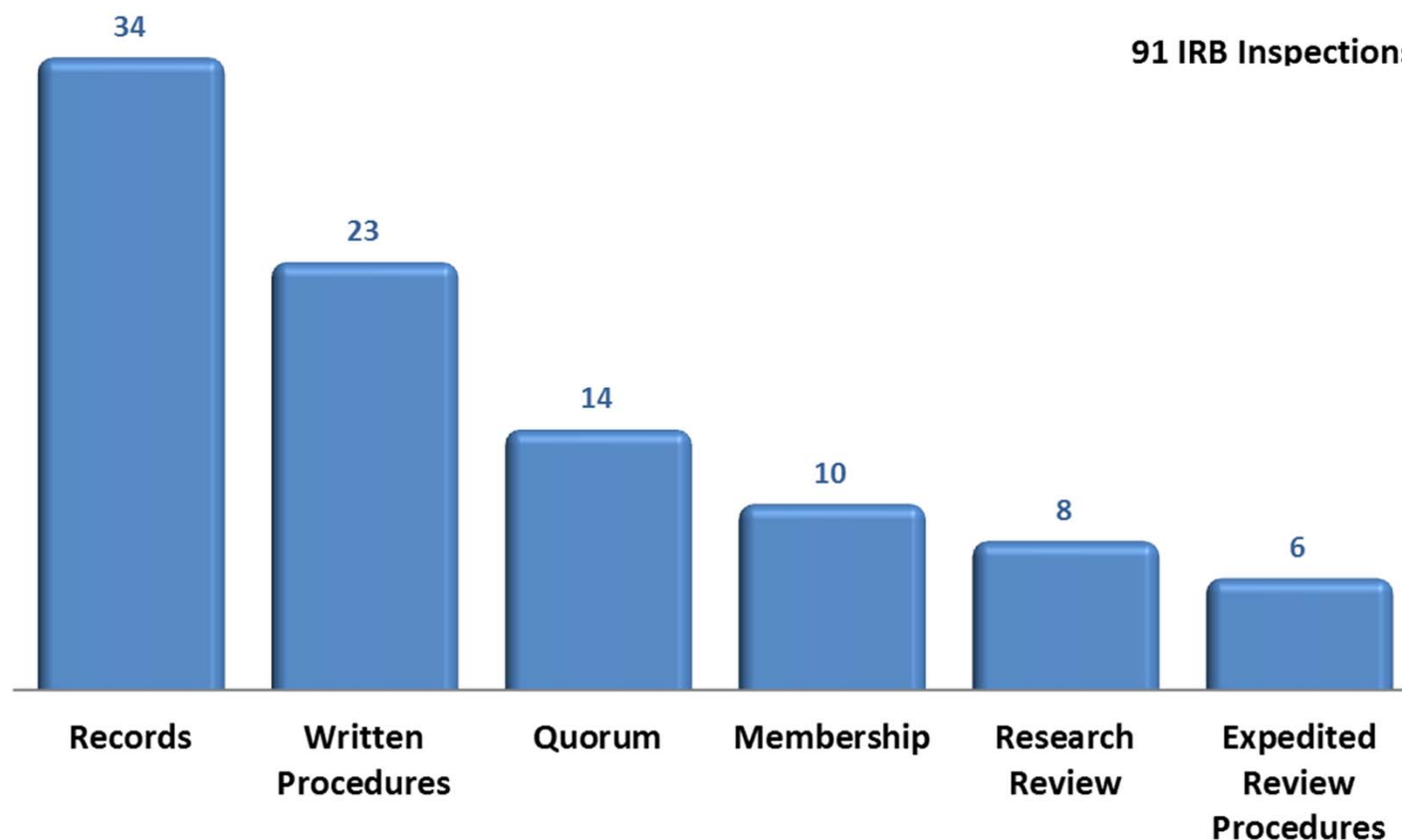


\*Based on letter issue date, [OSI database as of January 17, 2014]



## Frequency of IRB-Related Deficiencies Based on Post-Inspection Correspondence Issued\*

(CDER, FY 2013)



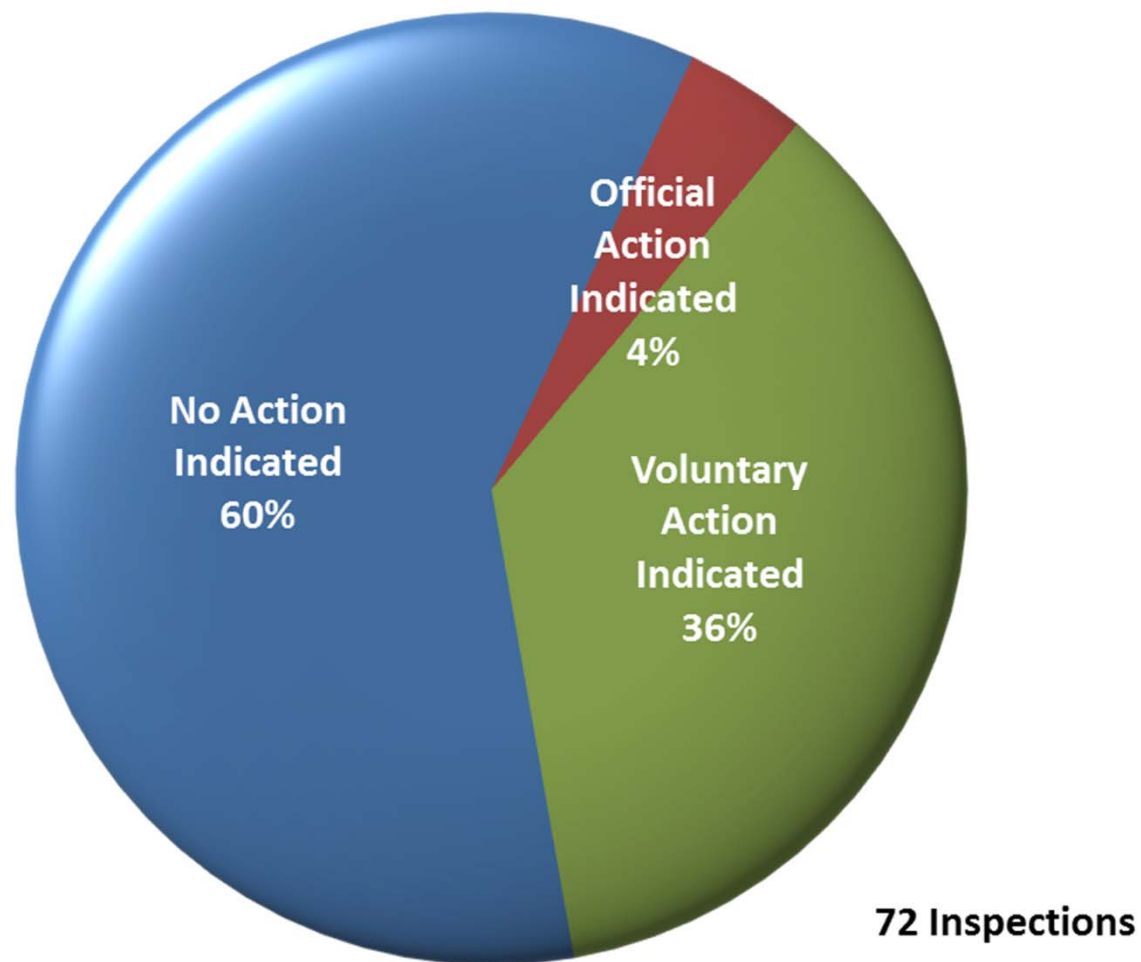
\*Based on letter issue date, [OSI database as of January 31, 2014]

Note that this does not denote number of inspections completed, but rather number of inspection reports evaluated and closed in FY2013



## Postmarketing Adverse Drug Event Inspections\*

(CDER, FY 2013)

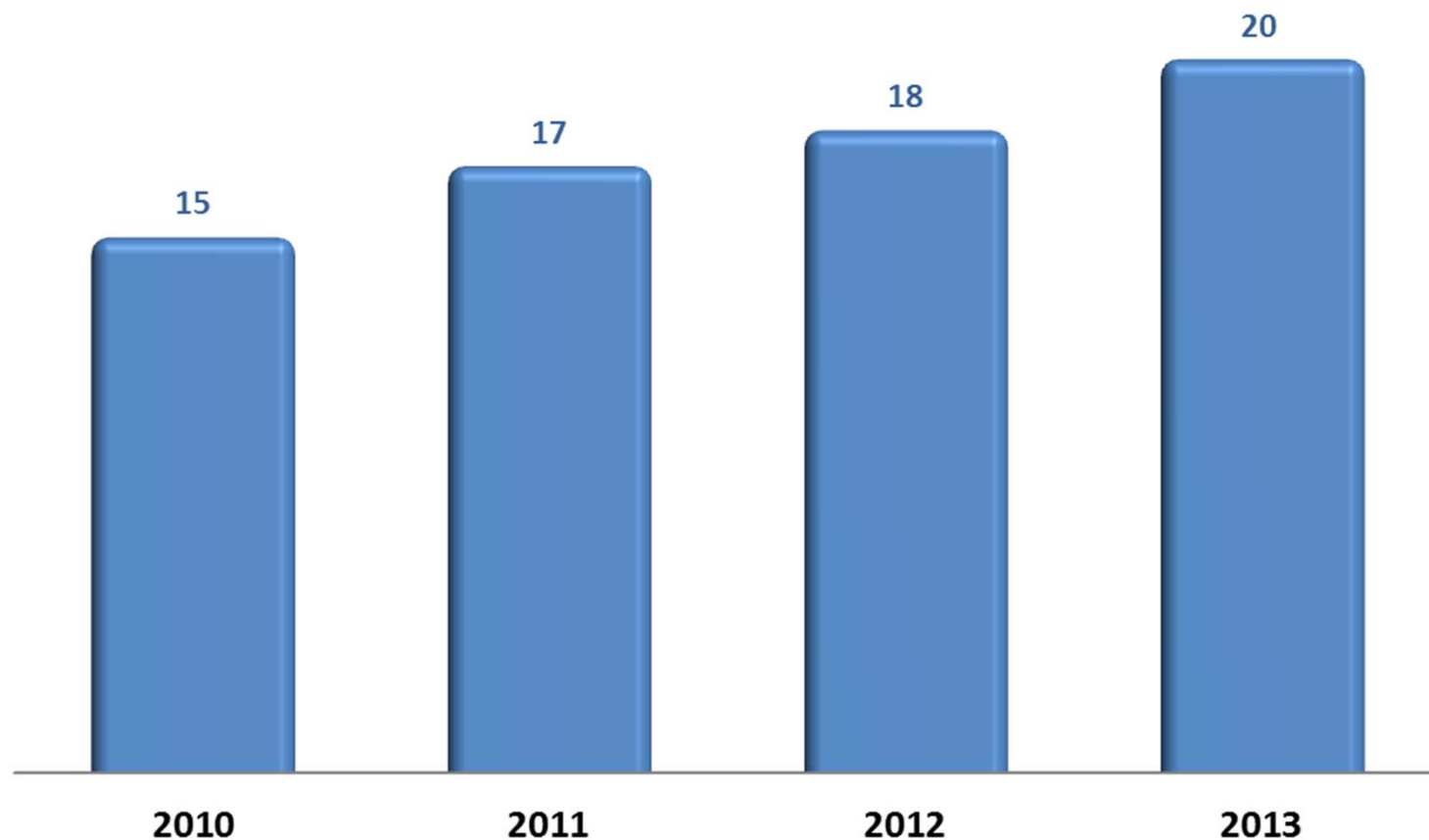


\*Based on date inspection completed



## Risk Evaluation and Mitigation Strategies Inspections\*

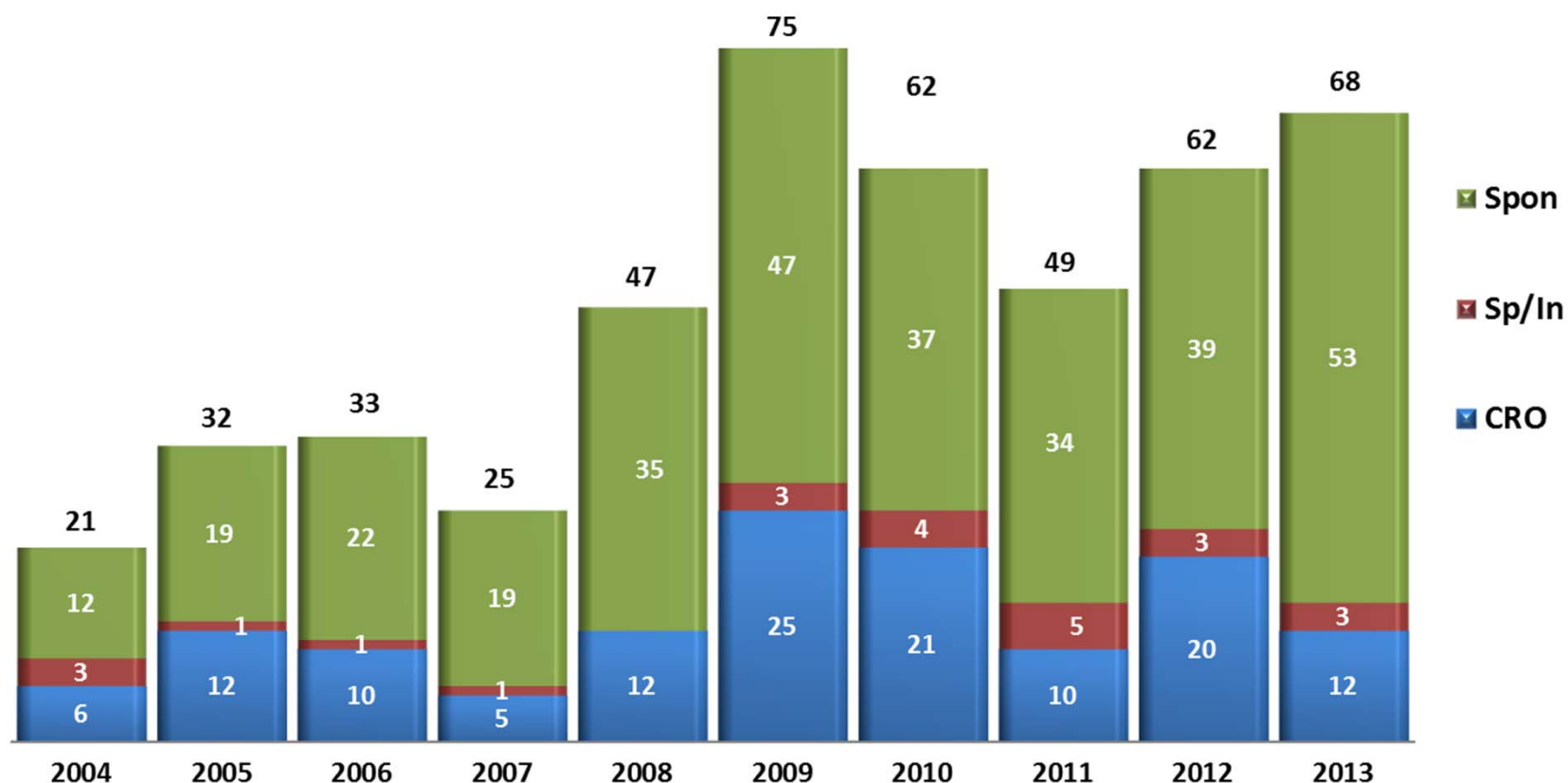
(CDER, FY 2013)



\*Based on date inspection completed, REMS inspection program began in FY10.



## GCP-Related Sponsor/Contract Research Organization Inspections\* (CDER, FY 2013)

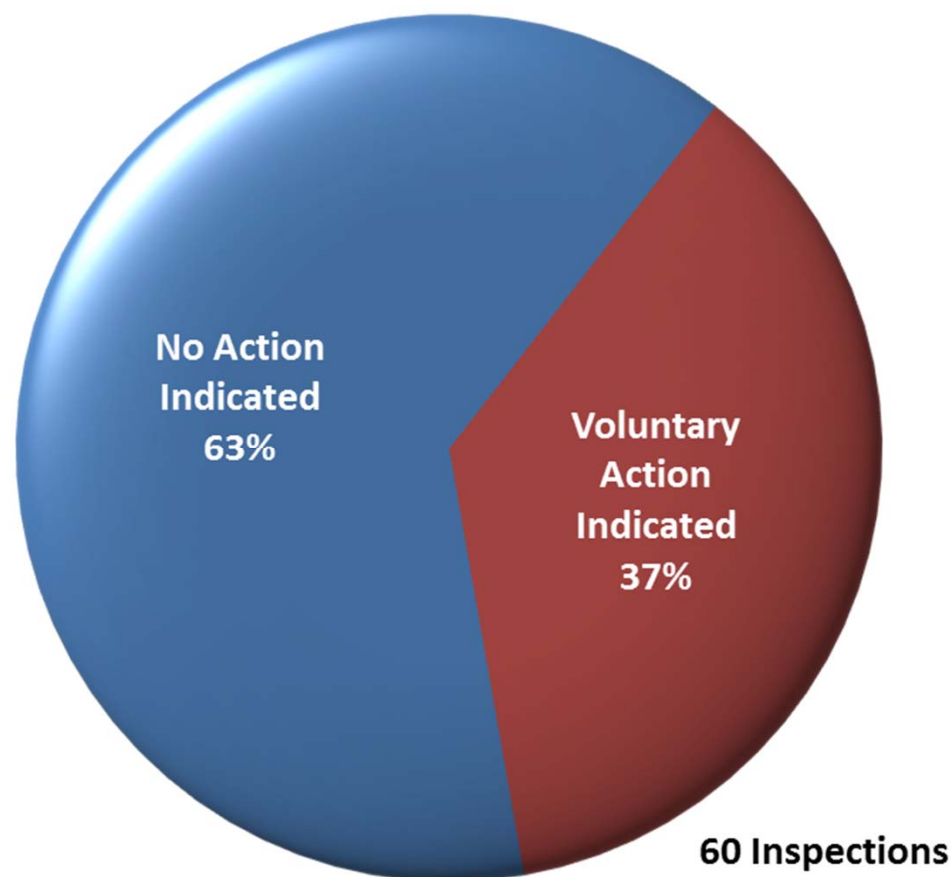


\*Based on inspection start date [OSI database as of January 31, 2014]

The Sponsor/CRO distribution shifted for FY09-12 in previous releases due to corrections in the OSI Database.



## GCP-Related Sponsor/Contract Research Organization Inspections Final Classification\* (CDER, FY 2013)



\*Based on letter issue date [OSI database as of January 31, 2014]  
Includes Sponsor-Investigator Inspections