



***DEALING WITH IRBS
TO PROMOTE TIMELY,
EFFICIENT AND
COMPLIANT REVIEW***

9/6/2006

Prepared by Lynn A. Meyer,
President, CIP, CIM

INTEG  **REVIEW**

Who is Responsible?



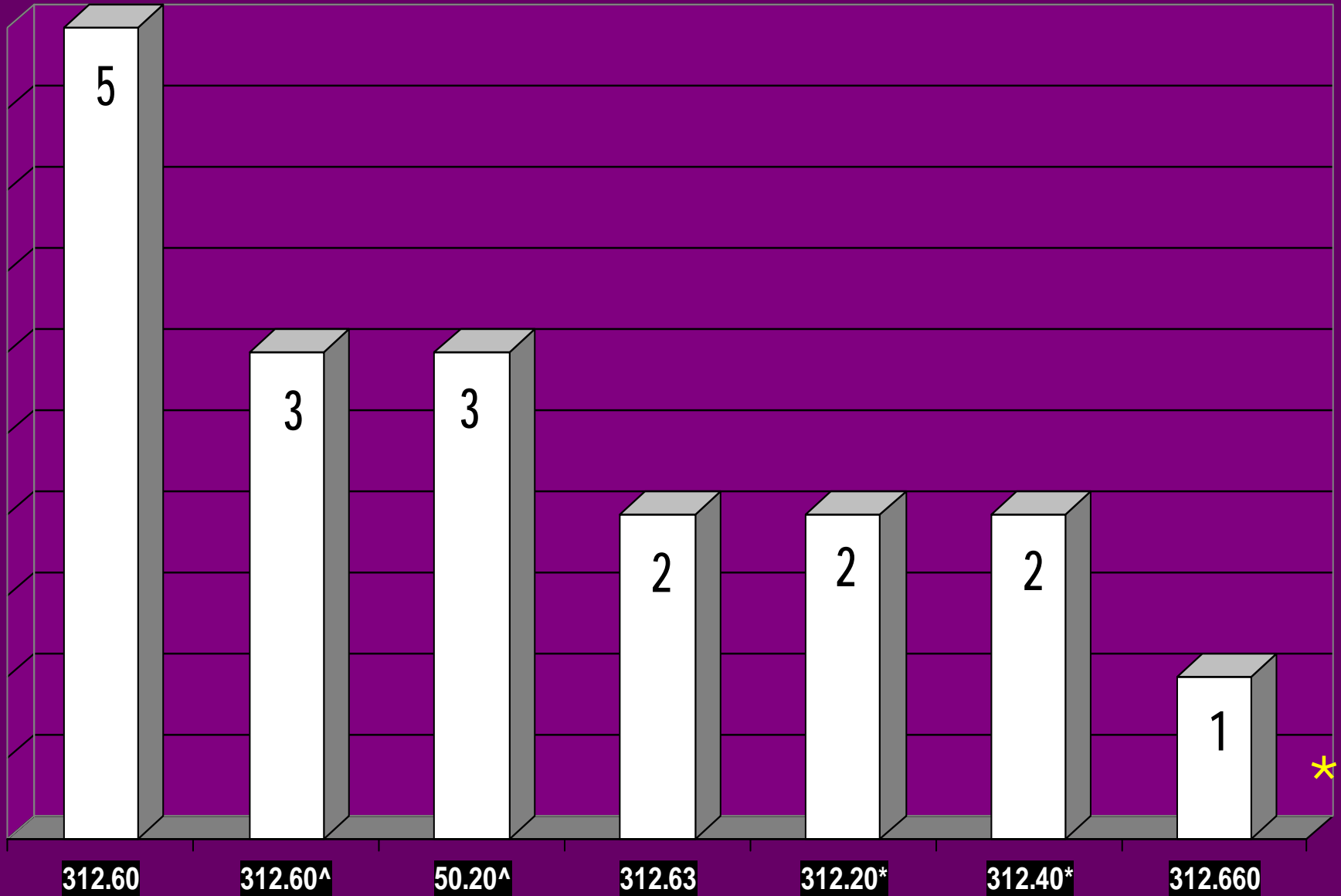
- **Investigator**
- **IRB**
- **Sponsor**

Non-Compliance Issues



INVESTIGATOR

INVESTIGATOR



Warning Letter Findings

312.60



Failure to:

- *Protect subjects*
- *Conduct investigation according to plan*
- *Obtain IC (50.20)*

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Warning Letter Findings

312.62



Failure to:

- *Maintain adequate case histories and drug disposition*

Warning Letter Findings

312.20 & 312.40



Failure to:

- *Conduct study under IND*

Warning Letter Findings

50.25



Failure to:

- *Provide IC*
- *Include elements of IC*
- *Promptly report changes to IRB*

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Warning Letter Findings

312.66



Failure to:

- *Report unanticipated problems to IRB*
- *Obtain IRB approval*

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Investigator Recommendations



- **SOPs**
- **Training**
- **Certification**

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Investigator Recommendations



- **OHRP self assessment**
- **Accreditation**
- **Internal audits**

*

Investigator Recommendations



<http://www.hhs.gov/ohrp/qi/>

**Quality Assurance/Quality
Improvement**

**A Guided Self-Assessment
for Human Research
Protection Programs**

Investigator Recommendations



- **Understand**
 - **Protocol**
 - **FDA Form 1572**
 - **Submission form**

Investigator Recommendations



- **Be compliant**
 - **Protocol**
 - **IRB**

Investigator Recommendations



- Utilize template IC
- Communicate
- Be available

Investigator Recommendations



- **Timely reporting**
 - **SAEs**
 - **Deviations**
 - **Amend/Revisions**

Non-Compliance Issues

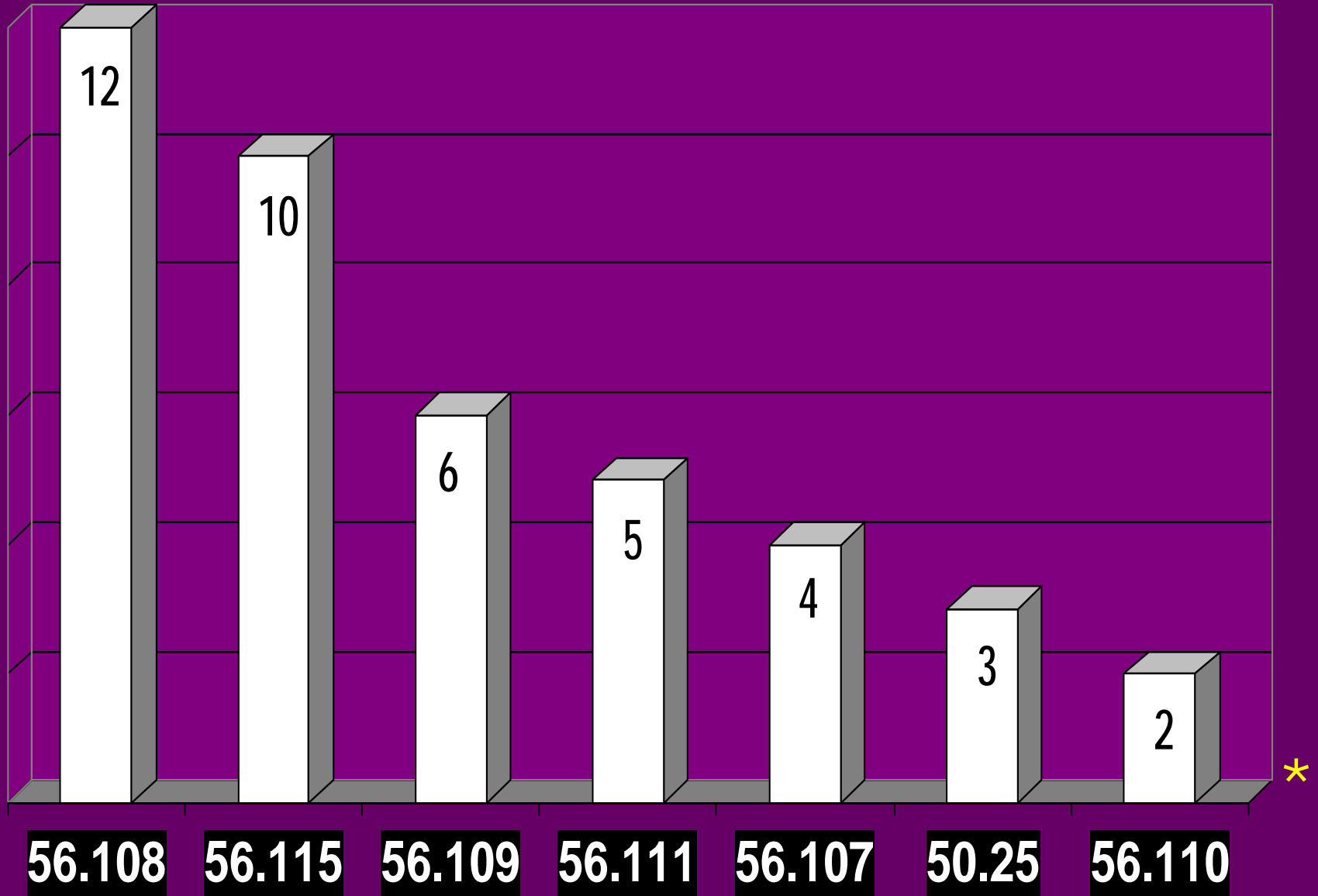


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IRB



Warning Letter Findings

56.108



Failure to:

- *Follow written procedures*
- *Have adequate written procedures*

Warning Letter Findings

56.108



Failure to:

- *Have written procedure to ensure prompt reporting of unanticipated problems*

Warning Letter Findings

56.108



Failure to:

- *Review research with majority*

*

Warning Letter Findings

56.115



Failure to:

- *Prepare/maintain adequate documentation of activities*
- *Follow written procedures*

Warning Letter Findings

56.109



Failure to:

- *Require basic elements of IC*
- *Notify PI in writing*

Warning Letter Findings

56.109



Failure to:

- *Conduct CR at appropriate intervals*
- *Require information to comply with Subpart D*

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Warning Letter Findings

56.111



Failure to:

- *Ensure IC*
- *Ensure risks were minimized*

Warning Letter Findings

56.111



Failure to:

- *Approve pediatric research in compliance with Subpart D*

Warning Letter Findings

56.25



Failure to:

- *Ensure basic elements
in IC*

Warning Letter Findings

56.110



Failure to:

- *Fulfill requirements for expedited review*

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Warning Letter Findings

56.107



Failure to:

➤ *Ensure no COI*

IRB Recommendations



- **SOPs**
- **Training**
- **Certification**

IRB Recommendations



- **Accreditation**
- **FDA/OHRP self assessment**
- **Internal audits**



SPONSORS

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Sponsor Recommendations



Ensure:

- *PIs are qualified*
- *Protocol is followed*
- *Adequate/timely reporting*

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Solutions



Work as partners

Establish relationship

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Questions/Comments



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