

# Summary of Results from Pregnancy Testing in Clinical Trials Survey

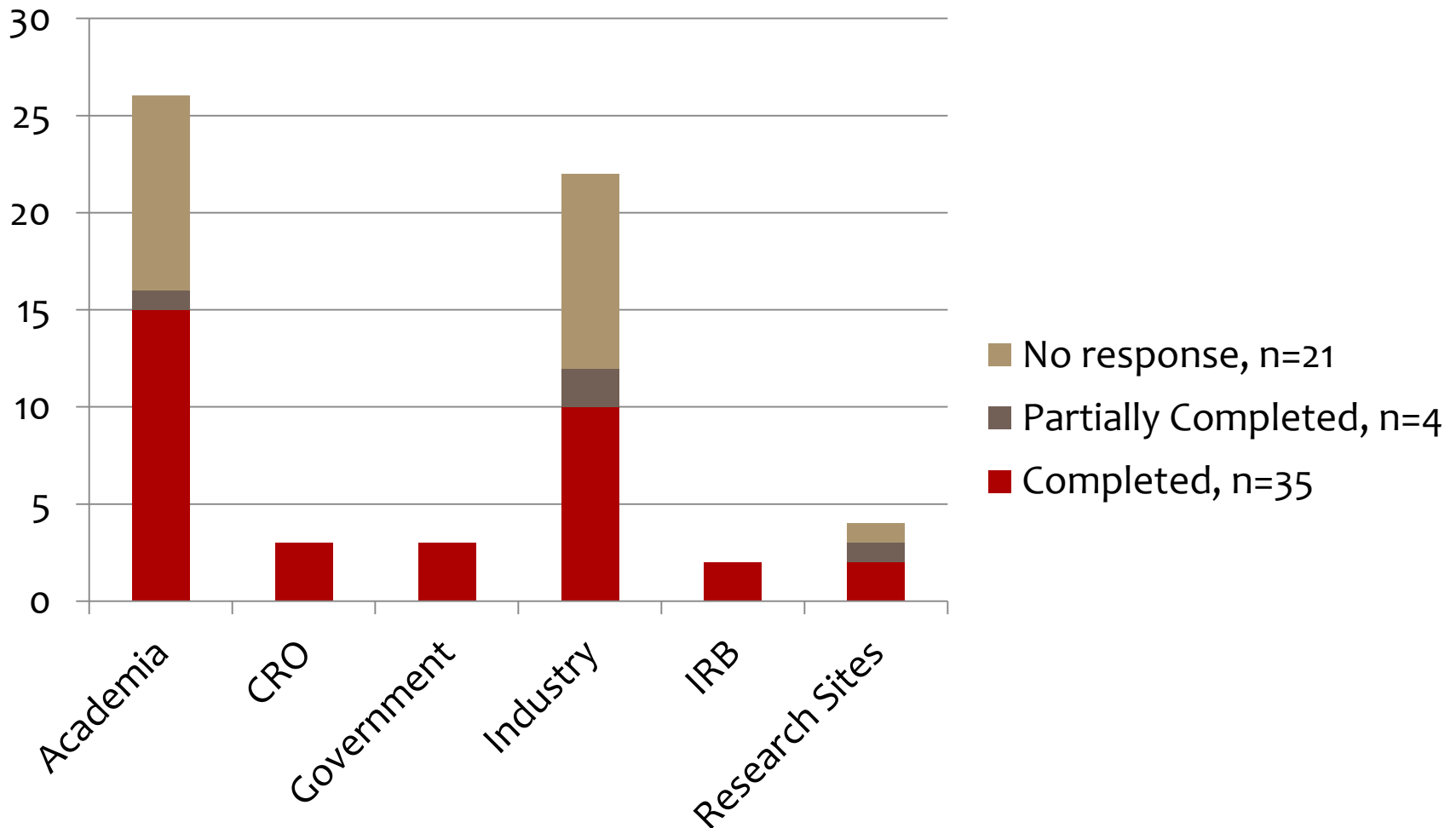
# Survey on Pregnancy Testing Protocols

- CTTI targeted stakeholders involved in the design, conduct, and evaluation of clinical trials
- Invited 58 individuals and received 35 completed surveys, 4 partially completed
- Web-based survey with questions regarding experience and opinions on appropriate pregnancy testing protocols in five clinical study scenarios

# Purpose of Survey

- Factors going into decision making about pregnancy testing
- Variability in
  - What decisions were made
  - What factors influenced decisions
- To inform discussion at this meeting, NOT to draw general inferences about the state of pregnancy testing in the research community!

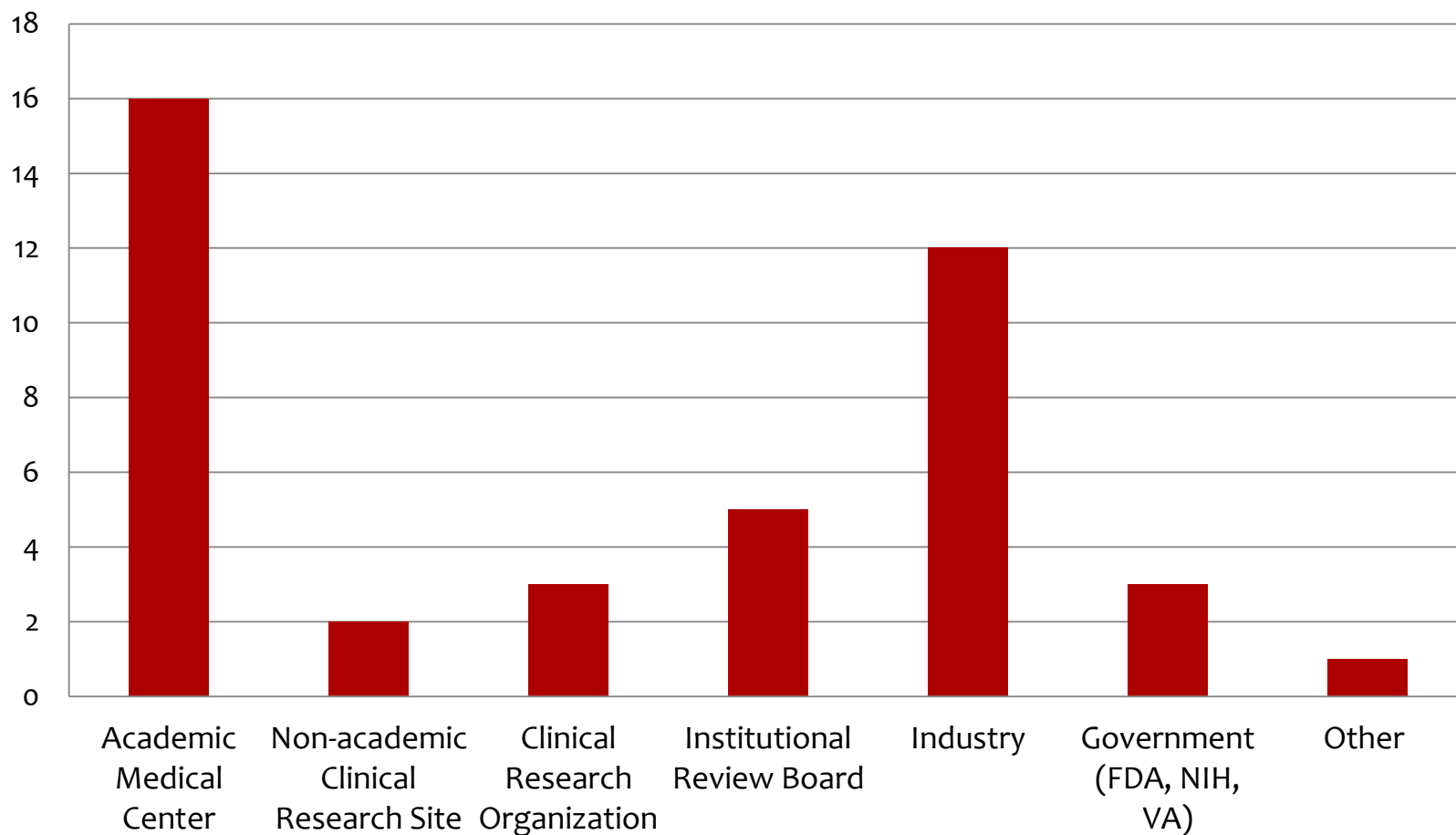
# Response Status



# Selected Data from Responses to Survey

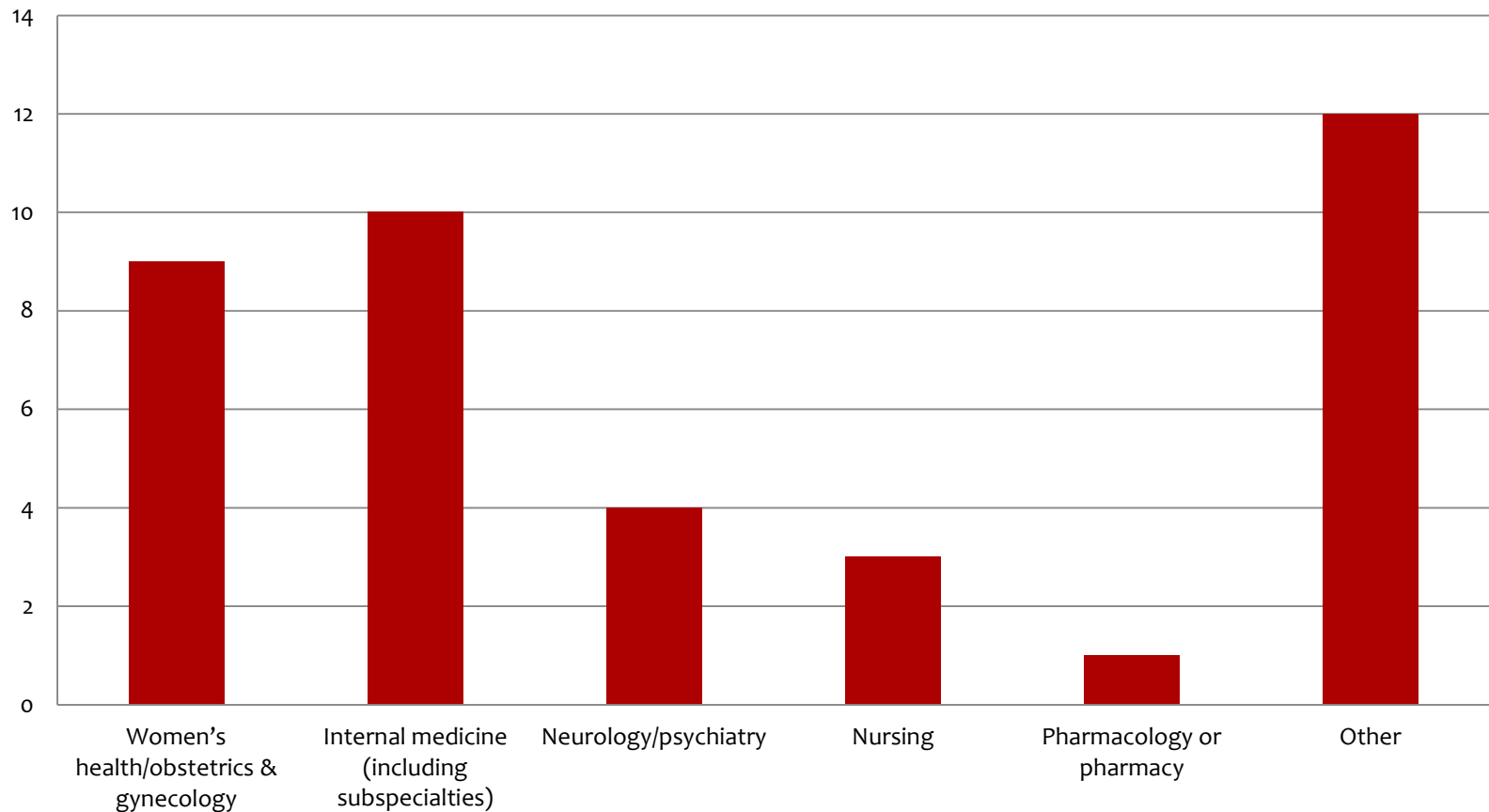
# Which best describes your organization?

Please check all that apply\*



\*42 responses. More than one response allowed, partial surveys included.

# Which do you consider your PRIMARY area of clinical experience/expertise?



# Survey Scenarios

## Scenario

Phase III study - new analog of thalidomide - administered for 12 months - assume two methods of highly effective contraception

Phase III - new indication for a currently marketed drug - administered for 6 months - currently classified as Pregnancy Category C - assume subjects using highly effective method of contraception.

Phase II study - new intravenous antiemetic for prevention of postoperative nausea and vomiting (PONV) - exposure limited to the perioperative period - drug elimination half-life is 6 hours - and preclinical studies show no signs of reproductive toxicity - assume subjects are using a highly effective method of contraception.

Phase I study - new chemotherapeutic agent - advanced cancer patient population - the agent is administered once weekly for 4 weeks - assume subjects are using a highly effective method of contraception.

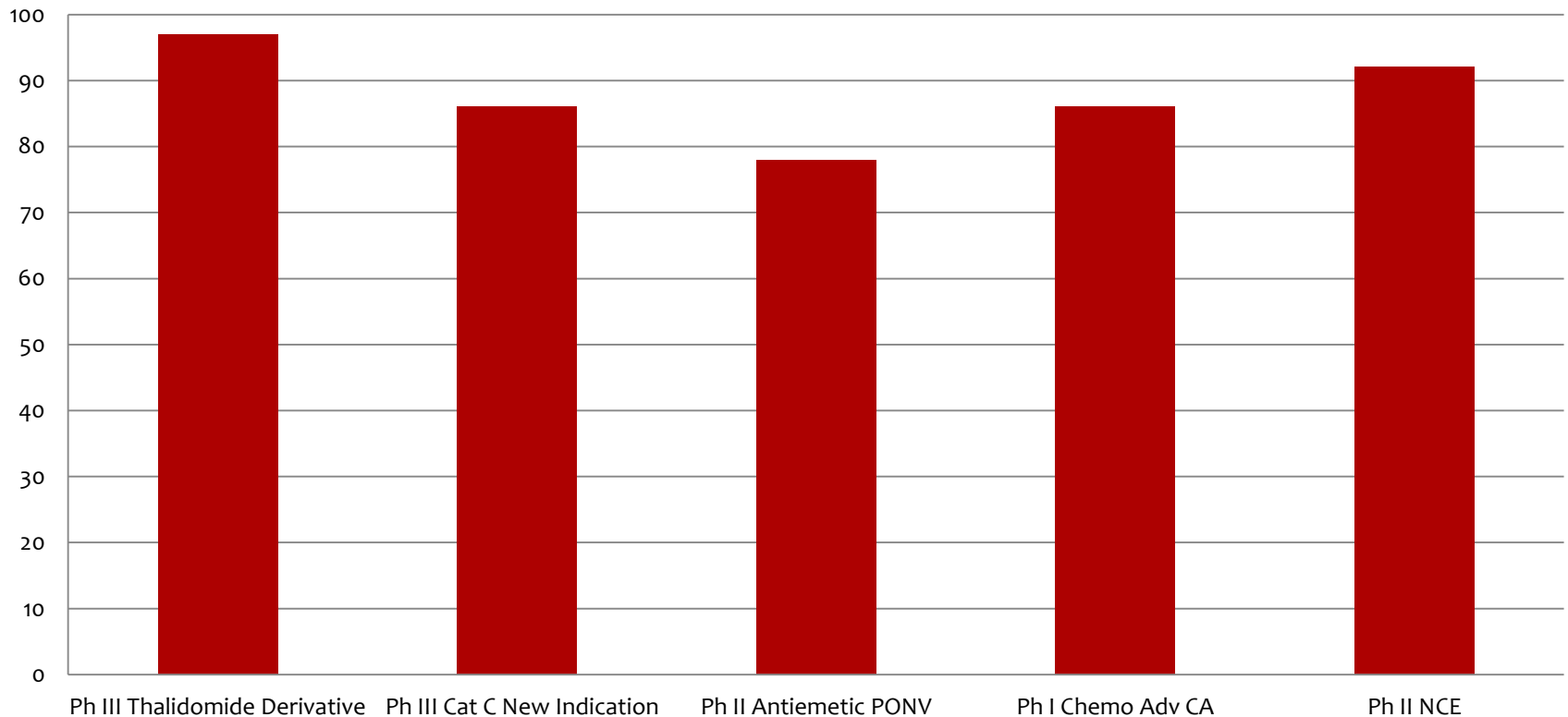
Phase II study of a new chemical entity (NCE) - with no worrisome preclinical data on reproductive toxicity - administered for 6 months - assume subjects are using a highly effective method of contraception

# Survey Scenarios

- Varied in degree of
  - Risk to embryo/fetus
  - Certainty about risk to embryo/fetus
  - Implicit risk of pregnancy
    - Condition
    - Duration of study
- Not much detail (on purpose!)
- Interested in how responses varied across risk
- Interested in free text responses

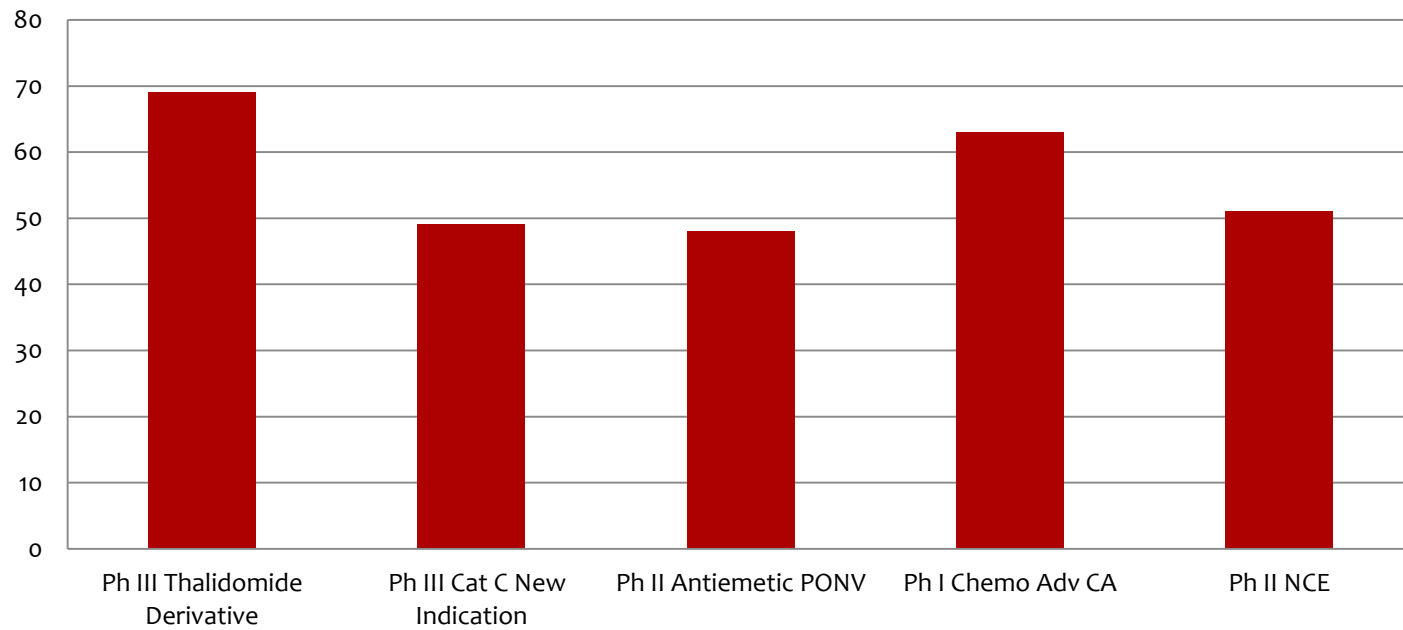
# Would you recommend excluding pregnant women from this study?

Percentage of Respondents Who Answered “Yes”



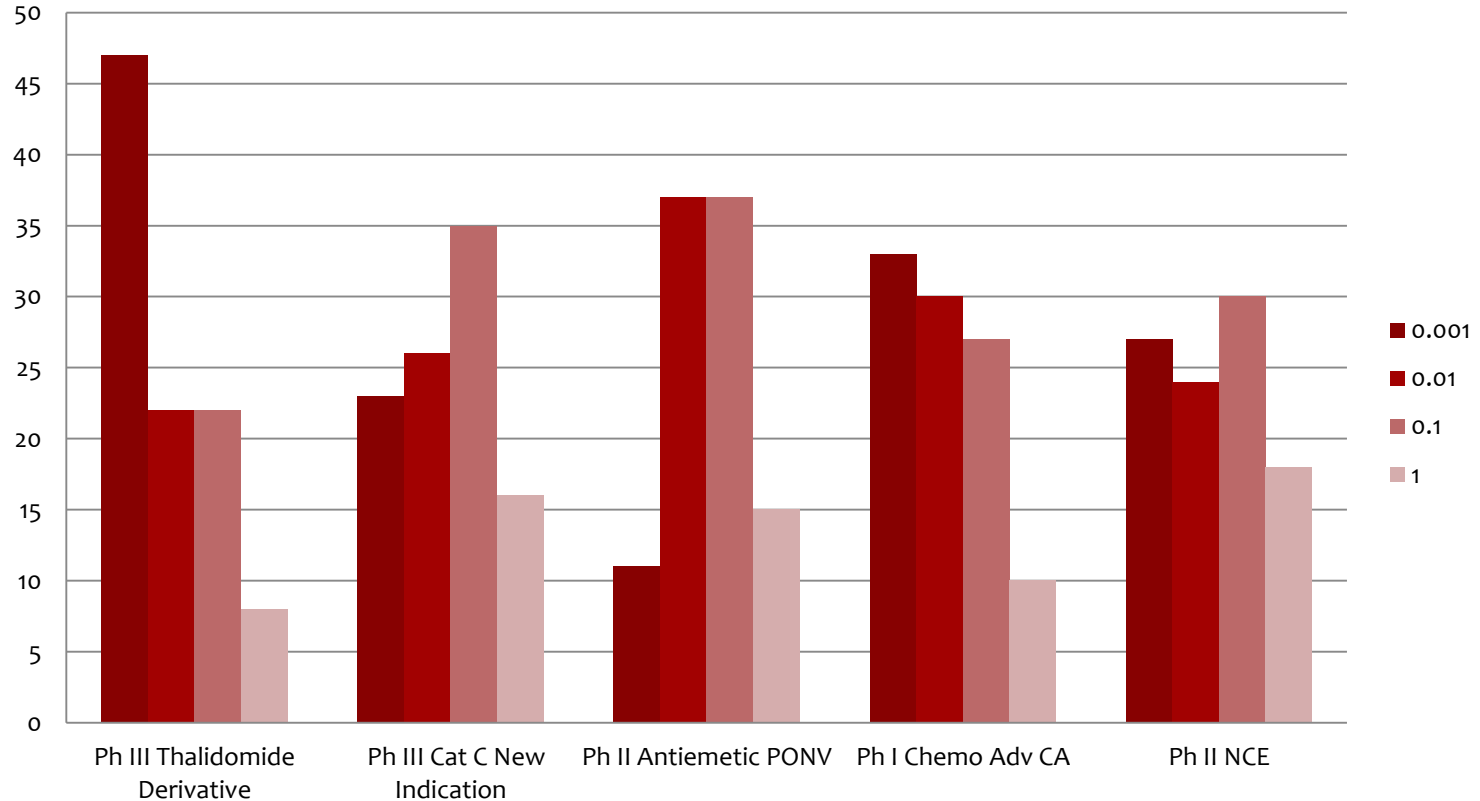
# What is the acceptable risk of a false negative pregnancy test?

Percentage Choosing .001% or .01% Risk of False Negative



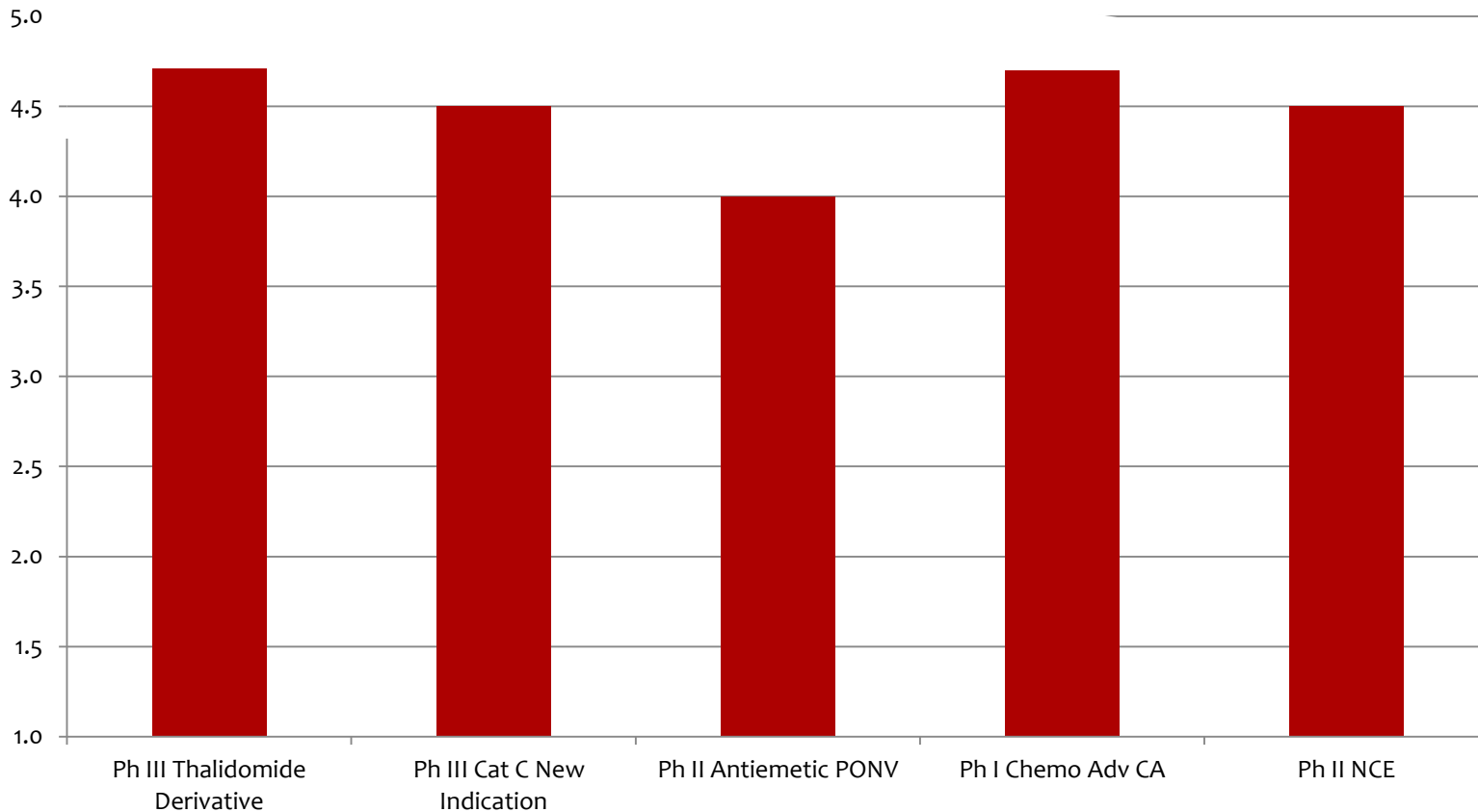
# What is the acceptable risk of a false negative pregnancy test?

## Percent Choosing Each Level of Acceptable Risk of False Negative

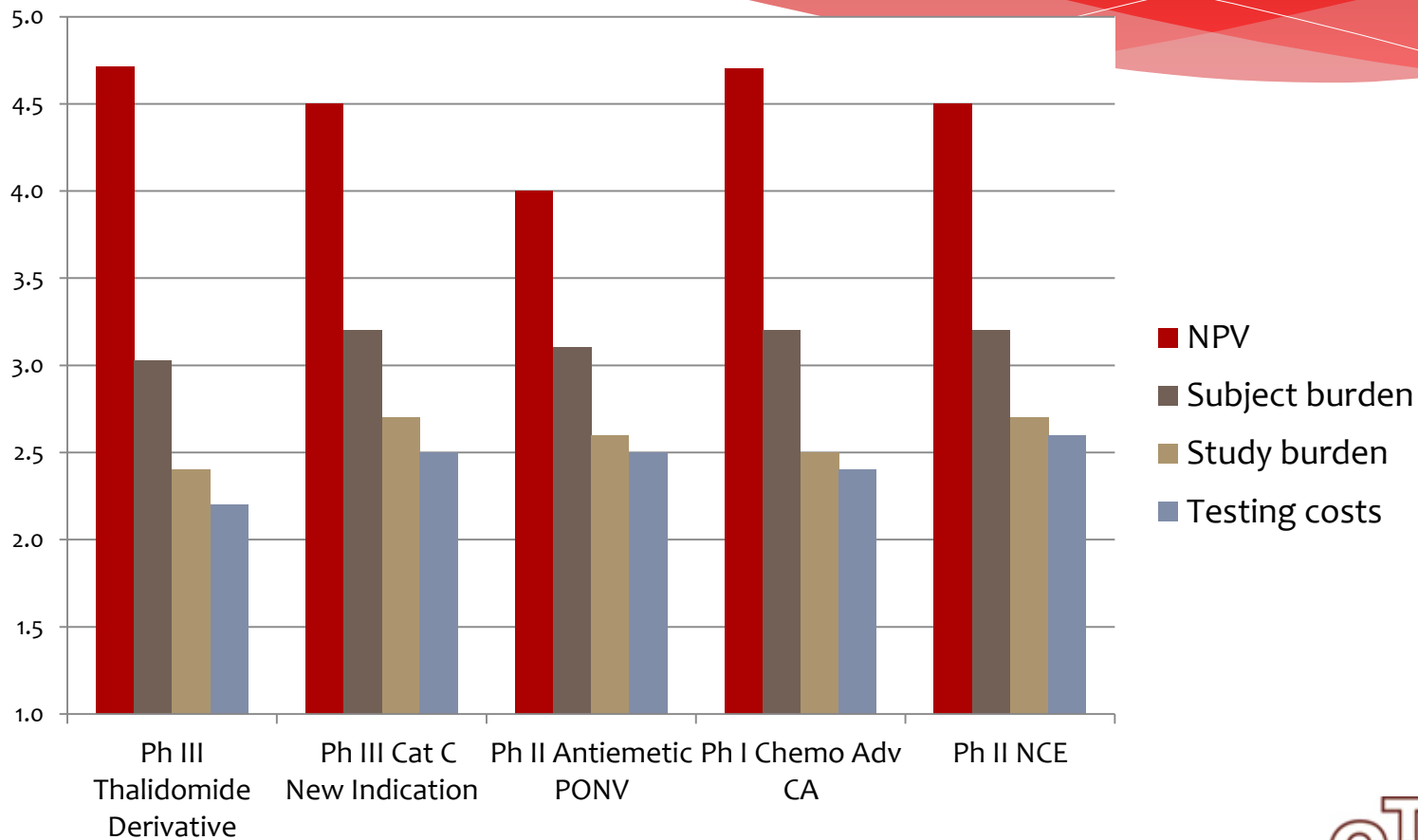


# Relative Importance of NPV, Patient Burden, Researcher Burden, Cost

Average Importance Rating of NPV

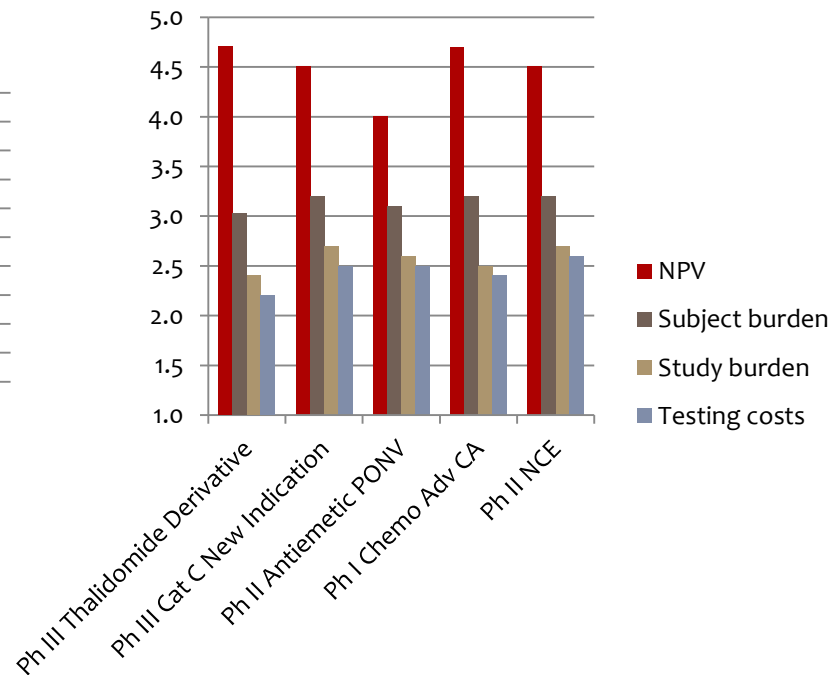
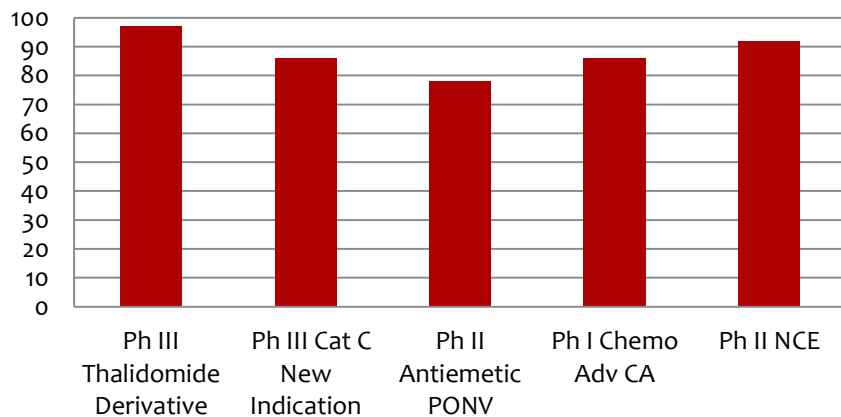


# Relative Importance of NPV, Patient Burden, Researcher Burden, Cost

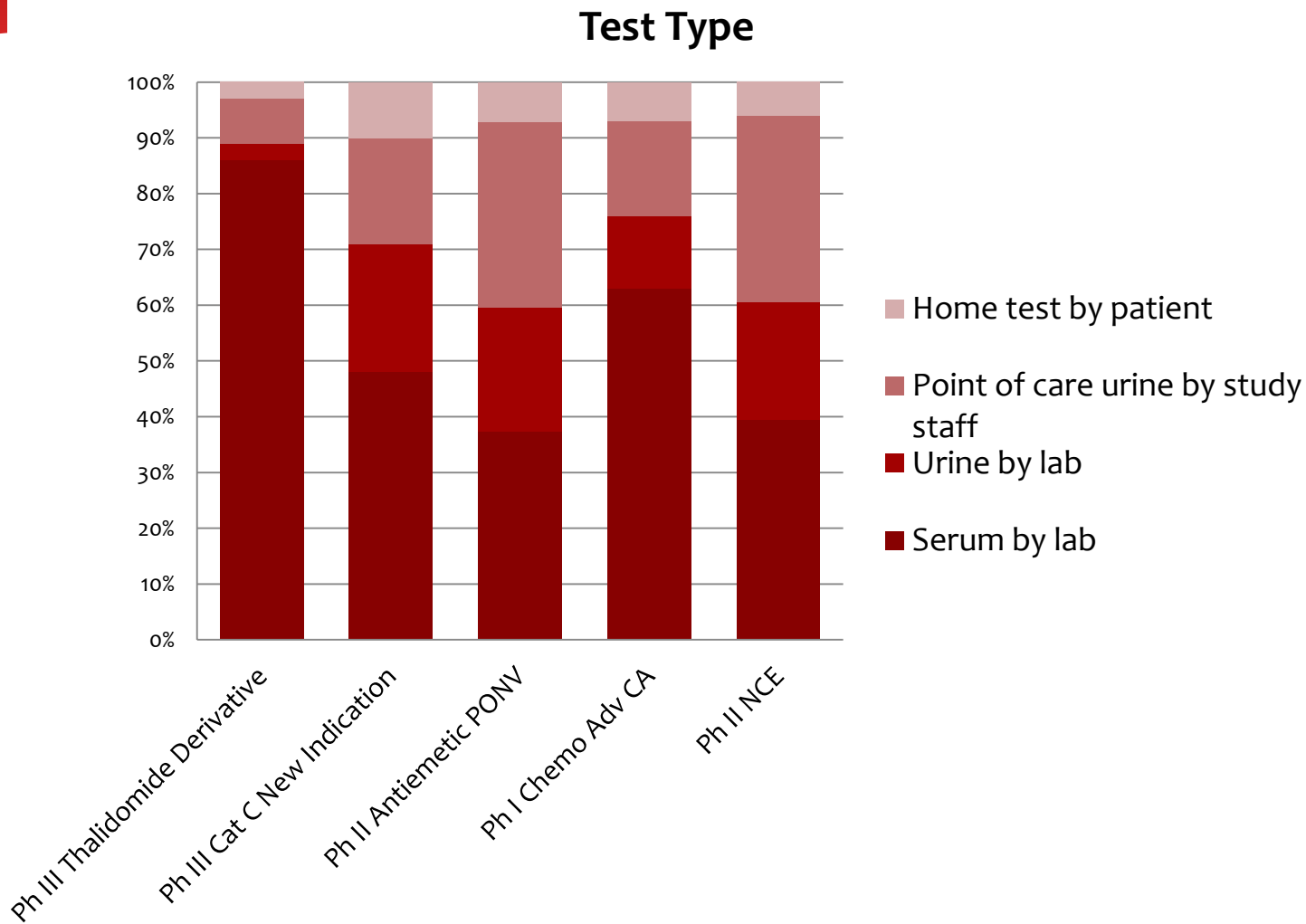


# Consistency!

## Recommend Exclusion

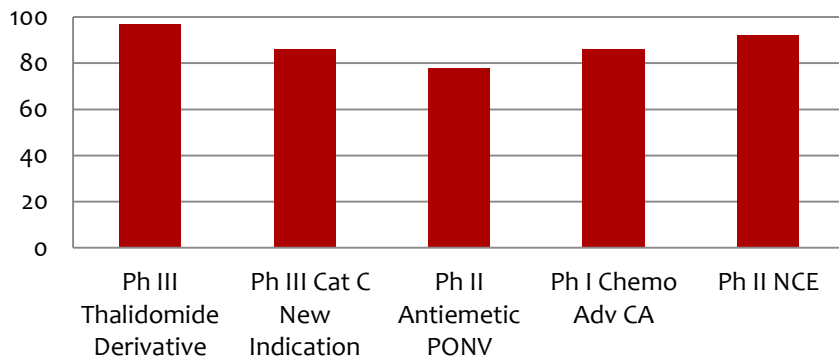


# Type of Test

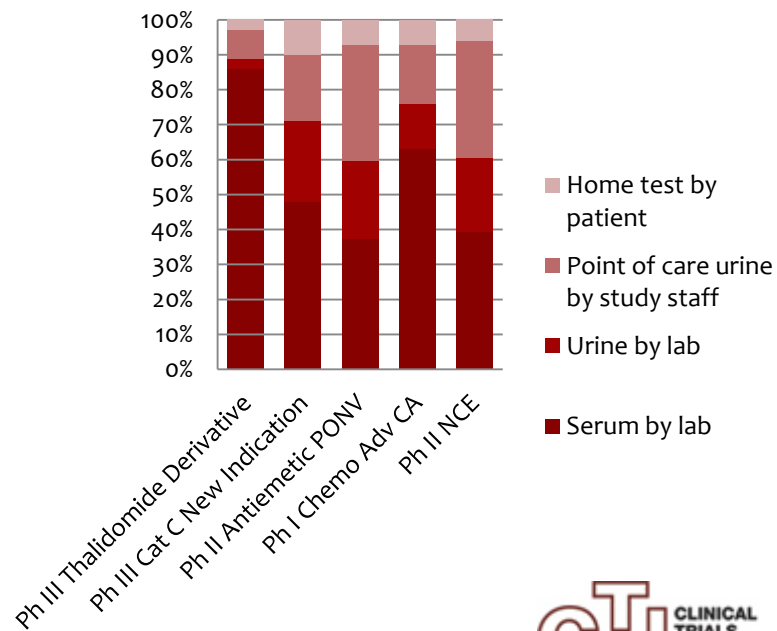


# Type of Test

## Recommend Exclusion

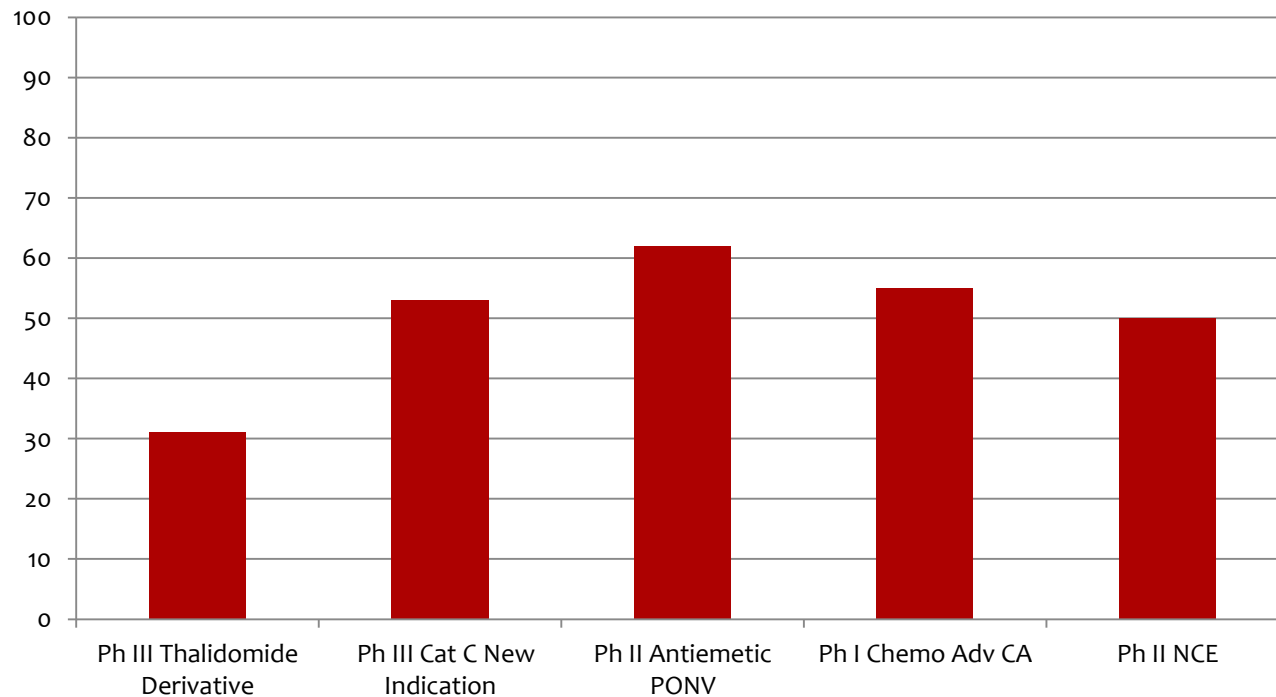


## Test Type



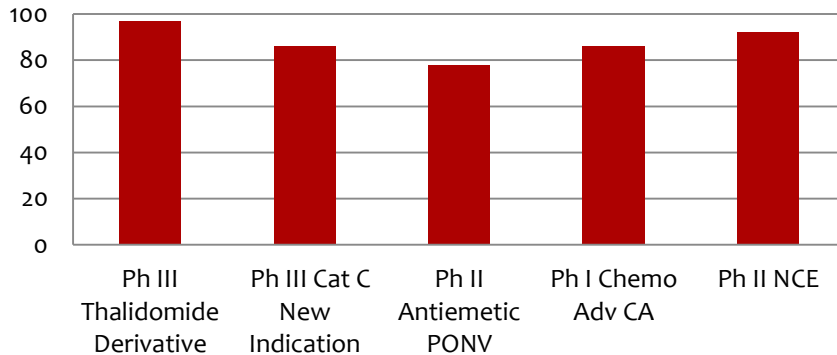
# Timing of Test

## Percentage Choosing Testing Whenever Convenient for Subject

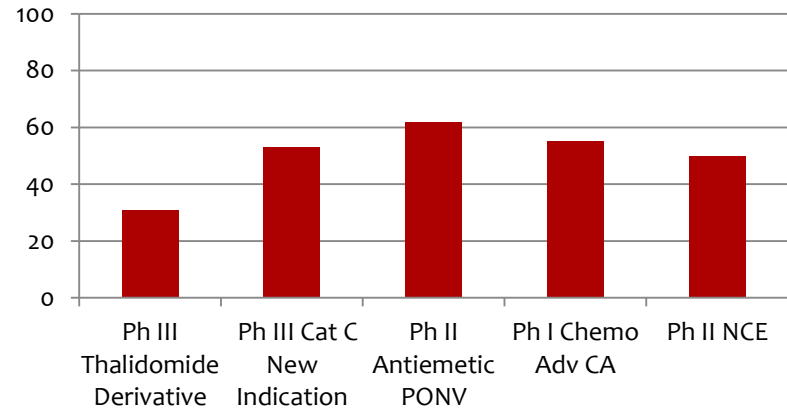


# Timing of Test

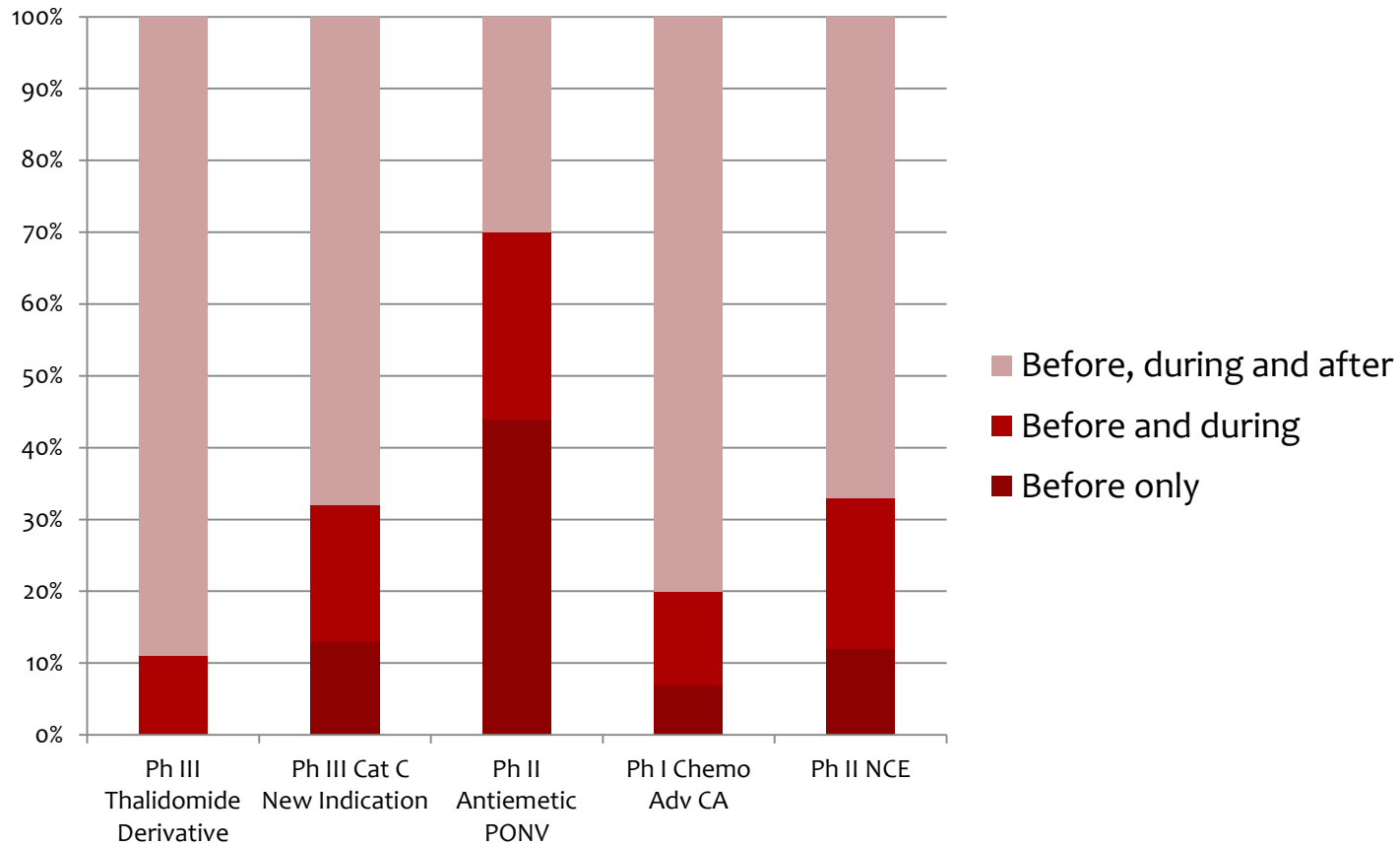
## Recommend Exclusion



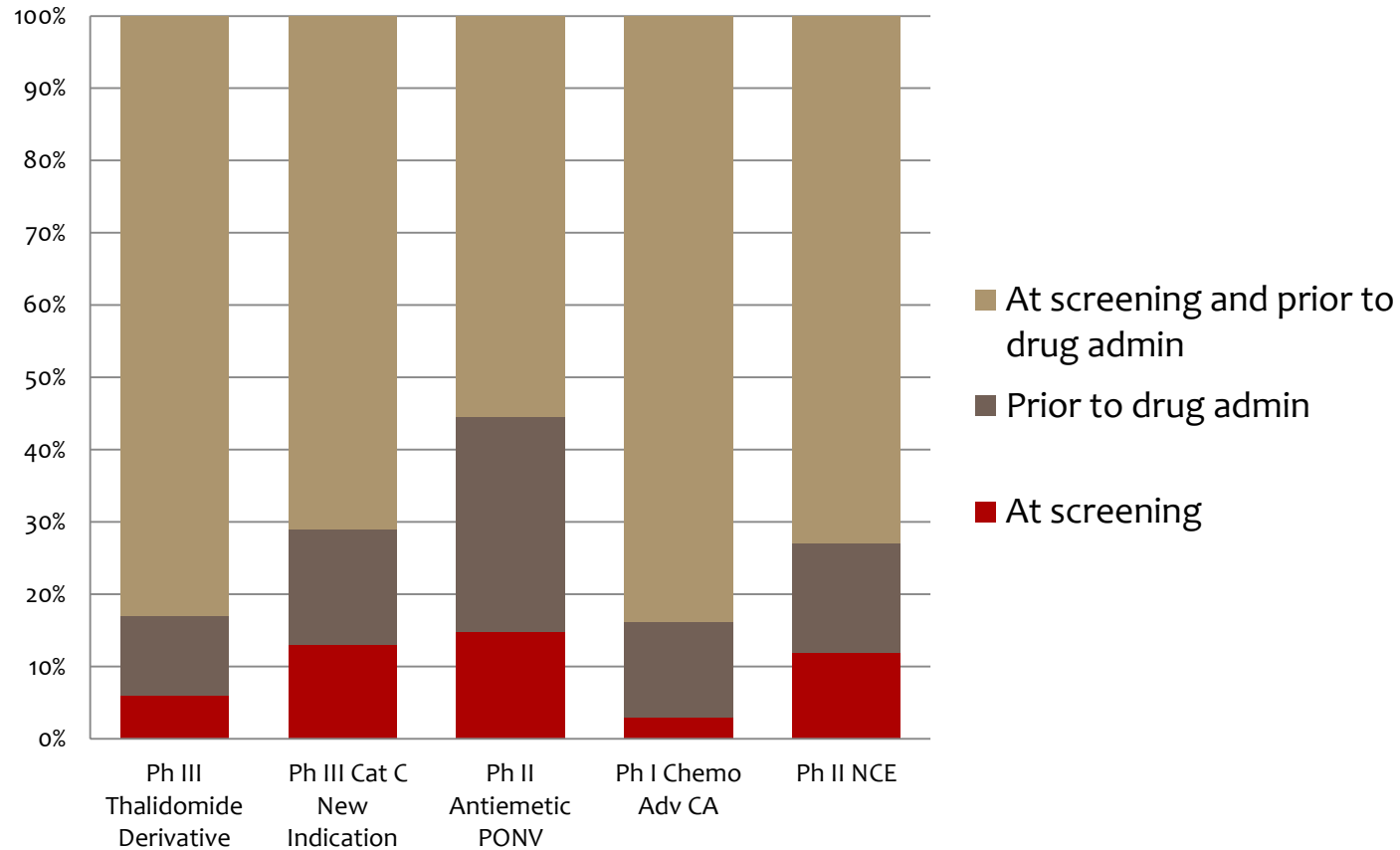
## Percentage Choosing Testing Whenever Convenient for Subject



# What Study Time Points for Testing?

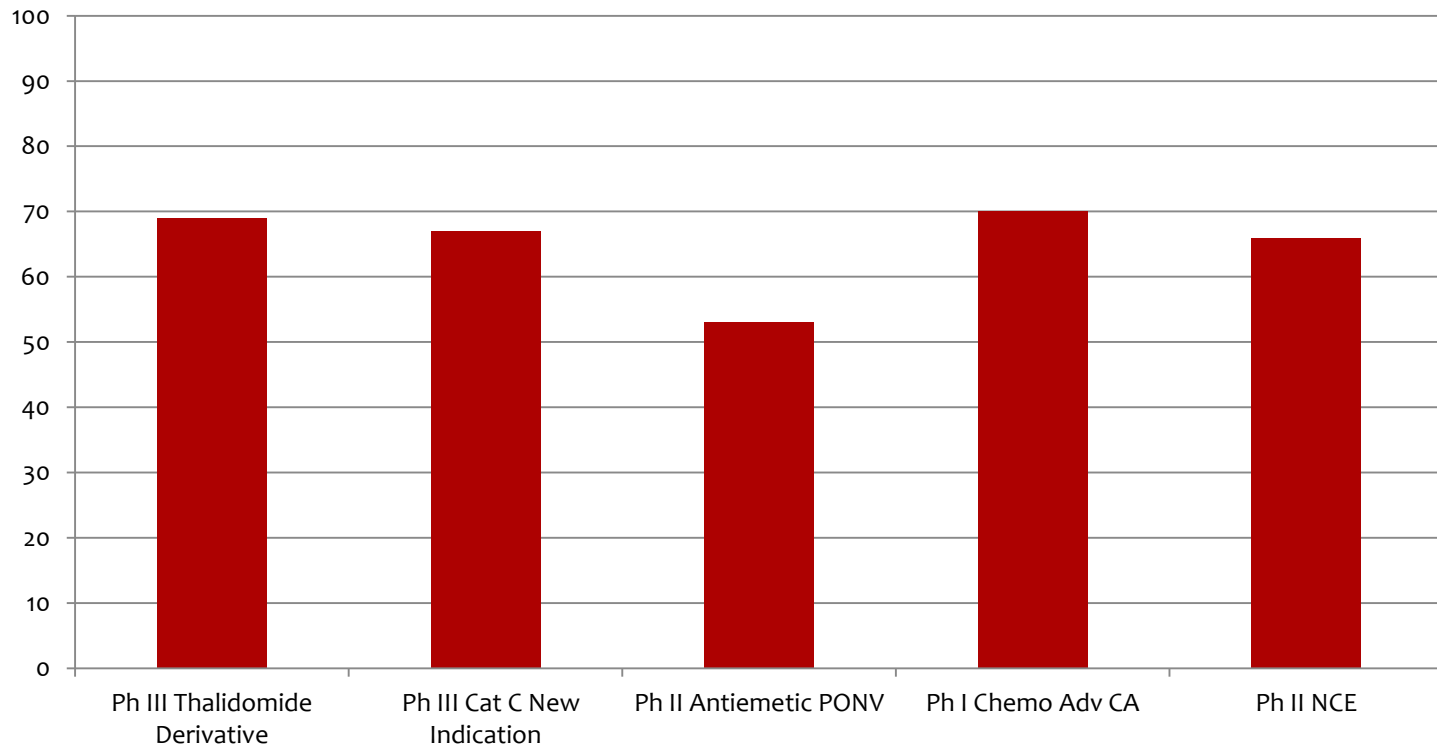


# Timing Relative to Study Drug



# Frequency of Testing

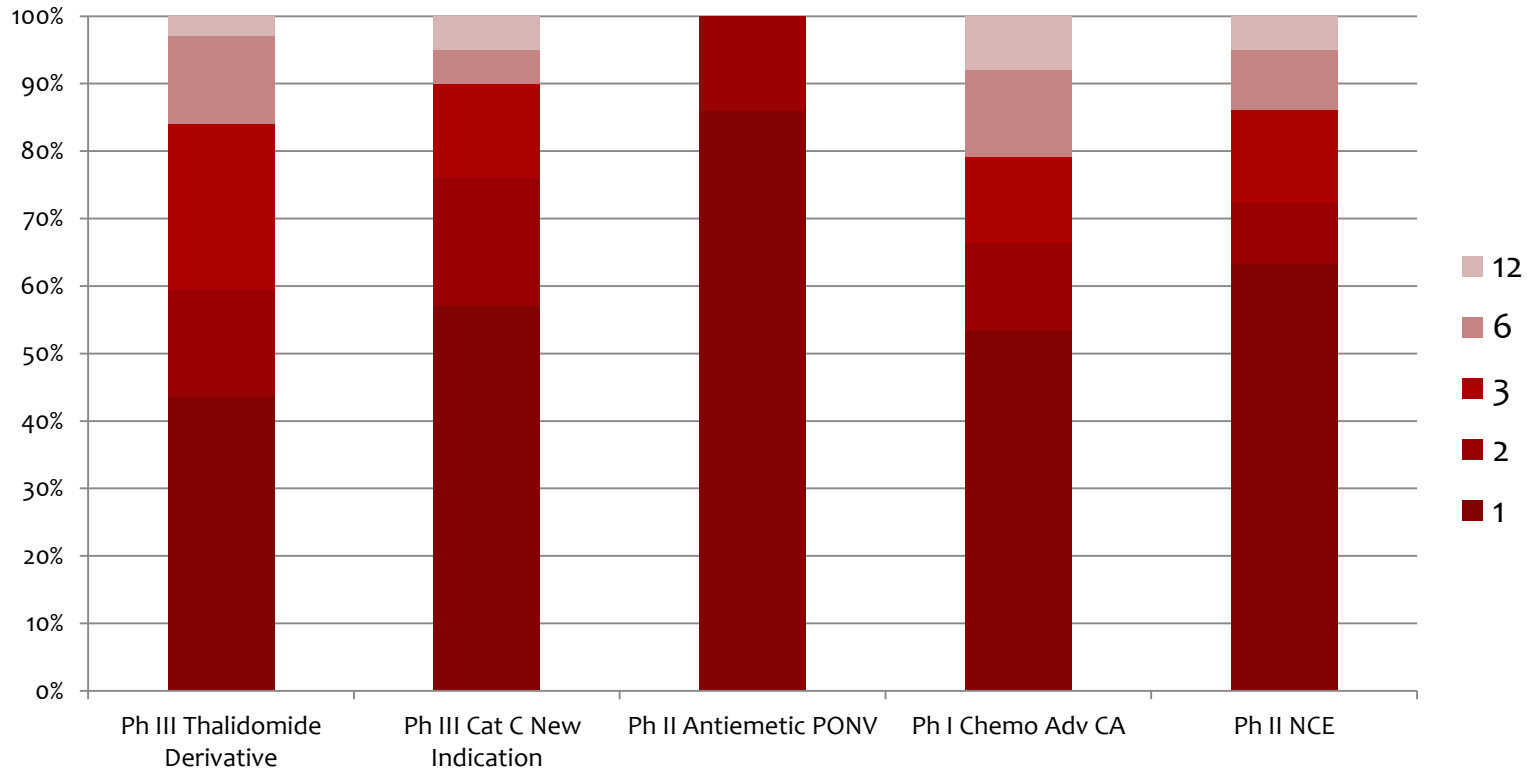
Percentage Choosing to Test Every Month During Study



# Frequency: Other Responses

- Per protocol
- Missed menses
- Subject missed contraception
- More frequently during first trimester
- Same interval as study visits
- Depends on effectiveness of contraceptive method

# How long after study would you follow-up with pregnancy testing?



# Other Issues/Feedback

- Ambiguity about effectiveness of contraception
- Ambiguity about drug metabolism relative to follow-up question
- Ambiguity about timing of testing--should have included “prior to study drug administration”
- Ambiguity about age of subjects
- ?Female partner of male patient taking drug?

# General Impressions

- NPV most important
  - Responses to other questions mostly consistent with that
- Factors affecting NPV (age, contraceptive method, type and timing of test) considered, but some variability

# Discussion