



# New Insights on How to Improve Site Relationships

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# Purpose of sharing site performance metrics

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- Sponsors increasingly under pressure to make better informed site selection decisions to avoid undue cost and relative time impacts on study delivery
- Data available, but often a one way communication (dear site, tell me about yourself – feasibility anyone?)
- Both sides want to manage a "site relationship", but no clear alignment on how the health of that relationship can be measured and mutually agreed upon

Sponsors Needs



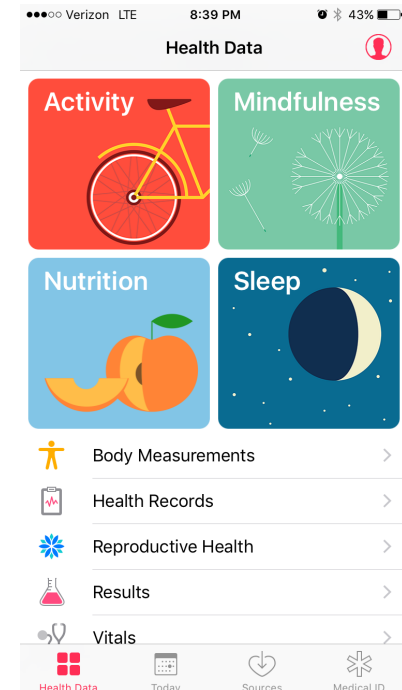
Sites Needs

# Patients are doing it – Why can't we?

- Clinical care rapidly moving to a big data approach of the patient owning their health performance data and sharing it with their physicians to engage and collaborate better on their pro-active care and treatment options:
  - Instrumentation data (wearables, diagnostic tools, etc.)
  - Smartphone data
  - Managing their own e-Medical records

Shouldn't sites have ready made metrics to share on?

- Cycle Time
- Patient Enrollment
- Data Quality
- Other data points?



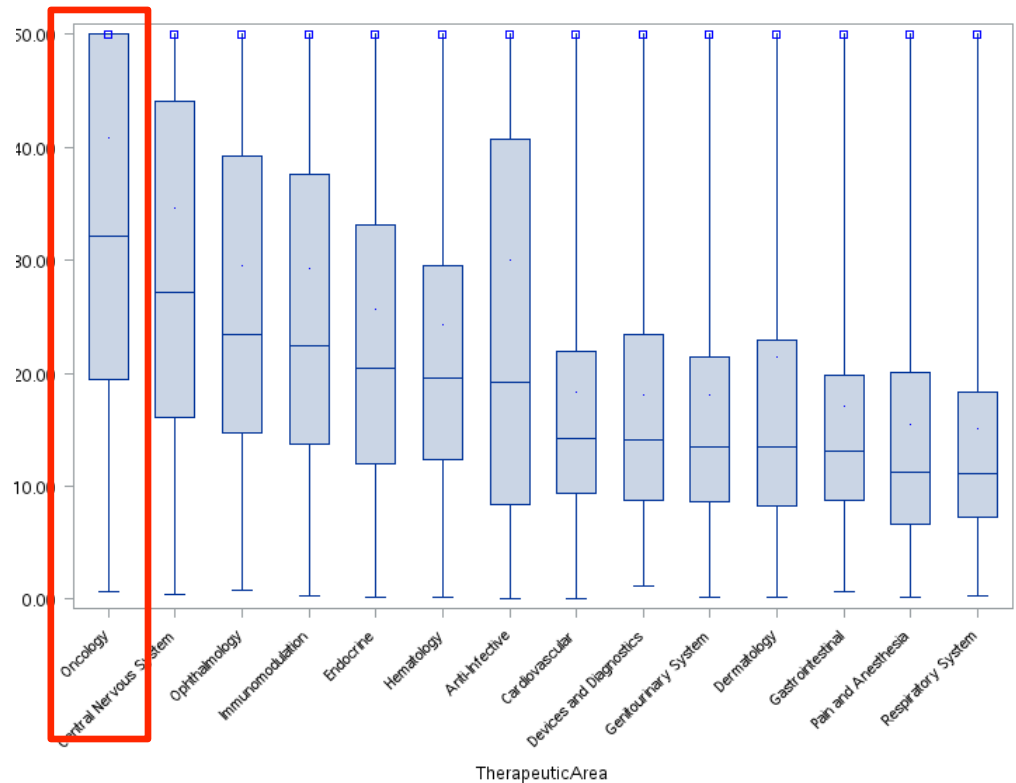
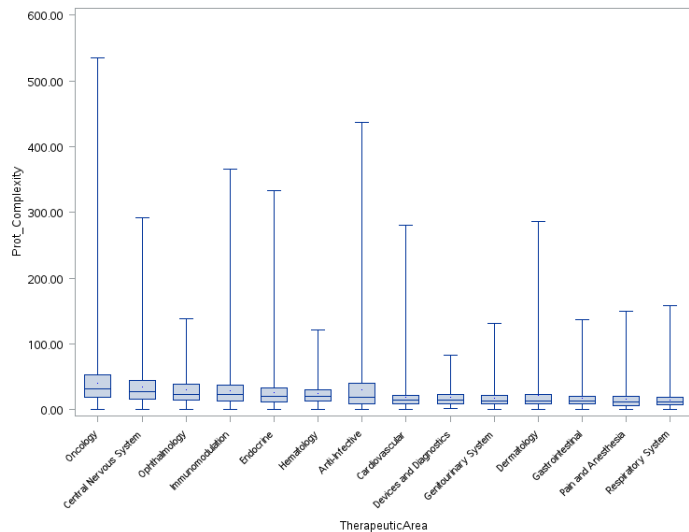
# How do we know what good looks like?

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- Measuring is just the first step – but we need to know what good looks like
  - We also want to know how we compare against the best practice
  - And finally, we want to know what we can do to improve
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- At Medidata, we've identified what good looks like across KPIs, and we have insights into what you can do to improve

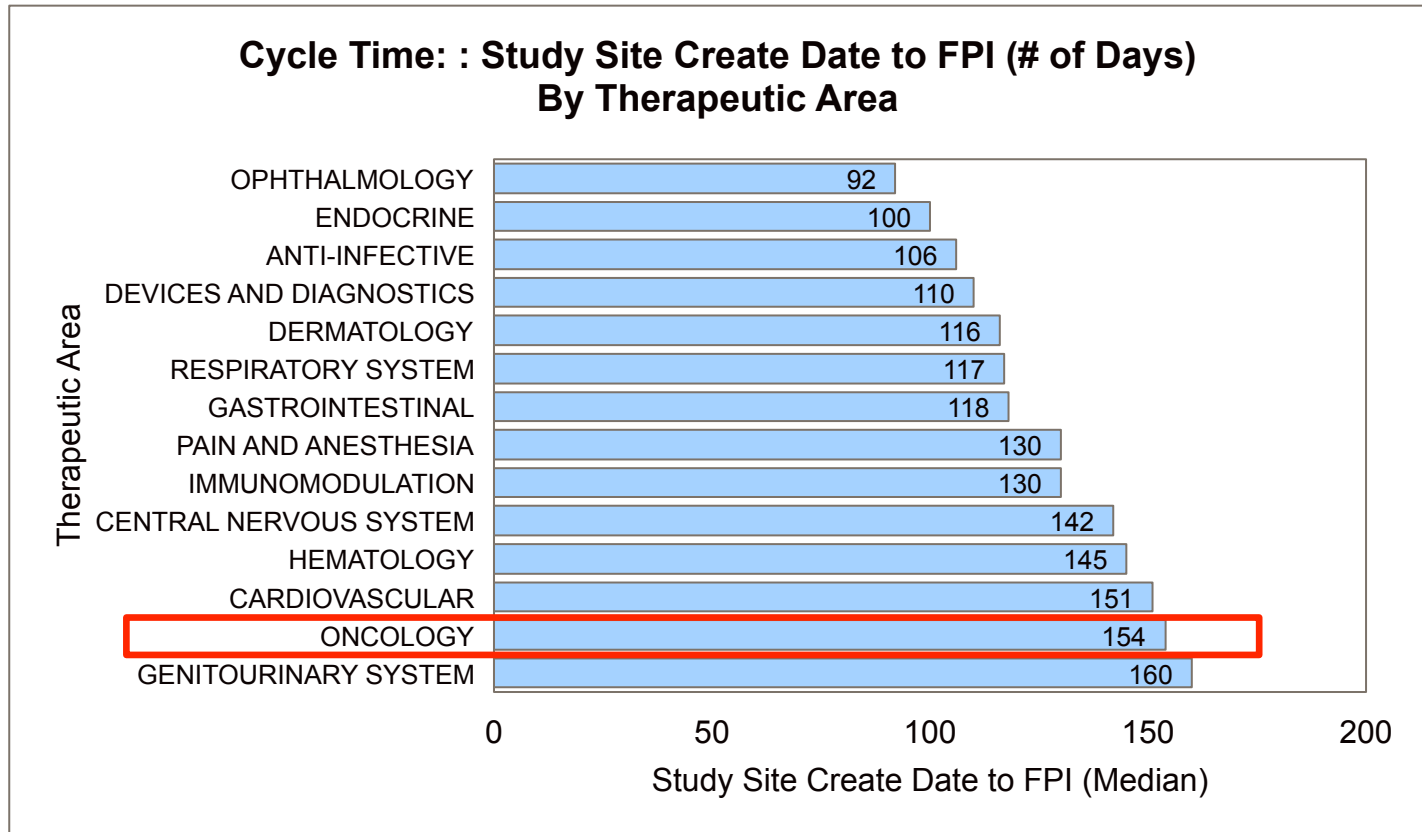
# Some Therapeutic Areas are naturally more complex

Distribution of Protocol Complexity by Therapeutic Area



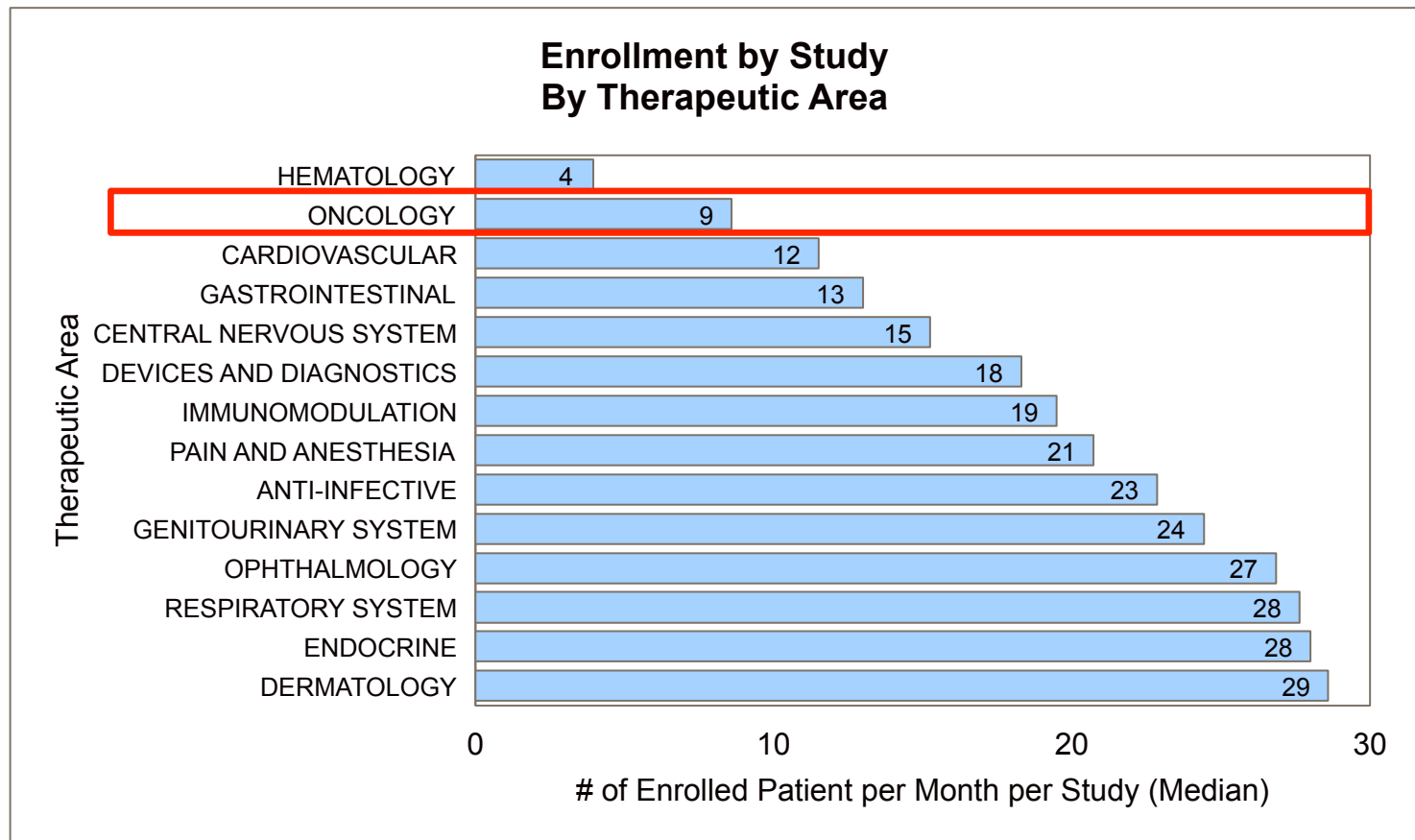
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# High TA complexity often results in longer cycle times...



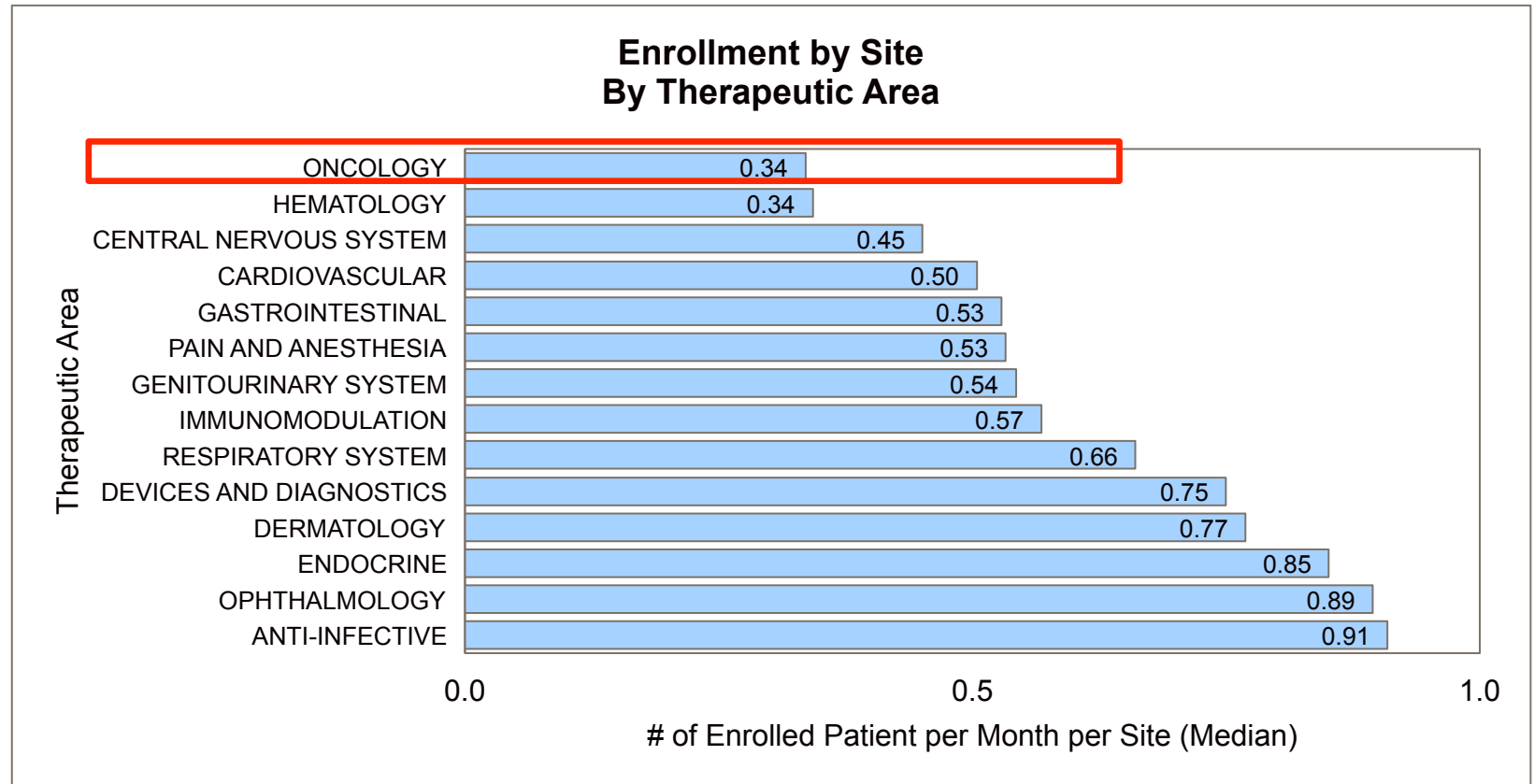
Enrollment Closed, studies > 10 sites  
N = 1,470 studies, phase II & III, all TAs, study FPI 2010-Present

... and is correlated with low enrollment by study...



Enrollment Closed, studies > 10 sites  
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... and with low enrollment by site.



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## What does this mean for sponsors and sites

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### Sites

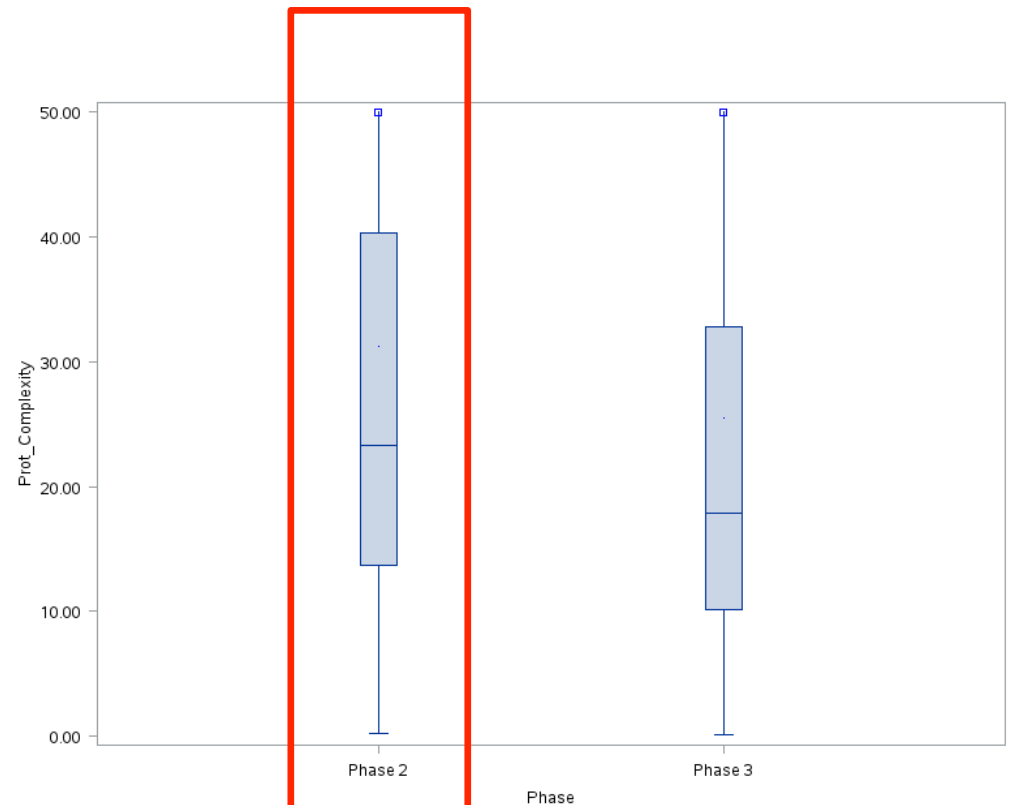
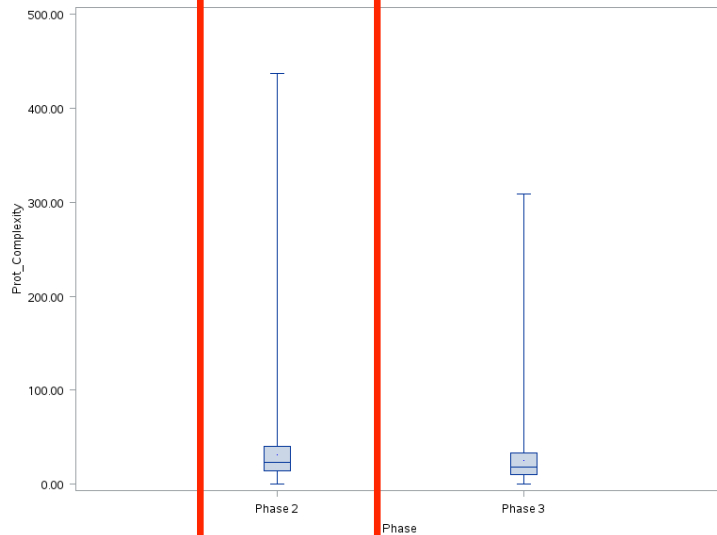
- Providing transparent feedback on enrollment capability based on trial complexity
- Maintaining metrics on these key areas to promote better performance than the average
- Keeping open dialogue on how the Sponsor can help improve site performance with better study design or eliminating barriers

### Sponsors

- Streamlining study design and eliminating as many enrollment barriers as possible in final protocols
- Providing sites with screening/enrollment lessons learned from high performing sites
- Appropriately planning timelines around subject availability limits

# Phase Complexity also has implications for our KPIs

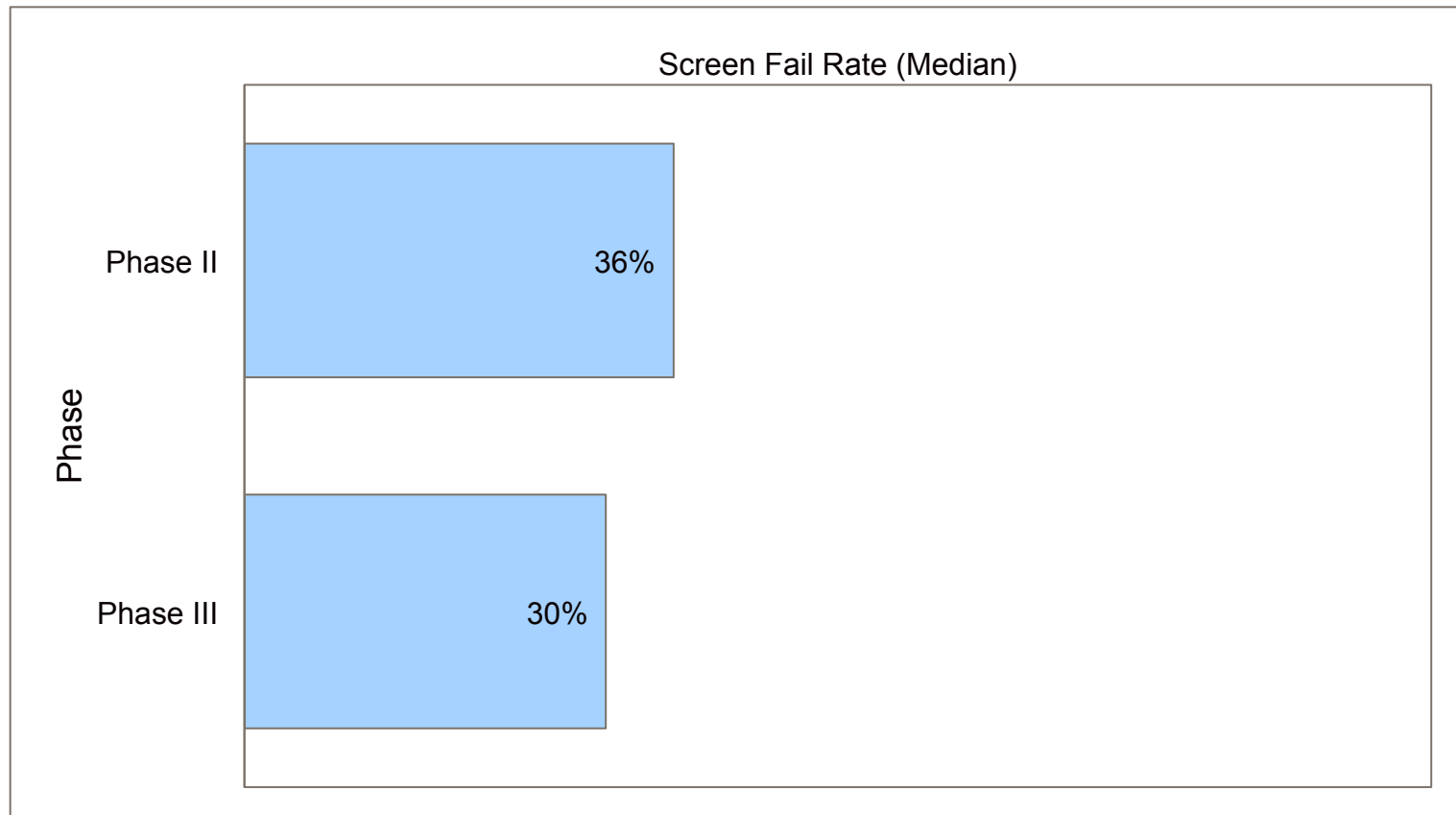
Distribution of Protocol Complexity by Phase



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## We see that complexity born out in higher screen failure rates for Phase II trials

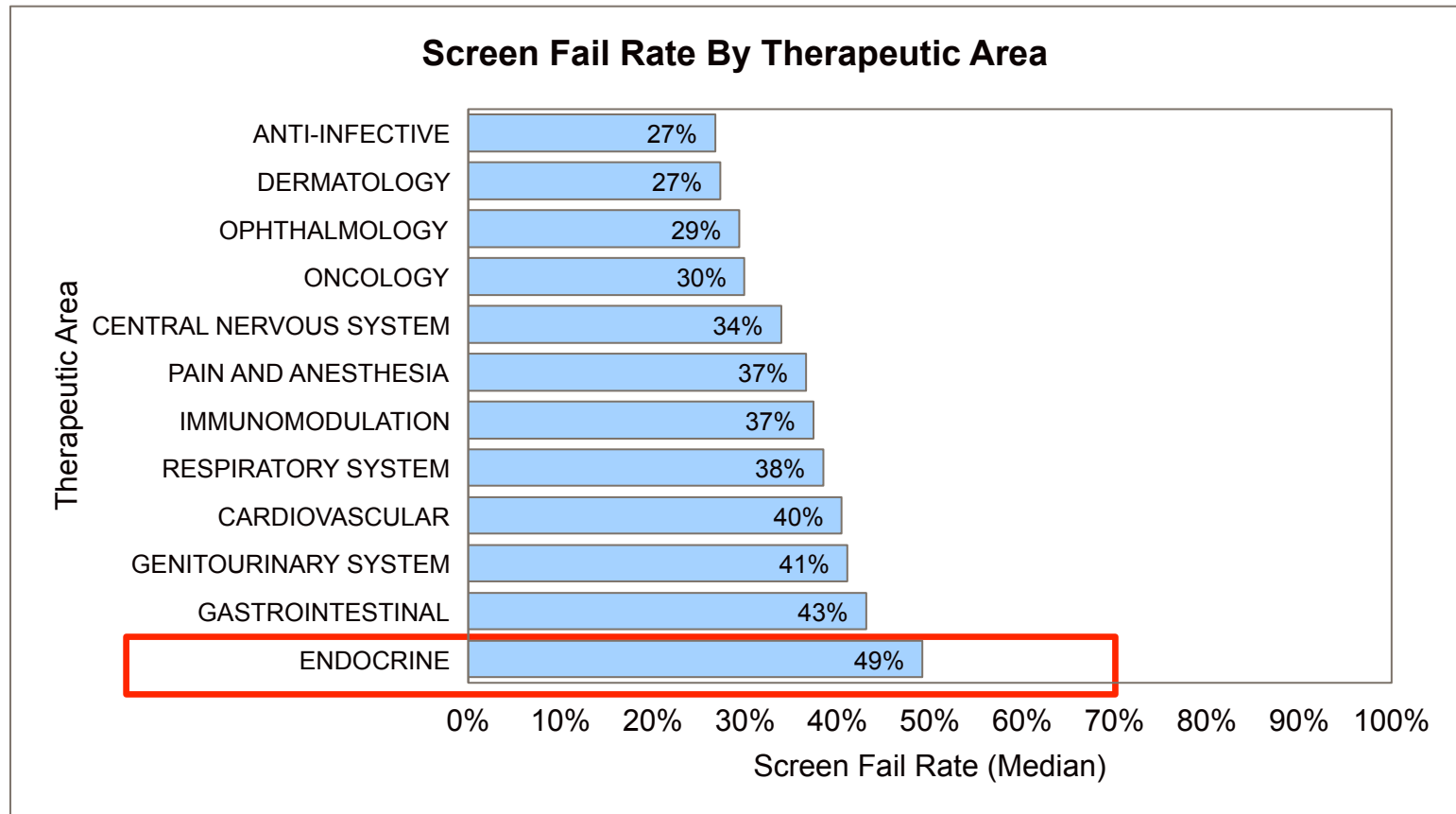
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Enrollment Closed, studies > 10 sites  
N = 1,470 studies, phase II & III, all TAs, study FPI 2010-Present

Screen Fail Rate = Percent of subjects that failed screening relative to the total number of subjects whose screening assessment is completed. This metric may be computed at various levels; e.g., site, site group, study, region, etc.

# Significant variation in screen fail rates across TAs



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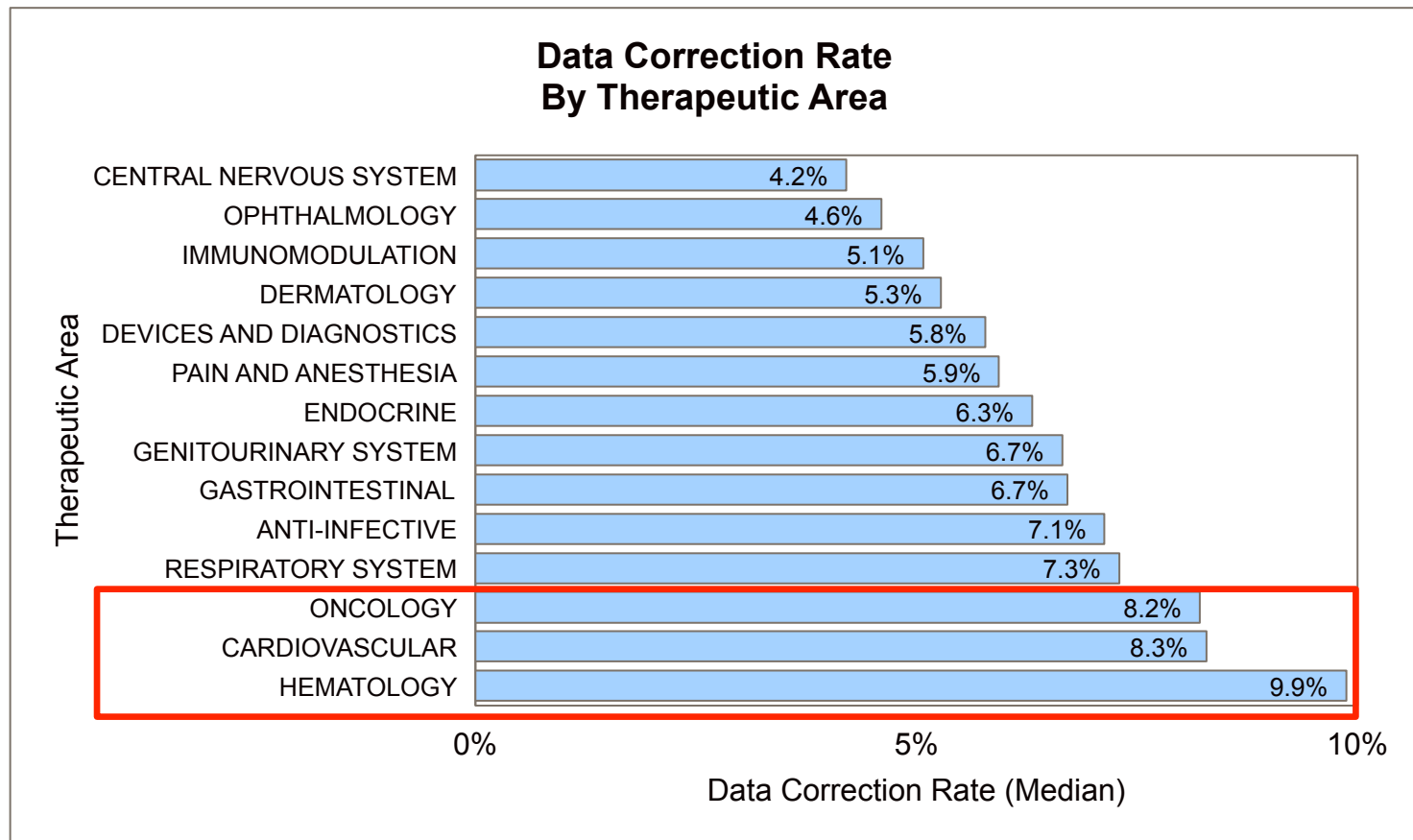
### Sites

- Sharing issues with inclusion/exclusion criteria with Sponsor (what criteria are posing the greatest challenge)
- Promoting capabilities of enrollment efficiency (staying under the average for studies)
- Keeping track of enrollment issues that can be controlled by the site that are not Sponsor issues & providing internal re-training

### Sponsors

- Communicating to all sites specific criteria causing study wide enrollment concerns and proactive ways to control issues (or amend protocol)
- Hold site collaboration sessions for high performing sites to share best practices
- Provide site performance metrics at end of study

# Consider a Targeted SDV approach given data correction rates, even for complex TAs



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## Wrap Up: Building better relationships

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### Sites

- Continue to promote data quality through quick time-to-entry after patient visit (the quicker you enter data, the faster the Sponsor/CRO can help clean up issues)
- Focus prep for monitoring visits on critical data aspects of the study, safety review, IP accountability and screening/enrollment issues
- Share performance metrics during course of trial and ask for comparison metrics

### Sponsors

- Continue to update sites on their performance relative to peers
- Ensure CRAs approach the site as a coach/teacher/mentor, NOT a task master
- Pay sites accurately and quickly for work they perform (at least monthly)

# Appendix



# What is Protocol Complexity?

- Protocol complexity or Site Work Effort is a metric which provides a quantifiable, repeatable measure of effort required to conduct a study.

$$\sum \left\{ \left[ \frac{\text{Number of times each procedure or clinical research activity is conducted}}{\text{Completed Patient}} \right] \times \text{Work Effort Unit} \right\} = \text{Site Work Effort}$$

- Work effort unit* is a mathematical expression representing the effort required to conduct each procedure and clinical research activity.

# What is Protocol Complexity?

Clinical Procedure	Study Frequency	Work Effort Unit (RVU)	Site Work Effort
Serum Pregnancy Test	2	0.22	0.44
Adverse Event Data Capture	13	0.20	2.60
Brief Visit w/ Vitals	11	0.17	1.87
CBC w/ Plate & Auto Diff	11	0.11	1.21
Chemistry Panel	11	0.33	3.63
CIBIC+ questionnaire	6	1.88	11.28
Comprehensive Hist & Vitals	1	3.00	3.00
ECG w/ Interpret. & Report	11	0.17	1.87
Follow up Visit and Vitals	2	0.45	0.90
Habits and Drug Use	1	0.20	0.20
Neuropsychiatric Inventory	11	1.38	15.18
Brain MRI With Contrast	7	1.78	12.46
Total	86		54.55