

UC BRAID IRB Metrics

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Rationale

- Why Track IRB Performance
 - Increasing attention to clinical research administration performance
 - Benchmarking and comparative reporting used to identify performance strengths and gaps
 - Drive performance improvement initiatives

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Project Goals

- Establish infrastructure to support the collection and sharing of harmonized metrics data across campuses
- Provide benchmarks for comparison and opportunities for collective learning
- Identify best practices and models that can be adopted
- Assess interventions over time

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What we did: Harmonization

- Harmonized definitions for IRB processes
- Harmonized metrics and data to be collected
- Input variables
 - Campus-specific Characteristics
 - Project Characteristics
- Created guidelines to facilitate uniform interpretation and data entry

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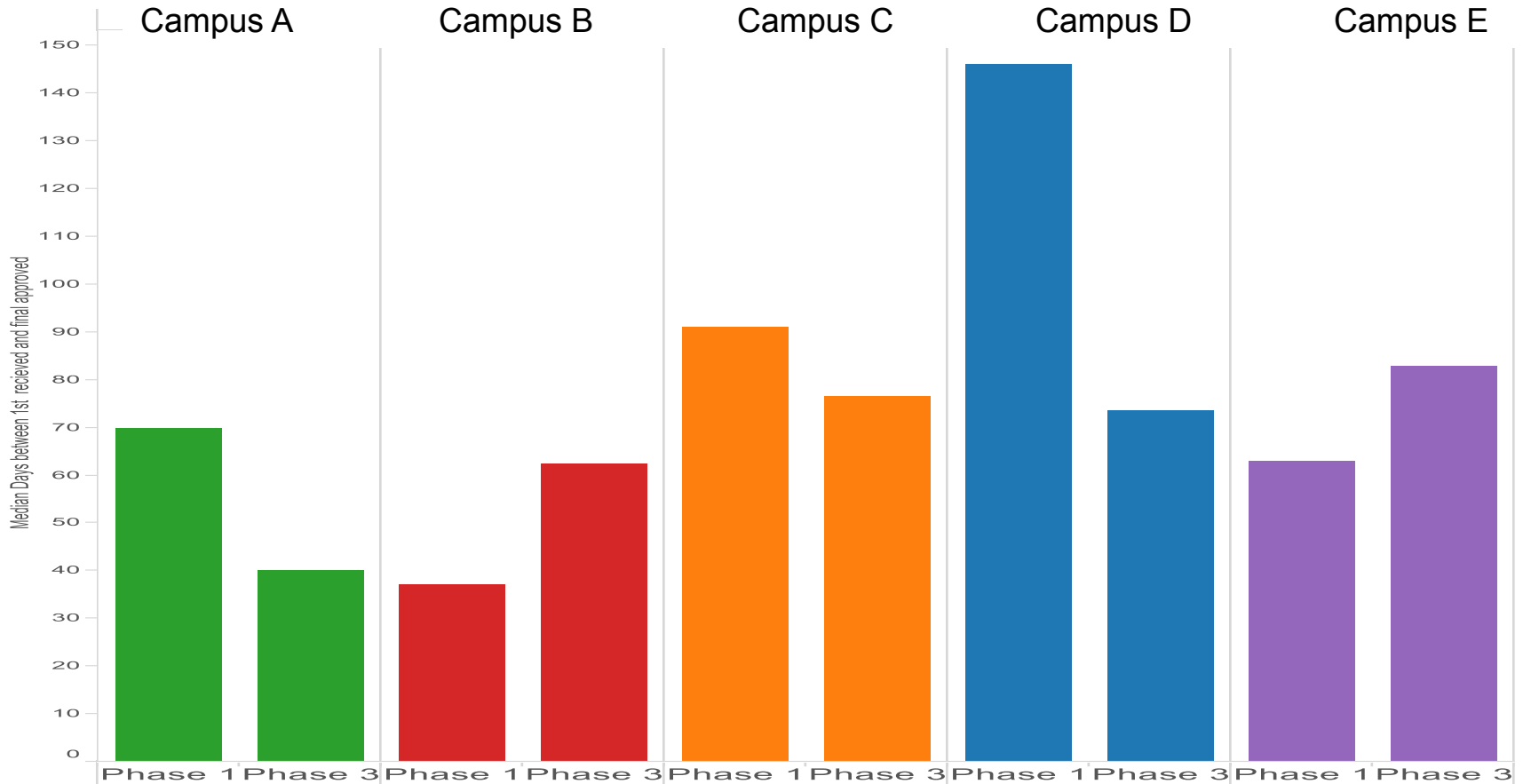
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	Mean	Median	1 st Quartile	3 rd Quartile	S.D.
Days between 1 st received and 1 st reviewed	35	24	16	37	41
Days between 1 st reviewed and approval	55	41	18	71	62
Days between 1 st received and approval	88	73	43	112	71
Number of ancillary reviews required prior to IRB approval	2	2	1	3	1.2
Phase 0 / Phase I / Phase II / Phase III/Device					
	3% / 18% / 33% / 32% / 10%				
Commercially authored	68%				
PI-authored	27%				
Federally funded	15%				
Private Foundation funded	28%				
Multi-site	67%				
Investigational device	10%				
Investigational device Exemption	3%				
Investigational drug	83%				
Oncology/Hematology	41%				
Scientific Review Committee Required	59%				
Radiation Safety Review Required	60%				
Medicare Billing/Coverage Analysis Required	86%				
Conflict of Interest Review Required	15%				
Biosafety Review Required	21%				

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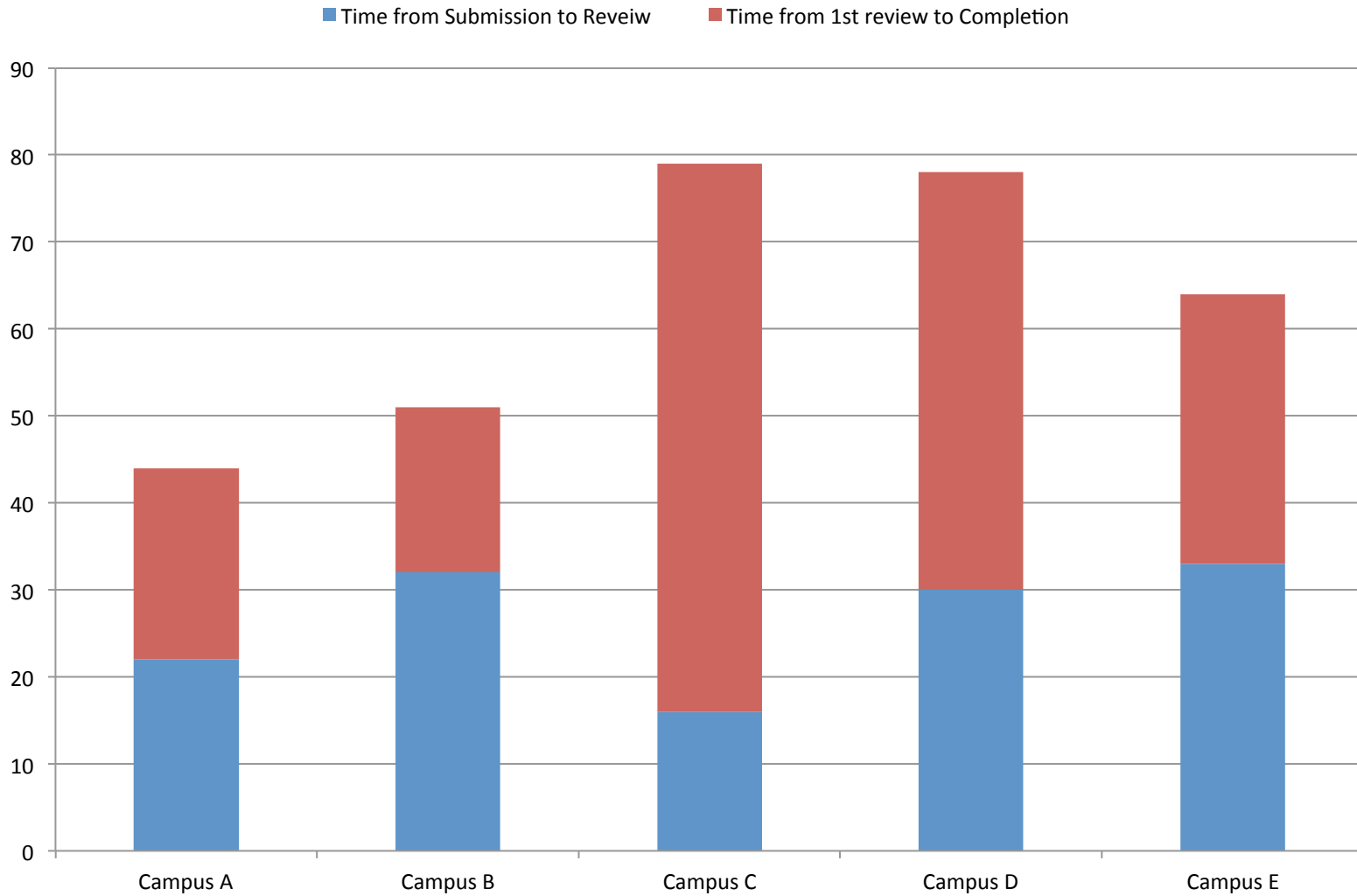
Median Days from Time of 1st Submission to Approval: Campus X Study Phase



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Comparing Time from Receipt to Time of Review and Time from Review to Approval



IMPACT

UC-BRAID IRB Metrics can

- Identify unintended sources of delay both locally and at the UC-System level
- Identify non-IRB sources of delay and opportunities for improving parallel processing
- Identify best practices and models that can be adopted

IRB is the “gatekeeper” but not the sole-or even major contributor to time required from study concept to approval

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Next Steps

- Complete initial data collection; analyze variances and identify interventions
- Long-term goal to collect these data on a periodic basis
 - for comparison and benchmarking
 - to assess process improvement projects over time

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“Per capire veramente
qualcosa, cercare di cambiarlo”
To truly understand something,
try to change it

Celso Fontanesi