



2014 CANCER CENTER BUSINESS SUMMIT

Building the Oncology System of the Future:

Transforming Patient Care Through Data Transparency and Analytics



Integrating Efficiency and Effectiveness through the Use of Strategic Analytics

Linking Mission, Science, Resources, and Execution

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Mandate

Our Goals

The [ORGANIZATION] is undertaking a broad effort to re-engineer its process and approach related to the development and opening of clinical trials including the protocol success, quality of review, length to open, strategic planning, staff training, and evaluation.

- We envision serving as a national model for cancer protocol development and review.
- We seek to decrease time required to open a clinical trial at [the organization] from scientific review to opening for patient accrual from 208 median calendar days to 60 days, while maintaining or increasing quality and safety.
- We seek to empower clinical staff involved in the protocol development process with the knowledge and tools to plan and carryout outstanding human subjects research.
- We will maintain high ethical standards and meet all regulatory requirements.
- We will continually improve through cyclical evaluation and responsive change.

Symptoms

Long Development Time

Overall Development Time	n	Median	IQR*	Min/Max
Scientific Review to First Patient Enrollment	263	208	142-308	47-1435

Low Enrollment Performance

- A total of ~15% of all trials opened and closed with no accrual
- A total of ~30% of studies did not achieve at least 20% of stated maximum accrual goals (minimal accrual goal data was not available so maximum was used)

Portfolio of Trials Decoupled with Research Mission

Evaluation of the portfolio of clinical research revealed that significant number of trials being conducted did not align to the definition of 'high impact' as translated from the clinical vision*

Inbalance of Trials in Portfolio



Net: In-flow *minus* out-flow = 21 new trials

*Preliminary Observations needing to be verified / validated

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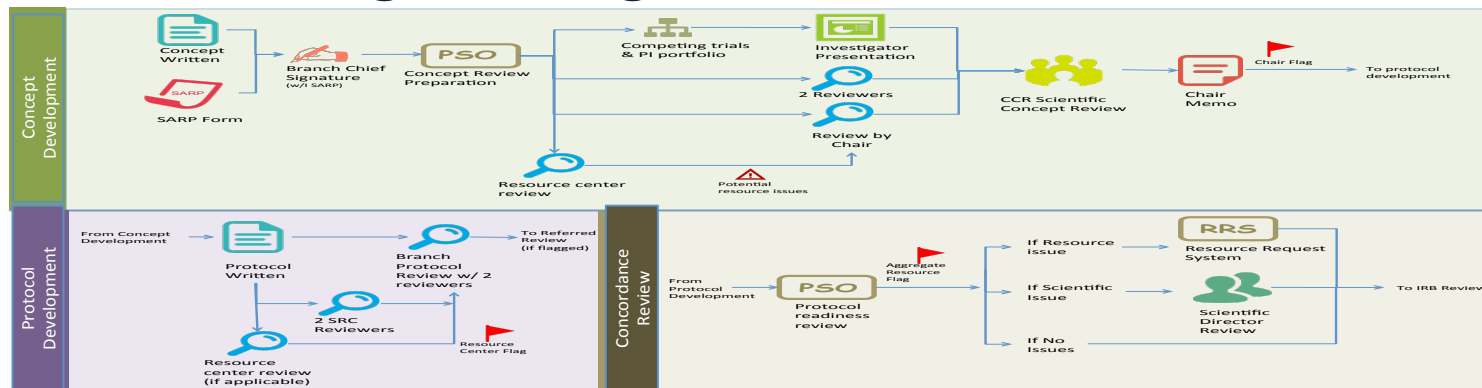
Parallel Reengineering Efforts

- Recently completed restructuring of the clinical program organization
- Defining Clinical Mission* & Translating into Action

1. Engage outstanding researchers in **consequential investigator-initiated** clinical research in a culture of **close interaction between basic and clinical science**
2. Provide the **flexible funding** necessary to support **innovative, high impact bench-to-bedside research** through access to the [core competency of institution]
3. **Collaborate** with **world-leading researchers** [within the institute] and throughout the [research] community

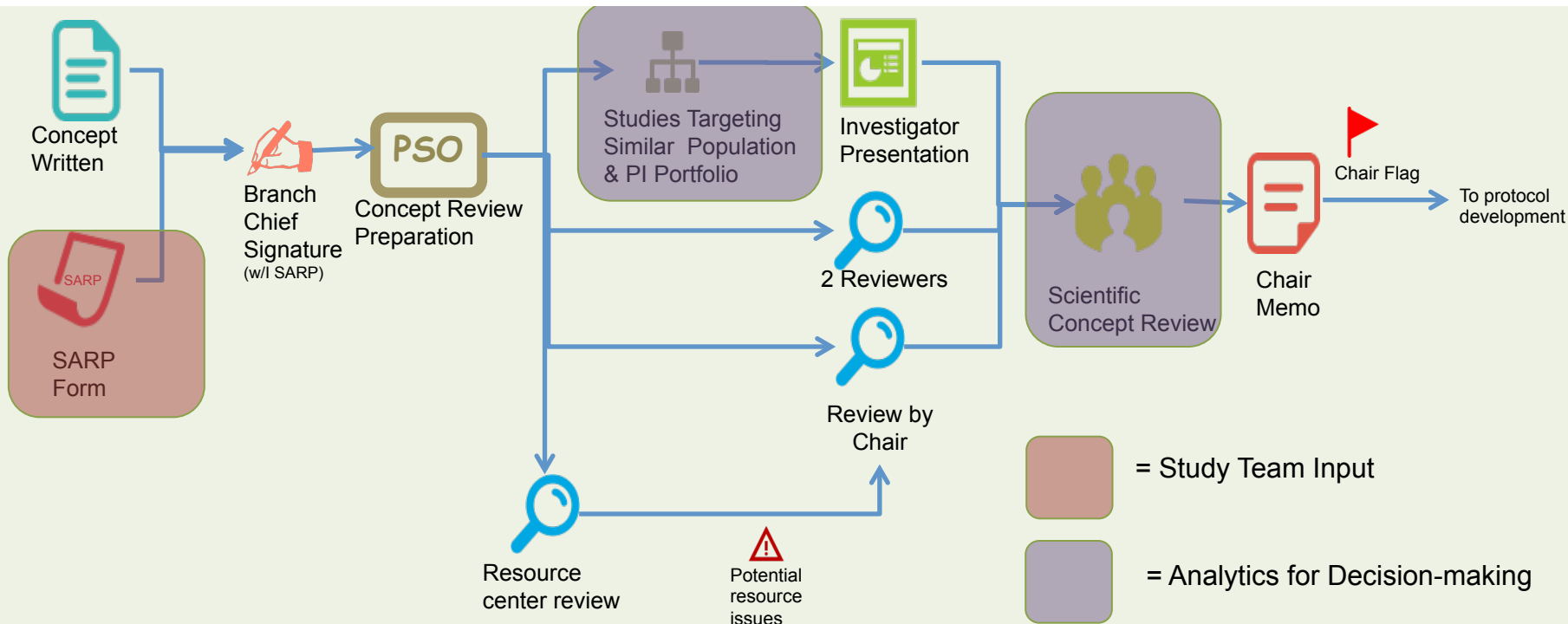
* Blinded to protect identify of institution

- Process reengineering of Clinical Trial Review

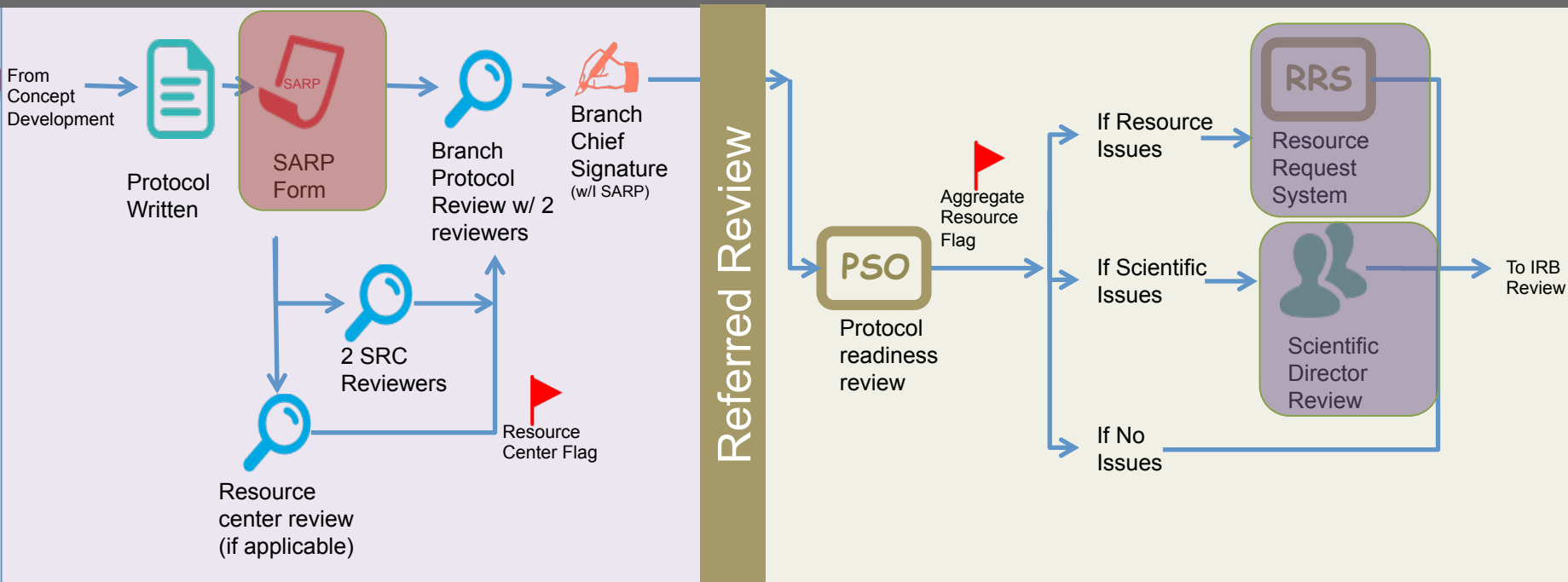


Integrate analytics for greater **efficiency** in clinical research operations while simultaneously improve the **effectiveness** of executing the organizational mission

Concept Development



Protocol Development



Framework for Analytics



Linkage of Analytic Tools to Clinical Mission and Metrics/Measures

		Analytics				
		Leadership Dashboards	SARP	Clinical Trial Flowsheets	Research Unit Dashboards	Simulation
Clinical Mission	Strategy	■	■	■	■	■
	Consequential Impact	■	■		■	■
	Resource Allocation	■	■		■	■
	Operational Feasibility	■	■	■	■	■
Metrics	Patient Demographics	◆	◆	◆	◆	◆
	Clinical Research Demographics	◆	◆	◆	◆	◆
	Clinical Research Performance	◆		◆	◆	◆
	Hospital Utilization	◆			◆	.
	Resources	◆	◆		◆	◆
	Personnel	◆	◆		◆	◆

Translation of the Mission to the Strategic Alignment & Resource Planning (SARP) Form

Clinical Mission and Vision

The image displays three screenshots of the Strategic Alignment and Resource Checklist (SARP) form, which is used for clinical mission and vision. The form is divided into several sections, each with a specific focus:

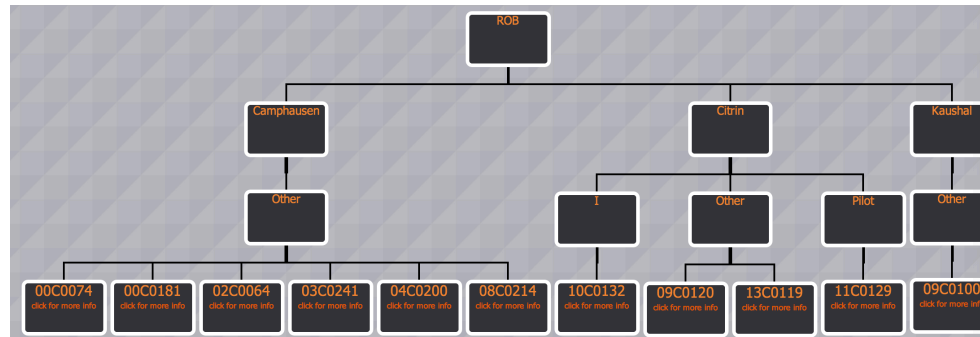
- Study Impact:** This section asks why the study is important for the organization to do now. It includes questions about the study's impact on the organization's mission and vision, and whether it is a translation of CCR laboratory research or an extension of a prior study phase completed at CCR.
- Study Demographics:** This section asks for targeted patient population information. It includes questions about the study's focus on specific patient groups, the need for research in this area, and the identification of unique resources used for the study.
- Continuity Planning of Protocols:** This section asks for information about the study's continuity. It includes questions about whether the study is an initiation of a new clinical area at CCR, a continuation of an existing area, or a study that is part of a long-term commitment and tolerance for a lack of significant early clinical impact.
- Study Utilization of Unique [Organizational] Resources & Operational Feasibility:** This section asks for information about the study's utilization of unique resources. It includes questions about whether the study is a new cancer or under-studied population, why the study is important to be conducted within CCR, and whether the study is a multi-institutional trial.
- Study Resource Needs:** This section asks for information about the study's resource needs. It includes questions about whether the study can be completed within the existing branch resources, whether additional CCR funds are needed, and whether the study requires additional resources from CCR to support the research.

The form also includes a section for PI & Chief Sign-off, where the Principal Investigator and the Chief of the branch must sign off on the study. The form is titled "Strategic Alignment and Resource Checklist" and is page 1 of 3.

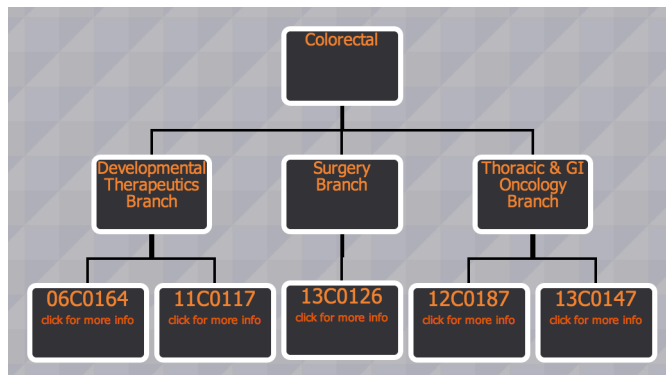
- SARP facilitates the linkage of protocols to the Clinical Mission & Vision, Assessment of Impact, Critical Strengths, and Portfolio Evaluation
- SARP integrated into the entire process to assess scientific importance, strategic priority, operational feasibility, and resource utilization

Clinical Trial Flowsheets

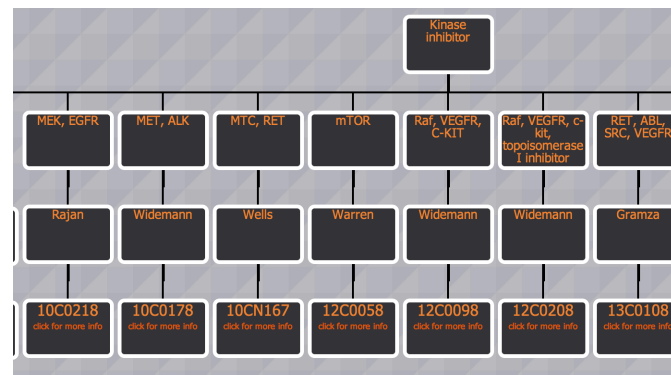
By Branch



By Diagnosis



By Mechanism



by Agent and Mechanism Detail

- Transparent & Accessible to all Basic and Clinical Researchers
- Created dynamically by researcher requests

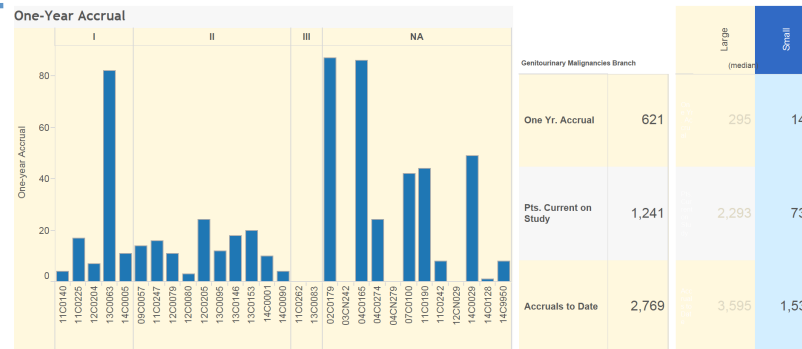
Research Unit Dashboards

Personnel Data

Research Unit Name							PIN 9,057
				Small			
Classification Clinical				Non-appropriated Clinical Resources Included			
5.0 Investigators (0 recruits)	1.0 Staff Clinicians & Scientists (0 recruits)	2.0 Physician Extenders (2 recruits)	6.0 Research Nurses (1 recruits)	2.0 Clinical Admin Support (0 recruits)	3.6 Data Managers (0 recruits)	\$2,887K * rollover to see excluded personnel costs	
	Investigator	Staff Clinician & Scientist	Physician Extender	Research Nurse	Clinical Admin Support	Data Manager	Est. Personnel Costs
Large	4.7	3.1	2.4	6.4	3.3	4.3	\$3,520K
Small	2.4	1.4	1.7	2.1	1.7	1.1	\$1,380K
Support	6.0	5.5		1.0	4.0		\$2,404K
Study Type All							

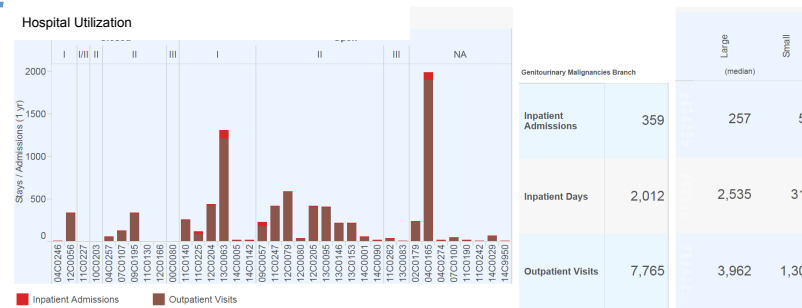
Parameters & Characteristics

Annual Accrual Data

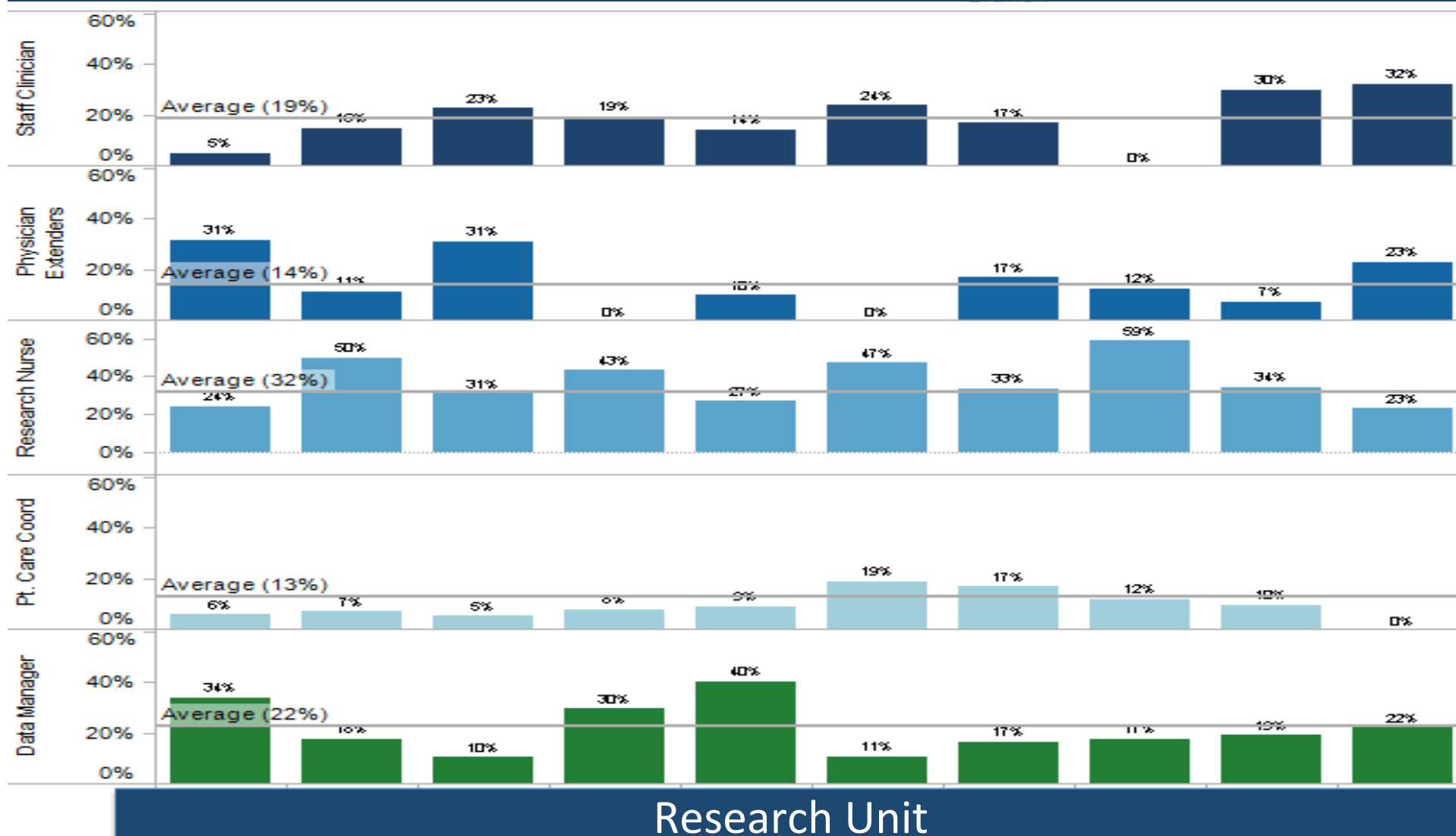


Research Unit Comparison Data

Hospital Utilization

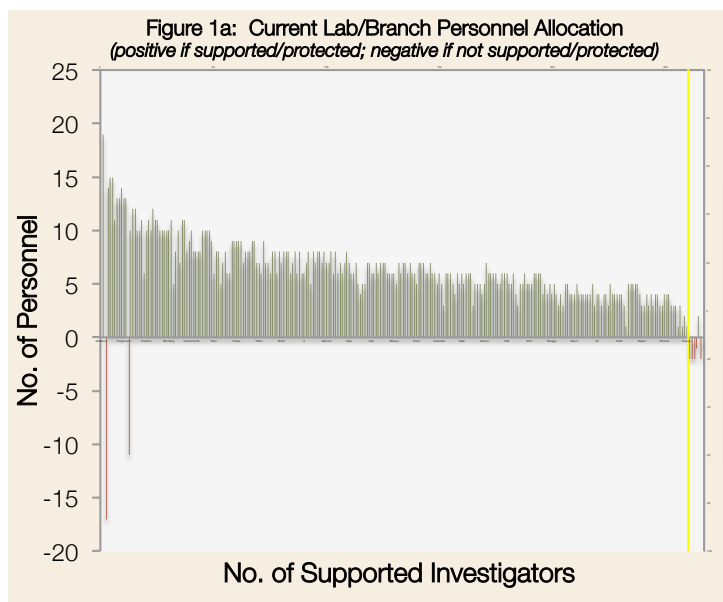


Simulation & Comparison: Clinical Staffing Levels Across Clinics



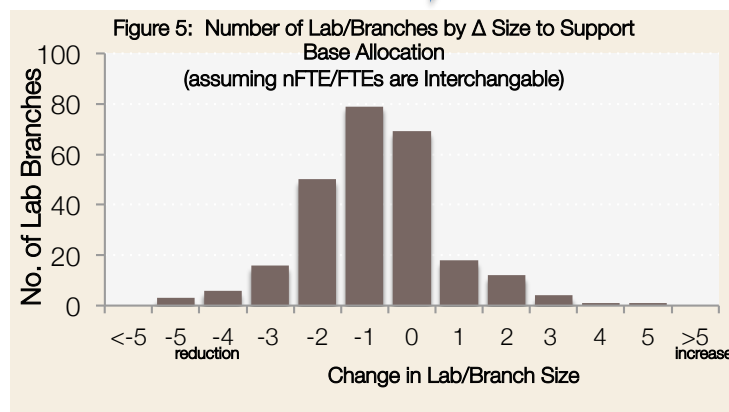
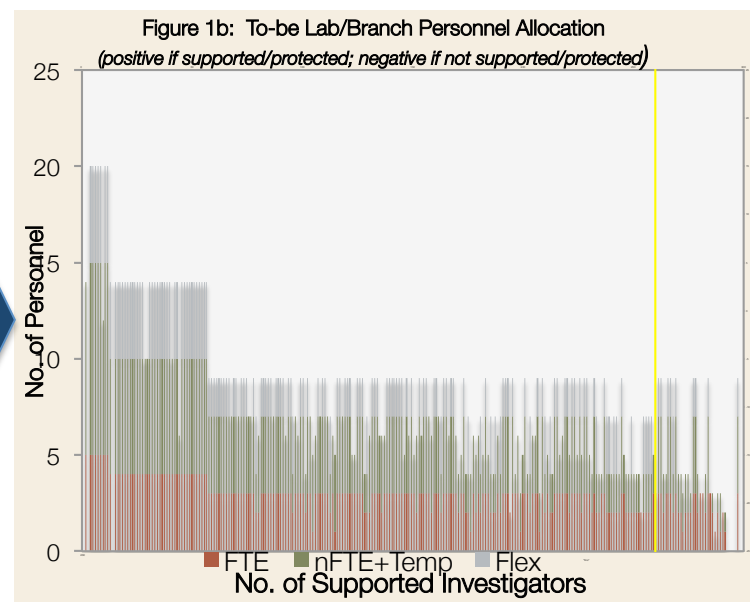
- Percent of Clinic FTE
- Line denotes average FTE

Simulation & Comparison: Implementing Standardized Staffing Models



Standardized staffing based on:

- Performance
- Volume / Intensity
- Productivity / Output



- Negligible Net Affect on Resources
- Consistent and Transparent Rules

Leadership Dashboards: Portfolio Level Views of Clinical Trials

Consequential Impact

Strategic Alignment and Resource Checklist
page 1 of 1

Study Information
Search Term: _____
Study Type: _____

1. Is this study a Phase I/II/III or ongoing/terminated program?
Yes ☐ No ☐

2. Is this study recommended by your MOC (study sponsor)?
Yes ☐ No ☐

3. Is this a translation of a Phase I/II/III study or an extension of a Phase I/II/III study?
Yes ☐ No ☐

4. Does this study have a clear impact on the clinical resources that exist at the site?
Yes ☐ No ☐

5. If YES, check the resource category(ies) and identify specific resource(s):
☐ Supportive care resources (e.g., dietitian, pharmacist, nurse, etc.)
☐ Laboratory resources (e.g., lab technician, lab manager, etc.)
☐ Imaging resources (e.g., radiologist, radiology technician, etc.)
☐ Radiation resources (e.g., radiation therapist, radiation oncologist, etc.)
☐ Other resources (e.g., medical social worker, etc.)
 Identify specific, which resource(s) are critical to the trial: _____

6. Does the trial use investigational drug(s) / device(s)?
Yes ☐ No ☐

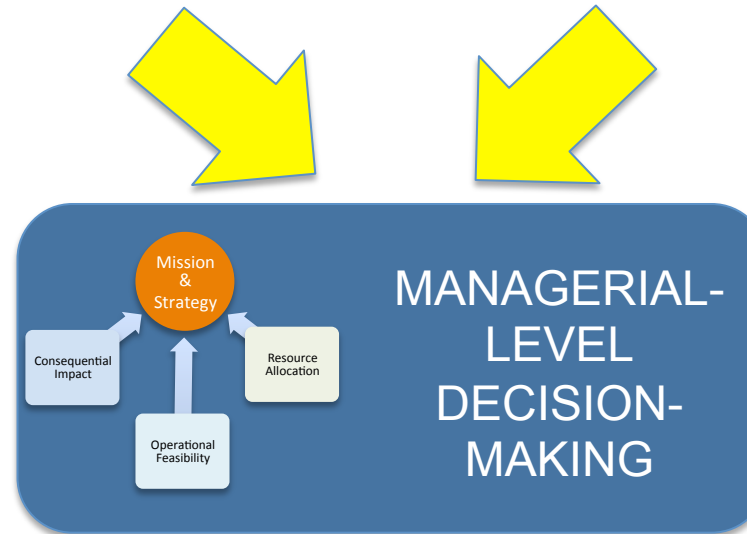
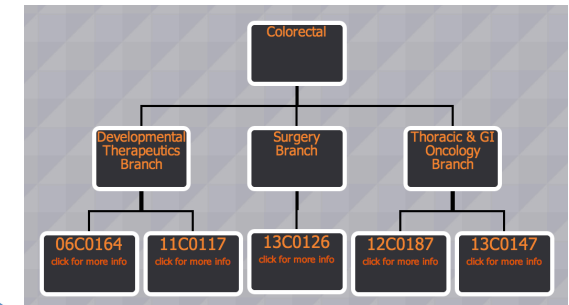
7. If YES, please identify where the drug/device was developed (check all that apply):
☐ CRO
☐ Other
☐ Other

8. Is the study a translation of a Phase I/II/III study or an extension of a Phase I/II/III study?
Yes ☐ No ☐

9. Is the study a translation of a Phase I/II/III study or an extension of a Phase I/II/III study?
Yes ☐ No ☐

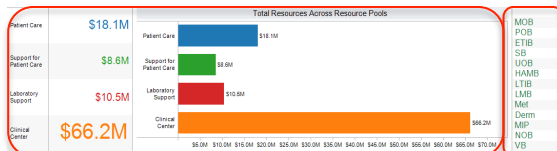
10. Is the study a translation of a Phase I/II/III study or an extension of a Phase I/II/III study?
Yes ☐ No ☐

Clinical Trial Flow Sheets

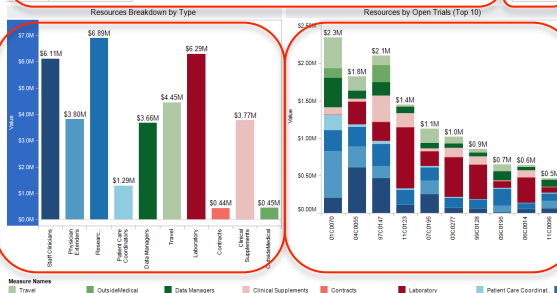


Resource Allocation

Total Resources stratified by Resource Pools

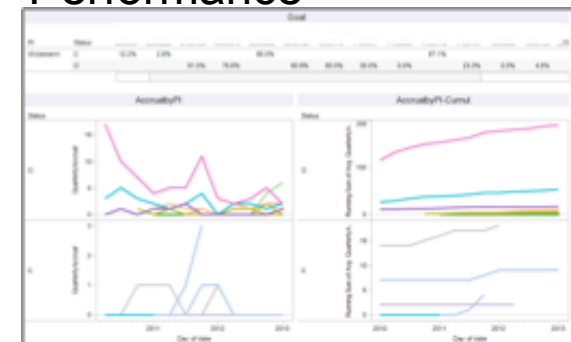


Resource Breakdown by category

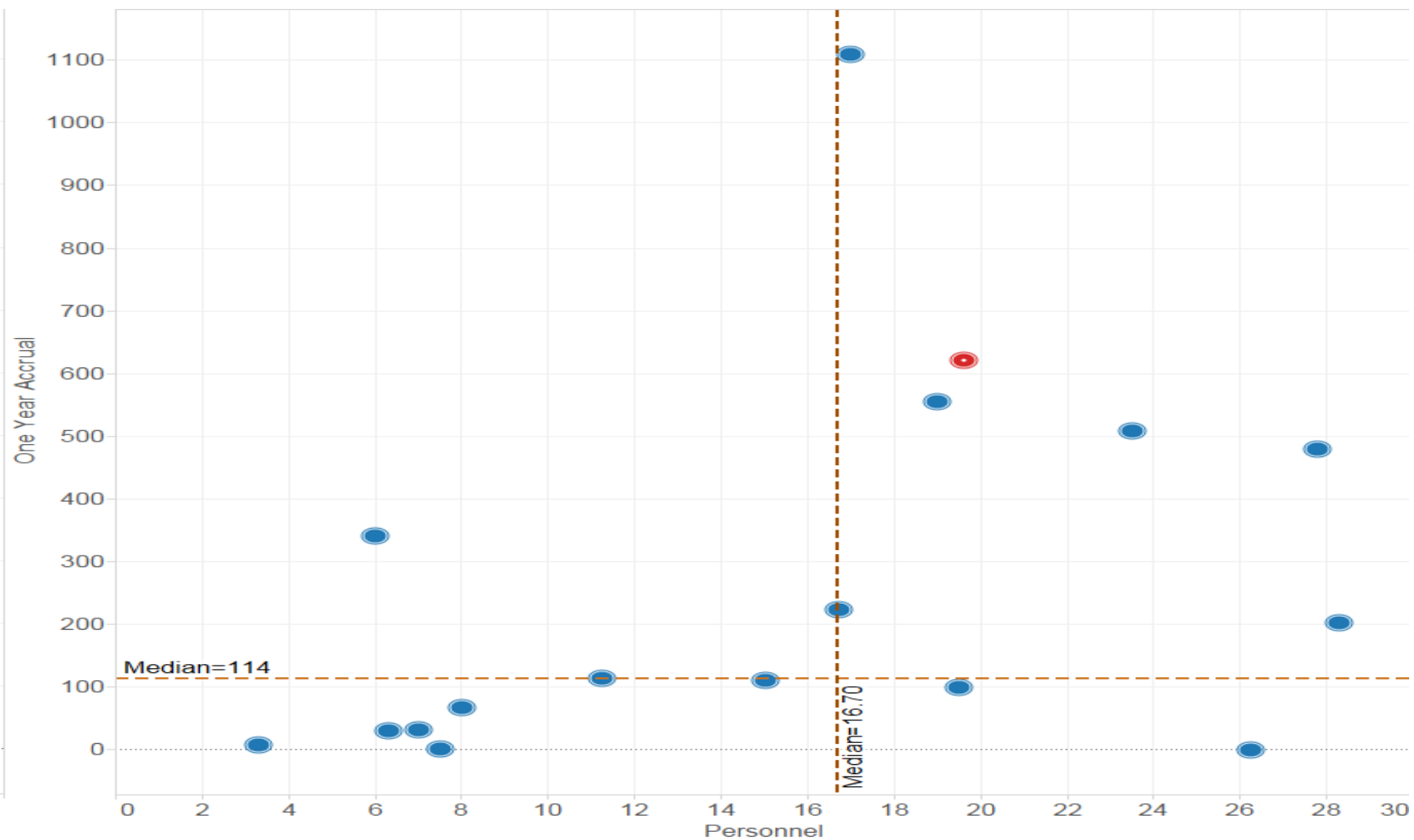


Breakdown of the top 10 resource-intensive trials

Accrual and Operation Performance

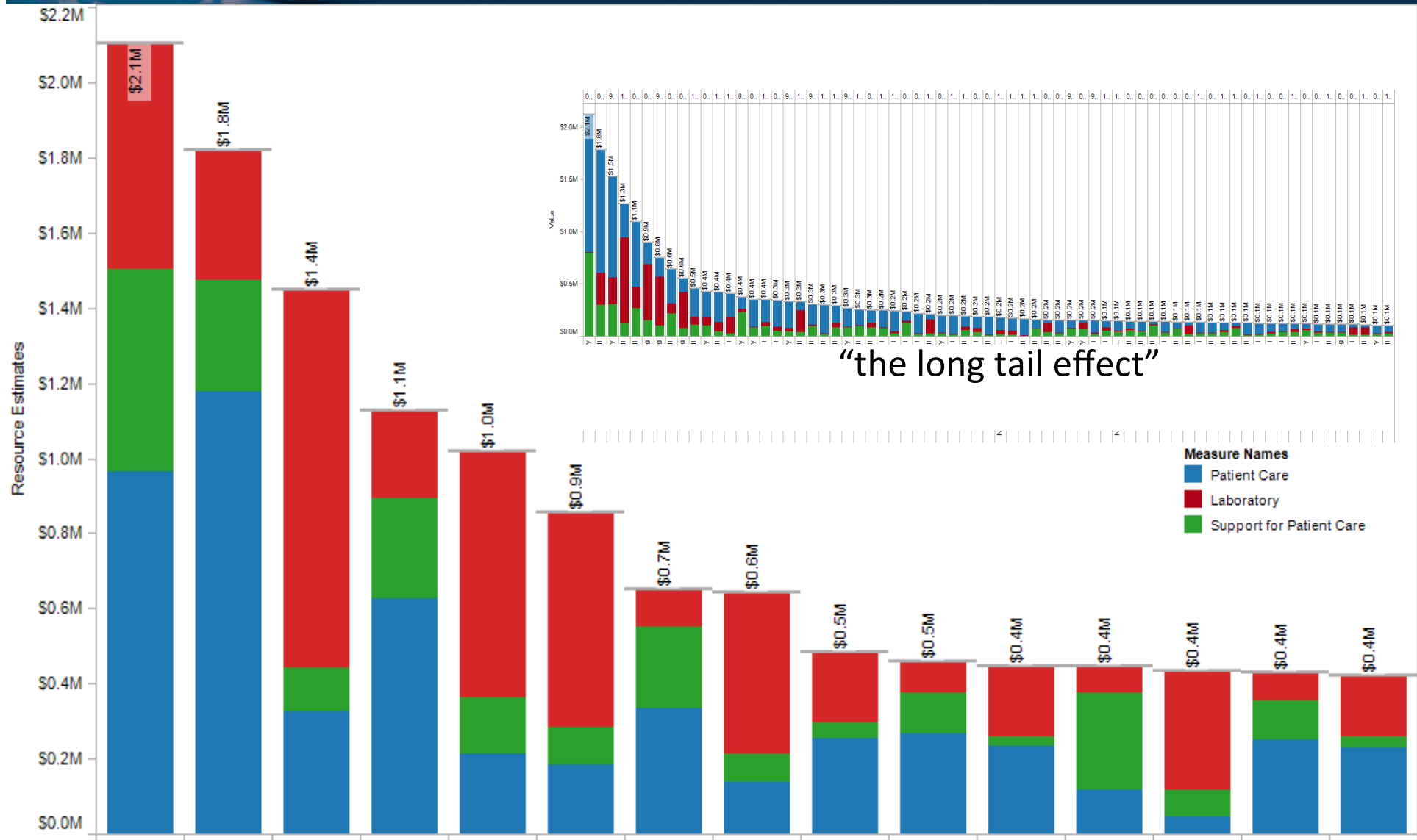


Leadership Dashboards: Personnel Vs Accrual by Research Units



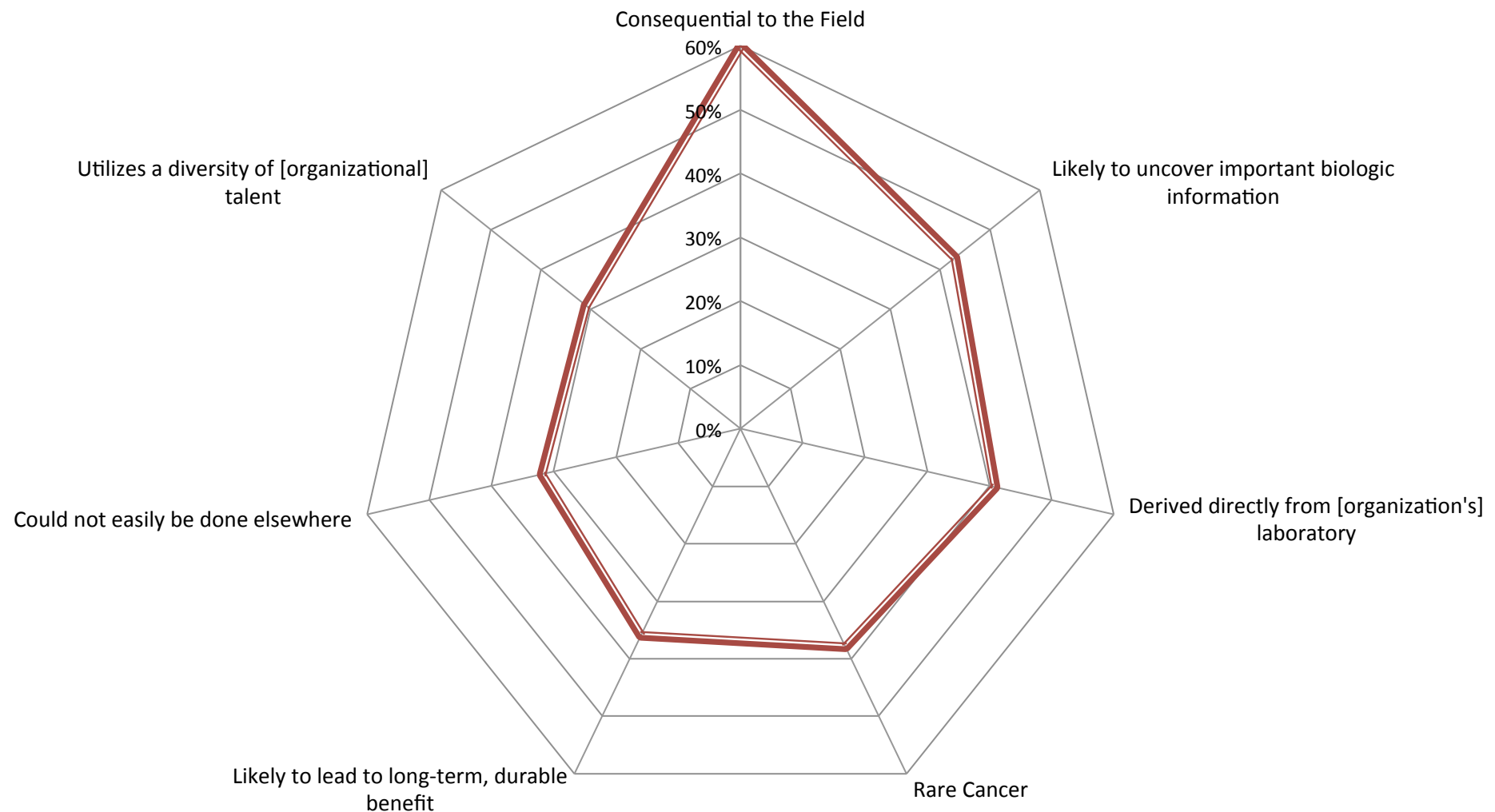
Leadership Dashboards:

Top 15 Trials by Average Annual Costs



* Does not including clinical center and other, unclassified costs

Leadership Dashboards: Assessing Critical Strengths of the Portfolio

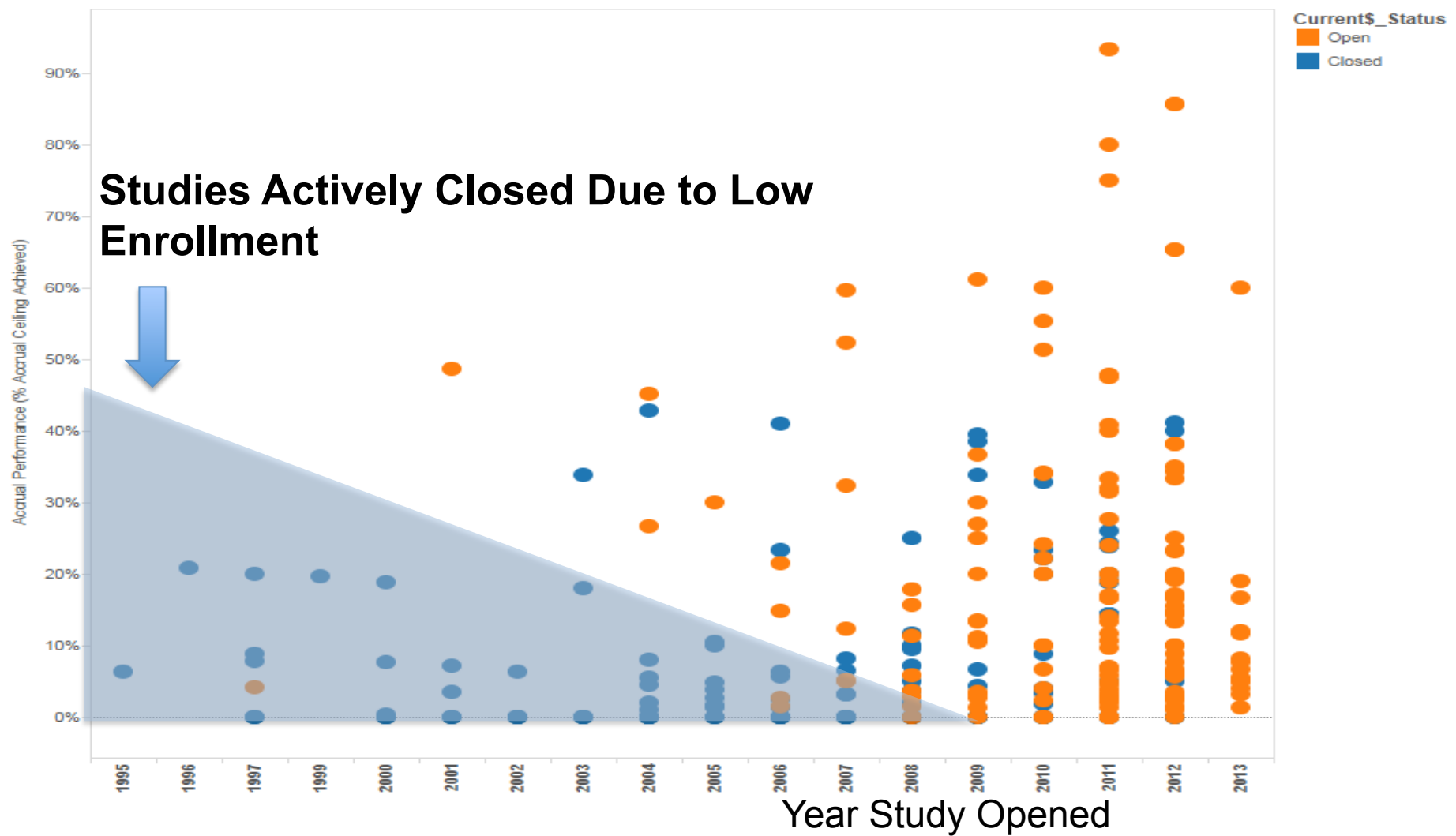


Number denotes ranking (high-low)
N=186 trials

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RESULTS

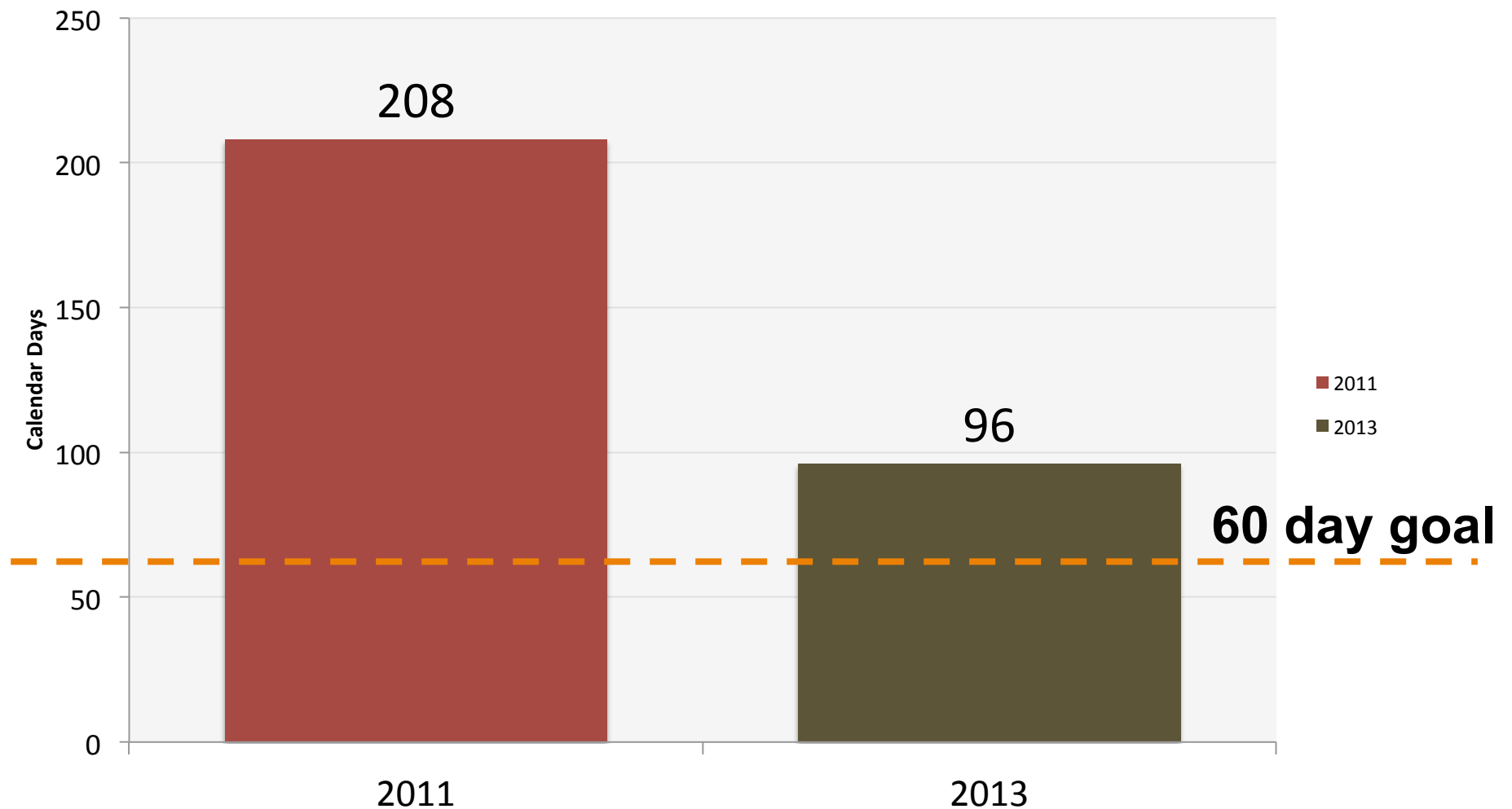
Evidence-base Decision Making



* Therapeutic Studies Only

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Reduction of Clinical Trial Development Time



Clinical Trial Portfolio (FY2014 vs FY2013)

Research Units and Clinical Research Portfolio are more aligned with Vision & Mission

- 52% reduction in number of studies opened

Metrics embrace transparency & embed accountability

- 54% reduction in median development time

Patients are directed on prioritized set of trials

- 2% increase in new patient enrollment
 - 4% increase in new patients enrolled on therapeutic trials
- 20% increase in closed studies with complete enrollment*
- 7% decrease in closed studies with non-enrollment**

* Complete enrollment = Within 75% of accrual ceiling

** Non-enrollment = below 25% of accrual ceiling

Through the translation of the strategic mission and the reengineering of the clinical research operations, we have taken initial steps to improve both efficiency and effectiveness of the clinical trial portfolio based on analytics. This allows for the achievement of the greatest returns within the limited set of resources. These analytical tools and models can be adapted for use into most cancer center organizations.



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