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

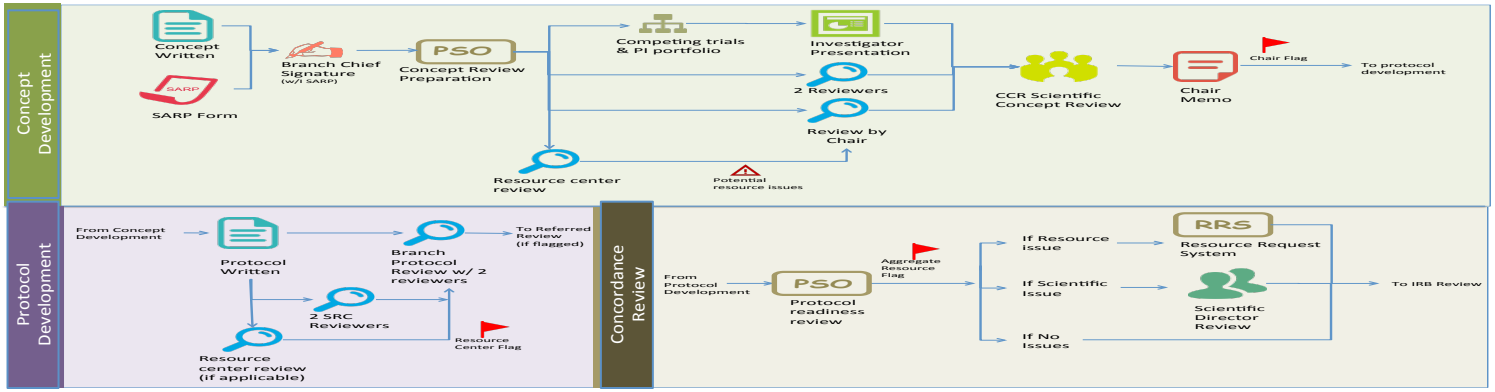
Parallel Reengineering Efforts

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

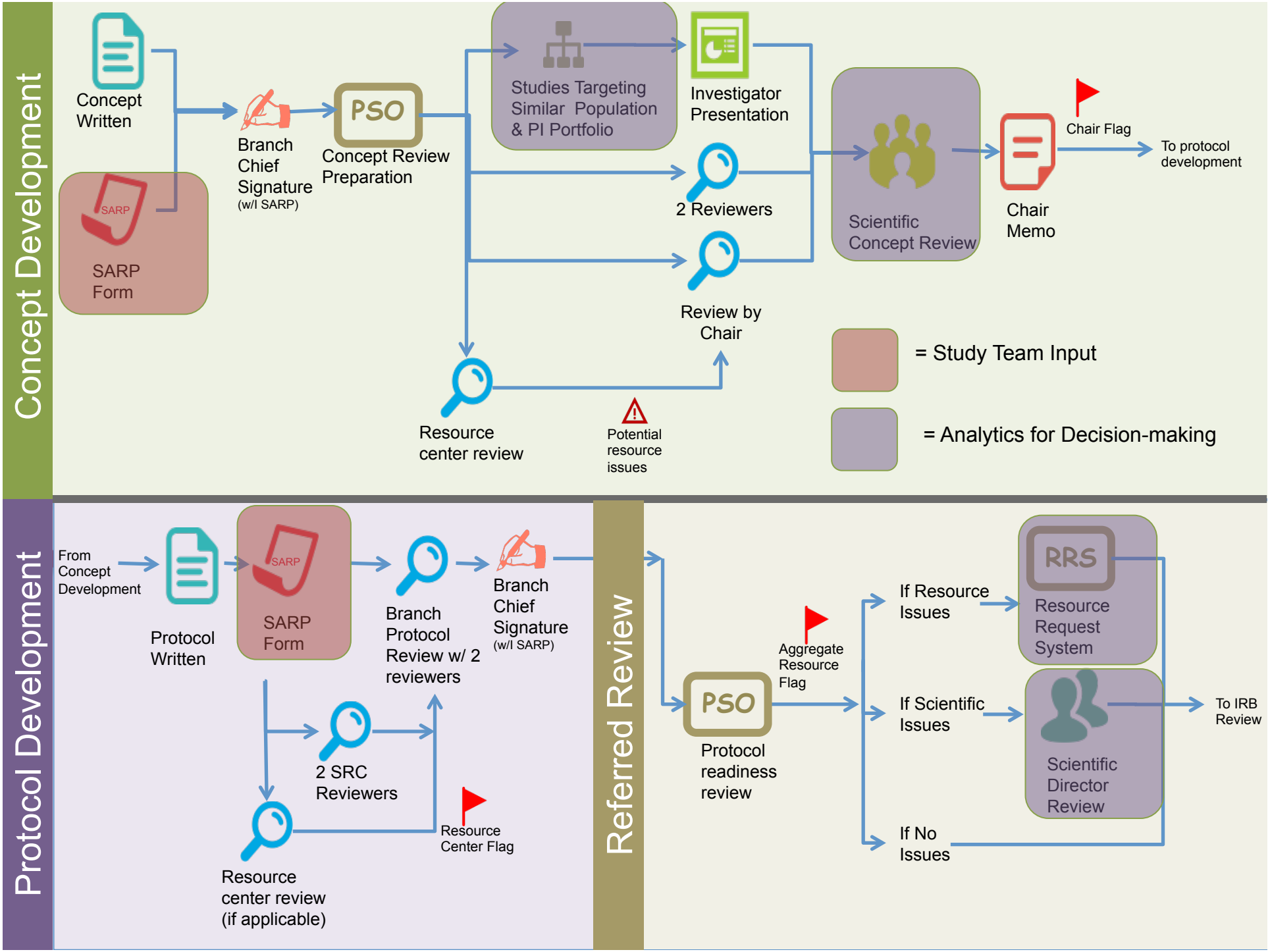
1. Engage outstanding researchers in **consequential investigator-initiated** clinical research in a culture of **close interaction between basic and clinical science**
2. Provide the **flexible funding** necessary to support **innovative, high impact bench-to-bedside research** through access to the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

* Blinded to protect identify of institution

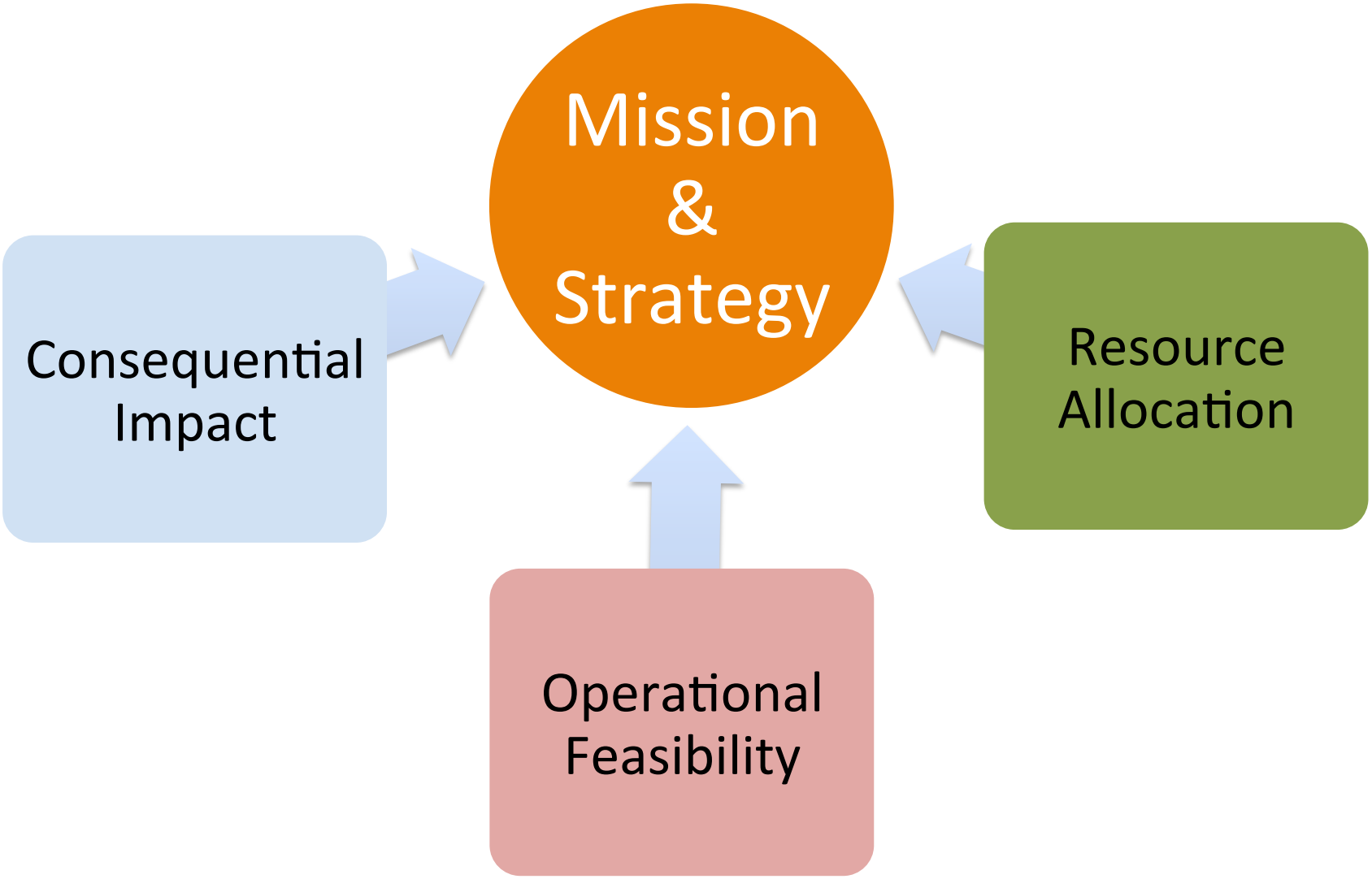
- Process reengineering of Clinical Trial Review



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


Concept Development
Concept Written
SARP
SARP Form
Branch Chief Signature (w/I SARP)
PSO
Concept Review Preparation
Studies Targeting Similar Population & PI Portfolio
Investigator Presentation
2 Reviewers
Review by Chair
Resource center review
Potential resource issues
Scientific Concept Review
Chair Memo
Chair Flag
To protocol development
= Study Team Input
= Analytics for Decision-making
Protocol Development
From Concept Development
Protocol Written
SARP
SARP Form
Branch Protocol Review w/ 2 reviewers
Branch Chief Signature (w/I SARP)
2 SRC Reviewers
Resource Center Flag
Resource center review (if applicable)
Referred Review
PSO
Protocol readiness review
Aggregate Resource Flag
If Resource Issues
If Scientific Issues
If No Issues
RRS
Resource Request System
Scientific Director Review
To IRB Review

Framework for Analytics

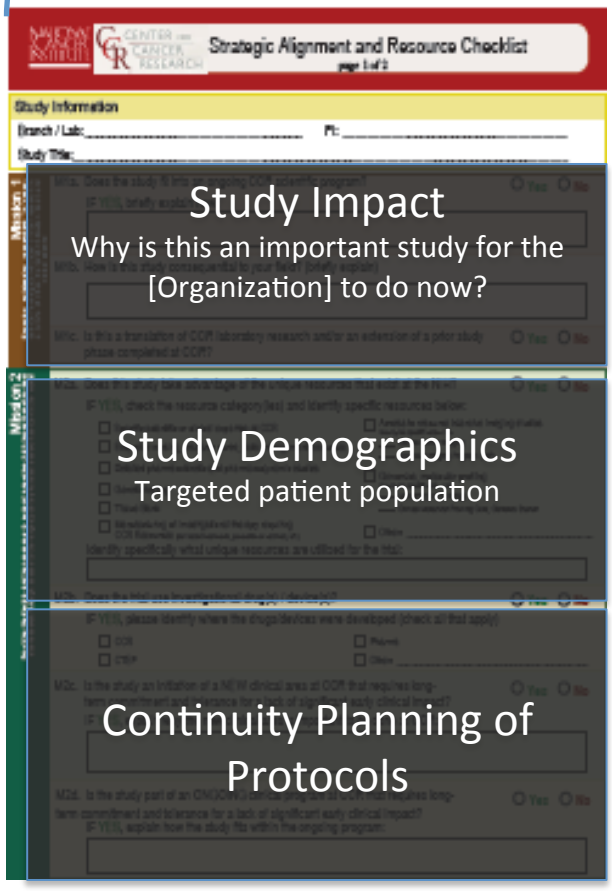


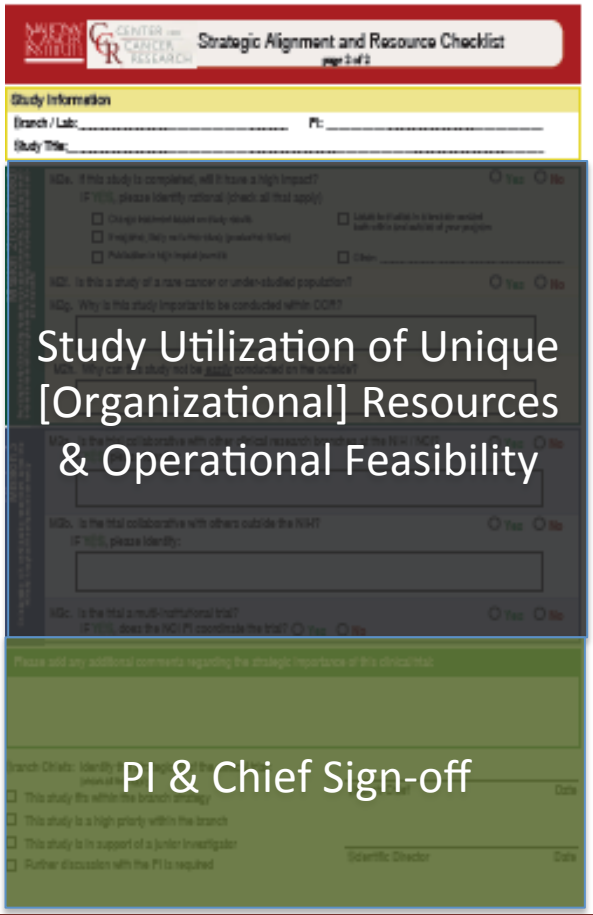
Linkage of Analytic Tools to Clinical Mission and Metrics/Measures

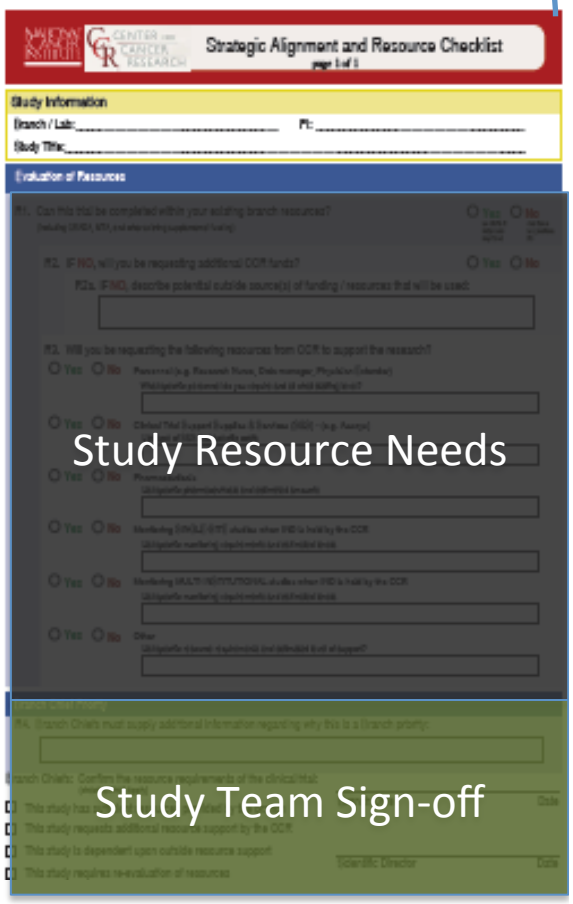
		Analytics				
		Leadership Dashboards	SARP	Clinical Trial Flowsheets	Research Unit Dashboards	Simulation
Clinical Mission	Strategy	■	■	■	■	■
	Consequential Impact	■	■		■	■
	Resource Allocation	■	■		■	■
	Operational Feasibility	■	■	■	■	■
Metrics	Patient Demographics	◆	◆	◆	◆	◆
	Clinical Research Demographics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

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

Clinical Mission and Vision



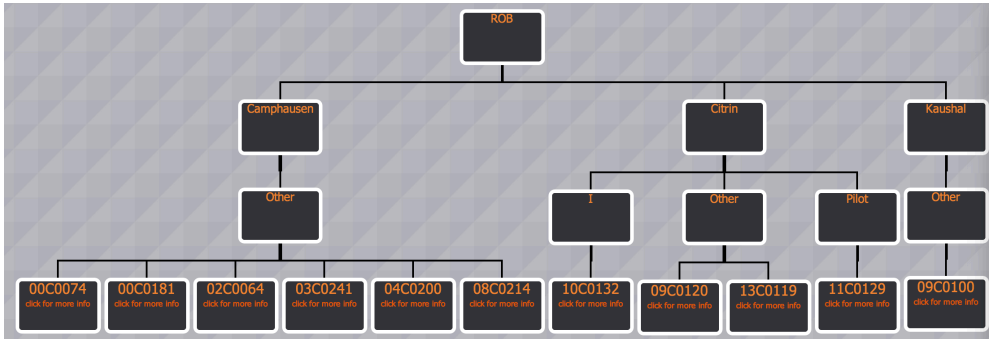




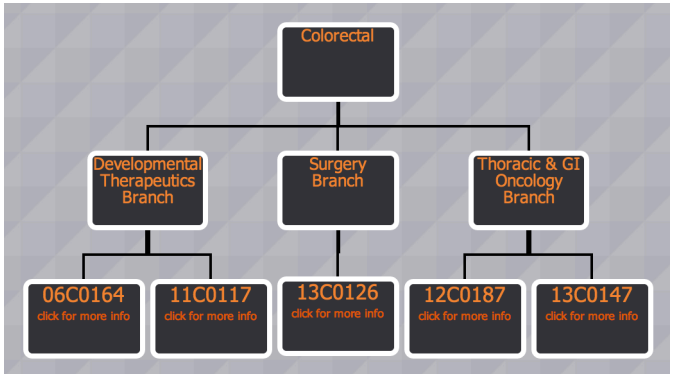
- SARP facilitates the linkage of protocols to the Clinical Mission & Vision, Assessment of Impact, Critical Strengths, and Portfolio Evaluation
- SARP integrated into the entire process to assess scientific importance, strategic priority, operational feasibility, and resource utilization

Clinical Trial Flowsheets

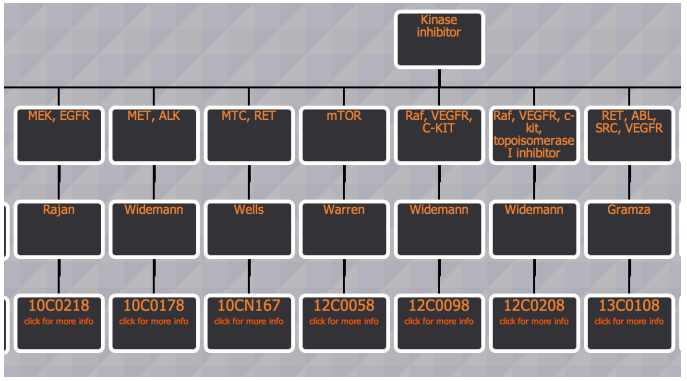
By Branch



By Diagnosis



By Mechanism



by Agent and Mechanism Detail

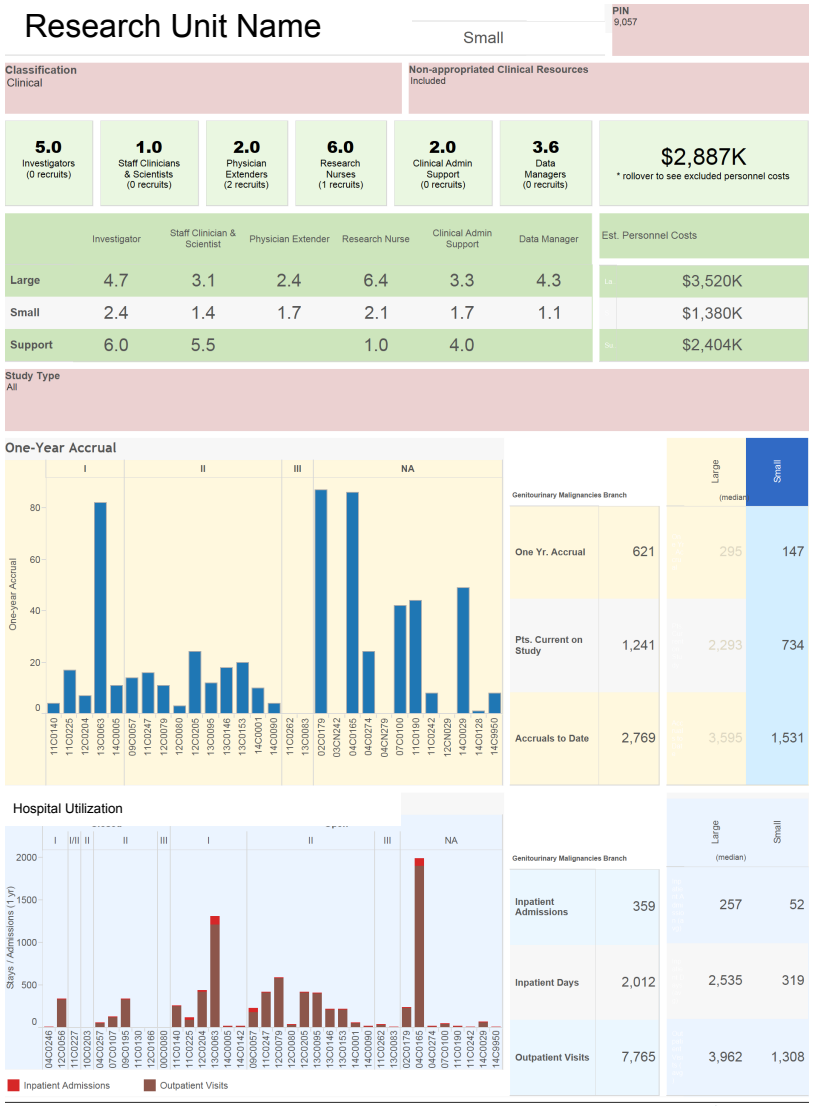
- Transparent & Accessible to all Basic and Clinical Researchers
- Created dynamically by researcher requests

Research Unit Dashboards

Personnel Data

Annual Accrual Data

Hospital Utilization



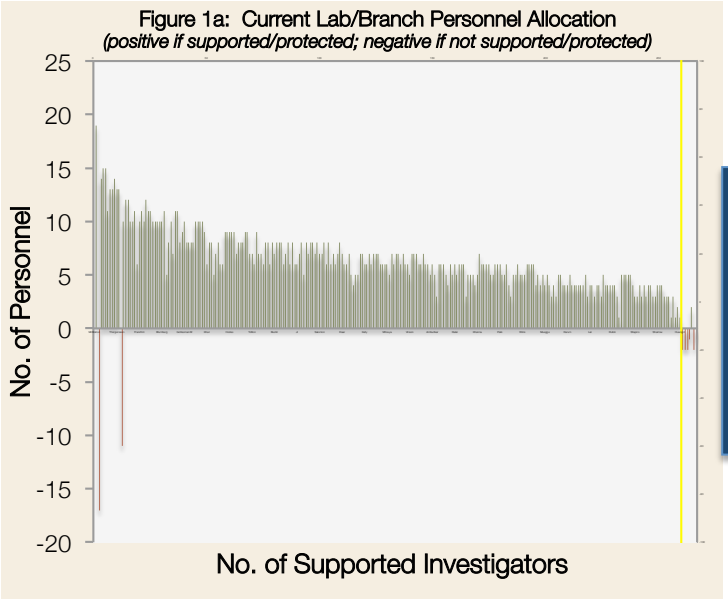
Parameters & Characteristics

Research Unit Comparison Data

Simulation & Comparison: Clinical Staffing Levels Across Clinics

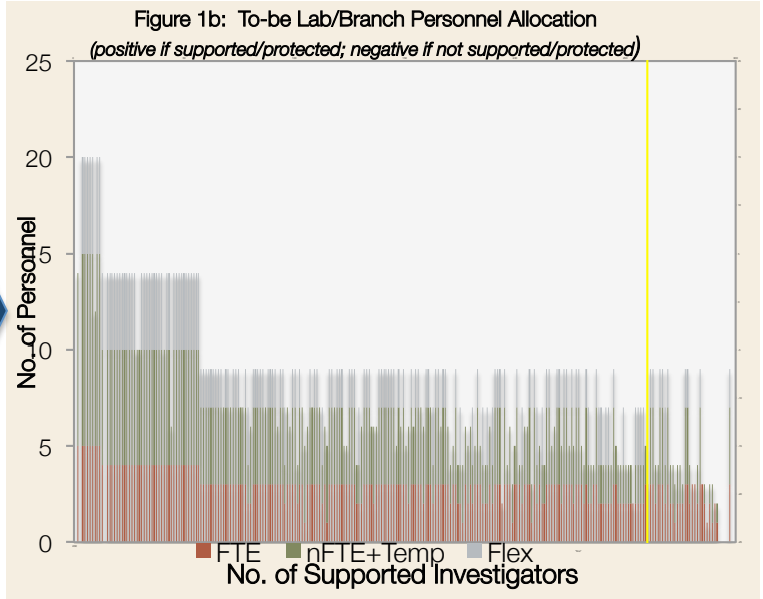
- Percent of Clinic FTE
- Line denotes average FTE

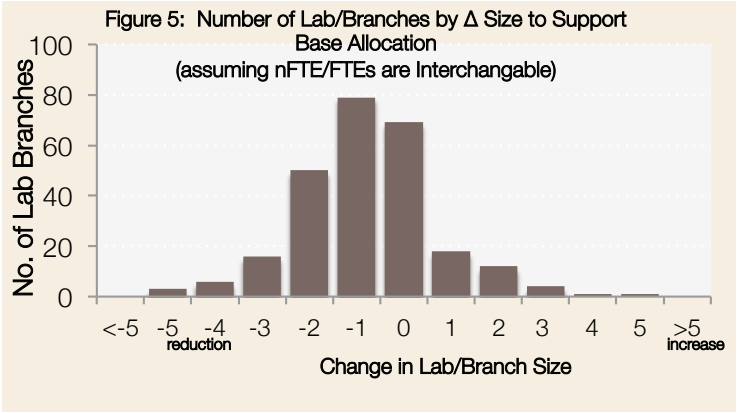
Simulation & Comparison: Implementing Standardized Staffing Models



Standardized staffing based on:

- Performance
- Volume / Intensity
- Productivity / Output



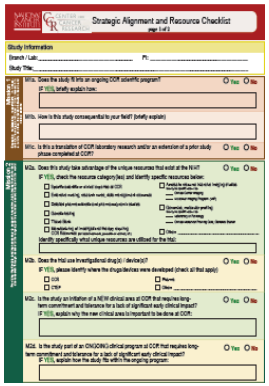


- Negligible Net Affect on Resources
- Consistent and Transparent Rules

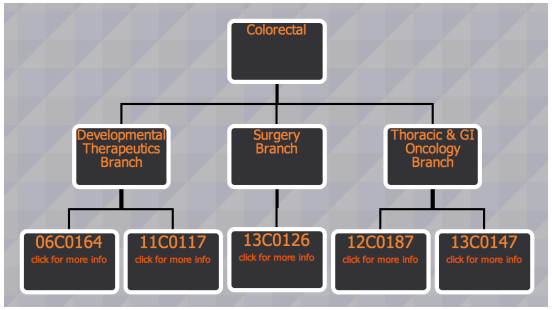
Leadership Dashboards:

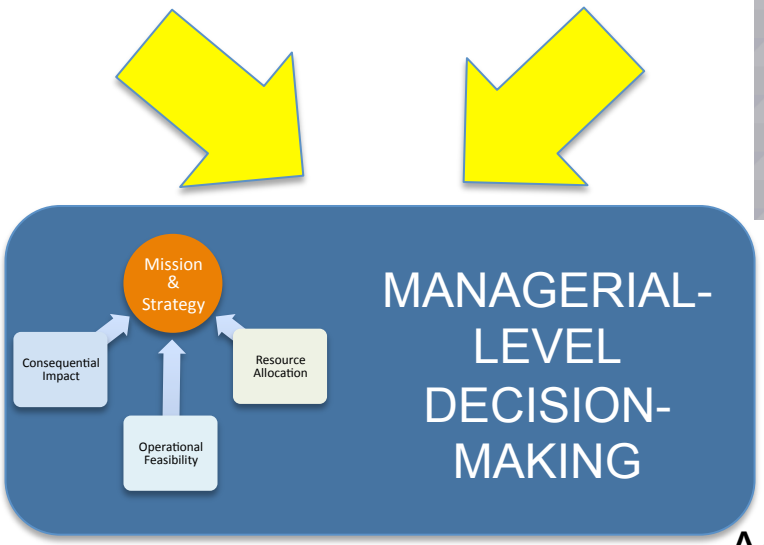
Portfolio Level Views of Clinical Trials

Consequential Impact



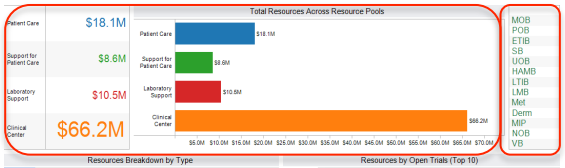
Clinical Trial Flow Sheets



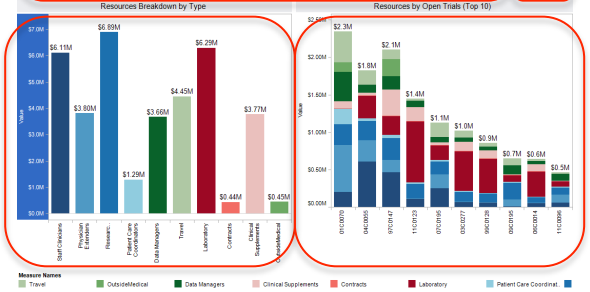


Resource Allocation

Total Resources stratified by Resource Pools

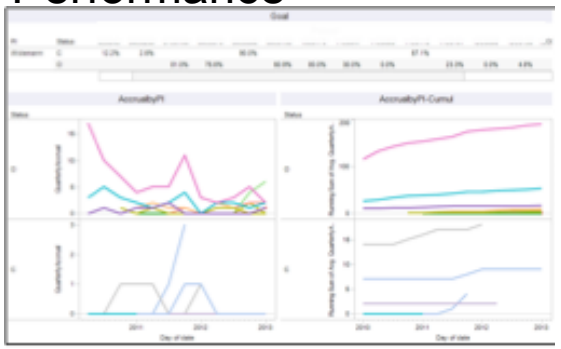


Resource Breakdown by category

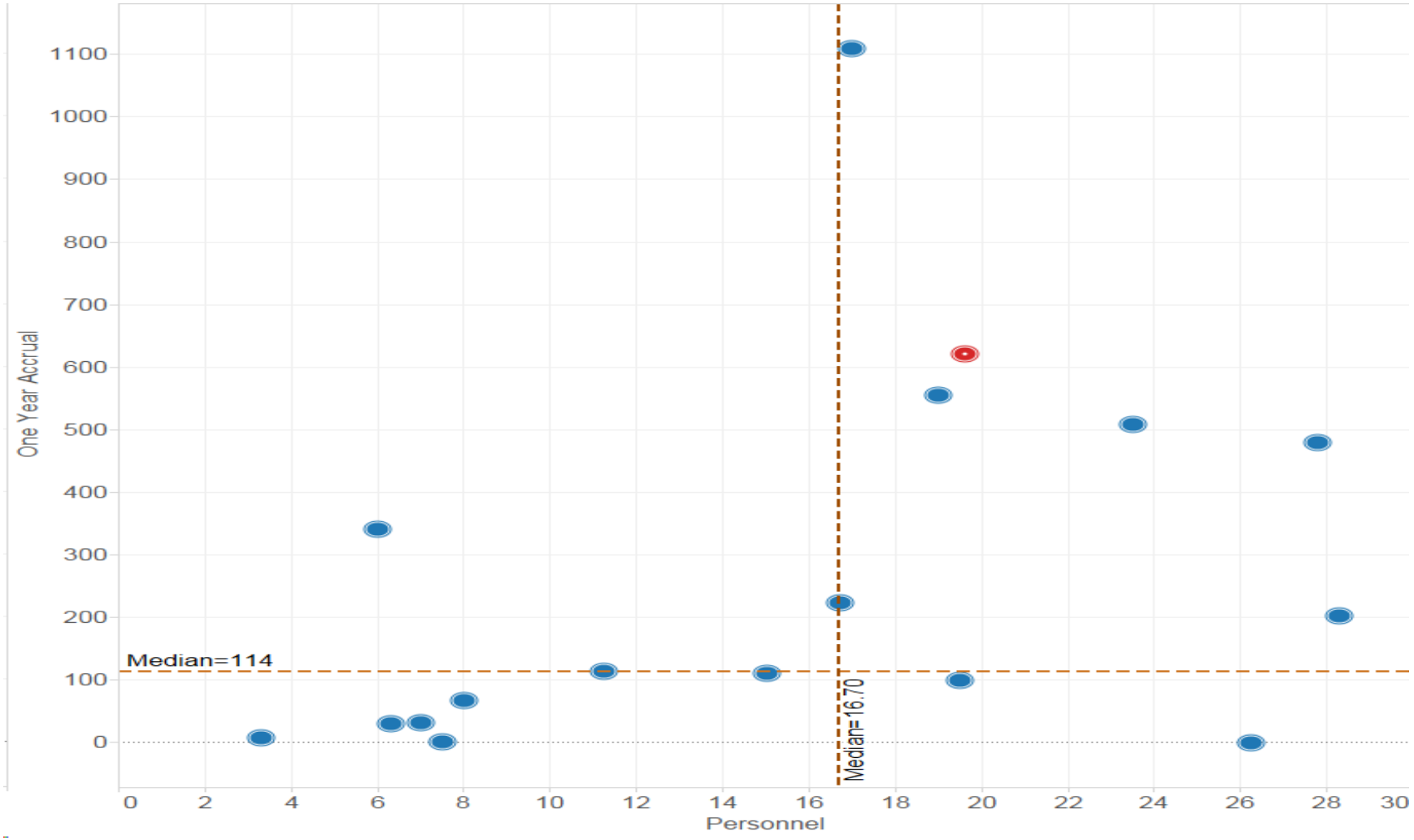


Breakdown of the top 10 resource-intensive trials

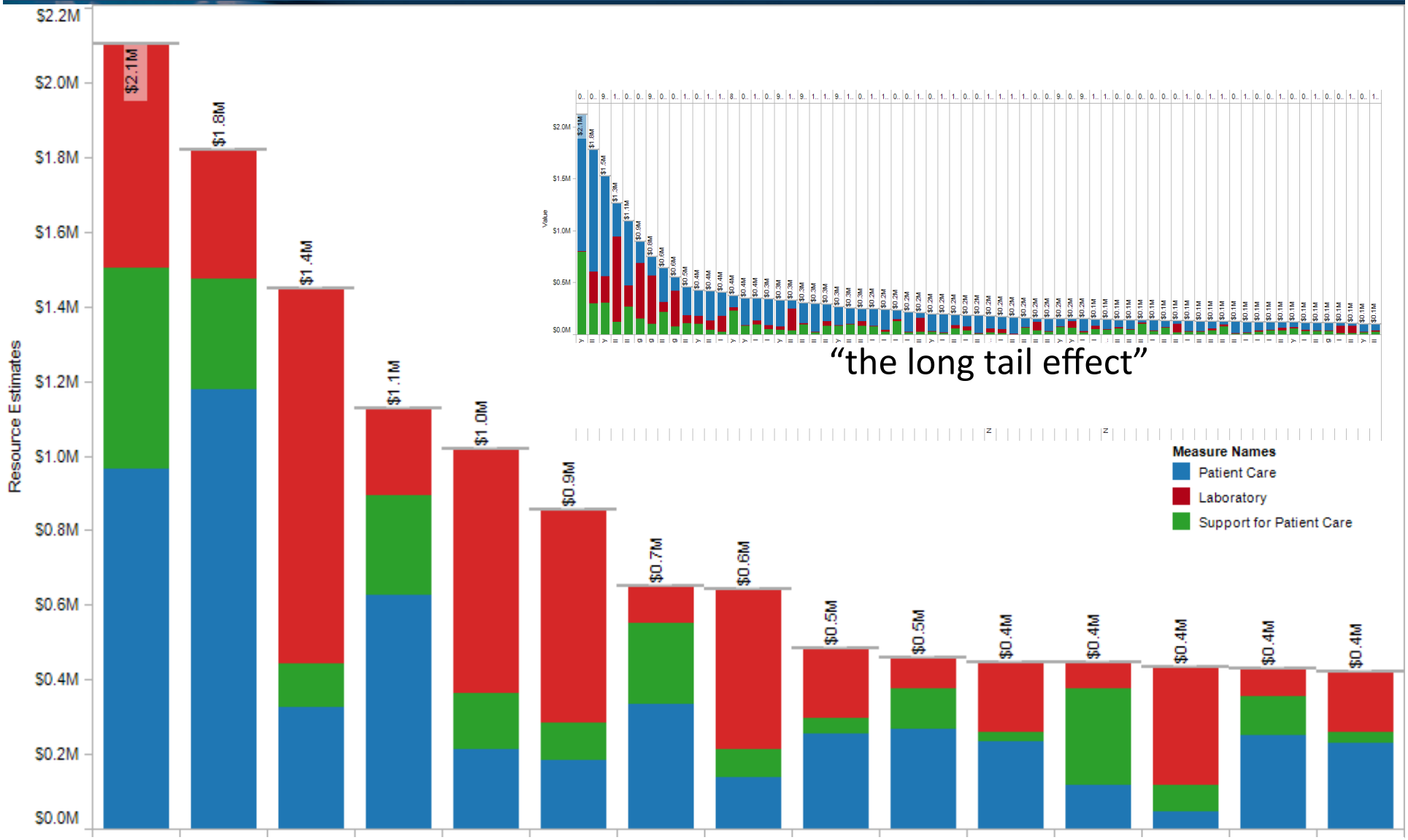
Accrual and Operation Performance



Leadership Dashboards:
Personnel Vs Accrual by Research Units

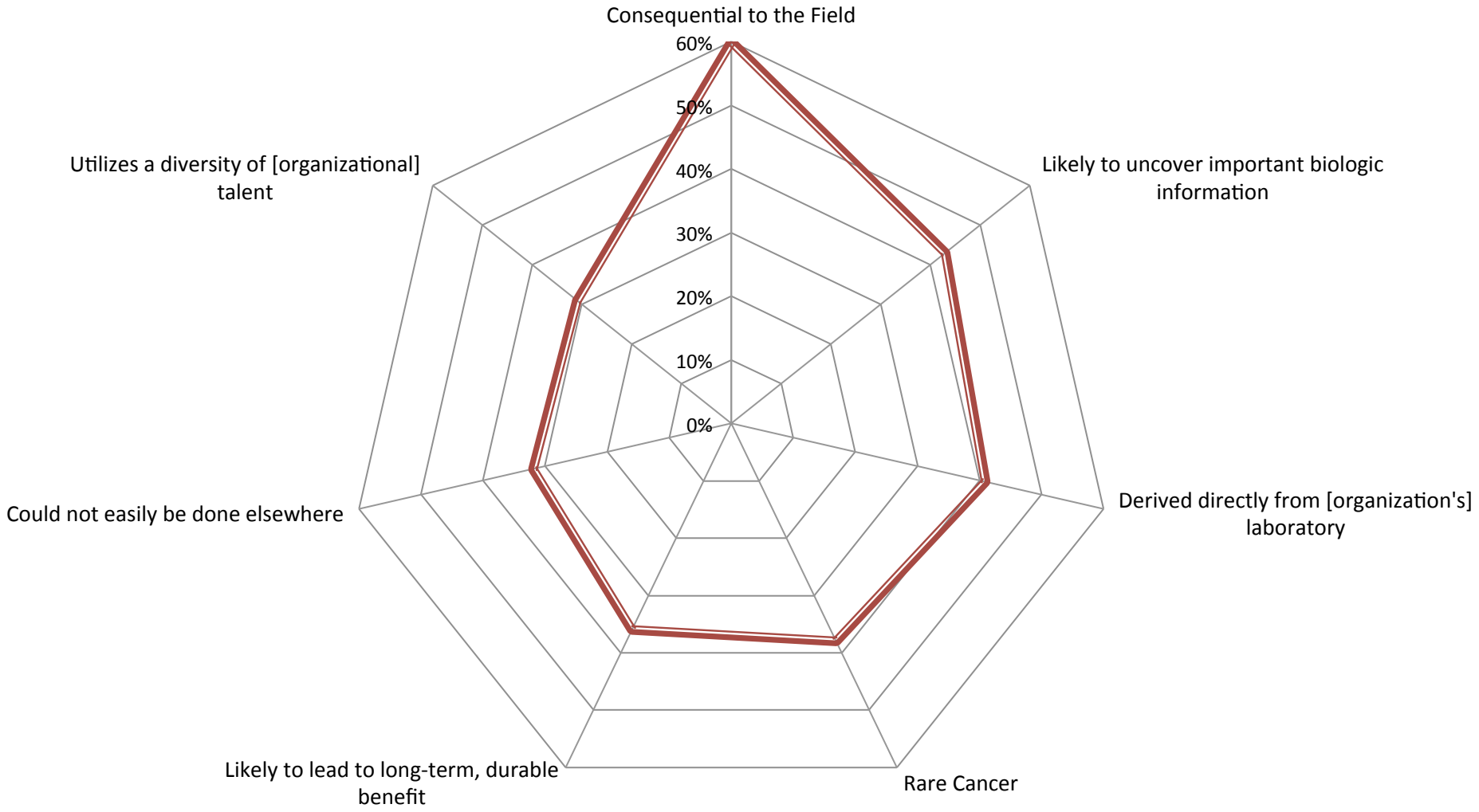


Leadership Dashboards:
Top 15 Trials by Average Annual Costs



* Does not including clinical center and other, unclassified costs

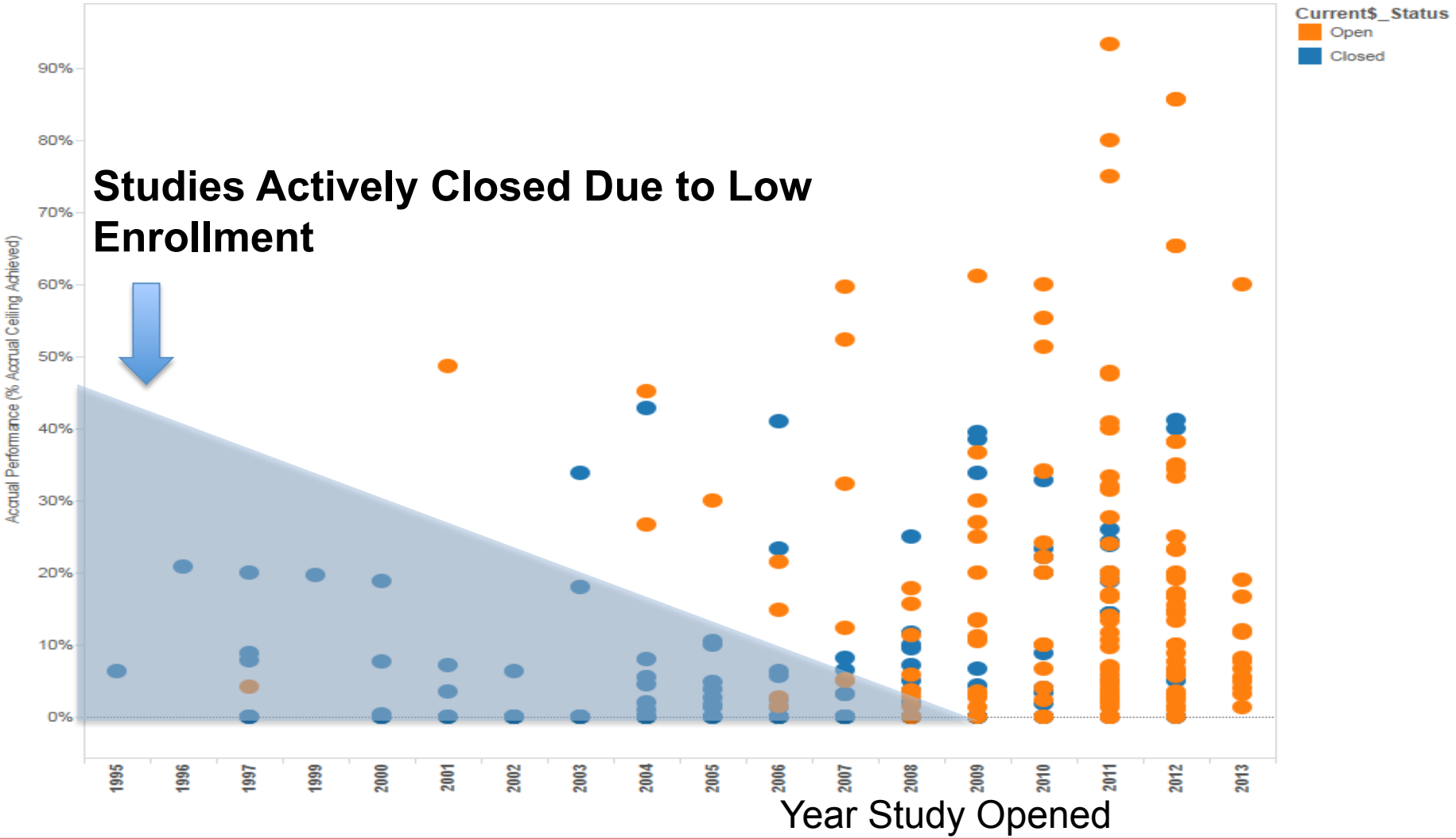
Leadership Dashboards:
Assessing Critical Strengths of the Portfolio



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

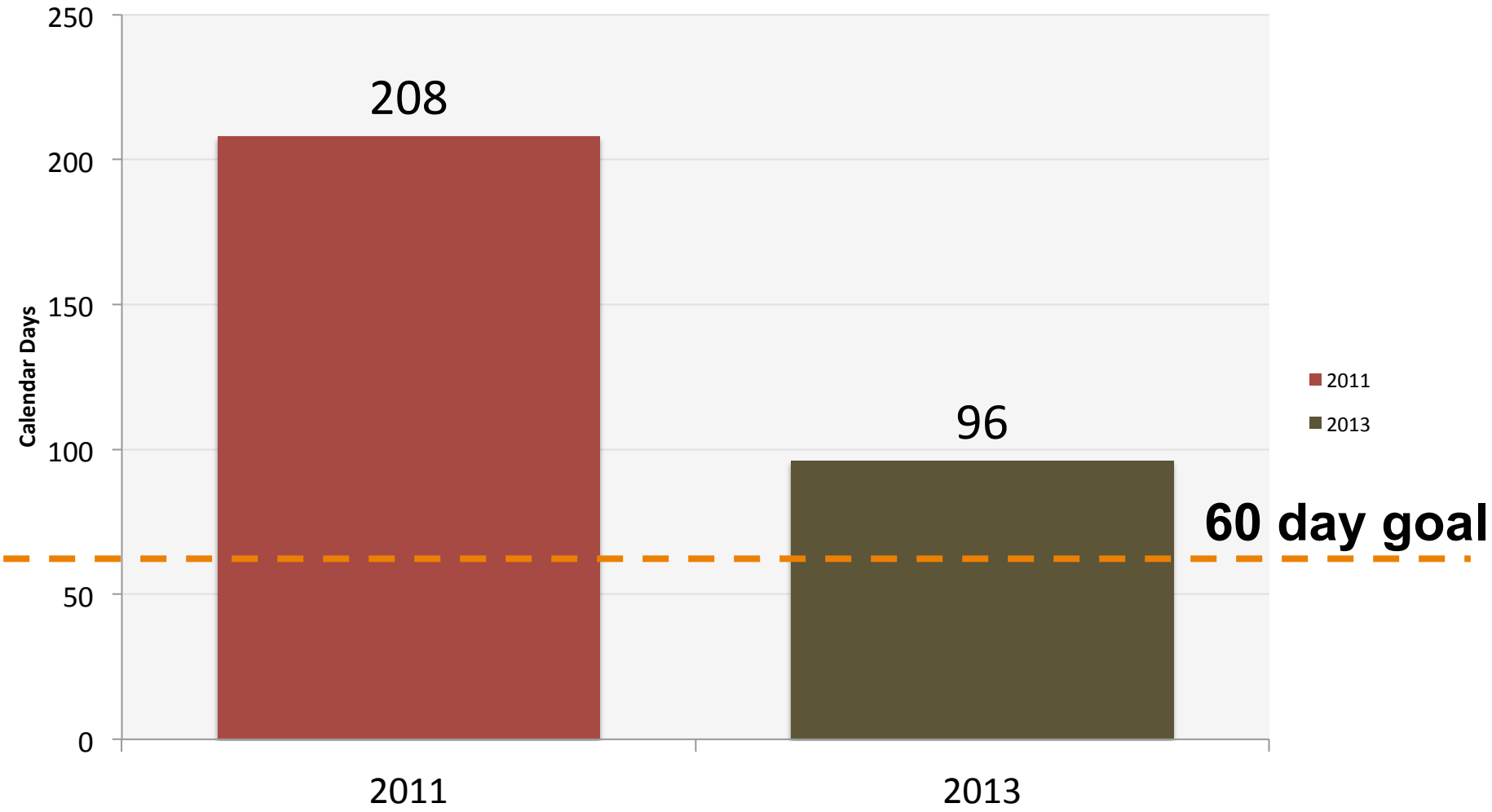
RESULTS

Evidence-base Decision Making



* Therapeutic Studies Only

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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