



BLOCK & TACKLE

Leveraging Process *for* Results

APQC'S 2012 Process Conference & Training
October 22-26, 2012
The Houstonian Hotel, Club & Spa - Houston, Texas

APQC®



VA
HEALTH
CARE

Defining
EXCELLENCE
in the 21st Century



Cooperative Studies Program Clinical Research Pharmacy Coordinating Center

Building Strong Process Management Capabilities

Designed to Exceed Customer Expectations!

Stan Johnson, MBA, CMQ/OE, CPGP
Chief, Quality Control



Our Context



Veterans Affairs

Veterans Health Administration

Veterans Benefits Administration

National Cemetery Administration

Office of Research & Development

Biomedical Laboratory R&D

Clinical Science R&D

Health Services R&D

Rehabilitation R&D

CSP

Genomics Lab & 4 ERICs

Pharmacy Coord. Center

5 Coordinating Centers



Our Mission

To improve the health of our Nation's Veterans by providing creative **pharmaceutical solutions** to global **clinical research**.



Our Business

Pharmaceutical expertise:

- Study design/protocol
- Investigational drugs
- Packaging and distributing to study sites
- Patient safety
- Regulatory compliance—FDA



Landmark Clinical Trials

An Aspirin a Day...



One of CSP's earlier studies determined that aspirin was effective in preventing heart attacks.

Shingles vaccine



The Shingles Prevention trial led to the FDA approval of a vaccine for those over 65 to prevent shingles, a painful, blistering skin rash.

Diabetes



CSP has participated in many trials related to the treatment of diabetes. One of the most recent found that lowering glucose in an effort to prevent cardiovascular events was not effective.

Robotics Help Stroke Victims



CSP also participates in device trials. A recent robotics trial proved that the use of robotics can help stroke victims have an improved quality of life.

Parkinson's Research



Deep Brain Stimulators improve motor control for Parkinson's patients, and proved more effective than the best medical therapy.

VA CSP Clinical Research Pharmacy Coordinating Center

- FDA Registered Facility
- ISO 9001:2008 and 15378
- Commitment to Quality



*VA Cary
Organizational
Excellence
Trophy Award
2004*

*VA Circle of Excellence
Awards
2006, 2007, 2009*



Baldrige Performance Excellence Criteria Framework



Baldrige Framework + Seven Tenants = Synergy

Baldrige Categories

- 1 – Leadership
- 2 – Strategic Planning
- 3 – Customer Focus
- 4 – Measurement, Analysis & Knowledge Mgmt.
- 5 – Workforce Focus
- 7 – Results



Both Baldrige PE Framework & APQC Seven Pillars Provide:

- Systems Perspective
 - Leadership focus on strategy, customers, stakeholders.
 - Central relationship between leadership and results.
 - Define processes and drive performance results.
 - Measurement, analysis, and knowledge management support performance improvement.

Key Decisions & Milestones



Regulatory Focus



1978 '93 '96 '03 '04 '09 2011-12

PCC Measures & Initiatives: A Five-Year Plan

2011-2012 focus

- Committee ownership of measures
- Further develop Vital Signs
- Further develop benchmarks
- Build consistency and competency in data analysis
- Continued HI development: leading & lagging indicators, thresholds and action levels defined.
- New: cycle time, FTE/study, sites/FTE & Green Team
- Ongoing: Dashboard V2
- Shared Data
- Use of ERP financial data in measures

***January 2009**
Strategic Planning
Conference
Measures Day

***August 2009**
Measures integration
conference

***Revised
Dashboard**



**To
infinity
and
beyond!**

2009

2010

2011

2012

2013

2014



***January 2010**
Strategic Planning Conf.
Measures Day Plus

2010 focus

- Committee measures
- CMC use of Vital Signs
- New measures: cycle time
- Dashboard Improved
- Shared Data for Measures



Sharpened focus:
Use of measures in making
business decisions & driving
performance excellence!



Systems Integration – Dashboard



Center Balanced Scorecard Health Indicators

Data as of February 15, 2012 7:50 PM
Fiscal Year Reporting Periods (unless noted as CY for calendar year)

CONFIDENTIAL: Internal Use Only

CUSTOMERS: Develop & maintain mutually beneficial customer relationships



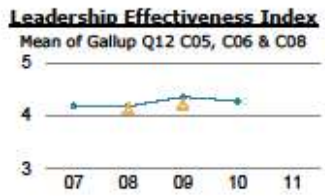
Legend

- Center results
- Comparative data (arrow indicates direction of)
- FY Fiscal Year
- LM Extramural
- K Thousands | M Millions
- ppm Parts per millions

PROCESSES: Increase capability & productivity



FINANCIAL: Increase funding

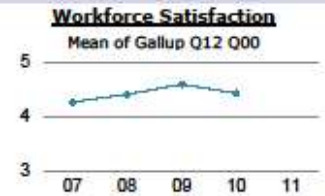


[Cycle Time]
Days
[Under Development]

Performance to Budget (%)	FY 10	FY 11
	99.53	99.99

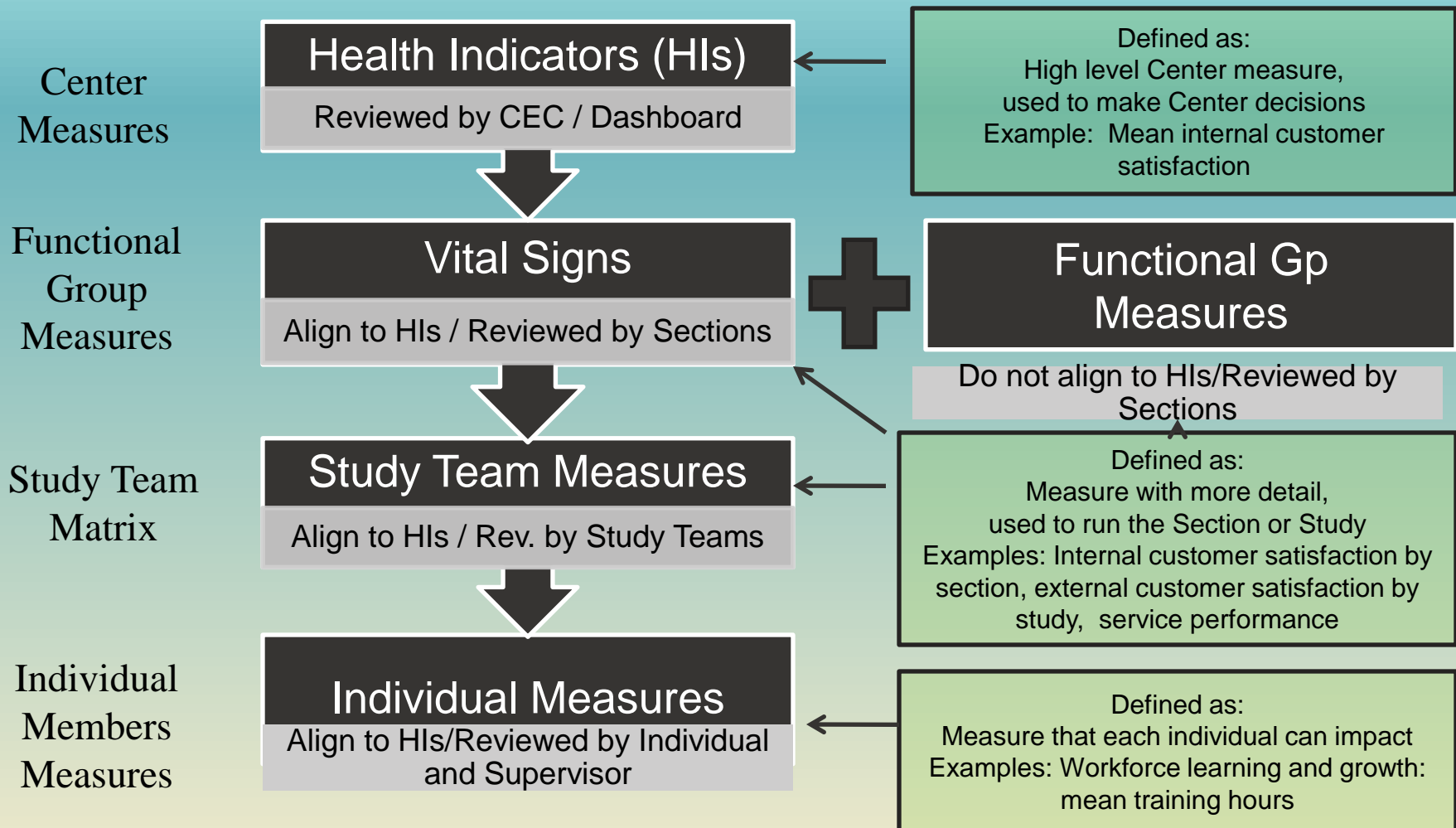


EMPLOYEES: Develop engaged workforce



[Under Dev.]	FY 10	FY 11
FTE		
Studies		
FTE/Study		
Sites		
Sites/FTE		
Units Shipped (K)	105.97	124.04

Measures Framework





Center Balanced Scorecard Health Indicators

CUSTOMERS: Develop & maintain mutually beneficial customer relationships

[Quarterly Results](#)

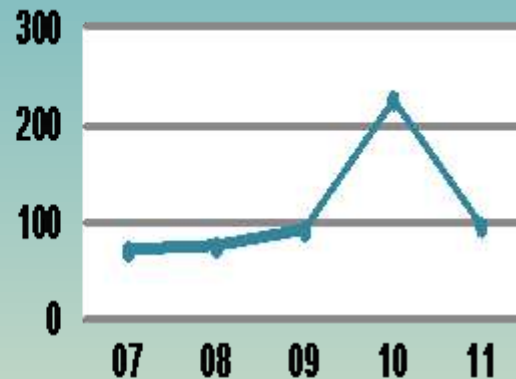
[About Measures](#)

[Measures List](#)

[Send Feedback](#)

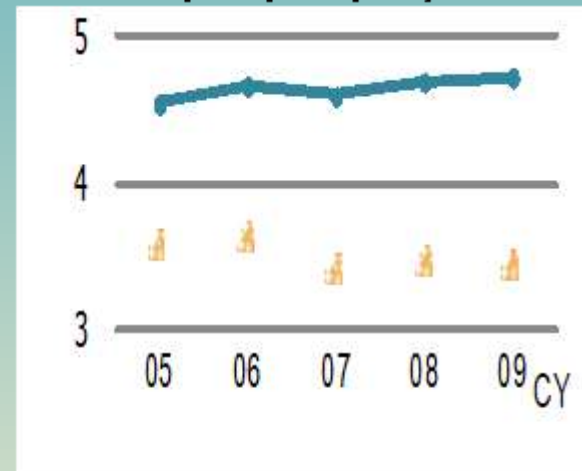
Customer Complaints

Complaints/Units Shipped (ppm)



Customer Satisfaction

All Study Composite (Mean) Score



PROCESSES: Increase capability & productivity

Adequate Clinical Supplies at Sites

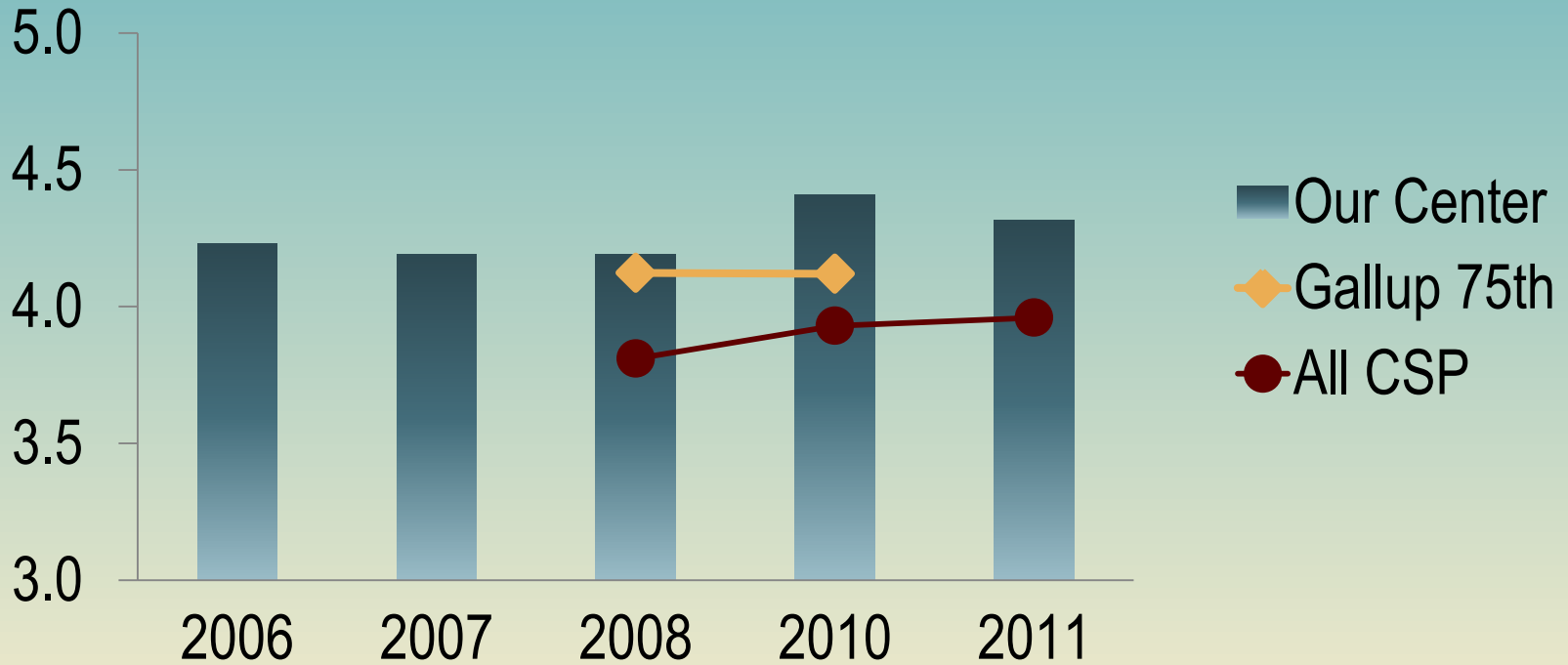
Internal Customer Satisfaction

Leadership Effectiveness

- I have confidence that management is leading this organization in the right direction.
- The leadership of my organization always treats me with respect.
- The leadership of my organization makes me feel enthusiastic about the future.
- I am confident in my organization's future.

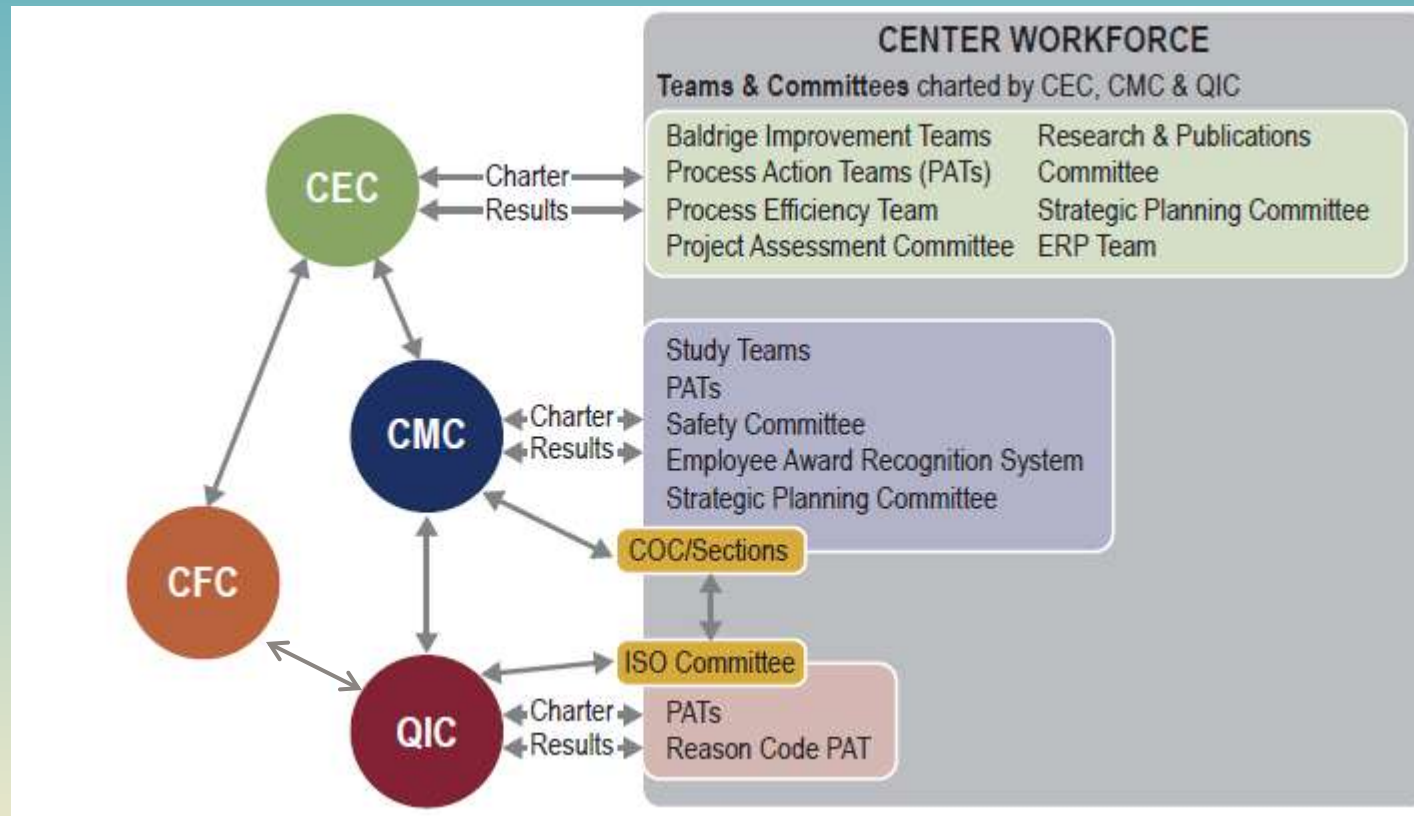
Leadership: Effectiveness Index

Mean Score of C05-C08 Survey Statements Scale of 1 to 5



Systems Integration

Key Interlocking Committees



Systems Integration – Dashboard 2

QIC: Quality Improvement Committee

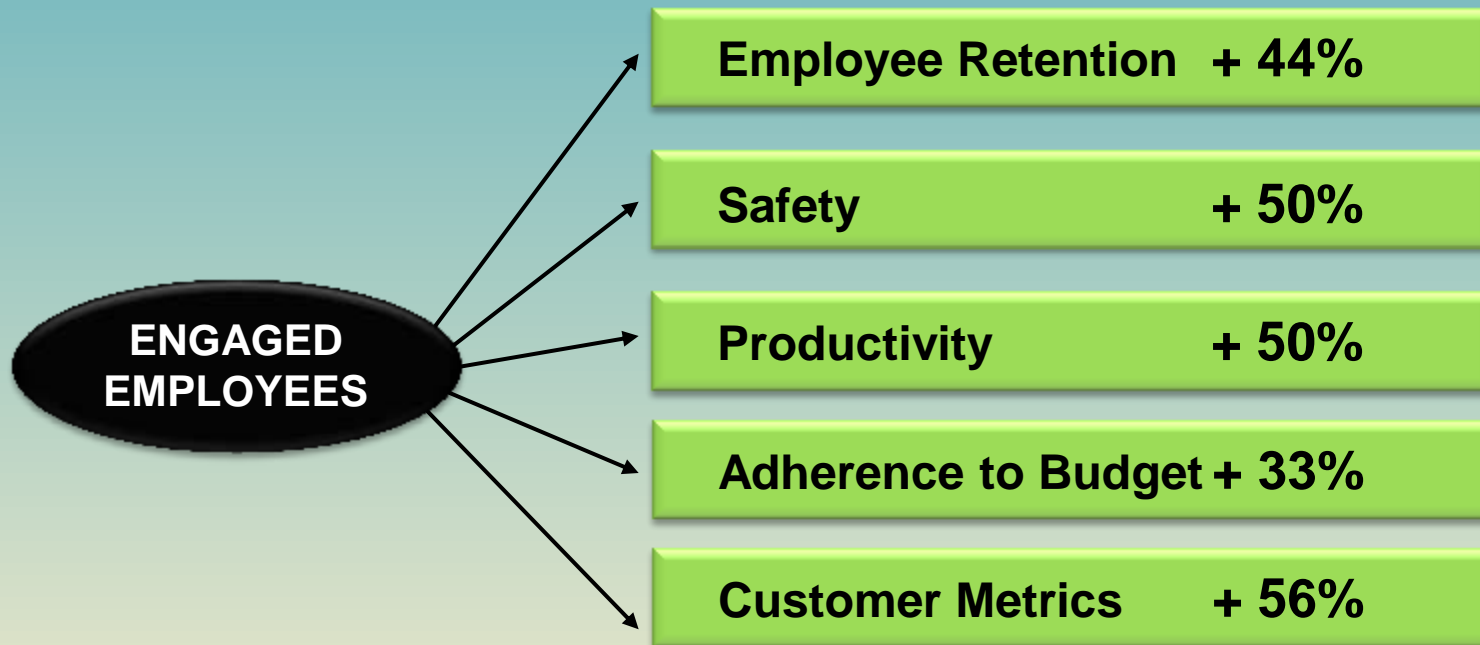
CAPA systems must focus on processes, not on people.

Punitive systems **MUST Not Be Used**

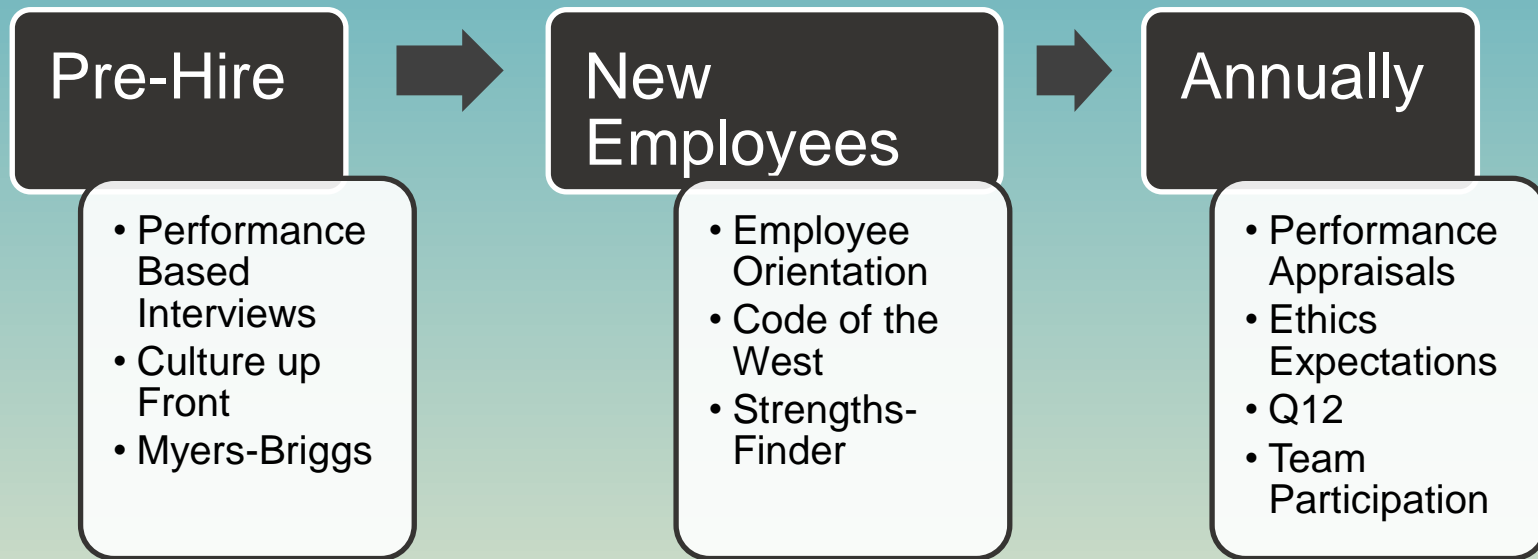


Metrics that Matter

↑ in probability of success when engagement is ↑



Engagement is a Process



SAW, Environmental Scans, SPEED, Teams, Community Outreach

Pre-Hire

Performance-Based Interviewing



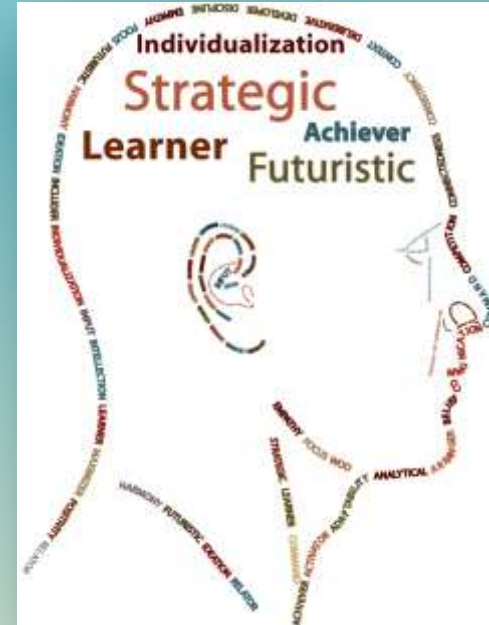
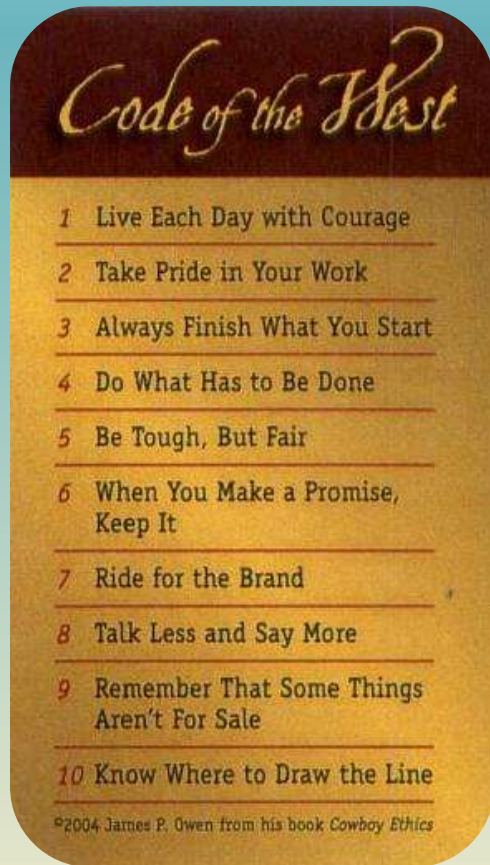
Assess Fit with Values

- Leadership
- Customer Service
- Safety
- Teamwork
- Continuous Learning

Define Culture

Styles: Myers-Briggs

On-Boarding



StrengthFinder©

- Development tool to help employees discover their Top 5 “signature themes”
- Consistent, near-perfect performance in a task = Strength

Ethics Expectations

Strengths-Based Approach



- Pharmaceutical Expertise
- Hallmark of quality
- Organizational Strengths Are:
 - ✧ Achiever
 - ✧ Learner
 - ✧ Responsibility
 - ✧ Deliberative
 - ✧ Relator

Daily Opportunities

Booth Duty



Hosting Visitors

Celebrations

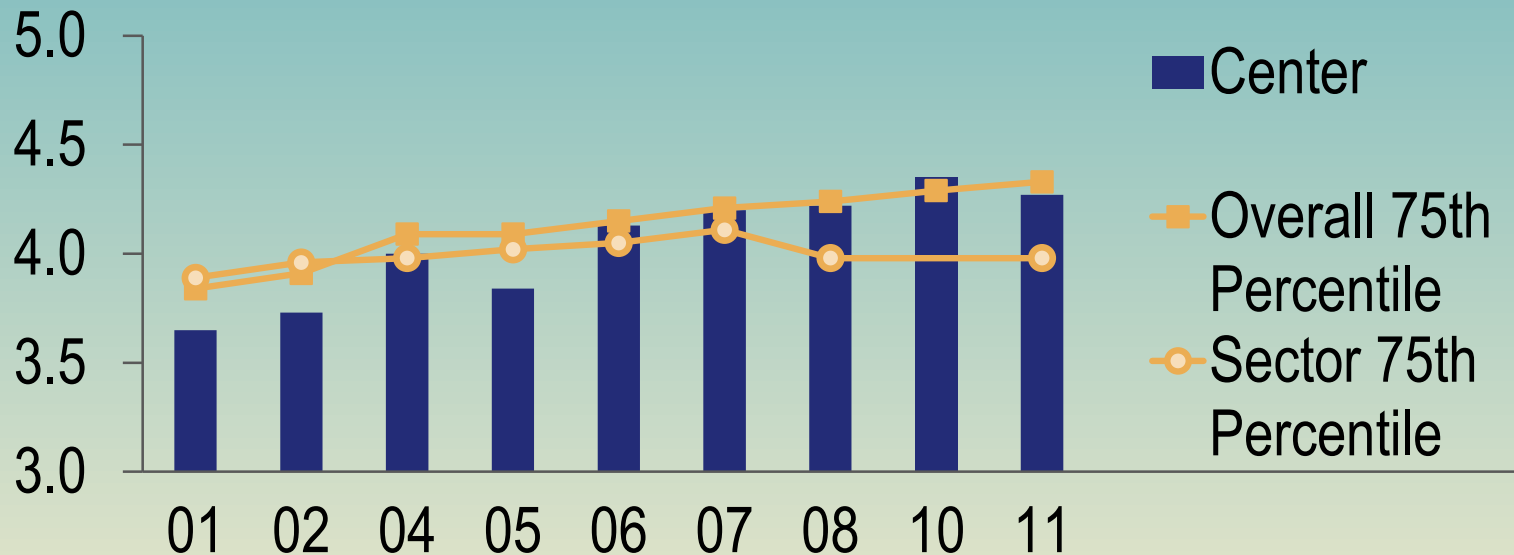


Workforce Engagement

Grand Mean Score

Scale of 1 to 5

▲ *Good*



Regular recognition is a key

“In the last seven days, I have received recognition or praise for doing good work” – Q04

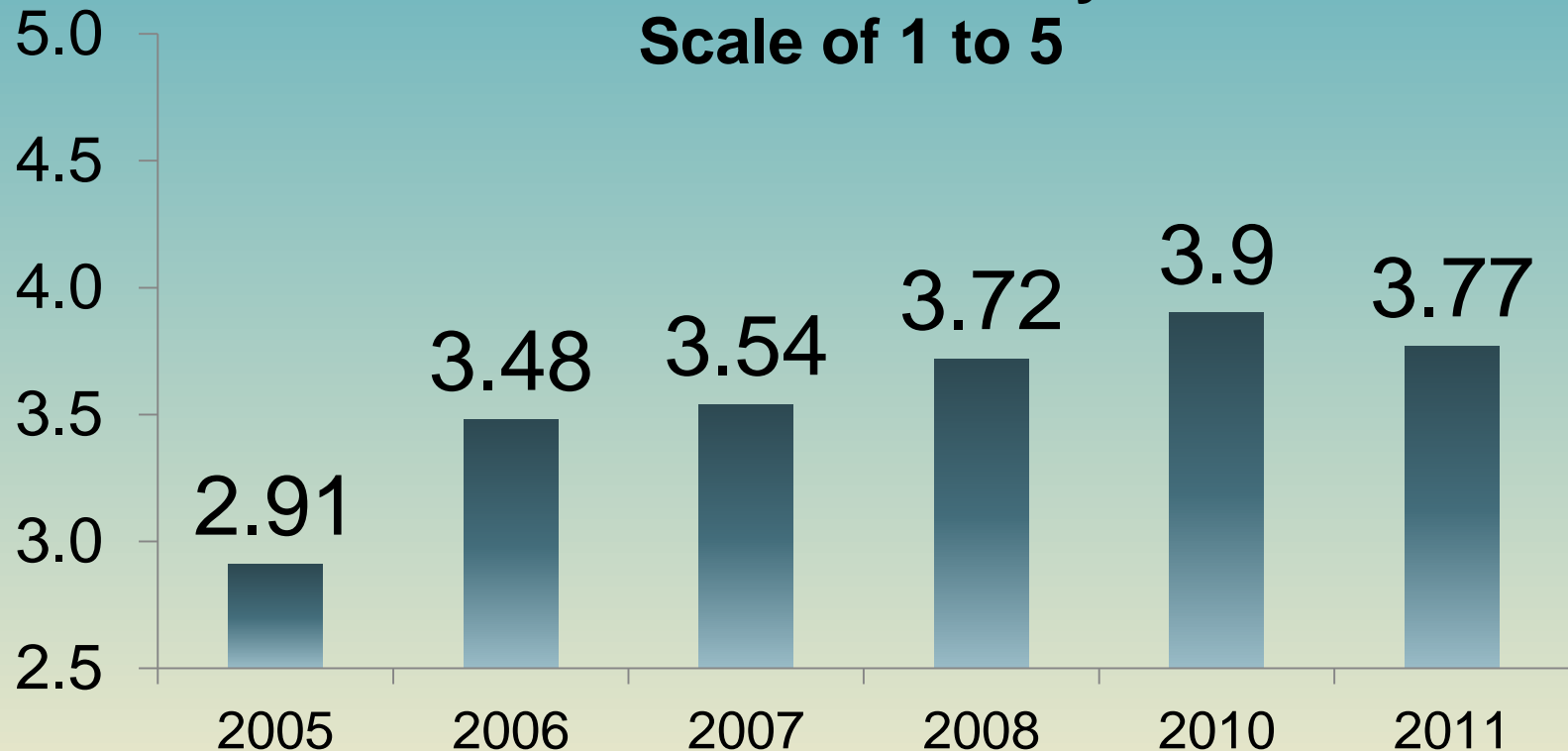


EARS –
Employee Award
& Recognition
System

Employee recognition

EARS

Mean scores of QO4 survey statement
Scale of 1 to 5



EARS implemented

Innovation Results

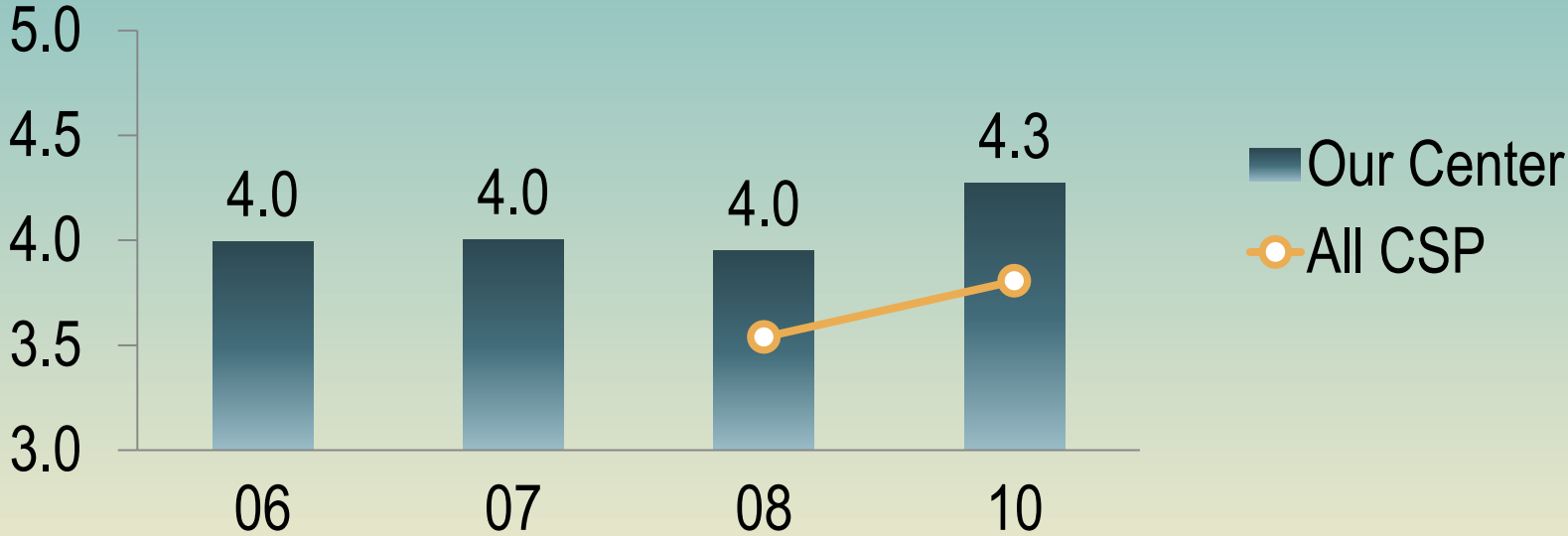
- I have enough time to innovate and discuss creative ideas with my colleagues.
- My current job brings out my most creative ideas.
- I feed off of the creativity of my colleagues.
- My organization encourages new ideas that defy conventional wisdom.
- I have a friend at work with whom I share new ideas



Innovation Index

Mean Score of Innovation-Related Survey Statements

Scale of 1 to 5



Building Blocks



Drivers

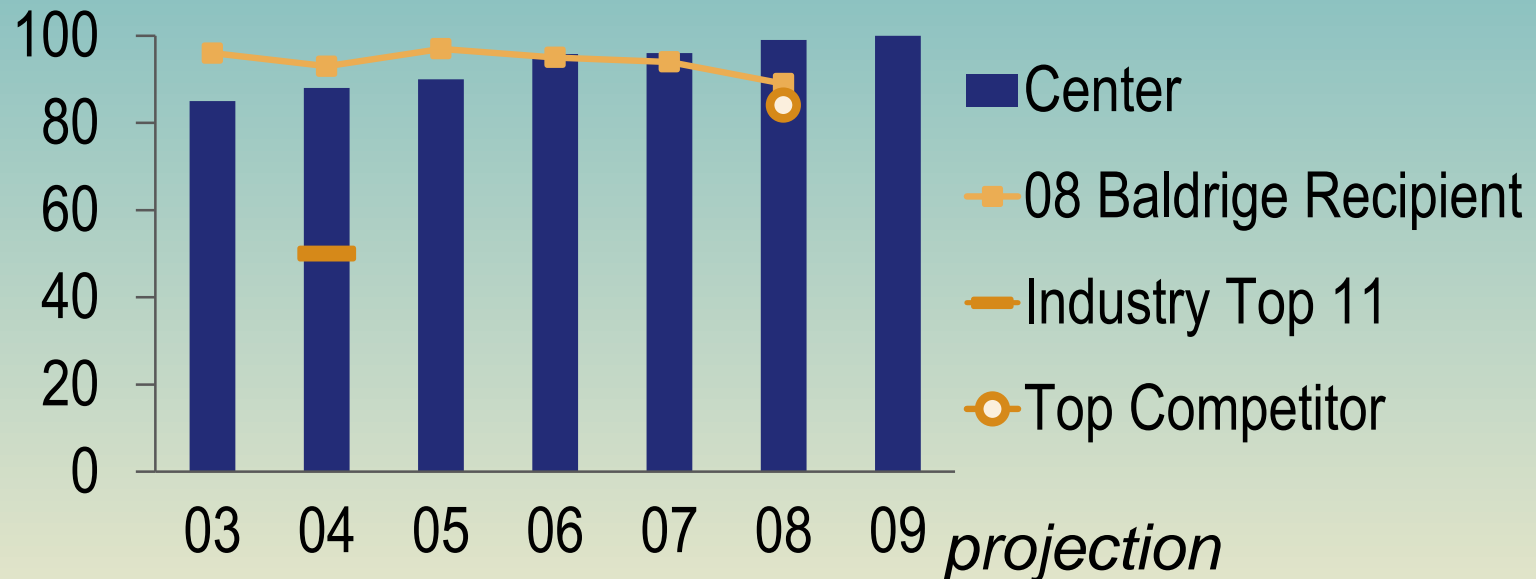
- PCC Staff always provides accurate & timely information about drug information & handling procedure changes.
- PCC Staff always provides the highest quality of communication to study team members.
- The information received from PCC is always timely.
- PCC Staff always provides the right amount of communication to study team members.
- The information received from PCC is always accurate.
- Drug/Device Accountability Forms are well-designed & easy to complete.
- PCC Staff is an exceptional source of pharmaceutical expertise at every phase in a study.

Overall Satisfaction: 2003 - 2009

Top Two Box Overall Customer Satisfaction

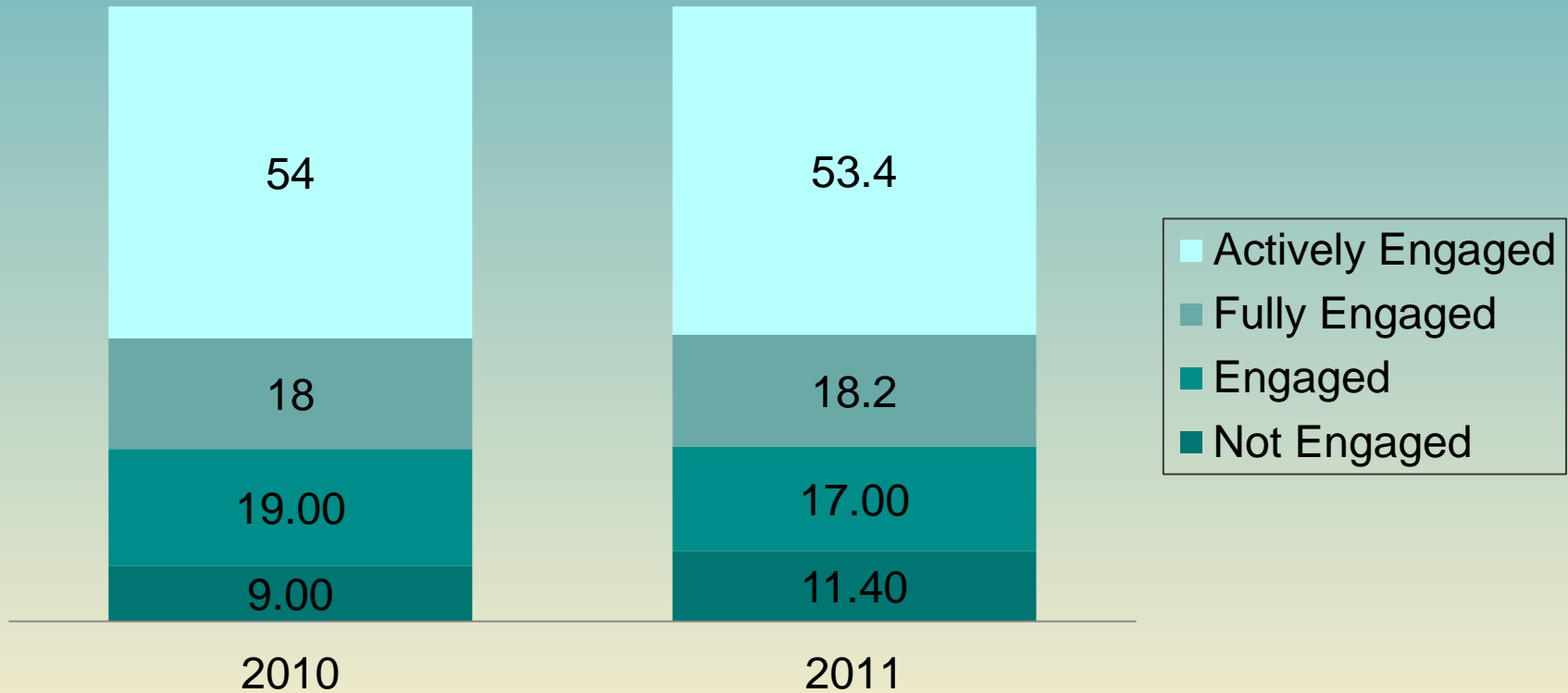
% of 4 & 5 Responses

▲ *Good*



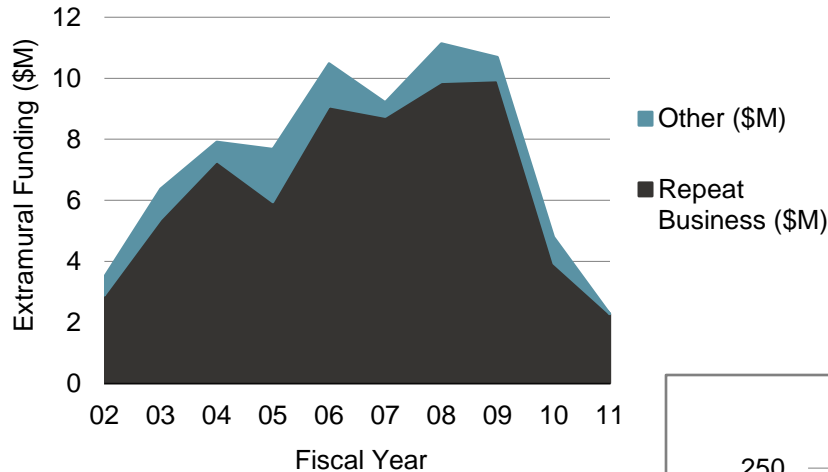
CE¹¹ Customer Engagement

**VA PCC exceeds Gallup 90th Percentile
Actively Engaged = 53%**



Strategy based on Results

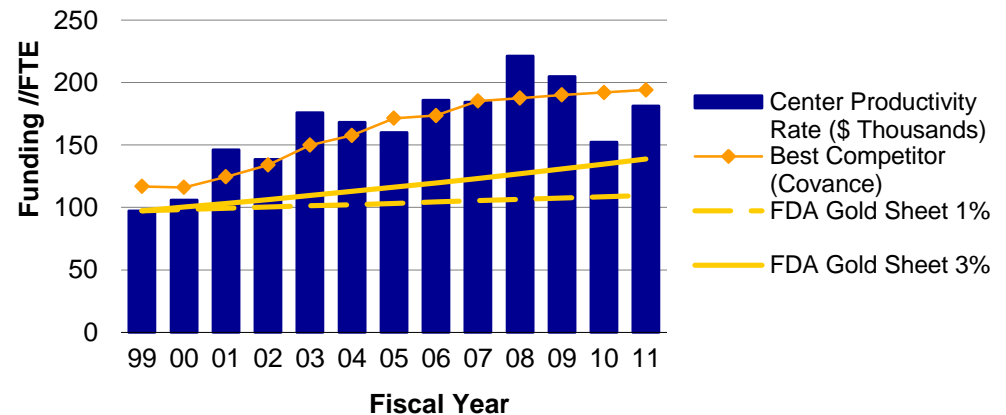
Customer Engagement: Repeat Business As Compared to Total Extramural Funding



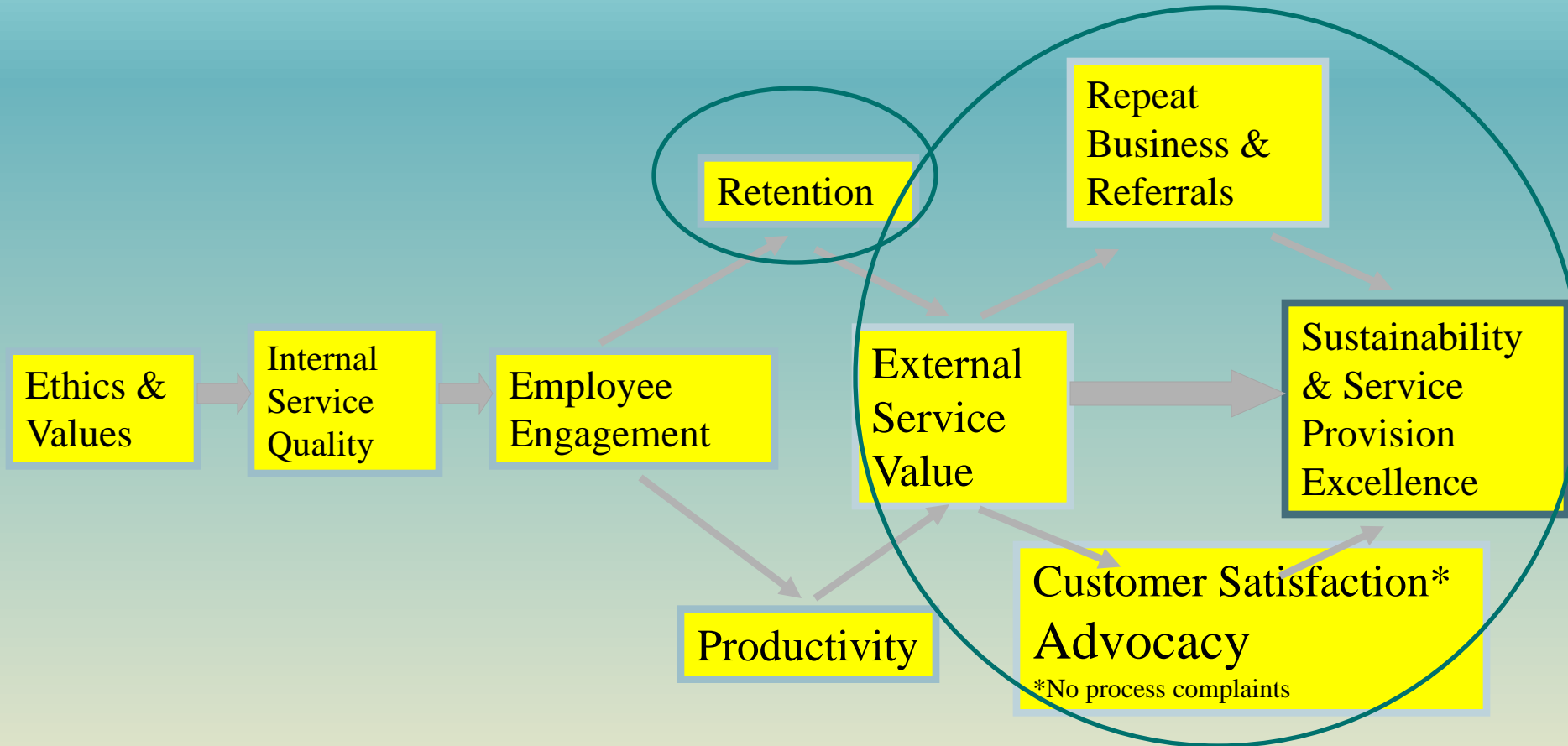
Increase repeat/referral business by identifying key factors to make us attractive to customers.

Increase Productivity through innovation and increased capabilities

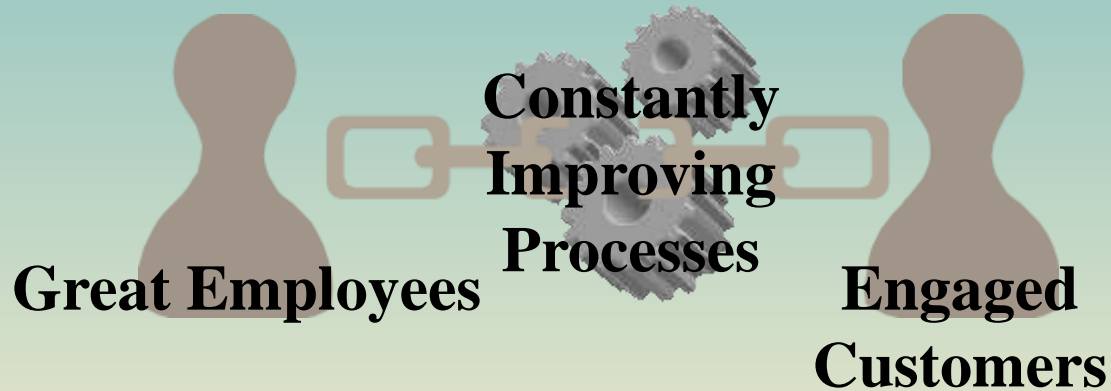
Productivity Rate



Results: Service-Value Chain



Holistic Approach



Where Do We Go From Here?

– Future Plans

- Measures Integration Team (MIT) develop measures designed to track strategy. (WIGS....wildly important goals)
- Dashboards for all major committees.
- Continue selecting appropriate Measures by aligning to key committees.
- Seek better benchmarks and comparative measures. What is World-Class?

Questions and Discussion!

