CSP ABQ

VA COOPERATIVE STUDIES PROGRAM

CLINICAL RESEARCH PHARMACY COORDINATING CENTER

Research and Development, Department of Veterans Affairs

Albuquerque, New Mexico
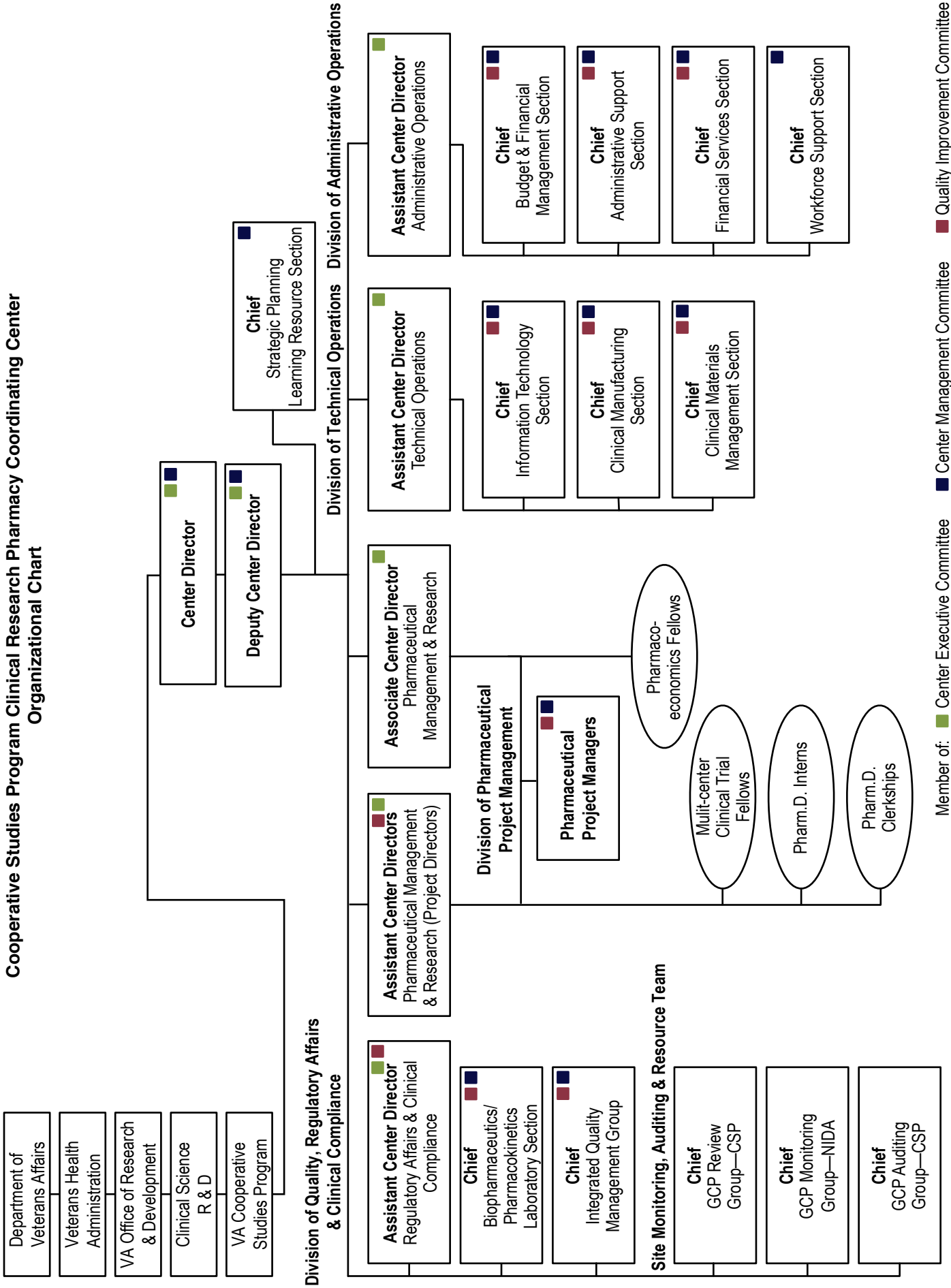

Malcolm Baldrige National Quality Award

2009 Application: Nonprofit Category

Public Version

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Cooperative Studies Program Clinical Research Pharmacy Coordinating Center Organizational Chart

- Department of Veterans Affairs
- Veterans Health Administration
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Center Director

Deputy Center Director

Chief
Strategic Planning Learning Resource Section

Division of Administrative Operations

Assistant Center Director
Administrative Operations

Chief
Budget & Financial Management Section

Chief
Administrative Support Section

Chief
Financial Services Section

Chief
Workforce Support Section

Division of Technical Operations

Assistant Center Director
Technical Operations

Chief
Information Technology Section

Chief
Clinical Manufacturing Section

Chief
Clinical Materials Management Section

Division of Pharmaceutical Project Management

Associate Center Director
Pharmaceutical Management & Research

Assistant Center Directors
Pharmaceutical Management & Research (Project Directors)

Pharmaceutical Project Managers

- Pharmaco-economics Fellows
- Mulit-center Clinical Trial Fellows
- Pharm.D. Interns
- Pharm.D. Clerkships

Division of Quality, Regulatory Affairs & Clinical Compliance

Assistant Center Director
Regulatory Affairs & Clinical Compliance

Chief
Biopharmaceutics/ Pharmacokinetics Laboratory Section

Chief
Integrated Quality Management Group

Site Monitoring, Auditing & Resource Team

Chief
GCP Review Group—CSP

Chief
GCP Monitoring Group—NIDA

Chief
GCP Auditing Group—CSP

Member of: ■ Center Executive Committee   ■ Center Management Committee

■ Quality Improvement Committee

Glossary of Terms and Abbreviations

A

ACCORD: Action to Control Cardiovascular Risk in Diabetes Clinical Trial
ACD: Assistant Center Director
ACSI: American Consumer Satisfaction Index
ADMS: Administrative Section
AE: adverse event
AMP: approved methods and procedure
AQL: acceptable quality level
ASTD: American Society for Training and Development

B

BEST: The American Society of Training and Development awards to organizations that demonstrate enterprise-wide success as a result of employee learning and development.
BFMS: Budget and Financial Management Section
BPLS: Biopharmaceutical/Pharmacokinetics Laboratory Section
BRINM: Biomedical Research Institute of New Mexico
BSC: Balanced Scorecard

C

CA/PA: corrective action/preventive action
CAGR: Compound Annual Growth Rate
CAP: College of American Pathologists
Carey award: Highest quality award in VA, uses Baldrige Criteria
CEC: Center Executive Committee
CenterWatch: Clinical trials industry publication.
CFC: Customer Focus Committee
cGMP: current Good Manufacturing Practices
clinical supplies: drugs, devices and ancillary supplies, such as syringes.
CMC: Center Management Committee
CMMS: Clinical Materials Management Section
CMS: Clinical Manufacturing Section
COC: Center Operations Committee
Cowboy Ethics: Owen, J. P. & Stoecklein, D. R. (2004) Cowboy ethics: What Wall Street can learn from the code of the west. Ketchum, ID: Stoecklein Publishing & Photography.
COE: Circle of Excellence
COOP: Continuity of Operations Plan
CPR: cardiopulmonary resuscitation
CRM: customer relationship management
CRO: contract research organization
CSP: Cooperative Studies Program
CTPP: Clinical Trial Project Plan
CTSC: Clinical Trials Support Center

D

DEA: Drug Enforcement Administration
DPM: Division of Project Management

E

EARS: Employee Award & Recognition System
EEOC: Equal Employment Opportunity Commission
EOP: Emergency Operations Plan
EPA: Environmental Protection Agency
EPAC: ERP Process Approval Change Board
eQMS: electronic Quality Management System
ERP: Enterprise Resource Planning

F

FAR: Federal Acquisition Regulation
FDA: Food and Drug Administration
Frost & Sullivan: Source of competitive market information.
FSS: Financial Services Section
FTE: Full-time Equivalent
FY: fiscal year

G

Gallup Q^{12}: The 12-question Employee Engagement Survey created by The Gallup Organization. Responses to the following questions range from 1 (Extremely Dissatisfied or Strongly Disagree) to 5 (Extremely Satisfied or Strongly Agree). Gallup and Q^{12} are registered trademarks of The Gallup Organization.
GCP: Good Clinical Practices
GDP: gross domestic product

H

Health Canada: Department of the Canadian government with responsibility for national public health
HIPAA: Health Insurance Portability and Accountability Act of 1996
HR: Human Resources

I

ICH: International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
ICON: CRO competitor
ICS: Incident Command System
ID: identification
IDP: Individual Development Plan
IQM: Integrated Quality Management Section
IRB: Institutional Review Board
ISO: International Standards Organization, internationally recognized standards that require products and services that meet or exceed customer requirements and regulatory standards, address customer satisfaction, ensure continual improvement and prevent nonconformances
IT: information technology
ITS: Information Technology Section

L

La Puerta: Clinical supply management and tracking system.
LAN: local area network

M

MBNQA: Malcolm Baldrige National Quality Award
MBTI: Myers-Briggs Type Indicator personality instrument
MedDRA: Medical Dictionary for Regulatory Activities

N

NCI: National Cancer Institute
NHLBI: National Heart, Lung, and Blood Institute
NIDA: National Institute on Drug Abuse
NIH: National Institutes of Health

O

OHRP: Office for Human Research Protections
OSHA: Occupational Safety and Health Administration

P

PAC: Project Assessment Subcommittee of CEC
PAT: Process Action Team
PET: Process Efficiency Team
Pharm.D.: Doctor of Pharmacy
PM: project management
PMR: Pharmaceutical Management & Research, group consisting of clinical research pharmacists and pharmaceutical project managers
ppm: parts per million
PPM: pharmaceutical project manager
PROQUIS: Integrated computer application for maintaining the quality management system.

Q

QIC: Quality Improvement Committee
QMS: quality management system
QNM: Quality New Mexico

R

R&D: research & development
RACC: Regulatory Affairs and Clinical Compliance
RFID: radio frequency identification
RFP: request for proposal
ROI: return on investment
RSD: relative standard deviation

S

SAE: serious adverse event
SAW: Strategic Awareness Wall
SMART: Site Monitoring, Auditing, and Resource Team
SOP: Standard Operating Procedure
SOW: Statement of Work
SP: Strategic Planning
SPC: Strategic Planning Committee
SPEED: Strategic Planning Employee Empowerment Day
SPLRS: Strategic Planning Learning Resource Section
SPP: Strategic Project Plan
SWOT: Strengths, Weaknesses, Opportunities and Threats

U

UNM: University of New Mexico
US: United States

V

VA: Department of Veterans Affairs
VACSP: Veterans Affairs Cooperative Studies Program
VAMC: Veterans Affairs Medical Center, now known as the New Mexico VA Health Care System
VHA: Veterans Health Administration

W

wiki: Online collaboration tool used to add and edit content.

Z

Zia: Quality New Mexico award for performance excellence.

P. Organizational Profile

The Veterans Affairs Cooperative Studies Program (VACSP) Clinical Research Pharmacy Coordinating Center (the Center), a small organization of approximately 112 people, supports and manages drug-related activities in clinical trials. Clinical trials study the effectiveness and safety of drugs in humans under stringently controlled research conditions. A trial can involve single or multiple sites in the US and internationally. The Center provides customized services to meet the clinical trial requirements for the production and distribution of drugs to the clinical trial sites. Medical and administrative personnel at the sites provide direct service to patients enrolled in the trials. While the Center has no direct contact with patients, we support patient safety through training of site personnel, site monitoring and ensuring regulatory compliance for all processes.

The first Cooperative Study involved a drug (streptomycin) for treating tuberculosis in World War II veterans. In 1972, VACSP was formally established in Washington, D.C., as a clinical trial research program within the Department of Veterans Affairs (VA) Office of Research and Development to improve the health and care of the veteran and the nation. VACSP includes five Coordinating Centers, which provide statistical and methodological guidance on conducting clinical trials. A sixth Center (our Center) was created to provide pharmaceutical ex-

pertise on VACSP trials.

The Center moved to Albuquerque, NM, and has expanded its support to clinical trials funded by organizations other than VACSP. At any time, the Center participates in more than 70 clinical trials, each lasting from a few months to over 14 years. As of May 2009, Center personnel are actively supporting 78 clinical trials. Over the last three years, the Center supported trials that average over 90,000 patients per year at approximately 1,576 sites using approximately 285 drugs.

P.1 Organization Description

P.1a(1) The Center's **main product offerings** support the pharmaceutical, safety and regulatory aspects of clinical trials. Figure P.1–1 describes the product and service offerings and associated **delivery mechanisms**. The scope of products and services provided varies with the length and complexity (such as number of drugs, patients, sites and technology requirements) of each clinical trial.

P.1a(2) The Center embraces an **open culture** characterized by respect, innovation and high performance. A deep understanding and appreciation of the importance of processes and systems run through the Center. The overall **purpose** of the Center is to improve the health of veterans and humankind through its work

Main Product & Service Offerings	Delivery Mechanisms
Pharmaceutical Study Design & Project Management	
For each study team, a clinical research pharmacist serves as project director. The project director oversees pharmaceutical requirements, and a pharmaceutical project manager (PPM) handles operations. The project director and PPM negotiate service delivery milestones with customers for each clinical trial.	▪ Scheduled meetings, project plans, site visits and status reports on pharmaceutical activities ▪ Ongoing phone and email communications ▪ Web-based applications to share and manage key information and documents
Safety & Regulatory Compliance	
GCP Training, Site Monitoring & Audits: The Center's Site Monitoring, Auditing, and Resource Team (SMART) provides Good Clinical Practices (GCP) training to site personnel, monitors sites and audits trials to assure adherence to regulations and procedures.	▪ Onsite GCP training ▪ Scheduled and for-cause (requested) site visits ▪ Ongoing phone and email communications ▪ GCP material and tools
Regulatory Compliance: The Center's Regulatory and Clinical Compliance (RACC) section categorizes and codes patients' adverse events (AEs) to clinical trial drugs. RACC uses the Medical Dictionary for Regulatory Activities (MedDRA), a medical classification dictionary, to code AEs and serious adverse events (SAEs), those that are potentially life-threatening. RACC prepares SAEs and AEs for the Data Monitoring Committees, Food and Drug Administration (FDA), the participating investigators and trial management.	▪ Center-developed system to receive raw data and send coded data ▪ Ongoing phone and email communications ▪ FDA Safety Reports
Drug Production & Shipping/Distribution	
Manufactured, Packaged and Labeled Drug Products: The Center manufactures tablets or capsules based on the requirements of a trial. For some trials, the Center modifies and/or repackages procured drugs already on the market. The Center manufactures both active drug and placebos (inactive substances) that appear identical to the active drug for blinded studies. The Center labels and packages drug products for shipment to clinical trial sites. **Drug Shipping/Distribution:** The Center maintains the drug inventory and ships to sites based on the requirements of the trial.	▪ Manufacturing, packaging, labeling and shipping systems supported by trained employees and written procedures in an International Standards Organization (ISO)-certified environment ▪ Custom web-based, phone or other systems for inventory tracking

Figure P.1–1 The Center's product and service offerings are customized to meet the requirements of each clinical trial.

on clinical trials that target current veteran health issues. Figure P.1–2 lists our mission, vision, ethics statement and core values.

Mission: To provide creative and innovative pharmaceutical, scientific, technical, operational and educational support to clinical trials conducted to improve the health and care of the Veteran and the nation.

Vision: We are the pioneers in developing and managing the pharmaceutical aspects of clinical trials, while setting industry standards and exceeding customer expectations.

Ethics Statement: We foster an environment where the culture is doing the "right thing" and accepting responsibility.

Core Values:
- **Leadership:** We are committed to become leaders in our areas of work to continuously improve the efficiency, effectiveness, productivity, and quality of the Center.
- **Customer Service:** We are committed to providing customers high quality products and services they can trust.
- **Safety:** We are dedicated to the safety of patients who volunteer for our clinical trials and to all Center personnel.
- **Teamwork:** We are committed to working together in a highly skilled team environment to promote cooperation, effective communication and knowledge/skill sharing.
- **Continuous Learning:** We will provide excellent training and education to our employees in an environment conducive to working together for the success of the Center.

Figure P.1–2 The Center's mission, vision, ethics and core values comprise our purpose.

Soon after the Center was established, leadership identified the Center's **core competency** as pharmaceutical expertise, which they recognized as the critical element required to fulfill our mission and to sustain our operation. The Center describes pharmaceutical expertise as a full range of customized services and expertise in clinical trials design and management; safety and regulatory compliance; and manufacturing, packaging, labeling and shipping of drug supplies.

Our core competency has continually evolved to accomplish our mission of "improving the health and care of the Veteran and the nation" and to maintain a strategic advantage over our competition. The timeline in Category 6 (Figure 6.0) outlines this evolution through added capabilities and improvements.

P.1a(3) The Center workforce combines over 100 full- and part-time permanent and temporary staff in professional, technical and administrative positions, including clinical research pharmacists, project managers, chemists, programmers and production technicians. The Center staff also includes fellows and student interns from the University of New Mexico (UNM) College of Pharmacy and other colleges.

The Center hires employees through VA and Biomedical Research Institute of New Mexico (BRINM), a not-for-profit supplier affiliated with the VA. A **bargaining unit** represents 32 VA employees. Figure P.1–3 lists **key benefits**, which are discussed further in 5.2b(2).

Every employee works in a functional section supervised by a management team member. Through our matrix manage-

Key Benefits	
- Health & Dental Insurance	- Retirement Savings
- Flexible Spending Accounts	- Tuition Reimbursement
- Paid Holidays, Vacation & Sick Leave	- Flexible Work Schedules & Compressed Work Week

Figure P.1–3 Our benefits package provides generous support for Center workforce.

ment work system (Figure 5.1–1), section chiefs assign employees to study teams led by a project director. This strong team focus across functional sections improves staff development and organizational learning (7.4a[2]). In addition, employees may serve as members of other teams, such as Process Action Teams, ISO Committee, Safety Committee, Customer Focus Committee and Process Efficiency Team (Figure 1.1–2).

We identify **workforce segments** by VA versus BRINM as well as division, education and tenure for purposes of reviewing employee data. However, our culture creates an environment where everyone contributes and is rewarded without regard to segment. We strive for a seamless organization of employees receiving equal treatment and benefits, and working toward common goals. Team membership provides all employees the opportunity to lead in their discipline, regardless of education or tenure.

Job diversity ranges from pharmacists to support personnel. The Center has a highly educated and trained staff with 12.5% holding doctoral degrees, 14.3% master's degrees, 24.1% bachelor's degrees, 6.3% associate's degrees, and 1.8% professional certification. The remaining staff have high school diplomas. Workforce tenure shows longevity with 2.0% of the staff employed for more than 30 years, 4.9% for 21–30 years, 24.5% for 11–21 years, 17.6% for 6–11 years, 35.3% for 2–6 years and 15.7% for fewer than 2 years. The education levels achieved by staff and their years of employment at the Center add breadth of experience and perspective to the organization. Diversity of management reflects diversity of our staff. Our Center Director holds the philosophy that employees of diverse talents, interests and experiences contribute to our success.

The primary **key factor** that motivates the workforce in accomplishing the Center's mission is the mission itself. The Center's mission fulfills an innate human need to help others and thus engages our workforce; our jobs enable us to participate in providing the best healthcare possible to veterans, individuals willing to lay down their lives to protect us and our freedoms. The research in which the Center participates not only aids veterans, but also helps our families and friends. The Gallup Q^{12} Engagement measure (Figure 7.4–1) includes the following question: The mission or purpose of my organization makes me feel my job is important. In 2008, the Center scored above the national Gallup average on this question.

Special Health & Safety Requirements: Although drug manufacturing and testing may involve hazardous substances, our safety rate exceeds all known benchmarks (Figure 7.4–13). The Center personnel safety requirement is zero incidence of accidents. Safety is an enduring core value and is reinforced through training, operating procedures and trial-specific documentation. Before working with any potentially harmful materials, employees receive required safety training and certification. Safety

Committee members perform safety inspections and ensure adherence to VA safety requirements. While we have no direct patient contact, we are committed to the design and implementation of patient safety systems. We have dedicated groups to support the protection of human subjects and to monitor adverse events within the trials. In addition, the Center provides current Good Manufacturing Practice (cGMP) and GCP training, which both have significant safety aspects.

P.1a(4) Facilities: The Center resides in a consolidated 68,000-square-foot high-security facility that includes an annex added in 2005 to meet growth needs. The annex increased overall facility size by nearly 50 percent. The facility includes offices, laboratory and environmentally controlled production suites and warehouses.

Technologies: We use a variety of programming languages and platforms to develop customized applications for producing, tracking, and monitoring drugs and trial-related data, including in-house and clinical trial sites inventory management and adverse events. The Center pioneers the use of various technologies for internal operations, including Radio Frequency Identification (RFID), bar coding and quality management systems. We are one of the first VA organizations to successfully implement Enterprise Resource Planning (ERP) to provide an auditable, integrated financial system.

Equipment: Production suites and highly specialized equipment support drug manufacturing, packaging, labeling and distribution. The Center maintains a state-of-the-art laboratory to support patient sample analysis and testing of drugs. The warehouses provide refrigerators, freezers and vault storage. The Center is one of the first two facilities in the world with the capability to manufacture liquid-filled hard gel capsules in a single innovative process. We recently acquired new equipment that allows continuous in-process analysis while mixing drug ingredients in our manufacturing process.

P.1a(5) The Center operates in a **highly regulated** environment, which includes mandatory regulatory compliance in drug manufacturing, patients' rights and safety, and organizational operations (Figure P.1–4). The Quality Hierarchy (Figure P.1–5) builds upon regulatory requirements and quality management to achieve performance excellence. The Center's expertise in monitoring, adhering to and regularly exceeding federal, state and local regulations (Figure 7.6–6) and guidelines enhances patient safety and regulatory oversight, and provides an advantage over less compliant competitors. Internal and external audits ensure regulatory and ISO compliance, and the external examination process ensures Baldrige Criteria compliance.

P.1b(1) The **organizational chart** represents reporting relationships among VA, VACSP and the Center. VACSP provides overall management, control, strategic direction, global standard operating procedures and guidelines. Federal policies, such as equal opportunity, accountability, human research protection and open government, flow to VACSP and Center policies. Albuquerque VA Medical Center provides fiscal, acquisition and human resources (HR) support to the Center.

P.1b(2) We categorize **market segments** by funding source:

Authority	Purpose/Oversight
Drug Manufacturing	
DEA	Registration for storing, manufacturing and disposing controlled drugs
FDA, Health Canada	cGMP regulations for manufacturing, packaging and distributing drugs and food
CAP*	Certification for bioanalytic and clinical chemistry laboratories
Patients' Rights & Safety	
FDA	Institutional Review Board (IRB), ICH, GCP and HIPAA regulations and guidelines for the rights, welfare and privacy of clinical trial subjects and data validity
OHRP	Accreditation and monitoring of IRBs, policy guidance and education
Operational	
EPA	Environmentally sustainable operations
VA	Research, fiscal, IT, HR and safety activities
FAR	Government purchasing
ISO 9001:2000*	Quality management system (QMS) including corrective actions
ISO 15378: 2006*	QMS requirements specific to packaging for medicinal products

Figure P.1–4 *The Center adheres to mandatory federal, state and local regulations as well as many voluntary regulations [marked with an asterisk (*)].*
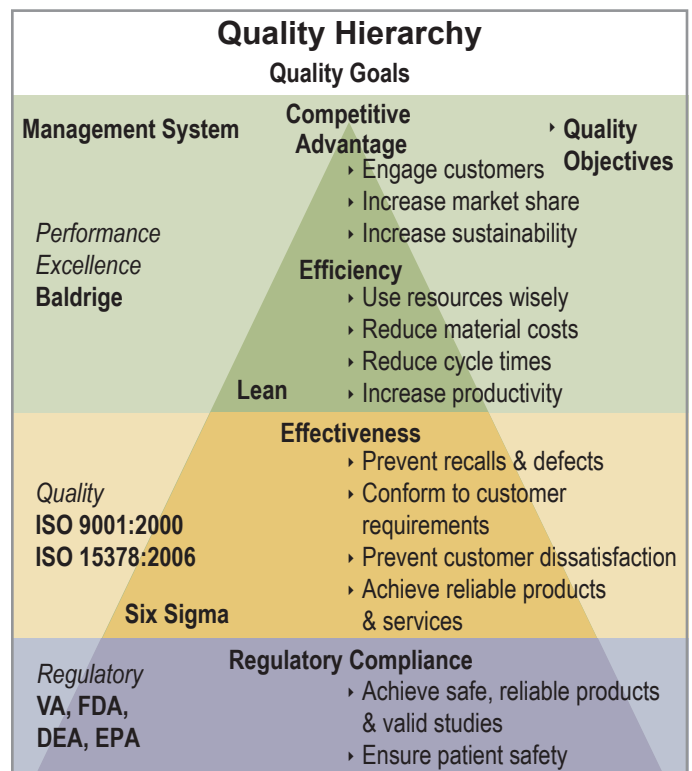

Figure P.1–5 *Center capabilities are enhanced through organizational culture and processes that embrace regulatory, quality and performance excellence management systems. See Figure P.1–4 for a complete regulatory compliance list.*

VACSP, Federal such as National Institutes of Health (NIH), and Industry (universities and drug companies). We refer to non-VACSP trials collectively as "extramural." Our direct **customer groups** are (1) investigators who initiate and oversee the clinical trial sites and (2) other site personnel who interact with enrolled patients. These customer groups have the same requirements (Figure P.1–6), which do not vary across market segments. **Stakeholders** are our key communities defined in 1.2c(2): veterans and national health, pharmaceutical education and quality communities. While we do not interact directly with veterans and patients enrolled in clinical trials, they are important beneficiaries of our clinical trial results.

Customer Requirements & Expectations
Zero Defects: Shipped drug (Fig. 7.1–1)
Operational/Scientific Integrity ▪ Center operations (Figures 7.1–2 & 7.1–3) ▪ GCP and clinical trial training (Fig. 7.1–4)
On-Time Delivery ▪ Adequate clinical supplies* at sites (Fig. 7.1–5) ▪ Satisfaction with clinical supplies maintained at sites (Fig. 7.1–6)
Responsiveness ▪ Information is adequate and timely (Fig. 7.1–7) ▪ Responsiveness to requests (Fig. 7.1–8)

*Figure P.1–6 Both key customer groups have the same requirements and expectations. *Clinical supplies include drugs, devices and ancillary supplies such as syringes.*

P.1b(3) The following key **supplier** types provide the Center with products and services that meet clinical trial requirements:
- Drug companies play unique roles as suppliers because clinical trials often use donated and/or purchased drug that the Center repackages to meet trial requirements.
- Shipping supplier provides overnight delivery of drug products to the trial sites.
- While the Center selects all personnel, VA and BRINM supply HR services to recruit and hire personnel and provide compensation and benefits. The Center's key requirements are cycle time to hire and equality of benefits (5.2b[2]).

Relationships with suppliers are defined in contracts, service agreements and statements of work. Through meetings, scheduled teleconferences, other phone conversations, emails and person-to-person interaction, Center personnel establish ongoing communication and strong personal relationships.

P.2 Organizational Situation

P.2a(1) As a very small non-profit government entity, our competitive options for pursuing customers are limited by regulation and must be consistent with the VA research mission. Within VA, we maintain a unique **competitive position** as the sole clinical research pharmacy coordinating center and have no direct competitors. External to VA, we selectively support clinical trials consistent with the VA mission from both the public and private sectors, in particular from NIH research projects.

Competitors are more than 800 contract research organizations (CROs) worldwide. The Center is a niche provider of a range of pharmaceutical research services that customers desire (Figure 3.2–2). If the Center were publicly traded, our market share would represent approximately 0.24% of the CRO market in the US. Figure 7.3–6 shows market growth.

P.2a(2) Four principle factors determine the Center's **success relative to competitors**:
- **Productivity:** The Center exceeds best in class for productivity as measured against top CROs (Figure 7.3–3).
- **Quality:** We define key quality measures as defect rates of our key work processes (Figure 7.5–4), workforce engagement (Figure 7.4–1) and customer satisfaction (Figures 7.2–1 and 7.2–2). The work performed by the Center exceeds known benchmarks and remains nearly defect-free. This is a result of our quality initiatives, such as our ISO certification, leadership in regulatory compliance, and implementation of the Baldrige Criteria (Figure P.1–5). Extensive investment in technology and employee training also contributes to this high performance.
- **Capabilities:** The Center's extensive capabilities enable us to provide a wide range of customized pharmaceutical services to meet the unique needs of each clinical trial. Our ability to support complex trials with numerous sites, patients, drugs and technology requirements provides a strong advantage. Many added capabilities are a direct result of customer requirements (Figure 3.1–3). As part of the VA system, our VA trials have access to the largest group of patients in a single healthcare system in the nation.
- **Reputation:** Our reputation for pharmaceutical expertise, product delivery, flexibility, patient safety, quality management systems and regulatory compliance results in customer engagement with over 80% of our clinical trials coming from past customers and referrals.

Key changes that affect our competitive situation are:
- Increasing operational requirements of clinical trials, which demand increased capabilities and ingenuity
- Decreasing number of CROs due to mergers, which increases their capabilities and resources
- Ever-increasing regulations, which led us to focus on GCP training and to take a leadership position in ISO certification for the entire VACSP

P.2a(3) The highly competitive nature of the CRO industry limits the availability of benchmarking data. Product, service and customer data are held as trade secrets within the industry. Performance and process data are virtually impossible to obtain from competitors, because disclosure may be used in an FDA inspection. Unlike industries such as banking and healthcare that have regularly published official sources of comparative data, there is no centralized data collection organization for CROs to provide consistent benchmark data over time. We recently contracted with a third-party firm to conduct a benchmarking survey for key measures. Of the nine competitors contacted, eight declined to participate even though we guaranteed anonymity.

As a small organization and in order to conserve taxpayer dollars and workforce resources, we focus on obtaining free and

low-cost benchmarking data (Figure 4.1–3). If external comparator data are not available at a reasonable cost, we use internal historical data to perform analyses and set goals to drive performance improvement. The Center uses two key publications from within the industry for market-share and primarily financial comparative and competitive data: *CenterWatch* and Frost & Sullivan reports and publications. Professional journals, magazines and competitors' websites also provide limited data.

Center management reviews state and national quality award recipients for benchmarks and best practices outside the industry. We use state and national labor statistics where appropriate. The Center also participates in national benchmark forums with organizations such as Gallup and American Society for Training and Development. We use quality standards, including six sigma, to monitor variability and provide benchmarks for processes. Our Center has been identified as a "best practice" organization for our ISO internal audit program (6.2b[2]), Employee Award and Recognition System (Figure 7.4–3) and as a learning organization (5.1b[1]).

P.2b Figure P.2–1 lists **strategic challenges and advantages** that address our competitive situation and drive Center planning and organizational **sustainability**. The strategic advantages

Area	Ref. #. Strategic Advantages
All	A1. Experience and reputation for pharmaceutical expertise
Business	A2. Funding mechanisms: ▪ VACSP, interagency agreements, BRINM A3. Increased funding due to increased federal spending for research, even as GDP contracts A4. Engaged customers
Business/ Operational	A5. ISO-certified quality organization A6. FDA-registered cGMP facility A7. We stand behind our work
Operational	A8. Adequate clinical supplies at sites A9. Zero defects
HR	A10. Culture of learning and leadership A11. Engaged workforce A12. Low turnover

Area	Ref. #. Strategic Challenges
Business	C1. Increase number of relationships with federal customers C2. Expand extramural funding through the award of large, long-term clinical trials C3. Obtain competitor data
Operational	C4. Implement new processes and capabilities quickly while maintaining productivity, quality and safety C5. Meet intermediate- and long-range space issues within government procurement process C6. Federal contracting process
HR	C7. Federal cycle time to recruit employees

Figure P.2–1 The Center's core competency of pharmaceutical expertise provides an overarching advantage, which supports the key advantages in each area. The identification of strategic challenges helps to define and prioritize strategic goals.

and challenges provide a foundation for decision making related to the Center's strategic objectives/goals, discussed further in 2.1b(2).

P.2c Our **performance improvement system** (Figure P.2–2) is built upon the framework of ISO 9001:2000 principles and standards which:

- ▪ Require a top-down review and evaluation of every quality-related process within the organization
- ▪ Drive the organization to focus on its mission, goals and core competencies
- ▪ Focus on internal process improvements by finding, correcting and preventing potential problems including customer complaints (Figures 3.2–1 and 4.1–1)
- ▪ Create an environment for innovation where new ideas are encouraged, documented and implemented (Figure 7.5–3)
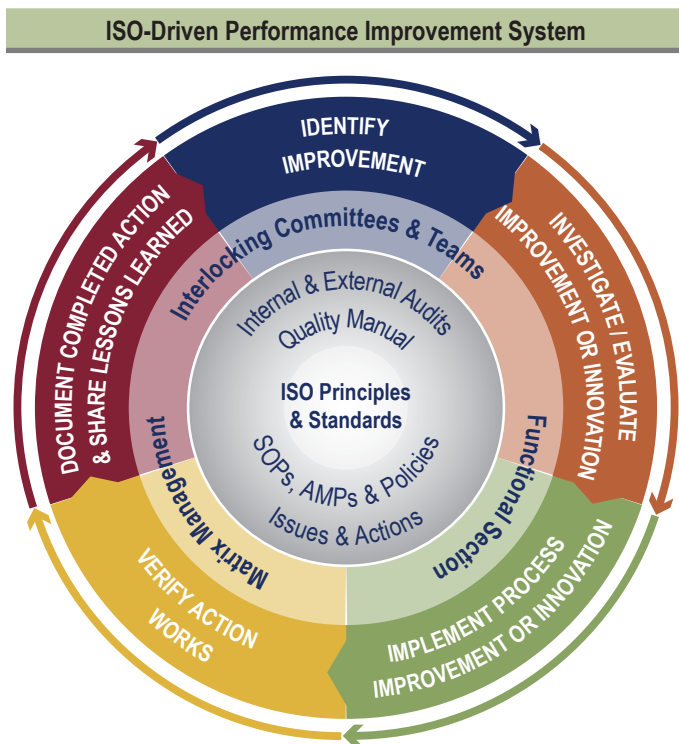

Figure P.2–2 ISO 9001:2000 principles and standards drive the Center's performance improvement system.

The ISO system is the central component of the Quality Hierarchy (Figure P.1–5) and is supported by an electronic quality management system (eQMS), which is fully deployed across the organization. The eQMS provides a complete closed-loop system to track audits, issues and actions as well as management and version control of key documents, including the Quality Manual. Results of the Center performance improvement system are shown in Figures 7.1–3, 7.5–12 and 7.6–4. Figure P.2–2 highlights key elements of the overall ISO-driven performance improvement system. The linkage of process improvements to innovation is shown in Figure 6.2–1.

1 Leadership

Leadership Improvements & Integration	
75	Employees: 4
85	Internal working agenda
90	Development of quality control lab
93	Interlocking committees*
96	Baldrige Quality Hierarchy
97	QNM Pinon recognition Formal strategic planning
98	QNM Roadrunner rec. GCP for VACSP (SMART)
99	Mission, vision & values Manufacturing
00	COC/SAW*
01	QNM Roadrunner rec. VA Carey Award VHA cat.
02	QNM Roadrunner rec. RACC VA Carey Award VHA cat.
03	CEC* ISO 9001 certification QNM Roadrunner rec. VA Carey award VHA cat.
04	QNM Zia winner VA Carey trophy winner
06	MBNQA pilot site visit VA COE award
07	MBNQA site visit VA COE award
08	Employees: 102
09	ISO 15378 certification QNM Compañero rec.

*Figure 1.0 Senior leaders have pioneered the growth of capability and workforce at the Center, while achieving recognition for high performance. *Indicates cycles of improvement*

1.1 Senior Leadership

1.1a(1) Our senior leaders **set** and **deploy** organizational **vision**, **values**, strategic goals and project plans to the **workforce**, key **suppliers** and **customers** and other **stakeholders** as part of our organizational culture (Figure 1.1–1) and through the strategic planning cycle (Figure 2.1–2). Our senior leaders include the Center Director and the Center Executive Committee (CEC) (highlighted in the organizational chart). Within our small organization, the interlocking committee structure provides valuable two-way communication among diverse groups and all levels of employees, which is an integral part of our leadership system (Figure 1.1–2). Milestones and cycles of refinement of our leadership system are highlighted in Figure 1.0. Key structures to deploy organization vision, values and direction include interlocking committees (formalized in 1993), the Strategic Awareness Wall (SAW) in 2000 and CEC in 2003.

Senior leaders' personal actions reflect each of the **organization's values**. Senior leaders follow the Center's "Ethical Expectations for Managers and Staff" to actively promote the **leadership** value by:
- Providing visionary leadership
- Maintaining high standards
- Actively supporting Center trials and initiatives
- Making necessary decisions
- Keeping the workplace free of threats or derogatory comments

Leaders' actions reflect the **teamwork** value by:
- Modeling cooperation and two-way communication (honest debate)
- Fostering knowledge and skill sharing among all employees
- Participating on cross-functional interlocking committees, matrix management teams and process action teams (Figure 1.1–2)

Leaders promote their commitment to the values of **customer service** and **safety** by:
- Treating each customer relationship as a priority
- Being responsive to internal and external customers
- Ensuring employee and patient safety by utilizing quality principles, high ethical standards, excellent product integrity and cutting-edge technology

Organizational Vision & Values		
How Leaders Set	• Review employee input from Strategic Planning Employee Empowerment Day (SPEED), internal customer satisfaction surveys, two-way topic specific meetings (i.e., ethics statement), staff meetings and daily interactions • Present "State of the Union" report and strategic plan at SPEED • Listen to customer feedback via daily telephone and email contact, in person at planning meetings and through customer comments • Review environmental scans • Discuss, develop and revise values based on inputs	
How Leaders Deploy To	Workforce	• Lead by example • StrengthFinders • Set ethical expectations for management and employees via signed pledges • Display vision, values, mission & ethics statements on wall posters, badge cards and intranet • Participate in teams and committees (Figure 1.1–2) • Review/reinforce periodically at staff meetings • Define and discuss at new employee orientation (matrix management, *Cowboy Ethics* (©2004 James P. Owen), leadership and self-deception) • Integrate values into employee review and rewards • Present strategic objectives, project plans and encourage participation at SPEED • Focus on continuous improvement through performance improvement system (Figure P.2–2)
	Suppliers	• Conduct regular face-to-face meetings and quality audits with key suppliers • Attend and present at industry and organizational excellence symposia, which often include current and potential suppliers • Participate with key suppliers in strategic planning, which includes affirming mission, vision and values (Figure 2.1–2)
	Customers	• Plan and conduct clinical trial and study meetings • Respond to customer expectations • State mission, vision and values in Center's brochure • Increase capabilities in line with our vision of innovation and via FDA/DEA/ISO registrations
	Stakeholders	• Veterans, national health and research communities: research publications (7.6–10) that contribute to improved healthcare practices • Pharmaceutical education communities: 80% of senior leader serve as university faculty • Quality communities: one-third of Center workforce are quality examiners at the state, VA and national levels

Figure 1.1–1 Our vision and values are manifested through deployment to workforce, customers, suppliers and stakeholders.

LEADERSHIP

CENTER WORKFORCE
Teams & Committees
chartered by CEC, CMC & QIC

Process Action Teams (PATs), Process Efficiency Team, Project Assessment Subcommittee, Research & Publications Committee, Strategic Planning Committee, ERP Team

PATs, Safety Committee, Employee Award Recognition System, Strategic Planning Committee

COC/Sections

ISO Committee

PATs
Reason Code PAT
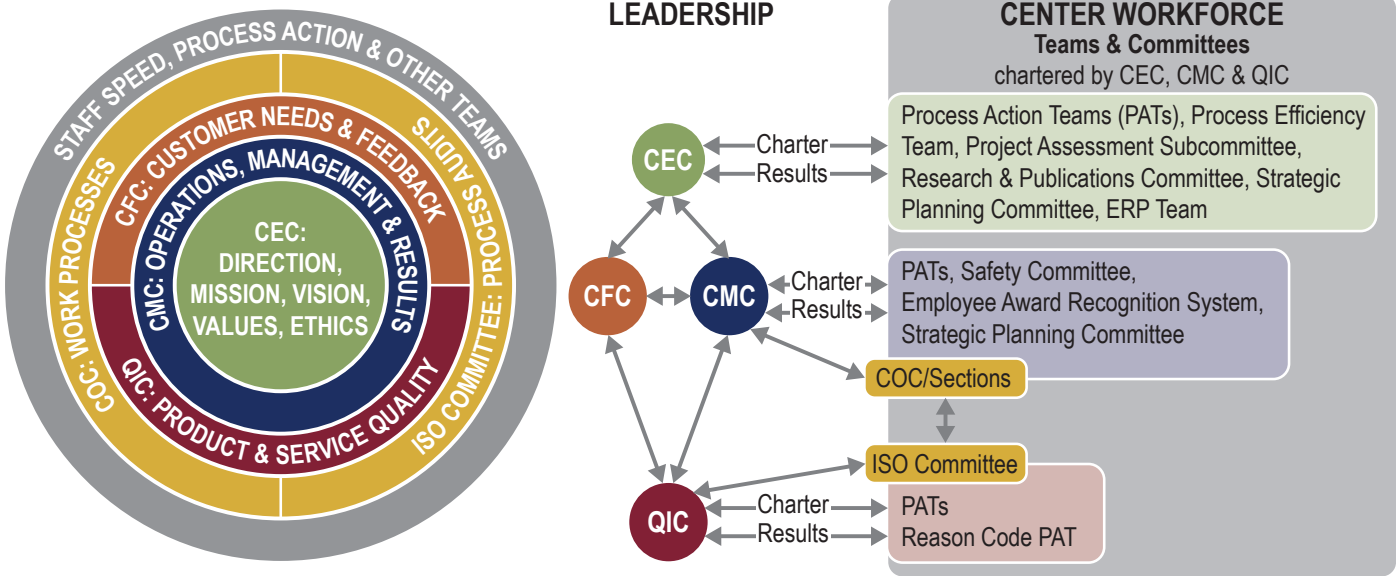
Center Executive Committee (CEC) Meets weekly	Center Management Committee (CMC) Meets monthly	Quality Improvement Committee (QIC) Meets monthly
▪ Creates policy & directs resource allocation ▪ Reviews strategic accomplishments ▪ Uses Health Indicators (Figures 7.6–1 & 4.1–2) for decision making ▪ Achieves system-level learning ▪ Allocates training funds ▪ Reviews need for increasing capabilities	▪ Focuses on Center operations & processes ▪ Reviews process improvement & quality objectives ▪ Uses vital signs ▪ Achieves process/system learning ▪ Approves training plan ▪ Reviews need for increasing capabilities	▪ Focuses on product & service quality & improvement ▪ Reviews CA/PA ▪ Measures issues & trends ▪ Achieves operational learning ▪ Provides quality tools & training ▪ Reviews customer complaints & feedback
Customer Focus Committee (CFC) Meets monthly	**Center Operations Committee (COC)** Meets weekly	**ISO Committee** Meets monthly
▪ Focuses on customer requirements & engagement ▪ Reviews customer satisfaction results, customer complaints & feedback ▪ Measures customer engagement ▪ Provides customer-focused organizational learning	▪ Focus on production work process/customer needs ▪ Review workload & priorities ▪ Use in-process measures ▪ Achieve agility & responsiveness, knowledge & skills	▪ Focuses on process & audits ▪ Reviews documentation ▪ Measures audit findings ▪ Achieves process learning

Figure 1.1–2 Center leadership system includes key interlocking committees with defined levels, reviews and measures.

Leaders promote the **continuous learning** value by:
▪ Encouraging and supporting innovation to improve Center processes
▪ Coaching coworkers to optimize performance and develop their full potential
▪ Mentoring employees regarding educational activities
▪ Utilizing the performance management system (Figure 5.1–3)

1.1a(2) Senior leaders personally promote an organizational environment that fosters, requires and results in **legal and ethical behavior** through personal example, systematic checks and balances, and training conducted by senior leaders or content ex-

perts for all employees (Figure 1.1–3). Our Center Director, Dr. Sather, frequently presents lectures to students and new employees on quality and ethics (Figure 1.1–4). The Center integrates ethical expectations and organizational values into the expectations of all employees to fully promote and align our culture of ethical and legal behavior.

1.1a(3) Senior leaders strive to maintain a balance between VA and extramural funding to provide for Center stability and **sustainability** (Figure 7.3–2). Senior leaders have also determined that large clinical trials leverage VA Cooperative Studies Program (VACSP) resources more efficiently and promote organizational agility. An additional effort was initiated to focus on large, long-term trials and to meet our strategic challenges

Ways All Senior Leaders Promote Legal & Ethical Behavior		
Personal Example	Checks & Balances	Training
▪ Sign ethics statement annually ▪ Complete ethical behavior pilot survey based on core values ▪ Promote & model legal & ethical behavior ▪ Consult with VA Attorney ▪ Publicize VA's hotline number for waste, fraud & abuse ▪ Recognize legal/ethical behavior	▪ Multi-discipline review & approval for budgets, contracts & clinical trial protocol ▪ Multi-discipline review & approval for manufacturing & packaging ▪ Independent in-house laboratory testing & quality review for approving product test results & releasing product ▪ Analysis of three-dimensional survey data ▪ Clinical trial monitoring & auditing by SMART ▪ Medical Adverse Event monitoring & reporting for patient safety for each trial ▪ Trial & section auditing by IQM & ISO multi-discipline audit teams	▪ Good Manufacturing Practices ▪ Good Clinical Practices for workforce & site personnel ▪ Conflict of interest ▪ Auditor training ▪ Ethical expectations (*Cowboy Ethics*, ©2004 James P. Owen) ▪ Harmonization Guidelines (ICH) & Human Subject Protection ▪ Leadership & Self-Deception

Figure 1.1–3 Support of legal and ethical behavior occurs through training, process design, internal monitoring and an ISO-registered quality management system.

Ten Principles of *Cowboy Ethics*	
©2004 James P. Owen from his book *Cowboy Ethics*	
▪ Live each day with courage. ▪ Take pride in your work. ▪ Always finish what you start. ▪ Do what has to be done. ▪ When you make a promise, keep it.	▪ Be tough, but fair. ▪ Ride for the brand. ▪ Talk less, say more. ▪ Remember that some things aren't for sale. ▪ Know where to draw the line.

Figure 1.1–4 The ten principles form the foundation for our manager and employee behavioral expectations.

of increasing relationships with federal customers (C1) and expanding extramural funding (C2).

Interlocking committees (Figure 1.1–2) provide the framework for creating **organizational performance improvement**. Each key committee maintains responsibility for specific areas and provides representatives to report to the other committees. For example, the CMC reviews quality objectives that tie to strategic objectives. If these reviews show a need for process improvement requiring a financial expenditure, the CMC representative presents the issue to the CEC, which reviews and decides whether to allocate resources to implement the improvement.

Leaders create an environment for organizational performance improvement, the **accomplishment of mission** and **strategic objectives**, **innovation**, **role model performance leadership, organizational agility**, and **organizational and workforce learning** using a variety of methods (Figure 1.1–5). The Center uses the SAW to review critical milestones and activities for all ongoing clinical trials (Figure 4.2–3). The SAW helps to determine priorities and resource allocation, to serve as a daily reminder of customer needs and schedules, and to communicate other Center activities to the workforce. All employees may participate in the weekly operations meetings at the SAW, which encourages and promotes two-way communication among all in-house groups. These interactions create an environment of teamwork, agility, innovation and workforce learning.

As a response to employee input, Center leadership provides annual management training to all managers to improve **personal leadership skills**. The training focuses on a specific theme or topic each year:

2002: Coaching

2003: Myers-Briggs Type Indicator and advanced project management training and certification
2004: Presentation skills and Emotional Intelligence
2005: Federal Executive Board Leadership Series
2006: Strategic mapping and Baldrige Criteria
2007: Gallup Great Leader Program and Art of Matrix Management
2008: Integration of measures and performance review, Gallup Summit and Good to Great, StrengthsFinder for all staff
2009: Gallup Summit

The federal government prohibits leadership from selecting and grooming specific successors to the Center Director or other key positions. Dr. Sather created CEC in 2004 and utilizes CEC to personally mentor senior leaders on the operational and management aspects of the Center as part of our **succession planning**. Center leadership designed and implemented the interlocking committee structure (Figure 1.1–2) as an innovative approach to support operations without dependence on specific individuals. Refined over many cycles (*Items in Figure 1.0), the leadership system provides the opportunity for members to take leadership roles and to receive feedback and advice (Figure 1.1–2). The Center also developed a Deputy Center Director position in 2008.

To develop **future organizational leaders** and promote organizational performance improvement as well as an environment of continuous learning, senior leaders also participate in succession planning by mentoring post-pharmacy doctorate participants in our Clinical Trials fellowship program and through involvement in a clinical trials master's program at UNM. The Center encourages all employees to grow through learning, training and experiencing multiple careers across the organization.

1.1b(1) Senior leaders **communicate** with and **engage** the entire workforce through study team meetings, design reviews with section chiefs (chiefs briefings), participation on interlocking committees and teams, bimonthly all-hands staff meetings, electronic media and one-on-one communications. At the beginning of each study, senior leaders present study overviews to all employees participating on a study. The overview provides the purpose of the study, the drugs and patients involved, and each employee's role. At the close of a study, project directors hold study results meetings open to all employees.

Ways All Senior Leaders Establish the Center's Environment in Various Areas			
Performance Improvement	▪ Internal & external audits as part of the ISO-driven performance improvement system (Figure P.2–2), including innovation (Figure 6.2–1) ▪ Interlocking committees (CEC, CMC, CFC & QIC) ▪ Matrix management teams & process action teams	▪ Semi-annual reviews for all employees ▪ Employee Award and Recognition System (EARS) ▪ Alignment of measures to strategic plan ▪ Post-doctoral fellowships (1.1a[3])	
Sustainability	▪ CEC formation ▪ Deputy Director ▪ Matrix management ▪ Balance between VA & extramural funding ▪ Stewardship of funds ▪ Capital investments ▪ Infrastructure investment ▪ Increasing capabilities	**Organizational & Workforce Learning**	▪ Senior leader training (1.1a[3]) ▪ ISO 9001:2000, 15378:2006 & Baldrige assessments ▪ Corrective action/preventive action (CA/PA) ▪ Quality/Technology systems: eQMS, La Puerta & ERP, processing software ▪ Strategic Awareness Wall (SAW) ▪ Staff learning & development; student mentoring ▪ Professional development & education ▪ Attendance & presentations at clinical trial & national meetings ▪ CEC performance review of health indicators
Organizational Agility	▪ Support to VA research & training; our rapid response to a VA research stand-down included training 15,000 VA employees in 60 days ▪ Involvement of all staff in strategic planning ▪ Rapid response to opportunities ▪ Feedback from potential customers ▪ Meeting customer expectations ▪ Establishment & development of Emergency Plan ▪ Rapid response to CA/PA	**Innovation**	▪ Support for new technology & innovation (Figure 6.2–1) ▪ SAW discussions ▪ Staff meetings ▪ Committee memberships ▪ Process action teams (PATs) ▪ Strategic planning project teams ▪ Involvement of staff in flowcharting & writing procedures
Performance Leadership	▪ Personal example of learning through university & professional affiliations ▪ Align performance appraisal to the Center's values ▪ Align the EARS award with the Center's values ▪ Creation & improvement of SMART; RACC	**Mission & Strategic Objectives**	▪ Strategic planning ▪ Project planning, tracking & review ▪ Resource allocation ▪ Environmental scans

Figure 1.1–5 Senior leaders use multiple organization-wide tools to guide and sustain our activities.

A variety of methods are used to meet the communication needs of a diverse workforce. An extensive intranet and an internal wiki provide learning, development and training opportunities, clinical trial details, process guidelines, links to Center resources and strategic planning information. All-hands staff meetings, held every other month, review ongoing Center activities and recognize award winners. Senior leaders then provide interactive project overviews. Dr. Sather and other leaders employ the "Management By Walking Around" principle.

Senior leaders encourage **candid, two-way communication** throughout the organization by providing an environment that allows for open discussion of issues. The Thomas Jefferson quote, "Every difference of opinion is not a difference in principle." hangs on the Center's main conference room wall to remind the entire workforce that senior leaders encourage the presentation of different opinions to foster an environment for creativity and innovation. We encourage critical thinking through a culture of active listening and open debate. Dr. Sather encourages employees at all levels to approach him with any concerns, observations or suggestions and takes the opportunity to personally praise and encourage employees' efforts and successes. This engages the workforce because communication flows in both directions and because they participate in generating ideas and implementing solutions. All employees are empowered to stop any

process that they believe is not meeting our quality management principles. Furthermore, senior leaders encourage employees to enter any issue into the eQMS for review and tracking.

Senior leaders communicate **key decisions**, such as each year's strategic goals, at the annual Center-wide Strategic Planning Employee Empowerment Day (SPEED), bimonthly all-hands staff, weekly SAW or other employee meetings. In addition, the Center posts information on the Center-wide intranet.

Senior leaders actively participate in the Center's **reward and recognition** system (Figure 5.1–3, Box D), which reinforces high performance and a customer and business focus. Three years ago the employees indicated that the reward and recognition program needed improvement. In response, CEC chartered a process action team (PAT) consisting of all workforce levels to develop a new program called EARS (Employee Award and Recognition System), which the team rolled out in 2005. In addition, the senior leaders reinforce high performance and customer and business focus by actively recognizing and rewarding employees during staff meetings, providing peer recognition.

1.1b(2) Senior leaders create a focus on actions to **accomplish the organization's objectives, improve performance and attain its vision** on interlocking committees and teams (Figure 1.1–2) by promoting employee involvement in the strategic planning cycle (Figure 2.1–2) and through periodic review

of health indicators (Figure 7.6–1). A future direction is to integrate Baldrige and ISO activities and capitalize on the synergies in our Quality Hierarchy (Figure P.1–5). Prior to each strategic planning conference, sections review and update objectives, and provide recommendations for new or improved Center objectives. Senior leaders then present strategic goals and project plans to all employees at the annual SPEED and encourage discussion. Teams are formed at SPEED, and each employee is encouraged to participate on at least one. The teams report their progress upon completing significant milestones or at Center-wide staff meetings. Because employees own their action steps and receive periodic management review, they maintain focus and momentum.

The health indicators depict customer, employee, process and financial performance measures that leaders regularly review for needed actions. At our 2008 and 2009 strategic planning conferences, Center leaders devoted extra days to defining, refining, aligning and integrating measures from the top to the bottom of our organization. Figure 1.1–6 shows one example.

Senior leaders **create** and **balance value** for **customers** and **stakeholders** by deploying a clear set of expectations for both managers and staff. These were developed around our five Center values. The expectations are posted on the intranet, introduced during new employee orientation and discussed annually at every employee's performance review. We consider customer and stakeholder needs and requirements through our strategic planning process and review of health indicators.

1.2 Governance and Societal Responsibilities

1.2a(1) As a federal agency, we do not have a board per se, but remain accountable to VACSP (see organizational chart), and ultimately to taxpayers. The Center defines governance as the obligation of our leadership to take actions that protect and improve the welfare of society as a whole while maintaining the vision and values of our organization. The Office of the Center Director and CEC have overall responsibility for the functions of the Center. Our governance system includes internal Center systems, VA requirements and external regulations as shown in Figure 1.2–1. It controls and guides how we manage our economic, legal, ethical and community responsibilities (Figure 1.2–1). Dr. Sather served as the first chair of a recently created VACSP board of directors, which governs the program and provides direction to Centers that influence strategic objectives. VACSP provides guidance to our operations through VACSP Guidelines and global standard operating procedures (SOPs).

We undergo many **external independent audits**, including Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), College of American Pathologists (CAP) and others (Figure P.1–4). Formal internal and external audits provide a key tool for measuring Center compliance to regulatory standards. For example, in 2006 we had an in-depth VA Central Office financial audit noting several best practices and zero findings, which demonstrates our **fiscal accountability**. Our leadership encourages external agencies and customers to audit us and assures the conduct of internal audits using ISO 9001:2000 criteria to verify that we meet our quality and regulatory responsibilities. To ensure **independence in internal audits**, guidelines for internal audit teams require employee

Performance Measure Deployment Example

Customer Satisfaction
Composite (Mean) Score for All Clinical Trials
Health indicator reviewed by CEC

Center

Composite (Mean) Scores for Each Trial
Vital signs reviewed by Center Director, Project Director, PPM & Study Team

Trial A | Trial B | Trial C

Question Composite (Mean) Scores for Each Trial
Reviewed by Functional Group ACDs, Chiefs & Study Team

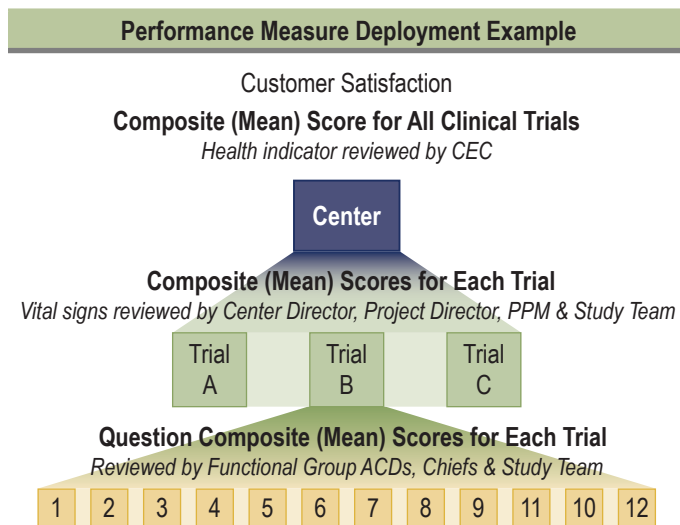1 2 3 4 5 6 7 8 9 11 10 12

Figure 1.1–6 The 2008 health indicators and vital signs were improved to create a clear line-of-sight of performance measures throughout the organization.

members to attend formal audit training and exclude individuals with a conflict of interest. Formal opening and closing meetings with management ensure appropriate scope and attention to team findings. The teams audit against written SOPs and approved methods and procedures (AMPs) via interviews and review of quality records. Team members present audit findings to QIC, then enter audit findings into the eQMS (a key component of our knowledge management system) and assign them to appropriate individuals to take corrective and preventive action (Figure 6.2–3), as part of our performance improvement system (Figure P.2–2). The Center addresses **accountability for management's actions** and **transparency in operations** through a variety of processes, including QIC review of issues and actions during monthly meetings and presentation of issues not resolved in a timely manner to CEC/CMC. Additionally, any employee may assign an issue for corrective or preventive action to any other employee or manager, including the Center Director.

We recently implemented an Enterprise Resource Planning (ERP) system that integrates our financial activities, providing a transparent and auditable system that enables **accountability** in all financial activities. In addition, the project accounting module of the ERP system ensures the fiscal accountability for each clinical trial.

VACSP Central Office has a high degree of trust in our fiscal responsibility and quality performance. This was demonstrated when the Center was exempted from a program-wide recompetition that the five Coordinating Centers were required to undergo.

1.2a(2) We utilize the following tools and processes to **evaluate the performance** of the Center Director and senior leaders:

- All employees complete the annual internal customer satisfaction survey (Figure 7.5–13).
- Supervisors conduct annual performance reviews for all employees; VACSP evaluates the Center Director.
- VACSP Central Office performs annual financial review.
- Customers complete satisfaction feedback at annual meetings (Figures 7.2–1 and 7.2–2).
- All employees complete the annual Gallup Q^{12} survey

Key Governance Factors	Control Systems								
	Center				VA				External
	eQMS	La Puerta	ERP	Ethical Expectations	Budgets to Coordinating Centers	Financial Reports	Financial Disclosure	Conflict of Interest	Regulatory/ Process Audits
Accountability for management's actions	★		★	★	★	★	★	★	★
Fiscal accountability	★	★	★		★	★	★		★
Transparency in operations	★	★		★	★	★			★
Transparency in selection and disclosure policies for employees							★	★	
Independence in internal and external audits	★			★		★			★
Protection of stakeholder interests	★	★	★	★	★	★			★

Figure 1.2–1 Every key governance factor has multiple control systems to ensure the highest degree of compliance.

(Figures 7.4–1 and 7.4–2).
- CEC reviews strategic plan progress at least quarterly.
- All employees review and sign ethical expectations pledge annually.
- Senior leaders and managers are evaluated for their ethical behavior through a pilot survey.

Performance reviews to improve the leadership system and effectiveness include the following evaluations:
- The annual ISO certification audit includes a management review (Figure 7.6–4).
- The annual Baldrige and COE application process, feedback reports and site visits provide significant review of the leadership system.
- Senior leaders complete an annual Center self-assessment through the Center Report to VACSP Central Office.

Senior leaders and CMC members use all of the above evaluation results and employee feedback to improve our **leadership system** and our **personal leadership effectiveness** by establishing action items for improvement.

Employee input is used to improve the leadership system via the Gallup employee survey (Figure 7.4–7) as well as section and all-hands meetings. For example, when employees expressed a desire to contribute to strategic planning, they recommended and leadership implemented process improvements to include section meetings designed to obtain employee recommendations and integrate them into the Center's strategic planning process through SPEED, as described in 2.2a(1).

1.2b(1) Figure 1.2–2 summarizes key **compliance processes**, **measures** and **goals** for achieving and surpassing regulatory and legal compliance. Protecting our clinical trial patients is paramount. Prior to initiating a clinical trial, the project director and pharmaceutical project manager assigned to the project, along with experts from other sections, conduct an extensive review of the proposed clinical trial protocol to identify issues that may cause one of our products, services or operations to **adversely impact** participants or society. The project director addresses and corrects these items prior to implementing the trial. In ad-

dition to our stringent review, all of our clinical trials also undergo review by Institutional Review Boards (IRBs), mandated boards with the ultimate responsibility to ensure patient safety by implementing federal regulations at trial sites.

Patient safety remains a serious concern during the conduct of a clinical trial. The Center **proactively addresses** patient safety for our customers and stakeholders through the Site Monitoring, Auditing, and Resource Team (SMART) and on a real-time basis through the Regulatory and Clinical Compliance (RACC) group. Figure 1.0 shows the timeline for these additions. The Center proactively addresses the adverse impact and risks of the clinical trial products on patients and society through the processes associated with our pharmaceutical expertise (Figure 6.1–1). We integrate regulatory compliance as the foundation of our Quality Hierarchy (Figure P.1–5).

We **anticipate public concerns** with current and future products, services and operations through participation in national conferences and through publications such as *CenterWatch*. Based on world events, we anticipate public concerns about access to pharmaceutical drugs in the event of biological terrorism or natural disasters. We develop project plans to address these concerns. Our Emergency Operations Plan addresses clinical trial support in the event of a disaster.

We also address the impact of our products, services and operations on society through the development of rigorous policies and procedures to exceed the requirements of regulatory agencies (Figure P.1–4) and to continuously improve our processes using our performance improvement system (Figure P.2–2). Our key processes help prevent drug mislabeling, which FDA identifies as a primary risk and one of the leading causes of recalls associated with pharmaceutical products. We utilize employee training and label verification, identification of products with barcodes, and analytical testing to verify that the product identity matches the labeling to prevent incorrect drug packaging or mislabeling (Figure 7.5–8). Our packaging and labeling processes meet our six sigma defect goal. We continue to seek innovative ways to minimize our risks in the labeling area by exploring new technologies, such as Radio Frequency Identification (RFID).

The Center strives to keep our compliance practices well ahead of proposed regulations. We participate in industry clinical supply groups and attend meetings where current and proposed regulations as well as industry standards are discussed. We invite industry consultants to review our processes and strive to maintain positive relations with regulatory bodies. In 2001, in response to a sharp rise in complaints across the US, FDA conducted a much higher number of inspections nationally. A third of those facilities received the most severe type of finding. By contrast, the Center has never received serious FDA findings (Figure 7.6–5).

As a small organization, the Center has a culture of improvement, including a strong commitment to conserving natural resources and to environmental stewardship. The Center maintains a constant focus on process improvement and efficiency, including the assessment of the environmental impact of our administrative operations and trial-related processes. The Center has recycling programs for paper, cardboard and aluminum. Used equipment, including manufacturing or lab equipment and computers, is repurposed through the VA Excess Program, which reuses or recycles the equipment. From study design to close-out, the Center has developed approaches to minimize environmental impact. The Center continually seeks new technologies that minimize the amount of chemical waste generated during the manufacturing process and regularly implements waste-reduction improvements in the packaging of drug products. Over the years, the Center has shifted from using kit boxes to cartons to trays, which use 65% less material and are recyclable. The Center is committed to total incineration of all non-useable drug products. This practice exceeds federal and state requirements and thus avoids landfill and groundwater contamination.

1.2b(2) Our organization promotes and ensures **ethical behavior** through a system of training and monitoring. Figure 1.2–2 lists key processes, measures and goals. VA requires and provides annual training to all managers regarding ethical behavior. All employees receive training on cGMP and GCP pertaining to their area of work. Managers monitor the ethical and legal behavior of their employees and respond to infractions appropriately. Integrated Quality Management, RACC and the employee internal audit teams ensure regulatory and SOP compliance, including ethical behavior. Vendor certification monitors ethical and safe practices.

The organizational culture integrates the ethical expectations into all activities. The Center Director discusses the ethical expectations during new employee orientation. Senior leaders and/or supervisors discuss ethical behavior with each employee as part of the interview process and during the annual employee reviews. Employees must sign a copy of these expectations upon hiring and again annually. Supervisors and internal customers evaluate managers and staff and give them a numerical rating based upon their compliance with these expectations. In addition, all senior leaders and managers evaluate the Center Director on ethics. We have begun deployment of the ethical behavior survey to the man-

agement level (Figure 7.6–7).

The Center emphasizes that every employee, including the Center Director, must, without exception, take the high road in dealing with each other, our sponsors, customers, suppliers, stakeholders and beneficiaries of the Center's products and services. We monitor and respond to breaches by entering regulatory breaches into the eQMS as issues that must be addressed in terms of corrective and preventive action, and improve performance as shown in Figure P.2–2. Other breaches of ethical and legal behavior are dealt with by administrative action. We proactively work with the VA's regional attorney on ethical and legal issues involving activities at the Center. To monitor our ethical behavior, we undergo cybersecurity, government credit card and travel voucher audits (Figure 7.6–8).

1.2c(1) **Societal well-being** and **benefit** are inherent in the Center's mission and vision and therefore integrated with the Center's strategy and daily operations. Our clinical trial results impact and improve healthcare of veterans and society as a whole. Safety permeates every process in Figure P.1–1. Approaches for how we consider environmental well-being through recycling, waste reduction and responsible drug disposal methods are described in 1.2b(1). The Center's approach to provide similar benefits between VA and BRINM employees contributes to the local **economic system**.

The Center's strong commitment to quality and safety promotes the well-being of the **social systems** to which the Center contributes. Examples include the prevention of drug mislabeling and cross contamination between production runs to ensure patient safety. We have never had a drug safety recall.

1.2c(2) Senior leaders identify our key stakeholder **communities** as those that receive positive impact from our products

Key Compliance Processes	Measure	Goal
Legal/Regulatory		
Facility/process certification	FDA & DEA compliance	No findings
ISO 9001:2000 & ISO 15378:2006 certification	Certification results	Zero non-conformances
Patient Safety		
Processing of materials	Defects	Zero defects
Shipping drugs	Defects	Zero defects
Risk of Products		
Trial protocol	Compliance to protocol	Active site monitoring, auditing
Operational/scientific integrity of Center operations	▪ GCP training ▪ cGMP training, audits	▪ 100% of site personnel & Center staff GCP trained ▪ All employees trained in cGMP areas
Ethics		
Ethical behavior survey	Pilot survey results	4.0 or higher
Ethics training	Workforce trained	100% trained

Figure 1.2–2 We address risks through well-defined key processes and measures that surpass regulatory and legal goals for all products and services.

and services:

- The veteran community, which receives improved the healthcare practice that results from trial and Center-supported publications (Figure 7.6–10)
- National health communities, which also receive the improved healthcare practice that results from trial and Center-supported publications
- Pharmaceutical education communities: We deploy our value of continuous learning by providing pharmacy fellowships and clerkship training for universities internationally. The Center actively supports our 14 senior leaders and managers who serve as university faculty (represents over 80% of CEC) in clinical research, law and ethics and quality management.
- Quality communities at the state, VA and national levels: Employees volunteer as examiners for Quality New Mexico (QNM), VA Carey and Malcolm Baldrige National Quality Award (MBNQA) programs (Figure 7.6–11).

We determine areas for **organizational involvement** based on our core competency of pharmaceutical expertise, employee interest, customer participation and alignment with our values. We then systematically select projects where our **support** will be most valuable by:

- Knowing the community both demographically and academically
- Identifying our resources (allotment of time, expertise)
- Monitoring activities (cost, time, level of involvement)

This process allows us to maximize the use of our talents and resources to **strengthen** these communities. The Center encourages employees to **contribute** to and **improve** communities by joining professional organizations, serving as officers or committee chairs and attending professional society meetings and education conferences. Senior leaders hold leadership positions in professional organizations, including service as president, treasurer, board member, editorial board member, and conference chair.

The Center also supports local community efforts, such as the Combined Federal Campaign, canned food drives, blood drives, Project Share, fund-raising for VA employee victims of Hurricane Katrina, donations to disadvantaged children of a local elementary school, and city-wide emergency preparedness programs. Center involvement in Project Share, which provides meals to the needy, including many veterans, resulted from employee interest in the neighborhood. Center employees volunteer as well as donate to this program every year (Figure 7.6–12).

2 Strategic Planning

2.1 Strategy Development

2.1a(1) The Center has many cycles of improvement in the conduct of strategic planning as shown in Figure 2.0. We developed our strategy map (Figure 2.1–1) to set climate, core competency, key processes, market segments and strategic goals. The map provides a visual tool for employees to understand the Center's strategic vision and how their jobs are linked to the overall goals of the Center. The Center's strategy map helps us

Strategic Planning Improvements & Integration	
93	1st Strategic Planning (SP) Conference
97	SP formalized*
00	PPMs invited to SP Conference* Annual Quality Day
01	Streamlined strategic goals*
03	Section SP meetings*
04	Strategic project plans* Focus groups
05	SPEED* Environmental scan process* Strategy map
06	Balanced Scorecard
07	Formal SWOT*
08	Strategic planning matrix*

Figure 2.0 Strategic planning has been refined through nine cycles of evaluation and improvement, each indicated with an asterisk (*).

clarify how our key processes relate to customer requirements. The foundation of the strategy map aligns our core competency with the mission, vision and values of our Center.

To strengthen organizational performance, market position and sustainability, the Center **conducts strategic planning** based on the annual strategic planning cycle (Figure 2.1–2). This formal process, which has evolved over the last 15 years (*Items in Figure 2.0), describes how the Center's annual strategic planning activities lead to detailed, focused strategic goals/objectives and strategic project plans (SPPs). Each activity is designed to provide input into the development of the Center's strategic plan and to initiate modifications to the current strategic planning process.

The strategic planning cycle includes the following **key process steps** and **participants**:

- Section Strategic Planning Meetings, in which all employees participate in offsite sessions for their section
- Environmental scans, an innovation to our process in 2005, which includes participants across the organization
- Formal strengths, weaknesses, opportunities and threats (SWOT) analysis, which includes participants across the organization
- Strategic Planning Conference, in which CEC and CMC participate along with key customers, suppliers, university affiliates and representatives from VACSP, VA, BRINM, based on each year's agenda
- Strategic Planning Employee Empowerment Day (SPEED), in which the entire organization participates

Figure 2.1–2 highlights the key process steps and related internal and external input and output. CEC uses the conference results of brainstorming by all participants to determine the Center's **strategic challenges, strategic advantages** and **needed core competencies**, which drive strategic decisions. Senior leaders systematically review our core competency at the conference as part of the SWOT analysis and environmental scan, and discuss with employees at SPEED. Changes to the 2006 Baldrige Criteria prompted a series of discussions at the state quality conference and at CEC, which reaffirmed our core competency of pharmaceutical expertise.

Employees develop the questions for the environmental scans. The Strategic Planning Committee (SPC) reviews the ideas and then develops themes and questions for further research. Employees then present the results of their research and scans at SPEED. This information is used to develop the SWOT. An environmental scan on space has been used as the foundation

Strategy Map

Long-Term Sustainability

- Impartial management of clinical trials
- Trials managed by clinical research pharmacists
- Reliable experienced staff
- Strong customer relationships
- Federal relationships

Strategic Goals

- Develop & maintain mutually beneficial customer relationships (engaged customers)
- Increase capability & productivity
- Increase funding
- Develop engaged workforce

Market Segments

VACSP	Extramural (non-VACSP)	
	▪ Federal	▪ Industry

Deliverables

Operational Excellence	Exceptional Service & Products	Collaborative Relationships

Work Processes

Pharmaceutical Study Design & Management	
Safety & Regulatory Compliance	Production

Organizational Core Competency

Pharmaceutical Expertise

Sets Climate

Leadership

Engaged Employees	Matrix Management
Ethical Climate	Quality Culture

Figure 2.1–1 Strategy mapping has given us alignment between strategic objectives, key processes, people, key measures and project plans. Due to space restrictions, we have provided a simplified version of our strategy map.

for the SPP for the new facility and a business development project with BRINM, our human resources (HR) supplier.

Based on the VACSP planning horizon and the rate of change in our industry, the Center defines **planning time horizons** as short-term (one-to-two years) or long-term (three-or-more years). Time horizons are influenced by the government budgeting cycle, the length of our research and development projects, the nature of the technology used in our industry and the inherent cyclical nature of clinical research. The strategic planning cycle **addresses** short- and long-term horizons through the SWOT analysis, environmental scans and strategic project plan deployment process, discussed in 2.2a(2). Much of the detail is found in the one-to-two year SPPs, with longer-term plans highlighting key milestones and revenue changes related to the duration of clinical trials (typically two-to-five years).

Goals and SPPs are deployed through cross-functional teams, which comprise employees at all organizational levels. Documentation of risks in the SPP addresses learning and integration. Team leads report to several of the Center's key committees (CEC, CMC), offering the opportunity for input, learning and integration in the strategic planning process. Quarterly updates allow CEC to assess the continuing relevance of the objectives and evaluate progress within the context of environmental and organizational changes. When necessary, CEC recommends changes to SPPs or reprioritizes strategic goals after reviewing opportunities and threats. To improve our strategic planning processes and identify potential blind spots, the SPC has conducted focus group interviews of managers, employees and external suppliers, and regularly reviews literature. Based on the results, the team makes recommendations to CEC regarding process changes, expansion of employee involvement and revisions of the strategy map.

2.1a(2) Figure 2.1–3 identifies **key factors** used in the strategic planning development process and how data are collected and used. Utilizing the strategy map, environmental scans, SWOT and known resource constraints, CEC evaluates and prioritizes potential strategic objectives for inclusion into the current plan. The strategic plan, through CEC review, is true to the Center's mission, vision and values and meets the Center's defined strategic goals and long-term sustainability. We integrate strategic goals with budget, capital improvements and HR plans, as shown in Figure 2.1–2. A process map was recently updated to ensure all elements are included annually.

2.1b(1) The Center uses the term "strategic goal" for strategic objectives. Figure 2.1–4 lists key **strategic goals**, which are also included in the strategy map (Figure 2.1–1). All are long-term goals for the Center.

The Center uses a balanced set of health indicators (Figure 7.6–1) that have been developed over the years. The measures in each quadrant are aligned with each of the Center's goals, as collective measure of organization performance and strategy accomplishment. In addition, the Center sets targets for the strategic projects that support the goals, as described in 2.2a(6).

2.1b(2) Figure 2.1–4 shows how the Center's **goals address strategic challenges** and capitalize on **strategic advantages**, including our **core competency**. The goals encourage developing opportunities for innovation in our products to increase capability and funding, innovation in operations to increase productivity, and innovation in our business model to develop and maintain mutually beneficial customer relationships. During the strategic planning conference, CEC discusses and prioritizes opportunities for innovation. Category timelines and Figures 3.1–3 and 6.2–1 highlight past innovations in products, operations and our business model, which support our goals.

Through CEC initial allocation of resources and quarterly review of environmental and organizational changes (Figure 2.2–2), all SPPs balance short- and long-term challenges by setting start times, duration and estimated completion. Quarterly updates of SPPs help CEC maintain focus on meeting defined strategic goals, innovation, maintaining customer service and assisting in the growth of employees. Balancing the needs of key stakeholders is ensured through the strategic planning cycle, which includes the use of environmental scans and input to consider the needs of key stakeholders, including veterans,
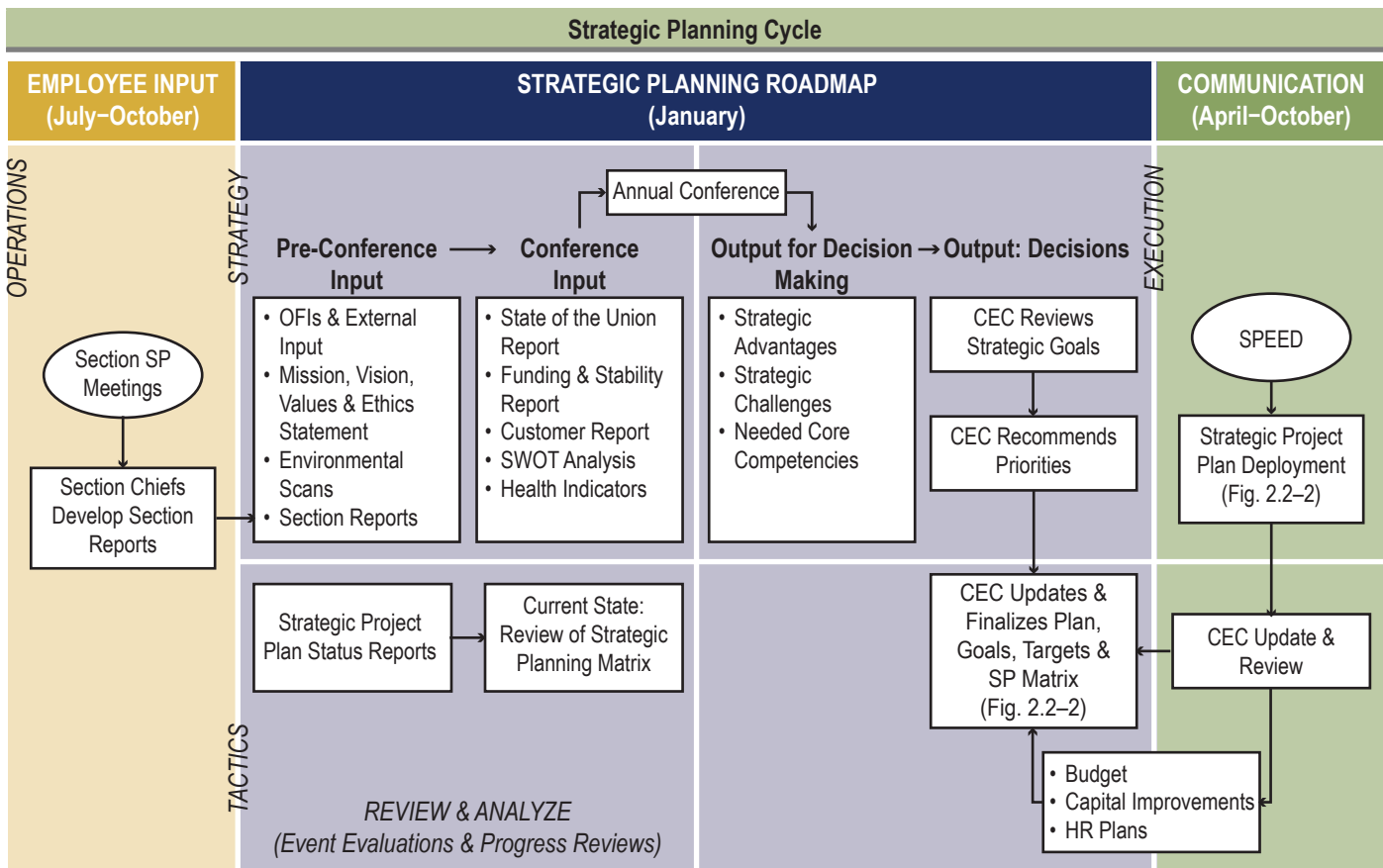
Strategic Planning Cycle

EMPLOYEE INPUT (July–October) | **STRATEGIC PLANNING ROADMAP** (January) | **COMMUNICATION** (April–October)

Figure 2.1–2 Our robust strategic planning cycle includes all employees to create organizational alignment.

national health communities, pharmaceutical education communities and quality communities. Our strategic planning approach is deployed to all employees and integrated with goals as shown in the strategy map. Learning is achieved through active review and improvement of the process by the cross-functional SPC and CEC.

2.2 Strategy Deployment

2.2a(1) Figure 2.2–1 provides examples of **key short- and long-term strategic project plans (SPPs)/action plans** that help to achieve the Center's strategic goals. Senior leaders deploy SPPs to all employees at SPEED. We improve and integrate SPEED through the Strategic Planning Committee. **Key planned changes to products** include the addition of tissue storage, which helps to achieve the strategic goals to increase capability and increase funding. **Planned changes in Center operations** include the ERP integration with BRINM, which supports the goal to increase productivity.

2.2a(2) The Center **develops and deploys strategic project plans** through the process shown in Figure 2.2–2. SPPs include owner, sponsor, customer, timelines, personnel, risks and measures of success. CEC deploys SPPs to all staff during SPEED, which is a time devoted to communicating strategic directions and goals, and educating employees about specific strategic project plans that have been developed during the strategic planning conference.

Key outcomes resulting from completed SPPs are documented in SPPs and tracked through changes in work design and

job responsibility. When approved, changes may be reviewed for incorporation into standard operating procedures. When an SPP is completed, it moves off the strategic plan, and results are incorporated into regular work activity. To ensure that outcomes of project plans are **sustained**, CEC and managers review health indicators, SPP performance measures and additional measures of productivity, customer satisfaction and other business results quarterly as well as at the strategic planning conference. We improve the deployment of SPPs, including allocation of resources, through the performance improvement system (Figure P.2–2).

2.2a(3) CEC reviews SPPs for **resource allocation**. CEC's first step is to prioritize strategic goals based on the Center's most urgent needs. CEC then reviews the SPPs for recommended resources (funding, equipment, labor hours and skills) and allocates resources based on the prioritized goals. Using estimates of the resources that will be available over the relevant planning horizons and estimates of resources required for each SPP, CEC balances resources between **current obligations** and project plans that have been proposed to address important strategic goals. The strategic planning matrix, a recent improvement to our strategic planning cycle (Figure 2.1–2) to manage and prioritize SPPs, provides a consolidated view of all SPPs in order to assist in balancing resources and prioritization.

2.2a(4) CEC reviews all proposed changes in each SPP at scheduled meetings. CEC provides final approval of all modified project plans. Changes include revisions of timelines and proposals for additional resources, including workload redistribution. As changes in the Center's business and operating envi-

How We Collect	How We Analyze

Key Strategic Factors	Strengths, weakness, opportunities & threats	
	▪ Sectional strategic planning input ▪ Gallup Q^{12} survey results ▪ Site visits/external audit reports ▪ VACSP strategic planning input ▪ PET & environmental scans	Collected data are reviewed & analyzed at the Strategic Planning Conference for decision making & prioritizing of strategic objectives.
	Shift in technology, markets, customer preferences, competition & regulatory environment	
	▪ Seminars & conferences to learn current trends & technologies ▪ Market conditions reported by CenterWatch, Frost & Sullivan, industry journals ▪ Study design process for customer preferences (Fig. 3.1–1) ▪ Monitoring of regulatory/competitive changes & changes reported through CMC, section meetings & environmental scan	Collected data are analyzed at the section, study team or the appropriate interlocking committee for operational & strategic purposes. An example of a new technology that became a Center strategic objective was the integration of radio frequency identification (RFID) within the Center operations. Publications are used to monitor changes in the clinical trial market, providing customer perspective on requirements, needs, market direction & benchmarks.
	Long-term organizational sustainability, including needed core competencies	
	▪ Monitoring of VA /BRINM staffing ▪ Results of SWOT analysis ▪ Review of Center Emergency Operations Plan & section response plans ▪ Review of capital improvement needs ▪ Funding portfolio (VACSP, Federal, Industry)	Collected data are reviewed & analyzed at the Strategic Planning Conference as a strategic objective &/or at the appropriate interlocking committee. For example, we balance staffing between VA & BRINM for sustainability & flexibility in responding to opportunities. Investments in capital improvements increase our capabilities & long-term viability.
	Ability to execute the strategic plan	
	▪ SPP deployment process (Fig. 2.2–2) ▪ Review of financial results, including leveraged funding & VACSP study funding for equipment & process development ▪ Review of health indicators (Fig. 7.6–1) ▪ Monitoring of employee retention	Subject matter experts develop SPPs, which are reviewed & approved by CEC. Funding & employee capability are routinely reviewed by CEC as part of the Balanced Scorecard.

Figure 2.1–3 *The collection and use of data is key to addressing the four key strategic factors.*

Strategic Goals (Objectives in Baldrige terms)	Strategic Advantages	Strategic Challenges	Key (Figure P.2–1)
G1. Develop & maintain mutually beneficial customer relationships	A1, A2, A3, A4, A7, A8, A9, A10	C1	**Strategic Advantages:** *A1. Experience and reputation for pharmaceutical expertise; A2. Funding mechanisms; A3. Increased funding; A4. Engaged customers; A5. ISO-certified quality organization; A6. FDA-registered cGMP facility; A7. We stand behind our work; A8. Adequate clinical supplies at sites; A9. Zero defects; A10. Culture of learning and leadership; A11. Engaged workforce; A12. Low turnover*
G2. Increase funding	A1, A2	C2	
G3. Increase capability & productivity	A1, A5, A6, A8, A9	C4, C5, C6	**Strategic Challenges:** *C1. Increase relationships with federal customers; C2. Expand extramural funding through the award of large, long-term clinical trials; C3. Obtain competitor data; C4. Implement new processes and capabilities quickly while maintaining productivity, quality and safety; C5. Meet intermediate- and long-range space issues within government procurement process; C6. Federal contracting process; C7. Federal cycle time to recruit employees*
G4. Develop employees	All	C7	

Figure 2.1–4 *The strategic planning cycle (Figure 2.1–2) identifies strategic advantages and challenges, which leadership uses to define goals.*

ronment occur, CEC reviews and reallocates resources across affected project plans, communicating changes to team leads. To implement any subsequent required changes, team leads confer with all involved parties, an approach well suited to our small organization under one roof. If a significant unexpected risk or opportunity that affects a project plan arises, other plans may be interrupted or postponed.

2.2a(5) We assess workforce needs for accomplishing the organization's short and longer-term SPPs and action items. The strategic plan outlines key HR plans for accomplishing G4. The Center Core & Clinical Trial Budget (process shown in Figure 5.2–1) and the Annual Learning Plan address specific staffing

Strategic Goals* (Objectives in Baldrige terms)	Short-term (ST) & Long-term (LT) SPPs [2.2a(1)]	Health Indicator (Figure) [2.2a(6)]	SPP Performance Measure/Indicator [2.2a(6)]	Projections [2.2b]	Comparisons [2.2b]
G1, G2	Visibility Plan/Increase Research (ST)	Customer Engagement (7.2–8) Leveraged Funding (7.3–4)	Number of new large NIH projects	Increase by one per year	Rate of increase in extra-mural funding as compared to GDP growth In-house comparison over time/past performance
G2, G3	Tissue Storage I and II (ST)	Budget Growth (7.3–2) Productivity (7.3–3 & 7.4–8)	Ready to receive samples: % of milestones met	FY10: 100% of milestones met (ready to receive samples)	In-house comparison over time/past performance
			Increase tissue storage revenue	FY10: Increase revenue by 3%/year ($0.63/sample/day)	LabCore: $2.50/sample/day
G3	ISO Program for VACSP Centers (ST)	Productivity (7.3–3 & 7.4–8) Customer Satisfaction (7.2–1 & 7.2–2)	FY09: % of VACSP Centers that have received ISO training	FY09: 100% Completion of ISO training at each VACSP center	Center's past ISO-certification performance
			FY10: Submission for ISO registration in FY10	FY10: ISO certification at all Centers	Center is first in VA to receive certification; VACSP group will be first VA group
G3	New Facility (LT)	Internal Customer Satisfaction (7.5–13) Productivity (7.3–3 & 7.4–8)	Increase square footage in an efficient facility that will support the organization for 10–15 years	Increase current space by 30%	In-house comparison over time/past performance
G3	ERP Implementation (ST)	Customer Satisfaction (7.2–1 & 7.2–2) Internal Customer Satisfaction (Figure 7.5–13)	% of systems integrated	FY10: 100% of systems integrated (Fig. 7.6–2)	In-house comparison over time/past performance
			Budget creation cycle time	10% reduction (Fig. 7.5–14)	Daiichi Sankyo: 14 days
G4	Gallup Journey (ST)	Workforce Engagement (7.4–1 & 7.4–2)	Results on Gallup Q[12] Question 4: Rewards & recognition within 7 days	Gallup Government 80th percentile	Gallup Best percentile

*Figure 2.2–1 We select and track key performance measures on SPPs to ensure progress is made to meet performance projections. Shown are a few examples within each strategic goal. *Figure 2.1–4 lists strategic goals.*

and training needs to support action plans, considering potential workforce impact and potential changes to workforce capability and capacity needs as described in 5.2a(1). Each SPP team reviews and evaluates workforce impacts—such as capabilities, including new skills required, skill obsolescence and training needs—and capacity, including the need for new staff or contracting for skills. For example, a 2005 SPP initiative on compressed work schedules resulted from our annual review of government HR flexibilities and BRINM benefits. A pilot began in January 2006, was implemented for all staff later that year, and was evaluated in 2007 for process and policy improvements.

2.2a(6) Figure 2.2–1 lists the **key performance measures/indicators** for tracking the achievement and effectiveness of strategic projects. The plan owner/team leader develops measures for the project and documents them in the SPP. CEC reviews and approves strategic plan measures. Overall success in strategic development and deployment is measured by our performance against our principal success factors: productivity, quality and capability. These are reported quarterly to CEC (Figure 2.1–2). The strategic planning matrix aligns strategic project plans with the Center's health indicators, by identifying direct and indirect relationships between project results and health indicators. Organizational alignment is further assured through rigorous leadership review, prioritization and approval of project plans and deployment of the strategy map. CEC reviews SPPs to ensure they cover all **deployment areas** and consider all **stakeholders**. Our overall measurement system addresses stakeholder needs as shown in Item 7.6.

2.2b Performance projections for key performance measures are listed in Figure 2.2–1. As individual SPPs are developed, the project teams determine the requirements of the project and take ownership of the project from beginning to end. Owners of SPPs are subject matter experts who determine appropriate performance indicators and projections, which are
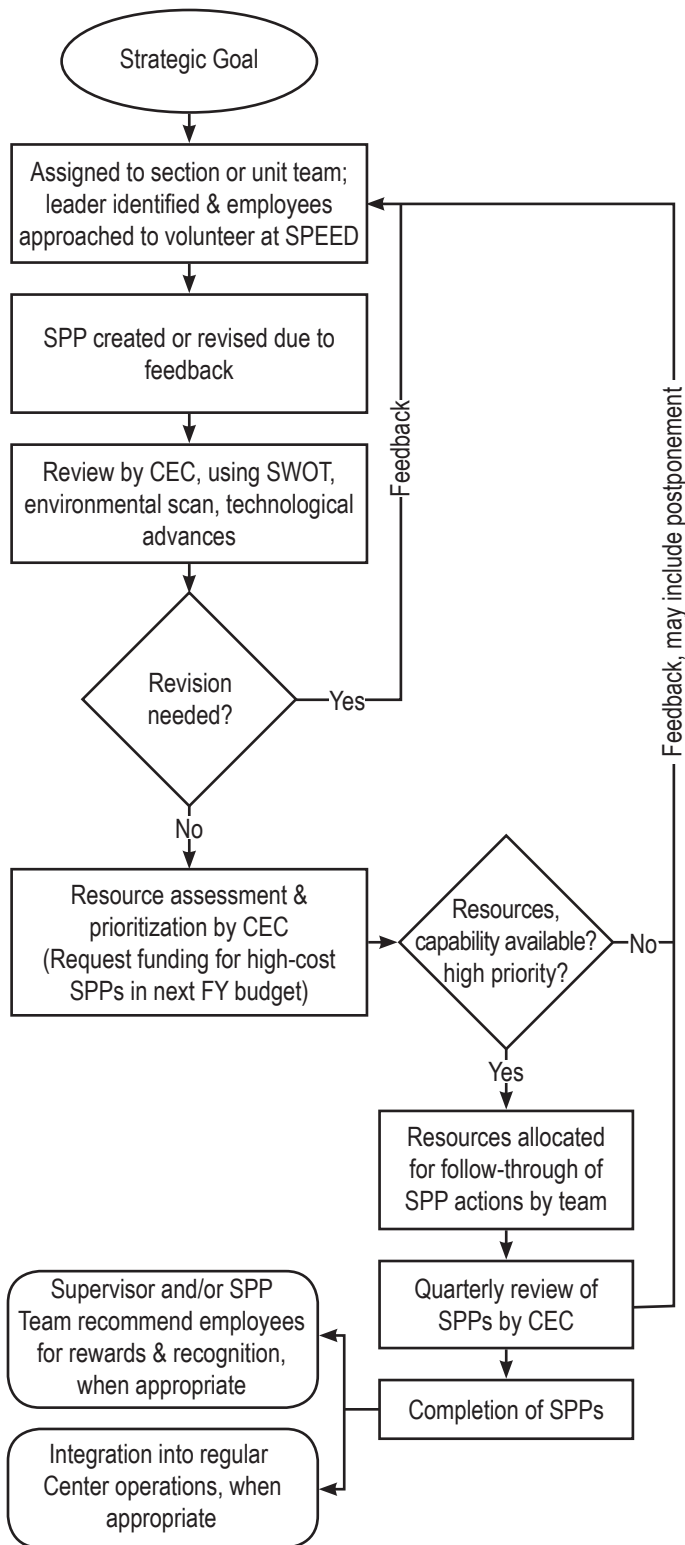
Figure 2.2–2 The Center deploys strategic goals through systematic project plans, which include resources, reviews and feedback.

then reviewed and discussed at CEC meetings. This allows each SPP to be reviewed independently in regards to progress, resources required and appropriateness of participants. All Center-approved SPPs include key performance indicators and projections. SPPs are tied to organizational measures and, where practical, projected and realized results are compared to competitors, comparable organizations and/or benchmarks. Figure 2.2–1 includes comparison information related to each SPP measure. P.2a(3) describes our limitations on the availability of benchmark data. Managers and employees regularly participate in professional and trade meetings to learn about industry trends and best practices. The results of this "intelligence work" are used in the Center's SWOT analysis process, which is an integral part of the strategic planning cycle (Figure 2.1–2). Gaps and opportunities identified are reviewed and addressed through this process. Where possible, these projections and measures are associated with relevant key performance indicators. Progress and gaps are addressed at quarterly CEC reviews.

3 Customer Focus

3.1 Customer Engagement

3.1a(1) For every clinical trial that the Center supports, we have a unique set of product offerings; therefore, we have developed a rigorous and systematic approach to **identify** the product offerings that will meet each customer's specific requirements (Figure 3.1–1). In order to proactively and continuously capture stated and unstated customer requirements and expectations, we provide products and services based on market segment. We provide the products and services in Figure 3.1–1 to all market segments dependent on customer needs.

For VACSP trials, we determine key customer requirements through the Center Planning Budget Requirements Checklist. For federal and industry (extramural) customers, a request serves as a structured approach to determine specific customer requirements for each trial.

To further define and identify extramural customer requirements, the Center developed a prospective customer questionnaire. The questionnaire prompts us to ask pertinent questions about clinical trial goals, deliverables, scheduling, and needed capabilities and opportunities for innovation. The Project Assessment Subcommittee of CEC (PAC) uses this information within the opportunity selection process (Figure 3.1–2) to determine whether customer requirements match Center capabilities and to assess the need to innovate our product offerings. This process, which is integrated with our process design and innovation pro-

Customer Improvements & Integration	
83	1st extramural project
99	Customer feedback tool* CTSC (VA only)
00	Site personnel conference calls
01	Email feedback tool*
02	Prospective customer questionnaire**
03	PAC
04	VA research pharmacist email group
05	Updated customer feedback tool* Internet CTSC
06	CTPP
07	Hired market analyst
08	CTSC automated data transfer (external)
09	Transformed customer questionnaire**
10	Customer Relationship Management (CRM)

Figure 3.0 *Listening to the voice of the customer has fueled the Center's phenomenal growth. *Cycles of improvement for feedback tool, **Cycles of improvement for questionnaire*

Study Design Process		
Formal	**Identify Initial Requirements for Products, Services & Opportunities for Innovation**	
	▪ Complete Center Planning Budget Requirements Checklist ▪ Review opportunities ▪ Complete Prospective Customer Questionnaires ▪ Participate on Study Executive Committees ▪ Participate on Study Planning Committees ▪ Conduct Chiefs Briefings	
	Identify Ongoing Product & Service Requirements & Opportunities for Innovation	
	▪ Participate in study kick-off meetings for every clinical trial ▪ Develop and maintain Clinical Trials Project Plan (CTPP) ▪ Participate in annual study meetings ▪ Conduct annual customer satisfaction feedback ▪ Conduct external audits/site visits	
Informal	▪ Participate in conference calls and daily communications ▪ Participate in professional conferences and trade shows ▪ Review professional and industry journals	

Figure 3.1–1 The Center's study design process includes formal and informal approaches to identify and customize our product and service offerings to meet and exceed customers' requirements and expectations throughout the customer life cycle.

cedure (Figure 6.2–1), drives product innovation, supports our strategic goal to increase capability and addresses our strategic challenge of expanding extramural funding (C2).

Based on organizational analysis and learning from the opportunity selection process, the Center identified the need to innovate in the area of web-based technologies, which led to the Clinical Trial Support Center (CTSC) website. The CTSC assistance of site personnel in conducting the clinical trial enables them to manage clinical trial inventories, order additional drugs and supplies, enroll patients and reprint trial documents. It also provides an added tool for general trial communications. The joint design between Center personnel and our customers refined the initial requirements prior to trial implementation. We use the process design and innovation procedure (Figure 6.2–1) to continually improve the CTSC (Figure 3.0).

The project directors also participate on study planning and study executive committees, which provide ongoing discussion of needs and documentation of requirements. Project directors hold a chiefs briefing with the chiefs from each functional section to discuss the requirements of every new clinical trial, develop scenarios, identify any modifications needed, and explore opportunities for **innovation** and exceeding customer expectations. These chiefs briefings, a process improvement, lead to multiple improvements and innovations to minimize associated labor at customer sites, minimize packaging and drug waste, and increase efficiency and accuracy. Customers trust our pharmaceutical expertise and look to the Center to propose innovative and improved solutions, which enhance the overall clinical trial.

Resulting changes to improve products flow through the process design and innovation procedure (Figure 6.2–1). These

Opportunity Selection Process

▪ Potential customer inquiries
▪ Repeat business from current customers
▪ Referrals
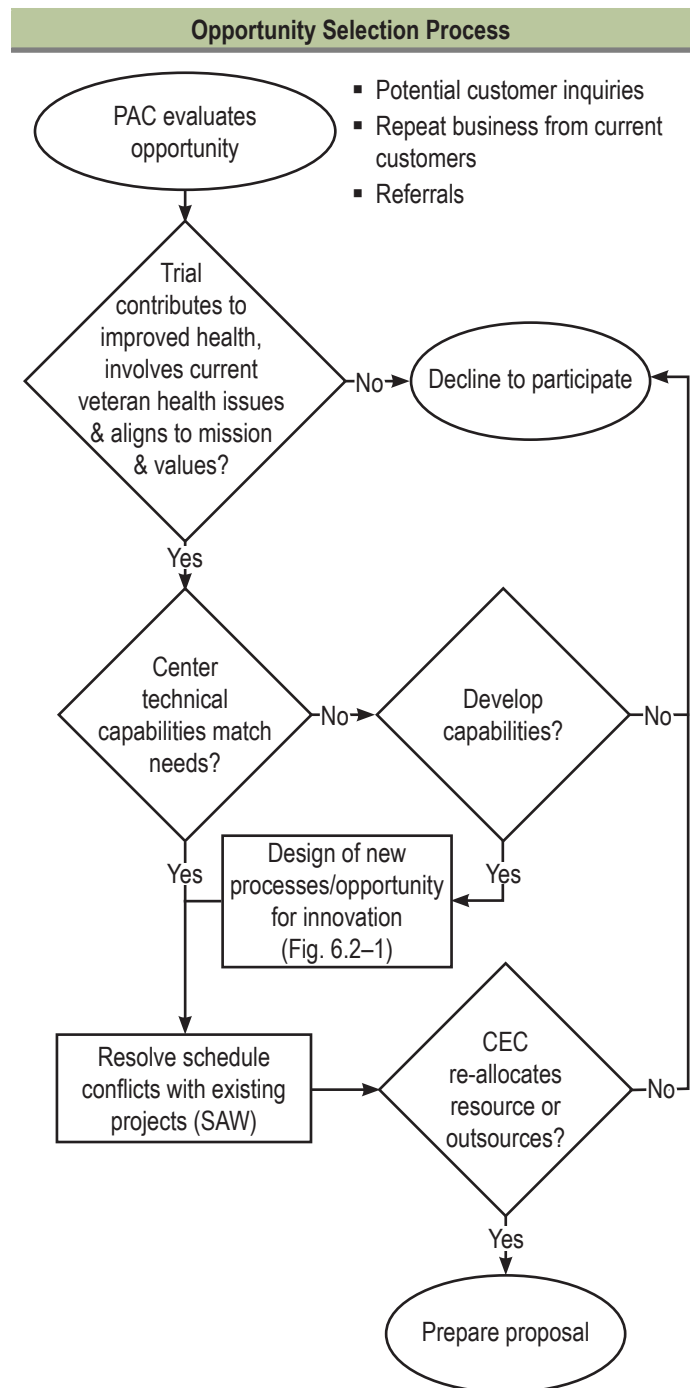
Figure 3.1–2 The opportunity selection process identifies requirements of existing and new customers as well as opportunities for innovation.

product enhancements not only expand relationships with current customers, but also help to attract new customers. Figure 3.1–3 lists product offering innovations that have expanded the Center's capabilities. During the planning phase for a dietary supplement trial, the Center discovered that the quantities of liquid-filled capsules needed were smaller than manufacturing firms were willing to produce. The Center purchased a Shionogi liquid fill encapsulating system to meet the needs of the trial and to provide small, custom production runs for other customers.

To identify product offerings to **attract new customers**

Innovations to Product & Service Offerings to Address Existing & Anticipated Customer Needs	
▪ RACC	▪ Bosch Replacement
▪ GCP Training & Resources	▪ Vector Coating Machine
▪ RFID	▪ Patterson Kelley Blender
▪ Shionogi Hard Capsule Filler & Sealer	▪ Clean Rooms
▪ Tablet Press	▪ Mass Spectrometry
▪ CTSC (web)	▪ Cartoner packages

Figure 3.1–3 The Center expands capabilities through innovations to our product and service offerings, which expand relationships with existing customers, and attract new customers and markets.

and **expand existing relationships**, we use the opportunity selection process (Figure 3.1–2) and environmental scans, which identify opportunities for innovation that are inputs for the process design and innovation procedure (Figure 6.2–1). We also participate in professional conferences, attend and host industry meetings, such as the Midwest Clinical Supplies Group conference, hold facility tours, and review industry publications, such as *CenterWatch*. At their scheduled meetings (Figure 1.1–2), CEC and CMC review and analyze information, comments and recommendations related to Center product offerings received from both formal and informal methods to better satisfy customer needs and to identify opportunities for innovation.

3.1a(2) We use the approaches in Figure 3.1–1, specifically the questionnaires and joint customer-Center participation on study committees, to identify the **key mechanisms** to support the use of our products and enable customers **to seek information** and **conduct business**. We further determine key customer **communication** requirements by asking each clinical trial customer the preferred modes and frequency of contact in our questionnaires. Most frequently, customers request scheduled teleconferences. Figure 3.1–4 lists the key means of customer support and communication.

The project director and PPM communicate customer support requirements at chiefs briefings, study overviews, study team meetings and the weekly COC meetings at the SAW, all of which include representatives from all sections involved in

customer support. We document teleconference minutes for deployment to study team members who might be involved in responding to a customer. Ongoing formal and informal project management activities and communication among study team members ensure that all processes involved meet the requirements. Additionally, the Clinical Trial Project Plan (CTPP), which is available to the entire workforce, provides detailed trial information, including support requirements. Our approach to customer support reflects our core values of leadership, customer service, safety, teamwork and continuous learning.

3.1a(3) Through the ongoing strategic planning cycle process, the Center keeps **approaches** for identifying and innovating product offerings and for providing customer support current with business needs and directions. At the annual Strategic Planning Conference, we formally evaluate changes in the marketplace through our annual environmental scan and strengths, weaknesses, opportunities and threats (SWOT) analysis (Figure 2.1–2). All conference participants and all employees at SPEED review the SWOT.

Our overall process for listening and learning has been continually refined to identify and capitalize on best practices. Improvements to our approach include the 2003 creation of the PAC to evaluate opportunities for the Center. The development of chiefs briefings has been a key improvement in our approach to innovating our product offerings and exceeding customer expectations.

3.1b(1) One of the Center's core values is customer service, and the Center is committed to providing customers with a high-quality **customer experience** with products they can trust. Our quality policy, stated in our Quality Manual and on badges carried by every employee, states:

> "Our commitment to quality is integral to the way we conduct our operations, treat our employees, and honor our commitments to customers. We reinforce our commitment to quality through visionary leadership, employee development, continuous improvement, and a systematic focus on safety and our customers."

We deploy this policy to the entire workforce through new employee orientation, ISO mandatory training and ISO internal auditor training. The cross-functional study teams (matrix management) also reinforce our organizational **culture** and values,

Key Means of Support & Communication	Customer Group & Market Variations
Study Handbook: We provide the customer with a study handbook that outlines drug handling and treatment procedures (DTHP) and the drug information report (DIR) for the drugs involved in each trial	▪ Used by site personnel and investigators ▪ Customized for each clinical trial and developed from the study protocol
Clinical Trial Support Center (CTSC): Customized, trial-specific web-based applications support data, drug assignment, patient enrollment, inventory management and document management of the clinical trial.	▪ Primarily used by site personnel ▪ While general support functions, such as inventory management, are common to most trials, each application is designed to meet customer requirements.
Phone and email communication: Dedicated pharmacist and project manager on each trial are available 24 hours a day, 7 days a week. Customers may also communicate with other study team members as needed.	For all customers across all customer groups and market segments
Scheduled and as-needed meetings	For all customers across all customer groups and market segments

Figure 3.1–4 The Center combines standard and customized communication mechanisms for each customer's needs.

particularly customer service, teamwork and continuous learning (Figure 5.1–1). In addition, senior leaders demonstrate the commitment to customer service and contribute to customer engagement, as described in 1.1a(1). We continuously improve our focus on customers and their **engagement** with us through the performance improvement system (Figure P.2–2). For example, through the eQMS used by all employees, we track both customer complaints and leading indicators of customer engagement, such as internal ISO audit findings. Through our CA/PA process, we exceed customer expectations by quickly resolving the few complaints that we receive (Figure 7.2–3).

Within our **performance management system**, employee performance standards are linked to Center values with specific standards for each employee on customer service (Figure 5.1–3, Box D). The Employee Award and Recognition System (EARS), which is described in 5.1a(3), links directly to the Center's mission, vision and values to recognize and reward high-performing employees. Customer service, which is directed at customer engagement, is one of the defined categories for recognition.

Quarterly updates of strategic project plans (SPPs) help CEC maintain focus on meeting defined strategic goals, maintaining customer service and assisting in the growth of employees, as described in 2.1b(2).

3.1b(2) Our engaged employees (Figure 7.4–1) have developed strong relationships with customers. Over 80 percent of our extramural business is from repeat customers, whom we define as "engaged" customers (Figures 7.2–1, 7.2–2, 7.2–6 through 7.2–8), resulting in financial growth and long-term sustainability of our organization (Figures 7.3–2, 7.3–3 and 7.3–6). We typically acquire new customers from referrals from current and past customers. Given the nature of supporting clinical trials at the Center combined with our small size, limited number of customers and the average length of trials, we promote and form strong customer engagement. Our customer life cycle includes the following stages: Pre-Planning (inquiries and consultation with investigators), Active Relationship and Ongoing Relationship (through multiple professional affiliations). Throughout each stage, the Center builds and manages relationships with customers to **meet and exceed their expectations** and **increase engagement** by providing:

- Direct communication with a senior leader (a clinical research pharmacist) for all inquiries (Pre-Planning)
- Ready access to healthcare professionals with the knowledge and ability to communicate directly with clinical trial physicians, pharmacists and coordinators (All stages)
- Pharmaceutical expertise across the organization, with all staff trained in cGMP specifically for drug manufacturing and labeling and GCP for patient safety and regulatory compliance (All stages)
- Stable staff as reflected in the tenure of our pharmacists and project managers (All stages)
- Multiple avenues of customer access to ensure 24/7 availability with live operators (All stages)
- Personal interactions at clinical trial and professional meetings (All stages)
- Active leadership of the Center Director on the VACSP Board of Directors and participation of Center leaders and managers on VACSP management groups

- Careful project planning through implementation of project management principles ensures all milestones and deliverables are met (CTPP, SAW, conference calls and email) (Active)
- A dedicated pharmacist, project manager and study team for each clinical trial, thus maintaining continuity in communications. Study team members remain available to customer after the trial. (Active and Ongoing)
- Creating customer focus through clearly defined and documented expectations for all study team members. At our recent strategic planning conference, specific expectations were discussed in detail on a section-by-section basis. (Active and Ongoing Relationship)

Along with the relationships we build and manage with customers, we maintain our standard of excellence to increase customers' satisfaction and engagement, so that the Center is the organization of choice for their needs and for referrals. To increase customer engagement, the Center invites customer representatives to the annual Strategic Planning Conference (Figure 2.1–2). The Center also supports employee attendance at other conferences to increase our visibility and reputation for pharmaceutical expertise, which increases engagement. We continuously improve customer relationships and keep current with business needs and directions through analysis of customer feedback data by the Customer Focus Committee (CFC). We foster a customer-focused culture through our federal interagency agreements, strategic advantage A2. For example, we have had an interagency agreement with the National Institute on Drug Abuse (NIDA) for over 19 years, which is updated each three-to-five years to keep current with business needs and directions.

3.1b(3) The Center keeps approaches for **creating a customer-focused culture and building customer relationships current** through our strategic planning cycle (Figure 2.1–2). One of the Center's strategic goals is to "develop and maintain mutually beneficial customer relationships," which underscores our commitment to fully engaged customers and to meet strategic challenges C1 and C2. CEC and CMC regularly review the strategic objectives and related SPPs that support this goal, which include customer relationship building.

To gain additional feedback on our approaches, we use a formal annual customer feedback tool to identify both current and future needs of all customers, and contacts such as face-to-face conversations at meetings, during conference calls and through the "VA Research Pharmacists" email forum. Organizational analysis of feedback is discussed at various management meetings. For example, CEC analyzes and improves customer relationships through strategies such as the VACSP exhibit booth and Center brochures, while CMC focuses on operational issues such as label design and packaging preferences that we learn through industry affiliations. We keep **customer access** current with business needs and directions through personal contact, conference calls, newsletters, email, annual clinical trial meetings and websites. A senior leader is assigned to each and every customer and has regularly scheduled teleconferences as well as discussions as needed. Biweekly meetings with the Center Director, pharmacists, PPMs and RACC ensure access and relationship concerns are aggregated and acted upon in a

timely manner. The planned purchase of the CRM module will further refine our approach to evaluate and improve customer relationships.

3.2 Voice of the Customer

3.2a(1) In order to obtain actionable information and feedback on our products, services and support, the Center **listens** to customers through a combination of formal and informal approaches. The methods in Figure 3.1–1 provide ongoing opportunities to listen, receive actionable information and feedback, and respond immediately to our customers. The items under "Identify Initial Requirements" occur during the pre-planning and active relationship stages of the **customer life cycle**; those under "Identify Ongoing Requirements" occur during the active relationship and ongoing relationship stages.

Our relatively small number of customers facilitates prompt and actionable feedback through frequent personal contact by the project director and PPM assigned to each clinical trial. Project directors, PPMs and other study team members have daily interactions with our customer groups through phone conversations, emails, scheduled and as-needed teleconferences, trial kick-offs and annual meetings. Approaches are similar across customer groups and market segments. In order to increase availability and decrease response time, project directors and PPMs use electronic devices for both voice and email communications with customers (Figures 7.1–7 and 7.1–8).

The annual customer satisfaction data, described in 3.2b(1), and the customer complaint management process, described in 3.2b(3), are two formal methods for capturing information, learning and improving through analysis by CFC.

3.2a(2) Center personnel attend trade shows, professional conferences and other industry events, which promote listening to **former and potential customers** and those of **competitors**, and obtaining actionable information related to the Center's products and support. The Center uses relevant information on current and former customers, including customer retention data and complaints to plan and develop future products and services. Two proposed SPPs for FY2009 will further enhance our current systematic process for analyzing and integrating customer data. Customer information is evaluated at section and committee meetings to develop or change products and services. In addition, the complaint management process, described in 3.2a(3), provides customer information for organizational learning.

3.2a(3) As part of our ISO-driven performance improvement system (Figure P.2–2), the Center's **complaint management** process (Figure 3.2–1) is an integrated approach that supports a complete and **effective** corrective action/preventive action (CA/PA) cycle (Figure 6.2–3) and process design and innovation procedure (Figure 6.2–1). Through an electronic quality management system (eQMS), the central tool within our performance improvement system (Figure P.2–2), all employees document customer complaints and CA/PAs. Should a customer notify the Center of a potential problem with a drug product, this issue would be classified as an external complaint and managed in compliance with federal regulations for rapid investigation, fault determination/root-cause analysis, CA/PA and timely response. The assigned project director or PPM is responsible for ensuring that the issue is **promptly resolved**, and for commu-

nicating directly with the customer to recover their confidence. This approach supports our endeavors to increase the number of relationships with all customers, including federal customers (strategic challenge C1).

The use of a central eQMS enables robust aggregation, data analysis and reporting. The Quality Improvement Committee (QIC) meets monthly to monitor any outstanding and overdue actions, ensure that complaints have been effectively resolved and that any necessary process changes have been made to prevent reoccurrence to minimize dissatisfaction and loss of repeat business. QIC aggregates and analyzes all external complaints for improvement throughout the Center. Figure 7.2–3 reports our very low level of customer complaints over the years.

3.2b(1) We measure **customer satisfaction** with our customer feedback tool, which has multiple cycles of improvement as shown in Figure 3.0. We measure **customer engagement** by repeat business as shown in Figure 7.2–8. All are measured within the customer category of our health indicators (Figure 7.6–1).

The Center uses our customer feedback tool at every annual clinical trial meeting. During these meetings, project directors personally gather customer satisfaction feedback from all study team participants including investigators, clinical trial site personnel and others, such as industry participants. Our target
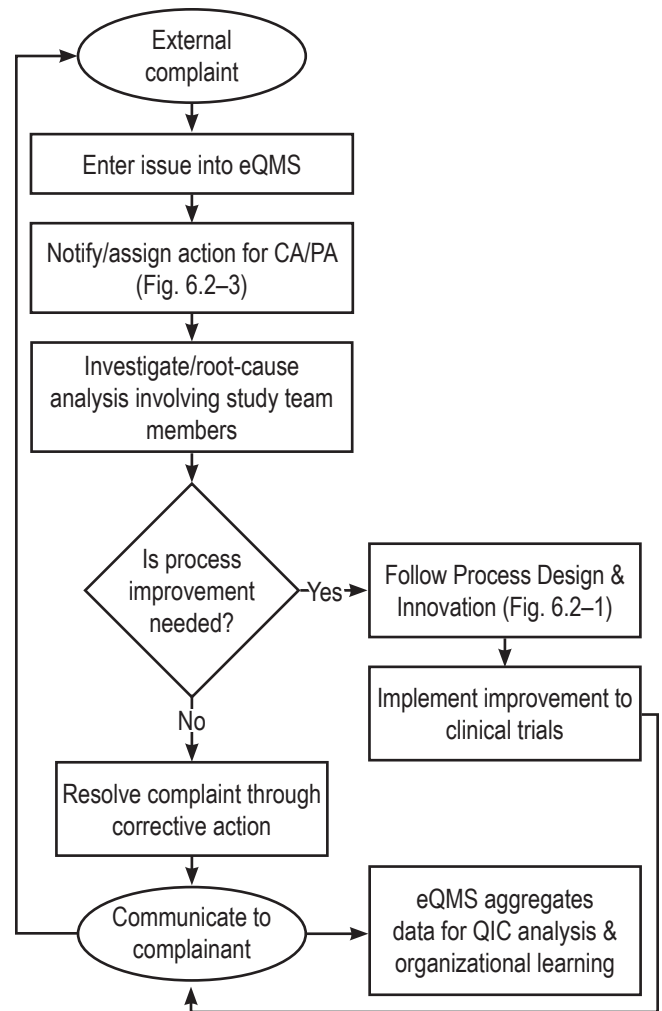

Figure 3.2–1 Our robust complaint management process meets stringent federal and ISO 9001:2000 requirements.

range is to achieve top two box ratings on the five-point scale (between 4.0 and 5.0). Feedback that does not meet the target range receives an action plan for improvement. Satisfaction data are shown in Figures 7.2–1 and 7.2–2. In addition, the feedback includes written responses, which also capture actionable information.

CEC reviews repeat business, an important indicator of customer engagement, which reflects our ability to manage expectations through all three life-cycle stages that are critical to organizational sustainability. We measure customer dissatisfaction through complaint rates (Figure 7.2–3) and use the information as described in 3.2a(3).

The customer feedback provides a clear line-of-sight performance measure throughout the organization, enabling **aggregation and analysis** of data. Figure 1.1–6 shows CEC review of the composite satisfaction rating for all clinical trials; review by the Center Director, project director, PPM and study team of the results for each clinical trial; and then review by division Assistant Center Directors (ACDs), section chiefs and study team members of composite scores for each trial. For example, SMART can focus on the feedback for training to identify areas of improvement (Figure 7.1–4).

In addition, as a small organization with a limited number of customers, the Center's regular, ongoing contact with our customers provides a rich opportunity to learn from customers, and to capture actionable information. These interactions are a leading indicator of satisfaction and provide opportunities for exceeding expectations. Weekly COC meetings at the SAW and study team meetings capture such customer-related discussions.

While **determination methods** are consistent across customer groups and market segments, we segment feedback by key customer groups.

3.2b(2) We obtain and use information on customer satisfaction **relative to competitors** by consistent and reliable feedback, as well as by comparing our services to our competitors in the industry (Figure 3.2–2). We use VA, industry and Baldrige satisfaction **benchmarks** to gauge our customer satisfaction levels (Item 7.2). While our process to obtain and use competitor data is limited due to constraints described in P.2a(3), we do obtain some information as shown in Figure 4.1–3. In our quest to improve, information from publications such as *CenterWatch* keep us abreast of new and enhanced customer "satisfiers."

3.2b(3) We **determine and measure customer dissatisfaction** through customer complaint rates (Figure 7.2–3). The complaint management process (Figure 3.2–1) uses the eQMS to capture complaints for immediate action and resolution and for possible improvement actions, as described in Figure P.2–2.

The Center measures the percent of customers who are dissatisfied (Figure 7.2–4). Analysis of data also identifies trials and specific areas that do not meet our target range and actionable information from open-ended feedback. The **analysis** and use of dissatisfaction data follow the approach for our complaint management process, described in 3.2a(3), and our approach for customer satisfaction data, described in 3.2b(1).

3.2c(1) The Center identifies customer groups based on two key roles within a clinical trial. The two groups are the investigators—typically physicians, who initiate the trial—and the clinical trial site support personnel at participating sites.

Ideal Product & Service Features	
Industry Competitors	**Center**
Possess therapeutic expertise	▪ Possess medical and therapeutic expertise
	▪ Pharmacist-directed trials ▪ Integration of lessons learned to add new capabilities, such as RACC (Fig. 3.1–3)
Capable of global research	▪ Ability to ship to national and international sites
High-quality reputation	▪ Certifications and awards (ISO, VA Carey, QNM Zia and others) (Figure 7.6–3)
Access to patient populations	▪ Access to qualified VA investigators, sites and patients ▪ Access to largest health care systems patient populations in affiliated university facilities
Capable of on-time delivery	▪ Low customer complaints (Figure 7.2–3)
Financial stability	▪ Financial stability of multiple funding sources (Figure 7.3–2)
Capable of strategic relationships	▪ Long-term relationships with NIH (Figure 7.2–6)

Figure 3.2–2 We provide all services desired by a customer that affect customer loyalty. Shaded items indicate differentiated services that go beyond industry competitors (CenterWatch), which are important to all phases of the customer life cycle.

The Center defines **market segments** by funding sources. VACSP is our first segment and the reason we exist. The second segment is other federal, such as National Institutes of Health (NIH), including the National Cancer Institute (NCI), NIDA and National Heart, Lung and Blood Institute (NHLBI). The third segment is industry, which includes universities. While requirements are similar for all market segments, segmentation is meaningful for two reasons. First, as a federal agency, the Center must account for revenue streams separately, and expenditures are governed by different rules. Second, we monitor the proportion of VA and extramural (federal and industry) funding that the Center receives in order to ensure our sustainability (Figure 7.3–4). We are opportunity-driven with an entrepreneurial culture that drives us to secure extramural funding. Extramural clinical trials leverage the capacity of the Center facility and employees, and generate additional income to improve our quality and capabilities.

We determine which customers and market segments to **pursue** in our extramural markets based on (1) potential for the clinical trials to contribute to improved health for veterans and humankind, (2) a good fit between clinical trial requirements and our current or future capabilities (Figure 3.1–2), and (3) meeting strategic challenges C1 and C2. Our key result is measured in the amount of extramural funding attracted. Annually we monitor our market position with publicly available information (Figure 7.3–6).

As part of our annual strategic planning process, our environmental scans include customer, market and product offering information that can be used to **anticipate future customer groups or market segments**.

3.2c(2) We obtain market studies through CenterWatch and other sources to identify and anticipate key customer requirements and expectations. Nearly 60 percent of potential customers suggest that therapeutic area expertise such as that provided by pharmacists is a key factor in selecting a contract research organization (CRO). Another important factor is the reputation of the CRO (Source: *CenterWatch*, January 2001). For over 30 years, the Center has provided pharmaceutical management of clinical trials with pharmacist-led teams. We compare favorably to industry competitors (Figure 3.2–2) and secure our market niche with high quality, productivity and capability.

We determine the importance and value of product and service features through comparison to our industry competitors and by analyzing what potential customers value.

Our clinical research pharmacist-led teams provide some of the highest levels of expertise in the industry. As part of the largest healthcare system in the nation, VACSP as a whole delivers a patient population that creates a competitive advantage for clinical research. Our reputation is evidenced by our high level of customer engagement (Figure 7.2–8).

3.2c(3) The Center uses customer, market and product offering information to **improve outreach to potential customers** through the development of the Center's brochure. The Center uses information to build a **customer-focused culture** by sharing customer-related performance measures with all employees and promoting organization learning. The eQMS is open to all employees for reporting issues, including customer issues, as well as learning from past issues and actions. These issues are then captured and acted upon via our performance improvement system (Figure P.2–2) and help us meet strategic challenges C1 and C2 (Figure P.2–1). Input for the process design and innovation procedure (Figure 6.2–1) includes customer, market and product offering information, which identifies needs and opportunities for innovation. Examples of innovations are listed in Figure 3.1–3.

3.2c(4) The Center keeps **approaches for customer listening** current with business needs and directions by reviewing customer feedback from annual study meetings, satisfaction results, repeat business and customer complaints by CFC and CEC and at the annual Strategic Planning Conference.

Our study design process (Figure 3.1–1), which includes key customer listening approaches, has gone through many cycles of improvement over the years, based on customer feedback, needs and other input. The annual environmental scans also provide insight on improvements to approaches. The annual section strategic planning meetings provide a formal opportunity to review and update our approaches. The Center utilizes Lean Six Sigma principles to identify areas of improvement. Recent projects initiated a change in our study design process to require a customer signature on the design criteria.

The Center keeps **approaches for determining satisfaction, dissatisfaction and engagement** current by updating and modifying data capture mechanisms every year, as shown in Figure 3.0, while trending data over time. The feedback tool

was improved in 2002, resulting in more data and more reliable results. In 2003 we modified the distribution approach. As a result, we began collecting data at clinical trial meetings to more finely discern our own best practices as well as identify areas for improvement.

Annual participation in VA and state quality conferences also provides the Center with award-winning models of approaches for customer listening, determining satisfaction and engagement, and use of customer data.

Other methods are evaluated to provide us better or more actionable data. For example, in 2000 we implemented eQMS, an integrated computer application that is part of our knowledge management system and facilitates nearly every aspect of maintaining an effective quality management system. The eQMS features for handling customer complaints require the recording, aggregation and closure of complaints, and are superior to the manual tracking system previously used. QIC tracks the timeliness of resolution of customer complaints and includes results in organizational learning (Figure 3.2–1).

4 Measurement, Analysis, and Knowledge Management

4.1 Measurement, Analysis and Improvement of Organizational Performance

4.1a(1) The Center **collects and integrates** data and information to support daily operations and organizational decision-making through in-process measures of functional activity and key processes. The measures of key processes are shown in Figure 6.1–1. These data are regularly reviewed at the functional section level and reported to the appropriate committees (Figure 1.1–2). The information derived from the data is utilized to support organizational decisions such as staffing, scheduling, prioritizing activities and identifying opportunities for improvement and innovation. Figure 4.1–1 depicts how the Center manages organizational knowledge, contributing to organizational learning. Overall performance measures/health indicators are shown in Figure 7.6–1. In pursuit of continuous improvement, the Center Management Committee (CMC) identified the need to expand and develop measures beyond those in the yearly State of the Union. We convened a measures summit to define health indicators to achieve our strategies and meet our strategic challenges. In a subsequent cycle of improvement, we refined the health indicators and then cascaded them down to vital signs to fully integrate measures and reviews for the entire organization. Center Executive Committee (CEC) and CMC review the measures annually and as needed throughout the year. Managers and leaders propose new measures throughout the year within the interlocking committee structure.

The Strategic Awareness Wall (SAW) provides critical schedule data to integrate daily operations and has multiple cycles of improvement (**Items in Figure 4.0). Data systems, including the electronic Quality Management System (eQMS) and La Puerta inventory management system, are continually refined and upgraded (*Items in Figure 4.0).

Leadership **selects** operational measures based on the extent of impact on key processes. For example, manufacturing defects

Measurement, Analysis & Knowledge Management Improvements & Integration	
97	*CenterWatch* comparative data
99	CTSC (VA only)*
00	COC/SAW**
01	SAW minutes** eQMS* QIC
02	La Puerta*
04	Benchmarking Committee
05	Internet CTSC* Emergency Prep. Plan SPEED
06	Expanded SAW** ERP* eQMS Enterprise
07	Wiki* LearnerWeb*
08	CTSC automated data transfer (external)* La Puerta upgrade*
09	Lab e-notebook software*
10	CRM*

*Figure 4.0 Our innovative use of data applications provides information for rapid decision making and harmonizes processes across work units. *Cycles of improvement for data systems, **Cycles of improvement for SAW*

are important in-process measures captured in the eQMS, because they affect all downstream processes (packaging, labeling, shipping) and the Center's ability to meet and exceed customer requirements. The Center selects organizational performance measures for decision making based on their ability to convey overall health, achievement of strategic objectives, or product and service quality predictive of customer satisfaction. Figure 4.1–2 shows how measures are **selected** and **used**. Progress relative to **strategic goals** is tracked through the use of strategic project plans /**action plans**. CEC approves and regularly reviews these plans, as shown in Figure 2.2–2.

Key performance measures are identified in the Center's health indicators (Figure 7.6–1). Based on a balanced scorecard approach, health indicators are high-level measures aligned with our strategic goals to determine the overall well-being of the Center. CEC regularly reviews health indicators as a means to assess **organizational performance** and support **decision making**. The health indicators measure customer satisfaction (Figures 7.2–1 and 7.2–2), process efficiency (Figure 7.3–3 and Figures 7.5–6 through 7.5–10), workforce engagement (Figures 7.4–1 and 7.4–2) and financial indicators (Figures 7.3–1 and 7.3–2). Vital signs are key performance measures at the functional section (work group) level, many of which are aligned with health indicators. Several health indicators are rolled up from one or more vital signs and/or in-process measures. Vital signs include measures such as performance and workload indicators, quality objectives, customer satisfaction and employee engagement at the section level. This information is regularly reported to CMC and is historically trended. CMC uses this information to assess functional work-group performance, support decision making and identify opportunities for improvement or innovation. Examples of the in-process quality measures reviewed by the Quality Improvement Committee (QIC) include nonconformances (Figure 7.5–10) and shipped drug quality (Figure 7.5–9). In-process checks and logs record variances in daily operations and are used to prevent defects and help us achieve the product and service outcomes in Item 7.1. Opportunities or issues identified through the use of health indicators, vital signs, or in-process quality indicators may be referred to various committees or teams for appropriate

action (Figure 1.1–2).

4.1a(2) Sources of **key comparative data**, application of data and selection criteria are shown in Figure 4.1–3. The basis for selection of benchmarks/comparisons includes pedigree of comparison, applicability, cost and usefulness. As stated in the Profile, industry comparative and trend data are extremely difficult to obtain.

The Center systematically evaluates and improves our approach to the use of best practices, benchmarks, and competitor and comparative data yearly. The process design and innovation procedure (Figure 6.2–1) shows how best practices and comparisons are translated into new products and services along with examples. This procedure strives to align these data with our principle success factors of productivity, quality and capabilities as well as customer and employee satisfaction.

Since 1997, the Center has utilized data from *CenterWatch*, an industry publication used by research centers around the world, to identify important competitive information. This information helps to monitor trends in key business areas and acts as a source of comparative data.

The Center established the Benchmarking Committee in 2004 to identify additional external benchmarks and the cost benefit of each source. This cross-functional group conducts literature searches and telephone interviews, and determines which sources to pursue (Figure 4.1–3). Our benchmarking process is shown in Figure 4.1–4.

4.1a(3) Key elements in keeping the **performance measurement systems current** and relevant include the regular review through the use of the interlocking committee structure, the strategic planning process, study teams' input, Baldrige assessments and the performance improvement system (Figure P.2–2). The performance management system is reviewed at the annual Strategic Planning Conference for improvement and alignment with current business needs and directions. The matrix management work design along with the interlocking committees structure (Figure 1.1–2) provides a setting for rapid identification and evaluation of changing business requirements and environments.

4.1b The Center reviews organizational performance and capability through our health indicators (Figure 7.6–1), the strategic planning process as well as review, analysis and discussion of external Baldrige assessments. We analyze data by trending, benchmarking, reviewing assumptions and identifying correlations. For example, we correlate feedback from VA and national Baldrige programs to prioritize opportunities for improvement.

Strategic objectives and project plans are regularly reviewed by CEC to ensure that they remain relevant, resources are available, and progress is being made. Regular review of health indicators allows the Center to continually evaluate **organizational success and competitive performance**. We analyze these data by examining trends and drilling down to vital sign data when questions of unfavorable trends occur (Figure 4.1–2). This allows the Center to identify and respond to **rapidly changing needs and challenges** in the operating environment. We use these reviews for rapid response to challenges, such as implementing new processes and capabilities quickly, while maintaining productivity, quality and safety. An example is the monitoring of RACC cycle time and workload as we developed new safety and regulatory capabilities (Figure 7.5–5).
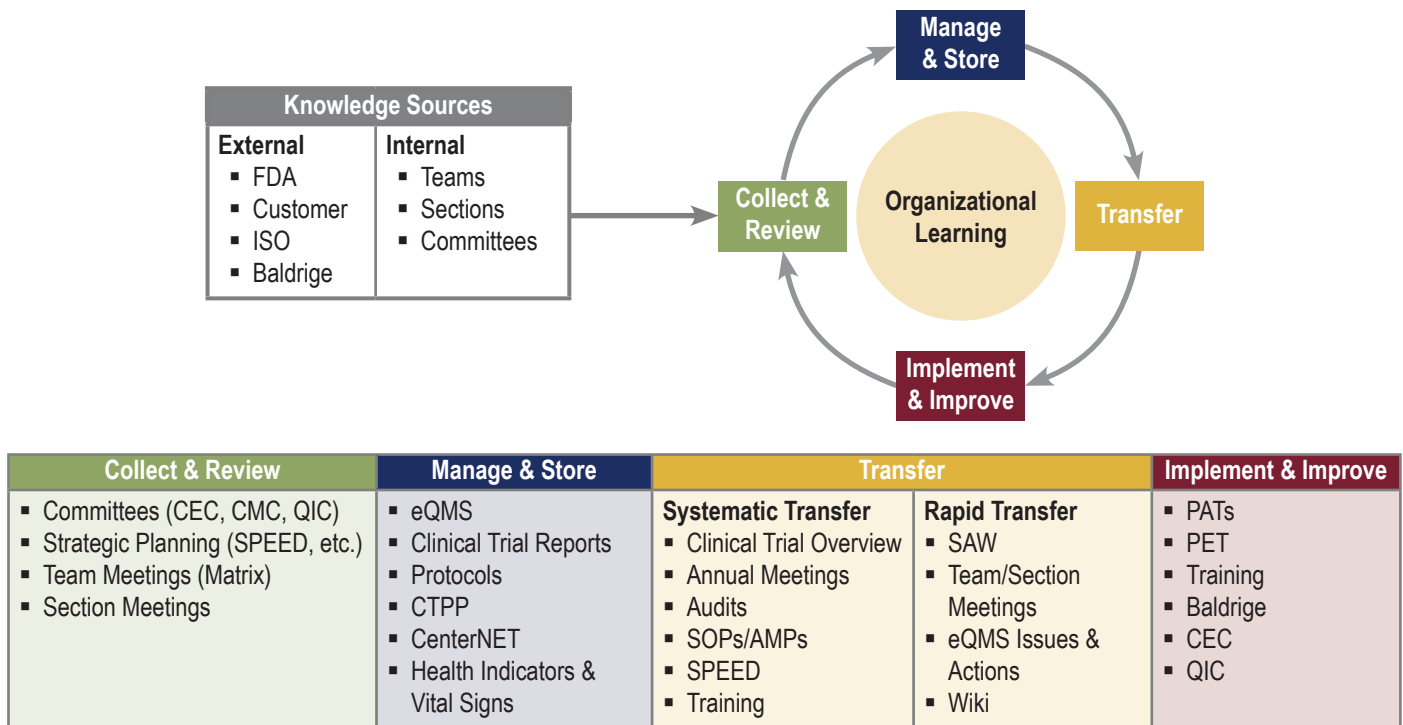
Organizational Knowledge Management

Collect & Review	Manage & Store	Transfer		Implement & Improve
▪ Committees (CEC, CMC, QIC) ▪ Strategic Planning (SPEED, etc.) ▪ Team Meetings (Matrix) ▪ Section Meetings	▪ eQMS ▪ Clinical Trial Reports ▪ Protocols ▪ CTPP ▪ CenterNET ▪ Health Indicators & Vital Signs	**Systematic Transfer** ▪ Clinical Trial Overview ▪ Annual Meetings ▪ Audits ▪ SOPs/AMPs ▪ SPEED ▪ Training	**Rapid Transfer** ▪ SAW ▪ Team/Section Meetings ▪ eQMS Issues & Actions ▪ Wiki	▪ PATs ▪ PET ▪ Training ▪ Baldrige ▪ CEC ▪ QIC

Figure 4.1–1 The collection, storage and transfer of relevant knowledge from our employees, suppliers and customers, and the rapid identification and implementation of best practices are central to the success of the Center.
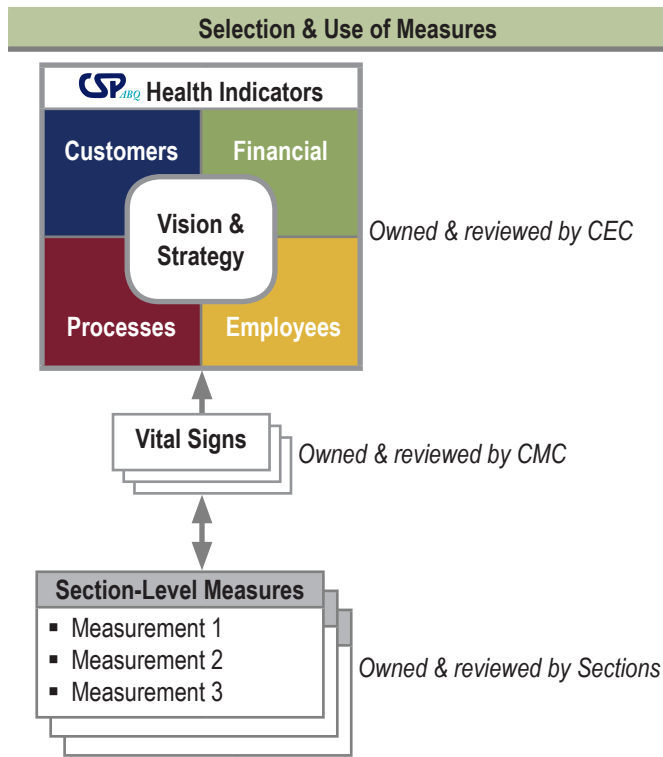
Figure 4.1–2 Measures for tracking daily operations (vital signs) are collected and integrated into organizational-level health indicators for tracking overall performance.

The key processes in Figure 6.1–1 have associated measures that allow the Center to predict how changes to processes will affect the entire system.

4.1c Performance review findings are **translated** into organizational priorities via the performance improvement system (Figure P.2–2) and reviews by interlocking committees. Leadership continually monitors organizational performance and tasks various committees, teams and functional sections with items for action. These groups regularly report back to leadership concerning their findings and progress. Learning and integration of data analysis are also represented in Figure 4.1–1.

When appropriate, the Center involves **suppliers** to ensure organizational alignment. Two recent strategic planning initiatives that improve the Center's performance include the Enterprise Resource Planning (ERP) project and RACC automated report generation for adverse events and serious adverse events reported in clinical trials. Both of these initiatives provided the Center continuous and breakthrough improvements. Analysis conducted at the FY2004 strategic planning conference identified a strategic goal for continuous improvement in data management systems. Over the course of the next two years, the strategic goal was expanded to include breakthrough improvement through the purchase of an ERP system to meet these needs. The Center involved our supplier BRINM in the planning and implementation of the ERP, resulting in BRINM implementing the same system. This will significantly streamline the interaction and information sharing with this supplier. This innovative project is the first ERP system to be implemented within VACSP.

Comparative Data Sources	Purpose/Type of Data	Selection Reasons	Category 7 Section					
			7.1	7.2	7.3	7.4	7.5	7.6
VA/Center	▪ Employee retention ▪ Productivity ▪ Satisfaction ▪ Safety ▪ Grievances ▪ Customer satisfaction	▪ Strategic direction ▪ Chain of command ▪ Personnel pool ▪ Historical performance	✓	✓	✓	✓	✓	✓
Other Government Agencies	US & government statistics	National comparisons		✓	✓	✓		
Similar Businesses & Competitors (*CenterWatch,* Frost & Sullivan)	▪ Market information, including market share & revenue ▪ Industry best customer satisfaction ▪ Competitor productivity & capability ▪ Quality	▪ Competitors & industry		✓	✓	✓	✓	✓
Businesses outside Industry	Breakthrough improvement	Best practices & innovation	✓	✓			✓	✓
Strategic (State & National Baldrige Quality Award winners, ASTD, Gallup)	▪ Customer satisfaction ▪ Productivity & turnover ▪ Safety ▪ Best practices	▪ National data ▪ Benchmarks ▪ Best practices, including government & not-for-profits ▪ Manufacturing ▪ Service	✓	✓	✓	✓	✓	✓
Industry Standards (6 sigma, 3 sigma, zero defects)	Quality	World-class quality levels	✓	✓			✓	

Figure 4.1–3 We use a robust set of comparative data to analyze our performance and learn from the best.
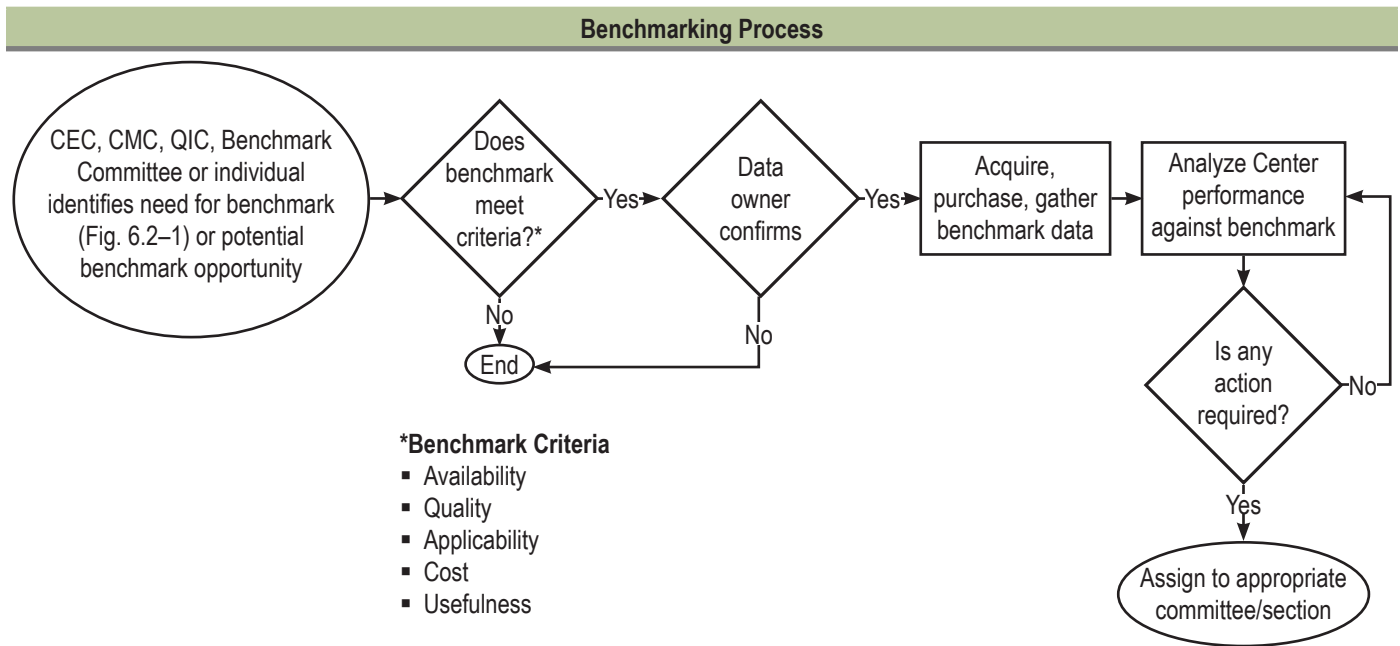
Figure 4.1–4 Our benchmarking process ensures the collection of appropriate data for comparison purposes.

4.2 Management of Information, Knowledge, and Information Technology

4.2a(1) The Center ensures the **accuracy** of data, information and organizational knowledge using data validation procedures throughout our processes. These procedures consist of both human inspection and electronic verification. Following our CA/PA process described in 6.2a(1), discrepancies are re-ported to the study team management and recorded in the eQMS issues log for investigation and follow-up as part of our performance improvement system (Figure P.2–2).

Integrity, reliability, security and confidentiality of data, information and organizational knowledge are ensured through conformance with established VA and Center hardware and software requirements (Figure 4.2–1). Continued vigilance is crit-

ical to the integrity, reliability, security and confidentiality of the Center's data (Figure 4.2–2). Patient confidentiality is ensured though blinded trials and associated procedures. Regularly scheduled internal audits help us confirm that our processes are continuing to function as expected. Employees use a web-based help desk system to report computer-related problems. Help desk tickets are automatically routed to key Information Technology Section (ITS) personnel, which enables timely and accurate response to customer support issues.

The Center's network was one of the first in the nation to receive an Authority to Operate from VA Office of Cyber and Information Security based on an extensive risk assessment and evaluation of both the implementation of the Center's security policies and contingency plans. This stringent assessment occurs minimally every three years. As a result, the Center has been able to quickly and effectively respond to information security concerns raised by VA leadership in light of recent data security lapses at other VA facilities. Data encryption and restrictions on network laptop usage are additional security practices.

The Center ensures the **integrity and reliability** of its data through clearly defined and documented processes, controlled access to data and network appliances, and custom software. A strictly managed permissions matrix specifically controls who can gain access to data, software, and/or sensitive areas of the facility. This matrix also helps ensure data confidentiality.

The **timeliness** of data, information and organizational knowledge is ensured primarily through the use of the Clinical Trial Project Plan (CTPP). The CTPP provides critical trial-specific information regarding timelines, risks, assumptions and resource requirements. Another example of processes used to ensure the accuracy of the clinical trial data is the use of barcode scanning technology in the processing of clinical trial materials. The use of the barcode scanning system helps ensure the **timeliness and accuracy** of data since the scanned data is verified and directly entered into the study databases.

Timeliness of data and information is also achieved through automated processes that update the Center's databases with the latest changes. Several of the Center's customers regularly provide data detailing clinical trial activity, such as drug usage and adverse events. Custom software developed at the Center processes and loads these files into databases, which ensures the workforce is working with the most current data available.

Rapid or unexpected changes in external requirements and internal capabilities are addressed at weekly Center Operations Committee (COC) meetings at the SAW and section briefings, allowing agile deployment of Center resources. At these meetings, key information and contingencies are shared regarding progress and barriers to effective and efficient performance im-

pacting each clinical trial (Figure 4.1–1).

The SAW was developed to enhance communications related to Center projects, customer requirements and operational matters (Figure 4.2–3) and has been improved multiple times (**Items in Figure 4.0). It is also used to give organizational insight to visiting customers. The SAW is a valuable operational tool, helping staff and visiting customers visualize and forecast requirements for human and equipment resources. It also provides a focal point for weekly discussion of issues and concerns.

4.2a(2) Information is **available** to Center employees on several platforms. For internal support, a local area network links all Center users and allows for the implementation of centralized databases and applications. All SOPs, production plans, master production records, clinical trial information and work request forms are located on the network and available to every employee at their desktop. All employees have accounts to an in-house wiki to collect, manage and share organizational learning.

Appropriate data are **accessible** to customers through applications developed by the Center for use in clinical trial management. Access is strictly controlled through layered security devices and applications. These applications require passwords and user registration, allowing customers and all Center staff access to a variety of data and information. The Clinical Trials Support Center (CTSC) website, a key customer support mechanism (Figure 3.1–4), provides data to the Center's customers to assist them in managing their clinical supplies, reprinting study documents and clinical trial data for day-to-day patient care. Shipment and usage data are available to customers through the CTSC to assist them in the management of the clinical trial at their site.

Several recent innovations to provide employees with even more useful and timely information include the production run

Security Measure	Security Action	
Internal	▪ Back-ups ▪ Offsite storage of tapes ▪ Intrusion detection	▪ Passwords ▪ Virus protection ▪ Access matrix ▪ Firewalls
External	▪ Physical access restrictions ▪ Fences, cameras & motion detectors	▪ Guards ▪ ID badges
Human	▪ Security awareness training	▪ User training

Figure 4.2–2 Data security is critical to the success of clinical trials. Systematic security measures ensure the integrity, reliability and confidentiality of the Center's data.

Validation Step	Purpose	Validation
Installation Qualification	Ensures hardware and/or software is installed correctly with adequate infrastructure for operation.	Server powers up correctly, provides expected responses and has adequate power, cooling, space, security and backup.
Operational Qualification	Ensures hardware and/or software operates as expected.	Servers communicate on the network and have adequate resources to run required systems.
Process Qualification	Ensures hardware and/or software runs the system with expected and reproducible results.	Software is beta tested to ensure new code works as expected in a production environment.

Figure 4.2–1 Validation procedures for computer systems ensure a systematic approach for data reliability and accuracy.

SAW Topics
▪ Center-wide activities ▪ Software development
▪ Drug arrivals ▪ Study milestones (kick-off,
▪ Manufacturing schedules annual meetings, etc.)
▪ Laboratory resources ▪ Clinical trials in planning

Figure 4.2–3 Analysis of progress, changes and barriers is performed at weekly COC meetings at the SAW. Results are documented and displayed for the staff.

dashboard and web-based clinical site inventory management capabilities in La Puerta, Internet access to clinical trial information on the National Library of Medicine website, and automated processing of patient safety data. A nightly automated process downloads site inventory usage for next-day inventory resupply. Access to VA systems is provided for timekeeping, payroll, purchasing, accounting and human resource applications. These applications are managed and maintained by VA.

The eQMS, the central tool of our performance improvement system described in P.2c, provides document control for all SOPs, AMPs and other controlled documents, systematically ensuring that employees have access to the most current version of policies, procedures and work instructions. As of April 2008, the eQMS contains 112 SOPs, 302 AMPs, 267 calibrated equipment items and 1497 total equipment items. The eQMS also maintains audit and issue records: 201 internal/external audits since 2000 and 2039 total issues since 2000.

La Puerta is a clinical trial management and reporting system that provides access to data entry, reports, shipment tracking, inventories, laboratory results and customer information. LearnerWeb, an electronic learning management system, maintains training records and enables all employees to register for upcoming training, view their training records and monitor the status of their training hours in relation to requirements.

4.2a(3) The Center manages organizational knowledge using the matrix team structure shown in Figure 5.1–1. This knowledge is collected, stored and transferred by the processes represented in Figure 4.1–1 and improved using our performance improvement system (Figure P.2–2).

Workforce knowledge is garnered through activities such as section and team meetings, the strategic planning cycle (Figure 2.1–2) and Process Action Teams (PATs). The wiki is also used to transfer knowledge by allowing collaboration of ideas among sections and record lessons learned with links to updates and improvements. Use of CTPPs and eQMS support knowledge collection and transfer. CTPPs, the intranet and eQMS are readily accessible to all Center employees from their desktop computers.

The Center **transfers** relevant knowledge gleaned from **customers** during the feedback process through section meetings and management reviews. Trended data is presented to all employees at SPEED for comprehensive analysis, review, and structured brainstorming sessions aimed at identifying areas of potential improvement.

Suppliers provide knowledge through regular contact, contractual reviews, vendor audits, trade shows, industry meetings, and participation in the Center's strategic planning cycle (Figure 2.1–2). Relevant information is captured and transferred to em-

ployees via staff, section and various team meetings. Clinical trial meetings provide additional opportunities for collaboration.

The Center identifies **best practices** through participation in state and national level Baldrige quality programs, ISO standards and principles, trade shows, study meetings and FDA Gold Sheets. The Center regularly identifies and implements best practices garnered at state- and national-level quality conferences. The ISO 9001:2000 and 15378:2006 processes provide an international set of standards by which to gauge performance, and the Center continually strives to exceed these standards. Trade shows and conferences allow employees to monitor and identify emerging and promising technology. The FDA Gold Sheet highlights best of industry regulatory practices, with a focus on quality control issues.

PATs and PET are utilized to **rapidly identify, share and implement** best practices. These small, agile teams are temporarily assembled to evaluate an opportunity or problem and are required to report their findings to the management committee that chartered the PAT/PET (Figure 1.1–2).

The assembly of knowledge for use in the **strategic planning cycle** (Figure 2.1–2) is gathered from SPEED, Baldrige assessments, environmental scans, annual section strategic planning meetings, performance reviews, and strengths, weaknesses, opportunities and threats analyses. This information is compiled and used by management at the Strategic Planning Conference for review and decision-making. The Strategic Planning Committee communicates the results of the strategic planning process to all employees.

4.2b(1) ITS utilizes the validation procedures (Figure 4.2–1) to ensure reliability of all critical hardware and software. A rigorous process of multiple testing cycles by multiple stakeholders ensures that in-house software applications are functional, reliable and **user-friendly**. Furthermore, new features or improvements are added to validated systems as small releases and are fully checked in a test environment before going live.

Reliability of clinical trial data involves the use of barcode scanning technology and reports to ensure all data loaded into clinical trial databases are accurate. Extensive use of barcode scanners virtually eliminates keyboard data entry errors. Currently, the Center is piloting the use of Radio Frequency Identification for processing clinical trial materials.

Security of clinical trial data involves tightly controlled physical access to network servers, security groups to limit access to data stored on the network, and the encryption of every laptop computer issued to Center personnel.

All reliability and security issues are entered into the eQMS for review and resolution by ITS.

4.2b(2) ITS has integrated emergency plans for providing access to data and information to our customers and employees in the **event of an emergency**. The emergency operations plan is updated annually and will be integrated with the COOP in 2009. Data stored on the Center's local area network (LAN) are backed up onto tape storage devices and kept in a secured offsite facility. We replace one third of PCs and laptops each year. We assess server and hardware needs annually and upgrade based on customer and workforce needs and organizational resources.

The Center recently deployed a Storage Area Network to efficiently manage, backup and restore data. Our robust data pro-

tection system provides the Center with the ability to rapidly recover from minor problems (such as deleted files). In the event of a disaster, the entire data structure can be restored within hours. Our full Emergency Operations Plan is described in 6.1c.

The Center utilizes email-enabled cell phones to support the continuity of operations by keeping employees in contact at all times, regardless of their physical location.

4.2b(3) Feedback from the study design process, voice-of-the customer processes and Project Assessment Subcommittee of CEC (PAC) analysis (3.1a[1]) drive **ITS improvements** by identifying capabilities desired by customers. An example is the CTSC, described in 4.2a(2). Drivers to ensure data and information remain **current and accessible** include employee input and frequent interaction with customers and suppliers. The Center's clinical trial-related software is custom developed for each protocol, giving staff and customers the capability to request changes as their needs evolve. Software developers are currently working on a new version of La Puerta that will augment common requirements while maintaining protocol-specific flexibility in order to reduce code duplication, development resources and time to implementation.

ITS personnel interact with professionals inside and outside VA to ensure that new technologies and systems exceed industry practices. They attend professional meetings, industry-sponsored training sessions and conferences with peers and are encouraged to research new technologies in order to design and implement innovative solutions. In addition, annual professional development and training is required for all information technology staff on topics such as computer system validations, network management, database and web-based system development, and information security. ITS also holds regular meetings for network administration personnel and software developers, which allow for the timely discussion of all current hardware and software issues affecting the Center's internal and external customers. ITS issues are also addressed through the performance improvement system shown in Figure P.2–2.

Center personnel collaborate with industry representatives who often visit the Center to review procedures, equipment, software, and data to ensure that the Center remains competitive and innovative.

The Center's strategic planning process also provides high-level guidance on software and hardware system requirements to address **emerging business needs and opportunities** and is integrated with our capital improvement plan. This usually takes the form of new technology required to increase competitiveness. Best practices are identified and shared using available comparative data as described in 4.1a(2). The environmental scan considers emerging or alternate technologies.

5 Workforce Focus

5.1 Workforce Engagement

5.1a(1) The Center **determines** key factors that affect workforce engagement through the annual Gallup Q^{12} survey. The evolution of our use, learning and integration of Gallup surveys is shown in Figure 5.0. The Gallup Organization has done extensive research to determine the factors that lead to workforce engagement, and the Center validates that correlation with

Workforce Improvements & Integration	
95	BRINM
98	All Stars*
99	Focus groups Employee survey** HR PAT
00	Bright Ideas* COC/SAW Annual Quality Day
01	Gallup Q^{12} survey**
03	Employee & Manager Expectations
05	*Cowboy Ethics* (©2004 James P. Owen) EARS* SPEED
07	LearnerWeb StrengthsFinder for managers**
08	StrengthsFinder for employees**

Figure 5.0 *The Center continuously updates HR processes to better meet workforce requirements and expectations. *Cycles of improvement for reward and recognition, **Cycles of improvement for employee satisfaction and engagement*

other literature research. Based on Gallup's and our research, employee satisfaction is an output of engagement, and therefore the factors that affect satisfaction are the same as those for engagement and **do not differ** across workforce groups or segments.

5.1a(2) The deployment of vision and values by leaders to the entire organization as well as participation by all employees in the interlocking committees (Figure 1.1–2) **fosters** an organizational culture of **open**, two-way **communication**, **high performance work** with a strong customer focus and **engaged workforce**. Matrix management, an outgrowth of our strong team culture, has existed at the Center since 1977 (Figure 5.1–1). Matrix management is a motivating factor to our workforce for three reasons. First, it provides employees with the opportunity to develop technical expertise and skills. Second, it allows employees to be supervised by a functional section chief who is a process and business content expert. Third, it allows staff the opportunity to participate on a cross-functional study team. Formed at the onset of clinical trials (Figure 5.1–2), these teams are composed of individuals from functional sections. They also reinforce our organizational culture and values, particularly customer service, teamwork and continuous learning.

The matrix organization ensures **open communication**, cooperation and skill-sharing across work units and functions. Study teams meet monthly or more frequently during planning and startup phases of the clinical trial.

Open, two-way communication among employees, supervisors and managers is achieved through sections, committees, process action teams, Center-wide staff meetings and performance appraisals. Employees are encouraged to approach supervisors and managers through our open-door policy.

Our Center Director has a strong belief in dealing with individuals rather than labels. He reinforces open communication by personally delivering a presentation at new employee orientation, which focuses on dealing with individuals and questioning self-deceiving assumptions about others. Our environment of open participation, communication and interlocking committees (Figure 1.1–2) benefits from the **diverse ideas, cultures** and **thinking** of our workforce. Most importantly, every employee's contributions are valued, regardless of grade or position in the workforce. Our matrix management system also leads to diverse ideas and thinking within our workforce, because each

Personal Learning
- Pharmaceutical expertise
- Technical expertise
- Career progressions
- Professional development
- Day-to-day supervision

Measures
- Productivity
- Workforce learning & growth
- Grade increases
- Training
- Engagement

Process Knowledge

Functional Sections Comprising the Clinical Trial/Study Team

ADMS	BFMS	FSS	ITS	CMS	CMMS	RACC	BPLS
Research Assistant	Financial Analyst	Budget Technician	Software Dev. Computer Asst.	Label Specialist	Manufacturing Specialist	Production Controller	Regulatory AE/ SAE Specialist	Chemist

PMR Leadership:
- Pharmaceutical Project Manager
- Pharmacist
- Clinical Research Pharmacist

Systems Knowledge

Personal Learning
- Customer focus
- Cross-functional teams
- Lessons learned

Measures
- Customer satisfaction
- Productivity
- Engagement

Figure 5.1–1 Our matrix management work system fosters high performance by bringing employees from functional sections to a study team under the leadership of a project director. Study teams execute key work processes (Figure 6.1–1), focus on customers and promote organizational and personal learning.

study team includes people from various sections with varying educational, tenure and cultural backgrounds. Most committees and teams comprise representatives from all segments of the workforce. Differences in education and backgrounds provide diversity of thought. In 2007 managers participated in the Gallup StrengthsFinder® to further identify and build upon diverse thinking and ideas. In 2008 employees participated, thereby completing four cycles of improvement of employee engagement (**Items in Figure 5.0).

5.1a(3) The Center's performance management system supports **high performance work** and **workforce engagement** by linking employee goals to the Center's strategic goals (Figure 5.1–3). The performance management system also links **workforce compensation, reward and recognition**, and **incentive practices** with strategic goals. Employee performance standards are linked to Center values with specific standards for each employee on customer service, safety, teamwork, leadership and continuous learning. High-performing employees receive monetary awards. Compensation and benefits allow us to meet customer requirements by attracting and retaining highly skilled professionals. Annually the Center assesses compensation, benefits and workforce flexibility to determine if changes are necessary to improve workforce engagement and business results. VA and BRINM employees have comparable compensation and benefits packages.

Our **recognition** and **reward** systems reinforce high performance through visible, tangible and consistent recognition for customer-focused results (Figure 5.1–3). The Employee Award and Recognition System (EARS) is the culmination of three cycles of improvement in rewarding high-performing employees (*Items in Figure 5.0) and has been identified as a best prac-

tice in the local quality community. EARS provides a mechanism for the Center's employees to recognize and reward high-performing peers. The process utilizes a point system to reward employees in conjunction with their performance. The process is designed to link EARS directly to the Center's mission, vision and values, reward all high-performing employees, and provide employees with an effective means to recognize one another for a job well done. The structure of EARS is three-fold: the Peer Recognition Program, the Incentive Program and the All-Star Team. The Peer Recognition Program is managed by the EARS committee, a cross-section of Center employees. The submitting employee characterizes the recognition using a predefined list of categories and point values. The Incentive Program is designated to allow employees to self-report noteworthy activities (e.g., course/degree completion) or activities that are in alignment with the Center's mission, vision and/or values. Employees who earn the most points throughout the rating period from both the Peer Recognition Program and the Incentive Program are recognized as members of the All-Star Team and receive monetary or time-off awards.

The Center's workforce performance management system communicates and **reinforces** a **business** and **customer focus** through our ISO-based performance improvement system (Figure P.2–2), our focus on Baldrige and CEC's balanced scorecard review of health indicators.

5.1b(1) Our learning and development system addresses our **core competency** of pharmaceutical expertise as well as **strategic challenges** and **strategic project plan** (action plan) accomplishments through the methods shown in Figure 5.1–4. Center leaders participated in the VA's first ever Learning Perception Survey in 2009. This survey, which was designed by
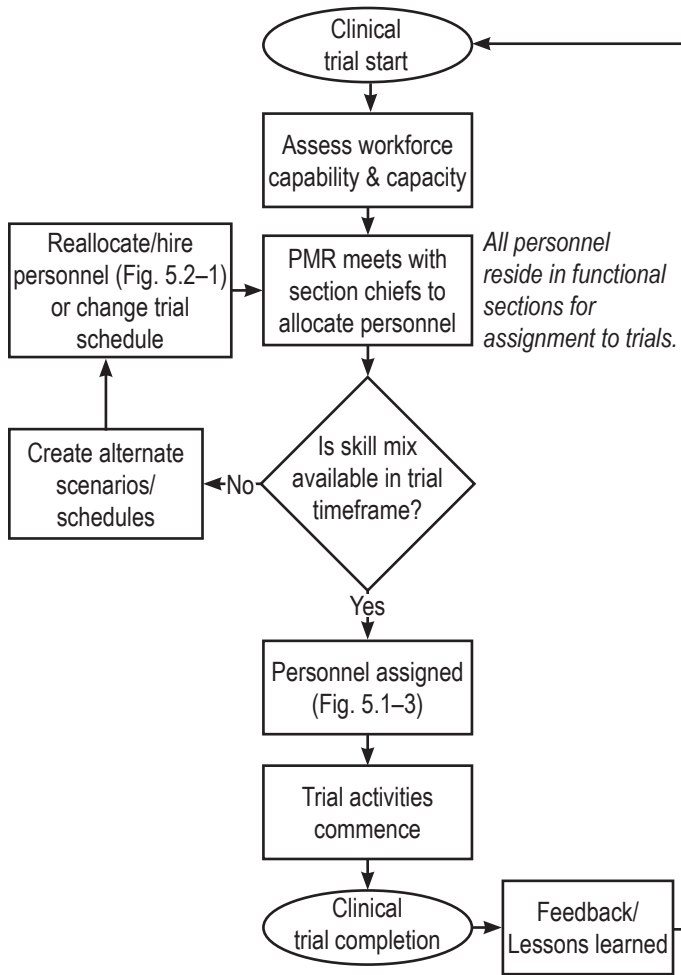
Figure 5.1–2 *The Center's rigorous staffing analysis for each clinical trial ensures optimal work design and effective allocation of personnel.*

Figure 5.1–3 *Our performance management system fosters high performance and a motivated workforce.*

the Harvard Business School (HBS) and administered through the VA's National Center for Organizational Development, measured responses in the following areas:

- Supportive Learning Environment creates appreciation for diversity of staff and encourages innovations.
- Concrete Learning Practices reflects a focus on data and analysis, training and transfer of knowledge assets.
- Leadership that Reinforces Learning ensures workforce development at all levels of the organization.

The Center outperformed all VA organizations and was identified as a best practice leader by HBS as we exceeded the HBS top quartile in each of the areas above (Figure 7.4–6).

Leaders champion each strategic project plan. All leaders are required to assume at least one additional significant role in the Center beyond their primary duties. Since 1996, one of our strategic objectives has been to apply for the Malcolm Baldrige National Quality Award, for feedback and improvement.

Periodically we conduct a **learning and development** assessment. Employees, supervisors and managers document future training needs, which are addressed through a variety of training formats and delivery choices. The plan identifies annual training in organizational **improvement**, **ethics**, compliance,

strategic initiatives and other areas identified by key committees. Training delivery mechanisms, such as **training, coaching, mentoring and work activities**, are selected as appropriate. The Center has been identifying training and development needs through the strategic planning process since 1999. Beginning in 2005, the project management template was modified to include formal identification of training needs related to project plans. If additional training needs arise throughout the year, they are

System Addresses	How Addressed	Examples	
Core competencies, strategic challenges & strategic project plans	▪ Strategic planning & training ▪ Project plans (template modified to include training/education needs)	▪ Pharmaceutical Expertise: pharmacy & industry conferences ▪ Regulatory compliance: VA mandatories, ISO training ▪ Strategy map training	▪ SPEED ▪ ERP Team: Governmental Accounting ▪ AE/SAE training ▪ Gallup Briefings & Great Manager training
Performance improvement & innovation	▪ Needs are identified by project plans ▪ Equipment purchased with training	▪ New equipment training ▪ Auditor training, quality tools & brown bag lunch sessions ▪ Performance Excellence: Baldrige examiner training	
Ethics & ethical business practices	▪ Ethical expectations ▪ Ethical behavior survey ▪ Ethics training	▪ All employees sign ethical expectations pledge annually ▪ Pilot survey program ▪ VA Rules of Behavior	
Education, training, coaching & mentoring	Individual Development Plan	▪ Coaching new employees ▪ Cross-training ▪ On-line education	▪ Satellite/teleconferences ▪ Tuition reimbursement
Needs & desires for learning & development	▪ Periodic needs assessment ▪ Individual development plans ▪ Competency assessments	▪ Staff competency assessments ▪ Manager & employee Individual Development Plans (IDPs)	
Transfer of knowledge from departing or retiring workers	▪ Process documentation ▪ Matrix management ▪ Succession planning	▪ AMPs & SOPs ▪ Membership on matrix management teams	▪ Cross-training ▪ Rotational committee assignments
Reinforcement of new knowledge & skills	Competency assessments	▪ Internal audits ▪ Computer labs	▪ Coaching built into contractor tasks

Figure 5.1–4 The Center workforce development and learning system addresses workforce, manager and leader factors through assessment, planning and training.

discussed at the appropriate committee meeting (Figure 1.1–2), prioritized and funded.

Matrix teams promote **innovation** to meet customer requirements by bringing together the best ideas and knowledge across the Center. **Change and innovation** are addressed through organizational support for leaders to attend industry and quality conferences, by membership and service in professional organizations, and by recruiting interns and fellows that bring new information and perspective.

The breadth of opportunities includes:
▪ Education and training (Figure 5.1–5)
▪ Coaching (project management, presentations, supervisory)
▪ Mentoring (project directors, committee roles)
▪ Rotating and interlocking committee responsibilities

5.1b(2) Based on annual learning, employees' development plans are jointly developed by supervisors and employees. Figure 5.1–3 is our systematic process for assessment, development and learning. Expectations for staff further reinforce our core value of leadership.

Organizational knowledge is captured and stored (Figure 4.1–1) through a variety of methods, and knowledge is transferred from departing or retiring employees through hiring overlaps, job manuals, standard operating procedures (SOPs), procedural documents and training modules. Cross-training is conducted in all sections to ensure that any departing employ-

ee does not have exclusive knowledge or skill. The transfer of knowledge from departing or retiring employees is captured through cross-functional representation on matrix management study teams. The Center reinforces knowledge and skills on the job through:
▪ Internal audits, which promote excellence and consistency among Center processes
▪ Competency assessments for individuals
▪ Annual continuing education units for licensing and professional certifications
▪ Current versions of all work instructions available to employees through the eQMS
▪ Sharing of information from educational experiences

Many operations within the Center are tightly regulated. In many instances, required training is specified and certification is necessary before an employee is allowed to work in a particular area or on a particular project. Detailed profile data are kept for all employees to document training and identify deficiencies. Additional elements of the workforce development and learning system are shown in Figure 5.1–4.

Matrix management enhances organizational learning by broadening skills, increasing employee involvement, productivity and development, and providing a lessons-learned process. All foster a sense of ownership and empowerment and promote system thinking. The Center's intranet provides information to employees on topics such as the strategic plan, quality efforts,

Needs & Desires	Examples of Learning & Development	
New Employee Orientation	Security Safety Conflict of interest FDA/Good Manufacturing Practices Emergency preparedness	
Diversity	StrengthsFinder Section team-building training Alternative dispute resolution	
Employee Development	Government accounting Records management ISO	Center project management eQMS
Ethical Business Practice	*Cowboy Ethics* (©2004 James P. Owen) Conflict of interest Ethical expectations GCP training	EEOC VA fiscal accountability Auditor training
Management & Leadership	Order from Chaos Time management Quality tools Leadership development	Strategy mapping Time & leave training Position description writers workshop
Workplace & Environmental Safety	LearnerWeb Emergency drills	Hazardous materials CPR training
Technology	Radio Frequency Identification ERP Production equipment training Lab content management system IT expansion	

Figure 5.1–5 Managers identify and prioritize specific courses to meet key needs based on the annual training and development plan and project plans.

educational offerings, human resource information and clinical trial profiles. The SAW supports effective communication by displaying deadlines, customer commitments and resource availability, allowing for rapid deployment of resources to meet emergent or urgent needs. Clinical Trials Project Plans (CTPPs) provide detailed trial information for all employees, allowing for a rapid response to changing customer or business requirements.

5.1b(3) The **effectiveness** of the learning and development system is **evaluated** in numerous ways, as shown in Figure 5.1–6. Staff report at staff meetings on content and quality of external training they attend. Evaluations assess attendees' perceived value of the training, who the targeted audience was (or should be), how the training compares to similar training offered by other vendors, and how the expected goals and outcomes of the training can be applied to meet Center needs.

The best test of development and learning systems is an improvement in organizational performance, such as employee productivity (Figures 7.3–3 and 7.4–8). Most of the Center's long-term training efforts are directed at culture change (project management, ISO/Baldrige, Gallup StrengthsFinder®, etc.).

Analysis Method	Deployment & Evaluation
Trainee satisfaction	All courses over four hours; lack of satisfaction led to recent contract termination
Competency	All compliance courses require post-tests
Behavior change/ achieve objective	All funded training documented on SF 182, an official VA record
Process change/ maturity	Large change initiatives, such as project management, use maturity model
Organization results	Percent of staff rated exceptional; employee productivity (Figures 7.3–3 and 7.4–8)
Workforce learning & growth	Figure 7.4–5

Figure 5.1–6 We analyze results of training efficiency and effectiveness to improve performance.

5.1b(4) The Center Director takes a personal interest in the **career progression of the workforce** and actively supports advanced academic learning through tuition reimbursement (Figure 7.4–14), release time for classes and other incentives available to all employees. Dr. Sather is a full professor at the University of New Mexico, and 13 other senior leaders and managers have faculty appointments. We have a career track for most positions to support our strategic goal for employee development and career progression. Even though we are prohibited by federal regulation from engaging in preselection, we have developed a number of methods to ensure that workforce progression needs are met. Interns and fellows are included in Center career progression. The training investment provided for career track promotions benefits both the organization and the employee and retains high-performing employees. We also track academic appointments and degrees granted to employees.

As a very small organization, we employ a number of formal and informal means of succession planning. The Center accomplishes **succession planning for managers and senior leadership** through the development of CEC, described in 1.1a(3). CEC members are actively involved in all facets of strategic planning and executive decisions, and the members of this group are eligible to apply for a more senior leadership vacancy within the Center or the VA.

Every section chief identifies and trains one or more qualified individuals to deal effectively with most issues that may arise in the absence of the incumbent. The Center has written policies for delegation of authority and management succession. We continually improve succession planning through the strengths, weaknesses, opportunities and threats (SWOT) analysis in our annual strategic planning (Figure 2.1–2).

Planning for other key positions throughout the organization is done through training, education, cross-training, details, coaching, mentoring, and other endeavors. The Center develops the next generation of pharmaceutical researchers through educational internships and fellowships, allowing students to have hands-on experiences with clinical trials. In addition, the Center supports the development of support staff through internships, information technology (a hard-to-hire federal field), administrative management, and the pharmaceutical laboratory.

Exposure of matrixed team members to other Center jobs and skills provides the opportunity for career development. For example, one of our administrative research assistants was recently hired into the manufacturing section.

5.1c(1) The Center **formally assesses workforce engagement** using the Gallup Q^{12}. The Gallup is a national best practice, which has been validated across all workforce groups and segments. As a high-performing organization, the Center target is to meet or exceed the Gallup 75th percentile on all questions. While methods do not differ for segments within our small organization, the results from our key surveys are segmented by division, tenure and education, which are the main segments of our workforce. Gallup results show no significant differences between segments. Based on the results from the 2005 survey, the Center elected to implement a new reward and recognition program (EARS) with the goal of improving employee recognition as measured on Question 04: "In the last 7 days I have received recognition or praise for doing good work." As a result, scores have steadily increased from 2.91 in 2005 to 3.72 in 2008.

In addition to the annual administration of the Gallup survey, the Assistant Center Director for Administration **reviews turnover** (Figure 7.4–11), **grievances** (Figure 7.4–12), **safety** (Figure 7.4–13) and reward and recognition data, and brings any issues to CEC. As a result of review of this data and other data related to quality and productivity, leaders evaluated a year-long pilot on compressed workweek and determined that one of the compressed workweek shifts (9–80 schedule) was effective in our environment. Engagement is also **assessed informally** through section and all-hands staff meetings.

5.1c(2) Managers review employee survey data and turnover rates in the context of overall organizational performance. Since industry customer dissatisfaction can occur as a result of high turnover and poorly trained personnel (*CenterWatch*), we directly relate our business results and high customer satisfaction to our low turnover and highly trained, professional staff. We consider staff education and tenure an important attribute of service quality and a key factor for success. The Gallup-correlated data further supports our belief that our investment in employees pays off in higher-than-average employee engagement, which directly affects key measures such as productivity, employee retention, safety and customer loyalty.

Higher scores on the Q^{12} lead to better business results, based on Gallup's rigorous research on the relation of survey **findings** to key business results. Opportunities for improvement based on the survey are addressed during strategic planning.

5.2 Workforce Environment

5.2a(1) The Center supports over 70 active clinical trial projects at one time, which can span anywhere from a few months to over 14 years. All staffing project budgets are consolidated by section and position to determine existing and future workload and staff predictions by the Associate Center Director working in conjunction with supervisors. **Capability** is indicated by productivity (Figure 7.4–8), cumulative grade increase (Figure 7.4–9) and turnover (Figure 7.4–11). We are able to predict **capacity** (Figure 7.4–10) by skill type. This information tells us if we need to increase staffing levels or seek new projects, based upon known workload.

In addition, we **assess workforce capability and capacity** during strategic planning. For each strategic objective, we assess workforce capability to determine the knowledge, skills and abilities required for success. These capability assessments are documented in the project plan.

Capability in the form of **skill and competency** assessments is determined by managers based on customer requirements when developing or updating position descriptions. When it is determined that a new skill is needed, we typically:

- Train existing employees;
- Recruit a new employee with the skill set; or
- Hire an outside contractor for intermittent work.

5.2a(2) We **recruit, hire** and **place** employees based on key skills identified in the position description and during strategic planning (Figure 5.2–1). Next, we complete a performance-based interviewing process that utilizes a cross-functional interview team and criteria based on job-specific skills required by the position, customer requirements, the study team as well as Center culture. This ensures a good fit between the Center, the applicant and the hiring organization. The manager creates performance-based review questions specific to each position. For example, an interview team for a research assistant would consist of a section chief, project director, project manager and current research assistant. This allows multiple facets of the study team to be involved in the selection process.

Employee engagement impacts **retention** by setting clear expectations and providing opportunities to participate, learn and grow. Every year, over half of our employees receive a salary increase (of ~3%), which retains high-performing employees.

As part of the VA, our hiring community has a focus on veterans preference. While Federal hiring criteria prohibits selection based on gender, race, religion, color, national origin, sexual orientation, age or geographic origin, we ensure that the workforce represents the **diverse ideas, cultures and thinking**, of our hiring communities by recruiting employees from colleges, universities, VA, professional and clinical trial meetings and the local community. Job diversity, described in P.1a(3), enhances our ability to meet the requirements of our trials.

5.2a(3) We organize and manage the workforce to accomplish centralized distribution of pharmaceutical products by using the matrix work design structure shown in Figure 5.1–1. We capitalize on our **core competency** of pharmaceutical expertise by assigning a clinical research pharmacist (project director) to every trial. The project director provides healthcare input to the design protocol, and is accessible to our customers when medical or other issues arise during the trial. Having expert clinical knowledge reinforces our **business commitment to our customer**. Since many of our contacts are doctors and nurses, a competitive advantage for the Center is that they are able to talk to another healthcare professional. An example of how we manage and organize our workforce to address the strategic challenge of hiring specialized employees capable of working in a highly regulated work environment is to use cross-functional teams for interviewing. We also follow the strategic planning process that includes project plans (Figure 2.1–2). This systematic approach enables us to respond to customer requirements, such as increasing expertise in international shipping.
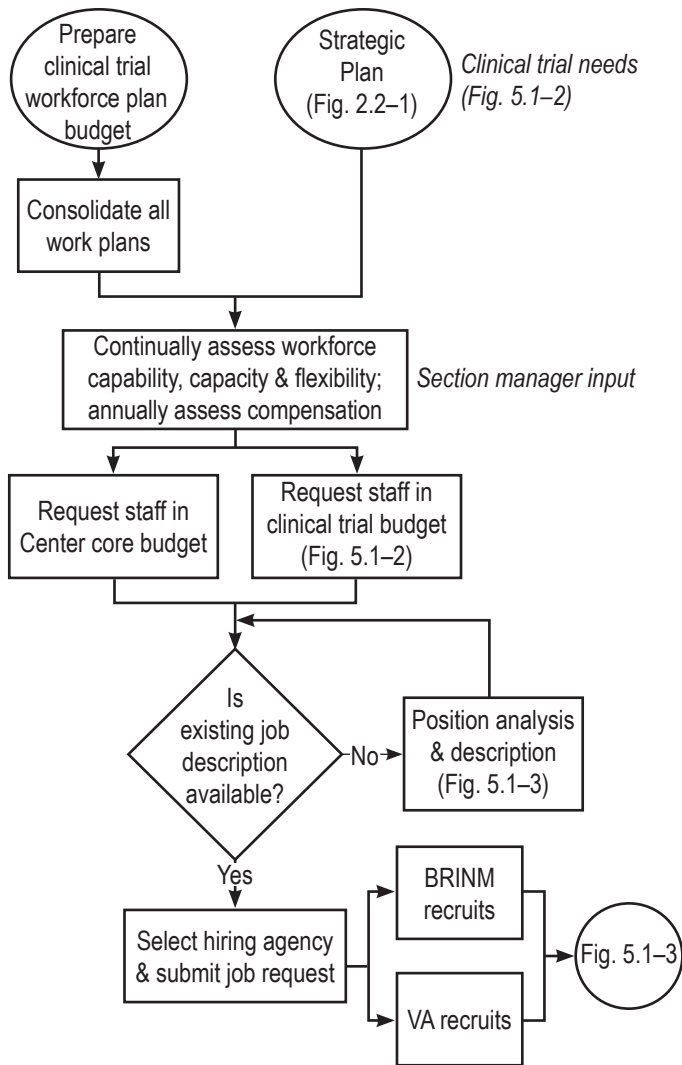
Figure 5.2–1 The Center deploys a robust process to identify and fill our workforce needs. VA recruitment practices are consistent with civil service regulations.

The Center reinforces a **customer** and **business focus** through a culture of high performance, professional development and training, and accessibility of the project director, pharmaceutical project manager and research assistant (Figure 5.1–1). Employees are provided the opportunity to **exceed expectations** through participation on study teams, PATs, committees, Strategic Planning Employee Empowerment Day (SPEED) and EARS. At SPEED, all employees have the opportunity to address our **strategic challenges** and **project plans**.

We manage our workforce to achieve **agility** through matrix management, cross-training, the delegation of authority, discussed in 5.1b(4) and our ability to hire employees through different hiring organizations. Though we are a small organization, by having multiple employees able to engage in every process, we can quickly respond to customer change. We achieve agility through the use of sectional checklists. We built upon this innovation at the Project Management Bootcamp held in 2005, where we identified milestones to segregate section checklists and allow even more concurrent tasks to be performed, a cycle of improvement for the section study checklist. Employee input during SPEED and section conferences ensure our agility to re-

act to changing business needs as they arise. We improve our work systems through our ISO-based performance improvement system, described in P.2c and Figure P.2–2.

5.2a(4) One of the ways we are able to be **pioneers**, set industry standards and exceed **customer expectation** is through the matrix management structure. We continuously improve our use of matrix management, as it is an integral component of performance improvement (Figure P.2–2). Capability changes and capacity needs are communicated from top down and bottom up, beginning with the strategic planning process outlined in Item 1.1. The Center provides employees with the tools and resources needed to efficiently perform their jobs, as measured by Gallup Question 02. Project directors reiterate clinical trial changes, projected changes and needs at the weekly SAW.

We also prepare our **workforce for changing capability** needs through our education and training programs described in 5.1b. We manage our workforce to prevent workforce reductions through careful analysis of clinical trial and Center needs. CEC requires a complete proposal and projection of requirements as well as funding sources (such as clinical trials) for each new position. The timing of various clinical trials in progress at any point in time requires a detailed forecast of future work requirements and capabilities in order to justify a new position, not just a current need. We operate in a lean environment to prevent any potential for workforce reductions. Although we have never had a reduction in workforce, and conservatively increase our workforce based only on known workload, succession planning minimizes the impact of workforce reductions due to departing or retiring employees, as described in 5.1b(4).

5.2b(1) Leaders and employees work together to **ensure workplace health, safety and security** by adhering to the training and guidelines provided by VA, BRINM and the Center. Our Emergency Operations Plan (EOP), Continuity of Operations Plan (COOP) and Safety Plan address health, safety and security. Together the Center and VA conduct mandatory health and safety courses throughout the year. Topics include fire safety, environmental safety and Good Clinical Practices (GCP). Health topics include ergonomics, pandemic flu, infection control and blood-borne pathogens.

In addition to training, we ensure the security of our employees and operations by providing a 24-hour security service, a fenced perimeter and swipe-card access to all areas of the Center. In addition, VA police officers perform an annual review of the facility. The contractor and installation vendor of the Center's security and fire systems perform quarterly audits as part of their maintenance contracts.

To ensure and **improve** workforce safety, the cross-functional Safety Committee performs bimonthly inspections of six defined zones (physical areas of the building) based on a safety checklist. Members enter findings into the eQMS and address any safety issues identified, following the corrective action/ preventive action system to ensure completion and deployment to employees (Figure 6.2–3). They also recognize exemplary safety behavior observed in the workforce through EARS. The Safety Committee meets monthly and reports via the interlocking committee structure (Figure 1.1–2).

Periodically, the Safety Committee uses an ergonomics consultant to assess the facility and work environment.

Work Environment	Key Environmental Factor	Measures/Performance Target	Section-Specific Actions to Achieve Target
Production	Work involves drug manufacturing, packaging, shipping and receiving	▪ 0 accidents ▪ 0 time lost to accidents	▪ Drug handling training ▪ Forklift safety equipment operation ▪ Protective gear ▪ Proper lifting techniques
Administrative	Work involves operating office equipment	▪ 0 accidents ▪ 0 time lost to accidents	▪ Ergonomic training specific to office equipment
Laboratory	Work involves drug handling and chemical testing	▪ 0 accidents ▪ 0 time lost to accidents	▪ Chemical spill procedures and exposure risk ▪ Eyewash/shower equipment operation ▪ Laboratory equipment safety

Figure 5.2–2 Workplace health and safety are addressed through establishing high goals in all Center environments.

Improvements are implemented based on the findings. EARS and the Safety Committee encourage and collect ongoing suggestions for improvement. Figure 5.2–2 addresses differences in workplace environments and provides measures and goals.

Support of employee health includes health benefits, employee assistance and wellness programs.

5.2b(2) Although the Center is composed of employees hired through different organizations, we support all workforce segments by offering a wide variety of progressive **services, benefits and policies** (Figure P.1–3). Examples of policies include a flexible work schedule, time off for health and family issues, and educational support. **Benefits**, such as employee assistance, health and life insurance and retirement, are tailored examples of how we meet the needs of a diverse workforce. The Center offers vacation, sick and family leave to all employees. Every employee is encouraged to participate in community activities and in federally-sponsored commemorative programs such as Women's Equality Day, Take Our Children to Work Day, Disability Awareness Month, ethnic awareness days and others. Private counseling, leave without pay and personal development are **services** that each employee has the opportunity to take advantage of without adverse action.

Our Associate Center Director starts with the VA benefits to ensure that BRINM matches those benefits as closely as possible and then uses employee feedback to identify potential new benefits, such as the compressed workweek described in 5.1c(1). We are currently piloting the feasibility of telework (remote/virtual locations) for employees.

6 Process Management

6.1 Work Systems Design

6.1a(1) Since 1977, the Center's work system design is a fully deployed matrix management system, which is continually evaluated to innovate our system process, products and services. Assembled at the onset of the clinical trial, the cross-functional study team (Figure 5.1–1) executes key work processes (Figure 6.1–1), promotes innovation to meet customer requirements, and also reinforces our organizational culture and values—particularly customer service, teamwork and continuous learning.

The matrix management work structure is fully integrated in each of our 78 clinical trials. Each trial has unique customer requirements, and we design our work system to deliver trial-specific products and services to maintain customer engagement

Process Improvements & Integration	
78	Investigational New Drug application compliance
79	Investigational Device Exemption compliance
87	Application of cGMP
93	FDA cGMP registration*
95	CAP accreditation* GCP Program for NIDA*
98	GCP Program (SMART) for CSP*
99	Manufacturing initiative
00	Fellowships
01	Emergency Operations Plan
02	Formal PM* Updated SOP/AMP* RACC*
03	ISO 9001 certification*
05	PM Bootcamp Process Efficiency Team
06	ERP Lean Six Sigma initiative
09	ISO 15378 certification*

*Figure 6.0 The Center's success is built upon systematic integration of capabilities and improvements. *Indicates cycles of improvement*

leading to repeat business. Every trial has a matrix management study team. With 78 active trials and approximately 112 employees, most employees are on multiple study teams, which increases organizational learning and transfer of knowledge. Trials may utilize all or portions of the key work processes of pharmaceutical study design and project management, safety and regulatory compliance, drug production and shipping/distribution. Figure 6.0 highlights many of the milestones for cycles of refinement and integration of process management.

We continue to adapt matrix management principles to our operating environment. For example, we are now redefining pharmaceutical project managers' (PPMs) budget responsibilities based on newly acquired capabilities in our ERP system. **Innovations** to matrix management include expansion of matrix team assignments, refinement of team member roles and responsibilities. In 2007. Dr. David Spong of Boeing, a two-time Baldrige winner, presented training and lessons learned on matrix management to assist with improved implementation.

We determine which work processes will be **internal** to the Center and which will use **external** resources through project evaluation within the opportunity selection process (Figure 3.1–2). Center capabilities and work processes are assessed and internal/external resources are identified as needed by the Project Assessment Subcommittee of CEC. Production or laboratory operations beyond the Center's capabilities are then outsourced.

6.1a(2) The Center's work system and key work processes relate directly to our **core competency** of pharmaceutical expertise. Each work process addresses specific aspects of pharma-

	Pharmaceutical Study Design	Pharmaceutical Project Management	Safety & Regulatory Compliance ■ GCP Training, Site Monitoring & Audits ■ Regulatory Compliance	Drug Production & Shipping/ Distribution ■ Manufacturing, Packaging & Labeling ■ Shipping/Distribution
Relation to Core Competency [6.1a(2)]	Knowledge & experience of pharmacist; use of pharmaceutical tools (study protocols, customer questionnaire, ISO Quality Manual); adherence to cGMP	Pharmaceutical project management knowledge & experience for clinical trials; CTPP; adherence to cGMP	Capitalizes on expertise in conducting safe clinical trials, monitoring sites & identifying/coding patient reactions to drugs in clinical trials	Master production records, production plan, production orders, AQLs, cGMP, ISO Quality Manual, ISO 9001 & 15378
Key Requirements (Figure) [6.1b(2)]	Operational/scientific integrity (7.1–2 through 7.1–4) On-time delivery (7.1–5 & 7.1–6) Responsiveness (7.1–7 & 7.1–8)	Productivity (7.3–3, 7.4–8) Performance to budget (7.3–5) On-time delivery (7.1–5 & 7.1–6) Responsiveness (7.1–7 & 7.1–8)	GCP regulations FDA reporting regulations Quality training	Zero Defects: ■ Manufacturing (7.5–6) ■ Packaging (7.5–7) ■ Active/Placebo ID (7.5–8) ■ Shipped drug (7.5–9) Drug manufacturing & operational regulations (P.1–4)
Customer & Supplier Inputs (Figure) [6.1b(2)]	Customer & supplier requirements from study design process (3.1–1) Customer questionnaire CTPP Protocol changes Drug retrievals	Statement of Work Customer questionnaire CTPP Drug retrievals	Statement of Work CTPP	Trial information from suppliers incorporated into test methods development & verification
Control & Improvement (Figure) [6.2b(1)]	Inventory monitoring Retrievals & replacements of drugs Ongoing trial reviews & communications Vital signs review PATs Effectiveness of performance improvement system (7.5–12) Monitoring SAEs	Cost control Vital signs review PATs Effectiveness of performance improvement system (7.5–12) Inventory monitoring Retrievals & replacement of drug	Clinical trial monitoring/ auditing RACC cycle time vs. workload (7.5–5) Effectiveness of performance improvement system (7.5–12) GCP training (7.1–4) Monitoring SAEs	Raw material inspections In-process product tests Label verifications Quality records & documentation Tracking & monitoring issues utilizing the eQMS Vital signs review PATs Final production order & checking procedures Effectiveness of performance improvement system (7.5–12)
In-Process Measures to Reduce Variability (Figure) [6.2b(1) & 6.2b]	Adequate clinical supplies at sites (7.1–5) Customer satisfaction (7.2–1, 7.2–2, 7.2–9) Customer complaints (7.2–3) Internal customer satisfaction (7.5–13)	Adequate clinical supplies at sites (7.1–5) Customer satisfaction (7.2–1, 7.2–2, 7.2–9) Budget cycle time (7.5–14) Performance to budget (7.3–5) Internal customer satisfaction (7.5–13)	RACC cycle time vs. workload (7.5–5)	In-process checks by quality managers (records available on site) Manufacturing & packaging rejects (7.5–6, 7.5–7) Shipped drug quality (7.5–9) Nonconformances (7.5–10) Active/Placebo ID (7.5–8) Internal customer satisfaction (7.5–13)

Figure 6.1–1 *Our work processes are driven by customer requirements and deliver ever-increasing value, as measured by total funding (Figure 7.3–2) and success in repeat business with engaged customers (Figures 7.2–8).*

ceutical expertise throughout a clinical trial from pharmaceutical design to publishing trial results. Figure 6.1–1 describes how each key work process relates to and capitalizes on our core competency. We improve work systems and key work processes to build upon and integrate our strategic advantage of experience and reputation for pharmaceutical expertise (A1) through

the performance improvement system described in P.2c.

6.1b(1) Figure 6.1–1 lists the Center's **key work processes**, **requirements**, **customer and supplier inputs**, and improvements and aligns with our products in Figure P.1–1. These work processes involve all employees and add **value** for customers and stakeholders by providing the mechanisms to test new therapies within safe and compliant clinical trials. They directly contribute to our **sustainable** growth through continuing funding from engaged customers. Our capital investments increase our capabilities in the design and conduct of clinical trials, and in manufacturing and packaging drugs (production). These investments contribute to our long-term financial return (Figure 7.3–2). Implementing Good Clinical Practices (GCP) training, monitoring and site auditing ensures regulatory compliance and patient safety as well as trust and value in our products and services. The regulatory compliance process adds to financial sustainability by providing added capabilities. Project management contributes to our financial sustainability and **success** by establishing a systematic approach for planning, risk management, scheduling and controlling clinical trial activities. We use the performance improvement system (Figure P.2–2) to attain our strategic goal to increase capability and productivity.

6.1b(2) We determine **work process** requirements incorporating input from suppliers and customers in the study design stage, described in 3.1a(1) and Figure 3.1–1. Study design processes are fully documented in multiple standard operating procedures (SOPs) and approved methods and procedures (AMPs). Key requirements (Figure 6.1–1), captured and documented in the Statement of Work (SOW), are used during the study design process to ensure that all key customer requirements are met. Other requirements, such as ISO 9001:2000, ISO 15378:2006, FDA and Drug Enforcement Administration (DEA) regulations, are also incorporated during the design phase. Studies are conducted according to protocol, and we train clinical trial site personnel, and monitor and audit clinical sites according to GCP standards. The study design process is continuously improved via our performance improvement system (Figure P.2–2). Key milestones in improvements to study design occurred at the PM Bootcamp in 2005 and the Lean Six Sigma initiative in 2008.

We communicate project requirements internally through the Clinical Trial Project Plan (CTPP), an in-house tool specifically designed for clinical trials and study team meetings.

Suppliers and vendors play a critical role in our production work process by providing necessary components for products and services. Suppliers provide drug products, packaging, and labeling materials. Critical suppliers complete a vendor certification process and may receive a site inspection by Integrated Quality Management, before being selected as a qualified supplier. We provide detailed specifications to meet customer and regulatory requirements in the clinical trial planning process. Our drug suppliers provide input that is used to develop the detailed clinical trial design and packaging reflected in the SOW (Figure 6.1–1).

6.1c The Center's **disaster and emergency preparedness system** includes the Center's Emergency Operations Plan (EOP), Continuity of Operations Plan (COOP) and section emergency plans. In the event of a local, regional or national emergency or disaster, the primary objectives are to maintain key operations to support clinical trials, provide continued supply of drugs to patients and, as necessary, to assist with unblinding (revealing which patients are on which drugs or placebos). The Center's Emergency Preparedness Team oversees the EOP. During the plan's development, the team met with section chiefs to identify critical systems, core business functions that need to continue in the event of an emergency. In addition, each section has its own emergency plan, which section chiefs review annually with their teams and update as necessary.

In conjunction with the EOP, the Center maintains a COOP and has designated the Integrated Quality Management Chief as the COOP Manager. The COOP addresses **continuity** of operations to support the site personnel and patients enrolled in clinical trials. Recent enhancements include integrating section disaster plans and the Center COOP into the overall preparedness framework consistent with the standardized Incident Command System (ICS) format. These harmonized plans and policies guide contingency operations under a variety of scenarios to ensure the continuation of mission critical and essential business with minimal or no interruptions. Scenarios include limited staffing due to a pandemic, necessity for alternate facilities, raw material supply chain interruption and customer access to services.

To address **prevention** and **management**, third-party groups perform external reviews of the Center's facility to evaluate safety and emergency exposure. New employee orientation includes emergency preparedness, continuity of operations, pandemic flu topics and other health and safety topics described in 5.2b(1).

The EOP includes orderly **recovery** procedures from the execution of the COOP to ensure operations are continued during recovery. The Center also has a Pandemic Flu Plan to address the unique aspects of such an event. The cross-functional training provided through the matrix management work system minimizes the impact of any event affecting resource availability.

Following the Center's policy process, the Center EOP, section emergency plans and COOP are all maintained in the eQMS for version control and assignment and tracking of reviewers and approvers. The Center EOP and COOP are in alignment with Federal Continuity Directives and VA policy and requirements for emergency planning and preparedness. Any changes to either would trigger review and any necessary update of our plans. In response to incidents such as 9/11 and Hurricane Katrina's impact on our customer's ability to receive drug shipments, we updated our EOP to more effectively address such emergency events. Approaches for how we ensure the availability of data and information in the event of an emergency are described in 4.2b(2). Results of our emergency preparedness planning, training and exercises are shown in Figure 7.5–2.

6.2 Work Process Management and Improvement

6.2a Figure 6.2–1 details a systematic design process that is used for new processes and to achieve **innovation** with existing **work processes**. For example, we conducted an innovative Project Management Bootcamp in 2005 that involved pharmacists, PPMs and section representatives. The purpose was to standardize, streamline and improve the design and conduct of clinical trials. We systematically created process flow charts and checklists for the planning and start-up phases of trials, and

identified key milestones to improve efficiency and effectiveness. We identified tasks that could be performed concurrently in order to reduce cycle time. New processes are currently being documented in SOPs for approval through the eQMS. An example of new technology to improve cycle time and reduce waste is in laboratory testing. New near-infrared technology and cutting-edge ion-mobilizing spectroscopy have enabled rapid drug identification testing with reduced hazardous solvent use, exposure and waste. Figure 6.2–2 summarizes how we incorporate factors into the design of work processes to meet key requirements. Process design and innovation may be championed by any member of the workforce and may involve a PAT or committee as shown in Figure 6.2–1.

6.2b(1) We **implement and manage work processes** to **meet design requirements** through documented procedures, internal audits, product testing, corrective action/preventive action (CA/PA)—to date supported by 112 SOPs and 302 AMPs—and removal and destruction of nonconforming product. Design requirements are ensured through the use of quality checks at critical steps in the work process. We monitor day-to-day per-
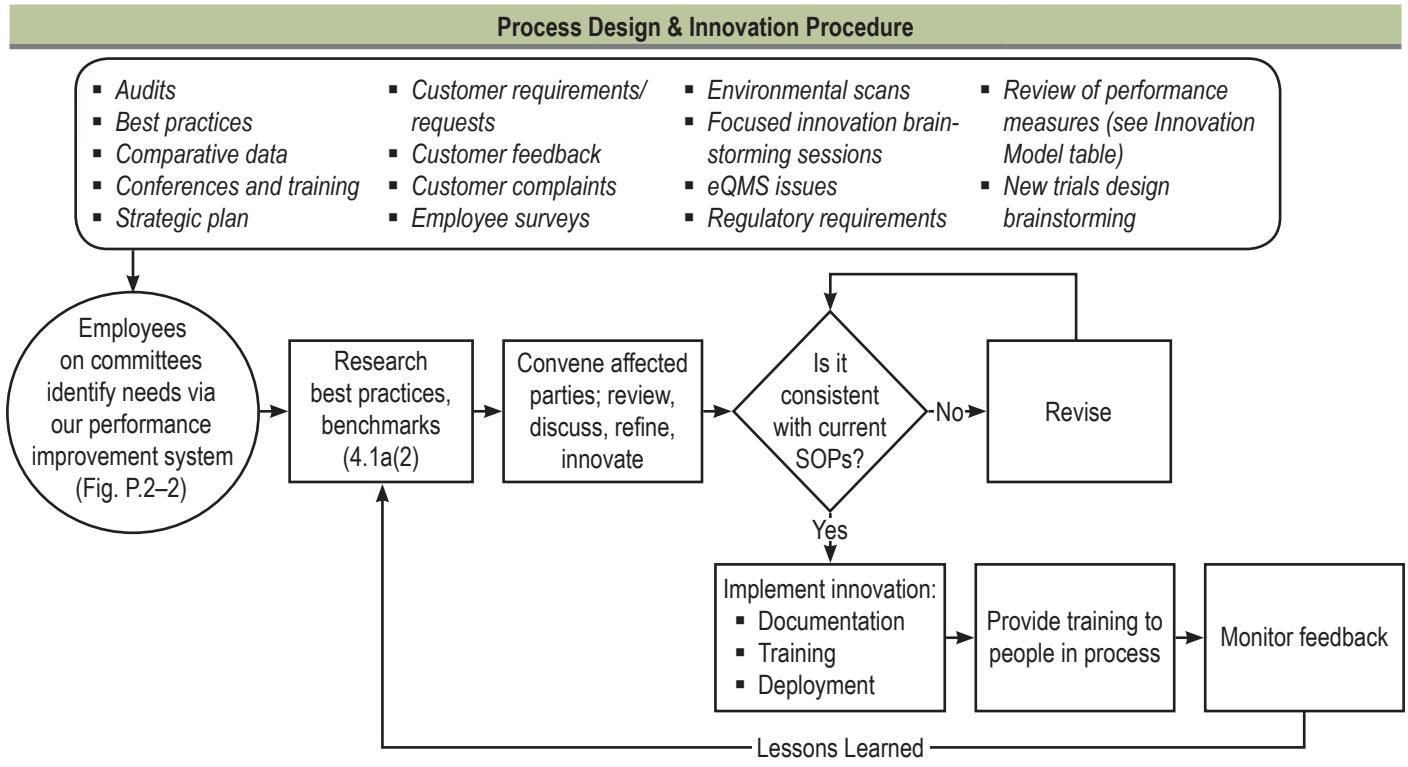
Innovation Model

Innovation Level	Charter/Monitor Responsibility	Measures	Examples of Innovation (Benchmark or Source of Idea)	
Organization/ Culture	CEC	Health Indicators	▪ *Cowboy Ethics* (©2004 James. P. Owen) ▪ Evolution of Matrix Management (Boeing) ▪ PM Bootcamp (Lockheed)	▪ Strategic Awareness Wall (NM Economic Development Department) ▪ Strategy Map (Quality NM)
Process	CMC, ISO, PET, ERP Process Approval Change Board (EPAC), Customer Focus Committee & employees	Vital signs In-process measures	▪ Cross-functional ISO Internal Audit team program (Best practice we developed based on Allied Signal and stated by our external ISO auditor)	▪ EARS (VAMC-Amarillo) ▪ ERP Process Approval Change Board (NASA) ▪ SPEED (Quest) ▪ Wiki (Employee suggestion)
Product & Service	QIC, Sections & PATs	Customer satisfaction In-process measures	▪ Cartoner (PACK EXPO/employee suggestion) ▪ Clinical Trials Support Center (Employee suggestion) ▪ Elimination of tear-off labels (PET review)	▪ Laboratory Electronic Content Management (Employee suggestion) ▪ Liquid filled hard gel capsule (customer requirement) ▪ Patient information handbook (VA)

Figure 6.2–1 Our formal process design and innovation procedure ensures consistent deployment of all processes.

formance of work processes to ensure they meet requirements through the in-process measures in Figure 6.1–1. We use results of internal customer satisfaction surveys from employees to monitor and improve the quality of products and services that sections supply to each other.

The cross-functional skill sets of study team members ensure appropriate workforce input. **Customer** and **supplier** inputs are initially captured on the prospective customer questionnaire and communicated in the SOW and project plan. Changes to a SOW, project plan or clinical trial protocol are communicated and deployed using the CTPP, chiefs briefings and study team meetings. Through a cycle of improvement, we have created a standardized change request process for SOW modifications. Customers provide regular input via project meetings, routine teleconferences and our feedback tool.

We improve supplier involvement and deployment through relationship building. For example, key suppliers have attended our strategic planning conference, and not only provided and received important information for strategic planning, but also participated in all developmental and team building activities. The Center CA/PA process and CMC and Quality Improvement Committee (QIC) reviews ensure that improvements are shared throughout the organization.

The measures we use for **control and improvement** are shown in Figure 6.1–1. Many measures are leading indicators of the success of work processes. Deviations from acceptable parameters are logged in the eQMS via our performance improvement system (Figure P.2–2) and corrective action is taken using the CA/PA process (Figure 6.2–3). We monitor the percent of preventive and improvement actions compared to all corrective, preventive and improvement actions (Figure 7.5–12). These continuous feedback loops ensure each clinical trial is on a path to success. At the section/functional level, in-process measures are tracked daily to ensure key measures are attained. For example, in production, environmental conditions (temperature and humidity) are continuously monitored during manufacturing runs to prevent non-conformance of products.

6.2b(2) Our performance improvement system (Figure P.2–2), based on ISO standards, uses data to continually identify improvements that reduce defects and cost. In order to **control overall costs**, our process designs are tested prior to deployment through formal validation and verification to produce a consistent and repeatable process. Validation and verification processes are documented in our Quality Manual and SOPs. The ISO system supplements and complements the regulatory requirements in Figure P.1–4. The formal third-party ISO validation of quality occurs during yearly surveillance audits, and a complete re-certification audit occurs every three years. In our quest for continuing improvement, the Center analyzed and documented processes to obtain an additional ISO 15378:2006 certification for packaging of medicinal materials in 2009. We are the first VA organization to achieve both ISO 9001 and 15378 certifications. Recently, the Center accepted the opportunity to lead ISO 9001 certification efforts for the entire VACSP.

Our use of test runs for manufacturing, packaging and labeling helps prevent **defects and rework**, and facilitates trouble-free introduction of products by proactive risk assessment and mitigation. The Clinical Materials Management Section incorporates a clinical trial design review based on the CTPP in their project plans, which are approved in the eQMS.

Inspection and testing is clearly defined for all processes, including those processes that are standard for all operations, such as receipt, storage and handling of drugs and devices.

External audits are performed and maintained for accreditation and certification by appropriate entities such as ISO, DEA and FDA. The Center minimizes the cost of inspections and reduces defects through internal audits performed by trained employees, use of in-process measures, process-specific checklists and our performance improvement system (P.2c). The frequency of internal quality inspection is reduced as the rate of incidents of nonconformance drops, minimizing the cost of inspections. We also minimize costs by preventing defects and rework through

Design Elements	How We Incorporate & Deploy	
Changing Customer Requirements	▪ Requirements reviewed during conference calls ▪ Customer feedback ▪ Change order process	▪ Project management review process documented in CTPP & study team meetings
New Technology	▪ Resource planning & project management process ▪ Individual section reviews & professional seminars ▪ Implementation of new capabilities	▪ Project management technology & bootcamp ▪ SAW ▪ CTPP
Design Quality	▪ Figure 6.2–1	▪ Quality checks embedded in work processes
Cycle Time/Agility	▪ Flow charting the design process	▪ Defining measurement points
Organizational Knowledge	▪ Documentation of issues & actions ▪ Corrective actions taken & management review of the effectiveness of corrective actions	▪ Formal lessons learned ▪ CTPP ▪ Methods shown in Figure 4.1–1
Cost Control	▪ Requirements are tracked in project management process & through cost analysis of labor-intensive activity	▪ Implementation of ERP
Productivity & Other Efficiency Factors	▪ CMC and study teams evaluate capacity utilization of equipment & employee efficiency factors & determines equipment/technology requirements during project management planning & SAW meetings	

Figure 6.2–2 Our design process incorporates key requirements for work processes. The table provides examples; several of the examples, such as CTPP, ERP and SAW, have many cycles of improvement.

CA/PA Process

- Reason for action in the eQMS (customer complaint, audit observation, etc.)
- Investigate
- Perform immediate corrective action
- Conduct root-cause analysis as needed
- Perform preventive & improvement actions
- Perform verification & effectiveness review
- Is verification successful? — No (back to Investigate) / Yes
- Review & approve closure
- Share lessons learned with all affected parties
- Close action in the eQMS

Figure 6.2–3 CA/PA process corrects deficiencies and prevents recurrences.

the use of in-process measures (Figure 6.1–1). Adequate clinical supplies at sites (Figure 7.1–5) ensures that our customers never experience productivity loss.

We reduce the overall costs associated with internal audits by using a standard format for internal ISO audits for each functional section. The standard format includes an easy-to-use checklist developed for each section. We train internal audit teams to use the checklist to verify that SOPs and AMPs are up to date and current. This approach also increases organizational learning, as each internal audit team is cross-functional.

Embedding quality controls in every process directly results in minimizing manufacturing rework and production rejects. This methodology is specifically designed to limit quality checks to those points in the process where criticality and risk can most efficiently and effectively be assessed. Our Process Efficiency Team (PET) is chartered to review all processes, efficiencies and resources within our work system. The PET reviews how projects are managed and how sections interact. The PET conducts employee interviews utilizing pre-defined questions. Team members meet multiple times to review data and discuss findings, and recommendations are developed and prioritized

based on importance to Center efficiency and effectiveness. This PET process enables the rapid identification, sharing and implementation of best practices throughout the Center (Figure 4.1–1). An example of PET activity is the Project Management Bootcamp, with the objectives of standardization of the project management process and training new project managers. This resulted in refinement of the planning steps for clinical trials. The CEC reviews PET findings and recommendations, and approves and allocates resources for deployment.

6.2c We **improve** and innovate **work processes** through the measures shown in Figure 6.2–1, as part of our ISO-driven performance improvement system (Figure P.2–2). Routine internal and external audits review work processes in all sections and proactively drive improvements. The Internal Audit Team conducts internal audits on functional section requirements and critical processes, with the results documented and analyzed for process improvement (Figure 7.1–2). Internal audits occur on a rotating schedule of Quality Manual sections and augmented as required based on prior audits trends and results.

The monthly QIC meeting also examines quality trends (via eQMS issues log and other reports) and internal audit findings, providing valuable management review of the quality management system. We document all internal and external audits in the eQMS. **Variability** is **reduced** as we measure performance and drive to zero defects. A primary goal of the QIC is to identify processes that are candidates for improvements based on issues entered into the eQMS and prioritized based on our challenges. These improvements are shared through mechanisms shown in Figure 4.1–1. Examples of improvements to our Drug Production work process include the addition of new packaging capability through our cartoner integrated packaging line. This capability was added to keep current with customer requirements and allows us to label, package and shrinkwrap multiple bottles or boxes of drugs. Advantages to our site personnel customers include less package handling and decreased storage space on pharmacy shelves. We significantly increased our efficiency by reducing scanning and final checking times.

Continued registration in ISO 9001:2000 since 2003 and our recent ISO 15378:2006 certification drive improvements in processes and supporting documentation. Baldrige assessments and feedback opportunities for improvement are analyzed, prioritized and implemented. Internal customer satisfaction results are used to improve processes (Figure 7.5–13).

Processes are kept current with business needs and industry direction through our strategic planning cycle (Figure 2.1–2). Objectives are implemented through project plans, such as the acquisition of the liquid capsule filling machine. When issues are identified, we use the CA/PA process (Figure 6.2–3) for problem resolution. Section chiefs and project managers keep current with the Center's business needs as active members of CMC and through participation in strategic planning. As experts in their fields, they stay abreast of industry direction by attending conferences and meetings, through regular communication with customers and by reading professional journals and newsletters.

The Center continually evaluates and implements new quality tools for improvement. Our quality culture supports continuous improvement and learning. Our 2008 Strategic Conference identified the use of Lean Six Sigma concepts as a strategic ob-

jective. In 2008 we conducted a pilot project using Lean Six Sigma to reduce complexity and cycle time of our budget development process (Figure 7.5–14). The project resulted in five recommendations, which are being implementing by five teams.

We use the results of organizational performance reviews (described in Figure 4.1–2) and associated actions plans to systematically evaluate and improve work processes. The CEC and CMC owner of each health indicator and vital sign documents the action required if unfavorable changes in performance occur. For example, one of our health indicators is Adequate Clinical Supplies at Sites (Figure 7.1–5). If performance decreased, QIC and the Division of Project Management would review and conduct root-cause analysis of the individual logged customer complaints in the eQMS.

Improvements as a result of **organizational performance reviews** are incorporated into key processes through updating SOPs, AMPs and associated training. AMP and SOP review occurs every two years at a minimum, with more frequent reviews based on performance review results. The PET performs ongoing reviews by section. As necessary, identified actions are delegated to functional workgroups or temporarily assembled teams called Process Action Teams (PAT). These workgroups or teams regularly report progress directly to the chartering committee. Other means of incorporating the results of organizational performance reviews include organizational planning meetings with key employees and the strategic planning process. For example, at SPEED the Center director presents a "State of the Union" address to all staff members. In breakout sessions and group discussions, employees analyze Center performance and formulate recommendations for improvement. Employees can volunteer to participate on cross-functional teams charged with implementing strategic objectives. Employees also participate in the implementation of objectives at the section level or through direct communication with their supervisor.

 Organizational learning is achieved in a variety of ways (Figures 4.1–1 and 5.1–1) and shared across the organization processes through weekly COC meetings at the SAW and staff meetings. Continuous innovation (Figure 6.0) is driven by the need to adapt new technology to achieve efficiency and productivity. This achieves our goal to increase engaged customers (Figure 2.1–1). Because improvements typically affect other processes within the Center, significant changes are shared at CMC prior to implementation for widespread improvement and organizational learning.

All improvement initiatives, such as PATs and the PET, as well as improvements that are a result of strategic objectives are chartered and reviewed by the appropriate interlocking committee, which ensures thorough deployment across the organization (Figure 1.1–2). **Organizational innovation** is achieved through the procedure shown in Figure 6.2–1 and occurs simultaneously with organizational learning as discussed above. Innovation is measured in the annual Gallup survey (Figure 7.5–3).

7 Results

As a federal government agency, the Center follows a fiscal year that runs from October 1 through September 30. Several measures, including many financial ones, reflect that period with the "Fiscal Year" label. The "Year" label reflects calendar year.

Year-to-date (YTD) results are designated through the month indicated in the figure (e.g., 6/09), while year-end results use the last two digits of the year.

7.1 Product Outcomes

7.1a(1) The key measures of the Center's products and services that are important to our key customer groups (investigators and site personnel) are listed in Figure P.1–6. Results for **zero defects** in drugs we ship (Figure 7.1–1) show the Center's strong **product performance** for this **key requirement**. We use six sigma, a measure of variability and a target for top performing companies, as our benchmark. The very tight tolerances of six sigma mean that only 3.4 errors per million can occur.

Zero Defects			
Year	Units Delivered	Quality Defects (ppm)	Allowable Defects Using Six Sigma (ppm)
2001	2,120,957	0.0	7.2
2002	24,513,121	0.0	83.3
2003	24,080,507	0.0	81.9
2004	53,613,946	0.0	182.3
2005	89,601,498	2.2	304.6
2006	60,067,179	0.0	226.0
2007	48,750,252	0.0	165.8
2008	50,324,400	0.0	171.1
6/2009	28,545,200	0.07	97.1
2009 proj	38,000,000	0.05	129.2

Figure 7.1–1 We greatly exceed six sigma standards and exhibit industry and benchmark leadership. Units Delivered represent the number of tablets, capsules, etc., shipped to sites. The 2009 projection for units delivered reflects the cyclical requirements of current and projected trials. We are supporting a larger proportion of trials that require fewer units per patient throughout the trial than previous trials did; therefore, units delivered will vary.

Our commitment to **scientific integrity** of Center operations and strict adherence to standard operation procedures (SOPs) is indicated by the number of internal (Figure 7.1–2) and external ISO audit findings (7.1–3). Internal ISO audits provide an ongoing and detailed evaluation of adherence to standard operating procedures. We encourage internal audit findings as this rigorous program provides organizational learning and drives Center performance improvement, which ultimately lead to fewer and fewer incidents that could impact the scientific integrity of Center operations. We encourage rigorous discovery by trained internal auditors, as internal ISO findings predict external ISO findings. Observations require no formal response. Projections are targets of the average of previous two years.
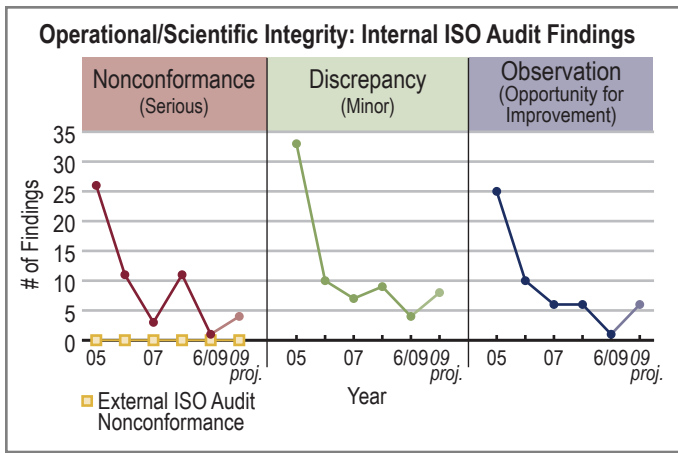
Figure 7.1–2 *Internal ISO audit findings are leading indicators of external ISO audit findings. We have had zero external ISO audit nonconformances each year since our initial external ISO audit in 2003.*
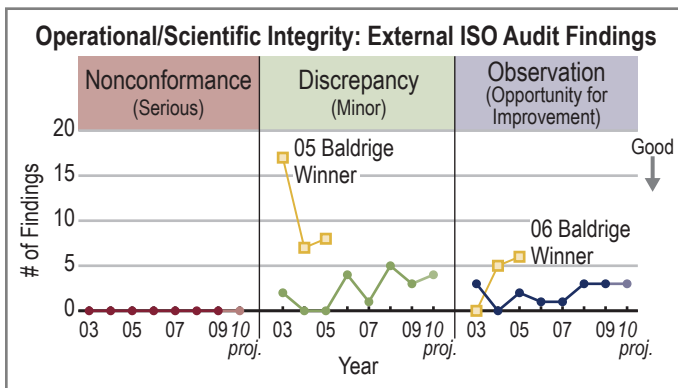
Figure 7.1–3 *Center results of zero nonconformances in seven years of external ISO audits validate our rigorous approach to operational/scientific integrity. Both benchmarks, 2005 Baldrige winner (DynMcDermott) and 2006 Baldrige winner (MESA Products, Inc.), are also ISO certified.*

Good clinical practices (GCP) training supported by strict adherence to well deployed SOPs provides the foundation of operational/scientific integrity of Center operations. An important requirement of site personnel is the quality of the GCP training and the training we provide on how to conduct the trial at their clinic or hospital (Figure 7.1–4). We are the benchmark for University of New Mexico's GCP training program.

For customer satisfaction results in Items 7.1, 7.2 and 7.6, Top Box % Satisfied results reflect percent of customers rating satisfaction as "Excellent," and Top Two Box % Satisfied results reflect percent of customers rating satisfaction as "Excellent" or "Good." We project customer satisfaction (Figures 7.1–4, 7.1–6, 7.1–8, 7.2–1 and 7.6–9) based on a five percent conversion of customers to our "top box" rating, which translates to a one percent increase per year for our customer population of around 300 customers, or 0.5 percent increase on a one-to-five rating (Figure 7.2–2). For ratings approaching 100 percent satisfaction (Figures 7.1–7 and 7.2–9), we project maintenance of these near-perfect ratings.
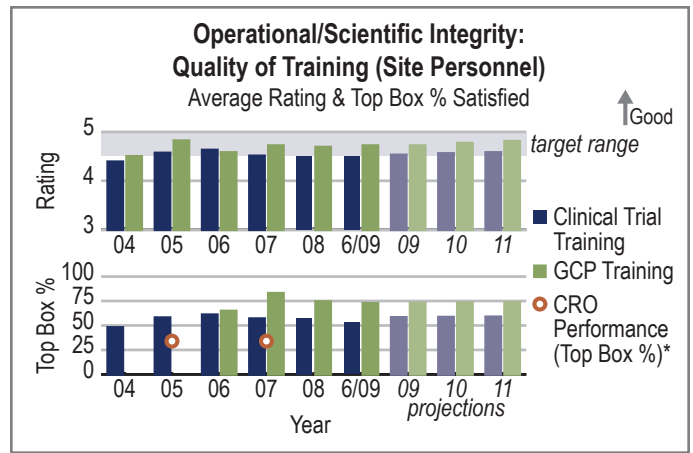
Figure 7.1–4 *Site personnel are very satisfied with the training we provide. *CenterWatch CRO survey*

Site personnel require adequate supplies at their sites throughout the clinical trial, an indicator of **on-time delivery** (Figure 7.1–5). The **CSP**_ABQ_ logo identifies health indicators in Items 7.1 through 7.5.
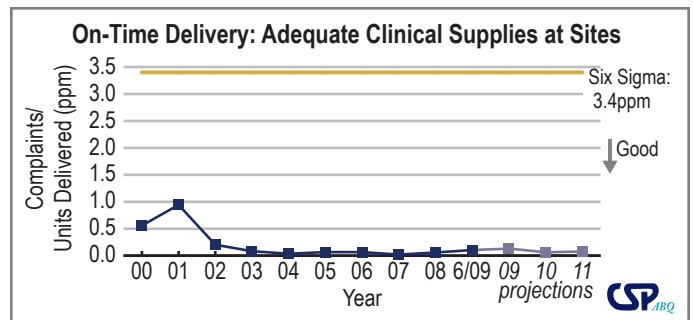
Figure 7.1–5 *We focus on adequate clinical supplies at sites to ensure the delivery of the right drug to the right patient at the right time. Results for 6/09 represent only three complaints, keeping performance far below six sigma standards for allowable errors.*

On-time delivery is also measured by satisfaction with maintaining clinical supplies in sufficient quantities to meet study schedules (Figure 7.1–6). Results support Figure 7.1–5.
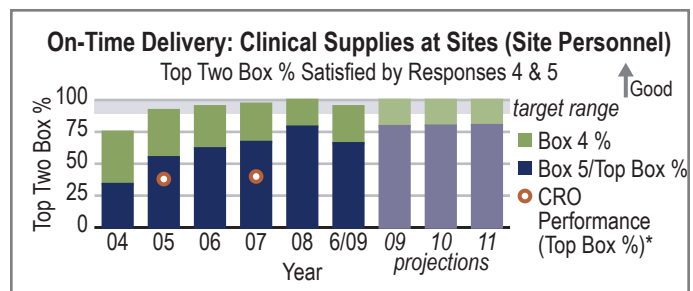
Figure 7.1–6 *In 2008 seventy-nine percent of site personnel rate our clinical supply service as "Excellent," well above best known CRO comparison. The Top Two Box % remains high at 95%. *CenterWatch CRO survey*

Responsiveness is an important requirement for investigators and site personnel. Clinical trial site personnel provide hands-on patient care; therefore, our responsiveness is criti-

cal to ultimate patient, stakeholder and trial outcomes. The Center measures responsiveness on two aspects: (1) ability to respond proactively to anticipated investigator and site personnel requirements (Figure 7.1–7); and (2) ability to respond to requests when customers contact us (Figure 7.1–8). We obtained a government benchmark from the WA Department of Ecology through an online literature search.
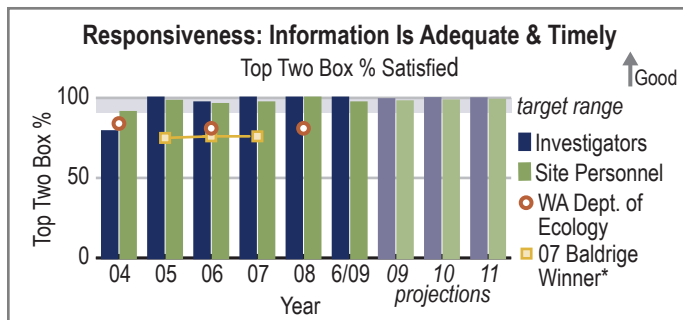
Figure 7.1–7 *Our responsiveness to anticipated investigator and site personnel needs fulfills a key customer requirement. *ARDEC, a 2007 Baldrige recipient, is a meaningful benchmark as it is also a research and development organization. Washington State Department of Ecology comparison data is best available governmental source.*
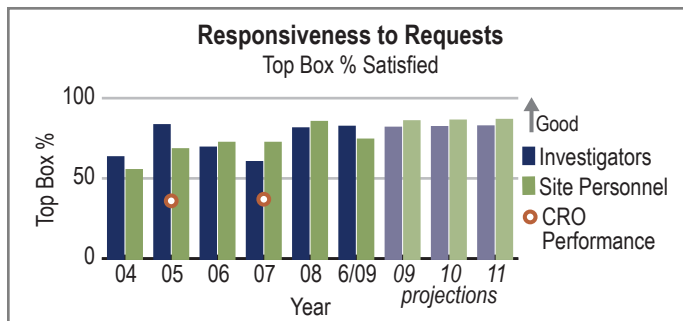
Figure 7.1–8 *We have sustained superior responsiveness to investigator and site personnel requests for 78 concurrent clinical trials. (Source: CenterWatch)*

7.2 Customer-Focused Outcomes

7.2a(1) Average overall **satisfaction** ratings for the Center's customer segments now exceed all known benchmarks. Figure 7.2–1 shows a comparison of the Center's average customer satisfaction scores for both customer groups compared with industry contract research organizations (CROs) competitors and other benchmarks.

All feedback uses a rating scale from 1 (Strongly Disagree) to 5 (Strongly Agree). For customer rating results in Items 7.2 and 7.6, charts show average values across all trials; however, the target range applies to every question for every trial.

We directly measure customer satisfaction for both customer groups for each of our current clinical trials at their annual study meetings (Figure 7.2–2).

Customer dissatisfaction is measured through complaints (Figure 7.2–3) and through the percent of customers who are dissatisfied as measured by our customer feedback (Figure 7.2–4). Through our complaint management and CA/PA processes, we have dramatically reduced complaints. Customer dissatisfac-

tion data show excellent levels and trends. The Center has exceeded six sigma standards since 1999.
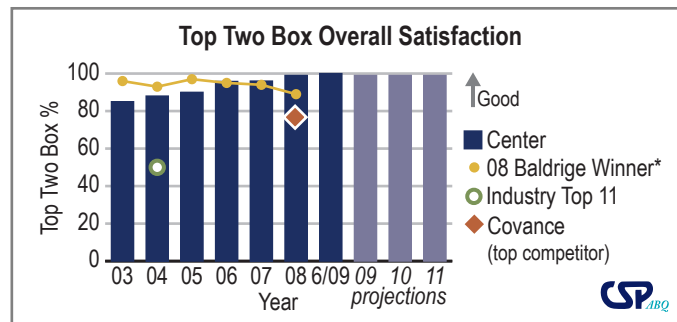
Figure 7.2–1 *The Center outperforms all known benchmarks in customer satisfaction. *City of Coral Springs selected as not-for-profit category source (Industry source: CenterWatch)*

Figure 7.2–2 *We exceed national and government benchmarks for customer satisfaction. [1]American Consumer Satisfaction Index for federal government, 2007 survey, [2]ARDEC*
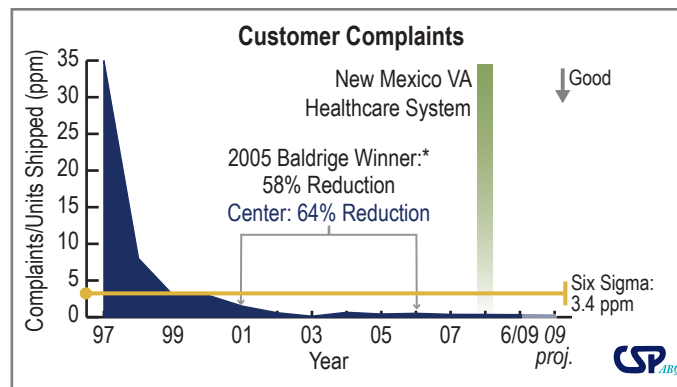
Figure 7.2–3 *A ten-fold decrease in customer complaints exceeds all known industry, Baldrige (*Park Place Lexus), benchmark and VA sources.*

Customer Dissatisfaction by Customer Group
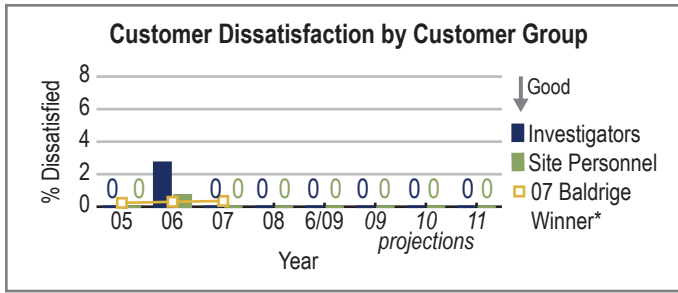
*Figure 7.2–4 Due to a very small sample size in 2006, one investigator's rating had a large impact on our rating. Fewer than 3% of investigators have ever been dissatisfied. *ARDEC*

7.2a(2) VACSP's continued support, as shown by funding (Figure 7.3–2), reflects **customer satisfaction** and **engagement** in our ability to deliver products and services to VA investigators and site personnel.

[Details removed]
Figure 7.2–5 Compound Annual Growth Rate Per Year

Customer relationship building in the extramural market, where customers have 800 CRO choices, is important to meet our strategic challenges. We value repeat business with federal customers as key to growth and sustainability. NIH is a stage-three life cycle customer. These 29 NIH repeat-business trials represent a substantial portion of our workload (Figure 7.2–6).

Life Cycle: Repeat Business Segmented by NIH Agency
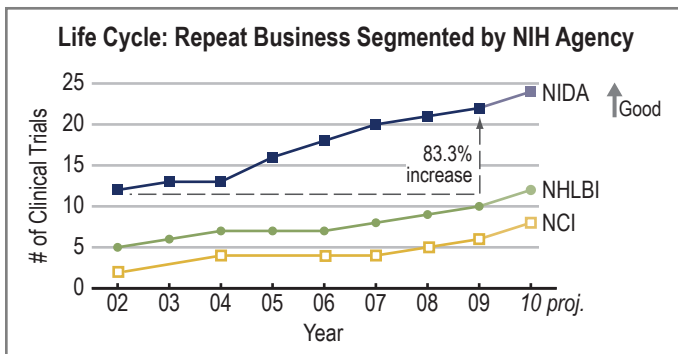
Figure 7.2–6 We have nearly doubled our repeat business with three key agencies within NIH, our fully engaged and largest federal customer.

For key extramural customers, we track the length of relationships in years and the percent of customers with longer than 10-year relationships (Figure 7.2–7).

Another meaningful customer value measure is percent of extramural funding from repeat business from current and past customers. Our growth in the extramural market is directly attributed to these engaged customers (Figure 7.2–8).

Final customer-focused outcomes include customer ratings on courtesy (Figure 7.2–9) and market segment recognition and awards (Figure 7.2–10).

Life Cycle: Long Relationships with Engaged Customers
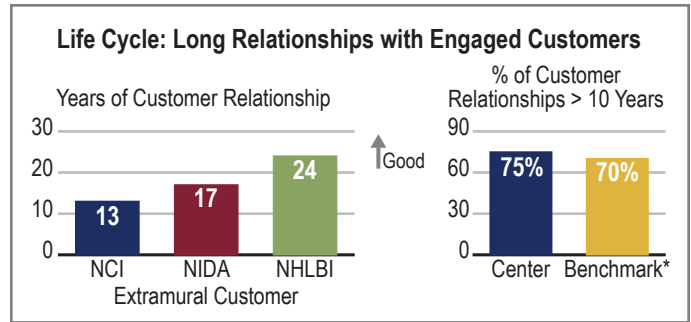
*Figure 7.2–7 The Center exceeds all known benchmarks for the percent of repeat customers who have been with us for over 10 years. The value of our products and services is evident in repeat business and long-term opportunities. *Two-time Baldrige winner Texas Nameplate*

Customer Engagement: Repeat Business As Compared to Total Extramural Funding
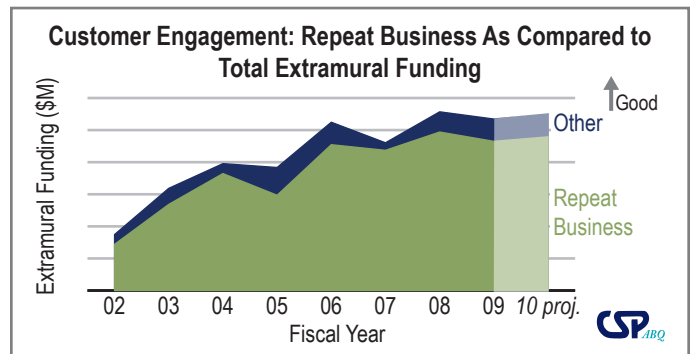
Figure 7.2–8 In 2009, 87% of extramural funding came from repeat business from engaged customers.

Communication Courtesy by Customer Group
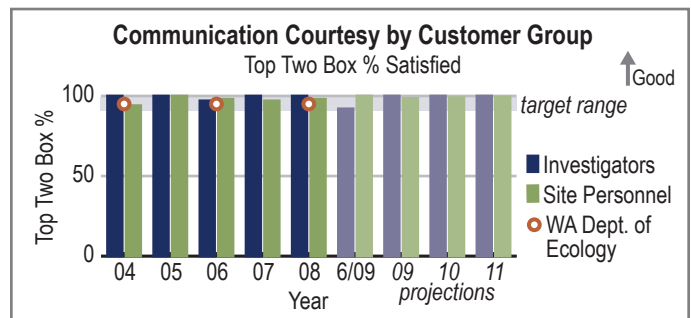
Figure 7.2–9 Courteous communication with investigators and site personnel demonstrates our customer-focused approach with results within our target range.

Quality Journey

2001: VA Carey Award VHA Category
2002: VA Carey Award VHA Category
2003: VA Carey Award VHA Category
     ISO 9001:2000 Certification
2004: VA Carey Trophy Award (Estimated score: 556)
2006: VA Circle of Excellence Award (Estimated score: 581)
     MBNQA Nonprofit Pilot Site Visit (Estimated score: 593)
2007: VA Circle of Excellence Award (Estimated score: 664)
     MBNQA Nonprofit Site Visit (Estimated score: 609)
2008: VA Circle of Excellence Site Visit (Estimated score: 623)
2009: ISO 15378:2006 Certification

Figure 7.2–10 Our excellent performance is recognized through numerous customer awards and certification from independent rating organizations.

7.3 Financial and Market Outcomes

7.3a(1) Our extramural growth is a testament to competitiveness and customer engagement in a broad market with over 800 CROs worldwide. Figure 7.3–1 shows total funding from our two extramural market segments: federal and industry. As shown in Figure 7.2–8, our growth is from engaged customers.
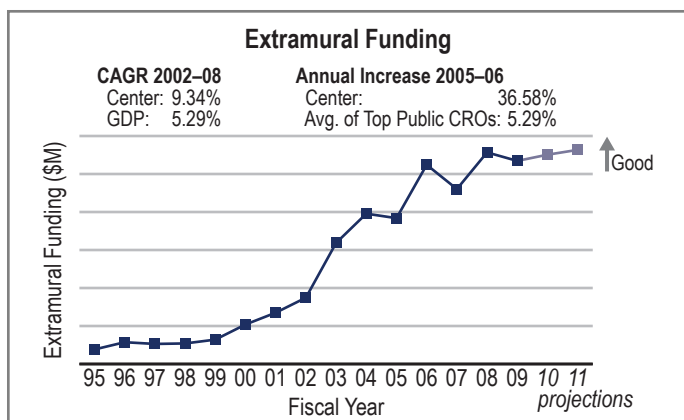
Figure 7.3–1 Our six-year compounded annual growth rate (CAGR) is almost twice the US economy as defined by Gross Domestic Product (GDP). (Source: Office of Management and Budget and Bureau of Economic Analysis for GDP data)

Figure 7.3–2 shows total budget growth. Our revenue mix of extramural and VACSP funding helps ensure the **financial viability** and **long-term sustainability of our organization**.

The Center's organizational productivity (Figure 7.3–3) provides **financial return** to our customers.

In 1995, we were mandated to support clinical trials outside VA on a fee-for-service basis to leverage VACSP funding. It is important to our VA market segment as a measure of financial return to the VA, and also increases our capabilities, experience and ability to deliver increased value to the VA (Figure 7.3–4). As of 2008, for every VA dollar received, the Center provided an additional cumulative average of $0.90 of healthcare value. In private sector terminology, this equates to a 90% return on investment to the American taxpayer, compared to a year-to-date return of -5% for the S&P 500, a major US stock market index.
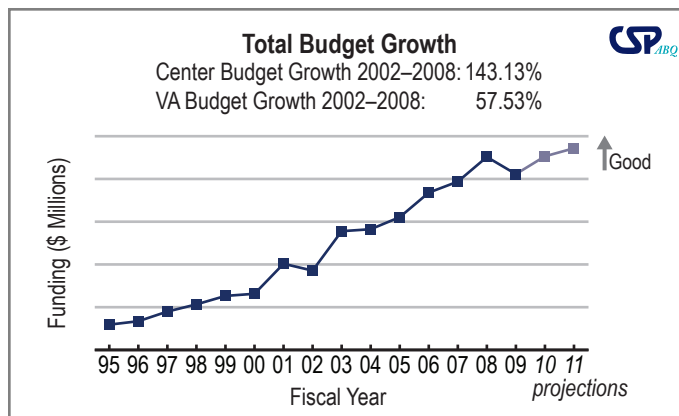
Figure 7.3–2 Budget growth is a key measure of Center success and sustainability. FY09 VA funding was impacted by a delay in the federal contracting process, which resulted in returned funding to be redistributed next year.
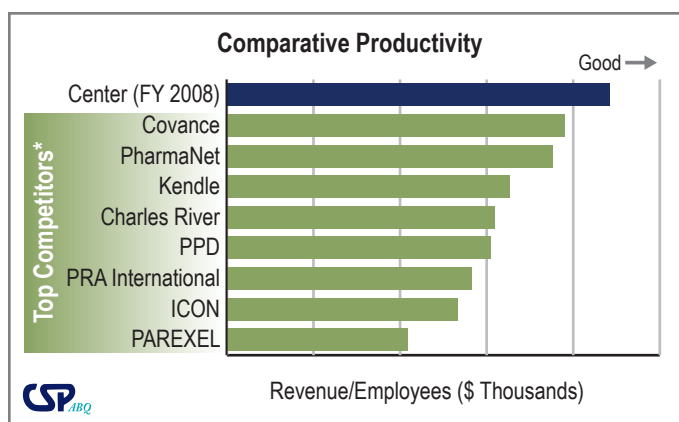
Figure 7.3–3 Our productivity is world class and distinguishes us in a competitive marketplace. Figure 7.4–8 shows trend data and projection. *Competitor data represent the last 12 months from their latest reported quarter. (Source: CenterWatch)
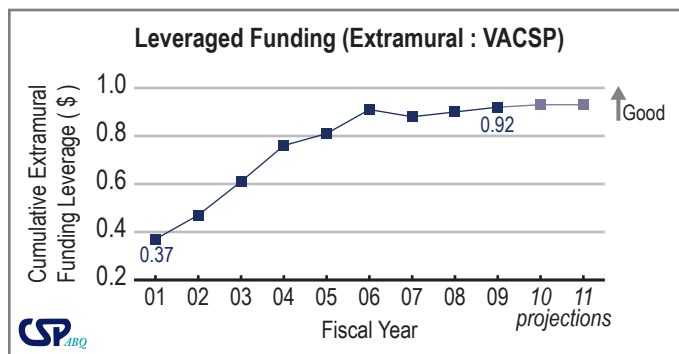
Figure 7.3–4 Our market-derived extramural funding leverages VA dollars. Values greater than zero represent a "bonus" to the VA and can be considered a rate of return on the VA investment.

Our **financial performance** as measured by performance to budget is shown in Figure 7.3–5.

Performance to Budget (%)								
FY02	03	04	05	06	07	08	09	*10 proj.*
99.96	99.83	100.00	100.00	99.99	99.98	99.99	99.99	*99.99*
05 Baldrige Winner* 90.00								CSP_{ABQ}

*Figure 7.3–5 As good stewards of VA funds, we are a benchmark for government agencies in performance to budget. *Richland College, only known published benchmark*

7.3a(2) Figure 7.3–6 shows six-year **growth** for the Center in a volatile **marketplace**. If the Center were publicly traded, our market share would represent approximately 0.24% of the CRO market in the US. Our strong customer relationships have increased our market growth, as measured by extramural funding. Manufacturing capabilities provide entry into new markets by adding capabilities desired by customers to allow us to conduct additional clinical trials.

To determine how we succeed in our **market share growth** in the federal market, we compare our non-VACSP federal funding, primarily from NIH, to NIH funding. Figure 7.3–7 represents our extramural funding compared to total NIH funding.

Extramural Market Growth 2002–2009
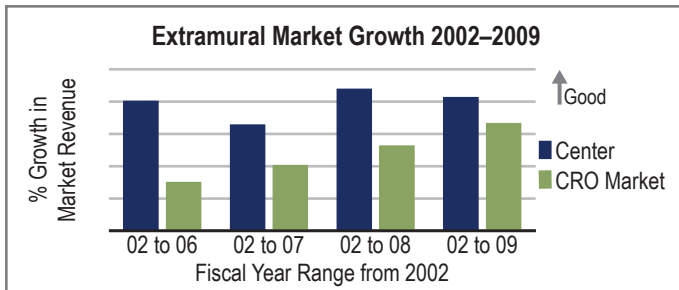
Figure 7.3–6 Increased market share is seen in our 206.25% extramural market growth rate since 2002, exceeding the industry growth rate for our competitors. Figure 7.3–1 shows trend data and projections. (Source: Frost and Sullivan)

Marketplace Performance:
NIH Trends Compared to Center Extramural Trends
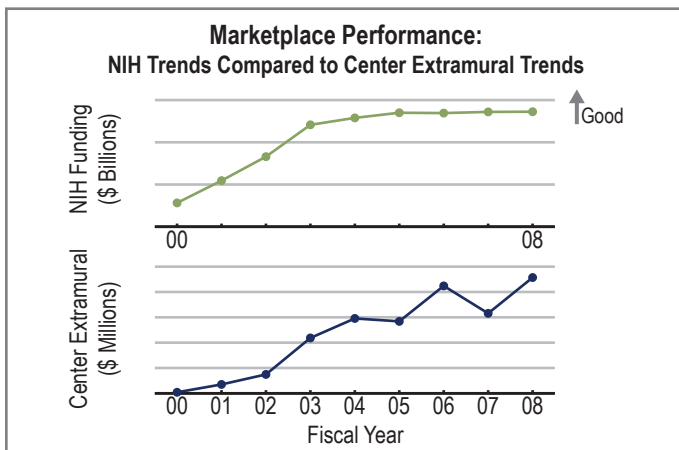
Figure 7.3–7 Our extramural funding growth tracks the funding growth of NIH and reflects the sustained market share of the Center with NIH. Fluctuations are due to the timing and funding of multi-year trials (Source: The NIH Almanac - Appropriations)

7.4 Workforce-Focused Outcomes

7.4a(1) The Gallup Q^{12} survey measures the aspects of **workforce engagement** that lead to positive business outcomes (Figure 7.4–1). Gallup has been administering the Q^{12} survey for over 15 years. Its research shows that engagement is a leading indicator of workforce **performance outcomes**. The most recent analysis included 681,799 employees in 23 countries and included 37 industries. Our target for all questions is to exceed the government and professional, scientific and technical services 75th percentiles, and our stretch goal is to exceed the Gallup overall 75th percentile. We segment data by divisions, education and tenure; however, there are no discernible differences in trends of segmented data. Data segmented by division is available on site. We base projections on a statistically significant increase each year, which Gallup defines as 0.1% for an organization our size.

Workforce Engagement: Gallup Q^{12} Grand Mean
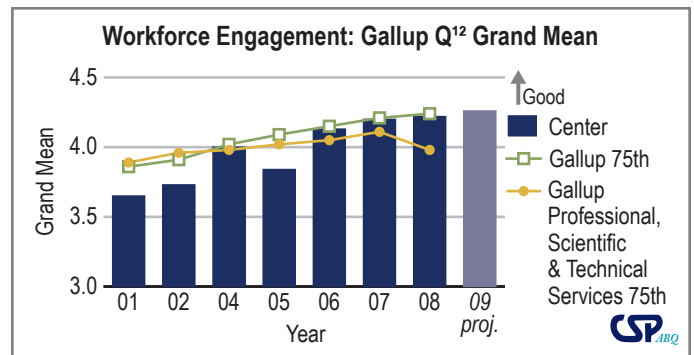
Figure 7.4–1 Our results over seven years have shown strong improvement.

Our **workforce satisfaction** is well above the Gallup 75th percentile (Figure 7.4–2).

Workforce Satisfaction: Gallup Q^{12} Q00
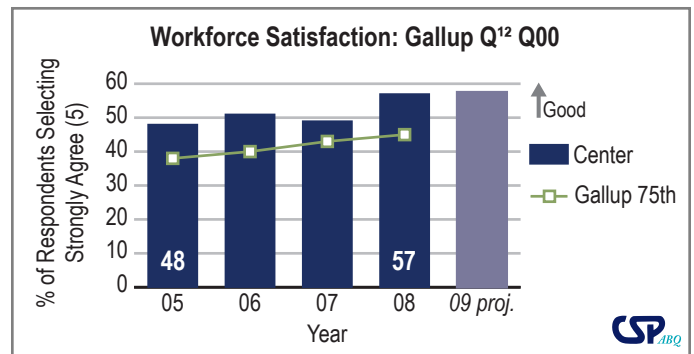
Figure 7.4–2 Gallup research shows that engagement is a leading indicator of workforce satisfaction, and we exceed the 75th percentile for all Gallup organizations.

Peer-to-peer recognition through the Employee Award and Recognition System (EARS), a best practice identified through QNM conference feedback, continues to increase (Figure 7.4–3).
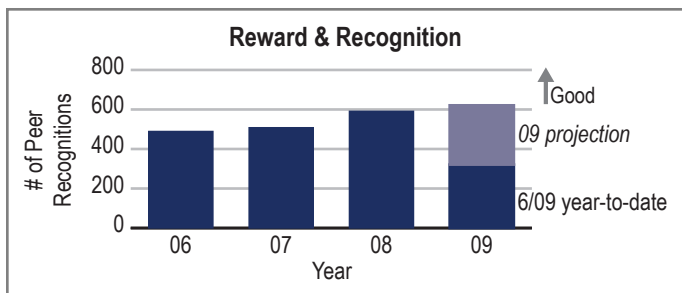
Figure 7.4–3 *The number of peer recognitions through EARS contributes to an environment for an engaged workforce.*

7.4a(2) Key measures of the **development** of the workforce include training investment and hours (Figures 7.4–4 and 7.4–5). ASTD Benchmark is an average of a broad cross section of 281 organizations. Selected through a rigorous review process, ASTD BEST award consists of 29 national and international companies (Source: ASTD 2007 State of the Industry Report).
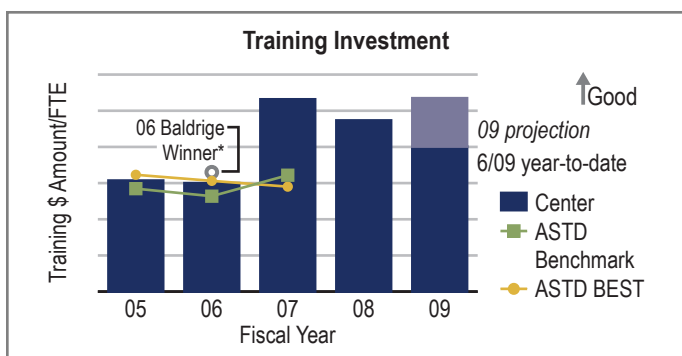
Figure 7.4–4 *Center training and development exceeds the ASTD industry benchmark. The spike in 2007 is due to increased dollars for ERP training. *MESA Products, Inc., is only known Baldrige benchmark.*
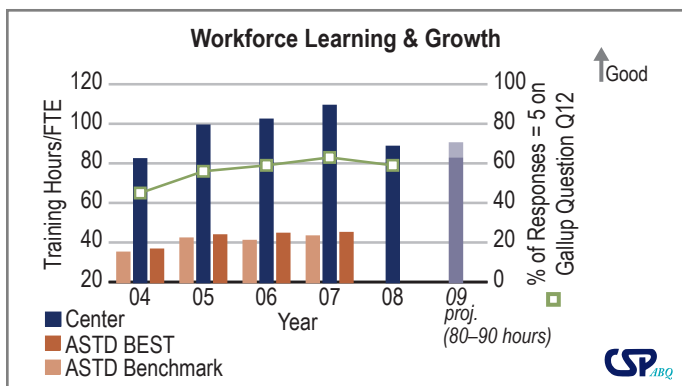
Figure 7.4–5 *Our workforce learning and growth shows that our significant training hour investment has led to a high percent of employees who are extremely satisfied with their opportunities to learn and grow (rating of 5 on Gallup question Q12).*

In 2008 we negotiated a separation of our training system with VA Medical Center Albuquerque. By doing so, we were able to decrease the amount of mandatory training that added no value to our work environment; thus, training hours decreased. As described in 5.1a(3), the Center outperforms all VA organizations in the Harvard Business School (HBS) Learning

Organization Perception results and exceeds the HBS top quartile in each area. Figure 7.4–6 presents key results; full survey results are available onsite.
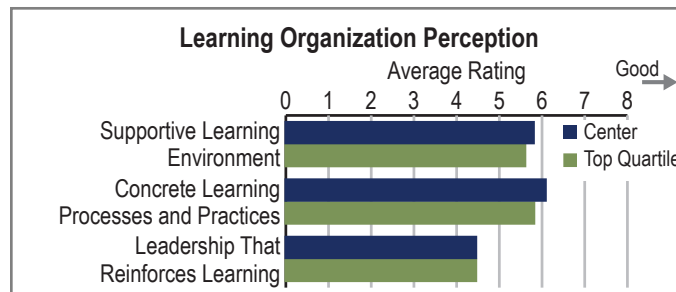
Figure 7.4–6 *The Center's strong performance across all three areas demonstrates a supportive environment for diversity, learning and innovation.*

The Leadership Effectiveness Index quantifies the effectiveness of the Leadership System from employees' perspective (Figure 7.4–7). Effective and systematic leadership is critical to the organization's ability to meet changing demands from customers and maintain an engaged workforce. By looking at the mean of questions Q6 through Q8 together, the Center has a high level view of overall effectiveness of our leadership processes.
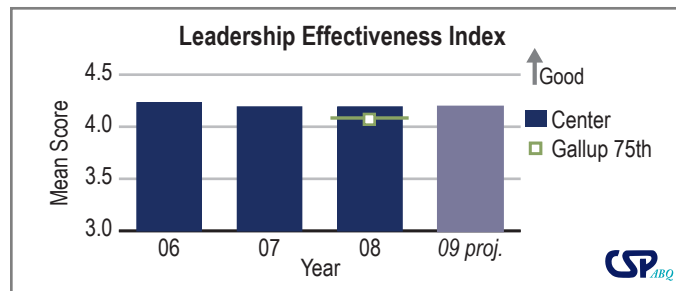
Figure 7.4–7 *High levels, stable trends and favorable comparisons to Gallup benchmarks of the Leadership Effectiveness Index captures the overall development of both workforce and leaders. Gallup has released a benchmark for 2008 only.*

7.4a(3) Key measures of work system performance are capability and capacity. **Productivity** is a measure of **capability** and is a direct result of work system design. It is measured by revenue per employee (Figure 7.4–8).

Our growth allows us to develop upward mobility within positions without becoming top-heavy, contributing to organizational learning, succession planning and **capability**, as measured by grade increases (Figure 7.4–9).

[Details removed (Figure 7.4–10)]

Stability of our staff reflects employee satisfaction. Although we experience some variability in our turnover rate over time, we remain well under US, industry, Baldrige and VA Carey averages (Figure 7.4–11).
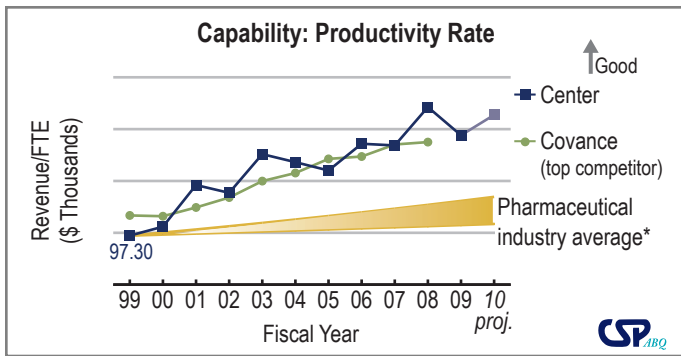
Figure 7.4–8 *Our productivity rate is world class, as shown over time in comparison to Covance, our top competitor. Although revenue is down slightly (Figure 7.3–2 caption), we have added staff to prepare for two large upcoming trials. Figure 7.3–3 shows additional competitive data. *Pharmaceutical industry average annual productivity improvement range (Source: FDA Gold Sheet, January 2009)*
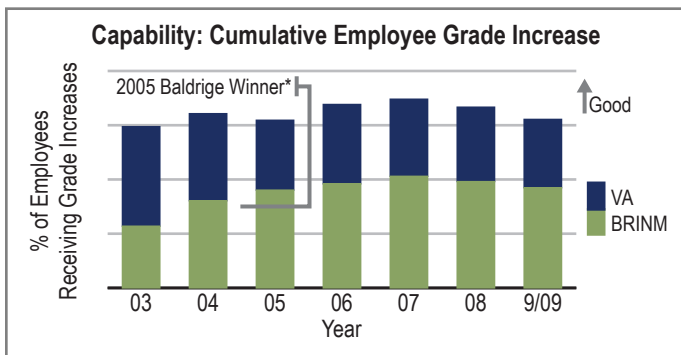
Figure 7.4–9 *Grade increases are twice the nearest known benchmark and reflect capability. Both VA and BRINM segments have similar rates, demonstrating our seamless organization. The overall trend is down slightly due to the number of new employees who are not yet eligible for a grade increase. *Internal promotions as percent of new hires (Park Place Lexus, only known benchmark)*

Figure 7.4–10 *Workforce Capacity*
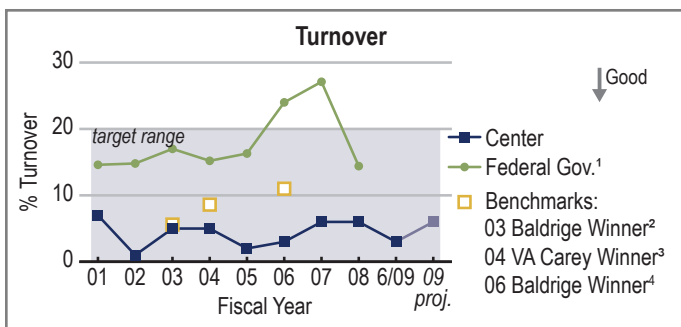
Figure 7.4–11 *We consistently outperform the federal government in turnover rate and currently exceed all other known benchmarks. [1]US Department of Labor, Bureau of Labor Statistics, [2]Medrad, which manufactures medical devices, serves as an appropriate comparator, [3]White River Junction VA Medical Center and [4]North Mississippi Medical Center*

7.4a(4) Key measures of **workforce climate** include Gallup

survey results (Figures 7.4–1 and 7.4–2) and grievances. We have an extremely low rate of employee grievances (Figure 7.4–12). Projection is based on past performance and goal.
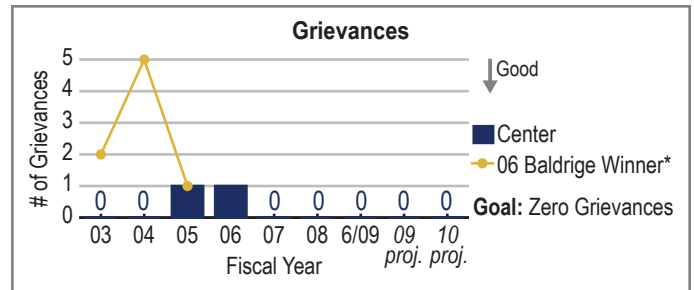
Figure 7.4–12 *High employee satisfaction and engagement contribute to low employee grievances.*North Mississippi Medical Center has a similar work environment and therefore is a reasonable benchmark for this measure for our organization.*

Just as patient safety is paramount in our trials, **workforce health and safety** is an important leadership responsibility. We strive to create a safe workplace for every employee. In 2005 we had our first lost time incident in five years (Figure 7.4–13).
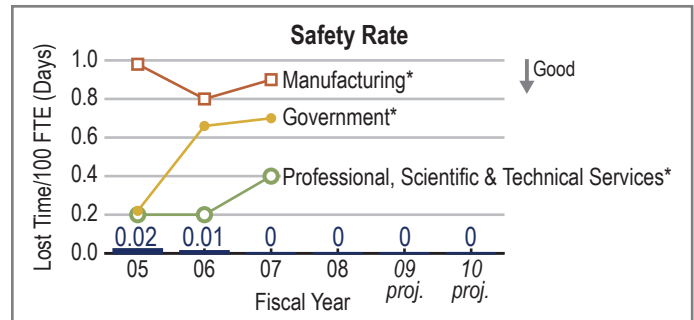
Figure 7.4–13 *Our robust safety practices netted zero lost time injuries in 2007 and 2008. Our results remain greatly below NM industry sectors in which we are reported (*NM Workers' Compensation, 2007; 2008 not yet available).*

An important **benefit** to our employees is tuition reimbursement (Figure. 7.4–14), which contributes to workforce engagement, development and capability.
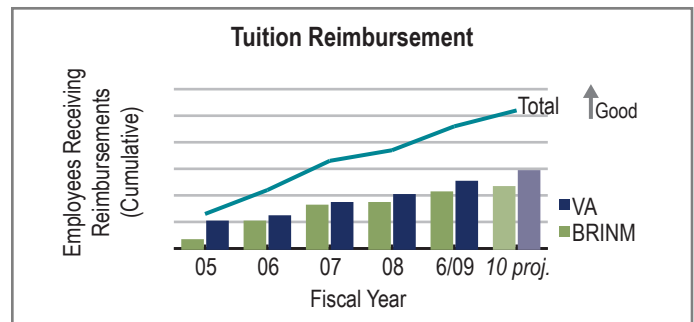
Figure 7.4–14 *Tuition reimbursement trends are increasing for both VA and BRINM segments of our workforce.*

7.5 Process Effectiveness Outcomes

7.5a(1) Matrix management (Figure 5.1–1) is our key work system. The **performance** of the matrix management system is productivity, customer satisfaction and total budget growth (Figure 7.5–1).

Measure	Productivity	Customer Satisfaction	Total Budget Growth
Levels	Figure 7.3–3	Item 7.2	Figure 7.3–2
Trends	Figure 7.4–8 Upward trend	Sustained, superior results	Upward trend
Comparisons	Industry competitors	Industry competitors, Baldrige, ACSI	Industry competitors, GDP, VA, NIH
Integration	Health Indicator & Success Factor	Health Indicator	Health Indicator

Figure 7.5–1 Work system performance is world class.

We have numerous processes to ensure **workplace** preparedness for disasters and emergencies. Figure 7.5–2 lists key processes and results. While readiness activities are business specific, we are able to benchmark common activities with a prior Baldrige winner on the Continuity of Operations Plan (COOP), information security training and building emergency drills.

The Gallup survey began measuring **innovation** in 2006 through a grouping of questions C09 through C13 (Figure 7.5–3). The slight decrease in 2008 was due to lower ratings on employees' "time to innovate," which was due to increased workload based on an overlap of trials in startup. We added staff to increase capability and project our 2009 innovation index score to return to its previous high level.

Figures 7.1–2 and 7.1–3 show internal and external ISO audit results. Figure 7.6–6 reports all external audit findings.

Figure 7.5–3 Our innovation process (Figure 6.2–1) results in levels and trends in innovation among the best in the US, according to our Gallup results briefing in March 2008.

7.5a(2) Our key processes and indicators of performance are shown in Figure 7.5–4.

Key Work Processes	Key Indicators of Operational Performance (Figure)
Pharmaceutical Study Design	Zero Defects (7.1–1)* Operational/Scientific Integrity: ISO Audits (7.1–2 & 7.1–3)* On-Time Delivery (7.1–5 & 7.1–6)* Responsiveness (7.1–7 & 7.1–8)*
Project Management	On-Time Delivery (7.1–5 & 7.1–6)* Productivity (7.3–3 & 7.4–8)* Performance to Budget (7.3–5)* Budget Cycle Time (7.5–14)
Safety & Regulatory Compliance	Operational/Scientific Integrity: GCP Training (7.1–4)* RACC Cycle Time (7.5–5)*
Drug Production & Shipping/Distribution	Manufacturing Quality (7.5–6)* Packaging Quality (7.5–7)* Active/Placebo Identification Quality (7.5–8)* Shipped Drug Quality (7.5–9)*

*Figure 7.5–4 Key indicators of work processes provide valuable information to assess effectiveness and efficiency. *Measures include 2009 projections of future performance.*

Readiness Activities	2005	2006	2007	2008	Projection	07 Baldrige Winner
Emergency Operations Plan (EOP)	Section-Level Plans	Draft	Yes	Yes	Integrate COOP	Yes
Continuity of Operations Plan (COOP)	No	1st Draft	3rd Draft	Yes	Integrate with EOP	NA
Information Security Training	95%	98%	100%	100%	100%	100%
Emergency Power Generator Testing	100% weekly	100% weekly + annual load test	100% weekly + annual load test	100% weekly + annual load test	100% weekly + annual load test	NA
Pandemic Flu Plan	No	No	Draft	Yes	Integrate with EOP	NA
Emergency Communications Call-in Line	Yes	Yes	Yes	Yes	Yes	NA
Telephone Recall Exercises	0	2	4	2	2	NA
Building Emergency Drills	75%	100%	100%	100%	100%	Yes
Overall Compliance Metric	< 75	< 90	> 90	> 90	> 90	NA

Figure 7.5–2 We are continually integrating and improving our preparedness for emergencies through planning, training and exercises. The Baldrige winner, ARDEC, is also a research organization in the not-for-profit category.

We added Regulatory and Clinical Compliance (RACC) to provide safety and regulatory activities. To meet our strategic challenge (C4) to improve new processes and capabilities quickly while maintaining quality and safety, we measure and improve **cycle time** (Figure 7.5–5). As RACC services are unique to the Center, we compare ourselves to past performance. Projection is based on linear trend.

RACC Cycle Time vs. Workload
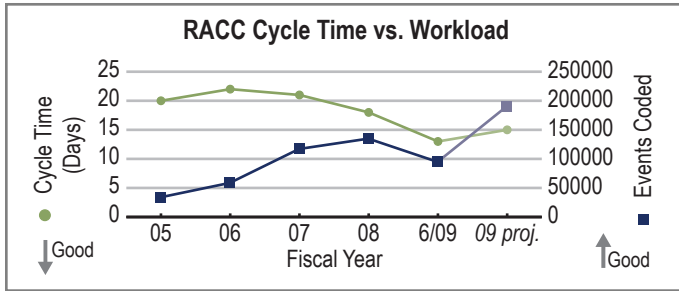
Figure 7.5–5 RACC cycle time has decreased significantly even while workload has increased.

Quality of production processes is our key measure of **process effectiveness**, as shown in Figures 7.5–6 through 7.5–9. In the absence of other benchmarks, we adopt six sigma (3.4 ppm) as our gold standard. We do not expend resources searching for benchmarks for processes that have achieved sustained zero-defect results. Projections are based on estimated future workload for upcoming trial kickoffs.

Manufacturing Quality
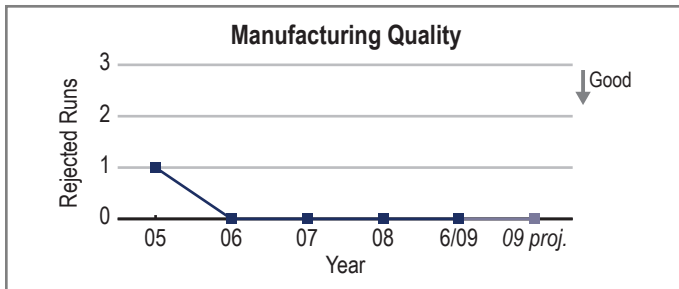
Figure 7.5–6 Having achieved zero defects for more than three consecutive years, we are the industry benchmark and do not spend resources to seek additional benchmarks. We detect errors through in-process measures (Figure 7.5–10) before defects occur.
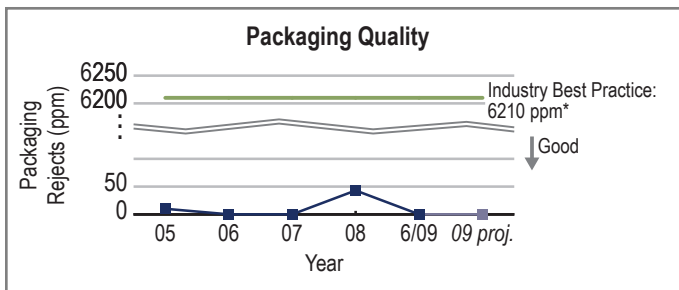
Packaging Quality

*Figure 7.5–7 We have achieved industry leadership in packaging quality. *Honeywell uses four sigma standards (6210 ppm) as a benchmark and goal for packaging.*

Active/Placebo Identification Quality
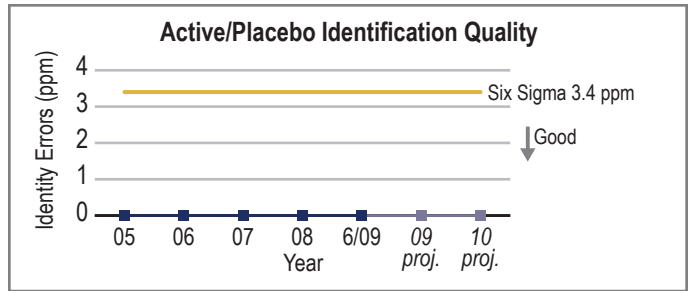
Figure 7.5–8 We have never had a defect in drug identity in the history of the laboratory, making it an industry benchmark.

Shipped Drug Quality
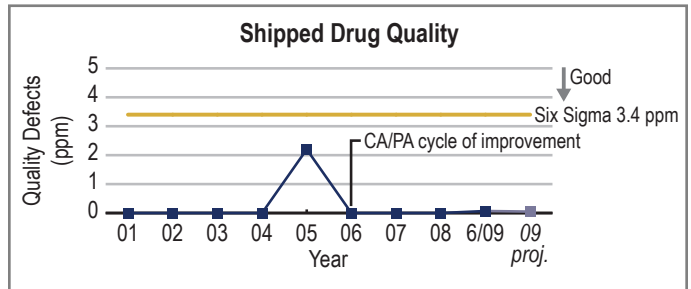
Figure 7.5–9 Rigorous analysis and correction of an in-process quality defect has returned us to a leadership position in the quality of shipped drug.

In addition to tracking quality and capacity, we also track in-process nonconformances as leading indicators of process performance. Shipping, labeling and manufacturing nonconformances are shown in Figure 7.5–10.

Discrepancies, Nonconformances & Customer Complaints
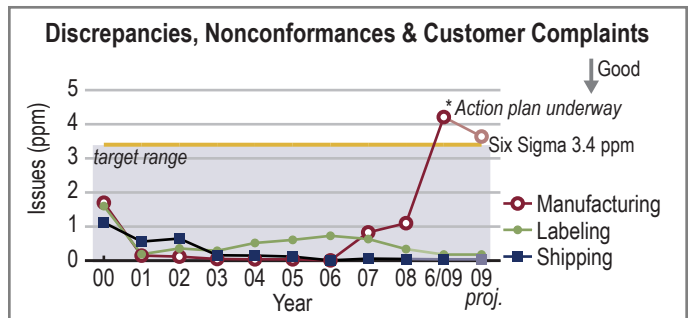
*Figure 7.5–10 Extremely low discrepancies and nonconformances help achieve zero defects in delivered products. *Manufacturing results for 6/09 include three non-validated customer complaints. We are attempting to retrieve bottles from the sites to validate the issues and perform root-cause analysis.*

Results from our laboratory testing are world class. Laboratory precision is measured by variation from the national standard mean (Figure 7.5–11). Smaller standard deviations are better and denote a more precise testing process. We have continuously exceeded the industry standard.
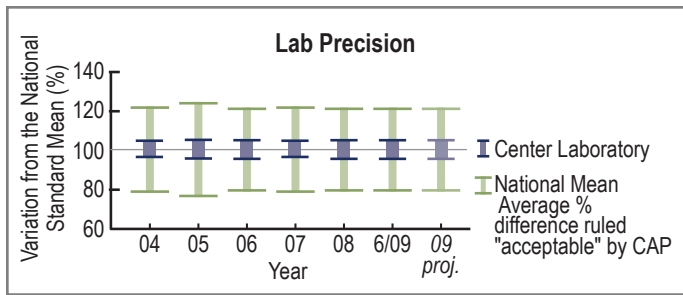
Figure 7.5–11 *Process control is a Center strength, and our laboratory variation is three times better than our accreditation agency mean. Relative Standard Deviation (RSD) is an accepted measure of process variability.*

As our performance improvement system (Figure P.2–2) matures, preventive and improvement actions as a percent of all actions are increasing (Figure 7.5–12).
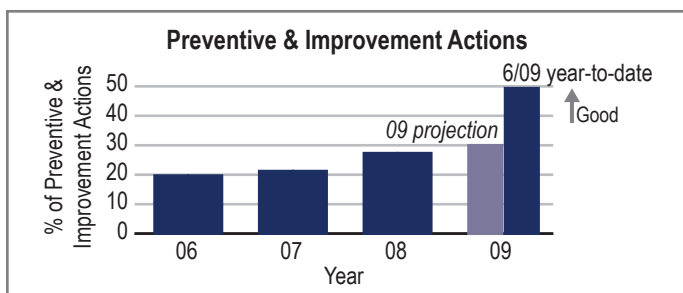
Figure 7.5–12 *Increasing preventive and improvement actions demonstrate process effectiveness, efficiency and innovation as we move from merely correcting deficiencies to proactively preventing problems and implementing continuous improvement.*

Another measure of **process effectiveness** is our internal customer satisfaction survey results from employees (Figure 7.5–13). Results segmented by division are available onsite.
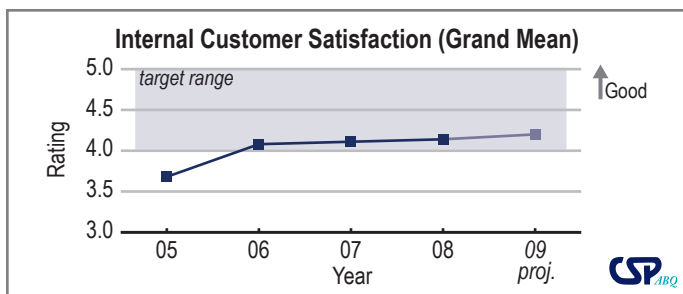
Figure 7.5–13 *Satisfaction surveys for internal processes provide feedback for improvement and continual improvement.*

Finally, an important measure of project management is on-time delivery (Figures 7.1–5 and 7.1–6) and quick preparation of budgets to meet customer demands. As described in 6.2c, we launched a Lean Six Sigma initiative to improve and integrate the budget development process. As a result, we improved the process and reduced budget **cycle time** as shown in 7.5–14. We obtained the benchmark from Daiichi Sankyo, a drug company, through our association with the Midwest Clinical Supply Group.

Average Internal Budget Development Cycle Time (Days)		
	July 08	April 09
Center Project Internal Cycle Time	11.50	9.06
Industry Benchmark (Daiichi Sankyo)	14.00	

Figure 7.5–14 *Already well below an industry benchmark, the Center has reduced internal budget cycle time by an additional 21% through the use of Lean Six Sigma techniques.*

7.6 Leadership Outcomes

7.6a(1) CEC reviews our health indicators as key measures for accomplishment of **organization strategy** (Figure 7.6–1).

In addition, performance measures for each action plan are reviewed. Example of accomplishment of action plans is the ERP implementation (Figure 7.6–2). ERP implementation causes a shift from functional-only processes to integrated processes. Enhancement occurs through automation and accessibility of data. Tracking new and enhanced processes is an indicator of standardization needed to "operationalize" an integrated system. Additional action plan measures are available onsite.

Success of organizational strategy is reflected in the significant milestones and achievements in our quality journey as measured by estimated Baldrige-based application and site visit scores (Figure 7.6–3). We have achieved the highest level of award in our state and within the VA. We have been ISO certified since 2003, and our internal audit process, in which over 50 percent of our employees are trained as internal auditors, was cited as an ISO best practice.

CSPₐᵦ𝑞 Health Indicators

Customers	Financial
Strategic Goal: Develop and maintain mutually beneficial customer relationships **Health Indicators (Figure)** ▪ Customer Satisfaction (7.2–1 & 7.2–2) ▪ Customer Complaints (7.2–3) ▪ Customer Engagement (7.2–8)	**Strategic Goal:** Increase funding **Health Indicators (Figure)** ▪ Total Budget Growth (7.3–2) ▪ Leveraged Funding (7.3–4) ▪ Performance to Budget (7.3–5)
Processes	**Employees**
Strategic Goal: Increase capability and productivity **Health Indicators (Figure)** ▪ Productivity ($/Employee) (7.3–3 & 7.4–8) ▪ Adequate Clinical Supplies at Sites (7.1–5) ▪ Internal Customer Satisfaction (7.5–13)	**Strategic Goal:** Develop engaged workforce **Health Indicators (Figure)** ▪ Workforce Engagement: Gallup Q^{12} Grand Mean (7.4–1) ▪ Workforce Satisfaction: Gallup Q^{12} Q00 (7.4–2) ▪ Workforce Learning & Growth (7.4–5) ▪ Leadership Effectiveness Index (7.4–7)

Figure 7.6–1 *The Center's health indicators represent a balanced scorecard of measures that CEC reviews.*

ERP Progress: Cross-Functional Process Development
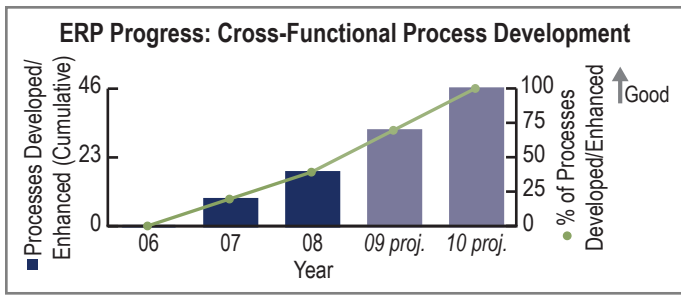
Figure 7.6–2 As a key strategic project plan to meet our strategic goal to increase capability and productivity (G3), ERP implementation increases efficiency and reduces redundancy through integrated processes.

Estimated Baldrige-Based Scores
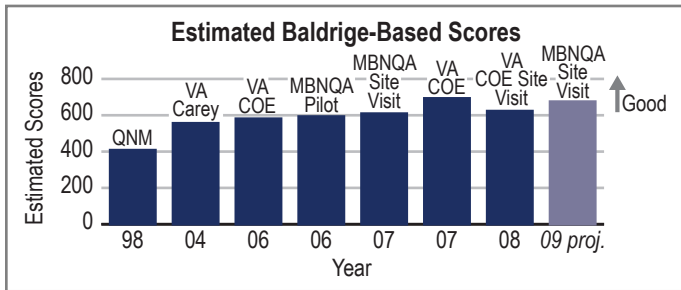
Figure 7.6–3 We use the Baldrige process as a continuous organizational performance improvement system.

We measure the effectiveness of our leadership system and interlocking committee structure through internal and external audits of the Management Review policy stated in the Center Quality Manual. Results are shown in Figure 7.6–4.

Management Review Audit Findings
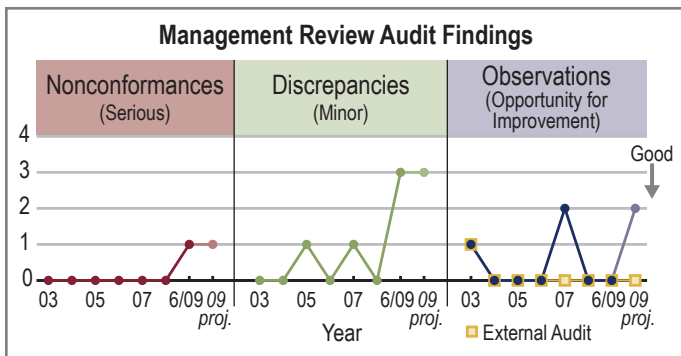
Figure 7.6–4 Management review audits measure the effectiveness of our leadership system. While internal audits have noted one nonconformance and three discrepancies, third-party external audits have found only one observation since 2003.

7.6a(2) Figure 7.3–5 reflects our performance to budget with our VA-provided funding, a key measure of fiscal accountability in government. Few government entities achieve 100% performance to budget. We had a VA financial audit in 2006 with no findings.

7.6a(3) Our key results for regulatory/legal compliance are adherence to VA, FDA and DEA regulations. We have had four FDA audits with no serious findings (Figure 7.6–5). The Center received exemplary comments from an external audit conducted by Merck in 2001 as setting "best practices for cGMP."

FDA Audit Findings		
Organization	Nonconformances (Serious)	Period
Center	0 per Audit	1992–2008
03 Baldrige Winner*	3 per Audit	1992–2005

*Figure 7.6–5 The Center's exemplary compliance record with FDA supports our strategic advantage of being an FDA-registered cGMP facility. *Medrad*

Figure 7.6–6 reflects serious findings, minor findings and observations for all types of quality audits (except ISO) by sponsors and federal agencies since 2003. Observations require no formal response.

External Audit Findings
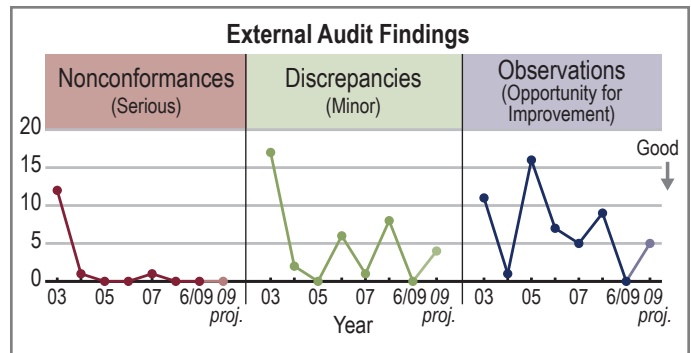
Figure 7.6–6 External audits demonstrate the Center's compliance to regulatory standards.

7.6a(4) Ethical behavior and stakeholder trust results include ethics surveys and training; ethical behavior as measured by cybersecurity, government credit card and travel reimbursement behaviors; our key customers' perception of our knowledge; and contributions to publishing manuscripts of study results (Figures 7.6–7 through 7.6–10). In 2005 we formally launched *Cowboy Ethics* (©2004 James P. Owen) described in Items 1.1 and 1.2. We measure ethical behavior through a series of questions grouped by the Center's core values of leadership, customer service, safety, teamwork and continuous learning (Figure 7.6–7).

One hundred percent of pharmacists have completed required training, and overall, 87% of employees have completed additional ethics training (not mandated by VA).

Ethical Behavior Pilot Survey
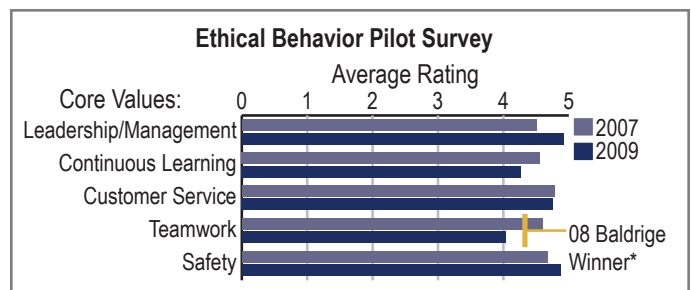
*Figure 7.6–7 Our Center director receives high marks from subordinates and sets the tone for ethical behavior throughout the organization. *Poudre Valley Health Systems*

We monitor many areas of ethics associated with operations at the Center. Cybersecurity training and audits have recent-

ly been a focus, as well as ongoing areas such as government credit card and travel vouchers. Breaches of ethical behavior are shown in Figure 7.6–8.

Governance/ Ethical Area	Control System	04	05	06	07	08	9/09	09 proj.
Cybersecurity	Section audits	NA	NA	7	12	16	17	17
	Findings	NA	NA	0	0	0	0	0
Government Credit Card	Audits	NA	4	4	5	4	4	4
	Findings	NA	0	0	0	0	0	0
Credit Card Benchmark*	Findings	0	0	1	2			
Travel Vouchers	Audits	190	201	254	263	350	317	368
	Findings	0	2	0	0	0	0	0

Figure 7.6–8 *Proactive leadership and consistent training support excellent ethical behavior. *ARDEC, 2007 Baldrige winner*

A key measure of trust is customer satisfaction with our healthcare professionals. Unlike our competitors, clinical research pharmacists and pharmaceutical project managers deal directly with investigators and site personnel. Their satisfaction with our knowledge is a key measure of trust (Figure 7.6–9).
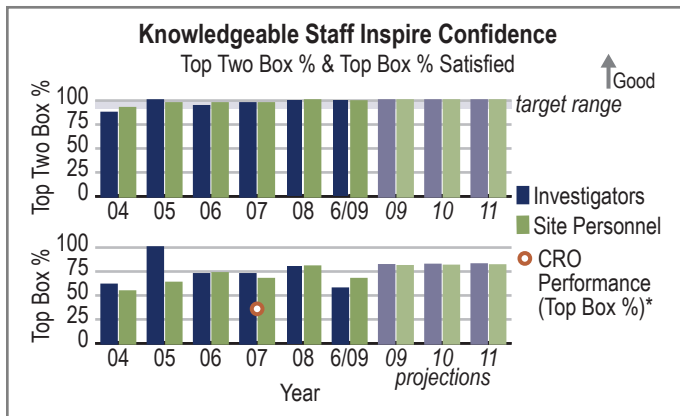
Figure 7.6–9 *Key customer groups are delighted with our knowledge, reflecting the value they place on our core competency of pharmaceutical expertise.*

We believe that our excellent record of engaged customers (Figure 7.2–8) is a bottom-line indicator of high levels of trust in our ability to ethically and legally design and conduct trials.

7.6a(5) Center leaders and employees participate in community citizenship activities that are aligned with our mission and values and meet stakeholder needs. We fulfill our **societal responsibilities** in many ways, most broadly through the health outcomes of the trials that we support, which contribute to the practice of medicine. To impact the practice of medicine, trial results must be presented and published. Figure 7.6–10 shows our contributions to publications, presentations and other forums.
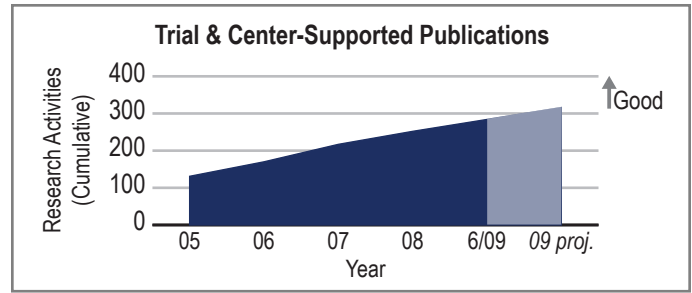
Figure 7.6–10 *By participating in publishing trial results and making presentations in many forms, we contribute to the entire body of knowledge in healthcare science.*

The Center also supports key communities through Project Share and holiday donations for veterans; teaching positions at UNM College of Pharmacy and numerous intern and fellowship programs; and serving as quality program judges, board members and examiners locally and nationally. Figure 7.6–11 shows the percent of employees who have volunteered as examiners for state, VA and national quality award programs.

We directly support our local community by donating time and money (Figure 7.6–12) to many charitable activities. In our small organization, we champion common causes, such as blood drives and Project Share, but we do not formally track employee hours or number of participants. The increase in 2006 was the result of a decision to transfer excess funds raised for another purpose to Project Share.
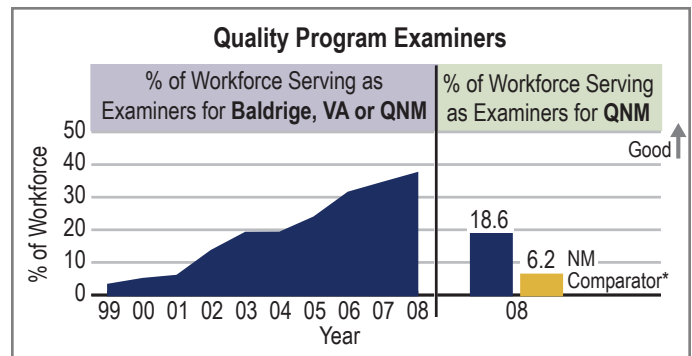
Figure 7.6–11 *Employees throughout the organizational have volunteered to serve as examiners. *Gila Regional Medical Center, selected due to its recognition from Quality New Mexico for the number of examiners the organization has provided.*
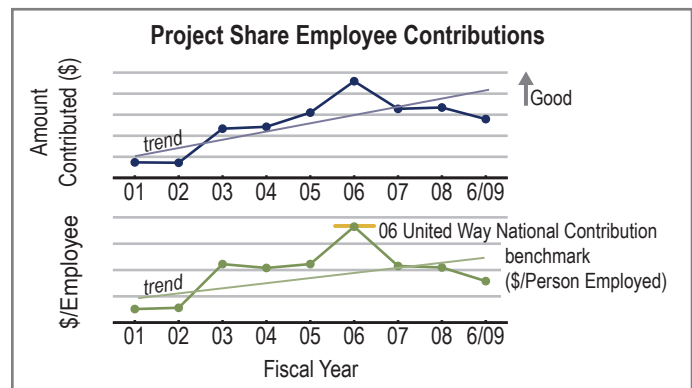
Figure 7.6–12 *Center employees are generous in contributing to local causes.*

Figure List