National Institutes of Health
Warren Grant Magnuson Clinical Center

Strategic and Annual Operating Plan 2003

"There's no other hospital like it!"

Message from the Clinical Center Director

The Clinical Center (CC) supports research that creates new visions for clinical health care and prevention. As most hospitals around the country must deal with what is needed today, the CC is in the unique position of being able to help create a new future in medicine. Accelerating social, technological, and economic trends make it very difficult to forecast the future. In fact, the speed of change has become so fast that our planning activities must also focus on what we must sustain such as the need for cutting-edge technology, flexible access to resources for innovative clinical research, quality patient care, and competent, decisive employees willing to take responsibility. Our challenge is to create innovative management strategies for sustaining these core activities.

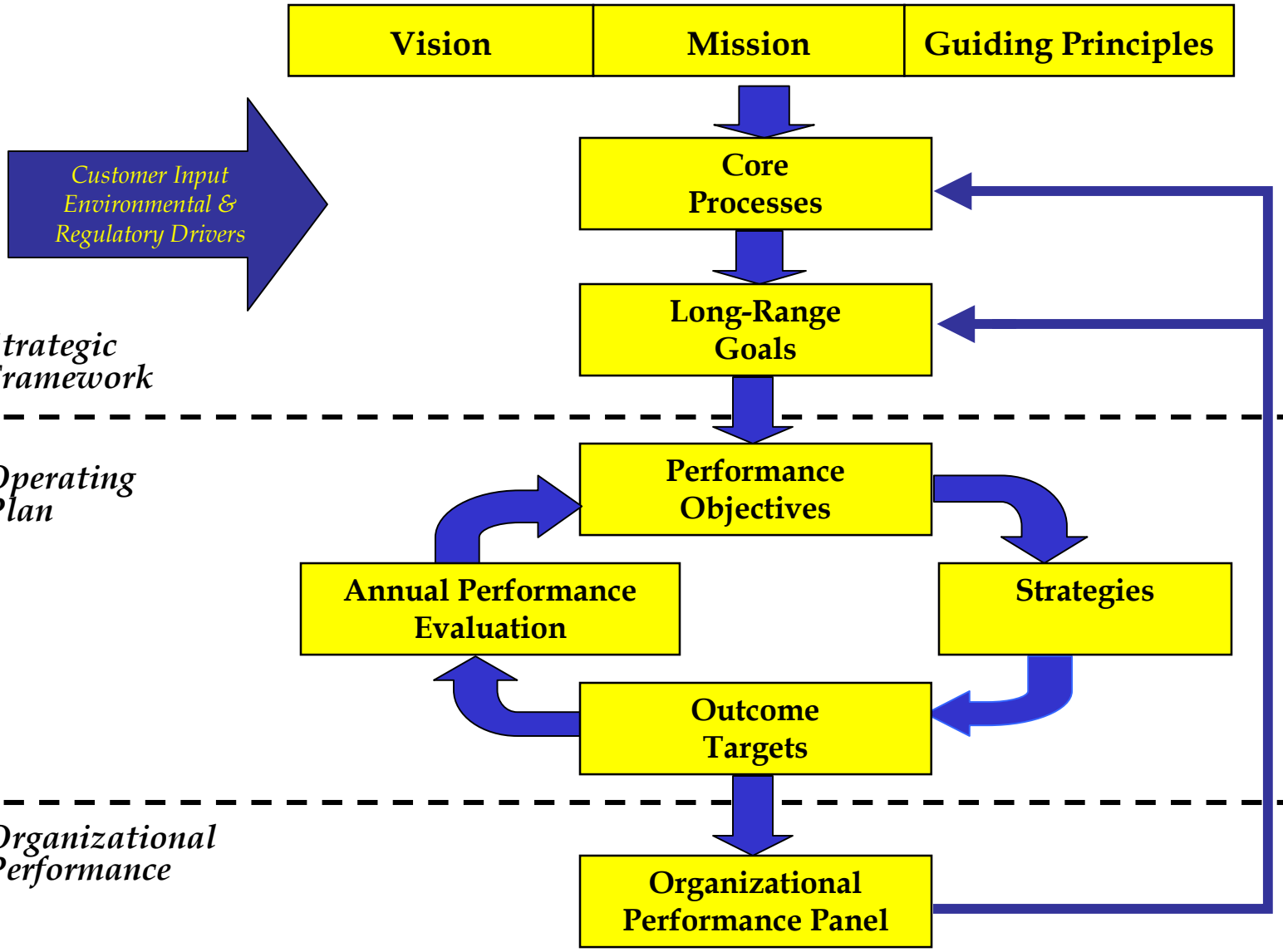
The CC infrastructure creates opportunity for unprecedented collaboration in areas of clinical research that only a few decades ago were seen as separate domains. The centralized physical location of the CC provides multiple Institutes with the resources to collaborate in revolutionizing both national research methods and health outcomes.

The goals established in the 2003 CC Strategic and Annual Operating Plan represent the highest priority issues facing the CC and provide the framework for guiding our work. These goals are particularly critical as we prepare for the 2004 move into the new Clinical Research Center (CRC). Coinciding with this effort is our alignment in supporting the goals of the new NIH director, Dr. Elias Zerhouni. Dr. Zerhouni is leading the NIH through the creation of a "road map" for the future which will identify the most compelling initiatives that the NIH should pursue over the next three to five years. Strategic planning is an ongoing process. We will continually reassess our goals and strategies and update our plan to ensure that our focus remains relevant, timely, and responsive to the priorities facing the Institutes and consequently, the Clinical Center.

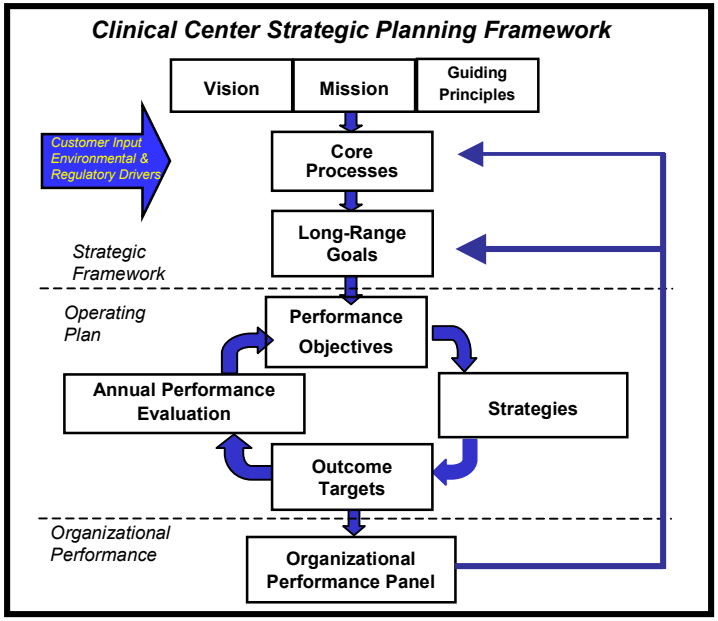
We strive to create a challenging environment for dedicated employees. As the new year begins, the implementation of the CC 2003 Strategic and Annual Operating Plan depends on everyone to support its success. Compassion, mutual respect, and trust are as necessary as ever. I ask that all employees implement this plan with those values in mind.

John I. Gallin, M.D.

Clinical Center
Strategic Planning Framework



Clinical Center Customers/Stakeholders



Customers/ Stakeholders

Customers/Stakeholders are internal or external groups of individuals who can directly affect us or who are affected by us.

Analyzing customer/stakeholder expectations will allow us to answer the questions:

- *To whom are we accountable?*
- *Do we understand the requirements for our different customers?*
- *Who has an interest in what we do or in a particular issue and its outcome?*
- *Who can influence us?*
- *Are there any "non-obvious" customers/stakeholders who can limit our options or change our plans?*

Clinical Center Customers/Stakeholders:

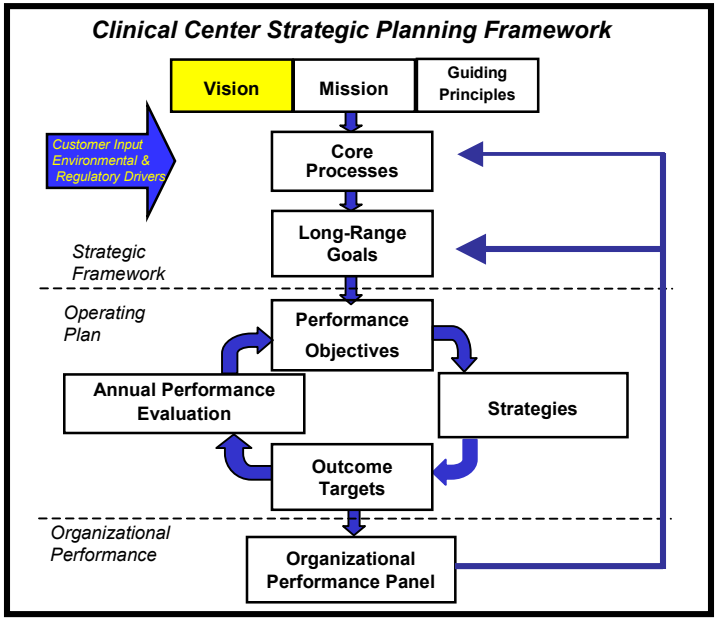
Primary Customers

- *Institutes*
- *Patients*

Other Key Customers/Stakeholders

- *Employees*
- *Referring Physicians*
- *NIH Administration*
- *Extramural Investigators and Collaborators*
- *DHHS*
- *Congress*
- *the Public*

Clinical Center Vision Statement

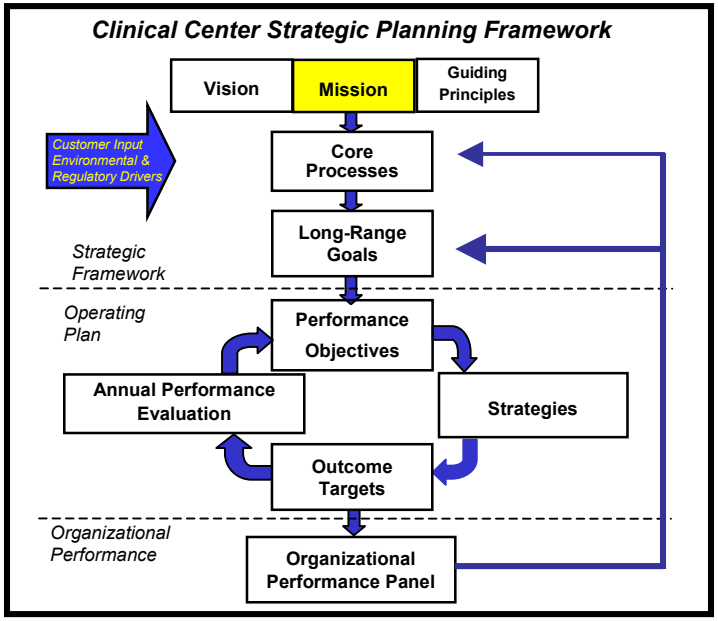


A Vision Statement:

- *answers the question: "What do we strive to be?"*
- *is influenced by our understanding of the environment in which we operate, the needs of our customers/stakeholders, and the values we want to uphold.*

The NIH Clinical Center will serve as a premier center for clinical research. A model of collaborative excellence, the NIH Clinical Center will lead in the design, conduct, training, and impact of clinical research.

Clinical Center Mission Statement

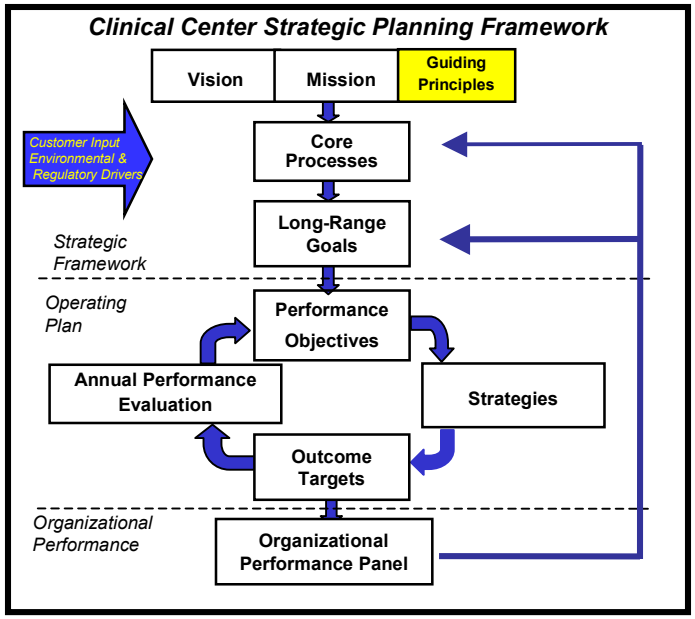


A Mission Statement:

- *answers the question: "What is our fundamental purpose?"*
- *is a way of expressing what programs and services we wish to provide, taking into account our resource capabilities.*

The NIH Clinical Center is the clinical research facility of the National Institutes of Health. It provides patient care, services, training and the environment in which NIH clinician-scientists creatively and ethically translate emerging knowledge to improve the detection, treatment and prevention of human diseases for the health of a diverse nation.

Clinical Center Guiding Principles

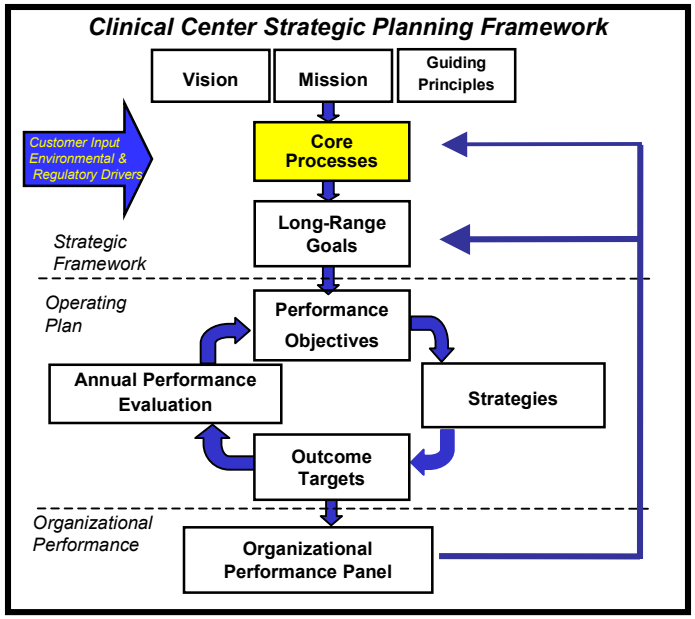


Guiding Principles:

- *answers the question: "What values will we uphold as we strive toward our vision?"*

- ***Integrity-***
  We have a social responsibility to improve the health of future generations. Guided by fundamental ethical principles and in compliance with related laws and regulations, we work with integrity in the pursuit of scientific knowledge.
- ***Security-***
  We are committed to doing everything possible to ensure the security of the Clinical Center. We work proactively with our patients, employees, and NIH security officials to define needs and maintain a secure environment.
- ***Respect-***
  Our patients and our workforce are our greatest resources. We are committed to a patient-centered research environment and workforce culture built on respect for diversity, trust, communication, and institutional teamwork.
- ***Quality-***
  We accomplish our objectives by using our resources to continually ensure the highest value for our customers/ stakeholders. The strategic planning process directs available resources to achieve the strategic goals in the most cost efficient and effective manner. We collaborate within the CC, across Institutes, and with our patients to deliver the highest quality results.

Clinical Center Core Processes



Core Processes:

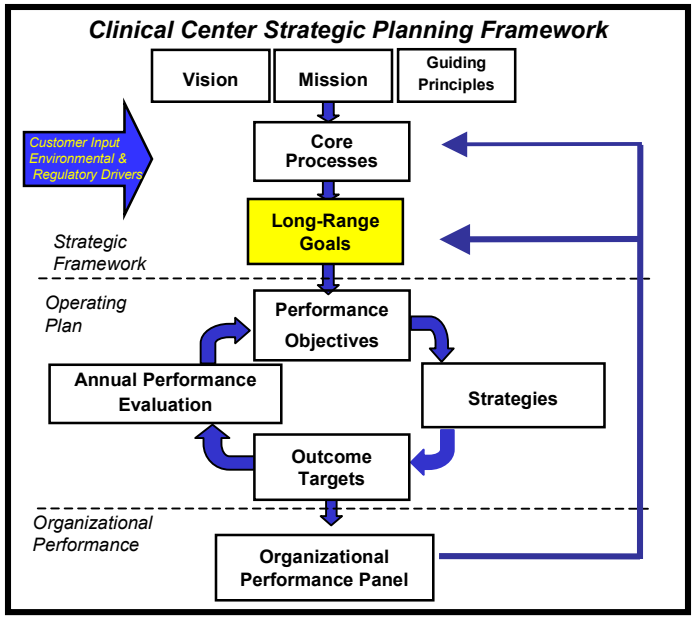
- *are the key elements designed to meet our mission and vision. They are linked activities that generate our primary products and services for Clinical Center customers.*

Clinical Research Support:
Provision of staff, services, and products that support clinical research

Patient Care:
Provision of the best available patient care to participants in clinical research studies

Operational Management:
Provision of resources such as personnel, budget and capital equipment in the most cost effective and efficient manner

Clinical Center Long-Range Goals



Long-Range Goals:

- *define the strategic direction of the organization by bridging the vision, mission and core processes with action plans and defined end-outcomes.*

- *Sustain and improve the safest, highest quality environment for conducting clinical research.*
- *Enhance organizational performance in response to customer needs with the highest degree of cost effectiveness and efficiency.*
- *Create state-of-the-art information management practices.*

Developing the CC Operating Plan - Institute Input

Institute Planning Process

Every fall the CC Director completes a series of planning meetings with individual Institutes. Attendees include: Clinical Directors, Scientific Directors, Institute Directors, and Clinical Center senior administrative and clinical staff. Also invited are Institute Directors, Institute Branch Chiefs, and Clinical Center Department Heads. Following these meetings, the Clinical Center generates a thematic summary of growth areas in the intramural clinical research program. Institute leaders verify plans, review resource projections, and identify any service support issues.

The overall purpose of the planning process is to:

- *obtain Institute plans for use of Clinical Center resources in the upcoming fiscal year and beyond;*
- *review and develop new objectives for the Clinical Center strategic and annual operating plan in alignment with Institute needs; and,*
- *elicit feedback from Institutes on the availability and quality of Clinical Center services.*

CC Research Steering Committee

The Clinical Center Research Steering Committee (CCRSC) consists of representatives from the largest user Institutes in terms of clinical activity as permanent members, and rotating members from the remaining Institutes. The CCRSC meets monthly with the CC Director to provide "user" feedback and advice relating to management policy, resource issues, and strategic planning for clinical research at the Clinical Center.

Medical Executive Committee

The Medical Executive Committee advises the Director, CC on clinical aspects of operations and develops policies governing standards of medical care in the CC. The Medical Executive Committee meets twice monthly. The group consists of Clinical Directors from each Institute and other senior clinical and administrative representatives.

Developing the CC Operating Plan - Institute Input

"What Are Institutes Telling Us?"

Themes from the FY 2004/2005 Clinical Center/Institute Planning Meetings:

Institutes report a need for additional Clinical Center support in the following areas over the next two fiscal years (see following pages for additional details):

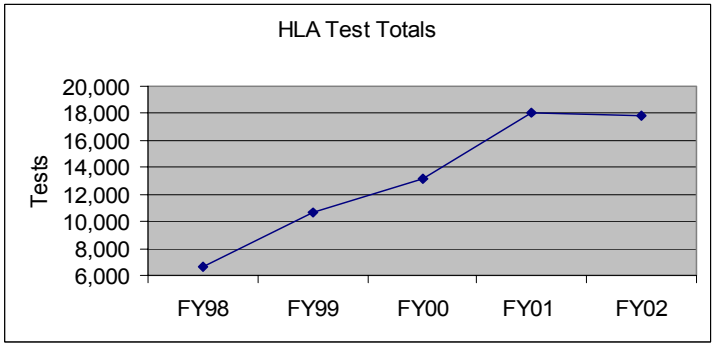
- *Transfusion Medicine*
- *Imaging Sciences*
- *Clinical Research Support*
  - *Investigational drug tracking and disposal*
  - *Increase GMP capacity for pharmaceutical products*
  - *Internal medicine services*
- *Off-Site Clinical Research*

Other areas requiring new or additional CC support (identified in two or more planning meetings):

- *Orthopedics*
- *Pediatrics*
- *Outpatient Surgery*
- *Genomics and Proteomics*
- *Consultative Services (e.g., gastroenterology and gynecological oncology)*

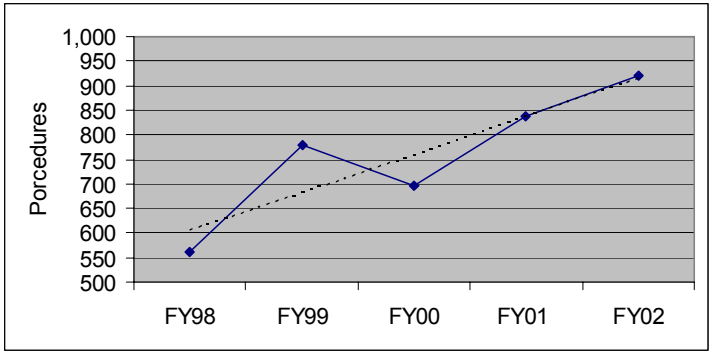
Cellular Therapies

The Clinical Center's Department of Transfusion Medicine (DTM) has continued to serve as an important resource for support of Institute clinical research. Institute demand for progressively more sophisticated services has increased steadily. Specifically, over the past three years, an increasing demand has been placed on both the DTM cell processing service and on the histocompatibility (HLA) laboratory services. The trend for HLA testing leveled off between fiscal years 2001 and 2002, most likely due to the service operating at the margins of capacity. Demand for cellular therapies and HLA support will continue to escalate, as several Institutes (NCI, NHLBI, NIAID, NIAMS, NIDDK, NHGRI) noted new initiatives and/or increased activity in these resource-intensive areas. The CC addressed these concerns in 2002 by providing DTM with additional FTE, as well as space and laboratory supplies to meet these needs. The CC established a new HLA/Immunogenetics section in DTM (with a tenure-track scientist supervising the laboratory services in the section).



DTM is also operating at, or very near to, capacity for cell processing services. If demand continues to increase at the same (or a very likely accelerated) pace, additional resources will be needed in the DTM. Unlike the Imaging Sciences Program (where a second and/or third shift will likely substantially reduce existing backlogs), because of the necessity for the DTM products to arrive during traditional laboratory working hours, second or third shifts would likely be of limited value. In addition, use of a third shift would likely necessitate pheresis of patients in the middle of the night – a circumstance unlikely to be viewed favorably by either patients or investigators.

Cell Processing Services Provided

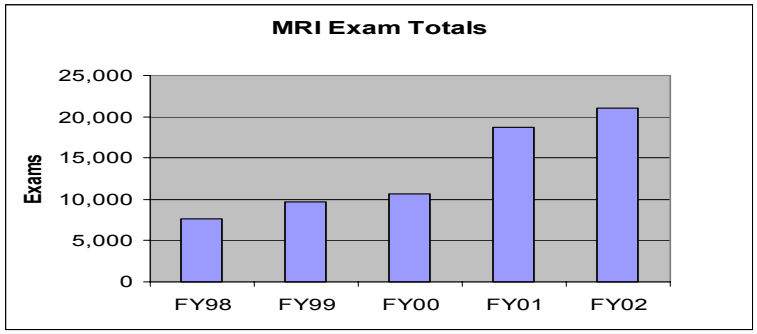


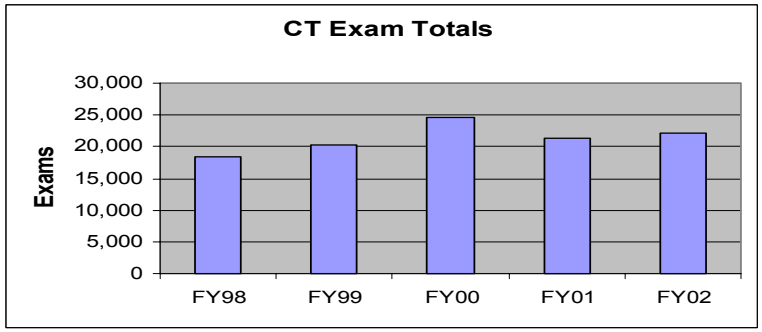
Demand for cell processing support for both stem cell transplantation (including studies attempting to treat aplasia, premalignant states, malignancies, and congenital defects) as well as tumor vaccine studies have also placed substantially increasing demands on Transfusion Medicine Department services.

This stable and/or increasing workload effectively precludes shifting resources in DTM to meet the increasing demand for cellular therapy and immunogenetics support. To even approach current and planned customer requirements, new resources will be required.

Imaging Sciences

Institute demand for magnetic resonance imaging (MRI), computed tomography (CT) and positron emission tomography (PET) support from the Imaging Sciences Program continues to be an area of emphasis. A multi-year renovation of the CC Imaging Sciences facility is underway and operational strategies are being implemented to address the prominent role that imaging modalities are playing, and will continue to play, in support of clinical research. The utilization data below shows continued growth in MRI and CT exams from fiscal year 2001 to 2002.





Several Institutes (e.g., NCI, NHLBI, NIAMS, NICHD, NIDCD, NIDCR, NIMH, NIEHS, and NCCAM) are pursuing studies that point to an increased demand and reliance on MRI, CT and both clinical and research PET studies for the coming years. Increased demand for several additional services from the Imaging Sciences Program were identified in this year's planning meetings, among them:

1. Increasing need for the quantitative, rather than qualitative, clinical image processing services that have been developed by the Imaging Sciences program during the past year to support clinical research;
2. An increasing need for 3.0 T MRI imaging, particularly of the head;
3. Continued requests for MRI imaging capability in the operating room to support neurosurgery, brachytherapy, and general surgical procedures;
4. A new molecular imaging facility that should provide trans-institute support for molecular and gene-based initiatives;
5. Increasing demand for thermal and radiofrequency ablation of tumors (interventional radiology);
6. Markedly increased demand on the PET program and facility, with a clear need to:
   a. Provide state-of-the-art clinical PET services, including a need for computed tomography in PET (PET/CT);
   b. Substantially increase the number of ligands available for translational research;
   c. Increase the overall number of PET study slots (both clinical and research) for IC investigators.
7. IC stakeholder requests for PET/CT services.
8. Progressively increasing need to increase program efficiency and effectiveness, underscoring the need for renovation of Imaging Sciences Program (ISP) space.
9. Requests to evaluate the feasibility of an initiative that would facilitate complex imaging of critically ill patients in the intensive care unit, using CT, PET/CT and MRI imaging strategies.
10. Improvement of the web based Picture Archiving and Communications System (PACS) to facilitate dissemination of radiology images.

Expanding Pediatric Services

A key theme emerging from this year's planning meetings is that several Institutes reported that they would be expanding their pediatric programs, specifically programs in NICHD, NCI, NIAID, NHGRI, and NIMH (e.g., NCI Radiation Oncology/Children's Hospital initiative). NIMH is continuing to expand its newly initiated program in child/adolescent studies. Several institutes have been working collaboratively to define how the new pediatrics space will function in the new Clinical Research Center (CRC). In response to these concerns a group of pediatric stakeholders has been convened to address these issues.

Clinical Research Support

A continuing theme from the Institutes is demand for the CC to provide additional clinical research infrastructure support. As the Clinical Center supports the large and varied portfolio of protocols in the intramural clinical research program, the organization gains a unique vantage point on the myriad infrastructure and support needs required. Occasionally these demands are specific to individual institutes and, in other instances, the requests represent more broad-based, crosscutting requests to support all ICs that have clinical programs.

The past fifteen years have seen a steady transition of clinical research support tasks from IC investigators to CC departments. Whereas centralization of many of these services often makes implicit, even intuitive, sense for the unique CC clinical research environment, such tasks fall well outside the typical 'standard care' construct and are often extremely labor-intense and expensive. Decisions to implement these 'clinical research support' initiatives must be uniformly accepted by the collegium of IC customers. Specific types of clinical research support services requested (some of which are consistent with last year's requirements) are noted below:

1. Improved clinical consult services, including increased/broadened general internal medicine support and better gynecological and gastroenterological consult services;
2. Increasing demand on the Rehabilitation Medicine Department to assist in study design, development of functional outcome measures, and in the actual measurement of outcomes;
3. A good manufacturing process facility for pharmaceutical products;
4. An 'unfilling' service in Pharmacy to facilitate investigators being able to account for investigational drugs;
5. Increasing demand for high frequency serial sampling, especially in endocrine studies;
6. Demand for highly specialized genetic tests and sequencing; and increasing requests for cytogenetic studies;
7. Increasing demand on the Department of Anesthesia and Surgical Services;
8. The need for renovation of the existing Ambulatory Surgery Program and the need for identification of additional clinic space for 'new' programs.

Support for Off-Site Clinical Research

Several institutes (NIAMS, NHLBI, NINDS, NCI, NIMH, NICHD and NIEHS) have either developed or are planning off-site clinical research programs. The need/requirement for CC support of these initiatives varies substantially. Certain of these programs represent community outreach activities, whereas others attempt to attract patient populations (such as Suburban Hospital's emergency room) not available in the CC. This 'off-shore' work poses special challenges to the CC, both with respect to the equity of the CC providing these services, as well as the Clinical Center's accreditation status with the Joint Commission on Accreditation of Healthcare Organizations (*JCAHO*), and will be resource-intense in some instances.

Developing the CC Operating Plan - Patient Input

Patient Advisory Group

In 1998, a group of former and current patients assembled to provide the patients' perspective on design of the new Clinical Research Center. Those discussions led to the creation of the Patient Advisory Group. This year the Patient Advisory Group (PAG) continued to increase momentum with a total of twenty patient advisors regularly attending quarterly meetings. The discussions from these meetings helped identify issues of concern and make recommendations that improve the Clinical Center's efforts to provide the highest quality research and patient care services. Suggestions from this year's meetings included: improved signage and more informed staff regarding the availability of valet parking, feedback on the need for patient identification badges, recommendations for improving the informed consent process, improved documents about patient safety, and improved processes for patient travel.

Patient Perception Survey

The Clinical Center, in partnership with the National Research Corporation, administered surveys to inpatients and outpatients in the Spring of 2002. The survey analyzed the following dimensions of care:

- *Access to care*
- *Respect for patients' values, preferences and expressed needs*
- *Coordination of care and integration of services*
- *Communications between patients and providers*
- *Physical care, comfort and alleviation of pain*
- *Emotional support*
- *Involvement of family and friends*

A response rate of 60% yielded a total of 1,250 surveys. Ninety-three percent of CC patients rate the quality of care at the Clinical Center very good or excellent. Eighty-eight percent of patients would recommend the Clinical Center to friends and family. The survey results indicate that the degree to which care-providers respect patients and the manner in which family and friends are involved in the patient's care are areas of exceptional strength at the Clinical Center. Patients identified coordination of care, communication about care, issues related to the informed consent process, and the management of pain as major areas where improvement is needed.

Developing the CC Operating Plan – Employee Input

Customer Service

The Clinical Center customer service initiative was launched in 2001. At the end of the eighteen months, over 2,500 employees participated in customer service training. An important component of this training elicited feedback from employees. Many best practices in customer service were identified across the Clinical Center. In addition, participants were asked to identify barriers to the delivery of service excellence. Four areas for improvement emerged:

- *Improve teamwork within departments and between departments;*
- *Improve service response times and effectiveness;*
- *Offer more positive recognition to employees; and*
- *Improve access to basic supplies, parking, space, and computers.*

Employee Survey

This year, Clinical Center employees had a second opportunity to provide feedback to management regarding their perceptions of the quality of patient care delivery in this clinical research setting, as well as their own job satisfaction. Thirteen hundred and twenty-nine employees participated in the survey (response rate was 50%). Initial analysis of the results found that over 90% of employees are willing to give extra effort toward the success of the Clinical Center. Ninety per cent of respondents perceived customer service as very good or excellent within their respective departments. Overall job satisfaction was rated as satisfactory or very satisfactory by 86% of the participants. Opportunities for improvement were identified in the following areas: coordination of care, consent management, communications, and timely access to clinical data.

Developing the CC Operating Plan – Alignment

Alignment with DHHS and NIH Goals

The **Clinical Center** is guided by and supports the goals of the Department of Health and Human Services (DHHS) and the National Institutes of Health. The goals and objectives contained within the Clinical Center's plan were developed taking the following DHHS and NIH goals into consideration:

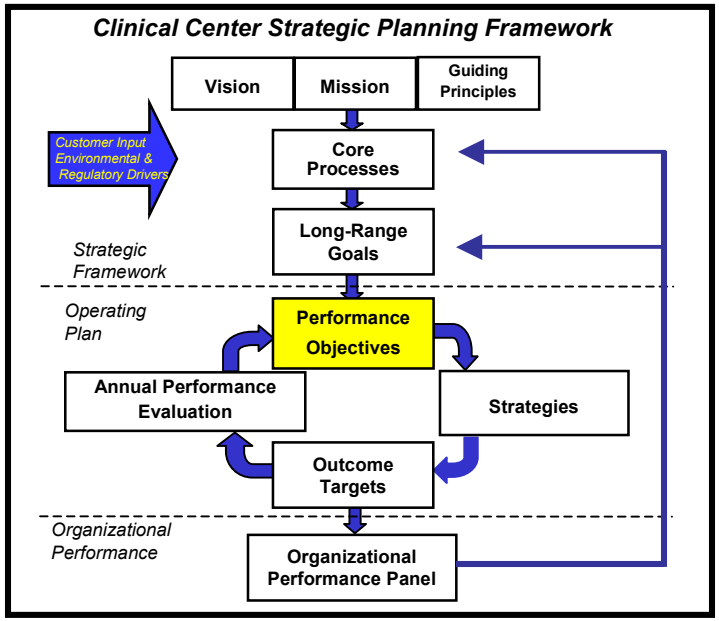
DHHS Goals for 2003-2008:

- **Goal 1** Reduce the major threats to the health and well-being of Americans
- **Goal 2** Enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges
- **Goal 3** Increase the percentage of the Nation's children and adults who have access to regular health care and expand consumer choices
- **Goal 4** Enhance the capacity and productivity of the Nation's health science research enterprise
- **Goal 5** Improve the quality of health care services
- **Goal 6** Improve the economic and social well-being of individuals, families, and communities, especially those most in need
- **Goal 7** Improve the stability and healthy development of our Nation's children and youth
- **Goal 8** Achieve excellence in management practices

NIH Goals: (currently under review)

1. Increase understanding of normal and abnormal biological functions and behavior
2. Improve prevention, diagnosis, and treatment of diseases and disabilities
3. Promote development of a talent base of well qualified, highly trained and diverse investigators capable of yielding the scientific discoveries of the future
4. Secure facilities for research that are modern, efficient, and safe

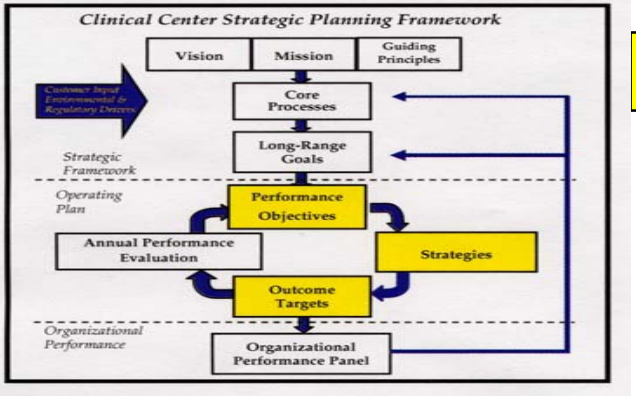
Clinical Center Performance Objectives for 2003



2003 Performance Objectives

- *specify the Clinical Center's strategic priorities over the next year to support the achievement of the long-range goals.*

- *Design plan for optimal utilization of the Clinical Research Center.*
- *Improve patient safety.*
- *Meet milestones in the Clinical Research Center activation plan for 2004 occupancy.*
- *Broaden access of the extramural community to the clinical research training curriculum.*
- *Redesign three key clinical processes to improve effectiveness and efficiency:*
  - *Outpatient surgery;*
  - *Interdisciplinary care;*
  - *Consent management.*
- *Implement core systems of the new Clinical Research Information System.*



2003 Performance Objectives

Strategies

Outcome Targets

Performance Objective :
Plan for optimal utilization of the Clinical Research Center.

Leader: *Lisa Lacasse, Acting Chief Financial Officer*

Strategies :

1) Hold retreat to elicit support from Institutes to develop strategies that will ensure optimal use of Clinical Research Center.
2) Build capacity for new & existing Institute clinical research program requirements in the following areas:
   - Transfusion Medicine
   - Pediatrics
   - Imaging
   - Consult Services

Outcome Targets :

1) Identify strategies by NIH/CC/IC leadership to ensure optimal use of the Clinical Research Center.
2) Establish a Principal Investigator Advisory Group.
3) Increase transfusion medicine services by 8% and open Immunogenetics Lab in FY 03.
4) Provide increased clinical pediatrics support (e.g., consultation, anesthesia).
5) Begin construction on imaging in the OR facility and design ICU imaging facility; implement PET/CT scanning; complete phase two renovation of Radiology Department.
6) Provide expanded consultative services to meet IC demand (Internal Medicine, Pain/Palliative Care, Gynecological and Gastrointestinal).

Performance Objective :
Improve patient safety.

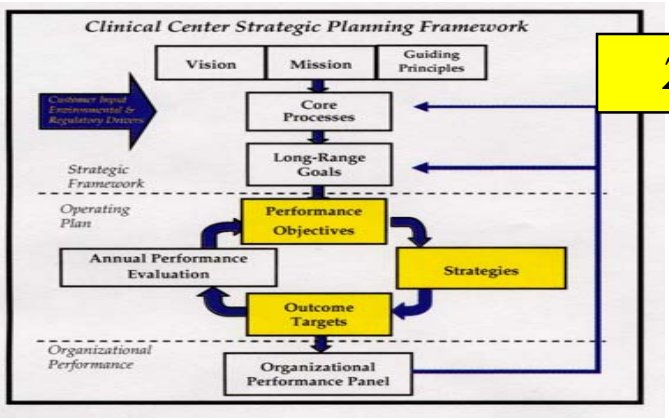
Leader: *David Henderson, M.D., Deputy Director for Clinical Care*

Strategies :

1) Educate staff about use of Root Cause Analysis for management of sentinel events and near misses.
2) Provide patients with tool to participate personally in patient safety effort.
3) Implement patient safety protocols (denominator study, bar-coding study, & disclosure study).
4) Use Occurrence Reporting System data to improve clinical care.

Outcome Targets :

1) Use Root Cause Analysis for ≥95% of events judged 'sentinel' or 'significant near misses' and implement 100% systemic changes prompted by this evaluation.
2) Provide 'Speak-Up' pamphlet to all patients at admission by April 1, 2003.
3) Distribute baseline survey results in 2003; let contract for bar-coding initiative by end of FY 03.
4) Reduce medication errors in three clinical processes.



2003 Performance Objectives

Strategies

Outcome Targets

Performance Objective :
Meet milestones in Clinical Research Center (CRC) activation plan for 2004 occupancy.

Leader: *Maureen Gormley, Chief Operating Officer*

Strategies :
1) Finalize CRC activation budget by Spring, 2003.
2) Identify facility modifications required to accommodate clinical research programs and provide estimate of associated one-time costs.
3) Forecast impact of CRC occupancy on CC operating budget.

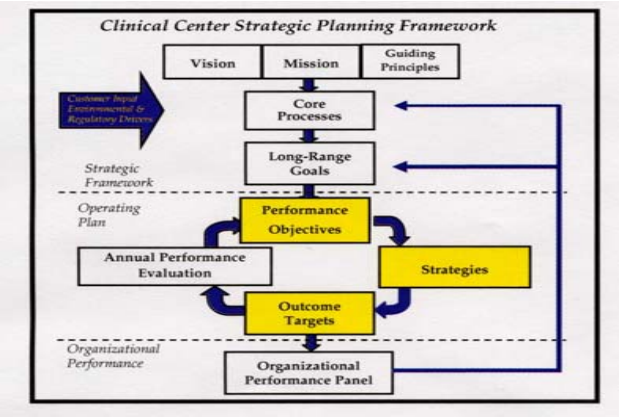
Outcome Targets :
1) Defined CRC activation budget.
2) Project CRC operations budget.

Performance Objective :
Broaden access of the clinical research training curriculum to the extramural community.

Leader: *DeNedra McPherson, Special Assistant to the Director*

Strategies :
1) Expand participation of training program to national and international locations through continued use of internet and videoconferencing technology.
2) Provide training tapes for NIH courses to any site requesting them.
3) Nurture existing relationships in clinical research training with extramural community by offering new NIH program opportunities.

Outcome Targets :
1) Train 150 students at NIH in each core course of the clinical research curriculum.
2) Provide access to courses at 6 offsite locations and 2 international locations.



2003 Performance Objectives

Strategies

Outcome Targets

Performance Objective :
Redesign three key clinical processes to improve effectiveness and efficiency.

Leader: *Clare Hastings, PhD, Chief, Nursing and Patient Care Services*

Strategies :
1) Redesign outpatient surgery.
2) Redesign interdisciplinary care.
3) Redesign consent management.

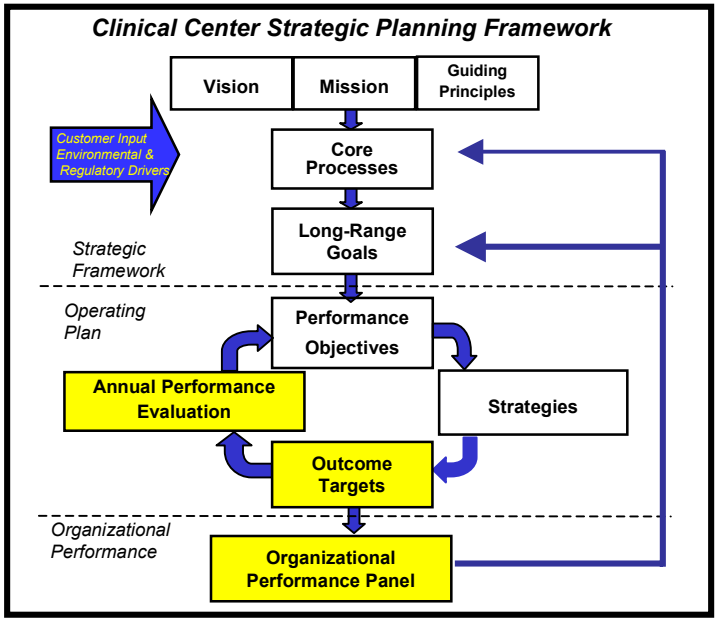
Outcome Targets :
1) Increase stakeholder satisfaction.
2) Improve performance on targeted process measures.

Performance Objective :
Implement core system for new Clinical Research Information System.

Leader: *Steve Rosenfeld, M.D., Chief, Department of Clinical Research Informatics*

Strategies :
1) Select system vendor and award contract.
2) Activate additional space & staff.
3) Provide training to computer staff, institute users, & CC staff on implemented components.
4) Select pharmacy system and award contract.
5) Implement nutrition system.
6) Select surgical services system and award contract.
7) Develop Earned Value Management tools for tracking all aspects of CRIS system implementations and contractor performance.
8) Develop and implement software for assisted protocol writing - ProtoType (under direction of *Robert Nussenblatt, M.D.*).

Outcome Targets :
1) Laboratory results available through the CRIS system by December 2003.
2) ProtoType implemented as a tool to assist protocol writing by 4th Quarter of 2003.



Two Levels of Assessment

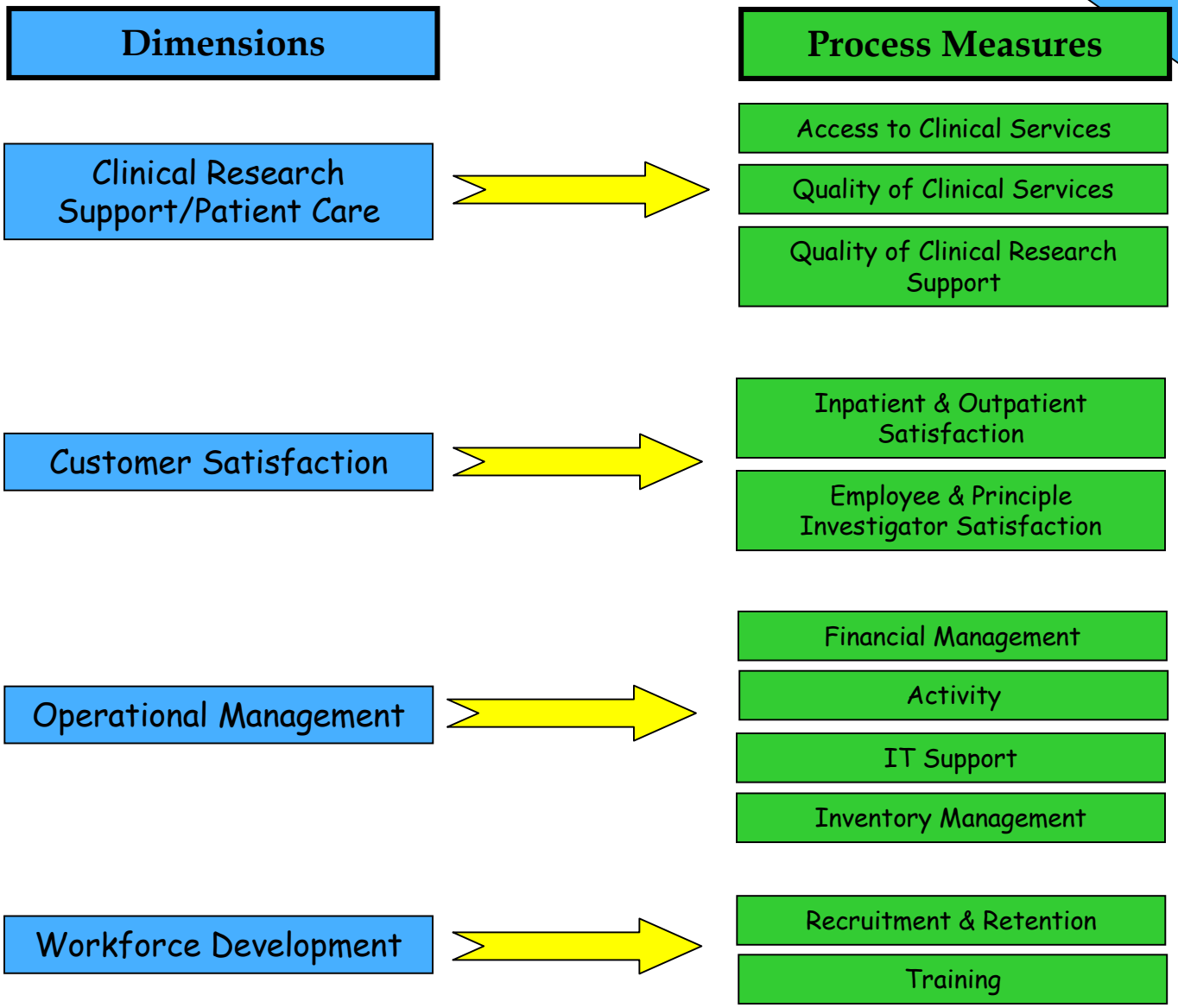
Organizational Performance Panel

Annual Performance : Outcome Targets

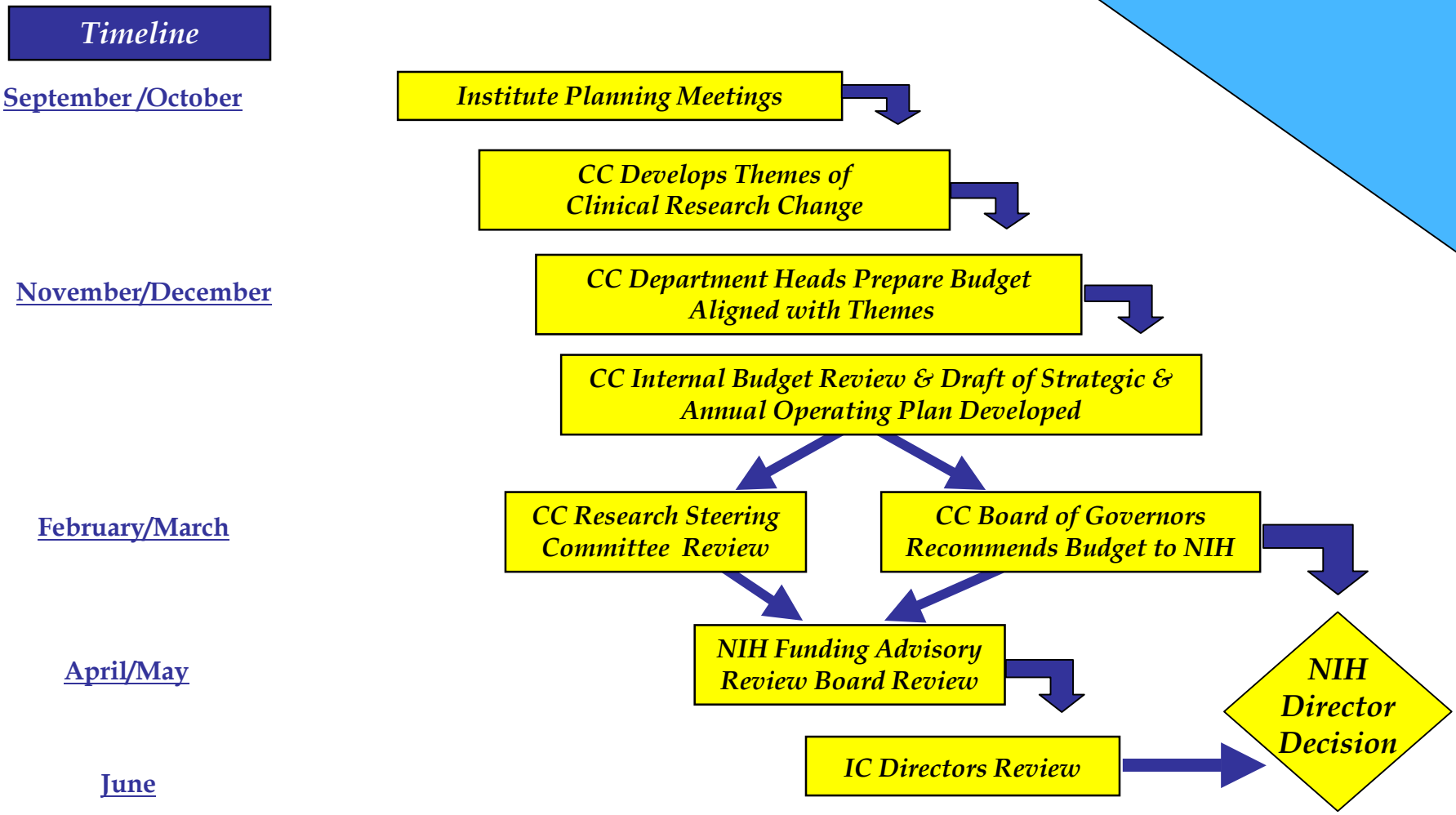
The Clinical Center's Performance Panel is one tool for assessing and communicating overall organizational performance. Measures are developed to evaluate the three core processes: clinical research, patient care and operations. These measures also help to assess the impact of new strategies on improving core process outcomes and meeting long range goals. This effort is in alignment with the Office of Management and Budget mandate that Federal agencies provide increasing evidence of effective organizational performance.

The measures within the Organizational Performance Panel are quantitative and qualitative measures developed from four key perspectives: clinical research and patient care, customer satisfaction, operational management, and workforce development. Targets are set to allow for normal variation. If the measures are outside of established acceptable levels, the data are reviewed to understand the problem.

Organizational Performance Panel



CC Planning and Budget Development Process



Key Drivers to Development of CC Budget

Resource Deployment

Although the development of the CC budget is influenced by the many drivers described in this plan, the CC budget development is organized in the context of three major categories: Commitment Base, Clinical Research Program Changes, and Hospital Infrastructure Requirements. This breakdown complies with the 'commitment base' format requested by the NIH Funding Advisory Review Board and creates a framework within which CC department heads can align requests.

During annual meetings with Institutes, areas of emphasis for clinical research within the intramural program are identified. The Clinical Center synthesizes the input and develops a thematic summary of areas of change and growth due to new or expanding programs. This information is provided to CC department heads who translate Institute research directions into resource requirements and related departmental budget needs.

Each year as the Clinical Center budget is developed, department heads consider ongoing costs in each of several categories of needs known in the federal sector as 'object classes'. For example, these categories include salaries and benefits, equipment, travel, supplies, training, and contracts. Although many of these ongoing costs (e.g. salaries and benefits, cost-of-living increases) are non-discretionary, the Clinical Center and its oversight groups evaluate each department's submission at the 'line item' level. This practice allows for evaluation of costs to identify improved efficiencies and facilitate realignment of priorities to meet new clinical research needs.

Hospital infrastructure requires changes that are organizational-wide and department-specific. Whereas clinical research program changes are in direct response to new areas of emphasis identified by the Institutes, this category of resources includes changes implemented for the good of the entire organization. To name a few, these changes might be regulatory-driven (e.g., adverse event reporting system), patient care-related (e.g., new patient safety program), and program-driven (e.g., purchase of updated software).

Often the CC identifies internal efficiencies and is able to fund these improvements within existing resources. This internal planning allows the CC to shift resources to support aspects of clinical research program changes without increasing the overall budget.