

Center for Cancer Research

Clinical Research Program

National Cancer Institute's Mission

Conduct and support research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

- Supports and coordinates research conducted by universities, hospitals, research foundations, and businesses through research grants and cooperative agreements.**
- Conducts research in its own laboratories and clinics.**
- Supports education and training in fundamental sciences and clinical disciplines.**
- Collects and disseminates information on cancer.**

NCI Intramural Research Program

- **Division of Cancer Epidemiology & Genetics**
- **Center for Cancer Research**
 - One of the world's largest cancer research centers
 - Combines basic and clinical research and promotes interaction of basic and clinical scientists
 - Over 300 Principal Investigators and 3,500 people
 - 54 Laboratories, Branches and Programs
 - Focuses on translational research



Clinical application of knowledge gained through basic research

Center for Cancer Research

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J. Carl Barrett, Ph.D.

**Clinical
Branches**

Cancer Therapeutics
Cancer Genetics
Experimental Transplant. Immunol.
Experimental Immunology
Tumor Immunol. & Biology
HIV & AIDS Malignancy
Metabolism

**Medical Oncology
Clinical Research Unit**

Neuro-Oncology
Pediatric Oncology
Surgery
Radiation Oncology
Radiation Biology
Pathology
Urologic Oncology

**Basic
Laboratories**

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**Clinical
Branches**

**Medical Oncology
Clinical Research Unit**

**Basic
Laboratories**

Clinical Research Units

Breast Cancer

GU/GYN

Vaccine

Lymphoma

Transplant

Immunotherapy

AIDS Malignancy

Other Resources

Fellowship training

Scientific review

Protocol support

Translational research

Pharmacokinetics core

Molecular targets core

Preclinical development core

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Clinical Branches

Cellular Oncology
Receptor Biology & Gene Expression
Gene Regulation & Chromosome Biol.
Cellular Carcinogen. & Tumor Prom.
Genetics
HIV Drug Resistance
Structural Biophysics
Genomic Diversity
Molecular Pharmacology
Biosystems & Cancer
Biochemistry
Regulation of Protein Function
Comparative Carcinogenesis

Medical Oncology Clinical Research Unit

Immunobiology
Experimental Immunology
AIDS Vaccine
Molecular Targets Disc.
Basic Research
Populations Genetics
Cell & Cancer Biology
Cell Regulation & Carcinogen.
Cancer & Developmental Biol.
Molecular Cell Biology
Experimental Carcinogenesis
Molecular Immunoregulation
Macromolecular Crystallog.

Basic Laboratories

↓
Immune Cell Biology
Resistance Mechanisms
Medicinal Chemistry
Exp. & Computational Biology
Molecular Biology
Cell Biology
Cellular & Molecular Biology
Regulation of Cell Growth
Human Carcinogenesis
Mouse cancer Genetics
Metabolism
Retroviral Replication

CCR Clinical Research Effort

- **Collaboration between basic and clinical research**
- **Concept-based (science-driven) clinical trials with correlative laboratory endpoints**
- **Emphasis on discovery and development of molecularly targeted agents**
- **Focus on understudied diseases and cancers with increasing incidence, poor prognosis, or involving special populations**
- **Long-range commitment of resources**

CCR Clinical Research Effort

Drugs that produce their effect through interaction with cellular macromolecules (e.g., proteins) that contribute to malignant transformation

- Signal transduction pathways (*bcr-abl, ras*)
- Apoptotic pathways (*bcl-2*)
- Cell cycle regulatory proteins (*p53*)
- Differentiation pathways (retinoids)

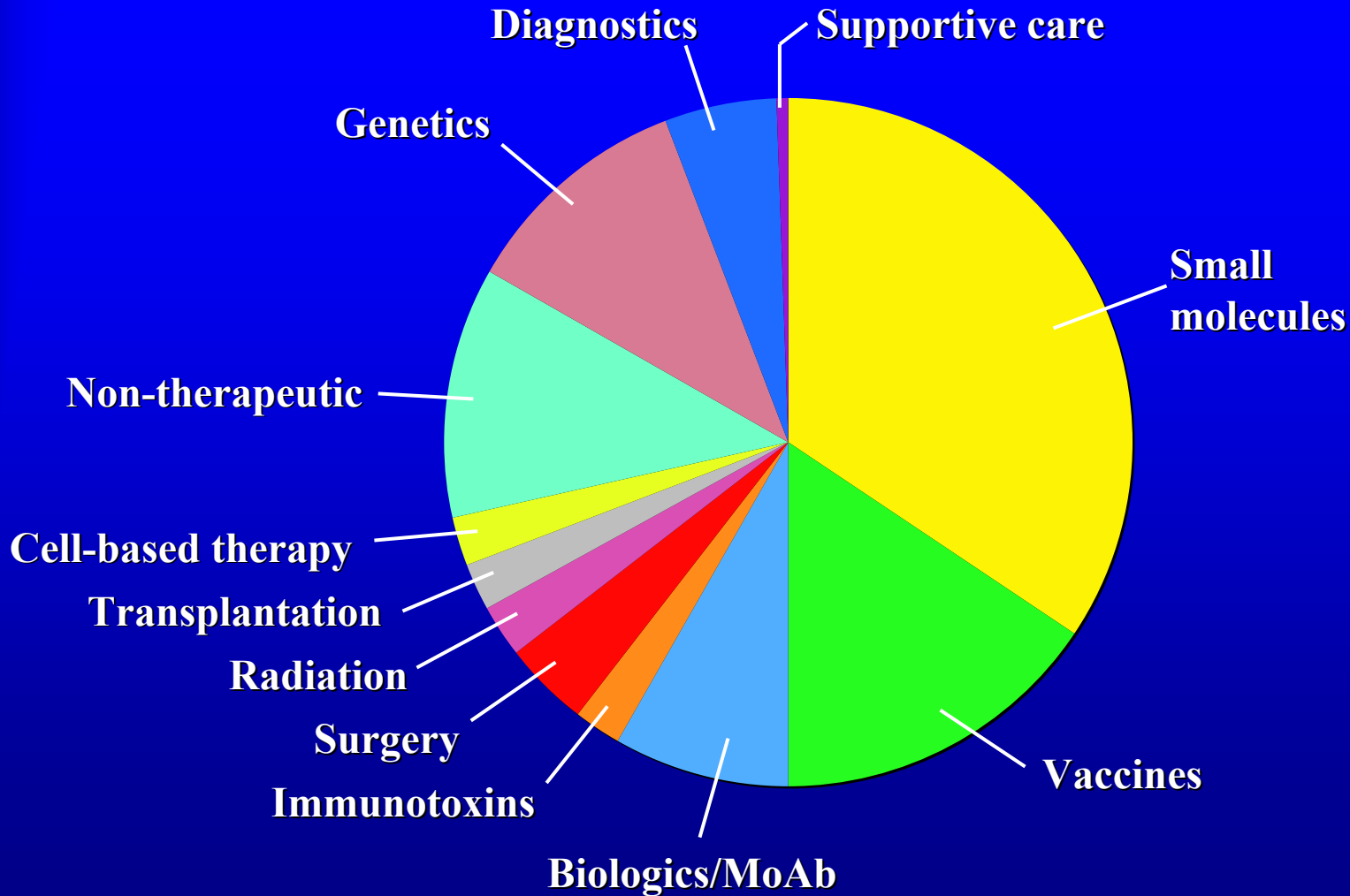
Clinical Research Infrastructure

- **Human Subjects Research Office (PRMC, IRB)**
- **Biostatistics & Data Management Section**
- **Clinical Trials Support Office (research nurses and data managers)**
- **Clinical trials informatics (database)**
- **Outreach program (Call center, website, brochures, continuing education, ads)**
- **Technology Development Branch**

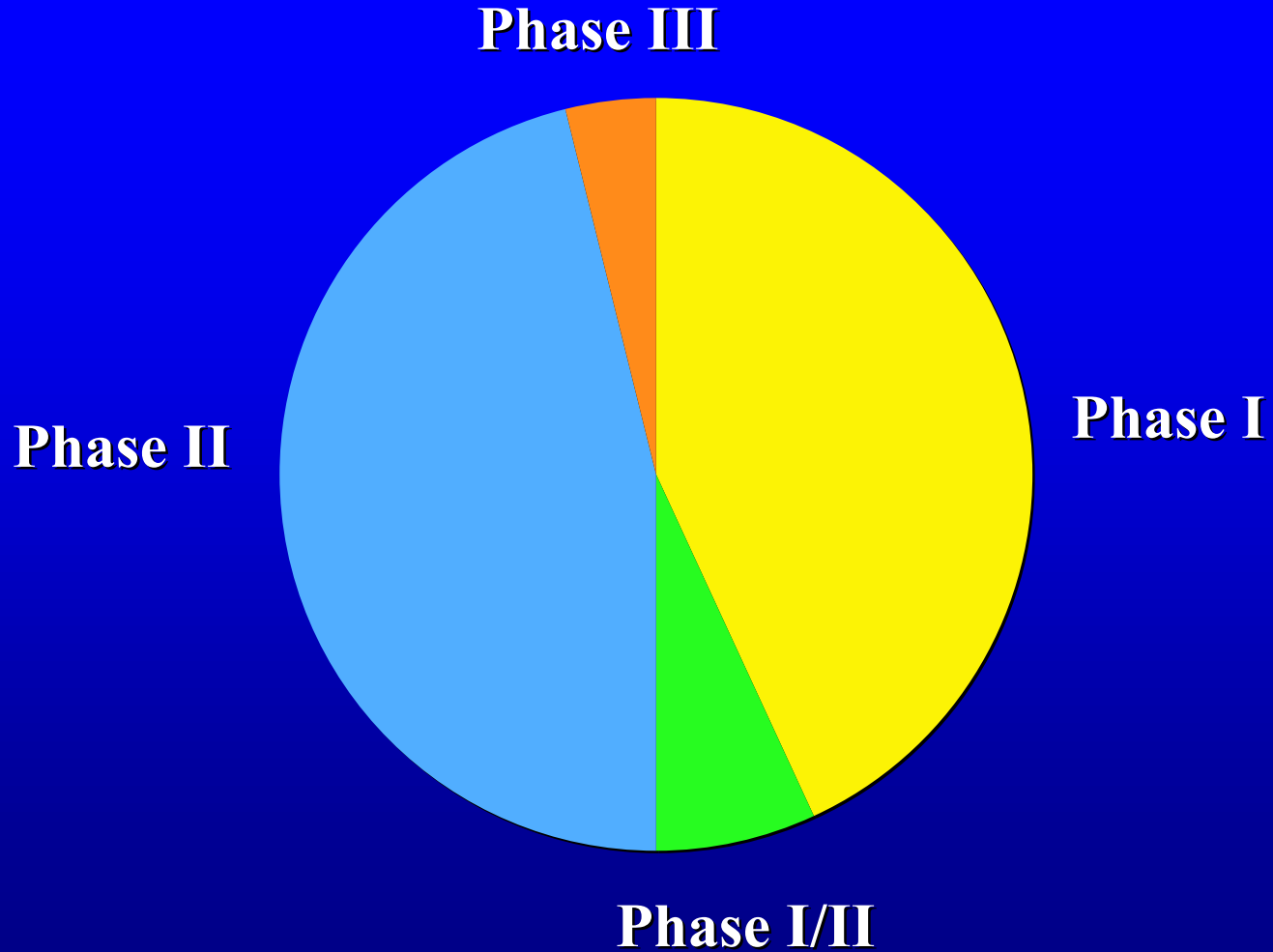
CCR Collaborations

- **Cancer Therapy Evaluation Program**
 - Drug discovery (natural products)
 - Co-development with Industry
- **Monoclonal Antibody & Recombinant Protein Facility (GMP)**
- **Pharmaceutical companies**

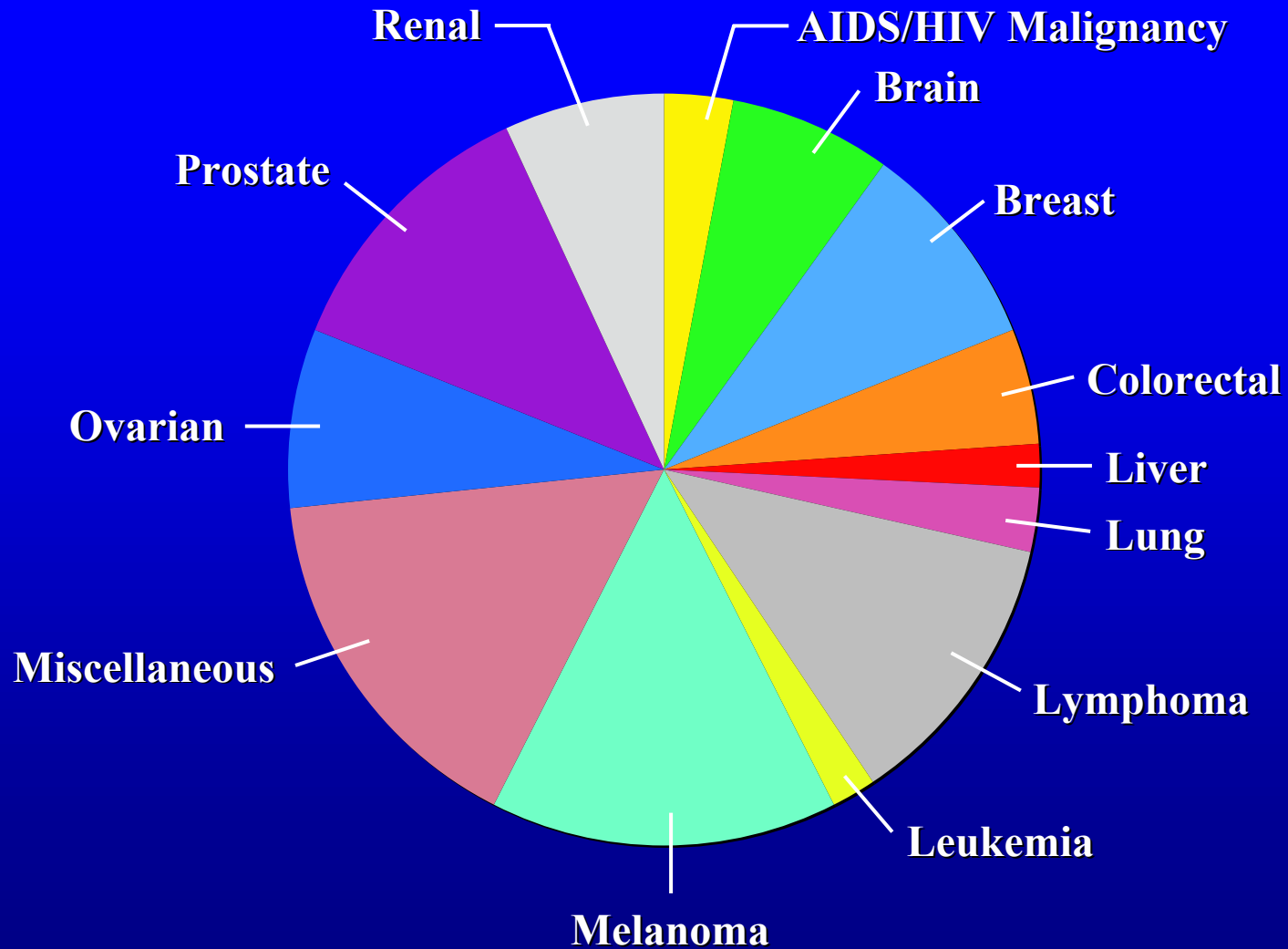
Types of Clinical Trials



Treatment Trials by Phase



Phase II and III Trials by Disease



New CCR Protocols for Nov '02

- The P-glycoprotein antagonist, Tariquidar, in combination with docetaxel in lung, ovarian, and cervical cancer.
- Randomized phase III trial of hyperthermic isolated limb perfusion and melphalan with or without TNF in advanced extremity melanoma.
- Non-myeloablative but lymphocyte depleting chemotherapy followed by *in vitro* sensitized lymphocytes reactive with melanoma antigen(s) for metastatic melanomas.
- Natural history and management of pancreatic lesions associated with Von Hippel-Lindau.
- Phase I trial of R115777 + radiation therapy for newly diagnosed glioblastoma multiforme.
- Intraprostatic RF-PSA 3(A)/Tricom vaccination for high-risk localized prostate cancer prior to radical prostatectomy.
- Phase II trial of BL22 immunotoxin in hairy cell leukemia.
- Immunization with HLA-A2- and HLA-A3-binding peptides from fibroblast growth factor 5 for metastatic renal cancer.
- Randomized comparison of peptide immunization for high risk melanoma.
- Immunization with recombinant gp100 protein and a class I restricted gp100 peptide antigen for metastatic melanoma.

Warren G. Magnuson Clinical Center

- **NIH's Clinical Research Center**
- **Current physical structure (1953)**
 - **14 Floors**
 - **267 beds (>50% of NIH-funded CRC beds in U.S.)**
 - **24 inpatient wards**
 - **15 outpatient clinics**
- **New CRC under construction since 1997**
- **10,000 new patients per year from across the country and around the world**

CC Infrastructure

- **Clinical/Microbiology Laboratory**
- **Anesthesia and Surgical Services**
- **Critical Care (Medical and Surgical ICUs)**
- **Pharmacy Department**
- **Rehabilitation Medicine**
- **Transfusion Medicine**
- **Imaging Sciences (Radiology, Nuclear Medicine, PET, LDRR)**
- **Bioethics**
- **Hospital Epidemiology**
- **Nursing**
- **Nutrition**
- **Social Work**
- **Clinical Research Informatics**
- **Medical Records**