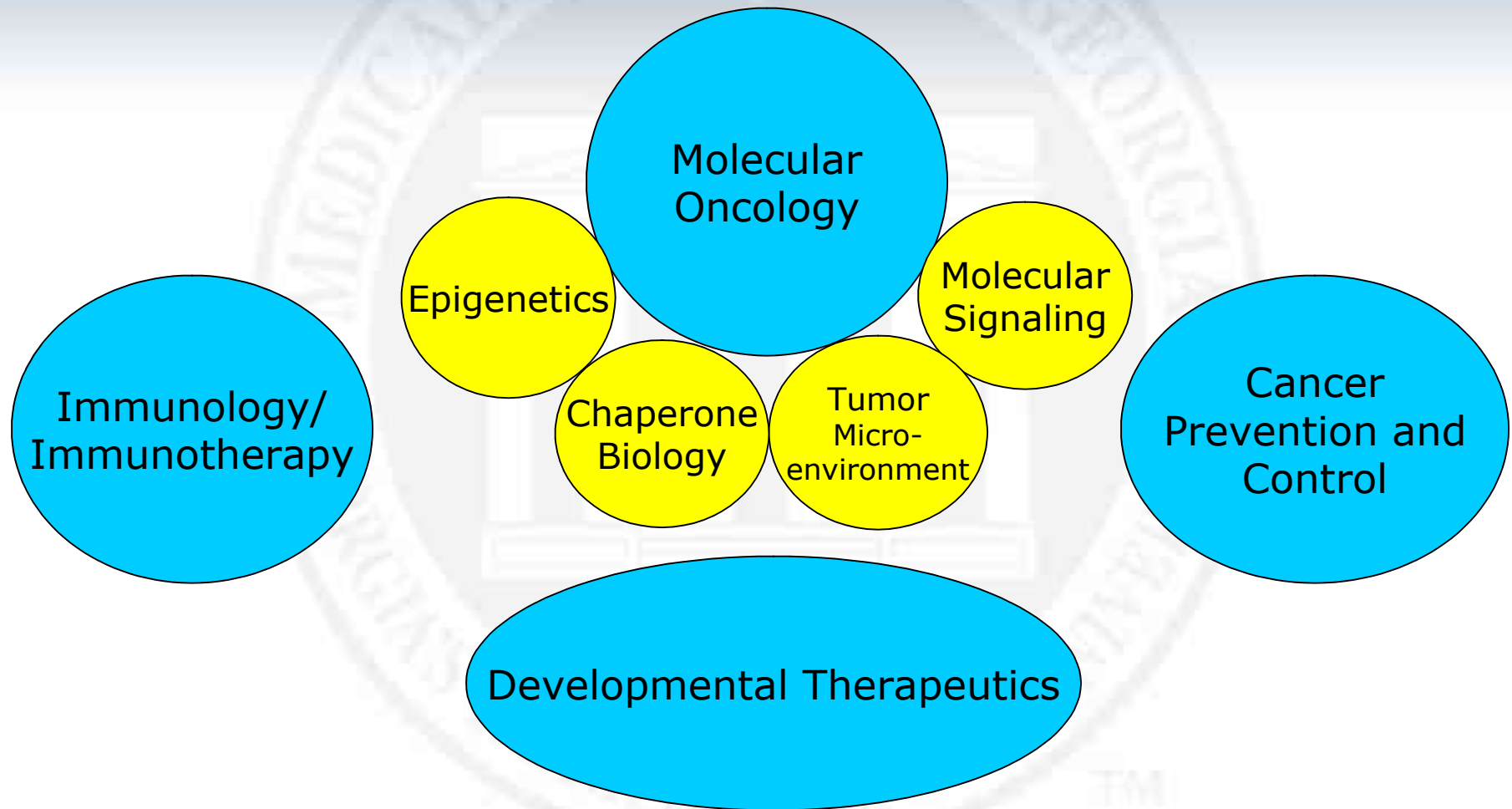




# MCG Cancer Center

“...to improve health and reduce the burden of illness in society...”

# Basic Science Programs at MCGCC



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CLINICAL RESEARCH

- Clinical Trials Unit
- Clinical Trials Office

TRANSLATIONAL RESEARCH

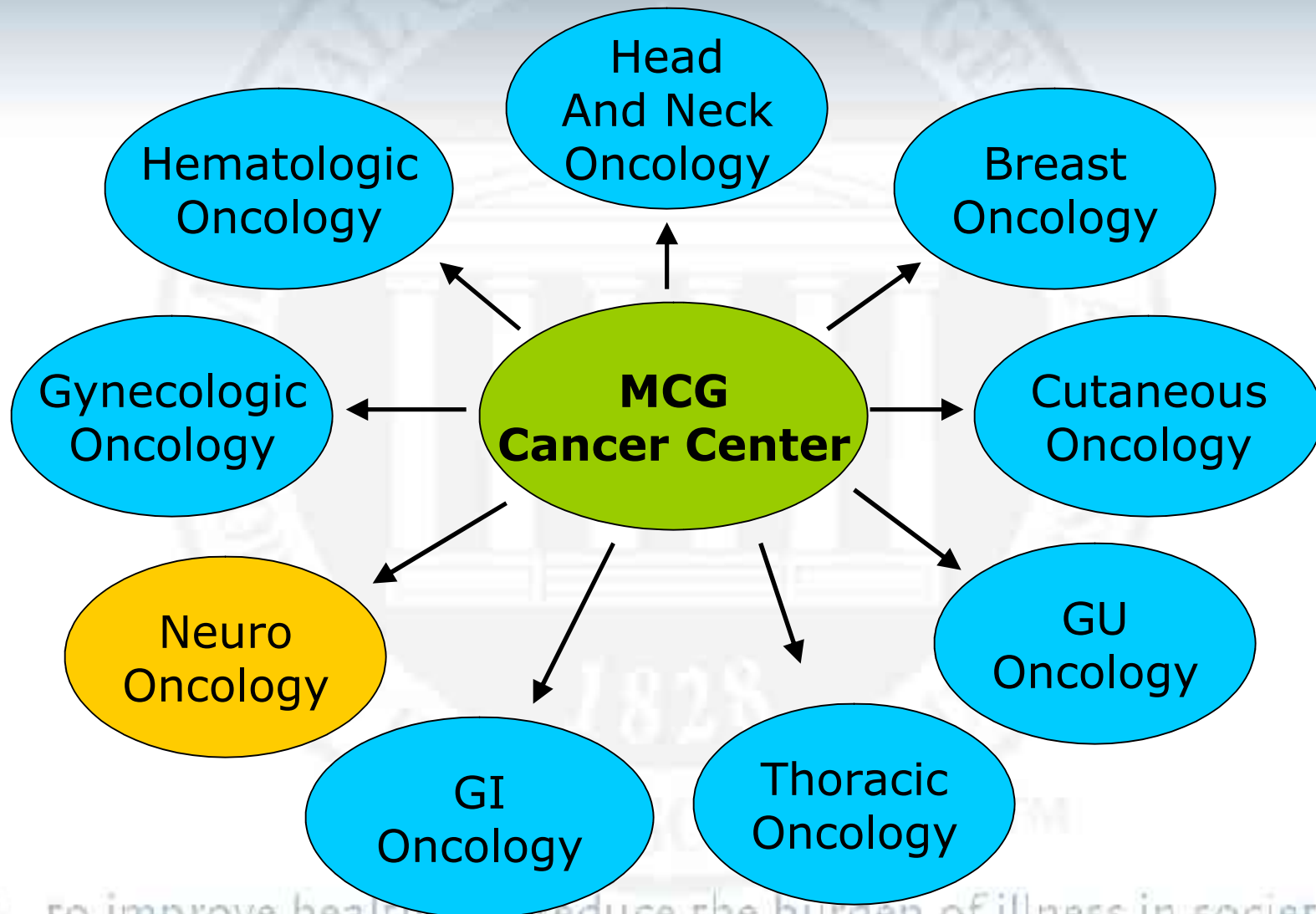
- Tumor Bank
- GPAC-TM

**MCG Cancer Center**

BASIC RESEARCH

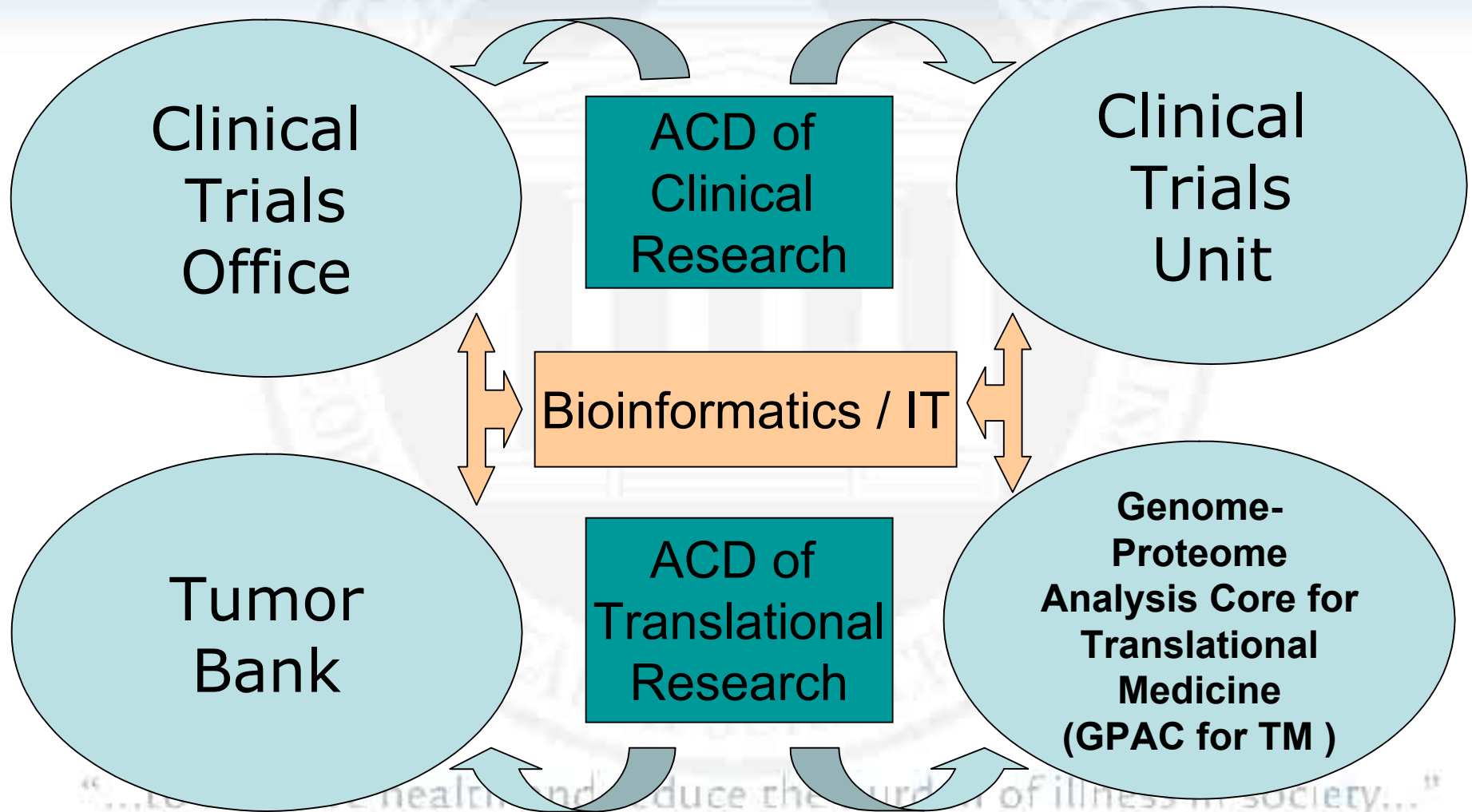
- PI Labs
- Core Facilities

# Multi-Disciplinary Clinical Research Teams



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# Clinical/Translational Research Infrastructure



"...to improve the health and reduce the burden of illness in society..."



# Outpatient Treatment Center



# Site Plan



# Second Floor Plan



# ACTIVE Clinical Research Unit Portfolio Protocols

- **Novartis LBH 2102**: A Phase IA/II, two arm, multi-center, open-label, dose-escalation study of LBH589 administered orally on two dosing schedules in adult patients with advanced hematological malignancies. **PI: Kapil Bhalla, M.D.**
- **Merck 008**: A Phase II Study of MK-0457 in Patients with Bcr-Abl T315I Mutant Chronic Myelogenous Leukemia and Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia. **PI: Kapil Bhalla, M.D.**
- **Pfizer A4061019**: A Phase I Dose-Finding Study of the Anti-Angiogenesis Agent, AG-013736 in Combinations of Paclitaxel/Carboplatin and Docetaxel/Carboplatin in Patients with Advanced Solid tumors. **PI: Thomas Samuel, M.D.**
- **Merck 056-01**: A Phase II/III Randomized, Double-Blind Study of Paclitaxel plus Carboplatin in Combination with Vorinostat (MK-0683) or Placebo in Patients with Stage IIIB (with pleural effusion) or Stage IV Non-Small-Cell Lung Cancer (NSCLC). **PI: Thomas Samuel, M.D.**

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# **ACTIVE Clinical Research Unit Portfolio Protocols, Continued...**

- **Novartis CLBH589B2201**: A Phase II Study of Oral LBH589 in Adult Patients with Refractory Cutaneous T-Cell Lymphoma. **PI: Kavita Natarajan, M.D.**
- **Novartis CLBH589B2212**: A Phase II Study of Oral LBH589 in Adult Patients with Refractory Cutaneous T-Cell Lymphoma and Prior HDAC Inhibitor Therapy. **PI: Kavita Natarajan, M.D.**
- **NCI 7868**: A Phase I-II Study of R115777 (Tipifarnib, Zarnestra®) Plus Sequential Weekly Paclitaxel followed by Dose-Dense Doxorubicin and Cyclophosphamide in Patients with Stage IIB-IIIC Breast Cancer. **PI: Thomas Samuel, M.D.**
- **NCI 7703**: A Phase I/II Study of a combination of Suberoylanilide Hydroxyamic Acid (Vorinostat) plus Paclitaxel and Bevacizumab in Patients with Advanced Metastatic and/or Local chest Wall Recurrent Breast Cancer. **PI: Thomas Samuel, M.D.**

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# PENDING Clinical Research Unit Portfolio Protocols

- ACRIN 6678 - FDG-PET/CT as a Predictive Marker of Tumor Response and Patient Outcome: Prospective Validation in Non-small Cell Lung Cancer. **PI: Hadyn Williams, MD**
- NLG 0101 - A Phase I/II Study of an Antitumor Vaccination Using  $\alpha(1,3)$ Galactosyltransferase ( $\alpha(1,3)$ GT) Expressing Allogeneic Tumor Cells in Patients with Recurrent or Refractory Non-Small Cell Lung Cancer. **PI: Thomas Samuel, M.D.**
- AMN-107 - A multi-center, open-label, exploratory study of Bcr-Abl kinetics in adult patients on nilotinib with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia in chronic phase (CML-CP) and a suboptimal molecular response to imatinib. **PI: Anand Jillella, MD**
- Infinity IPI-504-03 - A Phase 1/2 Study to Investigate the Safety, Tolerability and Potential Activity of IPI-504 in Relapsed and / or Refractory Stage IIIb (with Malignant Pleural or Pericardial Effusion), or Stage IV NSCLC Patients. **PI: Thomas Samuel, M.D.**

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# **PENDING Clinical Research Unit Portfolio Protocols, Continued. . .**

- **Infinity IPI-504-04** - A Phase 2 Open-Label Study to Investigate the Pharmacodynamics and Clinical Activity of IPI-504 in Patients with Castration Resistant Prostate Cancer Stratified by Prior Chemotherapy. **PI: Terry Coleman, MD**
- **Novartis AUY922** -A phase I dose escalation, multi-center, open-label study of AUY922 administered IV on a once-weekly schedule in adult patients with advanced solid malignancies including phase II expansion arms in patients with either Her2 positive or ER positive locally advanced or metastatic breast cancer. **PI: Thomas Samuel, MD**
- **Serenex SNX-5422** -A Phase I, Open-Label, Dose-Escalation Study of the Safety and Pharmacokinetics of SNX-5422 Mesylate in Subjects with Refractory Hematological Malignancies. **PI: Anand Jillella, MD**
- **AZA PK006** -A Phase 1, Open-Label, Multi-Center, Parallel Group Study to Assess the Pharmacokinetics and Safety of Subcutaneous Azacitidine in Adult Cancer Patients With and Without Impaired Renal Function. **PI: Asha Nayak, MD**

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# PENDING Clinical Research Unit Portfolio Protocols, Continued. . .

- **Wx60-006** - A Phase 2, two-arm, double blind, multi-center, randomized study of the combination of oral Wx-671 plus capecitabine vs. capecitabine monotherapy in first-line Her-2 negative metastatic breast cancer. **PI: Thomas Samuel, MD**
- **CLBH589-2109** - A phase IB, open-label, multicenter study to investigate the effect of oral LBH589 on dextromethorphan, a CYP2D6 substrate, and to assess the efficacy and safety of oral LBH589 in patients with advanced solid tumors. **PI: Asha Nayak, MD**
- **CRAF265A2101 (CHIR-265-MEL01)** -A Phase I/II, Open-label, Dose escalation Trial to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of RAF265 (CHIR-265) Administered Orally to Patients with Locally Advanced or Metastatic Melanoma. **PI: Amanda May, MD**
- **SYNDAX Protocol SNDX-275-0301** -A Phase 2, Randomized, Double-Blind, Multicenter Study of Exemestane With and Without SNDX-275 in Postmenopausal Women with Locally Recurrent or Metastatic Estrogen Receptor-Positive Breast Cancer, Progressing on Treatment with a Non-Steroidal Aromatase Inhibitor. **PI: Amanda May, MD.**

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# **PENDING Clinical Research Unit Portfolio Protocols, Continued. . .**

- **CRAF265A-2102** - A Phase I/II study of RAF265 in patients with metastatic colorectal carcinoma. **PI: Asha Nayak, MD**
- **Merck MK-003-01** - A Phase I Investigation of the Intravenous Administration of MK-4721 in Patients With Advanced Hormone Refractory Prostate Cancer. **PI: Teresa Coleman, MD**

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