

Development of a Clinical Trials Program in Radiation Oncology

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Overview: Clinical Trials Program Development

- ◆ Clinical trials in oncology are essential to improving outcomes for patients

- ◆ Clinical trials aim to answer timely questions about new treatments

Goals: What are we trying to accomplish?

- ◆ Increase awareness of clinical trials and identification of patients in radiation oncology

- ◆ ***Benchmarking Data***
 - Accrue a total of 60-75 patients per year in year when up and running

- ◆ Open new clinical trials
 - Cooperative groups (NCI funded studies)
 - Investigator-initiated studies

Goals: What are we trying to accomplish?

- ◆ Rutgers Radiation Oncology to become a national leader in clinical trials
 - To collaborate with NCI sponsored oncology groups to develop new trials to advance patient care
- ◆ Mentor junior investigators to develop trials to serve our patients
- ◆ To increase awareness of clinical trial processes in the clinic

Why is this important?

- ◆ Clinical trials
 - Advance patient care
 - Answer timely questions in oncology
 - Mission of Rutgers Cancer Institute of New Jersey (NCI-Designated Comprehensive Cancer Center)
 - Improves quality of care for patients
 - Elevates Cancer Center
 - Generate research presentations, publications, collaboration

Complexities of Clinical Trials

- ◆ Require additional time from the investigator and research staff
 - Submission of studies to the IRB
 - Preparation of forms to collect data
 - Clinical research nurses to help patients navigate complex treatment schedules
 - Long-term patient follow-up
 - Special expertise and equipment

Who got engaged throughout this project

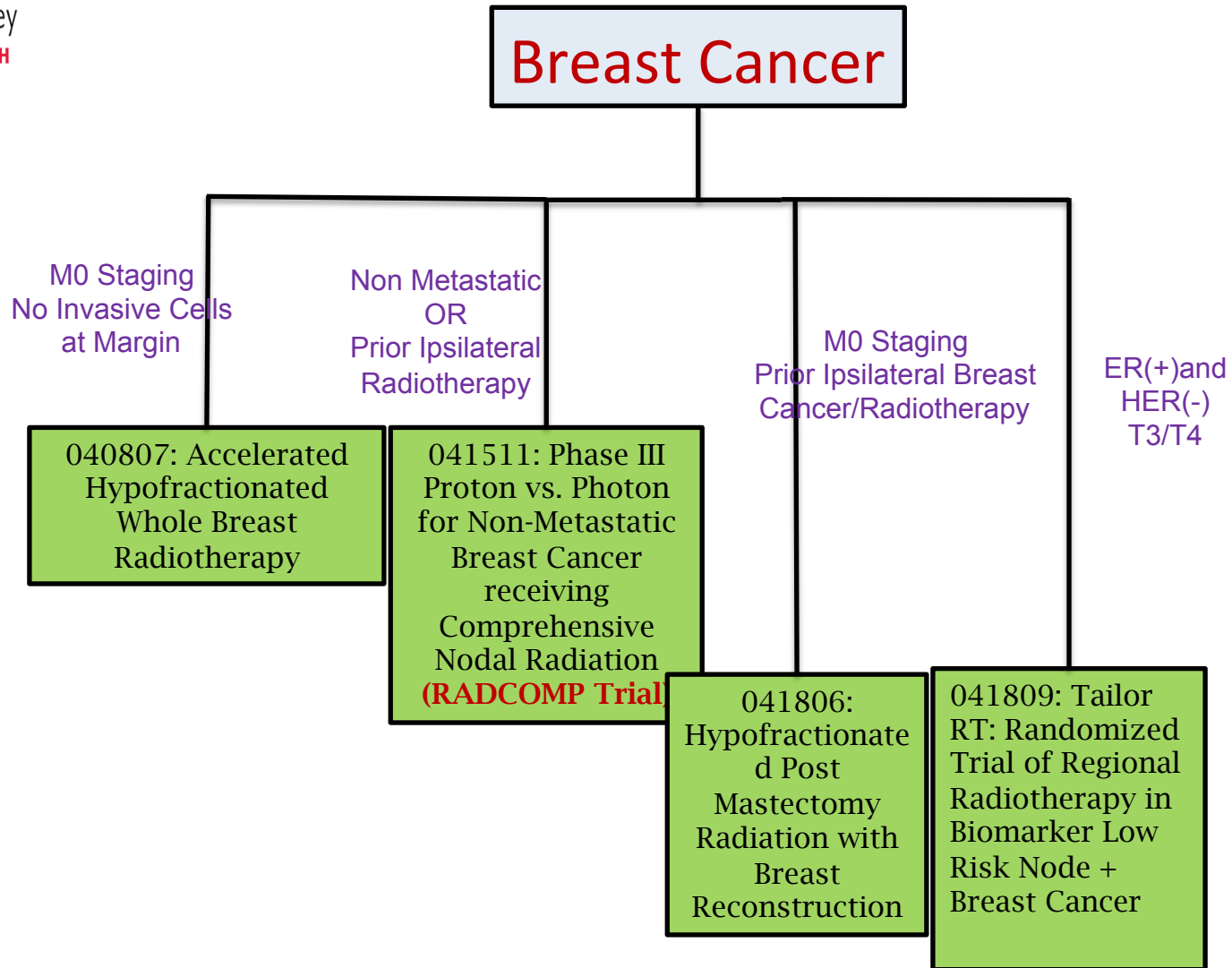
- ◆ Department of Radiation Oncology (i.e. clinical nurses, residents)
- ◆ Dr. Bruce Haffty, MD, Chair of Radiation Oncology
- ◆ Tracie Saunders, RN, Head of Office of Human Research, CINJ
- ◆ Dr. Howard Hochster, MD, Director of Clinical Research, CINJ

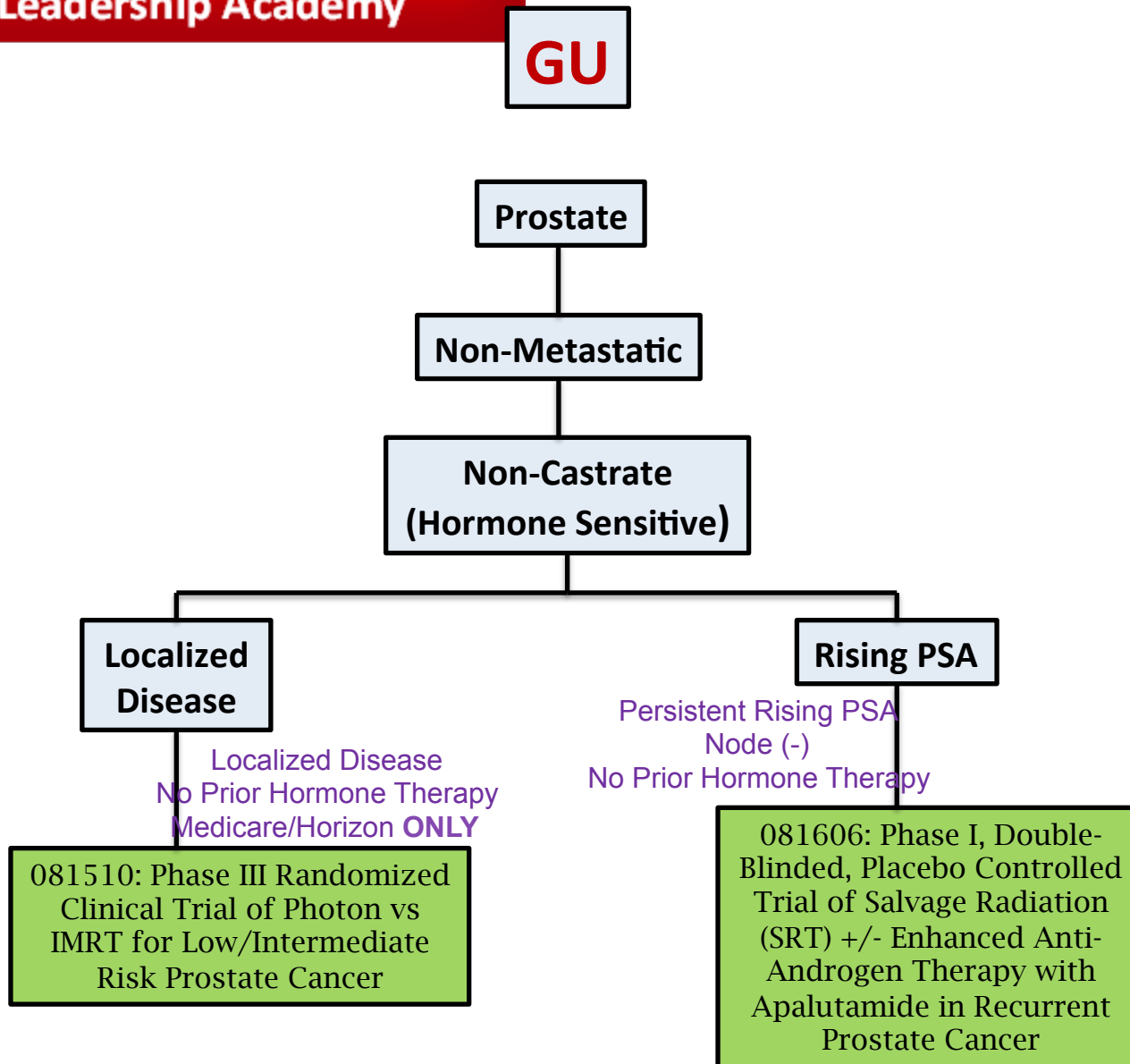
Current Status: What have we accomplished thus far?

- ◆ Hired a clinical trials specialist to be in our clinical location in RWJ
 - Most research staff in CINJ building

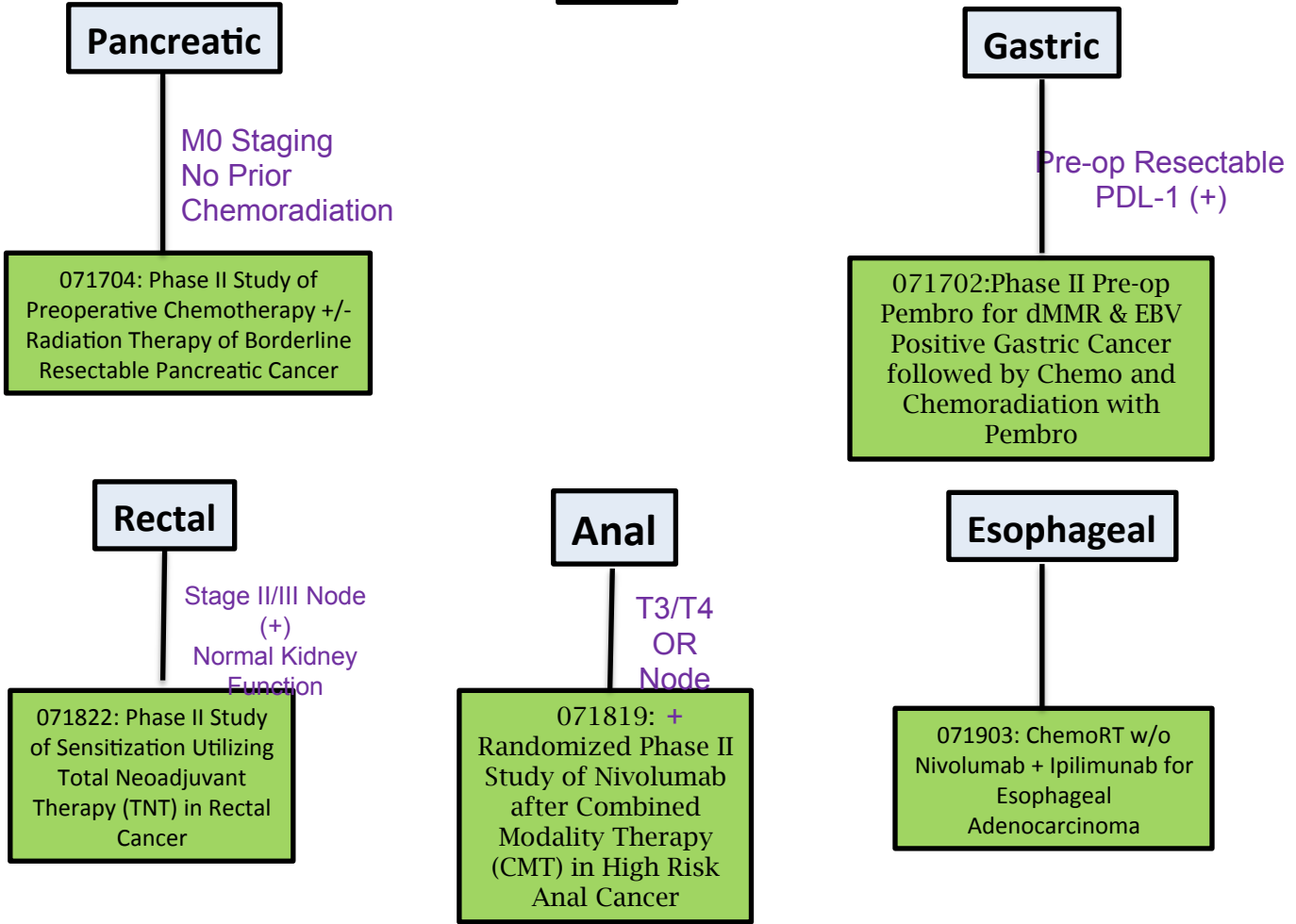
- ◆ Opened 7 new clinical trials
 - 3 breast cancer, 1 prostate cancer, 1 brain cancer, 1 esophageal cancer, 1 rectal cancer, 1 H & N cancer

- ◆ Education session about clinical trials for clinical (non-research) nurses





GI



Lung Cancer

NSCLC

Failed Response to PD-L1 Inhibitor

071706: Phase II Trial of MEDI4736 (durvalumab) and Tremelimumab Alone or in Combination with High/Low Dose Radiation in Metastatic Colorectal or NSCLC (Colon Cohort Closed)

Genomic Profiling – Tissue for Banking

Stage III (Inoperable)

NO Prior Immunotherapy
Stage IIA/IIIB

Locally Advanced
NO Cervical Nodes/
Prior Thorax Radiotherapy

031706: Phase II Study of Consolidation Immunotherapy w/ Nivolumab and Ipilimumab OR Nivolumab Alone Following Concurrent Chemoradiation for Unresectable Stage IIA/IIIB NSCLC

031807: Phase III Trial of Pembro in Combination with Platinum Doublet Chemotherapy and Radiotherapy for Participants with Unresectable, Locally Advanced Stage III NSCLC

Challenges and Obstacles

- ◆ Clinical trial funding for IIT's
- ◆ Time and bandwidth challenges

Action Items/Future Directions

- ◆ Develop process to screen/identify patients from time of consult
- ◆ Continue process of education for all members of the department
- ◆ Continue mentoring to develop investigator-initiated clinical trials
 - Faculty applications to clinical trials development workshops (RSNA or AACR courses)

Learning Points

- ◆ Getting buy in/consensus is important
 - Clinical trial specialist

- ◆ Like to get things done
 - Things take time!

- ◆ Focus on the goals!
 - Daily process

Thank you!

- ◆ RLA Program
 - Education and introspection

- ◆ Dr. Haffty
 - Support and positivity

- ◆ CINJ and Rutgers