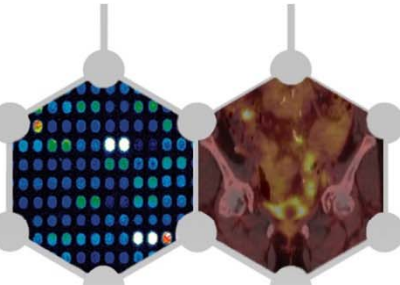
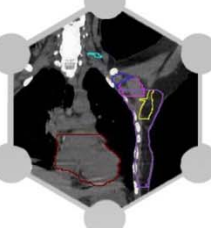


NRG ONCOLOGY

Advancing Research. Improving Lives.™

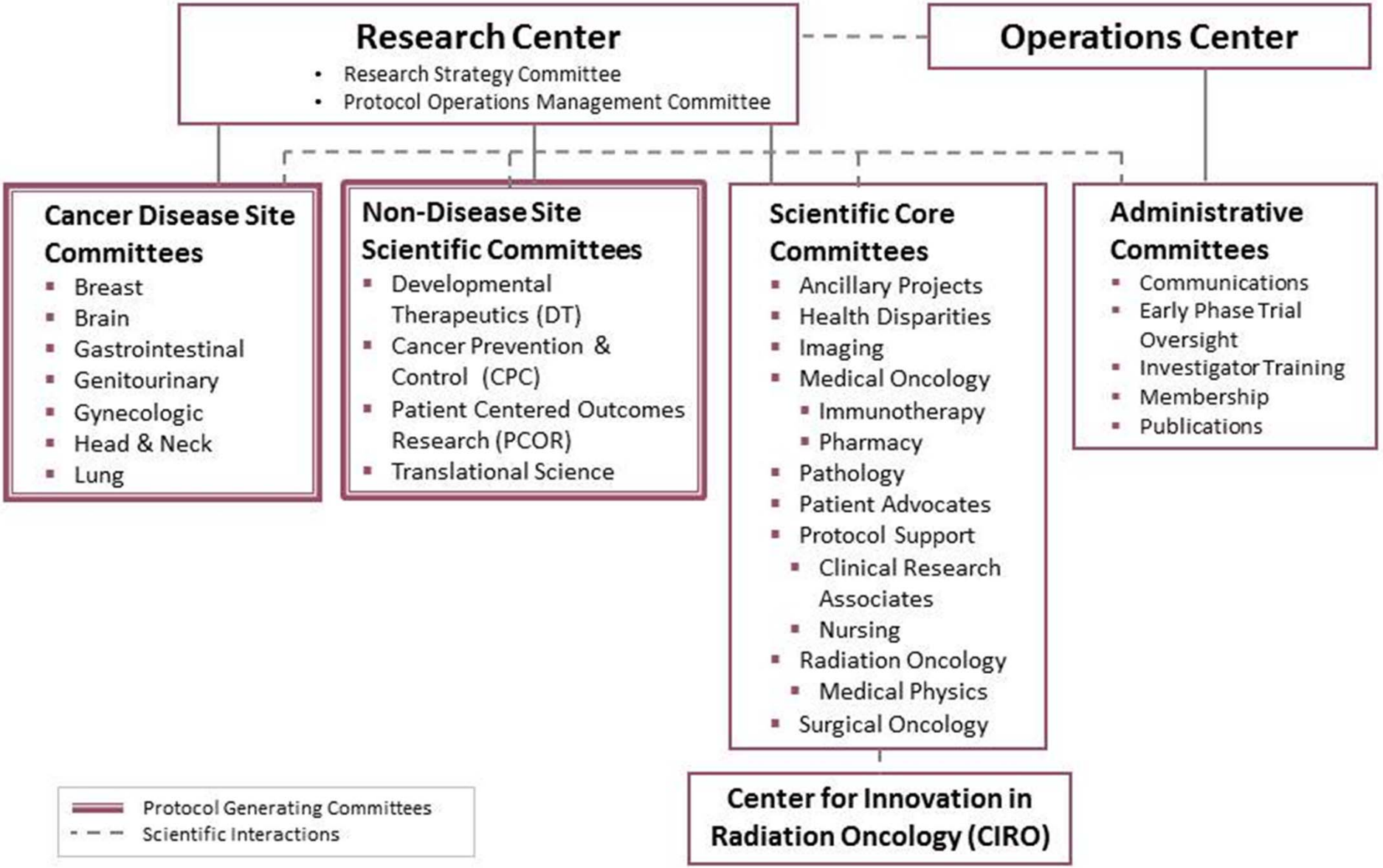


NRG Oncology Research Strategy Overview January 2018

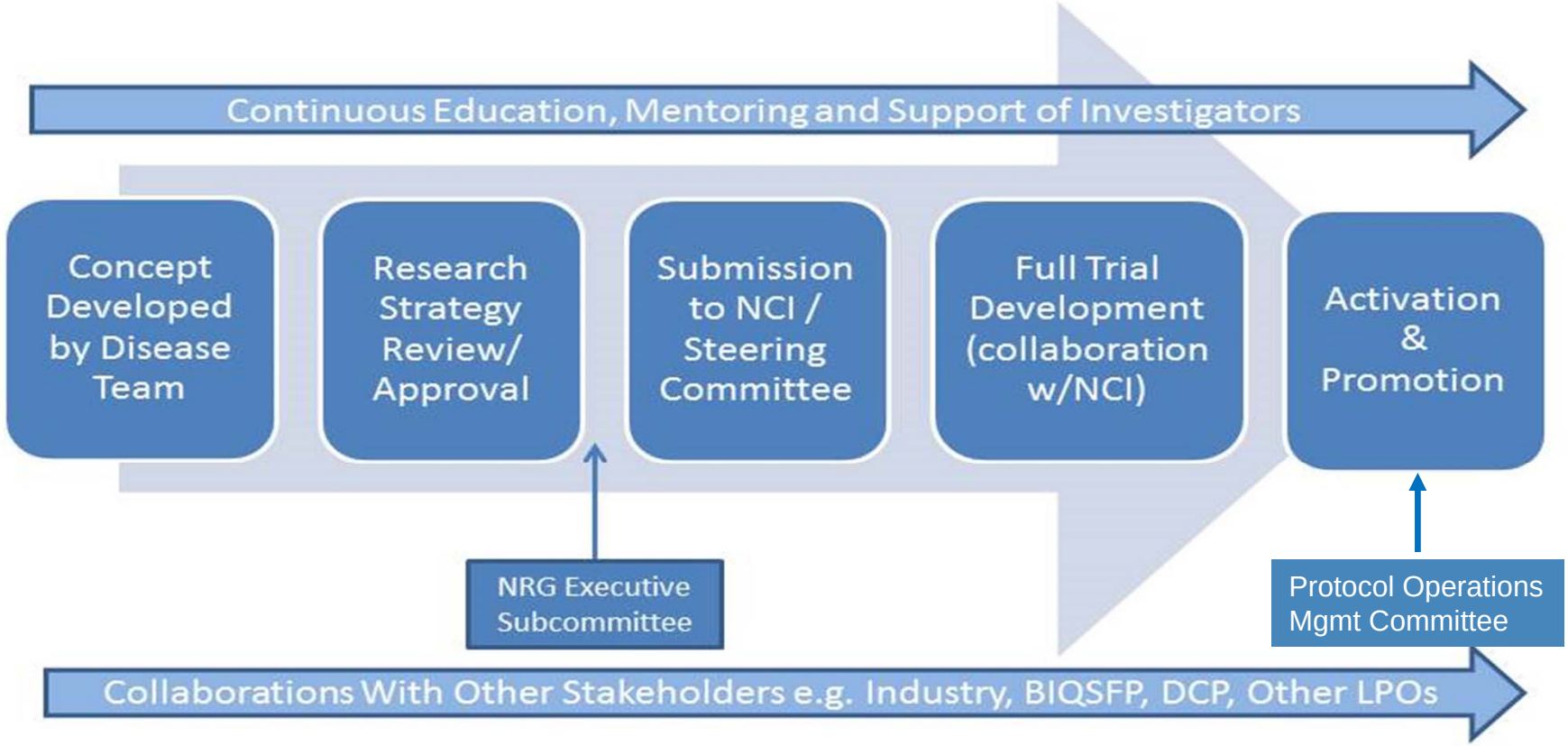
Mitchell Machtay, MD

Deputy Group Chair for Research

NRG Committees/Org Chart

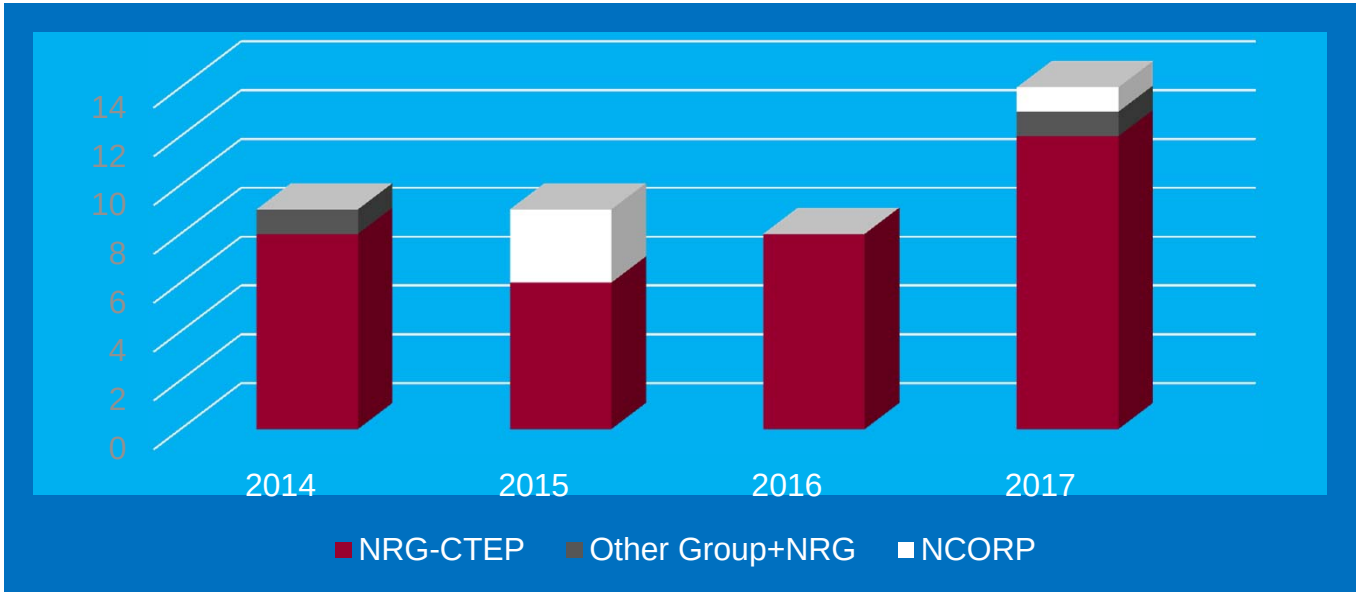


NRG Protocol Development Process



NRG Protocol Metrics

- To Date: 40 NRG trials have been activated/open to enrollment since birth of NRG (3/1/2014): 34 CTEP; 2 Intergroup; 4 NCORP
- 14 studies activated in 2017.
- 42 studies approved by NRG RSC and in development by NRG HQ.



NRG Activations: 2017
14 studies

- **SWOG 1418/NRG BR006**: Breast (TNBC), Adjuvant Pembro.
- **LU002:** Lung (IV): Consolidation RT after chemo.
- **BR005:** Breast: Neoadjuvant chemo/imaging/re-biopsies.
- **GY009:** Ovary (Pt-res): Doxil/Bev +/- Atezolizumab
- **CC004:** Breast/GYN: Buproprion sexual desire.
- **BN003:** Meningioma (Gr.II): Postop RT.
- **GI003:** Hepatocellular CA: Protons vs. Photon RT.
- **GU003:** Prostate (postop): Std. vs. HypoFx RT.
- **BN005**: Glioma: Protons vs. Photon RT.
- **GY011:** Endometrium: Megace +/- Entinostat:
- **DT001:** Sarcoma: RT/AMG-232
- **GI004:** Colorectal (Met, dMMR): Chemo +/- Atezo
- **GU005:** Prostate: RT vs. Radiosurgery
- **HN004:** Head/Neck: Rt/cetuximab vs. RT/durvalumab

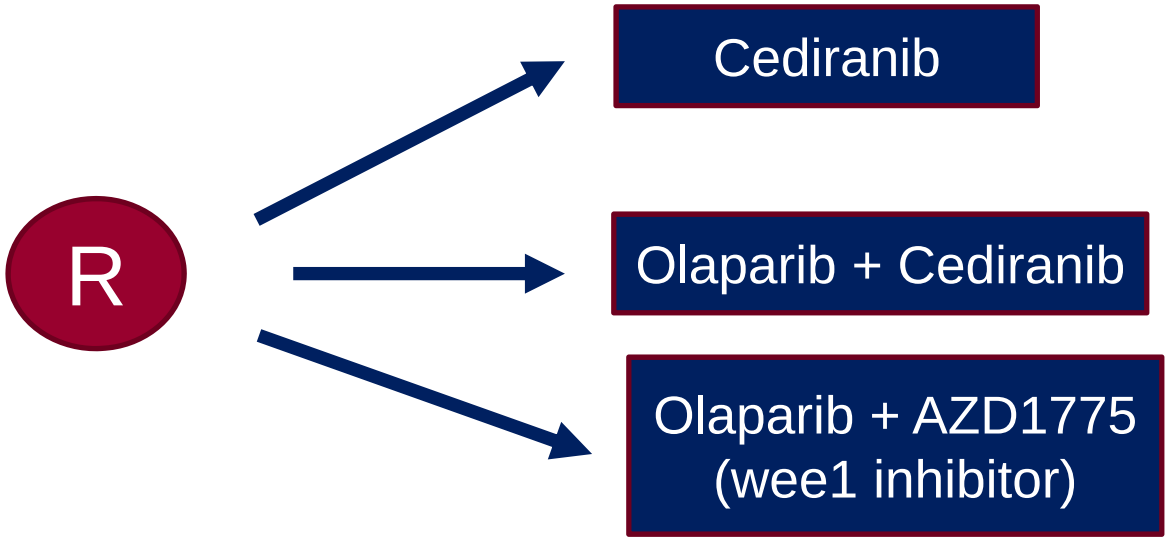
Selected Priorities of the NRG Research Center For the New Grant Period

- Scientific
  - Molecularly targeted/individualized therapies.
  - Circulating DNA/liquid biopsies.
  - Imaging Protocols and Endpoints.
  - Surrogate endpoints for OS.
  - Digital Health Studies.
- Operational
  - Responding to NCI PTMA's.
  - OEWG Timelines.
  - Eligibility Streamlining/Accrual Enhancement.
  - Junior Investigators' Engagement.
  - Ancillary Projects.

Coming Attraction Protocols

•**LU003:** Master CTEP protocol for Metastatic ALK+ NSCLC

•**GY012:** Molecular therapy for Metastatic Endometrial CA



Broadening Eligibility Criteria to Make Clinical Trials More Representative

Joint Recommendations of the American Society of Clinical Oncology and Friends of Cancer Research

Prioritized assessment of specific eligibility criteria: Brain Metastases, Minimum Age, HIV/AIDS, Organ Dysfunction, and Prior and Concurrent Malignancies

Eligibility Priorities
(More to Come)

- Brain Mets: Should not be an automatic exclusion even if not yet treated with local Tx.
- Minimum Age: Consider 12 y.o. threshold.
- HIV: Allow if low risk for AIDS-related outcomes, i.e. controlled with or without HAART.
- Organ dysfunction: Liberalize renal, hepatic, cardiac parameters for eligibility, especially for phase IIR/III studies.
- 2nd Cancer: Allow if > 2 yrs since prior Tx or even concurrent malignancy if treatment not required.

OEWG Timelines

- Phase I/II Studies (including IIR)
  - Target = 210 days from submission to NCI to Activation
  - Absolute Deadline: 450 days
- Phase III Studies
  - Target = 300 days from submission to NCI to Activation
  - Absolue Deadline = 540 days.
- NRG results have typically been closer to absolute deadlines than to targets.
- Goal: Gradual reduction in NRG timelines toward OEWG targets – continuous improvement in communication and anticipation.

Thank You!

NRG Research Strategy Committee:
Saturday 3 p.m.-6 p.m., Rm 102ABC
NRG Investigators welcome -- RSVP to mitchell.Machtay@uhhospitals.org

NRG: Keep Rockin' and Fly Like an Eagle!