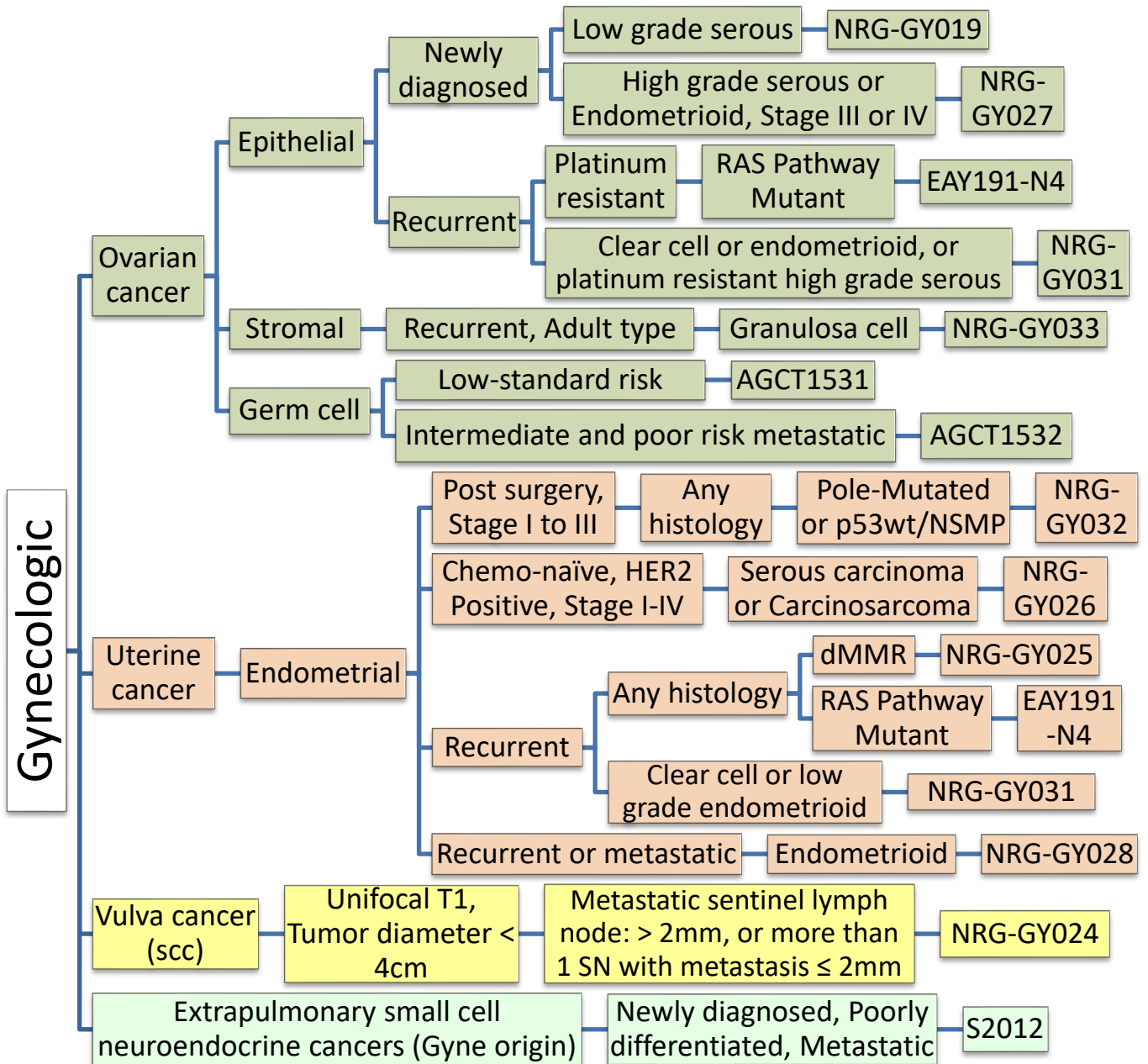# NCTN Gynecologic Cancer Trials Portfolio (Open as of 12/15/2024)
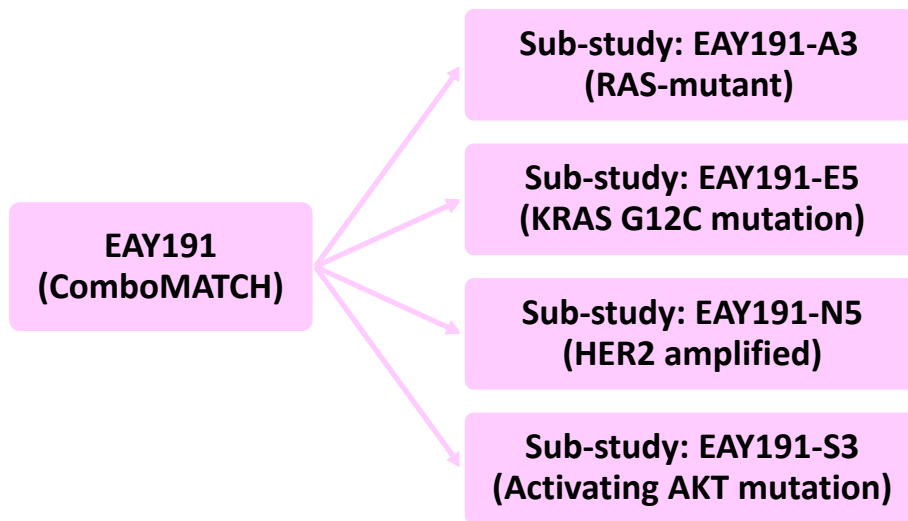
Each far right box includes the NCTN protocol number with a hyperlink to the associated ClinicalTrials.gov webpage. Click on it to view the protocol title and study information.

Gynecologic

- **Ovarian cancer**
  - **Epithelial**
    - **Newly diagnosed**
      - Low grade serous — NRG-GY019
      - High grade serous or Endometrioid, Stage III or IV — NRG-GY027
    - **Recurrent**
      - Platinum resistant — RAS Pathway Mutant — EAY191-N4
      - Clear cell or endometrioid, or platinum resistant high grade serous — NRG-GY031
  - **Stromal**
    - Recurrent, Adult type — Granulosa cell — NRG-GY033
  - **Germ cell**
    - Low-standard risk — AGCT1531
    - Intermediate and poor risk metastatic — AGCT1532

- **Uterine cancer**
  - **Endometrial**
    - Post surgery, Stage I to III — Any histology — Pole-Mutated or p53wt/NSMP — NRG-GY032
    - Chemo-naïve, HER2 Positive, Stage I-IV — Serous carcinoma or Carcinosarcoma — NRG-GY026
    - **Recurrent**
      - Any histology
        - dMMR — NRG-GY025
        - RAS Pathway Mutant — EAY191-N4
      - Clear cell or low grade endometrioid — NRG-GY031
    - Recurrent or metastatic — Endometrioid — NRG-GY028

- **Vulva cancer (scc)**
  - Unifocal T1, Tumor diameter < 4cm — Metastatic sentinel lymph node: > 2mm, or more than 1 SN with metastasis ≤ 2mm — NRG-GY024

- **Extrapulmonary small cell neuroendocrine cancers (Gyne origin)**
  - Newly diagnosed, Poorly differentiated, Metastatic — S2012

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Cross-disease trials:

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                              ┌──────────────────────────┐
                              │  Sub-study: EAY191-A3     │
                           ┌─▶│  (RAS-mutant)             │
                           │  └──────────────────────────┘
                           │
                           │  ┌──────────────────────────┐
┌──────────────────┐       ├─▶│  Sub-study: EAY191-E5     │
│  EAY191          │       │  │  (KRAS G12C mutation)     │
│  (ComboMATCH)    │───────┤  └──────────────────────────┘
└──────────────────┘       │
                           │  ┌──────────────────────────┐
                           ├─▶│  Sub-study: EAY191-N5     │
                           │  │  (HER2 amplified)         │
                           │  └──────────────────────────┘
                           │
                           │  ┌──────────────────────────┐
                           └─▶│  Sub-study: EAY191-S3     │
                              │  (Activating AKT mutation)│
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NCTN Gynecologic Cancer Trials (Open as of 12/15/2024)

Protocol Number	Phase	Protocol Title
AGCT1531	III	A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors
AGCT1532	III	A Randomized Phase 3 Trial of Accelerated Versus Standard BEP Chemotherapy for Patients with Intermediate and Poor-Risk Germ Cell Tumors
NRG-GY019	III	A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum
NRG-GY024	II	Groningen International Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V) III: A Prospective Phase II Treatment Trial
NRG-GY025	II	A Randomized Phase II Trial of Nivolumab and Ipilimumab Compared to Nivolumab Monotherapy in Patients with Deficient Mismatch Repair System Recurrent Endometrial Carcinoma
NRG-GY026	II/III	A Phase II/III Study of Paclitaxel/Carboplatin Alone or Combined with Either Trastuzumab and Hyaluronidase-oysk (HERCEPTIN HYLECTA) or Pertuzumab, Trastuzumab, and Hyaluronidase-zzxf (PHESGO) in HER2 Positive, Stage I-IV Endometrial Serous Carcinoma or Carcinosarcoma
NRG-GY027	I	Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Paclitaxel and Carboplatin with Ipatasertib as Initial Therapy of Ovarian Cancer PTMA 100805
NRG-GY028	I/II	A Phase IB and Randomized Phase II Trial of Megestrol Acetate with or Without Ipatasertib in Recurrent or Metastatic Endometrioid Endometrial Cancer
NRG-GY031	I	A Phase 1B Study of Combination ATR (M1774) and BET Inhibition (ZEN003694) to Exploit ARID1A Loss in Recurrent Ovarian and Endometrial Cancer
NRG-GY032	II	A Phase II Study of Tailored Adjuvant Therapy in Pole-Mutated and p53-Wildtype/NSMP Early-Stage Endometrial Cancer (RAINBO BLUE & TAPER)
NRG-GY033	II	A Phase II Study of Androgen Receptor (AR) Inhibition by Darolutamide in Combination with Leuprolide Acetate and Exemestane in Recurrent Adult-Type Ovarian Granulosa Cell Tumor
S2012	II/III	Randomized Phase II/III Trial of First Line Platinum/Etoposide with or Without Atezolizumab (NSC#783608) in Patients with Poorly Differentiated Extrapulmonary Small Cell Neuroendocrine Carcinomas (NEC)
EAY191	Other	Molecular Analysis for Combination Therapy Choice (ComboMATCH)
EAY191-A3	II	Palbociclib and Binimetinib in RAS-Mutant Cancers: A ComboMATCH Treatment Trial
EAY191-E5	II	A Randomized Phase II Study of AMG 510 (Sotorasib) with or Without Panitumumab in Advanced Solid Tumors: A ComboMATCH Treatment Trial
EAY191-N4	II	A Randomized Trial of Selumetinib and Olaparib or Selumetinib Alone in Patients with Recurrent or Persistent RAS Pathway Mutant Ovarian and Endometrial Cancers: A ComboMATCH Treatment Trial
EAY191-N5	II	A Randomized Trial of Neratinib, A Pan-ERBB Inhibitor, Alone or in Combination with Palbociclib, a CDK4/6 Inhibitor, in Patients with HER2+ Gynecologic Cancers and Other Solid Tumors: A ComboMATCH Treatment Trial
EAY191-S3	II	Phase 2 Study of Paclitaxel (NSC #673089) + Ipatasertib (NSC #781451) in Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors: A ComboMATCH Treatment Trial

This portfolio shows NCTN trials. For information about NCORP trials, please see: https://ncorp.cancer.gov/find-a-study/