

Gynecologic Cancer Clinical Trials



- NRG CC010: A Phase III Trial Of The Impact Of Sentinel Lymph Node Mapping On Patient Reported Lower Extremity Limb Dysfunction In Endometrial Cancer
- <u>SISTER study</u>: A prospective, open label, randomized controlled trial of social interventions to support Black people with high-risk EC recommended for adjuvant treatment
- NRG GY026: Testing the Addition of Trastuzumab or Trastuzumab/ Pertuzumab to the Usual Chemotherapy for HER2 Positive Endometrial Serous Carcinoma or Carcinosarcoma
- XPORT: Selinexor in Maintenance Therapy After Systemic Therapy for Participants with p53 Wild-Type, Advanced or Recurrent Endometrial Carcinoma (XPORT-EC-042)
- GOG3088: randomized phase II study of letrozole versus observation in patients with newly diagnosed uterine leiomyosarcoma
- NRG GY032: A Phase II Study of Tailored Adjuvant Therapy in POLE-Mutated and p53wildtype/NSMP Early-Stage Endometrial Cancer (RAINBO BLUE & TAPER)
- <u>S2012</u>: Evaluating the addition of immunotherapy drug atezolizumab to standard chemotherapy treatment for advanced or metastatic neuroendocrine carcinomas that originate outside the lung

Uterine Cancer Clinical Trials

Recurrence amenable to platinum therapy

- SISTER: A prospective, open label, randomized controlled trial of social interventions to support Black people with high-risk EC recommended for adjuvant treatment
- XPORT: Selinexor in Maintenance Therapy After Systemic Therapy for Participants with p53 Wild-Type, Advanced or Recurrent Endometrial Carcinoma (XPORT-EC-042)

- <u>SISTER</u>: A prospective, open label, randomized controlled trial of social interventions to support Black people with high-risk EC recommended for adjuvant treatment
- <u>DiRECT</u>: An Observational Research Study for Cancer Patients on Immune Checkpoint Inhibitors, DiRECT Study
- ACRIVON/GOG 3082: A phase Ib/2 basket study of CR-368 as monotherapy and in combination with gemcitabine in adult subjects with platinum-resistant ovarian carcinoma, endometrial adenocarcinoma and urothelial carcinoma based on ACRIVON Oncosignature Status.
- GOG 3095: Phase 3, Randomized, Active-controlled, Open-label, Multicenter Study to
 Compare the Efficacy and Safety of Sacituzumab
 tirumotecan Versus Treatment of Physician's Choice
 in Participants With Endometrial Cancer Who Have
 Received Prior Platinum-based Chemotherapy and
 Immunotherapy (MK-2870-005)
- DURAFAK: A phase 2 study of avutometinib plust defactinib in recurrent gynecologic cancers with known RAS mutation, BRAF (type I, II and III) mutation, NF-1 and/or RAS activation
- <u>EAY191-N4</u>: (RAS mutant ovarian or endometrial cancer treated with selumetinib and olaparib): Targeted therapy directed by genetic testing in treating Patients with Locally Advanced or Advanced Solid Tumors, the ComboMATCH Screening trial.

Recurrence beyond platinum therapy

Initial diagnosis





Cervical Cancer Clinical Trials

- Early stage:
- GOG 3043 (ROCC): A Randomized Controlled Trial of Robotic vs. Open Radical Hysterectomy for Cervical Cancer (ROCC Trial)
- · Advanced or locally advanced:
- <u>DiRECT</u>: An Observational Research Study for Cancer Patients on Immune Checkpoint Inhibitors, DiRECT Study
- S2012: Evaluating the addition of immunotherapy drug atezolizumab to standard chemotherapy treatment for advanced or metastatic neuroendocrine carcinomas that originate outside the lung

Initial diagnosis

Recurrent disease

- <u>DiRECT</u>: An Observational Research Study for Cancer Patients on Immune Checkpoint Inhibitors, DiRECT Study
- <u>STAR:</u> Phase II trial of niraparib in combination with dostarlimab in patients with recurrent or progressive cervix cancer (STAR)
- <u>SWOG s2012 (neuroendocrine)</u>: Evaluating the addition of immunotherapy drug atezolizumab to standard chemotherapy treatment for advanced or metastatic neuroendocrine carcinomas that originate outside the lung
- GOG 3101/Trofuse020: A phase III Randomized active-controlled, openlabel multicenter study to compare the efficacy and safety of Sacituzumab tirumotecan versus treatment of physician's choice as 2nd or 3rd line treatment for participants with recurrent or metastatic cervical cancer
- <u>DURAFAK</u>: A phase 2 study of avutometinib plust defactinib in recurrent gynecologic cancers with known RAS mutation, BRAF (type I, II and III) mutation, NF-1 and/or RAS activation

Ovarian Cancer Clinical Trials

•GOG 3068 (HOTT) Heated Intraperitoneal Chemotherapy Followed by Niraparib for Ovarian, Primary peritoneal and Fallopian Tube Cancer

Initial diagnosis

Platinum sensitive Recurrence

- Gloriosa / GOG 3078: A randomized. open-label, phase 3 study of mirvetuximab soravtansine with bevacizumab vs. bevacizumab as maintenance in platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer.
- •RAMP 301 (low grade): A Study of Avutometinib (VŠ-6766) + Defactinib (VS-6063) in Recurrent Low-Grade Serous Ovarian Cancer (RAMP 301)

- DIRECT: An Observational Research Study for Cancer Patients on Immune Checkpoint Inhibitors, DiRECT Study
- RAMP 301 (low grade): A Study of Avutometinib (VS-6766) + Defactinib (VS-6063) in Recurrent Low-Grade Serous Ovarian Cancer (RAMP 301)
- DURAFAK: A phase 2 study of avutometinib plus defactinib in recurrent gynecologic cancers with known RAS mutation, BRAF (type I. II and III) mutation. NF-1 and/or RAS activation
- EA191-A3: Cohort 2 (RAS Mutant Low grade serous ovarian cancer treated with palbociclib and binimetinib). Targeted therapy directed by genetic testing in treating Patients with Locally Advanced or Advanced Solid Tumors, the ComboMATCH Screening trial.
- EAY191-N4: (RAS mutant ovarian or endometrial cancer treated with selumetinib and olaparib): Targeted therapy directed by genetic testing in treating Patients with Locally Advanced or Advanced Solid Tumors, the ComboMATCH Screening trial.

Platinum resistant recurrence





Other trials

BASKET

- <u>DURAFAK</u>: A phase 2 study of avutometinib plust defactinib in recurrent gynecologic cancers with known RAS mutation, BRAF (type I, II and III) mutation, NF-1 and/or RAS activation
- <u>EAY191-E5</u>: Advanced solid tumors with KRAS G12C mutation treated with sotorasib and panitumumab: Targeted therapy directed by genetic testing in treating Patients with Locally Advanced or Advanced Solid Tumors, the ComboMATCH Screening trial.
- <u>EAY191-N4:</u> Advanced ovarian or endometrial cancers with RAS pathway mutation treated with selumetinib and olaparib: Targeted therapy directed by genetic testing in treating Patients with Locally Advanced or Advanced Solid Tumors, the ComboMATCH Screening trial.
- <u>EAY191-N5</u>: Advanced (non breast) HER2 amplified solid tumors treated with neratinib and palbociclib: Targeted therapy directed by gene tic testing in treating Patients with Locally Advanced or Advanced Solid Tumors, the ComboMATCH Screening trial.
- <u>EAY191-S3</u>: Non breast solid tumor, locally advanced unresectable or metastatic with activating AKT, PTEN mutation or deletion/loss of PTEN with ipasertib and paclitaxel: Targeted therapy directed by genetic testing in treating Patients with Locally Advanced or Advanced Solid Tumors, the ComboMATCH Screening trial.

RARE

- <u>S2012</u> (neuroendocrine): Evaluating the addition of immunotherapy drug atezolizumab to standard chemotherapy treatment for advanced or metastatic neuroendocrine carcinomas that originate outside the lung
- RAMP 301 (low grade): A Study of Avutometinib (VS-6766) + Defactinib (VS-6063) in Recurrent Low-Grade Serous Ovarian Cancer (RAMP 301)
- GOG3088 (uterine leiomyosarcoma): randomized phase II study of letrozole versus observation in patients with newly diagnosed uterine leiomyosarcoma

Prevention/cancer control

- NRG CC008/SOROC: A Study to Compare Two Surgical Procedures in Individuals With BRCA1 Mutations to Assess Reduced Risk of Ovarian Cancer
- <u>CC012/SYMON</u>: Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

Non-therapeutic

• <u>DIRECT</u> An Observational Research Study for Cancer Patients on Immune Checkpoint Inhibitors, DiRECT Study

Phase I trials



