NRG ONCOLOGY

Advancing Research. Improving Lives.™

The Recruitment Recipe: Ingredients for Trial Success

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NCI National Clinical Trials Network — a National Cancer Institute program

NCI Community Oncology Research Program — A program of the National Cancer Institute of the National Institutes of Health

Poll 1

How does your site recruit? Tell us in the chat function.

Pre-screening

- Pre-screening best practices
  - Weekly reviews of the next weeks clinic
  - Emails to the clinical team with a list of all active patients and what is needed for the visit and what potentials there are

Potential Patient List

- For patients that have been referred for a clinical trial review, it is helpful to track and review those patients at weekly meetings to ensure no one slip through the cracks
- Goal for UVA team is response to referring provider within 48 hours of the referral with a review

Internal V External	Referral Source	Name	MRN	Date of referral	Potential studies	CRC reviewing	Treating Doctor	Contact by study team	IV Date or next appointment	Notes	Last updated Date

Referral Email Process

- Stage/grade/histology at top
- Mutations
- Treatment History with line count (including hormonal therapies and RT)
  - Start and stop dates
- Review of trials that patient was prescreened for:
  - Including reason for exclusion or ineligibility is as important as being potentially eligible
- Email response back from referring MD confirms treatment history and line count
- Cross-trains staff on trials that they are not lead on

Example

Hello team,

I have reviewed her for clinical trials. Unfortunately she is ineligible for GY025 due to prior IO and mmr status.

Stage II Grade 1 Endometroid adenocarcinoma. MMRp AR+, PDL1+, PIK3CA PV, PIK3R1 PV, TP53 PV

History:

4/16/2021 TLHBSO
7/26/2021 RT w/ brachy
7/2024 recurrence
LINE 1: 8/6/2024-11/20/2024 6 cycles carb/tax
9/8/2025 progressed on imaging
LINE 2: 9/2025 Megace
12/30/2025 progressed on imaging
LINE 3: 1/23/2026 Lenvatinib/pembro

GY025- ineligible, prior IO and mmrp
DESTINY- ineligible, prior IO and too many prior lines
ACRIVON – ineligible, only allowing high grade, carcinosarc, or serous right now.
REPARE- Ineligible, no actionable mutations
N4- @Pittaro, Alexa M *HS could you review? Biopsy required
Constellation- ineligible, P53 mutated, too many prior lines
10486- ineligible, requires prior parp
NIKANG- ineligible, no actionable mutations
GY035- ineligible, no prior IO

Side note: for most mutations, “quality not suffiecient” on caris, could she benefit from additional testing? Would be helpful for trial screening.

Thank you,

Email Template

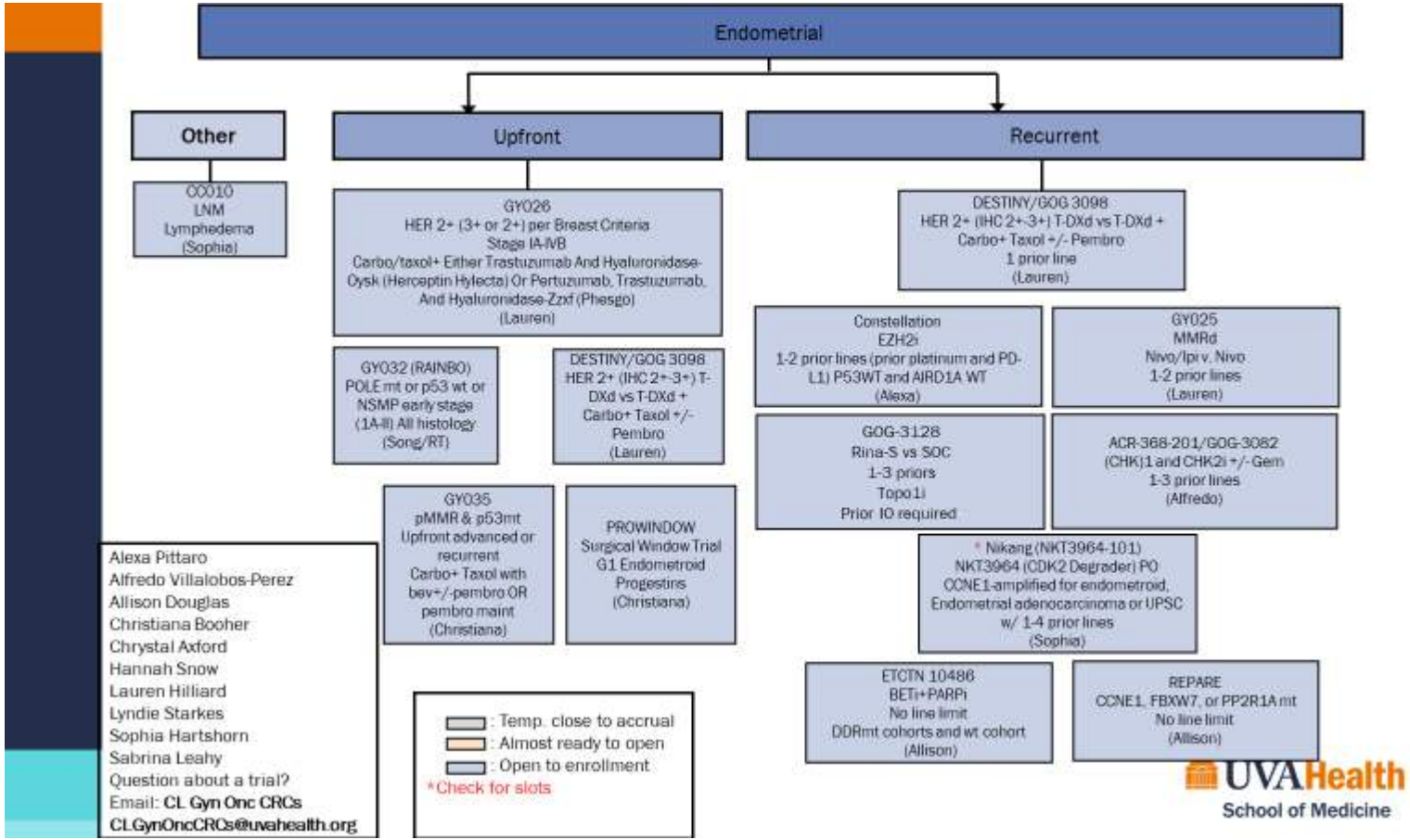
Monday, July 13th
Provider's Name
Patient Name, MRN, (Appointments of the day and times) IRB number, Name of study, Timepoint- what needs to happen that day - CRC name

[redacted](PI@9:40, Clinic @10;45, Inf@1:30) **HSR302306 MK5909-003 B-1 Cohort-4.0mg/kg R-DXd+Bev C10D1**– Needs AE/Con Med review, Symptom guided PE w/ ECOG, & Vitals (height & weight required) in clinic. CBC w/ diff, CMP,UA reflex, UPCR, Mag, Phos, Lipase, Tbili, & CA-125. Research tubes to be collected PRIOR to infusion START. -[redacted]

[redacted](1st Floor Lab@10:15, Clinic@10:45, CT @4:45) **GOG-3115 Protocol V4** HSR302543 Screening – Needs Complete Physical Exam (No Pelvic), MH, ECOG, AEs (related to carboplatin), ConMeds, Vitals w/height, CBC w/diff, CMP, Mag, Phos, Uric Acid, Direct Bili, CA-125, Urinalysis w/reflex micro, PROs, PT/PT-INR, PTT -[redacted]

Clinic Cheat Sheets

- Clinic “cheat sheets” showing key eligibility and what trials are available (we do a “trial tree”)
  - Primary tumor-> treatment setting-> Line Limit
  - Mutations/exclusionary prior treatments
  - If slots are required
  - Contacts for each trial within the CRC team
  - What is about to open
  - What treatments are involved
- Shared with referring providers
  - Based on info publicly available (clinicaltrial.gov)
    - Not an advertisement


Endometrial
Other
Upfront
Recurrent
CC010
LNM
Lymphedema
(Sophia)
GY026
HER 2+ (3+ or 2+) per Breast Criteria
Stage IA-IVB
Carbo/taxol+ Either Trastuzumab And Hyaluronidase-Oysk (Herceptin Hylecta) Or Pertuzumab, Trastuzumab, And Hyaluronidase-Zzxf (Phesgo)
(Lauren)
GY032 (RAINBO)
POLE mt or p53 wt or NSMP early stage (1A-II) All histology
(Song/RT)
DESTINY/GOG 3098
HER 2+ (IHC 2+-3+) T-DXd vs T-DXd + Carbo+ Taxol +/- Pembro
(Lauren)
GY035
pMMR & p53mt
Upfront advanced or recurrent
Carbo+ Taxol with bev+/-pembro OR pembro maint
(Christiana)
PROWINDOW
Surgical Window Trial
G1 Endometroid
Progestins
(Christiana)
DESTINY/GOG 3098
HER 2+ (IHC 2+-3+) T-DXd vs T-DXd + Carbo+ Taxol +/- Pembro
1 prior line
(Lauren)
Constellation
EZH2i
1-2 prior lines (prior platinum and PD-L1) P53WT and ARID1A WT
(Alexa)
GY025
MMRd
Nivo/Ipi v. Nivo
1-2 prior lines
(Lauren)
GOG-3128
Rina-S vs SOC
1-3 priors
Topo1i
Prior IO required
ACR-368-201/GOG-3082
(CHK)1 and CHK2i +/- Gem
1-3 prior lines
(Alfredo)
* Nikang (NKT3964-101)
NKT3964 (CDK2 Degrader) PO
CCNE1-amplified for endometroid, Endometrial adenocarcinoma or UPSC
w/ 1-4 prior lines
(Sophia)
ETCTN 10486
BETi+PARPi
No line limit
DDRmt cohorts and wt cohort
(Allison)
REPARE
CCNE1, FBXW7, or PP2R1A mt
No line limit
(Allison)
Alexa Pittaro
Alfredo Villalobos-Perez
Allison Douglas
Christiana Booher
Chrystal Axford
Hannah Snow
Lauren Hilliard
Lyndie Starkes
Sophia Hartshorn
Sabrina Leahy
Question about a trial?
Email: CL Gyn Onc CRCs
CLGynOncCRCs@uvahealth.org
: Temp. close to accrual
: Almost ready to open
: Open to enrollment
*Check for slots
UVA Health
School of Medicine

Endometrial - Upfront trials

Name	Status	Type	CRC/PI	Stage/histology/subtype/prior lines	Treatment
GY026 (HSR302261)	OTE: Phase 3	NRG	Lauren/Ring	• HER2-expressing (IHC 3+/IHC 2+) per Breast Criteria • Stage I-IV • All Histology's accepted • measurable/non-measurable/no measurable disease • pMMR • must be within 8 weeks of primary surgery • no prior chemo, RT, biologic therapy or targeted therapy for endometrial cancer (prior hormonal therapy allowed) • Brachy allowed on trial	Paclitaxel/Carboplatin Alone Or Combined With Either Trastuzumab And Hyaluronidase-Oysk (Herceptin Hylecta) Or Pertuzumab, Trastuzumab, And Hyaluronidase-Zzxf (Phesgo)
DESTINY/GOG 3098 (HSR302414)	OTE: Phase 3	GOG	Lauren/Gehrig	• HER2-expressing (IHC 3+/IHC 2+) pMMR primary advanced (Stage III or IV) or recurrent (Any stage) endometrial cancer (epithelial, all histologies except sarcomas, but carcinosarcoma IS allowed) • either chemo naive or for first recurrence 1 prior line • no prior IO • Stage III upfront must have measurable disease • Stage IV upfront and first recurrent doesn't have to have measurable disease	Trastuzumab Deruxtecan (T-DXd) with Rilvegostomig or Pembrolizumab versus Carboplatin and Paclitaxel with Pembrolizumab

GY032 (RAINBO)	OTE:	NRG	Songserea Wood/Romano	• Study A-1:
				  • Endometrial carcinoma (all histologies)
				  • P53wt, MMRp
				  • FIGO I-III
				• Sub-study B:
				  • Endometroid histology only
				  • ER+ (≥ 67% IHC), p53 wt, MMRp
				  • No substantial/extensive LVSI
				  • FIGO I-III
					Observation v Vaginal Brachytherapy

Importance of Cycle Checklists

✓ Keeps Protocols on Track	Clearly identifies protocol-required procedures, labs, imaging, and assessments for each treatment cycle.
✓ Improves Patient Safety	Ensures required safety assessments and treatment requirements are completed before treatment, when applicable.
✓ Supports Cross-Coverage	Provides a standardized roadmap so any Research RN or Research Scientist can quickly understand visit requirements.
✓ Reduces Missed Procedures	Organizes cycle-specific requirements to minimize omissions and protocol deviations.
✓ Improves Efficiency	Reduces time spent searching lengthy protocols and streamlines visit preparation.
✓ Enhances Audit Readiness	Supports complete, consistent documentation and regulatory compliance.

Example of Cycle Checklist

SCREENING (Sacituzumab Govitecan and Physician's Choice Chemo)

Within 28 days of C1D1:

- Informed consent (x3)
- Inclusion/exclusion criteria
- Medical history & Demographics
- Baseline AE & Con Med Assessment
- Full physical exam
- ECOG
- Vital signs (including height and weight)
- Tumor tissue availability
- MMR/MSI & HER2 status (if known)
- **ECG (enter MRN in referred by section)**
- **CT scan chest/abdomen/pelvis**
- **ECHO or MUGA**
- Labs:
  - CBC/diff
  - CMP
  - **Mg**
  - **P04**
  - **PT/INR & PTT or aPTT**
  - **LDH**
  - **Uric Acid**
  - **UA/C**
  - **HIV-1 & HIV-2 antibody (HIV Screen)**
  - **Hepatitis B surface antigen (HBsAg)**
  - **Hepatitis B core antibody (HBcAb)**
  - **Hepatitis C antibody (HCV)**
  - **Serum FSH & serum pregnancy test (WOCBP only)**

C1D1: (Sacituzumab Govitecan 21-day cycle)

- PRO Assessments on tablet (should be completed before physician sees pt.)
- Full physical exam
- ECOG
- Vital signs
- AE & Con Med Assessment
- Labs:
  - CBC/diff
  - CMP
  - **Mg**
  - **P04**
  - **Urine pregnancy test (WOCBP only)**
- Study Labs:
  - UG1A1 genotype
  - Blood sample for MSI testing
  - ctDNA
  - OPTIONAL blood sample for genomic analyses (prior to first dose of study drug)
  - PK (pre-dose ≤ 30min before start of infusion)
  - Immunogenicity/ADA serum samples (pre-dose ≤ 30min before start of infusion)
  - PK (EOI +10 minutes)

***Tests/procedures in bold text paid for by study**

Tumor assessments: Due every 6 weeks ± 7 days from the date of randomization for the first 30 weeks, then every 9 weeks ± 7 days thereafter

Standardized Documentation

- **Promotes Consistency**

  Ensures every research participant is documented using the same format across the team.

- **Captures Critical Trial Information**

  UNMCCC note templates standardize cycle/day, assessments, AEs, dose modifications, labs, concomitant medications, study procedures, and next required activities.

- **Supports Cross-Coverage**

  Allows any Research RN or Research Scientist to quickly understand a patient's study status.

- **Improves Compliance**

  Creates complete, consistent, audit-ready documentation that supports GCP, FDA, NCI, and sponsor expectations.

- **Enhances Patient Safety**

  Reduces omissions, improves communication, and strengthens data quality.

Standardized Documentation: Consent Note

Protocol Information	• Protocol number/name • Consent & protocol version • Screening ID	**Correct study documents**
Consent Timeline	• Consent date • HIPAA date • Regulatory timeline	**Key regulatory dates**
Informed Consent Process	• Alternatives discussed • Teach-back performed • Questions answered	**Participant understanding**
Interpreter Documentation	• Interpreter details • Language documented • HIPAA interpreted	**Accurate communication**

Standardized Documentation: Consent Note

Regulatory Compliance

- Patient copy provided
- Medical records updated
- CTMS System updated

Audit-ready records

Participant Eligibility

- Child-bearing status
- Contraception
- Sterile status

Eligibility & safety

RN/Coordinator Notes

- Study-specific notes
- Unique participant circumstances

Consistent documentation

Standardized Infusion Worksheet

💉 Improve Patient Safety
- Step-by-step protocol guidance
- Reduces missed assessments
- Supports safe study drug administration

⏰ Streamline Workflow
- Chronological visit timeline
- Coordinates labs, vital signs & observation
- Improves efficiency for complex visits

🤝 Enhance Communication
- Shared reference for research & infusion teams
- Clarifies protocol-specific instructions
- Supports laboratory coordination

✅ Promote Compliance
- Standardizes documentation
- Reinforces required timing windows
- Improves audit readiness

Standardized infusion worksheets simplify complex protocol requirements into a clear workflow that supports patient safety, nursing efficiency, and protocol compliance.

Standardized Infusion Worksheet: Example

Date: _____

Patient: _____ **MRN:** _____ **Subject ID:** _____

Cycle 1 Day 1

PROTOCOL:

Access port for study drug administration, but venipuncture will be needed post treatment for study lab collection below. Please call _____ for study lab pick up after each collection. Tubes will be provided to you upon patient's arrival to infusion suite.

STUDY TREATMENT ADMINISTRATION:

Administer the first infusion over 30 minutes

Pre-dose

- Study labs: Collect pre-dose study labs (PK-Tab, PK-ADC, PK-PL, ADA, BM, ctDNA) before infusion (≤ 60 minutes before start of infusion). **Can collect via port draw.

  Time collected: _____

  Infusion start time: _____
- Vital Signs: (Please record in Mosaiq)

  Within 30 minutes of start of Rina -S:

  Time VS obtained: _____

End of infusion

- Vital Signs: (Please record in Mosaiq)

  Within 10 minutes after completion of Rina -S:

  Time VS obtained: _____
- Study labs: Collect EOI study lab (PK) after infusion is completed (within 15 minutes). **Please perform a venipuncture for this lab draw.

  Infusion stop time: _____

  Time collected: _____

***Patients are required to be observed for 2 hours post infusion for C1D1:**

Observation START time: _____

Observation END time: _____

Infusion RN signature: _____ ***Date:*** _____

Outreach

- Clinical Population Outreach
  - Look for other clinical trial sites in your area and ways to collaborate
    - NRG Committees and meetings are a great way to do this
  - Foster relationships with external referral sources (i.e. private practice, non-research sites)
    - Emphasis on shared patient care
    - Not taking patients away from them
  - IRB approved advertising, if submitted properly, allows for emailing of trial information to external providers
    - Monthly email blasts about trials to
- Patient Population Outreach

Tips and Tricks

- Tumor board Attendance
  - If your site has a tumor board, attend and pre-screen there
  - Give “trial talks” or announce trials at tumor board to increase provider awareness
- Fellow/Resident Education
  - Since trainees are often prepping for clinics and seeing new referrals, it is helpful to give lectures as a part of their training for both them and the research team
- Resources
  - Familiarize yourself with clinicaltrials.gov
    - What other sites are in your area or in your patient’s area

Poll 2

Who consents at your site?

PI or CRC or other?

Who obtains consent?

- CRCs are easier to say no to then the patient's treating physician
- The treating physician can weigh in, introduce the trial and answer questions
- Best practice- have the CRC review the trial and answer non-clinical related questions without the treating provider present
    - Allows patient to be separated from participant during recruitment process

Eliminating Bias

- Prescreen patients blinding yourself to race/ethnicity, geographic location and socioeconomic factors
  - Do not include these in your initial review as what you are looking for is clinical fit to the trial
  - Language is important because you need the ICF in their language but should not limit who you approach
- Offering trial to every person eligible
  - Unless there is a true extenuating circumstance (unable to provide consent, unequal risk benefit ratio), do not take the decision making power away from the patient
  - Be easy to say no to

Matching Opportunities to Population

- Matching trials to population of your clinic
  - AKA looking for holes
  - Tracking the reasons people are not eligible for trials, (even without identifiers) allows you to better understand your clinic population
  - Matching trials and selecting astutely what you open will result in high accrual due to high match with the population
    - For instance, a survey of Native Alaskan population in the UVA catchment area would not be feasible as the clinic population has 0% Native Alaskan
- Understand geographically where trials are open and if possible complement each other as opposed to compete
  - If you and a neighboring clinic within driving distance have the same trial open, you are competing for the same population, but if you have an alternative option, you can refer back and forth

Any questions?