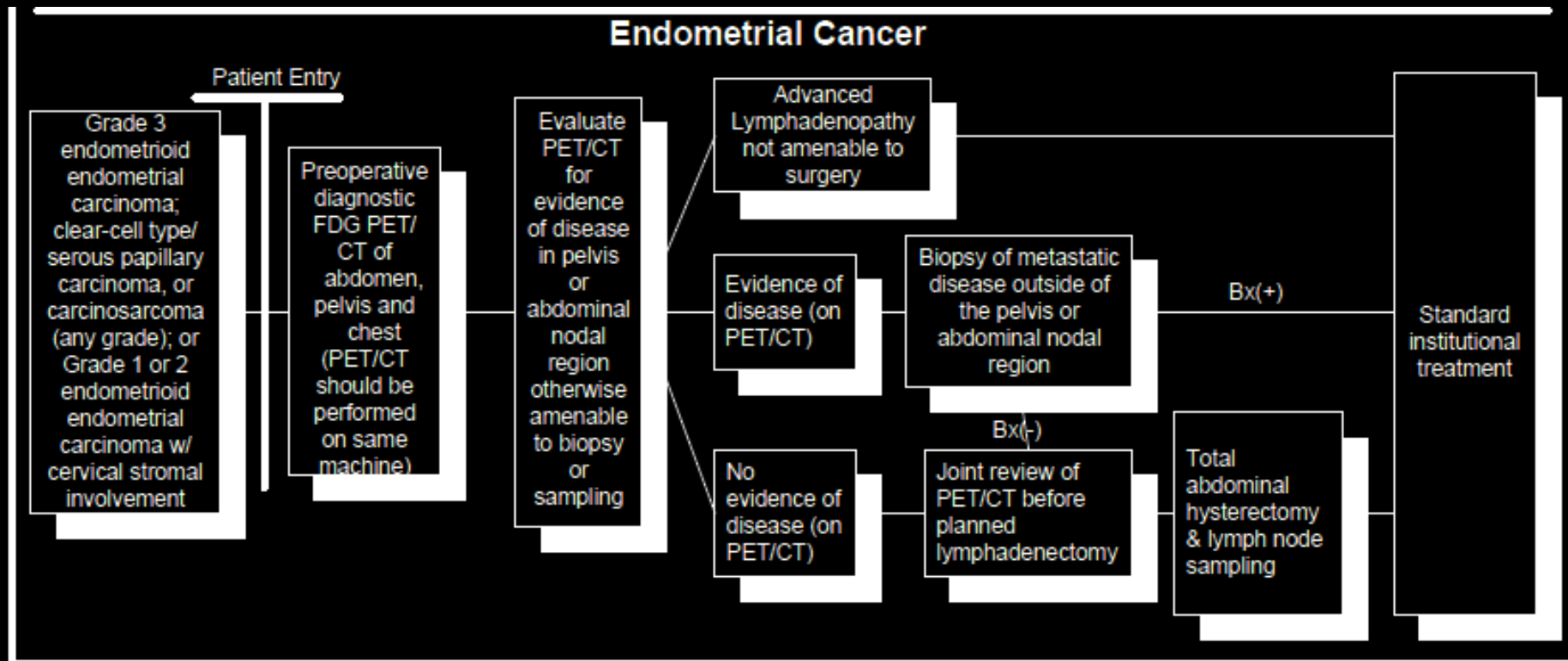


GOG

Uterine Corpus Committee

GOG0233/ACRIN 6671: Preoperative FDG-PET/CT to Detect Lymph Node Metastasis



Activated 9/24/07

Revised 6/9/08, 9/9/08, 11/12/08, 6/1/09, 11/16/09, 6/27/11, 7/2/12

Closed 12/3/12

Endometrial: Stage I/II Adjuvant

GOG 0249

Eligible:

- Stage I* endometrioid-type endometrial carcinoma, with high-intermediate risk factors with (+) or without (-) cytology
- Stage II* endometrial carcinoma (any histology), with or without risk factors
- Stage I-II* serous or clear cell endometrial carcinoma with negative cytology, with or without other risk features

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Regimen I:

- Pelvic Radiation Therapy (4500/25 fractions-5040 cGy/28 fractions) over 5-6 weeks
- Optional Vaginal Cuff Boost ONLY for Stage II patients and Stage I patients with papillary serous and clear cell carcinomas

Regimen II:

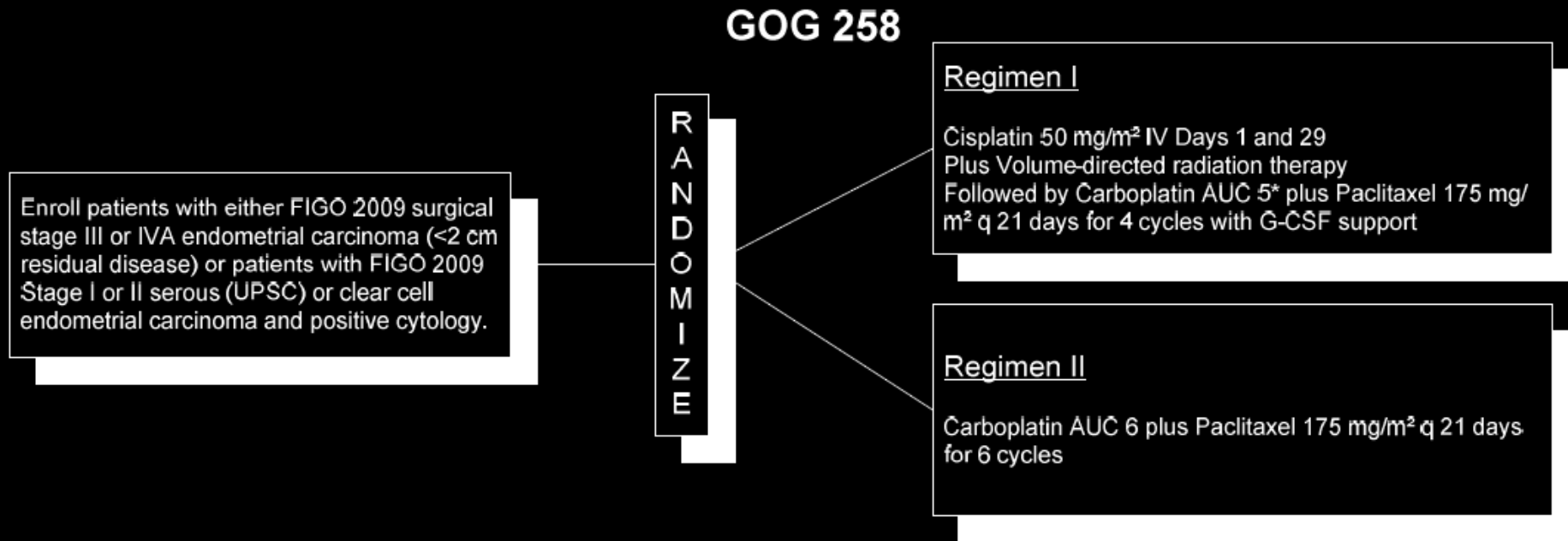
- Vaginal Cuff Brachytherapy + 3 cycles of chemotherapy* consisting of:
 - Paclitaxel 175 mg/m² (3hr) + Carboplatin AUC 6 q 21 days

*To start within 3 weeks of initiating brachytherapy

* FIGO 2009 Staging Criteria

- 3/23/2009 – 2/4/2013 Completed
- Endorsed by RTOG
- 562 accrued

Endometrial: Stage III/IV



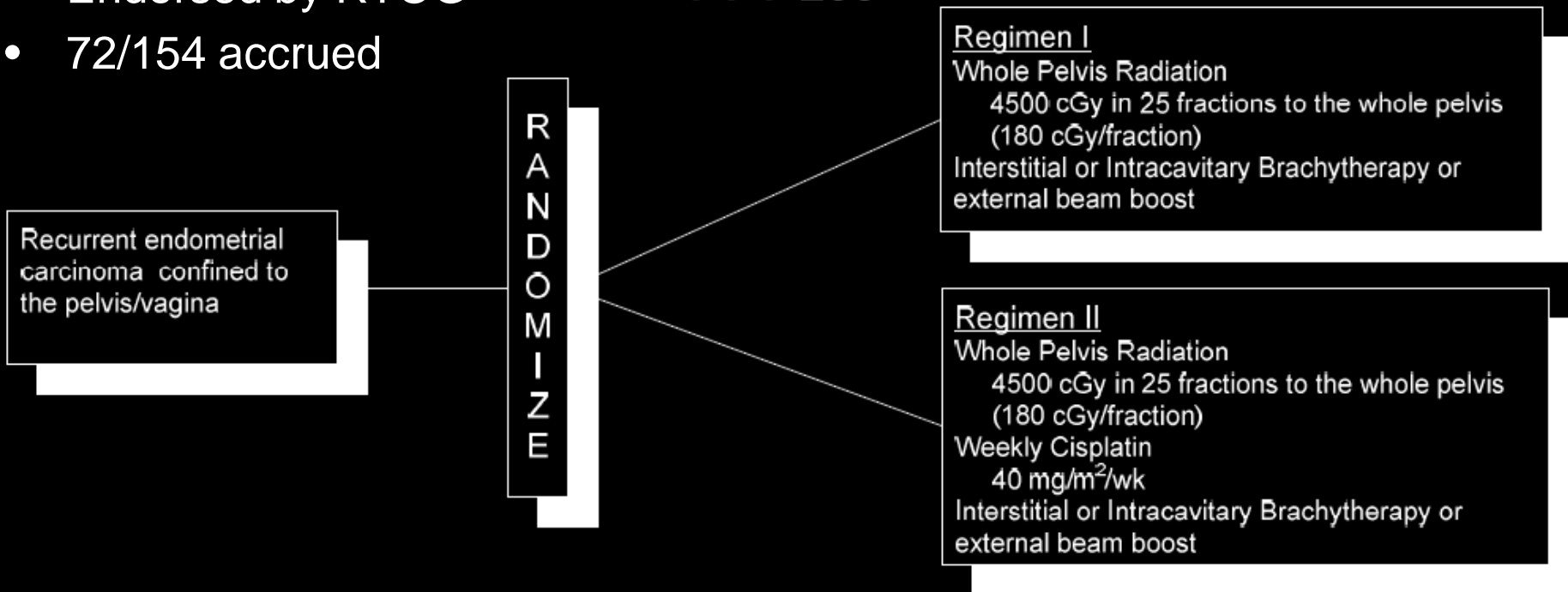
* first dose of Carboplatin will be at AUC of 5, in subsequent cycles the dose will be escalated to AUC 6, as described in Section 6.2

- 6/29/2009
- Endorsed by RTOG
- 676/804 accrued

Pelvic Recurrence

- 2/25/2008
- Endorsed by RTOG
- 72/154 accrued

GOG 238



Institution IMRT Credentialing is required when IMRT is to be used before registering any patient on this trial. A Knowledge Assessment for this study must be completed by the treating radiation oncologist before registering patients on this trial.

For patients with tumors involving the distal vagina and clinically negative groins, the bilateral inguino-femoral lymph node regions should be treated to 4500 cGy.

3-D conformal or IMRT boost is allowed for patients who are not candidates for brachytherapy.

Carcinosarcoma

GOG 261

Stage I-IV, Persistent or Recurrent Carcinosarcoma (chemotherapy-naïve)

Patients may have prior pelvic and/or vaginal radiation therapy

Stratification:

- History of Pelvic Radiation
- Disease Status/Stage at time of Study registration
- Measurable Disease

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Regimen I

Paclitaxel 175 mg/m²* IV over 3 hours day 1
Carboplatin (AUC=6*) IV day 1

Repeat q 3 weeks x 6 cycles (up to 4 additional cycles may be given to patients who entered study with measurable disease and have partial response after 6 cycles)

Regimen II

Ifosfamide 1.6 g/m²** IV days 1, 2, 3, Mesna
Paclitaxel 135 mg/m² by 3-hour infusion on day 1

Repeat q 3 weeks x 6 cycles (up to 4 additional cycles may be given to patients who entered study with measurable disease and have partial response after 6 cycles)

G-CSF Support: Filgrastim or Pegfilgrastim beginning day 4-6

* Initial dose reduced to Paclitaxel 135 mg/m² and Carboplatin (AUC=5) if prior whole pelvic radiotherapy (may be escalated if patient tolerates lower dose)

** Initial dose reduced to Ifosfamide 1.2 g/m²/day x 3 days if prior whole pelvic radiotherapy

- 8/17/2009
- 581/603 accrued

Leiomyosarcoma: Stage I

GOG 277

6/4/2012

4/216 accrued

- High-grade uterine LMS
- FIGO Stage I (uterus +/- cervix)
- Hysterectomy +/- BSO

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Regimen I

Gemcitabine

900 mg/m² IV day, 1 and 8

Docetaxel

75 mg/m² IV day 8

GCSF 5 mc/kg days 9-15 or pegfilgrastim 6mg day 9 or 10

Every 21 days Cycles 1-4

CT/MRI imaging to confirm disease-free

Doxorubicin

60 mg/m² IV

Every 21 days for Cycles 5-8

Regimen II

Observation

Leiomyosarcoma: Measurable

- 11/9/2009 – 4/29/2013
- 107/130 accrued
- Closed

GOG 250

Regimen I:*

Day 1:

Gemcitabine 900 mg/m² IV followed by Placebo (for Bevacizumab)

Day 8:

Gemcitabine 900 mg/m² IV followed by Docetaxel 75 mg/m² IV

Every 3 weeks

Regimen II:*

Day 1:

Gemcitabine 900 mg/m² IV followed by Bevacizumab 15 mg/kg IV

Day 8:

Gemcitabine 900 mg/m² IV followed by Docetaxel 75 mg/m² IV

Every 3 weeks

Until disease progression or adverse effects prohibit further therapy

-Uterine LMS
-Measurable disease
-No prior cytotoxic therapy

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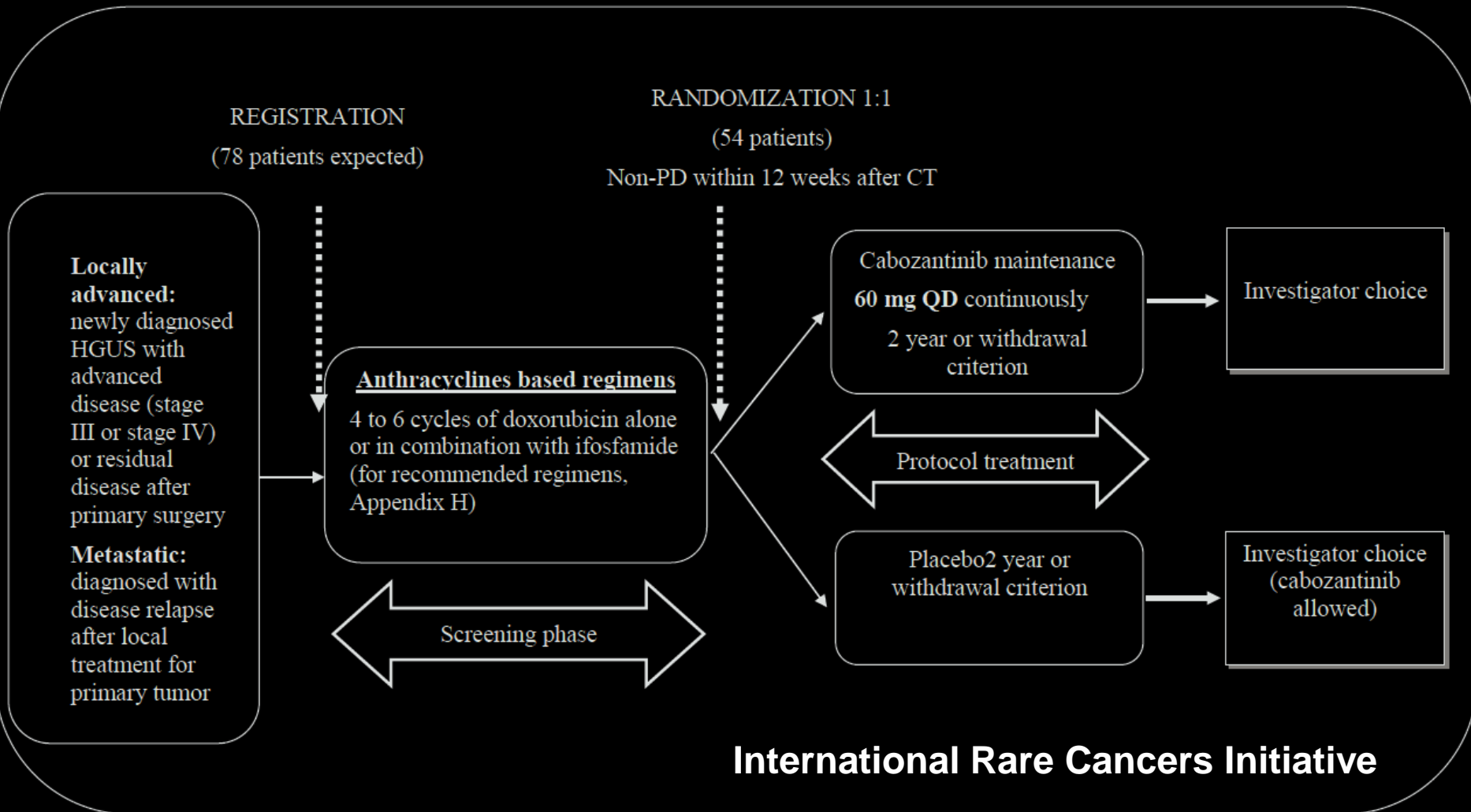
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* All patients will receive GCSF on day 9 of each cycle.

Patients with a history of prior pelvic RT receive lower doses of the gemcitabine and docetaxel: gemcitabine 675 mg/m² IV over 70-90 minutes Days 1 and 8 plus docetaxel 60 mg/m² IV Day 8.

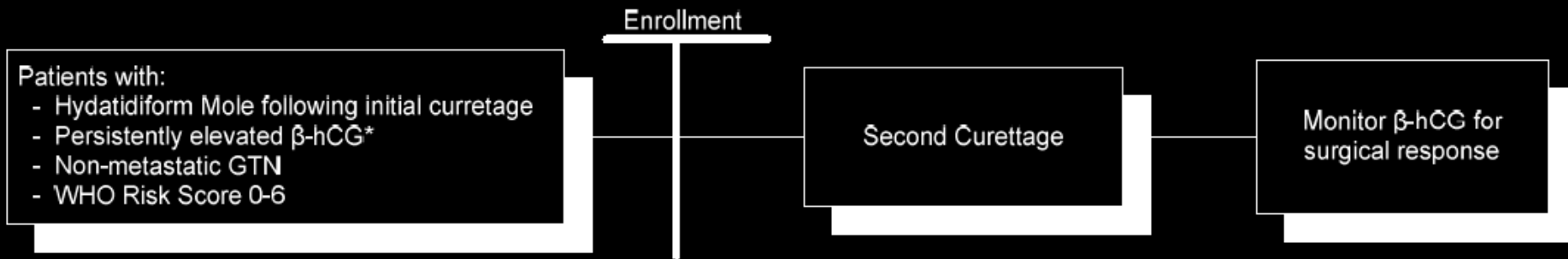
EORTC 62113-55115 / GOG UC1306

High Grade Undifferentiated Uterine Sarcoma



GTN: Second Curettage

GOG 242



*See section 3.11 for definition of GTN based upon persistently elevated β -hCG

- 10/9/2007 – 2/25/2013
- 64/66 accrued
- Completed

LOW-RISK GESTATIONAL TROPHOBLASTIC NEOPLASIA

GOG 275

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-Low-risk persistent GTN
-FIGO Stage I, II, and III
-WHO Score 0-6

Regimen I

Actinomycin-D

1.25mg/m², IV pulse
Every 14 days (2 mg max dose)

Regimen II

Patients will receive their institutional preference of either:

Methotrexate

0.4 mg/kg, IV
Daily for 5 days every 14 days. (25 mg max daily dose)

OR

Methotrexate

50 mg, IM
Days 1, 3, 5, 7 (4 doses per cycle) with
Leucovorin (15 mg) on Days 2, 4, 6, 8.
Repeat every 14 days.

Continue study treatment for three cycles after hCG < 5mIU/ml or until evidence of biologic or disease progression or adverse effects prohibit further therapy.

6/18/2012

9/381 accrued

GCIG collaboration