

NRG/GOG Foundation

Uterine Corpus Subcommittee

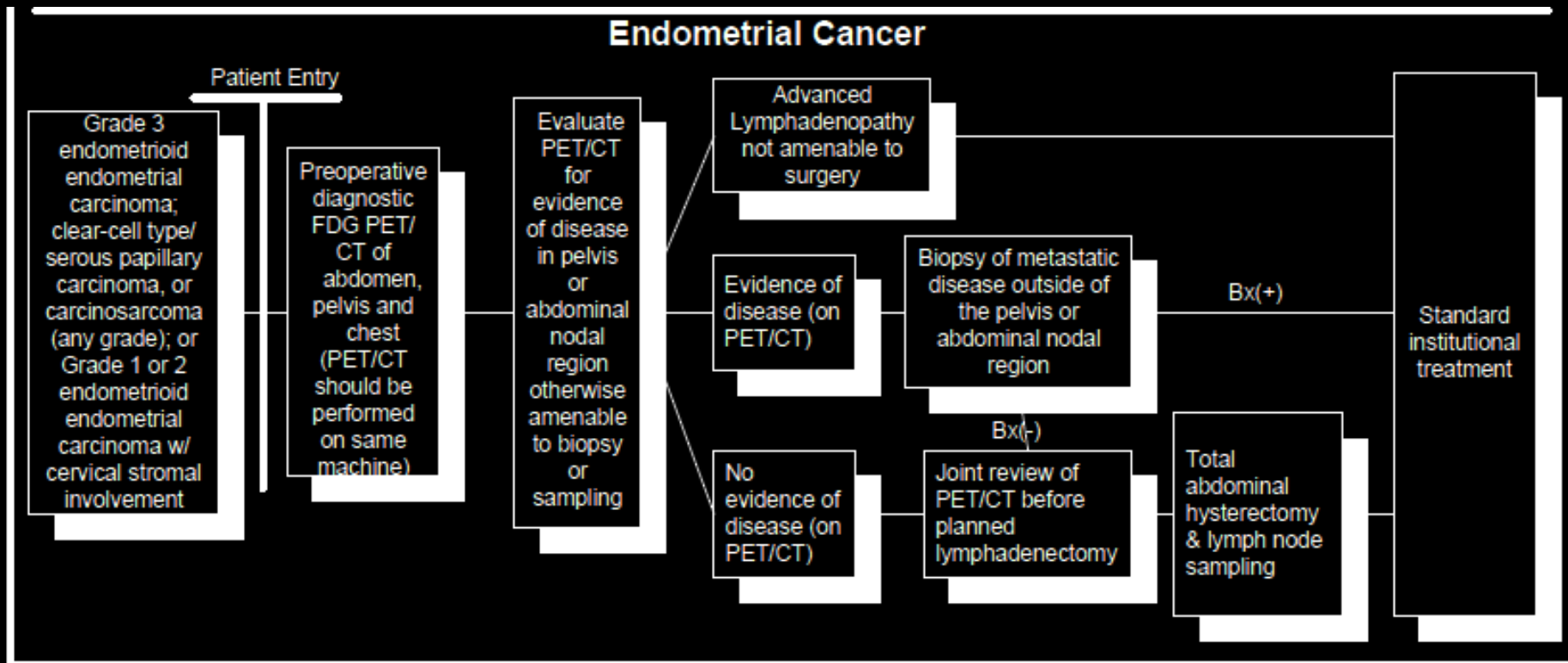


NIRG ONCOLOGY

Advancing Research. Improving Lives.™



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

Accrued: 384

Presented: ASCO 2011

Publication: Radiology (epub)

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:

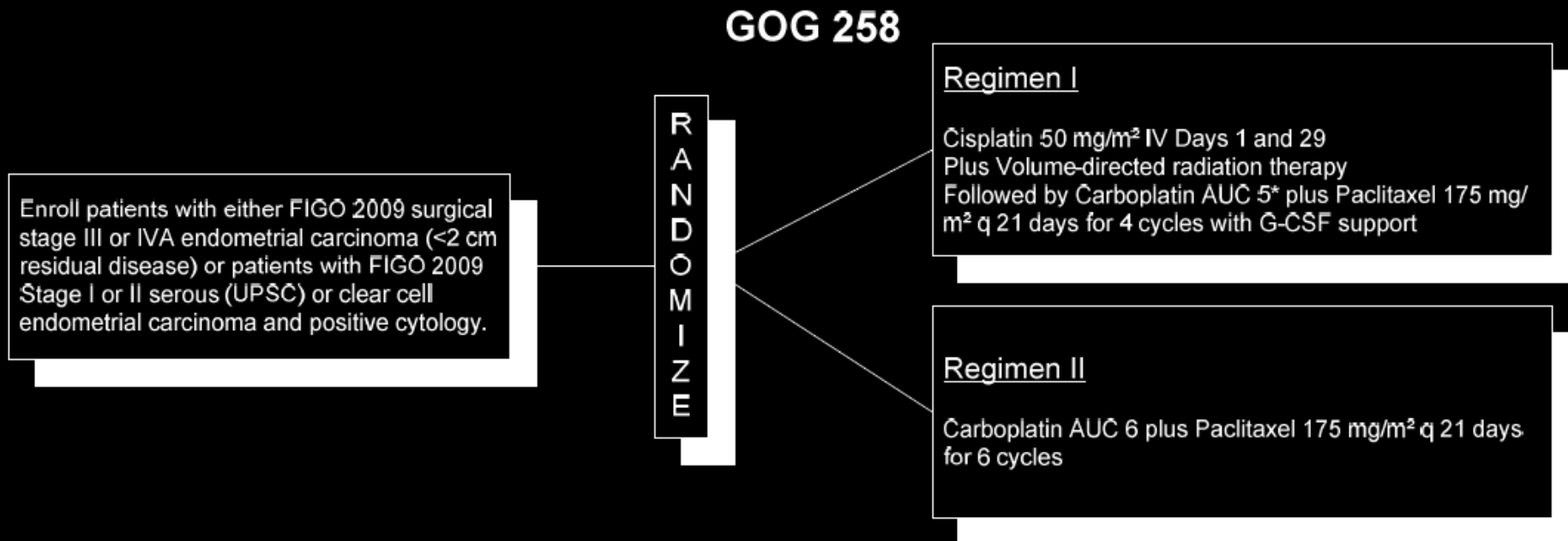
- Vaginal Cuff Brachytherapy + 3 cycles of chemotherapy* consisting of:
 - Paclitaxel 175 mg/m² (3hr) + Carboplatin AUC 6 q 21 days

*To start within 3 weeks of initiating brachytherapy

* FIGO 2009 Staging Criteria

- 3/23/2009 – 2/4/2013: Completed
- Endorsed by RTOG
- 562 accrued, 9% CCOP
- Presented: SGO 2014
- Publication: in preparation

Endometrial: Stage III/IV

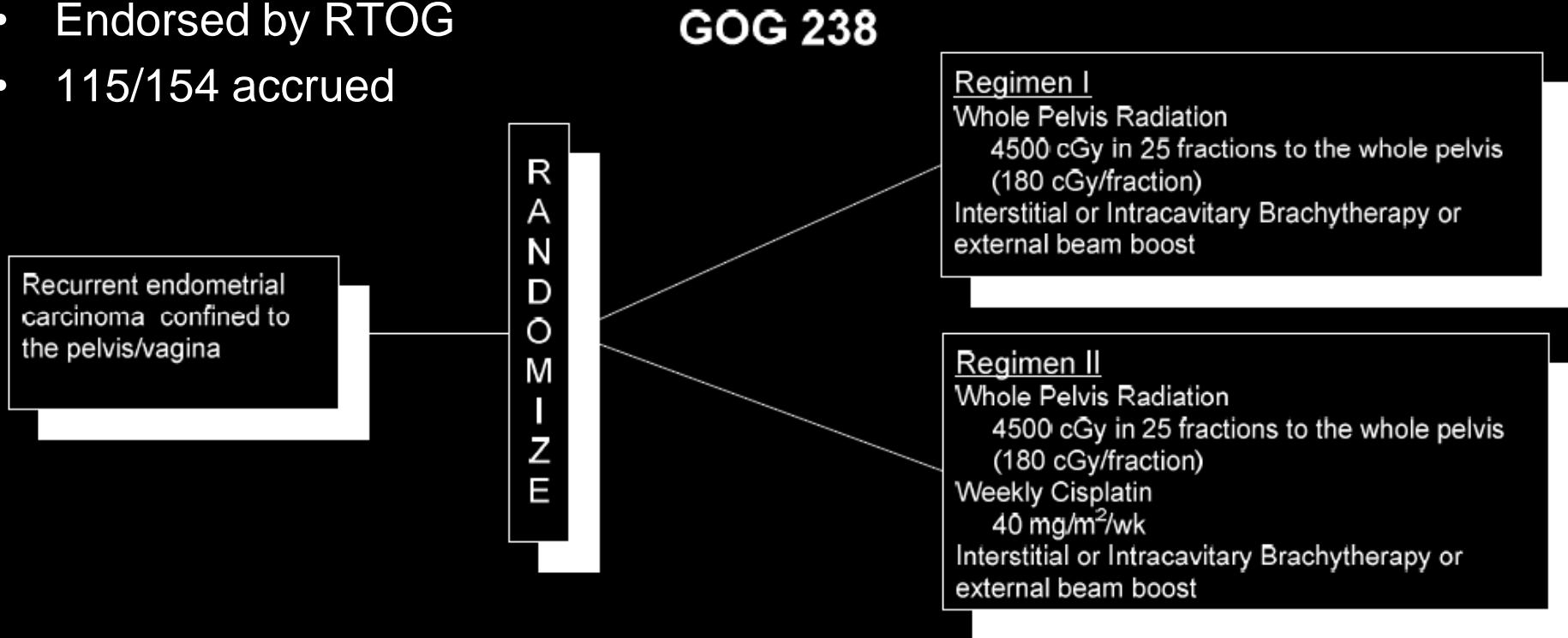


* first dose of Carboplatin will be at AUC of 5, in subsequent cycles the dose will be escalated to AUC 6, as described in Section 6.2

- 6/29/2009 – 7/28/2014: Completed
- Endorsed by RTOG
- 813/804 accrued
- Presentation: ASCO 2017

Pelvic Recurrence

- 2/25/2008
- Endorsed by RTOG
- 115/154 accrued



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.

Leiomyosarcoma: Stage I

GOG 277

- 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

4 Jun 2012 opened
38/216 accrued
9 Sep 2016 closed

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.

18 Jun 2012 opened
GCIG collaboration
57/384 accrued
20 Sep 2016 closed