GCIG Cervix Committee:
Sunday, November 17, 2013, 10:30 a.m. – 12:00 noon
Room 2+3, UCL Education Centre, London, UK.

Satoru Sagae (JGOG)
Bradley Monk (GOG)
Bill Small (RTOG) President elect
Publications:

M McCormack, et al. A phase II study of weekly neoadjuvant chemotherapy followed by Radical chemoradiation for locally advanced cervical cancer
Br J Cancer (2013) 108, 2464–2469

Closed studies:

GOG 240 (MANGO, NSGO): Cis/Paclitaxel +/- Bev vs Topo/Paclitaxel +/- Bev in stage IVB cervix cancer (Tewari) Presented at ASCO 2013 plenary

ACRIN 6671 (GOG, KGOG, JGOG) Utility of Preoperative FDG–PET/CT Prior to Primary Chemoradiation Therapy to Detect Retroperitoneal Lymph Node Metastasis in Patients With advanced cervical and endometrial Carcinoma
CURRENT ACTIVE/NEAR ACTIVATION RANDOMIZED TRIALS
WITH GCIG PARTICIPATION:

KGOG–Thai TACO: (RTOG, GICOM) (CCRN – Viet Nam, Thailand)
Randomized Clinical Trial of Weekly versus Tri–Weekly Cisplatin based
Chemoradiation in Locally Advanced Cervical Cancer     Ryu                      75/590

ANZGOG  OUTBACK (GOG, RTOG) (CCRN – India) : Chemoradiotherapy +/-
adjuvant chemotherapy                                                Mileshkin          254/780

NCRI: INTERLACE: (CCRN – Romania, Belarus) INduction ChemoThERapy in Locally
Advanced CErvical Cancer.                                         McCormack          14/700

NCIC–CTG CX 5 SHAPE: (DGOG, ) (CCRN -- ) A RANDOMIZED TRIAL
COMPARING RADICAL HYSTERECTOMY AND PELVIC NODE DISSECTION
VS SIMPLE HYSTERECTOMY AND PELVIC NODE DISSECTION IN PATIENTS
WITH LOW RISK EARLY STAGE CX CA:                         Plante                   11/700
GOG-0278 Conservative surgery (cone/nodes or hyst/(nodes) in early stage cervical cancer. (evaluation of physical function and QOL) Monk 9/220

GOG-0279 Phase II Trial Evaluating Cisplatin (NSC #119875) and Gemcitabine (NSC #613327) Concurrent with Intensity-Modulated Radiation Therapy (IMRT) in Treatment of Locally Adv. SCC of the Vulva Monk 9/52

KGOG-0801/GOG 263 (RTOG): RT vs CRT in intermediate risk cervix cancer after hysterectomy Ryu 145/480

RTOG-0724 (GOG): ChemoRT with and without adjuvant chemotherapy in high risk cervix cancer after hysterectomy Small <100/400

RTOG: A RANDOMIZED PHASE III STUDY OF STANDARD VS. IMRT PELVIC RADIATION FOR POST-OPERATIVE TREATMENT OF ENDOMETRIAL AND CERVICAL CANCER: TIME-C Small too early/284
DGOG GROINSS–V II (EORTC, GOG) : Groningen International Study on Sentinel
Nodes in Vulvar Cancer Creutzberg for van der Zee 1,037 cases

EORTC 55994: Randomized phase III study of NAC followed by RH vs CCRT in FIGO
stage Ib2, Ila>4 cm or Ilb cervical cancer Casado 594/625

PROPOSED OR DEVELOPING CONCEPTS:

JGOG1074: A New Protocol Concept for Advanced Cervical Adenocarcinoma of the
Uterine Cervix  CCRT–P (RT + CDDP 40 mg/m² weekly) VS CCRT–TP (RT + CD
DP 30 mg/m² + PTX 50 mg/m² weekly) Fujiwara 240
TACO

(Tri-weekly Administration of Cisplatin in LOcally Advanced Cervical Cancer)

Cervical cancer
Locally advanced cervical cancer
Stage IB2, IIB-IVA

Control Arm; Weekly Cisplatin
40mg/m2 6 cycles

Study Arm; Tri-weekly Cisplatin
75mg/m2 3 cycles
1. Enrollment

<table>
<thead>
<tr>
<th>Jan</th>
<th>2012</th>
<th>2013</th>
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- Estimated Accrual
- Enrolled Accrual

75 cases
RT-QA

- 3th RT–Film review at Seoul 2013.10

RPC Contract

- Radiological Physics Center’s Justification for staff needed to perform the radiotherapy quality assurance

IDMC

- IDMC meeting in GCIG(London 2013. 11)
- Status of study; enrollment, safety
A Phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone

Study Chair: Linda Mileshkin
Study Coordinator: Ilka Kolodziej
Current status

- 140 Sites open
  - 12 sites in Australia
  - 3 sites in New Zealand
  - 121 sites in the USA
  - 3 sites in Canada
  - 1 site in Saudi Arabia

- 254 Patients recruited
  - 58 patients from Australia
  - 9 patients from New Zealand
  - 185 patients from the USA
  - 2 patients from Saudi Arabia

- First interim analysis completed and approved by IDSMC

- 23 QA reports finalized
  - 5 major deviations
  - 13 minor deviations

- Ongoing high rate of SAEs during chemoRT
  - no SUSARS
Next steps

- Complete site activations in USA & Canada
- Start trial in Singapore (has now passed RTOG audit)
- Discuss proposal by Dutch Oncology Group to join with specific amendment to allow only them to use IMRT (9 centres)
  - need local arrangement for QA of their RT
INduction ChemoThERapy in Locally Advanced Cervical Cancer
INTERPLACE

Chief Investigator: Mary McCormack
GCIG Meeting – London
17th November 2013
INTERLACE

Randomise

Carboplatin AUC2 & Paclitaxel 80mg/m²
Weeks 1-6

Standard CRT

Standard CRT: 40—50.4Gy in 20-28 fractions plus Intracavitary brachytherapy to give total EQD2 dose of 78-86Gy to point A/volume. Weekly cisplatin 40mg/m² x 5 weeks

Follow-up

3 monthly for 2 years; 6 monthly for 3 years

Weeks 7 – 13 Standard CRT
Current Status – UK & International

- Target accrual – 770 patients
- Open to UK recruitment – September 2012
- 5 UK Sites open
- 14 patients recruited
- 40 UK Sites in set-up – RTQA cause for delay
- International:
  - Mexico in set-up (2 sites)
  - Eire in set-up (7 sites)

- **TOTAL = 54 Sites**
A RANDOMIZED TRIAL COMPARING RADICAL HYSTERECTOMY AND PELVIC NODE DISSECTION VS SIMPLE HYSTERECTOMY AND PELVIC NODE DISSECTION IN PATIENTS WITH LOW RISK EARLY STAGE CERVICAL CANCER

A Gynecologic Cancer Intergroup (GCIG) Trial led by the NCIC CTG

GCIG Trial Designation: The SHAPE Trial
NCIC CTG Protocol Number: CX.5

Chair: Marie Plante
SHAPE-UPDATE

Centers opened in Canada: 13
Accrual to date: 11

International groups status

- The Netherlands have received approval and funding!
- UK Group has received approval for funding and will be opened to accrual by Spring 2014
- Austria has received approval and will activate by the end of 2013.
- France and Germany will activate by Spring 2014.
- Ireland will activate by the end of 2013.
- The Nordic Society will activate by the end of 2013.
- The Belgium Group will activate by the end of 2013.
- Mexico, Korea, China and COGI (the group at Stanford Uni): ???
SHAPE-UPDATE

▫ Adjuvant treatment
  • Will be left at the discretion of each center based on local policy
  • Specific references to Cisplatin administration has been removed from the protocol
  • This amendment has been submitted to Health Canada (October 2013)

▫ Simplified randomization process
  • Maximum of 20 weeks from diagnosis

▫ The surgical approach is no longer a stratification factor

▫ All patients must undergo PLND
  • SLN optional
  • LSG optional (preferred)
Current GCIG Studies in the GOG

1. GOG 263 (KGOG)
2. GOG 0724 (RTOG)
3. GOG 0274 (ANZGOG)
4. GOG 233 (ACRIN)
5. TIME-C (RTOG)
6. GOG 270 (GROINSS-V II)
Randomized Phase III Clinical Trial of Adjuvant Radiation vs Chemoradiation In Intermediate Risk, Stage I/IIA Cervical Cancer Treated With Initial Radical Hysterectomy and Pelvic Lymphadenectomy

Cervical cancer
Stage I-IIA
Radical hysterectomy+BPLND
>2 of intermediate risk factors

Randomization

Control Arm; Radiation therapy

CRT Arm; Weekly CDDP 40mg/m² concurrent to radiation
# Eligibility Criteria
(GOG 263=GOG 92)

<table>
<thead>
<tr>
<th>CLS&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Stromal invasion</th>
<th>Tumor size</th>
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<tbody>
<tr>
<td>Positive</td>
<td>Deep 1/3</td>
<td>Any</td>
</tr>
<tr>
<td>Positive</td>
<td>Middle 1/3</td>
<td>≥2 cm</td>
</tr>
<tr>
<td>Positive</td>
<td>Superficial 1/3</td>
<td>≥5 cm</td>
</tr>
<tr>
<td>Negative</td>
<td>Deep or middle 1/3</td>
<td>≥4 cm</td>
</tr>
</tbody>
</table>

<sup>a</sup> Capillary lymphatic space tumor involvement.
Accrual of GOG 263

Golobal

Golobal
PROTOCOL GOG-0279
A PHASE II TRIAL EVALUATING CISPLATIN (NSC #119875) AND GEMCITABINE (NSC #613327) CONCURRENT WITH INTENSITY-MODULATED RADIATION THERAPY (IMRT) IN THE TREATMENT OF LOCALLY ADVANCED SQUAMOUS CELL CARCINOMA OF THE VULVA

NCI Version Date: 11/02/2012
Includes Revision #1

POINTS:
PER CAPITA - 20
MEMBERSHIP – 3
INCORPORATION OF BEVACIZUMAB IN THE TREATMENT OF RECURRENT AND METASTATIC CERVICAL CANCER

GOG 240: A PHASE 3 RANDOMIZED TRIAL OF THE GYNECOLOGIC ONCOLOGY GROUP

Carcinoma of the cervix
• Primary stage IVB
• Recurrent/persistent
• Measureable disease
• GOG PS 0–1
• No prior chemotherapy for recurrence
  (N=452)

Stratification factors:
• Stage IVB vs recurrent/persistent disease
• Performance status
• Prior cisplatin Rx as radiation-sensitizer

Activated: 4/6/09
Closed to accrual: 1/3/12

GOG 240: Objectives

• Primary end points to determine
  – If adding bevacizumab to chemotherapy improves OS
  – If a non-platinum doublet (topotecan + paclitaxel) improves OS
  – The tolerability of the four regimens (adverse events by CTCAE v3 and v4)

• Secondary end points to determine
  – Impact of bevacizumab and non-platinum doublet on progression-free survival (PFS) and overall response rate (ORR) by RECIST v1.0

• Exploratory end points
  – Impact on Health-Related Quality of Life (HRQoL):
    • Functional Assessment of Cancer Therapy – Cervix Ca Trial Outcome Index (FACT-Cx TOI)
  – Data not included in current presentation
    • Additional HRQoL: FACT/GOG-Ntx (neuropathy), BPI (Brief Pain Inventory)
    • Prospective validation of pooled clinical prognostic factors from prior phase 3 trials
    • Prevalence and impact of nicotine dependence on OS and PFS
    • Circulating tumor cells and VEGF isoform expression


Presented by: Krishnansu S. Tewari, MD, FACOG, FACS
### GOG 240: Demographics & Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Chemo Alone (n=225), %</th>
<th>Chemo + Bev (n=227), %</th>
</tr>
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<tbody>
<tr>
<td>Median age, years (range)</td>
<td>46 (20–83)</td>
<td>48 (22–85)</td>
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<tr>
<td>Histology, %</td>
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<tr>
<td>Squamous</td>
<td>68</td>
<td>70</td>
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<td>AdenoCa, unspec.</td>
<td>20</td>
<td>19</td>
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<tr>
<td>Race, %</td>
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<td>White</td>
<td>80</td>
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<td>African American</td>
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<td>5</td>
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<td>Pacific Islander</td>
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<td>Stage of disease, %</td>
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<tr>
<td>Recurrent</td>
<td>73</td>
<td>70</td>
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<tr>
<td>Persistent</td>
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<td>Advanced</td>
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<td>Performance status, %</td>
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<td>0</td>
<td>58</td>
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<td>1</td>
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<td>Prior platinum, %</td>
<td>74</td>
<td>75</td>
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<td>Pelvic disease, %</td>
<td>53</td>
<td>54</td>
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GOG 240: OS for Chemo vs Chemo + Bev

**Chemotherapy** (n=225)

- Events, n (%) 140 (62)
- Median OS, mos 13.3

**Chemotherapy + Bev** (n=227)

- Events, n (%) 131 (58)
- Median OS, mos 17.0

HR = 0.71 (97% CI, 0.54-0.94)

\( P = 0.0035 \)

Median follow-up 20.8 mos

Presented by: Krishnansu S. Tewari, MD, FACOG, FACS
GOG 240: PFS for Chemo vs Chemo + Bev

**Chemotherapy** (n=225) | **Chemotherapy + Bev** (n=227)
---|---
Events, n (%) | 184 (82) | 183 (81)
Median PFS, mos | 5.9 | 8.2
HR=0.67 (95% CI, 0.54-0.82) 2-sided P=0.0002
RR, % | 36 (CR, n=14) | 48 (CR, n=28) 2-sided P=0.00807

Presented by: Krishnansu S. Tewari, MD, FACOG, FACS
GOG 240: OS for Cisplatin + Paclitaxel vs Cisplatin + Pac + Bev

<table>
<thead>
<tr>
<th></th>
<th>Cis + Pac (n=114)</th>
<th>Cis + Pac + Bev (n=115)</th>
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<tbody>
<tr>
<td>Events, n (%)</td>
<td>69 (60.5)</td>
<td>67 (58.3)</td>
</tr>
<tr>
<td>Median OS, mos</td>
<td>14.3</td>
<td>17.5</td>
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<tr>
<td>HR=0.68 (95% CI, 0.48-0.97)</td>
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<tr>
<td>P=0.0348</td>
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<tr>
<td>RR, %</td>
<td>45 (CR, n=9)</td>
<td>50 (CR, n=17)</td>
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<td>2-sided P=0.5090</td>
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Presented by: Krishnansu S. Tewari, MD, FACOG, FACS
# GOG 240: Treatment Exposure and Specific Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event, n (%)</th>
<th>Chemo Alone (n=219)</th>
<th>Chemo + Bev (n=220)</th>
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<tr>
<td>Treatment cycles, median (range)</td>
<td>6 (0-30)</td>
<td>7 (0-36)</td>
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<tr>
<td>Grade 5 AE(s)</td>
<td>4 (1.8)</td>
<td>4 (1.8)</td>
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<td>GI events, non-fistula (grade ≥2)</td>
<td>96 (44)</td>
<td>114 (52)</td>
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<tr>
<td><strong>GI fistula (grade ≥3)</strong></td>
<td>0 (0)</td>
<td>7 (3)</td>
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<td><strong>GI perforation (grade ≥3)</strong></td>
<td>0 (0)</td>
<td>5 (2)</td>
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<tr>
<td><strong>GU fistula (grade ≥3)</strong></td>
<td>1 (0)</td>
<td>6 (2)</td>
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<td><strong>Hypertension (grade ≥2)</strong></td>
<td>4 (2)</td>
<td>54 (25)</td>
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<td>Proteinuria (grade ≥3)</td>
<td>0 (0)</td>
<td>4 (2)</td>
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<td>Pain (grade ≥2)</td>
<td>62 (28)</td>
<td>71 (32)</td>
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<td><strong>Neutropenia (grade ≥4)</strong></td>
<td>57 (26)</td>
<td>78 (35)</td>
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<tr>
<td>Febrile neutropenia (grade ≥3)</td>
<td>12 (5)</td>
<td>12 (5)</td>
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<tr>
<td><strong>Thromboembolism (grade ≥3)</strong></td>
<td>3 (1)</td>
<td>18 (8)</td>
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<tr>
<td>Bleeding</td>
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<tr>
<td>CNS (any grade)</td>
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<td>0 (0)</td>
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<tr>
<td>GI (grade ≥3)</td>
<td>1 (0)</td>
<td>4 (1)</td>
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<tr>
<td>GU (grade ≥3)</td>
<td>1 (0)</td>
<td>6 (3)</td>
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*p<0.05"
• Bevacizumab plus chemotherapy significantly improves OS in stage IVB, recurrent or persistent cervical carcinoma
  – Nearly 4-month improvement in OS is clinically significant
  – Increase in median PFS and ORR are also demonstrated
  – Cisplatin + paclitaxel arm is current standard of care and did not underperform
  – Benefit seen even when recurrent disease is in irradiated pelvis
• Bevacizumab treatment is associated with a higher rate of AEs
  – 3–8% rate of known bevacizumab-related AEs
• The improvement in OS with bevacizumab treatment was not accompanied by a decrease in HRQoL
• First targeted agent to improve OS in a gynecologic cancer
RTOG-0724 (GOG): ChemoRT with and without adjuvant chemotherapy in high risk cervix cancer after hysterectomy
Schema

STRATIFY

Intention To Use Brachytherapy:  No Yes
RT Modality: 3D-CRT  IMRT

RANDOMIZE

Concurrent weekly cisplatin plus 50.4 Gy tailored RT ± brachytherapy

Versus

Concurrent weekly cisplatin plus 50.4 Gy tailored RT ± brachytherapy
followed by 4 courses of carboplatin and paclitaxel

Arms/Regimens Arm 1: Concurrent weekly cisplatin 40 mg/m2 plus 50.4 Gy tailored RT ± brachytherapy

Arm 2: Concurrent weekly cisplatin 40 mg/m2 plus 50.4 Gy tailored RT ± brachytherapy followed by paclitaxel 175 mg/m2 and carboplatin AUC of 5 every 21 days for 4 cycles
A RANDOMIZED PHASE III STUDY OF STANDARD VS. IMRT PELVIC RADIATION FOR POST-OPERATIVE TREATMENT OF ENDOMETRIAL AND CERVICAL CANCER (TIME-C)
Eligibility: Women with endometrial or cervical cancer requiring post-operative pelvic radiation or chemoradiation

Stratification factors:
- **XRT dose**
  - 45 Gy
  - 50.4 Gy
- **Chemotherapy**
  - No Chemotherapy
  - 5 cycles of weekly cisplatin at 40mg/m²
- **Disease Site**
  - Endometrial
  - Cervix

Randomize:
- IMRT pelvic radiation treatment
- 4-field pelvic radiation treatment
Update
GROINSS-V-II

Update November 2013
Accrual GROINSS-V-II: December 2005 – October 2013 (n = 1037)

Cumulative inclusion 3-monthly

Mean = 32 inclusions / 3 months

After protocol amendment: 41 – 68 inclusions / 3 months!
GROINSS-V-II

777 patients data SN available:

- 600 negative SN (77%)
- 177 positive SN (23%)
  - Micrometastases ($\leq 2\text{mm}$) 85 (48%)
  - Macrometastases ($> 2\text{mm}$) 79 (45%)
  - 13 missing (7%)
- Pts with macrometastases now undergo inguinofemoral lymphadenectomy
- Until now safety border for SN+/micro (treated with radiotherapy) not crossed

- Final inclusion expected: end 2015
- Results expected: end 2017
Arm 1: Neoadjuvant QT

Cisplatin based chemotherapy:
- min. cumulative cisplatin dose of 225 mg/m²
- 25 mg/m² per week,
- final dose no later than D64

Followed by surgery (radical hysterectomy)

Arm 2: Concomitantly QT/RDT

Cumulative cisplatin dose 200-240 mg/m².
- Max 6 administrations.
- Dose 40 mg/m², max 80 mg

External radiotherapy (45-50 Gy) in fractions of 1.8 Gy to 2 Gy + external boost or brachytherapy
- min. 75 Gy EQD2 to point A (80 Gy to High Risk PTV) is mandatory
- overall treatment time ≤ 50 days
EORTC 55994. Current status

• Activation of new sites ongoing
• Recruitment (November 8th 2013): 594 patients

• Given the slow accrual and the very long-term follow-up needed to accumulate the required number of events both for OS and PFS, the required number of events will not be reached within a reasonable timeframe.
EORTC 55994. Current status

• The recommendation was then to redesign the trial with a binary endpoint.
• The first choice was OS rate at 5 years which was the initial objective of the trial.
• Under a 10% difference in OS rate at 5 years
  ✓ OS rate at 5 years of 67% in the control arm
  ✓ OS rate at 5 years of 77% in the experimental arm
  ✓ Sample size required (two sided type I error of 5% and power of 80%): 625 patients
Developing Concepts – Discussions
A New Protocol Concept for Advanced Cervical Adenocarcinoma of the Uterine Cervix

Department of Obstetrics and Gynecology,
Graduate School of Medical Science,
University of the Ryukyus,
Okinawa, JAPAN

Yutaka Nagai, M.D., Ph.D.
Prospective trials in larger series of patients undergoing CCRT with PTX and CDDP (CCRT-TP) are urgently needed for local advanced cervical adenocarcinoma.

Primary endpoint: 5-yr OS
Secondary endpoints: 5-yr PFS, 5-yr local PFS, 5-yr distant PFS, completion rate, and adverse events