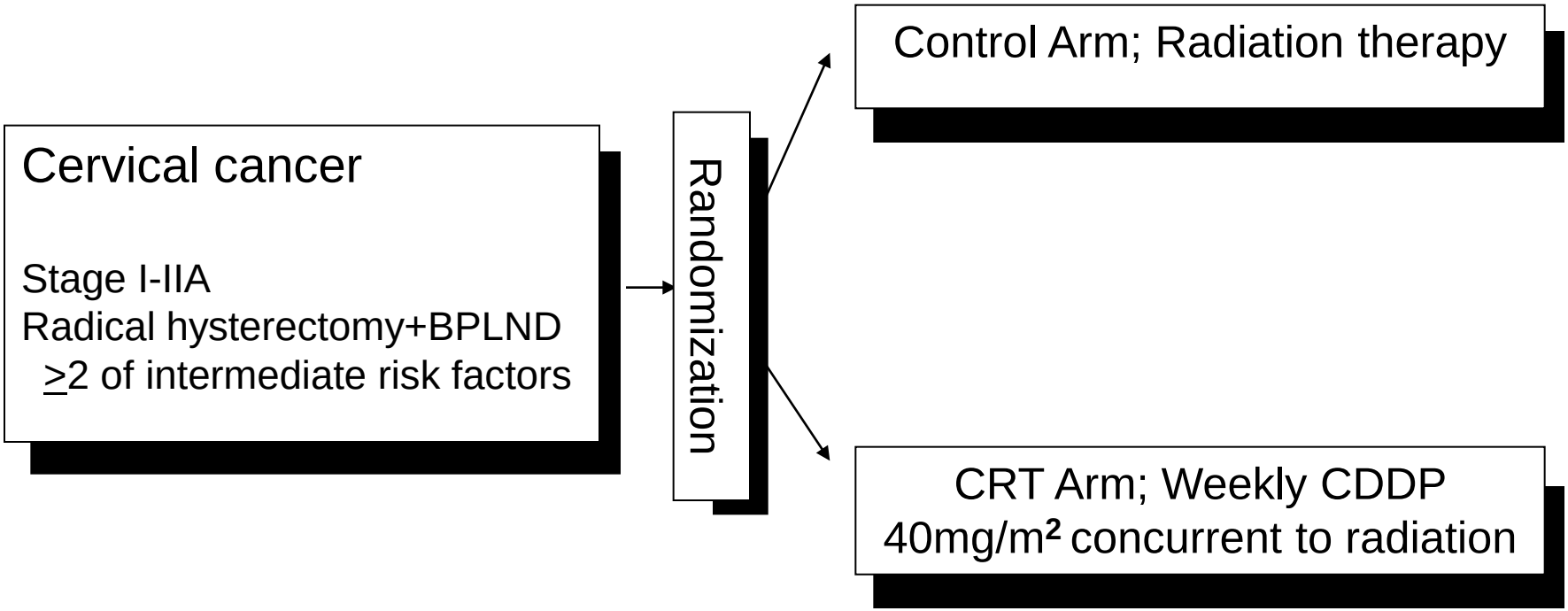
GOG 263/KGOG 1008

PI; Sang Young Ryu, MD

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



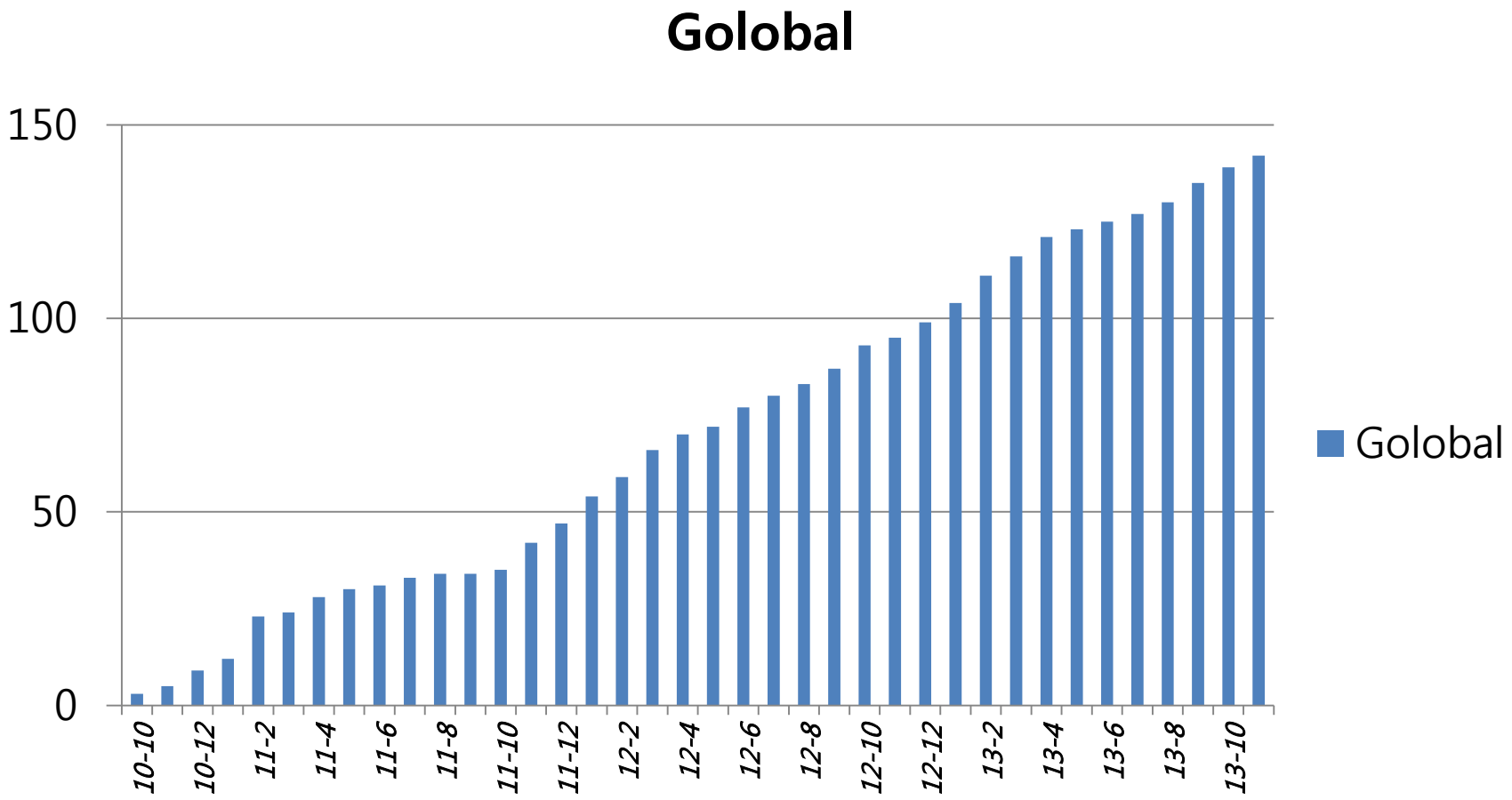
Eligibility Criteria
(GOG 263=GOG 92)

TABLE 1
Eligibility Criteria

CLS[a]	Stromal invasion	Tumor size
Positive	Deep 1/3	Any
Positive	Middle 1/3	≥2 cm
Positive	Superficial 1/3	≥5 cm
Negative	Deep or middle 1/3	≥4 cm

[a] Capillary lymphatic space tumor involvement.

Accrual of GOG 263



GYNECOLOGIC CANCER INTERGROUP

An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

KGOG Korean Gynecologic Oncology Group

ASGO Asian Society Of Gynecologic Oncology

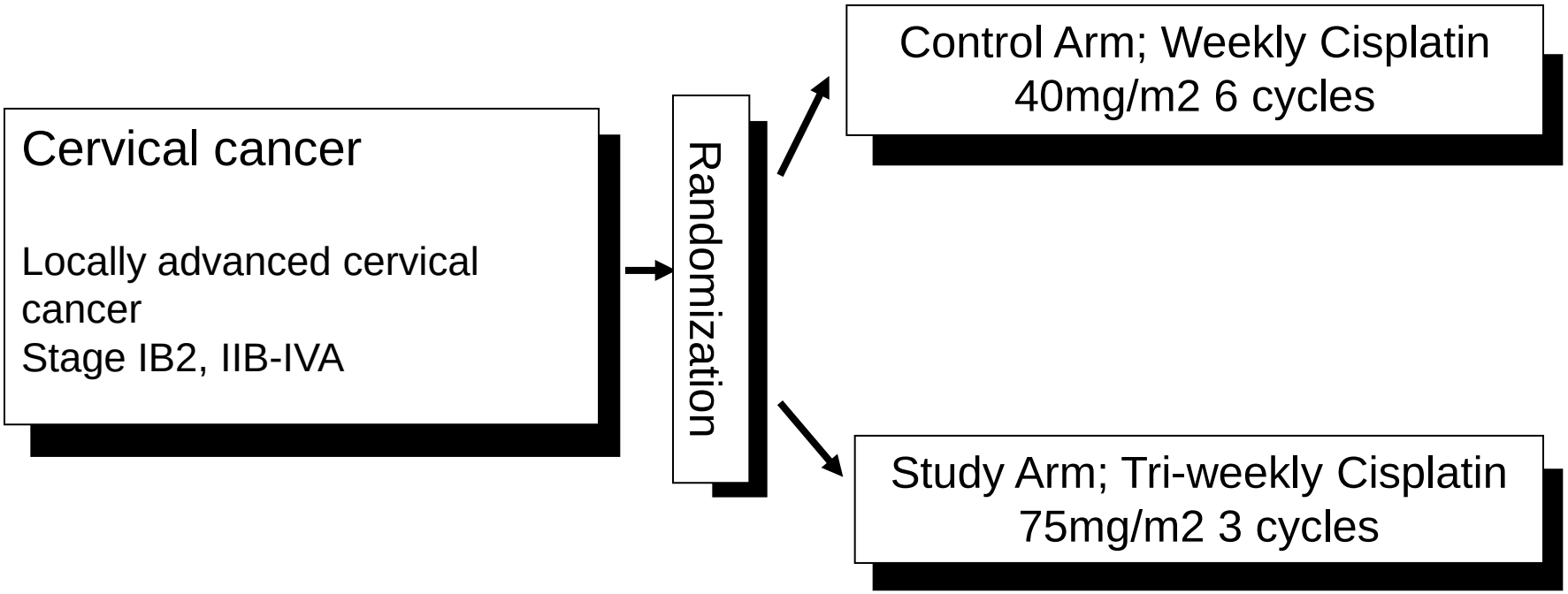
Wellcome to TACO!

TACO

GCIG/KGOG1027/TGCS2012: Randomized Phase III Clinical Trial Comparing Weekly vs Tri-weekly Cisplatin Based Concurrent Chemoradiation in Locally Advanced Cervical Cancer

TACO

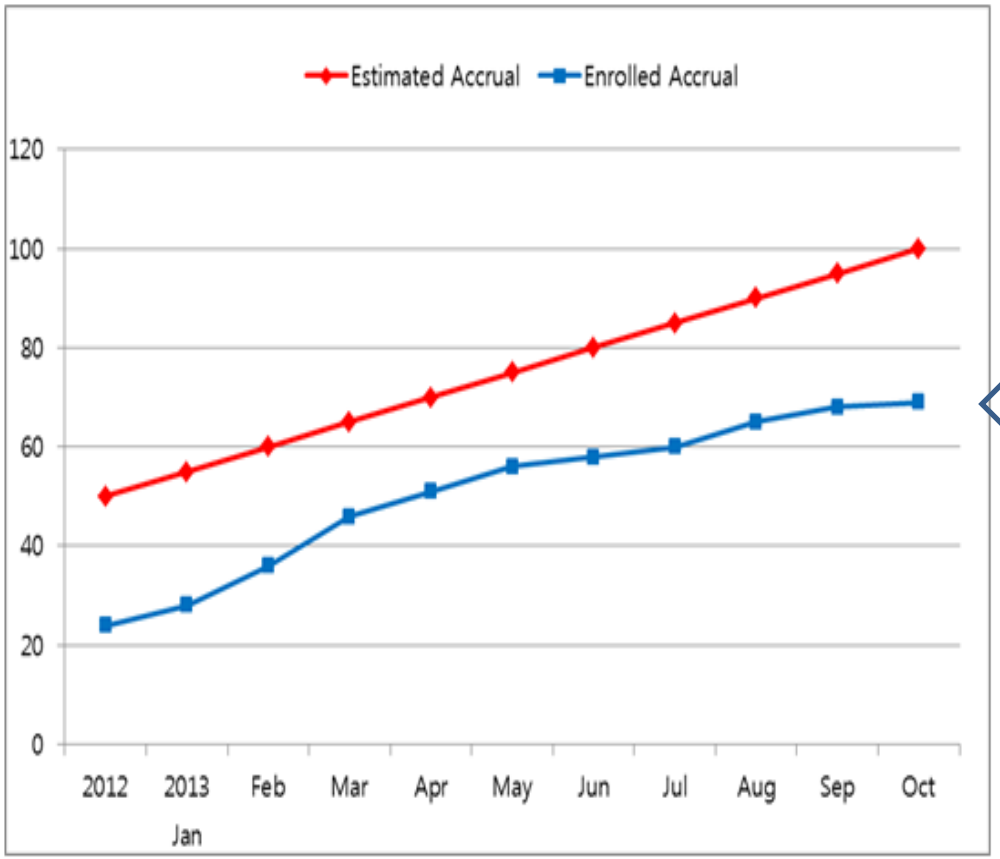
(Tri-weekly Administration of Cisplatin in LOcally Advanced Cervical Cancer)



GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

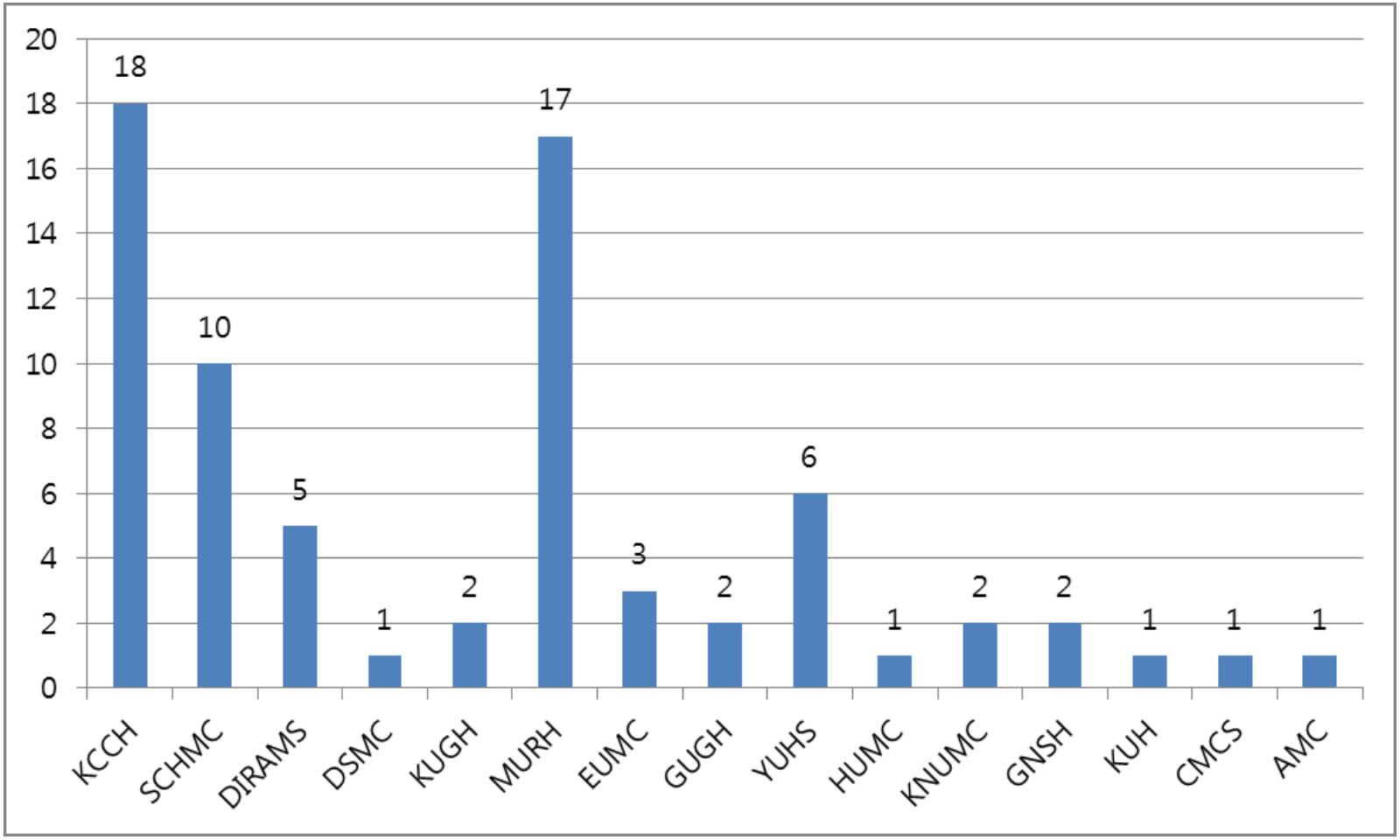
KGOG
Korean Gynecologic Oncology Group

1. Enrollment

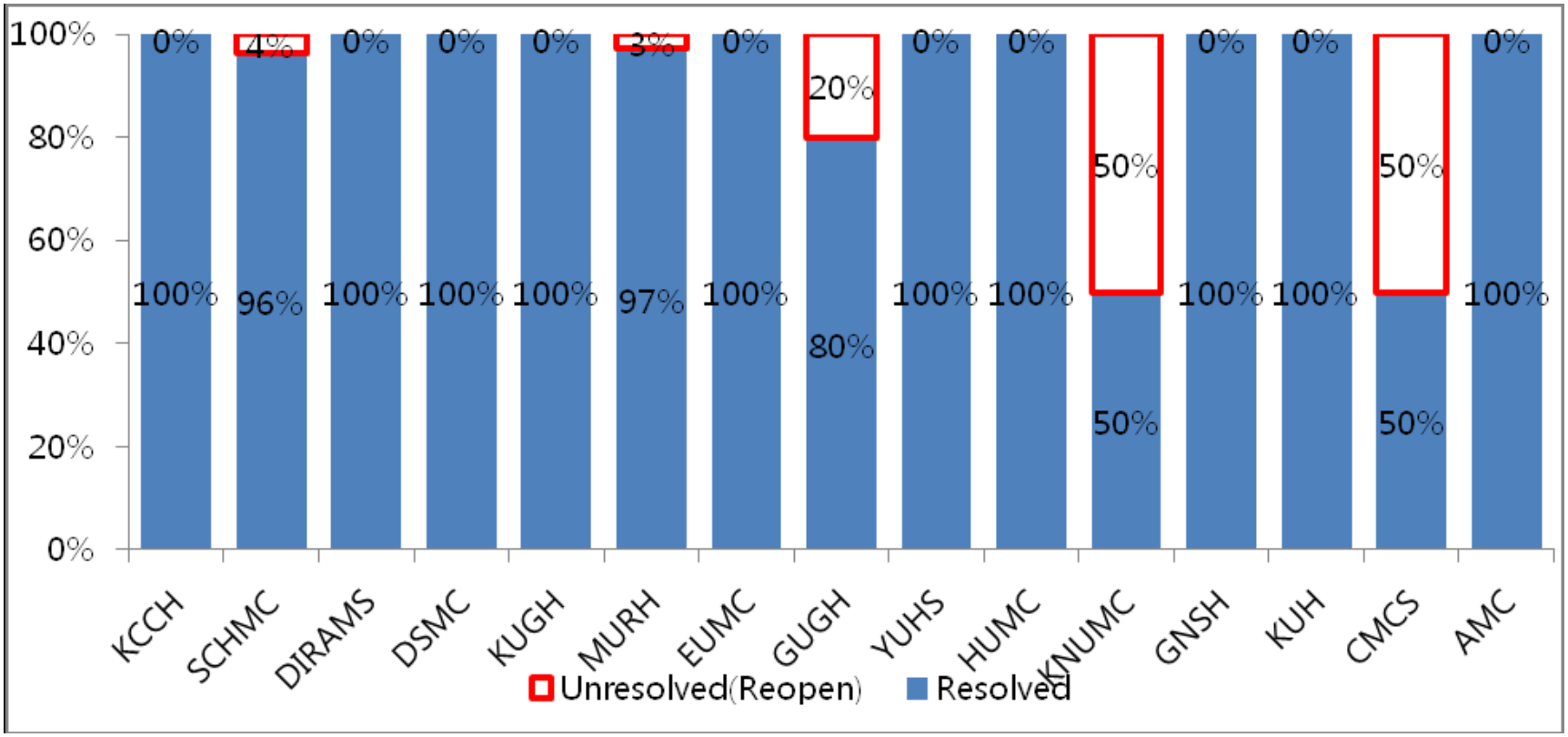


75cases

1. Enrollment



2. Query Summary



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 for:

THE TACO TRIAL; A Randomized Phase III clinical trial of weekly versus tri-weekly Cisplatin based chemoradiation in locally advanced Cervical Cancer.

.

The TACO study aims to accrue 590 patients within 4 years. This study will be an international study that may include, but is not limited to, the following countries: United States, Republic of Korea, Vietnam, and Thailand. The RPC has been approached by the Korean Gynecological Oncology Group (KGOG) to perform the quality assurance (QA) for the TACO study. It is likely that this study will accrue ~150 - 200 patients per year, resulting in a 4 year accrual period. However, if the study requires longer to accrue 590 patients, a no-cost extension will be granted. The study will receive QA work comparable to the procedures performed by the RPC for NCI supported GOG studies. These QA procedures include:

•A full independent review of the first patient chart from each of the participating radiotherapy institutions. This full review will include an independent calculation of dose received by the patient to verify the dose calculation algorithm. It will also include verification of point placement for points A, B, bladder, and rectum. Verification of correct patient dose reporting will also be conducted. If a disagreement exists between the RPC calculated dose and the institution's reported dose (outside of a 15% criterion), or in the placement of any point (outside of a 3 mm criterion), feedback will be given to the institution (and the TACO study PI) on how to correct the problem. The RPC will not review any further patient treatment cases from that institution until the TACO study Radiation Oncology PI and the institution's treating Radiation Oncology team have resolved the discrepancy and corrective actions have been implemented clinically.

The second patient from that institution will then undergo a cursory evaluation by the RPC to verify that the corrective actions suggested to the institution were implemented.

Dose calculations are based upon the details of treatment provided by the institution, but uses data collected by the RPC through visits to institutions to describe the radiation beams and radioactive sources used for treatment.

•A total of two patient records from each participating institution will receive a cursory review. This review will focus on the location of the A, B, bladder and rectum points, looking for deviations in the point placement outside a 3 mm criterion. The two patient charts reviewed may include the second patient record from an institution that did not meet criteria on their full review (as in (1) above). It may also include any chart that is suspected of having point placement errors as noted during integrity review (as in (3) below). Barring these situations, the cursory reviews will be done of the fifth and fifteenth patient chart from each participating radiotherapy institution. Any errors discovered will be communicated back to the submitting institution's Radiation Oncology team and the institution will be asked to submit revised doses accordingly.

•An integrity review of all other patient treatment records will be done to verify that the patient dose reporting form was completed correctly based on a review of the treatment record. Any errors discovered by the RPC will be corrected by the RPC on the reporting form and the institution will be notified of the dose modification.

•Each patient radiotherapy treatment record will be reviewed for compliance with the protocol.

To perform the volume of quality assurance work, the RPC is requesting funds for part of a dosimetrist's effort (variable by year) and part of an administrative assistant's effort (2%). The dosimetrist would be responsible for receiving and processing patient data, reviewing the data for completeness, requesting submission of any missing data, and performing a recalculation of the dose for both the external beam treatments and the brachytherapy treatments. The dosimetrist will evaluate an institution's treatment planning system data if the RPC's dose calculation for the external beam portion of the treatment does not agree with the institution's dose calculation by use of the RPC's standard dosimetry data. The funding is expected to allow ~50 patients entered on the trial to receive either a full or cursory review by the RPC dosimetrist. The dosimetrist will also review all other treatment records and dose reporting forms for reporting errors, and abstract data from the facility questionnaires. The administrative assistant will be responsible for the clerical duties related to the dosimetry group including entering data into the computer systems and database.

IDMC

- IDMC meeting in GCIG(London 2013. 11)
- Status of study; enrollment, safety