Gynecologic Cancer InterGroup
Cervix Cancer Research Network

QA for Cervix Cancer Trials in Asia

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Cervix Cancer Education Symposium, January 2016, Bangkok, Thailand

- **What is Quality Assurance (QA)?**
  - Independent examination of all trial-related activities and documents.
    - Activities were appropriately conducted
    - Data were generated, recorded, analyzed, and accurately reported according to protocol, standard operating procedures (SOPs), and good clinical practices (GCPs).

- **What is Good Clinical Practice (GCP)?**
  - *"a set of internationally recognized ethical and scientific quality requirements"*
  - *"for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects."*

Components for QA

- Standard operating procedures (SOPs) for trial execution
- A quality scientific and medical design of the protocol
- Clinical investigator and site pre-assessment and selection
- Regulatory agency and ethics committee approval
- Developing and providing appropriate informed consent
- Investigator meetings and training
- Adequate recording and reporting of data
- Periodic monitoring
- Audits

- **Components of data management (DM)**
  - Case report form [CRF] vs. protocol
  - CRF vs. source documents
  - Database vs. CRF
  - Tables, listings, and graphs (TLGs) vs. database
  - Data reported in the clinical study report (CSR) vs. TLGs
  - All are compliant with SOPs and GCPs

Benefit of QA

- QA promotes;
  - Confidence
  - Improves communication
  - Understanding of community needs and expectations
  - Increasing their job satisfaction and status in the community
  - Provides tools that gauge current performance levels and facilitate continuous improvement

Clinical Trial in Developing Countries

- Risk of **exploitation**:
  - Developing countries take the risks
  - But most of the benefits to developed countries
- Poverty, limited health-care services, illiteracy, cultural and linguistic differences, and limited understanding of the nature of scientific research

Clinical Trial in Developing Countries

- Collaborative partnership (Emanuel et al., 2004)
  - Partners representing developing country
  - Collaboration; sharing responsibility
  - Mutual respect
  - Minimize disparities
  - Fair benefits
  - Fair distribution of rewards of research

Cervical Cancer Research Network (CCRN)

- To promote high quality clinical research
  - Pre-visit questionaire
  - Site visit
  - Beam measurement program (TLD/OSLD)
  - Data input to IROC
  - Trial specific RT QA

Basic Requirements for EBRT

- OSLD/TLD every two years
- Credentialing procedures that include tabular data on department infrastructure (personnel, machines, beam profile data, etc…)
- Port films obtained ≥ weekly
- Physician visits documented weekly for trial patients
- Treatment plan signed by Radiation Oncologist prior to treatment
- Protocol specific knowledge assessment
- All fields must be filmed (simulation preferred).
- 2D therapy is permissible as well as Cobalt teletherapy. Central axis dosimetry is recommended (not mandatory for the lowest resource settings).

Basic Requirements for Brachytherapy

- Description of prescription volume or point
- Dose calculation signed by physicist and physician prior to treatment.
- Source activity documentation
- Brachytherapy questionnaire of resources: activity traceable to standard, dose calculation method

- **Clinical Management: Basic Requirements**
  - Charts must contain: Pathology report, stage, and consent
  - Clinical follow up ≤ every 6 months for two years, and then less often per trial.
  - In low resource trials, phone call documentation of vital status by an eye witness is acceptable.
  - Documentation of GCP recommended
  - Data Management process
    - Ability to complete CRFs
    - ethics submissions,
    - following schedules (investigations, etc), monitoring,
    - adequate [locked] pharmacy facilities,
    - Assuring FU capabilities

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INTERLACE; UK

OUTBACK: GOG

SHAPE: Canada

TACO: Korea/Thailand

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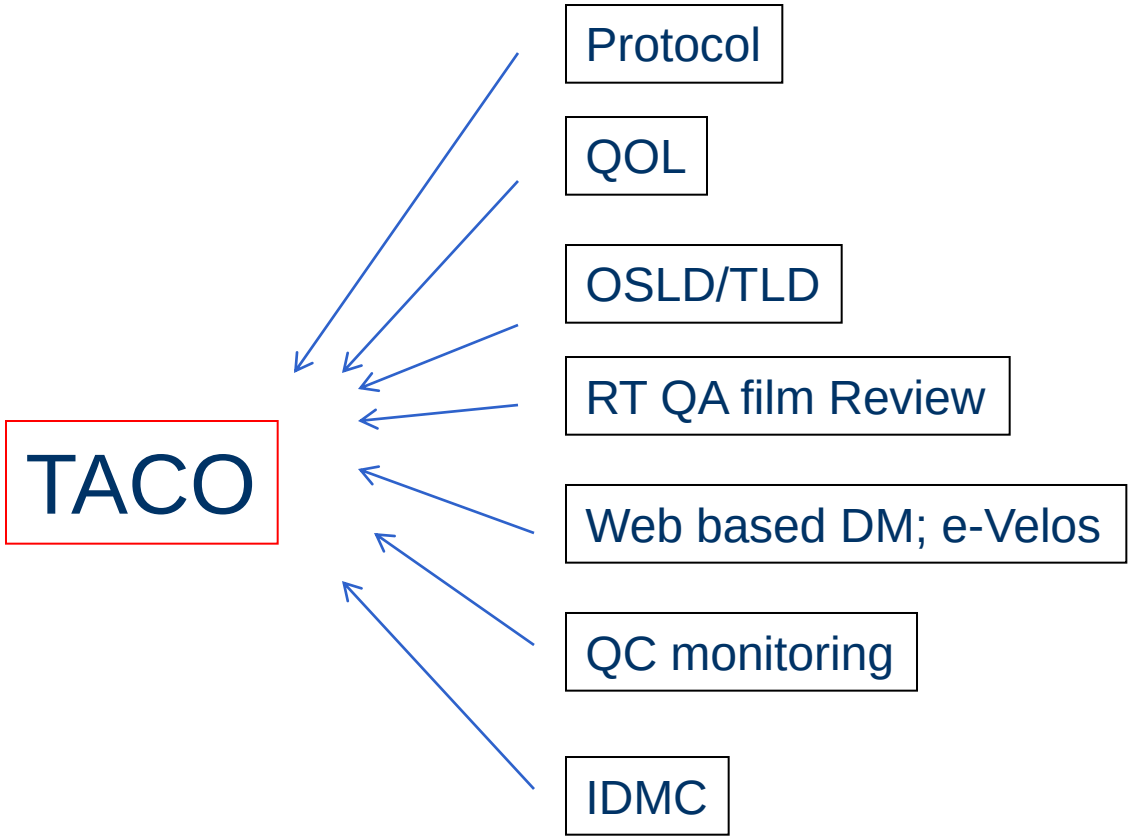

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Innovation is not a creation out of nothing, but

a new combination of things already known.

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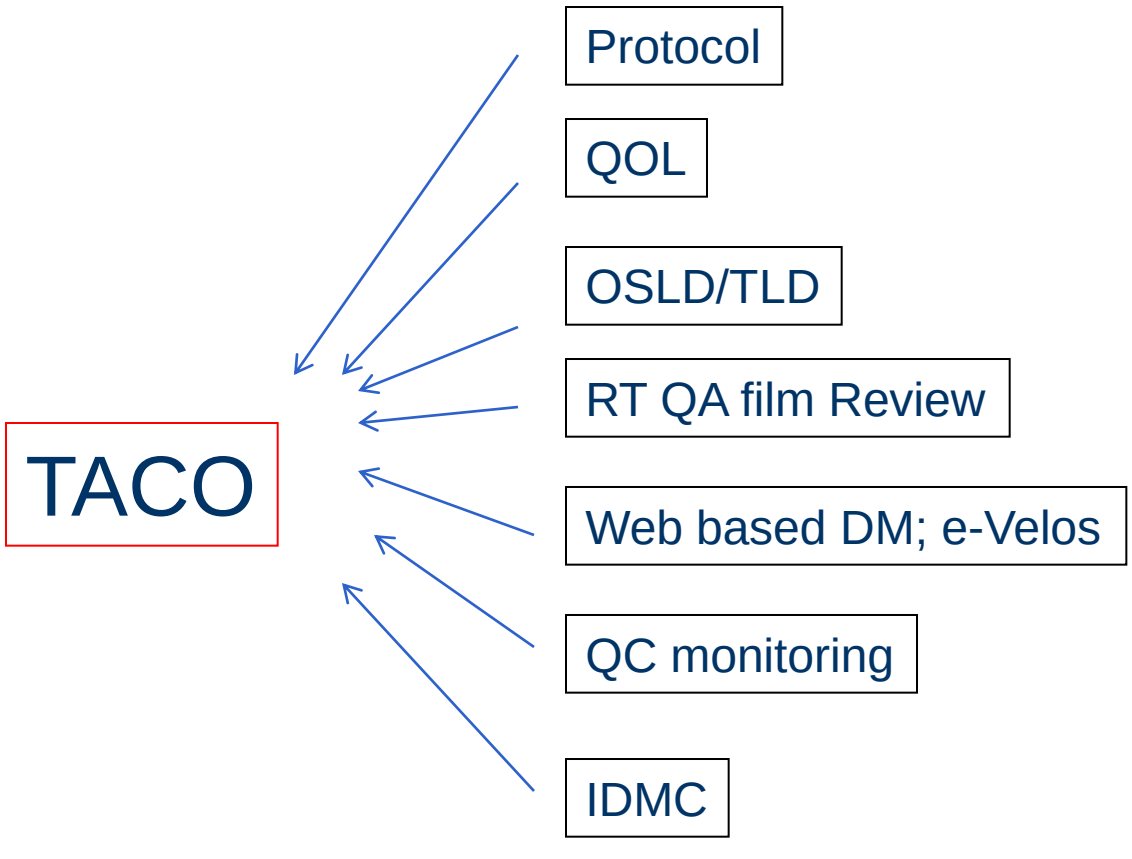

RT QA in TACO

- Pretreatment AP/Lat portal film review
  - within 24 hours
- Post treatment RT review
  - William Small, Chomporn Sitatanee, HackJae Kim
  - Biennial meeting
  - Acceptable/Deviation acceptable/Unacceptable

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KGOG
Korean Gynecologic Oncology Group

RT-QA

(1st RT-Film review 2012. 11)

(2nd RT-Film review at Bangkok 2013.4)

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RT QA in TACO

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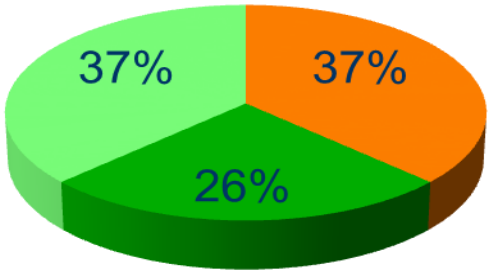
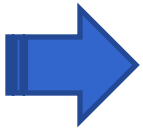
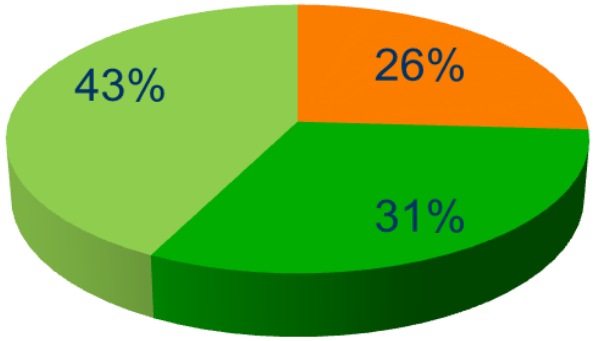
Deviation



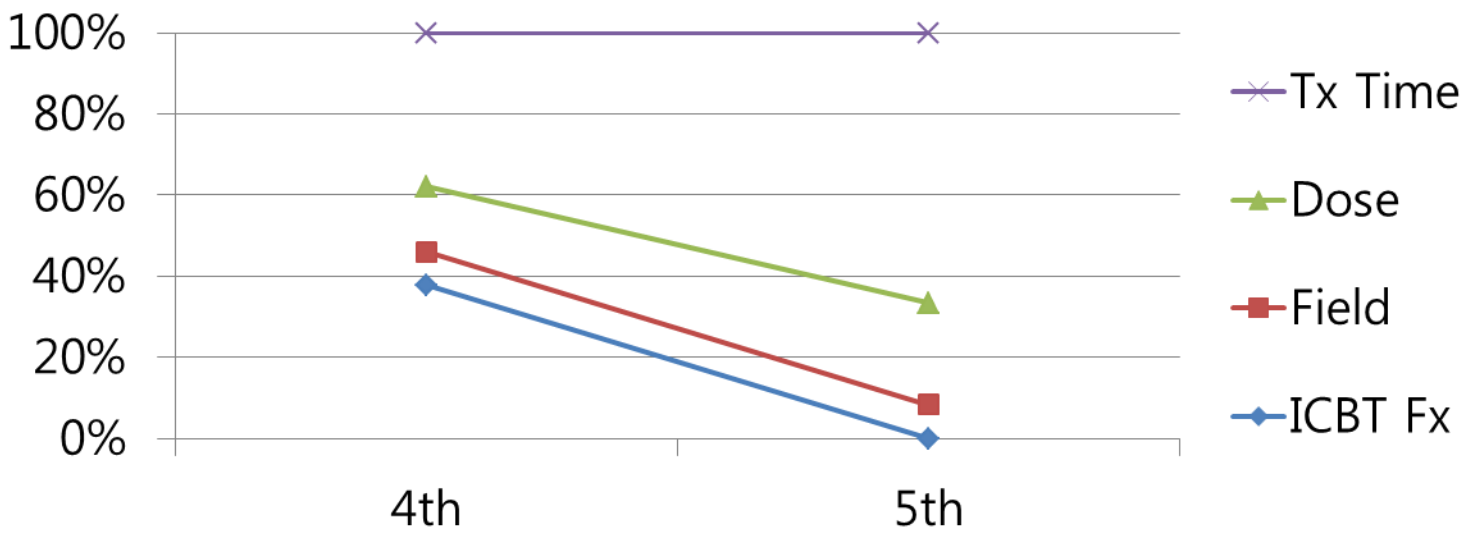


Deviation



Major
Minor
Per

RT QA in TACO



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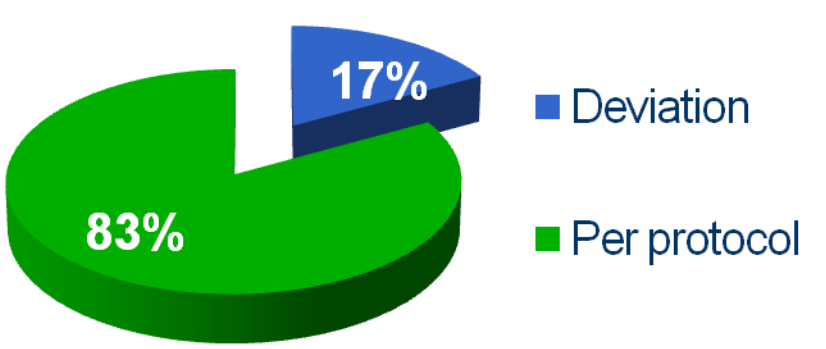
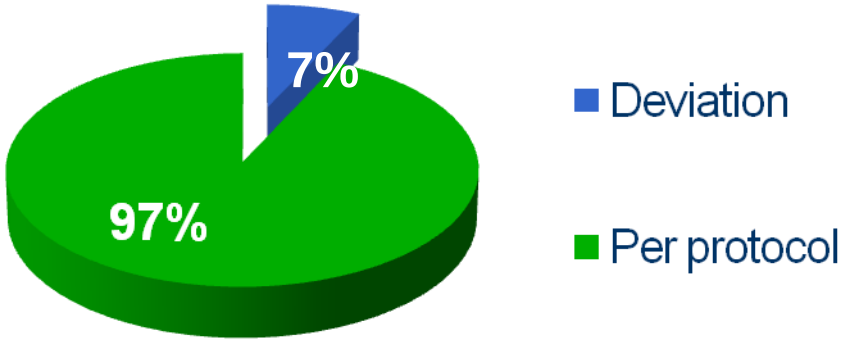
1st QC Deviation	2nd QC Deviation
17%	7%

1st QC Monitoring



2nd QC Monitoring



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Summary

QA in Clinical Trial

- Data were generated, recorded, analyzed, and accurately reported
- By protocol, SOPs, and GCPs

QA promotes

- Confidence
- Gauge current performance levels and improvement

Thank you for your attention.

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