Gynecologic Cancer InterGroup
Imaging & Pathology Brainstorming Day
October 2018 Munich

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

Pathology requirements in clinical trials

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The Pathology Manual

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Trial planning

- Inclusion of Pathologist at the design stage
- Pathology representation from trial groups
- GCIG- Pathology liaison group
- Advice and comment

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Definition of the disease in the trial

- Pragmatic
- Workable
- Consistent

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Definition of the disease

- Defining the pathological criteria
- Acceptable definition wording
- Recognition that this may be trial specific
- Determined by the collaborating groups
- International variations
- Acceptability
- Standardisation
- Minimising disagreement

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Diagnostic process

- Tissue requirements- histology-cytology
- Tissue preservation formalin or other
- Amount of diagnostic tissue
- Examination of the sample
- Ancillary tests and standardisation

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Determining stage

- Representative tissues
- Surgical trials
- Dissection protocol essential
- Lymph node dissection

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Need for review

- If the original definition is good and robust this should be easy and straightforward
- Quality
- Consistency
- Minimising variation
- Ensuring comparability

Review process

- Sensitive issue
- Reports
- Slides –stained ,unstained, standard of preparation
- Blocks
- Transport and communication
- Scanned images
- Accessibility
- Storage

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Review Process and Documentation

- Membership of the review panel
- Backup requirement
- Decision process
- Majority decision and its definition
- Signatures and alternatives
- Document version control
- Record keeping including emails

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Personal requirements

- Appraisal
- Good Clinical Practice
- IQA participation
- EQA participation

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COST

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Thank you