GYNECOLOGIC CANCER INTERGROUP

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

ENGOT LIAISON REPORT

Bénédicte Votan on behalf of Gabriele Elser

European Network of Gynaecological Oncology Trials group

ENGOT

ESGO

European Society of Gynaecological Oncology

NEW MEMBERS AND MENTORS

- Leora from ISGO – Mentor GINECO (Bénédicte)
- Ivana from CEECOG – Mentor AGO (Gabriele)
- Eva from NSGO – Mentor MITO (Jane)
- Leen from BGOG (Elke mentor)

RISK-BASED MONITORING

Example with the PAOLA study

CONCLUSION

- Long process to implement
- Needs to define clearly at the beginning the type of deviations and what to consider at risk for the study (safety, staff change,delay in data entry, no compliance with GCP…)
- Needs to evaluate at the end of study the real cost (costs for monitoring reduced but more time for data management people)

BUT it is a really interesting approach for a better evaluation of the quality of the sites (and then the quality of the study)

RISK-BASED MONITORING

- 2 initiatives on going
  - ADAMON study (randomized study with comparison of full monitoring versus adaptative monitoring)
  - TEMPO study

➔ Results of both studies available soon and presented at the next ENGOT administrative meeting

BUDGETING A TRIAL

Working in group" activity, assumptions:

Trial Design:

- National Randomized Phase III Trial in first line ovarian cancer.
- 40 sites
- N: 400 pts
- Recruitment period: 2 years
- Trial duration: 5 years
- Standard treatment (ST) vs ST+ X (experimental)
- Standard Treatment duration, 6 months
- Experimental treatment (X) duration, 12 months.
- X=IMP Approved medication used in other indication, provided by Pharma (Distribution in charge of Group).
- Blood and Tumor collection for TR (room temperature 1 shipment per site).
- CT scan every 8 weeks for the first 12 months
- ECG every 3 months for the first 12 months
- eCRF

- Different approches in budgeting the tasks

- countries are very different in terms of costing (insurance, fees for Ethics, cost for exam ie CT scan and personal hourly rate…)

➔Very complicating for budgeting an international study

Work for next time = survey among the groups to determine hourly rate average for everybody

Network Monitoring in Intergroup Trials

AIM :

- To exchange about knowledge and experience in the indication
- Preparation of monitoring material could be shared
- To be sure that monitoring is performed in the same way ➔ better quality of the trial ?
- To provide global monitoring service