

# Insurance and Indemnity

Update May 2017

# Insurance and Indemnity Manuscript

- Manuscript was shared with Harmonization Committee for comments on February 23rd, 2017
- Planned to submit the paper to Int J Gynecol Cancer in May 2017

# New idea based on following publication

- *Perrone et al.; Insurance for independent cancer trials*  
(*Annals of Oncology* 15(11):1722-3 · December 2004)
  - Authors collected data on 62 quotations from 12 non-profit Italian promoters of cancer trials.
  - Company A (14 quotations) :  
median cost per patient € 85.50  
(range 18.00 – 196.00)
  - Company B (22 quotations):  
median cost per patient € 80.00  
(range 30.00 – 165.00)
  - Cost was higher for more recent quotations, smaller sample size and phase II rather than phase III trials
  - Costs of policies is sharply increasing over time (see Figure 1)

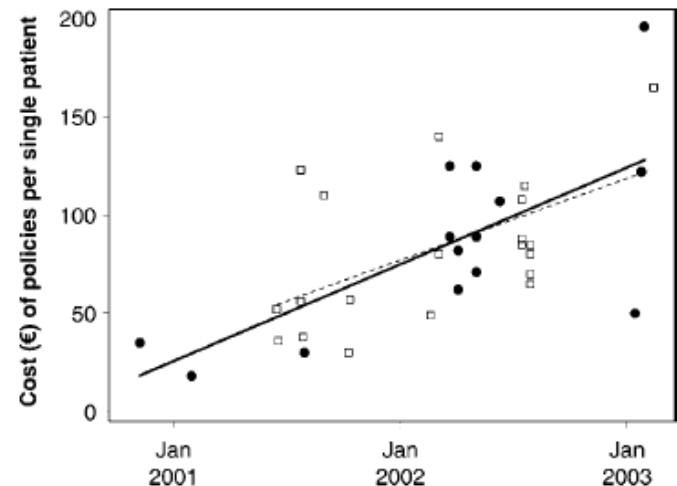
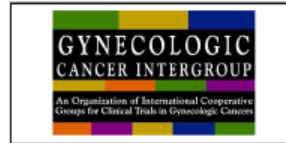


Figure 1. Correlation between cost of insurance and date of quotation for company A (filled circles, solid line) and company B (open squares, dashed line).

# New survey to collect information about costs of insurance per patient

- Aim is to collect information about costs of insurance per patient and its development over time
- Each group is asked to provide the following information for the most recent interventional clinical trials (Phase II and/or Phase III) in which the group provided a trial-specific insurance policy for any trial related side effects or injuries or trial-related deaths.
  - Cost of Insurance per patient
  - Sample size / Number of patients covered by the respective insurance policy
  - First Patient In (Month / Year)
  - ClinicalTrials.Gov number (optional)
- To assess the development this information will be collected again in two years (e. g. after EU portal and the EU database are fully functional)

# Final draft questionnaire



## Questionnaire – Cost of Insurance per patient

|                 |  |
|-----------------|--|
| Name:           |  |
| E-mail Address: |  |
| GCI Group:      |  |
| Country:        |  |

Please provide the following information for the most recent interventional clinical trials (Phase II and/or Phase III) in which your group provided a trial-specific insurance policy for any trial related side effects or injuries or trial-related deaths.

Please note: For intergroup trials, please provide the cost of insurance for your country only. If your group covers multiple countries, please complete this questionnaire for each country.

|   | Phase II | Phase III |
|---|----------|-----------|
| Cost of Insurance per patient   |          |           |
| Sample Size / Number of patients covered by the respective insurance policy in your country |          |           |
| First Patient In (Month/Year)   |          |           |
| ClinicalTrials.Gov number (optional)  |          |           |