Insurance and Indemnity

Update May 2015
• Preliminary results of survey were presented in London 2013 (responses from 13 groups)

• In April 2014, survey was revised to be more comprehensible by restructuring some questions and to capture more detailed data by adding specific questions to indemnification of trial-related side effects / injuries / deaths.

→ 7 additional items have been added (questions 6.i – 6.ii)
Status

- By now, responses received by 20 groups

- Response to additional questions (6i-6vii) is pending from:
  - ANZGOG

- Response to (complete) survey is pending from:
  - ACRIN, BGOG, COGI, G-GOC, KGOG, RTOG, SGOG

Non-responding groups are asked to provide completed insurance and indemnity survey
Results

• General rules in each country:
  – regulated by law in each country
    (results in difficulties, because the law is different in each country)

• Limitations of liability:
  – different in each country

No change compared to GCIG London 2013
Results

Relevance of health insurance

Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

- Yes
- No
- Different answer

![Bar chart showing responses to the question.](chart.png)
Are there any special requirements regarding indemnity or liability requested from your investigators/sites?

→ Special requirements are different in every country
Which kind of insurance are available/required by law in your country?

- Liability Ins. Site/Investigator
- Liability Ins. group/coordinating Centre
- Travel related Insurance
- Insurance for trial related side effects

- Yes
- No

[Bar chart showing the distribution of availability of different types of insurance by law within countries.]
Results

• Who has to establish:
  – travel insurance: if necessary, sponsor or PI’s site
  – insurance for trial related side effects: Sponsor or PI’s site

• Providance of compensation
  – not in general, only exceptions (most travel costs, parking and food expensive)
Indemnification of trial-related side effects / injuries / trial-related deaths

Indemnification source

- Private policy
- National mechanism
- Both
Indemnification of trial-related side effects / injuries / trial-related deaths

Indemnification type

Comparison with data provided by EORTC (info from policy broker): identical replies for 5 countries, different replies for 4 countries; no comparison possible for 4 countries due to missing reply by group or broker
Indemnification of trial-related side effects / injuries / trial-related deaths

Indemnification limits (maximum) imposed by law

- Per patient:
  - Yes: 7 groups (€ 250 000 - € 1 Mio)
  - None: 4 groups
  - Not specified: 4 groups

- Per trial:
  - Yes: 7 groups (€ 2.5 Mio - € 50 Mio)
  - None: 4 groups
  - Not specified: 4 groups

- Per year:
  - Yes: 2 group (€ 25 000 - € 10 Mio)
  - None: 8 groups
  - Not specified: 3 groups
Indemnification of trial-related side effects / injuries / trial-related deaths

Usual insurance sum in practice

- Per patient: € 250 000 - € 1 Mio
- Per trial: € 2 Mio - € 50 Mio
- Per year: if applicable, € 6.5 Mio - € 10 Mio

Cover period post study closure:

- Differs from 12 months up to 10 years
- Unlimited: 1 group
- Not specified: 1 group
- Policy based: 1 group
Indemnification of trial-related side effects / injuries / trial-related deaths

Who is ensured?

- Patient
- Inv/Site
- Sponsor
Indemnification of trial-related side effects / injuries / trial-related deaths

Is insurance already risk-based?

Is insurance / indemnification already risk based (ie. Is the risk of the clinical trial and/or the likelihood of damage to the trial participants been taken into account?)

- Yes
- No
Insurance for trial related side effects

• In which trials is an insurance required:
  – General in all trials: 14 groups
  – Required only in medicinal interventional trials: 5 groups

• Is there a minimum amount for indemnity per patient?
  – Yes: 9 groups
    differs from 500,000 Euro – 6.5 Mill Euros
  – No minimum stated by law: 6 groups
  – Depends on Phase/risk of trial: 4 groups
Insurance for trial related side effects

- Insurance policy to be submitted to EC/Health Authority prior to approval:
  - Yes: 11
  - No: 6
  - Depends on EC: 2

- Docs needed to receive insurance policy:

![Graph showing the distribution of documents needed]

Other documents needed: expected population, list of participating sites, number of patients, CV of PI and Co-I, Trial Drug prescription information or Investigator Brochure, local EC approval, contract, group specific appendix
Conclusion

- Nothing in common in all countries
- Harmonization seems to be impossible as each country has to establish insurance according to local law
- However, survey provides good summary for Insurance / Indemnity policy in each country
  - „Insurance & Indemnination“ - master file capture all data from the questionnaire → good resource of information
  - Pooled data for indemnification of trial-related site effects / injuries / deaths per group and country
Next steps

- Current versions will be provided for upload on GCIG homepage

- Document will be shared with all groups once a year or prior to each meeting asking for verification of data / providing additional information