

Insurance and Indemnity

Update May 2015

General

- 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

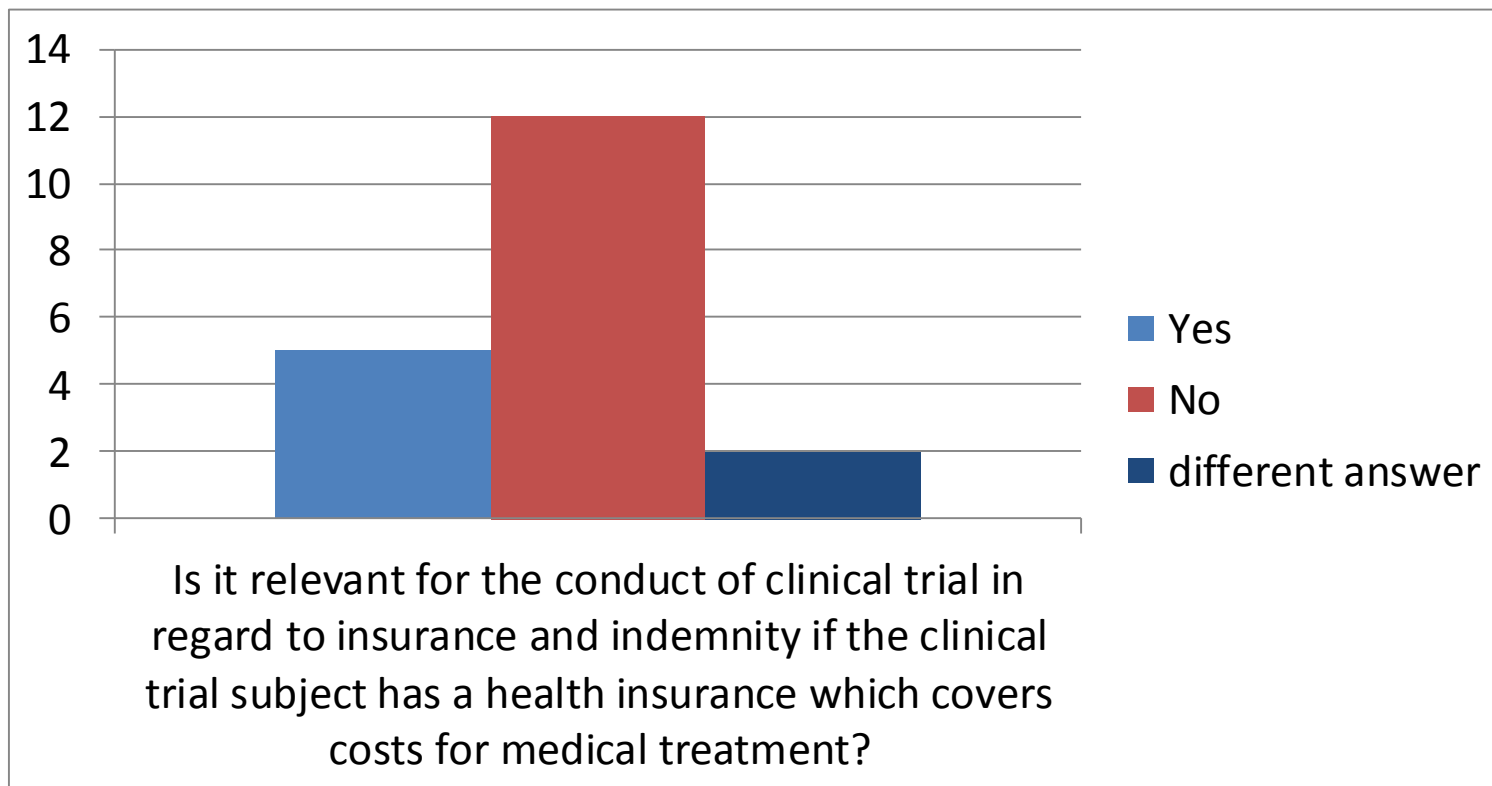
Results

- 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

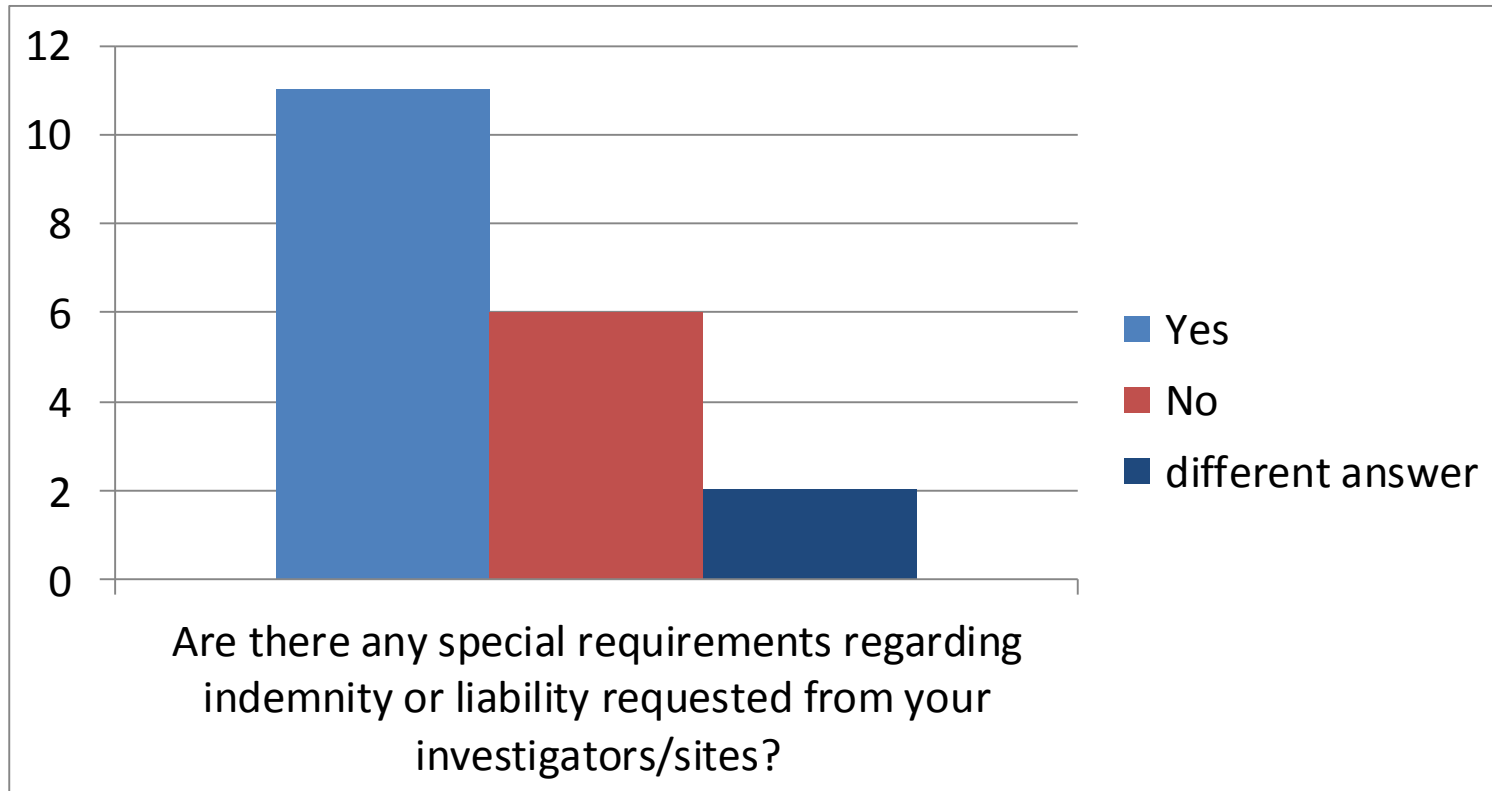
Results

Relevance of health insurance



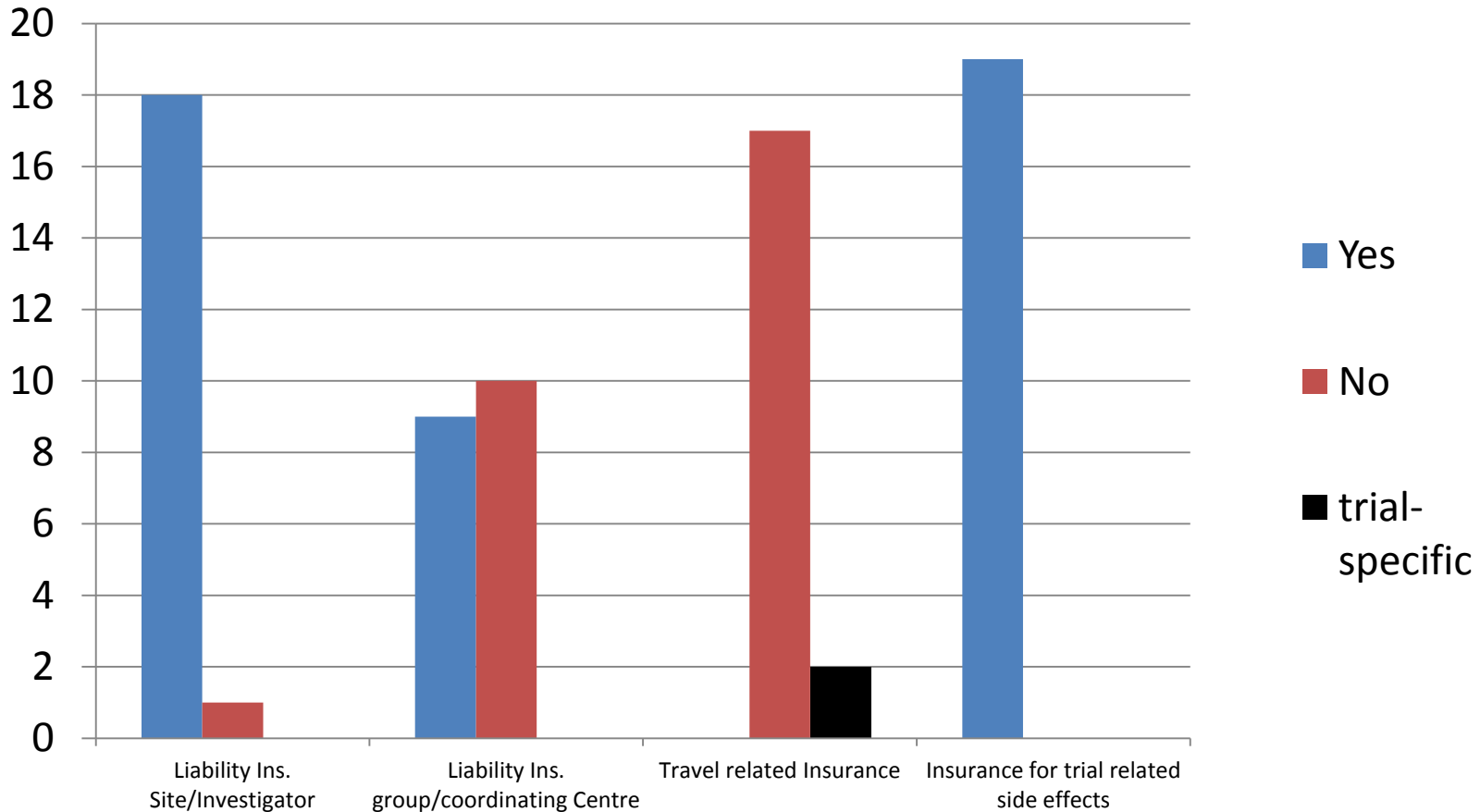
Results

Special requirements from Inv/sites



→ Special requirements are different in every country

Which kind of insurance are available/required by law in your country?

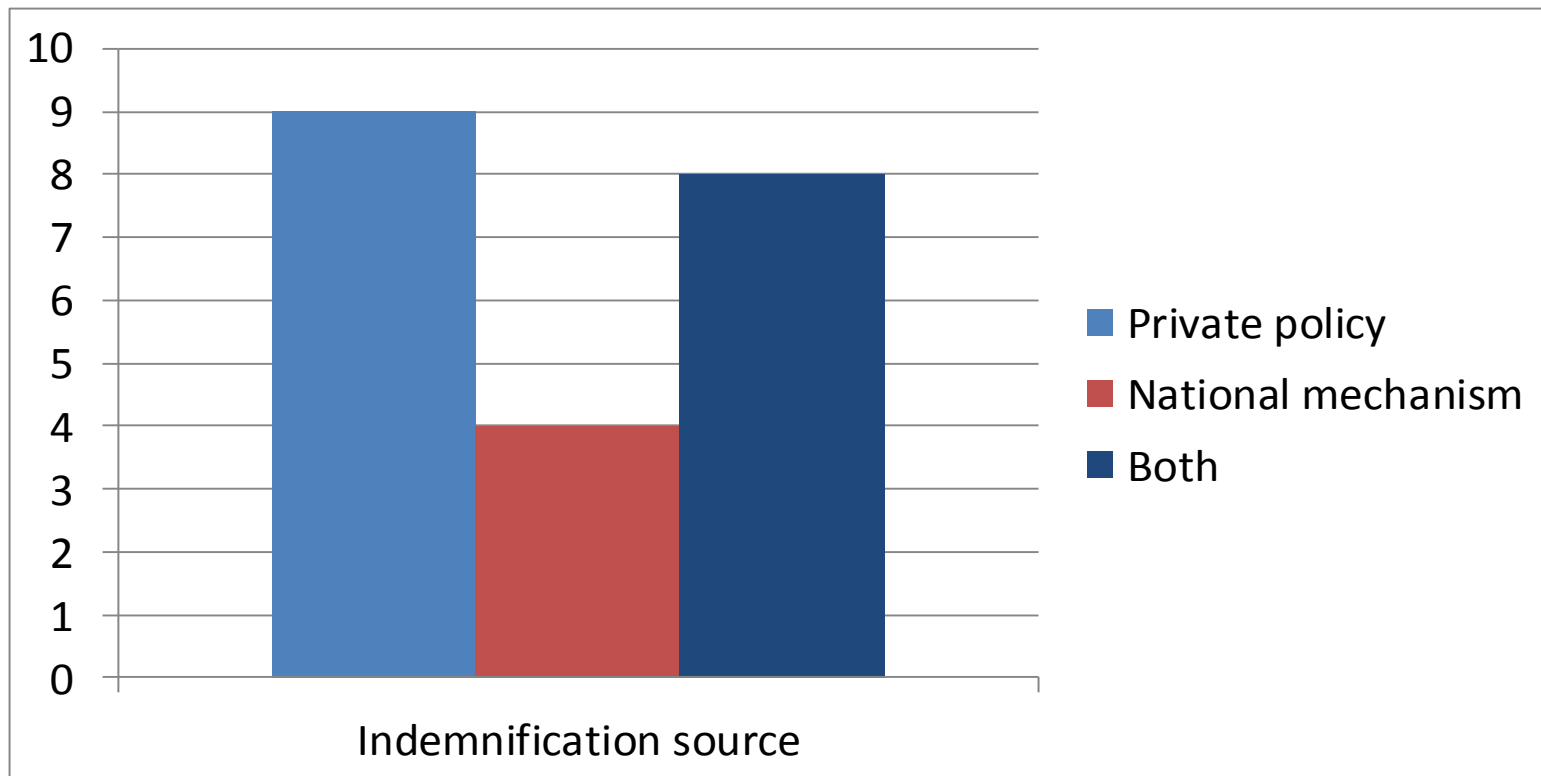


Results

- Who has to establish:
 - travel insurance: if necessary, sponsor or PI's site
 - insurance for trial related side effects: Sponsor or PI's site
- Provi dance of compensation
 - not in general, only exceptions (most travel costs, parking and food expensive)

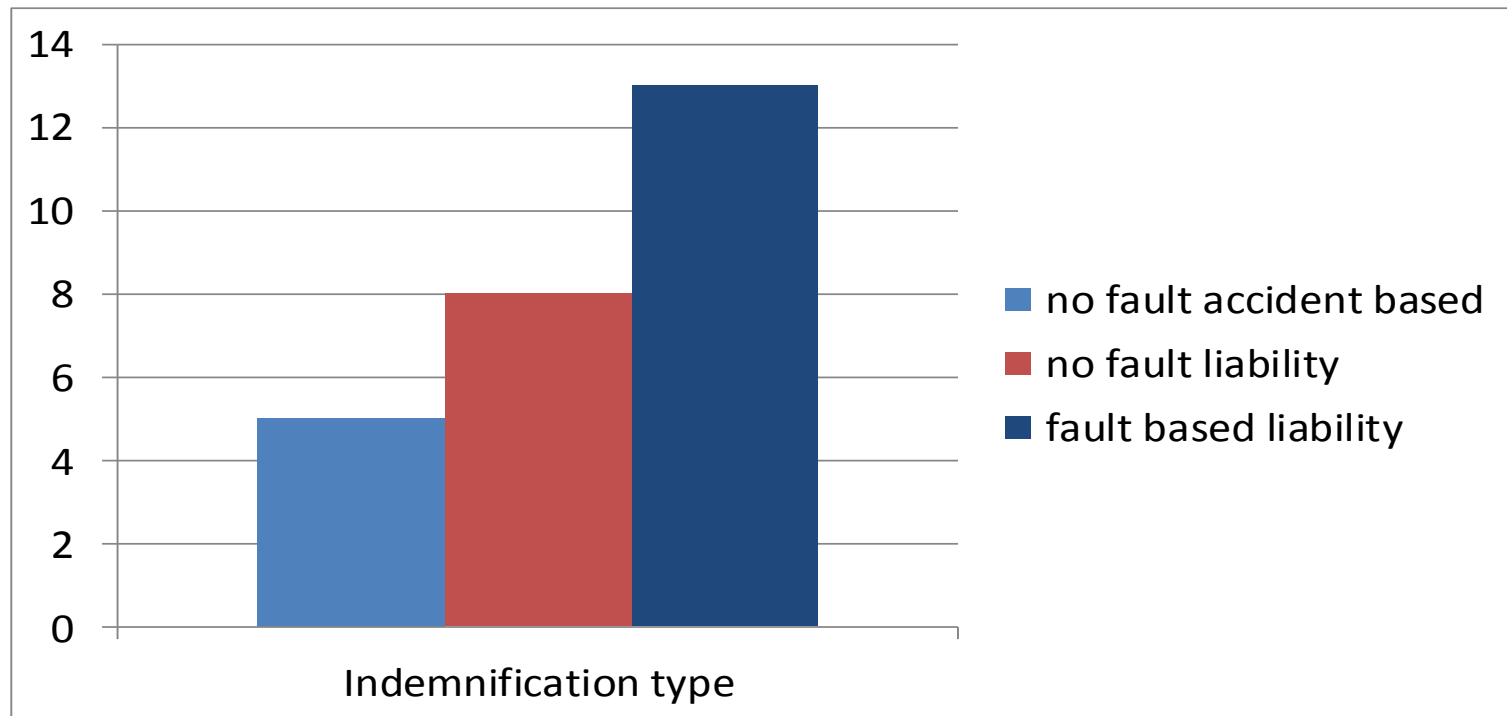
Indemnification of trial-related side effects / injuries / trial-related deaths

Indemnification source



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

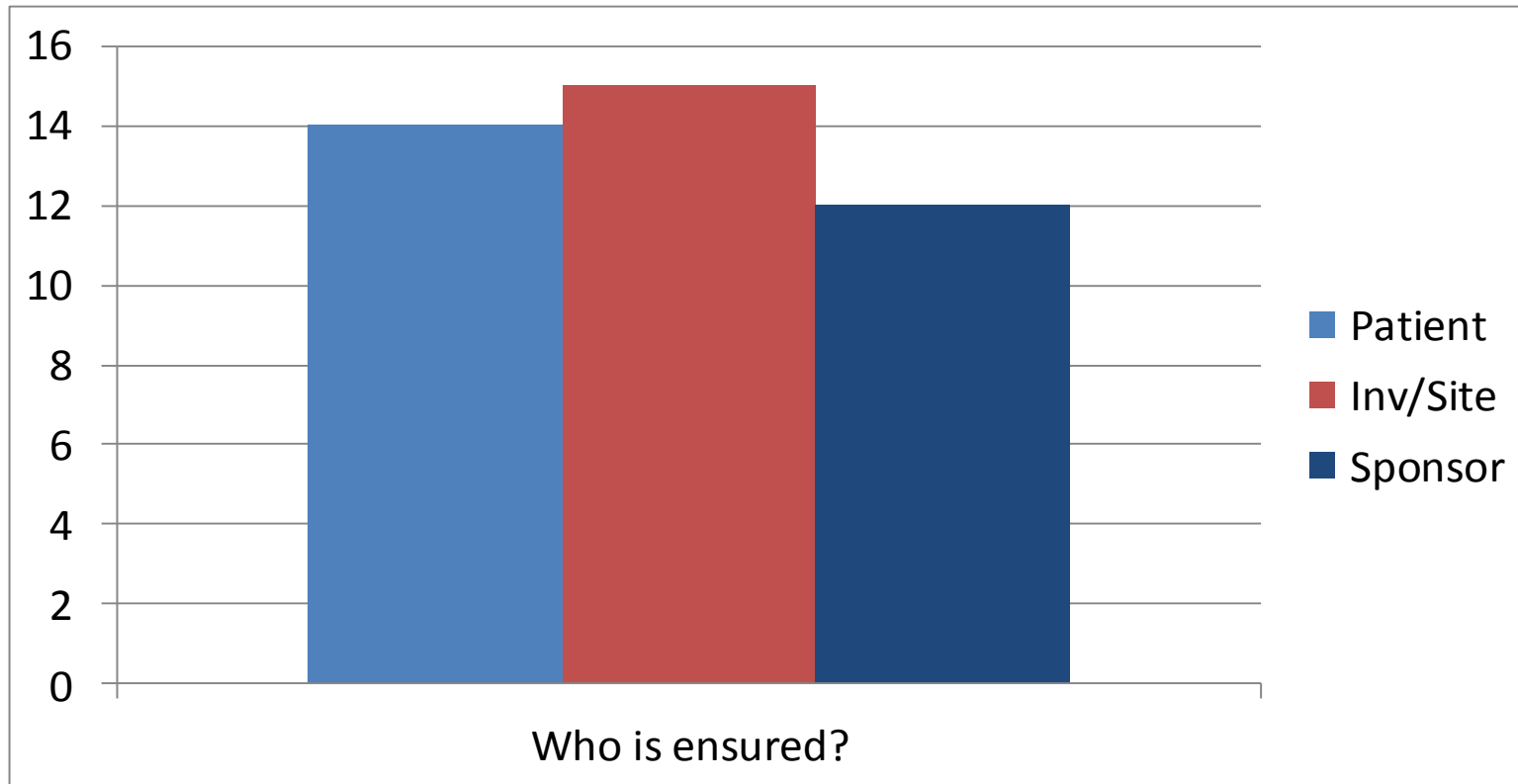
- Per patient: € 250 000 - € 1 Mio
- Per trial: € 2 Mio - € 50 Mio
- Per year: if applicable, € 6.5 Mio - € 10 Mio

Cover period post study closure:

- Differs from 12 months up to 10 years
- Unlimited: 1 group
- Not specified: 1 group
- Policy based: 1 group

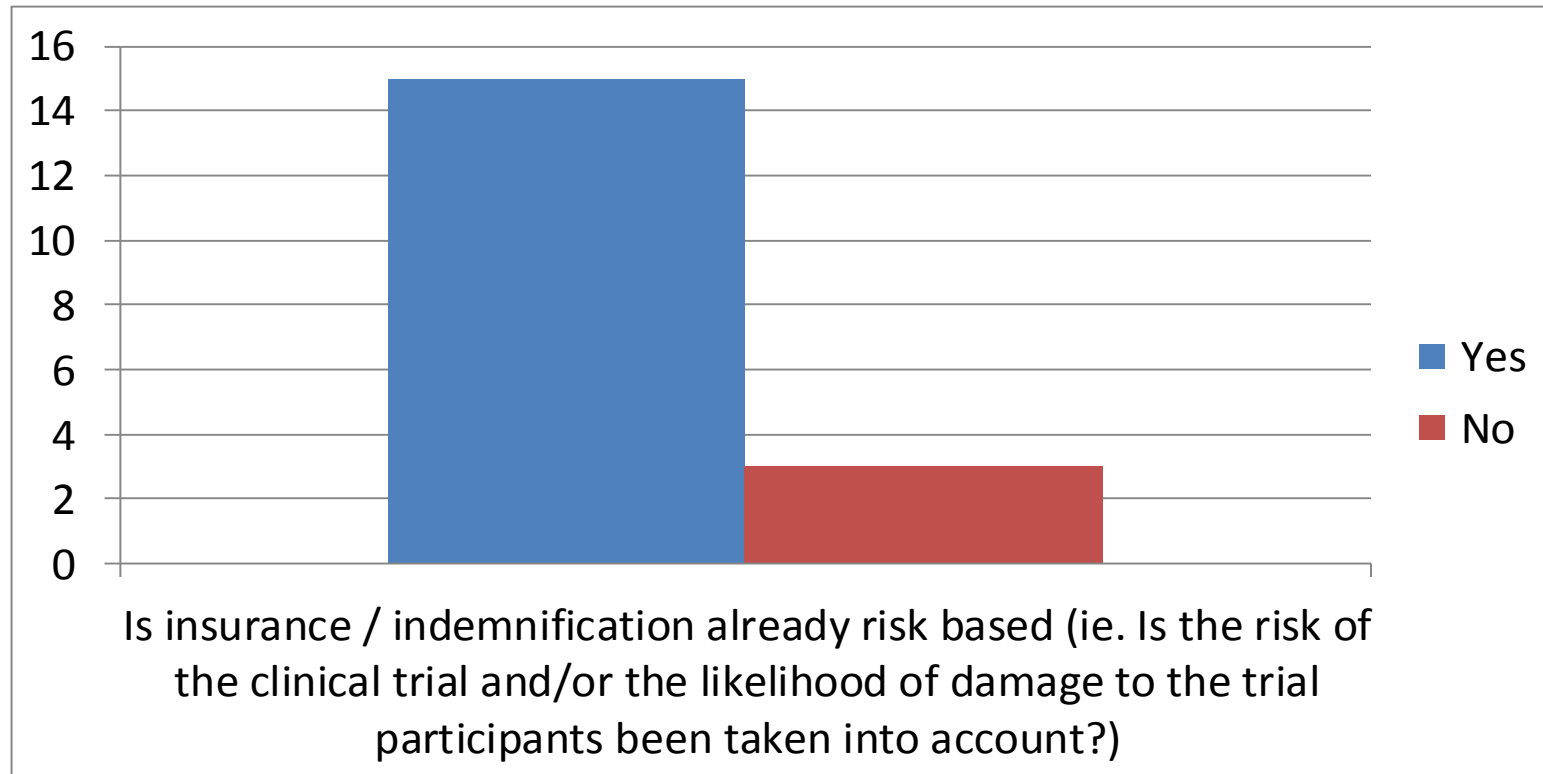
Indemnification of trial-related side effects / injuries / trial-related deaths

Who is ensured



Indemnification of trial-related side effects / injuries / trial-related deaths

Is insurance already risk-based?

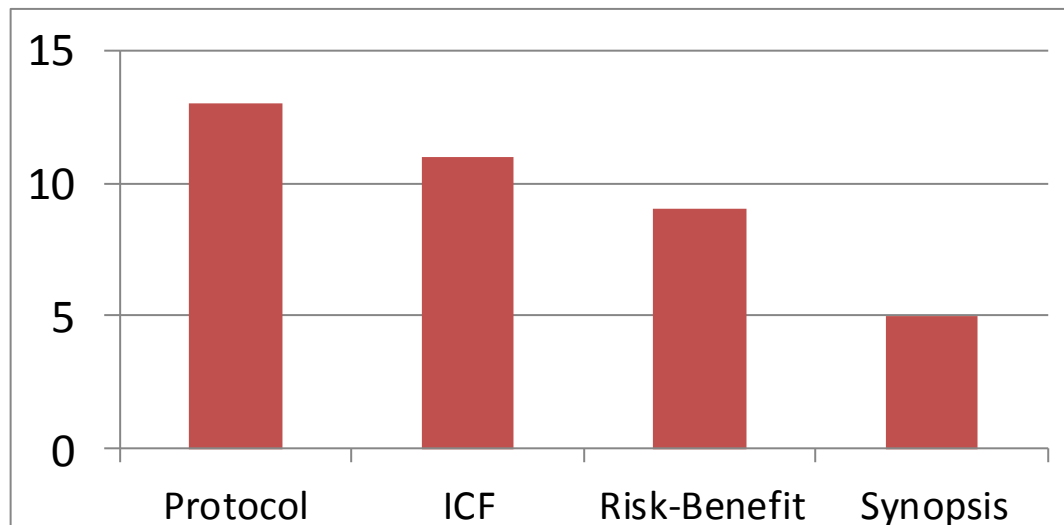


Insurance for trial related side effects

- 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:



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 & Indemnification“ - 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