

Group	Country	Indemn. Source	Indemn. Type	Limit imposed by law (Maximum)			Usual insurance sum in practice			Cover period after End of trial	Who is ensured?	Already risk-based?	Trials requiring insurance	Minimum amount for indemnity per patient	Insurance policy to be sent to EC/HA prior approval?	Docs to be provided to receive policv	Add. Information
		(1) private policies (2) nat. mechanism (3) both	(1) no fault accident (2) no fault liability (3) fault based liability	per patient	per trial	per year	per patient	per trial	per year								
ACRIN AGO Study Group	Germany	1	1	€ 500 000	€ 50 Mio.	NA	€ 500 000	€ 50 Mio.	NA	+ 5 years	1*	yes	trials with drugs (AMG) or medical devices (MPG)	€ 500 000	yes	1, 2, 4 and 5 (no. patients (total + national), sites, trial duration)	* site & sponsor have to have general liability insurance
AGO-A	Austria	3	2	none	none	none	€ 500 000	€ 3 Mio.			1, 2	yes	interventional trials, any risk to the welfare of the patient	no minimum stated by law	yes	1, 2	
ANZGOG	Australia	3	2	n/a	n/a	n/a	n/a	n/a	AUD\$ 20 Mio.	n/a, insurances are renewed annually	1,2,3	yes	all trials	no minimum stated by law	yes, certificate of currency usually required for site governance approval	4, 5 (Spreadsheet of all trials including study name, site locations and numbers of patients)	
BGOG	Belgium																
COGI	United States																
DGOG	The Netherlands	3	1, 2, 3	at least € 650 000	at least € 5 Mio	at least € 7.5 Mio	at least € 650 000	at least € 5 Mio	at least € 7.5 Mio	+ 4 years	1,2,3	yes*	all trials	€ 650 000	yes	5 (not to company, but to EC, they will decide on the requirements for the specific (standard)	* Trials of no added risk over normal treatment (e.g. questionnaires) can be allowed to have no specific insurance (other than each hospital's standard insurances) - the Ethics Committee will decide on such a request
EORTC*	Austria		2	none	none	none				+ 3 years	1, 3 2 in additional option					1, 2,3, 5 (no. patients, sites, start / end date)	
EORTC*	Belgium		2	€ 500 000	€ 3 Mio	€ 5 Mio				+ 5 years	1,2,3					1,2, 5 (no. patients, start / end date)	
EORTC*	Croatia		3		no limits; from € 50 000 to € 150 000 per protocol					+ 5 years	1.3					1, 3, 5 (Phase, PI and institution, no. patients)	PIs/ Investigators should have malpractice insurance themselves
EORTC*	Cyprus																!According to AON dbase there is no obligation in Cyprus on clinical trial insurance!

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		(1) private policies (2) nat. mechanism (3) both	(1) no fault accident (2) no fault liability (3) fault based	per patient	per trial	per year	per patient	per trial	per year								
EORTC*	Czech Republic		2	CZK 6 Mio	CZK 60 Mio	none					1,2,3					1, 2, 5 (list PI/institution)	Med. malpractice is not individually available and covered by clinical trial insurance
EORTC*	Denmark		2		no min. limits					+ 3 - 5 years recommended	1, 3			no minimum stated by law		1, 2, 5 (no. patients, name + address PI, start / end date)	when trial conducted within the frame of the law med. malpr. is covered by the Danish Compensation Act
EORTC*	Egypt				USD 1 Mio												no clear guidelines on AON dbase; no regulations available
EORTC*	Finland		2							Check if EORTC is member of the cooperative insurance policy; annual policy							A cooperative insurance policy is available that covers all studies from the registered cooperator; no specific documents are required to submit for adding a trial, the certificate for being member of the cooperative insurance is sufficient to submit to EC
EORTC*	France		2	€ 1 Mio	€ 6 Mio	€ 10 Mio				+ 10 years	1, 2, 3					1, 2, 5 (start / end date)	no standard malpractice on the market; to be checked with PI
EORTC*	Germany		1		€ 500 000 minimum tbd by pool					+ 5 years (?) after end of patients treatment or 10 years after the end of the study	1			€ 500 000		1, 2, 5 (Questionnaire)	Malpractice to be checked with site
EORTC*	Greece			€ 200 000	none	none					1					1,2, 5 (PI name and address, no. patients, start / end date)	medical malpractice is excluded from clinical trial insurance
EORTC*	Hungary		2	€ 600 000	€ 3 Mio	none				+ 5 years	1, 2, 3						
EORTC*	Ireland																
EORTC*	Israel		2	none	USD 3 Mio		none			extended reporting period 7 years	1, 2, 3						

[illegible]

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		(1) private policies (2) nat. mechanism (3) both	(1) no fault accident (2) no fault liability (3) fault based liability	per patient	per trial	per year	per patient	per trial	per year		(1) patient (2) Inv/site (3) Sponsor					(1) Protocol (2) ICF (3) Synopsis (4) Risk-benefit (5) Other	
EORTC*	Switzerland		3	Bodily injury CHF 1 Mio; Property damages CHF 50 000; Invasion of personal privacy	CHF 10 Mio	none				+ 5 years	1						
EORTC*	The Netherlands		2	€ 450 000	€ 3.5 Mio	€ 5 Mio if more than 1 clinical trial in same contract				+ 4 years after enrollment	1						
EORTC*	Turkey		1	€ 200 000 (bodily injury & property damages)	€ 2 Mio (bodily injury & property damages)					+ 3 years	1					request 6 EN and 6 TK for signature and retain 4 of each	
EORTC*	United Kingdom		2		€ 5 Mio + ABPI guidelines						+ 3 years recommended	1, 2, 3					
GEICO	Spain	1	1, 2	€ 250 000	€ 2.5 Mio	€ 25 000	€ 250 000	€ 2.5 Mio	€ 25 000	+ 12 months	1, 2, 3	yes	all trials	no minimum stated by law	yes	1, 2, 3, 5 (sites, Inv. information, summary expected toxicities)	
GICOM	Mexico	3	3	depending on the amount agreed in the Study Insurance	depending on the amount agreed in the Study Insurance					+ 3 years	2, 3	yes	all trials	no general minimum, depends on Phase / risk of trial	no	approved Protocol & ICF & IB/SmPC in Spanish, Inv. CVs, sites, EC & MOH approval	
GINECO	France	3	3	€ 1 Mio.	€ 6 Mio.	€ 10 Mio.	€ 1 Mio.	€ 6 Mio.	€ 10 Mio.	+ 10 years	1	yes	all trials	no general minimum, depends on Phase / risk of trial	yes	1, 2	insurance calculation is risk-based
GOG	United States	3	3	Policy based	Policy based	Policy based	Policy based	Policy based	Policy based	Policy based	2, 3	yes	all trials	no general minimum, depends on Phase / risk of trial	no	1, 2	
GOTIC	Japan	3	depending on type of insurance	not specified	not specified	not specified	Yen 100 Mio	Yen 300 Mio	NA	usually + 1 year	1, 2, 3 (depending on type of insurance)	yes*	indication trials	no minimum stated by law	depending on IRB	1, 3, 5 (group specific appendix)	*evaluation by insurance company; Product liability is usually covered by pharmaceutical or medical device company insurance. Definite fault of the Inv or the site is covered by the insurance for the Inv or sites themselves
G-GOC	United States																

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		(1) private policies (2) nat. mechanism (3) both	(1) no fault accident (2) no fault liability (3) fault based	per patient	per trial	per year	per patient	per trial	per year								
ICORG	Ireland	3	3		yes		€ 6.5 Mio per study/year		NA	NA	1, 2, 3 (if ICORG is sponsor) 1, 2 (if commercial sponsor)	no	all trials	€ 6.5 Mio per study/year	yes (ICORG/sponsor provides a copy of the clinical trials insurance certificate as evidence of such a policy being in place. This certificate is normally renewed annually.)	1 (occasionally), 3, 5 (summary of trial participation, EC approval*)	*This refers to a different document. A copy of the EC approval is provided to the insurer of the national Clinical Indemnity Scheme (CIS) in Ireland which covers clinical trial indemnity of public hospital sites. On receipt, the insurer will provide a letter confirming indemnity cover under the CIS for the specific study to be conducted at each site that has been approved by the EC.
JGOG	Japan	3	depending on type of insurance	not specified	not specified	not specified	Yen 100 Mio	Yen 300 Mio	NA	usually + 1 year	1, 2, 3 (depending on type of insurance)	yes*	indication trials	no minimum stated by law	depending on IRB	1, 3, 5 (group specific appendix)	*evaluation by insurance company; Product liability is usually covered by pharmaceutical or medical device company insurance. Definite fault of the Inv or the site is covered by the insurance for the Inv or sites themselves
KGOG MaNGO	Korea Italy	1 (Specific clinical trial policy)	3	at least € 1 Mio.	at least € 5 Mio. for < 50 pt, € 7.5 Mio. for 50-200 pt and € 10 Mio. for > 200 pt	no, but totals may be revised every 3 years	€ 120 - 150	at least € 50 000, increased with sample size	policy usually paid in 2 payments (at least € 25 000 each year)	injury within 24 months (reporting within 36 months), 10 years in pediatric trials / trials with genetic, cell and radiopharmaceutical therapies	2, 3	Yes, but by private insurer	all trials	€ 1 Mio.	yes	2, 3, 5 (sites, no. patients in Italy, length of study, profit/nonprofit sponsor, incl. Of minors or pregnant pat., use of gene or cellular therapy or radiopharmaceuticals)	
MITO	Italy	1 (Specific clinical trial policy)	3	at least € 1 Mio.	at least € 5 Mio. for < 50 pt, € 7.5 Mio. for 50-200 pt and € 10 Mio. for > 200 pt	no, but totals may be revised every 3 years	€ 120 - 150	at least € 50 000, increased with sample size	policy usually paid in 2 payments (at least € 25 000 each year)	injury within 24 months (reporting within 36 months), 10 years in pediatric trials / trials with genetic, cell and radiopharmaceutical therapies	2, 3	Yes, but by private insurer	all trials	€ 1 Mio.	yes	2, 3, 5 (sites, no. patients in Italy, length of study, profit/nonprofit sponsor, incl. Of minors or pregnant pat., use of gene or cellular therapy or radiopharmaceuticals)	
MRC/ NCRI	UK	1	2, 3	none	none	none	NA	NA	NA	unlimited	3	yes	all trials	no minimum stated by law	no	only if trial meet any of the exclusion for the sponsor insurance policy: 1, 2, 3	Sponsor insurance policy which will often cover a portfolio of trials. Usual indemn. limits for the entire research portfolio: GBP 15 Mio. any one claim and GBP 15 Mio. in the aggregate. Trial related side effects/injuries are treated free of charge by NHS.

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NCIC CTG	Canada	1	No standard as this is provincially based	NA	NA	NA	Unk	Unk	Unk		2, 3	yes	all trials	no minimum stated by law	no	None	Site insurance covers site, sponsor insurance covers sponsor
NOGGO	Germany	1	1	€ 500 000	€ 50 Mio.	NA	€ 500 000	€ 50 Mio.	NA	+ 5 years	1*	yes	trials with drugs (AMG) or medical devices (MPG)	€ 500 000	yes	1, 2, 4 and 5 (no. patients (total + national), sites, trial duration)	* site & sponsor have to have general liability insurance
NSGO	Denmark	2	2, 3								1, 2	no	all trials	yes	no	1, 3, 4	Compensation paid only if it is evaluated to exceed minimums of DKK 10000 / DKK 3000.
NSGO	Finland	2	2, 3								1, 2	no	all trials	yes	no	1, 3, 4	
NSGO	Norway	2	2, 3								1, 2	no	all trials	yes	no	1, 3, 4	
NSGO	Sweden	2	2, 3								1, 2	no	all trials	yes	no	1, 3, 4	
PMHC	Canada	1					\$ 5 Mio.						no	all trials	no minimum stated by law; \$ 5 Mio per occurence, by Sites policy	no	
RTOG																	
SGCTG	UK	1	1, 3	none	none	none	NA	NA	NA	not specified	1, 3	yes	all trials	no minimum stated by law	yes	3, 4	£ 10 Mio. any one case and all events occuring during any period of insurance. General clinical trials insurance policv which cover all trials
SGOG																	

information not provided

*Information received from broker

Abbreviations:

CA Competent Authority /

EC Ethics committee

Indemn. Indemnification

Inv. Investigator