

Clinical Trials

Clinical trials insurance covers the legal liabilities of the insured in respect of clinical trials for bodily injury arising from the trial. The coverage provided by Newline is on the basis of the specific territory's statutory limits, conditions and is written in the local language (where required).

Local overseas policies will be issued by or on behalf of Newline on a direct or, where a direct policy is prohibited by local law, reinsurance basis. A master policy can be provided to the Insured on a DIC/DIL basis above locally issued policies.

Local Trial Requirements

Below is a complete list of all insurable territories written by Newline on a direct/reinsurance basis with typical local policy contractual information, pre-bind requirements and territory standard extended reporting periods.

Argentina - Reinsurance

The limits for Argentina are USD 100,000 per patient and USD 1,000,000 per trial and in the aggregate. The deductible is nil.

2 years Extended Reporting Period

Additional information required prior to binding

Local CRO/Client including full name, address and contact details

Title of the Trial in Spanish

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Local Premium Payment (Payment direct from Foreign Client acceptable)

For Trials being conducted in Córdoba province, Proof of premium payment is required at the time of EC submission

Armenia - Reinsurance

The limit for Armenia is USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the trial and full investigator details in Local Language

Australia & New Zealand - Direct

The limit for Australia & New Zealand is AUD 20,000,000 each and every Claim and in the annual aggregate. The deductible is nil.

1 year Extended Reporting Period

Austria - Direct

The limits for Austria are EUR 500,000 per patient and EUR 3,000,000 per trial and in the aggregate. The deductible is EUR 1,500.

3 years Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Bangladesh - Reinsurance

The limit for Bangladesh is BDT 150,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Local Premium Payment prior to inception

Belgium - Direct

The limits for Belgium are EUR 500,000 per patient and EUR 3,000,000 per trial and in the aggregate. The deductible is nil.

3 years Extended Reporting Period

Additional information required prior to binding

Full name and address of a CRO/Client located in the EU, to act as Legal Representative

Bosnia & Herzegovina - Direct

The limit for Bosnia & Herzegovina is EUR 2,500,000 per trial and in the aggregate. The deductible is nil.

No Extended Reporting Period as trial is written on an Occurrence basis

Additional information required prior to binding

Local CRO/Client including full name, address and contact details (local regulation states that Policyholder has to be a local entity/company)

Full Title of the trial in Local Language

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes) in English & Local language

Bulgaria - Direct

The limits for Bulgaria are EUR 50,000 per patient and EUR 1,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of trial in Bulgarian as well as full investigator details in English and Local Language
Local Premium Payment prior to inception

Canada - Direct

The limits for Canada are CAD 1,200,000 per patient and CAD 5,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Chile - Reinsurance

The limit for Chile is USD 5,000,000 per trial and in the aggregate. The deductible is nil.

2 years Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)
Title of trial in Spanish
Local CRO/Client including full name, address and contact details (local regulation states that insured has to be a local entity/company)
Local Premium Payment (Payment direct from Foreign Client acceptable)
Local Client's RUT number (Tax ID number)

China - Reinsurance

The limit for China is USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the trial and full investigator details in Local Language
Local Premium Payment (Payment direct from Foreign Client acceptable)

Colombia - Reinsurance

The limit for Colombia is COP 5,000,000,000 per trial and in the aggregate. The deductible is nil.

2 years Extended Reporting Period

Additional information required prior to binding

Local CRO including contact details (local regulation states that insured has to be a local entity/company).

Local Premium Payment in COP must be paid by local client/entity

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Title of the Trial in Spanish

Costa Rica - Reinsurance

The limit for Costa Rica is USD 5,000,000 per trial and in the aggregate. The deductible is nil.

2 years Extended Reporting Period

Additional information required prior to binding

Local CRO/Client including full name, address and contact details (local regulation states that Policyholder has to be a local entity/company).

Local Signed and Stamped issuance order. This contains the clients general information, coverage details and applicable taxes. Local Client has to provide the compulsory "know your customer" information and will sign an agreement acknowledging the fronted policy

Title of the Trial in Spanish

Local Premium Payment (Payment direct from Foreign Client also acceptable)

Croatia - Reinsurance

The limits for Croatia are EUR 200,000 per patient and EUR 1,000,000 per trial and in the aggregate. The deductible is nil.

No Extended Reporting Period as trial is written on an Occurrence basis

Additional information required prior to binding

Title of the Trial in Local Language

Insured's - Company Registration No.

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Czech Republic - Direct

The limit for Czech Republic is EUR 5,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the trial and full investigator details in Local Language

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Denmark - Direct

The limit for Denmark is EUR 5,000,000 per trial and in the aggregate. The deductible is EUR 1,500.

3 years Extended Reporting Period

Dominican Republic - Reinsurance

The limit for the Dominican Republic is USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the trial and full investigator details in Local Language

Ecuador - Reinsurance

The limit for Ecuador is USD 5,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the trial and full investigator details in Local Language
Local CRO/Client including full name, address and contact details

Egypt - Reinsurance

The limit for Egypt is EUR 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the trial and full investigator details in Local Language

El Salvador - Direct

The limit for El Salvador is USD 5,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Contact Details of Local CRO/Client/Entity legally registered in El Salvador who will need to provide additional local documentation as follows
Register of commerce, DUI (Unique Identity Document) and NIT (Tributary number) of the Client/CRO. A copy of the certificate of incorporation
Insured must also complete the documents related to "Know Your Customer". These are a Comprehensive data sheet and Affidavit
Title of the trial in Spanish

Estonia

The limit for Estonia is EUR 5,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the trial and full investigator details in Local Language
Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)
Insured's - Company Registration No.

Finland

The limit for Finland is EUR 5,000,000 per trial and in the aggregate.
The deductible is EUR 1,500.

3 years Extended Reporting Period

France

The limits for France are EUR 1,000,000 per patient and EUR 6,000,000 per trial and in the aggregate. The deductible is EUR 1,500.

Additional information required prior to binding

Title of the trial and full investigator details in Local Language

10 years Extended Reporting Period

Georgia

The limit for Georgia is EUR 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the Trial in Local Language
Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)
Local CRO Details

Germany

Quotations will be provided by the German pool on the basis of 3 alternatives:

1. EUR 50,000,000 in the aggregate for the clinical trial; EUR 500,000 per patient
2. EUR 5,000,000 in the aggregate for the clinical trial; EUR 500,000 per patient
3. EUR 10,000,000 in the aggregate for the clinical trial; EUR 500,000 per patient

10 years Extended Reporting Period

Additional information required prior to binding

Title of the Trial in Local Language
Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)
Local CRO Details

Greece - Direct

The limits for Greece are EUR 200,000 per patient and

EUR 5,000,000 per trial and in the aggregate for up to 50 patients
EUR 7,500,000 per trial and in the aggregate for more than 50 patients

The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)
Title of the trial and full investigator details in Local Language

Guatemala - Reinsurance

The limit for Guatemala is USD 2,000,000 per trial and in the aggregate. The deductible is nil.

2 years Extended Reporting Period

Additional information required prior to binding

Title of the Trial in Local Language
Local CRO/Legal Entity including contact details
IVE Form (prescribed by anti money laundering laws) completed by local client

Honduras - Reinsurance

The limit for Honduras is USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the Trial in Local Language
Local CRO/Client including full name, address and contact details

Hong Kong - Direct

The limit for Hong Kong is USD 5,000,000 per trial and in the aggregate. The deductible is USD 1,500.

1 year Extended Reporting Period

Hungary - Direct

The limits for Hungary are EUR 100,000 per patient and EUR 1,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the Trial in Local Language

Iceland - Direct

The limit for Iceland is EUR 5,000,000 per trial and in the aggregate. The deductible is EUR 1,500.

3 years Extended Reporting Period

India - Reinsurance

The limit for India is USD 100,000,000 per trial and in the aggregate. The deductible is USD 2,500.

1 year Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Local CRO including contact details

Local Premium Payment prior to inception

Tax ID number of the premium paying entity (or Permanent Account Number (PAN)). If no PAN no. then a PAN exemption form must be completed

Indonesia - Reinsurance

The limits for Indonesia are USD 500,000 per patient and USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Ireland - Direct

The limit for Ireland is EUR 5,000,000 per trial and in the aggregate. The deductible is EUR 1,500.

1 year Extended Reporting Period

Israel - Direct

The limit for Israel is USD 3,000,000 per Occurrence and in the aggregate. The deductible is USD 2,500.

7 years Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Italy - Direct

The limits for Italy are EUR 1,500,000 per patient and

EUR 5,000,000 per trial and in the aggregate for 1-50 patients

EUR 7,500,000 per trial and in the aggregate for 50-200 patients
EUR 10,000,000 per trial and in the aggregate for more than 200 patients

The deductible is EUR 1,500.

3 years Extended Reporting Period

Additional information required prior to binding

Title of the Trial in Local Language
Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Japan - Reinsurance

The limit for Japan is JPY 500,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the Trial in Local Language
Signed Application form from the local CRO
Local CRO including contact details
Local Premium Payment prior to inception

Jordan - Reinsurance

The limit for Jordan is JOD 5,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Title of the Trial in Local Language
Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Kazakhstan - Reinsurance

The limit for Kazakhstan is USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Kenya - Reinsurance

The limit for Kenya is KES 100,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Latvia - Direct

The limit for Latvia is EUR 5,000,000 per trial and in the aggregate. The deductible is EUR 1,500.

1 year Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)
Insured's - Company Registration No.

Lebanon - Reinsurance

The limit for Lebanon is USD 5,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Lithuania - Direct

The limits for Lithuania are LTL 100,000 per patient and LTL 3,600,000 per trial and in the aggregate. The deductible is EUR 1,500.

5 years Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)
Insured's - Company Registration No.

Luxembourg - Direct

The limits for Luxembourg are EUR 500,000 per patient and EUR 5,000,000 per trial and in the aggregate. The deductible is nil.

3 years Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)
EU Legal Representative/CRO to appear on the Certificate

Macedonia - Reinsurance

The limit for Macedonia is EUR 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Malaysia - Reinsurance

The limits for Malaysia are MYR 2,000,000 per patient and MYR 8,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Local CRO/Client including full name and address (Only Malaysian Domiciled Entities can be named on the policy documents)

Malta - Direct

The limit for Malta is EUR 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Mexico - Reinsurance

The limit for Mexico is USD 5,000,000 per trial and in the aggregate. The deductible is nil.

2 years Extended Reporting Period

Additional information required prior to binding

Local CRO/Client including full name, address and contact details

Title of the Trial in Spanish

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Moldova - Reinsurance

The limits for Moldova are EUR 100,000 per patient and EUR 1,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Mozambique - Reinsurance

The limit for Mozambique is USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Netherlands - Direct

The limits for The Netherlands are EUR 450,000 per patient and EUR 3,500,000 per trial and in the aggregate. The deductible is nil.

4 years Extended Reporting Period

Nicaragua - Reinsurance

The limit for Nicaragua is USD 5,000,000 per trial and in the aggregate. The deductible is nil.

2 years Extended Reporting Period

Additional information required prior to binding

Local CRO/Client including full name, address and contact details

Title of the Trial in Spanish

Norway - Direct

The limit for Norway is EUR 5,000,000 per trial and in the aggregate. The deductible is EUR 1,500.

3 years Extended Reporting Period

Oman - Reinsurance

The limit for Oman is OMR 1,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Local CRO/Client including full name, address and contact details

Pakistan - Reinsurance

The limit for Pakistan is PKR 120,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Panama - Reinsurance

The limit for Panama is USD 5,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Local CRO/Client including full name, address and contact details
Conoce tu Cliente (know your client) - Form to be completed by local client

Peru - Direct

The limit for Peru is USD 5,000,000 per trial and in the aggregate. The deductible is nil.

2 years Extended Reporting Period

Philippines - Direct

The limit for Philippines is PHP 90,000,000 per trial and in the aggregate. The deductible is nil

1 year Extended Reporting Period

Poland - Direct

The limits for Poland depend on the number of patients as follows:

EUR 500,000	per trial and in the aggregate for 1-10 patients
EUR 1,000,000	per trial and in the aggregate for 11-25 patients
EUR 2,000,000	per trial and in the aggregate for 26-50 patients
EUR 4,000,000	per trial and in the aggregate for 51-100 patients
EUR 5,000,000	per trial and in the aggregate for more than 100 patients

The deductible is nil.

10 years Extended Reporting Period

Additional information required prior to binding

Title of the Trial in Local Language

Patient Split between Screened and Randomised Patients

If trial is based on a Medical Device, ensure broker is aware of reduced limits (1/10th of pharmaceuticals)

Portugal - Direct

The limits for Portugal are EUR 500,000 per patient and EUR 5,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Full Title of the trial in Local Language

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Romania - Direct

The limits for Romania are EUR 100,000 per patient and EUR 5,000,000 per trial and in the aggregate. The deductible is EUR 1,500.

2 years Extended Reporting Period

Additional information required prior to binding

Full Title of the trial in Local Language

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Saudi Arabia - Reinsurance

The limits for Saudi Arabia are USD 500,000 per patient and USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Serbia - Reinsurance

The limit for Serbia is EUR 2,500,000 per trial and in the aggregate. The deductible is nil.

No Extended Reporting Period as trial is written on an Occurrence basis

Additional information required prior to binding

Full Title of the trial in Local Language

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes) in English and Local language

Singapore - Direct

The limit for Singapore is USD 5,000,000 per trial and in the aggregate. The deductible is USD 1,500.

1 year Extended Reporting Period

Slovakia - Direct

The limit for Slovakia is EUR 250,000 per trial and in the aggregate. The deductible is nil.

3 years Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Slovenia - Direct

The limit for Slovenia is EUR 5,000,000 per trial and in the aggregate. The deductible is nil.

3 years Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

South Africa - Direct

The limit for South Africa is GBP 5,000,000 per trial and in the aggregate. The deductible is GBP 1,500.

1 year Extended Reporting Period

South Korea - Reinsurance

The limits for South Korea are KRW 625,000,000 per patient and KRW 2,500,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Local Premium Payment prior to inception

Local CRO/Client including full name, address and local company code

Spain - Direct

The limits for Spain are EUR 500,000 per patient and EUR 2,500,000 in the annual aggregate per trial. The deductible is nil.

2 years Extended Reporting Period

Additional information required prior to binding

Full Title of the trial in Spanish

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Sri Lanka - Direct

The limits for Sri Lanka are USD 500,000 per patient and USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Sweden - Direct

The limits for Sweden are EUR 5,000,000 per trial and in the aggregate. The deductible is EUR 2,500.

3 years Extended Reporting Period

Switzerland - Direct

The limits for Switzerland are CHF 1,000,000 per patient and CHF10,000,000 per trial and in the aggregate. The deductible is CHF 2,000 in respect of third party property damage only.

5 years Extended Reporting Period

Additional information required prior to binding

Full name and address of Swiss CRO/Client to act as Legal Representative
Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Taiwan - Reinsurance

The limits for Taiwan are USD 500,000 per patient and USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)

Tanzania - Reinsurance

The limit for Tanzania is USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Local CRO/Client including full name and address (local regulation states that Policyholder has to be a local entity/company)

Thailand - Reinsurance

The limit for Thailand is USD 5,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Local CRO/Client including full name and address

Tunisia - Reinsurance

The limit for Tunisia is EUR 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Local CRO/Client including full name, address and contact details (local regulation states that Policyholder has to be a local entity/company)

Turkey - Reinsurance

The limits for Turkey are EUR 500,000 per patient and EUR 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Investigator Details (Full Names of Dr's and Hospitals involved, including area codes)
Full Title of the trial in Turkish

United Arab Emirates - Reinsurance

The limits for The United Arab Emirates are USD 500,000 per patient and USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

United Kingdom - Direct

The limit for the UK is GBP 5,000,000 per trial and in the aggregate. The deductible is GBP 1,500

1 year Extended Reporting Period

Venezuela - Reinsurance

The limit for Venezuela is USD 2,000,000 per trial and in the aggregate. The deductible is nil.

Additional information required prior to binding

Local CRO/Client including full name and address
Local Premium Payment (Payment direct from Foreign Client acceptable)
Title of the Trial in Spanish

Vietnam - Reinsurance

The limit for Vietnam is USD 2,000,000 per trial and in the aggregate. The deductible is nil.

1 year Extended Reporting Period

Additional information required prior to binding

Local CRO/Client including full name and address

Local Premium Payment (Payment direct from Foreign Client acceptable)