**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 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.

1. 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.

1. 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)