

# Life science Research & development

Application form United Kingdom



## INTRODUCTION

The purpose of this application form is for us to find out more about you. Completion of this application form does not oblige either you or us to enter into a contract of insurance.

Following a reasonable search you must provide us with all information which may be material to the cover we offer in a clear and accessible manner. Information is material if it would influence our decision whether to insure you, what cover we offer you or what premium we charge you. If you are in any doubt whether a fact or circumstance is material you should disclose it.

## HOW TO COMPLETE THIS FORM

Whoever fills out the form must be a principal, director or partner of the applicant company. They should make all the necessary enquiries of their fellow senior management, employees and persons responsible for arranging the insurance to enable our questions to be answered.

If you require extra space to answer the questions or provide any other material information, please use the additional information section at the back of the form. Once you have completed the form please return it directly to your insurance broker.

## SECTION 1: COMPANY DETAILS

1.1 Please provide the following details:

Insured company:		
Contact name:		
Address:		
Postcode:		
Telephone:	Email address:	
Fax:	Website:	

1.2 Please state when your company was established:

Please answer question 1.3 only if you require Employers' Liability cover.

- 1.3 a) Please state your Employer Reference No. (ERN):
  - b) Do you have any subsidiaries in the UK?

If 'yes', please complete the Supplementary Information section at the back of this proposal form.

1.4 Please briefly describe below the nature of your business activities:

If you have a brochure, or company literature, please attach to this form.

DD / MM / YY

Yes

No



1.6

1.7

1.5 Please outline below your business development plans for the next 12 months, including the number of products under development and the stage of development for each:

If you have a copy of an up to date business plan, please attach to this form.

Plec	se state the number of employees:	
Plec	se provide estimates of your wageroll for the next 12	e months, broken down as follows:
a)	Administrative and managerial:	
b)	Laboratory based staff:	
c)	Other:	
lf 'o	ther', please provide full details:	

## SECTION 2: PREMISES DETAILS

2.1 Please provide below details of your premises:

PREMISES 1	
Address:	
	Postcode:
Details of usage (e.g. labs, storage, offices etc.):	
PREMISES 2	
Address:	
	Postcode:
Details of usage:	

Please continue on a separate sheet if more than 2 premises are to be insured.



2.2 Please provide details of the premises of your supply chain partners that carry out significant work on your behalf, including those where you require cover for damage to your property and those where you have a significant reliance on them for your business activities:

Name and address	Details of usage

## 2.3 Are all of the premises:

a)	Constructed with external walls of brick, stone or concrete and roofed with slate, tiles, concrete, metal, asbestos or any other non-combustible material?	Yes	No	C
b)	Free from cracks or other signs of damage that may be due to subsidence, landslip or heave and have not previously suffered damage by any of these causes?	Yes	No	C
c)	In an area free from flooding and not near the vicinity of any rivers, streams or tidal waters?	Yes	No	С
d)	In a good state of repair?	Yes	No	С
e)	Self contained with a lockable entrance door?	Yes	No	С
f)	Protected by fire and intruder alarms that are subject to an annual maintenance contract?	Yes	No	С
	TE: We may refuse to pay a claim if all of the devices for the protection security of your premises (including lo not put into full and effective operation whenever the premises are closed for business or left unattended.	cks and ala	rms)	
g)	Heated by a conventional electric, gas, oil or solid fuel heating system?	Yes	No	С
h)	Fitted with electrical installations which are inspected at least every 5 years by a qualified electrician and any defect remedied?	Yes	No	С
i)	Lifts, boilers, steam and pressure vessels inspected and approved to comply with all	Yes	No	С

i) Lifts, boilers, steam and pressure vessels inspected and approved to comply with all of the statutory requirements?

NOTE: Assuming you have answered 'yes' to questions h) and i) above, it is important to keep records of all relevant inspections as we may ask for evidence for these before paying a claim.

If you have answered 'no' to any of the above questions, please provide further details:



2.4 If any of the premises listed in 2.1 and 2.2 contain composite or sandwich panels, please provide details:

Address	Are panels exterior or interior?	Type of panel (Make, model, core material)	Are products LPS1181: 2003 or FMRC4880 (1994) approved?

# SECTION 3: ACTIVITIES

3.1 Do you directly work with, or store, radioactive or biohazardous materials at your premises?

Yes	No

If 'yes', please provide further details below including types of materials, quantities used and how you manage the process of using, storing and disposal:

3.2	ls yo	our stock sensitive to changes in environmental conditions?	Yes		No
	lf 'y	res', please answer the following:			
	a)	What proportion of stock is temperature sensitive?			%
	b)	Are your fridges/freezers less than 3 years old?	Yes		No
		If 'yes', please go to question 3.2 c)			
		If no, do you have a maintenance contract in place?	Yes		No
		If yes, does the maintenance contract provide free parts and labour? N/A	Yes		No
		Does the maintenance contract contain a provision that an inspection takes place at least N/A annually?	Yes		No
	c)	Is electricity delivered by underground cables, with no overhead power lines in the immediate vicinity?	Yes		No
	d)	Do all fridges / freezers have back up power generators?	Yes		No
		If 'yes', how many hours back up is provided?		ŀ	lour
	e)	Do you have an alarm system that activates if the temperature falls outside the prescribed range?	Yes		No
	f)	Is the alarm system monitored by a third party central station?	Yes		No
	g)	Is stock duplicated in more than one freezer on the same site??	Yes		No
	h)	Is stock duplicated in more than one freezer at different sites?	Yes		No
	i)	Do you have a formal Business Continuity Plan for a power outage or failure in storage arrangements?	Yes		No



3.3 Are specialist couriers utilised for stock transport?

	Yes		No
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If 'no', please provide details of the arrangements:

3.4 Please state stock consignment values:

	Annual value	Maximum value of one consignment
Domestic:		
Outside (domestic) country, but within the continent:		
Elsewhere in the world:		
5 Will you transport stock to areas where th If 'yes', please provide details below:	ne government currently advises against travel?	Yes No
Are you involved with R&D of your own p	roducts?	Yes No
If 'no', please go to question 3.10.		
7 Please state your annual gross expenditu	re:	
B Please state what proportion of your annu	al gross expenditure is attributable to:	
Fixed internal cost (including wagero	ll):	%
Variable internal cost (such as lab co	nsumables):	%
Contractually committed payments for	or services to third parties:	%
Third party contracts with full 'force r	najeure' provisions to your benefit:	%



3.9 Please provide details of your contingency plans to continue R&D activities, if damage at the premises listed in 2.2 means your supply chain partners are unable to fulfil contractual commitments:

Supplier name	Nature of reliance	Contingency plans

3.10 Do you receive income from products or services provided to third parties?

Yes		No
Yes		Nc

If 'no', please go to section 4.

If 'yes', please state the income received in the box below:

Location of client	Last complete financial year		Current financial year (estimate)		
	Products	Services	Products	Services	
Domestic:					
USA:					
Elsewhere in the world:					
Total:					

3.11 Please give details of the 3 largest contracts that you have carried out in the last 3 years:

Client Name	Client business	Nature of work undertaken for this contract	Your annual income from this contract	Start date	Completion date
				MM / YY	MM / YY
				MM / YY	MM / YY
				MM / YY	MM / YY
				MM / YY	MM / YY
				MM / YY	MM / YY

3.12 What approximate percentage of your income, in your current financial year, will be paid to sub-contractors?

3.13 Will sub-contractors carry the following insurance:

- a) Products liability for CMOs?
- b) Professional liability for CROs, contract research service providers and other consultants?
- c) Medical Malpractice (or equivalent government liability) for clinical investigators conducting your clinical trials?

Yes	No
Yes	No
Yes	No



3.14 Will your products be marketed for human consumption in the next 12 months?

If 'no', please go to section 4.

If 'yes', please attach literature for each of these products, including brochures, technical literature, sale conditions.

	nt parts	:	%
Are these products:			
a) Vaccines?		Yes	No
b) Gene therapy?		Yes	No
c) Cell therapy?		Yes	No
d) Acutane, amenorone forte, bupropion, canthaxanthin, cisapride, danthron, debendox, DEHF dexfenfluramine, diazepines, dicyclomine, diethylstilbestrol (DES), dioxins, ephedrine, fenfluramine fibrates, germanium, halogenated 8, hydroxy quinolines, hydroquinone, isotretinoin, lotronex, tryptophan, methylphenidate, nefazodone, oxazepines, paxil, pertussis vaccine, phenfluramine phentermine, phenylpropanolamine (PPA), piper methysticum, primodos, prozac, remoxipride retinoids, risperidone, serzone, silicone gel used as part of an injection or as part of an implantabl device, statins, swine-flu vaccine, thalidomide, thiazepines, thimerosol or thimersal, tretinoir troglitazone, tryptophan?	e	Yes	No
e) Implantable medical devices?		Yes	No
f) Skin whitening products?		Yes	No
g) Birth control products or devices?		Yes	No
If 'yes' to any of the above, please provide details:			

- a) Loss of life or injury to a person?
- b) Damage or destruction to physical property?
- c) Significant third party financial loss?

If 'yes' to any of the above, please provide details:

Yes	No
Yes	No
Yes	No



3.18	Is the delivery	of these	products	and	services	time	critical	to th	ne third	parties	using	them	(such	as a c	linical	
	trial)?															

Yes No

If 'yes', please provide details:

SECTION 4: CONTRACT MANAGEMENT

4.1	Is all work carried out (by you, or for you) under a written contract?	Yes	No
4.2	Are all contracts reviewed by independent, qualified legal advisers? If 'no', please outline the procedures used for developing and reviewing contracts:	Yes	No
	In no, pieuse comme me procedores used for developing and reviewing commucis.		
4.3	Are rights of recourse retained against CMOs, CROs, clinical investigators and all other supply chain partners?	Yes	No
	If 'no', please explain why:		

4.4	In your written contracts do you ever accept liability for consequential loss or financial damages greater than	_
	the value of the contract?	

	_
Yes	No





4.5 Do your written contracts ever contain 'Hold Harmless' or 'Indemnification' clauses in which you accept liability for loss of life, injury, property damage, or financial losses in circumstances other than where they are caused by your negligence?

No

No

If 'yes', please provide details:

4.6 In your written contracts, do you ever provide guarantees of products or services?

Yes	

If 'yes', please provide details:

#### SECTION 5: CLINICAL TRIALS Only complete this section if you require this

In respect of each of the clinical trials listed below, please attach the following (in English):

- a) Trial Protocol
- b) Patient Information
- c) Patient Informed Consent form
- d) A list of the Clinical Investigator sites
- 5.1 Please provide the following details of completed trials for which cover is required:

	Protocol number and description	Date treatment completed	Number of subjects	Country
_				
_				



5.2 Please provide below the details of ongoing trials, or trials that are expected to commence in the next 12 months, for which primary cover is required:

Protocol number and description	Start date	Expected end date	Number of subjects	Country
	DD / MM/ YY	DD / MM/ YY		
	DD / MM/ YY	DD / MM/ YY		

5.3 Please provide below the details of ongoing trials, or trials expected to commence in the next 12 months, for which a separate primary insurance policy will be in place and therefore excess cover only is required:

Protocol number and description	Start date	Expected end date	Number of subjects	Country	Insurer and policy number for underlying policy
	DD / MM/ YY	DD / MM/ YY			
	DD / MM/ YY	DD / MM/ YY			

5.4 Are you the sponsor in respect of each of the clinical trials listed above?

Yes No

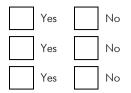
If 'no', please state the nature of your interest:

# 5.5 Are any of the clinical trials listed above testing products that are 'First in Man'?

Yes No



- 5.6 In respect of the clinical trials listed above, will any of the following be tested:
  - a) Vaccines?
  - b) Gene therapy?
  - c) Cell therapy?



Yes

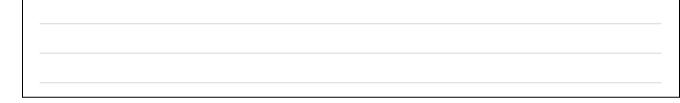
Yes

Yes

Yes

- d) Acutane, amenorone forte, bupropion, canthaxanthin, cisapride, danthron, debendox, DEHP, dexfenfluramine, diazepines, dicyclomine, diethylstilbestrol (DES), dioxins, ephedrine, fenfluramine, fibrates, germanium, halogenated 8, hydroxy quinolines, hydroquinone, isotretinoin, lotronex, l-tryptophan, methylphenidate, nefazodone, oxazepines, paxil, pertussis vaccine, phenfluramine, phentermine, phenylpropanolamine (PPA), piper methysticum, primodos, prozac, remoxipride, retinoids, risperidone, serzone, silicone gel used as part of an injection or as part of an implantable device, statins, swine-flu vaccine, thalidomide, thiazepines, thimerosol or thimersal, tretinoin, troglitazone, tryptophan?
- e) Implantable medical devices?
- f) Skin whitening products?
- g) Birth control products or devices?

If 'yes' to any of the above, please provide details:



5.7 In respect of any of the clinical trials listed in questions 5.1 to 5.3, are / were more than 25% of the research subjects under 16 years?

Yes No

No

No

No

No

If 'yes', please provide details:

5.8	In respect of any of the clinical trials listed in questions 5.1 to 5.3, are / were more than 25% of the researc
	subjects women of child bearing age?

No
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Yes



5.9 Are all clinical trials conducted in accordance with all relevant local laws and regulations?

Yes No

No

No

No

Yes

Yes

Yes

If 'no', please explain why:

5.10 In respect of all completed and ongoing trials, have you:

- a) Made all necessary filings?
- b) Received all required authorisations?
- c) Had the protocol approved by an independent Ethics Committee?

If 'no' to any of the above, please explain why:

5.11 Do you ever act as both tria	al sponsor and clinical investigator?
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If 'yes', please provide details:

5.12 Have you stopped or suspended any clinical trials for safety reasons	2
3. Z Flave you slopped of suspended any clinical finals for safety reasons	ç

Yes	No

Yes

No



5.13 Have any research subjects suffered death, injury, disease or illness (whether physical or mental) as a result of participation in a clinical trial sponsored by you, in the past 5 years?

Yes No

f	'yes',	please	provide	details:	

# SECTION 6: COVER LIMITS & SUMS INSURED

6.1 Would you like cover for damage to your property?

If 'no', please go to question 6.7.

If 'yes', please attach information regarding the value of the following property, including estimated maximum values at risk at any one time where applicable, at the premises listed in question 2.1 and 2.2:

- a) Buildings
- b) Tenants improvements, fixtures & fittings
- c) Laboratory equipment
- d) Fixed electronic equipment
- e) Portable electronic equipment
- f) Lab consumables and R&D Stock (including the cost of materials and other re-creation costs)
- g) Third party stock in your custody and control
- h) Research animals (showing the total value and the estimated maximum value of a single animal)
- i) Any other property not listed above
- 6.2 Would you like the policy to cover any of the following:
  - a) Spoilage of perishable stock?
  - b) Pollution or contamination?
  - c) Machinery breakdown?
  - d) Property in transit?
  - e) Terrorism?
  - f) Ideologically motivated attack (that is not declared an act of terrorism by the government)?
- 6.3 Would you like business interruption cover?

If 'yes', please state the 'First Loss' sum insured required:

Yes	No
Yes	No



6.5

6.6

6.7

6.4	Please state the sublimits required for Business Interruption following damage at the premises of your	
	supply chain partners listed in question 2.2:	

Yes		No
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Yes

No

Supply chain partner name	Business Interruption sublimit
Please state the Indemnity Period required (6 - 24 months):	Months
Would you like cover for Employers' Liability?	Yes No
Would you like cover for Public Liability?	Yes No

If 'yes', please state the Limit of Liability required:

6.8 Would you like cover for Products and Services Liability?

If 'yes', please state the Limit of Liability required:

## SECTION 7: CLAIMS EXPERIENCE & INSURANCE HISTORY

7.1 Please provide details of your current insurance:

	Expiry date	Retroactive date	Insurer
Property & Business Interruption:		N/A	
Employers' & Public Liability:		N/A	
Products Liability:			
Professional Liability:			
Clinical Trials:			
Directors & Officers Liability:			

- 7.2 Regarding all of the types of insurance to which this proposal form relates, AFTER ENQUIRY:
  - a) are you aware of any loss or damage, whether insured or not, that has occurred to any of the Companies to be insured (or to any existing or previous business of the partners or directors of any of the Companies to be insured) within the last 5 years, or
  - b) are you aware of any circumstances which may give rise to a claim against any of the Companies to be insured or any partners or directors thereof, or
  - c) have any claims or cease and desist orders been made against any of the Companies to be insured, or partners or directors thereof, or
  - d) have any partners or directors of the Companies to be insured been found guilty of any criminal, dishonest or fraudulent activity or been investigated by any regulatory body?

With reference to questions a, b, c and d above:



If the answer to the above is 'yes', then please attach full details including an explanation of the background of events, the maximum amount involved / claimed, the status of the claim(s) or circumstance(s) and any reserve(s) or payment(s) made by you and / or by Insurers, and the dates of all developments and payments.

## SECTION 8: DECLARATION

I declare that:

cfc

- after full enquiry the answers to the questions contained in this application form, and any other information supplied by me, are substantially true, accurate and correct;
- I will inform underwriters before cover incepts of any change to the information supplied by me; and
- I understand that if any of the information contained in this application form or provided elsewhere is substantially untrue, inaccurate or incorrect, or I have not disclosed any other information that is material, the Policy may be avoided without any return of premium, the terms and conditions may change, a higher premium may become payable or we may reduce the amount of any claim payment.

Signed:	 Full name:	
Position held at insured:	Date:	



SUBSIDIARY 1	
Company name:	ERN:
Address:	
	Postcode:
SUBSIDIARY 2	
Company name:	ERN:
Address:	
	Postcode:
SUBSIDIARY 3	
200201AKT 2	
Company name:	ERN:
Address:	
	Postcode:
SUBSIDIARY 4	
Company name:	ERN:
Address:	
	Postcode:

If you have more than 4 subsidiaries please continue your response in the Additional Information section.



# ADDITIONAL INFORMATION: