



IMPORTANT INFORMATION – PLEASE READ

This Application Form, which is designed specifically for Clinical Trials must be signed by the Applicant.

It is the duty of the Applicant to disclose all material facts. For the purpose of this Application Form, a material fact shall be deemed to be one that would be likely to influence the judgement of a prudent insurer in fixing the premium or determining whether to underwrite the risk.

Each section of this Application Form must be completed in full. Incomplete or unsigned forms will not be accepted.

Should there be insufficient room on any part of the Application Form to record all necessary details, please use the space provided in Section 3 with reference to the appropriate question.

An up to date copy of the Clinical Trial Protocol and Patient Informed Consent Form must accompany the completed application form.

Failure to disclose full and accurate details may entitle Insurers to void your contract of insurance and will mean that you are not entitled to any benefits of, nor make any claims against, your policy.

It is the responsibility of the Applicant to notify any future change of address or any changes in their professional circumstances.

Once completed, please sign and date the Declaration in Section 5 and return it to:

Challenge Insurance Brokers Limited
Challenge House, 11 Burnell Square,
Mayne River Way, Malahide Road,
D17 VY04.

Email: insurance@challenge.ie
Tel: +353 1 8395942

Should you have any questions, please contact Challenge Insurance Brokers Limited on +353 1 8395942

THE SIGNING OF THIS APPLICATION FORM DOES NOT BIND THE APPLICANT, OR INSURERS, TO COMPLETE A CONTRACT OF INSURANCE.

Section 1 – Sponsor Details

1. Full details of Sponsor
2. Sponsor Address
3. Sponsor Zip/Postcode
4. Sponsor Country
5. Email Address
6. Mobile Number
7. Trial Protocol Number
8. Study Title (*We only require the unique identifiable number for the clinical trial taking place*)

6. Trial Phase (Please Tick)

Phase 1

Phase 2

Phase 3

Phase 4

Medical Device Yes No

Drug Yes No

Section 2 – Country Specific Information

10.	Country *	Estimated Start Date	Estimated Life of Trial (Years)	Estimated number of patients
-----	-----------	----------------------	---------------------------------	------------------------------

Section 3 – Trials History

11. Have any trials been discontinued or suspended, whether by you, EMA, HPRA or another authority, for safety reasons?	Yes	No
12. Have any subjects had a serious adverse event (such as hospitalization, danger to life, death, congenital anomaly, malignancy) while participating in one of your clinical trials?	Yes	No
13. Has any insurance company cancelled or refused to renew your trial insurance? If yes, please explain	Yes	No
14. Provide a copy of Trial Claims History for the last 5 years. Please attach previous insurer loss runs if applicable.	Check here if none.	

Information Required:

Please include the following information with the above completed application form

- Clinical Trial Protocol
- Patient Informed Consent Form

Section 4 – Additional Information

Section 5 – Declaration and Disclosure

I declare and warrant that, after enquiry, all statements and declarations contained in the completed Application Form, together with any and all other information, statements and declarations made to Insurers, or their representatives, by or on behalf of the Insured, whether written or oral, are true and that no information whatsoever has been withheld which might increase the risk to Insurers or influence the acceptance of this Application Form. Should the above statements and declarations alter in any way, I will advise Challenge as soon as practicable. I understand that failure to disclose any material facts which would be likely to influence the acceptance and assessment of this Application Form may result in the refusal to provide indemnity or voiding the policy in every respect. I hereby accept that this Declaration shall be the basis of the contract between both parties if entered into. By signing this document, I authorise Challenge to release information to necessary third parties and give permission for Challenge to use my email address, as provided in Section 1, to send their quotations or correspondence.

Customer Signature	<input type="text"/>	Print Name
Date	<input type="text"/>	