Application Form for Investigator Initiated Research Trials (IIRs)

This form is intended for all principal Investigators based in the UK (or Europe with research sites in the UK), to submit Investigator Initiated Research trial (IIR) applications to Britannia Pharmaceuticals Ltd (BPL).

The application consists of several sections, each of which must be completed for your proposal to be considered and is comprised of:

- Basic information pertaining to you
- The research proposal you are submitting
- Final Principle investigator attestation in order to proceed with your application

Once completed, please submit your application by email to: research@britannia-pharm.com

Please refer the following attached documents to assist with your application:

- BPL research strategy current Areas of Interest (AOIs).
- BPL safety reporting requirements.
- IIR FAQ and Guidance.

If you have any questions regarding this application, please contact our medical team via the same email address. If you are an investigator based outside of the UK or Europe, please contact the medical team at our affiliate office in your local country for assistance. For further info, please email: research@britannia-pharm.com

Contents

This application comprises of the following 9 sections:

Introduction and background

BPL is committed to delivering innovative therapies to patients worldwide and the need to support ethical independent clinical research conducted by qualified third-party investigators that are aligned with BPL research strategies and Areas of Interest (AOIs). Please refer to the BPL current AOIs attached.

The value of the scientific research that is produced by such investigators is key to complementing BPL-sponsored research in helping ensure we better understand the benefit/risk profile of BPL therapies as well as explore new opportunities to address unmet medical needs. Such clinical research must set out to address meaningful scientific and/or clinical objectives supported by valid

study designs in which the privacy rights, safety and welfare of patients is of paramount importance.

Like other health care companies, BPL will support the funding of investigator Initiated Research Trials (IIRs) with defined processes and governance measures in place.

We define IIRs as: **"**Research studies with scientific and medical merit developed and sponsored by an independent investigator or academic sponsor. An IIR may be a clinical or non-clinical study conducted without the participation of BPL, for which the IIR sponsor requests BPL to provide either funding, drug product or both**."**

BPL provides financial support and/or drug product for IIRs pursuant to a written agreement, which requires that third-party sponsors comply with applicable local laws, rules, guidelines and regulations.

The overarching principles that govern evaluation of IIRs include:

- The validity of the scientific question being addressed, ensuring that any data generated by an IIR complement the existing body of evidence and not simply be a repetition of a previous study/experiment.
- The robust nature of the IIR experiment/investigation being conducted in terms of ethical and design elements.
- A commitment by the investigator/sponsor to disseminate the findings in an appropriate, transparent, and timely manner.

The IIR study is conducted independent of BPL. The investigator or affiliated study sponsor has responsibility for study conception, design, operational execution, data handling, data analysis/interpretation, subsequent reporting/ publication, and ensuring compliance with all local laws and regulations.

Principal Investigator Information

* indicates required field

1. Principal Investigator Full Name*:
2. Country*:
3. Address*:
4. City*:
5. County/Province:
6. Postal Code:
7. E-mail Address*:
8. Telephone:
9. Fax:
10. GMC #/Medical License ID (or Equivalent):
11. Medical Specialty:
12. Medical License/Proof of Right to Practice: Please attach file to your email
13. CV*: Please attach file to your email

Proposal Overview

14. Study Title*:

15. Study Type*:
(Interventional/Non-interventional)

16. Sponsor*:
PI/Primary Institution/Other (please specify)

Institution Information

17. Primary institution Name*:

18. Institution Country*:

19. Institution Address*:

20. Institution City*:

21. Institution Postal Code:

22. Institution E-mail Address:

23. Institution Telephone*:

24. Institution Fax:

25. Institution Type*:
Academic/Hospital/Other (please specify)

Investigator Qualifications

26. Has the Primary Investigator ever participated in a BPL sponsored study? *:

27. Years of Experience as a Primary Investigator*:

28. Number of Ongoing Clinical Studies*:

29. Has the Primary Investigator or their site been inspected by a Health Authority? *:

Study Design

30. Therapeutic Area to which this Program relates*:
Neurology/Other (please specify)

31. Primary Indication *:
PD/Other (please specify)

32. Secondary Indication, if applicable:

33. BPL Product Name (drug of focus) *:

34. Rationale for Study *:

(Summarize the rationale e.g. medical need, advantage of innovative approach over current best medical practice etc.)

35. Primary Objectives*:

36. Primary Endpoints*:

37. Do you have Secondary Objectives? *:

38. Do you have Exploratory Objectives? *:

39. Total Planned Number of Enrolled Patients/Subjects*:

40. Sample Size Justification and Statistical Analysis*:
(Provide sample size justification by clearly stating the statistical assumptions, level of significance and power. If no formal sample size calculation was done, provide an explanation why such a calculation was not done. Provide a brief description of the statistical hypothesis and methods for data analysis, focusing on the analysis of the primary objective if available)

41. Population*:

42. Key Inclusion Criteria*:
43. List Key Disease specific inclusion criteria

44. Key Exclusion Criteria*:
List Key Disease specific exclusion criteria

45. Gender*:

46. Minimum Age*:

47. Maximum Age*:

Safety Requirements

The minimum requirements for Adverse Event (AE) collection are presented in the section below. Please identify the type of study you are proposing and note the BPL requirements for what adverse event data must be collected during the course of the study. If your proposal is approved, these requirements must be reflected fully in the protocol. The requirements for the transfer of collected adverse event data to BPL, including timeframes, are defined in the IIR Agreement. Once the study concept is approved and the IIR agreement is executed, please refer to the IIR agreement for exact requirements for the type of trial you are proposing. Please review the attached BPL safety reporting requirements.

48. Do you have any comments on safety reporting requirements? *:

Study Setup and Plans

49. Total Planned Number of Countries*:

50. Total Planned Number of Centers*:

For all studies, final study report and publication plan are to be sent to BPL no later than 12 months after last patient last visit/end of data collection.

51. Planned Final Study Report (MM/DD/YYYY) *:

52. Planned Final Publication (MM/DD/YYYY) *:

53. Additional Comments:

54. Additional Files:
(name/description and attach to email)

Support Requested

55. Are you requesting funding support from BPL? *:

56. If Yes, what is the request amount and currency? *:

57. Is this study funded or supported by, or under consideration for funding or support from another institution or organizations? *:

58. If Yes, please specify the additional supporting institutions/organizations, the type and details of support requested *:

Funding Requested

59. If Funding is requested, please complete the full budget breakdown table below (add line items as necessary) or enter Zero Grand Total *

Item #	Fee Category Personnel/ Procedural/ Other	Sub-Category Who/What?	Description/Details of Spend	Request Amount	Currency €uro/GBP
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
Grand Total					

Attestation

BPL supports medically and scientifically sound independent research initiated by external Investigators and aimed at the advancement of scientific knowledge in therapeutic areas of Interest for BPL. BPL evaluates unsolicited proposals from independent researchers or their institutions for support.

I, as Principle Investigator, hereby attest that:

60. The research proposal I am submitting was independently conceived by myself and not solicited by any BPL employee*:

61. I have reviewed and will comply with BPL safety requirements hereby attached*:

Thank you for completing this IIR application.
Please email this along with necessary attachments to: research@britannia-pharm.com