British BioMedicine Clinical Trials (BBMCT)

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BBMCT Site Feasibility Questionnaire

1. Are you interested in participating in this study?

1 ☐ Yes ⇨ please review the Investigator Contact Information box below and complete pages 3-9.
2 ☐ No ⇨ please mark reason(s) below in Question 2, provide a response to 'Investigator's consent' on page 9, and email this PDF back to director@bbmclinicaltrials.com.

2. If you are <u>not</u> interested in participating, please indicate your reason. Please select all that apply.	
1 ☐ Too busy to participate	5 ☐ Budget/financial reasons
2 ☐ Inadequate staffing/support to conduct research	6 ☐ Other (specify):
3 ☐ Not interested in conducting research	7 ☐ Please remove me from your mailing list
4 ☐ Lack of appropriate patient population	

3. Investigator Contact Information: Please correct any information that is incomplete or incorrect.		
Investigator Name		
Department Name		
Address (1)		
Address (2)		
City/State/Zip		
Medical License Number		Email:
Phone		Fax:
Contact Name		Contact Email:
Completed by (Name)		Date Completed:
Position:		

Part 1: Staff and Facilities	
4. The above-named investigator is a:	1 ☐ Physician (MD/DO) 2 ☐ Nurse Practitioner 3 ☐ Physician Assistant 4 ☐ Other (please specify below): _____
5. What is the primary specialty classification or area in which the above-named investigator works?	1 ☐ Family/General Practice 2 ☐ General Internal Medicine 3 ☐ Infectious Disease Specialist 4 ☐ Other (please specify below): _____
6. What is the primary practice setting of the above-named investigator?	1 ☐ Private practice 2 ☐ Group practice, single specialty 3 ☐ Group practice, multi-specialty 4 ☐ Employed by or affiliated with academic/university setting 5 ☐ Other (please specify below): _____
7. Is the investigator affiliated with a Research Organization or Site Management Organization (SMO)?	1 ☐ Yes 2 ☐ No If Yes, please provide name of the Organization: _____ 3 ☐ Do not know
8. How many years has the above-named investigator been in practice?	_____Years
9. What types of research studies has the above-named investigator participated in? (Check all that apply.)	1 ☐ Phase I 2 ☐ Phase II-III 3 ☐ Phase IV 4 ☐ Randomized clinical trials 5 ☐ Outcomes research 6 ☐ Survey research 7 ☐ Observational research 8 ☐ Focus groups 9 ☐ No research experience

10. In the past 3 years, how many total studies has the investigator participated in?	_____ Total number of studies
11. Does the investigator have research experience conducting studies involving patients with Specific Disease?	1 ☐ Yes 2 ☐ No
12. Please complete the table for 2 of the most recent studies investigator has participated in, if applicable. Please include both the stop & start dates of the study (or if they are currently ongoing).	**Study 1:** Dates of study _____ Did you meet the study enrollment goals? 1 ☐ Yes 2 ☐ No 3 ☐ Not applicable **Study 2:** Dates of study _____ Did you meet the study enrollment goals? 1 ☐ Yes 2 ☐ No 3 ☐ Not applicable
13. Is the investigator currently conducting competing studies that would hinder your center's ability to participate in this study?	1 ☐ Yes 2 ☐ No If yes, please list brief study description(s) & dates: _____ _____ _____
14. Is there a study coordinator available at this site to assist with this study?	1 ☐ Yes → 1 ☐ Full-time 2 ☐ Part-time 2 ☐ No

Site Study Coordinator Information

Name	
Phone	
Fax	
Email	
Years of experience	

Site Contract Specialist Information Coordinator	☐ Not applicable ☐ Same as Study
Name	
Phone	
Fax	
Email	

15. Does the investigator utilize a central IRB, a local IRB, or both?	1 ☐ Central IRB 2 ☐ Local IRB 3 ☐ Central and Local IRB 4 ☐ Do not know
16. If the investigator must utilize a local IRB, how often does the IRB meet?	1 ☐ Weekly 2 ☐ Bi-Weekly 3 ☐ Monthly 4 ☐ >Monthly 5 ☐ Not applicable (use only Central IRB) 6 ☐ Do not know
17. If the investigator utilizes a local IRB, what is the average timeline from IRB submission to IRB approval?	1 ☐ <1 week 2 ☐ 1-2 weeks 3 ☐ 2-4 weeks 4 ☐ 4-6 weeks 5 ☐ >6 weeks 6 ☐ Not applicable (use only a Central IRB) 7 ☐ Do not know 8 ☐ What are your suggestions to accelerate the IRB approval process? _____ _____
18. If the investigator utilizes a local IRB, does the IRB allow for expedited review of non-interventional studies like this one?	1 ☐ Yes 2 ☐ No 3 ☐ Do not know
19. How long does the contracting process take at your site on average?	1 ☐ <2 weeks 2 ☐ 2-4 weeks 3 ☐ 4-6 weeks 4 ☐ >6 weeks 5 ☐ Do not know 6 ☐ What are your suggestions to accelerate the contracting process? _____ _____

20. Does your site have experience in Electronic Data Capture/ Remote Data Entry for clinical studies and access to a computer with internet access for data entry?	1 ☐ Yes 2 ☐ No
21. Does your site have available space for patients to complete patient questionnaires?	1 ☐ Yes 2 ☐ No

Part 2: Patient Population	
22. How many patients does the investigator see per month at your institution?	_____patients per month _____unable to provide this information
23. Of the patients with Specific Disease that the investigator sees each month at your institution, approximately what percent are a) Newly/initially diagnosed? b) Previously diagnosed?	_____% newly/initially diagnosed patients _____ % previously diagnosed patients _____unable to provide this information
24. Please query your database to specifically answer this question. How many ≥18-year-old treatment-naïve patients were first prescribed a therapy by the investigator during the past 12 months?	_____patients in past 12 months _____unable to provide this information
25. Please query your database to specifically answer this question. How many ≥18-year-old patients currently on first-line therapy does the investigator have listed in his/her own practice in the last 12 months?	_____patients in past 12 months _____unable to provide this information
26. Please query your database to specifically answer this question. How many ≥18-year-old treatment experienced patients were switched from first-line therapy to another therapy by the investigator during the past 12 months?	_____patients in past 12 months _____unable to provide this information

27. How many total patients who are initiating or switching therapy do you estimate your site can consent and enroll in 6 months (taking into consideration study eligibility criteria, competing trials, resource capabilities at your site, and patients' willingness to participate)?	_____estimated total number of patients who can be enrolled *Of those patients:* _____estimated total number of patients initiating therapies who can be enrolled _____estimated total number of patients switching therapies who can be enrolled
28. Please specify the languages spoken by your patients and percentage of patient population.	1 ☐____ English 2 ☐____ Hindi 3 ☐_____ Other, please specify:_____
29. Based on the current study design, do you anticipate any specific challenges that may make patient enrollment difficult?	

Part 3: Physician Referral		
30. Are you aware of any other physicians who may be interested in participating in this study?	1 ☐ Yes (see below) 2 ☐ No	
If yes, please provide the physician's name and contact information:		
Investigator Name		Specialty
Department Name		
Address		
City/State/Zip		
Email		Fax
Phone		
Primary Contact Name		

Investigator's Consent

(To Be Completed Regardless of Your Response to Question 1 Above)

By checking the box marked "yes" below, I unambiguously and expressly consent to:

1.) the processing (including the collection, use, disclosure and transfer) of my personal data which is submitted or confirmed by me to BBMCT, pursuant to any current or future study, or otherwise, inside and outside of the country;

2.) the inclusion of my personal data (i.e., contact details and professional information) in the BBMCT Global Investigator Database;

3.) being contacted by mail, facsimile, or by electronic mail or other electronic means about possible participation in current and future studies;

In each case, for the purposes of the possible participation in current or future research projects and studies and any other purpose set out in the BBMCT Global Privacy Policy*.

☐ Yes

☐ No, I wish for all personal information about me (other than that which is expressly or impliedly permitted or required by local law to be retained) to be removed from the BBMCT Global Investigator Database. I do not wish to be contacted in the future, and I consent to allow BBMCT to retain a minimal amount of my personal information for the limited purpose of complying with my request not to be contacted.

*Please email in writing to request a copy of the BBMCT Global Privacy Policy, to amend any details in respect to your personal data, or to request removal from the BBMCT Global Investigator Database.

…… ……

Investigator **Date**

Please submit your completed questionnaire to…

Email: director@bbmclinicaltrials.com

Thank you for your time and interest.

We look forward to working with you!