SITE IDENTIFICATION FORM
EXPRESSION OF INTEREST TO PARTICIPATE IN NEW STUDY OPPORTUNITY
COMMERCIAL

Study Title: Development of an internationally-diverse, linked genomic and longitudinal phenotypic research data asset to accelerate precision treatment pathways for patients with serious mental illness CPMS ID: **MENT 63880**
When the company confirms site selection, you will be notified accordingly. For any further updates, please contact your Local Clinical Research Network.
X Interested in participating in the study - please complete the form to confirm interest.

Site Contact Information **(for detailed feasibility discussions)**	
Research site	**The Chelsea Practice E87665**
Investigator	Name and Role: **Dr Claire Scudder** Email: claire.scudder@nhs.net Telephone: 07855331091
Main contact for feasibility discussions Research Setting	Name: **Dr Jan du Plessis** Research Coordinator Email: jan.duplessis@nhs.net Telephone: 07586321744 Please copy into all correspondence: Name: Ashnee Dhondee Email: ashnee.dhondee@nihr.ac.uk Senior Industry Research Facilitator
	Primary Care Y Secondary Care Y/N (_) Community Care Y/N (_) Other [insert detail here]
Supporting Network to be included in feasibility discussions (where applicable)	Industry Team NWL CRN Tel: 0203 313 4027 Email: Industry.crnnwlondon@nihr.ac.uk
Participant recruitment	
Where and how will participants be identified at the research site? Do you anticipate any challenges that may affect recruitment of this patient population?	**Identifying Participants** **Electronic Health Records (EHRs):** We will utilise the site's Electronic Health Record (EHR) system to identify potential participants based on the specified inclusion and exclusion criteria. This approach will allow us to efficiently pre-screen and identify suitable patients for the study. Additionally, we have a sister practice, Earls Court Surgery, from which we primarily recruit, leveraging our combined patient population of 10,000 individuals. Earls Court Surgery is known for its large diverse patient base, which will enhance the diversity of our recruitment efforts

PIC Sites – Brompton Health PCN: If permitted by the study design and protocol, we plan to recruit patients from PIC (Participant Identification Centre) sites within our Primary Care Network (PCN), Brompton Health PCN, which serves a total patient population of 140,000. Patient identification will be conducted via electronic health record (EHR) searches, with a particular emphasis on ensuring diverse recruitment through this approach.

To enhance recruitment among hard-to-reach patient groups, such as working individuals and those belonging to minority communities, we will implement a robust community engagement strategy. This strategy includes:

1. **Informational Sessions**: Conducting regular informational sessions within the local community to educate potential participants about the clinical research study. These sessions will provide comprehensive information about the study's purpose, procedures, benefits, and eligibility criteria.
2. **Neighborhood Navigators**: Utilising Neighborhood Navigators (staff members under the Additional Roles Reimbursement Scheme (ARRS) within our Primary Care Network (PCN)) to actively reach out to and engage with community members. These navigators will play a crucial role in building trust and facilitating communication between the research team and potential participants.
3. **Targeted Outreach**: Highlighting minority groups during Electronic Health Record (EHR) reviews and planning outreach with the input of Neighborhood Navigators and the PCN Community Corner. This approach ensures that our efforts are inclusive and tailored to meet the needs of diverse patient populations, particularly those who may be underrepresented in clinical research.

Potential Challenges in Recruitment

1. **Disease Severity and Patient Availability:**

- Moderate to Severe COPD: Patients with more advanced stages of COPD may experience significant physical limitations, making it difficult for them to attend frequent study visits or participate in extended clinical trials.
- Comorbidities: Patients with severe COPD often have multiple comorbid conditions (e.g., cardiovascular diseases, diabetes) which can complicate their eligibility for the study and their ability to participate consistently.

2. **Treatment Burden and Compliance:**

- Subcutaneous Administration: Introducing a new mode of drug delivery, such as subcutaneous injections, can be a barrier. Patients may be apprehensive, administration by the study team will negate concerns about self-administration. Dealing with potential side effects.
- Complex Regimens: Patients may already be on multiple medications, and adding an investigational product could lead to concerns about polypharmacy and potential drug interactions.

3. **Recruitment and Retention:**

- Patient Awareness: Ensuring that potential participants are aware of the study can be challenging. This requires effective communication strategies and community outreach.

	● Retention: Keeping patients engaged throughout the study duration can be difficult, particularly if they experience side effects, lack of perceived benefit, or logistical challenges in attending follow-up visits. **4. Socioeconomic and Demographic Factors:** ● Accessibility: Patients from lower socioeconomic backgrounds may face barriers such as lack of transportation, financial constraints, or limited access to healthcare facilities. ● Diverse Populations: Recruiting a diverse patient population can be challenging but is essential for generalizability. It requires tailored approaches to reach minority groups who may have different healthcare experiences and trust levels with clinical research. **5. Regulatory and Ethical Considerations:** ● Informed Consent: Ensuring that patients fully understand the implications of participating in a clinical trial involving an investigational product can be complex, especially for those with low health literacy. **Strategies to Overcome Challenges** **1. Enhanced Patient Education and Support:** ● Provide clear, accessible information about the study and the investigational product. ● Concerns relating to method of administration will be negated as no self-administration required, home visits for eligible patients. **2. Community Engagement and Outreach:** ● Use local community resources, such as patient advocacy groups, to raise awareness. ● Employ Neighborhood Navigators and PCN Community Corner initiatives to reach underrepresented groups. **3. Flexible Study Design:** ● Consider flexible scheduling for study visits or home visits. **4. Incentives and Reimbursement:** ● Offer travel reimbursements, stipends, or other incentives to reduce financial barriers. ● Provide comprehensive care packages that address both COPD management and comorbid conditions. By addressing these challenges with tailored strategies, you can enhance the recruitment and retention of patients with moderate to severe COPD in your study
Based on all the considerations outlined above and the information available at the time, please provide a realistic estimation of numbers of potential recruits by the end of the proposed recruitment period, including workings	*Disclaimer: This is an estimation only based on limited information regarding the study and therefore WILL NOT form part of the contract. Provision of additional study information, such as the protocol, is required to confirm the actual feasibility target proposed prior to site selection by the company.* 1. How many patients in this setting will be seen with this condition? ● **x patients** (Not including PIC Sites) 2. Using the exclusion criteria, how many of these patients would be eligible to take part in this study? ● **x patients**

	3. What percentage of these would you expect will be motivated to take part? • **60%** 4. Considering the answers above, how many recruits would you anticipate over the time period? • **x patients** 5. Planned recruitment strategy: • Discussed above
Please briefly outline any ongoing or planned studies at the research site which may compete with or impact recruitment to the study	Just completed CKD Study.
Available resource	
Please briefly outline the staff resource available to set-up, recruit and provide timely, quality data for this study (e.g. study coordinators, research nurses, data managers)	**Primary Investigator:** Dr Scudder – Clinical Lead Brompton Health PCN Covid-19 vaccination effort. **Research Coordinator**: Dr Jan du Plessis – 4 years experience as secondary investigator – dedicated research post in Cornwall. Recently Research Coordinator for The Good Practice – experience in conducting commercial clinical research across various clinical domains including a large Covid-19 vaccine study in 2021-22 – Highest recruiting site in the UK, Only Primary Care Site in the UK, high retention rate. **HCA** on site. Experienced **Research Nursing staff** via NIHR Experienced **research practitioners** in collaboration with NIHR
Please briefly outline the other infrastructure available to support participation in this study	Equipment available: Centrifuge, -80 Freezer, Vaccine Fridge. Lockable IP storage. Research space at Violet Melchett – centrally located in Chelsea.
Please describe any site-specific activities and how they may impact study timelines	No site specific activities will conflict with this study.
Site past performance data (including start-up timelines)	
We are a new research site The Chelsea Practice Dr Scudder collaborating with Research Coordinator Dr Jan du Plessis. We have the appropriate experience to effectively manage a complex study with a S/C investigational product. <u>Dr Scudder Research Experience:</u> DM PAD Study: Opportunistic Recruitment DM Patients, Target met. Med-Help Study 2023 -2024 -Attack Study CKD - Site setup < 4 weeks	

Dr Jan du Plessis: 2004 – 2008 Involved in 10 studies Commercial Clinical Research Projects: DM, Depression with Arogmelatin, Hypertension Studies and others - **Sub Investigator 4 sessions per week**. 2019 – 2023 Research coordinator The Good Practice 2018 - 2021 - Multiple Non-commercial studies. 2021 - **BASIL+** Study Behavioural Activation in Isolation – Covid19 Study – Highest recruiter (first to reach target of 50 participants) 2022 -2023 - **Sanofi VAT0002 Covid-19 Vaccine Study** (Highest recruiter in the UK, only Primary Care Site) - Site Setup < 3 weeks, 98% participant retention.

Network support available (where applicable)	
Please provide a brief outline of any unique elements of Network support that may be required for the site to participate in this specific study	CRN North West London has a delivery workforce who can assist with running clinics, pre-processing of samples and provide guidance on recruitment strategies in order for the study to deliver to time and target. The CRN can also assist with costing queries and offer other R&D support.

Additional information requested by the Sponsor	
1. Please confirm the potential recruitment numbers per month	2 participants per month.