Factors to Consider When Completing Commercial EOI Forms

Below is a comprehensive overview of points to include or expand upon when completing commercial Expression of Interest (EOI) forms for clinical research. By addressing these factors, your site can present a thorough and compelling EOI to potential commercial sponsors.

1. Participant Identification

Where and how will participants be identified at the research site?

- **Location within the practice or site:** Indicate if you have specific clinics or dedicated spaces for recruitment (e.g., diabetes clinic).
- **Electronic Health Record (EHR) usage:** Specify which EHR system(s) your site uses (e.g., EMIS Web, SystmOne). This helps sponsors understand your data-capture and patient-identification capabilities.
- **Practice list size:**
    - Show how your list size compares to other practices in your region.
    - Emphasize if you are the largest practice, or if you have a niche patient population relevant to the study.
- **Primary Care Networks (PCNs):**
    - State how many PCNs operate in your region.
    - Note if collaboration with these PCNs can increase potential participant numbers.

High Incidence Rates

- Clarify if your practice has a notably high incidence of the condition being studied, especially in comparison to national or global averages.

Ethnicity Data

- Commercial sponsors are placing an increasing focus on equality, diversity, and inclusion.
- If possible, include the ethnic breakdown of your patient population to show your ability to recruit a diverse set of participants.

Primary Care Clinical Research Facility (CRF)

- Mention if your site is a primary care CRF.
- Provide details, such as available facilities and staff, or a link to a CRF presentation or slide deck if applicable.

2. Recruitment Methods

How will you identify participants?

1. **EHR Searches:** Running database searches (e.g., EMIS, SystmOne) to find eligible patients.
2. **Opportunistic Recruitment:** Identifying participants during day-to-day clinics. For example, if the study is about diabetes, you may have specific diabetes clinics that can help identify potential participants.

3. **Community Clinics:** If your site is located in or near community centres with clinics, mention how you might partner with them to recruit.

4. **Text (SMS) Invitations:**

    - Sending out bulk text invitations.

    - Indicate if you will follow up these invites with phone calls or additional messages.

5. **PIC (Participant Identification Centres) Sites:** If the sponsor chooses site-selected PIC sites, describe how you might work with them to boost recruitment.

Potential Recruitment Challenges

- Language barriers (especially if study documents and consent forms are only available in certain languages).
- Access to technology (particularly for elderly populations who might struggle with online questionnaires or e-consent).
- Time constraints for working individuals.
- Concerns about side effects/risks.
- Cultural and religious beliefs that might impact participation.
- If you anticipate no specific challenges, explicitly state “No challenges anticipated.”

Planned Recruitment Strategy

- Be concise.
- Include expected response rates from SMS invites and approximate uptake from opportunistic recruitment.
- Describe your “Plan B.” For example, if response rates are lower than expected, you might collaborate with a PIC site or advertise in a local newspaper.

3. Staffing Resources and Capabilities

Staff Resource Availability

- **Roles and Responsibilities:** Describe who will set up the study, recruit participants, and handle data entry (e.g., research nurses, study coordinators, data managers).
- **Training and Experience:**
    - Confirm if staff members are Good Clinical Practice (GCP)-trained.
    - Highlight other relevant skills (e.g., prior experience with clinical trials in the same therapeutic area).
- **GPs with Special Interests (GPwSI):** Note if you have GPs who have additional expertise in the relevant specialty.
- **PCN Pharmacists or Federation Staff:** Mention if local PCN pharmacists or GP federation staff can support the study.
- **Languages Spoken:** Indicate if staff speak additional languages that could help with recruitment and consent processes.

4. Site Infrastructure and Equipment

Dedicated Research Space

- How many rooms do you have available for conducting study visits and procedures?

Pharmacy On-Site

- Note if you have an on-site pharmacy to handle investigational products.

Equipment

- **Centrifuge:** Specify if you have one (and how many).
- **Freezers:** Mention if you have a -20°C or -80°C freezer and how many are available.
- **Software Access:** List relevant software (e.g., EMIS Web, SystmOne, EDGE, WSIC, REDCap) that could facilitate data capture.
- **Wi-Fi Access:** Confirm if your site has reliable Wi-Fi for remote monitoring or eCRFs.
- **Wheelchair Accessibility:** Is your site easily accessible for participants with mobility issues?
- **Specialized Equipment:**
    - Ophthalmology equipment (if the study relates to eye conditions).
    - Temperature-monitored refrigerator.
    - Calibrated weighing scales and stadiometer (height measurement).
    - Spirometry (if relevant for respiratory studies).

5. Site-Specific Activities and Impact on Timelines

Other Ongoing Studies

- Mention if you're running multiple studies simultaneously that may affect timelines or staffing resources.

Staff Availability

- Note any impending long-term leave or changes in staffing that might impact study delivery.

Equipment Purchases

- If you need additional equipment for this study, estimate how long procurement and setup might take.

6. Site Past Performance Data

Recruitment Figures

- Provide data on how many participants you've recruited in the past six months for relevant studies.
- Include links or references to NWL primary care performance reports if applicable (e.g., NWL Primary Care Performance Reports).

Start-Up Timelines

- If possible, include information on how long it typically takes your site to open a study, from receiving the protocol to the first patient visit.

Research Awards and Milestones

- Highlight any research awards your site has won.
- Mention if you have ever recruited the first participant nationally or globally for a study.

NCVR Scheme

- If you have signed up to the NIHR's New Voluntary Community & Virtual Recruiter (NCVR) scheme, include details.
- For more info: New Voluntary Scheme for GPs to Speed Commercial Study Setup

7. Contract and Document Review

Document Review Timelines

- Estimate how long it typically takes to review Confidential Disclosure Agreements (CDAs) and contracts.
- Provide best-case and worst-case scenarios for sponsor expectations.

Final Tips

1. **Clarity and Conciseness:** Sponsors appreciate succinct, well-structured responses, with relevant data points highlighted.
2. **Evidence of Collaboration:** Emphasize partnerships (PCNs, local trusts, pharmacies) to show that you can recruit more efficiently.
3. **Demonstrate Readiness:** Clearly state your site's capabilities, resources, and any proactive measures taken to ensure timely start-up.

By incorporating the above details into your commercial EOI forms, you'll provide sponsors with a strong, detailed overview of your site's strengths, resources, and capabilities. This not only improves the clarity of your application but also increases the likelihood of a successful collaboration.

Jan, that's the expanded and reorganized version of the document. Let me know if you need any further clarifications, additions, or a different structure!