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JASON CARTER
CLINICAL TRIALS SEARCH & SUPPORT

Clinical Trials Search and Support Feature Trial Application

Application Submitter Name:
Application Submitter Role/Title:
Application Submitter Email:
Application Submitter Phone:
Trial Name*:
NCT Number*:

*For the application to be reviewed and the trial to be featured, the trial needs to be within scope of the Clinical Trials Search and Support (CTSS) **website**. Find more information **here**.

Please fill out each question below to the best of your ability. When finished, please email it to **contact@ctsearchsupport.org**. Applications will be reviewed for completion upon submission. If needed, you may be asked to provide further information. The submissions will be reviewed quarterly by the review committee according to the following schedule:

Submit by:	To be reviewed by:
August 15, 2021	September 15, 2021
November 15, 2021	December 15, 2021
February 15, 2022	March 15, 2022
May 15, 2022	June 15, 2022

Each trial will be scored by the review committee based on the following categories:

- High Impact (HI)
- Patient-Centered (PC)
- Diversity, Equity, and Inclusion Focus (DEI)
- Accessibility (A)
- Data/Trial Design (D/TD)

Each category is weighted to determine the final score. The high impact category is weighted at 25%, the patient-centered, diversity, equity and inclusion focus and data/trial design categories are weighted at 20% and the accessibility category is weighted at 15%.

It is not expected that every trial will meet every measure, but the committee will be looking for rationale for why certain criteria were not met to demonstrate that these elements were considered. Additionally, the more detail you can provide, the better the committee will be able to evaluate the application. If there is not enough detail, the Clinical Trials Search and Support team may contact you for more information. You'll see at the end of each question what category, or categories, the question corresponds to.

On average, the application takes a total of 1.5 – 2 hours to complete. Please feel free to split questions up among study team members who are best suited to answer the questions based on their expertise.

1. What important problem or critical barrier to progress in the field does this research address? (HI)

2. How is this trial unique? How are the concepts, approaches or methodologies, instrumentation or interventions novel to one field of research or novel in a broad sense? (HI)

3. How will completion of the aims change the concepts, methods, technologies, treatments, services or preventative interventions that drive this field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? (HI)

4. What are the plans for sharing results back with participants? If there is no plan, please explain why. (PC)

5. What are the plans for sharing results with the public? If there is no plan, please explain why. (PC)

6. What stakeholders (physicians, patients, advocacy groups, community members, etc.) were involved in the study design and the creation of research questions? How were these stakeholders involved? If they were not involved, please explain why. Please provide descriptions of their roles, not individuals' names. (PC, DEI)

7. Is the informed consent available in multiple languages? If not, please explain why. (PC, DEI)

8. What is the reading level of the informed consent? What tool(s) did you use to measure it (SMOG, Flesch-Kincaid, etc.)? (PC)

9. Does the trial include the collection of patient-reported outcomes (PROs)? If not, please explain why. (PC, D/TD)

10. What is the plan for sharing interim analyses with the public and/or scientific community? If there is no plan, please explain why. (PC)

11. What is the plan to ensure that participants mirror the population that would be using the treatment or intervention included in the trial? (PC, DEI)

12. How has the sponsor or other trial staff been involved in the community of those who are being asked to participate before and/or during the trial? What are the plans for being involved in the community after the trial is finished? (PC, DEI)

13. Does the trial cover the costs of travel and/or housing required for participating in the trial? If not, please explain why. (A)

14. Does the trial include the patient's own care providers in any portion of the trial (design, consent, recruitment and/or results being shared back directly to their providers)? (PC, DEI)

15. Are there trial sites available in both rural and urban areas? If not, please explain why. (DEI, A)

16. Are there opportunities for remote monitoring? For example, can participants who live in rural areas participate from home or with a local provider after initial treatment at another center? If not, please explain why. (A, D/TD)

17. What, if any, training does the trial staff have in anti-bias and/or identity conscious practice? If none, please note this. (DEI)

18. What was your approach to developing eligibility criteria with accessibility in mind? In other words, tell us how you made sure that the eligibility criteria did not unnecessarily exclude certain participants. (A)

19. What was your approach to developing the patient activities/requirements (visits, labs, tests, etc.) with accessibility in mind? In other words, tell us how you made sure that all patient activities/requirements are needed to get to designated endpoints and are not overly burdensome. (A)

20. Are there plans to regularly update changes to the trial and contact updates on ClinicalTrials.gov? (A)

21. What are the billing practices for the trial? How and when are these communicated to potential participants? (PC, A)

22. Please briefly describe the trial's plans to use statistical methods that allow the inclusion of all data for analysis, including diverse groups of participants who may have smaller representation? If there is not a plan to do this, please explain why. (DEI, D/TD)

23. Please briefly describe how the trial data is accessible to all researchers and sponsors and with the appropriate governance and controls? If it is not, please explain why. (D/TD)

24. Is clinical trial data collected via the electronic health record (EHR), with additional data collected only if unavailable in the EHR? If not, please explain why. (D/TD)

25. Were the scientific questions determined with the input and consideration of those who will use the results, including care providers, regulators and payers? If so, briefly describe which of these groups were involved. (D/TD)

I attest that the content included in the above application is true to the extent of my knowledge.

Signature: Date: