ASCO-ACCC Pilot Project to Increase Racial and Ethnic Diversity in Clinical Trials

FREQUENTLY ASKED QUESTIONS (FAQs)
Site Interest Application

Version: May 24, 2021

Thank you for your interest in this ASCO-ACCC initiative with the goal of improving how participation in cancer treatment trials reflects and involves the diversity of cancer populations. We are conducting a pilot project with domestic oncology research sites to understand clinical trial site-, clinician-, and research staff-level factors that may impact screening and participation for cancer treatment trials. This initial phase is a pilot project focused on clinical trial screening and participation outcomes for people who are Black and/or Hispanic/Latinx. ASCO and ACCC plan to modify the resources to address other underrepresented racial and ethnic groups as well in any potential subsequent efforts.

Individual research sites are encouraged to apply to participate in the pilot project by completing the Site Interest Application.

The following questions and answers provide further details about the initiative. If you have any other questions, please contact Jen Hanley Williams at research@asco.org.

1. **Why are ASCO and ACCC collaborating?**
   ASCO and ACCC are committed to working with our members in an effort to ensure that cancer treatment trials fully reflect and involve the diversity of people at-risk for or living with cancer. Our organizations are collaborating on this initiative aimed at establishing evidence-based practical strategies and solutions to help increase participation of people from historically underrepresented racial and ethnic groups in cancer treatment trials. Black and Hispanic/Latinx patients with cancer are two of several groups that continue to be underrepresented in clinical trials when compared with their percentages in the overall population of patients with cancer. The collaboration, which is led by the ASCO-ACCC Steering Group Co-chairs, ASCO President, Lori J. Pierce, MD, FASTRO, FASCO, and ACCC Immediate Past President Randall A. Oyer, MD, launched in July 2020 with a Request for Ideas to the oncology community seeking novel innovations to remedy this barrier.

2. **What is this project about?**
   The pilot project will test two resources (1 – Site Assessment Tool Pilot Study and 2 – Implicit Bias Training Program), each with the goal to help cancer clinical trial sites increase participation of people from racial and ethnic groups who have been historically underrepresented in cancer treatment trials. This initial phase is a pilot project focused on screening and participation outcomes for people who are Black and/or Hispanic/Latinx. In subsequent efforts, ASCO and ACCC plan to modify the resources to address other underrepresented racial and ethnic groups, as well (for additional detail on site eligibility, see question 7).

   The findings from this pilot project will help to inform ASCO and ACCC about the resources developed and potential for a larger, longitudinal interventional study that will compare the effectiveness of different strategies to increase representation of people from racial and ethnic minority populations in cancer treatment trials. At this time, ASCO and ACCC are only soliciting involvement in the pilot project, although participating pilot sites may later be invited to participate in the interventional study, if ASCO and ACCC

choose to proceed with one. However, participation in the pilot project will not be a prerequisite for participation in any later interventional study.

3. What is the Site Self-Assessment Tool and what is involved for a site participating in the Tool pilot study?

The Site Self-Assessment Tool (the "Tool") is intended to help research sites conduct an internal assessment of primarily structural and procedural factors that may impact patient screening and participation in clinical trials. The Tool has three main components and steps: 1. site profile, 2. performance assessment, and 3. opportunities for site improvement.

To complete the Tool, the site point of contact will need to obtain insights from multiple team members and data from a variety of sources from their clinical practice and trial site. This data collection and data entry may need to be completed in multiple steps, and the time required to complete the Tool may vary considerably between sites, depending on coordination and how readily available the data are for entry.

For the Tool pilot study, sites will be asked to complete the tool, provide feedback about its feasibility and utility, and make optional recommendations for enhancing the Tool. In total, the Tool pilot study is designed to take approximately 1 to 2 hours on average of a site's time, depending on how readily available the data are for entry.

4. What is the Implicit Bias Training Program and what is involved for a site participating in the Training pilot study?

The Training Program will feature two primary components: 1. a curriculum-based program, including a virtual convening (for all participants), and 2. an interventional exercise (for a randomly selected cohort). Training will be delivered over the course of 4 months with a total time commitment of 4 to 5 hours for individual participants.

As part of the application process, sites should identify at least one staff member (including investigators or research staff) to participate in the full Training Program. Any identified participants should be able to commit approximately 1 to 2 hours per month between July and October 2021. Participation will include:

i. Completing a self-directed, online training module;
ii. Attending a virtual, 2-hour workshop;
iii. Participating in a 60-minute interview as part of an interventional exercise (for select participants only); and
iv. Completing all evaluation components, including a 6-week follow-up survey.

5. Does my site have to participate in both the Site Self-Assessment Tool and Implicit Bias Training Program pilot studies?

No. Sites may choose to participate in any the following ways:

i. Site Self-Assessment Tool Pilot Study (refer to question 3 for more detail), or
ii. Implicit Bias Training Program Pilot Study (refer to question 4 for more detail), or
iii. Both of the above.

6. What are the potential benefits of participation?

The overall goal of this pilot project is to help sites improve their enrollment of underrepresented populations in research. Completion of the Site Self-Assessment Tool is designed to enable sites to gather data on aspects of their research program that are related to diverse clinical trial participation. The Tool will be framed in the context of quality improvement to help sites identify focus areas for improvement. The Training Program is grounded in existing training resources and will involve the opportunity for interactive reflection with other participants.

7. Who is eligible to participate?

ASCO and ACCC will select eligible sites from the pool of applicants based on criteria outlined in question 12. Sites located in the United States, including states and territories, are eligible to apply to participate. Sites must offer on-site cancer treatment trials. We are seeking trial sites from all types and settings to ensure broad representation of community-based and academic-based practices and research programs.

Research networks should not apply to participate; they should instead ask their interested affiliate sites to apply individually. Only individual research sites/practices will be selected to participate in the pilot project.

8. What if we have multiple sites?

If your practice or research program is part of a network of sites, please have interested individual sites submit an application on their own. For this pilot project, we request that only individual sites/locations participate, rather than an entire research network.

9. What is generally required of a site that is participating in this project?

It is ideal that the site can provide the data below from 2019 and 2020. However, a site will not be excluded if it does not have access to such data.

i. Number of patients with cancer seen in your practice by race/ethnicity (e.g., Black, Hispanic/Latinx, White, other races)
ii. Proportion of patients by race/ethnicity (e.g., Black, Hispanic/Latinx, White, other races) who were:
    a. Screened for a cancer treatment trial (i.e., in general or for specific trials),
    b. Qualified for a cancer treatment trial (i.e., met eligibility criteria),
    c. Offered a cancer treatment trial (i.e., trial was discussed), and
    d. Participated in a cancer treatment trial (i.e., consented to participate).

10. How does a site apply to participate in this project?

There are 3 steps to the application process:

i. Complete a Site Interest Application (refer to question 13)
    Note: You will be asked to provide a site Statement of Interest within the application (up to 500 words)
ii. Upload a Letter of Support into the Site Interest Application (refer to question 15)
iii. Review the example of the ASCO-ACCC Pilot Project Research Site Agreement
    Note: Selected sites will be expected to execute this agreement within 3 weeks after notification of selection by ASCO and ACCC (refer to question 16)

11. What is the deadline to submit an application?

The deadline to submit the Site Interest Application and Letter of Support is June 11, 2021.

12. What criteria will be used to select sites?

Once the application period closes, complete applications will be reviewed by the ASCO-ACCC Steering Group, which will select sites based on key considerations, including but not limited to:

i. Applicant site's expressed commitment to increasing representation of patients from historically underrepresented racial and ethnic populations in cancer treatment trials (as demonstrated in site's Statement of Interest [question 14] and Letter of Support [question 15]); and

ii. Diversity of types of research sites (i.e., geography, academic/community, size, office and hospital/health system based, types and number of trials offered, etc.).

13. What is a Site Interest Application?

The Site Interest Application should be completed by research sites that wish to participate in the ASCO-ACCC pilot project. The application includes questions related to the site's setting and engagement in research. It also provides applicants with an opportunity to state their interest in and suitability for participation. The responses will be used to help select a diverse group of sites to participate in the pilot project. A copy of the application is available here and on the webpage.

14. What is a Statement of Interest?

A Statement of Interest is required as part of the application and may be up to 500 words. The statement offers sites an opportunity to express their desire and commitment to increase enrollment of patients racial and ethnic minority groups historically underrepresented in cancer treatment trials and for the purpose of this pilot project, Black and/or Hispanic/Latinx patients in particular.

15. What is a Letter of Support?

A letter of support from your organization's leadership must be submitted as part of your application. The letter will be typically addressed to the Clinician Research Champion and Practice Research Administrator (primary point of contact for the pilot project) and signed by a person at the site in a leadership role, such as the Chief Medical Officer, Clinic Director, Director of Research, or equivalent. The letter should convey organizational support and commitment to participating in the project. A sample Letter of Support is provided for reference, but applicants are encouraged to customize the language.

16. What is the Site Agreement?

Each site selected to participate must execute an ASCO-ACCC Pilot Project Site Agreement to participate in any component of the pilot project. As part of the application process, sites have access to an example ASCO-ACCC Pilot Project Site Agreement for review. Your site does NOT have to sign the agreement at the time of Site Interest Application submission.

NOTE: ASCO and ACCC reserve the right to modify any of the provisions in the example site agreement prior to execution by the parties. The ASCO-ACCC Pilot Project Site Agreement must be submitted within 3 weeks from the date a site is notified that it has been selected to participate in the ASCO-ACCC pilot project.

17. **What is required of a Primary Contact Person?**
    One person at the site should be identified in the Site Interest Application as the primary point of contact for the project. This individual is responsible for coordinating the site's completion of the ASCO-ACCC project and could be the site's Practice Research Administrator/Director. They will be contacted by ASCO-ACCC staff with information about the initiative and next steps. They will be expected to facilitate data collection at the site, as well as identification of staff to complete the Training Program.

18. **Who is a Clinician Research Champion?**
    The Clinician Research Champion is an investigator at the site who is committed to the project and increasing racial and ethnic diversity in cancer treatment trials. The individual is responsible for overseeing the completion of the ASCO-ACCC project at the site.

19. **Are only ACCC or ASCO members allowed to participate?**
    The site submitting the application should be an ACCC member and/or ASCO member.

20. **Will participating sites receive financial support?**
    Sites that complete participation in one or more components of the pilot project will be offered a stipend. Separate stipends will be offered for the Tool and the Training pilot projects. Practices that complete both projects will be eligible to receive both stipends. Payments will be made directly to the participating site, not to individuals.

21. **How/When will a site know if it is selected to participate?**
    All respondents to the Site Interest Application will be notified by ASCO-ACCC staff as to whether they were selected to participate. Notices are expected to be sent at the end of June 2021.

22. **How will ASCO and ACCC use data submitted in the application and as part of the pilot studies?**
    ASCO and ACCC may use data from Site Interest Applications for selection of participating sites and may use aggregate application data for quality improvement efforts directly related to the goals of the collaboration. If any information is publicly shared, it will only be non-identifiable, aggregate information. ASCO and ACCC may publicly share the names of sites that are participating in the pilot project.

    Involvement in the pilot project will NOT involve submission of protected health information (PHI) on individual patients from participating sites. ASCO and ACCC volunteers and staff are required to keep all data confidential and will only use submitted data in accordance with the terms of the ASCO-ACCC Pilot Project Site Agreement. Access to identifiable data will be limited. Aggregate data will be used by ASCO and ACCC in analysis, publications, and presentations without the ability to link data to specific sites or individuals.

23. **Does this project have Institutional Review Board (IRB) approval?**
    The ASCO-ACCC Pilot Project will undergo IRB review prior to the launch of the Tool and Training pilot studies. All participating sites will have access to a copy of the determination letter.

24. **How can more information be obtained?**
    For more information, please contact Jen Hanley Williams at research@asco.org.