

## Return to Cancer Screening PDSA Quality Improvement Project and Clinical Study Frequently Asked Questions

**If a program submits a breast project for NAPBC credit, can the same breast project also be submitted for CoC credit?**

No. The maximum allowable number of standard credits that may be claimed per project is three. If a breast project is completed for NAPBC credit, then a second cancer site must be utilized in order to receive credit for CoC. The CoC and NAPBC programs within the facility should have a collaborative discussion to determine which route is best for their facility.

**Can participation count for all the standards indicated for 2021 or do programs need to choose one? In the past, we were not able to have one project count for multiple standards.**

If you complete one or more screening interventions, you will get credit for CoC standard 8.3 OR NAPBC standard 4.1. If you complete the interventions and the PDSA and post it in the PRQ in the future for your site visit you will get credit for CoC standards 7.3 and 8.3 OR NAPBC standards 4.1 and 6.1, and finally if you do the first two and you send your data on rates of screening in for the clinical research study you will get credit for all three for either the CoC OR the NAPBC. **Please note, programs that did not fill out the REDCap FORM A by the deadline are no longer eligible to receive credit for the clinical research study.**

**Is this project/study available for programs undergoing initial accreditation? Can new programs contribute to the clinical research study even if not accredited yet?**

Yes, we encourage participation by programs working toward its first accreditation.

**We have already had our first quarter meeting for 2021. Will there still be enough time to complete this project by the end of the year?**

Yes. The PDSA and clinical research study count for 2021 only. You will not be able to apply this PDSA or clinical study to 2022 standards. We realize that many programs may have selected a quality improvement project for 2021 and may not wish to participate in the PDSA or study. It is elective.

**Our institution was already planning to conduct a QI project looking at the impact of the new lung screening guidelines and how many additional people are now eligible. This will be very similar to the PDSA project, but slightly different. Since we will not be following the CoC PDSA project format exactly, can we still use the initiatives we implement to increase the number of eligible patients to fulfill standard 8.3 (screening) as well?**

This is hard to answer without knowing details. The PDSA is elective and if completed can give you triple credit for CoC Standards 7.3, 8.3, and 9.1. We did this as we know resources are thin this year during the pandemic. If your project is focused on screening and quality improvement (presumably increasing screening in lung cancer) then it will probably cover the two standards in 2021.

**Is it required that American Cancer Society guidelines be followed?**

No, as long as the guidelines followed are evidence-based.

**Our Breast Radiologist group follows the screening guidelines set forth by the ACR and SBI. Are we allowed to use our current guidelines and practices for our community messaging?**

While we offer screening guidelines in the study for convenience, you are welcome to follow your usual guidelines as long as they are evidence-based (as per the standard).

**Initially this PDSA for breast was only open to those participating in National Mammography Database with the ACR. You just opened this up to all centers w/ NAPBC accreditation.**

These initiatives are unrelated.

**Can just the PDSA project be done?**

Yes. But only credit for CoC Standards 7.3 and 8.3 or NAPBC Standards 6.1 and 4.1 may be claimed.

**My facility is a very small community hospital. We do, however, have a passion for reaching the underserved and uninsured in our community through a free screening mammogram program that has been impacted by COVID restrictions. Can we still participate and receive credit if we limit the screening program (breast) used for the "post pandemic return to screening " to the target population of underserved and uninsured vs the general public?**

You can target any population you choose as long as you follow the instructions and guidelines as outlined in the project.

**Are the deadlines identical for either participation in the QI project and the Clinical Research?**

Yes, the deadlines are the same for both the PDSA and the clinical study.

**What qualifies as a "screening"? Should we be reporting numbers reflecting of the first/initial screening procedure? Or should we also include patients who have been determined to be at higher risk and therefore require regular follow up with mammogram or colonoscopy (for example, prior history of polyps) in our screening numbers.**

No need to limit to the first screening since repeat evaluations is a normal part of any screening program and intervals between screenings vary based on risk but are still part of guidelines. While we would want you to exclude diagnostic studies for symptoms, we would not limit to first screening. Anybody scheduled or reported as screening, would be acceptable to count.

## IRB & Principal Investigators (PI)

**Does the individual entering the forms provided into REDCap need CITI Human Subjects Training completed?**

There will not be any human subjects' participation in this study. We are only reviewing changes in the rates of screening when programs apply evidence-based forms of screening interventions and following accepted screening guidelines. It is not expected that the forms need to be completed by someone with Human Subjects Training as there is no human subjects' information being shared.

**If there is not risk to human or data of a particular individual is not included, is consent necessary?**

There is no consent. There are no experimental interventions. All the screening interventions are part of existing practices and no human subject information is being collected so there is no need for consent of people.

**Where can documentation of the IRB exemption be obtained to share with local IRBs?**

It is included as part of the [updated protocol](#).

**Do we need to seek IRB approval at our individual institution?**

That is up to your local hospital research practices. Typically, a central IRB covers local institutions, but we recognize that each institution handles this differently so we advise you follow local research and regulatory practices as your hospital.

**Do we have to exchange assurance with the IRB granting exempt status?**

No. We are making the IRB exempt status information is available. You are advised to follow your local research practices as regards whether additional local sign-off is required.

**For the clinical research study portion of the PDSA, how is the local study Principal Investigator (PI) determined? Does the designated PI need to be someone with experience having served as a study PI before? Is publication as the PI optional?**

For the clinical research study, your cancer program will be responsible for selecting the local PI. We would like to have a local PI so that one person is responsible for the accuracy of the information provided. The local PI does not need to be a medical doctor. The local PI should be familiar with screening guidelines, how to verify the data source and verify the accuracy of screening rates that are being submitted at multiple time points. Ideally the local PI would be an active member of the cancer committee. For us to feel confident in the data being submitted for publication, we need to have one person at each program who is comfortable with the data on screening rates so we can be confident the study reports are accurate.

**Is a Principal Investigator needed if your program is only doing the PDSA?**

No.

**Who can be the Principal Investigator?**

This is left to the discretion of the facility. Some recommendations are the Cancer Liaison Physician, Cancer Committee Chair or other member, or the Clinical Research Coordinator.

**Can we have two Principal Investigators?**

This is left to the discretion to the program, but only one can be entered into the REDCap.

**Can one Principal Investigator be the PI for multiple hospitals?**

Yes.

**Can a CTR be the Principal Investigator?**

This is left to the discretion of the program.

**Is there specific work the PI will have to perform for the clinical study?**

The PI will be responsible for making sure the information submitted on FORMS A, B, and C are correct and submitted on time.

**If we choose two or three disease sites, can we have a separate PI for each, or does it have to be one PI?**

You are welcome to conduct more than one study. If you conduct one study in breast and another in colorectal, you could have one PI for each.

## Interventions

### **When should we start the intervention(s)?**

Interventions may be started at any time. To participate in the PDSA and/or clinical study, interventions must have started by June 1, 2021. At this time, the deadline has passed to participate in the PDSA.

### **Can interventions be added after June 1?**

Yes. Additional interventions may be added after June 1, especially if it is determined that the intervention is not having the desired impact on screening rates. One intervention should have started by June 1 and programs are encouraged to keep adding to increase the number of screenings that occur over the rest of the year.

### **Do we have to do all of the interventions listed in the project?**

No. A minimum of one intervention is required. It is expected that you will monitor the impact of your intervention and, as needed, increase the number of interventions to close your screening gap or reach 10% increase in screening rates.

### **Does the American Cancer Society toolkit need to be used?**

Yes. At least one intervention within the American Cancer Society toolkit must be implemented.

### **If an institution is participating in the PDSA QI project alone (not participating in the Clinical Research Study), does the first intervention still need to be performed by June 1<sup>st</sup>?**

Yes. The rules, forms, and dates are the same for the PDSA and the clinical study. The difference is the submission. The PDSA forms are kept for the future site visit and the clinical study requires that you submit the information requested in the forms to a REDCap survey. **Please note, programs that did not fill out the REDCap FORM A are no longer eligible to participate in the Return to Screening PDSA.**

### **Our program had already implemented interventions earlier this year. Are these counted? If you add interventions over time, how do you update the form?**

If you have implemented interventions earlier in the year, you can follow the existing standards templates and seek credit for 7.3 and 8.3 and you can use the PDSA to keep adding interventions if you wish. You may use the FORMS in the protocol if you add interventions.

It will be difficult to participate in the clinical research study as the dates of the interventions will not match up.

## Required Improvement

### **Can activity on this project extend into 2022?**

Yes, however, the compliance credit for all standards will apply to 2021 even if activity extends into 2022.

### **Will compliance still be counted for applicable standards if participants do not reach the pre-pandemic screening rates or the goal of a 10% increase is not achieved?**

Yes, participation will still qualify if the 10% increase goal is not met as long as there is documentation that there is continued effort to improve the rate. This includes but is not limited to, assessing your

improvement, and trying multiple interventions in an attempt to close the gap.

**Our pre-pandemic rate for lung screening for Sep 2019-Jan 2020 = 10.4/month. Our during-pandemic rate for Sep 2020-Jan 2021 = 10.6/month. Can we still participate with a goal to increase by 10%? When you look at 2019 (all 12 months) compared to 2020 (all 12 months) there is a 29% gap.**

Yes, you can participate. Your goal would be to increase screening by 10%.

**Which number do you have to increase by 10%--pre-pandemic numbers or the pandemic numbers?**

Pandemic numbers.

**When evaluating the specific months requested for screening volumes, our facility does not demonstrate a significant decline of more than 10% gap, however, we believe that a concentrated effort of applying proposed interventions of the study might drive screening volumes higher than current levels. Is a gap required for participation?**

The short answer is No. A gap is not required for participation. You may participate if your plan is to try to increase monthly screenings by 10% over your current screening rate.

**The instructions state that we are "expected to return to pre-pandemic rates of screening." What if our screening center still has limitations due to physical space (waiting area does not allow for us to return to full operation due to social distancing requirements) and staffing limitations? Can we still qualify and have a goal to increase by 10%? We feel that this is a reasonable goal, but we do not think we can return to pre-pandemic rates.**

We would not want you to increase screening if it would put your patients in harm's way. If you do not have the staffing and/or precautions to protect against Covid-19 infection, then best not to participate. If on the other hand you can safely increase by 10%, that would be reasonable as that is the minimum improvement we want to see.

## Data Collection

**Is data collection for only the months of September 2019 & January 2020 for Step 1e? Or is it September through January?**

It is data from September AND January (not September through January). We just need two months of data from screening activities pre-pandemic (9/2019 and 1/2020) and 2 months of data during the pandemic (9/2020 and 1/2021). The average of the two months (September and January) will help set the baseline for closing the gap in screening that has occurred due to the pandemic.

**Why were July and September specifically chosen as the months in the analysis?**

**Why is the data collected just July and September instead of July through September?**

The months are September and January. We did not want to burden the programs to have to collect a lot of information about monthly screening numbers, so we selected just two months from two different seasons and skipped months with a lot of holidays- September 2019 and January 2020 for "pre-pandemic" and we kept the same months for "during pandemic", September 2020 and January 2021.

**Can we choose months other than September or January for the research study or the PDSA?**

For the PDSA (CoC standard 7.3 and NAPBC standard 6.1) yes, it is reasonable to make some exceptions for the PDSA quality improvement study as long as you are examining pre-pandemic vs during-pandemic rates and trying to either close your screening gap OR increase by screening rates

by 10%. Keep clear notes for your future site visit (to be put in the PRQ) to ensure that you get appropriate credit for the standards.

For the clinical research study – no it is not possible to shift the dates as adding more variability (i.e., different programs giving us rates from different dates) defeats the purpose of limiting the number of variables. Adding more variation to the study will reduce our ability to interpret the results in a consistent manner.

**Do we have to include all disease sites?**

No. You need to include at least one disease site to participate.

**Do annual breast exams done during annual gynecological visits qualify toward the breast screening numbers?**

We are not aware that annual breast exams by themselves, without mammography, are sufficient to be considered standalone screening based on current evidence-based guidelines for breast cancer.

**Do stool-based tests count for colorectal screening numbers?**

Yes, stool-based tests (e.g. FIT) count.

**Is there a minimum number of screenings to participate?**

No, there is no minimum. It is all based on pre-pandemic and pandemic monthly rates of screenings so there should be no minimum.

**We did not have any screenings in January, can we still participate with just numbers from September?**

This seems a bit unusual to have no clinical screenings done in a full month. Regardless, you would still add September 2020 and January 2021 and divide by two as your baseline during pandemic.

**Is the screening rate number screened per month or a percentage of who is due/eligible?**

Screened per month.

**How is the screening rate calculated? What are the numerator and denominator?**

The screening rate is the number of screening tests done in each of the 4 months listed in the protocol (9/19; 1/20; 9/20; 1/21) (i.e. how many mammograms were done in those 4 months?).

This is not the same definition of screening rate used by other organizations; i.e. some groups use the term “rate” as the number screened (numerator) as compared with number in the community in need of screening (denominator)- this is NOT our use of the term “rate”.

**Which data sources should programs use to calculate the screening rates?**

We cannot advise on this, but we might suggest you start by going to the local radiology suite to figure out how many mammograms were done in the months listed in the protocol or go to colonoscopy suites for colorectal screening.

**Does the PDSA require us to capture information about the patients who return to screening and will each patient need to sign a participation agreement?**

No. Patients will not sign a participation agreement for the PDSA. We are not gathering any patient data. We do NOT want any patient information submitted to us. We are only asking for screening rate information at multiple time points.

**Who should we return the study forms A, B, and C to?**

If your program is participating to meet the screening and quality improvement standards, complete the forms and save them to include in the PRQ at the time you prepare for your site visit. If you are participating in the clinical research study, the data contained in study forms A, B, and C should be submitted to the designated REDCap.

**On #6 “Number of interventions selected” – are you looking for the number of which intervention(s) we are planning to utilize or the total number of interventions we will use?**

On Form A we only need to know how many interventions you plan to implement starting June 1. On Form C we ask for more detail on which interventions you implemented and when you started your implementation.

**When calculating screening numbers must we include outpatient facilities not related to our hospital? For example, do we only count the screening mammograms done at our imaging center or do we include all of the outpatient imaging centers in our community?**

Per the guidelines in Step 1b, outpatient imaging centers should be included.

**I am trying to fill out the Form A for enrollment and baseline data. It says to use the September and January screenings and divide by 2. Do I need the rate of those months and then divide by 2?**

Correct – if you are doing breast as your disease site, you will need to know the number of mammograms performed in the month of Sept 2019 and in the month of January 2020. You will add those two numbers together and divide by two to generate the average monthly breast screening rate before the pandemic.

**I understand that participation in the QI Project and the Clinical Research Study are separate, but it seems like the same forms (A,B, and C) are completed for both. Is this correct?**

Yes, the same three forms need to be completed for the PDSA and the clinical study. For the PDSA you fill out the forms and upload to the PRQ at the time of your site visit. For the clinical study you submit the information from form A before May 31<sup>st</sup> and forms B and C by the end of November 2021 to the designated REDCap.

**Is there something more involved for participating in the clinical research? The checklists for the PDSA (page 5) and the research (page 6) look identical.**

The only difference in the forms is that for the clinical study, the data from the forms must be submitted to a REDCap survey.

**If the same forms are submitted for both projects, how exactly do we indicate to which aspect (PDSA QI Project and/or Research Study) we wish to participate?**

For the screening and quality improvement initiatives, you complete the forms and retain them until your next site visit and upload them into the PRQ. For participation in the clinical study the information in the forms must be submitted to the designated REDCap by the defined deadlines.

**We have patients who get screening mammograms at several imaging centers in the community. Do we choose one for the study or we have to collect the data from all imaging centers?**

You would include any imaging center within your accreditation. In other words, any screening center that is included within your accredited programs Federal Tax ID Number (FEIN).

**Will data be gathered from any non-participating programs to assess if return to screening rates attributed to intervention versus natural rise related to softening of COVID related restrictions?**

That would be a great thing to do if programs were willing. We keep in our minds that the main reason we are doing this is to help patients keep from getting advanced cancers. If we can learn about what interventions helped increase screening that will be a bonus. We suppose we might do a look back and ask programs to submit such data on volunteer basis. There will be many factors affecting the screening rates and they will be different in different locations.

## Documentation Questions

**When do programs need to let CoC/NAPBC know we are participating in the clinical research portion of the project?**

May 31, 2021

**What do we need to submit to let the CoC/NAPBC know we are participating in the clinical research portion of the project? Where is it submitted?**

Programs should complete Form A, which is found within the clinical research study details. Information from Form A must be submitted to the related REDCap survey. **Please note, programs that did not fill out the REDCap FORM A by the deadline are no longer eligible to participate in the Return to Screening PDSA.**

**Do we need to notify CoC/NAPBC now if we are going to do the PDSA project for CoC Standard 7.3/8.3 or NAPBC Standards 4.1/6.1?**

No. The forms should be completed as directed and kept for PRQ submission at the time of the program's next site visit.

**What documentation are the programs to provide to demonstrate compliance to each of the 3 standards with the screening study?**

Programs should complete and upload into the PRQ study forms A, B, and C to demonstrate compliance for PDSA/screening event-only participation. So please use the project forms in lieu of the standard CoC or NAPBC templates if your program will be using this project for compliance. The information requested is included in the study forms. For clinical research study compliance, the required information must be submitted to the REDCap survey by the defined deadlines.

**Do we fill out Form A for the PDSA, the clinical study, or both?**

Both.

**Do programs have to enter data on individual patients?**

No, just aggregate data is required. The project is looking at rates of screening overall.

**Does software need to be purchased (e.g., REDCap) to do the clinical research study for CoC Standard 9.1 or NAPBC Standard 3.2?**

No.

**If we are just doing the PDSA, did we need to complete the REDCap?**

No.



## Clinical Research Credit for CoC Standard 9.1 & NAPBC Standard 3.2

### How does participation in the clinical research study meet compliance for CoC standard 9.1 and NAPBC standard 3.2?

Completing the research study (*i.e.*, completing and submitting required forms by deadlines) will fully meet CoC Standard 9.1 or NAPBC Standard 3.2. Even though programs will get full credit for CoC Standard 9.1 or NAPBC Standard 3.2 by completing this study, programs are still expected to complete and submit required documentation (*e.g.*, templates or PRQ questions) related to other cancer-related clinical research accruals for 2021 for internal quality improvement purposes and for discussion at future site visits.

### Is CoC standard 9.1 or NAPBC standard 3.2 satisfied? Can it be both?

No. To get credit for both CoC 9.1 and NAPBC 3.2 you must conduct two different studies. In other words, your program could choose to conduct a breast return to screening for NAPBC 3.2 and a colorectal, cervix or lung screening study to get credit for CoC 9.1.

### Different categories have different accrual requirements (percentage accruals) for CoC Standard 9.1. Is it full credit for any category?

If a program participates in the clinical research portion of this project, then they get full credit—no matter the percentage accrued in other trials. But programs still need to calculate the accrual outside the study (but program will not be penalized if they do not meet the percentage required by CoC Standard 9.1 or NAPBC Standard 3.2).

## NAPBC Specific Questions

### To qualify for NAPBC credit, does the return to screening project have to be focused on breast cancer?

Yes.

### If a NAPBC program does the Return to Screening PDSA and a physician specialty-specific quality improvement program, does it satisfy Standard 6.1 for 2021?

Yes, if the program does a physician specialty-specific study, then the return the screening PDSA can count as the in-house quality improvement study. These two efforts combined would fully meet NAPBC Standard 6.1.

### For NAPBC, do we still need to submit another study to meet Standard 6.1?

Yes. NAPBC Standard 6.1 requires two studies each year or one study and a physician specialty-specific quality improvement. This project only counts as one of those, so either an additional center-specific study or a physician-specialty quality improvement program will also need to be completed.

## CoC Specific Questions

### As a CoC and NAPBC site, can we study breast and submit it for CoC instead of NAPBC?

Yes. However, your program would not be able to use it for your NAPBC accreditation.

**By completing the PDSA - can sites get credit for BOTH CoC standard 8.3 and 7.3 for the same work? We know that usually this is not the case, and you can only get credit in one standard area for a project.**

We are giving double credit just this year for this project. Programs will get credit for both CoC standards 7.3 and 8.3 if they complete the PDSA.

**I have been under the impression CoC does not allow a project to cover more than one standard. Per the study, it says we can use this to fulfill CoC Standards 8.3, 7.3, and 9.1. Can we use this project to meet requirements for all 3 standards or are we supposed to decide on only one of the standards to use it for?**

If you complete the screening interventions, the quality improvement project, and the clinical research study you will be eligible to use them for compliance with all three CoC standards for 2021 and for this project only. This is a one-time allowance.

**Does an “event” have to occur to get credit for CoC standard 8.3 as stated in the standard definitions and requirements? The interventions listed are not all event related.**

An event does not have to take place to get credit. We expect programs to use at least one of the interventions listed as an alternative to events. Most “events” were in person and that has not been a safe or even permissible option, so we wanted to help programs find alternatives and then support them by giving them credit. It does not need to be a traditional event.

**Our program is planning to participate in the elective Return to Screening PDSA project. Our program is also in the process of addressing barriers to care for screening disparities for breast cancer in African American women ages 40-50. Can we use this elective project to also address CoC Standard 8.1 if we also collect screening information on race?**

This project does not apply to CoC standard 8.1.

**Can the screening study be used to satisfy deficiency resolutions for any or all of the 3 standards (7.3, 8.3, 9.1)?**

Yes, conducting and completing these requirements may be counted toward a deficiency resolution.

**If we complete the forms in the Return to Screening PDSA, do we also need to complete the Standard 7.3 Quality Improvement Initiative or Standard 8.3: Cancer Screening Event? templates?**

No. Only Forms A, B, and C are required. It will need to be uploaded to demonstrate your 2021 compliance in your Pre-Review Questionnaire during the year of your next site visit. However, the Clinical Research Template will still need to be completed even if you are participating in the clinical research study portion of the project.

**Under step 1A it says that each program should select a target screening area and lists out breast, colorectal, lung, and cervical. Prostate, head and neck, and skin cancers are not mentioned here. Does this mean these sites cannot be used for the PDSA project?**

The screening materials that are shared from the American Cancer Society are focused on breast, colorectal, lung, and cervical. The PDSA and clinical study are limited to those 4 sites. You are welcome to use the PDSA framework toward any cancer site. If you complete your own quality improvement project in these other disease sites, you may apply it for CoC Standard 8.3 and 7.3 credit if you can show the screening and quality improvement efforts. You will not be able to get credit for CoC Standard 9.1 as the clinical research study is not covering cancer sites other than colorectal, lung, cervical, and breast.

**We had a program goal for CoC Standard 7.3 to increase our lung screenings, which we were unable to do due to the pandemic. Can we participate in this project and use lung as our site?**  
Yes. It is assumed many of these interventions will be new tactics.

**For network (INCP/NCIN) programs, is this project done at the network parent level? Or must it be done at each of the children?**

The PDSA study may be done at the network parent level and integrated across the network. For the clinical study, each individual facility within the network would need to participate versus at the network level.

**If the INCP is two hospitals in same city and screening efforts are at the ambulatory sites associated within system, it would be near impossible to separate the screening data by hospital. How do we address this?**

Each facility needs to be separately submitted for the clinical research study. If you cannot attribute the screenings to a given facility there would seem two options:

- One option is to just submit as one facility and include all the screenings.
- A second option would be to split the screenings in half and submit each facility separately.

**We are applying for Network accreditation. Should we list ourselves as Network even if we haven't had a network survey before?**

If you are working toward your network accreditation this year, then you may list yourself as a network. If you are still in the development phase of the network and the accreditations are still separate, then it should be listed individually.