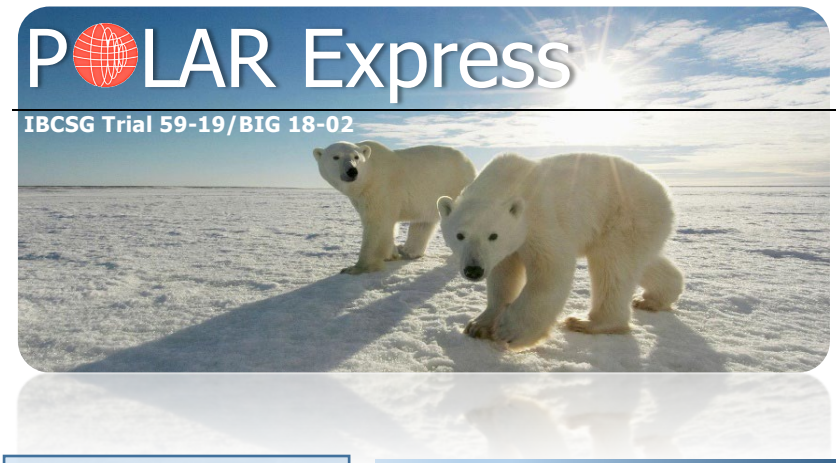

ETOP·IBCSG
Foundation for International Lung & Breast Cancer Research
IBCSG
BIG Breast International Group

February 2026 Volume 6, Issue 1

Of Special Interest

12-Feb-2026

Final Accrual: 405 patients

No. of Centers Activated to V3.0: 51

Last Patient Randomized: 27 January 2025

Contents

News About the Upcoming POLAR Trial Primary Analysis

Meredith M. Regan, POLAR Trial Statistician

With the successful completion of enrollment in January 2025, we now look forward to the primary analysis of the trial. The statistical design plans analysis after at least 66 iDFS events have been reported, which was expected within approximately 1.5 to 2 years of completing enrollment. Thus, we are now planning the primary analysis timeline, anticipating:

- visits through Q4'2026 will contribute to the primary analysis, and
- database lock will occur in late Q1.

A detailed timeline will be provided later in a separate communication.

During 2026, the IBCSG DMC and monitors will be closely watching the completeness of data submission, both for patients who continue in the protocol treatment phase and patients who are in the follow-up phase**. Your assistance with timely data submission during the forthcoming year will greatly benefit the preparations for reporting the trial results.**

In addition to the Data Managers Manual, other resources for data submission include the Frequently Asked Questions FAQs, DFexplore User Manual, POLAR Training Slides and the November 2023 (volume 4, Issue 2) of the POLAR Express for clarifications about reporting when patients reach the end of protocol therapy phase.

We appreciate all of your efforts! Please do not hesitate to contact the DMC at ibcsg59_polar@frontierscience.org for any clarifications or assistance with data submission.

Important Remarks and Reminders in Preparation for the POLAR Trial Primary Analysis

Adriana Karausch, POLAR Trial Data Manager

The POLAR Trial Primary Analysis is approaching and with it comes our commitment to have the data collected on time and with accuracy. Please keep these important points in mind when collecting and entering data in our database:

- Patients stopping Palbociclib therapy early should continue with ET and remain on the *treatment phase* of the trial.

  While this may not be an ideal clinical scenario, if an Arm A patient stops taking Palbociclib but continues with standard endocrine therapy, he/she remains on the POLAR Trial treatment phase. According to protocol Section 10, *"Patients who have unacceptable toxicity from Palbociclib should continue endocrine therapy wherever possible and continue in the 3-year protocol treatment phase."*

  The change in Palbociclib treatment should be reflected on:
  - The PV Form, question 5 by entering "yes, change in treatment". For future visits after the patient stops taking Palbociclib, question 5 of the PV Form should be "not applicable (never took/no longer taking)".
  - PALBO Form, question 7 by entering "permanently discontinued early." Please also enter the reason for discontinuation in question 8/9 (if applicable) and enter the date of the final Palbociclib dose in question 10.
  - Do *not* submit the EoT Form since the patient is not ending all protocol therapy, but only Palbociclib. The patient should continue the assessments schedule and clinic visits similar to the patients on Arm B (receiving ET only).

  Since patients stopping Palbociclib should continue ET, if a patient stops ET as well with no reason provided, it would be considered a protocol deviation.

- Data should be completed per protocol guidance and in a timely manner on every phase of the trial:
  - As screening and Baseline data should have been entered within 1 week of randomization to assure the medical review of patient's inclusion criteria, please complete any missing baseline form and answer any outstanding baseline query as soon as possible to avoid further delay in medical review.
  - Protocol Treatment should be reported for 3 years and the end of protocol therapy reported in the last treatment Forms, this is considered the treatment phase of the trial.
  - The EoT visit is of paramount importance as it reflects, along with the Treatment Forms, the effectiveness and tolerability of the protocol therapy.
  - Follow-up Phase start after the EoT Visit until the trial ends, this phase is very important to assess patient disease status, any additional ET the patient is taking beyond 3 years from randomization and any medical event.
  - If the patient cannot come to the clinic for the follow-up visits, please consider collecting the patient follow-up data through another method other than "patient seen", since some of these patients will be followed for their care by a physician externally.
  - The E-form specifically allows documenting on question 2, the method of contact for obtaining data (patient seen; other patient contact; other method, specify). This allows the sites to submit information about progression of disease, events, and vital status even if the patient is not seen in their clinic, as this is critically important to the trial analysis.
- The POLAR Trial protocol plans follow-up of all patients until approximately 4 years after the inclusion of the last patient (around January 2029), thus the trial intention is to collect follow-up data until the end of the trial, patient death, patient total withdrawal consent, or when the patient is lost to follow-up, whichever happens first. However, the patient binder in DFexplore collects data until the 120 Month Visit (10 years) because the first patients were enrolled in 2019.

Important Remarks and Reminders in Preparation for the POLAR Trial Primary Analysis (cont.)

- When data is not available for any reason, please mark the answer to the question as "Missing Value" in the missing value box by clicking on the green plus sign, selecting "missing value," and then clicking apply at the bottom. If possible, please provide the reason for the missing value clicking "Field" from the Toolbar and then "add reason for data value".
- The Idealized Scheduler generated at randomization for each patient is a guidance for scheduling patient visits and the form request is based on it.
- To check for any outstanding queries or what visits or CRFs are missing, please access your patients' records directly in DFexplore and remember to always contact the DMC or your Center Monitor for any questions related to the trial. We are happy to help you and provide guidance to complete the data on time.
- Please note that POLAR Quality Control (QC) Reports are currently scheduled to be sent more frequently during 2026 to keep centers continuously informed about their data submission status.

As we approach the Primary Analysis the timely submission of all patient follow-up, whether an event has occurred or the patient is doing well without any event to report, before the end of 2026 is our goal, please help us achieve it!

Training Logs and Acknowledgment of Receipt (AoR) Submissions

Dorene Polizzi, POLAR Trial Coordinator/Data Manager

In order to reduce workload and so that all involved may be as efficient as possible, complete the following **prior** to returning a Training Log, AoR or similar document:

- Write names neatly in print or fill them out electronically
- Verify all required staff signed the document (verify against Authorization Log when necessary)
- Make sure that Center Code and Center Name are completed
- Be sure to return them on or before the requested return date

Thank you in advance for your assistance with this. We know that completing paperwork can sometimes be a tedious job and we would like to make it as easy as possible to collect it. Your efforts in this regard are crucial to keeping the process efficient. Do not hesitate to reach out to us if questions come up, we are happy to assist you!

Requirements for Staff Changes

Dorene Polizzi, POLAR Trial Coordinator/Data Manager

What actions are required when there is a staff change at your Center? Most importantly, you need to notify the POLAR team right away at ibcsg59_polar@frontierscience.org. Also submit the following information so that we may update our systems:

- Updated Authorization Log listing the new staff member, as well as the stop dates of any staff that has left
- Contact details of new staff member
- Training log(s) of new staff member
- GCP certificate and CV signed within the last 2 years for Principal Investigators and Sub-Investigators

By supplying the above as soon as possible, it ensures an easy transition. We want to be able to provide access to systems as soon as needed as well as provide any important communications to the correct recipients.

Thank you so much for your support in this! Please reach out to us if any assistance is needed, we are happy to help!