



August 2024 Volume 5, Issue 1

Of Special Interest

30-Aug-2024
Current Accrual: 369
Accrual Goal: 400
No. of Centers Activated: 49
No. of Centers Recruiting: 44

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Accrual Update

Meredith Kissel, Trial Coordinator

The POLAR Trial is in the crucial final months of the accrual phase, having enrolled 369 of the planned 400 participants as of 30 August 2024. Your efforts have been outstanding and we thank you for all of your hard work and dedication to these patients. We hope to continue this momentum and reach our accrual goal by the end of 2024.

Centers	Number of Centers Activated	Number of Centers Recruiting	Number of Patients Randomized
Spain	14	13	112
Italy	10	10	100
France	11	11	107
Switzerland	9	7	29
Austria	4	2	18
Hungary	1	1	3
Total	49	44	369

Planned Sample Size: 400
Actual Accrual 369 as of 30 August 2024

News about the Upcoming POLAR Interim Analysis

Adriana Karausch, POLAR Data Manager

We are preparing for the interim analysis as specified in the protocol, which will be presented to the Independent Data Monitoring Committee at its meeting during the fourth quarter of 2024.

To accomplish this successfully, we would like to take this opportunity to ask the Centers for all outstanding queries to be answered and overdue data to be submitted by **September 16th, 2024** just before the next POLAR Trial Quality Control Report distribution on **September 23rd, 2024**.

To check for any outstanding queries or what visits or CRFs are missing, please access your patients’ records directly in DfExplore.

If you have any questions or concerns in reference to data submission for the analysis, please contact the POLAR Trial Team at: ibcsg59_polar@frontierscience.org

Important Remarks and Reminders about the End of Protocol Treatment Phase

Adriana Karausch, Data Manager

- For Arm A patients (palbociclib + standard endocrine therapy), if palbociclib therapy stops prior to endocrine therapy within the 3 year protocol treatment phase, then the patient should **continue endocrine therapy whenever possible until reaching 3 years** from randomization date, unless one of the reasons in Section 10 of the POLAR protocol occurs.

It is important to note that patients **do remain in the protocol treatment phase** if palbociclib stops and ET is continuing, until the patient reaches 3 years from randomization (or other reason in protocol Section 10). Only then does the patient have an End-of-Treatment (EoT) visit and transition to the trial follow-up phase.

Per the POLAR protocol, End of Treatment (EoT) visit is only reached before 3 years if all protocol therapy ends before 3 years, which is the end of the protocol treatment phase of the trial.

Endocrine therapy can continue beyond the protocol treatment phase during the follow-up phase of the trial at the discretion of the clinician according to local standards.

- When completing the EoT visit (59- EoT Form), if the patient is continuing ET beyond Year 3 of the protocol treatment phase, the “Date last protocol dose” reported should be the date patient took AI/SERM therapy for the last time until the 36 Month visit. If the Center cannot collect the exact last protocol dose date, the 36 Month visit date itself can be used. For Fulvestrant/LHRH/GnRH analogue the “Date last protocol dose” is the last injection patient received until the 36 Month visit.
- If the patient experienced a recurrence, all protocol therapy should stop and the EoT visit and transition to the follow-up phase should occur.
- If the patient has a recurrence, Questions 6 and 7 of the Follow-Up Form (59-E Form) should not be answered and be left blank.