



Of Special Interest

Current Accrual: 203

Accrual Goal: 400

No. of Centers Activated: 51

28-September-2022

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POLAR Has Reached an Important Milestone!

As of September 19th 2022, we have enrolled the 200th patient into the POLAR Trial, reaching 50% of the targeted accrual goal.

Thank you to all of the hard working POLAR study team members who helped to reach this important milestone!

We are very pleased to see that the POLAR Trial is running smoothly and is recruiting steadily.

POLAR is a very important trial in the CDK4/6 inhibitor landscape. It will help answer the question if adding palbociclib to standard endocrine therapy can prolong invasive disease-free survival in patients with HR-positive, HER2-negative resected isolated locoregional recurrence of breast cancer.

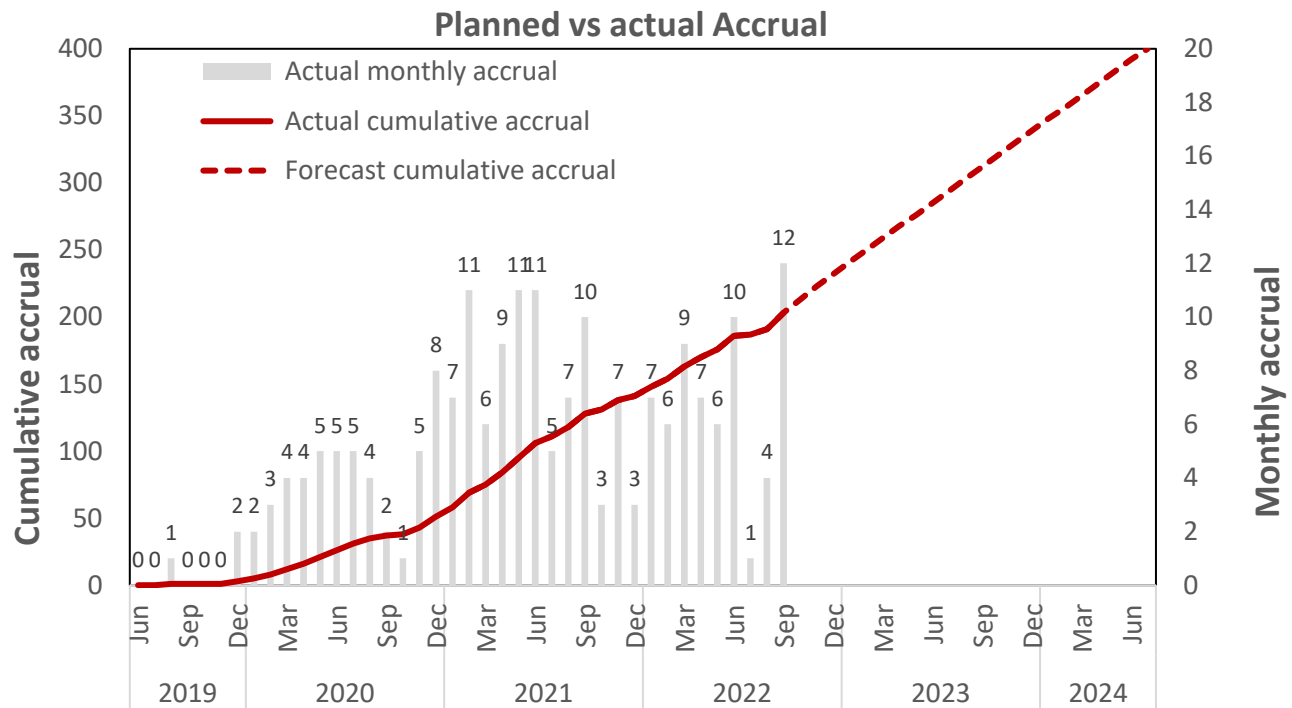
A big thank you to the Investigators and their teams across all 42 Centers in the 6 participating countries for the continuous support of the POLAR Trial and for all the screening efforts to help us enroll the remaining 200 patients.

Country	Planned	Activated	Recruiting	Randomized
Spain	14	14	13	61
Italy	10	10	9	57
France	13	12	10	54
Switzerland	10	10	7	19
Austria	4	4	2	9
Hungary	1	1	1	3
Total	52	51	42	203

Accrual and Activation Update

Target Sample Size: **400**

Actual Accrual as of 28 September 2022: **203**



Data Management Updates

The IBCSG Data Management Center recently resolved an issue with the POLAR PALBO Form and corrections have been made accordingly in DFExplore. This issue occurred after a Center reported **the first or a new Palbociclib dose reduction**.

When an Arm A patient has a Palbociclib dose reduction and the Center correctly reports "Yes, change in treatment" on question 5 of the PV Form, questions 5 through 8 on the corresponding PALBO Form are answered with the details for the change in treatment.

For the subsequent visits, if the Center answered Question 5 of the PV Form as "No change since last visit", the system would auto populate in Questions 5 through 9 of the PALBO Form with the same "new dose reduction" and details, even though there was NOT a new Palbociclib dose reduction during this period. This error has now been corrected.

Data Management Tips

Our goal with this section of the POLAR Express is to prevent some of the most common data management issues we have encountered in POLAR Trial and to lessen the number of queries and questions when entering data.

AE Form:

- When a patient experiences an adverse event, please answer all the questions referring to the specific AE (e.g., “Is this an SAE?”).
- Do not answer the question about SAE when the patient is not experiencing a specific AE.
- Remember to sign and date every CRF that requires it. The lack of signatures and dates is creating many unnecessary queries.

PV Form:

- Question 1 - Visit Date never should be the same as the Date of the Laboratory Investigations reported in Question 1 of the PALBO Form.
- Remember that Visit Date should be the end of the Month Visit and the Laboratory Investigations should be done at the beginning of the Month Visit.

PALBO Form:

- Always report the lab tests units of measurement and record the ULN as requested in the form.
- Question 10 of the PALBO Form “Date of final dose” should only be reported when Palbociclib is **permanently** discontinued.

Reminder: When data is not available for any reason, please mark the answer to the question as “Missing Value” in the missing value box. Click on the green plus sign, select “missing value” and then click “apply” at the bottom. If possible, please provide the reason of the missing value by clicking “Field” from the Toolbar and then “add reason for data value”.

Please do not enter information in the header of a form if there is no data to report or the patient is not receiving the specific therapy.

Meet the POLAR Team



Welcome Dorene to the IBCSG Polar Team! Dorene is an IBCSG Trial Coordinator/Data Manager. She works on a number of IBCSG trials and we are excited to welcome her to the POLAR Team.

Hello, my name is Dorene Polizzi and I have been a part of the IBCSG Team as a Trial Coordinator/Data Manager for several years. I have been a part of numerous trials that include METEORA, ALPHABET, DECRESCENDO, SASCIA and more recently STP and SNAP. I am excited to be joining the POLAR Team and taking a part in this important trial. I have an Associate Degree in Veterinarian Technology and a Bachelor's Degree in Liberal Arts. Outside of work I enjoy camping, hiking and cooking.