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RACC reaches 50% and interim analysis!

- The Gemelli-team with PI professor Scambia enrolled the 384th patient earlier today
- Shortly after, the 385th patient was randomized and we now have less than half remaining
- Half-time enrollment was reached 3 months earlier than previously predicted
- Since April, a total of 72 patients have been enrolled (median 22.5 patients/month)
- The amazing accrual would not have been possible without the fantastic efforts by all participating centers!

Interim analysis

The independent Data and Safety Monitoring Board (DSMB) has completed the first interim report (300 patients)

- 1. Accrual: The dramatic rise in enrollment past 3-4 months suggests that the trial can be closed for enrollment as per protocol (5 years) or earlier
- 2. Primary endpoint: the low number of reported events (recurrence/death) precluded interim analysis of oncologic outcomes
- 3. Intention To Treat: in order to perform ITT analysis of all randomized women, adequate follow-up of all patients is of utmost importance, especially those that have been excluded after randomization (for any reason)
- 4. Data quality: some minor concerns were raised, the DSMB stressed that all local PIs must ensure properly entered data on time
- 5. Summary: the DSMB approved continuation of the RACC-trial

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Save the Date! 1st in-person investigator meeting in Stockholm January 19-20, 2023

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