AtTEnd study

Phase III double-blind randomized placebo controlled trial of atezolizumab in combination with paclitaxel and carboplatin in women with advanced/recurrent endometrial cancer

Welcome Message

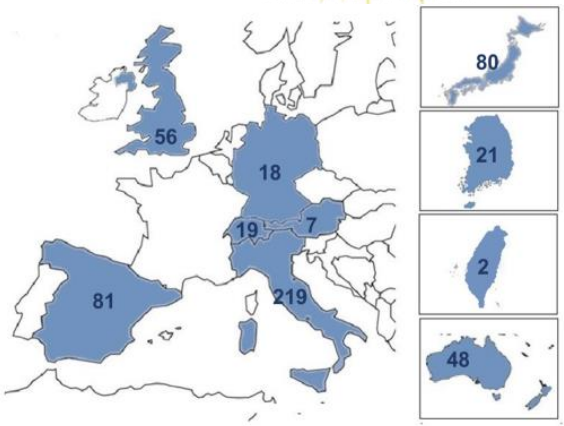
Happy New Year! Last year we made great work with the completion of global enrollment. Now it is time to have an even better year!

Final PFS analysis and interim OS analysis are planned to occur approximately in Q3 2023, as per projection assumptions, we have to work together to reach this target!

In preparation of the database lock, we kindly ask your support to intensify the data cleaning activities and to resolve data backlog.

Please comply with the deadlines on eCRF pages complition and queries resolution. All the requests need to be answered before the next planned data cut-off that will occur on April 3rd, 2023 for the safety IDMC analyses.

In addition, data entry backlog could be asssociated to a significant number of the patients in the study as 'potential lost to follow-up'. Please work on these patients in order to collect information about their survival status that is one of the primary outcomes of the study.

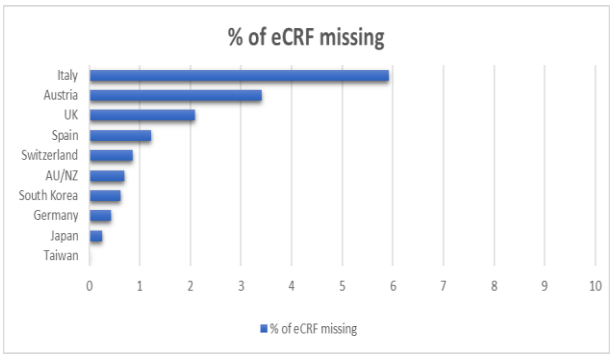


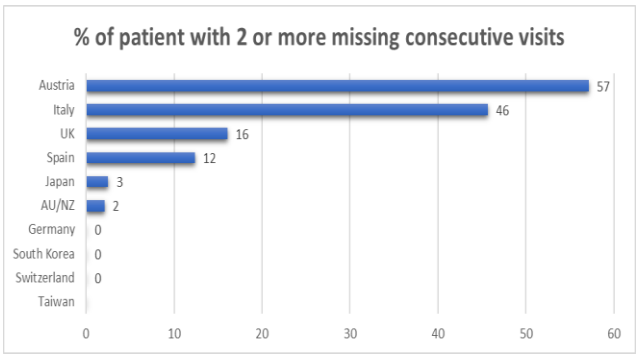
Thank you so much for your dedication and steadfast support in AtTEnd study!
Yours sincerely,
AtTEnd Team

Study Updates – Data Management

In order to be ready for the upcoming data cut-off for the PFS analysis, please make sure that ALL missing data are entered in Clincase. Any delay in data entry puts the upcoming milestones of analysis at risk.

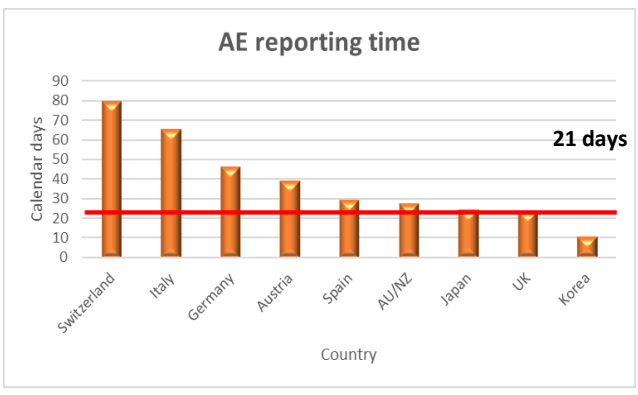
Please notice that the percentage of eCRF missing is very high for some countries.





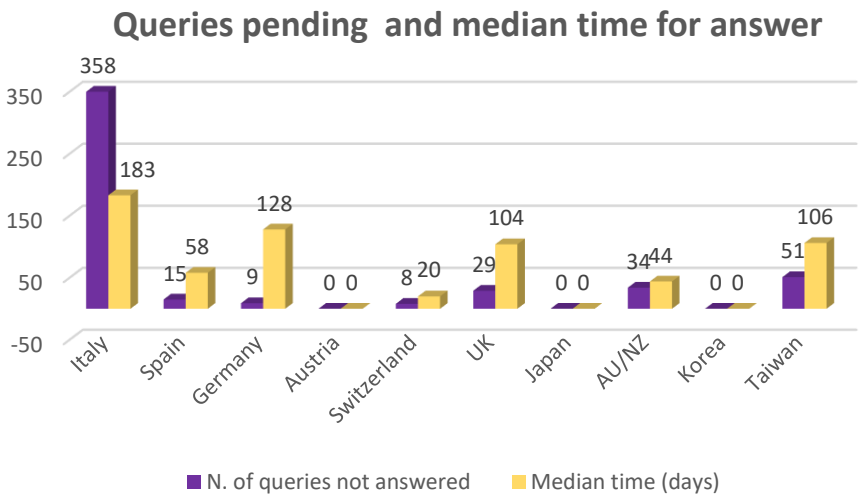
Adverse event

Please note that we considered as acceptable a threshold of 21 calendar days as delay to report the Adverse events into the eCRF. As you can see, some countries had a significant delay in the safety data reporting. At the last IDMC safety meeting the undereporting of adverse events for some sites was considered a critical aspect to be corrected/mitigated as soon as possible. Please check if all the adverse events occured during the study treatment have been already reported in the eCRF.



Pending queries

Please note that 30 calendar days is the acceptable time-window to solve the open-queries. As you can seen, many collaborative groups did not comply with this recommendation: we are kindly inviting you to catch up with the backlog of queries as soon as possible and to keep updated with the new requests.



To improve compliance with the data management activities please:

- **Update the missing pages (you should have received on January 10th the list of missing pages for each patient enrolled at your site)**
- **Answer to the edit checks and manual queries integrated into the EDC system**
- **On January 30th, you will receive the new Data Clarification Forms: please answer these requests in the dedicated paper form and send it back to the Sponsor according to the defined deadline.**

Highlights

The new ICF Addendum (1.0 or 1.1 according to what is approved in your Country) should be submitted to **all** patients, regardless of the status of the patient in the trial. This decision is resulting from a discussion with Roche, considering that immune-mediated events can occur at any time (sometimes early but are frequently delayed).

Until the approval in your country of the ICF Addendum that includes these new risks we kindly ask you to mention the identified new risks, reported in the last DILs to **all** the patients and they should verbally re-consent. The communication of the new risk to the patients should be documented in the patient's medical records.

Frequently asked question

Q: Clinicians had to perform an earlier CT to patient because of a suspicious mass to exclude progression. Would you mind confirming if subsequent scans are calculated from the latest scan date or should continue on the original schedule?

A: We confirm that subsequent CT assessment should always be considered from the latest CT scan date, but please remember to report also this CT scan in the EDC system.