ARIEL Newsletter - February 2024

Bringing you all the news about the ARIEL trial, in one place

The ARIEL study is a randomised phase IV UK trial. We will recruit patients with metastatic colorectal cancer (mCRC) who are Performance Status 0-1 and have a RAS-wt tumour, with the primary tumour having originated in the right colon (caecum, ascending, transverse colon (30% of mCRC)). Of these patients, 30% will have low EREG/AREG biomarker levels and will not be eligible for randomisation.

The study has a two stage recruitment with stage one (registration) allowing assessment of FFPE tissue for EREG/AREG biomarker. Stage two randomises patients who have medium to high EREG/AREG levels to standard of care chemotherapy +/- EGFR Mab (cetuximab or panitumumab).

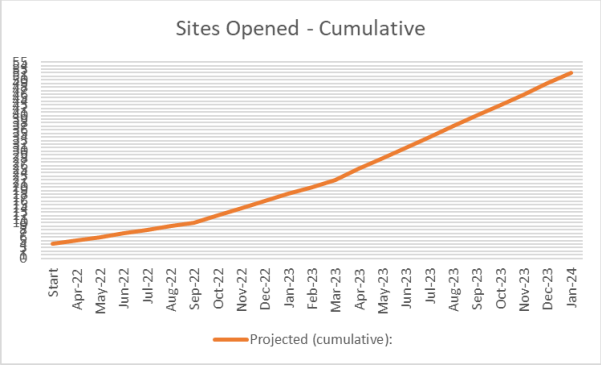
ARIEL Site Update

ARIEL currently has **31 trusts and 37 sites** open to recruitment!

Some of the recently opened sites include:

Southampton, Musgrove park, East Suffolk and North Essex NHS Foundation Trust.

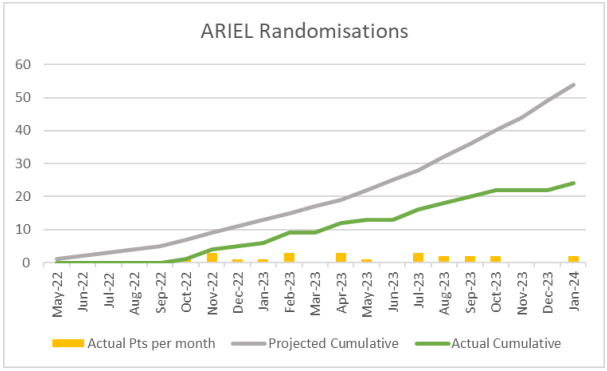
Welcome everyone!

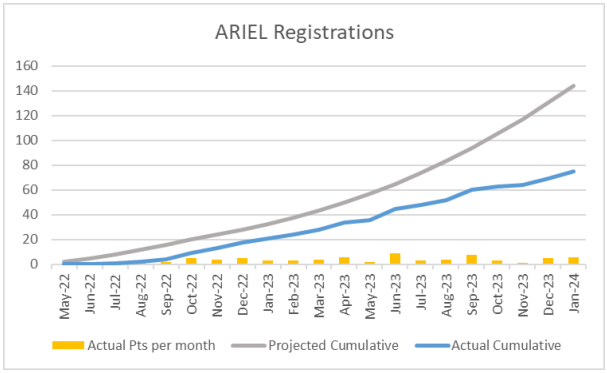


Recruitment

It has been a good few months for ARIEL as we have registered 11 participants! A special thank you also for Musgrove Park Hospital for registering their first patient!

Great job everyone!





The API Scheme

ARIEL is part of the NIHR Associate PI scheme. This is an opportunity for healthcare professionals interested in research to get involved by contributing to study delivery and PI tasks.

APIs are welcome to attend the ARIEL Trial Management Group meetings and engage in trial discussions. The CTRU team are happy to help with any queries about this.

7 Investigators have completed the scheme and 3 are currently registered.

Important Reminders

Pre-rand Treatment Cycle

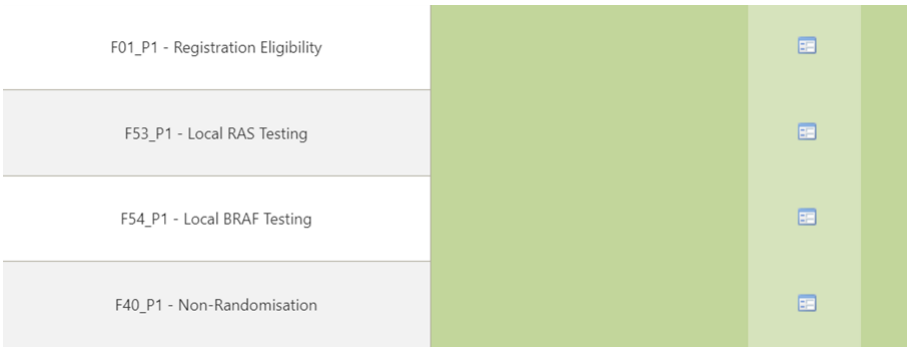
- We would like to remind sites that it is possible for a registered participant to receive a cycle of standard chemotherapy prior to being randomised. This caveat was put in place to aid in recruitment of patients who may otherwise have difficulty with tight turnaround times of lab samples.

Sending Consent Forms

- Registration and randomisation consent forms must be sent to the CTRU in order for us to confirm that consent has been taken as per protocol. If you receive a request from the CTRU, please send us the required consent form via Secure File Transfer as soon as possible.

Completing Baseline Forms

- Following participant registration, the F01 Registration eligibility, F53 Local RAS testing and F54 Local BRAF testing need to be completed as soon as possible. In cases of non-randomisation, the F40 will also need to be completed. Please aim to enter these eCRFs on MACRO as a priority once the data is available to you.



Investigator Sign Off

- Could we please remind sites that confirmation of investigator sign off on the MACRO database is critical for compliance. We understand that in most cases these signatures have already been acquired on paper CRFs, however, unless this is translated onto MACRO we do not know if investigator sign off has occurred. More specifically, this refers to registration eligibility, randomisation eligibility and other forms such as notification of death, withdrawal etc.

Locked out of Macro?

If you're locked out of MACRO and have not received a password reset email, have you tried this?

1. Please close all windows down before trying again.
2. Always use Microsoft Edge to access MACRO.
3. If you do receive a password reset email, always type your password, do not copy & paste it.
4. If this fails, get in touch with us!

Thank you for all your hard work!