31 March 2020

CTA number: 20363/0401/001-0007
EudraCT number: 2010-022209-16
REC reference: 11/LO/0043

Re: ICON8B closure to recruitment May 2020

Dear Colleague,

I am writing to notify you about the forthcoming end of recruitment to the ICON8B and to detail plans to implement this change.

BACKGROUND

ICON8B study opened in June 2015 originally designed with two efficacy comparisons, arm B3 vs B1 and arm B3 vs B2, and powered for both progression-free and overall survival. Following a revision to the study in May 2017, the study then became a two-arm comparison with a reduced sample size of 660.

Current accrual rates to the trial of 6 patients randomised per month on average over the last 12 months have led to a further redesign of the study. This is in part to prevent the longer than expected follow-up of trial participants. The sample size has been adjusted to 590 and the end-point will be progression free survival with overall survival performed only as a secondary outcome if a positive PFS is observed.

For this reason, all randomisations to ICON8B will stop on **Friday 8th May 2020 at 5pm (UK time)**.

Below, you will find a summary of actions resulting from this. Please do not hesitate to contact the ICON8B team with any questions or queries.

INFORMATION

:: The ICON8 Trials programme protocol is being amended to reflect the changes mentioned above and resulting changes to the follow-up schedule for ICON8B. Protocol V8.0 should be used once approved.

:: Follow up is expected to continue according to the protocol schedule. Serious Adverse Reactions and SUSARS will be also collected for these patients indefinitely as per trial protocol.

:: Translational research samples should continue to be collected as per protocol.

POINTS FOR ACTION

1. Please ensure you complete, sign and return the acknowledgement of receipt form (attached in this email) to the ICON8B team as soon as possible. You can either fax it to 0207 670 4818 or email it to mrcctu.icon8and8b@ucl.ac.uk

2. Please file this communication in the relevant section of your site file.
3. Please ensure that adequate preparation takes place when approaching patients in clinic for ICON8B screening and informed consent. It is important that any scans or screening are done before the end of randomisation on 8th May 2020
4. Please ensure the Pharmacy department is appropriately informed about this change

We would like to take this moment to thank each and everyone of you for your continued efforts and contribution to the ICON8B trial.

Best wishes

On behalf of the ICON8B Trial Management Team

This email was circulated to all First Point of Contacts, Research Nurses, Pharmacists and PIs available on our contact database. Omissions are possible although entirely unintentional. Please forward it to anyone in your team who you find appropriate. Thank you for your patience!