ISSUE 11 SEPT 2015

De-ESCALaTE newsletter

Determination of **E**pidermal growth factor receptor-inhibitor (cetuximab) versus **S**tandard **C**hemotherapy (cisplatin) early **A**nd **La**te **T**oxicity **E**vents in **H**uman **P**apilloma**v**irus-positive oropharyngeal squamous cell carcinoma

Total number of randomised patients: *(as of 03 Sep 2015)* **191**

☆

RECORD RECRUITMENT IN AUGUST

August was an amazing month for the De-ESCALaTE trial as we surpassed the monthly target and recruited a record number of patients (seven)! In each of the last two years we have only had two patients recruited in the month of August.

As a friendly reminder, the De-ESCALaTE Trial Team is constantly looking for ways to improve recruitment figures—if your site has any additional tips or would like to share feedback about what works (or what doesn't), the De-ESCALaTE Recruitment Guide, or anything else, please get in contact with the Trial Office.

Thank you to all the team members at our participating sites—both open and in set-up—for your hard work and continued efforts to make this study a success.

The* De-ESCALaTE *Trial Team

STUDY DOCUMENTATION

As many of you know, the last couple of months have seen the issuance of a flurry of new study documentation. Please see the article 'What's New?' on the next page for further details about the new study documentation.

EXTENSION OF PLANNED RECRUITMENT END DATE

The planned recruitment end date has been extended to 28/02/17 or until the target of 304 has been reached, whichever comes first. An email to the Principal Investigator and Main Contact at sites with further details will be sent out imminently.

GOLD & SILVER STAR AWARDS

As the trial soon approaches another major milestone, star recruiters will soon be receiving Gold and Silver Awards. Gold and silver status have been issued to the top eight recruiting sites as determined by the number of patients recruited over the number of full months the site has been open to recruitment.

To find out who were the recipients of the Gold and Silver Awards, tune in to the next Study Update!

RECRUITING SITES

SITE RECRUITMENT TRACKER

(Recruitment figures as of 03 Sep 2015)

Aberdeen	3
Bradford	12
Bristol	17
Castle Hill	12
Cheltenham	8
Clatterbridge	2
Glan Clwyd	0
James Cook Uni	6
Leicester Royal Infirmary	4
Nottingham	4
QE Birmingham	28
Royal Devon & Exeter	2
Royal Marsden	6
Royal Surrey	9
Royal United, Bath	8
Singleton	4
St James' Institute, Leeds	17
St. Luke's (Ireland)	2
UCL	0
UHCW	8
Velindre	6
VUMC (Amsterdam)	3
Western General	2
Weston Park	26

What's New?

The changes from Protocol V4.1 to V4.2 were very minor and did not require review by the Research Ethics Committee (Non-Substantial Amendment 19). For a full list of what's new, please see below—

New (current) Study Documents:

- Protocol V4.2 (emailed on 13/08/15)
- PIS V5.0 (emailed on 21/05/15)
- GP Letter V3.0 (emailed on 21/05/15)
- Consent Withdrawal Form V2.0 (emailed on 13/08/15)

New CRFs:

Please refer to the email sent on 14/07/15
Please NOTE that we are now collecting actual dose given in two units: milligram (mg) AND milligram per square meter (mg/m^2) at the request of the TMG and IDSMC.

New Documents for Investigator Site File (all emailed to sites on 13/08/15):

- Ethics Amendment Log V12.1
- Version Control Checklist V14.0
- Trial Reference & Coordination Details V4.0
- Skin Rash Management SOP V2.0

As always, if you need anything from the Trial Office or a copy of any of the above documents, please don't hesitate to get in touch.

CRFs

We've noticed a couple of errors on some of the newly distributed CRFs. Apologies for this. As a result, please note new versions of the following CRFs:
> DE11 Late FU 4-6 V4.1
> DE12 Late FU 7-9 V3.1
> DE13 Late FU 10-12 V4.1
The changes are minor and relate to the placement of toxicities within the wrong CTCAE category. These CRFs will be issued to sites shortly.

As a friendly reminder, please remember to initial and date every change! If you have any questions about how to complete the CRFs, please contact the Data Entry Clerk, Eva Kritzer at E.Kritzer@warwick.ac.uk

SITES IN SET-UP

If you have any queries or need any further documentation, please don't hesitate to email Tessa at ***m.t.fulton-lieuw@warwick.ac.uk****.*

SITE SET-UP TRACKER:

Beaumont (Ireland).....	IN SET-UP
Christie	IN SET-UP
Essex.....	IN SET-UP
Hereford County	IN SET-UP
Musgrove Park.....	IN SET-UP
New Cross.....	IN SET-UP
Norfolk & Norwich.....	*INTERESTED*
Northampton.....	IN SET-UP
Raigmore Hospital	IN SET-UP
Royal Derby	IN SET-UP
Royal Preston.....	IN SET-UP
Royal Shrewsbury.....	IN SET-UP
Southend.....	IN SET-UP

Warwick Medical School
CLINICAL TRIALS UNIT

INHANSE
Institute of Head and Neck Studies and Education

CANCER RESEARCH UK

Check out the De-ESCALaTE website at www.warwick.ac.uk/go/deescalate

Want to feature in our next newsletter? Just let us know!

For general enquiries please contact the Team at: deescalate@warwick.ac.uk

Site Initiation

One of the pre-requisites to opening the study at your site is to undergo a training session (perhaps misnamed as the Site Initiation as this can actually take place before all the necessary documentation are in place). The study requires that the local Principal Investigator, Main Contact/s, Research Nurse/s, and Lead Pharmacist "attend" the teleconference. Co-Investigator's and other site staff are also encouraged to attend. It lasts approximately one hour. A tailored Initiation specifically for Pharmacy staff is also available if requested.

Book your Site Initiation today!

OTHER NEWS

Written by Catharine West

RAPPER (Radiogenomics: Assessment of Polymorphisms for Predicting the Effects of Radiotherapy) is a blood sample collection study funded by CR-UK. It is NCRN badged and open at 65 sites in the UK. The study collects blood samples from patients undergoing/who underwent potentially curative radiotherapy and toxicity is/was assessed prospectively to a minimum of two years. RAPPER was set up to find the common genetic variants (SNPs) associated with risk of late radiotherapy toxicity. Late toxicity is dose-limiting and impairs quality-of-life in long-term survivors. The long term goal is to identify enough SNPs to develop a clinical test. Cancer pre-disposition studies showed the approach works but also the need for large patient numbers (>50,000). An international Radiogenomics Consortium (RGC) was established to facilitate the collaboration required. Other RGC groups are already collecting head and neck cohorts, and from work undertaken in prostate cancer we know we can pool multiple cohorts to identify SNPs. The RAPPER study is very much looking forward to recruiting De-ESCALaTE patients. For more information on RAPPER contact Joely Irlam at joely.irlam@ics.manchester.ac.uk or via phone at 0161 446 3282.