



Diamonds Site Randomisation Guideline

1. WHO?

Site staff delegated '5- Recruitment/Registration/Randomisation of Patients' on the delegation log and who have been trained on this guideline may randomise patients using the Sealed Envelope randomisation system either online or by telephone.

2. How?

NICTU will provide appropriately trained and delegated staff with a username and password for online login. Additionally, an investigator number will be provided to staff to enable telephone randomisation.

New Staff: To request a new user login, an email detailing site name, full name, type of account (notification only or investigator account) and email address of all new members of staff, should be sent to DIAMONDS@nictu.hscni.net when new site staff have completed appropriate training. Those with investigator accounts must be delegated '5- Recruitment/registration of Patients' on the delegation log. Please remember to forward a copy of any updated training and delegation logs to the NICTU. Please note that access will only be provided to users with an NHS email account unless otherwise agreed with the trial team.

3. ONLINE LOGIN AND RANDOMISATION

- Delegated site staff will be provided with individual login details. It is important to keep your username and password confidential at all times
- Please ensure your internet browser is enabled for Internet Explorer v8 or above
- Enter the Sealed Envelope website using the URL:
<https://www.sealedenvelope.com/redpill/diamonds>
- Users are required to login with their given username and password
- If you forget your password please email DIAMONDS@nictu.hscni.net or telephone **028 9063 5794** and a member of the DIAMONDS Team will re-issue a new password

3.1 Online Randomisation

(a) To Randomise a Patient

- Select 'Randomise'
- Complete the randomisation page with the following information:
 - Patient's initials (N.B. Two initials only)
 - Date of birth
 - Screening number (SXXXXXX)
 - BCdVA in the study eye at presentation
 - Previous use of anti-VEGF therapies in the study eye
 - Previous laser therapy to the macula in the study eye
 - Has the eligibility checklist been completed and the patient been confirmed as eligible for recruitment?
 - Please confirm that eligibility assessments have been recorded?
 - Has written informed consent been obtained?

- Please give date written informed consent was obtained
- Site
- Select randomise
- To generate a randomised allocation, you must enter your password again and click on the 'confirm' button

(b) Confirmation/Notification Email

You and any members of staff with a notification account will receive an email confirming:

Site: _____ (Site #), _____ (Site Name), United Kingdom
 Screening number: SXXXXXX
 Date of randomisation: Date & Time
 Patient ID: RXXXXXX
 Treatment group: Standard Laser/DSM Laser

The randomisation was performed by Name (ID XXXX).

****Ensure you print this email and file with the DIAMONDS trial documentation at site****

(c) Randomised in Error

A randomisation error may occur through duplication or input of incorrect data. If an error becomes apparent please do the following:

- Select 'Randomisations'
- Select the relevant Patient ID
- Select 'Create a new query'
- If the query is related to details entered on the randomisation form, select 'Study entry-Randomisation' from the drop down
- Choose the related question from the drop down as shown below
 In the 'title' field, provide a short description of the query

Query

Related form

Study entry - Randomisation ▾

Related question

Choose ...

Patient's initials
 Date of birth
 Screening number
 BCdVA in the study eye at presentation?
 Previous use of anti-VEGF therapies in the study eye?
 Previous laser therapy to the macula in the study eye?
 Patient ID
 Has the eligibility checklist been completed and the patient been confirmed as eligible for recruitment?
 Please confirm that eligibility assessments have been recorded?
 Has written informed consent been obtained?
 Please give date written informed consent was obtained
 Site
 Notes

- Enter any additional text into the message box
- Click 'create query'
- An administrator at NICTU will action the query and flag the error, see example below :

Subject ID	Site	Randomisation group	Date randomised	Status
001	Belfast	Intervention	4 Mar 2016 14:51	?
002	Belfast	Standard Care	7 Mar 2016 12:13	? 
003	Belfast	Standard Care	7 Mar 2016 12:19	

Randomisation was marked as randomised in error

- If your query is urgent please email DIAMONDS@nictu.hscni.net or phone **028 9063 5794** and request assistance.

(iv) General Query

- Select 'Randomisations'
- Select the relevant subject ID
- Create a new Query - If the query is not related to the randomisation form, select general query.
- Enter Text in message box
- Click 'create query'
- Please notify the DIAMONDS team by email DIAMONDS@nictu.hscni.net and an administrator at the NICTU will aim to action the query within two working days.

3.2 To View the Randomisation List

- Click 'Randomisations' to review the list of patients randomised at site.

3.3 To Create a Query or add information

- Any additional information, queries or notice of error can be entered in the notes section.

4. TELEPHONE RANDOMISATION

- Delegated site staff will be provided with an investigator number to access telephone randomisation. It is important to keep your investigator number confidential at all times.
- Log in details can be entered using a touchtone telephone.
- Call the DIAMONDS Sealed Envelope telephone line on: 020 3384 6368
- Enter study number _____
- Enter investigator number (3 digits)
- Enter patient DOB day (2-digits)
- Enter patient DOB month (2-digits)
- Enter patient DOB year (4-digits)
- Press 1 to continue or 2 to change your response
- Enter patient screening number (**NB. Only enter numerical digits**)
- Press 1 to continue or 2 to change your response
- BCdVA in the study eye at presentation
- Press 1 for ≥ 69 ETDRS letters, press 2 for 24-68 ETDRS letters
- Press 1 to continue or 2 to change your response
- Previous use of anti-VEGF therapies in the study eye

- Press 1 for yes or 2 for no
- Previous laser therapy to the macula in the study eye
- Press 1 for yes or 2 for no
- Has the eligibility checklist been completed, and the patient been confirmed as eligible for recruitment?
- Press 1 for yes or 2 for no
- Please confirm that eligibility assessments have been recorded?
- Press 1 for yes or 2 for no
- Has written informed consent been obtained?
- Press 1 for yes or 2 for no
- Enter Date of Consent day (2-digits)
- Enter Date of Consent month (2-digits)
- Enter Date of Consent year (4-digits)
- Press 1 to continue or press 2 to change your response
- The subject was randomised to <treatment group> and randomised on <date> and is patient ID <RXXXXXX>
- Press 1 to confirm you have recorded these details or press 2 to hear them again
- Hang-up
- You will receive an email confirming:

Site: _____ (Site #), Site Name, United Kingdom

Screening number: SXXXXXX

Date of randomisation: Date & Time

Patient ID: RXXXXXX

Treatment group: Standard Laser/DSM Laser

The randomisation was performed by Name (ID XXXX) via telephone.

5. ADDITIONAL INFORMATION

If for any reason you are unable to access Sealed Envelope please notify the DIAMONDS Team at NICTU. Email: DIAMONDS@nictu.hscni.net or telephone **028 9063 5794**.

In the event of a known system outage, the NICTU will inform all sites of the outage. If both the online and telephone Sealed Envelope randomisation system is unavailable, the NICTU will request that no further randomisations are attempted at site until a further communication is sent. When the system is restored, NICTU will notify sites when randomisations can be performed.

6. USEFUL PHONE NUMBERS

Phone number	Purpose
028 9063 5794	Password reset, urgent queries
020 3384 6368	Sealed Envelope randomisation phone number