RANDOMISATION PROCESS FOR RETROSPECTIVE READING STUDY
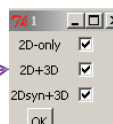
The cases from the TOMMY trial will be randomised using a programme called R.

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Click on the main icon ( ) to start the tool.

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Select which types of image(s) you wish to allocate to the available readers by unticking the boxes.

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Choose the input file. This is a spreadsheet with 3 columns, R2NUM, R2ID, Site Name. This details the patients whose images are to be allocated to a reader.
Next choose the readers file. This is a spreadsheet with 4 columns: SiteName, SiteCode, Reader, Capacity. The capacity is the number of images each reader can read per week.
(You will have the opportunity later to say how many weeks this allocation is to be read over.)
The format of these files must be strictly adhered to.

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Now select how many weeks this allocation will be read over. The total number of images that can be read in theory is the capacity times the number of weeks, added up over all the sites and all the readers.

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Choose the subdirectory folder called "Log" that contains all the output files that were previously generated.

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The tool will create an output text file that gives the allocations. If this file is used, then a copy needs to be stored in the subdirectory of this folder called "Log". The tool will use any files in this directory to check if the images for each case have previously been read and apply the randomisation rules as appropriate. No other files may be stored in this log.
A copy of this output file should then be emailed to Richard Black for the distribution of the correct images to the correct site. The data managers at each site will then allocate these cases to the specified reader.

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Copies of the input/output files created by the tool will be stored inside Z:\Cambridge Clinical Trials Unit\11. STUDY MANAGEMENT FILES\CCTU0091 - TOMMY\Randomisation and are archived in the relevant folders each time a new one is used. Such copies should be named and version controlled in the correct manner to enable the creation of an audit trail. The reader.csv file is expected to change less often than the Batch.csv file, which will update on a weekly basis/each time a new randomisation is required.

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Details of the allocation of each image will be captured in MACRO for each subject and an excel sheet completed to log how many cases have been randomised.