# Putting the R into Randomisation

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When introducing a new dynamic adaptive randomisation method to the clinical trials field the functionality and flexibility of *R* allowed the programming of the algorithm without any restrictions. Whilst using *R* for implementing randomisation procedures is not a new idea, expanding its use to include a modelling stage for optimisation of individual trials was a particularly useful addition.

The setting up of the novel randomisation procedure in *R*, linking it to Excel using RExcel for simulation purposes, validation of the processes and the possibilities for linking to the web for web based centralized randomisation processes will all be addressed.

The randomisation algorithm used is fully tuneable by setting model parameters, reproducing anything between deterministic allocation (minimisation) and simple randomisation. Simulation with *R* allowed investigation the robustness of the algorithm, the statistical properties of bias and loss in terms of a clinical trial and the plausible outcomes of a wide variety of possible situations that may arise. The algorithm can now be tuned before the trial starts to give confidence intervals around the split of the final allocation.

Inputs to the simulations allow trials to be customised for differing number of participants, number of treatment groups, ratios of allocation to treatment groups, number of stratification variables and their defined levels and sets of parameters to be tested. The algorithm is currently used in two ways: for sequential and for complete list randomisation. While the base code is the same the wrapper for the implementation varies slightly.

The use of *R* in clinical trials is slowly becoming more accepted and has certainly been discussed at length on the *R* help mailing lists. Validation of any system is integral to ensuring the system is functioning correctly. There have been instances where systems that have not been properly validated have resulted in significant costs within the clinical trial world. However, mistakes like this are not a reason to avoid using more complex methods altogether. All the code written within *R* was easily tested and validated within an expected operating range ensuring that the system is doing exactly what is expected.

Future work entails linking into web based system, developing reporting functionality of the simulation tool and improve the robustness of the tool for multiple users.

## References

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