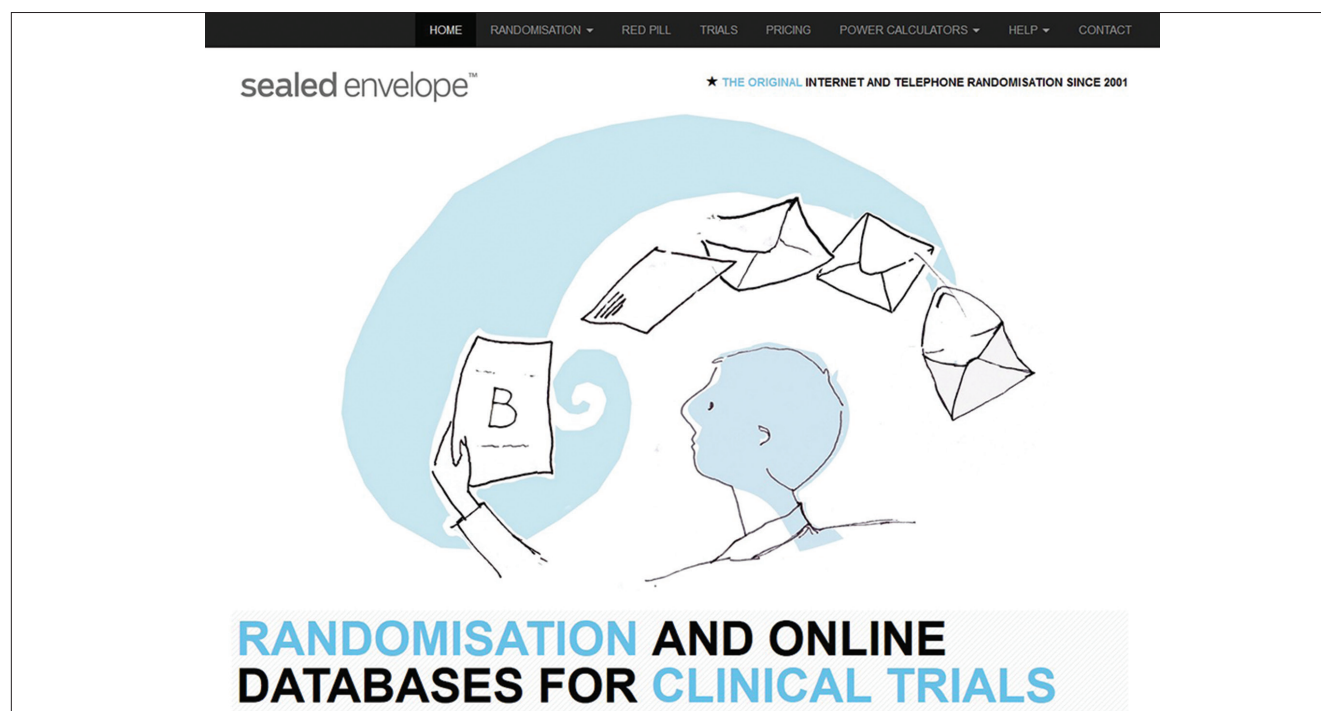


Randomization and online databases for clinical trials

Jatinder Singh

Section Editor, JPP



<http://www.sealedenvelope.com>

An essential part of any clinical trial design consists of random assignment of subjects to different treatment groups. This facilitates comparison of these groups and justifies the use of appropriate statistical methods for the analysis of results. The

use of probability to achieve the objective of randomization is available in the form of various techniques, each with divergent qualities in terms of achieving the required randomness and balance. Computers with appropriate software are commonly used to perform randomization.

Access this article online	
Quick Response Code:	Website: www.jpharmacol.com
	DOI: 10.4103/0976-500X.130155

Proper maintenance of records and their retrieval is an integral part of clinical trials. These records are used from time to time for generating reports or for the purpose of audit. Most records of the clinical trial process have been traditionally paper based which are not only unmanageable because of their bulk but also not easy for retrieval and analysis. The shift to the electronic format has been slow, but with increasing

Address for correspondence:

Jatinder Singh, Department of Pharmacology, Government Medical College, Amritsar - 143001, Punjab, India. E-mail: singh.jatinder@gmail.com

Singh: Randomization

adaptation of digital record keeping in hospitals, clinical trials are increasingly being linked to them. Such a system helps in identifying potential trial participants more quickly and with better precision, ensures better collaboration among different investigators and cuts down research costs tremendously.

Sealedenvelope.com is a British collaboration between some academic institutes and the National Health Services (NHS) and provides support services for clinical trials. They provide solution for processes like randomization, case report management and some essential calculations through a web-based design based on simple inputs and a transparent well-referenced methodology.

Randomization is accomplished by the use of a web browser and is available for all co-investigators connected by the internet. Each set up is customized for the clinical protocol being followed. The on-screen web based form is simple and based on the commonly used method of using random permuted blocks with stratification to achieve a balance in the numbers allocated to each treatment. The simulations generate a stratified randomization list by inputting treatment groups, block sizes, number of strata and specified sample size. An alternate method offered to randomize patients is by using telephone keypads, which is a more cumbersome and restricted process as compared to the web based one. A simple randomization service is available free for single-blind trials with two treatment groups. The results of randomization are sent either by an email or by a text message. The security and integrity of the codes follows the Food and Drug Administration (FDA) standards for electronic records and follows the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines. In case of the safety of the patient undergoing the trial being compromised, an emergency code breaking facility is available to the coordinators authorized to use the facility.

The best method of exploring the services is by running actual examples of simulations available under the randomization link. The results are expressed as a table as well as graphically in terms of the imbalance between groups at the end of the

trial with the assumption that each stratum receives the same number of randomizations.

The other service available from the site is Red Pill - An electronic data capture and management system for managing Case Report Forms (CRF) in clinical studies. This service is flexible and allows the investigator to generate custom-made forms and store them for easy retrieval. The CRF builder allows for entry of simple demographic data of the patient at the beginning of the trial and then builds queries for various sub-tasks including eligibility criteria. Standard reports can be generated from the CRF and a record of audits and revisions is stored in the form thus obviating the need for extensive paperwork.

A trials page lists all the published as well as unpublished trials that are using the Red Pill or the randomization services. This list of over a hundred different studies allows the investigator to log in and manage background data from this page.

The section on power calculators consists of calculators for power (sample size) and list trials with both binary and continuous outcomes, which include superiority trial, equivalence trial and non-inferiority trial. These calculators are powerful, list the formulae being applied and provide a reference for the methodology being used.

Comprehensive help is available at all times for setting up the system from scratch to advanced explanation of the organization of various components and their management. The simple two-color theme along with easy navigation makes the website uncluttered and user friendly.

The website with its convenient web-based interface based on open-source software is a useful tool for investigators and ancillary staff conducting medium to large-scale clinical trials, especially in an academic setting.

How to cite this article: Singh J. Randomization and online databases for clinical trials. *J Pharmacol Pharmacother* 2014;5:173-4.

Source of Support: Nil, **Conflict of Interest:** None declared.