

Test Smarter.

## Statement of Randomness

DrugPak Web can perform computer-generated random selections upon a pool of participants. The random selection algorithm, and the RandSel Tracking<sup>SM</sup> system work together to ensure that these selections are free from user bias.

The DrugPak Web random selection routine is written in C# .NET. We use the native .NET RNGCryptoServiceProvider class to generate scientifically valid “pseudo-random” numbers. Internally, RNGCryptoServiceProvider uses The CryptGenRandom functions provided by the Win32 API. While the exact implementation of this algorithm has not been published Microsoft has obtained validation from NIST (Certificate 1110i ). Additional testing has been done with the NIST Statistical Test Suite for randomness, (Publication 800-22rev1aii).

At the beginning of every Random Selection, the random selection algorithm builds a list of all eligible participants. Eligibility and selection rates are determined by user-specified parameters. The algorithm uses the RNGCryptoServiceProvider class to assign each eligible participant a randomly generated number ("Selection ID") in the range [0..2147483646]. Every Selection ID is confirmed to be unique before assignment. After every participant has been given a Selection ID, the list of eligible participants is sorted in Selection ID order. The specified number of participants is then selected. Participants with lower [random] Selection IDs are selected first. An individual participant's selection and testing history have no effect upon his/her likelihood of selection. These selections cannot be influenced by the user in any way other than by controlling pool membership and selection rate. Every eligible participant has the same probability of being selected.

DrugPak's RandSel Tracking system is a general term used to describe the safeguards which prevent tampering with or falsifying a Random Selection. For example, every eligible pool is stored in its entirety, and the audit trails for each random selection can be reprinted. The system also tracks changes to participant records, such as changes to personal identifiers, additions, and deletions. Furthermore, it is impossible for the user to "forge" a computer-generated Random Selection result record using our software interface. RandSel Tracking audit information is not readily available to end-users, and as such is not able to be modified or falsified by end users.

## Test Smarter.

If you have specific questions about the random selection process or RandSel Tracking system, please submit your inquiry through our technical support portal, <https://support.screenhubb.com>.

i <http://csrc.nist.gov/groups/STM/cavp/documents/rng/rngval.html>

ii [http://csrc.nist.gov/groups/ST/toolkit/rng/documentation\\_software.html](http://csrc.nist.gov/groups/ST/toolkit/rng/documentation_software.html)