Bracket's Guidelines on Block Pattern Distribution

The statistics group at Bracket is committed to generating the highest quality randomization lists. In each of our lists we check for the presence of selection bias. Selection bias was originally discussed at a fairly technical level by Blackwell and Hodges in 1957. Here, we'll motivate heuristically why we desire to minimize selection bias. The ability to guess the next treatment group to be assigned is termed selection bias. Imagine a study with 2 treatment groups {A, B} where the patients are randomly assigned to treatment using a permuted blocked list stratified by enrolling center with a blocksize of 2. There would be 2 permutations within this list [A, B] and [B, A]. Suppose by chance a stratum was allocated all of one permutation so that the list for that center looked like this: [A, B, A, B, A, B, A, B, …]. Because of the perfectly alternating pattern of treatment allocation there would be a high probability of guessing the next treatment, thus, a high selection bias. One way to reduce the selection bias would be to increase the blocksize to four. However, in many studies maintaining a high level of treatment group balance requires a blocksize of 2. The other method to reduce selection bias is to ensure all the permutations are represented in a relatively uniform distribution within each stratum. The statistics group at Bracket checks every randomization list for uniformity of permutation distribution within the strata. When our criterion is not met, we re-generate the list. When we receive a list generated by a sponsor we apply our criterion, and if it is not met we advise the sponsor so they can decide whether to generate a new list.

A direct approach to the problem of selection bias is Bracket's novel method called Precision Block Design[TM], which guarantees uniform block patterns within strata. To illustrate using a block size of 4, we would sample from the 6 possible block permutations without replacement until no more are available, then sample 6 more, and repeat until we have reached the desired number of blocks within each stratum. This method produces a uniform distribution of block patterns within each stratum. Therefore, an acceptance test is not required. There are certain randomization designs that lend themselves to the use of Precision Block Design[TM]:

1. A high number of strata
2. A low number of slots

In these cases, we advise the sponsor to utilize Precision Block Design[TM]. The use of Precision Block Design[TM] does not add additional time nor cost to the creation of the randomization list. For more information about selection bias and/or Precision Block Design[TM], please contact Bracket's statistics department.