questions on demographics (49). The user listens to pre-recorded prompts that list the various options available or that request responses to particular questions (50). If the IVR system finds the subject is eligible then it records subject details and stores the information into a database, while those failing may be given information about how to seek further advice for their condition. Then the IVR system generates an automatic alert to inform the study site or trained telephone caller to contact the subject. To reiterate, IVR systems enable the screening of subjects according to a list of inclusion/exclusion criteria, stratification and randomization of treatment assignments, and the collection of patient reported outcomes (51). IVR systems can be used for obtaining informed consent, registering subjects, randomizing study subjects, managing patient diaries, and keeping track of the number of enrolled subjects (52).

A vivid and instructive account of how an IVRS can be used is found in the following report of a clinical trial in oncology. Thus, "[s]imple stratified randomization with permuted blocks of size 4 was used by the sponsor to create a prospective randomization schedule that was provided to the vendor for the telephone-based interactive voice recognition system (IVRS). Random assignment of eligible patients was performed by designated personnel at each participating site using the IVRS in a double-blind fashion such that the investigator, sponsor, and patient did not know the treatment assignment" (53).

In addition to use for screening study subjects, enrollment, and randomization, IVRS are used to provide up-to-the-minute information on the number of subjects randomized, picking up medication, withdrawing from the study, completing the study (54), monitoring adverse events, medication compliance, emergency code breaking, and managing the study medication supply chain (55).

The following concerns interactions between the IVRS and study subjects. IVRS accommodate both incoming and outgoing calls (56,57). This concerns outgoing calls initiated by study subjects. Participants call a telephone number that directs them to a

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