study site and the subject. The instructions in the Protocol read (16):

> **Patient numbering and screening.** Patients ... will be asked to sign a study informed consent before a patient number will be assigned and before any study specific testing is performed for the purpose of determining a patient's eligibility for this study. Each patient in the study is uniquely identified by a **9-digit patient number** which is a combination of his/her **4-digit center number** and **5-digit subject number** ... [t]he procedures for subject numbering and cohort coordination between the sites involved will be provided in a separate document before study start. Upon signing the informed consent form, the patient is assigned a subject number by the investigator or his/her designee. Once assigned to a patient, a patient number will not be reused.

a. Allocation and Allocation Concealment

Allocation refers to the act, decision-making process, or automated process, of assigning each subject to one of the study arms. In short, allocation means the act of connecting a given subject to a given treatment. Allocation is not the same thing as randomization. Allocation can either be random or nonrandom. According to Schulz (17), "[t]o ensure unpredictability of that allocation sequence, investigators should generate it by a random process (e.g., computer generated numbers, random number tables, or coin flipping)."

Allocation concealment seeks to prevent selection bias, and protects the allocation sequence before and until assignment to one of the study arms. Without the protection provided by allocation concealment, investigators have been known to change who gets assigned to a particular treatment, for example, who gets assigned to the study drug arm or placebo arm (18). To provide a hypothetic example, where there is no allocation concealment, the clerk who admits participants could ascertain the upcoming treatment allocations and then route participants with better prognoses to the experimental group and those with poorer prognoses to the control group, where the clerk's goal is to make the study drug appear to have greater efficacy. Allocation concealment is not the same thing as blinding. In contrast to allocation concealment, blinding seeks to prevent the introduction of bias after allocation.

As explained by Poolman et al. (19), "[a]llocation in a trial is concealed when investigators cannot beforehand determine the allocated treatment of the next patient enrolled into their study. Allocation concealment is necessary to prevent selection bias, whereas blinding is important to prevent detection bias, i.e., a biased assessment of outcome."

Schulz et al. (20) distinguish between allocation concealment and blinding by way of an example. This example is a clinical study that involves surgery. In a hypothetical clinical

[16]Oncology Clinical Trial Protocol CLDK378X2101. A phase I, multicenter, open-label dose escalation study of LDK378, administered orally in adult patients with tumors characterized by genetic abnormalities in anaplastic lymphoma kinase (ALK); August 19, 2010.

[17]Schulz KF. Assessing allocation concealment and blinding in randomised controlled trials: why bother? Evid. Based Nurs. 2001;4:4–6.

[18]Schulz KF. Assessing allocation concealment and blinding in randomised controlled trials: why bother? Evid. Based Nurs. 2001;4:4–6.

[19]Poolman RW, Struijs PA, Krips R, et al. Reporting of outcomes in orthopaedic randomized trials: does blinding of outcome assessors matter? J. Bone Joint Surg. Am. 2007;89:550–558.

[20]Schulz KF, Chalmers I, Altman DG. The landscape and lexicon of blinding in randomized trials. Ann. Intern. Med. 2002;136:254–9.