



We are all familiar with these steps in the recruitment process, referred to as a funnel because at each point subjects or potential subjects are lost. Each step in the funnel should be analyzed and compared by site or recruitment channel or by subgroup (e.g. minority) and tied to timeline and cost data. Where a study loses most subjects should be the focus of attention.

Lasagna's Law

The incidence of patient availability sharply decreases when a clinical trial begins and returns to its original level as soon as the trial is completed. Hence over estimating potential accrual. The "law" is a common experience because investigators rely more on their impression rather than actual or experience to determine their likelihood of success in recruitment.

The major reason for the overly optimistic projection of available patient numbers relates to narrow in- and exclusion criteria which prevent many patients from enrolling that the investigator initially considered as viable subjects for the trial. It has more than a grain of truth that "the best time to plan a controlled trial is after the trial has finished", as all the questions you need to ask before starting have been already answered.

According to ICH E6 Guideline on Good Clinical Practice the investigator should be able to demonstrate a potential for recruiting the required number of suitable patients within the agreed recruitment period (chapter 4.2.1). Therefore it is not sufficient to

just make a guess but the investigator has to make an informed projection, i.e. based on concrete feasibility data. Recruitment data should allow you to assess the number of subjects or potential subjects at each step.