If the data, however, exceed the specification it may be necessary to replace the samples in the clinic by new ones. Therefore corresponding batches have to be kept in stock.

This is not easy to accomplish.

Therefore procedure 1 is preferred and consequently described in detail.

Stability information for clinical samples plays a very important role in the general assessment of the quality and safety of a medicinal product.

Continuous stability is assured for the transition from phase I to III, including pivotal and equivalence batches, to the finished drug product in the commercial form.

Stability programs for clinical samples now are based on the ICH Tripartite Guideline for Stability Testing of Drug Substances and Drug Products, although the guideline itself, as already mentioned, does not apply to clinical samples.

The basic principles of the ICH Tripartite Guideline correspond to the aforementioned eleven principles and now have to be adapted to deal with the specific problems encountered with clinical samples.

2. BASIC PRINCIPLES OF STABILITY TESTING APPLIED TO CLINICAL SAMPLES

2.1. Selection of Batches and Samples

The drug product is in the process of development. Several strengths are tested in clinical phase I and the formulation and dosage form are modified in the transition to II and III.

This developmental process has to be taken into account when selecting the batches. Especially in the initial phase of development, no representative batches are available. The following batches are put into storage with the aim of establishing the minimum shelf life for phases I to III:

Clinical phase I:	experimental batches
Clinical phase II:	clinical experimental batches
Clinical phase III:	clinical or pilot plant batches

2.2. Test Criteria

The criteria of the product are investigated

That are potentially subject to change during the course of storage

That have a particular bearing on the quality, safety, or acceptance of the product.

The relevant test criteria will become apparent during the course of development from phase I to phase III.

2.3. Analytical Procedures

The analytical procedures themselves undergo a process of development from phase I to phase III. The same applies for the validation.