The stability results obtained with clinical samples are a major factor for achieving a comprehensive assessment of the quality of a finished medicinal product. In this way it is possible to establish a link between the quality of clinical batches for phases I, II, and III and the quality of the finished drug product. If development is fully covered by stability data, then the quality, efficacy, and safety of the clinical batches will correspond to those of the finished medicinal product. Stability information gained by this broad-based approach thereby acquires a completely new dimension.

Pivotal and bioequivalence batches are also required for this comprehensive general strategy unless they are covered by batches from clinical phase III.

If this is not the case, pivotal and bioequivalence batches are included in the stability program.

Since the results are combined to produce a general statement, emphasis is placed not on the stress test but on the long-term test.

The stability program combines acceleration tests with long-term tests in accordance with the ICH Guideline. The storage period, however, is limited to 18 months (Table 23).

Table 23 Storage Conditions for Pivotal Batches

Storage conditions (°C)	Storage period and testing frequency (% rel. hum.) (months)						
25	60	0	3	6	9	12	18
30[a]	70[a]		3	6			
40	(75)		3	6			

[a] These conditions are only used if significant change occurs after storage at 40°C(/75%).

The test criteria, specifications, and analytical procedures are the same as those used for batches of clinical phase III and the marketing authorization batches.

6. TIME TO AVAILABILITY OF STABILITY INFORMATION

The stability program for clinical samples is designed to produce stability information as rapidly as possible. The time required until minimum shelf lives and stability information are available is an important factor for planning clinical trials and establishing the data of manufacture.

In phases II and III it we can differentiate between preliminary and final prediction. The preliminary is based only on the data of the stress investigation, whereas the final includes also the data of the samples stored at accelerated condition.

Table 24 gives an overview.

7. REQUIRED CAPACITY

In the course of the strategic planning it is important to estimate the required capacity for the different stress investigations. Since each development is different it will always be a range.