



R&D Briefing

Keys to Competition (2)

Benefits from benchmarking drug development

Analysis of micro and macro clinical cycle times

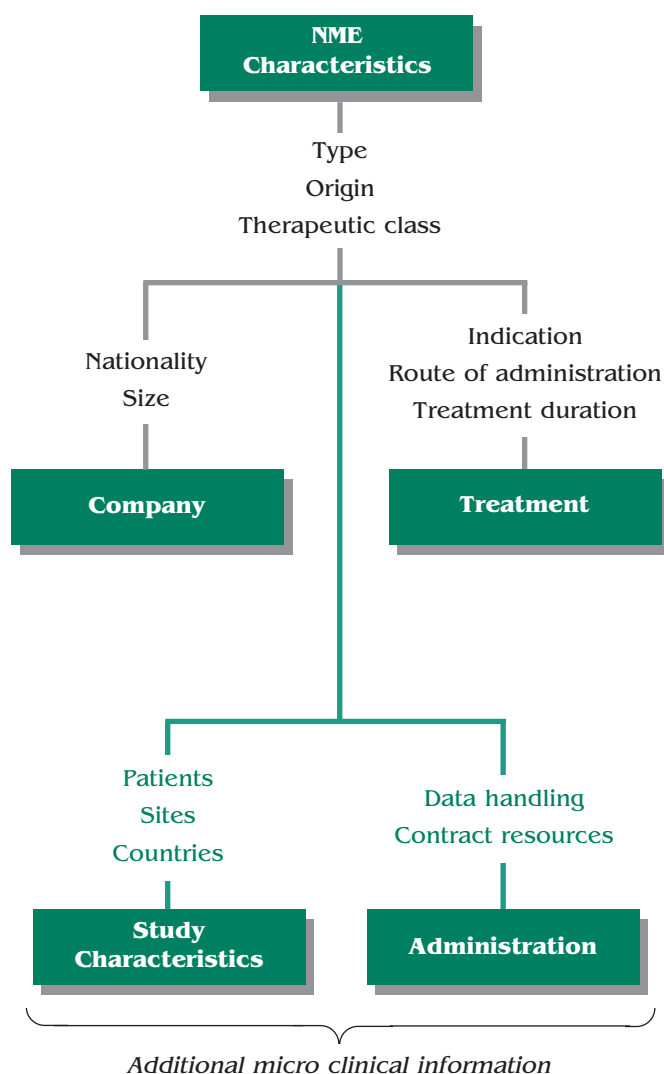


Figure 1 Characteristics of the new molecular entity (NME), development programme and company can be used to analyse the macro and micro clinical cycle times. In addition, more detailed analysis of the micro clinical cycle times is possible using information on the study design and the type of resources used.

- Identifying ways to expedite drug development has been a key challenge to the pharmaceutical industry throughout the 1990s, initially hampered by a paucity of reliable, up-to-date information on performance. This situation is changing as the potential benefits of the CMR International Benchmarking Programme, established in 1995, become increasingly apparent.
- What are realistic targets in the context of best industry performance? How does individual performance compare with that of competitors? What influences this performance? Where do the problems lie?
- Data generated by the Benchmarking Programme are now helping participating companies to answer some of these questions. The macro study's dataset on over 600 new molecular entities provides cycle times for the complete development process, whilst the micro study of clinical development currently embraces almost 800 clinical trials. Analyses can be industry-wide or tailored to the characteristics of specific companies, products or development programmes.
- With this wealth of information, companies are in a much stronger position to determine a course of action for improving performance in drug development.

Perspective

The first R&D Briefing on the CMR International Benchmarking Programme (Keys to competition: Benchmarking for efficient drug development, *R&D Briefing Number 6*) emphasised the potential value to be gained from a contemporary, ongoing source of information on company performance across the drug development process. This source is now well established and offers, for the first time, a unique benefit to all those pharmaceutical companies that participated in this programme.

The programme, established in 1995, was designed by the industry for the industry. It comprises a macro study that generates cycle-time data for the complete development process of a new molecular entity (NME), related as required to the size or nationality of the developing company or to characteristics of the NME (*Figure 1*). This enables companies to measure relevant milestones and set realistic targets on an annual basis.

The micro benchmarking study concerns clinical development, the most extensive and expensive phase of the R&D process. It can provide analyses of performance based on a variety of characteristics, from study size or site to indication or use of contract resources (*Figure 1*).

In addition, the Benchmarking Programme provides a forum for discussion between participating companies and the opportunity for individual company analyses.

Status of the Macro Study

The completion of three rounds of data collection (1994/5, 1996 and 1997) has resulted in the inclusion of 635 NMEs in the dataset. From this are derived cycle-time statistics between key milestones in development, such as synthesis, first dosing in man, the end of the last pivotal trial and completion of the international launch programme.

The potential value of this information is revealed by the composite graph (*Figure 2*) of cycle times for NMEs in development in 1994/5. This shows, for example, an average time from synthesis to first human dose of 3.4 years for the NMEs that passed the latter milestone in 1994/95. Similarly, the time from pivotal dose to submission of the registration document lasted, on average, 3.0 years for the NMEs that completed this interval in 1994/5.

Progress with the Micro Study

Currently, a total of 754 clinical studies are represented in the micro study database; the third round of data collection is scheduled for Autumn 1998. Already, this study has provided companies with a set of common milestones that relate to the sub-processes involved in the completion of a clinical study. There is now the opportunity to set performance targets for trials with differing characteristics, such as design, scope or indication.

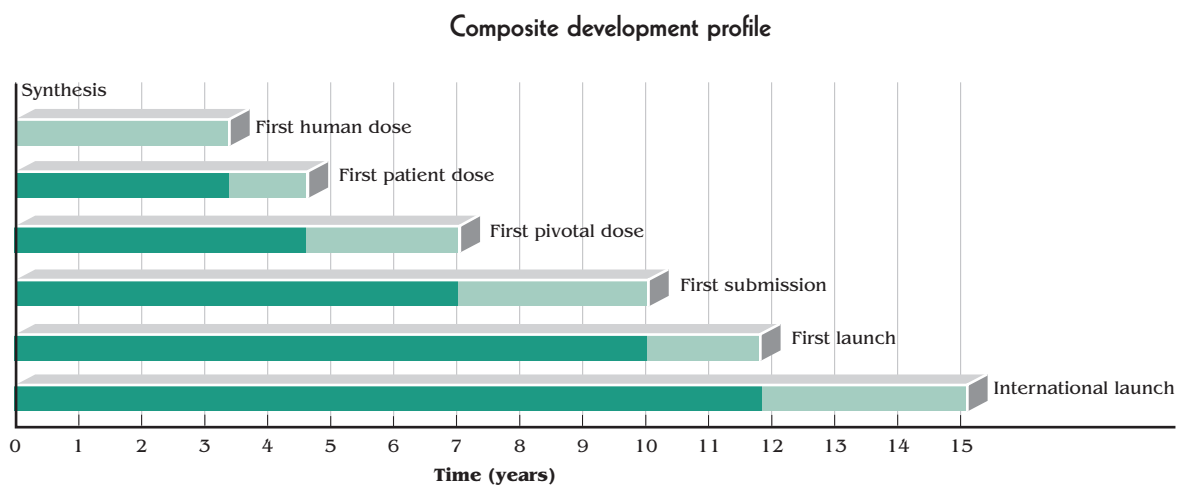


Figure 2 A hypothetical development profile has been created by summation of the mean values for key stages of drug development which were completed in 1994/5. Therefore, each of these intervals will reflect the development of different cohorts of NMEs. This type of analysis provides early insight into changes in development times, which may result in actual development profiles.

Average clinical study duration

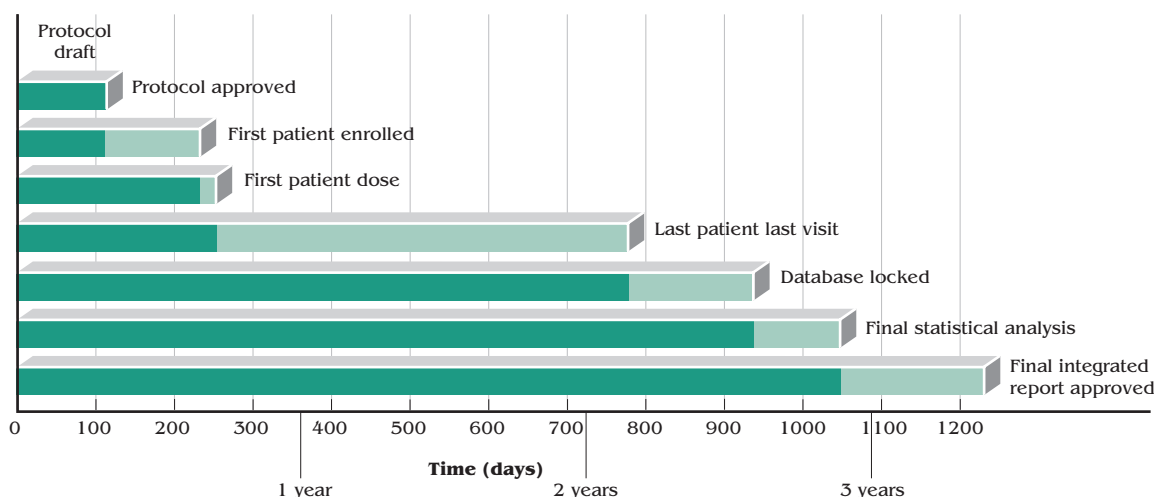


Figure 3 The mean duration of key stages of clinical studies completed in 1995 have been combined to present the breakdown of a typical clinical study into key activities. These averages are based on the maximum data available for each stage and thus in some cases may represent different cohorts of studies.

The composite graph showing cycle times in clinical development for unmarketed NMEs (Figure 3), is based on the average duration of each interval between key milestones for those trials which were completed in 1995.

A series of meetings has engendered a spirit of openness. The resulting free and frank discussion of industry-wide development issues is contributing to the efforts of individual companies to improve their drug development.

Forum Brings Benefits, Too

Participants in the Benchmarking Programme are provided with a much needed opportunity to exchange information with other organisations on R&D practices.

Aid to Individual Companies

How well a company is performing can only be judged by comparison with other leading companies. In the past the lack of information collected with the same methodology has hindered such judgements.

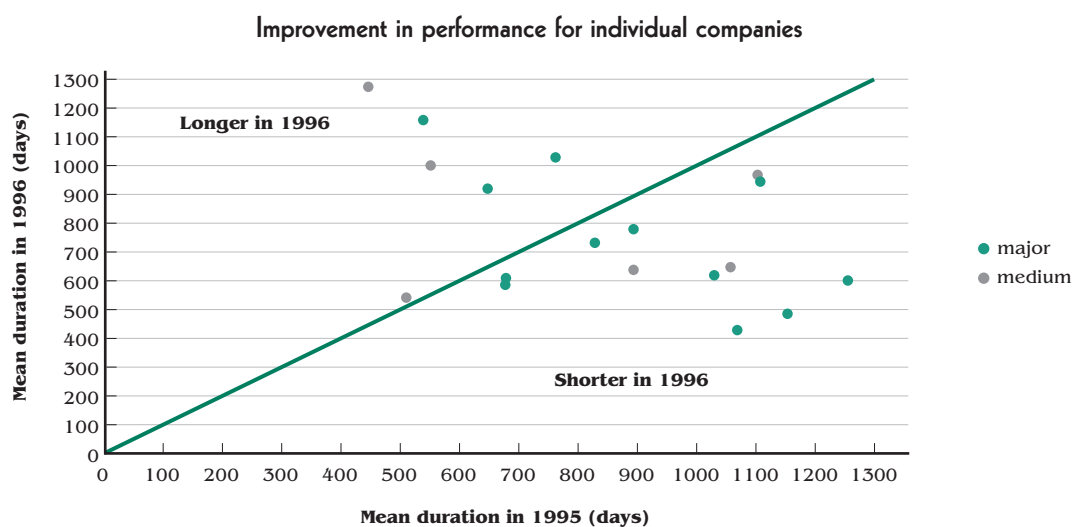


Figure 4 The mean value of total study duration (ie, time from protocol approval to approval of final integrated report) excluding treatment duration, for each company was compared for 1995 and 1996 to assess whether there was any difference. This type of analysis conducted over several years will illustrate where consistent changes in performance have occurred.

Through recourse to the benchmarking data, which are based on common measures, CMR International is able to provide a detailed, company-specific analysis, either in the form of reports or presentations, showing how performance measures up to that of competitors (*Figure 4*) and indicating areas for improvement. This further aids company efforts to define and accomplish performance targets and thereby improve efficiency and productivity in R&D.

A Lasting Benefit

Participation in the Benchmarking Programme, exclusive to sponsors of CMR International, benefits not just the individual company but, ultimately, the industry as a whole. Accumulation of further data over time will create a lasting benefit.

Companies participating in the Benchmarking Programme in 1998 are shown below.



Participation in the Benchmarking Programme is confined to CMR International Sponsoring Companies.

The full report is available to participants of the Benchmarking Programme.

Further information on sponsorship can be obtained from Professor Stuart Walker, Director, CMR International.

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