



R&D Briefing

Keys to Competition:

Benchmarking for Efficient Drug Development

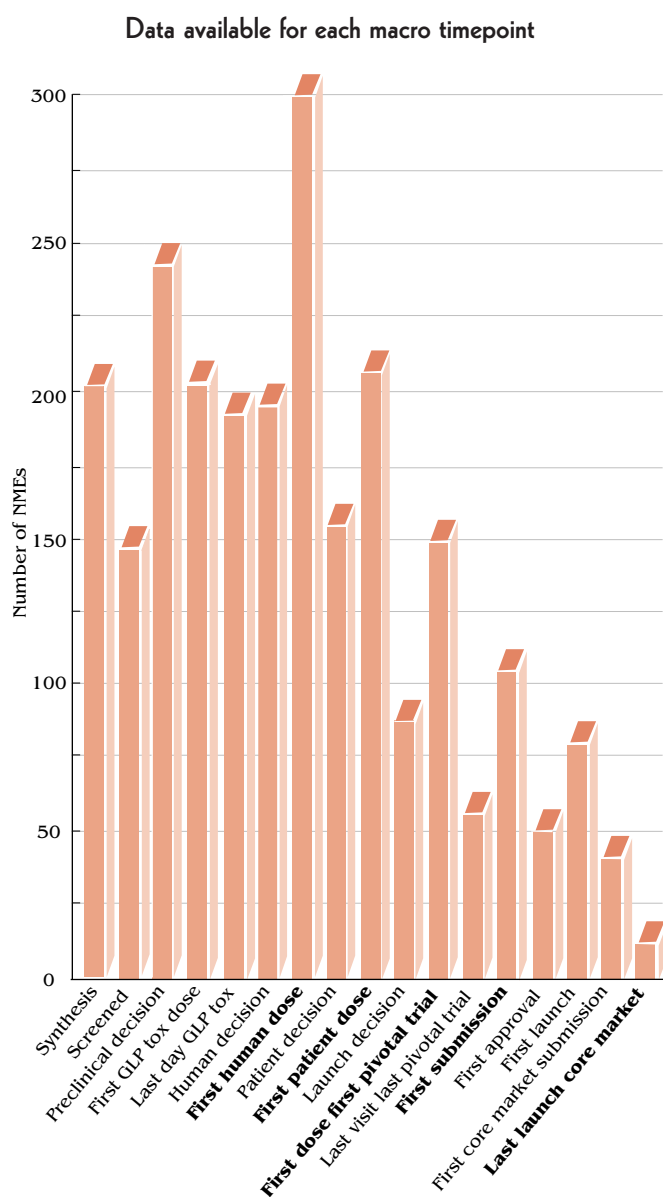


Figure 1 Thirty-three leading companies provided data related to activities completed in 1994/95 for 257 NMEs in the first round of data collection. The comprehensive information allows the cycle time data to be analysed on many dimensions.

- ❑ Internal benchmarking has been the pharmaceutical industry's mainstay for assessing the efficiency of drug development but such introspection does not accommodate external comparisons.
- ❑ Can a profile of cycle times in pharmaceutical R&D be generated across the industry? Do these intervals between key developmental milestones provide reliable measures of performance? Would such benchmarking data allow comparisons of products similar in terms of therapeutic effect, duration of treatment and dosage forms?
- ❑ Responding to industry interest in these issues CMR International has established a benchmarking programme. An on-going macro study provides current cycle times for the complete development process while the first in a series of micro benchmarking studies has generated detailed information on clinical research, a costly and extensive phase of development.
- ❑ Output from the benchmarking database enables participating companies to review their performance, learn from best practices and improve the efficiency of their R&D processes.

Perspective

Current changes within the research-based pharmaceutical industry demand skilful use of performance information and a readiness to learn from best practices around the world. Measurement of efficiency within pharmaceutical R&D, however, has generally been characterised by introspection and limited to internal comparisons of past performance.

Accurate, valid and comprehensive information on the complete development process across the industry would expand these horizons, so allowing companies to make comparisons with competitors' performance and define performance targets while providing a focus for performance improvement initiatives.

CMR International Benchmarking Programme

Centre for Medicines Research International has therefore initiated a programme of benchmarking studies to provide:

- cycle times for key stages in the development of a new molecular entity (NME);
- detailed information on micro timepoints within individual stages of development.

This programme incorporates regular discussion meetings with participating companies where results are discussed, ideas exchanged and future initiatives decided. The first two studies were conducted between July and September 1996, and these will be repeated annually.

Macro Study

The purpose of the macro study is to establish a database of information on individual NMEs as they reach key milestones in the drug development process. These milestones (*Figure 1*), from synthesis of a new chemical entity that has not been previously available for use in man, to its launch in the last of eight key markets (Canada, France, Germany, Italy, Japan, Spain, the UK and the USA), are defined in the study questionnaire.

Certain of the milestones (marked in bold on *Figure 1*) act as triggers to data collection by participating companies. Thus, if an NME has passed a trigger point during a pre-

defined period of time, data leading up to that point is recorded and transmitted to CMR International by post or electronically. As with all of the Centre's surveys, this highly confidential information is handled with integrity so that individual companies cannot be identified in any analytical output.

Development Times

Speed of development is monitored by analysing the time intervals between chosen milestones, such as the time from the last GLP toxicity dose to the first dose in humans. Such analyses can be based on the size or nationality of the developing company, on characteristics of the NME or on intended therapeutic indication (*Figure 2*).

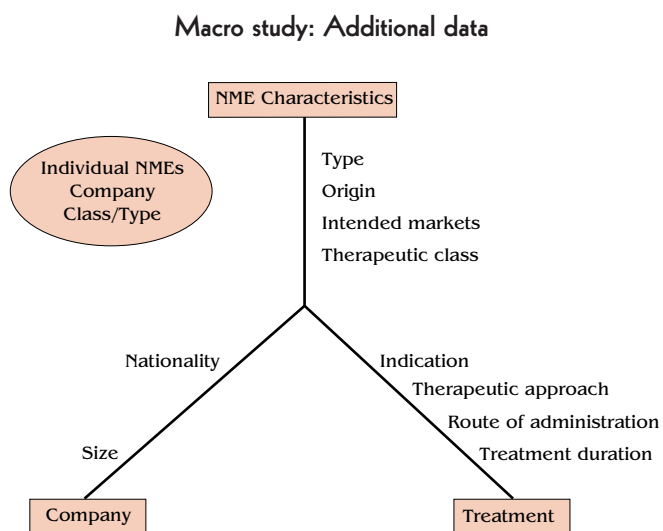


Figure 2 Additional information describing the NMEs allows specific analyses of clearly defined cohorts.

Current Status

The first round of full-scale data collection for the macro study concerned activities during 1994/95; and at the close of data collection in November 1996, 33 companies had provided information on a total of 257 NMEs.

Initially the rounds of data collection and analysis will focus on NMEs that have passed data triggers in the previous year; however, with time the database will provide the potential for analysing the complete development profile of an individual NME.

Data available for each micro timepoint

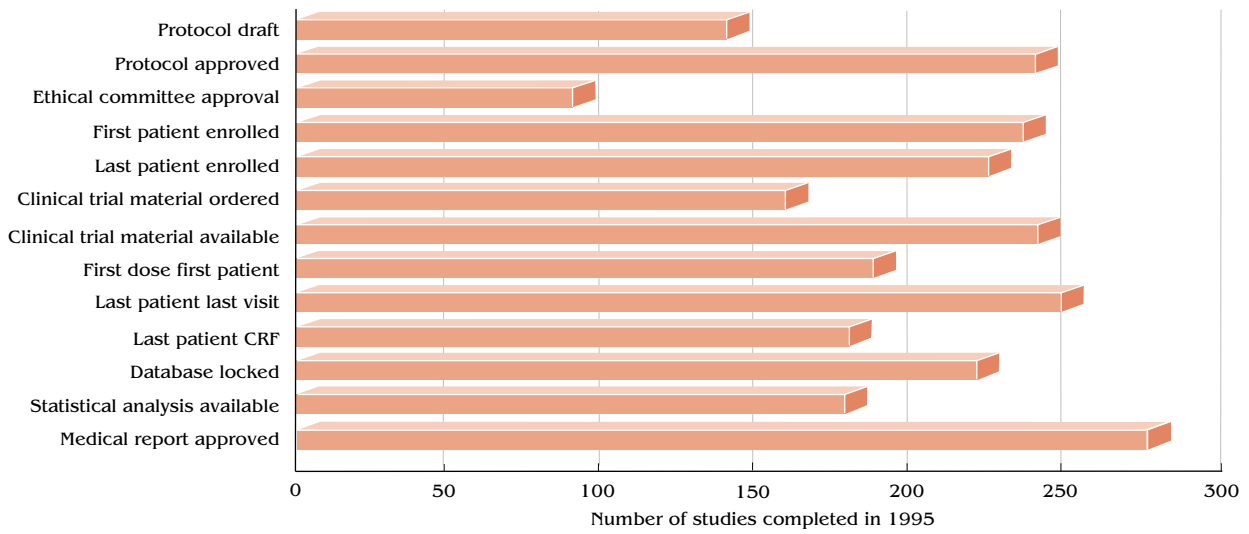


Figure 3 Twenty-seven companies provided data on 277 clinical studies; this wealth of data can be used to create an accurate profile of the intervals within clinical development and identify areas for improvement.

Micro Benchmarking

In parallel with the macro study has been the first in a series of micro benchmarking studies. Focusing on clinical research, the most extensive and expensive phase of development, this detailed study of the constituent parts of a given 'macro' time period, will increase understanding of the individual steps in the process.

The methodological approach has been the same as in the macro study. Common benchmarks throughout clinical development are identified and defined in the questionnaire (Figure 3) and analyses of key intervals performed. The range of dimensions for analysis is broader than in the macro study, embracing details of individual clinical trials and various administrative issues (Figure 4).

Micro study: Additional data

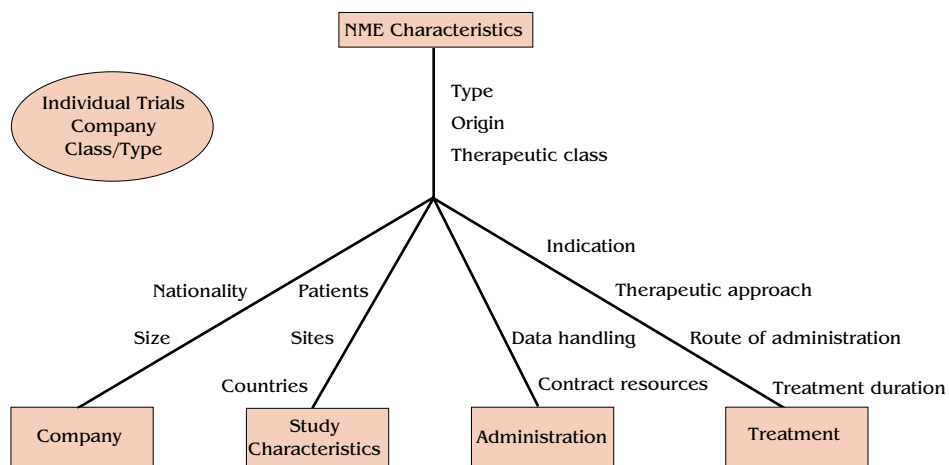


Figure 4 Additional information describing the clinical study permits selective analysis.

Participants in the CMR International Benchmarking Programme in 1996



Detailing Clinical Development

Data collection for the first micro study focused on all key clinical trials in patients with unmarketed NMEs that were completed in 1995. Completion was defined as internal approval of the final medical report for major safety and efficacy trials (Phase IIb or Phase III) eligible for inclusion in the regulatory submission to any of the eight core markets.

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Value

Benchmarking studies of this type have the potential to provide a contemporary and on-going source of information of value in performance management. The output will enable companies to set more competitive targets in the future and so improve the efficiency and productivity of the R&D process, to the ultimate benefit of the public health.

Participation in the Benchmarking Programme is confined to CMR International sponsoring companies.

Further information on this programme can be obtained from Dr Alison Drasdo at CMR International.

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