

## BENCHMARKING FOR EFFICIENT DRUG DEVELOPMENT

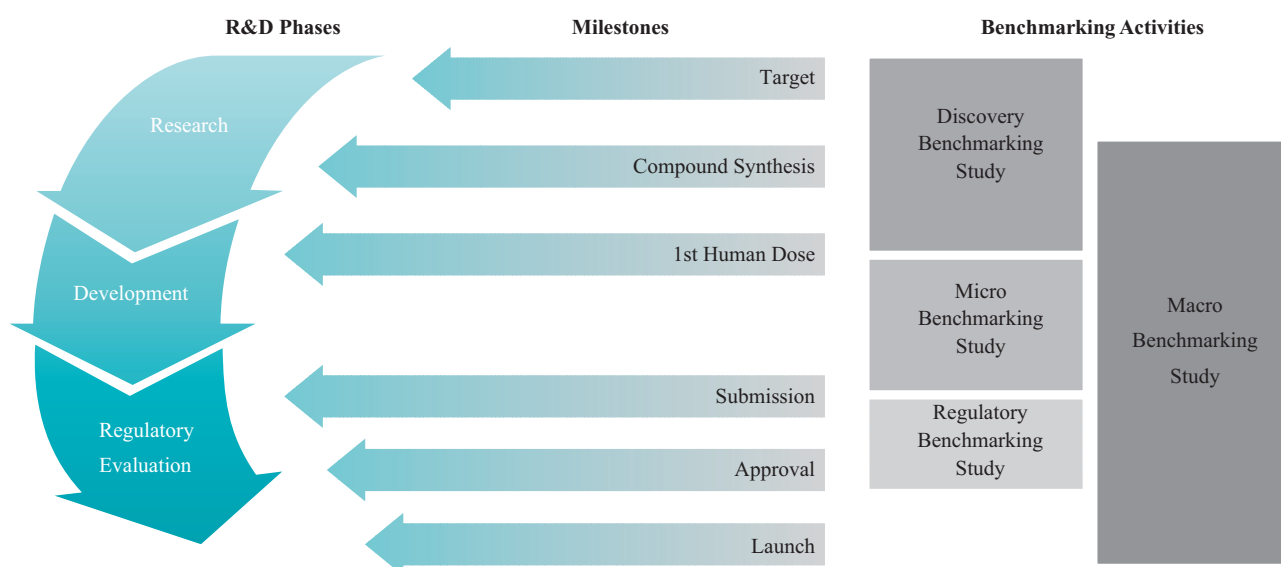
Since 1995 CMR International's development benchmarking programmes have provided strategic information enabling companies to make informed decisions within R&D in pursuit of reduced development times and improved efficiency.

Information from CMR International's benchmarking databases giving cycle times from discovery through to international launch and within pivotal clinical studies, allows participating companies to assess their own internal performance, gauge this against their competitors and put this into context within the global pharmaceutical environment.

The development benchmarking programme has information, collected from 40 of the world's top pharmaceutical companies, on over 1200 New Active Substances (NASs) in development between 1994 and 1999 and more than 4000 Phase II and III clinical studies active between 1995 and 1999.

Access to up-to-date information is critical for participants. To improve this, annual key cycle time reports and in depth analyses of data at forum meetings has been supplemented by a major new initiative, the CMR International On-line Benchmarking Analysis Tool (COBALT), giving on-line access over the internet to anonymous data from the development benchmarking databases.

Figure 1 *CMR International benchmarking activities*



## Background

In response to the limited information that was available to assess performance in R&D, CMR International established in 1995 a comprehensive benchmarking programme. This programme, uniquely designed by the industry for the industry, has been built on common definitions which allow robust cross-industry comparisons and meaningful multi-year trend analyses to be carried out. CMR International currently provides to sponsors three key studies which benchmark cycle times throughout the research and drug development process, and a fourth which has been carried out within regulatory authorities (Figure 1).

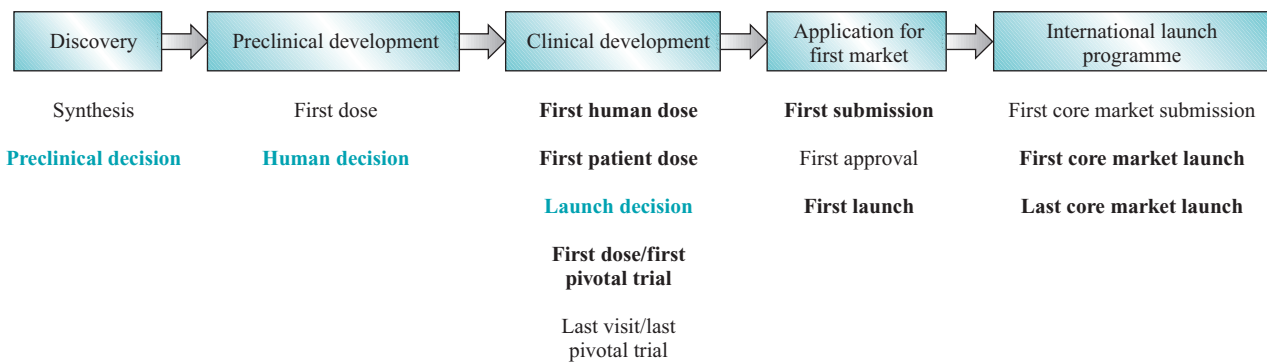
The macro programme generates cycle time data on New Active Substances (NASs) for the complete development process, from compound code assigned to international launch (Figure 2). This information can be related to characteristics of the compound (type, therapeutic area and other aspects of the development programme) and to

company size. Companies use this information directly to set realistic performance targets on an annual basis.

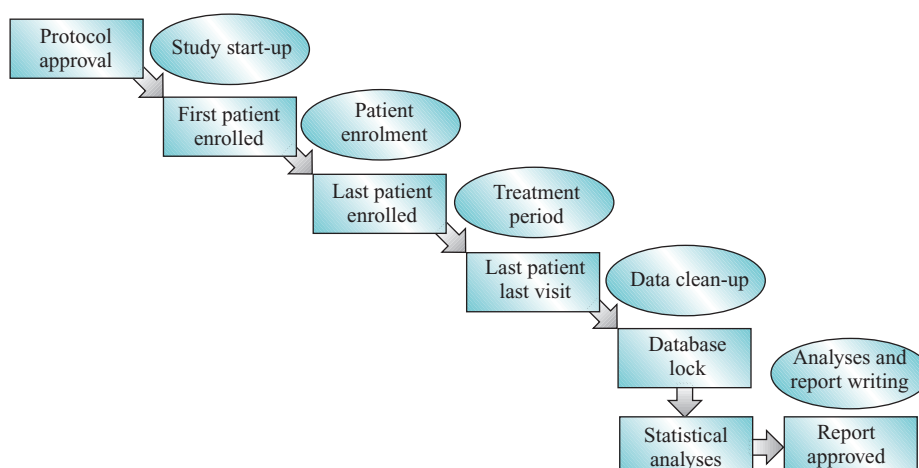
The micro benchmarking study examines the clinical phases of development which continue to be the most costly and time consuming part of the drug development process (Figure 3). In addition to key cycle times, other information pertaining to pivotal Phase II and III clinical studies is collected. This includes, size, location, purpose and design of trials, the technology used, the use of contract resources and the characteristics of the compound under investigation.

Annual forum meetings continue to be an important part of the programme giving company representatives the opportunity to examine and discuss the breadth of the datasets in more detail. Discussions also ensure that the information collected reflects participants needs while the crucial consistency of the core definitions is maintained.

**Figure 2** *Macro study: major milestones*



**Figure 3** *Micro Benchmarks in Clinical Development*



## Macro Programme

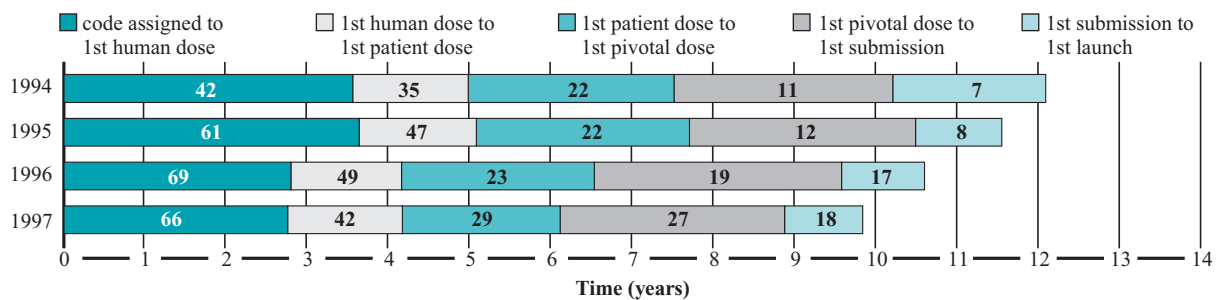
**Macro Development Survey Status** Data covering 1994-1999 1200+ NASs 35-40 companies/year

Performance in drug development is continually changing as shown in Figure 4. Therefore, macro benchmarking data allows companies to assess their own performance against the rest of the industry on an annual basis to ensure that internal processes are working efficiently. This information

is also used to set internal targets and stretch goals based on an assessment of the best practice cycle times which are provided to participants in confidential annual reports from the programme.

**Figure 4** Contemporary cycle times are decreasing

Composite development profiles comprising mean cycle times for NASs completing each activity between 1994 and 1997. Each interval represents a different cohort of NASs, but a common cohort of 23 companies for all years. (n=number of NASs completing each interval in each year)



## Micro Programme

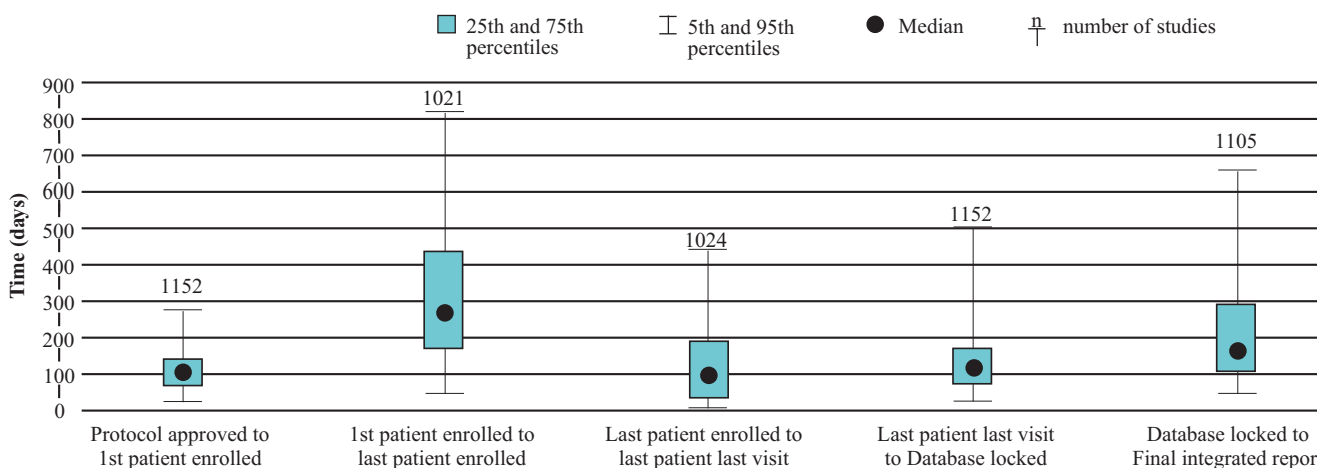
**Micro Clinical Survey Status** Data covering 1995-1999 4000 pivotal Phase II/III clinical studies 35-40 companies/year

The clinical period within drug development continues to consume the greatest proportion of resource and time. Therefore, it is imperative that processes within this period are examined closely to maximise efficiency. Figure 5 shows data from the micro clinical programme that breaks down the pivotal study into five key intervals. The enrolment period within a study requires the greatest amount of time. Using data from the micro programme to compare the enrolment in studies of a similar size and

therapeutic area to their own, participating companies can focus re-engineering efforts on this specific stage. By looking at the effect of new technologies such as internet recruitment and data transfer techniques, or trends in the location of clinical studies, participants in the benchmarking programme benefit from detailed insights into the R&D environment and can use this information to improve their strategic plans.

**Figure 5** Clinical Performance between 1995 and 1997

Industry performance in key stages of a clinical study. Data is presented for all clinical studies completing each interval between 1995 and 1997.



## Improving value through access to the data

Access to up-to-date benchmarking data is essential for companies to make informed decisions in drug development. To facilitate this, and to allow participants to interrogate a greater proportion of the benchmarking data than can be presented in the core reports, the CMR International On-line Benchmarking Analysis Tool (COBALT) has been developed. This web-based, subscription service facilitates access to anonymous data from the macro and micro benchmarking databases over the internet. A user-definable search tool provides results on multi-characteristic analyses in a format that can be converted into presentations for an individual's personal use.

### CMR International's Online Benchmarking Analysis Tool



## Providing insights to improve performance

The key strengths of CMR International's development benchmarking studies are that they are designed "by the industry for the industry" ensuring that the information provided is in line with industry needs, and that the data provided is comprehensive, comparable and of high quality, facilitating robust inter-company comparisons. The value of the information is illustrated through the continual participation from companies originally involved with the programmes and new companies providing data each year. CMR International's development benchmarking programmes are truly representative of drug development in the leading pharmaceutical companies in the world.

The large data sets that have built up over the last five years will return greater value to the industry than ever before. Initiatives such as the COBALT project mean that participants have a unique insight into current industry performance and trends in the development of new medicines and can harness these data to improve their own company's performance.

### Participating Companies 2000

Abbott	Knoll	R W Johnson PRI (including Janssen)
Allergan	Esteve	Sankyo
Almirall-Prodesfarma	Lundbeck	Sanofi-Synthelabo
Amgen	Merck KGaA	Schering AG
AstraZeneca	Merck & Co	Schering Plough
Aventis	Novartis	Scotia
Bayer	Novo Nordisk	SmithKline Beecham
Boehringer Ingelheim	Nycomed Amersham	Solvay
Bristol-Myers Squibb	Organon	Teva
British Biotech	Parke-Davis	Wyeth-Ayerst
Daiichi	Pfizer	
Eli Lilly	Pharmacia Corp.	
Esteve	Pierre Fabre	
Genzyme	Procter & Gamble	
Glaxo Wellcome	Roche	



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#### Reference

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.

Copies of R&D Briefings are available at <http://www.cmr.org>.

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