



R&D Briefing

Outsourcing in Operation

Contracting out Pharmaceutical R&D

Existence of company-wide policies for outsourcing

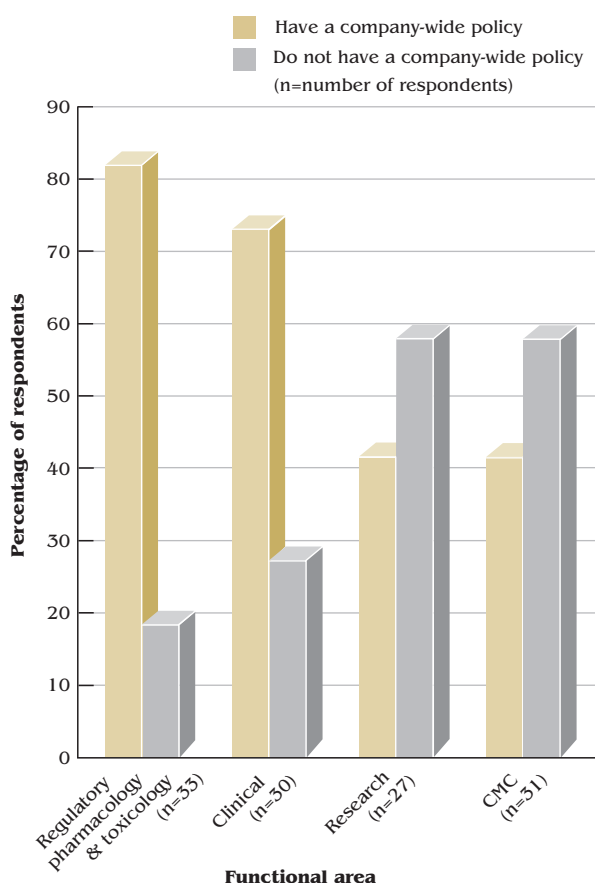


Figure 1 Company-wide policies for outsourcing are common amongst the 36 companies responding to a CMR International survey, reflecting wide acceptance of the practice. Among surveyed companies the majority already have outsourcing policies. Outsourcing strategies continue to be developed; in future over 90% of companies expect to have policies for regulatory pharmacology and toxicology and clinical development, as do 81% for Chemistry, Manufacturing & Controls (CMC) and 67% for discovery research.

- The practice of contracting out pharmaceutical R&D activities (outsourcing) has evolved rapidly in recent years, in a bid to reduce fixed costs, increase the company's skill base or cover gaps in capacity. It has now reached the point where outsourcing an entire drug development programme is a realistic option.
- Is this likely to happen? What is the strategic importance of outsourcing to the industry? Who within the pharmaceutical company manages the process? Which functional areas are most commonly contracted out and what are the sizes of the markets? Do contract research organisations compete with internal company departments?
- A detailed survey of pharmaceutical companies' current and future outsourcing strategies, conducted recently by CMR International, not only addresses these questions but also provides insight into the changing relationship between company and contractor.
- The survey resulted from a collaboration with Technomark Consulting Services and is the cornerstone of a new joint publication "Current Strategies and Future Prospects in Pharmaceutical Outsourcing". In addition the report:
 - Highlights the forces that act on the pharmaceutical industry, and which favour the expansion of outsourcing;
 - Analyses the outsourcing market and reviews strategic options for companies operating in the CRO industry sector;
 - Provides an in depth analysis of the financial aspects of the CRO industry from the viewpoint of the public markets.

Perspective

The range of drug development activities contracted out to external companies (outsourced) by the pharmaceutical industry continues to increase and change in its nature. Contract research organisations (CROs), once principally engaged in analytical or toxicological projects, can now cover all areas of R&D from discovery to post-marketing clinical trials. Such increased levels of outsourcing are leading to changes in

- The relationship between pharmaceutical company and contractor;
- The management of outsourced projects by the company.

CMR International conducted a questionnaire based survey of international pharmaceutical and biotechnology companies to explore current and future trends in outsourcing policies, the management of outsourced projects, and expenditure on CROs. This information was sought for four functional areas:

- Research (discovery)
- Clinical
- Regulatory pharmacology and toxicology
- Chemistry, Manufacturing and Controls (CMC).

This briefing solely concerns a cross-functional comparison for 36 respondent companies (in depth analyses for each functional area are presented in the report). The companies represented a cross section of the industry, with annual pharmaceutical R&D expenditure ranging from <50 million to >1 billion US dollars.

Policies Reflect Approach

Policies for outsourcing are common, particularly among smaller companies, reflecting wide acceptance of the practice. Among surveyed companies the majority already have outsourcing policies for regulatory pharmacology and toxicology, the vanguard of contracting out, and clinical development (*Figure 1*).

The use of centralised contracting groups to manage outsourcing

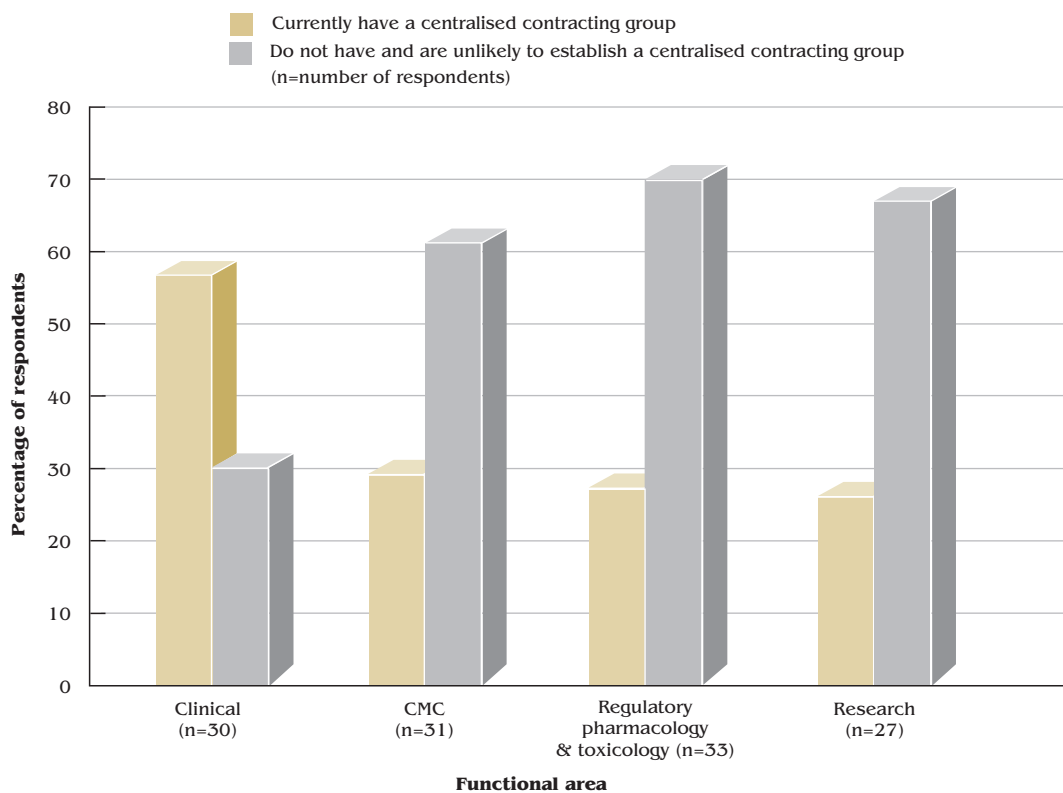


Figure 2 Some respondent companies have formed centralised contracting groups to liaise with the CROs and manage the process. Seventy percent of companies anticipate centralised management of clinical development outsourcing; less than 40% will establish centralised groups for the other three areas.

Outsourcing strategies continue to be developed; in future over 90% of companies expect to have policies for these two areas, as do 81% for CMC and 67% for discovery research.

Outsourcing appears to be largely tactical rather than strategic, as the policy in most companies is to review each project individually. This individual approach is less common for regulatory pharmacology and toxicology (52%) compared with the other three functional areas (around 80%).

Managing the Process

As outsourcing increases so does the amount of time and expertise required to manage projects. Some companies have therefore formed a centralised contracting group (Figure 2) that can liaise with the CROs and manage the process. This not only ensures a consistent approach and better communication but also helps develop expertise and reduce start-up times.

Seventy percent of companies anticipate centralised management of clinical development outsourcing; less

than 40% will establish centralised groups for the other three areas. This difference may reflect the greater expenditure on clinical outsourcing or differing approaches between functional areas. Thus, a functional manager generally initiates regulatory pharmacology and toxicology projects and monitors quality; for clinical projects there is rarely such individual responsibility.

What does it Cost?

Interestingly, many companies appear not to be able to answer this question. Expenditure data for the last financial year was available on regulatory pharmacology and toxicology work contracted to CROs for 83% of companies, but fewer were able to supply data for research (65%), CMC (56%) or clinical (42%) projects. The lack of information on clinical outsourcing is surprising since it is the area of highest expenditure, where most companies use a centralised contracting group.

The proportion of work outsourced in 1997 (Figure 3), based on company estimates where expenditure data were unavailable, shows that for research the proportion

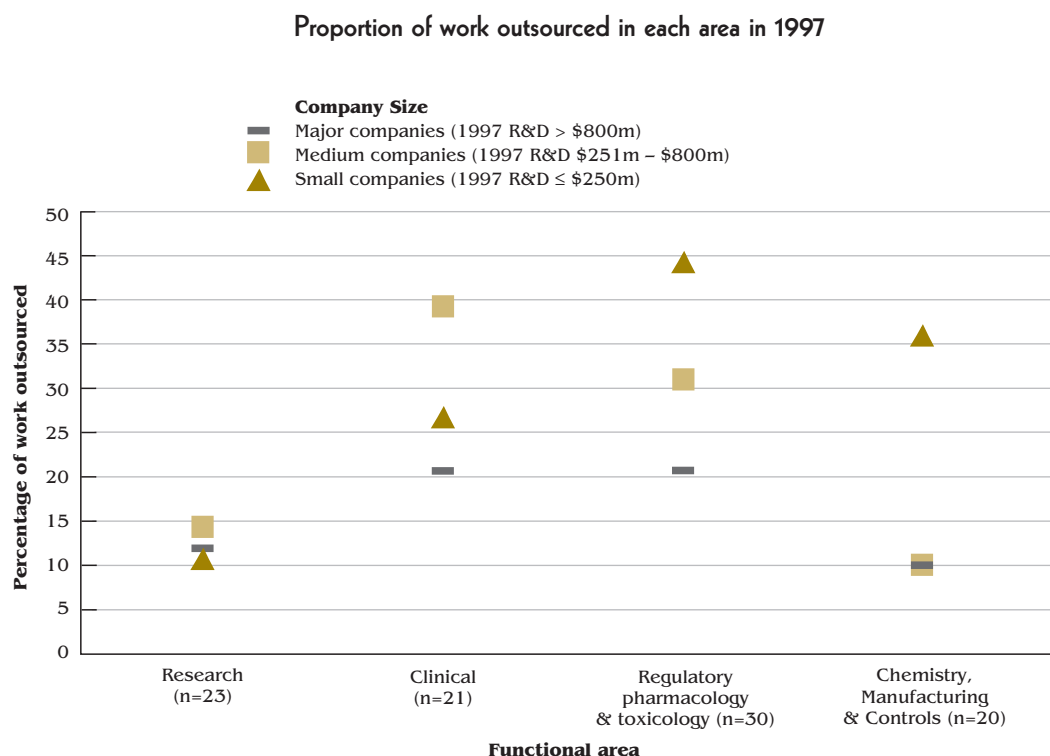


Figure 3 The proportion of work outsourced by the respondent companies, based on company estimates where expenditure data were unavailable, differed according to company size in all functional areas apart from research.

Estimated sizes of the outsourcing markets

Functional Area	Market Size (\$US billions)		% Increase (1997-2002)
	1997	2002	
Clinical	2.9	5.2	79
Research	1.3	1.8	38
Chemistry Manufacturing & Controls	0.9	1.4	56
Regulatory pharmacology and toxicology	0.5	0.9	80
Total (all four areas)	5.6	9.4	68

Table 1 The expenditure on outsourced work is likely to increase for all functional areas, as shown by the estimated sizes (US\$billions) of the outsourcing markets in 1997 and 2002.

is similar regardless of company size. This suggests that smaller companies, particularly start-up and biotech companies, have considerable expertise in the research area.

The expenditure on outsourced work is likely to increase for all functional areas, as shown by the estimated sizes (US\$billions) of the outsourcing markets in 1997 and 2002 (Table 1).

The greatest percentage increases are predicted in clinical (79%) and regulatory pharmacology and toxicology (80%), even though in clinical many survey respondents indicated that the actual cost of

outsourcing clinical work frequently exceeds either the estimated cost of doing it in-house or the budgeted contracting cost.

Future Competition for CROs

Internal departments already compete, at least sometimes, with CROs for work in up to half the companies surveyed. Such competition is expected to increase in all areas but is thought unlikely to become omnipresent.

It remains to be seen whether the common practice of outsourcing discrete areas within drug development will be replaced by much broader contracts with CROs. As yet, however, there is little evidence that traditional pharmaceutical companies are evolving into virtual organisations solely dependent on outsourcing R&D.

A copy of this R&D Briefing is available on the CMR International web site. Additional paper copies can be obtained free of charge from the Centre.

Copies of the report, Current Strategies and Future Prospects in Pharmaceutical Outsourcing (which contains a full report of the survey), are available at a cost of **£495 to CMR International Sponsoring Companies, and £595/\$1050 to other organisations**, from Technomark Consulting Services Ltd, King House, 5-11 Westbourne Grove, London W2 4UA, UK. Tel +44 (0)171 229 9239 Fax +44 (0)171 792 2587.

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