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WHY OUTSOURCE?

WHAT IS THE GOAL/REASON FOR OUTSOURCING?

Contract research organizations (CROs) provide a much needed service to the pharmaceutical sector. Full-service CROs offer a comprehensive selection of capabilities, whereas smaller “niche” CROs may focus on a narrow segment of services (e.g., clinical or analytical only). All of these organizations fulfill a need in that they provide the services necessary for the approval of new clinical entities or generic drug products. A sampling of these services is included in Table 12.1.

Many of the larger pharmaceutical companies have in-house capabilities for most, if not all, of these services. For example, many often have their own clinical and bioanalytical units that provide full support for Phase I studies. However, even these internal resources can become saturated due to the drive to develop more compounds in shorter time intervals.

Unlike their larger counterparts, the smaller companies, virtual firms, and generic companies do not have the luxury of their own dedicated clinical unit or