Knowing When to Outsource

Drug discovery and preclinical development require a wide range of expertise and resources, from medicinal chemistry to regulatory affairs, but academic labs and small biotech companies rarely have the internal infrastructure required to advance therapeutic programs into clinical trials on their own. Nearly every research activity, from target discovery to clinical trials, can be outsourced to contract research organizations (CRO), long used by the pharmaceutical industry to supplement internal R&D work. A growing number of academic institutions have also established drug discovery centers that work with academic and pharma sponsors that are primarily focused on early stage activities like high throughput screening and lead identification.

Deciding when to outsource depends on a variety of factors, including availability of internal resources, capabilities, expertise, and cost. Ultimately the need to outsource will grow as your program moves into the later stages of preclinical drug development.

Why outsource?

CROs and academic drug discovery centers provide specialized services, technical expertise, and consultation that fill critical gaps in resources and know-how at each stage of development. Outsourcing provides multiple benefits, including:

- **Access to resources:** CROs provide access to a wide range of resources including targeted compound libraries and established screening assays.
- **Drug discovery expertise:** Early-stage programs require extensive experience in assay development, medicinal chemistry, pharmacology, *in vivo* efficacy, safety and toxicology, and drug manufacturing. Outsourcing allows you to work closely with experienced study directors and technical staff to design and troubleshoot your projects.
- **Cost and time efficiency:** Evaluate the cost of supplies, expenses associated with adhering to standard operating procedures (SOP), and staff certifications needed to perform highly specialized tasks in-house, versus the costs of outsourcing. Consider how much time your staff would devote to drug discovery activities and the time involved in developing SOPs in your lab.
- **Key platform technologies:** Outsourcing provides access to automated equipment that produces robust and reproducible data (i.e. liquid handlers, plate readers, HPLC and LC-MS units, automated behavioral monitoring systems, and *in vivo* brain and body imaging systems).
- **Regulatory compliance:** The FDA stipulates that work required for an investigational new drug (IND) package is performed in good lab practice (GLP) and good manufacturing practice (GMP) certified facilities. The vast majority of academic institutions and small biotech companies lack the infrastructure to support the extensive training, monitoring, documentation and quality assurance required for IND-enabling studies.

Academic drug discovery centers vs. CROs

Drug discovery teams may use academic centers for some outsourced activities and CROs for others. While academic centers can offer easier materials transfer and convenient in-person communication (if at your home institution), they may not take projects from external organizations. Like CROs, some academic centers offer multiple services for different discovery and development stages, but most provide single specialized services. Most importantly, CROs can provide external validation of data, which increases the value of your program to potential partners and investors.

Visit the Academic Drug Discovery Consortium and ADDF ACCESS or Science Exchange to help you find the right organization for your outsourcing needs.

References

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