

**Outsourcing responsibilities of key roles in early clinical development:
An innovative type of strategic partnership for Eli Lilly and Aepodia**

Lilly has used a variety of strategic outsourcing strategies over the past several years. These strategies have primarily been focused on sourcing specific activities – eg, clinical study conduct, data management and analyses, etc. More recently Lilly has begun to explore options to outsource key clinical team roles in early clinical development to external parties such as Aepodia.

For several projects during the previous 2+ years, both scientific (clinical pharmacologist) and operational (project coordinators) consultants from Aepodia have fulfilled the roles previously played by internal Lilly staff within clinical development teams. In this unique relationship the accountabilities and responsibilities assigned to each role have been delegated to Aepodia staff in lieu of internal Lilly staff resulting in an effective augmentation of clinical support for the early phase development portfolio.

The presentation will review the model construct, accountabilities, metrics performance and benefits of this sourcing strategy from the perspectives of Lilly and Aepodia. As with other partnerships, the success of this model is highly dependent on clearly defining expectations of both parties and excellent implementation (eg, detailed roles and responsibilities for the sponsor and third party team members, effective governance for metrics definition and review...). Additional considerations to ensure the success of the model include verifying the skills and drug development experience of the partner company are adequate and suited to the development needs of the sponsor portfolio as well as determining the optimal timing for the external staff to “enter” the team.

This type of relationship is characterized by an optimization of internal resource management by the Sponsor Company, an efficient delegation of responsibilities (including the selection and management by Aepodia of external vendors) and optimization of joint operating processes. Through this successful collaboration, in less than three years, Aepodia have supported several challenging FIM and exploratory clinical development programs up to POM, POP or POC.

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