Public-Private Partnerships (PPP) for Drug Development

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Authors:

Neil Ganulin

As a result of huge costs and pricing pressures, many drug development players are now participating in public-private partnerships (PPP) to share the costs of drug development efforts. Hardly a week goes by without a news feature attacking a pharmaceutical company for charging consumers a high price for its drugs. The pharmaceutical company typically responds with statistics regarding the increasing costs of drug development, the success/failure rate of new drugs that actually make it to market, and the fact that the rate of return on a successful new drug must cover the costs of all the failed drugs. With these mounting pricing pressures, many drug developers are looking for alternative ways to share costs through a PPP.

What is a Public-Private Partnership?

A public-private partnership, often referred to as a "PPP" (also P3 or 3P), is a contractual relationship among one or more public entities and one or more private companies under which each party agrees to share its knowledge, data and resources to achieve a common goal. Generally, parties to a PPP are two or more of the following entities:

- Academic institutions
- Government agencies
- Pharmaceutical/biotechnology companies
- Governmental regulators
- Individual patients/organizations with a special interest in a drug's development

PPP Benefits

There are several reasons why stakeholders seriously consider and join PPPs:

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- It allows pooling of knowledge and resources, thereby allowing issues to be addressed about which a single company would not be knowledgeable, and thus expands the available knowledge and possibility of faster, more successful drug development.
- It provides a sharing of financial and other resources that reduces development costs and hopefully eliminates some duplicative development efforts.
- With a multi-stakeholder membership, it can prioritize research and development to focus on a greater need and provide a drug development risk analysis.

PPPs can occur at various stages of the drug development pathway. There can be research PPPs that collaborate on the initial stages in a drug's development, as well as PPPs that provide later-stage drug development and commercialization.

PPP Formation

Forming a PPP can be a lengthy and arduous process. One of the keys to a successful PPP is for all of the stakeholders to communicate well, both initially about their prospective goals and expectations as well as about the PPP's formation, operation and termination. Each stakeholder must understand its individual role, duties and obligations and agree on the PPP's goals and how to measure its success during the course of its existence. More specifically, the stakeholders need to address the following, among other items:

- The purpose of the PPP
- How to measure its success
    - Interim measurable benchmarks and consequences of failing to achieve those benchmarks
- Initial contributions to the PPP- funds, property in kind, and intellectual property, etc.
- Additional financing requirements
- Governance/decision making

- Management committee/subcommittees
- Decision-making requirements
    - Majority or supermajority
    - Veto rights
- Stakeholders' right to use developed IP
    - Joint ownership
    - Licensed rights-royalties
- Operational responsibilities
- Exit strategies
- Dispute resolution

Although it is a complex and time-consuming process, if each stakeholder to the PPP effectively communicates its individual goals and mutually establishes goals for the PPP, and all stakeholders understand their respective obligations, the PPP can be a successful collaboration and well worth the effort.

For more information about Public-Private Partnerships for Drug Development, please contact Neil Ganulin or any member of Frost Brown Todd's Health Care team.

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