



## ○ Featured Article

# Pharming It Out: Clinical Trial Strategies to Support Product Licensing

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The aftershocks of last year's economic crisis have created financial challenges for drug developers of all sizes.

Young biotech companies face a shortage of venture capital and a virtually nonexistent initial public offering window. Funding for smaller public drug companies continues to carry a high cost. Even larger pharmaceutical firms are under relentless bottom-line pressure from shareholders as they struggle to remain innovative.

All of which intensifies the need to out-license drug candidates as part of a cost-control strategy, a financing strategy and/or an exit strategy. This heightened emphasis on development and marketing partnerships has increased competition among sellers, and the ones winning the game are those who design a clinical program that maximizes the attractiveness of their asset to buyers.

Yes, the quality of the asset itself is the meat of the deal, but the supporting clinical trial program is the platter on which that meat is presented. The difference between a clinical program designed for internal advancement of a compound and one designed to support out-licensing can be the difference between serving up your filet mignon on a garbage can lid or on a silver platter.

The following are questions sponsors should consider when designing a clinical program specifically to support product out-licensing. And the earlier you begin thinking about these issues, the better. Waiting until a potential buyer asks the question can result in last-minute studies that are both expensive and time-consuming – delaying your deal or even derailing it altogether if the data turn up something unexpected or if external forces change the market while you're struggling to play catch up.

### Who are you targeting as a partner?

A large pharmaceutical firm with decades of licensing experience will want to see clean fundamentals, but they are unlikely to be swayed by a biotech's market research and launch plans. Chances are, they're familiar with the market opportunity. So while you might normally start marketing preparations during Phase II, you can save money by skipping this process if you plan to out-license to big pharma.

If you plan to out-license to a holding company or other financial group, however, time and effort spent on IMS data or to bring in a few key opinion leaders can pay significant dividends. Investment firms tend to be highly focused on market potential and returns, so budgeting additional resources to prove your worth on these fronts will help you talk their talk.

For those seeking to out-license to a mid-sized pharmaceutical or biotech company, managing risk is the name of the game. These companies have far fewer assets in their pipelines, so each one is that much more important. Highly transparent data can improve your asset's appeal. Additionally, while some preclinical work like analytical methods validation and long-term animal studies can be done in parallel with Phase III trials, getting that work started before you out-license to a smaller company can reduce the perception of risk and position your asset as more advanced. The return in terms of an increased deal price might prove well-worth the relatively small front-end investment.

### **Who is your competition?**

The way your product fits into the competitive landscape plays a significant role in determining the back-end economics of an out-licensing deal. Will you be first to market, or will you be a fast follower providing marginal improvements over the market leader? How you answer that question is critical to designing a clinical program that highlights your product's best attributes.

If your drug will play in a competitive field, potential buyers will likely want to see comparative studies. But even if your drug is first-in-class, you'll need to show how it interacts with any concomitant medications.

### **How much are you willing to give up?**

Are you selling your product lock, stock and barrel, or are you interested in out-licensing certain rights while retaining others? Who will end up holding the intellectual property associated with the product?

Before you can begin to answer these questions, you have to know what your drug is capable of. Imagine if Viagra had been developed by a biotech company and out-licensed as a therapy for heart disease. Only through patient feedback in clinical trials did its potential in erectile dysfunction become known, which, needless to say, would have altered the economics of any partnering deal substantially. A good licensing-targeted clinical program will identify and address all potential applications of your drug.

If your drug has applicability in multiple indications, you may be able to out-license rights in certain diseases to fund your own internal development in other diseases. If such partial licensing strategies are part of your plan, bear in mind that prospective buyers will want to see data that extend beyond the particular niche they're evaluating. They're also likely to request the bones of your marketing plan as proof that you think the product will be successful and you're truly planning to pursue it, not just wring a little cash out of an unsuspecting partner before ditching your own development.

### **Are you thinking globally?**

Regional partnerships in areas like Asia or Europe can provide vital funding to offset the costs of an internal clinical program aimed at supporting FDA approval. Additionally, for drugs targeting multiple indications, the geographic prevalence of certain target diseases may attract regional partners.

As noted above, any partial licensor is likely to want both clinical and marketing data that prove your commitment to your product. But in many regional deals, health economics research also plays an important role in determining the value of an asset. Although it isn't common in U.S. development programs and often doesn't come up until the end of ex-U.S. licensing discussions, health economics research is best tackled proactively if you know you'll be seeking regional deals.

### **What is your safety hurdle?**

Drugs to treat chronic diseases must endure more safety scrutiny than drugs that are taken for a limited period of time to resolve a certain symptom. The same goes for drugs addressing widespread conditions like obesity and prophylactics that will be given to otherwise healthy subjects. Out-licensing of such products can be facilitated by providing extensive preclinical toxicology and carcinogenicity data, as well as broad clinical safety data. Additionally, although you may plan to out-license your drug before reaching Phase III, the premature initiation of long-term animal safety studies may prove a relatively inexpensive investment in good will with the buyer, setting their mind at ease and even raising the value of your asset.

### **Do you have a back-up plan?**

In both licensing and drug development, everything takes longer than you expect and costs more than you expect – so plan accordingly. Additionally, while you may hope to out-license in Phase I or Phase II, you might not get the terms you want until after Phase III or even after approval. So while designing a clinical trial program that specifically supports out-licensing can improve efficiency and enhance a product's appeal, that program must be flexible enough to adapt to changing circumstances.

In the end, it isn't just a question of whether or not you can out-license an asset; it's a question of how you get from here to there. That's where the support of highly experienced strategic and regulatory consultants, with a depth of global industry expertise, comes into play. At INC Research, we provide this consultative support as part of a full service offering or as a discrete stand-alone agreement.

Our strategic expertise will serve as the GPS system for your out-licensing aspirations: tell us where you are, where you want to go, and your crucial driving parameters (time, cost, innovation, etc.) and the INC Research team will get you there. And by applying our Trusted Process – a metrics-driven methodology proven to deliver actionable results – we'll ensure your asset is presented on silver platter.

To understand how the Global Regulatory team at INC Research can support your licensing and drug development needs, please contact Wayne Whittingham at [wwhittingham@incresearch.com](mailto:wwhittingham@incresearch.com) or visit [www.incresearch.com](http://www.incresearch.com).

## About the Author

*Wayne Whittingham leads and is responsible for Global Regulatory Services at INC Research. His expertise in pharmaceutical and device regulations is culled from over 22 years of experience including four years working within FDA, four years with CROs and 12 years in pharma. His regulatory services experience includes pre- and post-approval applications and broad and extensive U.S. and EU experience as well as expertise submitting applications in Asia and South America. Mr. Whittingham has also acted as a representative of ex-US entities with the FDA. Mr. Whittingham has extensive IND and NDA/BLA submission experience as well.*