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COVANCE: EXPEDITED DRUG DEVELOPMENT WITH A NEW PROGRAMMATIC MODEL

Peter Sausen, PhD, VP, Early Phase Development Solutions, Covance

"More than 80% of small biopharmaceutical organizations tackle their drug development programs with a transactional approach," explains Peter Sausen, PhD, VP, Early Phase Development Solutions, Covance. "They buy a toxicology study today, perform a metabolism assessment tomorrow and so forth – often selecting various universities or vendors to perform the numerous studies required."

The venture capital model of funding drug development, prevalent in this sector of the industry, frequently drives this behavior, as investors dictate burn rate and supply additional rounds of investment based on milestone achievement. "This model may make sense from a risk management perspective," says Dr. Sausen; "however, it can prove to be costly and time-intensive."

Why is the current model inefficient?

"Much like building a new home, if you don't have an architectural plan documenting your desired end result and how the pieces strategically fit together, you may stumble and lose control of your project," explains Dr. Sausen. "This is even more challenging when you have multiple vendors engaged. The various contractors, consultants and stakeholders involved in the project may not deliver to your expectations if they don't fully understand your end goals."

In drug development, a transactional approach may result in:

- Downtime between studies due to the need for knowledge transfer between teams or vendors.
- Loss of historical knowledge.
- Increased time and cost of data handling and sharing, with risks of data loss or misinterpretation.
- Management of multiple vendors: time to research and select vendors, negotiate CDAs/MSAs, agree on legal terms and project scope, contract various work orders and perform vendor audits, etc.
- Missed ability to expedite timelines or take advantage of parallel processing of certain steps.
- Duplication of efforts.
- Handoffs and delays between nonclinical and clinical phases.

And the list goes on.

So, it comes as no surprise that small biopharmaceutical organizations are being driven to explore new organizational options and models. Choosing the right outsourcing model is critical to success. There are many hurdles, opportunities, risks and rewards that need to be considered in outsourcing any drug development function or process.

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When you consider the goals of emerging pharma, it gets even more complex. "There is one primary goal that small biopharmaceutical clients tell us they seek to accomplish," shares Dr. Sausen. "They want to sell or license their molecule to a development partner who can take it the rest of the way to market. However, in order to achieve this goal, biotech companies not only need compelling development data about their molecule, but they also need to make the asset marketable – adding value to successfully entice the right development partner."

On the acquirer side, the bar has been raised by development partners considering co-development scenarios. Partners are getting increasingly selective and putting tougher hurdles in place. "The new acquisition endpoint is moving later into the development journey, with proof of concept, (PoC®) or Phase I and regulatory packages being required in order for molecules to be considered," explains Sausen.

What if you could do drug development differently?

"What if you started with a full roadmap of your drug development journey – right from the get-go?" Suggests Peter. "A complete, well-thought-out plan that mapped the various studies and phases, and included a full articulation of your target product profile, timeline and cost?" This approach would enable you to start with the end in mind, according to Sausen, and could include a strategy and development plan document that you can share with stakeholders, as well as potential investors, partners and other suitors.

"Drug development is undergoing a major transformation in order to align with the new normal – replacing a transactional or just-in-time approach, with strategic programmatic outsourcing," says Dr. Sausen. "This new, programmatic model can better inform, convince and inspire all those involved – investors, stakeholders, drug developers, CROs and potential partners."

The future is available today

"Covance is providing this new programmatic model today," explains Sausen. "We call it Early Phase Development Solutions, and in 2016 nearly six dozen clients are conducting their drug development program under this new model, and experiencing demonstrable time, cost and risk avoidance benefits."

Some of the benefits that Early Phase Development Solutions clients report experiencing include:

- Working with a single, cohesive team of nonclinical, clinical, regulatory and market access experts who contribute to the molecule's development program for the duration of its journey.
- Receiving a singular strategy – a defined target product profile accompanied by a written Global Value Dossier – that enables line of sight to the entire drug development journey from start to desired milestone, improving communications with investors, partners and stakeholders.
- Enabling many opportunities for time savings. For example, a typical timeline for an IND-enabling package can take up to 12 months – something Early Phase Development Solutions has delivered in nearly half that time, on many occasions.
- Interfacing with regulatory experts who advise on ways to parallel multi-country approvals to save time.
- Understanding the market potential of a molecule upfront – information that can be shared with potential buyers or licensors.

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"Sometimes it takes an industry transformational change – such as the migration of early drug development from large pharma to smaller biotech players – to revolutionize the way we work," says Dr. Sausen. "Early Phase Development Solutions provides a real answer to the challenges small biopharmaceutical organizations face today, making it easier, more efficient and productive to create novel drugs."

By Peter Sausen
Partnering 360
October 24, 2016
http://bit.ly/2eLlrSz

To learn more about Early Phase Development Solutions or other drug development solutions designed specifically for the small and emerging biopharmaceutical organization, go to:
www.covance.com/thebioexperience

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