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Episode Guide

Emergence of Alternative Funding Arrangements on Biopharma Clinical Development

- Very expensive to bring a drug to market in terms of time and money (est. $2.6B per drug; 12 years from experimental compound to approval)
- Low chance of success - 1 in 1000 make it into human testing and of those 1 in 8 will be approved
- Emergence of companies with funding and clinical development capabilities which partner with biopharma companies to boost R&D productivity, lower cost and mitigate risks associated with clinical development

Overview on Alternative Funding Entities

- Pharma companies historically would go through externalization programs, out-licensing or spin-outs - they divest the asset, no continuing control on the development, minor financial interest in the asset
- Alternative funding arrangements - pharma company retains the product asset that may have been deprioritized but of still great interest to the company, funding can be supplied by a funding entity
    - Funding entities have the funding to conduct clinical trials - funding from royalty monetization entities, venture capital firms or private equity firms
    - Also have the expertise in terms of people with pharma-related backgrounds

Types of Agreements

- Usually during Phase 2B/Phase 3 programs - strong interest from the pharma company but might not be the biggest priority for them in terms of resources, so the alternative funding entities can come in with funding and expertise and take over the Phase 2B/Phase 3 studies
- There is a split in the level of involvement, decision making and clinical design
    - Pharma companies - need to know that the program and data from the studies will be something they can use in the application for market registration for the product
    - Funding entities - need to know that there is enough certainty for success in the studies and getting the product to market that it is worth the investment
    - Funding entities are investing at risk - paying large sums of money to fund the studies, ROI only comes when the product is launched, reaches the market and they get a portion of the sales
- Pharma company will pick up the product again if there are later Phase 3 studies that need to be done, or during marketing approval registration and launch activities

Due Diligence Done by Alternative Funding Entities

- Used to doing due diligence when providing funding for development stage biotech companies - essentially moving this expertise and applying it to the product opportunity with a pharma company
- Combination of financial due diligence, understanding the markets and actual clinical design due diligence

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Critical Things to Remember When Representing Either Side of These Deals

- Dependent on the obligations of each party
- Funding entity - Do they have the funds? Do they have the expertise to manage a large-scale clinical program? Who can they hire as vendors to do the CRO-related work and what sites can they conduct the trials at?
- Pharma company – Supply obligations for the clinical program, will there be any interruptions? They need to ensure that they will be able to supply the product or their CMO will be able to provide the materials on time for the studies
- Most heavily negotiated part of these types of deals - pharma companies need to define the success criteria of the program that confirms that the funding entity achieved their obligations
    - Pharma company will step up to their obligation to conduct additional clinical studies, get the marketing application filed and get product launched but will only do this if the labeling on product is what they pursued at the beginning of program

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