

Partnering between pharma, biopharma and diagnostics companies - the new deal ?

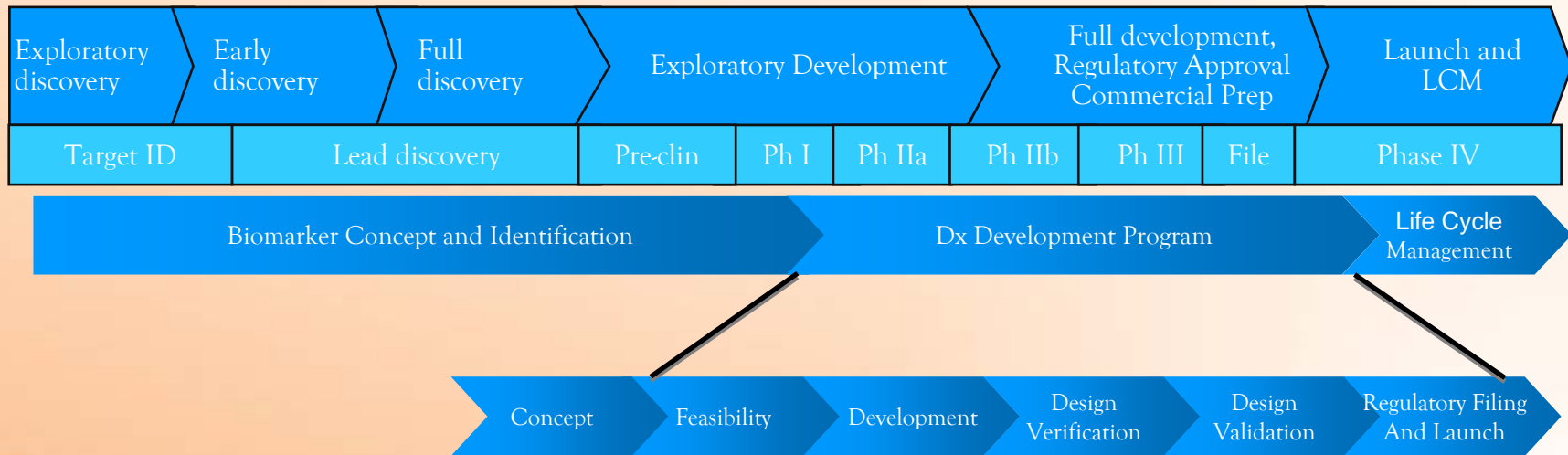
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Cultural Challenges in a RX - DX Collaboration

- Different development & manufacturing processes & timelines
- May not understand each other's issues
- Different language
- Different regulatory paths for independent product approvals, all the more challenging when combined
- Different business models with widely different cost structures
- Different expectations in pricing & reimbursement
- Different customers

Good communications & strong trust
between the partners is essential

Co-Development of RX/DX: Timing is Critical



Factors to consider for the RX partner

- Test quality – analytically & clinically validated
- Timing of Dx availability to coincide with Rx approval/launch
- Easy market access to the Dx where ever the Rx is marketed
- Coordination of messaging to the various customer audiences
- Dx cost should not become a barrier to patient access to the Rx

Additional DX partner Requirements

- Successful track record of innovative Dx product development
- Demonstrated quality manufacturing capabilities
- Regulatory sophistication to deal with complexity of joint product approval pathway
- Instrument platform presence in the global market
- Global distribution access with track record of success

Factors to consider for the DX partner

- Time to develop a collaboration is quite long
- Risk assessment – will the Rx ever make it to market?
- Development costs for a relevant Dx can be prohibitive
- Dx pricing and reimbursement is typically very low compared to the Rx
- Creating a financial win-win arrangement which takes into account the value brought by the Dx to the overall market offering
- Partnership structure should balance potential profit with the level of development risk the Dx partner accepts in the project

Creating Value for Early Stage Diagnostic Companies

Funding for early stage Diagnostic Companies

- Challenging for early stage diagnostic companies to demonstrate value
- Financial models not standard in diagnostic space
- Investment community has a difficult time evaluating value
- Technology and/or content not well developed
- Difficult to find good input from targeted customer base
- Often difficult for large IVD companies to see value
- Stay away from institutional funding until technology is proven and functioning

Value Inflection Points

- Prove technology/content
 - Develop a robust functioning system that actually works with a particular example
 - Clinical utility and validation
 - Demonstrate that product can be manufactured cost effectively
 - Demonstrate that technology can be applied to other markers
 - Biotech should stay away from “prototype” demonstrations and focus on one good example
- Commercialization
 - Have product on Market
 - Key customer support
 - Realized sales

Interest of Large Diagnostic Companies

- Do not have bandwidth to focus on new concepts
- Have a wealth of technologies/content to choose from
- Early technology/content is common and inexpensive
- Look for a strategic fit
- Potential for a pipeline of products
- Need to see some Market traction