



Drug Development in Emerging Companies ...A Virtual Model for the Future

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Historical Approach...Emerging Biotech Companies

- Identify technology
- Raise \$\$\$
- Recruit Discovery and Development staff
- Build infrastructure
 - Lease facilities
 - Outfit labs
- Identify lead candidate
- Race to IND with in house resources at outside vendors
 - Many times managed by inexperienced staff
 - Plans not well conceived
 - Eventually retain several independent consultants

Historical Approach...Emerging BioTech Companies

- Timelines are not aggressive
- Usually plan for 100-200% more cost than necessary to decrease risk
- Plans not integrated across disciplines
- Dollars and drug are wasted
- Clinical plans are the last item to be confirmed
- Milestones and success criteria are not clear
- Plans for interaction with FDA are not well prepared
- Fully Integrated BioPharmaceutical Company (FIBCO) may not be the future for Emerging Companies

Virtually Integrated Drug Development

- No need to recruit highly skilled Drug Development staff
 - Retain them and let them go
 - They must be engaged and committed
- Model for future to conserve cash and API and ensure regulatory success first time
- Investors (VCs, Angels and Pharma) are signing onto this model to protect investments, reduce risk and reduce time to go/nogo decisions
- Retain external firm with broad experience to manage Development and solve scientific issues
 - Staff will have 15-25 years of experience from API chemistry thru Phase 1-Phase 2 POC studies
 - De-risk development programs with experience

Virtually Integrated Drug Development

- Companies must do more with less, on time, right first time, on budget
- Outsourcing to the right partner who understands integrated drug development is essential
- Innovative relationships between sponsors, experts, vendors and investors is pivotal and can return value in risk sharing to sponsor
- Leads to accelerated development strategies and regulatory approvals first time
- Virtually Integrated BioPharmaceutical Company (VIBCO) is a path to success for the future

Virtual Model-Value Proposition

- Assuming NuCo ramp up over 4 years
- Considering only cost incremental to 3 executives and Discovery staff that would be required for insourced vs outsourced model
- Add 7 key Drug Development positions to insourced model over 3 years plus some external consultants
- Assuming incremental office space and associated costs in insourced model

Insourced vs Outsourced Labor (\$000)

	Year 1	Year 2	Year 3	Year 4	Total
Insourced Cost	50	1175	1898	1563	4689
NPV@12%	-	-	-	-	3327
Outsourced Cost	400	400	500	-	1300
NPV@12%	-	-	-	-	925
Cash Differential	-	-	-	-	3389
NPV Differential	-	-	-	-	2402

Comparable Costs to Deliver Phase 1 Data
Getting it Done Well the First Time is a Value Proposition

Aptuit Consulting Inc.

- Virtual partner in Development of small molecules, proteins, peptides, cell based therapies and vaccines
- Meet our staff on the web site:
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bricks and mortar vs virtual

bricks and mortar

- Greater flexibility for biology/pharmacology
 - inherently harder to contract out/distantly manage than chemistry, ADME/PK, toxicology that are more 'SOP' driven
 - even medchem (with apologies) can be more easily 'managed' at a distance than biology
- Less (valid) travel!
- Currently it is easier to staff a FIBCO
 - many (most?) technical people are not prepared for the virtual model
 - need to be able to 'walk into the lab'

virtual

- Potential for better skill fit
 - work with the right expertise out-side as opposed to the tendency to go with the expertise you have in-side
 - contract labs/academia are rapidly evolving to support the virtual model
- Less 'management' and logistical issues allowing more focus on moving a project forward
- Cheaper costs-
 - employees, support staff, bricks and mortar
 - more expense per task- but no down time
- Potential for shorter timelines
 - inherently fewer people making decisions

trigger points: FIBCO vs VIBCO

- its all about money, speed and ideas
 - some ideas necessitate a complexity of technology and iteration that require bricks and mortar
- its all about talent and opportunity

Measure success: FIBCO vs VIBCO

- success should be the same and dictated by the strategic goals of the company
 - successful phase I
 - successful phase II
 - successful phase III
 - etc.
- what about contract ex-US?
 - France, Austria, India, Finland, Sweden, Chile, UK...

Consultants

- Don't try this alone!
- Serious problems are often times more logically (calmly) viewed and solved with outside help
 - but don't wait until you have a problem
- Develop a trusting/working relationship- 'call anytime- including weekends' approach
 - I have a problem- help! (please)
- For the more routine assignments:
 - eg design and manage a tox study, tissue distribution study, safety study
 - clearly establish scope and level of detail
 - establish right level of communication
- Don't think your responsibilities are complete once the assignment is made