



Virtual/Accelerated Drug Development

A better approach to product development!

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What is Virtual Drug Development?

Virtual drug development (VDD) is a business model that refers to the practice of outsourcing all stages of the drug product life-cycle.

Objective – choose and manage outsourced product development activities

Internal

Staff program managers - *(typical)*

External Models

Single Consultants - *(outside, typical)*

Integrated group of consultants *(advanced)*

Consultant Agents – *(most advanced, combines integrated consulting with an advanced business model)*

What is Accelerated Drug Development?

Accelerated drug development (ADD) is a process in which approvable regulatory milestones (IND, NDA etc) are reached in the shortest possible time with the least resources.

What is meant by ADD

Three factors that have the most impact on product development speed and efficiency

white-space – *(Biggest!)*

reservations – *(Critical)*

eSub – *(Overlooked)*

Can ADD and VDD be combined?

(+) Yes, but only if you have control over the resources needed to complete the task

(+) It happens all the time in big pharma

(-) In smaller companies integration of resources is problematic

(-) Independent Virtual staff lack a common culture, purpose and interest in the client.

Drug development is a REGULATED RESEARCH activity!!

What is involved in drug development?

Creation of drug substance

Preclinical characterization of drug substance.

Creation of drug product

Clinical characterization of drug product

Interaction with regulatory authorities.

Many vendors involved

Preclinical

DS supply (API)
DP supply
Genotoxicity
Toxicology
Safety Pharmacology
Repro toxicity
Carcinogenicity
Bioanalytical services
Histopathology services

Clinical

Site Selection
IRBs
Regulatory
Enrollment specialists
Clinical investigators
Clinical laboratories
Monitors
Data management
Statistics/Reporting

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What is a VDD, Agent?

"A combined consulting/business arrangement"

As a Consultant:

- Consultants act as staff (*as usual*)
- Integrated group of consultants (*same firm*)
- Unbiased group of expert drug developers

As an Agent: - (*Consultants assumes*)

- scientific responsibility
- legal responsibility
- fiduciary responsibility (*accounting*)

This is a business model for management of outsourced drug development in which the consultant acts as an Agent of the sponsor, with assigned scientific, legal and fiduciary responsibilities for a project.

The Agent Concept

A relationship in which the Agent (*consultant*) is empowered to:

- *find and vet the required resources*
- *negotiate contracts under purchasing rules*
- *sign contracts*
- *monitor performance to contract specifications*
- *accept and approve invoices*
- *pay vendor invoices, (send single invoice to sponsor)*

The Agent Concept

Leaves the sponsor free from having to..

- incur legal expenses to approve contracts
- monitor vendors
- track payments, and
- make multiple payments to vendors

Advantages to the sponsor are ..

- frees up management time
- allows more time to raise funds for company survival
- a single product development contract for everything!

Sponsor/Agent relationship is based on:

frequent, meaningful, complete communications

use of modern communication tools, webinars, teleconferences, videoconferences, portals etc.

verbal agreement on matters of substance

a common goal to achieve a well defined end point such as a IND, NDA etc.

**The only incentive the Agent has is it's fee without bonuses.
The sponsor saves the time and money.**

Agent Time Scales

Two time-scale scenarios:

open-ended (*no time constraints*)

fixed (*unusual*)

- most efficient, (*reduces the most white-space*)
- easy to understand,
- easy to budget,
- more difficult to control than the open-ended time-scale.

What are the characteristic features and benefits of a Virtual Drug Development Agent

- a group of expert drug developers (6 or more depending on stage of development)
- who are real people that exist anywhere but your place
- who communicate instantly via modern communication processes
- who are responsible for devising a strategy that works, managing its execution

People

- experience, 20 plus years of drug development experience
- therapeutic generalists, expert in regulatory strategies
- experts in some scientific discipline (toxicology etc)

Finances

- fixed fee or hourly charges
- no overhead
- no legal and accounting charges

Time

- tracked
- time scales known up front
- compressed compared to traditional programs

Benefits

- a highly experienced partner whose business is service
- motivated to achieve milestones (payments)
- an independent 3rd party (preconceived notions or vendors)
- does not require investment in “bricks and mortar” or staff
- flexibility to adapt to rapidly changing priorities
- access to innovative ideas/emerging technologies (not available internally)
- better insight into changing regulatory initiatives (EU Clinical Trial Directive)
- finances
 - Cost effective - pay fixed fee or only for time used
 - Easier to budget
 - > % of funds raised are used for R&D costs, not overhead



Examples

Development Team Model - ASSUMPTIONS

Internal Team Model Project Timing:

- hire and build team in first 12 - 18 months before development can begin
- file IND during 30th month
- begin 9 Month Phase I Trial after IND filing
- complete Phase I Trial

Total Time = **39 Months**

Virtual Team Model Project Timing:

- retain virtual drug development team - begins development immediately
- file IND during 18th month
- begin 9 Month Phase I Trial after IND filing
- complete Phase I Trial

Total Time = **27 months**

Note:

Both scenarios include key executive team and exclude lab and CRO costs which would be incurred regardless of the development team model chosen.

Virtual vs Internal Drug Development Team Cost Comparison

	Year 1	Year 2	Year 3	Year 4	Total
INTERNAL TEAM MODEL					
Internal Team (excluding 3 key executives)					
Total Internal Team Cost	\$ -	\$ 720,000	\$1,440,000	\$ 1,440,000	\$3,600,000
Total Supplemental Consultant Team Cost	\$0	\$262,500	\$393,750	\$65,625	\$ 721,875
Depreciation Expense - 3 Year Life	\$0	(\$5,833)	(\$8,167)	(\$8,167)	\$ (22,167)
Recruitment Cost	\$0	\$120,000	\$0	\$0	\$ 120,000
Office Lease Incremental Cost	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 200,000
INTERNAL TEAM PRE-TAX CASH COST	\$ 50,000	\$ 1,175,833	\$1,898,917	\$ 1,563,792	\$4,688,542
NPV @ 12%					\$3,327,439
VIRTUAL TEAM MODEL					
VIRTUAL TEAM PRE-TAX CASH COST	\$ 400,000	\$ 400,000	\$ 200,000	\$ -	\$1,000,000
NPV @ 12%					\$818,376
CASH COST DIFF BETWEEN MODELS	\$(350,000)	\$ 775,833	\$1,698,917	\$ 1,563,792	\$3,688,542
NPV SAVINGS OF VIRTUAL TEAM MODEL					\$2,509,063

Problem: a firm needed a development team

What they got was:

- integrated team from the same organization
- 150 years of drug development expertise
- access to development resources
- reduced white-space
- no need for legal or accounting staff
- one all-inclusive payment per month

Advantages with Virtual Drug Development Agent

- Quicker start and earlier completion...
The internal team model can take up to 18 months to hire and build a team and then 18 months to develop the product. A virtual team can start development in month 1.
- No overhead burden at the end of the project.
You only pay for what you need when you need it.
- Consultants often recommend talented staff to join the company.
- Hire experienced staff later when you have proven milestones.
- Allow executives to focus on the next financing round and running the company versus managing staff and development details.



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