STRATEGIC CLIENT-CRO COLLABORATIONS AND SHARED RISK PROJECTS

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STRATEGIC COLLABORATIONS AND SHARED RISK

⇒ Introduction and Overview

⇒ Characteristics of Successful Strategic Collaborations

- Seven Key Concepts
- Three Rules
- Six Questions

⇒ Business Models

- Success Based Arrangements
- Equity for Services
- Equity Investment / Co-Investment for Service Portfolio Commitment

⇒ Examples, Successes, and Lessons
STRATEGIC COLLABORATIONS AND SHARED RISK

DEFINITIONS

A Strategic Collaboration is a process of identifying long-term overall aims and interests and the means of achieving them; through the action or process of working with someone to produce or create something.

- in the process of identifying long-term or overall aims and interests, and the means of achieving them; through the action or process of working together with a shared-risk partner to produce or create the commercial success.

So: Risk-sharing requires participation of all parties in both the costs and benefits of commercial success for a business partnership - the Strategic Collaboration.

- Risk Sharing partnership is a business partnership in which consequential costs and benefits are distributed amongst all participating partners. In doing so, partners rely on the commercial success of the business to receive part or all of their share of financial benefit from the enterprise while reducing the risk of loss involved if the enterprise loses money.
STRATEGIC COLLABORATIONS AND SHARED RISK

What Risks Can Your CRO Help With?

✓ Discovery Risk
✓ Development Risk
✓ Regulatory Risk
-/+ Commercial Risk
STRATEGIC COLLABORATIONS AND SHARED RISK

**The Pharma Model**

**STRENGTHS**

- Sharing both Risk and Value
- Focus on Life-cycle Valuation
- Intention is to Avoid NIH Bias
- Focus on Three Key Drivers: Innovation, Capital, Resources
- Flexible Deal Structures (Business Models)
- Pre-agreed Exits Values or First Option Rights

**WEAKNESSES**

- Special Lilly LP Rights
- Bias for Lilly-inspired Projects in Practice (GER&D, CBD, CBIF)
- Innovation Funnel Not Sufficiently Broad
- Development Heavily Dependent on CHORUS and service network - less time/capital efficient - capacity bottleneck

Nonetheless, Lilly’s initiatives – OID², PD², TD², CHORUS, Lilly Ventures and Mirror Funds are pioneering in shared-risk drug development.
STRATEGIC COLLABORATIONS AND SHARED RISK

Seven Key Concepts

1) Why - greater access to capacity, expertise, and capital

2) Both cost and value sharing

3) Broad collaboration to enable risk sharing discussions — not functional outsourcing

4) Long-term focus beyond the task at hand — must invest in joint planning and collaborative governance

5) Ongoing commitment of time, and valuation over the lifecycle of the program and anticipated products

6) Clear expectations on all sides, and processes for communicating, addressing and resolving differences

7) shared risk -> shared decision-making -> shared governance

SHARED RISK || GOVERNANCE || VALUE
STRATEGIC COLLABORATIONS AND SHARED RISK

ONE MIND

This

Not This

CRO

CLIENT

Left and right brain must work together

analytical
logical
precise
repetitive
organized
details
scientific
detached
literal
sequential

creative
imaginative
general
intuitive
conceptual
big picture
heuristic
empathetic
figurative
irregular

LEFT HEMISPHERE VS. RIGHT HEMISPHERE

TORREY PINES INVESTMENT
STRATEGIC COLLABORATIONS AND SHARED RISK

Three Rules

1) **Genuine Risk Sharing**
   - To avoid moral hazard, everyone must have skin in the game
   - Your sunk costs don’t count

2) **CROs can rarely be your lead investor**
   - CROs must cover their direct project costs from project revenue.
   - In general, CROs can only risk share their margin.

3) **CROs generally cannot fund your SG&A**
   - The CRO’s at-risk share comes from their margin

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**Client Cost Stack**

<table>
<thead>
<tr>
<th>Project A</th>
<th>Project B</th>
<th>Project C</th>
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<tbody>
<tr>
<td>Sales, General &amp; Administration</td>
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**Funding Stack**

- CRO At-Risk
- Capital Providers
- Founders
- Direct Project Cost

**CRO Cost Stack**

- CRO Margin
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Six Questions

1) Is your project/platform scientifically sound and commercially tractable?

2) Where (at what stage) is the project/platform today?

3) What are the program’s value infection points? and how big are they?

4) What resources are required to realize each value inflection?  
   - Talent, Time, Capital

5) What resources do you have in hand, and what do you need?

6) What are you prepared to give in return for needed resources?
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Shared Risk Business Models

*Risk Sharing Is Not Discounting* – key concept #2

- - > requires **both** cost and value sharing  < - -

- Success Based Arrangements
- Equity for Services
- Equity Investment / Co-Investment for Service Portfolio Commitment
STRATEGIC COLLABORATIONS AND SHARED RISK

Shared Risk Business Models

• Success Based Arrangements
  - basic R&D expenses are reimbursed by the Client
  - CRO’s profit (margin) is based on outcomes
  - many variations of this model
  - may also have attractive Balance Sheet and P&L impacts
Shared Risk Business Models

• Equity for Services

- Rarely, if ever, a cashless transaction; see Rule #3 (margin)
- equity might take the form of options, warrants, or restricted stock

- future economic interests in liquidity events

- can provide equity-like interests to the CRO, without the Client relinquishing control

- these models demand participatory decision-making
Shared Risk Business Models

- **Equity Investment / Co-Investment for Service Portfolio Commitment**
  - Strategic investment by a Capital Partner
  - All the characteristics of Equity Investment
  - Capital partner’s de-risking strategies include execution by a trusted Service Partner (CRO)
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New Developments and Variations in Risk Sharing

• Venture with Strategic Partner, Strategic First Option Rights, Pre-agreed Venture Terms and Exit Multiples
  – GSK + Avalon; similar to Lilly model with refinements

• Strategic and VC Joint Investment Agreements
  – Lilly model; HealthCare Ventures IX

• Equity for Services
  – Afraxis + ChemDiv/ successful
  - EnVivo + ChemDiv / not successful

• $30M Joint Ventures of Strategic, Venture, Academic Partners
  – Janssen and Torrey Pines’ Russian venture subsidiary, academic R&D scouting by MIPT BioPharma Cluster Northern

• $40M Joint Venture with BioMotiv
  Harrington Discovery Institute @ University Hospitals Case Medical Center for academic/precommercial research programs
STRATEGIC COLLABORATIONS AND SHARED RISK

New Developments and Variations in Risk Sharing

• Virtual biotech SPE for Pharma asset development, with/without Economic Development funding match, embedded service organization commitments – Roche (Viriom, TeaRX); Redox, Agenus, Janssen (NewVac); Pfizer, Dompe (SatRx), others. More in development.

• BioIncubators - ChemRar HTC, BioPharma Cluster Northern (MIPT), US West Coast, Boston area, state & local efforts

• Economic Development Funding (state, national, provincial) teamed as above

• Early stage university out-license for commercial feasibility assessment
  - minimal front $, R&D support for inventor’s lab, and larger academic share of milestones and royalties
  - R&D-only license with first option right for commercial license to IP
  - developed IP owned by university upon license expiry

• Academic scouting for new targets & strategies – AZ + Tufts
Specialized CRO Platforms

Bio-Pharma Investments

ChemDiv

CRI/CHEMRAR

CITOLEX

PRUDENTAS

Dialog Intellectual

DRUGS TECHNOLOGY

first line

PHARM SLAVL

TORREY PINES INVESTMENT

Health Care Ventures IX

afraxis

avineuro

TeaRx

Bio Integrator

RecoveryX

Virion

AVIonco

AVIRON