



Business Development Fundamentals

Process & Management of Strategic Alliances

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Topics to be covered

- Role of business development in strategic alliances
- Process: Establishing a strategic alliance
- Why partner? When to partner? The build, buy or ally hierarchy
- Representative deal approaches
- Recent deal trends



Role of business development in strategic alliances



Lets first define the term “Strategic Alliance”

- A structured strategic collaboration between two or more organizations, with the aim to achieve an agreed upon result neither of the partners can reasonably or easily achieve alone
- This form of cooperation encompasses a variety of transaction types ranging from straight out-licensing to mergers and acquisitions



Business Development Fundamentals

Strategic need for business development

Create optionality and long-term value at each stage of a company's life cycle





Business development in strategic alliances

What is optionality? What is long-term value?

“Optionality”

To create value for an organization by enabling pursuit of *multiple* opportunities, whether products or deals, which would be high-risk on a stand alone basis, but mitigated in combination

“Long-term Value”

To create value for an organization by enabling strategic alliances that offer sustained capital, prestige, or anything else a company seeks in order to grow and persist indefinitely

Business development ≠ “get-rich-quick” schemes



Business Development Fundamentals

Business development in strategic alliances

Wear multiple hats

Before Signing the Deal



Network



Strategy



Sales



Scout



Diligence



Negotiator



Financial

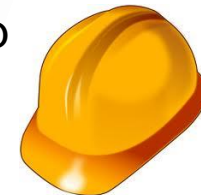
After Signing the Deal



Relationship



Contract



Amendments




Business Development Fundamentals

Fundamental elements of business development *Strategy and networking first, then execution*

STRATEGY

- What opportunities to pursue to create optionality and long-term value?
- When and how to pursue?
- How to prioritize best ones?
- What deal types make the most sense and why?
- How to pitch product or idea of partnership?
- Who are the targets? Why?
- How to access?

A bright yellow, multi-pointed starburst graphic with a black outline, containing text. It is positioned in the center of the slide, overlapping the two main content boxes.

“Winners” are systematically networked into the partners that matter and ready to seize a transformational opportunity when available

NETWORKING

- Crucial factor in getting in the door and keeping it open to facilitate a deal
- Increase visibility of organization, value proposition of product, or deal idea
- Investigate unmet needs
- Identify structure of decision making; connect dots
- Understand company culture and develop relationships on the inside



Business Development Fundamentals

Strategy and networking are the starting points

The “BD role” is a continuum of activities to close and manage a deal

Strategy & Networking

Scouting or Sales

Diligence

Negotiations



Alliance management

- See previous slide

- Sourcing or selling product(s) or deal idea(s) in accordance with strategy

- Coordinating technical and other diligence
- Deal valuation
- Business case or go/no-go recommendation
- High-level “buy-in”

- Negotiations: term sheets and contract
- Identify and resolve key issues, early if possible
- Drive process and maintain momentum

- See Michael Young’s slides

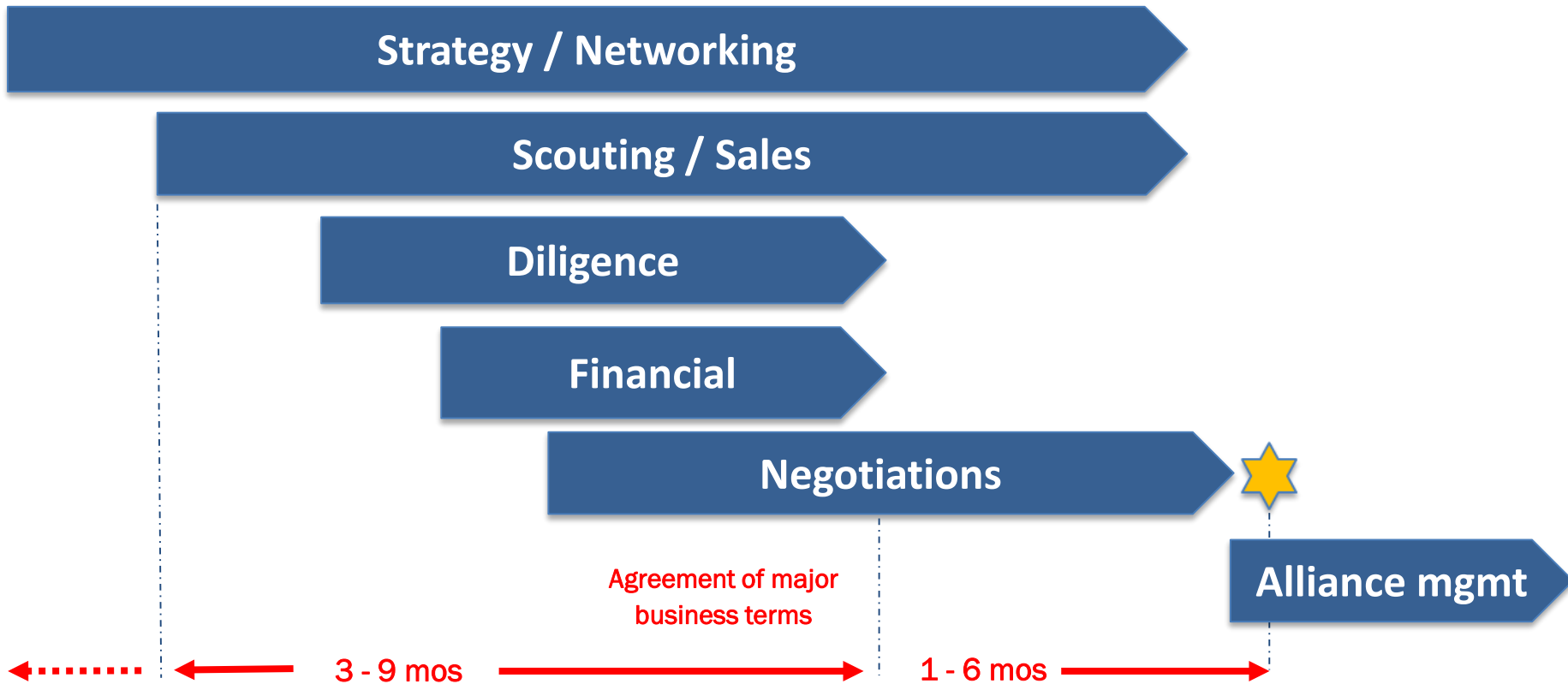


Process: Establishing a strategic alliance



Business Development Fundamentals

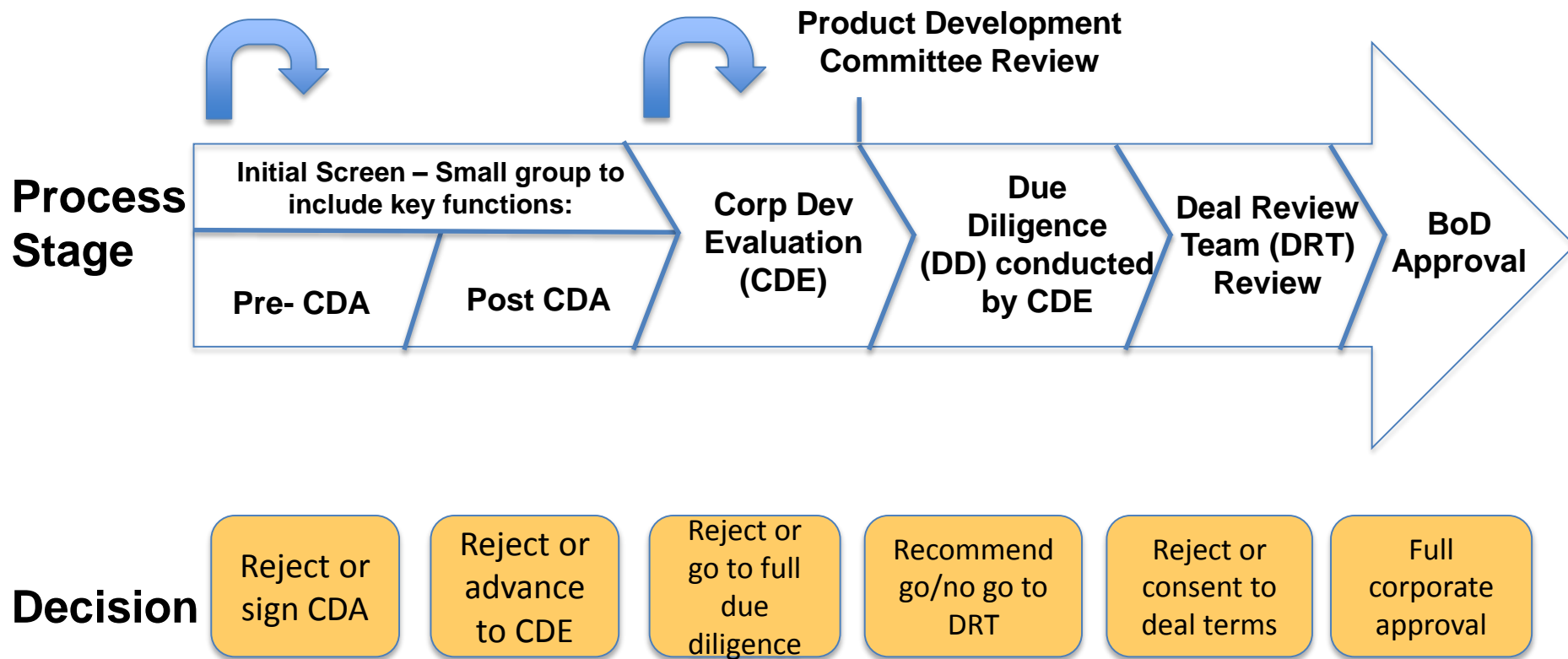
In reality, the process is not linear





Business Development Fundamentals

Partner's internal process





What is “Due Diligence”?

- Due diligence is the potential partner’s process of “getting under the hood” of your company/program
- Due diligence will be performed on several different fronts
 - Intellectual property
 - Technical (Science, Compound, Facilities)
 - Legal
 - Financial
- Due diligence is perhaps the key to the entire process
 - It shows both your ability to be prepared and professional as well as that of the potential partner
 - Learn from it
 - Do not become defensive
 - Be very responsive



Business Development Fundamentals

Staging access to due diligence documents

Out-licensing

Non-confidential

- Non-confidential document
- Publications and posters
- Published patents

Confidential

Stage 1

- Management Presentation
- Non-Clinical Reports (Pharmacology, Toxicology/Toxico-kinetics & PK/ADME)
- Regulatory Files (IB)
- Clinical Study Results & Reports (including data tables & listings)

Stage 2

- Ad-Hoc Presentations
- Regulatory Files (IND, Amendments, CTA, IMPD, Annual Reports, Correspondence & Safety Reports)
- Key CMC Reports (Upstream, Downstream, Formulation, Fill/Finish and Analytical)
- Patents (Additional information not available publicly, e.g., interference decisions, court proceedings, etc.)

Stage 3

- Raw data
- Contracts (applicable 3rd party agreements)

Upon significant progress during term sheet negotiations

Upon receipt of an acceptable term sheet



Due Diligence – Addressing Q&As

Out-licensing

- Ask the potential partner for a list of questions and documents in order to prepare
- Develop written answers to provide ahead of a call or visit
- *Convene your team AHEAD of time*
 - Discuss what each person's assignment will be
 - Are there any "off-limit" topics?
 - Answer only the questions asked
 - Encourage them to stick to the facts that they can back-up with evidence
- Tell your team members that it is better to say "I don't know" or to come get you if they don't know whether they should answer



Due Diligence – Hosting Site Visits

Out-licensing

- YOU are in charge
- Prepare an agenda (organize ad hoc presentations if needed)
- Have internal experts on call at all times
- Utilize it as an opportunity to build the longer-term relationship
- Make sure the labs are cleaned and offices are organized (if their team will be visiting any offices)
- Make sure all white-boards are clean and the meeting room doesn't have any left over notes on tables or shelves
- Make sure you and they understand your policy on copies of documents being removed from the building
- Check on progress but don't hover around your guests

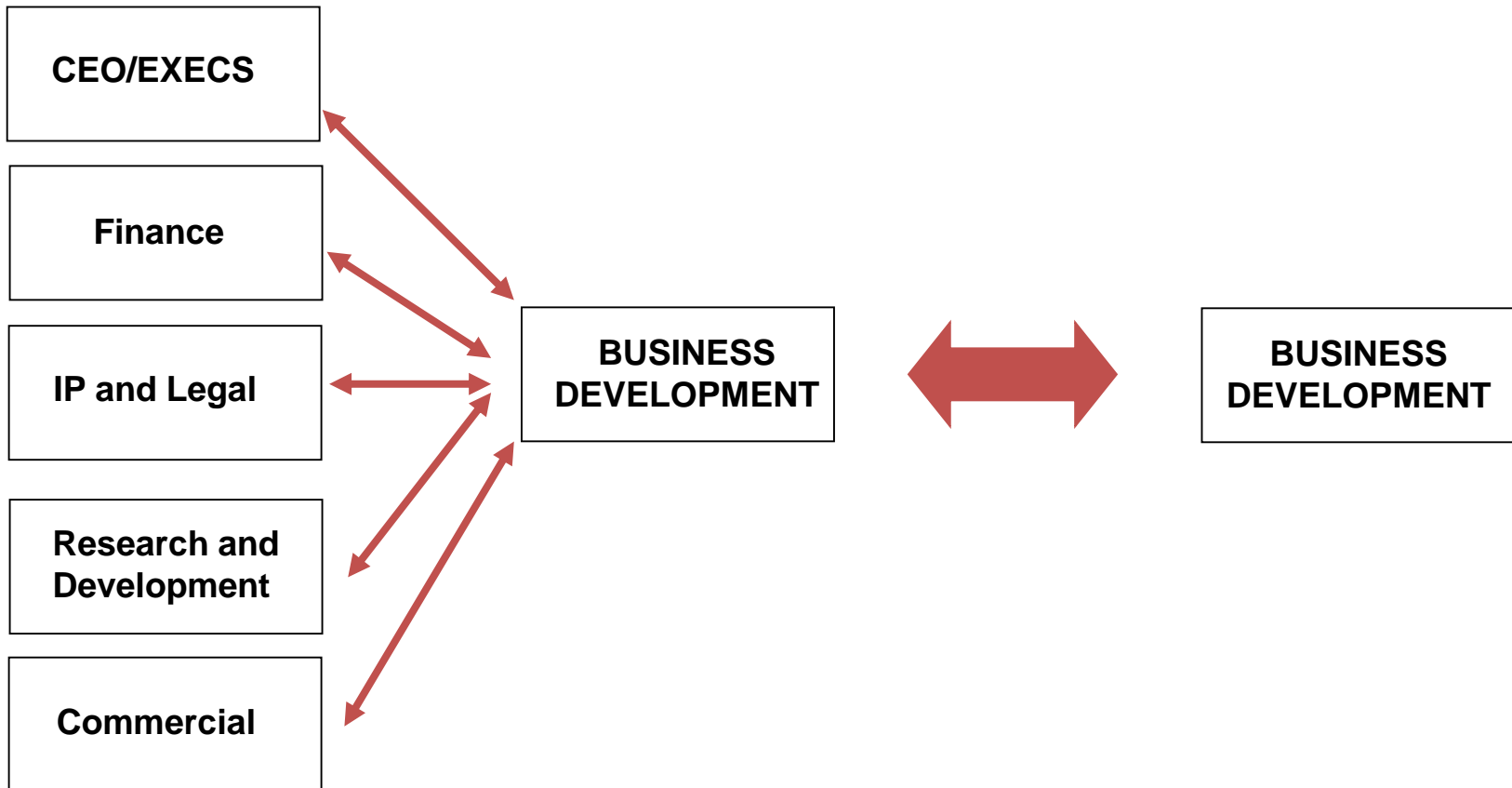


Business Development Fundamentals

Process-specific communications: The OLD way

Internal Team

Partner

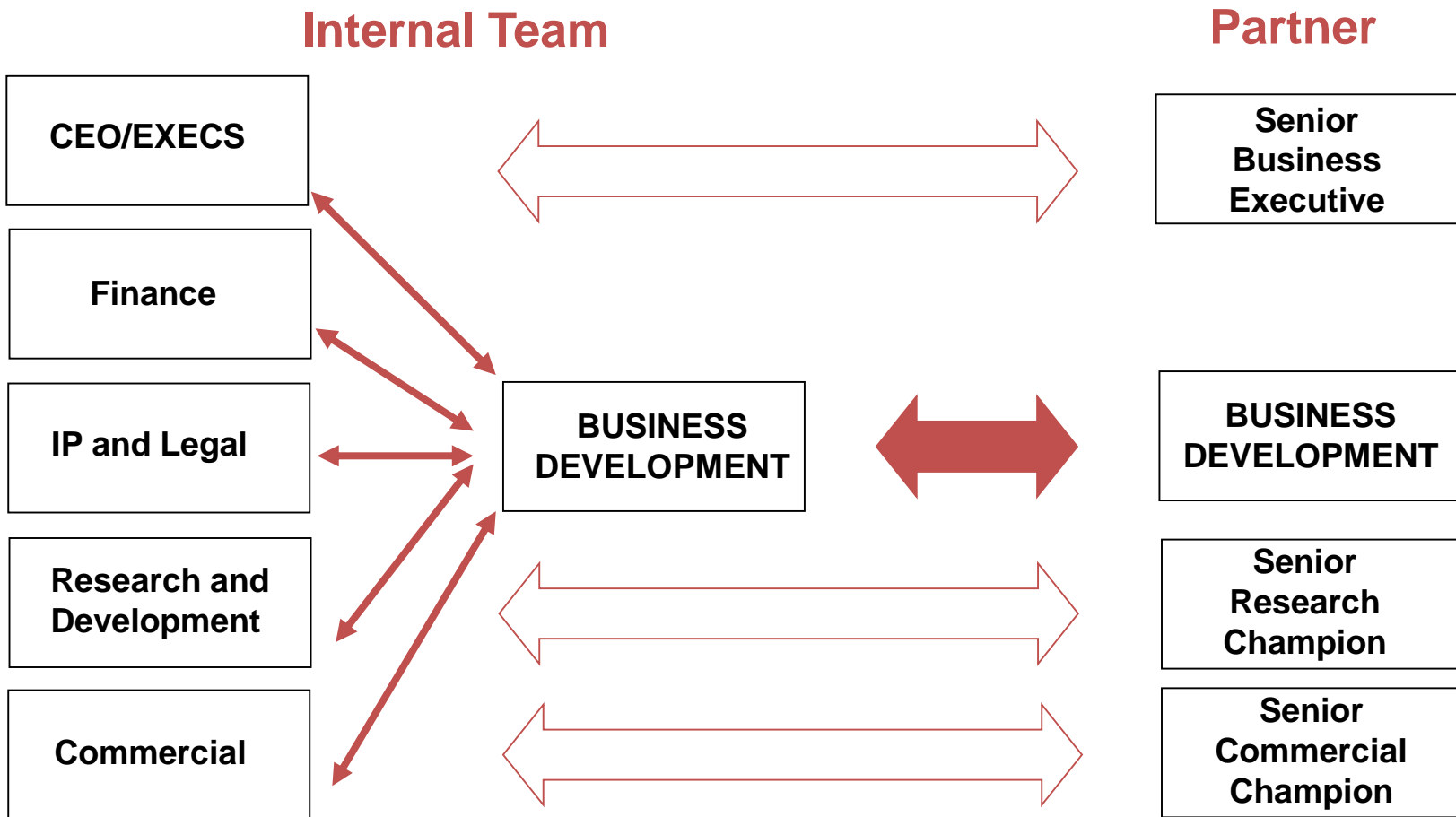




Business Development Fundamentals

Process-specific communications: The RIGHT way

Establish mechanisms to facilitate relationships without losing a coordinated message





Internal corporate objectives and planning

Out-licensing

- Weighting of purposes is important
 - Cash vs. capabilities (R&D and/or commercial)
- Define the market opportunity – be realistic, ask experts
 - Elaborate the commercial potential
 - Understand the competition, potential differentiators
 - Develop a financial model and understand how changing the numbers changes the profit sharing between licensor and licensee
- Benchmark potential deals and deal terms
- Create a communication plan within the company for a coordinated message
- Identify potential partners
 - Rolodex and conferences
 - NOT “blast e-mail” solicitations!



Components that are early in the process

Out-licensing

- Outreach: leverage existing relationships; build interest and new relationships
- Prepare and utilize non-confidential package in initial outreach
 - Have all relevant publications, posters, published patents, etc. ready in form to send out upon request so your partners don't have to track them down
- Negotiate a CDA quickly and efficiently
- Prepare confidential management presentation
 - Pre-clinical and clinical data; estimated development plan
 - Commercial opportunity
 - Try to anticipate the questions
- Be careful with really sensitive stuff (e.g. disclose compound structures until the deal is actually close to signing!)
- Rough term sheet discussions can occur (very rough)
 - Think in terms of structure, not the numbers (not yet!)



Components that are in the middle of the process *Out-licensing*

- Build the relationship
- MTA (if a “taste spoon” is appropriate)
 - This should be done quickly but carefully if a deal is contingent upon the outcome of experiments
- Detailed due diligence
- Negotiating non-binding term sheet(s)
- Sell the deal internally to management, BOD, and investors
 - Get clarity on deal-stopper issues
- Manage to a short list of issues
 - Ideally the non-binding term sheet is agreed to in full by the end of this process (subject to completion of due diligence and executive management approval)
- Coordinate any research, development or commercialization plans that need to accompany the contract



Components that are late in the process

Out-licensing

- Build the relationship
- Finalize diligence
 - This would include assuring that the patent ownership or registration is correct and valid
 - Providing final scientific updates if the process has taken a long time
- Negotiate the contract
- Refine the research, development or commercialization plans
- Final approvals
 - BOD, investors and/or shareholders
- **CLOSE the deal**
- Formal “hand-off” to alliance management

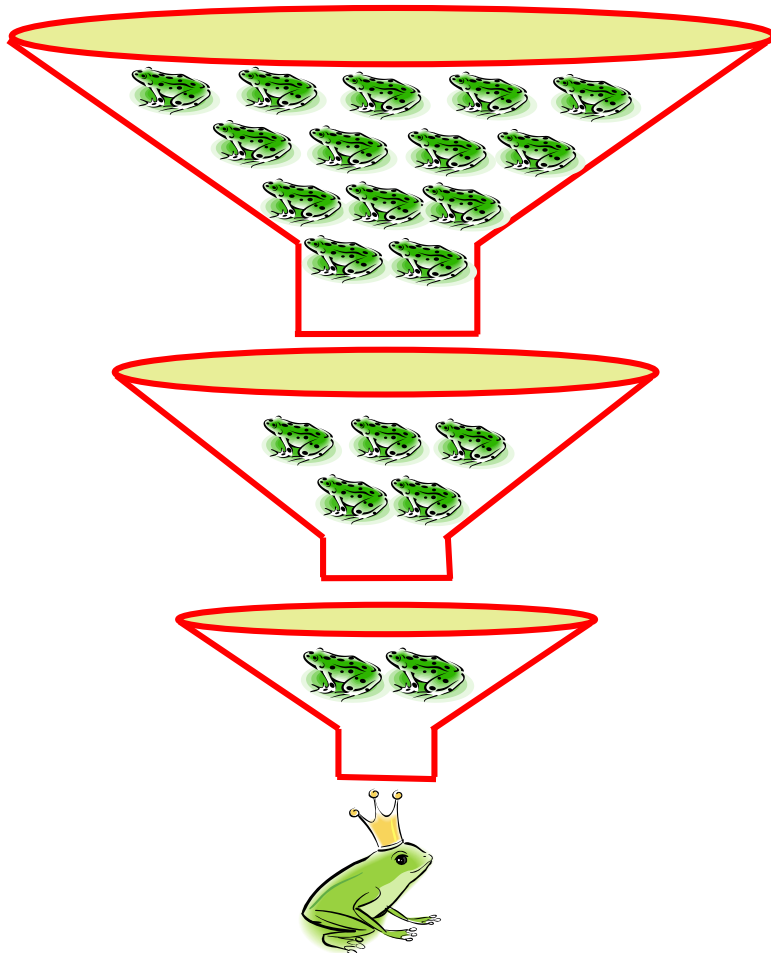


Formal deal process

- A formal deal process (or auction) with deadlines for key activities, such as term sheets & diligence, can help drive competition that will maximize deal value and speed time to close
- Not all deals are well suited
 - Need true competition for the asset – 4 or more potential partners moving forward with serious discussions
- Do not declare a process prematurely
- A failed process (no one meeting the deadlines you impose) is much worse than not having one at all
 - Make sure to be realistic in timeframes
 - Communicate clearly & consistently



You have to kiss a lot of frogs to find the prince



- 20+ target companies contacted
- 2-5 initial non-confidential meetings/phone calls per company

- 10+ Confidential Disclosure Agreements
- 2-4 confidential scientific meetings per company
- 5+ companies conduct due diligence
- 8-15 due diligence discussions/meetings/ updates per company including IP diligence

- 5 term sheets
- 5-10 negotiation sessions per term sheet
- 10-15 negotiation sessions for contract

- Numerous substantive interactions
- Multiple points of attrition



Ultimately, deal success relies on multiple factors

“Quantitative”

- Technical strength (data, MOA)
- Revolutionary v. novel v. evolutionary
- Stage of development and scope
- Superiority over competitors
- Commercial opportunity
- Intellectual property
- Type of deal and structure

“Qualitative”

- Relationship and trust
- Organized diligence process
- Quality of management and scientists
- Quality of business and investors
- Market forces and trends
- Savvy negotiating skills
- Flexibility in negotiations



Business Development Fundamentals

**Why partner? When to partner?
The build, buy, or ally hierarchy**

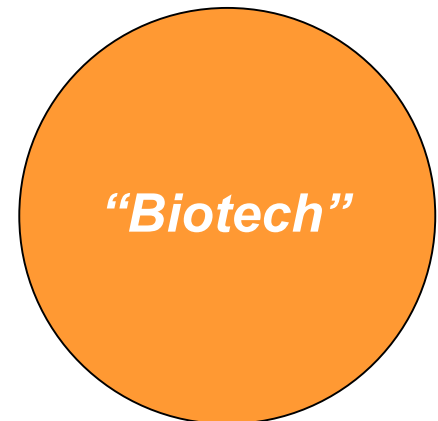


Business Development Fundamentals

Why consider partnering?



- Cash
- Development Scope
- Commercial Skills
- Share risk
- Technology validation



- Technical Skills
- Product Candidates
- Speed
- Innovation



Business Development Fundamentals

Value for the “Buyer”

- New product candidates
- New technologies (innovation)
 - Discovery
 - Development
- IP/Know-how
- Catalyst for change
 - Challenge internal capabilities
 - Speed
 - Decision making

Value for the “Seller”

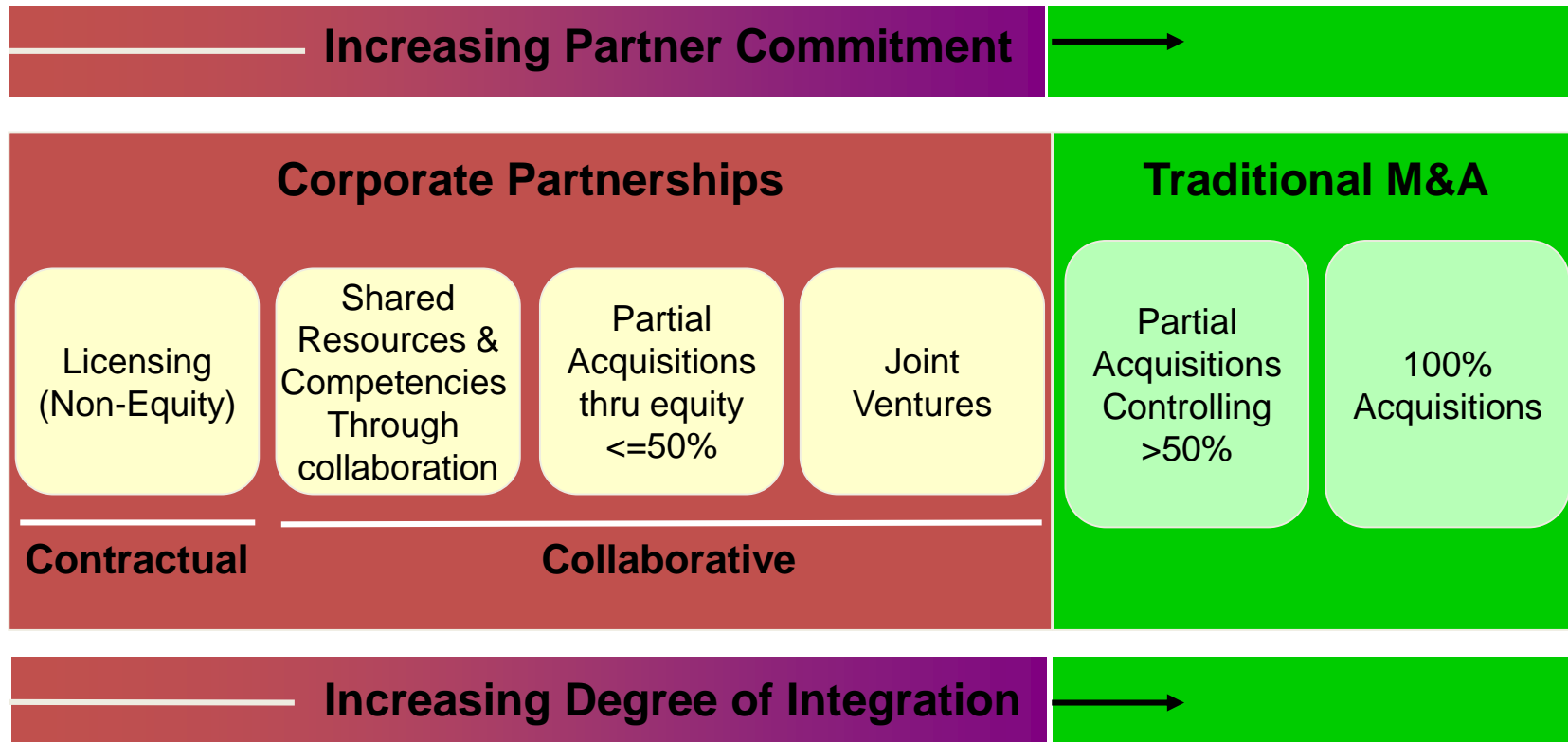
- Cash
- Ability to advance technology platform
- Ability to develop technology or therapeutic
- Ability to commercialize technology or therapeutic
- Underwrite development of infrastructure
- Market “validation”



Business Development Fundamentals

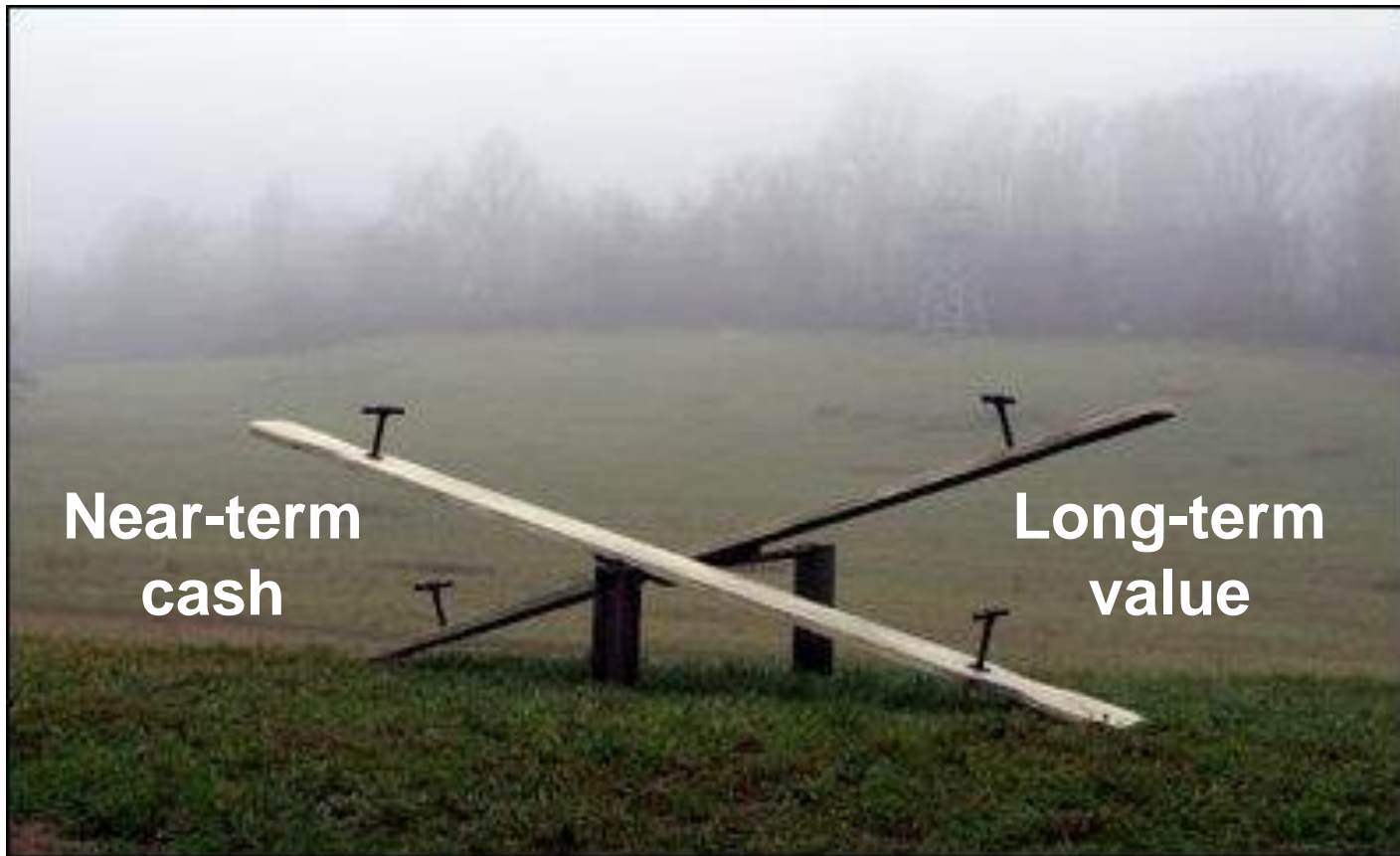
Partnerships come in a variety of forms

Unique dynamic between the buyer and seller in each





The challenge



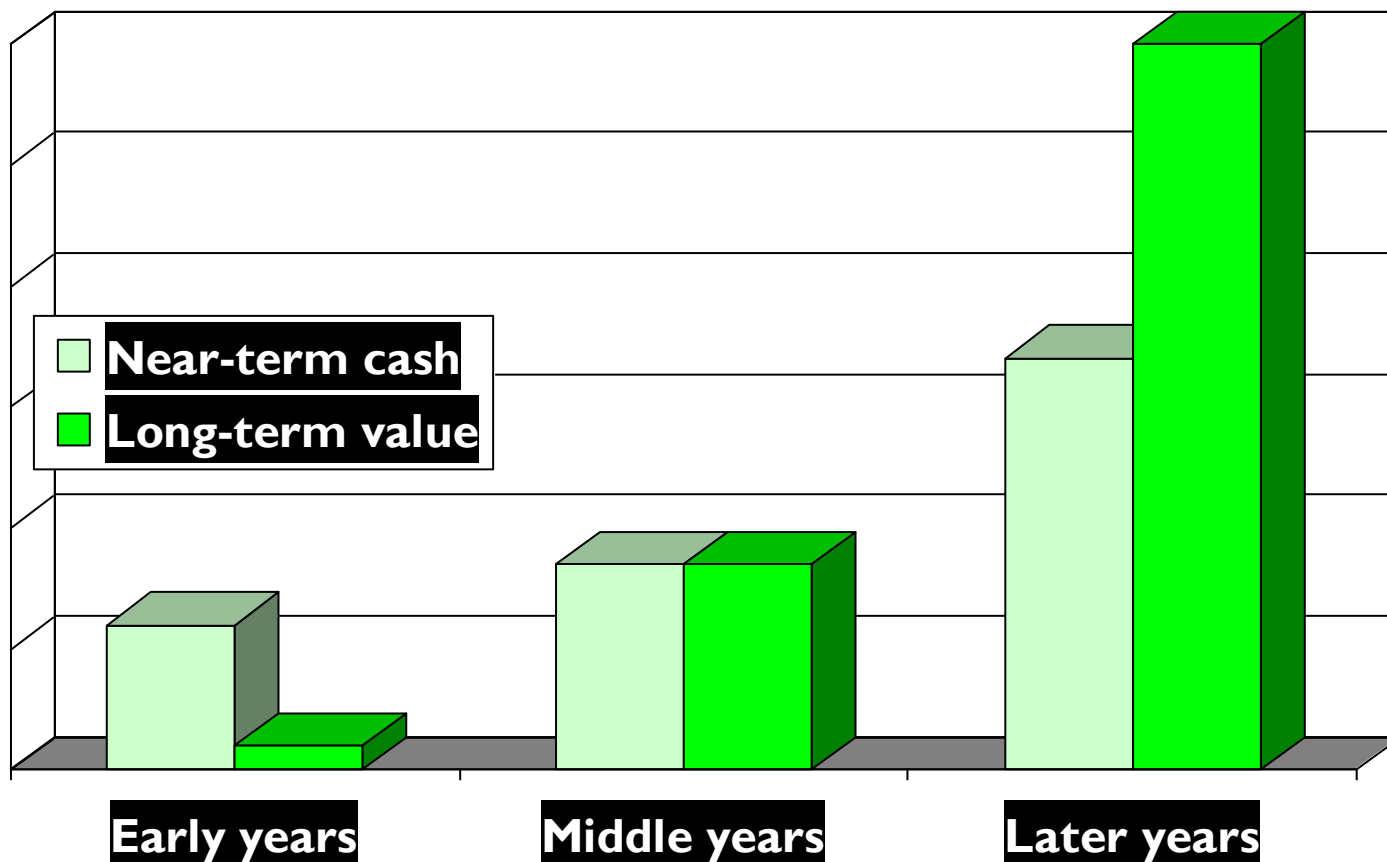
**Essential in
early years**

**Essential to attract and
keep investors**



Business Development Fundamentals

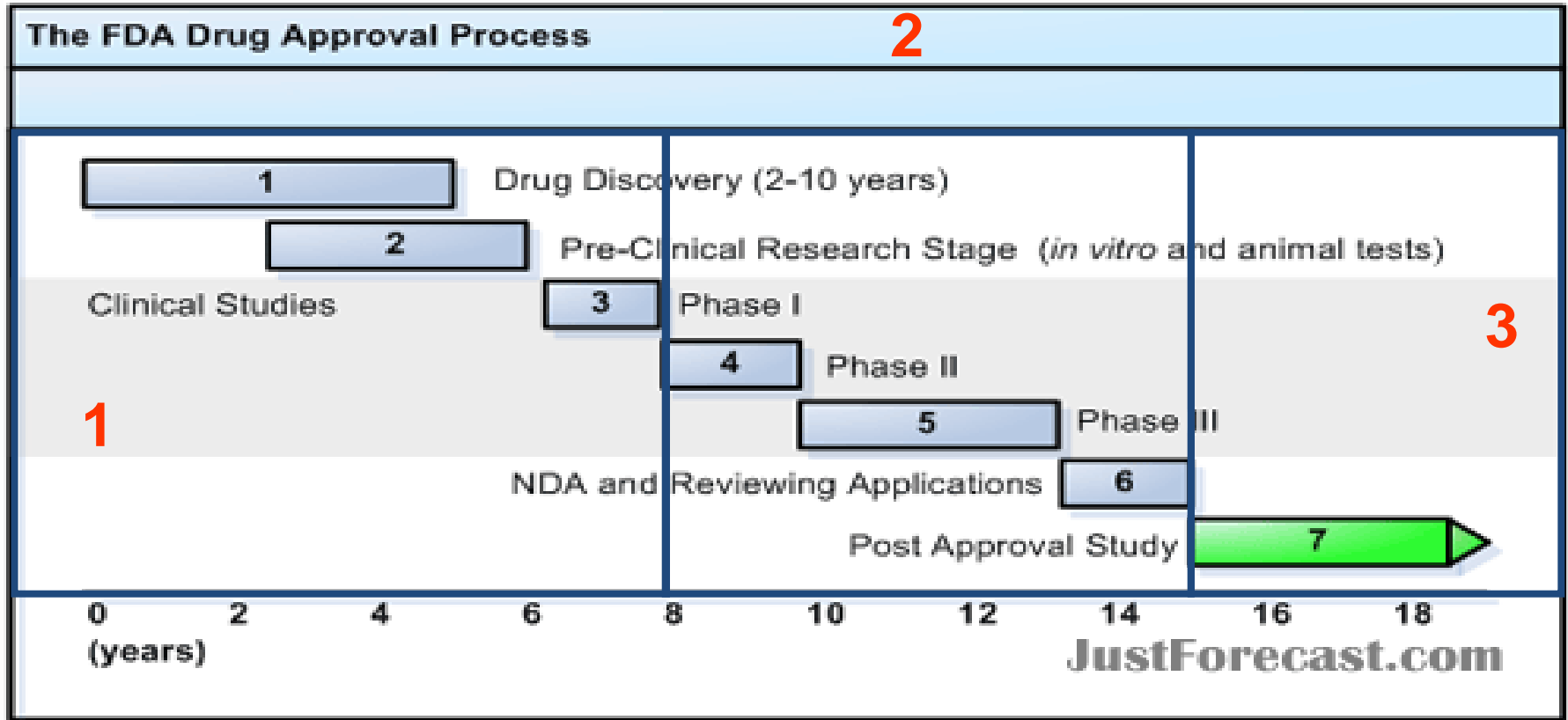
'Classical' evolution of deal structure over company lifecycle





Business Development Fundamentals

What is the right time to do the deal?

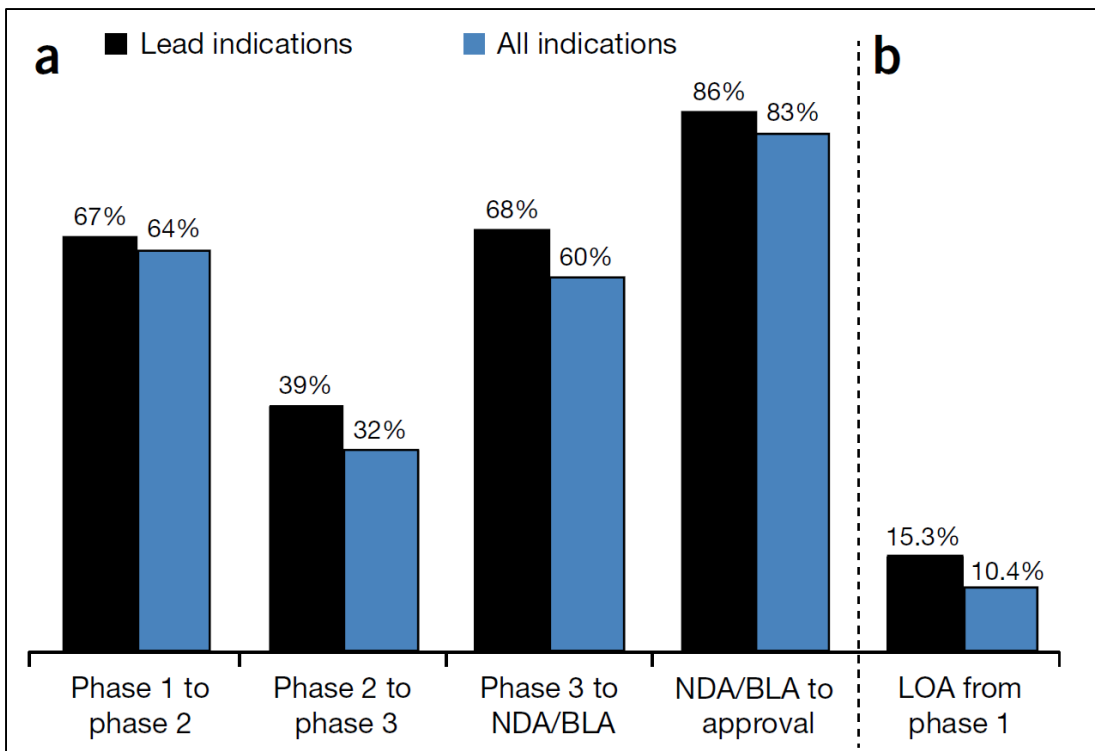


INVENTOR \$ > VC \$\$ > BIOTECH \$\$\$ > PHARMA \$\$\$\$



Will your product get approved?

Phase success and LOA rates



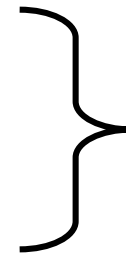
(a) Phase success rates for lead and all indications. The rates represent the probability that a drug will successfully advance to the next phase.

(b) LOA from phase 1 for lead and all indications. Rates denote the probability of FDA approval for drugs in phase 1 development.



What Kind of Transaction?

- Straight license agreement
 - Arm's length
 - No collaboration (not really an alliance)
- Research collaboration
- Development collaboration
- Promotion/Marketing collaboration
- Royalties vs. Profit sharing
- M&A (the ultimate alliance?)



***Varying degrees of
all three?***



What structure for a deal?

- Consider “life stage” of each partner
 - Needs of seed and early stage companies
 - cash & survival
 - Needs of companies with promising platforms
 - cash & proof-of-concept
 - Needs of companies with promising product candidates
 - cash & growth of infrastructure
 - Needs of the buyer vs. the seller
 - access to products, product candidates
- Additional considerations:
 - State of the seller’s portfolio
 - State of the buyer’s portfolio
 - Determining value of payments
 - Risk and NPV?
 - Comparables?
 - “Loading”: front end vs. back end



Business Development Fundamentals

What types of payments?

- Upfront payment
 - Proportion of costs to date (all or some fraction?)
 - Recognition of stage of development of IP and Know-how
- R&D Support
 - FTE basis
 - Rate? Tracking? Auditing?
 - Workplan?
- Milestones
 - Research/Technical achievements
 - Clinical achievements
 - Regulatory hurdles (filings vs. approvals? territories?)
- Royalties
 - Percentage of sales? Tiers?
 - Sales milestones?
 - Buy out of future revenue stream?



Forms of payment?

- Cash
 - Non-dilutive for seller
 - Equity
 - Spares P&L for buyer
 - unless written down?
 - Upside potential for buyer?
 - Loans
 - Forgivable?
 - Convertible?
- Research Support, Milestones**
- Upfront**
- More relevant to Development and Commercialization**



Business Development Fundamentals

What issues to consider in a deal?

Research

- Research term, options to extend, research plan, sponsored vs. self-funded, where is the hand-off?
- Roles and responsibilities
- FTE commitment
- Resource allocation and cost allocation
- Governance

Development

- Development plan, compound criteria, regulatory affairs, resource commitment, roles and responsibilities, cost sharing or reimbursement procedures
- Selection of development compounds
- Buy-in for initial development compound vs. follow-ons

Commercial

- Commercialization plan
- Manufacturing
- Resources
- Roles and responsibilities
- Cost sharing and reimbursement
- Trade-offs for retained rights
- Royalty vs. profit sharing



Business Development Fundamentals

How to value a deal?

Strategic

Value each partner's contribution/capabilities

- Increased probabilities of technical success?
- Shorter time to market?
- Broader clinical program, larger number of indications?
- Higher peak sales?
- Increased valuation of company from "marquee" deal?

Sharing risk, increasing shots on goal

- Consider ways to retain economics, while off-loading some costs
- Cost and profit share in compound
- Retain certain number of compounds/output resulting from collaboration
- Retain certain geographies
- Use financing vehicle to fund clinical development
- Funding mechanisms from pharma partner

Economic

Compare economics vs. strategic fit

- Near-term vs. long-term cash flows
- Contribution analysis
- Comparable deal analysis
 - Recent trends in similar transactions
- Net present value analysis
 - Determine anticipated annual net cash flows
 - Discount cash flows back to the present value
 - Reflects the time and risks associated with the business and product
- Options and Monte Carlo
 - Less utilized



Representative deal approaches



Business Development Fundamentals

Build to partner? or Build to sell?

PI3K inhibitor examples

Infinity

↓ Build to partner

- 2010: License to Intellikine's PI3K- delta/gamma compounds
- \$13.5M upfront, research funding for 2 years, \$25M in development milestones, \$450M in approval and sales milestones, 7-11% royalties
- Intellikine retains option to co-commercialize and profit share in US for oncology indications
- 2011: Takeda acquired Intellikine

- 2012: Infinity paid Takeda \$15M to buy out option
- 2014: Infinity paid Takeda \$5M to acquire an option to buy out royalty rights (exercise fee of \$52.5M)*

*Exercised in April 2015

- **2014: Global deal with Abbvie** to co-develop and co-commercialize (US) IPI-145
- \$275M upfront, \$405M in milestones prior to sales, \$125M in sales milestones, double digit royalties ex-US

Calistoga

Build to sell

- 2006: ICOS spin-off with license to ICOS PI3K-delta compounds
 - Deal terms not disclosed
- Raised over \$90M from premier VCs
- Advanced the program to Phase 3 ready; positive Phase 1/2 clinical POC data
- **2010: Acquisition by Gilead** for \$375M upfront and \$225M in earnouts



Build, partner, and then sell?

Pharmacyclics' BTK inhibitor (ibrutinib) example

Build

- 1991: Founded – initially focused on a class of molecules called “texaphyrins”
- Lead molecule did not pan out in clinical studies
- 2006: “Plan B”: In-licensed HDAC Inhibitor (Phase 1) and preclinical BTK inhibitor & Factor VIIa Inhibitor from Celera
- 2010: Clinical POC in CLL and MCL with BTK inhibitor
- 2010: Phase 2 trials initiated with BTK inhibitor

Partner

- **2011: Global deal with J&J** to co-development and co-commercialize ibrutinib
- \$150M upfront, \$825M in development and regulatory milestones
- Each company leads development for specific indications (per development plan); costs shared 40/60 (Pharmacyclics / J&J)
- Co-commercialize; US lead – Pharmacyclics; ex-US lead – J&J; share profits equally
- Shared governance

- 2013-present: Ibrutinib approved in 4 indications;
- Analyst estimated peak sales across multiple indications of \$6Bn

Sell

- **2015: Acquired by Abbvie for \$21Bn**
- For “half” of ibrutinib
- J&J and Novartis also bidders



Business Development Fundamentals

Partner to expand?

Astrazeneca anti-PD-L1 mAb, MEDI4736, example (limited)

AZ – Celgene

Partner

- 2015: Alliance for blood cancers
- \$450M upfront
- Celgene leads development; responsible for costs thru 2016, after which its split 25/75 (AZ/Celgene)
- Celgene responsible for global commercialization
- AZ manufactures, books all sales of MEDI4736
- AZ pays royalty to Celgene in blood cancers: 70% decreasing to ~half of the sales in blood cancers over four years

AZ – Innate Pharma

Partner

- 2015: Global co-development and commercialization collaboration for Innate's IPH2201 (Phase 2), an anti-NGK2A mAb (novel check-point inhibitor)
- \$250M upfront, \$100M prior to initiation of Phase 3, additional regulatory and sales milestones
- AZ will book all sales and will pay Innate double-digit royalties. Innate has right to co-promote in Europe for a 50% profit share

AZ – Juno

Partner

- 2015: Clinical trial partnership
- Jointly fund a Phase I study combining one of Juno's so-called CAR-T therapies with AZ's MEDI4736

Deals support broad program of immuno-oncology combination trials that AZ has planned and underway



Recent deal trends



Deal making in 2014

- 2014 was a record year for deal making in the bio/pharma sector
- Pharma's need for new products and pipeline bid up prices for acquisitions and licensing deals in certain therapeutic categories and for companies and products that address desirable targets
- Tax inversion craze became the next political football in M&A, only for activity to dim in the last quarter due to moves by the US to limit such financial engineering.
 - This derailed several transactions; e.g., AbbVie's move on Shire
- Stocks also set record highs, the IPO exhibited continued health and the VC industry was looking in better shape

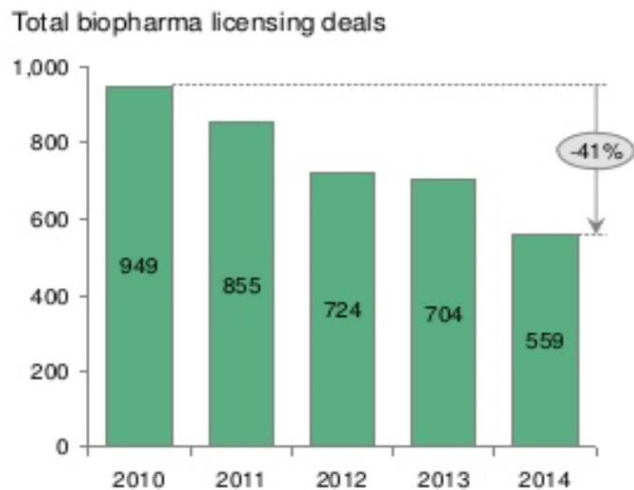


Business Development Fundamentals

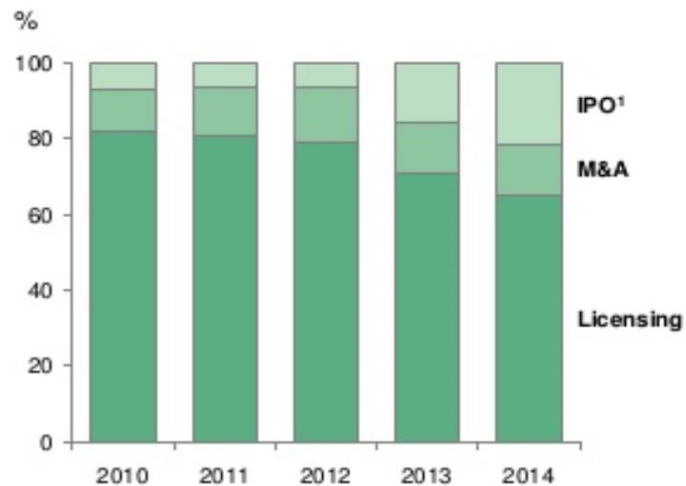
Deal making in 2014

Licensing deal volumes down 41%, while IPOs on the rise

Number of total deals



Share of deals by type



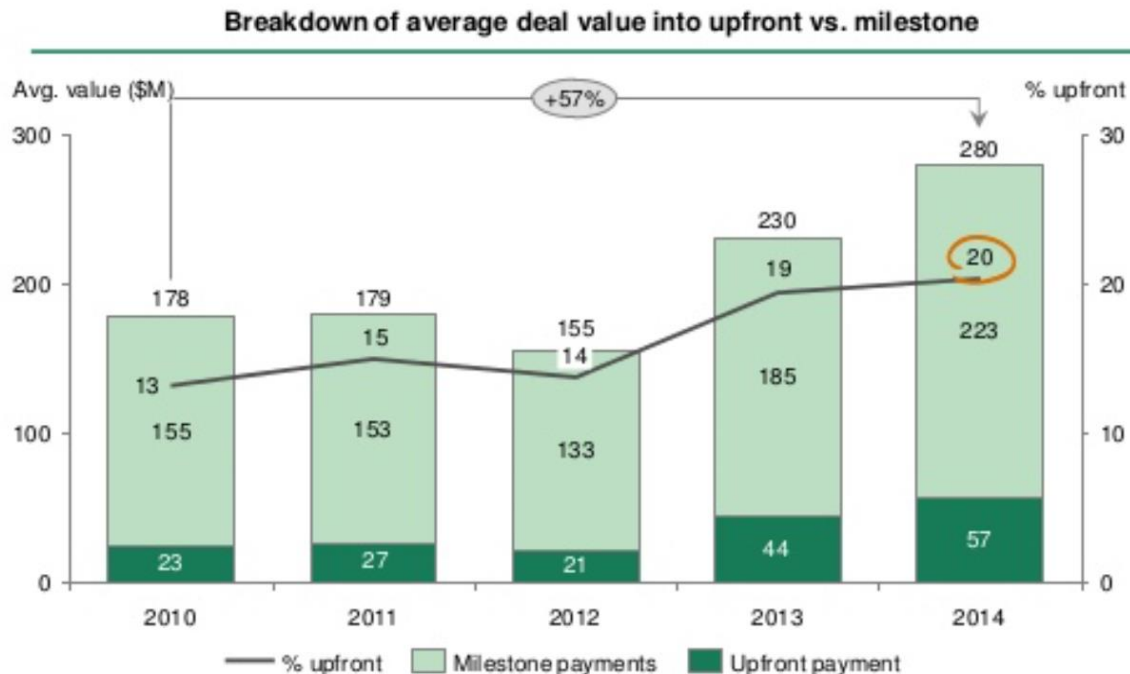


Business Development Fundamentals

Deal making in 2014

Licensing deal values up >\$100M since 2010

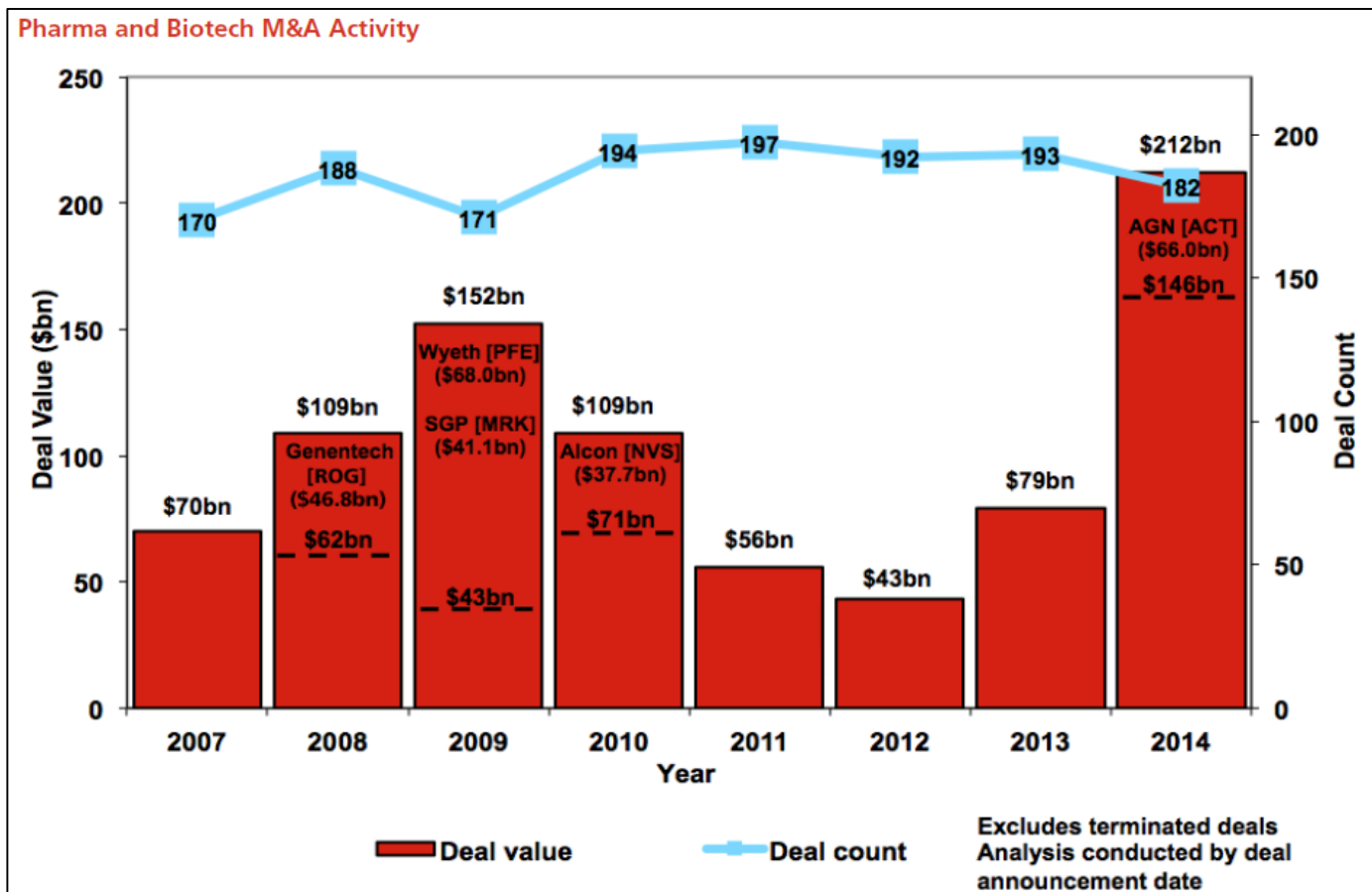
Upfront payments comprise a growing proportion of total value, up >2x absolute terms





Business Development Fundamentals

Deal making in 2014



Reference: Evaluate Pharma, Pharma and Biotech in Review, 2014



Outlook in 2015: Will the bubble burst?

- Difficult to beat records set by 2014 deals, but the 2015 “volume has only got louder in the first few months of the year, so maybe this amp does go up to 11”
- Ability and willingness of western healthcare systems to pay for high-priced products that offer only incremental improvements in efficacy and the perceived growing power of payers, will remain a growing concern
- Companies at the cutting edges of science, e.g., CAR-T companies and gene therapy, and their huge valuations remain highly susceptible to clinical setback and failure, which could easily infect investor confidence in other areas
- Ex-US, currency shifts are causing an impact on earnings guidance and unrest and instability in other parts of the world (i.e., Ukraine and Middle East) only likely to deepen and spread

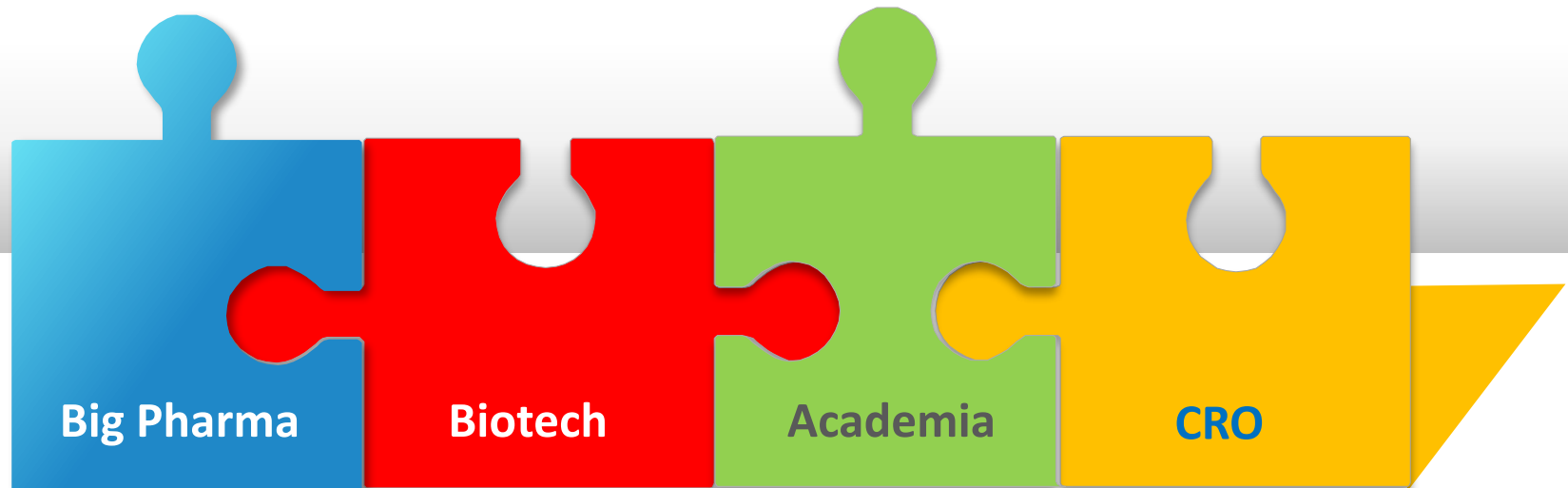


Business Development Fundamentals

**Collaboration Management:
Managing Alliances for Success**



Partnering in Life Sciences has many variations»



We're going to discuss issues and methods common to all of these types of collaboration and the role of Alliance Management as a **DISCIPLINE** in making these partnerships successful...



Commercialization Shift: Co-Development and Alliance Management

- In 1970, 80% of US drug development was done in a FIPCO vertical (in-house).
- By 2000, this had dropped to less than 40%. Client companies moving to FIPNET approach (e.g. Lilly)
- Estimates are that by the end of 2015, 60% + of the revenue generated by Big Pharma will come from licensed / alliance partner compounds.*
- Outsource / Alliance Drivers:
 - Big Pharma seeking to fill pipelines quickly and with less cost exposure than previously
 - Availability of nearly ripe biotech fruit (diagnostic, drug, and technology)
 - Mitigating risk of product failure (shared-risk)



Commercialization Shift: Co-Development and Alliance Management

- Nearly 70% of industry drug entities fail at Phase II despite strong indicators for success.
- Alliance development programs, well managed, can reduce the overall failure rate impact and associated costs.
- Published data suggests in-licensed compounds / outsourced development have a higher POS in reaching the market than in-house galenic programs.*
- Alliance development, for instance with CROs, in areas outside of the company's core competencies, allows in-house resources to remain focused.

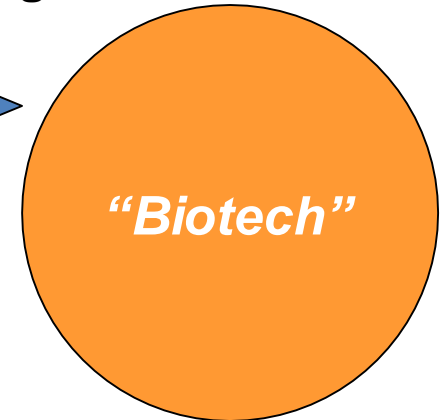
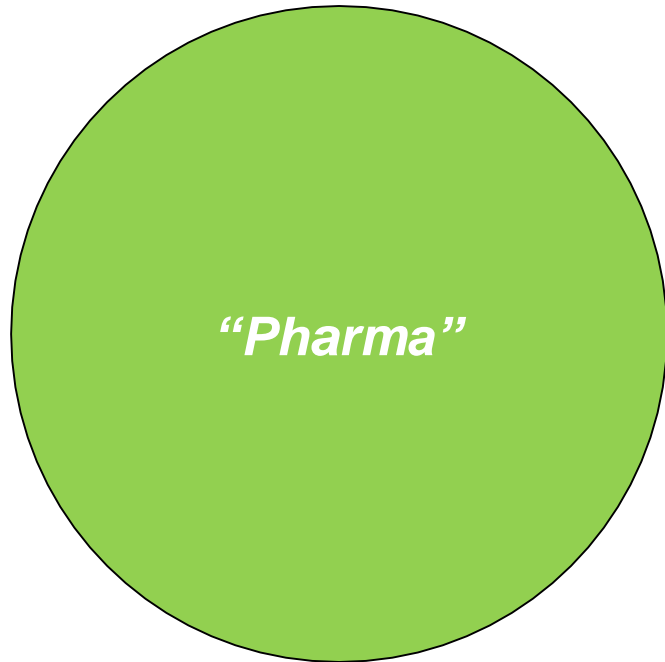


Pharma / Biotech growth linked to Alliances

- Over half of today's top-grossing drug products are the result of partnerships and outsourcing.
- Companies across the industry annually spend hundreds of millions of dollars to utilize other firms' discovery, development and marketing capabilities to meet shareholder expectations for growth.
- This pressure to maintain strong portfolios underscores the importance of alliance management.
- Keen interest in strategic alliances from the Street
- Alliance management has become a critical path capability in the deal-making process and assuring profits to a majority of pharma, biotech, and device enterprises.

Why Partner?

- Cash
- Development & Commercial Skills
- External Validation
- Risk Sharing or Increasing Shots on Goal



- Technical Skills
- Product Candidates
- Speed
- Innovation

But this view oversimplifies some complexities...



If the Objective is Sharing Risk Or Increasing Shots on Goal

- Consider ways to retain economics, while off-loading some costs
 - Cost and Profit share in compound
 - Retain certain number of compounds/output resulting from collaboration
 - Retain certain geographies
 - Use financing vehicle to fund clinical development
 - Funding mechanisms from pharma partner

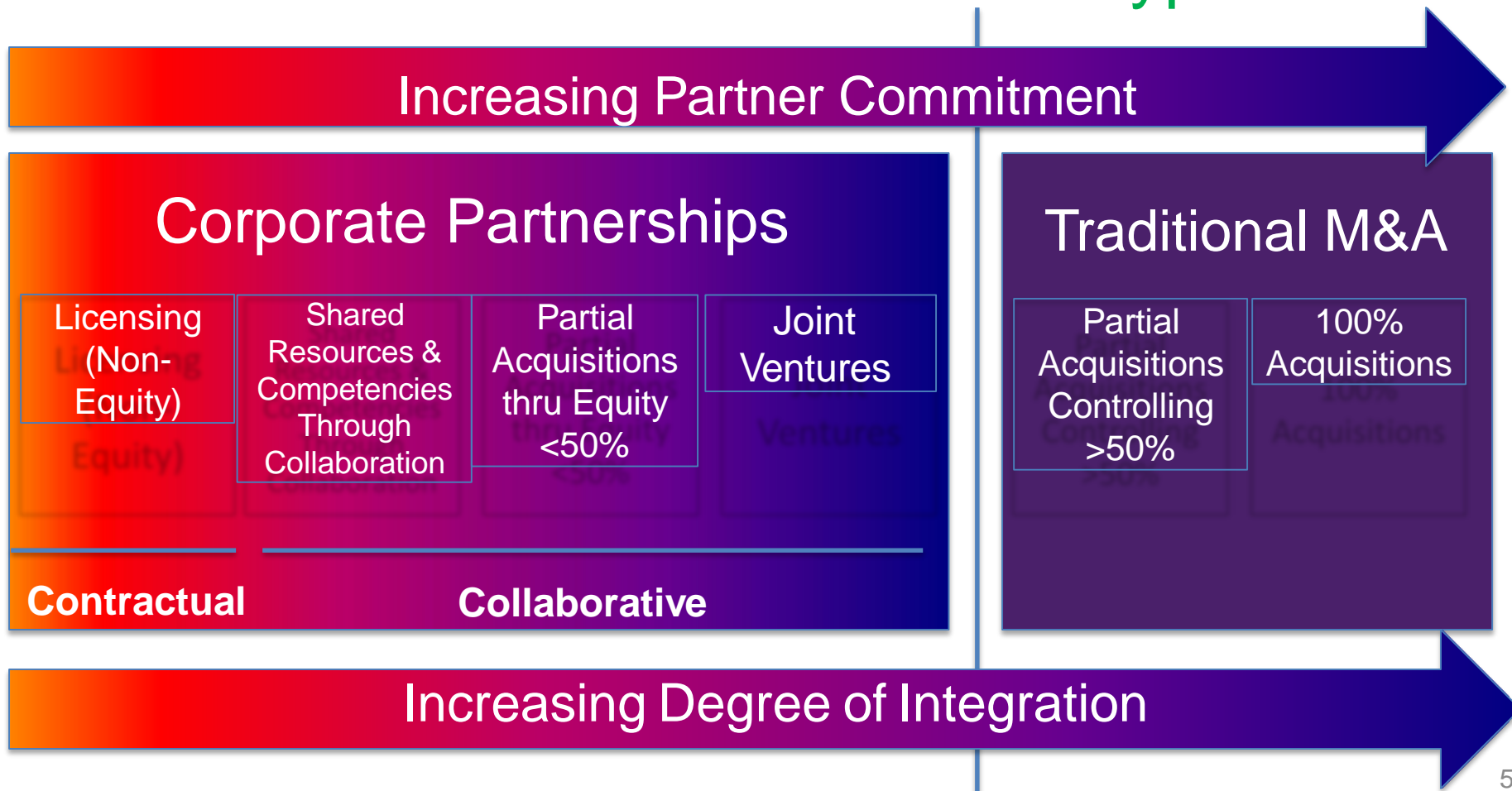


If the Objective is Access to Capabilities/Expertise/Validation

- Valuing the partner's contribution/capabilities
 - Increased Probabilities of Technical Success?
 - Shorter time to market?
 - Broader clinical program, larger number of indications?
 - Higher peak sales?
 - Increased valuation of company from “marquee” deal?



Partnerships Come in a Variety of Forms Continuum of Transaction Types





Continuum of Transaction Requires Variable Levels of Relationship Management

Alliance relationships:

- range from simple customer/vendor transactions to true outsourcing partnerships
- individual relationships vary over time.





Core Definitions

- **Strategic Alliance**

- A strategic alliance is a structured strategic collaboration between two or more organizations, with the aim to achieve an agreed upon result neither of the partners can reasonably or easily achieve alone.*

- **Alliance Management**

- Alliance Management is a senior leadership-supported discipline through which specific relationship management skills, governance frameworks, and co-developed metrics are used to assure the continuing stability and growth of a collaborative partnership which wisely uses resources to create incremental value (develop solutions), build collaborative trust, and manage risk.

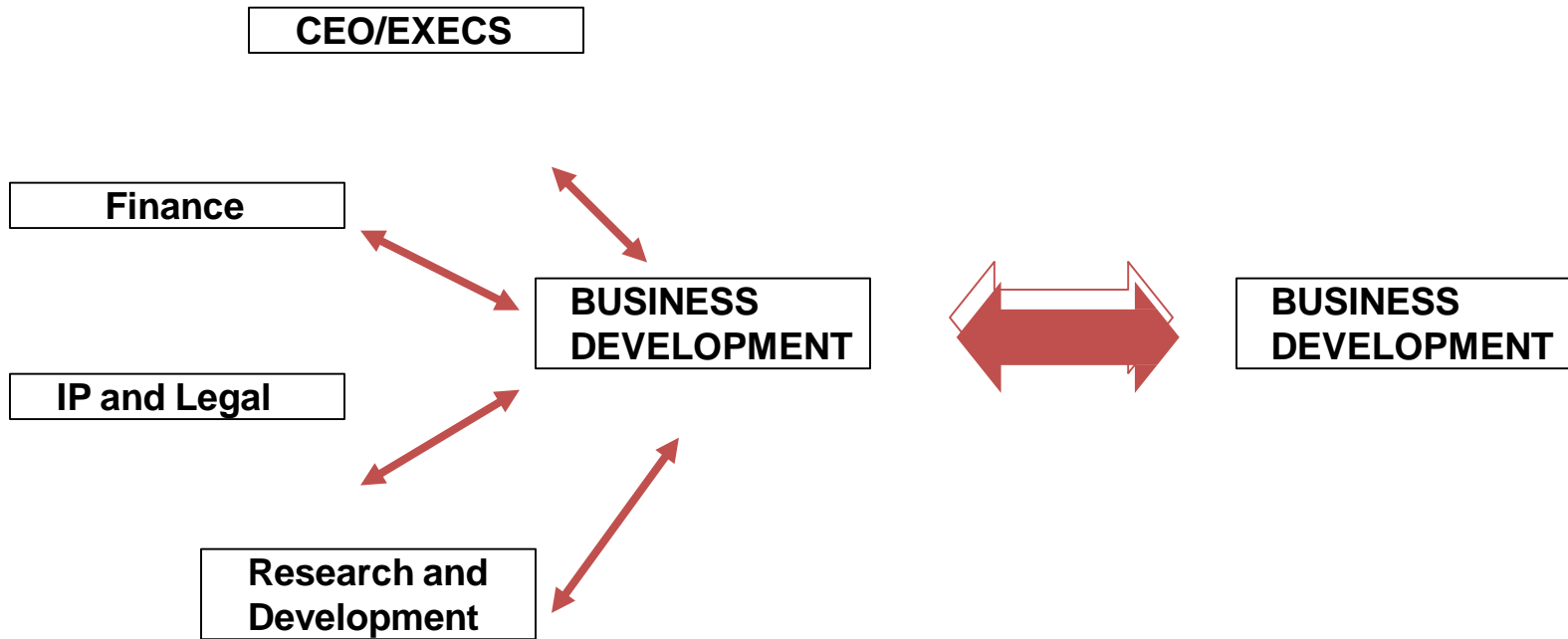
* Doz & Hamel, Alliance Advantage: The Art of Creating Value Through Partnering



Here's how most see partnering...

Internal Team

Partner

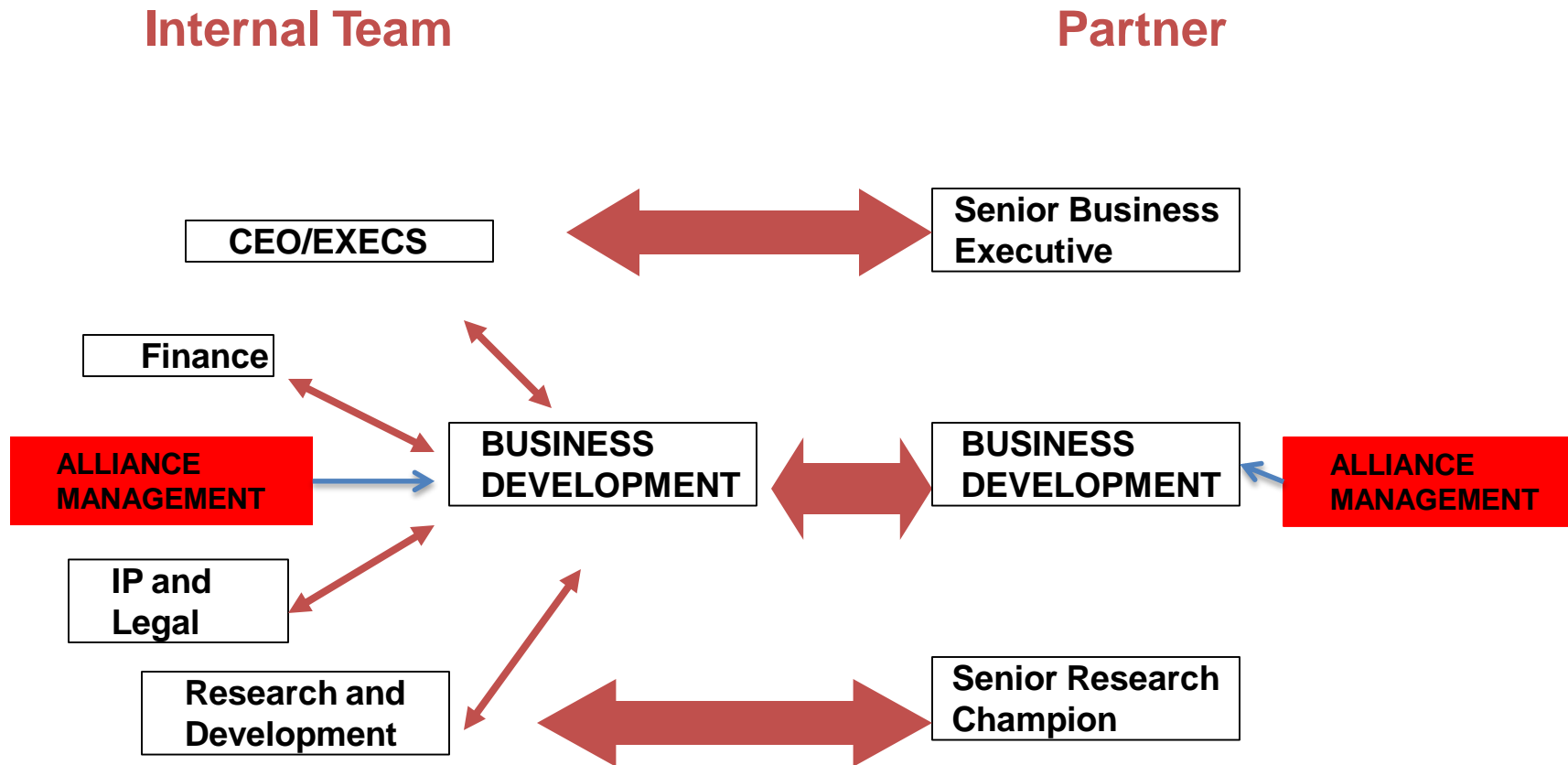




Business Development Fundamentals

Here's how it to make it successful

A coordinated message backed up by relationship building will help close the deal





ISO 11000 Practice Standard being established by TAG Working Group



Document: ISO/PC 286 WG 1

N 11

Date: 26 May 2015

Secretariat of ISO/PC 286 WG 1
Collaborative business relationships

The aim of this International standard is to provide a strategic framework to establish and improve collaborative relationships in and between organizations of all sizes. It addresses the operational influences and requirements that impact behavior and organizational culture to ensure they are effective, optimized and deliver enhanced benefit to the stakeholders through collaborative approaches.



Business Development Fundamentals

Alliance Intent: ISO 1100

Strategic

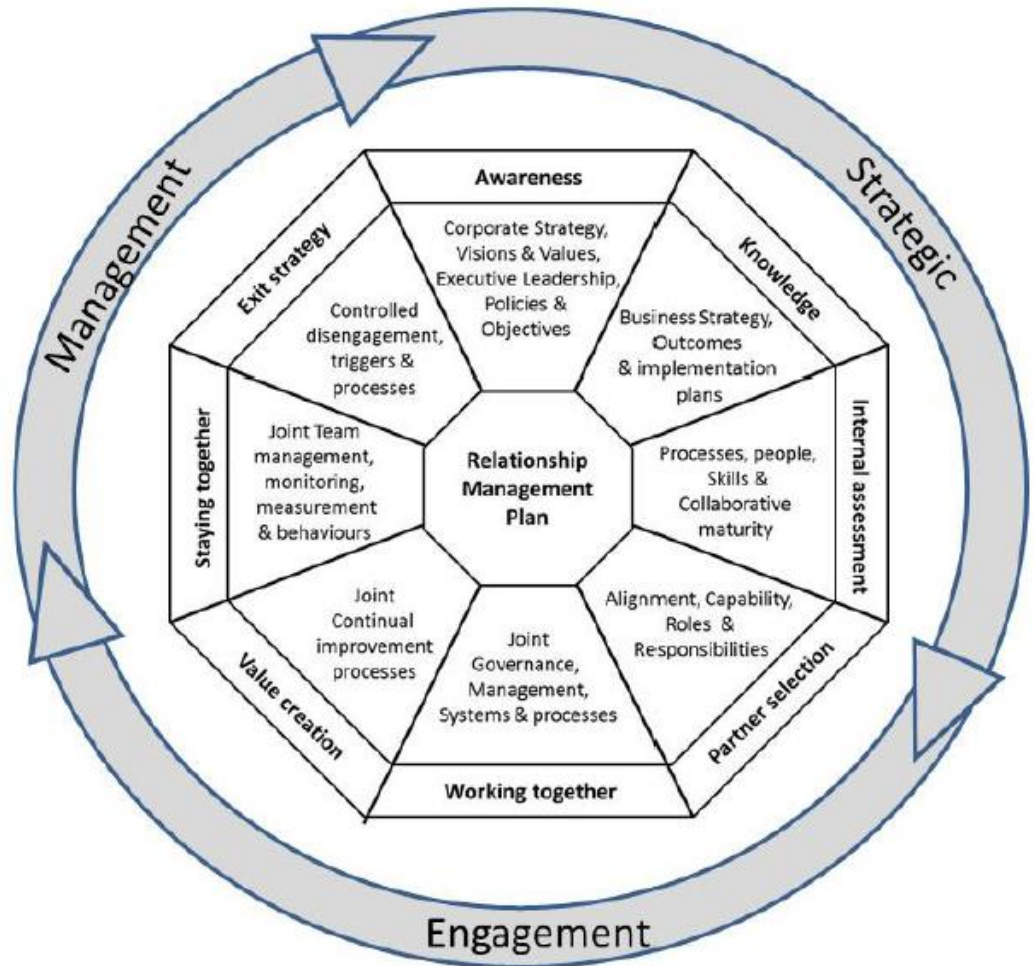
- Awareness - Establishing the organizations propensity for collaboration
- Knowledge - Evaluating specific collaborative benefits and business case
- Internal assessment- Assessing the organizations capability to collaborate

Engagement

- Partner selection- Establishing an appropriate selection process
- Working together- Establishing a joint governance model for collaboration
- Value creation- Establishing a joint process for continual improvement

Management

- Staying together – Managing, monitoring and measuring the relationship over time
- Exit strategy - Establishing a joint approach to disengagement and/or future





Getting Started

- Define the objectives of the deal (corporate strategy)
- Plan for timing – when does it need to be done?
- Have an internal communication plan
- Identify potential partners
- Identify pre-deal, in-deal, and post-deal stakeholders
 - include Alliance Management
- Prepare non-confidential package and confidential packages
- Begin preparing due diligence materials



Launching the Operating Relationship

- Joint Steering Committees
 - Project Teams
 - Work plans
-
- Research
Development
Commercialization
- The diagram shows three lines originating from the right side of the text "Joint Steering Committees" and pointing to the words "Research", "Development", and "Commercialization" respectively.



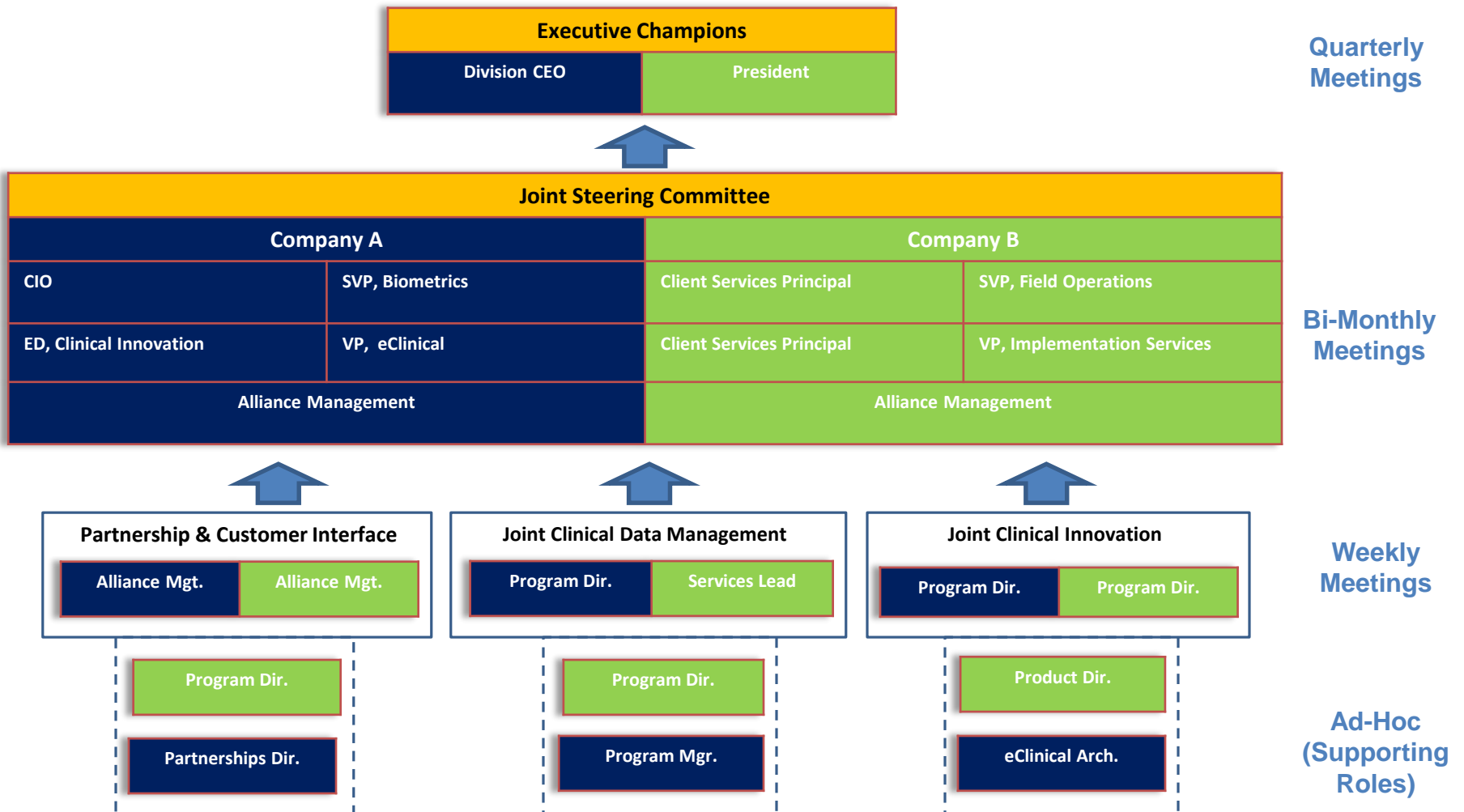
Joint Steering Committees

- Oversight for the collaboration
- Typically equal numbers of appropriately senior representatives
 - Most often 3+3
 - “Senior” most often means Directors and VPs
- Responsibilities
 - General oversight
 - Resource allocation decisions/approvals
 - Setting of goals/Determination of success
 - Authorizing 3rd party engagements (e.g. academic labs, CROs, etc.)
 - Resolving disagreements / escalation management
- Establish a mutually beneficial cadence (meet as often as seems mutually needed)
- Consider alternating headquarters meetings or neutral zones



Business Development Fundamentals

Company A – Company B Partnership Governance





Escalation Pathways / Dispute Resolution

- The contract will usually say...
 - JSC to resolve disputes
 - Failing that, escalation to senior executives
 - Failing that, typically either of binding arbitration or the more powerful party has final say
- The reality...
 - Should really be handled by the JSC with a goal of escalating the solution, not the issue.
 - If still not resolved then... you've probably got a major problem and the contract mechanism may not help
 - That's why relationship-building is so important



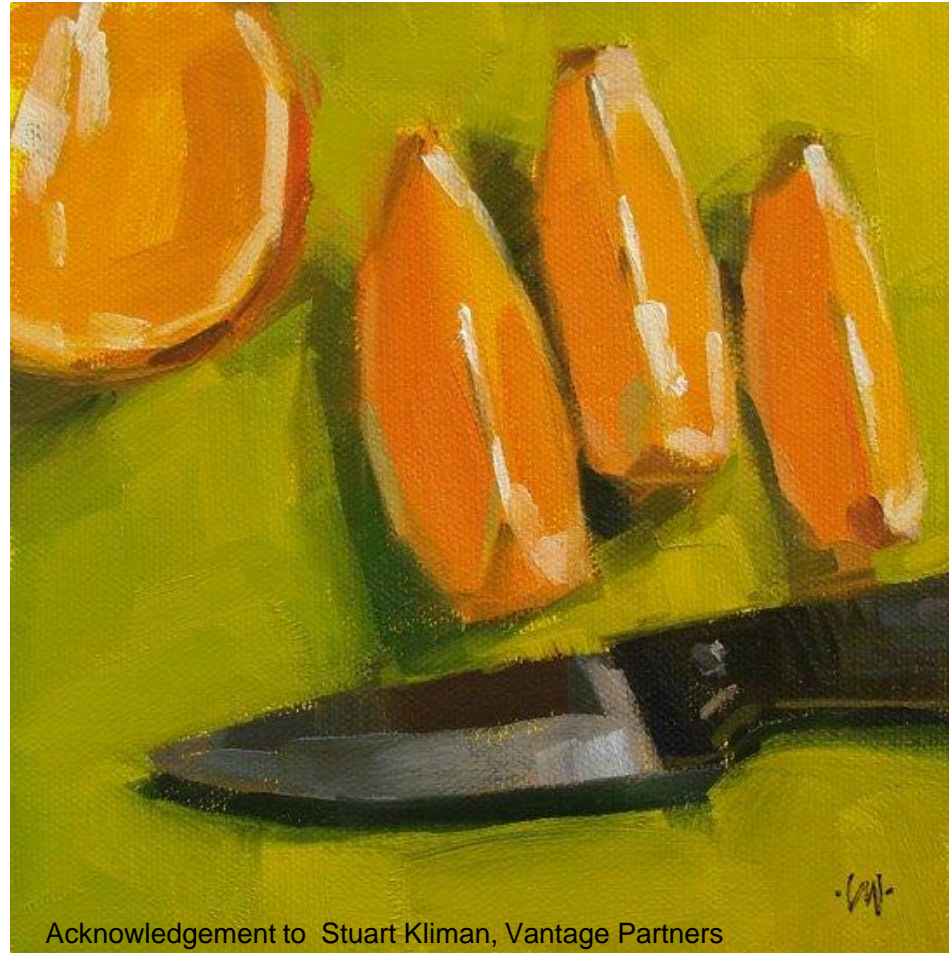
Assuring Alliances Achieve Objectives

Negotiation, Arbitration, And Creativity

Two Sisters, One Orange...

**When compromise is making
sure neither party gets what
they need.**

**And the alliance fails to achieve
its objectives.**



Acknowledgement to Stuart Kliman, Vantage Partners



Project Teams

- This is where the real work gets done
- Membership really depends on the stage of the program
- Core members
 - Project leaders (one from each side)
 - Senior Scientist or Clinician
 - Research Scientists/Research Associates
 - DMPK/Toxicology
 - Clinical
 - Regulatory
 - Manufacturing
 - Program manager
- Others?
 - Alliance Manager/Business Development (as needed)
 - Finance Manager
 - Corporate communications (as needed)



Project Team Activities

- Draft the project work-plan and update as required
 - Align scientific reality with business objectives
 - Make clear assignments of roles and responsibilities
 - Are the resource allocations appropriate?
 - Is the timeframe appropriate?
 - Does plan account for expected timing of milestone events?
 - Have the parties agreed to success criteria so that you'll know when the milestone has been met?
- Meet regularly to review activities/data
 - Weekly is typical
 - Keep minutes/ track action items
- Report to the JSC
 - Informal updates as often as warranted (“managing up”)
 - Formal presentations (at the quarterly meeting)



Business Development Fundamentals

	Critical Components of a Team Charter	Component Purpose(s)
1	Overview of the Alliance Governance Structure	Provide team members with the context necessary to fully understand how their team fits into and relates to alliance leadership, operations, and reporting / escalation structures
2	Committee Purposes and Membership	Ensure members are aligned around their overarching mission and key responsibilities of the team and define its membership
3	Relevant Contractual Provisions	Provide a reference to necessary contractual requirements (e.g., required activities, required number of meetings, etc.)
4	Key Committee Goals and Milestones	Define and align team around key 6-18 month goals, timelines, and milestones
5	Key Committee Challenges and Related Mitigation Strategies	Facilitate recognition of likely key cross-partner working together challenges and agree/document mitigation strategies
6	Decision-making Roles and Escalation Process	Clarify roles, responsibilities, and decision-making authority within and across teams, including necessary pre-decisionmaking consultation needs and post-decision-making inform needs
7	Operating Norms and Standing Agenda Items	Manage communications and meeting protocols regarding preparation, agenda creation, meeting distribution, etc. Defines the responsibilities of different team members and defines standing agenda items or agenda template for meetings



What Makes a Good Alliance Manager?

- Contextual Competencies: Certain skills are foundational elements to the Alliance Manager's ability to effectively perform:
 - Strong Communication Skills (Inbound & Outbound)
 - Conflict Resolution Experience
 - Corporate Relationship Management
 - Change Management Capability
 - Global Understanding and Mindset
 - Demonstrated Team Management Skills
 - Demonstrated ability to influence others without authority / coaching leaders and department heads
 - Able to synthesize collaboration from disparate sources (i.e.. Vision to see how things might fit together – non-linear thinking)



Business Development Fundamentals

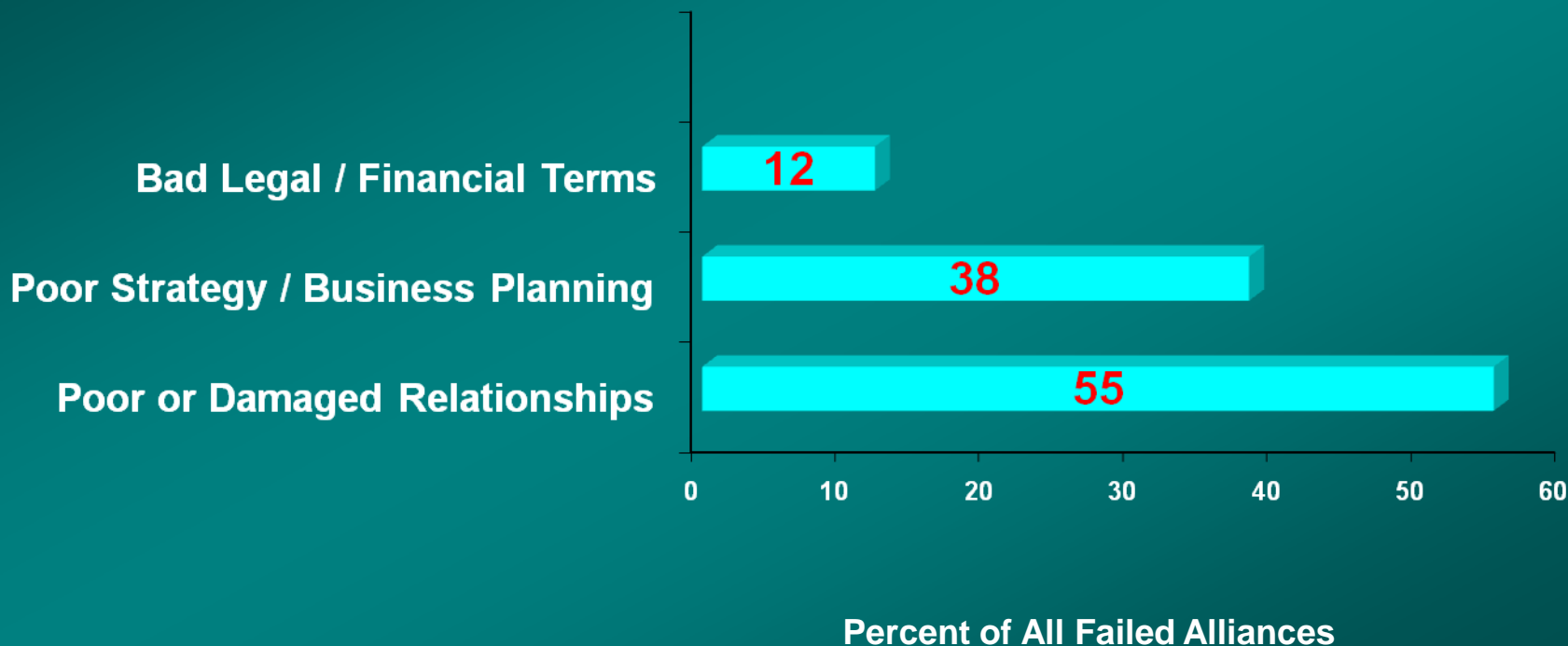
Contextual Competencies (cont.)

- Negotiation Skills (i.e.. Can they stand the heat?)
- Financial management
- Legal knowledge (e.g. Compliance)
- Regulatory knowledge (e.g. FDA, DEA)
- Time Management / Flexibility
- Contract Development and Negotiation
- Pharma / Biotech Industry knowledge (i.e. Need to know how their customers work and make their money)
- Critical strategic thinking / proactive vision
- Cultural sensitivity and management maturity
- Leadership skills / C-suite qualities / Professionalism
- Strong Networking capabilities / Social Media integration



After the Handshake...

Foremost Identified Causes of Alliance Failure





An Alliance Manager's Responsibilities

- To provide collaborative enterprise leadership to all alliance partners in order to achieve the corporate objectives every partnership.
- To contribute in a measurable manner to the achievement of annual corporate revenue goals.
- To assist in establishing new and improving existing alliance relationships with your partners.
- To provide continuity and compliance with all contractual agreements with an eye toward profits.
- To work in a collaborative fashion with internal stakeholders within the alliances.
- To provide effective mediation in the event of contractual complications or alliance issues between partners.



Business Development Fundamentals

Collaboration as a Lever to Drive Innovation & Productivity

Collaboration

“working together to achieve a common goal...it is more than the intersection of common goals, but rather a deep, collective determination to reach an identical objective”

Partnership

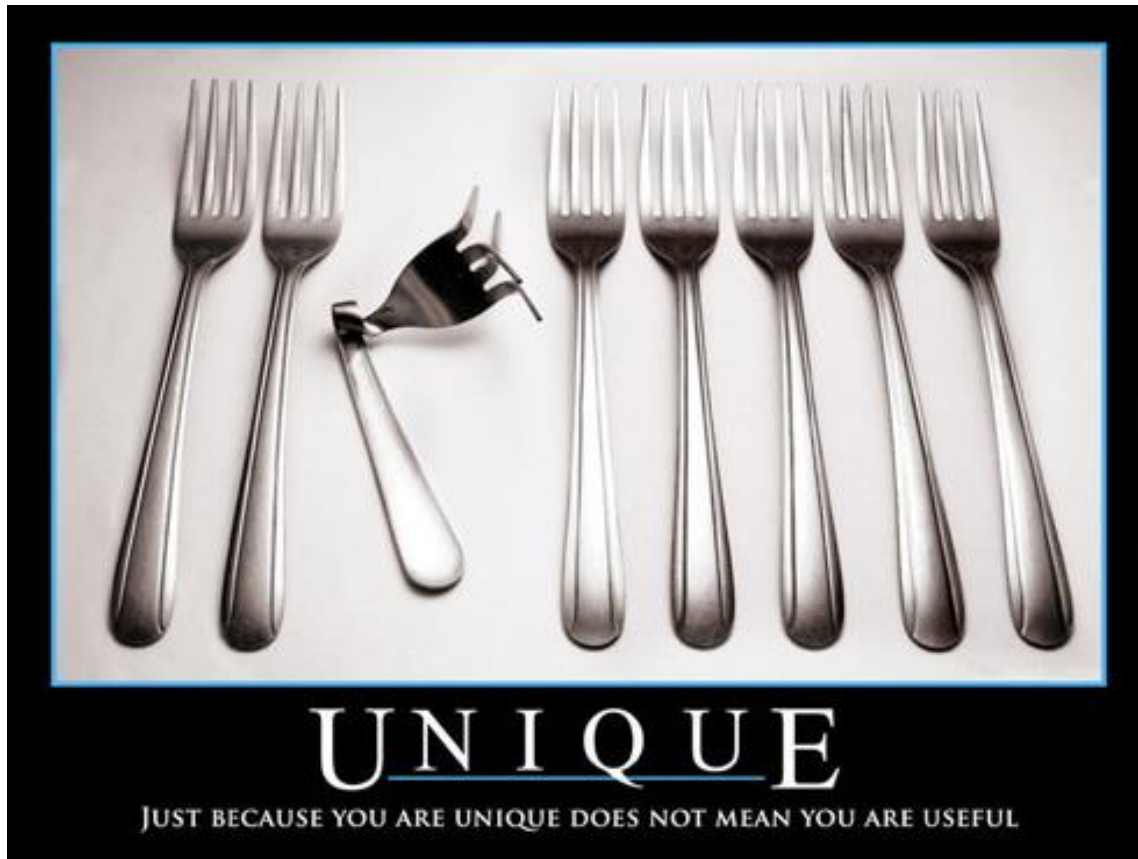
“is formed between one or more businesses in which partners (owners) co-labor to achieve and share in success (profits) and failures (losses)”



Business Development Fundamentals

Build, Buy, or Ally?

An alliance may be unique but its goals should be mutually useful and evident.





What is the Collaboration Goal / Deliverable?

Existing State

Company A

Company B



Desired State

**Integrated
Partnership**



Task Oriented

- Transactional
- Tactical execution
- Managing inputs
- Accommodating issues
- Many interfaces
- Diffuse accountability

Partnering as One

- Trust & relationship
- Strategic plan & execution
- Managing outcomes
- Proposing solutions
- Peer to peer points of contact
- Common Goals & Systems



Role of Alliance Management

- Elevate and strengthen the working relationship through strategic partnership
- Align company strategy and direction with business goals, competencies, and focus areas
- Considers a portfolio view of common projects to recommend best strategies
- Focus is on enterprise and franchise level initiatives vs. project specific initiatives
- Solutions-oriented strategies in response to high-priority shared problems vs. tactics in response to a prescribed solution
- Build executive-level networks between company A and company B



Creating Value within an Alliance

Beyond managed costs for development (procurement benefits), strategic alliances can drive significant long-term / intangible value:

- Access to New Markets
- Business Process Innovation
- Development Risk Mitigation
- Increased Brand Recognition
- Improved Strategic Planning
- Improved Partner Stability
- Increased Customer Loyalty
- Accelerated Knowledge Transfer
- Reduction in Competitive Threat
- Reduced Training Costs
- Key Employee Retention
- Improved Customer Satisfaction
- Portfolio Diversification
- Faster Time-to-Market
- Increased Market Penetration
- Reduced Development Oversight
- Increased R&D Momentum
- Higher development success rates
- Reallocation of Cost-savings to priority projects



People: Tactical Roles & Responsibilities

- Alliance team is responsible for the overall relationship with alliance partners
- Build, foster relationships with designated alliance team members
- Drive setting mutually beneficial strategic plans for the partnership
- Contribute to product development roadmap to support strategic objectives
- Serve as primary point of contact for the relationship; leverage resources as needed
 - Lead / Chair governance committees (ESC, JOC, etc.) as appropriate
 - Assist in development of relationship metrics, KPIs, alliance reports
 - Serve as conduit and interface with mutual sales groups to maximize new markets and revenue potential
 - Serve as conduit to subject matter expert (SME) on alliance product offerings, competition and product market
 - Serve as conduit to Marketing for partner communications; develop joint collateral; strategically manage joint commercial presence.



Process: Documents, Tools, Technology

- Development of core Alliance Agreements
- Direct On-boarding process: charter, governance, etc.
- Initiate Off-boarding process: risk management, soft landing
- Design Value-add metrics
- Oversee evolution and migration of Company B to partner B
- Connect teams to related SOPs – i.e. biz continuity/affects on deliverables
- Assure creation of communication tools, including internal, external, marketing campaigns, etc.
- Manage alliance transition/hand-off process for internal stakeholders



Ten Needed Capabilities for Successful Partnership Management

1. Building and maintaining internal stakeholder alignment
2. Evaluating and considering relationship fit with potential partners
3. Building strong working relationships while negotiating optimal deals
4. Establishing common ground rules and communication pathways for working together
5. Instituting dedicated alliance managers
6. Instilling collaboration skills in alliance-facing employees
7. Having a collaborative corporate mindset
8. Managing multiple relationships within the same partner
9. Monitoring, auditing and providing assessment of alliance relationships: Measurement of effectiveness, productivity, and profitability
10. Managing changes that affect alliances (M&A, asset failure, etc.)



Business Development Fundamentals

After the Contract,
the burden rests on
Alliance Management
personnel to
keep relationships
Healthy and Growing.



Ensuring a productive collaboration is a daunting
responsibility requiring many components:

- Ample senior-level and organizational support
- Efficient project coordination
- Effective conflict resolution and intervention
- And constant, open communication



Additional Alliance Management Resources

- **Strategic Alliances: Three Ways to Make Them Work**, Steve Steinhilber (VP, Strategic Alliances, Cisco), Harvard Business Review, 2008.
- **The Association of Strategic Alliance Professionals (ASAP):**
<http://www.strategic-alliances.org>
- **Right from the Start: the Seven Virtues of a Successful Alliance Launch**, Visoni, et.al., Int. J. Strategic Business Alliances, Vol. 1, No. 4, 2010
- **Harvard Business Review on Strategic Alliances**, HBR, 2002.
- **The New Successful Large Account Management**, Miller, Heiman, et.al., 2005.
- **Managing Alliances for Business Results: Lessons Learned from Leading Companies**, Weiss, et.al., Vantage Partners, LLC, 2006.