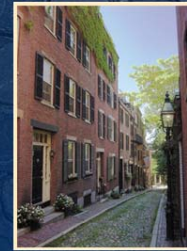




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Boston 2008

The Evolving Role of Project and Alliance Managers at Each Stage of Product Development

Session Chair:

Ailsa Mendez, MBA
Director, Project Governance
Functional Genetics

Session Speakers

Start of a Long Journey: Focus on Science in Early-stage Alliance Programs

Katya Kovalskaia, MSc, PMP
Associate Director, Product Development, Anthrax Vaccine
Emergent BioSolutions

Joint Clinical Development: Complexity of Project/Alliance Manager Role

Martine Zimmermann-Laugel, PharmD
Head of Department, regulatory intelligence and policy
H Lundbeck

The Alliance at Product Launch: Market Strategies and Life-cycle Management

Laurie Dubrovin, MS, PMP
Senior Project Manager, Product Portfolio Management
Genentech, Inc.



Collaboration between AM and PM



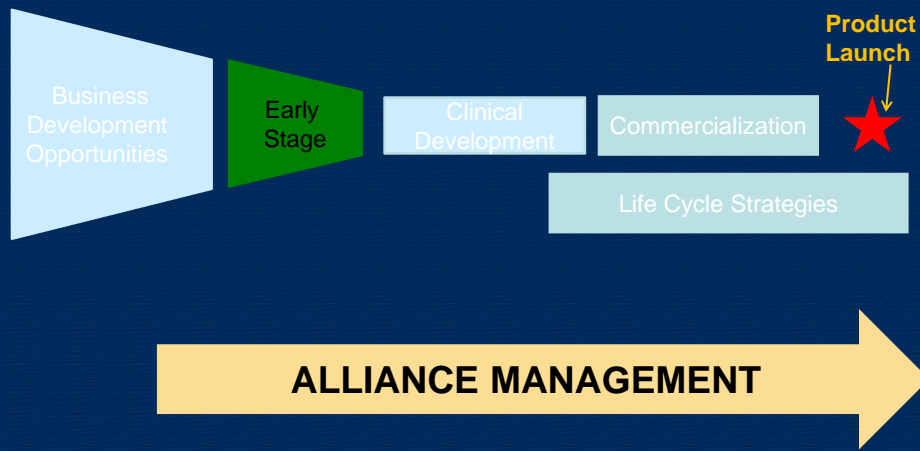
Courtesy of P. Bigot, Genentech Alliance Management



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Product Development Diagram



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Highlights from Katya's talk

Start of a Long Journey: Focus on Science in Early-stage Alliance Programs (Katya Kovalskaia, MSc, PMP)

At the early stage (late lead optimization/early preclin development) alliances are governed by a joint steering committee, involve a joint project team.

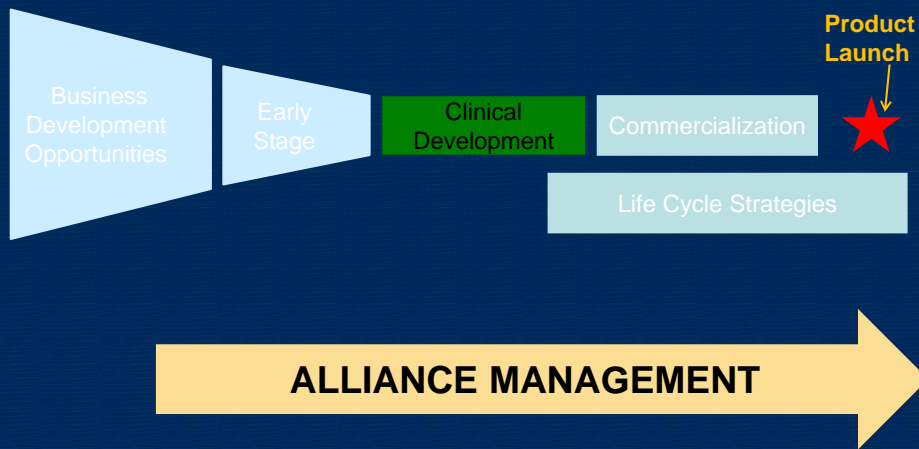
Trouble spots in early stage alliances (e.g. misalignment in organizational structures, misunderstanding of who pays for what, lack of clarity on decision-making roles) typically improve with increased/clearer communication.

Alliance manager role critical to establishing working partnership, understanding partner's structure and explaining partner's culture.

Early stage is where dual role (AM/PM) possible for an able and qualified individual



Product Development Diagram



Highlights from Martine's talk

Joint Clinical Development: Complexity of Project/Alliance Manager Role (Martine Zimmermann-Laugel, PharmD)

Overall governance structure remains, but individuals and expertise represented on the steering committee may adjust as program moves into clinical development,

Trouble spots in alliances during clinical development (e.g.) typically improve with

Alliance manager role critical to maintaining working partnership, resolving conflict, understanding partner's structure and explaining partner's culture.

May be beneficial to have separate individuals represent AM and PM.



The Alliance at Product Launch: Market strategies and Life-cycle Management

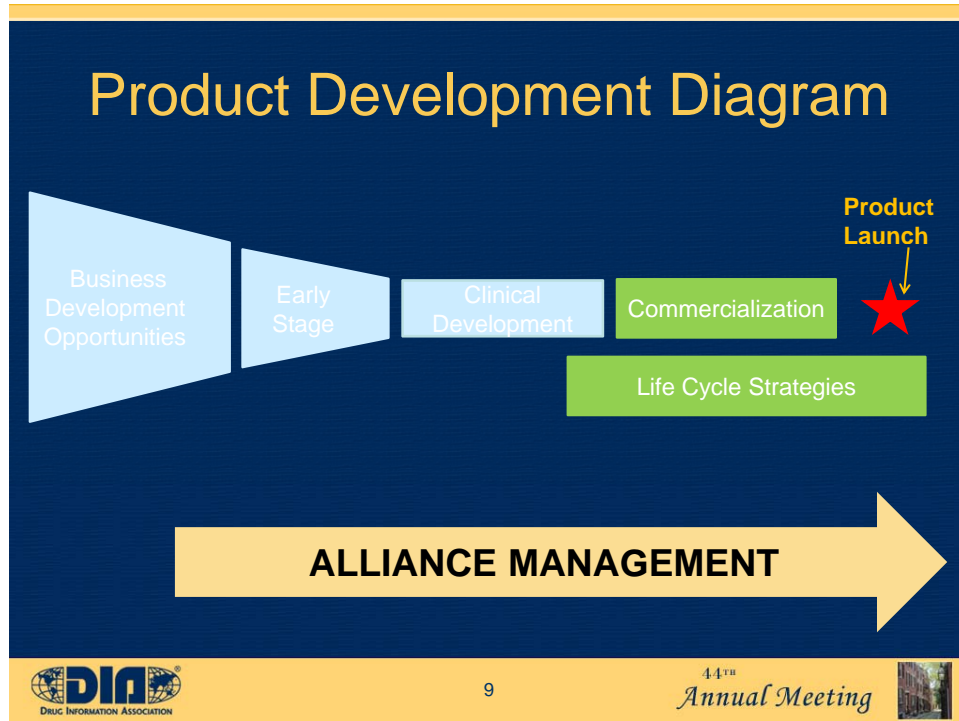


Boston 2008

Presenter: Laurie Dubrovin



Sr. Project Manager, Product Portfolio Management
Genentech

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Presentation Overview

- Changes in the team operating environment post-approval
- Potential trouble spots in marketed alliances
- Key skills for Alliance and Project managers of marketed projects


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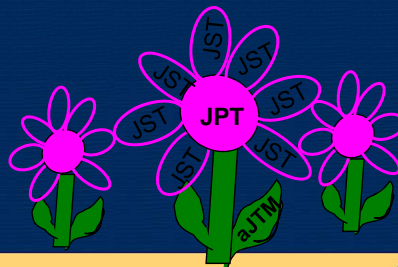
Typical Collaboration Governance Structure

Steering Committee – provides oversight
Role is defined in contract

Development committee

Finance committee

Commercial committee



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The Landscape

- Post-approval, team focus shifts to sales and future line extensions
 - Development team members still needed for post-marketing commitments, line extension development
- Joint team composition may change to reflect commercial focus (introduce sales, post-approval regulatory, post-approval drug safety, etc)
- Team documentation focuses on Brand Plan, other commercial-oriented plans



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Potential “trouble spots”

1. Last-minute adjustments to launch strategy
2. Sales not as forecasted
3. Maintaining updated safety information in product labels – US, EU, Japan etc.
4. Misalignment on plans for developing additional label claims (line extensions, treatment/delivery regimens, etc...)
5. Misalignment on publication strategy



Troublespot #2: Sales not as projected/forecasted

The Environment

- Each alliance partner has regional sales responsibilities
- Sales/forecast assumptions communicated across alliance
 - Forecast and assumptions are approved annually by the steering committee
- Joint project team meets regularly, includes commercial team representatives and sales updates



Troublespot #2: Sales not as projected/forecasted

The Situation

- Sales updates from one region indicates sales in that region are not as high as forecasted

The Issue

- Ensuring accurate information is conveyed, appropriate corrective actions are identified and taken

The Potential Alliance Trouble

- Erosion in confidence of partner's implementation and/or forecast
- Impact on alliance portfolio
- Potential symptom of larger issue in partner company



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Troublespot #2: Sales not as projected/forecasted

Keys to Success;

Alliance Manager skills/experience;

- Familiarity with sales/marketing, Profit & Loss statements, etc
 - Alliance manager may be the first to know that sales are lagging
- Familiar with 'alliance portfolio' – able to articulate value of this molecule/project to overall alliance collaboration
- Communication/listening – Alliance manager in key position to hear impact on other projects in alliance portfolio, etc
- Conflict management
- Negotiation
- Collaboration:
 - Alliance manager <-> partner
 - Alliance manager <-> project manager



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Troublespot #5: Misalignment on publication strategy

The Environment

- Each alliance partner has regional sales and marketing responsibilities
- Joint publication plan updated annually and approved by the team
- Publications must be approved by each partner's promotional review committee prior to manuscript or abstract submission
- Ongoing registrational studies, post-marketing studies, registries, etc... provide data via periodic reviews/datacuts
- Joint project team meets regularly, includes commercial team representatives and joint publication team representative



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Troublespot #5: Misalignment on publication strategy

The Situation

- No new 'news' expected from studies in upcoming year.
Project would have minimal presence at major conferences

The Issue

- Necessity for 'continuous stream' of info to support sales/marketing in one region conflicts with necessity for 'big news only' info release in other regions.

The Potential Alliance Trouble

- Team members unaware of 'cultural' differences across the regions
- Impact on alliance portfolio



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Troublespot #5: Misalignment on publication strategy

Key to success:

Project manager with understanding/experience in publishing articles/manuscripts.

Alliance manager skilled in identifying and resolving cultural clashes to ensure partnership remains healthy.



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AM:PM Collaboration is essential for marketed product alliance

- Alliance manager – Represents partner position and provides insight into the value of decision at hand to overall partnership.
 - Critical if decisions at project team or steering committee are getting delayed
 - view of ‘alliance portfolio’ is especially key if more than one project with a given collaborator
 - Responsible for the ‘health’ of the partnership



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AM:PM Collaboration is essential for marketed product alliance

- Project manager – provides insight into day-to-day activities and behavior of joint project team
 - Critical to early detection of problems/issues with health of the alliance
 - Key to aligning expectations within the company as well as across the collaboration
 - Crucial to ensuring appropriate transparency of ‘collaboration issues’ and project issues
 - Responsible for the ‘health’ of the project



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Technical knowledge and soft skills are key to successful alliance management

- For a healthy alliance, both the AM and the PM of a marketed project need technical knowledge:
 - Experience with commercial projects;
 - Familiarity with sales/marketing/P&L statements, etc
 - Understanding of post-approval regulatory and promotional practices
 - Awareness of commercial supply chain process
 - Understanding of Brand strategy and Clinical Development strategy
 - Ability to identify and resolve cultural (across companies as well as regions/races) clashes
 - Conscious acknowledgement of partner differences



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Technical knowledge and soft skills are key to successful alliance management

- For a healthy alliance, both the AM and the PM of a marketed project need strong soft skills:
 - Flexibility
 - Self confidence
 - Sensitivity to others
 - Ability to be constructively confrontational (e.g. devil's advocate)
 - Strong interpersonal and facilitation skills
 - Ability to build consensus and encourage teamwork in potentially very different cultures.



Appendix



Troublespot #1: Launch Strategy changes

The Environment

- Each partner has responsibility for filing in respective region, and managing the review process in that region (responding to questions, etc...), core documents (efficacy summary, safety summary, etc...) were nearly identical
- Regulatory approval expected within similar timeframe across all regions (i.e. global launch)
- Global launch strategy aligned across partnership, approved by steering committee
 - Each partner responsible for product launch in that region, messages aligned
- Joint project team meets regularly, includes commercial/launch team representatives



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Troublespot #1: Launch Strategy changes

The Situation

- Review process in one region faster than anticipated; approval in one region earlier than anticipated in launch strategy

The Issue

- Maintaining joint project team focus on execution/implementation of launch plans in both regions

The Potential Alliance Trouble

- Inability to re-align on launch strategy
- Erosion in confidence of partner's implementation



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Troublespot #1: Launch Strategy changes

Keys to success;

Alliance Manager skills/experience;

- Familiarity with launch plans, commercial strategy
- Strategic thinking/problem solving
- Conflict 'prevention'
- Sensitivity to others
- Negotiation
- Collaboration:
 - Alliance manager <-> partner
 - Alliance manager <-> project manager



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Troublespot #3: Maintaining updated safety info in labels

The Environment

- Each alliance partner has responsibility for regulatory updates in their region (post-marketing commitments, safety updates, etc)
- Both regions have ongoing studies (extension, post-marketing, registry, etc...)
 - Safety information from these studies must be consistently interpreted and incorporated into regional product labels.
- Joint project team meets regularly, includes clinical and safety representatives



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Troublespot #3: Maintaining updated safety info in labels

The Situation

- Update to EU label required 5 months prior to update to US label

The Issue

- Ensuring accurate information is conveyed, interpretation is consistent across regions, while maintaining timelines for required label updates.

The Potential Alliance Trouble

- Erosion in confidence of partner's implementation and/or strategy



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Troublespot #3: Maintaining updated safety info in labels

Keys to Success;

Alliance Manager skills/experience;

- Familiarity with post-approval regulatory and safety requirements
 - Alliance manager may be the first to know that updates are due
- Familiar with product marketing -
- Communication/listening – ability to discern subtle differences in interpretation of data and understand potential impact to label/use in either region
- Conflict management
- Negotiation
- Collaboration:
 - Alliance manager <-> partner
 - Alliance manager <-> project manager
 - Alliance manager <-> safety/regulatory managers



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Troublespot #4: Aligning on future development plans

The Environment

- Development of line extensions is shared (similar to initial indication)
 - Each partner has expertise in, and is responsible for, study conduct in their respective region.
 - Cost to develop line extensions is shared (similar to initial indication)
- Development plans are approved by steering committee prior to implementation
- Joint project team meets regularly, includes clinical development representatives



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Troublespot #4: Aligning on future development plans

The Situation

- Project team agrees on recommendation to pursue development of device/drug combination, yet steering committee approval remains elusive.

The Issue

- Slow decision-making, revisiting decisions and reluctance to approve plans may be early signs of project deprioritization within a company
- May distract team from implementation of commercialization plans and/or stagnate development team.

The Potential Alliance Trouble

- Erosion in confidence of partner's implementation
- May be a symptom of changes in strategic focus for the company/therapeutic area/project



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Troublespot #4: Aligning on future development plans

Keys to Success;

Alliance Manager skills/experience;

- Familiarity with development programs
- Strategic agility – ability to discern early signs of strategic misalignment
- Communication/listening – communication of change in priority/strategic focus is often minimal. Alliance manager may be first to hear, potentially via activities on related programs.
- Conflict management
- Facilitation/negotiation
- Collaboration:
 - Alliance manager <-> partner
 - Alliance manager <-> project manager – declining attendance at joint meetings may also be an early sign
 - Alliance manager <-> alliance manager



Alliance Management Skill Set

