

Building and Managing Corporate Alliances in an Academic Medical Center

Teri Melese*

University of California, San Francisco

ABSTRACT

Academic Medical Centers (AMCs) are in a position to help foster the development of better drugs by combining their considerable skills in the basic and clinical sciences with the compounds, medicinal chemistry and know-how of pharmaceutical and biotechnology companies to develop a more innovative and coordinated approach to therapeutic intervention. To capitalize on this opportunity AMCs will need to develop an integrated internal administrative process to develop, manage, and implement corporate alliances, design the optimum structure for these relationships, proactively negotiate the actual partnership agreements, provide project management for collaborative projects, and make informed business and administrative decisions in a timely manner^{1,2,3,4}. The development of an AMC “corporate alliance” team that functionally and philosophically unites the academic administrative offices traditionally involved in corporate partnerships (e.g., sponsored research agreements, clinical trial agreements, material transfer agreements, technology transfer, etc.) is essential^{5,6,7,8,9}. Oversight of this team will require individuals with business and alliance experience; an ability to think both strategically and opportunistically; a detailed understanding of the goals, responsibilities, and governance of AMCs; a first-hand knowledge of the biotechnology and pharmaceutical industries; an extensive network of industrial contacts; and an ability to effectively communicate a vision and build productive relationships at the level of the individual and the institution. Organizations exist that develop and promote “best practices” for alliance practitioners in the corporate sector and such practices will be highly beneficial if adopted in AMCs^{10,11}

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INTRODUCTION

Academic medical centers (AMCs) accept a remarkable challenge: to integrate and achieve with excellence four core missions: delivery of healthcare; education and training of future generations of clinicians and investigators; discovery of new knowledge through incisive, decisive research; and the export of knowledge through effective interactions with industry and government. Each mission is critical, and each must be interactive with and respectful of the others¹². We focus here on the particular challenges and opportunities of the AMC/industry interface, but we remain mindful of the broader spectrum of AMC responsibilities, and we consider as well the issues associated with structuring this interface in a way that facilitates integration with the other core missions.

The health of the AMC rests on its ability to make choices and timely decisions, especially in a time of reduced federal and state resources. Informed decision making is essential to leverage the value of existing resources and to assure that investments meet the needs of the relevant stakeholders and serve the mission of the AMC^{2,4,12}. Many opportunities are lost due to the lack of a defined process by which investigators become aware of, and connected to, existing campus or external resources, including (a) knowledge of potential collaborative research efforts, (b) technology resources, (c) corporate alliances, and (d) licensing opportunities.

A number of key general concepts are outlined to be considered when forming relationships with corporate partners in a biomedical setting. Suggestions are also made about how to improve the business and alliance environment such that working relationships can be effectively guided to enhance campus innovations and increase the interaction among corporate enterprises, campus core technology facilities and the campus research community.

THE CHANGING FACE OF BIOMEDICAL RESEARCH MAKES SOUND BUSINESS DECISIONS AND CORPORATE ALLIANCES AN IMPERATIVE

The practice of biomedical research is changing^{1,2,12}. It is evolving towards a bigger enterprise involving multiple investigators from multiple institutions, both academic and corporate¹. No single investigator can assemble all of the required technologies and expertise to understand complex disease mechanisms and to translate that scientific knowledge into disease treatment. To move discoveries effectively between bench and bedside requires close ties among the basic, clinical, and corporate research enterprises.

Federal agencies also realize the need to unite the core competencies of academia and corporations to develop better drugs for the treatment of disease^{13,14,15}. As an example, the National Institutes of Health developed the AP-4 Center Grants that asked academic institutions to identify corporate collaborations that would focus on treatment of orphan cancers (<http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-04-005.html>). However, such relationships have traditionally been compromised by distrust, the concern being that an academic/corporate engine cannot successfully focus on common and aligned goals^{1,16,17}. Finding a way past the inevitable doubts will be critical to improving patient treatment¹⁷. The good news is that for the first time it might actually be possible to know which medications will be truly effective for those patients receiving them, possibly resulting in less guess work and fewer negative side effects. As an example, it is clear that all stakeholders in the health care industry

will need to work together to successfully navigate the new area of “personalized” medicine or pharmacogenomics¹⁸.

THE VALUE PROPOSITION FOR CORPORATIONS THAT PARTNER IN BIOMEDICAL RESEARCH IS LESS CLEAR THAN IN HIGH-TECH

The ability to form an effective corporate consortium of partners to develop technology standards is deep in the history of some academic centers, but on close examination, happens largely within the engineering or materials science departments. These industries have historically managed to coalesce around the development of a specific technology (e.g., integrated circuits and automobiles), but such consortia applied to drug discovery and development are not readily observed in the biomedical industry¹⁹.

In the engineering areas cited above, there was a “tipping point” at which the technology could only be developed by a collaborative effort because the patented technology required to move the industry to the next level was held by multiple players, making it necessary to pool resources to advance the technology¹⁸. Thus, each partner stood to benefit from the collaboration, and it was clear how the technology advancement would directly affect each company’s product development and return on investment. In contrast, the high costs and risks associated with discovering and bringing a new drug to market and the potential financial rewards for doing so encourage pharmaceutical companies to retain, sequester, and control enabling intellectual property^{20,21}. In the biomedical science community collaborative projects are more readily built around collecting and sharing potentially valuable information as opposed to developing a specific product. An example is the human genome sequencing effort and the identification of single nucleotide polymorphisms (or “SNPs”, which are naturally occurring genetic variations in the human genome, some of which might correlate with disease risk, drug efficacy, drug side-effects, favorable or unfavorable prognosis, etc.). However, the immediate benefit of this information and how it will translate to commercial drugs and diagnostics is not yet clear. Thus, many medical centers struggle with how to define the basis of corporate relationships that expect clear outcomes related to commercial product development. In many ways it is often easier to align the goals in academic engineering departments with companies because they share a common applied focus, whereas biology mostly focuses on open inquiry, and medicine on outcome.

There is also a misconception that corporate alliances are beneficial solely because they provide financial support for research¹. The truth is that most biotechnology companies do not have large discretionary sources of capital given the high costs of drug development, and even pharmaceutical companies do not have a business model that readily supports funding of academic research projects: most critical research is accomplished within the company and outside investments are usually reserved for in-licensing or purchasing potential therapeutic candidates. To be successful an alliance must hold mutual interest and high value for both participants. In this context, corporate partners can offer capabilities and resources not present in academic environments, while academic investigators afford a broad knowledge of basic disease mechanisms and can be sources of biological specimens not available in any single company.

FORMING ALLIANCES IN AMCS HAS DISTINCT CHALLENGES

The art of forming alliances in an AMC poses some interesting challenges. For example, while alliances at a company are driven by strategic goals and implemented by teams of business development professionals, and are essential to the success of the company, at a medical center some investigators might not see the value in partnering, might be dissuaded by the differences in culture, or might prefer to control their own collaborations, which must be respected in an academic environment²².

The organized units of medical centers often present a clear identity that is “easy” to match with prospective corporate partners. For example, centers usually specialize in specific diseases such as diabetes, cancer, or cardiovascular disease. Patient advocates, federal funding agencies, and donors mandate that these centers develop products or information that can be used to guide the treatment of patients and thus provide the driving force for partnering.

A possible strategy is to work with the directors of these centers to develop a portfolio that describes the resources, technologies, and know-how that are essential for a particular institute or center to advance their research effort, and with this information in hand to identify potential corporate partners that might satisfy these needs. Collecting this input is a first step in capturing the global resource needs of the campus and makes it easier to prioritize strategic efforts in developing alliances²³. For example, if a number of campus institutes or centers often request materials or tools on an ad hoc basis from particular pharmaceutical companies, it is worth the campus’s effort to work on master or template agreements with those companies to formalize the partnership and expedite the process for transferring the needed materials to the campus investigators.

As an example, at the UCSF Comprehensive Cancer Center many clinician scientists requested compounds from a pharmaceutical company for studies on an ad hoc basis that required protracted negotiation of a contract for the use of each compound. A decision was made to facilitate the interactions between UCSF and the company by removing the contractual barriers. Acting as an alliance manager at the Cancer Center, the author worked with the company, University of California Office of the President, the UCSF Offices of Technology Management and Industry Sponsored Contracts to coordinate the effort to put a master agreement in place for investigator-initiated trials. The greater ease by which materials could be transferred from the company to UCSF became a driving force for the company to seek to broaden and formalize its working relationship with the Cancer Center. The company perceived that collaborative studies with UCSF would be easier and studies would happen on a quicker timescale.

As the AMC develops multiple template agreements with different pharmaceutical companies it becomes critical to develop a process by which the campus provides information to assure that the investigators involved in these collaborations understand the terms of the agreements so that there will be no conflicts should they decide to collaborate with more than one company. It is important that the investigators have freedom to collaborate with those companies they feel have the expertise or resources they need for their specific projects. A non-exclusive relationship with a number of companies will be more likely to meet the needs of campus investigators.

In discussions with multiple pharmaceutical companies and investigators at UCSF it is clear that both seek to develop best practices for more innovative research collaborations that would result in earlier academic input in to clinical trial design. One vision is to assemble formalized project

teams that include members from the company and the AMC. These teams work together in a timely and efficient manner to accomplish a mutually beneficial goal that is critical to both parties. The formation of such teams allows each party to bring its core competency to the project, encourages sharing of key resources, and includes funding that might be difficult to obtain through federal sources. A challenge will be to provide the infrastructure to assure that project execution goes smoothly and that concerns or issues are communicated to all project team members. The project teams answer another AMC mission: to provide the opportunity for the investigators and their students to better understand the culture of large pharmaceutical or biotechnology companies. Such an understanding will hopefully lower the barrier to forming such alliances in the future.

DEVELOPING A CAMPUS CORPORATE ALLIANCE TEAM UNDER INNOVATIVE LEADERSHIP IS NECESSARY FOR SUCCESSFUL PARTNERING

Most AMCs do not have designated employees whose job is to lead the development of strategic alliances based on specific projects involving technology or materials acquisition. Rather, the initial engagement of a corporate partner in research collaboration is often the sole responsibility of the investigator, who is unlikely to be able to follow through and manage the administrative process required to successfully negotiate a collaborative agreement. Few investigators have the time (or skills) to do this job effectively, and most campus administrators specialize in only one aspect of the process and may be discouraged from (or not rewarded for) acting more globally because of operational constraints (e.g., territoriality)²².

In fact, at many AMCs the process for identifying potential partners, initiating the formation of strategic partnerships, establishing the optimum structure for the partnership, and negotiating the requisite legal agreements with the corporate partner is fragmented and occurs across different offices. Although some AMCs have excellent technology transfer offices, these individuals are expected to focus their efforts on “selling” inventions, and the business relationships they develop with the corporate sector are in the context of technology licensing. Thus, these office(s) are typically not encouraged to develop business relationships around the early stages of collaborative research. As a result, the AMC may fail to take advantage of its resources, and its success in partnering suffers accordingly. Moreover, there is an increased desire for companies to engage in strategic research partnerships reflecting a general trend for companies to move away from licensing arrangements and towards building partnerships²⁴.

On the other hand, most contract officers within AMCs that negotiate research and collaboration agreements for acquiring technology resources are commonly not trained to make science or business decisions and are not experts in intellectual property. Consequently, they lack the skills required to balance scientific and intellectual property risk against the potential benefits of a business opportunity.

Thus, although the intellectual property and contract officers might perform their specific duties well, they might lack context or perspective on the roles of these alliances in the AMC’s broad missions. Money and time are wasted on administrative bottlenecks that might be alleviated if the offices were integrated both functionally and philosophically under creative leadership, to make decisions as an integrated unit, driven by a common objective and value system. Some institutions are taking the step to adopt operational processes that combine these offices and also to develop databases to track corporate partnerships; however, these are only two of the many steps needed to form successful partnerships in the biomedical sciences. There are financial and

scientific consequences for not implementing a process for promoting strategic business decisions within AMCs.

A serious consequence is that some senior investigators seeking to circumvent the campus blockade simply deny their interest in any intellectual property and encourage the university officers to accept inappropriate or unfavorable intellectual property terms from the partnership in order to get the deal done so the research can commence. As a result, the corporate partner might commercialize a lucrative invention without either the scientist or the university receiving fair consideration for its intellectual property.

AN EFFECTIVE CORPORATE ALLIANCE TEAM REQUIRES SCIENCE, BUSINESS AND ALLIANCE LEADERSHIP

To partner effectively, AMCs will require a leader or corporate alliance team with extensive business experience, solid strategic and opportunistic planning skills, first-hand knowledge of the biotechnology industry (its technology, needs, trends, and people), a wide network of connections in the corporate world, an understanding of biomedical research, knowledge of a wide range of technologies, and the skills to forge the right relationships and connect the “right” strategic partners. Within companies, the counterpart of this corporate alliance team is the business development group.

This type of leadership team must be able to move several partnerships along in parallel, and coordinate efforts across campus that have common goals, helping to leverage the value of existing resources. Optimally, a team member would be present at initial meetings between interested faculty and the prospective company partner, assuming a project manager role to assure that action items are completed, communications among partners are sustained and robust, and the partnership moves forward.

The group would have general knowledge of research programs, technology resources, people, and strategic goals across the campus and, as appropriate, would facilitate hand-off to other campus offices. As mentioned above, an effective facilitator not only has knowledge of industry trends and investigator needs, but also serves as a communicator, relationship builder, and project manager to assure follow-through on important initiatives, both internally and externally.

CORE FACILITY DIRECTORS PROVIDE INSTITUTIONAL DUE DILIGENCE

AMCs are creating an expanding network of high-technology research core facilities that offer access to a broad range of instrumentation and services, usually on a subsidized recharge basis, that lie beyond the scope of a single investigator. Campus core facility directors—the professional staff that operate these units—are the resident experts in these specific technologies and should advise the corporate alliance leadership team, rigorously evaluating the technology and suggesting the appropriate alliances to meet or exceed faculty needs. With the growing sophistication of the technologies, together with intense marketing by companies, few biomedical researchers will have experience, breadth, or time to critically evaluate the potential options.

Thus, core facilities can serve as effective interfaces between tool-based companies, AMCs, and individual investigators, with potential advantages for each. For companies, core facilities offer a single portal through which to negotiate supply costs, providing broader access without the need to market to individual researchers. For the institution, core facilities produce price negotiation

leverage. For investigators, they open a stream of appropriate frontline technologies that may otherwise have remained inaccessible and perhaps even unknown. Moreover, facility directors provide a stable base of expertise for technology training and communication that would otherwise be missing in the highly dynamic environment of graduate students, clinical trainees, and postdoctoral fellows who populate academic laboratories. It is not surprising that many tool-based companies embrace the notion of centralizing their technologies in core facilities that serve an entire campus.

CORPORATE ALLIANCES CAN PROMOTE OTHER AMC MISSIONS

Perhaps the greatest challenge to achieving the four key missions of AMCs (healthcare, education, research, and dissemination of knowledge) is the potential for these missions to be conflicting or contradictory. Can trainees be put on the wards and still deliver the finest patient care? Can partnerships be built with corporations without sacrificing the open intellectual inquiry needed for education and research? Can the most insightful discoveries be made in laboratories powered by students?

To avoid such conflicts requires that each mission be approached thoughtfully and in a manner that takes the other three into consideration. In turn, this demands close interaction and cooperation between those with primary responsibilities for each mission. Although it is not practical to govern these functions from a common office, explicit responsibility for vigilance and oversight at the highest administrative levels is essential for proper integration. Successfully done, the execution of each mission could enhance the other three. For example, thoughtfully crafted research alliances could serve not only to move knowledge beyond academic walls, but also to deliver novel technologies into the research and health spheres that indeed bolster the bridge between them, to strengthen both the conceptual underpinnings and the practice of education, and to provide resources that can help support the whole institution.

CONCLUSION

Partnerships require time, effort, expertise, and management by a corporate alliance team that unites key personnel, functions, responsibilities, and resource capabilities now commonly spread across multiple campus units. Together, this group can build and capitalize on a working knowledge of internal and external resources and develop a rich functional business network for campus investigators that leverages institutional resources.

Successful alliances are driven by complementary needs of the partners, and the joint perception that meeting those needs would benefit each partner. The right team would couple business expertise, a sophisticated knowledge of research within the AMC, and a robust network of corporate contacts and interactions to complete the entire process from the initial science discussions to the business and intellectual property discussions, the actual contract negotiation, and the monitoring the performance of the partnership against mutually agreed-upon milestones. Operating within an integrated institutional context, the corporate alliance team can advance many key goals of modern AMCs.

REFERENCES

1. Business Higher Education Forum, American Council on Education. (2001). *Working Together, Creating Knowledge: The University Collaboration Initiative*. Washington, DC.
2. Moses, H., III, S. O. Their, and D. H. M. Matheson (2005). "Why Have Academic Medical Centers Survived?" *JAMA* 293, 1495–1500.
3. California Business, Transportation and Housing Agency. (2003). *Recommendations for Improving the Effectiveness of the University of California Technology Transfer Process and Enhancing Technology Commercialization*. Sacramento, CA.
4. D. M. Aguirre, et al. (2005). *A Global Check Up: Diagnosing the Health of Today's Organizations*. Oslo, Norway: Booz|Allen|Hamilton.
5. Cerami, J. R. (2001). "Research in Organizational Design: The Capacity for Innovation in Large Complex Organizations." *The innovation Journal*, www.innovation.cc/discussion-papers/organizational-design.htm
6. Williams, P. (2002). "The Competent Boundary Spanner." *Public Administration* 80, 103–124.
7. Andriof, J. and S. Waddock (2002). *Unfolding Stakeholder Thinking: Theory, Responsibility and Engagement* (Sheffield, Greenleaf Publishing), pp. 19–42.
8. Maurer, M. and S. Sachs (2004). "Implementing the Stakeholder View—Learning Processes for a Broader Stakeholder Orientation." Paper presented to the International Association for Business and Society.
9. Gibbons, M. (1998). *Higher Education Relevance in the 21st Century*. New York: Association for Commonwealth Universities. Pp. 45–50.
10. <http://www.strategic-alliances.org/bestpractices/alliancecapability.pdf>
11. Draulans, J., et al. (2003). "Building Alliance Capability: Management Techniques for Superior Alliance Performance." *Long Range Planning* 36, 151–166.
12. Awasthi, S., et al. (2005). "Five Futures for Academic Medicine." *PLoS Med* 2, 1-8.
13. U.S. Department of Health and Human Services Food and Drug Administration (2004). *Challenge and Opportunity on the Critical Path to New Medical Products*. Washington, DC. Pp. 1–38.
14. Korn, D., and D. Stanski (2005). *Drug Development Science: Obstacles and Opportunities for Collaboration Among Academia, Industry and Government*. San Francisco: The Association of American Medical Colleges, Food and Drug Administration and Center for Drug Development Science at UCSF

15. The National Academies: Institute of Medicine (2004). *Forum on Drug Discovery, Development and Translation*. Washington, DC. Pp. 1–2.
16. Severson, J. A. (2003). “Tectonics in the University-Industry Research Partnership.” *Research Management Review* 13, 1–11.
17. Stossel, T. P. (2005). “Regulating Academic Industrial Research Relationships – Solving Problems or Stifling Progress.” *New England Journal of Medicine* 353, 1060–1065.
18. Lesko, L. J. and J. Woodcock (2004). “Translation of Pharmacogenomics and Pharmacogenetics: A Regulatory Perspective.” *Nature Reviews: Drug Discovery* 3, 763–769.
19. Grove, A. (2005). “Efficiency in the Health Care Industries: A View from the Outside.” *JAMA* 294, 1–3.
20. DiMasi, J. A. (2001). “Risks in New Drug Development: Approval Success Rates for Investigational Drugs.” *Clinical Pharmacology Therapy* 69, 297–307.
21. Thompson, T. B. (2003). “An Industry Perspective on Intellectual Property from Sponsored Research.” *Research Management Review* 13, 1–9.
22. Mintzberg, H. and L. Vander Heyden (1999). “Organigraphs: Drawing How Companies Really Work.” *Harvard Business Review* 77, 87–94.
23. Matkin, G. W. (1990). *Technology Transfer and the University*. London: Macmillan.
24. Warner, S. (2005). “Good-Bye Licensing Deal, Hello Partner!” *The Scientist* 19, 36–42.

ABOUT THE AUTHOR

Teri Melese is an Adjunct Associate Professor in the Department of Medicine at the University of California, San Francisco, and is Director of Research Technologies and Alliances in the UCSF School of Medicine Dean’s Office. Before joining UCSF in 2001, she ran an independent research laboratory in yeast genetics and molecular biology at Columbia University from 1988–1997 and in 1997 left Columbia to be founding member of Iconix Pharmaceuticals, a biopharmaceutical company in Silicon Valley. She has 4 patents for biomedical technologies and small molecule inhibitors and is the author of numerous scientific articles. In 1988, she was awarded a National Science Foundation Young Presidential Investigator Award. Melese holds an A.B. from the University of California, Berkeley, a Ph.D. in Cell Biology from UCSF (Regents Fellow), and was an American Cancer Senior Postdoctoral Fellow at the University of California, Los Angeles.
