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Pfizer's Centers for Therapeutic Innovation

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Abstract

Pfizer recently announced the formation of a network of academic collaborators to accelerate the translation of basic science into biologics-based drugs. Pfizer anticipates establishing local Centers at each partner site enabling Pfizer and Academic Medical Center teams to work closely together. The University of California, San Francisco (UCSF), has signed on as the first of multiple partners. The partnerships will follow a venture capital-funded biotechnology start-up model, whereby Pfizer funds preclinical and clinical development programs and offers equitable intellectual property and ownership rights. Pfizer has the goal of expanding the Centers to Europe and Asia in 2012. Assuming eight projects per CTI, this could bring dozens of differentiated entities against targets into Pfizer's pipeline.

1.0 Introduction

Pfizer recently announced the formation of a network of academic collaborators to accelerate the translation of basic science into biologics-based drugs. According to Mikael Dolsten, M.D., Ph.D., president of Pfizer Worldwide Research & Development, the Centers represents a novel open innovation paradigm, combining the competencies of top academic research institutions with Pfizer's leading drug development capabilities and research technologies. (Pfizer, 2010) The Centers for Therapeutic Innovation (CTI) will initially focus on collaborations within the U.S. Pfizer expects to expand into Europe and Asia in 2012. Each Center will be governed by a Joint Steering Committee (JSC) comprised of Pfizer and Academic Medical Center (AMC) representatives who will provide leadership and evaluate the success of each program through discovery and early stage clinical development. Through this innovation model, Pfizer will have the opportunity to broaden its pipeline with novel candidate drugs to treat diseases—addressing unmet medical need. (Pfizer, 2010)

2.0 The Partners

The University of California, San Francisco (UCSF), has signed on as the first of multiple partners in Pfizer's Global Centers for Therapeutic Innovation. UCSF will receive up to $85 million in research support and milestone payments over the course of the five-year partnership. Pfizer will open labs adjacent to the UCSF campus, where Pfizer scientists will work alongside university researchers to find new biologics targeting a range of diseases. Although Pfizer has an R&D site in South San Francisco, proximity to the UCSF campus is seen as critical to fostering an effective intellectual exchange according to Anthony J. Coyle, who will head CTI. (Jarvis, 2010)

In January of 2011, Pfizer Inc. further announced that seven major research-based medical centers in New York City joined Pfizer's CTI. The New York medical centers include: Rockefeller University, New York University Langone Medical Center, Memorial Sloan-Kettering Cancer Center, The Mount Sinai Medical Center, Columbia University Medical Center, Albert Einstein College of Medicine of Yeshiva University, and Weill Cornell Medical College. Pfizer has signed a lease at the Alexandria Center for Life Science—providing the company with research space to facilitate its New York City-based collaborations. The Alexandria Center is a life science park in New York City and home to a number of research organizations and leading life science entities. Its office and laboratory space encourages collaboration and

is ideally located to facilitate close working relationships between Pfizer and its academic partners. (GEN News, 2011)

3.0 The Open Innovation Model

A key aspect of the Centers for Therapeutic Innovation is Pfizer's commitment to establishing local Centers at each partner site. The partnerships will follow a venture capital-funded biotechnology start-up model, whereby Pfizer funds preclinical and clinical development programs and offers equitable intellectual property and ownership rights, as well as broad rights to publication. When programs are successful and advance according to the terms determined by a joint steering committee, Pfizer will grant milestone payments and royalties. (Rockefeller University, 2011)

"The concept is to make a transition away from the vertically integrated R&D model into smaller, decentralized groups of a truly global nature," says Pfizer's Anthony Coyle, who is heading up the program out of the company's Cambridge, Massachusetts, facilities. (Ratner, 2011) (Figure 1)

The CTI will provide the primary investigator (PI) with funding (postdoctoral support), technical support (dedicated Pfizer personnel with expertise in protein sciences and development), and infrastructure (laboratory space, libraries, robots). (Pfizer, 2011) The incentives, operating model, and goals for participating primary investigators and Pfizer colleagues will be designed to support achieving a positive Proof-of-Mechanism study in humans (PoM). PoM studies are small, investigator-led clinical trials that typically involve 10 to 30 human subjects and have defined mechanistic or therapeutic endpoints. (Pfizer, 2011)

4.0 Governance of the Projects

A call for proposals is going out to UCSF and a steering committee composed of four representatives each from Pfizer and the university will decide which projects to fund. CTI expects to accept up to eight programs annually from UCSF. (Jarvis, 2010)
The JSC will govern the partnership and has overall accountability for program progress—responsible for such activities as selecting high-quality projects, monitoring timelines and milestone achievements, overseeing management of potential conflicts of interest, and ensuring that leading PIs are involved in the program. By sharing equally in the decision-making process, Pfizer aims to establish a strong partnership and communication strategy.

At each critical milestone, the JSC will review study findings and make go/no-go decisions. Once a project has progressed to the stage of a candidate therapeutic protein, the JSC will review the data to determine if the project should progress to preclinical development. Specifically, the steering committee will have access to a flexible fund used either for additional biology or to allow the joint project team to move a compound into trials. There will be two clinical milestone payments—one at proof of mechanism and the other at successful proof of concept.

All joint inventions will be jointly owned, with Pfizer holding an exclusive option to license a drug after proof of mechanism. In the event Pfizer exercises its option, any jointly developed enabling intellectual property (IP) would be licensed from the institution. If Pfizer declines, IP and other joint assets revert to the institution. The compound may be licensed by the AMC or furthered through alternative means, including out-licensing to another organization or spin-out into a separate company. (Ratner, 2011) (Figure 2)

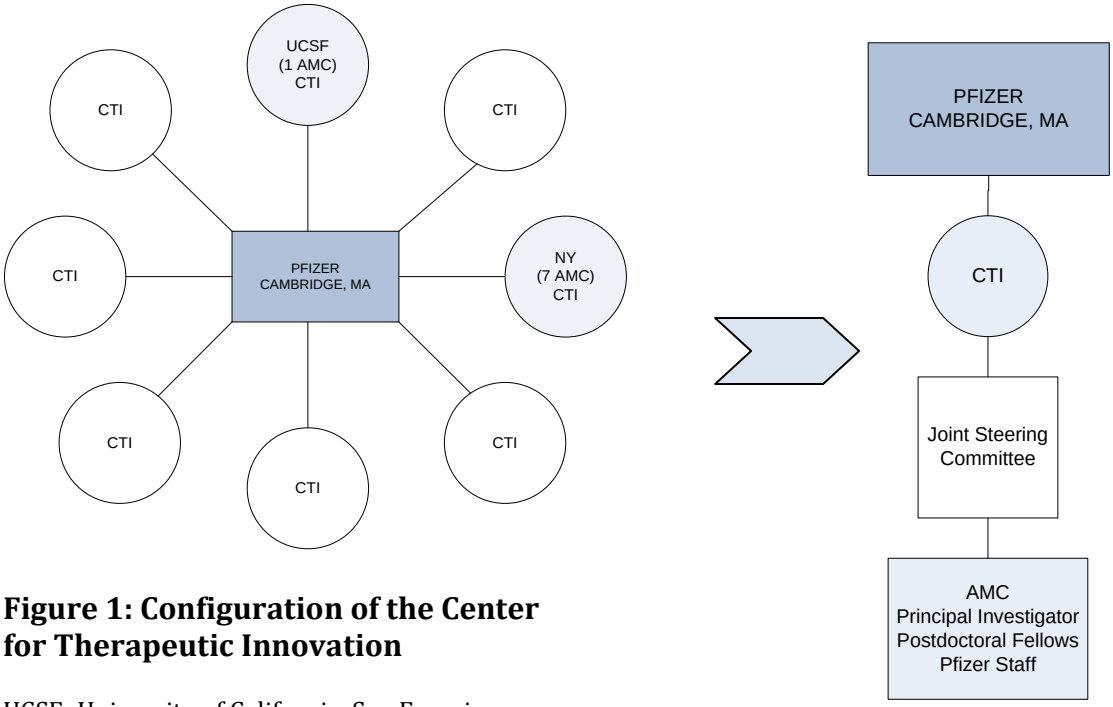

Figure 1: Configuration of the Center for Therapeutic Innovation

UCSF=University of California, San Francisco; CTI=Center for Therapeutic Innovation; AMC=Academic Medical Center; PI=Principal Investigator; PM=Project Manager; AE=Antibody Engineer; AB=Assay Biologist; PS=Protein Scientist; JSC=Joint Steering Committee; IP=Intellectual Property

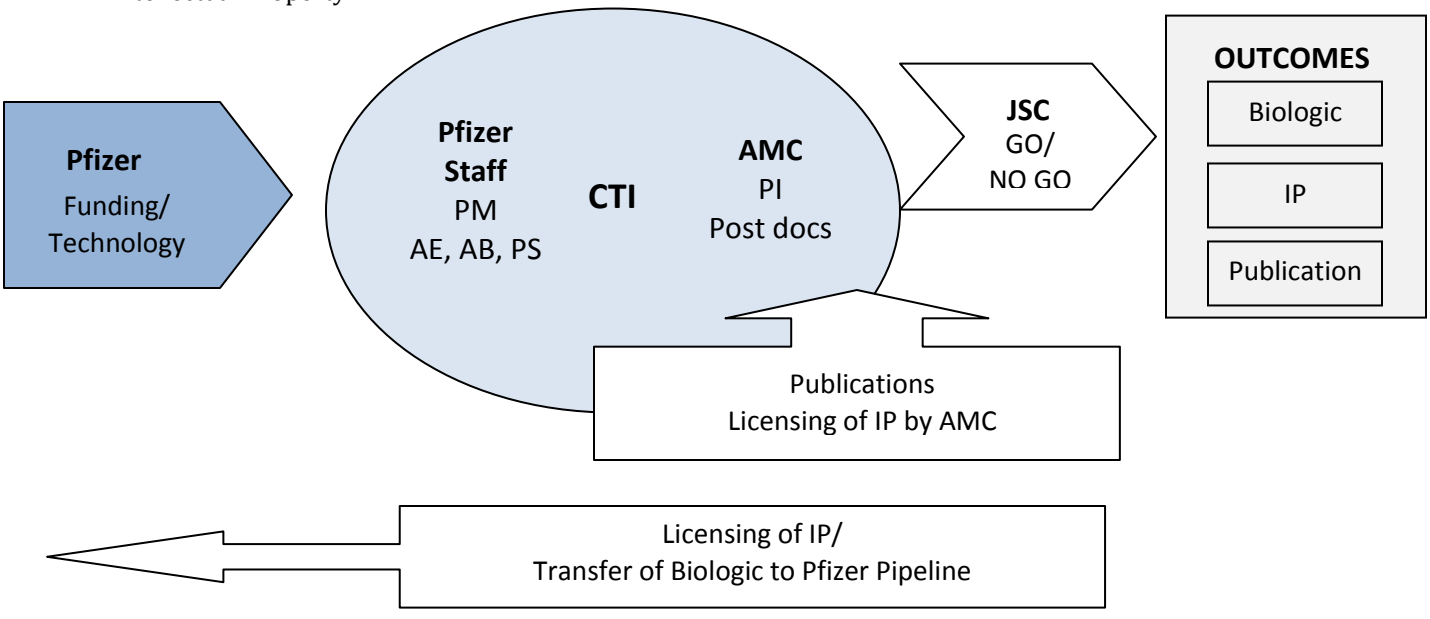

Figure 2: Investments and Outcomes from the Center for Therapeutic Innovation

5.0 Structural Organization: Roles and Resource Commitments

The CTI laboratory will be a small, flexible, and semi-autonomous unit located in close proximity to the Academic Medical Center (AMC). Laboratory staff includes both Pfizer employees dedicated to a specific function and AMC postdocs. A Pfizer colleague will lead the CTI laboratory and serve as the single point of contact and accountability. All CTI laboratory staff will actively support research efforts by providing technical guidance, project management, and other functions within the scope of their capabilities. In addition to the dedicated CTI laboratory staff, Pfizer may provide access to non–CTI-based Pfizer scientists who have specific expertise that may be of use to a program. (Pfizer, 2011)

Roles and functions of Pfizer colleagues assigned to laboratories include: Antibody Engineers, Assay Biologists, Cellular Immunologists, Protein Scientists, and Project Managers. Table 1 outlines the expertise that these investigators will provide.

Beyond funding, the CTI will provide unprecedented access for JSC-approved investigators and postdocs to specified proprietary antibody tools and technologies. These technologies and tools should enable programs to move forward as quickly as possible. The tools and technologies that may be available to investigators are outlined in table 2.

6.0 Anticipated Outcomes and the Future

UCSF anticipates initiating at least two to three new UCSF-CTI projects per year, up to 8 per year. Projects within the CTI will identify novel molecules that can be targeted by biologics, captured at the earliest stage—building on the existing understanding on the new target biology and the translational medicine expertise that resides with the PI and at UCSF. The UCSF-CTI center will focus on biotherapeutic modalities including antibodies, peptides, and proteins across all therapeutic areas. (UCSF, 2010)

Function	Expertise
Antibody Engineers	Expertise in antibody libraries and antibody generation
Assay Biologists/ Cellular Immunologists	Expertise to help translate biology into high-quality, effective assays for antibody discovery or development
Protein Scientists	Experience in protein pharmaceutical sciences (eg, formulation, cell-line development, protein analytics)
Project Managers	Overall project management capability, accountable for helping to achieve goals, tracking progress, and focusing team efforts

Table 1: Functions and Roles Assigned to CTI

Source: Pfizer, 2011.

7.0 Discussion

Chesbrough (2003; 2007) explains that innovation has become open through division of labour. In many industries, the vertically integrated organizational structure where innovation is solely an internal activity is gradually being transformed into a more fluid

Technology	Associated Tools
Libraries and Technologies	– In vitro lead generation: phage display library design, generation, and screening – In vivo lead generation: rodent hybridoma, B-cell selection, Avian mAbs – Humanization – PK engineering Human phage display libraries – Screening and optimization technologies – Human phage display libraries – Screening and optimization technologies
Biotherapeutic Engineering and Production	Rapid antibody generation – Protein engineering to improve potency, selectivity, pharmacokinetics – Protein modification (eg, PEGylation, HESylation, etc) – Biophysics and bioanalytics (eg, BIACore, DSC, Mass Spec, etc) – X-ray crystallography and NMR – Molecular modeling

Table 2: Resource Commitments

Source: Pfizer, 2011.

structure integrating internal and external sources of innovation. For example, companies are finding value through the licensing of intellectual property, the development of joint R&D ventures, or other arrangements to exploit technology outside the boundaries of the firm. (Chesbrough, 2003; 2007) From a knowledge perspective, in the closed model, human capital is employed within the boundaries of the organization. Knowledge is generated within and is owned by the originating firm. The organization's profit model revolves around the notion that knowledge is discovered, developed, and then embodied within firm-only products. (Chesbrough 2003) Appropriated knowledge is controlled by the originating firm. In the open model, human capital and knowledge are accessed both inside and outside the boundaries of the organization. External knowledge can create significant value for a firm; internal innovation processes are therefore also needed to evaluate and exploit this knowledge. Firms can profit from the embodiment of knowledge within internally developed products as well the embodiment of knowledge in products developed by other firms. (Chesbrough, 2003)

Given these developments, Corley et al. (2006) and Rampersad et al. (2010) discuss the increasing importance of networks for innovation success. Arguing that as research in the sciences and engineering becomes increasingly multidisciplinary, researchers and policy-makers are relying on and advocating the use of multi-disciplinary collaborations to handle the complexities of research and ultimately technology development. Corley et al. (2006) cite that policy in countries such as the US and the UK has moved from the decentralized support of small, investigator-initiated research projects to large scale and many times centralized, block grant-based multidisciplinary research. (Bozeman and Boardman, 2003) The pervasiveness of enabling technologies such as nanotechnology, biotechnology, and information and communications technology (ICT) have encouraged innovation networks to increase in dominance. These enabling technologies and their association to a variety of industries have lead to the blurring of organizational boundaries among research organization, with the end result large and dense networks. (Powell et at., 1996; Roijakkers and Hagedoorn 2006)

The need then exists to understanding innovative designs for multi-organizational research collaborations. Researchers have specifically called for an examination of the

management processes in innovation networks as these networks have not only grown in relevance, but also in terms of impact and the number of participants involved. (Geels 2002; Moller and Svahn, 2009; Rampersad et al., 2009; Allarakhia et al., 2010) Here we begin to analyze models of open innovation to better understand the organization of stakeholders, the governance of research activities, and the impact of collaborative activities in terms of successful drug development.

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