New Business Models for Drug Development

Networks, PPPs, Training Collaborations: Emerging Models of Open Innovation in Asia

Capacity Development for Chronic Disease Management in Asia
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- and commercialization complexities associated with technology transfer and product development.

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Contact Information:
Dr. Minna Allarakhia
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Innovation-Focused Clinical Trials: New Strategies and Business Models in Drug Development

By Tim Dietlin
VP of Alliance Development
INC Research

Biopharmaceutical companies are feeling increasing pressure to bring new drugs to market faster. At the same time, the clinical research organization (CRO) industry has developed more sophisticated infrastructure, processes and talent, which collectively are increasingly difficult for sponsors to replicate in-house, particularly on a global level. As a result, CROs are fast becoming recognized for leading innovations in partnership models, study design and in offering new ways of employing science and technology to significantly impact the overall clinical development process.

Widely acknowledged for their clinical trials and therapeutic expertise, CROs can help shrink timelines, deliver on budget and help biopharmaceutical companies remain competitive. Innovative partnership models coupled with a CRO's experience in developing and adopting game-changing advances in digital and scientific technologies are giving biopharmaceutical companies not only an edge in the marketplace on expertise, proprietary processes and faster execution, they're also benefiting from innovations developed by CROs to create greater efficiencies that help bring drugs to market faster.

Forward-Thinking Strategic Alliances

Faced with healthcare reform, the loss of blockbusters, and competition from generics and biosimilars, the pressure on biopharmaceutical companies to bring new drugs to market faster is more intense than ever. As a result, they have been reinventing their business models with an increased discipline to manage their bottom line and innovate their research and development efforts.

One such business model that is quickly emerging as a way for biopharmaceutical companies to benefit from CROs as innovation partners is the clinical delivery strategic alliance. Unlike project-specific outsourcing, clinical delivery alliances differ from traditional CRO partnerships because they are based in mutually furthering portfolio objectives, meaning CRO and sponsor are both incentivized to complete the scope of work efficiently, effectively and to a high level of quality. These incentives can take the form of key-milestone-based payments, sharing of risk or even co-investment in assets. Furthermore, strategic alliances enable CROs to focus more deeply on the commercial and regulatory viability of compounds much earlier in the drug development lifecycle.

Oncology, in particular, is a therapeutic area where the benefits of clinical delivery alliances are intensified. Given the complex nature of oncology R&D, which often includes the pursuit of multiple indications for each compound and may alter priorities several times over the course of a trial as new data develops, there is a greater need for flexibility, commitment and shared ownership of clinical development. The level of flexibility that comes from strategic alliances enables teams to quickly adjust to protocol changes, which is paramount when it is not known which tumor type will indicate the strongest signal.

When forming clinical delivery alliances for oncology drug development programs, CROs are able to build a portfolio management structure that includes executive-level strategic and operational oversight for a more holistic and standardized approach, creating significant efficiencies. Oncology strategic alliances also create a level of visibility into the entire portfolio of work and ultimate sponsor goals, which is not possible at a tactical level. This visibility into the sponsor's oncology pipeline and the pursuit of multiple indications also allows for better scientific and operational foresight.

Understanding outcomes from certain indications can have implications across other studies on that compound, and the team can make any adjustments needed. CROs have better wherewithal to reserve and allocate the right resources for upcoming projects. On the operational side, CROs offer practice leaders with deep oncology experience to assemble dedicated teams with specific medical and statistical knowledge and career commitment to various therapeutic treatments along with advanced alliance management systems that provide a real-time status of all projects and governance issues.

Because of the way a clinical delivery alliance is structured, CROs are able to extend their pipeline management expertise, establish custom metrics reporting and transparency, and manage development and commercialization opportunities for the duration of the alliance. This includes a senior-level governance team that drives the vision for the partnership.

Innovative Strategies for Informed Decision Making and Clinical Trial Agility

The cost of bringing a new drug to market has been estimated between $800 million and $1.2 billion, with the timeframe for approval and launch ranging from seven to 12 years. To accelerate early identification and selection of the most promising compounds, CROs are increasingly providing their clients with integrated, early-phase development strategies and expertise, particularly first-in-human and accelerated proof-of-concept studies.

Proof-of-Concept Studies

Accelerated proof-of-concept studies incorporate a CROs expertise and capabilities in the complexities of the healthcare industry, regulatory strategy, drug development and clinical pharmacology. They are growing in popularity among small pharmaceutical and biotechnology companies to demonstrate the early signals of a product's efficacy in increasing a company's net present value so they can avoid costly late-stage clinical development failures or situations where they are forced to sell the asset. For example, customized proof-of-concept solutions provided by a CRO might include the use of adaptive clinical trials and electronic data capture to accelerate access to study data. For sponsors looking to identify and select promising drug candidates earlier, proof-of-concept studies can help make better go/no-go decisions faster.

Adaptive Trials

For biopharmaceutical companies looking to accelerate the clinical trial process, shorten timelines and reduce costs, adaptive clinical trials offer an efficient approach to getting a product approved by giving the right medicine to the right patient in the right dose at the right time. Additionally, adaptive trials offer the ability to make adjustments while the trial is happening to maximize resources and minimize failures.

Adaptive trials also make it possible to involve fewer patients in studies that might eventually prove futile and reduce the number of patients treated with placebo. The most commonly made adjustments to adaptive trial elements in studies currently conducted by CROs include reducing sample size; stopping the study early due to safety, efficacy or futility; and eliminating non-responsive, inferior treatment arms.

Biomarkers

About 90 percent of new compounds entering the clinical trial phase fail before reaching approval. These failures may be due to such issues as lack of efficacy, inappropriate safety profile or risk/benefit ratio. One way CROs are reducing failures in clinical trials is by using biomarkers.

A biomarker is defined as a “characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes or pharmacologic responses to a therapeutic intervention.” Biomarkers are detectable and measurable by a variety of methods, including physical examination, laboratory assays and medical imaging. Advances in biomarker research are providing researchers with insights into the underlying genetic causes of disease that can lead to improved diagnosis and treatments. In Alzheimer's Disease, for example, clinical diagnosis is accurate only 10 to 15 percent of the time while recent biomarker-based tests identify the risk of Alzheimer's in more than 85 percent of patients.

Advances in biomarker research provide researchers with insights into the underlying genetic causes of disease that can lead to improved diagnoses and treatments. CRO researchers are using disease-specific biomarkers to improve the accuracy of diagnosis, stratify patients according to their genetic makeup, develop smaller, more targeted cohorts of patients for testing and predict drug efficacy and safety more quickly. By using biomarkers, CROs are helping sponsors make more informed decisions about their compounds faster.
**The Impact of Digital Technologies on Drug Development**

New technologies are providing breakthroughs to make healthcare more affordable, accessible and sustainable. In the clinical trial process, CROs have been driving the adoption of digital technologies to facilitate improved data capture and sharing, improve site monitoring and data verification, and accelerate patient recruitment.

**Electronic Document Management Systems**
For CROs, Electronic Adjudication Systems (EASs), web-based electronic systems that expedite the movement and online review of documents, scans and other medical materials by independent adjudicators, are quickly replacing the paper-based processes and are providing earlier confirmation of the benefits of drug candidates. EASs can decrease the costs associated with the overnight shipping of documents, X-rays or ECG readings because these documents are posted to a secure, central data depository accessible to physicians around the globe.

**Electronic Medical Records**
Electronic medical records (EMRs) are paving the way for the healthcare industry’s adoption of paperless solutions. The emergence of EMRs means many traditional clinical trial sites are shifting to electronic collection of all information. This data has multiple uses in clinical research, from identifying specific patient types to real-time protocol monitoring.

Eventually, the widespread availability of EMRs might force researchers and regulators to rethink the entire clinical trial process. The combination of EMRs with commercial genomic kits could change the way patients are identified and therapeutics are developed. For example, the controlled release of a medication to a limited population of patients who monitor their own health using home-based technologies could allow sponsors to see the effectiveness of new medications in real-time rather than enrolling them in traditional trials. Data mined from EMRs could be used to supplement the results of post-approval/Phase IV trials.

**E-patients**
The clinical trial recruitment process is also experiencing a revamping through new models that leverage the power of the Internet and e-patients. E-patients are health consumers who use the Internet to gather information about a specific health condition or use electronic communication tools to cope with medical conditions. The interest and active role that E-patients take in safeguarding their health have given pharmaceutical companies and CROs the ability to leverage the Internet to not only widen access to clinical trials for both physicians and patients and streamline and speed up the clinical trial process, but also to the ability to educate physicians and patients on emerging products and therapies and facilitate earlier and better decision-making by creating an information-rich environment.

CROs offer ways to leverage the Internet beyond just recruiting patients. The consent process could be entirely completed online and a pre-study visit could be conducted using Internet video technologies. Depending on the type of trial, medication could be dispensed without the patient needing to visit a study doctor, nurse or site in person. As data collection and analysis are already happening over the Internet, the idea of conducting a trial this way can save time and money.

**Social Media**
Social media is another tool being used to increase and accelerate trial enrollment. With an estimated 85 percent of all clinical trials being delayed due to poor patient enrollment, social media represents a tremendous opportunity for clinical trial sponsors, as many patients are already increasing their awareness of diseases and educating themselves through chat rooms and online research.

The major challenge of using social media as a patient enrollment strategy is the lack of clearly defined regulations to guide its use. Legal and regulatory concerns may cause corporate sponsors to limit the use of social media for any purpose, including clinical research. However, many patient recruitment companies and online patient communities are forging ahead and experimenting with social media to educate patients about clinical research and share information on new trials. Understanding that time to market is key, innovative CROs are using social media as a way to increase awareness and accelerate patient recruitment.

**The Future of Drug Development**
CROs are transforming the practice of clinical trials by applying digital and scientific innovations to accelerate new drug development. To meet society’s demand for affordable healthcare, biopharmaceutical companies must transform the drug development process, decrease costs and increase efficiencies to bring drugs to market faster.

The recent shift in the biopharmaceutical company-CRO relationship from project-specific outsourcing to clinical delivery strategic alliances has made it easier for these companies to benefit from CROs as innovation partners. Based on furthering portfolio objectives, these multi-year strategic alliances include more input from the CRO and leverage years of perspective, expertise and tactical approaches, enabling CROs to concentrate on the commercial and regulatory viability of compounds much earlier in the drug development lifecycle. Partnership models between biopharmaceutical companies and CROs that challenge assumptions and drive innovation have the most potential to impact products that improve patient health.

Tim Dietlin is vice president of Alliance Development at INC Research. He can be reached atmailto:Timothy.Dietlin@INCResearch.com.

**References:**

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Public Partnerships for Malaria: Engaging Stakeholders Within and on the Periphery of the Health Commons

Increased technological and market complexities associated with new drug development are drivers in the formation of a health commons. Used originally to describe the sharing of natural resources including the interactions that occur to manage such natural resources, the health commons refers to knowledge-based assets that are shared or owned in common by stakeholders found across the health value chain. This health commons offers several advantages including knowledge sharing, knowledge verification, joint and common knowledge creation. The Human Genome Project is perhaps a turning point in the creation of the health commons—with both varied resources such as information, biological materials, research-based tools and models, and even chemical compounds deposited into the commons; further, stakeholders from both the public as well as private sectors appear to be participating in its construction. The need for verification in the post-genome era gives the uncertainty of knowledge associated with disease processes and hence value creation, has become paramount. Further, the scale and cost of research is no longer manageable by isolated laboratories or firms.

Moving from early biological research, to compound development and then clinical testing, the notion of openness changes: beginning with open access to information, materials, tools, and compounds including public sector entities, private sector stakeholders, and uniquely, patients in the commons; evolving to dissemination of newly created resources via open licensing strategies including stakeholders functioning within and outside the health commons; and emerging as open collaboration between stakeholders acting on the periphery of the health commons. Worth noting is that upon approval and market entry, open access strategies may be used to distribute medical products to those at the bottom of the pyramid. In this article, the initial focus is on the role of public private partnerships for malaria as enabling for open innovation and the engagement of stakeholders either within or on the periphery of the health commons.

The incentive to engage in R&D targeting neglected diseases has typically been carefully managed through public-private partnerships (PPPs). These partnerships have the objectives to encourage the creation of new technologies and to ensure its availability to as many patients in disease-endemic countries. Taubman (2010) discusses that the World Health Organization has distinguished PPPs for product development for neglected diseases from PPPs focused on access to existing drugs (Merz, 1995). Product development PPPs are non-profit organizations that sponsor others to conduct R&D—be it discovery, preclinical, clinical, or manufacturing based activities. Access PPPs are instead non-profit organizations primarily concerned with expanding access to health-based technologies in existence, by collaborating with manufacturers and funding agencies, as well as developing countries. Through such collaborations, access PPPs play a role in the purchase and distribution of existing drugs, vaccines and other medical technology in developing countries (Merz, 1995; Taubman, 2010).

Product development PPPs carefully craft out agreements pertaining to both the rights to and exercise of background intellectual property (that is, IP) that is brought to and developed under a research program or project based IP (that is, IP generated from funded research and development). PPPs as such, must balance the need to encourage their private sector partners to engage in the necessary R&D including resource commitment where such R&D generally would not occur without sponsorship and the need to ensure broad access to the final products to patients in neglected markets. IP management in this case, may involve IP exercise rights segregated by market, with the private sector player maintaining ownership and/or exercise rights in developed markets while ceding rights for developing markets; access to IP beyond the scope of the sponsored research such as background technology required for final product development; march-in rights that ensure that IP will be transferred to the non-profit organization in the event that the private sector partner fails to meet its commitment; and access to necessary IP (including to test data, background technology, manufacturing know-how) provided for third parties in the event that the original private sector partner fails to meet the agreed upon criteria for dissemination of the new product in neglected markets (Taubman, 2004; Taubman, 2010).

Access PPPs may alternatively consider the optimal downstream distribution of a finished product and not give priority to ownership of IP. As a consequence, IP ownership can be traded in exchange for meeting specified distribution targets. In this case, ownership rights to IP generated through funded research, access to background IP, and provisions pertaining to licensing new technology particularly for developed markets, can be used as part of the trade-off for fair and broad technology distribution to neglected markets.

The trade-off will include distinct requirements for how the technology is to be distributed in target markets such as volume of distribution, preferential pricing, or access provided on the basis of non-market mechanisms (Merz, 1995; Taubman, 2004; Taubman, 2010; DNDi, 2011; IAVI, 2011).

While the literature is filled with discussions of PPP IP ownership and exercise rights provisions, further analysis reveals a multitude of other mechanisms employed by public sector and private sector stakeholders to promote openness including: the development of disease specific commons; open collaboration; humanitarian or preferential licensing; patent pools under a joint licensing scheme; patent commons with non-assertion pledges; and donation programs providing access to final products.

Medicines for Malaria Venture (MMV)

The discussion of strategies to develop technologies for the treatment of malaria typically begins with the Medicines for Malaria Venture (MMV) and Malaria Vaccines Initiative (MVI). MMV was launched in 1999. As a virtual organization, all of MMV’s R&D, access and delivery activities are undertaken in collaboration with partner organizations across the world (MMV, 2011). MMV has worked in partnership with more than 130 research institutions and companies. Pharmaceutical and biotech partners bring expertise and facilities in drug discovery and development, including access to cutting-edge technologies to speed up discovery by compound screening, as well as manufacturing capability. In the public sector, academic research institutions bring scientific research expertise and facilities in areas ranging from basic biology to clinical medicine and field expertise (MMV, 2011).

When MMV enters into contractual relationships with its partners, its primary goal is to make certain that the malaria drugs it develops and launches will be accessible to those most in need in malaria-endemic countries. To facilitate this goal, MMV requires special treatment of the intellectual property (IP) that is brought to and developed under a research program. Specifically, MMV and its partners decide on an appropriate strategy for managing existing and newly generated IP. Such a strategy includes whether IP generated under the program should be the subject of a patent application or should be dedicated to the public domain. (Table 1) This requires MMV and its partners to determine whether the IP has value as an incentive for the partners or others in later-stage commercialization of the resulting products. The decision is a matter of deposit then into the health commons or the decision to appropriate technology and move to the periphery of the health commons. If IP is generated during a given research program, it is not essential that MMV will take an ownership position in it to accomplish its mission. If, however, ownership of IP does not vest in MMV, MMV will insist on appropriate license rights to any compound(s) being developed under its portfolio (MMV and Intellectual Property Rights, 2011). Particularly in the event that partners cannot follow through with their original commitment, agreement provisions permit MMV to take ownership or appropriate licenses to both program and background intellectual property rights (IPR) to allow the project to be completed and the resultant drug to be launched in malaria-endemic countries. The provisions address exclusivity, royalties, and transferability rights (MMV and Intellectual Property Rights, 2011).

If MMV does not own the necessary IPR outright, it would insist on being granted an exclusive license to use the program IPR and any necessary background IPR. That license should be worldwide, to ensure maximum flexibility for later-stage activities such as manufacturing and distribution. Any such licenses are preferably royalty-free, at least in malaria-endemic countries, to help keep costs to a minimum and ensure that the drug will be sold at the lowest price possible in these countries (MMV and Intellectual Property Rights, 2011). The exclusive right enables MMV to control the broad dissemination of final products. Moreover, MMV does not conduct any R&D in-house or any manufacturing and, therefore, requires IPR that can be transferred to other partners—especially manufacturing partners as necessary. With respect to final products, MMV will negotiate for delivery to the poor in developing countries to be on a “no profit, no loss” basis (MMV and Intellectual Property Rights, 2011).

The PATH Malaria Vaccine Initiative (MVI)

The PATH Malaria Vaccine Initiative (MVI) also established in 1999 is a global program of the international non-profit organization PATH. MVI seeks to accelerate vaccine development through multiple approaches including partnering and the funding of promising projects. MVI has several partnerships in vaccine projects worldwide (Shortwell, 2007).
The Initiative establishes product development partnerships around promising malaria vaccine approaches through the application of PATH’s Guiding Principles for Private-Sector Collaboration. With respect to participants on proposed private sector collaborations, PATH considers three issues: Availability, Accessibility and Affordability (PATH’s Guiding Principles for Private-Sector Collaboration, 2011). In terms of availability, PATH ensures that the organization as well any associated collaborators can create a product-development program that will be sufficiently rigorous, funded, and prioritized to provide a reasonable opportunity for success. With respect to accessibility, PATH and any collaborators must develop a manufacturing and distribution plan that can lead to sufficient quantities of the product made available through appropriate channels to meet clearly defined public-sector demand in developing countries. Finally, affordability involves an open discussion and then agreement upon a product pricing approach that can result in widespread adoption in public-sector programs of developing countries over a reasonable time (PATH’s Guiding Principles for Private-Sector Collaboration, 2011). The Initiative in parallel has outlined several rules in-use for partner selection and management including assessment criteria, and the definition of roles, responsibilities and expectations respectively. Any agreement for example must include a clearly defined management, and decision-making structure for the collaboration and a clearly stated process for monitoring, evaluating, and terminating the collaboration (PATH’s Guiding Principles for Private-Sector Collaboration, 2011).

As a publicly funded organization, PATH has an obligation to ensure dissemination of the results of its private-sector collaborations. PATH explores a variety of approaches, incentives, and mechanisms to fulfill both public and private sector goals (PATH’s Guiding Principles for Private-Sector Collaboration, 2011). The management of intellectual property appears to be defined within the guidelines principally in terms of types of collaborations: technology transfer, product development support, and product introduction. The first two collaboration types are relevant to the discussion of technology and IP management. Transfer of a technology developed or owned by PATH may occur to a private sector collaborator including intellectual property for further development, manufacturing, and distribution. Ultimately then PATH supports collaborators by providing significant resources or expertise (such as funding, management, co-development, and assistance with clinical studies) to a private-sector collaborator. Here, the interactions occur on the periphery of the open access health commons. In this case, IP rights are utilized by PATH to ensure that a collaborator seeking to improve public availability, accessibility, and affordability of the technology in developing-country public health programs. PATH recognizes that commercial benefits are necessary in order to ensure a sustainable commitment to the collaboration (PATH’s Guiding Principles for Private-Sector Collaboration, 2011). (Table 1)

The Drugs for Neglected Diseases Initiative (DNDi)

The Drugs for Neglected Diseases Initiative (DNDi) is similarly, a not-for-profit product development partnership working to research and develop new treatments for neglected diseases, in particular the human African trypanosome, leishmaniasis, Chagas disease, malaria, paediatric HIV, and specific helminth-related infections. Since 2007, DNDi has delivered four products including a two-fixed-dose anti-malarials (AS AQ developed with Sanofi and ASMQ; DNDi, 2011). In the development of AS AQ with DNDi, Sanofi used differential pricing tailored to local conditions alongside discretionary IP enforcement. The company decided to forego its patent rights to the new formulation, while pricing was tailored for different distribution channels (Sanofi-aventis, 2007; Mansell, 2010). For example, in public sector markets, the new formulation is sold as AS AQ Winthrop at a no profit/no loss price, equivalent to less than $0.5 per day for children under five years of age and less than $1 per day for adults. A branded version, Coarsucam, is sold through public pharmacies at a regular price, and the combination product is also available under the Impact Malaria brand at a no profit/no loss price (Sanofi-aventis, 2007; Mansell, 2010).

As a move toward further open collaboration is the recent announcement by Sanofi and DNDi of a three-year research collaboration agreement for the research of new treatments for nine neglected tropical diseases (NTDs) to treat patients in endemic countries. The open collaboration will involve Sanofi bringing molecules from its libraries into the partnership, while DNDi and Sanofi will collaborate on research activities. Noteworthy is the agreed upon management of intellectual property generated through the collaboration (DNDi, 2011). The rights to results produced by this partnership will be co-owned by Sanofi and DNDi. Further, the partners will facilitate publication of the results (and hence deposit into the open access health commons) to ensure access to the wider community of researchers focusing on NTDs. The public sector will benefit from the drugs developed through this agreement with ease of access for patients in all endemic countries, irrespective of their level of economic development (DNDi, 2011). We see therefore, that the differential management of knowledge generated through the collaboration is a function of its form and structure. Technology generated through the partnership will be managed through the open collaboration partnership with research results deposited and managed through the health commons. (Table 1)

The discussion must however extend to the governance of varied knowledge types such as sequencing information, chemical compounds, and other materials. The increased use and participation in the health commons to manage these knowledge types is likely a result of several factors namely: changing paradigms with an increased focus on the underlying and upstream biological processes of a disease; an increase in the knowledge of such biological processes with the completion of the Human Genome Project; and the increased complexities associated with technology development that require broad access to upstream knowledge from multiple sources and providers. The attention surrounding malaria given its fatal impact in neglected markets should reveal the usage of unexpected mechanisms promoting openness—moving beyond the sole consideration of IP ownership and exercise, to the openness of resources across the product value chain.

### Table 1: PPP Participation in the Commons and on the Periphery of the Commons

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Participation in the Health Commons</th>
<th>Participation in Open Collaboration</th>
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<tbody>
<tr>
<td>MMV</td>
<td>Possible IP donation to the Health Commons.</td>
<td>Technology based partnership; IP management and IP transfer as necessary.</td>
</tr>
<tr>
<td>MVI</td>
<td>Technology based partnership; IP transfer as necessary.</td>
<td></td>
</tr>
<tr>
<td>DNDi</td>
<td>Research results deposited into the Health Commons.</td>
<td>Technology based partnership; Co-ownership of resulting IP.</td>
</tr>
</tbody>
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### References:

5. Sanofi and DNDi - Drugs for Neglected Diseases initiative - Sign an Innovative Agreement to Generate New Drugs for Neglected Tropical Diseases, May 30 2011.
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A Transnational Partnership: Eli Lilly Addressing the Burden of Non-Communicable Diseases in Developing Nations

Abstract

Eli Lilly recently launched the Lilly NCD Partnership, which will initially focus on diabetes—a core competency business area for Eli Lilly. The partnership will target communities in Brazil, India, Mexico, and South Africa and is based on the concept of shared value. The goal is to find sustainable approaches to patient care, which, depending on local needs, may require patient and provider education as well as increased treatment access. Through partnerships with leading health organizations, Eli Lilly will test new models of care for diabetes, including detection, screening, diagnosis, prevention, and treatment. While Lilly is addressing the need to augment healthcare capacity through the Lilly-NCD partnership, the organization has acknowledged the need to look across the value chain—from discovery to delivery to address the burden of NCDs particularly in less developed countries with poor innovative and healthcare capacity.

Introduction

Eli Lilly and Company announced a $30 million commitment in 2011 over five years to address non-communicable diseases in developing nations. Lilly is launching The Lilly NCD Partnership which will initially focus on diabetes—a core competency business area for Eli Lilly. The partnership will target communities in Brazil, India, Mexico, and South Africa. (Lillya, 2011)

“Non-communicable diseases are afflicting nations, communities and families around the world, with the most vulnerable bearing most of the burden,” said John C. Lechleiter, Ph.D., Lilly chairman, president, and chief executive officer. “We believe we have a responsibility—and are uniquely positioned—to assist in the global fight against these diseases. In partnership with leading health organizations, Lilly will contribute its deep expertise and the company’s broad research capabilities to help find solutions for these pressing societal needs.”

Partners that will develop country specific programs with Eli Lilly include:

• Brazil: Hospital Israelita Albert Einstein – Diagnostic & Preventive Medicine and Research Institute.
• India: The Public Health Foundation of India, Project HOPE, Population Services International.
• Mexico: The Carlos Slim Health Institute – Casalud.
• South Africa: The Donald Woods Foundation, Project HOPE.

(Lillya, 2011)

The World Health Organization (WHO) indicates that non-communicable diseases are the leading cause of death in the world. Of the 57 million global deaths in 2008, 36 million, or 63 percent, were due to NCDs. (WHO, 2011) By 2030, non-communicable diseases will account for 66 percent of the global disease burden and 80 percent of all NCD deaths occurring in low-and middle-income countries (Global Health Council, 2004; WHO 2011).

Jacques Tapiero, president of Lilly’s emerging market business group, noted, “NCDs in developing countries haven’t garnered the same attention that TB, HIV/AIDS and malaria have. There are few successful models of treatment for NCDs and limited international funding. Meanwhile, governments in developing countries are recognizing the need to focus resources on NCD treatment and prevention. The Lilly NCD Partnership will work closely with governments to identify, evaluate, and prioritize healthcare solutions that meaningfully reduce the burden of chronic diseases in cost effective ways.”

(Lillya, 2011)

Partnership Model

The partnership is based on the concept of “shared value,” and has the goal of finding sustainable approaches to patient care, which, depending on local needs, may require patient and provider training as well as increased treatment access. (Lilly, 2011; Potter and Kramer, 2011)

The partnership will use research, information sharing, and advocacy to identify new models of patient care that will increase treatment access and improve health outcomes for patients. (GBCHealth, 2011) Specifically, Eli Lilly is focused on strengthening clusters around the delivery of healthcare solutions for people with diabetes in developing countries. Through partnerships with leading health organizations Eli Lilly has the objective to test new models of care for diabetes, including detection, screening, diagnosis, prevention, and treatment. (Lillyb, 2011)

“The business community can and must play a vital role in addressing complex societal problems. And it’s clear that writing a check or donating products alone doesn’t have a lasting impact,” stated Lechleiter. “A growing body of evidence demonstrates that when a company engages with partners in an area in which it has deep expertise and a vested interest, society benefits and the company enhances its own performance.” (Kaustinen, 2011)

The Partners

The first phase of the Lilly NCD Partnership, which has been under development, will seek to:

• Strengthen diabetes care capabilities at primary care health clinics;
• Improve system efficiencies so that more patients are served;
• Increase appropriate use and medication compliance for improved patient outcomes;
• Replicate the efforts in similar clinic environments.

(Figure 1): (Lilly, 2011)

In Brazil, Hospital Israelita Albert Einstein (AEH) is a leading teaching and research hospital and is involved in a variety of projects to improve health care in the country, including partnerships to strengthen the government’s basic health clinics. In Brazil, the focus is on validation of diabetes screening tools specific to the local community, training of community health workers and professionals in diabetes care, the application of appropriate interventions in the case of health outcome improvement, and the use of Lilly’s disease management expertise to assess and improve the capabilities of primary healthcare clinics. (Lilly, 2011)

Partners in India include the Public Health Foundation of India—a public-private partnership whose mission is to strengthen training, research, and policy development in the area of public health, Project HOPE—the world’s largest social marketing organization, and Population Services International—a long term Eli Lilly partner. The objectives in India are to develop diabetes awareness, patient care and provider training, improve treatment access, and research program impact, cost, and best practices. (Lilly, 2011)

K Srinath Reddy, M.D., president of the Public Health Foundation of India, noted in a press release that prevention is just as important as early detection and effective treatment. It is also important, Reddy said, that “health systems in developing countries are strengthened, so that they can effectively respond to this challenge.” A comprehensive program, in which education is focused on prevention as well as treatment, can help these countries to target the cause rather than try to just deal with the outcomes of disease progression. (Kaustinen, 2011)

In Mexico Eli Lilly’s partner is the Carlos Slim Health Institute (CSHI)—chosen because of its proven medical, measurement and evaluation capabilities, its experience, extensive network, and its current commitment to diabetes care. Lilly Mexico will work with CSHI and others to help strengthen the diabetes care capabilities at primary health care clinics and related healthcare system components. Additional efforts will be undertaken to strengthen patient capabilities, introduce appropriate interventions, and encourage broader adoption of interventions. (Lilly, 2011)

Finally, the partners in South Africa are Project HOPE and The Donald Woods Foundation. In South Africa, Project HOPE launched the HOPE Center in early 2011 in partnership with local NGOs, government, and academic stakeholders to educate local communities on chronic diseases, and provide clinical services for the treatment and management of the diseases as well as support through peer group education. (Lilly, 2011) Lilly and Project HOPE will train community health workers, launch peer support to generate disease awareness and the management, and strengthen the capabilities of clinics. Lilly and The Donald Woods Foundation will conduct an assessment of current HIV-AIDS treatment capabilities and apply similar models to track provider and patient improvements as well explore the usage of novel ICT tools. (Lillyc, 2011)
Moving Beyond Health Access

The partnerships are currently focused on testing new models of care, including detection, screening, diagnosis, prevention and treatment. Companies can create shared value in three distinct ways: by designing and re-designing products and markets, by increasing productivity across the value chain, and building supportive clusters. (Porter and Kramer, 2011) While Lilly is addressing the need for cluster development to augment healthcare capacity through the Lilly-NCD partnership, Lechleiter has acknowledged the need to look across the value chain—from discovery to delivery to address the burden of NCDs particularly in less developed countries with poor innovative and healthcare capacity. (Lillyb, 2011)

Figure 1: Lilly-NCD Partnership Goals and Outcomes

References:
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2. Eli Lilly Launches Innovative NCD Partnership, GCBHealth, September 13 2011.
5. Lilly Invests $30 Million in Partnership to Address Non-Communicable Diseases, Eli Lilly(a), September 13 2011.
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The Ascend Research Network—Enabling Human Capacity Development

Abstract

In the world’s effort to control and prevent non-communicable diseases (NCD) it is critical to develop the necessary human capacity. The potential and benefits certainly exist for educational and collaboration program development involving NCD control/prevention initiatives, institutions and students in disease endemic countries. With the burden greatest in low and middle income countries (LMIC) the incentive exists for such countries to participate in the dialogue and creation of human capacity development programs. Partnerships between institutions in the developed world and those in LMIC will provide for unique knowledge transfer opportunities. One such example is the Ascend Research Network (ASCEND).

Introduction

The Ascend (Asian Collaboration for Excellence in Non-communicable Disease) Research Network was initiated through a US NIH Millennium Promise Award granted to Monash University Australia and its institutional partners in Malaysia, Sri Lanka, India, and the US. The goal of this network is to support the development of a research network to strengthen the research capacity in non-communicable diseases over five years (2010-2014) in Asia. (Ascend, 2012) Specifically, the ASCEND program aims to:

- Provide high quality research training to over 40 early career researchers from Asia.
- Strengthen NCD research capacity across Asia.
- Build a regional network of researchers and research institutions in Asia to improve the prevention and control of NCDs.
- To bring awareness of NCDs in Asia and to assist with integrating evidenced programs into policy and practice in partnership with government and non-government organizations.

(Ascend, 2011; 2012)

In this case, the Ascend Research Network will strengthen the research skills of its trainees as well as create a network of research institutions and mentors that can support its trainees throughout as well as upon completion of the training program. The ultimate impact will be on policy creation that can work cooperatively with such research endeavors to control and prevent NCDs in the associated LMICs.

Training Institutions and Governance of the Research Network

The Ascend Research Network partners include:

- Monash University, Australia
- Monash University, Malaysia
- Sree Chitra Tirunal Institute for Medical Sciences and Technology, India
- University of Colombo, Sri Lanka
- University of North Carolina, US

The first 3-week teaching block is held at Monash University, Malaysia (Sunway Campus) in Kuala Lumpur; however, it is expected that future programs will likely take place in other countries and at other institutions. (Ascend, 2011)

The research network is governed by program directors that are supported by the training advisory group. Academic personnel consist of both teaching faculty and local as well international mentors. To date, teaching faculty include those from Malaysia, China, India, Sri Lanka, Australia, Denmark, and the US.

The Program

The ASCEND program provides research training with respect to the prevention and management of non-communicable diseases and their risk factors with a predominant focus on diseases prevalent in the Asia Pacific Region. The aim is to understand NCDs, control and prevent such diseases at the individual, community, national, regional, and global levels. Equally critical is to understand the role of health services and health systems capacity development as part of disease management programs. (ASCEND, 2011)

The first group of 25 trainees from India, Sri Lanka, China, and Malaysia, have already participated in a three-week intensive program in non-communicable diseases. This first teaching block consists of four modules. These modules consist of:

- NCD concepts, epidemiology and prevention and control;
- Epidemiology and applied research methods;
- Tools and communication for public health research and;
- Developing, implementing and evaluating health promotion and intervention programs in communities, health services, and other community settings.

During this 3 week teaching block, students participated in field visits. Field visits made included to the:

- Institute for Medical Research Clinical Research Centre
- Institute for Public Health
- Institute for Health Systems Research
- Institute for Health Management
- Institute for Health Behavioural Research
- National Diabetes Institute
- Sunway Medical Centre

Following this, trainees have returned to their home country to continue a 12-month long research project being mentored by global experts in the field of chronic non-communicable disease. Noteworthy is the support of trainees through online web-based learning activities. (MEMS, 2011; IANPHI, 2012) In the second teaching block, trainees have the objective to develop translation and policy development skills. After presenting their work to faculty, mentors, and the training group, trainees will work to consolidate their research including the preparation of key manuscripts for publication and presentation at their home institutions and international meetings.

Project Examples

The focus of research activities includes cardiovascular diseases, diabetes, hypertension, chronic kidney disease, and the prevalence of chronic NCDs. (Table 1) Trainees have successfully published, presented posters, enrolled in further graduate studies, and assumed academic positions. The success of the first round is more than evident given the number of applications for the 2012 session. Beyond an increase in number, this next round has generated interest from other regions in Asia. The 2012 round of applicants includes researchers from Sri Lanka, India and Malaysia, Nepal, Bangladesh, and China.

Outcomes

At the conclusion of the 18 month program, trainees should be able to:

- Assess the individual and societal burden of diabetes, heart disease, and related conditions in low and middle income countries;
- Identify the role and contribution of lifestyle factors and other more ‘upstream’ influences in relation to these conditions in low and middle income countries;
- Design, appropriately conduct, write-up, and disseminate the findings of an appropriate research project that is relevant to the needs of the trainee’s country;
- Understand how different kinds of study methods, measurement approaches, and approaches to research can be used to strengthen the evidence base for health promotion and disease prevention; and
- Demonstrate how research findings can contribute to improved health practice and/or relevant policy and thereby, reducing the overall burden of diabetes, heart disease, and related conditions.

(Ascend 2012)
The Ascend Research Network has extended the goal of disease management in LMICs from neglected diseases to non-communicable diseases that have become increasingly prevalent in these countries. Beyond intervention and the sourcing of solutions from developed countries and MNCs, the Ascend Research Network seeks to develop the necessary human capacity in LMICs. With the announcement of similar programs by the recently established WIPO Re: Search initiative and the use of this model to train post-doctoral fellows from Africa in the area of neglected diseases, of value will be the documentation of outcomes and impact on disease management—providing a template for other stakeholders contemplating human capacity development program creation.

References:

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<th>Trainee Country of Origin</th>
<th>Focus of Research Activities</th>
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<td>Cardiovascular risk factors in a rural population in India</td>
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<td>Role of yoga and peer groups on glycaemic outcomes and adherence to therapy in Type II DM</td>
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<td>Risk factors of coronary heart disease in selected urban population in India</td>
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<td>Malaysia</td>
<td>Association of serum advanced glycation end products (AGEs) with risk of developing type 2 diabetes mellitus</td>
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<td>Development and validation of a measurement scale for type 2 diabetes in Asian population</td>
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<td>Sri Lanka</td>
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<td>Health management and intervention in NCDs</td>
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<td>China</td>
<td>Community based screening and intervention program for Stroke in Beijing China</td>
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</tbody>
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Table 1: Phase 1 Trainee Research
South Asia Network for Chronic Disease in India—Building Human and Research Capacity

Abstract

The South Asia Network for Chronic Disease in India is a collaborative venture between the Public Health Foundation (PHFI) of India and constituent colleges of the Wellcome Trust Bloomsbury Centre for Clinical Tropical Medicine. The South Asia Network for Chronic Disease is using multiple strategies to develop the necessary human capacity to manage the burden of such diseases in low and middle income countries. The mandate is to jointly develop research and intervention based capacity, whilst ensuring its participation in the development of priorities and practices for policy makers. Knowledge sharing, engaging of stakeholders at a national and international level, and linking the benchside to the bedside are the mechanisms creatively used to develop the necessary healthcare solutions.

Introduction

The South Asia Network for Chronic Disease in India is a collaborative venture between the Public Health Foundation (PHFI) of India and constituent colleges of the Wellcome Trust Bloomsbury Centre for Clinical Tropical Medicine. The Wellcome Trust awarded the London School of Hygiene and PHFI a €4.5 million grant to build capacity and conduct research on chronic diseases by setting up a research network based in New Delhi over five years. The goal is to build research capacity, harness scientific talent within the region, gain a voice and impact in health policy and practice for chronic disease management in South Asia. (SANCD, 2012)

The objectives of the South Asia Network for Chronic Disease are to:

- Establish and maintain an infrastructure and capacity of core interdisciplinary scientific staff;
- Build on ‘state of the art research’ based on a combination of excellent research methodology, research laboratory services, health databases, and research governance;
- Conduct translational research, health care evaluation studies, including RCTs, evidence synthesis, health systems, and health policy research;
- Mentor and provide career structures for researchers at all stages of their careers and;
- Network to facilitate dissemination of best evidence to support health care provision in chronic disease, the setting of priorities and practices for policy makers, practitioners and researchers.

Partnership Model

Network partners originate from Bangladesh, India, Pakistan, Sri Lanka, and the United Kingdom. Partners include:

- The International Center for Diarrhoeal Disease Research in Bangladesh.
- The Voluntary Health Services in Chennai.
- The Centre for Chronic Disease Control in New Delhi.
- Sangath in Goa.
- The Society for Nutrition, Education and Health Action in Mumbai.
- The Aravind Eye Care System in Pondicherry.
- The Aga Khan University in Pakistan.
- The Institute for Research and Development in Sri Lanka.
- The University of Bristol, in Bristol.
- The London School of Hygiene and Tropical Medicine in London.
- The Institute of Psychiatry, King’s College in London.
- The Institute of Child Health, UCL in London,
- Newcastle University in Newcastle.

Beyond the network partners, the network is staffed with several research personnel including visiting fellows. (SANCD, 2012)

The Research Projects

Several research projects are active in the South Asia Network for Chronic Disease. The projects are organized according to the following themes:

- Food and Nutrition Studies
- The PREMIUM Study
- Studies on Chronic Disease Epidemiology and Risk Factors
- Studies on Women and Child Health
- Pilot Studies

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<td>IMS</td>
<td>Socio-economic changes associated with migration as having relevance in explaining the high levels of obesity and diabetes among rural-urban migrants.</td>
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<td>APCAPS</td>
<td>Trans-generational study (involving parents and children) to examine a wide range of risk factors relevant to obesity, diabetes, and cardiovascular disease, thereby creating a three-generation resource for future research.</td>
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<tr>
<td>CDRF</td>
<td>A multi-centric study on Chronic Disease Risk Factors and Outcomes in the rural South Asian population.</td>
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<td>Global diabetes genetics consortia; EU GeneDive project on Epigene; Genetics and COPD Consortium Proposal; Genetic analysis of juvenile glaucoma.</td>
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<td>Health Economics</td>
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<td>Food and Nutrition</td>
<td>Food consumption patterns in India; Nutritional labelling in India; Food policy and practice in India.</td>
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<tr>
<td>PREMIUM</td>
<td>Program for effective mental health interventions in under-resourced health systems.</td>
</tr>
<tr>
<td>Epidemiology and Risk Factors</td>
<td>Risk factors and food consumption in diabetes; Risk factors and environmental impact on asthma; Health and healthcare disparities among the elderly in India; Hypertension in Indians; Tobacco consumption.</td>
</tr>
<tr>
<td>Women and Children</td>
<td>Health status and nutritional disadvantage among selected populations of Indian women; Risk factors for pre-eclampsia and eclampsia; Food consumption by children and socio-economic status.</td>
</tr>
<tr>
<td>Pilot</td>
<td>Study to assess follow-up rates in alcohol abusers in Goa.</td>
</tr>
</tbody>
</table>

Table 1: Research Programs at the SANCD

The Training Programs

Alongside the research program are the training opportunities provided by Sangath in Goa. Relevant training programs include “Development and Evaluation of Complex Health Care Interventions” and “Leadership in Mental Health”. Sangath is registered as a non-profit organization. Its mission is to promote health, with a focus on three areas—child development, adolescent and youth health, and mental health.

Sangath is driven by the following principles:

- Multi-disciplinary interventions with the belief that improving the health status of a community requires a combination of social, psychological, and medical interventions.
- Linking services with research with health programs based on the best evidence available.
- Participatory methods through engaging with beneficiaries and active involvement in the work conducted at Sangath.
- Inter-sectoral collaboration and the belief that existing community resources such as those in the public sector will provide the most sustainable setting for delivering interventions.

(Sangath, 2012)

‘Development and Evaluation of Complex Health Care Interventions’ aims to provide participants with a framework for understanding the methodology for developing and evaluating complex health care interventions. At the end of the course participants should be able to design protocols for systematically developing and evaluating complex interventions for public health problems of their interest. (Sangath, 2011) ‘Leadership in Mental Health’ is designed to equip participants in the methods to develop and scale up interventions for people with mental disorders in communities based on a population model. (Sangath, 2012)
5.0 A Model of Human Capacity Development

The South Asia Network for Chronic Disease is using multiple strategies to develop the necessary human capacity to manage the burden of such diseases in low and middle income countries. The mandate is to jointly develop research and intervention based capacity, whilst ensuring its participation in the development of priorities and practices for policy makers. Knowledge sharing, engaging of stakeholders at a national and international level, and linking the benchside to the bedside are the mechanisms creatively used to develop the necessary healthcare solutions. (Figure 1) The lessons learned and collaborative models employed by emerging networks charged with the management of NCDs should continue to provide insight for stakeholders not only in Asia, but those in Africa and in developed world—who equally seek to join the dialogue.

Figure 1: Stakeholders and Interactions in the South Asia Network for Chronic Disease

References:

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INDUSTRY NEWS

Biocon Opens Research Centre
April 6th 2012

A Rs. 200-crore integrated research and development centre was inaugurated recently at Biocon. The state-of-the-art research centre is aimed at conducting research on biologics that will address unmet medical needs.

Chairman and Managing Director of Biocon Group Kiran Mazumdar-Shaw said she hoped the centre would develop advanced yet affordable solutions for several diseases. She said the company will pursue the goal of developing affordable medicines in the focus areas of diabetes, cancer and autoimmune diseases. The research center will have multi-disciplinary capabilities in molecular biology, biologics process sciences, formulation research and preclinical and clinical development, functional assay development. Approximately 300 scientists will be recruited for the centre. The centre will have a Molecular Biology Lab, Biologics Process Science Labs, Formulations Development Lab, Molecular Characterization Lab, Functional Bioassay Lab, Preclinical and Clinical Development Groups.

Abhijit Barve, President Research and Development, Biocon, said the centre will allow a “cross pollination of ideas” across groups and breed a new culture of innovation.

Sources: Biocon
The Hindu
BioSpectrum Asia

Quintiles Launches Kun Tuo CRO
December 2011

As part of its commitment to China, Quintiles recently announced the launch of Kun Tuo, a local contract research organization (CRO) to service the unique needs of the Chinese biopharmaceutical industry and multinational biopharma companies operating in China.

Building on Quintiles’ unmatched success at the global level and experience in conducting clinical trials in China since 1997, Kun Tuo will focus on developing customized solutions to help local and global biopharma companies achieve successful registration of new medicines in China.

Kun Tuo will provide a full range of services, including comprehensive clinical trial management, regulatory submission preparation, biostatistics and data management. Kun Tuo will tap Quintiles’ global resources and expertise to develop customized offerings in key therapeutic areas, along with vaccines, late phase studies, medical devices and diagnostics.

“Kun Tuo will leverage Quintiles’ quality and training systems to offer customized, high-quality solutions best suited for local Chinese biopharma, as well as global biopharma local affiliates,” said Zhen Ling, general manager of Quintiles China. “We have an aggressive growth plan for China and anticipate doubling Quintiles total staff during 2012 as we look to provide our customers with the solutions they need to succeed in one of the world’s most dynamic marketplaces.”

Quintiles China today has more than 300 staff to cover all population centers and study sites in China. With more than 20,000 employees globally operating from offices in 60 countries, Quintiles forms partnerships with both global and local biopharmaceutical companies to conduct drug development in China.

Source: Quintiles Inc.

Quintiles Discusses the Transformation Potential of Asia
March 14 2012

Given current pressures, biopharmaceutical industry leaders must not settle on incremental innovation, but should look toward Asia as a unique opportunity for “radical transformation,” according to a paper from Quintiles, which says the need, the know-how, the resources and the will for innovation are all present in Asia.

“The pre-requisite, however, is that biopharmaceutical companies truly comprehend the emergence – or re-emergence – of Asia, and meet the challenge of understanding local, thinking local and being local,” writes the report’s author, Amar Kureishi, Regional Chief Medical Officer, Asia-Pacific, Quintiles.

Titled Tectonic Transformations: the Future of Biopharmaceuticals in Asia, the report says that a key element of the new biopharma model will be a re-focused need on alleviating individual suffering and addressing society’s healthcare needs.

“No longer will it suffice to develop an expensive new medicine which is accessible to only a small minority of patients, at a cost that siphons resources and leaves even larger healthcare issues unaddressed,” writes Kureishi. “The guiding question at the heart of the new model will be: How can science and technology create innovative solutions for patients that lead to healthier societies?”

Kureishi concludes that the role of Clinical Research Organizations (CROs) involves “bringing clinical research expertise and investments to tertiary care hospitals, crafting clinical development plans that address Asian medical needs, and nudging the evolving regulatory landscape in Asia in a direction that restores patients to the center of the healthcare system.”

Source: Quintiles Inc.

INC Research Releases New White Paper on Transformational Change in Global Drug Development
February 7 2012

INC Research, LLC, a therapeutically focused clinical research organization (CRO) with a trusted process for delivering reliable results, recently announced it has released a new white paper titled, “The Innovation Imperative: How CROs Are Driving The Transformation of Clinical Research.”

INC Research’s paper takes a critical look at the most significant innovations in science and technology and how CROs are implementing these advancements to transform the overall clinical development process.

“The drug development industry is experiencing a new wave of R&D innovation, primarily as a response to financial pressures,” said INC Research CEO James Ogle. “CROs are in a position to not only take costs out of the clinical development process, but also to spawn new approaches and techniques to the process itself. As a result, modern alliance partnership models will help bring better and safer drugs to market more efficiently.”

The recent shift in the biopharmaceutical company-CRO relationship from project-specific outsourcing to strategic alliances has created an environment in which biopharmas are considering CROs innovation partners. Based on furthering portfolio objectives, these multi-year alliances are based on higher levels of engagement with the CRO and leverage years of perspective, expertise and tactical approaches. INC Research’s white paper highlights how partnership models are evolving and explores the ways CROs are transforming the practice of clinical trials by applying digital and scientific innovations, including better study designs for more efficient endpoints and next-generation data management and patient recruitment strategies to accelerate new drug development.

INC Research is at the forefront of innovating all stages of the clinical trial process, from initial first-in-human clinical trial designs to Phase IV trials. Working with INC Research, customers access innovations that bring new life to existing clinical development programs and accelerate new ones, helping them to achieve their biggest R&D ambitions.

Source: Inc Research
INDUSTRY NEWS

DNDi and Abbott Expand Partnership for Neglected Tropical Diseases
January 30th 2012

The Drugs for Neglected Diseases initiative (DNDi) and Abbott have signed a four-year joint research and non-exclusive licensing agreement to undertake research on new treatments for several of the world’s most neglected tropical diseases, including Chagas disease, helminth infections, leishmaniasis and sleeping sickness. DNDi and Abbott scientists will focus initial efforts on discovering and advancing novel antimicrobial agents with activity against these neglected diseases.

Since 2009, Abbott has provided compounds for DNDi to screen for activity against neglected diseases. This new agreement expands this relationship, and provides DNDi access to selected classes of molecules and accompanying data generated by Abbott that are crucial for the development of effective and accessible new treatments for neglected diseases.

“Innovative product development partnerships have significant potential for addressing neglected diseases,” said Dr. John Leonard, senior vice president, Pharmaceuticals, Research and Development, Abbott. “By combining the unique scientific expertise and resources of DNDi and Abbott, we look forward to accelerating research to find practical new treatment options for people affected by these diseases.”

Abbott has demonstrated a great level of commitment by partnering with DNDi to share not only its compounds, but also its expertise and resources. For DNDi, this implies a new critical mass of knowledge to pursue our goals of addressing the unmet needs of neglected patients in the poorest areas of the world,” said Dr Bernard Pécoul, Executive Director of DNDi.

Equitable access to treatments for neglected diseases in all endemic countries, not only least-developed countries, is at the core of this agreement, and DNDi has committed to ensuring the lowest sustainable pricing for any products developed and distributed as a result of the agreement. Intellectual property (IP) related to this agreement, existing relevant Abbott IP and new IP generated by this collaboration will be subject to a principle of non-exclusive licensing to address neglected diseases in endemic countries. Under the agreement, Abbott has the right of first negotiation to become DNDi’s development and distribution partner. DNDi is free to engage other partners if Abbott chooses not to serve as a development and distribution partner.

Source: DNDi

OSDD and TB Alliance Form Partnership for New TB Drugs
March 23, 2012

On the World TB Day 2012, OSDD and TB Alliance announced a partnership last month to bring new TB drugs into clinical trials in India. “Today, there are a few new TB drugs being developed around the world, and it’s critical for India—which has the world’s highest burden of tuberculosis—to bring new drugs to its patients. OSDD will play a leading role in supporting and furthering innovation,” says Prof Samir K Brahmachari, Director General CSIR and Chief Mentor OSDD. “CSIR is able to leverage its platform—through our own laboratories and the National Institutes of Health (NIH).”

Equitable access to treatments for neglected diseases in all endemic countries, not only least-developed countries, is at the core of this agreement, and OSDD has committed to ensuring the lowest sustainable pricing for any products developed and distributed as a result of the agreement. Intellectual property (IP) related to this agreement, existing relevant OSDD IP and new IP generated by this collaboration will be subject to a principle of non-exclusive licensing to address neglected diseases in endemic countries. Under the agreement, OSDD has the right of first negotiation to become OSDD’s development and distribution partner. OSDD is free to engage other partners if Abbott chooses not to serve as a development and distribution partner.

Source: OSDD

Lilly Launches Open Innovation Drug Discovery Platform
September 26 2011

Eli Lilly and Company recently announced the launch of a new open innovation platform designed to help build the company’s pipeline of tomorrow and, from a philanthropic perspective, identify molecules that may have application for treating multi-drug resistant tuberculosis (MDR-TB). The new platform, titled Open Innovation Drug Discovery, is supported by an innovative new website available at openinnovation.Lilly.com. It builds on the success of Lilly’s Phenotypic Drug Discovery Initiative (PD2) that was launched in 2009 to facilitate research on molecules around the world that have the potential to ultimately be developed into medicines.

The new platform consists of three components:

TD2, or target drug discovery, a new component that screens submitted molecules for their potential to interact with known disease targets.

PD2, which continues to screen submitted molecules in complex cellular assays with the goal of identifying potential new medicines acting by novel mechanisms or pathways.

An additional new component that screens molecules for their potential in the fight against MDR-TB—a form of tuberculosis (TB) that is resistant to at least two first-line TB medicines—through the Lilly TB Drug Discovery Initiative. Lilly has long been involved in global efforts to stop the spread of TB and MDR-TB, which disproportionately affects underserved populations. Given the recent emergence of MDR-TB, there is an urgent need to find breakthrough treatments.

“I think of Open Innovation Drug Discovery as a platform consisting of multiple superhighways all pointed towards the final destination of discovering novel medicines that we believe have the potential to improve patients’ lives,” said Alan D. Palkowitz, Ph.D., vice president of discovery chemistry research and technologies, Lilly. “These superhighways connect scientists from all over the world with Lilly, for the common goal of finding new treatments for diseases where patients are in need and looking for answers, such as cancer, diabetes and MDR-TB.”

Many scientists have molecules they would like to explore as potential medicines, but for a range of reasons, including the lack of resources or barriers to engaging in the drug discovery and development process, they are not able to advance their work. The Open Innovation Drug Discovery platform is designed to minimize these obstacles and benefit continued research that supplements the innovation of Lilly’s scientists.

In addition to focusing on research areas in which Lilly has an internal strategic focus and expertise—cancer, endocrine, cardiovascular and neuroscience—the open innovation platform now will serve as a bridge between external scientists and the not-for-profit Lilly TB Drug Discovery Initiative, which is to accelerate early-stage drug discovery and help identify the TB medicines of the future. Leading members of the Lilly TB Drug Discovery Initiative include the Infectious Disease Research Institute (IDRI) and the National Institutes of Health (NIH).

How the Open Innovation Drug Discovery Platform Works

The Open Innovation Drug Discovery platform utilizes a secure website that offers Lilly’s proprietary computational and informatics tools to aid scientists in the design and selection of molecules. Once a scientist submits a molecule to the website and it meets certain specified requirements, Lilly tests it—free of charge—in a series of biological assay panels that evaluate it for its uniqueness and potential to be further optimized into a drug candidate. Comprehensive data reports are then provided to the submitting scientist.

In the case of the cancer, endocrine, cardiovascular and neuroscience screenings, in return for providing the data Lilly retains first rights to negotiate a collaboration or licensing agreement with the submitter. If no such agreement is reached, the external scientist retains “no-strings-attached” ownership of the data and can choose to use it in publications, grant proposals or to further refine his or her hypotheses about the molecule’s potential as a medicine. In the case of the MDR-TB screening, promising data could result in a collaboration between the submitting organization and the Lilly TB Drug Discovery Initiative.

“Our mission at Lilly is to help people live longer, healthier lives,” said Jan Lundberg, Ph.D., executive vice president, science and technology, and president, Lilly Research Laboratories. “In doing so, we look for where there is a need and forge ahead within our own labs and through partnerships. In that spirit, we recognize that there are many untapped sources of ideas and molecules outside of Lilly that would otherwise go unnoticed without initiatives like this one that advance science.”

Source: Eli Lilly
BIT’s 2nd Annual World Congress of Bioenergy

Time: April 25-28, 2012
Venue: Xi’an Qujiang International Conference Center, China

Highlights of the Conference:
- Consisting of 80 Sessions on Advances in Modern Bioenergy
- 300-400 Oral Presentations from Authority, Governmental Decision Makers, Distinguished Scientists, Engineers, Industrial Executives and Investors
- 50+ Exhibitors from Leading Biofuel Industries and Entrepreneurs and Research Institutes
- 100 Posters from both Industry and Academy

Programmed Tracks at a Glance:

Track 1: Global Bioenergy Economy and Policy
Track 2: Industrial Leadership Forums
Track 3: Breaking Research and Enable Biofuel Technology
Track 4: Biomass Feedstock I: Agricultural, Forestry Waste and Municipal Solid Waste
Track 5: Biomass Feedstock II: Dedicated Energy Crops
Track 6: Bioalcohols
Track 7: Biodiesel

Track 8: Algae Biofuel
Track 9: Biogases
Track 10: Biofuel & Electricity Generation
Track 11: Biofuel Based Automotives
Track 12: Aviation Biofuels
Track 13: Other Biofuels
Track 14: Biorefinery/Bioprocess Tech
Track 15: Biofuel Standards, IP, Regulations
Track 16: Biofuel Finance, Investment, Trade and Marketing

Exhibition & Being a Sponsor

WCBE-2012 Provides an Ideal Platform to Showcase Your Novel Technologies and Products in China. It is Developed to Offer Comfort to Delegates while Maximizing Exhibitor Exposure, The Coffee Breaks and Poster Sessions Will All Take Place in The Exhibition Area Promoting Frequent Repeated Opportunities for Delegates to Visit the Exhibits. Sponsorship Programs are Uniquely Designed to Meet Your Business Development Goals and Objectives. It Demonstrates Your Expertise to Those Top Decision-Makers from Industries, Academic Environmental Research Institutions, National Labs, Foundations, and Non-Profit Organizations.

Contact Information

Ms. Bella Yu
Organizing Committee of WCBE-2012
East Wing, 11F, Dalian Ascendas IT Park,
No. 1 Hui Xian Yuan,
Dalian Hi-tech Industrial Zone,
LN 116025, P.R.China
Tel: 0086-411-84799609 ext 833
Fax: 0086-411-84799629
Email: bella@bit-libio.com

UPCOMING EVENTS

World Vaccine Congress Asia 2012
Singapore
11/06/2012 - 14/06/2012
http://www.terrapinn.com/wvca

Biopharma Asia Congress
Singapore
10/09/2012 - 11/09/2012
http://www.biopharmasia-congress.com/

Open Innovation in Pharmaceutical R&D
Amsterdam, Netherlands
26/04/2012 - 27/04/2012
http://pharma.flemingeurope.com/innovation-pharma-rd/

UPCOMING EVENTS

Generics, Supergenerics and Patent Strategies
Copthorne Tara Hotel, London
14/05/2012 - 15/05/2012
http://www.smi-online.co.uk/generic-pharma15.asp

Clinical Trial Logistics
Marriott Regents Park, London, UK
22/05/2012 - 23/05/2012
http://www.smi-online.co.uk/2012logistics15.asp

Social Media in the Pharmaceutical Industry
Copthorne Tara Hotel, London
09/07/2012 - 10/07/2012
http://www.smi-online.co.uk/goto/social-media-pharma36.asp