

Innovation in Healthcare in Emerging Economies

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Introduction

Thanks for the opportunity to speak today on this important subject. I will speak from several vantage points: as an academic leader through my role as Chancellor of Health affairs at Duke University; as the President and CEO of a large health care delivery system; and as a physician-scientist who has been involved for many years with innovation and commercialization, and, more recently, in globalization.

Why we are here:

First, we all agree that pharmaceutical and biotech industries are facing productivity crises, with rising costs of research and development while fewer new products are reaching patients. One solution increasingly employed by industry is licensing and mergers & acquisitions. Another approach is cost cutting – increasingly through outsourcing manufacturing and directing research projects overseas. But I believe the most can be gained by growing the innovation capital of all economies – with the emerging world presenting particular opportunities for improvement and growth.

What are the determinants of innovation?

As you heard from Bob Go, to sustain innovation, one must consider the framework of development, ownership and diffusion. In addition to these considerations, I believe that there are at least 3 basic prerequisites of innovation and its successful implementation: ideas, people and integrity.

Without ideas, particularly original and disruptive ideas, there will be no innovation. The creation of transformative ideas takes people with the rare combination of creativity, vision and technical skills. A challenge for the emerging markets is how they should ensure a steady supply of intellectual firepower in order to generate a critical mass of innovators.

While there are many examples of China and India serving as a contractor for projects developed in other countries, I would argue that a sustainable model of innovation must go beyond outsourcing and, instead, builds a pipeline of human talent. While repatriation has been a common mechanism to improve the supply of talent, a more important long term driver is the pedagogical system that encourages and nurtures original and creative thinkers - complemented by a system that trains a technically skilled workforce.

The third prerequisite to innovation is “quality and integrity.” They represent a mix of both the inherent quality of the innovation itself, and the values and ethics of those implementing these ideas. In knowledge-based industries – where data is king and auditing proves challenging – quality and integrity will be more important than ever before.

This is especially true in the area of clinical trials. Here, the emerging world has the highest growth potential and is expected to be the source of large amounts of clinical data for drug and device approval.

However, as the quantity of overseas research increases, the FDA is becoming concerned about the quality of such clinical trial data. One internal FDA analysis of 16 major cardiovascular outcomes trials revealed that, in 13 of the 16 trials, the treatment effect was disproportionately driven by non-US sites compared to US sites. Whether this could be due to genetic influences, environmental factors, geographic differences in the standard of care, or the quality of data, etc., the ability to interpret and use foreign clinical trial data is an area of increasing concern for regulators – who may be forced to disregard the data altogether.

Quality and integrity extend to the discovery side, as well. Here we are talking about quality of research methods as well as the reliability, reproducibility and integrity of the data. Remember the infamous case of the South Korean stem-cell scientist – Hwang Woo-Suk?

To quote U.S. Treasury Secretary Paulson, “This is not an issue where you can inspect your way out of it. Quality has got to be built-in.”

It is clear that each of these fundamentals – ideas, people, and integrity - is necessary to creating an effective and sustainable ecosystem for innovation.

How can academia increase the output? Duke model of an Innovation Continuum.

As a generator of knowledge and an increasing source of early-stage companies, academia is a pivotal player in the ecosystem of innovation but there is a need to increase the outputs of our laboratories and hasten the translation to human application. Indeed, I believe that academic institutions like Duke can lead the Transformation of Medicine by creating the “Innovation Continuum” between discovery, translation, diffusion and globalization. This can be achieved through institutional reorganization, reprioritization of research, and, as I will talk about in more detail, the development of strategic public-private partnerships – or PPPs. At Duke, in order to achieve this innovation continuum from “bench to bedside to population,” we have established the Duke Translational Medicine Institute, the Duke Global Health Institute, and the Duke-National University of Singapore Graduate Medical School, and we have developed strategic alliances with Peking University and others.

We seek to create a “one stop shop” in which promising discoveries (especially early stage ones) are rapidly translated using project management teams that facilitate the research and development to proof-of-concept in man and to clinical trials. These initiatives will be supported by an internal investment fund using an LLC structure and the outcomes will be tested in well-characterized patients in our Clinical Research Unit and in the general population in our community. To achieve global impact and bring our research and training expertise overseas, we are currently expanding our successful Duke Clinical Research Institute – a \$100 million per year enterprise with over 1,000 employees – to Singapore, China and India by creating DukeMed Asia with its headquarters in Singapore.

We know we can’t do it alone. We are actively developing Public-Private Partnerships to combine the unique strengths of different stakeholders in order to develop solutions to advance common interests.

For example, Duke has partnered with the FDA to found the Clinical Trials Transformation Initiative (CTTI), a multi-stakeholder think-tank with the mission of improving the efficiency and productivity of clinical trials.

Academia has long served as institutions that encourage disruptive thinking and teach quality and ethics. Indeed academia can serve as an honest broker of research. For example, with Duke’s history of quality clinical research through its Duke Clinical Research Institute – we will be making a concerted effort to lend our support to ensure the quality and integrity of the work produced in these emerging economies and to train people to conduct proper and ethical science.

How is this model relevant to today’s topic?

I believe that this approach is relevant to the session’s topic because of the opportunity to build the Innovation Continuum from bench to bedside to population in the emerging world through public-private partnerships.

Countries have distinctive strengths and weaknesses, as well as differing levels of maturity and engagement of government and local industry. However, most face some form of human capital constraints, particularly in the life sciences, and sustaining this initiative will require a critical mass and pipeline of creative researchers. For example, a recent McKinsey Global Institute analysis revealed that China and India have over 1,200,000 young life science researchers combined, but less than 15% of them were adequately qualified. The U.S., on the other hand, has just 850,000 such researchers, but

80% of them were qualified. That translates to 150,000 qualified life sciences workers in India and China versus almost 700,000 in the U.S.

This human capital crunch can be seen in the area of clinical trials, as well, since emerging economies are poised for dramatic growth in clinical research. For example, a BCG analysis estimates that, in the next 3-4 years, India could be a site for 15% of global clinical trials – a ten-fold increase in the quantity of trials compared to today. And there are simply not enough research assistants, nurse coordinators and investigators with good clinical research training to meet the expected growth.

Singapore as an example of the continuum – a public-private partnership

To successfully build the Innovation Continuum in the emerging world, countries must identify gaps and develop strategies to close them. Singapore is an example of a country whose government is driving the creation of the entire continuum through PPP. In the year 2000, the Singapore government launched their ambitious Biomedical Sciences Initiative, investing over \$15 billion in educational infrastructure, research institutes, recruitment of world class scientists, training of PhDs and incentives to foreign industries.

They also recognized that there was a research gap between their new PhD scientists and clinicians – a gap that needed to be filled by physician-scientists. So Singapore partnered with the Duke School of Medicine – and through a \$400 million commitment – we founded a new graduate medical school with the explicit goal of increasing the supply of clinician-scientists to fill their gap. In so doing, they have created a pipeline of future innovators that, over the long-run, will help turn the government's vision into a reality. Indeed, Singapore recognized another gap – clinical and outcomes research - and is asking Duke to help establish the Singapore Clinical Research Institute and build health outcomes research. They are already reaping the early fruits of their labors – and we look forward to working with them into the future.

We recognize that Singapore is somewhat unique, but PPPs also have made good progress in countries such as India and China. For example, the Beijing Zhong guan cun Life Science Park includes investments by Peking University (a Duke partner), the government, and NovoNordisk.

How could this model be more successful if PPP were to develop? Why and how should industry be involved?

In summary, first I propose that the following fundamental be added to the analysis of the innovation potential of emerging economies - the innovation index. The quality and strength of the pedagogical system, the pipeline of human talent, the capacity of technically well trained individuals, and the credibility of research data are all important variables that influence innovation. In this context, academia – especially U.S. academic health systems – can step up and play an important role in helping to address these issues globally.

Second, I believe that there are significant opportunities for private-public partnership (government/university/industry) to develop the Innovation Continuum. My idea is to have the parties work together to establish “Centers of Innovation for Research and Training” that are co-funded by government and industry in collaboration with academia (local or foreign such as Duke) that can address the pipeline, quality and creative-thinking issues which are pivotal to the success of innovation. The PPP may also partner in research and development, licensing and commercialization. Taking an early lesson from Singapore, the exact nature of these partnerships should be country-specific and depend on the specific gaps that need to be filled. Importantly, they can benefit industry not only by creating intellectual property, but also by providing an important local source of scientists – pipelines for future recruitment.

Finally, as a leader of educational institutions, research enterprises and a health delivery system, I recognize the need for Duke to work with all the stakeholders in this room as we turn our eyes to emerging economies. We look forward to examining opportunities to engage in public-private partnerships that can mutually support the missions of our institutions.

Thank you.