

## Our Open Innovation

—Concept Paper for APAC’s Drug DA-EWG prepared for 3<sup>rd</sup> APAC—

The Asia Partnership Conference of Pharmaceutical Associations’ (APAC) is organized by twelve research-focused pharma industry organizations (from eleven Asian economies) that annually gather together regional stakeholders to collaborate on APAC's mission "To expedite the launch of innovative drugs for the peoples in Asia". This concept paper defines APAC's current approach to deliver on that mission by promoting drug-discovery through ‘open innovation’ in the Asia region.

### **What is the Mission and Vision of APAC’s Open Innovation?**

In line with APAC’s mission to rapidly deliver innovative drugs to peoples in Asia, APAC established the Drug Discovery Alliances (DA) Expert Working Group (EWG) as an impartial body focused on improving drug discovery across all nations in Asia through open innovation. The mission and vision of APAC’s open innovation is as follows:

#### **Mission**

Through open innovation, to promote collaboration across national borders within Asia to realize drug discovery.

#### **Vision**

APAC leverages an open innovation platform to promote collaboration on the discovery of drugs that meets patients’ needs across Asia.

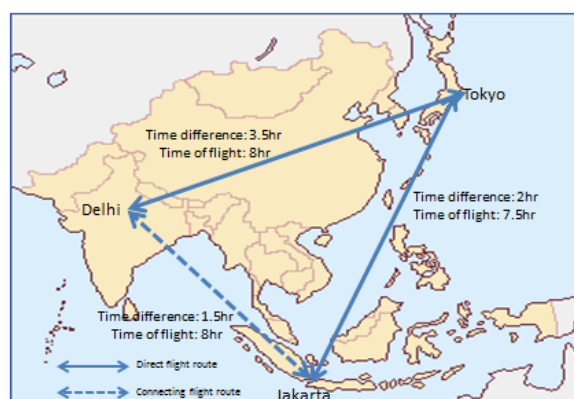
The following three pillars have been developed from this mission and vision to define the DAEWG's activities today:

- Regional-based Open Innovation (Asia focus)
- Industry Driven Open Innovation (industry initiated)
- Public-Private Partnership Focused Open Innovation (realized through government-industry collaboration)

### **What is Regional-based Open Innovation?**

In order to realize Asia originated drug discovery, there are three basic open innovation approaches.

- Domestic-Based Open Innovation: the focus is on domestic government increasing domestic drug discovery capacity and industry supporting platforms.
- Cross-Border Open Innovation: the focus is on leveraging competitive advantages in drug discovery and innovation of individual institutions irrespective of location.
- Regional-based Open Innovation: the focus is on a geographic region, like Europe or Asia, in order to realize the benefits of improved healthcare for the peoples in the region. This takes advantage of not only the merits of Cross-Border Open innovation as it



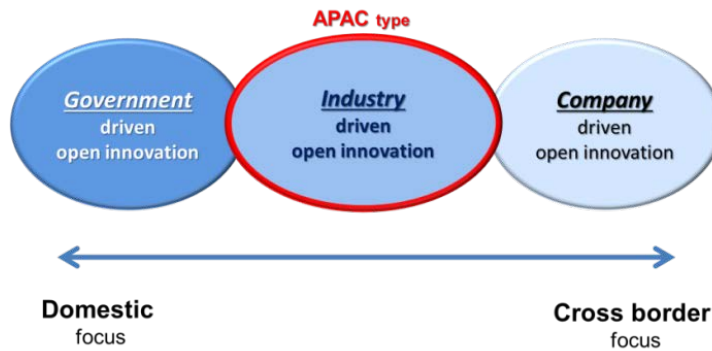
is described earlier, but convenience due to the close proximity and similarity of culture as well.

APAC's drug discovery activities are focused on promoting open innovation to establish and enhance drug discovery capabilities throughout the Asia region, therefore APAC's approach to realize drug discovery is regional-based open innovation.

**What is Industry Driven Open Innovation?**

APAC uses a relatively new approach to open innovation in that the platform is being initiated by an industry group that sees benefits of open innovation not only for themselves, but also for governmental and academic stakeholders, as well patients throughout Asia. Through a pan-Asia open innovation platform, APAC aims to both promote both domestic and cross-border innovation in order to benefit patients in the greater Asia region sooner.

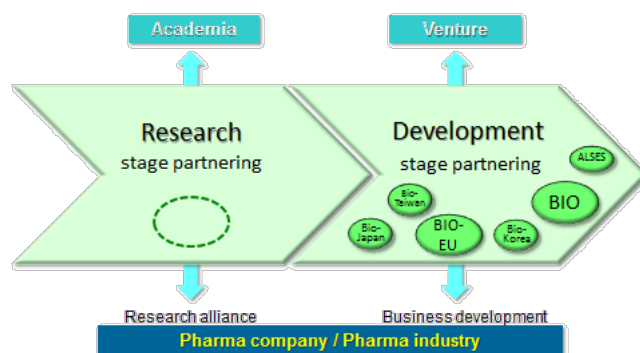
The positioning of Industry-driven versus government-driven and company-driven open innovation is shown below.



In trying to create a bridge between the government- and company-driven approaches, industry-driven open innovation has to acknowledge and strive to create shared value for all stakeholders. Improved capacity for drug discovery and healthcare is not a zero-sum game between nations and companies, and all stakeholders can benefit from the improved capacity of others to act. This is the strength of industry-driven open innovation.

As examples of APAC's approach, we have implemented various measures to exchange information among stakeholders, including academia, ventures, pharma companies and industry bodies in Asia—particularly in conjunction with Bio-conferences held in Asia. While, DAEWG believes that there are many partnering opportunities for development stage compounds through company-driven open innovation at existing bio-conferences not only in Asia, but in the U.S. and E.U. as well (such as at BioJapan in Japan, BIO in the U.S., and Bio-Europe in the E.U.), DAEWG acknowledges that there could be value in creating a joint Asia-wide Bio Conference to promote regional networking opportunities.

However, for research stage technologies, there are few partnering opportunities where stakeholders can confidently exchange information in an environment where IP issues have been sufficiently dealt with. As a result of this, there is no efficient mechanism for collaborators to identify one another, and research alliance representatives from pharma companies have to participate in numerous academic conferences in order to discover the seeds that they seek. Given this gap in needs and opportunity, DAEWG aims to create an information sharing system between academia and pharma that solves common issues in this area such as dealing with IP issues. By creating a pan-Asia platform, DAEWG plans to realize a novel open innovation platform for the region.



### **What is Public-Private Partnership Focused Open Innovation?**

The DAEWG includes voluntary participants from private pharma companies, pharma associations and public government bodies from a variety of Asian countries, such as China, India, Japan, Korea, Malaysia, Taiwan and Thailand. This kind of collaboration—which includes representatives from both public and private institutions sharing resources to realize a shared goal—is known as a public-private partnership.

The DAEWG's public-private partnership is built on relationships of trust between each country with no formal contracts or obligations. In order to realize the trust necessary for this collaboration, members of the Japan Pharmaceutical Manufacturers Association (JPMA) have worked bilaterally with each country to develop platforms that meet the needs of each economy specifically and it is expected to join these platforms in the future to create an Asia-wide platform in the future.

### **What is the long-term vision for the Public-Private Partnership?**

Though the DAEWG's bilateral meetings, it has become clear that Asia has its own unique and fundamental challenges, like basic research into Asia-specific diseases and bio-markers. Despite the need, there is currently no effective pan-Asia organization focused on supporting work on such crucial problems within the Asia region. Ideally, these challenges need to be resolved through APAC's platform for open innovation in Asia and may be best resolved by establishing a formal public-private partnership structure.

There are two examples of regional-based public-private partnerships focused on drug discovery and open innovation, such as the Innovative Medicines Initiative (IMI) in the European Union (EU) and more recently the Accelerating Medicines Partnership (AMP) in the United States (US). But Asia has some very real structural differences to the E.U. and the U.S., and Asia's approach to realizing a formal public-private partnership will need to be different.

Firstly considering the private sector as a stakeholder, while APAC was established in 2012 to promote collaboration among Asia's research-focused pharma industry organizations, APAC does not have collective funding and furthermore APAC does not directly represent all of the industry stakeholders in Asia. To act on its initiatives, APAC must rely on the resources of its

member associations and the goodwill of national governments and regional stakeholders. In order to build the necessary trust, as shown in the exhibit aside, APAC began by building strong bilateral relationships with the various stakeholders in Asia and is now working to broaden those bilateral relationships into multilateral relationships with willing stakeholders from other nations.



Secondly considering the public sector as a stakeholder, while the European Union has been working progressively towards creating a common economic market for more than 60 years, Asia does not have a shared representative body. Without this strong formal representative body to establish mutual trust built over many years, Asia has not come together to collaborate on a public-private partnership undertaking like those being proposed by APAC to date. In so saying, the need for a collaborative partnership in Asia may be even stronger than that in the EU—where many countries are already world leaders in drug discovery.

While the path may be challenging, the goal of better health for the peoples of Asia is a worthy one. If Asia wants to ensure that it has a capacity for sustainable drug discovery as well as the capacity to answer the problem of Asia-specific diseases, then Asia would be best served by coming together to establish an Asia-wide public-private partnership version of the IMI—much like the US did with AMP. Such a move would position Asia as an attractive place for pharmaceutical R&D and allow the nations of Asia to leverage the rapidly developing expertise and capabilities of their neighboring nations in the region.

### **What is the long-term roadmap of DAEWG's activities?**

A long-term roadmap of DAEWG's activities is shown in the following exhibit. During the first two years of APAC's activities, DAEWG firmly established the scope and definition of its activities through bilateral relationships. Having now built trust and with a better understanding of the needs within Asia, DAEWG will proceed to develop multilateral relationships by continuing to develop networking opportunities and an information sharing system in the next year, and will work to realize capacity building opportunities in the medium term as well. By broadening the platform structure to multilateral relationship over the medium term, the DAEWG intends to realize an integrated drug-discovery platform across Asia by 2020.

Platform Structure	Bilateral	Multilateral			Integrated	
	(FY) 2013	2014	2015	-	2020	2025
Definition	→ ●					
Networking opportunity						
Information sharing system		→ ●				
Capacity building			→ ●			
Asia originating drug					● Realization	
Asia specific disease / Pre-competitive research						● PPP Established

As mentioned in the public-private partnership section above, DAEWG recommends the establishment of a formal Asia-wide PPP focused on open innovation for drug discovery, which might be realized in 2025.

### **What are the specific proposals that APAC DAEWG is making?**

Today, by developing a base of trust among the Asian economies, APAC works to establish a roadmap for public-private partnerships and to progressively establish the necessary structures to promote the "expediting the launch of innovative drugs for the peoples in Asia". In regards to the DAEWG's activities, APAC is developing bilateral platforms to meet the needs of each country, which will be used as a roadmap to develop into a pan-Asia, drug-discovery open innovation platform.

Progress made to date consists of the following activities:

- Conducted bilateral teleconference meetings with China, India, Korea, Malaysia, Taiwan, and Thailand in order to develop the scope and definition of DAEWG's activities as well as exchange ideas on how to promote our DAEWG activities in each country.
- Conducted delegation visits to Taiwan and Thailand
- Conducted information sharing and partnering opportunities at bio-conferences in Japan and Taiwan
- Conducted panel discussions and presentations in Japan, Korea, Taiwan and Thailand

(NB: Further details on the process to date is available in the appendix of this paper)

Moving forward, the DAEWG is working towards realizing the following goals:

- Establish an Asia-wide information sharing and partnering system to promote pharma collaborations among industry, academia, and government
- Conduct delegation visits to Korea and Malaysia
- Conduct information sharing and partnering opportunities at bio-conferences
- Conduct panel discussions to promote drug discovery focused open innovation in Asia
- Establish over the long-term an Asia-wide bio-conference to promote development-stage partnering
- Establish over the long-term a formal Asia-wide public-private partnership in order to promote drug discovery and collaboration in Asia to benefit the patients of Asia

## Appendix:

### Who is APAC?

APAC is an annual conference organized by twelve organizations (from eleven Asian economies) affiliated with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) with a focus on further promoting industry ties within the region. The first annual APAC was held in Tokyo, Japan on March 16, 2012. The following APAC mission statement and goals were agreed upon at the initial meeting.

APAC Mission: “To rapidly deliver innovative drugs to peoples in Asia”

APAC Goals: “To achieve this mission, an information-sharing-platform will be built and used to disseminate information on each economy’s tasks and challenges, and for releasing the necessary proposals as the Asia Partnership Conference of Pharmaceutical Associations (APAC). Associations of various economies shall propose solutions for pharmaceutical tasks and challenges to stakeholders, including to their governments.”

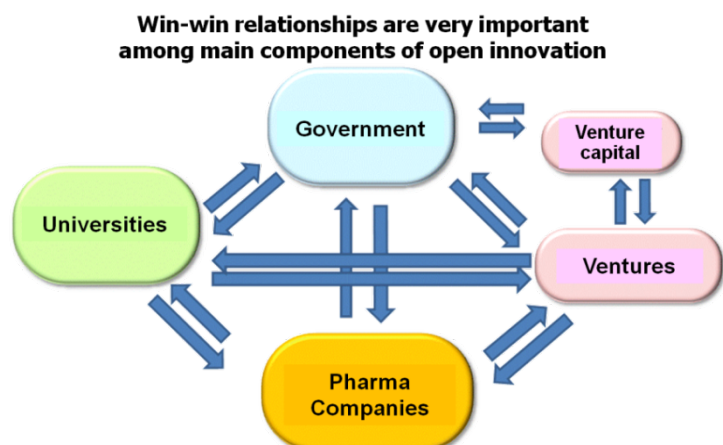
APAC subsequently established two expert working groups (EWGs)—the first in relation to regulatory matters and certifications/approvals, and the second in relation to promoting drug discovery in the region, drug discovery alliances (DA) EWG. Today, by developing a base of trust among the Asian economies, APAC works to establish a roadmap for public-private partnerships and to progressively establish the necessary structures to promote the "rapid delivery of innovative drugs to people in Asia". In regards to the DAEWG's activities, APAC is developing bilateral platforms to meet the needs of each economy, which will be used as a roadmap to develop into a pan-Asia, drug-discovery open innovation platform.

### What is Open Innovation?

In 2003, Henry Chesbrough of Harvard Business School defined open innovation as follows:

Open Innovation is a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as the firms look to advance their technology. Open Innovation combines internal and external ideas into architectures and systems whose requirements are defined by a business model. (Henry Chesbrough, Open Innovation: The New Imperative 2003)

Open innovation has since been embraced in a number of industries, such as the software industry, and has great potential to benefit the life sciences as well. One possible visualization of this model is given in the exhibit aside.



### **What is drug discovery?**

Drug discovery refers to the general process of developing a therapeutically active substance for a defined target molecule or pathway. The DAEWG includes in this definition both traditional and cutting-edge drug discovery approaches and disease mechanisms/pathways and other sciences, etc., necessary to achieve the drug discovery process, as well as the supporting activities that promote novel drug discovery, as well as.

### **What is the Drug Discovery Alliance Expert Working Group?**

The DAEWG acts as a public-private partnership including voluntary participants joining from pharma associations and government bodies from a variety of Asian economies, such as China, India, Japan, Korea, Malaysia, Taiwan and Thailand (alphabetical order). DAEWG promotes the establishment of an open innovation platform in Asia in order to realize Asia-based drug discovery and to swiftly deliver the resulting innovative drugs to people in Asia. While the DAEWG's focus does not include clinical development activities, its focus does include the networking and information sharing activities necessary to realize research alliance collaborations across borders in Asia.

### **Who is paying for this Open Innovation Platform?**

APAC is an organization of pharmaceutical organizations. APAC is neither a governmental nor non-governmental organization, and therefore does not have financial resources of its own, but rather operates on the goodwill and determination of member companies and organizations, as well as other partner organizations from the public and private arena throughout the Asia region.

### **Who benefits from this Open Innovation Platform?**

It is intended that all health stakeholders in Asia—both public and private—will ultimately benefit from APAC's open innovation platform. All stakeholders will benefit through access to better drug research that is targeted to the specific needs of Asian patients and furthermore each economy will benefit from the jobs and human security that is associated with a strong healthcare capability.

### **Why now for this drive to promote drug discovery and open innovation?**

Government support of drug discovery in Asia is commendable and many economies have already been investing in their drug discovery capacity for over 20 years. Furthermore, many economies have positioned healthcare innovation and biotechnology as a key pillar of their national policy as shown in the exhibit below. To this end, governments have been offering assistance, and numerous bio-clusters have been established in various economies. Despite Asia's drug discovery capabilities having developed considerably and considerable potential for Asia's capacity to develop even further, there is still a lot that needs to be done before Asia can catch up with the United States or Europe.

	<b>National Policy</b>	<b>Bio-clusters</b>
<b>China</b>	The 12th 5-year plan (~2015) designated seven sectors as strategic newly-emerging industries. One of these is biotechnology, and the government reportedly aims to increase the share of biotechnology industries in GDP from 4% in 2010 to 8% in 2015.	Bio-pharmaceutical industry parks are located in approximately 50 sites throughout the economy (in provisional divisions or higher). Numerous public financial investments have also been made.

<b>Hong Kong</b>	Same as China	Efforts typified by the Hong Kong Science Park.
<b>India</b>	“The 12th 5-year Plan (April 2012~)” which is under development is expected to follow the previous 5-year Plan to maintain increased public investment in healthcare	The former 5-year Plan included the promotion of innovation through the creation of bioclusters in its 3 Action Plan. Currently, there are clusters in the BT field in 3 areas of India.
<b>Japan</b>	“Strategies to Revitalize Japan” received Cabinet approval in July 2012. Life growth strategy was set forth as an important item, and a setup to assist the creation of innovative drugs and medical devices is being established.	International strategy comprehensive special zones and local revitalization comprehensive special zones were established, aimed at creating economic effects and jobs.
<b>Korea</b>	“Pharma Korea 2020” strengthens the competitiveness of bio-industry through development and globalization.	There are a total of 16 bio-clusters across 3 zones. International collaboration has been established.
<b>Malaysia</b>	Under Malaysia's Economic Transformation Program, there are 12 National Key Economic Areas (NKEAs) which receive prioritized government support. Healthcare is identified as one of these key areas.	As the biotechnology base, the Malaysian Government constructed Bio-Xcell in Nusajaya, Iskandar region in the Malaysian State of Johor, and completed it in 2010.
<b>Singapore</b>	Various measures (incl. Biopolis) enhance functions as a hub for manufacturing/R&D of high-tech fields including biotechnology.	Efforts typified by “Biopolis”.
<b>Taiwan</b>	A Biotechnology Takeoff Action Plan was enacted in 2009, backing up development efforts to turn Taiwan into a partner in the international biomedical field. The government also creates employment opportunities, aimed at reinvigorating the biomedical industry.	As a base for bio-industries, the New Hsinchu Science and Biopharmaceutical Industry Park was opened in 2008. Manufacturing bases focusing on a medical center as well as incubation facilities are currently being built.
<b>Thailand</b>	TCELS was established under the Ministry of Science and Technology to support bio-ventures.	Efforts typified by the Thailand Science Park.

Exhibit: Healthcare innovation and biotechnology as national policy

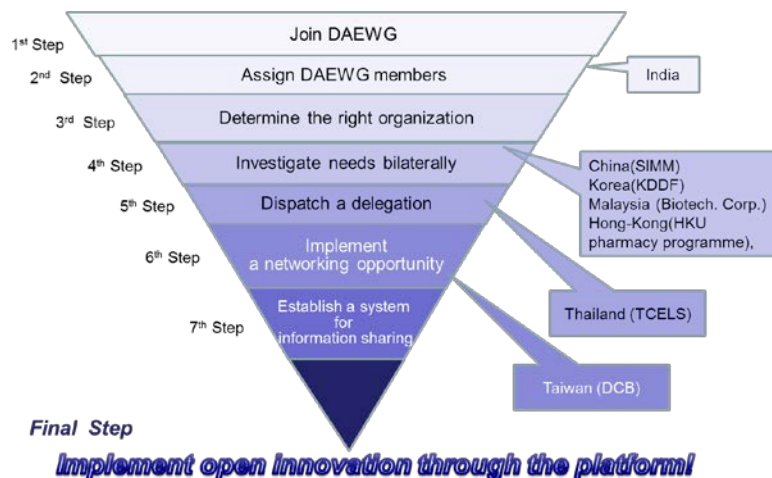
**How is APAC creating an Open Innovation Platform?**

The DAEWG acknowledges the great diversity in capabilities and expertise for drug discovery within Asia. Accordingly, in order to realize a platform that is designed to meet the needs of various Asian economies, the DAEWG has welcomed delegates from representative governmental organizations in the various economies into the DAEWG, and is designing a needs-focused platform for each economy that will also benefit the greater Asia region. The pharmaceutical associations of the various economies participate in the EWG as gatekeepers to the various governmental organizations within each economy and furthermore, they endeavor to act in such a way that optimizes the activities of APAC as a whole.



## The current status of progress in DAEWG

As of 10<sup>th</sup> Jan. 2014



While it will take more than a decade of sustained investment in order to realize the vision of a sustainable drug pipeline discovered within Asia, the DAEWG is working to provide tangible deliverables over time. To do this, the DAEWG has established the 8 step process shown in the inverted triangle above, which guides each country through increasing levels of engagement within DAEWG's activities. It is anticipated that platforms developed bilaterally will then be used as a roadmap to develop into a multilateral pan-Asia, drug-discovery open innovation platform.

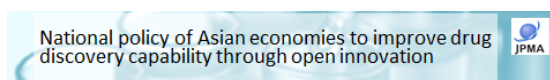
### **[Consensus reached at the 1st APAC in 2012]**

At the 1<sup>st</sup> APAC, members emphasized the importance of strengthening each economy's drug discovery capabilities, first and foremost, to achieve Asia-initiated drug discovery. Regarding drug discovery-related policies that are being aggressively implemented in various economies, members of APAC acknowledged the importance of making proposals and providing assistance to promote such alliance activities. (Please refer to reference materials below.)

### **[Reference materials: From presentation at the 1<sup>st</sup> APAC]**

National policy of Asian economies and economies to improve drug discovery capabilities through open innovation

Asian economies are investing funds from national budgets to gain favorable outcomes from open innovation just like the U.S. Our activities should respect and take into account such intentions of each economy. The first step of APAC's effort to promote a drug discovery alliance requires us to be fully aware of our role supporting each economy to improve their drug discovery capability. At the same time we must remember that drug discovery is a complicated process and Asian economies need to overcome a lot of challenging issues in order to develop



into drug discovery nations. Each Asian economy needs to improve its own ability to discover drugs in order to strengthen collaboration throughout Asia. I believe this will promote drug discovery in Asia and ultimately result in the whole of Asia benefiting from Asian-based drug discovery. Based on the background and current situation, alliances between Asian economies in science and technology have become a realistic approach to achieve drug discovery that originates in Asia. We intend to utilize Japan's rich experiences in drug discovery to develop and strengthen the Asia region.

**[Consensus reached at the 2nd APAC in 2013]**

Drug discovery alliances

In order to realize our vision of drug discovery originating from across the Asian region, we will initiate activities that facilitate information exchange, build networks that promote direct discussion, and establish an environment in which it is possible for industry, the public sector, academic institutions, and venture companies in Asia to cooperate. Our short-term goal is to create a platform for open innovation that creates and improves the drug discovery capabilities of each Asian economy.

To support this platform and in order to further foster partnerships in Asia that cross national borders, we will advance our activities for the promotion of open innovation through symposiums and conferences related to drug discovery in Asia.