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IQVIA APAC Insight

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Expediting innovative drugs' market access in China

Yan Chai, MD, *Associate Director, IQVIA, China*
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China's reform on drug review and approval policy has made remarkable achievements in the past few years. However, patients in China are still facing challenges brought by the inaccessibility of innovative drugs. Through research on innovative drugs approved by regulatory bodies such as the FDA, EMA, PMDA and NMPA between January 2009 to June 2019, we found that innovative drugs, inaccessible in China, can effectively reduce patients' disease burden. Therefore, the timely introduction of innovative drugs into the Chinese market is of great importance to provide more treatment options and meet the medical needs of patients.

Accelerating patient access to precision oncology in Asia Pacific

Sirinthip Petcharapiruch, *Head of Real World Insights, IQVIA, South East Asia*

Precision oncology can offer a path forward, delivering more targeted treatment options that will redefine the medical paradigm for cancer patients, and reduce the economic burden of cancer care. The advent of powerful Next-Generation Sequencing (NGS) technologies has led to the discovery of tumors with rare genomic signatures and can also enable better-informed treatment decisions. However, there are challenges to the uptake of precision oncology in APAC, including health technology assessments (HTA) and reimbursement of precision oncology, as well as clinical and data infrastructure.

Driving adoption of digital tools in post-marketing safety studies: patients and investigators weigh in

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Post-marketing safety surveillance studies are becoming commonplace in Asia Pacific, especially in markets like China, South Korea, Japan and Philippines. The COVID-19 pandemic has presented a need for digital methods of safety data collection to complement traditional site-based data collection methods. While digital adoption is the much-awaited golden goose of the next generation of clinical studies, its uptake is hindered by practical challenges that need to be addressed at the user-end level rather than the technical or business requirement of a digital tool. To support the introduction of direct-to-patient solutions alongside physician data collection, this paper divulges key considerations in the design and process development or evaluation of digital tools to be used. Insights from a market research study including investigators and patients using a simulated solution are shared to support decision making on future digital tools.

Design and refine: make patient support programs work for your patients

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Patient Support Programs (PSPs) are an umbrella term to describe initiatives led by pharmaceutical companies to improve access, usage, and adherence to prescription drugs. Now more than ever, PSPs are at the forefront of executive's minds. This article introduces a maturity assessment that can support managers in assessing programs across regions and therapy areas. Additionally, the article explores a modular framework that allows organization to adopt an agile approach to patient support.

Expediting innovative drugs' market access in China

China's drug review and approval reform has made remarkable progress in the past few years. However, patients in China are still facing challenges brought by inaccessibility of innovative drugs. We have conducted research on innovative drugs approved by FDA, EMA, PMDA and NMPA from January 2009 to June 2019 and have analyzed the current gap of innovative drugs by therapeutic area, to highlight the importance of accelerating innovative drugs market access to China market.

Research background

The Plan of Health China 2030 puts forward the strategic theme of "National Health by Co-building and Co-sharing ". The accessibility of innovative drugs has become increasingly critical for people's health improvement. In October 2017, General Office of the CPC Central Committee and the General Office of the State Council issued the *Opinions on Deepening the Reform of the Review and Approval System to Encourage Innovation of Drugs and Medical Devices.* With a series of policies to encourage innovation, China's drug evaluation, the reform has achieved remarkable progress and the efficiency of the innovative drugs review and approval is significantly elevated.

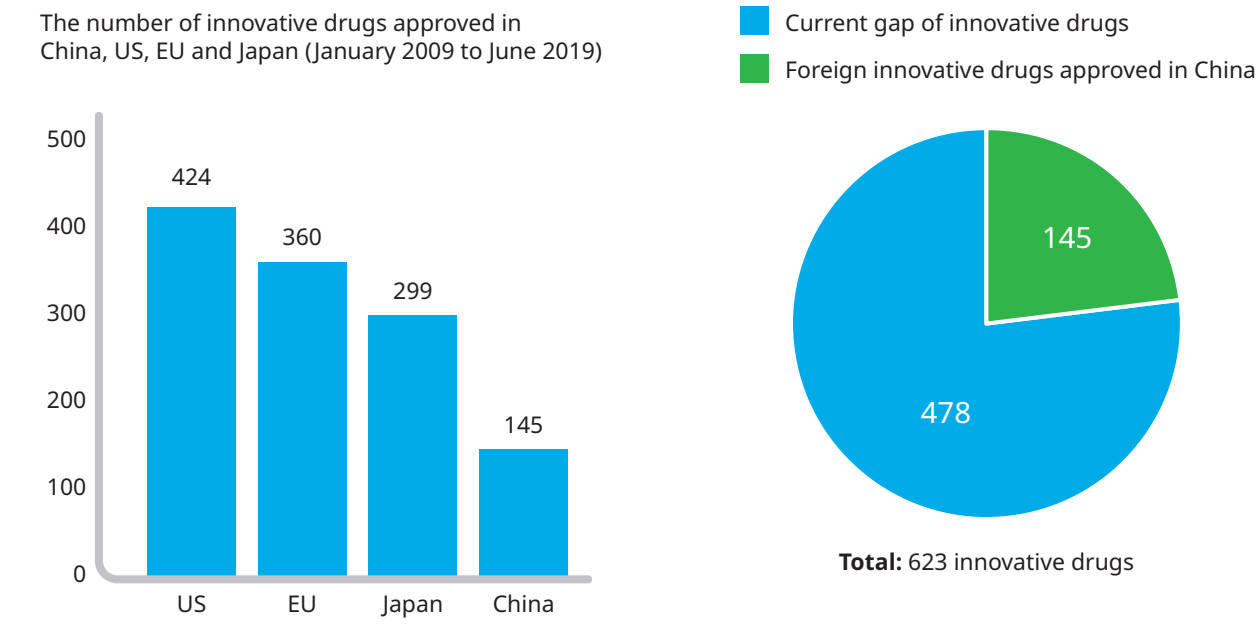
With the above mentioned, we conducted a research on innovative drugs in the United States, European Union, Japan and China, which were approved from 1st January, 2009 to 30th June, 2019, to understand China's current gap of innovative drugs compared with developed countries. We investigated the gap of innovative drugs by therapeutic areas and analyzed the role of innovative drugs in relieving patients disease burden to highlight the importance of accelerating innovative drugs market access in China.

Current innovative drug gap

CHINA'S INNOVATIVE DRUG GAP IS LARGE COMPARED TO US, EU AND JAPAN, BUT THE GAP HAS BEEN NARROWED IN RECENT YEARS

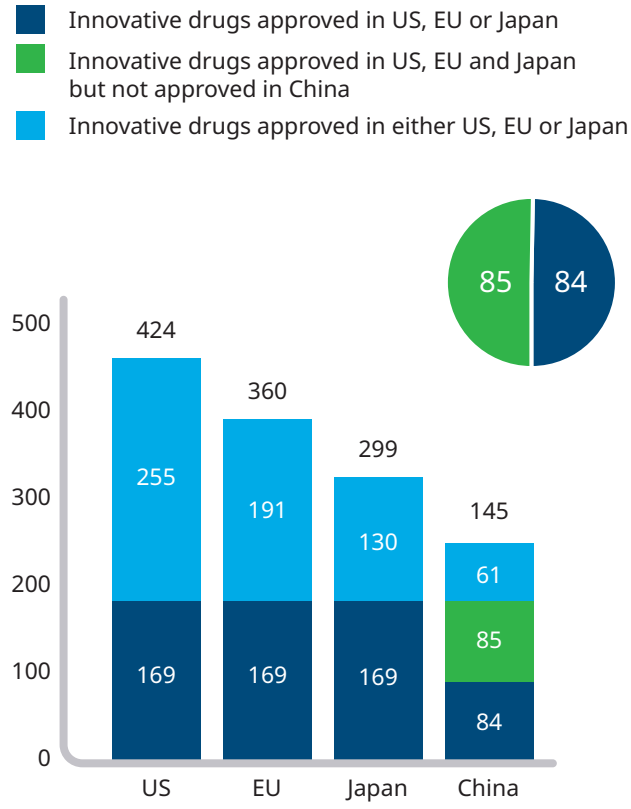
According to partial statistics, U.S. Food and Drug Administration (hereinafter referred to as "FDA"), European Medicines Agency (hereinafter referred to as "EMA"), Japan Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") have approved 623 innovative drugs from January 2009 to June 2019. Varying in countries, the three institutes approved 424, 360 and 299 innovative drugs respectively (innovative drugs refer to chemical drugs with new chemical molecular entities and originator biologics). The National Medical Products Administration (hereinafter NMPA, formerly known as the State Food and Drug Administration) approved 145 of the 623 innovative drugs, of which 478 products have not yet entered the Chinese market. However, stratified analysis showed that only 169 innovative drugs approved in all of the three countries, of which 84 were approved in China, with 85 products still have not entered China market (*Figure 1 and Figure 2*).

Figure 1: Innovative drugs approved in either US, EU or Japan vs. NMPA (January 2009 to June 2019)



Source: FDA, EMA and PMDA; DXY insight; IQVIA analysis

Figure 2: Innovative drugs approved in US, EU and Japan vs. China (January 2009 to June 2019)



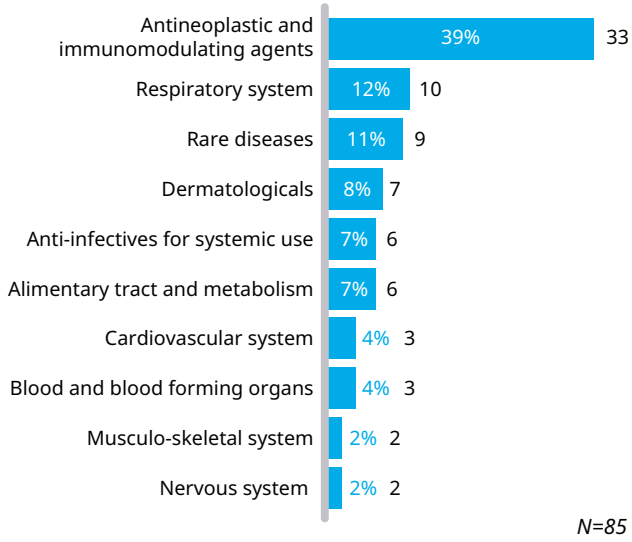
Source: FDA, EMA and PMDA; DXY insight; IQVIA analysis

Since the drug, review and approval reform in 2015, the number of foreign innovative drugs approved in China has increased year by year, significantly improving the accessibility to innovative drugs (*Figure 3*). Through gradually introducing the remaining 85 drugs into Chinese market, we can further narrow the gap of innovative drugs compared with US, EU and Japan.

THE CURRENT GAP OF INNOVATIVE DRUGS COVERS MANY THERAPEUTIC AREAS, AND CAN SATISFY PATIENTS' UNMET MEDICAL NEEDS ONCE ACCESSIBLE

The 85 innovative drugs in gap are mainly in the therapeutic areas of antineoplastic and immunomodulating agents, or the respiratory system. The former, antineoplastic and immunomodulating agents, account for the 39% of the gap (*Figure 4*).

Figure 4: Therapeutic areas of the 85 innovative drugs approved in US, EU and Japan, but not in China (Top 10)



Source: FDA, EMA and PMDA; DXY insight; IQVIA analysis

We have also analyzed the therapeutic areas in which the 478 products were approved in either US, EU or Japan but not in China. The results showed that these products were mainly in therapeutic areas such as antineoplastic and immunomodulating agents, anti-infectives for systemic use, alimentary tract and metabolism and nervous system. Of which, antineoplastic and immunomodulating agents accounts for 23% (*Figure 5*).

Figure 3: Innovative drugs approved yearly in China, US, EU and Japan (January 2009 to June 2019)

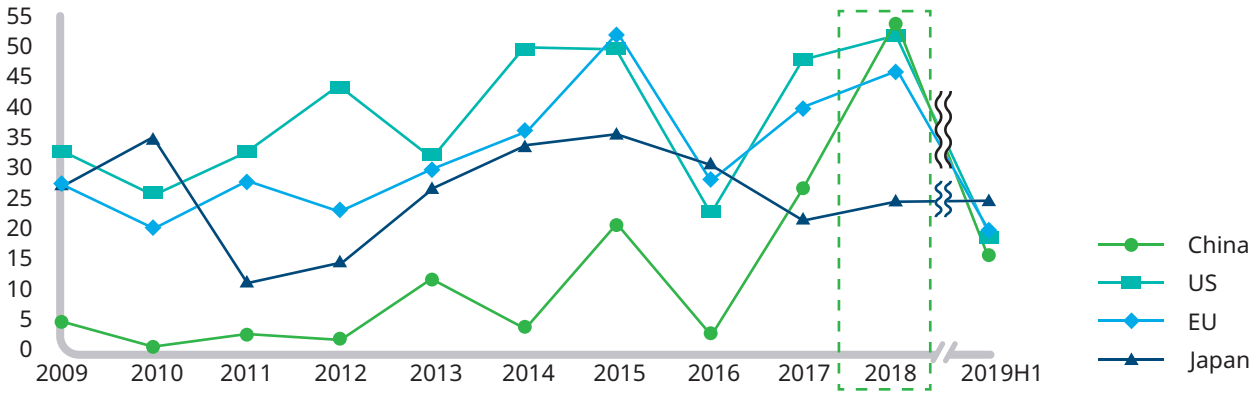
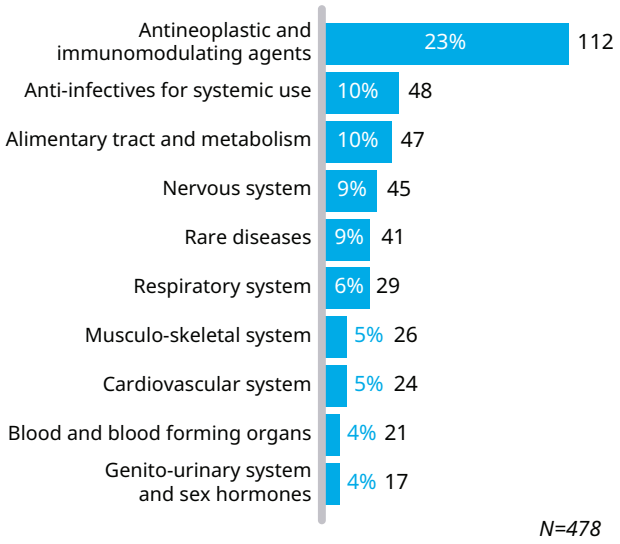


Figure 5: Therapeutic area distribution of the 478 innovative drugs approved either in US, EU or Japan, but not approved in China (Top 10)



Source: FDA, EMA and PMDA; DXY insight; IQVIA analysis

According to the China Health Statistics Yearbook 2019, cardiovascular diseases, cancer, respiratory diseases, alimentary tract and metabolism diseases and central nervous system disorders were the leading causes of death in China in 2018, where the patients' medical needs have not been met. However, of the 85 gap products approved in US, EU and Japan, a total of 60 products fall into the above therapeutic areas. Of the 478 innovative drugs approved in either US, EU or Japan, a total of 275 products fall into the below disease areas (*Figure 6*). Therefore, accelerating the market access of gap products can satisfy patients unmet needs and improve people's health.

In addition, currently there is a great demand for treatment of rare diseases in China. Most patients with rare diseases are facing problems with drug accessibility. Under the First List of Rare Diseases, 8 drugs for rare diseases are in the range of the 85 gap products approved in US, EU and Japan, and 44 drugs are in the range of 478 gap products approved in either US, EU or

Figure 6: Distribution of gap products in therapeutic areas that cause death in China

	DEATH COMPOSITION RATE (%) OF URBAN INHABITANTS	DEATH COMPOSITION RATE (%) OF RURAL INHABITANTS	NUMBER OF GAP PRODUCTS
CARDIOVASCULAR SYSTEM	43.8	46.66	3 21 24
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	25.98	22.96	33 112 112
RESPIRATORY SYSTEM	10.83	11.24	10 29 29
ALIMENTARY TRACT AND METABOLISM	5.68	4.57	6 41 47
NERVOUS SYSTEM	1.84	1.62	2 43 45
GENITO-URINARY SYSTEM AND SEX HORMONES	1.09	1.08	17
TOTAL	89.22	88.13	

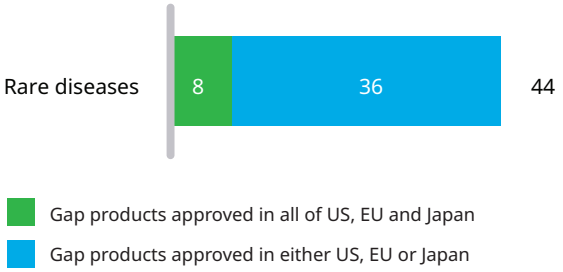
Gap products approved in all of US, EU and Japan N=60

Products approved in either EU, US or Japan N=275

* Death composition rate refers to the proportion of deaths caused by the disease area in relation to the total number of deaths.

Japan (Figure 7). Timely introduction of these innovative drugs will solve the drug inaccessibility problem for patients with rare diseases.

Figure 7: Distribution of gap products in rare diseases



Source: FDA, EMA and PMDA; DXY insight; IQVIA analysis

Conclusion

China has delivered significant achievements in accelerating the review and approval of innovative drugs, but there is still a gap compared to other developed countries. Previous analysis has shown that most of the gap products are able to reduce the disease burden of China. Therefore, the timely introduction of innovative drugs from abroad into Chinese market is of great importance in providing more disease treatment options and meeting the medical needs of patients.

The drug review and approval reform will continue to deepen as we move forward. With the continued enhancement of drug regulatory capacity, the implementation of the newly revised *Drug Administration Law and the Drug Registration Administration Law* as well as the continuous improvement of other regulatory documents and technical guidelines in the drug registration management system. It is expected that Chinese patients will eventually have quicker and ready access to world's new innovative drugs.

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Accelerating patient access to precision oncology in Asia Pacific

Precision oncology can offer a path forward, delivering more targeted treatment options that will redefine the medical paradigm for cancer patients, and reduce the economic burden of cancer care. Precision oncology is defined as an emerging approach for cancer prevention and treatment that uses molecular profiling of tumors to identify targetable alterations. Powered by Next-Generation Sequencing (NGS) technology, there has been a shift from evaluating single biomarkers to Comprehensive Genomic Profiling (CGP)[1]. Unlike conventional testing, CGP uses NGS to rapidly and broadly detect all four classes of gene alterations: DNA mutations, copy number variations, genomic signatures and gene fusions across the genome. By providing more comprehensive molecular insights, CGP enables better-informed treatment decisions.

The advent of powerful NGS technologies has led to the discovery of tumors with rare genomic signatures across diverse cancer types. This has ushered in the development and approval of treatments selected based on the specific variants identified that are agnostic to the tissue of origin, known as tumor-agnostic therapies (TAT)[2]. These therapies have transformed the outlook for several deadly cancers that harbor specific molecular alterations, including non-small cell lung cancer, renal cell carcinoma and colorectal cancer[3]. The number of approved TATs is on the rise and could become a major pillar for oncology treatment[4].

However, there are challenges to the uptake of precision oncology, including health technology assessments (HTA) and reimbursement of precision oncology, as well as clinical and data infrastructure. In Asia Pacific (APAC), HTA systems may not be designed to evaluate precision oncology.

Existing HTA evaluation frameworks are usually specific to a single drug or indication and many markets do not have specific pathways for medical technology or diagnostics test. This could create challenges for the adoption of precision oncology and become barrier for patient access.

Advances in precision oncology, including CGP and TAT, often target newly discovered causes of cancer and defy traditional treatment approaches. Hence there is a need for healthcare systems to evolve so they can accelerate patient access to these innovations and fully capture their health and economic benefits.

Bringing precision oncology to APAC

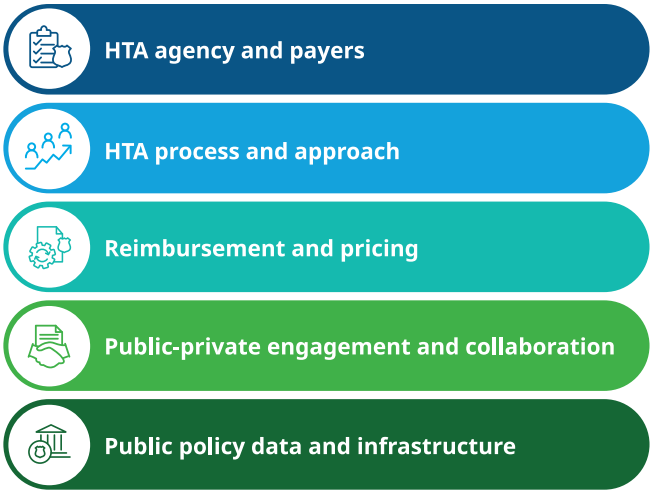
APAC is home to 60 percent of the world's population[5], which continues to be a growing and aging population. This has resulted in an increasing cancer burden, putting pressure on local healthcare infrastructure to deliver better and more cost-effective treatments.

The APAC region is highly attractive for the launch of innovative treatments, including precision oncology. However, there is a mix of mature and emerging markets, each with different political and healthcare priorities. Overall, there is an uneven uptake of precision oncology. In addition, HTA systems in APAC vary in their capabilities, assessment processes and evidence requirement. This means manufacturers will need to take a tailored approach to engaging stakeholders in each market. To ensure successful market access, a well-prepared evidence generation strategy that supports product value is a must. In addition, continuously raising awareness for precision oncology and communicating the benefits for patients, payers, and the healthcare community will be necessary.

HTA systems in APAC vary in their capabilities, assessment processes and evidence requirement. This means manufacturers will need to take a tailored approach to engaging stakeholders in each market.

Archetypes and their descriptions

This article aims to assess the adoption of precision oncology in APAC, delving into CGP and TAT as prime examples of diagnostic and treatment innovations that drive the shift towards precision oncology. To understand the priorities of HTAs across APAC, a comprehensive literature review was conducted. Based on the research findings a landscape assessment framework was developed. The five domains of this framework include:



Understanding market archetyping will help manufacturers understand the status and readiness of each market, so they can devise the right strategies to expand patient access to precision oncology, and overcome any obstacles in the marketplace.

A set of interviews with external stakeholders were undertaken to validate the market evaluation and recommendations to complement the literature review. Eighteen interviews with medical oncologists and HTA/health economic experts from six markets (China, Australia, South Korea, Taiwan, Malaysia and Thailand) were conducted from July to August 2020. In applying this assessment framework, we found varied levels of access and adoption of precision oncology across APAC, particularly CGP and TAT, which we characterized into three main archetypes:

THE INITIALIZING ARCHETYPE

Markets in this archetype, for example China, are formalizing their HTA frameworks and processes for adoption of precision oncology. The HTA bodies are still in the developmental stage, and HTA processes are not yet systematically incorporated into healthcare-decision making. Evaluation of diagnostics, irrespective of the evaluation methods, is not yet put in place and is still not required for reimbursement decisions. This could intensify the access challenges to precision oncology.

There is finite political support and low financial investment in building the testing and data infrastructure necessary for precision oncology in these markets. TAT is still a very new concept in many healthcare settings and drug evaluation is still largely based on indications. Coupled with the modest awareness of CGP and TAT in these markets, limited testing capabilities leads to a limited uptake of CGP in both specialized and tertiary hospitals. However, the launch of the Precision Medicine Initiative in China in 2016 is helping to build awareness of CGP and TAT among the HTA bodies and payers. Despite this, its use is still limited to a few leading institutions, mainly for research or trials.

Currently, involvement from stakeholders in HTA and reimbursement evaluation process is low. Payers and other public stakeholders prefer an organic approach to designing and customizing systems in accordance with demand, while collaborations between the stakeholders to drive precision oncology adoption in these markets are still evolving.

THE DEFINING ARCHETYPE



Markets in this archetype, for example Malaysia, Thailand or Taiwan are in the process of defining their precision medicines strategy and have established HTA bodies. Their appetite for precision oncology is growing, but formal processes regarding access and reimbursement are not yet in place.

Due to limited utility of CGP and TAT in clinical settings, payers and HTA agencies are still building their understanding of these health technologies and their potential benefits to patients. These technologies may not be reimbursed or limited to a few disease areas or specific patient groups.

Despite collaborative efforts among research and clinical institutions to enhance development of precision oncology, competing healthcare priorities and limited availability may reduce efforts to increase adoption of CGP and TAT, or to expand testing.

Data infrastructure is established but not sufficiently extensive yet to enable robust evidence generation. The Taiwan Biobank, for example, has an established genomic database but genomic data has yet to be linked with other health and phenotypical data in the electronic medical records due to data privacy concerns. Efforts are currently being pursued to develop a governance framework to support the convergence of these databases in Taiwan[6].

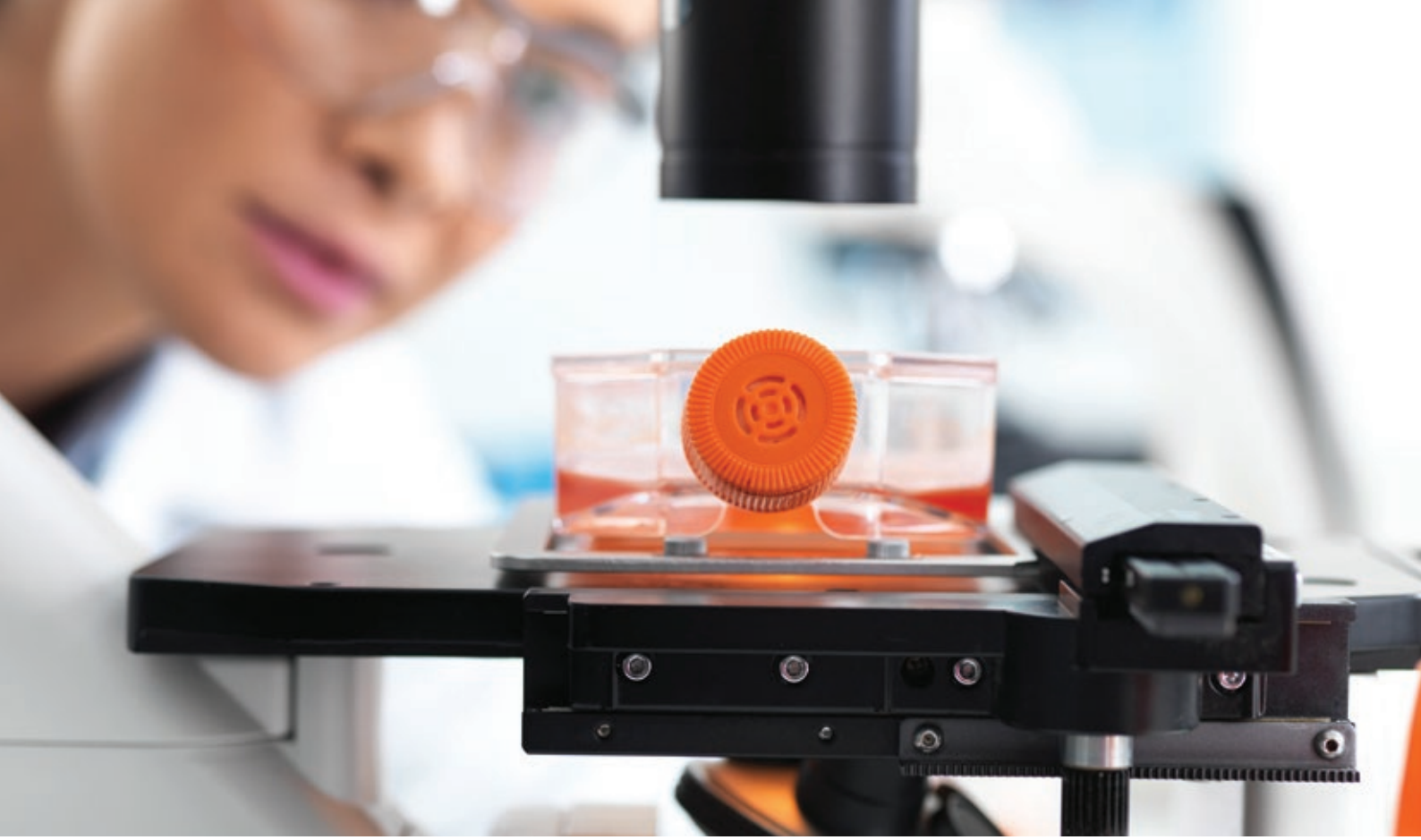
THE INNOVATING ARCHETYPE


Markets in this archetype, for example Australia or South Korea, have well-established HTA agencies with official guidelines and processes, and the knowledge of precision oncology among payers and HTA agencies is higher than in the other archetypes. Health policies driving the uptake of precision medicine are in place, and well-established data and testing infrastructure are available, resulting in a higher adoption of precision oncology.

Nevertheless, these countries still face the methodological challenge of allocating the costs of CGP to one specific treatment. Genomic testing can be used to inform a multitude of management strategies. As a result, a novel therapy can be penalized for being innovative, despite spillover effects from genomic testing that informs multiple subsequent therapies.

Markets within this archetype are better poised with technological know-how to direct efforts progressively at going beyond existing methodologies and fine-tuning evaluation strategies appropriate for their healthcare landscape. They often have established formal working groups, comprising members from public and private sectors, to further and align their precision medicine initiatives.

Payers and HTA agencies acknowledge the need to explore reimbursement for precision oncology through innovative pricing models, such as risk-sharing agreements. There is also strong government support for precision oncology in these markets, and they have an expansive network of testing infrastructure available. Genomic and clinical data is typically stored within each hospital's database; and a central data repository has yet to be constructed, a crucial step to enable population health studies. For example, K-MASTER, operated by Korea University, received US$70 million funding from the South Korean government to support three key goals in precision oncology over 5 years[7].



Conclusion

The advances in molecular profiling tools coupled with developments in novel cancer therapeutics have led to the era of precision oncology, where the management of cancer is enhanced by the identification of actionable genomic alterations, and the incorporation of advanced diagnostics, such as CGP, could aid early diagnosis, treatment selection and disease surveillance monitoring, leading to improved patient outcomes and more efficient use of healthcare resources. The dynamic HTA landscape of precision oncology offers both risks and opportunities for manufacturers. By considering the nuance local environment and market archetypes, strategic initiatives can be devised to address obstacles and incorporate precision oncology into the healthcare system. With better awareness and understanding of these archetypes, industry can better tailor their strategies and build sustainable partnership that help improve patient access to these treatments.

To learn more about the APAC archetypes and how they are evolving, download **Accelerating Patient Access to Precision Oncology in Asia Pacific**

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Driving adoption of digital tools in post-marketing safety studies: patients and investigators weigh in

In-depth interviews provide keys to increasing uptake of user-friendly apps that derive patient outcomes, safety data and market insights

The issue

Biopharma is rapidly introducing mobile digital tools to capture data in clinical and real-world research – including patient-centered outcomes, safety data and adverse event reports. These tools (often smart-phone apps) promise to streamline data recording from patients and providers, speed data delivery, and review, improve quality, and reduce the number of face-to-face patient-investigator interactions needed (especially critical in the age of COVID-19).

Mobile health (mHealth) developers worldwide are churning out these digital tools to solve the shortcomings of traditional data collection methods. However, these are dependent on patients, investigators and healthcare workers adopting the innovations, as well as regulators accepting them as better than the current, largely manual, processes.

Digital health tool adoption is challenging worldwide; it is especially pertinent in hotbeds of mHealth activity such as China, South Korea and the wider Asia Pacific. With

a target population of 4.3 billion and growing number of government-mandated post-marketing surveillance (PMS) requirements, Asia Pacific offers vast opportunities. From identifying the right motivations for patients, investigators and regulators to adopting culturally tailored data collection applications, the focus on patient-reported outcomes (PRO) and safety data digital tools is here to stay.

Furthermore, well-designed apps and survey methods can also give biopharma and device companies insights into market trends and consumer needs, increasing the return-on-investment in PMS and real-world evidence research.

This article explores the key considerations for digital tools uptake by patients and physicians and how Biopharma and clinical research partners can improve the design or selection of direct-to-patient data collection platforms in China, South Korea and other Asia Pacific markets.

Troubles with traditional methods

Post-market surveillance data traditionally has been collected via real-world patient studies or by spontaneous reporting: medical staff collecting

PHARMACOVIGILANCE

A field dedicated to analyzing and managing the risk posed by healthcare products once they have entered the market. Traditionally, post-marketing safety data or events are collected through spontaneous reporting by healthcare professionals, patients, or other individuals in the healthcare lifecycle. Complementing this process are post-marketing surveillance (PMS) studies mandated by a regulatory authority or proposed by Biopharma, Medical Device or Consumer Health manufacturers as part of their risk management plan.

PHARMACOVIGILANCE GAPS

Despite established guidelines in most countries, including China, there are deep problems in capturing real-world data about product safety. A study of 12 countries conducted by Hazell and Shakir reported that only 6% of adverse drug reactions are captured through the current pharmacovigilance system[1]. This is an alarmingly low percentage, that demonstrates the urgent need for better tools and greater adoption to detect safety signals.

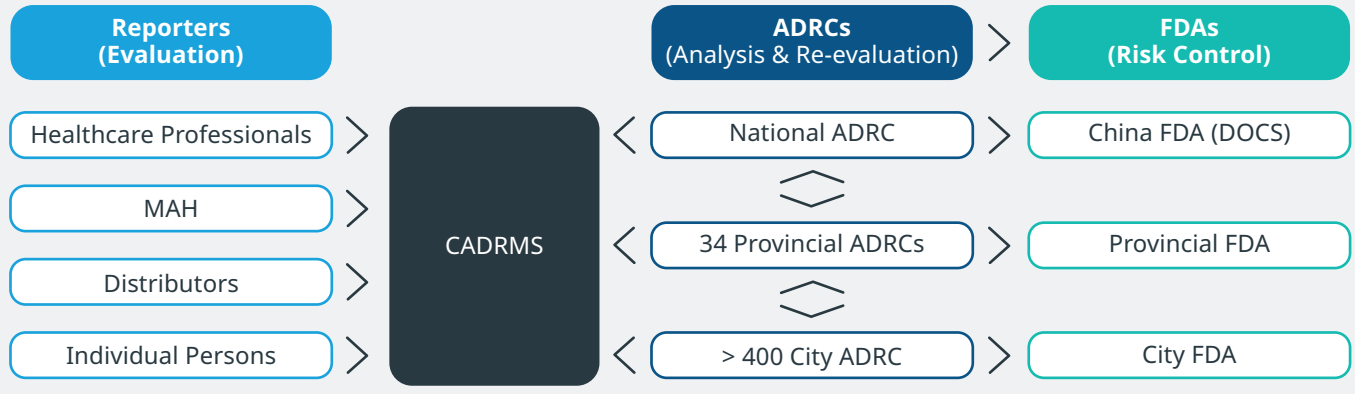
POST-MARKETING SURVEILLANCE STUDIES IN BRIEF

PMS studies or safety studies monitor the safety, efficacy and quality of approved products in the real-world setting[3, 4]. Safety is measured in the form of serious/ non-serious adverse drug reactions (ADRs) or risks associated with the exposure of the product, while efficacy is determined based on long-term clinical outcome.

DRUG INTENSIVE MONITORING STUDIES

As of 2011, NMPA introduced a preliminary guideline for drug intensive monitoring (DIM) to observe safety effects of new drugs entering the China market[5]. The primary focus of PMS studies, otherwise known as DIM studies in China, are to monitor the safety, efficacy and quality of approved products in the real-world/ routine clinical setting.

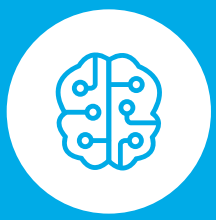
Figure 1: Overview of Pharmacovigilance in China



Source: Pharmacovigilance in China: Current Situation, Successes and Challenges, Li Zhang et.all.

Design thinking is a customer-centric approach to problem-solving, where teams engage with customers, to understand their needs and the obstacles they face in dealing with a product or process. This helps the teams develop empathy with their audience and can new solutions or feature to make a product more valuable and engaging for customers.

The key to design thinking, (or human centered design) is observing customers in their own environments to see how they perform tasks, and to talk to them about their pain points and what they'd like to change. That feedback is used to brainstorm relevant solutions, and to iterate on those ideas through continued feedback loops, until a fully formed product emerges.



One study conducted by IBM on the economic impact of design thinking found that teams who employ design thinking in product design achieve faster project execution, develop products that better meet users' needs, and are able to accelerate time-to-market, all of which translates into significant financial returns. The study also found that these projects see lower rates of failure resulting from teams that make assumptions about what customers want without incorporating their feedback in the process.[2]

information about patient drug use and adverse events through observations and interviews. These interactions may occur while the patient is in hospital, or during routine visits between patients and providers.

In Asia Pacific, five key markets have government-led post-marketing guidelines: Japan's Pharmaceuticals and Medical Devices Agency (PMDA), Republic of Korea's Ministry of Food and Drug Safety (MFDS), China's National Medicinal Products Administration (NMPA, previously known as CFDA), Philippines' Food and Drug Administration (FDA) and India's Central Drugs Standard Control Organisation (CDSCO).

While PMS regulations are well-defined and regulated in Japan and South Korea, the practice is evolving in countries like China and Philippines. In 2017, China's NMPA began increasing post-marketing surveillance oversight, including a stricter review processes and higher standards for timely real-world adverse event reporting, with penalties for non-compliance. This raised the stakes regarding the efficiency and thoroughness of traditional reporting processes.

A major drawback with the PMS studies is that physicians and patients have little incentive to participate: data collection is time consuming and tedious with little financial, medical or personal benefit in return. In addition, because most data is collected during infrequent patient visits, relevant information about symptoms, co-morbidities, self-medication, and changes in condition may not be accurately recorded into the health information systems.

Though digital solutions exist in the market, a bottleneck in adoption is an industry-wide reluctance to view patient-reported data as being objective. While there has been significant progress in psychometric validation of patient reported outcomes/ questionnaires, which are well accepted in estimating quality of life in clinical trials, there is a lack of inclusivity in the post-marketing space for evaluating long term safety and effectiveness of drugs.

The result: an unclear picture of patient safety trends, potential risk of not receiving license renewal and misinformation about product safety. Many events are missed entirely because patients neglect to report them or deem them irrelevant. Even if reported, the

pharmacovigilance process used in some countries and the internal processes of Biopharma requires multiple manual steps that deter interest and acceptance.

A direct-to-patient app for PRO and symptom reporting, complimented with a physician portal for reviewing the data in real time, has the potential to bridge the gap in several ways:

1. Increase compliance in reporting adverse drug reactions.
2. Pique patient interest in observational trial participation, especially when patient engagement with the physician is low.
3. Provide an opportunity for increased patient education on disease and symptom management from a trusted source (their physicians).
4. Create a secure and easy-to-use channel to track ad-hoc and on-call discussions.
5. Instill confidence in patients that their disease is being tracked and prioritized by healthcare providers.

Design thinking in mHealth development or selection

Too often companies create apps and platforms in isolation, making assumptions about what users will want. The result? A solution that may look exciting but does not meet user needs. Such costly mistakes can be avoided by engaging end users in development or having a thorough due diligence process while selecting a solution. This is much more likely to result in a tool that is user-friendly, reliable, robust and delivers value.

IQVIA pharmacovigilance case study

At IQVIA, we tested a prototype patient symptom reporting app in conjunction with a prototype physician review portal, using WeChat as an entry point, to gather feedback on the uptake of this digital tool in PMS studies in China. The IQVIA project teams then conducted in-depth interviews using a formal interview guide to gauge user responses and identify opportunities to improve the models.

The interviews generated compelling insights into the behaviors, attitude, and digital experiences of patients and physicians, which informed iterations in the platform and app designs, and provided insights into how the tools could be used by biopharma and device companies to improve marketing and engagement strategies across Asia Pacific.

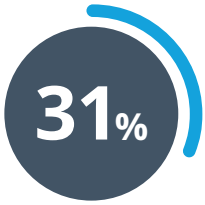
#1 DIGITALLY SAVVY PATIENTS & PHYSICIANS SEEK CONVENIENCE AND ACTIONABLE INSIGHTS

Patients interviewed ranged in age from 35 to 60, had participated in medical research or observational studies in the past five years, and were living with a chronic illness of diabetes, asthma and rheumatoid arthritis. All of them used digital tools on a regular basis, suggesting a level of comfort with technology that is consistent with data about the broader consumer population in China.

used WeChat (social messaging and lifestyle platform)

used apps daily, including Didi, Hungry, taxi services (food and transport)

used email



used hospital apps

They were also apprehensive about drug safety and side effects related to being a part of clinical research. Most said they trusted their doctors and Biopharma companies to keep them safe, and believed that the benefits of feeling better, losing weight and/or free medication outweighed any concerns.

Physicians, on the other hand, are facing technology fatigue with an overload of applications associated with medical products and disease management. To better manage time and patient information, they prefer having

60% of the 16 investigators interviewed said that under-reporting is a problem in their clinical research vs. 33% who had concerns about over-reporting

a one-stop solution for each study, rather than having to deal with multiple non-interoperable applications.

Dashboards that are well-designed, customizable and insight-generating were viewed as an important way to digest the influx of patient data during the study conduct. A key concern for safety data collection is the reporting of serious adverse events within a strict timeline of 24 hours from the point of identification. When asked, the investigators shared that daily review of dashboards that flagged serious adverse events (SAE) in a timely and appropriate manner is not a challenge; which was otherwise presumed by Biopharma as a burden to physicians and hospital staff.

#2 POOR GUIDANCE LEADS TO UNDER-REPORTING WHICH LIMITS INSIGHTS

Providing patients with an easy real-time solution to encourage an increase in consistency and prompt questionnaire and symptom reporting was a primary goal. The interviews underscored that need:

- Patients consistently showed confusion about when and what to report
- Investigators were frustrated by the inconsistency in reporting process and structure
- A common misconception for adopting a patient-centered reporting model by Biopharma is the over-reporting of symptoms or potential adverse events that might undermine the product prematurely.

Contrary to the belief by Biopharma about over-reporting, nearly 60% of the 16 investigators interviewed said that under-reporting is a problem in their clinical research vs. 33% who had concerns about over-reporting. They said that patients often forgot adverse events by the patient visit, and are frequently uncertain about the timing, severity and frequency of these events.

Patients said that lack of clarity about what they were expected to report and to whom contributed to under-reporting. Many said that if the symptom was mild, for example discomfort from low blood sugar or a minor cold, they would deal with it on their own and not mention it to their physicians.

They were more likely to report significant or surprising symptoms, such as leg numbness or blisters around injection sites, as soon as they occurred or at the physician visit. They were also more likely to report symptoms that their physicians specifically discussed. As one 60-year-old patients with rheumatoid arthritis said: “If I am told by the doctor about the side effects of the medication and experience a symptom he mentioned, I will go back to this doctor. If I experience other symptoms that he did not mention, I will go to other doctors for the other symptoms.”

This inconsistency in what and when symptoms are reported underscores the need for a more structured real-time digital reporting solution. An app that can be accessed around-the-clock would make it easier for patients to report symptoms in real-time and could provide clarity about what to report and what details to include through educational features or pop-up guidance tools.

It could also reduce patients’ concerns about overburdening the physician with their complaints. Several patients reported reticence to report minor symptoms, including one who said: “The doctor is so busy, when do they have time (to respond to me)?”

#3 EXCITEMENT AND CONCERNS OF DIGITAL ADOPTION TO BE ADDRESSED

Both patients and investigators had a positive response to the idea of using a digital solution. 94% of patients and 85% of physicians said they would be interested in using an app and platform like the one demonstrated for symptom reporting in a study. Though both groups also reported some concerns.

Patients: The patients interviewed currently use a combination of apps, diaries, and face-to-face meetings to communicate their symptoms to their physicians. Most (88%) believe the current reporting process is convenient, but they saw potential benefits from an all-digital approach. These included:

- *Speed of communication "like chatting" with the physician*
- *Convenience of capturing relevant information outside of the clinical setting*
- *Reassurance that someone will see the message*

While patients largely understood the goals of the tool, they also shared the feedback that after going through the entire process, if they didn't get a prompt response they would be disappointed. Other concerns included:

- *Lack of clarity on what to report and how to phrase things*
- *Uncertainty about who will read the feedback*
- *Uncertainty about who will respond and how quickly*
- *Preference to shut off phones outside of work*

To mitigate some of these issues, they suggested including a phone-in or voice-to-text option offering opportunities to connect directly with their physicians via the app; and providing disease information that is highly specific to their condition.

Investigators: Most of the investigators surveyed had either seen or expect to see uptake of digital solutions in other aspects of clinical research, and thought it was a viable solution to address issues related to adverse event reporting. As one investigator said: "Now is the tech era, and eventually everyone will use digital solutions."

However, some investigators felt that not all indications would be suitable for digital reporting. They were concerned that older patient groups may be less likely to adopt technology as part of their healthcare routine. They also worried that lack of confidence with technology, lack of education, and medical conditions such as poor eyesight and limited digital mobility could be barriers preventing patients from using these tools correctly. In these cases, a hybrid approach was thought to be a viable alternative, giving patients multiple ways to engage with the app (i.e. voice, voice-to-text), and/or multiple channels (app, phone, face-to-face) to report these events.

Some of their suggested additions to the solution included:

- *Automated reminders to report symptoms*
- *Opportunities to provide more detail and images to explain symptoms*
- *Automatic language translation*

New iterations: forging ahead

There is a positive trend to re-focus on post-marketed drug surveillance, possibly linked to a key change in country regulatory authorities accepting international data for medical product registration[6]. However, as the safety profile of the product might not be specific to the local population, it would increase the need to collect more safety data through PMS studies or improved spontaneous reporting methods. This calls for a change in the safety reporting framework; patient centered outcomes and patient enabled safety reporting by leveraging on the growing mHealth industry.

All the insights discussed above are critical in designing and/or validating digital tools to consider value-driven features that directly respond to the needs of the end-users. They highlight patients' and physicians' general familiarity and comfort with using apps, and the potential for including mhealth technology in traditional safety data collection and pharmacovigilance models.

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6 Pharmacovigilance in China: Current Situation, Successes and Challenges

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Design and refine: make patient support programs work for your patients

Patient Support Programs (PSPs) are an umbrella term to describe initiatives led by pharmaceutical companies to improve access, usage, and adherence to prescription drugs. These programs can have a financial component, support clinical investments, focus purely on education, or a combination.

Figure 1: PSP's Motivators and Drivers

There is a **wealth of evidence** that pharm-sponsored multi-channel patient support programmes (PSPs) can significantly improve health outcomes[1-7]

The most **impactful PSPs** are those that **understand the motivators and drivers of patient** behaviour, and deploy interventions matched to individuals' needs[2,8,9]

The **PSPs** that have shown the **most success** are those that **integrate high-touch HCP/nurse-led** support, with multi-channel digital and print support[2,8,10]

61% show improved clinical outcomes

64% show improved humanistic outcomes

61% Patients think the pharmaceutical industry should provide educational support

PSPs impact adherence **90%** after 12mo **75%** after 24mo

Source: IQVIA Secondary Research

One of the main challenges with PSPs is that they often have broad definitions and are often subject to misunderstandings and bias when being discussed with vendors, regulators or internal cross functional stakeholders. Though the definition of a PSP can be debated, the value PSPs bring to the community and company are inherent, and moreover expected of the pharmaceutical industry. IQVIA analysis demonstrated the most impactful PSPs are those that understand the motivators and drivers of patient behaviour and deploy interventions matched to need (*See Figure 1*).

PSPs are not a new concept, at IQVIA the longest running PSP was started in 2005. Now 15 years later, more than ever, patients and prescribers are seeking innovative solutions to engage with PSPs. With a plethora of health tech incubators and digital solutions across the APAC region, there are capabilities and technologies available to facilitate and execute PSPs that best fit patient and prescriber needs.

But are multinational pharmaceutical companies able to pivot, adapt and execute quickly enough to implement solutions that are demanded in a dynamic PSP landscape?

What is a PSP?

PSPs can be grouped into three main categories; adherence support, financial assistance, and clinical support —a single PSP could incorporate all aspects of these category types *(See Figure 2)*.

Figure 2: Categories of PSP

Case Study 1: Rare & Orphan Disease

Background

- April 2005 - Ongoing.
- Multiple Sclerosis Nurse Educators to address quality training and education.
- Current Home Heatlh Nurses do not specialize in MS.

Goals / Objectives

- Provide consistent, quality training on MS and therapy to new patients.
- Schedule adherence visits in-person.
- Support to Sponsor's sales organization to educate physicians, nurses and office staff.

Benefits to Customer

- Support from nurses is critical.
- Regular contact with patients, consistency of care & a trusting relationship.
- Development of several industry-supported nurse administred patient assistance support programs.

Results

- 40% improvement in 1-year adherence rates from year 1 to year 4.

Solution - Approach

- Nurse Educators participate virtually.
- Educators calls on neurologists & staff.
- Educator provides training.

Adherence PSPs

The support focuses on addressing patient's persistence with products who offer a complex regimen, side effect complexity, education to adherence especially where the effects are not readily noticeable to the patient, counselling, adverse event reporting or healthcare professional (HCP) load *(See Case Study 1)*.

Financial PSPs

As the name suggests, these focus on financial/ affordability issues for patients either starting or continuing treatment. Navigating the changing regulatory landscape can be challenging for pharmaceutical companies who want to provide and track appropriate funding mechanisms for eligible patients, whilst being compliant *(See Case Study 2)*.

Case Study 2: Implementation of a patient access program for patients ubable to afford Oncology, Immunuology and HCV drugs in the UAE

Situation

- Patients facing insurance coverage limitations in the UAE are unable to cover costs of their indicated treatments.
- In the UAE NGOs and Charity organizations are the soul contributors to financial aid.
- Patients are required to submit various documents for an eligibility assessment.

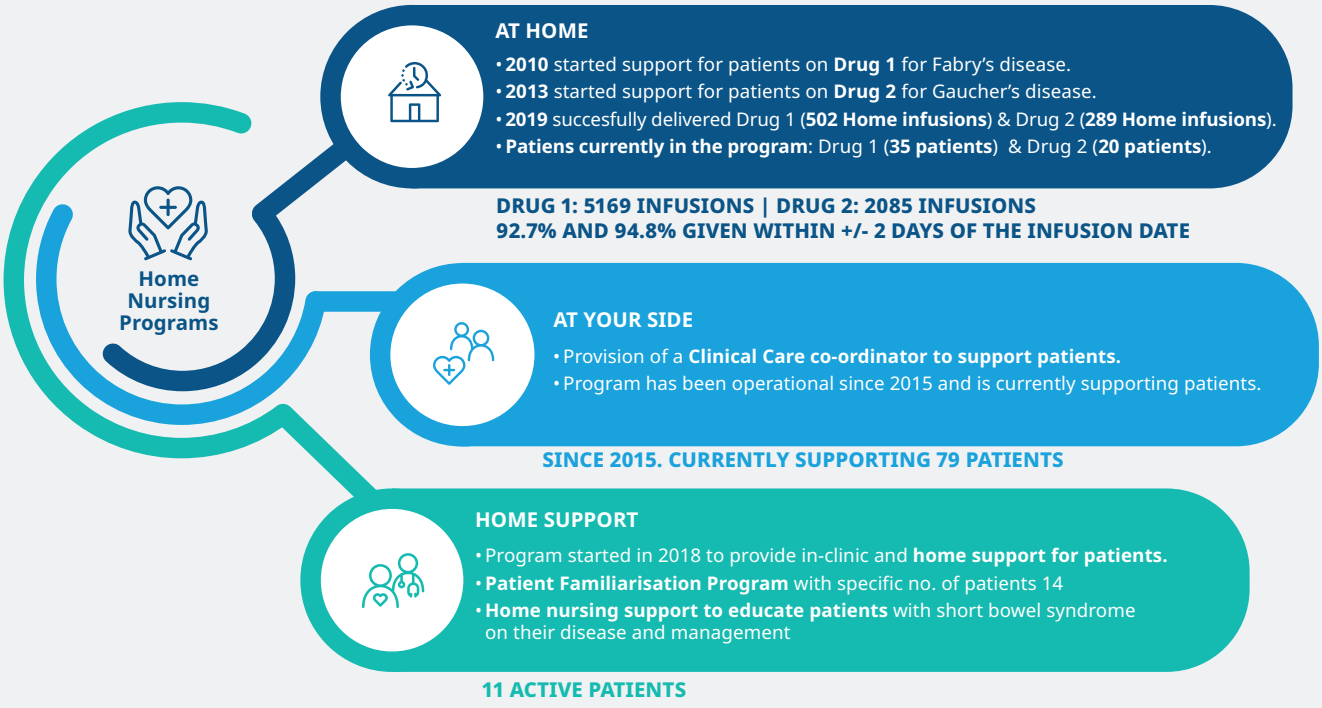
Solution

- Implementation of a Patient Access Program for patients unable to afford their indicated treatment.
- Mapping out the requirements of the identified charities.
- Acts as the Single Point of Contact (SPOC) for all stakeholders.
- Supports the "Patient Dossier" for submission.

Result

- Improved patient access to treatment.
- Patient and physician satisfaction.
- Treatment interrruptions have been avoided.
- Improved Patient Outcomes.

Case Study 3: Home Nursing Programs with Care Coordinators



Clinical PSPs

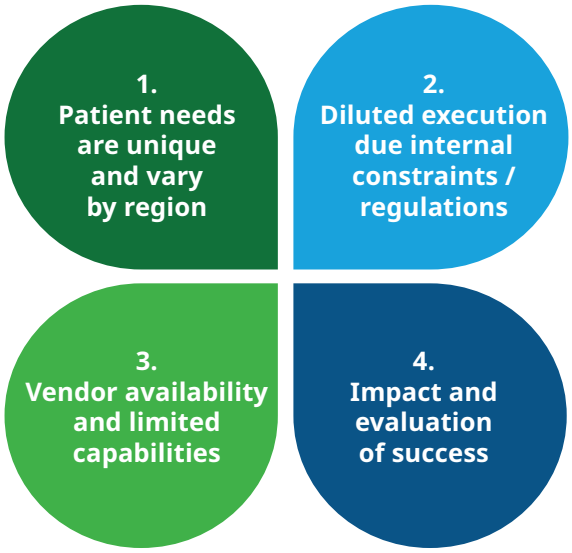
These may involve providing support should patients be unable to travel to clinics/hospitals for the administration of treatment; or may assist hospitals themselves with additional support for specific and challenging regimens, such as chemotherapy, whilst noting and being available on site for adverse events. Simply put, this could just be providing other support to the patients, based on their needs and the market scenario. During the COVID-19 pandemic, where it has been challenging for patients to travel to clinics/ pharmacies for prescription collection, concierge services or delivery of their drugs could be considered a PSP *(See Case Study 3)*.

DESIGN, IMPLEMENT AND MONITOR A PSP

IQVIA approaches PSPs with specific tools, this modular approach assists the design, implementation and continued monitoring of a PSP. As with all solutions, the first step is to understand the challenges you may face while balancing the opportunity.

Challenges associated with PSPs

Each type of PSPs has unique challenges, just as each a country, product or therapeutic area may have, but as a category there are four main reasons why PSPs can be perceive as difficult, to design, implement and monitor.



1. PATIENT NEEDS ARE UNIQUE AND VARY BY REGION

Each PSP is unique, and that is a challenge in of itself. There is opportunity to leverage learnings, but there is no plug-and-play method when it comes to PSPs. What is successful for one product in one region, will struggle to be directly lifted into a new region —namely because across countries and regions the patient journey will differ. Facilitating a patient journey mapping exercise and looking at pain points can enable regional or global learnings to be adapted and applied.

2. DILUTED EXECUTION DUE INTERNAL CONSTRAINTS / REGULATIONS

A challenge often faced by ambitious teams is how to navigate through internal compliance and legal regulations. Countries across the APAC region have specific rules regarding data privacy and patient protection constraints, and these laws are also rapidly changing. Without a strong PSP leadership at a company, internal departments may not have the latest information for their internal processes. The company may be limiting itself, and be stricter than the country, and thus limits a PSP managers ability to design the solution identified during the patient journey mapping. It's best practice to involve the compliance team early and often during the design of the PSP; by doing this the team will better understand the foundational issues and can help better support to ideate on solutions when regulations create a roadblock.

3. VENDOR AVAILABILITY AND LIMITED CAPABILITIES

PSPs are often run through a third-party vendor these vendors may also carry out the distribution of the product as well. In the APAC region there are a number of country specific vendors, but there are a limited number of vendors that span the region/ provide regional solutions. Aside from vendor presence, vendor capabilities can also be a challenge. A vendor can make or break a PSP, the worst scenario is a pharmaceutical company limited by a vendors capabilities and ability to build new capabilities quickly to fit the need for the PSP. When reviewing vendor RFPs look for vendors who can offer customized yet buildable solutions or have demonstrated the ability to work with other vendors to meet the need.

4. IMPACT AND EVALUATION OF SUCCESS

PSPs are multi-year investments that have a varying degree of growth. There are strict rules regarding how companies can measure patient support program success. In the past, pharmaceutical companies have designed PSPs and captured KPIs around enrolment numbers, but an increase in enrolment cannot be tied back to value add for the company. It is difficult for a company to measure, for example, the impact on health outcomes, but now we are seeing more companies using real world evidence (RWE) to show how PSPs are impacting disease prevalence.

PSP opportunities

The environment in APAC is ripe for innovative and comprehensive PSPs. Firstly, with an increasing prevalence of noncommunicable diseases (NCDs), adherence is a critical factor for chronic disease. Secondly, with the introduction of new drugs, with more complicated supply chain pathways, PSPs are necessary for patient treatment delivery. Precision and personalised medicine will never be able to thrive without corresponding personalised patient delivery. For example, the support required for a sick patient travelling to a major hospital and timing arrival perfectly to receive gene therapy for 3-4days —one example, ripe for a robust PSP to make it possible.

IQVIA has two product agnostic tools, that can be used across the three main categories of PSP, that we use to work with companies to better support strategic PSP decisions.

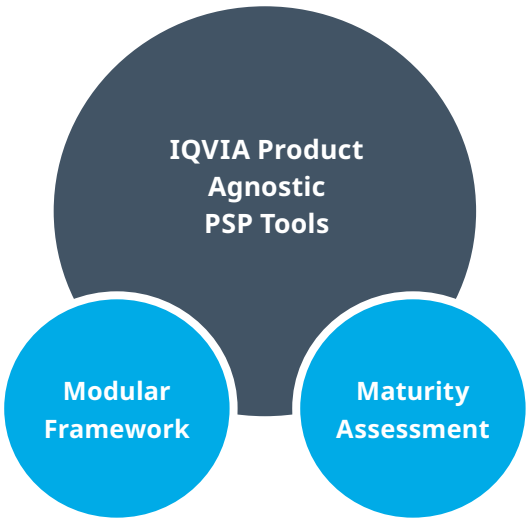
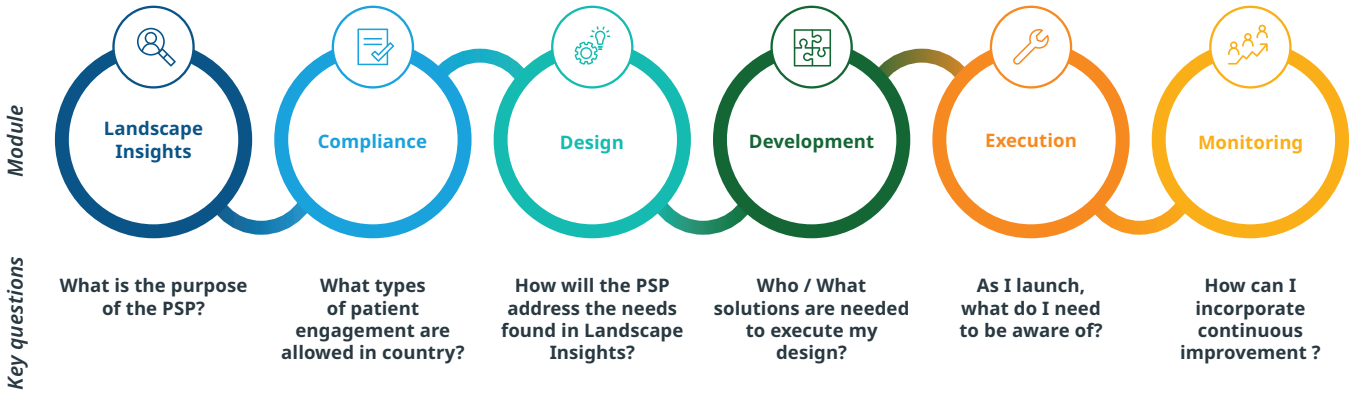


Figure 6: PSP Modular Framework



For existing PSPs, the Maturity Assessment can identify weak links before using the Modular Framework to bring these to gold standard. For a new PSP, starting with the framework and referencing the Maturity Assessment will bring the gold standard from the beginning.

Standardizing PSPs with a modular framework

The Patient Support Program Framework is a modular framework for the designing, executing, and monitoring of patient support programs. The framework is a designed to facilitate cross functional conversations to support a streamlined execution of the PSP.

Each module includes sub modules that dive into the why, what, and how of executing PSPs. Each sub module includes detailed information, research articles, and best practices collected across the company and provides a granularity to support regional heads as well as PSP Managers. The benefit of using this kind of framework is that the PSP Manager – or responsible person – can anticipate the needs of the program throughout the PSP lifecycle and work with key stakeholders to find optimal solutions.

The value of using a framework that is modular, as opposed to linear, is that it can easily be adapted and flexed to support a product or brand's specific needs. In addition, the framework allows the company to understand a any weakness in the PSP, regardless of where in the PSP journey they are.

1. WHY - why the steps and process within this module are important to complete and how and where they will impact the PSP in the long run.

2. WHAT - what tasks need to be accomplished in this module before moving to next steps, and goes into detail on how they interact with each other

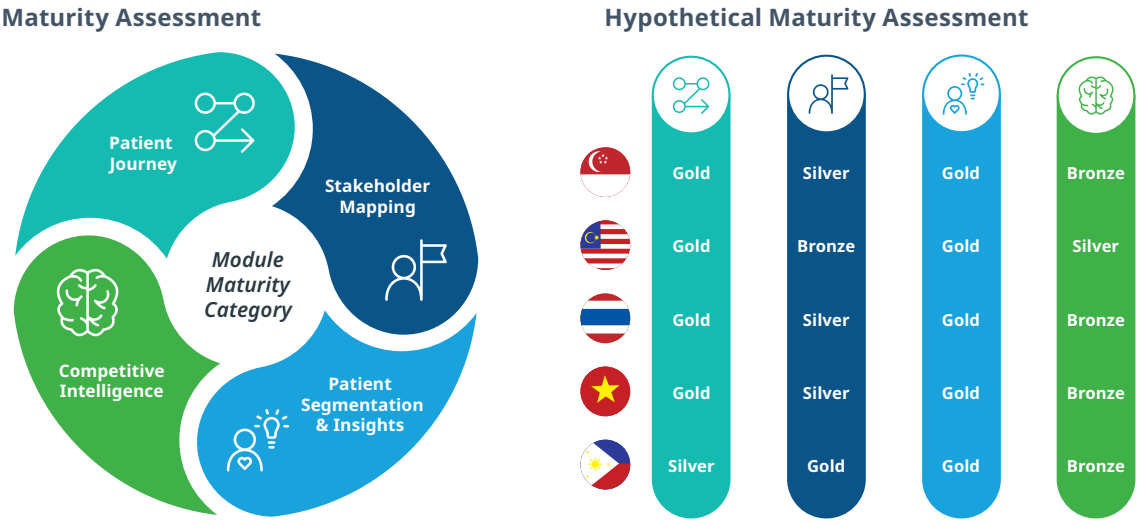
3. HOW - provides guidance and when to have conversations with the regional and local cross functional players. The guidance also includes what information is needed for which types of conversations throughout the PSP lifecycle *(See Figure 6)*.

This kind of framework provides continued value, it provides a structure and a common language for a company to speak. As noted in the challenge section above, PSPs have different meanings to different stakeholders. In APAC, with many different experiences and expertise coming through the region, having a common language and framework helps to align teams and alleviate the frustration felt with executing the PSPs.

Bringing a gold standard PSP with a maturity assessment

The challenge with PSPs is that there is no single view of what, 'good' looks like, especially across differing therapy areas and regions. Maturity Assessment for PSPs should pull on international PSP experiences to create a clear view of what 'good looks like' for PSP design, execution, and monitoring. This Maturity Assessment could be used

Figure 7: PSP Maturity Assessment & Hypothetical Maturity Assessment for BRAND X Patient Support Program in 5 key markets



by teams executing innovative CAR-T patient support programs or call centres for well-established drugs. A good patient support program is defined not by the complexity of the offering, but by the process that offering was designed and executed.

The IQVIA Maturity Assessment introduces global industry benchmarks using bronze, silver, and gold measurement. This assessment is used to understand the current state of an organizations PSP process, and can diagnose the sophistication of a PSP and detect untapped opportunities to strengthen the team's execution. The Maturity Assessment should be done as a baseline assessment to pinpoint areas of opportunity for strengthening internal operations and strategy concerning PSPs. The Maturity Assessment can be completed as an informal self-assessment or as a formal diagnostic by IQVIA.

The Maturity Assessment is especially helpful in APAC, where there is a high variability in the sophistication of PSP programs, and can be used for a fair comparison. For example, a basic PSP may be gold compared to digital PSP, if it was designed with longevity and adaptability. The rating is not based on the final offering, but rather on the journey to get to the product. For example, if a standard PSP call centre could receive an overall gold rating if it were designed and executed correctly.

When it comes to PSPs the goal is to design a program that relieves a certain pain point along the patient, caregiver, or HCP journey, and to measure and evaluate if the PSP has relieved this pain point.

What is the future of PSPs?

One of the major trends seen from the COVID-19 global pandemic, is an increase telehealth. As the point of enrolment into a patient support program goes digital, PSP programs need to adjust. This seismic shift in the way we seek and receive treatment will require companies to revisit and potentially update their, 'Landscape Insights', work (Module 1). Any findings during this research will require updates throughout the PSP, and a re-alignment from cross functional players — made easier with the modular framework.

With an increase in digital enrolment there are now more opportunities to capture data points and utilize technology. PSP sponsors can consider working with partners who have a platform that can easily be integrated across various vendors and partners. The goal is to have a platform that is all encompassing, yet customizable for different personas.

As the world continues to evolve, the needs of patients become more sophisticated and specific. A 'gold' maturity ranked PSP can be the difference in choice of therapy by a patient or prescriber.

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Accelerating patient access to precision oncology in Asia Pacific

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Driving adoption of digital tools in post-marketing safety studies: patients and investigators weigh in

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Design and refine: make patient support programs work for your patients

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