

White Paper

Transforming Real-World Evidence Generation Approach in Asia Pacific Through Mosaic Studies

Reimagining real world evidence generation with innovative approaches you can leverage today

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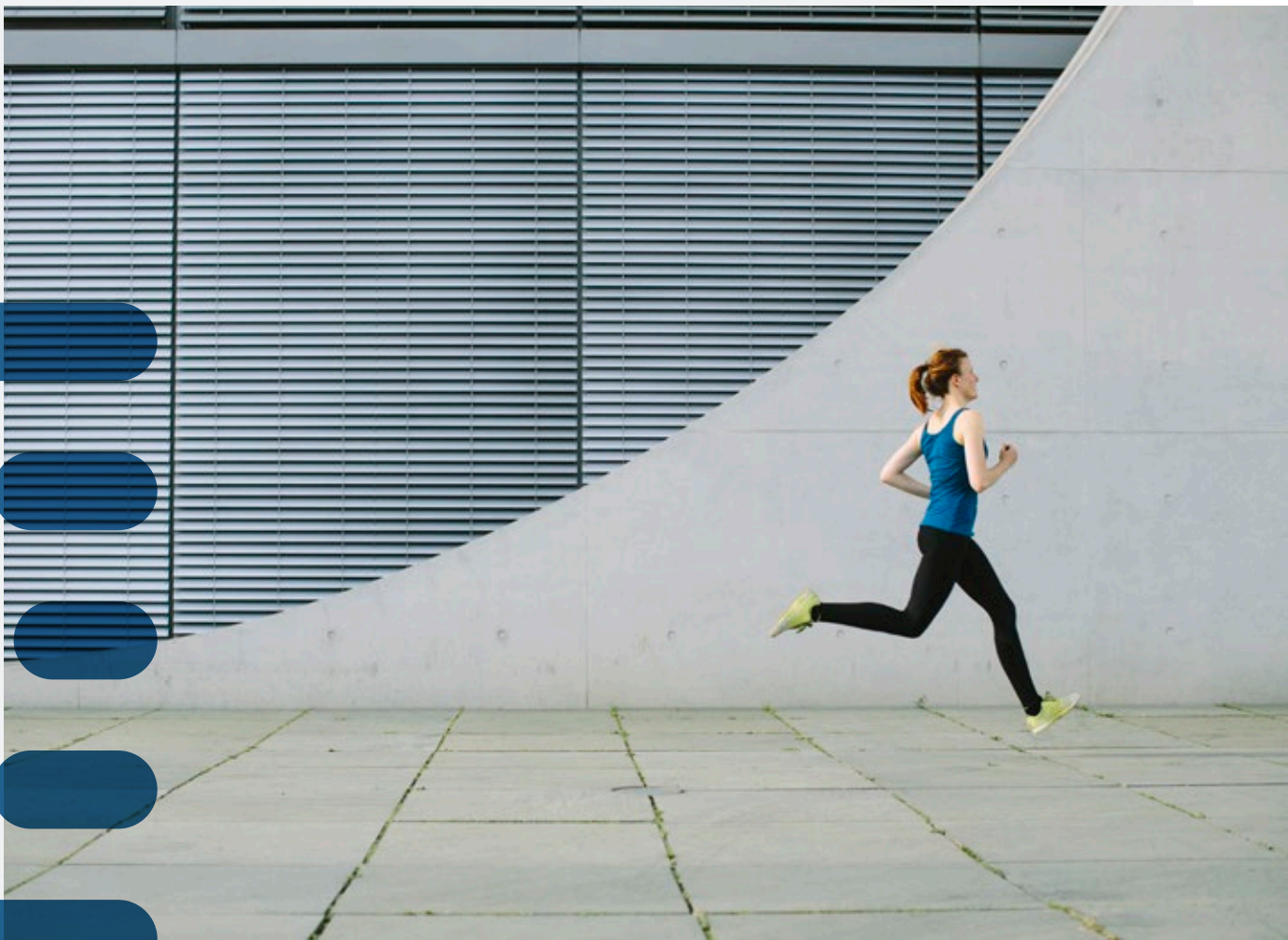


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Introduction

The power of data, insights and evidence can't be emphasized more when it comes to the healthcare industry. However, today's healthcare environment is more specialized, more competitive, and more cost sensitive than ever before. This white paper aims to highlight what is a Mosaic Study and how it is a game changer in transforming real world evidence generation across Asia Pacific (APAC).

Power of data in healthcare: "Data is the new oil"

Of late data has been – referred to as the 'new oil' by numerous industry experts and popular business publications. Just like oil, raw data isn't valuable but rather, the value is created when it is gathered completely and accurately, connected to other relevant data, properly analyzed, and done so in a timely manner. Insight derived from data helps multiple industry to react accordingly to the market dynamics whereas evidence generated from insights facilitate decision-making.

Stakeholders across the lifecycle need the right evidence to demonstrate the value of products and inform complex healthcare decisions. Evidence generated from real world setting (outside of the

randomized control trials environment) including using real world data, indeed plays a vital role for this health eco-system through addressing the gap between clinical trial and clinical practice. There is growing acceptance of real-world evidence (RWE) use from regulators, payers, prescribers, and patients - creating a new world of possibilities.

However, evidence generation from a complex, diverse, and heterogeneous landscape requires smarter approaches like, access to a wide spectrum of data and sourcing approaches from existing secondary data, primary data, registry collaborations, and patient reported outcomes. Mosaic Study is one of such smart, innovative, and forward-looking solution to transform evidence generation strategy via navigating increasingly complex patient and data pathways especially in the Asia Pacific region.

This white paper aims to highlight:

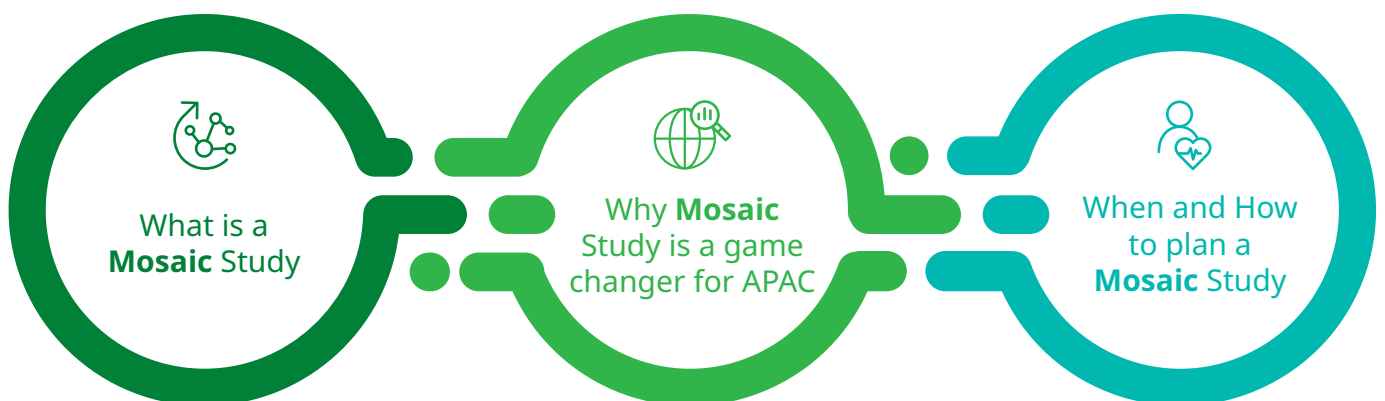
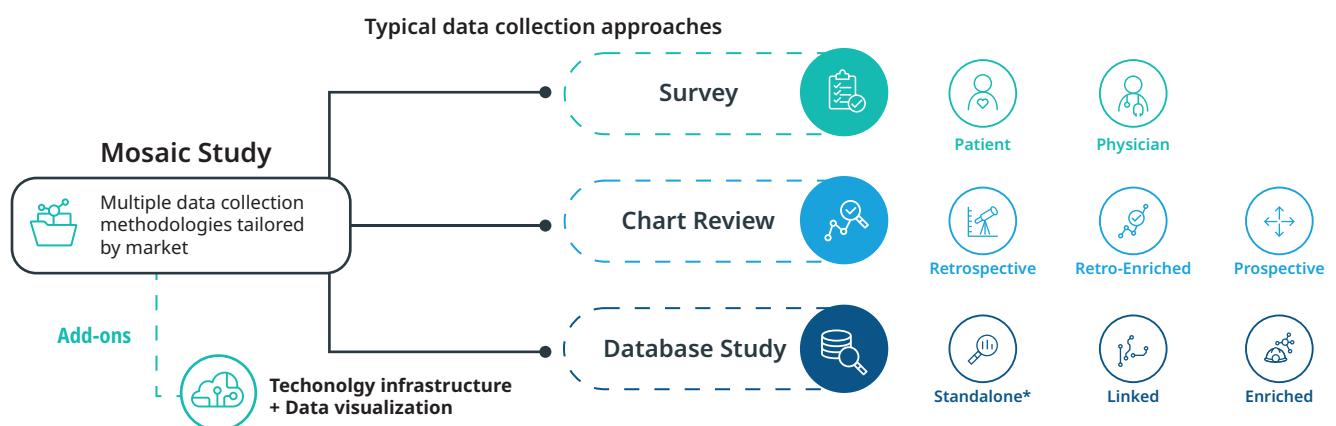




Table 1: Quick definition and IQVIA's internal diagram for Mosaic Study illustration

PRIMARY DATA	Data collected from first-hand sources within the parameters of a study e.g., through electronic Case Report Form (eCRFs), Patient Reported Outcome (PRO).
SECONDARY DATA	Data collected routinely for purposes not linked to a specific study e.g., Claims data, EMRs, patient registries, health 'apps' data. Secondary data could be analysed to address specific research question.
MOSAIC STUDY	A Mosaic Study uses a combination of data collection methods across diverse geographies to address specific research question. (Currently in APAC, combination of secondary data base analysis and retrospective chart review approach is most popular).
KEY DIFFERENCE BETWEEN MOSAIC STUDY AND ENRICHED STUDY	In Mosaic Studies, secondary data and primary data are integrated at the study level (aggregated statistical level) and not the patient level. In Enriched Studies, primary and secondary data are linked at the patient-level.



*Can be enhanced by clinical review



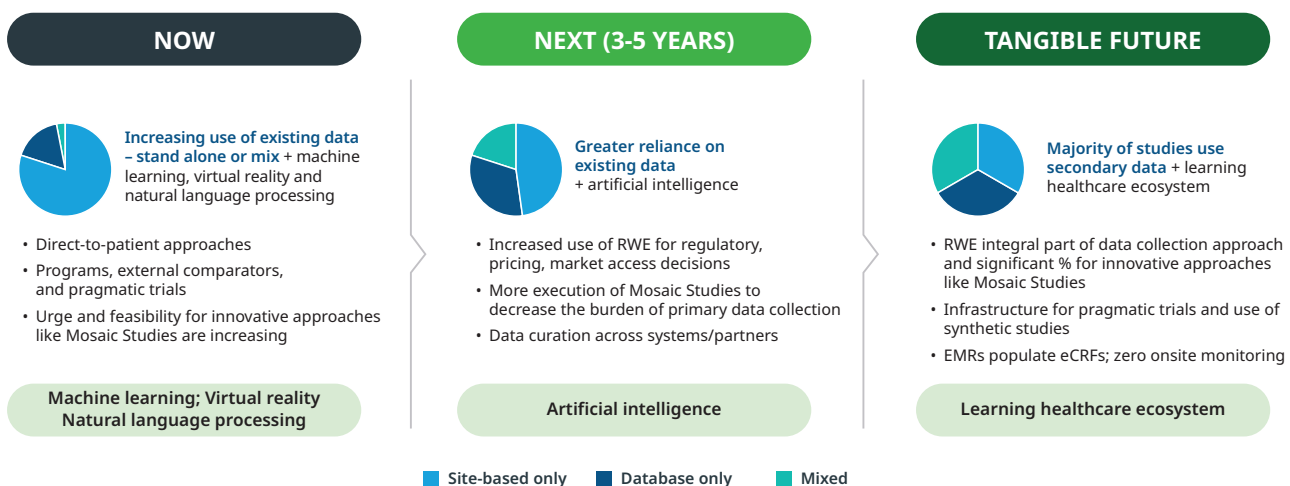
Strategic urge for data source use for smarter evidence generation planning

APAC is an enormously diverse region with varied macroeconomic and healthcare indicators, crippled by market access challenges. 60% of the global population are from this region however APAC is still underrepresented in global clinical trials. This gap could be complemented by real world evidence. From the spectrum of newer trends around evidence generation as illustrated in Figure 1 it is quite evident

that innovative study approaches which include mixing multiple data collection methods is expected to increase specially in APAC region. Different categories of real-world studies which contribute for healthcare evidence generation are demonstrated in Figure 2 with the help of recent VOC survey (voice of customer) conducted by IQVIA with our leading pharmaceutical clients.

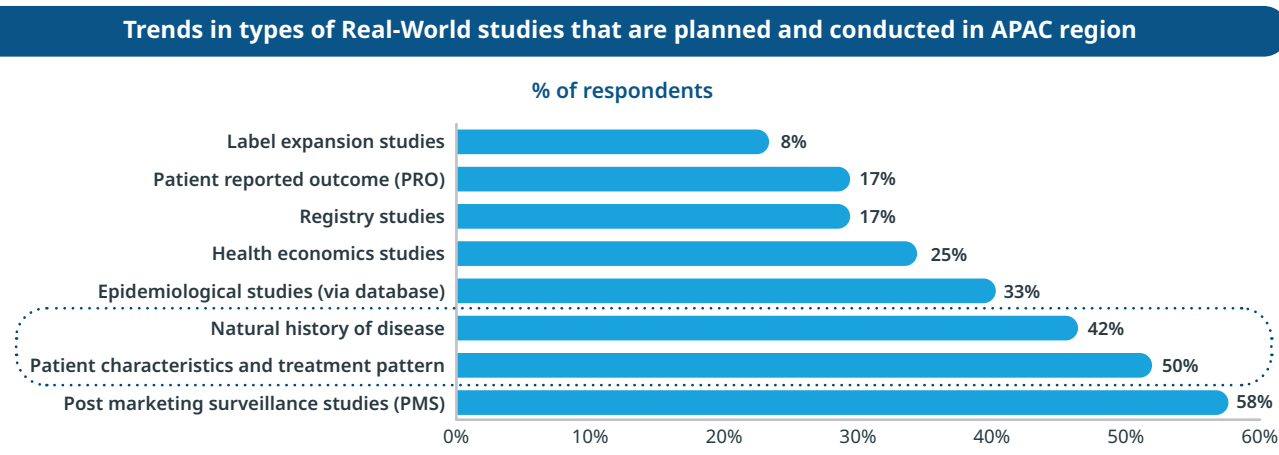
There are varying real world data (RWD) sources available within the APAC region that can be used to answer different research questions, however each data source has its own limitation. (e.g., treatment

Figure 1: Spectrum of newer trends around evidence generation



Source: IQVIA Internal analysis

Figure 2: Voice of Customer (VOC) Survey conducted by IQVIA



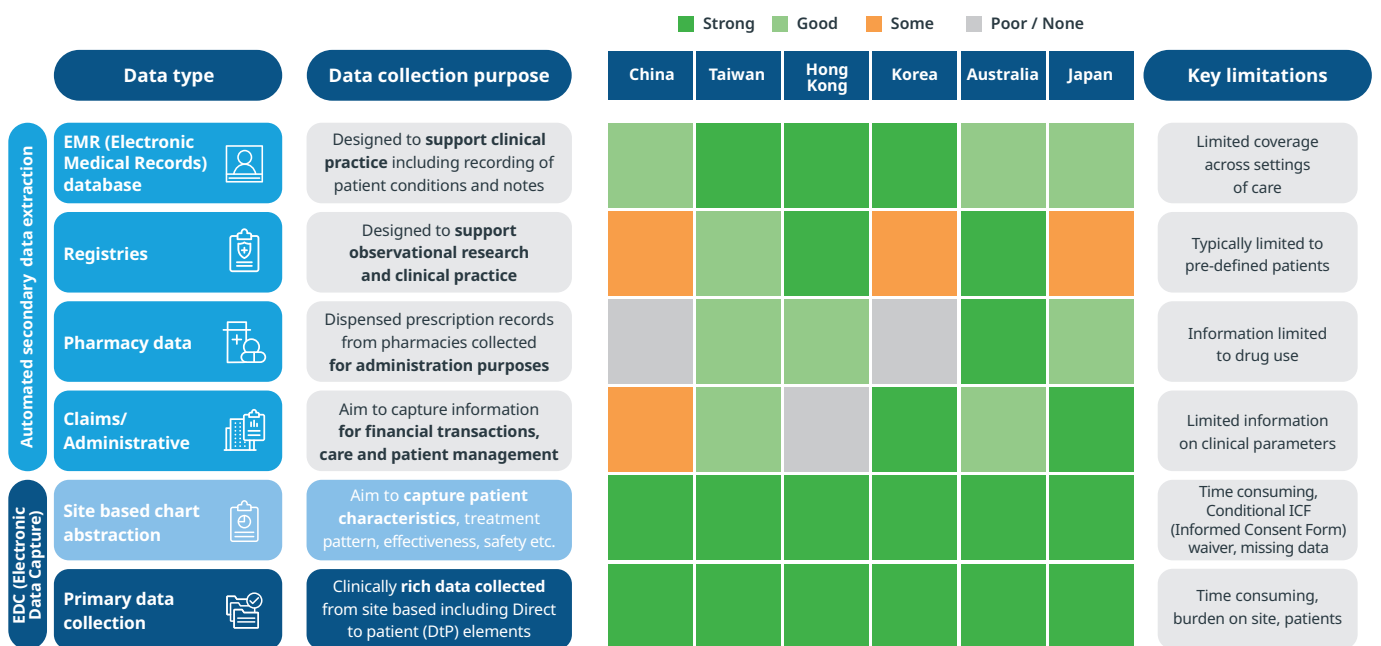
Opportunity for Mosaic Studies:
 From the graph it is evident that studies for exploring endpoints like **treatment patterns and patient characteristics (2nd highest in trends) and natural history of disease (3rd highest in the trends)** are mostly good fit for Mosaic approach.

Source: IQVIA internal survey with pharma clients

response is harder to assess in database approach; disease progression is still unstructured where manual curation is needed; Information regarding newer treatment could be limited due to data lag period etc.) On the contrary site-based chart abstraction method (retrospective, retro-enriched and prospective) is quite feasible to conduct with its own kind of limitation.

(e.g., time consuming, complex regulation like OHGRA- for Mainland China, missing data etc.). Study level linkage through Mosaic Study among different data sources potentially would yield a comprehensive view of the patient treatment patterns along with care pathway for a complex landscape like APAC.

Figure 3: Major data source for key APAC markets and their ability to address research questions



Source: IQVIA Internal Analysis (Database expertise)

Intrinsic value characteristics of Mosaic Study

A Mosaic approach begins with a feasibility assessment and parallel solution design to develop a recommended approach aligned with a shared vision and budget. The implementation of a Mosaic Study is often underpinned by technology and data visualisation enablers, which can capture novel data and deepen availability of data, whilst allowing:



1. BESPOKE YET EFFICIENT SOLUTION FROM A HETEROGENEOUS LANDSCAPE:

Mosaic Study provides a flexible data collection methodology to create a bespoke yet efficient solution from heterogeneous landscape. Single methodology approach like- claims, Electronic Medical Records (EMR), registries, site-based has its own challenges. By relying on a single methodology, we run the risk of excluding certain sites or countries of interest due to inconsistencies in data availability.



2. SUFFICIENT BREADTH AND DEPTH OF THE FINAL DATASET:

Analysis from Mosaic Study address sufficient breadth and depth which represents a middle ground approach in compared to individual data collection methodology and reflects a pragmatic balance between representativeness and richness.



3. CATER TO MULTIPLE RESEARCH NEED AND FOR MULTIPLE STAKEHOLDERS:

Mosaic Study design can tailor data collection methods by market to be fit-for-purpose for multiple stakeholders like regulators, Health Technology Assessment bodies, Payers, Health Care Professional etc.

Robust advance planning is the prerequisite for Mosaic Study

Mosaic Study allows for feasibility to run in parallel with solution design via an iterative approach as illustrated in Figure 4 below.

Figure 4: Iterative approach while planning

Illustrative

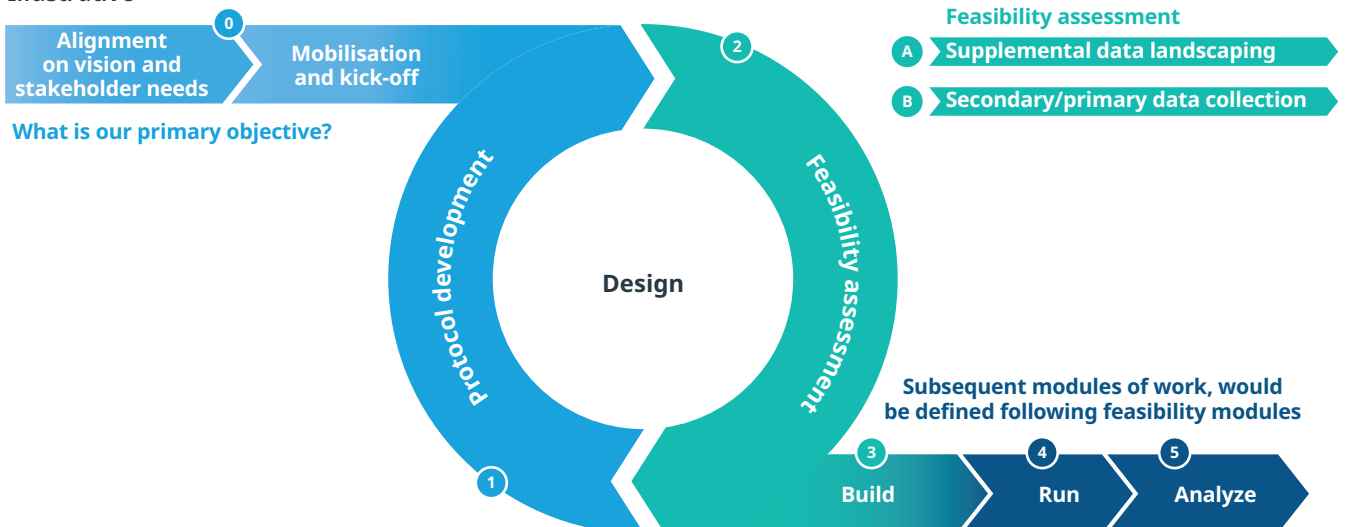





Table 2: When is a Mosaic Study the right solution?

Fundamentally, a Mosaic Study approach uses different data collection types and methods, which are fit-for-purpose by market. Mosaic Studies could be the option when:	
VOLUME OF DATA ASSETS 	Off-the-shelf data assets lack sufficient volume in structured data to fully address research need whereas mixture of both retrospective and prospective longitudinal data is needed to address research questions.
GEOGRAPHIC SCOPE 	We are navigating broad heterogeneous geographic scope with different existing data available by market and we need data beyond traditional physician provided mediums.
LEVEL OF OPENNESS 	There is willingness and openness for innovative study approach via early engagement.

What is your willingness to challenge the status quo?

Newly developed healthcare products face increasingly rigorous evidence thresholds that, if not satisfied, can significantly depress commercial potential. Emerging methods and solutions drive value and reduce burden. There's no better time than today to challenge our conventional thinking and embrace developing models like Mosaic wherever appropriate in line with dynamic market outlooks.



THIRST FOR DECODING CORRELATION BETWEEN PATIENT PATHWAY AND DATA PATHWAY:

It is increasingly difficult to demonstrate value of novel medicines in complex treatment landscapes, requiring data beyond physician-provided mediums (e.g., Direct to Patient (DtP) via Patient Reported Outcome (PRO), caregiver information, claims etc.). Triangulation between multiple data sources and methods would be required to address a complex research agenda.



MOMENTUM FOR PROGRAMMATIC APPROACH:

Existing real-world data (RWD) sources in different countries which can be leveraged to answer same research question. This is opening doors for tremendous opportunity to accommodate multiple markets within single evidence generation programs with a single protocol. Site based chart abstraction or primary data collection are only getting considered in those markets where secondary data source can't be accessed.



READINESS TO EMBRACE NEW APPROACHES AMONG DIFFERENT STAKEHOLDERS:

Generating real world evidence using secondary data source as first choice or mixing multiple data collection methodology as per the market-fit are getting greater preferences among the different stakeholder within the health eco-system like pharma client, regulators, payers, providers etc.

Case study: Leveraging Mosaic Study design for APAC



SITUATION:

Client was planning to launch a new drug in high-risk oncology patients, including both neoadjuvant and adjuvant therapy. However, information on treatment pattern, duration of treatment, and outcome of neoadjuvant and adjuvant treatment is not clear. The objective was retrospective analysis of clinical outcomes such as patient characteristics, biochemical PFS, pathological results, and healthcare resource utilization etc. The target market from APAC were Japan, South Korea, and Taiwan. Client was looking for consolidated CSR within predefined timeline as a critical milestone.



APPROACH:

Considering data landscape- a Mosaic Study approach was undertaken combining direct database analysis in Korea and Taiwan, and in parallel a site-based chart abstraction in Japan.



RESULT:

This consolidated approach provided client with a single strategy to access and analyze data from all 3 key markets in a single protocol and study timeline. This Mosaic data collection model will support a combined analysis a provide the client with a consolidated, multi-country report with sufficient breadth and depth.

Figure 5: Voice of early experienter from pharma clients

“Early planning among affiliates who are interested to generate similar evidence could potentially open the door for the innovative study design like Mosaic Studies”



“Carefully drafted research question is one of the key success factor while planning for a Mosaic Study”

“Proactive and integrated planning are important aspects for a multi-country innovative design like Mosaic Study”

DO YOU HAVE COMPLEX EVIDENCE GENERATION NEEDS? THINKING OF A MOSAIC STUDY APPROACH?

IQVIA is uniquely positioned to support you in building and running multi-country Mosaic Studies.

- Fluency in all types of RWD and therapeutic area expertise
- Global end-to-end capabilities as well as a dedicated team within APAC to navigate complex data landscape
- In-house technology capabilities with broad partnerships
- Leaders in innovative RWE Mosaic Studies and standard operating process align with GCP and GPP

About the author and key contacts



SAMIRAN MAITY
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Samiran is the Regional Strategy Manager of IQVIA Real World Solutions for the APAC region based in Kuala Lumpur, Malaysia. In his current role, Samiran is responsible for providing evidence generation strategy in real world settings to pharmaceutical sponsors for their numerous evidence generation needs throughout the product lifecycle. Samiran also leads newer study design category like Mosaic Study for the complex APAC landscape. Prior to joining IQVIA, Samiran led several clinical development departments for ~15 years for multiple pharmaceutical sponsors like Novo Nordisk, Wockhardt from different regions like Asia, Middle East and Northern Africa (MINA), Southeast Asia (SEA), and Oceania. Samiran has a bachelor's degree in Pharmaceutical Technology and has a post graduate diploma in Clinical Research.

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About IQVIA Asia Pacific

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions, and clinical research services to the life sciences industry. IQVIA creates intelligent connections across all aspects of healthcare through its analytics, transformative technology, big data resources and extensive domain expertise. IQVIA Connected Intelligence™ delivers powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialization of innovative medical treatments that improve healthcare outcomes for patients. With approximately 70,000 employees, IQVIA conducts operations in more than 100 countries.

With regional headquarters in Singapore and offices in 15 countries, IQVIA Asia Pacific provides technology-enabled services and solutions to meet the growing and rapidly changing needs of clients, both local and multinational, operating in Asia Pacific. IQVIA is committed to advancing healthcare by offering evidence-based insights and deep domain expertise in thought leadership, with the aim of improving understanding and accelerating innovation within the healthcare ecosystem. To learn more, visit www.iqvia.com/locations/asia-pacific.

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