

White Paper

Time to Discover the Power of Data for Improving Access and Care

2021 - Oncology data landscape in Middle East region

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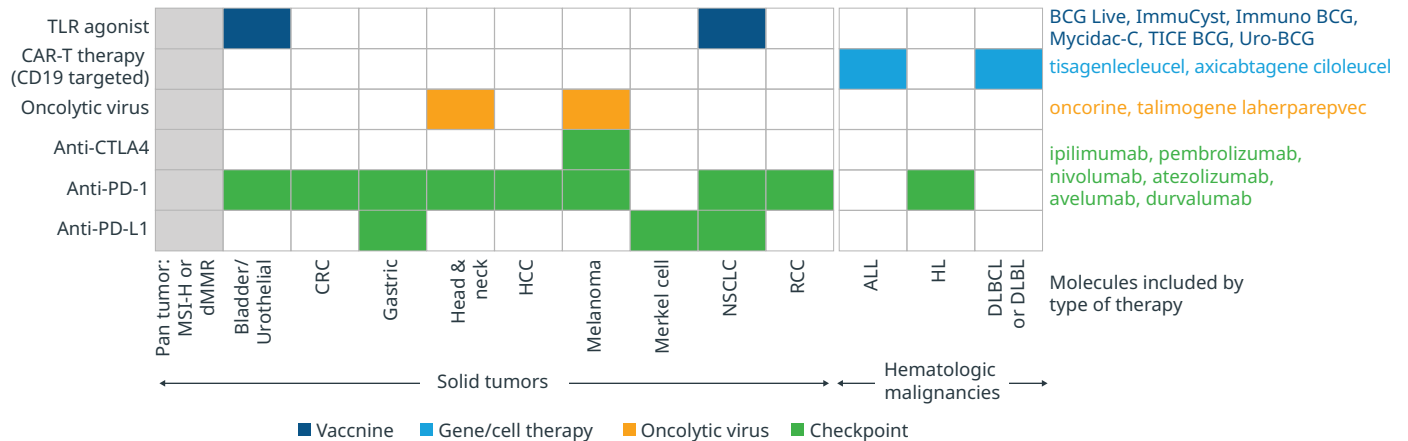
Introduction

Over the past decade, oncology has seen unprecedented innovation: treatment paradigms are shifting from tumour- to mutation- and biomarker-based paradigms, and gene editing is now within the realm of the possible. Today, healthcare stakeholders have already started recognising the transformation of single biomarker testing to next-generation sequencing (NGS) testing, to simplify the personalised treatment plan at beginning of diagnosis.

Targeted therapies and immunotherapies use the molecular aberrations of a cancer cell, the cancer environment, or cancer-fighting immune cells. Patients have benefitted greatly from these innovations: data show that more people are living longer, better-quality lives following cancer diagnosis. Also new technologies

such as CAR T-cell therapy will continue to push frontiers and challenge the ways in which cancer is approached. Presented below is a snapshot of recently approved checkpoint inhibitors and next generation biotherapeutics by mechanism of action and tumour type approvals¹.

Figure 1: Approvals of checkpoint inhibitors and next generation biotherapeutics by mechanism of action and tumour type approvals, USA

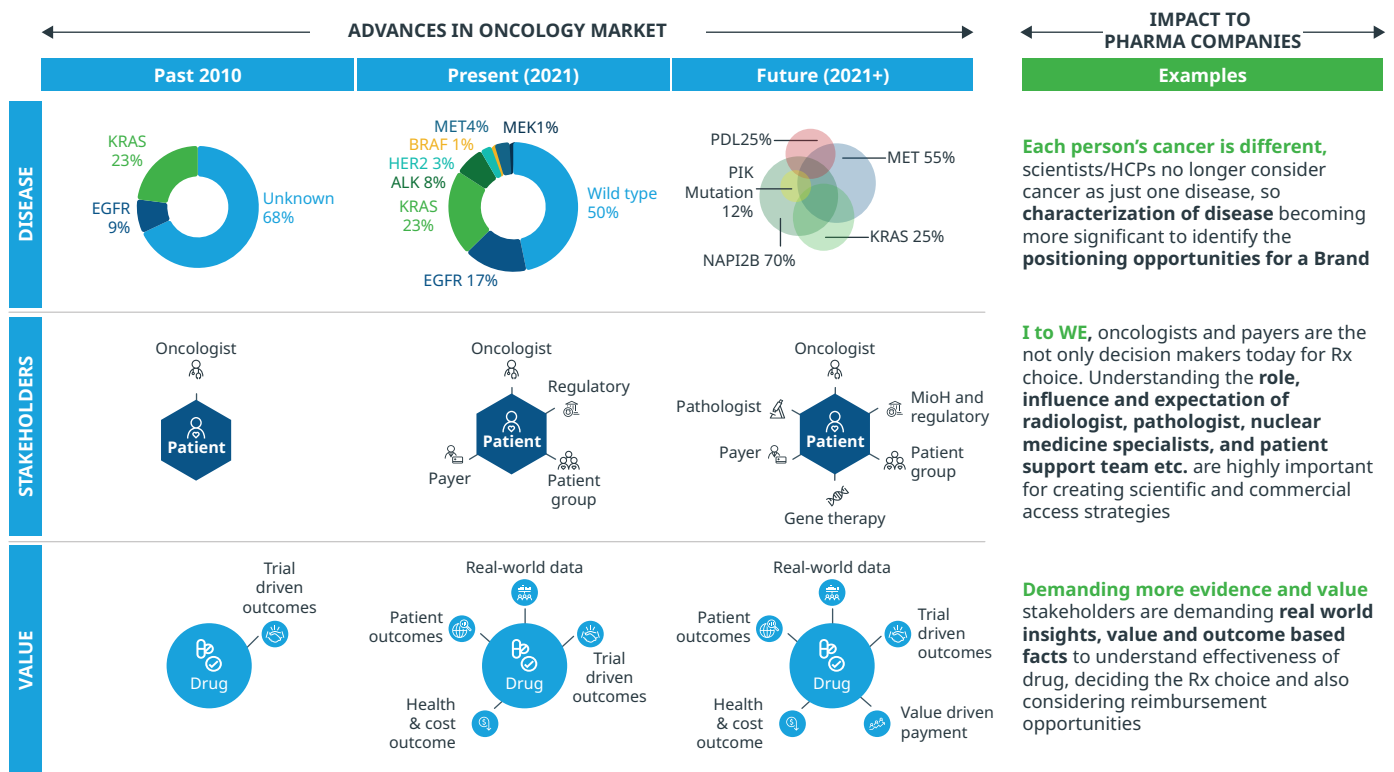


Source: Tang J, Shalabi A, Hubbard-Lucey VM. Comprehensive analysis of the clinical immuno-oncology landscape. Ann Oncol. 2018 Jan 1;29(1):84-91

In line with this innovation in oncology, the health data collected on cancer patients, their disease and treatment modalities are evolving rapidly. At the same time, the traditional requirements on Randomised Controlled Trial (RCT) data remains the gold standard for the FDA, Health Technology Assessment (HTA)

agencies, payers, providers, and pharmaceutical companies. However, granular-level data on patient characteristics and real-world data are becoming highly imperative for these healthcare stakeholders, to maximise patient access to innovation and improve patient care.

Figure 2: Transformation of stakeholder involvement and demand in oncology



Fuelling this continued innovation and need for disease and patient level granularity of data is the continued growth of the research and commercial market.

AN OPPORTUNITY TO CREATE DATA-RICH ENVIRONMENT FOR INNOVATION IN ONCOLOGY AND IMPROVE CANCER CARE

In this white paper, IQVIA considers select countries that represent the Middle East region and presents findings on the oncology data landscape, as well as proffering several models for collaboration to discover the power of clinically rich healthcare data, with the aim of improving access to innovation for patients in the Middle East region. The observations, facts, and information covered are as follows:

- Need for quality and granular data for healthcare organisations and life-sciences companies

- Informed decision-making by stakeholders; the scenario in western markets vs. the Middle East
- Availability of richness of oncology data in developed countries vs. the Middle East
- Current challenges and barriers related to oncology data in the Middle East
- Role of healthcare organisations in improving data structure, reporting and leveraging the power of data in the Middle East
- From oil to data-driven economies, the transition in the Middle East

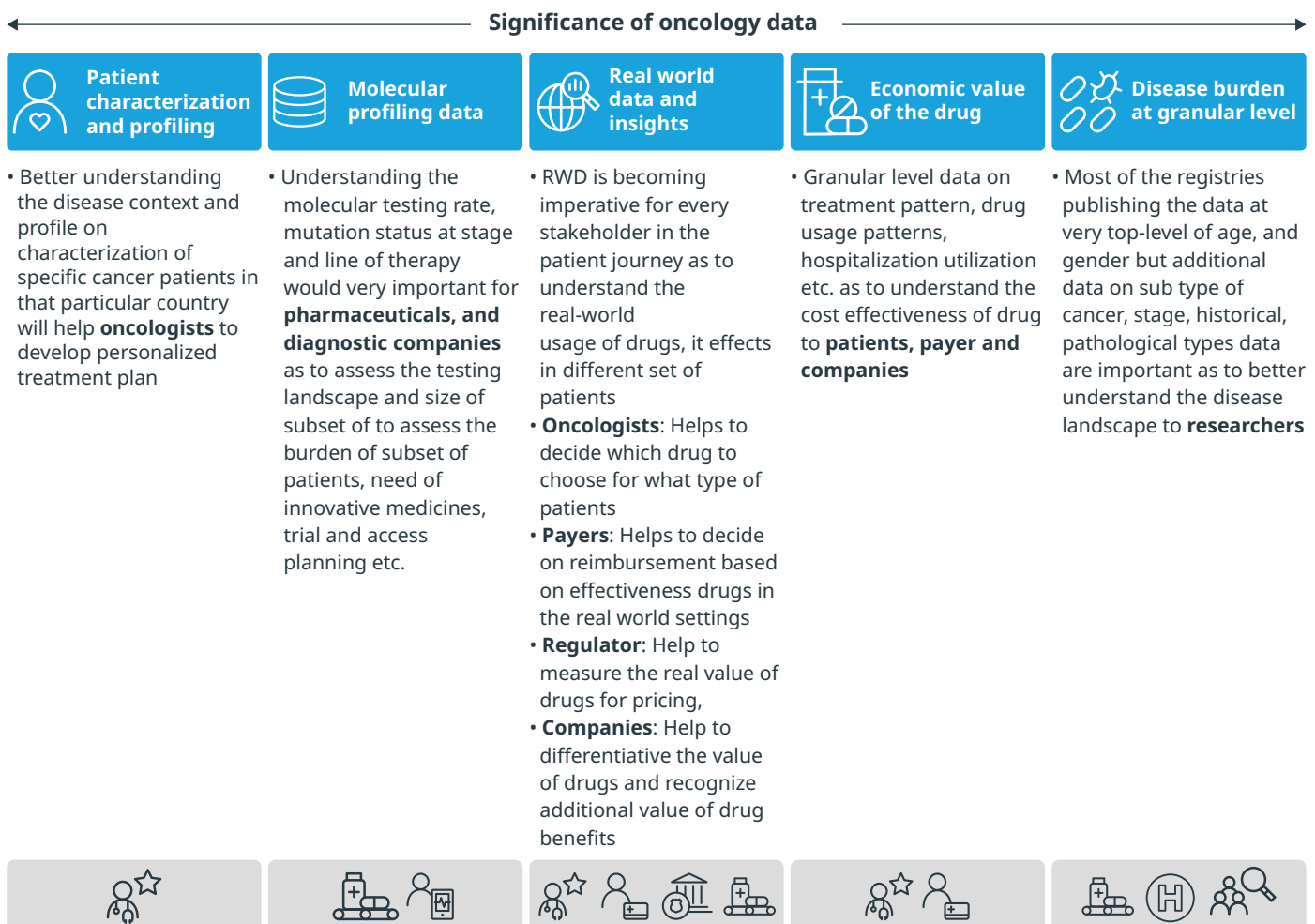
NEED FOR QUALITY AND GRANULAR DATA FOR HEALTHCARE ORGANISATIONS AND LIFE-SCIENCES COMPANIES

One-size-fits-all therapies are increasingly being replaced by individualised treatments and disease interventions. In cancer, standard therapies are ineffective in an average of three-quarters of patients, one of the highest therapy failure rates for all diseases. Precision oncology and personalised care hold the promise of improved efficiency, better care, and reduction of use of ineffective treatments and, thus, associated costs. However, a lack of fact-based insights is hindering healthcare stakeholders and life-sciences companies from strengthening personalised care and also in bringing innovative medicine to patients in the ME region. A growing number of health stakeholders are therefore turning to RWD to supplement RCTs, epidemiology data, claims data, omics data (e.g. genomic

and proteomic, prescription data, her, PROs, CROs, etc.)

At the same time, different health decision-makers tend to focus on leveraging data for different decision-making processes: for example, governments and policymakers require a better understanding of the healthcare context and treatment patterns to improve the quality of care and overall resource allocation, as the cost of innovative drugs in cancer is very high. Healthcare Professionals (HCPs) consider treatment patterns, the real-world clinical value of drugs and patient outcomes, in order to prescribe the most appropriate treatment for individual patients, based on their characteristics and response to drugs. Pharmaceutical, medical device, and biotech companies use RWD to inform conduct trials more efficiently, cost-effectiveness study, and support discussions with health authorities as to bring innovative access models.

Figure 3: Examples that indicate the significance of granular and clinically rich data in oncology ecosystem



**INFORMED DECISION-MAKING BY STAKEHOLDERS;
THE SCENARIO IN WESTERN MARKETS VS. THE
MIDDLE EAST**

Currently healthcare stakeholders in the oncology ecosystem from developed countries started using and applying fact-based decisions for designing personalised treatment plans, pricing and reimbursement approvals, adopting innovative value-based access models, etc. based on facts derived from well-established granular-level oncology databases.

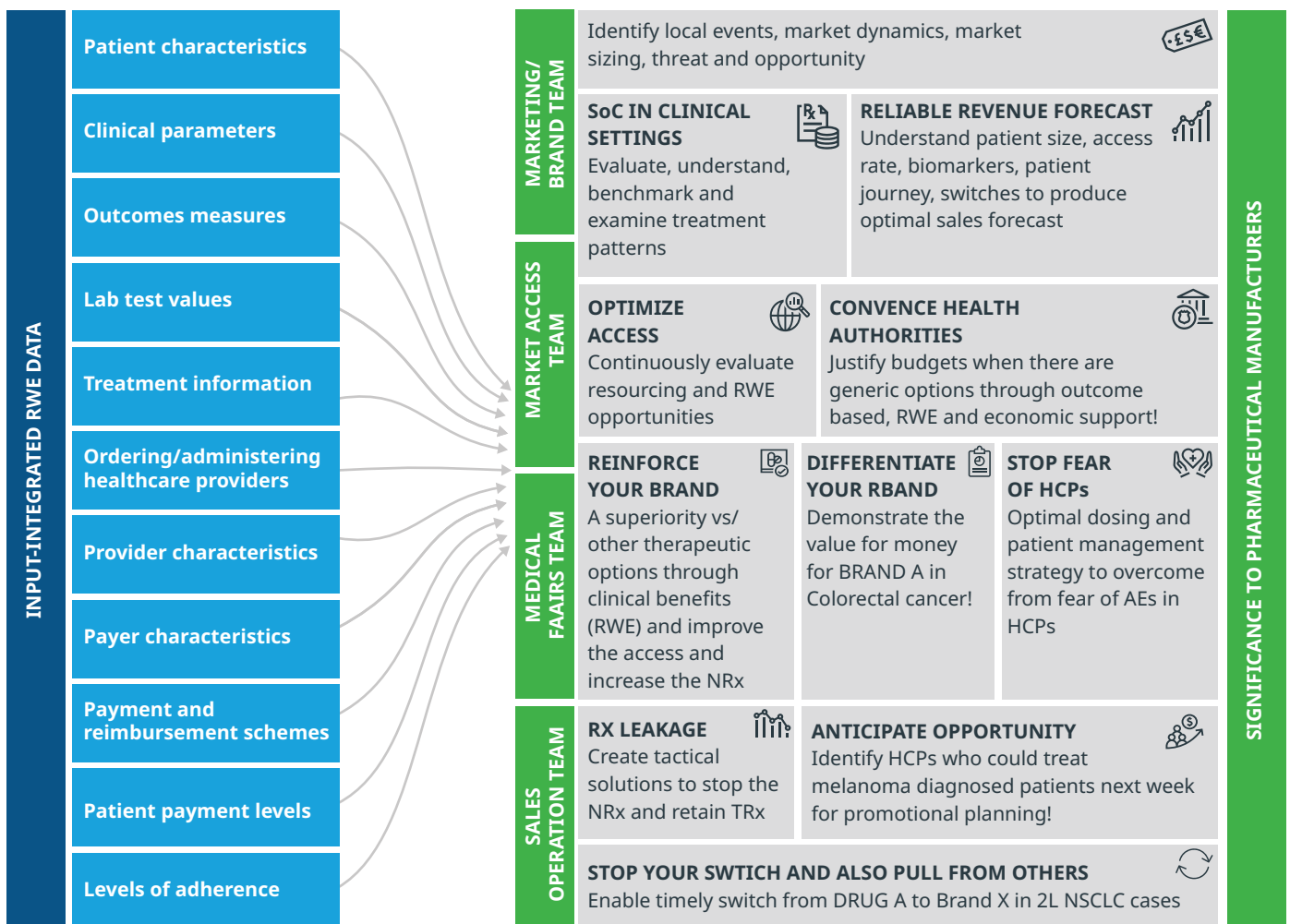
Pharmaceutical companies

Historically, the pharma industry was thought to be left out of the EHR data space, due to stringent promotional regulations and worries about privacy. However, increased adoption by physicians through meaningful use initiatives has opened opportunity

in two areas: positioning branded and unbranded messaging within the EHR system and collecting real-world evidence across the patient spectrum for improved clinical support.

At the same time, life-sciences companies are increasing their focus on personalised medicine. The large quantity of oncology data generated through HER, diagnostics, virtual clinical, patient forums, and patient registries, etc. would help manufacturers integrate it with clinical data and provide truly personalised healthcare that improves and saves lives. Below is a snapshot of how global pharmaceutical and biotech companies in developed countries use databases such as RWD, payer, HER, and cancer registries to address both strategic and tactical business questions to boost commercial success in the oncology market.






Figure 4: Importance of richness of integrated oncology data for life-sciences companies for making fact-based decisions



Other healthcare organizations

Below are a few examples detailing how the richness of oncology data has been helping healthcare stakeholders in making fact-based decisions in developed countries.

Figure 5: Applications and benefits of oncology RWD²

Application	Example of benefits
 <p>R&D enablement To support identification of promising compounds, investigation of genome and smart clinical trials</p>	<p>Europe The EHR4CR initiative enables more precise recruitment retention and site selection strategies via better patient level data</p>
 <p>Treatment patterns To understand the context of the disease, burden, usage of drugs, patient characterization etc.</p>	<p>UAE Dubai Health Insurance Corporation and IQVIA are extensively doing research as to support life sciences partners on treatment patterns, effectiveness etc.</p>
 <p>Real-world clinical value To measure the delivery of cancer interventions clinical promise in real world settings</p>	<p>USA In the USA, the FDA granted accelerated access to avelumab based on an open-label, single arm study supported by RWD in metastatic merkel cell tumor</p>
 <p>Reimbursement models To provide a mechanism for flexible pricing, based on use, indication and outcome</p>	<p>Italy In Italy, value based models are established, mostly for oncology drugs, where drug cost reimbursement is based on the outcome of the treatment</p>
 <p>Patient perspective To offer insights into Quality of Life (QoL), covering aspects of care beyond clinical outcomes</p>	<p>Patients LikeMe This portal allows better involvement of patients in clinical trial processes, facilitating research that responds to patient needs</p>

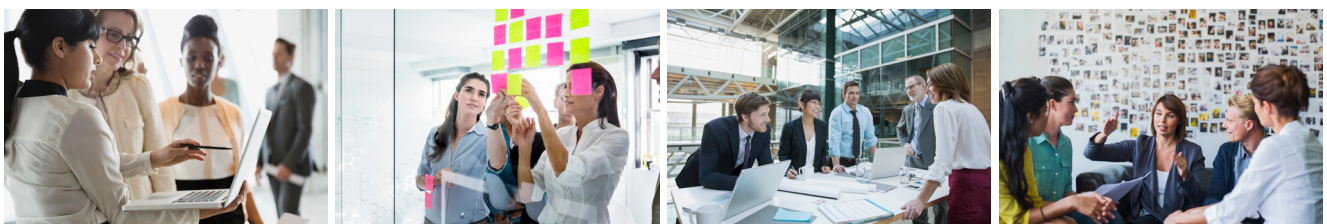
Source: Oncology health data landscape in Europe EFPIA, 2018 and IQVIA oncology research.

Stakeholders from the pharmaceutical and healthcare ecosystem in the ME region have been facing challenges in making fact-based decisions due to lack of robust granular-level data and also due to poor infrastructure for collecting and reporting data. This ultimately leads to a delay in answering key strategic questions in the field of scientific, commercial, and personalised care.

In the ME region especially, a lack of access to clinically rich oncology data from registries, EHR, claims

data, and any other patient-level longitudinal-level databases that are sitting in silo in the healthcare system can lead to life sciences companies losing an opportunity to enhance the better understanding of patient characterization, molecular profiling, NGS based treatment plan, and recognizing the effectiveness of drug in the real-world settings. It also leads to uncertainty among life-sciences companies and MoH regarding the disease burden, unmet needs, and demand for innovation.

Figure 6: Example of challenges for life-sciences companies in bringing innovation to ME region



Success requires robust data input to demonstrate value of brand and innovative marketing strategies to a broad set of stakeholders, including patients, providers, payers and regulators.

* Highlighted is ME region

AVAILABILITY OF CLINICALLY RICH ONCOLOGY DATA IN DEVELOPED COUNTRIES VS. MIDDLE EAST

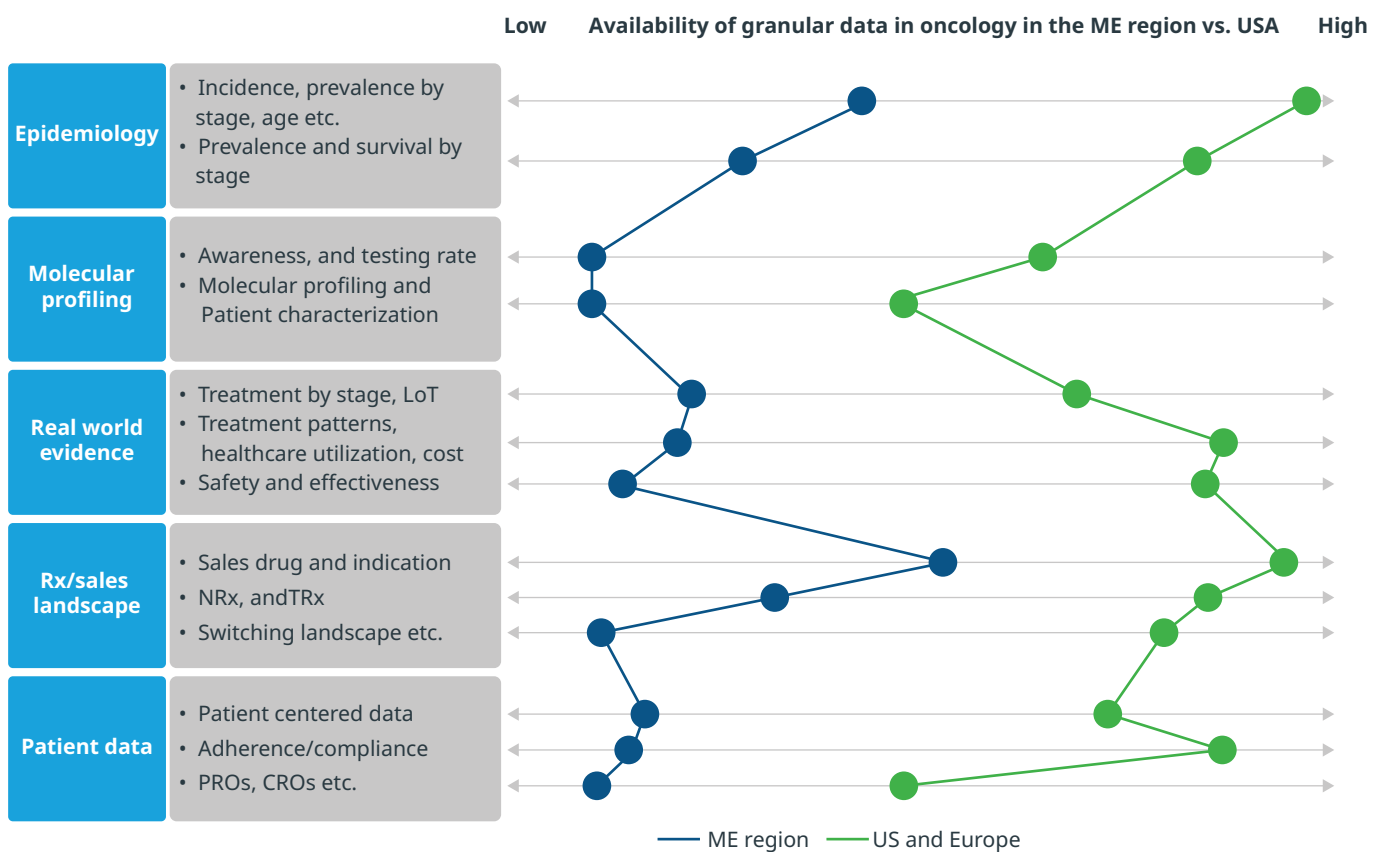
With the advent of new technologies, granular-level data are increasingly becoming available from a wide range of sources in the G7 countries, but data scarcity challenges remain in Middle East countries. This is particularly true for oncology, where registries, research organisation, and population health database providers are struggling to keep pace with the increasing speed of innovation and new treatment paradigms.

IQVIA attempted to understand the availability of data and infrastructure in select developed countries vs.

ME countries through the screening and evaluation of existing databases, registries, publications, real-world datasets in order to gain better visibility of the reporting system, infrastructure, and need of improvement and advancements.

Of note, 20–30% of granular-level data (based on the parameters mentioned in figure 8) are available in the public domain, such as journals, global cancer registries, country cancer registries, and MoH reports for Middle East countries. Larger data gaps are observed in the ME region as compared to the US and EU countries.

Figure 7: Comparison of availability of granular and richness of oncology data in developed countries vs. ME region



*Public and private domain considered are: Registries, publications, reports, govt databases, hospital reports, claims data, APLD databases, regional health databases, MoH databases, social media data, hospital websites etc.

Source: IQVIA Secondary research, PubMed, cancer registries

Cancer registries are playing a key role in providing quality data on the burden of cancers in every country. However, there are huge gaps observed in the reporting frequency, depth, and breadth of data

published by cancer registries in the US and European countries vs. the ME region. The following are example of gaps observed in recent times.

Table 1: Examples of richness of data covered or published by local cancer registries in different countries vs. ME region

	COVERAGE OF TUMOUR TYPE	GRANULARITY OF PATIENT DATA	PERIOD OF STUDY	DEPTH OF EPIDEMIOLOGY DATA COVERED	TREATMENT-SPECIFIC DATA COVERED	ACCESS TO LONGITUDINAL LEVEL DATA
DEFINITION	Inclusion of sub- and rare cancer types (example NHL, leukaemia, etc.)	Granularity of data available by stage, age, gender, line, sub tumour type, etc.	Data published in latest study period	Granularity of data for any specific cancer (example, survival rate by sub tumour type, stage, age, and gender)	Treatment information by tumour type, stage, and therapy type	Flexibility for partnering with researchers or industry to access longitudinal data collection by registries or for conducting RWE studies through registries
USA³	Very good	Very good	2017	Very good	Good	High
UK⁴	Good	Very good	2017	Good	Good	High
GERMANY⁵	Good	Good	2016	Good	Good	Medium
ITALY⁶	Good	Good	2017	Good	Good	Very good
NETHERLANDS⁷	Very good	Very good	2019	Good	Good	Very good
KSA⁸	Medium	Good	2015	Low	Low	Poor
UAE⁹	Low	Low	2017	Low	Low	Poor
OMAN¹⁰	Medium	Medium	2015	Medium	Low	Poor
IRAQ¹¹	Medium	Low	2017	Low	Low	Poor
EGYPT¹²	Medium	Medium	2015	Low	Low	Poor
AUSTRALIA¹³	Good	Very Good	2019	Good	Good	Good
INDIA¹⁴	Good	Medium	2015	Medium	Medium	Poor

Today, cancer registries in Europe have started expanding partnerships with manufacturers, research, and consulting organisation to exchange or share patient longitudinal-level registry data for conducting real-world evidence, value-based, burden of disease, and cost-effectiveness studies, etc. These partnership models are yielding benefits to registries

as revenue-generating sources, as well as contributing to improving cancer care. However, such partnership models are taking small steps in the ME region; Below are example of cancer registries partnering with industry for conducting real-world evidence or data-sharing models.

Table 2: Recently observed private and public partnerships in developed and ME countries to improve cancer care and access to innovation

COUNTRY	EXAMPLE OF PARTNERSHIP
UK	The UK has already taken steps towards providing the coordination required to maximise the benefit of the available data in the UK within cancer, namely through DATA-CAN: The Health Data Research Hub for Cancer – a UK-wide partnership hosted by UCL Partners in partnership with Genomics England, IQVIA, Leeds Teaching Hospitals NHS Trust, Queen’s University Belfast, and the University of Leeds. ¹⁵
USA	SEER stats database provides online access to researched based on the SEER Research Data Use Agreement (DUA) to access granular-level disease and treatment data for the period of 1975–2017.
Netherlands	Healthcare providers, researchers, and policymakers may apply for customised data sets from the Netherlands Cancer Registry to access anonymised patient-level longitudinal data. ¹⁶
Italy	Italian Association of Cancer Registers (AIRTUM) has implemented a partnership model to make data on the frequency of cancer available to the administrative authorities, to the bodies of the National Health Service and to the scientific community, in the interest of research, prevention, planning of care, facilitating access to care and evaluating their effectiveness. ¹⁷
UAE	Dubai Health Insurance Corporation (DHIC) has partnered with IQVIA to access claims data for research and support on commercial analytics and real-world evidence studies for pharmaceutical and biotech companies. ¹⁸
KSA	Council of Cooperative Health Insurance (CCHI) regulators have partnered with IQVIA for exchanging research activities to improve access through transformation of formulary system in KSA. ¹⁸

Source: IQVIA research

CURRENT CHALLENGES AND BARRIERS RELATED TO ONCOLOGY DATA IN MIDDLE EAST

In the Middle East region, there are various barriers to health data collection, access, exchange, analysis, and use in oncology. The first and foremost barrier is concern on data security and safety risks are limiting or delaying the use and sharing of various relevant datasets such as registries data, EHR, claims, diagnostics, and other anonymous longitudinal databases in oncology.

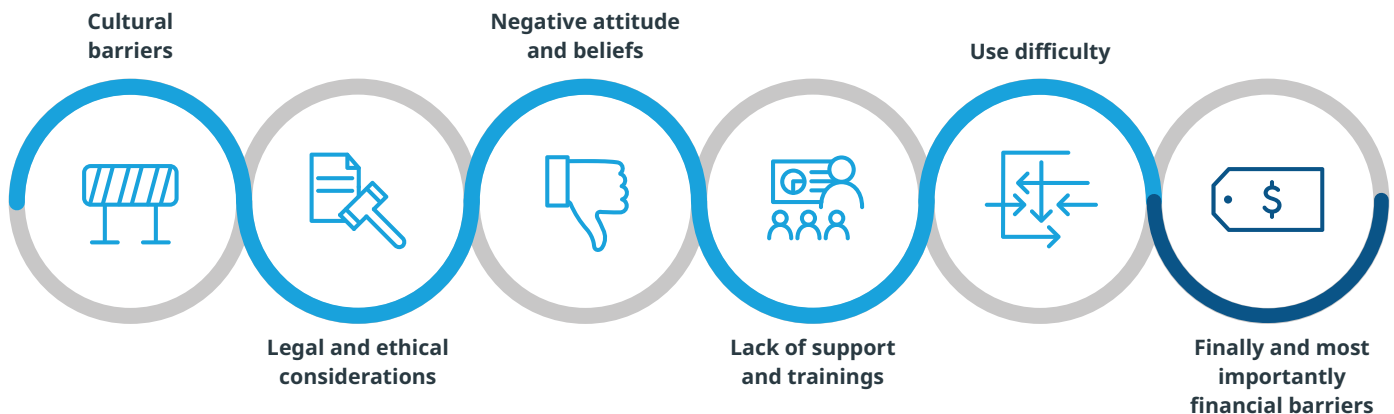
Recent years have witnessed efforts by both public and private organisation to recognise the value of data and form partnerships to generate data for improving the cancer care; however, there is still a long way to go. Below are a few major barriers to accessing oncology data in the Middle East region.

- **Heightened focus on data protection:** Patient data privacy, security, and risk of storage and transmission of patient data are major concerns among healthcare stakeholders while exploring for

data exchange and partnership models, and hence there is a need for creating awareness on how the data could be safe and secure with advanced technologies and cloud systems, along with educating stakeholders in the oncology sphere about the value of quality data.

- **Lack of required infrastructure (tools and technologies):** Software and platforms for health data collection and storage are rarely user-friendly, limiting the ability to collect sufficient high-quality data. Existing technologies may be outdated or are likely to become so in view of growing analytical and processing requirements.
- **Barriers to adopting and strengthening EHR:** In a recently published study based on a literature review, it was observed that GCC countries have unique and additional issues that include legal and ethical issues, cultural issues, as well as the availability of a competent workforce.¹⁹

Figure 8: Barriers to institutionalising EHR system in ME region



- **Knowledge of healthcare analytics:** Both public systems and private providers lack awareness of the significance of analytics for improving operations, clinical and patient care. Awareness levels are much lower compared to US and European healthcare systems.

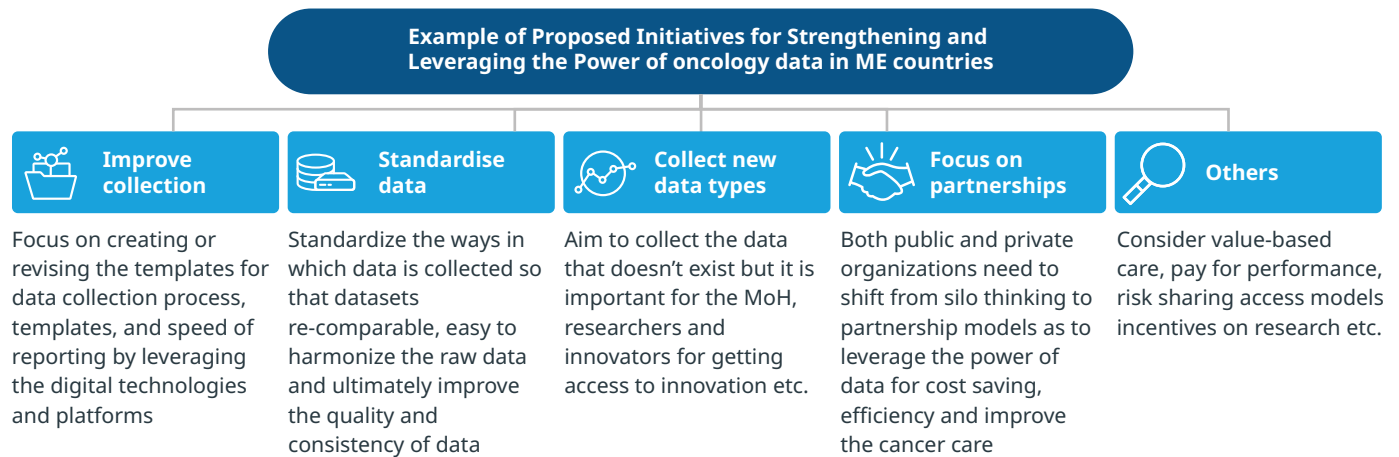
- » **Skills and manpower:** There is a clear lack of qualified people to undertake the increasingly complex and comprehensive task of collecting and analysing data. Many healthcare professionals have limited digital literacy or training in data collection.

ROLE OF HEALTHCARE ORGANISATIONS IN IMPROVING DATA STRUCTURE, REPORTING AND LEVERAGING THE POWER OF DATA IN MIDDLE EAST

Various research organisations, national cancer registries, and MoH in the Middle East region could start creating a roadmap for steps to be taken for

improving data collection and infrastructure as a first step in strengthening the richness of oncology data. The following are a few examples of steps or focus areas to strengthen and recognise the value of oncology data in the healthcare ecosystem.

Figure 9: Example of initiatives that could help strengthen, standardise, and exchange the richness of oncology data in ME region



- **Strengthen cancer registries through new funding models:** Population-based cancer registries in ME countries are required to enhance their data infrastructure capabilities, as current reporting structure, coverage of data, and publishing platforms are poor, especially compared to US and EU country-specific cancer registries. Thus, it is time for public and private systems to focus on funding and encouraging registries through various strategies; example are highlighted below.

- » **MoH or public system:** Cancer registries would require an enhanced funding support model, based on strengthening data, digital tools, and analytics.
- » **Strengthen the infrastructure:** The right structures and environment must be established to support the collection and use of oncology RWD from hospitals. This entails establishing a consistent approach to govern, fund, manage, and scale healthcare data projects across countries and health stakeholders.

- » **Partnerships:** Given the numerous efforts to improve cancer management and initiatives dedicated specifically to oncology data, there is a strong rationale to enable collaboration between cancer experts across and within countries.
- » **Openness:** Openness of cancer registries and collaboration with external partnerships could be beneficial in many ways, such as:
 - » Strengthen reporting and publishing capabilities, which would contribute to improving prevention and cancer care
 - » Help the society to access innovative medicines
 - » Can create a new revenue-generation model for registries used extensively in EU countries
- **Process:** Revisit the data collection process and sharing the data mechanisms.
- **Technology - Enabling solutions:** Governments have started exploring the potential of technology to improve healthcare in general. Of note, five out of

14 countries in the Middle East region have a well-defined digital transformation plan for healthcare in action. Once a national-level drive starts, there will be an improvement in digital data availability.

- **Focus on solutions to overcome from barriers in adoption of EMR:** Overcoming the barriers highlighted in the above section in the GCC region will ultimately ensure efficiency and patient safety. Thus, focusing on promoting and encouraging the acceptance and use of EHR systems by healthcare professionals, as well as educating and informing professionals on various barriers, may help overcome these barriers in the future.¹⁹
- **Encourage and strengthen public-private partnerships:** Today, most organisations within the healthcare system are still working in silo and are

not well interconnected. Thus organisations such as manufacturers, payers, providers, governments, and private consulting analytics companies are required to come forward to exchange views and best-fit models for uncovering the power of data. This could be highly beneficial for all concerned parties and to improve access to innovation, as well as ensuring better clinical and economic outcomes, etc.

- **Need for information governance, trust, and cooperation:** Technical advances will do little good if organisations are still reluctant to trust each other. Industry groups must reassure healthcare organisations that their investments are worthwhile, by laying out clear, comprehensive, and mutually beneficial frameworks for health information exchange.

FROM OIL TO DATA-DRIVEN ECONOMIES, THE TRANSITION IN MIDDLE EAST

From the Middle East standpoint, establishments have started setting ambitious plans to position themselves at the forefront of this digital data revolution. Most Middle East countries have recognised the importance and power of data and analytics and have designed forward-looking strategies. Besides healthcare, other

domains are also seeing a mandate to leverage data and advanced analytics for optimal results. Informed decision-making, smarter choices, population-level health interventions for disease prevention and control, and more importantly, being prepared for another potential pandemic are a few use cases that are being aspired for delivery through data and analysis.

Table 3: Examples that indicate the MENA region is headed towards data-driven decisions

EXAMPLE OF COUNTRY	FORWARD-LOOKING STRATEGIES AND VISION ^{18,20}
KSA	Saudi Data and Artificial Intelligence Authority (SADIA) established recently with mandate for AI in health as well as other sectors
UAE	Department of Health unveils world's most comprehensive genome programme, transforming health and well-being with genomics and artificial intelligence, the nation's leading strengths
Egypt	Egypt has a plan to establish a genome centre that will aim to prepare a map of the Egyptian human genome to discover and accurately determine the genetic characteristics of various diseases. EgyptRef is a reference genome for Egyptian and North African populations to complement the Genome Reference Consortium. The project could help Egypt enter the era of precision medicine, gene therapy, and future specialised drugs based on genetic combinations

Apart from the above initiatives, Middle East countries have started initiating larger genomic programmes to advance the emerging field of precision medicine use by predicting how an individual will respond to a drug or therapy based on their genome, underlining the need to capture the genetic diversity of the Middle East and improving the understanding of disease associations.

- KSA has taken the lead in GCC by starting many programmes for regenerative medicine and stem cell transplants and cellular therapies programmes. Of note, KSA has started localisation through private partnerships that bring about technology transformation by entering into an MoU with

Celltex in 2019 with the aim to transform KSA's economic infrastructure of stem cell technology. In addition, SFDA has invited industry feedback on newly enhanced cell and gene therapy registration guidelines on the classification of advanced therapies, which will be published very soon. KSA is aggressively funding genomic research, due to the increasing prevalence of genetic disorders. Major research centres in KSA have recognised that integrating genomics with medicine is going to be a hot topic for the next decade; without sufficient diversity in genomics data, there is no way of achieving the vision of personalised medicine in under-represented parts of the world.

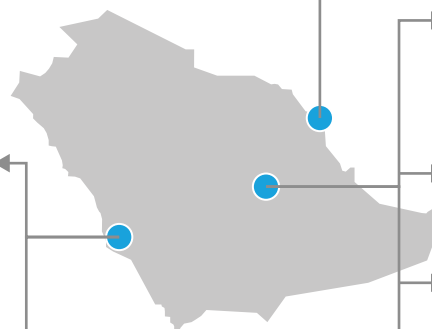
Figure 10: The following are examples of cell and gene therapy research capabilities focused on in local research centres in KSA

Stem cell and genetic research more in KSA as compared to CAR-T due to high prevalence of genetic disorders. diabetes, obese and rare diseases due to genetic are major research spots

Jeddah

KAU: King Abdul-Aziz University's research team has developed capabilities through Center of Innovation for Personalized Medicine, and has expressed interest in establishing a nation-wide coordination system around CT

KAUST: Well-funded R&D capability with focus on commercialization through the Innovation and Economic Development division, expressed interest to host a potential NT-X facility



KFSHD: King Fahad focuses on oncology and hematology, and has begun focusing on cell therapy with focus on leukemia and lymphoma

Riyadh

KAIMRC: Research focusing on stem cell isolation and characterization, bioengineered scaffolds, stem cells in liver fibrosis and in atherosclerosis

KFSHRC: Partnered with **Novartis** on cell treatments; conducts bone marrow transplants and has devoted R&D efforts to proteins and markers and mRNA stability

SPIMACO: Already in discussion with KAIMRC and commercial players, seeking to help commercialize CAR-T

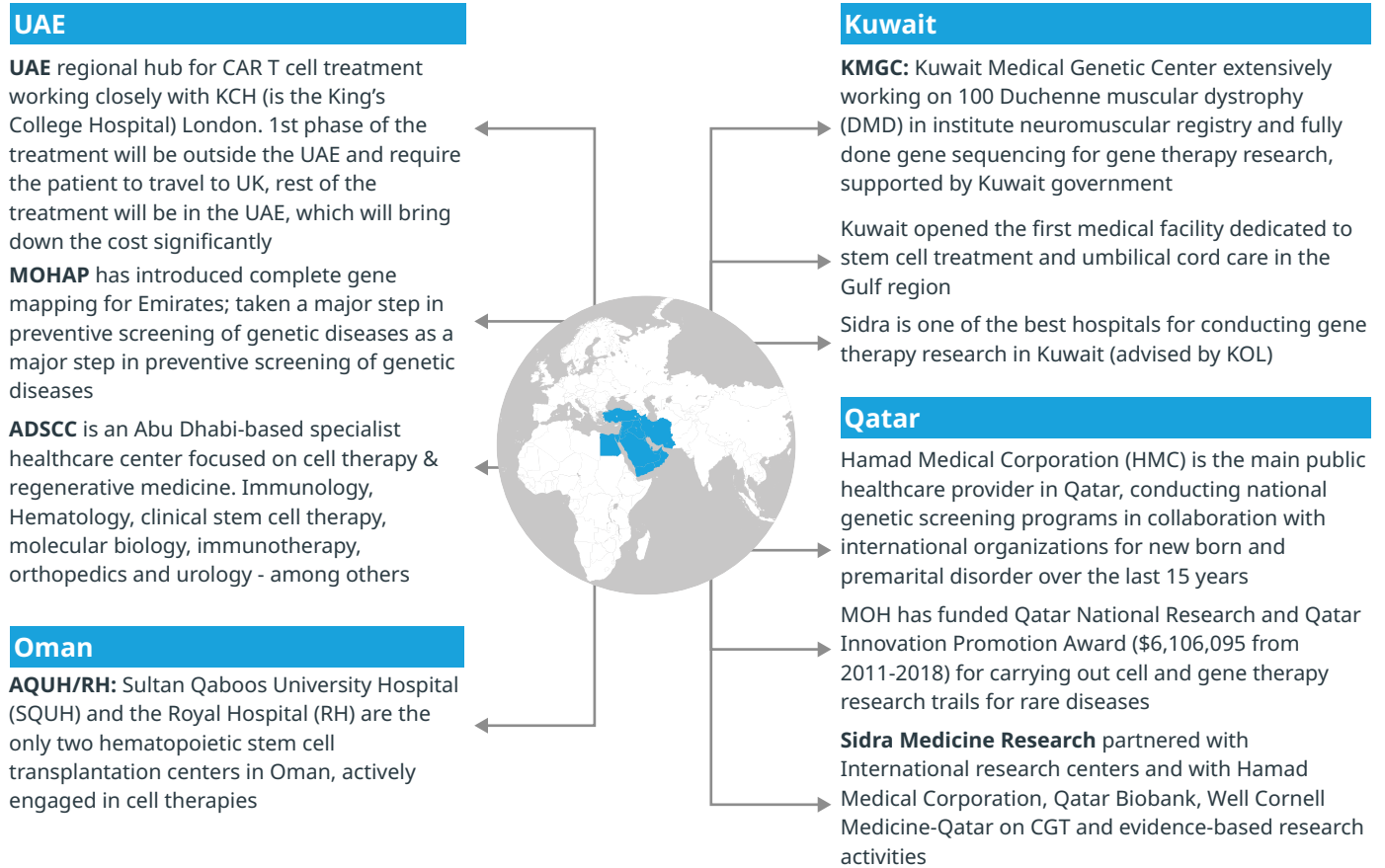
SFDA: Currently promoting use of Bridge and verification Priority Review to bring CGRx products into KSA

NGHA: Hospitals are currently planning to develop CAR-T Cell therapies



- The National Arab Genome project in the United Arab Emirates (UAE) aims to address this deficiency by using NGS technology to provide data to improve our understanding of the Arab genome and catalogue variants that are unique to the Arab population of the UAE.
 - » The Ministry of Health and Prevention has introduced complete gene mapping for Emirates at **Al Qasimi Hospital** in Sharjah as a major step in the preventive screening of genetic diseases.
- In Egypt, the National Cancer Institute at Cairo University, which is leading the Egyptian genome project, is planning to build an Egyptian reference database and then use it to micro-dissect Egyptian cancers.
- In Kuwait, US Stem Cell's attempted partnership in Kuwait represents a model that could bring basic autologous cell therapy services to the Middle East.
- Qatar MoH has funded **Qatar National Research** and the Qatar Innovation Promotion Award of \$6,106,095 for carrying out cell and gene therapy research trials for rare diseases.

Figure 11: Following are a few major active research programmes supported and funded by GCC countries to strengthen genomic data and encourage personalised care in the near future



IN A NUTSHELL

Middle East countries are highly focused on building a world-class healthcare system as part of the country specific nation’s vision 2030. In recent years, we have seen incredible advances in the creation, collection, analysis, and use of oncology health data across the USA and Europe – as well as better decision-making and improved patient outcomes. In the Middle East region, however, the many challenges and barriers discussed above are significant; still, recent years have witnessed many positive changes. Efforts are required to establish quality assurance or the right data infrastructure, creating confidence in stakeholders and assurance regarding data safety and security. The value of data-generation must be highlighted. Data-generation will help improve cancer care and require forward-looking

collaboration between stakeholders who stand to benefit from health data. In a nutshell, it is time to start a dialogue between public and private organisations for data and research collaboration, as part of the healthcare transformation vision of ME countries.

Apart from this, as most Middle East countries such as KSA have identified healthcare as one of the main focus areas of the ambitious Saudi Vision 2030 and National Transformation Program 2020 (NTP), which seek to improve the quality of healthcare services and facilities, the focus on creating a data-rich environment for innovation in oncology and creating partnering opportunities for bringing the world’s innovation to patients in the ME region could significantly benefit public and private healthcare systems in the ME region.

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Arun is a physician by training and has over 20 years of experience across various health sectors ranging from analytics, consulting, research, mHealth, writing and stakeholder engagement. He is a well published writer with ~30 publications in peer-reviewed journals. His primary area of work in the last decade has been in stakeholder engagement and real-world evidence in the AMESA region. He is also actively involved in AI-based projects as well as digital and tech interventions at a target customer and community level. He believes in the philosophy that the dynamicity of the high-growth economies necessitate novel and creative solutions.



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