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CURRENT OPINION

Promise of Real-World Evidence for Patient Centricity in Gulf Cooperation Council Countries: Call to Action

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Abstract

Presently, Gulf Cooperation Council countries are lagging in the generation of real-world data and use of real-world evidence for patient-centered care compared with the global average. In a collaborative effort, experts from multiple domains of the healthcare environment from the Gulf Cooperation Council countries came together to present their views and recommended key action points for the generation of robust real-world data and leveraging real-world evidence in the countries. The opinions of the experts are presented, along with existing barriers to the effective generation of real-world evidence in the countries. The Gulf Cooperation Council countries are undergoing transformative changes paving the way for improved healthcare measures; however, the challenges in generating reliable, robust, accessible, and secure real-world evidence are persistent. Hence, ongoing public–private engagements, as well as collaborations between regulators, policymakers, healthcare professionals, insurance and pharmaceutical companies, and patients, are warranted. A few notable examples of real-world evidence studies highlighting the benefits of real-world evidence for gaining valuable insights into patient-centric decision making are also discussed. The actionable steps identified for successful real-world evidence generation would provide long-term, real-world evidence-based patient-centric benefits for the countries.

Key Points

Real-world data are generating considerable interest in the Gulf Cooperation Council countries, and stakeholders there are eager to employ real-world evidence-based insights for healthcare technology, reimbursement, drug efficacy assessment, post-marketing safety of medications, cost effectiveness, and clinical decision making.

This article intends to demonstrate that creating strong, reliable, and real-world data calls for cooperation from all segments of the Gulf Cooperation Council countries' healthcare ecosystem.

When put into practice, pragmatic recommendations highlighted in the paper could enhance the adoption and utilization of real-world evidence for enhancing patient lives in the Gulf Cooperation Council countries.

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1 Introduction

Globally, healthcare systems are witnessing a radical change, with the increased adoption of a patient-centric approach. This approach puts the patient at the core of decision making, along with making healthcare professionals (HCPs) true partners in delivering continual care. The patient-centric treatment methodology aims at taking preventative and proactive steps rather than relying on the trial-and-error, non-personalized ("one-size-fits-all"), less efficient approach [1–3]. This approach also gives patients greater control by ensuring that healthcare systems and stakeholders put patients at the core of healthcare management. Therefore, with the advent of patient-centric innovative therapies, there has been a rising need for the generation and utilization of observational or real-world data (RWD) that tries to mimic and complement randomized clinical trial (RCT) data to justify the benefit-risk of any given therapy [4–6].

Traditionally, RCTs are considered the gold standard for determining the safety and efficacy of therapies; they allow regulatory agencies to approve new therapies and physicians to provide evidence-based treatment [7, 8]. Randomized clinical trials are designed as controlled structured trials involving selected patient populations with randomization or blinding to avoid bias. Randomized clinical trials further employ strict inclusion and exclusion criteria, which limits the inclusion of patients with comorbidities and concomitant medications. Therefore, RCTs provide high reliability with internal validity owing to their appropriate design, conduction, and reporting [7, 8].

However, RCTs have limitations with respect to resource utilization; they are time intensive and restricted to select patient populations, thereby lacking relative generalizability to real-world conditions and thus excluding a vast majority from availing themselves of the benefits of new drug trials [7–11]. The aforesaid limitations coupled with technological advancements and policy changes in many countries have prompted clinicians, regulatory authorities, and other HCPs to look into generating and using RWD and real-world evidence (RWE) [9, 11].

Real-world data, either prospective or retrospective, are data gathered from routine clinical care outside of RCTs [7]. According to the US Food and Drug Administration (FDA), RWD are "any data on health interventions in routine clinical practice and can be reported by providers, payers, or patients"[12]. These RWD, when collated and analyzed, generate clinically meaningful benefits or a risks assessment of a medical product, referred to as RWE [7, 12].

Real-world data come from a variety of sources, such as electronic health records, insurance claims and billing databases, patient registries, patient health records (observation charts, abstraction, laboratory, and pharmacy data), patient surveys, and digital health devices, such as wearables, mobile applications, and social media [7, 11–13]. Real-world data when analyzed provide valuable RWE and insights that can be leveraged to achieve a number of benefits in real-world scenarios, such as a clear picture on the outcomes with new therapies and the estimation and quality upgrade of new targets and interventions [13–15]. Real-world evidence further helps to approve improved methods of patient care and enhance health technology assessments, which have effects on market access and financial gains [16–20]. Therefore, RWE can be viewed as an important patient-centric decision-making tool that can be used by various stakeholders within the healthcare industry to influence global macro trends (Table 1 of the Electronic Supplementary Material).

The advantages of RWD and RWE are immense for patient-centric healthcare globally. In the last few years, RWE adoption in the Gulf Cooperation Council (GCC) countries has led to several successful studies, thus benefiting patient-centric care and for other stakeholder within the GCC countries (Table 1). Real-time insights generated by RWE help to better understand the enhanced value a drug, device, or innovative medicine and delivery care can bring to the patient and society in comparison with the conventional randomized trials [21, 22]. Additionally, with rapidly rising and unsustainable costs, potential new threats to patient safety and inappropriate uses. Real-world evidence is also important in identifying these problems so that patients' uses of medications can be made cost effective and safe. However, the GCC countries have not been able to fully utilize their potential benefits so far. A number of barriers restrict effective RWE efforts in the countries, such as the absence of regulatory guidance and frameworks, perceived fear and mistrust by the public in sharing personal health data, a lack of collaboration and partnership between institutions, variability in data sources, knowledge gaps, and a lack of technological prowess [21–23].

Acknowledging the aforesaid challenges, experts from GCC countries came together at an advisory board meeting in December 2020 to address and identify actionable points for generating robust RWD and leveraging RWE in the countries. This paper reports the perspectives and ideas generated during the meeting and aims to highlight the key opinions of the experts while also presenting critical challenges that need to be overcome in the acquisition of RWD and RWE in the GCC countries. This paper also presents a few notable examples on the successful implementation of RWE in the countries and its impacts. It further examines expert opinion in the context of the literature and the current status of RWE in the countries and recommends key steps to leverage wide-ranging RWE future benefits for all stakeholders in the GCC

Table 1 Case studies from Gulf Cooperation Council countries showcasing utilizing real-world evidence

Country	Case	Outcomes/impact	Reference
KSA	1. Incidence of HER2+ in Saudi Arabia	A retrospective, multicenter, observational, molecular epidemiology chart review study that estimated the percentages of patients with breast cancer positive for the HER2 receptor	[42]
	2. Health National Sickle Cell Registry	A multicenter national registry capturing data on prevalence of SCD in KSA. The patient registry captures data on the impact of novel treatment for disease management in the countries	[43]
	3. Treatment patterns and outcomes in prostate cancer	A prospective, longitudinal, multinational, observational study for insights into disease management, clinical outcomes, clinical decisions, and resource utilization for castrate-resistant and metastatic prostate cancers	[44]
	4. Financial impact of introducing biologicals for CD and UC	Assessment of financial impact of new biologics for treatment of CD and UC. The study showed a minimal increase (1–2.2%) in total costs for new therapies over a period of 5 years for both the conditions when compared with conventional therapy	[45]
UAE	1. Epidemiology study on lung cancer treatment pattern in UAE	An observational case-only prospective study in NSCLC diagnosis, at all stages and receiving treatment to understand the utilization of health resources. The study provided information on clinical management across Middle East and North Africa countries	[46]
	2. Multicenter registry for treatment and outcomes	A prospective, multicenter, observational registry of treatments and outcomes in patients with chronic lymphocytic leukemia or indolent non-Hodgkin's lymphoma. The registry provided insights on treatment profiles, patient distribution into subtypes, and their stage of disease	[47]
	3. Real-world claims data owned by DHIC	DHIC has claims data for 15 million anonymized patients since 2014 that can be used by stakeholders for insights into decision making. One retrospective database analysis was conducted to understand the antibiotic usages pattern for upper respiratory tract infection and another to understand treatment patterns for newly diagnosed type 2 diabetes mellitus	[48, 49]
Oman	Cost effectiveness for analysis of rotavirus vaccine	A cost-effectiveness analysis using a Markov model assessed that the healthcare burden of Oman can be significantly reduced by the universal rotavirus vaccination program for rotavirus-induced gastroenteritis. It also proved beneficial for both payers and the societal healthcare system	[50]

CD Crohn's disease, *DHIC* Dubai Health Insurance Corporation, *HER2* human epithelial growth hormone receptor 2, *KSA* Kingdom of Saudi Arabia, *NSCLC* non-small cell lung carcinoma, *SCD* sickle cell disease, *UAE* United Arab Emirates, *UC* ulcerative colitis

countries. Apart from establishing a narrative for encouraging the use of RWE to support a patient-centric approach in the countries, this paper aims to give an important message to policymakers about the adoption of RWE for informed decision making in the GCC countries.

2 Methods

An advisory board meeting was held in December 2020, involving ten experts and key opinion leaders from the GCC (Kingdom of Saudi Arabia, Oman, and United Arab Emirates) countries. The panel members included experts who were HCPs, data analysts, researchers, and government representatives across the GCC countries. They came together to define and identify key actionable items that could ensure the generation of robust RWD and effective utilization of RWE for maximal optimal benefits and informed decision making by all stakeholders within the countries. The key opinion leaders discussed the existing status of RWE in the GCC countries, identified key challenges, and recommended future steps for leveraging RWE in these countries. To back up the views and recommendations of the experts, we conducted a literature review using PubMed with the search terms "RWE," "RWD," "claims database," "electronic health records," observational studies," "regulatory framework,"

"claims database," and "Middle East" between the years 2016 and 2021. In addition, gray literature such as government and patient registries, and other relevant websites were also reviewed for additional references. No formal data analysis technique was applied to the collation of the qualitative findings generated from the meeting.

3 Results

During the meeting, the broader topics for discussion were: (1) elevating the importance of RWE in the GCC countries; (2) employing innovative approaches to improve understanding of the burden of disease and enhance diagnosis; and (3) engaging and assisting health authorities and stakeholders to address unmet needs in treatment protocols and the provision of quality healthcare. The following sections focus on the current landscape of RWD and RWE in the GCC countries, the barriers to the adoption and implementation of the RWE, and realizing the benefits of successful utilization of RWE in the GCC countries (Table 1).

3.1 Current Situation of RWD and RWE Generation in GCC

Although the GCC countries are behind developed countries in terms of generation of RWD and their use in healthcare policy decision making, they are still a rich source of RWD and, therefore, should not be ignored [21, 22]. The GCC countries are a dynamic region with respect to healthcare and therefore require renewed efforts in RWD data generation and the use of RWE. The factors that drive this need are: (1) demographic shifts and a rise in the aging population with chronic diseases; (2) a drive toward quality valued-based healthcare at par with the USA and Europe (Vision 2021 from the United Arab Emirates and National Transformation Plan, a part of Vision 2030 from the Kingdom of Saudi Arabia); (3) the modernization of healthcare systems and infrastructure with digitization capabilities for electronic data capture; (4) the rapidly increasing cost of healthcare and need for cost containment among payers; (5) regulators and clinicians insisting on the generation of local data; (6) the drive to bring innovative medicine to the countries; (7) the global push toward privatization and insurance-based healthcare; and (8) the influence of print and social media regarding access to data on health and treatment choices [21].

3.2 Barriers to Adoption of RWE in GCC Countries

The aforesaid points provide the impetus to drive RWD generation and use. However, there are several barriers to RWE generation in the countries, such as the low quality of RWD, lack of regulatory involvement, and the HCP behavior. Further research identifies a few key factors that impede the generation and use of RWE within the GCC countries, including: (1) the lack of guidance and frameworks from regulatory agencies; (2) the lack of public confidence and openness in sharing data; (3) the inability to trust RWD and avoidance of stakeholders in using RWE; and (4) the lack of partnerships and collaborations between data sources and the lack of real-time data dissemination [21–23].

3.2.1 Lack of Guidance and Frameworks from Regulatory Agencies

Regulatory bodies in developed countries provide RWE guidance. The US Food and Drug Administration (FDA) in December 2018 published the "Framework for FDA's RWE Program" to provide guidance for three important areas; (a) assessing the fitness of RWD with respect to reliability, relevance, and data gaps; (b) assessing sufficiency of evidence with innovative study designs and pragmatic trials and external comparators; and (c) assessing regulatory requirements and guidance for electronic data capture [24, 25].

Gulf Cooperation Council countries regulatory agencies are recommended to update and provide consistent guidelines on RWD and RWE that can capture reliable and useful RWE for patient treatment, cost coverage, regulatory, and health policy decisions [21, 22]. Guidance can be sought from the International Society for Pharmacoeconomics and Outcomes Research Special Task Force on RWE and collaboration with the International Society for Pharmacoepidemiology, and sponsors should ensure that transparency, validity of confounders, measurement lapses, selection bias, and missing data rates are optimized in the studies [26].

The major operational task in obtaining RWD is to have a governance framework that primarily ensures the safety and rights of patients while acquiring and using their data. Stakeholders in the GCC countries can take cues from existing regulatory guidance and frameworks from global counterparts in order to leverage RWD and generate high-quality RWE. These guidelines will then be region specific, justifying various needs such as safety, effectiveness, compliance to treatment, and budgetary concerns of the region.

3.2.2 Lack of Public Confidence in Sharing Data

Gulf Cooperation Council countries are not immune to personal data confidentiality and privacy violations, patient safety risks, and data integrity issues, allowing for the existence of mistrust when it comes to sharing personal health and non-health data in the general population [27, 28]. This perception also arises because of the suspicion of misuse and breach of personal data for financial gains, fear of discrimination, and doubts about perceived benefits [28]. Across the GCC and Middle East countries, legislation and

laws concerning the data protection need to be strengthened [28]. These uncertainties around patient data legislation could cause concern about data sharing by patients, thereby affecting the generation and usefulness of RWE in the GCC countries. This lack of public confidence holds significance for emerging markets and is a behavioral barrier to RWE generation and its utilization for clinical decision making in GCC countries [21, 22].

3.2.3 Skepticism and Lack of Trust of Stakeholders

One of the main reasons that mistrust originates in the realm of RWE is the lack of data sharing between key stakeholders such as the HCPs, insurance and pharmaceutical companies, and academic institutions [29, 30]. Mistrust arises with respect to the quality, integrity, security, and variability in data collection and is a cause of concern in the GCC countries [27]. The sources of RWD should have features such as generalizability across healthcare, relevance to the given research question, and accessibility to researchers to conduct analyses [30]. A limited set of data meets the relevance and quality criteria and is fit for use. Therefore, stakeholders in the GCC countries must strive to overcome mistrust and develop strategies that involve the sharing of comprehensive, reliable, and transparent RWD data that are accessible to the stakeholders [30, 31].

3.2.4 Absence of Partnerships and Long-Term Collaborations

To efficiently generate and disseminate data, stakeholders in GCC countries need to establish long-term partnerships with researchers and data owners [29, 30]. The varying levels of understanding and experiences of RWD, coupled with a lack of technical skills are obstacles to the formation of partnerships. Other obstacles include resource and knowledge gaps in data source owners, conflicting research goals, and technology updates in the GCC countries [22, 23, 30]. Therefore, appropriate educational training and support for analysis are needed to address these gaps and realize the full value of RWD and RWE [23, 29, 30, 32]. Several developed countries have taken key initiatives to engage and spread awareness among the population with regard to the benefits of data sharing, and the use of technology in healthcare and GCC countries could benefit from adopting similar measures [33–35]. Additionally, partnerships and collaborations between stakeholders and data source owners can be strengthened by reciprocity of data sharing and undertaking joint research endeavors to understand unmet needs with standard care and in mutually beneficial therapeutic areas with rapidly evolving treatment strategies [30].

3.3 Promise of RWE: Generating New Patient Insights to Enhance Health Outcomes

Although there are several barriers to generating RWE in the GCC, the countries are gradually moving toward capabilities for generation and leverage of RWD and RWE for patient-centric benefits. Real-world evidence greatly benefits all stakeholders involved in patient care, allowing them to make informed and insightful decisions [22, 23, 36]. A few key areas that stand to benefit from the use of RWE are presented in Fig. 1.

4 Discussion

The GCC countries are uniquely positioned when it comes to RWD, as they comprise many countries that are genetically, culturally, and linguistically similar and therefore have similar regulations, unified policies, and systems [37, 38]. This uniqueness ensures that the countries are a rich source of RWD that can be successfully mined for real-world insights and benefits for all stakeholders. The countries have witnessed renewed efforts to adopt RWE-based decision-making policies and procedures. Even so, the countries are still behind when it comes to the effective utilization of RWD and RWE [21–23, 36].

In an earlier review, Akhras et al. [21] reported the status of RWE and barriers to RWE use in GCC countries that need to be overcome in order to realize the value that RWE can bring to the countries. However, beyond the initial review published in 2019, there has been no report on the status and future directions of RWE in the countries. Hence, the authors of this paper acknowledge that the discussion from the meeting presented here is a first report from the countries that highlights current views from experts and provides key actionable steps for leveraging RWE in the countries. In addition, the paper identifies barriers to RWE use that still exist, while also highlighting cases of successful studies

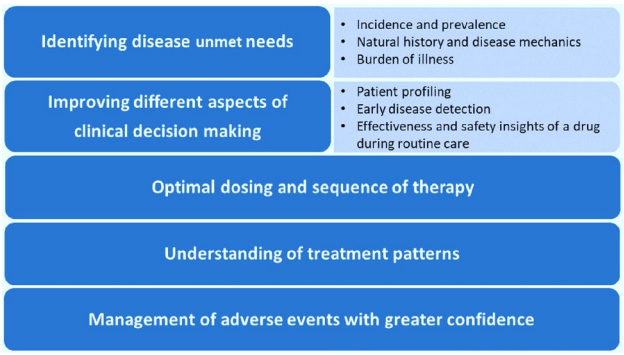

Fig. 1 Benefits of real-world evidence

adoption of RWE within the countries and their realized benefits

The difficulties encountered in the GCC countries in generating and benefiting from RWE, although challenging, are not unique to the countries [22, 23]. A few critical factors that were identified as major obstacles into the current adoption of RWE in the countries involved all segments of the healthcare ecosystem—patients, HCPs, insurance and pharmaceutical companies, regulatory authorities, and government policymakers. Regulatory and governmental agencies in some of the GCC countries have not kept pace with transformative healthcare changes in the countries to devise consistent governance policies, guidance, frameworks, and technical capabilities that would allow efficient RWD and RWE generation [22, 23, 36].

The experts further opined that despite existing shortcomings and knowledge gaps in the GCC countries, RWE holds great promise. The potential of RWE in generating insightful information for effective decision making and benefits for the GCC countries can be acknowledged from the various successful RWE case studies discussed here. Based on the expert opinions and views expressed at the meeting, several key actionable items were identified and listed (Table 2).

The first step that could be taken for efficient RWE generation is emphasizing the importance of RWE and treating real data as a valuable commodity: RWD, when harnessed correctly and regulated efficiently, could provide immense benefits [22, 23, 33, 35, 36]. The second step would be to enhance trust in the public, to facilitate voluntary sharing of health data. This could be brought about by ensuring patient confidentiality, confidentiality of patient health information, patient data integrity, and ensuing ethical data handling and processing policies are implemented and enforced [27, 28]. Guidance frameworks and policies can be designed by following principles of RWE programs from the USA and other countries [24–26]. The third step would include establishing a continuous and efficient healthcare plan and customizing healthcare plans and insurance policies that suit countries' needs. Healthcare plans and reimbursement policies that are effective in other developed countries might not be effective and beneficial for patients in the GCC countries. Hence, insurance company policies should tailor reimbursement packages and plans to cover medicines and treatments that cater to patients' needs in the GCC countries [39, 40]. The fourth step is maintaining high standards for high-quality RWE generation. The fifth step is the establishment of a common language for RWE in the GCC countries, based on the similarities [21]. This could be achieved by effectively educating and orienting stakeholders, thus bridging gaps between multiple stakeholders within the countries. The sixth measure is setting up robust and reliable databases to capture and process RWD [23]. Several databases exist in the United Arab Emirates countries such as Cerner, the Daman claims database, and the Epic system that could be used [41]. Finally, as the seventh priority step, the enhancement in technical capabilities and skills to design, execute, analyze, and interpret RWE studies for all stakeholders could ensure interoperability across institutions and national and countries' jurisdictions. These priority points when communicated to policymakers, acknowledged, and implemented by stakeholders would help stakeholders to work collaboratively and outside silos for RWE generation and dissemination, resulting in tangible benefits for the GCC countries.

Therefore, the GCC countries are expected to take continued measures that can overcome barriers to effective RWE generation by formulating governance and policy frameworks, as outlined by the FDA and the International Society for Pharmacoeconomics and Outcomes Research [24, 26]. These efforts along with uniform, reliable, transparent, and accessible RWD collection would foster long-term partnerships and collaborations for RWE generation, sharing, and dissemination in the countries.

5 Five-Year View

As the RWD and RWE landscape will continue to evolve and grow rapidly in the GCC countries, with the likelihood of increased investment in RWD generation and leveraging RWE platform infrastructure, significant financial gain could

Table 2 Key actionable points from key opinion leaders for leveraging RWE in Gulf Cooperation Council countries

1. Treating "real data" properly and collecting and regulating data
2. Ensuring patient confidentiality and respecting the integrity of patient data: putting ethical consideration into place
3. Establishing a continuous healthcare plan, and customizing health plans and beneficial packages to suit countries' needs
4. Adapting high standards for evidence generation
5. Establishing a common language for RWE in the countries; bridging gaps between multiple stakeholders; educating and orienting stakeholders
6. Investing in more robust databases, apart from UAE; Cerner; Daman claim database; Dubai claim database; Epic
7. Enhancing technical capabilities to design, execute, analyze, and interpret RWE studies for all stakeholder and ensuring interoperability across institutional, national, and countries' jurisdictions

RWE real-world evidence, *UAE* United Arab Emirates

be realized in terms of cost reduction in post-marketing engagements and conducting clinical trials. With robust data in place, strategic partnerships between stakeholder countries will see an increase in efficiently generated real-world insights across research value chains and clinical decision making. As adoption expands, evidence platforms will be integral to ongoing product success, providing continuous high-quality real-time data and insights to all critical stakeholders: physicians, payers, and regulators.

6 Conclusions

This paper aimed to convey that the generation of robust, reliable, and RWD is not a trivial undertaking and requires a concerted effort from all sections of the healthcare ecosystem in the GCC countries. These countries owing to their unique strengths, such as the presence of an effective legislative system, strong leadership focus, and a drive toward modernization and technological advancement, could move from nascency to a structured framework in a RWE domain. Therefore, against the backdrop of success from early RWE, it would be expected from GCC countries to quickly adapt, implement, and leverage the potential benefits offered by RWE for patient centricity.

7 Expert Opinion

An important aspect of evolving healthcare systems involves the ability to access patient data, which provide information about current standards of care, unmet needs, and health-related patient outcomes. These data come from numerous sources and constitute RWD that, when well integrated and presented, provide valuable insights to HCPs to make patient-centric treatment decisions.

The GCC countries are experiencing a huge interest in RWD, and stakeholders in the countries have a keen desire to use RWE-based insights for healthcare technologies, reimbursement, assessment of drug efficacy, post-marketing safety of drugs, cost effectiveness, and clinical decision making. Real-world data use can have a two-dimensional and operational aspect, i.e., utilizing RWE, and another from an economic dimension, to outweigh any unnecessary medical expenditure, guidelines, and amend current clinical practice guidelines. The GCC countries are rapidly modernizing and adopting newer digital technologies with infrastructure to support their needs. Clinicians in GCC countries are fully qualified and eager to adopt RWE-based value generation studies and practices. In addition, there is a concerted effort from regulatory agencies and governing bodies to harmonize various policies and frameworks. For the GCC to be at the cusp of RWE competencies, it is expected that the countries will continue to make determined efforts to streamline processes and practices surrounding RWE generation and use. The endeavor toward realizing the vast benefits of RWE could be further enhanced by continued education and technical skill development initiatives for healthcare providers, patients, and other stakeholders. The development of unified governance policies and the refining of existing guidelines and frameworks by regulators and policymakers would build trust and confidence in the RWE generated. Measures that ensure patient data confidentiality, data security, and reliability would further prioritize efforts for effective RWE generation. In addition, it is expected that RWE solutions would be designed taking into consideration countries' preferences and practices, thus ensuring maximal benefits to patients in the countries.

These pragmatic recommendations when implemented could help to maximize the adoption and leveraging of RWE for improving patient lives in the GCC countries. These priority actions could provide insights for resolving unmet patients and stakeholder needs and enable the government and pharmaceutical sectors to create an ecosystem that would enhance treatment approaches and thereby the overall quality of healthcare in the GCC countries.

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Consent to Participate Not applicable.

Consent for publication Not applicable.

Availability of data and material Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

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Author contributions All authors contributed equally towards the idea for the article, performed the literature search, conducted the data analysis, and drafted and critically revised the work. All authors read and approved the final manuscript.

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