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ZEST

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NEWSLETTER ISSUE 1

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Each edition of Zest will bring you an insightful analyses,

expert opinions, and exclusive updates that will keep you at the forefront of the healthcare industry's transformation.

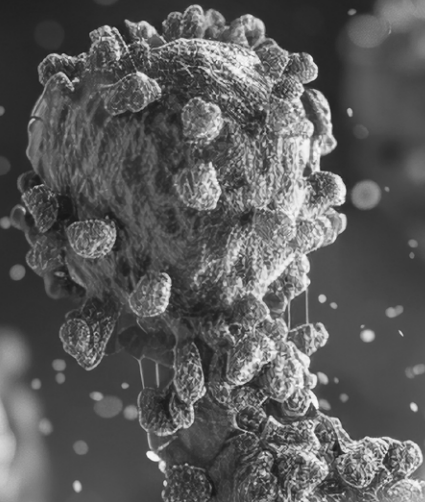


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Unlocking the Potential: T-cell Engagers in Solid Tumor Therapy

T-cell engagers (TCEs) are a promising new type of immunotherapy. It has shown significant success in treating hematological malignancies and holds the potential to revolutionize the treatment of solid tumors. TCEs are a class of drugs designed to harness the power of the body's immune system to fight cancer. TCEs work by bridging the gap between immune T-cells and tumor cells, allowing the T-cells to recognize and destroy cancer cells. This approach offers a more targeted therapy compared to traditional chemotherapy, potentially leading to fewer side effects and improved patient outcomes.

Mechanism Unveiled: How TCE Targets Solid Tumors



Target Recognition

TCE are engineered proteins comprising two main components: a binding domain specific to a tumor-associated antigen (TAA) and a binding domain specific to the T-cell receptor (TCR). The TAA-binding domain recognizes antigens on the surface of cancer cells, while the TCR-binding domain engages with T-cells.



Formation of Immunological Synapse

Once the TCE binds simultaneously to the cancer cell and the T-cell, it forms an immunological synapse between the two cells. This synapse brings the cancer cell and the T cell into proximity, facilitating direct cell-cell contact.



T-cell Activation

The binding of the TCE to the TCR activates the T-cell, initiating intracellular signaling cascades. This activation leads to the release of cytotoxic molecules, such as perforin and granzyme, alongside the secretion of pro-inflammatory cytokines like interferon-gamma (IFN- γ) and tumor necrosis factor-alpha (TNF- α).



Target Cell Destruction

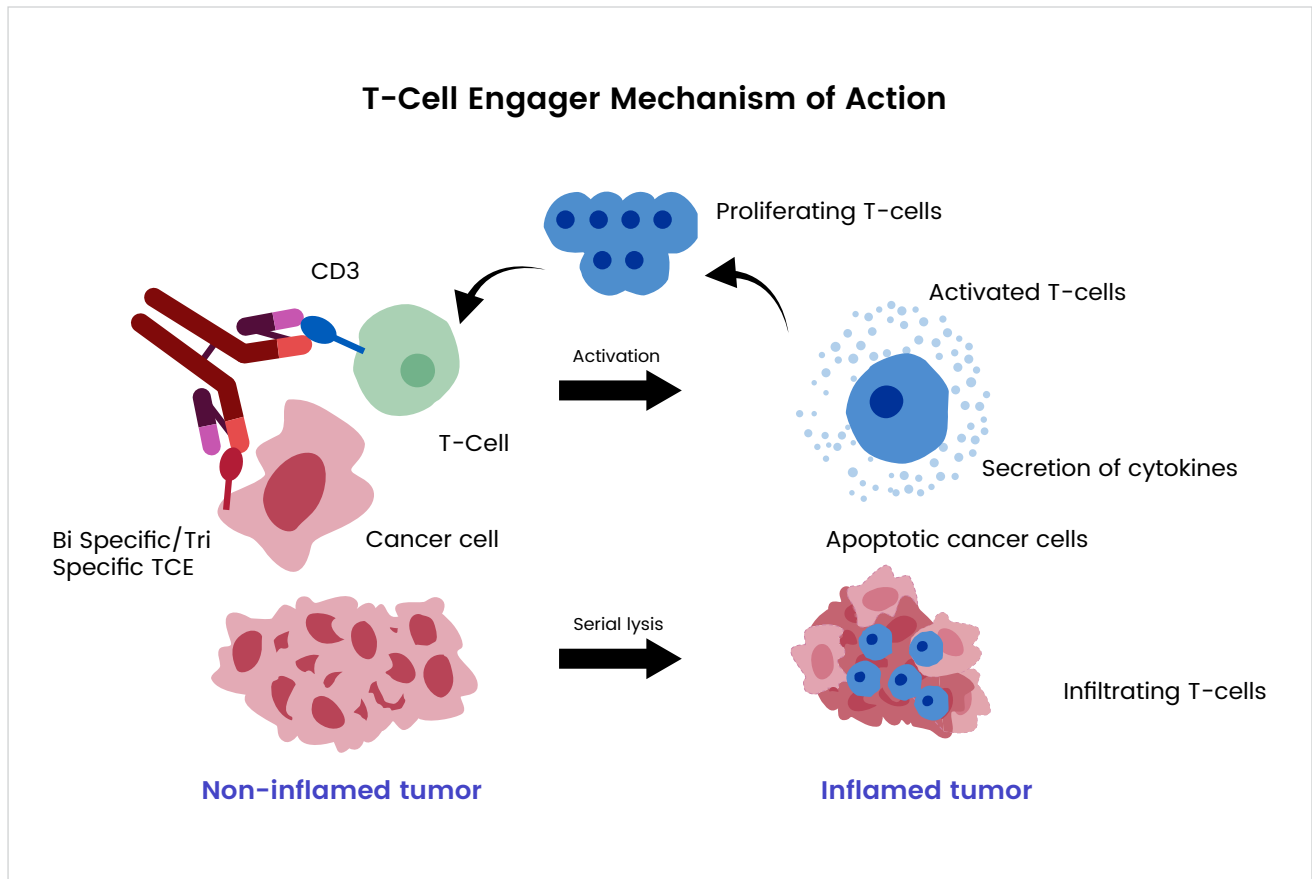
The activated T-cells then direct their cytotoxic activity specifically toward the cancer cells expressing the target antigen. Perforin creates pores in the cancer cell membrane, allowing granzyme to enter the cancer cell and trigger apoptosis (programed cell death). Additionally, the pro-inflammatory cytokines released by the activated T-cells further contribute to the destruction of the cancer cells.



Amplification of Response

TCEs have the potential to induce an amplified immune response. Once a cancer cell is destroyed, it releases additional tumor antigens, which can further activate nearby T-cells, leading to a cascade of immune-mediated destruction of cancer cells.

Figure 1: TCEs mechanism of action



Overcoming Barriers: Challenges in Applying TCEs to Solid Tumors

The success of TCEs in treating blood cancers has led researchers to investigate their potential for treating solid tumors. However, several challenges associated with using TCEs for solid tumors exist. These challenges include the immunosuppressive tumor microenvironment, heterogeneity of solid

tumors, and potential toxicity concerns. Despite these challenges, TCEs hold great promise for treating solid tumors, and ongoing research aims to address the hurdles and improve their clinical outcomes.

Some potential strategies to enhance the effectiveness of TCEs in solid tumors are:

1

Target Selection

Identifying the tumor-specific or tumor-associated antigens that are highly expressed in cancer cells but minimally expressed in healthy tissues is crucial. This helps to reduce off-target toxicity and enhance tumor specificity.

2

Tumor Microenvironment Modulation

Strategies to overcome the immunosuppressive nature of the tumor microenvironment include combination therapies with immune checkpoint inhibitors or cytokines to activate and expand T-cells within the tumor.

3

Enhancing T-cell Persistence and Function

Engineering T-cells to resist exhaustion and maintain cytotoxic activity within the tumor microenvironment can enhance TCEs' efficacy.

4

Optimizing Bispecific T Cell Engagers (BiTEs) Structure

Modifying the structure of BiTEs to improve their pharmacokinetics, stability, and binding affinity can enhance their efficacy and reduce side effects.

5

Combination Therapies

Combining TCEs with other modalities like chemotherapy, radiotherapy, or targeted therapies can enhance their antitumor activity by simultaneously targeting different aspects of the tumor's biology.

6

Local Delivery Systems

Using localized delivery systems such as nanoparticles or intratumoral injection can help concentrate TCEs within the tumor, minimizing systemic toxicity and enhancing efficacy.

Exploring Potential: TCEs in the Clinical Landscape

Table 1: Clinical trial landscape of TCEs in solid tumors

Clinical Trial Landscape of TCEs in Solid Tumor				
Drug Name	Indication	Current Phase	Target	Company
Tarlutamab	Small Cell Lung cancer	IIIb	anti-DLL3/anti-CD3	Amgen
	Neuroendocrine Prostate Cancer	I		
		I		
Tarlutamab	Small Cell Lung cancer Neuroendocrine Neoplasms	II	anti-DLL3/anti-CD3	Boehringer Ingelheim
LAVA-1207	Metastatic Castration Resistant Prostate Cancer	I/II	PSMA/FOLH1	Lava Therapeutics
BS-006	Uterine Cervical Neoplasms	I	anti-CD3/anti-PD-L1	Binhui Biopharmaceutical
BAY-2010112	Prostatic Neoplasms	I	CD3 agonist	Bayer
MEDI-565	Gastrointestinal Adenocarcinomas	I	CD3 agonist	MedImmune



Industry Insights: Recent Developments in TCE Therapies

Companies are adopting inorganic strategies, including acquisitions and partnerships, to achieve clinical milestones in the TCE space.

Figure 2: Gilead Sciences' and Merus' collaboration

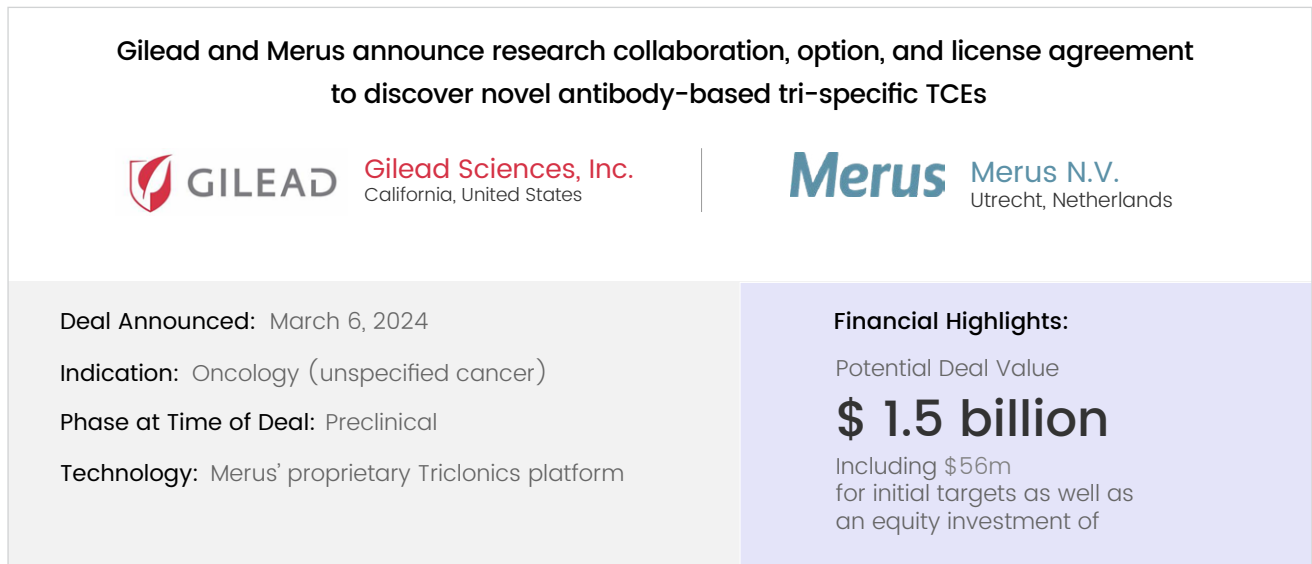


Figure 3: Merck's acquisition of Harpoon Therapeutics



Figure 4: CytomX Therapeutics collaboration with Astellas

<p>CytomX Therapeutics announced the achievement of a second clinical candidate nomination under the companies' TCE bispecific collaboration with Astellas</p>	
 <p>CytomX Therapeutics, Inc. California, United States</p>	 <p>Astellas Pharma, Inc. Tokyo, Japan</p>
<p>Milestone Payment Date: April 3, 2024</p> <p>Drug Details: Probody T-Cell Therapy (CD3 agonist)</p> <p>Indication: Oncology (unspecified cancer)</p> <p>Phase at Time of Deal: Preclinical</p>	<p>Financial Highlights:</p> <p>Potential Deal Value</p> <p>\$ 1.68 billion</p> <p>Including \$5m milestone payment</p>

Looking Ahead: Future Frontiers of TCE Therapies

In the solid tumors space, the future of TCEs holds promise through various avenues. Next-generation targeting strategies seek novel tumor-specific antigens for enhanced specificity. Personalized immunotherapy approaches tailor treatments to individual patient profiles, optimizing efficacy while minimizing off-target effects. Combinations of immune checkpoint inhibitors and targeted therapies synergize to overcome resistance mechanisms and broaden treatment options. Engineering T-cell fitness through genetic modifications enhances persistence and functionality within the tumor microenvironment. Biomarker discovery identifies predictive indicators for patient response and treatment monitoring. Innovative delivery systems localize TCEs to tumors, minimizing systemic toxicity. Inducing long-term immune memory ensures durable responses and guards against disease recurrence. Collaborative efforts between pharmaceutical companies, evidenced by recent partnerships and acquisitions, underscore the collective commitment to advancing TCEs as a transformative modality in solid tumor therapy. These concerted endeavors pave the way for continued innovation and progress in harnessing the potent capabilities of TCEs for the benefit of patients with solid tumors.



Unveiling the Future of Healthcare: A Journey Through Digital Health in 2024

Introduction



Digital Health

Digital healthcare refers to the instruments and services that employ information and communication technologies (ICTs) to enhance and optimize health and lifestyle management. It also plays a vital role in disease prevention, diagnosis, and treatment. The U.S. Food and Drug Administration (FDA) views the digital health field with a vast reach encompassing areas including wearable tech, telehealth and telemedicine, mobile health, health information technology, and customized medicine. One of the main goals of digital health is facilitating data transfer between patients, devices, and physicians. Ideas of customized, preventive, and predictive digital health are strongly connected.



Key Trends Shaping Digital Healthcare in 2024

Several key trends are likely to shape the landscape of digital health in 2024, from the growing significance of artificial intelligence (AI) to the increasing demand for personalized healthcare. These trends offer healthcare providers and patients new possibilities for improving healthcare delivery, enhancing patient outcomes, and fostering innovation. This article explores some key digital health trends expected to emerge in 2024.

15%

Healthcare cost can be saved through strategic digital investments

\$3

Return can be generated for every \$1 invested in digital health



Key Trends in 2024

Remote Patient Monitoring and Telehealth

The telehealth and remote patient monitoring (RPM) sectors are experiencing significant growth and innovation, driven by the need for more cost-effective healthcare services, the increasing geriatric population, and the rising prevalence of chronic conditions. These factors push healthcare providers to adopt telehealth and RPM technologies to improve clinical outcomes and make healthcare more accessible and efficient.

RPM has emerged as a cornerstone in the digital health domain, allowing healthcare providers to monitor patients outside the conventional clinical settings. This trend is beneficial particularly for chronic disease management, post-operative care, and elderly care, providing real-time data that leads to timely interventions and reduced hospital readmissions.

Telehealth has transcended its pandemic-era emergence as a necessity, becoming a staple in the healthcare delivery model. While RPM and telehealth hold promise globally, disparities in access to electricity and ICT infrastructure pose significant challenges in low-resource settings. Efforts to bridge these gaps through collaborative partnerships and innovative solutions are essential for realizing the full potential of remote healthcare delivery worldwide. In 2024, its integration with RPM systems has elevated patient care, allowing healthcare providers to track patients' health in real time, reduce hospital readmission rates, and offer timely interventions. This trend makes healthcare more accessible and proactive, as RPM devices can detect health issues before they become critical.

Interoperability and Connectivity

The need for healthcare interoperability solutions is continuously growing due to substantial investments in digitalizing healthcare infrastructure and the high adoption of electronic health records (EHRs). Focusing on different types of interoperability

solutions, such as EHR interoperability, lab system interoperability, and healthcare information exchange, emphasizes the diverse needs of the healthcare sector for seamless data exchange and integration. Enhanced connectivity also ensures patient data is accessible and usable across various platforms, improving care coordination and reducing the likelihood of medical errors. The need for interoperability solutions transcends borders, with diverse regulatory landscapes and infrastructure capabilities shaping implementation strategies. Global standards and collaborative frameworks are crucial to ensure seamless data exchange and care coordination across regions.

Cybersecurity Concerns

The healthcare sector experienced a 55% increase in cyberattack incidents in 2020 compared to 2019, as reported by IBM. As healthcare increasingly relies on digital platforms, the need for robust cybersecurity measures has never been more critical. Protecting sensitive patient data from cyber threats is a top priority, with healthcare institutions investing in advanced security protocols to prevent data breaches and ensure patient trust.

A notable example illustrating the impact of cybersecurity breaches in healthcare is the Anthem cyberattack, which affected nearly 78.8 million individuals. This breach, primarily caused by a phishing attack, compromised a wide range of personal information, highlighting such incidents' extensive financial, organizational, and personal repercussions. In response, Anthem invested heavily in cybersecurity improvements, spending \$260 million on various security enhancements.

The financial impact of cyberattacks in healthcare is particularly pronounced, with the average cost of a healthcare data breach reaching \$10.1 million, the highest across industries. This figure represents a significant increase from previous years, emphasizing the escalating costs associated with securing healthcare data and responding to breaches. Efforts to strengthen data security and privacy protections must be complemented by international collaboration and information sharing to stay ahead of evolving threats.

Growing Use of Wearable Devices

Wearable devices in healthcare are experiencing rapid growth and innovation, significantly impacting how healthcare is delivered and personalized. Deloitte Global predicts a significant increase in consumer health and wellness wearable device adoption, projecting shipments to reach nearly 440 million units by the end of 2024.

Devices like smartwatches and medical-grade “smart patches” are becoming more sophisticated, enabling continuous monitoring and management of chronic health conditions and detecting symptoms of serious illnesses. For example, smartwatches now feature sensors for 24x7 health monitoring, such as heart rate and blood oxygen saturation, which became particularly relevant during the COVID-19 pandemic. Smart patches, on the other hand, offer more targeted health monitoring and medication delivery, with some employing minimally invasive methods to provide accurate health data directly from the skin.

Generative AI in Healthcare

Generative AI is poised to significantly impact the healthcare sector in 2024, with transformative benefits anticipated across various domains, from remote patient monitoring, telemedicine administrative tasks, and clinical decision-making. The integration of generative AI in healthcare is expected to improve patient care by enabling real-time monitoring through wearable devices equipped with AI algorithms, offering early warnings for health complications, and reducing hospital readmissions. AI-powered virtual assistants could also enhance telemedicine by providing personalized medical advice, thus improving healthcare accessibility. Additionally, by analyzing vast datasets, generative AI can identify patterns and generate insights that human researchers might overlook, accelerating the pace of medical advancements.

Growing Use of Data Analytics

Data analytics is becoming increasingly integral to healthcare, enabling providers to make informed decisions based on comprehensive data analysis. This trend is driving improvements in patient care, operational efficiency, and health outcomes. Within data analytics, predictive analytics is crucial in personalized medicine, early risk detection, and

intervention strategies. For example, predictive analytics tools are used in hospitals to forecast patient admissions and manage staffing levels. A study found that implementing predictive analytics in a Chicago hospital reduced patient wait times by 15–20%. Capacity-building initiatives and knowledge-sharing platforms can empower healthcare professionals worldwide to leverage data-driven insights for more effective patient care.

Digital Empowerment of Patients

In 2024, patient empowerment is increasingly central to healthcare trends, driven by a more collaborative partnership between patients and healthcare providers. Digital tools empower patients, providing access to their health information, telemedicine consultations, and online health resources. Technologies like online scheduling, patient portals, and clinical chatbots offer patients access to their health information and care pathways.

Patient empowerment is changing the traditional doctor-patient dynamic, with patients now accessing their health data and even proposing treatment plans based on information found online. This trend is especially pronounced among younger populations, with a significant percentage of 18 to 34-year-olds actively engaging with their healthcare providers based on their online research. Patient empowerment through digital tools transcends cultural and linguistic barriers, yet access to these tools remains uneven. Multilingual platforms and culturally sensitive interventions can bridge these gaps, empowering patients worldwide to be more active in managing their health.

Digital Obesity Care

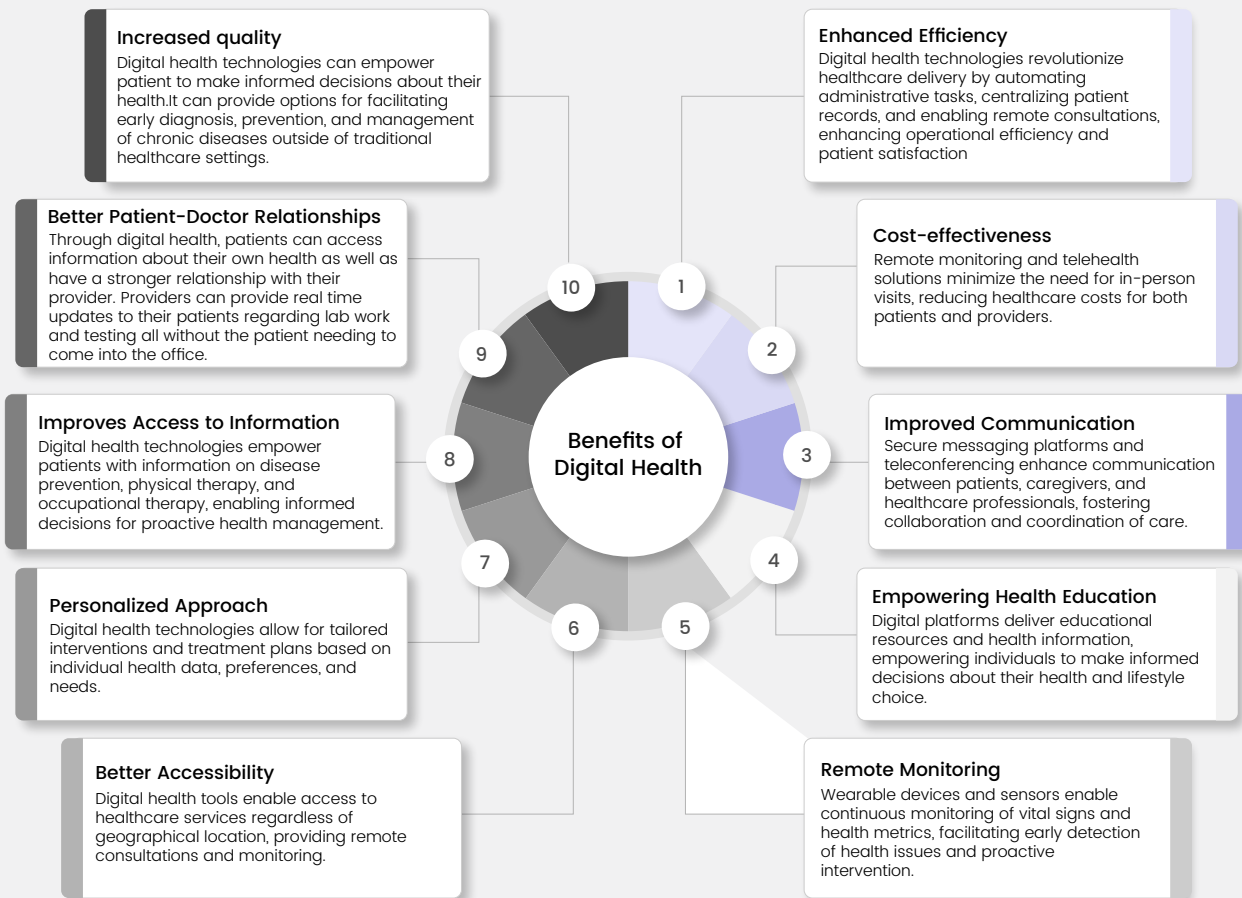
A noteworthy publication in the Journal of the American Medical Association (JAMA) revealed that participants engaged in digital health programs exhibited superior weight loss outcomes in compared to those not utilizing such interventions. Digital healthcare technologies are increasingly being recognized for their potential to address obesity through innovative, personalized care strategies. These digital interventions include tailored nutritional and physical activity plans, behavioral coaching, and continuous remote health monitoring, presenting a scalable and effective method for obesity management.

Specialized Mental Well-being Solutions

The mental health domain is currently experiencing significant advancements with the introduction of digital interventions designed to cater to a diverse array of needs, ranging from stress alleviation to the treatment of more profound psychological

conditions. These innovative digital platforms provide accessible and non-judgmental spaces for individuals in pursuit of mental health support, thereby facilitating a shift toward more inclusive mental health care.

Figure 5. Various benefits of a digital health ecosystem



Digital Health Challenges in Rural Areas

Despite enormous differences between high- and low-resource countries, access to adequate healthcare in rural and remote environments is a universal challenge. Telehealth care is only available when adequate electricity and ICT arrangements exist. Human and cultural factors such as language barriers and the lack of convincing evidence

from cost-effectiveness models that slowdown the investment opportunities. Patients also face technical issues during the implementation of telemedicine in rural areas. Technical challenges include network problems, frequent power cuts/lack of electricity, blurred images, poor sound quality/cut-off sound during video consultations due to a slow internet connection, and interrupted service due to poor network quality. Regulatory pathways for digital therapeutics are still evolving and vary significantly across geographies, further delaying the commercialization of products.



Digital Health Opportunities

Digital health offers various opportunities for education, training, and awareness among all stakeholders in the healthcare sector. These opportunities include platforms for health education, training programs, and raising awareness about health issues. For instance, medical students can engage in telesurgery and teleconsultation, while doctors can enhance their IT skills during healthcare delivery. Patients also benefit by learning how to use technical devices effectively.

One significant advantage of digital health is its cost-effectiveness in treatment. By reducing travel costs and eliminating excess consultation fees, patients from rural areas can access specialist consultations more conveniently.

Digital health also promotes equity and improves access to healthcare services. Patients from rural areas, who may face challenges accessing traditional healthcare facilities, show increased interest in digital health services. Telehealth services for various healthcare needs, including diabetic care, childcare, and maternal healthcare, are as effective in rural areas as in urban settings, making healthcare more affordable and accessible.

Furthermore, there is a growing interest in the future use of digital health. Pilot projects and case studies have demonstrated positive outcomes, paving the way for implementing digital healthcare policies on a larger scale. Training programs for healthcare professionals and patients are essential to ensure the smooth integration and utilization of digital health technologies in healthcare settings.



Improving Digital Healthcare: The Way Forward

One of the key considerations in providing digital health is understanding the needs and perspectives of patients. There can be many challenges and difficulties in integrating digital health into daily life, such as concerns about data security and privacy and the lack of alignment with patients' needs and values. To address these issues, it is important to develop robust systems with strong data security and privacy and to engage with technology developers and patients early on to ensure digital innovations address patients' concerns. It is also essential to involve healthcare professionals and adapt healthcare systems to use digital health. The current healthcare infrastructure may be unable to accommodate integrating new digital health technologies, and there may be concerns about reimbursement for these services. Many digital health solutions are still in their early stages and will need time to evolve and get approval for clinical accuracy. Improving the relationship between researchers, scientists, clinicians, regulators, and technology developers can help provide better healthcare and support for patients.

90%

of OECD countries have electronic health portals

only 42%

could access and interact with data through portal

Advancements in Diagnostics: A Look at the Disruptive Trends in the IVD Market (2024 and Beyond)

The in vitro diagnostics (IVD) sector is experiencing notable transformation despite a declining trend in the COVID-19 diagnostics market. This transformation stems from a rising awareness of early disease detection, personalized medicine, and precise healthcare interventions. Technological innovations, notably the integration of artificial intelligence (AI) and molecular diagnostics into diagnosis and treatment monitoring, are reshaping diagnostics and enhancing accuracy and efficiency.

While the surge in COVID-19-related demand for vaccines, drugs, and diagnostics has diminished, it has instilled unprecedented dynamism in the market, prompting intensified focus on point-of-care testing (PCOT) and the development of rapid diagnostic solutions. Consequently, the overall IVD market is poised for continued growth owing to the escalating rates of chronic illnesses, demographic shifts toward aging populations, and an escalating emphasis on preventative healthcare strategies.

However, persistent challenges about regulatory compliance, reimbursement protocols, and cost containment exert pressure on the market. Even so, the market is anticipated to adapt to consumer needs, with the overarching impact to be positive in the long term.

The latest market analysis and forecast for the IVD market is in the sample [Link](#)

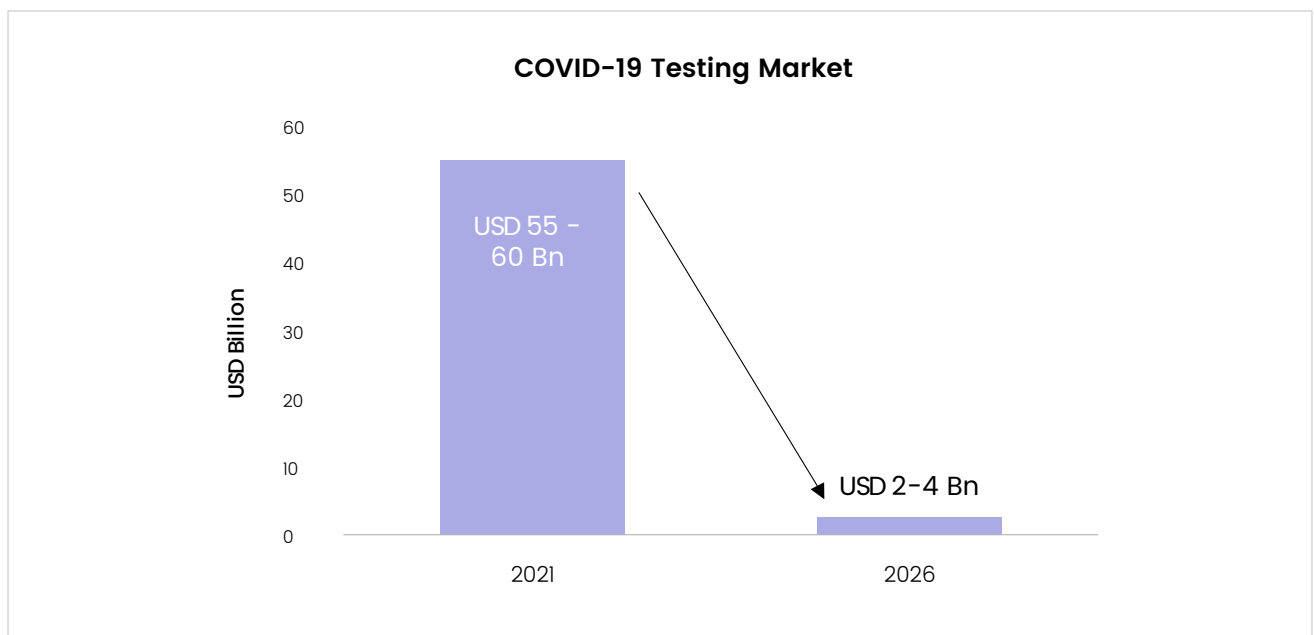
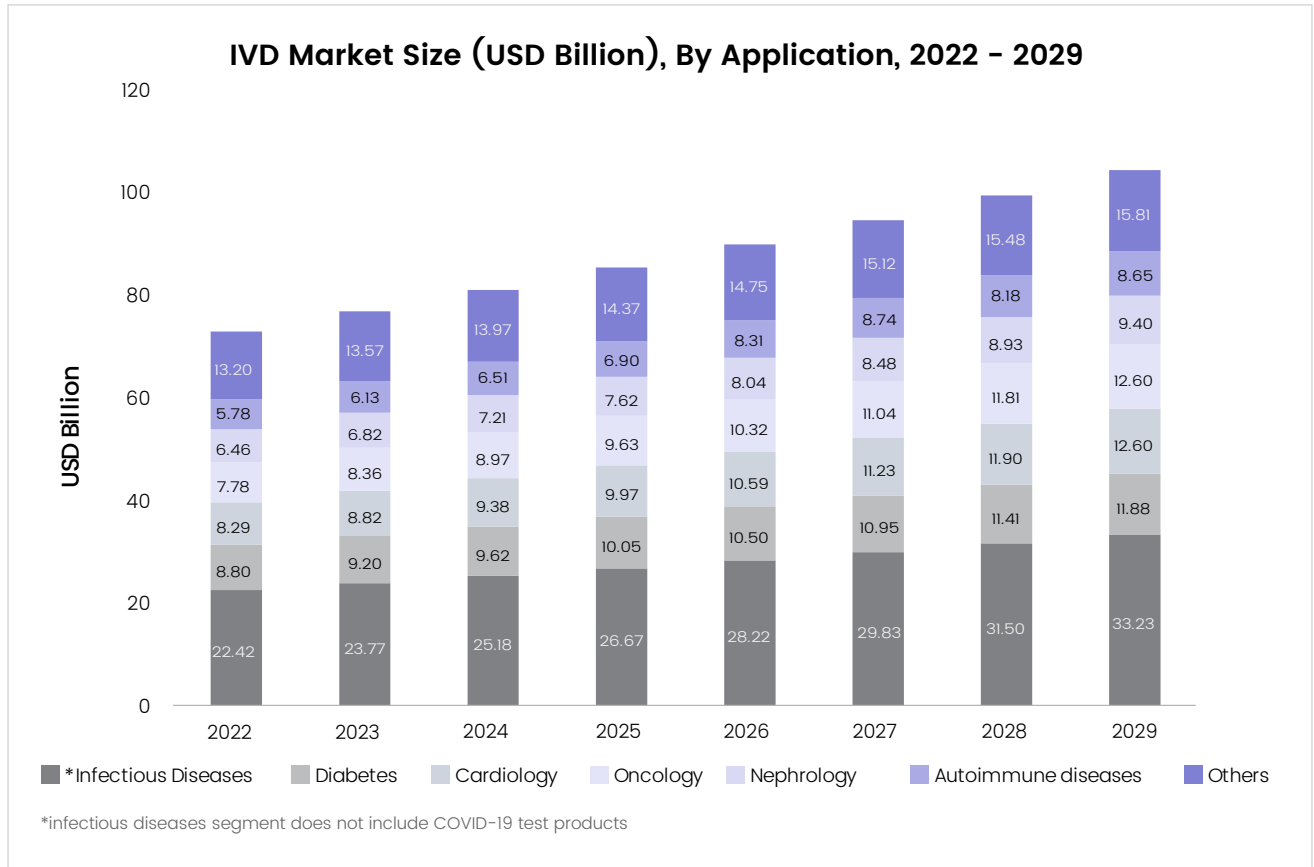
5-6%

Compounded annual growth rate of Global IVD market from 2023 – 2029

55-60%

Contribution of top 7 players in the IVD market by revenue for 2024

Figure 6: Although the COVID-19 diagnostics market has been in the declining phase, the overall market impact is positive due to high growth applications – Oncology and Autoimmune Diseases



Source: SGA estimates, SEC filings, press releases, investor presentation, scientific journals, publications and articles



Integration of AI into IVD

AI is revolutionizing IVD, ushering in a new era of data-driven healthcare. Companies like Roche are at the forefront, developing AI-powered tools that unlock newer insights from diagnostic tests. These intelligent IVD leverage machine learning (ML) to analyze complex patterns and improve diagnostic accuracy. This helps in earlier disease detection, better treatment decisions, and ultimately, translating to improved patient outcomes. Integrating AI with IVD holds immense potential to personalize medicine and optimize healthcare delivery. However, challenges like regulatory hurdles and data privacy concerns need to be addressed to ensure the responsible and ethical implementation of AI in IVDs. Despite these hurdles, the future of IVD is undeniably AI-powered, promising a new landscape of accurate, efficient, and personalized diagnostics.

Emergence of POCT

The POCT market is experiencing a surge in advancements, transforming diagnostics from hospital labs to near-patient settings. Miniaturized devices like finger-prick blood glucose monitors are commonly used, but the trend extends to more complex tests. Key players like Abbott and Roche develop portable analyzers for rapid infectious disease diagnosis. Startups are exploring POCT applications in areas like micronutrient deficiencies. Molecular tests, earlier restricted to labs, are now making waves in mainstream point-of-care (POC) diagnostics. As the pandemic accelerated the adoption of specifically RT-PCR technology in POC, a few companies also succeeded in bringing complex technologies such as RT-LAMP (LamPORE by Oxford Nanopore) near patients. This trend of decentralized diagnostics empowers medical professionals with faster results, allowing quicker treatment decisions and improved patient outcomes.



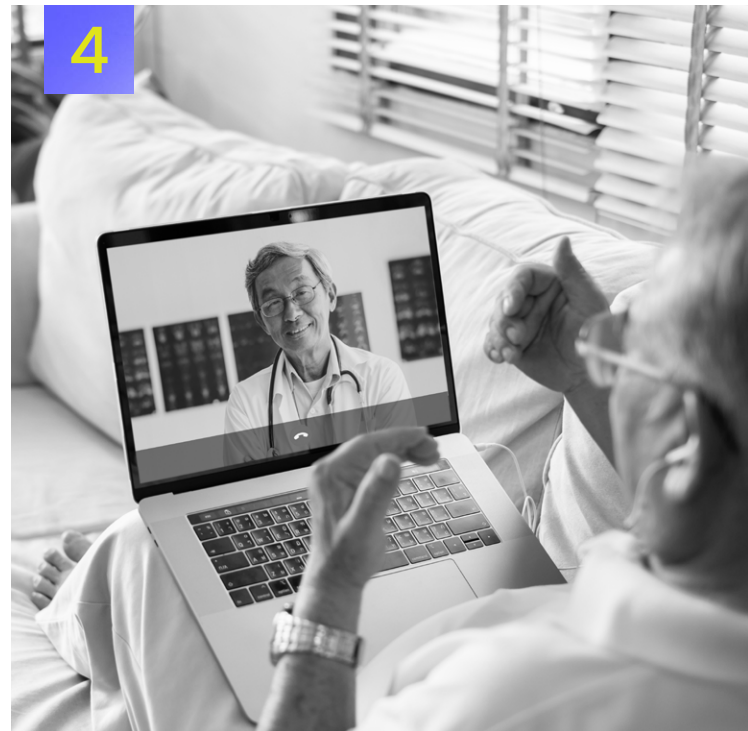


Telehealth and Remote Diagnostics

The healthcare landscape is transforming, with telehealth emerging as a powerful tool. IVD is also a part of this revolution, thus creating a dynamic duo. Companies have been trying and were successful to some extent in creating user-friendly home test kits paired with secure online consultations for swift diagnosis. Industry leaders like LabCorp and Siemens Healthineers are pioneering this approach. By introducing virtual consultations with at-home testing, healthcare providers are increasing access to healthcare, especially in remote locations and for chronic conditions. This powerful synergy between telehealth and IVD paves the way for a future of efficient, convenient, and personalized healthcare.

Personalized Medicine Revolution

The field of IVD is undergoing a revolution driven by personalized medicine. Key players like Roche, Abbott, and Illumina are significantly investing in developing IVD tests tailored to individual genetic makeup and health profiles. This trend is fueled by advancements in genomics and bioinformatics, enabling more precise diagnoses and targeted treatment plans. For instance, Roche's cobas® EGFR Mutation Test identifies lung cancer patients who can benefit from specific therapies. Abbott's companion diagnostics for immuno-oncology drugs help determine patients who are most likely to respond. This shift toward personalized IVD would improve patient outcomes, reduce unnecessary treatments, and pave the way for a future of proactive healthcare based on individual needs.



SGA VIEW

The revolutionary transformation of the IVD sector is due to AI-driven diagnostics, POCT, and telehealth advances. Various key companies are capitalizing on these trends, and a few emerging companies, such as QuantuMDx, are also making strides with innovative technologies.

To excel in this dynamic landscape, IVD firms must:

Commit to strategic AI investments to bolster data analytics and diagnostic capabilities

Embrace the paradigm of personalized medicine by forging partnerships for companion diagnostics

Develop intuitive and accessible POCT solutions to facilitate decentralized testing

Pursue integration with telehealth platforms to offer seamless remote patient care experiences

By strategically embracing these transformative trends, IVD companies can elevate healthcare outcomes, fortify their market positioning, and shape the future trajectory of diagnostics.

04

Navigating China's Pharmaceutical Market: Key Strategies for Access and Success



The Chinese pharmaceutical market is the second-largest market in the world, driven by rising healthcare needs. An increasing aging population represents a plethora of opportunities for biopharmaceutical companies. However, accessing this lucrative market requires navigating a regulatory and reimbursement maze.

This article explores the major factors needed to access the Chinese market, including the all-pervasive National Drug Reimbursement List (NRDL).

The Entry Door — Marketing Approval

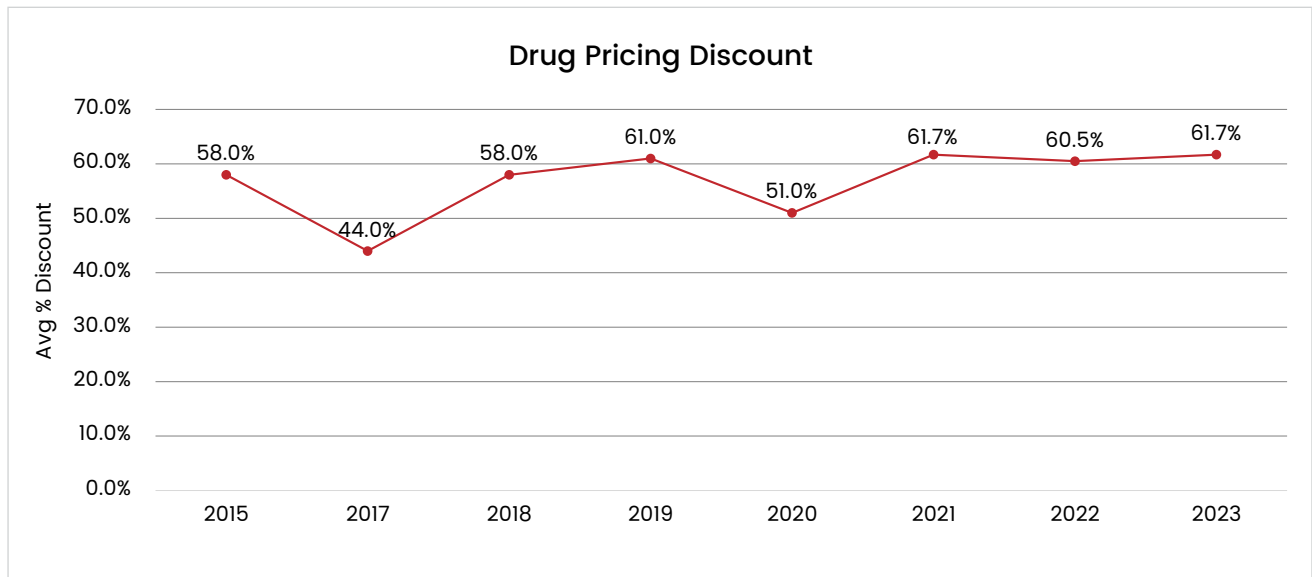
Every drug/device has to go through the rigorous National Medical Products Administration (NMPA) to validate product efficacy and safety before the go-ahead to market in China.

The Silver Bullet – NRDL Inclusion

The NRDL, with its coverage of over 90% of the Chinese population, ensures partial or full reimbursement for all drugs on the list. However, all products need to go through a strict negotiation process to be on the list. Companies should offer significant discounts, most often exceeding 60% to

book a spot and ensure reach to the vast Chinese market. Inclusion in the NRDL can be a double-edged sword. While access will be highly enhanced, profit margins will be squeezed. Moreover, owing to NRDL's inherent public nature, it can be a leading influencer for pricing strategies in neighboring markets.

Figure 7: Drug pricing discount 2016–2023



Source: Nature and media reports

A Multidimensional Approach

China has the second-highest rates of cancer. Additionally, the increasing shift toward Western lifestyles will fuel the demand for high-value innovative medicines. Innovator companies unwilling to trade off the value of their innovation for access can look at other approaches like commercial health insurance and other very China-specific approaches. There are increasing opportunities to explore early access via Hainan, the Great Bay Area, and Special Development Zones like Shanghai and Shenzhen. These afford clinical utilizations locally before the formal regulatory approval. More importantly, real-world evidence (RWE) collected during early access programs can help accelerate eventual approval. Some innovative therapies, including YUTIQ, went through this process and succeeded. In September 2022, EyePoint Pharmaceuticals and OcuMension Therapeutics partnered with Boao Lecheng Super Hospital (part of the Hainan pilot zone) to study YUTIQ as a treatment for chronic non-infectious

uveitis and the evidence collected helped in being included in the reimbursement list.

Manufacturers can also focus on other affordability axes, including commercial health insurance (CHI), innovative programs such as crowdfunding, rebate programs, and patient assistance programs. Of this, city CHI has emerged as a popular option with increased enrolment, moving from a few cities to over 150 cities and giving access to over 100 million people to their formularies.

A proven method of expanding access and reimbursement is looking at label expansion for already-covered products. For example, within a year in the market, abemaciclib, the first cyclin-dependent kinases (CDK)4/6 inhibitor to be covered in the list, was able to get broader approval to include adjuvant treatment for early breast cancer.



Conclusion

There is hope for innovator products as China continues to align more with common practices in the developed markets regarding HTA, value communication, and pricing. Steps such as doing away with the provincial reimbursement bodies help in centralizing the decision-making process for coverage and reimbursement. However, the prospect of a low digit GDP growth (for the first time in many years) will force a hand on cost containment measures.

The focus needs to be on the following:



Unmet needs of the Chinese population: The shift from traditional to western lifestyles and better healthcare facilities have improved diagnosis rates and the ability to detect diseases at an earlier stage. There are multiple disease areas that are underserved and can be tapped into. Moreover, using real-world data and evidence can be a key driving factor.



Longer term view: The rare diseases area is a small market but has significant attention from the Chinese authorities. While funds at the province level have dried up, there are efforts to push this at a national level, but given the priority, this might be a valuable pathway for manufacturers.



Understand and look for leverage: The dynamic Chinese healthcare market always has newer and improved access avenues. Thus, manufacturers need a strong market intelligence mechanism to pick up these cues at national and provincial levels.

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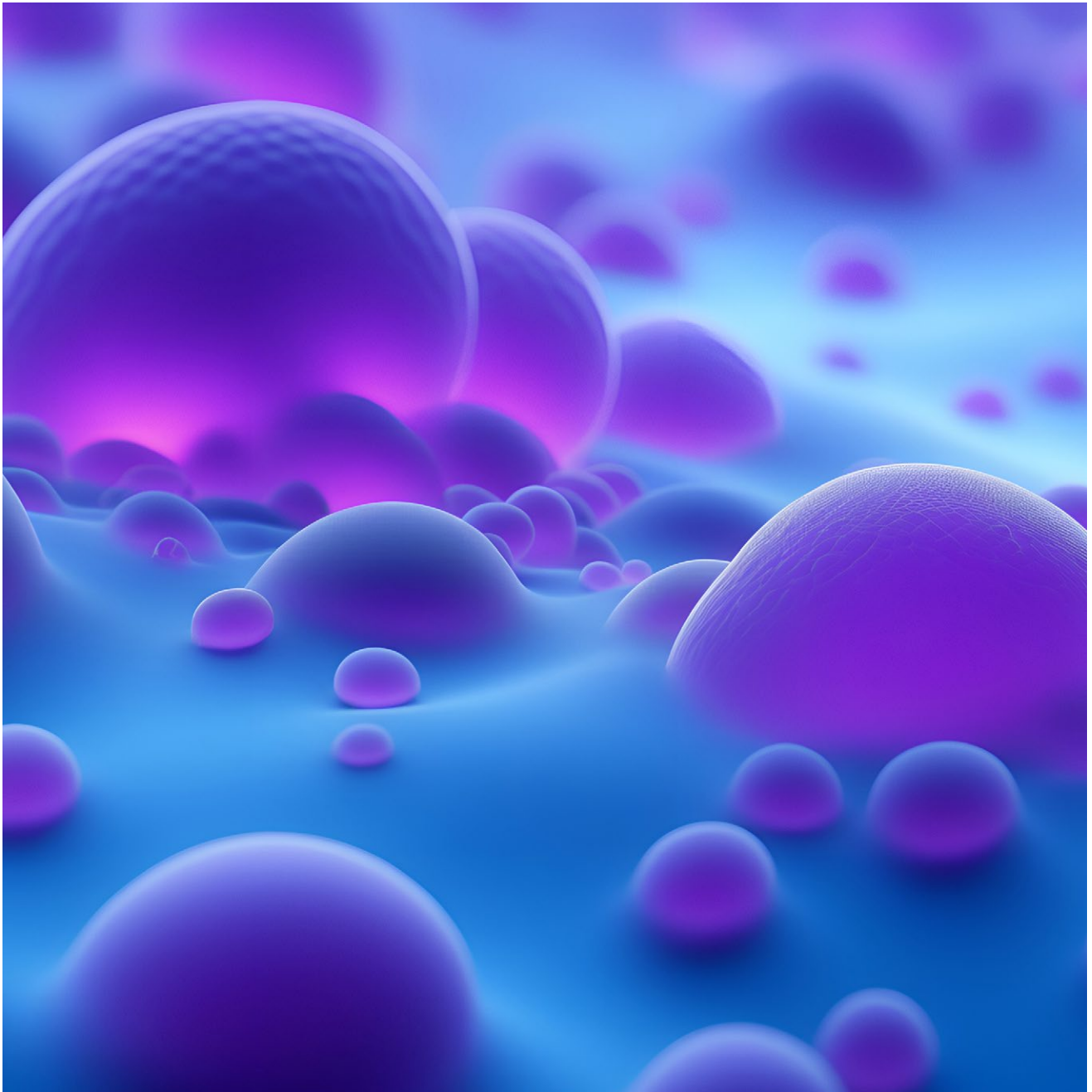
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