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ZEST

ONE-STOP SOLUTION FOR HEALTHCARE INSIGHTS

NEWSLETTER ISSUE 3

SG Analytics' premium healthcare monthly newsletter,

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

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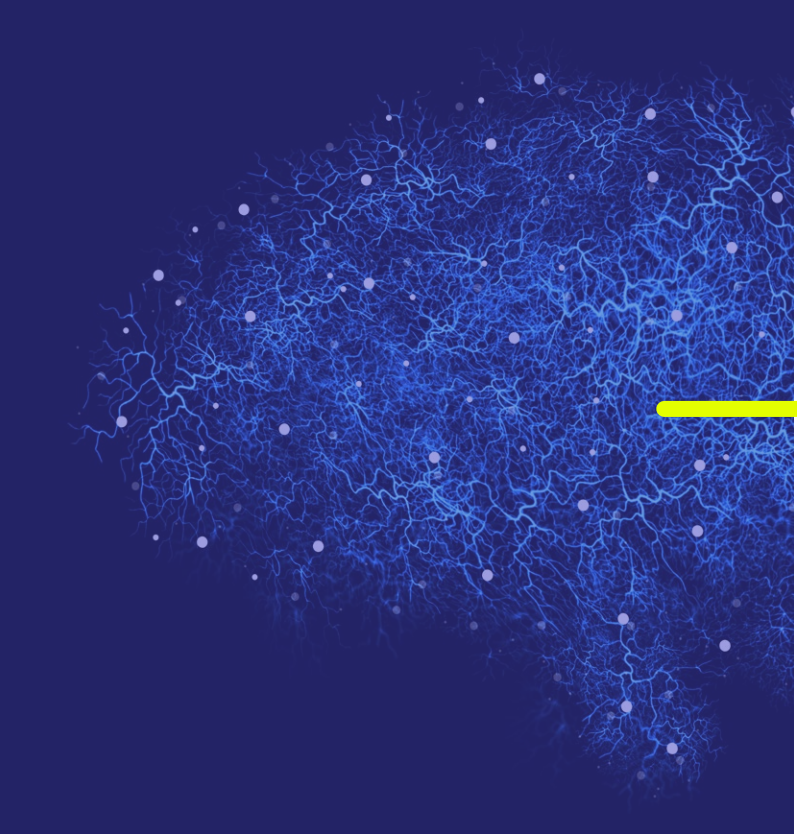
Life's Possible



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Behavioral Health: A Global Challenge and a Tech-driven Future

Behavioral health, encompassing mental health and substance use disorders, is a critical and often under-addressed aspect of overall well-being. It affects millions globally, impacting individuals, families, societies, and economies. SGA delves into the key issues in behavioral health, explores potential solutions with added nuances and examines the exciting role technology is playing in transforming the landscape.

1 billion

people globally live with a mental disorder

3 million

deaths annually attributed to alcohol and drug use disorders

Scope of Problem:

- **Global Impact:** According to the World Health Organization (WHO), nearly 1 billion people globally live with a mental disorder, with 3 million deaths annually attributed to alcohol and drug use disorders. This poses a significant burden on healthcare systems worldwide, requiring strategic resource allocation.
- **Economic Burden:** Mental health conditions cost the US economy an estimated $1 trillion annually in lost productivity and healthcare expenses. This cost is further compounded by the indirect costs associated with absenteeism, presenteeism (reduced productivity while at work), and increased healthcare utilization for physical ailments linked to mental health such as increased blood pressure or weight gain.
- **Widespread Prevalence:** In the US alone, an estimated 1 in 5 adults experiences mental illness each year. However, this statistic doesn't capture the full picture. Many individuals experience sub-clinical symptoms that significantly impact their quality of life but do not meet the diagnostic criteria for a formal disorder. Additionally, certain demographics, such as adolescents, young adults, and racial/ethnic minorities, face higher prevalence rates.
- **Social Determinants of Health:** According to the National Institutes of Health (NIH), over 3.6 million US youth aged 12 to 17 used illicit drugs in 2022. Alarmingly, an average of 22 youth aged 12 to 18 died each week from an overdose during that same period. More worryingly, most of them did not display the usual warning signs of substance use. The impact of housing stability on people who use opioids and stimulants has emerged as an important topic. Research has confirmed that people experiencing a fatal overdose involving stimulants were more likely to be homeless compared to overdose from opioids alone.

Common Behavioral Health Issues:

- **Mental Disorders:** This broad category includes a spectrum of conditions with varying levels of severity and impact. A few common examples include:
  - **Depression:** Characterized by persistent feelings of sadness, loss of interest, and changes in sleep and appetite.
  - **Anxiety Disorders:** Manifest as excessive worry, fear, and physical symptoms like rapid heartbeat and sweating.
  - **Bipolar Disorder:** Involves extreme mood swings between depression and mania.
  - **Schizophrenia:** Characterized by hallucinations, delusions, and disorganized thinking.
  - **Eating Disorders:** Characterized by abnormal eating habits and a distorted body image.
- **Substance Use Disorders:** Characterized by problematic use of alcohol, illicit drugs, or prescription medications. This can lead to dependence, addiction, and severe health consequences.

Factors Contributing to Behavioral Health Issues

A complex interplay of factors can contribute to behavioral health issues. Here's a breakdown with added details:

- **Biological Factors:** Genetics, brain chemistry, and hormonal imbalances can play a role. For instance, a family history of mental illness increases the risk, while imbalances in neurotransmitters like serotonin and dopamine can contribute to depression and anxiety.
- **Psychological Factors:** Adverse childhood experiences (ACEs) such as abuse, neglect, or household dysfunction can leave lasting emotional scars, increasing vulnerability to mental health problems. Additionally, negative thought patterns, like cognitive distortions, can fuel anxiety and depression.
- **Social Factors:** Poverty, discrimination, social isolation, and lack of social support can significantly impact mental and emotional well-being. Additionally, exposure to violence, trauma, and chronic stress can be major contributing factors.

Challenges in Addressing Behavioral Health

There are several significant hurdles to overcome in effectively addressing behavioral health issues:

- **Stigma:** Shame and social stigma surrounding mental health can prevent people from seeking help. This stigma can stem from a lack of understanding and misconceptions about mental illness.
- **Limited Access to Care:** Shortages of qualified professionals, particularly in rural areas, create geographical disparities in access to treatment. Additionally, long wait times and limited appointment availability can further discourage people from seeking help.
- **High Costs of Treatment:** The cost of therapy, medication, and hospitalization can be a major barrier, especially for those without adequate insurance coverage. This financial burden can force individuals to choose between essential care and other necessities.

Solutions: A Multi-pronged Approach with Nuanced Strategies

To effectively address these challenges, a multi-pronged approach is needed:

- **Increased Awareness and Education:** Public health campaigns and comprehensive educational initiatives can help reduce stigma and encourage help-seeking behavior. These campaigns should not only target the general public but also healthcare professionals, educators, and employers. Educational programs should promote mental health literacy and normalize seeking help for mental health concerns. In an historic and welcome move, the United States Preventive Services Task Force issued draft recommendations that adults under 65 be screened for anxiety.
- **Expansion of Mental Health Services:** Increasing the number of therapists, counselors, and psychiatrists, along with initiatives to attract professionals to underserved areas, is crucial. Additionally, exploring alternative models of care delivery, such as peer support groups and community-based mental health programs, can help bridge the gap. For example, Calm health provides access to easy to digest and engaging evidence based mental health content.

- **Legislative and Government Support:** Ensuring that mental health is covered at similar levels as physical health will remove financial burden for those seeking help. The federal Mental Health Parity and Addiction Equity Act, enacted in 2008, doesn't require insurance plans to offer mental health coverage – but if they do, the benefits must be equal with coverage for other health conditions. But despite the federal law, many insurers continue to charge higher copayments for mental health care, limit the frequency of mental health treatment, or impose more restrictive prior authorization policies. Hence the recent rule from the Biden administration takes action to make it easier to access in-network mental health care. This rule would make clear that health plans need to evaluate the outcomes of their coverage rules to make sure people have equivalent access between their mental health and medical benefits.

Targeted Innovations for Youth

The US Food and Drug Administration (FDA)-funded projects in association with National Institute of Drug Abuse (NIDA) are focusing on the following innovations with emphasis on adolescents and children.

1

AI-based Algorithms

Intelligent tools analyzing data for diagnosing or treating youth drug misuse.

Example

AI analyzing social media for substance misuse patterns.

2

Digital Therapeutics

Digital solutions for diagnosing and managing substance misuse.

Example

An app providing therapy exercises for managing cravings.

3

Wearable Technologies

Devices detecting and treating opioid-induced issues.

Example

A wristband monitoring vital signs to detect opioid overdose.

4

Therapeutic Devices

Innovations like neuromodulation improving substance use disorder treatment.

Example

A device using electrical stimulation to reduce cravings.

- **Also Advocate and Support Online Therapy in an Easy to Access Format:** Online therapy, mobile apps, and web-based resources can help. For example, Better Help, with over 30,000 licensed therapists, has covered millions of patients in an 100% online format and at significantly more affordable levels than brick and mortar therapy.
- **Require Integrated Data, Marketing, and Administrative Systems:** Being very fragmented, there is not a lot of integration or investment of technologies. Recent private equity investments in behavioral health care facilities are likely to help improve this. A recent study by Wharton University found that 6% of mental health facilities and 7% of addiction treatment facilities nationwide are now owned by private equity firms. In Colorado, Texas, and North Carolina, private equity firms hold roughly 25% of those facilities. To read more about private equity (PE) investments refer to Box 1.

A look at how PE firms are investing in behavioral health

KKR, a major player in private equity, has significantly impacted the behavioral health sector. They started with BlueSprig in 2018 to meet the needs of children with autism and recently led a $105 million funding round for Brightline, a virtual care provider valued at $705 million. KKR's interest in health tech led to acquiring Therapy Brands for $1.2 billion in 2021 and launching Geode Health, offering digital and in-person mental health services. KKR's investments, especially in technology, are shaping the industry's use of digital tools for outcome tracking in mental health care.

Table 1: Review of Key Online Therapy Apps

App	Costs	Insurance	Services	Privacy
Talkspace	Starts $69/month	Covered by a variety of insurance net-works (Premera, Optum, Blue Cross Blue Shield, Aetna, and Cigna); FSA/HSA also accepted	Virtual therapy and psychiatry for indi-viduals, teens, and couples	HIPAA compliant
Online-Therapy.com	Starts $50/week	Mostly out of pocket	Based on CBT - Live sessions via video, audio, text chat, plus texts, and worksheets	Privacy practices have been subject-ed to challenges, working with FTC to sort out
Better Help	$70-100 per week	Doesn't accept in-surance directly, but you may be eligible for reimbursement depending on your plan	Messaging, live chat, audio, and video sessions	
Grow Therapy	Starts at $24	Accepts more insur-ance with an ex-panding list	Best for in person and online (No app available)	Messaging, live chat, audio, and video sessions

Source - Healthline; SGA analysis

Note: FSA - Flexible Spending Account, HSA - Health Savings Account, HIPAA - Health Insurance Portability and Accountability Act, FTC - Federal Trade Commission, and CBT - Cognitive Behavioral Therapy.

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02

Omni Channel Analytics in Pharma: Challenges and Considerations

Traditionally, the pharma industry used to rely on their field sales teams and deep connects within the healthcare professionals (HCP) community to increase customer engagement. Although the COVID-19 pandemic led to an increase in digital interactions, it was not the only factor driving pharmaceutical companies to diversify their customer engagement strategies.

On one hand, HCPs have been increasing their digital awareness and willingness to adopt newer ways of absorbing information, while, on the other hand, marketing teams within pharma companies have been coming under increasing pressure to justify the spend on marketing efforts. However, COVID-19 pandemic served as a significant catalyst. What was a gradual progression was given a massive shot in the arm.

The return of face-to-face meetings and conferences did not mean going back to the old ways of working. Instead, it meant additional touchpoints from a customer (HCP) journey point of view. It has now become necessary to combine information from your sales team with information accessed by your HCPs in order to ensure that your marketing efforts are targeted and reaching the intended audience. This has propelled the growth of data being generated, made available, collated and then used effectively to generate insights.

36%

HCPs expect educational content from pharma companies to have a "higher influence on prescribing and product decisions

But there is a mismatch:

70%

HCPs feel that sales teams using digital content don't understand their needs and expectations

As channels of communication proliferated, marketing teams ended up grappling with creating 360o views of the customer. Imagine a situation where the sales team regularly updates details of face-to-face meetings in your CRM, your marketing efforts in terms of campaigns that are run and website information on customer visits are captured within your martech solutions, and you are trying to bring these two sources of information together. But wait! Aren't you forgetting the WhatsApp chats that the sales team was having with HCPs? What can you do about information from professional websites that the HCP would be actively (or passively) getting? The HCP is now armed with a lot more information than what the sales team has shared with them. You wouldn't want to inundate them with more information! Wasted marketing efforts not just cost you money but a disappointed (or worse irritated) customer, which is not going to contribute to revenue growth.

This is where omni channel analytics becomes a major aspect of your marketing efforts. It is not about reducing costs alone, but also about improving customer experiences, personalization, customer satisfaction, and above all an ability to quantify these and find ways to improve upon what is being done. Focusing on not just lead generation but on customer experience as a whole and across the customer value chain moves the value of marketing from just the top of the funnel to a more broad-based enabler of revenue outcomes.

McKinsey quotes a

10–20%

increase in marketing efficiencies and cost savings by adopting analytics and omni channel approaches

The start to any omni channel analytics initiative (as is with all analytics initiatives) is data. But enterprise data is often "dark data," a mix of unstructured and semi structured data, which requires varying degrees of cleansing and wrangling. Ensuring data is complete both in terms of breadth (collect data across all touchpoints) and depth (collect data in its entirety) is an equally important part of the process. For example, in the hypothetical situation above, combining your CRM and Martech data is essential, and doing that without any gaps will ensure depth of data coverage. However, for the data to be complete from a breadth perspective, you would need to include data from the emails, chats, and even professional online mediums where you (as a salesperson and as a brand) would be interacting with these HCPs.

So as a first step, ensure that all the data is in one place. Ensuring a robust data management system is almost table stakes in today's world. The struggle is with ensuring data coverage (both from a breadth and depth perspective). This is crucial as any analytics performed on half-baked data will result in insights which may not lead to correct conclusions. Going back to the above example, if the last communication captured by the CRM system is the email where the HCP has mentioned they would be interested in knowing more about a particular drug. However, if a subsequent chat suggests a different drug instead of the original one, and this chat is missed by your analytics team, then bombarding the HCP with incorrect information will definitely lead to a poor customer experience.

5–10%

increase in HCP satisfaction and experience can be achieved by implementing omni channel analytics

The other big challenge for most pharma organizations is that data across marketing and sales is often siloed. Data ownership is often with the functions themselves and gate keepers of data often are bottlenecks to sharing and ensuring uniform availability of updated data. In addition, the problems caused by legacy systems and the ability to have complete and real-time data for one source of truth is often a challenge that needs added professional support.

Once the data challenges are addressed, the next challenge is analyzing the data for insights. In most organizations, we have seen that functional experts are not augmented with capabilities of data and analytics. One cannot truly expect a marketer or

a salesperson to be delving into data to come up with insights. Several organizations have tried to solve this by having a centralized data and analytics function. While this does perform better than having no analytics at all, the challenge we have seen with our clients in this case is that there is a contextual layer missing from the analysis. Any analysis without a business context layer would leave a gaping hole in the insights delivered. For insights to be truly useful, a complete data management process, single source of truth, must have an overlay of analytics with a business context. Only then can the insights derived be applied across the enterprise for impact at scale.

Furthermore, Generative AI has now entered the already complex realm of data incompleteness and algorithmic model construction. Suddenly, there is a rush to embrace AI across all processes. The focus, however, should be to use AI effectively rather than just use it as another tool in the system.

40%

of what we do will be affected by gen AI within the year and more beyond that. Even though pharma will be a little behind, we have already started the journey

With technology commoditizing analytics and the cost of analysis falling, what becomes even more crucial in this process is the 'human in the loop,' the contextual layer that ensures that all the predictions, recommendations, and simulations are providing value to the business. AI, by itself, is not going to solve all gaps in the process, using AI effectively is what will be the differentiator. For gaining valuable insights, contextual understanding is essential as it helps remove AI bias, ensure compliance, and determine relevant input data. It goes back to the earlier point of having a professional mix of both AI/analytics experts and domain experts working in tandem to achieve organizational goals.

Additionally, the pharma industry is a highly regulated industry. Compliance standards like General Data Protection Regulation (GDPR) and Health Insurance Portability and Accountability Act (HIPAA) limit what can be shared and what channels can be used for sharing this information by pharma companies to HCPs.

So, while implementing a process of omni channel analytics, always start with the business problem which in this case would be improving customer experience, increasing revenue, and optimizing marketing costs. Post narrowing down on the outcome, ensure data governance across sources and silos including legacy systems, frequency (refresh rates across these sources), types (real time and batch ingestion) ensuring transparent and complete data. Overlay the analytics on top which is using the single source of data to glean insights, but it is not very useful to leave it there, embedding it into the business with the contextual knowledge and driving outcomes is the final process step. It is not just AI; machine predictions still require human judgement. AI can analyze large volumes of multidimensional, real-time data to generate intelligent recommendations but when you combine that with human judgment is when business outcomes can truly be achieved.

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03

Key Trends in the Medical Devices Sector: Shaping the Future in 2024

Introduction

The landscape of medical devices is rapidly evolving, driven by advancements in technology and innovative solutions that aim to enhance patient care, streamline healthcare processes, and improve overall health outcomes. The medical devices market is projected to achieve a staggering revenue of $509.90 billion by 2024. Looking ahead, the industry is expected to witness a steady annual growth registering a compound annual growth rate (CAGR) of 5.71% during 2024–2029, leading to a projected market volume of $673.10 billion by 2029. This underscores the global significance of the medical devices market.

Worldwide demand for medical devices is rapidly increasing, with countries such as the US and Germany leading in innovation and adoption.

$73.42

billion is the estimated market volume of Cardiology Devices, making it the largest among various markets in 2024.

$179.80

billion is the estimated revenue amount for the US in 2024, making it the leader in revenue generation on the global landscape.

This newsletter explores a few of the most exciting trends shaping the medical devices sector in 2024, from the transformative power of 3D printing to the integration of artificial intelligence and wearable technology.

3D Printing

The advancement in 3D printing, also known as additive manufacturing, is gaining prominence in the healthcare sector due to its potential to enhance treatment for specific medical conditions. For instance, a radiologist could generate a replica of a patient's spine for surgical planning and a dentist could scan a damaged tooth to craft a crown precisely tailored to fit the patient's mouth. In both scenarios, 3D printing allows healthcare professionals to create products that align precisely with a patient's anatomy. The application of this technology extends beyond surgical planning and personalized dental restorations such as crowns; 3D printing has facilitated the production of tailor-made prosthetic limbs, cranial implants, and orthopedic implants such as hips and knees. Simultaneously, its transformative impact on the manufacturing of medical products, particularly high-risk devices such as implants, introduces potential implications for patient safety, presenting new challenges for oversight from regulatory bodies like the Food and Drug Administration (FDA). The anticipated market value of medical 3D printing is forecasted to reach ~$6.08 billion by 2027, covering software, hardware, services, and materials.

Preoperative Planning

3D printing technology plays a crucial role in enhancing preoperative surgical planning in orthopedics, particularly for cases requiring complex 3D visualization of the underlying anatomy and determining the appropriate implant size for intraoperative use. This technology allows for the preoperative creation of 3D structures that accurately represent the patient's actual anatomy and pathology as encountered during surgery. These 3D models enable surgeons to plan their procedures based on the printed replica, determining the surgical approach, method of reduction, required implant size, position, orientation, and allowing for rehearsal of the procedure on the 3D-printed anatomical parts.

New Medical Devices and Instruments

Medical devices must adhere to various specifications, including meeting an optimal balance in terms of size and weight, conforming to the specific shapes of the human body, and successfully undergoing designated endurance tests. 3D printing can also help medical device developers and manufacturers reduce both cost and time to market. For instance, 3D printing has been employed to develop a prototype of an inhaler, complete with necessary fixtures and jigs, to reduce production time from one to two weeks to one to two days and achieve a cost reduction of 90%, dropping from £250 to £11 or $343 to $15.

Affordable Prostheses

Prosthetics 3D printing utilizes additive manufacturing, creating artificial body parts for patients in need. Amputation surgery may be required in severe cases. 3D-printed prosthetics can help in replacing the missing body parts, offering advantages such as reduced manufacturing time, cost, and weight compared to traditional methods. Traditional prosthetics involve complex processes, which are expensive (usually over $2,000) and have long waiting periods (3–6 weeks). In contrast, 3D printing is affordable, has a quick turnaround, and materials are easily accessible. A 3D-printed arm generally costs $395 and can be produced in one day.

Bioprinting, Tissue Engineering, and 3D Printed Organs

Progress in 3D printing has enhanced the possibility of synthesizing living tissues. Referred to as 3D bioprinting, this technique entails the precise layering of cells, biological scaffolds, and growth factors, aiming to generate bioidentical tissue for diverse applications. By utilizing computer-aided design (CAD) and manufacturing processes, 3D bioprinting enables the accurate placement of living cells, biomaterials, and biochemicals to construct functional human tissues and organs. The potential uses of this technology are extensive, encompassing drug testing and development, disease modeling, regenerative medicine, and, ultimately, organ transplantation.

Table 2: 3D Printing Clinical Trial Pipeline

Interventions (Procedure)	Conditions	Phases	Sponsors and Collaborators
VISTA Technique and 3D Printed PMMA Implant	Management of Gummy Smile	Phase III	Ain Shams University
Conventional Guided Bone Regeneration and Simultaneous Implantation	Bone Deformity	Phase III	Mansoura University
Virtual Surgical Planning (VSP) and Free-hand Surgery	Oral Cavity Cancer	Phase II/III	University of British Columbia
Three-dimensional Patient-specific Bioprinting Trachea Implantation	Thyroid Cancer	Phase I/II	Ja Seong Bae and Korea Health Industry Development Institute
3D Printing	Breast Reconstruction	Phase I	Xijing Hospital

Source: ClinicalTrials.gov

Deals Flash

Deal Announced: May 7, 2024

Osteopore

Deal Type	Equity Offerings
Deal Value	$2.9 million

Osteopore, a global leader in 3D-printed biomimetic and bioresorbable implants, successfully raised $2.9 million through an entitlement offering of shares. The funds will be utilized to bolster Osteopore's balance sheet, sustain sales momentum, and support the development of innovative products. Additionally, the capital will aid in securing market approvals, acquiring complementary technologies, exploring mergers and acquisition (M&A) opportunities, and enhancing working capital.

Deal Announced: March 06, 2024

DAI-ICHI LIFE instalimb

Deal Type	Acquisition
Deal Value	$0.66 million

The Dai-ichi Life Insurance invested $0.66 million in Instalimb to provide high-quality and affordable 3D-printed prosthetic limbs, aiming to improve the quality of life for people in developing countries. The company anticipates high financial returns from this investment. Additionally, Dai-ichi Life will offer financial support and continually monitor the progress of Instalimb's initiatives.

Deal Announced: March 06, 2024

CARCINOTECH Reinventing Cancer Research

Deal Type	Venture Financing
Deal Value	$5.33 million

Carcinotech has secured $5.33 million in venture financing to develop its 3D-printed micro-tumor technology. The company aims to build on its success in the UK and Europe, with plans for US expansion later this year.

A study in the US found that even at a low utilization rate of 5%, using 3D-printed anatomic models in orthopedic surgeries could save a hospital over $130,000 per year, accounting for the mean cost of surgery per minute. At a utilization rate of 20%, the annual savings could exceed half a million dollars. Furthermore, a 2023 survey of surgeons revealed that nearly 95% affirmed the value of 3D-printed models as a clinical tool for presurgical planning. Over 90% stated that these models were beneficial for patient communication and as an educational tool for trainees. Additionally, another survey of dentists indicated that the main reasons for using 3D printers were improved efficiency and reduced costs.

During 2001–2020, a total of 9,665 international patent families (IPF) were published among 3D printing technologies with health and medical applications globally. Medical equipment had the highest number of IPFs in this time with 4,120. While implants and prostheses followed just behind with 4,107 IPFs published.

Smart Technology and Wearables

Smart technology and wearable devices are becoming integral components of modern healthcare, offering real-time monitoring and personalized patient care. Today, the wearable market encompasses various devices, including smartwatches, fitness trackers, headphones, and extended reality (XR) devices such as virtual reality (VR) headsets and augmented reality (AR) glasses. As a promising segment of the consumer electronics industry, the wearable market is forecast to reach approximately 560 million device shipments in 2024, with this number expected to grow in the coming years.

1

Fitness Trackers

Devices such as Fitbit and Garmin track physical activity, heart rate, sleep patterns, and stress levels, providing valuable health data. Advanced features such as ECG monitoring, fall detection, and blood oxygen level tracking enhance their utility.

2

Wearable ECG Monitors and Continuous Glucose Monitors (CGMs):

Devices like KardiaMobile and CGMs such as Dexcom G6 and Freestyle Libre are vital for heart health monitoring and diabetes management, offering real-time data and trends without the need for regular finger-prick testing.

3

Smart Inhalers

Companies such as Propeller Health are developing smart inhalers that track medication use, remind patients to take their medication, and collect data to better manage respiratory conditions such as asthma and COPD.

4

Wearable Defibrillators

Devices such as the ZOLL LifeVest continuously monitor the heart and deliver life-saving shocks if necessary, providing a critical safety net for individuals at risk of sudden cardiac arrest.

5

Smart Hearing Aids

Advanced hearing aids from ReSound and Oticon not only amplify sound but also connect to smartphones, allowing users to adjust settings and stream audio directly, enhancing the overall hearing experience.

Table 3: Wearable Devices Clinical Trial Pipeline

Interventions (Device)	Conditions	Phases	Sponsors and Collaborators
RAE	Substance Use Disorders	Phase II/III	ContinueYou, University of Massachusetts, and University of Texas at Tyler
Sustained Acoustic Device with 2.5% Diclofenac Patch	Osteo Arthritis Knee	Phase II	ZetrOZ
Basimglurant with Crossover to Placebo	Tuberous Sclerosis Complex	Phase II	Noema Pharma
Care4AD System	Alzheimer Disease and Dementia	Phase I/II	Bijan Najafi and BioSensics
Sustained Acoustic Device with 2.5% Diclofenac Patch	Bone Fracture	Phase I	ZetrOZ

Source: ClinicalTrials.gov

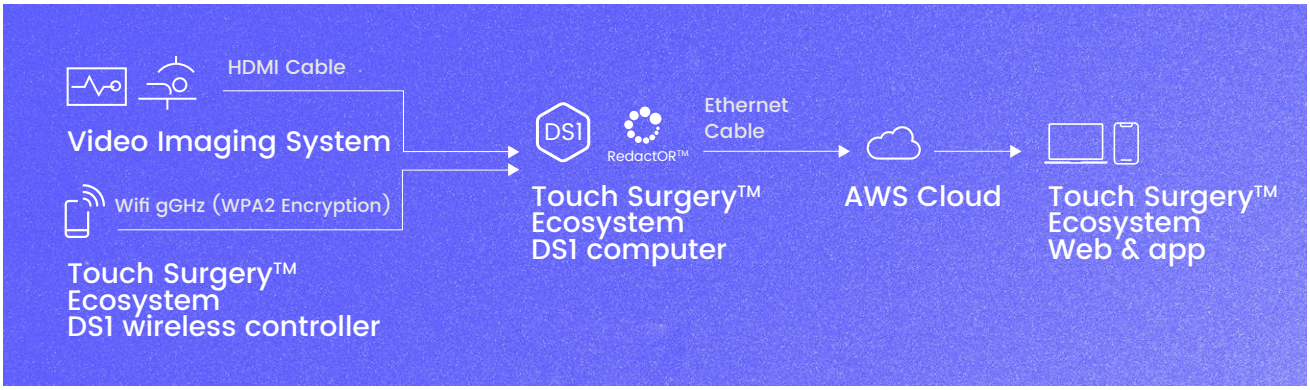
Advancements in Minimally Invasive Procedures

Robotic Surgery

Robotic-assisted surgeries are becoming increasingly prevalent, offering enhanced precision, reduced invasiveness, and faster recovery times. The integration of robotic, imaging, and sensing technologies has led to the creation of novel surgical platforms that provide surgeons with enhanced dexterity, precision, and surgical navigation while reducing the invasiveness and increasing the efficacy of interventions. Recent advancements focus on miniaturizing robotic devices, better integrating advanced imaging modalities intraoperatively, increasing the level of autonomy and cooperation with the clinical team, and improving integration within the surgical workflow.

On 16th July 2024, Medtronic announced the launch of its new Live Stream function for the Touch Surgery ecosystem of digital technologies in the US and Western European Union (WEU). In April, the company unveiled its Live Stream technology, which features AI capabilities to accompany the Touch Surgery digital offering. Touch Surgery Live Stream is an easy-to use intraoperative coaching platform that integrates seamlessly with the Touch Surgery ecosystem.

Figure 1: Touch Surgery Live Stream: A Security-first Approach to Data Flow



Source: ClinicalTrials.gov

Image-guided Interventions

Advanced imaging technologies are guiding minimally invasive procedures, improving accuracy, and reducing complications. Image-guided interventions support research on using novel image-directed technologies for guidance, navigation, tissue differentiation, and disease identification to reach specified targets during therapeutic procedures. These interventions span the continuum from noninvasive to minimally invasive to open surgical techniques, enhancing the precision and effectiveness of various medical treatments.

Table 4: National Institute of Biomedical Imaging and Bioengineering (NIBIB) Funded Projects for Image-guided Interventions in 2024

Project Title	Institution	Total Funding
3D Multi-Functional Catheter-based Imaging of Coronary Lesion Composition, Structure, and Hemodynamics in Intermediate Stenoses	Georgia Institute of Technology	**$609,287**
Improved Surgical Navigation Using Video-CT Registration	Johns Hopkins University	**$594,378**
Improved Arrhythmia Ablation via MR-guided Robotic Catheterization and Multimodal Clinician Feedback	Georgia Institute of Technology	**$592,997**
A Novel Paradigm of Sensitization of the Tumor Microenvironment with Image-guided Ultrasound Cavitation and Mechanotherapeutics for Targeted HCC Treatment	University of Washington	**$590,318**
Fluorescence Image-guided Surgery, Adjuvant PDT, and the Immune Response	Case Western Reserve University	**$586,967**
A Multi-robot System for Semi-automated Image-guided Vertebral Augmentation	Johns Hopkins University	**$546,252**
Image-guided Surgical Robotic System for Femur Fracture Reduction	Rowan University	**$502,056**
Advanced C-arm Imaging Platform for Histotripsy Treatment of Liver Tumors	University of Wisconsin-Madison	**$470,953**
Improving Image-guided Surgery Precision and Reliability with Real-time Modification Tracking in Endoscopic Sinus and Skull Base Surgery	Rochester Institute of Technology	**$459,375**
Easyvis: Flexible, Immersive Three-dimensional Laparoscopic Surgical Visualization through Multi-camera Arrays	University of Wisconsin-Madison	**$381,886**
Deformable Motion Compensation for 3D Image-guided Interventional Radiology	Johns Hopkins University	**$361,069**

Source: NIBIB

Cybersecurity and Data Privacy

Prioritizing security is not just a regulatory requirement for healthcare organizations; it's a cornerstone of patient care and trust in the modern healthcare ecosystem. As the adoption of telemedicine and remote patient monitoring tools continues to rise, so do concerns about cyberattacks and data privacy. To address these challenges, healthcare organizations must implement a robust framework of digital security measures, including advanced encryption, secure data storage, and stringent access controls. Compliance with regulations like HIPAA in the US and GDPR in Europe is essential to protect patient privacy and maintain trust.

Essential tools such as firewalls, intrusion detection/prevention systems (IDS/IPS), and data encryption are necessary to monitor network traffic and prevent unauthorized access. Healthcare providers must also implement data access controls, such as role-based access and multi-factor authentication, to ensure only authorized personnel can access sensitive data. Regular vulnerability scans and penetration testing are crucial to identify and address weaknesses before cybercriminals exploit them. Additionally, data backups and a robust disaster recovery plan ensure quick restoration of systems and minimize downtime in the event of an attack.

The human element remains a critical vulnerability, making regular training for staff on cybersecurity best practices—such as phishing email identification and password hygiene—essential to reduce the risk of successful attacks. The Health Insurance Portability and Accountability Act (HIPAA) mandates that healthcare providers protect patient data, requiring compliance with HIPAA's Security Rule, which outlines standards for safeguarding electronic protected health information (ePHI). Moreover, industry bodies publish best practices and guidelines to help healthcare organizations strengthen their cybersecurity posture.

Adopting cutting-edge cybersecurity solutions in healthcare environments ensures the integrity and confidentiality of patient records, ultimately enhancing the trust and safety of the healthcare ecosystem.

SGA Perspective

The medical devices sector is undergoing a transformative phase characterized by rapid technological advancements and innovative solutions designed to enhance patient care, streamline healthcare processes, and improve overall health outcomes. By 2024, the market is projected to achieve a revenue of $509.90 billion, with an expected CAGR of 5.71% from 2024 to 2029, reaching a market volume of $673.10 billion by 2029. This growth, driven by increasing global demand, particularly in countries like the US and Germany, brings significant changes for stakeholders across the industry.

- For manufacturers, advancements such as 3D printing and AI integration will necessitate investment in new technologies and training. These investments will aid the manufacturers in reducing production costs and faster time-to-market.
- Healthcare providers will benefit from more precise, personalized medical devices, enhancing patient outcomes and operational efficiency, but will also face challenges related to the adoption and integration of these new technologies into existing systems.
- Patients will experience improved treatment options and accessibility, especially through wearable technology and minimally invasive procedures.
- Regulatory bodies, on the other hand, will need to adapt to oversee the safety and efficacy of increasingly complex medical devices, while addressing cybersecurity threats and data privacy concerns.

Overall, the sector's evolution will foster a more dynamic, responsive healthcare ecosystem, requiring all stakeholders to remain agile and collaborative in navigating these changes.

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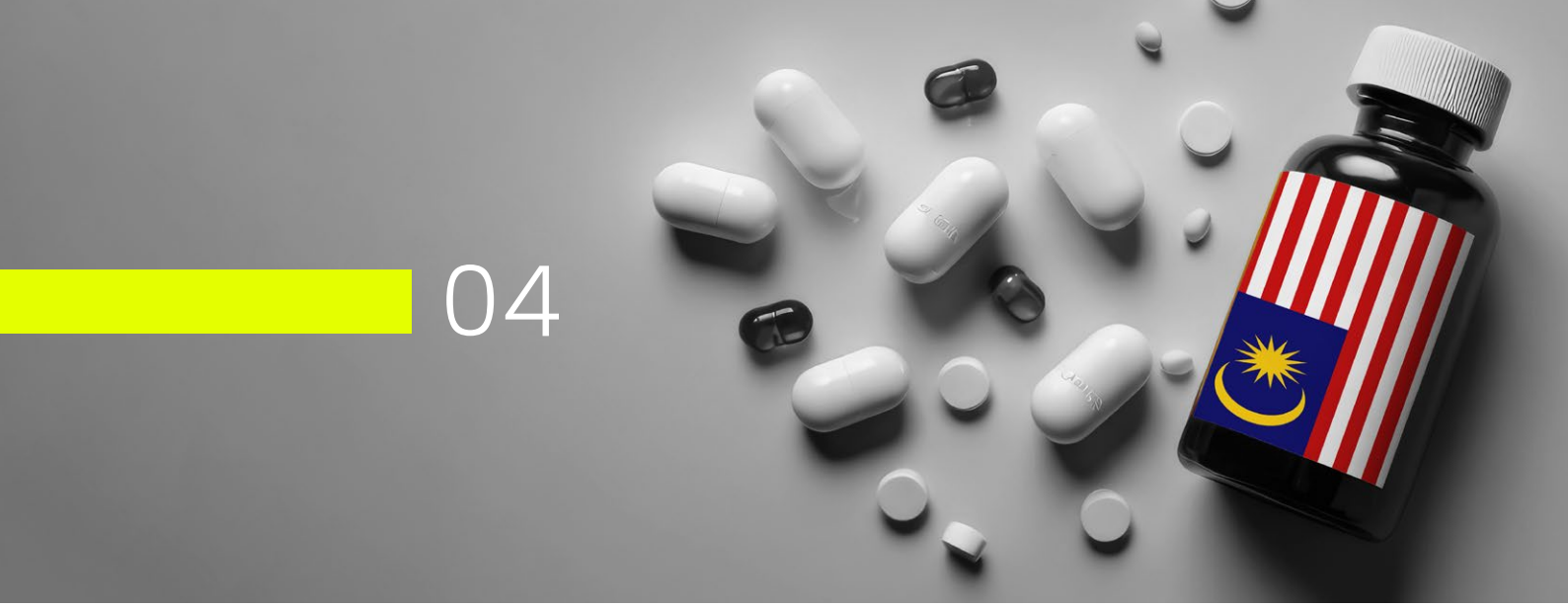


04

Navigating Malaysia Pharmaceutical Market: An Irresistible Opportunity for Global Players

Malaysia enjoys an internationally lauded healthcare system and is a medical tourism hub in Asia, attracting >1 million medical tourists annually. The Malaysian healthcare system has changed from a predominantly public healthcare system to a dual or two-tiered system where public and private healthcare expenditure are almost equal today. The pharmaceutical sector has grown at an average annual rate of 8% over the last decade. Imported and generic medicines account for 63% and 37% of the pharmaceutical market by value respectively.

Malaysia shares all the major attributes of an emerging market such as increasing market penetration and growing per capita income. This demands scrutiny with regards to the following:

1. Why is Malaysia not considered a Pharmerging market?

2. Why is Malaysia not a priority for global pharmaceutical companies, with only a few multinationals owning manufacturing facilities?

This article explores the opportunities & challenges faced by global players to leverage their capabilities & establish themselves in the high margin innovative & branded drugs market.

Opportunities

Steady Share of Patented Generics and Lack of Domestic Manufacturing Capacity

Although share of prescription drugs by value of patented drugs has reduced from over 67% a decade ago to 45%, the large trend is toward a steady share of patented drugs over the next foreseeable future. Pharma imports grew by a CAGR of 8.2% from 2010 to 2020. Local manufacturers produce only generic medicines and though the share of imported medicine has declined, it remains significant (63%). The presence of a strong traditional medicine is a significant barrier to prescription drugs. Malaysia is trying to become a global pioneer in the expansion of halal pharmaceutical products, a market expected to reach over $130 billion worldwide by 2030.

Growing Partnerships and Low R&D Of Domestic Firms

There is a spike in partnerships in Malaysian pharma market. Notable partnerships include Sanofi-Aventis and Hovid Bhd; Biocon Ltd contracting to Malaysia's biotechnology park BioXcell; and Malaysian company Inno Bio Ventures contract manufacturing clinical-grade material for Avesthagen. The industry is heavily regulated with Novartis, GlaxoSmithKline (GSK), Pfizer, Y.S.P. Southeast Asia (Y.S.P SAH), and Kotra Pharma being the major players in Malaysia. Domestic pharmaceutical companies focus on generic drugs, spending very little on R&D activities. This restricts the scope of domestic companies to establish themselves within Malaysia or through exports. Currently, the five leading domestic pharmaceutical companies are Pharmaniaga Berhad, Chemical Company of Malaysia Berhad (CCM), Yung Shin Pharmaceutical, Hovid, and Kotra Pharma.

Growing Lifestyle Diseases and Aging Population

Urbanization and globalization have resulted in dramatic increase in non-communicable diseases including cancer, diabetes, stroke, heart disease, and hypertension. Malaysia is considered the most obese country in southeast Asia. 73% of deaths in Malaysia are caused by non-communicable diseases. According to the National Health and Morbidity Survey, one in two adults is overweight or obese, with the highest prevalence among women at 54.7% and those aged 55 to 59 at 60.9%. Malaysia is expected to reach the status of an aged nation by 2030, with people over the age of 65 making up more than 14% of the population.

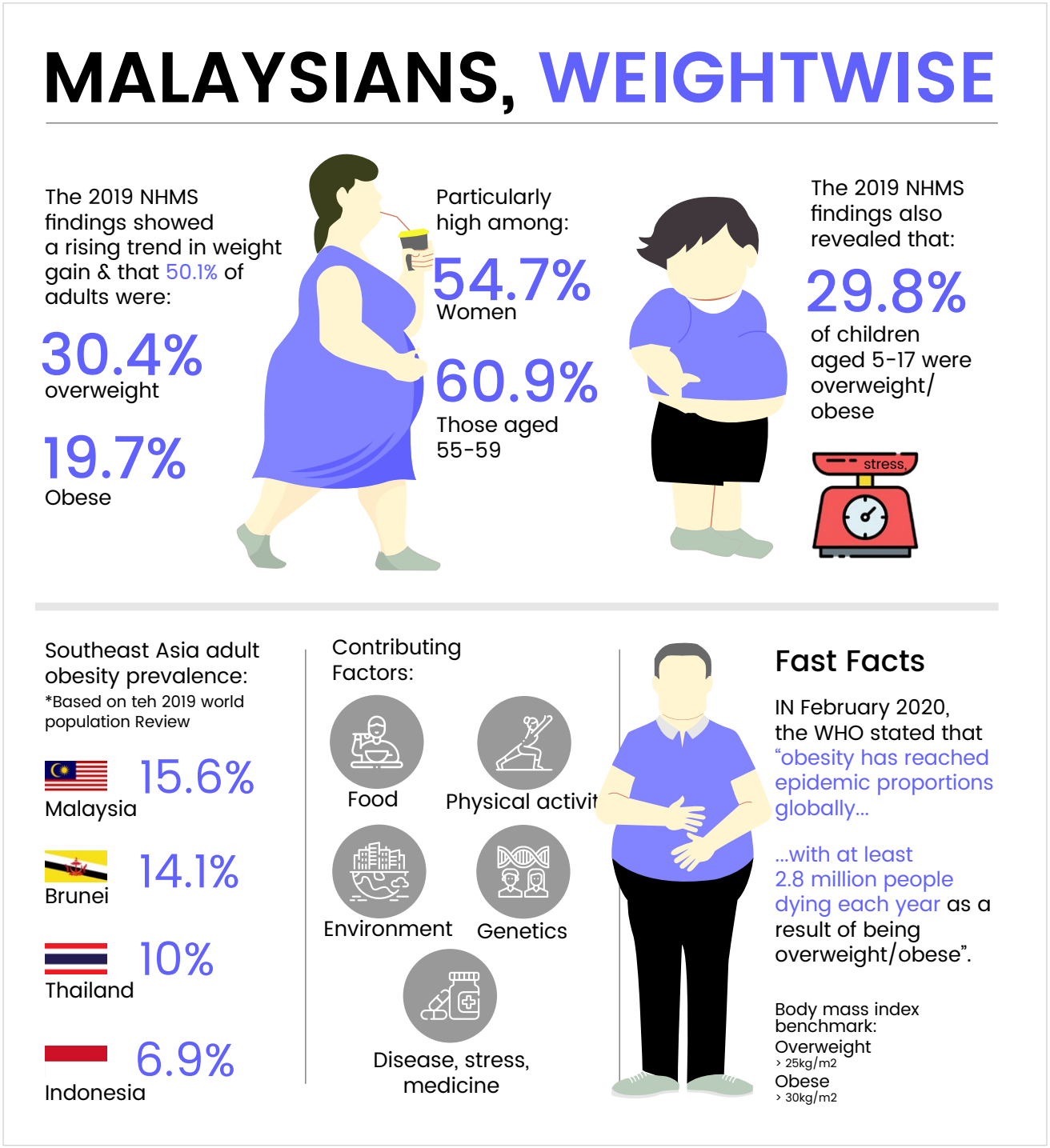
39%

of total healthcare expenditure is driven by out of pocket expenses in Malaysia

63%

of the pharmaceutical market by value is accounted by imported medicines

Figure 2: Malaysia Obesity Crisis



Source: National health and morbidity survey, WHO

Challenges

Low Health Insurance, High Out-of-pocket Expenses, and Complex Supply Chain

Government, private insurance, and out-of-pocket expenses (OOP) account for 52%, 9%, and 39% of total healthcare expenditure, respectively. The market structure is characterized by a three-level complex supply chain. The supply chain starts with manufacturers and importers of medicines at the first level, wholesalers and distributors at the second level, and providers at the third level. This complex supply chain causes procurement difficulties, marked up prices at every level and compromises the quality of medicines. The complex process is also a barrier to entry of new market players owing to anti-competitive conduct of incumbent firms.

Absence of Appropriate Governance for Patents

In Malaysia, the Patent Act does not exclude second medical use patent for pharmaceutical products, leading to monopolies and high prices for essential medicines. Several companies patent a new formulation with slight modifications of existing drugs. This allows companies to extend their monopoly on the products and prevent generic competition.

Biased Regulations in Favor of Domestic Companies

Biased regulations deter foreign companies from setting up manufacturing plants in Malaysia, instead importing their products and utilizing local distributors or their own sales teams. Companies with Malaysian operations structured in this way include Pfizer, Astra Zeneca, and Eli Lilly. The government also has indirect ownership in firms through various layers of holding and investment companies. These companies get favorable treatment from the state. For example, about 66% of revenue of Pharmaniaga came from the state contracts in 2020.

The Right Strategy

With the combination of right strategy, manufacturing investments, and expertise, global pharmaceutical companies can garner a significant share of the lucrative innovative drugs market. Hence, we propose a few strategies that can be leveraged by global players in the Malaysian market.

Collaboration with Local Partner

An effective approach to entering and establishing a presence in Malaysia involves partnering with a local entity that has strong connections to pharmaceutical distributors. This strategy not only helps navigate challenges related to distribution in Malaysia but also enhances brand awareness through established networks.

Expanding Manufacturing Operations and Government Support

Benefiting from the increasing support of the Malaysian government is an attractive alternative to partnering with local firms. Foreign companies have been expanding their in-country operations. YSP Industries, Xepa-Soul Pattinson, Novartis, and GSK have recently opened manufacturing plants in the country. Many Indian companies have operations in Malaysia with joint ventures accounting for about 60%. Indian companies with a manufacturing presence in Malaysia include Cipla and Dr. Reddy's Labs. For foreign drug companies looking to establish facilities in Malaysia, the government offers a variety of incentives, including duty exemptions, a 10-year tax holiday, and the ability to easily access other ASEAN markets through free trade agreements. The Malaysian Government has long emphasized the need to move up the value chain and have set up fully-integrated specialized parks with state-of-the-art infrastructure to cater to the needs of specific industries that focus on technology as well as R&D.

Conclusion

We expect a large gain in market share for innovative and ethical drugs, as Malaysia continues to align more with common practices in the developed markets regarding quality and pricing. We also expect Malaysia regulatory bodies to strengthen the intellectual property rights and resolve the challenges associated with biased laws which will encourage more FDI in pharma. Malaysia is emphasizing foreign direct investment (FDI) growth model to grow its pharma industry. With all possibilities we expect Malaysian pharmaceutical industry to expand its footprint through FDI rather than domestic investment. This presents an attractive opportunity for multinational firms to increase their footprint in Malaysian pharmaceutical industry.

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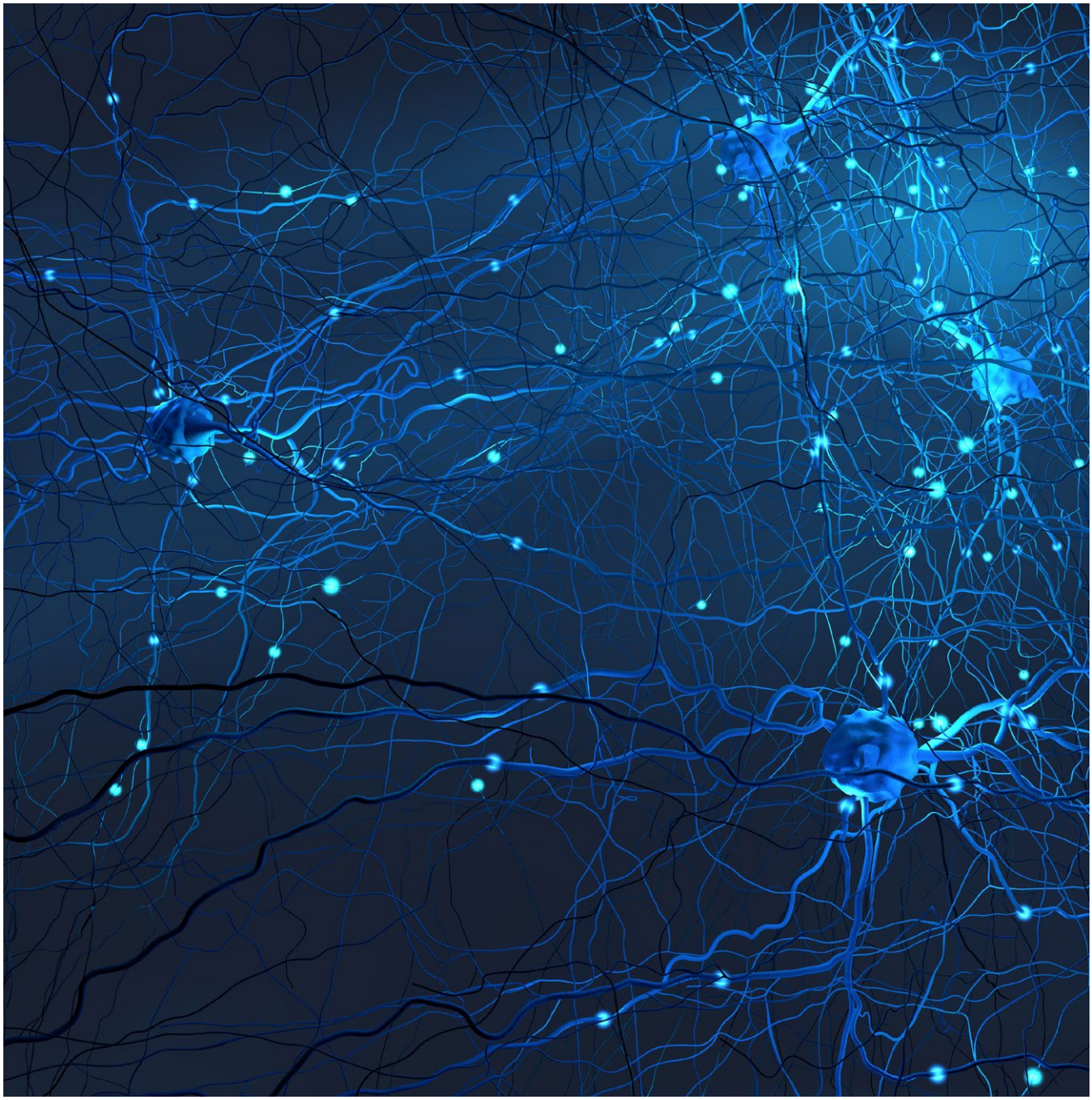

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