Trinity Student Managed Fund
Sector Reports

Non-Pharmaceuticals

September 2025

TRINITY SMF
STUDENT MANAGED FUND

Table of Contents

Authors

Lea Tsolov
Sector Manager

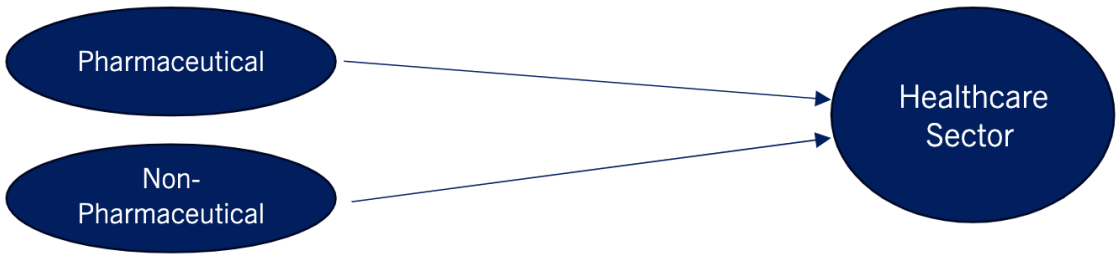
Gracie Mc Sharry
Senior Analyst

Kushal Gopal
Senior Analyst

Sector Overview

Sector Description

Within the healthcare industry, there are two primary sectors: pharmaceuticals and non-pharmaceuticals. The pharmaceutical sector is centered on drug research and innovation, while the non-pharmaceutical sector encompasses medical technology (medtech), biotechnology (biotech), and medical and health insurance providers. This report will focus specifically on the non-pharmaceutical sector, providing both an in-depth overview and a thorough analysis of our holdings. Given the similarities between the two sectors, some overlap may occur.



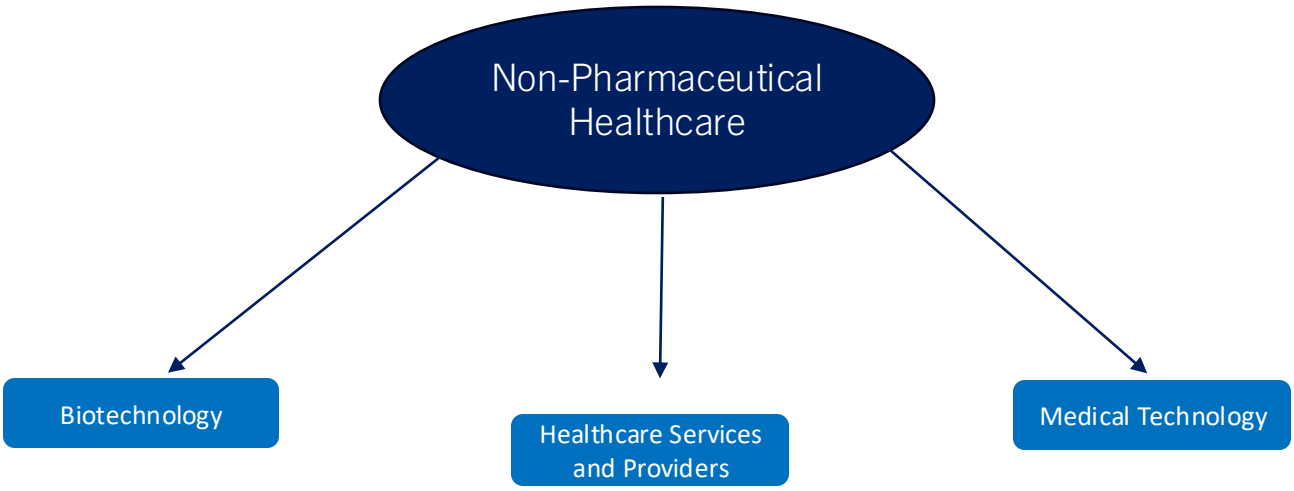
The healthcare sector currently holds a market weight of 8.71% with a total market capitalization of $6.278 trillion. Within this sector, med-tech, biotech, and healthcare plans collectively account for over 30%. Despite its size, healthcare stocks underperformed in 2024, overshadowed by high-growth trends such as Artificial Intelligence (AI). However, with valuations at relatively low levels, the sector presents strong opportunities for long-term investors.

According to PwC's 2025 Healthcare Outlook, several key dynamics are worth monitoring. First, medical cost trends are expected to continue rising. Notably, seven out of ten healthcare consumers report that they either cannot currently afford healthcare costs or will be unable to pay if costs increase further. Second, AI adoption in healthcare is accelerating. Approximately 77% of healthcare executives rank AI among their top three investment priorities for the next 12 months, indicating its growing role in shaping future operations. Moreover, consumers are increasingly open to AI integration, with one in five expressing willingness to use AI as a doctor's assistant for routine healthcare activities.

Finally, recent political developments, particularly the election, have left the healthcare sector vulnerable to potential policy changes. Key concerns include subsidies for health insurance exchanges and vaccine programs. As a result, close monitoring of regulatory and legislative developments will be critical in preparing for possible shifts in the sector.

Sub-Sectors Overview

Summary – Breakdown and Examples



The Non-Pharmaceutical Sector can be broadly divided into three main categories. However, it is often challenging to distinguish the scope of each category, particularly when differentiating between biotechnology and medical technology. While a detailed analysis of each will follow, the table below provides a concise introduction to these categories and outlines their primary functions within the sector.

	Biotechnology	Healthcare Services and Providers	Medical Technology
Core Focus/ Definition	The use of living systems for medical innovations.	Organizations and professionals that deliver medical services straight to the patient.	Tools, devices, and technologies that diagnose and monitor medical conditions.
Primary Functions	- R&D of new treatments - Diagnostics	- Improve access to medical care - Specialized care	- Patient Care and Treatment - Diagnostics
Examples	- CRISPR - MRNA vaccines - Cell Therapy	- Medical Insurance - Telehealth	- Imaging systems - Surgical equipment

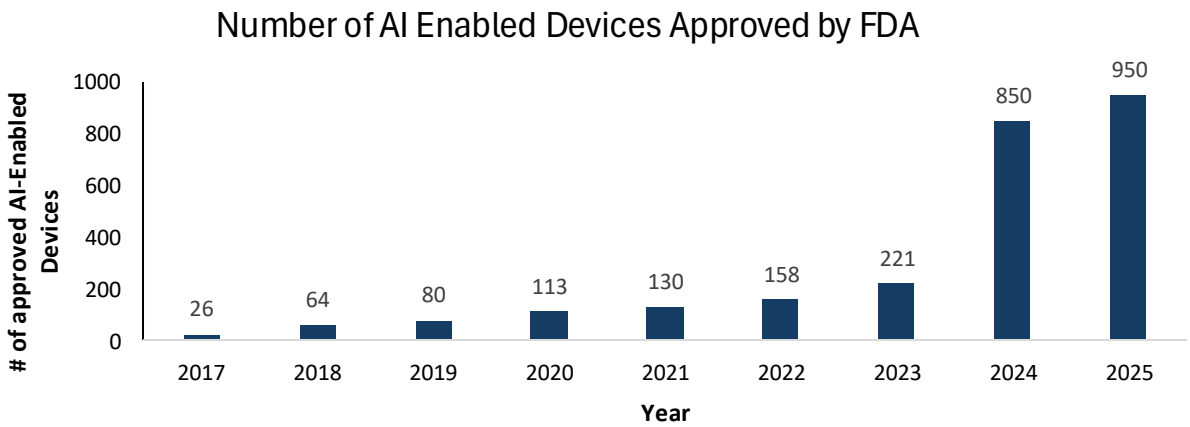
Sub-Sectors

Medical Technology

In recent years, medical technology has become incredibly crucial in many diverse settings, including surgery, prevention, screening, and the intervention of illnesses. There is an estimated 2 million different kinds of medical devices in the world, which are categorized into more than 22,000 generic device groups. These products range from complex imaging and genetic tests to thermometers and catheters. The United States remains the largest medical device market in the world, exporting over $103 billion worth of medical devices in 2023. This industry supports almost 2 million people in the U.S. directly and indirectly, as the medical device sector also relies heavily on several other industries such as microelectronics, biotechnology, and software development.

The Food and Drug Administration (FDA) regulates the sale and authorization of medical device products in the U.S., while the European Medicines Agency (EMA) is responsible for authorizations in the EU. Originally, FDA's medical technology regulations did not account for AI technology, but due to the increase in AI-enabled devices, the FDA published a proposal called the Predetermined Change Control Plan (PCCP), which allows manufacturers to make specific AI model updates without requiring a lengthy re-approval. This includes machine-learning devices, which use AI algorithms to improve performance by learning from past data. The FDA has authorized more than 850 AI-enabled devices—72 of which are for GE Healthcare, more than any other medical technology company.

Even with evolving regulations, AI models are continuously learning and improving. The question is no longer whether AI will transform healthcare, but whether regulators can keep up with the pace of transformation. At this stage, the best way to sustain this significant yet closely monitored evolution is by finding a middle ground that ensures transparency between regulators and the full capabilities of AI devices. Achieving this balance, however, may prove to be quite challenging.

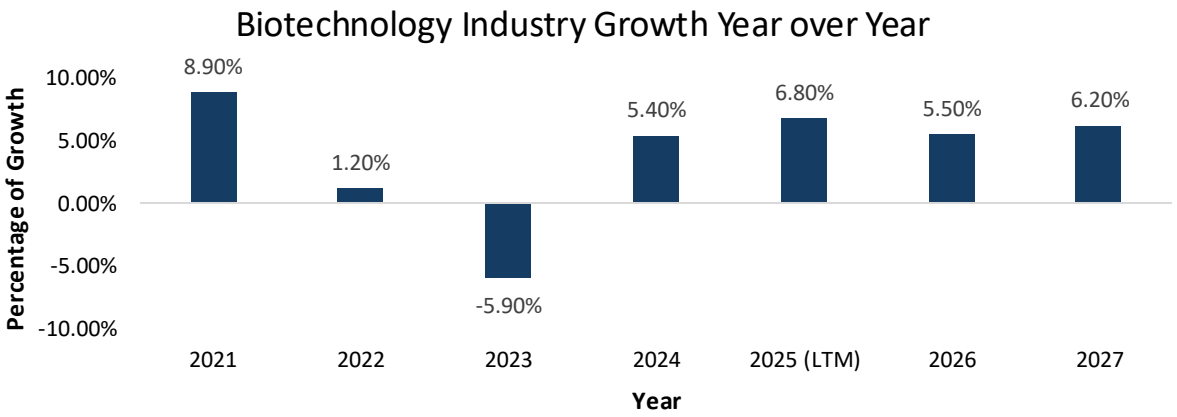


Sub-Sectors

Biotechnology

Biotechnology (Biotech) is a broad, multidisciplinary field that leverages living organisms to advance human health, agriculture, and environmental sustainability. Within the pharmaceutical sector, biotech plays a pivotal role in the research and delivery of innovative treatments, often described as the "technology of hope" due to its profound impact on patient outcomes. Although it is a relatively new discipline within healthcare, the future of biotech holds remarkable promise, with potential breakthroughs including the eradication of world hunger and the development of life-saving cures for diseases. Modern advancements have enabled scientists to adopt a more data-driven and multidisciplinary approach to understanding and manipulating living matter.

According to the EY Biotech Report, public company revenue over the last four years was $50 billion higher than in the preceding four-year period. Despite this growth, many companies continued to operate at a loss, reporting an aggregate deficit of $26.8 billion. In addition, the sector faces challenges stemming from the implementation of universal 10% tariff rates. While pharmaceutical products have historically been exempted from tariffs, potential complications may arise from tariffs on packaging materials. To mitigate further losses, biotech companies must adapt their business models to align with these new economic realities.



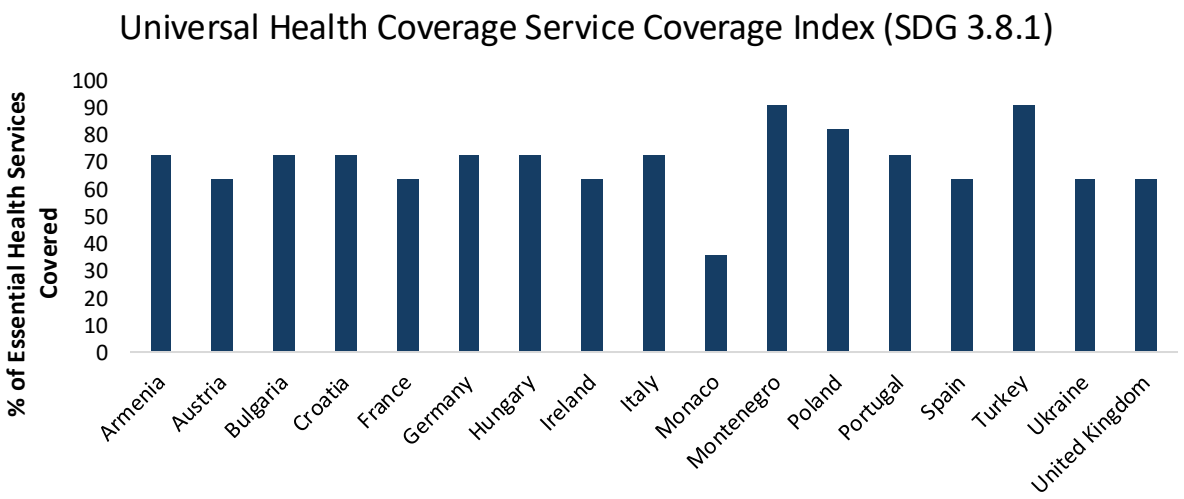
Similar to MedTech, artificial intelligence (AI) continues to emerge as a critical driver in optimizing healthcare outcomes. At present, 64% of healthcare organizations utilizing AI employ it primarily for patient engagement and predictive healthcare modelling, though in a limited capacity. However, higher-revenue organizations are increasingly leveraging AI for patient risk assessment, signalling a shift from preventive to more responsive and targeted interventions.

Sub-Sectors

Healthcare Providers and Services

This subsector can mainly be divided into two parts: healthcare providers and healthcare managing companies. Healthcare providers are individuals or entities that offer medical care or treatment, including doctors, nurse practitioners, hospitals, and labs. Healthcare managing companies refer to insurance networks that offer discounted rates on medical services for plan members.

Globally, demand for health insurance has risen following the traumatic impact of COVID-19. In 2021, 4.5 billion people lacked full coverage for essential health services. Additionally, 1 billion paid significant out-of-pocket expenses, and 455 million were pushed further into extreme poverty due to healthcare costs. The pandemic has underscored the critical need for comprehensive health insurance.

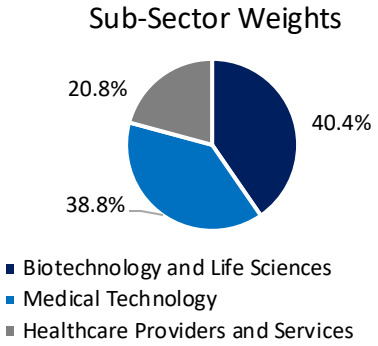


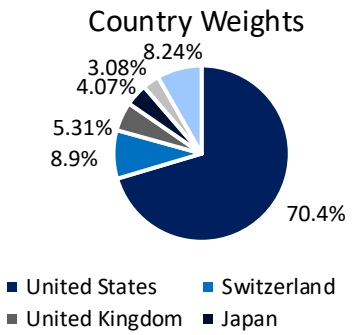
In the U.S., the health insurance sector is experiencing growing pressure from new legislation and regulation. The outlook is favorable for Medicare Advantage but less so for Medicaid, which faces major budget cuts. Enhanced Affordable Care Act (ACA) subsidies are also set to expire at the end of 2025; if not renewed, coverage could become more expensive, negatively affecting ACA insurers.

There is also increasing momentum for Pharmacy Benefit Manager (PBM) reform. PBMs handle drug price negotiations and manage prescription benefits. Although reform was removed from the 2024 year-end funding bill, support continues to grow. If passed, reform may lead to more transparent pricing and adjusted reimbursement models. This could slightly impact profitability or raise costs but is unlikely to cause widespread financial distress.

Sector Overview

Current Climate





Although all sub-sectors have their own defined role within the non-pharmaceutical field, Biotechnology still holds a leading influence obtaining 40.4% of the market share. Progress in AI-based drug discovery and the acceleration of gene-editing therapies reaching clinical stages strengthens Biotech's position. Flexibility in regulations around breakthrough medicines has also benefited the segment to garner investor interest.

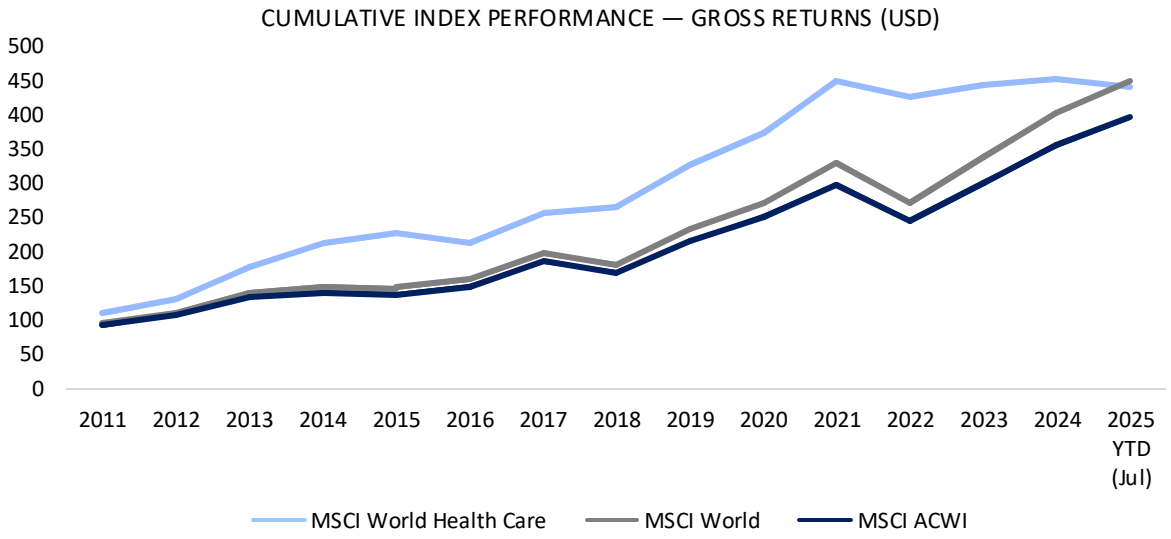
The medical technology segment strengthened this year now occupying 38.8%. A sub-sector being transformed by digital health integration like wearable diagnostic devices and in-hospital monitoring systems for the home that increase reach and efficiency. Increasing investment in surgical and rehabilitation robotics is also redesigning the patient care journey.

The healthcare providers and services segment, at 20.8%, remains steady but becomes increasingly shaped by the growth in value-based models of care and consolidation in the leading networks. Telehealth, previously a pandemic-fuelled trend, has transformed into a structural component of care provision. Population aging continues to underpin demand, but the move towards preventive healthcare and digital-centric infrastructure is becoming the superior long-term driver. Collectively, the combination heralds a shift from the R&D-centric focus in the prior year, demonstrating how technology uptake and care delivery innovation are now transforming sector dynamics.

Geographically, the United States continues to dominate the global healthcare industry, representing 70.4% of the MSCI World Health Care Index as of July 2025. Its predominantly private healthcare system fosters intense competition, innovation, and high levels of capital investment. Switzerland holds the second-largest share at 8.9%,reflecting its robust private healthcare market, followed by the United Kingdom (5.31%)and Japan (4.07%), both of which operate largely public healthcare systems. France accounts for 3.08% of the index, with the remaining developed markets making up 8.24%. Even these smaller percentage shares represent market capitalizations in the hundreds of billions of dollars, highlighting the scale and significance of healthcare globally.

Sector Overview

MSCI World Healthcare Index



The MSCI World Health Care Index serves as a global barometer of developed-market healthcare equity performance. With 23 developed markets and 124 constituents, the index is a useful tool for evaluation and helpful benchmark. The index has been heavily weighted towards industry giants like Eli Lilly, Johnson & Johnson, AbbVie, UnitedHealth Group, and AstraZeneca. These companies reflect the size and scope of the sector, from pharmaceuticals and biotechnology to healthcare equipment and services. While pharmaceuticals make up the majority with approximately 42% of the index, there are also substantial allocations towards equipment and supplies (18.6%) as well as biotechnology (15.7%), demonstrating the depth of innovation and operational strength infused across the healthcare value chain.

From a performance perspective, healthcare lags behind the broader equity markets so far this year particularly considering the robust equity rallies elsewhere. The MSCI World Health Care Index has declined –2.20% (06/30/25) compared with gains of +10.88% for the MSCI World and +11.54% for the MSCI ACWI. The divergence here is a consequence of the defensive nature of healthcare equities—they offer stability and predictable demand but often decline in the presence of strong cyclical or growth-driven surges. Even so, valuation dynamics remain positive, with the sector trading on a trailing P/E of ~19.1x and a forward P/E of ~15.5x, both slightly lower than wider market levels. Historically, healthcare has fared resiliently in downswings, often coming good as economic conditions tighten.

Looking ahead, we hold a positive outlook on sector positioning. Even in the near-term period of underperformance, the fundamentals for healthcare remain intact: structural demand growth fuelled by demographics, continued innovation in biotechnology and biopharmaceuticals, and the sector's critical role in world economies. When investor sentiment necessarily realigns toward defensives in the face of macro uncertainty, healthcare is well-positioned to recapture historical leadership. In our opinion, the index continues to offer not only a defensive haven within global portfolios but also access to some of the world's highest-quality, capital-efficient companies.

Sector Overview

KPI's

Operational efficiency in healthcare providers

One of the most important sets of indicators for non-pharma healthcare providers revolves around operational efficiency, impacting both costs and the quality of care. One core indicator is the average length of stay (ALOS). A lower ALOS often suggests efficient care delivery and effective discharge planning. GEHC benefits when hospitals adopt diagnostic tools that enable faster discharge, while BSX benefits from procedures (like transcatheter aortic valve replacements) that reduce open-heart surgery recovery times. High occupancy rates, where rates are close to or above 85%, are often good for med-tech providers like BSX and GEHC. Hospitals under pressure with greater than 85% occupancy face capacity strain. To relieve this, they often invest in, diagnostic machine, automation tools, and minimally invasive surgical devices that shorten recovery and reduce ALOS, creating growth for med-tech suppliers. However, if budgets are already overstretched due to overcrowding, hospitals may limit capital purchases to focuses on long term liabilities. Operational strain in this sector cuts both ways – while it challenges providers, new technology created in the process often benefit med-tech providers in the long term,

Regulatory Submission Speed

As companies embrace greater AI-driven processes and zero -based designs, non-pharmaceutical companies have accelerated their regulatory submissions dramatically – shifting from months to just 8-12 weeks after database lock (DBL), effectively cutting timeline by 50-65%. For a $1 billion asset, submitting just one month earlier could unlock around $60 million in NPV. For medical device and med-tech vendors like GEHC or BSX, this presents a powerful KPI – measuring time from product readiness to filing. By benchmarking against the pharma leaders' speed, med-tech providers can assess and drive transformative gains in time-to-market, competitive advantage, and value realisation, allocating investments in AI- enabled documentation tools and streamlined workflows to replicate similar financial and operational benefits.

Claims management

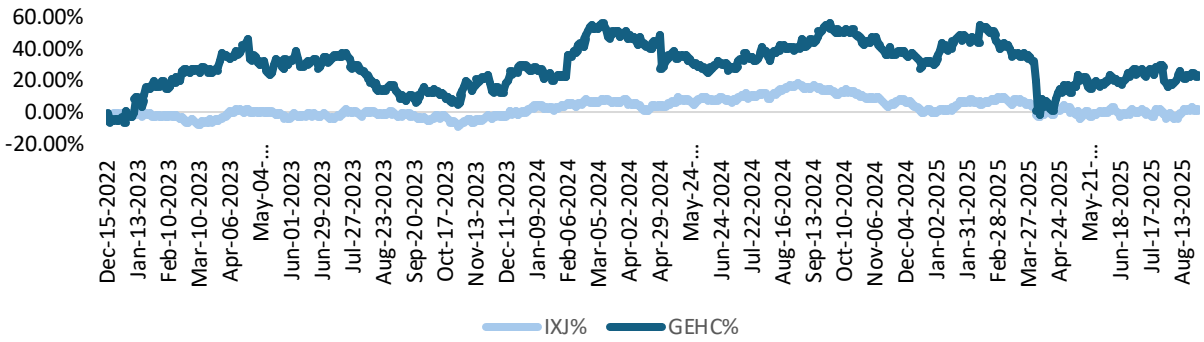
Within the broader non-pharma sector, insurance companies represent a critical stakeholder group, and their KPI's differ from providers. One of the most important indicators is the Claims Ratio. A high ratio indicates that most funds are going directly toward patient care, which is good for policyholders but can suppress insurer profitability. Additionally, fraud detection rates are vital, as fraudulent claims cost insurers billion annually and can raise premiums for all customers.

Current Holdings

GE Healthcare (NASDAQ: GEHC) Sentiment: Hold

GE Healthcare Technology, Inc is an American multinational medical technology and diagnostics company, offering solutions in imaging, ultrasound, monitoring, and digital health. Headquartered in Chicago, Illinois, the company operates in 160+ countries and has a strong footprint in the U.S., EMEA, and Asia. Since its spin – off from General Electric, GEHC has focused on driving innovation in AI, expanding its digital platform, and deepening its recurring revenue model.

While the company is showing strong execution and structural growth, near-term headwinds from tariff pressures and slowing EPS growth warrants a wait-and-see approach rather than increasing our position at current levels.



Digital and AI-Driven Healthcare: GEHC is actively integrating AI into its product lines (e.g. Voluson™ Expert ultrasound and AltiX AI.i edition for cardiology). Demand is growing for AI-powered diagnostics and scalable digital platforms, supporting a longer-term secular growth trend. GEHC continues to invest through acquisitions that enhance its AI and radiopharmaceutical capabilities. Recent deals include MIM Software, Intelligent Ultrasound and full ownership of Nihon Medi-Physics, expanding the company's reach in AI imaging and precision diagnostics, especially in cardiology and oncology, which remain priority investment areas in the U.S. market.

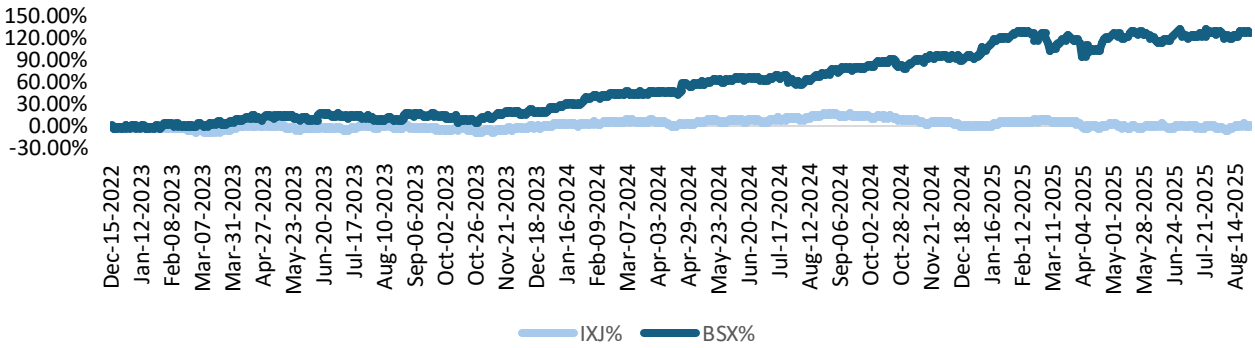
Strong operational execution: GEHC delivered 4% organic revenue growth and 10% organic growth order YoY in Q1 2025. GEHC expanded its adjusted EBIT margin by 30 bps YoY to 15.0%, reflecting higher volumes, new products and disciplined pricing. The company has signed $5 billion in strategic enterprise agreements since its spin-off including 5 new long-term deals in 2024 alone. These deals have not only strengthened the company's relationship with healthcare systems but also has expanded their revenue base.

Current Holdings

Boston Scientific (NYSE:BSX) Sentiment: Hold

Boston Scientific Corporation is an American medical devices company headquartered in Marlborough, Massachusetts. The company designs and manufactures a range of medical devices in cardiology, urology, and endoscopy in over 130 countries.

FY24 delivered strong operational growth for Boston Scientific with revenue rising 17.6% YoY to $16.75 billion. Growth was broad-based, with the U.S. leading at 21.2% and emerging markets up 19.6%. This highlights the company's global scalability and ability to execute in both mature and developing healthcare systems, providing resilience amid political and macroeconomic uncertainty.



Consistent Growth

Boston Scientific continues to deliver reliable growth, with EPS increasing from $2.05 to $2.51 in FY24. This performance was supported by strong demand for cardiovascular and structural heart products, driving double-digit growth.

Expanding Pipeline and Strategic Acquisitions

Recent acquisitions of Axonics, Silk Road Medical, and Cortex have expanded Boston Scientific's presence in neuromodulation, stroke prevention, and electrophysiology. New product rollouts such as the FARAPULSE™ pulsed field ablation system and LUX-Dx™ ICM, alongside FDA progress and remote monitoring expansion, are strengthening its market position. However, integration and cost absorption could weigh on near-term margins. The company has also decided to discontinue global sales of its two TAVR systems (ACURATE neo2 and ACURATE prime).

The stock is trading near historical highs with a forward P/E of 29. Much of the strong performance appears priced in, so maintaining a **Hold** rating is prudent while monitoring for a more attractive entry point.

Buy List

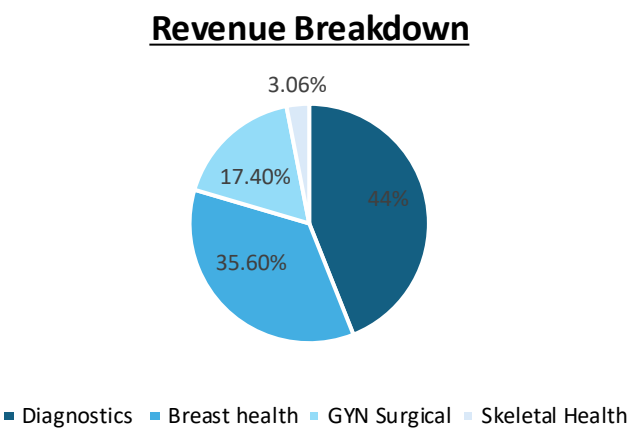
Hologic, Inc. (NASDAQ: HOLX)

HOLX 12 Month Price Prediction

Avg. Price Prediction - $65

High Price Prediction - $74.11

Low Price Prediction - $94



Company Overview and Breakdown

Hologic, Inc. is a medical technology company focused on advancing women's health. It develops, manufactures, and supplies diagnostic products, medical imaging systems, and surgical solutions designed specifically for female health needs. The company operates through four main segments: Diagnostics, Breast Health, GYN Surgical, and Skeletal Health.

Investment Thesis

Hologic reported $4.03 billion in revenue as of August 2025, putting it behind the largest healthcare players, but the company's strength is its focus on women's health and track record of innovation, including being the first to bring 3D mammography to market. As women's health continues to get more attention across the healthcare sector, Hologic is in a good position to benefit. Analysts expect revenue to reach $4.27 billion in 2026, a 4.47% increase year-over-year.

The company is also investing in AI for mammography. In a trial of 5,000 exams, Hologic's AI found 100 cancers that radiologists initially missed, showing real potential to improve outcomes. This research earned Hologic the 2025 MedTech Breakthrough Award for Best New Imaging Technology, and it sets the stage for the next cycle of mammography equipment upgrades, which could boost sales in Breast Health.

Financially, Hologic is solid. In Q3 FY25, it generated $343.2 million in operating cash flow, showing strong profitability and liquidity. While Breast Health revenue dropped to $365.2 million due to fewer mammography equipment purchases (something management expected because of the business cycle), the company is preparing for the next wave of demand driven by its new AI technology. On the other hand, surgical revenue grew 7.1% to $178.4 million, helped by the acquisition of Gynesonics, which expands Hologic's role in women's surgical care.

Overall, Hologic offers a mix of stability and growth. The company has a reliable base in diagnostics and services, while new innovations and acquisitions provide upside. With strong cash flow, a clear focus on women's health, and new technology on the horizon, Hologic looks well-positioned to keep growing steadily over the next few years.

Investment Theme

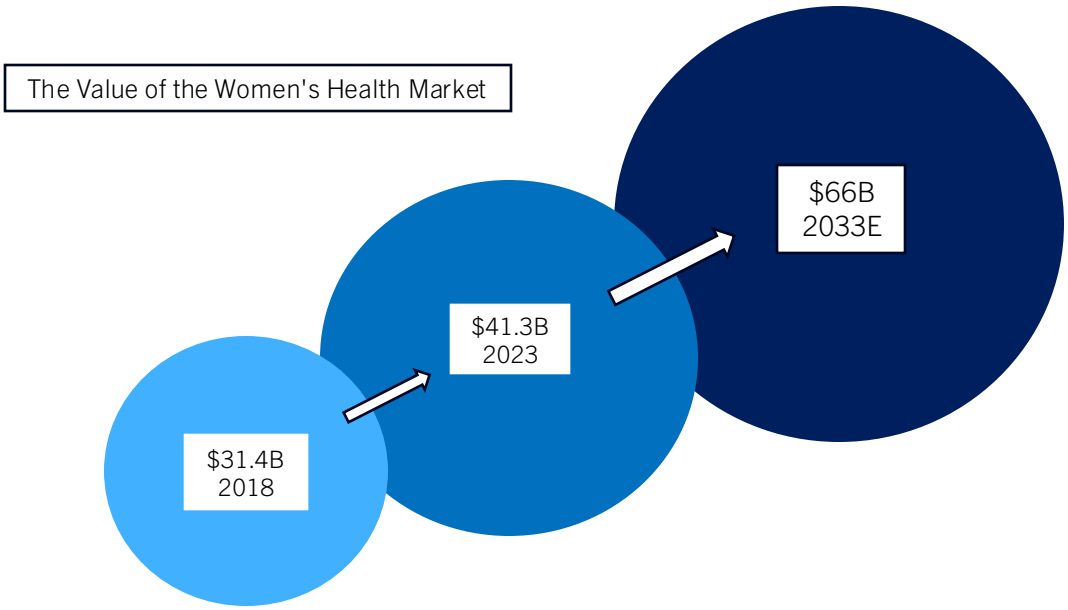
Women's Health

Women make up roughly 50% of the global population, yet historically only a small fraction of R&D spending, funding, and innovation has been dedicated specifically to female health needs. As a result, a vast portion of the healthcare sector remains underserved—despite its massive potential for both social impact and economic returns.

At the recent JPM Healthcare Conference, the WHAM (Women's Health Care Matters) report emphasized the business case for accelerating investment in women's health. The report argued that beyond being a moral imperative, it is also a highly compelling economic strategy. For example, an investment of $350 million in women's health research could generate an estimated $14 billion in economic return. Additionally, closing gaps in women's health outcomes could add $1 trillion to annual global GDP by 2040, creating a return of $3 for every $1 invested.

Consultancies such as BCG have highlighted areas of healthcare where women's needs are most underserved. Many women report that existing products and services do not adequately meet their needs. At the same time, this gap represents a significant opportunity for innovators and investors. Fertility technology, maternal health solutions, and digital health platforms are among the sectors targeted for strong growth.

The potential impact extends far beyond women alone. Healthier women lead to healthier families, more productive workforces, and stronger economies. Greater investment in women's health not only provides critical funding for research and innovation but also raises global awareness of an area that has long been overlooked.



Risks

Regulatory Volatility

The non-pharma sector faces increasing regulatory headwinds as governments and insurers tighten reimbursement policies amid fiscal pressures. Globally, health systems are expanding value-based models that reward outcomes over volume, forcing device manufacturers to justify cost premiums with clinical and economic data. The Italian Constitutional Court, in decisions No.139 and 140 (July 2024), upheld a controversial "payback" law requiring med-tech companies to reimburse regional health authorities for overspending- resulting in liabilities of up to 644 million euros in 2018 alone, with manufacturers required to repay 48% of that amount, signalling growing regulatory risks in core EU markets.

In the U.S, reforms by the Centers for Medicare and Medicaid services (CMS) and increasing use of health technology assessments (HTA's), add layers of uncertainty to coverage decisions. For investors, this may compress valuation multiples, especially for companies with products targeting niche, high-cost procedures or unproven technologies. Uncertainty in earnings may increase with reimbursement delays impacting cash flows.

Trade Tensions

The non-pharma sector remains vulnerable to global supply chain shocks and rising trade barriers. The US in 2024 imposed tariffs as high as 145% on a range of Chinese inputs – such as semiconductors, imaging equipment components, and plastics – used in essential medical technologies. This has created logistical issues for large MNC's like GE Healthcare and Medtronic, which source components from over 20 countries. The FDA has also acknowledged that it lacks a comprehensive shortage reporting system for medical devices, increasing the sector's exposure to silent supply risks. As geopolitical pressures persist- especially surrounding rare earths and the Taiwan strait- smaller med-tech firms may struggle to secure components without raising inventory or capex. For investors, this threatens gross margins and increases operational costs.

Cybersecurity Threats and Digital Vulnerabilities

As digital transformation increases across the non- pharmaceutical sector – integrating AI-based diagnostics, wearable ,monitoring, cloud-connected medical devices and telehealth infrastructure- cybersecurity emerges as a both a financial and reputational risk. In 2023 alone, there was a 43% year-over-year increase in FDA AI/ML medical devices, many of which depend on real-time data and remote updates. Yet industry reports and reports from the U.S. Department of Health and Human Services have repeatedly warned that connected devices, including pacemakers, insulin pumps and digital diagnostics platforms are vulnerable to cyber threats due to insufficient encryption and outdated firmware. A single data breach or a ransomware attack could compromise patient's health information, exposing firms to GDPR or HIPAA violations. As 2025 and 2026 bring even greater Ai and digital integration, med-tech companies will under immense scrutiny to meet cybersecurity compliance standards, increasing operation expenses and squeezing down margins. Failure to comply could result in class-action lawsuits, recalls or bans of public healthcare contracts.

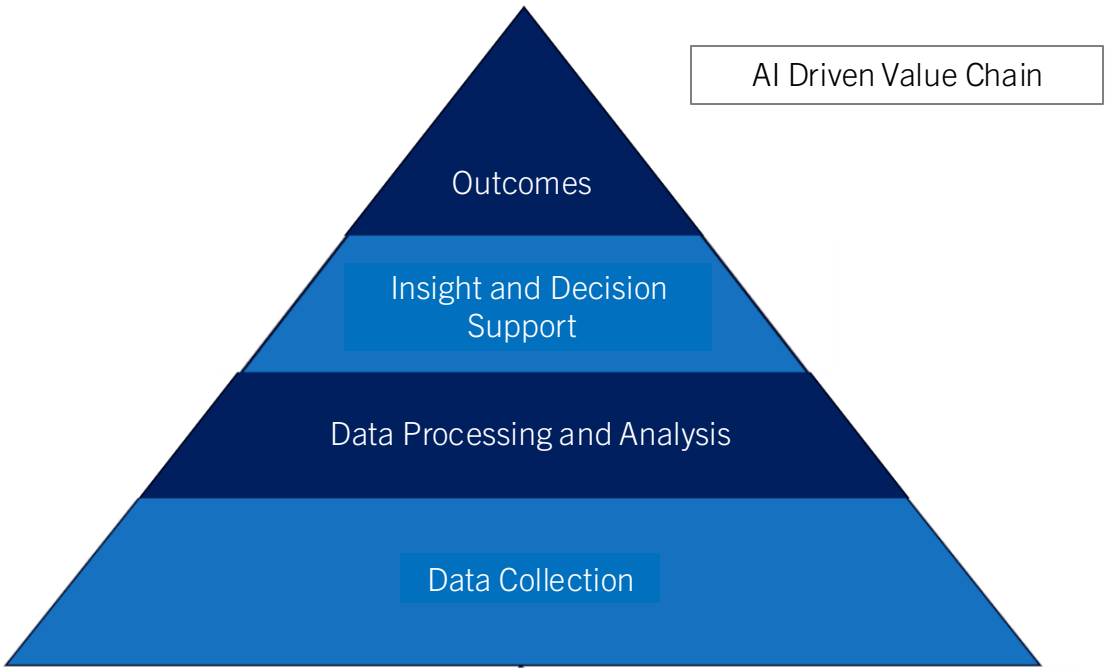
Outlook for the Year

Continuing the Integration of AI

The transformational power of artificial intelligence continues to reshape the healthcare sector, particularly in drug discovery, development, and patient care. One of the key trends is the rapid analysis of large datasets, which significantly shortens the time required to identify drug targets and streamlines development pipelines. This acceleration allows companies to bring novel therapies to market faster, enhancing overall efficiency in R&D processes.

Another important development is the growing emphasis on personalized medicine. AI enables the tailoring of treatment plans to individual patients by analyzing genetic profiles, medical history, and other patient-specific data. This capability not only improves patient outcomes but also supports predictive and preventive healthcare approaches, moving the sector toward more precise, data-driven decision-making.

Despite these opportunities, several challenges remain. Regulatory frameworks are still evolving to address the unique complexities of AI-driven healthcare technologies. Agencies are striving to ensure transparency, safety, and efficacy, yet concerns around data privacy, algorithmic bias, and adaptive policy management persist. Additionally, integration into existing healthcare systems requires investment in digital infrastructure and workforce training to fully realize AI's potential.



Disclaimer

The content present in this publication is for informational purposes only and should not be considered as investment advice. The Trinity Student Managed Fund does not endorse, recommend, or provide any warranties regarding the accuracy, completeness, or reliability of the information provided herein. All opinions expressed of those of the respective authors do not necessarily reflect the views of the Trinity Student Managed Fund.

Readers are strongly advised to conduct their own research and consult with qualified financial professionals before making any investment decisions. The Trinity Student Managed Fund disclaims any liability for any financial loss or damage arising from reliance on the information contained in this publication.

References

Allianz. (2025). Allianz Global Insurance Report 2025: Rising demand for protection. Available at: https://www.allianz.com/content/dam/onemarketing/azcom/Allianz_com/economic-research/publications/specials/en/2025/may/2025-05-27-global-insurance-report.pdf

Bloomberg Markets, 2025. Boston Scientific Corp Equity Valuation & Analyst Consensus. Available at: https://www.bloomberg.com/

Boston Scientific Corporation, 2024. Boston Scientific Announces Agreement to Acquire Axonics, Silk Road Medical, and Cortex. Available at: https://news.bostonscientific.com/

Boston Scientific Corporation, 2024. Boston Scientific Announces Decision to Discontinue Global Sales of ACURATE Neo2 and ACURATE Prime TAVR Systems. Available at: https://news.bostonscientific.com/

Boston Scientific Corporation, 2025. *B*oston Scientific Reports Strong Fourth Quarter and Full Year 2024 Financial Results. Available at: https://news.bostonscientific.com/

Cervicorn Consulting, 2025. Biotechnology Market Size to Worth Around USD 3.54 Trillion by 2033. Available at: https://www.cervicornconsulting.com/sample/2310

References cont'd

EY. (2025). Optimizing Health Outcomes for All – 2025 EY Report. Available at: https://www.ey.com/content/dam/ey-unified-site/ey-com/en-us/campaigns/health/documents/ey-final-optimizing-health-outcomes-for-all-report.pdf

FDA. (2025). Artificial Intelligence- Enabled Medical Devices. Available at: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices

FDA. (2025). Artificial Intelligence in Software as a Medical Device. Available at: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-software-medical-device

FDA. (2025). FDA's Role in Regulating Devices. Available at: https://www.fda.gov/medical-devices/home-use-devices/fdas-role-regulating-medical-devices

FDA. (2025). Medical devices supply chain vulnerabilities and the public health impact they have on our most vulnerable patients. Available at: https://www.fda.gov/medical-devices/medical-devices-news-and-events/medical-device-supply-chain-vulnerabilities-and-public-health-impact-they-have-our-most-vulnerable?

GE Healthcare. (2024). GE HealthCare Tops List for Third Year in a Row with Highest Number of AI-Enabled Medical Device Authorizations. Available at: https://investor.gehealthcare.com/node/9931/pdf

Mallela, K. (2010). Pharmaceutical biotechnology - concepts and applications. *Human Genomics*, *4*(3), 218. https://doi.org/10.1186/1479-7364-4-3-218

Mckinsey. (2025). Rewiring pharma's regulatory submissions with AI and zero-based design. Available at: https://www.mckinsey.com/industries/life-sciences/our-insights/rewiring-pharmas-regulatory-submissions-with-ai-and-zero-based-design?

Morgan Lewis. (2025). How the health tech investment act could reshape medicare reimbursement for algorithm-based services. Available at: https://www.morganlewis.com/pubs/2025/05/how-the-health-tech-investment-act-could-reshape-medicare-reimbursement-for-algorithm-based-services

MSCI, 2025. MSCI World Health Care Index (Gross USD) – Factsheet. Available at: https://www.msci.com/our-solutions/indexes/world-health-care

MSCI, 2025. MSCI World Index (Gross USD) – Factsheet. Available at: https://www.msci.com/our-solutions/indexes/world

MSCI, 2025. MSCI ACWI Large Cap Index (Gross USD) – Factsheet. Available at: https://www.msci.com/our-solutions/indexes/acwi

References cont'd

Yoon, E. (2024). Health care sector outlook | Fidelity. Available at: https://www.fidelity.com/learning-center/trading-investing/outlook-health-care

Saluja, R. (2025). When AI In Medical Devices Evolves Faster Than Regulations: How Do We Keep Up? Available at: https://www.forbes.com/councils/forbesbusinessdevelopmentcouncil/2025/04/16/when-ai-in-medical-devices-evolves-faster-than-regulations-how-do-we-keep-up/

S&P Global Ratings. (2025). U.S. Health Insurance Sector View 2025: Elevated Earnings Risks And Health Policy Uncertainty. Available at: https://www.spglobal.com/ratings/en/regulatory/delegate/getPDF?articleId=3324847&type=COMMENTS&defaultFormat=PDF

World Health Organization. (2023). Health technologies. Available at: https://www.who.int/europe/news-room/fact-sheets/item/health-technologies