Markets in Focus

Q4 2023

LIFE SCIENCES

Economic Overview & Market Update

IMA

2023 YEAR IN REVIEW

In the wake of the pandemic, life sciences companies were challenged to pivot to adopt new technologies and rethink existing operating models to sustain growth and deliver innovation at speeds unseen in the industry. As a result of the evolution of technology in this sector, the Food and Drug Administration (FDA) has taken significant strides in 2023 to modernize the 510(k) program and evolve guidance to incorporate technological advancements. All 510(k) submissions, unless exempted, must be submitted electronically using their eSTAR platform, which went into effect October 1, 2023. The FDA published final guidance regarding cybersecurity measures and quality system consideration concerning medical devices specific to using the 510(k) pathway.

The FDA also issued final guidance on the Informed Consent Process in 2023. The final guidance aimed to bring the process into the twenty-first century by acknowledging that new technologies may be used to obtain informed consent as an alternative to paper consent forms. The FDA is also encouraging researchers to use technology and innovative visual methods in the informed consent process to aid in educating and communicating with trial participants.

While the FDA continues to modernize its processes and update guidance for the industry, technological innovation is outpacing regulatory bodies and lawmakers' ability to keep pace. 2023 marked explosive growth in artificial intelligence (AI) technology and applications related to accelerating research and development, drug discovery and development, and data sharing. The uptick in the number of companies adopting this AI technology has created additional regulatory hurdles and concerns within the industry. Navigating the complexities of ever-changing technologies, supply chains, and workforce stability remained a top concern for life sciences companies.

The U.S. biotechnology sector in 2023 was a $119.3 billion industry; the industry forecasts growth by a modest 5% over the next two years, due partly to tightened access to investment capital, increased government oversight, and greater overseas competition.[1] Each global markets segment this report covers is projected to have their own substantial market size growth.

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PHARMACEUTICALS

In 2023, pharmaceuticals drove merger and acquisition (M&A) deals significantly higher than anticipated, even as M&A deal volume fell flat across many sectors in the life sciences vertical. Pharmaceuticals accounted for 49% of deal volume and over 75% of total deal value.

MEDICAL DEVICE & DIAGNOSTICS

The medical device and diagnostic segment saw modest growth through the first half of 2023, with M&A deal value up 4% to $7.8 billion. Venture funding activity, however, declined by 45% year over year. The diagnostics sector drove the decline of venture activity as demand for COVID-19 tests and related diagnostic products fell after the pandemic peak.

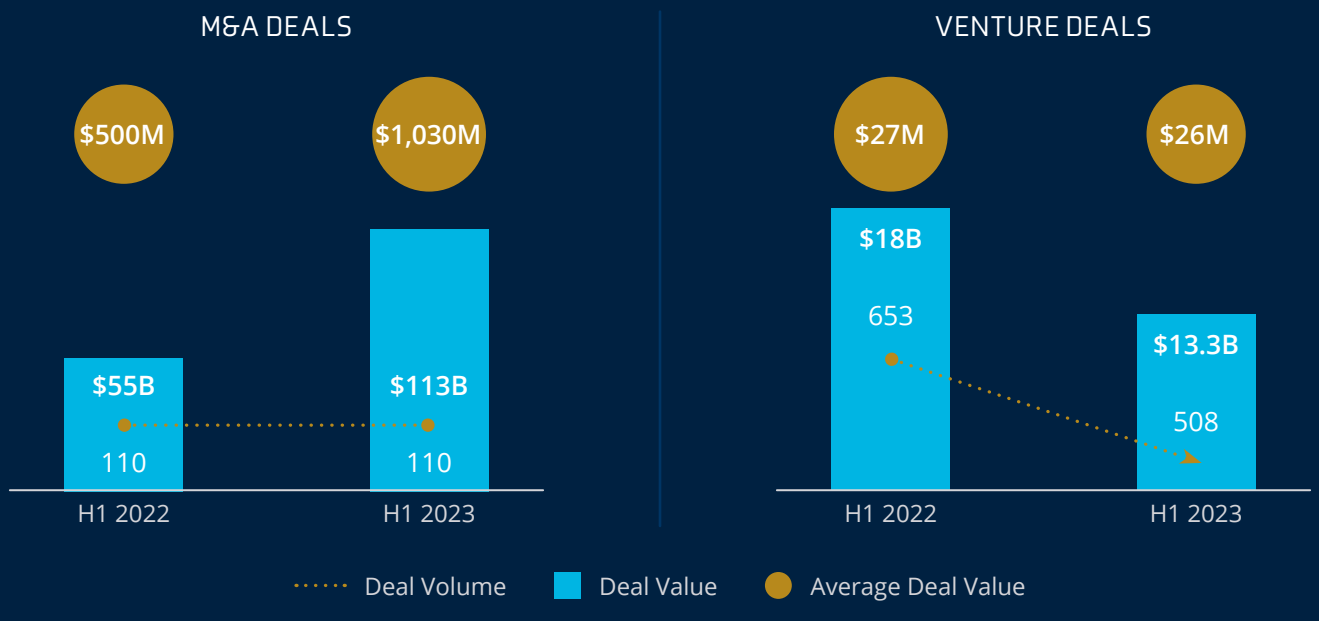
DIGITAL HEALTH AND HEALTHCARE INFORMATION TECHNOLOGY

2023 saw limited M&A activity within the digital health space due to a lack of transparent monetization and over-saturation from the explosive growth the telehealth segment experienced during the pandemic. However, venture capital in this segment accounted for one-third of money raised in the first half of 2023 and expect to see an increase in investment in this space continuing into 2024 due to heightened interest in artificial intelligence and next-generation digital health.[2]

M&A AND VENTURE ACTIVITY IN LIFE SCIENCES

2022-2023

Figure 1.
M&A and venture activity in life sciences (H1 2022-2023)



Source: Deloitte analysis of CapIQ and Crunchbase

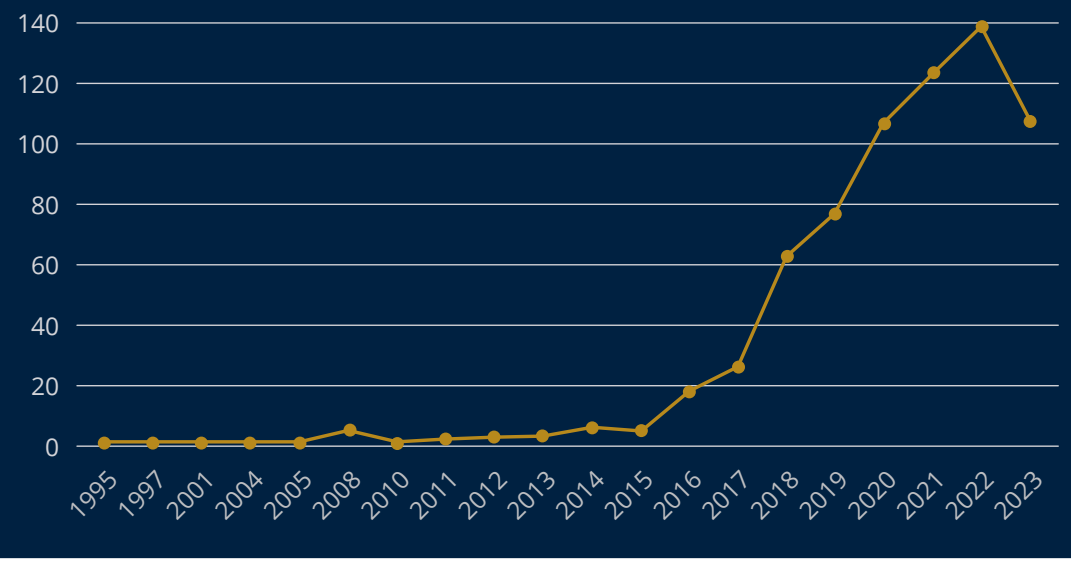
CELL AND GENE THERAPIES

Following the first successful launch of mRNA technology in COVID-19 vaccines, the market anticipates a rise in therapies utilizing this science. Prior to 2020, mRNA manufacturing had yet to keep pace with innovation. Significant advancements in personalized medicine have been made since that time using mRNA and the development of advanced technologies like mRNA printers to bring vaccines and made-to-order treatments to larger patient populations.

ARTIFICIAL INTELLIGENCE

The FDA had approved over 520 artificial intelligence and machine learning algorithms for medical use at the beginning of 2023. The first FDA approval for artificial intelligence for a medical purpose occurred in 1995, with only 50 other algorithms approved over the next 18 years. An overwhelming majority of the algorithms, over three hundred, were approved between 2019 and 2022. Dramatic acceleration in this space has created regulatory and logistical challenges for the FDA but a wealth of opportunity for the life sciences sector. With a wide range of applications, AI platforms are expected to see expansive growth in 2024 and beyond, with uses ranging from administrative operations to personalized medicine, drug discovery and development, disease diagnosis, and health risk prediction and remote monitoring capabilities. The AI market size globally for healthcare was estimated to be $15.1 billion in 2022 and is expected to surpass around $187.95 billion by 2030, growing at a CAGR of 37% during the forecast period of 2022 to 2030.[3]

FDA APPROVED ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING (AI/ML) ENABLED MEDICAL DEVICES



Source: Data from U.S. Food and Drug Administration. Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices[3]

In anticipation of accelerated development of AI, the FDA launched its Digital Health Center of Excellence in 2020 and began development of draft guidance relating to this technology. The FDA is prioritizing guidance on the use of artificial intelligence in 2024 and is anticipated to release draft guidance within the fiscal year relating to market submission recommendations for a predetermined change control plan for AI/ML-enabled device software functions.[4]

REGULATORY UPDATES

Looking ahead to 2024, the FDA will focus on the modernization of the clinical trial process.

The life sciences industry saw the implementation of many key elements in the FDA's Technology Modernization Action Plan that was developed in 2019. Key internal initiatives for the agency were implementing virtual data storage, problem-specific software development, and evolving solutions for efficient data exchange. The FDA focused on these areas to not only promote innovation regarding how the agency uses software in its work but also across the biomedical ecosystem.

In 2023, the 501(k) clearance process moved to a wholly digital platform, now requiring all submissions, unless exempted, to be electronically filed. In addition to technological updates on the filing process, the agency also released final guidance for medical device companies regarding their cybersecurity responsibilities, recognizing the increased potential and evolving nature of cyber security threats. The new guidance, aimed at premarket medical device submissions, requires device makers to submit a cybersecurity plan and additional information as required by the PATCH Act that was signed into law at the end of 2022.

Looking ahead to 2024, the FDA will focus on the modernization of the clinical trial process. In October 2023, the Center for Drug Evaluation and Research (CDER) announced that it is soliciting public comments to understand the state of innovation in both clinical conduct and trial design, requesting feedback on the barriers and facilitators to incorporating innovative clinical trial approaches in the drug development process. CDER, in partnership with Duke Margolis Center for Health Policy, will host a public workshop on March 19 and 20, 2024, regarding this topic.[5]

Innovations and opportunities are always on the horizon as the biopharma, life sciences, and Medtech sectors continue to grow at a rapid pace. The commitment of the FDA to bridging the gap between scientific advancements and the technologies needed to translate advancements into new treatments and therapies will aid in accelerating the drug development process and bringing new treatments to market.

KEY COVERAGES TO WATCH

PROPERTY

+ Climate change has been the largest contributing factor to the hardening property market in the last few years. Increased frequency and severity of billion-dollar weather-related events and catastrophic wildfires have caused significant property rate increases.
+ Inflation and market capacity are also contributing factors due to the increased cost of construction, materials, and labor driving up the costs of claims.
+ Insurance carrier capacity has become an increasing challenge for the marketplace as investor trust in the reinsurance segment has dwindled after six consecutive years of industry losses.

PRODUCT LIABILITY

+ The product liability capacity landscape for life sciences risks is flourishing, with several well-established carrier markets entering the life sciences segment in the last five years.
+ Domestic and international insurance carrier markets that have entered the biotechnology and life sciences segment can offer competitive options to select markets, resulting in a general softening of the market for this line of insurance coverage.
+ Coverage from newer entrants into the life sciences insurance market includes product liability coverage, with capacity for financial injury, and technology errors & omissions coverage.

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POLLUTION LIABILITY

+ Increasing demand for life sciences companies to carry environmental and pollution liability coverage due to litigation involving the use of ethylene oxide.

DIRECTORS LIABILITY

+ Very few lines of coverage see significant fluctuations based on macro and micro-economics as directors & officers liability. The impetus of environmental, social and governance (ESG), volatile geopolitical landscapes, litigation, and nuclear verdicts are only a few challenges to carriers in 2023-2024.

+ Ever-changing regulations worldwide meant continuous evolution in coverage, claims and legal responses. In 2023 alone, there have been significant updates to the FDA, FTC, and SEC regulations of cyber and how it affects directors & officers liability coverages.

CYBER

+ The regulatory landscape for medical device companies shifted significantly with the signing of the Consolidated Appropriations Act (H.R. 20617). The act mandated that the FDA institute express federal statutory cyber requirements for device manufacturers. The new statutes require device manufacturers to submit plans to the FDA outlining how device companies will identify, respond, and monitor post-market cyber security exploits and vulnerabilities.
+ A software bill of materials must be included for all off-the-shelf, open-source, and critical components that are part of the submitted device and commit to releasing post-market firmware, software, and patches throughout the device's lifecycle.
+ Between 2009 and 2022, 5,150 healthcare data breaches involving 500 or more records have been reported to the United States Department of Health and Human Services Office of Civil Rights. These breaches accounted for the exposure of 382,262,109 healthcare records.[6]
+ Insurance carriers remain vigilant in providing terms to risks that incorporate good cyber hygiene such as multifactor authentication (MFA), vulnerabilities testing, and best-in-class cyber risk management.
+ The demand for increased regulatory fines and penalties coverage under life sciences cyber insurance programs has increased due to the new FDA cyber security statutes.

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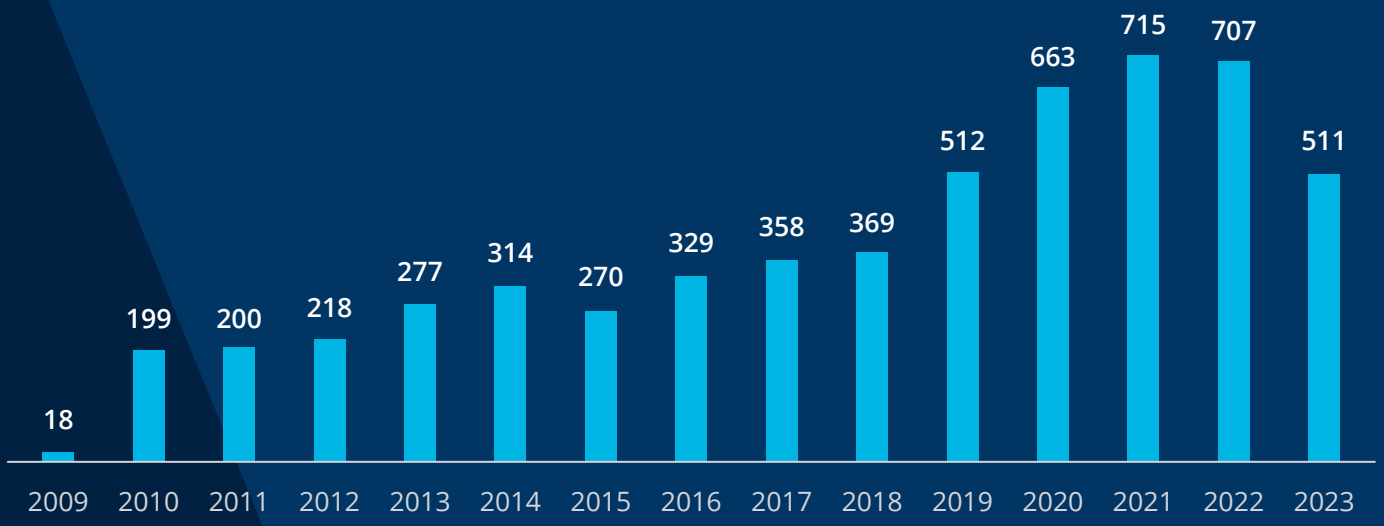
HEALTHCARE DATA BREACHES OF 500+ RECORDS

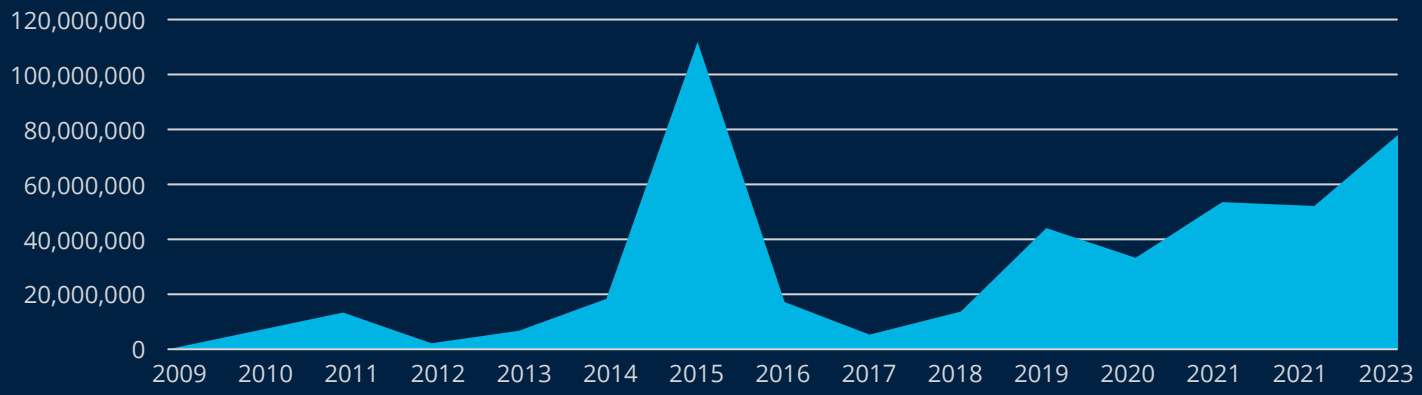
2009 – SEPT. 2023



HEALTHCARE RECORDS EXPOSED BY YEAR

INDIVIDUALS AFFECTED BY HEALTHCARE DATA BREACHES

2009 – SEPT. 2023



Source: The HIPAA Journal 2023, Healthcare Data Breach Statistics

GUIDANCE

START EARLY

Partner with your broker early to prepare for any changes to increase renewal success.

PARTNER WITH INDUSTRY EXPERTS

It is important to work with your broker's industry experts who understand the business and the market for placing the specific risk. Collaborating with a team that can best represent your risk and partner with your operations is more important than ever during this disciplined market we are experiencing.

HIGHLIGHT CYBER SECURITY & PROACTIVE RISK MANAGEMENT

IMA has a team solely dedicated to managing cyber risks. They offer expert assistance, including coverage analysis, financial loss exposure benchmarking, contract language review, in-depth cyber threat analysis, and strategic development of comprehensive, high-value cyber insurance programs.

CONTRACT REVIEW

Our contract review teams add value to our clients' overall risk management program by ensuring the indemnity language is market standard and doesn't expose our clients to unforeseen losses that may not be insurable.

ENGAGE SUSTAINABILITY

IMA invests heavily to deploy specialty niche teams concentrating on cutting-edge technology, green energy initiatives, and advanced manufacturing. As every client is different, our Sustainability Advisory team provides clients with education, advice, and access to tools and best practices to advance their sustainability resiliency and showcase their ESG performance for insurance underwriters.

Sources:

1 IBISWorld. (2023, September). Industry Report: Biotechnology in the US. IBISWorld. https://www.ibisworld.com/united-states/market-research-reports/biotechnology-industry/#IndustryStatisticsAndTrends

2 Deloitte. (n.d.). *M&A and venture trends in life sciences in 2023 Pharma M&A dominates deal activity.* Deloitte. https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/mergers-and-acquisitions-trends-survey-life-sciences.html

3 U.S. Food & Drug Administration. (n.d.). *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices.* FDA. https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

4 U.S. Food & Drug Administration. (n.d.). *CDRH Proposed Guidances for Fiscal Year 2024 (FY2024).* FDA. https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2024fy2024?utm_medium=email&utm_source=govdelivery#a

5 U.S. Food & Drug Administration. (n.d.). *Enhancing Adoption of Innovative Clinical Trial Approaches.* FDA. https://www.fda.gov/drugs/news-events-human-drugs/enhancing-adoption-innovative-clinical-trial-approaches-03192024#event-information

6 The HIPAA Journal. (n.d.). *Healthcare Data Breach Statistics.* The HIPAA Journal. https://www.hipaajournal.com/healthcare-data-breach-statistics/

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KEEP READING

PREVIOUS EDITION

GENERAL EDITION

EMPLOYEE BENEFITS BLOG

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