Insight Brief

Ten MedTech Trends to Watch in 2024

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2024 will be a year of diverse challenges for MedTech companies, some of which presage potentially significant changes before the decade is over. This insight brief covers ten of the top trends IQVIA MedTech experts see on the horizon and the implications for the MedTech industry.

1 GLP-1s: Keep calm and carry on

Glucagon-like peptide-1 (GLP-1) drugs are a topic of great interest coming into 2024 as these medications could potentially have a significant impact on the prevalence of type 2 diabetes and obesity. Manufacturers of devices that are indicated or highly correlated with those populations — certainly insulin measurement and delivery, but also joint replacement, dialysis, bariatric procedures, and CPAP therapy — are watching this area very closely. Furthermore, Wall Street has delivered its verdict, hammering the stock prices of many of these companies. However, the path for pharmaceuticals from successful clinical trials to broad, consistent commercial adoption can be bumpy. Adherence and compliance — particularly with drugs that are injected, but also those that require daily orals — tend to slip in the real world. Patients can weary of side effects, fail to refill prescriptions, or change jobs and insurance. Both a U.S. and a U.K. study showed that around half of patients discontinue GLP-1 therapy after the first year. A recent clinical trial sponsored by Eli Lilly indicated that patients on Zepbound gained about half of their weight back in the year after discontinuing use. This data may explain why an analysis by IQVIA indicates that, to date, obesity diagnoses are remaining stable despite the rise in GLP-1 uptake.

Coverage is another potential issue. Currently, Medicare is statutorily barred from covering medications specifically intended for weight loss due to an explicit policy built into the 2003 law that created Medicare Part D, driven in part by the controversy around fen-phen.

In light of this coverage restriction for weight loss, GLP-1 manufacturers are conducting studies with primary indications which could secure coverage, including for osteoarthritis, cardiovascular disease, sleep apnea, type 2 diabetes, and triglycerides. Some of these studies have readouts in 2024, for which there may be downstream impacts on devices. In the U.S., where much of the commercial coverage is driven by employers, an employer may be reluctant to cover the high cost for a drug that will deliver cost savings well down the road when the employee is likely to have moved on to a different employer and a different payer.

So, all things considered, we are yet to experience a world where a compliant, covered population is taking these drugs for a lifetime and, therefore, materially impacting the use of various medical devices.

On the bright side, there is a potential scenario where GLP-1s have a positive impact on MedTech. For instance, payers may be inclined to grant coverage for a temporary period in order for a dangerously obese patient to lose enough weight to safely undergo a procedure like joint replacement or bariatric surgery.

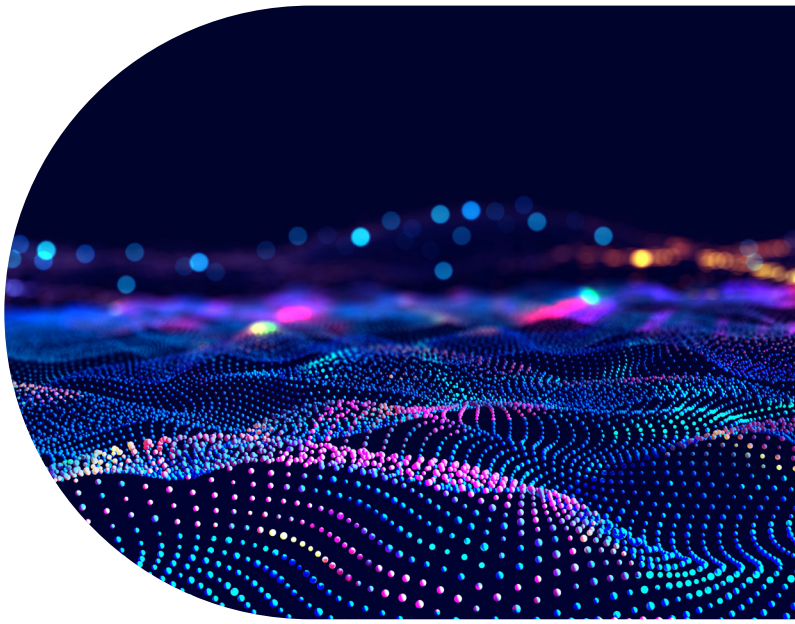
2 AI will remain a hot topic with limited clinical applications — for now

The clinical promise of artificial intelligence (AI) has been on the MedTech horizon for years now, but in reality, is still fairly limited. In fact, a 2022 report by the GAO and the National Academy of Medicine on AI bluntly states that “these technologies are not widely adopted.” About 75% of AI clinical applications sit in radiology, where the

inputs to an algorithm (i.e., digital images) and yes/no pathology reports are relatively straightforward to capture and analyze. Radiology AI tools have also benefited from the existence of extensive longitudinal data. On the other hand, many clinical decision tools can require multiple, complex, patient-generated inputs from different devices and settings, often constrained by privacy restrictions. These challenges have limited the development and testing of AI models, so there is limited longitudinal data on their accuracy. However, AI capabilities are expanding quickly, and technologies are making access and analysis of different kinds of healthcare data from multiple devices across varied settings of care more feasible.

Governing bodies are racing to catch up. In October 2023, the FDA announced the creation of a new Digital Health Advisory Committee to help the agency explore the complex, scientific, and technical issues related to digital health technologies, such as artificial intelligence/machine learning (AI/ML), augmented reality, virtual reality (VR), digital therapeutics, wearables, remote patient monitoring, and software. In November, the AMA published a set of principles for AI development and deployment in healthcare hoping to shape a "consistent governance structure for advancements in healthcare technology." Central to their concerns are that physicians understand how a tool was developed, what information was utilized, and how it was trained and validated. They worry that these tools will supersede the physician's judgement to the detriment of the patient, as they claim it is already happening in AI-driven payer decisions to deny care. Another worry, though less voiced, is where liability will lie. For example, if an AI tool misdirects a physician, who carries the fault — the developer, the physician, or the institution?

So, for 2024, expect more activity around concern and control, and less about actual applications. But that is likely to change quickly as the decade proceeds.



3 Labor shortages: Not just a problem for healthcare

There has been much written, and many statistics provided, about the exodus of trained, experienced healthcare workers either to retirement or to more lucrative, less stressful careers. The impact on healthcare institutions, particularly hospitals, is also well documented. In general, the impact this has on MedTech has been focused on the potential loss of revenue as staff reductions curtail a hospital's capacity for procedures. What is less covered, and comes up in conversations with MedTech executives, is the impact on MedTech labor.

MedTech manufacturers have traditionally provided a wide range of services to hospitals and Ambulatory Surgery Centers (ASCs), including healthcare provider (HCP) education and training, inventory management, benchmarking, clinical protocol and decision support, operational and workflow consulting support, and reimbursement support. However, traditionally they have provided support to these areas, not wholesale substitution.

But post-pandemic demands on MedTech manufacturers are growing. Training is a good example. Device manufacturers typically train a set of personnel who can then go on and train others in the institution. However, high staff turnover means that training needs to be repeated frequently, as either the trainer changes or they simply no longer have time to train their new staff. Equipment servicing is another example. Biomedical equipment technicians are in such short supply that they are now expected to perform all types of service on virtually any medical device, regardless of individual training and expertise. They, too, turn to manufacturer's service personnel for assistance. These increasing demands from providers come at a time when MedTech companies are tightening their belts and reducing staff — for example, MassDevice reported 18,000 layoffs since mid-2022.

Hospital staffing shortages, particularly in nursing, are global and not predicted to ease in the near-term. **Therefore, expect MedTech to increasingly invest in cost-efficient ways to meet increasing demands for support while allowing their representatives to focus on revenue-generating activities**. For instance, healthcare institutions are already implementing VR training. A recent survey conducted by Virti found that a third of healthcare organizations have implemented VR technology and many more plan to. MedTech investments in VR will accelerate for both clinical and servicing applications over this decade. MedTech companies will also likely scrutinize device design to maximize performance against three objectives: reduce labor, minimize the potential for errors or breakdown, and maximize the potential for remote training and servicing.

4 Health equity moving from request to requirement

Health equity has been inching forward as a national policy priority for years, but disparities in care were thrown into stark relief by the COVID-19 crisis. For the medical device industry, studies showing that commonly used technologies (such as pulse oximetry) routinely perform worse on patients of color, elevated the issue of health equity to a top priority for industry, regulators, and payers alike. Most of the efforts to date have focused on statements, guiding principles, and statements of intent. Moving forward, stakeholders have begun putting real incentives, rewards, and even consequences in place to advance this goal.

The FDA finalized guidance this year that includes language making advancements in health equity a qualifying attribute for the Breakthrough Device Program. Technology that addresses conditions disproportionately affecting underrepresented populations, or that is designed to increase access to care in those populations can now request designation as a Breakthrough Device. The 2023 omnibus spending bill requires development of clinical trial diversity action plans for FDA studies, and as a result, the FDA issued draft guidance to industry in April 2023 that recommends any sponsor of a medical product develop a Race and Ethnicity Diversity Plan early in the regulatory process and demonstrate diverse participation in all studies. Adding additional weight to this issue, several CMS measures include health equity requirements. Reporting social determinants of health was encouraged prior to 2023, but in 2024 becomes a provider requirement. The White House Initiative on Cancer Research, the Cancer Moonshot, and multiple funding opportunities from nearly every federal agency are adding momentum to the cause.

Similar initiatives can be found outside the U.S. The World Health Organization (WHO) adopted "The Health 2020" framework, aimed at improving population health and reducing inequalities, among other objectives.

The European Health Equity Status Report initiative was also initiated by WHO to ensure policies in the EU are focused on managing health inequalities. The Joint Action Health Equity Europe guarantees cooperation between countries and introduces measures to manage health gaps. Additionally, the U.K. is proposing inclusion and diversity requirements for clinical trials which go beyond those currently in place in the U.S.

With encouragement driven by these types of programs and funding, and the increasing consequences of neglecting potential health inequities, medical device companies will be pushed to incorporate health equity priorities into device design and testing.

5 Supply chain pressures are here to stay

Supply chain pressures makes the trend list for the second year in a row, as what was originally the COVID-19 pandemic disruption has evolved into ongoing regional conflicts and climate crises. Alloys that MedTech relies on are either sourced or manufactured in areas of geopolitical risk (such as China, Russia, India, Ukraine, and the Democratic Republic of Congo). Plastic is highly sensitive to fluctuations in the price of oil, and while 2022-2023 year-over-year pricing was relatively stable, intra-year fluctuations have been significant. Labor shortages and strikes continue to add risk, and intensifying weather events can create significant disruptions often concomitant with significant need for medical supplies in impacted areas. A recent study by Cross Dependency Initiative predicts that one in twelve hospitals worldwide are at risk of total or partial shutdown from extreme weather events.

As a further measure of the significance of this issue, the White House is getting involved. It has created a White House Council on Supply Chain Resilience to focus on a broad range of issues, with specific provisions for

healthcare, including the creation of a Supply Chain Resilience and Shortage Coordinator within the U.S. Department of Health and Human Services.

As a result, **MedTech supply chain design has to assume that disruption will occur and be structured to quickly respond to and overcome regional and material interruptions.** MedTech companies need to keep executing against the pillars of nimble manufacturing and distribution (e.g., near/friend shoring, forgoing some bulk discount in favor of keeping multiple suppliers on tap, and committing to increasing inventory and safety stock). In addition, supply chain databases (connected dashboards of data, key business metrics, and events) are increasingly implemented in order to more fully understand, prioritize, and resolve critical issues in real time.

6 The consolidation of health systems and insurers will pressure MedTech

Mergers and acquisitions continue to reshape the ecosystem of healthcare, with several multibillion-dollar transactions announced or expected to close in 2024, and more on the horizon. While these business deals are generally not a new phenomenon, the nature of recent consolidations is poised to affect MedTech to a larger extent than previously experienced.

Increasingly, high-profile deals between hospital systems, insurers and provider groups, and insurers purchasing other insurers have a common factor of the acquirer strengthening their presence in Medicare

Advantage and/or value-based care delivery. Among others, 2023 saw UnitedHealth complete its acquisition of LHC Group, and CVS close its purchases of both home healthcare service provider Signify Health and the Medicare Advantage-focused primary care network Oak Street Health. Most recently, barring antitrust issues, the November 2023 announcement of a merger between Cigna and Humana will result in further consolidation, creating one of the largest national Medicare Advantage books of business.

Many observers have focused on the potential impact of these mergers on drug pricing and distribution, but an overlooked consequence of these deals is the increased ability of payer stakeholders to exert pressure and competitive selectivity on MedTech as well. **Particularly for high volume products (e.g., diagnostics for high prevalence diseases and devices used to manage chronic conditions) and costly technologies with multiple manufacturers, we expect more payer and provider system demand for favorable pricing, or robust evidence to support premium price points**. MedTech innovators will need to incorporate these new pressures into the R&D and product lifecycle strategies, highlighting the need for disciplined, proactive planning across the industry.

7 An increasing focus on sustainability will require greater innovation

MedTech companies are increasingly facing diverse sustainability regulations globally, including the U.S. Securities and Exchange Commission's Proposed ESG Rules, South Africa's Environmental Impact Assessment Regulations, U.K.'s Producer Responsibility Obligations Regulations, U.K.'s Climate Change Levy, and EU's Corporate Sustainability Reporting Directive.

Certainly MedTech, with its heavy use of plastics, intensive packaging, and proliferation of disposables, is aware of its environmental responsibilities — especially as several reports cite healthcare as a significant contributor to emissions. But interestingly, in a recent survey by EY, only a third of life science CEOs believe that becoming a sustainability leader will provide a competitive advantage. Despite assertions that the investor community rewards sustainability initiatives, many of these same CEOs cite investor resistance as a concern.

However, based on pledges made as of March 2023, The 19 out of top 20 MedTech companies have established targets for reducing emissions. Several are already publishing impressive results. Current progress against these goals has been predominantly achieved by transforming their own operations and supply chains, rather than by redesigning their products, which is potentially a more difficult challenge.

MedTech is a highly regulated industry, with patient safety from infection or malfunction a primary concern. These manufacturers cannot simply change materials or packaging without running into regulatory considerations, which could require new submissions and evidence. Also, medical devices that cannot be recycled and/or contribute significantly to a hospital's waste are usually counted toward the hospital's carbon footprint, not the manufacturer's.

Given the overall awareness and interest in sustainability and reducing emissions, we expect providers to increase pressure on MedTech manufacturers to invest in improvements to device design and packaging to reduce their impact on emissions. These might include reconsidering reusable versus disposable devices, retrofitting older machinery to upgrade and resell, reducing non-recyclable materials overall, and designing more environmentally friendly packaging.

8 Advances in diagnostics are bumping up against complex regulatory and market access pathways

Diagnostic testing is a burgeoning area of MedTech growth. In particular, next-generation sequencing and panel testing have revolutionized molecular diagnostics and associated treatment decision making. However, the regulatory pathways are evolving across the globe, and payers are also revising the rules of the road.

From a regulatory standpoint, the FDA has historically maintained the position that it has the authority to regulate laboratory-developed tests (LDTs) as medical devices (specifically in vitro diagnostics (IVDs)). The agency has exercised enforcement discretion for LDTs developed within a single laboratory that are validated pursuant to the Clinical Laboratory Improvement Amendment standards. Should the FDA end this enforcement discretion and decide to regulate LDTs going forward, the industry will see a change in the landscape of laboratory testing in the U.S.

In an earlier trends blog, we noted that the EU's IVD Regulations (IVDR) greatly increases the number of IVD devices subject to regulatory oversight. But it also expands the overall scope of compliance. Since there is no grandfathering, legacy devices also need to meet performance evaluation requirements. With only ten (as of July 2023) IVDR-designated notified bodies so far, capacity is improving, but **devices that show significant gaps in clinical evidence risk being refused, particularly if those gaps cannot be closed in the timeframes stipulated for the notified body review**. The IVDR application refusal data show that manufacturers appear to struggle with their applications, often with incomplete data, wrong qualification and/or classification, as well as other reasons. In March 2023, the IVDR was amended with regards to transitional provisions for certain IVD medical devices with the removal of the sell-off period.

In terms of U.S. market access, Medicare's Molecular Diagnostic Services Program has recently emphasized developing evidence-based coverage and reimbursement policies for advanced molecular tests and prognostic/predictive multianalyte assays with algorithmic analyses. The program's influence has broad impact, but particularly for the newest, most sophisticated diagnostics. Commercial payers often pragmatically update commercial policies to parallel mandatory in-house Medicare Advantage benefit alignments, so stricter coverage requirements will be felt across the board.

9 TCET still alive and part of the drive to global HTA frameworks

We continue to await substantive progress on much-anticipated and long-delayed federal market access pathways for innovative medical devices and diagnostics. After multiple rounds of introduction, tabling, revision, and rebranding, the current proposal in Congress – now titled Transitional Coverage for Emerging Technologies (TCET) – has been formally supported by the White House and the Centers for Medicare & Medicaid Services (CMS) but enjoys less consensus support from legislators and MedTech industry voices.

Most informed commentary on TCET has rightly been focused on the limited eligibility criteria and opacity of the planned administrative processes for technologies with Breakthrough Device Designation that are able to leverage this pathway. However, one of the more impactful aspects of TCET that could remake the broader marketplace is how it proposes to expand CMS' remit to include more formal health technology assessment (HTA) responsibilities. Previously, CMS reserved most of their HTA work in service of creating guardrails for products with inconclusive clinical value through the Coverage with Evidence Development (CED) decisions attached to national coverage announcements. However, CED has been rarely deployed, with less than 30 total CED decisions since 2000. In contrast, TCET would mandate

that CMS conduct formal clinical and health economic evaluations and generate evidence development guidance for five or more products per year — with an ever-growing pipeline of at least 350 potentially eligible products.

Coupled with the medication pricing negotiation powers granted to CMS by the Inflation Reduction Act, enacting TCET would represent a formal leap for CMS more closely mirroring traditional HTA organizations such as the National Institute for Health and Care Excellence or Haute Autorité de Santé.

This prospective landscape shift creates a unique opportunity for thoughtful MedTech stakeholders to consider approaches to:

- Providing an advocate voice for shaping CMS best practices and processes.
- Creating integrated long-term data generation and real-world evidence programs to address CMS concerns.

10 A younger generation of physicians requires new approaches to communication

According to the European Commission's Eurostat, the baby boomer generation is reaching retirement age at around 62-67 years, and recent OECD data show that professionals are choosing to retire at a younger age. At the same time, the number of graduating doctors per 100,000 inhabitants increased in almost all EU member states. In the U.S., the stress and burnout caused by the COVID-19 pandemic drove a number of older doctors to retire early, and according to a study by Medical Economics, 60% of GenX physicians intend to retire by 60, with 12% already working part time.

With the generational shift, new communication strategies are expected. In regards to training, a variety of surveys and studies indicate that the preferred learning formats for the new generation of physicians are online lectures and courses, in addition to internet/self-directed search. According to a global survey by Indogene, approximately 77% of HCPs use digital channels primarily for learning and development, 68% for video conferencing for professional networking, 63% for telemedicine, and 58% for remote interaction with pharma companies. Given these statistics, it is not surprising that approximately 65% of HCPs in the United States spend at least four hours online every day.

Further, according to a survey performed in 2020 by HealthLink Dimensions, approximately 68% of doctors prefer email over any other marketing channel, and 21% of these emails are opened within the first hour.

To successfully engage and build strong relationships with the new generation of physicians, MedTech companies will need to develop more agile methods, an omnichannel approach, and quick, accessible, tailor-made content.

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