6

Emerging Medical Device Trends

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A Letter From Our President

With new technology and groundbreaking medical devices being introduced every week, there's never been a more exciting time to be involved in clinical research.

Even during the coronavirus pandemic, the pace of innovation has only accelerated.

We've seen the introduction of a device designed to split ventilators so they can be used by multiple patients at once.[1] We've marveled at sustainable, reusable face masks that are four times as effective as handmade cloth masks[2] and 3D-printed medical devices, such as oxygen valves.[3]

This is likely just the beginning. As this international crisis has continued, the FDA has made emergency allowances to put some of these life-saving devices on the fast track to approval. Some of these emergency measures could remain in place after the worst of the pandemic is over, leading to further advancements in medical devices and pharmaceutical drugs.

At IMARC Research, we celebrate innovation. We're constantly learning more about the latest medical device trends and regulatory updates that impact the teams who enlist our oversight. We know how important it is for professionals in this industry to stay informed, too. That's why we're eager to share six emerging trends we believe will transform clinical research as we know it.

We'd love to hear your thoughts on these trends and how you are applying them in your own research.

Sincerely,

Brandy Chittester,

President, IMARC Research

1. Artificial Intelligence

Artificial intelligence (AI) and machine learning have virtually unlimited applications. In the medical field, this technology is being used to more accurately diagnose conditions and provide more targeted treatment.

Some studies estimate there are as many as 12 million diagnostic errors each year in the United States alone.[4]

AI and machine learning could scan thousands of images in a fraction of the time it would take an experienced physician, recognizing patterns that could inform future diagnoses.

A recent study comparing the performance of deep learning algorithms and healthcare professionals showed the algorithms performed better on average when it came to both detecting the presence of disease and identifying a specific type of disease.[5]

The application of AI in medicine isn't intended to replace the wisdom and experience of medical professionals, but to give them additional resources.

In 2019, the FDA introduced new guidance for this emerging segment of the healthcare technology market, stressing the need to provide guardrails without stifling innovation.

Because these devices rely on algorithms that continually learn and adapt, the FDA approval process will need to be different than approvals for traditional devices. Developers will need to ensure the models for algorithms that power these devices are properly validated and documented. Any changes to the algorithm will also need to be documented, but not every change will require FDA approval, former FDA commissioner Scott Gottlieb said in a statement.[6]

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> The goal of the framework is to assure that ongoing algorithm changes follow pre-specified performance objectives and change control plans, use a validation process that ensures improvements to the performance, safety and effectiveness of the artificial intelligence software, and includes real-world monitoring of performance once the device is on the market to ensure safety and effectiveness are maintained.
>
> - Scott Gottlieb

2. Nanotechnology

Nanotechnology is an exciting field that involves inserting microscopic particles into the body to identify and treat diseases with targeted precision. While some traditional forms of in vitro diagnostics can be time-consuming, tedious and costly, nanotechnology introduces the potential for new devices that are much smaller, more cost-effective and easier to use, according to an article published by the National Institute for Biotechnology and Genetic Engineering in Pakistan.[7]

Examples include “imaging pills” that use sensors to provide faster data to physicians or magnetically-controlled nanobots that collect tissue from the body.

Additionally, “nano medical implants” can continuously deliver treatment in ways that are less invasive than current drug delivery devices. According to the same journal article, this technology could even be used to mark diseased cells with nanoparticles and treat those specific cells using forces outside the body, such as magnetic fields or lasers.

This could result in cancer treatment with fewer side effects because it is only targeting diseased cells without damaging healthy ones.

Researchers are also exploring “microbots” that could potentially create less invasive surgical tools.[8]

3. Robotics

From microbots to the da Vinci Surgical System, robotics show great promise in the medical device industry.

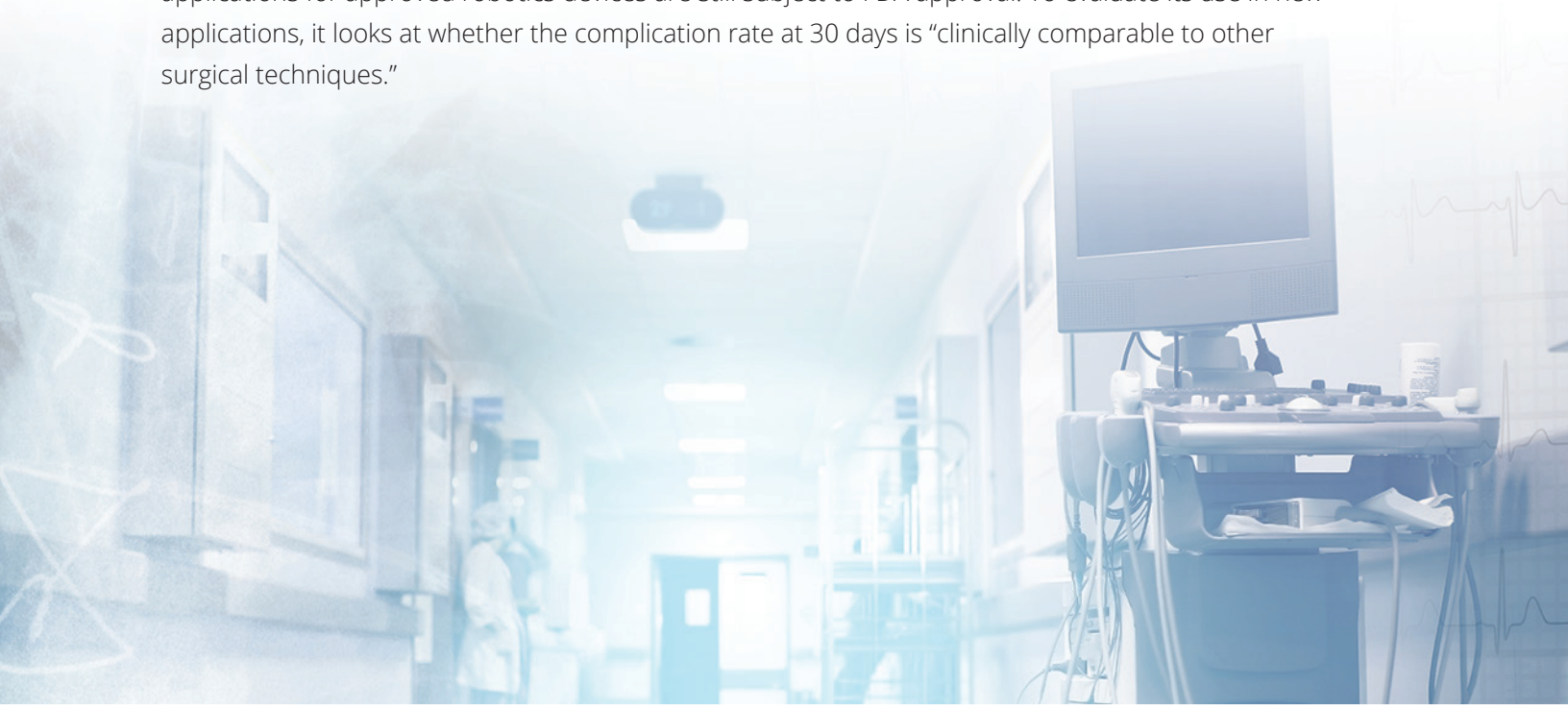
Analysts predict the global healthcare robotics market will reach $11.44 billion by 2025.[9]

In addition to improving surgical precision, robots can improve recovery and patient care.[10] One example is an exoskeleton that uses sensors on the skin to detect electrical signals and respond with movement, helping patients recover from spinal cord injuries and strokes. Robotics could also perform routine healthcare tasks like taking blood pressure or temperatures, allowing hospital staff to focus on more advanced patient care.

However, there are still significant risks to consider. The FDA has approved robotically-assisted surgical devices for certain procedures, such as hysterectomies, but not others, including mastectomies or any type of cancer treatment.[11]

Surgeons who use these devices also need proper training, which is not regulated by the FDA, leaving the responsibility to device manufacturers and healthcare facilities.

The FDA is still reviewing the risks and benefits of using robotically-assisted surgical devices. New applications for approved robotics devices are still subject to FDA approval. To evaluate its use in new applications, it looks at whether the complication rate at 30 days is "clinically comparable to other surgical techniques."



4. 3D-Printed Medical Devices

The growing demand for personal protective equipment (PPE) during the coronavirus pandemic has led to an increase in 3D-printed medical devices, such as face shields, masks and devices for ventilators.

Due to the urgent health risks of COVID-19, the FDA has issued emergency use authorizations (EUAs) for some of these devices that have yet to be approved,[12] including 3D-printed masks and other potentially life-saving applications, which are evaluated on a case-by-case basis using the FDA's latest guidance.

The FDA has created an emergency program, Coronavirus Treatment Acceleration Program (CTAP), designed to support clinical trials and new treatments using 3D-printed medical devices.

The NIH 3D Print Exchange also offers downloadable designs of 3D-printed medical device prototypes, built by America Makes in collaboration with the FDA, National Institutes of Health and Department of Veterans Affairs.

In the future, we can expect to see 3D-printed medical devices becoming standard for many other applications, including organs, tissues, bones and surgical equipment.[13]

What Manufacturers Need To Know About 3D-Printed Medical Devices

Here are a few key takeaways for manufacturers, based on IMARC's evaluation of the FDA's recent guidance for 3D-printed medical devices[14]:

- 3D-printed masks have not been approved by the FDA to provide air filtration or fluid protection that is equivalent to surgical masks and N95 respirators
- The need for validation, testing and approved clearance depends on the device's classification
- When 3D printing medical device components, manufacturers should use the same performance quality, device dimensions and specifications
- Manufacturers should consider the demand for specific products, device component compatibility and medical, government and regulatory guidelines before production

5. Wearable Devices

More than 772 million people owned wearable, connected devices in 2019, and that number is expected to increase to more than 1 billion by 2022.[15]

Even more people — over 3.5 billion — own smartphones.[16]

The potential of these devices to assist with data collection in clinical trials is huge. Patient-generated data is faster to collect and respond to, allowing researchers to monitor patients closely and intervene quickly when adverse events occur. Allowing participants to use these devices to collect health data in the comfort of their own home is more convenient and could make recruiting easier. As of June 2020, ClinicalTrials.gov, a global database of clinical trials, listed 837 trials with "wearable devices" or "wearable technology" in the description.

Potential applications include:

- Diagnosing and treating sleep disorders
- Using a Garmin chest band to detect atrial fibrillation
- Using wearables or smartphone apps to promote physical activity and improve outcomes for patients with diabetes and other health conditions
- Collecting data on the health impact of sleep deprivation for night shift workers

However, like other emerging medical device trends, they need to be considered carefully in clinical research. An article published in Clinical Pharmacology and Therapeutics outlined some of these concerns.[17]

For instance, researchers need to pay special attention to how they train study participants to use these devices to ensure consistency. They also need to consider how they collect and store patient data. Different devices may store data in different formats, which could lead to inconsistencies if study participants are using their own wearables or smartphones.

There are also legal and ethical challenges. For instance, while data obtained by medical devices is protected by patient privacy laws, those protections don't apply to wearable devices like fitness trackers. In addition to collecting data, wearable devices and smart devices also have the potential to assist with diagnosis and treatment.

The smart medical device industry is expected to reach almost $64 billion by 2024.[18]

Smart medical devices are being used in a variety of applications ranging from diagnosis, monitoring, therapy and injury prevention.

Examples include:

- Wearable sensors that analyze balance, gait patterns and other risk factors for falling among elderly patients
- A wearable blood pressure monitor
- A portable visor that sends low-energy radio waves through the brain to detect strokes in patients
- Smart socks that measure foot temperature to detect skin inflammation in people with diabetes, preventing ulcers that can lead to amputations

We expect to see many more applications in the coming years.

6. Increased Adoption Of Remote Research Activities

Clinical researchers have used remote monitoring and auditing for years to supplement on-site activities, but they've become lifelines during the pandemic. In March, the FDA issued new guidance for conducting clinical trials during the pandemic, including encouraging remote techniques when possible.

Shortly after, the FDA issued another policy that allows manufacturers of certain FDA-cleared non-invasive, vital sign-measuring devices to monitor patients remotely. The devices include those that measure body temperature, respiratory rate, heart rate, and blood pressure. They also released a guidance for remote ophthalmic assessments.

Although the FDA guidances limit these policies to the duration of the COVID-19 emergency, the clinical research industry has been ready to transition to more remote work for a long while. The pandemic will speed up the pace of adoption by allowing research teams to become more comfortable with leveraging the technology.

At clinical sites, subjects are being identified, screened and consented virtually, and in some cases entire clinical trials are being conducted remotely.

For sponsor oversight, remote monitoring and auditing are being implemented at a much higher rate than prior to the pandemic. Conducting this work remotely allows researchers to maintain their oversight (which is required by FDA guidance) without the added expense of travel costs.

These activities are ideal for researchers who are able to grant secure access to electronic medical records or use a secure file-sharing system so that data can be collected and reviewed in real time.

In the future, post COVID-19, considerations for utilizing remote research activities include:

- The complexity of the trial/device under investigation
- The experience level of the site/sponsor teams
- Whether remote data collection and/or monitoring could pose any additional risks to study subjects
- How enrollment and informed consent will be managed (using electronic signatures, for example)
- How remote visits with subjects will be conducted (via phone or video calls, for example)

While a remote approach may not work for every study or even every site within a study, often the advantages of real time data collection and oversight make the planning and coordination efforts worthwhile.

In our 21st year as a medical-device CRO, we enjoy watching the latest trends in the industry to ensure we are up to date and ready to partner with our clients to keep clinical trials moving forward.

IMARC Research is a right-size CRO with the experience to maintain compliance on the most up-to-date, complex medical device clinical trials.

To learn more about how we can help, request a free consultation today.

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WE'LL EARN YOUR APPROVAL.

As a global, ISO 9001:2015-certified, full-service medical device CRO, IMARC has over 20 years of experience helping manufacturers conduct compliant clinical research and ultimately earn approval.