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Unpacking Averages: Growth of AI/ML in Medicine as Evidenced by Clinical Trials

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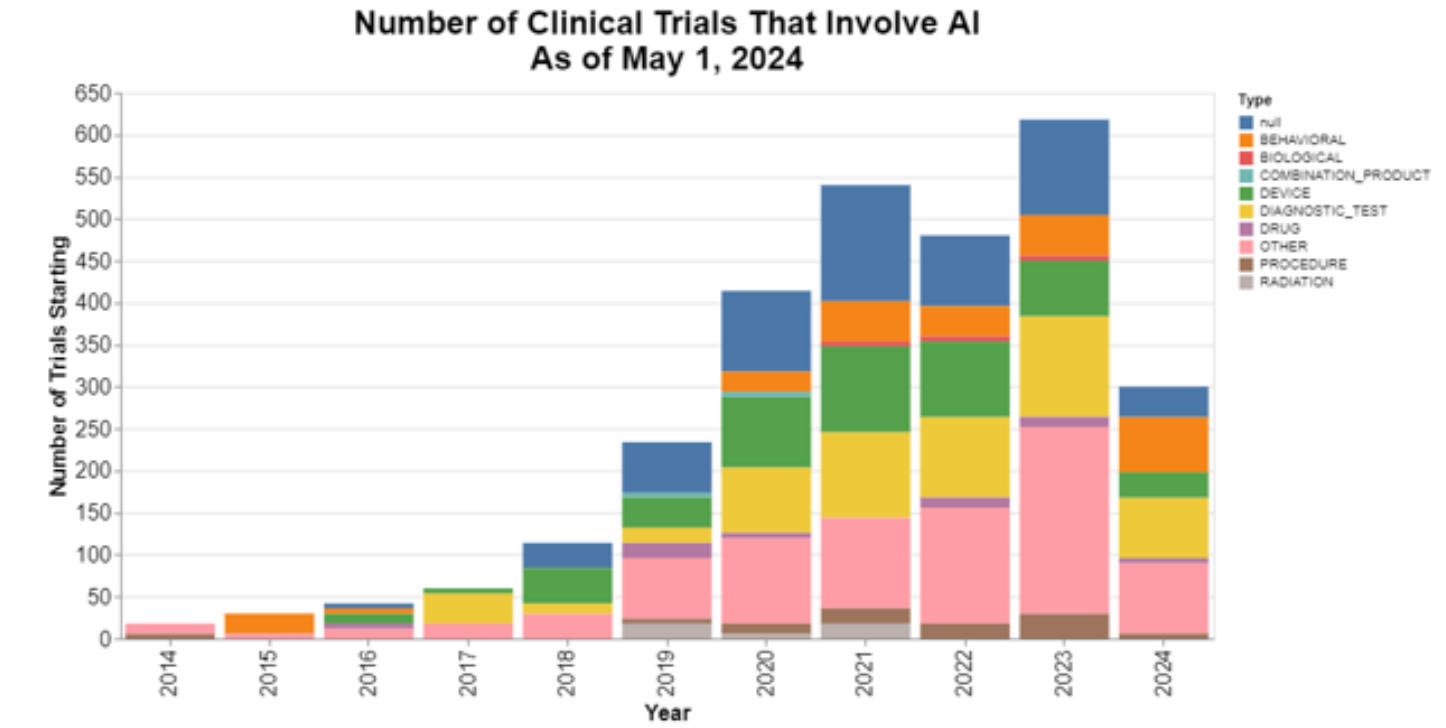
Most people have seen the growth in artificial intelligence/ machine learning (AI/ML)-based medical devices being cleared by FDA.

FDA updates that data once a year at the close of its fiscal year. Clearly the trend is up. But that's a bit backward looking, in the sense that we are only learning after the fact about FDA clearances for therapeutic applications of AI/ML. I want to look forward. I want a leading indicator, not a laggard.

I also want to focus on uses of AI/ML that are truly therapeutic or diagnostic, as opposed to the wide variety of lifestyle and wellness AI/ML products and the applications used on the administrative side of healthcare. As a result, in this post I explore the information on clinicaltrials.gov because not only are those data focused on the truly health related, they are also forward-looking. The more recent clinical trials involve products still under investigation and not yet commercially available or even submitted to FDA.

Findings

Looking back just over 10 years, here is the trend in clinical trials that somehow involve AI/ML, sorted by start date.



Click to enlarge the image.

Since the data are as of May 1, that means for 2024, the data include only 1/3 of a year. Thus, in your mind's eye, multiply that column by three, if progress continues at the pace of the beginning of the year.

Methodology

This month the methodology was straightforward. I use the API at clinicaltrials.gov to do a search of clinical studies that are registered on that site that use the phrase “artificial intelligence” or “machine learning” in connection with describing the trial.

I focused my search on the so-called “brief summary” provided to the clinical trials registry. Often that summary is quite brief, so if AI/ML is mentioned in it, chances are pretty good the technology plays a significant role. I limited my search to the last 10 years, not counting 2024 as it's a partial year.

For the intervention type, in creating the chart I took the first listed intervention. Many studies contain multiple arms, so there might be more than one intervention type. Taking the first arm intervention is somewhat arbitrary, but it looked to me as though often that first listed arm was the experimental arm, as opposed to the control arm, for example.

Analysis

For those of you who don't routinely use clinicaltrials.gov, it might help to read my prior post on analyzing data from that registry, as I include an explanation of exactly which studies need to be registered. Regarding the scope of medical device clinical trials that need to be registered, in that

post I explained, “The easiest way to summarize it is to say that all of those interventional clinical trials that must be conducted under an Investigational Device Exemption or IDE and are not a device feasibility study must register on the clinicaltrials.gov site. As you may know, a device must be investigated under an IDE granted by the FDA if it involves significant risk. A device feasibility study is less clearly defined, but it does seem clear that a feasibility study is not one that will be submitted to FDA in support of a marketing application.”

For these purposes, my point is that the clinicaltrials.gov registry is probably limited to significant risk medical devices as well as other products or procedures that present some level of serious risk. (I say “probably,” because low risk technologies are not precluded from registering; they just aren't required to be registered.) A large number of medical devices that are brought to market through the FDA’s 510(k) process are not investigated in clinical trials that trigger registration on clinicaltrials.gov.

Said another way, these clinical trials reported in the clinicaltrials.gov registry is a small sliver of technologies that ultimately FDA might clear or approve. Thus, there's probably a significant amount of AI/ML being currently developed that might someday be taken through FDA that are not be in this chart.

Is every AI/ML included in the chart a medical device? Nope. My search technique only identified that AI/ML that is somehow used in a clinical trial, but the use doesn't necessarily have to make the AI/ML a medical device nor is it even necessarily the clinical intervention itself.

Let me make this all a bit more tangible by including just a few examples from the underlying data:

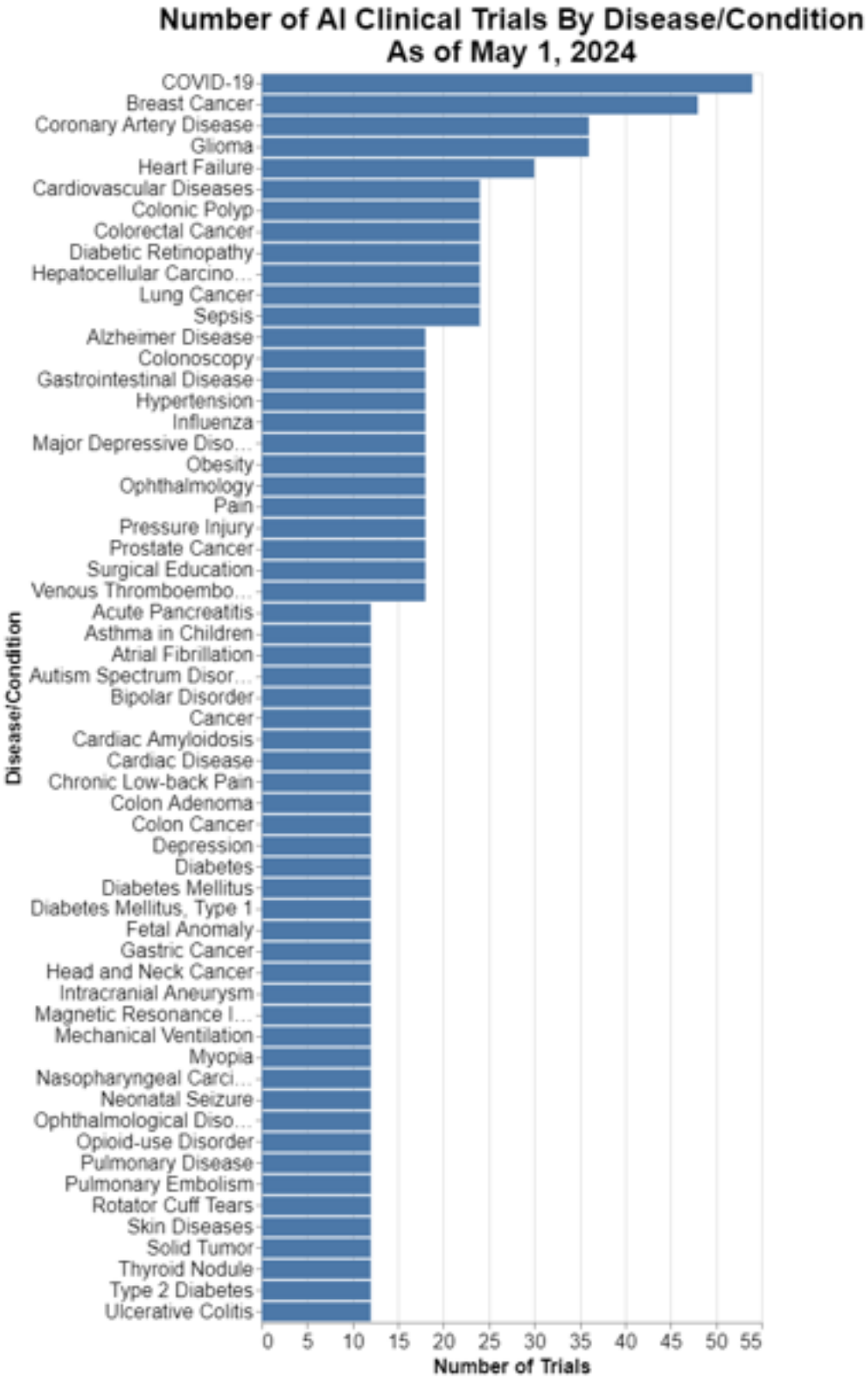
1. The Surgeons Clinical Outcomes Registry (SCOR) is a global registry designed to collect safety and performance data on commercially available Wright Medical products. Registry data may be used for publications, education and marketing materials, post-market surveillance, future regulatory submissions, research and development for product design, software improvements, and development of artificial intelligence learning and tools.
2. The Product is a machine learning software, that utilizes AI to provide real-time guidance to acquire diagnostic-quality ultrasound views of the heart.
3. The aim of the study is to identify morphological and functional biomarkers of post-operative recovery after vitreoretinal surgery, using decisional support systems (DSS), based on multimodal big-data analysis by means of machine learning techniques in daily clinical practice.
4. Viral respiratory tract infections (VRTI) are among the most common human illnesses, impacting billions globally. There is an unmet need to identify novel ways to detect, treat and prevent their spread. New wearable devices could address this need, using special biosensors worn by patients. This is a single centre, controlled, before and after, longitudinal, clinical trial. Participants will receive FluMist, a live attenuated influenza vaccine, which will act as a proxy to a viral respiratory tract infection and create a very minor response to the immune system. Vital signs and activity levels will be monitored continuously using wearable biosensors for 7 days prior to and 7 days following, along with symptom tracking and blood tests to measure immune responses. Artificial intelligence (AI) and machine learning (ML) algorithms will be used to analyse the data. AI and ML will identify subtle changes in vital signs and activity levels from the immune response to respiratory viruses. These data will help develop future methods to address important public health questions related to respiratory virus detection, containment and management. The purpose of this study is to explore whether wearable sensors can detect, track the progress and recovery from viral respiratory tract infection.

5. With the rapid development of artificial intelligence technology, more and more deep learning technology has been applied to medicine. Our research is to develop a set of quality control system for magnetic capsule gastroscope using deep learning technology, and conduct a randomized controlled trial to verify its practical efficiency.
6. The study hypothesis is that low-dose computed tomography (LDCT) coupled with artificial intelligence by deep learning would generate imaging biomarkers linked to the patient's short- and medium-term prognosis. The purpose of this study is to rapidly make available an early decision-making tool (from the first hospital consultation of the patient with symptoms related to SARS-CoV-2) based on the integration of several biomarkers (clinical, biological, imaging by thoracic scanner) allowing both personalized medicine and better anticipation of the patient's evolution in terms of care organization.
7. This prospective study aims at using Artificial intelligence to create a helpful unbiased machine learning-based model that predicts BCG unresponsiveness in high risk BCG-naïve NMIBC patients incorporating all potential clinico-pathological, radiological and/or molecular prognostic factors.
8. Nowadays, artificial intelligence technology with machine learning as the main means has been increasingly applied to the oral field, and has played an increasingly important role in the examination, diagnosis, treatment and prognosis assessment of oral diseases. Among them, machine learning is an important branch of artificial intelligence, which refers to the system learning specific statistical patterns in a given data set to predict the behavior of new data samples.
9. The study team previously demonstrated that patients are more likely to receive flu vaccine after learning that they are at high risk for flu complications. Building on this past work, the present study will explore whether providing reasons that patients are considered high risk for flu complications (a) further increases the likelihood they will receive flu vaccine and (b) decreases the likelihood that they receive diagnoses of flu and/or flu-like symptoms in the ensuing flu season. It will also examine whether informing patients that their high-risk status was determined by analyzing their medical records or by an artificial intelligence (AI) / machine-learning (ML) algorithm analyzing their medical records will affect the likelihood of receiving the flu vaccine or diagnoses of flu and/or flu-like symptoms.

Those examples, selected from the beginning and the end of the list of studies returned by my search, show the wide range of applications. Some of them, like the global registry, would not be an FDA regulated product. Many of the other examples would be. Some AI/ML models merely provide a supportive role, while others are the interventional product itself.

I've previously reported that FDA clearances are heavily skewed toward AI/ML applications in radiology. FDA itself reports that “Through the end of July 2023, 79% of devices authorized in 2023 are in Radiology (85), [and] 9% in Cardiovascular (10)….” Those numbers are down from the year prior where FDA reported “87% of devices on this list authorized in calendar year 2022 are in Radiology (122), followed by 7% in Cardiovascular (10)…” id. However, if you look at chart produced by the data from clinicaltrials.gov, only a very few of those trials over the last 5 years involve radiation. That’s an interesting development.

I want to peel the onion down one more level to see the specific diseases or conditions at which the trials were aimed. There are 2850 trials in my search result. By my count, those trials are aimed at 349 diseases or conditions. I present the most frequent diseases or conditions below:



Click to enlarge the image.

In making that chart, the number one condition listed was “artificial intelligence.” There were over 100 of those. I didn't consider that very useful, so I removed that row. To be honest, the entries in the database probably went on to give more information about a particular disease or condition, but my translation of the data didn’t capture that.

I am impressed with the wide variety of diseases or conditions that are now the subject of a clinical trial involving AI/ML, and the use cases have clearly gone well beyond radiology. Indeed, these cases don’t seem clustered around any particular therapeutic area but cut across a wide range.

Conclusion

It's no surprise that interest in using AI/ML directly in patient care is growing. These data suggest that the growth we are seeing in FDA clearances is perhaps modest in comparison to the substantial growth yet to come. As I mentioned above, because the vast majority of products that will be submitted to FDA do not involve clinical trials that trigger the registry requirement at clinicaltrials.gov, these data reflect only a small fraction of the products that are likely being developed. It's also clear that the applications of the AI/ML technology are now going well beyond the traditional radiology devices. I frankly look forward to the future that involves many of these creative applications, but at the same time recognize the risks that need to be managed.

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