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February 15th, 2025

Dear Regina,

Welcome to 2025 BioMarketing Insight's monthly newsletter.

Digital Health products have existed for a while, but became very popular when the pandemic struck, and healthcare professionals and patients were working remotely. Telehealth became the new normal for office visits. In addition, a lot of digital health companies have been formed to fill this new need of remote access. However, Digital health companies have faced headwinds over the past few years. To find out more as to where this market is heading, go to the Table of Content and click on Digital Health Trends: Five Factors to Consider in Developing a Successful Product.

If you missed last month's newsletter on 1) Surviving the New Normal, Tips from the Industry and 2) Women's Health is Facing a Crisis!, click on this <u>link</u>. The next newsletter will be March 15, 2025.

challenging times, click on the "<u>Inspiration</u>" link to give yourself a few minutes to relax and enjoy the music from the Berklee School of Music in their song "What the World Needs Now," and ending with Celine Dion and Josh Groban with "The Prayer".

We encourage you to share this newsletter with your colleagues by using the social media icons below, or by simply forwarding this newsletter or use the link below. Should you or your colleagues want to join my mailing list, click on "join my email list" link below.



Sincerely,
Regina Au
CEO, New Product Planning/Strategic Planning
BioMarketing Insight



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Join my mailing list



Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact <u>me</u> for an appointment. For successful commercial adoption of your product or looking to grow your business, contact <u>me</u> for an appointment.

For more information on our services, click on the links below:

Product Development

Market Development

Marketing Strategies

Scenario Planning - for more information, email me.

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AAPI Heritage Festival and Exhibit - May 9th - 10th, 2024

AAPIEC Inc. in collaboration with the Middlesex Community College (MCC) held our 2024 AAPI Heritage Festival and Exhibit on Thursday, May 9th, 2024. Thank you to MCC for hosting the Festival and we, AAPIEC Inc. displayed our "Contributions AAPIs Have Made to American History" Exhibit. The exhibit was also on display May 9th - 10th. Admission and parking was free.





We had a jammed packed schedule of speakers and performers. Here is a list of them:

To see more photos of this years Festival and Exhibit, click here.

Keynote Speaker: Paul Watanabe, Director and Professor in the Department of Political Science at UMass Boston

Performers:

Blessing Dance performed by Indras Artistic Creation Group

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Fishing Dance and Coconut Dance performed by Morodok

Chinese Zither performed by Entain Lee, Kaitlyn Tat, and Callie Tat.

Music Performance by MCC's Music Club

Lion Dance performed by Calvin Chin Martial Arts Academy

EXHIBIT: We are also pleased to be able to share the history and numerous contributions of the following American ethnic groups: Everyone should be proud of their heritage.

- 1) Chinese American, 2) Japanese American, 3) Indonesian American, 4) Laotian American, 5) Samoan American, 6) Vietnamese American, 7) Tibetian American,
- 8) Asian Indian American, 9) Native Hawaiian American, 11) Cambodian American, 12) Filipino American, 13) Maori American, 14) Fijian American, 15) Saudi American

Next year there will be more American Ethnic groups added to the list.



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Tentative Program

Second Round of Abstract Submission Closes on June 15, 2024,

Early Bird Registration Closes on June 14, 2024

CFB SECRESHIED

4th Edition of

International Vaccines Congress

October 24, -26, 2024, | Baltimore, MD, USA

4th Annual International Vaccine Congress (IVC 2024) Conference on October 24-26, 2024 in Baltimore, MD

I am pleased to announce that I was a Key Note Speaker and a Scientific Committee Member at the IVC 2024 Conference in Baltimore, MD on October 24 - 26, 2024. The title of my presentation is "Why Antimicrobial Resistance is a Global Threat and Its Impact On Everyone". Information on Scientific Committee members, click here. For more information on the conference, click here.

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Inspirations

Enjoy the song "What the World Needs Now" virtually with the students from the Berklee School of Music.

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Practice Good Hygiene Every Day.



Let's End with Celine Dion & Josh Groban Singing "The Prayer"

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One Biotech Executive's View on the COVID-19 Vaccine

I am pleased to announce that my article on the COVID-19 Vaccine was published in Lioness Magazine. To read my article click on the link <u>here</u>.

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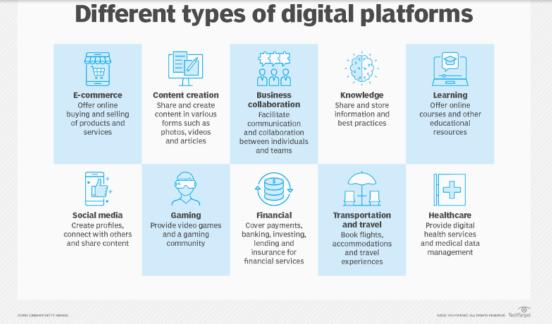
<u>Digital Health Trends:</u>
<u>Five Factors to Consider in Developing a Successful Product</u>

Source: Freepik

Digital Health has been used for a while, but became very popular when the pandemic struck, and healthcare professionals and patients were working remotely. Telehealth became the new normal for office visits. In addition, a lot of digital health companies have been formed to fill this new need of remote access to achieve better healthcare. However, Digital health companies have faced headwinds over the past few years.

Before we dive into Digital Health, we need to define what Digital Health is because it can mean a lot of different things. For this newsletter, digital is defined as electronic technology that generates, stores and processes data in terms of positive and nonpositive states.

There are 10 different digital platforms as shown below:



Source: limeart/getty image

In Healthcare, digital health products that are the most useful are those that diagnosis, treat and remotely monitor patients. Ultimately, within these categories of products, for example diagnosis, the test will diagnose if a patient has a certain disease or not. In addition, scientists/engineers are also trying to develop tests that can predict whether a patient with certain risk factors etc, will likely or probably develop this disease within a certain time frame or preemptive diagnosis. There is early research using AI tools for preemptive diagnosis.

To achieve these three categories of diagnosis, treat and remote monitoring, a number of these platforms above can be incorporated into these products.

For example, a gaming platform for physical therapy (PT) in treating an injury. While a patient goes for PT at a physical therapist's office, the therapist will give the patient home exercises between sessions. We all know not every patient will be diligent at doing these exercises since they are not monitored and there is no motivation to do them unless one is a professional athlete. To encourage the patient to do his/her exercise, depending on the injury the therapist may recommend that the patient play a virtual game.

<u>Wii Sports</u> a sports simulation video game has become very popular with Therapists because they all involve dynamic stability and movements. For patients recovering from shoulder, elbow, and hand injuries, playing Wii tennis can help improve range of motion and strengthen core and upper extremity muscles. Bowling can assist in hand-eye coordination and balance, benefiting those with any shoulder, elbow, hand, or balance issues.



Source: Freepik

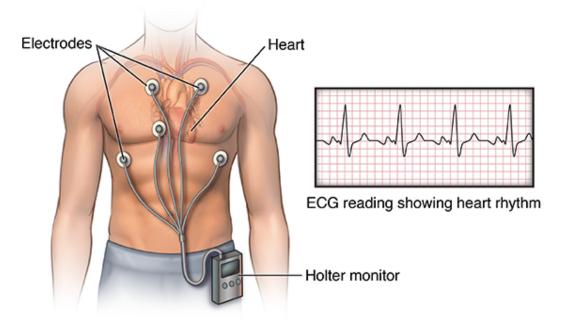
There are endless possibilities in what one can develop in digital health. However, this does not mean all digital products will automatically be successful. There are five factors that engineers/scientists need to consider in developing a product to be successful in the market.

- 1. The product must meet or resolve a critical unmet need according to the customer/healthcare professional and not what the company thinks is a critical unmet need. If it is a "nice to have", it will be harder to convince people to use it.
- 2. The product must be consistently accurate and reliable:
- 3. What value is it bringing to the patient and the healthcare worker?
- 4. The product must be easy to use for the patient and the healthcare worker:
- 5. Is the market opportunity large enough to meet the company's goal?

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Source: John Hopkins Medicine

A good example is a 24-hour remote holter monitor that monitors ECG readings to detect abnormal heartbeat or arrhythmia in real time and then intervene. If a patient is in atrial fibrillation (afib), which can be life threatening, the physician is alerted immediately in saving a patient's life. Devices have improved since the original holter monitors pictured above.

1. Critical unmet need?

- Yes. Even though there are a number of remote EKG monitoring devices currently on the market, there are a number of issues that still need to be resolved with these devices. This will be explained further in the next four factors outlined below.
- 2. The product must be consistently accurate and reliable. Does the device capture EKG recordings every second of the day?
 - This is important because for the device to capture the readings, it must have secure contact with the skin, otherwise one will either get an error message, no contact or the readings will fall below a percentage threshold to be considered an accurate recording and is now considered garbage. The greater percentage of garbage in all the recordings, the physician has less data for an accurate diagnosis.
 - If the device is not recording, heart arrhythmia could be missed and be detrimental to the patient depending on the type of arrhythmia.
 - To have good secure contact with the skin, the medical grade adhesive must be strong enough to prevent the device from coming off when the patient

- If the placement of the device is not accurate, it may not capture the
 readings. For a 12 lead EKG, the 12 electrodes are placed in various places
 of the chest, arm and leg. If the device is just one piece, then where it is
 placed and how it is placed can be crucial.
- Depending on whether the device is replaced everyday or once a week, the
 concern is that the adhesive doesn't cause a rash due to irritation of the skin
 or an allergic reaction when replacing it everyday. If the device stays on for a
 week, the concern is the hygiene of the device. Similar to wearing a bandage
 all day, it gets dirty and may cause irritation to the skin.
- 3. What value is it bringing to the patient and the healthcare worker?
 - For the patient, s/he has peace of mind that the device is accurately capturing all abnormal rhythms 24/7 and if the patient has an irregular heartbeat of concern, the physician is alerted immediately and someone will intervene.
 - For the healthcare professional, the healthcare professional also has peace of mind the patient is being monitored 24/7 and can diagnose the type of arrhythmia with enough information.
- 4. The product must be easy to use or comfortable for the patient and easy to use for the healthcare worker:
 - For the patient, if the instruction for using the device is complicated or it must be precise on where they place the device to obtain good data, the patient will either not use it or use it wrong. If the patient is using it wrong, this will result in bad data.
 - o For the healthcare professional, they don't want to receive the recorded data 24/7 since it is significantly large, and then review all this data especially if the heart beat is normal. They only want to be alerted to critical abnormal heartbeat in real time. If the patient's recorded data has no alerts, they want accurate data, not large amounts of "garbage" that doesn't represent accurate or quality data for the 24/7 period. They shouldn't have to accept small amounts of data that is considered "good enough" to make their diagnosis.
- 5. Is the market opportunity large enough to meet the company's goal?
 - The questions to ask are:
 - How large is the market?
 - Is it a satisfied or unsatisfied market?
 - How many players are in the market and what is the market share of each player?
 - Is your product better (customer's opinion, not the company's opinion) than the product currently on the market in meeting a critical unmet need?
 - Is your product innovative or disruptive in meeting the market needs and what is the regulatory path?

a class III which has more requirements to meet.

- Is there currently reimbursement for your device and does it at least cover the cost of your device?
 - 1. A product can be considered innovative or disruptive technology, but if there is no reimbursement, the technology will not be used.



Source: Alivecor Website

Alivecor, founded in 2011, developed Kardia, an innovative technology, that detects afib by pressing your two fingers, index and middle on the keypads and sends it to a mobile phone. As oppose to other devices that is adhered to a patient's chest. As an observer, this company has gone from an original two lead device plus iterations and later added a 6-lead device and a 12-lead device. They are highlighting the ease of recording an ECG anywhere with a two-lead device in the form of a very small device or credit card size device. These additional offerings are probably due to the due diligence on the 5 factors mentioned above.

In conducting due diligence, it is clear that these digital health products has to be disease specific to be beneficial similar to personalized medicine.

IQVIA's report on Digital Health Trends has 4 key finding:

beyond mental health and chronic diseases to encompass other conditions.

- Approval and reimbursement of digital tools is accelerating as payers recognize
 clinical utility and cost savings; of the more than 360 software-based digital
 therapies commercially available,140 prescription digital therapeutics (TX) are
 approved for patient use at home and over 220 therapies are used within digital care
 or in clinics.
- Sensor-based digital biomarkers that track patient health using wearables now
 monitor patients in care and research, and the first digital endpoints have been
 approved by regulators in the U.S. and Europe.
- More than 103 digital diagnostics for disease assessment are now commercially available and used to evaluate disease risk, accelerate diagnosis and monitor patient health; many of these are enabled by artificial intelligence and machine learning (AI/ML).

Digital health companies have faced headwinds over the past few years. Funding has been reduced and companies that have obtained product approval have struggled to grow revenue and expand their customer base. Some have gone bankrupt. However, these early companies have paved the way for regulatory approval and reimbursement pathways. More work still needs to be done

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Closing Thoughts

There is a lot of competition out there and the way to succeed is to be better than what is currently out in the market and any future products. This is accomplished by doing your due diligence as discussed above.

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due diligence, if your customers don't like it, they will never use it again no matter how much you improve it. As the old saying goes, the first impression is a lasting impression. And once it is out in there, like the internet, you can never take it back.

Doing the due diligence will save your company time, money and reputation.

Need help in doing the due diligence, feel free to contact me at regina@biomarketinginsight.com or call me at 617-404-8826.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition, target product profile and economic value of your product for reimbursement, feel free to contact me at 617-404-8826 or regina@biomarketinginsight.com.

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