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March 15, 2018

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

We have a new look to our newsletter. Love to receive your [feedback](#).

In November, I covered "Eliminating the Stereotypes of the Elderly." If you missed last month's article, click [here](#) to read it. This month we'll cover "Highlights from the HealthcareIoT (Internet of Things) Conference, Feb. 13-14, 2018"

Read on to learn more about this topic and other current news. The next newsletter will be published on April 15th, 2018.

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.

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Please email [me](#), Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
Principal, New Product Planning/
Strategic Commercial Consultant
[BioMarketing Insight](#)



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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 [me](#) for an appointment. For successful commercial adoption of your product or looking to grow your business, contact [me](#) for an appointment.

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

[Product Development](#)

[Market Development](#)

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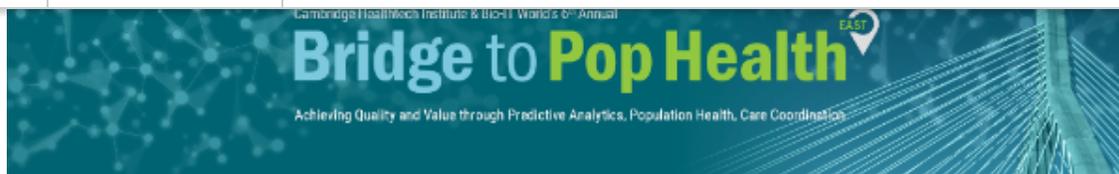


Brandeis University
INTERNATIONAL BUSINESS SCHOOL

Seventh Annual 3 Day Startup (March 23-25, 2018)

I am pleased to announce that I will be a [Judge](#) for the final pitches at the Brandeis University Seventh Annual 3 Day Start-up Competition, March 23-25th. For more information on the competition, click [here](#).

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Save the Date: Bridge to Pop Health, May 14-15, 2018, Seaport World Trade Center, Boston, MA

Formerly the Medical Informatics World Conference, this is the 5th year that I will be attending this conference. I highly recommend this conference as it brings together thought leaders from the provider, payer, healthcare finance, as well as the analytical and technological communities for an insightful discussions on maximizing clinical quality.

The two-day executive conference will cover operational performance in risk-based contracts, integrating predictive models into clinical workflow, innovating a clinical care delivery model in a value-based world, and implementing a population health management strategy to transition from a fee-for-service to a value-based care model. The conference promises to be a productive step forward for the industry.

For information on the conference and to register, click [here](#).

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Save the Date: BIO Convention, June 4-7th, 2018, Boston Convention Center

I am pleased to announce that I will be moderating a panel discussion entitled "Our Microbiome and Its Relationship to Various Diseases" under the Next Generation Biotherapeutics Track. This session is scheduled for Monday, June 4th 2018 from 1:00 PM - 2:15 PM. The location is Room 210B, Level 2 at the Boston Convention Center. The session will focus on the application and implication of our microbiome specifically looking at microbiome signatures (dominance and absence of certain species) for different diseases and its implication in restoring symbiosis.

Please join me for a very informative and interactive panel discussion with some of the top researchers and companies working in this space. My speakers cover a broad perspective on the subject matter that includes academia, entrepreneurs to big pharma.

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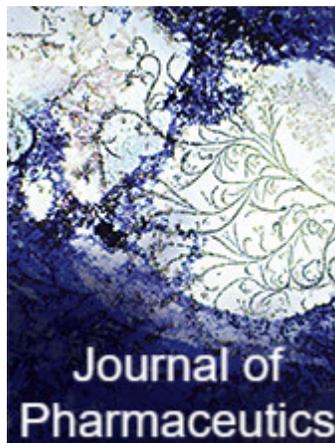
**International Journal of
Clinical Pharmacology
& Pharmacotherapy**
Open Access



Why Our Microbiome is Important to Our Physiology and Diseases

I am pleased to announce that my article entitled "Why Our Microbiome is Important to Our Physiology and Diseases" was published in the International Journal of Clinical Pharmacology & Pharmacotherapy. This article reviews the results of the Human Microbiome Project and the factors that affect our microbiome in relation to our healthy state and dysbiosis or disease state. To read the article, click [here](#).

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**Immunooncology: Can the Right Chimeric Antigen
Receptors T-Cell Design Be Made to Cure All Types of Cancers
and Will It Be Covered?**

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Antigen Receptors T-Cell (CAR-T) Design Be Made to Cure All Types of Cancers and Will It Be Covered?" has been published in Journal of Pharmaceutics. This article reviews the mechanism, design and administration of CAR-T cells, and whether payers will pay for this new technology. To read the article, click [here](#).

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Highlights from the HealthcareIoT (Internet of Things) Conference, Feb. 13-14, 2018

Today's digital evolution has spurred a enormous amount of web-enabled products and services including the Cloud, smart and connected devices to help deliver better healthcare. However, along with these advance technologies there are equally concerned about the challenges in privacy, cybersecurity, data interoperability, and patient engagement, and product adoption for all stakeholders that come along with it.

This conference was created to bring together all stakeholders and their expertise involved to share their ideas and experiences in a collaborative efforts toward the adoption and implementation of IoT.

There were many informative sessions throughout the two day conference, more than the scope of this newsletter. I will cover the two keynote speakers: 1) William Morris, MD, Associate Chief Medical Information Officer, Cleveland Clinic and 2) Seth Carmody, Cybersecurity Program Manager, FDA and 3) My panel discussion of Product Adoption and Market Access in order for a product to be success in the market. I will address the main points on the challenges that IoT faces and how to resolve them.

1) **William Morris**, MD, Associate Chief Medical Information Officer, Cleveland Clinic presentation was entitled "**People, Process and Technology: The Strategic Alignment of IoT Transformation.**"

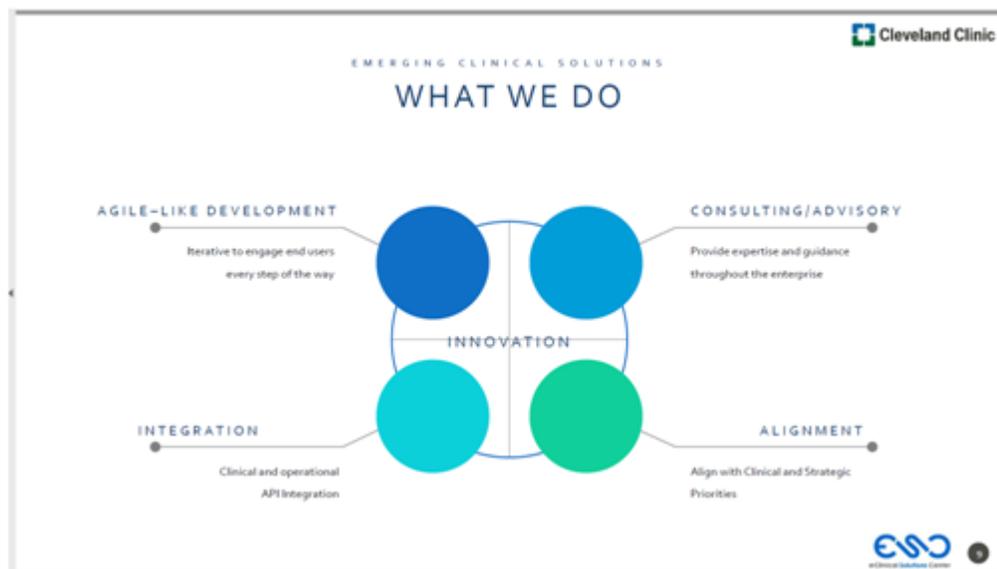
The goal of the healthcare industry is to provide better care for the sick where patients come first. However, to achieve this goal, People, Process and Technology needs to aligned and fully integrated. Dr. Morris' formula for this is:

IoT (Internet of Things) x AI (Artificial Intellingence) x CareRedesign = Transformation

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Right data/right time x Right format/device x right people/right cost = better quality/lower cost

One needs all three in order for this equation to work. To accomplish this, one must "Drive innovation and efficiency through ongoing ideation and development" said Morris.



This diagram illustrates his solution to what we need to accomplish innovation and efficiency.

- 1) Agile-like development: involving all end users for input to accomplish buy-in, which is done with reiteration until it is satisfactory for all users one of the factors for innovation.
- 2) Integration: Both clinical and operational processes; routine, protocol and tools need to be incorporated into the application program interface (API) in order to satisfy the end users needs in making their work easier.
- 3) Consulting/Advisory: providing expertise and guidance throughout the enterprise and process. Expertise is needed to incorporate the needs of the users in order for the software to be user friendly and adopted by all users. This is especially critical for training as there will be a huge learning curve for everyone and guidance is needed throughout the process as unexpected things will ultimately come up and people will need help to resolve the situation. This is another reason reiteration is important to improve the system.
- 4) Alignment with Clinical and Strategic Priorities: If clinical and strategic priorities are not aligned, there will be confusion among everyone as to which one to follow which defeats all the work done in each.

Dr. Morris goes on to give some examples regarding using technology and process that provides the important information in delivering better care and to make it easily assessable

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In conclusion Morris gave four (4) key advice in implementing a successful program:

- 1) IoT - be weary of solutions looking for a Problem. In other words, identify the problem first and then find the solution through technology. Don't be admired by the technology.
- 2) AI - augment a workflow. The problem usually lies in the workflow, this is where AI can help people and achieve product adoption or buy-in.
- 3) Care Redesign - develop where the work is performed. The benefit is for the people who perform the work to achieve product adoption or buy-in.
- 4) Agile discipline - organize around the work, not the tools. To achieve product adoption, it has to be beneficial to the end user.

II) **Seth Carmody**, Cybersecurity Program Manager, Center for Devices & Radiological Health, US FDA presentation entitled "**Medical Device Cybersecurity**."

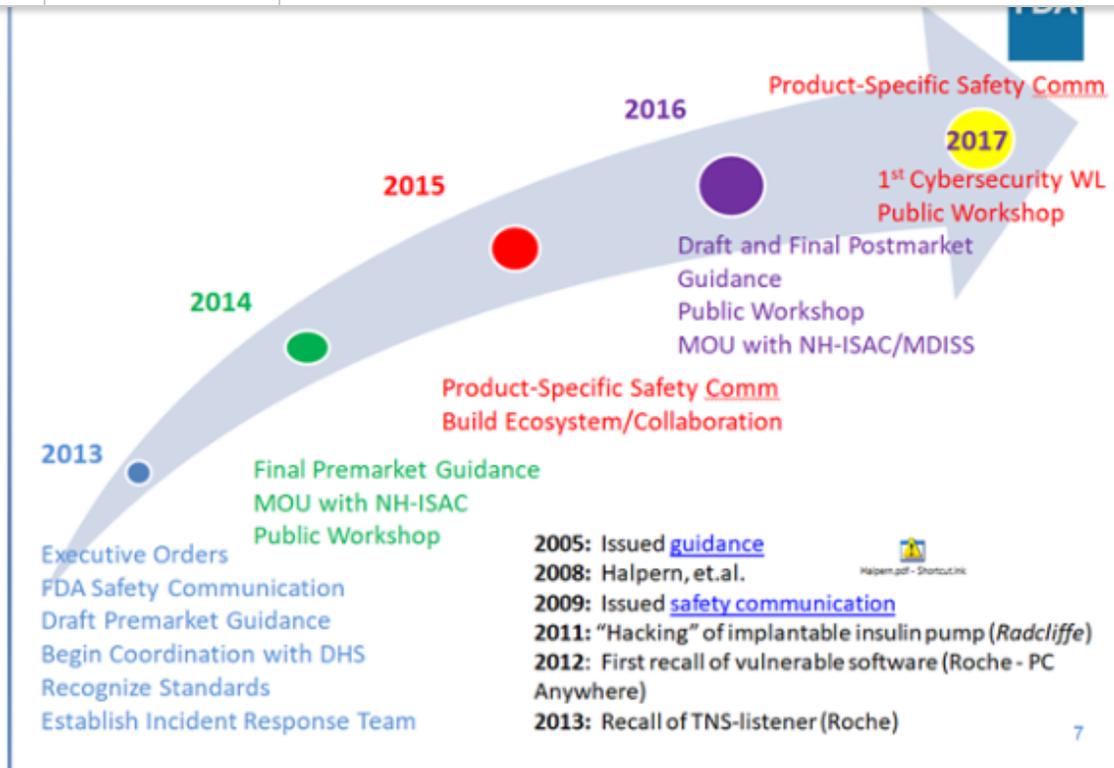
Since the invention of the internet and wifi, obtaining information and sending information worldwide has become very easy which has been beneficial for people and businesses. However, there is always two sides to everything as hackers have made it a business to steal information and money, and manipulate things for their own benefit.

Seth Carmody shared with us an Executive Orders (EO), Presidential Policy Directives, that was passed to create a Framework to Strengthen Cybersecurity and Critical Infrastructure to protect patients' privacy and safety against potential hackers.

He also dispelled a few myths due to misunderstanding among the industry because cybersecurity is relatively new for this industry in implementing protocols in satisfying this Executive Order.

Myths:

- 1) "**The FDA is the federal entity solely responsible for the cybersecurity of medical devices.**" Everyone, the entire ecosystem; industry, professional societies, regulators, payors, healthcare providers, patients, venture capital, and researchers need to be concerned about cybersecurity and take measure to ensure safety on their part.

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The FDA provides guidance and workshops under the title of "safety communication" to help people to plan accordingly and the following events occurred.

In 2011, it was revealed on the potential hacking of implantable insulin pumps.

In 2012: First recall of vulnerable software (Roche - PC Anywhere)

2013: Recall of TNS-listener (Roche)

2)"The FDA tests for cybersecurity of medical devices:" The FDA only provides guidance and reinforcements.

3)"Cybersecurity for medical devices is optional:

Medical device manufacturers must comply with federal regulations. Part of those regulations, called quality system regulations (QSRs), requires that medical device manufacturers address all risks, including cybersecurity risk. The pre- and post- market cybersecurity guidances provide recommendations for meeting QSRs."

In conclusion, cybersecurity is mandatory and all parties involved (medical device ecosystem) must do their part in ensuring everyone's privacy and safety.

III) My panel discussion entitled "**Medical Devices and Wearables – Product Adoption (Compliance) and Market Access**"

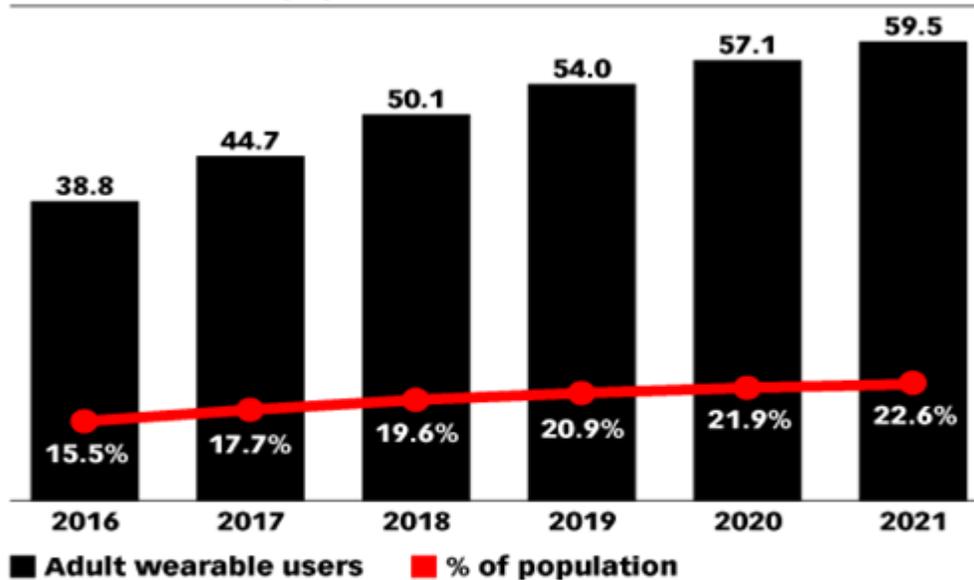
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everyone, the medical device ecosystem needs to be concerned with Cybersecurity and be responsible for their part in taking measures to ensure privacy and safety for medical devices.

This same philosophy holds true when any company develops a product. One needs to meet the needs of all stakeholders involved in order to achieve product adoption that results in market access or product availability for patients and/or healthcare providers depending on the product.

A good example is the Wearable Device Market. In 2010, this market was projected to reach \$12.6 Billion, a 41% compounded annual growth rate (CAGR) to 2018, majority of it was fitness and one of the main drivers was Google Glass. Today, we find that product adoption was slow and Google Glass is no longer in the consumer or medical market.

US Adult Wearable Users and Penetration, 2016-2021 millions and % of population



Note: at least once per month; individuals ages 18+ who wear accessories or clothing embedded with electronics, software or sensors that have the ability to connect to the internet (via built-in connectivity or tethering), which in turn collects and exchanges data with a manufacturer, operator or other connected devices
Source: eMarketer, Dec 2017

233964

www.eMarketer.com

There was also a slow adoption for mobile apps. There are literally hundreds of medical apps released every month. However, if these apps are too confusing, overwhelming and are not easy to use, these apps will not be successful.

In addition, physicians were concerned that these apps were not accurate and reliable. For the Blood Pressure (BP) apps, physicians were concerned of the accuracy of a BP when

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concerns were applied to a pulse oximeter reading with no instrumentation.

Why did these apps fail? Product Adoption or Compliance. The following questions need to be answered for product adoption:

- How are you meeting their needs?
- Each customer/stakeholder has their own needs.
- What are the benefits to them?
- Easy to use (compliance)?
- Fit the product to the patient, one size does not fit all
- Long-term motivation
- Benefit/risk/cost ratio

These mobile apps, BP and pulse oximeter failed because they did not meet the needs of the physicians. There are seven (7) stakeholders whose needs must be satisfied in order to achieve product adoption and market access or product availability to the patient or physician depending on the product.

Here are the 7 Stakeholders or 7 Ps.

1. Patient – benefits
2. Physician
3. Other Professional (Hospital admin.)
4. Policy (FDA)
5. Payors (Insurance)
6. Politics (Government)
7. Public (Advocacy grps.)

Each stakeholder has their own needs and if any stakeholder's needs are not satisfied, the product will not be available (market access) to the end users.

My panel speakers from various areas of expertise: 1) Lynn Carroll, clinical decision-support tools, HealthshareBlox; 2) Karl Hess, Population Health, Collain Healthcare; 3) Ravi Kuppuraj, Apps and Widgets, Philips Connected Sensing and Wearables; all gave examples to reinforce this philosophy by connecting with their stakeholders before they developed their products.

In addition, as a Policy stakeholder, Seth Carmody, PhD, Cybersecurity, US FDA, gave advice on how to satisfy the FDA as mentioned above and Ramya Palacholla, Data Science & Analytics, Partners Connected Health Innovation gave advice on the type of data that would be useful and relevant for the healthcare professional.

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Closing Thoughts

It was a consensus from all the speakers at the conference that in order to deliver better patient care resulting in lower cost to the healthcare system, any program that anyone implements must involve everyone who is involved and that there must be a benefit to all involved in order to achieve product adoption.

As Dr. Morris stated, all processes and technology must revolve around the people, the work performed by the people, the workflow that is performed by the people and flexibility in the organization on the work in meeting the needs of the people to deliver better care to patients.

It's a complex process that needs to be thoroughly understand and it can't be rushed. It will take time and people will have to be patient in sticking it out for the long haul, but in the end it is well worth it. Sustaining this strive for excellence in healthcare also requires management to revisit this process from time to time to ensure that the process is still relevant to the needs of today and the future.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition and economic value of your product, feel free to contact me at 781-935-1462 or regina@biomarketinginsight.com.

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