



# **Actigraphy Monitoring Wearables in Clinical Trials:** Overcoming Barriers to Adoption & Strategies for Successful Technology Implementation

ActiGraph White Paper

Genevieve Baley and Jeremy Wyatt

©2018 ActiGraph, LLC. All rights reserved.

# Table of Contents

3	.....	Authors
3	.....	About ActiGraph
4	.....	Summary
5	.....	Introduction
6	.....	Data Quality and Interpretation
8	.....	Adoption Cost and Uncertain ROI
9	.....	Increased Study Complexity
10	.....	Regulatory Concerns
11	.....	Patient Adherence and Burden
12	.....	Conclusion
13	.....	Citations

# Authors



**Genevieve Baley**

Chief Marketing Officer,  
Senior VP Corporate Communications



**Jeremy Wyatt**

Chief Technology Officer,  
Senior VP Product Development

# About ActiGraph

ActiGraph is the leading provider of medical-grade physical activity and sleep monitoring solutions for the global scientific community. ActiGraph's wearable actigraphy monitors and robust analytics platform have been widely used in academic and population health research for nearly two decades. In recent years, the company's monitoring solutions have been steadily adopted by biopharma and life sciences organizations seeking to capture real-world objective outcomes related to physical activity, mobility, and sleep behavior for patients enrolled in clinical trials.

ActiGraph's innovative CentrePoint technology ecosystem, which includes a cellular home data hub, patient-facing mobile application, and API, supports near real-time remote actigraphy monitoring and flexible integrations with other wearables, mHealth tools, and third party EDC platforms. The company offers a suite of end-to-end clinical trials services that leverage years of advanced data capture and management expertise, along with their global network of subject matter experts with extensive experience in the collection, analysis, and interpretation of actigraphy data for various disease and patient populations.

Please visit [actigraphcorp.com/clinicaltrials](http://actigraphcorp.com/clinicaltrials) to learn more about ActiGraph's wearable actigraphy monitoring solutions, the CentrePoint technology ecosystem, and end-to-end clinical trial services. For more information, please contact [pharma@actigraphcorp.com](mailto:pharma@actigraphcorp.com).

# Summary

New and emerging digital technologies offer clinical trial sponsors an unprecedented opportunity to capture a wide variety of real-world, patient-generated outcomes that have the potential to improve data quality, accelerate study timelines, reduce costs, and better engage patients in their treatment. One of the more prevalent tools within this mHealth ecosystem are wearable medical-grade actigraphy monitoring systems, which are increasingly being used in clinical trials to collect objective physical activity and sleep-related patient outcomes. This continuous-time, highly granular actigraphy data allows sponsors to identify even the most subtle changes in behaviors that occur with or in the absence of therapeutic interventions.

“In this white paper, we will discuss five major perceived barriers to actigraphy adoption and identify strategies to help sponsors develop a successful technology implementation plan and navigate the common challenges that can derail any mHealth data collection initiative.”

Despite the clear benefits of actigraphy monitoring within the context of drug development research, implementation of any novel technology system in a such a complex and highly regulated environment will almost certainly involve complications and unanticipated challenges. Concerns and uncertainties relating to data quality, cost, study complexity, regulatory acceptance, and patient adherence can negatively influence a sponsor organization's willingness to adopt an actigraphy program, thereby preventing them from realizing the long-term value and benefits associated with objective, real-world patient outcomes. In this white paper, we will discuss these five major perceived barriers to actigraphy adoption and identify strategies to help sponsors develop a successful technology implementation plan and navigate the common challenges that can derail any mHealth data collection initiative.

# Introduction

## Actigraphy Monitoring Wearables in Clinical Trials: Overcoming Barriers to Adoption & Planning for Successful Implementation

We are in the midst of a digital technology revolution that is rapidly transforming the traditional healthcare paradigm as we know it. By the year 2020, it's estimated that more than 36 million patients will use some form of remote monitoring technology, and the market for clinical-grade wearables will reach \$18.9 billion.<sup>1, 2</sup> Within the clinical research industry, an influx of new mobile health applications, biosensors, wearables, and other mHealth tools are providing sponsors and CROs with an unprecedented opportunity to tap into real-world patient behaviors and capture more robust data, while simultaneously engaging patients in their treatment more so than ever before. The insights gleaned from this abundance of novel patient-generated data are being used to inform earlier treatment assessments and accelerate the pace of clinical decision-making, gradually moving the needle towards the ultimate promise of faster, more efficient, and less expensive trials.

One of the more prevalent applications of biosensor technology in clinical research is the continuous-time monitoring of patient physical activity and sleep behavior using a wearable device called an actigraph. Actigraphy monitoring has been used to quantify human movement in academic research for more than 20 years, and because most diseases and their treatments can have a measurable impact on activity, mobility, or sleep, its applications in drug development research are obvious. More recent advances in wireless communication and cloud-based computing and data management have further increased the value proposition by making it possible to remotely monitor patients in real time during a trial. Some medical-grade actigraphy systems have the ability to capture, store, and transfer large volumes of high-resolution raw data, which allows for more sophisticated analysis today, while also helping to pave the way for big data processing methods of the future.

Despite the clear benefits that actigraphy monitoring offers within a clinical research environment, adapting the standard randomized controlled trial (RCT) or observational study blueprint to accommodate new technologies of any kind can be a daunting process full of unanticipated complications. **In this white paper, we will discuss five major perceived barriers to actigraphy adoption and identify strategies to help sponsors develop a successful technology implementation plan and navigate the common challenges that can derail any mHealth data collection initiative.** Although this white paper focuses specifically on wearable actigraphy systems, many of the same barriers and rationales apply to other new and emerging digital mHealth tools that offer similar benefits.

### Common Barriers to Actigraphy Adoption

- 1 Data Quality and Interpretation
- 2 Adoption Cost and Uncertain ROI
- 3 Increased Study Complexity
- 4 Regulatory Concerns
- 5 Patient Adherence and Burden

As the popularity of consumer wearables has skyrocketed in recent years, the value of using these types of devices to collect real world patient data during a clinical trial has become increasingly apparent. According to a 2016 Validic survey, while only 33% of respondents in the biopharma and life sciences industry have used a wearable activity tracker in a trial, 67% said they would like to do so in the future.<sup>3</sup> Despite this positive outlook, uncertainties about the quality and usability of collected data can hinder a sponsor's willingness to include an actigraphy monitoring procedure within a study. Without a clear understanding of the reliability and usefulness of the data, it's difficult to justify such a considerable investment of time and resources. According to the same Validic survey, the top three concerns associated with using digital health technologies within a clinical trial were data accuracy, standardization of data, and how to analyze the data in a meaningful way.<sup>3</sup> Prior to initiating any wearable monitoring program, sponsors must carefully consider each of these issues and then develop a strategic plan detailing how and when data will be collected, processed, and interpreted. Leveraging the expertise of a knowledgeable actigraphy partner during this early planning phase can help to ensure captured outcomes are valid and relevant to the study population and investigative objectives.



## Device Accuracy

There are literally hundreds of wearable activity monitors and sleep trackers on the market today, and although they typically use the same accelerometer-based measurement technology as medical-grade actigraphy devices, only a handful of these products were developed specifically for scientific applications. Despite the aesthetic appeal and relative low cost of consumer-oriented trackers, a growing body of research has cast doubt on the accuracy of some of the most popular devices, which typically derive their outcomes from proprietary “black box” algorithms. Inconsistent metrics, low correlation with criterion measures, and this lack of data processing transparency have led many researchers to advise that these consumer devices be used with extreme caution in clinical environments.<sup>4,5</sup> Most medical-grade actigraphy systems, on the other hand, derive physical activity and sleep outcomes from publicly available algorithms that were independently developed and validated by members of the scientific community. Consumer devices, which were essentially developed to assess the behavior of the general public, presumably utilize equations that are based on a healthy adult population. Actigraphy monitoring has been used extensively in chronic disease research over the past two decades, which has led to the development of disease and population-specific algorithms and data processing methods that have the ability to deliver more precise outcomes for different patient populations.

## Data Standardization

Standardization of actigraphy data is a murkier issue because stakeholders are continuously working to develop and qualify new biomarkers that are meaningful for various disease populations in the context of drug development. Standards for mHealth data continue to evolve as the technologies mature, and therefore capturing the most rudimentary element of measurement is the best way to ensure future compatibility with whatever standards

eventually persist. Similar to the vast amount of information contained in a DNA sample, high-resolution raw actigraphy data could hold the keys to future biomarkers that have yet to be considered, while providing the basic foundation from which all existing physical activity and sleep-related outcomes and data standards are derived.

In the case of actigraphy, “raw” data is the measure of a body’s acceleration against gravity, captured by an accelerometer at a sample rate ranging from 1 to 100 times per second. More sophisticated actigraphy devices utilize triaxial accelerometers, which measure motion in three dimensions for better sensitivity and precision. The inevitable tradeoff for capturing this continuous-time, highly granular raw data is the significant IT infrastructure and resources that are needed to transfer, process, and store such large volumes of data. In response, some actigraphy providers have developed advanced technology platforms that leverage cloud-based analytics and data storage in order to offload much of the data management burden from sponsors and sites. Within this framework, physical activity and sleep measures derived from existing analysis methods are available in near real time. With recent advancements in cloud-based system capabilities, some providers have even evolved their cloud-based solutions to perform deep analytics on big data produced by these monitors in order to extract novel and previously unrealized value.

## Meaningful Outcomes

Regardless of its accuracy and granularity, outcome data is essentially useless without a clear understanding of what is meaningful for a specific study population. What is considered to be “normal” physical activity or sleep behavior for an oncology patient undergoing chemotherapy is vastly different in a COPD patient and a healthy subject. Sponsors are strongly encouraged to “begin with the end in mind” by consulting with a qualified technology provider with clinical trial experience to identify the specific outcome measures that are meaningful and relevant for their study population and investigational objectives. Once these target outcomes have been clearly defined, sponsors are able to make better informed decisions relating to device selection, data collection protocol, and how to analyze and manage the data to maximize its relevance and value within the context of the study.

“Wearable devices cannot support R&D, drug discovery and patient care by themselves, but will need the help of scientific experts who are able to make sense of the data and understand clinical inferences.”<sup>8</sup>

“Wearable devices cannot support R&D, drug discovery, and patient care by themselves, but will need the help of scientific experts who are able to make sense of the data and understand clinical inferences,” said Tim Hoctor, Vice President of Professional Service at Elsevier R&D Solutions, in a recent thought leadership article.<sup>8</sup> Because actigraphy has been used so extensively in academic health and population research, there are many seasoned actigraphy experts within the scientific community who are highly experienced in the collection, analysis, and interpretation of activity and sleep data for different disease and patient populations. Some actigraphy providers offer sponsors the opportunity to connect and collaborate with qualified subject matter experts throughout the study, with services ranging from protocol consultation, endpoint validation, and algorithm development to in-trial or post hoc data analysis. Leveraging these expert resources with specific patient-population actigraphy experience is perhaps the best way to ensure that the right outcomes are being measured and the data is being interpreted in a clinically meaningful way.

Adoption costs are often cited as one of the most prohibitive factors to consider when making the decision to introduce a new technology system into a clinical research protocol. In a 2016 survey conducted by Scorr Marketing, 76% of respondents reported that they were very or somewhat concerned about the costs associated with using wearables in clinical trials.<sup>9</sup> These are valid concerns because implementation of any new mHealth technology



system is going to involve considerable up-front costs for devices, software, ancillary equipment, and personnel training. Yet the complex, long-term nature of a clinical trial makes it difficult to establish a direct ROI to justify this investment. In reality, it could be years until any ROI becomes evident. Collecting actigraphy data on a patient population today, for example, can pay off down the road when comparative data analysis helps to reveal improvements in the efficacy of a new drug. Some of the top pharma and biotech innovators have known this for years and are now beginning to leverage historical data as part of their decision making processes.

While incorporating actigraphy assessment into a trial may not result in immediate financial returns, it should be regarded as a long term investment into the quality of the study and the trial data. Besides the intrinsic value of objective activity and sleep metrics, actigraphy data also lends context and value to other biomarkers and patient-generated outcomes, such as vital signs, ePRO responses, medication adherence data, and so on. This rich combination of objective and contextual data supports a more holistic understanding of patients and their experiences during the trial.

## A Better Way to Collect Data

Until very recently, paper-based diaries and questionnaires were the primary means of collecting information about patient activity and sleep during a clinical trial. In addition to the well documented reliability problems associated with self-reported data, relying on patients, who are often times very ill, to log this information consistently over the course of a trial is unnecessarily burdensome.<sup>10, 11</sup> Automation of data collection through the use of a passive wearable system improves the quality and reliability of the data, while also simplifying the process for both the patient and the clinical staff.

Investing in a “connected” actigraphy system will further maximize its efficiency and value. Due to the high volume of data generated, many medical-grade actigraphy monitors store captured data on board the device until it can be downloaded to a PC during a site visit. A connected system, on the other hand, uses a cloud-based technology architecture, which enables remote uploads to the system during deployment through mobile, wireless, or cellular data transfer protocols. This type of platform supports near real-time patient monitoring, meaning that actionable insights are available faster and more efficiently than with a traditional actigraphy system.

## Prevent Costly Mistakes

Once the decision to invest in actigraphy monitoring has been made, a well developed implementation plan is critical in order to fully realize the long term cost-saving benefits. Failure to properly plan for details such as device provisioning, loss and replacements, training material development, data management, and analytics can result in start-up delays, lost or incomplete data, and a slew of additional costs. Rather than trying to navigate this unfamiliar territory alone, sponsors can avoid costly, time-consuming pitfalls by partnering with an experienced actigraphy technology provider who offers end-to-end support services throughout the trial. By leveraging these clinical trials services, which may include protocol development and subject matter expert consulting, site training, site shipping logistics, in-trial data screening, data configuration and transfer, and advanced data analysis, studies run more efficiently and sponsors can avoid the dreaded “costs of doing it wrong.”



Clinical trial designs and procedures have become increasingly complicated in recent years. Studies with a high level of complexity take longer, require more personnel and financial resources, and they can have an unintended negative impact on patient recruitment and retention. According to research from the Tufts Center for the Study of Drug Development, between 2001 and 2015, the total number of endpoints within a typical phase III trial grew 86%, and the number of procedures grew by 70%.<sup>12, 13</sup> As is the case with any new technology system implementation, actigraphy assessment adds new layers of complexity, from protocol design and planning to vendor qualification and onboarding, technology provisioning, personnel training, data monitoring, and so on. While some of the larger, more progressive sponsor organizations and CROs have responded by creating “digital innovation” or similar departments that specialize in mHealth technology implementation, many smaller organizations do not have dedicated resources with the expertise and bandwidth to handle these new challenges.

Source: Getz KA Campo RA™

Typical Phase III Protocol (Mean of Total Numbers)	2001-2005 THEN	2011-2015 NOW	Increase in Complexity
Endpoints	7	13	+86%
Procedures	110	187	+70%
Eligibility Criteria	31	50	+61%
Investigative Sites	40	65	+63%
Data Points Collected	494,236	929,203	+88%

## Leveraging Internal and External Resources

Sponsors can reduce much of the added complexity by leveraging internal resources even before bringing a technology provider on board. Initial planning activities should always involve a coordinated effort to learn about any previous actigraphy monitoring experience within the sponsor organization. If another research group has conducted this type of assessment, they will be able to provide insights and make recommendations based on first hand experience and organizational knowledge. This may also mean that vendor qualification has previously been carried out and many of the initial onboarding hurdles have already been cleared. Once selected, a qualified actigraphy partner can provide guidance on technical feasibility and workflow optimization during protocol development and early planning phases, in order to preempt some of the complications and inefficiencies that commonly occur during a study.

## The Ecosystem Approach

When a clinical trial involves the use of other digital or mHealth technologies in addition to actigraphy monitoring, some of the compounded technical and operational complexities can be lessened by adopting the ecosystem



approach. A connected medical-grade actigraphy system that supports out-of-the-box integrations with multiple wearable devices and mHealth tools alleviates many of the operational and IT challenges associated with collecting, storing, and transferring data from disparate systems. For example, in a trial that includes actigraphy monitoring, smart inhaler usage, and daily ePRO questionnaires, this type of integrated system could passively acquire data from each device and transfer it to a centralized study database or third party EDC system. By supporting this type of technological multitasking, the connected ecosystem approach not only streamlines clinical site workflows and data management workload, but it also lowers the patient burden by minimizing device and system interactions.

The drug development industry is risk-averse by nature, and a lack of clear regulatory guidance governing the use of wearable sensors within a clinical trial may be problematic for some sponsor organizations. Without specific guidelines from the U.S. Food and Drug Administration (FDA) or other international regulatory bodies, sponsors may find themselves weighing the benefits of collecting real-world actigraphy outcomes against the potential risk of not being able to use the data to support regulatory cases or labeling claims. The investment of time and resources, along with the patient burden that accompanies any additional procedure, may be difficult to justify without a clear understanding of the capacity in which the data can be used.

## Moving in the Right Direction

The FDA readily acknowledges the important role wearables and other digital health tools play in ongoing efforts to reduce inefficiencies, improve access, reduce costs, and support personalized medicine.<sup>14</sup> In May 2017, the FDA established a digital health unit within the Center for Devices and Radiological Health (CDRH) with the primary objective of bringing regulatory clarity to this rapidly evolving industry. The agency released their Digital Health Innovation Action Plan in August 2017, which outlines their efforts to foster innovation and to modernize and adapt their processes so that the full potential of digital health technologies can be recognized. One such initiative is the Software Precertification Program, currently in its pilot phase, which is investigating a pathway for more streamlined and efficient regulatory review of software-based medical devices from manufacturers that have previously met specific quality standards.<sup>15</sup> According to the Action Plan, over the next year, the FDA also intends to update current policies and issue new guidance that provides clarity on the 21st Century Cures Act and the agency's approach to digital health technologies.<sup>16</sup>



The key takeaway here is the FDA's efforts to advance their digital health initiatives are gaining momentum, however uncertainties will likely remain until these new guidelines are issued and existing policies are clarified. In the meantime, sponsors are encouraged to establish an early and robust dialog about their wearable device implementation plans with the FDA, which has shown willingness to engage in these types of discussions. Many sponsors have opted to use medical-grade FDA-classified actigraphy monitors with 510(k) clearance as a means to mitigate this regulatory risk. These devices have demonstrated safety and effectiveness, and their manufacturers are subject to FDA quality system inspections at any time. Additionally, selecting an actigraphy partner who has adopted Good Clinical Practice (GCP) processes and understands and abides by global regulatory requirements will help ensure the integrity of study data and the organizational procedures regarding the handling of sensitive patient data.

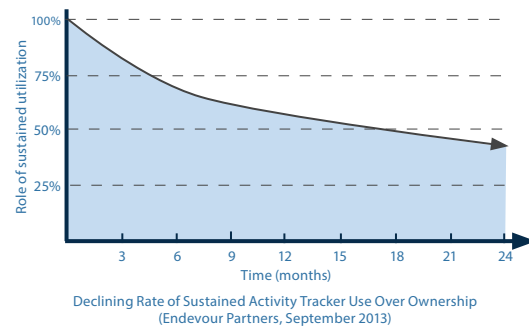
Patient adherence presents arguably the biggest challenge that sponsors will face when incorporating any kind of long-term assessment using a wearable device or other mHealth tool into a clinical trial. It doesn't matter whether an actigraphy monitor is accurate or if the data interpretation strategy is sound if the patient doesn't actually wear the device. Despite the immense popularity of commercial wearable activity trackers in recent years, more than half of U.S. consumers who own one of these devices no longer use it, and a third of U.S. consumers stopped using it within six months.<sup>17</sup> This fickleness is especially disconcerting when you consider that a large proportion of these consumers likely selected and purchased the activity tracker themselves, meaning they were at least somewhat invested in the product at one point.

## Striking the Right Balance

Examination of wear compliance trends in subjects undergoing actigraphy monitoring within the context of a research study reveals similar levels of attrition. This trend of declining compliance over time may be partially attributable to human nature, however factors like comfort, aesthetics, and ease of use all play an important role in a patient's willingness to wear a device for extended periods. In order to maximize wear compliance, sponsors are advised to carefully evaluate the specific needs of the patient population. Factors like age, dexterity, technology familiarity, and social habits are just a few of the considerations that will aid in the development of an actigraphy regimen that patients are likely to follow.

Patient-centricity in clinical trials has become a dominant theme in recent years, and there has been much discussion around the ability of wearables and other mHealth tools to better engage patients in their treatment. The degree to which a patient interacts with a wearable device, along with the perceived value they derive from its use, can influence their adherence to the protocol. In the case of an objective monitoring tool like an actigraph, this can be a slippery slope. Engaging the patient by providing feedback on their activity and sleep levels, for instance, can lead to behavior changes that could compromise the assessment. This is just one example of how new technologies in general are causing sponsors and regulators to rethink the traditional clinical trial process.

The patients' acceptance of an actigraphy monitor is of paramount importance to the success of the assessment, however the technical capabilities of the device must also be taken into consideration. For example, a very compact and streamlined actigraphy monitor may be more aesthetically pleasing to a patient, however the tradeoff is that it may not support raw data collection or any form of wireless communication. Similarly, some actigraphy monitors have a very long battery life, but they use lithium coin cell batteries, which must be periodically changed by the manufacturer. For these reasons, sponsors must first define the specific data collection and connectivity requirements for a study, and then carefully balance them against a device's physical attributes and ease of use in order to support long-term patient compliance.



# Conclusion

There is little doubt that the use of wearables and other mHealth tools to collect objective, real-world patient data is helping to drive the rapid transformation of clinical research as we know it. As the value of actigraphy assessment becomes more apparent and widely adopted within the drug development industry, more and more sponsor organizations will be faced with decisions about whether to leverage this technology and how to do so in order to add maximum value to the study. The barriers to adoption discussed in this white paper present a valuable opportunity for sponsors to gain awareness of the unavoidable challenges and common pitfalls they are likely to face when incorporating a wearable mHealth tool into a trial. Thorough consideration of each of these complex issues, along with early collaboration with internal resources and a qualified technology partner, will help sponsors develop the blueprint for a successful actigraphy assessment and the acquisition of high quality, meaningful real-world patient outcomes.

For more information about wearable, medical-grade actigraphy monitoring, please contact [pharma@actigraphcorp.com](mailto:pharma@actigraphcorp.com) or visit [actigraphcorp.com/clinicaltrials](http://actigraphcorp.com/clinicaltrials).

# Citations

1. <https://www.beckershospitalreview.com/healthcare-information-technology/4-key-statistics-on-remote-patient-monitoring-growth.html>
2. <https://www.outsourcing-pharma.com/Article/2016/05/31/wearables-market-to-reach-18.9bn-by-2020>
3. [http://pages.validic.com/rs/521-GHL-511/images/Digital\\_Health\\_Survey\\_Results\\_Pharma\\_2016.pdf](http://pages.validic.com/rs/521-GHL-511/images/Digital_Health_Survey_Results_Pharma_2016.pdf)
4. Shcherbina A, Mattsson CM, Waggott D, Salisbury H, Christle JW, Hastie T, Wheeler MT, Ashley EA. Accuracy in Wrist-Worn, Sensor-Based Measurements of Heart Rate and Energy Expenditure in a Diverse Cohort. *Journal of Personalized Medicine*. 2017; 7(2):3.
5. Schneider M, Chau L. Validation of the Fitbit Zip for monitoring physical activity among free-living adolescents. *BMC Research Notes*. 2016;9:448. doi:10.1186/s13104-016-2253-6.
6. Wanner M, Hartmann C, Pestoni G, et al Validation of the Global Physical Activity Questionnaire for self-administration in a European context *BMJ Open Sport & Exercise Medicine* 2017;3:e000206. doi: 10.1136/bmjsem-2016-000206
7. Cleland, CL, Hunter RF, Kee F., Cupples ME, Sallis JF, Tully MA. Validity of the Global Physical Activity Questionnaire (GPAQ) in assessing levels of change in moderate-vigorous physical activity and sedentary behavior. *BMC Public Health*. 2014; 14:1255
8. [http://www.pharmatimes.com/web\\_exclusives/the\\_wearable\\_revolution\\_1195884](http://www.pharmatimes.com/web_exclusives/the_wearable_revolution_1195884)
9. <https://www.scormarketing.com/wp-content/uploads/SCORR-ACT-mHealthWearablesReport-2016.pdf>
10. Prince, SA, Adamo, KB, Hamel, ME, Hardt J, Gorber, SC, Tremblay, M: A comparison of direct versus self-report measures for assessing physical activity in adults: a systematic review. *Int Journal of Behavioral Nutrition and Physical Activity*. 2008; 5:56 doi.org/10.1186/1479-5868-5-56
11. Lauderdale DS, Knutson KL, Yan LL, Liu K, Rathouz PJ. Sleep duration: how well do self-reports reflect objective measures? The CARDIA Sleep Study. *Epidemiology (Cambridge, Mass)*. 2008;19(6):838-845. doi:10.1097/EDE.0b013e318187a7b0.
12. KA Getz, RA Campo. New benchmarks characterizing growth in protocol design complexity. *Therapeutic Innovation & Regul Sci*. 2017, in press; updated data provided through correspondence with Tufts Center for the Study of Drug Development.
13. [http://pharma-docs.pharma.org/industryprofile/pdfs/2017IndustryProfile\\_TheDynamicUSResearch.pdf](http://pharma-docs.pharma.org/industryprofile/pdfs/2017IndustryProfile_TheDynamicUSResearch.pdf)
14. <https://www.fda.gov/MedicalDevices/DigitalHealth/default.htm>
15. <https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM577331.pdf>
16. <https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf>
17. <https://blog.endeavour.partners/inside-wearable-how-the-science-of-human-behavior-change-offers-the-secret-to-long-term-engagement-a15b3c7d4cf3>