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A New Paradigm for Conducting Nutritional Research Studies: Live Clinicals™

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Abstract

Funding for nutritional studies, like all medical research, is scarce. This leaves many high-quality investigators under-funded and seeking other means of support. We propose a novel way to conduct clinical, nutritional, research studies in real-time within a corporate setting. We have trademarked the concept as Live Clinicals™, which involves a partnership among a food company's senior management, nutritional researchers, and the public, including customers. The fundamentals of conducting clinical research using the Live Clinical model are like in an academic setting. All components of clinical trials are adopted, but co-planned by senior management and the researcher. All data collected first needs to be useable by the company, and secondarily, be robust enough to be published. What is new with Live Clinicals is that the data are obtained in real-time. This capability has only recently been realized and embraced by consumers. The duration and cost of a Live Clinical is substantially less than using an academic center. Companies go at risk for what the participants report, but there is tremendous upside in the excitement surrounding the favorable comments. An example of a Live Clinical from a food company is presented.

Keywords: Nutritional Studies; Live Clinicals™; Clinical Trials; Research Funding

Introduction

Competition is steep for scarce research dollars for all medical-related studies, including nutrition. Today, less than half of the funded research is from government grants [1]. Inflation-adjusted, government-funding of all medical research has been declining for the past 40 years. Between 2003 and 2015, the National Institutes of Health (NIH) lost 22% of its capacity to fund research [2]. Of the few NIH dollars that remain, only a fraction goes toward nutrition and obesity-related research [3]. From the total $33B NIH budget in 2017, 4% was spent on nutrition; only 2% was earmarked for obesity, which is responsible for 30% of deaths in the United States. Until 2020, the NIH budget will remain roughly the same [4].

Research dollar deficits are somewhat made up by industry, philanthropy, and universities, with industry funding the most [1]. Drug company investment in basic research soared from $3 billion in 2008 to $8.1 billion in 2014. Changes in funding patterns with less money from NIH and more from drug companies have left many nutritional researchers with little or no support.

The Problem: Why Nutritional Researchers are Particularly Affected?

Non-government funding for nutritional and obesity research has been particularly hard hit for several reasons. Food companies are the likely candidates to fund nutritional research. However, these companies typically don't fund studies, because rarely health claims can be made like those for pharmaceuticals. The Food and Drug Administration (FDA) only allows 13 drug-like health claims on food and supplements [5]. However, these aren't attractive to companies, because they lack exclusivity [6].

For example, claims such as "calcium may reduce the risk of osteoporosis" or "fruits and vegetables, as part of a low-fat diet, may reduce the risk of some types of cancer," while compelling, are not appealing for a single company to fund because so many sell these commodities. The first company-sponsored health claim was for oat beta glucan and cholesterol-lowering. Quaker Oats filed the claim with the FDA, but General Mills capitalized on it for its oat cereal, Cheerios. General Mils grew its brand without paying for the research. Ever since this, other companies have been leery to vie for a health claim.

The fear of a financial conflict of interest with little up-side is another real problem, precluding food companies from funding nutritional research [7]. For example, the University of Colorado School of Medicine returned $1 million gift from Coca-Cola after it was revealed that the money had been used to establish an advocacy group that played down the link between soft drinks and obesity [8]. This group of scientists urged people to focus more on exercise and worry less about what they eat and drink – something that is not supported by the bulk of research studies.

The current norms for disclosure of nutritional researchers are inadequate and greater transparency is needed [7]. Unlike other scientific studies, such as looking at a rare form of cancer, nutritional studies have inherent investigator biases, because everyone eats. To overcome this, some have suggested that the nutritional preferences of the investigator be disclosed. For example, if a scientist shows that vegan diets are superior to other types and does not divulge that he or she is a vegan, then this could be perceived as investigator bias. In addition, unlike other scientific fields, the public is intensely interested in nutrition and often exposed to scads of unscientific information. Thus, food companies may pay for a high-quality study, with no one believing the findings.

The Solution: Live Clinicals™

Today, nutritional researchers lack proper funding, yet are still curious and available to conduct research. Clearly new strategies are needed, because the current funding pattern is unlikely to change. We propose a new model of collecting data in real-time, the Live Clinical™. This model involves a triad of a company, the public including a company's customers, and nutritional researchers. A company embracing this model must first be curious about how their foods perform, and second be willing to accept null or negative findings. The tenants of conducting research remain intact: hypothesis generation, data collection, statistical analysis, and manuscript preparation and submission (Table 1).

Part of a clinical study	Traditional method	Live Clinical
Hypothesis generation	Researcher determines	-Partnership between food company and researcher -Corporate executives need to be curious how their foods perform and be willing to take the risk of real-time comments
Informed consent	Obtained	Obtained
Methodology	Researcher determines	-Capture information that can be use by the company for marketing, such as posts on social media (text and video) –Meaningful, measurable, and reliable enough for a publication, which could include anthropometric measures, questions about quality of life, etc.
Statistical analysis	The researcher could do this, but often outside consultants are hired, who have expertise in	Same as traditional method

	statistics	
Results	Review data, which is usually from medical tests (e.g., anthropometric measurements, blood, others like MRI)	-The company can report some conventional data like body weight, but prefers to leverage other things like participants' comments and videos -For publishing, the researcher will use participant-reported data (e.g., change in body weight, blood pressure, blood tests, questionnaires about quality of life issues). An academic researcher may serve as co-author. The researcher will not use video, photos, or social media posts.
Publication	Submit to high impact journal	Submit to journal that has a fast review time

Table 1: Overview of a Live Clinical™.

Some differences between the traditional research model and Live Clinicals exist. Hypothesis generation has more involvement from management to assure that the data collected are usable to the company for marketing its foods. Data collection is self reported and in real-time with full visibility to public. In the Live Clinical model, participants post videos, photos, and comments on the corporate website and their own social media. Hard data measurements are also obtained like changes in body weight and quality of life indicators. The nutritional researcher analyses these findings after the Live Clinical is over with the intent of preparing a manuscript suitable for publication.

Five Novel Aspects of the Live Clinical exist

Cost: Using an academic center to conduct clinical research is costly in terms of the tests performed, patient recruitment, and overhead paid to the university. Contract research organizations are just as costly. A food company could expect to pay around $1,000,000. In contrast, a typical Live Clinical costs about $100,000.

Duration of a Clinical Study: Typically, a clinical study in an academic center takes one to three years to complete. This includes securing a contract with the external relations department and gaining Institutional Review Board approval, which could take six months. A Live Clinical can be as long as the company wants, but typically two to eight weeks is the norm. Granted, there is preparation time to accrue participants and set up ways to collect data, but these are accomplished faster by company employees.

Transparency: The public is skeptical about food companies, wondering if their advertising is true [7]. A Live Clinical model captures information from regular people eating the foods that the company sells. The participants are found through the company's customer list and social outreach. They are asked to make regular posts on social media. All information is self-reported and in real-time, so the company needs to be willing to go at risk, if unfavorable remarks are made. Once started, data from a Live Clinical are there for the public to view and are unable to be redacted or influenced by the financial underwriter. Trust is established with the public, because the comments are unfiltered and generated by peers.

This contrasts the lack of transparency at an academic center, where data are collected, filtered, and assembled for a scientific audience. With academic studies, the public learns nothing about how the participants feel or perform while eating the food. Even more troubling is that up to 85% of the published scientific literature may be wrong, with nutritional studies being among the worst [7,9]. The need to publish only positive results fuels the problem. In 2015, 93% of the published studies funded by food companies favored the sponsor's interest [10].

Failure of Scientific World to Deliver Messages on Healthy Eating: Social Networking: For the last 50 years, the prevalence of overweight and obese individuals has steadily increased [11]. This has lead to increases in chronic disease like cardiovascular disease, type 2 diabetes, stroke and hypertension, cancer, and cognitive dysfunction. The messaging on healthy eating to the public has not worked, and new ways of communication are needed.

The old model for nutritional research has investigators sharing the results with their peers. Few studies are picked up by the media, and sometimes, those that are; do not convey the message properly. Social media has changed most areas of society and the scientific community is no exception [12]. It is engaging and can be experienced in real-time. User generated content creates more cognitive trust than marketer-generated content. In the new, Live Clinical model, data collection is in real-time and self reported from the participants. These go out to the public in a variety of social media outlets (e.g., Facebook, Instagram, YouTube, Twitter, etc.).

Over the past ten years, consumer purchasing habits are more shaped by what others think and less by what scientific findings say or what corporate advertising dictates. The recorded data from a Live Clinical can be obtained daily and are analogous to online marketing [13]. Most people (88%) trust online reviews from strangers as much as a personal recommendation. Having more reviews, whether they are good or bad, leads to a higher conversion rate, because the presence of bad reviews shows that the company isn't to hide anything, and makes the good reviews seem more sincere.

Start of "big data" for Healthcare: Healthcare is under attack by consumers, who are no longer shy about stating their dissatisfaction. People want their healthcare to be consumer-driven, user-friendly, convenient, transparent, and private [14]. Online shopping and banking are ubiquitous, so why can't healthcare? Google, Amazon, and Apple are headed in this direction. These cash-flushed companies know how to collect data on all facets of someone's life, develop profiles, and deliver an actionable recommendation. Partnerships are already forming between these giants and others with established healthcare systems. Amazon has partnered with Berkshire Hathaway and JP Morgan Chase, and CVS bought Aetna. The scientific world should embrace the new direction of healthcare, and through research, oversee that it's done correctly.

An Example of a Live Clinical™

Nutrient, hereafter referred to as the Company, conducted its first Live Clinical in February, 2018. More than 150 people were recruited from the Company's customer database. The purpose of the Live Clinical was to determine the effect of the Company's foods on quality of life (e.g., sleep, energy, hunger) and weight loss in a healthy population. About two-thirds of the participants were overweight or obese. Subjects were grouped by teams, with each having a coach to guide them. The Company provided each participant with five meals daily for 15 days at no charge. In exchange, subjects signed a consent, agreeing to provide regular videos and posts on social media about their experiences. Social media encompassed not only posting on the Company's website, but also on the participants' own sites.

In addition, participants completed daily data forms about their weight change and quality of life. In an attempt to reduce bias, the Company hired a statistician to manage data collection and complete the data analyses. In addition, the Company seeks outside scientists to assist with identifying methodologies, reviewing statistics and results, and becoming a co-author for a scientific manuscript. The Company's researcher will prepare a manuscript for publication. For this Live Clinical, the Company developed a ranking system for evaluating each team, according to the number of social posts, completion of data collection forms, and weight loss. Each member of the winning team received $1,000.

Summary

The era of academic centers conducting clinical nutritional research studies funded by government entities is nearly over. Food companies are unlikely to step in, because they see no up-side and end up with data that they can't leverage. The Live Clinical is the wave of the future for food companies and investigators. Intellectual curiosity is satisfied, and new information is generated in a rigorous scientific way. A company learns how its food performs in a real-time setting and gets usable marketing materials to promote its products. Researchers obtain new data suitable for publishing. It's a win-win model for the future.

Conflicts of Interest

Dr. Bell is a full-time employee at Nutrient, a company that manufactures and sells nutrient-dense foods, and uses the Live Clinical™ model. Mr. Marsland and Mr. Castleman founded the company. Live Clinical™ and Live Clinicals™ were trademarked as "providing information in the field of nutrition, health, and wellness."

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