Food for Health®
National Institutes of Health "Suzy" Study Summary

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Objective: to prove that food-as-medicine is an effective therapy to treat Pre-diabetes (PD) and Type 2 Diabetes (T2D) AND that the Food for Health App is the catalyst to behavioral change and adoption of healthy food alternatives.

1. Intellectual Property

Our patented "Efficacy Engine®" system, method, and software is the only solution to COMPUTE food efficacy simultaneously across multiple co-morbidities and wellness goals. It utilizes unbiased, third-party, peer-reviewed clinical studies published n peer-reviewed literature, from authors from the Cleveland Clinic, The Mayo, Johns Hopkins, and thousands of additional highly esteemed and scientifically accredited organizations. There are 830 diseases and conditions and 223 wellness goals in the system at present. Complexity increases exponentially with every comorbidity. Diets, ingredients, allergies, sensitivities, regimes, protocols, personal preferences, and Rx usage are analyzed with contraindications, depletions, and adjuvants. We have 5 issued patents in the United States (US11437134), Korea (KR1020140088118, KR1020180107274, and KR1020190029785) and India (IN437344), with multiple continuances, iterations, and derivatives in various stages of prosecution in 38 other countries. There are dozens of complimentary medical, health, wellness, fitness, diet, menu, recipe, calorie counting, meal planning, food, and grocery Apps where we can augment the functionality and be a catalyst for the collection of unique datasets, they would otherwise not be accessible. Our Efficacy Engine® creates an inimitable proprietary dataset containing personalized precision medicine and recommendations for each user along with cohort trends, statistics, and analysis that have never been compiled before. We have a 13-year technological and intellectual property lead in the marketplace over potential entrants. Our patent prosecution, management, licensing, and defense strategy are the brainchild of Adam Southam, the principal inventor. Adam has 25 years of experience in conceiving, prosecuting, defending, and monetizing patents worldwide, with 33/33 wins in Federal Court against former infringers. His strategy involves multiple intellectual properties of cross-related patents intertwined with non-published processes and trade secrets, making replication by infringers extremely difficult. Southam also employs the practice of engaging defense counsel to defeat patent claims during patent prosecution.

2. Technology Innovation

The Technology Innovation is to use our patented approach to scan food label package codes, providing an urgently needed solution to inadequate food labeling and comprehension. Despite decades-long governmental efforts to improve food package consumer nutritional labeling, current labeling does not enable consumers to make optimal food selection choices based on the increasing prevalence of obesity, diabetes, heart disease, chronic inflammation, etc. Consumers do not understand how to interpret labeling information, nor do they have the patience to read it.

Food for Health is used on a desktop computer, laptop computer, tablet, mobile device, and/or an in-store wireless digital device attached to or integrated in a shopping cart. Users first select their medical conditions (e.g., PD) and T2D, then their specifications including wellness goals (loose fat), allergies, sensitivities, diets, taste preferences, prescriptions, etc.). Then their biometric, genomic, and lab results (Specs) are imported from their Electronic Medical Record (EMR); and they use their device camera to scan food, beverage, or supplement barcodes (UPC/PLU/EAN). Our proprietary database holds vast ingredient and nutritional information per code. This results in a "Go" or "No" product rating based on medical conditions and Specs. Food for Health rating is an alpha-numeric grade derived from a patented algorithm, relating the efficacy of each product ingredient to the user's medical conditions and Specs. Healthier alternatives to graded products are presented from highest to lowest efficacy. Ingredients contradicting medical or health conditions result in a "No" rating. Grocery store Point-of-Sale (POS) systems tabulate products purchased by user credit card transactions.

The resultant data provides a detailed list of: products scanned sequentially and purchased; the frequency, quantity, and time of purchases; the rating/grade of products relative to medical conditions or Spec; the mapping of consumer proximity to all products and grades in the store; and motivators (coupons, rebates) and rewards.

The App delivers consumer reports to share with physicians, health insurance, life insurance, employers, etc. App precision increases as consumer's biometric markers, test results, health history, and original food selections are added. Baseline food selections are tabulated by consumers to shop in the App prior to using the App.

Upon subsequent grocery shopping, the App provides recommendations for more efficacious product purchases. Scans establish user intent towards commitment. Future scans and purchases define/reinforce behavioral changes. Periodic biomarker testing and use of wearable devices show changes resulting from Food for Health engagement, providing proof of health improvement from dietary/behavioral modification. Detailed reports and graphs are generated, and physician/advisor can provide monthly analysis of data reports, biometric markers, and wearable device metrics, along with health coaching for improved outcomes.

Other Apps available prove positive reinforcement of gradual, incremental change results in long-lasting changes. Food for Health is the first App to provide real-time education and guidance at the point of decision-making to choose foods to improve glucose control and avoid foods exacerbating users' health conditions to reverse PD changes, rather than progressing to T2D; and helps T2Ds reverse to a more normal state. As the population of PD and T2D patients is large, Food for Health has a huge impact potential. 413 other conditions are also considered. A detailed competitive analysis is available. Certain proprietary modifications to the APP are anticipated prior to initiation of the study, to improve efficacy for a PD and T2D populations.

3. Objectives & Challenges

The technology development goal is to conduct a clinical trial to provide proof of principle (POP) that the App can improve the health outcomes of PDs and T2Ds. The

study will also allow us to make important algorithmic and stylistic improvements to the current version of the App, not be possible without the proposed controlled clinical trial.

Engagement with the Food for Health Application will promote dietary and behavioral changes that will: a) lessen the incidence of PD; b) delay or prevent progression from PD to T2D; and c) help T2Ds revert back to normal blood glucose levels (complete remission) or to PD levels (partial remission). In this STTR, we will evaluate the App with a combination of PDs and non-insulin-dependent T2Ds.

The technical questions are to determine which biomarker biomarkers to focus on in the future if certain foods are more or less impactful for diabetic improvements by brand, class (for starches-rice vs potatoes vs pasta), or type (brown vs white rice). Different phraseology in the App can be used to improve user engagement and commitment. The research involves the development of systems for intake, monitoring, testing, reporting, interaction, and outcome conclusions for the test group. Included in this effort are the processes, surveys, testing protocols, permissible variances, defined communication objectives and limitations to avoid influencing test participants, third-party oversight and audit, correlation with academia and program physicians, participant requirements, physician requirements, and program staff requirements.

The technologies already native to the App provide significant data; however, some technologies need to be augmented, and the entire environment needs to be migrated to be HIPAA compliant and secure. In addition, the analysis of resultant data will be intense because it not only measures outcomes but also consumer behavior (with/without influence; with/without coaching; analysis of product proximity to positively and negatively graded products; time spent with product selection, all mapped against biometric markers, survey responses and test results).

The technical objectives and tasks are broadly to define what varying degrees of influence upon a consumer are needed to obtain an outcome, the propensity to adhere to programming, the circumstances that partial participation or complete defection, and the influence that geographic, psychographic, economic, physical, societal, vocational and employment variables present. The outcome of the study will also show what conditions will cause a tipping point for various cohorts as well as what cohorts are most likely to succeed or fail. Specifically, we will be evaluating success outcomes in PDs and T2Ds as described above.

4. Clinical Trial Details & Tasks

This pilot study is anticipated to require 500 subjects, either PDs, T2Ds, or a combination, depending on subject availability and other logistical parameters. The formal sample size will be calculated based on variance, predicted magnitude of change in a key parameter, and dropout rate in consultation with a statistician. As well, the statistical approaches used to interpret the data, formal statistical hypothesis testing, primary and secondary variables, covariates, intention to treat, dropouts, outliers, etc., will be developed in consultation with a statistician. For the study design, changes will be assessed in subjects on Day 1 of the Treatment phase to the end of the treatment phase (12 months); and from the end of the intervention phase at 12 months to up to 3 years after the trial has been

completed to monitor post-intervention changes. Additionally, we will consider a control group that will consume their habitual diets throughout the 12-month intervention phase but using a modified version of the App that will only monitor what foods the subjects consume, but without any guidance nor recommendations to change their choices of foods consumed.

Study Design:

Run-In, Baseline: The study population will be instructed on the use of the App. During a period of one month, subjects will use the App, and all data collected by the App will be reported back to the Sponsor, but no actions will be taken (guidance to improve food intake, etc.). Subjects will be instructed to consume their habitual diets and not to make any lifestyle changes such as increased exercise.

Treatment phase: The active or treatment phase will be the same as the baseline period, except now, the App will be used to help participants make informed changes to their diet and exercise. Subjects will make dietary and behavioral changes using the App for a 12-month period. Subjects will receive semi-monthly coaching sessions with a registered dietician trained in the use of the App to answer questions and provide additional background on why certain changes are being suggested. A total of 24 sessions are included during the 12-month period. On-demand support are offered and count toward the 24-session total. Adaptive coaching intensity based upon user engagement, results and risk stratification will be engaged.

Post Treatment phase: Post-intervention follow-up will occur at 3, 6, 12, 18, 24, and 36 months to assess with measured parameters conducted and questionnaires.

Inclusion Criteria: Participants must have full insurance coverage and be willing to engage in quarterly biometric testing, surveys, and 30-minute interviews. Other inclusion criteria, such as gender, age, and ethnicity (to name a few), will be determined in consultation with the principal investigator at the selected clinical site.

Exclusion criteria: to include limits on alcohol use, no smoking, no insulin usage, limitations on concurrent drug usage, no bariatric surgery, obesity limited to a specific range of basal metabolic index (BMI), etc., will also be determined in consultation with the principal investigator at the selected clinical site.

Parameters to be measured during the Run-In, Treatment and Post-Treatment phase:

Body weight: Total body weight, lean body mass, BMI, adiposity (skin fold, other), and aerobic capacity, as well as other standard basic measurements, will be assessed.

Blood Glucose (BG): BG will be measured with a CGM (Abbott Free Style Libre 3 or Dexcom G7), with data automatically reported to investigators. This will enable us to understand fasting blood glucose (FG), post-prandial BG, and rate of increase/decrease in BG after a meal.

Impaired Glucose Tolerance (IGT): BG above 140 2-hrs after consuming food carbs is referred to as IGT. In 2021,10% of adults worldwide had IGT (541 million people), and IGT is a marker in PD and T2D. Related, the area under the curve (AUC) for peak post-prandial BG, ascending and descending rates to baseline, and time below baseline are readily measured with CGMs and calculated from data. Generally, a slower rate of increase and decrease in post-prandial peak BG is beneficial.

Impaired fasting glucose (IFG): Elevated BG in fasted state (above 70 mg/dL) is referred to as IFG and is due to insulin resistance (IR). 319 million adults had IFG, and IFG is also a marker for PD and T2D, generally thought to be less dangerous than IGT for transitioning from PD to T2D.

Time in Range (TIR): TIR is the amount of time the subject spends in the optimal range of 70-140 mg/dL. In a 24-hour period, the goal is to be nearly 100% in this optimal range. Those with poor BG management are mostly out of range, and many are 30% out of range.

Insulin Resistance (IR): This will be measured at the beginning of the study with an oral glucose tolerance test (OGTT) with 75 g glucose. Various techniques are used to assess IR. The euglycemic clamp technique is considered the gold standard and will be considered.

Glycosylated markers: Glycosylated Albumin and Glycosylated red blood cell (RBC) Hemoglobin (HbA1C) will be measured to assess one- and three-month elevations in blood glucose.

5. Market Opportunity

The International Diabetes Federation estimated that in 2021, there were 860 million PDs worldwide, and by 2025, there will be 1.2 billion PDs! Without drug or nutritional intervention, 26%-50% of PDs will deteriorate to T2D within five years of diagnosis. T2D has many health complications, increases healthcare costs, and shortens life expectancy. Even in PD, there was an increased risk of cardiovascular disease, coronary heart disease, stroke, and all-cause mortality in PD versus persons with normal blood sugar levels. These are conditions normally observed in T2Ds, but there is now evidence that PDs have concomitant damage to the eyes, kidneys, blood vessels, and heart. Experts agree that PD and T2D are conditions/diseases reversible with diet and lifestyle changes. Existing food label schema have been largely ineffective in reversing the increasing incidence of PD, T2D, associated metabolic syndrome, and overweight/obesity. Food for Health is expected to improve outcomes for PDs and T2D.

The App is infinitely scalable without technological obstacles for consumers. The greatest outcomes of any T2D program include medical practitioner involvement in the recommendation, adherence, and coaching of patients engaged in the program. The market opportunities to involve a myriad of partners in proliferate programs utilizing the App as the catalyst and measurement tool for success include health insurance, life insurance, hospital systems, clinics, physicians, nutritionists, dieticians, dietary programs, chiropractors, naturopaths, nutritional influencers, dentists, grocery stores, telehealth,

chronic care management and home healthcare organizations who can all benefit through patient participation and revenue sharing from the App.

6. Company and Team

Food for Health® is a Food-Healthtech Enterprise SaaS company. Consumers are demanding healthy food choices. 80% of chronic disease is caused by food. 71 million grocery shoppers currently food read labels to discern what is good or bad for them and 1) less than 1% comprehend labels, 2) even fewer have any knowledge about food and ingredient efficacy; 3) most are confused by conflicting product claims and marketing misdirection 4) spend 0.5 to 3 minutes reading without definitive results, 5) are not qualified to verify facts.

Our patented Food for Health® App determines food efficacy. Just like Uber replaced the method by which we travel from A to B with a superior, succinct, reliable, and trusted solution, Food for Health replaces label reading with scanning and delivers precision, certainty, speed, and clarity as to what foods are good or bad for you to treat/prevent disease, advance wellness goals, and more. It is based on unbiased, independent, peer-reviewed clinical studies. Consumers engage in managing Food-as-medicine and reap financial rewards for healthy choices. Our App is fully personalized and will include biomarkers, genomics, likes, allergies, diets, restrictions, Rx usage, etc. Recipes and restaurant menu items will also be analyzed, giving consumers 100% control over their food.

Dr. Alvin Berger, Ph.D., is the PI for the clinical trial and scientific work for Food for Health. Dr. Berger is a seasoned senior executive with extensive experience conducting nutritional clinical trials in startup and Fortune 500 companies over the last 25 years (LinkedIn).

7. Requirements & Intended Limitations

- **a.** Study participants must have access to a personal mobile device connected to the Internet.
- **b.** While physical activity, sleep, stress management and other holistic lifestyle changes are likely beneficial to the study participants, this study explicitly excludes introducing these variables under the program. Participants are free to pursue such lifestyle changes on their own and must include any available data that results.
- **c.** The study will consider socioeconomic variables limiting food access, affordability, education, cultural, age, racial, gender, or other facts and present findings as a whole and divided into any number of cohorts that reflect variances from the whole relative to those and other factors stated above.
- **d.** Post-interventional follow-up.

8. Scientific and Technical Literature

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