**Overview:** The software will be used to monitor and change eating pattern in clinical studies. Overall, a typical study will be run in specific geographic locations (say San Diego, Seattle, etc.). At each location, a study coordinator will oversee the overall study. The study will begin at each location with advertisements to recruit subjects. The subjects will enter basic information and answer questions to see if they qualify for the study. If they do, they will be scheduled to come to a doctor’s/nurse’s/study coordinator’s office (the office). At the office, some basic measurements are taken (vital signs) and the user is given an overview of the study and is asked to sign the “informed consent” if he decides to participate. Then the user starts 10-21 days of recording everything s/he eats/drinks (baseline). After baseline recording, the user again comes to the office to see his report and the study coordinator decides if the user will go through the intervention period of 12-16 weeks (Intervention). Some lab tests are done on the person’s blood samples before the intervention begins. During 12-16 weeks intervention the user continues to record food/drinks and gets continuous feedbacks. After intervention period, the person returns to the office, answers some questions and takes another blood test. The study continues for a year. But after 16 weeks the user is free to record or ignore recording food/drinks intake. At 1 year, again the person returns to the office/lab for some measurements/lab tests. During the entire study period depending on the location and hospital that runs the study the user may also answer several additional questionnaires, may come to lab/office more frequently and may take his/her own measurements of body weight, blood pressure, blood sugar etc. at home. Also, if the person is on some medication or nutrition supplement, there may be a system to record when the person is taking medication and prompt him/her to take medication at right time.

The system will have a smartphone app, web interface for some data input in lab/office, a backend data-storage and analysis system. It will serve the following purposes

1. Study recruitment
2. Filtering the recruits based on inclusion/exclusion criteria
3. Scheduling visits to office and labs
4. Monitoring and changing users eating patterns
5. Producing reports and feedbacks
6. Integrating other sources of inputs – lab reports, questionnaires, activity, body weight etc.
7. Dash board for the study coordinator
8. Dash board for the user – where the user can see his/her progress and reports. (OPTIONAL)

**Summary**

1. Which data will come from the phone to the server
   1. One time sign up data and account activation
   2. Daily input
      1. Food picture (If a person annotates the food, this *may* come along with ii)
      2. Food name annotation
      3. Food text (from text entry TAB)
      4. Commonly used food (From Commonly used food TAB)
      5. Bar code for food (Bar code TAB)
      6. Time stamp and time zone
      7. Location coordinates
      8. Location annotation (name of the place if available)
   3. Periodic inputs from phone to the server
      1. Weight (plus date and time and place)
      2. If used for a diabetic – blood sugar levels (plus date and time and place)
   4. Questionnaire from phone or web to the server
      1. PSQI
      2. Standard wellness questionnaire
      3. Chronotype questionnaire
      4. 24 h recall questionnaire
      5. Food frequency questionnaire
      6. Any other questionnaire a study might include
   5. Lab reports (there may be more than one lab report input to the system, mostly by a lab tech using a web portal)
      1. Fasting blood sugar
      2. Triglyceride
      3. LDL cholesterol
      4. HDL cholesterol
      5. Dissolved O2
      6. Etc.. There may be multiple fields
   6. Queries from the user
2. Which data will come from server to the phone?
   1. Push notifications (text)
   2. Reminders (text)
   3. Feedograms (data/figures)
   4. Reports (data/chart)
   5. Optional charts
   6. Nutrition tips (as text)
3. Which additional data will be input to the database
   1. If the app can capture fitbit or equivalent device data it will be transmitted to the server
   2. A person may wear an accelerometer and the data can be downloaded as tab delimited file and integrated to the database
4. Study monitoring dash board
   1. Will have summary of the study and ability to analyze or export results

Eating Duration

Weekend Jetlag

Tue

Wed

Thu

Fri

Sat

Sun

Mon

Wed

Thu

Fri

Sat

Sun

Mon

Tue

Feedogram

Today’s progress