Automated Analysis of Retinal Imaging

Millions of people in the United States are affected with retinal diseases, and imaging technologies are used to monitor the extent and progression. While these current tools are useful for visualizing the disease, it’s difficult to objectively quantify and interpret progression of disease or the effects of treatment.

The Solution

A University of Michigan team, Thiran Jayasundera, M.D. and Matthew Johnson-Roberson, Ph.D., developed EyeAnalyze—a computer-based service that allows for quick, accurate, automated analysis of retinal fluorescein angiography (FA) and autofluorescence (AF) imaging. EyeAnalyze reduces the time spent interpreting images, increases work efficiency, and provides image analysis at a quality equal or superior to that of a clinical trial grader. By increasing the efficiency of image analysis, the patient’s disease progression can be identified early and enable clinicians to adjust therapy.

Images are uploaded to the EyeAnalyze website and quickly processed on a server that runs the analysis software. The results depict the regions of disease and give quantification of the affected area. Serial images taken over a period of time (months to years) can be uploaded to generate an image comparison that measures and highlights disease progression.

This project was funded by the University of Michigan Translational Research and Commercialization for Life Sciences Program, also known as MTRAC. MTRAC works to “fast forward” projects that have a high potential for commercial success, with the ultimate goal of positively impacting human health.

MTRAC has been made possible by the Michigan Economic Development Corporation, the Michigan Institute for Clinical and Health Research, and the generosity of friends of the University of Michigan.
**EyeAnalyze is a new computer-based service** that performs automated identification and quantification of change in retinal diseases.

**Significant Need**
Currently, analysis of fluorescent images is time consuming, largely subjective, and unable to establish temporal changes. EyeAnalyze will make fluorescein angiography (FA) and autofluorescence (AF) images interpretable by a greater number of physicians/optometrists quickly and accurately—ultimately leading to efficient image analysis and improved patient care.

**Compelling Science**
A computer-based service that quickly performs automated analysis of retinal FA and AF imaging.

**Competitive Advantage**
Automated, quantifiable, reproducible measures of disease progression based on FA and AF image analysis will improve patient care and disease therapy. Current imaging technology interpretation is subjective, time-consuming, and lacks a quantitative measure for disease burden.

**MTRAC Project Key Milestones**

- Complete development of FA non-perfusion detection and quantification algorithm.
- Process the SCORE2 study data to demonstrate the high correlation between the algorithm and clinical trial graders.
- Prepare and submit 510(k) application to FDA.
- Assess how to distinguish EyeAnalyze “new” procedure from current procedures (CPT codes). Strategize the application to AMA for a new CPT code.
- Document FDA-acceptable software.
- Provide EyeAnalyze to Key Opinion Leaders to obtain feedback on product design and utility.
- Legally form an LLC.
- Obtain funding from angel investors and Michigan state support programs.

**Overall Commercialization**

**Commercialization Strategy**
Form a start-up company.

**Regulatory Pathway**
Initial regulatory assessment performed by Michigan Institute for Clinical and Health Research. Submit a preSub to obtain FDA feedback on the proposed clinical study plan.

**Intellectual Property**
Two patent applications filed and converted to utility patents. One provisional patent application filed.

**Engage Investors/Company Launch Strategy**
EyeAnalyze — Following completion of studies to establish the clinical utility of the algorithm, EyeAnalyze will incorporate, retain experienced senior management, and approach venture investment community.

MTRAC funding has been critical as we work to validate the efficacy of the EyeAnalyze system. And the business support and advice is extremely helpful as we maneuver the path to commercialization.