

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Roser, Mark

eRA COMMONS USER NAME (credential, e.g., agency login): Results-PI

POSITION TITLE: Principal Investigator

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	Completion Date MM/YYYY	FIELD OF STUDY
University of Pennsylvania (School of Engineering)	B.S.	1987	Mechanical Engineering and Applied Mechanics

A. Personal Statement

I am the inventor of the proposed novel exo-tendon assistive device, and have received three issued US patents for this technology thus far, with multiple other global patents pending. I am committed to the success of this program and have invested years of effort into the development of this exciting new approach, and am building my knowledge month by month.

I am a Secretary within the Wearable Robotics Association, providing me with access to a wealth of colleagues focused on assistive technology and has provided the opportunity to initiate collaboration planning with a number of them. This association includes companies that are developing both passive wearable robots such as Laevo and Strong Arm as well as powered exo-skeletons such as Suit-X and Harvard’s Wyss Institute.

Having led one product launch program starting at SBIR Ph I / II as the PI from inception to publication and then onto commercial revenue in the field of diagnostics for Diabetic Retinopathy and Macular Degeneration, I believe that I have demonstrated my ability to work well with doctors, academic researchers, patients, the business community and the whole spectrum of people and agencies required to move programs forward. I will bring that same passion and deeper experience to this program.

As a mechanical engineer with a strong life-sciences background, I have a deep respect for the complexities of bringing a new product to market. In my years of consulting work with companies such as Pfizer and Genentech, I have come to appreciate the degree of effort required to establish safety & efficacy.

Having worked with large engineering companies such as ITT, Cummins, Caterpillar and Eaton, I also bring a sense of passion for product development and team work. I have led teams in both scientific and engineering pursuits and am excited and enthusiastic about driving this new product concept forwards towards clinical evaluation and commercialization. My knowledge of working with teams in both life sciences and engineering will be of great assistance as we move this program forward within the SBIR framework. My experience in working with large companies will also be helpful as we develop collaborations with future sponsors that lie beyond our Phase II program.

I have demonstrated my capabilities by translating the success of our company's prior Phase I / II SBIR effort into commercialization. Within months of completing our ophthalmic Phase II study, our small company received orders for our home vision monitoring system, and is now distributed nationally and internationally.

B. Positions and Honors

Results Group LLC / Open Innovators - Tolland, Connecticut, 1996-Present

Founder

Principle Investigator for studies in several therapeutic areas:

- NIDILRR SBIR Ph I - Focused on off-loading assistive exo-skeleton for Diabetic Foot Ulcer
- National Eye Institute SBIR Ph I / Ph II - Development of novel vision monitoring, educational & adherence tools for patients with diabetic retinopathy and macular degeneration (Collaboration with Johns Hopkins).
- Multiple IRB approved in-home patient interview studies in the fields of head trauma, drug adherence, ophthalmology, cardio-vascular surgery, satiety, and the human factors of home vision monitoring

Manager of full time, part time & contract staff

Consultant, focused on new product strategy, innovation and portfolio management for a variety of clients:

- Pfizer Global R&D – Reporting to the VP of Research Strategy
- Pfizer Global R&D – Reporting to the Global Director of Project Management
- Pfizer Global Manufacturing
- Genentech
- CVS / Health Corporation
- Eaton Corporation
- Cummins Corporation
- Caterpillar Corporation
- PACCAR Corporation

International Macular and Retinal Foundation - Windham, Maine, 2015-Present

Co-Founder of 501(c)(3) non-profit organization, established to distribute vision-saving eye tests and educational materials developed under SBIR program to patients with chronic eye diseases, including diabetic retinopathies and macular degeneration. The Foundation has distributed over 15,000 vision tests without charge through partnering non-profit organizations.

Pitney Bowes Corporation, Dictaphone Division 1994-1996

Senior Product Manager - responsible for multiple digital voice & data logging systems tailored towards the health informatics market.

Program Manager - for novel open-architecture Windows-based voice & data system for small clinical office deployment

FoxRose LLC; 1992-1994

Founder - start-up focused on fax & voice response system to automate storage & retrieval of technical & material safety data information for corporate clients.

Business sold successfully.

ITT Corporation; Flygt Division 1986-1991

Hydroturbine Engineer - responsible for computational fluid dynamics associated with impeller blade design

Project Leader - responsible for deployment of multi-megawatt hydroturbine facilities for sustainable electricity

C. Contributions to Science

C1 - Conception, Engineering, Patenting and Initial Development of Novel Off-Loading Footwear


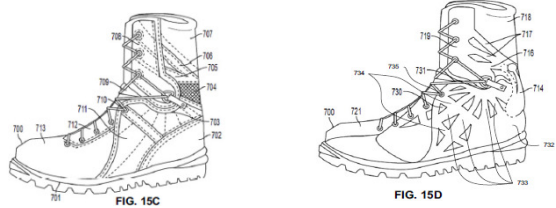
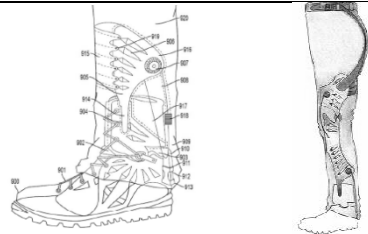
I have been working on this novel approach for more than 7 years and am committed to delivering it through to commercialization. The inspiration for the device came as a thought-experiment of how a supplemental muscle-tendon could be anchored to the ankle and foot. After countless hours in the workshop and a series of iterations that failed, the idea became more clear - that the integration of an exo-skeleton together with an exo-tendon was designed to off-load force underfoot through harvesting force from the leg.

Related Publications / Posters

Roser MC, Canavan PK, Najafi B, Cooper Watchman M, Vaishnav K, Armstrong, DG, Novel In-Shoe Exoskeleton for Offloading of Forefoot Pressure for Individuals with Diabetic Foot Pathology, J Diabetes Science & Technology, 2017 (In Press).

David Armstrong, Bijan Najafi, Marcy Watchman, Kairavi Vaishnav, William Roser, Paul Canavan, Mark Roser, Evaluating Novel in-Shoe Exoskeleton for Offloading of Forefoot Pressure for individuals with Diabetic Foot Pathology Poster presentation at the 2017 Diabetic Foot Conference (April 2017)

Intellectual Property related to Offloading Footwear (Patents in Ophthalmic Diagnostics and others not shown):

US ® Trademark 2014	Trademark granted for exo-skeleton footwear	FlyBand®
US Patent 8438757 2013	Exo-skeleton integrated into footwear for low-cost distribution	
US Patent 9282783 2015	Exo-skeleton with adjustability integrated into footwear	
US Patent 9572395 2017	Exo-skeleton footwear integrated with body-worn powered and passive exo-skeletons	

Appointments:

- *Wearable Robotics Association - Secretary of the Opportunities Committee 2016 to present*

C2 - Conception, Engineering, Patenting and Full Development of Novel Ophthalmic Diagnostics

Having lost my vision in my left eye after progressive surgeries, I developed my own set of diagnostic tools for monitoring the progression of macular lesions at home. This evolved into a multi-year process to formalize and patent those diagnostics. Our team worked with Johns Hopkins to conduct SBIR Ph I and II testing and publish highly successful findings. Since then, the team has launched a new non-profit organization dedicated to raising money so that these tests can be given away for free to patients in need. Thus far, over 16,000 tests have been given away at no cost.


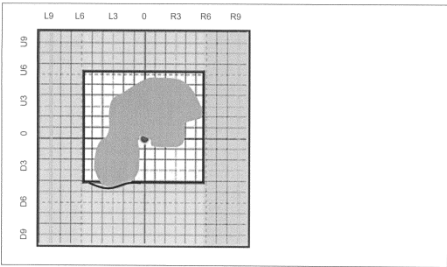
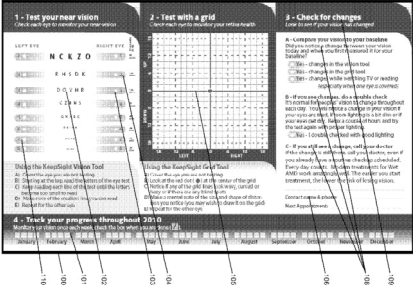
Bittner AK, Torr-Brown S, Arnold E, Nwankwo A, Beaton P, Rampat R, Dagnelie G, Roser M. *Improved Adherence to Vision Self-monitoring with the Vision and Memory Stimulating Journal for Age-Related Macular Degeneration during a Randomized Controlled Trial.* J Clin Exper Ophthalmol, (2014).

Selected Talks:

- *Tools to Improve Monitoring of AMD - Association of Research in Vision & Ophthalmology (ARVO) annual meetings 2013, 2012, 2010*
- *Overcoming presentation delay in Diabetic Retinopathy and Macular Degeneration - Foundation Fighting Blindness NY meeting 2012*
- *Advancements in Monitoring of Macular Degeneration - American Academy of Optometry 2011 annual meeting*
- *Trends in AMD Monitoring - Visions Conference for Low Vision 2011 annual meeting*

- *Tips and Tricks for Living with AMD - A talk routinely given to community groups, 6x / year (public libraries, senior centers, retirement communities) in southern New England (CT, MA, RI) 2010, 2011, 2012, 2013, 2014*

Salient Intellectual Property (Patents in Ophthalmic Diagnostics and others not shown):

US ® Trademark 2011	Trademark granted for diagnostic vision tests	
US Patent 7,798,645	Novel Testing Grid for Patients with Macular Degeneration	
US Patent 8,636,363	Home Vision Monitoring System for Macular and Retinal Disease	

C4 - Transformation of Customer Intimacy in Pharma R&D

Developed processes, Informed Consent documentation, IRB rationale, and data analysis techniques to enable direct interviewing of patients subsequent to their participation in a clinical trial. Provided this as a consulting service to a top tier Pharma R&D organization as lead of the project.

C5 - Member of team that led to the commercialization of first heavy duty commercial hybrid powertrain

As a consultant in new product development, I have helped in numerous engineering efforts in the fields of commercial vehicle powertrain design and the development of the first hybrid delivery trucks now in use by FedEx and UPS.

C6 - Member of team that led to the shift of product strategy at a major US Pharmacy

As a consultant in new product development, I have helped one of the top two US Pharmacies redesign their patient interface strategy, and foster new programs focused on long term adherence to treatment.

C7 - Member of team that launched new hospital information management system

As an employee of Pitney Bowes/Dictaphone, I was a product manager in charge of launching two new products that focused on integration of digital voice files with early hospital information management systems.

C8 - Commercialized and sold business

Started a successful interactive voice response service bureau and sold the business profitably.

D. Additional Information: Research Support and/or Scholastic Performance

- *Windham Memorial Hospital, Willimantic, CT - Advisory Board 2001-2007*