Oculogica

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Disclosures

- Intellectual Property related to concussion and brain injury assessment
- Intellectual Property related to assessment of dementia after brain injury
- Intellectual Property related to treatment of intracranial hemorrhage

Grant funding, salary/employment, consulting fee, honorarium or equity

Abbott Diagnostic Laboratories
Continuing Legal Education in MN, NY
Hennepin County Medical Center
Hennepin Health Foundation
Integra Corporation
Islamic Medical Association of North America
Medtronic Corp
Minnesota Brain Injury Alliance
Minnesota, Texas, Louisiana, Wisconsin, Wyoming High School Coaches Association
National Football League
National Neurotrauma Society
North American Brain Injury Society
Oculogica Inc
Steven and Alexandra Cohen Foundation for Veteran Post Traumatic Stress and Traumatic Brain Injury
United States Veterans Administration and Office of Research and Development
USA Football

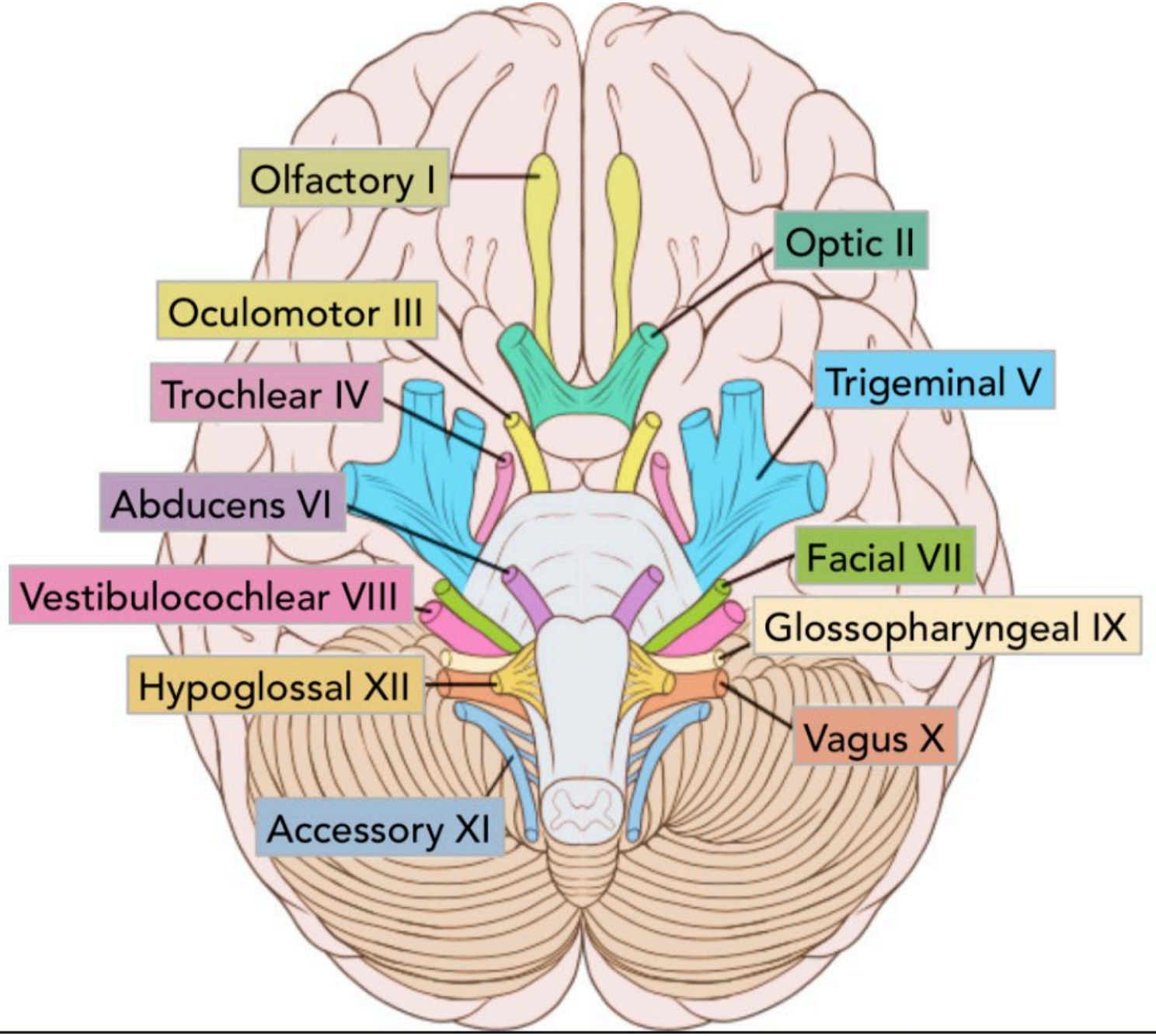
EyeBOX® Test

- 220 seconds
- Non-invasive
- Instant results
- No pre-injury baseline required

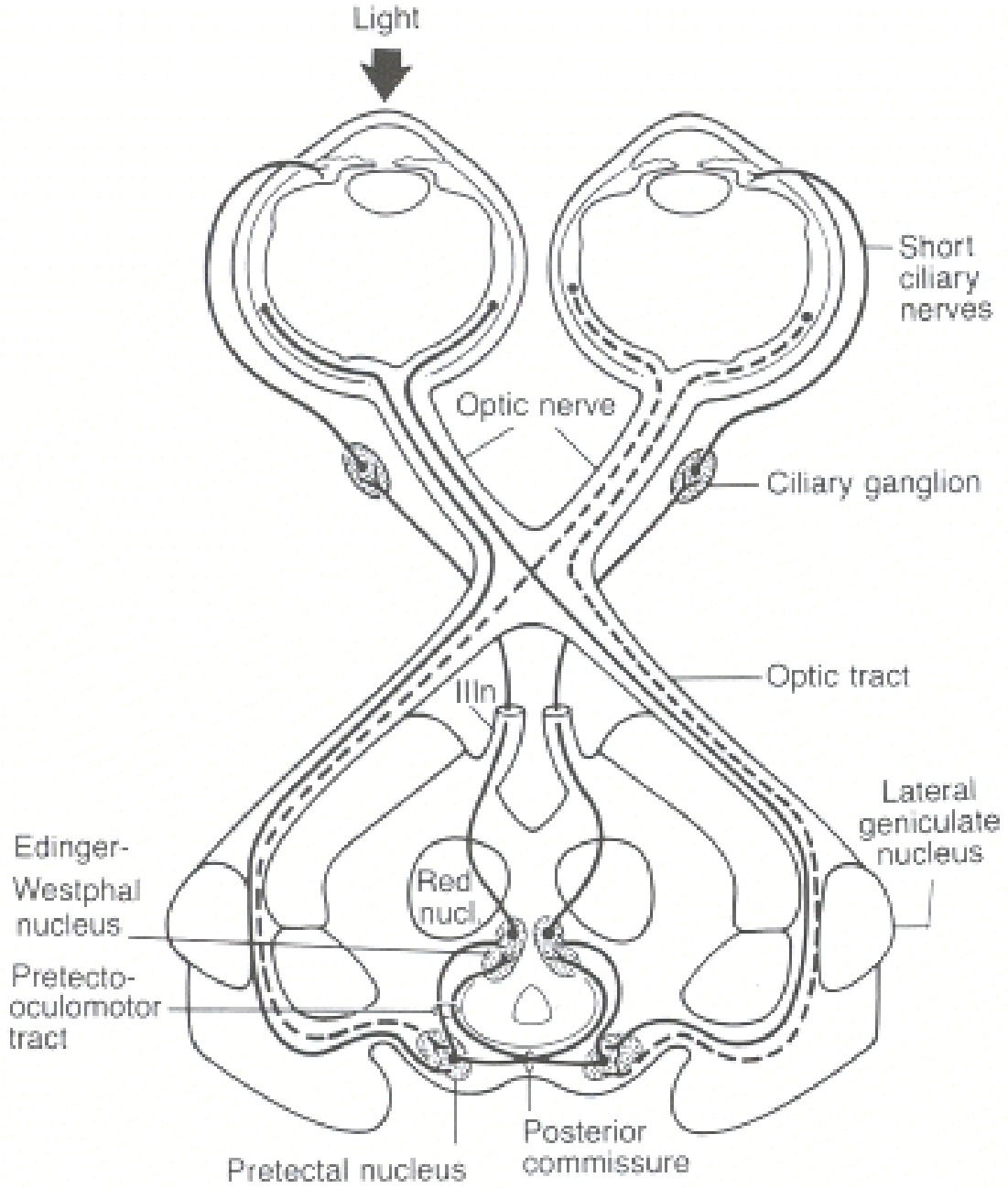
Rationale

Cranial nerve functions:

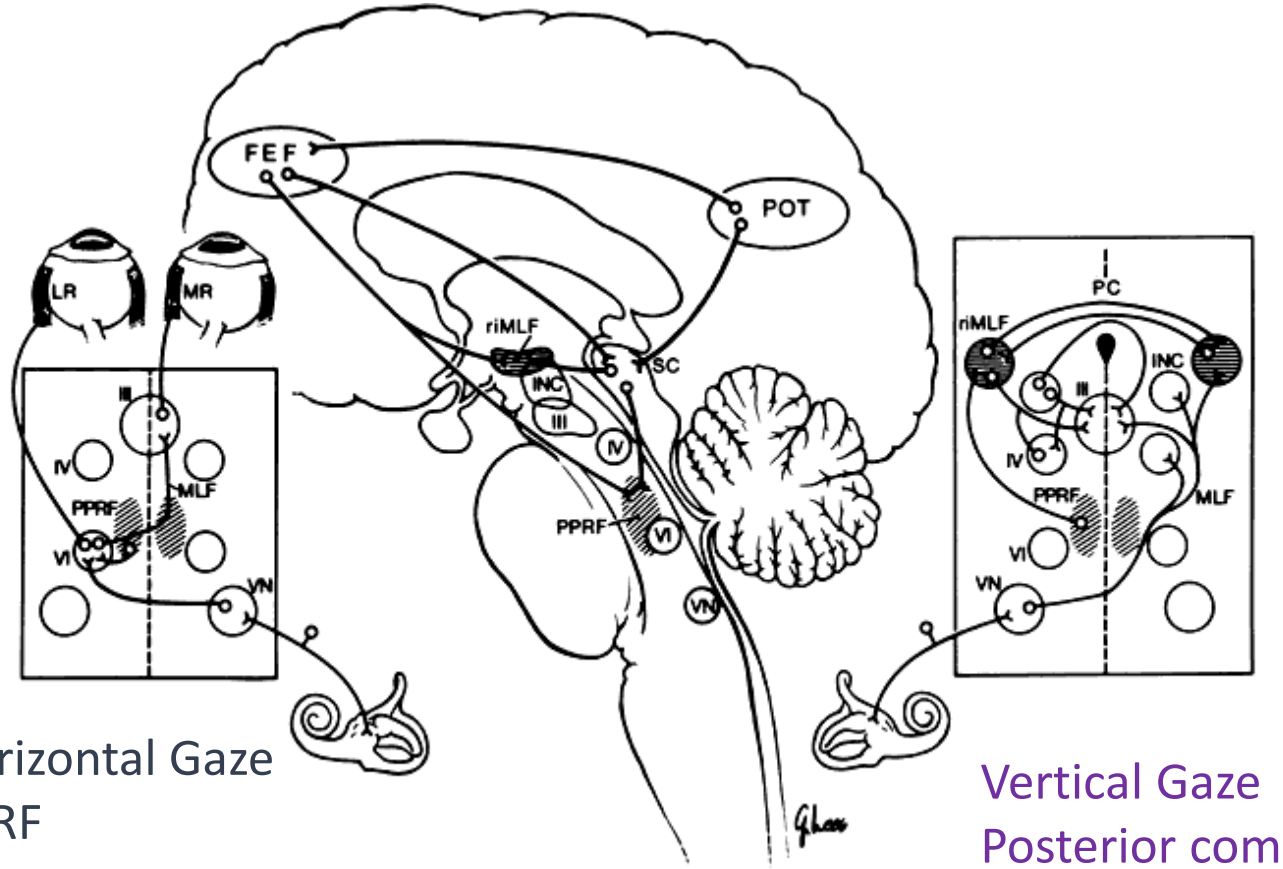
Easy to measure
Reflexive (not volitional)
Minimal heterogeneity
Sensitive to injury
- large catchment



https://teachmeanatomy.info/head/cranial-nerves/summary/



http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=cm&part=A1745



Horizontal Gaze
PPRF

Vertical Gaze
Posterior commisure
riMLF

Supranuclear control of eye movements
http://oculist.net/downaton502/prof/ebook/duanes/pages/v1/ch004/002f.html

JNS JOURNAL OF NEUROSURGERY
OFFICIAL JOURNALS OF THE AANS SINCE 1944

Detection of third and sixth cranial nerve palsies with a novel method for eye tracking while watching a short film clip

Uzma Samadani, MD, PhD, Sameer Farooq, Robert Ritlop, M Eng, Floyd Warren, MD, Marleen Reyes, BA, Elizabeth Lamm, BA, Anastasia Alex, BS, Elena Nehrbass, BS, Radek Kolecki, MS, Michael Jureller, BS, Julia Schneider, Agnes Chen, BA, Chen Shi, BS, Neil Mendhiratta, BA, Jason H. Huang, MD, Meng Qian, PhD, Roy Kwak, MD, Artem Mikheev, MS, Henry Rusinek, PhD, Ajax George, MD, Robert Fergus, PhD, Douglas Kondziolka, MD, Paul P. Huang, MD, R. Theodore Smith, MD, PhD

December 12, 2014

Concussion

Sensitivity and specificity of an eye movement tracking based biomarker for concussion

Uzma Samadani, MD, PhD, Meng Li, MS, Meng Qian, PhD, Eugene Laska, PhD, Robert Ritlop, M Eng, Radek Kolecki, MS, Marleen Reyes, BA, Lindsey Altomare, Je Yeong Sone, Aylin Adem, BS, Paul P. Huang, MD, Douglas Kondziolka, MD, Stephen Wall, MD, Spiros Frangos, MD, Charles Marmar, MD

August 6, 2015

Journal of Neurotrauma

Eye Tracking Detects Disconjugate Eye Movements Associated with Structural Traumatic Brain Injury and Concussion

Uzma Samadani, MD, PhD, Robert Ritlop, M Eng, Marleen Reyes, BA, Elena Nehrbass, BS, Meng Li, MS, Elizabeth Lamm, BA, Julia Schneider, David Shimunov, Maria Sava, Radek Kolecki, MS, Paige Burris, Lindsey Altomare, Talha Mehmood, MD Theodore Smith, MD, PhD, Jason H. Huang, MD, Christopher McStay, MD, S. Rob Todd, MD, Meng Qian, PhD, Douglas Kondziolka, MD, Stephen Wall, MD, Paul P. Huang, MD

April 15, 2015

Reliability of Objective Eye-Tracking Measures Among Healthy Adolescent Athletes

David R. Howell, PhD, Anna N. Brilliant, BS, Christina L. Master, MD, William P. III Meehan, MD

June 21, 2018

Elevated intracranial pressure and reversible eye-tracking changes detected while viewing a film clip

Radek Kolecki, MS, Vikalpa Dammavalam, BS, Abdullah Bin Zahid, MD, Molly Hubbard, MD, Osamah Choudhry, MD, Marleen Reyes, BA, ByoungJun Han, BS, Tom Wang, BA, Paraskevi Vivian Papas, BS, Aylin Adem, BS, Emily North, BSE, David T. Gilbertson, PhD, Douglas Kondziolka, MD, Jason H. Huang, MD, Paul P. Huang, MD, Uzma Samadani, MD, PhD

March 2018

Will eye tracking change the way we diagnose and classify concussion and structural brain injury?

Uzma Samadani, MD, PhD

August 15, 2015

A new tool for monitoring brain function: eye tracking goes beyond assessing attention to measuring central nervous system physiology

Uzma Samadani, MD, PhD

August 2015

De novo FDA clearance

Intended use population
- ages 5 to 67

Compared to SSS and SAC of SCAT3

Eye tracking for classification of concussion in adults and pediatrics

Uzma Samadani[1]*, Robert J. Spinner[2], Gerard Dynkowski[3], Susan Kirelik[4,5], Tory Schaaf[1], Stephen P. Wall[6] and Paul Huang[7]

[1]Minneapolis Veterans Administration Health Care System, Minneapolis, MN, United States, [2]Mayo Clinic, Rochester, MN, United States, [3]Beaver Dam Community Hospital, Beaver Dam, WI, United States, [4]Rocky Mountain Pediatric OrthoONE Center for Concussion, Denver, CO, United States, [5]Rocky Mountain Hospital for Children, Denver, CO, United States, [6]Ronald O. Perelman Department of Emergency Medicine and Department of Population Health, NYU Grossman School of Medicine, New York City, NY, United States, [7]Bellevue Hospital and New York University Department of Neurosurgery, New York City, NY, United States

Introduction: In order to obtain FDA Marketing Authorization for aid in the diagnosis of concussion, an eye tracking study in an intended use population was conducted.

Methods: Potentially concussed subjects recruited in emergency department and concussion clinic settings prospectively underwent eye tracking and a subset of the Sport Concussion Assessment Tool 3 at 6 sites. The results of an eye tracking-based classifier model were then validated against a pre-specified algorithm with a cutoff for concussed vs. non-concussed. The sensitivity and specificity of eye tracking were calculated after plotting of the receiver operating characteristic curve and calculation of the AUC (area under curve).

Results: When concussion is defined by SCAT3 subsets, the sensitivity and specificity of an eye tracking algorithm was 80.4 and 66.1%, The AUC was 0.718. The misclassification rate ($n = 282$) was 31.6%.

Conclusion: A pre-specified algorithm and cutoff for diagnosis of concussion vs. non-concussion has a sensitivity and specificity that is useful as a baseline-free aid in diagnosis of concussion. Eye tracking has potential to serve as an objective "gold-standard" for detection of neurophysiologic disruption due to brain injury.

U.S. FOOD & DRUG ADMINISTRATION

Oculogica, Inc.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

December 28, 2018

Re: DEN170091
Trade/Device Name: EyeBOX
Regulation Number: 21 CFR 882.1455
Regulation Name: Traumatic brain injury eye movement assessment aid
Regulatory Class: Class II
Product Code: QEA
Dated: December 22, 2017
Received: December 22, 2017

Dear Janice Hogan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the EyeBOX, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion within one week of head injury in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion.

Mechanisms for Assessing the Central Nervous System

Physical and psych examination – physiology	fxl heterogeneity, skilled examiner, time, bias
Plain films (xray) – what it looks like	radiation, not much information
EEG – electrical activity	technician, interpreter, time,
Angiography – what it looks like	radiation, not full information, $
EMG/NCS/SSEPS – assesses integrity	painful, technician, time,
CT scan – what it looks like	radiation, technician, time, $
TCDs, orbital, transcutaneous flow – blood flow.	technician, arbitrary #
MRI scan - what it looks like, some fx	time, technician, claustrophobia/instability, $$
ICP /licox monitoring – pressure, brain O_2	risk of devastating hemorrhage, arbitrary #, $$
Uncalibrated eye movement tracking	patient needs to be able to open eyes

- **fully automatable, objective, agnostic to language/culture/education, non-risky, non-radiation exposing, non-invasive, potentially remote**
- **The only method (other than examination) that is physiologic.**

10.31.19

New Category 3 CPT Code for Eye-Tracking Test for Concussion Diagnosis

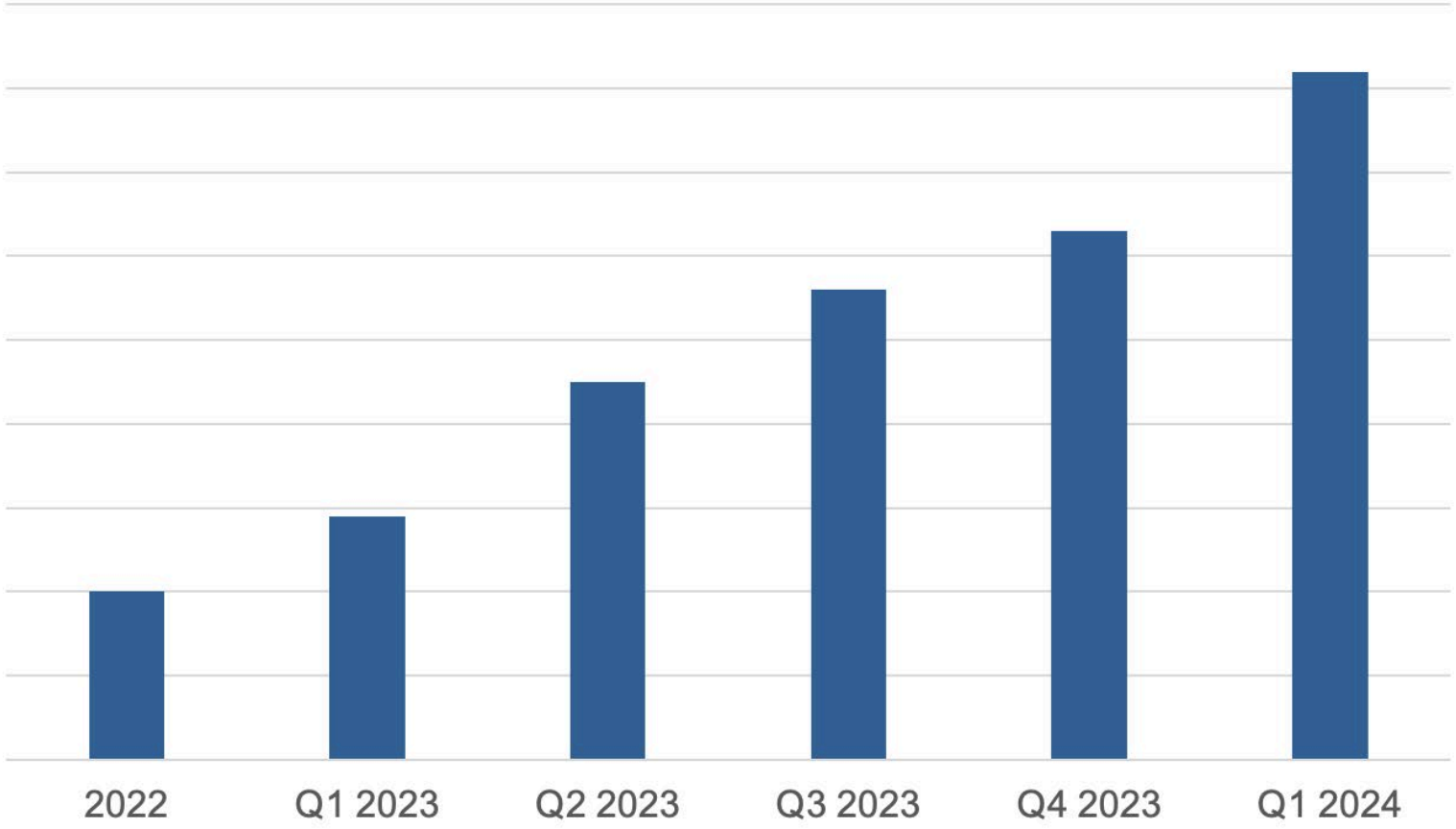
TBI

KEYWORDS: Brain Concussion • Brain Injury

The American Medical Association (AMA) has confirmed the addition of a new code for an eye-tracking diagnostic procedure for concussion (Eyebox; Oculogica, New York, New York).The category 3 CPT Code, 0X17T, eye movement analysis test without spatial calibration,allows clinicians to appropriately report the services related exclusively to the eye exam.

Oculogica is experiencing growing market success

Total EyeBOX Units Installed



The single greatest barrier to wider incorporation?

Reimbursement!

Insurance companies want to see diagnostics change management before they reimburse

But we don’t have therapeutics because we don’t accurately classify with diagnostics
(trials fail due to heterogeneity)

Would you run a clinical trial for “chest pain” with history and exam as your classifier? And an 8 pt outcome measure?

Causes of chest pain

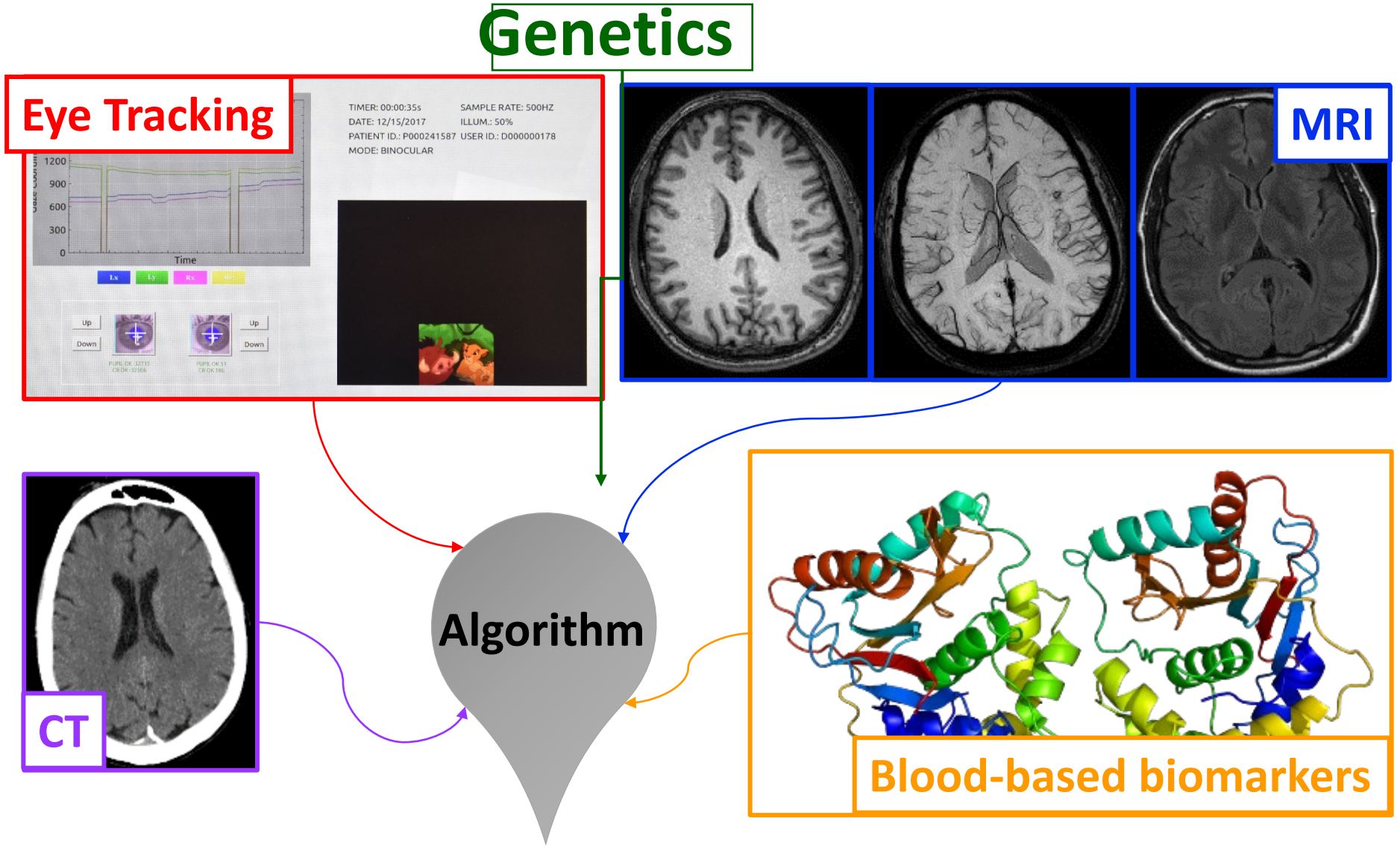
- Cardiovascular
  - A.C.S.
  - Pericarditis
  - Aortic dissection
  - Aortic stenosis
- Pulmonary
  - Pulmonary embolism
  - Pleurisy
  - Pneumothorax
  - Pneumonia
- Pediatrics
  - Kawasaki disease
  - Hypertrophic cardiomyopathy
  - Congenital heart disease
- Gastrointestinal
  - Esophageal reflux
  - Esophageal spasm
  - Esophageal rupture
  - Peptic ulcer disease
  - Gallbladder disease
  - Pancreatitis
- Chest Wall Pain
  - Herpes Zoster
  - Costochondritis
  - Cervical radiculopathy
  - Rib fracture
  - Anxiety

Hugh Helmsley, MD

treat

1 Death
2 Vegetative state
3 Lower severe disability
4 Upper severe disability
5 Lower moderate disability
6 Upper moderate disability
7 Lower good recovery
8 Upper good recovery

Better Classification of Brain Injury will be Hierarchical and Multimodal!



Molecule: https://commons.wikimedia.org/wiki/File:Protein_UCHL1_PDB_2etl.png

How do we get insurance companies to reimburse brain injury diagnostics?

Write to your societies! Call and email their AMA-CPT representatives!

Ask them to support Category 1 Codes for reimbursement at AMA CPT meeting

American Academy of Neurology
American Academy of Ophthalmology

American Academy of Pediatrics
Physical Medicine and Rehab
American College of Emergency Physicians
American Association of Neurological Surgeons
Congress of Neurological Surgeons
Radiology Society of North America

Without reimbursement for diagnostics:

No improved therapeutics

No early intervention for patients at risk for poor outcomes

No investment in the diagnostic space!

Collective lobbying of AMA is the best solution