Treatment of Stroke in the Ambulance with an Artificial Intelligence Diagnostic: **The Faucet**

Mark Borsody, M.D., Ph.D.
Chief Executive Officer

mark@faucet.works

The Faucetworks Team

Mark Borsody, M.D., Ph.D. - Chief Executive Officer

- Fellowship-trained vascular neurologist and neurophysiologist
- 13-years' executive medical and regulatory experience with pharmaceutical and medical device projects
- Inventor of the VitalFlow stimulator, a medical device in development for the emergency treatment of neurological emergencies
- Raised $8.1 M in largely non-dilutive funding to advance the VitalFlow into clinical testing

Renata Barreto - Vice President of Regulatory Affairs

- Jurisprudence and Social Policy Ph.D. candidate at the University of California – Berkeley School of Law
- Graduate focus is on regulatory and legal issues surrounding the use of artificial intelligence
- Eugene-Cota Robles Fellowship awardee and Fellow of the American Political Science Association

Grace Montenegro - Vice President of Engineering

- 13 years managing information technology and computer services for major European and Latin American corporations
- Completing Masters program in computer and electrical engineering at Sonoma State University (May 2019)
- Focus on hardware-software interface

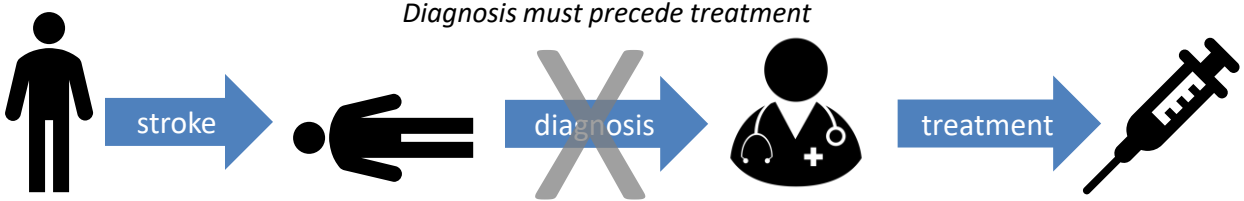
- 3 computer programmers based in the east San Francisco Bay area
- 4 engineering advisors with expertise in artificial intelligence uses in neurological emergency diagnosis
- 4 medical advisors including paramedics, neurologists, and emergency medicine physicians
- 2 regulatory advisors experienced in emergency medicine space

The Problem: Stroke

- 16 M victims yearly, 5 M fatal
- #1 cause of disability, #2 cause of death
- Ischemic stroke: blockage of a brain artery by a blood clot
- Emergency treatments for acute ischemic stroke (AIS) include ‘clot-busting’ intravenous tissue plasminogen activator (rtPA)
- But few stroke patients receive emergency treatment because they cannot be diagnosed quickly enough

Blockage of a brain artery causes ischemic stroke

Diagnosis must precede treatment



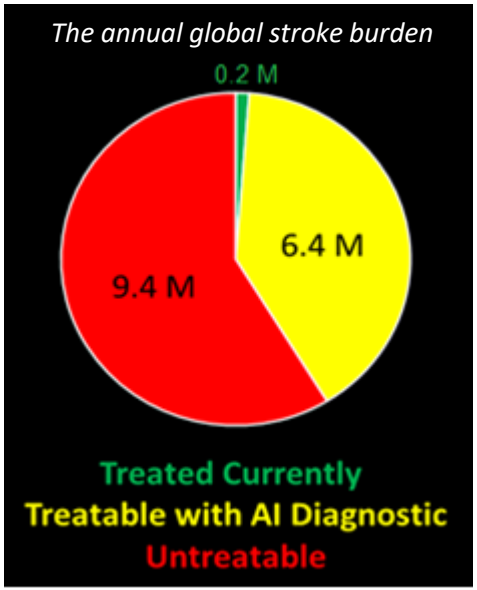
The Solution: The Faucet

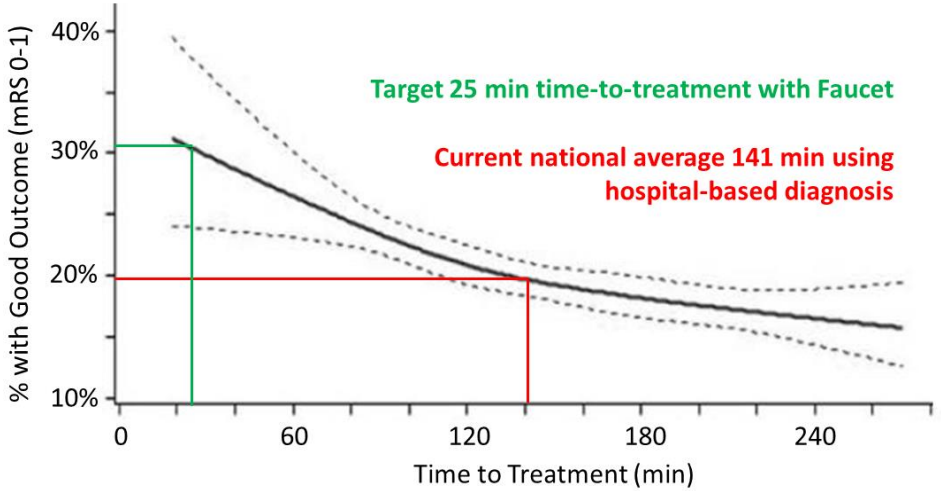
(it turns blood flow to the brain back on for stroke patients)

- A cloud-based artificial intelligence diagnostic (AID) with natural language and visual recognition capabilities
- Makes routine stroke diagnoses, determines rtPA treatment, and routes the patient to an appropriate hospital for further treatment
- Useful in any ambulance and underserved hospital emergency departments
- Increase use of rtPA from 5% to 40% of AIS patients
- Benefit: save 2.4 M quality-adjusted life years and $155 B healthcare costs & lost productive annually

The Value Proposition

- Quicker stroke treatment = better patient outcomes
- More stroke patients treatable (4-fold increase in U.S.)





- Increased ambulance service reimbursement due to higher level of care and longer transports
- Hospitals receive healthier and appropriate patients = shorter hospitalizations and less resource utilization

Is It Possible?

- Proof-of-Concept: rtPA use in "Mobile Stroke Units"

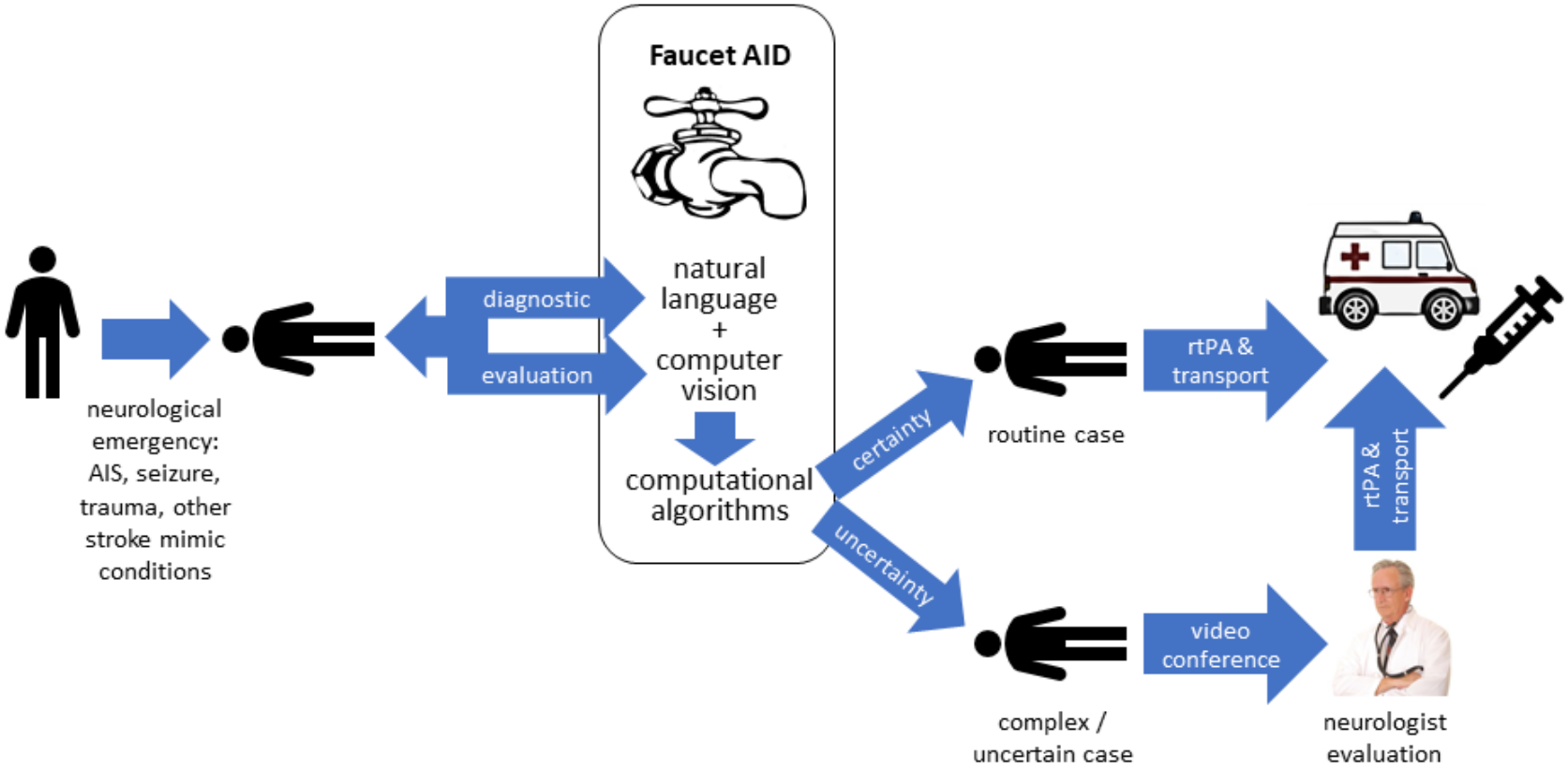
Faucet will replace on-board neurologists, making every ambulance a Mobile Stroke Unit

- Mobile Stroke Units shorten the time-to-treatment of stroke
- Mobile Stroke Units are cost effective

but

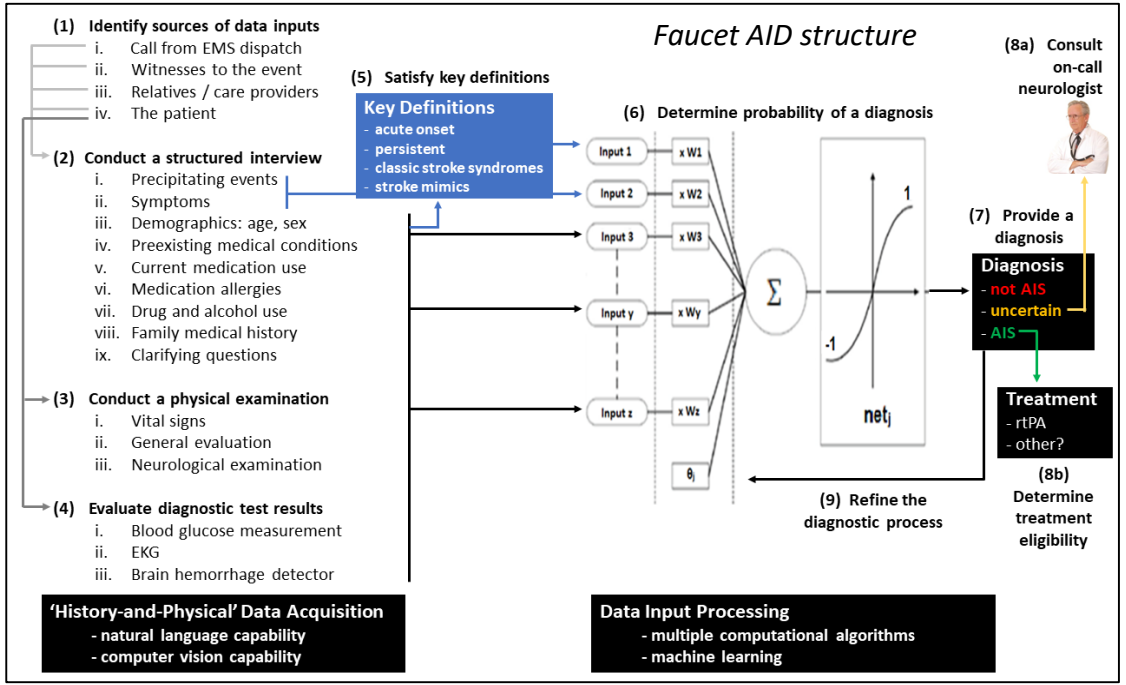
- Mobile Stroke Units are not a scalable solution
  - 81 k ambulances in the U.S.
  - 2 k stroke neurologists in the U.S.

How The Faucet Works



Faucet Prototype & IP

- Current diagnostic accuracy of 91%, comparable to a neurologist's accuracy
- Requires only 16 data inputs, all of which can be obtained from direct communication and evaluation of the patient in the ambulance
- Copyrights on code
- Patent protection for several design features
- Strategic partnerships with hardware manufacturers in development

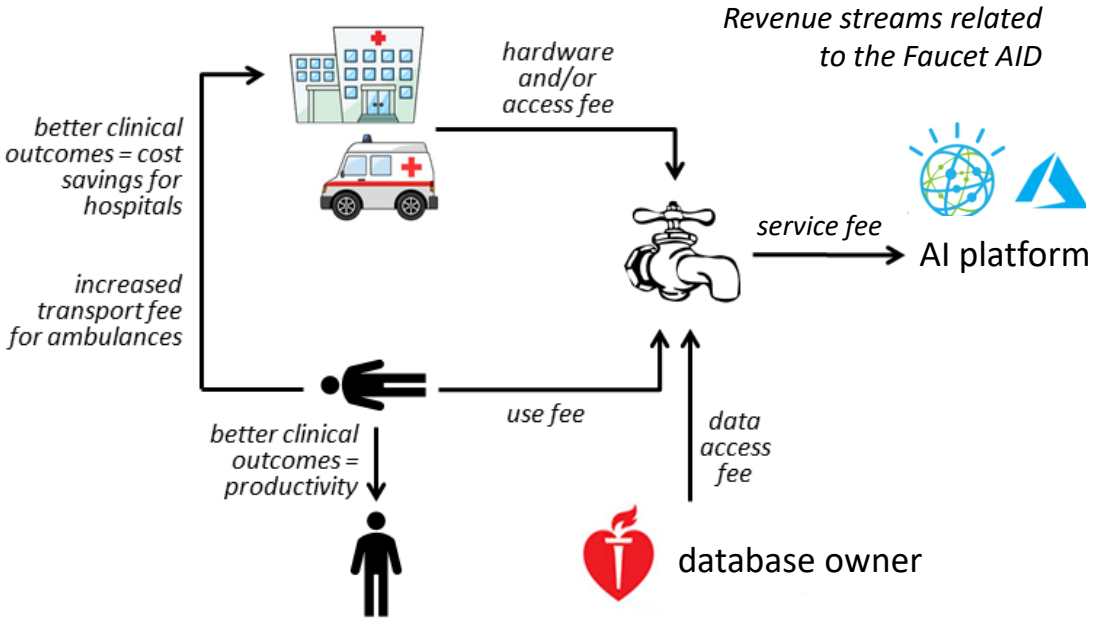


Regulatory Strategy

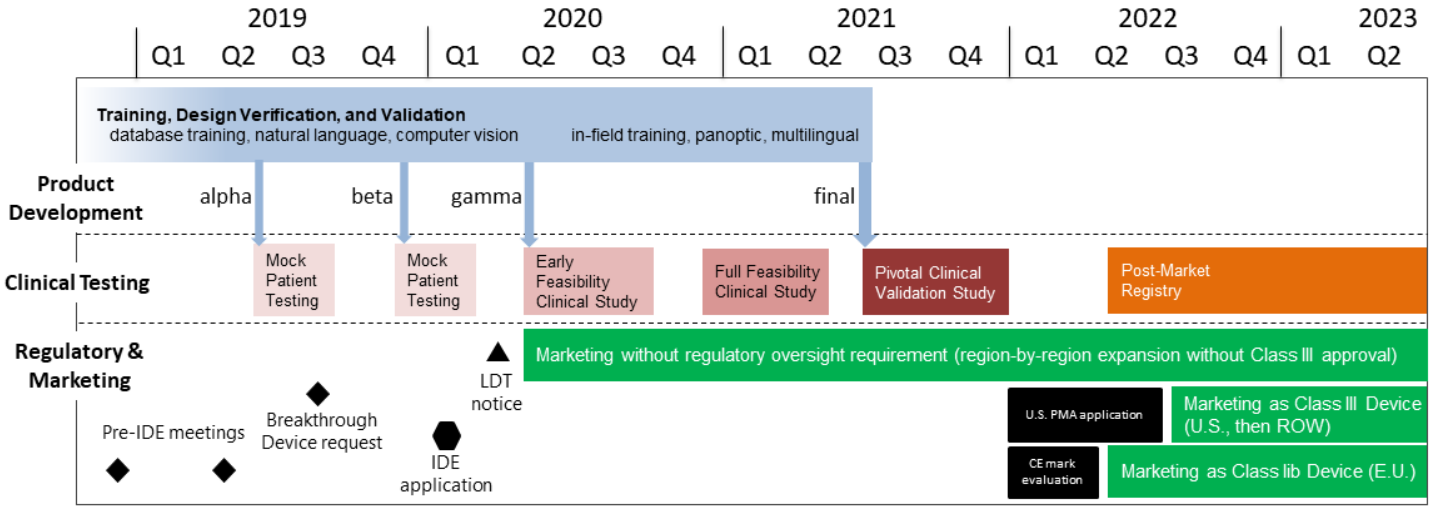
- Market entry after declaring Laboratory-Developed Test status in 2020
- Once established, pursue PMA approval under Breakthrough Device status
  - Regulatory benefits: approval based on biomarkers of clinical effectiveness (i.e., providing an accurate diagnosis versus a neurologist)
  - Reimbursement benefits: comparative effectiveness versus physicians supports reimbursement claims
  - Market benefits: protection against competition; limited liability for adverse outcomes related to device use; convincing clinical effectiveness data
- PMA approval and emergency medicine professional society guidelines *force* market adoption in U.S. and E.U.
  - End result: routine placement of Faucet in all ambulances by ambulance manufacturers, and mandated retrofitting of existing ambulances

Reimbursement, Revenue, and Market

- Faucet reimbursement on-par with physician consult ($153 per patient) from CMS
- Revenue: per consult fee > service subscription, hardware sales, data access
- 9.8 M potential consults in the U.S. each year
- Global TAM: $11.5 B
- Break-even by 2023
- Market entry driven by government mandate, not user or purchaser preference
- Initial market survey: > 90% of emergency medicine physicians and paramedics would find Faucet useful



Timeline, Investment, and Milestones



$4.3 M Series A	$4.6 M Series B	$16.0 M Series C
- alpha → gamma prototypes - performance testing - patent filings	- in-field training - clinical studies - first market entry - market-ready device	- pivotal study comparison against neurologist - regulatory applications - U.S. & E.U. market launches - post-market registry

Exit into local marketing
$8.9 M total program cost

Exit into global marketing
$24.9 M total program cost

Next Steps

- Rolling-close Series A raise, beginning with $500 k in convertible notes
- Retain team as full-time employees
- On-board Chief Regulatory and Technology Officers
- Complete and test alpha prototype Faucet
- Establish regulatory pathway and Breakthrough Device status with FDA


Faucet works