



2021

# AUDACITY

AUDIOLOGY UNLEASHED

OCTOBER 25-27 PORTLAND, OREGON

# Audiology Unleashed

*Kevin Franck PhD MBA*

*Monday October 25, 2021 4:45-5:45 PM*



# Disclosures of Conflict of Interest

## Frequency Therapeutics

- SVP, Strategic Planning and New Product Planning
- Receive salary and stock as compensation

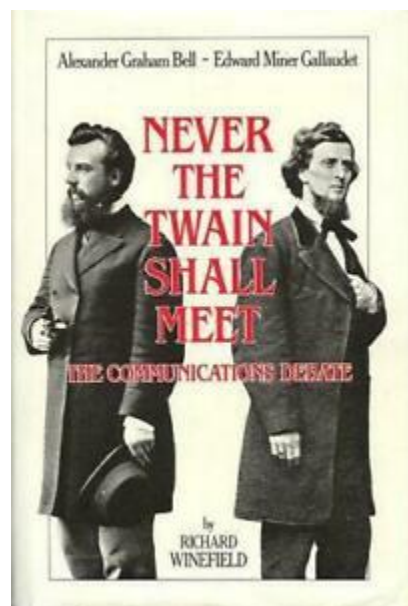


## Hearing Loss Association of America

- Board Chair

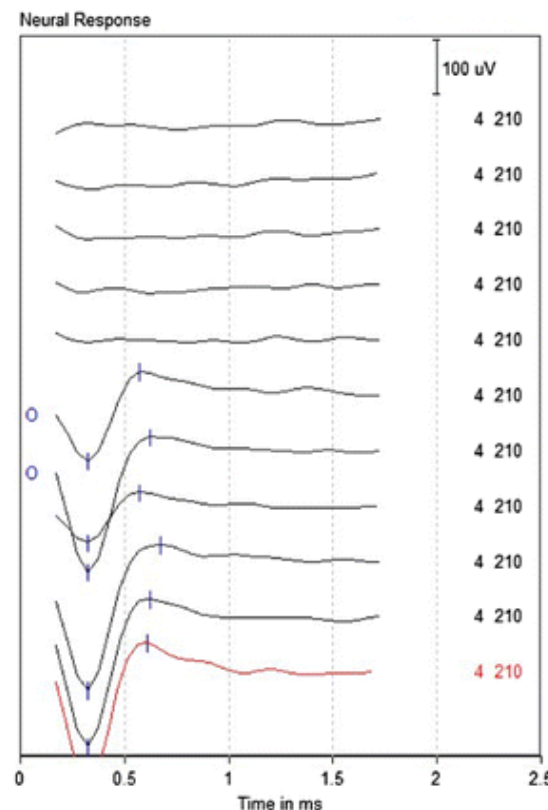
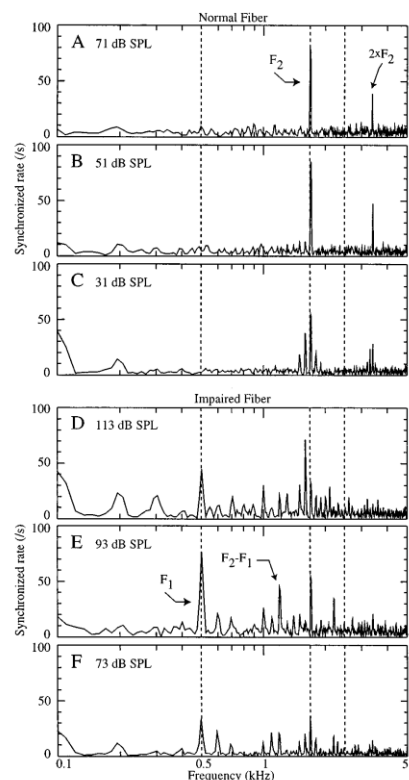


# Why Audiology – 1980s





# Biomedical Engineering of Hearing – 1990s





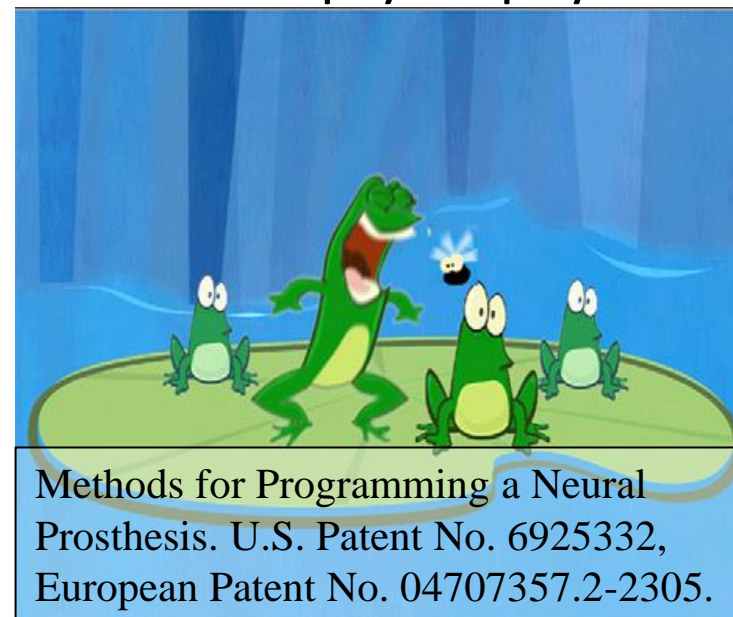
# Cochlear Implant Academic/Clinician – 2000s

- Clinic

- Small fraction of those who need help benefit from it
- Business model is limited by channel, nature of intervention
- Overcomplicated programming

- Research

- Non-behavioral methods
- Trick kids into psychophysics

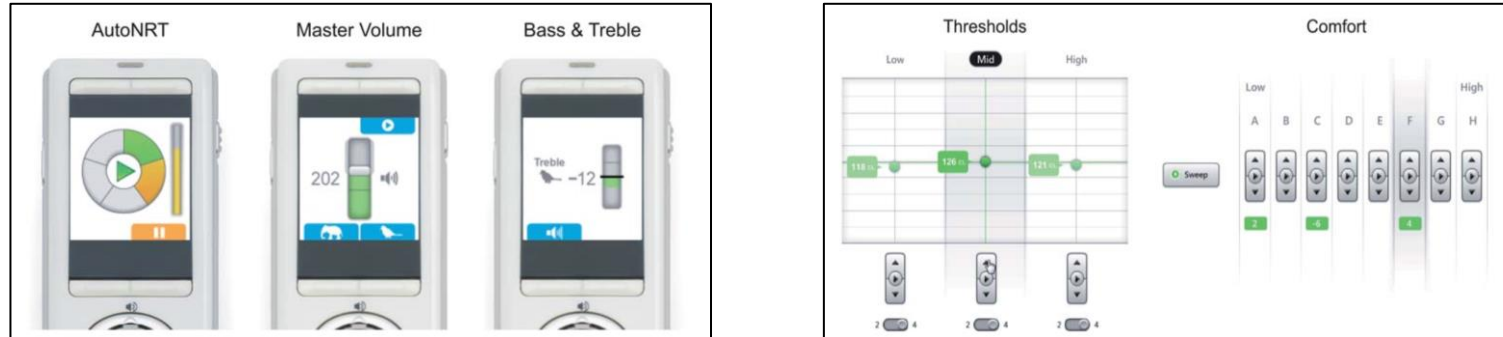


# MBA – 2000s (con't)

- Know who your customer is
- Delight your customers and the business model will follow
- Incentivize those who bring business to you
- Built a business plan to rearrange cochlear implant clinical care, engaging non-hospital audiologists

# Cochlear Ltd, Sydney Australia – Late 2000s

- Focused on “scalability suite” empowering non-hospital stakeholders to do more
  - Audiologist-enabled self-programming and enhanced troubleshooting, hearing-aid clinician integration



- 2020 launched as new Custom Sound features and Remote Check



# External Perspective – 2010s

## Profession

-  **ARTISAN**  
Healthcare Consulting
-  **BiOM**  
Personal Bionics

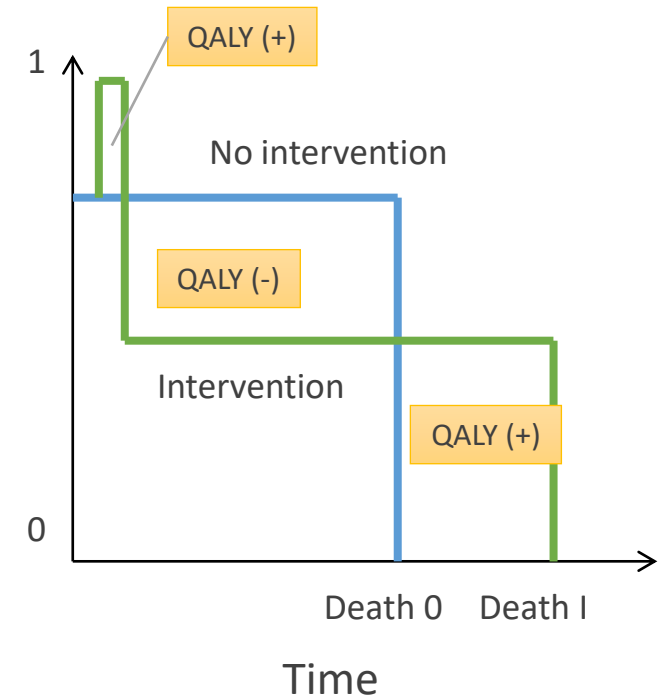
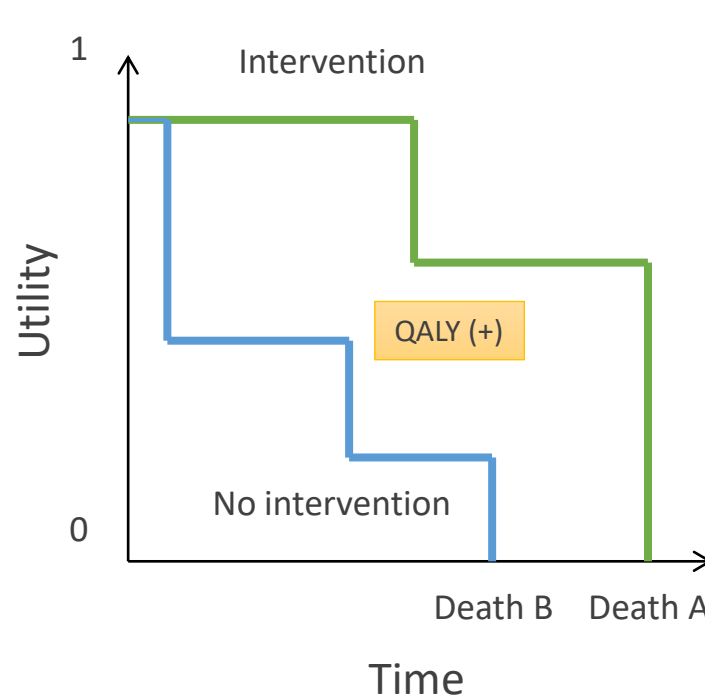
## Non-Profit Board Member

-  **Clarke Schools**  
for Hearing and Speech
-  *Alexander Graham Bell*  
ALEXANDER GRAHAM BELL  
ASSOCIATION FOR THE DEAF AND HARD OF HEARING
-  **HLAA**

# Disease Burden Measures

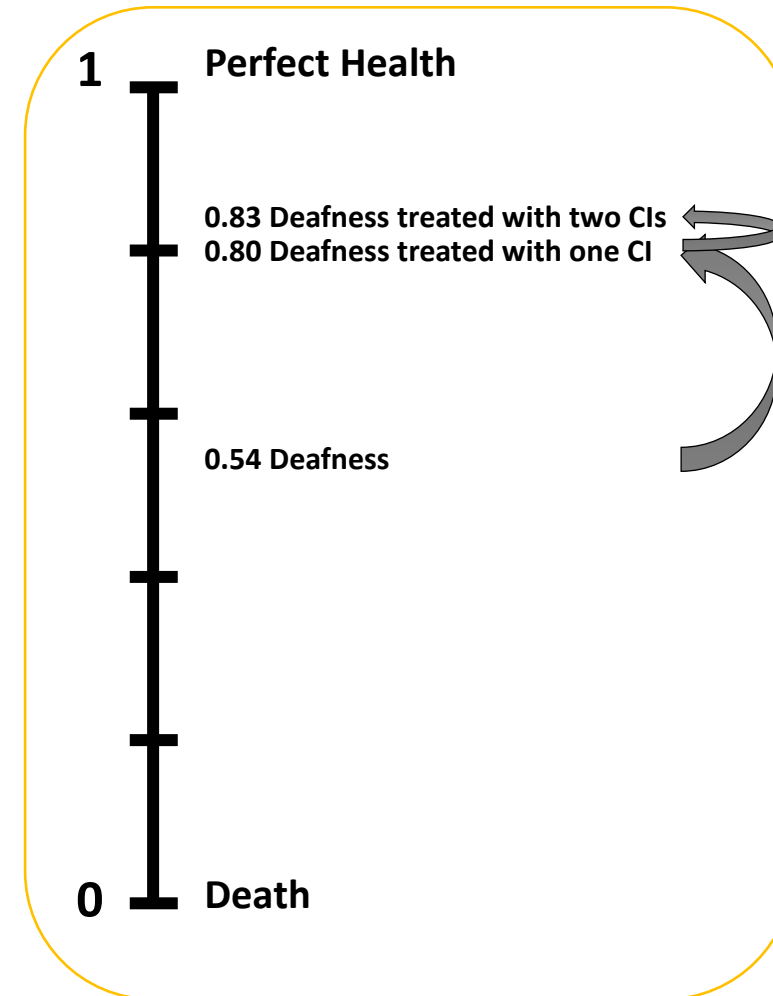
## Enable Comparison

- Health-related quality of life (HRQoL) goes beyond efficacy
- Patient-reported outcomes (PRO) measure health utility
- Quality Adjusted Life Year (QALY) integrates time



# CI is Cost Effective

- Costs
  - Device \$35,000
  - Surgery (discounted when simultaneously implanted) \$50,000 (\$30,000)
  - Ongoing maintenance \$10,000
- Other economic factors
  - No alternatives for profound deafness
  - Reduced special education expenses
  - Increased wages / tax revenues
  - No consideration for other comorbidities
- Cost efficacy
  - Pediatric unilateral \$11k / QALY
  - Pediatric bilateral \$35k / QALY
  - Adult unilateral \$22k / QALY
  - Adult bilateral \$80k / QALY

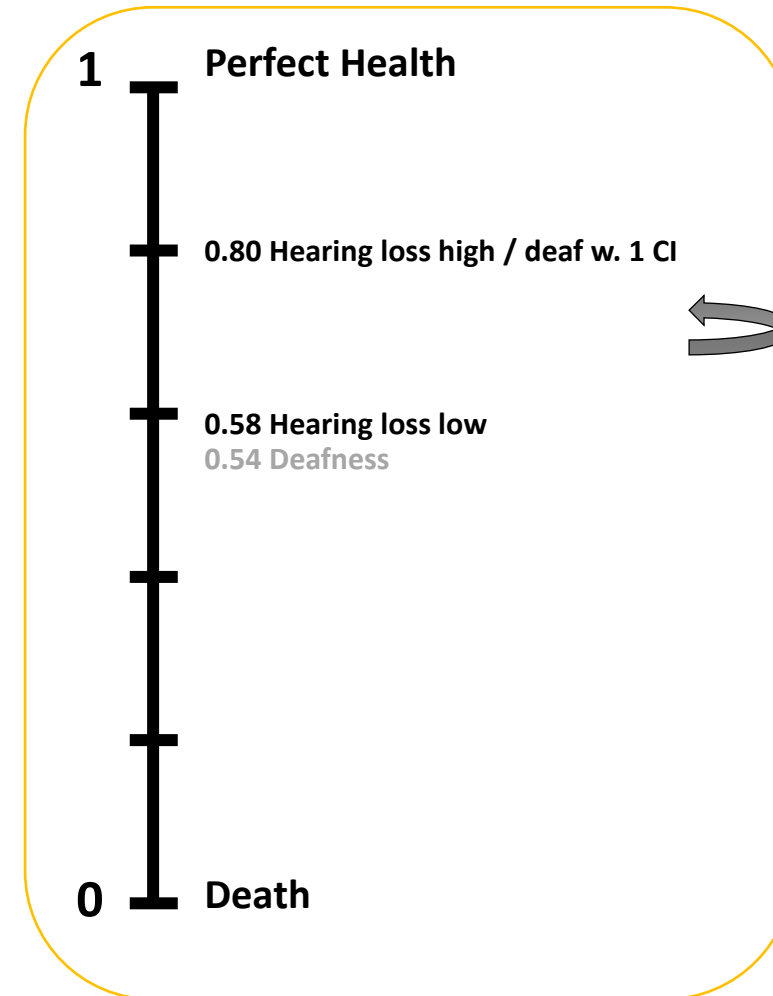


Sources:

- Cheng and Niparko, *Arch Otolaryngol Head Neck Surgery*, November 1999.
- Chen et al, *Laryngoscope*, 2014
- O'Neill et al, *Laryngoscope*, 2000

# Hearing Aid

- Hearing aid HU =  $\sim 0.05$ 
  - VSB = 0.09-0.15<sup>1</sup>
  - HA = 0.01-0.06<sup>2</sup>
  - Baha = 0.07<sup>3</sup>
- Cost = \$5,200
  - \$4,800 / pair
  - \$400 repair beyond warranty
  - Cost savings
    - Reduction of comorbidities?
    - Wage / independence?
- Time = 6 years
- Cost efficacy = **\$17k / QALY**

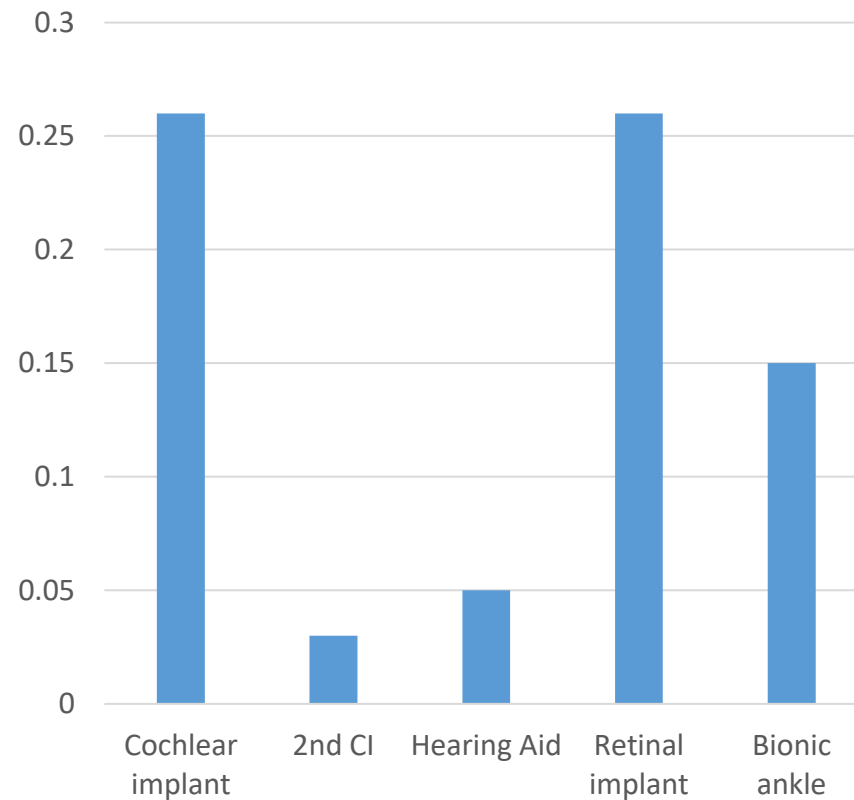


Sources:

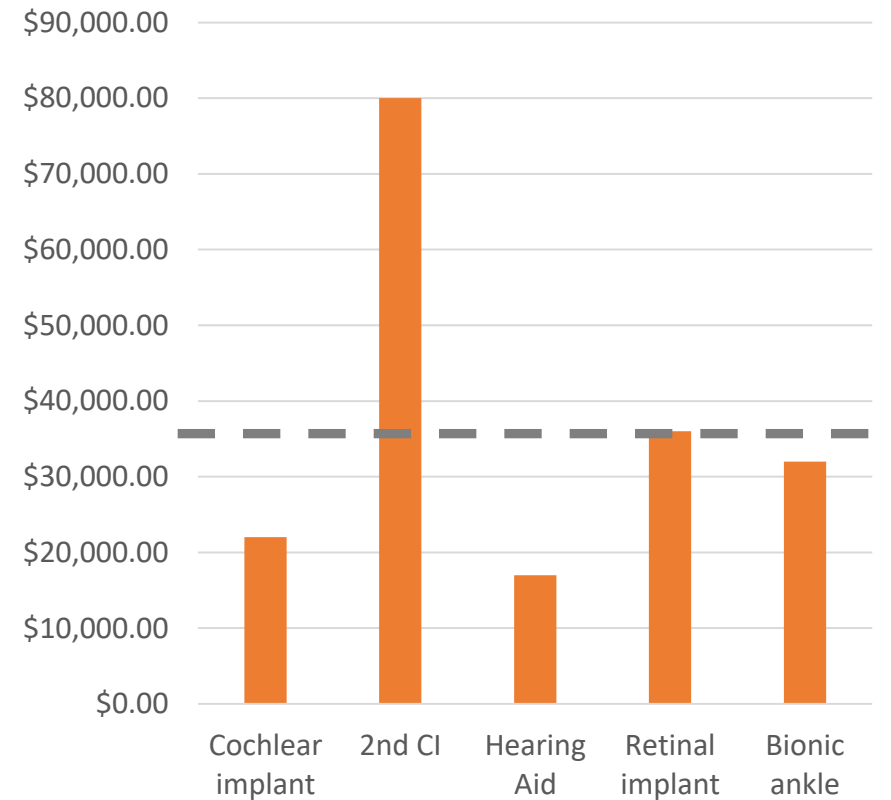
1. Edfeldt et al, *Acta Otolaryngol.* 2014 Jan;134(1):19-25
2. Barton et al, *Appl Health Econ Health Policy.* 2004;3(2):103-5
3. Monksfield et al, *Otol Neurotol.* 2011 Oct;32(8):1192-7

# Comparing Prosthetics

## Utility



## Cost / QALY



### Cochlear Implant

- Cheng and Niparko, *Arch Otolaryngol Head Neck Surgery*, November 1999.
- Chen et al, *Laryngoscope*, 2014
- O'Neill et al, *Laryngoscope*, 2000

### Hearing Aid

- Edfeldt et al, *Acta Otolaryngol.* 2014 Jan;134(1):19-25
- Barton et al, *Appl Health Econ Health Policy.* 2004;3(2):103-5
- Monksfield et al, *Otol Neurotol.* 2011 Oct;32(8):1192-7

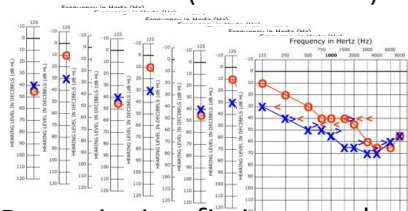
### Retinal Implant

- Vaidya et al, *BMC Ophthalmol* 2014

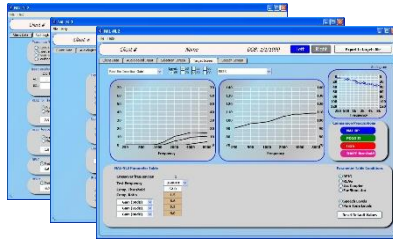


# Can Self-Fitting Reduce Hearing Aid Cost?

Large databases of hearing losses  
(>30k users)



Prescriptive fitting methods(>50 yrs research)



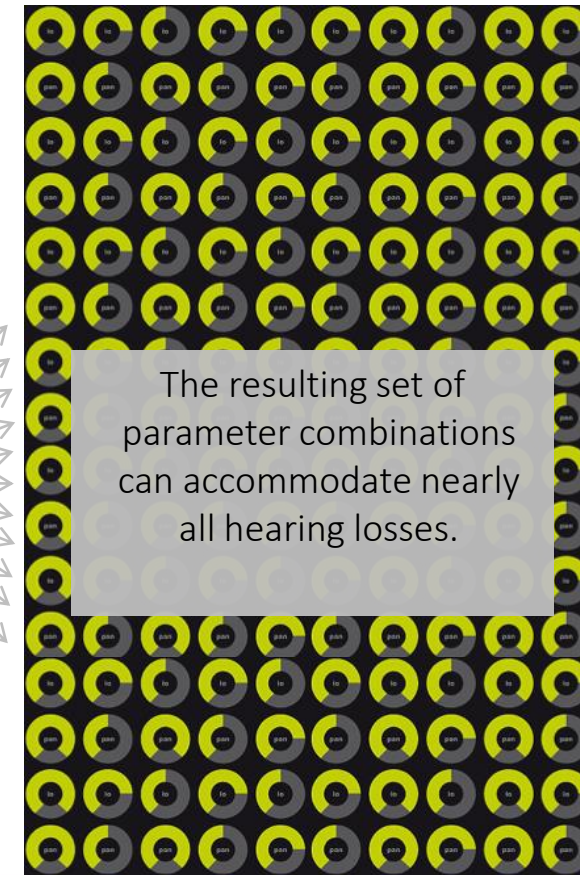
Peer-reviewed pubs



Intuitive UI



Control 100s of signal processing parameters



The resulting set of parameter combinations can accommodate nearly all hearing losses.

# Ear Machine Approached Bose to Enter Hearing Aid Market - Acquired in 2014

## 2016: Market Test with PSAP Hearphones

- Active noise cancellation for occlusion mitigation
- 4-mic beamforming
- Wide bandwidth
- Full headphone functionality
- Ear Machine fitting
- \$499

## 2018: Regulatory Approval for Self-Fit Hearing Aid

- Based on Hearphone UX
- *de novo*
- Not OTC (recently announced)

## 2020: Study and Publish Outcomes

- Gain within 1.8 dB
- Better sound quality
- No differences in standard clinical measures of hearing aid benefit or speech perception in noise

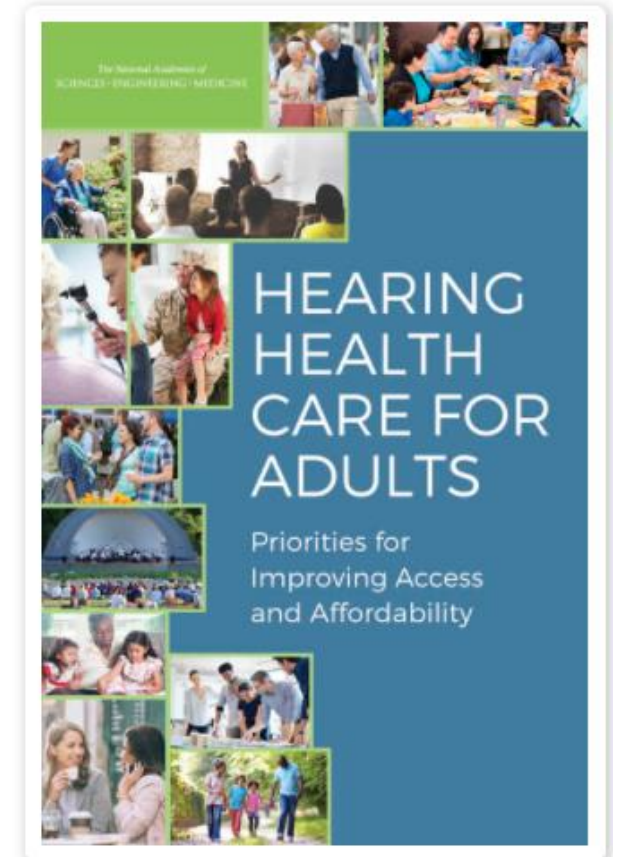
## Late 2021 Launch Self-Fit Hearing Aid

- 2-mic beamforming
- Ear Machine fitting
- \$850



# NASEM (2016) – Audiology Unleashed

- HEARING HEALTH CARE SERVICES: IMPROVING ACCESS AND QUALITY
  - 2. Align and promote best practices and core competencies; implement mechanisms to ensure adherence; and research, develop, and implement quality metrics to evaluate hearing health care services
  - 4. Ensure accessibility throughout rural and underserved areas, increase diversity and cultural competency in the hearing health care workforce
  - 6. Promote hearing health in regular medical and wellness visits
- HEARING TECHNOLOGIES
  - 7. New OTC hearing devices for mild to moderate hearing loss (diagnosed by self-test) exempt from state dispensing laws
- IMPROVING AFFORDABILITY OF SERVICES AND TECHNOLOGIES
  - 9. Improve affordability for consumers through fee transparency, insurance coverage, vocational public awareness about coverage
  - 10. Demonstration projects and studies about innovative payment and delivery models
- ENGAGING A WIDER COMMUNITY: AWARENESS, EDUCATION, AND SUPPORT
  - 11. Improve public information on hearing health, hearing health care and hearing-related technologies and services
  - 12. Support and manage hearing health and foster environments that maximize hearing and communication for all individuals





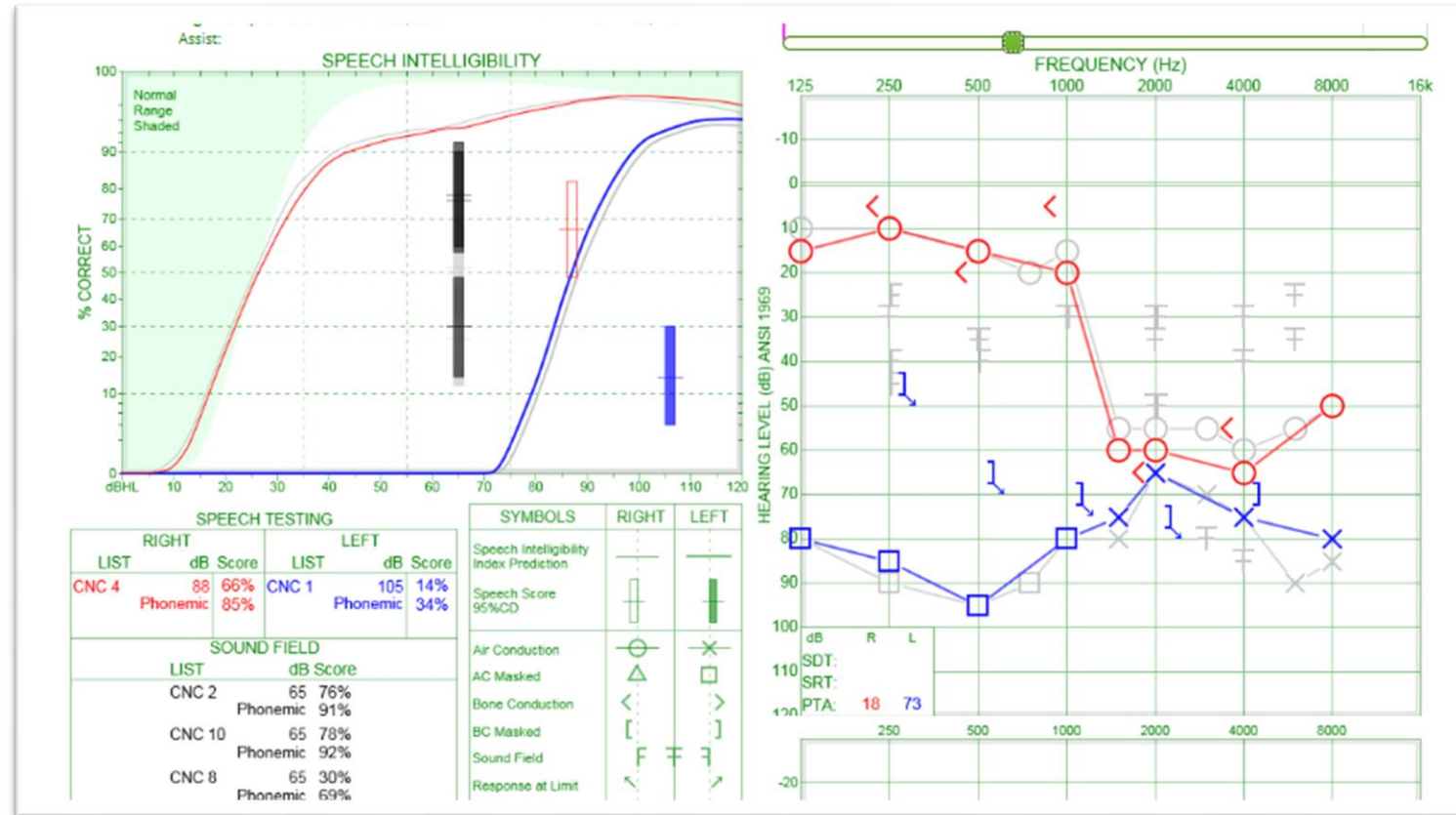
# Return to Academic/Clinician – Late 2010s

- One audiology
  - No separation between diagnostic, intraoperative, hearing aid, cochlear implant, rehabilitation
- Embraced self-tests in referring departments
- Sold PSAPs to prepare for OTC
- Unbundled
  - Communication Needs Assessment one of the most valuable services
  - Fitting services for PSAPs
- Prepared for pharmaceuticals
  - High-frequency audiometric thresholds
  - Speech perception in noise





# Speech Perception WRT Audibility

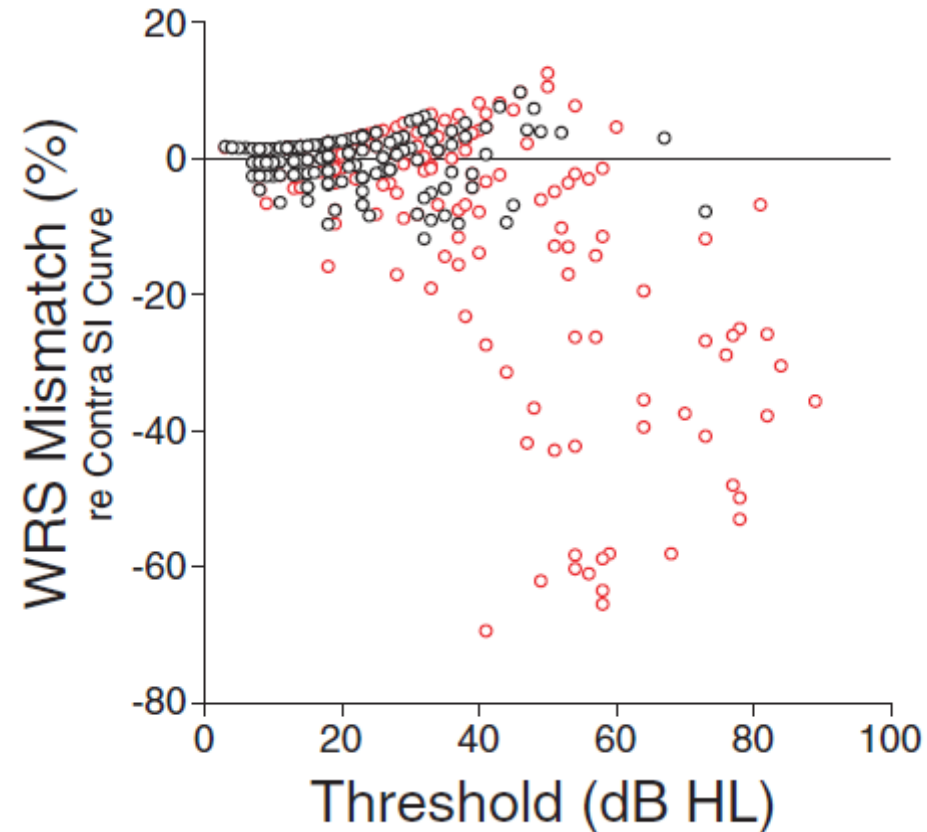






# Speech Perception WRT Audibility

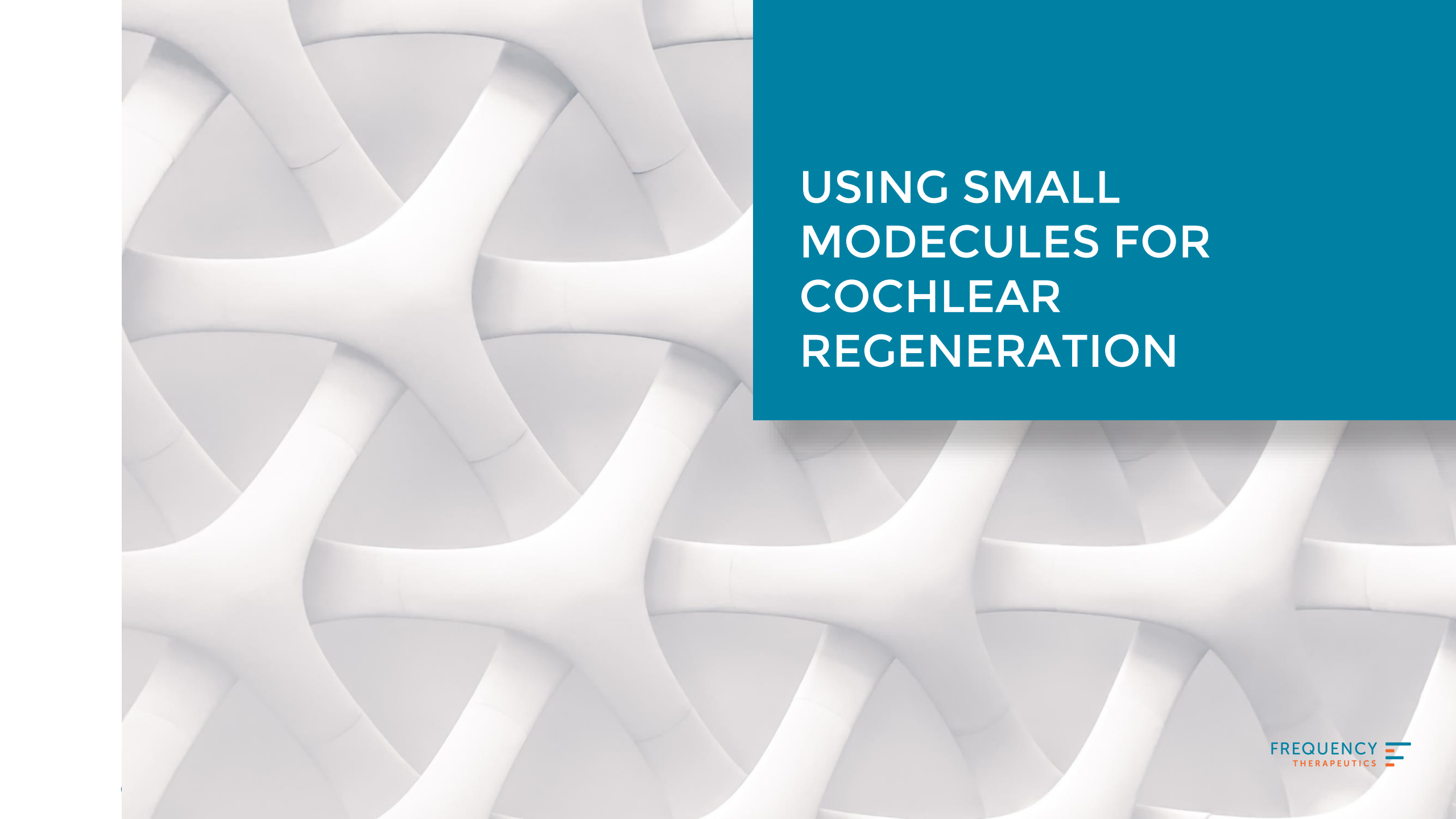
**PMID 25380123:** “patients have poorer WR scores than predicted by the residual loss of audibility”





# Pharmaceuticals for Hearing Loss

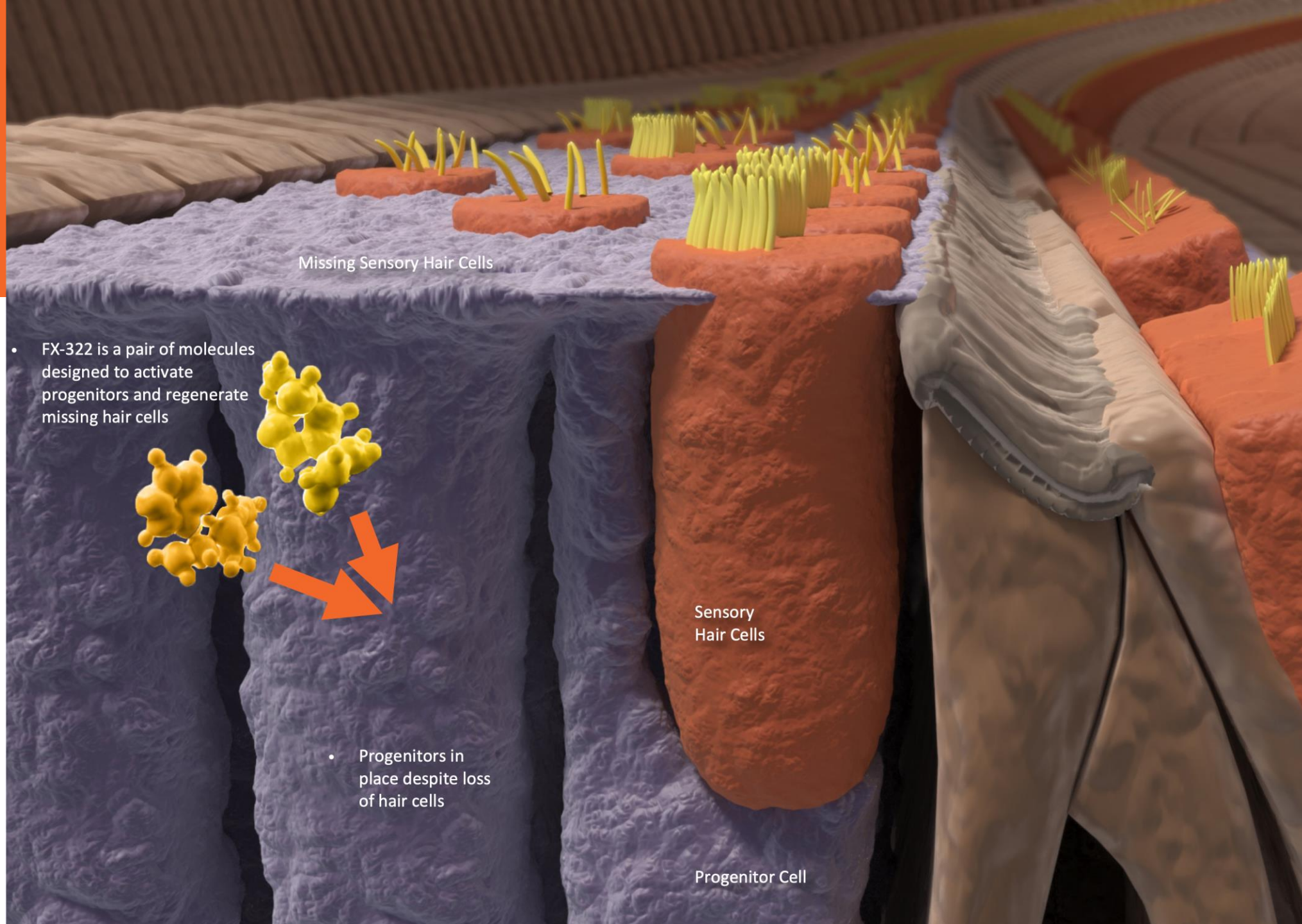
- Genetic treatment
  - Small population of babies with monogenic hearing loss (Otoferlin)
  - Clinical trials will compete with cochlear implant efficacy
- Blocking damage
  - Protection from noise, chemotherapy
- Regeneration
  - Targeting multiple pathways
  - ~Mid-2020s?



# USING SMALL MOLECULES FOR COCHLEAR REGENERATION

# Solution: A Therapy to Address the Underlying Pathology

Synergy between pathways aims to activate progenitor cells and regenerate sensory cells in the cochlea



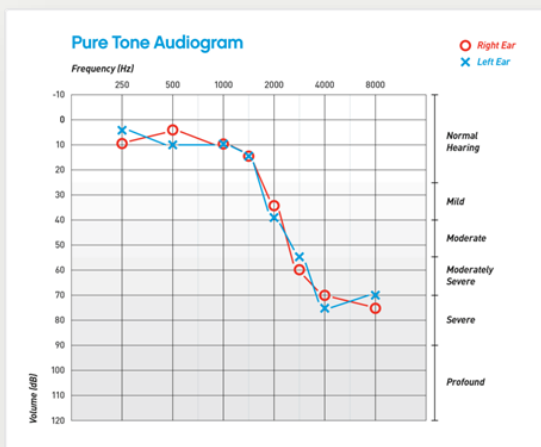


# Increasing Focus on Hearing Clarity

Audibility (Loudness)  
measured with pure  
tone test



Intelligibility (Clarity)  
measured with word recognition  
and words-in-noise tests



## Word Recognition Test

- List of 50 monosyllabic words
- Single words played in quiet

## Words-in-Noise Test

- Background noise from multiple voices
- Played at different signal-to-noise ratios

*“When you develop SNHL, the issue is not just that you can't hear soft sounds. That's why if you ever talked to anyone who has a hearing loss, what they'll say is it's not that I can't hear you...it's I can't understand you.”*

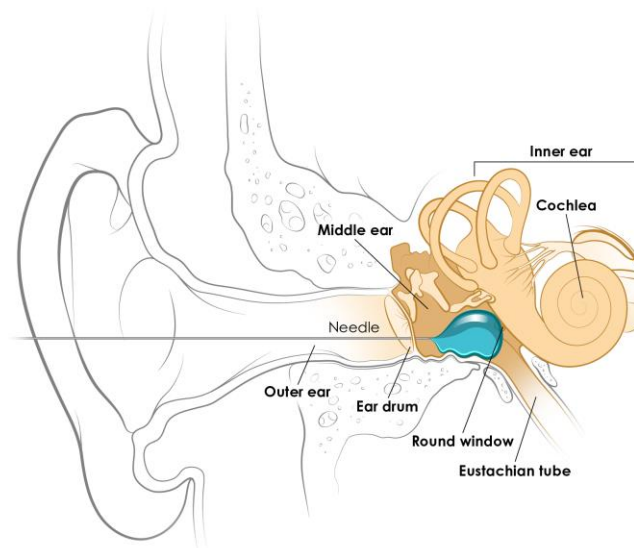
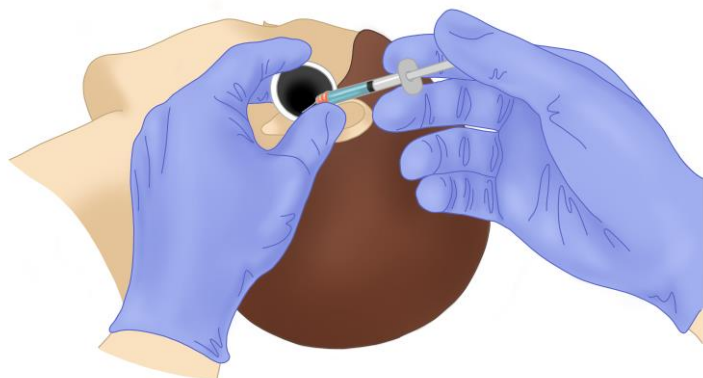
- Dr. Frank Lin from Externally-Led Patient Focused Drug Development program on SNHL, June 2021



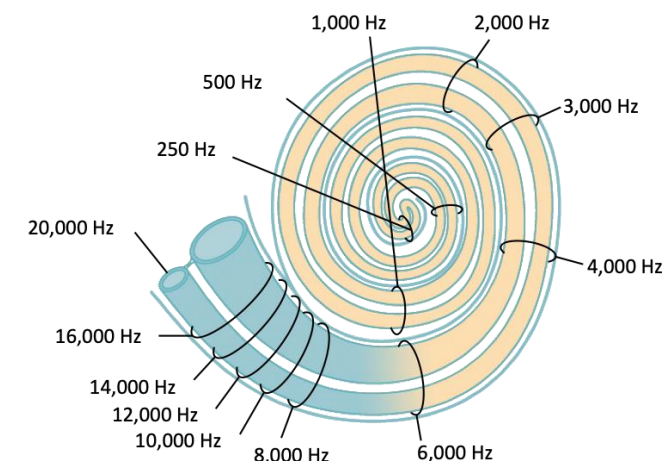
# FX-322: Directly Targeting the Regeneration of Sensory Hair Cells in the Cochlea

FX-322 is administered via a standard intratympanic injection, a routine procedure performed by ENTs

The injection concentrates FX-322 in the cochlear region critical for speech intelligibility



*Not to scale- for illustrative purposes only.*



# FX-322 Clinical Profile Informed by Broad Range of Learning Studies

Enrolled

Phase 1/2 (FX-322-201)	Phase 1b (FX-322-111)	Phase 1b (FX-322-112)	Phase 2a (FX-322-202)	Phase 1b (FX-322-113)
Subjects with mild-to-moderately severe SNHL	Subjects with mild-to-severe SNHL	Subjects with presbycusis (age-related hearing loss) mild-to-mod. severe	Subjects with mild-to-moderately severe SNHL	Severe sensorineural hearing loss
Subjects with Noise-Induced or Sudden SNHL	Subjects with Noise-Induced or Sudden SNHL	<i>NO SUBJECTS</i> with Noise-Induced or Sudden SNHL	Subjects with Noise-Induced or Sudden SNHL	Subjects with severe SNHL
Age 18-65; N=23	Age 18-65; N=33	Age 66-85; N=30	Age 18-65; N=95	Age 18-65; N=31
Single administration	Single administration	Single administration	Four administration regimen	Single Administration
<ul style="list-style-type: none"> <li>• Double-blind, placebo controlled, multi-center, randomized study</li> </ul>	<ul style="list-style-type: none"> <li>• Open-label, multi-center, randomized study</li> <li>• FX-322 injected in one ear – contra lateral ear acted as control</li> </ul>	<ul style="list-style-type: none"> <li>• Placebo controlled</li> <li>• Multi-center, randomized</li> </ul>	<ul style="list-style-type: none"> <li>• Double-blind, placebo controlled, multi-center, randomized study</li> </ul>	<ul style="list-style-type: none"> <li>• Single administration</li> <li>• Placebo controlled</li> <li>• Multi-center, randomized</li> </ul>
<ul style="list-style-type: none"> <li>• Clinically meaningful and statistically significant improvements in word recognition scores in patients with measurable word recognition deficits</li> </ul>	<ul style="list-style-type: none"> <li>• Clinically meaningful and statistically significant improvements in word recognition scores in patients with measurable word recognition deficits</li> </ul>	<ul style="list-style-type: none"> <li>• No significant treatment effect observed with FX-322 compared to placebo</li> <li>• No response in placebo groups or in untreated ears</li> </ul>	<ul style="list-style-type: none"> <li>• Unexpected increase in word rec (WR) scores in placebo group suggests bias due to trial design.</li> <li>• Lack of reliable baseline scores, left company unable to evaluate hearing improvements across cohorts</li> </ul>	<ul style="list-style-type: none"> <li>• Study enrolled</li> <li>• Data anticipated in Q4 2021</li> </ul>
Favorable safety and tolerability profile	Favorable safety and tolerability profile	Favorable safety and tolerability profile	Favorable safety and tolerability profile	

[Detail from subjects *across all single-dose studies* will provide key insights into potential responders]

# Two Independent Studies (FX-322-201, FX-322-111) Show Hearing Improvements with Single Dose

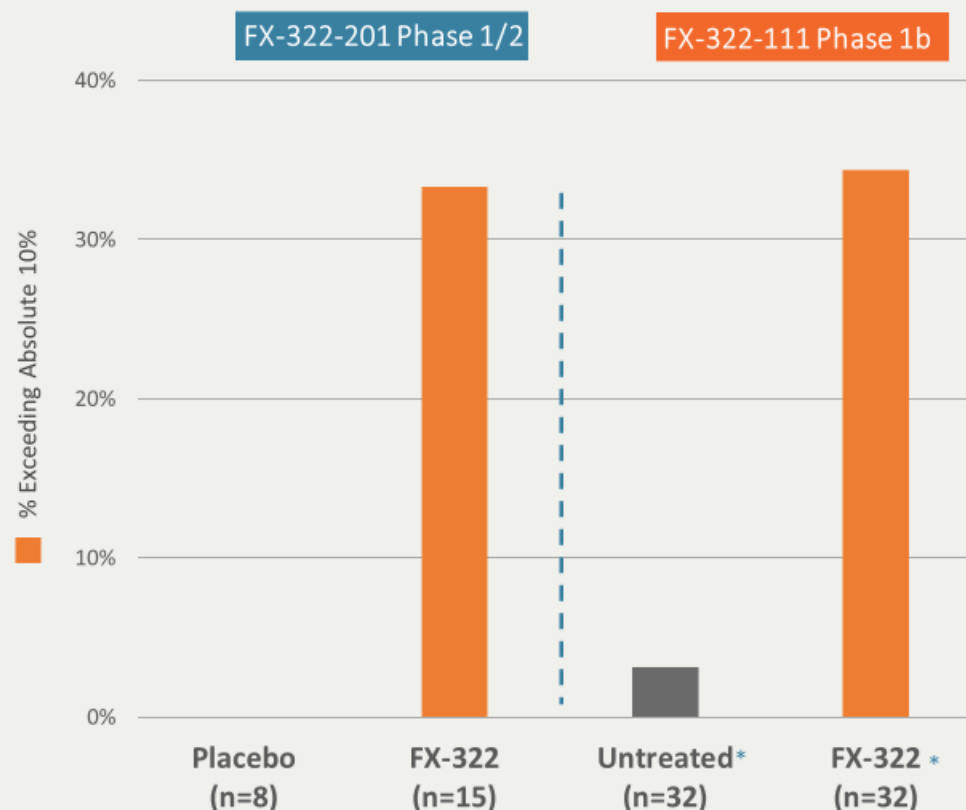
## Phase 1/2 Study FX-322-201 Overview

- Placebo-controlled, multi-center, randomized study
- Mild to moderately severe subjects, age 18-65 (n=23)
- NIHL/SSNHL

## Study Results

- 33% of subjects achieved 10% or greater absolute improvement in word recognition in treated ear
- Statistically significant *and* clinically meaningful improvements in WR
- No meaningful changes in placebo group
- Favorable safety profile

## Day 90 Word Recognition Scores Across Studies



## Phase 1b Study FX-322-111 Overview

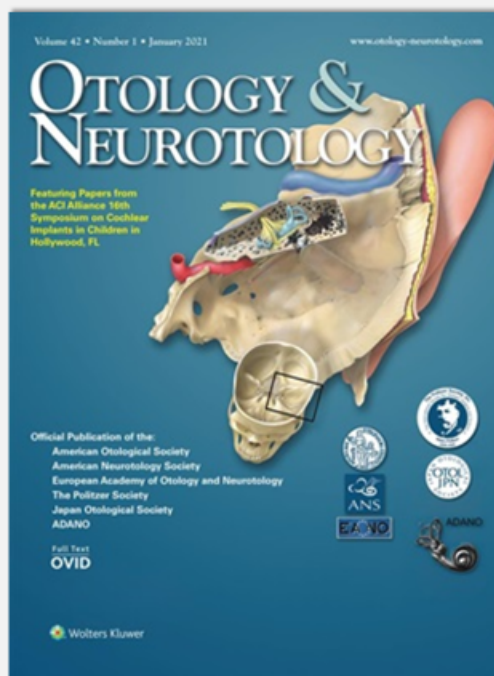
- Compared different FX-322 administration conditions
- Open-label, multi-center, randomized study
- Mild to severe subjects, age 18-65 (n=33)

## Study Results

- 34% of subjects achieved 10% or greater absolute improvement in word recognition (WR) in treated ear
- Statistically significant *and* clinically meaningful improvements in WR
- Favorable safety profile

*\*Total of 33 patients enrolled in study, 32 subjects completed 90-day clinical assessment period*

## FX-322 Clinical Data Published in Leading Journal



DOI: 10.1097/MAO.0000000000003120

### FX-322 Phase 1/2 and drug delivery studies

- *Improved Speech Intelligibility in Subjects with Stable Sensorineural Hearing Loss Following Intratympanic Dosing of FX-322 in a Phase 1b Study* (W.J. McLean, et. al. 2021)
- Pre-eminent, peer-reviewed journal in the field

# Aligning with Existing Treatment Paradigms

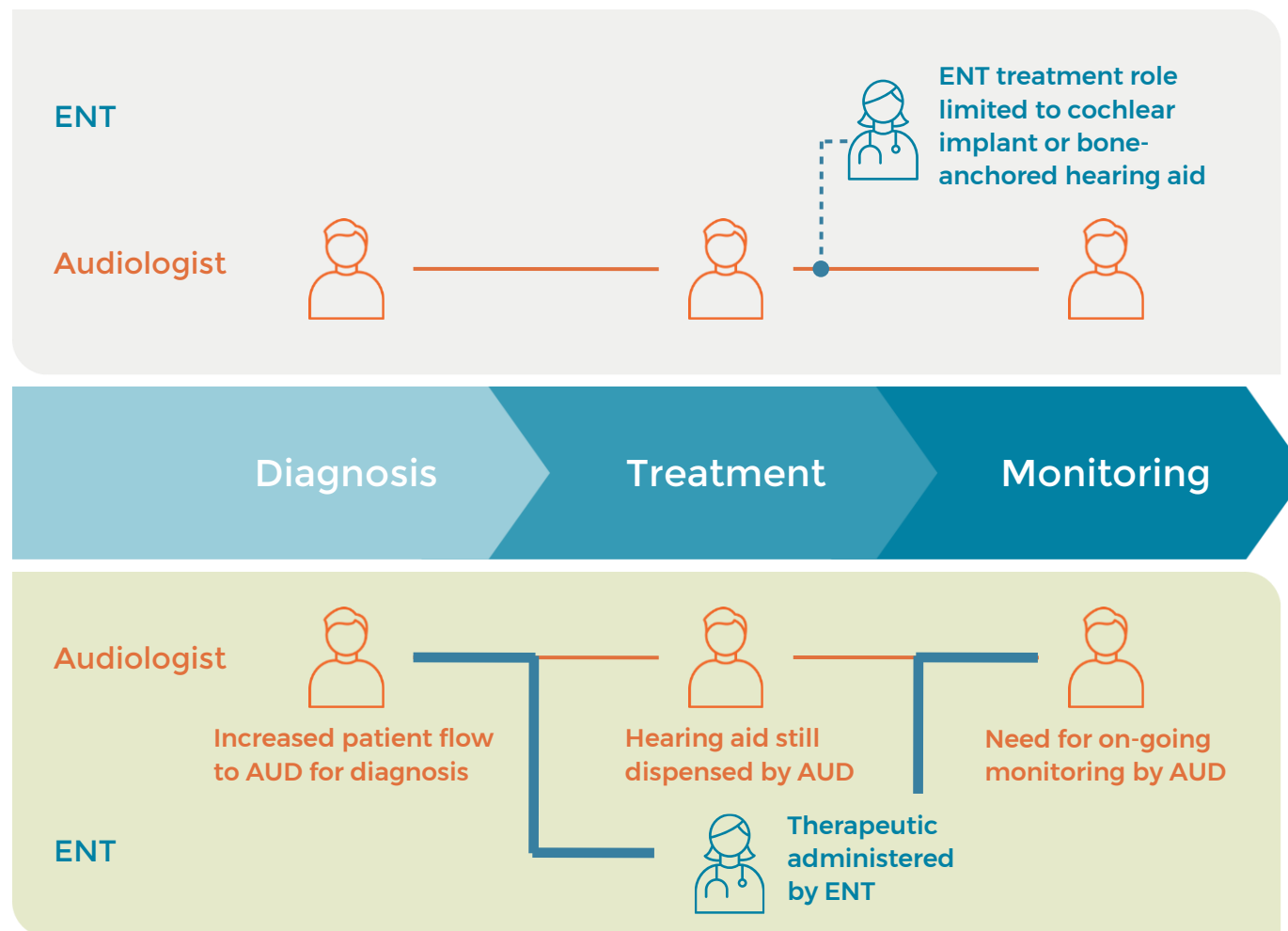
Empowers ENT's  
with a  
therapeutic  
intervention

Anticipate  
Audiologists will  
see increased  
patient flow

Without  
Therapeutics  
(Current  
State)

Patient  
Journey

With  
Therapeutics  
(Future State)





# Aligning with Existing Diagnostic Protocols

**Audibility (Loudness)**  
measured with pure tone test



**Intelligibility (Clarity)**  
measured with word recognition  
and words-in-noise tests



## Standard, Validated Tests

### Word Recognition Test

- List of 50 monosyllabic words
- Single words played in quiet

### Words-in-Noise Test

- Background noise from multiple voices
- Played at different signal-to-noise ratios

# How to Unleash Audiology?

- Provide unique benefits
  - As audiologists provide unique benefits for patients, the business model will follow
- Democratize hearing counseling, measurement and intervention
  - Allied professionals and technologies are needed to reach the number of people who need help
- Diversify outcome measures
  - Speech perception and PROMs measure different things than audibility, and important dimensions of hearing
- Get excited for the future
  - OTC hearing aids and drug therapies will increase the need for and impact of audiologists
  - Hearing loss has made its way to national policy