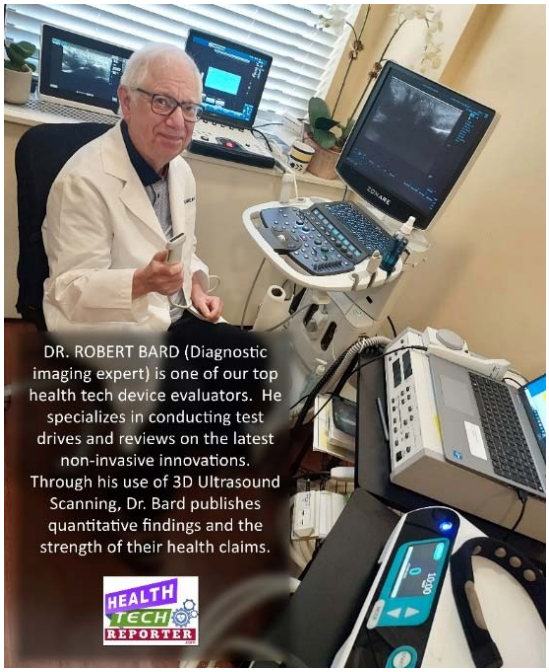
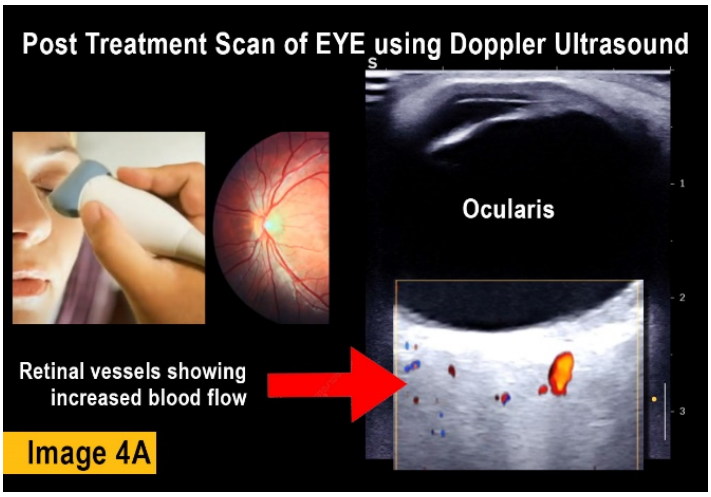
PRE-PROPOSAL AND CLINICAL RESEARCH PROTOCOL:

IRB-BASED VALIDATION STUDY / VISUAL AND QUANTIFIABLE REPORTING OF NON-INVASIVE THERAPEUTICS THROUGH MEDICAL IMAGING PROTOCOLS



By the year 2000, the vast majority of non-invasive wellness devices on the public market have deep rooted themselves into the WELLNESS and FUNCTIONAL communities, leading to the sales of 'invisible treatments'. These devices employ one of a number of technology based modalities including: pulsed electromagnetic frequency, biofeedback, shockwave sonic pulse as well as light-related energy therapies like cold laser, blue light and infrared just to name a few.

The concept behind 'MEDICAL VALIDATION' underscores the complex commitment of "ensuring that the medical device being manufactured will consistently provide the intended benefits for its use condition. Clinical validation is usually done through a series of tests and inspections." [1] To conduct this medical validation officially can be offered through various protocols, an Institutional Review Board approved by the HHS and FDA regulations. One protocol that can be available for consideration by the IRB panel is the use of medical grade 3D Doppler Ultrasound imaging. The use of medical imaging technologies like an ultrasound alongside the interpretation of a certified clinical radiologist may offer biometric assessment and analyses of all scanned readings and the collection of ample data to confirm or validate a health device's effects on the body as marketed.

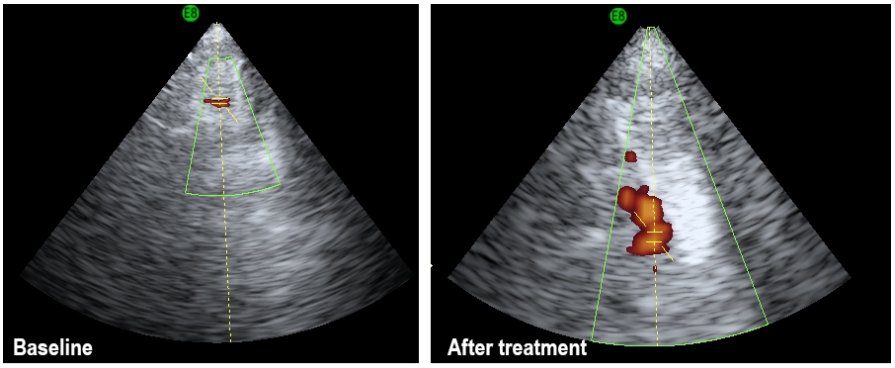


VALIDATION SUPPORTS PUBLIC CLAIMS

Especially when a product is a health-related solution, testing is an important and highly critical step from a legal standpoint. This step is directly involved in a developer's statements and claims about the device. Before any device is to be promoted for a specific pathology, a series of formal performance exams must be conducted to suit regulatory acceptance by an outside agency or clinical team approved by a federally backed review board. Considerations for validation include: range of physiological effects, warnings about the possible hazards, physical risk to the user in regular use, adverse

reactions (potential side effects)- and all these elements are from data acquired during a validation study [2][3]. To confirm (or validate) that a product is effective within the statements and claims that it provides the public, the manufacturer would need to invest in an exclusive and dedicated lab or agency that is poised to perform this level of testing. Said lab must acquire enough data (according to the IRB board) to supports the aspired claims. If/when enough data has proven the hypothesis true, this would add to the product's marketing credence as well as confirms the device's ability as a health or wellness product. Any other type of observational testing outside of the authority of an IRB is considered ANECDOTAL and must be established as such- which holds no credence as an industrywide claim whatsoever.

BIOMETRIC DATA GATHERING (CLINICAL TRIALS) vs. ANECDOTAL REPORTING



Case Study #3: scan of the BASILAR ARTERY shows significant increase in blood flow. As a possible reaction to the device under review, this scan indicates an increase in oxygen-rich blood supply to the brain.

Dr. Robert Bard is a certified Radiologist and has been hired as a co-primary investigator in various clinical trials and commercial testing to employ medical ultrasound and clinical interpretation to support pharmaceutical solutions and energy based treatments. His reporting has added to double-blind studies where a range of participants are dedicated to the application & exposure to treatment or intervention. He has also joined other teams to record any and all reactions to specific treatments as part of data collection. These types of IRB based studies are private and are often formally linked to a given institution or an accredited health product manufacturer/developer. The collected data would eventually make their way toward a pass-fail verdict and would determine if said product would earn the ability be marketed under specific claims. ANECDOTAL reviews and reporting are by no means directed to support the marketing of any brand, company or developer. Mention of any brand (if at all) are only to credit those used in the tech review as "source" but the anecdotal objective of exploratory "test drives" and even his use of ultrasound imaging is to offer a one-time academic finding purely from a personal (single user) report, but is by no means a usable data for public, commercial or marketing claims.

OTHER QUANTITATIVE IMAGING OPTIONS FOR CLINICAL STUDIES

- **Transcranial Doppler** US Scan of Basilar Artery
- **Extracranial Doppler** of Temporal Artery
- **Transorbital Doppler** of the ophthalmic and central retinal vessels
- **Elastogram:** imaging class that maps the elasticity of soft tissue for the presence/ status of disease
- **OCT (Optical Coherence Tomography):** uses low-coherence light to capture micrometer-resolution
- **Thermography:** a test that uses an infrared camera to detect heat patterns and blood flow in body tissues

DR. ROBERT BARD and his research team are available to review all IRB-based validation testing and clinical studies of medical protocols, therapeutic solutions and diagnostic devices in all stages of development. For more information, contact us at: 631-920-5757 or email us at: lg@nycralliance.org

Part 2:
TRACKING THERAPEUTIC EFFECTS THROUGH BLOOD FLOW REACTIONS

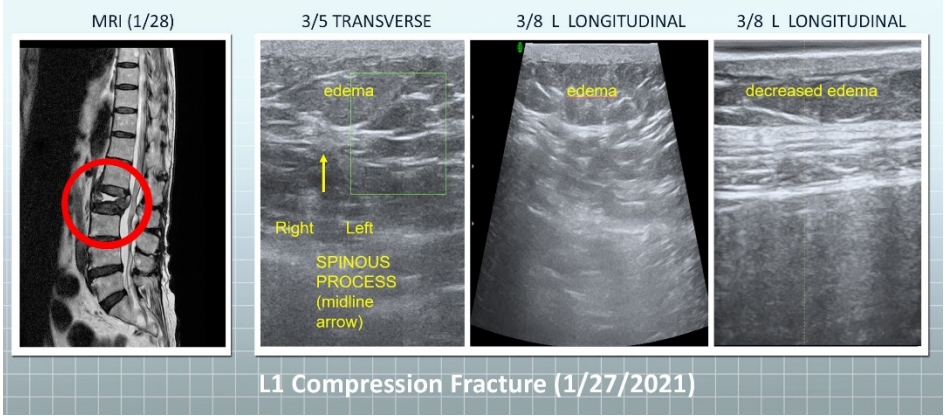
To date, the ultrasound's ability to evaluate abnormalities within the soft tissue such as cysts, tumors and inflammation is used to help identify an expanded set of pathologies in the body. Since the early 1970's, Dr. Robert L. Bard (NYC Cancer Radiologist) has used diagnostic imaging for pre and post procedural guidance, and diagnostic care (screening and monitoring) of his patients. Dr. Bard is also recognized for his use of ultrasound in pharmaceutical research and clinical trials, where his leadership in analytical interpretation is sought after worldwide for identifying markers and therapeutic efficacy.

Throughout his career, Dr. Bard has employed this imaging strategy to detect, track and confirm the body's reaction to a variety of therapeutic interventions. He has conducted private studies reviewing the effects of injectable therapies (PRP, Stem Cell therapies, etc) as well as non-invasive therapeutic interventions in studies of neuro-stimulation, electrostimulation and electromagnetic field treatments. His approach involves the comparative study of measurable scanning data or quantitative ultrasound (QUS) which **aims at recording interactions between the behavior and activity of biological tissue** microstructure and ultrasound waves [5][6]. From a time-based comparative study of the treated area (before and after studies), Dr. Bard applies the use of blood flow detection technology or hemodynamic data gathering protocols to confirm and potentially validate the existence of measurable therapeutic effects through collected measurable information.

Courtesy of Axiobionics.com

Independent Test Drivers of Medical and Health Related Innovations

When considering the purchase of any health or wellness device, today's consumer is more demanding of answers about what is on the market. With high speed access to web research are at our fingertips, cutting through the jungle of marketing ads and product hype (to access proven science and technical data) is part of the modern culture of the 'smarter shopper'. With a little web research, we can make far better choices thanks to user reviews, company background checks, case studies or testimonials.



Especially in the case of medical devices and health products, public interest for true quality and performance calls for a more critical eye, one that is not influenced by conventional sales and marketing methods. The value of a good review from **AN OUTSIDE, INDEPENDENT TESTER** (led by an uncompromised team) can offer a more confident understanding and technical credence

about the product in question. It is the process of this type of 'test drive' that can offer valuable insight from actual clinical professionals.

HEALTH TECH REVIEWS* aims to bring this unquiue evidence and SCIENCE based observation about the effects of the selected health innovations under review.

A MORE INVOLVED & UNBIASED TEST DRIVE

The AngioFoundation is one of the major non-profit groups who supports the awareness about modern, alternative and NON-INVASIVE INNOVATIONS. Through a network of clinical professionals and credentialed health advocates, the HEALTH TECH REPORTER* program was formed to conduct case studies and research reviews on health related innovations. Combining multiple modalities of evaluation protocols (including the use of diagnostic imaging, behavioral studies and efficacy assessments), an unbiased focus group is designated for each project review to conduct a thorough user exam. Reports may include videos, imaging scans, recorded biometric tracking, user experience and other vital information to substantiating an intelligent review (and consumer activity). Our reviews are submitted for public access and digital distribution through our network of science news outlets.

SCANNING TECH PERFORMANCCE AND PHYSIOLOGICAL RESPONSE

This public education effort is lead in part by diagnostic imaging researcher DR. ROBERT L. BARD and an evaluation team (assembled around each device). This test phase may be comprised of using a 3D Doppler Blood Flow Ultrasound Imaging to add to biometric logging and monitoring of a time-based study on the effects of the device under review. This review can be accessed in the newsletter called **JOURNAL FOR MODERN HEALING**, a public blog-style site where we present quantifiable scanning reports and interpretation analyses of all scanned readings. We provide this review to the public as part of an educational initiative to support beta testing with multiple modalities, valuation based on multiple opinions and use of non-invasive imaging.

EFFICACY STUDIES & PUBLISHING

Our HEALTH TECH Reviews* are free of commercial influence by the device manufacturers and is by no means directed to supporting the marketing of any brand, company or developer. The objective of HEALTH TECH Reviews* is to report findings on the immediate physiological effects of any health device under review. All results are based on a BEFORE-AND-AFTER visual response comparison, quantifiable biometrics and a sound description of the clinical imaging - thus aiming to show the body's potential reaction to that device (if any) by virtue of a post-treatment applied scan. Dr. Bard's imaging team provides scan studies designed to assess, confirm or challenge (if necessary) any device's claims to confirm the device's impact on the body.

HEALTH TECH Reviews* are usually small, private demo reports and mini-case studies offering **ANECDOTAL** reports from professionals who provide both observational and clinical imaging. The HEALTH TECH REPORTER* are to be conducted by our team's evaluators, where scans and reports are limited to personal evaluations. For those who desire a more rigorous evaluation, our team is also experienced with IRB-approved clinical trials, programs involving major research institutes and recruiting a large number of consenting patients.

EDUCATION and AWARENESS about non-invasive technologies are the major objectives behind our HEALTH TECH REPORTER*. All our findings and reviews are published in our public newsletter, backed by health advocates and non-profit associations in support of research and improved health solutions.

TYPES OF APPLICATIONS

1) "USE AS INSTRUCTED": All devices under FDA approval (via 510K) are presented publicly to perform a specific function under an exact application. Dr. Bard's beta testing and scanning review provides a visual review of the device's effects on the body as labeled.

2) "OFF-LABEL USE": Certain devices are accepted in HEALTH TECH REPORTER* under the sole discretion of Dr. R. Bard for exploratory research if the concept of the technology protocol (not necessarily the specific model in hand) may show published potential response to manage or address other disorders that may have not yet earned FDA clearance or approval. Exploratory reviewing is completely academic in its nature, seeking to duplicate these experimental un-cleared applications for any evidence of the pre-published statements in the name of science.

3) OTHER EVALUATORS: Aside from Dr. Bard's imaging, other volunteer users of the product may be involved in the tech review experience, where their personal experiences, their viewpoints and other thoughts on the product may also be shared as part of HEALTH TECH REPORTER*.

4) TECH EVALUATION PROCESS: For any review to carry the necessary validity, our professionals undergo specific protocols that conform to our reporting standards. We hand select a team of health professionals who hold specific certifications that pertain to the device under review. For example, testing a wearable neuro-stimulation device calls for us to partner with the likes of physical therapists, chiropractors, orthopedists or neurologists. Such professionals can offer the kind of analysis and feedback supported by their experience and clinical background. Once we receive the technology and understand the proper operating instructions, our testing group detaches from the manufacturer as we conduct our test drive, exploring and challenging the product's claims. All data acquired are carefully logged and all observations are formally recorded, to be assembled into one comprehensive review for public access. It is this level of diligence that raises the bar of our reviews in support of public education or user advocacy.

6) TECH REPORTER INTERVIEWS 2: As an educational function, the reporting initiative of HEALTH TECH REPORTER* is not limited to the direct product testing of non-invasive or portable devices. Our publishers are also committed to searching for the latest innovations and sharing direct insight on technologies that may be too large (or too involved) to test drive. This level of reporting is for major medical innovations or upgrades in health facilities. They are recognized as ground-breaking technologies that shape the future of their designated functions or protocols. They are often hospital grade and oversized units or systems where our publishing team covers private interviews with their science officers & engineers.

References:

1) Medical Imaging/FDA: https://www.fda.gov/radiation-emitting-products/radiation-emitting-products-and-procedures/medical-imaging#:~:text=Medical%20imaging%20refers%20to%20several,monitor%2C%20or%20treat%20medical%20conditions.
2) https://sonosimaging.com/press-corner/understanding-the-different-types-of-imaging/
3) https://www.fda.gov/radiation-emitting-products/medical-imaging/ultrasound-imaging
4) Diagnostic imaging to detect and evaluate response to therapy in bone metastases from prostate cancer: current modalities and new horizons https://pubmed.ncbi.nlm.nih.gov/26956538/
5) Quantitative Ultrasound (QUS) in the Management of Osteoporosis and Assessment of Fracture Risk https://pubmed.ncbi.nlm.nih.gov/28739081/
6) NIH- "Quantitative ultrasound imaging of soft biological tissues: a primer for radiologists and medical physicists" - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8429541/#:~:text=Quantitative%20ultrasound%20(QUS)%20aims%20at,ultrasound%20waves%20and%20tissue%20microstructure.

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