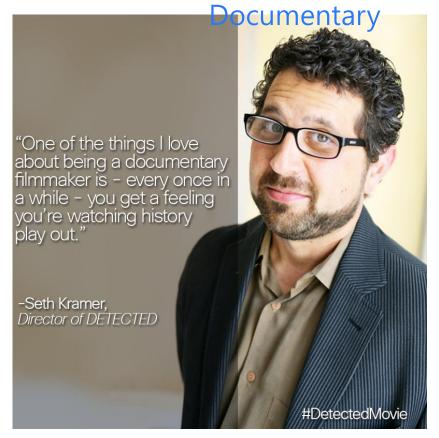




Migrating Fitness to Wellness: Population Health Wearables for Early Breast Cancer Detection

What if one invention could change the fight against breast cancer forever?

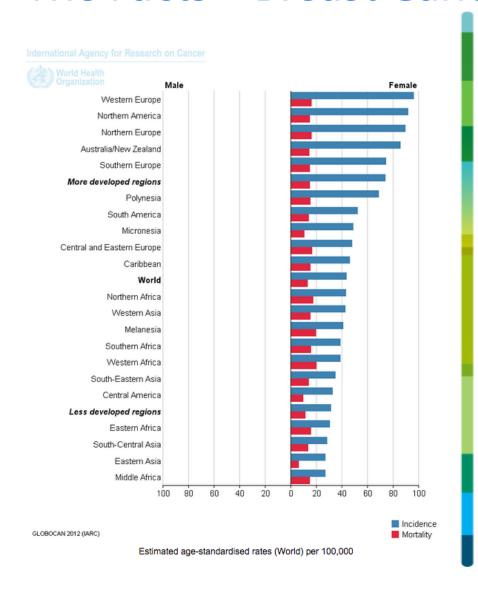
Cisco Systems Sponsored







The Facts – Breast Cancer



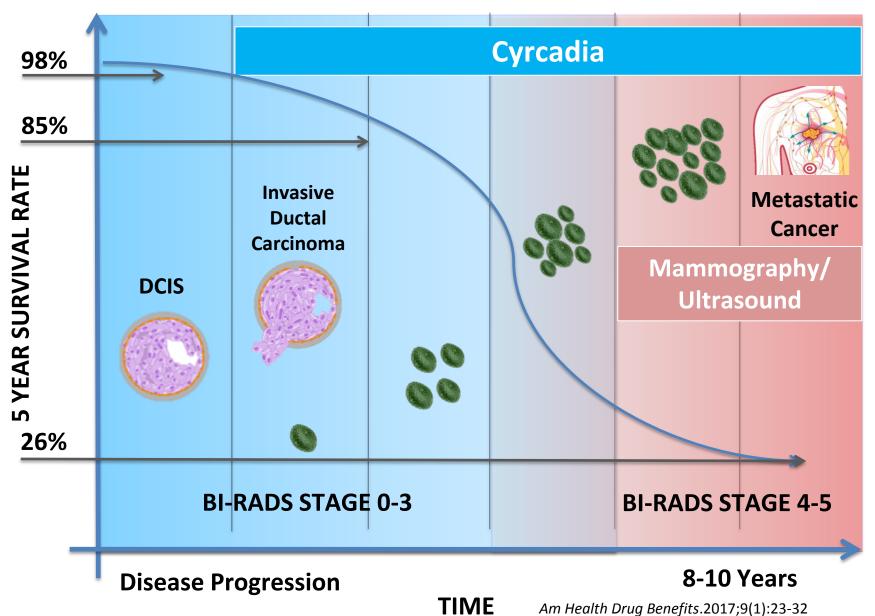
Breast cancer is the 2nd most common cancer in the world and, by far, the most frequent cancer among women

1.67 million new cancer cases diagnosed in 2015 (25% of all female cancers)

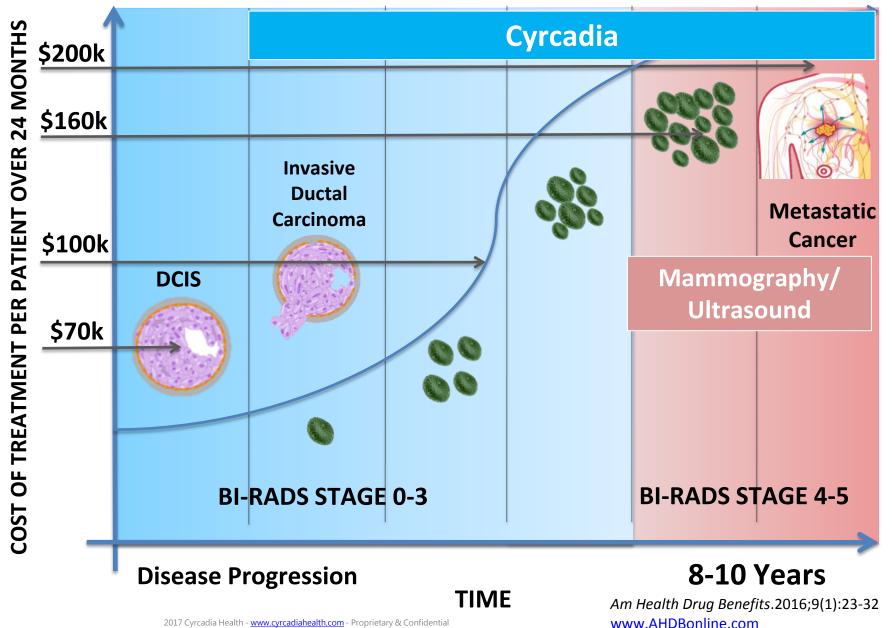
One in eight women will be diagnosed with breast cancer

Early detection is critical to saving lives, but current screening is archaic and **far** too late

The Situation – Early vs. Late Stage Screening



The Situation – The Economic Burden



What We Do



Bluetooth[®]

Automated Alerts

CYRCADIA

HEALTH

Patient, Doctor, Insurance provider

Smart Device Enabled





Global Breast Cancer Database



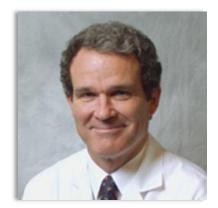
Adjunctive with/or supplemental to:



Wearable Insert (2 Hours)

Mammography Compression/Radiation

What We See



William B. Farrar, MD



Cyrcadia Health (CH) Circadian Breast Cancer Profile



CH Fibroadenoma (Non-cancerous) Profile



"... preliminary data suggest that the monitor may be useful for screening those women with difficult mammographic interpretation (dense breast tissue). The monitor was positive for three cancers missed by mammography, with tumor sizes as small as 0.5 as well as micro-calcifications. Patient data which are positive on the monitor in the absence of mammographic or physical evidence of cancer does not preclude the presence of cancer at its earliest stage..."

How We Do It







80%+ Accuracy for all tissue types

The Situation – World

Cancer registries cover the majority of populations in developed regions—but almost none in emerging economies.



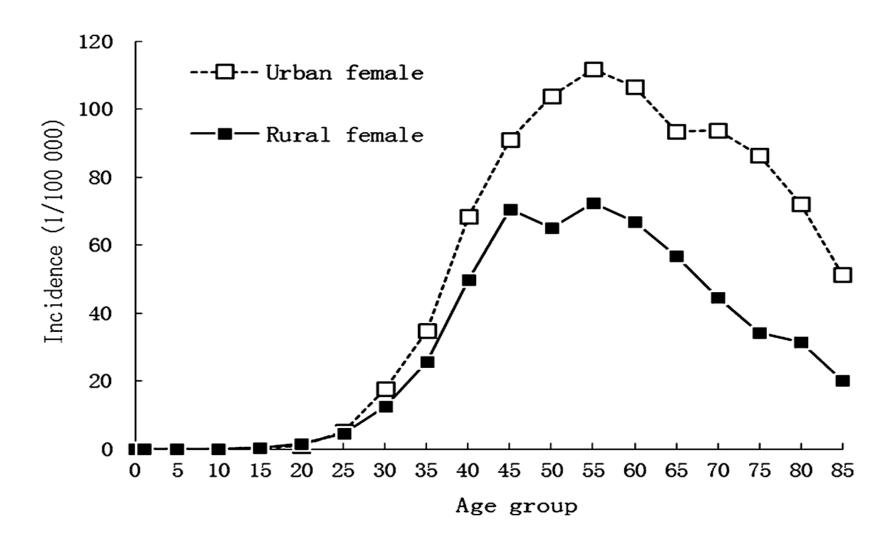
The Situation - China

- Unlike Western cultures no standardized nationalized screening has been established
- ➤ Beijing Study: 5.2% of new Breast Cancer cases found by mammographic screening vs. approx. 60% in US
- Conclusion: Breast cancer has been a great social and economical burden for China, but there is still quite a long way to improve the prevention.
- > Breast cancer control efforts should include not only health-care delivery, but also public participation to increase awareness and promotion of early detection.

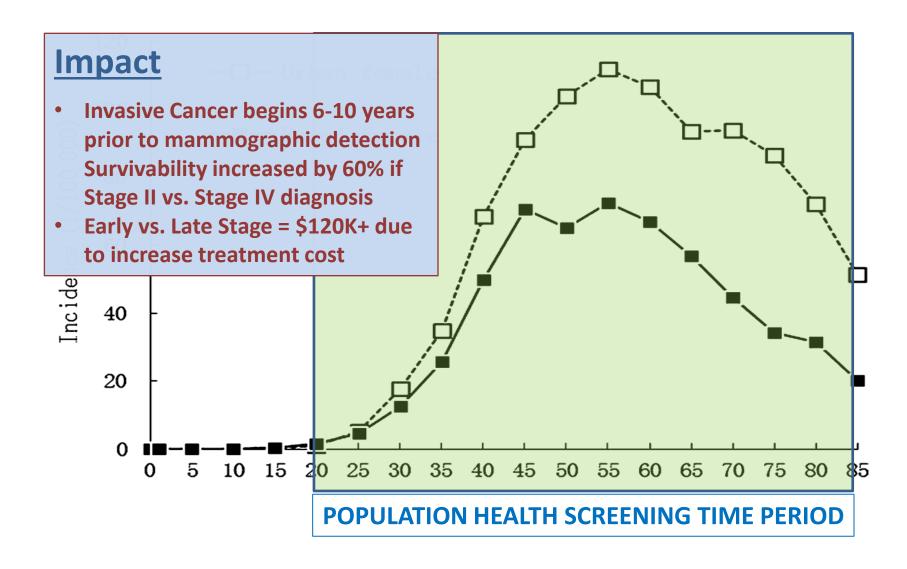
"Current status of breast cancer prevention in China"

Chronic Diseases and Translational Medicine Volume 1, Issue 1, March 2015, Pages 2–8

China Breast Cancer Incidence

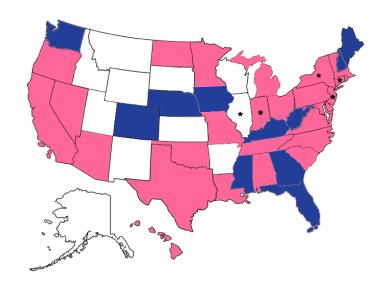


Recommended Population Health Screening



The Density Challenge

40%+ of all Women Worldwide have Dense Breast Tissue



PINK: Enacted Law — RED: Introduced Bill — BLUE: Working on Bill — WHITE: No Action — BLACK: Insurance Coverage Law

Are You Dense Advocacy, Inc.

www.areyoudense.org

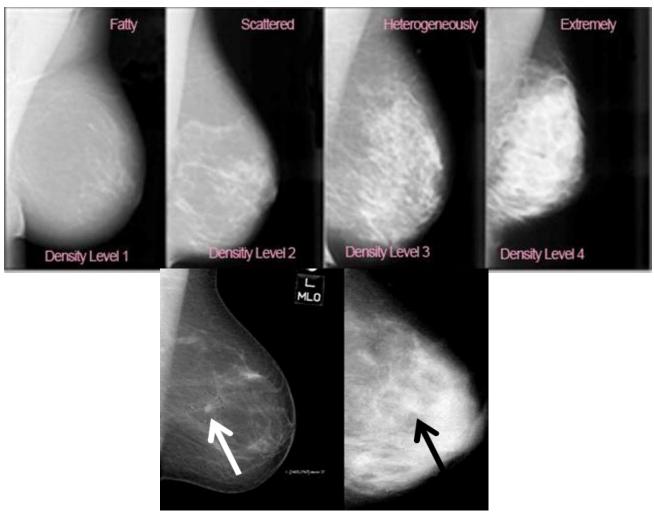
US State mandated communication from physician to patient

- "Due to your condition, you have an increased chance of cancer (2X+)"
- "Current Diagnostic Modalities are Challenged with your condition"
- ➤ Mammography has a documented 48% accuracy with the densest of tissue (1)

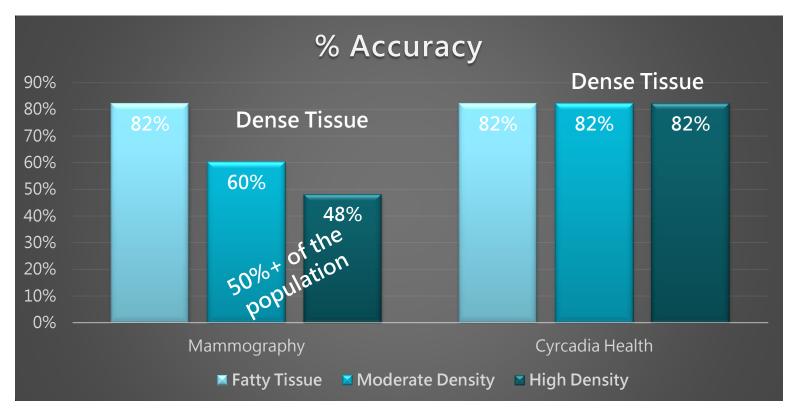
(1) Radiology. 2002 Oct;225(1):165-75. Kolb TM1, Lichy J, Newhouse JH.

NO CURRENT ADEQUATE SCREENING SOLUTION EXISTS

The Imaging Challenge - Mammography and Ultrasound



How We Perform: Density Screening* Cyrcadia will Greatly Improved Dense Tissue Accuracy



- Women with dense breast tissue have a 4X to 6X higher propensity for cancer
- Mammography accuracy is greatly reduced with density, down to 48% accuracy with the densest of
 - Cyrcadia will provide a tissue agnostic solution to over 40% of the population
 - *Physician based diagnosis when utilizing Cyrcadia adjunctive results

2017 Global KOL Pilot Launch Potential





- Global Launch for General Screening of Population
 - Targeting early detection through personalized screening
 - General Population ages 21-80 with Dense Tissue Focus
 - Screening and blood pathology trial protocol for early identification
 - Patents must be screened if positive result
- Multi-site Pilot Launch Potential
 - China, HK Shanghai Cancer Hospital, United Family Healthcare
 - Singapore National University Hospital
 - Japan, S. Korea Location TBD
 - India Apollo Hospital Group, Tata Medical
 - USA Stanford base plus Brigham and Woman's, JHU, Ochsner Clinic, Dignity Health expressed interest
 - Europe L'Ospedale San Raffaele Milan, Italy

Global Breast Cancer Research Portal

Cyrcadia Health Data

Repository



Government

- Global Genotype/Phenotype Differential
- Familial History Trending
- % Patient Increase via. Personalized Screening
- Global Fatty vs. Dense Breast Tissue Data
- Earliest Predictive Outcomes All Ages
- Earliest Biomarker Indication Coordination



University



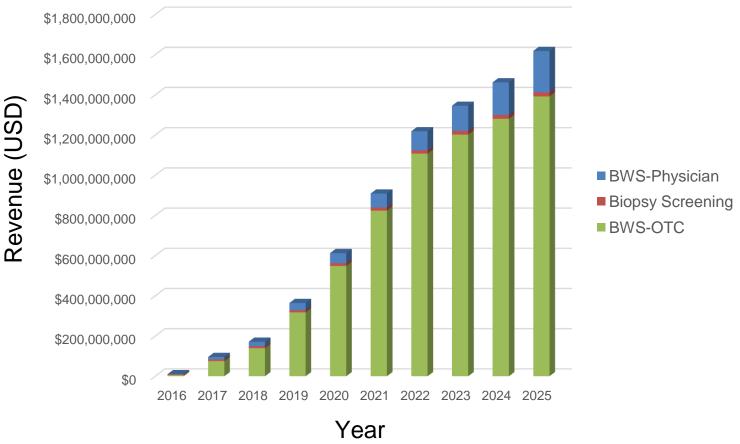
The Value is in the Data



Industry

MetLife Japan/S. Korea/China Allianz – Germany + others Third party survey of 2000 women, 300 physicans and 5 payor groups lead to the following US model assessment. OTC System revenue forecast approaches \$1.4B. US forecasts for the Physician Office Systems exceed a total of \$225M driven by the anticipated adoption of the technology in clinical breast exams and biopsies.

US REVENUE FORECAST FOR BREAST WELLNESS & PRE-BIOPSY SCREENING SYSTEMS*



*Forecast assumes 12 hour wear time.



Global Launch Sequence 2018*

Asia / European Union

1. CE/FDA Regulatory Process

- Defined Time line to allow launch in FDA regulated countries H12018, CE countries H2 2018

2. Initial Countries of Launch 2018

- Hong Kong, Malaysia, Indonesia, India, Singapore, Japan, S. Korea
- 3. Insurance Provider High Interest
 - TBD By Country / Region

4. Breast Cancer Leads Mortality

- Represents Highest Cancer Mortality for All Women in Asia
- No Density Screening available Globally

5. Immediate High Scan Volume

- Predictive Analytics = progressively increased accuracy +80%
- Significant Value-add to Global Valuation with CH Core Lab Data

North America

1. FDA Regulatory Clearance

- Cyrcadia Predicate 510K Class II exists now
- Sales can begin in US and other FDA guided countries H2 2017
- 2. US Density Legislation has no screening solution
 - Affects 40%+ of the Population
- 3. \$1.6B current market exists for improved biopsy screening
 - 1.2M Unnecessary Biopsies/yr.

4. Monthly breast exam suggested by ACS

- Effective Screening Solution Nonexistent Today
- Early Cancer Detection is Key to Improved Survival Rates

Insurance Reimbursement

1. Dense Tissue Screening Precedent CPT Codes

- 76645 Ultrasound/Mammo
- Cyrcadia Dense Tissue
 - CH Screening Impacts 50% of Female Population
- 2. Improved Surgical Outcomes Precedent CPT Codes
 - 77061 Tomosynthesis/Mammo
 - = 6% Reduction in Biopsy Rate
 - With Cyrcadia + Mammo
 - = 50%+ Reduction in Biopsy Rate







Thank You!

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