Welcome to ***Medical Devices: Partnering for Innovations***

April 24, 2014

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William A. Hawkins, President & CEO – Immucor, Inc.

MEDTECH INNOVATION: A CASE STUDY FOR COLLABORATION

IMMUCOR

It’s Good to be Back in Atlanta!

1998 - 2002

Novoste™

2002 - 2011

Medtronic

2011 - Present

TPG

IMMUCOR

Atlanta has a lot of exciting things going on!

TPG Capital Overview

- Founded in 1992, TPG Capital is a leading global private investment firm with $54.4 billion of assets under management
- TPG's invests across a number of industries, including:

Consumer	Retail	Tech	Healthcare	Energy	Transports	Industrials	Business Services

- TPG has been among the most active healthcare investors, with more than $5 billion of equity committed over the past 4 years in 20 companies

- **TPG's investment thesis for Immucor: invest in and grow the business**

Selected Investments in Healthcare Companies

SCA Surgical Care Affiliates
APTALIS™
PAR PHARMACEUTICAL
ims INTELLIGENCE. APPLIED.
QUINTILES
IMMUCOR
Healthscope
IASIS HEALTHCARE
BIOMET
Fenwal™

Overview of Immucor

Company Profile

- ***A global leader in immunohematology in vitro diagnostics for more than 30 years***
- #1 in North America; #3 worldwide
- Headquartered in Norcross, Georgia; founded in 1982
- FY13 proforma annual revenue of $386 million

Echo®

Primarily Focused on Transfusion and Transplant Diagnostics

- Developer of automated instruments and reagents
- Products include both serology and molecular offerings
- Acquired LIFECODES in March 2013, providing entry in transplantation diagnostics
- Customers include hospitals, donor centers and reference labs

Neo®

Our Mission

"We strive to create a world where anyone, anywhere in need of blood or an organ **gets the right blood or organ** that is safe, accessible and affordable…"

Innovating to Ensure Safe Transfusions and Transplants

Pioneered a range of rare antisera reagents

Introduced automation to donor centers and hospital blood banks

Market leader in molecular immunohematology; currently awaiting FDA approval

Investing in adjacent markets, such as transplant diagnostics and investing in our product pipeline

LIFECODES®

Immucor has a **strong history of innovating** in transplant and transfusion diagnostics

Medtech Innovation: A Case Study for Collaboration

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- Q&A

Global Healthcare Industry

Significant in Size

- Healthcare is estimated to be a **$5+ trillion industry** worldwide and around a $3 trillion industry in the U.S.
- Diagnostics and Medtech industries are a combined **$125+ billion in size**

Highly Regulated

- Companies that provide healthcare products and services are **monitored by government regulatory bodies** both in the US (FDA) and internationally
- New products take **significant time and investment** to bring to market

Fragmented Industry

- Innovation has resulted in waves of small healthcare companies, making this a **very fragmented industry**
- We regularly see **larger healthcare companies acquire these smaller players** to help bolster product lines, achieve scale and expand into adjacent markets

Medtech & Diagnostics: A Unique American Success Story

Longer Lives

- **Life expectancy in the US has increased by almost 20 years since 1930**
  - Avg. life expectancy in the U.S., 1930 – 59.7 years
  - Avg. life expectancy in the U.S., 2010 – 78.7 years

Job Creation

- **Analysts estimate that 1 in 8 Americans work in healthcare**
- Wages in healthcare-related jobs also carry a premium to comparable roles in other industries

Favorable Balance of Trade

- The U.S. healthcare industry **exported over $117 billion** in 2011, up over 25% since 2007
- Opportunities for **growth in emerging markets** will help continue this trend

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Innovation and Collaboration Have Paved the Way

Innovation is the lifeblood of our industry…

- Research discoveries in the clinic as well as the academic research lab have been a **rich source of innovation**, creating new products and in some cases, new healthcare markets

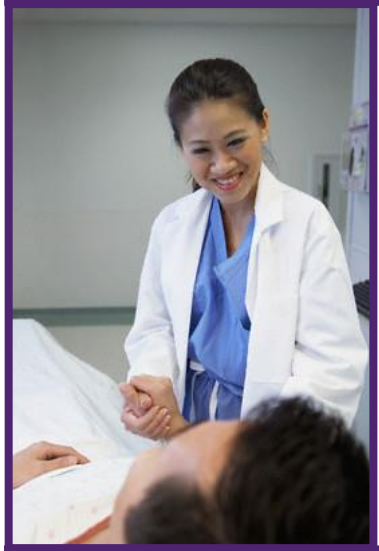
…and our ability to collaborate has unlocked significant value

- Innovation in our industry has spurred collaboration and successful **collaborations have spurred continued innovation**

Innovation and Collaboration in Healthcare

Innovation in medtech and diagnostics has come primarily from collaboration with physicians and industry

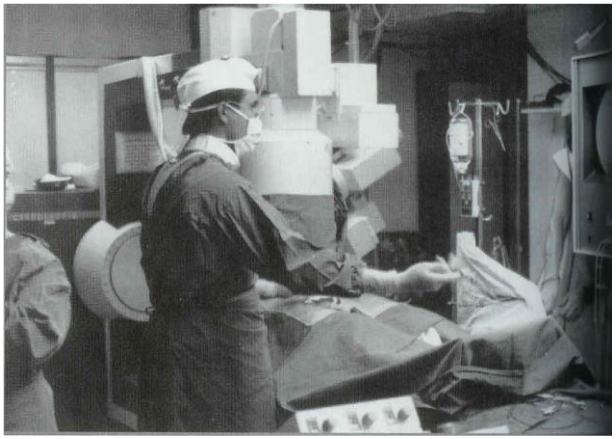
BEDSIDE - BENCH - BEDSIDE

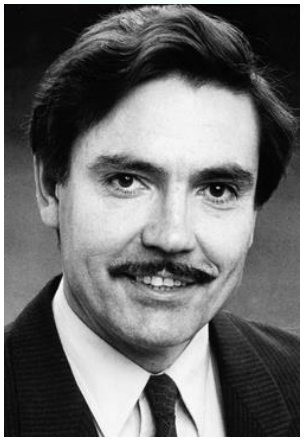


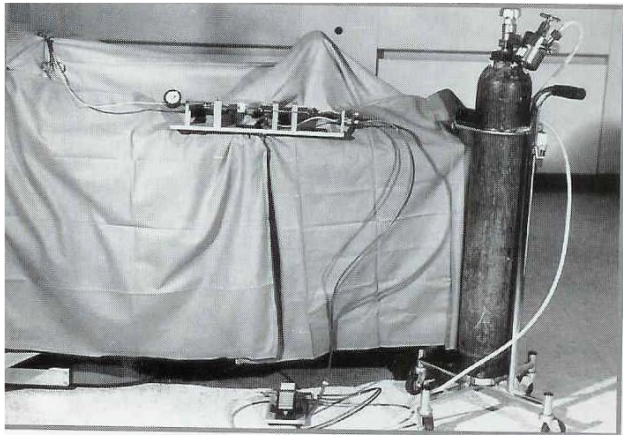
82% of new capabilities for scientific instruments were developed by the users*

**New York Times, March 25, 2007*

Most Innovation Has Come From Clinicians (Bench-Bedside-Bench)







Dr. Andreas Gruentzig (above) – Coronary Angioplasty
Earl Bakken and Dr. C. Walton Lillehei (below) – Pacemaker

In The Early Days of Medtech, The Challenges Were Different

Cost was less of an issue

Patients put more **trust** in doctors and caregivers

Life expectancies were shorter and chronic diseases were only just **beginning to emerge**

We didn't know what we didn't know

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Trends Driving Innovation in Today's Healthcare Industry

Prevalence of Chronic Disease

Aging Population

Emerging Market Needs

Personalized Medicine

BRACAnalysis®

Healthcare Consumerism

Challenges in Today's Healthcare Industry

Rising Costs of Healthcare

Increasing Burden of Overregulation

FDA

Access to Care in Emerging Markets

Society's Growing Intolerance of Risk

Security / Privacy

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Technology Is Enabling a New Paradigm of Care

Convergence of Medical Technology and Information Technology

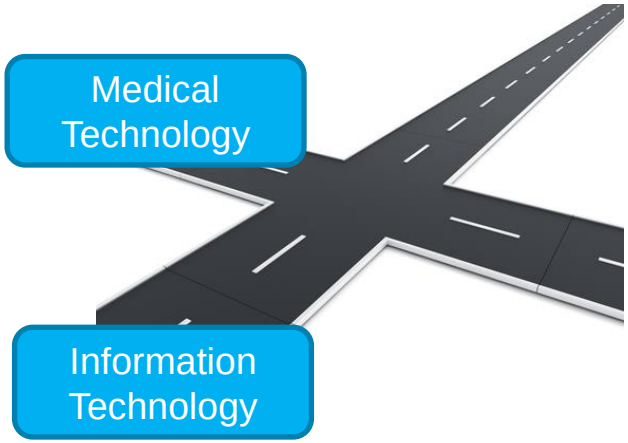
- Information is enabling patients to better manage care

Personalized Medicine is Becoming a Reality

- Diagnostic capabilities are outpacing therapeutic solutions

Healthcare is Increasingly Delivered Outside the Hospital

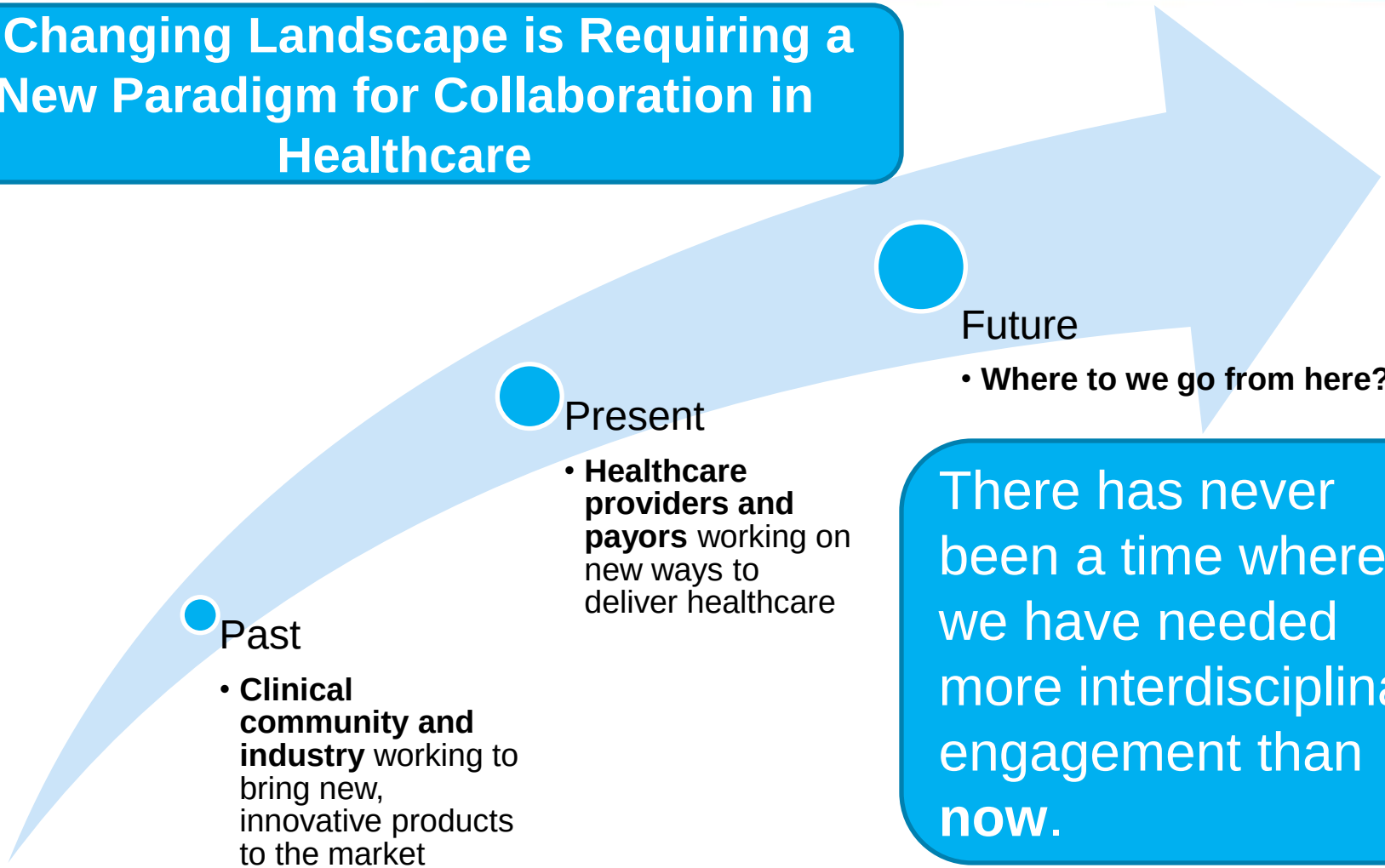
- Personal devices, like insulin pumps, allow patients to receive healthcare outside of a hospital or doctor's office



23andMe

The Healthcare Collaboration Continuum

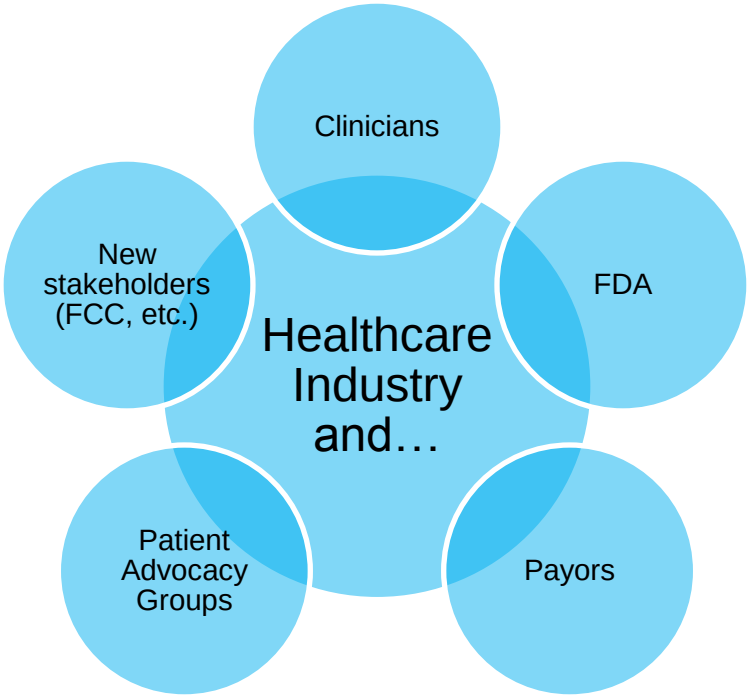
A Changing Landscape is Requiring a New Paradigm for Collaboration in Healthcare



There has never been a time where we have needed more interdisciplinary engagement than **now**.

Where are we headed?

Future will demand more up-front collaboration between a broader range of stakeholders:



As behaviors, expectations and outcomes change in healthcare, we will need to have a **new conversation** with a range of stakeholders

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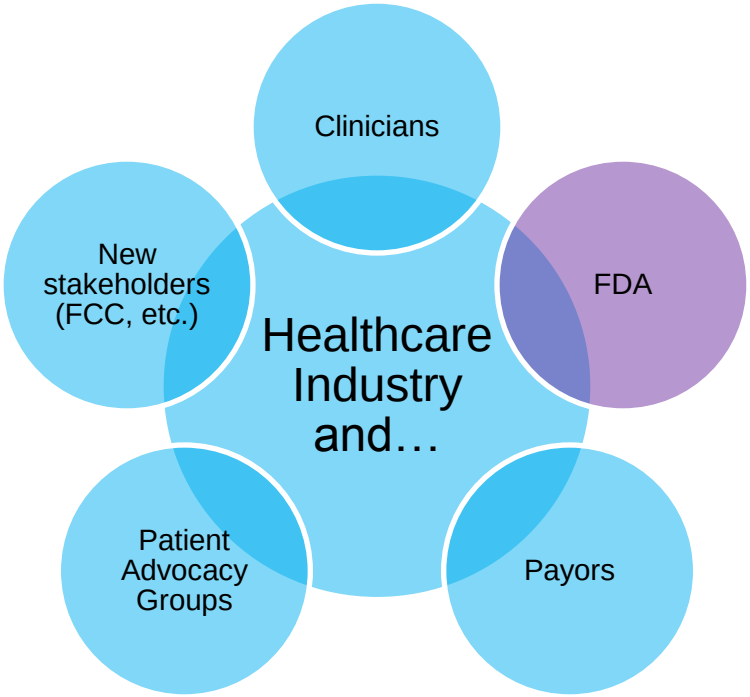

One example is between the Healthcare Industry and FDA

Regulatory Challenges as a Result of the New Healthcare Landscape

Medical discoveries are happening so quickly today, regulators like FDA are **having a hard time keeping up**

Advances in *regulatory science* have not been able to keep with the pace of scientific discovery, creating a need for collaboration to help regulators and to bring products to market faster

Industry & FDA: Collaborating to Advance Regulatory Science

What is Regulatory Science?	**Provides the tools, standards, and approaches needed to evaluate the safety, effectiveness, performance, and quality of medical products**
Potential Benefits Include	Ability to speed the rate of important technologies reaching market
	Reduces time and resources needed for device development, assessment, and review

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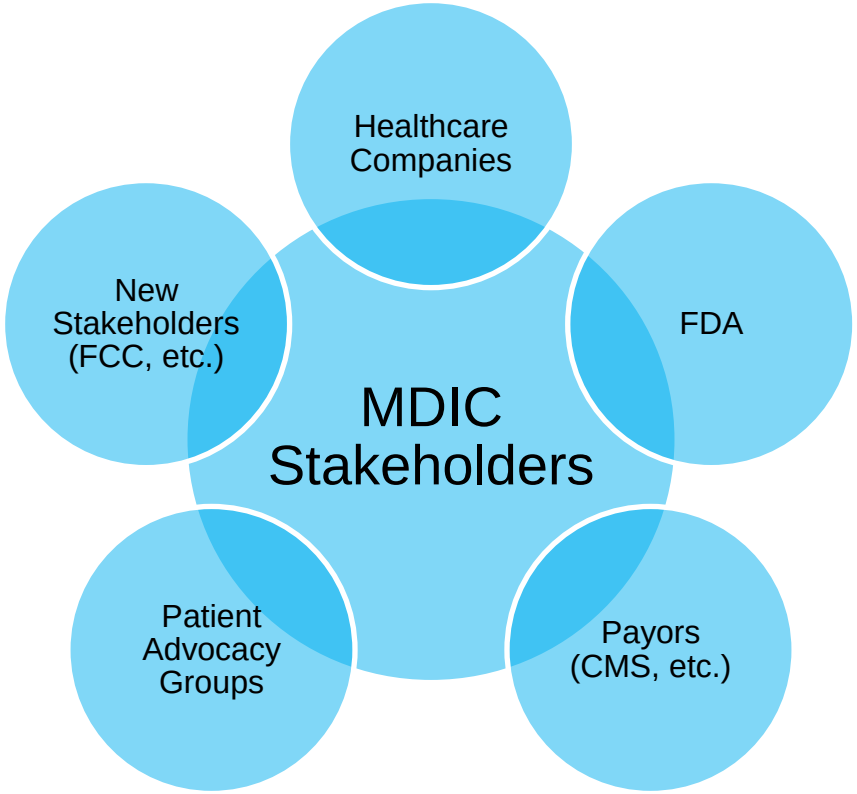
One Example of Industry and FDA Collaborating: the MDIC

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

What it is:

- First ever public-private partnership created with the **sole objective of advancing medical device regulatory science**



MDIC: Committed to Advancing Regulatory Science via Collaboration

MDIC's strategies support the organization's mission

"Create a **forum for collaboration** and dialogue, working within a flexible governance structure to encourage broad **participation from the medical device industry stakeholders, including non-profits, industry, and government**."

"Make **strategic investments in regulatory science**, utilizing working groups to identify and prioritize key issues and to request, evaluate, and implement project proposals that support the MDIC's mission."

"Provide tools to drive **cost effective innovation**, emphasizing education and the development of new methods and approaches with well documented data and details to enable implementation."

3 Major Projects at MDIC: Collaboration in Action

1. Computational Modeling & Simulation
2. Patient-Centered Benefit-Risk Assessments
3. Clinical Trial Innovation & Reform

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Approach

Publish MDIC Vision and Funding Priorities for Clinical Trial Innovation and Reform (CTIR).

- *Foundation for alignment on issues, causes, consequences and potential actions in support of investment decisions.*
- *Draws numerous 3rd party activities into dialogue for potential collaboration.*

Commission select activities in support of Vision and Action Plan.

- *Assess 3rd party request for funding vs MDIC vision. Fund either 3rd party or organic activities.*

Budget

Personnel	$ TBD pending allocation
Travel	$ TBD pending allocation
Supplies/Licenses	$ TBD pending allocation

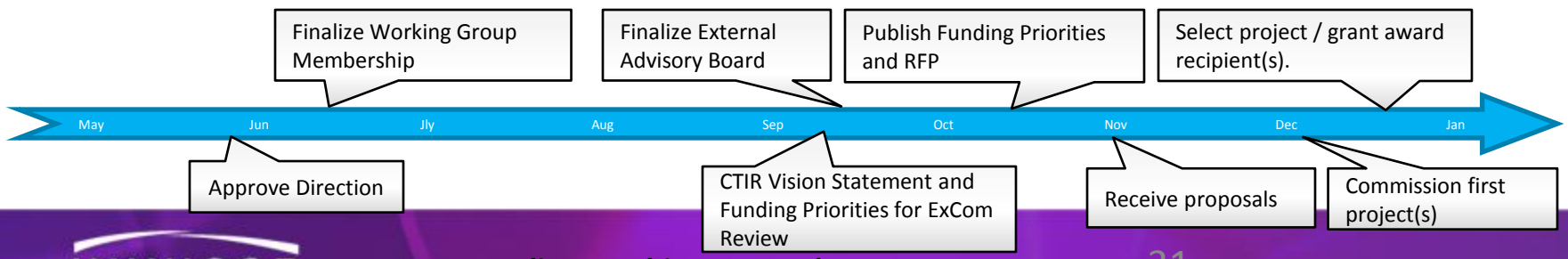
Structure

CTIR Steering Committee
Board Champion: Rick Kuntz, MD Medtronic
Co-Chair: Jeff Popma, MD
Program Manager: TBD
FDA: Bram Zuckerman, MD Kathryn O'Callaghan
NIH: TBD
Others

CY 13 Deliverables

- MDIC CTIR Vision Statement
- MDIC CTIR Funding Priorities
- Commissioning documents for initial project(s)

Timeline



Clinical Trial Innovation & Reform

Clinical trial innovation has the potential to **improve the safety and effectiveness** of products being introduced into the market and **yield earlier access** to beneficial innovative technologies for U.S. patients.

Clinical trials are **increasingly complex, expensive and slow,** and are increasingly performed outside the U.S.

The MDIC aims to **improve the efficiency of this clinical study process and drive a coordinated effort to fundamentally change the methodologies for clinical research** as necessary to restore the U.S. to a leadership role in establishing standards for clinical excellence and medical technology innovation and ensuring that the U.S. can support first-in-man timelines in the global clinical environment.

Collaborating to Accelerate Products to Market

Today, there are constantly **increasing requirements** for clinical evidence to bring products to market

Increasing Demands for High Quality Evidence

High quality evidence is increasingly required for all products in all geographies (US: more PMAs, higher quality 510k submissions)

Evidence of performance is demanded **over the life of the product** rather than on pre-market short-term performance

Evidence-based **requirements vary** country by country

Coverage / uptake is increasingly decided upon based on the presence or absence of high quality data

Collaborating to Accelerate Products to Market

Today, there are constantly **increasing requirements** for clinical evidence to bring products to market

To provide this evidence, **companies often need to invest heavily** in large, randomized, prospective studies

Evidence Needs to Demonstrate More than Simply "Does it Work?"

The **universe of stakeholders is expanding**. Broadened beyond the physician, lab tech, etc., and now includes others like: Hospital Administrators, Health Plan/Payors, Government Health Agencies, Patients and Caregivers

It is also necessary to **prove more than efficacy** and include considerations about economic metrics, the value proposition for health care systems, etc.

Finally, work needs to be done today **to account for as diverse a patient population as possible** (taking into account geography, ethnicity, genetic/phenotypic makeup, etc.)

The Cost of Getting This Evidence is Rising

The cost of obtaining high quality evidence to being products to market is **increasing exponentially**

The all-in cost for trials, etc. represents the **highest expense item** for all medical device manufacturers

It is not sustainable to meet the evidence demands of products that will address unmet patient needs and improve access to important global care solutions

Collaborating to Accelerate Products to Market

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To provide this evidence, **companies often need to invest heavily** in large, randomized, prospective studies

Concerns about the product's ability to perform over the long-term **threaten the positive impact** of introducing these products today

Sacrificing Speed-to-Market to Minimize All Risk

Regulatory requirements are not compatible with bringing new medical devices to market quickly

Regulators and the public have unrealistic expectations for pre-market studies for new products

As a result, **pre-market studies carry the burden of answering all important product questions**, thus delaying product releases and access to new technology

Collaborating to Accelerate Products to Market

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To provide this evidence, **companies often need to invest heavily** in large, randomized, prospective studies

Concerns about the product's ability to perform over the long-term **threaten the positive impact** of introducing these products today

Changes in clinical trial strategies are necessary to ensure the public benefits from breakthrough innovations as quickly as possible

Collaboration Between Industry and FDA

Agree on a structure that serves patients and satisfies the clinical research arena

- Develop a sense of urgency
- Acknowledge secular trends
- Achieve consensus on the goals of a product, satisfying current clinical research today without dwelling on the unknowns of future potential

Collaboration Between Industry and FDA

Evaluate new products with the total life cycle in mind

- Refocus from “pre-market – post-market” mindset to a total product life cycle mindset
- Perform rigorous analyses over the product life cycle, adapting as necessary
- Shift surveillance methods from passive reliance on voluntary complaints/issues and perform more active product analysis post-commercialization

Collaboration Between Industry and FDA

Adopt advanced clinical research methods to design studies

- Eliminate unnecessary large and burdensome randomized controlled trials
- Leverage programs that improve ease-of-use with large simple trials
- Adopt advanced observational methods where appropriate
- Advance new methods that simplify consent and review
- Participate in the open science revolution to gain trust and stakeholder engagement in clinical research

Collaboration Between Industry and FDA

Consolidate stakeholder efforts

- Open Industry-FDA-patient collaboration to meet this goal
- Consider paralleling execution of pre-clinical requirements that reduces time consuming analysis, reporting and processing
- Better use of computational modeling
- Development of agile safety systems that allow external objective oversight and quick actions

Conclusion

The Healthcare Model is Changing

- Healthcare delivery is in the midst of **significant change**
- Macro changes from the **Affordable Care Act**, **reimbursement pressure** and **increased regulatory oversight** are a few of the major challenges underway
- Meanwhile, consumer-patients are becoming more sophisticated and are making **more informed healthcare decisions**

Innovation Will Continue to be the Lifeblood of Our Industry

- Healthcare has a **rich history of innovation**, which has come from clinicians, academic researchers and OUS sources.
- Our industry has thrived as these innovations have led to **meaningful improvements in healthcare outcomes.**

Collaboration With Industry and Stakeholders will Unlock Value

- We must be ready to find ways **to collaborate with a wide range of stakeholders, especially regulators** to capitalize on these changes, exploit new market opportunities and drive growth

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Thank You

IMMUCOR

Break

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Georgia Tech Research Institute

Panel: Obstacles & Opportunities in Academic & Industry Device Collaborations

Grace Powers, C.R. Bard, Inc.

Ravi Bellamkonda, PhD, Georgia Tech/Emory University

Lou Malice, Luma Strategies, LLC

Todd Sherer, PhD, Emory University

Lilly Immergluck, MD, FAAP, Morehouse School of Medicine/
Children's Healthcare of Atlanta

Moderator: Tiffany Karp, Global Center for Medical Innovation (GCMI)

Break

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CiDrep INFORMATICS

Georgia Tech Research Institute

Success Story:
Institutional Collaborations

Atlantic Pediatric Device Consortium

Wilbur A. Lam, MD, PhD

Assistant Professor
Department of Pediatrics
Division of Pediatric Hematology/Oncology
Emory University School of Medicine
Wallace H. Coulter Department of Biomedical Engineering
Georgia Institute of Technology and Emory University

Co-founder and Chief Medical Officer
Cellscope, Inc.

Georgia Tech
Wallace H. Coulter Department of Biomedical Engineering
at Georgia Tech and Emory University
EMORY UNIVERSITY
Aflac Cancer & Blood Disorders Center
CHILDREN'S HEALTHCARE OF ATLANTA

Atlantic Pediatric Device Consortium

The Atlantic Pediatric Device consortium is an FDA funded consortium whose mission is to enhance the lives of children through the development of novel pediatric medical devices, which are both safe and effective.

Georgia Tech

Children's Healthcare of Atlanta

EMORY UNIVERSITY

Pediatric Device Consortia Grant Program

MEDICAL DEVICES FOR CHILDREN

Food and Drug Administration

Atlantic Pediatric Device Consortium

- **Provides a national platform to translate ideas through the product development pathway all the way to commercialization.**
- **Fosters an environment of creativity, where innovative ideas will be reviewed, tested and developed.**

Executive Committee

David Ku, MD, PhD
Barbara D. Boyan, PhD
Kevin Maher, MD
Wilbur Lam, MD, PhD
Franklin Bost, IDSA, MBA

Georgia Tech

Children's Healthcare of Atlanta

EMORY UNIVERSITY

Pediatric Device Consortia Grant Program
MEDICAL DEVICES FOR CHILDREN
Food and Drug Administration

Goals

- Establish infrastructure for technology development.
- Develop, produce and assist in commercialization of medical devices that address unmet clinical needs for the pediatric population (neonate through adolescent).
- Connect existing clinical, engineering and inventor and funding resources for development of devices for pediatric healthcare, diagnosis and treatment.
- Foster an environment of creativity, where innovative ideas will be reviewed, tested and developed.
- Seek external resources for Consortium's sustainability.

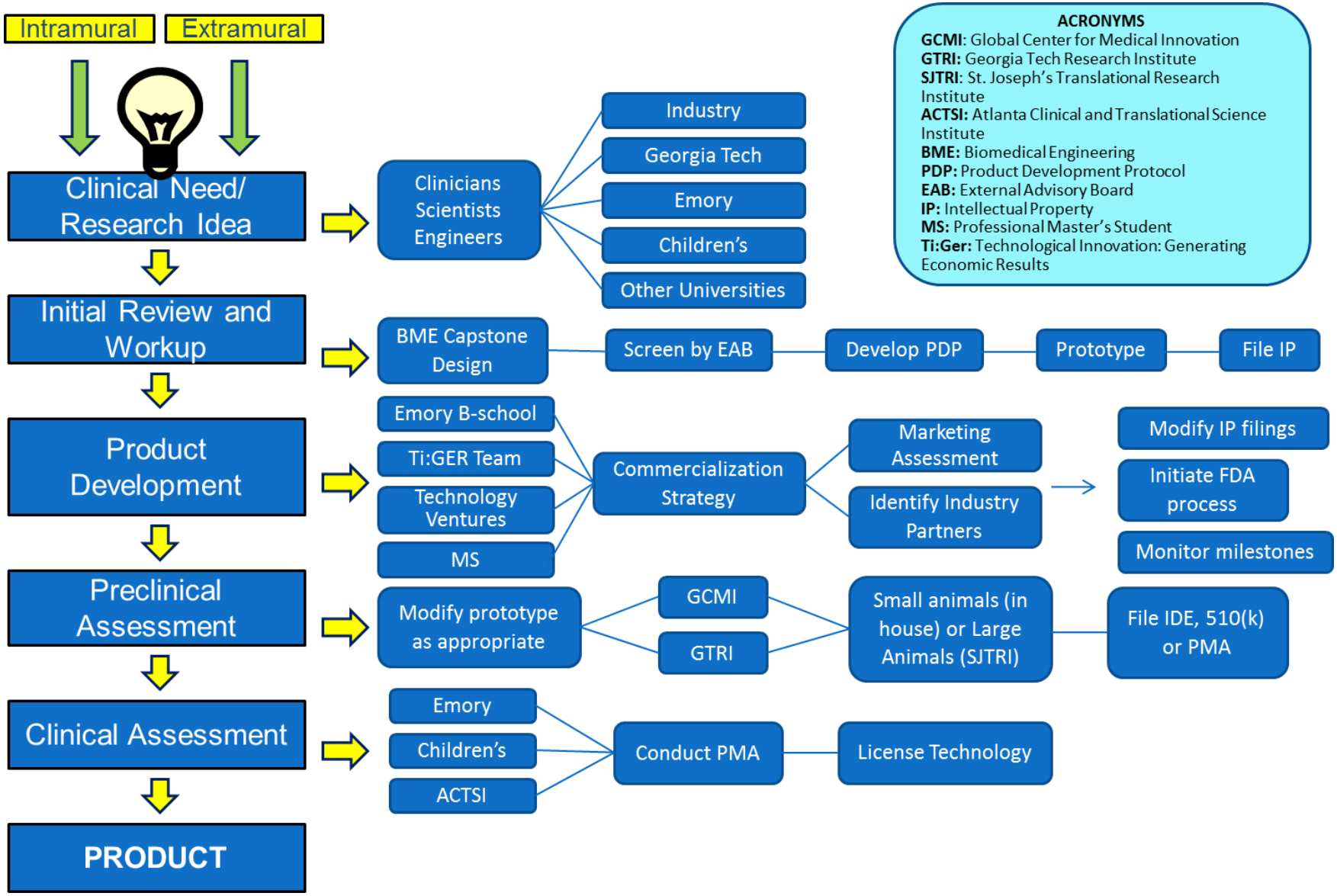
Our Local Partners

- Access to renowned Engineers from a top ranked university.
- Advanced Technology Development Center (ATDC) biotechnology company incubator
- Georgia Tech Research Institute (GTRI)
- Global Center for Medical Innovation (GCMI)
  - Good manufacturing practice (GMP) production

- The largest pediatric hospital in the United States
- Access to thousands of patients
- Help identify clinical needs

- Access to a world class Medical School
- Hosts our Biostatistics Core
- Hosts our Marketing Core
- Atlanta Clinical and Translational Science Institute
- T3 labs (formerly STJRI) - Good Laboratory Practices (GLP) certified animal research facility.
- Phase 1 clinical trials lab

Key to Success:
Product Development Pathway



Atlantic Pediatric Device Consortium

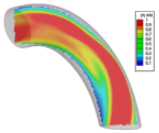
APDC Industry / Small Business Projects

- Sensiotec – Virtual Pediatric Assistan

- AI Medical Devices, Inc. - Pediatric FlexBlade

- Splash Medical Devices, LLC - Easiear

- PECA Labs - A Valved Conduit for the Norwood Procedure



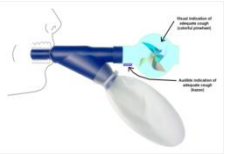
- Double Balloon Catheter for the Treatment of Intussusception

Atlantic Pediatric Device Consortium

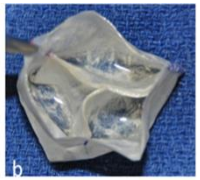
APDC Industry / Small Business Projects

- Cellscope – Cellscope Oto

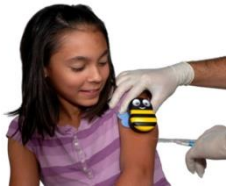
- MD Innovate – PneumoKazoo



- Corematrix – Prosthetic Tri-leaflet Valve



- MMJ Labs, LLC - Buzzy

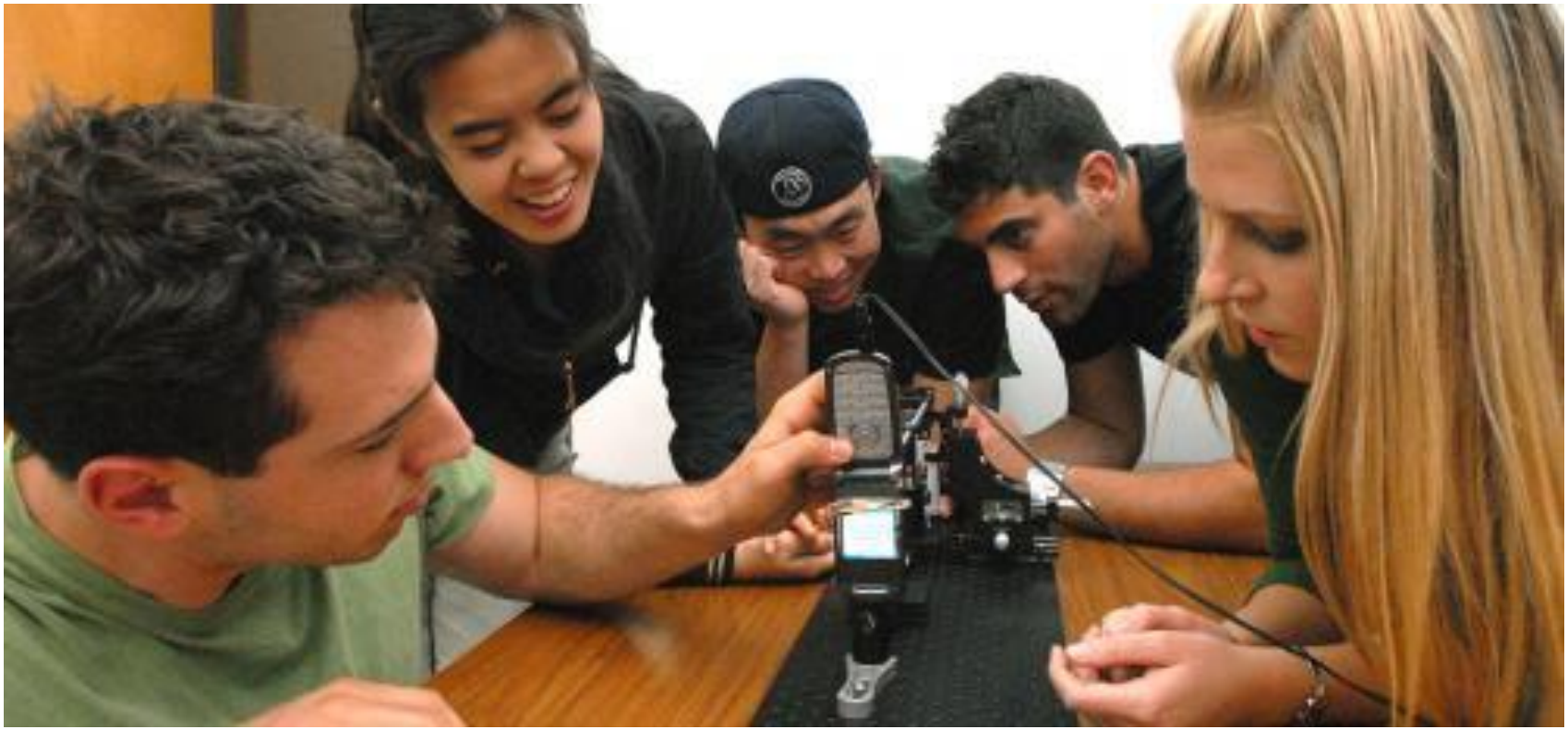


- ICON Interventional Systems – Biosorbable Pediatric Stent

- Cnicus - SureTube

2006

teaching optics to bioengineering undergrads…

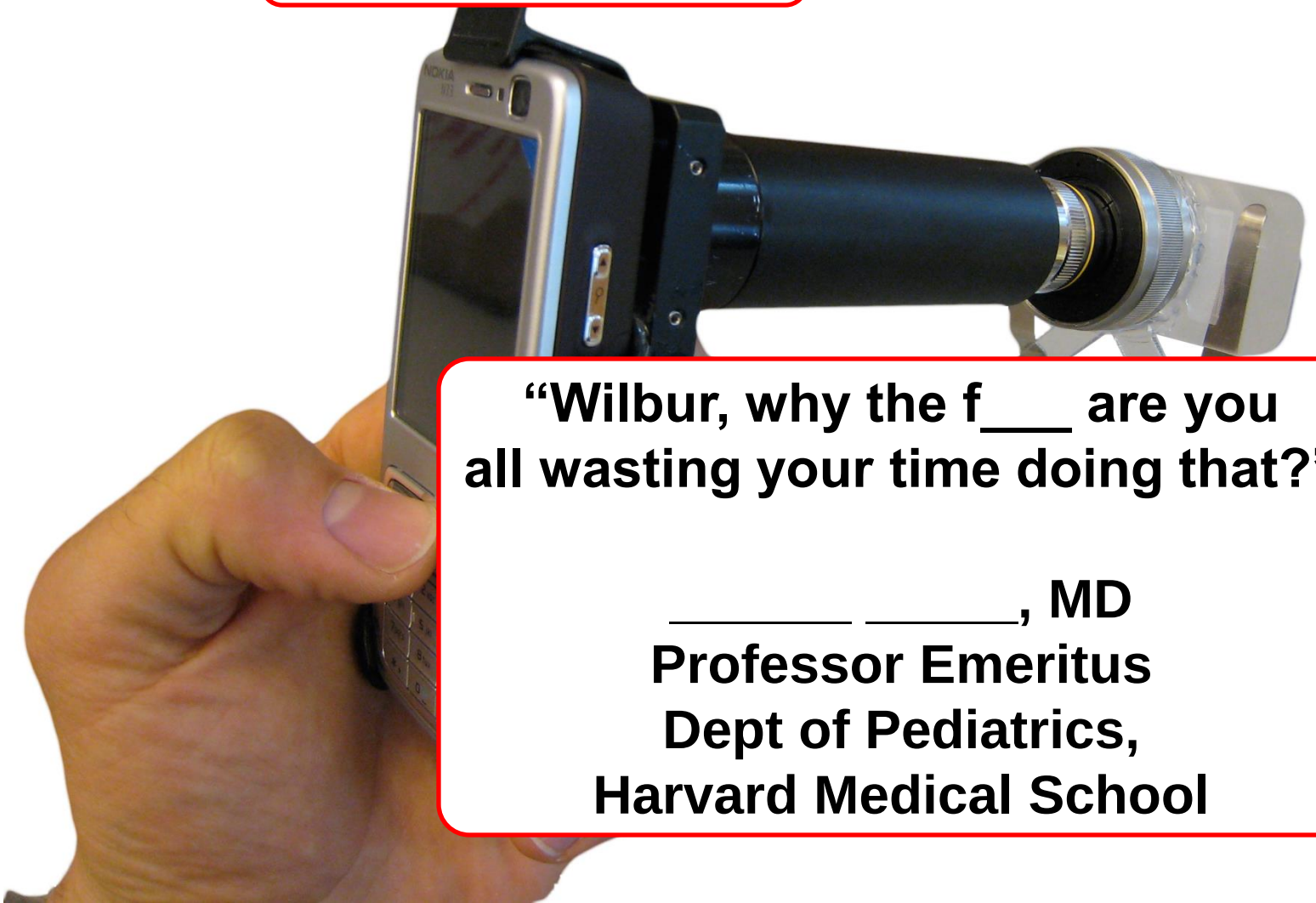


2008

Georgia Tech

2008

OK, but now what?



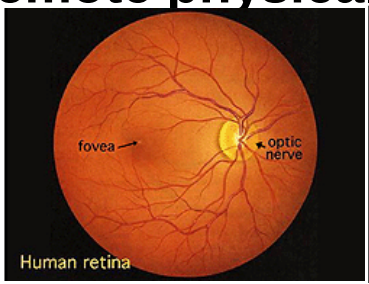
"Wilbur, why the f___ are you all wasting your time doing that?"

_____ _____, MD
Professor Emeritus
Dept of Pediatrics,
Harvard Medical School

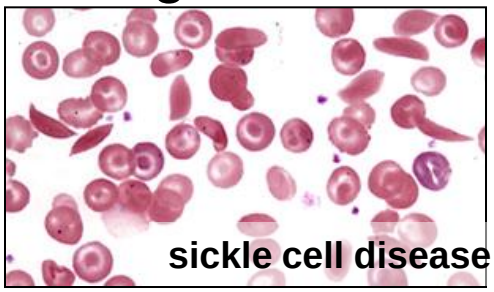
Potential telemedicine applications for the CellScope

2008

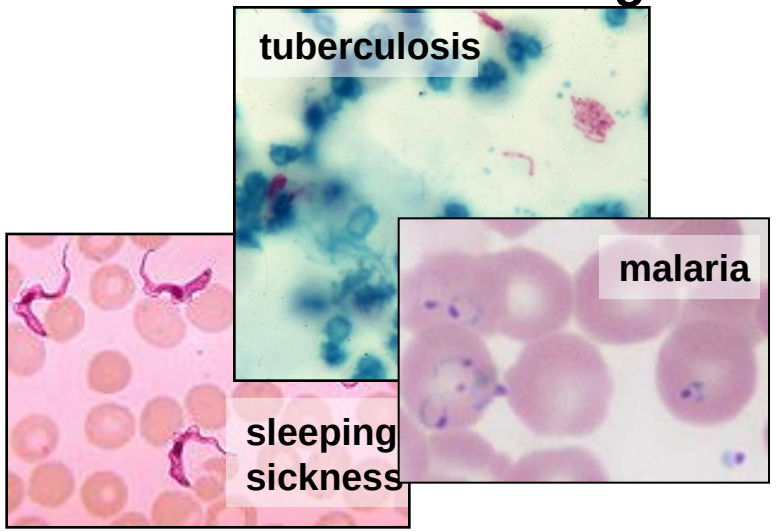
remote physical examination



screening for blood diseases



infectious disease diagnosis

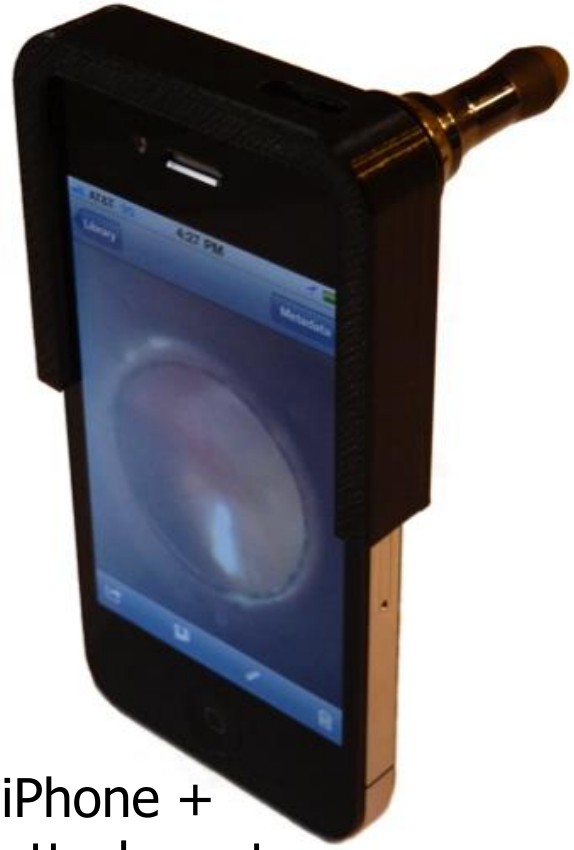


Goals:

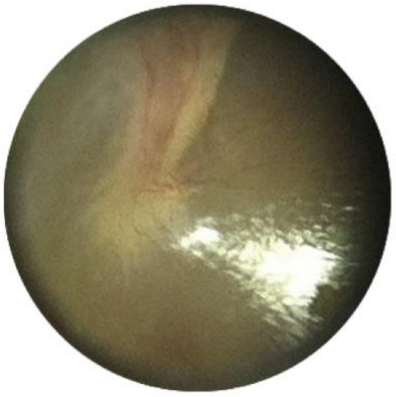
1) Address unmet clinical need
2) Rapid adoption to practice
3) Broad impact

with the advent of the smartphone, Cellscope Inc. was formed….with no $ yet

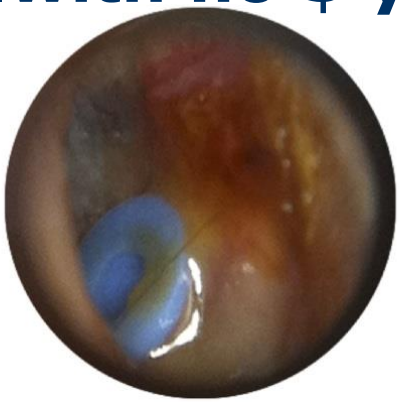
2010



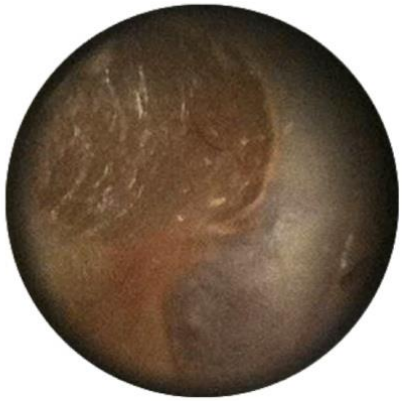
iPhone +
attachment
+ custom app by GTRI



Healthy TM

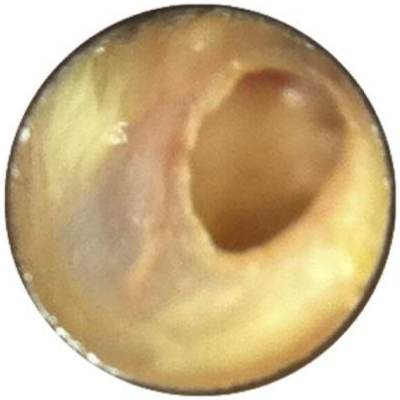


Infection and tube

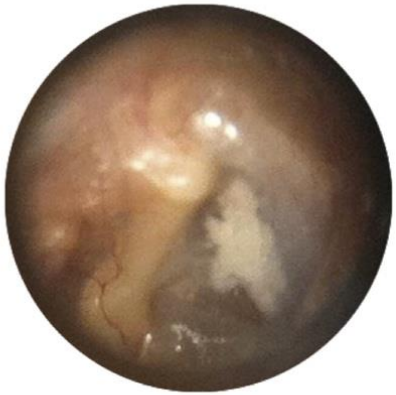


Infection and scarring

Healthy TM



Perforated TM



Infection

Ear infections (acute otitis media):

- 16 million pediatric encounters per year
- $3 billion dollar health care costs per year
- most frequent emergency room pediatric diagnosis

funding CellScope

2011

khosla ventures

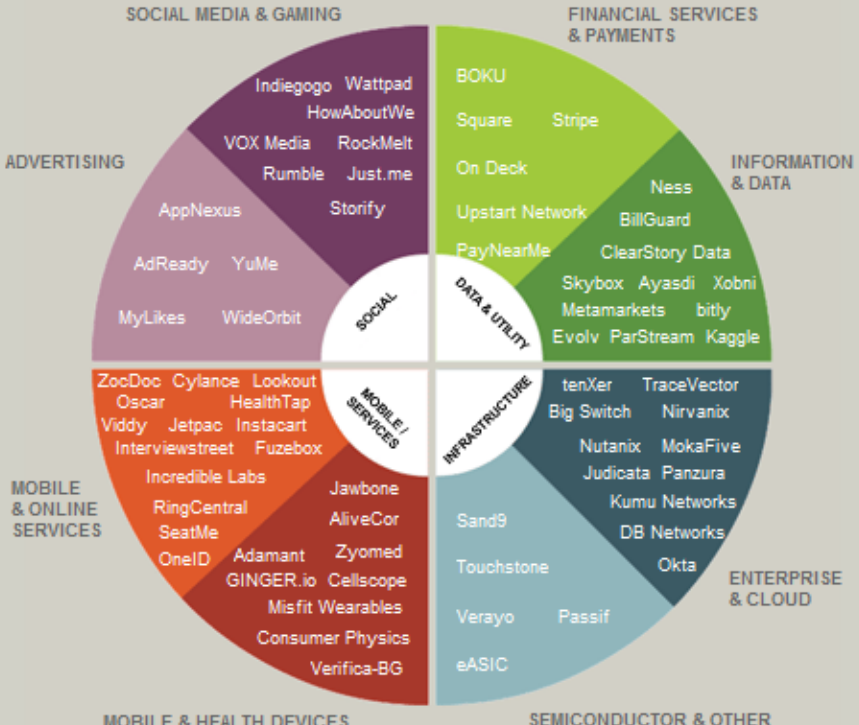
venture assistance, strategic advice, venture capital

contact us | careers | khosla impact

information technology
sustainability
case studies

our focus: assisting entrepreneurs | our people & us | what we look for | our portfolio | entrepreneurial resource

portfolio: information technology



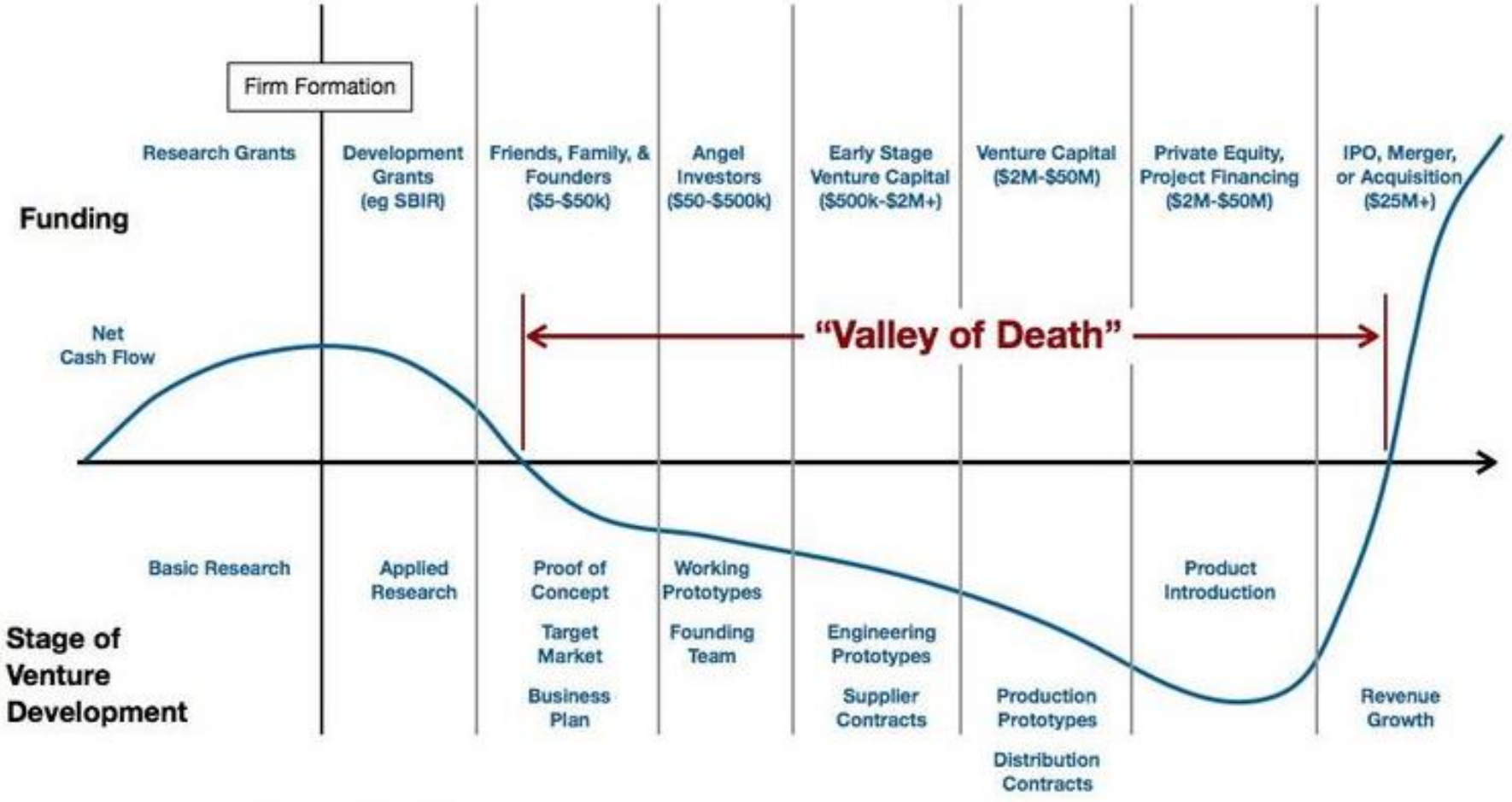
Cellscope

CellScope builds systems for at-home disease diagnosis using smartphone cameras connected to a web platform

- initially funded by ACTSI and then APDC
- enabled seed funding from Khosla Ventures, but it wasn't easy…

entering the deepest depths of the valley of death…

Forbes, 2013



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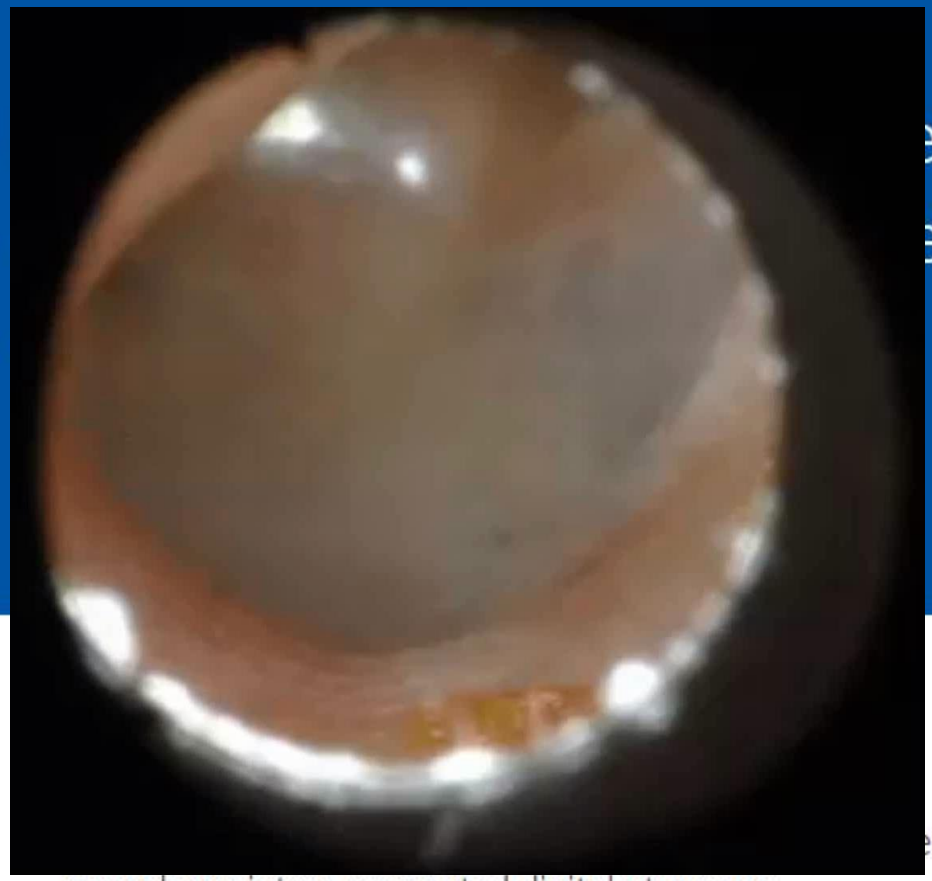
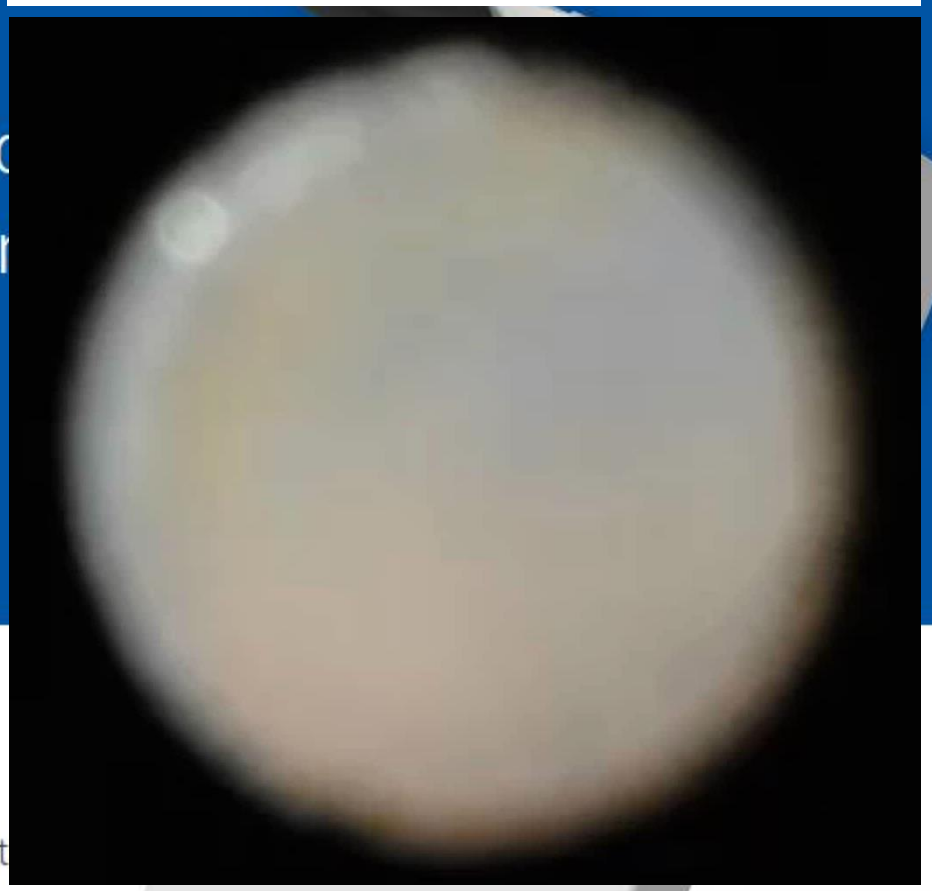
cellscope COMPANY PRESS BLOG CONTACT

2013

normal ear	infected ear





your phone into a connected digital otoscope.

A Combination of Sleek Hardware and Smart Software

received Round A funding

completion of clinical assessment study at Children's Healthcare of Atlanta

Kathryn Rappaport, MS4
Emory Medical Student
Discovery Project

Andi Shane, MD, MPH, MSC
Pediatric Infectious Diseases
Emory/CHOA

- 63 pediatric patients diagnosed with ear infection in ER
- physician panel detected no difference in image quality between CellScope Oto and camera-fitted conventional otoscope

ongoing activities:

- distributing current prototypes to pediatricians
- assessing change in practice patterns for ear infection management
- assessment as training tool (residents, medical/nursing students)
- incorporating data/images into CHOA's electronic medical records

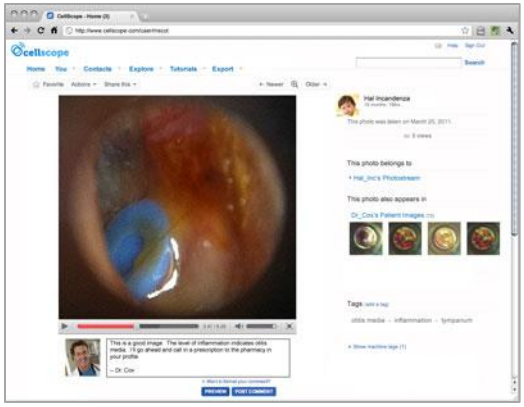
long term goal: remote diagnosis of ear infections

1

Parent uses CellScope Oto to snap photo or take HD video of eardrum.

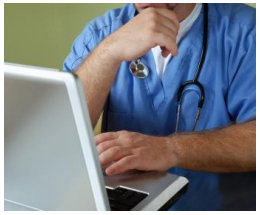
2

Seamless upload of images/videos & other clinical information to HIPAA-compliant web platform.



3

Incorporation of data into patient's EMR. Remote provider views image and develops management plan.



CellScope's current challenges

- business model at whim of investor
- currently lacking bandwidth to investigate new applications for cell phone-enabled diagnoses
- conflict-of-interest issues may impede scientific publications and academic progress
- even when academic/industry agendas align, timelines often do not

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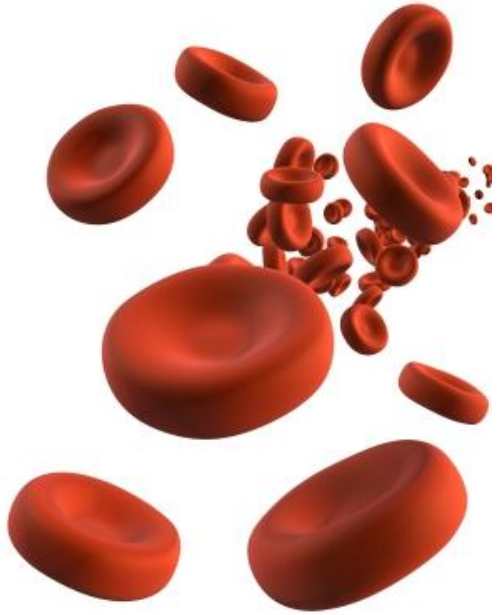
AnemoCheck – what is anemia?

- anemia = low hemoglobin levels
- affects 2 billion people worldwide
- major consequences for health and social and economic development
- occurs at all stages of life, more prevalent in pregnant woman and young children
- nutritional deficiencies (e.g. iron) → most common cause



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populations at risk for anemia in US

Demographics	Population Size in US
>60 years of age	57,000,000
pregnant females	6,000,000
chemotherapy patients and chronic kidney disease (severe) patients	2,700,000
patients with chronic hematologic diseases and immunologic diseases at risk for chronic anemia	5,500,000
infants, pre-school, elementary school children	12,500,000
TOTAL	**83,700,000**

patients with chronic anemia

Primary hematologic disease • Sickle cell disease • Thalassemia • Immune-mediated hemolytic anemia • Bone marrow disorders • Leukemia
Immune system disease • Systemic Lupus Erthymatosis • HIV • Rheumatoid arthritis
Cancer patients undergoing radiation and chemotherapy
Chronic kidney disease/dialysis patients

- Currently require frequent monitoring
- Patients may develop acute severe anemia that could be life-threatening

global health and anemia

- In developing countries, anemia affects >40% of young children and women
- the Big Three global health threats (HIV, tuberculosis, malaria) all cause anemia
- malaria → acute severe anemia is a major cause of mortality
- Lack of medical resources → diagnosing and screening for anemia is cost prohibitive

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problem: current diagnostic method for anemia

- standard test for anemia is a complete blood count (CBC) via a hematology analyzer

- current CBC systems are:
  - expensive
  - electronic
  - only found in clinics & hospitals, not home use
  - requires a skilled technician to draw blood and process the sample

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proposed solution: AnemoCheck

Erika Tyburski, BS
BME GT
Senior Capstone Project

- color-based test for hemoglobin levels in single drop of whole blood
  - simple
  - rapid: results in less than 1 minute
  - patient/parent-operated
  - inexpensive: currently costs $0.25/test
  - standalone: does not require additional equipment (reader) or electrical power
  - disposable
- funded by CHOA, APDC (FDA), Georgia Center of Innovation for Manufacturing, and Georgia Research Alliance since 2012

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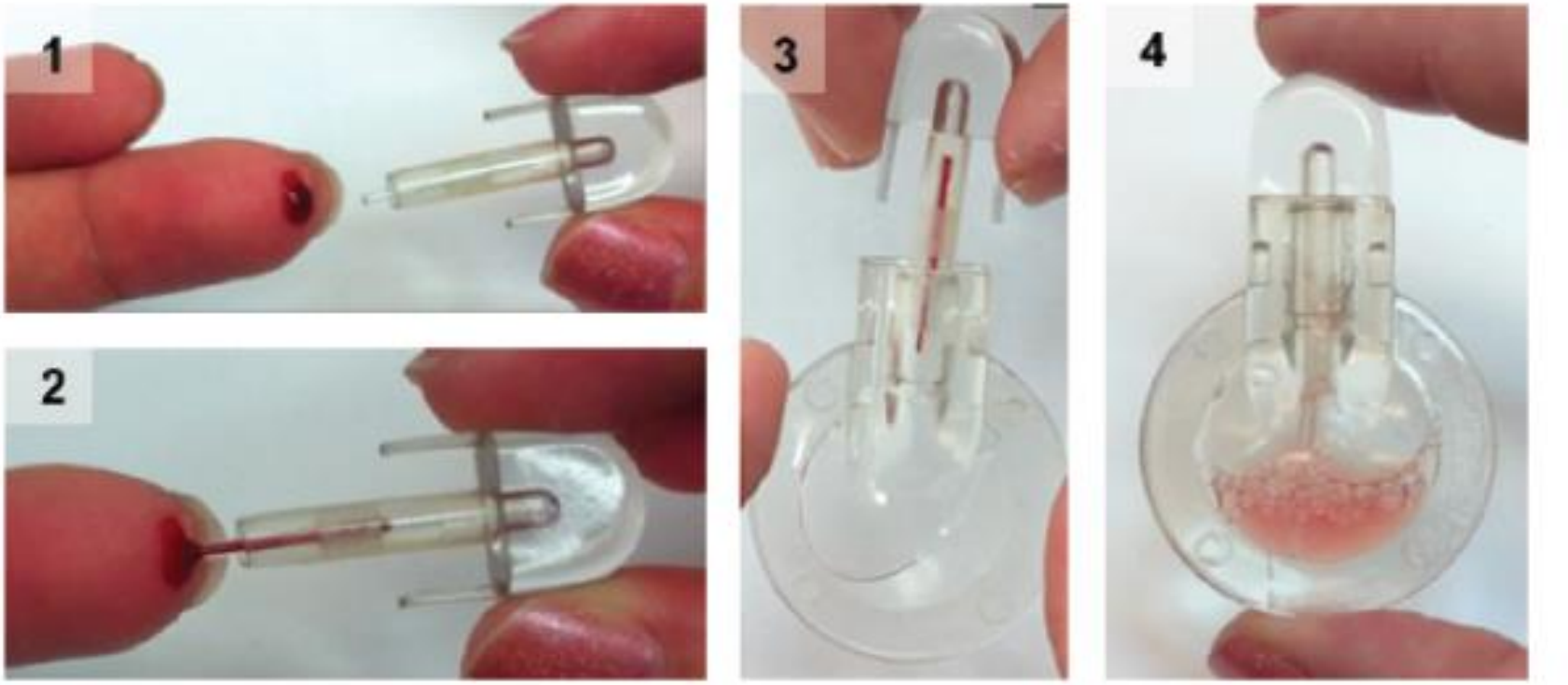
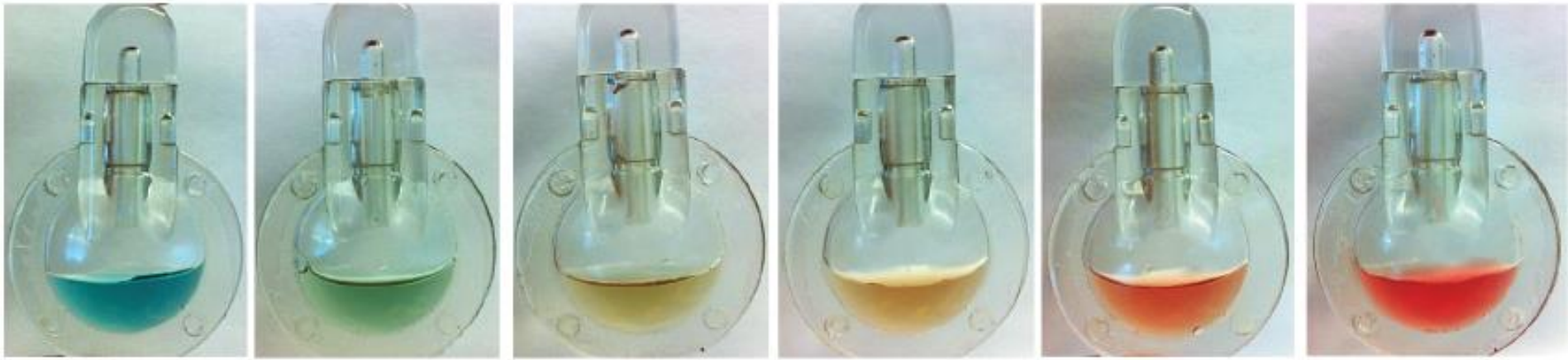
AnemoCheck



prototype developed in collaboration with GCMI

AnemoCheck results



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demonstration of the AnemoCheck

8.0 g/dL **11.5 g/dL** **15.1 g/dL**

hemoglobin levels of each sample

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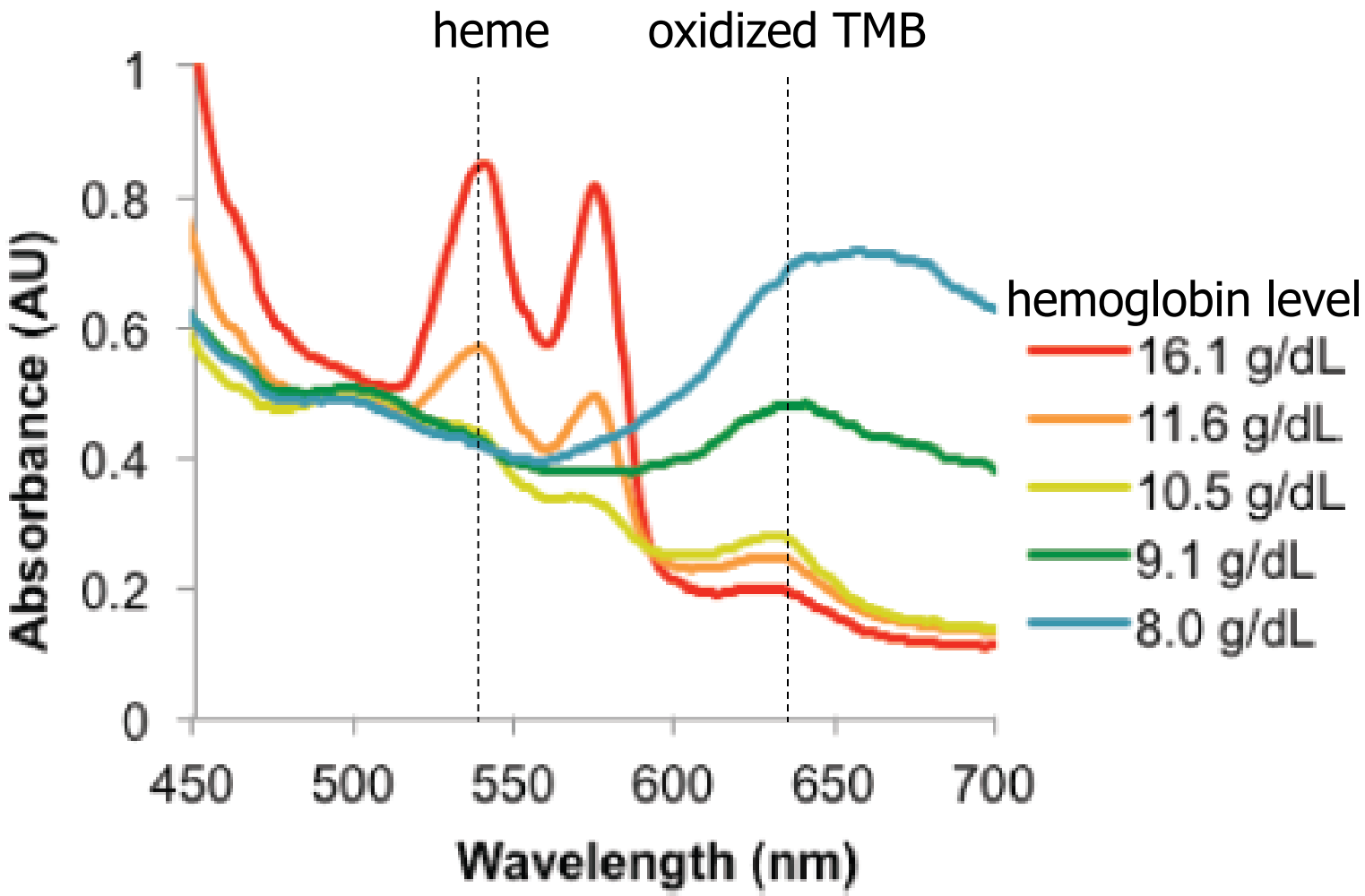
how does the system work?



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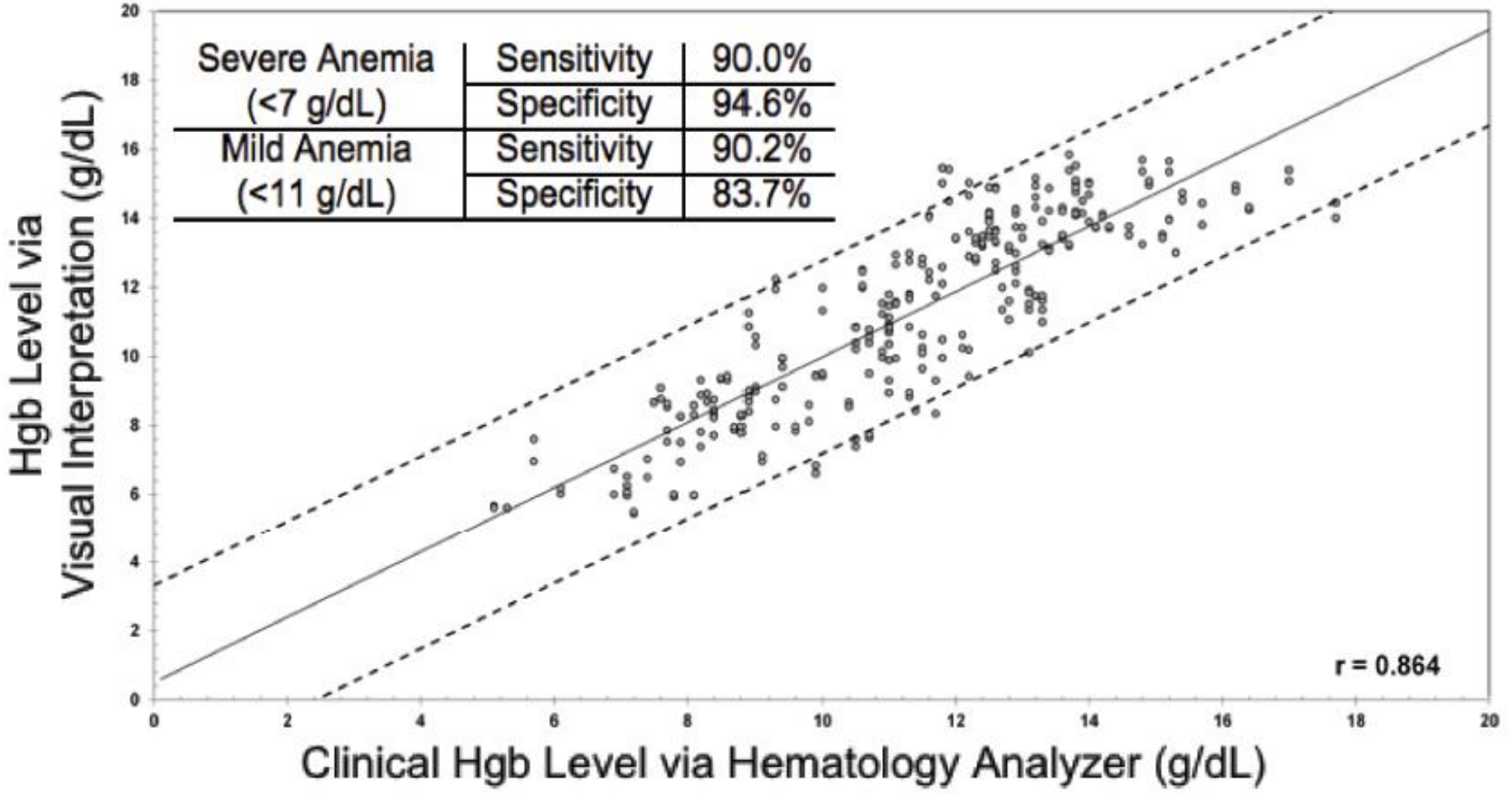
clinical assessment at CHOA and Emory comparing AnemoCheck visual interpretation vs. clinical CBC



n = 238 patients with anemia of different degrees and causes

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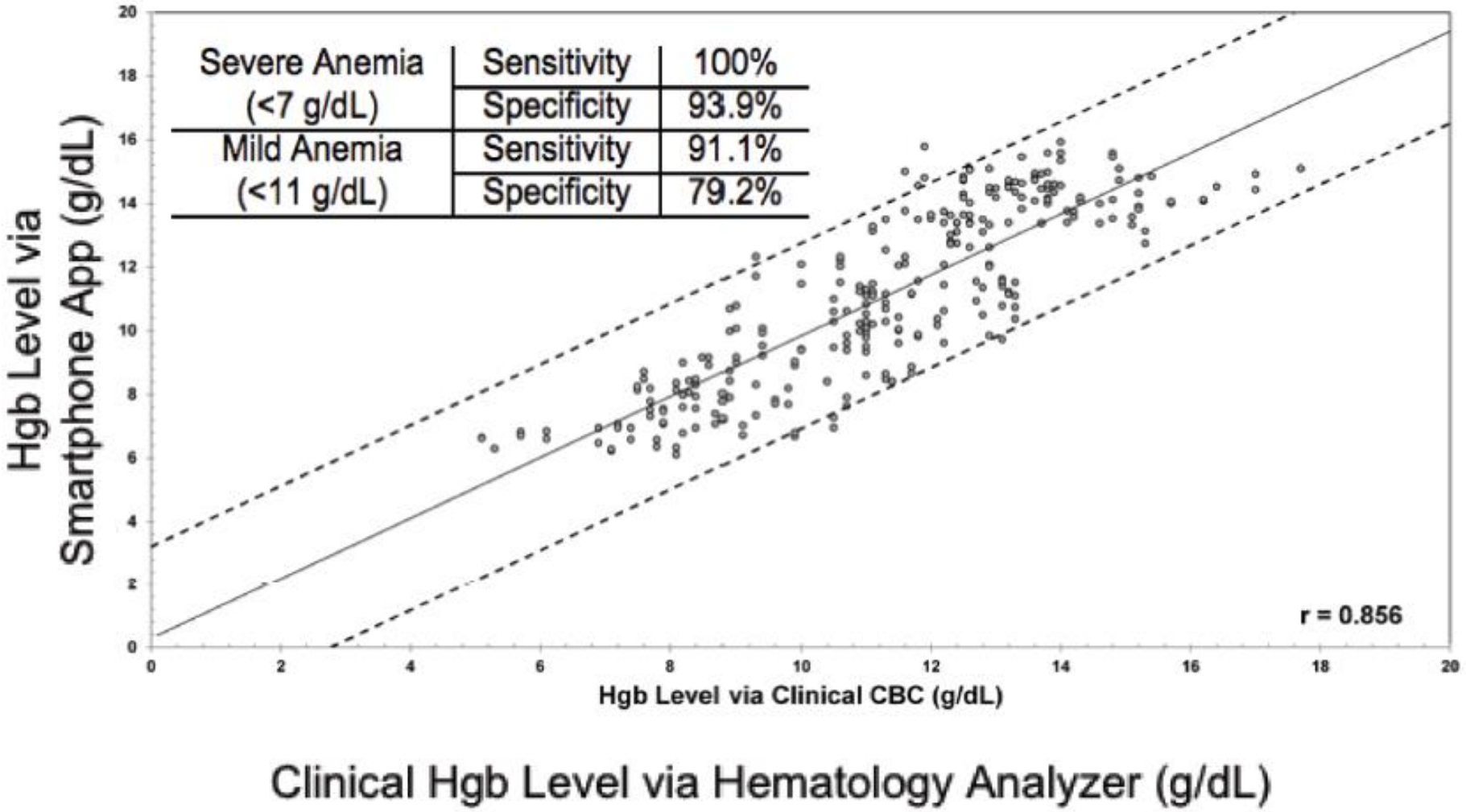
clinical assessment at CHOA and Emory comparing optional custom smartphone app vs. clinical CBC



n = 238 patients with anemia of different degrees and causes

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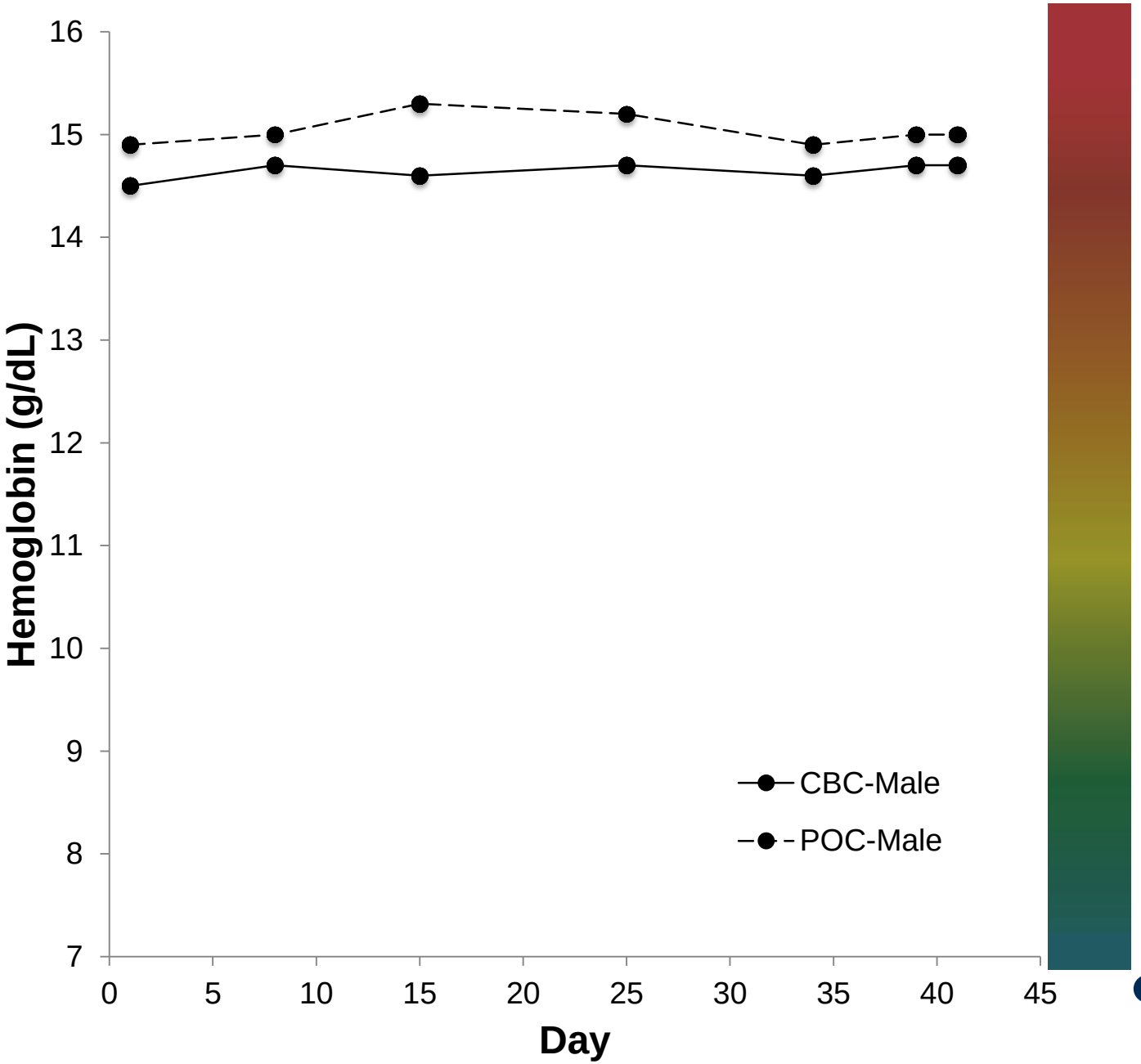
serial AnemoCheck measurements over 45 d



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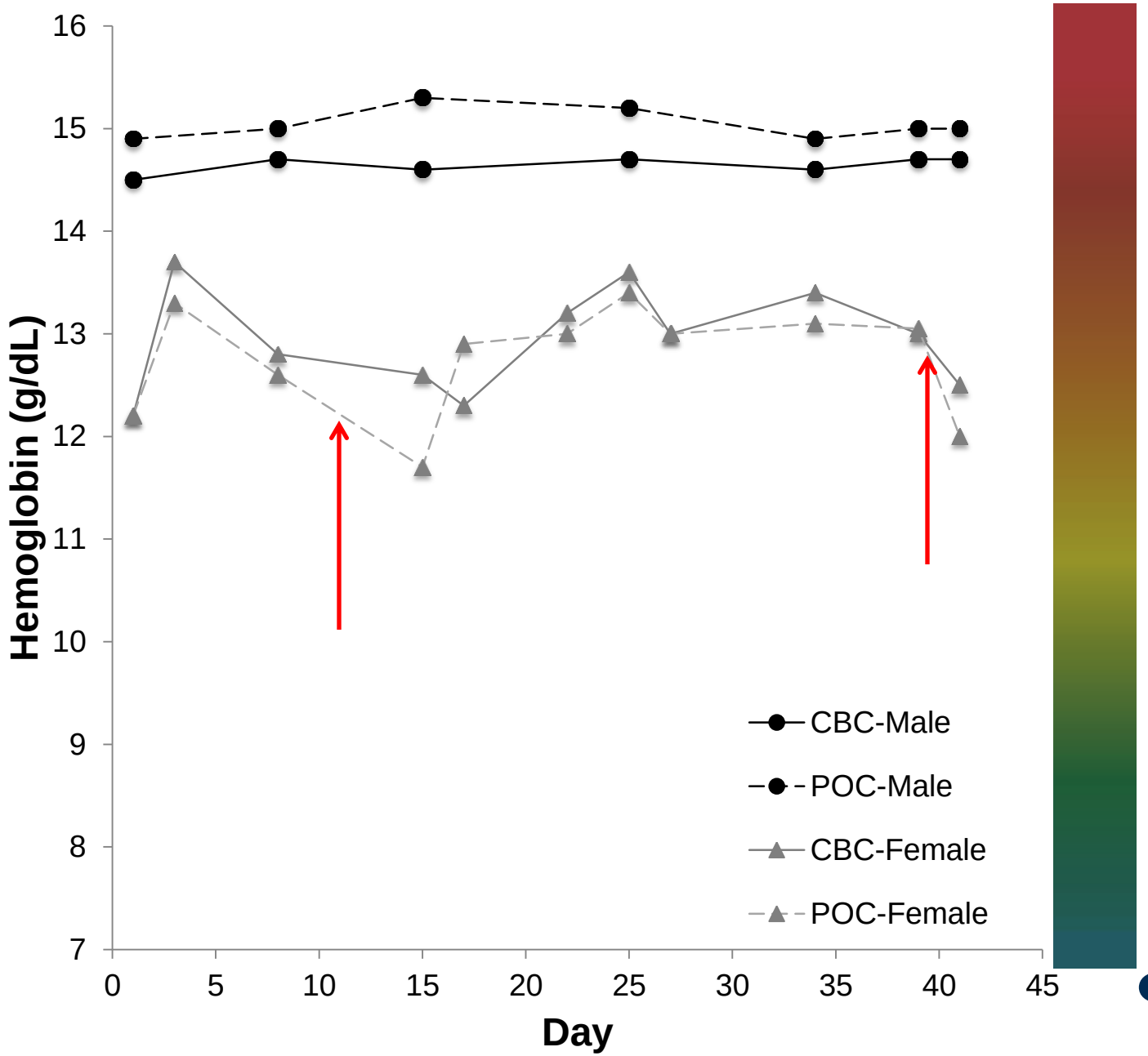
serial AnemoCheck measurements over 45 d



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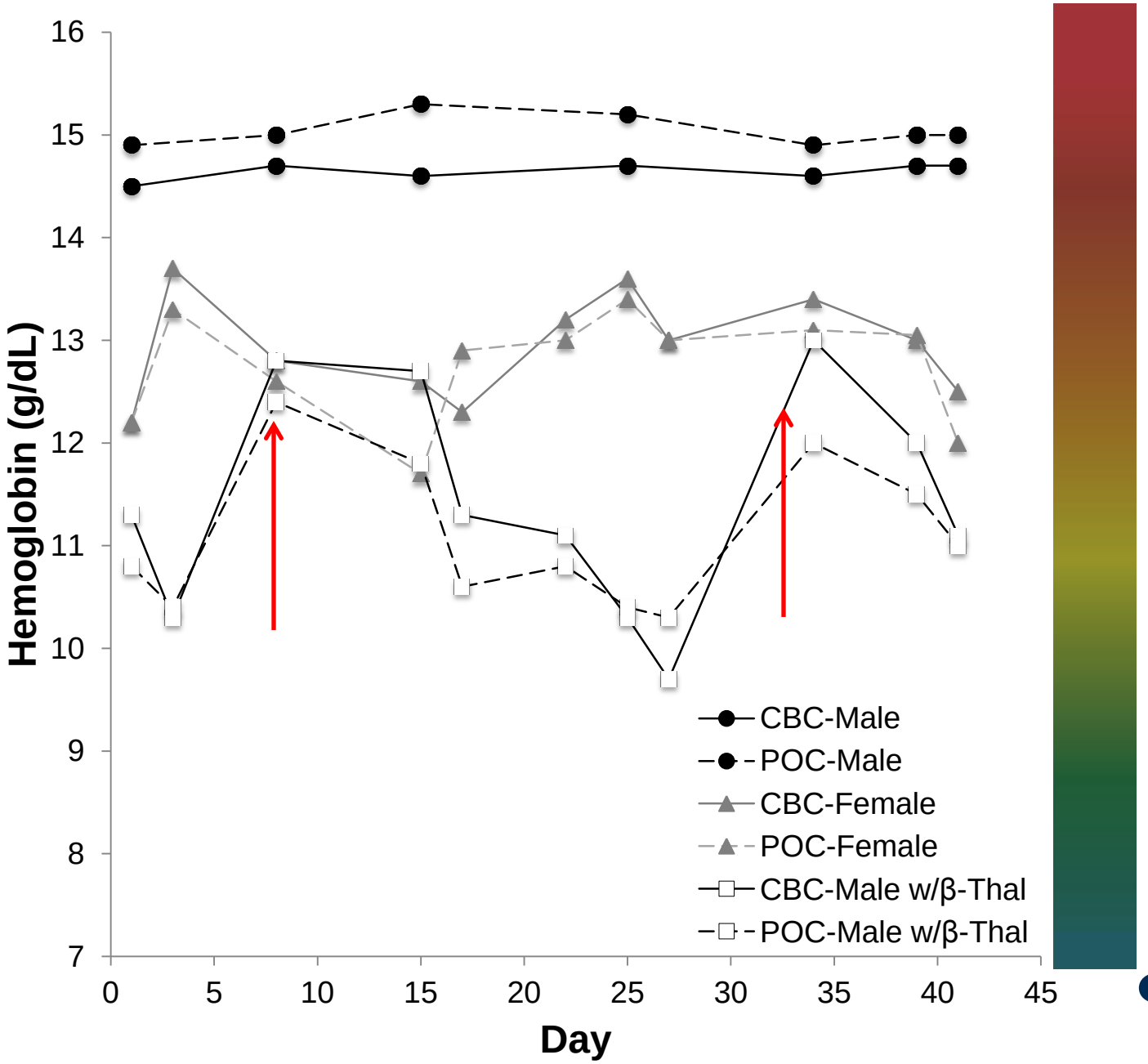
serial AnemoCheck measurements over 45 d



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how would the AnemoCheck be used?

1. Anemia self-screening for adults and children
2. Self-monitoring of anemia for patients with chronic diseases.
3. Inexpensive alternative to CBCs in resource-poor or global health settings

- scientific manuscript under review
- IP – Emory OTT filed worldwide patent rights (PCT) – expires 2/2015
- working with GRA-assigned business consultant
- meeting with regulatory consultants and IP lawyers
- about to enter the "Valley of Death"

acknowledgements

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- Jeanne Boudreaux, MD

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