



# *Unlocking Biomarker Discovery to Transform Medicine*



*Swedish Embassy  
May 7, 2010*

**Stockholm  
November 11, 2020**

**Larry Gold  
SomaLogic, US**





## Flow for This Talk

What I did last May in Washington at the Swedish Embassy  
(which led to my being invited to come today)

What SomaLogic (and previous related companies)  
accomplished

How SomaLogic is building its business

What SomaLogic and Sweden might consider doing...

Summary: How “SomaSweden” might lead a healthcare  
revolution toward Personalized and Evidence-Based Medicine

***Note: This is not a technical talk, but all the ideas are  
supported by an immense amount of data...***



## What You Read about What I Would Say

“At what stage can one diagnose disease? Can one diagnose serious diseases before the onset of symptoms? Can early diagnosis positively alter outcomes? Can early intervention lower healthcare costs?

Professor Larry Gold is specially invited to give us an overview of the development of biomarkers and their many uses. He will describe a new platform for rapid biomarker discovery and the first products that allow early detection of serious diseases. Through analysis of a few case studies, he will argue that biomarker discovery positively impacts all elements of healthcare, from pharmaceutical research through quality of life.”

*And all of this is right...even though I didn't write it...in my talk last May at the Swedish Embassy I proposed SomaSweden and I want to more fully explore that idea today*



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## SELEX and Aptamers Were Invented in 1990

The technology was invented by Craig Tuerk and me in 1990 – the technology can be used for therapeutics, diagnostics (blood tests, pathology, and *in vivo* imaging), and basic science research

Many companies have improved the technology – **Archemix, Becton Dickinson, Eyetech, GSK, Gilead, Merck AG, NEC, NeXstar, Otsuka Pharmaceuticals, Pfizer, Schering AG, SomaLogic, Quest Diagnostics**

Many universities have improved the technology, including Harvard, University of Colorado, University of Texas, Yale

Almost 4,000 papers have been published, and probably more than 600 patents have been issued or submitted

More than \$2B was spent developing the applications (**and most of this has been through my efforts**)



## SOMAmers (*improved aptamers*) and Diagnostic Applications

The major, unique applications of the improved technology are for diagnostics – biomarker discovery, blood tests, pathology, and *in vivo* imaging

No other technology allows biomarker discovery in a robust manner – many billions of dollars have been spent on alternative strategies and ***no powerful platform has emerged***



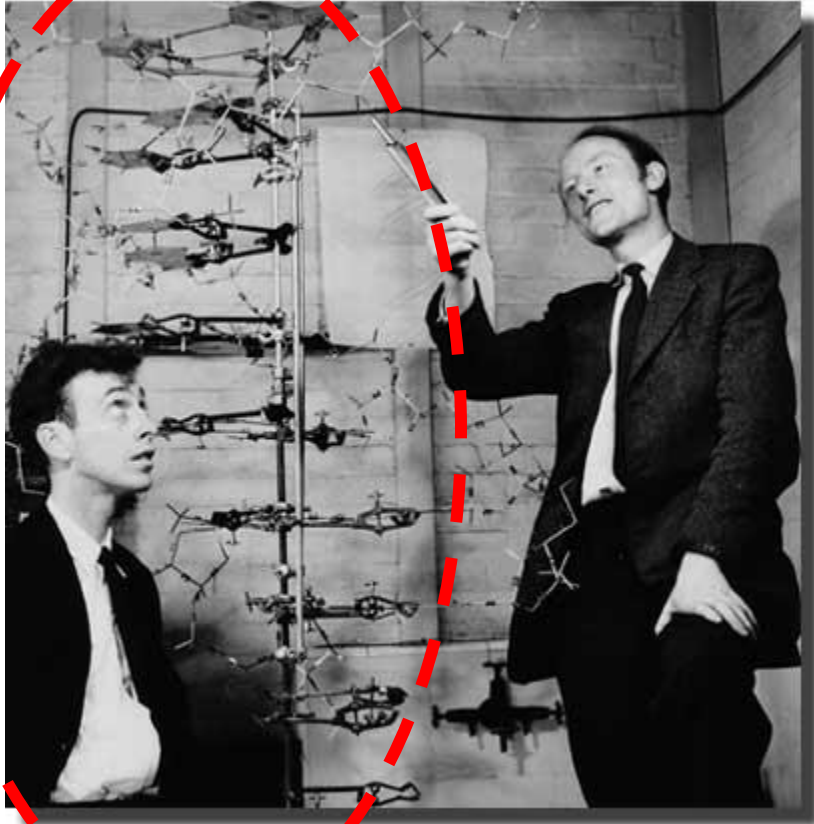
## **SomaLogic Has Worked for More than a Decade to Do Proteomics Aimed at Extant Disease**

**We figured out how to measure many human proteins at once, using only a drop of blood, to identify and stage early stage disease – many circulating proteins are disease biomarkers**

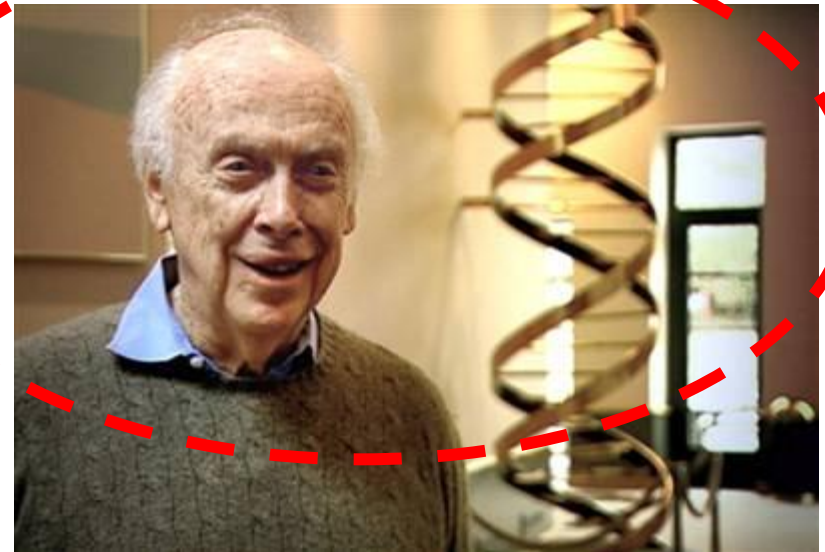
**We do proteomics, not genetics (which are largely about the risk of disease rather than its presence)**

**Imagine BRCA mutations in women – for those women the annual incidence of getting breast or ovarian cancer is 1% (while for other women it is 0.1%) and that knowledge is barely actionable (and this is a strong genetic marker)**

**When a healthy child is born, the DNA in that child is largely the DNA present in the older person that child becomes (this is an exaggeration, but a small one)...**

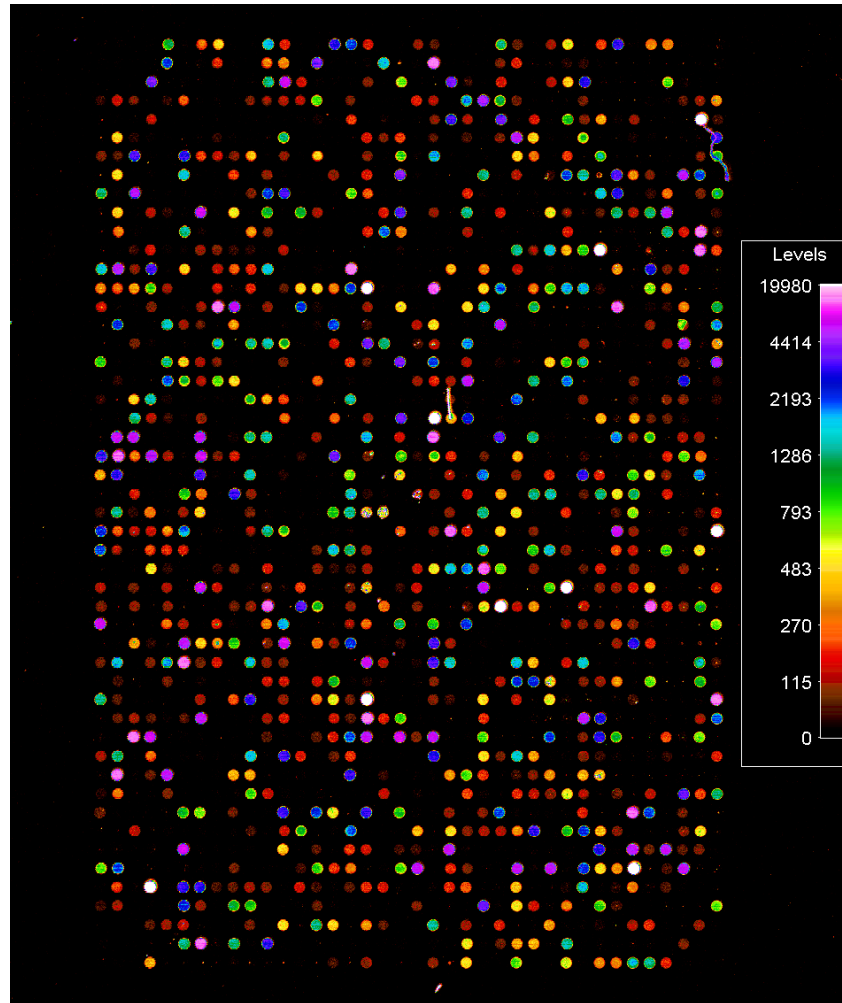


***About the Same Genome***



***Different Health Status***

# SomaLogic Measures Human Proteins in Blood: Each Feature Quantifies a Single Protein





## Definition of SOMAmers

SOMAmers are a special class of aptamers that have unique chemical and kinetic properties, while they are made of nucleic acids (like classic aptamers), they utilize modified nucleotides that provide entirely different binding to their target proteins and entirely unprecedented intramolecular nucleic acid structures (that have never been observed in natural nucleic acid structures)

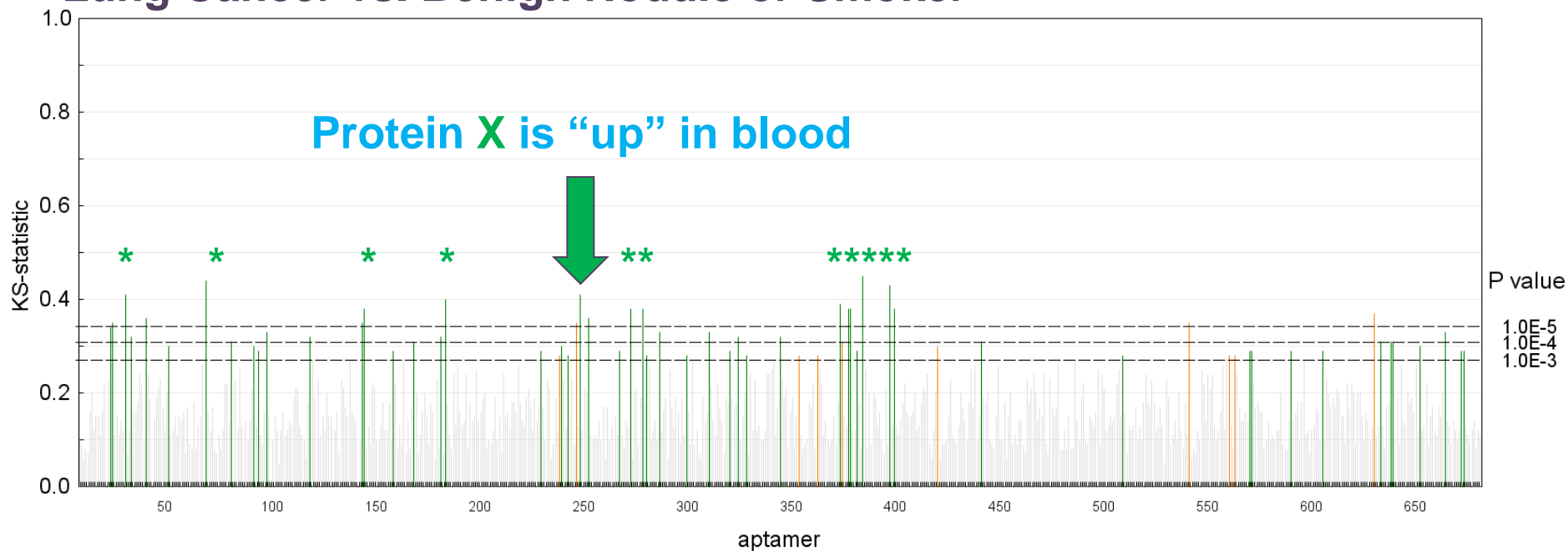
*We invented a magnificent way to do this, over two decades, by spending an unbelievable amount of money*

**Slow Off-rate Modified Aptamers = SOMAmers**

# Blood Biomarkers

## Disease vs. Non-disease

### Lung Cancer vs. Benign Nodule or Smoker



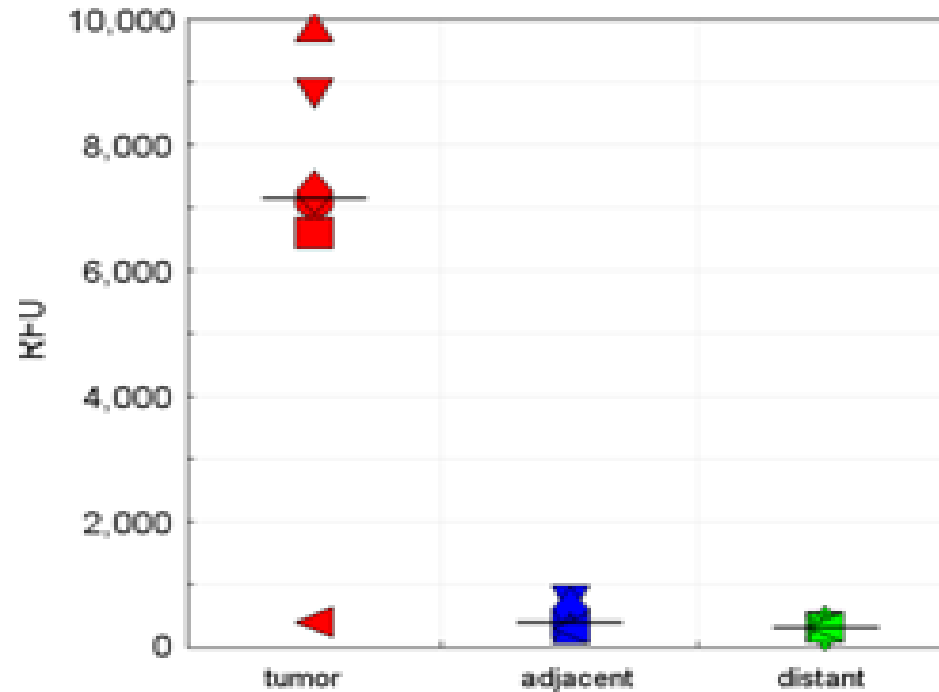
Green: up regulation in cancer (p value < 0.001)

Orange: down regulation in cancer (p value < 0.001)

# Tissue Biomarkers in Homogenized Biopsies

## *Disease vs. Non-disease*

### Protein X

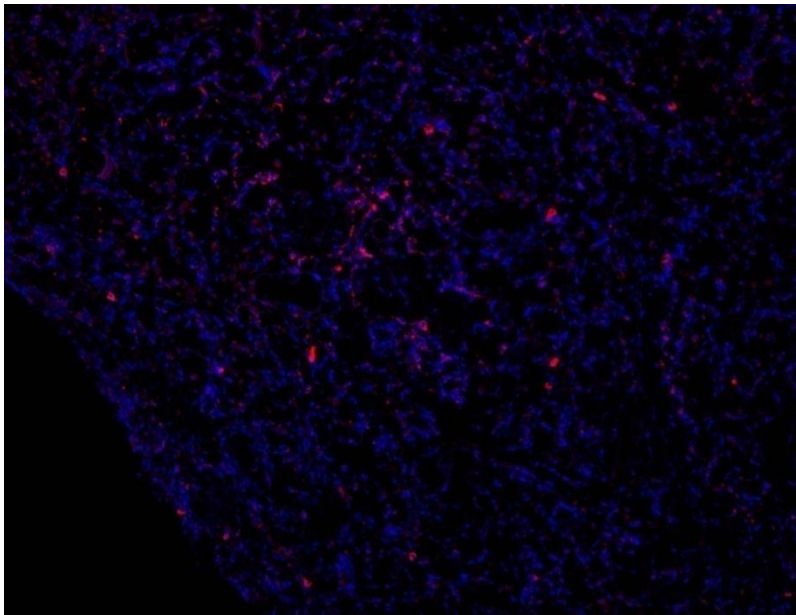




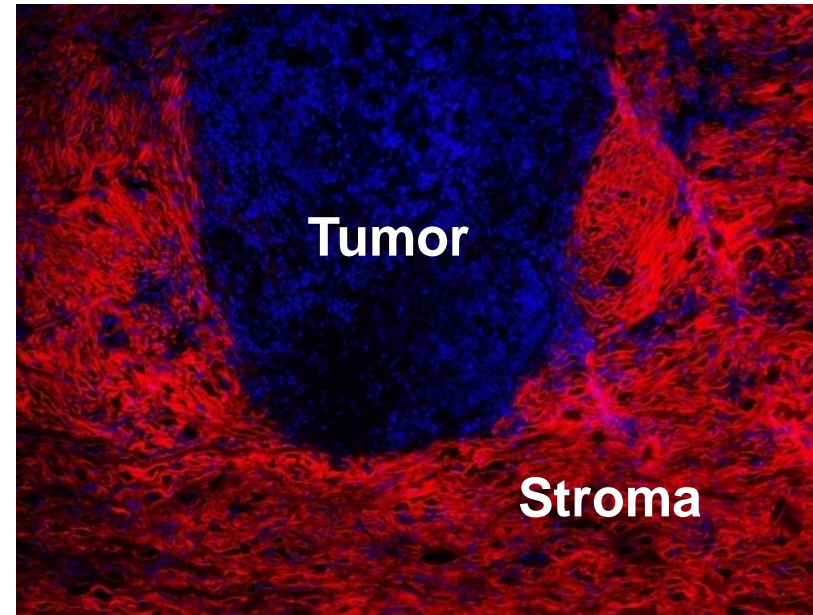
# Tissue Biomarkers in Tissues

*Disease vs. Non-disease*

Adjacent Lung Tissue



NSCLC Tissue



Tissue stained with SOMAmer specific for protein X

# Diagnostic Pipeline Development Process...

## Rapid Development of New IVD Products for Virtually Any Disease

SomaLogic has transformed the productivity of diagnostics development

New clinical tests can be developed in <6 months, repeatedly





## What SomaLogic Does, Repeatedly

1. Obtain clinical plasma or serum samples from sick people and controls
2. Measure many proteins in every sample
3. Identify those proteins that go up or down in sick people (*the biomarkers*)
4. Use those proteins to build a diagnostic “classifier”
5. Test the classifier on a “blinded” set of samples
6. Repeat for additional clinical questions...



# The Pipeline

Lung, Pancreatic, Ovarian, and Bladder Cancer

Mesothelioma and Melanoma

ALS, Alzheimer's Disease

Parkinson's Disease

Cardiovascular and Metabolic Disease

Kidney Disease

***and so on...we have studied more than 10,000 human blood samples thus far...we know how to do this at scale...***



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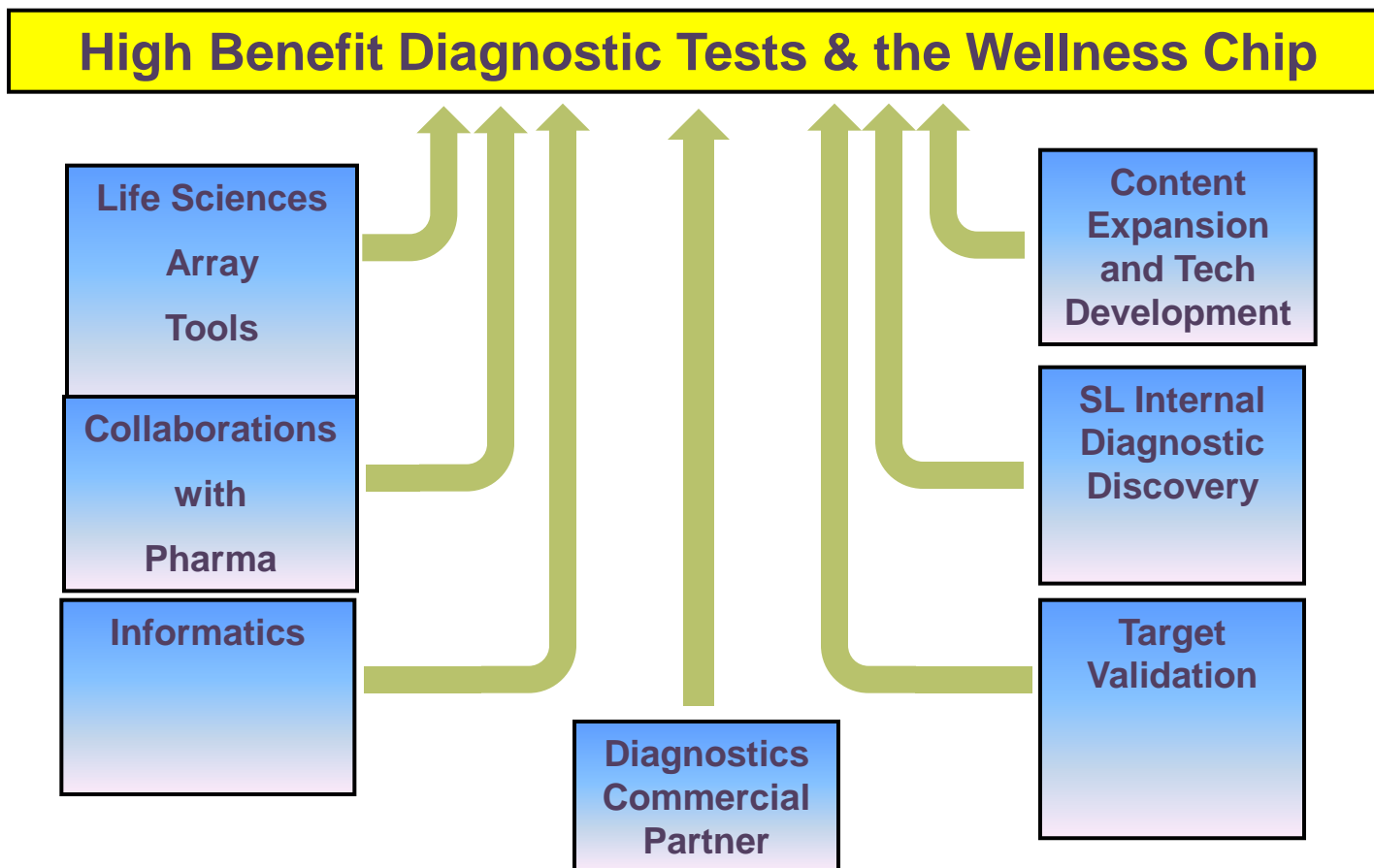
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# SomaLogic Partner Strategy Today: Integrated Drive toward Diagnostics





## The Need for Major Clinical Partners

SomaLogic has significant partnerships with Otsuka Pharmaceuticals, Quest Diagnostics, and NEC

The company is financially stable and currently preparing for three human diagnostic product launches

We are building a large product pipeline

The most difficult part of the plan is related to clinical trials – sample acquisition, medical records, and health economics

With a strong clinical partner we would have the opportunity to alter healthcare more quickly

We have spent five years identifying the right clinical partner and one good choice is **Sweden** (there are other reasonable choices, each of which we are pursuing)



## Qualities Required for a Major Clinical Partner

**National health service – fearless (but cost conscious) payers (all by itself this eliminates all of the United States except the Veterans Administration and perhaps Kaiser-Permanente)**

**World class basic science enterprise – fearless scientists**

**World class biotechnology and device companies – fearless entrepreneurs**

**World class medical system – fearless physicians**

**Healthy citizens who would like to be even healthier, and who understand that being part of a large-scale clinical trial is good for everyone – Swedish citizens are mindful of the “commons”**

**Political desire – a desire to lead the world toward better healthcare**



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## SomaSweden: The Idea

*The Name of Our Joint Effort Is Sure to Change*

Embrace the entire Swedish population (or a fraction of it) in a clinical/medical discovery effort

Perform semi-annual full-plex proteomic measurements (on SL's validated SOMAscan platform) and bioinformatics

Provide full information to physicians, patients, and scientists (protected and de-identified) for patient management and research

Develop meaningful healthcare economic goals, models, and data

Provide systematic entry of validated diagnostics to physicians for immediate benefits

Facilitate an enhanced Swedish biotech and device community

***Provide SOMAmer-based diagnostics to Sweden to advance national healthcare***

# The Wellness Chip: Coming Soon

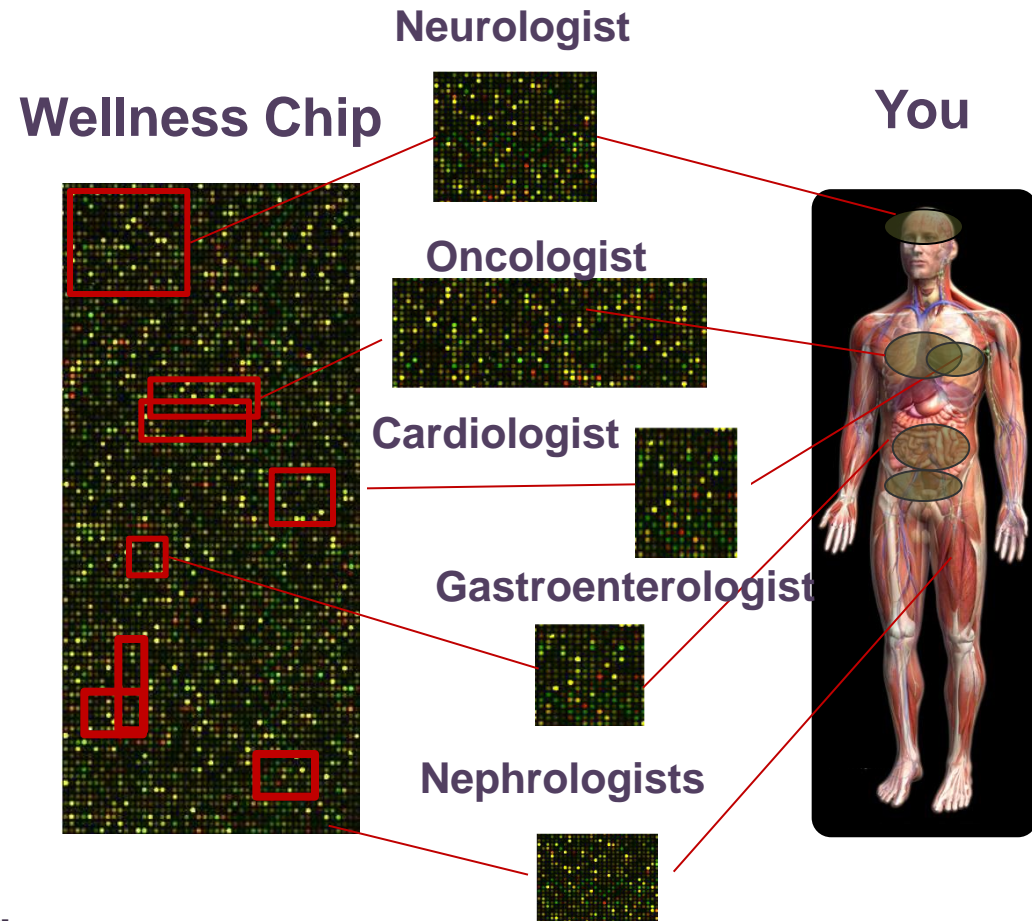
**Affordable blood test  
incorporated into standard  
health management**

**Simultaneous measurement of  
thousands of protein analytes at  
low COGs**

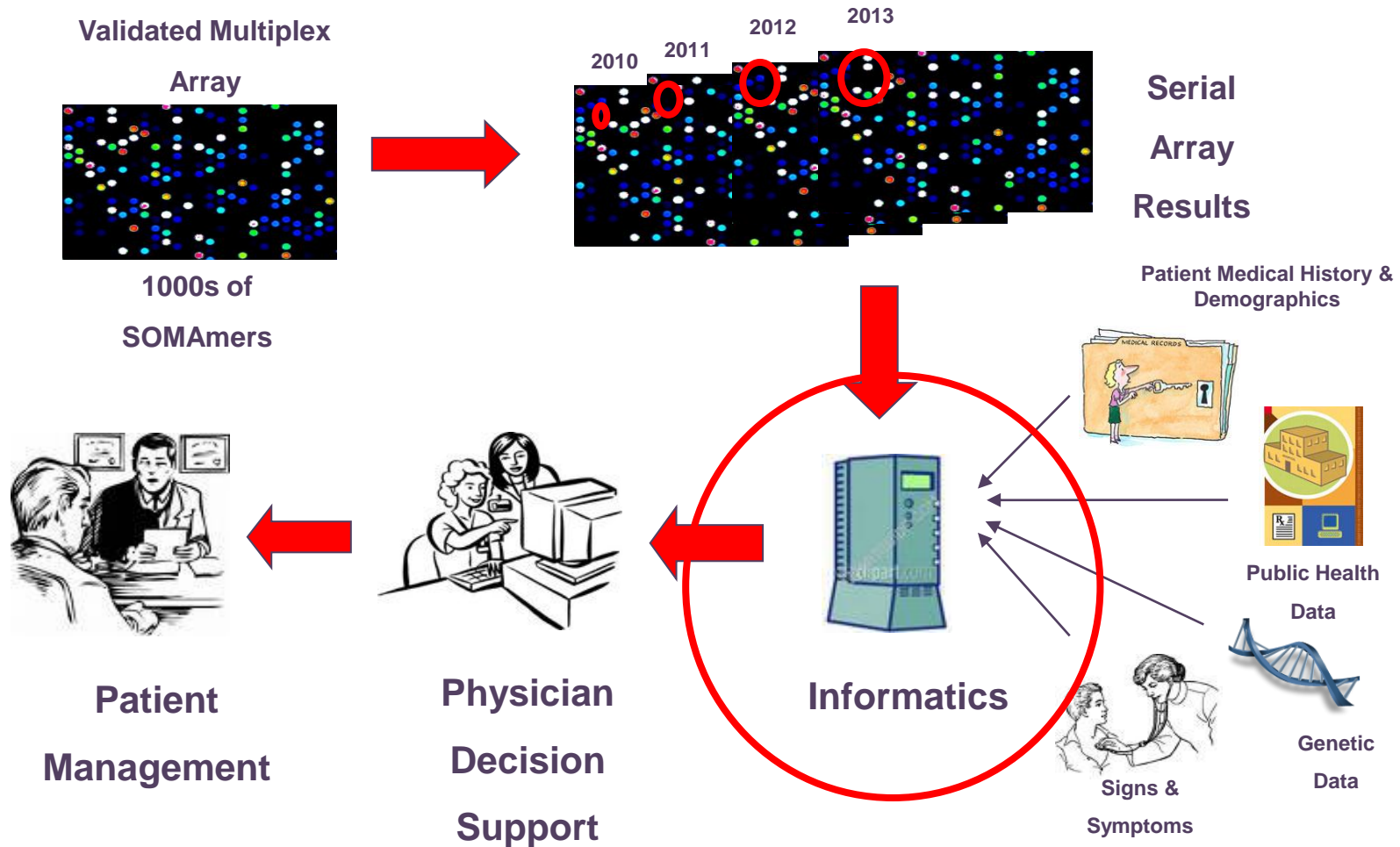
**Combines these analyte  
measurements into disease  
signatures**

**Aggregates hundreds of disease  
signatures appropriate to various  
clinical specialties and patient  
presentation**

**Longitudinal data collection along  
with patients electronic medical  
records**



# Longitudinal Diagnostics: A Critical Step



**Informatics-based decision support tools complement IVD tests**



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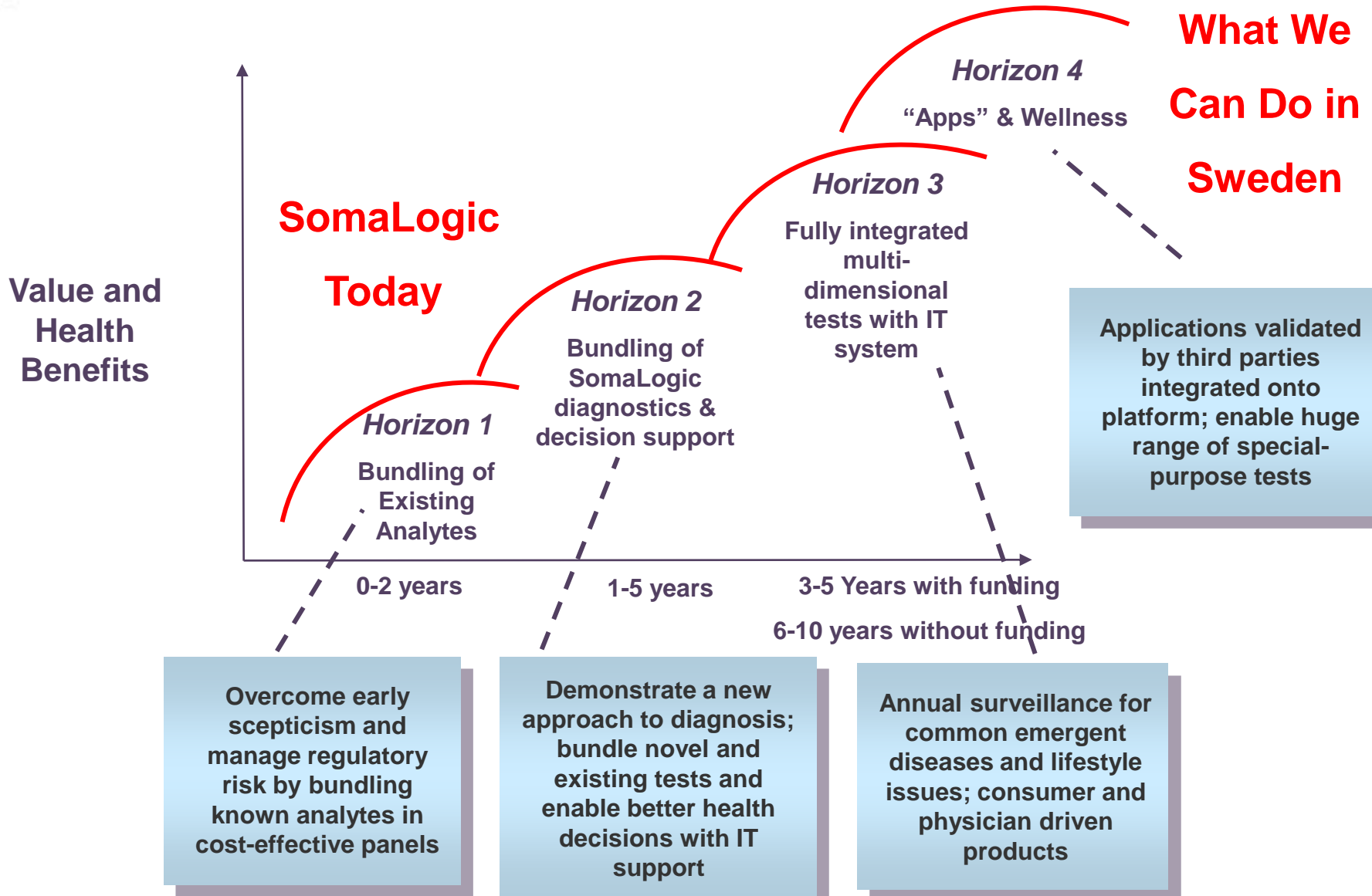
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# We Have an Extraordinary Opportunity





# My Extraordinary Swedish Friends Are Necessary

**Mathias Uhlen, Stockholm (pathology, blood tests)**

**Carl Borrebaeck, Lund (blood tests)**

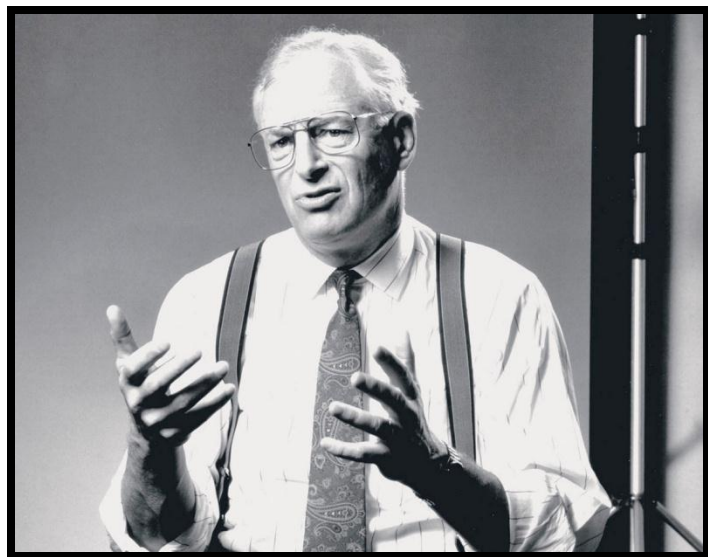
**Ulf Landegren, Uppsala (pathology, blood tests)**

**Ove Ohman, Uppsala (medical devices, including POC)**

**Jakob Lindberg, Investor AB (smart about medicine)**

**Each of these friends ought to work with us to make this happen**

# Healthcare in the Promised Land -The Evolution Toward Consumer-Driven Medicine



*David Lawrence, M.D.*

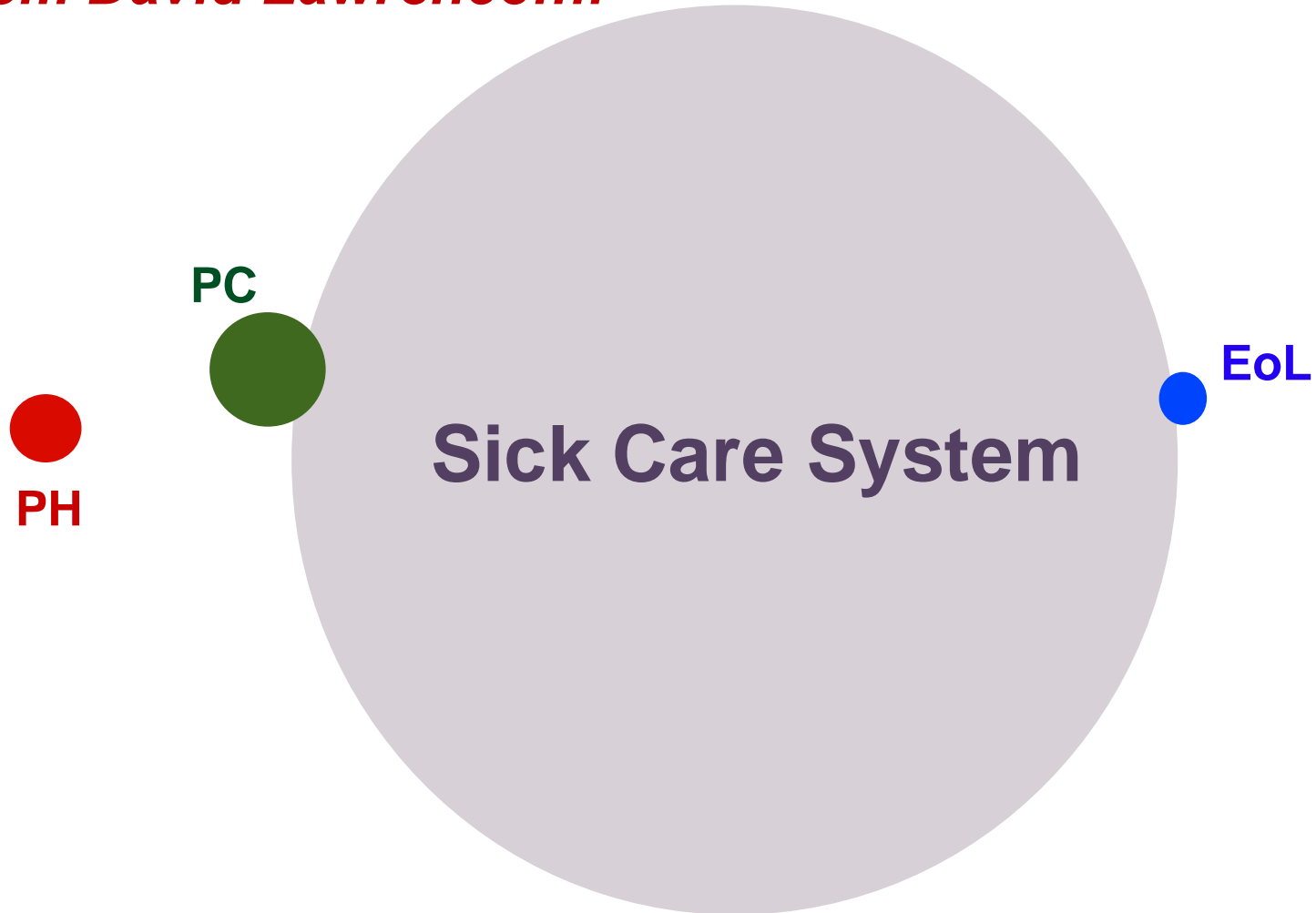
*Former CEO and Chairman, Kaiser-Permanente*

***My dear friend David has been working with us at SomaLogic to get this right – one would only do something this ambitious with David's help***



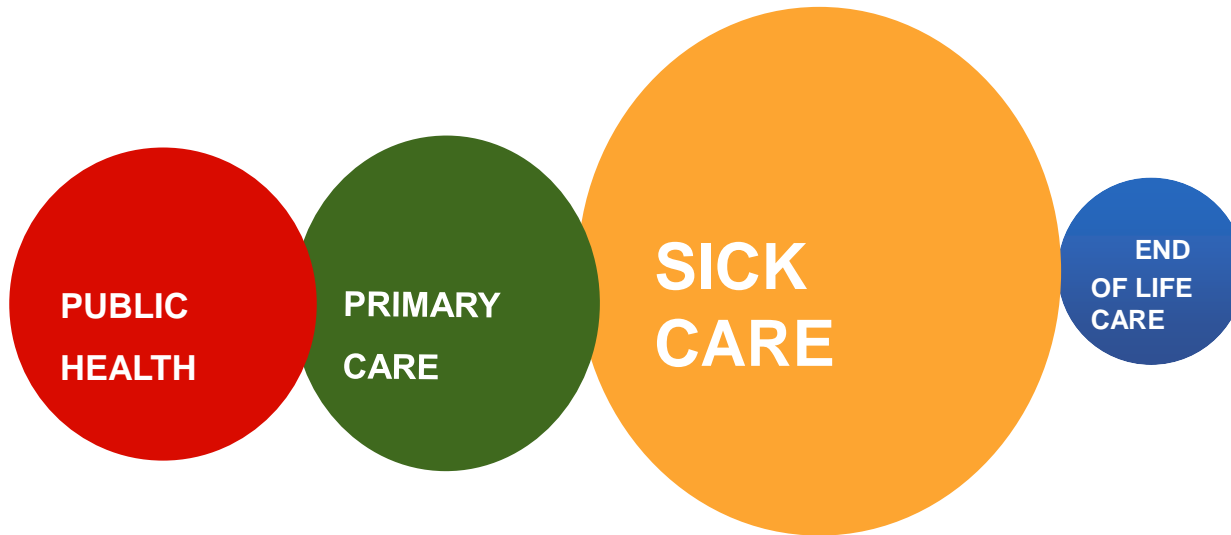
# Healthcare Today

*....from David Lawrence....*



# A MORE BALANCED HEALTH CARE SYSTEM

*....from David Lawrence....*





# Technology Enables Patient-Centric Healthcare: The Wellness Chip Is Critical

**We intend to transform information flow in healthcare**

**We have discovered and developed a unique technology that allows us (and forces us) to aim high**

**We have powerful data for many important diagnostic products, demonstrating the disruptive nature of our technology (this is a fact, not a dream)**

**We see a bold path toward the vision of the Wellness Chip**



## Next Steps

**We have set SomaLogic up for success...we have important partners who can join us, with others in negotiations**

**We are already a vigorous and acknowledged healthcare entity**

**We have identified potential leaders for a Swedish Consortium**

**Going forward SomaLogic will accelerate steps toward the achievement of our long term vision – we will write a “Business Plan” for the largest clinical trial in history, centered on blood-based measurements, pathology, medical records, medical economics, and patient well-being**

**SomaLogic will enhance patient lives through new paradigms for diagnosis of human disease and population wellness**

***Would you like to be part of planning this effort over the next year or two?***