

CHALLENGES OF CLINICAL BIOMARKER DEVELOPMENT:

WHAT CAN HIGH SENSITIVITY DO FOR YOU?

Philippe Goix

President and CEO

Sponsored by:



June 16, 2011

Corporate Overview

- Founded in 2004, 90 employees
- Headquartered in Alameda, CA
- Pioneer in high-definition immunoassay systems
- Strong IP portfolio & patented technology
- Pharma product launch in 2007
- CLIA certified laboratory since 2008
- European HQ in Lyon (France) since 2010
 - Customer support & service
 - Sales
 - R&D partnerships



**Full Commercial Launch in 2011 of
Erenna Immunoassay System and Assay Menu**

Vision

*Deploy our proprietary digital immunoassay platform
to enable personalized disease management*



Research

Disease Management

Diagnostics

Challenge of Clinical Biomarker Development

Use the right drug and the right biomarker for the right patient.



- Is this the right disease?
- What is the population that has the disease?
- What is the population that respond to the drug?

NEED: More sensitive biomarker Assays

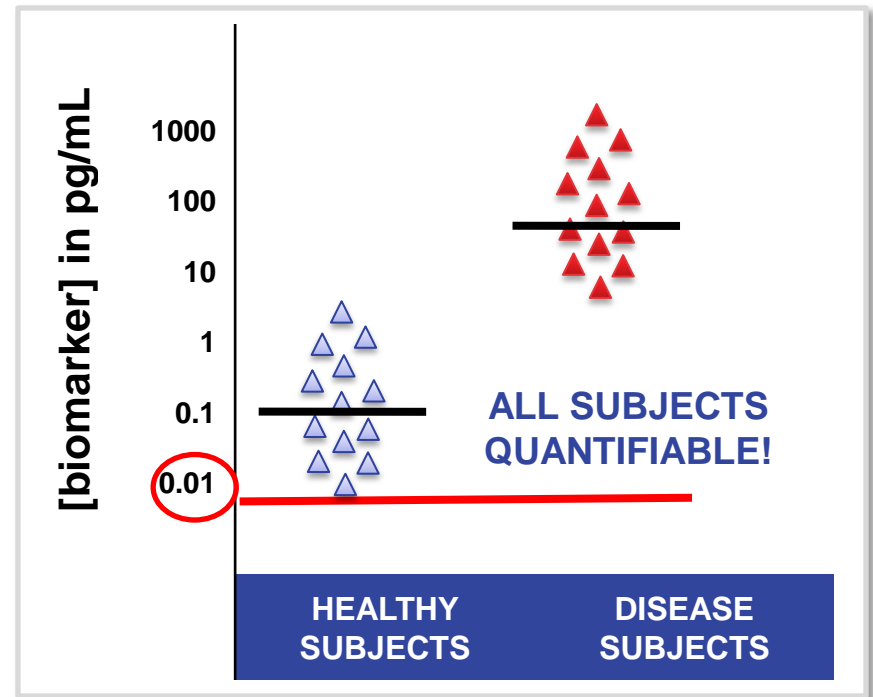
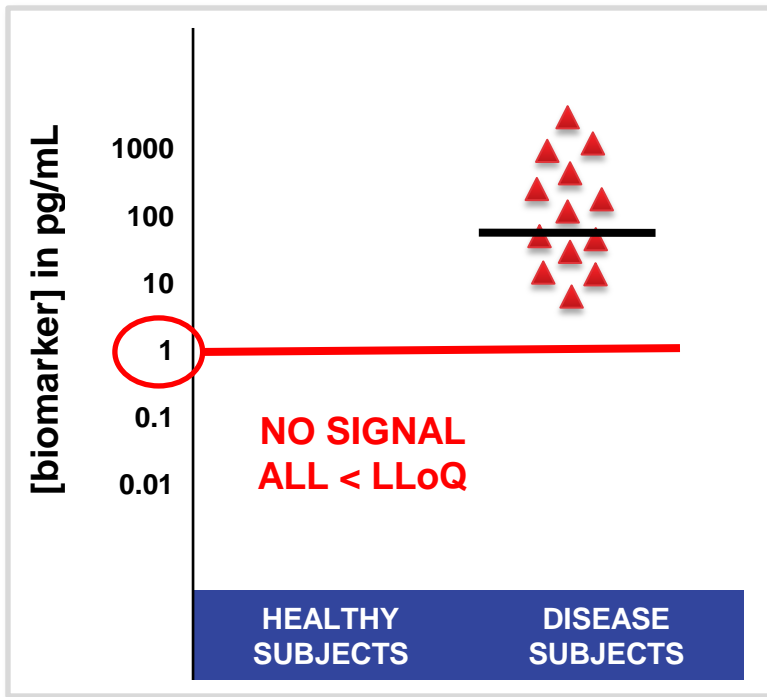
Sensitive quantification of biomarkers = Discovery

Healthy vs. Disease Unknown

Sensitivity

Discovery

Healthy vs. Disease understood
Responders vs. Non-responders



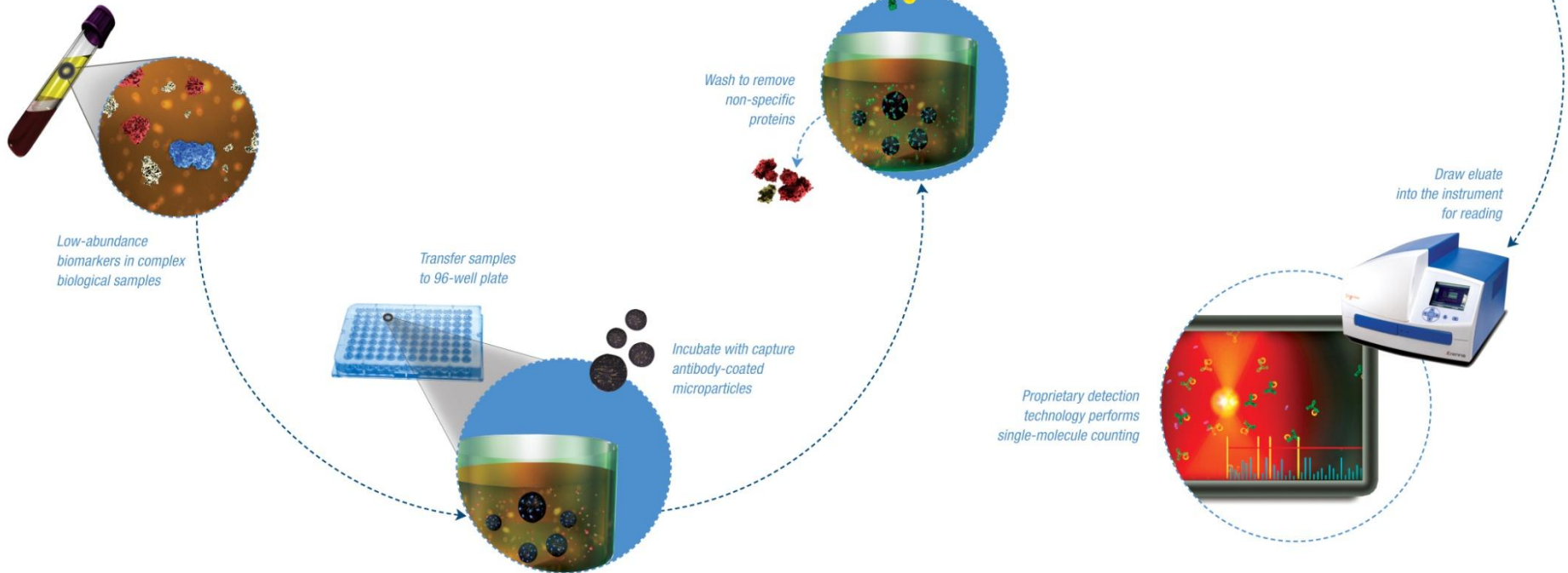
Proprietary Digital Immunoassay Technology

The **Sp_xHD™** Immunoassay Advantage

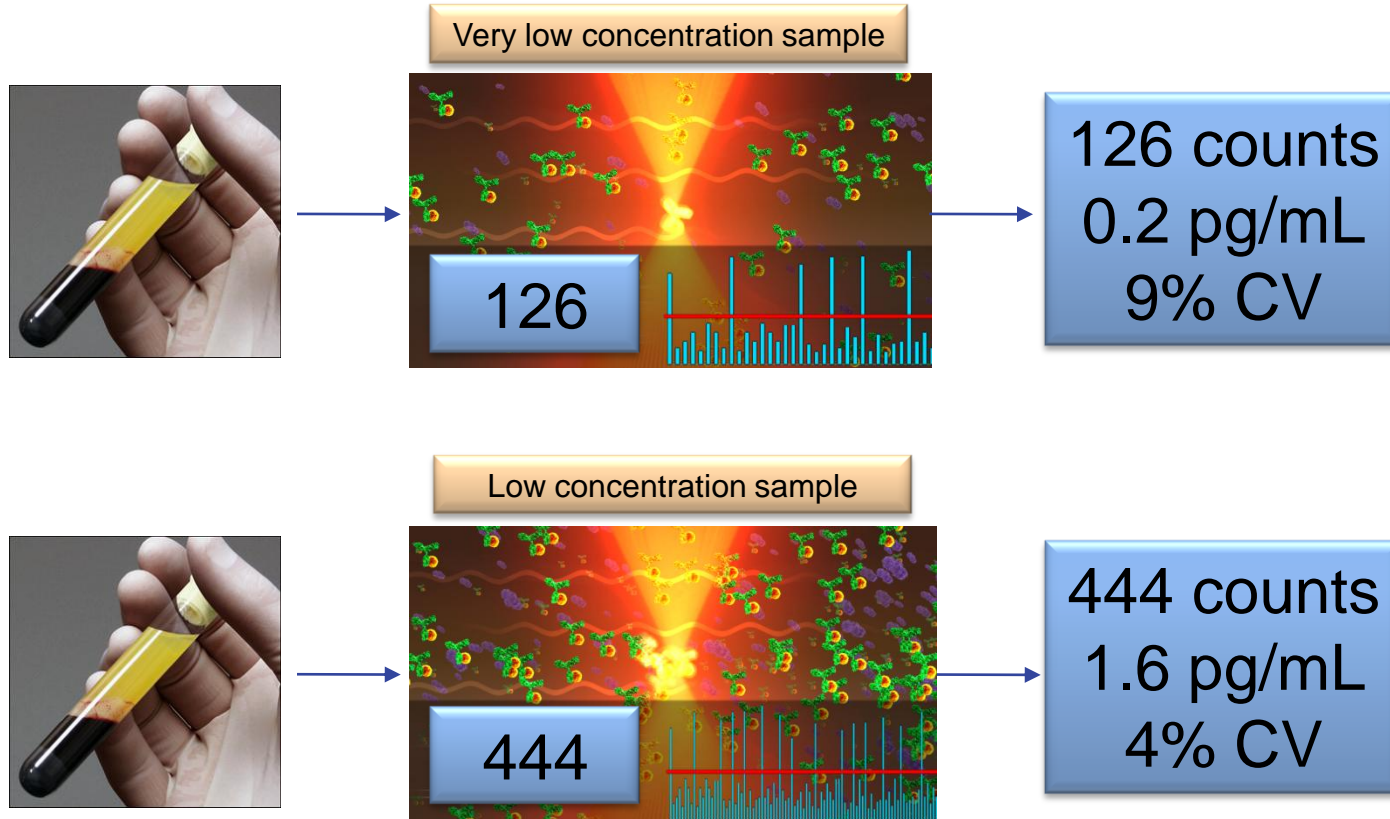
Powered by Singulex® Technology

PLAY VIDEO

<http://www.singulex.com/technology.htm>



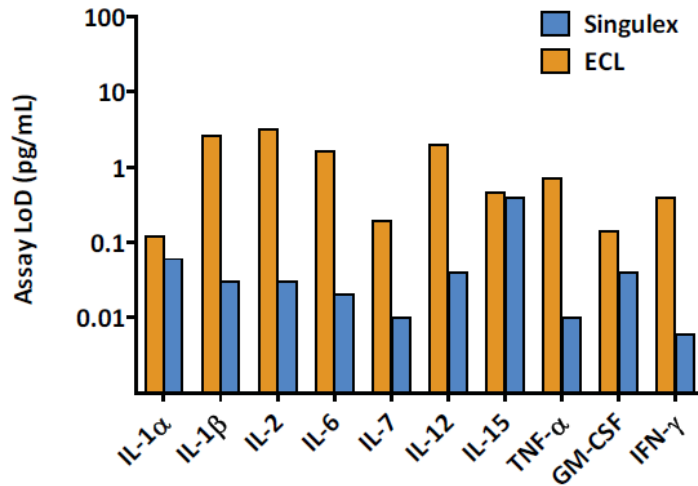
Sgx HD™ allows monitoring low abundance biomarkers



Singulex 40X to 50X more sensitive than MSD/ECL

40x better LoD!

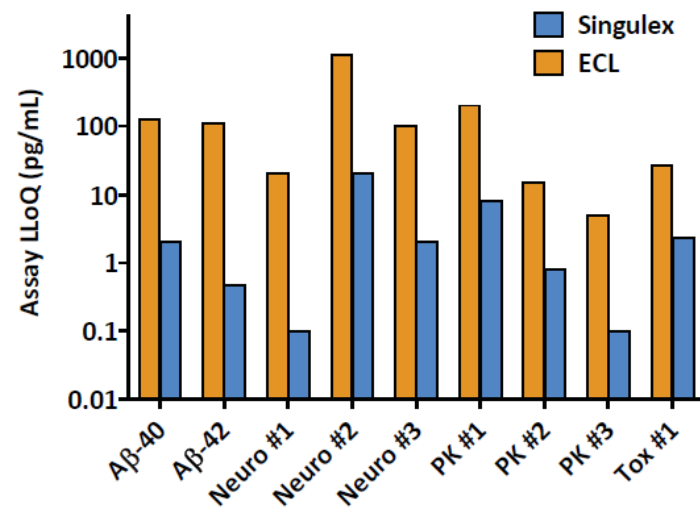
Based on reported product insert specs from manufacturer



* Assays for use in plasma

50x better LLoQ!

*Head-to-Head Evaluation
By 9 Academic & Pharma Partners*



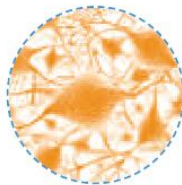
* A β -40 & A β -42 in CSF; Neuro Markers in plasma; Pharmacokinetics (PK) Markers in Plasma; Toxicity (Tox) Marker in Urine.

Portfolio of Products & Services



Erenna Immunoassay System

Our award winning Erenna Immunoassay System provides the most sensitive immunoassay instrumentation available, utilizing single-molecule detection for high-definition quantification of low-abundance biomarkers.



Assay Menu

We offer an extensive assay menu covering several disease areas. We are committed to provide assays with the utmost sensitivity and precision to help evaluate drug safety and efficacy.



Sample Analysis

The Singulex Service Lab provides sample analysis services while maintaining the highest quality standards. Our stringent QA/QC standards ensure that your results are reliable and reproducible.



Custom Development

We provide customized assay development services beyond our product menu. We work closely with you to ensure that our assays and the Erenna Immunoassay System are integrated seamlessly into your workflows.

Singulex Assay Menu



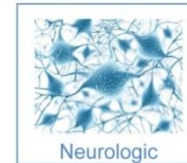
Cardiac

- cTnl
- MMP-9



Toxicity

- cTnl



Neurologic

- Aβ-40
- Aβ-42



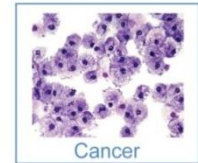
Metabolic

- GLP-1, active
- GLP-1, total
- Insulin (human)
- Insulin (mouse)



Inflammatory

- G-CSF
- GM-CSF
- IFN-γ
- IL-1α
- IL-1β
- IL-2
- IL-4
- IL-5
- IL-6
- IL-7
- IL-8
- IL-10
- IL-12
- IL-15
- IL-17a
- IL-17f
- IL-21
- IL-22
- MIP-1α
- RANTES
- TNF (human)
- TNF (mouse)
- VEGF-A (human)



Cancer

- AKT1, phospho
- AKT1, total
- EGFR
- GSK3β, phospho
- GSK3β, total
- JNK2, phospho
- JNK2, total
- MMP-2
- MMP-2/TIMP-2
- PSA, free
- PSA, total
- RANTES
- TIMP-2
- VEGF-A (human)

Clinical Applications Beyond Traditional Diagnostics

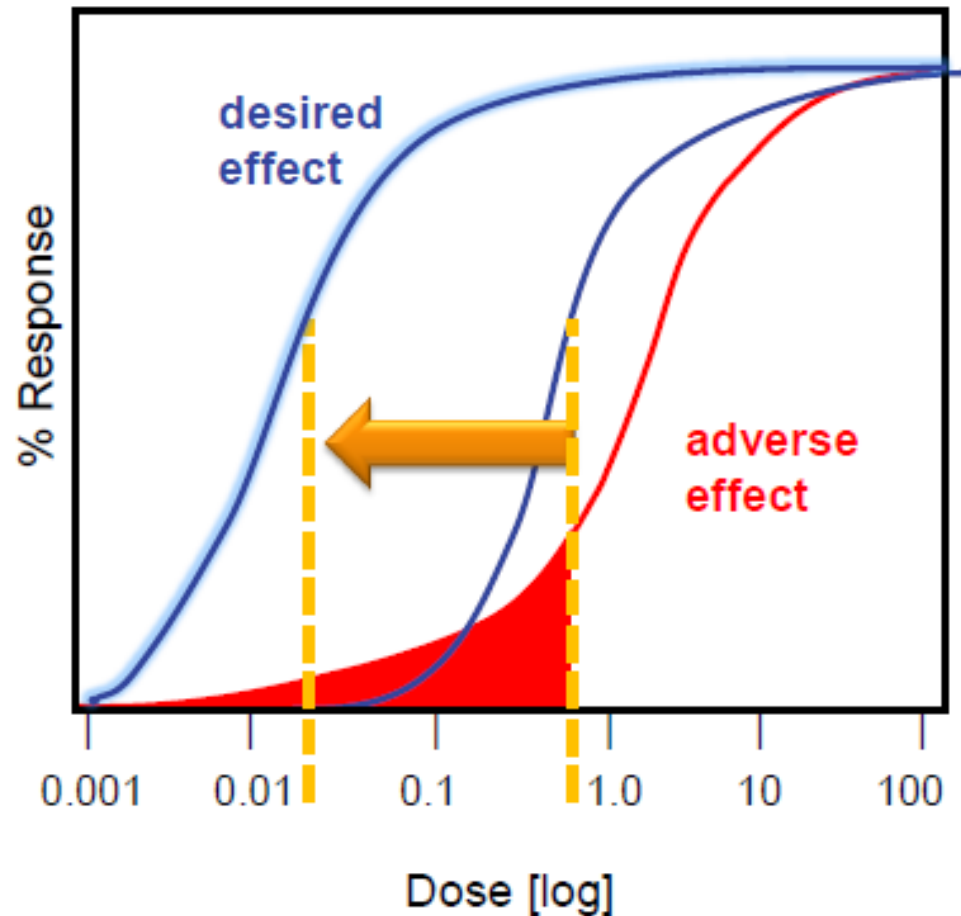
Use the right drug and the right biomarker for the right patient.

Biologic Drug Development

- PK/PD
- surrogate endpoints

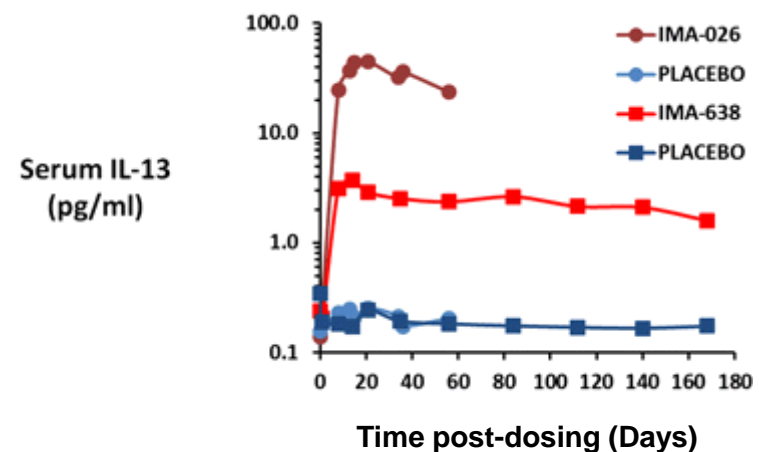
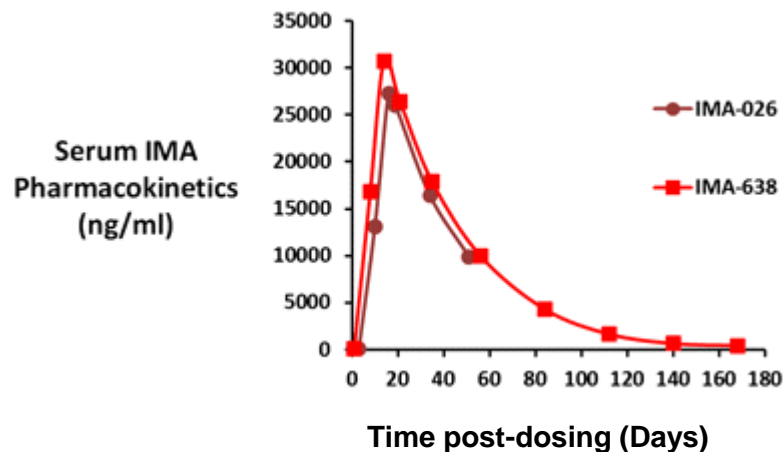
Using sensitivity to lower therapeutic index to minimize adverse effects

- High value PK/PD data at low doses
- Optimize therapeutic index at low doses
- Clear understanding of safety and efficacy
- Informed Go/No-Go decisions in Phase I/II
- Reduced attrition and development cost



High Sensitivity Assays to better measure drug response

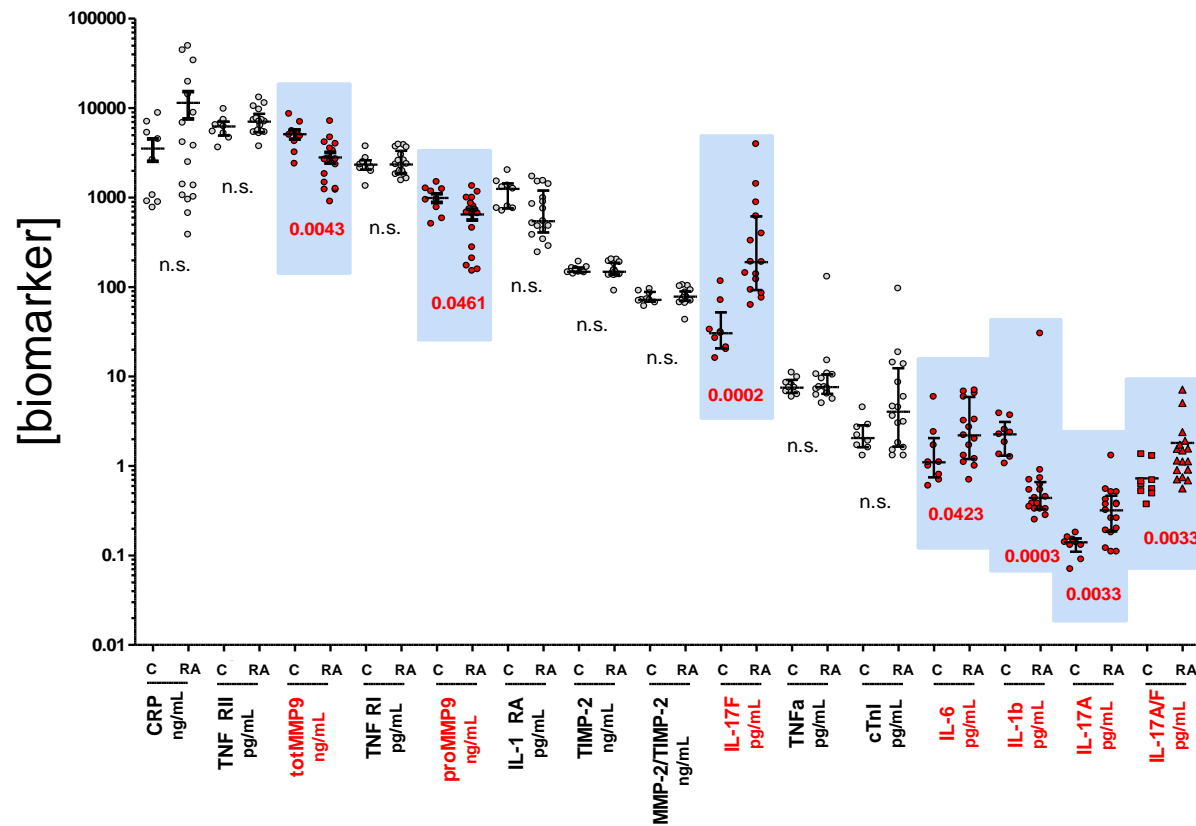
- Ex: IL-13 targeted therapy for asthma



Immunoassay	Format	LLoQ (pg/mL)	Fold Improvement
Original IL-13 ELISA	ELISA (in house)	300	—
Erenna MP assay	MP	0.07	4,000X

*Gauvreau et al, Am J Resp Crit Care Med 2011
and St. Ledger et al, J Immunol Methods 2009 Wyeth/Pfizer*

High Sensitivity identifies relevant biomarkers in RA



- N = 25 Patients
- 10 Control - 15 RA
- 154 μ l serum / patient
- 15 biomarkers analyzed
- 7 specific biomarkers

In Collaboration with Dr. J. Greenberg, NYU

Clinical Applications Beyond Traditional Diagnostics

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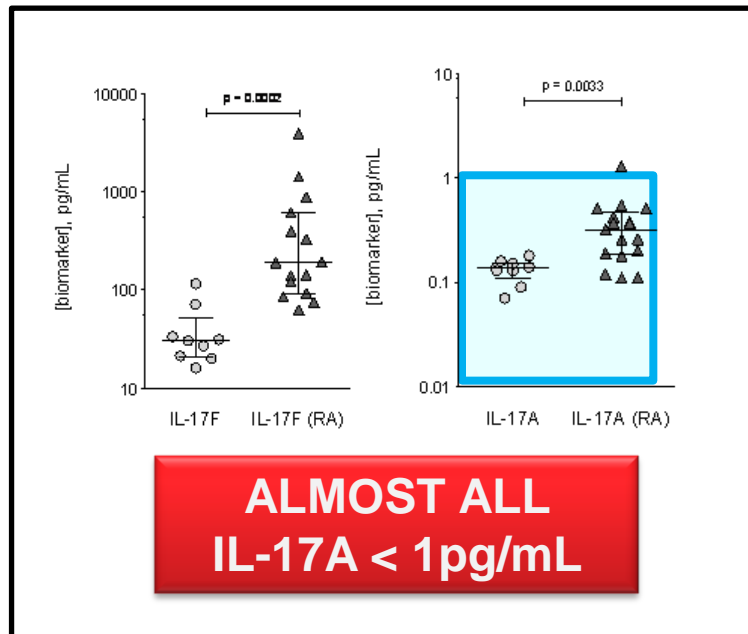
Companion Diagnostic

- patient selection

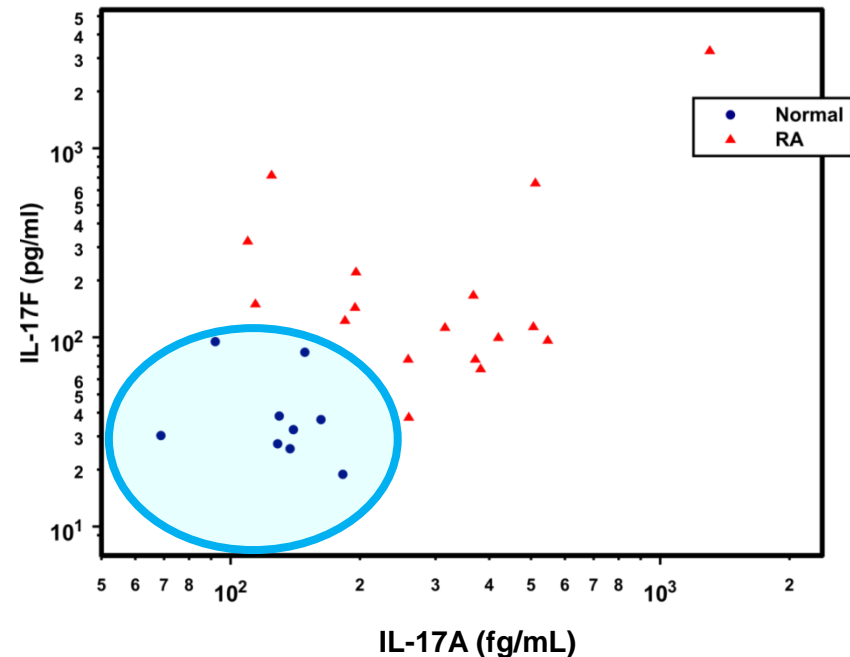
The Right Patient: high-sensitivity better specificity

**IL-17F and IL-17A
Healthy vs. RA Patients**

**100% Specificity for RA patients with
combined IL-17 A and IL-17F**



Log IL-17F vs. Log IL-17A



Presented by Dr. Jeff Greenberg, NYU @ EULAR 2011

Clinical Applications Beyond Traditional Diagnostics

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Biologic Drug Development

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Companion Diagnostic

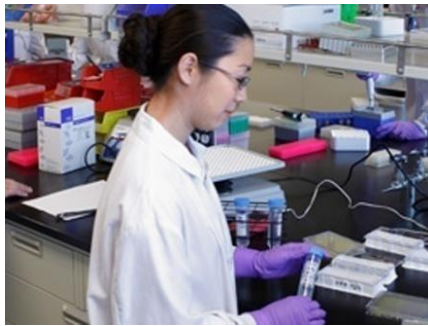
- patient selection

Personalized Medicine

- patient monitoring
- disease recurrence

Vision

*Deploy our proprietary digital immunoassay platform
to enable personalized disease management*

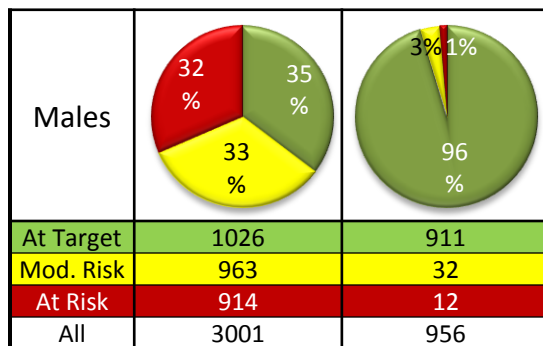
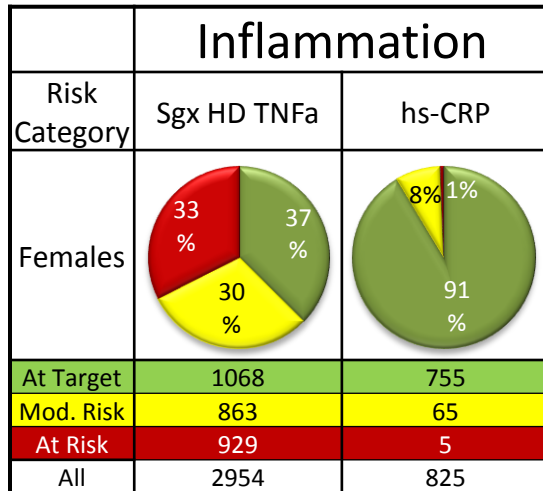


Research

Disease Management

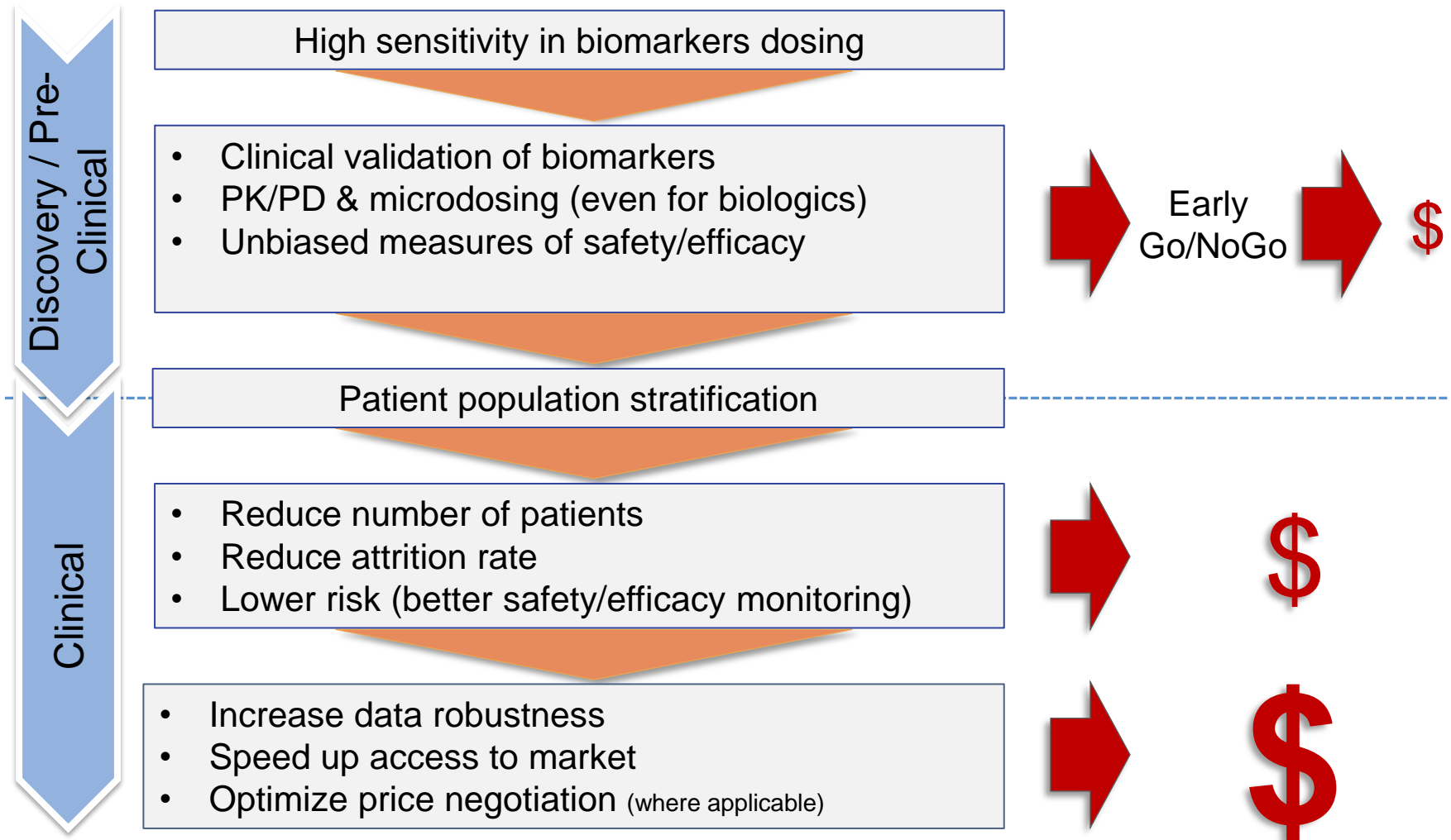
Diagnostics

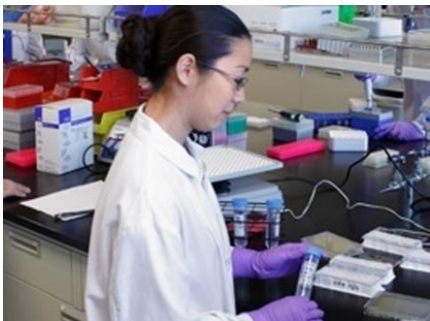
Mining knowledge from our CLIA Biomarker database



- Today Inflammation Markers are not sufficient (hs-CRP)
- TNFa is undetectable in Normal and Disease Mode with conventional technology
- High Sensitivity Assay technology segments disease and healthy TNFa levels in both Women and Men
- TNF-a provides better insight into vascular inflammation and hence CVD risk assessment
- TNF-a can potentially be an effective biomarker for other inflammatory diseases RA and CNS

High Sensitivity Assays improve clinical R&D ROI





Singulex®

Thank You

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