

BIO 2019 • June 5<sup>th</sup> 2019  
Kevin Hrusovsky, Chairman & CEO

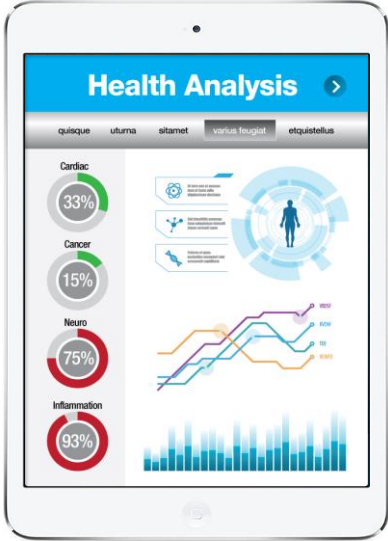
This presentation contains “forward-looking” statements that are based on our beliefs and assumptions and on information available to us as of the date of this presentation. Forward-looking statements include all statements that are not historical facts. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The risks and uncertainties that we face are described in our most recent filings with the Securities and Exchange Commission. Except as required by law, we assume no obligation to update these forward-looking statements, even if new information becomes available in the future.

1. Compelling Strategic and Financial Opportunity
2. Compelling Milestones Achieved with Attractive Growth Catalysts
  - a. Record 2018 and Q1'19 Growth, Gross Margin and Growth Acceleration
  - b. \$50M Raise, New Head Quarters, China Launch, Consumable Expansion
  - c. SP-X Launch for Oncology and HD-X Launch Announced for Neurology
3. Revolutionizing Drug Development and Healthcare with Precision Health

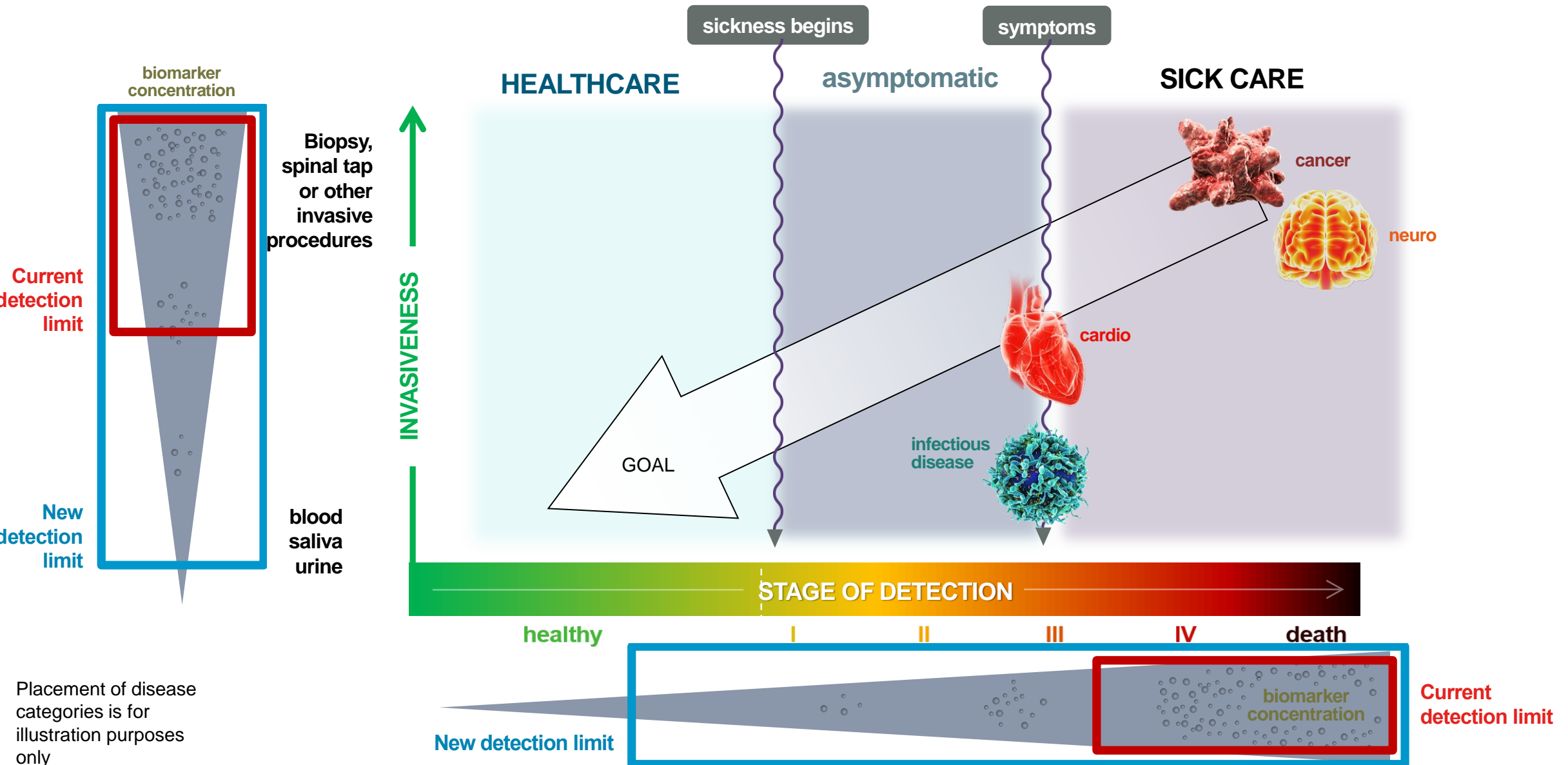
## Today: Invasive and Late



## Tomorrow: Non-invasive and Early



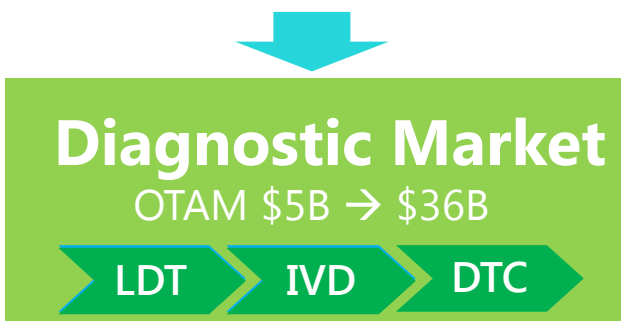
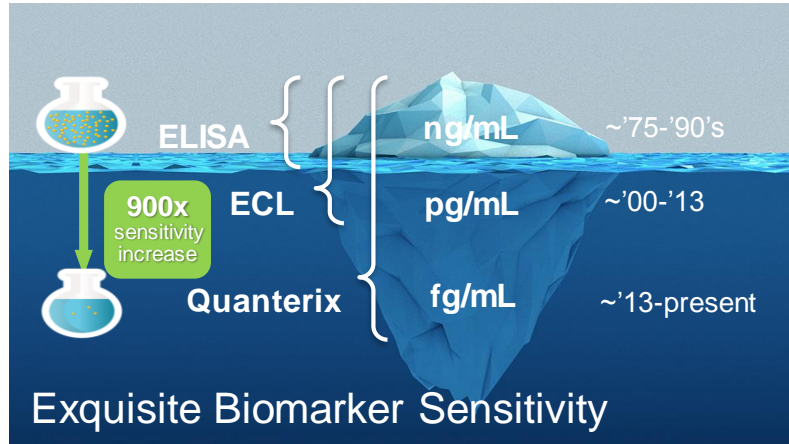
# Simoa Sees Health to Disease Continuum



Placement of disease categories is for illustration purposes only

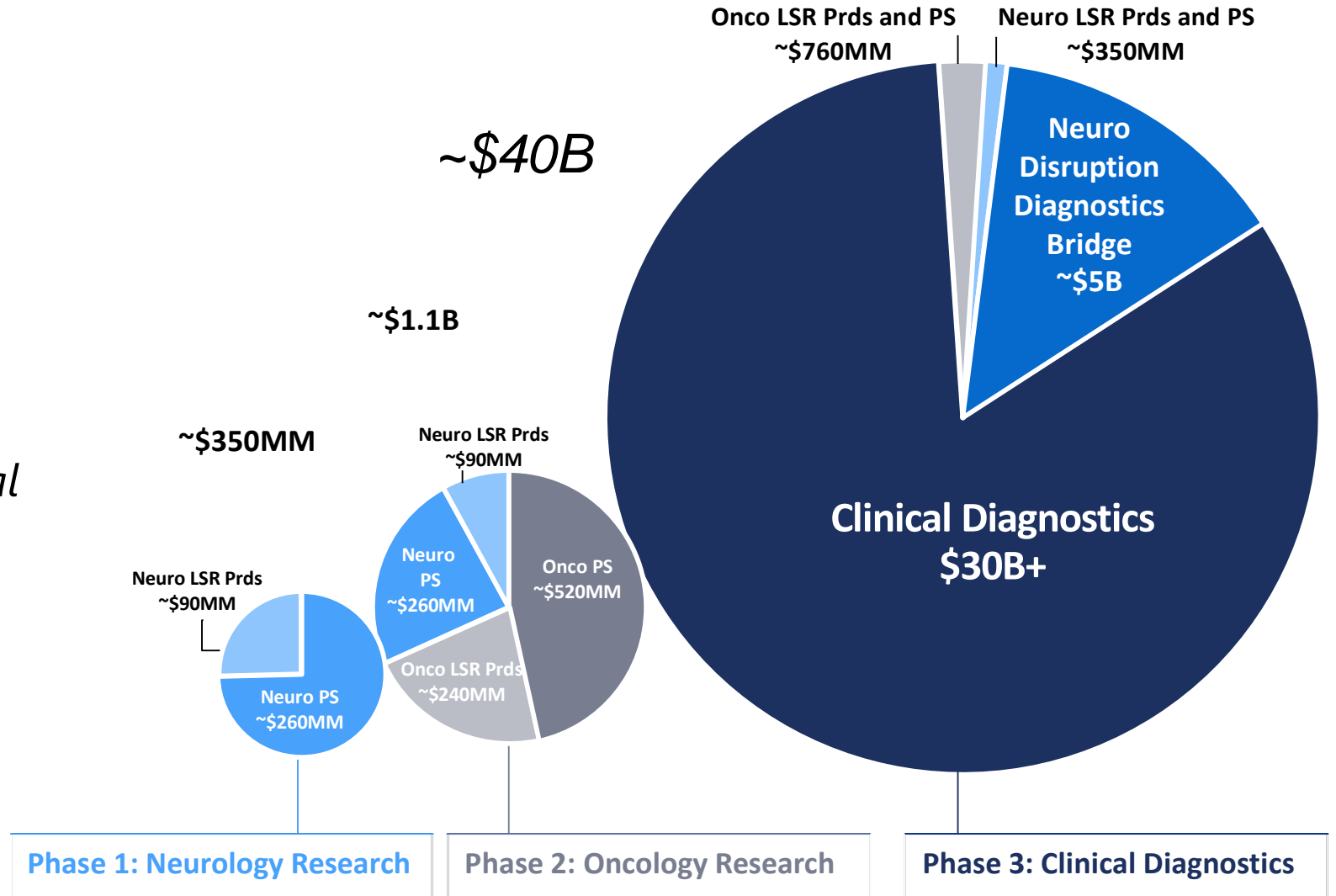
# Strategic Direction Remains Unchanged . . .

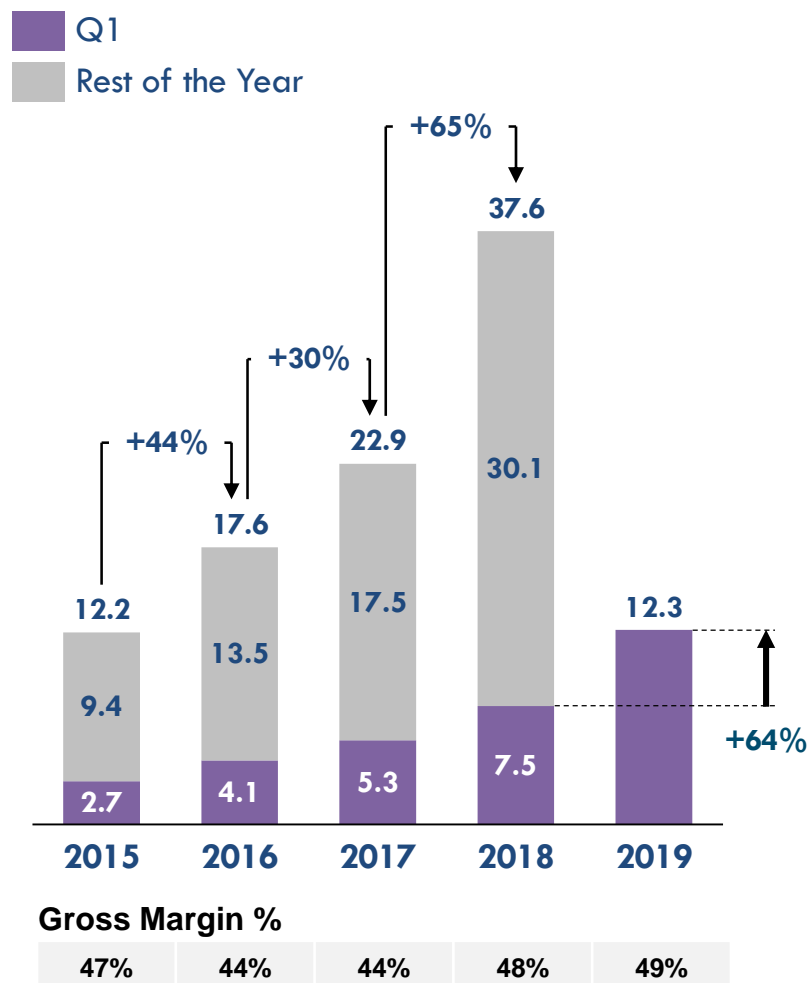
Capture major market opportunity through our disruptive technology



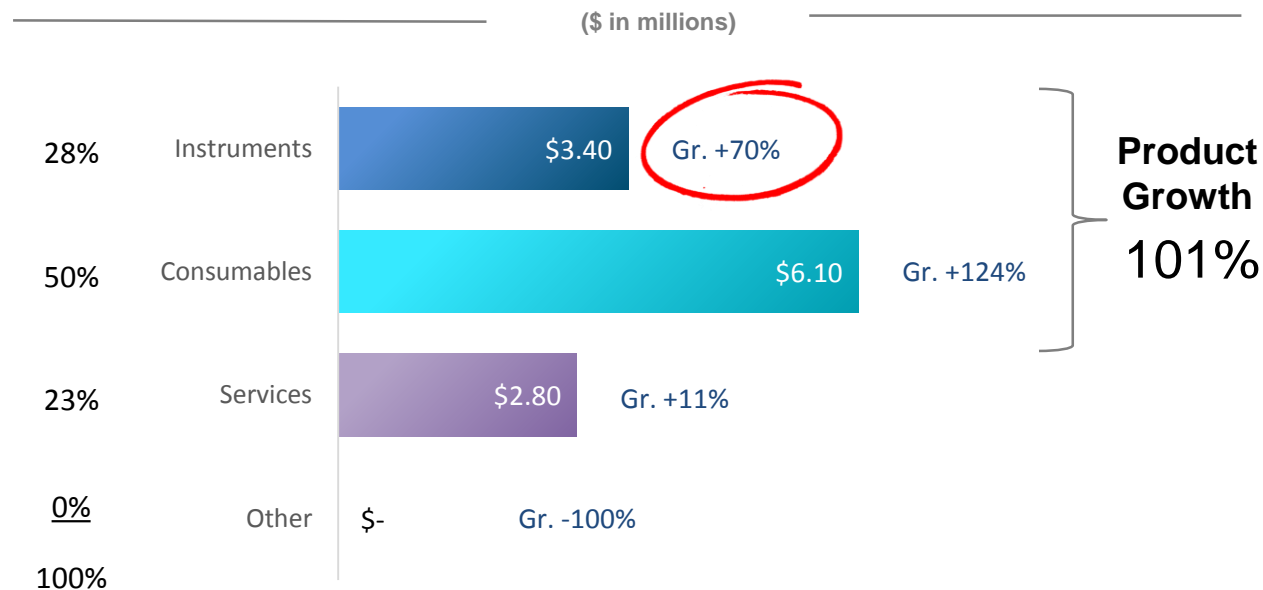
Analytical  
Validity  
\$

Clinical  
Validity  
\$

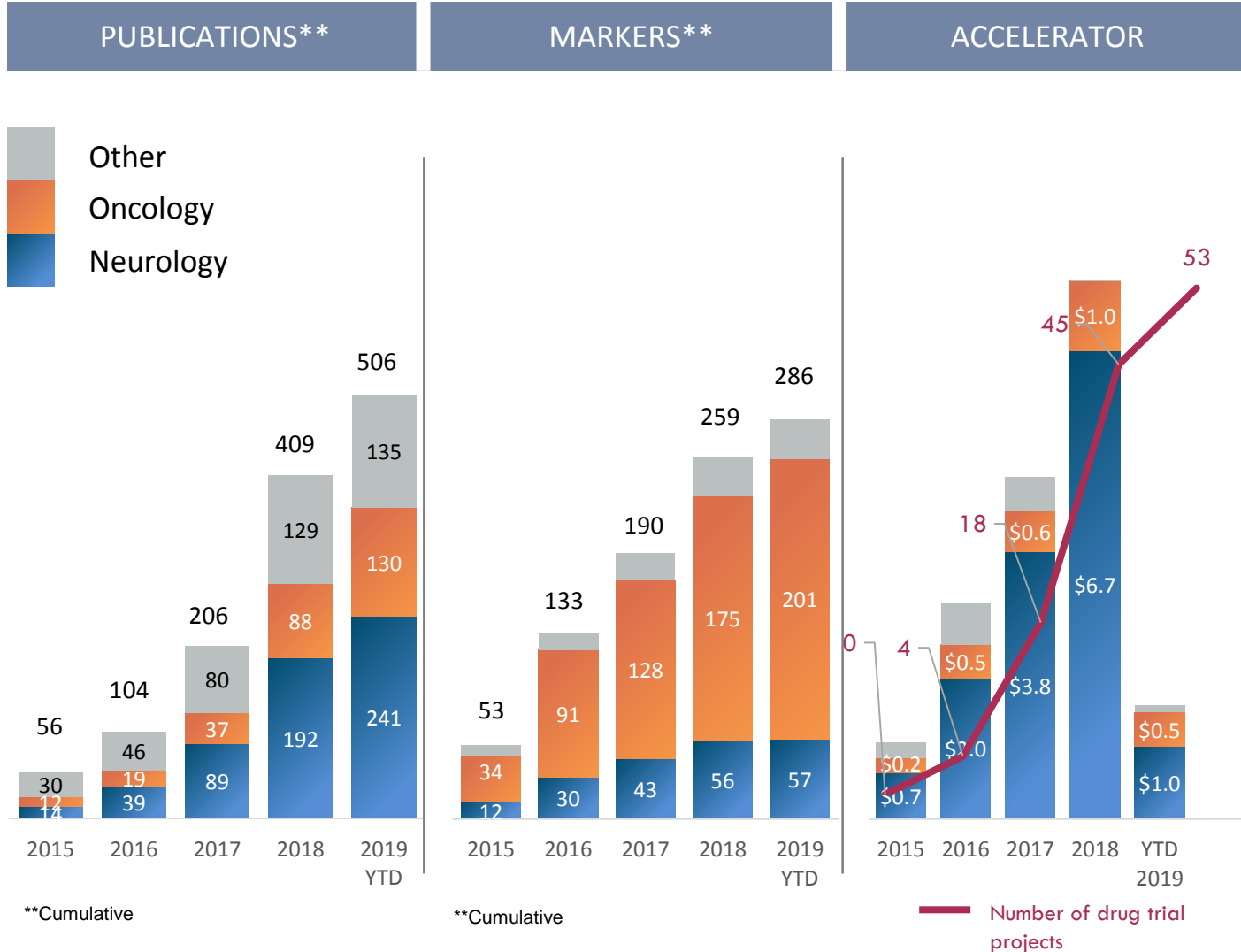




- 64% Growth, Total GM 49%, + 650bp
- High margin mix accelerating
- Consumables growth +124%



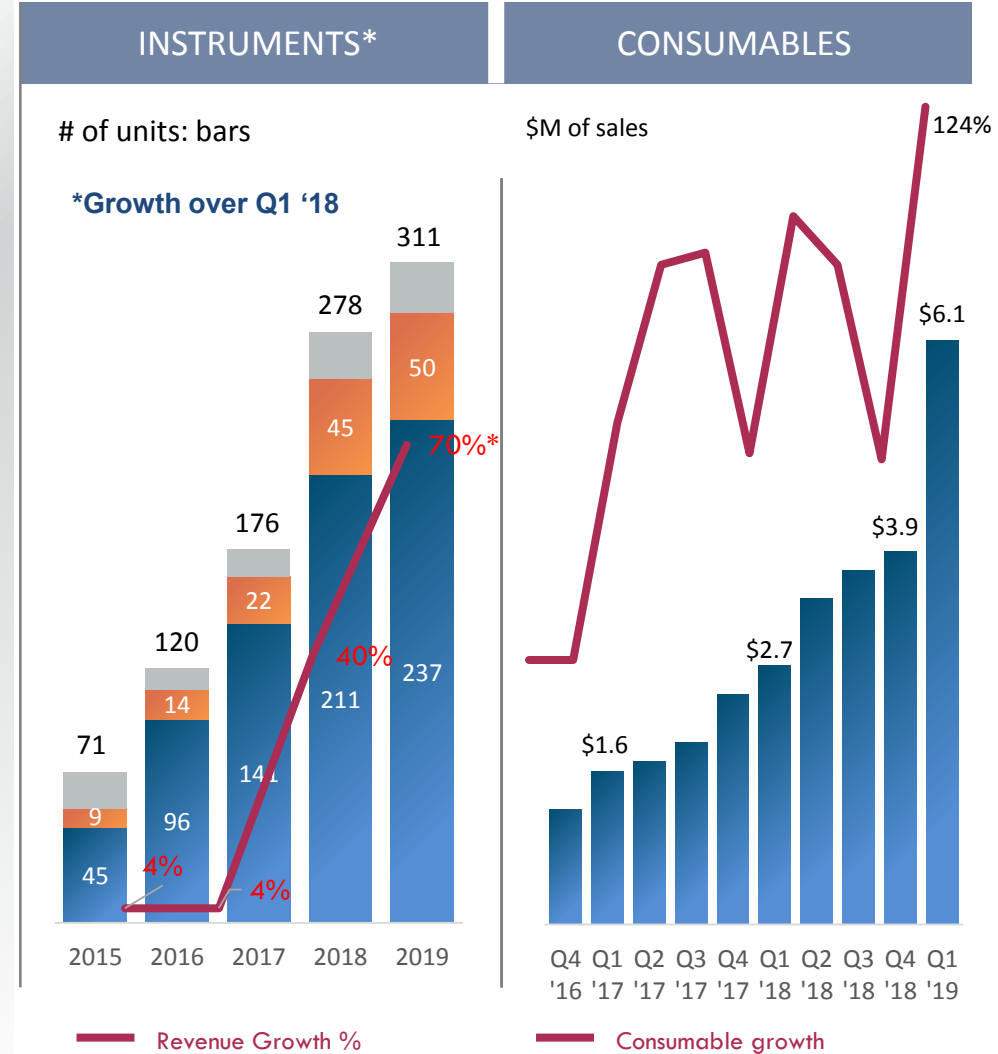
# Scientific Research is Driving Brand Awareness, Performance and Utilization



\*\*Cumulative

\*\*Cumulative

— Number of drug trial projects



\*Instrument segmentation estimated based on consumables sold

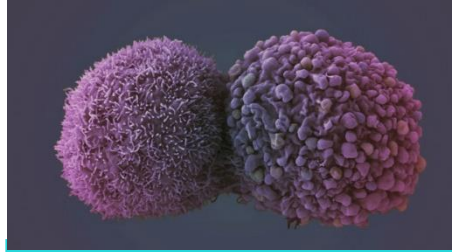


# Objectives 2019

Large strides in Q1 towards securing our 2019 objectives



Neurology  
<10% Penetrated



Oncology  
3x Neuro



Strategy  
Dx via Biopharma



Financials



Technology

High double digit growth with high utilization

Add 25 assays and globalize

- **+70% growth**

Launch penetration in Oncology market

Immuno therapy focus

- **Launched SPX and 10 Simoa panels in Q2'19**
- **Impactful webinar, high utilization, early launch success**

LDT/IVD partnerships

50 phase I, II, III trials

M&A: Ab's, Clinical Lab

- **Clinically validate Nf-L for 2<sup>nd</sup>ary endpoint & DP**
- **Partnerships progressing**
- **Abbott blood screening**

LT Growth: 40%

Gross Margin: +300 bps

Instrument Growth: +25%

- **Revenue growth +64%**
- **Gross Margin +650 bps**
- **Instrument growth +70%**

100x sensitivity by '21 YE

New frontier of medicine

Protein Translational Modifications

- **40X defined**
- **Prototype developed**

## Instruments

## Assay kits

## Services



HD-1 / HD-X Q4'19

Floor-standing integrated  
Assay prep and detection  
400+ publications



SR-X

Benchtop semi-automated assay prep



SP-X Q2'19

Simoa planar assay  
Benchtop semi-automated assay prep  
Multiplex capabilities



Plate

Bead

250+ assays  
Homebrew kits  
Singleplex and multiplex \



Accelerator

Contract research & testing  
Custom assay development & reagent production  
**CLIA and LDT capabilities**

# We are Addressing a Significant Unmet Need in Drug Development

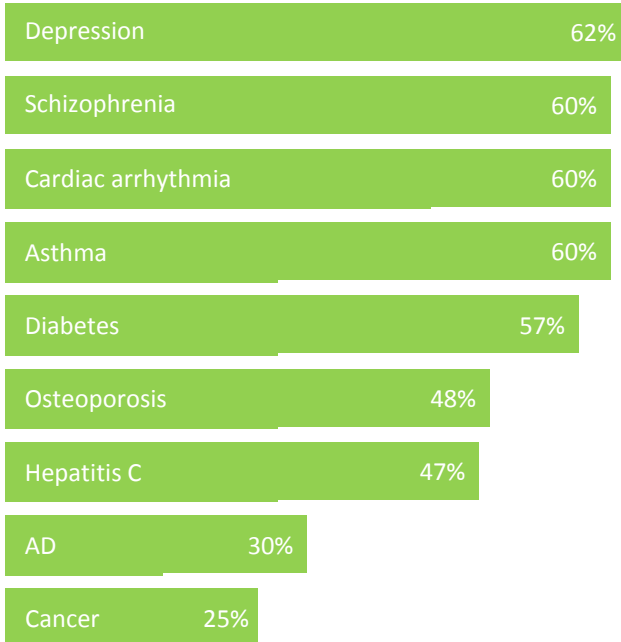
FDA Announces Office of Drug Evaluation Science - ODES

## DRUG PERFORMANCE

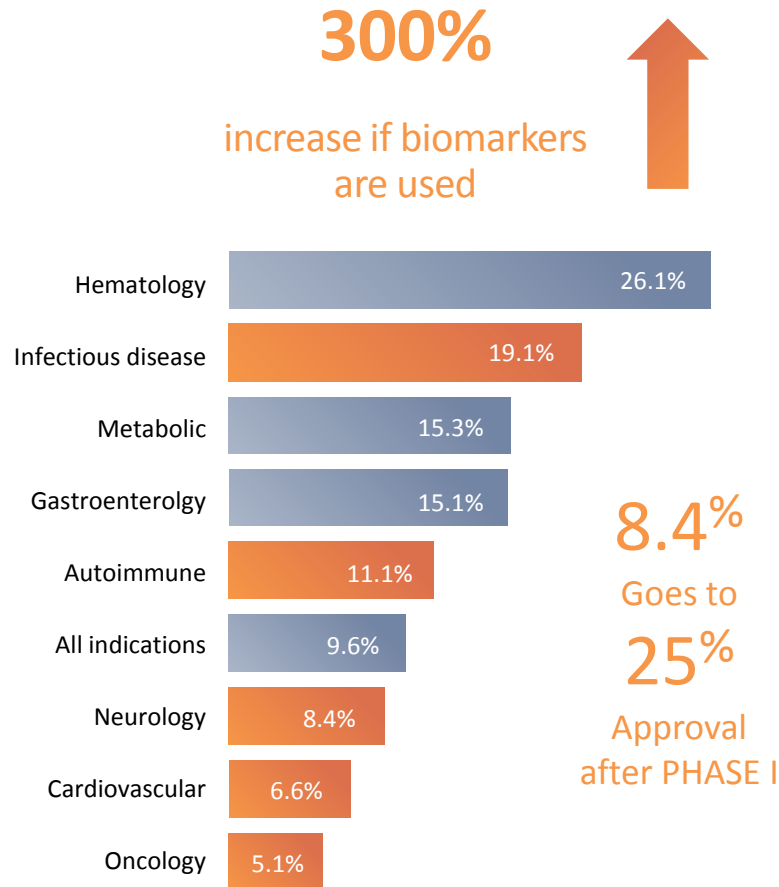
### TOXICITY

Adverse drug events are a substantial cause of Death in USA

### EFFICACY

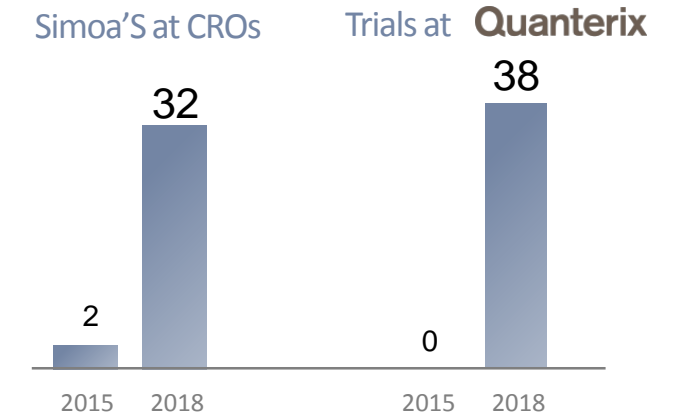


## PROBABILITY OF DRUG APPROVAL

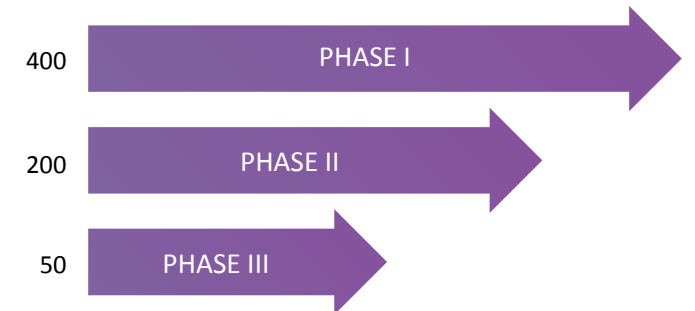


Probability of phase III approval after Phase 1 approval

## VALIDATION OF SIMOA IMPACT



**650 clinical trials with Simoa at single CRO**



MYRIAD RBM.

## Research Institutions

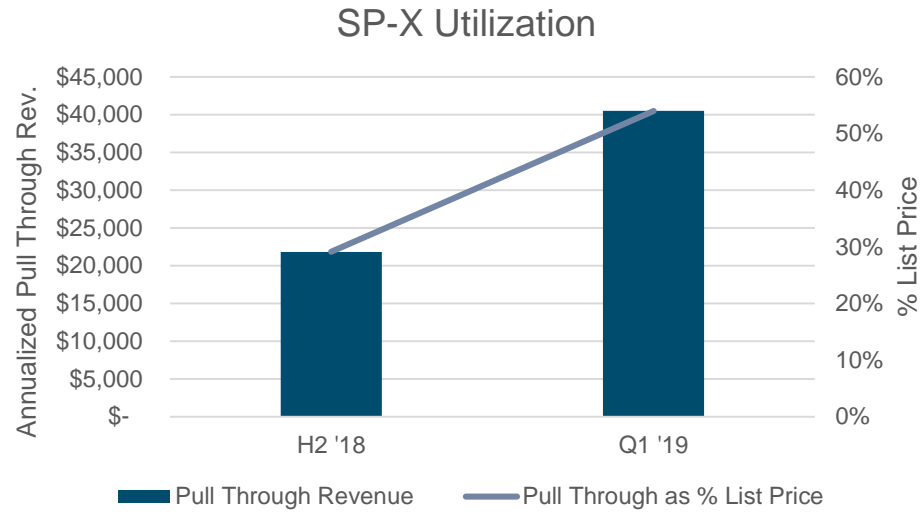
## Biopharma

## Other



# SP-X Launch in Oncology

## Exceptional Utilization at Key Accounts



### Robust Demo Program



- **5** SP-Xs sold, **+86%** growth in utilization for top 3 customers
- 10 new multiplex panels across **52** immune & oncology biomarkers
- Equivalent sensitivity with HD-1

# Launching Simoa HD-X Analyzer ahead of schedule Delivering digital biomarker disruption that you can count on



**Re-engineering ultra-sensitivity, leveraging years of experience**

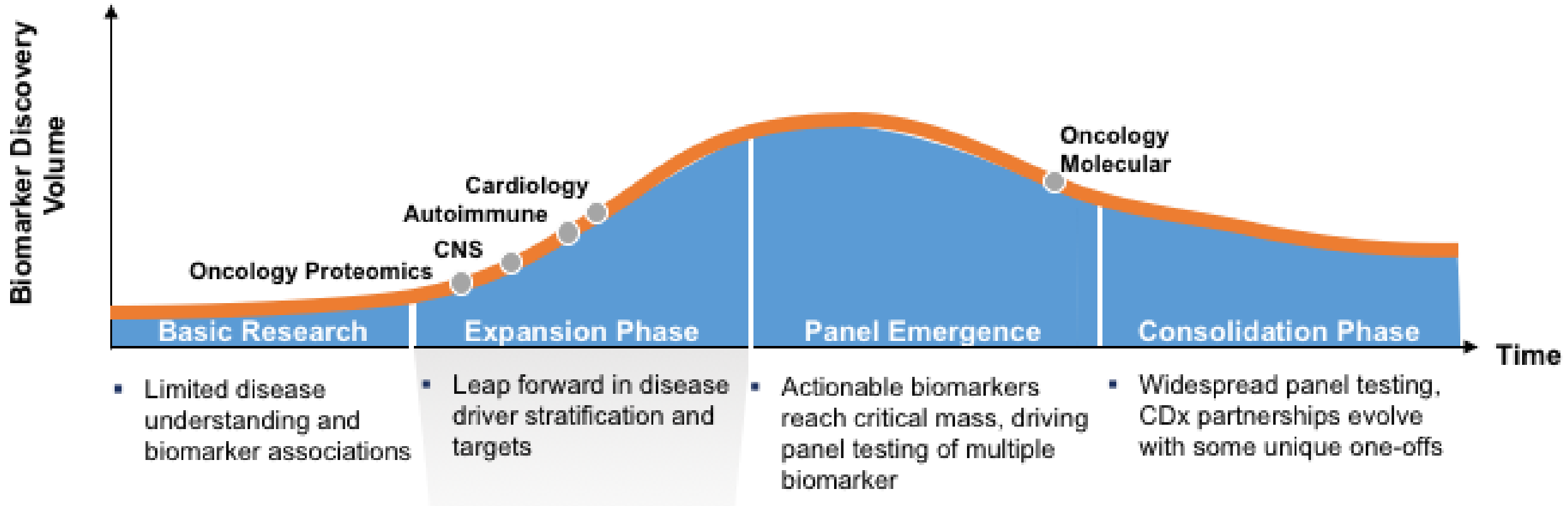
**Major productivity improvements, greater flexibility and unparalleled sensitivity**

**Best-in-class assay performance** across a **broad assay menu** to empower biomarker research and accelerate drug development.

**Regulatory Compliance** – Enables 21CFR Part 11 compliance with streamlined run reports and user management

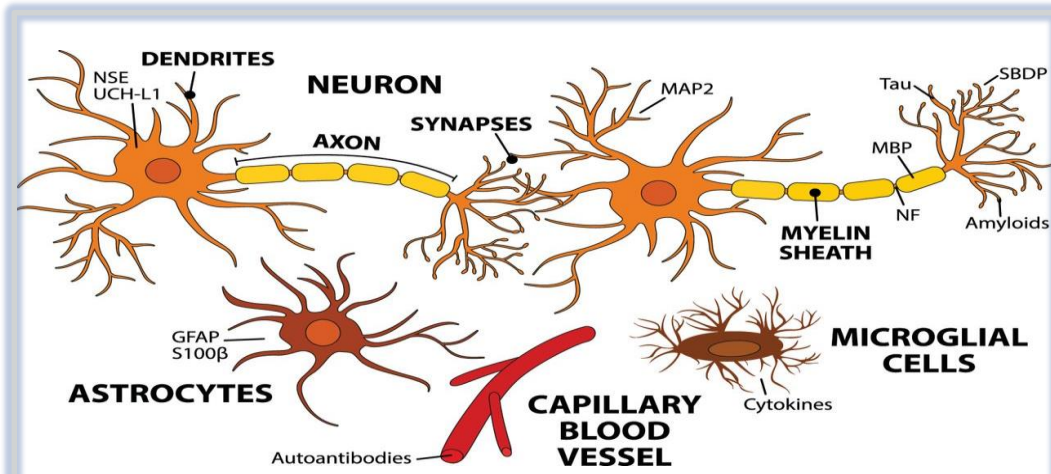
- Taking orders, shipping Q4
- Trade-in program available

## Biomarker Discovery Lifecycle



# Unmet Need

*Development of neurological disease diagnostics has been slow due to disease complexity.*



**Neuro health has become national Health Priority** due to veteran PTSD, opioid addictions, AD demographics mental health issues, and healthcare burden of neurological conditions

Biopharma industry discouraged by lack of returns and use of **subjective cognitive endpoints**



1

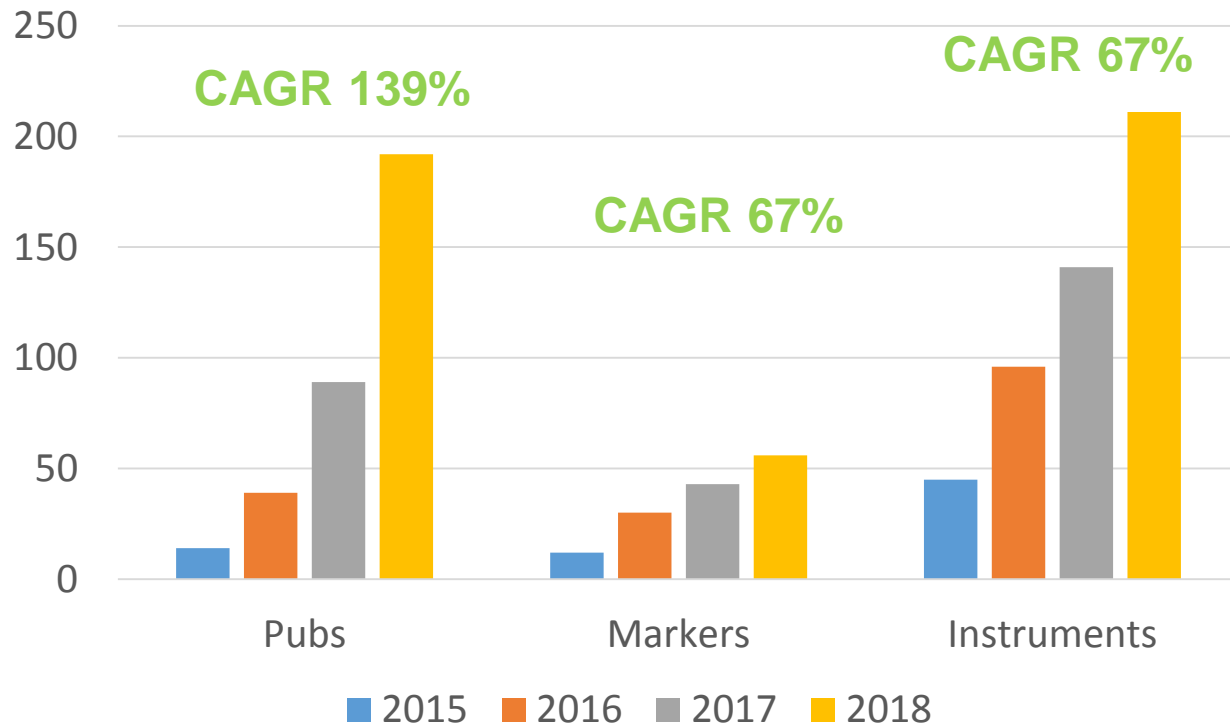
FDA issuing guidance to enable use of biomarkers in drug trials for early stage disease cohorts

2

Biopharma deploying biomarker approaches to trial design



Neurology Momentum



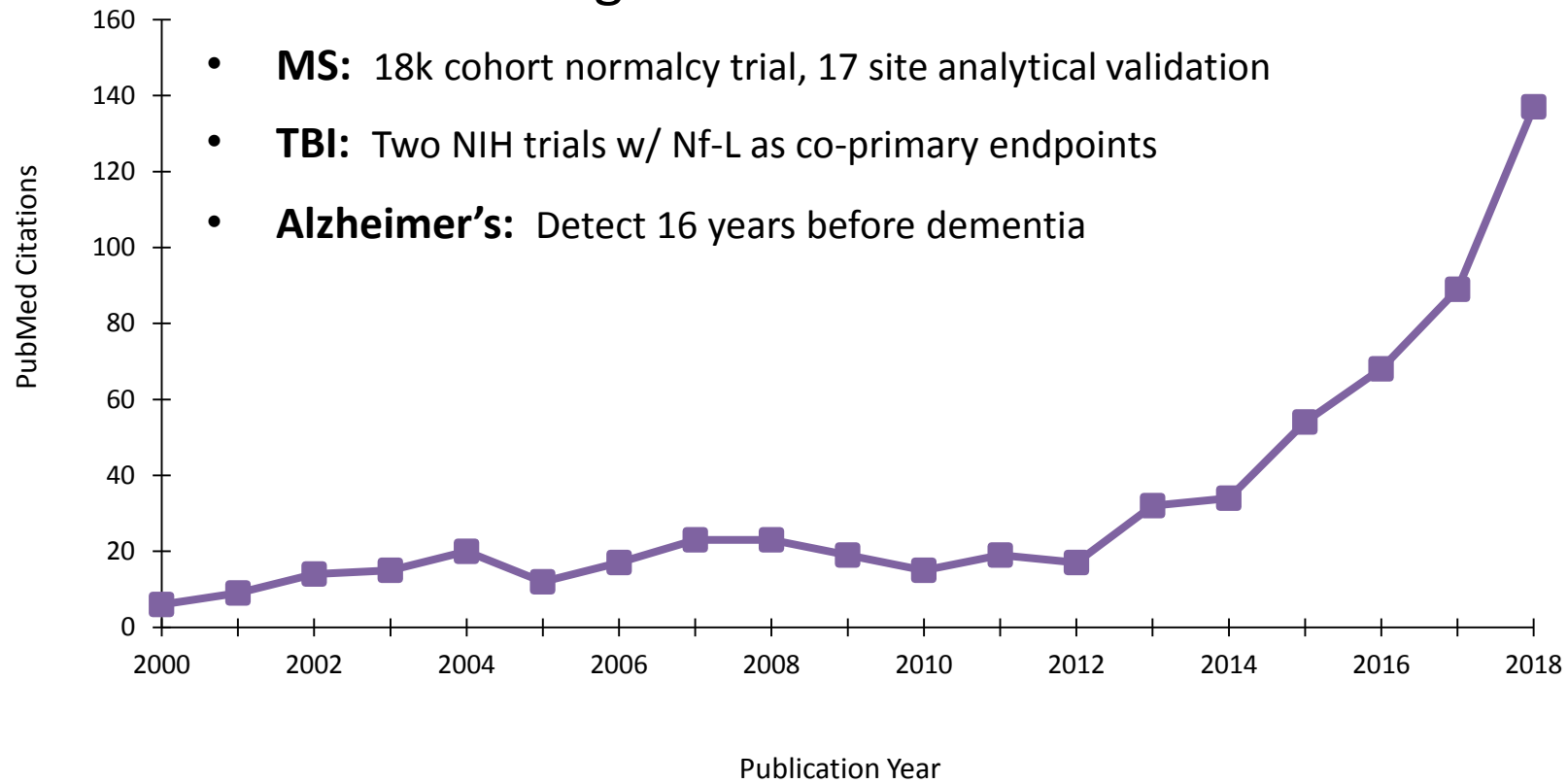
- Nf-L showing tremendous potential for key clinical applications in top peer-reviewed pubs; FDA interest
- Better AUC measuring AB40/42 than breakthrough device exemption for Alzheimer's
- Promise of blood-based neurology tests based on publications (CNN, Forbes, Bloomberg, Washington Post, GMA, etc.)
- Deep adoption by leading academic and pharma with strong network of world-leading KOLs



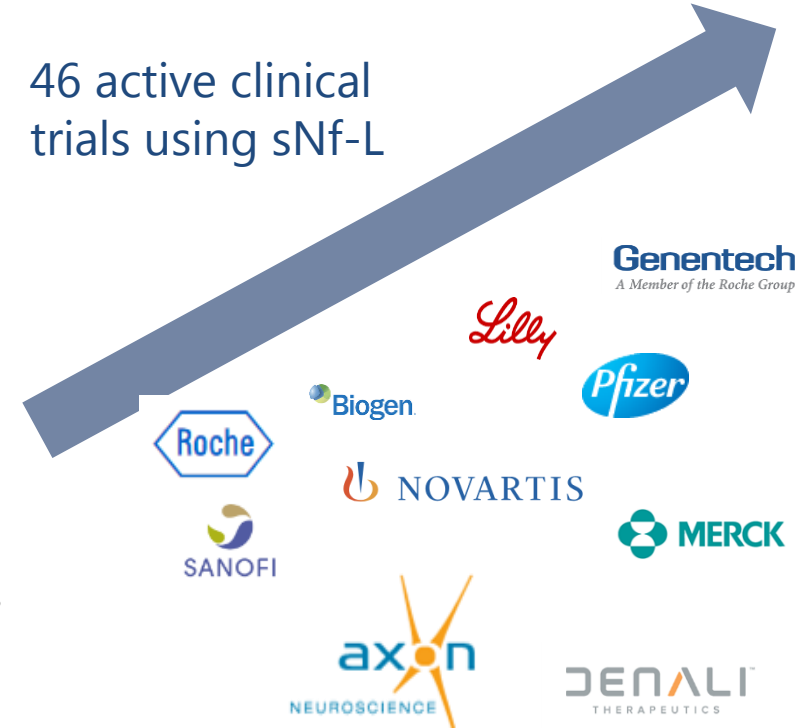
## RESEARCH PUBLICATIONS ON NFL

### Three shots on goal:

- **MS:** 18k cohort normalcy trial, 17 site analytical validation
- **TBI:** Two NIH trials w/ Nf-L as co-primary endpoints
- **Alzheimer's:** Detect 16 years before dementia

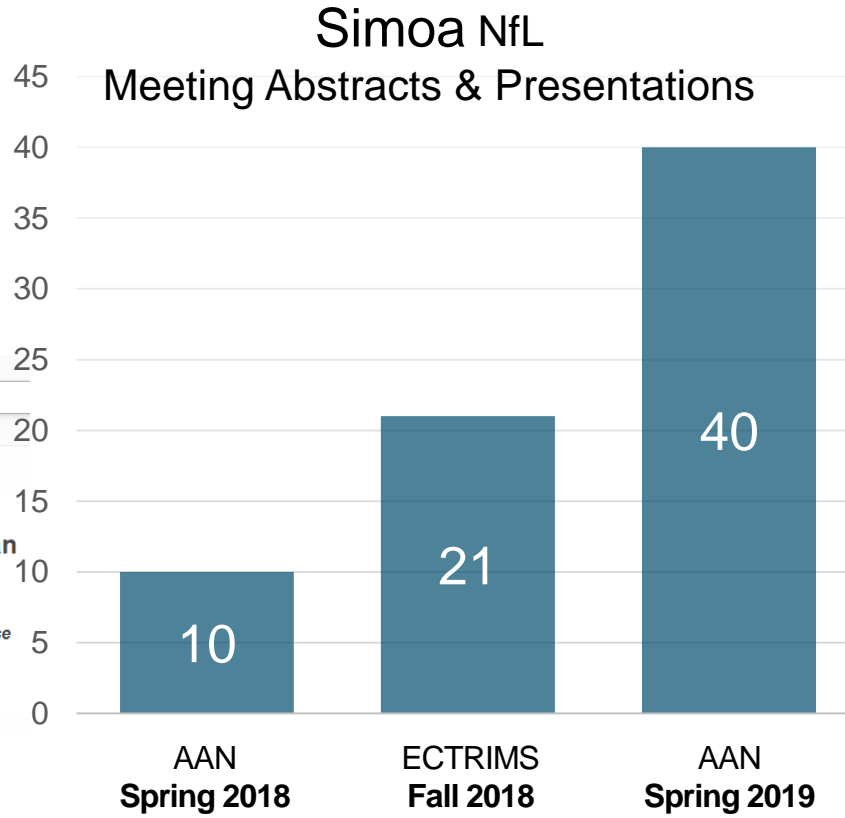
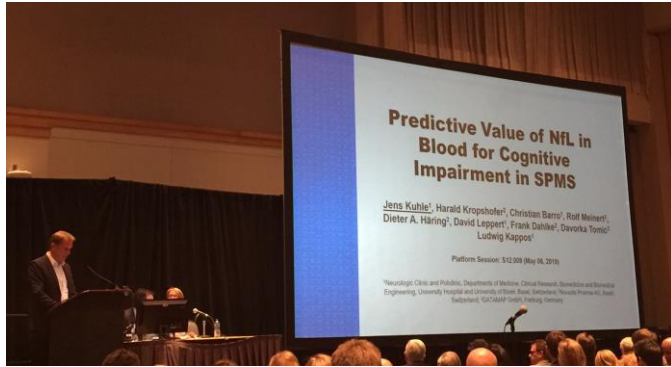


46 active clinical trials using sNFL



Source: Health Advances analysis, PubMed.

# AAN 2019: Explosive momentum of Simoa NfL



## Serum Neurofilament Light (NfL) for Disease Prognosis and Treatment Monitoring in Multiple Sclerosis Patients: Toward Implementation Into Clinical Care.

Peter A. Calabresi,<sup>1</sup> Jens Kuhle,<sup>2</sup> Douglas L. Arnold,<sup>3</sup> R. Philip Kinkel,<sup>4</sup> Ludwig Kappos,<sup>2</sup> Carol M. Singh,<sup>5</sup> Dipen Sangurdekar,<sup>6</sup> Carl De Moor,<sup>7</sup> Bob Engle,<sup>8</sup> Ray Su,<sup>9</sup> Aaron Deykin,<sup>9</sup> Elizabeth Fisher,<sup>9</sup> Alfred Sandrock,<sup>9</sup> Bernd C. Kieseier,<sup>9</sup> Richard A. Rudick,<sup>9</sup> Tatiana Plavina<sup>9</sup>

<sup>1</sup>Department of Neurology, Johns Hopkins University School of Medicine, Baltimore, MD, USA; <sup>2</sup>Neurologic Clinic and Policlinic, Departments of Medicine, Biomedicine and Clinical Research, University Hospital Basel, Basel, Switzerland; <sup>3</sup>Montreal Neurological Institute, McGill University, Montreal, QC, Canada; <sup>4</sup>Department of Neurosciences, University of California, San Diego, CA, USA; <sup>5</sup>Biogen Inc., Cambridge, MA, USA



## Natalizumab Reduces Serum Concentrations of Neurofilament Light Chain in Secondary Progressive Multiple Sclerosis Patients From the Phase 3 ASCEND Study

Raju Kapoor,<sup>1</sup> Finn Sellebjerg,<sup>2</sup> Hans-Peter Hartung,<sup>3</sup> Douglas Arnold,<sup>4</sup> Mark S. Freedman,<sup>5</sup> Douglas Jeffery,<sup>6</sup> Aaron Miller,<sup>7</sup> Keith R. Edwards,<sup>8</sup> Carol M. Singh,<sup>9</sup> Ih Chang,<sup>10</sup> Zhang Ren,<sup>11</sup> Dipen Sangurdekar,<sup>12</sup> Bing Zhu,<sup>13</sup> Devangi Mehta,<sup>14</sup> Pei-Ran Ho,<sup>15</sup> Nolan Campbell,<sup>16</sup> Michael Edwards,<sup>17</sup> Elizabeth Fisher,<sup>18</sup> Bernd C. Kieseier,<sup>19</sup> Richard A. Rudick,<sup>20</sup> Tatiana Plavina<sup>21</sup>

## Long-term Effect of Fingolimod in Reducing Blood Neurofilament Light Levels in Patients with Relapsing-remitting Multiple Sclerosis

Jeffrey Cohen,<sup>1</sup> Ludwig Kappos,<sup>2</sup> Nadia Tenenbaum,<sup>3</sup> Jackie Han,<sup>4</sup> Harald Kropshofer,<sup>5</sup> Davorka Tomić,<sup>6</sup> Jens Kuhle<sup>7</sup>

<sup>1</sup>Cleveland Clinic, <sup>2</sup>Neurologic Clinic and Policlinic, Department of Medicine, Clinical Research, Biomedicine and Biomedical Engineering, University Hospital and University of Basel, <sup>3</sup>Novartis Pharmaceuticals Corporation, <sup>4</sup>Novartis Pharma AG

**Objective:** To assess the effect of long-term treatment with fingolimod on blood neurofilament light chain (NfL) levels in patients with relapsing-remitting multiple sclerosis (RRMS).

**Background:** NfL, a cytoskeleton protein, is elevated in blood upon neuroaxonal damage. Blood NfL is a promising biomarker for monitoring disease activity, treatment response, and prognosis in MS.

**Design/Methods:** This post hoc analysis was based on data from patients who received fingolimod 0.5 mg once daily or placebo/interferon β-1a (IFN) 30 µg once weekly in pivotal studies (24-month FREEDOMS/12-month TRANSFORMS), and then fingolimod in the open-label LONGTERMS extension study for up to 10 years. The analysis included a subset of patients who had blood NfL assessments at baseline, end of core (EoC) in pivotal studies, and end of study (EoS) in LONGTERMS. Patients were categorized into two groups: a continuous group (n=37) who received fingolimod throughout the studies and a switched group (n=42) who transitioned from placebo/IFN group to fingolimod in the LONGTERMS. NfL was measured using Single Molecule Array (SIMOA™) immunoassay. The geometric mean change in NfL levels from baseline to EoS was analyzed using Wilcoxon signed-rank test.

**Results:** The mean exposure to fingolimod was 3483 days in the continuous group and 2822 days in the switched group. In the continuous group, baseline NfL levels of 33 pg/mL were significantly reduced by approximately 40% at both EoC and EoS (20 pg/mL, P<0.0001 and P=0.0002, respectively). In the switched group, baseline NfL levels of 29 pg/mL were reduced by 15% at EoC (25 pg/mL, P>0.44) and 41% at EoS (17 pg/mL, P<0.0001).

**Conclusions:** Fingolimod 0.5 mg significantly reduced blood NfL, maintaining its low levels with continuous treatment for up to 10 years. NfL levels were reduced to a lesser extent during treatment with IFN but decreased further with switch to fingolimod, demonstrating the greater impact of highly effective therapy in RRMS.



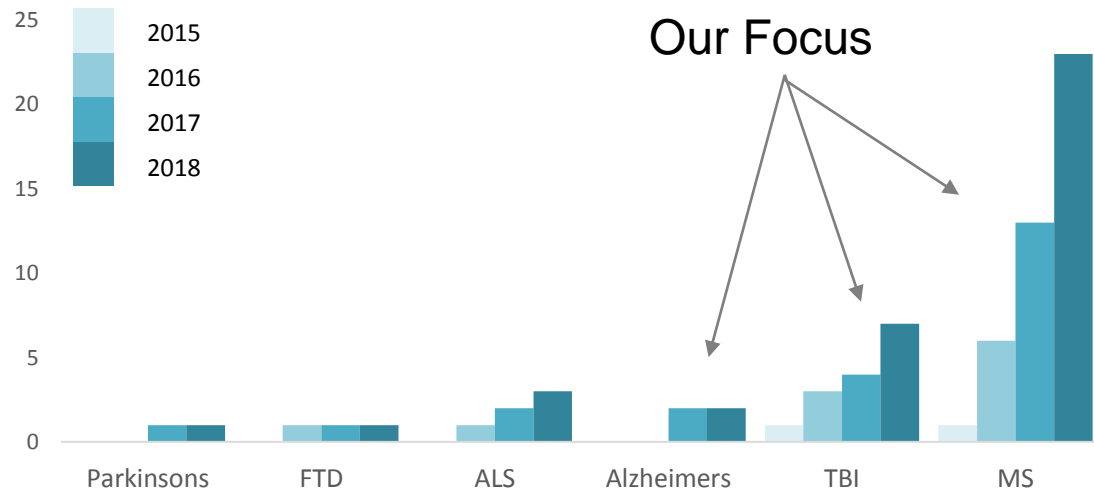
Quanterix' Simoa Technology Powers More Than 85 Percent of Neurofilament Light Biomarker Research to be Unveiled at American Academy of Neurology Annual Meeting

Leading global neurology conference will feature 36 new Simoa-powered studies validating the use of Neurofilament light chain (Nf-L) as a potential diagnostic and prognostic biomarker for neurodegeneration



5 Phase III trials across >1600 MS patients demonstrate clinical utility of Simoa NfL

## NFL PUBLICATIONS

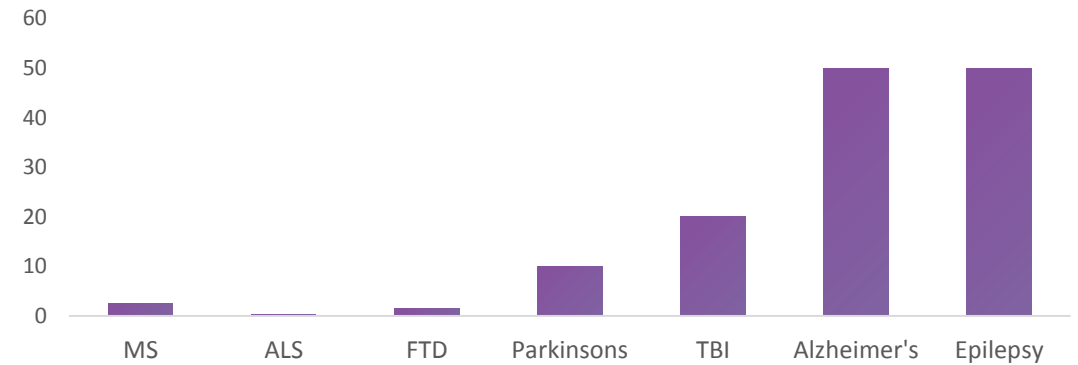


### STUDIES CONFIRM NFL CLINICAL UTILITY:

- Disease activity monitoring
- Drug efficacy monitoring
- Relapse/severity prognostic

Majority of published data obtained with Simoa NfL

## WW DISEASE INCIDENCE (MILLIONS)



### MULTIPLE SCLEROSIS:

- Avg. age of onset: 34 yrs; avg. life expectancy after onset: 30 yrs
- Standard of care: MRI 1-2X/yr
- NfL as MRI replacement: 3.5M tests/yr

Clinical Validation of NfL for MS is a Key Beachhead

# Poised to Disrupt Healthcare and Create Significant Value

