Point of Care Testing in Molecular Diagnostics: What it Takes to Win?

2016 Financial Analyst Briefing

RICHARD S. CREAGER, PHD

DISCLOSURES

- THIS PRESENTATION HAS BEEN PREPARED SOLELY FOR INFORMATIONAL PURPOSES
- THE INFORMATION REPRESENTS THE PERSONAL VIEWS OF THE PRESENTER

Richard S. Creager, PhD

- PhD in Microbiology
- > 35 years IVD Experience
- > 150 commercial products (510k, PMA)
- Senior Executive/GM for Fortune 500 IVD companies
- Former SVP of MDx IVD company
- Former CSO leading IVD company
- Current, IOI Partners/NaviDx

Agenda

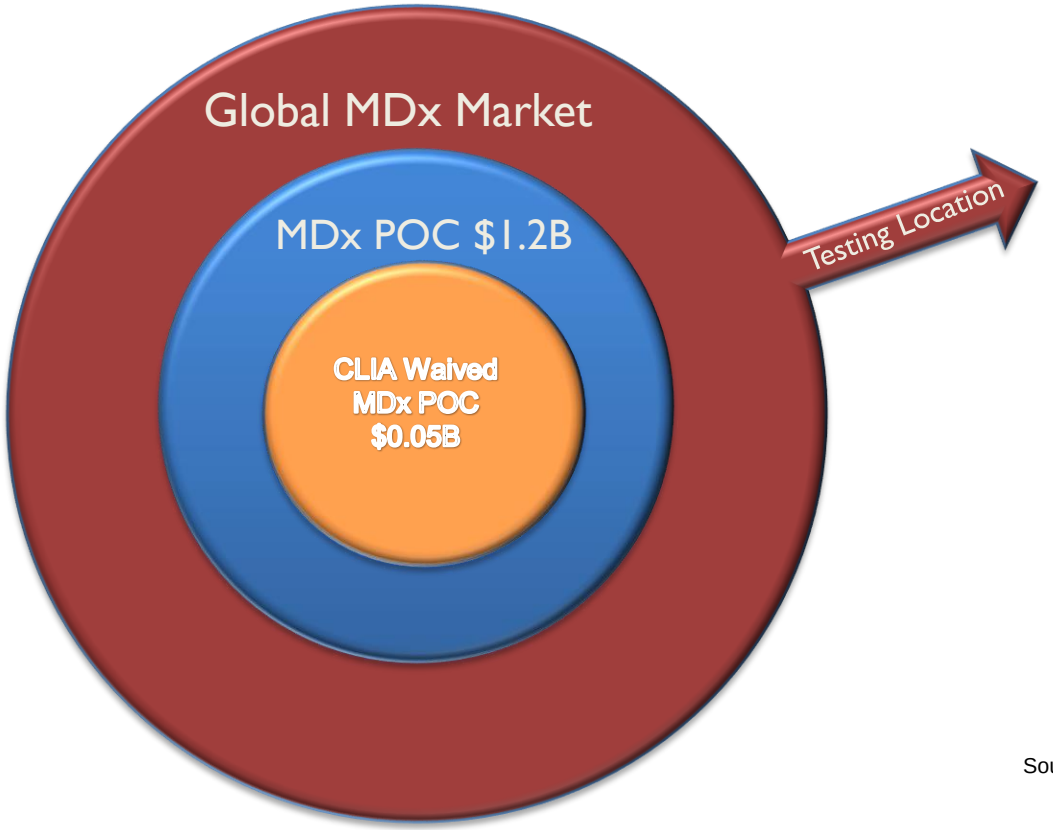
- Molecular Diagnostics Point of Care Market
- Customer Requirements
- Market Barriers
- Point of Care Systems: Current and Future
- Summary

Molecular Diagnostics POC Attracting Attention

More Than $1B in Acquisitions, Investments, Financings, and Public Offerings Since 2009

Molecular Diagnostics Market

2015 Global MDx Market size: $6B



- Hospital Labs
- CLIA High Complexity Labs
- Reference Labs

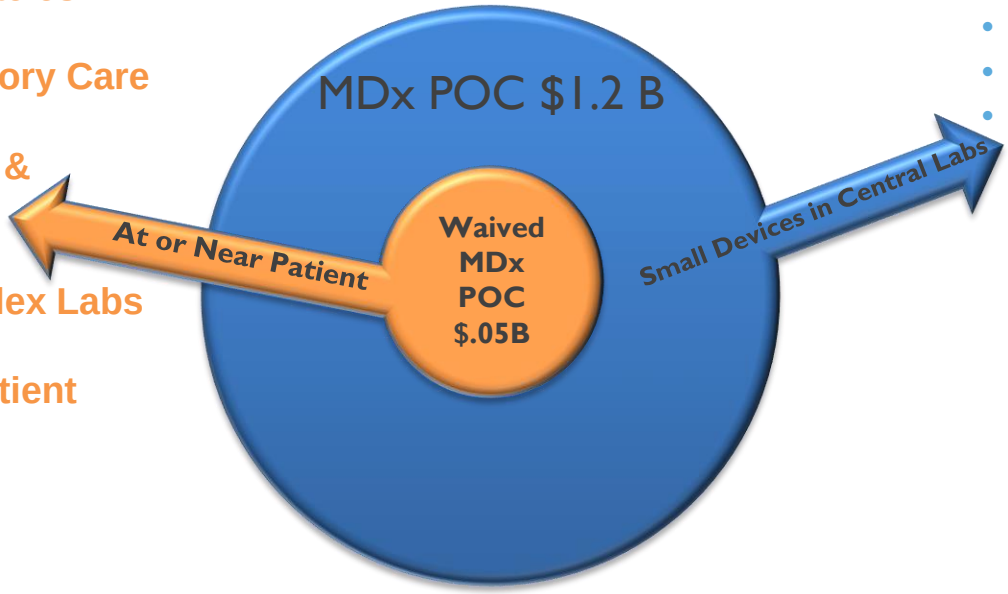
Sources: Grand View Molecular POC 2015 report

Point of Care Represents ~ 20% of Total MDx Market Today

MDx POC Share of Total MDx Market

2015 Global MDx Market size: $6B USD

- Retail Clinics & Pharmacies
- Student Health Clinics
- Neighborhood Ambulatory Care Clinics
- Physician Offices (GPs & Specialists)
- CLIA Waived Labs
- CLIA Moderately Complex Labs
- Hospital Clinics
- Hospital Floor (Near Patient Bedside)
- Emergency Rooms
- Intensive Care Units
- Rural Health Clinics
- Nursing Homes, Assisted Living Residence



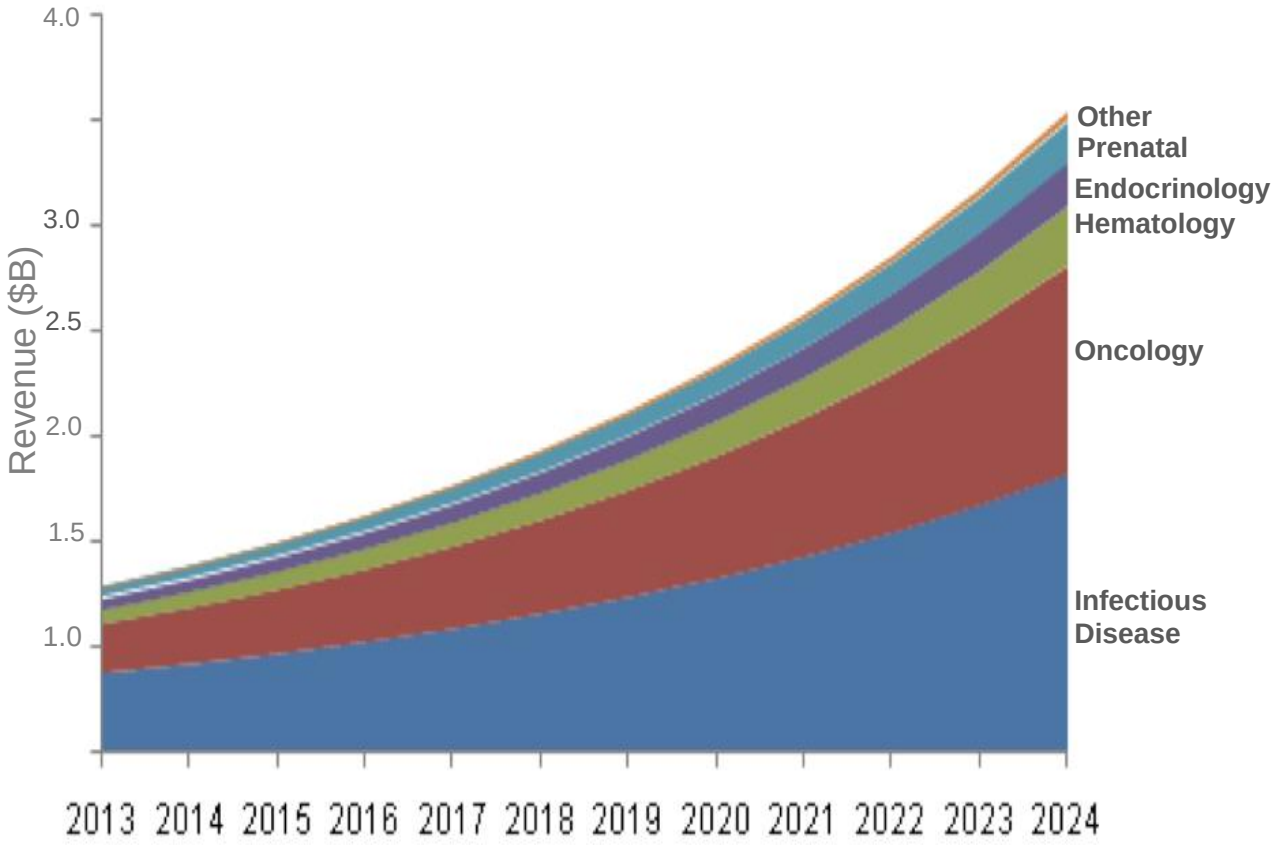
- Hospital Labs
- Moderately Complex
- Highly Complex Labs
- Reference Labs

Source: Grand View Molecular POC 2015 report

Only $50M of the $1.2B MDx POC is CLIA Waived

~ 100% of CLIA Waived POC is Respiratory Testing (Flu & Strep)

Global MDx POC Market Growth



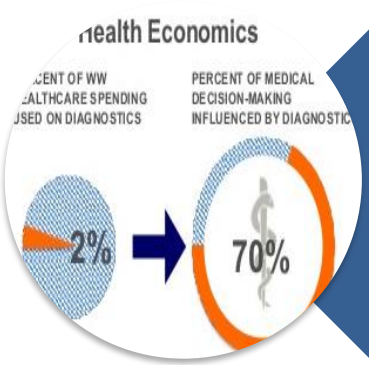
Source: Grand View Molecular POC 2015 report

MDx POC Market Expected To Triple By 2024
Infectious Disease and Oncology Assays will Dominate

MDX POC Market Drivers

Patient Focused Drivers

- Rapid results impacts patient treatment decisions
- Personalized medicine (new therapies, the right antibiotic, etc.)

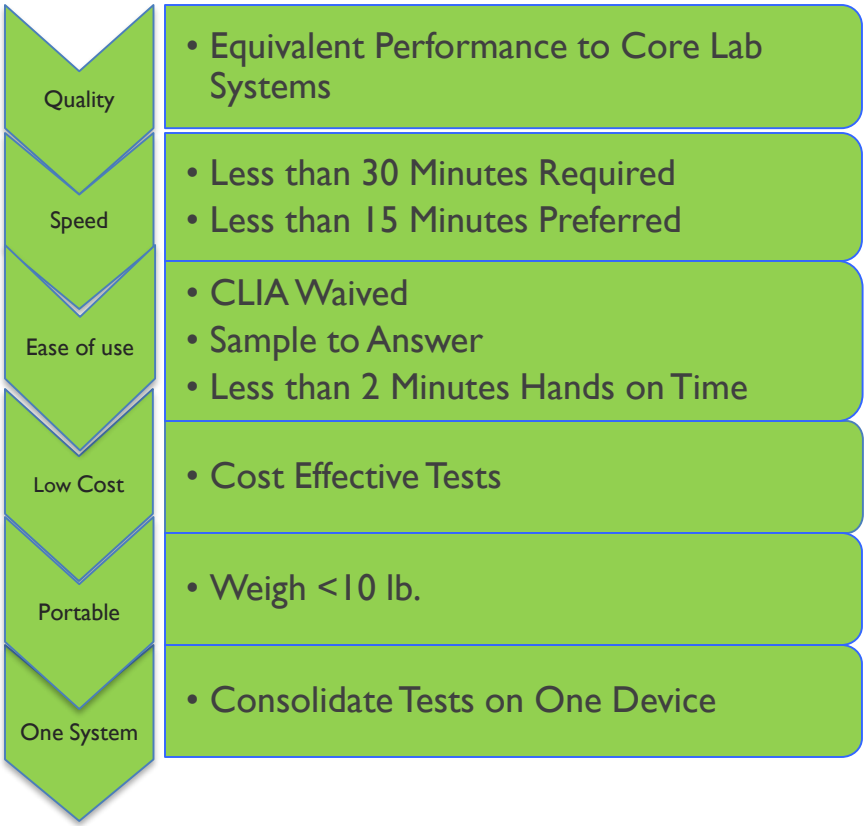


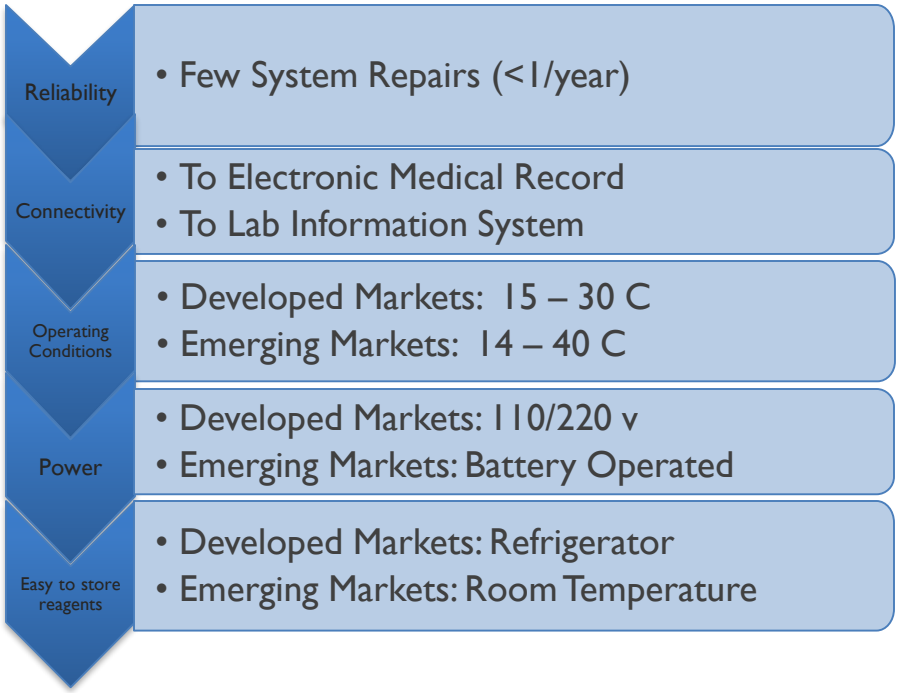
Economic Drivers

- Healthcare Reform – more covered patients
- Ageing Populations - treatment in non-hospital settings (assisted living, nursing care, at-home care, etc.)
- New Healthcare Delivery Models (retail, self-testing, etc.)
- Healthcare Decentralization (China, India, rural USA, etc.)
- Epidemics, Pandemics, Emerging Pathogens (SARS, Zika, Ebola, Chikungunya)
- Faster Results: Reduce length of hospital stays, reduce time in ERs

Patient & Economic Benefits are Key Drivers

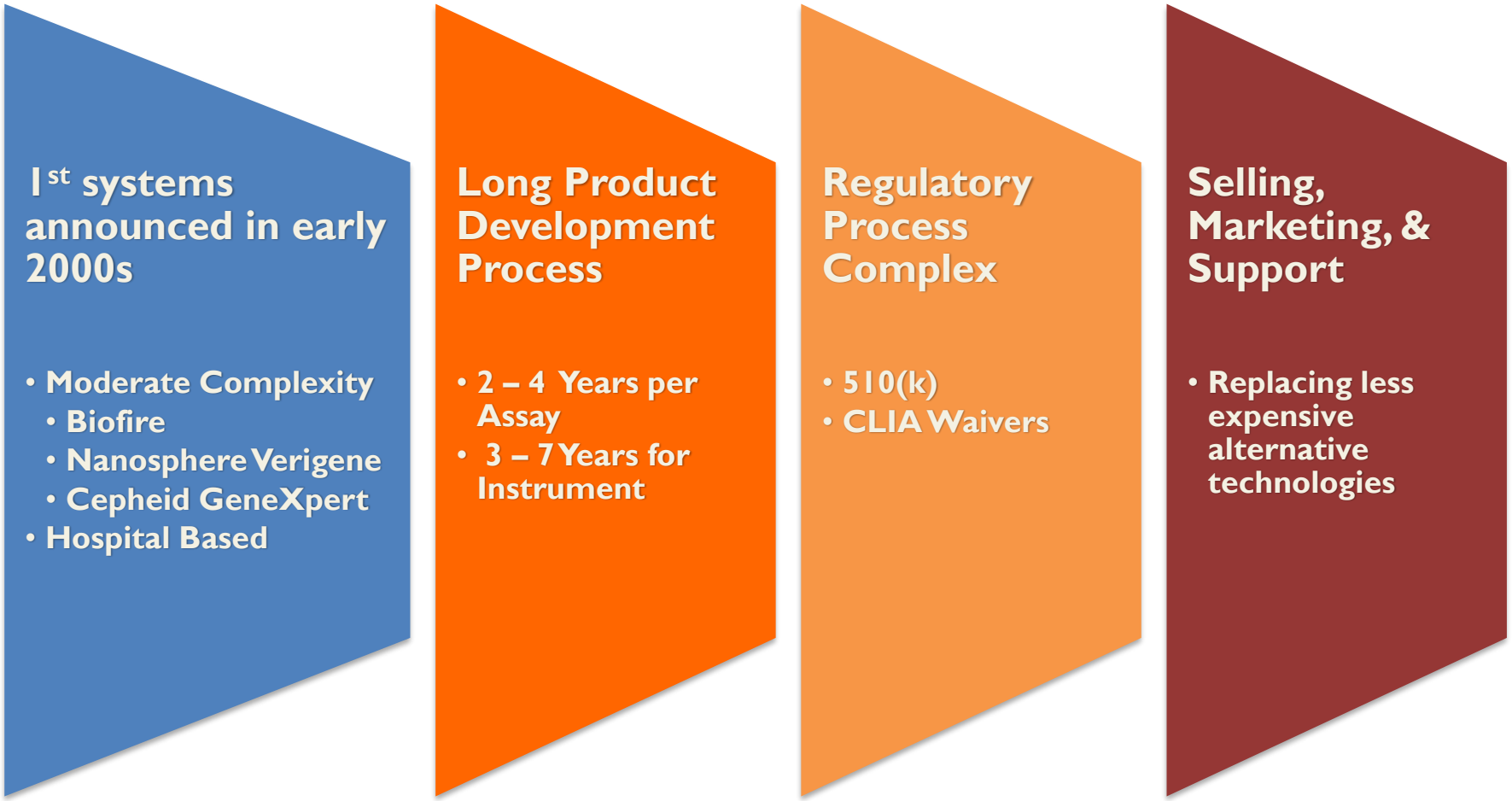
What Customers Want





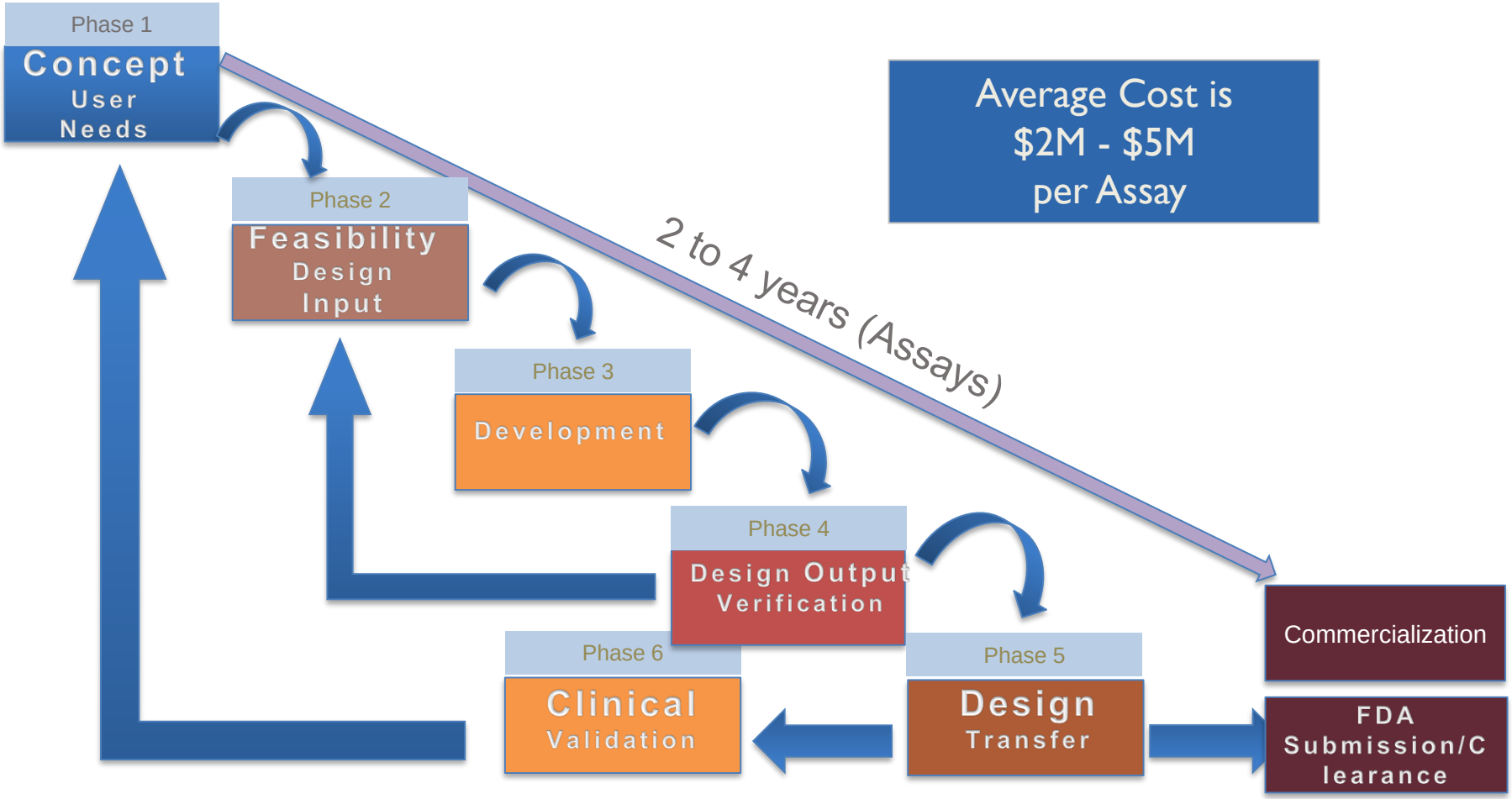
Improved Patient Management: Core Lab Quality, Cost, Easy To Use, and Fast Results are Key Drivers for Adoption

Key Development Challenges



Development is a Long & Expensive Process

Regulated Product Development



Long Process: Missteps and Do-Overs

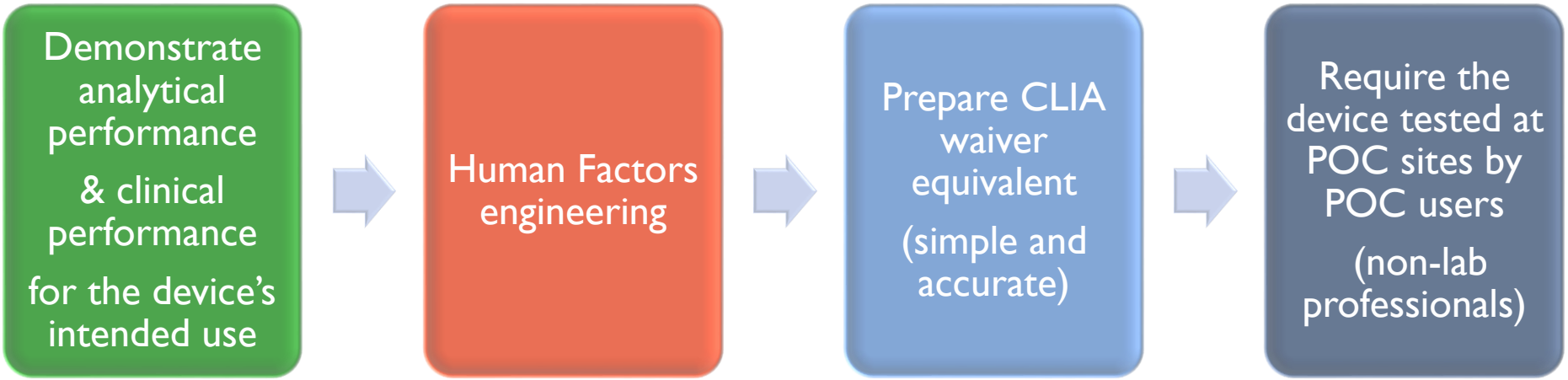
CLIA WAIVER TESTING

By CLIA Definition, Waived Tests are:

- Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible
- Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

*Clinical Laboratory Improvement Amendments of 1988; FDA Consensus Guidance of 2005

POC Product Design Requirements



POC Regulatory Requirements Equivalent to Core Lab Systems

Clinical Studies

Influenza virus (1,000 – 2,000 patients)

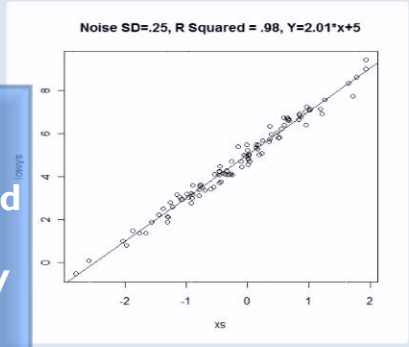
Large # of Patients

Chlamydia/ Gonorrhea (5,000 – 7,000 patients)

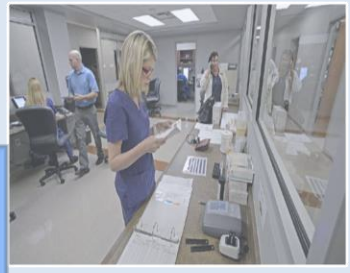
Some tests require multiple sample types (e.g. urine, endocervical, vaginal, urethral, fecal, throat)

Multiple Sample Types

Method comparison and precision & reproducibility studies



3 POC sites, e.g. ED, physician's office, nurse's station, etc.



High Amount of Resources

At least 3 unskilled operators at each site

- Clinical studies take 6 – 12 months

- Costs from $500k to $2M

Clinical Studies Tend to be Large, Complex, & Expensive

Regulatory Review

FDA Clearance

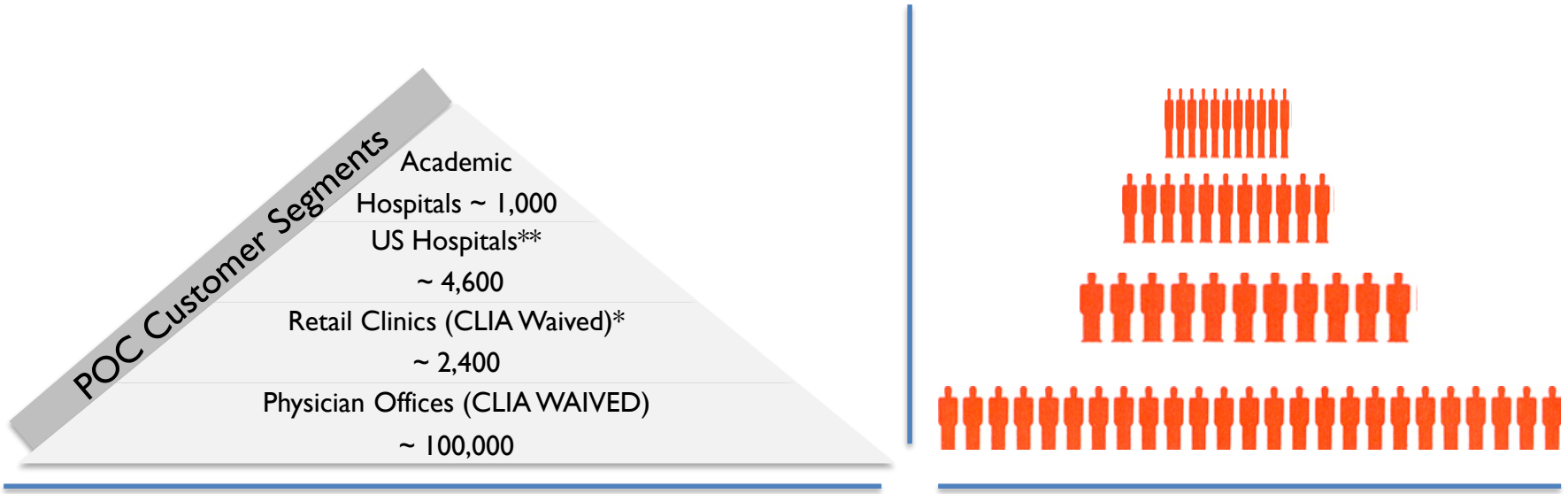
- Recommended: pursue CLIA waiver, in parallel with 510(k)
- Class: Clearance Class II device (CT/NG, Flu A/B, Strep A)
- Review Time: ~3 - 6 months

CE Mark

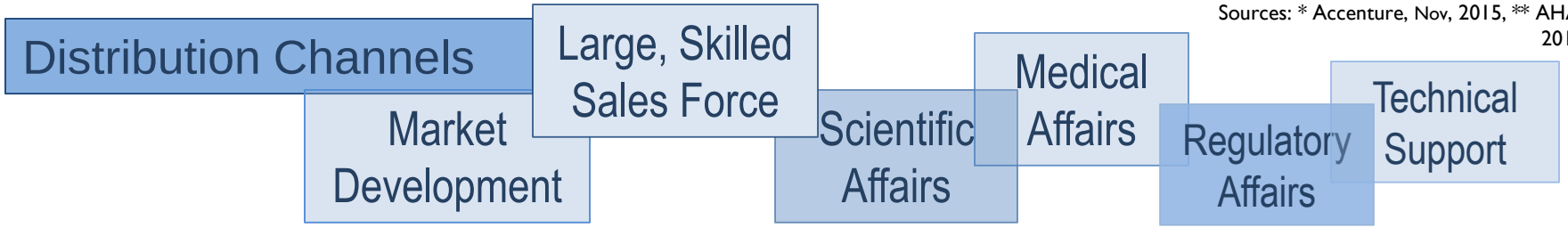
- Class: CE Mark Class C device (POC)
- Review Time: ~ 2 – 4 months

US, China, Japan Review Times Longer than Europe

MDx POC Commercialization



Sources: * Accenture, Nov, 2015, ** AHA, 2016



Commercial Success Requires Adequate Staff Sales and Support

Today's Products

Moderate Complexity


Nanosphere Verigene


Meridian Illumigene


Diasorin Simplexa


Cepheid GeneXpert


Biocartis Idylla


Quidel Solana


bioMérieux FilmArray


bioMérieux FilmArray Torch

- Slower test times: ~ 1 – 2 hours
- Skilled operators
- Tend to be large/heavy (10 – 55 lbs.)
- Limited menu (except Cepheid, Diasorin)
- Hospital-based

CLIA-Waived

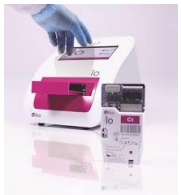

Roche Liat


Alere Alere i

- Fast test times: ~ 8 – 20 minutes
- Non-skilled operators
- Light weight/portable (7 – 8 lbs.)
- New customer segments
- Strong distribution channels
- Limited menu

Simplicity (CLIA-Waived): Expanding Market Penetration

Up and Coming Products



Atlas Genetics Io System

Cepheid Omni

QuantumDx Q-POC

Nanomix eLab

Epistem GeneDrive

Micronics PanNat

Spartan Biosciences Cube

Mesa Biotech Dock

- Promise fast test times: ~ 10 - 30 minutes
- Non-skilled operators
- Most ultra-light weight/portable (1 – 5 lbs.)
- Launching 2017 - 2018

Smaller, Faster, Lighter with Potential of Broad Market Reach

What Will it Take to Win in MDx POC?

The Right Product/Technology: Core Lab Quality Results, Easy, Fast, Simple (CLIA-Waived), Reliable	Cost-Effective (displace inexpensive lateral flow devices)	Scalable Platform: Match test volume needs for each test setting
Broad Menu in Infectious Disease	Distribution Channels	Marketing, Sales, & Support

Summary

MDx POC market

Significant upside potential

A lot of players

Major IVD companies & new entrants

Significant hurdles

Expensive ($2M - $5M/assay; $50M - $100M/system)

- Menu (>10 – 15 years for full menu)
- Complex clinical studies & regulatory approvals
- Requires adequate marketing & sales staff
- Pricing (Margins) as more players enter market

Thank You!

- For more information or follow-up:

  - Richard S. Creager, PhD
  - rscreager@navidx.com
  - IOI Partners & NaviDx
  - *ioipartners.com*