

Investor Day

November 12, 2020

Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation: the impact and duration of the novel virus (COVID-19) global pandemic; funding and compliance risks relating to government contracts, including the ability to meet key deliverables and milestones under our NIH RADx-ATP contract; our ability to accurately forecast demand for our products and products in development, including in new market segments; adverse changes in competitive conditions, the reimbursement system currently in place and future changes to that system, changes in economic conditions in our domestic and international markets, lower than anticipated market penetration of our products, our reliance on sales of our influenza and COVID-19 diagnostic tests, fluctuations in our operating results resulting from the timing of the onset, length and severity of cold and flu seasons, seasonality, government and media attention focused on influenza and other respiratory or novel viruses and the related potential impact on humans from such viruses, the quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors, and changes in the healthcare market and consolidation of our customer base; our development, acquisition and protection of proprietary technology rights; our ability to develop new technologies, products and markets and to commercialize new products; our reliance on a limited number of key distributors; our exposure to claims and litigation that could result in significant expenses and could ultimately result in an unfavorable outcome for us, including the ongoing litigation between us and Beckman Coulter, Inc.; intellectual property risks, including but not limited to, infringement litigation; our ability to finance our capital or operating needs; the financial soundness of our customers and suppliers; acceptance of our products among physicians and other healthcare providers; competition from other providers of diagnostic products; failures or delays in receipt of new product reviews or related to currently-marketed products by the U.S. Food and Drug Administration (the "FDA") or other regulatory authorities or loss of any previously received regulatory approvals or clearances or other adverse actions by regulatory authorities; changes in government policies; costs of and adverse operational impact from failure to comply with government regulations in addition to FDA regulations; compliance with government regulations relating to the handling, storage and disposal of hazardous substances; third-party reimbursement policies and potential cost constraints; our failure to comply with laws and regulations relating to billing and payment for healthcare services; our ability to meet demand for our products; interruptions or shortages in our supply of raw materials and other components; product defects; business risks not covered by insurance; costs and disruptions from failures in our information technology and storage systems; our exposure to data corruption, cyber-based attacks, security breaches and privacy violations; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, compliance with legal requirements, tariffs, exposure to currency exchange fluctuations and foreign currency exchange risk, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, social, political and economic instability, increased financial accounting and reporting burdens and complexities, taxes, and diversion of lower priced international products into U.S. markets; changes in tax rates and exposure to additional tax liabilities or assessments; our ability to identify and successfully acquire and integrate potential acquisition targets; our ability to manage our growth strategy and identify and integrate acquired companies or technologies and our ability to obtain financing; the level of our deferred payment obligations; that our Revolving Credit Facility is secured by substantially all of our assets; the agreements for our indebtedness place operating and financial restrictions on us and our ability to operate our business; that an event of default could trigger acceleration of our outstanding indebtedness; that we may incur additional indebtedness; dilution resulting from future sales of our equity; volatility in our stock price; provisions in our charter documents and Delaware law that might delay or impede stockholder actions with respect to business combinations or similar transactions; and our intention of not paying dividends. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "future," and similar words, although some forward-looking statements are expressed differently.

Forward-looking statements in this presentation include, among others, statements concerning: our outlook for the business, including, among others, projections about our revenue, revenue profile, gross margins, free cash flow, indebtedness, capital expenditures, expenses, including research and development ("R&D") and sales and marketing ("S&M"), EBITDA, market opportunities, geographic expansion, and development, manufacturing, regulatory and commercial activities; our strategic initiatives, goals and objectives; our merger and acquisition ("M&A") strategy. The risks described in reports and registration statements that we file with the Securities and Exchange Commission (the "SEC") from time to time, should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this presentation. Except as required by law, we undertake no obligation to publicly release any revision or update of these forward-looking statements, whether as a result of new information, future events or otherwise.

- **Projections:** The projections and estimates used in this presentation are based on numerous variables and assumptions, which are inherently uncertain, including factors related to the impact of the COVID-19 pandemic, continuity of supply of raw materials and other components, general economic and competitive conditions. Accordingly, actual results could differ materially from those set forth in the projected or estimated numbers. Inclusion of such projected and estimated numbers in this presentation should not be regarded as a representation that such results will be achieved. See "Forward-Looking Statements" above.
- **Non-GAAP Financial Measures**: This presentation contains adjusted EBITDA, which is a non-GAAP financial measure. Such non-GAAP financial measures are presented as supplemental financial measurements in the evaluation of our business. We believe the presentation of these financial measures helps investors to assess our operating performance from period to period and enhances understanding of our financial performance and highlights operational trends. Such measurements may not be comparable to those of other companies in our industry, which limits their usefulness as comparative metrics. Such metrics are not required by or calculated in accordance with generally accepted accounting principles ("GAAP") and should not be considered as substitutes for net income or any other measure of financial performance reported in accordance with GAAP or as a measure of operating cash flow or liquidity. You can find a description and other important information regarding adjusted EBITDA in the financial section of this presentation, and a reconciliation of the most directly comparable GAAP financial measure.



Agenda

Investor Day 2020

Topic	Presenter	Duration
Introduction and Overall Strategy	Doug Bryant	10 mins
Growth Drivers (pre-COVID)		30 mins
Savanna	Johannes Kehle and Tammi Ranalli	
hs-Troponin	Bill Ferenczy	
Sofia	Rhys de Callier	
Growth Drivers (current state)	Doug Bryant	5 mins
COVID-19 product pipeline		
Big Ideas		20 mins
Project “Sniffles”	Karen Gibson	
Project “Leapfrog”	Werner Kroll	
M&A and Financial Update	Randy Steward	20 mins
Live Q&A Session	Doug Bryant, Randy Steward	60 mins

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Savanna®

Johannes Kehle, PhD
VP, Research & Development, Savanna



Savanna key development factors & differentiators

1 Proven robust technologies

- Magnetic bead based nucleic acid isolation
- 4 color PCR multiplexing for up to 12 analytes/ run

2 Fast turnaround time

- Fast data readout by unique light fiber optics
- qPCR with 45 cycles in < 12min

3 Simplicity and ease-of-use

- Direct swab and liquid sample compatibility
- Reagents stable at room temperature

4 Instrument modularity

- Main bay drives up to 3 auxiliary bays
- Auxiliary bays added vertically or horizontally

5 Assay versatility

- Qualitative/ quantitative assays compatible
- Combined pathogen/ AST testing in one assay run

6 Assay development strategy

- Develop critical mass of assays near launch time
- Scalable assay manufacturing concept

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Savanna’s disposable cartridge

Robust technologies

PCR chambers

Four independent chambers for up to 12 analytes per run through very fast qPCR



Simplicity and ease-of-use

Swab sample port

Direct swab addition

Liquid sample port

Accommodating sample volumes from 50µl to 200µl (overflow chamber for simple liquid sample addition and correct volume introduction into cartridge)

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- Small Footprint
- Intuitive touch screen
- Illuminated cartridge bay
- Integrated bar code reader
- Full, built-in connectivity
- Up to 3 auxiliary bays

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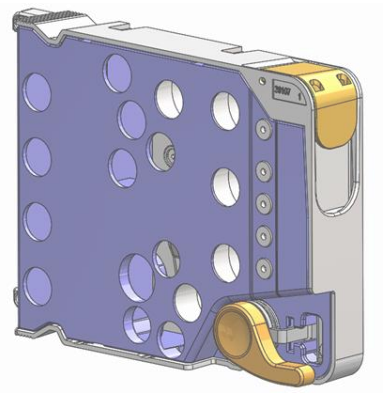
Savanna® offers true sample-in, result-out operation.

1



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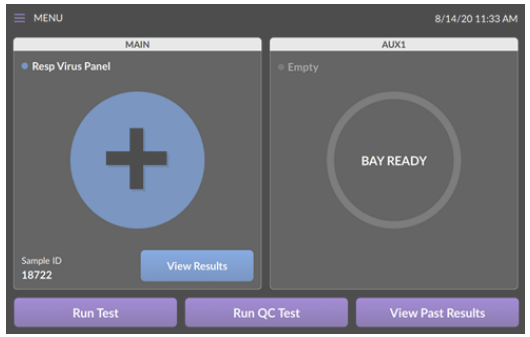
3



Results in <20mins (RVP10 Panel)

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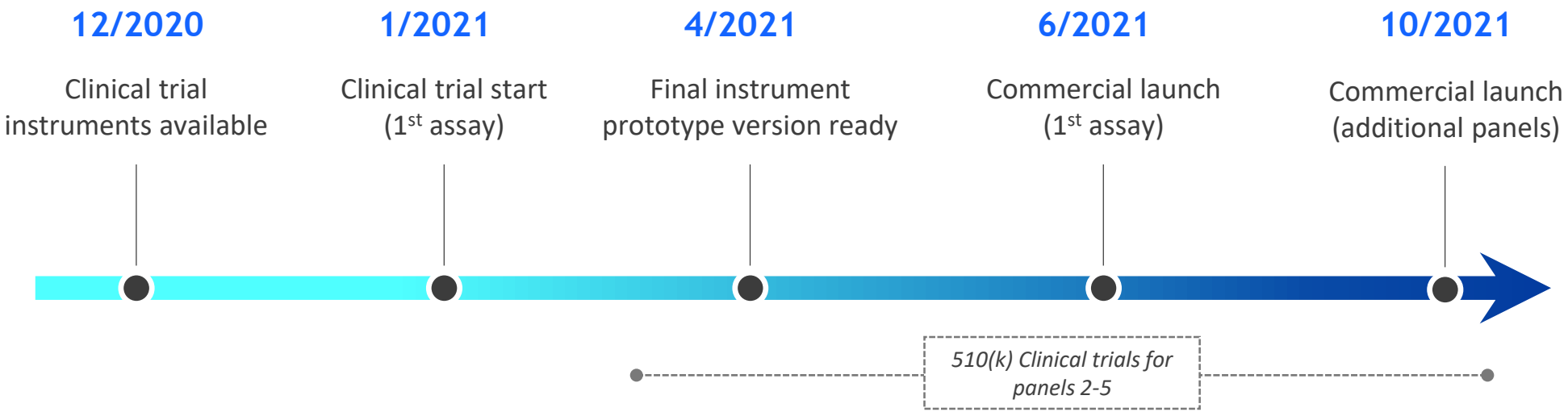
Savanna® Timeline



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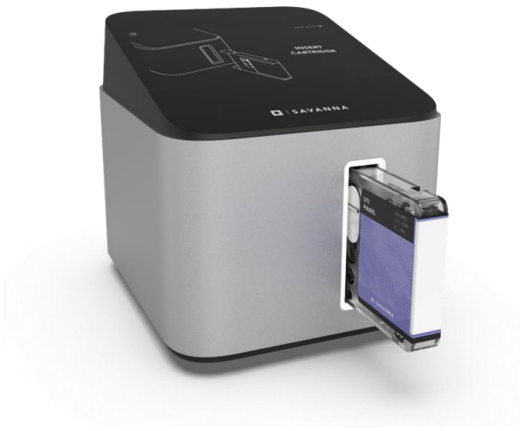
Savanna®

Tammi Ranalli, PhD
SVP, Molecular Dx



Covid has had a large impact on the global market with PCR and Immunoassay modalities absorbing this new volume

Global respiratory diagnostics testing volume

Number of tests in millions

	2019	2020	2021	2022	2023	2024	CAGR
Micro	509.6	493.8	489.8	485.8	481.9	477.9	-1.3%
PCR	**1,281.3**	**3,986.0**	**3,040.0**	**2,641.0**	**2,750.0**	**2,891.0**	**17.7%**
NGS	174.7	385.0	403.0	285.0	303.0	318.6	12.8%
IA	**1,528.8**	**2,697.0**	**2,764.0**	**2,286.0**	**2,150.0**	**2,065.0**	**6.2%**
Other	145.6	146.6	146.8	147.0	147.3	147.5	0.3%
Total	**3,640.0**	**7,708.3**	**6,843.6**	**5,844.9**	**5,832.1**	**5,900.0**	**10.1%**

- **United States: CAGR ~18%**
- **EMEA: CAGR ~16%**
- **APAC: CAGR ~18%**
- **ROW: CAGR~15%**

Source: Biopharma-research

Current competitive platforms



TAT: 30’-50’
Menu: Broad
Panels: Up to 4 analytes, no test select
Cost: Moderate
Performance: Excellent
Base: 11,000 Cepheid placements



TAT: 20’
Menu: Respiratory
Panels: Up to 3 analytes, no test select
Cost: Moderate
Performance: Excellent



TAT: 45‘
Menu: GI/Resp/Meningitis
Panels: Large, inflexible
Cost: Expensive >$100 panels
Base:10,400 BioFire placements

Savanna® platform



Fast

High performance

Flexible panels

Scalable

Broad test menu

Cost effective

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Savanna Menu

Develop critical mass of target sized mini panels (4 to 12 analytes)

- Provide differentiating therapeutically actionable clinical results
- Provide CLIA waived solution that solve the needs in simplicity, hands-on time, turn around time
- Address limitations of single parameters as delivered by current systems
- Addresses and implements move from fee for service medicine to value-based diagnostics
- Address reimbursement issues created by large array panels or NGS based assays

Savanna Launch Strategy



EUA
Address immediate need with EUA of respiratory panel in 2021 prior to 510k clearance



Partner
Partner with leading institutions to quickly demonstrate utility and clinical performance: Northwell, UPMC, Georgetown, Yale, Barnes Jewish, Mercy Health, NY Presbyterian, Baylor, Scott & White



Capitalize

Capitalize on relationships accelerated through launch of Covid molecular products

- Lyra Covid customers
- Solana customers



Solidify & Expand
Solidify and Expand customer base with additional relevant menu

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Looking Beyond Covid-19: Savanna Menu

- **Sexually Transmitted Disease**
  - Herpes/Syphilis Panel
  - Vaginitis Panel
  - STI Panel/STI resistance Panel
- **Gastrointestinal Disease**
  - Bacterial/Viral Panel
  - Parasite Panel
- **Hospital Acquired Infections**
  - MRSA
- **Respiratory Disease**
  - RVP-10 Panel
  - Pharyngitis Panel

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TriageTrue® High Sensitivity Troponin

Bill Ferenczy
SVP, Cardiometabolic Business Unit



Triage® Cardiac Marker Business Overview



Conditions:

- **Heart Attack (MI)**
- Heart Failure
- Thromboembolism

Cardiac Product Portfolio

Worldwide

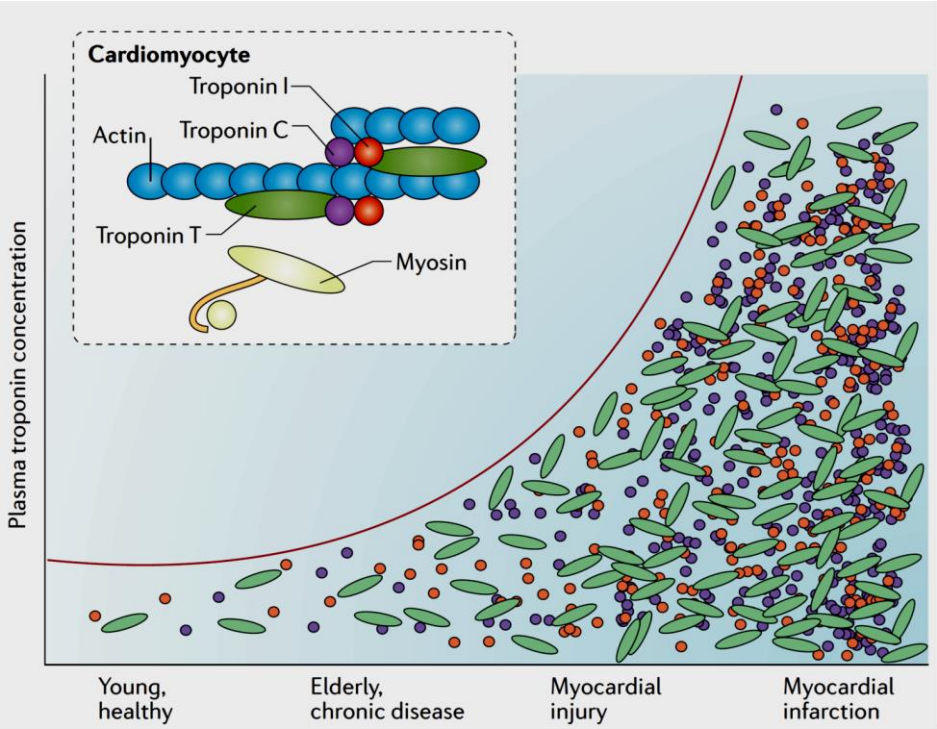
Triage BNP Test
Triage BNP for Beckman Coulter
Triage D-Dimer Test
Triage Cardiac Panel

Outside US only

Triage NT-proBNP Test
Triage Cardio2 Panel
Triage Cardio3 Panel
Triage Profiler SOB Panel
TriageTrue High Sensitivity Troponin I

- Strong player in heart failure and thromboembolism:
  - Triage® NP and d-dimer assays best fit in **POCT and low volume settings**
  - Triage® BNP CLIA-waiver expands availability to more clinics
  - BNP for Beckman Coulter addresses automated **high-volume settings**
  - COVID driving awareness and demand for rapid d-dimer testing
- Multiplex panels differentiate Triage® in OUS markets
  - Hospital/POCT in China
  - Clinic based testing in Europe
- Challenge: market transition to high- sensitivity troponin
  - Continuous evolution of troponin assays that run on “big iron” analyzers
  - Significant sensitivity gap between these assays and Triage/other POC tests
  - OUS: Longtime hsTn availability has greatly reduced ER POCT
  - Ongoing adoption in US a threat to Triage over next 5 years
- Opportunity: TriageTrue™ high sensitivity troponin

Evolution of cardiac troponin assays



Westermann D, et al. Nat Rev Cardiol. 2017;14:472-483.

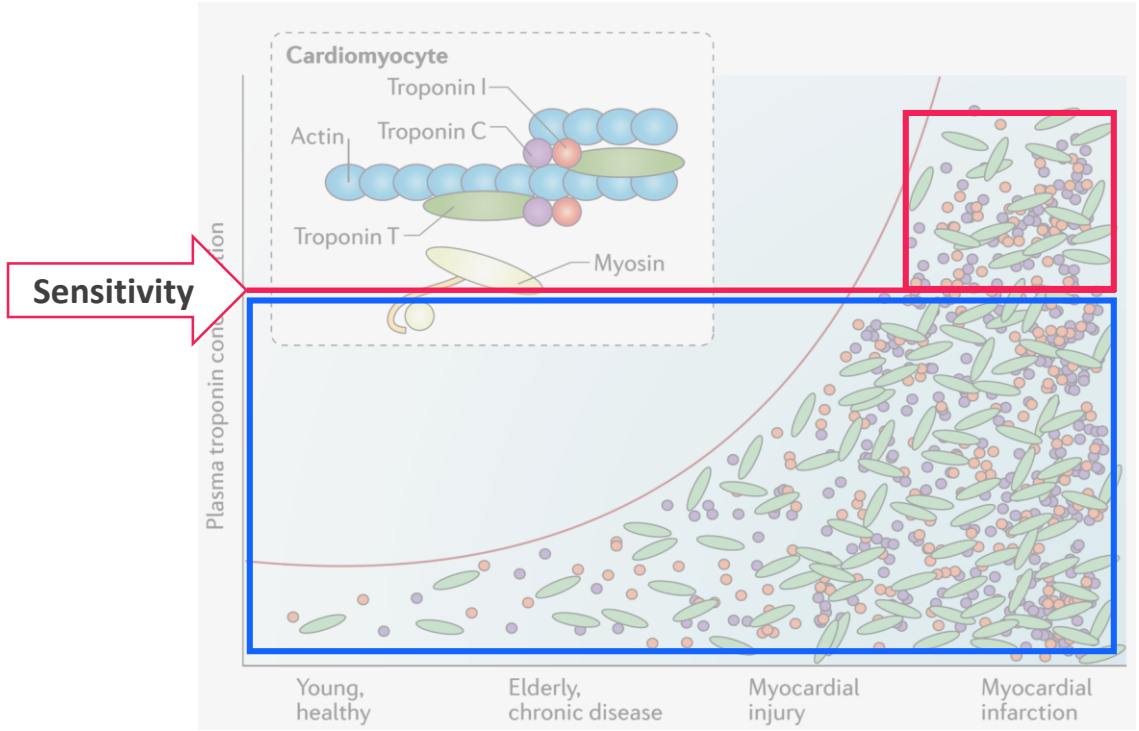
Troponin is released when heart muscle is injured

Levels: very low in healthy people to very high in MI patients

In chronic disease, levels are elevated but stable

In acute events such as MI, levels rise quickly and then fall

Early troponin assays



Westermann D, et al. Nat Rev Cardiol. 2017;14:472-483.

Specific, but not sensitive

If detected, interpretation easy = MI

But when not detected, challenging:

- Acute coronary syndrome can not be ruled out
- Patients often held for 12+ hours to allow time for Tn to rise to a detectable level
- Many patients unnecessarily admitted

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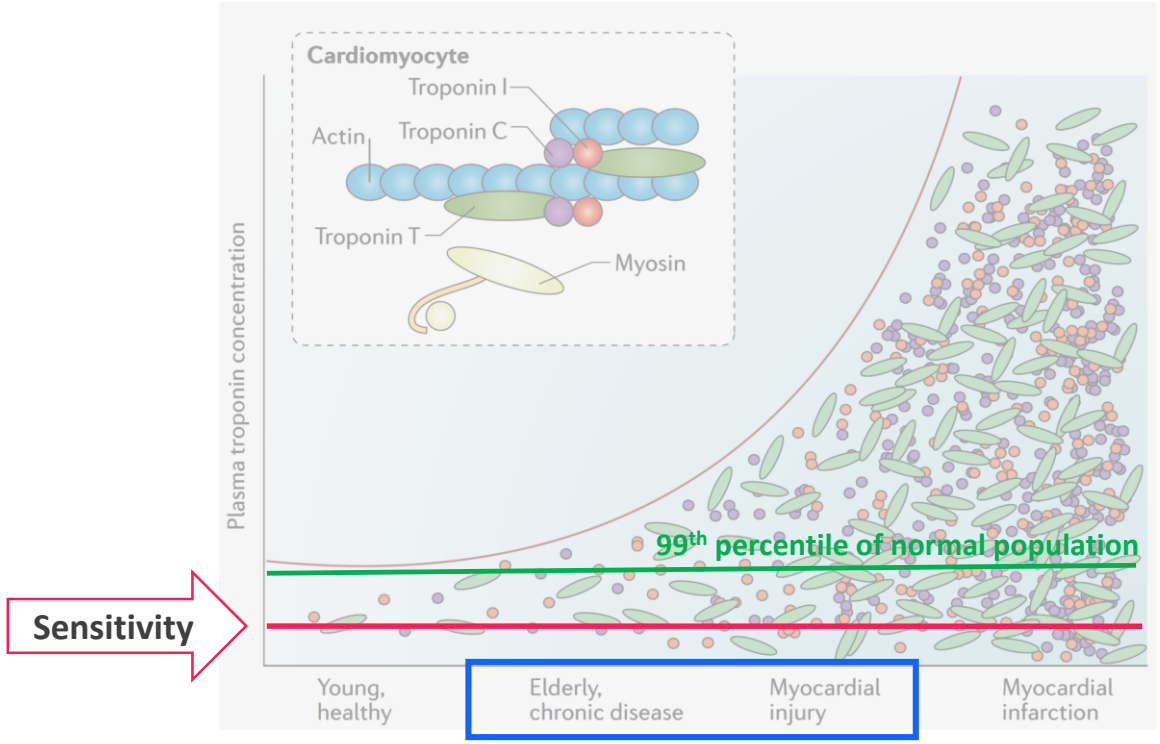
High sensitivity troponin assays



Very sensitive and accurate

- Detect troponin in ≥50% of normal healthy people
- Very precise even at low concentrations

Easy, if Tn not detected or below 99th % = no MI

But, rule-in more difficult since Tn detected in many non-MI patients

Addressed with algorithms that combine Tn level and change over time

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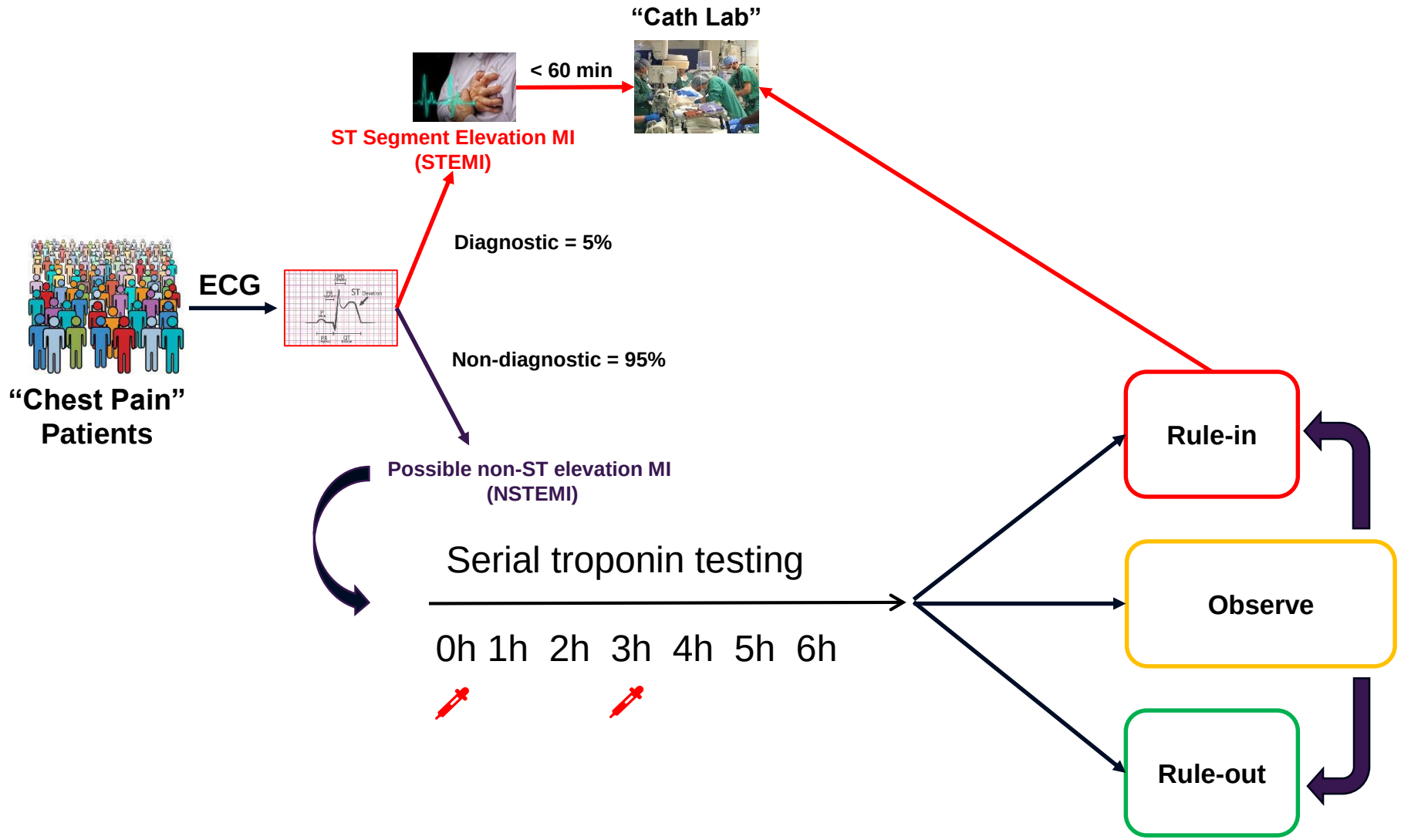
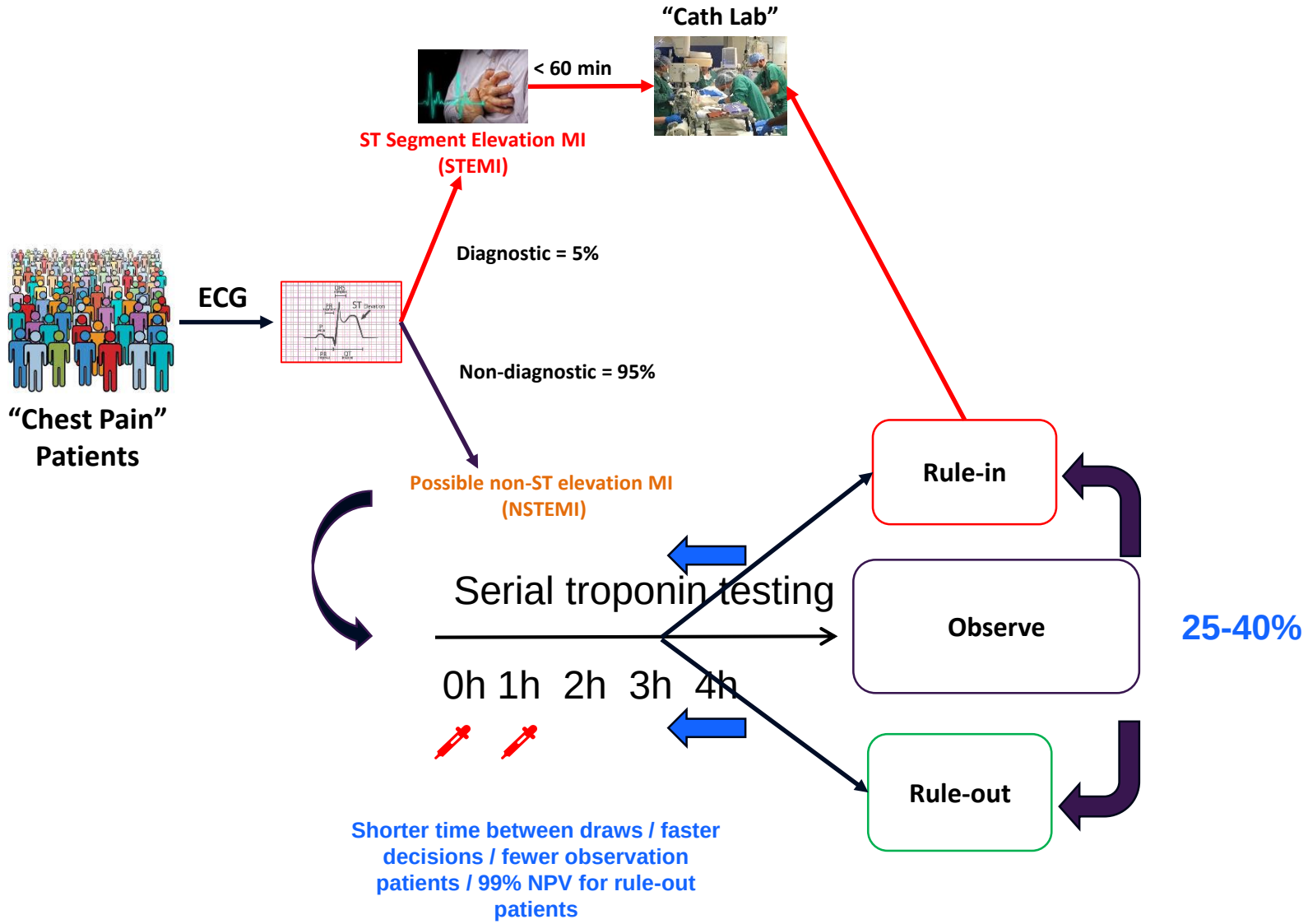
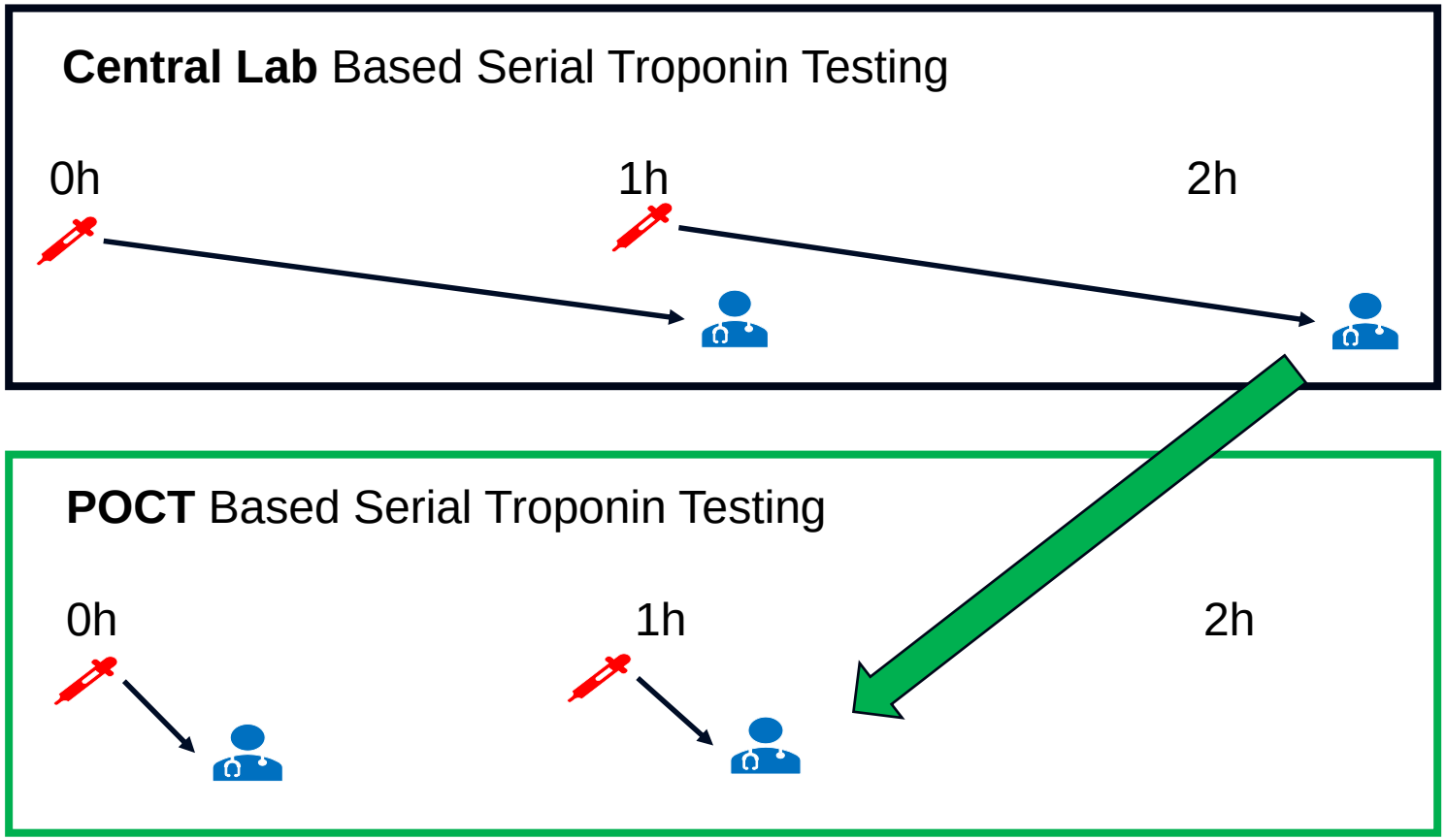
Myocardial infarction Dx algorithms



With hsTn, diagnosis is faster and safer



Why POCT?



"Faster is Better": Reduce time to patient disposition 33-50% by eliminating time to transport/receive/process samples in central lab

“POCT” platform addresses needs in multiple settings

POCT in busy EDs: reduce total time to patient disposition:

- Allows clinicians to focus on the right patients
- Increases ED throughput and efficiency
- Greater patient satisfaction



Simpler and more cost-effective approach for **low volume testing** in the laboratories of **small hospitals** with fewer chest pain presentations.



“Democratization” of hsTn testing to urgent care centers and other non-hospital sites by enabling safe, rapid disposition of low-risk chest pain patients



But can a POC assay meet the challenging hsTn analytical and clinical requirements established by central lab analyzers?

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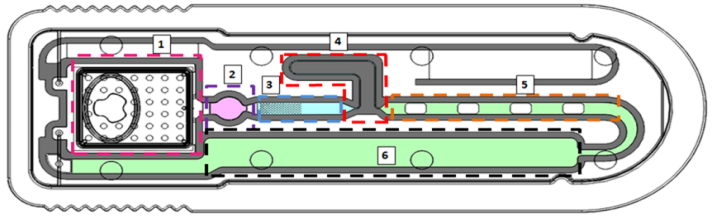
TriageTrue® High Sensitivity Troponin I Test



Runs on Existing Triage® MeterPro

- True hsTnI performance
- Whole blood or plasma specimens
- Simple procedure
- Results in <20 minutes



New Cartridge Design Drives Improved Sensitivity and Precision

- Improved microfluidics slow and control flow through the diagnostic lane
- Improved filtration system reduces variation
- Control spots normalize signal and help eliminate background noise

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Launch Strategy Guided by KOL Advisors

Multiple reviews of product performance and go-to-market strategies



Recommendation: Controlled market launch based on regulatory trial timing and scientific studies critical to market adoption:



1. Obtain CE Mark and execute a structured launch in Europe as fastest path to market and to gain real-world experience



2. Conduct major scientific study to validate assay clinical performance prior to initiating expensive, complex FDA trial



3. Leverage published study to fully drive market adoption OUS while the FDA trial underway

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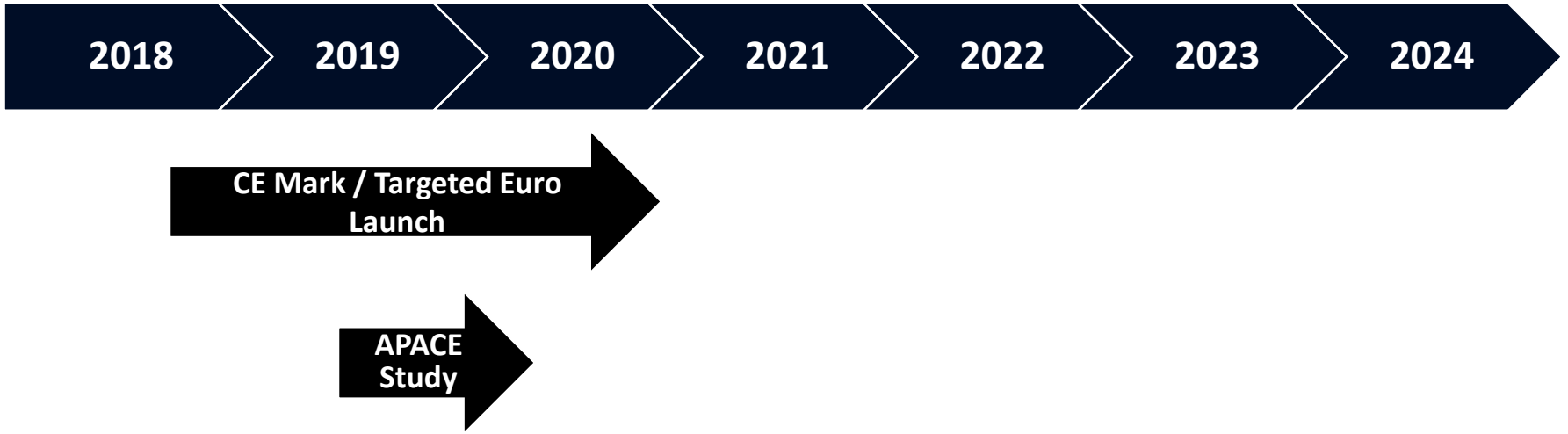
TriageTrue® Launch Timeline



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Early Diagnosis of Myocardial Infarction With Point-of-Care High-Sensitivity Cardiac Troponin I

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ABSTRACT

BACKGROUND Until now, high-sensitivity cardiac troponin (hs-cTn) assays were mainly developed for large central laboratory platforms.

OBJECTIVES This study aimed to assess the clinical performance of a point-of-care (POC)-hs-cTnI assay in patients with suspected myocardial infarction (MI).

METHODS This study enrolled patients presenting to the emergency department with symptoms suggestive of MI. Two cardiologists centrally adjudicated the final diagnosis using all clinical data including cardiac imaging. The primary objective was to directly compare diagnostic accuracy of POC-hs-cTnI-TriageTrue versus best-validated central laboratory assays. Secondary objectives included the derivation and validation of a POC-hs-cTnI-TriageTrue-specific 0/1-h algorithm.

RESULTS MI was the adjudicated final diagnosis in 178 of 1,261 patients (14%). The area under the curve (AUC) for POC-hs-cTnI-TriageTrue at presentation was 0.95 (95% confidence interval [CI]: 0.93 to 0.96) and was at least comparable to hs-cTnT-Elecsys (AUC: 0.94; 95% CI: 0.93 to 0.96; $p = 0.213$) and hs-cTnI-Architect (AUC: 0.92; 95% CI: 0.90 to 0.93; $p < 0.001$). A single cutoff concentration <3 ng/l at presentation identified 45% of patients at low risk with a negative predictive value (NPV) of 100% (95% CI: 99.4% to 100%). A single cutoff concentration >60 ng/l identified patients at high risk with a positive predictive value (PPV) of 76.8% (95% CI: 68.9% to 83.6%). The 0/1-h algorithm ruled out 55% of patients (NPV: 100%; 95% CI: 98.8% to 100%), and ruled in 18% of patients (PPV: 76.8%; 95% CI: 67.2% to 84.7%). Ruled-out patients had cumulative event rates of 0% at 30 days and 1.6% at 2 years. This study confirmed these findings in a secondary analysis including hs-cTnI-Architect for central adjudication.

CONCLUSIONS The POC-hs-cTnI-TriageTrue assay provides high diagnostic accuracy in patients with suspected MI with a clinical performance that is at least comparable to that of best-validated central laboratory assays. (Advantageous Predictors of Acute Coronary Syndromes Evaluation Study [APACE]; NCT00470587) (J Am Coll Cardiol 2020;75:1111-24)
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Boeddinghaus, J. et al, J Am Coll Cardiol. 2020;75(10):1111-24

APACE prospective international multicenter study

Clinical performance: 1,261 “suspected MI” patients:

- Fully adjudicated Dx by two cardiologists
- Comparison to Roche and Abbott hsTn assays

Outstanding results evidenced by validation of a safe and effective 0/1-hour algorithm

- Very high rule-out safety: 100% sensitivity
- No adverse events at 30 days in rule-out patients
- High rule-in accuracy:
- High efficacy: 74% of patients ruled in or out at 1 hour. Only 26% held for observation

Conclusion:

“POC-hs-cTnI TriageTrue® provides very high diagnostic accuracy in patients with suspected MI. Its clinical performance is at least comparable to that provided by the best validated central laboratory-based assays.”

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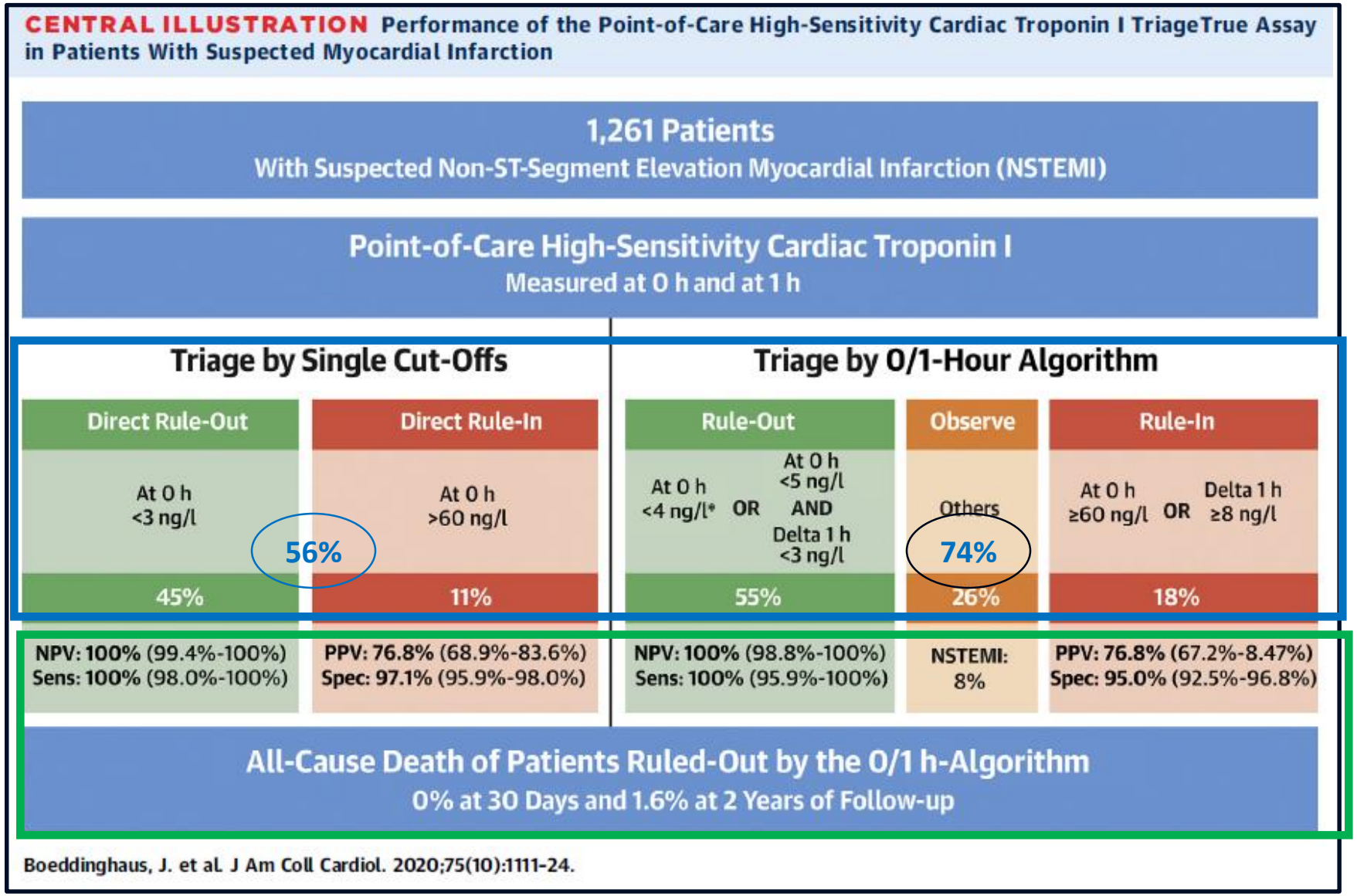
TriageTrue® performance in APACE Study



TriageTrue® now included in European Society of Cardiology Guidelines for 0h/1h and 0h/2h algorithms

0 h/1 h algorithm	Very low	Low	No 1hΔ	High	1hΔ
hs-cTn T (Elecsys; Roche)	<5	<12	<3	≥52	≥5
hs-cTn I (Architect; Abbott)	<4	<5	<2	≥64	≥6
hs-cTn I (Centaur; Siemens)	<3	<6	<3	≥120	≥12
hs-cTn I (Access; Beckman Coulter)	<4	<5	<4	≥50	≥15
hs-cTn I (Clarity; Singulex)	<1	<2	<1	≥30	≥6
hs-cTn I (Vitros; Clinical Diagnostics)	<1	<2	<1	≥40	≥4
hs-cTn I (Pathfast; LSI Medience)	<3	<4	<3	≥90	≥20
hs-cTn I (TriageTrue; Quidel)	<4	<5	<3	≥60	≥8
0 h/2 h algorithm	**Very low**	**Low**	**No 2hΔ**	**High**	**2hΔ**
hs-cTn T (Elecsys; Roche)	<5	<14	<4	≥52	≥10
hs-cTn I (Architect; Abbott)	<4	<6	<2	≥64	≥15
hs-cTn I (Centaur; Siemens)	<3	<8	<7	≥120	≥20
hs-cTn I (Access; Beckman Coulter)	<4	<5	<5	≥50	≥20
hs-cTn I (Clarity; Singulex)	<1	TBD	TBD	≥30	TBD
hs-cTn I (Vitros; Clinical Diagnostics)	<1	TBD	TBD	≥40	TBD
hs-cTn I (Pathfast; LSI Medience)	<3	TBD	TBD	≥90	TBD
hs-cTn I (TriageTrue; Quidel)	<4	TBD	TBD	≥60	TBD

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Eur Heart J 2020 Aug 29;ehaa575. doi: 10.1093/eurheartj/ehaa575. Online ahead of print.

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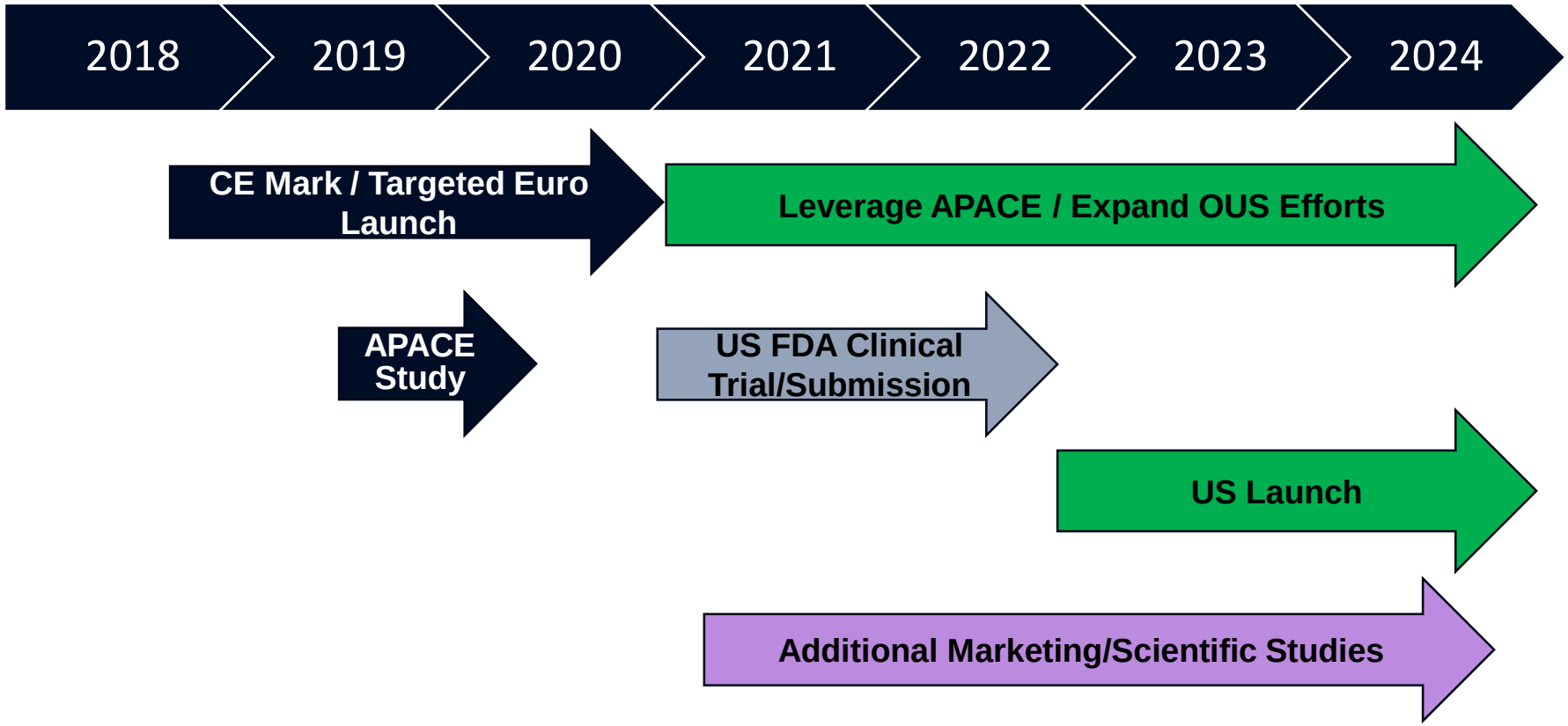
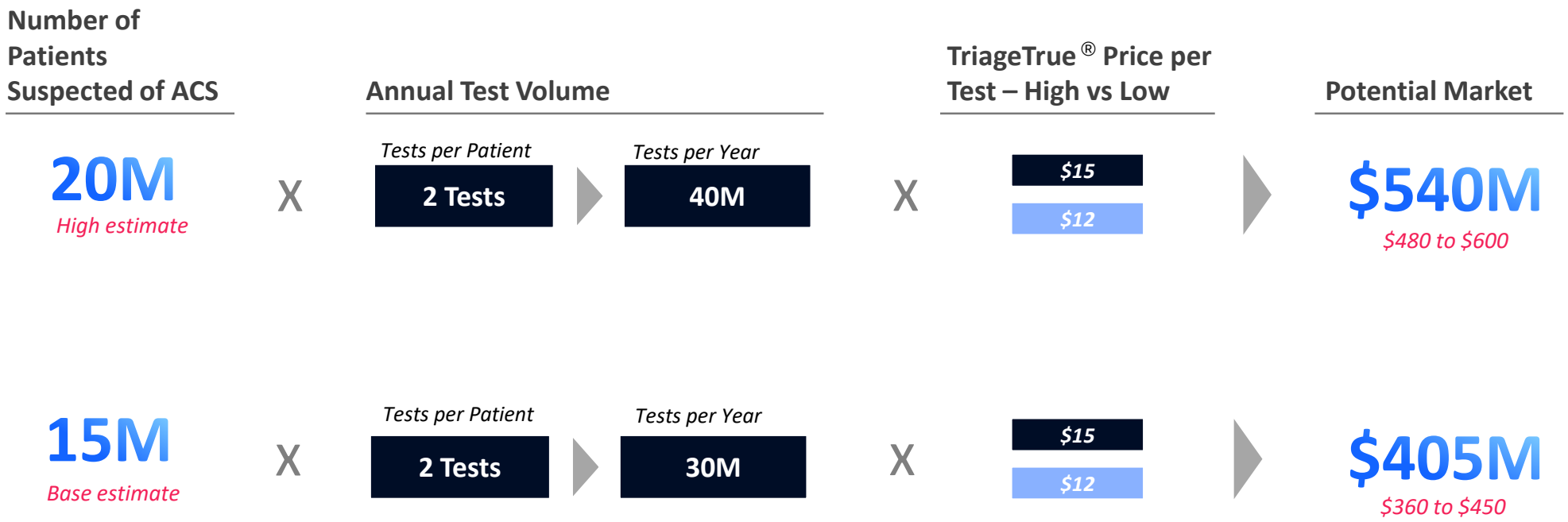
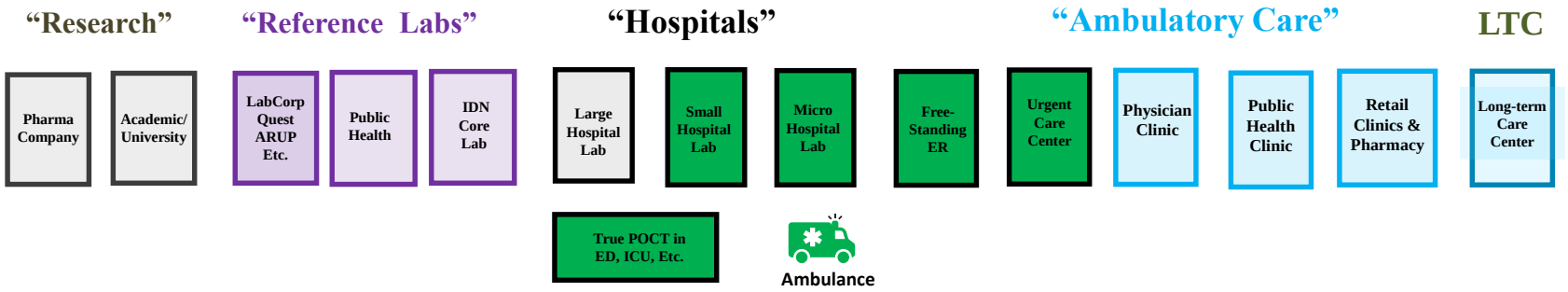
TriageTrue® Launch Timeline



Potential Market (US/Europe)



TriageTrue® Targets



Target Segment	Positioning	Opportunities (US)	Assumptions
Small & Micro Hospitals (In the Lab)	Most convenient and cost-effective approach for low volume testing	3500+ hospitals (< 200 beds) 100 micro hospitals with number growing steadily	Secure existing accounts and quickly convert new accounts to gain solid share in segment
POCT in ED	Faster disposition of patients in busy, high volume facilities	1500 hospitals with busy emergency departments	Fewer targets and longer sales cycle, but very high volume per site
Free Standing EDs	Faster disposition and cost/test at low volumes	500+ facilities	Secure and expand share with significant penetration
Urgent Care Centers	Rapid and convenient rule-out for low-risk patients. Help decompress busy nearby EDs	10,000 locations. Most do not handle suspected MI cases today due to "liability", but hsTn offers potential for safe, rapid disposition	Market development required – initial adoption slow, but can expand quickly via large multi-site UCC chains
Ambulance	Rapid rule-out. Transport to appropriate facility.	TBD	First need proof of performance in moving vehicles.

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Hospital Penetration Key to Success

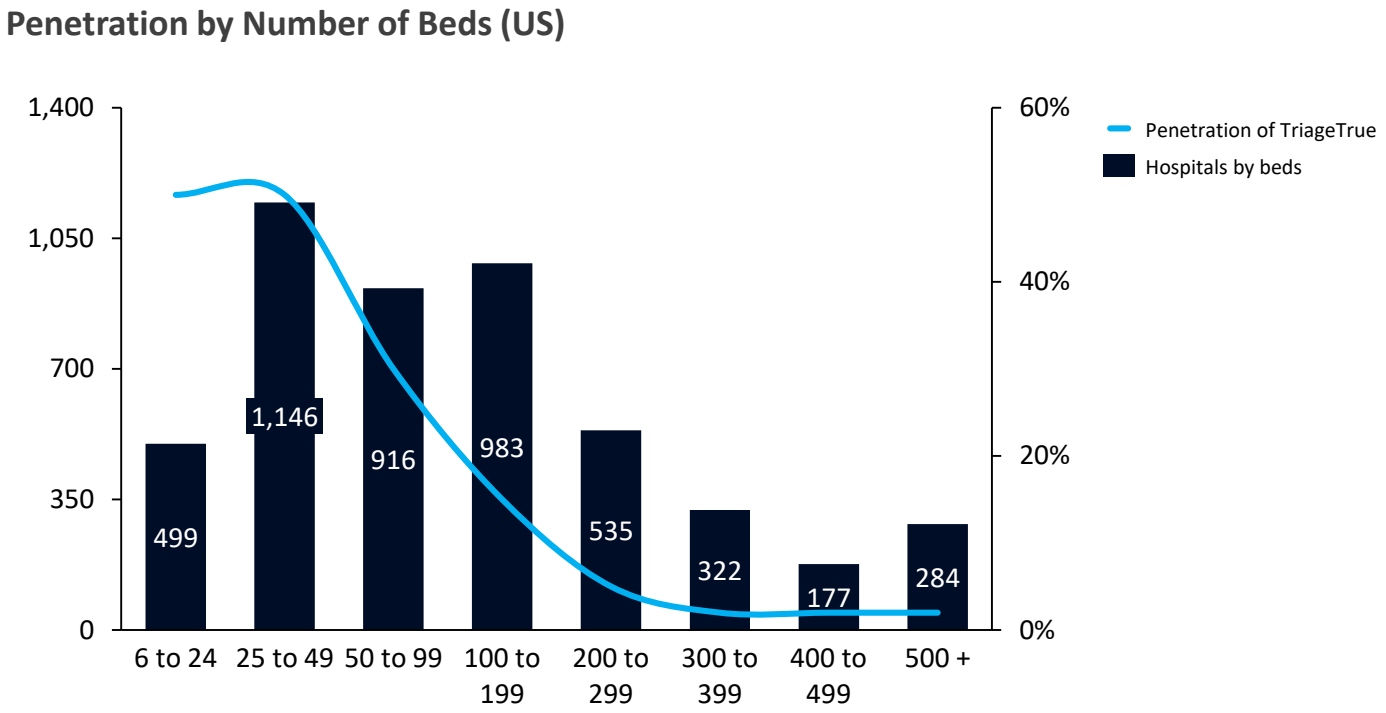
Positioning and penetration based on number of beds per hospital

Good penetration in small hospitals

- Shorter sales cycle
  - Testing done in lab
  - TriageTrue is more cost effective
- Rapid uptake
- Low volume/site

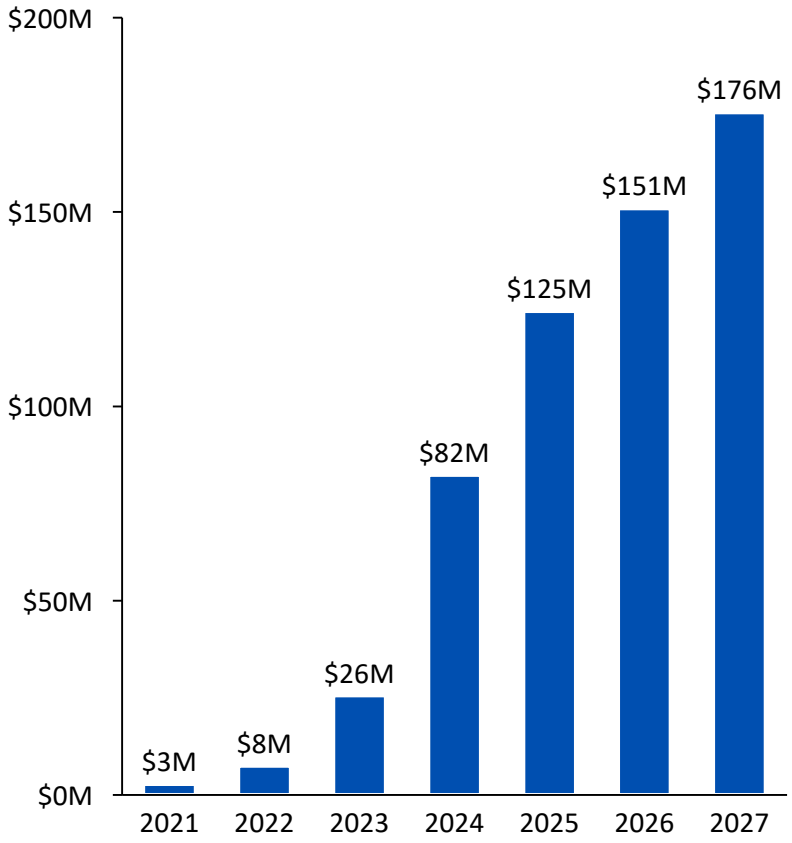
Limited penetration in large hospitals

- Longer sales cycle
  - Testing in the ED
  - Triage speeds patient disposition
- High volume/site
- Support with outcome studies



What We Believe We Can Get

TriageTrue estimated revenue by Year



Based primarily on US and Europe

- Well developed hsTn markets
- TriageTrue fit across multiple target segments
- Adequate reimbursement
- Hospital biggest segment but growing contribution from other settings
- Includes some pull through of other Triage tests

China opportunity TBD

- hsTn market still at early stages
- Hospital centric market
- Registration challenges and timing
- Current Triage business already at POCT and/or in higher volume settings – at outset TriageTrue would likely cannibalize existing business

Very limited revenue from ROW at this point

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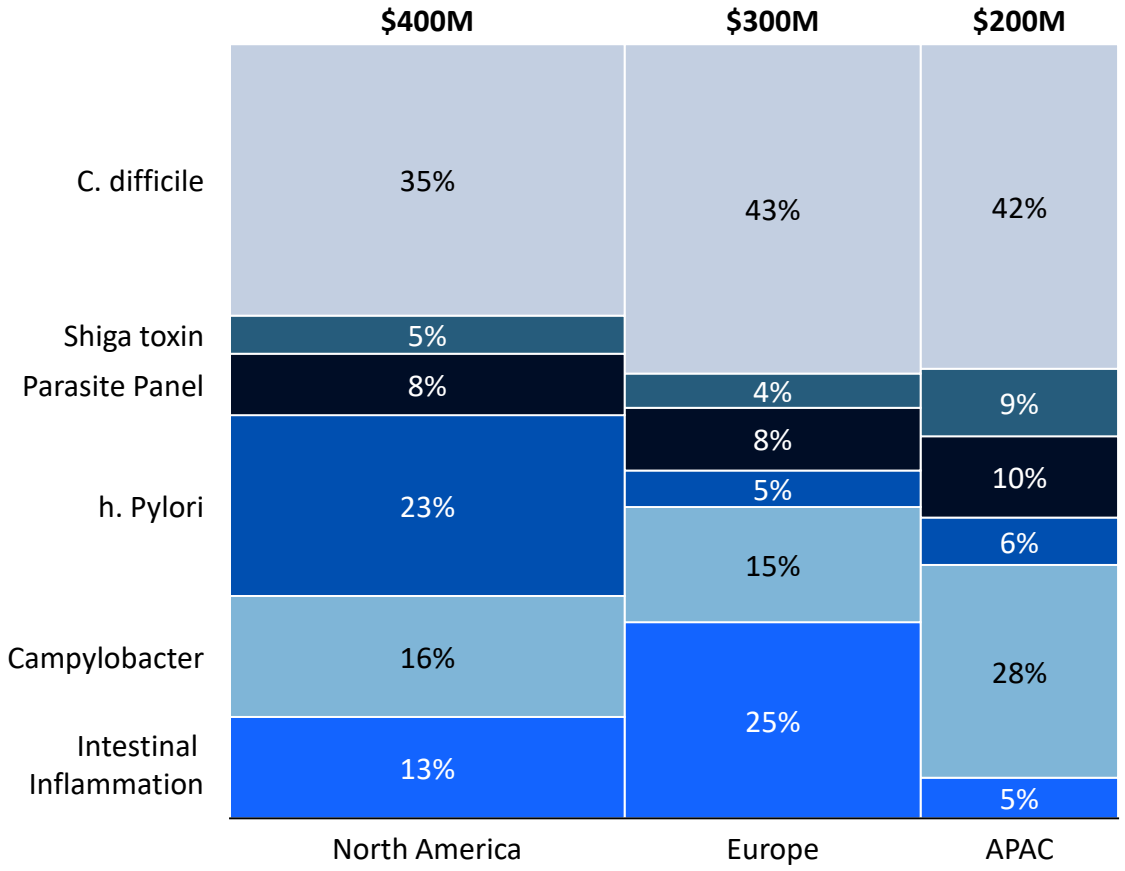
Sofia®

Rhys de Callier
VP, Strategy & Portfolio Management



In the near-term, we're building a highly competitive GI portfolio with distinct advantages.

Market potential of a global GI portfolio

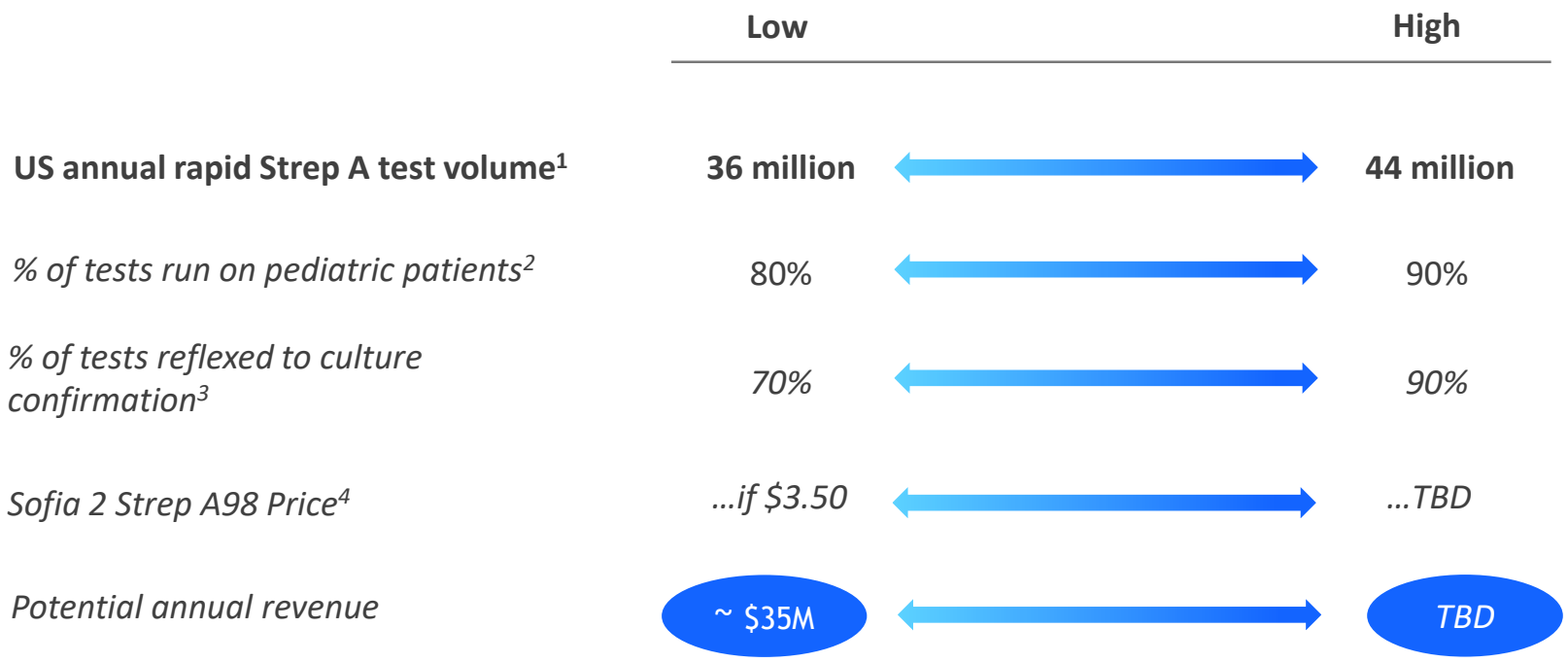


- We expect Sofia® C.diff performance to compare favorably with the leading visual immunoassay in the market while providing much needed improvements to workflow and data management
- Our H.pylori stool antigen assay will target a market dominated by a single player
- Other GI products will also benefit from Sofia's platform features including objectivity, connectivity and performance over culture and visually read assays

Sources: GHX, IDMM, Transparency Market Research, Competitive company annual reports

We are confident in our ability to launch a more cost-effective Strep A test...

...and we believe Sofia can capture roughly 25% to 30% of this volume



Range of revenue estimates driven by uncertain reimbursement scenarios

1. GHX data for rapid Strep A tests sold through distribution. Annual Strep A market volume does experience some volatility.
2. VOC. Most tests performed on children (5-18yrs).
3. VOC / field sales. Not all physicians are backing up negatives. Some portion of physicians will treat empirically.
4. Distributor Transfer Price. Variance based on existing (base case) vs. higher (aspirational case) reimbursement.

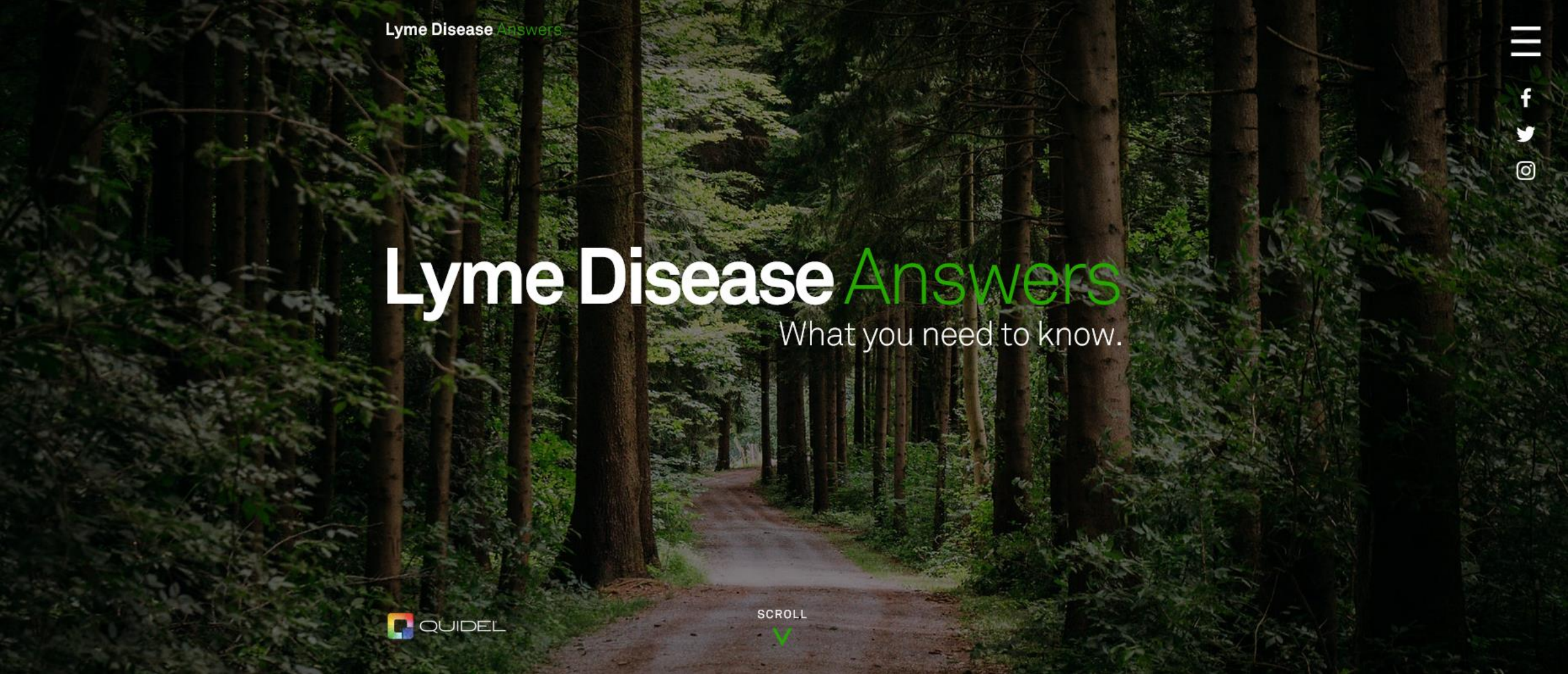






Lyme Disease

Despite a significant drop in PCP visits due to COVID, we've continued driving awareness



> 600 customers and counting!

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Sofia’s future remains bright.



Planned product launches

- Strep 98
- c.Difficile
- Campylobacter
- h.Pylori
- Lactoferrin
- Shiga Toxin
- Parasite Panel



Areas of high interest

- Inflammation
- Infectious diseases
- TOX / DOA
- Allergy
- STIs
- UTI

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COVID-19 Growth Drivers

Doug Bryant, President & CEO

In addition to the 4 COVID assays already launched, we continue to invest in R&D to fully address the urgent need.

COVID Assays in Development



1	2	3	4	5	6	7	8
QuickVue	**Solana**	**Lyra**	**QuickVue**	**Sofia 2**	**Lyra**	**Savanna**	**Sofia 2**
SARS Antigen for professional use	SARS-CoV-2	Flu + SARS (Extracted)	SARS Antigen for at-home use	SARS-CoV-2 Antibody	Direct Flu + SARS	SVP4 (Flu A, Flu B, RSV and SARS)	RVP4
In EUA Review 10/16/20	Target EUA submission 11/13/20	Target EUA 11/30/20	Target EUA submission 12 / 2020	Target EUA submission 12 / 2020	Target EUA submission 1 / 2021	Target EUA submission Q1 / 2021	Target EUA submission 03 / 2021

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“Sniffles” Platform

Karen Gibson
SVP, Digital Health

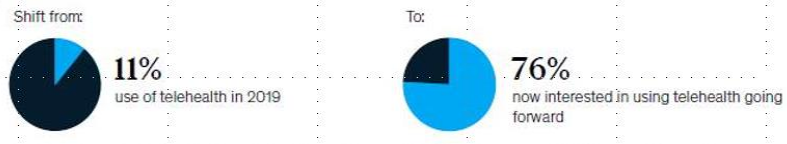


COVID has changed diagnostic testing forever

- Pandemic has highlighted the need for affordable and scalable diagnostic testing
- New patient care delivery models have exploded, but they still lack the ability to diagnose with certainty. Diagnostic testing is a huge value-added service to improve the provider and patient experience
- Healthcare industry and regulatory agencies are adopting new technology at faster pace than ever before … it is becoming the norm
- Diagnostics is becoming digitized

McKinsey Telehealth Survey

1 Consumer



2 Provider

50–175x

the number of telehealth visits pre-COVID.[4]

3 Regulatory

Types of services available for telehealth have greatly expanded, with the Centers for Medicare & Medicaid Services (CMS) temporarily approving more than

80 new services

and lifting restrictions on originating site, allowing Medicare Advantage plans to conduct risk assessments via telehealth, and adding other regulatory flexibilities to increase access to virtual care.[6]

[1] McKinsey COVID-19 Consumer Survey, April 27, 2020.
[2] McKinsey COVID-19 Consumer Survey, May 20, 2020.
[3] McKinsey COVID-19 Consumer Survey, April 13, 2020.
[4] Ibid
[5] McKinsey COVID-19 Physician Survey, May 2020.
[6] Medicare telemedicine health care provider fact sheet, March 17, 2020, cms.gov.

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Introducing project ‘Sniffles’

- A small diagnostic device (about the size of a Grande coffee cup) able to read a standard Sofia Fluorescent Immunoassay Cartridge
- Images of the cassette are captured on the Sniffles device and transmitted via Bluetooth to a mobile device
- The result is then interpreted using a proprietary AI software model that is downloaded to a mobile device.



Benefits of ‘Sniffles’ platform



Affordability

- Sniffles device costs <20% of Sofia 2 to manufacture



Mobility/Connectivity

- Cellular connectivity enables testing in new markets beyond traditional Point of Care
- Will integrate results to proprietary Virena data management and other software platforms



Scalability

- 3rd party to manufacture 100K+ devices; Delivered in Q1 ‘21
- Expansion capabilities to 1M+

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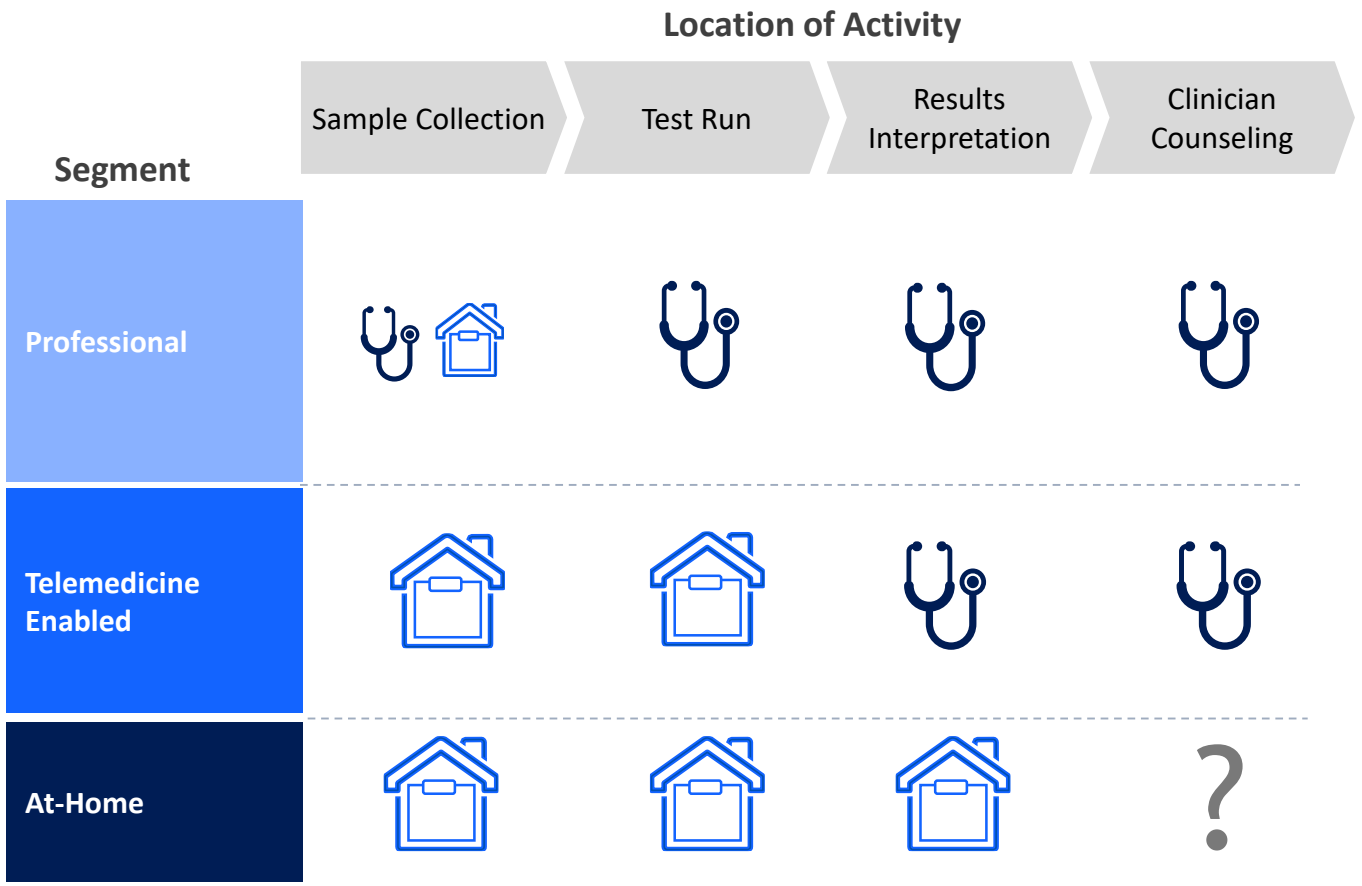
‘Sniffles’ has broad application

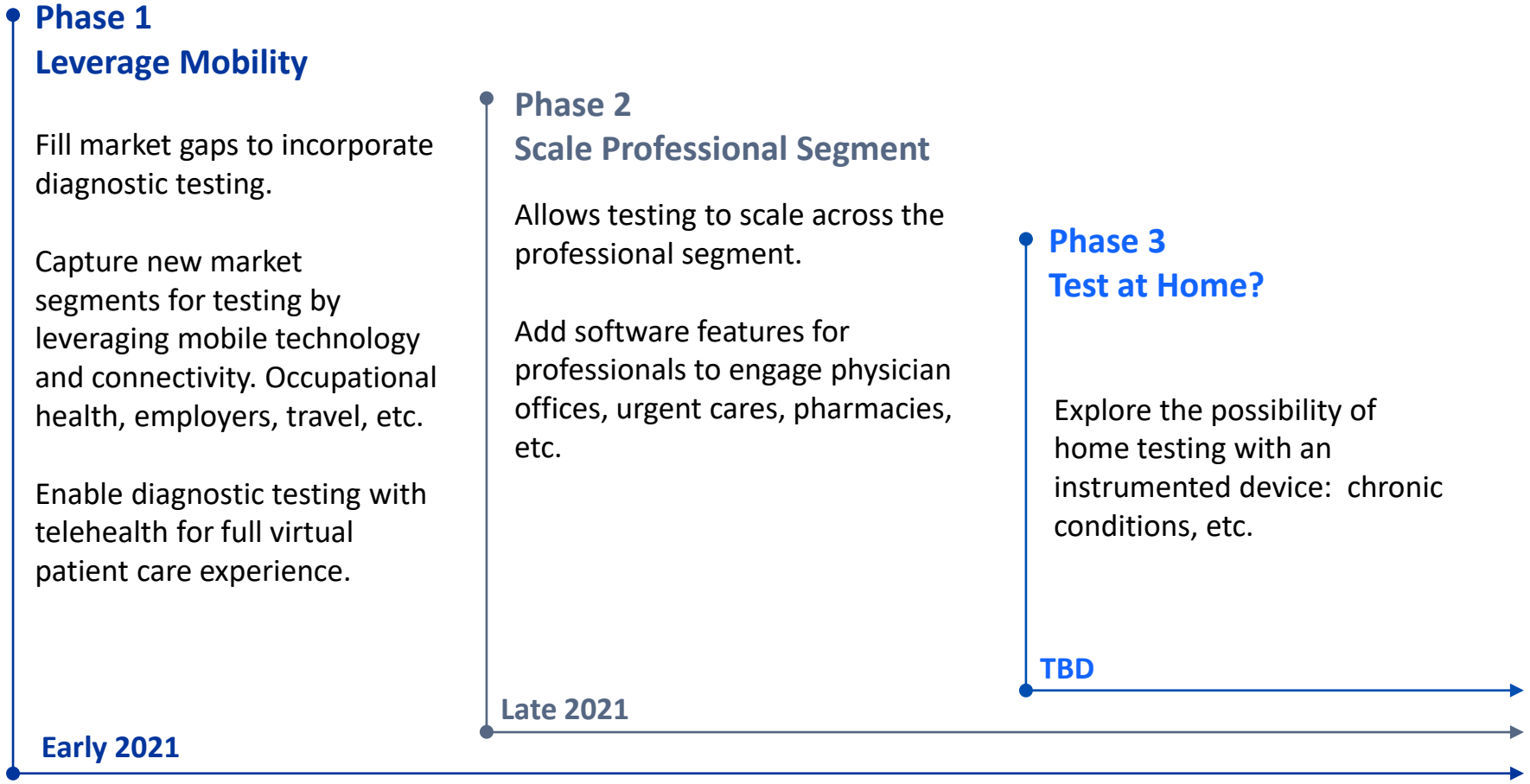


Market Applications

- Physician Office
- Occupational Health
- Concierge Medicine
- Travel, Employer,
- Entertainment, etc.
- Telemedicine
- Consumer

Legend: Performed at provider Performed in home

“Sniffles” go-to-market strategy





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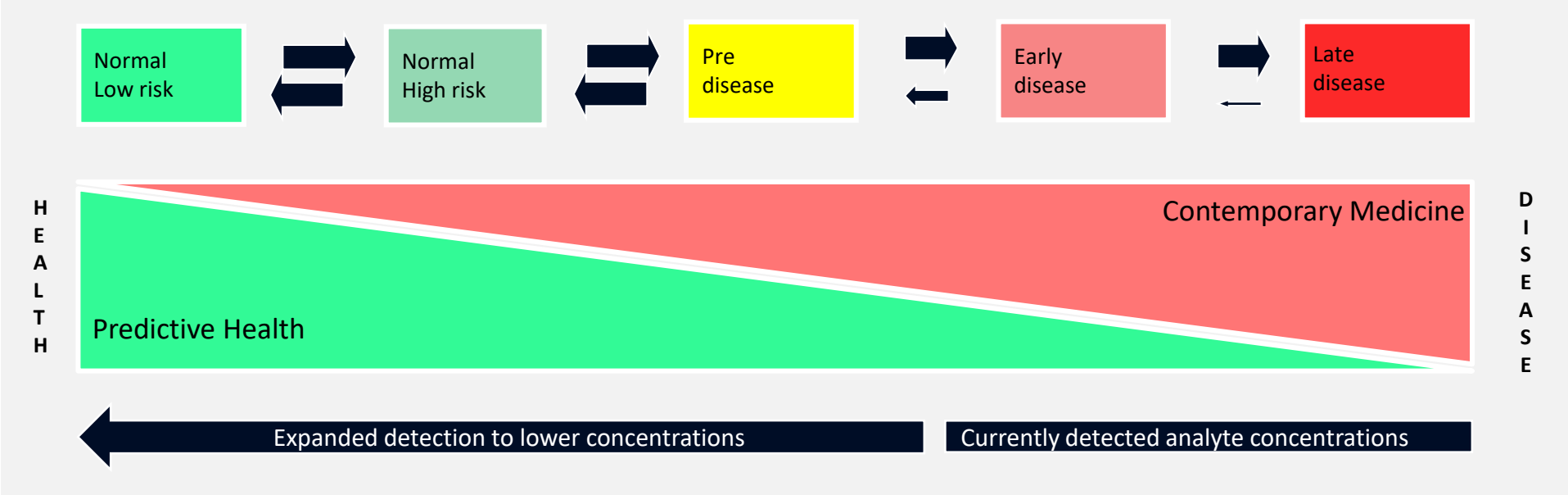
Big Ideas

Werner Kroll, PhD
SVP, Research & Development

The health / disease continuum

Leapfrog digital immunoassay technology enables earlier detection of acute infections and the paradigm shift to preventative in vitro diagnostics personalized healthcare of chronic diseases



Changes on health/disease status are most directly reflected by protein levels. Early detection which requires lower marker concentration to be detected allow to slow, stop or even reverse the progression of chronic diseases.

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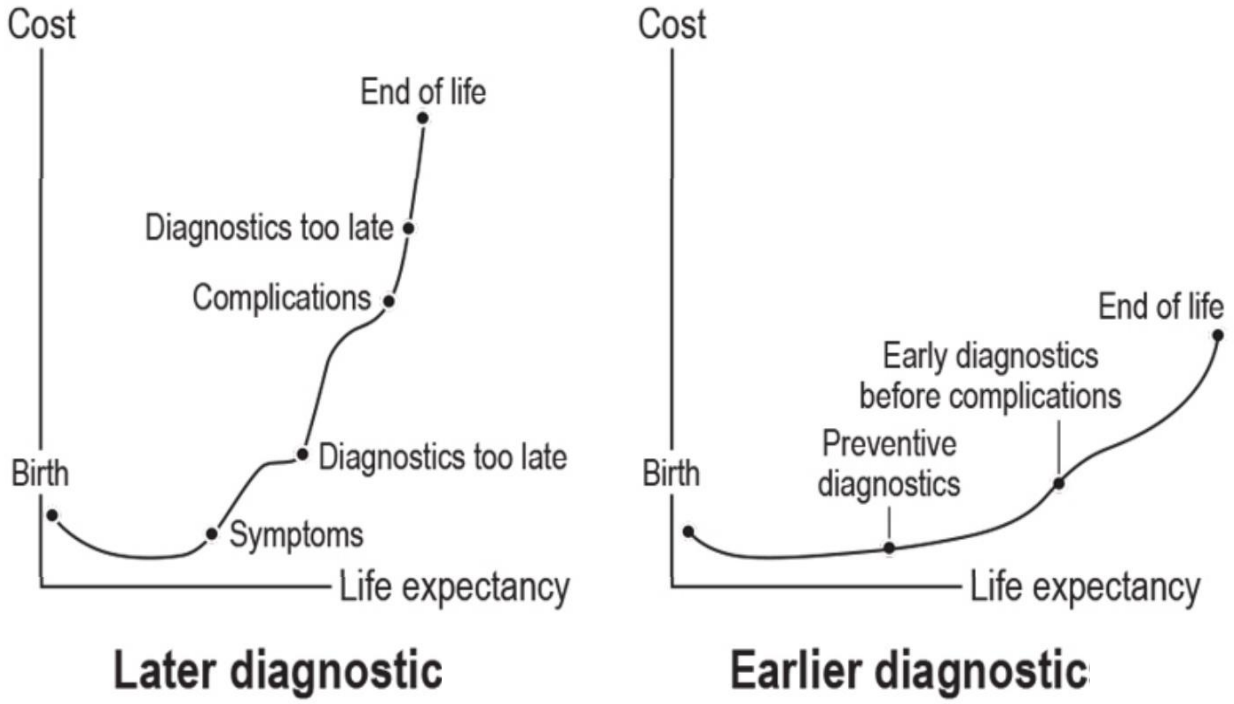
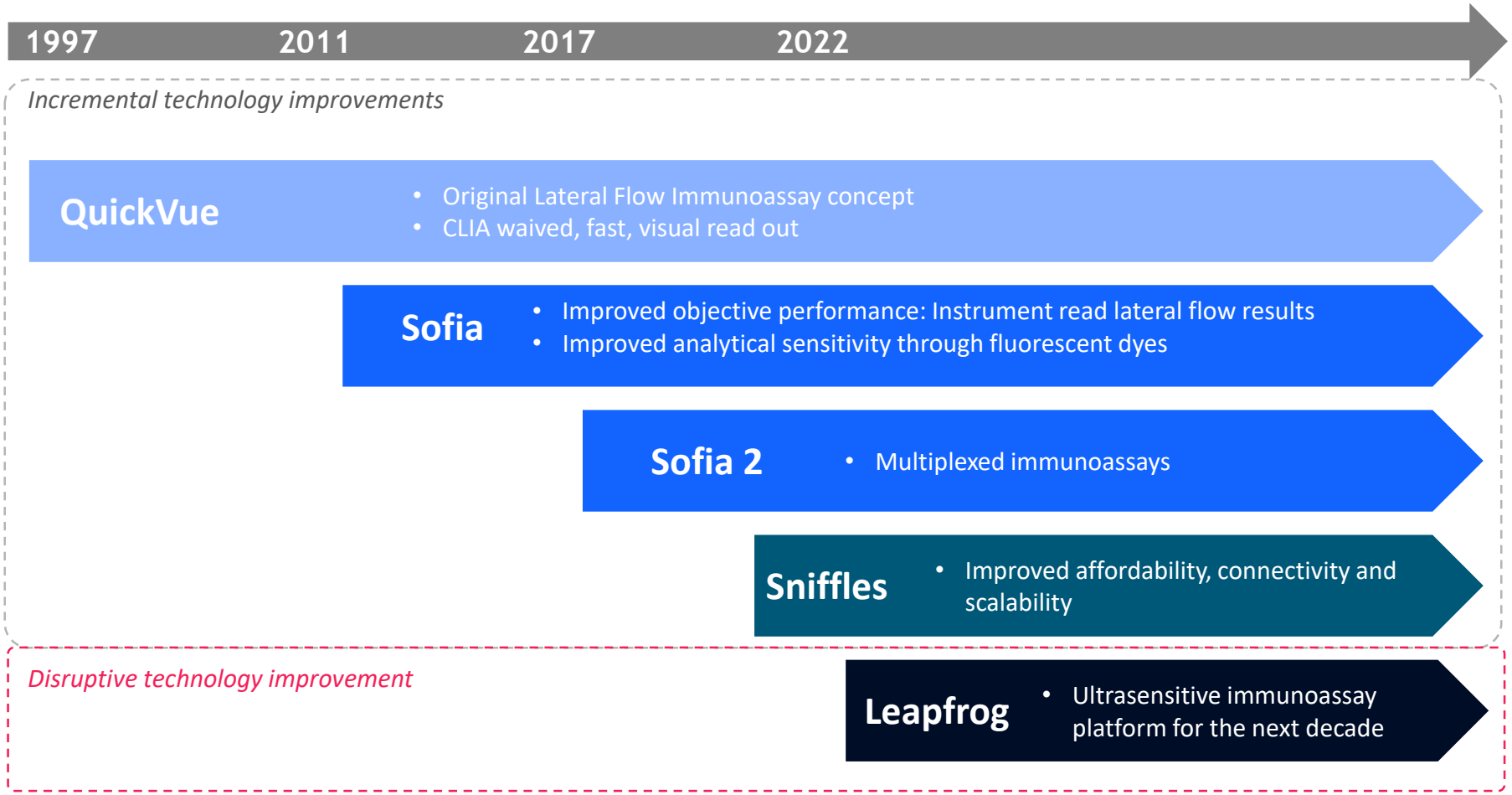
The earlier a diagnosis is achieved, and intervention initiated, the lower the overall treatment cost.

Since biochemical changes are small at early disease stages, more sensitive detection methods are required



Binder, C. et al.; Swiss Med. Wkly., 2017; 147:w14546

Innovative product developments combined with systematic evolutionary improvements of successful product lines



Develop next generation ultrasensitive immunoassay technology to enable

- Significant improvement in earlier detection of acute infections
- Detection of pre-symptomatic concentrations of disease marker changes
- CLIA waived applications

Product features and drivers

Technology Performance Requirements

- **Ultrahigh sensitivity: digital immunoassay (single fg/ml)**
- **Fast time-to-result**
- **Multiplexing**
- **Integrated sample handling and introduction**
- **Self learning cell algorithms for improved readout**
- **CLIA waivable technology**
- **Full mobility and connectivity**
- **POC compatible low-cost platform**
- **Modular manufacturing**

Localized plasmon resonance as basis of disruptive digital point-of-care immunoassay technology

New methodology provides improved signal to noise ratio and provides LoD in low fg/ml concentration range

Digital to analogue detection

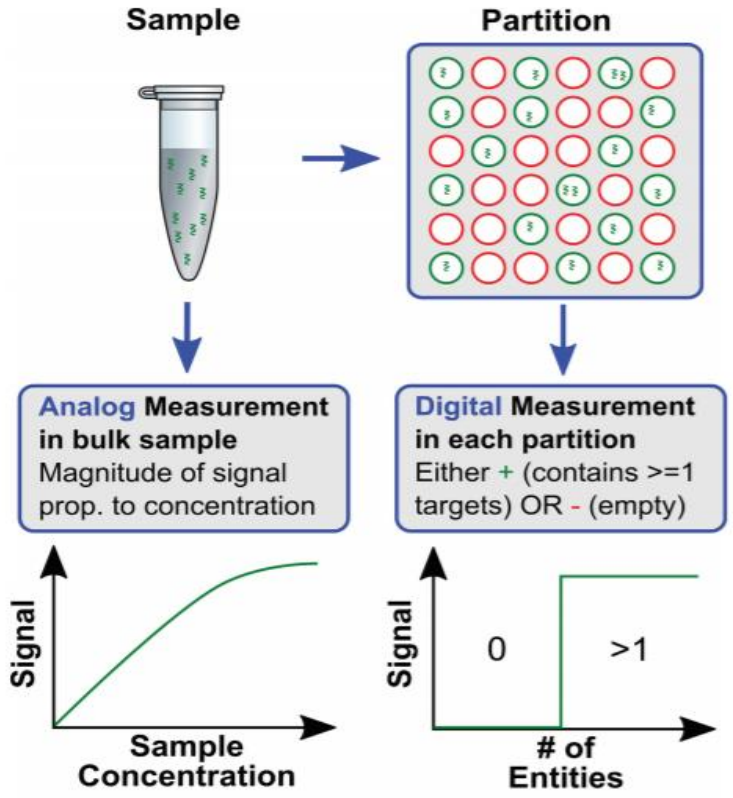
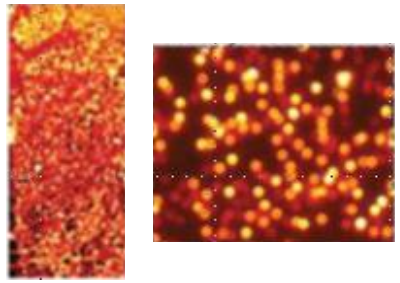


Image sensor



- Darkfield image of sensor after interaction with analyte specific nanoparticles marked antibodies
- When the analyte concentration is higher, a switch to analogue signal measurement extends the dynamic range of the assay

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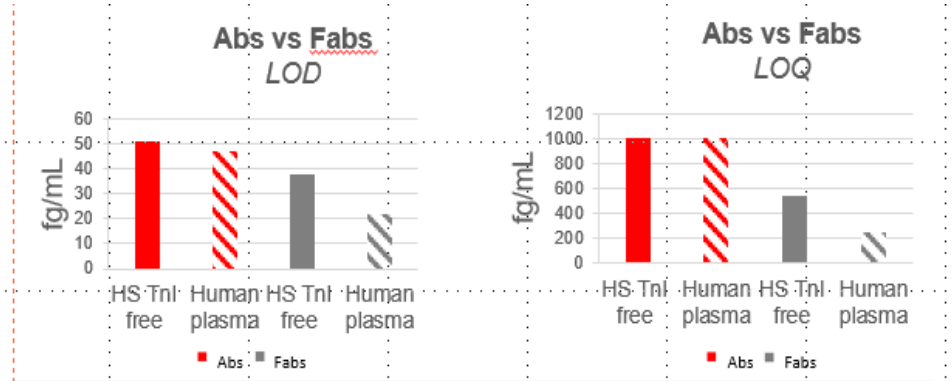
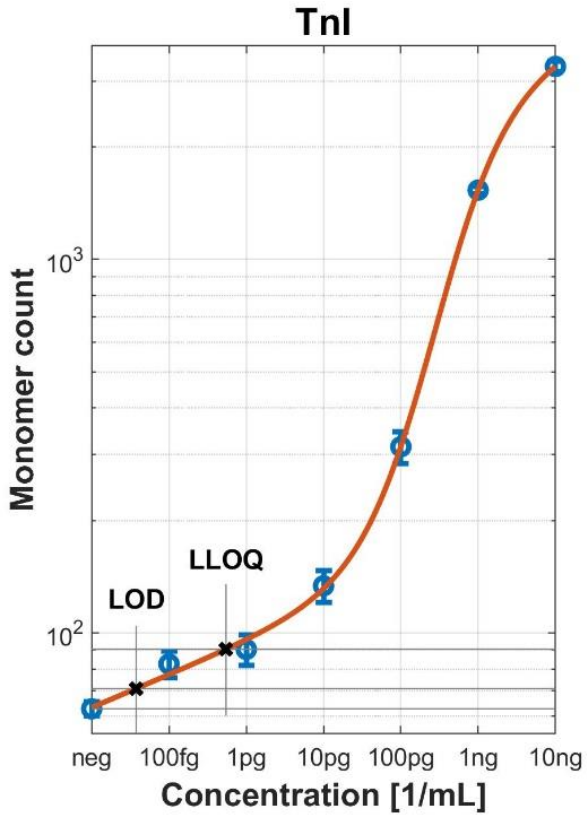
Demonstration of feasibility

Application of ultrasensitive immunoassay for troponin I allows expansion of clinical use and significant reduction of treatment cost



	Abs		Fabs	
	HS TnI free	Human plasma	HS TnI free	Human plasma
LOD	51 fg/mL	47 fg/mL	38 fg/mL	22 fg/mL
LOQ	1 pg/mL	1 pg/mL	546 fg/mL	247 fg/mL
CV	6 %	3 %	6 %	7 %



- Our TNI feasibility assay provides robust LOD in the double digit fg/ml level and an LoQ of about 250 fg/ml with CVs of less than 10 %
- The dynamic range spans 6 logs allowing the coverage of rule in and rule out application without dilution

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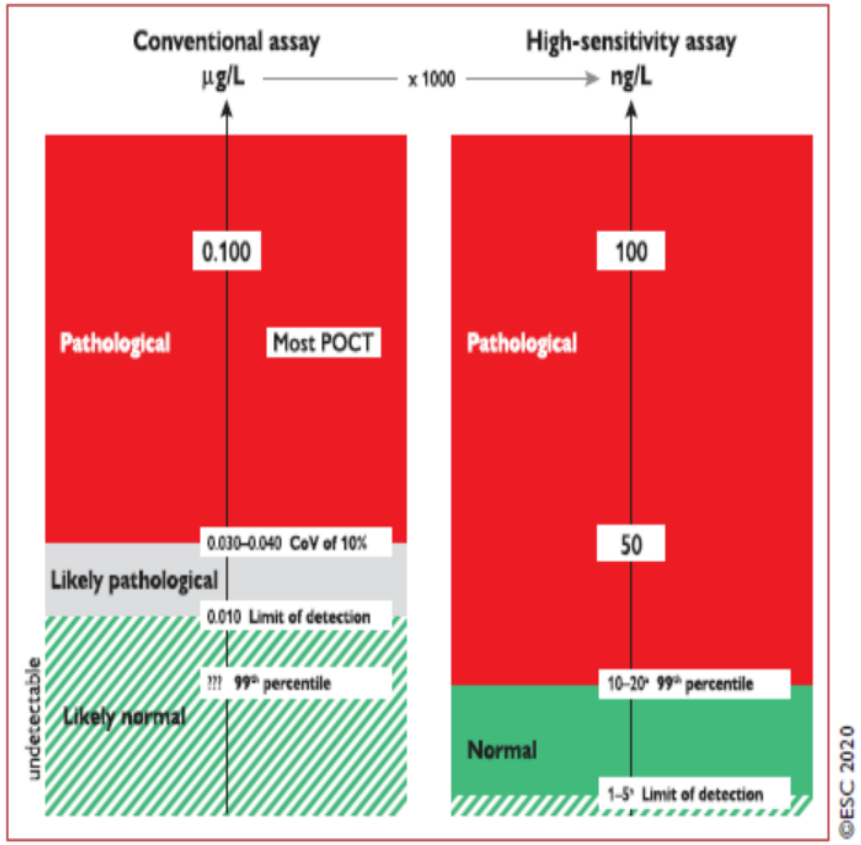
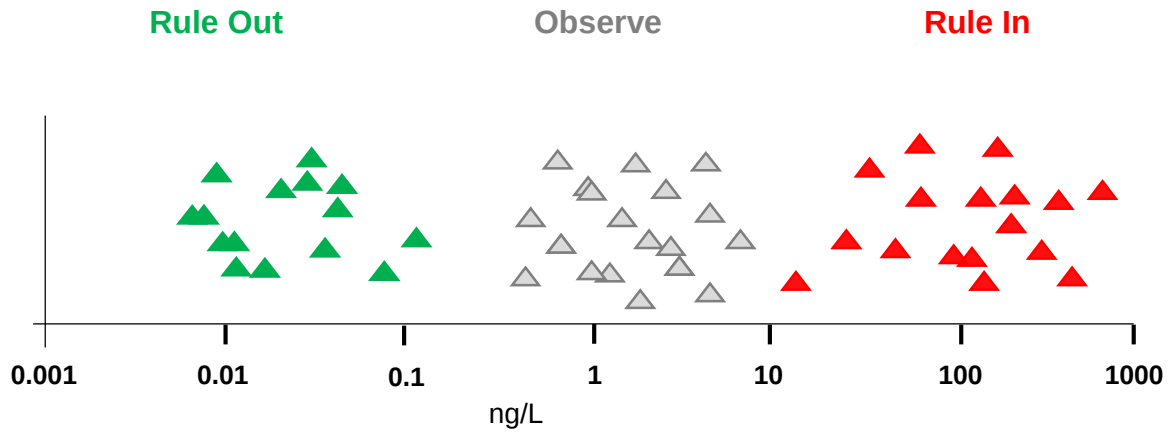
Clinical application

Based on the demonstrated performance the assay can be used for effective rule out of MI in the ER and allows for faster discharge of about 45% to 55%* of suspected MI cases and thereby significant cost savings.





*Boeddinghaus, J. et al. J. Am. Coll. Cardiol. 2020; 75 (10): 1111-24

Sample to result process: The disruptive technology must deliver a complete solution

Individual process steps contribute differently to clinical performance



Sampling

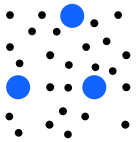
Solutions for sampling of all easily accessible matrices will be developed and integrated in workflow

- Urine
- Fingerstick blood
- Saliva
- Swabs



Sample Preparation

Sample pretreatment and metering integrated in sampling device or assay cartridge; no manipulation required by user



Sample Analysis

Sample analysis in fully automated device enabling interaction with ready to use reagents without any manual handling. All reagents in cartridge.



Data Analysis

Instrument based data analysis.

Self learning AI via cloud access improves data analysis



Communication

Broad communication features supporting advanced e-health requirements

Integration of mature AI models supporting consumer guidance

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Financial Update / M&A

Randy Steward, CFO

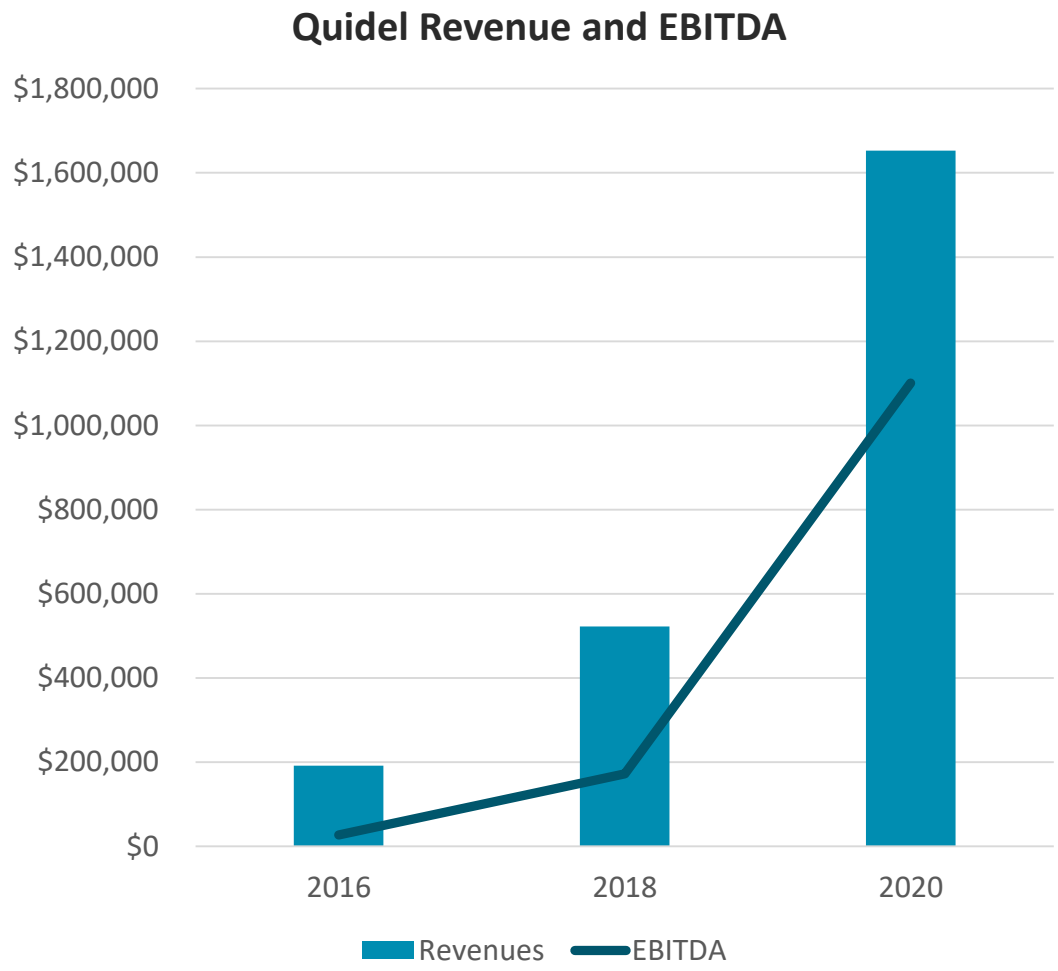
Transformational Years for Quidel

2017 purchased Cardiometabolic Business from Abbott

- Global commercial enterprise – sell in >100 countries
- Global management and infrastructure capabilities
- Expanded revenues, earnings and cash flows

2020 SARS product launches

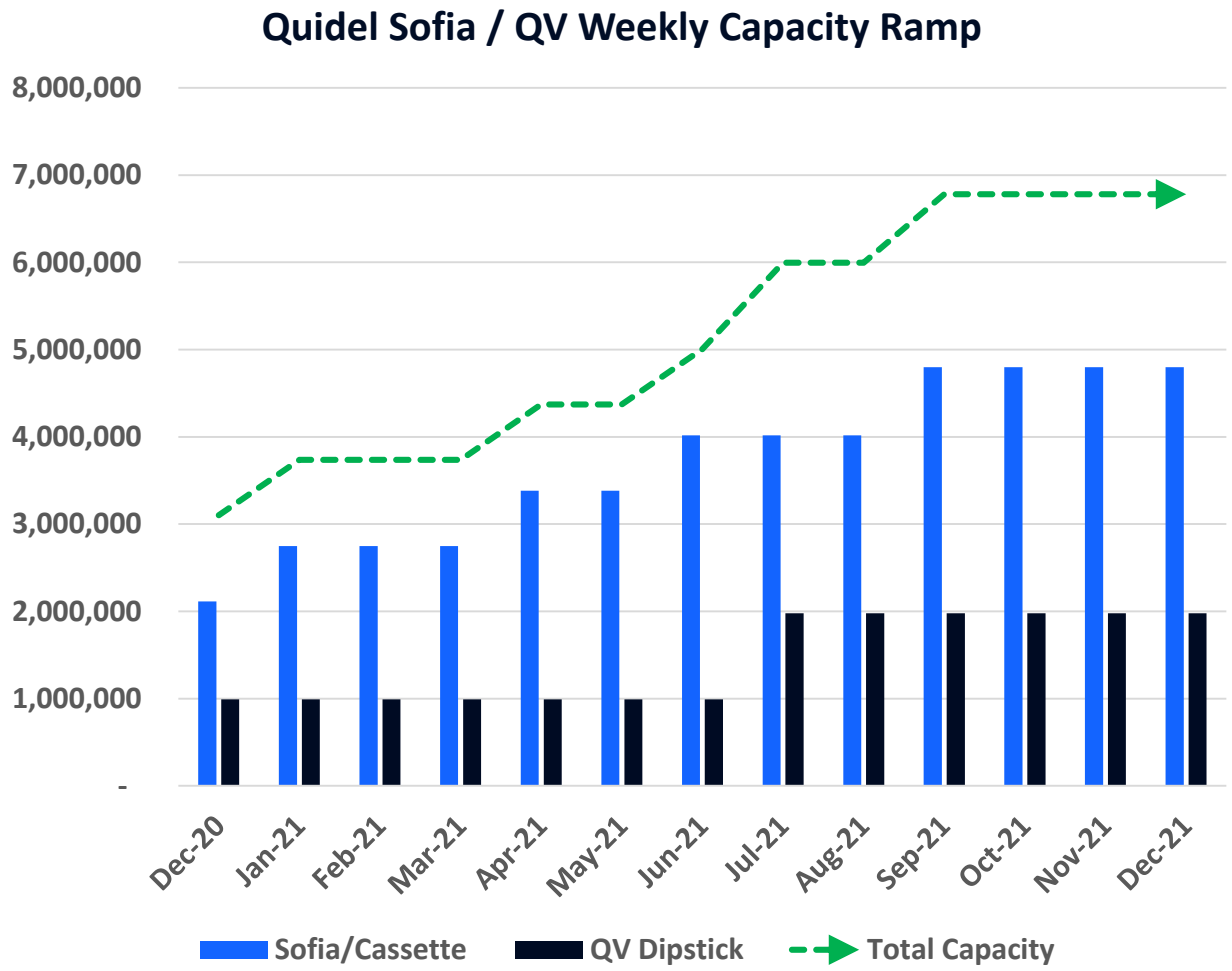
- R&D capabilities – first with Antigen and Flu/SARS combo
- Operations expertise in ramping production
- Rapid action on global supply chain



Quidel Immunoassay Capacity Build

Current path to capacity expansion

- Maximized initial Sofia production at 1.8M tests weekly
- Converted existing manufacturing lines to achieve 2.1M tests weekly
- Committed $70M to add four additional manufacturing lines to achieve a minimum of 4.8M tests weekly
- Adding QuickVue dipstick poucher to double capacity to 2.0M tests weekly



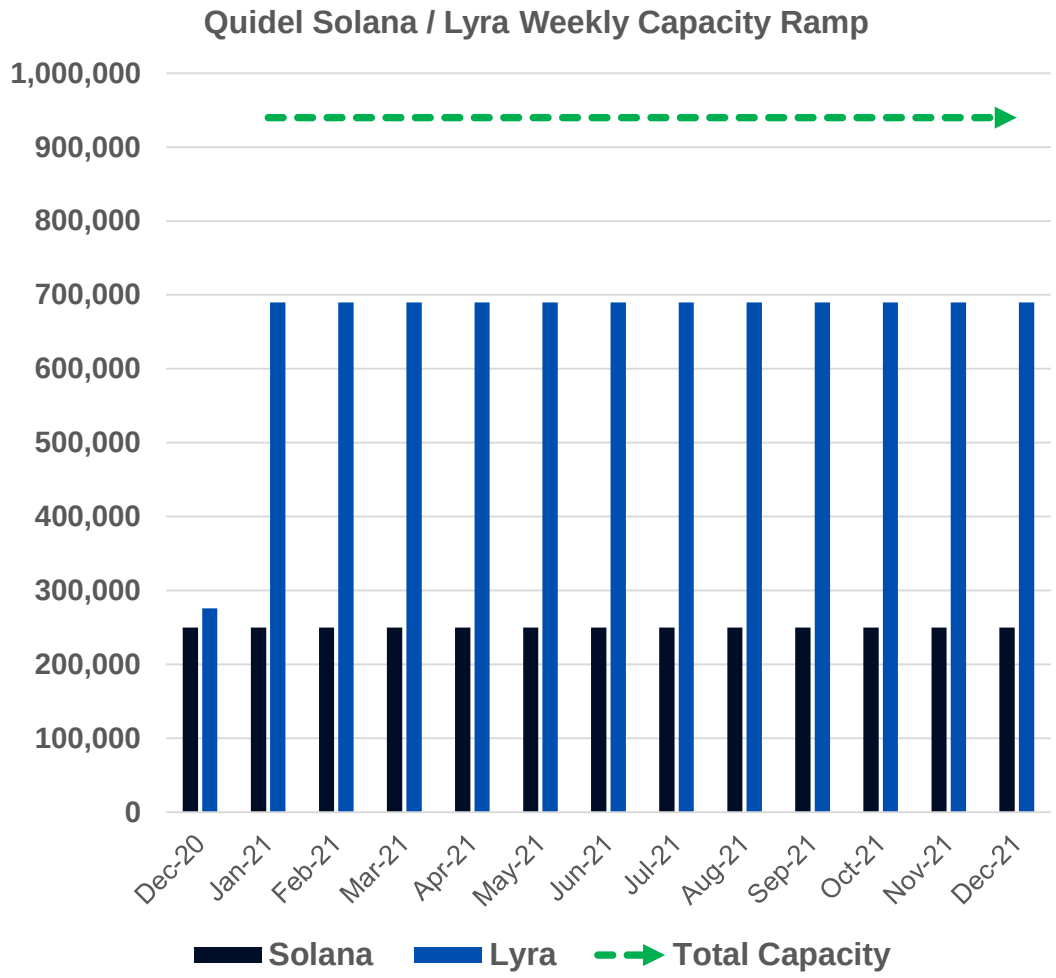

McKellar Facility Expansion


Line 7 Installation
SmartLase C350


New Distribution Site

Quidel Molecular Capacity Build

- April 2020 ramped up capacity to 480K tests per week
- Through several process improvement initiatives increased capacity to 690K tests per week
- Adding new lyophilization equipment December 2020 to increase capacity to 940K tests per week



Strong Quidel Revenue Growth

Short-term

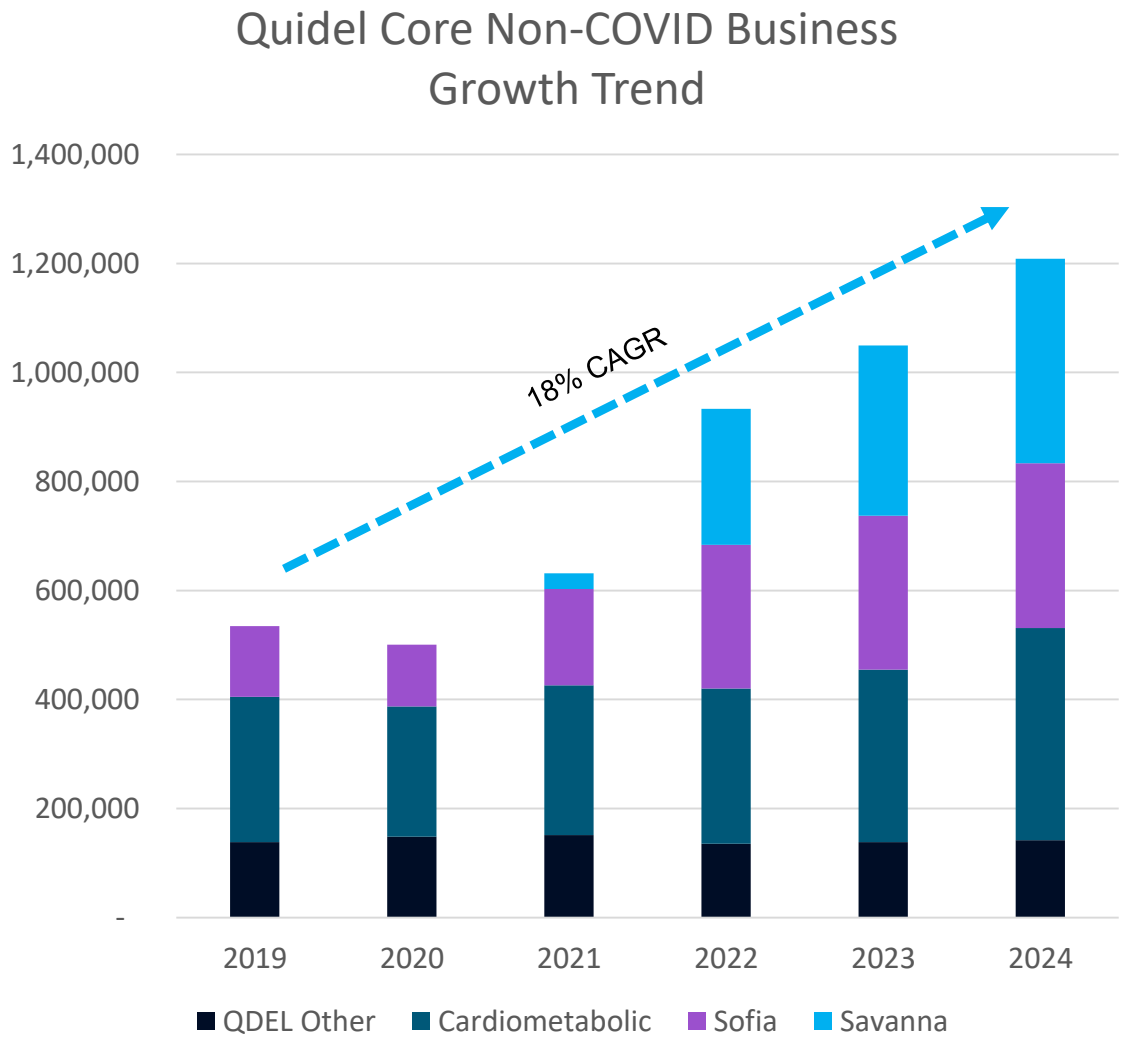
- Exit 2020 with Sofia install base @ 75,000 creating a larger customer base for respiratory menu
- Expanded Sofia menu, Gastrointestinal, Strep98, others

Medium-term

- Savanna launch 2H21 with respiratory panel
- hsTnl clinical trials in 2021

Long-term

- Savanna menu expansion
- US Launch for hsTnl



Capital Structure

Debt Type	Initial Date	Amount	Balance at 12/31/2020
Convertible Bond Debt	December 2014	$172.5 million	$0
Term Loan Debt	October 2017	$245 million	$0
Revolver Debt	October 2017	$10 million	$0
Deferred & Contingent Consideration (Abbott)	October 2017	$280 million	$136 million

- De-levered from >$700M debt to $136M in just over 3 years
- Consummated sale-leaseback transaction for $146 million in January 2018
- Repurchased >96% of convertible bonds prior to maturing (weighted avg price of $61.43)
- Utilized cash flow from operations to reduce loan debt and contingent consideration
- Strong balance sheet – positioned for future investment opportunities

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M&A can further enable our strategy

We have three criteria against which we are constantly evaluating opportunities



Strategic Fit

- **Leverages existing assets**
  - R&D capabilities
  - Existing sales call points and distribution partners
  - Sofia installed base
- **Platform for future growth**
  - New/adj market segments
  - Product portfolio extends
  - Production capacity
- **Secures supply chain**



Financial Fit

- **Accelerate top-line growth**
- **Margins**
  - ~65% product GM
  - ~35% EBITDA
- **ROIC**



Ability to Execute

- **Integration assessment**
- **Confidence in achieving synergies**

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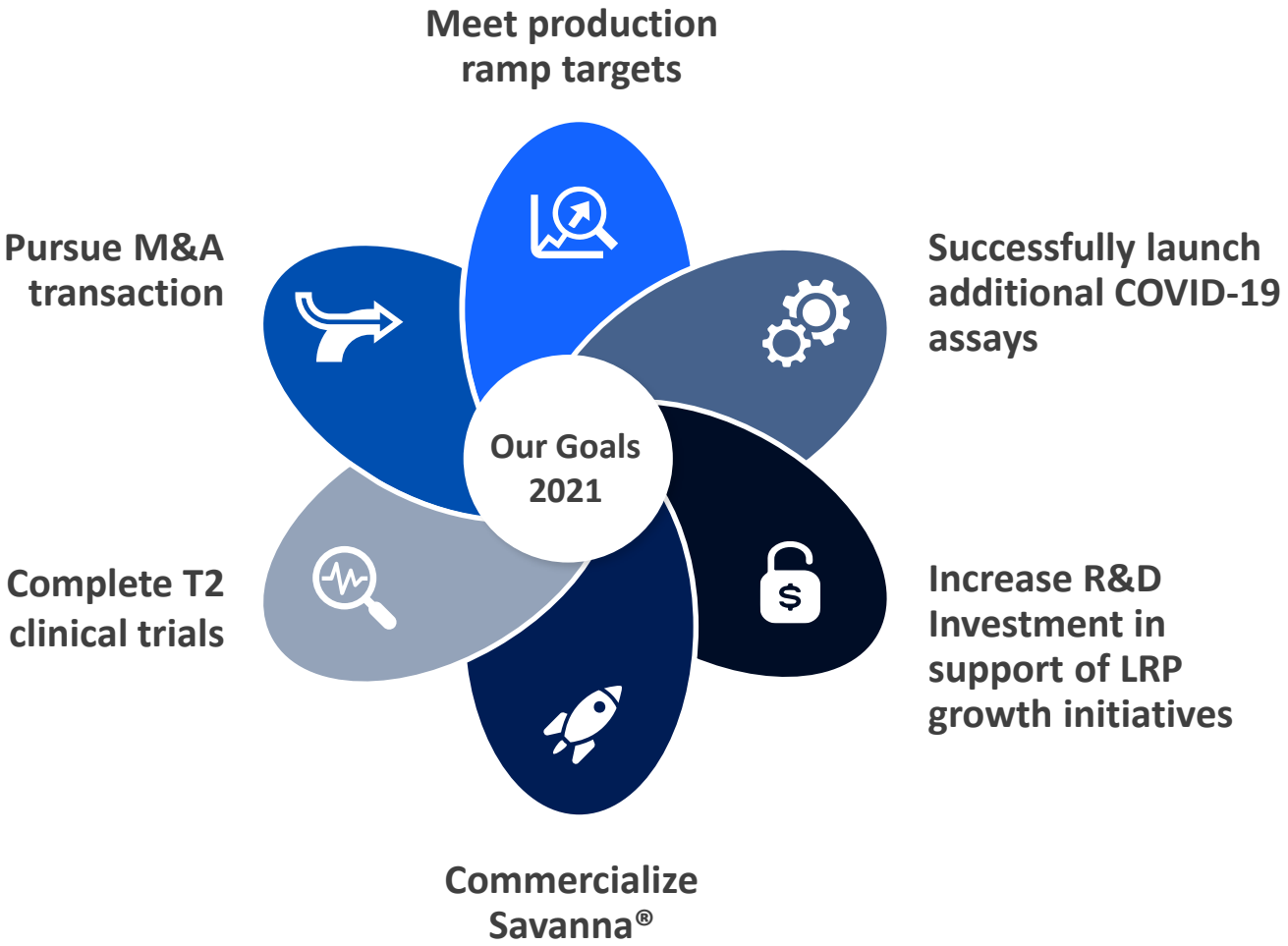
Goals for 2021





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