

# CARDIEX

Biomarker technologies for  
cardiovascular health

## CORPORATE PRESENTATION

29 September 2023





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# Corporate Overview

- ASX listed MedTech (ASX:CDX).
- US corporate based.
- Developer of non-invasive vascular biomarker technologies.
- Creating a new standard of care and prevention for CVD.
- Capital raise to accelerate go-to-market strategy for multiple world-first technologies.
- Largest shareholder (~20%) – C2 Ventures (Craig Cooper (CEO) & Niall Cairns (Chairman)).





# Investment Thesis

Immeasurable  
Global Health Impact

“A targeted, category-based medtech strategy correlates directly with profitability and winning.”

**BAIN & CO**

<https://www.bain.com/insights/why-category-leadership-matters-more-than-ever-in-medtech/>

\*Refer to “Significantly Expanding Our Market Opportunity” slide for further details

**\* Unique opportunity to own a significant health & diagnostic category for digital vascular biomarkers.**

Connected medical devices targeting a \$293 billion market opportunity\* from multiple revenue streams.

Pioneering arterial health technology used by customers over the last 20 years.

Strong IP portfolio with protection.

**\* Strong pipeline of products and anticipated regulatory applications to drive growth and shareholder value.**

Near term business opportunities showing strong initial market traction.

Financing to drive market & customer acquisition strategy.

**Scientific, Research, & Regulatory Validation**



**Full Commercialization & Revenue**



# What Are Vascular Biomarkers?

## Peripheral Pulse Pressure Measurements

1871

Accessible to all

Limited pressure metrics



## Central Aortic Pulse Pressure and Arterial Stiffness Measurements

1950

Complete pressure metrics

Invasive

ICU/Hospitals Only



**"Biomarker"**  
/'bīō,märkər/

A measurement used to monitor and predict a state of health



# We Invented Non-invasive Vascular Biomarker Devices

1990

**Dr. Michael O'Rourke**  
ATCOR Founder

2002



**Complete pressure metrics**

**Non-invasive**

Limited  
Accessibility

Cost

**ATCOR** 

XCEL & Oscar 2

**C O N N E Q T**

Pulse & Band

2023



**Complete pressure metrics**

**Non-invasive**

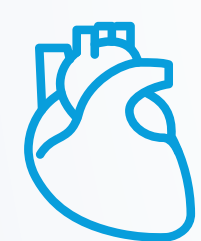
**Accessible to all**



# A \$1 Trillion+ Problem

Cardiovascular (CV) disease is the

# #1



## Killer

of humans globally

Incidence rate continues to rise

## Total Cost of Cardiovascular Disease (CVD) Annually\*

# \$363B

2020

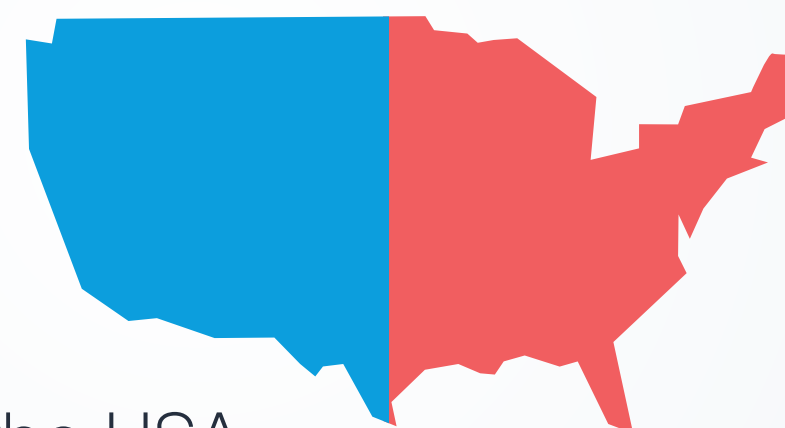


# \$1.1 Trillion

2035

# 113M

Hypertensives in the USA  
(50% of US Adults)

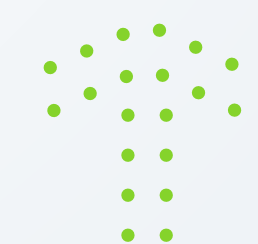


# 19M

Heart Disease Deaths Globally  
(1 Every 36 Seconds in USA)

# 33%

Global Deaths  
Related to CVD



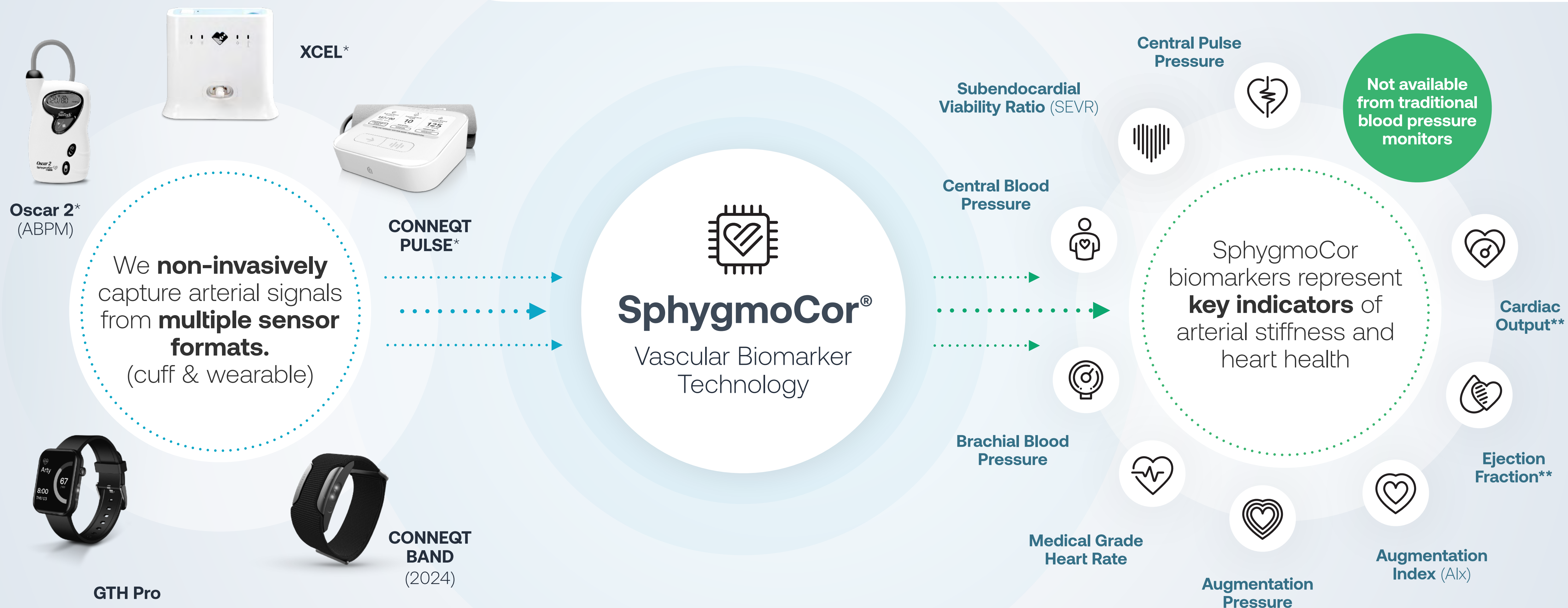
# 38%

Rise in Blood Pressure  
Related Deaths  
(2005 - 2018)

\*Source: Centers for Disease Control & Prevention/World Heart Federation/Eur Heart Journal, McEneaney et al/American Heart Association

# Our Solution

## SphygmoCor® Vascular Biomarker Technology



\*\*2024

5X **FDA**

\*Only FDA cleared devices for full arterial waveform analysis in adults.



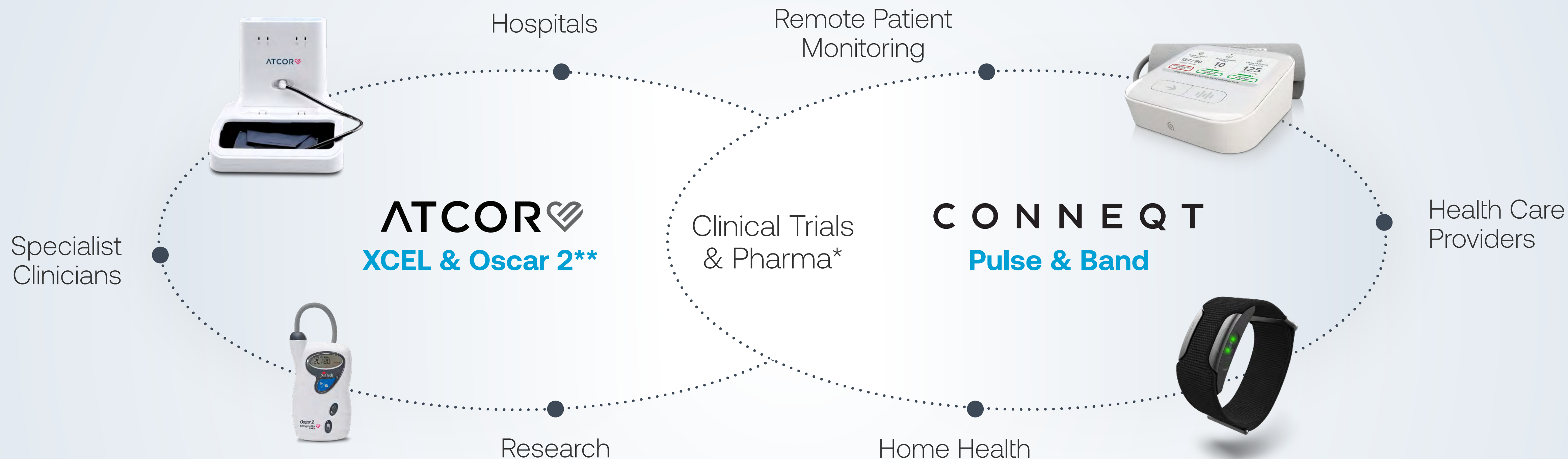
UNIQUE CPT Code: 93050

19

Patents covering significant applications in cardiovascular health and consumer wearables

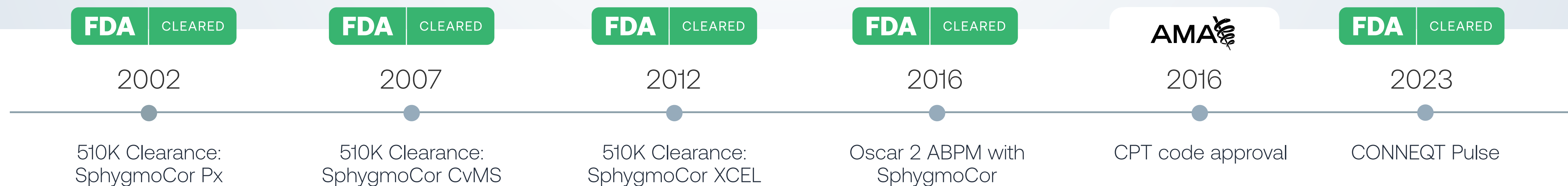


# A Complete Ecosystem of Vascular Biomarker Solutions



\*ATCOR provides on-site devices and data management solutions. CONNEQT provides devices and solutions for decentralized trial management

\*\*Oscar 2 with SphygmoCor® is subjected to a Development, Sales, Manufacturing and Distribution Agreement between SunTech Medical, Inc and ATCOR Medical Pty Ltd dated January 13, 2012.





# Application Across Multiple Disease States

“Beyond Blood Pressure”

“Beyond Hypertension”

Our technology extracts data that impacts multiple disease states beyond hypertension.



Actionable consumer & medical insights that drive better decision making and patient outcomes.



# Our Vascular Biomarkers in Practice: A New Standard of Care

**Early identification  
and prevention** of  
vascular disease

**More predictive of future cardiovascular events** than standard brachial blood pressure.

**Vascular stiffness precedes the development of hypertension** allowing earlier intervention.

**Multiple clinical insights** beyond hypertension (brain, kidneys, maternal health, sexual health).

**Economic impact** (cost savings of medication and ongoing patient management).

**More accurate identification of patients that are being over- or undertreated** (1.3B global hypertensives).

**Better risk assessment** for insurers, employers, payers, and healthcare system

Lifetime



Disease  
progression

“Lancet Commission on Hypertension”



# Central Blood Pressure Studies “Highlights Reel”

“Central blood pressures have been shown to correlate more strongly with vascular disease than do routine peripheral blood pressure measurements.”

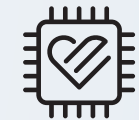
Cleveland Clinic

“In a study of 1100 patients **central pulse pressure was a powerful predictor of major cardiovascular events, while brachial blood pressure was not**”

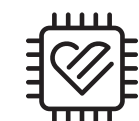
Jankowski et al, Hypertension, 2008

“In a study of 3,500 high risk adults **central pulse pressure is 32% better than brachial blood pressure** in predicting cardiovascular events”

The Strong Heart Study, Roman et al, Hypertension, 2007.



In a study of 2199 patients central aortic pressure was shown to be a better independent predictor of cardiovascular and kidney outcomes. – CAFE Study, 2006



“New methods that assess arterial pressure and flow dynamics, beyond focus on conventional upper-arm blood pressure, are needed”

Lancet Commission on Hypertension





“Central pressure measurement is essential because you don't die from an “arm attack” you die from a “heart attack”.”

**J. Cockcroft M.D**

Professor of Cardiology, Heart Research Institute



# Our Current Customer Base



Pharma/Biotech



Clinical Research Organizations



Academic Researchers



Specialist Healthcare Practices



**ATCOR** 



**XCEL**



**Oscar 2**  
(ABPM)



**Sale | Data Services | Lease | Licensing**



**250+ research programs**  
have used SphygmoCor  
biomarkers.\*

**6 Continents / 34 Countries**

**4000+ Installs**

**All "US News" Annual Top 20 Hospitals**

\*Studies registered on the [clinicaltrials.gov](https://clinicaltrials.gov) registry



# Our Bluechip Customers

6 Continents / 34 Countries

4000+ Installs

All "US News" Annual Top 20 Hospitals

## Research and pharmaceutical companies

For clinical trial services related to hypertension, cardiovascular disease, diabetes and renal disease



8 out of the Top 10 Pharma companies uses SphygmoCor® in their clinical trials.

## Major IDNs and specialist physician practices

Cardiology, Nephrology and Endocrinology



4000+ papers have been published in leading peer-reviewed journals like Hypertension, Journal of Clinical Hypertension, and the Journal of American College of Cardiology.

## Medical and consumer device licensing

Licensing algorithms and sale of technology





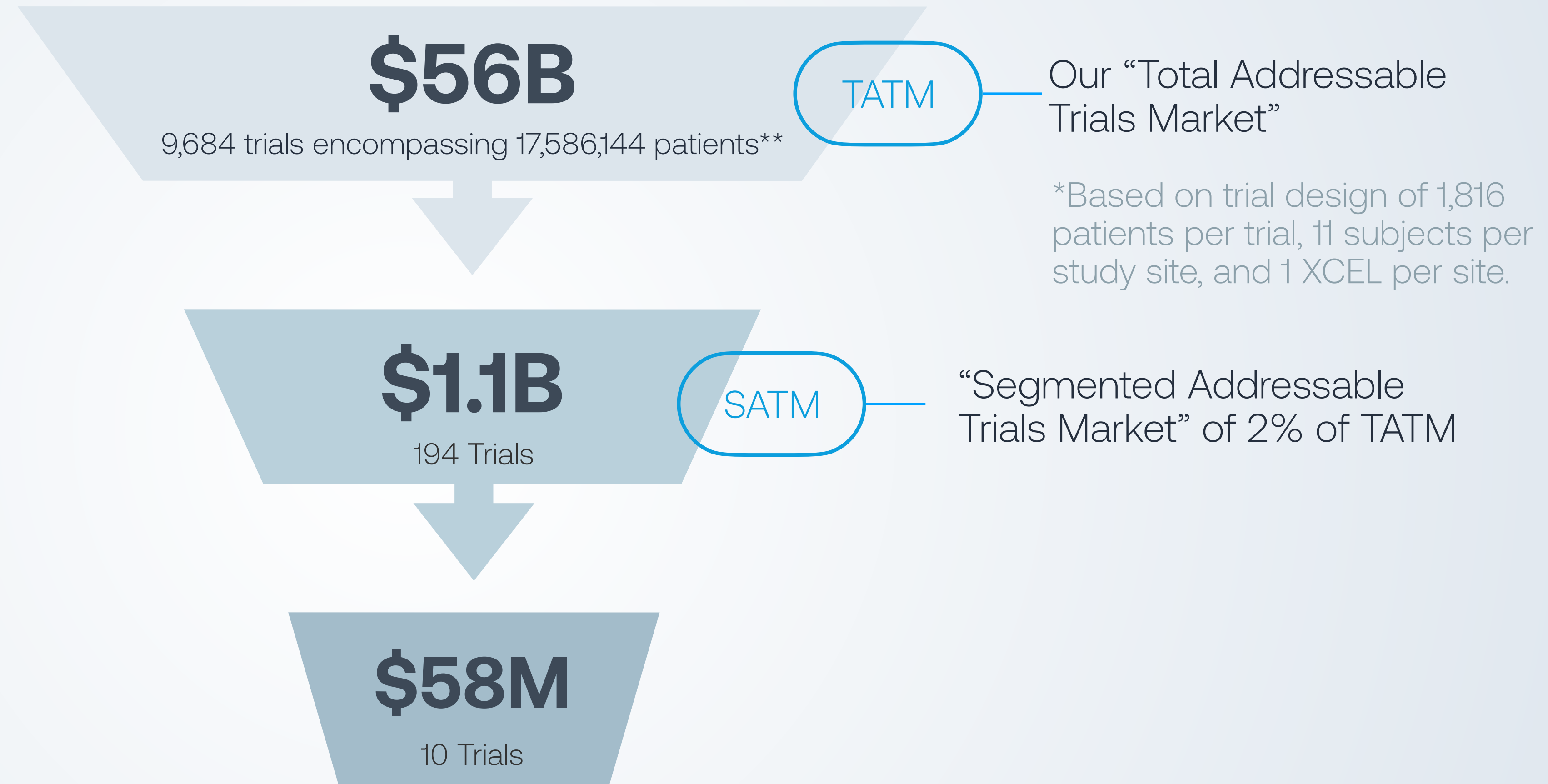
# Our Clinical Trial Business

**~\$35,000**

System Revenues Per Site

**~86%**

Net Trial Profit Margins



\*\* Source: data from clinicaltrials.gov & economics from existing trials



# Major Ongoing Trials and Studies

120+

Research Studies in Process Using Our Technology

46

Clinical Trials To Date



## Andwin Trial

2022 initiated trial between Andwin Scientific, Syneos Health and Philip Morris.

ATCOR's XCEL device is used for multiple endpoints including determination of clinically relevant arterial health outcomes based on aortic augmentation index (AIx) and arterial stiffness - key biomarkers of arterial health.



## CARTESIAN Study

World's largest study on hypertension and COVID-19

ATCOR's SphygmoCor XCEL was selected to assess vascular consequences of COVID-19.



UK NHS



## Heart Failure & Kidney Disease Study

Assessing the effects of arterial stiffness on heart failure and kidney disease.

ATCOR's SphygmoCor provides Arterial Stiffness and Central Aortic Blood Pressure as part of the overall assessment of patients.



## Panacea Trial

Assessment of vascular biomarkers in heart failure patients

A trial for 150 adult patients (male and female) with heart failure and left ventricle <50%. This trial uses SphymoCor to capture vascular biomarker data.



# Other Users of SphygmoCor® Technology

Research and  
pharmaceutical  
companies



**For clinical trial services related to hypertension, cardiovascular disease, diabetes, and renal disease**

8 out of the top 10 Pharma companies have used SphygmoCor® in their clinical trials.

Major IDNs  
and specialist  
physician practices



**Cardiology, Nephrology, and Endocrinology**

4000+ papers have been published in leading peer-reviewed journals like Hypertension, Journal of Clinical Hypertension, and the Journal of American College of Cardiology.

Medical and  
consumer  
device licensing



**Licensing of algorithms and sale of technology**

Smart-watches and ambulatory blood pressure monitors (ABPM's).

**6 Continents / 34 Countries**

**4000+ Installs**

**All "US News" Annual Top 20 Hospitals**



# Our Growth Strategy

From specialist clinician & research to value based cardiovascular healthcare at scale.

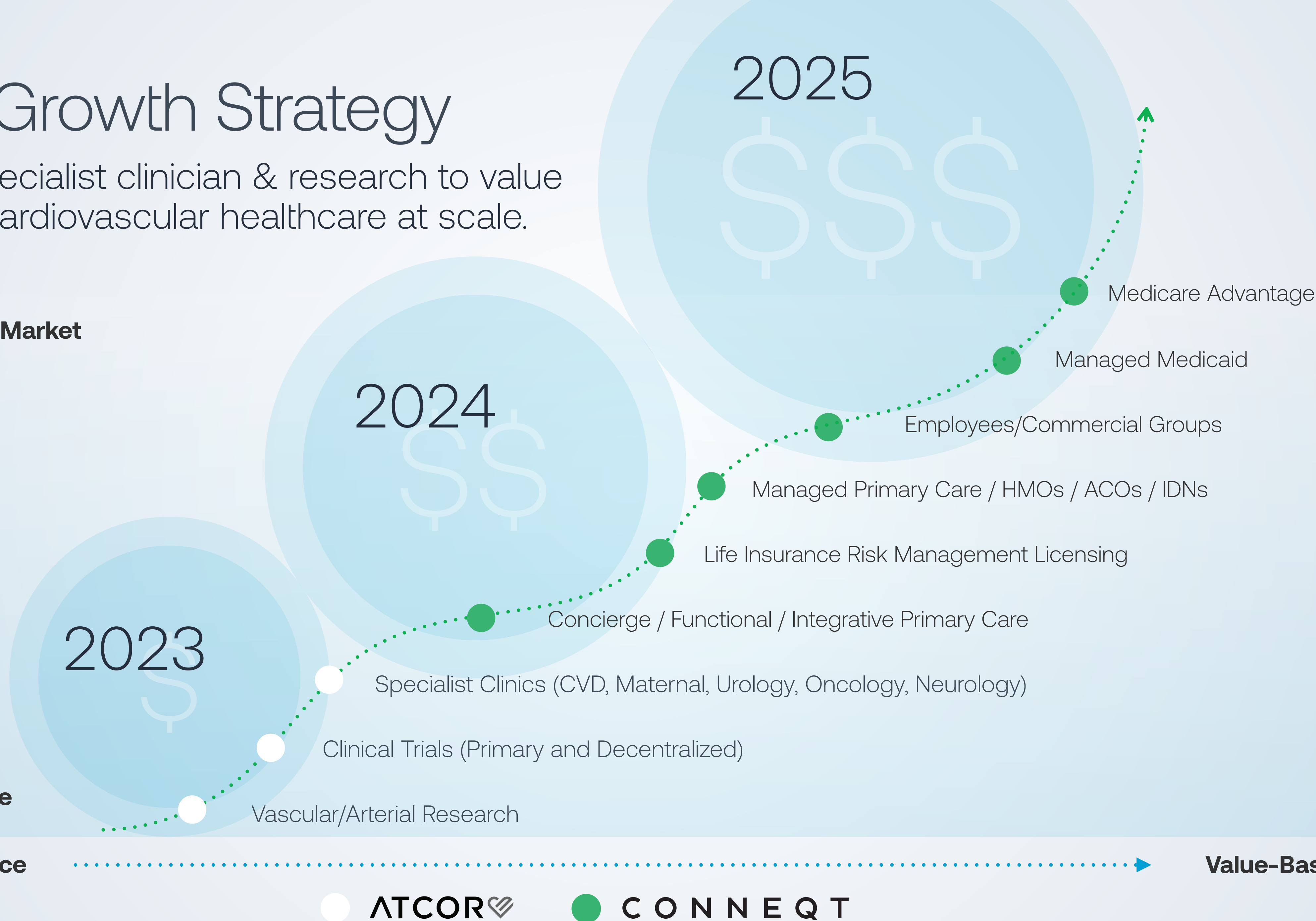
**Broad/Mass Market**



**Narrow/Niche**

**Fee for Service**

**Value-Based Care**

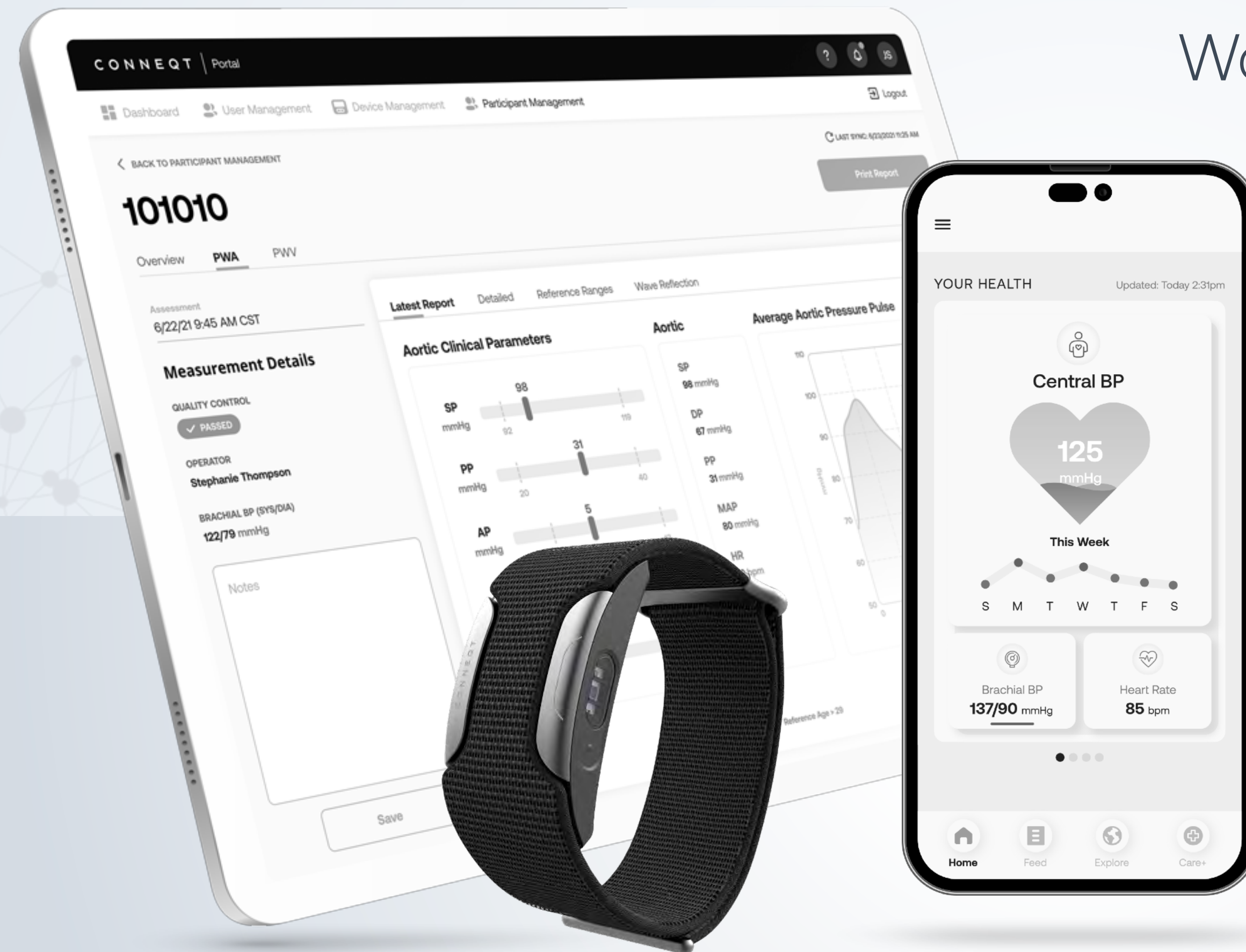




# Growth Fueled by New Products and Solutions

World-first Vascular Biometrics Monitor

**CONNECT PULSE**



**FDA** CLEARED

April/2023



**CONNECT BAND**

World-first Dual-Sensor Arterial Health Wearable

Anticipated FDA clearance Q1/24



# World First Dual-Sensor Medical Grade Wearable



- Patent-pending side-sensor.
- Dual health/fitness + vascular biometrics.
- Medical grade (on anticipated FDA clearance).

Anticipated FDA clearance Q1/24

**C O N N E Q T B A N D**



# Continuing Technology Validation



The award recognizes the achievements of innovative health tech companies that are dramatically improving healthcare through the use of technology in the digital health industry.



The National Institutes of Health has awarded CardieX \$415K to accelerate the development of our arterial health monitoring technology for use in maternal health.



# Significantly Expanding Our Market Opportunity

Remote  
Patient Monitoring



**\$175B**

**2027**

(Markets and Markets)  
<https://www.marketsandmarkets.com/Market-Reports/remote-patient-monitoring-market-77155492.html>

Health  
Wearables



**\$104B**

**2027**

(Grand View Research)  
<https://www.bloomberg.com/news/newsletters/2020-12-14/apple-oura-devices-can-help-detect-covid-19-early-studies-show>

Decentralized  
Clinical Trials



**\$14B**

**2026**

(Medi-Tech Insights)  
<https://www.globenewswire.com/en/news-release/2022/05/26/2451326/0/en/Global-Decentralized-Clinical-Trials-DCTs-Market-valued-at-US-8-8-billion-2021-is-set-to-witness-a-healthy-growth-rate-of-10-to-reach-US-14-2-billion-by-2026.html>



# Our Cloud-based Arterial Health Ecosystem (2023/24 Launch)

**+ Clinical**

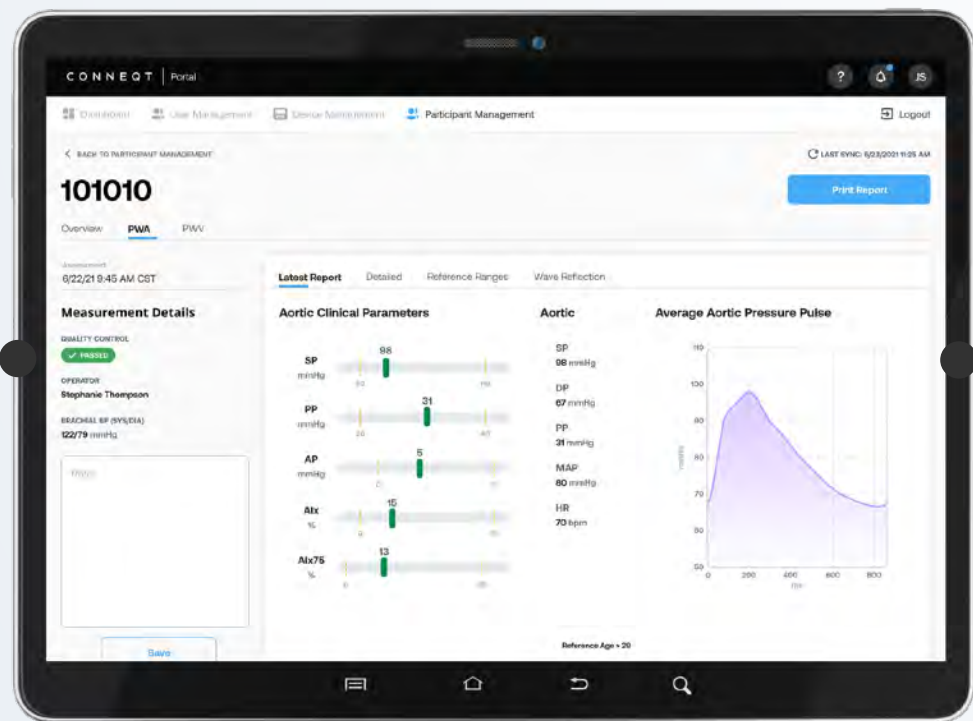
- Clinician-Facing
- Decentralized Trials

**Personalized, Fully Customizable Arterial Health Insights**

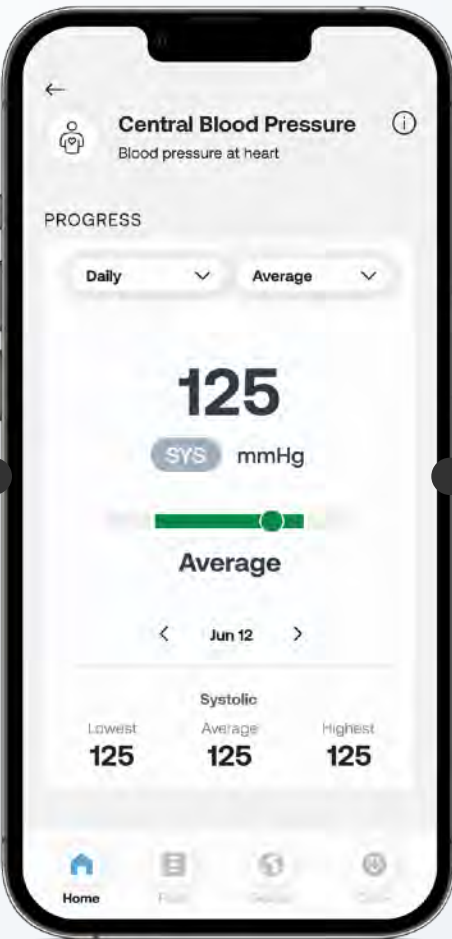
**Consumer**

- General Consumer
- Patient-Facing
- Research Participant

**CONNQTPULSE**  
Professional Use



**CONNQTPORTAL**  
Physician Portal



**CONNQTTAPP**  
Mobile App

**CONNQTPULSE**  
Home Use

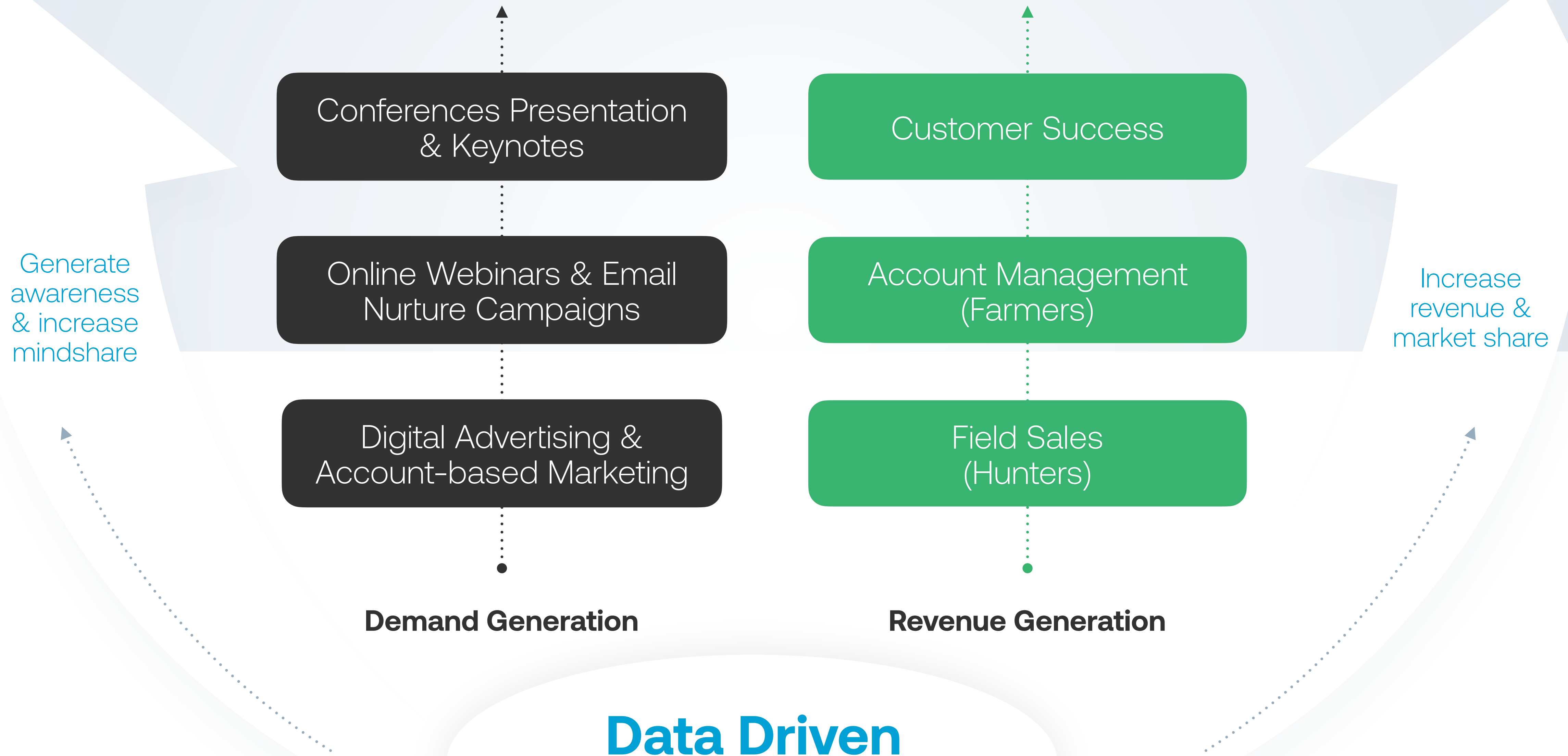


**CONNQTBAND**  
Wrist Wearable\*

\*Commercial launch will depend on FDA review and clearance. There is no guarantee the FDA will grant clearance or that it will do so on the timeline indicated



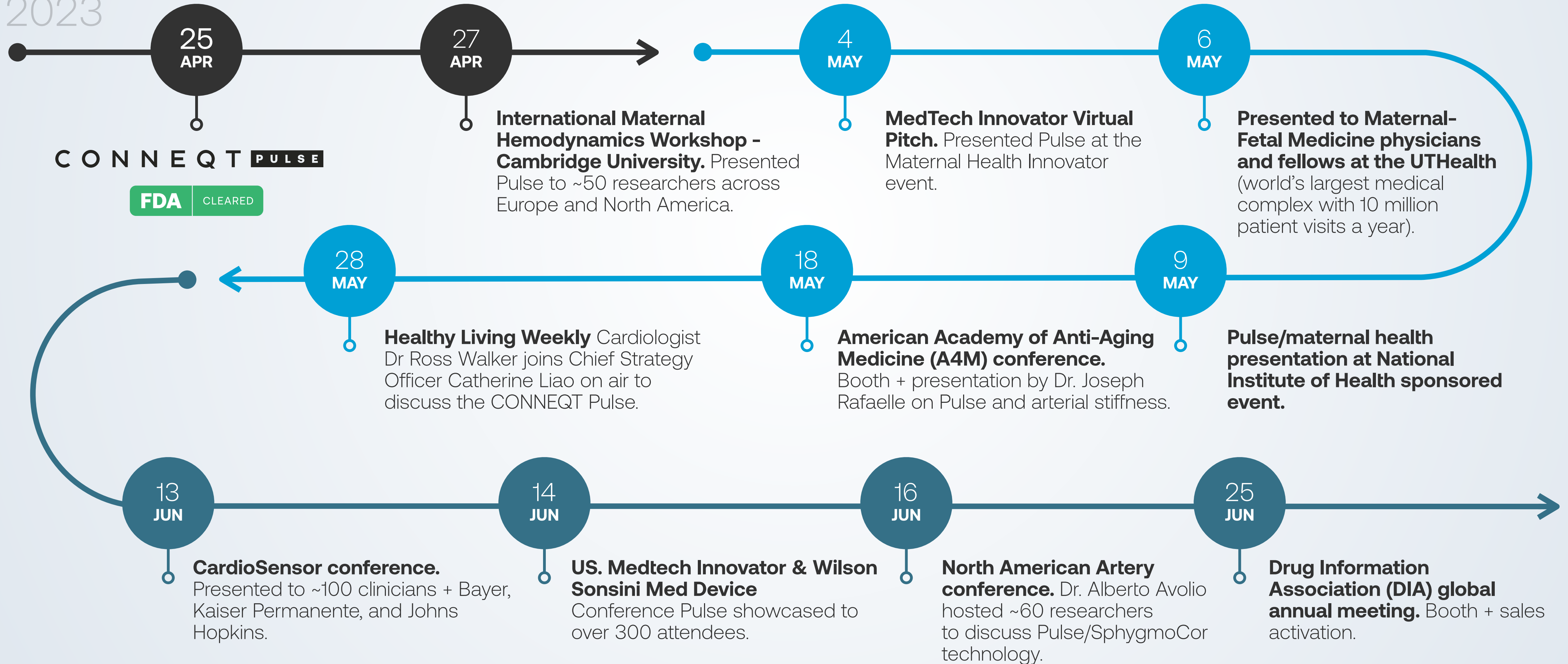
# Customer Acquisition Playbook



# Go-To-Market activities since FDA Clearance

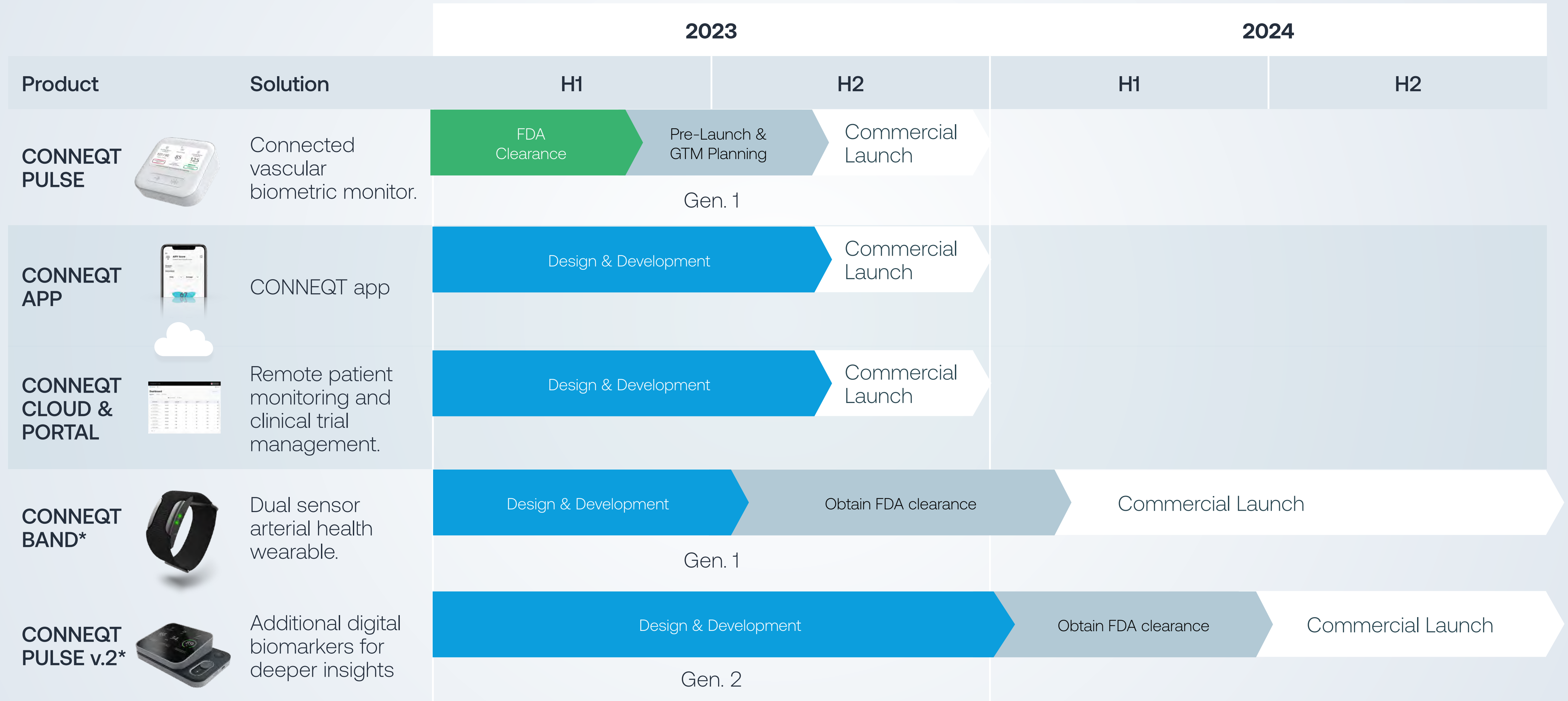
Leveraging industry, clinician, healthcare, and KOL channels

2023





# 2023/24 Anticipated Product Launch Schedule



\*Commercial launch will depend on FDA review and clearance. There is no guarantee the FDA will grant clearance or that it will do so on the timeline indicated



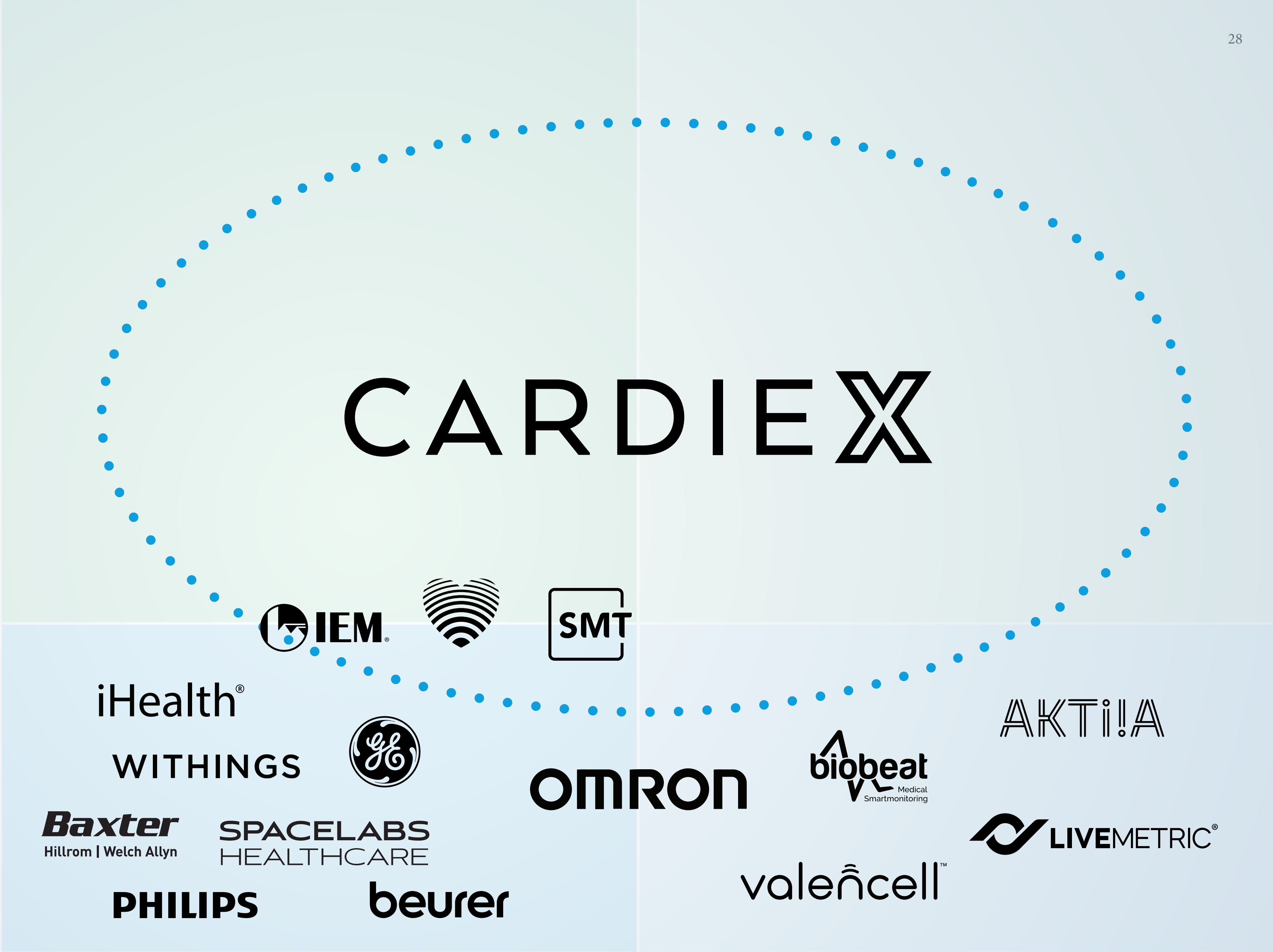
# Competition

Digital Vascular Biomarkers

Blood Pressure

Cuff

Wearable





# Our Competitive Moat

Established presence, market validation, and category focus give us a competitive stronghold.

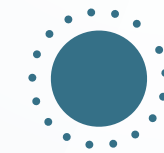
Only Blood Pressure Devices that Allow Physician Reimbursement for Full Arterial Health Measurements



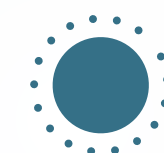
Scientific and industry validation



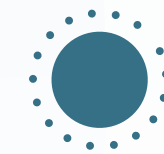
Category inventor



20+ years of research & development



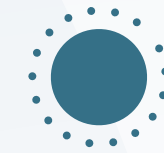
Technology, process complexity & category focus



Industry leading sector expertise



World class engineering team



Robust sensor patent portfolio



# Looking Ahead

(6-12 months)

- **Multiple** new product launch, partnership, and sales opportunities.
- **Launch** of brand, education, and demand generation campaigns for CONNEQT.
- **Expanded channel & customer marketing** for ATCOR clinical trial services.
-  **FDA clearance** for the Pulse and digital companions.
- **Anticipated commercial launch** of CONNEQT Pulse CYQ4/2023.
- **Anticipated additional FDA-clearances on Pulse** for targeted therapeutic areas (maternal health)\*.
- **Strong revenue growth** from our Clinical Trial Solutions group.
- **New clinical trial contracts** and expansion of existing trials.
- **Launch of multiple new studies** for ongoing research and therapeutic validation of biomarkers.
- **Continuing new product development** (Pulse V.2, Band V.2, other connected devices).
- Anticipated **FDA clearance and launch for the CONNEQT Band\***.
- **Accelerating revenue contributions** from new product releases (SaaS, app subscription, lease revenues, product sales).

\*Commercial launch will depend on FDA review and clearance. There is no guarantee the FDA will grant clearance or that it will do so on the timeline indicated



# To Summarize

- **Opportunity to be “category leader” in worlds largest health market.**  
(Resmed, DexCom, Masimo).
- **Micro-cap valuation** – unique entry opportunity.
- **Significant valuation comps** in health wearables market (WHOOP \$3.8b/Oura \$1.8b).
- **Low R&D & regulatory risk.**
- **Multiple** short & longer term price inflection points.
- Immediate near term opportunities show **strong initial market traction.**
- **Quantifiable success metrics** (devices deployed (sale/lease), subscription revenues).