

CADScor® System

ACARIX AB

LIFE SCIENCE INVESTOR

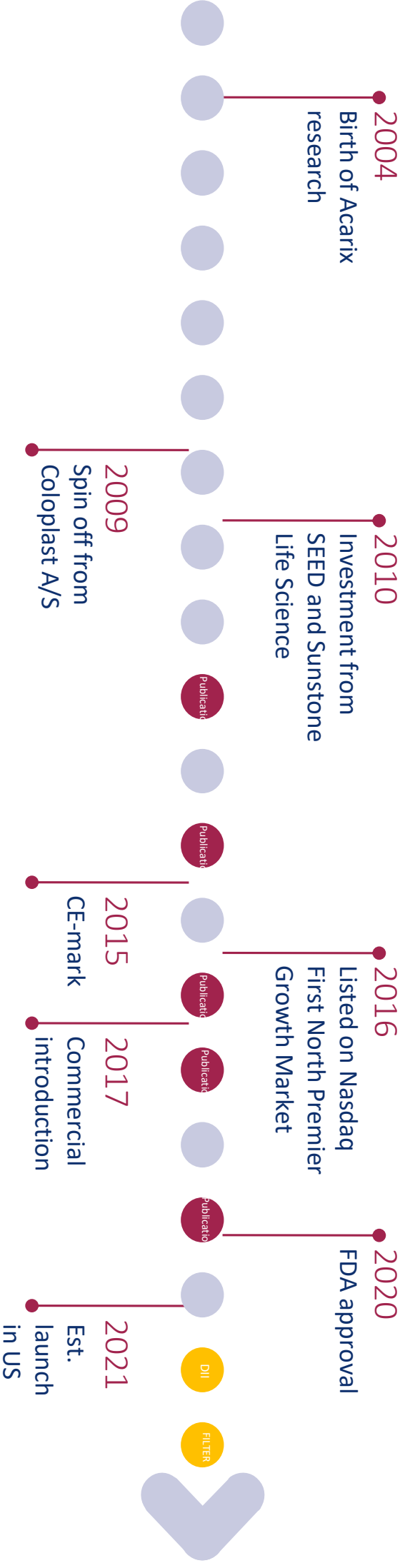
MAY 26

PER PERSSON, CEO



ACARIX – COMPANY INTRODUCTION

Acoustic Cardiac Diagnostics >> ACARIX



2020 ACHIEVEMENTS- IMPACT WITH CONTINUED VALUE CREATION

Acarix receives US market approval for the CADScor® System

Acarix AB (publ) today announced that the US Food and Drug Administration (FDA) has approved the company's De Novo application for marketing approval of the CADScor® System in the US.

"This is a major achievement and a significant recognition of our technology and how it can improve the diagnosis of patients with potential Coronary Artery Disease". "In addition, it will contribute significantly to the value creation of Acarix. This approval enables us to take all measures to prepare the market launch in the USA." said Per Persson, CEO of Acarix".

The De Novo process is used for new products where there is no predicate device with a comparable indication in the US market to support a standard 510 (k)

Positive results from Acarix study presented at ISPOR, a leading health economics conference

Acarix AB (publ) today announced that the company's real-life data analysis made in co-operation with clinics in Germany and Austria is

Acarix announces the last patient included in DAN-NICAD II study

After the inclusion of 1726 patients, Acarix announces that the last patient has been included in DAN-NICAD II, a study of non-invasive diagnostic testing in patients with suspected Coronary Artery Disease (CAD).

The DAN-NICAD II, including 1726 patients referred to coronary CT with symptoms suggestive of stable

Further establish the diagnostic accuracy of the to other stratification alternatives commonly used ing more validated clinical data for further r® Algorithm.

Positive preliminary data from Acarix's exploratory heart failure study SEISMO

ACARIX:

January 13, 2021 Positive preliminary data from Acarix's exploratory heart failure study SEISMO Acarix AB (publ) today announced positive preliminary data from the ex ...

Press release Malmö, Sweden,

ACARIX – COMPANY INTRODUCTION

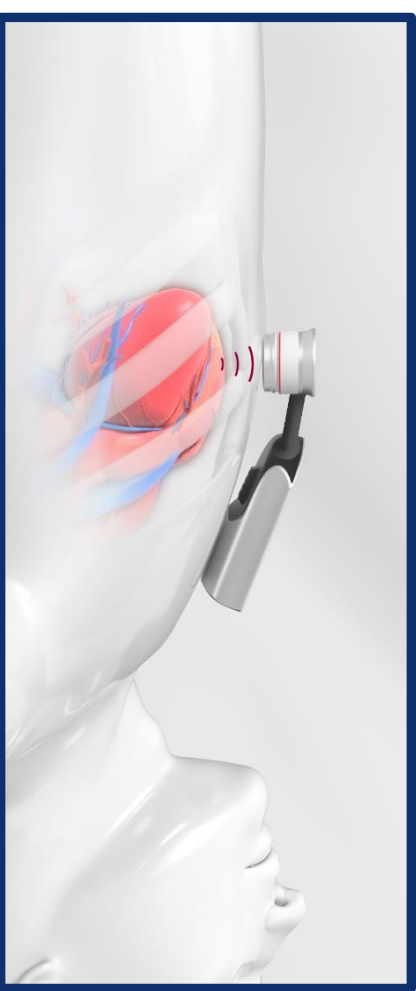
Acarix, a Swedish Medtech company, listed on Nasdaq First North in Sweden since December 2016.

The CADScor® System:

Diagnostic Aid enabling rapid and accurate Rule Out of patients suffering from stable Coronary Artery Disease

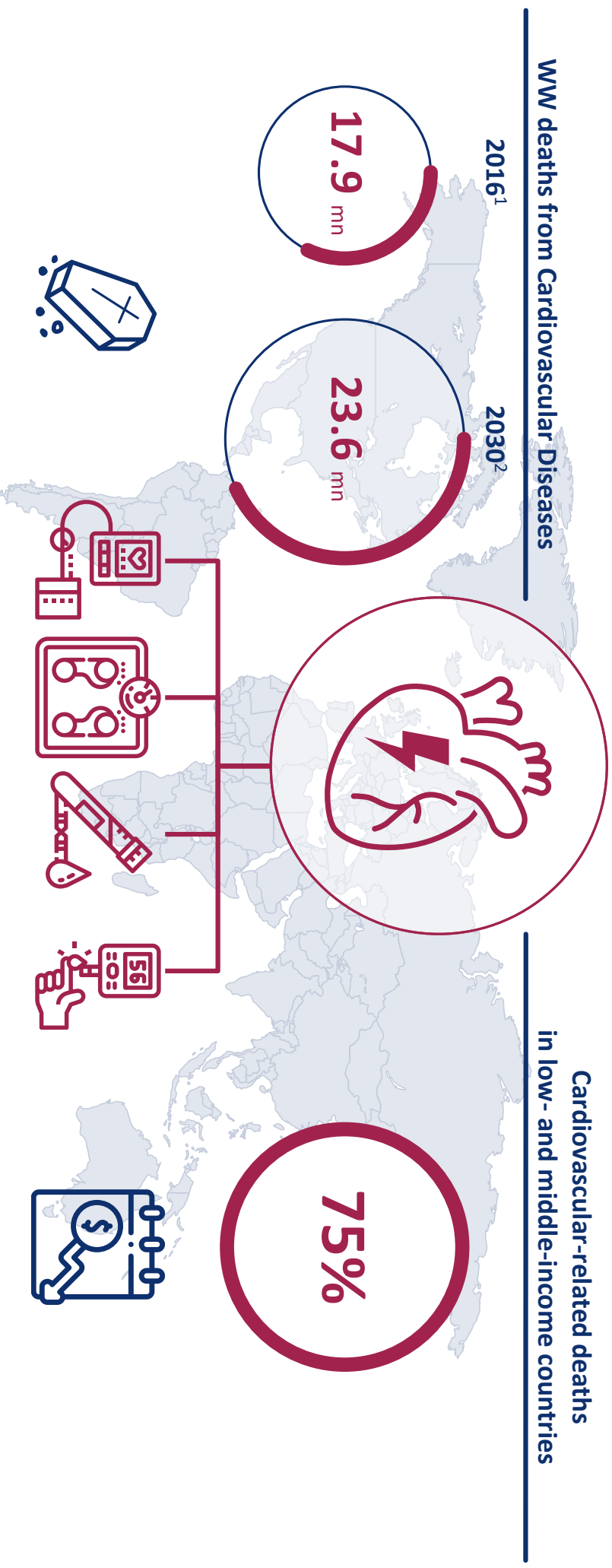
The CADScor® System:

Translates the acoustics of blood to a signal recorded and reported as a numeric score, defining a patient's risk of Coronary Artery Disease



THE MARKET IS SIGNIFICANT AND GROWING

WHO reports...





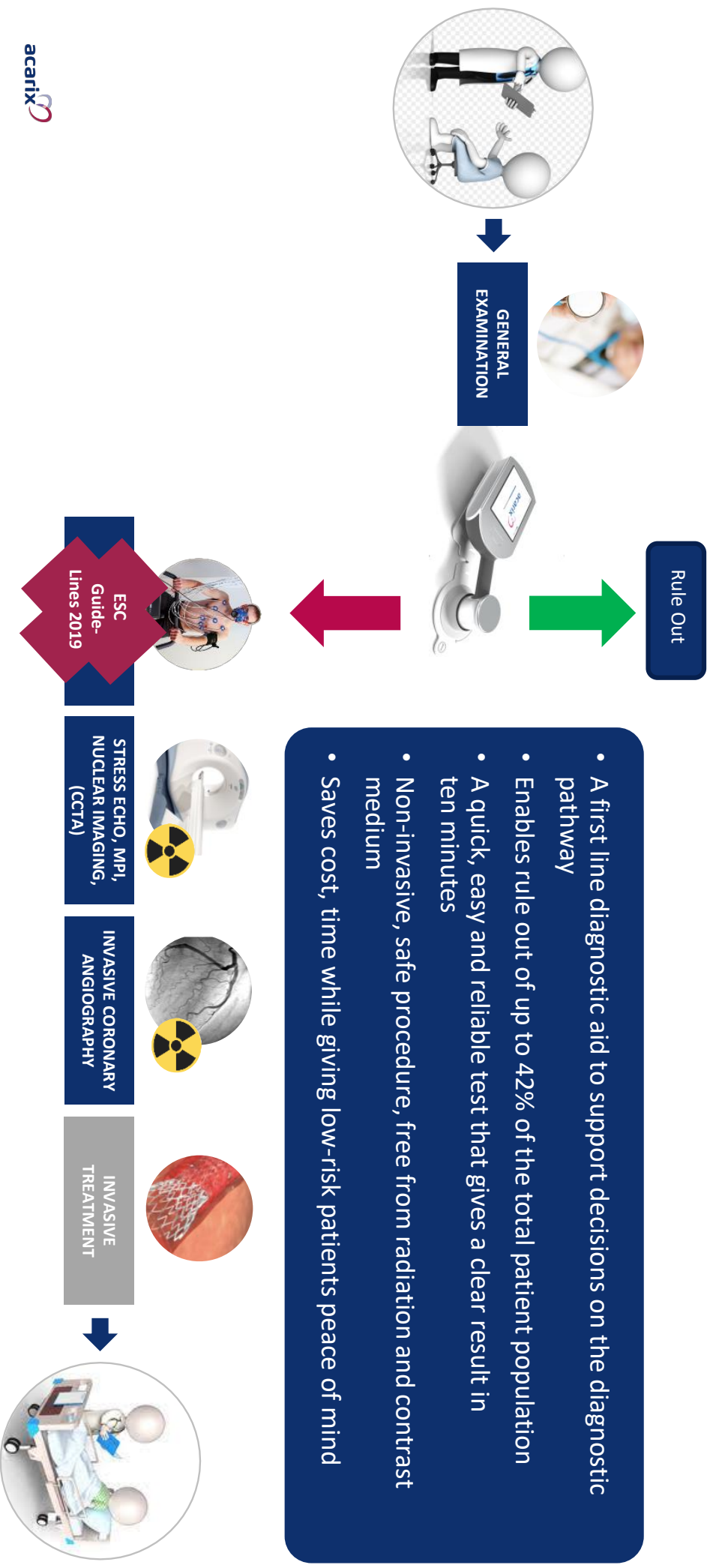
However, approx. 90% of all incoming patients
with stable chest pain do not suffer from

Coronary Artery Disease

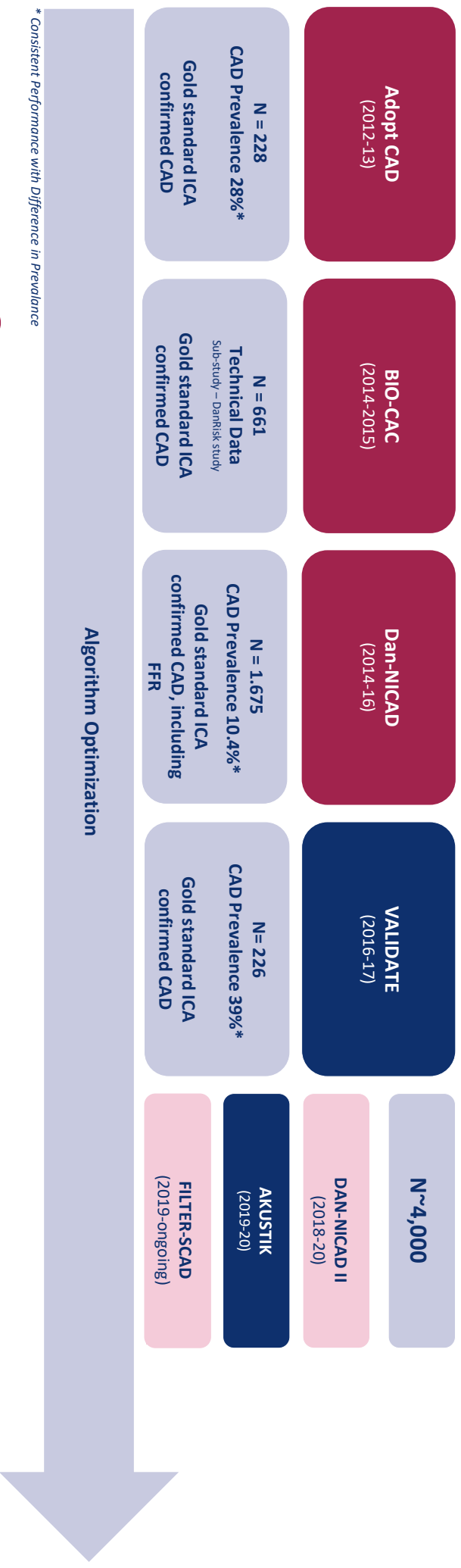
CADScor[®]System

Early Rule Out optimise Patient Pathway

CADSCOR® – IMPROVES PATIENT PATHWAYS & SUPPORT BETTER USE OF RESOURCES



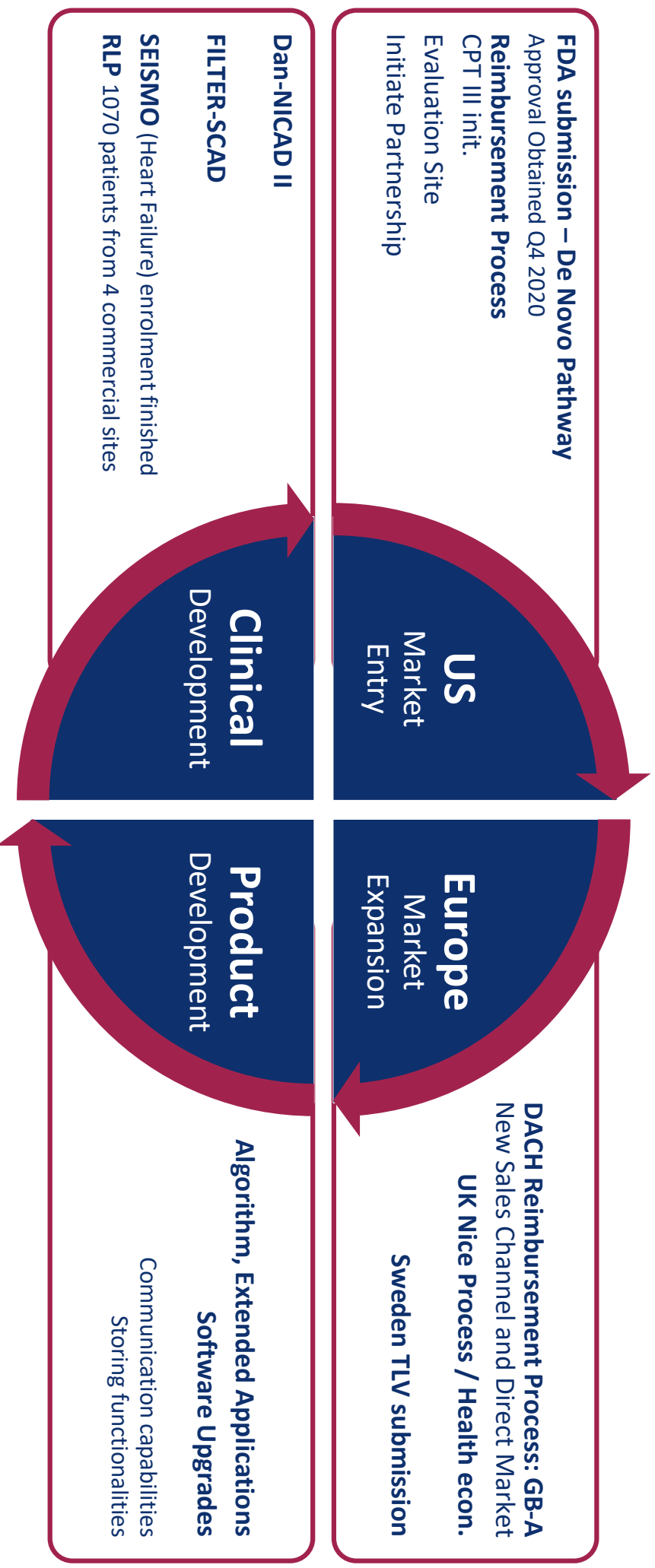
OVER 3K PATIENTS STUDIED AND ANOTHER 4K IN ONGOING STUDIES TO CONTINUALLY OPTIMIZE ALGORITHM



- Included in the FDA Submission
- Key Studies: Ongoing/Reporting Phase



ACARIX 2021 – PRIORITIES AND FOCUS



US STRATEGIC FOCUS AREAS

FDA Approval

Obtained November 2020

Reimbursement Strategy

CPT Code application >> CPT III (Step I) ACC Hearing March 30th- Stated Endorsement
Local Product evaluation US Site selection-

Product & Supply

Required SW updates, IFU, messaging

Distribution, Sales, Service and Logistics

Distribution, Warehouse & Service, Warranty, Price and Payment Structure

Awareness, Pinoneers, Health Management Systems & Local Evaluations

Implement aligned marketing and communication plan and utilise learnings from initiated local cooperation to build awareness and initiated local evaluations

To make the CADScor® to the natural choice of diagnostic aid in the early assessment of cardiac and vascular diseases and to become a recognized technology in acoustic diagnosis of the vascular system

REIMBURSEMENT PROCESS GERMANY

KBV Submission 2018

Changes in regulatory pathway early 2019 towards G-BA

G-BA Submission

Updated dossier submitted March 2019 for consultancy by G-BA
Hearing with focus group July 2019

Next Step: Status as Potential (Q2 2020)

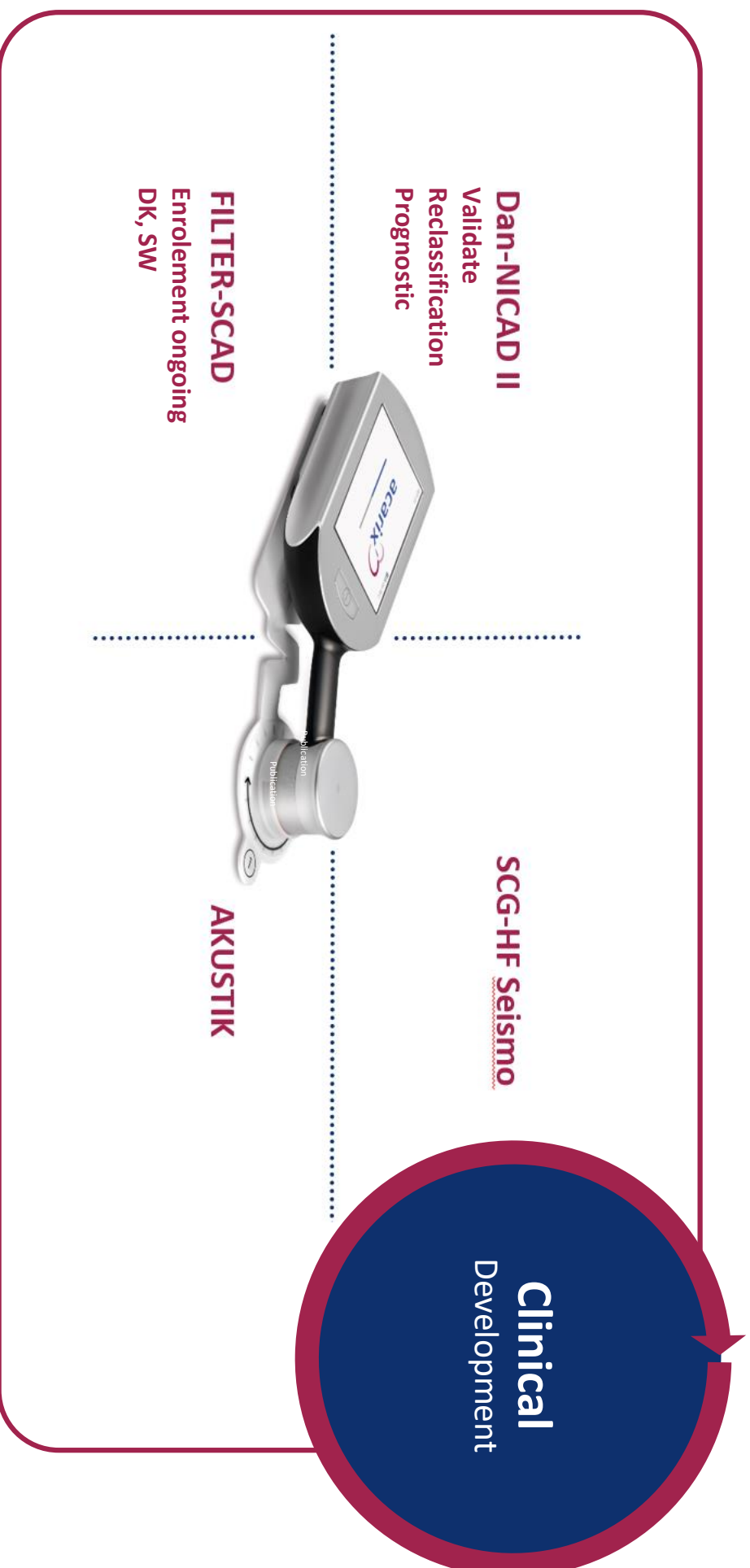
Public announcement from G-BA: recognizing Acoustic technology: Invite for study proposal in Q3 2020
Acarix proposal October 2020

G-BA Hearing (March 30th)

Hearing with invited participants from German expert groups
Key topic to identify comparative testing strategy (study) proving the potential of Acoustic Technologies
Main direction to perform a study in Germany potentially an extension of already ongoing studies.
Timing, terms and conditions

To make the CADScor® to the natural choice of diagnostic aid in the early assessment of cardiac and vascular diseases and to become a recognized technology in acoustic diagnosis of the vascular system

ACARIX 2021 – CLINICAL PRIORITIES AND FOCUS



ACARIX- 2021

US Entry

Reimbursement: CPT III

Commercial Progress; Partner Selection, Evaluation

Germany

Reimbursement/Study

Continued Commercial Development

Clinical Program

Seismo (HF*)

Dan-NICAD II Publication

Filter SCAD

Health Economic Publication (UK)

New Markets- WW interest

THE END

Q&A