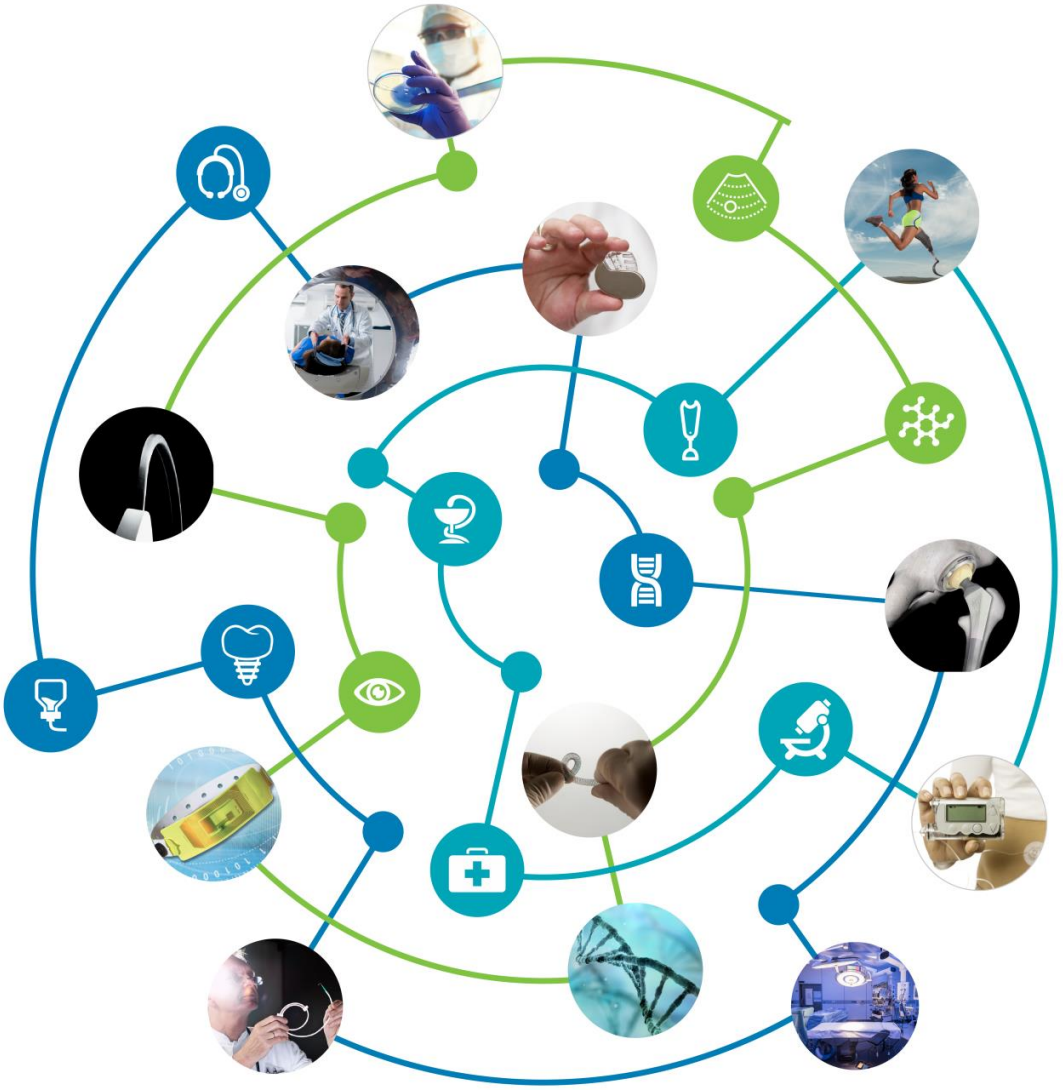
AdvaMed Medtech Value Assessment Framework *in Practice*



Application of the Medtech Value Assessment Framework to Siemens Coronary Computed Tomography Angiography (CCTA)

SIEMENS

AdvaMed
Advanced Medical Technology Association

Value Framework Overview

In response to the growing need to demonstrate how medical technologies fit into the emerging value-based paradigm for providers, payers, and patients, AdvaMed launched a Strategic Value Initiative to develop an approach to value assessment for medical technologies that can be used by Medical technology companies as well as by health systems, payers, and other stakeholders.[1]

AdvaMed's Value Assessment approach goes beyond traditional Health Economic Outcomes Research (HEOR) and clinical efficacy metrics to assess the value that medical technologies may contribute to improving patient care and experience, economic outcomes, and the overall health of populations. This approach uses four broad categories, or "value drivers," to describe the value of medical technologies: clinical impact, non-clinical patient impact, care delivery revenue and cost impact, and
public/population impact relevant to an array of stakeholders who may evaluate and measure value differently.

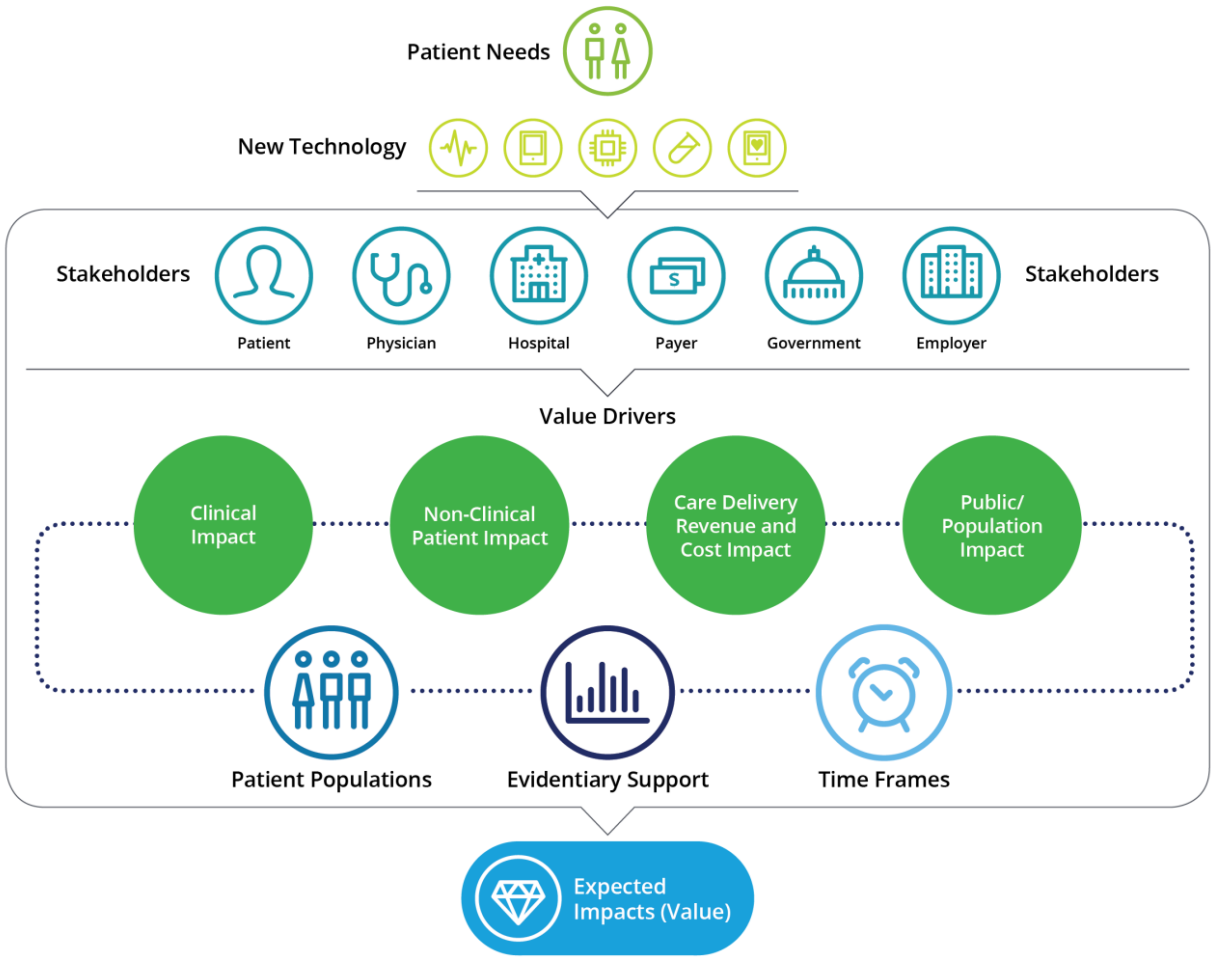
The AdvaMed Value Assessment approach can be used to guide the development of a value proposition that successfully communicates the full breadth of expected impacts offered by medical technologies while taking into account the demands of the changing health care ecosystem. The collection of information associated with the value drivers reflects quantitative and qualitative metrics of value, gives appropriate weight to patient experience and societal impacts, and also accounts for the consideration of evidence collected through a variety of methods. An illustration highlighting the value drivers and components of AdvaMed's approach is on the following page.

In order to demonstrate the application of this framework across different types of technologies, AdvaMed has partnered with member companies to develop use cases. These use cases address the clinical need for the technology, alternative and existing technologies on the market, the expected impacts of the technology, and the evidence to support such a value assessment. The use cases have been developed as a way to directly demonstrate the application of the AdvaMed Value Framework to the featured technology and should not be construed as an endorsement or promotion thereof.

Siemens

This use case demonstrates the value of the Siemens Coronary Computed Tomography Angiography (CCTA) across all of the identified value drivers and for a range of stakeholders.

Illustration of AdvaMed's Value Assessment Approach



Source: "A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem", co-developed with Deloitte Consulting LLP

Siemens CCTA

Medtech companies with a new product concept in development should start early, not only to address the FDA requirements, but also the value proposition that the technology conveys to patients, providers, and the health care system.

The use of CCTA in the emergency department (ED) demonstrates value across all of the drivers and serves as an example of the appropriate application of the AdvaMed value assessment approach in establishing value for a range of stakeholders.

> CCTA is a heart imaging test that detects plaque buildup in patients' arteries. This innovation in imaging offers a wide-range of benefits across all value drivers.

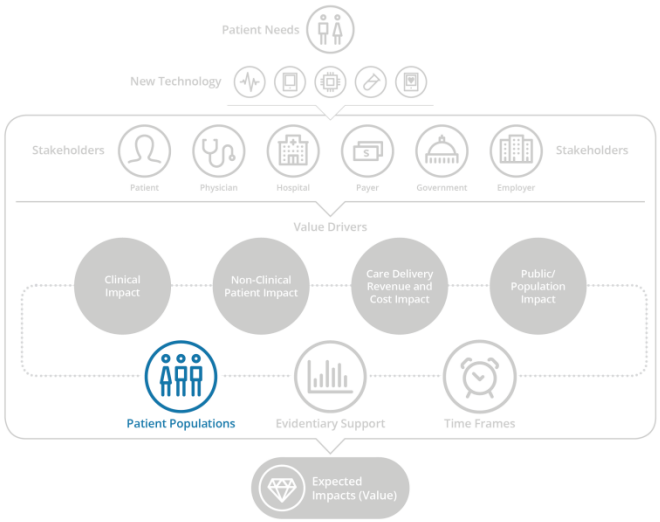
Clinically, CCTA delivers quicker, more efficient diagnoses to patients and ED physicians. This results in improved patient outcomes. CCTA also produces non-clinical impacts. The patient experience is improved since they get diagnosed quicker and more accurately. Patient economics are also improved because CCTA can reduce costly, non-essential follow up tests and observation. This leads to a more efficient use of hospital resources and time. Finally, CCTA adds societal benefits as well. The efficient use of resources can reduce overall health care costs for the population, and more accurate diagnoses lead to less time off work.

Unmet Need

AdvaMed's assessment process begins with understanding and addressing the unmet need and value imparted through the new technology.

Unmet patient need can be framed in terms of clinical efficacy, safety, patient preferences, costs, quality of care, ease of use, etc.

Coronary artery disease (CAD) is the leading cause of death in the United States, and nearly 8 million patients per year in the United States go to emergency departments (EDs) with acute chest pain. Identifying patients with a sufficiently low risk of acute coronary syndrome (ACS) – and thus, a low risk of heart attack or other serious health event – is challenging because 85-95% of these patients are ultimately diagnosed with something other than ACS. As many as 60% of these patients will have unnecessary hospital admissions and tests to exclude ACS. Emergency testing for ACS comes at a high cost to society at approximately $10 billion per year.[2] A misdiagnosis, however, is just as costly because those patients are sent home with worsening ACS syndromes and can even experience a more severe cardiac episode that results in death. In the US, the rate of misdiagnosis can be as high as 5%.



Patient Populations

Assessments should consider the extent to which a technology may be more or less effective for various patient populations and align with the population focus of the stakeholder evaluating the technology.

This section demonstrates the value of the technology to patients by addressing the need for the technology in the context of the affected patient sub-population and the available alternatives to treat their condition.

Current triage strategies are not always effective in correctly identifying patients suffering from ACS, and the diagnostic workup of patients presenting with acute chest pain continues to represent a major challenge for ED personnel. By incorporating Coronary Computed Tomography Angiography (CCTA) into a triage strategy, hospitals can improve the diagnostic accuracy of patients with chest pain and reduce the risk of a serious cardiac event. The appropriate use of cardiac CT imaging in the ED can therefore allow for more efficient use of hospital resources and for improved outcomes.

Time Frames

The assessment should identify time frames that are important in understanding the value of the technology.

When considering the value of CCTA and its associated time frames, there are three relevant patient populations: patients with ACS, patients with non-ACS, and patients with non-ACS but low-to-moderate cardiac issues. Use of CCTA allows ACS patients to get proper care almost immediately. It also allows patients without ACS to get out of the ED as soon as possible. Finally, it helps patients without ACS, but with low-to-moderate cardiac issues, get discharged from the ED quickly and receive necessary follow up cardiac care.

Value can also be defined in terms of length of treatment. Care can be administered in the ED for treatment lasting less than 1 day. Patients diagnosed and admitted for treatment of ACS may require follow-up care. Treatment for these patients can last 1-3 days and may require additional follow-up care in the months following discharge.

Stakeholders

The intended audience for a value assessment affects the framing of the assessment and the drivers and metrics that could be highlighted.

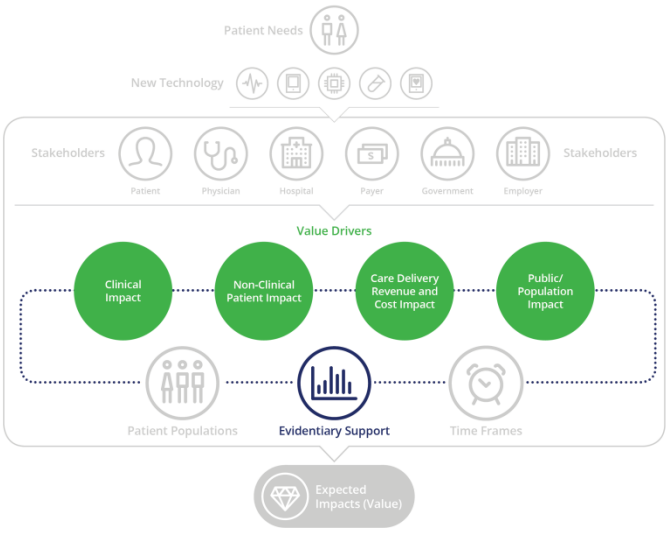
Both the intended audience/stakeholders and the purpose of the assessment should dictate which types of value are considered and emphasized via the assessment process, as well as the types and quality of evidence needed to support evidence development needs and appropriate strategies for collecting annual performance information.

It is important for stakeholders to consider the full range of value drivers and impacts.

The following chart highlights potential value for various stakeholders based on use of the CCTA technology in the ED setting.

Siemens CCTA Value Drivers Impact by Stakeholder

	Clinical Impact	Non-Clinical Impact	Care Delivery Revenue and Cost Impact	Public/Population Impact
Patient	• Faster and more accurate diagnosis • Shorter ED length of stay (LOS) after CCTA – 5.8 hours vs. 12.2 hours • Shorter total hospital LOS – 5.9 hours vs. 25 hours	• Improved patient treatment experience • Lower out of pocket costs • Fewer follow-up appointments • Reduced LOS	• Reduces co-pay and out-of-pocket costs	• Less missed work due to unnecessary hospital admission
Physician	• Faster and more accurate diagnosis • Ease of administration		• Reduces costly, non-essential follow up tests and observation • Reduction in misdiagnoses • Decreased malpractice risk for practitioners	• Lowers overall ACS treatment costs • Increases overall survival rates
Hospital	• Faster and more accurate diagnosis		• Reduces costly, non-essential follow up tests and observation • Reduction in misdiagnoses • Decreased malpractice risk for ED practitioners • Reduced readmissions for heart pain • Reduction in unnecessary admissions • More efficient resource/staff time use • Reduced LOS	• Lowers overall ACS treatment costs • Increases overall survival rates
Insurer	• Faster and more accurate diagnosis		• Reduces costly, non-essential follow up tests and observation • Reduced re-admissions for chest pain • Reduction in unnecessary admissions	• Lowers overall ACS treatment costs • Increases overall survival rates



Evidence Across the Value Drivers

Medical Technology innovators must determine the best way to show value with evidence.

It is critical to identify and evaluate the quantity and quality of available types of evidence for the technology early in product development and on an ongoing basis to determine how each can be used across the relevant drivers to offer robust evidentiary support.

Many studies have been published to support the effectiveness of CCTA and to demonstrate the value that it brings to the health care system. Economic studies, for example, have shown the cost-savings potential of using CCTA across many different patient populations, from low-to-high risk, with acute chest pain. Other studies have looked at the effect of CCTA on the incidence of recurring chest pain.

The chart on the following page shows evidence applicable to TKA, OA, and ACL patient populations:

Siemens CCTA Value Drivers by Evidence Source

Evidence	Type of Evidence	Clinical Impact	Non-Clinical Patient Impact	Care Delivery Revenue and Cost Impact	Public/Population Impact
7-year CCTA results at a high-volume, single-center, tertiary referral hospital (Published)[3]	Retrospective Study	• Significant reduction in the incidence of repeat CCTA testing when patient was found to have no coronary artery disease (CAD) or non-obstructive CAD vs. obstructive CAD		• Lower per-patient costs in the no CAD and non-obstructive CAD groups	
1,518 patients evaluated in ED, inpatient, or outpatient settings (Published)[4]	Retrospective Study	• Major adverse cardiovascular events (MACE) rates were higher with obstructive CAD compared to non-obstructive CAD and no CAD • More frequent repeat CCTA testing in patients with CAD			
12-month CCTA results at a single-center, tertiary referral hospital (Published)[5]	Prospective Study	• Shorter follow-up period for MACE after CCTA – 9 months vs. 11.1 months • Shorter ED length of stay (LOS) after CCTA – 5.8 hours vs. 12.2 hours • Shorter total hospital LOS 5.9 hours vs. 25 hours		• Significant reduction in total payer costs when using CCTA	
Health Economics Analysis of ROMICAT study (Published)[6]	Health Economics Outcomes/ Analysis			• CCTA-guided triage could reduce CAD patient hospital costs by up to 23%	
SCOT-HEART Study with 4,146 patients[7]	Prospective Study	• More appropriate use of invasive coronary angiography (ICA) • Fewer downstream preventive therapies prescribed • Fewer coronary revascularization procedures			
CONSERVE Study with 1,500 patients[8]	RCT	• 78% reduction of ICA • 41% reduction of coronary revascularization		• 50% reduction in cardiovascular costs	
PROMISE Study[9]	Prospective Economic Study			• CCTA and functional diagnostic testing strategies had similar costs through 3 years of follow-up - $2,494 vs. $2,240	

Expected Impacts (Value)

The value assessment should clearly demonstrate the impact of the technology across select value drivers including clinical impact, non-clinical patient impact, care delivery revenue and cost impact, and societal impact.

These impacts would be offset by the cost of acquiring the technology to derive the total expected value impacts.

Clinical Impact Value – CCTA delivers significant clinical impact to patients by improving diagnoses in a quicker, more efficient manner. CCTA is an effective way to evaluate and appropriately triage patients with possible ACS. This leads to greater and more efficient utilization of ED services. The absence of obstructive disease on CCTA is also associated with fewer follow-up evaluations for chest pain, resulting in fewer repeat tests. Unnecessary catheterizations and coronary stent procedures, which are both expensive and complicated, are also avoided – the CONSERVE study found a 78% reduction in invasive coronary angiography (ICA) procedures and a 41% reduction in coronary revascularization when using CCTA. Finally, CCTA is associated with a shorter ED length of stay – 5.8 hours vs. 12.2 hours – and a shorter hospital length of stay – 5.9 hours vs. 25.0 hours.

Non-Clinical Impact Value – CCTA produces beneficial non-clinical impacts for patients as well. The patient experience is improved through faster and more accurate diagnosis. This also reduces the number of follow-up visits and creates a more streamlined administrative scheduling process. Additionally, the use of CCTA can reduce costly, non-essential follow-up tests for many patients, reducing out of pocket costs.

Care Delivery Revenue and Cost Impact Value – CCTA delivers economic impacts as well. When there is an absence of coronary artery disease (CAD) upon receiving initial CCTA, there is decreased downstream utilization of services for that patient population. This leads to lower costs and may lead to a potential savings of over 20%.[10]

Public/Population Impact Value – The use of CCTA can produce societal benefits as well. By being diagnosed properly, patients will miss less work due to unnecessary hospital admissions or immediately get the care that they need— resulting in lower overall healthcare costs. More accurate diagnosis can also impact overall survival rates.

[1] "A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem", available at www.advamed.org and co-developed with Deloitte Consulting LLP

[2] ROMICAT Study.

[3] Thomas et al. "The lack of obstructive coronary artery disease on coronary CT angiography safely reduces downstream cost and resource utilization during subsequent chest pain presentations." *Journal of Cardiovascular Computed Tomography* 9.4 (2015): 329 –336.

[4] Ahmadian et al. "Effect of Coronary Computed Tomography Angiography Disease Burden on the Incidence of Recurrent Chest Pain." *International Scholarly Research Notices* (2014).

[5] Jones et al. "Safe and rapid disposition of low-to-intermediate risk patients presenting to the emergency department with chest pain: A 1-year high-volume single-center experience." *Journal of Cardiovascular Computed Tomography* 8.5 (2015): 375 –383.

[6] Hulten et al. "Cost and Resource Utilization Associated with Use of Computed Tomography to Evaluate Chest Pain in the Emergency Department: The ROMICAT Study." *Circulation: Cardiovascular Quality and Outcomes* 6.5 (2013): 514–524.

[7] Williams et al. "Use of Coronary Computed Tomographic Angiography to Guide Management of Patients With Coronary Disease." *Journal of the American College of Cardiology* 67.15 (2016): 1759–1768.

[8] Chang et al."The CONSERVE Trial." Severance Cardiovascular Hospital, Yonsei University Health System, Seoul, South Korea.

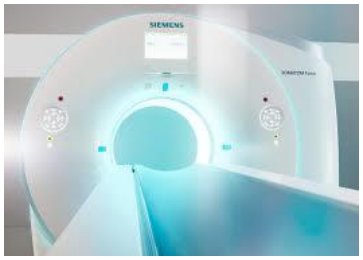
[9] Van der Wall. "The PROMISE Study: A Clear Promise for Functional Stress Testing in Patients with Suspected Coronary Artery Disease." Netherlands Heart Journal 23.6 (2015): 297–298.

[10] ROMICAT Study. Researchers determined that in comparison with usual care (UC), CCTA-guided triage, whereby patients with no CAD are discharges, could reduce total hospital costs by 23% ($p<0.001$).

Medtech Value Assessment Framework *in Practice*

Siemens: Coronary Computed Tomography Angiography (CCTA)

Coronary artery disease is the leading cause of death in the United States. Nearly 8 million patients per year in the United States go to emergency departments (EDs) with acute chest pain (ACS). As many as 60% of these patients will have unnecessary hospital admissions and tests, which account for over $10 billion in costs per year.



Patient Needs

New Technology

Stakeholders

Patient | Physician | Hospital | Payer | Government | Employer

Stakeholders

Value Drivers

Clinical Impact

- Faster and more accurate diagnosis
- Reduced ED and hospital length of stay (LOS)

Non-Clinical Patient Impact

- Improved patient treatment experience
- Fewer follow-up appointments

Care Delivery Revenue and Cost Impact

- Reduced cost of care
- Reduction in misdiagnosis
- Reduction in non-essential follow-up visits

Public/ Population Impact

- Reduction in unnecessary admissions
- Increased overall survival rates

Patient Populations

- ED patients presenting with:
  - Acute Coronary Syndrome (ACS)
  - Non-ACS
  - Non-ACS with low to moderate cardiac issues

Evidentiary Support

- 7-year retrospective study
- 1,518 patient retrospective study
- 12-month prospective study
- Health Economics Analysis of ROMICAT study
- SCOT-HEART study
- CONSERVE study
- PROMISE study

Time Frames

- ED care
- Hospital care
- Long-term follow-up care

Expected Impacts (Value)

- Improved diagnosis–quicker and more accurate
- Reduced ED LOS–5.8 hours v. 12.2 hours; and hospital LOS 5.9 hours v. 25 hours
- Improved patient experience
- Fewer follow-up visits and streamlined scheduling process
- Decreased downstream utilization of healthcare services
- Potential savings of over 20% per episode
- Faster return to work and productivity
- Greater overall survival rates

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