

# **Fully Connected Digital Ecosystems within Hospitals – AI/ML Solutions for Improved Patient Care**

By

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and

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## ABSTRACT

Cardiogenic shock (CS) in the context of acute myocardial infarction (AMI) remains a significant challenge in critical care, with high mortality rates despite the availability of advanced mechanical circulatory support (MCS) devices like the Impella pump. However, adoption of these devices in clinical practice remains limited. This thesis explores two complementary strategies to address these challenges: developing machine learning (ML) models to predict shock severity and assessing the feasibility of integrating hospital Electronic Medical Record (EMR) data into Abiomed’s digital ecosystem to support standardized shock care.

In the first phase, ML models were trained on multiple clinical datasets to predict Society for Cardiovascular Angiography and Interventions (SCAI) shock stages based on patient data. While these models demonstrated strong predictive performance, feature analysis revealed that SCAI stages often reflect physician treatment decisions rather than purely patient physiology. This raises concerns about their utility as real-time clinical decision tools and suggests that ML applications may be better suited to prompting early data collection and intervention before severe shock develops.

The second phase evaluated the feasibility of EMR integration to support the broader adoption of standardized shock protocols. After considering regulatory, operational, and technical factors, third-party data aggregation emerged as the most practical path forward. Integrating EMR data could improve outcome tracking, support protocol adoption, and strengthen partnerships between Abiomed and hospitals, creating a foundation for more consistent and proactive shock management.

Together, these findings highlight the need for predictive tools that guide early clinical action and infrastructure that supports seamless data integration. By advancing both, Abiomed can expand its role in cardiogenic shock care, improve patient outcomes, and lead the evolution of data-driven, standardized treatment strategies.

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# Chapter 1: Introduction and Background

## 1.1 Executive Summary

Cardiogenic shock (CS) remains one of the most critical conditions in acute myocardial infarction (AMI) management, with high mortality rates despite advances in mechanical circulatory support (MCS) technologies like Abiomed's Impella pump. However, despite its clinical value, Abiomed faces two persistent challenges: the identification and escalation of appropriate patients remain limited, with only approximately 5% of eligible patients receiving Impella support and just 3% experiencing escalation to advanced therapy. This thesis addresses these challenges through two parallel efforts: the development of machine learning (ML) models to predict shock severity using the Society for Cardiovascular Angiography and Interventions (SCAI) shock stages and an assessment of the feasibility of integrating Electronic Medical Record (EMR) data into Abiomed's ecosystem to drive clinical and strategic growth.

The first phase of this work focused on developing and evaluating ML models to predict SCAI shock stages across three major datasets: RECOVER III, Impella Quality (IQ), and the National Cardiogenic Shock Initiative (NCSI). A stacked ensemble model, leveraging Random Forest, XGBoost, and CatBoost algorithms, demonstrated strong predictive accuracy, particularly within the diverse IQ dataset, achieving a 94% overall accuracy. Feature importance analyses consistently identified the number of inotropes and vasopressors administered, along with lactate levels, as the most critical predictors of shock severity. However, this finding revealed a fundamental limitation: SCAI shock stage predictions are heavily driven by the care decisions already made by physicians, rather than the underlying patient physiology alone. This suggests that while SCAI staging provides a valuable academic framework, it may be less

effective as a real-time clinical tool to drive early intervention. Instead, ML tools should focus on prompting clinicians to collect and monitor key physiological markers—such as lactate trends—earlier in the care process, supporting timelier escalation to Impella support and improving patient outcomes.

The second phase of the thesis explored the feasibility of integrating hospital EMR data into Abiomed’s systems, identifying three potential methods: direct hospital integration, partnerships with device vendors, and outsourcing to third-party data aggregators. After assessing technical, regulatory, and operational considerations, third-party integration emerged as the most practical and scalable solution. This strategy minimizes regulatory burdens, accelerates deployment timelines, and leverages existing Johnson & Johnson resources following Abiomed’s acquisition. More importantly, EMR integration offers the opportunity to enhance outcome reviews with hospitals, support standardized care protocols, and ultimately promote the broader adoption of the NCSI shock protocol—a proven framework associated with improved survival rates and early Impella use. By facilitating real-time data exchange and promoting evidence-based protocols, Abiomed can strengthen hospital partnerships and drive higher utilization of its devices across the industry.

In summary, this thesis recommends a dual strategy: refining ML models to support earlier clinical decision-making through physiological monitoring and pursuing third-party EMR integration to advance standardized shock care and scale Abiomed's market presence. Together, these initiatives position Abiomed to transform cardiogenic shock management

through proactive intervention, improved patient outcomes, and expanded adoption of Impella technology.

## **1.2 Background**

### **1.2.1 Abiomed Company Overview**

Abiomed specializes in developing, manufacturing, and commercializing circulatory support and oxygenation technologies, focusing strategically on heart recovery rather than permanent replacement [1]. Founded in 1981, Abiomed has evolved its mission to prioritize technologies such as the Impella family of heart pumps, which provide temporary hemodynamic support for patients experiencing acute heart failure, cardiogenic shock, or undergoing high-risk percutaneous coronary interventions (PCI) [2].

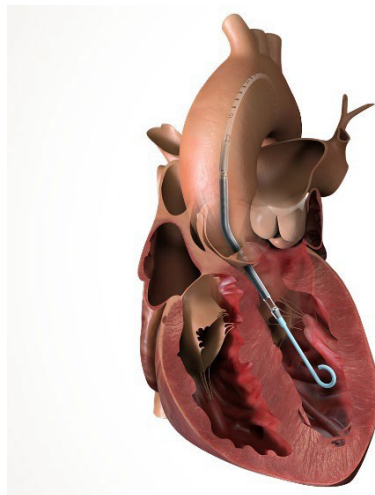


Figure 1.1: Impella Pump [1]

In December 2022, Johnson & Johnson's MedTech segment acquired Abiomed for approximately \$16 billion—the largest medtech acquisition in history. Abiomed now

operates as a standalone entity within Johnson & Johnson's MedTech Segment, leveraging its resources to expand its global market presence.

The Impella platform, Abiomed's flagship product, has driven significant growth, securing five FDA approvals and accumulating over 1,400 patents by 2022, reflecting a robust intellectual property portfolio [3]. Abiomed's unique position stems from its capability to collect real-time patient data through Impella devices deployed in critical care settings worldwide. This data, combined with clinical registries, provides a foundation for predicting Society for Cardiovascular Angiography and Interventions (SCAI) shock stages to identify and escalate more patients effectively. Furthermore, Abiomed aims to integrate electronic medical records (EMRs) into its data strategy to advance AI-powered diagnostics and clinical decision support, ultimately improving patient outcomes while promoting operational and financial growth in cardiovascular care.

### **1.2.2 Abiomed Role in Cardiac Care and Data Collection**

Abiomed has transformed the management of cardiogenic shock and high-risk percutaneous coronary interventions (PCI) with its Impella platform. The Impella devices, among the smallest percutaneous ventricular assist devices (pVAD) available, help the heart during severe failure by taking over some of its work [4]. In simple terms, the Impella pump is a tiny device inserted through a small tube into the heart, where it pulls blood from the left ventricle (the heart's main pumping chamber) and pushes it into the aorta, the body's largest artery. This helps get more blood flowing to the body while giving the heart a chance to rest and heal, especially when it's too weak to pump enough on its own during a crisis like cardiogenic shock. The device also uses built-in sensors to measure things like heart pressure and output, giving doctors real-

time information to make better decisions during procedures and improve patient outcomes. Studies show that using Impella in cardiogenic shock patients leads to better survival rates, emphasizing the need for careful patient selection and management [5]. If a patient is missed, it is often due to the lack of standardization and use of Impella pumps across the medical field.

The Impella Connect platform streams data from these devices to a HIPAA- compliant cloud, allowing healthcare teams to monitor patients remotely 24/7 [6]. This data- driven capability positions Abiomed to address strategic challenges, offering a foundation for predictive modeling to increase market penetration and improve care delivery.

However, this robust data collection is currently siloed, limiting its integration with broader clinical systems like electronic medical records (EMRs). Integrating this data could enhance real-time decision-making for Society for Cardiovascular Angiography and Interventions (SCAI) shock staging and patient escalation. This gap sets the stage for exploring EMR integration to unlock comprehensive data access and drive Abiomed’s strategic growth in cardiovascular medicine.

### **1.2.3 Overview of Electronic Medical Record (EMR) Integration in Healthcare**

Healthcare data integration involves aggregating and harmonizing diverse data sources—such as electronic medical records (EMRs), medical imaging, wearable device outputs, and procedural registries—into a unified, accessible framework to support clinical decision-making,

operational efficiency, and improved patient outcomes [7]. The proliferation of digital technologies in modern healthcare systems has generated an exponential increase in data volume and complexity, yet this wealth of information remains underutilized due to persistent integration challenges [8].

Within hospitals, patient data is often siloed across disparate systems, fragmented by proprietary formats, inconsistent standards, and limited interoperability, creating significant barriers for clinicians seeking comprehensive, real-time insights, particularly in time-sensitive scenarios like cardiogenic shock management [9]. Such delays in accessing holistic patient information can compromise care, limiting the ability to identify and escalate patients effectively.

For medical device companies like Abiomed, the need for seamless data integration is particularly acute, as its Impella heart pumps generate valuable hemodynamic data that could enhance patient care if fully integrated with EMRs and other clinical datasets. Studies have identified key obstacles to this integration, including data inconsistency, where variations in terminology, units, or timestamps across systems hinder aggregation, as well as the lack of standardized protocols[8]. Interoperability issues further complicate the landscape, as legacy hospital systems often fail to communicate effectively with newer technologies, a challenge exacerbated by the heterogeneity of device-generated data. Additionally, data privacy concerns, governed by regulations such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States, impose stringent

requirements on how patient information is shared and stored, necessitating robust security measures that can slow integration efforts [10].

Despite these challenges, the potential benefits of healthcare data integration are substantial. Integrated systems enable a longitudinal view of patient health, combining historical EMR data with real-time device metrics to inform personalized treatment strategies [8]. For instance, integrating Impella-derived metrics with EMR data, such as lab results and medication histories, could provide clinicians with a more complete picture of a patient's condition, facilitating timely interventions to capture more patients and escalate care, addressing Abiomed's desire to serve more patients. Research demonstrates that organizations adopting integrated data ecosystems report improved clinical outcomes, such as reduced mortality rates in critical care settings, alongside operational gains like shorter hospital stays and lower costs [8]. A systematic review of healthcare interoperability efforts has shown that successful integration projects often rely on middleware solutions or cloud-based platforms to reconcile disparate data sources, though scalability remains a challenge in resource-constrained environments [8].

In the broader healthcare landscape, data integration underpins emerging paradigms like precision medicine, where aggregated datasets fuel predictive analytics and population health management. For Abiomed, the integration of its device data with hospital EMRs could unlock similar opportunities, enhancing the ability to predict and manage cardiogenic shock stages as outlined by the Society for Cardiovascular Angiography and Interventions (SCAI). However, achieving this vision requires overcoming technical barriers—such as developing

APIs (Application Programming Interfaces) tailored to Abiomed’s systems—and navigating regulatory landscapes to ensure compliance without stifling innovation.

#### **1.2.4 SCAI Shock Staging and Its Importance**

The Society for Cardiovascular Angiography and Interventions SCAI shock staging system, introduced in 2019, is a structured framework designed to classify the severity of cardiogenic shock (CS), a life-threatening condition marked by inadequate cardiac output, systemic hypoperfusion, and organ dysfunction [12]. Developed by a multidisciplinary expert panel, the SCAI classification delineates five stages—Stage A (at risk), Stage B (beginning shock), Stage C (classic shock), Stage D (deteriorating), and Stage E (extremis)—based on clinical, hemodynamic and biochemical markers, including blood pressure, lactate levels, and evidence of end-organ failure [13].

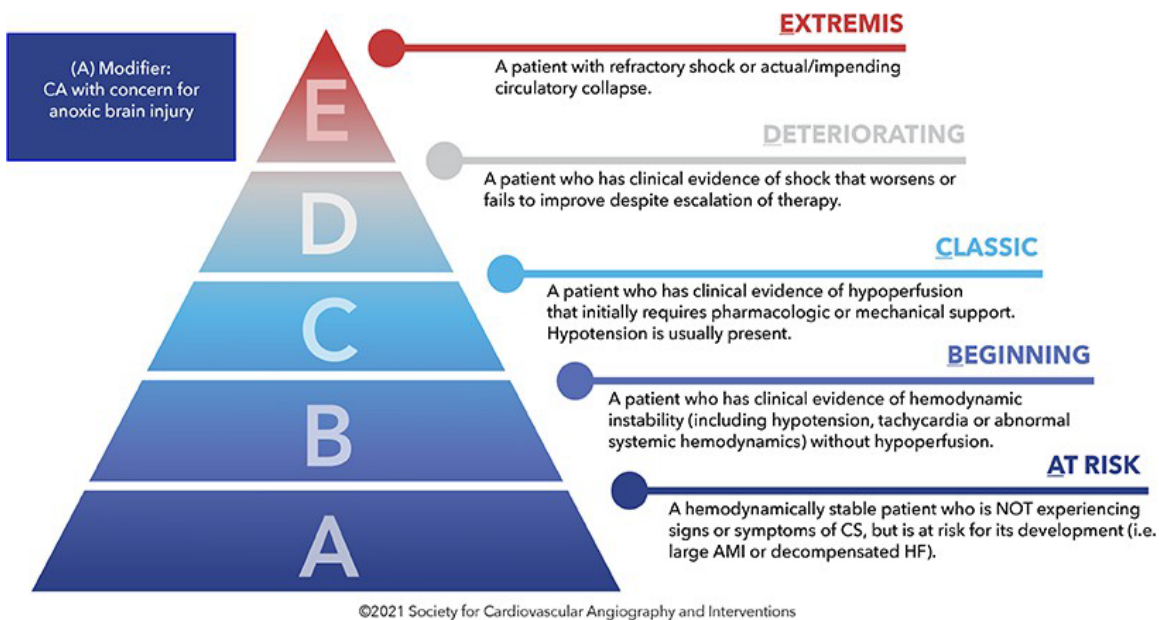


Figure 1.2: SCAI Shock Staging [13]

This system emerged as a response to the need for a standardized, practical tool to stratify cardiogenic shock patients, enabling clinicians to assess disease progression, guide therapeutic interventions, and predict outcomes consistently across diverse care settings [12]. The importance of SCAI shock staging lies in its ability to bridge clinical observation with actionable decision-making, particularly in critical care environments where rapid patient deterioration is common [13]. Unlike earlier approaches, which often relied on subjective assessments or single-parameter thresholds (e.g., systolic blood pressure <90 mmHg), the SCAI framework integrates multiple dimensions of patient status—such as physical exam findings, laboratory data, and hemodynamic parameters—offering a more nuanced and reproducible classification [13].

Studies have validated its prognostic value, with higher stages (e.g., D and E) strongly correlated with increased mortality rates, highlighting its utility in identifying patients requiring escalated interventions [13]. For Abiomed, this stratification is pivotal, as it identifies candidates for mechanical circulatory support (MCS) devices like the Impella pumps.

In cardiac care, SCAI staging has become a cornerstone for standardizing treatment protocols and advancing research into CS management. For example, the National Cardiogenic Shock Initiative (NCSI) utilizes this classification to optimize the timing of Impella deployment, demonstrating that early intervention in Stages B and C can improve survival compared to delayed support in later stages [14]. Similarly, studies like the DanGer Shock trial continue to build on SCAI staging's utility in identifying MCS candidates and reinforcing its role in evidence-based practice [15].

For this thesis, the SCAI shock staging system is central to the first component—developing an AI-driven predictive model to accurately identify CS stages using clinical data, as a case study to demonstrate its potential for capturing more patients and escalating care effectively. The importance of this approach lies in its potential to deliver real-time, actionable insights to clinicians, reducing diagnostic delays and tailoring interventions to individual patient trajectories, thereby addressing Abiomed's low penetration rates. By leveraging this framework, empowered by machine learning and data integration, this project aims to elevate the precision and timeliness of CS management at Abiomed-supported facilities, setting the stage for the subsequent exploration of electronic medical record (EMR) integration in Section 1.3 to access comprehensive data and drive strategic growth.

### **1.3 Problem Statement**

Patient data within hospitals is frequently siloed and fragmented, creating significant challenges for clinicians to access comprehensive and immediate patient information necessary for optimal clinical decisions, particularly in acute myocardial infarction cardiogenic shock (AMICS) management. Despite Abiomed's unique position in collecting real-time patient data through its Impella heart pumps, substantial limitations persist in fully integrating this data with patients' Electronic Medical Records and other device outputs. These limitations include data inconsistency, where variations in terminology, units, or formats across systems hinder aggregation; lack of standardization, complicating interoperability; interoperability issues between disparate hospital systems and device technologies; and potential data privacy concerns, governed by regulations such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States. Consequently, the inability to aggregate data seamlessly restricts the ability to provide holistic patient care and hinders clinical efficiency, limiting Abiomed's capacity to identify and escalate patients effectively.

To address these challenges, this thesis adopts a dual-component approach. First, it focuses on building a compelling case for EMR integration at Abiomed by conducting a technical feasibility assessment, evaluating regulatory considerations, and devising implementation strategies that demonstrate how such integration can enhance patient outcomes and ultimately increase revenue. By articulating strategic, operational, and financial rationale—such as reducing diagnostic delays and boosting market penetration from its current 5% for patient identification and 3% for escalation—this project aims to secure organizational buy-in and establish EMR integration as a viable, value-driven initiative. This strategic focus aligns with

company business goals, emphasizing Abiomed’s competitive advantage and financial growth in cardiovascular medicine. Most importantly however this project aims to increase the number of patients served, following the Abiomed ethos of “Patients First”.

Second, this project investigates the feasibility of accurately identifying the level of cardiogenic shock a patient is experiencing, using the Society for Cardiovascular Angiography and Interventions (SCAI) shock staging system as a structured criterion, serving as a case study to explore the potential of full EMR integration. By leveraging artificial intelligence (AI) and machine learning (ML) tools to predict SCAI shock stages—ranging from Stage A (at risk) to Stage E (extremis)—using comprehensive data from fully integrated EMRs, and integrating these insights into Abiomed’s display systems, clinicians can receive real-time insights to capture more eligible patients and escalate care effectively. This technical approach, grounded in the MS MechE perspective, aims to demonstrate the value of predictive modeling in improving patient care precision and timeliness, addressing Abiomed’s low penetration rates. Together, these components underscore the thesis goal of enhancing Abiomed’s ability to manage cardiogenic shock, setting the stage for the literature review in Chapter 2 to explore existing research on data integration and SCAI classification.

## Chapter 2: Literature Review

This chapter synthesizes existing research to provide a foundation for developing an artificial intelligence (AI) and machine learning (ML) model to predict Society for Cardiovascular Angiography and Interventions (SCAI) shock stages, addressing Abiomed's challenge of capturing more patients with cardiogenic shock and escalating care effectively, followed by evaluating electronic medical record (EMR) integration to access comprehensive data. By reviewing healthcare data integration, AI/ML applications in healthcare, SCAI shock classification, and key cardiogenic shock studies, this analysis supports the thesis's dual goals of technical innovation and strategic growth, focusing on improving patient outcomes and operational efficiency at Abiomed.

### **2.1 Healthcare Data Integration**

Healthcare data integration involves consolidating disparate data sources—such as electronic medical records (EMRs), imaging, laboratory results, and medical device outputs—into a unified, accessible system to enhance clinical decision-making, operational efficiency, and patient outcomes [16]. The digitization of healthcare has generated an unprecedented volume of data; however, its utility is often limited by fragmentation across siloed platforms, posing persistent challenges in modern medical systems [17].

Within hospitals, patient information is frequently scattered among incompatible systems, characterized by inconsistent formats, lack of standardization, and poor interoperability, which hinders clinicians' ability to access comprehensive patient profiles in real time—particularly critical in acute conditions like cardiogenic shock [17].

For medical device companies like Abiomed, whose Impella heart pumps generate real-time hemodynamic data (e.g., cardiac output, pressure gradients), integrating this information with EMRs offers a strategic opportunity to enhance care delivery. However, significant barriers persist, including data inconsistency arising from variations in terminology, units, or recording intervals, which complicate aggregation. The absence of universal standards like HL7 FHIR (Fast Healthcare Interoperability Resources) further impedes progress toward seamless data exchange [18].

Interoperability challenges are compounded by legacy hospital systems that struggle to interface with advanced device technologies, creating gaps in data flow. Additionally, privacy regulations, such as the Health Insurance Portability and Accountability Act (HIPAA), impose stringent safeguards on data sharing, requiring secure architectures that can delay implementation [19].

Despite these obstacles, the benefits of integrated healthcare data are well-documented. By merging device-generated metrics with EMRs, clinicians gain a longitudinal view of patient health, enabling timely, personalized interventions to manage cardiogenic shock progression effectively [20]. Research indicates that integrated systems can improve clinical outcomes in critical care settings, often through solutions that reconcile disparate data sources, aligning with Abiomed's goal of predicting SCAI shock stages to capture more patients and enhance outcomes [20].

For instance, combining Impella data with clinical records could provide a holistic snapshot of a patient's condition, supporting the objective of improving precision and efficiency in cardiogenic shock management. This positions data integration as a critical enabler for

Abiomed’s strategic objectives, linking to the subsequent exploration of AI/ML for SCAI prediction in Section 2.2.

In the context of this thesis, healthcare data integration is foundational to addressing Abiomed’s challenge of siloed patient data. By linking Impella outputs with hospital EMRs, the project aims to enable real-time SCAI shock stage prediction, enhancing clinical precision and efficiency. The literature underscores that overcoming technical and regulatory hurdles is essential to realizing this potential, positioning integration as a strategic priority for improving patient outcomes and operational value at Abiomed.

## **2.2 Artificial Intelligence and Machine Learning in Healthcare**

Artificial intelligence (AI) and machine learning (ML) have emerged as transformative tools in healthcare, leveraging computational capabilities to analyze complex, multidimensional data and enhance clinical practice [21]. AI encompasses systems that emulate human intelligence, while ML, a core subset, refers to algorithms that iteratively learn patterns from data without explicit programming, enabling predictive and diagnostic advancements [21]. In healthcare, these technologies excel at processing vast datasets—such as electronic medical records, imaging, genomic profiles, and real-time device outputs, including those from Abiomed’s Impella heart pumps—offering applications in diagnostics, treatment optimization, and predictive modeling [21]. The proliferation of digital health records and advanced monitoring devices has fueled the adoption of AI and ML, enabling clinicians to transition from traditional heuristics to data-driven decision-making, particularly in critical conditions like cardiogenic shock [22].

The potential of AI and ML in healthcare lies in their capacity to uncover actionable insights from heterogeneous data, improving accuracy, timeliness, and efficiency in clinical scenarios [21]. For instance, integrating Impella-derived hemodynamic metrics with EMR data could enable real-time prediction of cardiogenic shock (CS) severity, a central goal of this thesis.

However, challenges persist, including data quality issues such as missing or inconsistent inputs, the need for interpretable models to gain clinician trust, and regulatory complexities under frameworks like the U.S. Food and Drug Administration's (FDA) oversight of AI-enabled medical devices [23]. These hurdles underscore the importance of rigorous methodologies, particularly for applications like predicting Society for Cardiovascular Angiography and Interventions (SCAI) shock stages, where precision and speed are paramount [22].

The literature highlights AI and ML's transformative promise, positioning them as key enablers for this project's aim to enhance clinical outcomes through integrated, predictive systems at Abiomed, while also driving operational and financial growth.

### **2.2.1 Machine Learning Technology in Medical Diagnostics**

Machine learning (ML) has revolutionized medical diagnostics by identifying patterns within complex, multidimensional datasets that traditional methods often overlook, enabling precise classification of conditions and prediction of outcomes [24]. Algorithms such as logistic regression, support vector machines, and deep neural networks analyze diverse inputs—

including vital signs, laboratory results, imaging, and real-time device data—to achieve high diagnostic accuracy, frequently surpassing human performance in controlled studies [24].

In cardiology, ML applications have successfully detected arrhythmias from electrocardiograms (ECGs), predicted heart failure risk using echocardiograms, and stratified patient severity, demonstrating transformative potential for critical conditions like cardiogenic shock (CS) [25]. For instance, ML models leveraging hemodynamic variables, clinical markers, and device outputs—such as those from Abiomed’s Impella pumps—have shown promise in assessing CS severity, though many studies rely on static datasets rather than continuous, real-time inputs, limiting their applicability for real-time decision-making [25].

This thesis builds on these advances by targeting Society for Cardiovascular Angiography and Interventions (SCAI) shock stage prediction, utilizing data from registries such as the National Cardiogenic Shock Initiative (NCSI), Recover III (R3), and Impella Quality (IQ) datasets. Successful ML diagnostics require high-quality inputs, robust handling of missing or inconsistent data, and rigorous validation across diverse patient cohorts, all of which are critical for translating Impella’s real-time hemodynamic capabilities into actionable clinical insights.

The literature underscores ML’s diagnostic potential, particularly when paired with integrated data systems, to redefine CS management, aligning with this project’s focus on precision and timeliness. By enhancing predictive accuracy for SCAI stages, ML can support Abiomed’s strategic goal of increasing market penetration and improving patient outcomes, setting the stage for the

subsequent exploration of electronic medical record (EMR) integration in Section 3.2 to enable comprehensive data access.

### **2.2.2 Ensemble Methods and Meta Learners**

Ensemble methods and meta-learners are advanced machine learning (ML) techniques that enhance predictive performance by combining multiple models, offering robust solutions for complex datasets prevalent in healthcare [26]. Ensemble methods aggregate predictions from diverse algorithms—such as decision trees, logistic regression, or neural networks—to produce more accurate and stable outputs than individual models, effectively reducing variance, bias, or both through model diversity [26].

Random forests exemplify this approach by averaging predictions across numerous decision trees, each trained on random subsets of data and features, achieving high accuracy and resilience to overfitting in noisy or imbalanced datasets [27]. Similarly, gradient boosting methods, like XGBoost, iteratively refine predictions by emphasizing misclassified instances, demonstrating superior performance in structured data tasks, particularly in healthcare applications [27].

Recent advancements, such as CatBoost, further optimize these methods by natively handling categorical variables and improving computational efficiency, as evidenced by their dominance in publicly available data science benchmarks [27]. Studies have demonstrated that random forests excel in classification tasks with imbalanced classes—a common challenge in medical datasets, such as those predicting Society for Cardiovascular Angiography and Interventions (SCAI) shock stages, where severe stages (e.g., D, E) are less frequent but critical for Abiomed’s goal of capturing more patients [26].

Gradient boosting variants like XGBoost and CatBoost have proven robust in handling missing or noisy data, a frequent issue in healthcare where incomplete records (e.g., lactate or inotrope data) can skew single-model predictions, aligning with this thesis’s focus on cardiogenic shock management [27].

Meta-learners extend the ensemble paradigm by introducing a higher-level model that learns how to combine or weigh the outputs of base learners, often improving overall predictive performance [28]. Stacking is a prominent meta- learning technique wherein a secondary algorithm—such as linear regression or a neural network—trains on the predictions of initial models to optimize their integration, frequently outperforming simple averaging or voting methods [28].

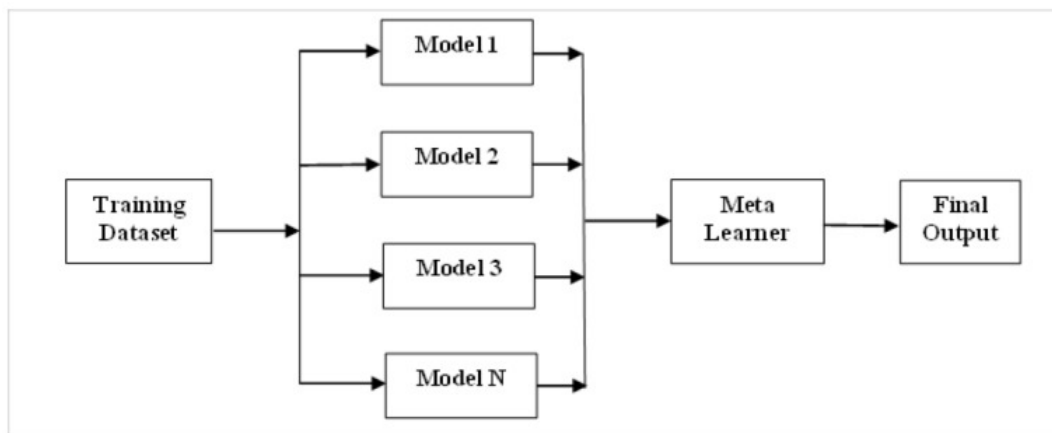


Figure 2.1: Meta Learner Framework [27]

Studies show that stacking thrives in scenarios with heterogeneous data, where individual models capture complementary aspects of underlying patterns, a finding supported by empirical comparisons across benchmark datasets [28]. In healthcare, meta-learners have demonstrated superior results in tasks like mortality prediction in intensive care units, refining ensemble outputs to achieve higher sensitivity and specificity, particularly in small-sample or noisy environments [29].

This approach is particularly relevant for this thesis, as stacking a logistic regression meta-learner with Random Forest, XGBoost, and CatBoost could enhance SCAI shock stage prediction.

### **2.3 SCAI Shock Classification**

The Society for Cardiovascular Angiography and Interventions (SCAI) shock classification system provides a structured approach to categorize the severity of cardiogenic shock (CS), a critical condition characterized by inadequate cardiac output and systemic hypoperfusion [30]. This framework defines five stages—Stage A ("at risk") through Stage E ("extremis")—using a combination of clinical signs, hemodynamic measurements, and biochemical indicators, such as lactate levels, blood pressure, and evidence of organ failure [30]. Designed to standardize the assessment of CS across diverse clinical settings, the SCAI system offers a practical tool for stratifying patients, guiding treatment decisions, and predicting outcomes, addressing inconsistencies in earlier, less comprehensive approaches to shock management [31].

Studies validating this system underscore its prognostic utility, demonstrating that higher stages correlate strongly with increased mortality, with rates escalating from approximately 10–20% in Stage C ("classic" shock) to over 60% in Stage E, where patients exhibit refractory shock despite maximal therapy [31]. This graduated scale enables clinicians to identify patients who may benefit from aggressive interventions, such as Abiomed's Impella devices, versus those requiring alternative strategies, aligning with this thesis's goal of capturing more eligible patients and escalating care effectively. Research also highlights its role in standardizing protocols, as seen in quality improvement initiatives that use the classification to optimize timing and type of interventions, improving consistency and outcomes in CS management [32]. The simplicity and reproducibility of SCAI staging position it as a cornerstone for clinical practice and research, setting the stage for predictive modeling to enhance Abiomed's strategic objectives in cardiovascular care [33].

The SCAI shock classification emerged from a 2019 consensus effort by a multidisciplinary panel of experts—comprising cardiologists, intensivists, and surgeons—convened to address the lack of a unified definition for cardiogenic shock [30]. Prior systems, such as the Killip classification for heart failure and the Forrester hemodynamic profiles, focused narrowly on myocardial infarction outcomes and lacked the breadth to encompass modern CS etiologies and treatments, including temporary mechanical circulatory support (MCS) devices [32].

Recognizing these limitations, the SCAI panel sought to create a broader, stage-based system applicable to diverse patient populations and care contexts, drawing inspiration from trauma and sepsis staging models, which offer tiered, data-driven frameworks [33].

Initial development involved synthesizing clinical expertise with existing data, proposing a five-tier framework that progresses from preclinical risk (Stage A) to irreversible decline (Stage E) [30]. Early feedback from practitioners and researchers prompted refinements, particularly in clarifying diagnostic criteria—such as specifying lactate thresholds or vasopressor requirements—to enhance interrater reliability and clinical utility [31]. By 2020, validation studies using large registries confirmed its predictive accuracy, cementing its relevance in critical care cardiology [31]. Collaborative efforts with trials and quality improvement programs, such as the National Cardiogenic Shock Initiative, further refined its application, integrating real-world evidence to ensure it reflected contemporary CS management trends, including the growing use of devices like Abiomed’s Impella pumps [34]. This evolution underscores a shift toward data-driven, standardized approaches in cardiogenic shock management, positioning SCAI staging as a foundation for predictive modeling efforts to increase Abiomed’s ability to help more patients.

## **2.4 National Cardiogenic Shock Initiatives (NCSI) and its Implications**

The National Cardiogenic Shock Initiative (NCSI), launched in 2016, is a prospective, single-arm, multicenter study evaluating a standardized protocol for treating acute myocardial infarction complicated by cardiogenic shock (AMICS) [36]. Spanning 80 U.S. hospitals, the study enrolled 406 patients from 2016 to 2020, focusing on early mechanical circulatory support (MCS) with Abiomed’s Impella devices [37]. The NCSI protocol prioritized rapid Impella placement—within 90 minutes of hospital arrival—before percutaneous coronary intervention (PCI), paired with right heart catheterization for hemodynamic monitoring and minimized use of inotropes or vasopressors [38]. Unlike traditional approaches where physicians decide based on individual assessments, NCSI’s unique, clearly defined playbook ensured patients meeting specific criteria, such as severe hemodynamic instability, consistently received an Impella, promoting uniformity in care [38]. The cohort, with a mean age of 64 years, was 24% female, and 67% presented in shock on admission, indicating a high-acuity group [38].

Key findings from the study reported a survival-to-discharge rate of 71% among all participants, with over 90% achieving native heart recovery, a significant improvement over historical benchmark [36]. For patients in SCAI stages C or D (classic or deteriorating shock), survival rates were 79% at discharge, 77% at 30 days, and 62% at 1 year, while SCAI stage E patients (extremis) experienced lower rates: 54% at discharge, 49% at 30 days, and 31% at 1 year [39]. Historically, AMICS survival rates hovered around 50%, as documented in earlier studies like the SHOCK trial, underscoring NCSI’s protocol efficacy [40]. Procedural survival reached 99% for stages C/D, reflecting the effectiveness of early Impella deployment in stabilizing patients during intervention [41].

The NCSI findings reinforce Abiomed’s position as a leader in AMICS management, providing robust, real-world evidence supporting the efficacy of its Impella devices [54]. The 71% survival rate—compared to the historical 50% benchmark—highlights the potential of early Impella use, particularly when deployed pre-PCI, to improve patient outcomes, aligning with Abiomed’s strategic goal of enabling native heart recovery, with over 90% of survivors avoiding long-term device dependence, a key differentiator from alternatives like intra-aortic balloon pumps (IABP) or extracorporeal membrane oxygenation (ECMO) [38]. The study’s scale—encompassing over 400 patients across diverse settings, including community hospitals—demonstrates Impella’s feasibility beyond academic centers, expanding its practical applicability and market potential [43].

For Abiomed, NCSI validates the Impella platform’s role in protocol-driven care, influencing clinical guidelines, hospital adoption, and regulatory support. NCSI’s integration with the Impella Quality (IQ) Database enriches Abiomed’s evidence base, positioning Impella as a standard of care in AMICS and setting the stage for predictive modeling and EMR integration to enhance real-time decision-making, as explored in Section 3.2 of this thesis [42].

## **2.5 DanGer Shock Study and Its Implications**

The DanGer Shock trial, a randomized controlled trial (RCT) conducted across Denmark, Germany, and the UK, evaluated the efficacy of Abiomed’s Impella CP against standard care in patients with acute myocardial infarction complicated by cardiogenic shock (AMICS) [44]. Published in 2024, it enrolled 355 patients with ST-elevation myocardial infarction (STEMI) and cardiogenic shock (CS), randomizing them to either Impella CP support before percutaneous coronary intervention (PCI) (n=179) or standard medical therapy (n=176) [45]. Inclusion criteria

targeted severe CS, defined by systolic blood pressure <100 mmHg, lactate levels  $\geq 2.5$  mmol/L, or the need for vasopressors [44]. The primary endpoint was all-cause mortality at 180 days, with secondary outcomes including hospital stay duration and adverse events [45].

Results demonstrated a significant survival benefit with Impella CP: 180-day mortality was 45.8% in the Impella group versus 58.5% in the control group, yielding a 12.7% absolute risk reduction [44]. Among survivors, the number of days alive and out of the hospital was similar between the pump and standard care groups at 82 and 73 days, respectively [45]. However, the Impella group experienced higher rates of severe bleeding (24.0% vs. 6.2%), limb ischemia (5.6% vs. 1.1%), and renal replacement therapy (41.9% vs. 26.7%) [46]. Notably, 57% of Impella placements offered pre-PCI, reinforcing the role of early intervention in improving outcomes [44].

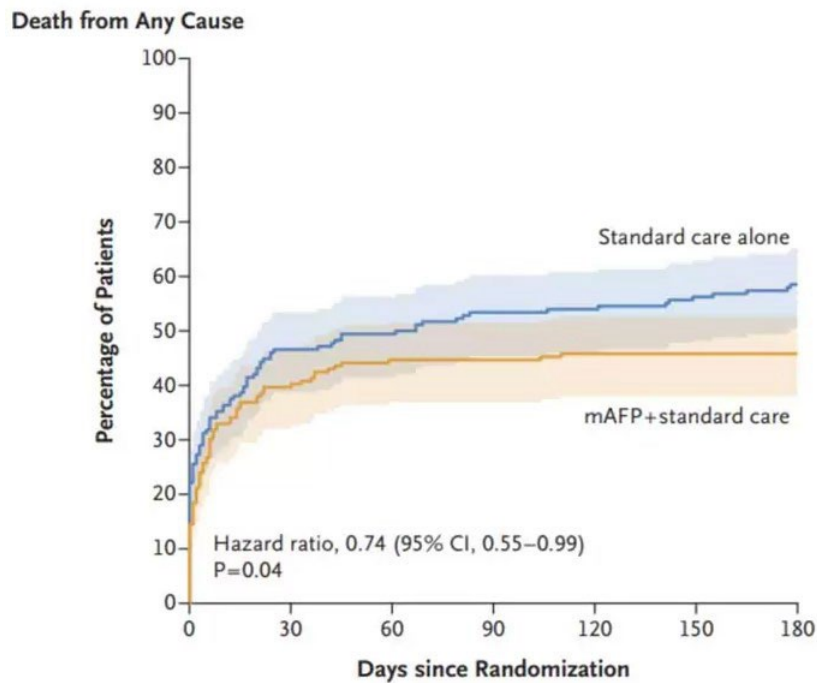


Figure 2.2: DanGer Shock Mortality Rate [45]

The DanGer Shock trial marked a landmark moment for Abiomed, providing the first RCT evidence of a mortality reduction with Impella CP in AMICS, a milestone unmatched by prior mechanical circulatory support (MCS) trials [49]. The 12.7% survival improvement strengthened Abiomed’s case for positioning Impella CP as a frontline therapy, distinguishing it from intra-aortic balloon pumps (IABP), which showed no mortality benefit, and extracorporeal membrane oxygenation (ECMO), which lacks robust RCT data [47]. The trial’s rigorous, randomized, multicenter design enhanced Impella’s credibility over observational studies like the National Cardiogenic Shock Initiative (NCSI), reinforcing its strategic value in expanding market adoption [45].

For Impella use, DanGer Shock underscored the efficacy of early deployment, aligning with Abiomed's strategic push for pre-PCI protocols to capture more patients and improve outcomes [44]. However, increased rates of bleeding and renal complications raised safety concerns, prompting Abiomed to refine training protocols and device management strategies to mitigate risks [46]. While not definitive due to its sample size and specific population, DanGer Shock established a benchmark for future RCTs, reinforcing Impella's role in evidence-based CS care and setting the stage for predictive modeling and electronic medical record (EMR) integration to enhance real-time decision-making.

## **2.6 Potential of Standardized Care with Impella Pumps**

Both the NCSI and DanGer Shock studies highlight the transformative potential of standardized, protocol-driven care using Abiomed's Impella pumps for cardiogenic shock management, offering a compelling vision if such practices become the norm. NCSI's 71% survival rate and DanGer Shock's 12.8% mortality reduction demonstrate that early, systematic Impella deployment—pre-PCI and tailored to SCAI stages—can significantly improve outcomes. If standardized protocols, such as those tested in these studies, were widely adopted, Impella could become the default MCS option in AMICS, reducing variability in care, enhancing patient survival, and driving Abiomed's market expansion. This standardization would require integration of real-time data and predictive tools, such as those proposed in this thesis, to ensure timely identification and escalation, positioning Abiomed to lead in CS management and operational efficiency. The synergy of these findings with EMR integration, as explored later, could further amplify these benefits, supporting the thesis's strategic and technical objectives.

## Chapter 3: Methods

### 3.1 Machine Learning Model Development for SCAI Shock Prediction

The first portion of the project was to analysis various datasets and to build a model that would utilize EMR data to accurately predict patients' level of shock using the SCAI Shock criteria.

#### 3.1.1 Approach

The development of a machine learning (ML) model to predict SCAI shock stages followed a structured framework aimed at transforming heterogeneous, adjudicated patient data into a predictive tool to identify the stage of shock that a patient is in. This exploratory process gathered clinical data from Abiomed's Impella Quality (IQ) Database, alongside the RECOVER III (R3) study and the National Cardiogenic Shock Initiative (NCSI) dataset, which provided variables such as lactate levels, vasopressor use, and patient hemodynamic data, all tied to SCAI stages assigned by physicians post-collection; detailed descriptions of these datasets appear later in this work. Data processing standardized these inputs—overcoming multi-study challenges by reconciling format disparities and missing entries—to ensure compatibility with ML model construction. The final phase iteratively built and tested predictive models using ensemble techniques to classify SCAI stages (A-E), refining them to balance accuracy with simplicity and avoid overfitting, with the dual objectives of identifying patients shock level and laying groundwork for future models to signal pump upgrades (e.g., to larger or right-sided devices) based on persistent shock severity. Key challenges included securing access to these datasets, necessitating extensive coordination with Abiomed and study collaborators, and processing the data to achieve consistency across diverse registries with differing structures. Model creation required careful design to prevent over-complexity, ensuring practical utility for

clinical decision-making while leveraging standardized inputs from the IQ, RECOVER III, and NCSI datasets to deliver robust predictions of the severity of shock.

### **3.1.2 Data Collection and Preprocessing**

#### **3.1.2.1 Recover III Dataset**

The RECOVER III dataset originates from a prospective, multicenter, single-arm observational postapproval study conducted across 41 U.S. centers between April 2016 and March 2020, following the FDA’s 2016 approval of the Impella device for acute myocardial infarction complicated by cardiogenic shock (AMICS) [50]. This study enrolled 418 patients who received Impella support during percutaneous coronary intervention (PCI) [50]. The cohort had a mean age of 64.0 years, was 75.8% male, and exhibited significant acuity—59.5% had experienced cardiac arrest prior to enrollment, with baseline lactate levels averaging 8.0 mmol/L, indicative of severe shock [51]. Collected variables included clinical data at admission and during hospitalization, such as lactate levels (mmol/L), creatinine (mg/dL), vasopressor use, systolic blood pressure (mmHg), heart rate (beats/min), and oxygen saturation (% SpO<sub>2</sub>), along with demographic details (age, sex) and procedural specifics (e.g., PCI timing) [50]. These data were extracted from electronic medical records and compiled into a spreadsheet for analysis, reflecting real-world clinical assessments rather than continuous device outputs [50]. A notable aspect of the RECOVER III dataset is that SCAI shock stages (C–E) were not assigned in real-time but were retrospectively adjudicated by physicians based on compiled data [50]. At baseline, using the 2019 SCAI criteria, 16.5% of patients were classified as Stage C, 11.4% as Stage D, and 72.2% as Stage E, reflecting a predominantly critical population [50]. This adjudication relied on clinical parameters like lactate elevation (>2 mmol/L), hypotension (systolic blood pressure <90

mmHg), and vasopressor needs within the first 24 hours of admission [50]. A reassessment at  $\leq 24$  hours post-Impella initiation showed a shift to 26.4% Stage C, 33.2% Stage D, and 40.0% Stage E, demonstrating dynamic changes in shock severity captured in the dataset through this post-hoc staging process based on static clinical snapshots [50].

### **3.1.2.2 IQ Dataset**

The IQ Dataset was compiled from Abiomed's Impella Quality (IQ) system, a proprietary clinical database designed to track real-world outcomes and quality metrics for patients treated with Impella devices across participating U.S. hospitals. Established following the Impella's FDA approval in 2008, the IQ system aggregates data from Abiomed Field Representatives reports, amassing over 44,000 patient records by 2016, with continuous updates on going [52]. For this study, a subset of 543 patients from 2024 was extracted, focusing on entries with SCAI shock stages recorded. This subset captured a high-acuity cohort, with a mean age of 63 years ( $\pm 11$  years), 68% male.

Within the IQ Dataset, SCAI shock stages (A–E) were not manually assigned by clinicians but auto populated using an algorithmic process mirroring the SCAI Shock Application, a tool developed to standardize stage classification based on the 2019 SCAI criteria [53]. This process employed a series of conditional statements—e.g., lactate  $> 2$  mmol/L or systolic blood pressure  $< 90$  mmHg indicating hypoperfusion, combined with vasopressor use for Stage D or higher—to assign stages from static clinical data points [54]. Each of the 543 patients had two SCAI shock scores: one pre-Impella (baseline upon admission) and one post-Impella (typically within 24 hours of device support), offering a dual-perspective snapshot of shock severity evolution.

The IQ Dataset included a comprehensive set of clinical parameters for these 543 patients, encompassing pH, cardiac output, cardiac power output, diastolic blood pressure, left ventricular ejection fraction, cardiac index, lactate (mmol/L), sex (binary), age, and number of drugs used (inotropes and vasopressors). These variables, sourced from EMRs and procedural logs, were compiled into a spreadsheet, reflecting point-in-time measurements rather than continuous monitoring, aligning with the project's focus on broadly available clinical markers.

### **3.1.2.3 NCSI Dataset**

The National Cardiogenic Shock Initiative (NCSI) dataset comprised of 406 patients across 80 U.S. hospitals between July 2016 and December 2020, targeting acute myocardial infarction complicated by cardiogenic shock (AMICS) treated with a standardized protocol emphasizing early mechanical circulatory support (MCS) via Impella 2.5 or CP devices [56]. The cohort had a mean age of 64 years ( $\pm 12$  years), with 24% female and 67% presenting in shock upon admission, including one-third who had suffered cardiac arrest prior to enrollment, reflecting a high-acuity population [56].

The dataset comprised clinical variables collected at admission and during treatment, including lactate levels, vasopressor use, systolic blood pressure, heart rate, and oxygen saturation, alongside demographic details (age, sex) and procedural markers (e.g., time to PCI). These parameters were compiled from electronic medical records (EMRs) and right heart catheterization reports into a spreadsheet format, capturing static clinical snapshots rather than real-time device outputs [56].

In the NCSI dataset, SCAI shock stages were adjudicated post-collection by physicians based on the spreadsheet data, not assigned in real-time during patient care. The study categorized

patients as either in Stage C/D or E, combining C/D due to Stage D being considered a transitory stage for this study.

#### **3.1.2.4 Processing and Handling of Missing Data**

Following the retrieval of the Recover III, Impella Quality (IQ), and National Cardiogenic Shock Initiative (NCSI) datasets, an extensive preprocessing phase was initiated to refine the data for SCAI shock stage prediction, focusing on removing irrelevant information and addressing missing values. A significant challenge was accessing these datasets, despite the published outlines of the studies, due to logistical barriers, including restricted access protocols, coordination with Abiomed and study collaborators, and varying institutional policies, which required extensive effort to secure comprehensive clinical data. However, the fact that all datasets were de-identified prior to acquisition, with patient identifiers stripped in compliance with Health Insurance Portability and Accountability Act (HIPAA) standards, facilitated their use by mitigating ethical and privacy concerns, allowing seamless integration into the analysis pipeline.

A notable obstacle in preprocessing was the presence of missing data across all three datasets, attributable to inconsistencies in data collection practices among the studies and contributing hospitals—such as variations in reporting lactate levels, vasopressor use, or hemodynamic parameters. To address this, a sex-stratified mean imputation strategy was employed, calculating the average value for each clinical parameter separately for male and female patients within each dataset and inserting these averages into missing entries [80]. For example, missing lactate values were replaced with the average lactate level for males or females within the respective dataset, accounting for known physiological differences in shock cohorts—such as potential variations in baseline lactate or blood pressure by sex—while

preserving data distributions and avoiding biases introduced by simpler methods like global mean imputation. This approach, validated in ML literature for maintaining statistical integrity when missingness is random and demographic stratification is feasible, ensured robust handling of the heterogeneous data, aligning with the thesis's technical goal of developing a precise SCAI prediction model [58].

### **3.1.3 Background on Machine Learning Techniques**

The SCAI shock stage prediction model leveraged ensemble machine learning (ML) methods to classify patients into stages A–E using static, adjudicated clinical data from the IQ and NCSI datasets. Three base models—random forests, CatBoost, and XGBoost—were individually trained to capture the complex, nonlinear relationships among variables like lactate, vasopressor use, and creatinine, addressing the project's goals of identifying Impella candidates and signaling pump escalation potential. These models were then integrated into a meta-learner using categorical regression, stacking their outputs to enhance overall accuracy and robustness. This section introduces each technique, detailing their individual mechanics and execution, followed by their combination into the meta-learner, providing a foundation for understanding subsequent model performance.

#### **3.1.3.1 Random Forest, CatBoost, and XGBoost**

**Random Forests:** Random forests build an ensemble of decision trees, each trained on a random subset of the data and features, with predictions aggregated via majority voting for classification tasks. Each tree splits the dataset based on feature thresholds (e.g., lactate >2 mmol/L), creating a hierarchy of decisions that collectively reduce variance and overfitting through randomization. This approach excels at handling noisy, high-dimensional data—common in healthcare—

offering stability and feature importance scores, though it risks underperforming on imbalanced classes like Stage A due to its averaging nature [64].

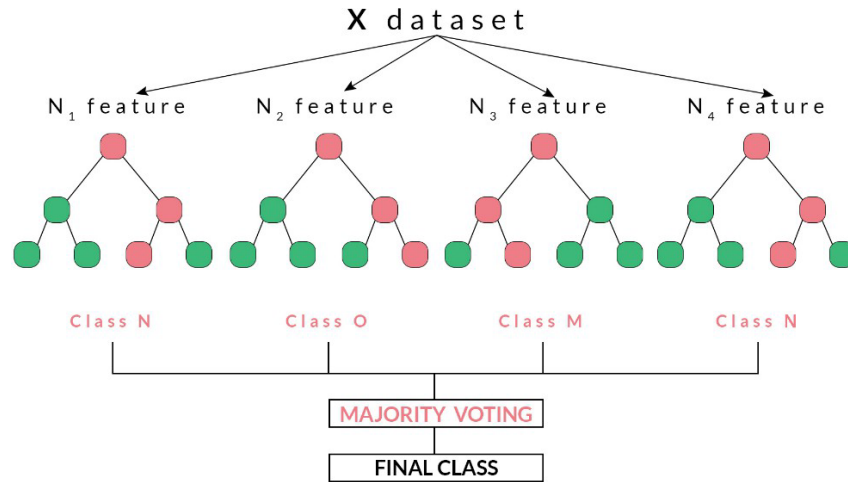


Figure 3.1: Random Forset Visualtizon [65]

**XGBoost:** XGBoost (Extreme Gradient Boosting) constructs sequential decision trees, where each tree corrects the errors of its predecessors by minimizing a regularized loss function, such as log-loss for multiclass classification [66]. Unlike random forests' parallel trees, XGBoost's boosting iteratively refines predictions, weighting misclassified cases (e.g., Stage E patients) more heavily in subsequent trees. Applied to the dataset, XGBoost processed the same clinical features, leveraging gradient descent to optimize splits and incorporating regularization to prevent overfitting—a key concern given the dataset's moderate size and variability across sources. Its ability to prioritize influential predictors (e.g., vasopressor dosage) and handle missing values natively made it precise, though computationally intensive, requiring careful parameter tuning for efficiency [66].

**CatBoost:** CatBoost enhances gradient boosting by natively managing categorical variables and reducing bias through ordered boosting [67]. It builds symmetric trees, adjusting for categorical

inputs (e.g., sex, vasopressor type) without preprocessing into numerical formats, unlike random forests or XGBoost, which often require one-hot encoding. CatBoost utilized the full dataset, processing both continuous (e.g., lactate) and categorical features (e.g., binary drug presence) efficiently via target statistics—mean-encoding labels within the training set to minimize leakage. Its design mitigated overfitting in smaller subsets (e.g., NCSI’s 406 cases) and offered faster training than XGBoost, making it a practical choice for iterative testing while maintaining accuracy across the adjudicated SCAI stages [67].

Each model was executed independently, trained on the preprocessed dataset to predict SCAI stages. These standalone runs provided baseline predictions—confusion matrices to compare each other with.

### **3.1.3.2 Meta-Learner Using Categorical Regression**

To combine the individual strengths of random forests, CatBoost, and XGBoost, a meta-learner was implemented using categorical regression, specifically multinomial logistic regression, to stack their outputs into a unified prediction. Stacking trains a secondary model on the predictions of base learners, exploiting their complementary capabilities to boost overall performance [68]. For this project, each base model was first trained on a 70/30 split, generating probability estimates for SCAI stages A–E for each patient—resulting in a 15-feature matrix (5 stages × 3 models) per instance. These probabilities, reflecting each model’s perspective (e.g., XGBoost’s precision on Stage E, CatBoost’s balance across categories), were then fed into the meta-learner.

The meta-learner, a multinomial logistic regression, was trained on this matrix to predict the final SCAI stage, optimizing a cross-entropy loss function that assigned weights to each base

model's output based on its predictive reliability [69]. For example, if XGBoost consistently outperformed on severe stages (D/E), its probabilities received higher weighting, while random forests' stability bolstered less frequent stages (A/B). A penalty was applied to regularize the regression, preventing over-reliance on any single model's quirks and ensuring generalizability across the diverse IQ and NCSI data [70].

This stacking process ran on the remaining 30% as a holdout set, combining the base models' outputs into a probabilistic classification that balanced accuracy and simplicity, offering clinicians interpretable stage predictions with uncertainty estimates. By synthesizing the individual runs—random forests' robustness, XGBoost's precision, and CatBoost's efficiency—the meta-learner provided a cohesive, optimized solution for SCAI shock stage prediction, priming the reader for the performance results to follow.

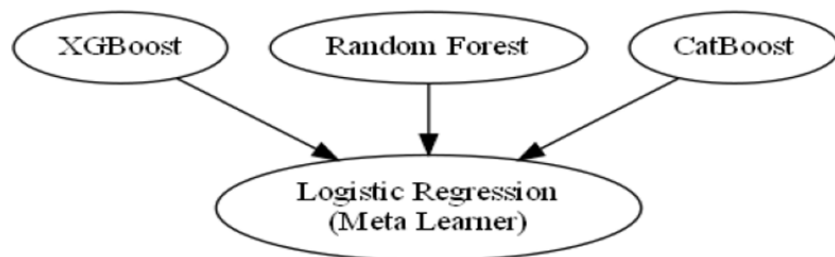


Figure 3.2: Stacked Model

#### 3.1.4 Recover III Model Baseline

The RECOVER III (R3) dataset, containing the fewest parameters per entry among the three datasets with 419 patients, was selected as the initial foundation to explore a rule-based approach for predicting SCAI shock stages, aiming to emulate physician decision-making

through a series of if-then statements tailored to its limited scope of Stages C, D, and E [71].

These rules were informed by primary studies that shaped the 2019 SCAI shock criteria, including Schrage et al. (2019), Thayer et al. (2020), Jentzer et al. (2019), Lawler et al. (2020), and Pareek et al. (2021), which highlighted clinical thresholds such as lactate >5 mmol/L for severe shock or vasopressor use for instability. Specifically,

**Stage E** was assigned if any of the following conditions were met: the patient received CPR (in-hospital or out-of-hospital), pre-Impella pH was below 7.2, or pre-Impella lactate exceeded 5 mmol/L, reflecting severe hypoperfusion or shock.

**Stage D** was designated if multiple vasopressors (>1 drug) were used with lactate below 5 mmol/L or missing, or if a single vasopressor was combined with an intra-aortic balloon pump (IABP) or extracorporeal membrane oxygenation (ECMO), indicating deteriorating shock requiring escalation.

**Stage C** was applied if a single vasopressor was used with lactate below 5 mmol/L or missing, or if pH exceeded 7.2 with no CPR, cardiac arrest, or significant drug/device support, defaulting to C for stable cases otherwise.

These deterministic rules were applied to the R3 dataset's pre-Impella clinical variables to generate predicted SCAI stages for all 419 patients, establishing a baseline to assess whether such logic could mirror the physician adjudication process detailed in the SCAI framework.

### **3.1.5 Hyperparameter Tuning for Meta-Learner**

Once the meta-learner combining random forests, CatBoost, and XGBoost with categorical regression was constructed, a comprehensive hyperparameter tuning process using the Python package Optuna was conducted to optimize its performance, specifically using the IQ dataset of

544 patients from 2024. This focused tuning effort, executed over nearly four days, targeted the IQ subset due to its detailed pre- and post-Impella clinical variables—such as lactate, pH, and vasopressor counts—offering a robust sample to refine the model before broader application. The approach systematically explored a wide hyperparameter space, testing combinations of settings like model complexity, learning rates, and regularization through a tree-structured search technique that balanced exploration and exploitation, aiming to minimize a multiclass classification error metric [72].

### **3.1.6 Train/Test Splits**

To mitigate overfitting and ensure robust evaluation of the meta-learner’s performance across both IQ and NCSI datasets, a 70/30 train/test split was implemented, a standard practice in machine learning to balance model training and validation [73]. The training set was used to fit the random forests, CatBoost, XGBoost, and subsequent meta-learner, leveraging the tuned hyperparameters from the IQ subset to learn SCAI stage patterns from clinical variables like lactate and vasopressor use. The test set served as an independent holdout to assess generalizability, ensuring the model’s predictions for stages A–E were not overly tailored to the training data—a critical concern given the dataset’s moderate size and adjudicated nature [73]

Recognizing sex-based physiological differences observed in shock cohorts (e.g., higher lactate in females [72]), the split was stratified to maintain an even distribution of males and females within each set. This stratification prevented skew from sex-specific patterns, ensuring equitable representation of demographic variability across the adjudicated SCAI stages (C, D, E dominant in RECOVER III; A–E in IQ and C/D, E in NCSI). This

deliberate 70/30 split, executed with careful sex balancing, underpinned the model's ability to generalize across datasets.

### **3.1.7 Validation and Testing**

After constructing and tuning the meta-learner using the IQ dataset, the identical model configuration was applied to the NCSI dataset to validate its performance and robustness. This validation aimed to compare predictive accuracy and identify the primary clinical predictors driving SCAI shock stage classifications (A–E), such as lactate, vasopressor use, or creatinine, by examining feature importance scores derived from the base models.

To enhance stability and reduce variance in these predictions, a bagging technique was employed, where each base model—configured with its optimal hyperparameters (e.g., XGBoost with 180 estimators, random forests with 438)—was replicated across 10 iterations, each trained on a random subset of the data with replacement, a method known as bootstrap aggregating [73]. This process, applied individually to random forests, CatBoost, and XGBoost, generated multiple instances of each model, with their predictions averaged to mitigate overfitting and improve generalizability, particularly valuable given the moderate dataset sizes and adjudicated stage variability [73].

These bagged models were then stacked, feeding their combined outputs into the logistic regression meta-learner, which was cross validated across 10 folds to ensure reliable integration of the base predictors. The final model, trained on the IQ dataset's 70% split, was tested on its 30% holdout, then identically applied to NCSI's full set, allowing direct comparison of accuracy, confusion matrices, and per-stage classification metrics (e.g., precision, recall) between datasets. This approach not only validated the model's consistency but also highlighted key predictors—consistently high-weighted features like lactate or drug count—informing its utility for

identifying Impella candidates and escalation triggers, with bagging enhancing confidence in these insights across real-world clinical contexts [73].

### 3.1.8 Confusion Matrix

To evaluate the performance of the meta-learner in predicting SCAI shock stages (A–E), a **confusion matrix** was used to provide a detailed breakdown of correct and incorrect predictions across all stages. In multi-class classification like SCAI staging, the confusion matrix extends beyond binary classification by comparing predicted versus actual stages across five categories (A, B, C, D, E).

	Predicted Positive (Stage X)	Predicted Negative (Not Stage X)
Actual Positive (Stage X)	True Positive (TP)	False Negative (FN)
Actual Negative (Not Stage X)	False Positive (FP)	True Negative (TN)

Figure 3.3: Confusion Matrix [74]

**True Positives (TP):** The number of patients correctly classified as a specific stage (e.g., correctly predicting Stage E when the true stage is Stage E).

**False Positives (FP):** Cases where the model incorrectly predicts a patient as a certain stage (e.g., predicting Stage D when the patient is actually Stage C).

**False Negatives (FN):** Cases where the model fails to identify a patient who truly belongs in a stage (e.g., missing a Stage E patient and labeling them Stage D).

**True Negatives (TN):** Patients correctly identified as not belonging to a specific stage. [75]

Beyond simply measuring accuracy—the proportion of all correct predictions—the confusion matrix supports the calculation of additional performance metrics essential for assessing model reliability in clinical contexts. **Precision** measures the proportion of correct positive predictions for each stage, reflecting how often the model’s predictions of a specific shock stage are

accurate. **Recall** (also known as sensitivity) captures the model's ability to correctly identify all actual cases of a stage, minimizing the risk of missing critical patients, such as those in Stage E [94]. The **F1 score**, calculated as the harmonic mean of precision and recall, balances these two metrics and is particularly useful in this project due to the imbalanced distribution of SCAI stages, where extreme stages like A and E are less frequent [77]. Together, these metrics provide a nuanced understanding of the model's strengths and weaknesses, ensuring that predictive performance aligns with the clinical goal of accurately identifying shock severity while minimizing harmful misclassifications. In this analysis, confusion matrix outputs were analyzed for both the IQ and NCSI datasets, with particular attention paid to the model's ability to maintain high precision and recall across all SCAI stages, reinforcing its utility in supporting real-time decision-making and escalation of care in cardiogenic shock management.

### **3.2 EMR Integration Feasibility Assessment**

The feasibility of integrating hospital Electronic Medical Record (EMR) data into Abiomed's ecosystem was assessed to evaluate the potential for enabling advanced applications, such as real-time SCAI shock stage predictions. The ultimate objective of this integration is to expand Abiomed's ability to identify and escalate care for more patients, thereby increasing its market penetration beyond the current 5% share. This assessment focused on bridging the gap between siloed hospital data and Abiomed's Impella platform, creating a foundation for enhanced clinical insights and decision support. The methodology was structured around three core pillars: engaging key stakeholders, assessing technical feasibility, and identifying viable methods to achieve secure, reliable connectivity between hospital EMRs and Abiomed's digital infrastructure.

### **3.2.1 Approach**

The feasibility assessment utilized a multi-faceted, iterative framework to evaluate the integration of EMR data into Abiomed's digital ecosystem, with the specific objective of merging Impella telemetry with hospital EMRs to enhance clinical decision-making and support market expansion. This approach was designed to test the hypothesis that EMR integration could reduce data silos and facilitate the standardization of cardiogenic shock protocols across hospitals. The rationale for pursuing this connectivity is supported by benchmark outcomes from major studies: the National Cardiogenic Shock Initiative (NCSI), which demonstrated a 71% survival-to-discharge rate with early Impella use, and the DanGer Shock trial, which reported a 12.8% improvement in survival with Impella CP compared to standard care. These findings highlight the potential for real-time data integration to improve patient outcomes while expanding Abiomed's clinical and commercial impact.

#### **Stakeholder Engagement:**

This phase focused on identifying the needs, barriers, and potential benefits of EMR integration through direct engagement with key internal and external stakeholders. Semi-structured interviews were conducted with nine individuals across Abiomed's organization, including members of the Impella Connect Team, the General Manager of Digital Patient Solutions, Platform Risk and Security Personnel, Field Team Representatives, Sales Analysts, the Associate Director of Data Engineering, a Product Manager, the Field Reimbursement Team, and additional personnel. These discussions provided critical insights into the operational, technical, and regulatory considerations of integrating EMR data into the Impella ecosystem.

#### **Feasibility Assessment:**

A systematic feasibility assessment was conducted to explore the regulatory, technical, and operational challenges of EMR integration, focusing on both U.S. and international considerations. This included analysis of U.S. Food and Drug Administration (FDA) requirements for medical device-EMR interoperability, specifically addressing Software as a Medical Device (SaMD) guidelines and Class III device regulations governing the Impella platform. Data privacy and security frameworks were also reviewed, including compliance with HIPAA (U.S.) and GDPR (EU), to ensure any solution adhered to patient privacy standards and cybersecurity best practices.

A major challenge identified was the heterogeneity of hospital EMR systems, including variations in data formats, proprietary standards, and legacy infrastructure, which collectively complicate real-time data integration and hinder standardization across care environments. This phase drew on best practices from healthcare informatics research to evaluate strategies for overcoming these barriers, with a focus on enabling real-time SCAI shock stage predictions and supporting consistent application of shock management protocols across diverse clinical settings.

#### **Deployment Strategies:**

- **Direct Partnerships with Hospitals:** Establishing individual agreements with hospital systems to access and integrate EMR data directly into Abiomed's infrastructure.
- **Collaborations with Major Industry Partners:** Forming strategic partnerships with large EMR vendors or medical technology companies, such as Epic or Philips, to leverage their existing integrations and data-sharing frameworks.

- **Engagement with Third-Party Data Aggregators:** Working with external health data companies that specialize in aggregating and standardizing hospital data for use in artificial intelligence (AI) and machine learning (ML) applications.

## Chapter 4: Results

### 4.1 Machine Learning Model Performance

#### 4.1.1 Recover III

##### 4.1.1.1 Performance Metrics

The RECOVER III (R3) dataset, consisting of 419 AMICS patients with adjudicated SCAI Stages C, D, and E, was evaluated using a rule-based approach built on if-then statements designed to replicate physician decision-making based on defined clinical thresholds.

The R3 cohort included:

- **Stage C:** 16.14% (68 patients)
- **Stage D:** 11.08% (47 patients)
- **Stage E:** 71.57% (298 patients)

Key clinical parameters used for classification included lactate levels, pH, out-of-hospital cardiac arrest (OHCA), in-hospital cardiac arrest (IHCA), CPR presence, number of inotropes/vasopressors, and pre-existing device support (IABP/ECMO).

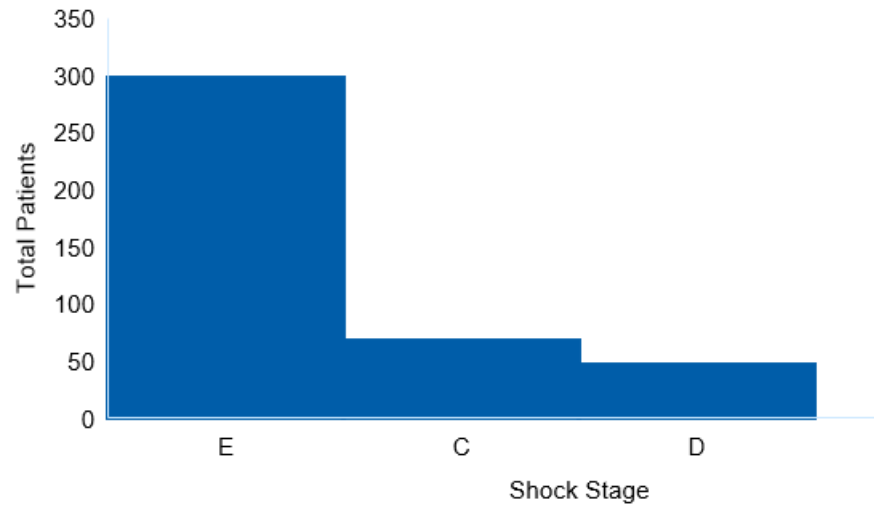


Figure 4.1: Shock Distribution for R3

The rule-based approach achieved an overall **accuracy of 90%**. The performance by stage was as follows:

- **Stage C:**
  - Precision: 0.78
  - Recall: 0.97
  - F1-score: 0.86
  - Correctly classified: 66 of 68 patients (97.06%)
- **Stage D:**
  - Precision: 0.68
  - Recall: 0.60
  - F1-score: 0.64
  - Correctly classified: 28 of 47 patients (59.57%)
- **Stage E:**

- Precision: 0.97
- Recall: 0.94
- F1-score: 0.95
- Correctly classified: 279 of 298 patients (93.62%)

Overall model performance:

- **Macro Average:**

- Precision: 0.81
- Recall: 0.83
- F1-score: 0.82

Pre-Stage	Precision	Recall	F1-Score	Support
C	0.78	0.97	0.86	68
D	0.68	0.60	0.64	47
E	0.97	0.94	0.95	298

Figure 4.2: R3 Classification Report

These results demonstrate strong performance of the rule-based method, particularly for identifying Stages C and E. However, Stage D showed lower recall, reflecting the difficulty of distinguishing moderate shock in a population dominated by severe cases.

#### 4.1.1.2 Observations and Analysis

The rule-based approach on the RECOVER III dataset demonstrated strong alignment with physician adjudication, particularly for Stages C and E, by leveraging clear clinical thresholds such as CPR presence, elevated lactate levels (>5 mmol/L), and pH below 7.2.

Stage E's high F1-score (0.95) reflected the dominance of severe clinical markers within the dataset, which included 245 patients with CPR, 170 with in-hospital cardiac arrest (IHCA), 107 with out-of-hospital cardiac arrest (OHCA), 97 with pH below 7.2, and 112 with lactate levels exceeding 5 mmol/L. This concentration of extreme cases aligned with the dataset's 71.57% distribution of Stage E patients.

Stage C achieved near-perfect recall (0.97) due to conservative rules that assigned this stage to patients with single-drug support and stable pH levels above 7.2. However, its precision (0.78) was reduced by two Stage E patients misclassified as Stage C, likely due to missing lactate or CPR data.

Stage D showed a weaker performance (F1-score of 0.64), with misclassifications driven by overlapping criteria. Specifically, 13 patients were incorrectly classified as Stage C and six as Stage E. These errors often involved patients with moderate instability—such as those receiving multiple vasopressors with lactate levels below 5 mmol/L or those supported by IABP or ECMO devices—where clinical presentations were less distinct.

In total, 40 misclassifications occurred across the dataset:

- 2 Stage C cases misclassified as Stage E
- 13 Stage D cases misclassified as Stage C
- 6 Stage D cases misclassified as Stage E
- 6 Stage E cases misclassified as Stage C
- 13 Stage E cases misclassified as Stage D

These patterns suggest that while the rule-based model performed well in identifying clear-cut severe cases, it struggled with the nuanced transitions between moderate stages, particularly Stage D. The dataset's heavy skew toward Stage E and its limited parameter set reinforced the

rule-based method's strengths in identifying severe shock but also highlighted the limitations of deterministic logic in capturing the complexity of real-world clinical variability. These findings support the need for adaptive machine learning models to handle more subtle distinctions and dynamic patient presentations.

## 4.1.2 IQ

### 4.1.2.1 Performance Metrics

The IQ dataset, consisting of 543 AMICS patients from 2024, was evaluated through a multi-step process to predict SCAI stages A–E. The process began with applying the rule-based if-then approach originally developed for the Recover III dataset. These rules assigned Stage E for severe cases (e.g., CPR, pH <7.2, lactate >5 mmol/L), Stage D for patients on multiple vasopressors or with IABP/ECMO support, Stage C for those on a single vasopressor with stable markers, and Stages A/B for stable cases with minimal support.

When applied to the IQ dataset, this rule-based method achieved an overall accuracy of 0.43, significantly lower than its performance on Recover III. The IQ dataset had a broad distribution of shock severity, including 19.15% (104 patients) in Stage A, 4.51% (24 patients) in Stage B, 16.57% (90 patients) in Stage C, 31.08% (169 patients) in Stage D, and 28.73% (156 patients) in Stage E. Clinical parameters available included lactate, pH, cardiac index (CI), cardiac output (CO), cardiac power output (CPO), diastolic blood pressure (DBP), left ventricular ejection fraction (LVEF), hemoglobin (Hgb), heart rate, left ventricular end-diastolic pressure (LVEDP), mean arterial pressure (MAP), systolic blood pressure (SBP), oxygen saturation (O<sub>2</sub> Sat), number of inotropes/vasopressors, age, gender, and device use (IABP/ECMO).

Stage-specific performance of the rule-based method showed the following results:

- **Stage C:** Precision of 0.31, recall of 0.98, F1-score of 0.47 (support: 90 patients)
- **Stage D:** Precision of 0.51, recall of 0.10, F1-score of 0.17 (support: 169 patients)
- **Stage E:** Precision of 0.78, recall of 0.46, F1-score of 0.58 (support: 156 patients)

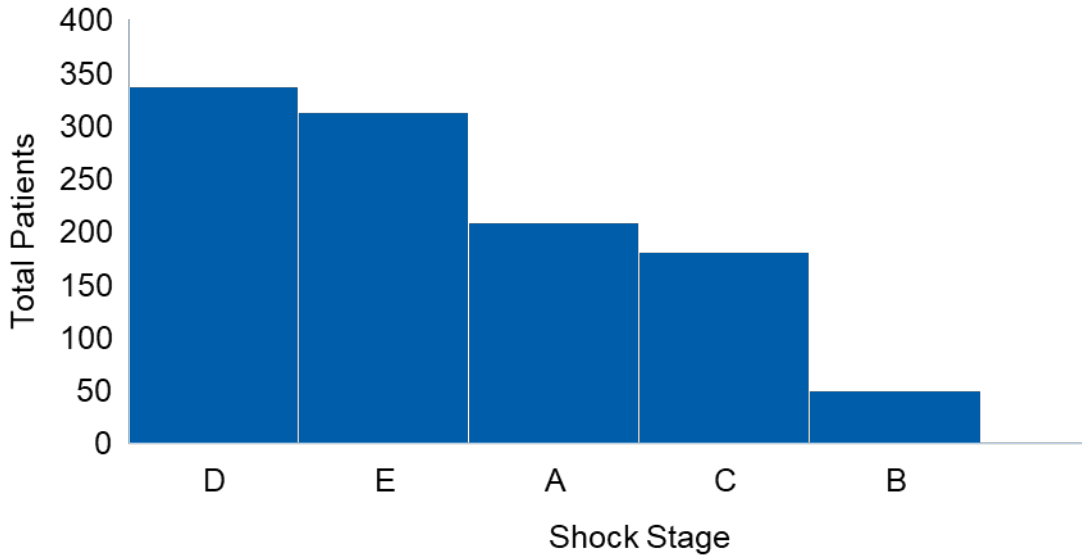


Figure 4.3: Shock Distribution for NCSI

Pre-Stage	Precision	Recall	F1-Score	Support
C	0.31	0.98	0.47	180
D	0.51	0.10	0.17	337
E	0.78	0.46	0.58	312

Figure 4.4: NCSI Classification Report Using R3 Rules

Stages A and B had minimal correct classifications, contributing to the overall low accuracy.

After the rule-based evaluation, the dataset was analyzed using individual machine learning models trained on the same clinical parameters. Performance improved significantly:

- **Random Forest:** Accuracy of 0.88, with F1-scores from 0.87 (Stage B) to 0.95 (Stage E).

- **XGBoost:** Accuracy of 0.901, with F1-scores from 0.89 (Stage B) to 0.96 (Stage E).
- **CatBoost:** Accuracy of 0.92, with F1-scores from 0.90 (Stage B) to 0.97 (Stage E).

Finally, an ensemble model was implemented by stacking Random Forest, XGBoost, and CatBoost using a logistic regression meta-learner. This approach achieved the best results with an overall accuracy of 0.94. Stage-specific metrics for the stacked model included:

- **Stage A:** Precision of 0.95, recall of 1.00, F1-score of 0.98
- **Stage B:** Precision of 0.87, recall of 0.92, F1-score of 0.90
- **Stage C:** Precision of 0.89, recall of 0.86, F1-score of 0.88
- **Stage D:** Precision of 0.91, recall of 0.95, F1-score of 0.93
- **Stage E:** Precision of 0.99, recall of 0.93, F1-score of 0.96

Pre-Stage	Precision	Recall	F1-Score	Support
A	.95	1.00	.98	63
B	.87	.93	.90	14
C	.93	.88	.90	58
D	.91	.96	.93	96
E	.99	.93	.96	95

Figure 4.5: NCSI Meta Learner Classification Report

These results demonstrate the effectiveness of ensemble learning for handling the IQ dataset’s diverse stage distribution and extensive clinical feature set, achieving high accuracy and balanced performance across all SCAI stages.

#### 4.1.2.2 Observations and Analysis

The multi-step evaluation of the IQ dataset highlighted the limitations of applying the Recover III rule-based approach to a more balanced population of shock stages. The rule-based

model achieved only 43% accuracy, primarily due to the IQ dataset's broader distribution of stages and the reduced prevalence of extreme markers, such as CPR and cardiac arrest, which the rules heavily relied on. Unlike Recover III, where Stage E accounted for over 70% of cases, the IQ dataset included a more even distribution: Stage A (19.15%), Stage B (4.51%), Stage C (16.57%), Stage D (31.08%), and Stage E (28.73%).

This balanced distribution exposed the rule-based model's weaknesses, particularly for Stage D, which had a low recall of 0.10 and F1-score of 0.17. Most Stage D patients were misclassified as either Stage C (152 instances) or Stage E (17 instances), indicating that the binary thresholds used in the rules struggled to differentiate moderate shock from adjacent categories. Stage E also showed underperformance, with 84 cases misclassified as either Stage C or D, reflecting the challenge of identifying severe shock in a dataset with fewer extreme presentations. Stages A and B were rarely predicted correctly, often being grouped into Stage C due to overlapping stability markers.

In contrast, machine learning models—including Random Forest, XGBoost, and CatBoost—significantly outperformed the rule-based approach by capturing complex relationships across the diverse clinical parameters of the IQ dataset, such as lactate levels, LVEF, and cardiac output. Random Forest provided stable, consistent results with 88% accuracy. XGBoost excelled in handling more severe cases with 90.1% accuracy, and CatBoost leveraged its strength in processing categorical data (such as device usage and patient sex) to achieve 92% accuracy. However, all models continued to show some difficulty with the less common Stage B due to its small sample size. The ensemble stacked learner, which combined these models through a logistic regression meta-learner, achieved the highest overall accuracy at 94%.

An analysis of feature importance within the stacked machine learning model revealed that the number of inotropes and vasopressors administered was, by a substantial margin, the most influential variable in predicting a patient's SCAI shock stage. This feature consistently outperformed all others in determining shock severity, with lactate levels emerging as the second most important factor.

This finding suggests that SCAI shock classification is, to a large extent, driven by clinical decisions—specifically, the choice to initiate pharmacologic support with inotropes and vasopressors. Rather than solely reflecting passive physiological deterioration, the shock stage is closely linked to the interventions applied by the care team. In essence, the physician's decision to escalate pharmacologic support becomes a defining marker of shock severity, reinforcing the observation that SCAI staging is not just a measure of patient status but also a reflection of treatment intensity.

This dynamic highlights an important consideration for future predictive modeling: because physician-driven interventions heavily influence shock stage classification, models may, in part, be learning patterns of clinical decision-making rather than purely objective patient physiology.

### **4.1.3 NCIS**

#### **4.1.3.1 Performance Metrics**

The NCSI dataset, comprising 413 AMICS patients, was evaluated using a meta-learner combining Random Forest, CatBoost, and XGBoost models with a categorical regression layer. The meta-learner was configured with hyperparameters optimized from the IQ dataset and

applied to predict SCAI shock stages, simplified into a binary classification of Stages C/D (labeled as 0) and Stage E (labeled as 1).

The model achieved an overall accuracy of **0.91**, demonstrating strong performance on this binary task. Stage-specific results showed:

- **Stages C/D:** Precision of **0.91**, recall of **0.98**, and F1-score of **0.94** (support: 89 patients).
- **Stage E:** Precision of **0.92**, recall of **0.73**, and F1-score of **0.81** (support: 33 patients).

The macro average yielded a precision of **0.91**, recall of **0.85**, and F1-score of **0.88**, while the weighted average matched the overall accuracy at **0.91**, reflecting consistent performance across the dataset.

The confusion matrix indicated strong classification reliability, with:

- 87 correct predictions for Stages C/D.
- 24 correct predictions for Stage E.
- 2 Stages C/D misclassified as E.
- 9 Stage E cases misclassified as C/D.

These results suggest only minor overlap between stages, reinforcing the model's effectiveness in distinguishing between moderate and severe shock.

#### 4.1.3.2 Observations and Analysis

The meta-learner's performance on the NCSI dataset confirmed its generalizability and robustness across different patient cohorts. Feature importance analysis revealed **lactate** as the most influential predictor, followed by age, and hemoglobin. Other variables, such as cardiac output and pH, contributed minimally.

The dominance of lactate, a key marker in SCAI criteria for severe shock, underscores its importance in identifying patients who may require escalated Impella support, particularly in cases of persistent elevation where larger or right-sided devices may be needed.

Stage E's lower recall (**0.73**) suggests some difficulty in distinguishing the most severe cases, likely due to overlapping clinical profiles (e.g., moderate lactate levels, pressor use) shared with Stages C/D. Conversely, the high recall (**0.98**) for Stages C/D highlights the model's strong reliability in identifying moderate shock states.

While the binary classification (C/D vs. E) simplifies staging for this dataset, it may underestimate variability within the combined C/D group. However, this was mitigated through the use of stacking and bagging techniques (with 10 iterations per base model), which reduced variance and improved stability across NCSI's multi-center data.

Finally, the feature importance trends closely matched those observed in the IQ dataset, reinforcing the model's consistency across datasets and its potential utility for real-world cardiogenic shock management and Impella support decisions. Although the NCSI dataset did not include the number of inotropes or vasopressors for the patient cohort analyzed—preventing this variable from contributing to the model—the prominence of **lactate** as the most critical feature paints a consistent and clinically relevant picture. Elevated lactate, a well-established indicator of shock severity, underscores the model's capacity to identify high-risk patients, supporting its potential role in guiding escalation decisions and optimizing Impella use.

#### **4.2 EMR Integration Findings**

The feasibility assessment confirmed that EMR integration into Abiomed's digital ecosystem is technically viable, offering significant clinical, operational, and strategic benefits for managing

acute myocardial infarction complicated by cardiogenic shock (AMICS). This section synthesizes stakeholder insights, technical outcomes, compliance considerations, and the business case, culminating in actionable recommendations.

#### **4.2.1 Stakeholder Assessment and Observations**

Stakeholder interviews underscored the strategic importance of integrating Impella data with electronic medical records (EMRs) to enhance patient outcomes and hospital efficiency.

Feedback from a diverse group within Abiomed highlighted three primary unmet needs: improving protocol adherence, reducing clinician documentation burden, and enhancing decision-support tools for care teams. These insights align with Abiomed's goal of leveraging data-driven solutions to optimize acute myocardial infarction complicated by cardiogenic shock (AMICS) management.

Stakeholders emphasized that EMR integration could streamline clinical workflows by consolidating Impella telemetry with patient data, enabling real-time monitoring and comprehensive outcome analysis. This would support clinicians in adhering to standardized shock management protocols, such as the National Cardiogenic Shock Initiative (NCSI) protocol, which achieved a 71% survival-to-discharge rate. Other stakeholders noted that improved data availability would enhance predictive modeling for patient identification and escalation, though immediate benefits lie in operational efficiency.

The broader opportunity lies in using EMR integration to standardize shock care across hospitals. By embedding data-driven workflows into hospital systems, Abiomed could facilitate consistent application of evidence-based protocols, improving outcomes and increasing the number of eligible patients receiving Impella support.

#### **4.2.2 Deployment Strategy**

The deployment strategy explored three potential methods for integrating EMR data into Abiomed's digital ecosystem, evaluating their ability to support clinical decision-making, improve AMICS outcomes, and increase market share.

##### **Method 1: Direct Hospital Integration**

This approach would involve establishing direct interfaces between hospital EMR systems and Abiomed's infrastructure via application programming interfaces (APIs). While technically, this method presents significant regulatory challenges, including extensive FDA submissions for a Class III medical device and compliance with Software as a Medical Device (SaMD) guidelines.

Furthermore, the variation in EMR systems, proprietary standards, and legacy technologies across hospitals adds considerable complexity, making this method the most resource-intensive and operationally burdensome.

### **Method 2: Device Vendor Partnerships**

Partnering with existing device vendors (such as Philips or Edwards) would allow Abiomed to integrate Impella telemetry with vendor platforms, circumventing some direct EMR hurdles. However, this strategy risks incomplete datasets and limited patient visibility, as these platforms often do not capture comprehensive clinical parameters essential for accurate SCAI stage prediction. Regulatory hurdles remain significant due to device interoperability requirements, making this method more feasible than direct integration but still operationally complex and limited in scope.

### **Method 3: Outsourcing to Data Aggregation Partners**

The most feasible solution identified was outsourcing EMR integration to third-party data aggregation partners. These companies specialize in consolidating clinical data across diverse EMR systems and already operate within compliant regulatory frameworks. By leveraging partners with existing infrastructure, Abiomed can focus internal resources on core competencies while benefiting from Johnson & Johnson's broader support network following the 2022 acquisition. Aggregation partners handle data cleaning, compliance, and anonymization, ensuring privacy under HIPAA and GDPR while delivering standardized, high-quality data to Abiomed. This strategy offers the least operational and regulatory friction, enabling scalable integration that

supports SCAI shock prediction, addresses data silos, and drives both patient outcomes and strategic growth. The biggest challenge from this angle would be scaling, but the JnJ network and resources could be leveraged to achieve this.

## Chapter 5: Conclusion

This chapter synthesizes the findings from Chapters 3 and 4, discussing the implications of the machine learning (ML) model for (SCAI) shock stage prediction and EMR, and providing recommendations to enhance Abiomed's strategic position in acute myocardial infarction complicated by cardiogenic shock (AMICS) management.

### 5.1 Discussion

The machine learning (ML) models developed in this work—averaging feature importance across XGBoost, Random Forest, and CatBoost—revealed a consistent hierarchy of predictors for SCAI shock stage classification. Across all models, the number of inotropes and vasopressors administered emerged as the most influential variable, closely followed by lactate levels, a well-established marker of tissue perfusion and shock severity. While these findings validate the physiological relevance of lactate in cardiogenic shock (CS) management, they also highlight a deeper issue: the models are highly sensitive to treatment-based variables that reflect physician decision-making rather than the underlying progression of shock itself.

This raises a critical question: Are these models predicting the true physiological severity of shock, or are they simply capturing a record of how aggressively clinicians have already chosen to intervene? When variables like inotrope use dominate the model, the output risks becoming circular—effectively predicting a patient's shock stage based on the treatment decisions that assigned them to that stage in the first place. This feedback loop could limit the model's utility in proactively identifying candidates for Impella support or guiding timely escalation, as it

becomes a retrospective assessment of clinical actions rather than an early warning of physiological decline.

In practice, this means SCAI shock stages—while useful for retrospective classification and research standardization—may fall short as real-time clinical decision tools. SCAI stages primarily codify the severity of shock once it has already been identified and managed, rather than offering proactive insight that could shift treatment earlier in the deterioration curve. As such, SCAI shock is best viewed as an academic framework, valuable for study design and outcome comparison, but less suited for driving bedside interventions in dynamic clinical environments.

Moving forward, Abiomed’s focus should shift from SCAI shock as a predictive endpoint toward real-time physiological markers. Integrating continuous variables—such as lactate trends, left ventricular ejection fraction (LVEF), and cardiac power output (CPO)—may offer more actionable insights. These data points could enable the development of tools that prompt early identification of patient deterioration before shock fully manifests, potentially improving survival rates by supporting earlier escalation to mechanical circulatory support.

This reorientation of focus is essential if Abiomed aims to improve its capture of eligible patients. By reducing reliance on SCAI shock as a downstream, treatment-confirmed state and emphasizing upstream, physiologic indicators of decline, Abiomed can better position its technology as a proactive solution within the AMICS care pathway.

The second focus of this thesis explored the feasibility of Electronic Medical Record (EMR) integration within Abiomed’s digital ecosystem. The findings indicate that while multiple

pathways for EMR integration exist, ranging from direct hospital interfaces to third-party data aggregation partnerships, the purpose and value of such integration remain interpreted differently across Abiomed's internal teams. Stakeholder interviews revealed that various groups—ranging from field representatives to digital solutions leadership—see distinct benefits, from streamlining charting workflows to enhancing real-time patient monitoring. However, a consistent, unified vision of why EMR integration is strategically essential has yet to be fully articulated across the organization.

From this assessment, two key conclusions emerge. First, EMR integration is technically feasible and can be achieved through scalable partnerships or internal development. Second, and more importantly, the strategic purpose of this integration needs to be clearly communicated and aligned across Abiomed's teams to ensure focused implementation.

Based on this research, the most compelling opportunity for EMR integration is to support more robust, data-driven outcome reviews with hospitals. By linking Impella performance data directly with hospital EMR records, Abiomed can generate comprehensive outcome reports that demonstrate the real-world benefits of early mechanical circulatory support. These reports can serve as powerful tools to drive hospital adoption of standardized protocols, particularly the NCSI shock protocol, which centers on the early deployment of Impella support in patients with acute myocardial infarction complicated by cardiogenic shock (AMICS).

In practice, this could allow Abiomed to transition from offering just a device to supporting full shock care pathways, with EMR-integrated data validating adherence to protocolized care and showcasing improved patient outcomes. By replicating the NCSI's

reported 71% survival-to-discharge rates across hospitals through protocol adoption, Abiomed can not only drive better clinical outcomes but also significantly expand its market penetration, turning retrospective trial success into a repeatable, scalable standard of care.

Ultimately, EMR integration should not be pursued merely as a technical upgrade or operational efficiency. Instead, it should be positioned as a strategic enabler to:

- Institutionalize standardized shock care protocols.
- Demonstrate the value of early Impella use through real-time, verifiable data.
- Support hospitals in achieving NCSI-like outcomes on a national scale.

Aligning the organization around this vision will be critical for successful execution and sustained growth.

## 5.2 Recommendations

Based on the findings of this research, two key recommendations are proposed to guide Abiomed's strategy in advancing cardiogenic shock (CS) management and expanding its market presence. First, the development of SCAI shock prediction models should shift focus from classifying shock stages after deterioration has occurred to proactively supporting early clinical decision-making. Rather than emphasizing SCAI stages as an endpoint, future models should be designed to nudge physicians to collect and monitor key physiological indicators, particularly lactate levels, earlier in the patient's care. Lactate remains one of the most reliable markers of tissue perfusion and shock severity, and prompting its timely measurement would allow clinicians to identify potential Impella candidates sooner and escalate care before patients progress to severe, irreversible stages of shock. This approach moves SCAI shock beyond an

academic framework and positions it as a real-time decision-support tool that drives earlier intervention, ultimately increasing both patient survival and pump utilization.

The second recommendation is for Abiomed to pursue EMR integration through third-party data aggregation partners. This method offers the most practical balance of cost, speed, and regulatory efficiency. Established third-party aggregators already have the necessary technical infrastructure and regulatory approvals, which would allow Abiomed to minimize its internal development efforts and avoid the most burdensome FDA approval processes. By outsourcing EMR integration, Abiomed can leverage Johnson & Johnson's resources to rapidly scale across hospital systems, creating a broad and sustainable network of connected hospitals without overextending internal teams. However, the ultimate strategic value of EMR integration extends beyond operational efficiency. The greater opportunity lies in using this connectivity to drive the widespread adoption of standardized shock protocols, such as the National Cardiogenic Shock Initiative (NCSI) protocol, across the medical industry. With improved data access and analytics, Abiomed could help hospitals consistently implement early shock intervention strategies, directly increasing Impella utilization and improving patient outcomes. Together, these recommendations present a unified vision for combining machine learning tools and EMR connectivity to not only enhance patient care but also significantly expand Abiomed's impact and market share in the treatment of cardiogenic shock.



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