Axia Healthcare Consortium Project 1

Axia Institute: Delivering Value Chain Solutions®

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Contents

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The exponential growth of multiple edge technologies (barcodes, sensors, RFID, etc.) has made it necessary to build an integrated system to access, manage, process, and share healthcare records securely across the value chain. However, the healthcare technology available does not provide a complete solution due to privacy, security, and entire ecosystem interoperability limitations. In this landscape, interoperability is a significant factor in delivering reliable exchanging resources across the value chain considering patient-driven data. The grand challenge is to develop capabilities of different information legacies systems, devices, and applications to access, exchange, and integrate data flows within and across organizations, considering regional and national boundaries, to provide seamless interconnectivity and optimize the health of individuals and populations globally. The goal is to remove barriers and shift from the silo perspective to facilitate data exchange while protecting individual privacy.

Relevancy for Axia – The Axia Institute focuses on solving grand challenges and conducting cross-disciplinary research in Value chains. The Healthcare value chain requires finding innovative ways to integrate and create a seamless and transparent operation between stakeholders. Axia's proposal promotes "value chain thinking" to achieve efficiency and effectiveness in the overall process of delivering the proper care to the patient. Axia has defined the healthcare industry as one of its strategic verticals and built the Axia Healthcare Consortium. In December 2021, Axia held a virtual meeting with different participants across the healthcare value chain to learn more about current issues and opportunities. The Institute then reconvened with healthcare consortium partners at the end of January 2022 to present a portfolio of proposed research initiatives, as shown in Figure 1. This project charter outlines the first project of the project portfolio, and it will be described in the following sections.

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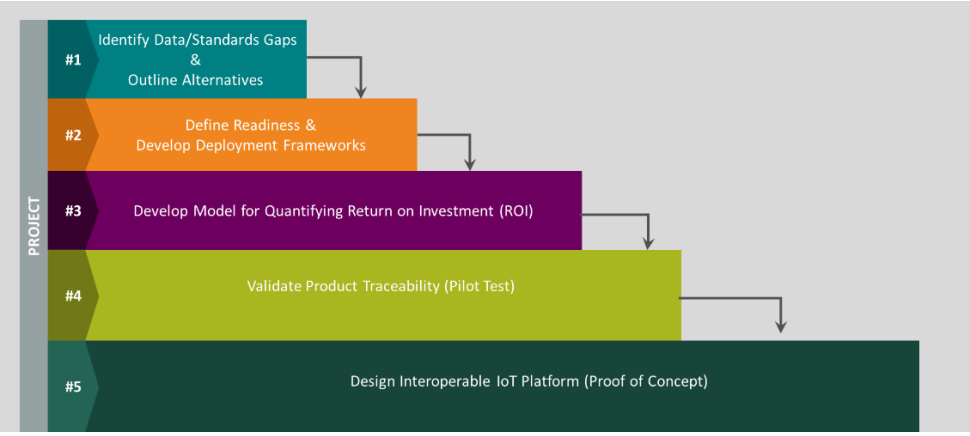

Figure 1 Axia Healthcare Consortium Research Portfolio for Data Interoperability in the Healthcare

Problem statement - To date, a comprehensive systematic literature review of research on value chain interoperability in healthcare that specifies extensive metrics, trends, and challenges is missing or has been partially addressed. This study will provide comprehensive state-of-the-art data interoperability with a developed taxonomy and current challenges across the healthcare value chain. To this end, our study aims to answer the following research questions:

• What are the significant dimensions metrics behind interoperability in the healthcare value chain?

• What research scopes exist for data interoperability in the healthcare value chain?

• How a taxonomy for current technologies, approaches, and challenges for data interoperability should be built into the healthcare value chain?

Significance of the study - Smooth data exchange across the value chain is the highest priority for healthcare organizations. Achieving interoperability grants multiple stakeholders in the healthcare value chain access to rapidly collect, combine, and share electronic health information and securely boost patient-centric requirements. However, numerous incompatibilities and variations in data standards, lack of adequate financial resources, data breaches, and legacy systems represent the significant limitations to achieving steady and robust interoperability. This study will provide value chain stakeholders with a baseline interoperability maturity to document gaps for a desired future state, through rigorous research in the following pillars:

- Providing a holistic baseline interoperability maturity by gathering the disparate systems, different software platforms, and document management systems across the value chain.
- Identifying structural interoperability by defining structure or format and data standardization required for operation to ensure data exchange is consistent and straightforward for sharing between systems.
- Building semantic interoperability across the value chain to leverage data standardization.

Most all healthcare value chain stakeholders will benefit from the results of this project.

II. Project Business Case

A. Grand Challenge

Developing a robust interoperability framework to classify existing technologies, challenges, and trends taxonomically across the healthcare value chain will boost the understanding of the data-driven patient integration. The main challenge is to build a reliable framework to understand, characterize, and develop

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interoperability holistically across the value chain. Outlining open-source platforms that provide stable and robust connections across the value chain with appropriate standards will offer smooth communicability among different technologies and applications.

Literature Review - Multiple studies have highlighted that scalability poses a significant challenge in dealing with non-homogeneous data schemes, data center infrastructure, and other adaptive I.T. architectures. Interoperability and standardization for large-scale applications are challenges in the healthcare domain (Miyanaga, Jabbar, Ullah, Khalid, & Khan, 2017; PwC, 2022; Gupta, 2021). Current studies show that even though there is a comprehensive range of implementation of ERP systems in the healthcare value chain, there is still a substantial gap between the information managed in the system and the data required in terms of quality, completeness, and reliability (Ellingsen, 2011). Different studies mentioned the difficulties of data extraction and ensuring data quality and the various approaches to tackle them. Furthermore, several studies emphasize no evident robustness of the data management in the healthcare spectrum (Ullah, 2017; Renner, 2001; Hamilton, 2006; Marais, 2021; Sivasangari, 2022). (Ullah, 2017; Renner, 2001; Hamilton, 2006; Marais, 2021; Sivasangari, 2022). Moreover, essential stakeholders have highlighted and developed different initiatives to build vocabulary and terminology standards, procedures, and certifications, such as the Trusted Exchange Framework and Common Agreement, The U.S. Core Data for Interoperability, The ONC Interoperability and Information Blocking Final Regulation, and the ONC Interoperability and Information Blocking Final Regulation (HIMSS, 2022).

A wealth of research found in the literature focused on examining data production, data management, and data sharing. The commonality is treating fragmented data that cannot circulate or be aggregated regardless of their origins (Star, 2000). Data is mainly generated in localized work. In a collaborative work setting, the data is analyzed on an ongoing basis; it requires a constant understanding of the original data and recontextualized for different applications for proper reuse. Scholars have examined various standardized schemes and dictionary approaches to data to create standardized data elements. However, attaining semantic interoperability demands that all value chain entities involved can exchange standardized coded data (Jardim, 2013; Borgman, 2015; Desai, 2016; Blobel, 2009; Eklund, 2008; Aldwean, 2022; Rajawat, 2022; Venaik, 2022). Regulations, incompatible systems, and fragmented health records provoke slow I.T. developments, and it represents a challenge for data exchange (Mani & Prakash, 2022; Jain & Jat, 2022; Chabani & Chabani, 2022).

Other studies have shown how a lack of collaboration and data sharing between the healthcare stakeholders is visible; hence, most of the data are in silos databases with limited accessibility in patient-centric applications (Pirtle C, 2018). Moreover, additional challenges highlight security issues in data management with a growing number of data breaches and malicious attacks (Singh, 2022; Mani V. &., 2022; Anand, 2022).

Current initiatives - The Food and Drug Administration (FDA) will insist pharma stakeholders comply with interoperability requirements by November 27, 2023, the deadline mandated in the U.S. Drug Supply Chain Security Act (DSCSA). According to the DSCSA, the transaction information (T.I.) must include the product identifier (i.e., serial numbers and expiration dates). Thus, the U.S. pharmaceutical supply chain will use the Electronic Product Code Information Services (EPCIS) as the standard for the industry[1]. Office of the National Coordinator for Health Information Technology (ONC) has launched a new initiative called USCDI+ with three pillars: (1) collaboration across federal partners, health care providers, and the health I.T. community, (2) harmonization of adopted data sets, standards, implementation specifications, and certification criteria, and (3) Specification to ensure that the use and adoption of standards[2]. However, a holistic value chain interoperability analysis represents underdeveloped research in the literature.

Research Methodology - Our research study will not solely be a technology topic. It will consider technical and business —clear measures of financial metrics and business motivations—aspects of achieving data interoperability to patient-centric long-term solutions.

1. *Survey* - Axia will survey about 100 technology executives from providers, manufacturing, suppliers, analytics leaders at health systems, and other stakeholders in the healthcare value chain with a specific volume of operation to be determined. The sample size has been determined assuming: (1) a population of 20,000 companies, (2) a confidence level of 90%, and (3) a margin of error of 8%.
2. *Interviews* - Axia will conduct ten interviews to investigate these issues in more depth. Interviewees will include health systems leaders, regulators, associations, Health I.T. experts, and technology providers. The difference between the survey approach and the in-depth interview value will be to ingest unstructured information about how stakeholders know about future trends, current constraints, and challenges. Interview-based research will enable us the development of new frameworks.
3. *Survey Structure -* This survey will gather systematic information on the three major phases in the data management scope across the healthcare value chain: i) Data generation: from different stages in the value chain to collect and generate the necessary data from various sources and devices. ii) Data processing: gather different applications for data analysis tools. ii) Data consuming: required by decision-making performed by different stakeholders in the value chain. The study will evaluate the status of the Integration of internal data platforms, entities, and processes across the value chain to measure the level of seamless and timely external exchange, streamlined access to information for health care stakeholders, and access to and insights from health data. The survey will consider three pillars: Data Dimension Metrics, taxonomy, and current challenges, as described in the following paragraph.

Metrics dimensions- The survey will gather and analyze seven dimensions metrics across the value chain, as shown in Figure 2.

Figure 2 Metrics Dimensions

a) *Accuracy* is a significant issue in healthcare systems; gathering information on how precise the current system captures and completes data regardless of technology represents valuable information regarding the existing capability and the potential gaps.
b) *The performance* will be assessed by measuring efficiency in collecting accurate data, processing the data, and different parameters such as throughput, latency, etc.
c) *Interoperability's* current state will be assessed by measuring the current level of exchange data accurately, consistently, and effectively.
d) *Security and privacy* are crucial; the capability to protect data, preserve privacy, and prevent unauthorized access will be measured.
e) *Scalability's* capacity will be measured by estimating the current expanding capability based on ongoing and future I.T. projects. The study will gather data from existing network infrastructures, new hardware or services required.

f) *Reliability* will be measured through the current system's ability to perform tasks successfully under different hypothetical conditions

g) *The cost* has multiple borders. The study will gather as much information as possible referring to the cost of data management, such as computational price, data storage, etc.

Taxonomy- Literature and healthcare data is widely diverse, and the survey will provide systematic arranging of relevant research and data collection. Our proposed taxonomy will classify the data gathered as shown in Figure 3, which will be evaluated in terms of the dimensions metrics such as accuracy, performance, reliability, time, cost, etc.

Figure 3 Taxonomy

a) *Sensor-based data* captured will be the information regarding all the technologies such as Barcodes, Quick Response (Q.R.) Code and other sensing technologies such as Radio Frequency Identification (RFID) are used in healthcare settings.

b) *Resource allocation applications* will gather to capture the resource heterogeneity applications with current data technology. This survey subsection will focus on optimal and efficient resource utilization and resource allocation.

c) *Communication technologies* will collect information about the healthcare system that uses different technologies such as specifically smart mobile, RFID infrastructure, and WSN for tracking and monitoring.

d) For *healthcare applications*, the survey will bring together information about application-based approaches. We will focus on prediction, detection, monitoring, and recommender systems developed, ongoing, or planned for implementation.

e) For *Security-based applications*, the survey will gather the current accessibility, privacy, authentication, and confidentiality approaches.

f) For *Standard-based*, the survey will collect the current data standards for format, structuring, tagging, transmission, manipulation, use, and data management.

g) For Regulation, the questions will focus on collecting the I.T. current application and data generated to comply with reporting requirements for federal and state agencies

Data Challenges- The third pillar will collect the current challenges for interoperability, mobility, scalability, trust, privacy, energy management, and future trends, as shown in Figure 4.

Figure 4 Challenges

4. Healthcare Dashboard Interactive Platform

The study will perform comprehensive data analytics, including descriptive analytics, correlation analysis, and high-level graph visualization. All the results will show in an Interactive Dashboard.

Applicability based on industry needs. - Literature shows a consensus that interoperability is beneficial, and that the technology is available. However, there exists an understanding that the healthcare industry is too far from reaching systemwide interoperability.

B. Alignment & Relevancy

Alignment- The Healthcare value chain continuously focuses on enhancing quality production, preventing drug shortages, and ensuring adequate supplies, as shown in the literature and recent practitioner studies. However, there is a consensus among the Healthcare stakeholders that interoperability is crucial for the long-term and sustainability. Our proposed research is fully aligned with all the stakeholders across the value chain. Lowering the cost of care, improving customer experience, and enhancing patient outcomes are linked to robust and resilient data interoperability.

C. Value Created

The following outlines the expected value created by the project:

Economic benefits - The study will provide a baseline for the healthcare stakeholders with a comprehensive comparison of technologies (Categorization of recent papers in the technology-based approaches), evaluation techniques, tools, and metrics. Also, it will consist of a high level of visualization with an interactive dashboard for decision-makers. This tool will be accessible to Axia members.

Impact on scientific knowledge - This study will provide a systematic literature review based on only JCR-indexed journal articles to identify, compare systematically, and classify existing investigations and build a taxonomy for the Healthcare value chain.

Societal benefit – According to the Government Accountability Office (GAO), many health providers are still manually matching patients' data, and data is often imprecise, inadequate, and/or inconsistently formatted. This study will provide more knowledge and insights to evaluate potential alternatives to evidence of the direct and indirect economic and social benefits of data access and sharing, such as increasing transparency, traceability, and empowerment of users.

D. Project Deliverables

Deliverables

1. A report on the results of the Survey
2. A report on the results of the Interviews
3. Publish the results of the Systematic Literature Review on one of the targeted peer-reviewed journals:
    a. Journal of Industrial Information Integration IF 10.063
    b. Sustainable Cities and Society IF 7.587

c. International Journal of Information Management IF 14.098

4. A comprehensive report summarizing the findings and developing a *Healthcare Dashboard Interactive Platform*

Milestones

Early-stage milestones

1. Design approval of Project Charter
2. Project Planning

Mid-project milestones

1. Completing critical tasks
2. Receiving feedback from stakeholders

Final stages milestones

1. Testing
2. Defects Fixing

III. Project Plan

A. Scope

This study will develop a statistical representative model of the entire Healthcare Value chain analysis by mapping and responding to the constraints and opportunities. The complexity of the private health sector is reflected by its fragmentation in the relations between companies of different service providers, product suppliers, manufacturers, policymakers, government ministries, and consumers.

Limitations of the project:

- The study defines three research questions; however, other problems can be proposed.
- The study describes seven dimensions of metrics and taxonomy with seven components; other classes might be possible.

B. Technical Advisory Board (TAB) Meeting Deliverables

- TAB #1: Data Collection-Survey-Interviews
- TAB #2: Summarize the Findings
- TAB #3: Healthcare Dashboard Interactive Platform
- TAB #4: Final Report

C. Assumptions and risk (see Appendix A)

D. Action Plan (see Appendix B)

IV. Budget

A. Detailed budget

- Provide detailed funding by:
  - P.I.: Carlos Marino: 60 % time
  - Co-PI: Richard Spreng - 16 hours per month

- Co-PI: Chris Brown - 20 hours per month
- One Graduate student for Data collection and Data Analytics
- Software: ATLAS.ti.

V. Project Ecosystem

A. Champions (Identified by Axia leadership team)

Sponsor Champion – Axia Consortium members

- Technical Champion – TAB member TBD.
- Jeanne Sirovotka from F.K.

B. Team Members/Collaborators

- P.I.: Dr. Carlos A. Marino: He has extensive experience as a senior data scientist. Before his role at A.I. Millennium Lab, he worked for the Department of Defense in the U.S. Air Force Operations Research & Supply Chain, A.I. Division. Carlos has also held supply chain positions at Nestlé and Coca-Cola. In this position, he will work with Axia Institute staff and researchers from across MSU and other collaborators while leading the Institute's value chain digitization efforts. Carlos earned his Ph.D. in Industrial and Systems Engineering from Mississippi State University. He also earned an M.A. in Transportation & Logistics Management Reverse Logistics from the American Military University and his M.S. in Engineering Management from California State University. He has a Professional Engineering (P.E.) License in California and earned a Graduate Certificate in Data Science from Harvard University.
- Collaborators:
  - Richard Spreng: He is an Associate Professor of Marketing. He received his Ph.D. in Marketing from Indiana University in 1992. Previously he was a Regional Operations Manager for a retailing and importing firm. He has published over 60 articles in publications such as Journal of Marketing, Journal of Consumer Research, Journal of Retailing, Decision Sciences, Journal of Product Innovation Management, Journal of the Academy of Marketing Science, Journal of Service Research, Psychology, and Marketing, and various conference proceedings. Dr. Spreng's primary research interest is consumer satisfaction/dissatisfaction and post-purchase evaluation. His research has focused on the determinants of satisfaction, including measuring key satisfaction variables. At Michigan State, Dr. Spreng has taught retailing, sales management, and consumer behavior at the undergraduate level, customer-driven strategies at the MBA level, and the weekend MBA program. Dr. Spreng's consulting experiences have included marketing research for various government, education, and business organizations. He specializes in helping organizations develop customer satisfaction measurement systems. He has conducted research for numerous public, private, and nonprofit organizations. Dr. Spreng is also co-founder of SureVista Solutions, LLC, a marketing research firm specializing in customer satisfaction measurement systems. Clients include hospitality, retailing, education, government, and nonprofit organizations.
  - Chris Brown RFID Subject Matter Expert, TSC Printronix Auto ID – He has been part of the AIDC industry for over 20 years. He has extensive global expertise with large manufacturing and supply chain companies and RFID technology specializing in encoding and numbering standards. As an active member of several AIM and RAIN RFID workgroups, Brown has been a vocal participant in helping to identify, discuss, and educate on industry challenges. Brown's work has included extensive insights into the RFID numbering systems specified by the ISO and GS1 standards. Brown recently published an article in the RFID Journal, introducing the industry to the basics of ISO-based RFID encodings. Brown's contributions have advanced our mission to help our partners and customers deploy high-quality RFID solutions while furthering AIM's mission to bring cooperation, development, and standardization of AIDC technologies.

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Appendix A: Risk Management

Deliverable & Risk	Probability	Severity	Mitigation Plan
First Quarter (after project kick-off) Deliverable: Data Collection-Survey-Interviews Risks: ○ Collecting data and literature with bias ○ No gather representative data	Low	High	Task 1: Pre-Survey Task2: Data collection by applying statistical parameters rigorously.
Second Quarter Deliverable Deliverable: Summarize the Findings Risks: ○ Considering systematic error. ○ Applying effects outside the context of the study.	Medium	High	Task 3: Applying statistical tools to measure study robustness.
Third Quarter Deliverable Deliverable: Healthcare Dashboard Interactive Platform Risk: ○ No risk if the data collection is accurately	Low	Medium	Task 4: Building a basic Dashboard.
Fourth Quarter Deliverable Deliverable: Final Report Risk: ○ No risk if the data collection is accurately	Low	Medium	Task 5: Manuscript Draft Task 6: Final Report

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Appendix B: Action Plan

Tasks/Actions	Milestones/ Deliverables	Timeline
Task 1	Data Collection	June – July 2022
Task 2	Interviews	July- August 2022
Task 3	Findings	August- September 2022
Task 3	Publication draft	October-November/2022
Task 4	Dashboard Interactive Platform	November-December 2022
Task 5	Final Report	December 2022

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ABOUT THE AXIA INSTITUTE

Located in Midland, The Axia Institute®, formerly the Midland Research Institute for Value Chain Creation, is a premier research and education center dedicated to developing effective and sustainable solutions to improve public and private value chains. Established by Michigan State University in 2013, The Axia Institute® partners with industry to solve grand challenges and conduct cross-disciplinary research in areas of value chain optimization, data analytics, engineering, smart packaging, anti-counterfeiting, and water and food safety. The Institute was founded by leaders in value chain creation and development at MSU, including the Eli Broad College of Business, the College of Agriculture and Natural Resources, the College of Engineering, the College of Social Science, and the School of Packaging. Founding donors include The Dow Chemical Company, Dow Corning Corporation, Herbert H. & Grace A. Dow Foundation, Rollin M. Gerstacker Foundation, The Dow Chemical Company Foundation, and the Charles J. Strosacker Foundation.

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