**CROSS-ENTERPRISE DOCUMENT SHARING (XDS) IMPLEMENTATION BASED ON BLOCKCHAIN TECHNOLOGY**

**PETNATHEAN JULLED**

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Thesis

entitled

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|  | …………………………………….......  Mr. Petnathean Julled,  Candidate |
|  | …………………………………….......  Assadarat Khurat,  Dr. –Ing. (Computer Security)  Major advisor  …………………………………….......  Pattanasak Mongkolwat,  Co-advisor  …………………………………….......  Asst. Prof. Thitinan Tantidham,  Dr.rer.nat. (Computer Science)  Co-advisor |
| …………………………………….......  Pattanasak Mongkolwat,  M.D., Ph.D. (Biochemistry)  Dean  Faculty of Graduate Studies  Mahidol University | …………………………………….......  Assoc. Prof. Vasaka Visoottiviseth,  Ph.D. (Computer Engineering)  Program Director  Master of Science Program in Cyber Security and Information Assurance  Faculty of Information and Communication Technology  Mahidol University |

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|  |  |
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|  | …………………………………….......  Mr. Petnathean Julled,  Candidate |
|  | …………………………………….......  Assadarat Khurat,  Dr. –Ing. (Computer Security)  Major advisor  …………………………………….......  Pattanasak Mongkolwat,  Co-advisor  …………………………………….......  Asst. Prof. Thitinan Tantidham,  Dr.rer.nat. (Computer Science)  Co-advisor |
| …………………………………….......  Pattanasak Mongkolwat,  M.D., Ph.D. (Biochemistry)  Dean  Faculty of Graduate Studies  Mahidol University | …………………………………….......  Assoc. Prof. Vasaka Visoottiviseth,  Ph.D. (Computer Engineering)  Program Director  Master of Science Program in Cyber Security and Information Assurance  Faculty of Information and Communication Technology  Mahidol University |

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I would like to thank the entire respondent who was the sampling in this study…………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

Petnathean Julled

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| CROSS-ENTERPRISE DOCUMENT SHARING (XDS) IMPLEMENTATION BASED ON BLOCKCHAIN TECHNOLOGY  PETNATHEAN JULLED 5936474  M.Sc. (CYBER SECURITY AND INFORMATION ASSURANCE)  THESIS ADVISORY COMMITTEE: ASSADARAT KHURAT, Ph.D.,  PATTANASAK MONGKOLWAT, Ph.D., THITINAN TANTIDHAM, Ph.D.  ABSTRACT  On the increasing demand for better quality of healthcare service, there is the topic that involve healthcare information technology in term of operation efficiency. Healthcare information sharing and interoperability between healthcare organizations is one of major solution to improve healthcare service quality. But, there still many challenge inhibit the solution to become reality. There found initiatives to standardize healthcare information sharing method. To address issue about health document sharing between different enterprises, Integrating Healthcare Enterprise (IHE) initiative have proposed Cross-Enterprise Document Sharing (XDS.b) Profile. The profile allow the adopted organizations to share health document between each other simultaneously.  As well as other industry, there also emerging cyber-security threats threatening healthcare information domain. These threats increase difficulty to development of health information sharing network and causing damage to healthcare enterprises. These cyber-threats can cause damage to the industry in many aspect, especially those cyber-attack that targeting integrity and availability of data. These kind of cyber-attack can severe the continuity of medical operation which potentially can result as the cost of patient’s life. There are many solutions technology proposed to deal with these kind of cyber-attacks. One of the technology that on the trend to deal with cyber-threats threatening integrity and availability of data is Blockchain technology.  There are several researches and concepts that proposed about using Blockchain technology to solve health information sharing issue. But there still many limits prevent Blockchain technology to effectively integrated with data like health information. In this work, we propose another approach for integrate Blockchain technology with health information. We see that standard like IHE XDS.b profile could be use with Blockchain technology to allow health document sharing through decentralized network while address cyber-security issue through unique characteristics of Blockchain technology.  KEY WORDS: HEALTH INFORMATION / INTEROPERABILITY / INFORMATION SHARING / INFORMATION SECURITY / BLOCKCHAIN / SMART CONTRACT / IHE / XDS  40 pages |

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**LIST OF ABBREVIATIONS**

**ตัวอย่างหน้าบทคัดย่อภาษาอังกฤษ**

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| XDS | Cross – Enterprise Document Sharing | 1 |
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# CHAPTER I

# INTRODUCTION

On the increasing demand for better quality of healthcare service, there is the topic that involve healthcare information technology in term of operation efficiency. Healthcare information sharing and interoperability between healthcare organizations is one of major solution to improve healthcare service quality. Patient’s health document data are scattered across different healthcare organizations, due to the foundation of healthcare informatics are separately developed by different organizations. Each healthcare organizations have their own method to process and handle healthcare information. This make it hard for one healthcare information to interoperate with other. To enable health information sharing from just one organization with one another can cost much more than benefit they can gain. This even did not regard concern about business value. Sharing health information with not fully-trusted party exposing vulnerabilities to business model. The risk that benefit the organization gain from sharing their patient information with other may not sustain the risk and cost they need to take. This create high friction for one organization to share their information with others. It even more difficult for individual patient to integrate their healthcare between different providers. It revealed that these interoperation problem cause huge decrease in efficiency on healthcare operation and result as lower quality of healthcare service (Carestream Health, 2015; Dr.David Hay, n.d.; Healthcare Information and Management Systems Society, 2013; HIMSS, n.d.; Interoperability, 2016; Oracle, 2010; Paige Goodhew, n.d.; PolicyMedical, n.d.).

That why there are many initiative that start to standardize healthcare information technology with the goal to allow healthcare organization to be able to interoperate with each other. Integrating Healthcare Enterprise (IHE) is one of well-known initiative that provide materials for healthcare informatics standardization. IHE provide implementation framework and guideline for developing health informatics system. For health document sharing between different organizations, they provide Cross-Enterprise Document Sharing (XDS.b) profile. The profile act as guideline for system developer to implement their system to meet the requirement where the system can share health document with other organizations. This profile will be the main tool for this work, to deal with health information sharing problem.

# Motivation

In the current age of information digitalization, cybersecurity has become an issue for many organizations and individual. Anyone can become a target of cyber-attacks. Amongst many kind of organization, healthcare industry is one of major target that become victim of cyber-attacks each year (Le Bris & Asri, 2017). Followed by digitalization of hospital operation and information system, amount of cyber-attack and variation rise as the technology developed. These incidents variant from breached in personal health information to larger size of attack which can potentially halt hospital operation for a period of time. Halted in operation surely cause damage in various kinds. It may cost hospital for more than million, or even cost individuals’ life as a result of the incident for the worst.

There are many kinds of incidents targeting healthcare industry. In recent years, one of major incidents found throughout the industry is hospital data breach. Data breach often appeared in a form that hospital data got compromised by hacker unnoticed by hospital employees. The compromised data can be valuable in dark market as it can be further used for various kind of more advanced attacks like identity theft, blackmailing, or social engineering, due to these data mostly included patients’ personal information and their health condition. This kind of incident can potentially cost hospital ‘a trust’ from their customer if they showed a poor quality of incident mitigation, as individuals’ safety and privacy are being put on the stake. Also, there are the case that not just gain unauthorized access to patient’s private data but, take over the data or even wipe all important data out of existence. ‘Ransomware’ and ‘Wipeware’ are the main cause of these threats. Ransomware take over an ownership over data away from hospital system and encrypt all the data which often take an important roles on hospital operation. At the same time, Wipeware will delete all the data from the victim machine. This mostly cause great disruption on hospital operation as consequence. Incidents that showed up in recent years seem to target healthcare organization more frequently, as the industry still have poor cybersecurity practices (Healthcare IT News, n.d.-a). Many incidents (Healthcare IT News, n.d.-a, n.d.-b; HIPAA Journal, n.d.) showed that social engineering launched on healthcare employees are on risen. The threat have potential to seamlessly blend into hospital workflow and made it hard to be noticed. However, follow these incidents, many stakeholders in healthcare domain start to implement cyber-security to their organization infrastructure.

At the foundation, each organization must start with educating their employees on cyber-security awareness to reduce risk of cyber-incident that may cause by human error or human vulnerabilities. Next, define organization policy and management plan that help prepare against cyber-incident. When employees and management level of organization have prepared cyber-security, then, the organization will focus on cyber security of technology layer. There are various kind of tools and technology that was invented to mitigate cyber-incidents. Some may have been made to prevent exploitation of existing technology while some may have been made to directly deal with known and upcoming threats.

One of many concept invented to mitigate these threats is decentralization of data. The concept of decentralization was made to mitigate most incident and threat that involve single-point of failure vulnerability. For the case of healthcare industry where loss of patient’s data can cause many major damage to the affected organization and their patient, decentralization of data can help reduce damage caused by the case. There are more than one benefit that healthcare document data can gain from decentralization. Decentralization allow patient’s data that scattered across healthcare domain in different organization to link to each other. As healthcare document data can scattered across different organization within healthcare industry, it also increase a chance that its copies can survive cyber-incidents. Even in case that document in one organization got compromised, there is a chance that copies of compromised data also exist in other organization. The survived copies can make substitute for the original that got compromised. However, this only possible if there are the point that let every organization in the network known which document exist in which organization. This is where the concept of IHE Cross-Enterprise Document Sharing Profile fit in. Combined with Blockchain technology that make the Document Registry entry persist and immutable, this ensure that every organization in the network will always know whereabouts of document they need within the network while the entry itself cannot be tempered or deleted by any actor with ill intention.

This work will introduce another way to allow health document sharing between healthcare organizations with increased protection against cyber-threats, by using combination of Blockchain and IHE Cross-Enterprise Document Sharing (XDS.b) Profile.

# Problem statement

To allow sharing of healthcare document between different healthcare organizations which require maintain of its confidentiality while mitigate emerging cyber-threats on healthcare domain that tamper with integrity and availability of data, there need document registry that have distributed, decentralized, persistent, and immutable characteristics.

# Objective

# 1.3.1 Design and implement Document Registry Blockchain that follow requirement for document registry defined in XDS.b integration profile from IHE.

1.3.2 Design and implement Blockchain smart contract that give main function to Document Registry Blockchain as healthcare document registry.  
 1.3.3 Design and implement Blockchain smart contract that give additional function to record healthcare document exchange between participate node.  
 1.3.4 Deploy and evaluate functionality of Document Registry Blockchain.

# 1.4 Scope of project

# 1.4.1 Design and implementation of Document Registry Blockchain that followed requirement defined in XDS.b integration profile from IHE. 1.4.2 Design and implementation of Blockchain smart contract within Document Registry Blockchain that give main function as healthcare document registry and additional function as healthcare document exchange history record.

# CHAPTER II

# LITERATURE REVIEWS

**2.1 State of Cyber Security and Cyber Threats in Healthcare Domain**

**2.1.1 Digital transformation of healthcare**

Transition from the age of paperwork, healthcare industry is now undergoing digital transformation. Efficiency and continuity is the main factors that driven healthcare industry to change. Paperwork start falling behind when the huge amount of data are produced by healthcare service operation from day to day. Health information undeniably becoming an important component on developing efficient healthcare service. (Bullhound, 2015; Cisco, 2017; Marcelo et al., 2018; Meskó et al., 2017; Shaw et al., 2000; Weinelt, 2016)

**2.1.2 Interoperability of healthcare information**

One of major issue that are common amongst healthcare industry is the issue about interoperability between each unit of healthcare system. Especially, the interoperability between different organizations. Lack in interoperability, prevent many opportunities for healthcare service quality improvement. Patient may need to take extra repetitive care procedure when visit new hospital. Mistake in communication between different physicians can cause misdiagnosis. So, there are many demand from patient side that want their health journey to be connected together and allow improvement in healthcare service quality. However, interoperability is extremely difficult issue for each single organization to solve. The foundation of healthcare informatics was developed separately by each organizations. Each system have their own design and method to handle health information. That mean there still have open issue on how to solve interoperability in the field of healthcare. (Carestream Health, 2015; Healthcare Information and Management Systems Society, 2013; Interoperability, 2016; Oracle, 2010)

**2.1.3 Assets in healthcare domain and cyber-security risks**

In order to define effective risk mitigation plan, the first step is to identifying key assets that require protection against cyber threats. In healthcare domain, the most critical asset is patients’ health. Patients can be permanently or temporarily injured through direct actions such as launching attack to turn off critical active medical devices or indirect actions aiming at disrupting care such as altering patient health records, compromising medical information systems, or cutting off power supply in operating room; can cause harmful consequence toward patients’ health (Le Bris & Asri, 2017).

The next important asset in healthcare domain is patients’ health record. This record mostly contains valuable information personally identifiable information (PII) included social security number, health care provider information, credit card information, name, address, date of birth, etc. Patients’ health record also contains protected health information (PHI) which potentially included information about patients’ physical or mental health condition, and etc. which can be used to identify the patient. This mean, Patients’ health record can potentially be used for variety of harmful activities included identity theft, insurance fraud opportunities, social engineering, or even terrorism.

Availability of healthcare services is also a major asset in healthcare domain. There are two distinct categories: critical services and administrative services. The critical services ensure continuity of care including active/passive medical devices, medicine delivery systems, and surgery equipment. The disruption of these services may result as disaster of patients’ health. The administrative services are services that keep efficiency of healthcare operation included work orders control, medicine management, financial transactions, and medical appointment. It is less critical if the system become unavailable for a short duration of downtime.

In some case, healthcare facilities can host research labs. Activities of research labs will involve intellectual property assets. For example, experimental procedures for surgery, test and studies results, test subject information or drug formulas. These kind of asset can be valuable amongst competitor parties which lead possibility of the assets to become cyber-attacks target. Researchers’ contribution and money invested in the research can be wasted to nothing in the case of successful cyber-attacks. At the same time, alteration of these assets can lead to miserable consequences or even cause negative impact to patients’ health during the research.

Eventually, as patient place their health and their lives in the hand of medical staff. They need to know that they can trust their care provider. Failing to secure the service against cyber-attacks can cause great negative impact to the reputation of the care provider if it disclosed to the public. It can even damage reputation and career of medical staff in the case of identity theft where identity of specific medical staff is used to perform the attack (such as impersonation, credential theft, etc.).

**2.2 Integrating the Healthcare Enterprise (IHE)**

IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively. This help enable seamless and secure access to health information that is usable whenever and wherever needed. IHE providing specifications, tools and services for interoperability. IHE also engages clinicians, health authorities, industry, and users to develop, test, and implement standards-based solutions to vital health information needs. (IHE International Inc, n.d.-a) IHE initiative have purpose to provide convenient and reliable way of specifying a level of compliance to standards sufficient to achieve truly efficient interoperability.

IHE brings together users and developers of healthcare information technology (HIT) in an annually recurring four-step process (IHE International Inc, n.d.-b):

1. Clinical and technical experts define critical use cases for information sharing.
2. Technical experts create detailed specifications for communication among systems to address these use cases, selecting and optimizing established standards.
3. Industry implements these specifications called IHE Profiles in HIT systems.
4. IHE tests vendors’ systems at carefully planned and supervised events called *Connectathons*.

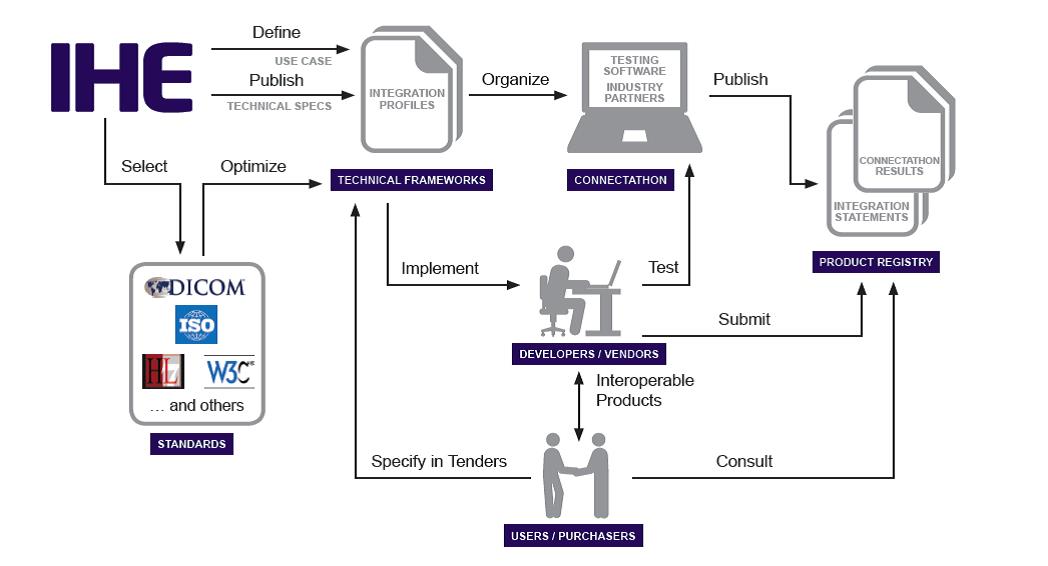


Figure 1 IHE Process to create guideline for implementation of health information technology (IHE International Inc, n.d.-b)

The process ensure that the resulting IHE Profiles provide benefit for implementer and make it compatible with unique environment of healthcare industry.

**2.3 IHE Information Technology Infrastructure (ITI) Technical Framework**

IHE IT Infrastructure Technical Framework (ITI TF) defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. It is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The framework identifies a subset of the functional components of the healthcare enterprise, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. The framework divided into four volumes. The first volume describes concept detail of IHE ITI Integration Profiles. The second volume divided into four sub-volumes; a, b, c, and x which describe concept detail of all transactions present in the framework. The third volume provide further explanation into the specifications of cross-transaction and content used in Document Sharing Profiles. The fourth volume provide additional national extensions related to the framework.

IHE ITI Integration Profiles (IHE Profile) are set of specification and implementation guide that produced from IHE four-step process. These profiles organize and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards, such as DICOM, HL7 W3C and security standards. They provide precise definitions of how standards can be implemented to meet specific clinical needs. (IHE International Inc, n.d.-c) IHE Profile offer a clear implementation path for IT developer to develop and implement IT system for healthcare organization that meet the need and compatible with environment of healthcare industry. At the same time, IHE Profiles also help reduce the cost which can be wasted if organization need to go through trial and error in development of their IT system. The Profile also help reduce workload for IT developer on various kind of communication standard exist within healthcare IT domain.

**2.4 Cross-Enterprise Document Sharing Set-b (XDS.b) Profile**

The Cross-Enterprise Document Sharing Set-b (XDS.b) IHE Integration Profile facilitates the registration, distribution and access across health enterprises of patient electronic health records. (IHE International Inc, 2008) The profile is focused on providing a standards-based specification for managing the sharing of documents between any healthcare enterprises, ranging from a private physician office to a clinic to an acute care in-patient facility. XDS is generic term to reference all XDS profiles which are Cross-Enterprise Document Sharing Profiles. XDS.a and XDS.b are implementation profiles that describe technically how the implementation will be done. XDS-I is an XDS implementation specifically for medical imaging. (dkorolyk, 2012) In IHE IT Infrastructure Technical Framework Vol.1 latest published in 2018 declared that term XDS within the ITI Technical Framework refers generically to any flavor of XDS, currently only XDS.b. (IHE International Inc, 2008) The main goal of XDS.b profile is to allow XDS Affinity Domain members to share health document via XDS Document Registry. That mean, its process mainly about make metadata of document within XDS Document Repository available on XDS Document Registry entry. This allow any XDS Document Consumer to visit XDS Document Registry and seek for the document they need, before retrieve it from the XDS Document Repository that the document belong to.

**2.4.1 XDS Process Flow**

The process overview of Cross-Enterprise Document Sharing (XDS.b) profile is described in Figure 2. The figure also showed sequence of process along with involving XDS actors and XDS transaction format. At the beginning, each health document will be created from its sources along with its metadata attributes. These sources will be called ‘XDS Document Source actor’ which can be any machine involved in healthcare service. For example, CT scanner, laptop in each physician office, or central computer in medical lab. Next, these created documents along with its metadata will be sent to data storage which act as document repository. These repositories will be called ‘XDS Document Repository actor’ which usually be some kind of computer or server that was assigned to keep medical document available for use. According to XDS.b profile, XDS Document Source will send document metadata in the format of Provide and Register Document Set-b (ITI-41) format. In some case, XDS Document Source and XDS Document Repository may integrated together. This made it called ‘XDS Integrated Document Source Repository actor’. The XDS Integrated Document Source Repository function the same way as XDS Document Source and XDS Document Repository will do but, combined together.

After the document and its metadata was sent to XDS Document Repository, the repository will index and make the document available for usage. At the same time, XDS Document Repository register metadata along with identifier and locator of the repository itself to local document registry. The message transaction in this process will follow format of Register Document Set-b (ITI-42). The document registry will be called ‘XDS Document Registry actor’. XDS Document Registry is software or machine that keep all document metadata and its corresponding repository from all connected repositories available for discovery. Commonly, XDS Document Registry should be database that keep document metadata from all connected repositories available for discovery through database query. However, there are no restriction from XDS.b profile for method to keep these data and how to discover each document metadata using specified document metadata attributes. There are just requirement that require XDS Document Registry to be able to accept value of specified document attributes from XDS Document Consumer and return the matched document to the consumer.

In XDS.b profile, ‘XDS Document Consumer actor’ can be any kind of software or machine that allow user like healthcare employees to access health document or medical document they need. There are no restriction in XDS.b profile that specified XDS Document Consumer actor to be different software or machine from other actors. XDS Document Consumer actor will just require user to specify value of known document metadata attributes which will allow XDS Document Repository to search for matching document metadata in its database. After received document attributes value from its user, XDS Document Consumer actor will send the specified attributes to XDS Document Registry. This message transaction will follow format of Registry Stored Query (ITI-18). Then, XDS Document Registry process received attributes by search for matching document metadata and return full document metadata which it found to XDS Document Consumer. XDS Document Consumer actor show founded result to its user. The user pick the right document they need and issue to XDS Document Repository corresponding to the document for document retrieval via XDS Document Consumer actor. XDS Document Consumer will send document retrieval request transaction in the format of Retrieve Document Set-b (ITI-43). After XDS Document Repository received document retrieval request from XDS Document Consumer, the repository will seek for the specified document and return the document to XDS Document Consumer. XDS Document Consumer actor will make the retrieved document available for user to use.

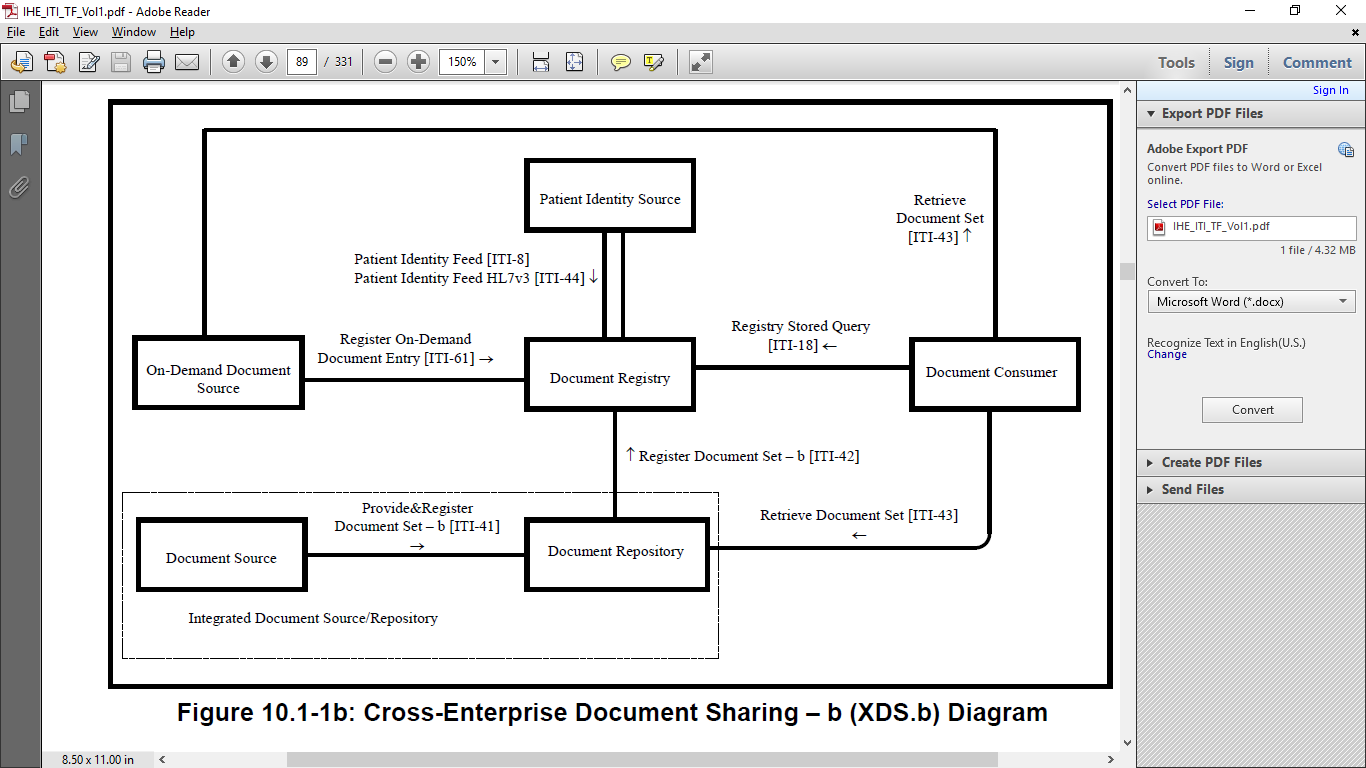


Figure 2 Cross-Enterprise Document Sharing - b Diagram (IHE International Inc, 2008)

**2.4.2 XDS Transaction Format Types**

In XDS.b profile, all messaging transaction will be in the form of XML format with schema depend on each types of transaction. Types of XDS transaction format vary upon involving actors and its purpose.

2.4.2.1 Provide and Register Document Set – b (ITI-41)

Provide and Register Doccument Set – b (ITI-41) transaction format define XML schema for message that send metadata of document from XDS Document Source actor to XDS Document Repository actor for store into document repository. This type of transaction mainly require XDS Document Source to include all available metadata attributes of created document for other XDS actor. XDS Document Repository actor will need to acknowledge to XDS Document Source if it successfully received document and its metadata.

2.4.2.2 Register Document Set – b (ITI-42)

Register Document Set – b (ITI-42) define XML schema for message that send metadata of available document in repository from XDS Document Repository actor to XDS Document Registry actor to register the document into document registry entry. Main purpose of this type of transaction is to pass document metadata stored in repository to XDS Document Registry actor addition with attributes about the repository. XDS Document Registry actor will need to respond back to XDS Document Repository actor when received the transaction and register it to document registry entry.

2.4.2.3 Registry Stored Query (ITI-18)

Register Stored Query (ITI-18) is general XML schema format that used by one actor to query for data from other actor in entire IHE IT Infrastructure Framework. In this work, the transaction will be used by XDS Document Consumer actor to request for document metadata it seek from XDS Document Registry actor. Any document metadata attributes known by XDS Document Consumer will be included in the transaction. XDS Document Registry will use specified metadata attributes to search for matching document metadata inside document registry entry. XDS Document Registry will need to respond to XDS Document Consumer actor that it received the request. XDS Document Registry also need to return search result to XDS Document Consumer.

2.4.2.4 Retrieve Document Set (ITI-43)

Retrieve Document Set (ITI-43) define XML schema for XDS Document Consumer to request document retrieval from XDS Document Repository. Different to other transactions involved in XDS.b profile, Retrieve Document Set transaction only contain few essential attributes to allow retrieval of document from document repository. XDS Document Repository will need to acknowledge to XDS Document Consumer when received the transaction before return the requested document.

**2.4.3 Transaction Object Type and Attributes**

In each transaction, there are set of metadata attributes that represent the document. These metadata attributes are categorized to three sections. SubmissionSet represent information associated with submission of document since it was created by the source. Folder represent group that the document belong to. DocumentEntry represent the document itself.

2.4.3.1 SubmissionSet

Table 1 SubmissionSet Metadata Attributes

|  |  |
| --- | --- |
| **SubmissionSet Metadata Attributes** | **Description** |
| author | The humans and/or machines that authored the SubmissionSet. This attribute contains the sub-attributes: authorInstitution, authorPerson, authorRole, authorSpecialty, authorTelecommunication. |
| availabilityStatus | The lifecycle status of the SubmissionSet. |
| comments | Comments associated with the SubmissionSet. |
| contentTypeCode | The code specifying the type of clinical activity that resulted in placing the associated content in the SubmissionSet. |
| entryUUID | A globally unique identifier used to manage the entry. |
| homeCommunityId | A globally unique identifier for a community. |
| intendedRecipient | The organizations or persons for whom the SubmissionSet is intended. |
| limitedMetadata | A flag that the associated SubmissionSet was created using the less rigorous metadata requirements as defined for the Metadata-Limited Document Source. |
| patientId | The patientId represents the primary subject of care of the SubmissionSet. |
| sourceId | Identifier of the entity that contributed the SubmissionSet. |
| submissionTime | Point in time at the creating entity when the SubmissionSet was created |
| title | The title of the SubmissionSet. |
| uniqueId | Globally unique identifier for the SubmissionSet assigned by the creating entity. |

2.4.3.2 Folder

Table 2 Folder Metadata Attributes

|  |  |
| --- | --- |
| **Folder Metadata Attributes** | **Description** |
| availabilityStatus | The lifecycle status of the Folder. |
| codeList | The set of codes specifying the type of clinical activities that resulted in placing DocumentEntry objects in the Folder. |
| comments | Comments associated with the Folder. |
| entryUUID | A globally unique identifier used to manage the entry. |
| homeCommunityId | A globally unique identifier for a community. |
| lastUpdateTime | Most recent point in time that the Folder has been modified. |
| limitedMetadata | A flag that the associated Folder was created using the less rigorous metadata requirements as defined for the Metadata-Limited Document Source. |
| patientId | The patientId represents the primary subject of care of the Folder. |
| title | The title of the Folder |
| uniqueId | Globally unique identifier for the Folder. |

2.4.3.3 DocumentEntry

Table 3 DocumentEntry Metadata Attributes

|  |  |
| --- | --- |
| **DocumentEntry Metadata Attributes** | **Description** |
| author | The humans and/or machines that authored the document. This attribute contains the sub-attributes: authorInstitution, authorPerson, authorRole, authorSpecialty and authorTelecommunication. |
| availabilityStatus | The lifecycle status of the DocumentEntry |
| classCode | The code specifying the high-level use classification of the document type (e.g., Report, Summary, Images, Treatment Plan, Patient Preferences, Workflow). |
| comment | Comments associated with the document. |
| confidentialityCode | The code specifying the level of confidentiality of the documented. |
| creationTime | The time the author created the document. |
| entryUUID | A globally unique identifier used to manage the entry. |
| eventCodeList | This list of codes represents the main clinical acts, such as a colonoscopy or an appendectomy, being documented. |
| formatCode | The code specifying the detailed technical format of the document. |
| hash | The hash of the contents of the document. |
| healthcareFacility TypeCode | This code represents the type of organizational setting of the clinical encounter during which the documented act occurred. |
| homeCommunityId | A globally unique identifier for a community. |
| languageCode | Specifies the human language of character data in a document. |
| legalAuthenticator | Represents a participant within an authorInstitution who has legally authenticated or attested the document. |
| limitedMetadata | Indicates whether the DocumentEntry was created using the less rigorous requirements of metadata as defined for the Metadata-Limited Document Source. |
| mimeType | MIME type of the document. |
| objectType | The type of DocumentEntry (e.g., On-Demand DocumentEntry). |
| patientId | The patientId represents the subject of care of the document. |
| practiceSettingCode | The code specifying the clinical specialty where the act that resulted in the document was performed (e.g., Family Practice, Laboratory, Radiology). |
| referenceIdList | A list of Identifiers related to the document |
| repositoryUniqueId | The globally unique identifier of the repository where the document can be accessed. |
| serviceStartTime | The start time of the service being documented. |
| serviceStopTime | The stop time of the service being documented. |
| size | Size in bytes of the document. |
| sourcePatientId | The sourcePatientId represents the subject of care’s medical record identifier (e.g., Patient Id) in the local patient identifier domain of the creating entity. |
| sourcePatientInfo | This attribute contains demographic information of the source patient to whose medical record this document belongs. |
| title | The title of the document. |
| typeCode | The code specifying the precise type of document from the user perspective (e.g., LOINC code). |
| uniqueId | Globally unique identifier assigned to the document by its creator. |
| URI | The URI for the document. |

**2.5 Blockchain Technology**

Blockchain is a list of records, or “blocks”, that are linked to one another and cryptographically secured (Luke et al., 2018). Blockchain is a technology that allows data to be stored and exchanged on a peer-to-peer basis. Structurally, Blockchain data can be consulted, shared and secured thanks to consensus-based algorithms (PwC, n.d.). Blockchain is a sequence of blocks, which holds a complete list of transaction records like conventional public ledger (Zheng et al., 2017). Blockchain is tamper evident and tamper resistant digital ledgers implemented in a distributed fashion and usually without a central authority. At their basic level, they enable a community of users to record transactions in a shared ledger within that community, such that under normal operation of the Blockchain network no transactions can be changed once published (Yaga et al., 2018). Participants in a Blockchain network have records of every transaction and these records are stored locally on the computers of all participants in that Blockchain network. Any kind of regime or protocol change to a Blockchain network requires consensus between the users of the network. In 2008, the Blockchain idea was combined with several other technologies and computing concepts to create modern cryptocurrencies which is electronic cash protected through cryptographic mechanisms instead of a central repository or authority.

This technology became widely known in 2009 with the launch of the Bitcoin network, the first of many modern cryptocurrencies. In Bitcoin, and similar systems, the transfer of digital information that represents electronic cash takes place in a distributed system. Bitcoin users can digitally sign and transfer their rights to that information to another user and the Bitcoin Blockchain records this transfer publicly, allowing all participants of the network to independently verify the validity of the transactions. The Bitcoin Blockchain is independently maintained and managed by a distributed group of participants. This, along with cryptographic mechanisms, makes the Blockchain resilient to attempts to alter the ledger later (these include modifying blocks or forging transactions). Blockchain technology has enabled the development of many cryptocurrency systems such as Bitcoin and Ethereum. Because of this, Blockchain technology is often viewed as bound to Bitcoin or possibly cryptocurrency solutions in general. However, the technology is available for a broader variety of applications and is being investigated for a variety of sectors. (Yaga et al., 2018)

According to the document “Blockchain Technology Overview” which published by National Institute of Standards and Technology from U.S. Department of Commerce, Blockchain can be informally define as: A distributed digital ledgers of cryptographically signed transactions that are grouped into blocks. Each block is cryptographically linked to the previous one (making it tamper evident) after validation and undergoing a consensus decision. As new blocks are added, older blocks become more difficult to modify (creating tamper resistance). New blocks are replicated across copies of the ledger within the network, and any conflicts are resolved automatically using established rules.

**2.5.1 Key components of Blockchain**

2.5.1.1 Transaction and ‘Block’

Each of individual information represent change or cause of actions in information system are stored within Blockchain as “Transaction”. Several transaction being publish to Blockchain within the same time interval are put in the same “Block”. To form each single block, miner or validator need to hash transaction together. The resulting hash value represent integrity of each blocks. If there are any change apply to transaction in the block, it will cause hash value of the block to change. Format of block vary depend on each Blockchain platform and its use case. Some platform may published in a form of plaintext just to act as the source of truth for every participating node to look without constraint. Some platform may bound transaction or block to unique address to extend variation in accessibility. Some platform may encrypt block to maintain confidentiality of data. Transaction and Block are the key component which determine purpose and application of Blockchain.

2.5.1.2 Cryptographically hashed ‘Chain’

Other than the concept of “Block”, The Blockchain concept also introduced the concept of “Chain. As integrity of each Block represent by its hash value, integrity of entire Blockchain represent by all hash value of all Block within “Chain”. The foundation of “Chain” concept is by chaining hash value of all block together. This can be done by include hash value of block formed in previous time interval into the current block to generate its hash value. Any changes made to any one single block will alter hash value of the entire chain that come after. This make it harder to alter data that published within Blockchain. It require anyone who want to alter the data to apply change to all block that come after the target block until the current one to make the change valid. Combined with decentralization characteristic of Blockchain network, this make data exist in Blockchain nearly impossible to alter.

2.5.1.3 Distributed network of participate ‘Node’

Any machine participate in the Blockchain network are call “Node”. Node represent population of each Blockchain network. Each node keep the exact same copied of data in Blockchain. If there are any different in data between nodes, the version of data being held by minority of participating node will be clarify as false and will not be accepted by the entire Blockchain network. In each Blockchain network, some node may participate as miner or be elected as validator of the network at each different time interval. Miner node and validator node have duty to perform task assigned by the network to maintain its consensus. The Blockchain can be alive only if there at least one participating node maintain it, while strength of its immutability depend on number of participating node. More participating node mean stronger immutability.

2.5.1.4 Consensus

Each Blockchain network have its own method to maintain consensus within the network. Consensus mostly maintain by let participating node to perform computational task upon publishing of every block. There are many variation of consensus invented. The most commonly used method is Proof of Work (PoW). Proof of Work require miner node to solve mathematical problem before allow it to publish Block of current time interval. For example, in the most notable Blockchain network like Bitcoin, the Proof of Work require miner node to randomly find ‘nounce’ number that included in Block and result as hash value with selected amount of ‘0’. The task can only be performed effectively by investing computational resource. Only the fastest node that found the right ‘nounce’ number by chance can validate block at the time interval. This guarantee that there are no specific miner to process any specific block exist in the network, render man-in-the-middle attack to become nearly impossible in Blockchain (this is not included data in transition before reaching Blockchain).

**2.5.2 Key characteristics of the Blockchain**

Key characteristics of the Blockchain can be vary depend on its setup and environment of usage. According to many sources, key characteristics of the Blockchain may be summarized as followed:

2.5.2.1 Decentralization

Decentralization is the foundation of Blockchain technology as response to problem of centralized system. In centralized system, especially centralized database, there is a chance that the database got compromised by hacker. Other than rely on backup data, there are very few options to deal with the incident. This make the compromised database become single point of failure which prevent follower system to operate. Decentralization of data was proposed to scatter the chance of single database from getting compromise. This make decentralized database network have more resistant against incident threatening centralized data. Even hit by incident that aim to compromise the data. If at least half of decentralized network survived the incident, the data survive the attack.

2.5.2.2 Immutability

With utilization of cryptographically hashed chain combined with decentralized network, the Blockchain technology ensure that any data published on Blockchain cannot be deleted or modified. If there are any modification made to content of published data, it will cause change on the hash chain and detected the network. Any action that cause change to hash chain will be negate by majority of the network. This mean if anyone want to temper with published data on Blockchain, they will need to compromise the entire network at once. Any survived node have chance to notify the abnormal to the entire network.

2.5.2.3 Transparency

As the foundation of Blockchain is to have all participant nodes have the exact same copy of Blockchain ledger, it passively give transparency to published data. It is impossible for anyone to secretly hide something inside Blockchain without let other participants in the Blockchain network know.

2.5.2.4 Distributed

Blockchain have distributed characteristic by design. All node will have exactly the same Blockchain ledger. Any content published to Blockchain ledger are passively distributed to all Blockchain node. With consensus algorithm, it require that the publishing content either sent to all nodes before accept to publish or being accepted then send to all node, to complete consensus. So, Blockchain ensure that any data published to the chain are distributed to all connected node.

2.5.2.5 Trust

In public network where anyone can participate or in permissioned network where participants are not completely trust each other, trust is the main factor that define usability of decentralized network. Along with Blockchain technology, consensus solve the issue about trust by eliminate the chance of any single node participate in Blockchain to have absolute control over publishing data when certain condition are met. It can rely either on randomness or specially designed algorithm depend on each consensus method. When none of any single node can have absolute control over publishing data on the Blockchain, made it extreme difficult for someone to temper with target data. Many consensus method ensure that it will much more expensive for anyone to attempt on tempering with publishing data when compare to benefit they can get. This passively establish trust between all participant nodes.

**2.5.3 Blockchain variant and community – move public private here**

Followed the trend about decentralizing data, many Blockchain communities has been developed and growth respectively. Each platforms and communities have their own technical design and use case. Many Blockchain platform developed specifically to use as cryptocurrency while other was created to act as backend infrastructure of various applications.

**2.6 Ethereum** **and Smart-Contract**

Ethereum are one of well-known open source Blockchain platform. The platform initially invented by developer named Vitalik Buterin and further develop by Ethereum community. Main approach of Ethereum Blockchain is about use Blockchain technology for application other than cryptocurrency. The platform proposed concept about ‘smart contract’.

**2.6.1 Smart Contract**

The concept of smart contract was initially proposed by Ethereum. Now the word ‘smart contract’ become common word to describe feature that allow developer to design the content that publish to Blockchain and its computational behavior. In Ethereum, smart contract code written with Solidity programming language. Smart contract define what behavior the contract will do when open/view by user. Smart contract rely on Ethereum Virtual-Machine (EVM) which allow host machine of Ethereum client to be able to execute smart contract Solidity code. EVM was designed to allow portability of Ethereum platform and always packed with Ethereum client. Now there are many interface tools developed by Ethereum community that allow Ethereum client to work with major programming languages. This further extend usage of smart contract to infinite possibilities.

**2.6.2 Solidity – Ethereum Blockchain programming language**

Solidity is javascript-like programming language that specifically design to use with Ethereum smart contract. The main purpose of the programming language is to act as the middle between human-understandable language and computer language. It reduce difficulty for developer to design behavior of their smart contract on Ethereum Blockchain. The language is update and maintain by Ethereum community.

**2.7 Related Work**

There are many research proposing about decentralize healthcare information with Blockchain technology. The goal of decentralization and implementation of each work have many variant. These are several works that proposed interesting idea and concept about implement healthcare informatics system based on Blockchain technology.

**2.7.1 A Blockchain-Based Approach to Health Information Exchange Networks** (Peterson et al., 2016)

The work proposed about using Blockchain like central hub for health information exchange. The main goal of this Blockchain concept is to connect all bread and crumb of patient health information together by allow participate node to discover health information data they seek and its location within Blockchain ledger. Increase interoperability in health information exchange. Their main contribution is the concept that suggest use of FHIR health information exchange standard combine with Blockchain technology. Each transaction on Blockchain will contain FHIR locator of actual data along with its index which make each transaction available for search. Due to the limit of health information that it require certain amount of confidentiality, this make it not really compatible with platform open to public like Blockchain. Store actual data somewhere else outside Blockchain and put its locator into Blockchain for use. With known secure index, this Blockchain help connect patient information that scattered across healthcare industry together. The work also gave suggestion about how health information Blockchain should look like and what it should have by common. There also other major contributions that proposed about using secure index for searching on encrypted data and ‘Proof of Interoperability’. This work suggest that if health information are kept within Blockchain in encrypted form, it should also contain secure index which will allow data search even the data is encrypted. This should reduce the difficulty of implementing health information with Blockchain. And other major concept proposed in this work is ‘Proof of Interoperability’. Based on Proof of Work consensus, the work suggest that computational resource should not be wasted unnecessarily. Instead of put computational resource to competition for consensus, it should be used to verify interoperability of participate health data instead. However, they didn’t proposed about how the consensus should work in detail. This work gave a good example of how Blockchain can have potential to solve issue that common in healthcare industry like interoperability. Additionally, they also proposed many concepts that can be a good foundation for using Blockchain technology with health information.

**2.7.2 A Case Study for Blockchain in Healthcare: “MedRec” prototype for electronic health records and medical research data** (Ekblaw et al., 2016)

Main goal of MedRec is to provide Blockchain that act as a middle for health information exchange while allow Blockchain participants to gain benefit from participation. They chose Ethereum as Blockchain platform for the system. Ethereum provide smart contract and address based access for the work. This work assume that miner/validator nodes are health institution that have demand for large amount of health information data to use in their research. Miner/validator node will be rewarded with anonymized health data which can be used in research involve health data analysis. Additionally, MedRec proposed about allowing patient to have consent about usage on their data. Give more control over individual health data. The work also adopted cryptographic key scheme proposed by Zyskin et al. (Zyskind et al., 2015), to ensure that only authorized party can access patient health information published on Blockchain. Additional to these main contributions, they also gave suggestions about factor that should keep continuity of Blockchain and how Blockchain element provided by platform like Ethereum can be useful. One of interesting concept is about using Ethereum address as patient identifier. Due to all identity exist on Ethereum Blockchain are assigned with unique address, these unique address can reduce complexity in patient identifier management if designed properly. MedRec gave a good example of concept that needed to maintain continuity of Blockchain network by allow participant to gain benefit from participation in some way. At the same time, MedRec is another good example that using Blockchain technology to aid health information exchange issue. And the last, MedRec have shown flexibility of smart contract and how it can be useful when implement with healthcare information.

**2.7.3 Blockchain-Based Data Preservation System for Medical Data**(Li et al., 2018)

This work proposed about using Blockchain to keep data that need to have confidentiality preserved. Regardless of what kind of data, this Blockchain allow user to design what data they want to keep in Blockchain. The chosen data will be encrypted before publish into Blockchain. The goal of this Blockchain concept is to preserve medical data inside Blockchain away from any tempering attempt while keep it secret and always available for its owner. Instead of let data available to public, this work have demonstrated how Blockchain technology can be used in different approach like keeping medical data available to only authorized entity.

# CHAPTER III

# METHOD

This chapter will explain about method of how the Blockchain was designed to operate under IHE XDS.b profile process flow. The chapter is separated to three parts. The first part introduce about architecture design and roughly define how we integrate Blockchain components into IHE XDS.b profile process flow. The second part will explain the first part further into the aspect of Blockchain components. This part will more focus about how we adopt and setup existing Blockchain platform to match our requirement for usage in our scenario. The last part will further explain the first part in term of integrating IHE XDS.b profile with Blockchain. This part focus on how we create and adapt each components in our work to meet the requirement specified by IHE XDS.b profile.

**3.1 A Use Case Scenario**

As shown in *Figure 1*, user at Hospital A needs to start with specifying value corresponding to XDS META-data attributes (Patient name, ID, etc.) that unique to the event specific for Mr.Bob and use it to search for associated registry using Document Registry Searcher program. Document Registry Searcher uses specified values to find for registered META-data attributes set in smart-contract. When matched, Document Registry Searcher returns the whole META-data attributes set of those matched one to the user at Hospital A. In this case, it may return more than one registry set that associated with Mr.Bob. User at Hospital A may need to seek for the one with latest timestamp or the one they needed to use. When the registry set was picked, they may need to use repository URI included in META-data attributes set to request for actual document in Hospital B. After that, Hospital B will response by allow Hospital A to access content of the document.

Due to unique nature of healthcare environment that emphasizes on confidentiality of data, this cause limit in implementation of the technology in the environment. Patient data cannot be put directly into Blockchain as it will become persistent by decentralization of Blockchain network as well as it will become more difficult to ensure confidentiality of data when its replica are distributed over the entire network [25], [36], [37]. We propose another approach to make the technology more compatible with implementation on healthcare information. IHE XDS.b Profile serves its purpose as central hub for health document exchange between different enterprises. This makes the profile best compatible with Blockchain technology as it will secure availability of health information exchange. In this implementation, we further extend the usability of the profile by allowing the organization that shared health documents from its source to act as data backup for the original by providing additional access points (URLs) for the document. This increases the survival chance of medical operation continuity when one organization compromised by ransomware as they may have a replica of data available on others in the network.



Figure 3 Use case scenario flow chart

**3.2 Network Design**

In our scenario, we declare that participants of the network are members of XDS Affinity Domain which assumes to be hospitals and healthcare institutions. Each member will need at least one computational machine to keep operate and maintain Blockchain ledger, thus becoming ‘Blockchain Node’. As the Blockchain allows only XDS Affinity Domain members to participate as node, so this Blockchain will be classified as permissioned chain. And for networking protocol between each node in the network, it relies on the adopted Blockchain platform invented by provider or community.

**3.3 Blockchain Components and Consensus**

The main components of Blockchain comprise of the backbone engine which allows the network to form, operate, and maintain Blockchain ledger addition with consensus mechanism which maintain integrity of the network. In this work, we adopt Ethereum Blockchain platform as engine to operate components regarding cryptographical components forming ‘Block’ and ‘Chain’, Blockchain networking, actor identifying, transaction mapping, and maintaining the ledger. By ensure integrity of every ‘Block’ and ‘Chain’ identified by its hash value, this guarantees that no one can ever be able to modify anything published to Blockchain. This made all data within Blockchain to become persistent and always available to access if most of the network still exist. That means even if there are incident happened to one node, it will have no effect on the chain which is an advantage gaining from Blockchain compared to centralized database. Additionally, with the extend usage of XDS.b, the more times document got shared with node members mean the more alternative data backup for the source of the document. Even the source got compromised, they still have the document available to those network members who shared the document before the incident happened.

For consensus, it needs to be the consensus that can process large amount of Blockchain transactions at certain time due to continuous nature of medical operation and the loss of even single transaction is unaffordable. At the same time, it cannot be those mechanisms that consume excessive amount of computational resource from each node as most of participant will have limited resource to invest in Blockchain network. Combined with nature of permissioned chain which allow only selected participant to participate as node, this led the design to rely on consensus that based on majority of participant nodes are being reliable. i.e., PBFT. This kind of consensus require at least 2/3 of participant node to approve authenticity of transactions block being publish into the chain. The mechanism took the key role which guarantees that no one will be able to attempt modifying any publishing transaction before it entered the chain. The concept passively ensures that every data published in the chain was not differed from the original version introduced to the network by its owner. With these main components of Blockchain combined, it guarantees integrity of data from the moment it was introduced to the network until it successfully published into the chain as transaction and remain there as it became persistent and immutable in the network. All these mechanisms gave transparency in process of publishing data and keep it in the Blockchain, generate ‘trust by design’ for the network.

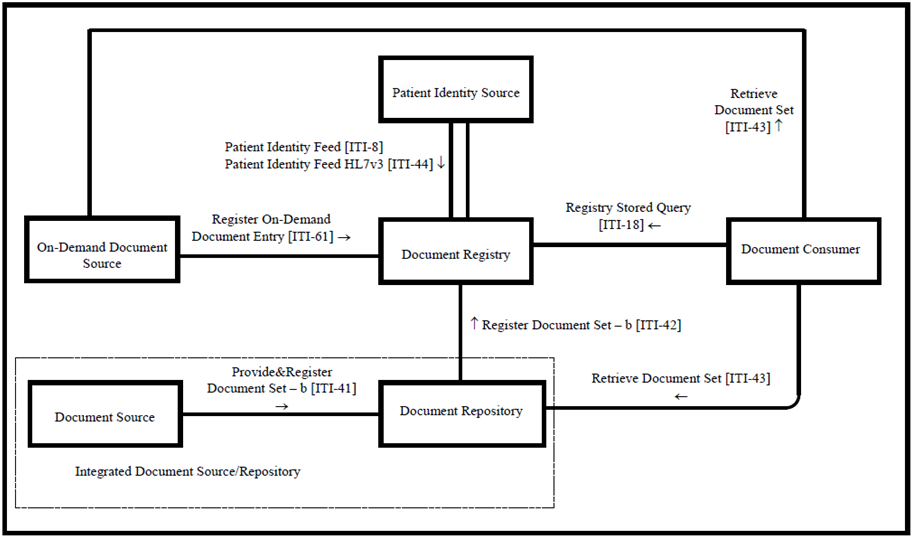
**3.4 Establish foundation of trust amongst the networks**

Foundation of ‘trust’ was formed from its core components in Blockchain. However, as strength of Blockchain rely on number of participants being reliable node, there still need a method to recruit new participants into the network. Blockchain participant nodes must be verified by member of the network before allowed to participate and interact with Blockchain. This can be done by establishing agreement or policy that requires the applicant to comply. It will vary depend on business model and common of interest amongst potential participant of the network. With an aid of ‘trust by design’, there are less factors to consider for joining the network in technical term. In this work, we assume that common of interest of the network is to be able to share their health document with each other using XDS.b Profile while ensure that the central registry created by the profile cannot be compromised by any kind of incident as if majority of the network was not affected. Then this allows the network to have health document sharing available even some amount of its members became victim to cyber incidents.

**3.5 Integrating Blockchain with XDS.b**

In IHE ITI Technical Framework, they specified that XDS Document Registry actor who act as hub that registered all essential information about all health documents generated and kept by XDS Affinity Domain, should be a database that allows Document User to query for information of health Document they seek. The existing solution for the database is utilization of SQL or non-SQL centralized database. In this work, we propose replacing of these centralized databases with Blockchain ledger as shown in *Figure 4*. According to *Figure 2*, our Blockchain design will take the role of Document Registry. That means each Blockchain node will keep, operate, and maintain copy of Blockchain ledger that contains entire health document registry entry. Following guideline provided by IHE ITI Technical Framework, all nodes will receive ITI-42 transaction from its local Document Repository. The node then interprets the transaction and convert it into Blockchain transaction before broadcasting it to all nodes in the network via Blockchain protocol. At the same time, every node will interpret ITI-18 transaction from Document Consumer and query for information of health document via Smart-contract. For current work, we assume that ITI-61 transaction will be further implement to the Blockchain concept in the future. Additionally, we assume that patient identification was standardized amongst all the network beforehand, so it eliminates the need of ITI-44 transaction in our implementation. In summary, data content that going to be published into Blockchain is META-data attributes of available health document which specified information essential for health information sharing software complied with IHE XDS.b Profile to discover and retrieve document in other enterprise.

Compare to original Cross-Enterprise Document Sharing Framework (XDS Framework), we replaced traditional database for XDS Registry Actor with blockchain ledger. With blockchain applied, this new XDS Registry now gained blockchain characteristics. Immutability keep XDS Registry persist as the network still exist. All members within XDS Affinity Domain always have up-to-date version of XDS Registry as distributed characteristics of blockchain force every member to maintain the same copy of ledger at all time. With decentralization and consensus mechanism deployed, the blockchain network now gain transparency in Block addition process and can be guaranteed that no one have absolute right to manipulate transaction in blockchain at their own will. This given the foundation of “trust” which allows different healthcare enterprises to share their documents with each other even they are not fully trust one another. Additionally, to allow compatibility of new XDS Registry to be able to operate with existing XDS transaction of XDS Framework, we also implemented XDS transactions interpreter to act as the middle between original framework and blockchain. This allow our new XDS registry blockchain to work almost seamlessly with existing system currently complied to XDS Framework.



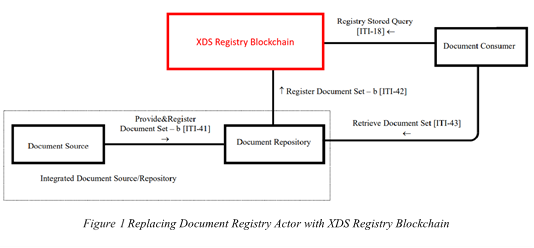


Figure 4 Comparing XDS Registry Blockchain Design (Bottom) with original XDS.b (Top)

**3.6 XDS Blockchain and Smart-contract Design**

As shown in *Figure 5*, Smart-contract will be the main component that takes the role to keep all set of META-data attributes containing information of existing health document in the network Each set of information differentiated by characteristics of its original document, within Blockchain ledger. When Document Registry Searcher program was triggered by ITI-18 transaction, it will perform iteration search on all META-data attributes set existing on the chain. All matched set will return as query result to Document Consumer as a list for its user to pick the one they needed. After the user picked the set they needed, user-side program within Document Consumer will trigger Smart-contract to return the whole set of META-data attributes of the selected set. Eventually, user-side program will use information provided by retrieved META-data attributes to access actual document in its repository in document owner hospital.

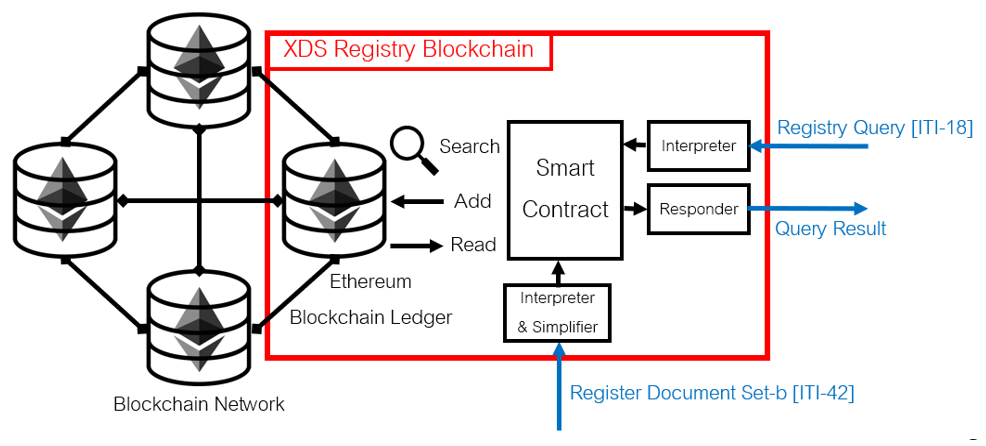


Figure 5 Overview of the design to integrate Blockchain with XDS.b Profile Framework

**3.7 An augmentation to mitigate data-corruption incident**

In original XDS Framework, the sole purpose of the framework is to allow health document sharing between different enterprises. In this work we also propose utilization of Blockchain technology to further help in mitigation against data-corruption incident like ransomware or wipe-ware. It is almost impossible that one organization can absolutely guarantee that they will not be affected by any cyber-incident forever so, a data backup will always be needed to ensure the availability of data to allow continuity of operation even if the organization was hit by cyber-incidents. Our implementation allows an alternative investment in data backup by allowing other node members who shared the document to act as decentralized data backup driven by the need for health information sharing. That means the document source may need lesser investment on their data backup to secure availability of the data while achieving the benefit of document exchange for increasing in healthcare operation performance. This can be done by requiring those members node to use their XDS Repository to act partially as data-backup for one another in the blockchain network. After certain nodes have retrieved a copy of the health document from another node using the information provided in the XDS Registry. XDS Repository of the node with a replica of shared health document simply needs to update additional access pathway for the copy into the registry of the original document within XDS Registry (shown in Figure 5) as to provide an alternative pathway to access the document. By doing so, even the original repository affected by data-corruption incident and lost data of the original document, there still have alternative pathways to access copy of the document available. Consider healthcare operation which requires huge amount of health information sharing by nature, a lot of available alternative pathway for health document can be expected in actual deployment. This concept will help member of the network in better mitigation against raising cyber-incident that cause data-corruption. The more they share their information with other, the more alternative copy of certain health document become available. This concept further motivates the network to maintain XDS Blockchain and share their health document with one another, empowering healthcare industry and its cyber-security performance.

# Chapter IV

# IMPLEMENTATION

This chapter will focus on technical explanation on concept implementation. This chapter divided into three parts. The first part introduce about XDS Toolkit which is the source of XDS transaction sample for our implementation and also act as validation tool to verify if our implementation comply to XDS.b profile. The second part will explain about technical setup of Blockchain platform for our implementation. The third part then jump to implementation of software that act as component to integrate Blockchain to XDS.b process flow. These software will act as the middle between function of XDS Document Registry actor and function as Ethereum Blockchain node. The last part will explain behavior of smart contract that we designed in technical aspect.

**4.1 XDS.b Profile review, requirement gathering, and transaction analysis**

For an adaptation of IHE XDS in this work, we assumed that XDS Domain focuses only on exchanging stable health documents and XDS affinity domain members are using a shared patient identifier. This means if following Figure 1, On-Demand Document Repository Actor and Patient Identity Feed Actor can be excluded from our implementation which reduces the complexity of concept demonstration. At the same time, XDS Document Sources Actor will also be excluded from our scope of interest as it is not directly interacting with our implementation of the Blockchain concept. In this work, we required to substitute the relational database of the XDS Document Registry Actor with the Blockchain ledger. This Blockchain implementation needs to have most of the capabilities that a common relational database could do included adding, query, retrieve, and update. However, insert and delete operation may not be able to achieve due to the limitation of Blockchain which makes it impossible to remove data from its ledger or replace its sequence and the main purpose of implementing IHE XDS with Blockchain is to make it immutable. The Blockchain needs to be able to operate seamlessly with XDS Document Registry Actor. XDS Document Registry Actors in this implementation must have interoperability with XDS Document Repository Actors and XDS Document Consumer Actors while having these actors modified from specification in IHE ITI Framework at least possible. This should allow a simpler adoption process for those organizations with IHE XDS already implemented.



**Figure 6 XML Code snippet of Registry Document Set-b [ITI-42] transaction sample**

**4.2 Acquiring IHE ITI transaction samples**

As to test if this implementation can operate with XDS Actors in a common XDS system, we use transaction samples provided by the IHE ITI framework with modified attributes value to evaluate the system. Transaction samples provided by the framework are including ITI-42 Register Document Set-b transaction, ITI-18 Registry Stored Query transaction, and its corresponding response transaction. However, these transaction samples have limited capabilities as an example due to much more specification provided in the framework so, there is some transaction need to be defined manually from example and requirement provided in the framework.

**4.3 XDS Document META-data attributes analysis**

META-data attributes are those attributes value and elements used to describe its original health document which allows interoperability between each actor in IHE ITI Framework. The attributes mainly compose of attributes that describe originating of the document, information related to event represented by the document, document identifier, information of patient participating the event, information of healthcare personal and facility performing the event, document location, communication protocol in healthcare domain for document interpretation, and document technical information. Having META-data attributes allow XDS Actor to discover and exchange health document from other actor within its affinity domain. In our adaptation of XDS, XDS Document Registry Blockchain must be able to response to query from XDS Document Consumer Actor with specified META-data attributes value as search keyword.

**4.4 XDS Document Registry Blockhain process flow**

The flow is separated into two parts including document registering and document query. For document registering, XDS Document Repository Actor register document META-data attributes into XDS Document Registry Actor using IHE ITI-42 transaction. XDS Document Registry Actor then interprets the transaction into a programmable object before check if the transaction is ITI-42. Then, the actor proceeds to pass the retrieved object into Blockchain smart-contract and publish it into a Blockchain ledger. For document query, XDS Document Consumer query for document META-data attributes stored within XDS Document Registry Blockchain providing search operation type and some META-data attributes value as search keyword via ITI-18 transaction. XDS Document Registry will check if the transaction is ITI-18 before performing search operation matching specified search type using provided keyword META-data attributes value. The search operation will be performed by consequently call for each registered smart-contracts until all contracts with matched attributes value were found. XDS Document Registry Actor then returns all query result in XML format following specification for ITI-18 responding. Upon receiving the query response, XDS Document Consumer then interprets the transaction and displays the result to the user in a human-understandable format.

**4.5 Define Blockchain environment requirement**

According to our use case scenario, each Blockchain node will be maintain by hospital or healthcare institution. Each maintainer may have more than one Blockchain node active depend on their usage of XDS Document Registry Actor on actual situation. For this implementation, we declare that each Blockchain node represent one of hospital or healthcare institution participate as XDS Affinity Domain members due to limited computational resource for demonstration. Following the design in chapter IV, it is better to use consensus which require small number of node and require as low as possible resource to maintain.

**4.6 Blockchain setup**

To directly command the behavior of each Ethereum Blockchain node, we require the "Geth" client which allows the user to issue commands to the node like start-stop mining and start sync Blockchain data with other nodes. For programming smart-contract, Ethereum providing a web-based IDE for Solidity language that can compile and deploy smart-contract to local Ethereum node called “Remix” [38]. To interface our program to Ethereum smart contract, we can use Ethereum API tools which is Web3 [39] as a middle. Web3 allows smart contract control through preferred programming language and transitions logic and variables from the language to Solidity. Then, the Blockchain platform is ready for smart contract design and implementation of the XDS.b profile

**4.7 Choosing consensus and Blockchain components**

Consider scenario and Blockchain environment, so we choose to use Practical-Byzantine False Tolerance (PBFT) as consensus for Blockchain. PBFT suit best with permissioned Blockchain with known members. The consensus can maintain Blockchain with small number of validator node. Fortunately, there is Ethereum forked named “Quorum” which allow usage of consensus other than Proof of Work and Proof of Stake. In Quorum, PBFT was modified to suitable with Ethereum and being called “Istanbul-Byzantine False Tolerance (IBFT)”. Quorum provided “7 nodes example” which act as simulator for actual Quorum network with 7 active validator nodes that can be used for demonstration of proposed concept.

**4.8 Utilize Quorum**

Quorum is a Blockchain platform forked from Ethereum with the goal to expand the usability of Ethereum Blockchain for a wider variety of environments regard consensus and its member nodes. Following our design, Quorum can help reduce complexity in utilizing Ethereum smart-contract under PBFT consensus for the work. Quorum also provides virtual "7-Nodes" environment which comprises seven virtual Blockchain nodes for concept demonstration

**4.9 Define XDS Document Registry Actor**

In the implementation of this work, XDS Document Registry actor will be the main actor that will be converted from using common database to use Blockchain ledger to keep associated data. The software program must be able to communicate with XDS Document Repository actor and XDS Document Consumer actor. At the same time, the software will need to act as the middle between XDS system and Blockchain. Then, Blockchain platform is ready for smart contract design and implementation of XDS.b profile.

**4.10 Utilize Javascript with NodeJS**

As we have seen from HL7 and FHIR, current healthcare information exchanged related standards are majorly web-based protocol. Additionally, development of IT infrastructure to support healthcare operation require the capability to handle a huge amount of transaction in a limited amount of time so, it requires our system implementation to be able to handle multitask properly. With asynchronous nature and compatibility with website integration, Javascript is one of the best choices for our implementation of this work. In this implementation, we adopt the "Node.js" variant of Javascript as it was made to build scalable network applications that handle many connections concurrently. Furthermore, Node.js also providing simple access to community-made node modules which offer a wide variety of useful APIs for software development which may reduce difficulty in our implementation further.

**4.11 Utilize Web3JS**

As mentioned in F, Web3 also provided a programming API for Javascript called "Web3JS" which allows the Javascript program to interact with Ethereum based   
smart-contract. The API can be accessed using the node module provided via Node.js.

**4.12 Implementing Document Registry Smart Contract**

Smart-contract was developed to store programming logic or algorithm as blockchain transaction. These smart-contract transactions can be compiled by Ethereum client which will give the result of its script or code (for example, read or return specific value). So, we design smart contract which when executed, it will spawn smart contract that stores given document META-data attributes value within number labeled smart-contract instances which encoded in Blockchain transaction. When these instances were called, it will return the stored metadata attributes value back. Allow the search program to identify the set. At the same time, this allows document registry to store within Ethereum Blockchain. These composed to function as Document Registry Smart Contract.

**4.13 Implementing Document Search function over smart-contract**

As required in IHE ITI Framework, Document Registry Actor must be able to respond to the query from the Document Consumer by returning the META-data attributes of the registered document matched with the query to the consumer. In a traditional database, this can be done by utilizing a query of a relational (SQL) database. However, for Blockchain, the structure of stored data are different from relational database but similar to NoSQL. That mean, search operation will need to rely on a sequential search algorithm. The program will need to take a look at all published transactions one-by-one from the first until the result was found. Each transaction will require the program to call on smart-contract for reviewing the stored value before comparing it with the specified value used for search. When all of the values called from the smart-contract are matched with the value specified for search, the value called will be marked as a search result which will be returned to XDS Document Consumer Actor via ITI-18 format.

**4.14 Interprete XML messages with xml2js module**

All actors within IHE XDS Profile communicate with each other using XML message transaction. As we utilize Javascript as main programming language for the implementation, these XML messages need to be interpreted into programming object to allow simpler handling method within the program. Javascript Object Notation (JSON) is a lightweight data-interchange format of programming object which was invented to serve the purpose. It is easy for humans to read and write and easy for machines to parse or generate. That mean, all XML message transactions sent to XDS Document Registry actor program will be converted into JSON. For this implementation, we utilize NodeJS “xml2js” module for the task.

**4.15 Implementing IHE ITI-42 transactions interpreter**

IHE ITI-42 is XML format transaction used for registering META-data attributes of new document storing in XDS Document Repository actor into XDS Document Registry actor. The transaction specified with header “RegisterDocumentSet-b” and compose of META-data attributes of corresponding document. The content of the attributes varies upon type of document and the event represent by the document. For this implementation, XDS Document Registry actor will open TCP connection to receive the transaction on specified port. After ITI-42 transaction is received, the actor then converts XML message into JSON using xml2js. After that, the program extracts META-data attributes and prepare it for smart-contract.

**4.16 XDS Document Registry actor**

When ITI-42 was interpreted into JSON, the actor then passes the object into smart-contract. For the implementation, smart-contract was designed to store string value and will return the stored value when called by Geth client. The prepared JSON must be converted into string before entering smart-contract. This is due to limit of Ethereum smart-contract which can cover limit number of programming variable so, we simplify our program to avoid that limit by storing whole JSON in string form as single variable. However, because of Ethereum Blockchain require certain amount of gas to execute smart-contract, the length of the variable may cause error in the process if there was not enough gas supplied. That mean, we need to increase limit amount of gas for executing smart-contract from default value. Although, this change is not affecting this implementation for concept demonstration but, it may affect the network where its member prefers to use actual cryptocurrency like Ether to maintain Blockchain. This may accelerate depletion of currency circulating in the network and severe maintainability of the chain. By these smart-contract design, XDS Document Registry actor can keep META-data attributes of each document by store it as JSON string variable inside Blockchain using one smart-contract per document. At the same time, the actor can perform search operation by sequentially call upon each published smart-contract one-by-one until the result was found or until the last in the case which no matching result. Publishing of smart-contract require gas to execute while calling smart-contract not consuming Blockchain resource.

**4.17 Implementing IHE ITI-18 transactions interpreter**

Similar with IHE ITI-42 transaction handling, XDS Document Registry actor also wait for ITI-18 on TCP channel. The received transaction will be converted into JSON. The transaction specified with header “QueryResponse” and compose of META-data attributes value input by Document Consumer. These values will be used in search operation which will seek for the smart-contract with matching META-data attribute values. After the result was found, the actor then proceeds to create response XML message following the format provided by IHE ITI Framework.

**4.18 XDS Document Consumer actor**

Following IHE XDS Profile, XDS Document Consumer actor is where the user specifies search keyword values of META-data attributes for system to query for matching document exist within XDS Affinity Domain. For this implementation, we design that user interface will take a form of command line program that can be run via Windows command prompt or Linux terminal. The program will prompt the user to specify search type, including META-attributes value, and specify the value. The actor then accepts these values to create XML message following ITI-18 format before sending it to local or accessible XDS Document Registry actor to query for matching document and start search operation.

**4.19 Performance Evaluation**

In this implementation, we evaluate the result concept demonstration by measuring performance of each major process. This will reflect compatibility of the concept to healthcare operation environment which require continuous and huge amount of process at short amount of time.

# Chapter V

# RESULT

This chapter showing result of implementation and result of performance evaluation.

**5.1 Implementation End-Design**

**5.2 Performance Evaluation Result**

The evaluation measure time the program needs to finish each process, consist of registering document into XDS Document Registry Actor Blockchain and when XDS Document Consumer Actor query for the registered document using specified keywords. It took average 4.797 ms for ITI-42 to be sent from XDS Document Repository Actor to XDS Document Registry Actor locally using TCP connection. XDS Document Registry Actor took an average of 5 seconds and 174.691 ms to the published transaction into Blockchain. With a minimum number of keywords, it took an average of 221.884 ms to finish search operation on Blockchain with 10 samples smart-contract published beforehand while it took an average of 260.480 ms for XDS Document Consumer Actor to received query response after the query was sent to XDS Document Registry Actor. With a maximum number of keywords, it took an average of 264.937 ms to finish search operation on Blockchain with 10 samples smart-contract published beforehand while it took an average of 304.457 ms for XDS Document Consumer Actor to received query response after the query was sent to XDS Document Registry Actor.

# Chapter VI

# CONCLUSION

This chapter concluding the work.

**6.1 Answering Problem Statement**

XDS Registry Blockchain allow sharing of healthcare document between different healthcare organizations which require maintain of its confidentiality while mitigate emerging cyber-threats on healthcare domain that tamper with integrity and availability of data, there need document registry that have distributed, decentralized, persistent, and immutable characteristics.

**6.2 Implementation Source Code**

We are providing source code of the implementation at (https://github.com/semiangel/XDSchain.git). However, must be noted that this implementation relies on virtual

nodes provided by Quorum “7 Nodes Example”. Any implementation on additional physical node or separated virtual machine may require additional adjustment on network connection between nodes.

# Chapter VII

# DISCUSSION

This chapter discussing about the work.

**7.1 Limit of implementation based on current technology**

**7.2 Suggestion for concept adoption**

**7.3 Suggestion for future work**

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**APPENDICES**

**APPENDIX a**

**ETHICAL APPROVAL DOCUMENT**

**APPENDIX**

**ETHICAL APPROVAL DOCUMENT**

**BIOGRAPHY**

|  |  |
| --- | --- |
| **NAME** | Petnathean Julled |
| **DATE OF BIRTH** | 22 October 1992 |
| **PLACE OF BIRTH** | Nakhon Si Thammarat, Thailand |
| **INSTITUTIONS ATTENDED** | Mahidol University, 2011-2021 |
|  | Bachelor of Engineering (Biomedical) |
|  | Mahidol University, 2011-2015 |
|  | Master of Science (Cybersecurity and Information Assurance) |