St. MARY'S UNIVERSITY
SCHOOL OF GRADUATE STUDIES
DEPARTMENT OF PROJECT MANAGEMENT

ASSESSMENT OF THE ETHIOPIAN ELECTRONIC REGULATORY INFORMATION SYSTEM (ERIS) PROJECT: THE CASE OF THE ETHIOPIAN FOOD AND DRUG AUTHORITY

BY
LAEKEMARIAM DIBABU

JUNE, 2023
ADDIS ABABA, ETHIOPIA

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A THESIS SUBMITTED TO ST. MARY'S UNIVERSITY SCHOOL OF GRADUATE STUDIES IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF ARTS IN PROJECT MANAGEMENT

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APPROVED BY THE BOARD OF EXAMINERS

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Declaration

I, the undersigned, declare that this thesis is my original work, prepared under the guidance of Dr. Misganaw Solomon. All sources of materials used for this thesis have been duly acknowledged. I further confirm that this thesis has not been submitted either in part or in full to any other higher-learning institution for any academic purposes.

Name: Laekemariam Dibabu

Signature:

Date of Submission:

Endorsement

This thesis has been submitted to St. Mary's University, School of Graduate Studies for examination with my approval as a university advisor.

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Advisor Signature

St. Mary's University Addis Ababa, June 2023

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List of Acronyms

DBMS:	Data Base Management System
EFDA:	Ethiopian Food and Drug Authority
eRIS:	electronic Regulatory Information System
GOE:	Government of Ethiopia
HTTPS:	Hypertext Transfer Protocol Secure
ICT:	Information Communication Technology
IT:	Information Technology
MoH:	Ministry of Health
OS:	Operating System
PC:	Personal Computer
SDGs:	Sustainable Development Goals
SPSS:	Statistical Package for Social Sciences software
TCP/IP:	Transmission Control Protocol/Internet Protocol
US:	United States

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Acknowledgment

First and foremost, I would like to thank the Almighty GOD who gave me strength and capability to go through all the difficult times in conducting this study from the beginning to the end.

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Laekemariam Dibabu

Abstract

The study sought to assess the practice and challenges of implementing an electronic regulatory system project in the case of the Ethiopian Food and Drug Authority. For this study, the researcher used both a Mixed Approach as well as a Descriptive Design. The researcher used primary data collection tools such as structured questionnaires and semi-structured interviews. Of the 186 employees, who use the shared portal (eRIS), the researcher took 127 professional permanent employees as a sample size for this study using a simple random sampling technique. The findings revealed that the Ethiopian Food and Drug Authority's practice of electronic Regulatory Information System project implementation was good when measured from the perspectives of electronic Regulatory Information System practices such as efficiency, security/privacy, fulfillment, and system availability. The project site's service performance was successful on the first request; the site provided prompt service and can be retrieved quickly enough; the project site was tailored to each user's needs and was compatible with their preferred browser. Additionally, the website included up-to-date information and was user-friendly and well-organized. The study came to the additional conclusion that when viewed from the perspective of challenges like the inconvenience of downloading or uploading data on the site forms, ease of accessibility, and a lack of necessary knowledge to address user inquiries, the practice of electronic Regulatory Information System project implementation was in a good position. This conclusion was drawn from the fact that the project did not experience any significant issues concerning employees' capacities for eliciting confidence and trust, their inability to exhibit a sincere interest in resolving users' issues, their promptness in responding to users' queries, and their provision of unnecessary data for authentication. Regarding technology and infrastructure, the project didn't face any significant obstacles. The project's implementation, however, was challenged by stakeholder resistance to change and unwanted data produced by site visitors. The study recommends that management should implement the necessary corrective actions to raise awareness among its important stakeholder groups, including businesses and government authorities. Additionally, it is recommended that the management should understand the reasons and effects of unintentional data shared by site visitors and take proper action in response.

Key Words: *eRIS (electronic Regulatory Information System), e-service, e-government, portal*

CHAPTER ONE
INTRODUCTION

1.1 Background of the Study

Electronic government (e-government) is the utilization of innovative information and communication technologies (ICT) platforms, particularly web-based Internet applications, to provide information and services to citizens, businesses as well as to improve service quality, and enhance opportunities for fair and equitable participation (E-SPIN, 2023). The term "e-government" is also known by other names including, e-governance, digital government, online government, and e-gov, among others.

E-government services have received interest all over the world, because it paves the way for a government to exercise its functions efficiently and effectively, hence transforming its relations with citizens, businesses, or other arms of government (Almarabeh & AbuAli 2010).

Based on the nature of services that the government provides to different segments, types of e-government can be classified into four main categories: government-to-citizen (G2C), government-to-business (G2B), government-to-government (G2G), and government-to-employee (G2E). Of the four types, the G2B application incorporates the different services exchanged between government and business sectors, for obtaining current business information, new regulations, downloading application forms, lodging taxes, renewing licenses, registering businesses, obtaining permits, and many others. G2B transactions bring significant efficiencies to both governments and businesses, enhance the efficiency and quality of communication and transactions with businesses, and increase the equality and transparency of government contracting and projects (E-SPIN, 2023).

The Ethiopian government has developed and been making use of e-services in different public sectors since a few years back. One of the areas in that the government has made interventions with e-service is the food and drug sector, whereby the government through the Food and Drug Authority (EFDA) implements the electronic Regulatory Information System (eRIS) project to process licensing, registration, import applications of businesses in the sector.

Since enacting its national drug policy in 1993, Ethiopia has worked tirelessly to increase public access to safe, high-quality, and effective medications while encouraging their responsible use. With political commitment, effective leadership, community involvement, and teamwork, The EFDA is in charge of ensuring the efficacy, safety, and quality of pharmaceutical items that are sold on the market. Patient safety is significantly impacted by the availability of shoddy, illegally distributed, and falsified (SF) medications from unidentified sources. (EFDA, 2022).

The EFDA plays an essential role in the "information revolution" and in ensuring that these facilities have the quality medicines and health products they need.

The Ethiopian Food and Drug Authority (EFDA) is mandated to ensure safety, efficacy, and quality as well as rational use of medicines. Article 19 sub-article 1 of the proclamation decrees that "the rigor of regulatory assessment of medicines shall be commensurate with the products type, nature and potential risk to human health" (Ethiopian Food and Medicine Administration, Proclamation No.1112/2019). EFDA through eRIS, a locally created and maintained software system, facilitates the chain of information for licensing, registration, and import as well as quality assurance.

E-government initiatives still receive huge investment and thus their long-term success is of paramount importance, especially for developing countries that are facing challenges such as limited budgets and donor dependence (Hanna, Qiang, and Kimura, 2009; Dzhusupova, Janowski & Estevez, 2011). However, the researchers contend that the majority of e-government implementations in developing countries are not successful. Of these, 35% were deemed total failures (e-government was either not implemented at all or was implemented but immediately abandoned), and 50% were deemed partial failures (the majority of the goals were not achieved and/or there were not desirable outcomes).

Similarly, the study conducted by Heeks, R., & Stanforth, C. (2007) has found that an estimated amount of over US $3 trillion was spent on ICT projects by governments during the ten years between 2000 and 2010 with an overall estimated failure rate of 60%.

On the other hand, while many governments have invested heavily in e-government projects in the last decade, relatively little is known about the return value of these investments from the public

value perspective. Hence, government administrators need external and objective feedback on their e-government efforts and effects to have a better understanding of the benefits and return on their investments (Tadele B., 2020).

This study therefore seeks to assess the assessment of the Ethiopian electronic regulatory information system (eRIS) project, in the case of the Ethiopian Food and Drug Authority (EFDA).

1.2 Statement of the Problem

The Ethiopian government has been making interventions to strengthen the healthcare system in the country, also with a view of aligning it with the Agenda 2030 Sustainable Development Goal. Owing to this, the US International Trade Administration says the government has been strengthening EFDA so that it boosts its regulatory oversight for the registration, importation, and quality of medicines, supplies, and equipment into the Ethiopian Market. EFDA is mandated to regulate practices, facilities, professionals, and products in the health sector (Tadele B., 2020).

The Ministry of Health (MoH) has developed a national "Information Revolution Roadmap" that contains actionable and measurable interventions. The Ministry aims to focus on enhancing data usage to positively impact the healthcare sector by maximizing the availability and accessibility of high-quality data at all levels in the healthcare system (MoH, 2022).

The total health care facilities in Ethiopia are health posts, providers of basic health care and family planning in the rural areas: 17,550 available and 425 under construction; health centers (which manage 5 health posts): 3,735 available and 96 under construction; hospitals: 353 available and 107 under construction; private clinics: 3,867 and private hospitals: 43 available in Ethiopia but still health sectors have not been networked over the country. In addition to increasing the number of healthcare facilities in the country, the MOH is working to improve services to reduce health-related burdens by using soft wares (MoH, 2022).

As an electronic Regulatory Information System, the eRIS automates the current paper-based regulatory information system in the country and provides an integrated and centralized platform for licensing-related activities such as the issuing, renewal, suspension, and revocation of health sector licenses National Information Platforms for Nutrition (NIPN), 2022). The Authority (EFDA) oversees the market authorization and import permit approval for both medical and food

products for a wide variety of vendors from multiple countries using the electronic Regulatory Information System (eRIS). Fully online, both applicants and EFDA use eRIS to manage the licensing, registration, and import application process using this shared portal (EFDA, 2022).

However, according to Allahawiah & Alsaraireh (2014), many users of e-government services revert to the traditional ways of acquiring information such as personal visits and telephone inquiries after the initial trial of e-government services despite its various advantages.

Challenges in the healthcare sector in Ethiopia include a lack of transparent and accountable pharmaceutical and logistics management system; shortage of foreign currency hindering timely procurement of equipment, supplies, and pharmaceuticals; foreign exchange shortages which result in payment delays; delays in the bidding process; poor data management and reporting for proper decision making; and lack of capacity (MoH, 2022).

Biniam T. (2020) has conducted a study entitled "the quality of e-government Service and its Role in achieving customer satisfaction: The Case of Ethiopian Food and Drug Authority". The study aimed to analyze the impact of the quality of e-government services dimensions including Efficiency, Trust, Reliability, and Support that are provided by the Ethiopian Food and Drug Authority in achieving customer satisfaction. The researcher collected data through a Google Forms online questionnaire that was developed and distributed to a sample of beneficiaries of the e-services provided by the Ethiopian Food and Drug Authority. The sample of the study was made up of 168 participants and a systematic random sampling technique was used to conduct the study.

In his study entitled "Most eGovernment-for-development projects fail: how can risks be reduced?" Heeks R. (2003) described that the eGovernment can make a valuable contribution to development. The study explained that at present, the majority of e-government-for-development projects fail either totally or partially. According to the study, the underlying cause of failure was the oversize gaps between project design and on-the-ground reality (known as 'design-reality gaps'). The dimensions of these gaps are identified, as are archetypal situations in which failure is likely to occur. On the other hand, the paper provided a step-by-step guide to identifying and addressing failure risks for e-government projects. The research concludes with a real-world case study of using the design-reality gap approach to reduce risks in an e-government project. The researcher explained that working estimates were produced for e-government projects in

developing/transitional countries: 35% are total failures, 50% are partial failures, and 15% are successes.

However, researches are very limited and those that are available focus mainly on the implementation, challenges, and opportunities of e-government (Kitaw, Y. 2006). The research which was conducted previously could not effectively assess the assessment of the Ethiopian Electronic Regulatory Information System (eRIS) project, in the case of the Ethiopian Food and Drug Authority (EFDA). Rather they aimed to assess the quality of e-government service, implementations of e-government in developing countries, and the like in other countries and organizations.

In addition, to the researcher's best knowledge, no research was conducted in the area of study and the case organization. Due to these reasons, this research tried to fill the gap seen in previous research by using appropriate methodologies, data collection instruments, and better data analysis methods.

This study, therefore, assessed the practice and challenges of electronic Regulatory Information System project implementation in the case of the Ethiopian Food and Drug Authority (EFDA).

1.3 Research Questions

To address the stated problem, this study primarily focused on answering the following basic research questions:

i) What is the practice of electronic regulatory system project implementation in the case of the Ethiopian Food and Drug Authority?
ii) What are the major challenges of electronic regulatory system project implementation in the case of the Ethiopian Food and Drug Authority?
iii) What possible recommendation can be provided to address the challenges with eRIS of the Authority?

1.4. Objectives of the Study

1.4.1 General Objective

The general objective of the study is to assess the practice and challenges of electronic regulatory system project implementation in the case of the Ethiopian Food and Drug Authority (EFDA).

1.4.2 Specific Objectives

The specific objectives of the study are described as follows:

i) To examine the practice of electronic regulatory system project implementation in the case of the Ethiopian Food and Drug Authority.
ii) To find out the major challenges of electronic regulatory system project implementation in the case of the Ethiopian Food and Drug Authority.
iii) To provide possible recommendation that helps in addressing challenges with eRIS of the Authority.

1.5 Delimitation of the Study

Though there are different types of electronic regulatory system (e-government) projects implemented in Ethiopia that can be studied from different perspectives; conceptually the scope of the study was delimited to only the eRIS implementation. Hence, other e-government projects and electronic regulatory systems are beyond the scope of this study.

In addition, the scope of this research was delimited to the Ethiopian Food and Drug Authority (EFDA), and hence the study did not consider e-government services implemented by other government organizations.

The study was also delimited methodologically as the data collection instruments for the study are questionnaires and interviews. Therefore, data was not collected through desk review, physical observation, or other primary as well as secondary data collection methods.

1.6 Significance of the Study

This research has significance to the senior management of EFDA to get a better understanding of the practices and major challenges of electronic Regulatory System Project implementation.

The study can fill the existing gap in the literature by adding more knowledge to the few available ones. Besides, this study helps to enrich the literature on the subject matter. This is mainly because there is no such comprehensive study that was made on the practices and major challenges of electronic Regulatory System Project implementation, in the case of EFDA.

The researcher is therefore highly convinced that the study can serve as a baseline input to researchers, academicians, policymakers, and the like by providing inputs, insights, and relevant data related to the topic under study.

1.7 Organization of the Study

The research paper is organized into five chapters. The first chapter introduces the background information, statement of the problem, research questions, general and specific objectives, and significance of the study. It also includes the scope and limitations of the research. Chapter two introduces a review of relevant literature on the research problems under question. Chapter three discusses the research design adopted for the research and outlines the methodology for carrying out secondary and primary data collection. Chapter four presents the findings of the research on the assessment of the practice and challenges of electronic Regulatory Information System project implementation in the case of the Ethiopian Food and Drug Authority (EFDA) along with the researcher's analysis and interpretation of the respondents' opinions. Chapter Five covers a discussion of a summary of the findings, conclusions, and recommendations.

CHAPTER TWO

REVIEW OF RELATED LITERATURE

The Ethiopian Food and Drug Authority (EFDA) oversees the market authorization and import permit approval for both medical and food products for a wide variety of vendors from multiple countries using the electronic Regulatory Information System (eRIS). Fully online, both applicants and EFDA use eRIS to manage the licensing, registration, and import application process using this shared portal. This has dramatically increased processing efficiency and transparency and facilitated one unbroken chain of information – from application to port.

This chapter reviews existing literature on the subject of the study. It also outlines the literature review of the theoretical, empirical review and conceptual frameworks of the study.

I. THEORETICAL LITERATURE

2.1. Overview of Electronic Regulatory Information System (eRIS)

Food and Medical device registration information system ensure good governance, transparency, accountability, traceability, and speed of work. In addition to this, the medicine registration information system increases access to registered medicines information to different types of users in this endeavor (EFDA, 2023).

The Food and Medical device registration and licensing directorate strives to offer quality, safe and effective medicines in the pursuit of protecting public health through its competent and dedicated staff. Currently, the directorate consists of pharmacists, pharmacologists, public health specialists, clinical pharmacists, pharmaceutics experts, biomedical engineers, and secretaries.

eRIS is an electronic Regulatory Information System that gives authority for customers, particularly importers, exporters, wholesalers, and manufacturers, to apply for the certificate of competency, apply for and receive medicine registration, apply for and receive permits to import medicines online and the admins to manage these applications online.

The Ethiopian Food and Drug Authority (EFDA) oversees the regulation of medical devices in Ethiopia, by evaluating the quality, safety, and effectiveness of the medical devices before registration and marketing authorization.

eRIS contains three main apps incorporated. The first one is i-License, an online application for requesting a license, the second one is i-Register where users apply for and receive medicine registration certificates. The final one is i-Import which lets importers for applying and receive permits to import medicines.

eRIS is the umbrella system at EFDA comprised of sub-systems that work together:

- i-License which allows entities to apply for a certificate of competency to register and import products.
- i-Register which is used to manage the Medicine, Food, and Medical Device registration process when an applicant seeks to register a pharmaceutical in Ethiopia for later import.
- i-Import which used to manage the import process, once registered in Ethiopia.
- i-Verify which is used to verify and check the legality and authorization status of medicines by EFDA and monitor the movement of medicines from the manufacturer to the point of issue.

The government of Ethiopia has issued Proclamation 661/2009 to protect public health from unsafe, inefficacious, and poor-quality medicines that are either imported or locally manufactured to be made available on the Ethiopian market. Medicine's safety, efficacy, and quality will be ensured through different mechanisms including: - Inspection, Evaluation, Analysis, and Monitoring.

2.2. Purposes and Functions of Electronic Regulatory Information System (eRIS)

eRIS is an electronic regulatory information system that will automate the current paper-based regulatory information system in the country and will provide an integrated and centralized platform for licensing-related activities including the issuing, renewal, suspension, and revocation of health sector licenses (National Information Platforms for Nutrition, 2022).

i-License –used to apply for a certificate of competency to register and import products. a mobile application designed to track and trace health commodities from the manufacturer to the point of issue and verify product authenticity at any point in the supply chain (EFDA, 2023).

i-Register–used to manage the market authorization process where an applicant seeks to register a Medical and Food product. An application that allows importers to apply for market authorization and certification, to help users access information about their application process (EFDA, 2023).

i-Import–used to manage the import process for medical products, once registered in Ethiopia. This allows importers to apply for and receive permits to import medicines and medical devices, to allow EFDA and clients to access most product types in the same place (EFDA, 2023).

2.3. Key Requirements and System Constraints for eRIS

Some key requirements and system constraints have a significant bearing on the architecture. They are:

1. The existing eRIS System must be accessed to retrieve all registry, license, and import information for the current semester. The eRIS must support the data formats and DBMS of the legacy data.

2. The eRIS System is implemented as a client-server system. The client portion resides on PCs and the server portion must operate on Google Cloud Linux Server.

eRIS system uses a Client-Server architectural pattern, in designing the architecture of the software. The pattern is used, in the communication between users of the applications with the remote servers' database system (EFDA, 2023).

eRIS uses an agile software development approach. The Waterfall model was also followed. It is a relatively linear sequential design approach for certain areas of engineering design. In software development, it tends to be among the less iterative and flexible approaches, as progress flows largely on direction ("downwards" like a waterfall) through the phases of conception, initiation, analysis, design, construction, testing, deployment, and maintenance (EFDA, 2023).

Agile software development is an approach to software development under which requirements and solutions evolve through the collaborative effort of self-organizing and cross-functional teams and their customer(s)/end user(s) or succeeding in an unpredicted and turbulent environment. It

advocates adaptive planning, evolutionary development, early delivery, and continual improvement, and it encourages rapid and flexible responses to change (EFDA, 2023).

eRIS (electronic regulatory information system) is hosted on a “Google Clouds” Linux server. Being a web-based application, this underlying client OS can be any PC operating system. (Windows, Linux, Apple). Postgres 10 will be used as the central database server. All communication with the client has to comply with public HTTPS, TCP/IP communication protocol standards (EFDA, 2023).

Users will be able to access eRIS only online. Clients/users are expected to use a modern web browser such as Mozilla Firefox 10, Internet Explorer 9, Google Chrome, or Safari to get a full user experience (EFDA, 2023).

All the data is saved on the central server. This is a relational database that implements the 3rd normal form. (PostgreSQL). To maintain ACID (Atomicity, Confidentially, Integrity, Durability) some measures have been taken such as encrypting passwords, using transactions for all database commits, etc (EFDA, 2023).

The system has been subjected to several testing operations (Integration testing, system testing) before deployment to make sure that the system is reliable. The PostgreSQL database server can respond to many numbers of clients at a given moment without losing consistency and data integrity.

The system responds to any request under standard database and web server script timeouts (30 seconds) from a Windows machine (16GB ram, core i7 2.8GHz) using Chrome browser V. 4.0+, also system performance can depend on available hardware, network, and internet connection capabilities. Especially the statistical information generation tasks may take a comparatively high time (EFDA, 2023).

2.4. Component Diagrams in eRIS

The purpose of the component diagram is to show a structural relationship between components in eRIS System. Considering the broad range of eRIS implementation, there are three modules under the eRIS projects: these are - iImport, iRegister, and iLicense.

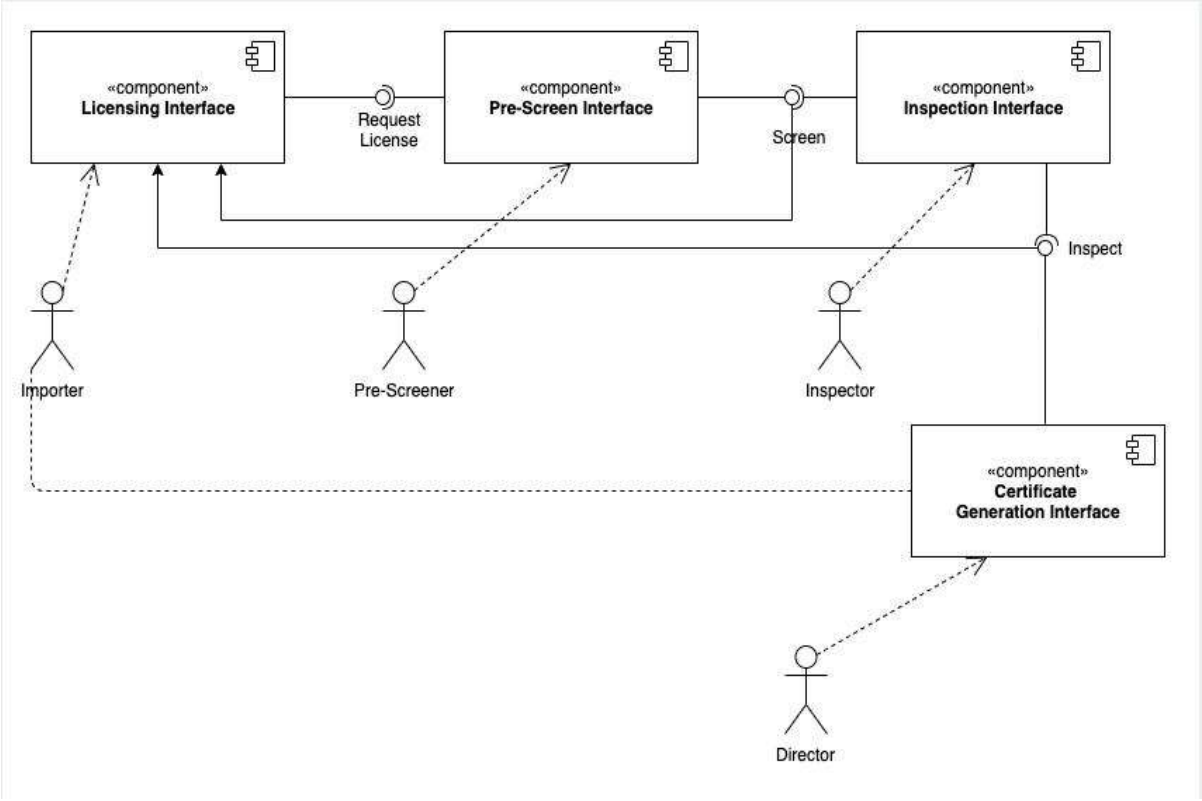

Figure 1: Component Diagram for i-License

Source: - EFDA, 2023

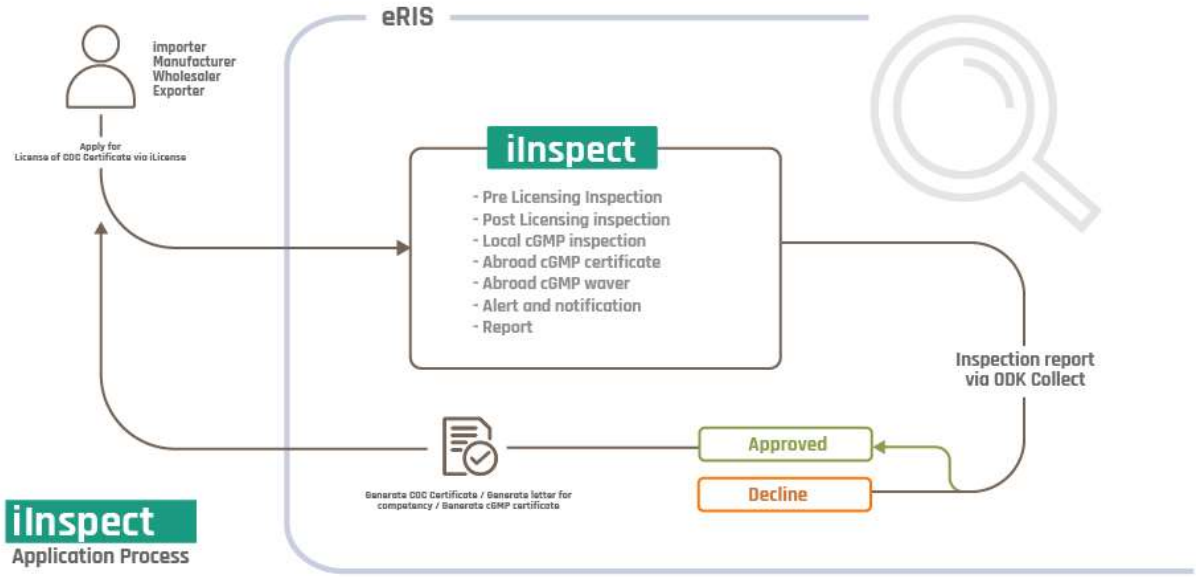

Figure 2: Component Diagram for i-Inspect

Source: - EFDA, 2023

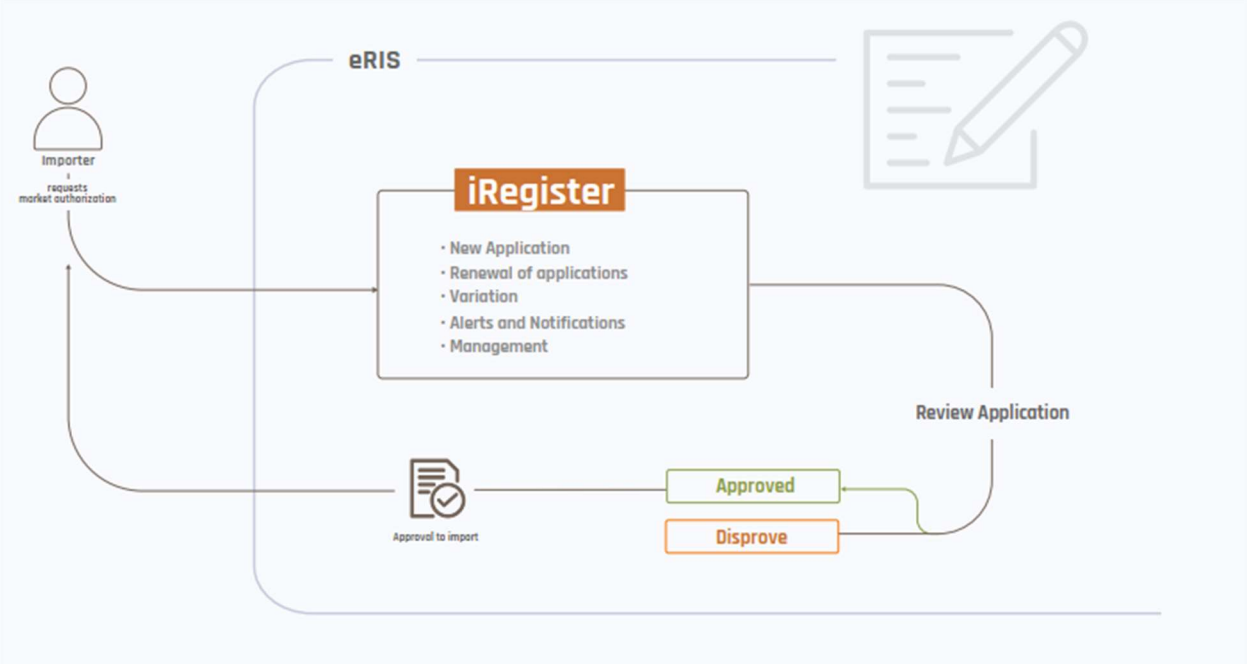

Figure 3: Component Diagram for i-Register

Source: - EFDA, 2023

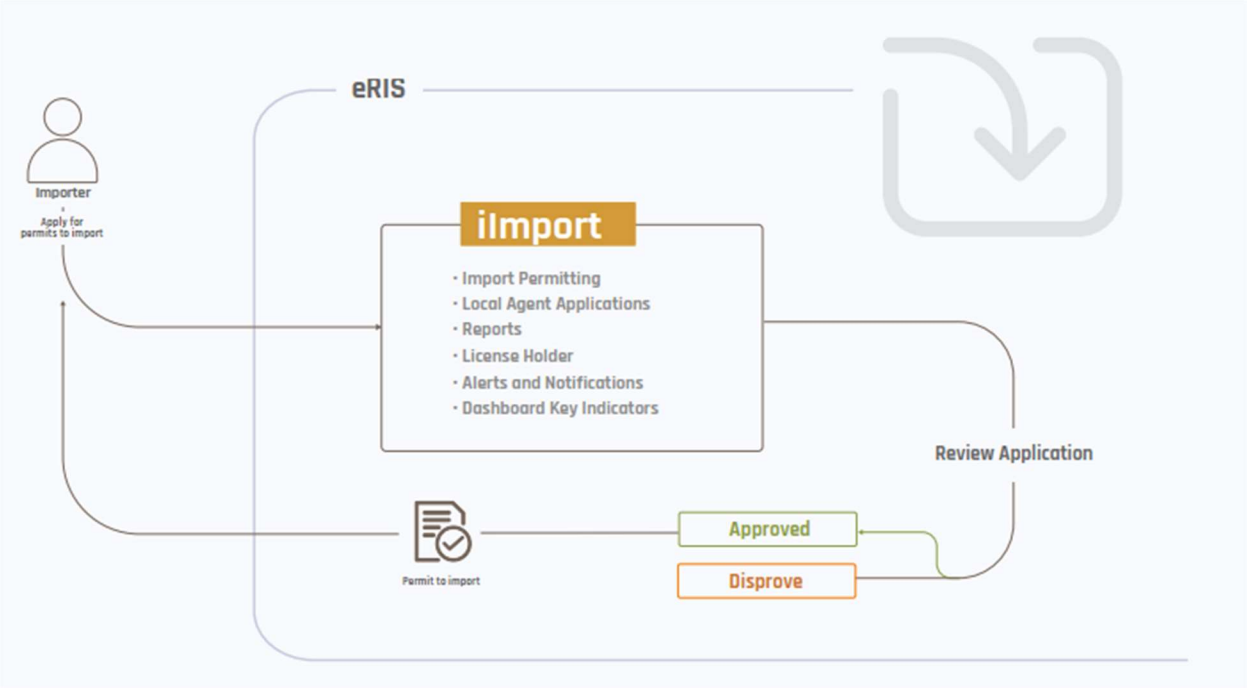

Figure 4: Component Diagram for i-Import

Source: - EFDA, 2023

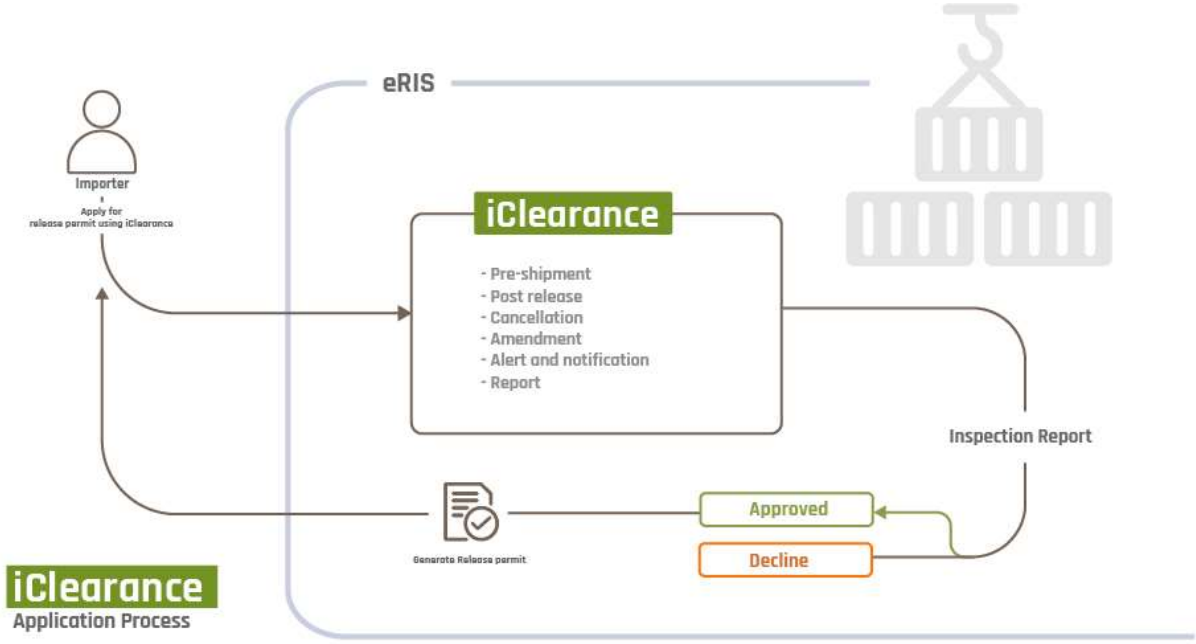

Figure 5: Component Diagram for i-Clearance

Source: - EFDA, 2023

2.5. Challenges of Electronic Regulatory Information System (eRIS)

Networked information sources and services proved to be an indispensable part of our everyday lives. We get access to a wide variety of bibliographic, full-text, and multimedia databases through the intranets, extranets, and the Internet. Information and communication technologies available in different settings (e.g., workplace, home, library, and Internet cafés) facilitate our access to such online services as e-banking, e-government, e-learning, and e-entertainment. Although some advanced information processing and networking capabilities are available to us, we still experience difficulties in searching, finding, gathering, organizing, retrieving, and using information. Trying to find information among billions of electronic sources is likened to trying to "drink water from a fire hydrant." Well-designed electronic information management systems and services are needed to better manage information that is useful in the private and professional lives. The availability of such systems and services is of paramount importance to all organizations large and small (Yaşar Tonta, 2004).

As more information sources are born digital (or later become digital) and publicly accessible through the Internet, the relative importance of the management of information at personal, organizational, and societal levels also increases tremendously. This makes the management and retrieval of information from large quantities of electronic sources all the more important. Users are expected to know how to discover, find, filter, gather, organize, store, and get access to recorded information. In addition, users need to manage information successfully and be avid "consumers" of information to successfully manage their professional and personal lives.

2.6. Overview of Ethiopian Food and Drug Authority (EFDA)

The Ethiopian Food and Drug Authority (EFDA) is mandated, in Proclamation 661/2009, to ensure the safety, quality, and efficacy of medicines. To achieve this, the authority has been working on different regulatory activities. The medicine market authorization system is one of the top priority areas that have been implemented. In addition to the dedicated assessors, the authority uses a national drug advisory committee for the assessment and registration of medicines. This has evolved through the years to improve the medicine dossier evaluation system. As the Socioeconomic development of the nation is transforming, there is a high flow of investments in healthcare (EFDA, 2023).

However, the market authorization system available at this time is yet unable to satisfy and fully accommodate the demands coming into the country. To address these issues, automation emplacement is demanded by the government. Hence, EFDA has developed a medicine registration information system that is a conversant and demanding system to implement.

The Ethiopian Food and Drug Authority (EFDA) oversees the market authorization and import permit approval for both medical and food products for a wide variety of vendors from multiple countries using the electronic Regulatory Information System (eRIS). Fully online, both applicants and EFDA use eRIS to manage the licensing, registration, and import application process using this shared portal. This has dramatically increased processing efficiency and transparency and facilitated one unbroken chain of information – from application to port.

Medical device refers to any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or another similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose (s) of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- Providing information using in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Medical devices in Ethiopia are regulated by the EFDA (Ethiopian Food and Drug Administration) regulatory authority.

II. EMPIRICAL LITERATURE REVIEW

According to the Digital Health Activity Annual Report (2020), the Information Revolution is one of the transformational agendas of the National Health Sector Transformation Plan. The Information Revolution Agenda is driven by diversified and increased demand for health information and opportunities presented by advancements in information and communications technology. Digitization of the Health Management Information System and promoting data use culture are two pillars of the Information Revolution.

Only a few researches had been conducted with electronic Regulatory Information Systems (eRIS). Biniam Tadele (2020) conducted a study on the quality of e-government service and its role in achieving customer satisfaction. The study was conducted in the case of the Ethiopian Food and Drug Authority. The study aimed to analyze the impact of the quality of e-government services dimensions including Efficiency, Trust, Reliability, and Support that were provided by the Ethiopian Food and Drug Authority in achieving customer satisfaction. To achieve the objectives of the study, data were collected through a Google Forms online questionnaire that was developed and distributed to an appropriate sample of beneficiaries of the e-services provided by the Ethiopian Food and Drug Authority.

The sample of the study was made up of 168 participants and a systematic random sampling technique was used to conduct the study. Pearson's Correlation coefficients and Multiple Linear Regression were used to determine the relationship between the independent variables and the perceived overall satisfaction. The statistical analysis revealed that there exists a statistically significant positive relationship between all the e-government service quality dimensions and customers' satisfaction with the Ethiopian Food and Drug Authority. The Reliability dimension was found to have the highest impact on customer satisfaction. A practical implication of the current investigations suggests improving the service quality which can progress customer satisfaction. The findings of this study provide valuable information to administrative authorities of e-government development regarding electronic regulatory information systems, as well as for future researchers and projects in the domain of e-services.

On the other hand, Heeks R. (2003) in his study entitled "Most eGovernment-for-development projects fail: how can risks be reduced?" explained that eGovernment can make a valuable

contribution to development. The researcher also described that at present, the majority of e-government-for-development projects fail either totally or partially. The research findings showed that the underlying cause of failure was the oversize gaps between project design and on-the-ground reality, which is also known as 'design-reality gaps'. According to the researcher, the dimensions of these gaps were identified as archetypal situations in which failure is likely to occur. Furthermore, the paper provided a step-by-step guide to identifying and addressing failure risks for e-government projects. Finally, the researchers concluded that using the design-reality gap approach can reduce risks in e-government projects.

However, the research which was conducted previously could not effectively assess the assessment of electronic Regulatory Information System (eRIS) in the case of EFDA, rather they were aimed to assess the quality of e-government service, the role of eRIS on customer satisfaction, and the like.

In addition, to the researcher's best knowledge, no research was conducted entitled "Assessment of the assessment of electronic Regulatory Information System (eRIS) in the case of Ethiopian Food and Drug Authority.

Due to the aforementioned reasons, this research attempted to fill the gap seen in previous research by using appropriate methodologies, data collection instruments, and better data analysis methods and assessed the real assessment of electronic Regulatory Information System (eRIS) in the case of EFDA.

2.7 Conceptual Framework of the Study

The study was guided by the following conceptual framework which is used to explain the relationship between the independent variable – assessment of eRIS (efficiency, security/privacy, fulfillment, and system availability) and eRIS implementation.

After reviewing the theoretical and empirical literature, the researcher developed the following conceptual framework:

CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

The research aimed to assess the assessment of the Ethiopian electronic Regulatory Information System (eRIS) project: the case of the Ethiopian Food and Drug Authority. This chapter presents the research methodology to be employed for data collection as well as analysis of research findings. In addition, in this chapter, relevant statistical and analytical tools are described in detail. In general, the purpose of this chapter is to provide a clear understanding of the research design, the study population, sample size, sampling techniques, data sources, data collection instruments, and the method of data analysis.

3.1. Research Approach

A research strategy is determined based on the type of research issue being addressed, the researchers' own experiences, and the study's target audiences. There are three basic approaches to research (a) qualitative (b) quantitative (c) mixed methods.

The study has required a strategy that contains various methods and tools relevant to get the desired research outcome. Accordingly, the researcher employed both qualitative and quantitative (mixed) approaches for this study. Tashakkori and Teddlie (2003) argue that mixed methods research can provide a more complete understanding of the phenomenon being studied, as it allows for the triangulation of data and the ability to verify findings from one method with those of another. They also suggest that a mixed-methods approach is particularly useful when the research question is complex and multifaceted, as it allows for the examination of the problem from multiple perspectives. Moreover, Creswell and Plano Clark (2007) suggest that mixed methods designs can be used to address questions that quantitative or qualitative methods alone cannot address, such as testing a theory using quantitative data and then exploring the reasons behind the theory using qualitative data, or examining a phenomenon in a real-world setting and then using laboratory experiments to explore the underlying mechanisms.

Hence, a quantitative and qualitative approach was used for the study to search for data that can be generalized about the assessment of electronic Regulatory Information Systems in the case of

EFDA. The purpose of the qualitative approach (strategy) is to seek information that can supplement the gap which might not be captured by the quantitative research approach.

3.2. Research Design

Mugenda & Mugenda (2003) classify the types of research into three categories based on the research objective: These are i) descriptive research; ii) explanatory (causal) research, and iii) exploratory research. As the study has been conducted to assess the assessment of electronic Regulatory Information Systems in the case of EFDA, the researcher has adopted a descriptive research design for the study. Descriptive research design is a systematic technique that entails observation and describes the actions of a focus item in a precise manner (Mugenda & Mugenda, 2003). Therefore, the researcher used descriptive research to generate statistical information on features of the study's subject matter that is of concern to policymakers and considered fit for this study as it helps to describe the connection between the variables of the study.

3.3. Data Source and Types

Mugenda, O.A. (2003) elucidates that there are two data types and sources: primary and secondary data types/sources. Primary data refers to raw facts or empirical data collected for the first time, while secondary data are cooked information and readily available for use in describing or analyzing the subject matter under discussion. In this study, the researcher has collected the primary data from EFDA, employees including the management staff, through interviews and structured questionnaires, and the secondary data by browsing and visiting relevant online sites and referring other pertinent sources. The primary data sources were mainly exploited to gather facts about the assessment of electronic Regulatory Information Systems in the case of EFDA, while the secondary data have been used to develop and enrich the contents in the different key segments of the research paper including, background information, statement of the problem, literature review and the methodology part. The researcher has used the primary data sources to fully answer the research questions.

3.4. Data Gathering Instruments

The researcher has used questionnaires and semi-structured interviews to gather primary data from employees of EFDA, including those at the management level. The questionnaire contains only structured questions in a Likert scale to establish a relationship between the dependent and independent variables. The questionnaires that contain the five scale Likert questions were distributed through email and Google forms to sample respondents from the Head Quarter of the Ethiopian Food and Drug Authority and its five branches. The researcher followed up the process to get the desired data on time. The questionnaires were distributed using the online google forms method with a window period of one week. Firstly, the questionnaires were sent to a pilot sample of 15 participants to ensure that the questionnaire is clear and precise. The need for a questionnaire arises because it provides sufficiently valid descriptive information about the opinions of the respondents. Since the research design consisted of the distribution of questionnaires, the questionnaire is divided into two sections: the first section comprised of the demographic factors of the respondents, and the second section comprised of questions regarding the assessment of the electronic Regulatory Information System (eRIS) project.

3.5. Target Population and Sampling Techniques

3.5.1. Target population

The population is the entire aggregation/total of items from which samples can be drawn. Determining the type and method of sampling mainly depends on the types of the population that the study covers (Kothari, 2004). The target population of the study is all those EFDA employees who use the shared portal, eRIS for the process of licensing, registering, and importing applications for both medical and food products. Excluding those employees in management positions, who were approached with interviews, a total of 186 professional personnel, whose jobs are related or linked to eRIS, have been identified as the target population of the study, to whom questionnaires were distributed to gather the primary data. These employees were chosen from several departments of the Authority, including food and medicine registration, food and medicine licensing, and information technology.

3.5.2. Sampling Design and Sampling Techniques

The researcher used a simple random sampling technique to select respondents for this particular study. This technique was applied because all respondents would have an equal chance of being selected from a sample. The rationale behind the selection of this sampling technique is its advantages in providing representative samples and adequate data for the study. In addition, the researcher chose simple random sampling to make generalizations about a population and for its advantages of simplicity and addressing bias.

3.5.3 Sample Size

In this study, for a target population of 186 employees, a simple random sampling technique has been taken that enables the researcher to gather the necessary data that helped in answering the research questions and meeting the research objectives.

At a confidence level of 95%, from a total population of 186, a sample size of 127 was determined by the statistical formula of Yemane (1967):
n=N/ (1+N*e2) = 186/ (1+186*(0.05)2) = 186/1.465= 127
Where N=population, n= sample size and e= level of precision

The sample respondents for the interview were based on a convenience sampling technique which can result in an appropriate and relevant response.

3.6 Data Analysis Methods

To answer the study questions and goals, a self-administered questionnaire was utilized to collect primary data, and IBM SPSS Statistics 26 and Microsoft Excel version 2013 were used for descriptive statistics and quantitative analysis. The analysis enabled us to conclude the assessment of assessment of the Ethiopian electronic Regulatory Information System (eRIS) project, in the case of the Ethiopian Food and Drug Authority (EFDA).

Descriptive statistics like the means, percentages, and standard deviations of the variables were used to describe the characteristics of the respondents. Then, the results of the analysis were presented by using simple statistical tools like tables, charts, and other methods.

On the other hand, the qualitative data collected using interviews were analyzed by in-depth discussion and interpreted to support the findings of the questionnaire.

3.7 Ethical Considerations

Privacy, confidentiality, data protection, and the voluntary nature of participation were considered significant ethical issues for this study. Every effort was made to minimize the risk or discomfort to the participants arising from these issues. Before the distribution of questionnaires, the researcher asked respondents for permission to conduct the research with sample employees of EFDA.

Maximum efforts were made to make respondents feel secure and confidentiality was maintained so that no harm can happen to them. All assistance, collaboration of others, and sources from which information is drawn were also acknowledged.

The study followed thoroughly the research ethics. Accordingly, the study purpose was clearly stated to the respondents and all the collected data was kept confidential. Moreover, all citations were referenced in ethical ways.

3.8 Validity and Reliability

The internal consistency of the subjects in the survey items is measured by reliability. In other words, if an object is measured numerous times with the same equipment, the results should be roughly the same each time, with little or no measurement error. (Kerlinger and Lee, 2000).

Cronbach's coefficient alpha is broadly used as a reliability criterion.

Since a standard survey questionnaire was not employed in this study, completing a pilot study became critical to ensuring the reliability and validity of the questionnaire questions.

As a result, pilot research was carried out before delivering the survey to actual survey participants. The Cronbach Alpha coefficient (.816) suggested that the survey questionnaire was credible since it was larger than the minimal alpha value of 0.7. Following that, the reliability test was repeated using full-scale data, and the result (.869) demonstrated the survey instrument's internal consistency and dependability.

However, a significant value of alpha may be obtained by having a large number of items, which leads to bias in the dependability. As a result, it is thought necessary to evaluate the dependability of each of the themes (directors, team leaders, inspectors, dossier assessors, and officers) to obtain a more dependable outcome. As a consequence, an additional reliability study was performed using Cronbach's alpha results for directors (.814), team leaders (.843), inspectors (.823), dossier assessors (.806), and officers (.844). As a result of the reliability testing, the study is considered reliable.

Many different steps were also taken to ensure the validity of the study such as - data was be collected from reliable sources, from respondents who are more experienced in using eRIS; survey questions were made based on literature review and frame of reference to ensure the validity of the result; the questionnaire was pre-tested by a group of respondents before starting the survey. In addition, data were collected within a week; this ensured that no major event was changed with the related topic.

On the other hand, the internal consistency reliability scale assesses the degree to which the items that make up the scale all measure the same underlying attribute. The most commonly used measure of internal consistency is by conducting Cronbach's coefficient (α) alpha reliability test.

Therefore, a reliability estimate that is 0.70 or higher suggests good reliability, whereas reliability between 0.60 and 0.70 may be acceptable provided that other indicators of a model's construct validity are good, as the lowest acceptable limit for Cronbach's coefficient (α) is 0.70.

CHAPTER FOUR

DATA PRESENTATION AND ANALYSIS

This chapter presents the findings of the study based on the data collected through structured questionnaires and interviews. It also presents the socio-demographic profile of the respondents. In addition, the chapter presents the findings of the study using analysis of descriptive statistics for independent variables and dependent variables. Finally, the chapter closely examines the relationship between the independent variables and the dependent variable.

4.1 Response Rate

Out of a total of 127 questionnaires that were distributed to the sample respondents, 115 questionnaires were properly replied to, making the percentage of respondents 90.5%. It shows that the responses were sufficient enough to make the data analysis and conclusions.

4.2 Demographic Profile of Respondents

The demographic profiles of the study sample have been described using descriptive statistics. Descriptive statistics were done using frequency counts and percentages for demographic information such as age, gender, educational background, experience with EFDA or in EFDA, job position, and how often the respondents accessed or viewed eRIS. The result of the analysis is presented in the table below:

Table 1: Age Distribution of Respondents

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	26-35	29	25.2	25.2	25.2
	36-45	63	54.8	54.8	80.0
	46-55	15	13.0	13.0	93.0
	56 and above	8	7.0	7.0	100.0
	Total	115	100.0	100.0	

(*Source: own survey results, 2023*)

As shown in Table 1 above, 29 (25.2%) of the respondents were within the age group of 26-35 years old whereas 63 (54.8%) of them fall under the age category of 36-45 years. Furthermore, 15 (13%) of the respondents were between the age of 46 and 55 years, and 8 (7%) of the respondents were found in the age category of 56 and above years. This implies that the majority (80%) of the staff were below 45 years, who are relatively younger and considered to be in better condition than those who are older than them, and thereby they can actively engage themselves in properly going through the questionnaires and provide sufficient information.

Table 2: Gender Distribution of Respondents

Gender distribution

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Male	62	53.91	53.91	53.91
	Female	53	46.90	46.09	100.0
	Total	115	100.0	100.0	

(*Source: own survey results, 2023*)

Table 2 above presents the distribution of the 115 staff who participated in this study by gender. From the total 115 responses submitted 53 (46.9%) respondents were Female, and 62 (53.91%) respondents were Male.

Table 3: Educational Background of Respondents

Educational Background

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Diploma	16	13.9	13.9	13.9
	First degree	83	72.2	72.2	86.1
	Masters degree	16	13.9	13.9	100.0
	PhD	-	-	-	-
	Total	115	100.0	100.0	

(*Source: own survey results, 2023*)

Table 3 shows that, 16 (13.9%) of the respondents were Diploma holders whereas 83 (72.2%) of them were first Degree holders. On the other hand, 16 (13.9%) of the respondents were Masters degree holders. This indicates that the majority of the respondents have at least a first degree and hence they can understand the research area, know the contents of the questionnaire easily, and provide relevant responses accordingly.

Table 4: Experience of Respondents

Experience in EFDA (in Years)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	<2	18	15.7	15.7	15.7
	3-5	36	31.3	31.3	47.0
	6-10	50	43.5	43.5	90.4
	>11	11	9.6	9.6	100.0
	Total	115	100.0	100.0	

(*Source: own survey results, 2023*)

As shown in Table 4 above, 18 (15.7%) of the respondents have less than 2 years of experience in EFDA whereas 36 (31.3%) of them have between 3 to 5 years of experience. Furthermore, it also shows that 50 (43.5%) of the respondents have been working in the organization for about 6 to 10 years. Only 11 (9.6%) of the respondents have 11 and more years of experience in EFDA. This implies that the majority of the respondents are directors, team leaders, inspectors, dossier assessors, and other staff who have been working in EFDA for more than 5 years and this shows that they are relatively familiar with the system and provide relevant responses.

Table 5: Job Position of Respondents

Job Position

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Inspectors	18	15.65	15.65	15.65

	Dossier assessor	16	13.91	13.91	29.56
	Director	14	12.17	12.17	41.74
	Team Leader	20	17.39	17.39	59.13
	Officers	47	40.87	40.87	100.0
	Total	115	100.0	100.0	

(*Source: own survey results, 2023*)

Table 5 shows that 18 (15.65%) of the respondents are inspectors using the services of EFDA whereas 16 (13.91%) of the respondents are dossier assessors. On the other hand, 14 (12.17%), 20 (17.4%), and 81 (70.4%) of the sampled respondents are directors, team leaders, and officers respectively within the organization. This shows that the majority of the respondents are familiar with EFDA and can provide relevant information as they can answer the questions appropriately.

Table 6: Frequency of Access or View of eRIS by the Respondents'

How often do you access or view eRIS?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Multiple times a day	7	6.1	6.1	6.1
	A few times a week	39	33.9	33.9	40.0
	Once a day	26	22.6	22.6	62.6
	A few times a month	28	24.3	24.3	87.0
	Less than once a month	15	13.0	13.0	100.0
	Total	115	100.0	100.0	

(*Source: own survey results, 2023*)

It can be shown in Table 6 that 7 (6.1%) of the respondents replied that they access the eRIS site multiple times a day. On the other hand, 39 (33.9%), and 26 (22.6%) of the respondents replied that they access the site a few times a week and once a day respectively. Furthermore, 28 (24.3%) and 15 (13%) of the respondents said that they access or view the site a few times a month and less than once a month respectively. It can be learned from the presentation that the majority of the

employees who do Multiple times a day, few times a week and once a day (62.6%) access the system frequently. And this implies that majority of respondents know the eRIS system well.

4.3 Data Analysis of Respondents' Opinion

4.3.1 Respondents' View of Practices of eRIS in EFDA

Table 7: Respondents' View on Practices of eRIS in EFDA

Descriptive Statistics

	N	Mean	Std. Deviation
The EFDA's eRIS site performs the service successfully upon the first request.	115	4.08	1.236
The EFDA's eRIS site provides service on time.	115	3.84	1.174
The eRIS site pages of the EFDA can be downloaded quickly enough.	115	3.74	1.207
The eRIS site of the EFDA works properly with your default browser.	115	4.22	.925
The EFDA's eRIS site is customized to individual users' needs.	115	4.05	.887
The eRIS site provided by EFDA is easy to use.	115	4.29	1.074
The EFDA's eRIS site map is well organized.	115	4.13	1.174
The eRIS site of the EFDA provides information that is up-to-date and fresh.	115	4.29	.792
The Acquisition of user name and password for EFDA's eRIS site is secure.	115	4.06	.976
Data provided by users on the EFDA's eRIS site are securely archived.	115	4.17	.954
PRAC	115	4.0861	.2982
Valid N (listwise)	115	4.086	

(*Source: own survey results, 2023*)

As shown in Table 7 above, the EFDA's eRIS site performed the service successfully upon the first request as the mean value was 4.08. On the other hand, the data in the table shows that the EFDA's eRIS site provided service on time with a mean value of 3.84.

The table also shows a mean score of 3.74 for the statement that stated the eRIS site pages of the EFDA can be downloaded quickly enough. The respondents also indicated that the eRIS site of the EFDA worked properly with their default browser and the site was customized to individual users' needs as the mean score was 4.05 and 4.22 respectively. On the other hand, with a mean score of 4.29, respondents say that the eRIS site is easy to use and well organized.

Based on the information found in Table 7 above, the average scores of 4.29, 4.06, and 4.17 indicated that the eRIS site of the EFDA provided information that was up to date and fresh; the Acquisition of user name and password for EFDA's eRIS site was secure, and data provided by users on the EFDA's eRIS site were securely archived, respectively. In general, the overall mean score of 4.0861 was an indication of the good practice of the eRIS project in the case of EFDA.

This implies that the EFDA's eRIS site's service performance was successful upon initial request. The eRIS site of the EFDA also offered service promptly, and the EFDA's eRIS site pages can be retrieved rapidly enough. Additionally, the EFDA's eRIS site was tailored to each user's needs and was compatible with their default browser. Additionally, the EFDA's eRIS site was user-friendly, well-organized, and updated with the latest information. On the other hand, the username and password that were acquired for the EFDA's eRIS site were likewise safely stored.

4.3.2 Respondents' View of Challenges of eRIS in EFDA

Table 8: Respondents' View of the Challenges of eRIS Implementation in EFDA

Descriptive Statistics

	N	Mean	Std. Deviation
EFDA is challenged by unintended data provided by users on its eRIS site.	115	4.37	.800
Forms on the EFDA's eRIS site are not convenient to download or upload data in a short period.	115	2.02	1.043

The EFDA's eRIS site is not easily accessible whenever the need arises.	115	1.63	.832
In my opinion, EFDA's employees do have the necessary knowledge to respond to users' inquiries.	115	2.43	1.236
EFDA's employees can convey trust and confidence.	115	4.23	1.119
EFDA's employees couldn't show a sincere interest in solving users' problems.	115	1.75	.972
EFDA's employees couldn't give prompt replies to users' inquiries.	115	2.00	1.051
Unnecessary data are provided for authentication on the E FDA's eRIS site	115	1.83	1.017
There is a lack of infrastructure and technological capabilities for EFDA's eRIS site.	115	1.59	.857
Resistance to change from stakeholders, including government officials and businesses is considered a challenge to the implementation of the Ethiopian electronic Regulatory Information System (eRIS)	115	3.45	1.223
Limited internet connectivity or power supply causes problems in accessing or updating the system	115	1.64	.860
One challenge for the implementation of eRIS is ensuring data accuracy and completeness	115	2.05	1.206
The limited technical skill of the users causes difficulty in using the system properly.	115	1.88	.975
CHAL	115	2.3759	.2843
Valid N (listwise)	115	2.37	

(*Source: own survey results, 2023*)

Table 8 above shows that EFDA was challenged by unintended data provided by users on its eRIS site as the mean score is 4.37, which is, according to Zaki and Ahmad (2017), considered to be a

high value However, the mean score of 2.02 indicated that it was not a challenge for eRIS implementation that forms on the EFDA's eRIS site are not convenient to download or upload data in a short period. Similarly, the EFDA's eRIS site was not being challenged regarding ease of accessibility whenever the need arises. The above Table shows that with a moderate mean score of 2.02, the respondents said that forms on the EFDA's eRIS site are not convenient to download or upload data in a short period. And it also shows that the mean score of the EFDA's eRIS site is not easily accessible whenever the need arises is 1.63.

On the other hand, for the personal opinion that EFDA's employees do have the necessary knowledge to respond to users' inquiries is shown again with a moderate mean score of 2.43. The same Table also shows that EFDA's employees can convey trust and confidence with a high mean score of 4.23. With regard to EFDA's employees couldn't show a sincere interest in solving users' problems, the above Table shows that the mean score is 1.75. It also shows that EFDA's employees couldn't give prompt replies to users' inquiries with a mean score of 2.00, while it is with a low mean score of 1.83 that unnecessary data is provided for authentication on the E FDA's eRIS site. It can also be learnt from the above Table that the mean score is very, very low with 1.59 that there is lack of infrastructure and technological capabilities for EFDA's eRIS site. It also reveals that the resistance to change from stakeholders, including government officials and businesses is considered a challenge to the implementation of the Ethiopian electronic Regulatory Information System (eRIS) has been recorded with a mean score of 3.5.

Table 8 also shows that the mean score for an item, limited internet connectivity or power supply causes problems in accessing or updating the system is very, very low of 1.64. The mean score of one challenge for the implementation of eRIS is ensuring data accuracy and completeness is 2.05, while the limited technical skill of the users causes difficulty in using the system properly is low score 1.88.

It can be learnt from the above presentation that the EFDA's eRIS site is easily accessible whenever the need arises, and the employees can also convey trust and confidence while displaying sincere interest in solving users' problems. It is also shown that that unnecessary data is not provided for authentication on the E FDA's eRIS site, and that there is no lack of infrastructure and technological capabilities for EFDA's eRIS site. It is also revealed that there is resistance to change from stakeholders, including government officials and businesses is considered to be a

challenge to the implementation of the Ethiopian electronic Regulatory Information System (eRIS) has been recorded with a mean score of 3.5. Table 9 also shows that the mean score for an item, limited internet connectivity or power supply causes problems in accessing or updating the system is very, very low of 1.64.

In general, the overall mean score of 2.3759 indicated that it was not a challenge for EFDA's eRIS site that employees do have the necessary knowledge to respond to user's inquiries; and have the ability to convey trust and confidence. Similarly, the data also showed that EFDA's eRIS project was not challenged by the inability of its employees to show a sincere interest in solving users' problems and provide prompt replies to users' inquiries.

The table also indicates that unnecessary data provision for authentication; lack of infrastructure and technological capabilities were not a challenge for EFDA's eRIS project implementation. Similarly, limited internet connectivity, power interruption, data accuracy and completeness as well as the limited technical skill of the users could not be considered as a challenge for the implementation of the project. However, resistance to change from various stakeholders was considered a challenge to implement the project.

This shows that the majority of the factors, such as the inconvenience of downloading or uploading data on eRIS forms in a short period; ease of accessibility; and lack of necessary knowledge to address user inquiries, did not pose a challenge to the EFDA's eRIS project. It also implies that the eRIS project of the EFDA did not counter difficulties concerning the employees' capacity to inspire confidence and trust, the employees' inability to demonstrate a sincere interest in resolving users' problems, the provision of prompt responses to users' inquiries, the provision of unnecessary data for authentication, a lack of infrastructure and technological capabilities. However, the data implies that EFDA's eRIS project has been challenged by unintended data provided by users on the site and resistance to change from various stakeholders.

4.3.3 Analysis of Interview Findings

Interviews were conducted with directors to have data that have qualitative nature and it also helps the researcher enhance the reliability of the study as the findings are related through triangulation.

The interview findings show that respondents believe that the EFDA's eRIS site is easily used and customized to individual users' needs. This also reinforces the finding that has been got by the data gathered with questionnaire, whereby the mean score of the item that the EFDA's eRIS site is not easily accessible whenever the need arises is very, very low with a value of 1.63. The same finding has also been got by both the quantitative and qualitative data that the site provides services on time as the respondents confirmed it through their responses to the relevant question of the interview.

On the other hand, for the question "How do you explain the security of the eRIS SITE? Do you think that user name and password, and other private information are protected?" the respondents said that the site's security is quite excellent, and they feel that user names and passwords, as well as other sensitive information, are secured by a proper encryption method with a captcha code to defend against robot testing. This in turn also enhances the reliability and reinforces the finding through quantitative approach that the acquisition of user name and password for EFDA's eRIS site is also secure with a mean score of 4.0861, and the data provided by users on the EFDA's eRIS site are also securely archived with high mean value.

The responses of respondents also showed that EFDA's eRIS site works properly with the user's default browser and that the site can provide up-to-date information to users. This finding is also compatible with that of the quantitative approach that the eRIS site of the EFDA also works properly with default browser with mean score of 4.05. Therefore, the reliability of the finding is enhanced. Respondents also said that the data provided by users on the EFDA's eRIS site is securely archived.

Furthermore, for the question that says "Is the EFDA's eRIS site available and accessible by users whenever the need arises?" the respondents replied that they believe that the site is available and accessible by users whenever the need arises. The respondents said that they believe that EFDA's employees have the necessary knowledge, ability, and sincere interest to respond to users' inquiries and convey trust & confidence. All these indeed reinforce the findings through the qualitative approach.

Interviewees were also asked about their opinion on the practice of the Ethiopian electronic Regulatory Information System (eRIS) project, especially about the Ethiopian Food and Drug Authority. And they indicated that the practice of the overall Ethiopian electronic Regulatory Information System (eRIS) project in EFDA is somehow satisfactory in site performance, securely archived users document, easy to use, organization of the site, and security but needs improvement in some areas. For instance, the eRIS site needs to be more customized to individual user's needs and the site should provide service even in faster pace.

For the question regarding the possible solution for the observed challenges of the Ethiopian electronic Regulatory Information System (eRIS) project, the respondents said that measures should be taken to minimize, if possible, to avoid, unintended data provision by users on its eRIS site. In addition, they said that forms on the EFDA's eRIS site should be convenient to download or upload data in a short period; the site should be easily accessible whenever the need arises; there should be sufficient infrastructure and technological capabilities for EFDA's eRIS site.

4.4 Discussion

The findings of the study showed that the EFDA's eRIS site provided successful service for the initial request. The study also demonstrated that the EFDA's eRIS website offered service quickly and permitted speedy retrieval of its website's pages. This finding was in line with several other research, particularly those by Biniam (2020) and Heeks (2013).

The other finding of this research was that the EFDA's eRIS site was found to be user-friendly and compatible with each user's default browser. The research also showed that the EFDA's eRIS website was user-friendly, organized, and updated with the most recent information. It is also found that the EFDA's eRIS site's username and password were also securely stored. This finding is also inconsistent with the research findings of Allahawiah, & Alsaraireh (2014).

With regards to the challenges, the research result revealed that the inconvenience of quickly downloading or uploading data on eRIS forms, ease of accessibility, and the lack of knowledge required to respond to user inquiries, did not present a challenge to the EFDA's eRIS project. This finding is inconsistent with the findings of other researchers such as Heeks R. (2013) and Allahawiah, & Alsaraireh (2014).

Additionally, the study found that the eRIS project of the EFDA didn't run into issues with the employees' ability to garner confidence and trust, the employees' inability to show genuine interest in helping users solve their problems, the provision of prompt responses to users' inquiries, the provision of unnecessary data for authentication, a lack of infrastructure and technological capabilities. Most of these findings were the same as previous study findings such as Biniam Tadele (2020), Allahawiah, S. R., & Alsaraireh, M. Y. (2014).

CHAPTER FIVE

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

5.1 Summary

The major findings of the study are summarized as follows:

- The service performance of the EFDA's eRIS site was successful upon initial request.
- The EFDA's eRIS site provided prompt service, and its eRIS site pages can be retrieved quickly enough.
- The EFDA's eRIS site was tailored to each user's needs and was compatible with their preferred browser.
- The EFDA's eRIS website was user-friendly, well-organized, and up-to-date with the most recent information. The user's name and password obtained for the EFDA's eRIS site, on the other hand, were also securely stored.
- User unintentional data provision and the inconvenience of downloading or uploading data on eRIS forms in a short period did not pose a challenge to the EFDA's eRIS project.
- Ease of accessibility and a lack of necessary knowledge to address user inquiries were not considered major challenges for the implementation of EFDA's eRIS project.
- EFDA's eRIS project encountered no major difficulties in terms of employees' ability to inspire confidence and trust, employees' inability to demonstrate a genuine interest in resolving users' problems, prompt responses to users' inquiries, and the provision of unnecessary data for authentication,
- The EFDA's eRIS project encountered no major challenges in terms of infrastructure and technological capabilities.
- The EFDA's eRIS project has been challenged by unintended data provided by site users and resistance to change from a variety of stakeholders.

5.2 Conclusion

Based on the findings of the study, it can be concluded that the EFDA's eRIS site performs the various services successfully upon the first request, while it provides services on time with a mean value of 4.08. The eRIS site pages of the EFDA has been found to be downloaded quickly enough. The eRIS site of the EFDA also works properly with default browser and the site is customized to

individual users' needs as the mean score is 4.05 and 4.22 respectively. On the other hand, with a mean score of 4.29, the eRIS site has been found to be easy to use and well organized.

The findings of the study show also that the eRIS site of the EFDA provides information that is up to date and fresh, while the acquisition of user name and password for EFDA's eRIS site is also secure with a mean score of 4.0861, and the data provided by users on the EFDA's eRIS site are also securely archived. In general, the overall mean score of 4.0861 is an indication of the good practice of the eRIS project in the case of EFDA. Therefore, it can be concluded that the EFDA's eRIS site's service performance is successful upon initial request. The eRIS site of the EFDA also offers service promptly, and the EFDA's eRIS site pages can be retrieved rapidly enough. Additionally, the EFDA's eRIS site is tailored to each user's needs and was compatible with their default browser. Additionally, the EFDA's eRIS site is user-friendly, well-organized, and updated with the latest information. On the other hand, the username and password that are acquired for the EFDA's eRIS site are likewise safely stored.

It can also be concluded from the findings presented earlier that that the EFDA's eRIS site is easily accessible whenever the need arises, and with a mean score of with a high mean score of 4.23 the employees can also convey trust and confidence while displaying sincere interest in solving users' problems. It is also shown that with a very low mean value of 1.83, unnecessary data are not provided for authentication on the E FDA's eRIS site, and that there is no lack of infrastructure and technological capabilities for EFDA's eRIS site. It is also revealed that with a high mean score of 3.45, there is resistance to change from stakeholders, including government officials and businesses, which is considered a challenge to the implementation of the Ethiopian electronic Regulatory Information System (eRIS). It can also be concluded that there is no problem in connection with internet connectivity or power supply in accessing or updating the system as the score value which shows the problem in this regard is very, very low of 1.64.

The overall mean score of 2.3759 indicates that it is not a challenge for EFDA's eRIS site that employees do have the necessary knowledge to respond to user's inquiries; and have the ability to convey trust and confidence. Similarly, the findings also show that EFDA's eRIS project is not challenged by the inability of its employees to show a sincere interest in solving users' problems and provide prompt replies to users' inquiries.

This shows that the majority of the factors, such as the inconvenience of downloading or uploading data on eRIS forms in a short period; ease of accessibility; and lack of necessary knowledge to address user inquiries, do not pose a challenge to the EFDA's eRIS project. It can also be concluded that the eRIS project of the EFDA do not counter difficulties concerning the employees' capacity to inspire confidence and trust, the employees' inability to demonstrate a sincere interest in resolving users' problems, the provision of prompt responses to users' inquiries, the provision of unnecessary data for authentication, a lack of infrastructure and technological capabilities.

5.3 Recommendation

Based on the conclusions of the study, the researcher forwards the following recommendations:

1. It has been found that the EFDA’s eRIS site is easily accessible coupled with sincere interest of employees in solving users’ problems. And this should be maintained with committed efforts.

2. The findings of the study also show that stakeholder resistance to change was identified as a challenge for the implementation of EFDA's eRIS project. Therefore, the Management of EFDA should take appropriate corrective measures about awareness creation for its key stakeholder groups such as government officials and businesses.

3. One of the major findings of the study is that unintended data provided by site users posed challenges for EFDA's eRIS project implementation. Therefore, EFDA’s management should know the causes and consequences of this issue and take appropriate measures accordingly.

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Annexes

Annex I: Questionnaire

St. Mary's University
School of Graduate Studies
Department of Project Management

Dear participant,

This questionnaire is designed to assess the **Assessment of the Ethiopian Electronic Regulatory Information System (eRIS) Project: The Case of Ethiopian Food and Drug Authority (EFDA).** Completion of the questionnaire is completely voluntary. There are no correct or incorrect answers. Your anonymity is ensured. The information obtained through the questionnaire will be treated as confidential and will only be used strictly for academic purposes.

Returning this questionnaire will be considered as your consent to participate in the survey. The study is to be conducted in partial fulfillment of the requirements for the Master of Project Management.

- Please answer all questions.
- Your participation will be highly appreciated.

Thank you in advance for all your cooperation and kind consideration.

Best regards,

Laekemariam Dibabu

Directions: -

- Make only a tick mark (✓) on the space provided to show your answer.
- Please don't write your name in this questionnaire.

Part I - Basic Personal Data

1. Age (in Years)

A. 18 – 25 [ ] B. 26 – 35 [ ] C. 36 – 45 [ ] D. 46 – 55 [ ] E. 56 and above

2. Gender Male [ ] Female [ ]

2. Educational Background

A. High School [ ] B. Diploma [ ] C. First Degree [ ]

D. Master's Degree [ ] E. Ph.D. [ ]

4. Experience with EFDA or in EFDA (in Years):

A. <2 [ ] B. 3 – 5 [ ] C. 6 - 10 [ ] D. >11 [ ]

5. Job Position of Respondents:

A. Inspectors B. Dossier Assessor C. Director D. Team Leader E. Officer

Other, please specify _____

6. How often do you access or view eRIS?

A. Multiple times a day B. A few times a week C. Once a day

D. A few times a month E. Less than once a month F. Not at all

PART II – Please indicate your response regarding the Assessment of the Ethiopian Electronic Regulatory Information System (eRIS) Project: in the case of the Ethiopian Food and Drug Authority (EFDA).

Please indicate your level of agreement on the items listed below.

The scale is underscored as follows:

Strongly Agree=5 Agree =4 Neutral =3 Disagree = 2 Strongly Disagree =1

S/N.	Questions/Statements	5	4	3	2	1
I	**Practices of the Ethiopian Electronic Regulatory Information System (eRIS)**					
1	The EFDA's eRIS site performs the service successfully upon the first request.					
2	The EFDA's eRIS site provides service on time.					
3	The eRIS site pages of the EFDA can be downloaded quickly enough.					
4	The eRIS site of the EFDA works properly with your default browser.					

5	The EFDA's eRIS site is customized to individual users' needs.					
6	The eRIS site provided by EFDA is easy to use.					
7	The EFDA's eRIS site map is well organized.					
8	The eRIS site of the EFDA provides information that is up-to-date and fresh.					
9	The Acquisition of user name and password for EFDA's eRIS site is secure.					
10	Data provided by users on the EFDA's eRIS site are securely archived.					
II	**Challenges of the Ethiopian Electronic Regulatory Information System (eRIS)**					
1	EFDA is challenged by unintended data provided by users on its eRIS site.					
2	Forms on the EFDA's eRIS site are not convenient to download or upload data in a short period.					
3	The EFDA's eRIS site is not easily accessible whenever the need arises.					
4	In my opinion, EFDA's employees do have the necessary knowledge to respond to users' inquiries.					
5	EFDA's employees can convey trust and confidence.					
6	EFDA's employees couldn't show a sincere interest in solving users' problems.					
7	EFDA's employees couldn't give prompt replies to users' inquiries.					
8	Unnecessary data are provided for authentication on the E FDA's eRIS site					
9	There is a lack of infrastructure and technological capabilities for EFDA's eRIS site.					
10	Resistance to change from stakeholders, including government officials and businesses is considered a challenge to the implementation of the Ethiopian					
11	Limited internet connectivity or power supply causes problems in accessing or updating the system					
12	One challenge for the implementation of eRIS is ensuring data accuracy and completeness					
13	The limited technical skill of the users causes difficulty in using the system properly.					

14. Please mention some other major challenges, if any, for the implementation of the eRIS project

_____

_____

THANK YOU!

Annex II: Interview Questions

Dear Mr./Mrs _____,

First, I would like to thank you for accepting my invitation and giving your precious time to respond to this interview. This interview is designed to assess the assessment of the Ethiopian electronic Regulatory Information System (eRIS) project, in the case of the Ethiopian Food and Drug Authority.

1. In your opinion, is the EFDA's eRIS site easy to use and customized to individual users' needs?

_____
_____

2. Do you think that the EFDA's eRIS site provides service on time?

_____
_____

3. How do you explain the security of the eRIS SITE? Do you think that user name and password, and other private information are protected?

_____
_____

4. Do you think that the EFDA's eRIS site works properly with user's default browser?

_____
_____

5. Can the eRIS site of the EFDA provide up-to-date information to users?

_____
_____

6. Do you think that the data provided by users on the EFDA's eRIS site securely archived?

_____
_____

7. Is the EFDA's eRIS site available and accessible by users whenever the need arises?

_____
_____

8. Do you believe that EFDA's Employees have the necessary knowledge, ability, and sincere interest to respond to users' inquiries and convey trust & confidence?

_____
_____

9. In your opinion, what seems the practice of the Ethiopian electronic Regulatory Information System (eRIS) project, especially about the Ethiopian Food and Drug Authority?

10. What do you think is the possible solution for the observed challenges of the Ethiopian electronic Regulatory Information System (eRIS) project, in the case of the Ethiopian Food and Drug Authority?

_____

_____