Challenges and Success Factors in Mobile Commerce Customer Relationships Management: A Systematic Literature Review Protocol

Muhib Ullah^{1,2}, Siffat Ullah Khan^{1,2,3}

¹Software Engineering Research Group (SERG) University of Malakand, ²Department of Computer Science & IT, University of Malakand, ³Department of Software Engineering, University of Malakand, Khyber Pakhtunkhwa, Pakistan.

ABSTRACT: CONTEXT-- Mobile commerce (M-Commerce) is an emerging business paradigm in which the buying and selling of products and services is done through mobile equipment. These equipments are mobile phones, personal digital assistant (PDA) or other hand held wireless devices. M-commerce vendor organizations face many challenges regarding customer relationships management.

OBJECTIVE: The objective is to develop a systematic literature review protocol for the identification of the challenges and success factors faced by mobile commerce vendors in building and strengthening of relationships with customers.

METHOD: A Systematic Literature Review (SLR) methodology will be used for the identification and assessment of relevant literature. SLR is based on a structured protocol, and is therefore, different from ordinary literature review. SLR gives more prescribe results than ordinary review.

EXPECTED OUTCOME: The expected outcomes of this systematic literature review will be a list of challenges and success factors faced by M-commerce vendors in establishing and strengthening of relationships with customers in an M-commerce business paradigm. Our ultimate goal is the development of a Mobile Commerce Customer Relationships Management Model (MCCRMM). The SLR will provide the first phase in the development of the model.

Keywords – Mobile commerce, m-commerce, customers Relationship management, mobile commerce vendors, customers.

I. Introduction

Information and communication technologies (ICTs) are changing rapidly. Mobile devices are the results of the advancement ICTs. With the use of latest ICTs m-commerce has become a part of daily life. It assures to provide information anywhere and anytime. It increases the interaction between the business and customer and also makes it easier like the internet. Internet is a base for m-commerce. Market research industries show a large market for mobile services which will shift the customer's activities from "E-decade" to "M-decade" [1]. With the invention of wireless and mobile technologies, a new wave of technology-driven commerce has started-mobile commerce (m-commerce) in the world. Although in literature both the terms "wireless" and "mobile" are used interchangeably to refer to mobile application. However, there is a slight difference between these terms. The "wireless" indicates the way in which basically the data transmission is performed. Wireless means to transmit the data through airwaves to the end user [2, 3]. The term 'mobile' refers to applications which are developed for clients on the move, i.e. for applications in which the users are not dependent of his/her location [3]. It means that every wireless application is not a mobile application.

M-commerce is the type of e-commerce activities performed by using a mobile device such as phone or PDA, which make possible transactions through a wireless telecommunication network [4]. Mobile internet is unique and important over the stationary (motionless) internet because user can connect anytime everywhere to internet they want. Enhance features available on the mobile internet; promoters claim that m-commerce will surpass e-commerce in growth and scale. One of the key factors of m-commerce is to provide added value for the clients on the move. In Japan most of the people use mobile internet rather than stationary internet. With increasing growth of mobile technology, m-commerce has been promoting as major application for both enterprise and consumers. "Technology development and innovation create marketing opportunities and challenges. From I990s onwards, we have been witnessing a great shift in methods of doing business with the emergence of the electronic commerce (e-commerce). Nowadays, advanced and increasingly mature wireless and mobile technologies are facilitating e-commerce conducted from a wired network to a wireless network. When users conduct e-commerce such as e-banking or purchase products, they do not need to use a personal computer system. Indeed they can simply use some mobile handheld devices such as mobile phones and

personal digital assistants (PDAs) to conduct various e-commerce activities. Such way of conducting business can be defined as m-commerce, viewed as a subset of e-commerce" [5].

M-commerce is the advance form of e-commerce which works with in a mobile device using a mobile network infrastructure. M-commerce is a new technology and like e-commerce it has a number of issues and concerns. "M-commerce technology depends upon the network and telecommunication infrastructure. It also depends on the existing e-commerce, e-banking and payment systems of the country. The legislation and network security of the country are other key issues in implementation of m-commerce [6]. "Besides the mobile adoption, there are many challenges for the technology to be developed where end users by nature are slow to adopt new knowledge and have some kind of resistant to change. Thus, most of the studies in mobile commerce concentrated on how the organization develops appropriate strategies to promote mobile services with deep understanding of the users' perspectives" [7]. One of the major challenges faced by mobile content providers relates to the policy and management irregularities. This create several problems, e.g. delivery of illegal and pornographic content; service providers' forcing subscription of services by users without their prior consent; underdeveloped billing methods; and declining revenues in general [8, 9].

Like traditional businesses it is extremely important to have a deep understating of the customers and have good relationship with customers. Customer relationship management (CRM) means that how customer should be managed by organization. CRM is a commerce strategies that enhance organization's competitive aptitude, it make a winning strategies for understanding the customer's necessities, promoting the rising rate of organization and uphold customer in a high competitive market environment. CRM is needed because it will improve customer expectation, trustworthiness and satisfaction [10]. Customer's trust is one of the important factors for the development of M-commerce. However, it is hard to develop as it involves technology and commerce practices. Moreover, it is a continuous struggle form initial trust formation to continuous trust development [11]. From the literature review on CRM, it is cleared that it's a durable to catch the attention of a new customer then to maintain the relationship with exiting one. Giving proper concentration and worth to customer has good impression on customer [12].

Because of the importance of the customer relationship management in the m-commerce we are interested in the identification of challenges and critical success factors for m-commerce vendor organizations. A systematic literature review protocol has been developed. The following two research questions motivated the research:

RQ1. What are the challenges, as identified in literature, faced by mobile commerce vendors in building and strengthening of relationships with customers?

RQ2. What are the success factors (SFs), as identified in literature, to be developed by mobile commerce vendors for establishing and maintenance of long term relationships with customers?

II. Background

M-commerce is a type or subset of m-business and "denotes the transaction oriented part of mobile business towards the end customer" [13]. E-commerce is a part of e-business which can be defined as, "buying and selling of information, products and services via computer networks." i.e. Electronically [14]. M-business has also been defined as "a collection of mobile technologies and applications used to support processes, value chains and entire markets using wireless technology" [13]. M-commerce refers to the communication, interaction, and transaction via high-speed connection to the internet using handheld wireless devices [15]. M-Consumers refer to individuals that a consumer may need or want to interact with each other wirelessly for personal purposes. "M-commerce refers to commercial transactions conducted through a number of mobile devices over a wireless telecommunication network in a wireless environment" [5, 16]. Simply m-commerce is any e-commerce which is done in a wireless environment, especially via the internet. Main idea of m-commerce is to make business in a mobile way, it provides the opportunity of access of information and services anytime from any place to the user on his/her personal mobile device, use his/her mobile device to buy tickets for events or public transport, download contents and even order books or CD's [15].

Latest developments in ICTs have provided different types of mobile applications. Cell phone and mobile equipments allow people to communicate, play game, check email, surf the internet and also allow checking prices of different things in the market. Mobile commerce provide the facilities to peoples to access information anytime and anywhere [17]. The use of mobile phone has been dramatically increased in developed countries as well as in developing countries. However, this may be a reason that due to mobile phone users, the purchase of mobile products and services also increased. The rapid development of mobile applications has given rise to a new word: m-commerce. M-commerce is defined as the application of wireless communications [18]. Due to wireless and mobile communication the customers are now able to access information and services any time anywhere. i.e. (access banking financial statement and pay bills, receive store quotes and initiate buy/sell dealings, or receive special promotions [19]. With the emergence of latest technology, customers of mobile devices are able to access services and content anytime, anyplace. For example they can be able to pay

bill and access bank account, receive stock quotes and perform buy/sell transaction, or receive special promotion and generate orders from anywhere at any time. The word m-commerce is all about the wireless e-commerce, in which business activities can be done on the internet by using the mobile devices.

The extraordinary increase in the use of mobile phones and, more in recent times, also of wireless enabled Personal Digital Assistants (PDAs), is giving rise to yet another revolution in the commerce world. This revolution is focused on conducting business on the move or m-Commerce. This tendency increases the customer interest to access business services or to communicate with other customers anytime at anyplace. It is also motivated by the interest of the business community to extend their reach to customers at all times and at all places [5]. Less than a decade after the e-commerce revolution and its related global impact on business world, it comes into view that advancement has been made to the evolution network computing. The technology changed from wired to wireless networks, the latest buzz in the business is mobile commerce or m-commerce [20].

Researchers broadly define m-commerce to explore the possible benefits of the wireless technology. They analyze that m-commerce as the use of wireless technologies, especially mobile handheld devices and mobile internet, which provide the facility of transaction, searching information and the performance of user task in consumer, business-to-business and intra-enterprise communication [21]. Apart from transactions, M-commerce also supports value added services [22]. M-commerce is a subset of e commerce. M-commerce is an advance form of e-commerce as they share basic principles of business, but in addition m-commerce acts as another channel which added value to e-business activities. It also provides a new way which potentially met the needs of involving customers [23]. Consumers and businesses are two different types of customers exist in the m-commerce industry.

There are many factors that cause m-commerce to grow, some of these factors are internet enabled mobile handsets, portable computers and personal digital assistants (PDA) are becoming more familiar among consumer users and business. Another factor that wireless network infrastructure and support are constantly being upgraded by vendors to provide faultless access [15]. There has been a high growth in wireless in the last decade. This advancement has changed how people perform business in m-commerce environment. In short and simple term, we can say: M-commerce = E-commerce + Wireless Web [24].

Due to highly personalization and confidential user information, the mobile phone needs to be protected according to the highest security standards. The communication through air between mobile device and network introduce security threats. Generally many of the e-commerce application also apply to m commerce, for example, online e-stock trading, internet banking and online shopping. Auction site are starting to use m-commerce like sending an alert text-message when an auction is about to close [15]. M-commerce have many characteristics including ubiquity, convenience, interactivity, personalization and localization [15].

There are a lot of commonalities and similarities between m-commerce and e-commerce. They both provide much of the same functionality that facilitates e-business activities over the internet. However there are some differences exist in the type of devices that access the internet, the development language and communication protocols, the mode of communication, as well as the technologies used to support each environment [25].

To compare e-commerce with m-commerce, many disadvantages and advantages will be appear for m-commerce. The advantages of m-commerce that the use of wireless devices allowing the user to make transaction and receive information anywhere, at anytime. Also enable user to be reachable anytime and anyplace. One of the main advantage of m-commerce provide the ability to access the real time information [15]. Like other technologies the m-commerce also has disadvantages, such as mobile devices offer limited capabilities like limited display. Also, mobile is exposed to theft and destruction than PC devices.

Handheld and mobile devices are different from desktop and laptop computers in several ways. They generally have smaller screen sizes and limited input capabilities. There are some issues and challenges in mobile commerce like input output, bandwidth and security. A wide array of concerns exists in this area, including ubiquity, usability, privacy, cost, timeliness, freshness, and accuracy of information. Ubiquity, discussed under connectivity, is important, as mobile users should be able to access information irrespective of their location and device/network type. Consumer concerns surrounding connectivity involve the issues of security, reliability, download times, and cost [26].

III. Systematic literature review protocol for Challenges and success factors in Mobile Commerce Customer Relationships Management

The purpose of this paper is to design the systematic literature review (SLR) protocol for challenges and success factors in mobile commerce customer relationship management following the Kitchenham and Charters guidelines (2007).

Kitchenham defines three main steps in a systematic review process: planning, conducting, and reporting [27]. In this paper we describe the first step of a systematic review (i.e. planning the review). The

output from this step is a systematic literature review protocol that defines the purpose and procedures for the review. Kitchenham notes that a pre-defined protocol is necessary to reduce the possibility of researcher bias [27].

IV. Research Questions

RQ1. What are the challenges, as identified in literature, faced by mobile commerce vendors in building and strengthening of relationships with customers?

RQ2. What are the success factors (SFs), as identified in literature, to be developed by mobile commerce vendors for establishing and maintenance of long term relationships with customers?

a. Constructing Search Term

The following details will help in designing a search term relevant to our research questions.

Population: Mobile commerce vendors and customers.

Intervention: Factors, barriers, critical success factors, challenges, characteristics

Outcomes of relevance: Establishing long lasting relationships, trust building, Strengthening relationship

Experimental Design: Empirical studies, theoretical studies, case studies, experts' opinions.

An example of the Research Question containing the above details is:

RQ1:

[What are the challenges]-----"INTERVENTION"

faced by

[M-commerce vendors]----"POPULATION"

In building and strengthening

[of relationships with customers]-----"OUTCOMES OF RELAVANCE"

V. Search Strategy

5.1. Trial Search

A trial search was conducted using the following search string on IEEEXplore, ACM and ScienceDirect digital libraries.

(("Mobile commerce" OR "m-commerce" OR "Mobile Business" OR "m-business" OR "mobile trade") AND (relationships OR association OR collaboration OR relation OR interaction OR dealing) AND (factors OR factor OR characters OR challenges OR issues OR barriers OR problems) AND (vendors OR supplier OR customer))

The papers retrieved through this search string will be used as a guide for the development and validation of the major search terms.

5.2. Identifying Search Terms

The following search strategy is used for the construction of search terms.

- a) Use the Research Questions for the derivation of major terms, by identifying population, intervention and outcome:
- b) For these major terms, find the alternative spellings and synonyms;
- c) Verify the key words in any relevant paper;
- d) Use of Boolean Operators for conjunction if the database allows, in such a way, to use 'OR' operator for the concatenation of alternative spellings and synonyms whereas 'AND' for the concatenation of major terms.

Results for a)

RQ1: Mobile commerce, vendors, challenges, relationships, customers

RQ2: Mobile commerce, vendors, success factors, relationships, customers

Results for b)

(i) RQ1:

Mobile commerce: ("Mobile commerce" OR "m-commerce" OR "Mobile Business" OR "m-business" OR mcommerce OR "portable commerce" OR "Portable Business" OR "nomadic commerce")

Challenges: (challenges OR problems OR barriers OR issues OR obstacles OR troubles OR hurdles OR "risk Analysis" OR "critical factors")

Vendors: (vendor OR vendors OR service-provider OR dealer OR trader OR marketer OR seller OR developer OR salesperson OR retailer OR stakeholders OR marketer OR broker)

Relationships: (Relationships OR "teamwork" OR collaboration OR co-ordination OR alliance OR associations OR partnerships OR dealings OR contract OR interaction OR relations OR affairs OR correlation OR interrelationship OR fellowship)

(ii) RQ2:

Mobile commerce: ("Mobile commerce" OR "m-commerce" OR "Mobile Business" OR "m-business" OR mcommerce OR "portable commerce" OR "Portable Business" OR "nomadic commerce")

Factors: (factors OR drivers OR motivators OR elements OR characteristics OR parameters)

Vendors: (vendor OR vendors OR service-provider OR dealer OR trader OR marketer OR seller OR developer OR salesperson OR retailer OR stakeholders OR marketer OR broker)

Relationships: (Relationships OR "teamwork" OR collaboration OR co-ordination OR alliance OR associations OR partnerships OR dealings OR contract OR interaction OR relations OR affairs OR correlation OR interrelationship OR fellowship)

Results for c)

Mobile commerce, m-commerce, mobile commerce relationships, customer relationships management, customers

Results for d)

Only one major term is used in RQ2 which is different from RQ1 that is factor so we have defined a single search string for both questions containing factor's synonyms as show below

(("Mobile commerce" OR "m-commerce" OR "Mobile Business" OR "m-business") AND (factors OR drivers OR motivators OR elements OR characteristics OR parameters) AND (Challenges OR problems OR barriers OR issues OR obstacles OR troubles OR hurdles) AND (Vendor OR vendors OR "service provider" OR dealer OR trader OR marketer OR seller OR developer OR salesperson OR retailer OR stakeholders) AND (Relationships OR "teamwork" OR collaboration OR co ordination OR alliance OR associations OR partnerships OR dealings OR contract OR interaction OR relations OR affairs))

5.3. Search Term Break up

We will use the search string mentioned in 5.2(d) as our search terms. As some of the databases don't allow the lengthy search strings we will split the search term into smaller sub strings and will do separate search for each of these search strings. Finally we will summarize the search results by removing the redundancy. It should be noted that while using IEEExplore digital library, the search strings mentioned in 5.2(d) will be used with a technique that it should be put in the pane instead of text-boxes provided in the advance search.

The breakups of the search string mentioned in 5.2 (d) are mentioned below.

Substring 1

(("Mobile commerce" OR "m-business") AND (Challenges OR problems) AND (factors OR drivers) AND (Vendor OR service provider OR dealer) AND (Relationships OR "teamwork" OR collaboration OR co ordination))

Substring 2

(("m-commerce" OR "Mobile Business") AND (barriers OR issues OR obstacles) AND (motivators OR elements) AND (vendors OR seller OR developer OR salesperson) AND (Relationships OR partnerships OR dealings OR contract))

Substring 3

(("Mobile commerce" OR "m-business") AND (troubles OR hurdles) AND (characteristics OR parameters) AND (trader OR marketer OR retailer OR stakeholders) AND (alliance OR associations OR interaction OR relations OR affairs))

5.4. Resources to be searched

- ➤ IEEEXplore
- > ACM Portal
- ScienceDirect(www.sciencedirect.com)
- Emerald (www.emeraldinsight.com)
- ➤ Google Scholar (scholar.google.com)
- > SpringerLink

5.5. Search Constraints and Validation

We are searching for all published papers related to our research and hence don't put any date boundaries. A prior search was conducted using a set of major search terms (("Mobile commerce" OR "m-commerce" OR "m-business" OR "mobile trade") AND (relationships OR association OR collaboration OR relation OR interaction OR dealing) AND (factors OR factor OR characters OR challenges OR issues OR barriers OR problems) AND (vendors OR supplier OR customer)) and we found certain relevant papers on IEEEXplore, ScienceDirect and ACM digital libraries. Prior to undertake the review process, these relevant papers will be used for the validation of search strings.

5.6. Search Result Management

Primary source references will be stored electronically in a separate directory. The results of each search will be stored in a directory as html pages. Moreover the primary selection list will be in the following format. It should be noted that the Tracing no. is the no. found for a particular paper during its search. If a paper is referenced in more than one database, then it will be entered once in the final selection list to avoid duplication. The "S.No" field of the final list is the primary key for a paper being selected in the review.

S.No	Tracing Number	Database	Paper title
1	497	ScienceDirect	MOBILE E-COMMERCE TO DRIVE VOICE-BASED AUTHENTICATION
2	14	IEEE <i>Xplore</i>	THE EFFICIENT BOND AMONG MOBILE COMMERCE, CRM AND E-LOYALTY TO MAXIMIZE THE PRODUCTIVITY OF COMPANIES.
3	1172	ACM	A USER ADAPTIVE MOBILE COMMERCE SYSTEM WITH A MIDDLET APPLICATION

5.7. Search Documentation

Search results will be documented in the format as shown in the table below.

Name of database	Search strategy	Search phase	Date of search	Year covere d by search	Number of publications found	Initial selection decision	Final selection decision
IEEEXpl ore	(("Mobile commerce" OR "m-commerce"	ce" OR <u>E</u> .	20/06/2012	All	129	21	
ACM	OR "Mobile Business" OR	Search	2012		1,850	107	
ScienceD irect	"m-business" OR "mobile trade") AND (relationships OR association OR collaboration OR relation OR interaction OR dealing) AND (factors OR				1,178 (1000 access)	54	

factor OR			
characters OR			
challenges OR			
issues OR			
barriers OR			
problems) AND			
(vendors OR			
supplier OR			
customer))			

VI. Publication Selection

This section contains three subsections namely inclusion criteria, exclusion criteria and the selection of primary sources, in order to choose only those search results which are relevant to the research questions. We will only consider papers/reports/books relating to m-commerce and m-business.

6.1. Inclusion Criteria

The inclusion criteria we used to determine which piece of literature (papers, technical reports, or 'grey literature' or book) found by the search term will be used for the data extraction. We will only consider papers related to m-commerce and written in English. The criteria are listed below:

- Studies that describe factors/motivators for m-commerce customer relationships management.
- > Studies that describe factors/motivators for m-commerce customer relationships strengthening
- > Studies that describe challenges/barriers for m-commerce customer relationships management.
- > Studies that describe challenges/barriers for m-commerce customer relationships strengthening
- ➤ Studies that describe challenges or success factors for m-commerce vendor organizations
- ➤ Studies that describe criteria for a successful m-commerce relationships
- Studies that describe issues in m-commerce relationships
- > Studies that describe factors affecting m-commerce customer relationships

6.2. Exclusion Criteria

This section describes the exclusion criteria in order to decide which piece of literature found by the search term will be excluded /ignored. The criteria are listed below:

- > Studies that is not relevant to the research questions.
- > Studies that don't describe m-commerce customer relationships.
- > Studies that don't describe barriers/challenges for m-commerce customer relationships.
- > Studies that don't describe factors/success factors for m-commerce customer relationships.
- > Studies other than m-commerce.

6.3. Selecting Primary Sources

Initial selection of the primary sources will be performed by reviewing the title, keywords and abstract. The purpose is to exclude/ignore only those results which have no relevance to the problem/research questions. The primary sources chosen in the initial selection process will be checked against the aforesaid inclusion/exclusion criteria by reviewing carefully through full text of the studies. The source will be sent to the secondary reviewer, for review in case of any uncertainty regarding the inclusion or exclusion decision. The record of inclusion/exclusion decision regarding each primary source will be sustained properly. This will describe the reasons/justification whether or not the primary source has been included in the final review.

Researcher Responsible: Muhib Ullah, Software Engineering Research Group (SERG), University of Malakand, Pakistan.

VII. Publication Quality Assessment

The measurement of quality is performed after final selection of publications. The quality of publications is assessed in parallel at the time of data extraction. The quality checklist contains the following questions:

- ➤ Is it clear how challenges/barriers were measured/evaluated in m-commerce customer relationships management and Strengthening?
- ➤ Is it clear how the CSFs (critical success factors) for m-commerce customer relationships management and Strengthening were identified?
- Is it clear how the CSFs (critical success factors) for long lasting relationships between customers and m-commerce vendors were identified?

Each of the above factors will be marked as 'YES' or 'NO' or 'Partial' or 'N.A'.

A secondary reviewer will score a small subset for validation.

VIII. Data Extraction Strategy

8.1. Primary Study Data

The purpose of the study is to collect the data, from the publications, which is focused on satisfying the research questions for the review. The following data will be extracted from each publication.

- ➤ Publication details (Title, Authors, Journal/Conference title, etc)
- Data that address the research questions.

To address the research questions, the following data will be extracted:

RQ1:

➤ Background information, Challenges for m-commerce customer relationships management and Strengthening

RQ2:

➤ Background information, Success Factors (SFs) for long lasting relationships between customer and vendor organizations in m-commerce

The following table presents the data to be captured in the data extraction form.

Data to be extracted

- Date of review
- > Title
- Authors
- Reference
- Database
- Methodology (interview, case study, report, survey, SLR etc)
- Sample Population
- > Target Population
- Publication Quality Description
- Organization Type (software house, university, research institute etc)
- Company size (small, medium, large)
- Country / location of the Analysis
- > SPI certification
- > Year
- > Challenges in building and strengthening of m-commerce customer relationships
- Success Factors (CSFs) for long lasting relationships between customer and vendor organizations in m-commerce?

Sim et al [28] defines sample and target populations as follow.

"Sampling is the selection of a group of cases from a large collection of such cases, according to a specific procedure. These 'cases' may be persons, institutions, objects or events. The target population is the collection of cases in which the researcher is ultimately interested, and to which he or she wishes to make generalizations."

8.2. Data Extraction Process

The review will be undertaken by a single researcher, who will be responsible for the data extraction. A secondary reviewer will be approached for guidance in case of an issue regarding the data extraction. The interrater reliability test will be performed after the data extraction process by the primary reviewer. The secondary reviewer will select few publications randomly from the list of publication already chosen by the primary reviewer. The secondary reviewer will independently extract the data from the randomly selected publication. The results will then be compared with the results produced by the primary reviewer.

Primary Reviewer: Muhib Ullah, Software Engineering Research Group (SERG), University of Malakand, Pakistan

Secondary Reviewers: Dr Siffat Ullah Khan (siffatullah@uom.edu.pk)

8.3. Data Storage

The summarized data for each publication will be kept as a Microsoft Word/SPSS document and will be stored electronically.

IX. Data Synthesis

Due to two research questions, the synthesis will also be categorized into two parts. For the Research Question1, the data will be synthesized by creating one summary table having the columns (S.No, challenges/barriers, Frequency, Percentages) showing the list of all the challenges/barriers along with their frequencies and percentages. The complete detail of every barrier mentioned in the Summary table will be recorded in a separate table which will hold the following the columns (Barrier/Challenge group name, S.No of reference, Barrier/Challenge subgroups, Paper reference/Paper title). For the Research Question 2, the same process will be performed as for the RQ1 mentioned above.

X. Validation of the Review Protocol

The protocol was initially reviewed by my Supervisor Dr Siffat Ullah Khan. It was further reviewed by our research fellows, Muhammad Ilyas Azeem, Abdul Wahid and Muhammad Salam. Finally the protocol was presented to Software Engineering Research Group at University of Malakand (SERG_UOM) for validation.

XI. Divergences

In case of any divergence from the protocol, which may occur during the study, we will record any change in a new Appendix to this document.

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