CHAPTER 3
RESEARCH DESIGN AND METHODOLOGY

3.1 Research design for the study

3.1.1 Objective of Research

According to Sekaran’s model of business research, a research study presents an organized, a systematic and a scientific inquiry proposal with an objective of fitting the problems under consideration using a suitable method [307]. Edmondson and Mcmanus refer such methodological fit as an internal consistency among elements of a research study, such as research question, prior work, research design, and theoretical contribution [309].

Following Wallace’s conception regarding research methodology, this study institutes scientific and business processes to evaluate the truth of statements by dissecting the research problems into multiple appendages of inquiry [301]. Consequently, running multiple methods, not only to solve diverse and multidimensional nature of problems but also to gain insights from the findings, seem to be essential. Earlier, Best and Kahn made use of a literature-driven study implemented in careful collection of subjective data [311], expecting to represent a larger population [312]. The next section endeavours to define research process to address theoretically driven research question.

3.1.2 Research Design Strategy

A research design is a framework or plan for a study, employed as a guide for collecting and analyzing data (Creswell, 2010) [313]. Selecting appropriate methodology can be accomplished after systematic investigation of reported methods that cater to a specific research objective [314]. Based on the quantitative or qualitative method approaches, this research study adopts best procedures to produce valid results, meeting the objective of addressing the research question.
In quantitative research, variables are measured on the instruments and analysis is carried out using statistical procedures. Methodologists [315-316] conceptualize quantitative research as a structured, predetermined methodology with a narrow focus emphasizing on the selection of adequate sample size to quantify a phenomenon for generalizing the total population.

However, in essence, qualitative research follows a flexible open approach to enquiry, describing and interpreting some human phenomenon, often in the words of selected individuals also known as the informants [313,316]. Strauss [249], Lincoln and Guba [255], suggested employing qualitative research methods (such as ethnographic field study, single case study, etc.) and accordingly design specific research procedures (e.g., such as, long interviews, observation etc.) for setting enquiry into complex research problems. According to Maykut and Morehouse [317], integrating the concepts about the reality, associated with the phenomenon under study, the data collected through in-depth interviews (also known as inductive research) depends on researchers interpretations.

3.1.3 Research Question, Objective and Proposition

Today, both quantitative and qualitative research methodologies are better analyzing the complex problems which are not yet debated. According to Edmondson and McManus[309], in a given field study, the current theories inform methodological decision based on the levels of prior work and has been classified as nascent, mature and intermediate research. Intuiting on the methodological research frame, nascent, mature and intermediate levels of prior work correspond to three respective approaches—qualitative, quantitative and hybrid.

Drug adoption literatures address complex disease (such as HIV) management using mixed mode, employing both quantitative and qualitative research methodologies [318, 319]. Here, researchers have investigated the factors associated with negative health outcomes to provide a holistic understanding of such drug adoption process [318-319]. Creswell and Plano Clark [293] also suggest that the hybrid research methodology provides a richer understanding of complex social issues.
The objective of the study is to further the understanding of drug adoption phenomenon so that the firm’s investment on quality drug manufacture provides desired healthcare benefits to consumers. The reader is reminded that the term ‘firm’ in the proposition refers to pharmaceutical drug producers and ‘marketers’ and ‘consumers’ refer to either patients or doctors or both depending upon the significant relationship with drug adoption. This section helps in understanding the concept of drug adoption in private Indian hospitals. It builds on the main theme in order to answer the research question, namely:

**Why healthcare performance of India, particularly for managing NCD is poor, given the condition that of most of the late-entrants drugs fail to get adopted in healthcare system while only a few succeeds?**

Here, a broad research question, to understand the impact of medical information communication on adoption of a prescription drug, has been framed.

Following Patton [320], this study, in a real-world situation, is neither driven by the predetermined hypothesis nor is an attempt made to test the existing theory. In essence, to unpack the drug adoption concepts, the understanding of a local drug adoption situation, as opposed to global adoption process, is essential. This necessitates the use of literature review where a statistical manipulation has been conducted (as represented in Tables 3.1 and 3.2) to gain insights into the research problem [319]. Hence, a set of research objectives and propositions is formulated in the context of drug adoption. The purpose of the proposition is to facilitate the operationalisation of each objective by formulating a set of hypotheses. These objectives and relevant propositions are summarised in Figure 3.1, representing a type of Response Model to conceptualize the relationship among stakeholders involved in decision-making for adoption of quality drugs. Moreover, it becomes imperative to know if the prescription decision is influenced by patients’ disease state, age, smoking habits, etc. while adopting late-entrant drugs. This dissertation conducts a case study on hypertensive patients, by analyzing their records from private hospitals, was evaluated. Knowledge-mining tool such as data mining was chosen for analysis.
A 5-stepped Research Design for Action Research on Identifying factors and developing a Scale for Drug Adoption

Purpose:
(a) To understand how to improve the adoption level
(b) Discussion of problem based on new findings and suggestion will help to take future decision

Purpose:
(a) To understand what determines low drug adoption
(b) To refine hypothesis and retest the findings using larger sample size

Purpose:
(i) Literature Review
(ii) Patient Characteristics

Purpose:
(a) Identify high and low prescription in patient treatment—literature analytic method
(b) Data mining using classification technique using patient characteristic to understand if patient related factor influence drug adoption

Purpose:
(i) Pilot Quantitative study on doctor: Survey Questionnaire
(ii) Pilot Qualitative study on specialist doctor: Focus group interview

Purpose:
GATHERING DATA AND ANALYSIS—LARGE SCALE
Explanatory model: What are the communication drivers for drug adoption based on 2 and 3 Steps Pivotal study

Purpose:
GATHERING DATA AND ANALYSIS—SMALL SCALE

Knowledge Gain on issue based on the findings

Research Process of Studying Drug Adoption

Figure 3.1 Research design: A Response Model
Classification technique for adapting data mining method was employed in an exploratory study design. The objective of the study was to understand if the patient characteristics influence the new drug adoption process. A binary logic is assumed, based on mutually exclusive cases, in the proposed response model:

(i) Either patient characteristic is considered by doctors while prescribing new hypertension treating drugs

or

(ii) Patient characteristic is an insignificant factor while prescribing new late-entrant drug

Based on the research questions, discussed in ‘Introduction’, research objectives have been defined. For organizational strategy, organization is a construct and is the unit of analysis. If an individual opinion difference is measured, then the individual is the unit of analysis. There is, however, organization-level or individual-level variation in drug adoption, depending on the socio-economic status of a nation. Medical decision is at individual level (i.e., physician level) in India unlike the organizational level (i.e., HMO—Health Medical Organization—participation) for LEGPD adoption in developed nations. In India, drug adoption is not an organizational construct, and at individual level, it needs to be explored. The expectation in health and wellness for the nation from the physicians end becomes the centre point of investigation. Hence, three phases of this action research explain as to what is the unit of analysis selected to determine LEGPD adoption successes in challenging environmental conditions.

From the research objective, stems the proposition that supports in building hypothesis. By developing the hypothesis, the proposed direction for testing relationships between the constructs is executed. The propositions are first discussed phase-wise, in Table 3.1, depicted by PHASES I, II and III. Propositions derived from healthcare communication framework (please refer figure 1.3) are tested in exploratory manner (employing qualitative study) and empirically (using quantitative study) in a cross-healthcare industry samples of 250 medical practitioners in India.
<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>RESEARCH QUESTIONS (RQ)</th>
<th>RESEARCH OBJECTIVES</th>
<th>PROPOSITIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHASE I</td>
<td><strong>RQ #1.</strong> Given that the level of pharmaceutical adoption for prescription purposes in India is low in comparison with the adoption rate for developed countries, what specifically and precisely are the sources of medical information that influence domestic adoption decision and how do these relate to one another based on disease complexity?</td>
<td>To investigate how sources and nature of medical information lead to variations in the local drug adoption situation against the global drug adoption process. This dissertation attempts to confirm (a) that private hospitals in India receive fragmented information from drug-producers (b) that responsive decision-making system are unavailable</td>
<td>[1] The conditions of (a) and (b) lead to relatively low levels of drug adoption as such decisions are based on disease complexity. [2] Private hospitals in India receive fragmented information from drug-producers that lead to low-levels of drug adoption</td>
</tr>
<tr>
<td>PHASE II (a)</td>
<td><strong>RQ #2.</strong> How the practice of informed decision-making, dependant on disease complexity, is related to clinical symptoms that can lead to higher adoption of late-entrant drugs</td>
<td>To determine if patient related disease characteristic is related to adoption decision of late-entrant drug prescription</td>
<td>As doctors in developed nations practice shared decision-making with their patients, lower consideration of patient characteristics leads to low level of drug adoption in India</td>
</tr>
<tr>
<td>PHASE II (b)</td>
<td><strong>RQ #3.</strong> What are the diverse sources of medical information that doctors consider in clinical setting to adopt new late-entrant prescription?</td>
<td>To determine the drug adoption processes that doctors at private healthcare institutions in India intend to employ, based on certain demographics traits</td>
<td>The internal and external information sources along with individual knowledge and experience will influence the firm’s promotional effort for higher level of drug adoption</td>
</tr>
<tr>
<td>PHASE III</td>
<td><strong>RQ #4.</strong> What are the communication drivers that support or impede new prescription drug adoption?</td>
<td>To examine the communication and prescriber-related factors that impacts drug adoption decision</td>
<td>Communication drivers will support or impede drug adoption decision based on prescriber’s intention that varies with their experiences</td>
</tr>
</tbody>
</table>
(a) PHASE I

Adopting an inductive approach to identify the key variables for new drug prescription, the stakeholders involved in such decision-making in Indian private hospitals are targeted in this study. It is imperative to first understand the influence of patient characteristics in prescription decisions at private hospitals of India so as to clearly and succinctly identify and explain the problem within the framework of the theory.

Due to limited evidence available, an exploratory research method has been proposed for the PHASE I research cycle. Since the purpose of the study is to further understand how medical information has been exchanged by drug producers to achieve a high level of drug adoption, conducting a field study for a real-time prescription environment becomes essential. The PHASE II research cycle employed a field study design that involved doctor’s opinion for new drug adoption.

(b) PHASE II

A small-scale (pilot) descriptive study at the private hospitals of India, chosen randomly in urban cities, was designed before undertaking this study. Based on the findings of PHASE I, key constructs were again defined in order to develop a project design. Subsequently, it is necessary to prevent the study being restricted to partial empirical view only. As discussed, mixed mode research is justified to tackle this type of research problem [318,319] that has not reached a mature conceptual stage.

More specifically, in the light of the analyzed quantitative data, it is prudent to employ qualitative study to understand how the prescription knowledge is defined contextually and shared in a real-time clinical setting. The flexibility offered by the inductive approach and supplemented with multiple methods of data collection has been the essence of this study. The research questions address an area that has not been
previously explored. Employing the inductive approach that underpins phenomenological concepts, a focused group study was implemented. The purpose of interspersing a qualitative study in-between two quantitative studies is to check if the hypothesis fits the proposed framework.

The quantitative data analytics in PHASE II, subsequently explained by a qualitative study, supports the design of a research project in PHASE III. Employing Platt’s model of hierarchical triangulation [79], the research project develops into a methodological model. Embedding PHASE I and PHASE II cycle for design of a research instrument develops into a contingency framework for drug adoption, as explained in Phase III. Both the communication drivers and prescriber-related demographic factors are proposed to influence the drug adoption decision that indicates better health performance of consumers (Figure 3.1).

(c) Phase III

With the data triangulation approach applied to the findings of PHASE II mixed-mode research, explanatory research has been argued to be appropriate as both the definition of key constructs and their relationships were established. Based on the derived methodological model, a survey at a pivotal scale had been conducted by adapting a deductive approach. Execution of theoretically driven, contextually supported model had been tested with a refined hypothesis. Multivariate data analysis techniques used in this research project design have enabled the production of quality analytical data, with acceptable reliability and validity. Consequently, an appropriate measurement instrument, sources used for data gathering, selecting suitable sampling strategy and framing appropriate questionnaire have been deemed as the crucial steps for predicting drug adoption. Finally, multi-models were evaluated to provide insight into the research implications, theoretical contribution and managerial applications.
Figure 3.2 A schematic representation of cyclical research process

OUTCOME
LINKING METHODS

Secondary Data Collection
- Literature Analytic Method (i)
- Patient Record from Private hospitals - Manipulation with
- Data Mining technique using Classification Method (ii)

Primary Data Collection
2 Pilot Scale Studies (A & B)
A. Survey - MLR analysis
B. Phenomenological interview with Focus Group -
   Q)Cognitive Mapping &
   (ii)Reparatory Grid

Primary Data Collection
1 Pivotal Study
i. Quality data: Reliability and Validity using Multivariate Data Analysis
ii. MLR, SEM techniques
iii. Practical Implication, Theoretical Contribution and Managerial Application
Following Bertoluci [322], Figure 3.2 represents a cyclical process in which each phase moves the wheels of the research process, sequentially. Adopting Marchand [323], the research question develops into a ‘posterior wheel’ to move the ‘outcome wheel’, implemented as per the proposed research objectives.

3.2 Instrument Development

3.2.1 Data collection process and sampling

Since medical practitioners are always occupied with patients and are stressed with time pressure, conducting surveys at their clinic is challenging. Again, estimation of rate of prescription drug adoption has not been the objective of study, so a longitudinal approach arguably is an inappropriate. Furthermore, this research study aims to define the drug adoption process and simultaneously endeavours to minimize variations in prescription behaviour. In total, adopting a cross-sectional design for data gathering, at a single point of time, has been deemed as the most appropriate one.

The selection of sampling is crucial for the success of a research project and survey is conducted to measure the characteristics of a population. For specialized disease domains in healthcare, where population selected for the study is sparse, non-probability sampling method is usually followed [324–326]. One of the further ramifications of non-probability sampling, snow-ball concept, complimented with network sampling methodology, always remain as the best option for selecting the specialized expert in the domain [327].

As sample surveys require a frame for reaching the target population, in some cases frames in which each target population element is linked becomes inaccessible or highly expensive to use because the target population is either restricted or very rare, respectively. In such a challenging situation, to increase the feasibility of the survey,
frames in which target elements have multiple associations or linkages with sampling units are used. The number of linkages between target element and a frame is called element’s multiplicity. A survey employing such frames is called ‘surveys with multiplicity’ or ‘network surveys’ [325]. Multiplicity sampling has been widely used in healthcare (rare disease) survey estimation [326-327] as it improves screening efficiency for identifying elements of a rare population, increases the scope of survey yields and also decreases sampling errors. The dissertation argues that such sampling method is appropriate for cancer surveys and specialist doctors (such as cardiologist and oncologist)as they are highly inaccessible or restricted due to their extremely busy schedules involving patient’s life.

3.2.2 Sampling and questionnaire strategy

The population related to this study is vast. Literature review showed that the drug adoption was impeded by variations in prescription decisions due to multiple factors, such as skills, attitude, commitment, dedication, experience, qualifications and doctor’s orientation with the latest developments in methodology of treatment or healthcare services and available drugs to cure diseases. The services of doctors are always merit-based and highly skilled, with their demands being heterogeneous in nature. A subset of such doctors is usually found in branded multispecialty hospitals of the private sector, and it is difficult to carry out a survey, despite repeated efforts. In such cases, the non-response rate is high, probability-sampling method cannot be adopted as it is not left on the choice of the researcher.

Research in this area is, however, equally important. The time taken to conduct this study was more than two years, yet the sample size was small. In such studies, it is difficult to frame the probability sampling method and maintain the essence of quality research. That is why, snowball sampling method was adopted, where initial respondents were selected randomly and the referral system continued to recruit more and more samples. This study, following Sirken and Levy [325], argues for non-
probability sampling multiplicity approach, was undertaken for probing into the causes of drug adoption [326] using rare population of respondents (doctors were hardly accessed during their practice hours and multiple visits were required for collecting their unbiased-opinions).

In order to construct a valid survey questionnaire, the initially created survey questionnaire was pretested before being employed as an instrument for quantitative study. Subsequently, with a qualitative approach in a focus group setting, this instrument was refined using section of semi-structured questions. The approach of using an unstructured, open-ended questionnaire explores the responses from the structured questionnaire in the first section as well as supports and better confirms the meanings that respondents ascribe to the concerned phenomena. In this context, Saunders and others [324] made use of such semi-structured and unstructured interviews to verify findings from structured questionnaires implemented in quantitative study, thereby utilizing principles of qualitative study [327]. Following Saunders and others [324], the wording of responses received from doctors participating in the focus group refined the research instrument. Following Jick’s triangulation concepts in mixed method research [328], two face-to-face surveys were designed using a structured questionnaire: one pilot study on sources of medical information that influence drug adoption and the other pivotal research on the communication drivers impacting individual physicians’ adoption of late-entrant drugs.

These two quantitative studies were spaced by a qualitative, open-ended, undisguised study, employing focus group survey methodology. Since its purpose is to understand the causes of variation in drug adoption responses, in light of the first quantitative study findings, the undisguised route was preferred because it gave the researcher the perception of reality about the drug adoption phenomenon. Moreover, the qualitative approach, applying the cognitive map and repertory grid analysis to develop theoretically driven hypotheses linked to practical experiences had been justified earlier.
Therefore, two pilot survey studies, i.e., quantitative followed by qualitative, based on the principles of primary study collection were undertaken.

### 3.3 Methods of measure for Phase I and Phase II studies

#### 3.3.1. Analysis on global adoption

The intent of a doctor’s prescription is conceptualized as an example of thrust in psychological research where proposition is developed to reflect a person’s activities, interests, and opinions and consumption behaviour [81]. The focus on behaviour involves a description of the activity with respect to the various components. A person’s intention refers to the individual’s anticipated or planned future behaviour. The number of people who answer that they definitely buy or probably would buy is often combined to indicate likely reaction to the new product or service [82]. However, behavioural intentions do not actually predict behaviour as conceptualized through a series of study undertaken.

Variation in drug adoption can be physician-related or situational [123,201-211]. The largest proportion of non-communicable diseases (NCD) deaths is caused by cardiovascular diseases [4,75]. In terms of deaths, with assigned cause, high blood pressure is one of the leading behavioural and physiological risk factor to which thirteen per cent of global deaths are attributed. This situation directs the healthcare industry to focus on the manufacture of drugs treating hypertension, as this NCD has received a status of global concern. The healthcare market in USA is growing due to huge requirements of antihypertensive drugs. The five different classes of drugs are prescribed routinely. For launching late-entrant drug in hypertension treatment, marketing strategies in USA, an established market will provide with an insight of quality medicine that is very safe and widely prescribed. The market shares of antihypertensive drugs in USA, reflecting physician’s prescription pattern, has been framed in Table 3.2.
Table 3.2: Prescribing patterns of anti-hypertensive (drugs) in USA

<table>
<thead>
<tr>
<th>Class of CVS Drugs</th>
<th>Total prescriptions (Million)</th>
<th>Share of HTN MARKET (%)*</th>
<th>Sales($) in Billion</th>
<th>Market Share (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ace inhibitors (ACE)</td>
<td>164.8</td>
<td>30</td>
<td>1.2</td>
<td>9</td>
</tr>
<tr>
<td>BETA-BLOCKERS (BB)</td>
<td>127.5</td>
<td>24</td>
<td>1.9</td>
<td>14</td>
</tr>
<tr>
<td>Calcium channel blockers (CCB)</td>
<td>98.1</td>
<td>18</td>
<td>1.4</td>
<td>10</td>
</tr>
<tr>
<td>Angiotensin receptor BLOCKER</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ARB)</td>
<td>83.4</td>
<td>15</td>
<td>7.4</td>
<td>53</td>
</tr>
<tr>
<td>Alpha adrenergic blockers</td>
<td>25.2</td>
<td>5</td>
<td>418.1</td>
<td>3</td>
</tr>
<tr>
<td>Others (diuretics,etc.)</td>
<td>42.5</td>
<td>8</td>
<td>1.6</td>
<td>11</td>
</tr>
</tbody>
</table>

3.3.2 Local situation of drug adoption

After a thorough literature research, the perspectives emerged are used to develop research propositions for the study. Hypertension, despite being a non-infectious disease, is reported to be the fourth contributor to premature deaths in developed markets and the seventh in emerging markets [4,6]. It was reported that the prevalence rates of coronary artery disease and stroke have more than tripled in the Indian population. Promoting awareness about hypertension and its related risk behaviours cannot be expected to control the rising hypertension cases in India unless higher level of quality drugs get adopted in prescription system of prescribers in private hospitals.
Analysis of reported literature data depicts significant variation in adopting ARB categories of drug in India, despite being the best sellers in USA. Table 3.3 shows the prescribing patterns of different classes of antihypertensive drugs as linked with chemical moiety, cited as examples.

### Table 3.3: Antihypertensive drug adoption in Indian hospitals

<table>
<thead>
<tr>
<th>Generic Name (Chemical Molecule)</th>
<th>Approx. Cost/month in India (Rs)</th>
<th>Monotherapy Consumption (%) in Eastern Indian Hospital</th>
<th>Monotherapy Consumption (%) in Southern Indian Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ramipril, Enalpril*</td>
<td>92*</td>
<td>16.5</td>
<td>19</td>
</tr>
<tr>
<td>Metoprolol, Atenolol*</td>
<td>90*</td>
<td>8.2</td>
<td>17.5</td>
</tr>
<tr>
<td>Amlodipine*, Diltiazem, Verapamil</td>
<td>75*</td>
<td>22</td>
<td>32.5</td>
</tr>
<tr>
<td><strong>Losartan</strong>, <strong>Valsartan</strong></td>
<td><strong>110</strong>*</td>
<td><strong>42.2</strong></td>
<td><strong>15</strong></td>
</tr>
<tr>
<td>Prazosin XL*, Guanfacine</td>
<td>230*</td>
<td>0.1</td>
<td>3.5</td>
</tr>
<tr>
<td>Hydrochlorothiazide*, Chlorthalidone</td>
<td>33*</td>
<td>11</td>
<td>12.5</td>
</tr>
</tbody>
</table>

Table 3.3 provides insight that even with the consumption level of ARB category of antihypertensive drug, though widely adopted in a developed nation, like USA, there remains a variation in prescribing decisions between eastern and southern Indian hospitals. Multiple information sources accessed by physicians and lack of cognitive abilities to remember all the factors while adopting late-entrant drug has been discussed using Fish Bone Diagram (FBD) [329]. The reported literatures show that ARB consumption is lower, despite having a strong market base in USA.
Such poor consumption might be due to occasional brand switching due to improper identification of communication factors. The high variation in ARB adoption relates to uncertainty in marketing success in drug manufacture in hypertension segment. Doctors’ prescribing practices have considerable bearing on the effectiveness of healthcare treatments particularly in diseases like hypertension, antidepressants or cancer, to name a few. There are many factors influencing the prescriptions, e.g., the existing laws and regulations, types of patients, different insurance schemes, informal payments, drug promotion, medical product representatives and other incentives. Therefore, questions concerning appropriateness of treatment are of interest among healthcare professionals, policy-makers, administrators and researchers. Examining consumer characteristics in understanding the behavioural intentions of physicians is based on cognitive capabilities and communication intelligence to address the challenges of new branded extension adoption [87-88]. The dissertation argues drug adoption is not at matured concept, indicating secondary data analytics using literature synthesis, brain storming approach is best suited at the primary level of proposition conception.

3.3.3 Measures from survey data in Phase II

In this study, research propositions are explored with qualitative evidence and are usually descriptive and when turned into a hypothesis are explanatory in nature and follow quantitative path of deductions.

With understanding the research proposition, quantification and subsequent analyses of stakeholder relationships offer a relatively objective way to approach adoption problems of late-entrant drugs treating hypertension. A great deal of research examines the linkages between these relationships and influence on rate of adoption, peer effect in influencing the intentions behind prescriptions, late-entrant drug adoption and effect of communication intelligence in drug adoption. Good producer (firms)—provider (physicians) relationships are consistently found to be associated with communication diffusion. One of the many reasons, for the lack of perfect predictive
validity of provider–consumer relationships, is that these relationships for fixed treatment procedures like hypertension are usually weak or insignificant [48]. In the following research, the study demonstrates communication framework developed to measure drug adoption in practice.

3.3.4 Explanatory variables and hypotheses

Quantitative research methodologies that are used in this research employ multiple linear regression (MLR) analysis for identifying information source that act as predictors of drug adoption and structural equation models to measure adoption using scale based on communication factors that affect prescriptions.

The communication dimensions for physicians’ preference to sources of potential medical information can be derived from four primary sources: (a) drug benefit perceived from the basis of physician’s knowledge or memory; (b) commercial information promoted by organizations; (c) exposure to guidelines, seminars and symposia; (d) information from word of mouth. The below-mentioned explanatory variables, as computed in Table 3.4, have emerged from the research propositions and, subsequently, have been used in developing hypotheses for examining the sources of information that influence drug adoption.
Table 3.4: Dimensions for questionnaire development

<table>
<thead>
<tr>
<th>Source of information</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOI1</td>
<td>Promotional/scientific/advertisement material, will lead to the development of more awareness and increase the likelihood of drug acceptance</td>
</tr>
<tr>
<td>SOI2</td>
<td>Higher the visits by detail man, more will the physicians remember drug benefits leading to higher prescriptions</td>
</tr>
<tr>
<td>SOI3</td>
<td>Organizational/Professional societies hosting educational programmes/seminar for physicians to expose physicians to medical knowledge</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment Opinion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOP 1</td>
<td>Follow physician’s initiative for prescribing new antihypertensive drugs</td>
</tr>
<tr>
<td>TOP 2</td>
<td>Follow hospital colleague’s prescription for hypertension treatment</td>
</tr>
<tr>
<td>TOP 3</td>
<td>Follow colleague’s prescription for hypertension treatment</td>
</tr>
<tr>
<td>TOP 4</td>
<td>Follow patient’s choice/ideas while prescribing antihypertensive drugs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Formulation Characteristics</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRC 1</td>
<td>More the patient friendly dosage system, higher will be drug adoption</td>
</tr>
<tr>
<td>DRC 2</td>
<td>More the efficacy in lowering blood pressure, reducing morbidity and controlling end organ diseases, higher the adoption</td>
</tr>
<tr>
<td>DRC 3</td>
<td>Lower the side effects, higher is the adoption</td>
</tr>
<tr>
<td>DRC 4</td>
<td>Greater experience, greater will be the drug adoption</td>
</tr>
<tr>
<td>DRC 5</td>
<td>Lower the cost, higher is the drug adoption</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Doctors’ Characteristics</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOC 1</td>
<td>Individual trait/demography-age, sex, years of practice after graduation, hours of practice, patient size, practice type significant affect adoption</td>
</tr>
<tr>
<td></td>
<td>Higher the frequency of attendance of educational programmes conducted by professional society or pharmaceutical organizations, more is the practical knowledge gained, higher will be the drug adoption</td>
</tr>
<tr>
<td>DOC 2</td>
<td></td>
</tr>
</tbody>
</table>
These factors will influence doctor’s drug adoption decision and vary with the years of practicing experience that they have. On the basis of our literature review, a conceptual model is presented in Figure 3.3, employing Fish Bone Diagram (FBD) principle [329]. Ishikawa’s FBD to demonstrate the cause–effect analysis has been depicted below to understand the relationship between stakeholders:

![Ishikawa’s FBD for relationship among constructs](image)

**Figure 3.3: Ishikawa’s FBD for relationship among constructs**

This model depicts hypothesized relationships among the dimensions, linked with internal and external sources of information. Antihypertensive drug adoption by physicians varies with the abovementioned variables. The attitude models have found a wider application in explaining consumer adoption and diffusion of information system...
Roger’s adoption model indicates that the characteristic of innovation depends on the information it carries to the potential adoptee. The degree of adoption will also be determined by the characteristics of adoptee and these communication dynamics have been identified in Table 3.5. Based on the literature reviewed with special emphasis on factors favouring drug adoption in India [10,50-52, 63,71-72,87-88], arguments are hypothesized as follows:

**Table 3.5: Hypotheses for drug adoption**

| HYPOTHESES: Element constructs with all independent variables based on research objective of drug adoption (DA) |
| Reliance on Knowledge and Memory for Drug benefit (RKMD), i.e., perceived drug risk has a mediating effect on the relationship between DA integration and commercial communication quality |
| RKMD1 | Patient friendly dosage system/schedule is negatively related to DA unless perceived risk is understood |
| RKMD2 | Cost of medicine is negatively related to adoption |
| RKMD3 | Efficacy in lowering blood pressure is negatively related to DA unless there is brand loyalty |
| RKMD4 | Efficacy in reducing morbidity and controlling end organ diseases is negatively related to DA unless perceived risk is understood |

| Exposure to commercial information (CINFO) positively influence DA if competition from other brand, i.e., environmental risk has been minimized |
| CINFO1 | Exposure to firm’s promotional material is positively related to DA |
| CINFO2 | Positive perception of detail men’s visit is positively related to DA |
| CINFO3 | Advertisement and reading organizational communication on medicine is positively related to DA |
CINFO4 Organizational drive for pharmacovigilance, monitoring side effects is positively related to DA

<table>
<thead>
<tr>
<th><strong>HYPOTHESES: Element constructs with all independent variables based on research objective of drug adoption (DA)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation in events/guidelines reference (PEGR) is positively related to DA if trialability is perceived against adoption risks</td>
</tr>
<tr>
<td><strong>H3</strong></td>
</tr>
<tr>
<td><strong>PEGR1</strong> Reading compendium, guidelines is positively related to DA</td>
</tr>
<tr>
<td><strong>PEGR2</strong> Participation in seminar or symposia is positively related to DA</td>
</tr>
<tr>
<td><strong>PEGR3</strong> Exposure to educational programmes, health campaign is positively related to DA</td>
</tr>
<tr>
<td><strong>H4</strong></td>
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<tr>
<td><strong>WOM1</strong> Colleague physicians’ prescription, is negatively related to DA unless feedback is solicited</td>
</tr>
<tr>
<td><strong>WOM2</strong> Hospital physicians’ prescription, is negatively related to DA if opinion leader physicians are involved</td>
</tr>
<tr>
<td><strong>WOM3</strong> Hospital physicians’ prescription of new drug, is negatively related to DA due to lack of persuasion from company</td>
</tr>
<tr>
<td><strong>WOM4</strong> Patient’s own experience with antihypertensive use is positively related to drug adoption if physicians rely less on firm’s first launch</td>
</tr>
</tbody>
</table>

Experience of physician has moderating effect on DA (ADOPT) when external competition (Competitor uncertainty) from other firms overpowers new firm’s launch due to environmental uncertainty.

Hypothesis testing is undertaken to explain the variations in dependent variables, i.e., drug adoption as well as to predict the organizational outcome of
pharmaceutical firm, after a newly launched branded prescription drug as shown in Figure 3.4.

Figure 3.4: Conceptual information framework for drug adoption

Based on the above-stated four hypotheses (as provided in Table 3.5) evaluating prescription decision at Indian hospitals, a theoretical model emerges to show the communication sources of medical information impacting drug adoption (as depicted in Figure 3.4).

3.4 Unit of analysis for Phase II quantitative study
The unit of analysis for exploratory, descriptive and explanatory studies has been summarized as follows:

i. Patient data involving two thousand sample sets, collected from private hospitals of Delhi–NCR was analyzed. Classification technique of data mining method was employed to understand the disease characteristics of patients, influencing the prescription intentions of practitioners.

ii. The quantitative survey of Phase II research was completed using seventy three completed datasets, out of one hundred three respondents. Considering user-reported data from 73 usable completed questionnaire responses, a cross-sectional study, at a pilot scale, was undertaken. With further addition of subjects to the pilot study such that 54 per cent of senior physicians participated in survey and total number of participants were one hundred and two. The insights, obtained after increasing the sample size in pilot study, provide the premises for determining the sample size in the pivotal study.

iii. After conducting quantitative study, qualitative study was executed involving twenty five informants in focus group. Such interview was facilitated by a moderator, experienced in the field of drug dispensing to patients and was conducted based on the principles of phenomenological interview.

iv. Following an explanatory research model, as discussed in Section 3.2, a quantitative pivotal study was conducted on 200 physicians from private hospitals of Delhi–NCR. A total of 151 usable responses were received and used in data analysis, representing an overall response rate of 75.5per cent.
The drug producers, desirous of investing in new antihypertensive pill, usually conduct cross-sectional study to assess the likely demand for the new product. In accordance with the objective of studying the prescription decision of late-entrant branded drug, a non-probability multiplicity sampling frame was used as discussed in Section 3.2.2.

3.4.1 Data collection and pretested questionnaire

Prior to administering the survey to the physicians, the study conducted a one-day focus group interview with a cardiologist, general practitioners and few other specialists. Their suggestions were useful in designing and administering the survey. Unstructured questionnaires were framed. In the unstructured–undisguised questionnaire, the purpose of the study is clear but responses to the questions are open-ended. Here, the initial question is constant, and the respondent is allowed to talk freely about his attitudes towards the prescribing behaviour. After presenting this initial question, the interview becomes much unstructured as the interviewer probes more deeply (often known as depth interview) and the respondents’ subsequent answer determines the direction of interviewer takes next and so on. The freedom that was permitted to the interviewer in conducting these depth interviews reveals the major advantages and disadvantages of the method. This type of qualitative focus group-interview enabled researcher to obtain deeper, richer descriptions than surveys with fixed alternative responses. This approach was used to derive the questionnaire to administer in the quantitative pilot study.

Physicians attached with private hospitals from urban areas of Uttar Pradesh and Kolkata were involved in the survey for deriving reliable information. The focus group stressed that an instrument that required less than 20 minutes for completion and was linked to incentives for participating in survey enhanced the response rate of respondents. Sharing the insights from survey as motivation for participation was discussed with respondents. These suggestions limited the scope of the current research. The questionnaire items and format were pretested for clarity and face validity with five
physicians and were revised accordingly, before undertaking the survey at a pilot scale involving local physicians.

It is difficult to comment as to what extent the sample is representative of all physicians, as mostly young and fresh physicians formed a significant population group in the survey. Physicians were highly engaged in private hospitals in treating patients. Due to the brevity of the instrument, detailed questions about patient characteristics had not been tapped for ARB drugs, competing against the non-ARB prescriptions in the Phase II research phase. In this context, it is further argued that the patient characteristics revealed insignificant relationship with drug adoption in the Phase I research cycle

3.4.2 Multivariate data analysis approach

Theoretical approaches ranging from the communication diffusion [320] to evolutionary and social-cognitive dimensions [136] predict variations in adoption decision, due to producer–provider relationships influenced by demographic characteristic of both physicians and patients, albeit for unidentified reasons. Studying the variation in drug adoption, stemming from market dynamics, revealed the uncertainty in the adoption of late-entrant drugs. Employing multivariate data analysis to examine communication models for drug adoption provides additional opportunities to increase predictive accuracy, as well as to arrive at a more complete understanding of how provider–consumer interactions influence the prescribing behaviour or switching intentions from ARB brands to other hypertension treating late-entrant drugs. The secondary data analytics by using data-mining techniques provides scope to understand variation in adoption of antihypertensive drugs in India.

Multivariate data analysis has been introduced and normality of data was evaluated. To use maximum likelihood estimation, it is necessary to make the additional assumption that observed variables are derived from population distributions with roughly the same multivariate kurtosis as that of a multivariate normal distribution. The strength of measures was checked to establish reliability and validity. While studying the communication model, factor analysis was conducted to understand
the antecedent of drug adoption [41]. Following Hair et al. [277], the regression analysis approach has been linked to the Exploratory Factor Analysis (EFA) and Principal Components Analysis (PCA). Poorly defined factors, with either low loadings or cross-loadings, were candidates for reduction due to low commonality. Orthogonal rotation assumes that the factors are independent, and the rotation process maintains the reference axis of the factors at ninety degree. While, oblique rotation allows for correlated factors and does not require the reference axis to be maintained at ninety degree. Though oblique rotation was investigated and adequate pattern matrices were obtained, varimax, an orthogonal rotation method, provided the best suited solution for the model.

As with most applications of inferential statistics, statistical power is important for multiple linear regression [278]. Collecting large samples for specifying models with theoretical support may represent good practice for validating a proposed model, but may offer little protection against the cases where arranging large sample size may not be feasible practically. Despite the ability to test the specific hypothesized trends, in literature, the previous attempts in healthcare-analytics were limited to single aspect modeling of medical decision. Probably, studying multidimensional aspects of drug adoption either remained unpublished or generated only superficial findings or inconclusive findings. Although the focus of this study is on model development and evaluation, it is usually preferable not to specify and evaluate models in isolation, but rather to compare competing, theoretically derived models, given the unavoidable limitation of sample size. In a subsequent section the premise for Phase II research has been built to match the drug adoption outcome with the contextual environmental challenges.

3.4.3 Model specification and parameter interpretation

Initially, a pilot study, using a questionnaire survey, was designed to identify the factors influencing drug adoption. The survey was completed by using the practitioners from the urban areas of Uttar Pradesh regions and Kolkata.
In the first phase, more than twenty per cent of the practitioners due to time constraints either left the survey in between or handed over incomplete answer sheets to the moderator of the survey, while the views of seventy three physicians were completed and so usable. Extremity bias was checked before proceeding with analysis and factor analysis, determining a composite variable based on multiple similar variables, was executed. The adoption determinants were aggregated together using additive algebraic property and their individual role was explained by computing descriptive statistics using psychometric scales (Likert measures) [322], following Gerving and others’ approach [48]. Questionnaire design of the proposed instrument using proper randomization of question set has been discussed in the appendix (section AX1 pg. 229).

The other type of questionnaire, adapting Guttman scaling with dichotomous responses, focused on physician’s characteristic demographic features [323]. The adoption of antihypertensive drugs follows an important property of Guttman’s model that a physician’s entire set of responses to all items can be predicted from their cumulative score because the model has been deemed deterministic. The mutually exclusive factors like sex, age, physician’s experience are computed for testing the hypotheses, based on an independent sample T-test. Multivariate data analysis was conducted to examine the preference of ARB over non-ARB drug prescription.

Univariable analyses and data reduction procedures were followed to reduce the number of variables. The determinants of adoption were studied by linking physician related characteristics and views to their actual prescribing behaviour and factor analysis was conducted to check the potential factors that can account for maximum variance of our model. All multivariate analyses were performed using SPSS package, version 13 [324]. The word-of-mouth (WOM) communication was carried out mostly with young professional physicians, and was found to be an insignificant dimension with seventy-three sample datasets.

Based on the identified constructs, a multivariate model was developed and was presented in tabular form with predicted direction. The statistical significance of model
was evaluated at 1 per cent (**) and 5 per cent (*) significance levels for the independent variables. The pilot-quantitative study also focuses on determining whether differences in mean scores between groups are due to chance factors or area result of the study’s experimental treatment. The independent sample $T$-test was performed for identifying the relationship of physician’s age and sex with each of the IVs. Additionally, the paired sample $T$-test was also performed for evaluating physicians’ attitude against each of the IVs. Assuming linear relationships between physicians’ adoption (DOC), the dependent variable (DV) and their determinants like exposure to drug information (SOI), perceived treatment influence (TOP) and perceived drug benefit (DRC) regression model is specified as:

$$\text{DOC} = a + b*\text{SOI} + c*\text{TOP} + d*\text{DRC} + i$$

where $a$ is constant for explanatory variables, summated at individual levels to account for the fixed effect, while $i$ represents residual variation as it depicts random effect of assumed model. The fixed effect of the model assumes that the slope coefficient of the explanatory variables remains identical for all determinants. The random effect model (also called error component model) assumes that the intercept of each determinant is the result of a random deviation from the mean intercept. The prescriber and patient-related factors have been deemed as IVV (intervening variable) and the role of demography/personal traits to mediate drug adoption intention has been explored [45,46].

Following Wu and Li [325], the communication impacting exposure to various sources of medical information has been integrated as IV (independent variable). The adoption of antihypertensive drugs [i.e., the dependent variable (DV)], boosted by prescription intention of the physician has been also considered. The physicians’ views are taken as proximal determinants to increase the likelihood of antihypertensive drug acceptance. Integrating Technology Acceptance Model [136, 296,325] with the Theory of Planned Behaviour [199] in the implementation framework [326], the communication diffusion has been studied in the context of drug adoption.
3.5 Phase II qualitative and Phase III quantitative study

3.5.1 Advantages of Focus group interview

The focus group interview is a method of collecting data based on a research strategy. According to Lincoln, research strategies are ‘a flexible set of guidelines’ that connect the research question to collection methods and particular data sources for testing the proposed hypothesis. In their most basic form, focus groups are structured or semi-structured meetings with a small group of individuals (i.e., ‘informants’ or ‘participants’) that allow for the exchange of information, opinions and feedback related to a single topic. Focus groups include, at a minimum, a meeting facilitator and informants and can be used inductively to generate research ideas or deductively to operationalise theory as argued by Strauss [249]. Although the results from the focus group cannot be generalized without supportive quantitative research, the discussions identify shared concerns more quickly than individual interviews.

Based on the fact that an intimate connection of focus group qualitative approach and empirical reality exists, the pattern of drug adoption has been explored to make the theory building approach fruitful. More precisely, this study applied the focus group research method to understand the doctor’s role on constructing views for adopting a late-entrant generic prescription drug, prior to undertaking a full-fledged quantitative study.

3.5.2 Qualitative pilot study strategy

A pilot study, at Phase II research, was conducted to test the hypotheses in order to bridge the literature gap. Qualitative study finds both the strength and weakness of a proposed model and assists in developing sharper hypotheses. As discussed, focus group qualitative technique was adopted for examining convergence and divergence among diagnosis, treatment and recovery experiences of patients that doctors remember while sharing their experience with newly launched late-entrant drugs. After the
conduct of a pilot quantitative study, focus group interview in the form of semi-structured meetings with a small group of specialists (cardiologists and oncologists) was necessary to complement the data and generate ideas for new inquiry in Phase III research. Informants recruited to participate in focus groups seldom represent the actual population because the focus group is not a research tool to suit population-wide inquiry. Instead, the potential focus group participants are identified purposively to find the root cause of research problem. The study touches senior specialist members to have an impression on the findings of a pilot scale survey study. Nonetheless, informant selection is crucial in generating results that can be applied to the defined questions or issues of a given study.

Additionally, prior specification of construct is important for the study to have a firmer empirical grounding for emergent theory with the progress of research in phases. Prior to undertaking a full-fledged quantitative study, cognitive mapping and repertory grid techniques as discussed in Chapter Two, were employed to shape the initial design of theory building research. This study applied qualitative focus group study to understand the doctor’s role on constructing views on adopting a late-entrant drug. Admittedly, based on the insights of a qualitative study, pivotal quantitative study was strategized and executed consequently.

3.5.3 Quantitative pivotal study strategy

Based on non-probabilistic multiplicity sampling approach, face-to-face survey/interview was designed after tuning the questionnaires used in pilot study. In healthcare sector, face-to-face interviews even with close ended questionnaire provides deeper insights into the resolving problem as these are clearly structured, flexible and adaptable. They are based on personal interaction and can be controlled within the survey environment. Only respondents linked to private hospitals were sampled. Based on pilot study results and the theoretical sampling concept (i.e., cases are chosen for theoretical and not statistical reasons, Glaser and Strauss), sample size was determined for the pivotal quantitative study.
Consequently, two hundred potential respondents medical practitioners from the hospitals located in NCR (National Capital Region) of India were targeted. The respondents had prescribing experience of hypertension treating drugs and had provided their background information, such as education, experience level, patients prescribed in a week and the number of years they have worked in the hypertension management field in the current healthcare institution. Validity and reliability was determined using multivariate data analysis technique and structural equation modeling techniques. Achieving validity (such as construct, discriminant and convergence validity) is a primary concern in developing new instrument for an action research based model [290]. The mediation and moderation effect of the constructs were, henceforth, introduced to replicate or extend the emergent theory from the results of three research phases.

3.5.4 Non-Response Bias Analysis

Non-response bias in survey research can result in inaccurate findings and evaluation of nonresponsive is essential to determine data reliability and validity for a limited sample-set survey, supposed to represent a larger population. Independent sample T-tests were conducted on key constructs and demographic variables. Most of the non-response bias in the study was due to the fact that doctors have tremendous time pressure and they managed to respond after three or four visits. In most cases, whenever, the questionnaire was left to be answered, the same remained incomplete as mostly the doctors are unfamiliar with survey settings. Incomplete data did not reveal any pattern and neither demographic variables nor constructs were found to be related to non-response bias. However, time constraint and lack of motivation to fill the questionnaire later led to response bias. Moreover, both constructs and demographic variables indicated that the differences in their mean values were not significant at 0.05 levels, confirming that the survey data does not possess response bias.
The subsequent chapters, drawing conclusions from Phase I and Phase II research, establish hypothesized relationship to provide insights on patterns of drug adoption. In the light of the studies, executed using hybrid research methodology, the results and discussion in the next chapter, prepare this dissertation to undertake a confirmatory pivotal study using SEM principles. Consequently, the statistical power of the proposed studies was determined in Chapter Four.