5 Conclusion

The introduction of this thesis outlined the need to undertake such a study, by providing perspectives on medicine, pharmacy, development of hospitals throughout the world, internet era, and the Indian context relating to modern medicine as well as Ayurveda. Insights ts from the thought leaders in the field of Ayurveda are profound and they call for modern methods, new approaches and innovative strategies to be attempted to take Ayurveda science forward. There is a reflection on the type of evidence generated through controlled experiments (RCTs) and life experiments (Observational, Experiential) – some evidence about how these multiple approaches could yield meaningful results. This chapter asks a few questions from diverse points of views and seeks answers – some of these answers are hidden in everyday Ayurvedic clinical practice – which is still largely untapped, prompting the following: how can data analysis of electronically captured data help in advancing our understanding of Ayurveda as a practice and science?

Next section of this thesis elaborated on the technical details of a hospital HMIS based database and the associated EMR. We highlighted technical details about the hospital database: how many source tables, how they stored in ~200+ tables, out of which ~20 to 25 tables were used to generate datasets useful for further analyses. Subsequently we displayed flowcharts outlining ~50+ steps to go from Live source to Staging data to transformed data to ~30+ source variables + ~30+ derived variables in 01adsl_met_rmsd dataset: patient level data covering treatment and disease information. This formed the basis of possible operational and clinical analyses going forward.

Clinical data understanding section showed how individual observations can be transformed into meaningful patient narratives. This section explained how the usage of operational and clinical part of the data can benefit varied stake holdersand emphasized the need to convert “a thought from a doctor’s mind” into an “actionable and consistent data point” in the database for future use. While studying both the structure and the content of the hospital database, it was observed, that standardization of database along with effective curation towards good data quality is needed. It was highlighted that this type of data could provide a gold mine of information which when summarized could lead us to many insights which could potentially increase operational efficiencies and progress the Ayurvedic practice. It laid down the foundation for “understanding demographics and patient characteristics” as a basis.

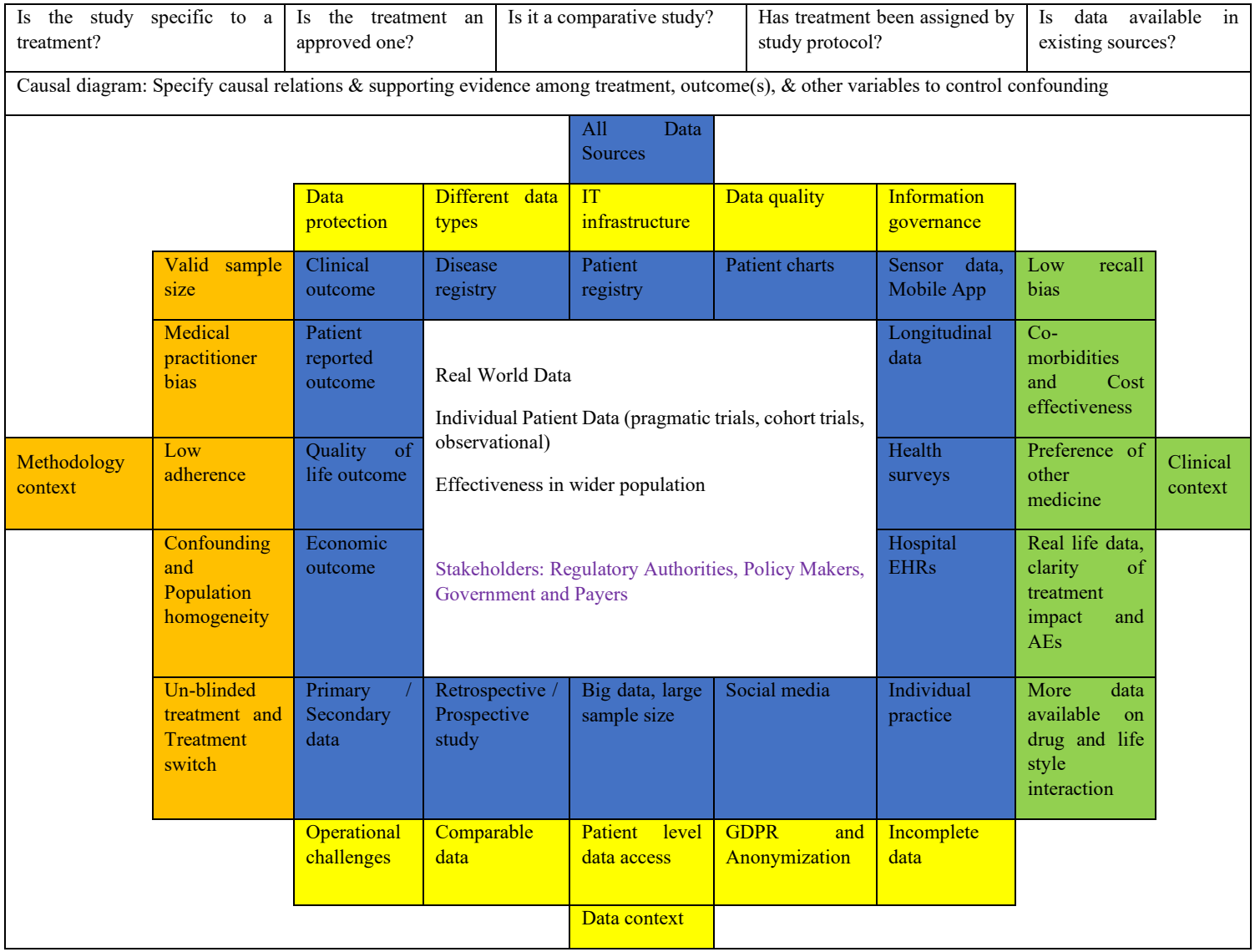
The demographic and patient characteristic analysis provided good insights into different components of the data which can feed more generally into the public health domain. It was observed that the health and healthcare requirements of a population can benefit through disease surveillance and population health insights. It also provided actionable inputs to hospital management on efficient operations, practicing doctors and for research publications.

Diagnostics and interventions section showed complex relations between diseases and interventions. Comorbidities as well as combinations of interventions showed the complex clinical decision-making process as followed by Ayurveda physicians. The disease and treatment comorbidity analyses was performed and presented using a variety of plots and heatmaps. These analyses showed how individual observations can be transformed into meaningful insights and data stories.

Day-to-day transactions at hospitals involve people from many backgrounds like, hospital administration, patients, doctors, nurses, pharmacists, pathologists, representative from insurance companies, lawyers, etc. These interactions generate a lot of information and are the primary data generators. Same set of people and a few additional professionals are the end users of the data e.g., scientists, statisticians, database developers, etc. This study has provided preliminary insights into various aspects of HMIS based EMR data generated during real time consultation at I-AIM.

A variety of analysis and summarization of the hospital data was conducted with a view to derive meaningful outcomes which confirm the Ayurvedic principles. As a final summary of all that has been said previously is represented in the figure below (Figure 5-1). First part of the diagram covers how to define the underlying question, which is followed by defining the hypothesis. Researchers should logically think about clinical context and methodological context. For converting this theoretical thinking into a real-world study, we need to have the necessary IT infrastructure which will enable data related components. Middle of the diagram shows potential stakeholders. This concise representation shows how the HMIS based EMR can shape up Real World Evidence generation.

Figure 5-1: Real World Evidence life cycle



Due to the above-mentioned outcomes, the following contributions can be possible:

1. Contribution to Public health data creation based on large data at our disposal which is not marred by artificial boundaries imposed on patient disease conditions and treatments prescribed as followed in a designed randomized clinical trial.
2. Make recommendations to the practitioners for standardized way of data collection, analyses and reporting which will support future EMR based RWD studies
3. Understand the hidden wealth of data for Transdisciplinary expansion of thoughts
    a. Sustainable treatment solutions for diseases readily available
    b. Thought provoking work to generate new needs through unconventional use of the data
    c. Expand the use of modern IT solutions like IT infrastructure, electronic health records, cloud, etc. within Ayurvedic area where appropriate – Ayur IT solutions.
    d. Take advantage of freely available cutting-edge software(s) to create new approaches
    e. Introduce statistical programming (Ayurdata analyst) as a tool to Ayurvedic area

A lot of work carried is out by health authorities, pharmaceutical companies, and nonprofit organizations. Some of these resources could be used as reference to become a world class data generator:

Clinical Data Interchange Standards Consortium (CDISC) is a global nonprofit charitable organization with administrative offices in Austin, Texas, with many people contributing across the world. CDISC brings experts together to create and advance data standards. This allows for accessibility, interoperability, and reusability of data for competent research that has greater impact on global health [118]. Many of the leading health authorities use the standards developed by the CDISC teams in various parts of drug applications.

TransCelerate BioPharma Inc. is a nonprofit organization with a mission to collaborate across the global biopharmaceutical research and development community to identify, prioritize, design, and facilitate the implementation of solutions designed to deliver high quality new medicines. They have many open-source solutions which could be used to improve delivery model [120].

Based on the 21st century act, 2016, the US FDA has created a regulatory framework for the Real-world data (RWD) and real-world evidence (RWE) which are playing increasing role in the health care decisions [121], [122]. The European Medicines Agency (EMA) has established a center to provide timely and reliable evidence from real world healthcare databases on the use, safety, and effectiveness of medicines for human use, including vaccines, across the European Union (EU). This capability is called the Data Analysis and Real-World Interrogation Network (DARWIN EU®) [123].

These resources provide a lot of material to enhance overall understanding and allows researchers to be compliant with the regulatory requirements.

This thesis outlines many tools which can be used by various stakeholders. They are free and easy to use. They allow multi-dimensional display of complex data in a very short amount of space. The tools can create evidence for multiple stakeholders. Free softwares like, R, python, Java,

tableau and many more have made it possible to harness the power of data in many ways. There is a need to have a profession of a "Statistical programmer" or a "clinical programmer" or an "Ayurdata expert". This role can contribute to database development, data collection, data cleaning aspects, creating analyses ready datasets, and to finally analyses and reporting. This role should have capabilities related to information technology, data management techniques for generating quality data, in addition to knowing basic and advanced statistical and data science concepts. The computational advances in the world of computer science could be leveraged via appropriate software. Theoretical ideas can be converted into practical interactive visualizations and interactive analyses using multiple technologies. These will help convert individual data observations into summaries then into stories thus enabling knowledge generation.

Ayurdata expert can contribute to creating documents for medical journalism, medical education, medical marketing of healthcare products, publications, research documents, and regulatory documents by collaborating with other experts (Table *5-1*). We believe that this would be a pioneering effort within ayurvedic EMR area.

Table 5-1: Different types of documents

Medical Reporting	Medical Teaching	Medical advertising of products	Publication
• Newspaper & magazine articles • Mostly for public • Written in simple, non-technical language	For doctors • Textbooks, • Continued Medical Education programs, • Slide decks, • Online learning material For Patients learning material	• Promotional information for healthcare professionals • Product profiles • Brochures • Sales force training • Online learning material	• Abstracts • Journal articles, case reports, review articles • Posters & presentations for scientific conferences

Research Documents	Regulatory documents #	
• Research proposals • Clinical trial protocols • Investigators' Brochure • Informed Consent Documents • Study reports	• Package Inserts • Patient Information Leaflets • Clinical study reports • Web synopses • Subject narratives	Aggregate safety reports such as • Periodic Safety Update Reports

	Common Technical Document (CTD) modules such as • nonclinical and clinical overviews & summaries • expert reports • PK, Safety, Efficacy summaries	• Periodic Adverse Drug Experience Reports • Annual safety reports • Policy papers

#: Presently, some of these documents are not applicable within Ayurvedic area

Work carried out for this thesis is typically reflective of work done by a team of people.In a mid to large sized pharmaceutical organization, this type of work is carried out by (1) Clinicians and statisticians design clinical protocol, (2) Database development team creates database and data flow components, (3) Data management team reviews and cleans the data on an ongoing basis, (4) Statistical programming team and statisticians create the necessary analyses, (5) Writing team generates Clinical Study Report / Publication, and last but not the least (6) IT team handles various systems so that the data and information flow is managed appropriately.

Much more details about the database and programming done for analyses and visualization are available in the appendices.

This is not an end but just a beginning of Ayurdata experts ...

There is a lot of additional analysis carried out during PhD work which has not be written in the main text of the thesis document. This paragraph outlines some of this work and ideas about new work which can be carried out in future: (1) Work with the university and hospital management for updates to the data capture process, (2) Attempt to work with other hospitals and carry out similar analysis, (3) Use Sequential Pattern Mining library developed by Phillipe Fournier-Viger, having more than 100 algorithms to discover patterns in data, (4) Use Co-morbidity package in R programming language to identify disease comorbidities using different statistical tests and metrics, (5) Use Natural Language Processing approaches using tensor flow methodologies to discover underlying patterns in the data, (6) Work with the ayurvedic physicians in the hospital on specific disease areas like Chronic Kidney Disease (CKD), and Parkinson disease data – these are the areas, hospital is working actively working on.