Declaration by the candidate:

THE UNIVERSITY OF TRANS-DISCIPLINARY HEALTH SCIENCES AND TECHNOLOGY

Private University Established in Karnataka by ACT 35 of 2013

BENGALURU – 560064

DECLARATION BY THE CANDIDATE

I declare that this thesis entitled "Analysis of hospital based Ayurvedic clinical practice to gain Real World data knowledge" submitted for the award of Doctor of Philosophy to THE UNIVERSITY OF TRANS-DISCIPLINARY HEALTH SCIENCES AND TECHNOLOGY, Bengaluru, is my original work, conducted under the supervision of my guide Dr. Ashwini Godbole and co-guides, Dr. Girish Tillu and Dr. Ashwini Mathur. I also wish to inform that no part of the research has been submitted for a degree or examination at any university. References, help and material obtained from other sources have been duly acknowledged.

I hearby confirm the originality of the work and that there is no plagiarism in any part of the dissertation.

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Ashwini W. Mother

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List of Figures

Figure 1-1: RCTs on ClinTrials.gov	2
Figure 1-2: Screenshot of a dashboard from AYUSH website	
Figure 1-3: Ayurvedic practitioners and patients from AYUSH dashboard	
Figure 2-1: Pictorial representation of analysis	
Figure 2-2: Flow diagram from data source to final usage by various usage types	24
Figure 2-3: A glimpse of data tables used to store source data from the database	28
Figure 2-4: Extraction of relevant data from Source database	29
Figure 2-5: Staged data converted into 6 datasets	30
Figure 2-6: Staged data	31
Figure 2-7: Final dataset with 39 source variables and 33 new derived variables	32
Figure 2-8: Data flow from source data to interpretable results	33
Figure 3-1: A snippet of disease table by gender	61
Figure 3-2: Variable classification by categories	61
Figure 3-3: Visit pattern analysis	63
Figure 3-4: Patient visit profile – Horizontal view	64
Figure 3-5: Patient visit profile – Vertical view	64
Figure 3-6: Total Number of Patients	
Figure 3-7: Country-wise Visualization	
Figure 3-8: Age distribution by country, age distribution by gender	66
Figure 3-9: Blood-group Distribution by gender	
Figure 3-10: Number of Visits, and Visit Types	67
Figure 3-11: Descriptive summary statistics by number of Diseases by Age and Gender	
Figure 3-12: Data tabulation for patients reporting RMSD and Metabolic diseases	
Figure 3-13: Disease distribution by age and gender	
Figure 3-14: Patient visit duration for Disease categories by Gender	
Figure 3-15: Disease distribution by Seasonal Variations and gender	
Figure 3-16: Pre and Post Disease Classification Analysis	
Figure 3-17: ICD classification by Gender	
Figure 3-18: Age distribution by ICD classification and Gender	
Figure 3-19: Visit distribution by ICD classification and Gender	
Figure 3-20: Duration distribution by ICD classification and Gender	
Figure 3-21: Disease classification by Prakriti and Gender	
Figure 3-22: Co-morbidity analysis approach 1 example 1: Vaatavyadhi	
Figure 3-23: Co-morbidity analysis approach 1 example 2: Pandu	
Figure 3-24: Co-morbidity analysis approach 1 example 3: Madhumeha	
Figure 3-25: Co-morbidity analysis approach 2	
Figure 3-26: Co-morbidity analysis approach 3: collapsible tree view	
Figure 3-27: Patient Disease and Treatment administration by Study Day	
Figure 3-28: Patient Disease by Study Day and Treatment administration by Study Day	
Figure 3-29: Patient Cumulative Disease and Treatment administration by Visit	86

Figure 3-30: Area graph representation of diseases	86
Figure 3-31: Mosaic plot: Disease and treatment representation example 1: Prameha	87
Figure 3-32: Disease and treatment example 2: P5.0: Prameha and Oil: Kottamchukkadi	89
Figure 3-33: Disease and treatment example 3: P5.0: Prameha and Vati: Diabecon DS	90
Figure 3-34: Mosaic plot Disease and treatment representation example 4: Treatment: Oil:	
Kottamchukkadi	91
Figure 3-35: Cross tabulation of prescribed treatments and disease group by gender Examp	ple 192
Figure 3-36: Cross tabulation of prescribed treatments and disease group by gender Examp	ple 293
Figure 3-37: Circular view: Co-occurrences of disease – disease Example 1	94
Figure 3-38: Circular view: Co-occurrences of disease – treatment Example 2	94
Figure 3-39: Pre and Post distance analysis for disease: M2.0: Madhumeha	95
Figure 3-40: Pre and Post distance analysis for medicines given for diseases: P5.0, V2.23,	V2.63
	95
Figure 3-41: Radar plot	96
Figure 3-42: Dynamic bubble plot: Example 1: Disease: A6.0: Amavaata	98
Figure 4-1: Treatment principles defined in different texts	102
Figure 4-2: Data understanding from an observation – patient – disease to a clinical picture	e 106
Figure 5-1: Real World Evidence life cycle	119

List of tables

Table 2-1: Visit window table for Pre and post analysis	37
Table 2-2: Proposed methods and analysis use cases	43
Table 3-1: Versions of data used for analysis	59
Table 3-2: Summary statistics and t-test for bhasma usage	93
Table 4-1: Proposed vital sign data structure	100
Table 4-2: Proposed idea for clinical coding timetable	103
Table 5-1: Different types of documents	121
Table 6-1: Details of the Reference Dataset "01adsl met rmsd"	124
Table 6-2: Metabolic and RMSD disease code and de-code	
Table 6-3: All variables in the source database	136

Acronyms

ACD: Ayurvedic Classification Dictionary

A-HMIS: Ayurveda Hospital Management Information System

AYUSH: Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy

CCRAS: Central Council for Research in Ayurvedic Sciences CDISC: Clinical Data Interchange Standards Consortium

COPD: Chronic Obstructive Pulmonary Disease

COSTART: Coding Symbols for Thesaurus of Adverse Reaction Terms

CTC: Clinical Toxicity Grade

DARWIN EU: Data Analysis and Real-World Interrogation Network

EHR: Electronic Health Record EMA: European Medicinal Agency EMR: Electronic Medical Record

EU: European Union

GCP: Good Clinical Practice

GCRP: Good Clinical Research Practice

GDP: Gross Domestic Product HM: Hospital Management

I-AIM: Institute of Ayurveda and Integrative medicines

ICD: International Classification of Diseases

ICH: International Council for Harmonization of Technical Requirements for Pharmaceuticals

for Human Use

IDC: International Data Corporation IDC: International Data Corporation

IP visit: In-Patient visit

ISO: International Organization for Standardization

LOINC: Logical Observation Identifiers Names and Codes MedDRA: Medical Dictionary for Regulatory Activities

NCI: National Cancer Institute, USA NEJM: New England Journal of Medicine

OP visit: Out-Patient visit

PMDA: Pharmaceuticals and Medical Devices Agency (Health Authority Japan)

RCT: Randomized Controlled Trial

RMSD: Rheumatic and Musculoskeletal disease

RWD: Real World Data RWE: Real World Evidence SQL: Structured Query Language

TDU: The University of Trans-Disciplinary Health Sciences & Technology

THERAN: THE Research Application Nexus TKDL: Traditional Knowledge Digital Library

UHC: Universal Health Coverage

US FDA: US Food and Drug Administration

WHO: World Health Organization

WHO-ART: World Health Organization Adverse Reactions Terminology

WHO-DDE: World Health Organization Drug Dictionary Enhanced