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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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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