Title: Analysis of hospital based Ayurvedic clinical practice to gain real world data knowledge (retrospective study of anonymized patient level data at IAIM hospital)

This document outlines the comments from SASC which took place in October 2020, the updated text in the protocol is in Green colour.

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| Page | Section | Updates |
| 7 | 1. Introduction | Added text to the introduction section to explain the use of real world data in overall healthcare industry |
| 9 | 2.2 Objective of the study | Updated the objectives section to clearly outline primary and secondary objectives |
| 10 | 2.3 Time perspective | Time taken for study: to develop tools and analyze the data for 3 years, retrospective data for ~6 years would be analysed. |
| 10 | 2.4 Study outcome measures | Updated the Study outcome measures |
| 14/15 | 3.5 Study design / Procedure | Additional flow diagram outlining the technical details is presented |
| 15 | 3.1 Inclusion criteria | Modified the inclusion criteria: Cancer  Added the following text:  In order to keep the work for PhD course within practical timing limits, only a few areas will be studied in greater details. The conceptual learnings will be applicable to all other areas which are not fully studied. |
| 16 | 5.2 Patient population(s) for analysis | Modified text as below:  Source data for patients as per the inclusion / exclusion criteria will be used. |
| 17 | 7. Data handling and record keeping | The text in this section is revised after the SASC meeting  Various kinds of data will be generated and collected during the course of the study and it would be organized in appropriate manner as per the applicable guidelines and Privacy laws. Instructions of data handling and record keeping are:   * PI will be responsible for data safety and confidentiality until data would be at the investigational site. * PI would delegate study related tasks to the staff that must be documented in study delegation log. * All documents (in appropriate formats) will be stored in the trial master file at the investigational site during the study period and will be accessed by authorized persons as mentioned in delegation log. * The data collected will be entered in data collection form without any errors or manipulations. * If data is transformed during processing, it should always be possible to compare the original data and observations with the processed data. * Any change in entered data will be done by an authorized person only and will be signed and justified in document history/ note. |
| 17 | 9. Publication Plan | The text in this section is revised after the SASC meeting  Study results will be published in peer reviewed journals and all rights of publications related to this study are with TDU- IAIM.  All of the following topics and decisions will be owned by the TDU - IAIM management:   * The ownership of all the data analysis * Monetization of data usage by licensing it to other research institutes, insurance companies - additional ethical permissions to be sought from the ethics committees * Conceptual developments of tools through this PhD work |