**Progress report – Oct 2020**

**Updated title:** Analysis of hospital based ayurvedic clinical practice to gain real world data knowledge

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Summary: The following progress has been made so far between Dec 2019 and Oct 2020

All the work done so far has been written as 5 chapters so far. Refinement and updates are expected as the research work continues. There is a 250 word document exercise carried out (as per Dr. Tillu’s instructions) to outline the objectives and outcomes of this thesis – please find the work outlining the ongoing work:

Title: Analysis of hospital based ayurvedic clinical practice to gain real world data knowledge:

Various electronic media like computers, mobile devices, wearables and other sensors collect and store huge amounts of health-related data. This explosion of data carries potential to better design and conduct clinical studies to answer questions previously thought infeasible. Advancement of cutting-edge analytical capabilities is allowing researchers to analyze and comprehend this data at greater depths, permitting medical product development and approval at an accelerated speed.

Approval of Ibrance by US FDA for male breast cancer, a drug already approved for females, French health authorities allowing a RWE study of 600+ patients, over a period of 18 months, for a conditional re-imbursement scheme in COPD, are a couple of examples of approvals using RWD data. A study carried out by Clarivate Analytics, USA, reports 27 (non-exhaustive list), <5% of all approved drugs, examples of drug approvals by US FDA, EMA, Japan’s PMDA and Health Canada, across broad spectrum of medicines between years 1998 and 2019. Real world data from Electronic Health Records and registries were used either as primary data, when non-comparative data were available to demonstrate tolerability and efficacy, or as a supportive data when validating findings.

This provides increasing usage of “naturally reported data” in drug approvals in modern biomedicine. These examples provide evidence of novel use of data, which may have otherwise gone unused. The power available to society would have never been unearthed if not for this way of use.

Is Ayurvedic area dealing with the same type of challenge of not realizing the potential of available data? Just to give a glimpse of enormity of data: more than 10 crore number of patients have been reported on AYUSH website (As of May 2020), more than 140+ countries have population of less than 10 crores.

It is safe to assume that the conceptual developments in ayurvedic knowledge base have taken place through every day observations and basic laws of nature. These fundamentals have been adjusted to the relevant times as per the passage of time based on observations and experiences. Ayurveda like any other system of medicine, is practiced more in clinics than in clinical research setting, where there are no artificial restrictions on usage of medicines, duration of treatment or type of patients to treat, which is next to impossible in a protocol driven clinical trial setting.

Taking inspiration from respected Prof Patwardhan’s quote, “Charaka would not have ignored modern technologies if they had been available during his time”, this study attempts to discover hidden wealth of ayurveda related information in EHRs created at TDU hospital using modern methods of data sciences and statistical programming. Since 2011 to Oct2017, the hospital database contained data for >51,000 patients, >1,50,000 visits, > 900 disease types, >3,000 variations of medical procedures.

Real world data is the information relating to patient health status and/or the delivery of health care routinely collected from a variety of sources to answer questions previously thought infeasible. The study targets the methodological and learning framework covering short, mid and long term influences in following categories:

1. Hospital managements, clinicians and patients
2. Universities and learning institutes – clinical communication, researchers to build vital evidence-base
3. Policy makers – AYUSH and relevant ministries
4. Healthcare providers - Ayurveda Healthcare systems, General healthcare systems

The contents of thesis are covered in chapters defined as follows:

1. Converting clinical life data into analyzable format
2. Clinical data understanding
3. Studying demographics and patient specific factors
4. Diagnostics and treatment data
5. Outcome and effect
6. Prediction / NLP

On the similar lines, the work done so far has been covered in a slidedeck of ~50 to 70 slides. The slidedeck will be attached along with the progress report document.

The presentation of the proposed protocol was done to the SASC on 14th Oct 2020, the protocol has been approved by the committee. The updated version of the protocol based on the committee’s comments has been submitted to the committee.

Paper submission and rejection:

* A paper was submitted to the “European Journal of Integrative Medicine”, in July 2020, it was rejected.
* Another paper was submitted to the “biorxiv.org” for pre-prints in Sept 2020 and it was rejected.