

Abstract

Various electronic equipment 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 [1]. Real world data (RWD) is the information relating to patient health status and/or the delivery of health care routinely collected from a variety of sources like epidemiological studies, clinical practice, already published articles to answer questions previously thought infeasible.

Approval of Ibrance by US FDA for male breast cancer, a drug already approved for females and French health authorities allowing a Real World Evidence (RWE) study of 600+ patients, over a period of 18 months, for a conditional re-imbursement scheme in COPD, are a couple of recent 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 using RWD from Electronic Health Records and registries. These data 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 of RWD [2].

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 [3].

It is safe to assume that the conceptual developments in Ayurvedic knowledge base have taken place through everyday 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, 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 [4] [5].

Taking inspiration from respected Prof Patwardhan's quote, "Charaka would not have ignored modern technologies if they had been available during his time" [6], 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 October 2017, the hospital database contained data for approximately 51,000 patients, more than 1,50,000 visits, close to 900 disease types and more than 3,000 variations of medical procedures [7]. The

proposed study “Analysis of hospital based Ayurvedic clinical practice to gain Real World data knowledge” targets the methodological and learning framework as well as creation of many tools based on free softwares for various stakeholders in following categories:

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