

Clinical Studies Should Neither Be For **Headline** Nor **Bottom-line**

Recently released Peterson Health Technology Institute's controversial, incomplete and biased study titled **'Digital Diabetes Management Solutions – Health Technology Assessment'** has kindled a need for a debate regarding the evaluation of Digital Therapeutics (DTx) in Chronic Disease Management (CDM).

While the benefits of DTx are undeniable, a comprehensive understanding requires a nuanced approach. The Peterson study, due to its limited scope and methodological shortcomings, is insufficient to definitively evaluate the impact of DTx on health outcomes and cost reduction in type 2 diabetes. Concerns regarding generalization arise from the study's narrow focus on a restricted set of DTx tools (n=8) and a specific patient population (type 2 diabetes only). The vast array of innovative DTx solutions available in the market demands a broader analysis incorporating a wider range of experts. Additionally, relying solely on HbA1c as the primary metric for analysing cost saving limits the evaluation of DTx's potential impact on other aspects of diabetes management such as lifestyle interventions. By addressing the identified flaws, such as selection bias, sample bias and recall bias, we should be able to design robust studies.

Health Parliament and Academy of Digital Health Sciences' report, "**The Promise and the Potential of Digital Therapeutics (DTx) for DCDM- A New Therapeutic Field**," acknowledges the challenges some DTx startups have faced. However, focusing solely on these failures paints an incomplete picture. Many DTx solutions are exploring diverse pathways to address chronic disease, each requiring dedicated long-term evaluation.

We believe DTx holds immense potential, particularly in regions facing high disease burden and limited access to traditional healthcare services. A nuanced approach, considering diverse needs and long-term impacts, is essential for unlocking the true potential of DTx in creating a healthier future for all. We hope that the researchers do not conduct such studies for grabbing headlines, and focus on patient engagement and improved clinical outcomes. For us, DTx is the future of CDM and it requires;

- **Long-term comparative studies to assess DTx effectiveness against traditional methods.**
- **Prioritize research on DTx solutions tailored to specific needs of resource-constrained regions.**
- **Collaboration between researchers, healthcare providers, and DTx developers for continuous improvement.**

The Asia Pacific DTx Leadership Alliance under Health Parliament, is committed to being at the forefront of DTx innovation. We advocate for rigorous, long-term studies that explore the full potential of DTx in Chronic Disease Management. Generalizing the American market's experience as a "failure" is misleading and studies should not be conducted for headlines or bottom-line but for improving patient engagement for clinical outcomes.

Additionally, we are launching **'TRx' (Technology Prescription)** on 6th April 2024 during **International Patients' Union Conference 2024** reinforcing our belief in using technology to improve patient outcomes.

Let's work together to transform healthcare!