

Digital endpoints offer significant opportunities to improve what we know about patients' biologic processes and responses, how they feel, function, and survive in both clinical trials and routine clinical care. DiMe's Library of Digital Endpoints is a crowdsourced resource focused on industry-sponsored studies of new medical products or new applications of existing medical products.

The Patient Matters in the End(point)

By Pip Griffiths, Diana Rofail, Rea Lehner & Vera Mastey

- » Griffiths, et al. discuss how digital health technologies (DHTs), such as apps, sensors, and wearable devices, are increasingly used in clinical trials and result in various endpoints which may not be meaningful to the patient.
- » The authors leveraged <u>DiMe's Library of Digital Endpoints</u> to contextualize the increased interest of digital endpoints and frame the discussion around why DHTs have yet to be leveraged in any FDA label claim.
- Examples from the Library of Digital Endpoints, such as step count, are cited to explore patients' value derived from the current use of endpoints.

[As of publication] DiMe's database shows that > 49 individual clinical trials in Phase 2 or 3 have included DHTs measuring over 114 different endpoints as a secondary or even primary trial endpoint. Despite these advances, DHTs have yet to be leveraged in any FDA label claim. — Griffiths, et al.

Read the full article here

DiMe's Library of Digital Endpoints