Evidence generation for digital health solutions

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Evidence generation for AI

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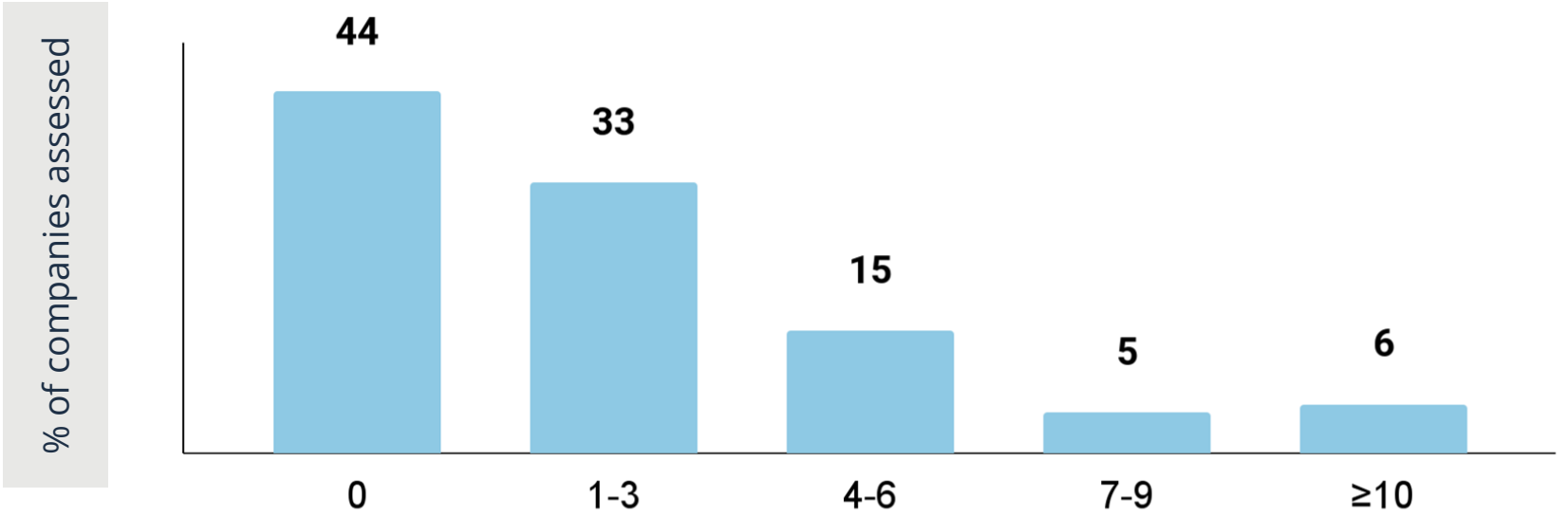
In boom times, evidence was overlooked

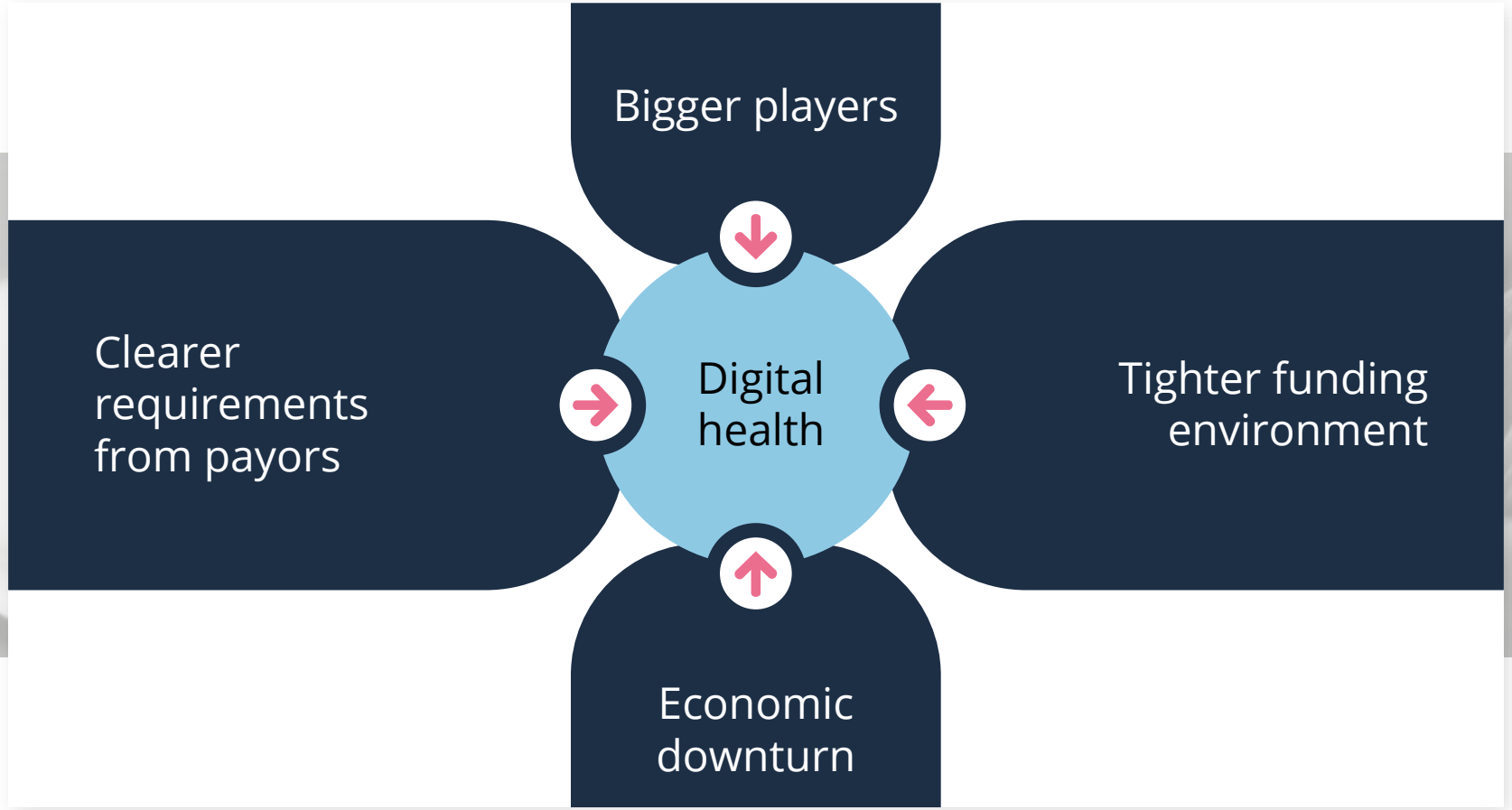
4 out of 5 top-funded digital health solutions had no or little evidence supporting them



Clinical Robustness Score (no. of regulatory filings + no. of clinical trials)

Adapted from 'Assessing the Clinical Robustness of Digital Health Startups: Cross-sectional Observational Analysis', Sean Day et al.

Four trends are driving the importance of evidence



Digital health investors are (finally) prioritising evidence

HEALTH TECH, SYN

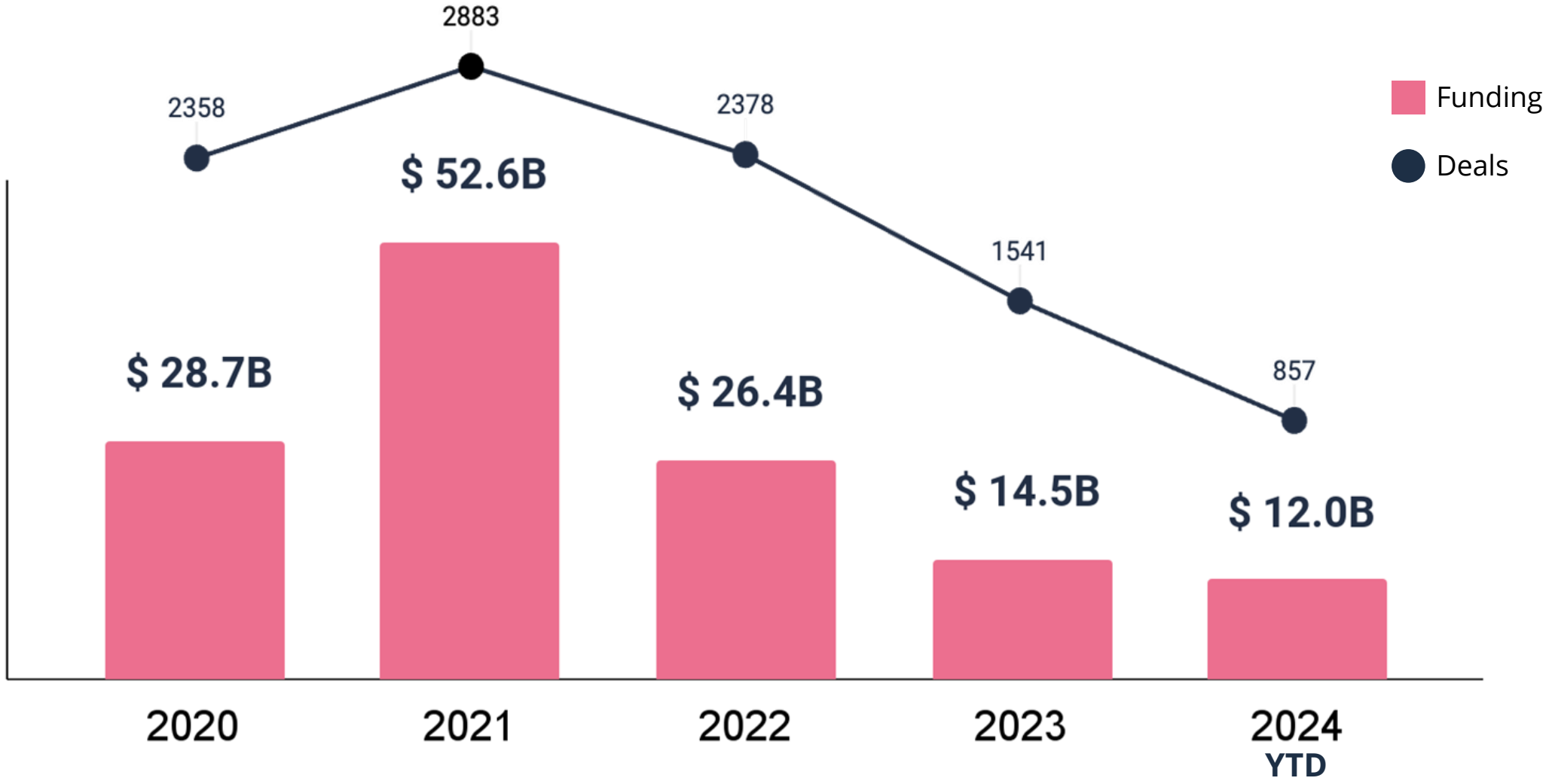
ROI and Clinical Validation Will Determine Digital Health Startups' Success in 2023, Investors Say

Going into 2023, investors think the abilities to demonstrate ROI and clinical validation will be the most important factors determining digital health companies' success, according to a new report. While the ROI factor is a given, clinical validation "is the best signal of patient value and historically has been under-captured in digital health," said Sunny Kumar, a partner at GSR Ventures.

94% of respondents said that ROI was "important" or "very important" to company success

79% said the same for clinical evidence and trials.

Annual equity and funding in digital health



Innovators face a vicious cycle of evidence generation

Payors are clarifying requirements

National Institute for Health and Care Excellence (NICE) Evidence Standards Framework for Digital Health Technologies

Digital Healthcare Act (Digitale-Versorgung-Gesetz, DVG)

FDA **Digital Health Software Precertification Program (2019/20)** and **AI/ML-Based SaMD Action Plan (2021).**

PECAN fast-track **reimbursement process** for digital health

Innovators should prioritise evidence generation across the product lifecycle

Digital health innovators

Innovation in evidence generation methods is the solution

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PERSPECTIVE OPEN

Challenges for the evaluation of digital health solutions—A call for innovative evidence generation approaches

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The field of digital health, and its meaning, has evolved rapidly over the last 20 years. For this article we followed the most recent definition provided by FDA in 2020. Emerging solutions offers tremendous potential to positively transform the healthcare sector. Despite the growing number of applications, however, the evolution of methodologies to perform timely, cost-effective and robust evaluations have not kept pace. It remains an industry-wide challenge to provide credible evidence, therefore, hindering wider adoption. Conventional methodologies, such as clinical trials, have seldom been applied and more pragmatic approaches are needed. In response, several academic centers such as researchers from the Institute of Global Health Innovation at Imperial College London have initiated a digital health clinical simulation test bed to explore new approaches for evidence gathering relevant to solution type and maturity. The aim of this article is to: (1) Review current research approaches and discuss their limitations; (2) Discuss challenges faced by different stakeholders in undertaking evaluations; and (3) Call for new approaches to facilitate the safe and responsible growth of the digital health sector.

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INTRODUCTION

Digital health has evolved rapidly since the concept was first introduced in 2000 by Seth Frank[1,2]. The FDA considers digital health as a broad scope that includes categories such as mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine[3], a definition we follow in this article. Indeed, the numbers of digital health solutions are booming, for example, more than 300,000 health applications exist with more than 200 added daily[4]. Digital solutions can be grouped as follows, based on potential risk to patients[5]: (1) Solutions that improve system efficiency but with no measurable patient outcome benefit; (2) Mobile digital health, that inform or deliver basic monitoring, and encourage behavior change and self-management; (3) Clinical decision support (CDS), and prediction models, that guide treatment, deliver active monitoring, calculate and/or diagnose.

The evidence requirements of regulators are determined by a product's intended use claims, as such, a large proportion of digital health solutions (e.g. administrative tools and wellness apps) fall outside of their jurisdiction. Therefore, a huge challenge for end users, such as patients and providers (e.g. healthcare professionals, hospital administrators), is how to determine a new solution's credibility and compliance with standards. Furthermore, end users have different thresholds for acceptance of innovation and can be grouped into five archetypes: innovators, early adopters, early majority, late majority, and laggards[6]. In addition, aging adults, considered amongst the most digitally divided demographic group[7], present unique challenges and dedicated efforts exist to develop strategies for implementation[8–10]. Conversely, challenges exist for healthcare innovators to best demonstrate solution impacts and to ensure compliance with standards, these include: unclear end-user expectations; uncertainty of evidence generation approaches; and, keeping up to date with the evolving compliance landscapes.

This article discusses the challenges for providing timely and robust evidence, to meet end-user expectations, in the context of digital health solutions. Specifically, we consider how the cadence of traditional research approaches are misaligned with the "fail fast, fail often" mantra espoused by technology start-ups. In addition, we introduce clinical simulation-based research as a potential opportunity to bridge the evidence gap.

A RAPIDLY EVOLVING GUIDANCE AND REGULATORY LANDSCAPE

Over the last 10 years a plethora of guidance has been developed for digital health innovators. In Table 1, we highlighted 10 of the key guidance (e.g., Continua Design Guidelines 2010, WHO monitoring and evaluating digital health solutions 2016, NICE evidence standards framework 2019; US FDA pre-certification program—a working model 2019, and FDA Proposed Regulatory Framework for modifications to Artificial intelligence/Machine learning-based Software as a Medical Device 2019). We ordered them by date first published and provided for each guidance a brief summary, applicable areas within digital health, releasing organization, and its main activities (Table 1). We observed that development of such documents follows a pattern: initial development by industry, optimization by non-government organizations, and finally refinement by government agencies. In addition, academic initiatives and institutions have produced critical thought leadership, often acting as counterbalance to industry proposals (Table 2; The digital health scorecard 2019). In Table 2, we highlighted five academic recommendations relevant to undertaking evidence generation studies for digital health solutions.

Until recently regulators relied upon modifications to existing medical device (software) regulations and innovators were encouraged to conform to development standards, as shown in Table 3, where we highlighted eight regulations and standards relevant to digital health solutions (e.g., IEC Medical device software, ISO Health informatics—requirements for an electronic health record architecture). However, the speed of development,

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Methodological gap exists for faster and high-quality evidence generation

Increasing evidence level

Innovative & pragmatic approaches

Prospective RCT studies

Retrospective observational studies

Prospective observational studies

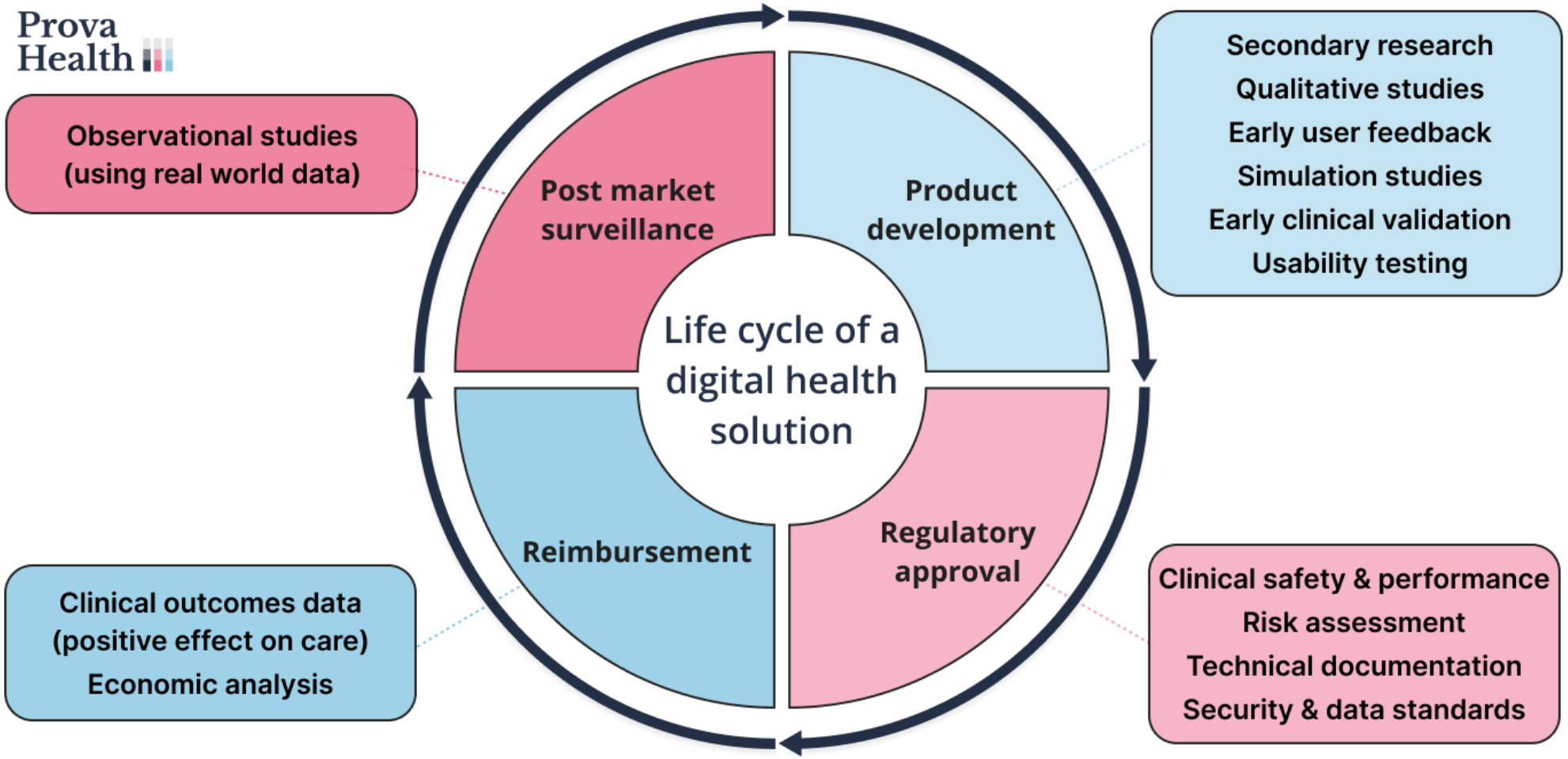
Survey and interviews (incl., usability testing)

Expert opinion / case example

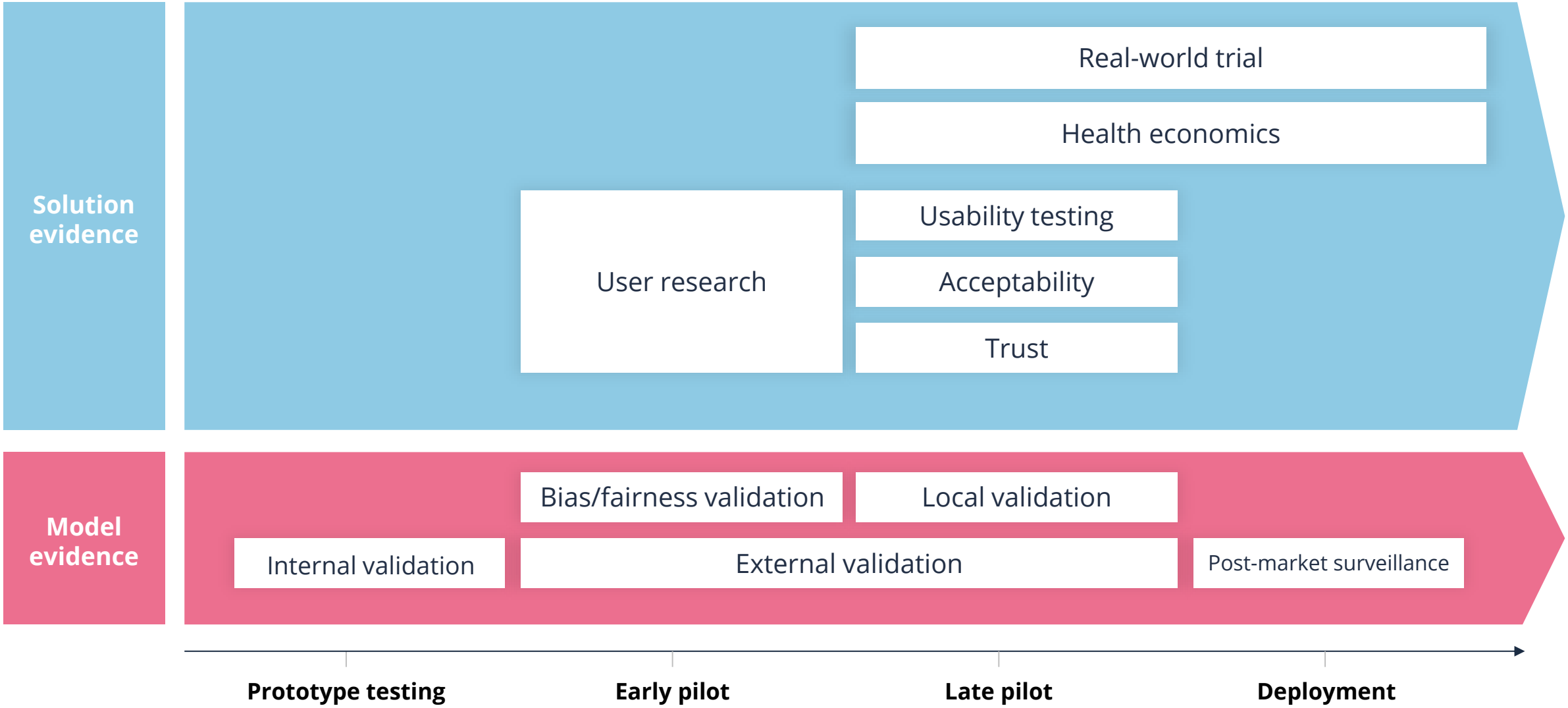
Faster time to evidence generation

Longer time to evidence generation

Innovators should prioritise evidence generation across the product life cycle



AI solutions need to show multiple layers of evidence



How to conduct end-to-end evaluations for AI solutions