Refereersesssie eHealth implementatie en evaluatie

Dinsdag 6 December 2022

Vitaal Twente

De sessie van vandaag:

- **Paper** – *The regulatory gap in digital health and alternative pathways to brigde it* by Iqbal & Biller-Andorno (Health policy and Technology 11, 2022)

- Vervolg refereer bijeenkomsten

Introduction: the floodgates are open (1)

- Digital Health Technology (DHT):
  - Digital technology applied to the execution of medical functions and their support to desease or conditions of human health.
  - The potential value that DHTs provide to patients, physicians and payors has resulted in their uptake across major health systems…
  - … receiving tailwind for the COVID-19 crisis.
- Research-to-practice gap:
  - Evidence-based practices (EBPs) require a long time to be implemented into clinical practice with only about 50% making it.

Introduction: the floodgates are open (2)

- …Physicians and patients cannot easily cut through the noise individually…

- Normally, regulatory agencies play a key role in limiting the number of new products entering the healthcare space through their approval processes for pharmaceutical drugs and medical devices, among others.

→ In this paper, we argue that the current situation in the United States and European Union amounts to a “regulatory gap”, i.e. the lack of effective regulation of digital health technologies

Introduction: the floodgates are open (3)

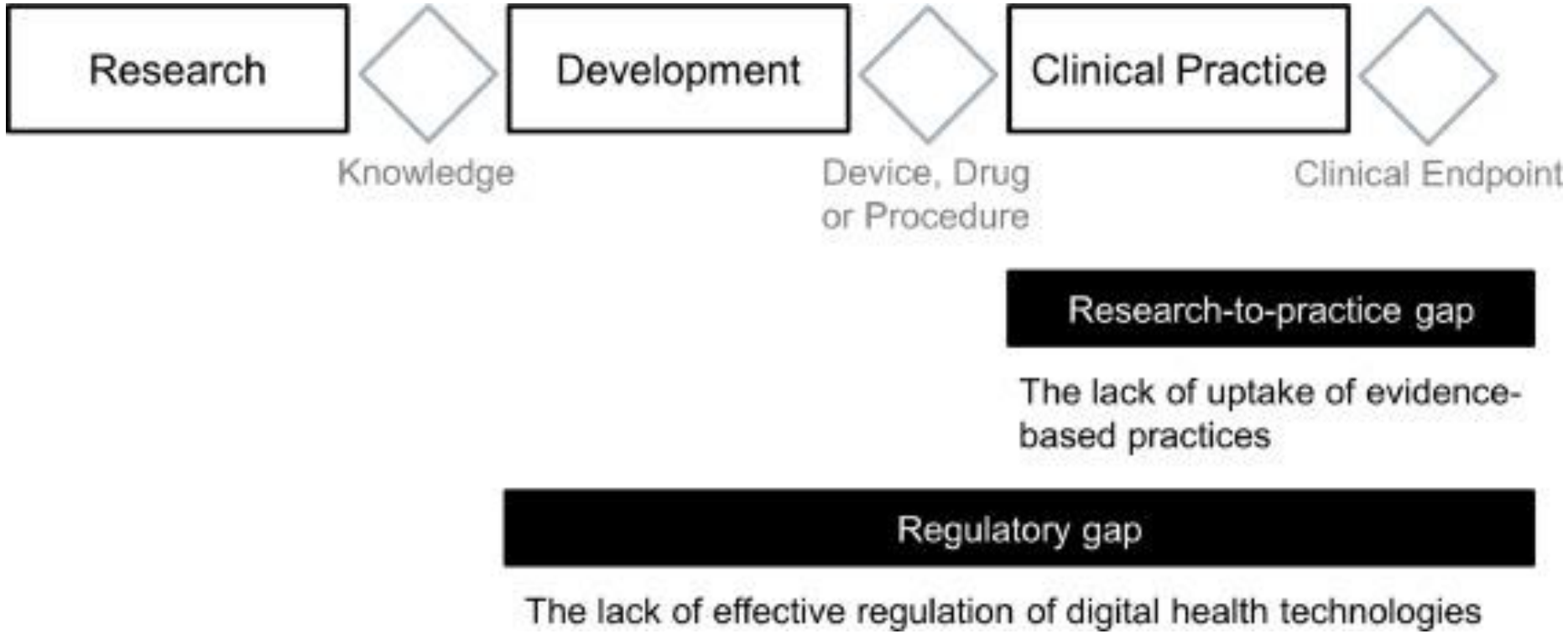
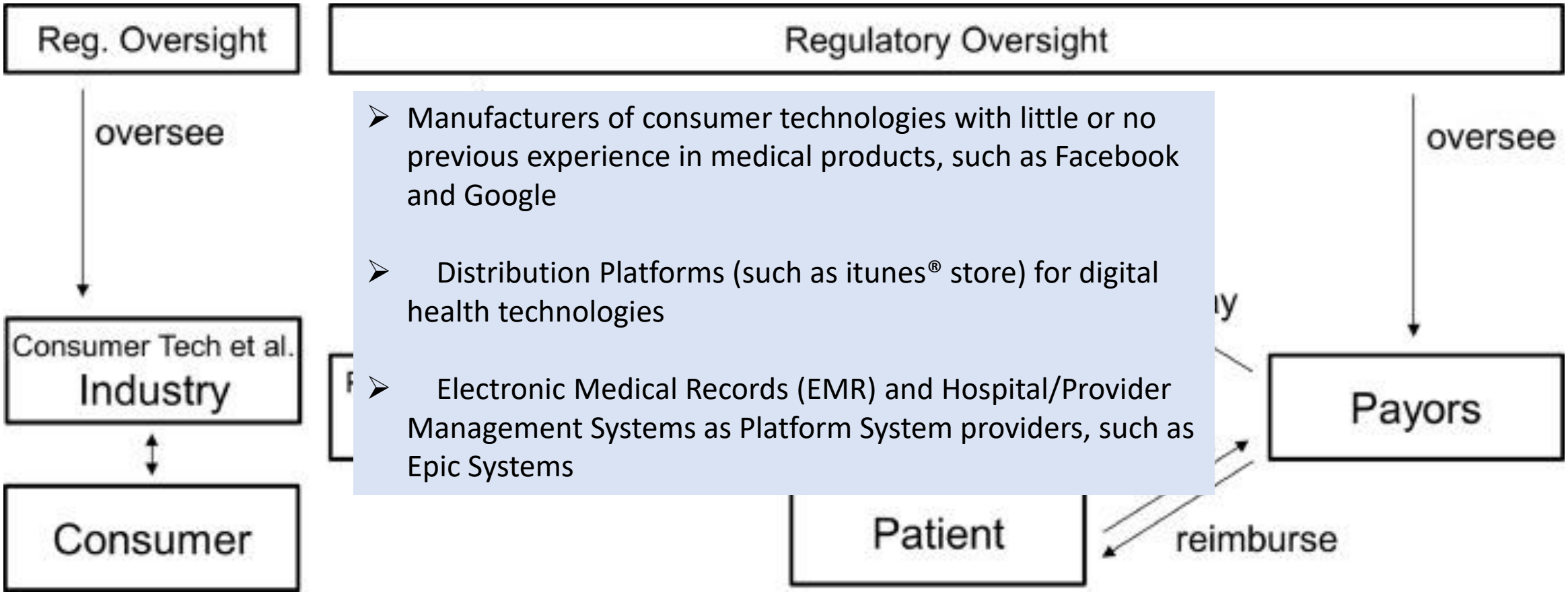


Fig. 1. Regulatory gap and research-to-practice gap in context of research-to-clinical practice lifecycle.

DHTs differ from established MedTech

- DHTs present new challenges from a product side versus established MedTech: their high adaptability (*fast pace of innovation*), variability (*self-learning nature*), variety and novelty and accessibility (*different distribution*).

DHTs actors differ from established healthcare actors



- Manufacturers of consumer technologies with little or no previous experience in medical products, such as Facebook and Google
- Distribution Platforms (such as itunes® store) for digital health technologies
- Electronic Medical Records (EMR) and Hospital/Provider Management Systems as Platform System providers, such as Epic Systems

Fig. 2. Traditional industry-structural separations between providers and payors and consumer tech and Pharma/MedTech industry are dissolving.

Changing roles of actors in healthcare

- Traditional – HCP serves as a filter to prescribe and oversee the use of pharmaceaticals and/or medical devices to the patient.

… DHTs are procured and used without or diminished oversight by HCPs directly by patient-consumers.

New delivery models vs. heritage delivery models

- The traditional unimodal provision of care (“in-office visits only”) is being supplemented and/or replaced.

- … permit extended provision of healthcare outside of traditional settings.

DHTs and inadequancy of regulation

- The goals of regulation in medical and health-associated uses lie in ensuring quality, safety, and efficacy of products.
- A marketing authorization for medical devices normally signals to parties that an independent party has verified and validated a device using evidence of a sufficiently high standard, depending on the risks posed and benefits claimed by a device before regular medical use. This is currently not the case with DHTs.

The following problems contribute to this regulatory gap:

Regulatory gap (1)

- There is no regulatory class specific to Digital Health Technologies
- There is little to no binding regulation specific to Digital Health Technologies
- Low-risk classification, exemptions from medical device regulation and enforcement
  - The FDA has also made clear that it will exercise enforcement discretion even when certain DHTs would fall under medical device classification.
- Lower evidence standard required for Digital Health Technologies
  - Clinical studies are mandated only for some classes of medical devices – typically Class-III and Class-IIb but not Class-IIa – the default classification of most DHTs.
- Substantial equivalency loophole in the United States

Regulatory gap (2)

- Purpose loophole
  - Problematic in context of DHTs is the intended use component of the definition: any device that could fulfill these purposes and may be used in such a way but is not intended to do so, does not fall under the legal definition of a medical device and therefore what little regulation there is.
  - With variety, quantity and easy availability of DHTs to patient-consumers versus more experienced and trained HCPs, patient-consumers may be prone to use devices in ways not approved.
- DHT products currently cannot be evaluated in regard to their quality, safety, and efficacy
  - …well-established tests do not yet exist for DHTs where even basic tenets establishing safety and efficacy are not followed…
- DHT products currently cannot be evaluated in regard to their conformance with other evolving ethical requirements
  - Measuring conformance to these principles is difficult.
  - The ethical requirements applicable towards DHTs going beyond what is currently required of medical devices challenges the regulatory processes underlying the category never designed for this.

Alternative plathways

- Existing health systems stakeholders
  - Payors: private insurances, public payors?
  - Providers beyond the individual HCP: hospitals, provider, networks?
  - Providers & patients: medical societies and patient advocacy groups

- Evolving healthcare system stakeholders
  - New entrants: tech companies
  - Hybrid actors: payor-providers

Conclusion: a real threat, no real alternative to regulation (1)

- While they typically fall under the Medical Device regulatory category, regulators in the United States and Europe do currently not fulfill their statutory role in enforcing market access only to those devices that are safe and efficacious.

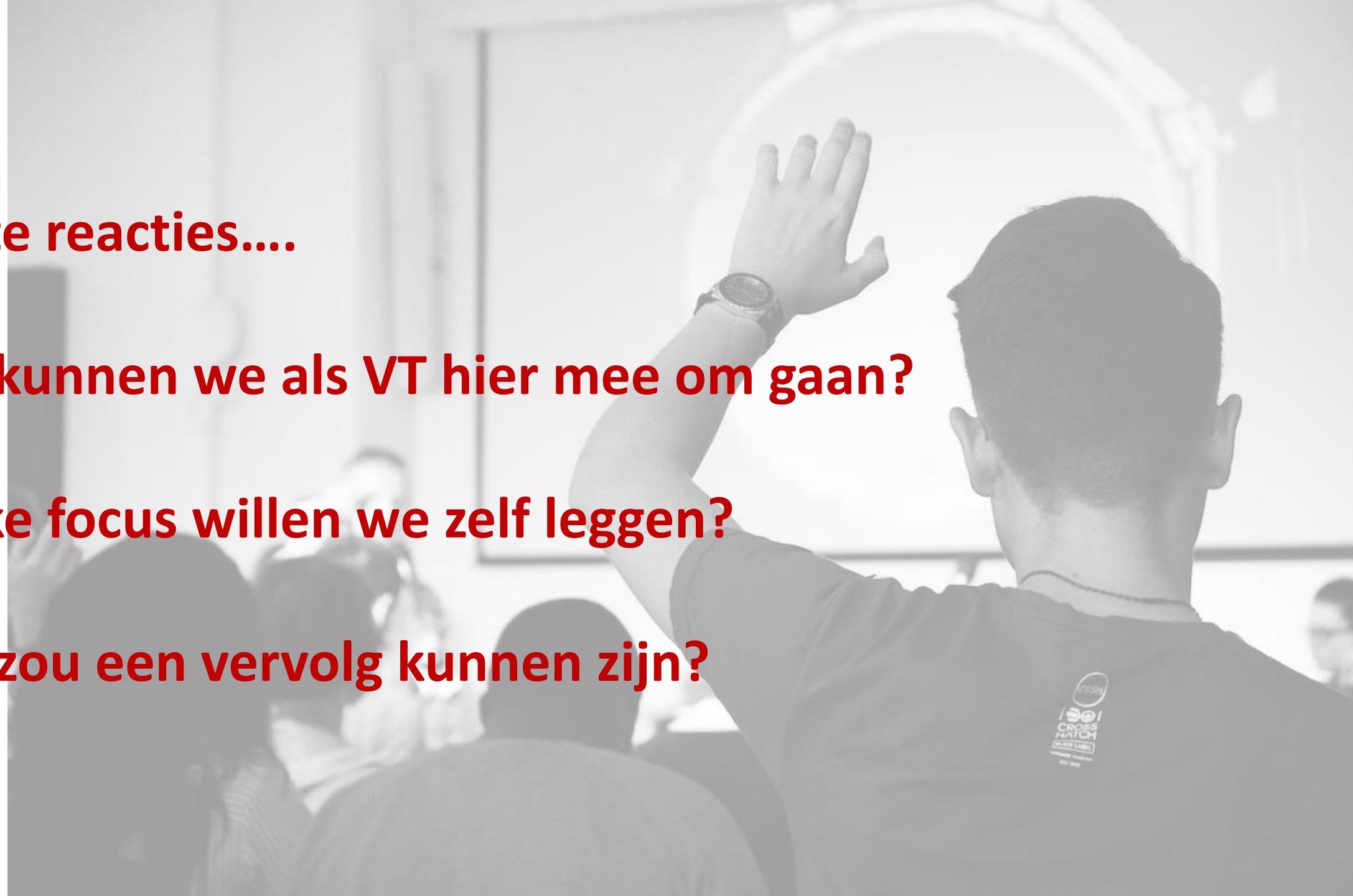
- High-quality labels – potentially fed by academic expertise on evaluation techniques and ethical requirements – could offer an opportunity to bridge the gap until regulators have caught up or provide additional signaling in terms of ethical dimensions that may not fall under regulatory testing, such as privacy policies.

- Regulatory assessments go beyond just establishing some level of safety and efficacy of a medical device. They signal to physicians, patients and other stakeholders some level of trustworthiness of a device.

Conclusion: a real threat, no real alternative to regulation (2)

- “No evidence, no implementation – no implementation, no evidence paradox”

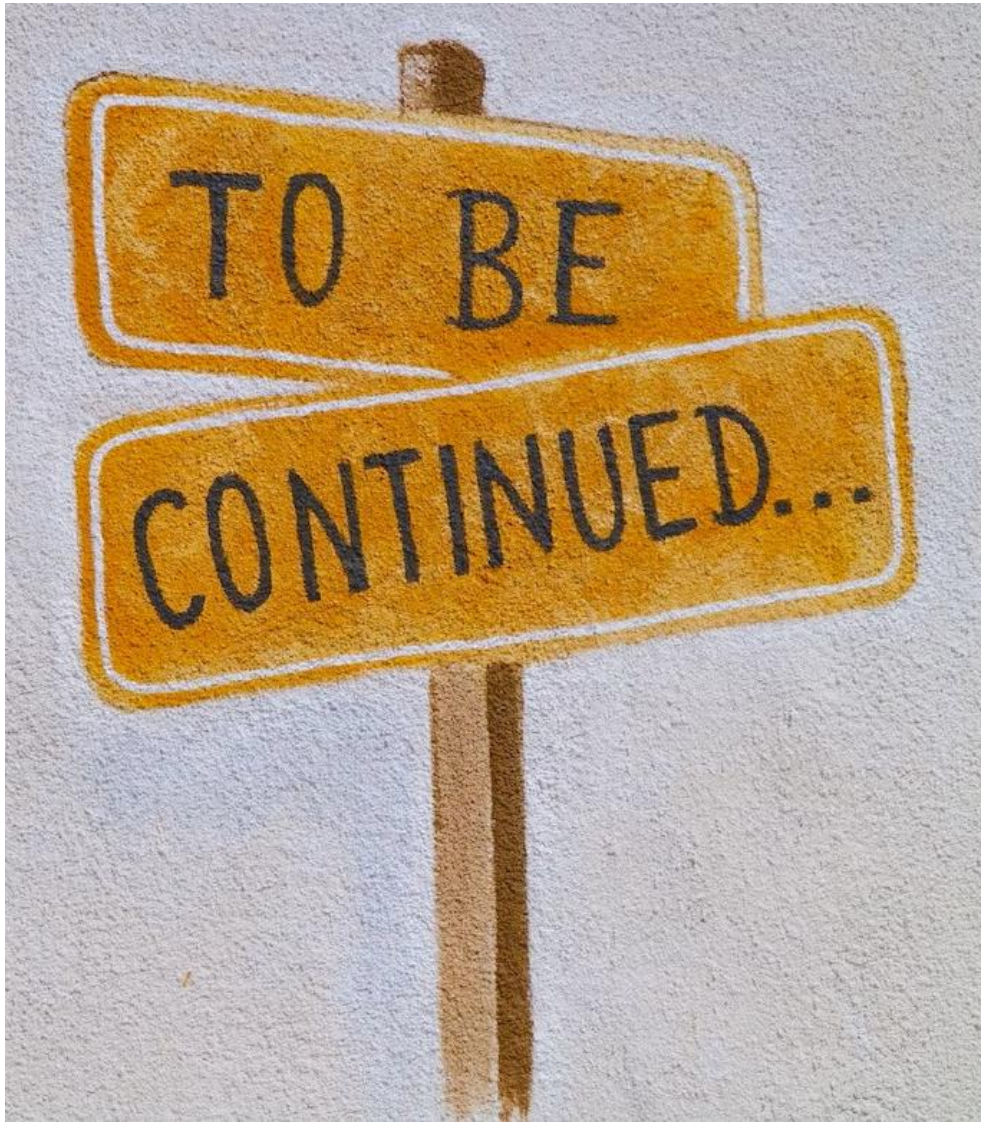
- In light of the dangers of the regulatory gap in the core area of lives and health, we need to call for the opposite: A strengthening of regulatory agency's roles and increased investment in the development of pre-approval evaluation techniques. Ultimately, this will help lasting adoption of DHTs by avoiding scandals and signaling the trustworthiness that is missing today.



- Eerste reacties….
- Hoe kunnen we als VT hier mee om gaan?
- Welke focus willen we zelf leggen?
- Wat zou een vervolg kunnen zijn?

eHealth implementatie en evaluatie

- Vitaal Twente
  - Van werkgroep “Monitoren & evalueren” naar “Leren Innoveren”
    - Instrumenten
    - Thema bijeenkomsten
    - Workshops
    - Stroomdiagram
    - Netwerk
- **Refereersesssie** eHealth implementatie en evaluatie
  - 1x per maand (45 minuten)
  - Bespreking paper
- 2023???



eHealth implementatie en evaluatie - 2023

- 3 Januari
- 7 Februari
- 7 Maart
- 4 April
- 2 Mei
- 6 Juni
- 5 September
- 3 Oktober
- 7 November
- 5 December

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