

The Business of Medtech: Miracle or Malpractice?

SABEW One-Day Workshop for Journalists

Tentative Agenda

8:30 a.m.

Coffee and gather

9:00 – 9:30 a.m.

Welcome & Context Setting

- Overview: How AI and Medtech are transforming care, costs, and coverage

9:30 – 10:30 a.m.

What's a Medical Device Now? From Wearables to AI

- How the FDA defines and regulates devices (510(k), PMA, EUA)
- AI-enabled diagnostics, wearables (e.g. Apple Watch ECG, continuous glucose monitors)
- Real-world risks and benefits
- Case Study: Pulse oximeter bias and racial equity

10:30 – 10:45 a.m.

Break/networking opportunity

10:45 – Noon

Follow the Money – Devices as Big Business

- Wall Street's healthcare gold rush: ResMed, Dexcom, Medtronic, Eli Lilly
- Startup boom and fast exits in medtech
- Investigating conflicts of interest (Open Payments, ClinicalTrials.gov)

Noon – 1 p.m.

Working Lunch (with Case Study presentation)

- Topic: "How We Investigated a CPAP Device Recall"

1 – 2 p.m.

Medtech, AI, and the Future of Access

- Telehealth, online clinics, and care in underserved areas
- The promise and pitfalls of AI-driven triage and diagnosis (e.g. symptom checkers, chatbots)

2 – 2:45 p.m.

Safety, Surveillance, and Cybersecurity

- Postmarket surveillance flaws (MAUDE database, device recalls)
- Data privacy and cybersecurity risks for connected devices
- Toolkit: Finding and analyzing device failure reports

2:45 – 3:00 p.m.

Break/networking opportunity

3 – 4:15 p.m.

Regulation in a Rapid Fire World.

- How FDA, Congress, and states are responding (or not) to the pace of innovation
- Coverage of Right to Repair, transparency mandates, AI legislation

4:15 – 5:15 p.m.

Wrap-Up + Story Brainstorm (Group Exercise: 'Pitch the Device Story')