



The Role of Digital Health Technologies in Drug Development

Session IV: Digital Tools for Post Registration Surveillance

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Digital Health Technologies for 21st Century Surveillance

Empower patient participation in continuous and shared learning

Key Opportunities:

- Real time longitudinal data collection
- Advance surveillance beyond safety to include effectiveness and outcomes
- Include populations not represented in pre-approval clinical trials
- Partner with patients in real world evidence generation as citizen scientists

Key Requirements:

- Patient-informed principles to guide tool design, data protection and privacy
- Patient-centric strategies to ensure new knowledge and insights are shared

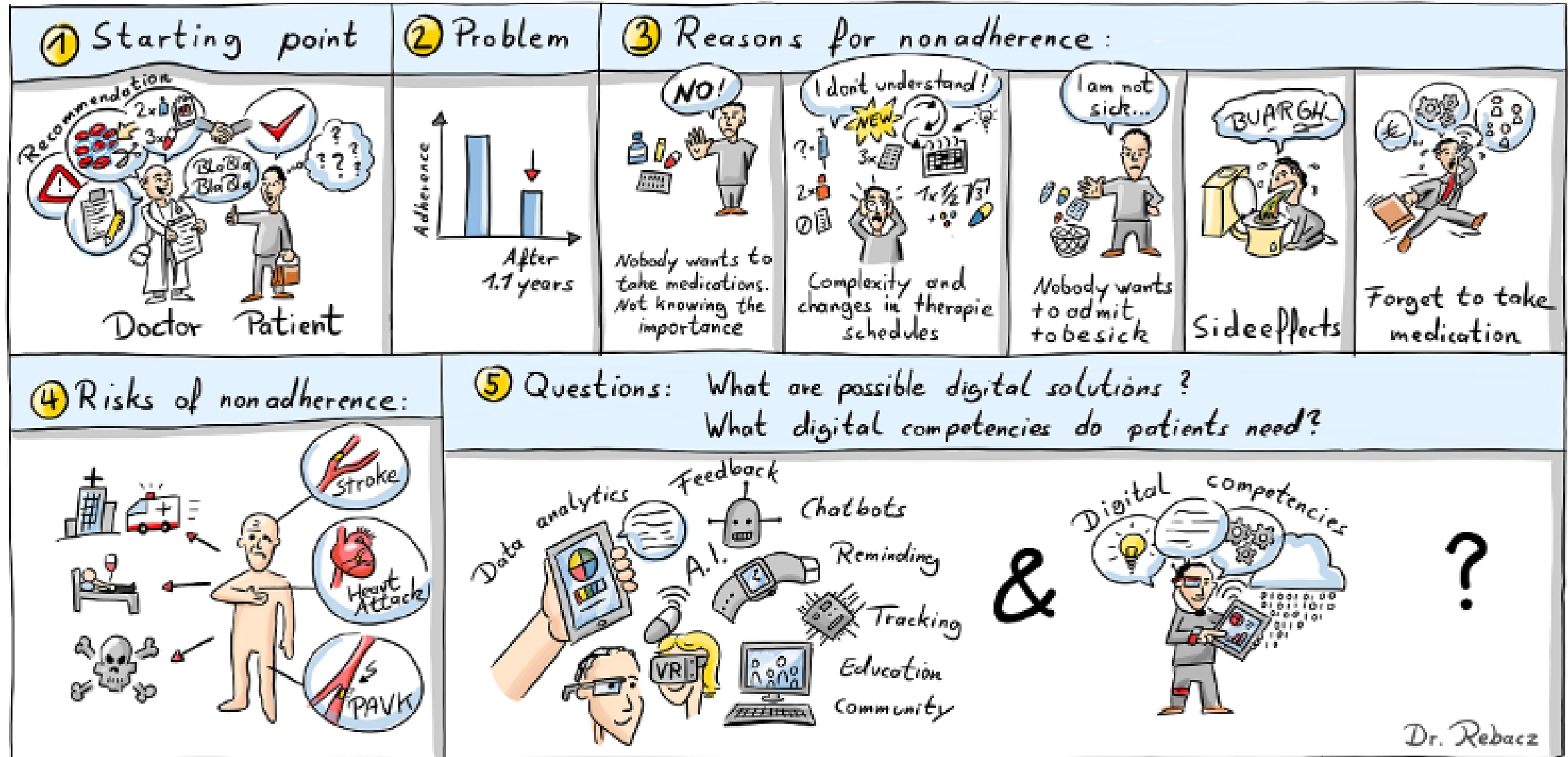
The real voyage of discovery is not
in seeking new landscapes but in
having new eyes

marcel proust

Digital tools can illuminate data related to patient experience



Digital tools can provide new solutions for old problems



Patient-informed principles can provide guidance

Measurement principles

Measurement principles should inform and help to create patient-centric health measures.

Clear I understand what it means

Answerable it's information I have

Efficient it respects my time

Relevant describes my experience

Educational what is and isn't part of my condition

Harmless doesn't make me sad and symptomatic

Actionable helps me change, discuss with MD

Design principles

We exist to:

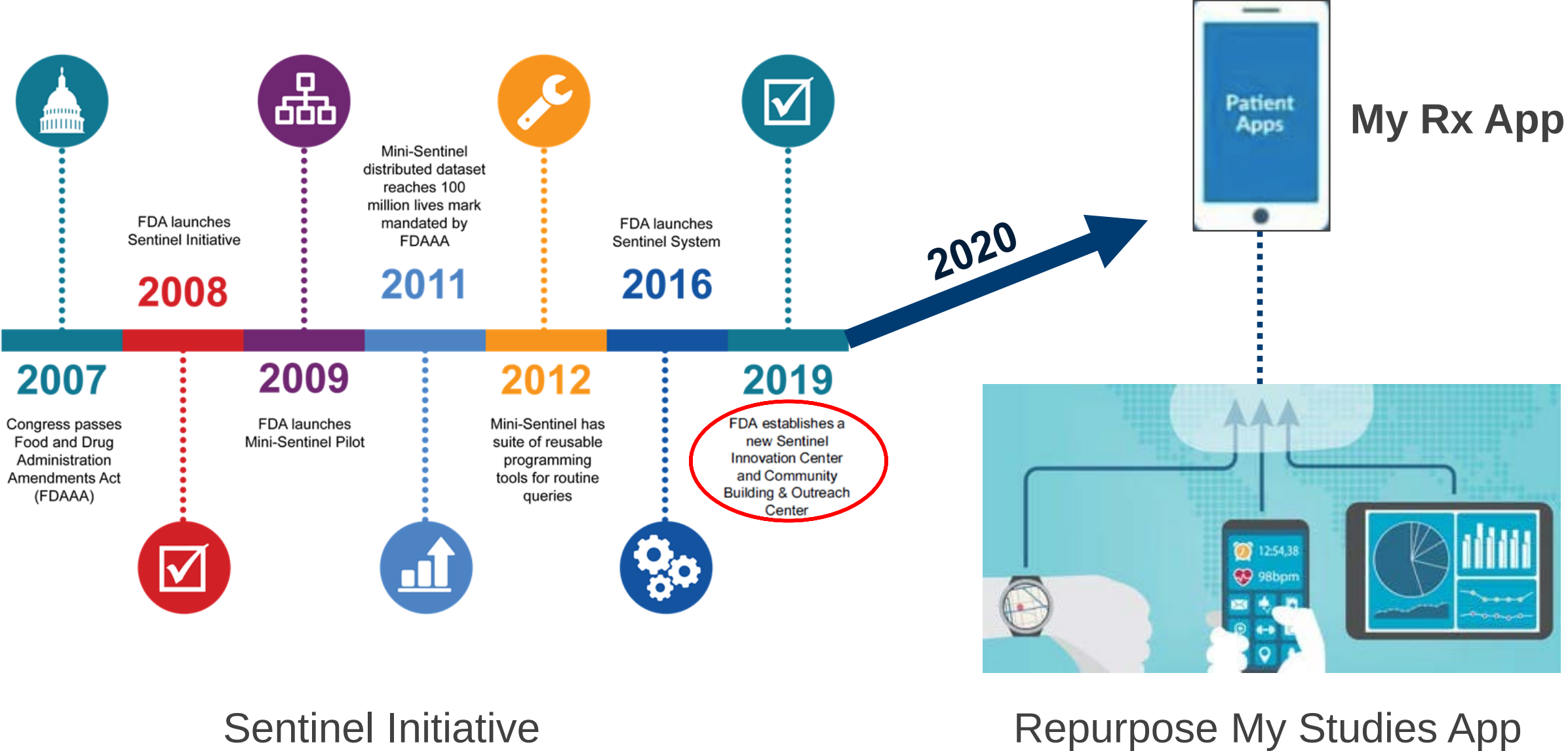
Get the data that makes a difference.
Without it, we can't accomplish our purpose.

Help people achieve better outcomes.
Promote informed decisions & actions

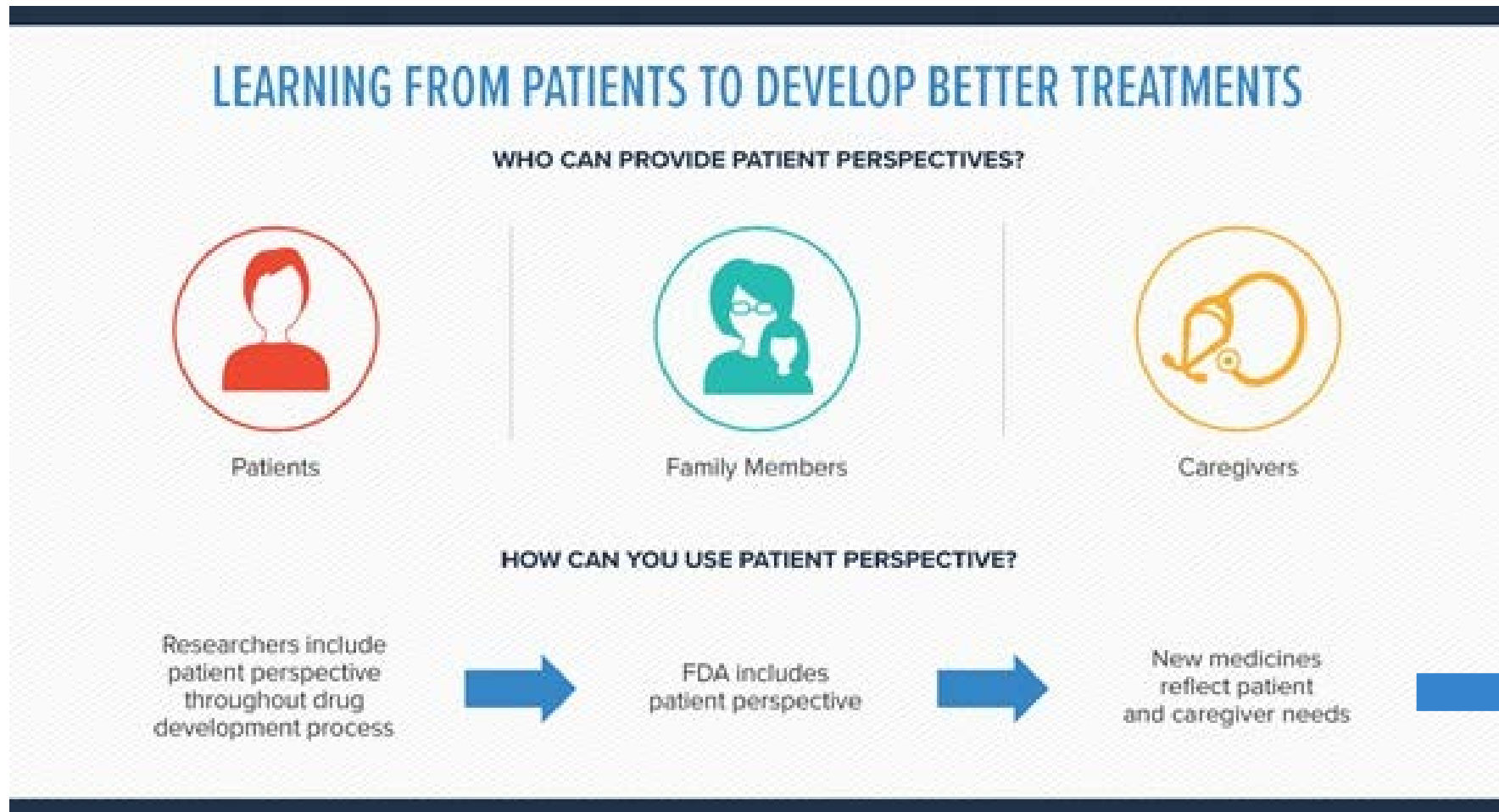
Every patient wants us to:

- See me as a whole person.**
My doctors often don't. That's part of the problem.
- Come with me on my journey.**
In different times & places, I need different things.
- Help me capture my truth.**
It bugs me if I can't accurately reflect my own experience.
- Let me define who is like me.**
They share my experiences and values.
- Help me feel in control.**
Life feels out of control; I need to know I'm in charge.
- Put my needs first.**
Address my needs before demanding I address yours.
- Inspire confidence.**
Show me that PLM is worthy of my effort and trust.
- Build on what I already want to do.**
I already spend time on my health, take advantage of it.
- Prioritize.**
I have limited energy; show me where to put it.
- Minimize my work.**
I may have dexterity, fatigue, cognitive, or memory challenges.

Existing systems can provide platform to maximize PGHD



Digital tools bring Patient Focused Drug Development full circle



Digital Health Tools can help us continuously learn from real-life experiences in real-time from real-people about

- Safety
- Effectiveness
- Outcomes

“ to learn listen well
to the experiences
voiced by patients first ”