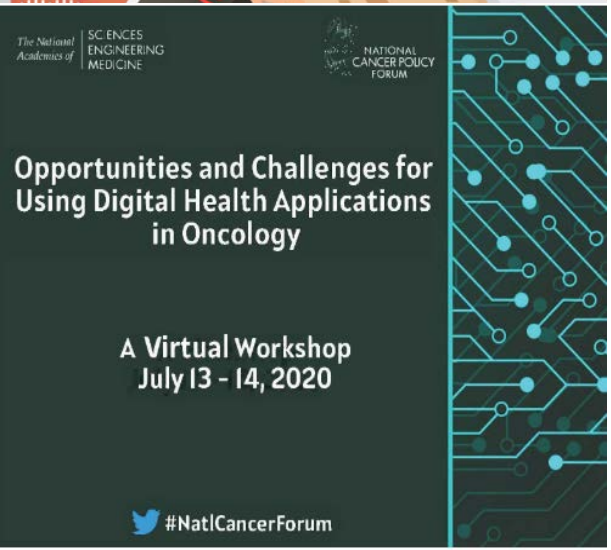

Wearable, Mobile and Remote Monitoring Technologies in Oncology: Current Evidence and Future Opportunities

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Making Cancer History®

Wearable, mobile and remote monitoring for health

Smartwatch

Activity and sleep monitor

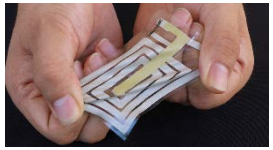
Virtual assistant

Blood pressure monitor

Weight scale

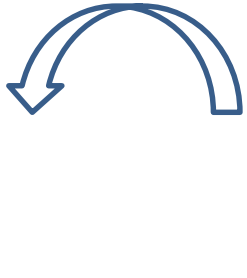
Hearables

UV exposure monitor



Stickers/tattoos

Smart clothing



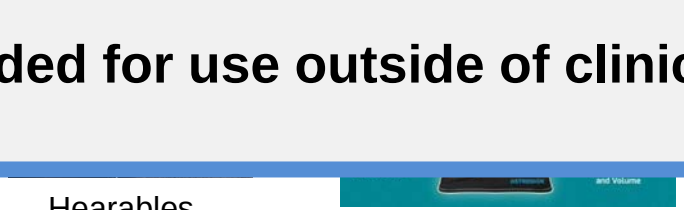
Mobile app

Platforms to integrate, analyze, & display data

Wearable, mobile and remote monitoring for health

Key Characteristics

- **Collect health-related measurements with potential clinical utility**
- **Consumer-friendly, require little or no clinician involvement**
- **Include a sensor element & software component**
- **Connect to internet or another device (via Bluetooth, app, USB)**
- **Portable, intended for use outside of clinic or facility**



Hearables

Smart clothing

analyze, &
display data

Tools for a new brand of multidisciplinary care & research

Unprecedented approach to measure key physiological & behavioral outcomes

- Continuous, passive data collection
- Reduce barriers, limitations (distance, self-report)
- Identify early intervention signals to prevent or mitigate problems
- Wireless data transmission, large storage capacity
- Goals: Scalable, cost-effective

May reduce reliance on in-person, physical contact (COVID-19)

- Facilitate transition to remote clinical trials
- Enhance virtual visits
  - MDACC: Home-based digital monitoring for COVID-19 & validation of COVID symptom PRO measure

Peterson, Patrick, *Oncology Informatics*, 2016

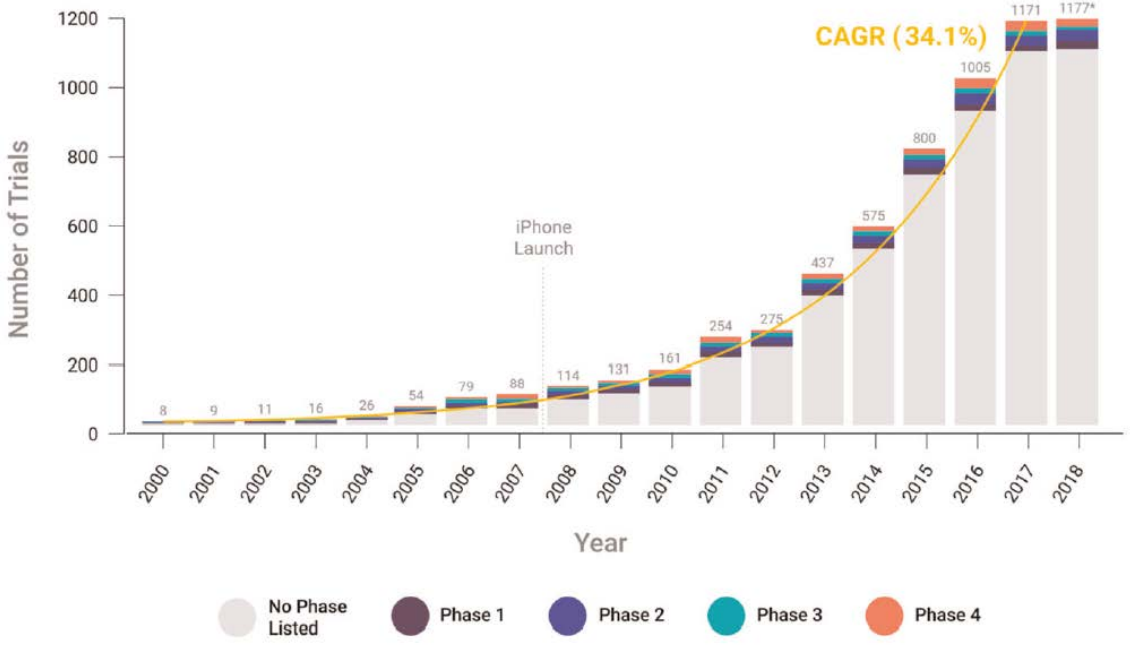
Patient perspectives

- **Mobile technology use is consumer-driven**
  - **81% own smartphones, ~ 50% own tablets**
  - **61% age 65+ own smartphones, 91% own any cellphone**
- **Most cancer care is experienced away from clinic setting**
  - **Opportunities for enhanced monitoring for varied and complicated side effects**
  - **Less burden for clinical trials participation**
- **Acceptability, feasibility are favorable when technology is perceived as adding value to care**
- **Large survey of patients with chronic conditions: mixed responses about acceptance of wearables, concern about losing in-person contacts[1]**

▸ **Need high tech + high touch, ongoing attention to patient engagement**

[1]Tran, NPJ Digit Med 2019

Inclusion of connected digital devices in clinical trials, 2000-2018



22 cancer trials reported in 2018

4 primary uses:

- **Validate functionality**
- **Test clinical usability**
- **Capture endpoint data**
- **Digital therapeutic intervention**

b

Most Recent 4 Yrs (2015-2018)

	No. of trials (2015-18)	Industry funded[1]	Designated as Phase 1, 2,3, or 4[1]	Interven -tional trials[1]
Smartphone	1207	0.14	0.07	0.85
Mobile app / mHealth	693	0.15	0.05	0.90
Actigraph	400	0.05	0.08	0.86
Fitbit	311	0.11	0.07	0.88
iPad	232	0.12	0.05	0.83

Marra, NPJ Digit Med 2020

Wearable activity monitors

- **Expansion of consumer-grade monitors, smartphone trackers**
  - **Measure step count, sleep, heart rate, energy expenditure**
- **Immediate feedback on step count + behavioral strategies (e.g., goal setting) may improve activity levels**
- **Recent evidence: Higher step count associated with lower all-cause mortality[1]; sedentary behavior associated with higher cancer mortality[2]**
- **Most oncology studies using wearable monitors have focused on changes in activity levels as outcome (n=41 studies)[2]**

[1]Saint-Maurice JAMA 2020; Hall IJBNPA 2020; [2]Gilchrist 2020

Wearable activity monitors & performance status (PS)

- **Can wearables improve accuracy of PS & physical function assessment, reduce bias in assessment, & help guide and monitor therapy?**
  - **Positive correlation between step count, provider-assessed PS, PROs (fatigue, QOL, depressive symptoms)[1,2]**
  - **+1000 steps/day associated with fewer hospitalizations & adverse events, better survival[2]**
  - **Longitudinal evaluation of activity, PS, QOL, clinical outcomes[3]**

[1]Beg, J Onc Pract 2017; [2]Gresham, 2018; [3]Peterson, Overman, Raghav (R01 CA243554-01)

Connected digital devices & ePROs in multifunction platforms

Palliative chemotherapy for gynecologic cancers [1]

- Activity, heart rate, symptom ePRO
- Symptom management guidance tailored to response thresholds
- Avg. 80% completion
- Identified subsample with multiple worse outcomes

Home-administered chemotherapy for advanced GI cancers[2]

- Sleep, body weight changes, daily circadian rest-activity rhythm (*CircAct*), symptom ePRO
- Provider intervention tailored to response thresholds
- Avg. 67% completion; indicated tolerance for a multi-drug regimen

[1]Wright, 2018; [2]Innominato, 2018

ePROs and remote monitoring for dehydration during radiation treatment for head and neck cancer

Bluetooth-enabled blood pressure + pulse monitor

Mobile app records patient-reported outcomes (symptoms, nutrition, medications, fluid intake/output)

Bluetooth-enabled scale to monitor weight loss

Data transmission to home-based hub

Interface with CYCORE multifunction platform

Data available to providers for clinical decision-making and intervention

- 85% of assessments completed
- Remote monitoring group: fewer symptoms, better QOL

Patrick, 2011; Peterson, 2013; 2018

Advancing the use of mobile and wearable technology in cancer clinical trials

Identify problem, data needs, purpose of application →

Feasibility
- Patient acceptance, satisfaction, adherence
- Functional (battery life, connectivity)
- Multiple vs. single function; cost; resources

Validity
- Accuracy
- Predictive capability

Clinical utility
- Timing and quantity of data
- Meaningfully informs clinical care or research
- Adoption by patients and providers into work flow

Digital Health Innovation Action Plan **(FDA, 2017)**

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Digital Health Technologies Recommendations

Feasibility Studies Database
(12 cancer trials: 10 physical activity)

Summary and future directions

- **Increase the evidence base for use of connected digital technology in cancer**
  - **Expand focus beyond activity monitors**
  - **Identify and test patient-centered use cases that optimize technology applications**
  - **Address the cancer continuum from primary prevention to long-term survivorship**
  - **Leverage the current disruption of COVID-19 to identify opportunities for innovation**

- **Infrastructure to support access to mobile and wearable technology, particularly among underserved populations**

- **Incentivize the creation of a connected digital ecosystem**
  - **Interoperable components with open interfaces to accelerate development of new multicomponent systems**