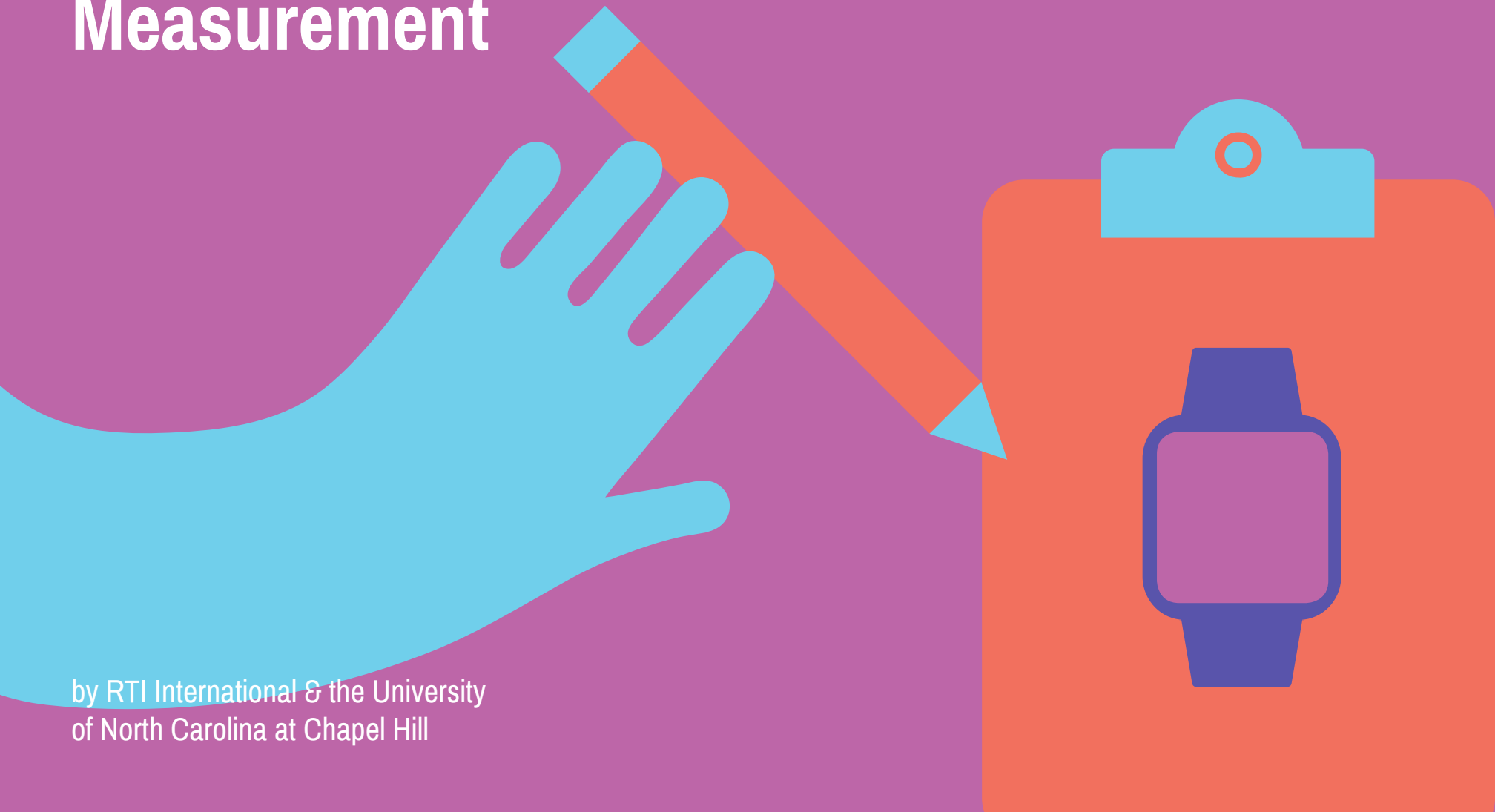


Collaborative Healthcare Using Patient-Generated Data

# Standardizing and Evaluating Consumer Wearable Device Measurement



by RTI International & the University  
of North Carolina at Chapel Hill



Support for this initiative was provided by the Robert Wood Johnson Foundation. The views expressed here do not necessarily reflect the views of the Foundation.

Produced by Reos Partners  
December 2017

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All the materials produced are available at the Reos Partners website:  
[www.reospartners.com/pgd](http://www.reospartners.com/pgd)

If you have other ideas for how to build on these use cases, please let us know:  
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#### **Acknowledgment**

The use case methodology is adapted from *Writing Effective Use Cases* by Alistair Cockburn.

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# Technology has made it easy for people to capture data about their health, giving users insights that are more accurate and accessible than ever.

From counting steps to tracking fertility, people are drawn to using new tools to bring transparency and self-awareness to their well-being. Despite its promise, it is still unclear how to transform this wealth of self-generated data into meaningful improvements to the partnership between a patient and their healthcare provider. Proactive patients who wish to improve their personal health, as well as stakeholders from across the healthcare and health research field, are invested in finding ways to use patient-generated data (PGD, also known as PGHD or patient-generated health data) to inform healthcare and to transform it to be better, safer, more efficient, and more collaborative than before.

To provoke innovation within this emerging space, the Robert Wood Johnson Foundation engaged Reos Partners, an international social enterprise with experience in bringing collaborative innovation processes to life. Reos defined the scope of this inquiry through the question: **How might the use of patient-generated data enhance collaboration between patients and providers to improve individual health outcomes?** In two phases of work, Reos Partners investigated the opportunities and challenges facing thought leaders and researchers around this question. Reos Partners started with interviewing leaders and stakeholders from the healthcare field, including patients, healthcare providers, academics, technologists, designers, and representatives from public institutions. The outcome was a report that synthesized these conversations to capture insights, trends, and actions that could most directly improve health outcomes for patients.

With this research foundation, Reos Partners initiated a second phase of work by inviting four health innovation teams from across the United States to propose approaches that could use patient-generated data to make healthcare more collaborative. Over three months, these teams produced a series of scenarios that articulate how PGD could be used to improve the clinical encounter between a patient and their care team (a methodology known as “use case”).



While the initial Reos Partners report identified a number of emerging challenges and opportunities in the PGD landscape, these four teams were asked to pursue research advancing one or more of the following focus areas:

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## Shift Toward Trust

Patient-generated data should be viewed as a trusted, valid, and reliable input to the clinical encounter that enables collaborative decision-making between patients and their care team.

- > How might we increase clinicians' receptivity to using patient-generated data in the clinical encounter?
- > How might we find the balance between clinically generated and patient-generated data?
- > How might we establish rigor within the context of patient-generated data?

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## Identify Mechanisms for Meaningful Collaboration Between Patient and Provider

Patient health and well-being should be co-produced with providers through meaningful communication and collaboration.

- > How might we translate and present large amounts of data into comprehensible and relevant information that can be used by patients and providers?
- > How might we improve the quality of data-driven conversations between patients and their care team?
- > How might we use patient-generated data to meaningfully incorporate patients' experiences into decisions about care and treatment plans?

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## Bring Patient Stories into the Clinical Encounter

The day-to-day lived experience of patients should be understood to be important and reliable data that can inform their healthcare options.

- > How might we track behaviors that promote wellness and well-being?
- > How might we track and synthesize qualitative data that enables patients to tell their whole story?
- > How can the burden of recording large amounts of data be reduced?

Each innovation proposed a unique approach to integrating patient-generated data, through several use cases that explore different perspectives and outcomes within the same topic (referred to as "use case suites"). By publishing these use case suites, along with a how-to guide to create your own use case, we aim to inform the future of using patient-generated data to make healthcare more collaborative.

# Four research teams investigated various ways to co-produce improved health outcomes using patient-generated data.

Each team's use cases are outlined in a respective document and corresponding video overview, available at: [www.reospartners.com/pgd](http://www.reospartners.com/pgd)



### **Using Patient-Generated Data Reports to Individualize Care for COPD**

by Propeller Health

Using an inhaler sensor that pairs with a smartphone app, researchers created a platform to collect and reflect data about inhaler usage from patients living with chronic obstructive pulmonary disease (COPD). For this use case suite, the patient-generated data is translated into reports to be used by patients to help self-manage their care as well as by physicians to help improve their methods for creating individualized treatment plans for their patients.

### **Integrating Wearable Device Data into Mental Health Care for Veterans**

by Northwestern University & Rush University Medical Center

Researchers created recommendations for ways to integrate Fitbit devices into a mental health treatment program for veterans living with post-traumatic stress disorder (PTSD). This team speculates how providers might be trained to use patient-generated data to provide physiological insights that could be used as a point for reflection and conversation with patients.

### **Standardizing and Evaluating Consumer Wearable Device Measurement**

by RTI International & the University of North Carolina at Chapel Hill

By analyzing the broad use of wearable technology in health studies, researchers established an evidence-based protocol to evaluate the reliability and validity of these devices. This framework is designed to evolve and scale as patient-generated data technology expands and improves.

### **Mobile Apps for Generating and Sharing Food-Related Data**

by the University of Washington

To help patients identify opportunities for healthy change within their diet, researchers developed a suite of mobile phone applications that empower users to monitor symptoms and form hypotheses about what might be affecting them. Foodprint is a photo-based diary that patients can use to capture visual records of what they eat, as well as notes detailing ingredients and symptoms. TummyTrials is a mobile app that structures low-impact diet experiments that the user can explore on their own to better understand what elements of their diet might be triggering undesirable symptoms. These apps help the patient make more informed food choices and improve communication between the patient and their health provider.

# What are use cases and why are we using them?

A use case is a story that tells the journey of a person as they work to achieve a specific goal within a defined scope or “system.” Use cases, as a problem-finding methodology, were first created by software designers to discover what needed to be in place for the software user to engage with a program successfully. By starting with understanding users’ needs and possible challenges as they attempt to navigate a system, designers could then create with this journey in mind as well as anticipate where things could go wrong.

For this initiative, we have taken the use case methodology and adapted it to explore the question:

**“How might the use of patient-generated data enhance collaboration between patients and providers to improve individual health outcomes?”**

*If you are interested in knowing more about use case methodology, please see the appendix for an overview.*

Fully Dressed Use Case Template		Team Name
<b>Patient Generated Data Focus Area</b> <input type="checkbox"/> Shift Toward Trust <input type="checkbox"/> Mechanisms for Meaningful Collaboration Between Patient and Provider <input type="checkbox"/> Bring Patient Stories into the Clinical Encounter		<b>Patient Generated Data Challenge</b> Tell us about the specific challenge your team is trying to address within the focus area you have identified
<b>Use Case Name</b> The name should be the goal as a short action oriented statement		
<b>Design Scope</b> Describe the system within which the use case is taking place	<b>Goal Level</b> Is this a summary or a user-centered goal?	
<b>Primary Actor</b> Who is trying to achieve a successful outcome within this use case?	<b>Stakeholders &amp; Interests</b> List all stakeholders and key interests that are impacted by this use case	
<b>Preconditions</b> What conditions need to exist for this use case to be relevant or actionable?	<b>Triggers</b> What are the events or actions that start the use case?	
<b>Minimal Guarantees</b> What will be achieved in the course of the use case no matter what?	<b>Success Guarantees</b> What are the outcomes if the use case goal is successful?	



# Standardizing and Evaluating Consumer Wearable Device Measurement

by RTI International & the University of North Carolina at Chapel Hill



## About This Use Case Suite

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The rising popularity of wearable devices (activity trackers) in the mainstream consumer world has inspired researchers to use patient-generated data to complement traditional data collection. As of November 2017, there were 424 wearable devices available from 266 vendors. Despite concerns over the validity, reliability, and usability associated with self-tracking data, researchers are widely using wearable technologies in their public health interventions and clinical trials. As evidence, the Fitabase Research Library has inventoried more than 450 studies published between 2012 and 2017. While the breadth of the application of this technology is promising, a closer look across these studies reveals dissonance in the methods of data collection, analysis, and accessibility. For example, there have been 95 studies published on the validity and/or reliability of Fitbit devices since 2012, but no two studies follow the same methods of establishing device measurement.

In response to this lack of scientific standard surrounding wearable devices, our team at RTI International and the University of North Carolina defined a protocol structure for guiding researchers to an evidence-based position on whether or not a device is valid and reliable for their studies. Supported by an ongoing repository of data and analysis that adheres to this framework, we hope this protocol will evolve as consumer wearable device technology continues to develop and grow in popularity.

Our use case suite unpacks the recommended process for creating a device-specific scientific standard. Using three phases of data collection (in both lab environments and free-living environments), researchers can analyze the data—using our suggested protocol—into a report that can be shared and studied for future research that involves that device.

This protocol will add rigor to the accuracy and credibility of research involving data collected from wearable devices, providing reassurance and transparency to patients, providers, and stakeholders across the healthcare field.

### Research Team

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**Fei Yu, PhD**  
Health Sciences Library, UNC-Chapel Hill

### Use Cases in this Suite

#### Summary Use Case 1

1

**Standardizing and evaluating consumer wearable device measurement**

#### User Goals x2

1.1

**Collecting consumer wearable data**

1.2

**Analyzing consumer wearable data**

Use Cases 1.1 and 1.2 are User Goals, which define specific goals that the primary actor is trying to achieve in order to achieve the larger goal (Summary Goal) described in Use Case 1.

# Standardizing and evaluating consumer wearable device measurement



## Focus Area & Challenge

The specific patient-generated data challenge addressed

How can we gain certainty in the quality and trustworthiness of data from consumer wearable devices for use in all clinical encounters?

## Scope

The system within which the use case is taking place

We are focused on the study of wearable devices in clinical, research, and free-living environments. Each of the three environments corresponds to a phase of the study:

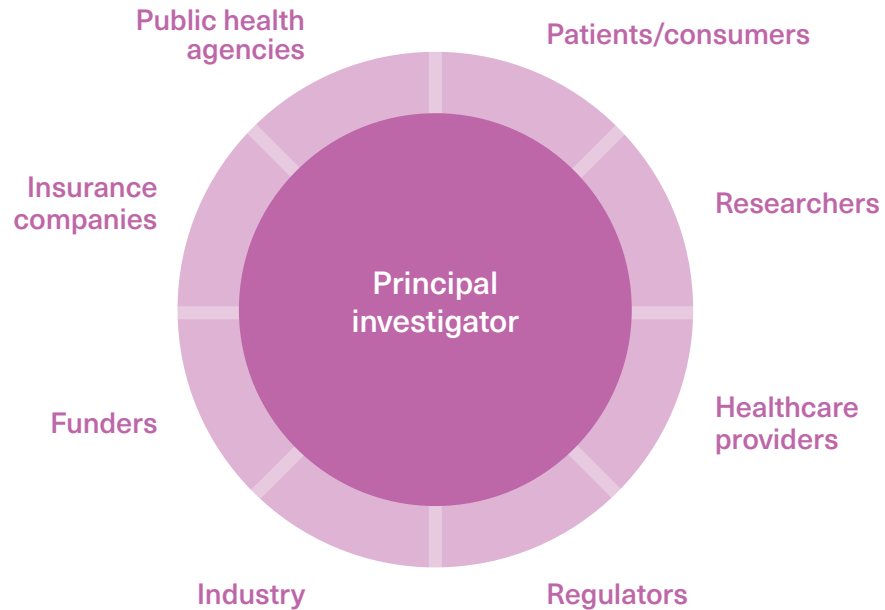
- **Phase I – Laboratory environment:** Devices are tested on a shaker table (a piece of laboratory equipment that produces vibration) to measure for inter-device reliability (similarity in measurement across devices), with no human feedback required.
- **Phase II – Research environment:** Devices are worn by research subjects, who complete structured activities in a highly controlled laboratory environment, such as walking on a treadmill at a certain pace with the device worn properly.
- **Phase III – Free-living environment:** Devices are worn by research subjects “out in the world” going about their normal life for several days, with no controls or structured activities.

**Primary Actor**

The person/people trying to achieve a successful outcome within this use case

**Principal investigator**

- lead member of research team



**Stakeholders & Interests**

The stakeholders and key interests that are impacted by this use case

**Patients/consumers**

- health and quality of life for them and their families
- generating accurate data that is applicable to their lives

**Researchers (including research team personnel)**

- accuracy and credibility of their research findings
- trustworthy data produced by measuring instruments

**Healthcare providers**

- trustworthiness of data for shared decision-making or goal tracking with patients

**Regulators**

- assurance that products are safe, effective, and reliable so that no harm will come to users through the device or how the data is used

**Industry (device manufacturers)**

- demonstrate that the data is reliable, credible, and trustworthy for clinical research

**Funders (public health organizations, research funders)**

- assurance that the data is credible and that research studies completed over time are comparable

**Insurance companies**

- accuracy of data from a large group of people to inform public health trends
- help create programs to reward healthy lifestyle

**Public health agencies**

- accuracy of data from a large population to inform public health surveillance

## Preconditions

The conditions that need to exist for this use case to be relevant or actionable

### Patients/consumers

- Patients/consumers use wearable devices in support of personal, clinical, public, and population health

### Healthcare providers

- Rapid proliferation of devices within the healthcare field
- Inadequate appreciation or understanding of the validity and reliability of wearable devices
- Use of non-medical devices for medical purposes (for example, a patient who is at risk for cardiovascular disease may be encouraged by their physicians to wear a device to track their level of physical activity and amount of exercise on a daily basis)

### Researchers

- Lack of data standards between researchers and industry accountability
- Lack of device-testing standard in terms of method and protocol

### Industry

- Lack of accountability for data standards

### Regulators

- Regulatory ambiguity for standards of measurement

## Triggers

The events or actions that start the use case

- A healthcare provider, researcher, or public health professional wants to use an activity tracker (or data from a device) for health intervention;
- The wearable device industry releases a product for which there is no validity and reliability evidence;
- The health industry and wearable device industry want to deploy a product in a new population that differs from prior validity and reliability studies;
- A stakeholder needs to know product limitations and ideal conditions (for example, if a patient with a heart condition wants to track their heart rate, they need to know how reliable a particular device is at measuring heart rate; or physicians would like to integrate patient-generated data from wearables into electronic health record systems so that they can know what occurred between patient visits); or
- Researchers need to test new devices for equivalency against existing devices.

## Minimum Guarantees

What will be achieved in the course of the use case, no matter what

- Researchers gain knowledge about the device, testing, and the current environment.

## Success Guarantees

The outcomes if the use case goal is successful

- Researchers identify the best device to use for the scenario appropriate for the population.
- Researchers generate evidence and share data for more robust validity and reliability studies.
- Other researchers and stakeholders adopt the protocol.

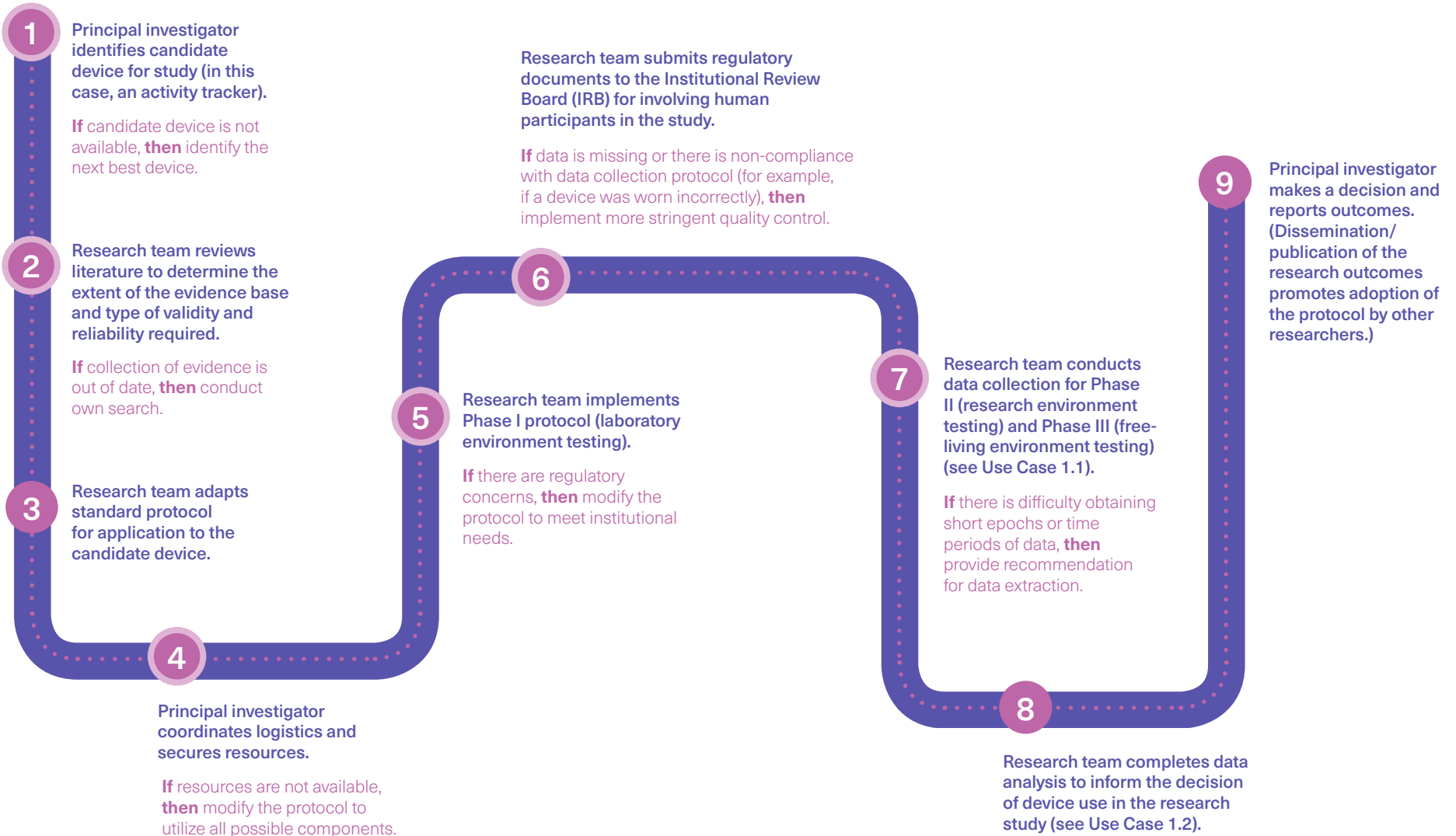


## Success Scenario

The narrative sequence of events (steps) that lead from the preconditions and trigger to the completion of the goal by the primary actor

## “If...then...”

Crucial breakdowns in the main Success Scenario steps, and the way in which the breakdown will be handled



# Collecting consumer wearable data

*This use case articulates the details of how to successfully achieve step 7 from the Success Scenario described in Use Case 1.*



Image credit: Rachel Kalmar's datapunk quantified self sensor array 2, Institute for the Future, Palo Alto, California, USA by Cory Doctorow, CC BY-SA 2.0

## Focus Area & Challenge

The specific patient-generated data challenge addressed

How can we collect data in service of gaining certainty in the quality and trustworthiness of the data from consumer wearable devices?

## Scope

The system within which the use case is taking place

Research environment in the context of a study to define a protocol for determining the validity and reliability of wearable devices



### ● Primary Actor

The person/people trying to achieve a successful outcome within this use case

#### Research personnel

- analyst, member of research team



### Stakeholders & Interests

The stakeholders and key interests that are impacted by this use case

#### Research team

- accuracy and credibility of their research findings
- trustworthy data produced by measuring instrument

#### Potential human participants

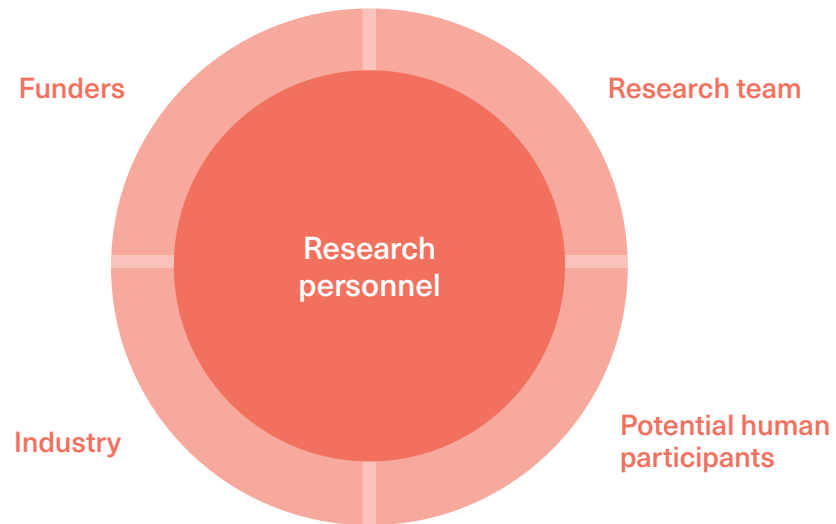
- successful participation in the study

#### Industry (device manufacturers, “workplace wellness” entities)

- demonstrate that the data is reliable, credible, and trustworthy for clinical research

#### Funders (public health organizations, research funders)

- assurance that the data is credible and that research studies completed over time are comparable



### Preconditions

The conditions that need to exist for this use case to be relevant or actionable

#### Research personnel

- Protocol must be written.
- Data collectors must be trained.
- Equipment must be functioning as desired.

### Triggers

The events or actions that start the use case

- Principal investigator defines the research question, ensuring that the protocol is ethical;
- Research team selects device;
- Research team facilitates regulatory approval from the Institutional Review Board; and
- Research team determines resource allocation (budget).

### Minimum Guarantees

What will be achieved in the course of the use case, no matter what

- Data set available for analysis

### Success Guarantees

The outcomes if the use case goal is successful

- Clean and complete data set adherent to protocol for analysis.

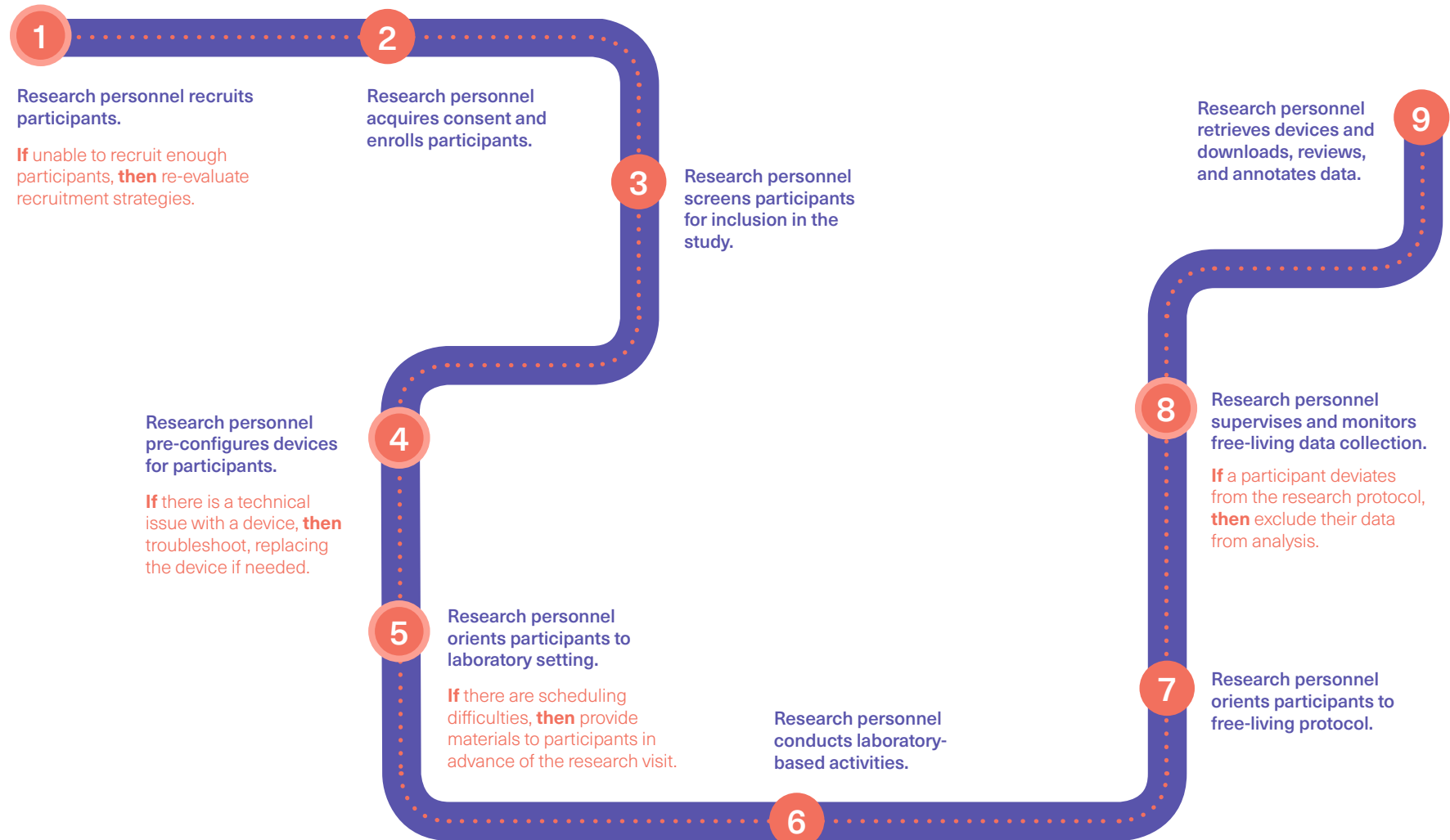


## Success Scenario

The narrative sequence of events (steps) that lead from the preconditions and trigger to the completion of the goal by the primary actor

## “If...then...”

Crucial breakdowns in the main Success Scenario steps, and the way in which the breakdown will be handled



# Analyzing consumer wearable data

*This use case articulates the details of how to successfully achieve step 8 from the Success Scenario described in Use Case 1.*



## Focus Area & Challenge

The specific patient-generated data challenge addressed

How can we analyze data in service of gaining certainty in the quality and trustworthiness of data from consumer wearable devices?

## Scope

The system within which the use case is taking place

Research environment in the context of a study to define a protocol for determining the validity and reliability of wearable devices

### Primary Actor

The person/people trying to achieve a successful outcome within this use case

#### Research personnel

- analyst, member of research team



### Stakeholders & Interests

The stakeholders and key interests that are impacted by this use case

#### Research team

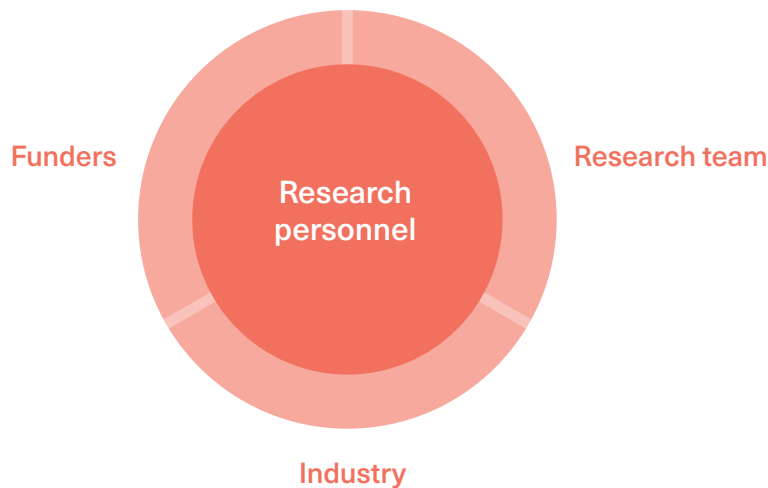
- accuracy and credibility of their research findings
- trustworthy data produced by measuring instrument

#### Industry (device manufacturers, “workplace wellness” entities)

- demonstrate that the data is reliable, credible, and trustworthy for clinical research

#### Funders (public health organizations, research funders)

- assurance that the data is credible and that research studies completed over time are comparable



### Preconditions

The conditions that need to exist for this use case to be relevant or actionable

#### Research personnel

- Protocol must be written.
- Data analysts must be trained.
- Data analysis plan must be developed and tools ready.

### Triggers

The events or actions that start the use case

- Research team completes data collection in adherence to research protocol

### Minimum Guarantees

What will be achieved in the course of the use case, no matter what

- Results available from data analysis

### Success Guarantees

The outcomes if the use case goal is successful

- Insightful results for stakeholder decision-making

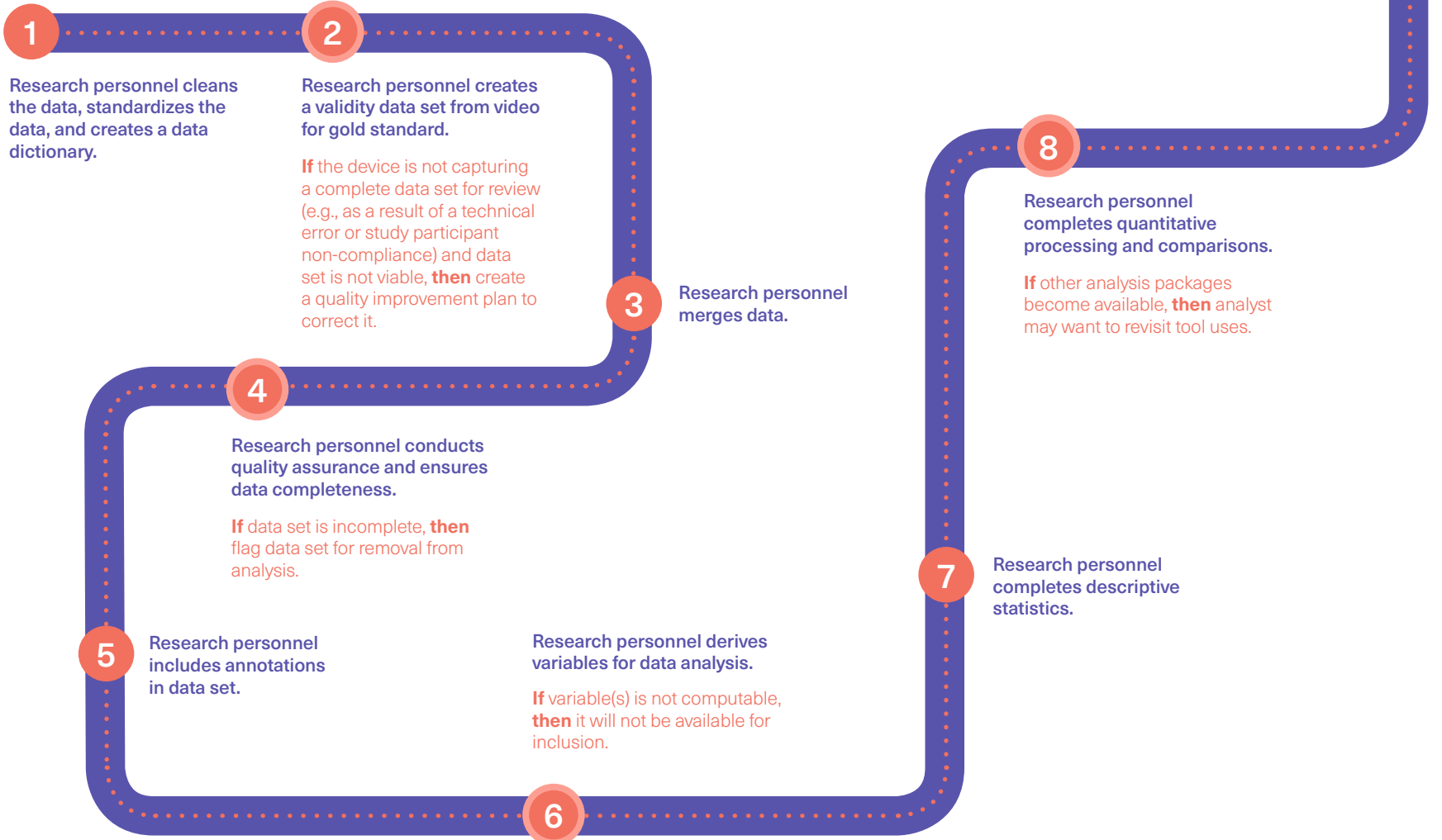
## Success Scenario

The narrative sequence of events (steps) that lead from the preconditions and trigger to the completion of the goal by the primary actor

## “If...then...”

Crucial breakdowns in the main Success Scenario steps, and the way in which the breakdown will be handled

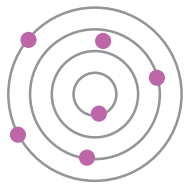
Principal investigator interprets the results.



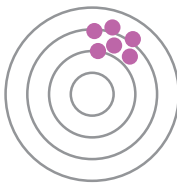
## Related Information

Other information or details important to this suite of use cases

- “Consumer wearable device” is a generic term for what is often referred to as an activity tracker. These devices use sensors to gather data about human performance, such as physical activity. Newer devices also track biometric data, such as oxygen in the blood, and other health indicators.
- As new devices come to market that can measure an increasing number of indicators, a standard approach for determining the validity and reliability of data is needed. In this use case, we measured physical activity; this same process can be applied to measuring sleep, heart rate, etc.—or to establish a standard approach for whatever you want to measure.
- Throughout this research process, we created several artifacts that could be made available to other researchers: systematic review, protocol, and implementation collateral (recruitment fliers, IRB protocol template).
- We want measurements to be both valid and reliable. Validity is the extent to which a device measures against a gold standard (something that is known). Reliability is the consistency by which the device performs over time and across different measuring instruments.



Not reliable  
or valid



Reliable but  
not valid



Both reliable  
and valid

## Emerging Questions

Further questions that surfaced from this work

- > How accurate is “accurate enough”? Does your study require a valid and reliable instrument? The need for a particular degree of accuracy is defined by the research questions. Sometimes crude data will suffice; sometimes data needs to be very precise and reliable.

For example, if a patient is at risk of cardiovascular disease, and an activity tracker is used to encourage the patient to get regular exercise, the patient-generated data does not need to be precise in order to encourage positive health benefits.

However, if a patient has a severe cardiovascular condition and is taking a beta blocker that suppresses heart rate, and their physician has advised the patient to ensure their heart rate does not exceed 100 beats per minute during exercise, then more precise data could be much more important. The device would need to be calibrated and very reliable in order to ensure that the patient-generated data is trustworthy and up to the gold standard.

### About Use Cases

Use cases—as a methodology—were designed to discover the “requirements” needed when designing computer software. These requirements are what the software system needs to be able to do for the “primary actor” who is seeking to achieve a goal. The requirements would tell the software designers what they need to build if the primary actor is to be successful in reaching their goal and alert them to the pitfalls that could be encountered along their journey. Important in this process is that “a use case only documents a process, it doesn’t reengineer or redesign it.” **Use cases are narratives that articulate the journey of someone (a “primary actor”) as they interact with a system in order to achieve a goal.** An example would be someone logging into a website to find a specific piece of clothing, buy that piece of clothing, and have it shipped to their home.

For this initiative, we have taken the use case and adapted it to explore the question: “How might we enhance the collaborative use of patient-generated data among patients and providers to improve individual health outcomes?” While the use case methodology was originally designed to create solutions for mechanical systems, this adaptation offers a contextual shift in order to articulate solutions for a human social system. The work shared here is based on the work of Alistair Cockburn and his book *Writing Effective Use Cases*.

### Articulating the Situation

The use case methodology is an effective way of articulating a current situation. When a group of people work together to identify key aspects of a situation, they create a shared understanding and build the design requirements: what must be considered as they develop a response to the current situation. The five areas a group needs to articulate to develop a use case are:

#### Scope

The scope identifies the boundaries of the current situation you are trying to address. There is no way to address the entirety of any situation, so we need to clearly delineate the area of focus for our work. This is also referred to as the **system under discussion (SuD)**.

#### Actors

This is the list of anyone or anything within your scope that has behavior. By “behavior,” we mean anyone or anything that acts within the SuD. In this way, an actor can be a person, an organization, or a community.

#### Primary actor

The actor who initiates an interaction with the SuD to achieve a goal (and whose journey we follow through the use case).

#### Goal (and goal level)

This is naming what the primary actor is trying to achieve by interacting with the SuD. The two areas of focus with regard to the goal level are whether it is a **summary goal** (a goal whose achievement encompasses the entire SuD) or a **user goal** (a goal whose achievement completes a specific part of a summary goal within the SuD).

#### Stakeholder

Someone or something with a vested interest in either the primary actor or the system under discussion (SuD). A stakeholder is like an actor; the difference is that they may or may not behave within the SuD but are impacted or have interest in what occurs as a result of the behavior of the primary actor as they pursue their goal within the SuD. Communities are stakeholders when they are not acting within the SuD but rather have an interest or may be impacted by what happens as the primary actor seeks to achieve their goal.

## Working Across a Continuum: Creating greater levels of precision

There is no one way to apply the use case methodology in a healthcare setting. Rather, it is best to begin and then start iterating on what you create. Regardless of where you begin, there is real benefit in working on greater levels of precision on the use case as you move forward, both to frame your ongoing experiments and as a way of capturing the insights and options created by your work.

The first layer of precision is to articulate your best understanding of the five areas defined on the previous page. We are not trying to achieve a “right answer” with this work, but rather we are trying to articulate what we know now. Throughout the process, we can revise our previous work. With that in mind:

- > What is the scope of your project?
- > What are the boundaries of the situation you are looking to explore?

Now create a three-column list. In the first column, list all actors who have “behavior” within the scope identified. In the next column, name the goals that each of these actors have within the scope (what are they seeking to achieve?). In the last column, identify the goal level of these goals (is it a summary goal or a user goal?). Once you complete the list, circle the actors with summary goals. These are places to begin creating use cases.

Actor	Goal	Goal Level

There are three levels of detail you can work at while creating a use case: **narrative use case**, **casual use case**, and **fully dressed use case**. As a way of starting, we suggest you develop a narrative brief and then a casual use case for one of the primary actors. From that, you can begin to work and develop a fully dressed use case as you continue. At this point, these use cases end in success (and are therefore speculative). Later, when using them as a way for framing experiments, you will move the use case to being an outline of what needs to happen.

### Narrative Use Case

This is a two- to six-sentence description of the actions of the primary actor as they pursue their goal within the SuD. The purpose is to get an understanding of the arc of the project and begin to get a sense of the complexity.

### Casual Use Case

This builds on the narrative use case and begins to pull out detail in some areas. For this, you can use the following structure, filling in each area:

**Use case name:** usually the goal that is being pursued

**Primary actor:** identifying who they are or their role

**Scope:** brief outline of the situation and the boundary

**Goal level:** either summary goal or user goal

**Main success scenario:** the narrative of actions that the primary actor takes (and the reactions from the SuD) in achieving their goal

### Fully Dressed Use Case

This is the most detailed version of the use case and is created in stages as you come to understand, through action, the nuances of the SuD. The structure for a fully dressed use case is:

**Use case name:** usually the goal that is being pursued

**Context of use:** a longer statement of the goal

**Scope:** outline of the situation and the boundary

**Goal level:** either summary goal or user goal

**Primary actor:** identifying who they are or their role

**Stakeholders and interests:** list of stakeholders and their key interests in the use case

**Preconditions:** what we expect is already the state of the world

**Trigger:** what starts the use case, which may be a time event

**Minimum guarantees:** what we can guarantee as outcomes, no matter what happens

**Success guarantees:** what happens if everything goes well

**Main success scenario:** the steps of the scenario, from trigger to the successful achievement of the goal by the primary actor (minimum of three steps, maximum of nine steps)

**"If..., then...":** the steps to take if there is a failure in one of the main success scenario steps

**Related information:** whatever additional information is important for your project

For an outline of the fully dressed use case, refer to the template (PDF) used by the research teams:

[www.reospartners.com/pgd](http://www.reospartners.com/pgd)





Reos Partners is an international social enterprise that helps people move forward together on their most important and intractable issues.

We design, facilitate, and guide processes that enable teams of stakeholders—even those who don't understand or agree with or trust one another—to make progress on their toughest challenges. Our approach is systemic, collaborative, and creative.

We partner with governments, corporations, and civil society organizations on challenges such as education, health, food, energy, environment, development, justice, security, and peace. Our work is pragmatic, professional, and tailored to the needs of the specific situation.

Our name comes from the Greek "rheos," which means "flow."

[www.reospartners.com](http://www.reospartners.com)



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