Findings from the IMC Rapid Pilot Study

Assessing the User Experience of a Wireless Pill Bottle and Wireless Blister Pack with a Companion App

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Study Objectives

The primary objective of this study was to assess the user experience of the eCAP™ pill bottle and the Med-ic® blister pack with an app called CertiScan®.

The secondary objective of this study was to assess the technical feasibility of adherence monitoring devices for capturing and transmitting the data remotely in a consistent and complete format with an app that was used by the participant.

Study Site

All on site study activities were conducted at HITLAB located: 175 Varick Street, New York, NY 10014.

Technology

Information Mediary Corporation (IMC) provided 2 medication adherence devices: the Med-ic® smart blister package and the eCAP™, smart pill bottle. They also provided access to the CertiScan® mobile application, which is a companion app for these devices. The CertiScan® app utilizes the HIPAA compliant CertiScan® Cloud Portal.

Study Methods

This was a single-arm, single phase, mixed methods study to assess the usability, acceptability, and feasibility of the eCAP™ pill bottle and the Med-ic® blister pack with a companion app called CertiScan® among multiple users over a period of one week. This study engaged 10 participants who are healthy adults ages 21+ who are currently on a long-term medication or supplement. This study also engaged 1 individual who has a background in clinical research for the purposes of obtaining experiential user data about the clinical investigator portal from the CertiScan® Cloud Portal accessed through the CertiScan® app.

All of the survey data will be entered on HIPAA-compliant electronic report forms using the Qualtrics platform. All qualitative data will be audio recorded and notes will be taken for analysis. Data will be reported in aggregate with individual data reported using a deidentified marker.

Executive Summary of Findings and Recommendations

Participant Characteristics

Summary

- **All participants reported having good/expert level of familiarity with technology** and 60% were comfortable/somewhat comfortable using technology to manage their medications
- However, **only 10% of participants actually used technology to manage their medications** and only 40% of participants have heard of adherence technologies.
- **90% of participants reported forgetting to take their medications.** 80% of participants also reported forgetting to get their prescriptions.
- Participant's scored an average of 24 points on the self-report adherence scale at baseline, while the lowest was 16 and 33 the highest (a lower score indicates better adherence).

Key Opportunities

- Generally, participants have developed mechanisms to help them remember to take their medications but **still find that they have barriers to taking medication adherently**. This highlights the need for support for individuals taking long-term medications.
- **Over half of the participants did not know about adherence technologies, highlighting the need for consumer education on how they can use technology to increase their adherence.**

Usability and Acceptability

Key Opportunities

- **Most of the participants (80%) found the CertiScan App installation and onboarding process easy and straight forward.** Some participants used the QR code while most directly searched in the app store.
- Overall, participants found that the variety of features in the app were supportive for adherence, with **reminders identified as the most helpful feature.**
- **All participants would consider purchasing the eCAP pill bottle** if it were available in a drug store (for personal use or someone they know).

Key Challenges

- **Some participants (40%) expressed confusion with the app scanning function.** For some participants they were directed to the IMC product website. For others, they could not determine if the scan was successful without going back into the app.
- **Some participants missed the reminder notifications** because they did not hear them, or it blended in with their other notifications.
- Multiple versions of the CertiScan app show up in the app store and can be confusing for new users.

➢ **One user experienced a glitch in which the app was unavailable to open,** impeding them from scanning and using the app.

Key Recommendations

➢ **Reminders:** Include greater flexibility of timeframe for reminders (rather than just 3 choices), allow user to choose varying notification sounds/volume, and allow for text message notification options.
➢ **Scanning feature:** Incorporate clear feedback when scanning (e.g., a message indicating "successfully scanned").

Feasibility

Key Opportunities

➢ **The majority of participants didn't think the CertiScan app impacted their normal routine.** Most felt that it wasn't disruptive throughout their week.
➢ **More than half of participants indicated that they would continue to use the smart pill bottle and the CertiScan app for another six months.** This emphasizes that participants would be willing to use this technology in their everyday lives.

Key Challenges

➢ **The majority of participants did <u>not</u> think they would continue using the blister pack for another month.** Many viewed the blister pack as not useful for long-term treatment regimens.
➢ **Many participants felt the blister pack was difficult to open or that the instructions were not intuitive.** For some participants, the pill fell on the floor during the baseline visit.
➢ While some participants had high adherence throughout the study period, **others had poor adherence indicating missed or incomplete days**. While non-adherence in this study was *not* due to device malfunctions or glitches, **the types of device malfunctions that did occur are general barriers to adherence.**

Key Recommendations

➢ While participants expressed interest in purchasing the pill bottle, **some gave feedback on potential pricing and reusability of the product.**
  o Participants desired a pill bottle that would be reusable, consider emphasizing this feature.
  o Common price ranges given for this product are $15-20 (40% of participants suggested a price in this range), and $5-10 (20% suggested a price in this range). **It was suggested to be included in patient insurance plans,** as some participants emphasized that they would not use it unless there were no out of pocket costs.
➢ **Consider providing adherence dependent feedback to participants.** For example, non-adherent participants would get a push notification or pop up with tips and tricks for adherence.

➢ **Allow participants to submit feedback on their own personal barriers to adherence** (e.g. financial, forgot, medication ran out). This data can be utilized to gain a deeper understanding of common barriers to adherence.

Investigator Role

Summary

➢ A clinical investigator with a background in digital health was interviewed regarding the med-ic, eCAP, and CertiScan app.
➢ The investigator thought the CertiScan app could be useful in clinical trials, but they felt it should provide more direction within the app about features and options.
➢ The clinical investigator mentioned existing barriers to adherence in clinical trials (e.g., unclear instructions, time constraints) and some currently used methods for reminding participants (e.g., written calendars, phone alarms, apps).
➢ They suggested the app add more guidance on adherence data practices for investigators. In addition, the investigator felt med-ic seemed like a better measure of adherence in clinical trials than the smart bottle.

Key Opportunities

➢ The CertiScan app could be useful in clinical trials but should provide more directions within the app about features and options. The app could add more value to clinical trials by including guidance on what to do with the data collected to improve adherence.
➢ The blister pack may be useful for clinical trials because it's a more accurate measure of adherence with less room for measurement error.

Key Challenges

➢ The smart bottle was viewed as a limited measure of adherence due to the potential for measurement error, as it is just a measure of the number of times the bottle was opened and closed.
➢ The lack of instructions and/or a guideline for adherence data use may impact usability of the app.

Key Recommendations

➢ A walkthrough or tutorial on the initial page of the app upon first downloading should be implemented to ensure user understanding.
➢ A basic guideline for investigators would ensure that the adherence data is scored/used properly for the purposes of the specific clinical trial.

Detailed Results

Study Population Characteristics

HITLAB collected data from a total of 10 healthy adults, over the age of 21, who take long term medications/supplements. HITLAB also collected data from an individual researcher (n=1), who represented a clinical researcher.

Demographic Table of Study Participants

Characteristics	Categories	N (n%)
Age	21-45	8 (80%)
	≥ 46	2 (20%)
Sex	Male	4 (40%)
	Female	6 (60%)
Gender	Men	4 (40%)
	Women	6 (60%)
Highest Education	Postgraduate/Professional	8 (80%)
	College (2 year or 4 year)	2 (20%)
Race*	White or Caucasian	5 (50%)
	Hispanic/Latinx	3 (30%)
	Asian	3 (30%)
Household Income	Decline to answer	1 (10%)
	≤ $20,000	2 (20%)
	$35,000 to $49,999	0 (0%)
	$50,000 to $74,999	4 (40%)
	$75,000 to $99,999	1 (10%)
	≥ $100,000	2 (20%)
Health rating	Excellent	1 (10%)
	Very good	5 (50%)
	Good	4 (40%)
	Fair	0 (0%)
	Poor	0 (0%)
Family helps with medication	Yes	0 (0%)
	No	10 (100%)
Interest in new technologies	Very uninterested	1 (10%)
	Somewhat uninterested	0 (0%)
	Somewhat interested	4 (40%)
	Very interested	3 (30%)
	Neutral	2 (20%)
Familiarity with technology	Expert	3 (30%)
	Good/Improving	7 (70%)
	Beginner	0 (0%)
	Little to no familiarity	0 (0%)
Heard of adherence technology	Yes	4 (40%)
	No	6 (60%)
Comfortable using technology to manage medications	Very uncomfortable	0 (0%)
	Somewhat uncomfortable	0 (0%)
	Somewhat comfortable	4 (40%)
	Very comfortable	2 (20%)
	Neutral	4 (40%)

Use devices to manage medications	Yes	1 (10%)
	No	9 (90%)
Excitement to participate in study	Very unexcited	1 (10%)
	Somewhat unexcited	0 (0%)
	Somewhat excited	6 (60%)
	Very excited	3 (30%)
	Neutral	0 (0%)
Phone Type	iPhone	9 (90%)
	Android	1 (10%)

*Not mutually exclusive, some participants identified as more than one race.

Participant's Perceptions on Adherence

Key Takeaway: Generally, participants have developed mechanisms to help them remember to take their medications but still find that they have barriers to taking medication adherently. Some participants identified technology as a supportive measure to keep them adherent.
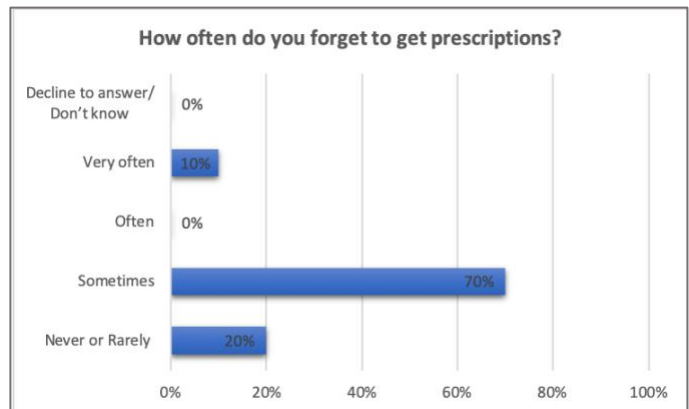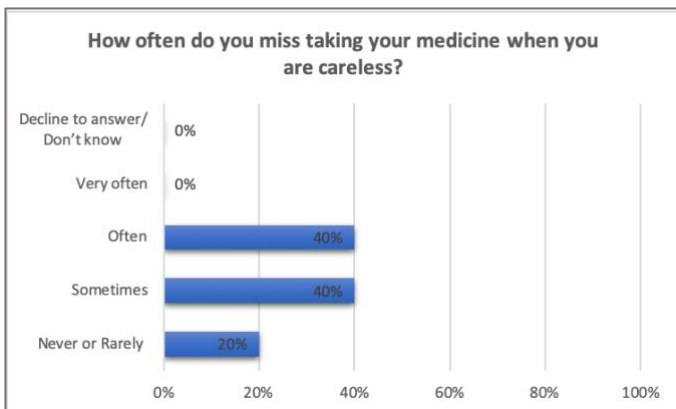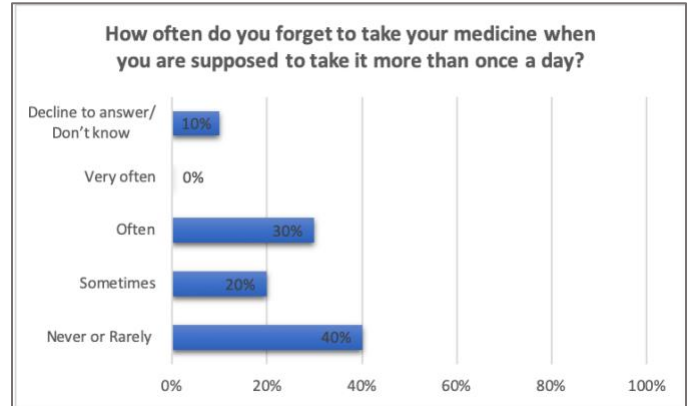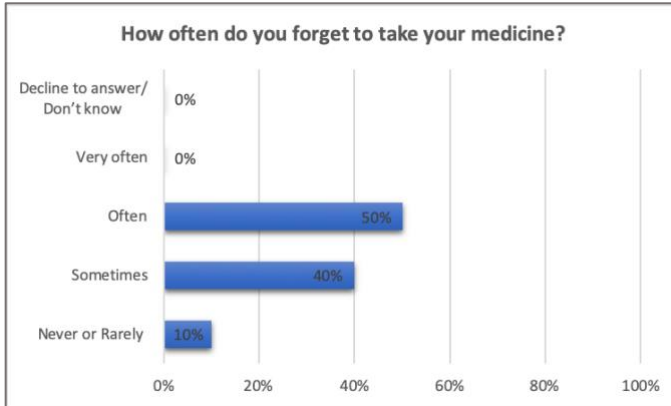
➢ **Self-reported mechanisms that help participants stay adherent to their medication:**
- 3/10 reported leaving them somewhere they can see.
- 2/10 reported that they remember by integrating with daily routine: e.g., after showering.
- 1/10 participant used the app "Pillbox."
- 1/10 participant used the "physiological reminder" of symptoms they experience when they initially forget a dose to take it.

➢ **Participants recognized several barriers to their medication adherence:**
- 5/10 cited their sporadic or inconsistent schedules as a barrier to taking medication.
- 2/10 mentioned the barrier of not being at home or not having medication on them when expected to take dose.
- 1/10 mentioned one of their medications having irregular dosing time as a barrier to remembering to take it

➢ **Participants identified ways in which they could be supported to be more adherent:**
- 3/10 mentioned that an app could/would be helpful.
- 3/10 said a reminder is the type of support needed (not necessarily through an app)
  - 1 participant clarified that the reminder should **not** be disruptive to their schedule
- 1/10 mentioned having a spare medication as supportive, and mentioned their sibling having a small pill bottle on a keychain in case of missed dose.
- 1/10 mentioned Amazon Echo as supportive in remembering medication due to the ease of voice access
- 1/10 mentioned the importance of having a provider explain the medication schedule

Self-reported Medication Adherence at Baseline

(See *Appendix I* for all medication adherence questionnaire data)

How often do you forget to take your medicine?

Decline to answer/ Don't know	0%
Very often	0%
Often	50%
Sometimes	40%
Never or Rarely	10%

How often do you forget to take your medicine when you are supposed to take it more than once a day?

Decline to answer/ Don't know	10%
Very often	0%
Often	30%
Sometimes	20%
Never or Rarely	40%

How often do you miss taking your medicine when you are careless?

Decline to answer/ Don't know	0%
Very often	0%
Often	40%
Sometimes	40%
Never or Rarely	20%

How often do you forget to get prescriptions?

Decline to answer/ Don't know	0%
Very often	10%
Often	0%
Sometimes	70%
Never or Rarely	20%

90% of participants reported forgetting to take their medications and 50% of participants reported forgetting to take their medications that have multiple doses. 80% of participants also reported forgetting to get their prescriptions and 80% reported that they missed their medication when they were careless. The average score on the adherence scale was 24 while the lowest was 16 and 33 the highest (a lower score indicates better adherence). This highlights the need for supports for individuals taking long-term medications.

Participants' Initial User Experience on eCAP™, med-ic®, and CertiScan®

> Post-training on how to use the eCAP™, med-ic®, and CertiScan® app, participants were asked about their first thoughts on the devices.

Key Takeaway: Participants found the CertiScan app installation process easy and straightforward. Most participants could see themselves buying and using the eCAP but not the medi-ic. The main reasons included the reusability and easy usability of the eCAP.

➢ **Some participants felt that the user manual instructions and app onboarding process was straightforward, while a few felt that it was too text heavy and overwhelming. Most (8/10) participants thought the app installation process was easy.**

- 2/10 felt the amount of written instructions were overwhelming or confusing, however 3/10 described the instructions as straightforward or easy to follow.
- 8/10 found the app installation and onboarding process to be easy.
- 2/10 pointed out that the CertiScan Lite version of the app shows up first in the app store which was confusing to participants.
- Android note: no scan button, instead it sends an alert to ensure the user holds the phone next to the device for long enough for data to be collected
- 2/10 said the researcher explanation, in addition, to the written instructions was necessary and helpful.

"For me, it was self-explanatory other than having issues opening the blister pack. But I think it would take longer without having someone to explain it to you. Especially if you don't know how to scan the QR code or tapping your phone against these."

"The instructions are counter intuitive and unclear on which side is what for pulling the tab off and getting the pill out."

➢ **Participants expected the devices to fit into their schedules using a variety of techniques to primarily assist with remembering.**

- ➢ 5/10 expected problems remembering to use the devices as instructed.
- No participants expected needing support to complete the study activities.
- 4/10 indicated that the app reminders would help them incorporate the study activities into their daily schedule; 1/4 said they would set their own reminders in addition to app reminders.
- 3/10 mentioned bringing the devices with them everywhere; e.g. in backpack or purse.
- 2/10 mentioned leaving them out for the visual cue; e.g. near toothbrush.

- 1/10 mentioned the interactivity of scanning as helpful to remember.
- 1/10 thought participating would remind them to take their real medication.

Quote: *"When I do this, I'll remember to take my actual medications."*

➤ **Participants first impressions of the eCAP and med-ic included themes such as ease of use, reusability concerns, and size of the products.**

- Half (5/10) had trouble opening or using med-ic, some of whom (2/5) had the pill fall on the floor while opening.
    - 2/10 said the med-ic instructions were not intuitive.
- A few (3/10) participants thought the eCAP was easy to use.
    - 3/10 noted eCAP was larger than the typical pill bottle.
- One participant mentioned it would be easier without the scanning feature, describing the bottle as "not fully automatic" due to the scanning feature.
- One participant liked the reusability and "green-ness" of the bottle.
- A few (2/10) explained that the med-ic would be better for short term treatment regimens than for long term treatment.
- A few (2/10) expressed concern about the wastefulness of the med-ic product/packaging and would want to be able to recycle the blister pack.

"It [med-ic] is really big, so it wouldn't fit my normal purses that I wear on the weekends. I would be more inclined to use the pill bottle instead, and it was harder to open."

"Every time I get a new prescription, I can tell my doctor to put it in here with my name on it."

➤ **On first impression, participants seemed disinterested in purchasing the med-ic device, citing product size and affordability as reasons. But may be willing to purchase eCAP.**

- 4/10 would not buy or use the med-ic upon first impression
    - 1/10 said they would only buy or use the product if paid for by insurance.
    - 3/10 indicated that they would rather buy/use the pill bottle.
    - 7/10 participants thought the blister pack was large which influenced their decision regarding if they would buy or use it.
- 2/10 said a provider recommendation may entice them to buy it

- 2/10 said they would not buy it; reasons given include saving money and viewing the product as not necessary; 1/10 said they maybe would buy it.

➢ **Participants first impressions of the CertiScan app were generally positive, however clearer instructions were desired.**
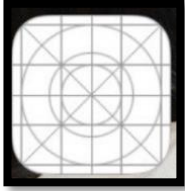
- 1/10 want the ability to sync with other health apps, and for their doctors to be able to access their data.
- 3/10 thought the app was well written, intuitive, and clear.
- 1/10 participant suggested to add an explanation of the histogram including what it is and what it's doing.
- 1/10 thought that the written instructions are intimidating but the app made it easier.

Participants' Experience with eCAP™, med-ic®, and CertiScan® After 7 days

After 7 days of use the eCAP™, med-ic®, and CertiScan® app, participants were asked about their experience with the devices.

Key Takeaway: Participants experienced a few technical difficulties, particularly with the scanning function, however most felt the study was not disruptive to their routine, and felt the reminders were a helpful feature. Key areas of improvement identified by participants include integration with other technologies (like a smart watch or Alexa) and improved reminders that were more prominent and flexible.

➢ **Some notable technical difficulties arose throughout the 7-day study, depicted in the chart below.**

Issue Category	Details from Participant Self-Report	Phone Type
NFC Scanning	Reported that scanning from outside didn't always work, felt it was more efficient to open the app first, and then scan.	iPhone 11
NFC Scanning	Scanning was not working 100% of the time. Participant sometimes had to scan multiple times, and they reported that the scan was not strong enough.	Android Samsung Galaxy S7
NFC Scanning	Reported that the scanning wasn't picking up properly for the blister pack, and sometimes for the smart cap as well (from within the app).	iPhone X
NFC Scanning	Scanning from outside the app opened the website, not the app.	iPhone X
NFC Scanning	Scanning from outside the app didn't work.	iPhone X
App Icon	The app icon appeared as a white square with grey lines through it (pictured below), and the app was unusable. Participant reported that this had happened about 1 or 2 times. *Figure 1. CertiScan glitch*	iPhone 11

➢ **Feasibility: the majority of participants (6/10) felt the app didn't affect their normal routine, and/or wasn't disruptive throughout the week.**

- 1/10 said the app was "a little disruptive" due to leaving the device at home instead of bringing it with them.
- 1/10 felt this technology would make taking medications harder, because they would have to do all the procedures (e.g., scanning), instead of just taking the meds when they usually take them.
- 1/10 the android user in the study said peeling the blister pack open was difficult and took time, and that the scanning sometimes took multiple tries to work.

➢ **Usability: Almost all (8/10) participants reported using the reminders feature, and (6/10) thought they were the most helpful feature.**

- Of the 2 participants who did not use the reminders due to perceived lack of usefulness, 1 said the reminders would likely be more helpful for time-sensitive medicines.
- One (1/8) said the reminders only worked in the morning (not the evening), and one (1/8) said they "didn't pay attention to the reminders"
- A few (2/10) participants thought the history was the most helpful feature due to the ease of viewing what doses were taken and missed. 1 participant mentioned the calendar and histograms specifically as most useful.

➢ **Choice of reminder time varied among participants, who reported different reasons for using them.**

- 5/10 participants specified which reminder time they used; 1/5 used the early reminder, 2/5 used the middle reminder, and 2/5 used the late reminder.
  - Both (2/2) participants who used the middle reminder liked it because it gave them time to get the medication.
- One participant wanted more than 3 choices for reminders, as they had to adjust reminders based on their varied schedule
- One participant did not read the instructions and didn't realize how to add the reminders to use in the app. They "accidentally" found the reminders screen and reported that setting them up was not intuitive.

➢ **Participants' thoughts on the scanning function varied, as some felt it was easy/helpful, but others found it to be difficult or didn't work correctly.**

- 2/10 reported scanning was helpful to know when they had violated the schedule and to see how much time they had to take the medication.
- 2/10 reported scanning was easy.
  - 1 of whom said it would *not* be easy without the in-person researcher training
- 2/10 thought that scanning worked well, and 2/10 felt that scanning didn't always work, and said they often had to scan multiple times.

- Key barriers to scanning reported include leaving devices at home/forgetting, and not remembering to bring the phone to the devices when taking the medication.

➢ **Thoughts on the data visualization (7-Day Score, Dose Rings, Calendar, and Histogram) within the app revealed that many participants did not use all of the features available, and that opinions on whether certain features were intuitive varied.**

- Nearly half (4/10) reported not using the histogram, and 1/4 did not notice the histogram during the study period.
  - 1/4 liked the histogram, finding it "interesting and cool," despite not using it.
- A few (3/10) participants reported that they liked the calendar, and 1/3 felt the calendar was more helpful than the histogram because the user can see the dates.
  - 1/10 participant didn't like the calendar, and 1/10 did not use the calendar.
- A few (2/10) reported that both calendar and histogram were confusing/not intuitive.
  - A few (2/10) felt the dose rings were intuitive and easy to understand, but 1/10 said it was not intuitive or helpful.
- 2/10 felt the score and dose rings were a good indicator, as it let them know they were non-adherent, or motivated them to increase adherence:

Quote: "It made me want to do better."

- 2/10 wanted better visualization of the adherence history, one participant cited that yellow and red markings were not indicative of the taken/missed scenario.

Quote: "I didn't know what the numbers meant."

➢ **Participants mentioned improvements they would make to the app related to scanning, reminders/schedule, and other additional features desired.**

- **Scanning:**
  - Nearly half (4/10) participants found scanning from outside the app to be confusing (see chart above for specific details organized by phone type).
  - 2/10 felt the scanning process (and instructions) should be easier and clearer.
  - 2/10 indicated that they would rather not have to scan the bottle at all, preferring a fully automatic device.
- **Reminders & Schedule:**
  - 2/10 wanted different types of reminders. For instance, one said the notification should be louder or more prominent, and that they would prefer a phone call, and one said they would prefer a text message to a push notification.

- o 1/10 wanted greater flexibility of the reminders (they felt 3 options was not enough), wanted the choice of their own reminder times, and preferred a different reminder sound.
- o 1/10 preferred to see the entire dosing schedule ("dose details") rather than just each day on the app.
- **Other:**
  - o 2/10 were interested in integration with other devices (e.g., an apple watch).

➢ **Acceptability: many participants agreed that they would recommend the app to someone or use it themselves:**

- Half (5/10) of participants reported they would use the app for themselves.
- Many (6/10) participants said they would recommend the app to others; specifically mentioned were people with complex medication regimens, older adults (who may either be forgetful or have complex medication regimens), or someone on short-term medication such as antibiotics (emphasis on Blister Pack for short-term regimens).

➢ **Participants' views on smart adherence tracking technology may have improved over the course of the study, and participants were largely aware of the effects of "fake" medication (tic-tacs) impacted their behavior within the study.**

- Nearly half (4/10) of participants reported that after completing the study they are more open to it/more likely to use a product such as this.
- A few 2/10 participants noted that their adherence may differ when the devices are used with real medication. One said knowing it was not their real medication influenced adherence.

Quote: "There were times, where I just wanted to take all the tic-tacs all at once. But I knew I had to take it as instructed."

➢ **Participants overwhelmingly agreed that they would consider purchasing the eCAP, but no participants expressed interest in med-ic.**

- 10/10 participants would consider purchasing the Pill Bottle.
  - o 4/10 participants suggested a price range between $15-$20.
  - o 2/10 participants suggested a price range between $5-$10.
  - o 1 participant said they would pay between $8-16.
  - o 1 of the 10 specified that they would only purchase the pill bottle if it was reusable, and 1 of them specified that they would only purchase the pill bottle if it was portable (could fit in a small bag, as is the eCAP was too big)

- o   2/10 said they would not pay anything out of pocket and that it would need to be fully covered by insurance; one participant emphasized that their medication already costs money so they wouldn't want to pay an additional cost for this.
- All (10/10) participants would not consider purchasing the med-ic.
  - o   Some reasons cited include the product not being reusable, and perceived as unnecessary
    - ▪   Despite not wanting to purchase med-ic, some participants gave price suggestions within the range of $3-10 per blister pack.

Quote: "I did like the feel of the bottle, and I would consider buying it. I'm not a fan of the blister pack, everyone was asking what it was."

7-day Post-Questionnaire Usability Highlights

(See *Appendix III* for all Participant Endline Survey data)

|	
I would continue to use this pill bottle for another month. 3 1 6 ■ Strongly Agree/Agree ■ Strongly Disagree/Disagree ■ Neutral	**I had problems with the intelligent blister package.** 1 4 5 ■ Strongly Agree/Agree ■ Strongly Disagree/Disagree ■ Neutral
I think that using this companion app every morning and every evening would be inconvenient. 2 5 3 ■ Strongly Agree/Agree ■ Strongly Disagree/Disagree ■ Neutral	**I would continue to use this companion app for another month.** 2 2 6 ■ Strongly Agree/Agree ■ Strongly Disagree/Disagree ■ Neutral

Reporting of Quantitative Adherence Data from CertiScan® App

Quantitative adherence data from the CertiScan® app was collected and analyzed to give insights about participant adherence rates.

Coding details: Participants were given one point per each adherent day and zero points per each non-adherent day out of the 7 days. Adherent days were defined as 4 or more doses, and non-adherent days were defined as 3 or fewer doses. Everyone was categorized as adherent for day 1 to account for varying baseline appointment times.

Key Takeaway: While some participants had good adherence scores, others had poor adherence scores indicating missed or incomplete days. While non-adherence in this study was *not* due to device malfunctions or glitches, the types of device malfunctions that did occur are general barriers to adherence.

- A few (3/10) participants had a perfect adherence rate of 100% (7/7 adherent days), and 4/10 had an adherence rate of ≥ 86%.
  - Note that this includes days where participants exceeded the required dosing regimen.
- Nearly half (4/10) of participants had a low adherence rate of 43% (3/7 adherent days).
- A trend in the data indicated that there was a drop off in total adherence toward the middle of the study period (days 3-5). The highest adherence rates among participants occurred at the beginning and end of the study period (days 1-2 and 6-7).

All Participant Adherence Rates
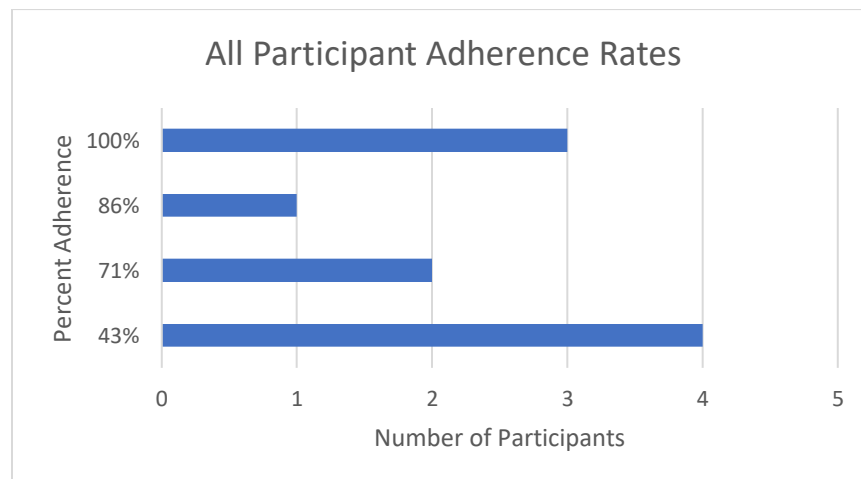
Clinical Investigator Role User Experiences

Key Takeaway: The CertiScan app could be useful in clinical trials but should provide more directions within the app about features and options. The app could add more value to clinical trials by including guidance on what to do with the adherence data collected to improve adherence.

An investigator with a background in digital health and clinical trials was interviewed on their opinion of the app in the context of clinical trials.

➢ **Barriers exist to adherence in clinical trials, and the investigator mentioned some currently used methods to assist in remembering.**

- Barriers include misunderstanding and/or unclear instructions from the beginning, participants forgetting to take medication, time constraints, and perception of taking medication as unimportant or prioritizing other responsibilities as more important.
- Common methods to help participants remember include written schedules and/or calendars, digital reminders and phone alarms, apps, and Pill packs (e.g., Monday-Sunday pop-open containers).

➢ **More support is needed to increase adherence in clinical trials.**

- Better communication and value alignment during participant enrollment into the study. Better explanation as to why they are taking the medication and the importance of taking it as a priority.
- Researchers must better understand the participant's baseline routine and ensure medication regimen (and reminders) will integrate well into their everyday actions.
- Reminders should catch participants at a convenient time when they can cooperate.

➢ **The CertiScan app could be useful in clinical trials, but adjustments are needed.**

- Some parts are intuitive to use, but some aren't. The app should have a walkthrough or better instructions in the initial screen upon first downloading.
- The app does not currently provide guidance on what to do with the data, a clinical investigator would likely have a separate protocol for their team on what to do with the information (e.g., push notifications, emails, phone calls) to increase adherence.
- Histogram is simple/basic, and important for the investigator to know the exact date/time med is taken.
- A better understanding of the limitations of the data is needed to achieve accurate readings.
- The app relies on phone connectivity which could impact the data quality if the Wi-Fi/data plan wasn't working.

➢ **Med-ic may be a better measure of true adherence that could be of use in clinical trials more so than the smart bottle.**

- The smart bottle is a limited measure of adherence with more room for measurement error, as it is just measuring how many times the bottle has been opened and closed. The smart bottle was perceived as not as useful by the investigator, because the data are not as helpful.
- The investigator emphasized that med-ic is more relevant for clinical data and seems like a better measure of adherence.

Appendix I: Medication Adherence Survey

Medication Adherence

Questions	Categories	N (n%)
How often do you miss scheduled appointments?	Never or Rarely	7 (70%)
	Sometimes	1 (10%)
	Often	1 (10%)
	Very often	1 (10%)
	Decline to answer/Don't know	0 (0%)
How often do you forget to take your medicine?	Never or Rarely	1 (10%)
	Sometimes	4 (40%)
	Often	5 (50%)
	Very often	0 (0%)
	Decline to answer/Don't know	0 (0%)
How often do you decide not to take your medicine?	Never or Rarely	8 (80%)
	Sometimes	2 (20%)
	Often	0 (0%)
	Very often	0 (0%)
	Decline to answer/Don't know	0 (0%)
How often do you forget to get prescriptions filled?	Never or Rarely	2 (20%)
	Sometimes	7 (70%)
	Often	0 (0%)
	Very often	1 (10%)
	Decline to answer/Don't know	0 (0%)
How often do you run out of medicine?	Never or Rarely	5 (50%)
	Sometimes	5 (50%)
	Often	0 (0%)
	Very often	0 (0%)
	Decline to answer/Don't know	0 (0%)
How often do you skip a dose of your medicine before you go to the doctor?	Never or Rarely	5 (50%)
	Sometimes	5 (50%)
	Often	0 (0%)
	Very often	0 (0%)
	Decline to answer/Don't know	0 (0%)
How often do you miss taking you medicine when you feel better?	Never or Rarely	6 (60%)
	Sometimes	2 (20%)
	Often	1 (10%)
	Very often	0 (0%)
	Decline to answer/Don't know	1 (10%)
How often do you miss taking your medicine when you feel sick?	Never or Rarely	5 (50%)
	Sometimes	4 (40%)
	Often	0 (0%)
	Very often	0 (0%)
	Decline to answer/Don't know	1 (10%)
How often do you take someone else's medicine?	Never or Rarely	9 (90%)
	Sometimes	1 (10%)
	Often	0 (0%)
	Very often	0 (0%)
	Decline to answer/Don't know	0 (0%)

How often do you miss taking your medicine when you are careless?	Never or Rarely	2 (20%)
	Sometimes	4 (40%)
	Often	4 (40%)
	Very often	0 (0%)
	Decline to answer/Don't know	0 (0%)
How often do you change the dose of your medicines to suit your needs?	Never or Rarely	5 (50%)
	Sometimes	4 (40%)
	Often	1 (10%)
	Very often	0 (0%)
	Decline to answer/Don't know	0 (0%)
How often do you forget to take your medicine when you are supposed to take it more than once a day?	Never or Rarely	4 (40%)
	Sometimes	2 (20%)
	Often	3 (30%)
	Very often	0 (0%)
	Decline to answer/Don't know	1 (10%)
How often do you put off refilling your medicines because they cost too much money?	Never or Rarely	7 (70%)
	Sometimes	3 (30%)
	Often	0 (0%)
	Very often	0 (0%)
	Decline to answer/Don't know	0 (0%)
How often do you plan ahead and refill your medicines before they run out?	Never or Rarely	0 (0%)
	Sometimes	4 (40%)
	Often	4 (40%)
	Very often	2 (20%)
	Decline to answer/Don't know	0 (0%)

Appendix II: Baseline Post-Demonstration Survey

Combination Usability

Questions	Categories	N (n%)
I think that I would expect to have problems using this combination of devices every day.	Strongly Agree/ Agree	2 (20%)
	Strongly Disagree/ Disagree	5 (50%)
	Neutral	3 (30%)
I would expect the combination is too complicated to use every day.	Strongly Agree/ Agree	1 (10%)
	Strongly Disagree/ Disagree	7 (70%)
	Neutral	2 (20%)
I would expect to need the support of a technical person to be able to use this combination.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	9 (90%)
	Neutral	1 (10%)
I would expect problems with the devices.	Strongly Agree/ Agree	4 (40%)
	Strongly Disagree/ Disagree	5 (50%)
	Neutral	1 (10%)
I would expect most people would learn to use this combination without training.	Strongly Agree/ Agree	5 (50%)
	Strongly Disagree/ Disagree	4 (40%)
	Neutral	1 (10%)
I would expect that the combination is easy to use.	Strongly Agree/ Agree	5 (50%)
	Strongly Disagree/ Disagree	2 (20%)
	Neutral	3 (30%)
I would expect that using this combination every day would be inconvenient.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	6 (60%)
	Neutral	4 (40%)
I would expect to feel very confident using this combination.	Strongly Agree/ Agree	8 (80%)
	Strongly Disagree/ Disagree	2 (20%)
	Neutral	0 (0%)
I would expect that I need to learn a lot of things before I can get going with this combination.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	8 (80%)
	Neutral	2 (20%)
I would expect to have problems keeping track of all of these devices.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	5 (50%)
	Neutral	5 (50%)
I would expect others that take long term medications would be able to use this combination of devices every day.	Strongly Agree/ Agree	8 (80%)
	Strongly Disagree/ Disagree	2 (20%)
	Neutral	0 (0%)
I would need family support in order to use this combination every day.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	9 (90%)
	Neutral	1 (10%)

Appendix III: Participant Endline Survey (Post 7 Days of Use)

eCAP™ Usability

Questions	Categories	N (n%)
I think that I would have problem using the smart pill bottle every morning and every evening.	Strongly Agree/ Agree	1 (10%)
	Strongly Disagree/ Disagree	7 (70%)
	Neutral	1 (10%)
This smart pill bottle is too complicated to use.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	10 (10%)
	Neutral	0 (0%)
I think that I would need the support of a technical person to be able to use this smart pill bottle.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	10 (100%)
	Neutral	0 (0%)
I think that most people would learn to use this smart pill bottle without training.	Strongly Agree/ Agree	8 (80%)
	Strongly Disagree/ Disagree	2 (20%)
	Neutral	0 (0%)
I had problems with the smart pill bottle.	Strongly Agree/ Agree	1 (10%)
	Strongly Disagree/ Disagree	9 (90%)
	Neutral	0 (0%)
This smart pill bottle is easy to use.	Strongly Agree/ Agree	10 (100%)
	Strongly Disagree/ Disagree	0 (0%)
	Neutral	0 (0%)
I think that using this smart pill bottle every morning and every evening would be inconvenient.	Strongly Agree/ Agree	3 (30%)
	Strongly Disagree/ Disagree	6 (60%)
	Neutral	1 (10%)
I felt very confident that I was using this smart pill bottle correctly.	Strongly Agree/ Agree	10 (100%)
	Strongly Disagree/ Disagree	0 (0%)
	Neutral	0 (0%)
I needed to learn a lot of things before I could start using this smart pill bottle.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	10 (100%)
	Neutral	0 (0%)
I think I would have problems keeping track of this smart pill bottle.	Strongly Agree/ Agree	1 (10%)
	Strongly Disagree/ Disagree	9 (90%)
	Neutral	0 (0%)
Others with taking long term medications would be able to use this smart pill bottle daily.	Strongly Agree/ Agree	9 (90%)
	Strongly Disagree/ Disagree	0 (0%)
	Neutral	1 (10%)
I would need family support in order to use this smart pill bottle.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	10 (100%)
	Neutral	0 (0%)
I would continue to use this smart pill bottle for another month.	Strongly Agree/ Agree	6 (60%)
	Strongly Disagree/ Disagree	1 (10%)
	Neutral	3 (30%)
	Strongly Agree/ Agree	6 (60%)
	Strongly Disagree/ Disagree	1 (10%)

	Neutral	3 (30%)
I would continue to use this smart pill bottle for six months.		

Medic-ic® Usability

Questions	Categories	N (n%)
I think that I would have problems using the intelligent blister package every morning and every evening.	Strongly Agree/ Agree	3 (30%)
	Strongly Disagree/ Disagree	3 (30%)
	Neutral	4 (40%)
This intelligent blister package is too complicated to use.	Strongly Agree/ Agree	1 (10%)
	Strongly Disagree/ Disagree	7 (70%)
	Neutral	2 (20%)
I think that I would need the support of a technical person to be able to use this intelligent blister package.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	10 (100%)
	Neutral	0 (0%)
I think that most people would learn to use this intelligent blister package without training.	Strongly Agree/ Agree	5 (50%)
	Strongly Disagree/ Disagree	1 (10%)
	Neutral	4 (40%)
I had problems with the intelligent blister package.	Strongly Agree/ Agree	4 (40%)
	Strongly Disagree/ Disagree	5 (50%)
	Neutral	1 (10%)
This intelligent blister package is easy to use.	Strongly Agree/ Agree	4 (40%)
	Strongly Disagree/ Disagree	3 (30%)
	Neutral	3 (30%)
I think that using this intelligent blister package every morning and every evening would be inconvenient.	Strongly Agree/ Agree	7 (70%)
	Strongly Disagree/ Disagree	1 (10%)
	Neutral	2 (20%)
I felt very confident that I was using this intelligent blister package correctly.	Strongly Agree/ Agree	10 (100%)
	Strongly Disagree/ Disagree	0 (0%)
	Neutral	0 (0%)
I needed to learn a lot of things before I could start using this intelligent blister package.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	10 (100%)
	Neutral	0 (0%)
I think I would have problems keeping track of this intelligent blister package.	Strongly Agree/ Agree	2 (20%)
	Strongly Disagree/ Disagree	7 (70%)
	Neutral	1 (10%)
Others taking long term medications would be able to use this intelligent blister package daily.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	10 (100%)
	Neutral	0 (0%)
I would need family support in order to use this intelligent blister package.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	10 (100%)
	Neutral	0 (0%)
I would continue to use this intelligent blister package for another month.	Strongly Agree/ Agree	1 (10%)
	Strongly Disagree/ Disagree	3 (30%)
	Neutral	6 (60%)

	Strongly Agree/ Agree	1 (10%)
I would continue to use this intelligent blister package for six months.	Strongly Disagree/ Disagree	4 (40%)
	Neutral	5 (50%)

CertiScan® App Usability

Questions	Categories	N (n%)
I think that I would have problem using this companion app every morning and every evening.	Strongly Agree/ Agree	4 (40%)
	Strongly Disagree/ Disagree	5 (50%)
	Neutral	1 (10%)
This companion app is too complicated to use.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	9 (90%)
	Neutral	1 (10%)
I think that I would need the support of a technical person to be able to use this companion app.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	9 (90%)
	Neutral	1 (10%)
I think that most people would learn to use this companion app without training.	Strongly Agree/ Agree	6 (60%)
	Strongly Disagree/ Disagree	3 (30%)
	Neutral	1 (10%)
I had problems with this companion app.	Strongly Agree/ Agree	1 (10%)
	Strongly Disagree/ Disagree	8 (80%)
	Neutral	1 (10%)
This companion app is easy to use.	Strongly Agree/ Agree	9 (90%)
	Strongly Disagree/ Disagree	0 (0%)
	Neutral	1 (10%)
I think that using this companion app every morning and every evening would be inconvenient.	Strongly Agree/ Agree	5 (50%)
	Strongly Disagree/ Disagree	3 (30%)
	Neutral	2 (20%)
I felt very confident that I was using this companion app correctly.	Strongly Agree/ Agree	9 (90%)
	Strongly Disagree/ Disagree	0 (0%)
	Neutral	1 (10%)
I needed to learn a lot of things before I could start using this companion app.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	10 (100%)
	Neutral	0 (0%)
Others with taking long term medications would be able to use this companion app daily.	Strongly Agree/ Agree	8 (80%)
	Strongly Disagree/ Disagree	0 (0%)
	Neutral	2 (20%)
I would need family support in order to use this companion app.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	10 (10%)
	Neutral	0 (0%)
I would continue to use this companion app for another month.	Strongly Agree/ Agree	6 (60%)
	Strongly Disagree/ Disagree	2 (20%)
	Neutral	2 (20%)
I would continue to use this companion app for six months.	Strongly Agree/ Agree	6 (60%)
	Strongly Disagree/ Disagree	2 (20%)

	Neutral	2 (20%)

Combination Usability

Questions	Categories	N (n%)
I think that I would have problems using this combination of devices every day.	Strongly Agree/ Agree	2 (20%)
	Strongly Disagree/ Disagree	5 (50%)
	Neutral	3 (30%)
The combination is too complicated to use every day.	Strongly Agree/ Agree	2 (20%)
	Strongly Disagree/ Disagree	5 (50%)
	Neutral	3 (30%)
I think that I would need the support of a technical person to be able to use this combination.	Strongly Agree/ Agree	1 (10%)
	Strongly Disagree/ Disagree	9 (90%)
	Neutral	0 (0%)
I had problems with the devices.	Strongly Agree/ Agree	1 (10%)
	Strongly Disagree/ Disagree	9 (90%)
	Neutral	0 (0%)
I think that most people would learn to use this combination without training.	Strongly Agree/ Agree	6 (60%)
	Strongly Disagree/ Disagree	4 (40%)
	Neutral	0 (0%)
The combination is easy to use.	Strongly Agree/ Agree	7 (70%)
	Strongly Disagree/ Disagree	0 (0%)
	Neutral	3 (30%)
I think that using this combination every day would be inconvenient.	Strongly Agree/ Agree	4 (40%)
	Strongly Disagree/ Disagree	4 (40%)
	Neutral	2 (20%)
I felt very confident using this combination.	Strongly Agree/ Agree	9 (90%)
	Strongly Disagree/ Disagree	1 (10%)
	Neutral	0 (0%)
I needed to learn a lot of things before I could get going with this combination.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	8 (80%)
	Neutral	2 (20%)
I think I would have problems keeping track of all of these devices.	Strongly Agree/ Agree	3 (30%)
	Strongly Disagree/ Disagree	4 (40%)
	Neutral	3 (30%)
Others taking long term medications would be able to use this combination of devices every day.	Strongly Agree/ Agree	6 (60%)
	Strongly Disagree/ Disagree	0 (0%)
	Neutral	4 (40%)
I would need family support in order to use this combination every day.	Strongly Agree/ Agree	0 (0%)
	Strongly Disagree/ Disagree	9 (90%)
	Neutral	1 (10%)