

# FDA MYSTUDIES APP: A PATIENT CENTERED OUTCOMES RESEARCH TRUST FUND ENABLER FOR DISTRIBUTED CLINICAL TRIALS AND REAL WORLD EVIDENCE STUDIES

## APPENDICES

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# FDA MyStudies App: A Patient Centered Outcomes Research Trust Fund Enabler for Distributed Clinical Trials and Real World Evidence Studies

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## I. APPENDIX 1: EXIT INTERVIEW SUMMARY

### A. INTERVIEW GUIDE

#### 1. Overall Impressions

- Did you do the study using an iPhone or an Android phone?
- What motivated you to take part in this study?
- Overall, how was your experience of participating in this study?
- What, if anything, did you like about taking part in the study?
- What was frustrating about your participation?
- What was your experience first using the app? Can you describe anything about that you found helpful or frustrating?
- What do you think about the information you were given about the study before you joined? (for example, was it enough, understandable or accurate).
- How did you feel about using an app to answer study survey questions?
- Did you watch the video?

#### 2. Surveys

Let's talk a little more about the surveys that you were completing during the study.

- What was your sense of the number, frequency and length of the surveys? How manageable were they?
- When did you end up taking the surveys? Would you typically do it at the same time of the day or did it vary?
- In terms of content, were any of the surveys problematic for you to answer? If so which ones and why?
- How well did the app work for answering the surveys? Did you have any trouble with entering the information and, if so, how?
- How well did the notification about new surveys work for you?
- Did you stop responding to surveys at some point or did you continue to answer them until the study ended? If you stopped, why do you think you stopped?

#### 3. App

In addition to the surveys, the app had several other features, such as feedback and resources.

- Did you use any of these other features? If so which ones?
- Which, if any, app features did you find helpful? What made these features useful to you?
- Is there anything you would change about the app to improve it?
- Is there anything else you'd like to tell us about your experience in the study?

**Table 1. StudyID 400017 Exit Interview**

<b>StudyID</b>	400017
<b>Phone</b>	iPhone
<b>Bugs Found</b>	None
<b>Motivation</b>	Easy enough to do to help out. App was free, and easy to use. Wanted to help out and give info to other women.
<b>Overall experience</b>	Didn't take too much time. Wasn't negative, felt like helping people.
<b>What you liked</b>	Each survey didn't take too much time. Not required to complete every one. Verbiage easy to understand.
<b>What was frustrating</b>	Surveys only available during a certain time frame.
<b>First experience</b>	Language easy to understand.
<b>Information</b>	Lots of details. Informative. I understood what it was. Receiving all the information helped make decision to participate.
<b>Using an app</b>	[not reported]
<b>Video</b>	Didn't know it was there
<b>#, frequency, length</b>	Each survey quick to complete. Some surveys were short and easy for breaks, and some were a bit too long for breaks.
<b>When</b>	When had a break at work, in evening before bed, or when reminders popped up.
<b>Content</b>	Hard to determine what date to use for start date with ongoing issues. Also asked every time, and didn't auto populate. Confusing what date to use when asked repeatedly. Some content seemed repetitive.
<b>How worked</b>	No trouble - app worked great
<b>Notifications</b>	Worked great - reminded to do surveys.
<b>When stopped (please include details re: problems with end date.)</b>	May have stopped unintentionally. Not sure. Stopped when she gave birth [early Jan].
<b>App features</b>	Didn't use/notice features
<b>Improvements</b>	Change repetitiveness of longer surveys, and shorten them.
<b>Additional information</b>	Was concerned about confidentiality before joined. Didn't know who would get information. One of my doctors encouraged me to participate, that made it okay. Never been part of research before.

**Table 2. StudyID 40037 Exit Interview**

<b>StudyID</b>	400037
<b>Phone</b>	iPhone
<b>Bugs Found</b>	None
<b>Motivation</b>	Done research as a grad student. Believes in helping with research. On a medication, and thinks there's a lack of good information on safety of meds during pregnancy.
<b>Overall experience</b>	Wasn't huge time commitment. Well organized. Questions were repetitive.
<b>What you liked</b>	Purpose of the study. Adding to body of knowledge. Good questions and phrasing. Interface was good, easy to work with.
<b>What was frustrating</b>	Notifications were vague. Need indication which surveys are complete. Not sure which ones to do.
<b>First experience</b>	Wasn't confusing, seemed appropriate because of links to medical record.

<b>Information</b>	Not clear up front how often I should go in.
<b>Using an app</b>	[not reported]
<b>Video</b>	[not reported]
<b>#, frequency, length</b>	Yes, manageable after initial log on, when there were quite a few to complete. Was able to fit it in without making time for it.
<b>When</b>	On the bus, when had a few minutes. Sometime during work day - in the midst of other responsibilities.
<b>Content</b>	Clear phrasing. Questions at times repetitive. At times wanted more options available for conditions. Felt like some things weren't covered. (can't remember what)
<b>How worked</b>	No trouble.
<b>Notifications</b>	The alerts made it sound like I was overdue for the survey. When I clicked on it, wouldn't know which one to fill out.
<b>When stopped (please include details re: problems with end date.)</b>	Not sure if went through the end. Had baby in early Dec. At some point, stopped getting notifications so stopped filling surveys out. Never clear when it started or when completed. Not sure if it stopped when she had her baby.
<b>App features</b>	Didn't use/notice features
<b>Improvements</b>	Auto populate repeated questions. Wished there was an indication which surveys were completed or due.
<b>Additional information</b>	None

**Table 3. StudyID 400041 Exit Interview**

<b>StudyID</b>	400041
<b>Phone</b>	iPhone
<b>BUGS</b>	When "clicking on it" went "blank" a few times, and would have to re-open it. Set up to automatically open, but a few times while opening the app it blanked out, and would have to sign in with a password. Don't know if it was the phone or the app.
<b>motivation</b>	Think research is good in general. Likes helping people.
<b>overall experience</b>	Enjoyed doing the surveys. Once reported birth, app continued to ask questions.
<b>what liked</b>	Fun to fill out surveys, really motivated to fill out surveys early on.
<b>frustrating</b>	Continued to get surveys after not pregnant, and didn't think they were relevant. Don't have a scale so hard to report weight.
<b>first experience</b>	[not reported]
<b>information</b>	[not reported]
<b>using an app</b>	Comfortable using an app for research.
<b>video</b>	[not reported]
<b>#, frequency, length</b>	Very manageable.
<b>When</b>	Same time of the day, when waiting on the bus to work.
<b>content</b>	Content not a problem.
<b>How worked</b>	[Bugs - reported in bug column.]
<b>notifications</b>	Still got notifications after delivered.

<b>When stopped (please include details re: problems with end date.)</b>	After delivered, did one or two more surveys, then got annoyed about the questions and deleted the app so would stop getting the notifications. Used the app for about a month.
<b>app features</b>	Didn't use
<b>improvements</b>	Wished the surveys would stop after she delivered. Some answers didn't change survey to survey, wish could have asked "has anything changed?", instead of the same question over and over.
<b>additional info</b>	None

**Table 4. StudyID 400088 Exit Interview**

<b>StudyID</b>	400088
<b>Phone</b>	Android (601)
<b>Bugs Found</b>	Got kicked out at one point, and had to re log in.
<b>Motivation</b>	Figured it could be useful to us.
<b>Overall experience</b>	Very easy and simple.
<b>What you liked</b>	Keeping track of weight was fun.
<b>What was frustrating</b>	Didn't get notifications. Got kicked out, and needed to re-sign in.
<b>First experience</b>	Straightforward.
<b>Information</b>	Accurate and enough information
<b>Using an app</b>	Don't mind this way to complete surveys
<b>Video</b>	Can't remember
<b>#, frequency, length</b>	Very manageable. Took 1-2 minutes for each survey.
<b>When</b>	When remembered it.
<b>Content</b>	Conditions - hard to answer. Hard to report start and stop because conditions were off and on all the time.
<b>How worked</b>	No problems.
<b>Notifications</b>	Didn't get notifications. Ended up missing one of the surveys. Tried to change settings, didn't work.
<b>When stopped (please include details re: problems with end date.)</b>	Answered until the study ended. App told her when the study ended, said "99% completed".
<b>App features</b>	Liked weight tracker.
<b>Improvements</b>	Anything added might bog it down - should be just about surveys.
<b>Additional information</b>	None

**Table 5. StudyID 400096 Exit Interview**

<b>StudyID</b>	400096
<b>Phone</b>	iPhone
<b>Bugs Found</b>	None
<b>Motivation</b>	Any support around pregnancy is helpful, any information about medications helpful.
<b>Overall experience</b>	Used it only when I needed to. Used it to look up different medication recommendations.
<b>What you liked</b>	Extra level of care (resource section). Quicker than contacting OB/GYN
<b>What was frustrating</b>	When had time to enter information, sometimes surveys not available.
<b>First experience</b>	[not reported]

<b>Information</b>	[not reported]
<b>Using an app</b>	[not reported]
<b>Video</b>	[not reported]
<b>#, frequency, length</b>	Pretty easy and manageable.
<b>When</b>	Varied. If I was off work, or in the evening after work.
<b>Content</b>	All straightforward.
<b>How worked</b>	No problems.
<b>Notifications</b>	Didn't get notifications. Would go into the app for the surveys.
<b>When stopped (please include details re: problems with end date.)</b>	Continued as long as getting new surveys. October possibly.
<b>App features</b>	Used resource section to look up medication safety. More of a reliable source than looking up things on the internet, because it was from a medical provider.
<b>Improvements</b>	Be able to do many surveys at once. Get notifications. Add an interactive, even like connection to a provider or a chat bot.
<b>Additional information</b>	None

**Table 6. StudyID 400192 Exit Interview**

<b>StudyID</b>	400192
<b>Phone</b>	Android
<b>Bugs Found</b>	None
<b>Motivation</b>	Worked in research for 8 years
<b>Overall experience</b>	Confusing. Unclear when to enter and what information she should enter. Redundancy in questions. Difficult to remember medications and dosages.
<b>What you liked</b>	Doesn't remember there being any highlights.
<b>What was frustrating</b>	Her understanding from when she started is that there would be more information provided to her or that she would be able to look up information but that was not the case. Was not clear what had been done and wished responses could have been correlated to prior response rather than having another question about the exact same thing. Having to log and remember start and stop dates of medication was confusing and felt redundant.
<b>First experience</b>	Easy
<b>Information</b>	Thinks so
<b>Using an app</b>	[not reported]
<b>Video</b>	No
<b>#, frequency, length</b>	Manageable, especially by having it on the app.
<b>When</b>	Whenever I got the notification. During work day when had a moment
<b>Content</b>	No, just start and stop dates with medication was difficult.
<b>How worked</b>	No problems
<b>Notifications</b>	Yes, would not have remembered to do any surveys without it.
<b>When stopped (please include details re: problems with end date.)</b>	Answered until the study ended.
<b>App features</b>	Looked at resources but wasn't super clear so bailed on that quickly.

<b>Improvements</b>	No
<b>Additional information</b>	Expected there to be more and didn't feel like she answered a ton of surveys.

**Table 7. StudyID 400275 Exit Interview**

<b>StudyID</b>	400275
<b>Phone</b>	iPhone
<b>Bugs Found</b>	Needed to do full log in again at some point (got kicked out of the app).
<b>Motivation</b>	MPH. Works in research.
<b>Overall experience</b>	It was easy.
<b>What you liked</b>	Liked that it was on an app. Didn't have to log in every time.
<b>What was frustrating</b>	Got kicked out of app, and had to do a full log on. Not sure if did something wrong or when study ended because of strange message when logged back in. Wished could have hit N/A for some questions. Some questions didn't seem to apply, and didn't know if I should answered.
<b>First experience</b>	[not reported]
<b>Information</b>	[not reported]
<b>Using an app</b>	Liked that it was on an app. Has phone all the time, so it was easy.
<b>Video</b>	[not reported]
<b>#, frequency, length</b>	Fine. Didn't take too long, and didn't seem like too many
<b>When</b>	Varried. If alert came up, and had time, would do it right then. Not sure if completed all the ones she didn't respond to right away.
<b>Content</b>	Question about drugs and conditions - don't think there was an option to input own response not in drop down, or else, didn't know how to use the "other" response option.
<b>How worked</b>	"Other" category not obvious. Needed to log in again at some point.
<b>Notifications</b>	[not reported]
<b>When stopped (please include details re: problems with end date.)</b>	Don't remember. Intent to do it as much as possible. Got kicked out and had to do a full log on at some point, and didn't have the log in information. Then when had information and tried to log in, the app said, "you are finished". This was confusing. Wasn't in the study very long.
<b>App features</b>	Didn't use / didn't notice
<b>Improvements</b>	Would be nice to have a number to call if had questions while taking part. Keep log in easy.
<b>Additional information</b>	None

**Table 8. StudyID 400302 Exit Interview**

<b>StudyID</b>	400302
<b>Phone</b>	iPhone
<b>Bugs Found</b>	None
<b>Motivation</b>	Felt like should participate because I'm a researcher.
<b>Overall experience</b>	Easy.
<b>What you liked</b>	Good accessibility. Easy to use remotely.
<b>What was frustrating</b>	No reminders. Didn't realize there were so many surveys, and couldn't fill them all out at once. Didn't get notifications. Annoyed by questions about illicit drug use, and alcohol. Didn't know I was going to be asked this.
<b>First experience</b>	[not reported]



<b>Information</b>	Don't remember being told about drugs and alcohol questions up front. Seemed like the purpose of the study was to ask questions about drugs and alcohol, and actually weren't interested in medication use as was told over the phone by recruiter. Felt deceived about purpose of study, as we didn't state we were asking these questions this up front. More invasive than thought initially, and would probably not have participated if knew about this ahead of time.
<b>Using an app</b>	Fine with using app for research.
<b>Video</b>	[not reported]
<b>#, frequency, length</b>	Manageable. Seemed like a lot at first.
<b>When</b>	Mostly in the evening.
<b>Content</b>	Annoyed by drug and alcohol use questions. Felt deceived and decided not to answer questions.
<b>How worked</b>	No problems
<b>Notifications</b>	Didn't receive them.
<b>When stopped (please include details re: problems with end date.)</b>	Never got any reminders from the study, so didn't really use it more than once or twice.
<b>App features</b>	[not reported]
<b>Improvements</b>	Make purpose of study more explicit - to study drug and alcohol use in pregnancy.
<b>Additional information</b>	Worried about confidentiality, and wouldn't have participated if knew the study was about alcohol and drug use. Wondered why this was an FDA app, and worried about where the data was stored and might have been added to a national repository.

**Table 9. StudyID 400360 Exit Interview**

<b>StudyID</b>	400360
<b>Phone</b>	iPhone
<b>Bugs Found</b>	None
<b>Motivation</b>	Health care worker - thinks research is important. Frustrating not knowing what medications are safe.
<b>Overall experience</b>	Easy.
<b>What you liked</b>	Questions weren't invasive. Didn't take a lot of time or effort. Allowed fingerprint access.
<b>What was frustrating</b>	Couldn't figure out how to get notifications. Missed some surveys. App would ask specific dates, which was challenging to answer. Had things off and on, and couldn't explain this.
<b>First experience</b>	Can't remember.
<b>Information</b>	Understandable and accurate.
<b>Using an app</b>	Easy and convenient way to do studies. No concerns about entering information.
<b>Video</b>	Maybe, but don't remember.
<b>#, frequency, length</b>	Short length and small number of surveys made participation easy.
<b>When</b>	Did it on the bus.

<b>Content</b>	Using specific dates didn't match on and off nature of symptom, and made questions hard to answer. Also, couldn't remember dose at times. Some questions repetitive. Didn't answer all weight questions because home scale wasn't accurate.
<b>How worked</b>	No problems.
<b>Notifications</b>	Didn't get any. Tried to turn them on, but couldn't figure it out.
<b>When stopped (please include details re: problems with end date.)</b>	Continued to the end. The app told me it was the end.
<b>App features</b>	Didn't use
<b>Improvements</b>	Include standard doses on medication questions. Leave some opportunity for open ended responses. Instead of asking for specific dates, ask "in the past week".
<b>Additional information</b>	Found odd when study ended, and tried to delete app, the app warned that her data would be deleted when deleted the app.

**Table 10. StudyID 400464 Exit Interview**

<b>StudyID</b>	400464
<b>Phone</b>	Android (Samsung phone)
<b>Bugs Found</b>	Stopped a month in. After being out for a while, app asked her to re-register- the app went back to the first "page". Didn't have a way to log back in, because didn't have info needed to get back into the app. Gave up. Doesn't know why it did this.
<b>Motivation</b>	Always interested in contributing to knowledge.
<b>Overall experience</b>	Had a condition app didn't ask about, and taking a med app didn't ask about. Coded both "other".
<b>What you liked</b>	Liked the detail in first survey. Liked the focus on medications in pregnancy. Think it's valuable study. Appreciated paper packet from KP.
<b>What was frustrating</b>	Waiting to answer surveys was frustrating. Had to check in regularly to do this. Weight tracking was tricky - had to skip that a lot. Had to input password every time went into the app.
<b>First experience</b>	Very streamlined. Easy to find app, download, and register.
<b>Information</b>	Understandable. Maybe a little bit too much information. Perhaps better if there were an option to skip.
<b>Using an app</b>	[not reported]
<b>Video</b>	Didn't know it was there
<b>#, frequency, length</b>	Number of surveys good. Length convenient. Easy to do.
<b>When</b>	Took sporadically. Afternoon, evening.
<b>Content</b>	Nowhere to add her condition and medication. Weight difficult to do weekly.
<b>How worked</b>	No problems.
<b>Notifications</b>	Didn't get any.
<b>When stopped (please include details re: problems with end date.)</b>	Stopped a month in. After being out for a while, app asked her to re-register- the app went back to the first "page". Didn't have a way to log back in, because didn't have info needed to get back into the app. Gave up. Doesn't know why it did this.
<b>App features</b>	Didn't use / notice features

<b>Improvements</b>	Fix the issue with kicking her out to the beginning of registration. Have a way to input information in each survey. Get notifications.
<b>Additional information</b>	None

**Table 11. StudyID 400471 Exit Interview**

<b>StudyID</b>	400471
<b>Phone</b>	Android
<b>Bugs Found</b>	Occasionally would get kicked out, and needed to do full log on again. Had to go through all consents again. This happened at least twice.
<b>Motivation</b>	"Why not". Don't mind helping.
<b>Overall experience</b>	Fine. Required more thought than expecting, because only got notification at the very end, and weren't accurate.
<b>What you liked</b>	Liked weight tracker.
<b>What was frustrating</b>	Notifications didn't show up until last 2-3 weeks. When they did, they were not accurate. Occasionally needed to completely log back in.
<b>First experience</b>	Not a problem.
<b>Information</b>	Sufficient. Felt like a lot, but understand it's important.
<b>Using an app</b>	Comfortable using an app for research, because not concerned about answers.
<b>Video</b>	Didn't know it was there
<b>#, frequency, length</b>	# was fine.
<b>When</b>	Usually did them in the evening, and weight in the morning.
<b>Content</b>	Some could have been condensed - like a in the form of a list to select what conditions did apply. Had to go through all questions of conditions, which was tedious. One survey about if you lost the baby. Opened by accident and it stayed there, which was weird. Sometimes difficult to answer date or dose questions.
<b>How worked</b>	No problems.
<b>Notifications</b>	Didn't get any until last 2-3 weeks. When did get them, they referred to surveys not available, or that were already completed.
<b>When stopped (please include details re: problems with end date.)</b>	Attempted to complete all the surveys. The last few timed out before could do them.
<b>App features</b>	Liked the weight tracker.
<b>Improvements</b>	Get notifications fixed. Not get kicked out of app.
<b>Additional information</b>	None

**Table 12. StudyID 400478 Exit Interview**

<b>StudyID</b>	400478
<b>Phone</b>	Android
<b>Bugs Found</b>	None
<b>Motivation</b>	Interested in research projects.
<b>Overall experience</b>	Fine. Easy and straightforward.
<b>What you liked</b>	Liked that it was on the phone, made it convenient.
<b>What was frustrating</b>	Some of the timing of questions was confusing - did some surveys after given birth, and the design of questions didn't fit.
<b>First experience</b>	Easy

<b>Information</b>	Needed more information about time sensitive and repeated surveys. Didn't know that up front.
<b>Using an app</b>	[not reported]
<b>Video</b>	Didn't know it was there
<b>#, frequency, length</b>	Manageable.
<b>When</b>	When I would remember.
<b>Content</b>	Content not a problem.
<b>How worked</b>	No problems
<b>Notifications</b>	Probably turned off notifications. Wasn't initially clear that the surveys would come repeatedly.
<b>When stopped (please include details re: problems with end date.)</b>	Don't think completed all surveys, and missed time window because notifications turned off. Tried to go back and finish after gave birth.
<b>App features</b>	Didn't use
<b>Improvements</b>	Provide more up front info around the frequency and #, and time sensitivity of surveys up front.
<b>Additional information</b>	None

**Table 13. StudyID 400634 Exit Interview**

<b>StudyID</b>	400634
<b>Phone</b>	iPhone (6s)
<b>Bugs Found</b>	Late in the study. Sometimes would freeze when trying to enter a survey. Sometimes it would allow one page, then would freeze when trying to click "next". One thing didn't allow to answer was pregnancy outcome, so kept on getting surveys after gave birth.
<b>Motivation</b>	Interested in medical research. Maybe it would help women in the future.
<b>Overall experience</b>	Good.
<b>What you liked</b>	Nice to keep track of stuff for own information, and know might be helping other's down the road. Prompting questions to ask doc about.
<b>What was frustrating</b>	Freezing bug.
<b>First experience</b>	Can't remember - probably means it was fine.
<b>Information</b>	Fine.
<b>Using an app</b>	Like using an app for surveys. Better than paper or on computer.
<b>Video</b>	Didn't know it was there
<b>#, frequency, length</b>	Manageable.
<b>When</b>	Varied. Tried to do when notification popped up, or if not, when had a break.
<b>Content</b>	Reporting dosage hard, because needed bottle there to answer. Also question about when condition started and ended hard to answer because had condition every day. When asked again about the start date of a condition, hard to remember the date previously entered.
<b>How worked</b>	App froze near end, otherwise easy.
<b>Notifications</b>	Sometimes got a notification for surveys not available yet.

<b>When stopped (please include details re: problems with end date.)</b>	App started freezing late in the study around the time gave birth. Because of freezing bug, couldn't answer questions about giving birth, and the app thought still pregnant, so kept getting surveys. Looked up in the paperwork the study end date.
<b>App features</b>	Liked weight tracker, but was using one in another app. Looked at resources.
<b>Improvements</b>	Auto populate start date from previous responses. Fix freezing.
<b>Additional information</b>	None

**Table 14. StudyID 400698 Exit Interview**

<b>StudyID</b>	400698
<b>Phone</b>	Android
<b>Bugs Found</b>	One or two times, got kicked out and needed to fully sign back in. Had to remember email address and password.
<b>Motivation</b>	Participating in research is important for others.
<b>Overall experience</b>	App flow easy. Questions clear and uncomplicated.
<b>What you liked</b>	Liked the idea of the study. Liked how the app worked. Liked the 4-digit passcode.
<b>What was frustrating</b>	Tums was not listed, and had to get the bottle and write down dosage. One time had missed responding, and emailed to ask about why app saying I was late. Never got a response to email.
<b>First experience</b>	Can't remember. Probably was easy, because if it was frustrating wouldn't continue.
<b>Information</b>	Wish there were more of a background of why doing the study.
<b>Using an app</b>	Thought it was smart to use app for research, and simple. Wasn't worried about sharing information in this way.
<b>Video</b>	Didn't know it was there
<b>#, frequency, length</b>	Wanted to do them all at once, instead of waiting a week.
<b>When</b>	Did when she got notification, would do it that day when had time.
<b>Content</b>	Tums should be listed as it's the most common med for women. Otherwise, easy to answer.
<b>How worked</b>	No problems.
<b>Notifications</b>	A couple times didn't see notification for survey found in the app. One that said I missed a survey, and don't think I did. Otherwise notifications are helpful.
<b>When stopped (please include details re: problems with end date.)</b>	Continued until the end (when she gave birth). Clear when I finished, because it said I was at 100% mark.
<b>App features</b>	Used feature to email with questions, never got a response.
<b>Improvements</b>	Nice if had remembered meds previously entered.
<b>Additional information</b>	Smart way to get study information. If had to sign into computer, I would be less likely to do the study.

**Table 15. StudyID 400716 Exit Interview**

<b>StudyID</b>	400716
<b>Phone</b>	iPhone
<b>Bugs Found</b>	None
<b>Motivation</b>	Background in social justice and has participated in research studies before. Important to participate in studies that will help women and children in the future.
<b>Overall experience</b>	Good. Surprised by brevity of the questions expected to do more but was nice not to have to.
<b>What you liked</b>	Liked the idea of the study.
<b>What was frustrating</b>	Recurring need to login entirely anew. Frustration of this process almost outweighed her desire to do the study.
<b>First experience</b>	[not reported]
<b>Information</b>	Comprehensive and easy to understand but felt like people from different backgrounds may have had challenges.
<b>Using an app</b>	[not reported]
<b>Video</b>	Don't thinks she did
<b>#, frequency, length</b>	Easy
<b>When</b>	When she had time and when she received reminders.
<b>Content</b>	No. Questions around anxiety and depression didn't allow for sharing what was happening to her at the moment. Because responses were limited to yes or no it didn't allow for any elaboration of circumstances that may have explained things more accurately.
<b>How worked</b>	App worked well and no trouble entering info.
<b>Notifications</b>	Great
<b>When stopped (please include details re: problems with end date.)</b>	Stopped before end of the study but was required to re-login with all information and couldn't remember password easily.
<b>App features</b>	No
<b>Improvements</b>	Just to be able to stay logged in once she has gone thru initial login process.
<b>Additional information</b>	None

**Table 16. StudyID 400763 Exit Interview**

<b>StudyID</b>	400763
<b>Phone</b>	iPhone
<b>Bugs Found</b>	Last few weeks, (Nov or Dec) kept freezing up. Would enter a survey, and the app would freeze when I tried to enter a response. Wouldn't record response and would freeze there. Would close the app, and get back into the app. Then would freeze again in same spot. By time app started working, the survey timed out. Happened with weight tracker, and possibly current medications.
<b>Motivation</b>	Wanted to help women in the future.
<b>Overall experience</b>	Really great until last couple weeks. Kept freezing up when trying to enter weekly responses.

<b>What you liked</b>	Nice interface, not intrusive. Easy to use while commuting. Notifications not annoying.
<b>What was frustrating</b>	The app would freeze.
<b>First experience</b>	Can't remember.
<b>Information</b>	Info understandable, study ended up meeting expectations.
<b>Using an app</b>	Sometimes wonder about privacy.
<b>Video</b>	Didn't know it was there
<b>#, frequency, length</b>	Manageable amount.
<b>When</b>	Killing time on the bus to work.
<b>Content</b>	Most challenging was a medication with questions about dose and dates.
<b>How worked</b>	App froze near end, otherwise easy.
<b>Notifications</b>	These worked well.
<b>When stopped (please include details re: problems with end date.)</b>	Tried to finish, but hard because of freezing issue. Didn't stop because of the freezing, but thinks some of her surveys weren't complete.
<b>App features</b>	Used feedback feature to email about freezing. Didn't get response.
<b>Improvements</b>	Fix the freezing bug.
<b>Additional information</b>	None

**Table 17. StudyID 401002 Exit Interview**

<b>StudyID</b>	401002
<b>Phone</b>	iPhone
<b>Bugs Found</b>	Got locked out and she couldn't reset password. Didn't receive e-mails to help her reset password. Did get back in eventually by pressing on one of the notifications which somehow was easier than just trying to login on herself. Not sure if it was original password because she tried so many to get in.
<b>Motivation</b>	First pregnancy and is hard to find information on medication safety during pregnancy.
<b>Overall experience</b>	Really good at first but then it wouldn't let her reset password. Also felt like many of the questions that didn't apply to her and wished she could have given more info on other behaviors.
<b>What you liked</b>	The idea of the study and being able to easily participate by just recording regular behaviors.
<b>What was frustrating</b>	When she couldn't sign in. Inconsistency in notifications.
<b>First experience</b>	Yes
<b>Information</b>	Yes
<b>Using an app</b>	Loved it, very convenient.
<b>Video</b>	Can't remember
<b>#, frequency, length</b>	Manageable.
<b>When</b>	Evenings after work
<b>Content</b>	No. Wished there was more behaviors that we covered.
<b>How worked</b>	Worked well until she got locked out and couldn't reset password.

<b>Notifications</b>	Didn't receive notifications on when surveys available and missed some because of this. Would receive notifications that she hadn't logged in in a while when she had logged in very recently. Still receiving notifications after the app is deactivated.
<b>When stopped (please include details re: problems with end date.)</b>	Stopped when she couldn't get in due to not being able to remember password and unable to reset properly. Got back in towards the end of the survey by pressing on notification from the app.
<b>App features</b>	No. Getting that kind of info from other apps and books.
<b>Improvements</b>	Easier sign in process Be able to save login information and have less complicated password requirements.
<b>Additional information</b>	None

**Table 18. StudyID 401016 Exit Interview**

<b>StudyID</b>	401016
<b>Phone</b>	iPhone
<b>Bugs Found</b>	One time got logged out, and took a long time to get codes to log back in.
<b>Motivation</b>	Academic, and have benefited reading articles on pregnancy. Thought it would be great to contribute.
<b>Overall experience</b>	Pretty good experience.
<b>What you liked</b>	Liked to contribute.
<b>What was frustrating</b>	Would get notifications saying I had a survey to do, but I didn't. One survey that looked open, but when went in, it said "don't take unless pregnancy ended unexpectedly". This hung in the queue. Got kicked out once, and had to log back in completely. Weight question hard to answer every time.
<b>First experience</b>	Longer process than expected.
<b>Information</b>	Someone called me, and it was helpful to talk to someone to explained the reason for the study, and made me feel excited.
<b>Using an app</b>	Not a problem.
<b>Video</b>	Didn't know it was there
<b>#, frequency, length</b>	Manageable.
<b>When</b>	Whenever I got the notification.
<b>Content</b>	Weight questions sometimes difficult to answer when didn't have access to scale. Sometimes didn't know the date, dose etc, and would skip the question, or guess.
<b>How worked</b>	Good interface.
<b>Notifications</b>	Notifications worked well, but sometimes not accurate.
<b>When stopped (please include details re: problems with end date.)</b>	Stopped responding when stopped getting notifications. At one point assumed the study was over. (before Thanksgiving.)
<b>App features</b>	Didn't use.
<b>Improvements</b>	Didn't know which surveys were complete or not- surveys in queue did not get marked when completed. Make logging on not as cumbersome. Make notifications more accurate.
<b>Additional information</b>	None



**Table 19. StudyID 401182 Exit Interview**

<b>StudyID</b>	401182
<b>Phone</b>	iPhone
<b>Bugs Found</b>	None
<b>Motivation</b>	Work in health care, and might benefit someone.
<b>Overall experience</b>	Overall experience annoying. Got notifications all time, sometimes of things already done or not needed to be done. Turned them off, and then couldn't log on again.
<b>What you liked</b>	Being "in on research".
<b>What was frustrating</b>	Notifications very annoying. Tried to turn them off, and kicked me out. Didn't have the information to log back in.
<b>First experience</b>	Can't remember.
<b>Information</b>	Can't remember.
<b>Using an app</b>	[not reported]
<b>Video</b>	[not reported]
<b>#, frequency, length</b>	Manageable.
<b>When</b>	Varied. Commuting. When I had down time.
<b>Content</b>	Content not a problem.
<b>How worked</b>	Good interface.
<b>Notifications</b>	Got notifications all time (at 4 in the morning), sometimes of things already done or not needed to be done. Turned them off, and then couldn't log on again.
<b>When stopped (please include details re: problems with end date.)</b>	Stopped when couldn't log in. (Got kicked out when turned notifications off, and didn't have login information.) Early Dec.
<b>App features</b>	Weight tracker helpful, but hard to go back and see past weights or trends. However, wouldn't use a survey app for pregnancy information.
<b>Improvements</b>	Could turn it into a pregnancy app with helpful features to get more people interested.
<b>Additional information</b>	None

## II. APPENDIX 2: USER ACCEPTANCE TESTING FEEDBACK REPORT

### A. TESTING STRUCTURE AND PHASES

The participating Sentinel Data Partner in this project, Kaiser Permanente Washington Health Research Institute (KPWHRI), conducted two phases of user testing for the mobile application project. The first phase, entitled Feature Testing, took place in April 2017. The second phase, entitled User Testing, took place in June and July 2017. In the Feature Testing Phase, a focus group of six women explored an early test version of the application and provided feedback on usability, structure, and appearance of the application. During the User Testing phase, six study team members from KPWHRI and three Harvard Pilgrim Health Care Institute (HPHCI) team members reviewed the near final version of the application and provided feedback on bugs, questionnaire functionality, and overall application functionality. All feedback was sent to the HPHCI team and incorporated into the final version of the application.

### B. FEATURE TESTING FEEDBACK

Focus group members agreed that they would be motivated to use the application, particularly due to its utility for the pilot study use case, medication use by pregnant women. One group member stated that “during my first pregnancy, I had to go on antibiotics, and there were lots of unknowns and I felt that no one was 100% sure about how the antibiotics would affect my baby.” She felt that if this information would help other women in the future, she would be willing to participate even if it would not help her immediately. Members also agreed they would prefer to complete short weekly questionnaires of two to three minutes each rather than longer questionnaire sessions. Group members were concerned about their ability to recall the dates they took medications. Group members agreed that including a learning element or resources in the application would help to maintain engagement and that they would not have concerns about receiving reminders to log in to the application.

### C. USER TESTING FEEDBACK

Beginning in June 2017, the nine testers provided feedback on the mobile application and pilot study use case. Three used Android phones for testing and six used iPhones. Testers were given access to a near final test version of the app via Apple’s TestFlight tool for iOS or a direct download link for Android. Testers reviewed the application registration process, appearance, functionality, notifications, study consent process, questionnaire content and functionality, study resources, and study dashboard. Testers provided consolidated feedback to the HPHCI team on a weekly basis throughout this period and alerted the HPHCI team to any significant application bugs when they occurred. The HPHCI team verified all bugs and worked with the application developer, Boston Technology Corporation (BTC), to resolve any issues related to functionality via a web-based bug tracking tool.

Questionnaire content feedback was reviewed with the project’s FDA lead, Dr. David Martin. The HPHCI team and Dr. Martin worked with the KPWHRI team to resolve and implement content feedback. Overall tester feedback assisted in finalizing the app elements listed above as well as the overall usability of study resources for pregnant women. Testers identified and provided feedback on technical defects which the BTC team was able to resolve prior to study launch. Defects included inability to sign out of the application successfully, application crashes, and incorrect appearance of questionnaire items.

### III. APPENDIX 3: PREGNANCY STUDY QUESTIONNAIRES

**Questions (or Modules) highlighted in green will be asked repeatedly over time.**

**Questions highlighted in blue are form steps**

*Each section below will appear in the app as a separate questionnaire.*

**Activity short title: CoreBaseline**

**Title: Pregnancy status**

**[CB] Core Baseline Questions – Establishing status of pregnancy and outcomes if no longer pregnant**

**1. Are you pregnant right now?**

- Yes → Go to Q2 for initial baseline. Go to current question module when this question is asked as part of a repeat questionnaire
- No → Go to question module at the end of this document (page 26) for women who respond “No” at baseline (i.e. women who are recruited, consent to participate, but are no longer pregnant at the time they respond to Q1). Go to Q12 for enrolled women who respond “No” when this question is asked as part of a repeat questionnaire.

***[Questions for women currently pregnant]***

2. Congratulations! What is your due date? {duedate}
  - Calendar response
3. Did you receive an ultrasound exam? {ultrasound}
  - Yes → Q4 {True}
  - No → Q5 {False}
4. When did you have your first ultrasound exam? {firstultrasound}
  - First trimester {First Trimester}
  - Second trimester {Second Trimester}
  - Third trimester {Third trimester}
5. About how far along were you when you found out you were pregnant? {faralong}
  - Free text - # weeks
  - Not sure
6. Is it a multiple pregnancy? (e.g. twins, triplets, etc.) {Multiplepregnanc}
  - Yes {Yes}
  - No {No}
  - Not sure {Unsure}
7. Was your pregnancy planned? {Planned}
  - Yes {Yes}
  - No, but it was not completely unplanned {False1}
  - No, it was not planned {False2}
8. For this pregnancy, did you become pregnant while undergoing infertility treatment? (we mean: medications, artificial insemination, IVF or other procedures) {infertility}
  - Yes → Q9 {True}
  - No → Q9 {False}
9. What was your weight right before you became pregnant? {prepregweight}
  - Number – with unit as pounds

10. What is your height? {height}
- Select from drop down

Questions for women who answer “No” to Q1 at initial baseline questionnaire (are you currently pregnant). These are women who are recruited, consent to participate, but are no longer pregnant at the time they respond to Q1. (continuation of baseline survey, not a new survey)

11. When was your due date? {pastduedate}
- Calendar response
12. Did you receive an ultrasound exam? {ultrasound1}
- Yes → Q13 {true}
  - No → Q14 {false}
13. When did you have your first ultrasound exam?
- First trimester {First trimester}
  - Second trimester {Second trimester}
  - Third trimester {Third trimester}
14. About how far along were you when you found out you were pregnant? {faralong1}
- Free text - # weeks
15. Was your pregnancy planned? {Planned}
- Yes {true}
  - No, but it was not completely unplanned {false1}
  - No, it was not planned {false2}
16. For this pregnancy, did you become pregnant while undergoing infertility treatment? Fertility treatments include: medications, artificial insemination, IVF or other procedures.
- Yes {True}
  - No {False}
17. Did you have a live birth?
- Yes → Q39 {True}
  - No → Q18 {False}

**[Questions for women NOT currently pregnant without a live birth]**

18. Did you experience a miscarriage (loss of the pregnancy prior to 20 weeks)?
- Yes → Q19
  - No → Q23
19. We are very sorry for your loss. We hope you will consider completing the study. What we learn from you could help other women in the future. Approximately when did the miscarriage occur?
- Calendar response
20. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.
- Yes → Q21
  - No → Q22
21. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the next medication exposure questionnaire in the app to continue.
22. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off

in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.

23. Did you have a stillbirth (death of the fetus after 20 weeks but prior to delivery)?
  - Yes → Q24
  - No → Q30
24. We are very sorry for your loss. We hope you will consider completing the questionnaire. What we learn from you could help other women in the future.  
Approximately, when did the stillbirth occur?
  - Calendar Response
25. Were any birth defects identified?
  - Yes
  - No
  - Not sure
26. If you can recall the name of the birth defect, please enter it here:
  - Free text
27. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.
  - Yes → Q28
  - No → Q29
28. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the next medication exposure questionnaire in the app to continue.
29. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.
30. Did you have an abortion?
  - Yes → Q31
  - No → Q33
  - Other – free text → Q35
31. Approximately, when did the abortion occur?
  - Calendar response
32. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.
  - Yes → Q33
  - No → Q34
33. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the questionnaire labeled “Final Exposure Survey” in the app to continue.
34. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.
35. Please enter the outcome of your pregnancy here:
  - Free text

36. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.
  - Yes → Q37
  - No → Q38
37. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the questionnaire labeled “Final Exposure Survey” in the app to continue.
38. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.

***[Questions for women NOT currently pregnant with a live birth]***

39. What day was your baby born?
  - Calendar response
40. At what gestational age was your baby born?
  - Number field for weeks
  - Not sure
41. Newborn information: please enter all the information you can recall about your newborn
  - Birth weight
  - Length
  - Head circumference
  - Apgar score
42. *Some women experience sad or challenging outcomes. We would like to know about these so we can try to keep women and their babies healthy. We hope you will be willing to answer some questions even though it might be hard. Knowing this will help us work to help you and other women have a healthy future.*
43. Were any birth defects identified?
  - Yes → Q40
  - No → Q41
  - Not sure → Q41
44. If you can recall the name of the birth defect, please enter it here:
  - Free text
45. Did your baby have to go to intensive care?
  - Yes
  - No
46. Is your baby still alive?
  - Yes → Q43
  - No → Q46
47. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.
  - Yes → Q44
  - No → Q45
48. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the next medication exposure questionnaire in the app to continue.

49. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.
50. We are very sorry for your loss. We hope you will consider completing the questionnaire. What we learn from you could help other women in the future.  
Approximately, when did your baby die?
- Calendar response
51. What did your baby die of?
- Free text
52. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.
- Yes → Q49
  - No → Q50
53. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the next medication exposure questionnaire in the app to continue. *[Note: this cohort will receive exposure questionnaires for ongoing conditions and vaccines only.]*
54. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.

### **Weight Questionnaire – repeating**

55. Please enter your weight on the next screen. This is optional, but if you enter your weight you can track your weight over time on the study dashboard.

### **56. What is your current weight?**

- Number – with unit as pounds

**Activity short title: PregnancyOutcome**

**Title: Pregnancy Outcome Questionnaire**

**Schedule: One time**

**Launch date:**

**Times to repeat: 0**

1. Title: Please only continue this questionnaire if you are no longer pregnant. {OutcomeInst}  
Content: This questionnaire will tell us about the outcome of your pregnancy. If you're still pregnant, please close this questionnaire and do not continue.
2. Did you have a live birth?
  - Yes → Q24
  - No → Q3

***[Questions for women NOT currently pregnant without a live birth]***

3. Did you experience a miscarriage? (Loss of pregnancy prior to 20 weeks.)
  - a. Yes → Q4
  - b. No → Q8

4. We are very sorry for your loss. We hope you will consider completing the study. What we learn from you could help other women in the future.  
Approximately when did the miscarriage occur?
  - a. Calendar response
5. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.
  - a. Yes → Q6
  - b. No → Q7
6. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the questionnaire labeled “Final Exposure Survey” in the app to continue.
7. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.
8. Did you have a stillbirth (death of the fetus after 20 weeks but prior to delivery)?
  - a. Yes → Q9
  - b. No → Q15
9. We are very sorry for your loss. We hope you will consider completing the questionnaire. What we learn from you could help other women in the future.  
Approximately, when did the stillbirth occur?
  - a. Calendar Response
10. Were any birth defects identified?
  - a. Yes
  - b. No → Q12
  - c. Not sure → Q12
11. If you can recall the name of the birth defect, please enter it here:
  - a. Free text
12. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.
  - a. Yes → Q13
  - b. No → Q14
13. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the questionnaire labeled “Final Exposure Survey” in the app to continue.
14. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.
15. Did you have an abortion?
  - a. Yes → Q16
  - b. No → Q18
  - c. Other → Q20
16. Approximately, when did the abortion occur?
  - a. Calendar response
17. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.



- a. Yes → Q18
  - b. No → Q19
18. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the questionnaire labeled “Final Exposure Survey” in the app to continue.
  19. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.
  20. Please enter the outcome of your pregnancy here:
    - a. Free text
  21. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.
    - Yes → Q37
    - No → Q38
  22. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the questionnaire labeled “Final Exposure Survey” in the app to continue.
  23. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.

***[Questions for women NOT currently pregnant with a live birth]***

24. What day was your baby born?
  - a. Calendar response
25. At what gestational age was your baby born?
  - a. Number field for weeks
  - b. Not sure
26. Newborn information: please enter all the information you can recall about your newborn
  - a. Birth weight
  - b. Length
  - c. Head circumference
  - d. Apgar score
27. *Some women experience sad or challenging outcomes. We would like to know about these so we can try to keep women and their babies healthy. We hope you will be willing to answer some questions even though it might be hard. Knowing this will help us work to help you and other women.*
28. Were any birth defects identified?
  - a. Yes
  - b. No → Q26
  - c. Not sure → Q26
29. If you can recall the name of the birth defect, please enter it here:
  - a. Free text
30. Did your baby have to go to intensive care?
  - a. Yes
  - b. No
31. Is your baby still alive?
  - a. Yes → Q28
  - b. No → Q31

32. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.
  - a. Yes → Q29
  - b. No → Q30
33. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the questionnaire labeled “Final Exposure Survey” in the app to continue.
34. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.
35. We are very sorry for your loss. We hope you will consider completing the questionnaire. What we learn from you could help other women in the future.
 

Approximately, when did your baby die?

  - a. Calendar response
36. What did your baby die of?
  - a. Free text
37. Would you like to answer any more questions about your medication exposure since the last time you used the app? Understanding the medications you took since the last time you used the app could help other women.
  - a. Yes → Q34
  - b. No → Q35
38. Thank you for agreeing to continue to answer questions about your medication exposure. Please go to the questionnaire labeled “Final Exposure Survey” in the app to continue.
39. Thank you for your participation and the information you have provided us. Your answers will help other women in the future. To no longer receive app notifications, you can turn app notifications off in your user profile. If you want to formally leave the study, please go to the study resources section and follow instructions to leave the study.

**Activity short title: SmokeBaseline**

**Title: Baseline Smoking and Vaping Exposure Questionnaire**

**Schedule: One time**

***Baseline Smoking and Vaping Exposure***

1. *The next few questions are going to be about your exposure to smoking before and after you became pregnant. Your responses are confidential and will only be used for research purposes. If you would like more information on smoking exposure and pregnancy, please look in the resource section of this app.* {SmokeInstruct}
2. Did you smoke cigarettes before becoming pregnant? {Smoke}
  - Yes {True}
  - No {False} → Q6
3. How many cigarettes, on average, did you smoke per day? {SmokeAmnt}
  - 1-4 per day {1}
  - 1/2 pack (5-14) per day {2}
  - 1 pack (15-24) per day {3}
  - More than 1 pack (25 or more) per day {4}

4. Have you smoked cigarettes since you became pregnant? {Smoke1}
  - Yes {True}
  - No {False} → Q6
5. How many cigarettes (on average) do you smoke per day? {SmokeAmnt1}
  - 1-4 per day {1}
  - 1/2 pack (5-14) per day {2}
  - 1 pack (15-24) per day {3}
  - More than 1 pack (25 or more) per day {4}
6. Did you smoke electronic cigarettes (e-cigs, vaping) before becoming pregnant? {Vaping}
  - Yes {True}
  - No {False} → End questionnaire
7. Before becoming pregnant, how often did you vape or use an e-cigarette for tobacco? {VapingAmnt}
  - Every day {1}
  - A few days a week {2}
  - A few days a month {3}
  - Once a month or less {4}
8. On days when you vaped or used an e-cigarette before you became pregnant, how many puffs, on average, did you take? {VapingAmnt1}
  - Numerical field {Integer}
9. Have you smoked electronic cigarettes (e-cigs, vaping) since you became pregnant? {Vaping1}
  - Yes {True}
  - No {False} → Q12
10. How often do you vape or use e-cigarettes? {VapingAmnt2}
  - Every day {1}
  - A few days a week {2}
  - A few days a month {3}
  - Once a month or less {4}
11. How many puffs, on average, do you take? {VapingAmnt3}
  - Numerical field {Integer}
12. Since you became pregnant, have you taken any medications to stop smoking? {SmokeMed}
  - Yes {True}
  - No {False} → End questionnaire
- {SmokeMedForm}
13. What medication did you take? {SmokeMed1}
  - drop down for smoking cessation meds
14. If your medication is not in this list, please enter it here: {SmokeMedText}
  - Free text
15. What dose do you take? {SmokeMedDose}
  - Free text
16. How often do you take this? {SmokeMedFreq}
  - Once a day {1}
  - Twice a day {2}
  - Three times a day {3}
  - Less than once a day but at least once a week {4}
  - Other {4} – free text

17. When during your pregnancy did you start taking this medication to stop smoking? {SmokeMedStart}

- Calendar response

18. When did you stop taking this medication? {SmokeMedStop}

- Calendar response
- Still taking this medication

**Activity short title: RepeatSmoke**

**Title: Questionnaire about current smoking exposure**

**Schedule: Monthly**

**Launch date: 6/13/2017 at 5pm for UAT**

**Times to repeat: 4**

### **Repeat Smoking Questionnaire**

1. Have you smoked cigarettes since you last answered this question in this app? {Smoke2}
  - Yes {True}
  - No {False} → Q3
2. How many cigarettes (on average) have you smoked per day? {SmokeAmnt2}
  - 1-4 per day {1}
  - 1/2 pack (5-14) per day {2}
  - 1 pack (15-24) per day {3}
  - More than 1 pack (25 or more) per day {4}
3. Have you taken any medications to stop smoking since you last answered this question in this app? {SmokeMed2}
  - Yes {True} → Q4
  - No {False} → End questionnaire

{SmokeMedForm1}

What medication did you take? {SmokeMed3}

- drop down for smoking cessation meds

4. If your medication is not in this list, please enter it here: {SmokeMedText1}

- Free text

5. What dose do you take? {SmokeMedDose1}

- Free text with dial for mg, mg/mL, etc.
- Not sure

6. How often do you take this? {SmokeMedFreq1}

- Once a day {1}
- Twice a day {2}
- Three times a day {3}
- Less than once a day but at least once a week {4}
- Other {4} – free text

7. When during your pregnancy did you start taking this medication to stop smoking? {SmokeMedStart1}

- Calendar response

8. When did you stop taking this medication? {SmokeMedStop1}

- Calendar response

- Still taking this medication

**Activity short title:** RepeatVaping

**Title:** Questionnaire about current e-cigarette exposure

**Schedule:** Monthly

**Launch date:** 6/13/2017 at 5pm for UAT

**Times to repeat:** 4

### **Repeat Vaping Questionnaire**

1. Have you smoked electronic cigarettes (e-cigs, vaping) since you last answered this question in this app? {Vaping2}
  - Yes {True}
  - No {False} → End questionnaire
2. How often do you vape or use e-cigarettes? {VapingAmnt4}
  - Every day {1}
  - A few days a week {2}
  - A few days a month {3}
  - Once a month or less {4}
3. How many puffs, on average, do you take? {VapingAmnt5}
  - Numerical field {Integer}

**Activity short title:** RepeatVaccine

**Title:** Questionnaire about current vaccine exposure

**Schedule:** One time

**Start date:** 6/19/2017 at 5pm for UAT

**End date:** 6/22/2017 at 5pm for UAT

**Times to repeat:** 0

### **Vaccine Exposure – repeat at the end of the study period**

1. Have you gotten any vaccines since you last answered this question in the app? {Vaccine2}
  - Yes {True}
  - No {False} → End questionnaire
2. What vaccine did you get? {Vaccine3}
  - Flu vaccine {1}
  - Tdap vaccine (also known as Pertussis or Whooping Cough vaccine) {2}
  - HPV vaccine {3}
  - Other – free text {4}
  - Not sure {5}
3. Approximately, when did you get this vaccine? {VaccineDate1}
  - Calendar response
  - Not sure

**[CB] Core Baseline Questions – Establishing ongoing medication use as well as stopping medications due to pregnancy**

***Ongoing medication use – These questions will recur. Language for recurring questions begins on page 14 of this document***

1. Has a doctor or other healthcare provider told you that you have one of the following conditions? If you have a condition that is not listed select “Other” and write the name of the condition.
  - Diabetes
  - Hypertension or High Blood Pressure
  - High Cholesterol
  - Seizures or Epilepsy
  - Asthma
  - Hypothyroidism
  - Lupus
  - Crohn’s Disease
  - Irritable Bowel Syndrome
  - Migraines
  - Fibromyalgia
  - Psoriasis
  - ADHD
  - Depression
  - Anxiety or panic attacks
  - Bipolar Disorder
  - Other → Free text
  - I have no ongoing conditions → End questionnaire

**FOR ALL CONDITIONS EXCEPT DIABETES, HIGH BLOOD PRESSURE, OR SEIZURES/EPILEPSY**

2. Are you currently taking any medications for this condition?
  - Yes
  - No → Q9
3. What medication do you take?
  - Drop down of common meds for this condition
4. If your medication is not in this list, please enter it here:
  - Free text
5. What dose do you take?
  - Free text with dial for mg, mg/mL, etc.
  - Not sure
6. How often do you take the medication?
  - Once a day
  - Twice a day
  - Three times a day
  - Less than once a day but at least once a week
  - Other – free text
7. Did you start taking this medication during your current pregnancy?
  - Yes → Q8
  - No → Q9

8. What was the earliest week of pregnancy when you took this medication?
  - Select from week range (weeks 1-40)
9. Have you taken any medications for this condition in the last year?
  - Yes → Q10
  - No → End questionnaire
10. What medication did you take?
  - Drop down of medications for this condition
11. If your medication is not in this list, please enter it here:
  - Free text
12. When did you stop taking the medication?
  - Calendar response
13. Why did you stop taking the medication?
  - The health condition went away
  - My healthcare provider recommended that I stop because I was pregnant
  - My health care provider recommended that I switch to a different medication because I was pregnant
    - I decided not to take it on my own because I was pregnant
    - I decided to switch to another medication on my own because I was pregnant
  - Other - free text

#### **QUESTIONS FOR DIABETES:**

14. What type of diabetes do you have?
  - Gestational, that is during the current pregnancy only → Q15
  - Type I Diabetes also called juvenile diabetes → Q16
  - Type II Diabetes also called or Adult onset diabetes → Q16
  - Don't know → Q16
15. How far along were you in this pregnancy when you were diagnosed with Gestational Diabetes?
  - Select from week range → Q17
  - Not sure → Q17
16. How old were you when you were diagnosed?
  - Age drop down
17. Have you taken insulin during this pregnancy?
  - Yes
  - No → Q22
  - Not sure → Q22
18. What was the earliest week of pregnancy when you took insulin?
  - Select from week range
19. Are you taking insulin now?
  - Yes
  - No → Q22
  - Not sure → Q22
20. Which type of insulin do you take?
  - Insulin drop down
21. If your medication is not in this list, please enter it here:
  - Free text
22. Are you currently taking any other medications besides insulin for diabetes?

- Yes
  - No → Q29
23. What medication do you take?
- Drop down of common meds for diabetes
24. If your medication is not in this list, please enter it here:
- Free text
25. What dose do you take?
- Free text with dial for mg, mg/mL, etc.
  - Not sure
26. How often do you take the medication?
- Once a day
  - Twice a day
  - Three times a day
  - Less than once a day but at least once a week
  - Other – free text
27. [Will not see if select gestational diabetes] Did you start taking this medication during your current pregnancy?
- Yes → Q28
  - No → Q29
28. What was the earliest week of pregnancy when you took this medication?
- Select from week range (weeks 1-40)
29. Have you taken any medications for this condition in the last year besides insulin?
- Yes
  - No → End questionnaire
30. What medication did you take?
- Drop down of medications for this condition
31. If your medication is not in this list, please enter it here:
- Free text
32. When did you stop taking the medication?
- Calendar response
33. Why did you stop taking the medication?
- The health condition went away
  - My healthcare provider recommended that I stop because I was pregnant
  - My health care provider recommended that I switch to a different medication because I was pregnant
    - I decided not to take it on my own because I was pregnant
    - I decided to switch to another medication on my own because I was pregnant
  - Other - free text

**QUESTIONS FOR HYPERTENSION OR HIGH BLOOD PRESSURE**

34. Were you ever diagnosed with high blood pressure or hypertension before this pregnancy?
- Yes
  - No → Q45
  - Not sure
35. Are you currently taking any medications for this condition?



- Yes
  - No → Q40
36. What medication do you take?
- Drop down of common meds for this condition
37. If your medication is not in this list, please enter it here:
- Free text
38. What dose do you take?
- Free text with dial for mg, mg/mL, etc.
  - Not sure
39. How often do you take the medication?
- Once a day
  - Twice a day
  - Three times a day
  - Less than once a day but at least once a week
  - Other – free text
40. Have you taken any medications for this condition in the last year?
- Yes
  - No → End questionnaire
41. What medication did you take?
- Drop down of medications for this condition
42. If your medication is not in this list, please enter it here:
- Free text
43. When did you stop taking the medication?
- Calendar response
44. Why did you stop taking the medication?
- The health condition went away
  - My healthcare provider recommended that I stop because I was pregnant
  - My health care provider recommended that I switch to a different medication because I was pregnant
    - I decided not to take it on my own because I was pregnant
    - I decided to switch to another medication on my own because I was pregnant
  - Other - free text

***[Women who said they did not have HBP before pregnancy]***

45. Were you diagnosed with high blood pressure or hypertension for the first time during this pregnancy?
- Yes
  - No
  - Not sure
46. What was the earliest week of this pregnancy when you were diagnosed with high blood pressure or hypertension?
- Select from week range (weeks 1-40)
47. Did your doctor or healthcare provider say that you had Gestational Hypertension?
- Yes
  - No
  - Not sure

48. Did your doctor or healthcare provider say that you had Pre-Eclampsia?
- Yes
  - No
  - Not sure
49. Are you currently taking any medications for high blood pressure or hypertension that started during this pregnancy?
- Yes
  - No → End questionnaire
50. What medication do you take?
- Drop down of common meds for this condition
51. If your medication is not in this list, please enter it here:
- Free text
52. What dose do you take?
- Free text with dial for mg, mg/mL, etc.
  - Not sure
53. How often do you take the medication?
- Once a day
  - Twice a day
  - Three times a day
  - Less than once a day but at least once a week
  - Other – free text
54. What was the earliest week of pregnancy when you took this medication?
- Select from week range (weeks 1-40)

**FOR SEIZURES OR EPILEPSY:**

55. Were you ever diagnosed with seizures or epilepsy before this pregnancy?
- Yes
  - No → Q66
  - Not sure
56. Are you currently taking any medications for seizures or epilepsy?
- Yes
  - No → Q61
57. What medication do you take?
- Drop down of common meds for seizures or epilepsy
58. If your medication is not in this list, please enter it here:
- Free text
59. What dose do you take?
- Free text with dial for mg, mg/mL, etc.
  - Not sure
60. How often do you take the medication?
- Once a day
  - Twice a day
  - Three times a day
  - Less than once a day but at least once a week
  - Other – free text
61. Have you taken any medications for this condition in the last year?

- Yes
  - No → Q66
62. What medication did you take?
- Drop down of medications for this condition
63. If your medication is not in this list, please enter it here:
- Free text
64. When did you stop taking the medication?
- Calendar response
65. Why did you stop taking the medication?
- The seizures went away
  - My healthcare provider recommended that I stop because I was pregnant
  - My health care provider recommended that I switch to a different medication because I was pregnant
    - I decided not to take it on my own because I was pregnant
    - I decided to switch to another medication on my own because I was pregnant
  - Other - free text
66. Were you diagnosed with seizures for the first time during this pregnancy?
- Yes
  - No
  - Not sure
67. What was the earliest week of pregnancy when you were diagnosed with seizures or epilepsy?
- Select from week range (weeks 1-40)
68. [Since the last time you used the app,] Are you taking any medications to prevent seizures?
- Yes
  - No → End questionnaire
69. What medication do you take?
- Drop down of common meds
70. What dose do you take?
- Free text with dial for mg, mg/mL, etc.
  - Not sure
71. How often do you take the medication?
- Once a day
  - Twice a day
  - Three times a day
  - Less than once a day but at least once a week
  - Other – free text
72. What was the earliest week of pregnancy when you took this medication?
- Select from week range (weeks 1-40)
73. Since the last time you answered questions about medication use, have you experienced a seizure?
- Yes
  - No → End questionnaire
  - Not sure → End questionnaire
74. On what date did you experience a seizure?
- Calendar response → End questionnaire

**Recurring ongoing medication use**

1. Has a doctor or other healthcare provider told you that you have one of the following conditions? (can choose more than one) Please still select a condition even if you have previously told us you have this condition in an earlier questionnaire.
  - Diabetes
  - Hypertension or High Blood Pressure
  - High Cholesterol
  - Seizures or Epilepsy
  - Asthma
  - Hypothyroidism
  - Lupus
  - Crohn's Disease
  - Irritable Bowel Syndrome
  - Migraines
  - Fibromyalgia
  - Psoriasis
  - ADHD
  - Depression
  - Anxiety or panic attacks
  - Bipolar Disorder
  - Other → Free text
  - I have no ongoing conditions → End questionnaire
2. Is this a new condition?
  - Yes → Q3
  - No → Q7
3. Are you currently taking any medications for this condition?
  - Yes
  - No → Q15
4. What do you take?
  - Drop down of common meds for this condition
  - Other and Free Text
5. What dose do you take?
  - Free text with dial for mg, mg/mL, etc.
  - Not sure
6. How often do you take the medication? (End section for all response options)
  - Once a day
  - Twice a day
  - Three times a day
  - Less than once a day but at least once a week
  - Other – Free text
7. Are you taking any new medications for this condition since the last time you answered questions about this in this app?
  - Yes → Q12
  - No → Q8
8. Has the dosage changed for your current medication for this condition?
  - Yes → Q9
  - No → Q10

9. What is the new dosage?
  - Free text with dial for mg, mg/mL, etc.
  - Not sure
10. Did the frequency you take this medication change since the last time you answered questions about this in this app?
  - Yes → Q11
  - No → Q15
11. How often do you take this medication now? (End section for all response options)
  - Once a day
  - Twice a day
  - Three times a day
  - Less than once a day but at least once a week
  - Other – free text
12. What do you take?
  - Drop down of common meds for this condition
  - Other and Free Text
13. What dose do you take?
  - Free text with dial for mg, mg/mL, etc.
  - Not sure
14. How often do you take the medication?
  - Once a day
  - Twice a day
  - Three times a day
  - Less than once a day but at least once a week
  - Other – free text
15. Have you stopped any medications for this condition since the last time you answered questions about this in this app?
  - Yes
  - No → End of questionnaire
16. Which medication did you stop?
  - Drop down of common meds for this condition
  - Other and Free text

**[CB] Core Baseline Questions – Establishing episodic medication use during pregnancy**

1. *Initial Question:* Have you experienced any of the following symptoms or conditions during this pregnancy? (select all that apply) [Note for development team: terms in brackets below ([]) are to indicate condition type and will not appear in the questionnaire text.]

**Recurring Question:** Have you experienced any of the following symptoms or conditions since you last answered this question in this app? (select all that apply)

- Nausea related to pregnancy
- Gastroenteritis (stomach bug, diarrhea, vomiting) [infection]
- Heartburn or acid reflux
- Constipation
- Cold [respiratory illness]
- Flu [respiratory illness]
- Bronchitis [respiratory illness]

- Pneumonia [respiratory illness]
- Outdoor or indoor allergies
- Headaches
- Sleeping problems
- Urinary tract infection [infection]
- Sinus infection [infection]
- Vaginal yeast infection [infection]
- Other fever
- Pain bad enough to take a medication
- Anxiety or panic attacks
- Depression
- None of these → End questionnaire

2. When did your symptom or condition start?

- Calendar response

3. When did your symptom or condition stop?

- Calendar response
- Ongoing

4. Did you take any medications for this?

- Yes
- No → End questionnaire

5. What medication was it?

- Drop down from common meds

6. What was the dose of the medication?

- Free text with dial for mg, mg/mL, etc.

7. How often did you take it?

- Once a day
- Twice a day
- Three times a day
- Less than once a day but at least once a week
- Other – free text

8. When did you start taking this medication?

- Drop down for week #/range/month

9. When did you stop taking this medication?

- Drop down for week #/range/month
- Still taking this medication

10. Did your health care provider prescribe this medication?

- Yes → End questionnaire
- No → Q11

11. Did you discuss this medication with your health care provider?

- Yes
- No

**For pregnancy related nausea when selected “ongoing” to Q3 in this section:**

12. Since you are having nausea related to pregnancy, we’d like to know more about how you’re feeling. In the last 12 hours, for how long have you felt nauseated or sick to your stomach?

- Not at all

- 1 hour or less
  - 2 to 3 hours
  - 4 to 6 hours
  - More than 6 hours
13. In the last 12 hours, have you vomited or thrown up?
- 7 or more times
  - 5 to 6 times
  - 3 to 4 times
  - 1 to 3 times
  - I did not throw up
14. In the last 12 hours, how many times have you had retching or dry heaves without bringing anything up?
- No times
  - 1 to 2 times
  - 3 to 4 times
  - 5 to 6 times
  - 7 or more times

**FOR CONDITIONS ASSOCIATED WITH FEVER (gastroenteritis, respiratory, infections, other fever):**

15. Did you have a fever with this condition?
- Yes
  - No → End questionnaire
16. How long did this fever last?
- A few hours
  - 1 day
  - 2 days
  - More than 3 days
17. Did you take your temperature?
- Yes
  - No
18. What was the highest temperature you had?
- Numeric field: allow 3 digits before the decimal and 1 decimal place after. Range check

**STOP Core Baseline [CB] “Chunk”**

**Activity short title: PregHist**

**Title: Questionnaire about your pregnancy history**

**Schedule: One time at baseline**

**Start date:**

**End date:**

**Times to repeat: 0**

**Other Baseline Chunks are interspersed over the weeks in order of priority:**

***Prior Pregnancy History & Maternal and Paternal History of Birth Defects Module***

1. Have you been pregnant before? {PastPreg}
  - Yes {True}
  - No {False} → End questionnaire
2. On the next screen, we're going to ask about pregnancy outcomes. {PastPreg2}
3. How many of your previous pregnancies ended with: {PastPreg1}
  - Live birth {LiveBirth}
  - Stillbirth (pregnancy loss after 20 weeks) {Stillbirth}
  - Miscarriage (before 20 weeks) {Miscarriage}
  - Abortion {Abortion}
  - Ectopic pregnancy (pregnancy that occurs outside the uterus) {Ectopic}
  - Other {Other} – free text
4. In any of your pregnancies, did you have any health problems or pregnancy complications? {PregComp}
  - Yes {TRUE} → Q5
  - No {FALSE} → Q6
  - Not sure {UNSURE} → Q6
5. What health problem(s) did you have? *You can choose more than one.* {PregComp1}
  - Gestational diabetes {1}
  - High blood pressure {2}
  - Preterm birth (before 37 weeks gestation) {3}
  - Other {4} – free text
6. In any of your pregnancies, did your baby have any birth defects? {PastDef}
  - Yes {1} → Q7
  - No {2} → Q8
  - Not sure {3} → Q8
7. What birth defect(s) were your child(ren) diagnosed with? {PastDef1}
  - Free text
8. Were you diagnosed with any birth defects when you were a child? {MomDef}
  - Yes {TRUE} → Q9
  - No {FALSE} → Q10
  - Not sure {UNSURE} → Q10
9. What birth defect were you diagnosed with? {MomDef1}
  - Free text



10. Was the baby's father for your current pregnancy diagnosed with any birth defects when he was a child? {DadDef}
  - Yes {TRUE} → Q11
  - No {FALSE} → End questionnaire
  - Not sure {UNSURE} → End questionnaire
11. What birth defect was the baby's father for your current pregnancy diagnosed with? {DadDef1}
  - Free text

**Activity short title: Race**

**Title: Questionnaire about your race and ethnicity**

**Schedule: One time at baseline**

**Start date:**

**End date:**

**Times to repeat: 0**

**Maternal Race/Ethnicity Question**

1. What is your race or ethnicity? *You can select more than one response.* {RaceEth}
  - White {1}
  - Hispanic or Latina {2}
  - Black or African American {3}
  - Asian {4}
  - Native Hawaiian or Other Pacific Islander {5}
  - Native American or Alaska Native {6}
  - Other {7} – Free text
  - Not sure or prefer not to answer {8}

**Activity short title: BaselineVitamin**

**Title: Questionnaire about your vitamin use**

**Schedule: One time at baseline**

**Start date:**

**End date:**

**Times to repeat: 0**

**Baseline Vitamin Module**

1. Do you take a prenatal vitamin? {Prenatal}
  - Yes {TRUE}
  - No {FALSE} → Q4
  - Not sure {UNSURE}
2. When did you start taking this prenatal vitamin? {Prenatal1}
  - Before pregnancy {1}
  - After I found out I was pregnant {2}
  - Not sure {3}
3. How often do you take this prenatal vitamin? (go to Q11 of this section for all responses) {Prenatal2}
  - Once a day {1}
  - 3-6 times per week {2}

- 1-2 times per week {3}
  - Less than once a week {4}
  - Other {5} – free text
4. Do you take folic acid, separate from a prenatal or a multivitamin? {Folic}
    - Yes {TRUE}
    - No {FALSE} → Q8
  5. When did you start taking folic acid? {Folic1}
    - Before pregnancy {1}
    - After I found out I was pregnant {2}
    - Not sure {3}
  6. How often do you take folic acid? {Folic2}
    - Once a day {1}
    - 3-6 times per week {2}
    - 1-2 times per week {3}
    - Less than once a week {4}
    - Other {5} – free text
  7. Do you know the dosage of the folic acid you take? {Folic3}
    - Free text with dial for mg, mg/mL, etc.
    - Not sure
  8. Do you take a multi-vitamin other than a prenatal vitamin? {MutiVit}
    - Yes {TRUE}
    - No {FALSE} → Q11
  9. When did you start taking this multi-vitamin? {MultiVit1}
    - Before pregnancy {1}
    - After I found out I was pregnant {2}
    - Not sure {3}
  10. How often do you take this multi-vitamin? {MultiVit2}
    - Once a day {1}
    - 3-6 times per week {2}
    - 1-2 times per week {3}
    - Less than once a week {4}
    - Other {5} – free text
  11. Do you take other vitamins? {OtherVit}
    - Yes {TRUE}
    - No {FALSE} → End questionnaire
  12. What other vitamins do you take (select only 1)? {OtherVit1}
    - Vitamin D {1}
    - B12 {2}
    - DHA {3}
    - Other {4} – free text
  13. When did you start taking this vitamin? {OtherVit2}
    - Before pregnancy {1}
    - After I found out I was pregnant {2}
    - Not sure {3}
  14. How often do you take this vitamin? {OtherVit3}
    - Once a day {1}

- 3-6 times per week {2}
  - 1-2 times per week {3}
  - Less than once a week {4}
  - Other {5} – free text
15. What dose of this vitamin do you take? {OtherVit4}
- Free text with dial for mg, mg/mL, etc.
  - Not sure
16. Do you take any other vitamins? {OtherVit5}
- Yes {TRUE} → Q17
  - No {FALSE} → End questionnaire
17. What other vitamins do you take? {OtherVit6}
- Vitamin D {1}
  - B12 {2}
  - DHA {3}
  - Other {4} – free text
18. When did you start taking this vitamin? {OtherVit7}
- Before pregnancy {1}
  - After I found out I was pregnant {2}
  - Not sure {3}
19. How often do you take this vitamin? {OtherVit8}
- Once a day {1}
  - 3-6 times per week {2}
  - 1-2 times per week {3}
  - Less than once a week {4}
  - Other {5} – free text
20. What dose of this vitamin do you take? {OtherVit9}
- Free text with dial for mg, mg/mL, etc.
  - Not sure
21. Do you take any other vitamins? {OtherVit10}
- Yes {TRUE} → Q22
  - No {FALSE} → End questionnaire
22. What other vitamins do you take? {OtherVit11}
- Vitamin D {1}
  - B12 {2}
  - DHA {3}
  - Other {4} – free text
23. When did you start taking this vitamin? {OtherVit12}
- Before pregnancy {1}
  - After I found out I was pregnant {2}
  - Not sure {3}
24. How often do you take this vitamin? {OtherVit13}
- Once a day {1}
  - 3-6 times per week {2}
  - 1-2 times per week {3}
  - Less than once a week {4}
  - Other {5} – free text

25. What dose of this vitamin do you take? {OtherVit14}
  - Free text with dial for mg, mg/mL, etc.
  - Not sure
26. Do you take any other vitamins? {OtherVit15}
  - Yes {TRUE} → Q27
  - No {FALSE} → End questionnaire
27. What other vitamins do you take? {OtherVit16}
  - Vitamin D {1}
  - B12 {2}
  - DHA {3}
  - Other {4} – free text
28. When did you start taking this vitamin? {OtherVit17}
  - Before pregnancy {1}
  - After I found out I was pregnant {2}
  - Not sure {3}
29. How often do you take this vitamin? {OtherVit18}
  - Once a day {1}
  - 3-6 times per week {2}
  - 1-2 times per week {3}
  - Less than once a week {4}
  - Other {5} – free text
30. What dose of this vitamin do you take? {OtherVit19}
  - Free text with dial for mg, mg/mL, etc.
  - Not sure

**Activity short title: RepeatVitamin**

**Title: Questionnaire about your recent vitamin use**

**Schedule: Monthly**

**Start date:**

**End date:**

**Times to repeat: 0**

**Repeat Vitamin Module**

1. Have you taken any new vitamins since you last used this app? {NewVit}
  - Yes {TRUE}
  - No {FALSE} → End questionnaire
2. What vitamin did you take? {NewVit1}
  - Prenatal vitamin {1}
  - Folic acid, not as part of a prenatal vitamin {2}
  - Vitamin D {3}
  - B12 {4}
  - DHA {5}
  - Other {6} – free text
3. When did you start taking this vitamin? {NewVit2}
  - Calendar response

4. How often do you take this vitamin? {NewVit3}
  - Once a day {1}
  - 3-6 times per week {2}
  - 1-2 times per week {3}
  - Less than once a week {4}
  - Other {5} – free text
5. What dose of this vitamin do you take? {NewVit4}
  - Free text with dial for mg, mg/mL, etc.
  - Not sure
6. Did you take any other new vitamins since you last used this app? {NewVit5}
  - Yes {TRUE} → Q7
  - No {FALSE} → End questionnaire
7. What other vitamin did you take? {NewVit6}
  - Prenatal vitamin {1}
  - Folic acid, not as part of a prenatal vitamin {2}
  - Vitamin D {3}
  - B12 {4}
  - DHA {5}
  - Other {6} – free text
8. When did you start taking this vitamin? {NewVit7}
  - Calendar response
9. How often do you take this vitamin? {NewVit8}
  - Once a day {1}
  - 3-6 times per week {2}
  - 1-2 times per week {3}
  - Less than once a week {4}
  - Other {5} – free text
10. What dose of this vitamin do you take? {NewVit9}
  - Free text with dial for mg, mg/mL, etc.
  - Not sure
11. Did you take any other new vitamins since you last used this app? {NewVit10}
  - Yes {TRUE} → Q12
  - No {FALSE} → End questionnaire
12. What other vitamin did you take? {NewVit11}
  - Prenatal vitamin {1}
  - Folic acid, not as part of a prenatal vitamin {2}
  - Vitamin D {3}
  - B12 {4}
  - DHA {5}
  - Other {6} – free text
13. When did you start taking this vitamin? {NewVit12}
  - Calendar response
14. How often do you take this vitamin? {NewVit13}
  - Once a day {1}
  - 3-6 times per week {2}
  - 1-2 times per week {3}

- Less than once a week {4}
  - Other {5} – free text
15. What dose of this vitamin do you take? {NewVit14}
- Free text with dial for mg, mg/mL, etc.
  - Not sure
16. Did you take any other new vitamins since you last used this app? {NewVit15}
- Yes {TRUE} → Q17
  - No {FALSE} → End questionnaire
17. What other vitamin did you take? {NewVit16}
- Prenatal vitamin {1}
  - Folic acid, not as part of a prenatal vitamin {2}
  - Vitamin D {3}
  - B12 {4}
  - DHA {5}
  - Other {6} – free text
18. When did you start taking this vitamin? {NewVit17}
- Calendar response
19. How often do you take this vitamin? {NewVit18}
- Once a day {1}
  - 3-6 times per week {2}
  - 1-2 times per week {3}
  - Less than once a week {4}
  - Other {5} – free text
20. What dose of this vitamin do you take? {NewVit19}
- Free text with dial for mg, mg/mL, etc.
  - Not sure
21. Did you take any other new vitamins since you last used this app? {NewVit20}
- Yes {TRUE} → Q22
  - No {FALSE} → End questionnaire
22. What other vitamin did you take? {NewVit21}
- Prenatal vitamin {1}
  - Folic acid, not as part of a prenatal vitamin {2}
  - Vitamin D {3}
  - B12 {4}
  - DHA {5}
  - Other {6} – free text
23. When did you start taking this vitamin? {NewVit22}
- Calendar response
24. How often do you take this vitamin? {NewVit23}
- Once a day {1}
  - 3-6 times per week {2}
  - 1-2 times per week {3}
  - Less than once a week {4}
  - Other {5} – free text
25. What dose of this vitamin do you take? {NewVit24}
- Free text with dial for mg, mg/mL, etc.

- Not sure
26. Did you take any other new vitamins since you last used this app? {NewVit25}
- Yes {TRUE} → Q27
  - No {FALSE} → End questionnaire
27. What other vitamin did you take? {NewVit26}
- Prenatal vitamin {1}
  - Folic acid, not as part of a prenatal vitamin {2}
  - Vitamin D {3}
  - B12 {4}
  - DHA {5}
  - Other {6} – free text
28. When did you start taking this vitamin? {NewVit27}
- Calendar response
29. How often do you take this vitamin? {NewVit28}
- Once a day {1}
  - 3-6 times per week {2}
  - 1-2 times per week {3}
  - Less than once a week {4}
  - Other {5} – free text
30. What dose of this vitamin do you take? {NewVit29}
- Free text with dial for mg, mg/mL, etc.
  - Not sure

**Activity short title: BaselineAlcohol**

**Title: Questionnaire about your exposure to alcohol before and since you've been pregnant**

**Schedule: Baseline**

**Start date:**

**End date:**

**Times to repeat: 0**

***Baseline Alcohol Module***

1. *The next few questions are going to be about your exposure to alcohol before and after you became pregnant. Your responses are confidential and will only be used for research purposes. If you would like more information on alcohol and pregnancy, please look in the resource section of this app.*
2. Did you drink alcohol in the 3 months before you found out you were pregnant?
  - Yes {TRUE}
  - No {FALSE} → Q5
3. How many drinks per week did you usually have before you found out you were pregnant (a drink is 1 glass of wine, 1 beer, 1 shot or mixed drink)?
  - 1 drink or less per week {1}
  - 2-4 drinks per week {2}
  - 5-7 drinks per week {3}
  - More than 7 drinks per week {4}
  - Not sure {5}

4. What was the greatest number of drinks you had on one occasion in the 3 months before you found out you were pregnant (a drink is 1 glass of wine, 1 beer, 1 shot or mixed drink)?
  - 1-2 {1}
  - 3-4 {2}
  - 5 or more {3}
  - Not sure {4}
5. Did you drink alcohol after finding out that out you were pregnant?
  - Yes {TRUE}
  - No {FALSE} → End questionnaire
  - Not sure {UNSURE} → End questionnaire
6. How many drinks per week did you usually have after you found out you were pregnant (a drink is 1 glass of wine, 1 beer, 1 shot or mixed drink)?
  - 1 drink or less per week {1}
  - 2-4 drinks per week {2}
  - 5-7 drinks per week {3}
  - More than 7 drinks per week {4}
  - Not sure {5}
7. What was the greatest number of drinks you had on one occasion after you found out you were pregnant?
  - 1-2 {1}
  - 3-4 {2}
  - 5 or more {3}
  - Not sure {4}

**Activity short title: RepeatAlcohol**

**Title: Questionnaire about your recent exposure to alcohol**

**Schedule: Monthly**

**Start date:**

**End date:**

**Times to repeat: 4**

**Repeat Alcohol Module**

1. Did you drink alcohol since you last answered this question in the app?
  - Yes {TRUE}
  - No {FALSE} → End questionnaire
  - Not sure {UNSURE} → End questionnaire
2. How many drinks per week did you usually have since you last answered this question in this app (a drink is 1 glass of wine, 1 beer, 1 shot or mixed drink)?
  - 1 drink or less per week {1}
  - 2-4 drinks per week {2}
  - 5-7 drinks per week {3}
  - More than 7 drinks per week {4}
  - Not sure {5}
3. What was the greatest number of drinks you had on one occasion since the last time you answered this question in this app (a drink is 1 glass of wine, 1 beer, 1 shot or mixed drink)?
  - 1-2 {1}



- 3-4 {2}
- 5 or more {3}
- Not sure {4}

**Activity short title: BaselineMarijuana**

**Title: Questionnaire about your exposure to marijuana or cannabis before and since you've been pregnant**

**Schedule: Baseline**

**Start date:**

**End date:**

**Times to repeat: 0**

***Baseline Marijuana Module***

1. *The next few questions are going to be about your exposure to marijuana before and after you became pregnant. Your responses are confidential and will only be used for research purposes. If you would like more information on marijuana exposure and pregnancy, please look in the resource section of this app.*
2. Did you use any type of marijuana/cannabis before becoming pregnant?
  - Yes {TRUE}
  - No {FALSE} → Q5
3. How often did you use marijuana/cannabis before becoming pregnant?
  - More than once a day {1}
  - Once a day {2}
  - 2-6 days a week {3}
  - Once a week {4}
  - 1-3 times a month {5}
  - Less than once a month {6}
4. How did you most often use marijuana/cannabis before becoming pregnant?
  - Inhale--Smoke (ex: joint, bong) {1}
  - Inhale—Vapor {2}
  - Eat/ingest orally (ex: edibles, capsules, sublingual spray) {3}
  - Absorb through the skin (ex: patch, cream or gel) {4}
  - Other – free text {5}
5. Have you used marijuana/cannabis since you became pregnant?
  - Yes {TRUE}
  - No {FALSE} → End questionnaire
6. How often have you used marijuana/cannabis since you became pregnant?
  - More than once a day {1}
  - Once a day {2}
  - 2-6 days a week {3}
  - Once a week {4}
  - 1-3 times a month {5}
  - Less than once a month {6}
7. During pregnancy, how have you most often used marijuana/cannabis?
  - Inhale--Smoke (ex: joint, bong) {1}

- Inhale—Vapor {2}
- Eat/ingest orally (ex: edibles, capsules, sublingual spray) {3}
- Absorb through the skin (ex: patch, cream or gel) {4}
- Other – free text {5}

**Activity short title: RepeatMarijuana**

**Title: Questionnaire about your recent exposure to marijuana or cannabis**

**Schedule: Monthly**

**Start date:**

**End date:**

**Times to repeat: 4**

**Repeat Marijuana Module**

1. Have you used marijuana/cannabis since you last answered questions in this app?
  - Yes {TRUE}
  - No {FALSE} → End questionnaire
2. How often have you used marijuana/cannabis since you last answered questions in this app?
  - More than once a day {1}
  - Once a day {2}
  - 2-6 days a week {3}
  - Once a week {4}
  - 1-3 times a month {5}
  - Less than once a month {6}
3. How have you most often used marijuana/cannabis since you last answered questions in this app?
  - Inhale--Smoke (ex: joint, bong) {1}
  - Inhale—Vapor {2}
  - Eat/ingest orally (ex: edibles, capsules, sublingual spray) {3}
  - Absorb through the skin (ex: patch, cream or gel) {4}
  - Other – free text {5}

**Activity short title: Education**

**Title: Questionnaire about your education history**

**Schedule: Baseline**

**Start date:**

**End date:**

**Times to repeat: 0**

**Maternal SES Proxy Question**

1. What is the highest level of school you have completed? *If currently in school, tell us the highest degree you have received.*
  - Some high school no degree
  - High school or GED
  - Some college, Associates Degree, Technical Degree
  - 4 year college degree
  - Master's degree
  - More than a Master's degree (MD, PhD, JD, etc.)

### **Baseline Recreational/Illegal Drugs**

*The next few questions are going to be about your exposure to recreational or “street” drugs before and after you became pregnant. Your responses are confidential and will only be used for research purposes. If you would like more information on recreational or “street” drug exposure and pregnancy, please look in the resource section of this app.*

1. Did you use any recreational or “street” drugs in the 3 months before you became pregnant?
  - Yes
  - No → Q5
  - Not sure → Q5
2. Which drug did you use? *Enter only one.*
  - Free text
3. How often did you use this drug?
  - Once a day
  - More than once a day
  - Once a week
  - 2-6 days a week
  - 1-3 times a month
  - Less often than once a month
4. Did you use any other drugs?
  - Yes → Return to Q2
  - No
5. Have you used any recreational or “street” drugs since you became pregnant?
  - Yes
  - No → End questionnaire
  - Not sure → End questionnaire
6. Which drug did you use? *Enter only one*
  - Free text
7. How often do you use this drug?
  - Once a day
  - More than once a day
  - Once a week
  - 2-6 days a week
  - 1-3 times a month
  - Less often than once a month
8. Are there any other drugs that you take?
  - Yes → return to Q6
  - No → End questionnaire

### **Repeat Recreational/Illegal Drugs**

1. Have you used any recreational or “street” drugs since you last answered questions in this app?
  - Yes
  - No → End questionnaire
  - Not sure → End questionnaire
2. Which drug did you use? *Enter only one*
  - Free text
3. How often do you use this drug?

- Once a day
  - More than once a day
  - Once a week
  - 2-6 days a week
  - 1-3 times a month
  - Less often than once a month
4. Are there any other drugs that you take?
- Yes → return to Q2
  - No → End questionnaire

## IV. APPENDIX 4: RECRUITMENT MATERIALS

<Date>

Dear <Name>:

Pregnant women often wonder about what they can do to make their baby as healthy as possible. Some women need to take medications but worry about whether they are safe. Until now, there has been very little information about what medications are safe for pregnant women and babies – and this can make it really hard for women and doctors to make decisions.

We want to change all that by making it easier to study what medications are safe in pregnancy. We are inviting women like you to participate in a study that could transform how we learn about medications in pregnancy. You can help us try to make things better for women in the future. We are researchers in your health care system, Kaiser Permanente. With partners at Harvard and the Food and Drug Administration (FDA), we are conducting a study about how mobile apps can help us learn more about medications and pregnancy. We are telling you about this study because your electronic records indicate you may be pregnant now. If this describes you, we hope you will consider taking part in this research.

This study is being funded by the Food and Drug Administration (FDA).

### **What does the study involve?**

- If you are pregnant now, and use an Android version 4.4 or above, or an iPhone IOS version 8 or above, you are eligible to participate.
- There will be you will be several surveys a week. Together, they will take about 10 minutes to complete.
- We will ask you many questions about illnesses, symptoms and medications you take for them.
- We will also ask about some sensitive topics like depression and tobacco, alcohol and illegal drug use. This is important because these things can also affect your pregnancy.
- You will be notified of new surveys until 12/31/2017. You can always turn off notifications of new surveys through the app.
- The app provides some features we hope you might find useful, such as a fetal movement counter, and a list of on-line resources for pregnant women.
- Researchers at Kaiser Permanente will collect some information from your medical record, and match this to your answers from the app.
- All information we collect about you will be kept confidential. We will not give our collaborators at Harvard and the FDA any information that identifies you.
- Please read the enclosed consent form for more detailed information.

*Please turn the page to find out how to join:*

## How Do I Join?

- It's easy! To join the study, simply download the **FDA MyStudies** app to your phone.

YOUR UNIQUE TOKEN CODE: [TOKEN CODE]

- On your Android or iPhone, go to the app store, and find the app called **FDA MyStudies**. Download this to your phone.
- Register for the app by entering an email address.
- Tap "Join Study".
- Enter your token code.
- You will then be presented with information about the study. If you want to participate, follow the prompts to check boxes and sign indicating your consent.

Being in this study is voluntary. You can choose to say no now or to leave the study any time later. Either way, your decision will not affect your care or benefits at Kaiser Permanente.

**Please call us at [STUDY CONTACT NUMBER] if you want to learn more about the study**, or if you need help downloading or navigating the app. Please leave a message with your full name and phone number. We may contact you by phone to remind you about the study, and see if you have questions.

Thank you for considering this research opportunity. We hope to talk with you soon!

Best regards,

Sascha Dublin, MD, PhD  
Research Investigator  
Kaiser Permanente Health Research Institute

p.s. We apologize if you think you received this letter in error or would like no further contact from us. Feel free to contact us at [STUDY CONTACT NUMBER] to let us know.

<First Name> <Last Name>  
<Address>  
<City>, WA <Zip>



Kaiser Permanente Washington  
Health Research Institute

## Mobile App Study: Consent Form

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### Researchers

#### Kaiser Permanente Washington Health Research Institute

Sascha Dublin, MD, PhD  
206.287.2870

Predrag Klasnja, PhD  
206.442.5207

Catherine Lim, Mdes  
206.442.5250

#### Harvard Pilgrim Health Care Institute

Richard Platt, MD, MSc  
617.509.9971

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We are asking you to be in a research study. This form explains the details of the study.

Please take as much time as you need to read through this information and make your choice. Ask questions if anything isn't clear or if you would like more information.

You do not have to be in this study. If you say yes, you can quit the study at any time.

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### What is this study about?

In this study, researchers at Kaiser Permanente Washington Health Research Institute and Harvard Pilgrim Health Care Institute (HPHCI) are trying to learn more about how medications affect pregnancy. We have developed a smartphone app that will be used to find out more about the safety of things pregnant women may be exposed to on a daily basis (such as over the counter medicines.) We will do this by asking pregnant women to download a mobile application on their cell phone. Women will then be asked to answer questions about health conditions, medications, and daily exposures on the mobile application over the course of their pregnancy. This data will be linked to a limited set of data from your Kaiser Permanente Medical Record at Kaiser Permanente Washington Health Research Institute. This study is being funded by the Food and Drug Administration (FDA).

### What will happen if I take part in this study?

If you join the study, we will ask you to:

- **Download the Mobile App to your phone:** The first step would be to go to your app store on your phone and download the mobile application called [NAME]. This app will be periodically updated during the course of the study.

- **Complete the surveys on the app.** There will be one new survey a month during the course of your pregnancy. In the survey, you will be asked questions about things like chronic health conditions you may have, medications you may take, your pregnancy now and other pregnancies you may have had. You will also be asked about things like your race and education level. Some of the questions are on sensitive topics such as depression, mood, alcohol use, and the use of tobacco and illegal drugs. The surveys will take between 2 and 10 minutes to complete. You can skip any question you want to.

This data you enter will be stored at an outside company called LabKey. Only the researchers at Kaiser Permanente Washington Health Research Institute, and staff maintaining the data storage at LabKey will have access to that data.

- **Let us collect some information from your Kaiser Permanente Foundation Health Plan of Washington (KP Washington) medical record about health care provided to you from [February 2016] to [today].** We won't need to look at the notes your doctor writes. We will use a computer to collect information lab tests, medications, and trips to the hospital, your age, ethnic background, diagnosis, disease history, and response to treatments.

We will combine the data you enter to the app with this medical record data. This set of combined data will be stored at Kaiser Permanente Washington Health Research Institute. It will not be released to LabKey, Harvard Pilgrim or the FDA.

#### **Will there be any costs to me?**

There will not be any costs to you.

#### **Will being in this study help me?**

This study will not help you personally, but we hope the results of this study will help improve care for women and their babies in the future.

#### **Can anything bad happen to me from being in this study?**

You might feel uncomfortable answering some study questions. You may skip any questions you don't want to answer.

It's possible that someone other than the researchers could find out you were in the study or see your private study information. The steps we take to keep this from happening are described below.

There is a risk that others outside the research study could see the data we collect from you. We are asking you to enter information into a mobile application, and that information will be stored outside Kaiser Permanente by a company called LabKey. Although we are working with LabKey to keep this data you enter secure, we cannot guarantee the privacy of the information entered into the app that is sent to and stored by LabKey.

We are not aware of other risks associated with this study.

#### **How will you protect my confidentiality?**

This study is being done by researchers at Kaiser Permanente Washington Health Research Institute (KPWHRI), and Harvard Pilgrim Health Care Institute (HPHCI). They are listed above.



These researchers have all completed training on how to protect the rights and privacy of individuals who participate in research.

The researchers listed on the first page and their staff will use your study information for research only. We won't use your name in study reports or add it to your survey answers from the mobile application. Instead, we will label everything with a code number only. We won't tell your doctor whether or not you join this study or add information to your medical record.

We plan to keep your study information as described in this form until January 2023. At that time, we will destroy any study records that include your name or other information that points to you.

#### App Data:

The answers (data) you enter into the mobile app will be transmitted and stored with an outside company called LabKey. We will not send any information from your medical record to LabKey; the only data they will store is the data you enter in the app. Staff at Group Health will be able to access the test data.

#### **How does HIPAA apply to this study?**

Your health information is protected by a federal privacy law called HIPAA. KP Washington must follow this privacy law. According to HIPAA, the information collected by the researchers for this study is part of that protected health information. HIPAA requires that the researchers tell you the following:

By signing this form, you are giving KP Washington permission to allow the researchers to collect, use, and share the following information about you for this study:

1. Your survey answers from the mobile application.
2. Your medical record information as described above

It is possible that staff from KP Washington and the funding agency may look at our study records for oversight. We will not share the information we collect for this study with anyone else except as allowed by law.

The HIPAA privacy law does not always apply to those who are given protected health information. Once KP Washington has given out health information, the person who receives it may re-disclose it. Privacy laws may no longer protect the information.

In order to be in the study, you must agree to this use of your health information. This permission for the researchers to obtain your health information for this study ends on January 2023.

#### **Do I have to be in this study?**

No, being in this study is up to you. You are free to say no now or to leave the study at any time later. Either way, there will be no penalty. Your decision won't affect the health care you receive or benefits that you are entitled to.

What happens if I say yes, but change my mind later?

You may change your mind any time about letting us use your information for this study. If you change your mind, you may take back your consent by writing to:

Sascha Dublin, MD, PhD  
Kaiser Permanente Washington  
Health Research Institute  
1730 Minor Ave, Suite 1600  
Seattle, WA 98101

If you take back your consent, it will not affect your health care or benefits at KP Washington. We may still use the study information we collected before we received the letter taking back your consent. But we will destroy any record of your name or other information that could identify you.

**Who do I call if I have questions?**

- If you have questions or concerns about the study, please call the project manager, Linda Kiel at **206-442-4032**.
- If you have questions about your rights as a research participant, please call the KP Washington Human Subjects Review Office at 206-287-2919.

**Subject's Statement**

This study has been explained to me. I volunteer to take part in this research. If I change my mind later, I may leave the study at any time. I've had a chance to ask questions, and they've been answered to my satisfaction. If I have more questions later, I may call the researchers listed in this form or their staff. I will get a copy of this form to keep.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Please **PRINT** your name

\_\_\_\_\_  
Signature of study staff obtaining consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of study staff obtaining consent

“After I got pregnant, I realized there’s not a lot known about how medications will affect your baby because it’s too dangerous to test a medication in women who are pregnant. My doctor said, ‘Well, we need to take care of you.’ But taking a medication or not was a scary decision to make.”

— New Mother  
Seattle, Washington

Moms-to-be like you need answers about which medications are safe to take in pregnancy. We want to see if a smartphone app can help us find those answers.

### Will you help?

“I studied medication safety in older people for a long time. Then I had two babies. When I was pregnant, my doctor prescribed two medications for minor problems. But like many women, I didn’t take them because I was concerned about harms they might cause that we just don’t know about.

Certain medications have been around so long that probably everyone assumes we’d be able to tell if they were causing harm during pregnancy. The truth is that sometimes we really aren’t sure. But with the right kind of research, we can give women and their doctors the answers they need to make informed decisions.

We hope this study will be a step in the right direction.”

— Sascha Dublin, MD, PhD  
Kaiser Permanente Washington  
study leader

*Funding for this study comes from the U.S. Department of Health and Human Services (DHHS).*



**Are you pregnant?  
Do you have a  
smartphone?**



Learn about a research study that’s using a mobile app to find out more about the safety of medications for pregnant women and babies.



### What is this study about?

This study is about finding the best way to learn which medications are safest in pregnancy. It's been hard for traditional research to answer this question because most clinical trials don't include pregnant women.

As a result, many women avoid taking over-the-counter and prescription medications when they're pregnant. For some, this means they suffer through a minor illness instead of taking something to ease their symptoms. But for women who have depression or other chronic conditions, not taking their medications while they're pregnant can cause serious problems.

That's why we are tapping into smartphone technology to find a new way.

### How does the app work?

- If you decide to join this study, you will download a free smartphone app. The app will prompt you to answer questions each week until the end of this year.
- The questions will ask about any medications you are taking and health events that happen to you and your baby. We will also collect information from your and your baby's medical records. We want to know if this combined approach can work. If so, in the future it could help us learn about health effects of medications that other studies may not have detected.
- All the information we collect about you through the app will be kept confidential. Your answers will not go into your medical record.
- The app has some other features that you might find useful, such as a weight tracker and links to online resources for pregnant women.



### How do you sign up?

#### Signing up is easy!

- First, please read the enclosed consent form to learn more about what this study involves.
- Then, if you're interested in signing up, simply download the **FDA My Studies** app to your phone. Be sure to use the instructions and token code on the back of the letter that came with this brochure.



### Have questions? Need help with the app?

Please call us if you'd like to hear more about the study or need help downloading or using the app: **1-866-648-1775** (toll free). Leave your full name and phone number, and we'll call you back as soon as we can.



## V. APPENDIX 5: PREGNANCY STUDY RESULTS TABLES

**Table 20. Participant Characteristics**

	N	%
<b>Maternal Race/Ethnicity</b>	(N=48)	
Hispanic or Latina	3	6%
Black or African American	0	0%
Asian	2	4%
Native Hawaiian or Other Pacific Islander	0	0%
Native American or Alaska Native	0	0%
White	39	81%
Multiple Races Reported	4	8%
Other	0	0%
Not sure or prefer not to answer	0	0%
<b>Maternal Education</b>	(N=48)	
Some high school, no degree	0	0%
High school or GED	0	0%
Some college, Associates Degree, Technical Degree	3	6%
4-year college degree	16	33%
Master's Degree	17	35%
More than a Master's Degree (MD, PhD, JD, etc)	12	25%
<b>Maternal Age</b>	Mean (Range)	
	33.5 (23-43)	
<b>Estimated Gestational Age at start of study</b>	(N=64)	
First Trimester	8	13%
Second Trimester	43	67%
Third Trimester	13	20%
<b>Pre-pregnancy BMI</b>	(N=58)	
Underweight	2	3%
Normal	31	53%
Overweight	13	22%
Obese	12	21%
<b>Ultrasound</b>	(N=59)	
Yes	59	100%
No	0	0%
<b>Trimester of first ultrasound</b>	(N=59)	
First Trimester	55	93%
Second Trimester	4	7%
Third Trimester	0	0%
<b>Planned Pregnancy</b>	(N=59)	
Yes	48	81%
No, but it was not completely unexpected	8	14%
No, it was not planned	3	5%
<b>Infertility Treatment</b>	(N=59)	

	N	%
Yes	5	8%
No	54	92%
<b>Any Medication Use</b>	(N=56)	
Yes	46	82%
No	10	18%
<b>Any Vitamin Use</b>	(N=40)	
Yes	40	100%
No	0	0%
<b>Any Vaccine</b>	(N=44)	
Yes	33	75%
No	11	25%
<b>Any Acute Condition Reported</b>	(N=53)	
Yes	53	100%
No	0	0%
<b>Any Chronic Condition</b>	(N=58)	
Yes	29	50%
No	29	50%

**Note:** 64 women consented to the app and thus have age and gestational age at consent. Only 61 of the 64 women went on to answer at least one question in the app beyond consenting.

**Table 21. Conditions Reported**

Condition	Women Reporting Condition	Women with Condition Who Took Any Medication	Women with Condition Who Discontinued Any Medication
<b>Chronic Conditions (N=58 Respondents)</b>			
Anxiety or Panic Attacks	19	11	6
Asthma	3	3	1
Attention-Deficit/Hyperactivity Disorder (ADHD)	1	0	1
Bipolar Disorder	1	1	1
Crohn's Disease	0	0	0
Depression	16	7	4
Diabetes	1	0	0
Hypertension or High Blood Pressure	2	0	0
Hypothyroidism	2	2	0
Irritable Bowel Syndrome (IBS)	2	0	0
Migraines	7	1	1
Psoriasis	0	0	0
Seizures or Epilepsy	0	0	0
<b>Acute Conditions (N=53 Respondents)</b>			
Cold	35	9	0
Constipation	34	13	0
Fever	5	0	0
Flu	0	0	0

Condition	Women Reporting Condition	Women with Condition Who Took Any Medication	Women with Condition Who Discontinued Any Medication
Gastroenteritis	17	4	0
Headaches	34	23	0
Heartburn or Acid Reflux	36	25	0
Nausea Related to Pregnancy	38	12	0
Outdoor or Indoor Allergies	10	8	0
Pain Bad Enough to Take a Medication	3	3	0
Pneumonia	1	1	0
Sinus Infection	1	1	0
Sleeping Problems	28	5	0
Urinary Tract Infection	3	3	0
Vaginal Yeast Infection	3	3	0

**Table 22. Medications Used for Acute Conditions**

Condition (N Reporting Condition or Medication)	N	%
<b>Cold</b>	<b>(N=28)</b>	
Participants reporting taking medication	9	26%
Patients reporting not taking medication	19	54%
Acetaminophen	2	6%
Caught drops	1	3%
Chlorpheniramine	1	3%
Dextromethorphan	1	3%
Guaifenesin	1	3%
Medication not reported	5	14%
<b>Constipation</b>	<b>(N=34)</b>	
Participants reporting taking medication	13	38%
Patients reporting not taking medication	21	62%
Bisacodyl	1	3%
Docusate sodium	4	12%
Milk of Magnesia or Magnesium Supplement	3	9%
Polyethylene glycol	2	6%
Psyllium	2	6%
Colace	1	3%
Medication not reported	7	21%
<b>Flu</b>	<b>(N=0)</b>	
Participants reporting taking medication	0	0%
Patients reporting not taking medication	0	0%
<b>Fever</b>	<b>(N=5)</b>	
Participants reporting taking medication	0	0%
Patients reporting not taking medication	5	100%
<b>Gastroenteritis</b>	<b>(N=17)</b>	
Participants reporting taking medication	4	24%
Patients reporting not taking medication	13	76%

<b>Condition (N Reporting Condition or Medication)</b>	<b>N</b>	<b>%</b>
Fiber supplement	1	6%
Ondansetron	1	6%
Loperamide Hydrochloride	1	6%
Pepto bismol	1	6%
Medication not reported	2	12%
<b>Headaches</b>	<b>(N=34)</b>	
Participants reporting taking medication	23	68%
Patients reporting not taking medication	11	32%
Acetaminophen	18	53%
Ibuprofen	1	3%
Chlor-trimeton	1	3%
Sumatriptan	1	3%
Medication not reported	20	59%
<b>Heartburn or acid reflux</b>	<b>(N=36)</b>	
Participants reporting taking medication	25	69%
Patients reporting not taking medication	11	31%
Calcium carbonate	2	6%
Omeprazole	1	3%
Ranitidine	8	22%
Tums	10	28%
Medication not reported	8	22%
<b>Nausea related to pregnancy</b>	<b>(N=38)</b>	
Participants reporting taking medication	12	32%
Patients reporting not taking medication	26	68%
Diphenhydramine	1	3%
Doxylamine Succinate/Pyridoxine Hcl	3	8%
Ondansetron	4	11%
Promethazine	1	3%
Unisom	3	8%
Vitamin B-6	4	11%
Medication not reported	8	21%
<b>Outdoor or indoor allergies</b>	<b>(N=10)</b>	
Participants reporting taking medication	8	80%
Patients reporting not taking medication	2	20%
Cetirizine HCL	2	20%
Fluticasone Propionate	2	20%
Loratadine	3	30%
Medication not reported	0	0%
<b>Pain bad enough to take a medication</b>	<b>(N=3)</b>	
Participants reporting taking medication	3	100%
Patients reporting not taking medication	0	0%
Acetaminophen	3	100%
<b>Pneumonia</b>	<b>(N=1)</b>	
Participants reporting taking medication	1	100%
Patients reporting not taking medication	0	0%



Condition (N Reporting Condition or Medication)	N	%
Azithromycin	1	100%
<b>Sinus infection</b>	<b>(N=1)</b>	
Participants reporting taking medication	1	100%
Patients reporting not taking medication	0	0%
Mucinex	1	100%
<b>Sleeping problems</b>	<b>(N=28)</b>	
Participants reporting taking medication	5	18%
Patients reporting not taking medication	23	82%
Melatonin	1	4%
Unisom	4	14%
Medication not reported	1	4%
<b>Urinary tract infection</b>	<b>(N=3)</b>	
Participants reporting taking medication	3	100%
Patients reporting not taking medication	0	0%
Cefdinir	1	33%
Nitrofurantoin	1	33%
Phenazopyridine HCL	1	33%
<b>Vaginal yeast infection</b>	<b>(N=3)</b>	
Participants reporting taking medication	3	100%
Patients reporting not taking medication	0	0%
Clotrimazole	1	33%
Fluconazole	1	33%
Miconazole	1	33%

**Table 23. Medication Use for Chronic Conditions**

Condition *(N Reporting Condition or Medication)	N	%
<b>Anxiety or Panic Attacks</b>	<b>(N=19)</b>	
Participants reporting taking medication	11	58%
Patients reporting not taking medication	8	42%
Alprazolam	1	5%
Citalopram	1	5%
Escitalopram	2	11%
Lorazepam	1	5%
Sertraline	7	37%
<b>Asthma</b>	<b>(N=3)</b>	
Participants reporting taking medication	3	100%
Patients reporting not taking medication	0	0%
Albuterol	1	33%
Quavr	1	33%
Medication not reported	1	33%
<b>Attention-deficit/hyperactivity disorder (ADHD)</b>	<b>(N=1)</b>	
Participants reporting taking medication	0	0%
Patients reporting not taking medication	1	100%
<b>Bipolar Disorder</b>	<b>(N=1)</b>	
Participants reporting taking medication	1	100%

<b>Condition *(N Reporting Condition or Medication)</b>	<b>N</b>	<b>%</b>
Patients reporting not taking medication	0	0%
Effexor	1	100%
Lamotrigine	1	100%
<b>Crohn's Disease</b>	<b>(N=0)</b>	
Participants reporting taking medication	0	0%
Patients reporting not taking medication	0	0%
<b>Depression</b>	<b>(N=16)</b>	
Participants reporting taking medication	7	44%
Patients reporting not taking medication	9	56%
Budeprion/Bupropion	2	13%
Citalopram	1	6%
Escitalopram	2	13%
Sertraline	6	38%
Venlafaxine	0	0%
<b>Diabetes</b>	<b>(N=1)</b>	
Participants reporting taking medication	0	0%
Patients reporting not taking medication	0	0%
<b>Hypothyroidism</b>	<b>(N=2)</b>	
Participants reporting taking medication	2	100%
Patients reporting not taking medication	0	0%
Tirosint	2	100%
<b>High Blood Pressure</b>	<b>(N=2)</b>	
Participants reporting taking medication	0	0%
Patients reporting not taking medication	2	100%
<b>Irritable Bowel Syndrome (IBS)</b>	<b>(N=2)</b>	
Participants reporting taking medication	0	0%
Patients reporting not taking medication	2	100%
<b>Migraines</b>	<b>(N=7)</b>	
Participants reporting taking medication	1	14%
Patients reporting not taking medication	6	86%
Sumatriptan Succinate	1	14%
<b>Psoriasis</b>	<b>(N=0)</b>	
Participants reporting taking medication	0	0%
Patients reporting not taking medication	0	0%
<b>Seizures or Epilepsy</b>	<b>(N=0)</b>	
Participants reporting taking medication	0	0%
Patients reporting not taking medication	0	0%

\*Reported medication usage is not mutually exclusive within a condition

**Table 24. Medication Discontinuation**

	Alprazolam	Concerta	Excetra	Lorazepam	Metroprolol	Methyl-phenidate	Propranolol	Sertaline	Sumatriptan Succinate	Trazadone
<b>Reason for Discontinuation</b>	<b>Total N Discontinued</b>									
The health condition went away	--	--	--	--	--	--	--	--	1	1
My healthcare provider recommended I switch because I was trying to get pregnant	--	--	--	--	--	--	--	--	--	--
My healthcare provider recommended that I stop because I was pregnant	1	1	1	--	1	1	--	--	1	1
My healthcare provider recommended I switch to a different medication because I was pregnant	--	--	--	--	--	--	--	--	--	--
I decided not to take it on my own because I was pregnant	--	--	--	--	--	--	--	1	--	1
I decided not to take it on my own because I was trying to get pregnant	--	--	--	1	--	--	1	2	--	--
Other reason for medication discontinuation	--	--	--	--	--	--	--	1	--	--

**Table 25. Medication Use**

Medications for Episodic and Chronic Conditions	Patient Reported Use	Local Sentinel Data	Concordance	Total Women*
<b>Over-the-counter Medications</b>				
Acetaminophen	23	3	1	25
Bisacodyl	1	0	0	1
Calcium Carbonate	2	0	0	2
Cetirizine	3	0	0	3
Chlorpheniramine	1	0	0	1
Clotrimazole	2	0	0	2
Dextromethorphan	1	0	0	1
Diphenhydramine	2	0	0	2
Docusate	5	0	0	5
Doxylamine	3	0	0	3
Famotidine	3	0	0	3
Guaifenesin	1	0	0	1
Ibuprofen	3	3	0	6
Loperamide	1	0	0	1
Loratadine	3	0	0	3
Milk of Magnesia	3	0	0	3
Melatonin	1	0	0	1
Pepto Bismol	1	0	0	1
Phenazopyridine	1	0	0	1
Vitamin B6	3	0	0	3
Psyllium	2	0	0	2
Ranitidine	10	1	1	10
Tums	10	0	0	10
Unisom	7	0	0	7
<b>Prescription Medications</b>				
Acyclovir	0	2	0	2
Albuterol	2	2	2	2
Alprazolam	1	1	1	1
Amoxicillin	0	3	0	3
Azithromycin	1	1	1	1
Beclomethasone	0	1	0	1
Budeprion	2	2	1	3
Cefdinir	1	0	0	1
Cephalexin	0	1	0	1
Ciprofloxacin	0	1	0	1
Citalopram	1	0	0	1
Clindamycin	0	1	0	1
Effexor	1	0	0	1
Escitalopram	2	1	1	2
Estradiol	0	1	0	1
Fluconazole	1	1	1	1

Medications for Episodic and Chronic Conditions	Patient Reported Use	Local Sentinel Data	Concordance	Total Women*
Fluticasone	2	2	0	4
Fosfomycin	0	1	0	1
Furosemide	1	0	0	1
Glyburide	1	1	1	1
Ipratropium	0	1	0	1
Lamotrigine	1	1	1	1
Letrozole	0	1	0	1
Lorazepam	1	0	0	1
Mesalamine	0	2	0	2
Metformin	0	2	0	2
Methylphenidate	0	1	0	1
Metoclopramide	0	1	0	1
Metronidazole	0	3	0	3
Metoprolol	1	0	0	1
Miconazole	1	0	0	1
Nifedipine	0	1	0	1
Nitrofurantoin	1	4	1	4
Norgestimate	0	1	0	1
Omeprazole	1	1	1	1
Ondansetron	5	8	5	8
Oseltamivir	0	2	0	2
Oxycodone	0	1	0	1
Polyethylene	3	1	0	4
Prochlorperazine	0	2	0	2
Progesterone	0	2	0	2
Promethazine	1	1	0	2
Propranolol	1	0	0	1
Sertraline	10	9	8	11
Sumatriptan	2	0	0	2
Tacrolimus	0	1	0	1
Tirosint	2	6	2	6
Trazadone	1	0	0	1
Triamcinolone	0	2	0	2
Venlafaxine	0	1	0	1

*\*Total Number of Women who either reported taking the medication or had a dispensing in Sentinel or both reported it and had a dispensing*

*Note: Sentinel medication data for acute conditions were pulled 30 days prior to app start date (earliest date at which the participant opened and used the app) through the end of the app. Medications for chronic conditions were pulled from Sentinel up to 110 days prior to app start date to allow for dispensings with long days' supply plus adherence factor.*

**Table 26. Medication Use Among Select Conditions**

Condition	Women Completing Survey*	Women Reporting Condition	Medication Name	Women Reporting Use	Women Reporting Medication Use		Women Reporting NO Use	Women Reporting NO Medication Use		Women NOT Reporting the Condition with >=1 dispensing in Sentinel
					with >=1 dispensing in Sentinel	with NO dispensing in Sentinel		with >=1 dispensing in Sentinel	with NO dispensing in Sentinel	
<b>Chronic**</b>	<b>58</b>									
<b>Anxiety</b>		<b>19 (33%)</b>		<b>11</b>	<b>8</b>	<b>3</b>	<b>8</b>	<b>2</b>	<b>6</b>	<b>1</b>
			Alprazolam	1	1	0	--	0	0	0
			Citalopram	1	0	1	--	0	0	0
			Escitalopram	2	1	1	--	0	0	0
			Lorazepam	1	0	1	--	0	0	0
			Sertraline	7	6	1	--	2	0	1
<b>Depression</b>		<b>16 (28%)</b>		<b>7</b>	<b>5</b>	<b>2</b>	<b>9</b>	<b>5</b>	<b>4</b>	<b>2</b>
			Budeprion/Bupropion	2	1	1	--	1	0	0
			Citalopram	1	0	1	--	0	0	0
			Escitalopram	2	1	1	--	0	0	0
			Sertraline	6	4	2	--	3	0	2
			Venlafaxine	0	0	0	--	1	0	0
<b>Acute*^</b>	<b>53</b>									
<b>Sleep Problems</b>		<b>28 (53%)</b>		<b>5</b>	<b>0</b>	<b>5</b>	<b>23</b>	<b>0</b>	<b>23</b>	<b>0</b>
			Melatonin	1	0	0	--	0	0	0
			Unisom	4	0	0	--	0	0	0
<b>Nausea</b>		<b>38 (72%)</b>		<b>12</b>	<b>3</b>	<b>9</b>	<b>26</b>	<b>3</b>	<b>23</b>	<b>2</b>
			Diphenhydramine	1	0	1	--	0	0	0
			Doxylamine	3	0	3	--	0	0	0
			Ondansetron	4	3	1	--	2	0	1
			Promethazine	1	0	1	--	1	0	0
			Unisom	3	0	3	--	0	0	0
			Vitamin	3	0	3	--	0	0	0
			Prochlorperazine	0	0	0	--	1	0	0
			Metoclopramide	0	0	0	--	0	0	1
			Promethgan	0	0	0	--	1	0	0

Condition	Women Completing Survey*	Women Reporting Condition	Medication Name	Women Reporting Medication Use			Women Reporting NO Medication Use		Women NOT Reporting the Condition with >=1 dispensing in Sentinel	
				Women Reporting Use	with >=1 dispensing in Sentinel	with NO dispensing in Sentinel	Women Reporting NO Use	with >=1 dispensing in Sentinel		with NO dispensing in Sentinel
UTI		3 (6%)		3	1	2	0	0	1	
			Cefdinir	1	0	1	--	0	0	0
			Nitrofurantoin	1	1	0	--	0	0	1
			Phenazopyridine	1	0	1	--	0	0	
Pain		3 (6%)		3	0	3	0	0	6	
			Hydrocodone/Acetaminophen	3	0	3	--	0	0	3
			Ibuprofen	0	0	0	--	0	0	3
			Oxycodone	0	0	0	--	0	0	

\*Answered at least one question on the survey, women answering "true" when asked whether they take a medication for this condition.

\*\*For chronic conditions, medication dispensings were included up to 110 days prior to a woman's app start date through app closing date.

\*^For acute conditions, medication dispensings were included up to 30 days prior to a woman's app start date through app closing date.

**Table 27. Vaccine Use**

	N	%
Women Reporting Any Vaccine	<b>*44</b>	
Flu vaccine	27	61%
Tdap vaccine	10	23%
HPV vaccine	0	0%
Other	0	0%
Not sure	0	0%

\*Rows do not equal 44 as some women reported vaccine use but did not indicate specific vaccine

**Table 28. Vitamin Use**

	Prenatal Vitamin	Folic Acid	Vitamin D	Vitamin B12	DHA	Other Multivitamin
<b>Total Reporting Use</b>	<b>40</b>	<b>5</b>	<b>5</b>	<b>0</b>	<b>5</b>	<b>11</b>
Started before she found out she was pregnant	28	3	5	0	3	4
Once a day	25	3	3	0	1	3
3-6 times per week	3	0	1	0	2	1
1-2 times per week	0	0	1	0	0	0
Less than once a week	0	0	0	0	0	0
Other	0	0	0	0	0	0
Started after she found out she was pregnant	12	2	0	0	2	7
Once a day	7	1	0	0	2	5
3-6 times per week	4	1	0	0	0	1
1-2 times per week	0	0	0	0	0	1
Less than once a week	0	0	0	0	0	0
Other	1	0	0	0	0	0
Not sure	0	0	0	0	0	0

**Table 29. Changes in Behavior Before, During, and After Pregnancy**

Substance	Total Responding	Used Before Pregnancy		Used During Pregnancy		Stopped During Pregnancy		Started During Pregnancy	
		N	%	N	%	N	%	N	%
Alcohol	39	33	85%	7	18%	26	67%	0	0%
Cigarettes	47	2	4%	1	2%	1	2%	0	0%
E-Cigarette	45	2	4%	1	2%	1	2%	0	0%
Street Drug	39	1	3%	1	3%	0	0%	0	0%
Marijuana	39	10	26%	2	5%	8	21%	0	0%

**Table 30. Substance Use Before and During Pregnancy**

	Before Pregnancy		During Pregnancy	
	N	%	N	%
<b>Average Drinks Per Week</b>	N=39		N=26	
1 or less	9	23%	7	27%
2-4	16	41%	1	4%
5-7	8	21%	0	0%
More than 7	2	5%	1	4%
Not sure	0	0%	0	0%
<b>Most Drinks in One Sitting</b>	N=39		N=26	
1 or less	12	31%	8	31%
2-4	16	41%	0	0%
5-7	5	13%	1	4%
Not sure	0	0%	0	0%



	Before Pregnancy		During Pregnancy	
	N	%	N	%
<b>Cigarettes Usage Frequency</b>	N=47		N=45	
1/2 pack (5-14)	1	2%	0	0%
1-4 per day	1	2%	1	2%
1 pack (15-24)	0	0%	0	0%
More than 1 pack (25 or more)	0	0%	0	0%
<b>E-Cigarette Usage Frequency</b>	N=47		N=45	
Every day	1	2%	0	0%
A few days a week	0	0%	0	0%
A few days a month	0	0%	0	0%
Once a month or less	1	2%	0	0%
<b>Street Drug Usage Frequency</b>	N=39		N=26	
More than once a day	0	0%	0	0%
Once a Day	0	0%	0	0%
2-6 Days a Week	0	0%	0	0%
Once a Week	1	3%	1	4%
1-3 Times a Month	0	0%	0	0%
Less than Once a Month	0	0%	0	0%
<b>Marijuana Usage Method</b>	N=39		N=26	
Inhale smoke	5	13%	1	4%
Inhale vapor	0	0%	0	0%
Eat/ingest orally	5	13%	1	4%
Absorb through the skin	0	0%	0	0%
Other	0	0%	0	0%
<b>Marijuana Usage Frequency</b>	N=39		N=26	
Once a day	0	0%	0	0%
More than once a day	1	3%	0	0%
2-6 days a week	0	0%	0	0%
Once a week	1	3%	0	0%
Less than once a month	8	21%	1	4%
1-3 times a month	0	0%	0	0%

**Table 31. Birth Outcomes**

	Patient Reported		Sentinel Data*	
	N	%	N	%
<b>Live birth</b>	6	9%	10	16%
<b>Miscarriage</b>	0	0%	0	0%
<b>Abortion</b>	0	0%	0	0%
<b>No response</b>	58	91%	N/A	
<b>Total</b>	64		64	

\*Presence of live delivery code in Sentinel between date of app initiation and date of app closing. Some women likely stopped using the app prior to the closing date and, thus, did not report live birth outcome.

## **VI. APPENDIX 6: ENROLLMENT PROCESS**

### **A. COHORT IDENTIFICATION AND PARTICIPANT CONTACT PROCESS**

#### **1. Cohort Identification**

The participating Sentinel Data Partner in this project, Kaiser Permanente Washington Health Research Institute (KPWHRI), identified the desired cohort, pregnant women, using KPWHRI electronic medical record data. Women were identified as pregnant based on the presence of an estimated delivery date recorded by a health care provider within an active episode of pregnancy care. Women were included if they were between the ages of 18 and 45 (inclusive) at the time of the data pull, 36 weeks gestational age or less based on estimated delivery date, English-speaking, and enrolled in a health plan (excluding Medicaid) during the preceding month. Estimated date of last menstrual period (LMP, start of pregnancy) was imputed based on the number of weeks between the data pull and the recorded estimated delivery date. Women were excluded if they had any code for possible miscarriage between imputed LMP and estimated delivery date, or if they have previously indicated that they do not wish to participate in research.

#### **2. Cohort Randomization Process**

All women in their first trimester of pregnancy were included in the cohort. At the time of the initial cohort pull, approximately equal numbers of women in their second and third trimesters were randomly selected into the cohort such that each trimester represented about a third of the sample. Due to project delays, the cohort was updated approximately six weeks after the initial cohort was identified. All women greater than 36 weeks gestational age as of the refresh date were dropped from the cohort and replaced with as many newly pregnant women as could be identified based on the criteria above. All women were randomly assigned an enrollment token, and half of women were randomly selected to receive a phone call in addition to the recruitment mailing. Approximately four weeks after the first sample refresh, another batch of women in their first trimester of pregnancy were identified and added.

#### **3. Mailing Process**

Study recruitment involved a two-wave mailing. Each mail package was sent by KPWHRI and contained an invitation letter, brochure describing the study, and a copy of the consent form. These materials follow this report. 872 women were contacted with the first mailing on September 25<sup>th</sup>. A separate cohort of women (N=199) will be contacted with a second mailing on October 17<sup>th</sup>.

#### **4. Phone Recruitment**

KPWHRI randomly identified 536 women from the first mailing for phone follow-up. One attempt to call the 536 women will be made during a first round of phone follow-up between September 29<sup>th</sup> and October 13<sup>th</sup>. Beginning on October 16<sup>th</sup>, KPWHRI will begin a second round of phone follow-up to previously contacted women who they were unable to reach on the first call attempt. Up to three call attempts will be made and up to three phone messages were left. These phone calls will continue until October 27<sup>th</sup>. During the call, women will be reminded of the materials mailed to them and encouraged to join the study. Women will be given the opportunity to ask questions about the study and have the study described to them. The enrollment rate for the call and non-call groups will be compared to determine the effectiveness of phone follow. The phone script follows this report.

## B. CONTACT SCRIPT

### Contact

Hello, may I please speak with (RESPONDENT)?

**1 R available or comes to phone [SKP Intro]**

#### RESPONDENT NOT AVAILABLE

My name is (NAME) and I'm calling from Kaiser Permanente Washington Health Research Institute about a study. Can you suggest a convenient time when I could reach her?

**R can't come to phone/not home [MAKE NOTE OF CALL BACK TIME/NUMBER]**  
**R refuses or some other problem [SKP ThanksExit]**

#### RESPONDENT AVAILABLE

### Intro

Hello, this is (INTNAME) from Kaiser Permanente Washington Health Research Institute.

About a week ago, we sent you a letter about a research study. In this study, we are using a mobile app to find out more about how medications affect pregnancy. This study is being funded by the Department of Health and Human Services.

Do you remember getting the letter?

**1 YES [SKP Study1]**  
**5 NO [SKP NoLtr]**  
**7 NOT GOOD TIME [SKP CB]**  
**9 R refuses or some other problem [SKP ThanksExit]**

### NoLtr

Okay, I can send you another letter. Can you confirm we have your correct mailing address?

**1 CONFIRMS ADDRESS [SKP CONTINUE]**  
**8 R refuses to be interviewed [SKP ThanksExit]**

Thank you! Would you like to hear more about the study now?

**1 YES – SKIP to Study2**  
**2 NO – SKIP to StudyThanks**  
**3 Other [skp to ThanksExit]**

### Study 1

Did you get a chance to read the letter?

**NO – Can I take a few minutes to tell you about the study?**

**YES – SKIP to Study 2**  
**NO – SKIP to Questions**

**YES – SKIP to Questions**

## **YES AND SIGNED UP ALREADY**

That's great! Thank you so much for helping with our research.

### **SKIP to Questions**

#### **Questions**

Did you have any questions about the study, or need any help with the app?

### **ADDRESS QUESTIONS, AND HELP WITH APP INSTALLATION AND ACCESS AS NEEDED.**

#### **IF CANNOT ANSWER TECHNICAL QUESTION,**

I'm sorry I can't help you with this problem. Can I get someone here to call you back to help you with this? [**record details of problem, and call back best times.**]

### **SKIP to StudyThanks**

#### **Study 2**

In this study, researchers at Kaiser Permanente Washington Health Research Institute and Harvard Pilgrim Health Care Institute are trying to learn more about how medications affect pregnancy.

We have developed a smartphone app that will be used to find out more about the safety of things pregnant women may be exposed to.

To join the study, you will download a mobile app to your phone, and fill out several surveys per week. You need to have an Android version 4.4 or above or an iPhone version 8 or above to run the app. The survey questions are about health conditions, medications, and other exposures. This study will help us find out if using a mobile app can give us more information about what's safe for women and their babies.

I'm calling now to see if you got the mailing, and ask if you would take a few minutes to read through the materials and consider joining.

I could also tell you more about the study now over the phone if you have time. Would you like me to tell you more now about what was in the mailing?

#### **YES – continue**

#### **NO – SKIP to Questions**

If you decide to join the study, you will go to your app store on your phone and download the mobile application called *FDA My Studies*. You will be asked to enter your email address in order to confirm your registration. There is a unique token code that came in your letter you will use to join.

Would you like for me to look up your token code for you now?

#### **Yes – provide token code**

#### **No – continue**

After you join, there will be a few short surveys each week to complete. Depending on when you join the study, you may already have several of these to complete. A notification will pop up on your cell phone letting you know when there is a new survey. You will continue to get new surveys from when you join through December 2017. You can turn off notifications for new surveys in the app at any time. In the surveys, you will be asked questions about things like chronic health conditions you may have, medications you may take, your pregnancy now and other pregnancies you may have had. You will also be asked about things like your race and education level. Some of the questions are on sensitive topics such as depression, alcohol use, and the use of tobacco and illegal drugs. Each survey will take between 1 and

10 minutes to complete, but most will take much less than 10 minutes. You can skip any question you don't want to answer.

If you join, we will also collect some information from your Kaiser Permanente medical record about health care provided to you from July 2015 until the end of November 2017. We won't need to look at the notes your doctor writes. We will use a computer to collect information lab tests, medications, trips to the hospital, your age, ethnic background, diagnosis, disease history, and response to treatments.

We will also collect some information in Kaiser Permanente's electronic medical records about your baby from their birth date through December 2017. We will do this because we are trying to understand how certain medications might affect things like pre-term birth or low birth weight. We will look at things like diagnosis, gestational age, birth defects and emergency care.

Your and your baby's medical record information collected by staff at Kaiser Permanente Washington Health Research Institute will not be released to anyone else.

- 1 CONTINUE
- 8 REFUSED STUDY [skp to ThanksExit]

Do you have any questions for me?

**ADDRESS QUESTIONS, SKIP TO STUDY THANKS**

**ThanksExit**

Thank you. I'm sorry to have caused you any inconvenience.

- 1 End Contact
- CB**

Is there a time and number that's generally good to reach you?

**MAKE NOTE OF BEST TIME AND NUMBER**

**END CONTACT**

**StudyThanks**

We are hoping women join to help us with our important research on the safety of medications use during pregnancy.

Thank you for talking with me today. Please give us a call at [STUDY CONTACT NUMBER] if you have any questions.

END CONTACT

**FU NOTES**

Is there anything we need to know for future contact with this respondent?

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## VII. APPENDIX 7: ICD-10 LIVE BIRTH CODES

Table 32. Appendix 7: ICD-10 Live Birth Codes

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
10D07Z3	PX	10	delivery	'IP*'	DEF
0W8NXZZ	PX	10	delivery	'IP*'	DEF
10D07Z4	PX	10	delivery	'IP*'	DEF
10D07Z5	PX	10	delivery	'IP*'	DEF
10S07ZZ	PX	10	delivery	'IP*'	DEF
10D07Z6	PX	10	delivery	'IP*'	DEF
10D07Z8	PX	10	delivery	'IP*'	DEF
10900ZC	PX	10	delivery	'IP*'	DEF
10908ZC	PX	10	delivery	'IP*'	DEF
10907ZC	PX	10	delivery	'IP*'	DEF
10904ZC	PX	10	delivery	'IP*'	DEF
10903ZC	PX	10	delivery	'IP*'	DEF
10D07Z7	PX	10	delivery	'IP*'	DEF
10E0XZZ	PX	10	delivery	'IP*'	DEF
10D00Z0	PX	10	delivery	'IP*'	DEF
10D00Z1	PX	10	delivery	'IP*'	DEF
10D00Z2	PX	10	delivery	'IP*'	DEF
O6012X0	DX	10	delivery	'IP*'	DEF
O6023X9	DX	10	delivery	'IP*'	DEF
O6023X5	DX	10	delivery	'IP*'	DEF
O6023X4	DX	10	delivery	'IP*'	DEF
O6023X3	DX	10	delivery	'IP*'	DEF
O6023X2	DX	10	delivery	'IP*'	DEF
O6023X1	DX	10	delivery	'IP*'	DEF
O6023X0	DX	10	delivery	'IP*'	DEF
O6022X9	DX	10	delivery	'IP*'	DEF
O6022X5	DX	10	delivery	'IP*'	DEF
O6022X4	DX	10	delivery	'IP*'	DEF
O6022X3	DX	10	delivery	'IP*'	DEF
O6022X2	DX	10	delivery	'IP*'	DEF
O6022X1	DX	10	delivery	'IP*'	DEF
O6022X0	DX	10	delivery	'IP*'	DEF
O6014X9	DX	10	delivery	'IP*'	DEF
O6014X5	DX	10	delivery	'IP*'	DEF
O6014X4	DX	10	delivery	'IP*'	DEF
O6014X3	DX	10	delivery	'IP*'	DEF
O6014X2	DX	10	delivery	'IP*'	DEF
O6014X1	DX	10	delivery	'IP*'	DEF
O6014X0	DX	10	delivery	'IP*'	DEF
O6013X9	DX	10	delivery	'IP*'	DEF
O6013X5	DX	10	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
O6013X4	DX	10	delivery	'IP*'	DEF
O6013X3	DX	10	delivery	'IP*'	DEF
O6013X2	DX	10	delivery	'IP*'	DEF
O6013X1	DX	10	delivery	'IP*'	DEF
O6013X0	DX	10	delivery	'IP*'	DEF
O6012X9	DX	10	delivery	'IP*'	DEF
O6012X5	DX	10	delivery	'IP*'	DEF
O6012X4	DX	10	delivery	'IP*'	DEF
O6012X3	DX	10	delivery	'IP*'	DEF
O6012X2	DX	10	delivery	'IP*'	DEF
O6012X1	DX	10	delivery	'IP*'	DEF
P0700	DX	10	delivery	'IP*'	DEF
P0710	DX	10	delivery	'IP*'	DEF
P0701	DX	10	delivery	'IP*'	DEF
P0702	DX	10	delivery	'IP*'	DEF
P0703	DX	10	delivery	'IP*'	DEF
P0714	DX	10	delivery	'IP*'	DEF
P0715	DX	10	delivery	'IP*'	DEF
P0716	DX	10	delivery	'IP*'	DEF
P0717	DX	10	delivery	'IP*'	DEF
P0718	DX	10	delivery	'IP*'	DEF
P0730	DX	10	delivery	'IP*'	DEF
P0720	DX	10	delivery	'IP*'	DEF
P0721	DX	10	delivery	'IP*'	DEF
P0722	DX	10	delivery	'IP*'	DEF
P0723	DX	10	delivery	'IP*'	DEF
P0724	DX	10	delivery	'IP*'	DEF
P0725	DX	10	delivery	'IP*'	DEF
P0726	DX	10	delivery	'IP*'	DEF
P0731	DX	10	delivery	'IP*'	DEF
P0732	DX	10	delivery	'IP*'	DEF
P0733	DX	10	delivery	'IP*'	DEF
P0734	DX	10	delivery	'IP*'	DEF
P0735	DX	10	delivery	'IP*'	DEF
P0736	DX	10	delivery	'IP*'	DEF
P0737	DX	10	delivery	'IP*'	DEF
P0738	DX	10	delivery	'IP*'	DEF
P0739	DX	10	delivery	'IP*'	DEF
P0821	DX	10	delivery	'IP*'	DEF
P0822	DX	10	delivery	'IP*'	DEF
O80	DX	10	delivery	'IP*'	DEF
P030	DX	10	delivery	'IP*'	DEF
P032	DX	10	delivery	'IP*'	DEF
P033	DX	10	delivery	'IP*'	DEF
P034	DX	10	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
P035	DX	10	delivery	'IP*'	DEF
O670	DX	10	delivery	'IP*'	DEF
O678	DX	10	delivery	'IP*'	DEF
O679	DX	10	delivery	'IP*'	DEF
O1002	DX	10	delivery	'IP*'	DEF
O1092	DX	10	delivery	'IP*'	DEF
O1042	DX	10	delivery	'IP*'	DEF
O1012	DX	10	delivery	'IP*'	DEF
O1022	DX	10	delivery	'IP*'	DEF
O1032	DX	10	delivery	'IP*'	DEF
O134	DX	10	delivery	'IP*'	DEF
O1404	DX	10	delivery	'IP*'	DEF
O1494	DX	10	delivery	'IP*'	DEF
O1414	DX	10	delivery	'IP*'	DEF
O1424	DX	10	delivery	'IP*'	DEF
O114	DX	10	delivery	'IP*'	DEF
O164	DX	10	delivery	'IP*'	DEF
O1204	DX	10	delivery	'IP*'	DEF
O1224	DX	10	delivery	'IP*'	DEF
O1214	DX	10	delivery	'IP*'	DEF
O2662	DX	10	delivery	'IP*'	DEF
O2672	DX	10	delivery	'IP*'	DEF
O99354	DX	10	delivery	'IP*'	DEF
O9812	DX	10	delivery	'IP*'	DEF
O9822	DX	10	delivery	'IP*'	DEF
O9832	DX	10	delivery	'IP*'	DEF
O9802	DX	10	delivery	'IP*'	DEF
O9862	DX	10	delivery	'IP*'	DEF
O9842	DX	10	delivery	'IP*'	DEF
O9852	DX	10	delivery	'IP*'	DEF
O9872	DX	10	delivery	'IP*'	DEF
O9882	DX	10	delivery	'IP*'	DEF
O99834	DX	10	delivery	'IP*'	DEF
O9892	DX	10	delivery	'IP*'	DEF
O2402	DX	10	delivery	'IP*'	DEF
O2412	DX	10	delivery	'IP*'	DEF
O2432	DX	10	delivery	'IP*'	DEF
O2482	DX	10	delivery	'IP*'	DEF
O2492	DX	10	delivery	'IP*'	DEF
O9902	DX	10	delivery	'IP*'	DEF
O99324	DX	10	delivery	'IP*'	DEF
O99314	DX	10	delivery	'IP*'	DEF
O99344	DX	10	delivery	'IP*'	DEF
O24420	DX	10	delivery	'IP*'	DEF
O24424	DX	10	delivery	'IP*'	DEF



Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
O24425	DX	10	delivery	'IP*'	DEF
O24429	DX	10	delivery	'IP*'	DEF
O99814	DX	10	delivery	'IP*'	DEF
O252	DX	10	delivery	'IP*'	DEF
O99284	DX	10	delivery	'IP*'	DEF
O9952	DX	10	delivery	'IP*'	DEF
O9962	DX	10	delivery	'IP*'	DEF
O9972	DX	10	delivery	'IP*'	DEF
O99824	DX	10	delivery	'IP*'	DEF
O9A12	DX	10	delivery	'IP*'	DEF
O9A22	DX	10	delivery	'IP*'	DEF
O9A32	DX	10	delivery	'IP*'	DEF
O9A42	DX	10	delivery	'IP*'	DEF
O9A52	DX	10	delivery	'IP*'	DEF
O99334	DX	10	delivery	'IP*'	DEF
O99214	DX	10	delivery	'IP*'	DEF
O99844	DX	10	delivery	'IP*'	DEF
O9912	DX	10	delivery	'IP*'	DEF
O7582	DX	10	delivery	'IP*'	DEF
O68	DX	10	delivery	'IP*'	DEF
O770	DX	10	delivery	'IP*'	DEF
O778	DX	10	delivery	'IP*'	DEF
O779	DX	10	delivery	'IP*'	DEF
O755	DX	10	delivery	'IP*'	DEF
O76	DX	10	delivery	'IP*'	DEF
O7589	DX	10	delivery	'IP*'	DEF
O759	DX	10	delivery	'IP*'	DEF
O632	DX	10	delivery	'IP*'	DEF
O690XX0	DX	10	delivery	'IP*'	DEF
O690XX1	DX	10	delivery	'IP*'	DEF
O690XX2	DX	10	delivery	'IP*'	DEF
O690XX3	DX	10	delivery	'IP*'	DEF
O690XX4	DX	10	delivery	'IP*'	DEF
O690XX5	DX	10	delivery	'IP*'	DEF
O690XX9	DX	10	delivery	'IP*'	DEF
O691XX0	DX	10	delivery	'IP*'	DEF
O691XX1	DX	10	delivery	'IP*'	DEF
O691XX2	DX	10	delivery	'IP*'	DEF
O691XX3	DX	10	delivery	'IP*'	DEF
O691XX4	DX	10	delivery	'IP*'	DEF
O691XX5	DX	10	delivery	'IP*'	DEF
O691XX9	DX	10	delivery	'IP*'	DEF
O692XX0	DX	10	delivery	'IP*'	DEF
O692XX1	DX	10	delivery	'IP*'	DEF
O692XX2	DX	10	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
O692XX3	DX	10	delivery	'IP*'	DEF
O692XX4	DX	10	delivery	'IP*'	DEF
O692XX5	DX	10	delivery	'IP*'	DEF
O692XX9	DX	10	delivery	'IP*'	DEF
O6981X0	DX	10	delivery	'IP*'	DEF
O6981X1	DX	10	delivery	'IP*'	DEF
O6981X2	DX	10	delivery	'IP*'	DEF
O6981X3	DX	10	delivery	'IP*'	DEF
O6981X4	DX	10	delivery	'IP*'	DEF
O6981X5	DX	10	delivery	'IP*'	DEF
O6981X9	DX	10	delivery	'IP*'	DEF
O6982X0	DX	10	delivery	'IP*'	DEF
O6982X1	DX	10	delivery	'IP*'	DEF
O6982X2	DX	10	delivery	'IP*'	DEF
O6982X3	DX	10	delivery	'IP*'	DEF
O6982X4	DX	10	delivery	'IP*'	DEF
O6982X5	DX	10	delivery	'IP*'	DEF
O6982X9	DX	10	delivery	'IP*'	DEF
O6989X0	DX	10	delivery	'IP*'	DEF
O6989X1	DX	10	delivery	'IP*'	DEF
O6989X2	DX	10	delivery	'IP*'	DEF
O6989X3	DX	10	delivery	'IP*'	DEF
O6989X4	DX	10	delivery	'IP*'	DEF
O6989X5	DX	10	delivery	'IP*'	DEF
O6989X9	DX	10	delivery	'IP*'	DEF
O693XX0	DX	10	delivery	'IP*'	DEF
O693XX1	DX	10	delivery	'IP*'	DEF
O693XX2	DX	10	delivery	'IP*'	DEF
O693XX3	DX	10	delivery	'IP*'	DEF
O693XX4	DX	10	delivery	'IP*'	DEF
O693XX5	DX	10	delivery	'IP*'	DEF
O693XX9	DX	10	delivery	'IP*'	DEF
O694XX0	DX	10	delivery	'IP*'	DEF
O694XX1	DX	10	delivery	'IP*'	DEF
O694XX2	DX	10	delivery	'IP*'	DEF
O694XX3	DX	10	delivery	'IP*'	DEF
O694XX4	DX	10	delivery	'IP*'	DEF
O694XX5	DX	10	delivery	'IP*'	DEF
O694XX9	DX	10	delivery	'IP*'	DEF
O695XX0	DX	10	delivery	'IP*'	DEF
O695XX1	DX	10	delivery	'IP*'	DEF
O695XX2	DX	10	delivery	'IP*'	DEF
O695XX3	DX	10	delivery	'IP*'	DEF
O695XX4	DX	10	delivery	'IP*'	DEF
O695XX5	DX	10	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
O695XX9	DX	10	delivery	'IP*'	DEF
O699XX0	DX	10	delivery	'IP*'	DEF
O699XX1	DX	10	delivery	'IP*'	DEF
O699XX2	DX	10	delivery	'IP*'	DEF
O699XX3	DX	10	delivery	'IP*'	DEF
O699XX4	DX	10	delivery	'IP*'	DEF
O699XX5	DX	10	delivery	'IP*'	DEF
O699XX9	DX	10	delivery	'IP*'	DEF
O700	DX	10	delivery	'IP*'	DEF
O701	DX	10	delivery	'IP*'	DEF
O7020	DX	10	delivery	'IP*'	DEF
O7021	DX	10	delivery	'IP*'	DEF
O7022	DX	10	delivery	'IP*'	DEF
O7023	DX	10	delivery	'IP*'	DEF
O703	DX	10	delivery	'IP*'	DEF
O709	DX	10	delivery	'IP*'	DEF
O704	DX	10	delivery	'IP*'	DEF
O740	DX	10	delivery	'IP*'	DEF
O741	DX	10	delivery	'IP*'	DEF
O742	DX	10	delivery	'IP*'	DEF
O743	DX	10	delivery	'IP*'	DEF
O744	DX	10	delivery	'IP*'	DEF
O745	DX	10	delivery	'IP*'	DEF
O746	DX	10	delivery	'IP*'	DEF
O747	DX	10	delivery	'IP*'	DEF
O748	DX	10	delivery	'IP*'	DEF
O749	DX	10	delivery	'IP*'	DEF
O750	DX	10	delivery	'IP*'	DEF
O751	DX	10	delivery	'IP*'	DEF
O82	DX	10	delivery	'IP*'	DEF
O7581	DX	10	delivery	'IP*'	DEF
O8802	DX	10	delivery	'IP*'	DEF
O8812	DX	10	delivery	'IP*'	DEF
O8822	DX	10	delivery	'IP*'	DEF
O8832	DX	10	delivery	'IP*'	DEF
O8882	DX	10	delivery	'IP*'	DEF
O9942	DX	10	delivery	'IP*'	DEF
Z370	DX	10	delivery	'IP*'	DEF
Z372	DX	10	delivery	'IP*'	DEF
Z373	DX	10	delivery	'IP*'	DEF
Z3750	DX	10	delivery	'IP*'	DEF
Z3751	DX	10	delivery	'IP*'	DEF
Z3752	DX	10	delivery	'IP*'	DEF
Z3753	DX	10	delivery	'IP*'	DEF
Z3754	DX	10	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
Z3759	DX	10	delivery	'IP*'	DEF
Z3760	DX	10	delivery	'IP*'	DEF
Z3761	DX	10	delivery	'IP*'	DEF
Z3762	DX	10	delivery	'IP*'	DEF
Z3763	DX	10	delivery	'IP*'	DEF
Z3764	DX	10	delivery	'IP*'	DEF
Z3769	DX	10	delivery	'IP*'	DEF
Z379	DX	10	delivery	'IP*'	DEF
Z3800	DX	10	delivery	'IP*'	DEF
Z382	DX	10	delivery	'IP*'	DEF
Z3801	DX	10	delivery	'IP*'	DEF
Z381	DX	10	delivery	'IP*'	DEF
Z3830	DX	10	delivery	'IP*'	DEF
Z385	DX	10	delivery	'IP*'	DEF
Z3831	DX	10	delivery	'IP*'	DEF
Z384	DX	10	delivery	'IP*'	DEF
Z3861	DX	10	delivery	'IP*'	DEF
Z3863	DX	10	delivery	'IP*'	DEF
Z3865	DX	10	delivery	'IP*'	DEF
Z3868	DX	10	delivery	'IP*'	DEF
Z388	DX	10	delivery	'IP*'	DEF
Z3862	DX	10	delivery	'IP*'	DEF
Z3864	DX	10	delivery	'IP*'	DEF
Z3866	DX	10	delivery	'IP*'	DEF
Z3869	DX	10	delivery	'IP*'	DEF
Z387	DX	10	delivery	'IP*'	DEF
59400	PX	C4	delivery	'IP*'	DEF
59409	PX	C4	delivery	'IP*'	DEF
59410	PX	C4	delivery	'IP*'	DEF
59510	PX	C4	delivery	'IP*'	DEF
59514	PX	C4	delivery	'IP*'	DEF
59515	PX	C4	delivery	'IP*'	DEF
59610	PX	C4	delivery	'IP*'	DEF
59612	PX	C4	delivery	'IP*'	DEF
59614	PX	C4	delivery	'IP*'	DEF
59618	PX	C4	delivery	'IP*'	DEF
59620	PX	C4	delivery	'IP*'	DEF
59622	PX	C4	delivery	'IP*'	DEF
64101	DX	09	delivery	'IP*'	DEF
64111	DX	09	delivery	'IP*'	DEF
64121	DX	09	delivery	'IP*'	DEF
64131	DX	09	delivery	'IP*'	DEF
64181	DX	09	delivery	'IP*'	DEF
64191	DX	09	delivery	'IP*'	DEF
64201	DX	09	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
64202	DX	09	delivery	'IP*'	DEF
64211	DX	09	delivery	'IP*'	DEF
64212	DX	09	delivery	'IP*'	DEF
64221	DX	09	delivery	'IP*'	DEF
64222	DX	09	delivery	'IP*'	DEF
64231	DX	09	delivery	'IP*'	DEF
64232	DX	09	delivery	'IP*'	DEF
64241	DX	09	delivery	'IP*'	DEF
64242	DX	09	delivery	'IP*'	DEF
64251	DX	09	delivery	'IP*'	DEF
64252	DX	09	delivery	'IP*'	DEF
64261	DX	09	delivery	'IP*'	DEF
64262	DX	09	delivery	'IP*'	DEF
64271	DX	09	delivery	'IP*'	DEF
64272	DX	09	delivery	'IP*'	DEF
64291	DX	09	delivery	'IP*'	DEF
64292	DX	09	delivery	'IP*'	DEF
64301	DX	09	delivery	'IP*'	DEF
64311	DX	09	delivery	'IP*'	DEF
64321	DX	09	delivery	'IP*'	DEF
64381	DX	09	delivery	'IP*'	DEF
64391	DX	09	delivery	'IP*'	DEF
64421	DX	09	delivery	'IP*'	DEF
64501	DX	09	delivery	'IP*'	DEF
64511	DX	09	delivery	'IP*'	DEF
64521	DX	09	delivery	'IP*'	DEF
64522	DX	09	delivery	'IP*'	DEF
64601	DX	09	delivery	'IP*'	DEF
64611	DX	09	delivery	'IP*'	DEF
64612	DX	09	delivery	'IP*'	DEF
64621	DX	09	delivery	'IP*'	DEF
64622	DX	09	delivery	'IP*'	DEF
64631	DX	09	delivery	'IP*'	DEF
64641	DX	09	delivery	'IP*'	DEF
64642	DX	09	delivery	'IP*'	DEF
64651	DX	09	delivery	'IP*'	DEF
64652	DX	09	delivery	'IP*'	DEF
64661	DX	09	delivery	'IP*'	DEF
64662	DX	09	delivery	'IP*'	DEF
64671	DX	09	delivery	'IP*'	DEF
64681	DX	09	delivery	'IP*'	DEF
64682	DX	09	delivery	'IP*'	DEF
64691	DX	09	delivery	'IP*'	DEF
64701	DX	09	delivery	'IP*'	DEF
64702	DX	09	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
64711	DX	09	delivery	'IP*'	DEF
64712	DX	09	delivery	'IP*'	DEF
64721	DX	09	delivery	'IP*'	DEF
64722	DX	09	delivery	'IP*'	DEF
64731	DX	09	delivery	'IP*'	DEF
64732	DX	09	delivery	'IP*'	DEF
64741	DX	09	delivery	'IP*'	DEF
64742	DX	09	delivery	'IP*'	DEF
64751	DX	09	delivery	'IP*'	DEF
64752	DX	09	delivery	'IP*'	DEF
64761	DX	09	delivery	'IP*'	DEF
64762	DX	09	delivery	'IP*'	DEF
64781	DX	09	delivery	'IP*'	DEF
64782	DX	09	delivery	'IP*'	DEF
64791	DX	09	delivery	'IP*'	DEF
64792	DX	09	delivery	'IP*'	DEF
64801	DX	09	delivery	'IP*'	DEF
64802	DX	09	delivery	'IP*'	DEF
64811	DX	09	delivery	'IP*'	DEF
64812	DX	09	delivery	'IP*'	DEF
64821	DX	09	delivery	'IP*'	DEF
64822	DX	09	delivery	'IP*'	DEF
64831	DX	09	delivery	'IP*'	DEF
64832	DX	09	delivery	'IP*'	DEF
64841	DX	09	delivery	'IP*'	DEF
64842	DX	09	delivery	'IP*'	DEF
64851	DX	09	delivery	'IP*'	DEF
64852	DX	09	delivery	'IP*'	DEF
64861	DX	09	delivery	'IP*'	DEF
64862	DX	09	delivery	'IP*'	DEF
64871	DX	09	delivery	'IP*'	DEF
64872	DX	09	delivery	'IP*'	DEF
64881	DX	09	delivery	'IP*'	DEF
64882	DX	09	delivery	'IP*'	DEF
64891	DX	09	delivery	'IP*'	DEF
64892	DX	09	delivery	'IP*'	DEF
64901	DX	09	delivery	'IP*'	DEF
64902	DX	09	delivery	'IP*'	DEF
64911	DX	09	delivery	'IP*'	DEF
64912	DX	09	delivery	'IP*'	DEF
64921	DX	09	delivery	'IP*'	DEF
64922	DX	09	delivery	'IP*'	DEF
64931	DX	09	delivery	'IP*'	DEF
64932	DX	09	delivery	'IP*'	DEF
64941	DX	09	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
64942	DX	09	delivery	'IP*'	DEF
64951	DX	09	delivery	'IP*'	DEF
64961	DX	09	delivery	'IP*'	DEF
64962	DX	09	delivery	'IP*'	DEF
64971	DX	09	delivery	'IP*'	DEF
64981	DX	09	delivery	'IP*'	DEF
64982	DX	09	delivery	'IP*'	DEF
650	DX	09	delivery	'IP*'	DEF
65101	DX	09	delivery	'IP*'	DEF
65111	DX	09	delivery	'IP*'	DEF
65121	DX	09	delivery	'IP*'	DEF
65131	DX	09	delivery	'IP*'	DEF
65141	DX	09	delivery	'IP*'	DEF
65151	DX	09	delivery	'IP*'	DEF
65161	DX	09	delivery	'IP*'	DEF
65171	DX	09	delivery	'IP*'	DEF
65181	DX	09	delivery	'IP*'	DEF
65191	DX	09	delivery	'IP*'	DEF
65201	DX	09	delivery	'IP*'	DEF
65211	DX	09	delivery	'IP*'	DEF
65221	DX	09	delivery	'IP*'	DEF
65231	DX	09	delivery	'IP*'	DEF
65241	DX	09	delivery	'IP*'	DEF
65251	DX	09	delivery	'IP*'	DEF
65261	DX	09	delivery	'IP*'	DEF
65271	DX	09	delivery	'IP*'	DEF
65281	DX	09	delivery	'IP*'	DEF
65291	DX	09	delivery	'IP*'	DEF
65301	DX	09	delivery	'IP*'	DEF
65311	DX	09	delivery	'IP*'	DEF
65321	DX	09	delivery	'IP*'	DEF
65331	DX	09	delivery	'IP*'	DEF
65341	DX	09	delivery	'IP*'	DEF
65351	DX	09	delivery	'IP*'	DEF
65361	DX	09	delivery	'IP*'	DEF
65371	DX	09	delivery	'IP*'	DEF
65381	DX	09	delivery	'IP*'	DEF
65391	DX	09	delivery	'IP*'	DEF
65401	DX	09	delivery	'IP*'	DEF
65402	DX	09	delivery	'IP*'	DEF
65411	DX	09	delivery	'IP*'	DEF
65412	DX	09	delivery	'IP*'	DEF
65421	DX	09	delivery	'IP*'	DEF
65431	DX	09	delivery	'IP*'	DEF
65432	DX	09	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
65441	DX	09	delivery	'IP*'	DEF
65442	DX	09	delivery	'IP*'	DEF
65451	DX	09	delivery	'IP*'	DEF
65452	DX	09	delivery	'IP*'	DEF
65461	DX	09	delivery	'IP*'	DEF
65462	DX	09	delivery	'IP*'	DEF
65471	DX	09	delivery	'IP*'	DEF
65472	DX	09	delivery	'IP*'	DEF
65481	DX	09	delivery	'IP*'	DEF
65482	DX	09	delivery	'IP*'	DEF
65491	DX	09	delivery	'IP*'	DEF
65492	DX	09	delivery	'IP*'	DEF
65501	DX	09	delivery	'IP*'	DEF
65511	DX	09	delivery	'IP*'	DEF
65521	DX	09	delivery	'IP*'	DEF
65531	DX	09	delivery	'IP*'	DEF
65541	DX	09	delivery	'IP*'	DEF
65551	DX	09	delivery	'IP*'	DEF
65561	DX	09	delivery	'IP*'	DEF
65571	DX	09	delivery	'IP*'	DEF
65581	DX	09	delivery	'IP*'	DEF
65591	DX	09	delivery	'IP*'	DEF
65601	DX	09	delivery	'IP*'	DEF
65611	DX	09	delivery	'IP*'	DEF
65621	DX	09	delivery	'IP*'	DEF
65631	DX	09	delivery	'IP*'	DEF
65641	DX	09	delivery	'IP*'	DEF
65651	DX	09	delivery	'IP*'	DEF
65661	DX	09	delivery	'IP*'	DEF
65671	DX	09	delivery	'IP*'	DEF
65681	DX	09	delivery	'IP*'	DEF
65691	DX	09	delivery	'IP*'	DEF
65701	DX	09	delivery	'IP*'	DEF
65801	DX	09	delivery	'IP*'	DEF
65811	DX	09	delivery	'IP*'	DEF
65821	DX	09	delivery	'IP*'	DEF
65831	DX	09	delivery	'IP*'	DEF
65841	DX	09	delivery	'IP*'	DEF
65881	DX	09	delivery	'IP*'	DEF
65891	DX	09	delivery	'IP*'	DEF
65901	DX	09	delivery	'IP*'	DEF
65911	DX	09	delivery	'IP*'	DEF
65921	DX	09	delivery	'IP*'	DEF
65931	DX	09	delivery	'IP*'	DEF
65941	DX	09	delivery	'IP*'	DEF



Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
65951	DX	09	delivery	'IP*'	DEF
65961	DX	09	delivery	'IP*'	DEF
65971	DX	09	delivery	'IP*'	DEF
65981	DX	09	delivery	'IP*'	DEF
65991	DX	09	delivery	'IP*'	DEF
66001	DX	09	delivery	'IP*'	DEF
66011	DX	09	delivery	'IP*'	DEF
66021	DX	09	delivery	'IP*'	DEF
66031	DX	09	delivery	'IP*'	DEF
66041	DX	09	delivery	'IP*'	DEF
66051	DX	09	delivery	'IP*'	DEF
66061	DX	09	delivery	'IP*'	DEF
66071	DX	09	delivery	'IP*'	DEF
66081	DX	09	delivery	'IP*'	DEF
66091	DX	09	delivery	'IP*'	DEF
66101	DX	09	delivery	'IP*'	DEF
66111	DX	09	delivery	'IP*'	DEF
66121	DX	09	delivery	'IP*'	DEF
66131	DX	09	delivery	'IP*'	DEF
66141	DX	09	delivery	'IP*'	DEF
66191	DX	09	delivery	'IP*'	DEF
66201	DX	09	delivery	'IP*'	DEF
66211	DX	09	delivery	'IP*'	DEF
66221	DX	09	delivery	'IP*'	DEF
66231	DX	09	delivery	'IP*'	DEF
66301	DX	09	delivery	'IP*'	DEF
66311	DX	09	delivery	'IP*'	DEF
66321	DX	09	delivery	'IP*'	DEF
66331	DX	09	delivery	'IP*'	DEF
66341	DX	09	delivery	'IP*'	DEF
66351	DX	09	delivery	'IP*'	DEF
66361	DX	09	delivery	'IP*'	DEF
66381	DX	09	delivery	'IP*'	DEF
66391	DX	09	delivery	'IP*'	DEF
66401	DX	09	delivery	'IP*'	DEF
66411	DX	09	delivery	'IP*'	DEF
66421	DX	09	delivery	'IP*'	DEF
66431	DX	09	delivery	'IP*'	DEF
66441	DX	09	delivery	'IP*'	DEF
66451	DX	09	delivery	'IP*'	DEF
66461	DX	09	delivery	'IP*'	DEF
66481	DX	09	delivery	'IP*'	DEF
66491	DX	09	delivery	'IP*'	DEF
66501	DX	09	delivery	'IP*'	DEF
66511	DX	09	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
66522	DX	09	delivery	'IP*'	DEF
66531	DX	09	delivery	'IP*'	DEF
66541	DX	09	delivery	'IP*'	DEF
66551	DX	09	delivery	'IP*'	DEF
66561	DX	09	delivery	'IP*'	DEF
66571	DX	09	delivery	'IP*'	DEF
66572	DX	09	delivery	'IP*'	DEF
66581	DX	09	delivery	'IP*'	DEF
66582	DX	09	delivery	'IP*'	DEF
66591	DX	09	delivery	'IP*'	DEF
66592	DX	09	delivery	'IP*'	DEF
66602	DX	09	delivery	'IP*'	DEF
66612	DX	09	delivery	'IP*'	DEF
66622	DX	09	delivery	'IP*'	DEF
66632	DX	09	delivery	'IP*'	DEF
66702	DX	09	delivery	'IP*'	DEF
66712	DX	09	delivery	'IP*'	DEF
66801	DX	09	delivery	'IP*'	DEF
66802	DX	09	delivery	'IP*'	DEF
66811	DX	09	delivery	'IP*'	DEF
66812	DX	09	delivery	'IP*'	DEF
66821	DX	09	delivery	'IP*'	DEF
66822	DX	09	delivery	'IP*'	DEF
66881	DX	09	delivery	'IP*'	DEF
66882	DX	09	delivery	'IP*'	DEF
66891	DX	09	delivery	'IP*'	DEF
66892	DX	09	delivery	'IP*'	DEF
66901	DX	09	delivery	'IP*'	DEF
66902	DX	09	delivery	'IP*'	DEF
66911	DX	09	delivery	'IP*'	DEF
66912	DX	09	delivery	'IP*'	DEF
66921	DX	09	delivery	'IP*'	DEF
66922	DX	09	delivery	'IP*'	DEF
66932	DX	09	delivery	'IP*'	DEF
66941	DX	09	delivery	'IP*'	DEF
66942	DX	09	delivery	'IP*'	DEF
66951	DX	09	delivery	'IP*'	DEF
66961	DX	09	delivery	'IP*'	DEF
66971	DX	09	delivery	'IP*'	DEF
66981	DX	09	delivery	'IP*'	DEF
66982	DX	09	delivery	'IP*'	DEF
66991	DX	09	delivery	'IP*'	DEF
66992	DX	09	delivery	'IP*'	DEF
67002	DX	09	delivery	'IP*'	DEF
67012	DX	09	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
67022	DX	09	delivery	'IP*'	DEF
67032	DX	09	delivery	'IP*'	DEF
67082	DX	09	delivery	'IP*'	DEF
67101	DX	09	delivery	'IP*'	DEF
67102	DX	09	delivery	'IP*'	DEF
67111	DX	09	delivery	'IP*'	DEF
67112	DX	09	delivery	'IP*'	DEF
67121	DX	09	delivery	'IP*'	DEF
67122	DX	09	delivery	'IP*'	DEF
67131	DX	09	delivery	'IP*'	DEF
67142	DX	09	delivery	'IP*'	DEF
67151	DX	09	delivery	'IP*'	DEF
67152	DX	09	delivery	'IP*'	DEF
67181	DX	09	delivery	'IP*'	DEF
67182	DX	09	delivery	'IP*'	DEF
67191	DX	09	delivery	'IP*'	DEF
67192	DX	09	delivery	'IP*'	DEF
67202	DX	09	delivery	'IP*'	DEF
67301	DX	09	delivery	'IP*'	DEF
67302	DX	09	delivery	'IP*'	DEF
67311	DX	09	delivery	'IP*'	DEF
67312	DX	09	delivery	'IP*'	DEF
67321	DX	09	delivery	'IP*'	DEF
67322	DX	09	delivery	'IP*'	DEF
67331	DX	09	delivery	'IP*'	DEF
67332	DX	09	delivery	'IP*'	DEF
67381	DX	09	delivery	'IP*'	DEF
67382	DX	09	delivery	'IP*'	DEF
67401	DX	09	delivery	'IP*'	DEF
67402	DX	09	delivery	'IP*'	DEF
67412	DX	09	delivery	'IP*'	DEF
67422	DX	09	delivery	'IP*'	DEF
67432	DX	09	delivery	'IP*'	DEF
67442	DX	09	delivery	'IP*'	DEF
67451	DX	09	delivery	'IP*'	DEF
67452	DX	09	delivery	'IP*'	DEF
67482	DX	09	delivery	'IP*'	DEF
67492	DX	09	delivery	'IP*'	DEF
67501	DX	09	delivery	'IP*'	DEF
67502	DX	09	delivery	'IP*'	DEF
67511	DX	09	delivery	'IP*'	DEF
67512	DX	09	delivery	'IP*'	DEF
67521	DX	09	delivery	'IP*'	DEF
67522	DX	09	delivery	'IP*'	DEF
67581	DX	09	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
67582	DX	09	delivery	'IP*'	DEF
67591	DX	09	delivery	'IP*'	DEF
67592	DX	09	delivery	'IP*'	DEF
67601	DX	09	delivery	'IP*'	DEF
67602	DX	09	delivery	'IP*'	DEF
67611	DX	09	delivery	'IP*'	DEF
67612	DX	09	delivery	'IP*'	DEF
67621	DX	09	delivery	'IP*'	DEF
67622	DX	09	delivery	'IP*'	DEF
67631	DX	09	delivery	'IP*'	DEF
67632	DX	09	delivery	'IP*'	DEF
67641	DX	09	delivery	'IP*'	DEF
67642	DX	09	delivery	'IP*'	DEF
67651	DX	09	delivery	'IP*'	DEF
67652	DX	09	delivery	'IP*'	DEF
67661	DX	09	delivery	'IP*'	DEF
67662	DX	09	delivery	'IP*'	DEF
67681	DX	09	delivery	'IP*'	DEF
67682	DX	09	delivery	'IP*'	DEF
67691	DX	09	delivery	'IP*'	DEF
67692	DX	09	delivery	'IP*'	DEF
67801	DX	09	delivery	'IP*'	DEF
67811	DX	09	delivery	'IP*'	DEF
67901	DX	09	delivery	'IP*'	DEF
67902	DX	09	delivery	'IP*'	DEF
67911	DX	09	delivery	'IP*'	DEF
67912	DX	09	delivery	'IP*'	DEF
72	PX	09	delivery	'IP*'	DEF
720	PX	09	delivery	'IP*'	DEF
721	PX	09	delivery	'IP*'	DEF
722	PX	09	delivery	'IP*'	DEF
7221	PX	09	delivery	'IP*'	DEF
7229	PX	09	delivery	'IP*'	DEF
723	PX	09	delivery	'IP*'	DEF
7231	PX	09	delivery	'IP*'	DEF
7239	PX	09	delivery	'IP*'	DEF
724	PX	09	delivery	'IP*'	DEF
725	PX	09	delivery	'IP*'	DEF
7251	PX	09	delivery	'IP*'	DEF
7252	PX	09	delivery	'IP*'	DEF
7253	PX	09	delivery	'IP*'	DEF
7254	PX	09	delivery	'IP*'	DEF
726	PX	09	delivery	'IP*'	DEF
727	PX	09	delivery	'IP*'	DEF
7271	PX	09	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
7279	PX	09	delivery	'IP*'	DEF
728	PX	09	delivery	'IP*'	DEF
729	PX	09	delivery	'IP*'	DEF
73	PX	09	delivery	'IP*'	DEF
730	PX	09	delivery	'IP*'	DEF
7301	PX	09	delivery	'IP*'	DEF
7309	PX	09	delivery	'IP*'	DEF
731	PX	09	delivery	'IP*'	DEF
732	PX	09	delivery	'IP*'	DEF
7321	PX	09	delivery	'IP*'	DEF
7322	PX	09	delivery	'IP*'	DEF
733	PX	09	delivery	'IP*'	DEF
734	PX	09	delivery	'IP*'	DEF
735	PX	09	delivery	'IP*'	DEF
7351	PX	09	delivery	'IP*'	DEF
7359	PX	09	delivery	'IP*'	DEF
736	PX	09	delivery	'IP*'	DEF
738	PX	09	delivery	'IP*'	DEF
739	PX	09	delivery	'IP*'	DEF
7391	PX	09	delivery	'IP*'	DEF
7392	PX	09	delivery	'IP*'	DEF
7393	PX	09	delivery	'IP*'	DEF
7394	PX	09	delivery	'IP*'	DEF
7399	PX	09	delivery	'IP*'	DEF
740	PX	09	delivery	'IP*'	DEF
741	PX	09	delivery	'IP*'	DEF
742	PX	09	delivery	'IP*'	DEF
744	PX	09	delivery	'IP*'	DEF
749	PX	09	delivery	'IP*'	DEF
7499	PX	09	delivery	'IP*'	DEF
7630	DX	09	delivery	'IP*'	DEF
7632	DX	09	delivery	'IP*'	DEF
7633	DX	09	delivery	'IP*'	DEF
7634	DX	09	delivery	'IP*'	DEF
7636	DX	09	delivery	'IP*'	DEF
7680	DX	09	delivery	'IP*'	DEF
7681	DX	09	delivery	'IP*'	DEF
V27	DX	09	delivery	'IP*'	DEF
V270	DX	09	delivery	'IP*'	DEF
V271	DX	09	delivery	'IP*'	DEF
V272	DX	09	delivery	'IP*'	DEF
V273	DX	09	delivery	'IP*'	DEF
V274	DX	09	delivery	'IP*'	DEF
V275	DX	09	delivery	'IP*'	DEF
V276	DX	09	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
V277	DX	09	delivery	'IP*'	DEF
V279	DX	09	delivery	'IP*'	DEF
V30	DX	09	delivery	'IP*'	DEF
V300	DX	09	delivery	'IP*'	DEF
V3000	DX	09	delivery	'IP*'	DEF
V3001	DX	09	delivery	'IP*'	DEF
V301	DX	09	delivery	'IP*'	DEF
V302	DX	09	delivery	'IP*'	DEF
V31	DX	09	delivery	'IP*'	DEF
V310	DX	09	delivery	'IP*'	DEF
V3100	DX	09	delivery	'IP*'	DEF
V3101	DX	09	delivery	'IP*'	DEF
V311	DX	09	delivery	'IP*'	DEF
V312	DX	09	delivery	'IP*'	DEF
V32	DX	09	delivery	'IP*'	DEF
V320	DX	09	delivery	'IP*'	DEF
V3200	DX	09	delivery	'IP*'	DEF
V3201	DX	09	delivery	'IP*'	DEF
V321	DX	09	delivery	'IP*'	DEF
V322	DX	09	delivery	'IP*'	DEF
V33	DX	09	delivery	'IP*'	DEF
V330	DX	09	delivery	'IP*'	DEF
V3300	DX	09	delivery	'IP*'	DEF
V3301	DX	09	delivery	'IP*'	DEF
V331	DX	09	delivery	'IP*'	DEF
V332	DX	09	delivery	'IP*'	DEF
V34	DX	09	delivery	'IP*'	DEF
V340	DX	09	delivery	'IP*'	DEF
V3400	DX	09	delivery	'IP*'	DEF
V3401	DX	09	delivery	'IP*'	DEF
V341	DX	09	delivery	'IP*'	DEF
V342	DX	09	delivery	'IP*'	DEF
V35	DX	09	delivery	'IP*'	DEF
V350	DX	09	delivery	'IP*'	DEF
V3500	DX	09	delivery	'IP*'	DEF
V3501	DX	09	delivery	'IP*'	DEF
V351	DX	09	delivery	'IP*'	DEF
V352	DX	09	delivery	'IP*'	DEF
V36	DX	09	delivery	'IP*'	DEF
V360	DX	09	delivery	'IP*'	DEF
V3600	DX	09	delivery	'IP*'	DEF
V3601	DX	09	delivery	'IP*'	DEF
V361	DX	09	delivery	'IP*'	DEF
V362	DX	09	delivery	'IP*'	DEF
V37	DX	09	delivery	'IP*'	DEF

Code1	CodeCat1	CodeType1	Descrip	caresettingprincipal	t4_index
V370	DX	09	delivery	'IP*'	DEF
V3700	DX	09	delivery	'IP*'	DEF
V3701	DX	09	delivery	'IP*'	DEF
V371	DX	09	delivery	'IP*'	DEF
V372	DX	09	delivery	'IP*'	DEF
V39	DX	09	delivery	'IP*'	DEF
V390	DX	09	delivery	'IP*'	DEF
V3900	DX	09	delivery	'IP*'	DEF
V3901	DX	09	delivery	'IP*'	DEF
V391	DX	09	delivery	'IP*'	DEF
V392	DX	09	delivery	'IP*'	DEF

## VIII. APPENDIX 8: PROJECT DESCRIPTION

### A. INTRODUCTION

The Food and Drug Administration (FDA) Sentinel initiative is a multi-institutional distributed network that conducts medical product safety surveillance studies as directed by the FDA. The Sentinel distributed database includes 18 Data Partners (DP) with over 193 million individuals with 351 million person-years of data transformed into the Sentinel Common Data Model. Each locally-stored DP's database contains administrative medical and pharmacy insurance claims and demographic data, augmented with some electronic health record (EHR) information. Healthcare outcomes, exposures, and confounder information necessary for comparative safety and effectiveness research is not readily available in health care claims or EHR data. Person reported data is also not easily obtained or recorded in electronic health systems. An alternative approach, assembling research cohorts such as patient registries, is time consuming and resource intensive. Sentinel has conducted hundreds of medical products safety assessments, but certain assessments cannot be done because of these gaps in the Sentinel distributed database. This pilot project addresses this limitation.

Widespread mobile device ownership creates an opportunity to collect information directly from individuals for use in comparative safety and effectiveness research. Data collected through a mobile device application can be matched to existing Sentinel data to support and expand the capabilities of FDA to perform medical product safety assessments.

The project represents a proof of concept that the data collected from a mobile application can be matched to data in the existing Sentinel distributed dataset maintained by a single data partner, Group Health Research Institute (GHRI). No outcome of interest is being studied.

As part of this project, feedback on the usability of the mobile application will be collected.

### B. METHODOLOGY

The FDA has contracted with The Harvard Pilgrim Health Care Institute (HPHCI) to design and build the following to achieve the proof of concept described above:

- Two identical mobile applications, based on the Apple ResearchKit and Google ResearchStack frameworks respectively
- A web-based administrative application (study designer) for configuring questionnaires distributed via the mobile application
- A HIPAA and FISMA compliant storage environment in which questionnaire and active task responses will be stored
- A web-based portal from which questionnaire and active task responses can be downloaded<sup>3</sup>

HPHCI has sub-contracted with two software vendors, LabKey Software (LabKey) and Boston Technology Corporation (BTC), to perform the development work. BTC will develop the mobile applications and study designer. LabKey will develop the HIPAA and FISMA compliant storage environment and web-based portal for downloading responses. Development of the mobile application will occur between January and June of 2017 and be divided into 2 development cycles. The first cycle will conclude in March 2017, the 2<sup>nd</sup> cycle will conclude in June 2017. Development of the storage environment will take place from October, 2016, to April, 2017.

The mobile applications will be available on both iOS and Android app stores and will act as a gateway to access questionnaires for various assessments. Questionnaire content, consent information, eligibility criteria and other app elements will be configurable via the study designer. Resources, such as links to



websites, can be made available in the mobile application. A dashboard for each study is also available for each study in the application; it shows the number of questionnaires answered out of the total number in the study, any upcoming questionnaires or tasks, and trends over time based on responses. Study participants can only see data about themselves, they cannot see other users' data. Questionnaires can be configured to utilize participant tokens as part of eligibility criteria to allow retrospective or prospective matching to external datasets. Participant tokens can be formatted to be a randomly generated number which will prevent participant identification. This ensures the application can securely collect and store data from a previously specified cohort, as required for the proof of concept, or from the general population of application users.

The storage environment is divided into three distinct servers: a server to store responses, a server to store user registration information (email, and an ID representing each study-participant combination), and server to store study metadata (questions, files, and images). In the response server, each participating Data Partner will have its own folder, and each study will be a folder within the organization folder. Roles and data access controls are applied at the folder level in each server. The response server will also automatically create new database schemas for every new questionnaire created. Access to each server will be controlled by project administrators at HPHCI and FDA.

The pilot project is the first use of the system for data collection and matching to an external dataset. The project will be divided into three phases.

## **1. Phase 1: Feature Testing**

This phase will take place between April 1, 2017 and June 30, 2017.

GHRI will recruit 4-10 recently pregnant women to test and provide feedback on a prototype version of the mobile application, which will be available at the conclusion of the first development cycle. These women will be recruited from: 1) volunteers who are acquaintances of GHRI staff; 2) women who have participated in focus groups regarding pregnancy in the past and who filled out a contact form saying they were willing to help with future research design with investigator Sascha Dublin; or 3) staff at GHRI. The project's two patient advisors (recruited from among women participating in GHRI focus groups in the past) will also attend the groups as participants.

Participants in Phase 1 will be instructed to download the application on their mobile phone via a URL sent directly to them by GHRI. The URL will be created by BTC and provided to GHRI by HPHCI. As the mobile application will still be in development during this phase, it will not be available for download in public app stores. Participants may also view printed mock-ups of the mobile application visual design for components of the application which are under development.

The feature testing groups will be structured in a focus group-style where participants will discuss the features of the application they did and did not like. The feature testing group facilitators will not have a specific questionnaire for participants, but will utilize an open discussion style for the groups. The facilitators will follow a developed guide for all sessions. GHRI will hold between 1 and 5 sessions of the group depending on availability of the participants.

Harvard Pilgrim staff and investigators will not participate in these feature testing groups run by GHRI and will not have any contact with the testing group. Feedback collected from the testing group will be aggregated by GHRI and provided to Harvard Pilgrim investigators and staff as well as project collaborators BTC, LabKey, FDA, and UC San Diego. This feedback will contain information about the usability and functionality of the mobile app and will not contain any details about the women

participating in the group. All feedback will be anonymous. The feedback will be used in development of the mobile application.

## 2. Phase 2: Data Collection

Phase 2 of the project will include data collection and will take place from July 1, 2017 – October 31, 2017.

GHRI will identify a cohort of an estimated 50 pregnant women who will be asked to download the mobile app. The recruitment process will be outlined in the Phase 2 IRB application to be submitted later in 2017. The cohort will include women who are active patients in an obstetrics practice affiliated with GHRI and who have a record in the Sentinel distributed datasets held by GHRI. The purpose of this pilot project will be explained to them during recruitment by GHRI, but participants will provide informed consent via the mobile application.

HPHCI will use the storage environment to create a set of unique participant tokens for distribution to the cohort. HPHCI will distribute these tokens to GHRI study administrators, and GHRI will assign and distribute a token to each participant as they identify and enroll them in the cohort. GHRI will maintain a record of token assignments that will contain the token and patient ID (PatID) from the Sentinel distributed dataset maintained by GHRI. This record (crosswalk) will be used in doing matched data analysis

Once at least 50 women are identified and agree to participate in data collection, they will be instructed to do the following by GHRI:

- Download the application from the Apple App Store or Google Play Store.
- Enroll in the study via the mobile application. Enrollment involves actively selecting the study from a list, completing an eligibility screening, and completing an informed consent process from within the mobile application. The eligibility screening will require each participant to enter the participant token previously given to them by GHRI.

Once enrolled, questionnaires and active tasks will be presented to participants on scheduled intervals over the 4 month data collection period.

A separate IRB application will be submitted for Phase 2 and will include:

- Mobile application questionnaire details, informed consent documents, and eligibility criteria
- [Details on participant recruitment](#)
- Details on the security features of the application and data storage environment
- Details on resources that will be made available to participants in the mobile application
- Details on the trends and statistics available to each user in the study dashboard section

HPHCI investigators and staff will not have any contact with the pregnant women in the cohort. No data collection will begin until IRB approval is complete at GHRI and HPHCI. A separate IRB application will be completed for this phase of the work.

## 3. Phase 3: Analysis

Study administrators from GHRI will be given access to the study folder on the response server that contains questionnaire and active task responses for the participant cohort. They will download response files in SAS, Excel, or CSV files.

GHRI will then utilize the crosswalk file described in the data collection phase to combine data elements from the response file with data elements in the Sentinel distributed dataset. Data will be combined in a way that ensures data elements that represent the same unique person in the Sentinel distributed dataset and the downloaded response files are matched. Specific data elements that will be combined into a single matched dataset will be defined in a subsequent IRB applications.

Descriptive analysis will be performed by GHRI on the matched dataset. Specific statistical analysis to be performed will be defined in a subsequent IRB application. HPHCI investigators and staff will not have access to the matched dataset. A separate IRB application will be completed for this phase of the work.

### References

1. Behrman RE, Benner JS, **Brown JS**, McClellan M, Woodcock J, Platt R. Developing the Sentinel System - A national resource for evidence development. *N Engl J Med* 2011; 364:498-499.
2. Curtis LH, Weiner MG, Boudreau DM, Cooper WO, Daniel GW, Nair VP, Raebel MA, Beaulieu NU, Rosofsky R, Woodworth TS and **Brown JS**. Design considerations, architecture, and use of the Mini-Sentinel distributed data system. *Pharmacoepidemiol Drug Saf.* 2012;21(S1): 23–31.
3. ResearchStack to Extend ResearchKit(™) Studies to Android [Internet]. Cornell Tech. 2016 [cited 1 May 2016]. Available from: <http://tech.cornell.edu/news/researchstack-to-extend-researchkit-studies-to-android>

## IX. APPENDIX 9: PREGNANCY STUDY APP ANALYTIC TABLES

**Table 33. Questionnaire Completion By Name**

Questionnaire Name	Women that Completed at Least 1 Run of the Questionnaire	%	*Number of Times Completed
	N=64		
Current Weight	59	92%	264
Initial Study Questionnaire	59	92%	59
Medical Condition History	58	91%	58
Pregnancy Status	58	91%	288
Short Term Illness History During Pregnancy	53	83%	54
Pregnancy History	50	78%	50
Information About You	48	75%	48
Smoking and Vaping History	45	70%	45
Vaccine History During Pregnancy	44	69%	44
Vitamin Use History	40	63%	40
Current Medical Condition Information	39	61%	106
History of Alcohol Exposure	39	61%	39
History of Marijuana or Cannabis Exposure	39	61%	39
History of Recreational Drug Exposure	39	61%	39
Recent Short Term Illnesses	36	56%	92
Current Smoking and Vaping Exposure	31	48%	45
Current Vitamin Use	30	47%	44
Current Alcohol Exposure	26	41%	26
Current Marijuana or Cannabis Exposure	26	41%	26
Current Recreational Drug Exposure	26	41%	26
Vaccine Exposure Update	13	20%	14
Current Pregnancy Outcomes	7	11%	7

*\*Across all recurring instances of the Questionnaire*

**Table 34. Days of Engagement**

Days Engaged	Number of Women	%
0-14	19	30%
15-30	13	20%
31-45	6	9%
46-60	10	16%
61-75	8	13%
75-90	8	13%
<b>Total</b>	64	100%

**Table 35. Questionnaire Completion by Date**

<b>Date</b>	<b>Number of Questionnaires Submitted</b>
28-Sep	18
29-Sep	14
30-Sep	18
1-Oct	12
2-Oct	5
3-Oct	15
4-Oct	15
5-Oct	9
6-Oct	9
7-Oct	18
8-Oct	14
9-Oct	9
10-Oct	4
11-Oct	19
12-Oct	20
13-Oct	3
14-Oct	11
15-Oct	12
16-Oct	18
17-Oct	17
18-Oct	13
19-Oct	22
20-Oct	32
21-Oct	16
22-Oct	57
23-Oct	46
24-Oct	10
25-Oct	29
26-Oct	27
27-Oct	38
28-Oct	38
29-Oct	25
30-Oct	10
31-Oct	41
1-Nov	13
2-Nov	7
3-Nov	28
4-Nov	32
5-Nov	8
6-Nov	34
7-Nov	18
8-Nov	5
9-Nov	36

Date	Number of Questionnaires Submitted
10-Nov	9
11-Nov	16
12-Nov	26
13-Nov	8
14-Nov	8
15-Nov	16
16-Nov	5
17-Nov	14
18-Nov	13
19-Nov	29
20-Nov	27
21-Nov	5
22-Nov	24
23-Nov	26
24-Nov	2
25-Nov	25
26-Nov	32
27-Nov	20
28-Nov	21
29-Nov	17
30-Nov	11
1-Dec	19
2-Dec	6
3-Dec	11
4-Dec	10
5-Dec	13
6-Dec	6
7-Dec	12
8-Dec	9
9-Dec	11
10-Dec	7
11-Dec	2
12-Dec	5
13-Dec	9
14-Dec	16
15-Dec	4
16-Dec	12
17-Dec	9
18-Dec	7
19-Dec	16
20-Dec	11
21-Dec	11
22-Dec	17
23-Dec	7
24-Dec	19

Date	Number of Questionnaires Submitted
25-Dec	8

**Table 36. Questionnaire Completion by Time of Day**

Time	Number of Questionnaires Submitted by Hour
12:00:00 AM	53
1:00:00 AM	10
2:00:00 AM	9
3:00:00 AM	17
4:00:00 AM	22
5:00:00 AM	20
6:00:00 AM	70
7:00:00 AM	93
8:00:00 AM	103
9:00:00 AM	77
10:00:00 AM	88
11:00:00 AM	89
12:00:00 PM	58
1:00:00 PM	94
2:00:00 PM	49
3:00:00 PM	72
4:00:00 PM	57
5:00:00 PM	74
6:00:00 PM	43
7:00:00 PM	98
8:00:00 PM	93
9:00:00 PM	80
10:00:00 PM	49
11:00:00 PM	38

**Table 37. Frequency of Questionnaire Completion**

<b>Number of Questionnaires Completed</b>	<b>Number of Women</b>	<b>%</b>
0	3	4.69%
1-5	9	14.06%
6-10	8	12.50%
11-15	7	10.94%
16-20	5	7.81%
21-25	5	7.81%
26-30	5	7.81%
31-35	8	12.50%
36-40	2	3.13%
41-45	4	6.25%
46-50	4	6.25%
51-52	3	4.69%
53	1	1.56%
<b>TOTAL</b>	<b>64</b>	<b>100.00%</b>



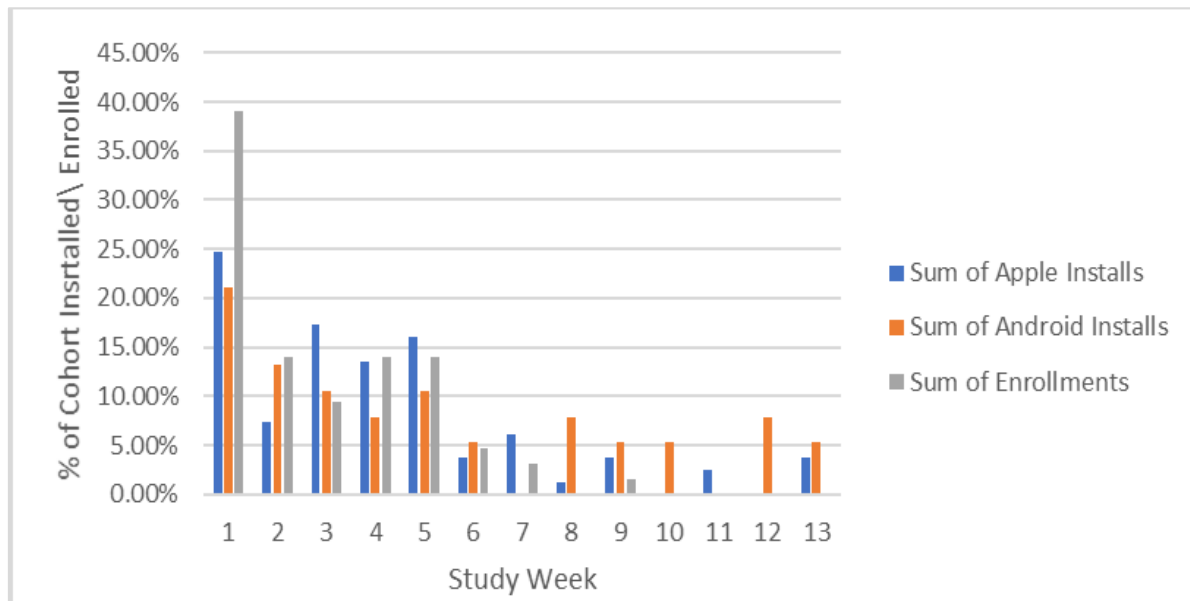
**Table 38. Number of Responses by Questionnaire**

Questionnaire	First Launch Date	Days Post Launch										Total Responses
		0-1	2-3	4-5	6-7	>7						
<b>Recurring</b>												
*Current Weight	9/26/2017	77	29%	60	23%	91	34%	36	14%	0	0%	264
*Pregnancy Status	10/3/2017	80	28%	53	18%	109	38%	46	16%	0	0%	288
Current Medical Condition Information	11/1/2017	37	35%	34	32%	14	13%	8	8%	13	12%	106
Recent Short Term Illnesses	11/9/2017	49	53%	24	26%	7	8%	4	4%	8	9%	92
Current Smoking and Vaping Exposure	11/19/2017	25	56%	5	11%	6	13%	3	7%	6	13%	45
Current Vitamin Use	11/20/2017	18	41%	12	27%	5	11%	3	7%	6	14%	44
Current Marijuana or Cannabis Exposure	11/25/2017	13	50%	5	19%	1	4%	3	12%	4	15%	26
Current Recreational Drug Exposure	11/26/2017	11	42%	6	23%	2	8%	2	8%	5	19%	26
Current Alcohol Exposure	11/27/2017	9	35%	7	27%	3	12%	2	8%	5	19%	26
<b>One-Time</b>												
Initial Study Questionnaire	9/26/2017	0	0%	11	19%	10	17%	4	7%	34	58%	59
Medical Condition History	9/27/2017	6	10%	10	17%	5	9%	5	9%	32	55%	58
**Current Pregnancy Outcomes	10/3/2017	0	0%	0	0%	0	0%	0	0%	10	100%	10
Short Term Illness History During Pregnancy	10/5/2017	10	19%	10	19%	3	6%	5	9%	26	48%	54
Pregnancy History	10/12/2017	9	18%	5	10%	5	10%	6	12%	25	50%	50
Information About You	10/18/2017	11	23%	8	17%	9	19%	3	6%	17	35%	48
Smoking and Vaping History	10/19/2017	15	33%	7	16%	6	13%	3	7%	14	31%	45
Vaccine History During Pregnancy	10/20/2017	11	25%	13	30%	3	7%	3	7%	14	32%	44
Vitamin Use History	10/21/2017	12	30%	8	20%	5	13%	4	10%	11	28%	40
History of Marijuana or Cannabis Exposure	10/25/2017	11	28%	9	23%	2	5%	4	10%	13	33%	39
History of Recreational Drug Exposure	10/26/2017	12	31%	9	23%	6	15%	0	0%	12	31%	39
History of Alcohol Exposure	10/27/2017	16	41%	3	8%	5	13%	3	8%	12	31%	39
Vaccine Exposure Update	12/20/2017	5	36%	5	36%	4	29%	0	0%	0	0%	14
<b>All Questionnaires</b>	-	437		304		301		147		267		539

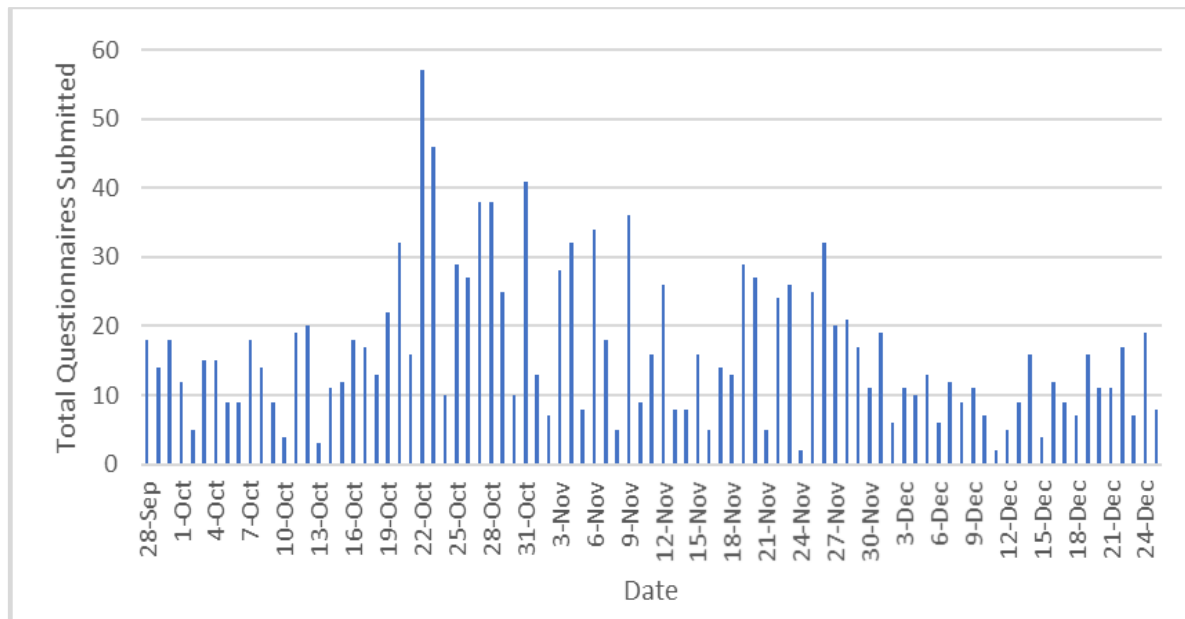
\*Expired weekly, cannot have a response submitted >7 days post launch

\*\*Only women who had a real pregnancy outcome were instructed to take this Questionnaire

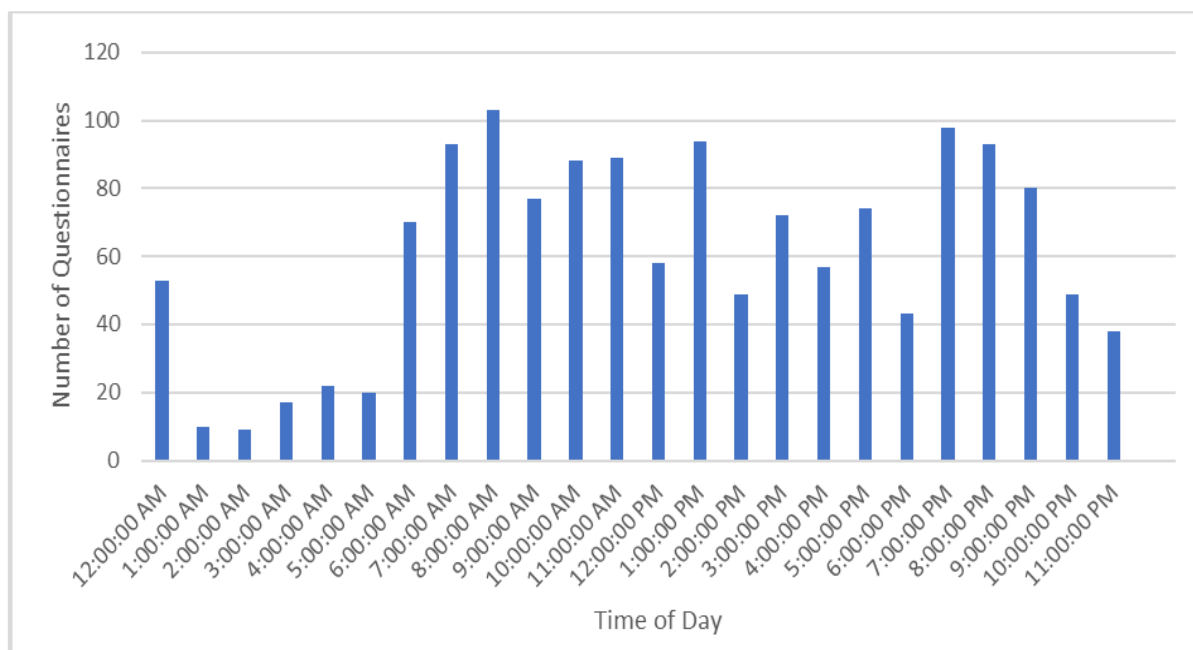
**Figure 1. Installations and Enrollments Over Time**



**Figure 2. Number of Questionnaires Submitted**



**Figure 3. Number of Questionnaires Submitted by Time of Day**



**Figure 4. Number of Questionnaires Submitted by Day of Week**

