Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Page K, Melia MT, Veenhuis RT, et al. Randomized trial of a vaccine regimen to prevent chronic HCV infection. N Engl J Med 2021;384:541-9. DOI: 10.1056/NEJMoa2023345

Supplementary Appendix Supplement to: Page K et. al. Randomized Trial of a Vaccine Regimen to Prevent Chronic HCV Infection

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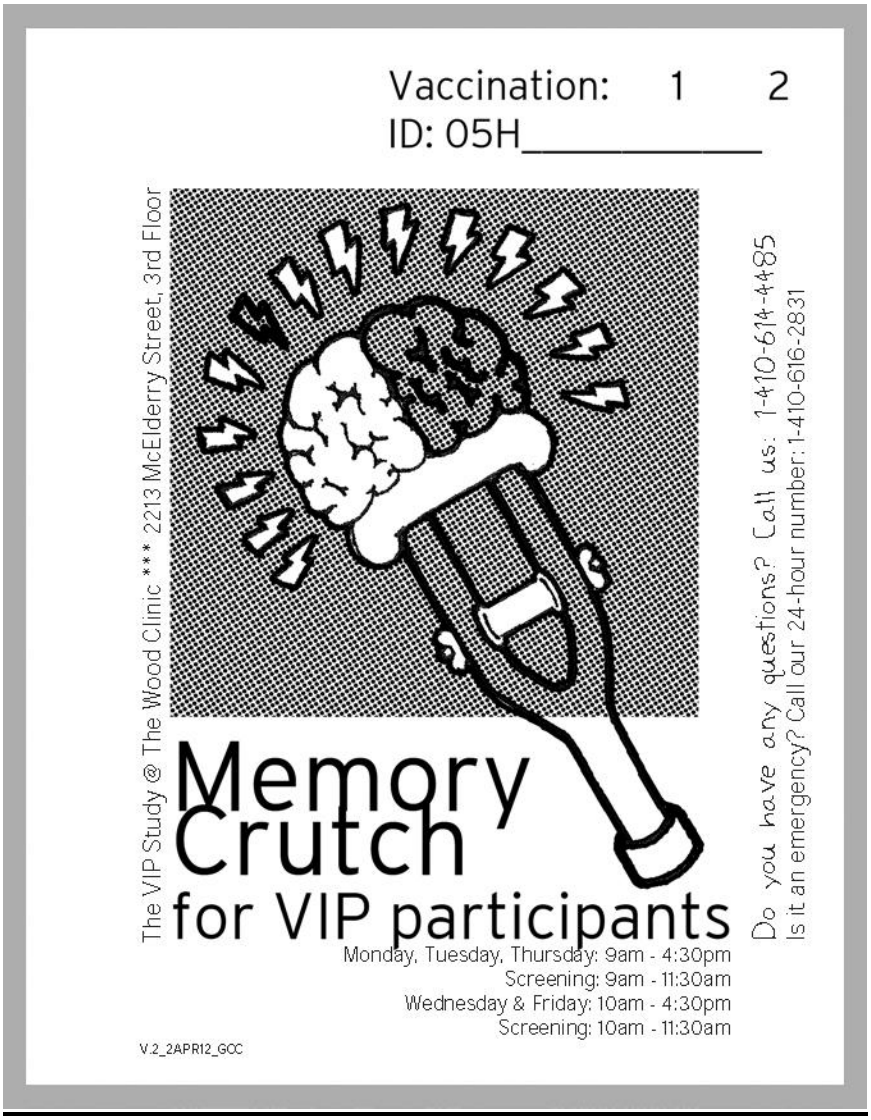
Appendix I Collaborators

We thank all the trial participants for their participation in the study and commitment to advancing knowledge regarding HCV prevention. We appreciate the data and safety monitoring board; Sharon Frey (chair), Hugo Rosen, Raymond Chung, and Steven Gange. We are grateful for the advice and expertise of David Thomas. We thank the study staff - Caycee Cullen, Scott Shapiro, Kelsey Maher, Emma Miller, Hannah Tierney, Gurjot Gill, Shaneca Bowden, Donald Brown, David Hudson, James Trudeau, Wanda Snow, Jessi Morton, Venita Tapp, June Gaddy, Joan Nelson, Jackline Lasola, Nicholas Karnazis, and Kirsten White for their dedication to the success of the study implementation. The authors would like to express gratitude to Anne Rinaldi and the FHI360 team as well, who provided outstanding support throughout the trial, and to Marian Ewell, Michelle Green, Hannah Kwak, and David Styers at Emmes and Rebecca Hoagland at COTA Enterprises, who designed, implemented, and maintained the data system and clinical forms, performed data management, and supported the statistical analyses throughout the trial. Lastly, we would like to thank Peter Wolff, MHA, Rajen Koshy, PhD, and Carolyn Deal, PhD for their vital assistance in trial design, support, and completion. The trial would not have been possible without their tireless efforts.

Appendix 3 - Diary for recording temperature and the presence and intensity of post-vaccination AEs (*Memory Crutch for VIP Participants*)



HOW TO USE ME!

* You have to fill out a page EVERY DAY for 8 days. Day of vaccination is Day 0, last day is Day 7.
* Fill it out in the evening (after 4pm, but before midnight), after you've thought about how you feel.
* You have to fill in ALL of the spaces every day. If you don't have any symptoms, write 0 in all the boxes.
* If you forgot to fill out the page one day leave it blank. We'll be happy to go over it with you the next time you come in.
* Any other medical issues happen that day? Write them at the bottom of the page.
* Did you go to the doctor or ER that day? Check that box at the bottom of the page.
* Did you start taking any new meds, or change meds you were taking? Write it at the bottom. You don't have to write down anything you've been taking, just if you change meds or add something new.
    * This includes taking any pain reliever (aspirin, ibuprofen), cough syrup, cold medications, stomach relievers (pepto bismol), etc.

Do you have a fever (over 100.4°F)?
Are you so sick you can't move?
Do you have any questions?
Call us: 410-614-4485
Is it an emergency? Call: 410-616-2831

Page 1

HOW TO TAKE YOUR TEMPERATURE AND MEASURE SYMPTOMS

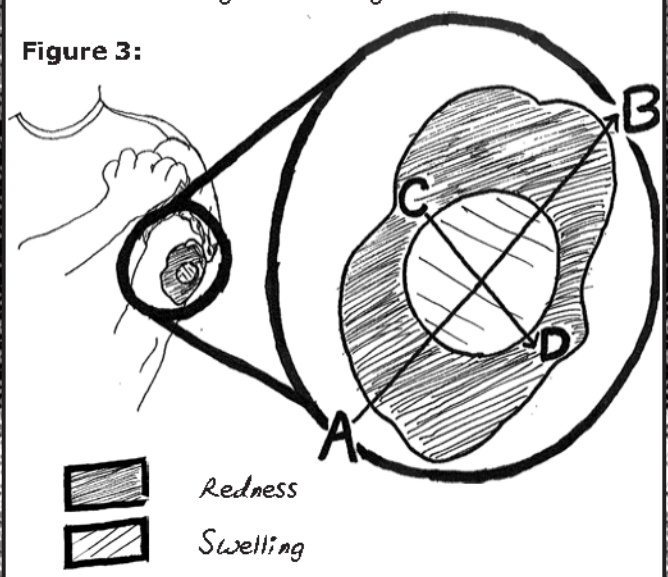
Using the Tempa-DOT thermometer

* Store them in a cool place colder than 86°F. (Don't let them get crushed!)
* Take your temperature at about the same time each day. If you take your temperature more than once, write down the highest one.
    * Don't eat, drink, or smoke for 15 minutes before taking your temperature.
* Put the Tempa-Dot thermometer in your mouth, under your tongue, the same way you would a regular thermometer. It should touch the back of your tongue and stick out of either side of your mouth.
* Keep your mouth closed and leave the thermometer in your mouth for at least 1 minute, but no longer than 2 minutes.
* Remove the thermometer from your mouth and wait 10 seconds. Write down the temperature next to the last blue dot on the thermometer. Ignore any skipped dots.
* If your temperature is less than 97.0°F, wait 15 minutes, do not smoke, or eat or drink anything, and then take your temperature again. Write down the highest temperature.

Page 2

Measuring swelling and redness

Figure 3:



Redness

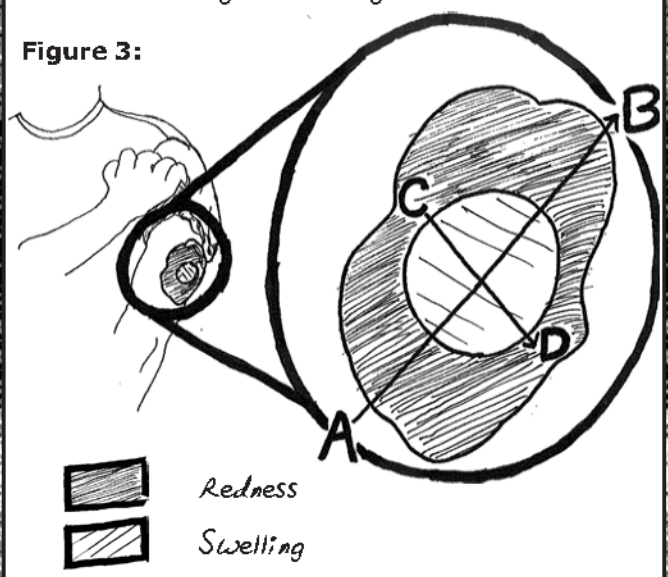
Swelling

- If you have swelling or redness where you got the vaccine, write it down. Use the ruler we gave you or use the edge of this booklet (there's a ruler on the back cover).
- Measure the area with *redness* at the widest part (*From point **A** to **B** in **Figure 3***). Measure the width of any swelling at the widest part (*From point **C** to **D** in **Figure 3***).
- *Use millimeters (mm) to measure!*
- Write down all measurements for each day.

Page 4

Measuring swelling and redness

Figure 3:



Redness

Swelling

- If you have swelling or redness where you got the vaccine, write it down. Use the ruler we gave you or use the edge of this booklet (there's a ruler on the back cover).
- Measure the area with *redness* at the widest part (*From point **A** to **B** in **Figure 3***). Measure the width of any swelling at the widest part (*From point **C** to **D** in **Figure 3***).
- *Use millimeters (mm) to measure!*
- Write down all measurements for each day.

Page 4

Measuring intensity

(how bad it feels)

Use the scales below to record the intensity of *General Body Symptoms* and *Local Vaccination Site Reactions* each day.

General Symptoms

0 = *None*
1 = *Mild*, no interference with activity
2 = *Moderate*, some intereference with activity
3 = *Severe*, significant intereference, prevents daily activity

Pain (experienced without touching injection site)

0 = *None*
1 = *Mild*, subject is aware of pain but it doesn't interfere with daily activity **&** no pain medication was taken
2 = *Moderate*, subject is aware of pain; there is interference with daily activity **or** it requires use of pain medication
3 = *Severe*, subject is aware of pain **&** it prevents daily activity

Tenderness (hurts only when injection site is touched)

0 = *None*
1 = *Mild*, area immediately surrounding the injection site hurts only when touched **&** does **not** interfere with daily activity
2 = *Moderate*, area immediately surrounding the injection site hurts when touched **&** interferes with daily activity
3 = *Severe*, area immediately surrounding the injection site hurts when touched **&** prevents daily activity

Warmth

0 = *None*
1 = *Mild*, does not interfere with activity
2 = *Moderate*, interferes with activity
3 = *Severe*, prevents daily activity

Page 5

Day 0 Date_____ [You got the injection today!]

Temperature ___ ___ ___ . ___ °F
Thermometer used: [ ] Tempa-DOT [ ] Other
If your temperature is less than 97.0°F, wait 15 minutes, and then take your temperature again.
Write down the highest temperature.

General Body Symptoms
Record intensity level as 0, 1, 2, or 3.

Headache	_____
Fatigue (decreased energy)	_____
Body Aches	_____
Nausea	_____
Vomiting	_____
Chills	_____
Stomach Pain	_____
Joint Pain	_____

Local Vaccination Site Reactions
Record intensity level as 0, 1, 2, or 3

Pain –Intensity	_____
Tenderness –Intensity	_____
Warmth –Intensity	_____

Record size in millimeters (mm).

Redness –Size (mm)	___ ___ ___mm
Swelling –Size (mm)	___ ___ ___mm

Other symptoms today?
_____ What intensity? _____

New or changed medications today?
_____ Dose _____ Frequency _____
Reason _____

Visit to doctor or ER today? (other than regular checkup)
[ ] Yes [ ] No

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Day 1 Date_____

Temperature ___ ___ ___ . ___ °F
Thermometer used: [ ] Tempa-DOT [ ] Other
If your temperature is less than 97.0°F, wait 15 minutes, and then take your temperature again.
Write down the highest temperature.

General Body Symptoms
Record intensity level as 0, 1, 2, or 3.

Headache	_____
Fatigue (decreased energy)	_____
Body Aches	_____
Nausea	_____
Vomiting	_____
Chills	_____
Stomach Pain	_____
Joint Pain	_____

Local Vaccination Site Reactions
Record intensity level as 0, 1, 2, or 3

Pain –Intensity	_____
Tenderness –Intensity	_____
Warmth –Intensity	_____

Record size in millimeters (mm).

Redness –Size (mm)	___ ___ ___mm
Swelling –Size (mm)	___ ___ ___mm

Other symptoms today?
_____ What intensity? _____

New or changed medications today?
_____ Dose _____ Frequency _____
Reason _____

Visit to doctor or ER today? (other than regular checkup)
[ ] Yes [ ] No

Page 7

Day 2 Date_____

Temperature ___ ___ ___ . ___ °F
Thermometer used: [ ] Tempa-DOT [ ] Other
If your temperature is less than 97.0°F, wait 15 minutes, and then take your temperature again.
Write down the highest temperature.

General Body Symptoms
Record intensity level as 0, 1, 2, or 3.
Headache _____
Fatigue (decreased energy) _____
Body Aches _____
Nausea _____
Vomiting _____
Chills _____
Stomach Pain _____
Joint Pain _____

Local Vaccination Site Reactions
Record intensity level as 0, 1, 2, or 3
Pain –Intensity _____
Tenderness –Intensity _____
Warmth –Intensity _____
Record size in millimeters (mm).
Redness –Size (mm) ___ ___ ___mm
Swelling –Size (mm) ___ ___ ___mm

Other symptoms today?
_____ What intensity? _____

New or changed medications today?
_____ Dose _____ Frequency _____
Reason _____

Visit to doctor or ER today? (other than regular checkup)
[ ] Yes [ ] No

Page 8

REMEMBER

You're scheduled for a 3-day follow-up visit with us. Bring me with you!

Date _____

Time of appointment _____

The VIP Study @ The Wood Clinic
2213 McElderry Street, 3rd Floor
Baltimore, MD 21205

NOTES: Anything else you think we should know about?

BUS ROUTE STOPS near our clinic are on Monument & Collington or Madison & Collinton for bus numbers 5, 13, 15, & 35

DIRECTIONS FROM SUBWAY

JHU Final Stop, exit through hospital to McElderry St., Wood Clinic is 3 blocks south on McElderry.

Call us if you have any questions
410-614-4485
24 hour emergency #: 410-616-2831

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Day 3 Date_____

Temperature ___ ___ ___ . ___ °F
Thermometer used: [ ] Tempa-DOT [ ] Other
If your temperature is less than 97.0°F, wait 15 minutes, and then take your temperature again.
Write down the highest temperature.

General Body Symptoms
Record intensity level as 0, 1, 2, or 3.
Headache _____
Fatigue (decreased energy) _____
Body Aches _____
Nausea _____
Vomiting _____
Chills _____
Stomach Pain _____
Joint Pain _____

Local Vaccination Site Reactions
Record intensity level as 0, 1, 2, or 3
Pain –Intensity _____
Tenderness –Intensity _____
Warmth –Intensity _____
Record size in millimeters (mm).
Redness –Size (mm) ___ ___ ___mm
Swelling –Size (mm) ___ ___ ___mm

Other symptoms today?
_____ What intensity? _____

New or changed medications today?
_____ Dose _____ Frequency _____
Reason _____

Visit to doctor or ER today? (other than regular checkup)
[ ] Yes [ ] No

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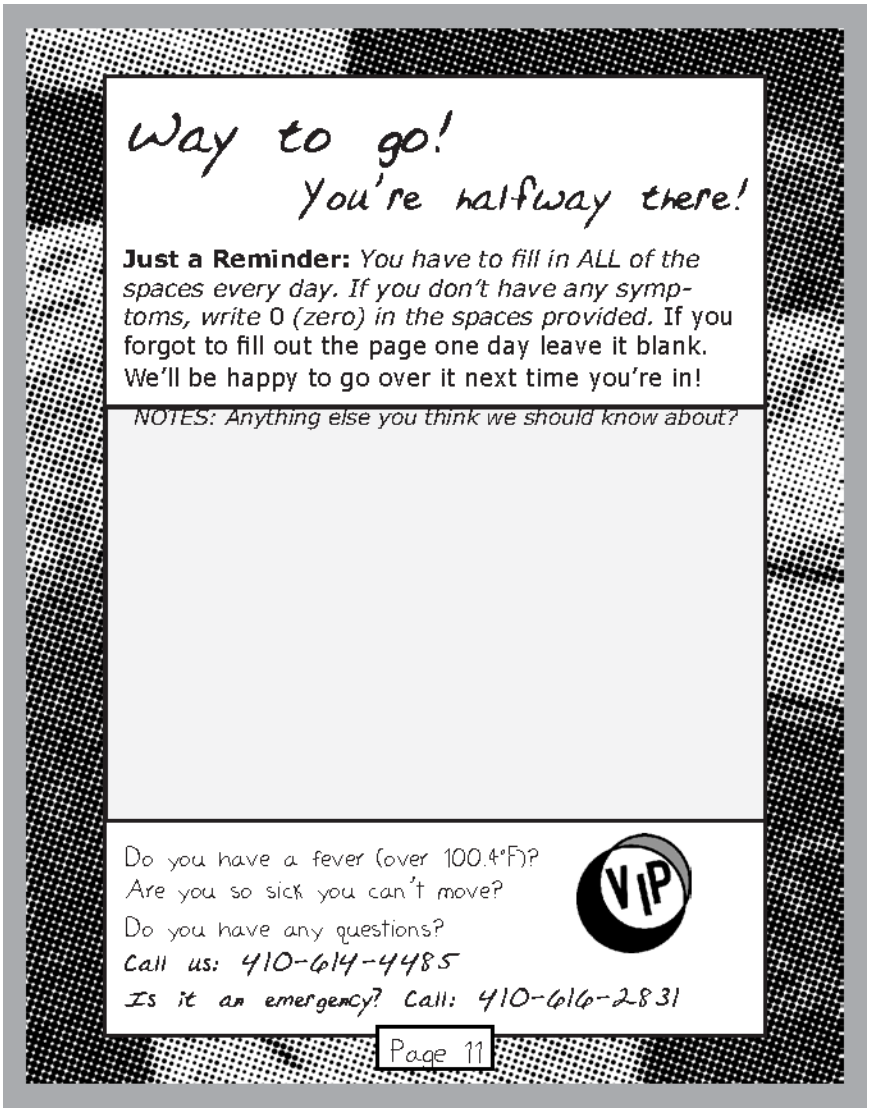
Way to go!
You're halfway there!
Just a Reminder: You have to fill in ALL of the spaces every day. If you don't have any symptoms, write 0 (zero) in the spaces provided. If you forgot to fill out the page one day leave it blank. We'll be happy to go over it next time you're in!
NOTES: Anything else you think we should know about?
Do you have a fever (over 100.4°F)?
Are you so sick you can't move?
Do you have any questions?
Call us: 410-614-4485
Is it an emergency? Call: 410-616-2831
VIP
Page 11

Day 4 Date_____

Temperature ___ ___ ___ . ___ °F
Thermometer used: [ ] Tempa-DOT [ ] Other
If your temperature is less than 97.0°F, wait 15 minutes, and then take your temperature again.
Write down the highest temperature.

General Body Symptoms
Record intensity level as 0, 1, 2, or 3.
Headache _____
Fatigue (decreased energy) _____
Body Aches _____
Nausea _____
Vomiting _____
Chills _____
Stomach Pain _____
Joint Pain _____

Local Vaccination Site Reactions
Record intensity level as 0, 1, 2, or 3
Pain –Intensity _____
Tenderness –Intensity _____
Warmth –Intensity _____
Record size in millimeters (mm).
Redness –Size (mm) ___ ___ ___mm
Swelling –Size (mm) ___ ___ ___mm

Other symptoms today?
_____ What intensity? _____

New or changed medications today?
_____ Dose _____ Frequency _____
Reason _____

Visit to doctor or ER today? (other than regular checkup)
[ ] Yes [ ] No

Page 12

Day 5 Date_____

Temperature ___ ___ ___ . ___ °F
Thermometer used: [ ] Tempa-DOT [ ] Other
If your temperature is less than 97.0°F, wait 15 minutes, and then take your temperature again.
Write down the highest temperature.

General Body Symptoms
Record intensity level as 0, 1, 2, or 3.
Headache _____
Fatigue (decreased energy) _____
Body Aches _____
Nausea _____
Vomiting _____
Chills _____
Stomach Pain _____
Joint Pain _____

Local Vaccination Site Reactions
Record intensity level as 0, 1, 2, or 3
Pain –Intensity _____
Tenderness –Intensity _____
Warmth –Intensity _____
Record size in millimeters (mm).
Redness –Size (mm) ___ ___ ___mm
Swelling –Size (mm) ___ ___ ___mm

Other symptoms today?
_____ What intensity? _____

New or changed medications today?
_____ Dose _____ Frequency _____
Reason _____

Visit to doctor or ER today? (other than regular checkup)
[ ] Yes [ ] No

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Day 6 Date_____

Temperature ___ ___ ___ . ___ °F
Thermometer used: [ ] Tempa-DOT [ ] Other
If your temperature is less than 97.0°F, wait 15 minutes, and then take your temperature again.
Write down the highest temperature.

General Body Symptoms
Record intensity level as 0, 1, 2, or 3.
Headache _____
Fatigue (decreased energy) _____
Body Aches _____
Nausea _____
Vomiting _____
Chills _____
Stomach Pain _____
Joint Pain _____

Local Vaccination Site Reactions
Record intensity level as 0, 1, 2, or 3
Pain –Intensity _____
Tenderness –Intensity _____
Warmth –Intensity _____
Record size in millimeters (mm).
Redness –Size (mm) ___ ___ ___mm
Swelling –Size (mm) ___ ___ ___mm

Other symptoms today?
_____ What intensity? _____

New or changed medications today?
_____ Dose _____ Frequency _____
Reason _____

Visit to doctor or ER today? (other than regular checkup)
[ ] Yes [ ] No

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Day 7 Date_____

Temperature ___ ___ ___ . ___ °F
Thermometer used: [ ] Tempa-DOT [ ] Other
If your temperature is less than 97.0°F, wait 15 minutes, and then take your temperature again.
Write down the highest temperature.

General Body Symptoms
Record intensity level as 0, 1, 2, or 3.

Headache	_____
Fatigue (decreased energy)	_____
Body Aches	_____
Nausea	_____
Vomiting	_____
Chills	_____
Stomach Pain	_____
Joint Pain	_____

Local Vaccination Site Reactions
Record intensity level as 0, 1, 2, or 3

Pain –Intensity	_____
Tenderness –Intensity	_____
Warmth –Intensity	_____

Record size in millimeters (mm).

Redness –Size (mm)	___ ___ ___mm
Swelling –Size (mm)	___ ___ ___mm

Other symptoms today?
_____ What intensity? _____

New or changed medications today?
_____ Dose _____ Frequency _____
Reason _____

Visit to doctor or ER today? (other than regular checkup)
[ ] Yes [ ] No

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CHECK IT

You're scheduled for a 1-week follow-up visit with us. Bring me with you!

Date _____

Time of appointment _____

The VIP Study @ The Wood Clinic
2213 McElderry Street, 3rd Floor
Baltimore, MD 21205

BUS ROUTE STOPS near our clinic are on
Monument & Collington or Madison & Collinton
for bus numbers 5, 13, 15, & 35

DIRECTIONS FROM SUBWAY
JHU Final Stop, exit through hospital to McElderry St., Wood Clinic is 3 blocks south on McElderry.

Have you had any symptoms or problems that have continued past Day 7? *If so, how severe? Use the Notes Section found on the next two pages to write these down.*

Remember to use the 0-to-3 scales you've used throughout this booklet.

Call us if you have any questions
410-614-4485
24 hour emergency #: 410-616-2831

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NOTES

Anything else you think we should know about?

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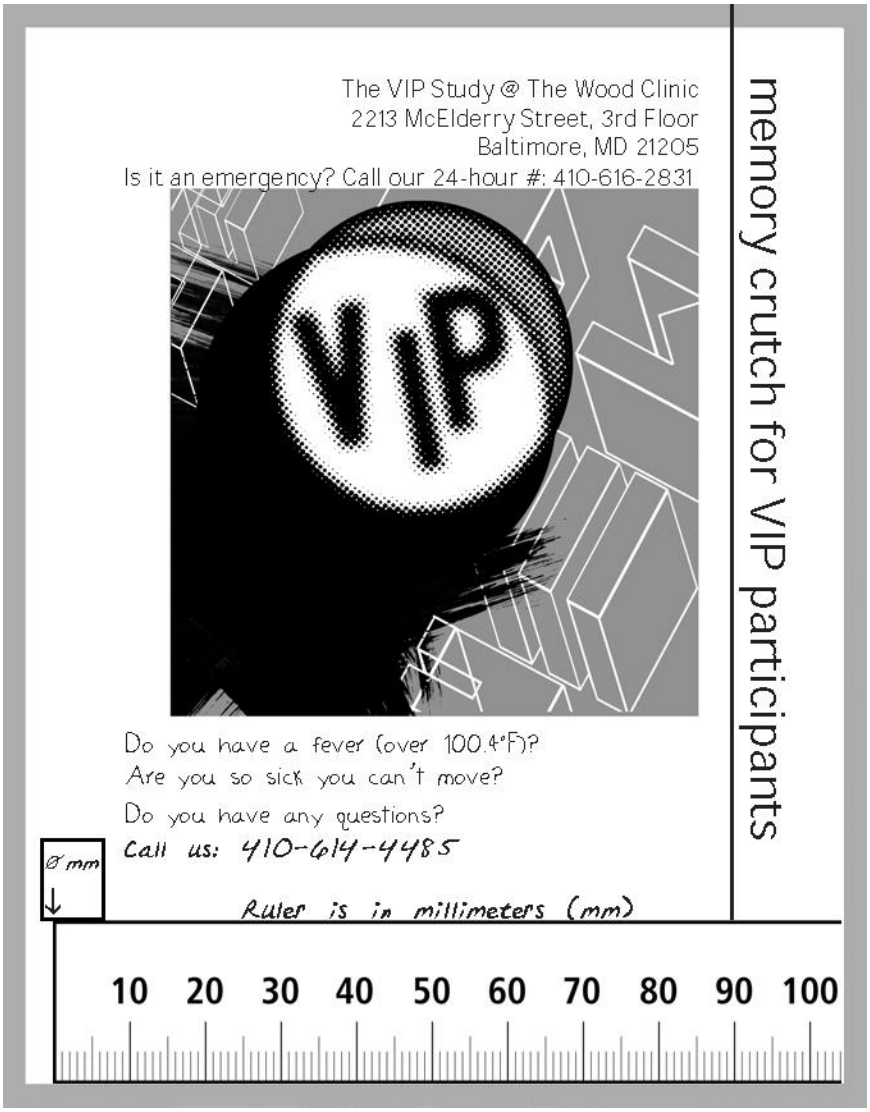
NOTES

Anything else you think we should know about?

Page 18


The VIP Study @ The Wood Clinic
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Is it an emergency? Call our 24-hour #: 410-616-2831
VIP
Do you have a fever (over 100.4°F)?
Are you so sick you can't move?
Do you have any questions?
Call us: 410-614-4485
Ø mm
Ruler is in millimeters (mm)
10 20 30 40 50 60 70 80 90 100
memory crutch for VIP participants

Appendix 3: Supplemental Statistical Analysis Information

Analyses of primary and secondary outcomes:

Sample size calculations were based on the assumption of detecting a 60% reduction in incidence of 6-month chronic infection among vaccinated subjects compared to unvaccinated controls in the ATP analysis. A total of 43 observed events of chronic infection in the ATP sample would provide power of 85% for a two-sided log rank test conducted at the significance level of 0.05 to detect such a reduction. The incidence of chronic infection among controls was assumed to be 14% annually, thus a total of 292.5 subjects in the ATP sample followed for 1.5 years would provide on average 43 events. Assuming 85% of enrolled subjects would be retained in the ATP sample, target enrollment was originally estimated as 344 subjects.

The protocol called for a blinded sample size re-estimation analysis to be presented to the trial's DSMB. Over the course of the trial, two sample size re-estimation analyses were presented to the DSMB. Due to low overall rates of chronic infection observed at each of these interim analyses, the enrollment target was increased to 450 and 540 subjects, respectively.

Because the statistical analysis plan did not include a provision for correcting for multiplicity for the secondary or other outcomes, results are reported as point estimates and 95% confidence intervals. The widths of the confidence intervals were not adjusted for multiplicity, so the intervals should not be used to infer definitive treatment effects for the secondary or other outcomes.

Analyses of exploratory efficacy outcomes:

Exploratory Objective 1: To determine if AdCh3NSmut1 and MVA-NSmut HCV vaccines will reduce incidence of incident HCV infection compared to placebo among HCV-uninfected IDU.

The reduction in incident HCV incidence will be calculated from the hazard ratio of a stratified Cox model. The stratification factors that will be used are gender and IL28B status (i.e. there will be four strata: Female & CC, Female & CT/TT, Male & CC, Male & CT/TT). The model to be fit for subject *i* is:

$$\log h_i(t) = \alpha_j(t) + \beta x_i$$

where h(t) is the hazard function at time t, $\alpha_j(t)$ is the logarithm of the baseline hazard function for strata j, x_i is a binary indicator for membership in the vaccine as compared to the placebo group.

Vaccine Efficacy = 1 – Hazardratio;

Lower 95% CI= 1 – HRUpperCL which is the same as 1 – exp(estimate + Φ^{-1}(.975)*stderrratio)

Upper 95% CI= 1 – HRLowerCL which is the same as 1 - exp(estimate – Φ^{-1}(.975)*stderrratio)

Exploratory Objective 2: To determine if AdCh3NSmut1 and MVA-NSmut HCV vaccines will reduce 9-month incidence of chronic HCV infection compared to placebo among HCV-uninfected IDU.

The analysis of this objective will follow exactly the analyses for the primary outcome of 6-month chronic infection with the following modification:

- For subjects in the ATP (mITT) cohort without HCV infection, the 9-month chronic infection endpoint will be coded as censored, with time to event defined as the elapsed time from the second (first) vaccination, to the end of 26 month follow up, or to the last observed visit before loss to follow-up or of a criterion listed under the censoring criteria for the ATP (mITT) cohort.
- For subjects in the ATP (mITT) cohort who develop HCV infection, the 9-month chronic infection endpoint will be coded as an observed event if the 9-month chronic infection endpoint definition is met, and as censored otherwise, with time to event defined as the elapsed time from the second (first)

vaccination to the date of the sample collection with available test result nearest to the target assessment date of nine months after primary incident infection.

Exploratory Objective 3: To determine if AdCh3NSmut1 and MVA-NSmut HCV vaccines will reduce peak concentration (magnitude) of HCV RNA compared to placebo, in blood samples of persons with incident HCV infection.

HCV RNA concentrations will be summarized by treatment group and by each month from HCV Infection for the ATP and mITT populations. Summaries will include n (number observed), minimum, maximum, geometric mean and the associated 95% confidence interval as well as geometric fold rise from the concentration at the first HCV RNA detection and the associated 95% confidence interval. For each subject, the peak concentration from the first HCV RNA detection to the 6 month blood collection will be identified. The logarithmic peak concentrations will be compared between the vaccine and placebo groups using a two-sided t-test.

Exploratory Objective 4: To determine if AdCh3NSmut1 and MVA-NSmut HCV vaccines will reduce duration of HCV viremia (shorter time to spontaneous resolution) during incident infection (6-month period following incident HCV infection) compared to placebo in blood samples of persons with incident HCV infection.

The duration of incident infection (time to spontaneous resolution) is expected to decrease 4-fold in vaccinated subjects who develop viremia (similar to that observed in subjects with HCV reinfection), compared to the placebo group, after 6 months of observation following incident infection. The midpoint between infection and clearance dates will be used to determine duration. For subjects without observed clearance, the resolution endpoint will be coded as censored, with time to event defined as the elapsed time from the incident infection, to the end of the 6 month follow up, or to the last observed visit before loss to follow-up or to the earliest time any criterion listed under the censoring criteria for the ATP (or mITT) cohort was met.

Analyses of this objective will follow the proportional hazards analysis plan for the primary outcome.

Exploratory Objective 5: To determine if AdCh3NSmut1 and MVA-NSmut HCV vaccines will reduce incidence of chronic HCV infection with genotype 1 compared to non-genotype 1 among HCV-uninfected IDU.

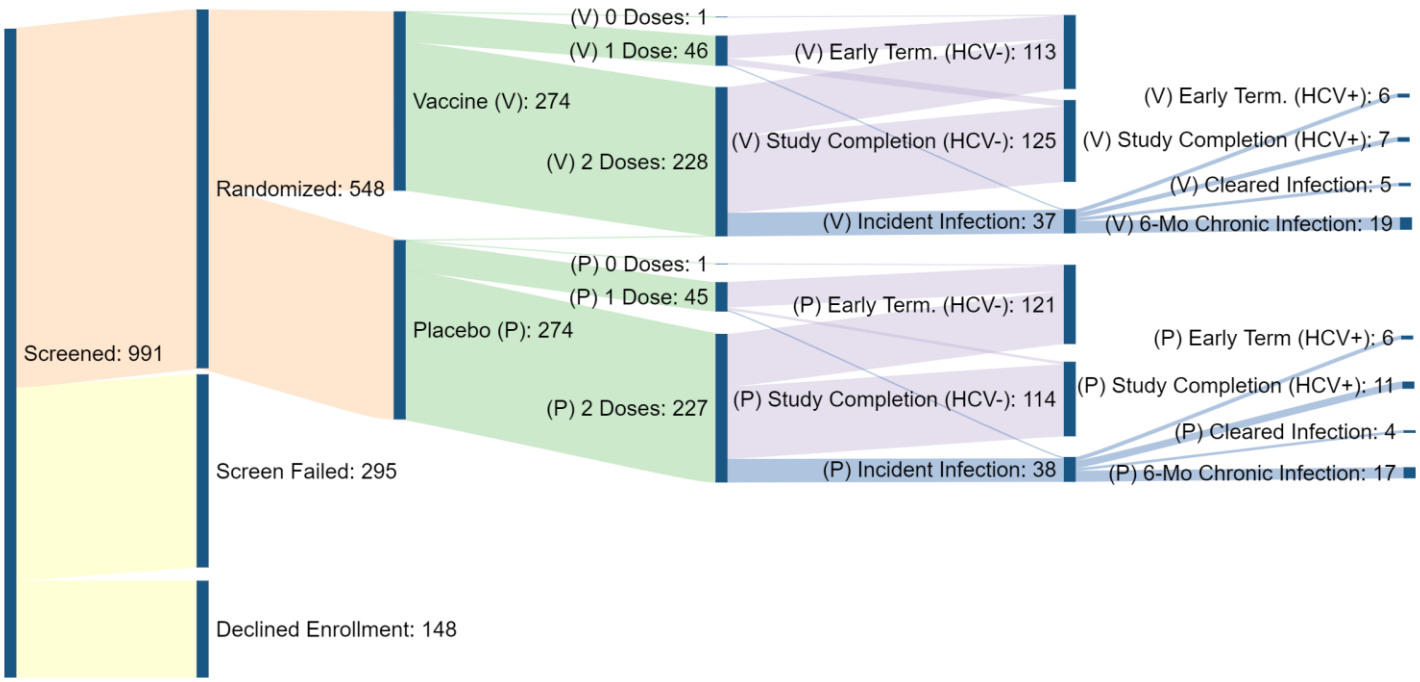
A chronic HCV infection genotype 1 will be defined as a chronic HCV infection at 6 months with the additional requirement that the infection is genotype 1 as determined from blood samples obtained at the first HCV viremic visit, provided sufficient sample is available.

Because the vaccine is developed from HCV genotype 1b sequences, we hypothesize that we may see greater reduction in chronic infection with HCV genotype 1, compared to other genotypes as a result of stronger genotype specific immune responses: 75% reduction in chronic infection with genotype 1 compared to 45% reduction in chronic infection with non-1 genotypes. These exploratory analyses will be based on estimates of the incidence of HCV genotype 1 infection and non-1 genotypes in each study group using methods for censored survival regression with competing risks (Fine-Gray proportional hazards).

Analyses of this objective will use the Fine-Gray proportional hazards model where two separate models will be fit:

- The primary event of interest is chronic HCV with genotype 1 and the competing event is chronic HCV with genotype other than 1.
- The primary event of interest is chronic HCV with genotype other than 1 and the competing event is chronic HCV with genotype 1.

Figure S1. Disposition of all participants throughout the study.



Term=termination from the study

Figure S2. Kaplan-Meier Curves for 6-Month Chronic HCV Infection According-to-Protocol Sample.

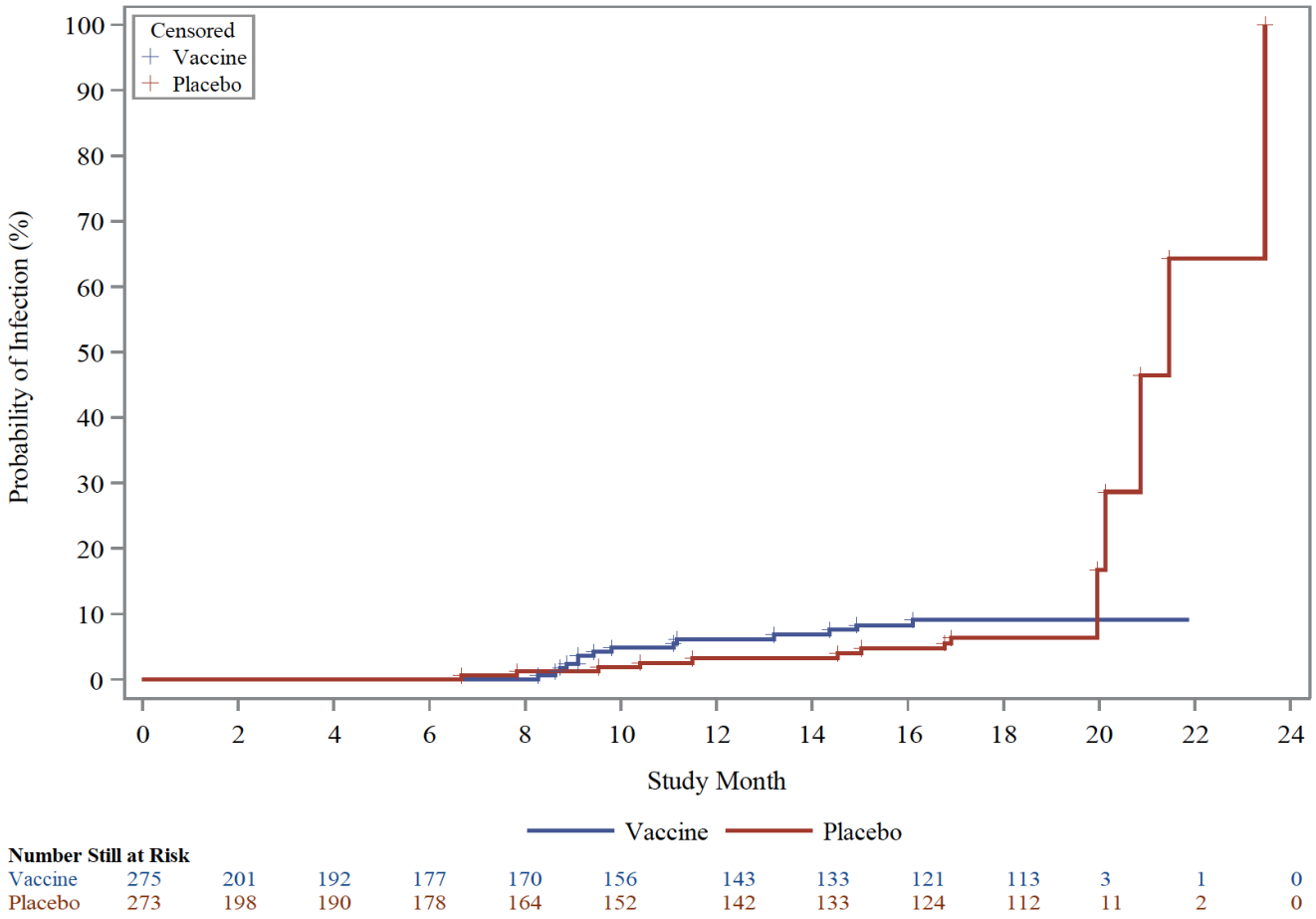


Table S1: Number and percent of screened participants excluded from trial participation based on not meeting inclusion or exclusion criteria, or who declined enrollment.

Inclusion/Exclusion Category	Inclusion/Exclusion Criterion	Number of Participants[a]	Percentage of Screened Participants (%)
Inclusion and Exclusion	Number of participants failing any eligibility criterion	295	30
Inclusion	Any inclusion criterion	180	18
	Comprehension of informed consent	1	<1
	18-45 year old men or women with acknowledged active IDU in the past 90 days and have no travel plans that would interfere with ability to meet the study visit schedule	22	2
	In good general health as determined by a participating study physician and results within acceptable ranges for clinical laboratory evaluations	103	10
	Negative for antibodies to hepatitis C virus	17	2
	Negative for HCV RNA	19	2
	Negative antibodies to HIV	13	1
	Negative for HBsAg	5	<1
	Able and willing to comply with all study requirements	16	2
	Willing to allow the investigators access to their medical records	3	<1
	Willingness to practice continuous effective contraception from the screening visit through 90 days after the last vaccination	2	<1
	Among females, a negative pregnancy test within 24 hours prior to vaccination	2	<1
	Agreement to refrain from blood donation during the course of the study	1	<1
	Provide written informed consent prior to initiation of any study procedures	1	<1
	Willing to provide contact information for study follow-up activities, including the address, name and contact information of three people who can be contacted to facilitate follow-up compliance	4	<1
Exclusion	Any exclusion criterion	129	13
	Any confirmed or suspected immunosuppressive or immunodeficient state, including: HIV infection; asplenia; recurrent, severe infections	4	<1
	History of clinically significant contact dermatitis or other significant dermatological conditions such as psoriasis	4	<1
	History of cancer	2	<1
	History of severe psychiatric illness, including severe depression, history of suicidal ideation, suicidal attempts, or psychosis requiring medication.	42	4
	Any other serious chronic illness requiring hospital specialist supervision	1	<1

Inclusion/Exclusion Category	Inclusion/Exclusion Criterion	Number of Participants[a]	Percentage of Screened Participants (%)
	Suspected or known current alcohol abuse as defined by a score of 10 or more on the Alcohol Use Disorders Identification Test (AUDIT) C test	9	<1
	At high risk of HIV infection	6	<1
	Any other significant disease, disorder or finding, which in the opinion of the investigator, may put the participant at risk	5	<1
	History of or current diagnosis of Diabetes mellitus	6	<1
	History of or current diagnosis of autoimmune disease	4	<1
	History of or current cardiac disease including history of myocardial infarction or arrhythmia	6	<1
	History of seizure disorder or currently taking anti-convulsant therapy	15	2
	Uncontrolled hypertension	33	3
	History of splenectomy	2	<1
	Long term immunosuppressive use	1	<1
	Immunization against another pathogen within 14 days of planned injection	1	<1
Declined Enrollment	Any reason declined enrollment	148	15
	Time commitment	8	<1
	Concern of potential risks	3	<1
	Number of procedures/blood draws	6	<1
	Unable to contact participant	59	6
	Arm closed	3	<1
	Other	110	11

Note: Denominator for percentages is the total number of participants screened.
[a]More than one criterion may be marked per participant.

Table S2: Definitions of clinical safety laboratory adverse events

	Grade 1	*Grade 2*	*Grade 3*	*Grade 4*
Hemoglobin (g/dl) Male: Female:	 11.0-12.4 9.6-10.8	 9.6-10.9 8.4-9.5	 8.3-9.5 7.2-8.3	 <8.3 <7.2
Platelets (per cubic mm)	84,500-117,000	65,000-84,499	25,000-64,999	< 25,000
WBCs (thousands/mcl) Decreased Increased	 2.5-2.9 11.9-15.1	 1.9-2.4 15.2-21.6	 1.0-1.8 21.7-25.0	 <1.0 >25
ALT (SGPT)	>1.25 - 2.5 x ULN*	>2.5 – 4 x ULN	>4 -8 x ULN	> 8 x ULN
Creatinine	1.2 - 1.5 x ULN	>1.5- 2 x ULN	>2 x ULN	Dialysis required

*ULN upper limit of the normal range

Table S3: Treatment Discontinuation and Early Termination Reasons

	Vaccine		Placebo	
	n	**%**	**n**	**%**
Discontinued Treatment	**47**	**--**	**46**	**--**
Missed Dose* Supplemental Figure 1 shows fewer participants terminating early because a subset of participants terminated early, but after they met the 6-month chronic infection endpoint.	19	40	23	50
Lost to Follow-up	12	26	10	22
Investigator/Study Decision	5	11	1	2
Pregnancy	3	6	2	4
Not Otherwise Eligible	0	0	2	4
Other Illness/Injury	1	2	0	0
Other	7	15	8	17
Terminated Early	**122***	**--**	**128***	**--**
Lost to Follow-up	67	55	61	48
Voluntary Withdrawal by Participant	26	21	38	30
Incarceration	18	15	20	16
Withdrawal by Investigator	3	2	4	3
Death*	5	4	1	1
Enrolled but not Dosed/Treated	1	1	1	1
Non-Compliance/Protocol Deviation	1	1	0	0
Other	1	1	3	2

***** There were 7 deaths overall among trial participants; five in participants in the vaccine arm and two in the placebo arm. The second death in the placebo arm is not listed in Table S2 because it occurred after the participant had achieved the primary endpoint. Deaths resulted from drug overdose (3) suicide (3), and food aspiration in the setting of acute polydrug intoxication causing respiratory arrest and anoxic encephalopathy (1).

Table S4: HCV Infection Summary for infected participants.

Treatment Group	Received Dose 1	Received Dose 2	End of Study Status	Final Study Day	Study Day of Incident HCV Infection	Infection Genotype	Study Day of HCV Clearance	Met 6-Month Chronic Infection Endpoint
Vaccine	Y	Y	Completed	274	24	1a	.	Y
Vaccine	Y	Y	Completed	274	24	1a	.	Y
Vaccine	Y	Y	Completed	281	24	1a	.	Y
Vaccine	Y	Y	Completed	298	31	1a	.	Y
Vaccine	Y	Y	Completed	356	54	3a	.	N
Vaccine	Y	Y	Completed	400	151	1a	.	N
Vaccine	Y	Y	Completed	401	147	1b	.	Y
Vaccine	Y	Y	Completed	402	144	1a	.	N
Vaccine	Y	Y	Completed	404	146	1a	.	Y
Vaccine	Y	Y	Completed	417	145	1a	.	Y
Vaccine	Y	Y	Completed	420	151	1a	.	Y
Vaccine	Y	Y	Completed	423	150	1a	.	Y
Vaccine	Y	Y	Completed	424	147	1a	.	Y
Vaccine	Y	Y	Completed	441	176	1a	.	Y
Vaccine	Y	Y	Completed	458	206	2b	.	Y
Vaccine	Y	Y	Completed	470	175	3a	291	N
Vaccine	Y	Y	Completed	484	234	3a	.	N
Vaccine	Y	Y	Completed	488	216	3a	.	Y
Vaccine	Y	Y	Completed	516	181	1x	.	N
Vaccine	Y	Y	Completed	585	326	3a	.	Y
Vaccine	Y	Y	Completed	596	344	1a	428	N
Vaccine	Y	Y	Completed	600	320	3a	.	Y
Vaccine	Y	Y	Completed	620	362	1a	.	Y
Vaccine	Y	N	Completed	621	357	3a	.	N
Vaccine	Y	Y	Completed	630	356	3a	414	N
Vaccine	Y	Y	Completed	751	476	1a	.	N
Vaccine	Y	Y	Completed	753	504	1x*	673	N
Vaccine	Y	Y	Completed	797	537	1a	680	N
Vaccine	Y	Y	Early Terminated	145	115	U	.	N
Vaccine	Y	Y	Early Terminated	182	85	1a	.	N
Vaccine	Y	Y	Early Terminated	253	122	1a	.	N

Vaccine	Y	Y	Early Terminated	290	50	3a	.	Y
Vaccine	Y	Y	Early Terminated	324	85	1a	.	N
Vaccine	Y	Y	Early Terminated	364	117	2b	.	Y
Vaccine	Y	Y	Early Terminated	365	134	1a	.	N
Vaccine	Y	Y	Early Terminated	452	285	1a	.	Y
Vaccine	Y	Y	Early Terminated	528	387	3a	.	N
Placebo	Y	Y	Completed	287	24	2b	.	Y
Placebo	Y	Y	Completed	291	26	1a	.	Y
Placebo	Y	Y	Completed	292	27	3a	.	N
Placebo	Y	Y	Completed	295	1	1a	.	Y
Placebo	Y	Y	Completed	329	50	1a	.	N
Placebo	Y	Y	Completed	348	91	1a	.	Y
Placebo	Y	Y	Completed	368	91	1b	211	N
Placebo	Y	Y	Completed	373	114	1a	.	N
Placebo	Y	Y	Completed	380	114	1a	.	Y
Placebo	Y	Y	Completed	395	145	1a	.	N
Placebo	Y	Y	Completed	403	134	2b	.	N
Placebo	Y	Y	Completed	435	167	3a	.	Y
Placebo	Y	Y	Completed	440	181	1a	.	N
Placebo	Y	Y	Completed	462	209	1a	.	Y
Placebo	Y	Y	Completed	481	146	1b	.	N
Placebo	Y	Y	Completed	554	266	1a	.	N
Placebo	Y	Y	Completed	569	299	1a	442	N
Placebo	Y	Y	Completed	574	325	3a	.	Y
Placebo	Y	Y	Completed	611	328	1a	.	Y
Placebo	Y	Y	Completed	617	355	2b	.	N
Placebo	Y	Y	Completed	639	386	1a	.	Y
Placebo	Y	Y	Completed	647	386	2b	.	Y
Placebo	Y	Y	Completed	707	448	1a	560	N
Placebo	Y	Y	Completed	724	475	1a	.	Y
Placebo	Y	Y	Completed	729	474	1a	.	N
Placebo	Y	Y	Completed	754	505	1a	564	N
Placebo	Y	Y	Completed	757	506	1a	.	Y
Placebo	Y	Y	Completed	758	478	1a	.	Y

Placebo	Y	Y	Completed	776	512	1a	.	Y
Placebo	Y	Y	Completed	810	540	1a	.	N
Placebo	Y	Y	Completed	831	575	1a	.	Y
Placebo	Y	N	Early Terminated	116	26	1b	.	N
Placebo	Y	Y	Early Terminated	141	55	1a	.	N
Placebo	Y	Y	Early Terminated	208	58	2b	.	N
Placebo	Y	N	Early Terminated	350	290	1a	.	N
Placebo	Y	Y	Early Terminated	357	207	1a	.	N
Placebo	Y	Y	Early Terminated	505	235	1a	.	Y
Placebo	Y	Y	Early Terminated	568	414	3a	.	N

*1x- genotype 1 infection with unknown subtype
U= unknown

Table S5. Subject disposition: Total eligible for 6 month per-protocol analysis or reasons for exclusion.

		Vaccine (N=275)		Placebo (N=273)		All Subjects (N=548)	
Eligibility Category	**Reason Subjects Excluded**	**n**	**%**	**n**	**%**	**n**	**%**
Eligible for 6 Month per-protocol analysis throughout follow-up		202	73	199	73	401	73
Censored early from 6 Month per protocol analysis	Any Reason	73	27	74	27	147	27
	Did not receive at least one vaccination	1	<1	1	<1	2	<1
	Was HCV infected at the first vaccination	-	-	1	<1	1	<1
	Did not have sufficient follow-up to be evaluable for efficacy	44	16	50	18	94	17
	Received treatment for acute HCV infection	1	<1	-	-	1	<1
	Found to have been ineligible at enrollment	4	1	4	1	8	1
	Did not receive both doses of vaccine or control	46	17	45	16	91	17
	Acquired HCV infection prior to receipt of the second vaccination	6	2	7	3	13	2
	Received the wrong (non-randomized) product at either dose	1	<1	-	-	1	<1
	Received the second dose fewer than 42 days or more than 70 days after the first dose	2	<1	2	<1	4	<1
	Received an immunosuppressant other than inhaled or topical steroids	1	<1	1	<1	2	<1
	Were immunized against another pathogen or received immunoglobulins or other blood products within 14 days of either dose of study vaccine	1	<1	-	-	1	<1
	Have autoimmune disease	1	<1	-	-	1	<1
	Have a confirmed or suspected immunosuppressive or immunodeficient state	-	-	1	<1	1	<1

Note: N=Number of enrolled subjects.
Treatment group is the treatment group to which a subject was randomized.

In the per-protocol analysis, 202 vaccine recipients and 199 placebo recipients were eligible for the 6-month analysis throughout their follow-up or until their visit 6 months after infection, whichever came first. In total, 73 of 275 vaccine recipients and 74 of 273 placebo recipients were excluded because they met one or more exclusion criteria before that time point. Per the analysis plan, if a subject was eligible throughout their follow-up or through the visit 6 months after infection (whichever came first) but did not meet the definition of chronic infection, they censored. All such subjects are added to 202 and 199 to get the 261 and 259 shown in Table 2.

In the Vaccine arm, there were 275 total subjects, of which 202 were censored prior to the end of their follow-up or the 6 month infected visit (whichever came first). Of the remaining 73 subjects, 14 became chronically infected while the other 59 did not and were coded as censored. Thus, a total of 59 + 202 = 261 censored subjects for the analysis are in Table 2. For the Placebo arm, there were 273 total subjects, 199 of which were censored prior to the end of their follow-up or the 6 month infected visit (whichever came first). Of the remaining 74 subjects, 14 became chronically infected while the other 60 did not (and were thus censored). Thus, the number of censored placebo subjects displayed in Table 2 is 199 + 60 = 259.

Table S6. Outcome of exploratory trial endpoint analyses.

Exploratory Efficacy Outcome	Analysis Sample	Vaccine (N=275)		Placebo (N=273)		Vaccine Efficacy*	95% CI for Vaccine Efficacy†	Hazard Ratio*	95% CI for Hazard Ratio†
		Number of Censored participants	Number of Infections	Number of Censored Participants	Number of Infections				
Incident HCV infection	ATP Sample	239	36	236	37	0.02	-0.55, 0.38	0.98	0.62, 1.55
	mITT Sample	238	37	235	38	0.04	-0.51, 0.39	0.96	0.61, 1.51
9-month chronic HCV	ATP Sample	264	11	257	16	<0.01	-1.47, 0.60	0.99	0.40, 2.47
	mITT Sample	261	14	257	16	-0.29	-2.06, 0.46	1.29	0.54, 3.06
6-Month Chronic HCV Genotype 1 Infection	ATP Sample	255	9	253	11	-0.39	-2.63, 0.47	1.39	0.53, 3.63
	mITT Sample	250	12	252	9	-0.70	-3.00, 0.28	1.70	0.72, 4.00
Exploratory Efficacy Outcome	Analysis Sample	Vaccine (N=275)		Placebo (N=273)		Vaccine Efficacy*	95% CI for Vaccine Efficacy†	Hazard Ratio*	95% CI for Hazard Ratio†
		Number Censored/ Cleared	Mean duration[1] (days (sd))	Number Censored/ Cleared	Mean duration[1] (days (sd))				
Duration of Incident HCV Infection	ATP Sample	31/5	58.5 (24.1)	33/4	55.1 (17.6)	0.33	-1.55, 0.82	0.67	0.18, 2.55
	mITT Sample	32/5	58.5 (24.1)	34/4	55.1 (17.6)	0.10	-2.68, 0.78	0.90	0.22, 3.68

N = Number of participants in the specific treatment group. Counts include the two participants (one in each treatment) group that received no doses. Vaccine count includes the one participant who was randomized to placebo but administered vaccine.
* Vaccine efficacy and hazard ratios are obtained from stratified Cox regression.
† 95% CI = 95% confidence interval obtained from stratified Cox regression.
1 Duration calculation is restricted to participants who cleared infection.

Table S7. Geometric Mean (GM) HCV RNA (IU/mL) Concentrations with 95% Confidence Intervals by Study Day and Treatment Group.

		ATP Sample		mITT Sample	
Time Point (Months from HCV Infection)	**Statistic**	**Vaccine (N=36)**	**Placebo (N=37)**	**Vaccine (N=36)**	**Placebo (N=37)**
Incident HCV Infection	n	36	37	37	38
	GM	**193.80 x 10^3**	104.05 x 10^3	**152.51 x 10^3**	93.07 x 10^3
	95% CI	**44.7 x 10^3, 840 x 10^3**	18.8 x 10^3, 577 x 10^3	**33.5 x 10^3, 686 x 10^3**	17.3 x 10^3, 500 x 10^3
1 Month	n	25	27	32	34
	GM	76.98 x 10^3	**1078.09 x 10^3**	38.15 x 10^3	**1804.93 x 10^3**
	95% CI	14.2 x 10^3, 417 x 10^3	**265 x 10^3, 4378 x 10^3**	4.38 x 10^3, 332 x 10^3	**565 x 10^3, 5764 x 10^3**
2 Months	n	27	26	34	33
	GM	8.04 x 10^3	59.48 x 10^3	9.19 x 10^3	66.79 x 10^3
	95% CI	0.52 x 10^3, 124 x 10^3	7.67 x 10^3, 461 x 10^3	0.80 x 10^3, 106 x 10^3	11.1 x 10^3, 403 x 10^3
3 Months	n	26	27	33	33
	GM	2.57 x 10^3	5.43 x 10^3	2.01 x 10^3	2.57 x 10^3
	95% CI	0.13 x 10^3, 51.2 x 10^3	0.70 x 10^3, 42.2 x 10^3	0.13 x 10^3, 31.9 x 10^3	0.29 x 10^3, 22.5 x 10^3
4 Months	n	24	22	30	27
	GM	7.14 x 10^3	5.95 x 10^3	14.23 x 10^3	4.12 x 10^3
	95% CI	0.36 x 10^3, 141 x 10^3	0.28 x 10^3, 128 x 10^3	1.23 x 10^3, 165 x 10^3	0.26 x 10^3, 65.3 x 10^3
5 Months	n	23	19	29	22
	GM	5.89 x 10^3	13.21 x 10^3	15.32 x 10^3	9.62 x 10^3
	95% CI	0.19 x 10^3, 181 x 10^3	0.60 x 10^3, 292 x 10^3	0.95 x 10^3, 246 x 10^3	0.65 x 10^3, 142 x 10^3
6 Months	n	17	22	24	26
	GM	15.80 x 10^3	3.25 x 10^3	29.13 x 10^3	6.60 x 10^3
	95% CI	0.22 x 10^3, 1.16 x 10^4	0.09 x 10^3, 118 x 10^3	1.32 x 10^3, 642 x 10^3	0.30 x 10^3, 145 x 10^3
7 Months	n	19	20	25	24
	GM	11.48 x 10^3	10.21 x 10^3	14.86 x 10^3	6.61 x 10^3
	95% CI	0.16 x 10^3, 832 x 10^3	0.28 x 10^3, 369 x 10^3	0.58 x 10^3, 382 x 10^3	0.24 x 10^3, 185 x 10^3
8 Months	n	18	24	24	28
	GM	1.31 x 10^3	7.44 x 10^3	5.33 x 10^3	2.64 x 10^3
	95% CI	0.01 x 10^3, 149 x 10^3	0.30 x 10^3, 183 x 10^3	0.14 x 10^3, 208 x 10^3	0.10 x 10^3, 67.5 x 10^3
9 Months	n	19	23	25	27
	GM	2.61 x 10^3	12.10 x 10^3	4.21 x 10^3	6.06 x 10^3
	95% CI	0.04 x 10^3, 157 x 10^3	0.58 x 10^3, 254 x 10^3	0.18 x 10^3, 101 x 10^3	0.35 x 10^3, 105 x 10^3

N = number of participants in specific treatment group.

n = number of HCV-infected participants with sample collected at the particular time point.

Peak GM HCV RNA are noted in bold type

Table S8: Solicited Systemic Adverse Events Occurring in ≥10% of Participants in Either Treatment Group

	Vaccine (N=274)		Placebo (N=272)	
Sign or Symptom	**n**	**%**	**n**	**%**
Elevated Oral Temperature	28	10	8	3
Headache	95	35	64	24
Malaise	114	42	99	36
Myalgia	112	41	69	25
Nausea	51	19	48	18
Vomiting	26	9	26	10
Chills	51	19	35	13
Abdominal Pain	45	16	34	13
Arthralgia	63	23	37	14

N = number of participants in specific treatment group.

n = number of participants with that sign or symptom.

Table S9: Laboratory AEs (all grades) within 30 Days of Vaccination (+7 Day Visit Window)

		Post Dose 1		Post Dose 2		Post Either Dose	
Laboratory Parameter	Toxicity Grade	Vaccine n / N / %	Placebo n / N / %	Vaccine n / N / %	Placebo n / N / %	Vaccine n / N / %	Placebo n / N / %
ALT*** (HCV Infected)	None	3 / 4 / 75	4 / 5 / 80	2 / 8 / 25	5 / 9 / 56	2 / 8 / 25	6 / 10 / 60
	Grade 1	0 / 4 / 0	1 / 5 / 20	0 / 8 / 0	0 / 9 / 0	0 / 8 / 0	0 / 10 / 0
	Grade 2	0 / 4 / 0	0 / 5 / 0	2 / 8 / 25	1 / 9 / 11	2 / 8 / 25	1 / 10 / 10
	Grade 3	1 / 4 / 25	0 / 5 / 0	1 / 8 / 13	1 / 9 / 11	1 / 8 / 13	1 / 10 / 10
	Grade 4	0 / 4 / 0	0 / 5 / 0	3 / 8 / 38	2 / 9 / 22	3 / 8 / 38	2 / 10 / 20
ALT*** (HCV Uninfected)	None	244 / 258 / 95	249 / 258 / 97	201 / 213 / 94	209 / 217 / 96	237 / 262 / 90	244 / 260 / 94
	Grade 1	11 / 258 / 4	9 / 258 / 3	10 / 213 / 5	7 / 217 / 3	20 / 262 / 8	15 / 260 / 6
	Grade 2	2 / 258 / 1	0 / 258 / 0	2 / 213 / 1	0 / 217 / 0	4 / 262 / 2	0 / 260 / 0
	Grade 3	1 / 258 / <1	0 / 258 / 0	0 / 213 / 0	0 / 217 / 0	1 / 262 / <1	0 / 260 / 0
	Grade 4	0 / 258 / 0	0 / 258 / 0	0 / 213 / 0	1 / 217 / <1	0 / 262 / 0	1 / 260 / <1
Creatinine	None	258 / 258 / 100	259 / 259 / 100	219 / 220 / >99	223 / 224 / >99	261 / 262 / >99	260 / 261 / >99
	Grade 1	0 / 258 / 0	0 / 259 / 0	1 / 220 / <1	1 / 224 / <1	1 / 262 / <1	1 / 261 / <1
	Grade 2	0 / 258 / 0	0 / 259 / 0	0 / 220 / 0	0 / 224 / 0	0 / 262 / 0	0 / 261 / 0
	Grade 3	0 / 258 / 0	0 / 259 / 0	0 / 220 / 0	0 / 224 / 0	0 / 262 / 0	0 / 261 / 0
	Grade 4	0 / 258 / 0	0 / 259 / 0	0 / 220 / 0	0 / 224 / 0	0 / 262 / 0	0 / 261 / 0
Hemoglobin	None	213 / 258 / 83	234 / 259 / 90	173 / 220 / 79	196 / 224 / 88	199 / 262 / 76	218 / 261 / 84
	Grade 1	41 / 258 / 16	25 / 259 / 10	44 / 220 / 20	25 / 224 / 11	58 / 262 / 22	40 / 261 / 15
	Grade 2	4 / 258 / 2	0 / 259 / 0	3 / 220 / 1	3 / 224 / 1	5 / 262 / 2	3 / 261 / 1
	Grade 3	0 / 258 / 0	0 / 259 / 0	0 / 220 / 0	0 / 224 / 0	0 / 262 / 0	0 / 261 / 0
	Grade 4	0 / 258 / 0	0 / 259 / 0	0 / 220 / 0	0 / 224 / 0	0 / 262 / 0	0 / 261 / 0
WBC****	None	239 / 258 / 93	239 / 259 / 92	201 / 220 / 91	213 / 224 / 95	229 / 262 / 87	234 / 261 / 90
	Grade 1	12 / 258 / 5	17 / 259 / 7	14 / 220 / 6	11 / 224 / 5	24 / 262 / 9	24 / 261 / 9
	Grade 2	7 / 258 / 3	3 / 259 / 1	5 / 220 / 2	0 / 224 / 0	9 / 262 / 3	3 / 261 / 1
	Grade 3	0 / 258 / 0	0 / 259 / 0	0 / 220 / 0	0 / 224 / 0	0 / 262 / 0	0 / 261 / 0
	Grade 4	0 / 258 / 0	0 / 259 / 0	0 / 220 / 0	0 / 224 / 0	0 / 262 / 0	0 / 261 / 0
Platelet Count	None	257 / 258 / >99	259 / 259 / 100	219 / 220 / >99	223 / 224 / >99	260 / 262 / 99	260 / 261 / >99
	Grade 1	0 / 258 / 0	0 / 259 / 0	1 / 220 / <1	1 / 224 / <1	1 / 262 / <1	1 / 261 / <1
	Grade 2	0 / 258 / 0	0 / 259 / 0	0 / 220 / 0	0 / 224 / 0	0 / 262 / 0	0 / 261 / 0
	Grade 3	1 / 258 / <1	0 / 259 / 0	0 / 220 / 0	0 / 224 / 0	1 / 262 / <1	0 / 261 / 0
	Grade 4	0 / 258 / 0	0 / 259 / 0	0 / 220 / 0	0 / 224 / 0	0 / 262 / 0	0 / 261 / 0

The denominator for percentages (N) is based on the number of participants who received at least one dose in the respective treatment group for each Dose Number and had laboratory parameter data available within the reporting window.

Confidence intervals (CI) are 95% Blaker CI.

***ALT AEs were separated into HCV infected and uninfected groups because ALT elevation is characteristic of HCV infection. ALT elevation within 30 days (+7 day window) of receipt of vaccine or placebo in the HCV infected group was attributed to HCV infection. Infected rows correspond to samples collected after a confirmed HCV infection. Uninfected

rows correspond to samples collected before any confirmed HCV infection. A subject may be counted in both infected and uninfected rows.
****WBC White blood cell count

Table S10: Geometric Mean (GM) ELISpot Responses (Across all Pools) with 95% Confidence Intervals by Study Day and Treatment group - Immunogenicity Sample, HCV uninfected timepoints

Time Point	Statistic	Vaccine (N=135)	Placebo (N=134)
Day 1 (Dose 1)	n	132	122
	GM	33.8	31.2
	95% CI	28.8, 39.8	24.7, 39.5
Day 30	n	127	117
	GM	68.1	35.5
	95% CI	51.7, 89.7	30.3, 41.7
Day 56 (Dose 2)	n	111	106
	GM	77.3	33.2
	95% CI	63.8, 93.7	23.9, 46.3
7 Days Post-dose 2	n	115	111
	GM	374.0	41.0
	95% CI	291.7, 479.6	33.8, 49.7
Day 90	n	108	99
	GM	234.0	31.1
	95% CI	188.9, 289.9	21.8, 44.5
Day 240	n	73	63
	GM	166.4	44.8
	95% CI	132.9, 208.5	37.6, 53.5
Day 600	n	74	69
	GM	158.1	58.3
	95% CI	130.3, 191.9	47.8, 71.0

Note: N = the number of participants who received at least one dose and have post-baseline immunogenicity data available.

Participants who did not receive the second dose are excluded from post-dose 2 timepoints.
n = number of HCV-negative participants with complete ELISpot data available at the particular time point.

Reported units are SFC/million PBMC.