

# ADVANCES IN CHRONIC HEPATITIS C: MANAGEMENT AND TREATMENT

REPORTING ON EASL 2016

## COMPREHENSIVE EXPERT REVIEW AND DISCUSSION OF KEY PRESENTATIONS

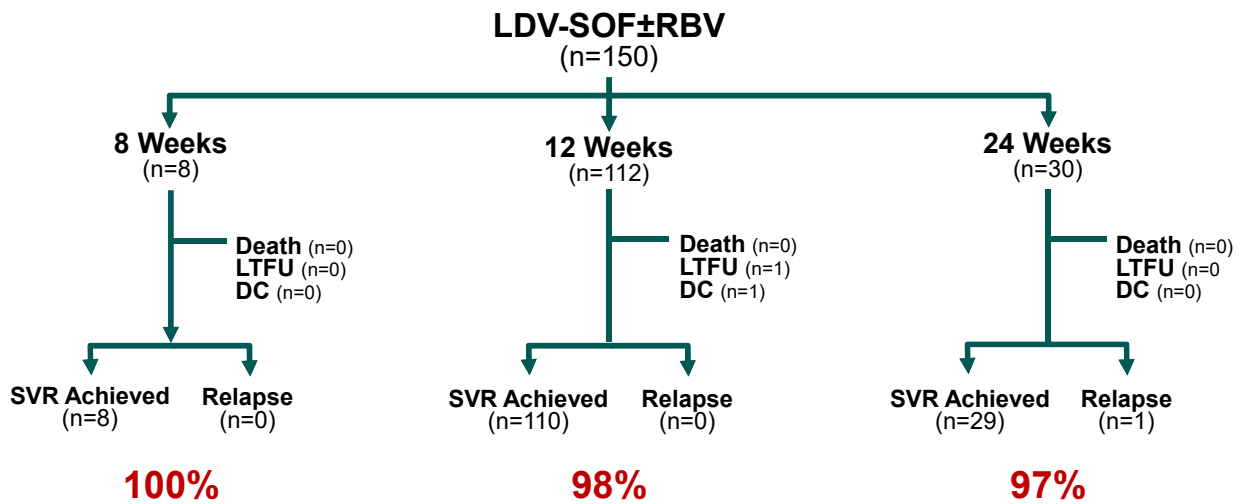
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### LEDIPASVIR/SOFOSBUVIR+/-RIBAVIRIN IN PATIENTS CO-INFECTED WITH HCV AND HIV: REAL-WORLD HETEROGENEOUS POPULATION FROM THE TRIO NETWORK

*Douglas T. Dieterich, Bruce Bacon, Michael Curry, Steven L. Flamm, Lauren Guest,  
Kris Kowdley, Yoori Lee, Zobair Younossi, Naoky Tsai, and Nezam Afdhal*

Abstract SAT-134

## Patient Disposition



## Baseline Demographics

Group - no. (%)	LDV-SOF +/- RBV n =150
<b>8 Week Regimen - no. (%)</b>	8 (5%)
<b>12 Week Regimen - no. (%)</b>	112 (75%)
<b>24 Week Regimen - no. (%)</b>	30 (20%)
<b>Academic Practice - no. (%)</b>	68 (45%)
<b>Age - mean (range)</b>	56 (36-84)
<b>Male - no. (%)</b>	105 (70%)
<b>Patient Ethnicity - no. (%)</b>	
Non Black	109 (73%)
Black	32 (21%)
Unknown	9 (6%)
<b>Baseline Labs</b>	
ALT - mean (s.d.)	67 (51), n=99
AST - mean (s.d.)	66 (55), n=100
Hb - mean (s.d.)	14 (3), n=99
Platelets <100 K/ml - no. (%)	15 (10%)
Platelets ≥100 K/ml - no. (%)	83 (55%)
<b>Fibrosis - no. (%)</b>	
0 - No Fibrosis	6 (4%)
1 - Mild	17 (11%)
2 - Moderate	19 (13%)
3 - Severe	28 (19%)
4 - Cirrhosis	53 (35%)
No Cirrhosis - Score Unknown	27 (18%)

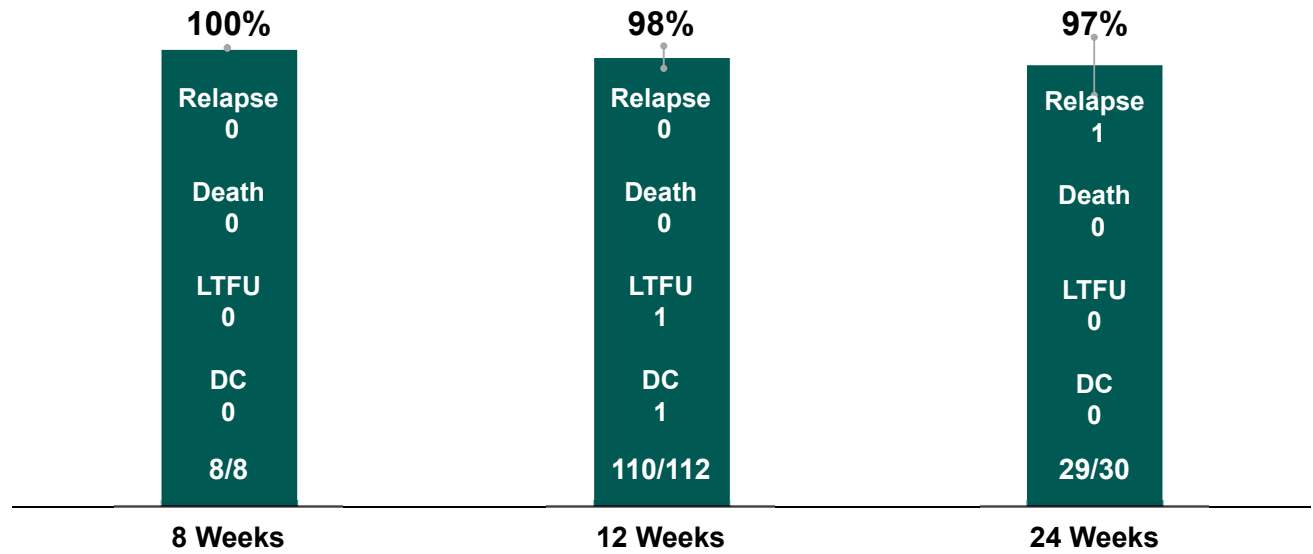
Dieterich D, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-134.

## Baseline Demographics cont.

Group - no. (%)	LDV-SOF +/- RBV n =150
<b>Genotype - no. (%)</b>	
1a	120 (80%)
1b	28 (19%)
1Unknown	2 (1%)
<b>Initial Viral Load - no. (%)</b>	
<800K IU/ml	50 (34%)
800K<2MM IU/ml	35 (23%)
2MM<6MM IU/ml	33 (22%)
6MM+ IU/ml	32 (21%)
<b>Prior Treatment - no. (%)</b>	
PEG + RBV	19 (26%)
BOC + PEG + RBV	1 (1%)
TVR + +PEG + RBV	6 (9%)
SMV + SOF +/- RBV	2 (3%)
SOF + RBV	1 (1%)
Prior Regimen Unknown	43 (60%)
<b>Prior Response - no. (%)</b>	
Discontinued	2 (3%)
Null Responder	12 (17%)
Responder Relapse	11 (15%)
Unknown	47 (65%)

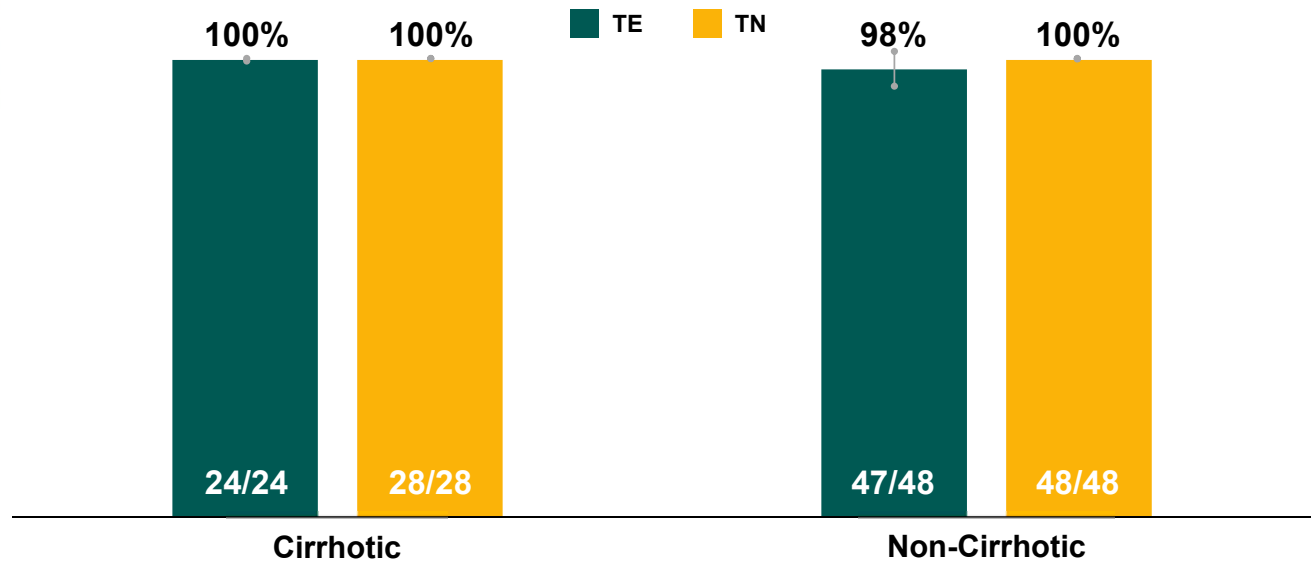
Dieterich D, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-134.

## SVR12 Rates by Duration- ITT



Dieterich D, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-134.

## SVR12 Rates by Cirrhosis & Prior Treatment Experience - PP



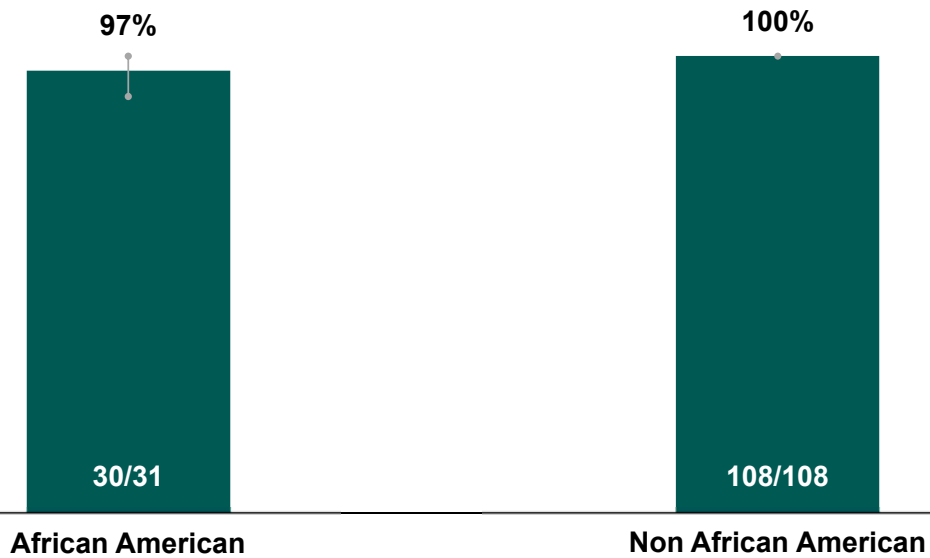
Dieterich D, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-134.

## SVR12 Rates by PPI Use - PP



Dieterich D, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-134.

## SVR12 Rates by Ethnicity - PP



Dieterich D, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-134.

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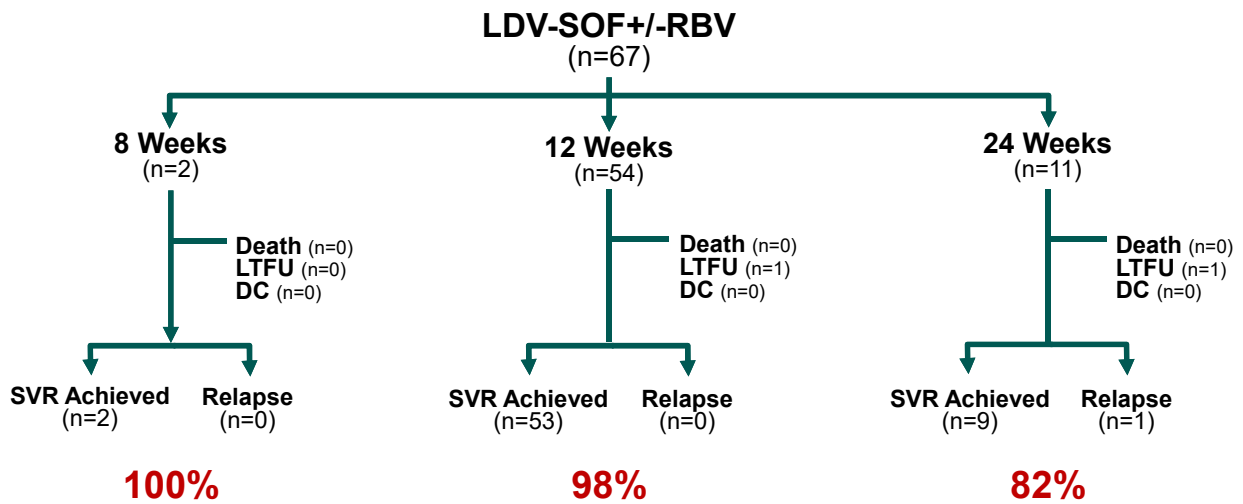
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### LEDIPASVIR/SOFOSBUVIR ± RIBAVIRIN IN HCV POST-TRANSPLANT PATIENTS: REAL-WORLD HETEROGENEOUS POPULATION FROM THE TRIO NETWORK

*Steven L. Flamm, Bruce Bacon, Michael Curry, Douglas T. Dieterich, Lauren Guest,  
Kris Kowdley, Yoori Lee, Naoky Tsai, Zobair Younossi, and, Nezam Afdhal*

Abstract SAT-269

## Patient Disposition



## Baseline Demographics

Group - no. (%)	LDV-SOF +/- RBV n= 67
<b>8 Week Regimen - no. (%)</b>	2 (3%)
<b>12 Week Regimen - no. (%)</b>	54 (81%)
<b>24 Week Regimen - no. (%)</b>	11 (16%)
<b>Academic Practice – no. (%)</b>	53 (79%)
<b>Age - mean (range)</b>	61 (36-78)
<b>Male - no. (%)</b>	51 (76%)
<b>Patient Ethnicity - no. (%)</b>	
Non Black	52 (78%)
Black	10 (15%)
Unknown	5 (7%)
<b>Baseline Labs</b>	
ALT - mean (s.d.)	67 (49), n=64
AST - mean (s.d.)	65 (49), n=64
Hb - mean (s.d.)	14 (2), n=67
Platelets <100 K/ml - no. (%)	10 (15%)
Platelets ≥100 K/ml - no. (%)	54 (81%)
<b>Fibrosis - no. (%)</b>	
0 - No Fibrosis	6 (9%)
1 - Mild	16 (24%)
2 - Moderate	19 (28%)
3 - Severe	2 (3%)
4 - Cirrhosis	21 (31%)
No Cirrhosis - Score Unknown	3 (5%)

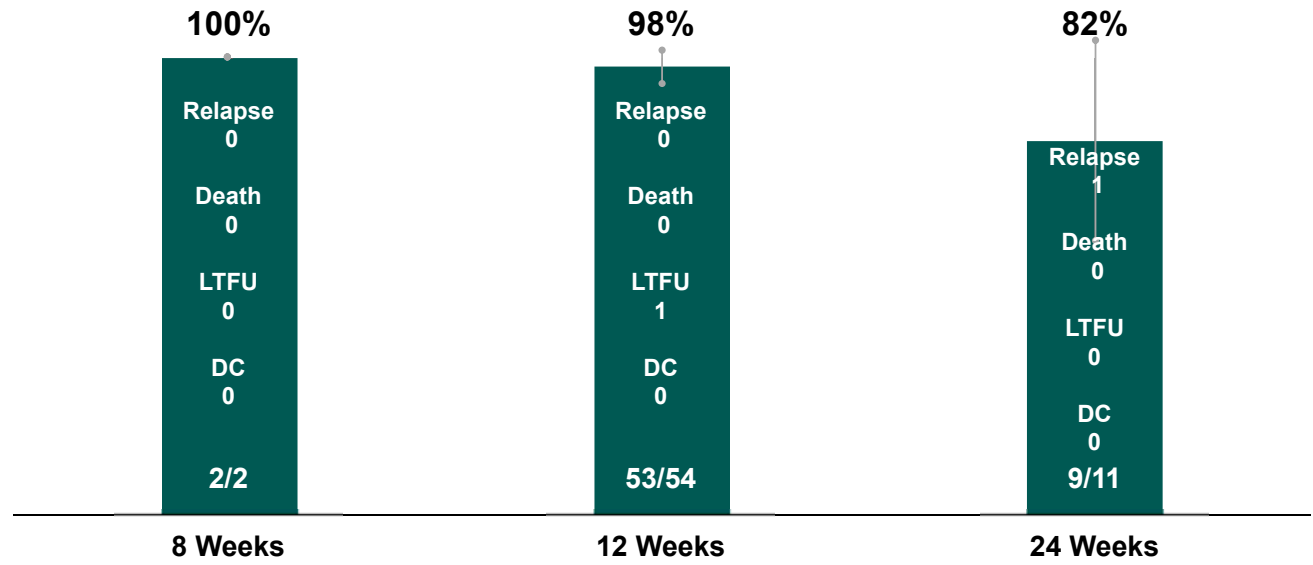
Flamm S, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-269.

## Baseline Demographics (cont'd)

Group - no. (%)	LDV-SOF +/- RBV n= 67
<b>Genotype - no. (%)</b>	
1a	44 (66%)
1b	18 (28%)
1Unknown	4 (6%)
<b>Initial Viral Load - no. (%)</b>	
<800K IU/ml	14 (21%)
800K<2MM IU/ml	14 (21%)
2MM<6MM IU/ml	20 (30%)
6MM+ IU/ml	19 (28%)
<b>Prior Treatment - no. (%)</b>	
PEG + RBV	22 (59%)
BOC + PEG + RBV	3 (8%)
TVR + +PEG + RBV	1 (3%)
SMV + SOF +/- RBV	1 (3%)
SOF + RBV	1 (3%)
Prior Regimen Unknown	9 (24%)
<b>Prior Response - no. (%)</b>	
Discontinued	14 (38%)
Null Responder	10 (27%)
Responder Relapse	13 (35%)
Unknown	44 (66%)

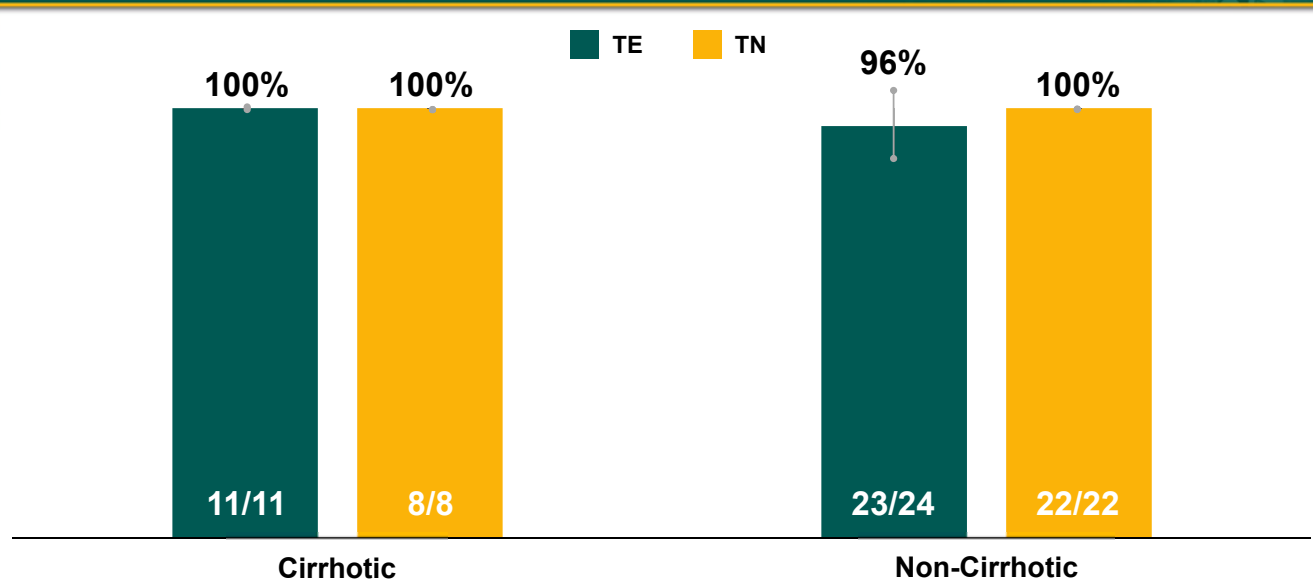
Flamm S, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-269.

## SVR12 Rates by Duration



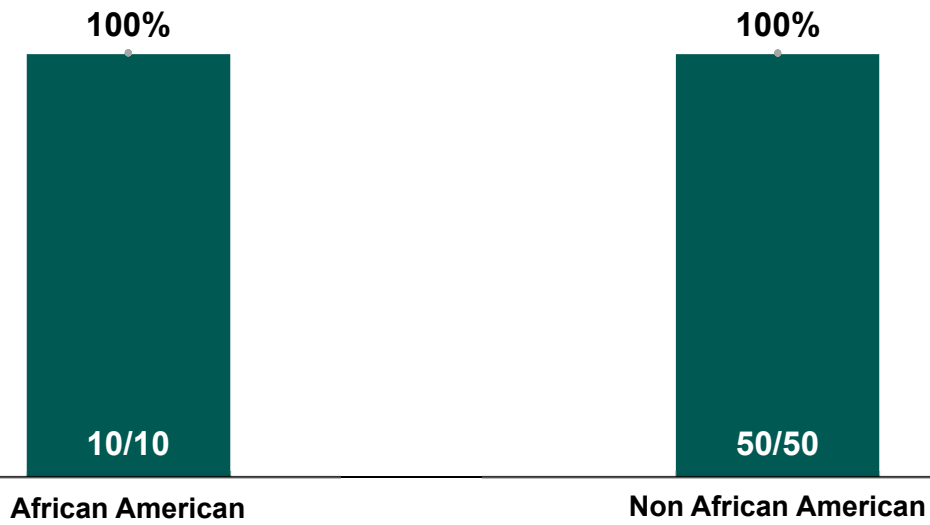
Flamm S, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-269.

## SVR12 Rates by Cirrhosis and Prior Treatment Experience - PP



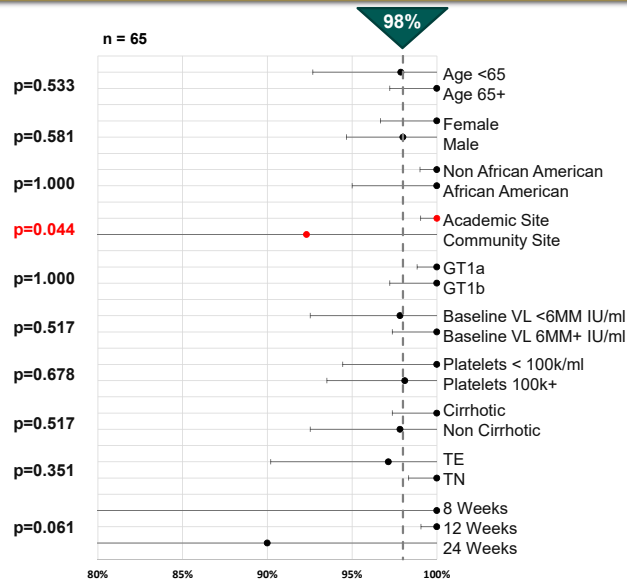
Flamm S, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-269.

## SVR12 Rates by Ethnicity- PP



Flamm S, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-269.

## Predictors of Response All Treatment Regimens - PP



Flamm S, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. SAT-269.

\*Closed circles = proportions; whiskers = 95% confidence interval; dotted lines = overall SVR12; 2-side asympt. p-value via Pearson  $\chi^2$ .