

# MAY2013-02-01 - Pre-Registration Checklist Data Dictionary

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## Document Summary

Property	Value
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# MAY2013-02-01 - Pre-Registration Checklist: Data Dictionary

## Section 1: Identifiers

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Class	Variable	Label	Description	Format Text
01. Principal	<b>subject</b>	Data Center ID		Char

## Section 2: Pre-Registration Checklist

Class	Variable	Label	Description	Format Text
01. Principal	<b>age</b>	Age		Char
01. Principal	<b>auth_ca</b>	Participant Has Given Permission To Collect And Store Blood For Future Use In Research To Learn About, Prevent, Treat Or Cure Cancer		"n"="No" "y"="Yes"
01. Principal	<b>auth_oth</b>	Participant Has Given Permission To Collect And Store Blood For Future Use In Research About Other Health Problems		"n"="No" "y"="Yes"
01. Principal	<b>auth_out</b>	Participant Has Given Permission To Send Blood Sample(s) To Researchers At An Outside Institution		"n"="No" "y"="Yes"
01. Principal	<b>auth_res</b>	Participant Has Given Permission To His/Her Doctor To Contact Them In The Future To Ask Them To Take Part In More Research		"n"="No" "y"="Yes"
01. Principal	<b>casedetailid</b>	Case Number		Numeric
01. Principal	<b>consntdt</b>	Date Informed Consent Signed		SAS Date
01. Principal	<b>ctep_arm</b>	TAC/TAD Code		"TAC-0 (Signed informed consent document and before intervention.)"="TAC-0 (Signed informed consent document and before intervention.)" "TAC-0"="TAC-0"
01. Principal	<b>date_mod</b>	Date Modified		SAS Date
01. Principal	<b>dc_num</b>	Protocol Number		"MAY2013-02-01"="MAY2013-02-01"
01. Principal	<b>EnrollDT</b>	Enrollment Date		SAS Date
01. Principal	<b>eresnum</b>	ERES Number		"0000-106262"="0000-106262"
01. Principal	<b>exclu001</b>	Failure Of Previous HCV Therapies		"n"="No" "y"="Yes"
01. Principal	<b>exclu002</b>	HIV Infection		"n"="No" "y"="Yes"
01. Principal	<b>exclu003</b>	Any Previous Treatment For HCV <=6 Months Prior To Registration		"n"="No" "y"="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	<b>exclu004</b>	Other Uncontrolled Immune-Compromising Illness		"n"="No" "y"="Yes"
01. Principal	<b>exclu005</b>	Autoimmune Disorders, Transplant Recipients, Other Immunosuppression Including Any Concurrent Condition Requiring The Use Of Immunosuppressive/Immunomodulating Agents. Exception: Eye Drop-Containing And Infreq		"n"="No" "y"="Yes"
01. Principal	<b>exclu006</b>	Ongoing HBV Infection		"n"="No" "y"="Yes"
01. Principal	<b>exclu007</b>	Documented Evidence Of Fibrosis Or Cirrhosis (Metavir 2, 3, And 4) And Subjects With Significant Extrahepatic Manifestations Of Hepatitis C		"n"="No" "y"="Yes"
01. Principal	<b>exclu008</b>	Other Known Causes Of Significant Liver Disease Including Chronic Or Acute Hepatitis B, Acute Hepatitis A, Hemochromatosis, Or Homozygous Alpha-1 Antitrypsin Deficiency		"n"="No" "y"="Yes"
01. Principal	<b>exclu009</b>	Active Malignancy. Exception: Non-Melanoma Skin Cancer(s) For Which Diagnosis And Treatment Was Completed >=3 Years Prior To Pre-Registration		"n"="No" "y"="Yes"
01. Principal	<b>exclu010</b>	History Of Major Organ Transplantation With An Existing Functional Graft		"n"="No" "y"="Yes"
01. Principal	<b>exclu011</b>	Uncontrolled Intercurrent Illness Including		"n"="No" "y"="Yes"
01. Principal	<b>exclu012</b>	History Of Cardiac Arrhythmia, Controlled Or Uncontrolled, Including Ventricular And Supraventricular Arrhythmia		"n"="No" "y"="Yes"
01. Principal	<b>exclu013</b>	Pregnant Or Nursing Women.		"n"="No" "na"="N/A"

Class	Variable	Label	Description	Format Text
01. Principal	<b>exclu014</b>	Current Diagnosis Or History Of Cardiac Pre-Excitation Syndromes (E.g., Wolff-Parkinson-White)		"n"="No" "y"="Yes"
01. Principal	<b>exclu015</b>	Metal Implants On Same Limb As Intended Administration Site		"n"="No" "y"="Yes"
01. Principal	<b>exclu016</b>	Tattoos, Scars, Active Lesions, Or Rashes <=2 cm Of The Intended Site Of Treatment		"n"="No" "y"="Yes"
01. Principal	<b>exclu017</b>	Documentation Of History Of Seizure Within Previous 5 Years		"n"="No" "y"="Yes"
01. Principal	<b>exclu018</b>	Pacemaker Or Other Implanted Device		"n"="No" "y"="Yes"
01. Principal	<b>exclu019</b>	Any Condition That, In The Clinical Judgment Of The Investigator, Would Place A Participant At Unreasonably Increased Risk		"n"="No" "y"="Yes"
01. Principal	<b>form</b>	Form		Numeric
01. Principal	<b>FormName</b>	Form Name		"PreReg - chklist"="PreReg - chklist"
01. Principal	<b>hipaa_dt</b>	Date Of Authorization		SAS Date
01. Principal	<b>inclu001</b>	Presence Of Chronic HCV Infection. Note: Chronic HCV Infection Is Defined By (1) Presence Of Plasma Or Serum HCV RNA In A Participant With HCV Antibody For >=180 Days, OR (2) Two Documented HCV RNA Positive Re		"n"="No" "y"="Yes"
01. Principal	<b>inclu002</b>	Age >=18 Years		"n"="No" "y"="Yes"
01. Principal	<b>inclu003</b>	Should A Female Partner Of A Male Study Participant Become Pregnant While The Male Is Participant Is On Study, The Male Participant Should Inform His Study Physician Immediately.		"na"="N/A" "y"="y"

Class	Variable	Label	Description	Format Text
01. Principal	<b>inclu004</b>	Willingness To Avoid Excessive Use Of Alcohol During The Study. Note: Excessive Use Is Defined As Drinking >=8 Alcoholic Drinks Per Week On Average		"n"="No" "y"="Yes"
01. Principal	<b>inclu005</b>	Willingness To Provide Blood Samples For Research Tests Specified In The Protocol		"n"="No" "y"="Yes"
01. Principal	<b>inclu006</b>	Ability To Understand And Willingness To Sign A Written Informed Consent Document		"n"="No" "y"="Yes"
01. Principal	<b>pielig</b>	Is The Participant Eligible For Inclusion On This Study?		"n"="No" "y"="Yes"
01. Principal	<b>prev_id</b>	If Yes: Prior Participant CPN ID Number		Char
01. Principal	<b>previous</b>	Has The Participant Been Pre-Registered Previously To This Study?		"n"="No" "y"="Yes"
01. Principal	<b>reg01</b>	All Participants Will Automatically Be Registered To The Correlative/Translational Components Of This Study (See Section 13)		"n"="No" "y"="Yes"
01. Principal	<b>reg02</b>	Consent Form Signed And Dated		"n"="No" "y"="Yes"
01. Principal	<b>reg03</b>	Existence Of Authorization For Use And Disclosure Of Protected Health Information (USA Institutions Only). If Not A USA Institution (Select Na)		"na"="N/A" "y"="y"
01. Principal	<b>reg04</b>	Baseline (Screening) Evaluations Must Be Completed Within The Guidelines Specified On The Schedule Of Events		"n"="No" "y"="Yes"
01. Principal	<b>reg05</b>	All Baseline Symptoms Must Be Documented And Graded		"n"="No" "y"="Yes"
01. Principal	<b>studyid</b>	Study ID		Numeric
01. Principal	<b>version</b>	Version Number		Numeric

