

# MAY2013-02-01 - Registration Checklist Data Dictionary

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## Document Summary

Property	Value
Document Title	MAY2013-02-01 - Registration Checklist: Data Dictionary
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Sections	2
Entries	28
Document Filename	dictionary_chklist_reg.rtf

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# MAY2013-02-01 - 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: Registration Checklist

Class	Variable	Label	Description	Format Text
01. Principal	<b>Arm</b>	Treatment Arm		"A"="Dose Escalation" "B"="INO-8000" "C"="INO-8000 + INO-9012 (0.3 mg)" "D"="INO-8000 + INO-9012 (1 mg)" "E"="INO-8000 + INO-9012 (3 mg)"
01. Principal	<b>casedetailid</b>	Case Number		Numeric
01. Principal	<b>ctep_arm</b>	TAC/TAD Code		"TAC1 (INO-8000: 6 mg IM on Day 0 and at Weeks 4, 12 and 24)"="TAC1 (INO-8000: 6 mg IM on Day 0 and at Weeks 4, 12 and 24)" "TAC2 (INO-8000: 6 mg IM + INO-9012: 0.3 mg IM on Day 0, and at Weeks 4, 12 and 24)"="TAC2 (INO-8000: 6 mg IM + INO-9012: 0.3 mg IM on Day 0, and at Weeks 4, 12 and 24)" "TAC3 (INO-8000: 6 mg IM + INO-9012: 1 mg IM on Day 0, and at Weeks 4, 12 and 24)"="TAC3 (INO-8000: 6 mg IM + INO-9012: 1 mg IM on Day 0, and at Weeks 4, 12 and 24)" "TAC4 (INO-8000: 6 mg IM + INO-9012: 3 mg IM on Day 0 and at Weeks 4, 12 and 24)"="TAC4 (INO-8000: 6 mg IM + INO-9012: 3 mg IM on Day 0 and at Weeks 4, 12 and 24)"
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>doselevl</b>	Dose Level		"0"="INO-8000" "1"="INO-8000 + INO-9012 (0.3 mg)" "2"="INO-8000 + INO-9012 (1 mg)" "3"="INO-8000 + INO-9012 (3 mg)"
01. Principal	<b>EnrollIDT</b>	Enrollment Date		SAS Date
01. Principal	<b>eresnum</b>	ERES Number		"0000-106262"="0000-106262"
01. Principal	<b>exclu001</b>	Receiving Any Other Investigational Agents <=6 Months Prior To Registration		"n"="No" "y"="Yes"
01. Principal	<b>exclu002</b>	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To INO-8000 And INO-9012		"n"="No" "y"="Yes"
01. Principal	<b>form</b>	Form		Numeric
01. Principal	<b>FormName</b>	Form Name		"Main - chklist"="Main - chklist"

Class	Variable	Label	Description	Format Text
01. Principal	<b>group</b>	Group		"1=Dose Escalation Cohort"="1=Dose Escalation Cohort" "2=Expansion Cohort"="2=Expansion Cohort"
01. Principal	<b>hep_c</b>	HCV RNA Level At Baseline 1=Less Than 800,000 IU/mL 2=Greater Than Or Equal To 800,000 IU/mL		"1=<800,000 IU/mL"="1=<800,000 IU/mL" "2=>=800,000 IU/mL"="2=>=800,000 IU/mL"
01. Principal	<b>inclu001</b>	Serum Or Plasma HCV RNA Level >=10,000 IU/mL		"n"="No" "y"="Yes"
01. Principal	<b>inclu002</b>	Screening HCV Genotype, Demonstrating Genotype 1		"n"="No" "y"="Yes"
01. Principal	<b>inclu003</b>	Alpha Feto Protein (AFP) Levels Within Normal Institutional Limits Or Judged To Be Not Clinically Significant By The Investigator.		"n"="No" "y"="Yes"
01. Principal	<b>inclu004</b>	ECOG Performance Status (PS) 0 Or 1		"n"="No" "y"="Yes"
01. Principal	<b>inclu005</b>	Screening Laboratory Values Within Institutional Normal Range Or Judged To Be Not Clinically		"n"="No" "y"="Yes"
01. Principal	<b>inclu006</b>	12-Lead ECG Showing Normal Heart Rhythm. If There Are Abnormalities, Then The Abnormalities Must Be Judged To Be Not Clinically Significant		"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>ps</b>	ECOG Performance Status 0 Or 1		"0"="0" "1"="1"
01. Principal	<b>reg01</b>	Intervention Cannot Begin Prior To Registration And Must Begin <=14 Days After Registration		"n"="No" "y"="Yes"
01. Principal	<b>reg02</b>	Intervention Must Take Place At A CPN Member Institution Under The Supervision Of A CPN Physician		"n"="No" "y"="Yes"
01. Principal	<b>rxst_dt</b>	Anticipated Start Date Of First Treatment		SAS Date

Class	Variable	Label	Description	Format Text
01. Principal	<b>studyid</b>	Study ID		Numeric
01. Principal	<b>version</b>	Version Number		Numeric