

MAY2013-02-02 - Analysis Data Dictionary

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Document Summary

Property	Value
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MAY2013-02-02 - Analysis: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	SUBJECT	Participant ID		Char

Section 2: Analysis

Class	Variable	Label	Description	Format Text
01. Principal	age	Age		Numeric
01. Principal	bmi	BMI		Numeric
01. Principal	CIGHIST	Cigarette History		"Current smoker"="Current smoker" "Never smoked"="Never smoked" "Quit/former smoker"="Quit/former smoker"
01. Principal	ctep_arm	TAC/TAD Code		"TAC-1 (Erlotinib 50 mg PO Q am x 7 days [empty stomach])"="TAC-1 (Erlotinib 50 mg PO Q am x 7 days [empty stomach])" "TAC-1B (Non-Surgical Cohort B: Erlotinib 50mg PO Qam x 7 days [empty Stomach])"="TAC-1B (Non-Surgical Cohort B: Erlotinib 50mg PO Qam x 7 days [empty Stomach])" "TAC-2A (Surgical Cohort A: Erlotinib 25mg PO Qam x 7 days [empty Stomach])"="TAC-2A (Surgical Cohort A: Erlotinib 25mg PO Qam x 7 days [empty Stomach])" "TAC-2B (Non-Surgical Cohort B: Erlotinib 25mg PO Qam x 7 days [empty Stomach])"="TAC-2B (Non-Surgical Cohort B: Erlotinib 25mg PO Qam x 7 days [empty Stomach])" "TAC1 (Erlotinib 75 mg PO Q am x 7 days [empty stomach])"="TAC1 (Erlotinib 75 mg PO Q am x 7 days [empty stomach])"
01. Principal	dose_cohort	Dose Cohort		1="Dose Escalation/De-Escalation Cohort" 2="Dose Expansion Cohort"
01. Principal	dose_level	Dose Level		1="0" 2="1" 3="2"
01. Principal	ENDATRSN	Off Study Reason		"Adverse event"="Adverse event" "Death"="Death" "Disease Progression"="Disease Progression" "Ineligible (Includes Screen Failures)"="Ineligible (Includes Screen Failures)" "Lost to Follow-up"="Lost to Follow-up" "Other"="Other" "Participant Withdrawal"="Participant Withdrawal" "Patient Refused Follow-up"="Patient Refused Follow-up" "Physician decision"="Physician decision" "Protocol Violation"="Protocol Violation" "Study complete"="Study complete"

Class	Variable	Label	Description	Format Text
01. Principal	ethnicity	Ethnicity		"Hispanic or Latino"="Hispanic or Latino" "Not Hispanic or Latino"="Not Hispanic or Latino" "Not reported"="Not reported" "Unknown"="Unknown"
01. Principal	eval	Evaluable For Primary Endpoint		0="No" 1="Yes"
01. Principal	pctchangeec_avg	Percent Change In Average Ratio (%)		Char
01. Principal	pctchangeec_med	Percent Change In Median Ratio (%)		Char
01. Principal	pctchangeec_min	Smallest Percent Change In Ratio (%) From Pre-Intervention To Post-Intervention		Char
01. Principal	pctchangeec_pre1_post1	Percent Change In Ratio (%) From Pre-Intervention Sample 1 To Post-Intervention Sample 1		Char
01. Principal	pctchangeec_pre1_post2	Percent Change In Ratio (%) From Pre-Intervention Sample 1 To Post-Intervention Sample 2		Char
01. Principal	pctchangeec_pre1_post3	Percent Change In Ratio (%) From Pre-Intervention Sample 1 To Post-Intervention Sample 3		Char
01. Principal	pctchangeec_pre2_post1	Percent Change In Ratio (%) From Pre-Intervention Sample 2 To Post-Intervention Sample 1		Char
01. Principal	pctchangeec_pre2_post2	Percent Change In Ratio (%) From Pre-Intervention Sample 2 To Post-Intervention Sample 2		Char
01. Principal	pctchangeec_pre2_post3	Percent Change In Ratio (%) From Pre-Intervention Sample 2 To Post-Intervention Sample 3		Char
01. Principal	pctchangen_avg	Percent Change In Average Ratio (%)		Numeric
01. Principal	pctchangen_med	Percent Change In Median Ratio (%)		Numeric

Class	Variable	Label	Description	Format Text
01. Principal	pctchangen_min	Smallest Percent Change In Ratio (%) From Pre-Intervention To Post-Intervention		Numeric
01. Principal	pctchangen_pre1_post1	Percent Change In Ratio (%) From Pre-Intervention Sample 1 To Post-Intervention Sample 1		Numeric
01. Principal	pctchangen_pre1_post2	Percent Change In Ratio (%) From Pre-Intervention Sample 1 To Post-Intervention Sample 2		Numeric
01. Principal	pctchangen_pre1_post3	Percent Change In Ratio (%) From Pre-Intervention Sample 1 To Post-Intervention Sample 3		Numeric
01. Principal	pctchangen_pre2_post1	Percent Change In Ratio (%) From Pre-Intervention Sample 2 To Post-Intervention Sample 1		Numeric
01. Principal	pctchangen_pre2_post2	Percent Change In Ratio (%) From Pre-Intervention Sample 2 To Post-Intervention Sample 2		Numeric
01. Principal	pctchangen_pre2_post3	Percent Change In Ratio (%) From Pre-Intervention Sample 2 To Post-Intervention Sample 3		Numeric
01. Principal	pctratio_post1	Post-Intervention Ratio (%): Sample 1		Char
01. Principal	pctratio_post2	Post-Intervention Ratio (%): Sample 2		Char
01. Principal	pctratio_post3	Post-Intervention Ratio (%): Sample 3		Char
01. Principal	pctratio_postavg	Post-Intervention Ratio (%): Average		Char
01. Principal	pctratio_pre1	Pre-Intervention Ratio (%): Sample 1		Char
01. Principal	pctratio_pre2	Pre-Intervention Ratio (%): Sample 2		Char
01. Principal	pctratio_preavg	Pre-Intervention Ratio (%): Average		Char

Class	Variable	Label	Description	Format Text
01. Principal	pospix_post1	Post-Intervention Positive Pixels: Sample 1		Char
01. Principal	pospix_post2	Post-Intervention Positive Pixels: Sample 2		Char
01. Principal	pospix_post3	Post-Intervention Positive Pixels: Sample 3		Char
01. Principal	pospix_pre1	Pre-Intervention Positive Pixels: Sample 1		Char
01. Principal	pospix_pre2	Pre-Intervention Positive Pixels: Sample 2		Char
01. Principal	race	Race		"American Indian or Alaska Native"="American Indian or Alaska Native" "Asian"="Asian" "Black or African American"="Black or African American" "Native Hawaiian or Other Pacific Islander"="Native Hawaiian or Other Pacific Islander" "Not Reported"="Not Reported" "Unknown"="Unknown" "White"="White"
01. Principal	reg_dt	Registration Date		SAS Date
01. Principal	response_avg	Response For Average		0="No" 1="Yes"
01. Principal	response_best	Best Response		0="No" 1="Yes"
01. Principal	response_med	Response For Median		0="No" 1="Yes"
01. Principal	response_pre1_p ost1	Response For Pre-Intervention Sample 1 To Post-Intervention Sample 1		0="No" 1="Yes"
01. Principal	response_pre1_p ost2	Response For Pre-Intervention Sample 1 To Post-Intervention Sample 2		0="No" 1="Yes"
01. Principal	response_pre1_p ost3	Response For Pre-Intervention Sample 1 To Post-Intervention Sample 3		0="No" 1="Yes"
01. Principal	response_pre2_p ost1	Response For Pre-Intervention Sample 2 To Post-Intervention Sample 1		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	response_pre2_post2	Response For Pre-Intervention Sample 2 To Post-Intervention Sample 2		0="No" 1="Yes"
01. Principal	response_pre2_post3	Response For Pre-Intervention Sample 2 To Post-Intervention Sample 3		0="No" 1="Yes"
01. Principal	sex	Sex		"Female"="Female" "Male"="Male"
01. Principal	SITE	Site		"Case Western Reserve University"="Case Western Reserve University" "Cleveland Clinic Foundation"="Cleveland Clinic Foundation" "Massachusetts General Hospital Cancer Center"="Massachusetts General Hospital Cancer Center" "Mayo Clinic in Florida"="Mayo Clinic in Florida" "Mount Sinai Hospital"="Mount Sinai Hospital"
01. Principal	SITENUMBER	Site Number		"FL080"="FL080" "MA034"="MA034" "NY021"="NY021" "OH027"="OH027" "OH029"="OH029"
01. Principal	surgical_cohort	Surgical Cohort		1="Surgical Cohort" 2="Non-Surgical Cohort"
01. Principal	totpix_post1	Post-Intervention Total Pixels: Sample 1		Char
01. Principal	totpix_post2	Post-Intervention Total Pixels: Sample 2		Char
01. Principal	totpix_post3	Post-Intervention Total Pixels: Sample 3		Char
01. Principal	totpix_pre1	Pre-Intervention Total Pixels: Sample 1		Char
01. Principal	totpix_pre2	Pre-Intervention Total Pixels: Sample 2		Char