



# Validation Checks Performed by WebSDM™ Version 2.6 on SDTM version 3.1.1 Datasets

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## Validation Checks Performed by WebSDM™ Version 2.6 on SDTM version 3.1.1 Datasets

The WebSDM™ product, offered by Phase Forward's Lincoln Technologies safety division, is a software product that was developed for use by the FDA under a Cooperative Research and Development Agreement to validate and review data in CDISC SDTM format. The WebSDM™ product may also be licensed for use by pharmaceutical and biotechnology sponsors who are submitting data to the FDA in CDISC SDTM format to support product marketing applications.

The table below lists the current set of validation checks performed by WebSDM™ Version 2.6 on data provided as SAS Transport files or as Oracle tables or views according to version 3.1.1 of the [CDISC Study Data Tabulation Model Implementation Guide: Human Clinical Trials](#) (SDTMIG) and the [FDA's Study Data Specifications](#). Additional errors may result from problems with a sponsor-created define.xml file that does not conform to the [CDISC Define.xml](#) schema or conflicts with the CDISC SDTMIG. Note that these rules have been updated and expanded from those used in previous versions of WebSDM™. Section I below is a complete listing of all rules implemented in WebSDM version 2.6.957 for SDTM version 3.1.1; section II summarizes the new, changed, and deleted rules compared to those that were implemented in WebSDM version 1.5.733.

In the tables below, the "ID" column records the control number applied to each check.

The "APPLIES" column identifies which SDTM object may be affected by that particular check. A check may apply to all domains, a general class of domains (such as findings), an individual domain, or a set of variables in a given role (such as timing variables as indicated).

The "RULE DESCRIPTION" column explains in human readable form the general logic behind the check performed by the WebSDM™ product.

The "SEVERITY" column explains the relative significance of an anomaly detected by a check, rated LOW, MEDIUM or HIGH. Note there is no direct correlation between a severity value and a decision by FDA reviewers as to whether the data is acceptable for review or not. Instead, Severity is meant only as an indicator of potential problems or anomalies in the data and the error's potential to affect the interpretation or use of the data for specific purposes.

The "COMMENTS" column provides additional relevant information concerning a check. This may indicate whether a check is scheduled to be deprecated in the future, or special considerations about its implementation.

It is important to note that the actual list of checks used by the FDA will evolve over time to reflect input received from FDA reviewers as they gain more experience with SDTM and different sponsor submissions in this format. Therefore, sponsors should be cautioned that additional or modified checks may be implemented in the WebSDM product prior to release of a new published version of these checks.

Section I – all rules implemented in WebSDM version 2.6.957 for SDTM version 3.1.1:

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
IR4000	All	Identifies domain table that has zero rows and therefore contains no data.	Medium	Null tables are normally not submitted
IR4001	All	Identifies a null (empty) value found in a column where (Standard) Core attribute is 'Req'	High	Required variables may not be null
IR4002	All	Identifies records where the value for a date doesn't conform to the ISO 8601 standard.	Medium	
IR4003	All	Identifies records where the value in the Domain Abbreviation column doesn't match the name of Domain	Low	
IR4004	All	Identifies records where non-unique values for Sequence Number variable exist within a subject	High	
IR4005	Findings	Identifies subjects where there are no records with a value of 'Y' in the baseline flag variable (Baseline Flag), excluding Arm Code='SCRNFAIL'	Low	Check of Arm Code value is case-insensitive
IR4006	LB	Identifies Short Name of Measurement, Test or Examination values where standard units value (Standard Units) is not consistent across all records	Medium	
IR4007	AE	Identifies records where the value for the Preferred Term could not be found in the MedDRA dictionary	Medium	
IR4008	AE	Identifies records where Serious Event='Y' but none of Involves Cancer, Congenital Anomaly or Birth Defect, Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event, or Occurred with Overdose equals 'Y'	Medium	
IR4009	All	Identifies records where Result or Finding in Original Units and Status both have a value, or where both are null and Derived Flag is not equal to 'Y'	Medium	
IR4010	All	Identifies records where the value for Visit Number is formatted to more than three decimal places	Medium	

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
IR4011	DM	Identifies records that violate the condition [If Arm Code='SCRNFAIL' then Description of Arm must equal 'Screen Failure', and vice versa]	Low	Checks of Arm Code and Arm values are case-insensitive
IR4012	TA	Identifies records that violate the condition [If Arm Code='SCRNFAIL' then Description of Arm must equal 'Screen Failure', and vice versa]	Low	Checks of Arm Code and Arm values are case-insensitive
IR4100	All (Timing)	Identifies records that violate the condition [(Study Day of Start of Observation less than or equal to Study Day of End of Observation)], limited to records where [Study Day of Start of Observation is not null and Study Day of End of Observation is not null]	High	
IR4101	All (Timing)	Identifies records that violate the condition [(Start Date/Time of Observation less than or equal to End Date/Time of Observation)], limited to records where [Start Date/Time of Observation is not null and End Date/Time of Observation is not null]	High	
IR4102	Findings	Identifies records that violate the condition [Baseline Flag either 'Y' or null]	Medium	
IR4103	Findings	Identifies records that violate the condition [Derived Flag either 'Y' or null]	Medium	
IR4104	Events, Interventions	Identifies records that violate the condition [End Relative to Reference Period in ('BEFORE', 'DURING', 'AFTER', 'DURING/AFTER', 'U')], limited to records where [End Relative to Reference Period is not null]	Medium	
IR4105	Findings	Identifies records that violate the condition [Fasting Status in ('Y', 'N', 'U')], limited to records where [Fasting Status is not null]	Medium	
IR4106	Events, Interventions	Identifies records that violate the condition [Occurrence in ('Y', 'N')], limited to records where [Occurrence is not null]	Medium	
IR4107	All	Identifies records that violate the condition [Status='NOT DONE'], limited to records where [Status is not null]	Medium	

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
IR4108	Events, Interventions	Identifies records that violate the condition [Start Relative to Reference Period in ('BEFORE','DURING','AFTER','U')], limited to records where [Start Relative to Reference Period is not null]	Medium	
IR4109	Interventions	Identifies records that violate the condition [Dose greater than or equal to 0], limited to records where [Dose is not null]	High	
IR4110	All (Timing)	Identifies records that violate the condition [Duration greater than or equal to 0], limited to records where [Duration is not null]	High	
IR4112	Findings	Identifies records that violate the condition [Result or Finding in Standard Format is not null], limited to records where [Derived Flag='Y']	Medium	
IR4113	Findings	Identifies records that violate the condition [LENGTH(Name of Measurement, Test or Examination) less than or equal to 40 characters]	Low	
IR4114	Findings	Identifies records that violate the condition [LENGTH(Short Name of Measurement, Test or Examination) less than or equal to 8 chars, cannot start with a number or contain special chars]	Low	
IR4115	TS	Identifies records that violate the condition [LENGTH(Trial Summary Parameter) less than or equal to 40 chars]	Low	
IR4116	TS	Identifies records that violate the condition [LENGTH(Trial Summary Parameter Short Name) less than or equal to 8 chars, cannot start with a number or contain special chars]	Low	
IR4117	All (Timing)	Identifies records that violate the condition [End Relative to Reference Period is not null], limited to records where [End Date/Time of Observation is null] and [Occurrence doesn't equal 'N']	Low	
IR4118	All (Timing)	Identifies records that violate the condition [Start Relative to Reference Period is not null], limited to records where [Start Date/Time of Observation is null] and [Occurrence doesn't equal 'N']	Low	

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
IR4119	EX	Identifies records that violate the condition [Planned Elapsed Time from Reference Pt greater than or equal to 0], limited to records where [Planned Elapsed Time from Reference Pt is not null]	High	
IR4120	All (Timing)	Identifies records that violate the condition [Evaluation Interval greater than or equal to 0], limited to records where [Evaluation Interval is not null]	High	
IR4121	Events	Identifies records that violate the condition [Toxicity Grade is a valid number], limited to records where [Toxicity Grade is not null]	Medium	
IR4122	All	Identifies records that violate the condition [Reason Not Done is null], limited to records where [Status is null]	Medium	
IR4123	Findings	Identifies records that violate the condition [Date/Time of Collection is not null], limited to records where [End Date/Time of Observation is not null]	Low	
IR4124	Findings	Identifies records that violate the condition [Date/Time of Collection less than or equal to End Date/Time of Observation], limited to records where [Date/Time of Collection is not null and End Date/Time of Observation exists]	High	
IR4125	Findings	Identifies records that violate the condition [Original Units is not null], limited to records where [Result or Finding in Original Units is not null]	Low	
IR4126	Findings	Identifies records that violate the condition [Original Units is null], limited to records where [Result or Finding in Original Units is null]	Low	
IR4127	Findings	Identifies records that violate the condition [Normal Range Upper Limit-Standard Units greater than or equal to Normal Range Lower Limit-Standard Units], limited to records where [Normal Range Upper Limit-Standard Units is not null and Normal Range Lower Limit-Standard Units is not null]	High	

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
IR4128	Findings	Identifies records that violate the condition [Standard Units is not null], limited to records where [Result or Finding in Standard Format is not null]	Low	
IR4129	Findings	Identifies records that violate the condition [Standard Units is null], limited to records where [Result or Finding in Standard Format is null]	Low	
IR4130	All (Timing)	Identifies records that violate the condition [Start Date/Time of Observation or Start Relative to Reference Period is not null], limited to records where [End Date/Time of Observation or End Relative to Reference Period is not null]	Low	
IR4131	All (Timing)	Identifies records that violate the condition [Planned Time Point Name is not null], limited to records where [Planned Time Point Number is not null]	Low	
IR4132	All (Timing)	Identifies records that violate the condition [Planned Time Point Number is not null], limited to records where [Planned Time Point Name is not null]	Low	
IR4133	All (Timing)	Identifies records that violate the condition [Time Point Reference is not null], limited to records where [Elapsed Time from Reference Point is not null]	Medium	
IR4134	Interventions	Identifies records that violate the condition [Dose Units is not null], limited to records where [Dose is not null] and (Standard) Core attribute is 'Perm'	Low	Analog to IR4138
IR4135	Findings	Identifies records that violate the condition [Result or Finding in Standard Format is not null], limited to records where [Result or Finding in Original Units is not null]	High	
IR4136	All	Identifies records where values are not found in the study-specific codelist attached to a variable	Low	
IR4137	All	Identifies records that violate the condition [Study Day of Visit/Collection/Exam doesn't equal 0]	Low	
IR4138	Interventions	Identifies records that violate the condition [Dose Units is not null], limited to records where [Dose is not null] and (Standard) Core attribute is 'Exp'	Medium	Analog to IR4134



ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
IR4139	SUPPQUAL	Identifies records that violate the condition [Related Domain is not null]	Medium	
IR4140	DV	Identifies cases where Protocol Deviation Term and Protocol Deviation Coded Term do not map 1:1	Medium	Replacement for deleted rule (R4104)
IR4250	All	Identifies a column that was described in the domain description but not included in the SAS dataset for that domain	Low	
IR4251	All	Identifies a column where the expected datatype inferred from the description file does not match the actual datatype in the dataset	Medium	
IR4252	All	Identifies a column listed in the domain description as Required ('Req') but not included in the SAS dataset for that domain	High	
IR4253	All	Identifies a column listed in the domain description as Expected ('Exp') but not included in the SAS dataset for that domain	Medium	
IR4254	All	Identifies a column that appears in the SAS dataset but is not listed in the domain description	Medium	
IR4255	AE	Identifies a Sponsor-provided Flag Variable for 'Treatment emergent AE' where the derivation can't be executed	Medium	Relevant when using CTSD safety analysis tools only
IR4256	LB	Identifies a Sponsor-provided Flag Variable for 'Clinically Significant Lab' where the derivation can't be executed	Medium	Relevant when using CTSD safety analysis tools only
IR4257	VS	Identifies a Sponsor-provided Flag Variable for 'Clinically Significant Vital Sign' where the derivation can't be executed	Medium	Relevant when using CTSD safety analysis tools only
IR4258	SUPPQUAL	Identifies a domain that appears to contain supplemental qualifier data but does not contain the Unique Subject Identifier variable	High	
IR4259	All	Identifies a variable where datatype in (study specific) description is not consistent with datatype implicit in SAS dataset	Medium	
IR4260	All	Identifies a variable present in SAS dataset but not present in (study specific) description file	Medium	
IR4261	All	Identifies a domain that is referenced in a description file but for which there is no source data	Medium	
IR4262	All	Identifies a domain whose source data failed to load	High	
IR4263	All	Identifies a variable that uses an unsupported Event Dictionary	Low	

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
IR4500	All	Identifies non-Demographics domain subjects not found in the Demographics domain	High	
IR4501	All	Identifies Unique Subject Identifier+Visit Name+Visit Number combinations not found in the SV domain	Medium	
IR4502	DM	Identifies records where the value for Arm Code is not found in the TA domain, excluding 'SCRNFAIL'	Medium	Check of Arm Code value is case-insensitive
IR4503	All	Identifies records where the value for Subject Element Code is not found in the TE domain	Medium	
IR4504	IE	Identifies records where the value for Inclusion/Exclusion Criterion Short Name is not found in the TI domain	Medium	
IR4505	DM	Identifies Demographics subjects where no record for the subject is found in the Disposition domain	Medium	
IR4506	DM	Identifies Demographics subjects where no record for the subject is found in the Exposure domain	Medium	
IR4507	DM	Identifies Demographics treatment arms (Description of Arm+Arm Code combination) not found in the TA domain, excluding 'Screen Failure','SCRNFAIL'	Medium	Checks of Arm and Arm Code values are case-insensitive
IR4508	CO	Identifies CO domain reference to an unknown related domain	High	
IR4509	RELREC	Identifies Related Records domain reference to an unknown related domain	High	
IR4510	SUPPQUAL	Identifies Supplemental Qualifiers domain reference to an unknown related domain	High	
IR4511	RELREC	Identifies Related Records domain reference to a key variable that isn't defined in the target domain	High	
IR4512	SUPPQUAL	Identifies Supplemental Qualifiers domain reference to a key variable that isn't defined in the target domain	High	
IR4513	RELREC	Identifies Related Records domain reference to a record that doesn't exist in the target domain	High	
IR4514	SUPPQUAL	Identifies Supplemental Qualifiers domain reference to a record that doesn't exist in the target domain	High	

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
R4006	DM	Identifies records that violate the condition [Age greater than or equal to 0], limited to records where [Age is not null]	High	
R4007	DM	Identifies records where value for [Sex] is not found in Codelist [SEX]	Medium	
R4008	DM	Identifies records where value for [Country] is not found in Codelist [COUNTRY]	Medium	
R4019	AE	Identifies records where value for [Serious Event] is not found in Codelist [YESNO]	Medium	
R4023	AE	Identifies records where value for [Congenital Anomaly or Birth Defect] is not found in Codelist [YESNO], limited to records where [Congenital Anomaly or Birth Defect is not null]	Medium	
R4024	AE	Identifies records where value for [Persist or Signif Disability/Incapacity] is not found in Codelist [YESNO], limited to records where [Persist or Signif Disability/Incapacity is not null]	Medium	
R4025	AE	Identifies records where value for [Results in Death] is not found in Codelist [YESNO], limited to records where [Results in Death is not null]	Medium	
R4026	AE	Identifies records where value for [Requires or Prolongs Hospitalization] is not found in Codelist [YESNO], limited to records where [Requires or Prolongs Hospitalization is not null]	Medium	
R4027	AE	Identifies records where value for [Is Life Threatening] is not found in Codelist [YESNO], limited to records where [Is Life Threatening is not null]	Medium	
R4031	IE	Identifies records where value for [Inclusion/Exclusion Category] is not found in Codelist [INCEX], limited to records where [Inclusion/Exclusion Category is not null]	Medium	
R4043	AE	Identifies records where value for [Concomitant or Additional Trtmnt Given] is not found in Codelist [YESNO]	Medium	
R4045	AE	Identifies records where value for [Involves Cancer] is not found in Codelist [YESNO], limited to records where [Involves Cancer is not null]	Medium	

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
R4046	AE	Identifies records where value for [Other Medically Important Serious Event] is not found in Codelist [YESNO], limited to records where [Other Medically Important Serious Event is not null]	Medium	
R4047	AE	Identifies records where value for [Occurred with Overdose] is not found in Codelist [YESNO], limited to records where [Occurred with Overdose is not null]	Medium	
R4062	DM	Identifies records where value for [Age Units] is not found in Codelist [AGEUNITS2], limited to records where [Age Units is not null]	Medium	
R4071	IE	Identifies records where value for [I/E Criterion Original Result] is not found in Codelist [YESNO], limited to records where [I/E Criterion Original Result is not null]	Medium	
R4072	IE	Identifies records where value for [I/E Criterion Result in Std Format] is not found in Codelist [YESNO], limited to records where [I/E Criterion Result in Std Format is not null]	Medium	
R4073	IE	Identifies records that violate the condition [I/E Criterion Original Result = I/E Criterion Result in Std Format]	Low	
R4083	SUPPQUAL	Identifies records where values for [Study Identifier, Unique Subject Identifier, Identifying Variable, Identifying Variable Value, Qualifier Variable Name] variable(s) are not unique	Medium	
R4096	DM	Identifies records that violate the condition [Subject Reference Start Date/Time is not null], limited to records where [upper(Arm Code) doesn't equal 'SCRNFAIL']	Medium	Check of Arm Code value is case-insensitive
R4097	DM	Identifies records that violate the condition [Subject Reference End Date/Time is not null], limited to records where [upper(Arm Code) doesn't equal 'SCRNFAIL']	Medium	Check of Arm Code value is case-insensitive
R4101	TE	Identifies records that violate the condition [Rule for End of Element is not null or Planned Duration of Element is not null]	Medium	
R4102	AE	Identifies records that violate the condition [Results in Death='Y'], limited to records where [Outcome of Adverse Event='FATAL']	Medium	

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
R4103	AE	Identifies records that violate the condition [Outcome of Adverse Event='FATAL'], limited to records where [Results in Death='Y']	Medium	
R4105	SE	Identifies records that violate the condition [Description of Unplanned Element is not null], limited to records where [Subject Element Code='UNPLAN']	Medium	
R4106	DM	Identifies records that violate the condition [Age Units is not null], limited to records where [Age is not null]	Low	

Section II

A. New rules (additions present in 2.6.957 that were not in 1.5.733):

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
IR4138	Interventions	Identifies records that violate the condition [Dose Units is not null], limited to records where [Dose is not null] and (Standard) Core attribute is 'Exp'	Medium	Analog to IR4134 for records where (Standard) Core attribute is 'Exp'
IR4139	SUPPQUAL	Identifies records that violate the condition [Related Domain is not null]	Medium	
IR4140	DV	Identifies cases where Protocol Deviation Term and Protocol Deviation Coded Term do not map 1:1	Medium	Replaces deleted rule R4104
IR4261	All	Identifies a domain that is referenced in a description file but for which there is no source data	Medium	
IR4262	All	Identifies a domain whose source data failed to load	High	
IR4263	All	Identifies a variable that uses an unsupported Event Dictionary	Low	

Section II - continued

B. Changed rules (rules in 2.6.957 that were changed relative to the same rule in 1.5.733)

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
IR4005	Findings	Identifies subjects where there are no records with a value of 'Y' in the baseline flag variable (Baseline Flag), excluding Arm Code='SCRNFAIL'	Low	Added exclusion criterion for records where Arm Code = (case-insensitive) 'SCRNFAIL'
IR4009	All	Identifies records where Result or Finding in Original Units and Status both have a value, or where both are null and Derived Flag is not equal to 'Y'	Medium	Added check of Derived Flag value where both variables of interest are null
IR4010	All	Identifies records where the value for Visit Number is formatted to more than three decimal places	Medium	Changed text to match logic of check (threshold at three or more decimal places)
IR4011	DM	Identifies records that violate the condition [If Arm Code='SCRNFAIL' then Description of Arm must equal 'Screen Failure', and vice versa]	was: High now: Low	Changed severity from High to Low; made check of literal values case-insensitive
IR4012	TA	Identifies records that violate the condition [If Arm Code='SCRNFAIL' then Description of Arm must equal 'Screen Failure', and vice versa]	was: High now: Low	Changed severity from High to Low; made check of literal values case-insensitive
IR4108	Events, Interventions	Identifies records that violate the condition [Start Relative to Reference Period in ('BEFORE','DURING','AFTER','U')], limited to records where [Start Relative to Reference Period is not null]	Medium	Added allowable value 'U' to list
IR4117	All (Timing)	Identifies records that violate the condition [End Relative to Reference Period is not null], limited to records where [End Date/Time of Observation is null] and [Occurrence doesn't equal 'N']	Low	Added condition to exclude records where Occurrence = 'N'
IR4118	All (Timing)	Identifies records that violate the condition [Start Relative to Reference Period is not null], limited to records where [Start Date/Time of Observation is null] and [Occurrence doesn't equal 'N']	Low	Added condition to exclude records where Occurrence = 'N'
IR4125	Findings	Identifies records that violate the condition [Original Units is not null], limited to records where [Result or Finding in Original Units is not null]	Low	Changed condition to check Original Units rather than Result or Finding in Original Units

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
IR4126	Findings	Identifies records that violate the condition [Original Units is null], limited to records where [Result or Finding in Original Units is null]	Low	Changed condition to check Original Units rather than Result or Finding in Original Units
IR4127	Findings	Identifies records that violate the condition [Normal Range Upper Limit-Standard Units greater than or equal to Normal Range Lower Limit-Standard Units], limited to records where [Normal Range Upper Limit-Standard Units is not null and Normal Range Lower Limit-Standard Units is not null]	High	Corrected lattermost comparand to Normal Range Lower Limit Standard Units rather than the previously referenced STNRHI
IR4130	All (Timing)	Identifies records that violate the condition [Start Date/Time of Observation or Start Relative to Reference Period is not null], limited to records where [End Date/Time of Observation or End Relative to Reference Period is not null]	Low	Added checks of Start Relative to Reference Period and End Relative to Reference Period
IR4134	Interventions	Identifies records that violate the condition [Dose Units is not null], limited to records where [Dose is not null] and (Standard) Core attribute is 'Perm'	Low	Added condition limiting check to records where (Standard) Core attribute is 'Perm'
IR4502	DM	Identifies records where the value for Arm Code is not found in the TA domain, excluding 'SCRNFAIL'	Medium	Added exclusion criterion for records where Arm Code = (case-insensitive) 'SCRNFAIL'
IR4505	DM	Identifies Demographics subjects where no record for the subject is found in the Disposition domain	was; High now: Medium	Changed severity from High to Medium; corrected description to refer to Demographics.
IR4506	DM	Identifies Demographics subjects where no record for the subject is found in the Exposure domain	was; High now: Medium	Changed severity from High to Medium; corrected description to refer to Demographics.
IR4507	DM	Identifies Demographics treatment arms (Description of Arm+Arm Code combination) not found in the TA domain, excluding 'Screen Failure', 'SCRNFAIL'	Medium	Added exclusion criterion for records where Arm Code = (case-insensitive) 'Screen Failure' and Arm Code = (case-insensitive) 'SCRNFAIL'; corrected description to refer to Demographics.
R4096	DM	Identifies records that violate the condition [Subject Reference Start Date/Time is not null], limited to records where [upper(Arm Code) doesn't equal 'SCRNFAIL']	was; High now: Medium	Changed severity from High to Medium; changed exclusion criterion to be case-insensitive on value of Arm Code



ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
R4097	DM	Identifies records that violate the condition [Subject Reference End Date/Time is not null], limited to records where [upper(Arm Code) doesn't equal 'SCRNFAIL']	was; High now: Medium	Changed severity from High to Medium; changed exclusion criterion to be case-insensitive on value of Arm Code

Section II - continued

C. Deleted rules (rules no longer present in 2.6.957 that were present in 1.5.733)

ID	APPLIES	RULE DESCRIPTION	SEVERITY	COMMENTS
IR4111	Findings	Identifies records that violate the condition [Result or Finding in Original Units is null], limited to records where [Derived Flag='Y']	Medium	Rule deprecated. The Implementation Guide allows sponsors to populate this variable.
R4005	DM	Identifies records where values for Unique Subject ID variable(s) are not unique, limited to records where [Unique Subject ID is not null]	Medium	Rule deprecated. Rather than firing the rule, WebSDM 2.6 does not load the study if this situation is encountered. The study would be unusable with duplicate Subject IDs.
R4104	DV	Identifies records that violate the condition [count (distinct Protocol Deviation Term) = count(distinct Protocol Deviation Coded Term)], limited to records where [Protocol Deviation Term is not null]	Medium	Rule replaced by IR4140