Cancer Report Validator (CRV) Tool Version 1.0.4 Known Issues
11-14-16

This document addresses known issues that have been identified in the Cancer Report Validator test tool v1.0.4. These issues may, in some instances, indicate errors in test cases when there are in fact no errors. This document provides detail on how to identify those known errors and how the document can be validated via visual inspection.

CDC, ONC, and the tool developer have reviewed the reported issues and a new release of the tool is planned in the near future.

Should you identify issues with the tool other than those listed, please direct them to the mailing list dedicated to this tool: https://groups.google.com/d/forum/cancer-reg-testing-tool.

Known Issues:

Issue 1: Node expressions with invalid index
Issue 2: Match on ICD9 and ICD10 codes doesn't allow for decimal point
Issue 3: Match on ICD-O-3 codes doesn’t allow for 4 digit code variation
Issue 4: TNM Staging Vocabulary issues
Issue 5: Medication Vocabulary issues
Issue 6: Invalid value errors for document level language value set
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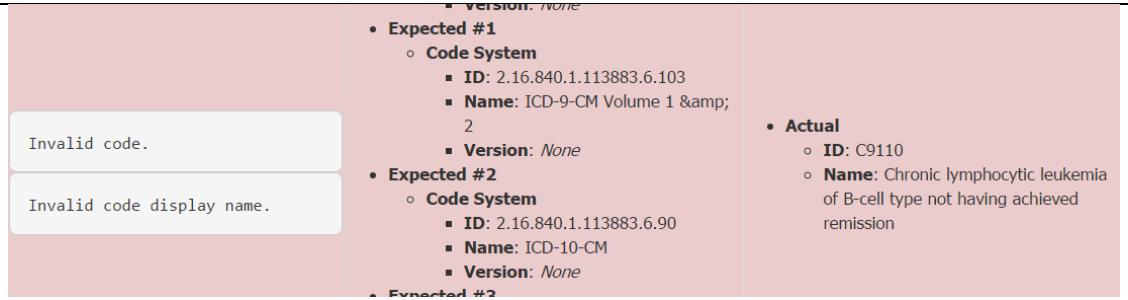
Issue 1	**Node expressions with invalid index**
Description	For **Test Data Conformance Events**, there is a problem with the way the tool iterates through multiple instances of certain data elements in the CDA document. It causes the tool to indicate errors on a 2nd or 3rd instance (node) of elements where there is actually only one instance.
Example	**Example 1:** Under "Location" in Test Data Conformance **Events** results, the "Node Expression" states that there is a mismatch error in this location: /ClinicalDocument/recordTarget/patientRole/addr[3]/city/text() and that the "Expected Result" is "Seattle" but "Actual Result" is "None". Visual inspection of the file shows that the address city element is correctly populated with "Seattle": <city>Seattle</city> **Example 2:** Under "Location" in **Test Data Conformance Events** results, the "Node Expression" states that there is a mismatch error in this location: /ClinicalDocument/recordTarget/patientRole[2]/patient/administrativeGenderCode/@code and that the "Expected Result" is "F" but "Actual Result" is "none". Visual inspection of the file shows that the @code attribute is correctly populated with value of "F": <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1" />
Resolution—Instructions for visual inspection	If error messages are seen indicating a mismatch and the node expression includes a "[2]" or higher for any of the data elements in the CDA header, visual inspection needs to be performed to determine whether the content is valid according to the test data.
Issue 2	**Match on ICD9 and ICD10 codes doesn't allow for decimal point**
Description	ICD9 and ICD10 code systems allow for codes to be provided in 2 formats, either with or without a period/decimal point. For **IG Conformance Events**, CRV produces an "invalid code" error message when the decimal point is **not** present. For **Test Data Conformance Events**, the tool produces a mismatch error message when the decimal point **is** present.
Example	**IG Conformance Event:**

<table>
<tr><td></td><td>


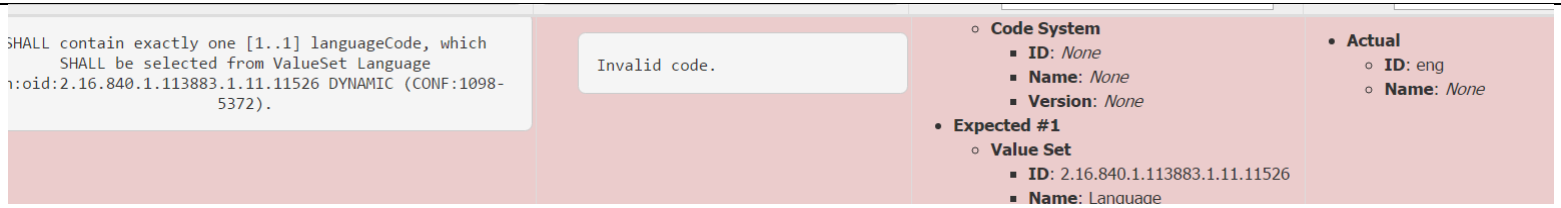
Test Data Conformance Event:


</td></tr>
<tr><td>Resolution—Instructions for visual inspection</td><td>If error messages are seen indicating invalid code or mismatch for ICD9 or ICD10 codes, visual inspection needs to be performed to determine whether the content is valid according to the test data. Values should be considered valid either with or without use of the decimal point.</td></tr>
<tr><td>Issue 3</td><td>Match on ICD-O-3 codes doesn’t allow for 4 digit code variation</td></tr>
<tr><td>Description</td><td>ICD-O-3 histology codes can be represented in 2 formats, either 5 digits (e.g., "8000/3") or 4 digits (e.g., "8000").
For IG Conformance Events and Test Data Conformance Events, CRV produces an “invalid code” or “mismatch” error message, respectively, when the 4 digit code is used.</td></tr>
<tr><td>Example</td><td>IG Conformance Event:</td></tr>
</table>

	The @code for histologic type of tumor, if present, SHALL be selected from: (a) ICD-O-3 (CodeSystem: 2.16.840.1.113883.6.43.1) or (b) Morphologic Abnormality of Neoplasms Value Set (ValueSet: 2.16.840.1.114222.4.11.7256) or (c) ICD-9-CM Appendix A-Morphology of Neoplasms Invalid code. Invalid code display name. **Test Data Conformance Event:** Mismatch — *None* — • 8742/2 • 61217001 • M8742/2 Visual inspection of file shows a valid 4 digit code: <value xsi:type="CD" code="8742" codeSystem="2.16.840.1.113883.6.43.1" codeSystemName="ICD-O-3" displayName="Hutchinson's melanotic freckle">
Resolution—Instructions for visual inspection	If error messages are seen indicating invalid code or mismatch for ICD-O-3 code for histologic type, visual inspection needs to be performed to determine whether the content is valid according to the test data. Values should be considered valid when either the 4 or 5 digit code is used. **Assertion ID:** a-1169-32473-c
Issue 4	**TNM Staging Vocabulary issues**
Description	**a. For IG Conformance Events** and **Test Data Conformance Events,** CRV produces an invalid code or mismatch error, respectively,

	for TNM Clinical and Pathologic Stage Group if Arabic instead of Roman Numerals. **b.** **For IG Conformance Events** and **Test Data Conformance Events,** CRV produces an invalid code or mismatch error, respectively, for the following data elements if upper case letters are used instead of lower case letters: TNM Clinical T, TNM Clinical N, TNM Clinical M, TNM Pathologic T, TNM Pathologic N, TNM Pathologic M. For example, for TNM Clinical T, the tool expects "T4a" and produces an error for "T4A". **c.** **For IG Conformance Events** and **Test Data Conformance Events,** CRV produces an invalid code or mismatch error, respectively, for the following data elements if the "T", "N" or "M" prefix is omitted: TNM Clinical T, TNM Clinical N, TNM Clinical M, TNM Pathologic T, TNM Pathologic N, TNM Pathologic M.
Example	a. **IG Conformance Event:** Invalid code. ○ **Code System** ▪ **ID**: 2.16.840.1.113883.15.6 ▪ **Name**: TNM 7. Edition ▪ **Version**: *None* • **Expected #1** ○ **Value Set** ▪ **ID**: 2.16.840.1.113883.3.520.4.20 ▪ **Name**: TNM Pathologic Stage Group ▪ **Version**: *None* • **Actual** ○ **ID**: 2B ○ **Name**: *None*
Resolution—Instructions for visual inspection	If error messages are seen indicating invalid code or mismatch for any of the TNM data elements, visual inspection needs to be performed to determine whether the content is valid according to details above and/or to the test data. Values should be considered valid when any of the variations described here are used.
Issue 5	**Medication Vocabulary issues**
Description	At the time of test data development, we used RX Norm medication codes in the test cases which have since been retired as obsolete or have other reasonable names/codes. Therefore, EHR systems may not have these exact codes in their current dictionaries. For **Test Data Conformance Events**, Test Cases 1a/1b, CRV produces a mismatch if the exact RX Norm codes and display names identified in the test data are not used.

	The RX Norm medication codes are also used in the xPaths of some of the other validation tests, so the use of alterative valid RX Norm codes could cause mismatch errors for other elements in this entry as well.
Example	Currently, the test data requires an RX Norm Code of "1148919" and display name of "gemcitabine 38 MG/ML injectable solution". This code is now obsolete. A mismatch error is produced if other codes or display names are provided. Currently, the test data requires an RX Norm Code of "577348" and display name of "ramelteon 8 MG Oral Tablet".
Resolution—Instructions for visual inspection	If error messages are seen indicating invalid code or mismatch for these medications, or any other Medication Activity elements, visual inspection needs to be performed to determine whether the content is valid according to the test data. Valid alternative codes/names for Gemcitabine: 3. RXCUI:1720960 Full Generic Name: 26.3 ML gemcitabine 38 MG/ML Injection 2. RXCUI: 1720977 Full Generic Name: 5.26 ML gemcitabine 38 MG/ML Injection 3. RXCUI: 1720975 Full Generic Name: 52.6 ML gemcitabine 38 MG/ML Injection Valid alternative code/name for Ramelteon: Rx CUI: 603162 Branded Drug Name: Rozerem 8 MG Oral Tablet
Issue 6	**Invalid value errors for document level language value set**
Description	For **IG Conformance Events**, CRV produces an "invalid code" error message that a value of "eng" is not valid for the clinicalDocument/languageCode element. "Eng" is a valid value in the value set, but appears to be missing from the vocabulary file. For **IG Conformance Events**, CRV produces an "invalid code" error message that a value of "en-US" is not valid for the clinicalDocument/languageCode element.

Example	
Resolution—Instructions for visual inspection	If error message is seen indicating invalid code for language code, visual inspection needs to be performed to determine whether a valid value of “eng” or “en-US” was provided. Both of these values should be considered valid. **Assertion ID: a-1098-5372**
Issue 7	**Globally Unique ID error**
Description	For **IG Conformance Events**, CRV produces an error message stating the document “SHALL contain exactly one [1..1] id (CONF:1098-5363). This id SHALL be a globally unique identifier for the document (CONF:1098-9991).”, even though a globally unique id (@root only) is provided in the test case.
Example	
Resolution—Instructions for visual	If error message is produced, it should be ignored. **Assertion ID:** a-1098-5363

inspection	
Issue 8	**Histology Code—Error if coded value provided but original text is absent**
Description	For **IG Conformance Events**, CRV produces an error message stating that "If value/@code not present then This value SHALL contain exactly one [1..1] originalText (CONF:1169-32537)". Visual inspection shows, however, that the value/@code **is** present in the test case. The tool appears to produce an error when value/@code is present and originalText is absent instead of only checking for presence of originalText if value/@code is absent.
Example	 Visual inspection of the file shows that the value element for histologic type is correctly populated with value of "61217001": <value xsi:type="CD" code="61217001" codeSystem="2.16.840.1.113883.6.96" displayName="Hutchinson's melanotic freckle">
Resolution—Instructions for visual inspection	If this error is produced, manual review must be performed to determine whether the histology code is present and valid according to the test data. **Assertion ID:** a-1169-32537
Issue 9	**Vital Signs—Null flavor required on entry**
Description	For **Test Data Conformance Events,** CRV produces a mismatch error because it expects a null flavor of "NA" on the <entry>. According to the IG the Vitals Section is a nullable section; in other words, an @nullFlavor on the <section> denotes that there are no entries. Therefore, the null flavor requirement should have been on the section rather than the entry.

Example	Test results show:
	Actual Result: “none”
	Expected Result(s): “NA”
	Location: Node Expression:
	“ClinicalDocument/component/structuredBody/component/section[templateId[@root=’2.16.840.1.113883.10.20.22.2.4.1’ and @extension = ‘2014-06-09’]]/entry/organizer/component/observation/code/@nullFlavor”
	
	Visual inspection of the file shows Vital Signs Section with a valid null flavor at the Section Level;
	
	`<section nullFlavor=”NI”>`
	`<!-- ** Vital Signs Section (entries required) (V2) ** →`
	`<templateId root=”2.16.840.1.113883.10.20.22.2.4” extension=”2014-06-09”/>`
	`<templateId root=”2.16.840.1.113883.10.20.22.2.4.1” extension=”2014-06-09”/>`
	`<code code=”8716-3” codeSystem=”2.16.840.1.113883.6.1” codeSystemName=”LOINC” displayName=”VITAL SIGNS”/>`
	`<title>VITAL SIGNS</title>`
	`<text>Vital signs not taken</text>`
	`</section>`

Resolution—Instructions for visual inspection	If error message is produced, visual inspection must be performed to determine whether the Vital Signs Section does have a null flavor at the Section Level; if it does, it should be considered valid.
Issue 10	**Display Name Exact Match**
Description	For **IG Conformance Events** and **Test Data Conformance Events**, CRV produces “invalid display name” and “mismatch” error messages, respectively, when the @displayName attribute for a coded data element is not an exact match to the value set or test data.
Example	Example of **valid** display name with equivalent meaning: Test Data Valid Display Names: “Hutchinson’s melanotic freckle” or “Lentigo Maligna” Visual inspection: “Hutchinson’s melanotic freckle, NOS”

	Example of **invalid** display name because meaning is not equivalent: Test Data Valid Display Name: Nodular melanoma Visual inspection: Basal cell carcinoma
Resolution—Instructions for visual inspection	If error messages indicating mismatch on @displayName are produced, visual inspection must be performed to determine whether the @displayName has an equivalent meaning to the @displayName indicated in the test data. The tester must evaluate the display names in a submitted report whenever a discrepancy is indicated with a display name. (Note: These instructions to testers were included in the CRV Documentation.) CDC Subject Matter Experts are available for assistance in determining valid equivalent meaning if needed.
Issue 11	**Patient Address Usable Period requires <High> element to have Null Flavor**
Description	For **Test Data Conformance Events,** CRV produces a mismatch error if the @nullFlavor attribute is not an exact match to the test data for a single specific null flavor, rather than allowing all null flavors to be valid or allowing the element to be missing entirely for the Patient Address Usable period <high> element.

Example	Test results show:
	Actual Result: “none”
	Expected Result(s): “NA”
	Location: Node Expression: “/ClinicalDocument/recordTarget/patientRole/addr[1]/useablePeriod/high/@nullFlavor”
	
	Visual inspection of the file shows address with useablePeriod with <high> element missing rather than providing a null flavor:
	
	`<addr use=”H”>`
	`<streetAddressLine>111 Main Street</streetAddressLine>`
	`<streetAddressLine>`
	`</streetAddressLine>`
	`<city>Seattle</city>`
	`<state>WA</state>`
	`<postalCode>98101</postalCode>`
	`<country>US</country>`
	`<useablePeriod xsi:type=”IVL_TS”>`

	<low value="20050623" /> </useablePeriod> </addr>
Resolution—Instructions for visual inspection	If error message indicates a mismatch for the null flavor on this element, visual inspection should be performed and the error can be ignored if any null flavor is provided OR if the <high> element is missing completely from the file.
Issue 12	**Payer type value set**
Description	For **Test Data Conformance Events**, a mismatch error will be produced if the EHR vendor submits a different vocabulary than the one specified in the test data. The specification conformance is SHOULD on which value set(s) are to be used, so other valid value sets that accurately represent the "payer type" concept will be allowed.
Example	Visual inspection of the file shows a different payer type code system and code, but should be considered valid since it accurately represents the payer type concept: <templateId root="2.16.840.1.113883.10.20.22.4.61" extension="2014-06-09" /> <id root="Group Authority" extension="Group number" /> <code code="HM" codeSystem="2.16.840.1.113883.3.88.12.3221.5.2" displayName="Health Maintenance Organization (HMO)"/>
Resolution—Instructions for visual inspection	If an error message for mismatch, invalid value, or invalid code system is produced for payer type, visual inspection must be performed to determine whether the code provided has equivalent meaning to the one in the test data.
Issue 13	**Specific Null Flavors required**
Description	For **Test Data Conformance Events**, there are several data elements for which CRV will produce a mismatch error message if a **specific** Null Flavor (e.g., "unknown" or "not applicable") is not provided. We have decided that the tool should be updated to allow for any null flavor to be provided in these instances. The data elements affected are: Patient Birth Place State; Patient Birth Place Country; Patient Marital Status; Patient Race; Patient Ethnicity; Author Address Useable Period Low and High; Plan of Treatment

	Section, Planned Encounter, performer/id (NPI); Plan of Treatment Section, Planned Medication Activity, Medication Information, code; Plan of Treatment Section, Planned Procedure, code; Procedures Section, procedure code; Radiation Oncology Section, various; Social History Section, Employment History Organizer; Vital Sign Observation, code; Cancer diagnosis observation, value/qualifier (Grade).
Example	Test results show: Actual Result: "UNK" Expected Result(s): "NI" Location: Node Expression: /ClinicalDocument/recordTarget/patientRole[1]/patient/birthplace/place/addr/state/@nullFlavor Visual inspection of the file shows a valid alternative null flavor used for the data element: <birthplace> <place> <addr> <state nullFlavor="UNK"/> <country nullFlavor="NI"/> </addr> </place> </birthplace>
Resolution—Instructions for visual inspection	If error message indicates a mismatch for the null flavor on any of the elements listed in the description above, visual inspection must be performed to verify that **any** valid null flavor is provided.
Issue 14	**effectiveTime requirement with Time included**
Description	For **Test Data Conformance Events**, Test Cases 1a/b only, there is instances of a specific time (rather than just date) required that could cause CRV to produce errors if the EHR system is in a different time zone. Basing any test on a specific time without considering offset shifts could be a problem (shifting the offset changes the numbers recorded but doesn't change the point in time). This time specification is also used in the xPaths of some of the other validation tests, so it could cause mismatch errors for

	other elements in this entry as well.
Example	Test results show: Actual Result: “none” Expected Result(s): “gemcitabine 38 MG/ML injectable solution” Location: Node Expression: /ClinicalDocument/component/structuredBody/component/section[templateId[@root=’2.16.840.1.113883.10.13.13’ and @extension=’2014-08-8’]]/entry[substanceAdministration[consumable[manufacturedProduct[manufacturedMaterial[code[@code=’1148919’]]]]][effectiveTime[low[starts-with(@value,’201410250800’)]]]]/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/code/@displayName Visual inspection of the file shows a valid content for this entry: <consumable> <manufacturedProduct classCode=”MANU”> <!-- ** Medication information ** → <templateId root=”2.16.840.1.113883.10.20.22.4.23” extension=”2014-06-09”/> <id root=”2a620155-9d11-439e-92b3-5d9815ff4ee8”/> <manufacturedMaterial> <code code=”1148919” displayName=”gemcitabine 38 MG/ML injectable solution” codeSystem=”2.16.840.1.113883.6.88” codeSystemName=”RxNorm”> <originalText> <reference value=”#MedicationName_3”/> </originalText> code> </manufacturedMaterial> </manufacturedProduct> </consumable>
Resolution—Instructions for visual	If error message indicates a mismatch on the Medication Activity Start Date (effectiveTime) or any other Medication Activity elements, visual inspection must be performed to determine if the content is valid according to the test data.

inspection	
Issue 15	**Specific order required for Patient's Race**
Description	For **Test Data Conformance Events**, CRV expects the values for Black/African American to be in raceCode and the values for White to be in sdtc:raceCode. Either order should be acceptable, because some EHR systems record a list of races with no precedence applied to any particular value, thus the sequence of items are not guaranteed.
Example	Mismatch 2106-3 • 2054-5 Mismatch 2054-5 • 2106-3 Visual inspection of the file shows a valid content for both race codes, but in the reverse order of what is in the test data: <raceCode code="2106-3" displayName="White" codeSystem="2.16.840.1.113883.6.238" codeSystemName="Race & Ethnicity - CDC"/> <sdtc:raceCode code="2054-5" displayName="Black or African American" codeSystem="2.16.840.1.113883.6.238" codeSystemName="Race & Ethnicity - CDC"/>
Resolution—Instructions for visual inspection	If error message indicates a mismatch on patient's race for either raceCode or sdtc:raceCode, visual inspection must be performed to determine if both (all) races provided are valid according to the test data, regardless of order.
Issue 16	**Required LOINC Code for Vital Signs Weight observation**

Description	For **IG Conformance Events**, CRV produces an error message stating that the LOINC Code of "29463-7 [weight]" is an invalid value. The IG conformance statement is "**SHALL** contain exactly one [1..1] **code**, which **SHOULD** be selected from ValueSet **Vital Sign Result** urn:oid:2.16.840.1.113883.3.88.12.80.62 **DYNAMIC** (CONF:1098-7301)." Therefore, we believe CRV should actually not test valid values in this Value Set, since the Value Set is not a SHALL requirement. For **Test Data Conformance Events,** a mismatch error on both the code and display name will be produced if the EHR vendor submits a LOINC Code of "29463-7 [weight]" rather than the code/display name specified in the test data "3141-9 [weight measured]". The LOINC code is necessary to indicate what type of vital sign value is being reported, but we believe that both of these are acceptable codes to indicate that the observation provided is the patient's weight. Therefore we think the test data and tool should be updated to allow either LOINC code to be used.
Example	
Resolution—Instructions for visual inspection	If error message indicates an invalid value or a mismatch on Vital Sign Result Weight code or display name, visual inspection must be performed to determine if the other valid LOINC code/display name of "29463-7" and "Weight" was provided.
Issue 17	Closed section template, open entry template

Description	For **IG Conformance Events**, CRV produces an error message stating 'urn:hl7ii:2.16.840.1.113883.10.13.21:2014-08-08' is a closed template, only defined templates are allowed.”
Example	

Resolution— Instructions for visual inspection	If this error message is seen, visual inspection must be performed to confirm that only the 2 highlighted templates are provided at the **Entry** level. All templates below this level should be considered valid.
	
	`<section>`
	`  <templateId root="2.16.840.1.113883.10.20.22.2.5" extension="2014-06-09"/>`
	`  <templateId root="2.16.840.1.113883.10.20.22.2.5.1" extension="2014-06-09"/>`
	`  <templateId root="2.16.840.1.113883.10.13.21" extension="2014-08-08"/>`
	`  <code code="11450-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="PROBLEM LIST"/>`
	`  <title>PROBLEMS</title>`
	`  <text>Lentigo maligna on left upper arm; malignant melanoma on back of neck</text>`
	`  <entry>`
	`  <act classCode="ACT" moodCode="EVN">`
	`  <templateId root="2.16.840.1.113883.10.20.22.4.3" extension="2014-06-09"/>`
	`  <templateId root="2.16.840.1.113883.10.13.22" extension="2014-08-08"/>`
	
	Assertion ID: a-1126-4278-CL