RECIST

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RECIST: Round 5

RECISTv1.1 Module Definition

The Response Evaluation Criteria in Solid Tumors (RECIST) CRF module is used to document the questions collected when assessing the change in tumor burden as part of the clinical evaluation of cancer therapies using the RECIST guidelines. This working group utilized a proposed set of questions and data elements that were the result of a joint National Cancer Institute – Clinical Data Interchange Standards Consortium (NCI-CDISC) standardization effort that completed just prior to the initiation of the Round 5 working group activities.

This module is constrained to content in the RECISTv1.1 guidelines, and is not inclusive of the earlier RECISTv1.0 guideline or extensions of the standard in guidelines by other organizations such as the World Health Organization (WHO) and the CDISC. There is one exception, the inclusion of a single CDISC question which is conditional when an organization may be reporting their RECIST data based on the CDISC Study Data Tabulation Module (SDTM) format.

- RECIST Module CDEs 05-01-2015
- RECIST CSI Compare 05-01-2015
- RECIST CRF Specification 09-30-2013
- RECIST v1.1 Guideline (please contact Christina Warmington (christina.warmington@nih.gov) for a 508 complaint version

The RECISTv1.1 CRF module variables, or questions, have been divided into 4 groupings as viewed by researchers and statisticians:

1. Imaging Event – describes administrative data collected as part of an imaging procedure used to examine a tumor based on the RECISTv1.1 guidelines. At a minimum the method of assessment and date of the imaging are required, with additional questions like study timepoint and lesion measurement date being optional. To support reporting to the FDA via the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) system, the tumor identification method is provided for that use case only.
2. Lesion - describes characteristics of the lesion such as whether it is measurable or non-measurable, the type of lesion, and its size as physically measured. The lesion is also identified as a target or non-target. For post baseline timepoints, new lesion may be identified. All lesions are defined by their location and assigned a unique identifier to be used in follow up imaging studies. T he presences or absence of lymph nodes may also be tracked depending on the study requirements. NOTE: The lesion measurement question is unique in that it was partitioned differently based on its use. A measurement is conditional if a protocol includes the possibility of collecting target lesion data; optional for non-target lesions.

3. Imaging Cycle - describes the observations following the initial or baseline assessment. The questions collect information on target and non-target lesion with regard to their response to treatment using the response criteria defined in the RECISTv1.1 guideline. The questions collect information on the overall tumor burden and response, as well as lesion response, at a specific timepoint. In a number of the CRFs reviewed, an optional comment field was included to capture textual information beyond the specific response values for each target and non-target lesion.
4. Computed - describes summary variables which are computed based on information and assessment of timepoint results. There was some discussion as to whether these needed to be included as in some instances the values were calculated based on the data collected and not recorded on a CRF. Since these values were included in a results table as part of the RECISTv1.1 guideline, it was decided to include them in the module for completeness.

Downloads

RECIST v1.1 NCI CRF Standards created on October 30, 2018

- RECIST v1.1 NCI CRF Standards created in Excel

iRECIST NCI Standards created on October 30, 2018

- iRECIST NCI CRF Standards created in Excel

irRECIST NCI Standards created on October 30, 2018

- irRECIST NCI CRF Standards created in Excel

irRC NCI Standards created on October 30, 2018

- irRC NCI CRF Standards created in Excel

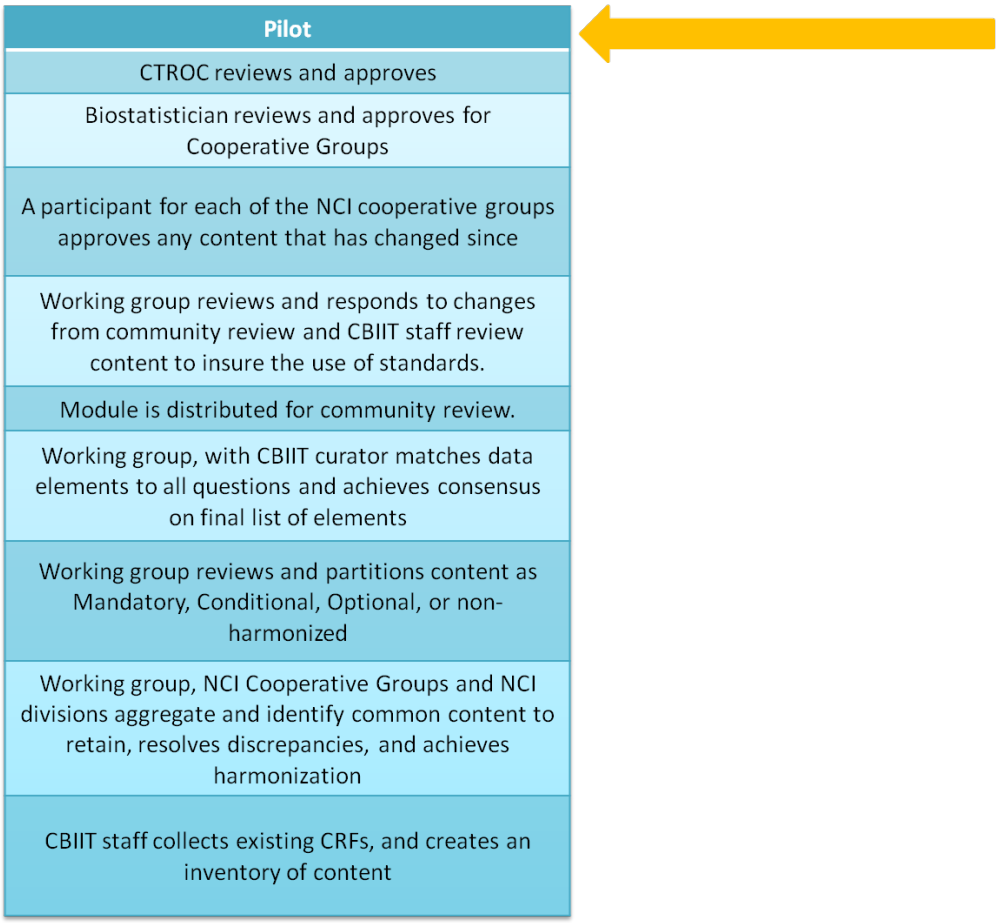
RECIST NCI CRF Standards created on June 11th, 2018

- Until the latest release of the NCI CRF Standards has been posted to the Wiki, please send a request for a copy of the module to caDSR.RA@mail.nih.gov.

RECISTv1.1 NCI CRF Standards created on December 9th, 2013

- RECISTv1.1 NCI CRF Standards created in Excel

Status



Metrics

CRF Stars: Working Group Membership

** Represents working group leads*

No.	First Name	Last Name	Affiliation
1	Brian	Campbell	CTEP
2	Joe	Chen	
3	Janice	Chilli	SAIC
4	Mary	Cooper	SAIC
5	Jean	Cormack	ACRIN
6	Neesha	Desai	Essex Management
7	Kristen	Engel	GOG Statistical and Data Center
8	Dena	Flamini	ACRIN
9	Kerry	Higgins	ECOG
10	David	Hillman	Mayo
11	Eleanor	Leung-Hollins	CALGB/Alliance Statistics and Data Center (Duke)
12	Pat	Mongkolwat	Northwestern University
13	Elizabeth	Ness	CCR
14	Susan	Panonni	City of Hope
15	Rebecca	Paulus	RTOG
16	Dianne	Reeves	NIH

17	Frank	Spina	Essex Management
18	Tina	Taylor	ACRIN
19	Mary	Vienneau	ECOG
20	Christina	Warmington	Essex Management