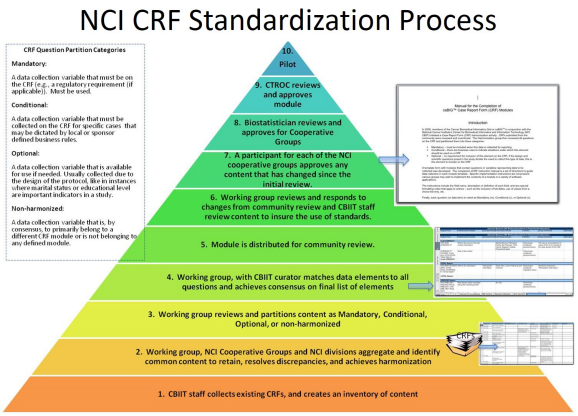
CRF Harmonization and Standardization

Harmonization/Standardization Process

The CRF Harmonization and Standardization initiative has undertaken the task of harmonizing and standardizing case report forms for cancer clinical trials by first dissecting the CRF into modules and tackling smaller sections of the CRF 5 areas at a time. The general process includes collecting an inventory of forms related to the information generally captured in that module, for example, On-Study Forms are collected to gather Agent information. The group then goes through all the forms and identifies those fields that are relevant to that module (area), partitions the fields as either Mandatory, Conditional or Optional, and then identifies appropriate Common Data Elements (CDEs) or creates new CDEs to accurately capture the metadata for the harmonized fields. Once the group identifies all the fields and CDEs to be collected in that module, these are sent to the Clinical Trials Community for review and comment, the comments are addressed, and the final list of fields are presented to the Clinical & Translational Research Operating Committee (CTROC) for final approval. After CTROC approval, the CDEs are brought to the Vocabularies & Common Data Elements (VCDE) Workspace for review as caBIG Standards. Once the CDEs are made standard, the module is officially available for use on cancer clinical trials.

In October of 2009, the need for an Expanded Committee Review was identified. A change in the community review process was instituted in the Spring of 2010. The revised process is as follows:



Status of CRF Activities

The first Round of the CRF Harmonization and Standardization Project addressed a single module, Demography. This work began in June 2007, and the module has gone through the the entire process and has been approved by CTROC, and the CDEs have been made standard. The module is undergoing implementation/deployment for use in cancer clinical trials.

Round 2 included Adverse Events, Baseline Assessment, Participant Identification, Registration & Enrollment, and Protocol Deviations. Seven modules were completed from those 5 areas, which are Adverse Events, Medical History, Physical Exam, Participant Identification, Registration, Enrollment, and Protocol Deviations. These seven modules have been vetted by the Community and approved by CTROC. In the spring of 2010 the seven modules entered expanded community review. Community review completed three rounds of evaluation through 2010 and in March of 2011 was forwarded to NCI leadership for finalization.

Round 3 modules included Agents (looking at both standardizing vocabulary and the variables to be collected), End of Form, Footer, Header, Laboratory Tests/Results, Outcome Measures, and Staging /Extent of Disease. These modules were reviewed by the Community, presented to CTROC, and finalized in April of 2011.

The Round 4 modules included Consent, Diagnosis (Administrative), Diagnosis (Intervention), Eligibility, Equipment, Image Quality, Off Study, Off Treatment, PET Scan, PET Equipment QC, PET Imaging Agent, PET Patient Prep, Radiation Therapy, Screening, Surgery and Vital Signs were reviewed by and approved by NCI representatives in May 2013 and all modifications were completed and released in September.

Round 5 modules included CT Image Acquisition, CT Image Agent, Diagnosis Gross Pathology, Diagnosis Metastasis, Diagnosis Microscopic Pathology, Diagnosis, Survival/Follow-up, Image Administration, Lost to Follow-up, Progression, Response and RECIST. A final review of the Round 5 content was completed in early 2018. With the exception of the RECIST form, all other forms were finalized and released in June 2018. The RECIST working group has additional comments regarding this content and will make recommendations for updates.

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Module Status Table

*** Modules are alphabetized*

*** Content that is marked Final is ready for use. Content that is marked Under Review is candidate status and is available to use but please note that this content could change in the final release.*

CRF Modules	Round #	Status	Status Description
Adverse Events	2	Final	Total of 29 CDEs built in three CRF standard modules – CTCAE v3.0 reporting requirements, CTCAE v4.0 reporting requirements and CTCAE v5.0 reporting requirements. AE modules include Serious Adverse Event (SAE) CDEs.
Base Interventions	3	Not Needed - Removed	The intent of the Base Interventions module was to group all commonly-used CDEs need for primarily intervention studies. In one module CDEs for start date, stop date, dose, Unit of measure, dose, etc., were grouped. Reviewers did not feel this was the best way to categorize the elements. So the pertinent elements in the Base Interventions module were instead added to each intervention/agent module. The Base Interventions module is retired, and not part of the final Standard CRF set.
Concomitant Medication	3	Final	Total of 13 CDEs built in one CRF standard module.
Consent	4	Final	Total of 6 CDEs built in one CRF standard module.
CT Image Acquisition	5	Final	Total of 19 CDEs built in one CRF standard module.
CT Imaging Agent	5	Final	Total of 19 CDEs built in one CRF standard module.
Demography	1	Final	Total of 15 CDEs built in one CRF standard module.
Diagnosis (Administrative)	4	Final	Total of 7 CDEs built in one CRF standard module.
Diagnosis (Intervention)	4	Final	Total of 6 CDEs built in one CRF standard module.
Diagnosis	5	Final	Total of 14 CDEs built in one CRF standard module.
Diagnosis Gross Pathology	5	Final	Total of 19 CDEs built in one CRF standard module.
Diagnosis Metastasis	5	Final	Total of 4 CDEs built in one CRF standard module.
Diagnosis Microscopic Pathology	5	Final	Total of 19 CDEs built in one CRF standard module.
Drug Compliance	3	Not Needed - Removed	Review demonstrated that 5 of the 8 CDEs in this module are repeated in the Study Administration CRF module. So the remaining 3 CDEs were merged with the Study Administration CRF standard module, and the Drug Compliance module removed as a separate CRF module.
Eligibility	4	Final	Total of 9 CDEs built in one CRF standard module.
End of Form	3	Final	Total of 8 CDEs built in one CRF standard module.
Enrollment	2	Final	Total of 5 CDEs built in one CRF standard module.
Equipment	4	Final	Total of 10 CDEs built in one CRF standard module.
Follow-Up	5	Not Needed - Combined with Survival	
Follow-Up /Survival	5	Final	Total of 18 CDEs built in one CRF standard module.
Footer	3	Final	Total of 5 CDEs built in one CRF standard module.
Header	3	Final	Total of 11 CDEs built in one CRF standard module.

Image Administration	5	Final	Total of 17 CDEs built in one CRF standard module.
Image Quality	4	Final	Total of 7 CDEs built in one CRF standard module.
Laboratory Tests and Results	3	Final	Total of 14 CDEs built in one CRF standard module.
Lost to Follow-up	5	Final	Total of 7 CDEs built in one CRF standard module.
Medical History	2	Final	Total of 7 CDEs built in one CRF standard module.
Outcome Measures	3	Not Needed - Removed	The outcome module was created in round 2. At the time of delivery the limitations in the content were recognized, and we had a plan to expand the content at some point and also look mainly at response results in nonsolid tumors, like the leukemias and lymphomas. So round 5 was envisioned as expanding two main areas in round 2 – 1) responses had to be expanded beyond the solid tumors, and 2) survival had to be expanded. Therefore, Outcomes in round 2 have now been replaced by content in round 5.
Off Study	4	Final	Total of 3 CDEs built in one CRF standard module.
Off Treatment	4	Final	Total of 3 CDEs built in one CRF standard module.
Participant Identification	2	Final	Total of 11 CDEs built in one CRF standard module.
PET Emissions Scan	4	Final	Total of 12 CDEs built in one CRF standard module.
PET Equipment QC Assessment	4	Final	Total of 2 CDEs built in one CRF standard module.
PET Imaging Agent	4	Final	Total of 22 CDEs built in one CRF standard module.
PET Patient Prep	4	Final	Total of 7 CDEs built in one CRF standard module.
Progression	5	Final	Total of 8 CDEs built in one CRF standard module.
Physical Examination	2	Final	Total of 6 CDEs built in one CRF standard module.
Prior/Post Therapy Agents	3	Final	Total of 17 CDEs built in one CRF standard module.
Protocol Deviations	2	Final	Total of 8 CDEs built in one CRF standard module. The use of a Protocol Deviation module is NOT recommended. Deviation data should be recorded in the appropriate form (agent administration, AE, etc.). However, if a sponsor mandates the use of an additional Protocol Deviation module, the identified variables should be used.
Radiation Therapy	4	Final	Total of 31 CDEs built in one CRF standard module.
RECIST	5	Under Review	
Registration	2	Final	Total of 19 CDEs built in one CRF standard module.
Response	5	Final	Total of 31 CDEs built in one CRF standard module.
Screening	4	Final	Total of 4 CDEs built in one CRF standard module.
Staging /Extent of Disease	3	Final	Total of 28 separate CRF modules for major disease groups, including Leukemia, Lymphoma, and Solid tumors. There is no generic stage CRF module content. All CRF modules begin with 'Staging' and then have the specific diagnostic group. CDEs in these modules are largely but not exclusively based on AJCC edition 7.0 collaborative staging criteria.
Study Agent Administration	3	Final	Total of 21 CDEs built in one CRF standard module.

Surgery	4	Final	Total of 31 CDEs built in one CRF standard module.
Survival	5	Not Needed - Combined with Follow Up	
Vital Signs	4	Final	Total of 24 CDEs built in one CRF standard module.

Metrics

The CRF Harmonization & Standardization project was initiated to provide a harmonized and standardized set of variables to be collected for oncology clinical trials that could be implemented to facilitate data entry, and study aggregation, comparison and analysis. The CRF collection process for Rounds 1-3 only collected Case Report Forms specific for that module. However, prior to Round 4, the Workgroup Leads recommended collecting CRFs for all areas and doing a single CRF inventory for all remaining modules, current and future Rounds

CRF Project Wiki Child Pages

- CDISC Aligned NCI Standard Case Report Forms
- CRF Project Metrics
- CRF Round 4 Wiki