

# Study Agent Administration

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## Study Agent Administration NCI CRF Standards: Round 3

An agent is a distinct substance or ingredient (as defined by FDA's prEN ISO/CD 11238) or compound/product/mixture thereof, contained in drugs, biologics, foods, and devices that act to produce a specific effect (commonly health related). This can include radiopharmaceutical, nutritional, complimentary and alternative medicine (CAM), molecular components of devices (that is, silicon in implants) and nano-technologic agents but does not include whole devices, or procedures (that is, surgeries). Individual agents included in a treatment regimen or therapy (that is, Taxotere, Adriamycin and Cytoxan) are included in this definition, however, whole regimen names or other broad classification of therapies (that is, "CHOP", "chemotherapy", etc), are not.

## Downloads

Study Agent Administration NCI CRF Standards created on October 19th, 2018

- [Study Agent Administration NCI CRF Standards in Excel](#)

Study Agent Administration NCI CRF Standards created on June 21st, 2016

- [Study Agent Administration NCI CRF Standards in Excel](#)

Study Agent Administration NCI CRF Standards created on September 5th, 2014

- [Study Agent Administration NCI CRF Standards in Excel](#)

## Changes made from September 5th, 2014 to October 19th, 2018

Module	CDE	CDE Public ID	Change
Study Agent Administration	Frequency	2003322	Added PV - every month for 3 months
Study Agent Administration	Frequency	2003322	CDE 2003322 - Added additional value
	Therapy Type	64208	1. q6wk
	Units of Measure	3028750	CDE 64208 - Added additional values 1. Radiopharmaceutical Therapy 2. Systemic Therapy 3. Targeted Therapy 4. Vitamin CDE 3028750 - Added additional values 1. 10 <sup>6</sup> {TCID50} 2. 10 <sup>7</sup> {TCID50} 3. 10 <sup>8</sup> {TCID50}

## Status

Pilot
CTROC reviews and approves
Biostatistician reviews and approves for Cooperative Groups
A participant for each of the NCI cooperative groups approves any content that has changed since
Working group reviews and responds to changes from community review and CBIIT staff review content to insure the use of standards.
Module is distributed for community review.
Working group, with CBIIT curator matches data elements to all questions and achieves consensus on final list of elements
Working group reviews and partitions content as Mandatory, Conditional, Optional, or non-harmonized
Working group, NCI Cooperative Groups and NCI divisions aggregate and identify common content to retain, resolves discrepancies, and achieves harmonization
CBIIT staff collects existing CRFs, and creates an inventory of content



## Metrics

### CRF Stars: Working Group Membership

*\* Represents Working Group Leads*

No.	First Name	Last Name	Affiliation
1	Bill	Hess	FDA
2	Chris	Barkley	St. Jude
3	Wendy	Bergantz	RTOG
4	Amy	Biggi	Westat
5	Yancey	Bodenstein	NCI NCCAM
6	Dan	Boring	NCI DCP
7	Linda	Bressler	CALGB
8	Larry	Callahan	FDA
9	Stephen	Dorian	RTOG
10	Nancy	Emenaker	NCI DCP
11	Rhonda	Facile	CDISC
12	Lara	Fournier (L)	OHSU
13	Deb	Grant	RTOG
14	Pamela	Harvey	RTOG-ACRIN

15	Beth	Hasenauer	COG
16	David	Hillman	Mayo - NCCTG
17	Rebecca	Hills	University of Washington
18	Rodney	Howells	NCI CTEP
19	Lisa	Krueger	NIH
20	Angela	Kuras	Gynecologic Oncology Group (GOG)
21	Betty	Lee	SAIC
22	Eric	Lickerman	Daedalus Software
23	Brenda	Maeske	SAIC
24	Bev	Meadows	NCI DCP
25	Riki	Ohira	Booz Allen Hamilton
26	Betty	O'Meara	RTOG
27	Susan	Pannoni	City of Hope
28	Diane	Paul	Patient Advocate
29	John	Postiglione	CALGB
30	Vikram	Purohit	Booz Allen Hamilton
31	George	Redmond	NCI CTEP
32	Dianne	Reeves	NCI CBIIT
33	Anne	Ryan	NCI DCP
34	Harold	Seifried	NCI DCP
35	Azita	Sharif	Daedalus Software
36	Frank	Switzer	FDA
37	Tina	Taylor	ACRIN
38	Anne	Tompkins (L)	NCI DCP
39	Joseph	Uhimov	NCI CBIIT - TerpSys
40	Teresa	Watkins	FDA
41	Larry	Wright	NCI CBIIT
42	Dan	Xi	NCI OCCAM