NATIONAL CANCER INSTITUTE

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NRDS Content Working Group
Tuesday December 8, 2015
Meeting Minutes

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Agenda Topics

Meeting Recap/Holiday Schedules

- Neesha provided an overview of the recap notes from the last meeting
- The Dec 22nd and Dec 29th meetings will be cancelled for the holidays; we will resume on Jan 5th

Review CDUS Reporting Content

Patient Form

- PV/VM Comments was added to highlight the difference between the CDUS (CTEP) before and OPEN.
- CDE ID 2746541 – Enrollment date
  - Brenda: We want to understand which data and how you are collecting the data. If the data is derived, where is it derived from?
    - Ginger: Most of the groups are derived from OPEN. We use step 0, step 1, etc. to denote different levels of registration.
    - Tina: We are hoping to obtain a list of derived elements to compare where these all come from.
  - Judi: Do you have the definition from the CDUS manual?
    - Shauna: Yes, but we seem to be interpreting it differently. It would be nice to note what is expected to ensure we all do it the same.
    - Ginger: I am trying to capture that information and I will get back with you
  - Thalia: The registration date may have been collecting the date from the system for the abbreviated studies.
    - ****ACTION** Brenda: We need to look more into when it is derived (possibly step 1).
    - Theradex: We do not start with step 0, we start with 1.
    - Vanita: We also have 1, 2, and 3
- CDE ID 2192796 – Lead Institution
  - Ginger: This is derived from OPEN
  - Shauna: Are you talking about the registering institution or the current institution?
    - Brenda: It notes the lead institution
    - Ginger: I believe this is produced by OPEN
- CDE ID 3314240 – Enrolling Site CTEP ID
  - Brenda: They are likely using the same set of codes as Lead Instition
- CDE ID 2453595 – Is the patient currently receiving treatment on study?
  - Shauna: We would derive that; we derive it from the date off treatment but other may do it differently
  - Peter: Derived, we would use it when the patient goes on treatment.
  - Tina: Derive
  - Tina: CDUS is using numeric codes, are you ok with mapping to this or should we use text
    - Shauna: if we are not going to collect it directly from RAVE, I imagine it will happen through the Theradex mapping.

- Tina: That is a valid point.
- To be consistent, it would be good to have Yes/No
  - Shauna: Once the decision is made on how to derive this, we would need to have it for all to use at the same time.
    - Peter: We may want to discuss the mapping at a later conversation

- CDE ID 2453219 – Off treatment reason
  - Shaula: This is not a derived field
  - Brenda: The standard is a coded list currently
  - Thalia: There will be mapping for the "other" category, depending on the value.
  - Brenda: Should we suggest to remove the codes and use the PVs?
    - Peter: The value meaning seem a bit long
    - Judi: I think we should keep the codes
    - Tina: It would be cleaner
    - Peter: I am good with the codes

- CDE ID 65167 – Date of last treatment
  - Cathy: We capture it in Rave

- CDE ID 2453215 – Off study reason
  - This is a CDE Standard. Should we keep the codes?
  - Judi, Shauna: We do not collect this; it is a derived field (outside of Rave).
  - Peter: Theradex collects this right in Rave

- CDE ID 2003605 – Off study date
  - Judi, Shauna: We do not collect it, it is derived
  - Peter: We collect it.

- CDE ID 1925 – Participant subgroup code/Subgroup code
  - Shauna: We have a field in Rave but it is derived and pushed into that field (like being collected).
  - Judi: We derive it and do not push it to Rave but could; OPEN is now pushing all of this into Rave. So we may not need to derive it for newer studies.
  - SWOG does the same
  - Peter: We collect it in Rave
  - This can be derived from other databases (Open pushes into Rave)

- CDE ID 1235 – Is the participant eligible for inclusion on this study/Ineligibility status
  - Judi: We code it internally and enter that code in Rave. In the beginning, everyone is assumed to be eligible unless proven otherwise (i.e. all yes until changed to no).
  - Angela: We do not usually put this into Rave
  - Shauna: We do get the indicator, but you would have to deem if they are eligible or not – through a backend derivation.

- CDE ID 2003315 – Performance status (Zubrod)/Baseline performance status
  - Brenda: Some of the PV meanings may be harder to capture in Rave (<> signs). Do you collect it in Rave?
  - Angela: We do
  - Judi: We call it the ECOG performance status, but yes, we collect it every cycle
  - ****Action** New Value Domain Required.

- CDE ID 62676 – Total number of prior chemotherapy regimens
  - Judi: We probably enter this directly
  - Angela: SWOG collects it directly
  - Shauna: I think we derive it
  - Peter: I believe we derive it outside of Rave but it is something we can easily put in

- CDE ID 2004425 – MedDRA code/Patient disease code
  - Shauna: This would be directly from Rave
  - Angela, Judi: We have this in Open
- CDE ID 2453597 – Disease evaluable response code/Response evaluation status
  - Brenda: This is coded
  - Shauna, Angela: Derived
  - Peter: We collect it in Rave
  - Judi: This is mapped for us
- CDE ID 2453199 – Baseline abnormalities flag
  - Shauna: We would derive it
  - Peter: We derive it
  - Angela: We do collect it directly from Rave
- CDE ID 2008450 – MedDRA code/Prior therapy type (MedDRA code)
  - Peter: We collect directly from Rave
  - Judi: We have yes/no for each type of therapy but I do not think we have the MedDRA code.
  - Angela: We hard code these in CDISC and then use the PVs in Rave / it is a hybrid of collection collect the PV from Rave and derive the code.
- CDE ID Current cycle number/Course (Cycle) - Current cycle number/Course (Cycle)
  - Brenda: Do you need to look at the "Current" cycle?
  - Tina: The other CDEs just have cycle/course/visit number but this one specifies current
    - Angela: I think it would depend on the context, a form that is summarizing something and you need the most recent cycle, this could be important.
    - Judi: I think this will be important; we will be reporting cumulative information on a study and this would identify where the patient is in their treatment and course.
  - Brenda: This is not consistent with the AE form
    - Shauna: It is a derived field from cycle information
  - Tina: What about the alternate text?
    - Peter: This is ok
- CDE ID 2453200 – Adverse event occurrence code/Patients experiencing an adverse event during the current course of therapy
  - Shauna: We derive it
  - Angela: I am accounting this to a question of reporting other AEs from the cycle, but maybe that is different from what this is?
    - Shauna: I think this is what you will report
    - Cathy: I am unsure how this question maps to our system
    - Angela: We do not collect solicited AEs
  - Judi: We do, I think there is a trigger question for any AEs prior to this cycle and a new form would role out.
    - Shauna: We would derive this information. IF they didn't enter the form at all, we would say too early, if they had all 0s we would say no, and if there was any other response we would answer yes.
    - Angela: I don't know when we would map to too early; if we have a cycle 1 AE form submitted, they would have already answered yes or no. If we are required to report even when there is no data, that would be when we would have too early maybe.
    - Peter: We probably do derive it because we have a yes/no question for have an AE occurred. If the course has not been completed and the question has not been

> answered, I imagine it would be too early. I think we derive it outside of Rave based on the date inside of Rave
>
> - Cathy: I agree
- **Action** Tina: The definition needs to be changed because there are 3 values

- CDE ID 2357 – Agent SC/GPI identifier number/Investigation agent administered
  - Peter: We currently collect an 8 digit code; I believe this will happen in the Theradex mapping utility
  - Judi: We have a mapping code and we do a derivation outside of Rave; it is done at the protocol level, not the patient level in Rave

Next Steps

- Priority 1 – CDUS Dataset (Complete)
- Priority 2 – 3 OPEN Forms
- Next meeting is scheduled for Dec 15 @ 4:00 pm (ET)

Attendance:

Name	Affiliation
Shauna Hillman	Alliance
Thalia Beeles	COG
Wendy Wong	COG
Ginger Riley	CTSU
Judi Manola	ECOG
Christina Warmington	Essex Management
Joe Martucci	Essex Management
Neesha Desai	Essex Management
Andrea Denicoff	NCI
Vanita Patel	NRG
Brenda Maeske	SAIC
Tina Taylor	SAIC
Cathy Rankin	SWOG
Angela Smith	SWOG
Peter Clark	Theradex