

Examples of the Changes to the CCSG Data Guide and How to Implement Them at Your Cancer Center

Moderator: Dr. Shannon Silkensen

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Coordinator: ...and thank you for standing by. All participants will be in a listen-only mode for the duration of today's conference.

This conference is being recorded. If anyone has any objections you may disconnect at this time.

Dr. Silkensen, you may begin.

Dr. Shannon Silkensen: Hi all. My name is Shannon Silkensen and I'm a Program Officer at the NCI's Office of Cancer Centers.

We're excited that you're joining us today for a discussion about changes to the CCSG Data Guide and how to implement them at your cancer center.

Today we are joined by three members of the NCI's Office of Cancer Centers. Dr. Henry Ciolino, a Program Officer, Chi Dinh, our IT Specialist, and myself, Dr. Shannon Silkensen, a Program Officer.

However, before we begin I'd like to cover a few housekeeping details with you.

To see the slides you'll have to have Live Meeting installed on your computer. This works best if you close all the other applications.

You will hear the audio portion of today's presentation by the telephone number listed in the webinar invitation. Unfortunately you cannot hear it through your computer.

To ask a question, please use the question box at the top of your screen. You may type a question in at any time in the presentation and we'll read them aloud during the Q&A portion of this presentation.

You can open the Q&A box by clicking on the Q&A option at the top navigation panel of your screen. I like it best when you drag it over to the right-hand portion so you can see both the slide and the Q&A box.

So without any other further fanfare or housekeeping details, I'd like to turn the presentation over to Henry, who's going to introduce the data tables and talk a bit about their purpose and who they serve.

Dr. Henry Ciolino:

Thank you, Shannon. First thing we would like to do is to thank everyone out in the cancer centers community who has helped us by giving us your feedback and suggestions and answering questions. We could not have produced as good a product without your help.

The first thing to note is that there are no more summaries; there are data tables. NIH felt that a summary should contain some sort of narrative, and these contain only data so we have renamed them.

The purpose of the data tables in competing years is to ensure that your peer reviewers have the exact same information in the exact same format from every cancer center that they're going to be reviewing that year.

In noncompeting years, the purpose of the data tables is to help the Office of Cancer Centers to monitor scientific progress. So, it's an important part of the annual progress report.

And in addition, it helps us produce reports. We get inquiries about cancer center activities from the media, from congressional offices, and from senior programmatic leadership at NCI. The data you provide is used in our responses.

We'd like to stress the need for accuracy. Because we are producing these reports we want them to be as accurate as possible to properly document cancer center activities, so we ask you to be accurate in your reporting.

And also in our new IT format — which Chi is going to talk about later — we need to use the proper format. We take the information that you submit in Excel or Access files and upload it into the OCC database.

Using improper abbreviations, improper clinical trials designations, even things as trivial as placing a space in a field that should be blank, will prevent us from uploading this data. In the future we're going to ask you to resubmit the data if it is not in the proper format.

So in competing applications, centers will submit Data Tables 1 through 5 in hard copy along with their applications. If your Center is on a paid extension, submit Data Tables 1 through 4. Also submit Data Tables 1 through 4 along with your noncompeting progress reports.

Data Table 1 comes with the hard copy of the progress report, Data Tables 1 through 4 are submitted electronically. And extensions that are not funded, please consult with your Program Director. Technically NIH does not require you to submit these data, but we're going to try to convince you why you should.

The information that we're going to present in today's webinar can be found on the Office of Cancer Centers' website, the URL is listed here. [<http://cancercenters.cancer.gov/index.html>]

We have several tools for you: CCSG Data Guide, Summary of the changes to the Data Guide, and Electronic Data Guide. Data Guide FAQ that's going to be updated periodically as you submit questions. We have revised ICD codes. And of course you can always contact your Program Director.

The new data table formats are implemented as of January 25, 2013, with the applications coming in then. For that first cycle of competing applications, the decision has been made in consultation with the Division of Extramural Activities that Data Tables 3 and 4 will remain in their the old format.

No decision has been made about the May 2013 applicants. We will let you know as soon as a decision is made.

For noncompeting applications, for those of you that were evaluated under the old guidelines, you will be adhering to the new guidelines in the new data table formats.

The implementation for this is going to proceed as follows. For the Fiscal Year 2013 progress reports, we ask you to format to the new data tables as best as you can. Make a good faith effort to do so. By FY14 your progress reports should adhere to the new data table format.

The material we're going to present today is Data Tables 1 through 5. We're not going to cover 1 and 5 since they're so simple and they really haven't changed all that much. But you're welcome to submit questions about them. You can submit questions about Data Tables 2 through 4 as we go through them.

We're not going to entertain questions about the guidelines themselves; I don't think we'll have time to do so. But you're always welcome to contact your Program Director and ask about them.

Shannon?

Dr. Shannon Silkensen: Thanks Henry. That was a really great introduction. I think you set us up nicely for today's webinar.

So Data Table 2A, it really conveys quite a bit of information, specifically it covers six main things.

First off, it shows how many research projects are presented in each of your cancer centers' research programs.

Second, it shows the money. It shows the annual direct and total costs associated with those research projects.

Third, it shows who's paying you. Who's supporting the research at your center? Is it the NCI, ACS, or pharma?

Fourth, it shows the breadth of grant mechanisms that support the research in your programs. It shows whether a research program is predominantly an R01 shop or if it's supported in part by large multi-investigator grants.

Fifth, it shows the beginning and end dates of your funding. This information provides insight into the continuity of funding for the research program.

And lastly, Data Table 2A shows who has the funding in the research program. Do many members have funding or do several members have the majority of funding?

One of the goals of today's webinar is to work towards uniform reporting of data into the data tables. With uniform reporting among centers, reviewers will be able to more accurately judge the financial base of a research program.

Before we get into the examples, let's take a look at the high level of organization of Data Table 2.

So for Data Table 2 you're going to begin with an alphabetized list of the funded research projects at your Center. Then, you're going to break that list into two groups, the peer review group that's shown here in blue, and the non-peer reviewed group shown in pink.

Once you've separated your projects into peer reviewed or non-peer reviewed funding, you're going to further break that apart into either research project or training and career development awards.

At the end of the day you're going to have four alphabetized lists. One for peer reviewed research projects; one for peer review training and

career development awards; one for non-peer reviewed research project; and the fourth for non-peer reviewed training and career development awards.

So let's get into the examples.

Example 1 is the most straightforward and probably even the most common type of grant that you'll enter into Data Table 2.

So, the first several columns in Data Table 2 are really descriptive. Let's take a look.

You have a PI, in this example you have Alfred. The specific funding source is the NCI. You'll include the complete project number, in this case it's 1R01CA059736. And then the project start and end date. This grant begins in June of 2010 and runs through May 30th of 2015.

You'll include the whole project title, *Regulation of Mitochondrial Inheritance in Yeast*. And that's really the descriptive part of the data that's captured in Data Table 2.

Let's get into the budget portion, which is really the last six columns.

In this example you'll include the cancer-relevant annual direct and total project costs. In this example for Alfred it's \$200,000. And 100% of those costs are allocated into a Research Program 4.

So the dollars that you include in the program direct and total costs are equivalent to those of the project direct and total cost.

The Christy example here is similar to the Alfred example. The descriptive data is captured in the first several columns. You see that the PI is Christy. The specific funding source is the ACS. The complete project number is listed here.

This research project began January 1 of 2005 and runs through December 31 of 2010 and the project title is listed here.

The budget is similar. The annual cancer-relevant project direct costs are \$104,000. The corresponding project total costs are listed here. And 100% of Christy's research fits into Research Program 2. This sort of process is the basis for entering data into Data Table 2.

Let's up the complexity a little bit and look at Example #2.

So Example 2 shows how you would account for an individual project that's awarded to a single investigator at your center. But the research is

split between two or more research programs within your institutions. So again, let's look at the first half of this table, which is the descriptive data.

So this is the Dubois example. And for each research program that receives funds, you're going to submit a separate row or entry for them.

The descriptive data remains the same, the PI is Dubois. The specific funding source is the NCI. The complete project number, start and end date remain the same, as well as the project title.

It's really the second half of this data table that shows the differences. List the total cancer-relevant budget (project direct and total costs) only once. I think it's most convenient if you list it in the top line that you're referring to.

And then in this example 60% or \$60,000 of the annual direct costs are coded for Research Program 1, whereas 40% of the costs, or \$40,000 of the direct costs, fit nicely into Research Program 5.

Got it? If you have any questions, please ask us at the end.

Let's move on to the third example.

So the third example really deals with how to account for national trials that are authored by a PI at your center.

Again, we've walked through the descriptive data at the beginning. In this example Persky is a PI at your center. We had a specific funding source as the NCI. The complete project number's start and end date are listed, as well as the project title.

So let's look at the dollars. So the dollars in this example, \$215,000 of the cancer-relevant annual direct costs go to your center, and 100% of them are located in Research Program 5. Therefore the program direct and total costs match the project direct and total cost.

Let's up the complexity a little bit more by taking a look at how you report multi-investigator grants, such as SPOREs that are awarded to your center. These are a little bit trickier.

So in this example (#4) Lee, the PI, has received a SPORE grant in lung cancer. Its annual cancer-relevant direct costs are \$1 million, and they are listed only once across the top.

However, the SPORE grant has several projects and core facilities associated with it. In this example, two research projects and one core is associated with this grant.

So the second line down shows the second research project. In this example project, Lee is the leader. So Lee is the only PI that's listed in the PI column. The specific funding source, complete project number, start and ends dates remain the same. Under the project title, you include the name of the specific project. In this case, 100% of the funds or \$90,000 are allocated to Research Program 2.

The next line down, the Lee grant example shows us that this is an administrative core. So the leader for Core C of this SPORE is Grant. And 100% of this core is coded ZY. All cores are coded ZY, and then 100% of the funds — or \$4000 in this example — goes toward the ZY category.

The final line in this example is the Lee / Sherman example. In this case, again Lee, the PI of the SPORE is listed here. And the project, Project 1 PI is Sherman. A hundred percent of these cancer-relevant funds, or \$120,000, are allocated to Research Program 1.

Again, if you have questions please ask and we'll discuss them at the end.

So the next example, Example 5 is a little bit tricky and this deals with subcontracts.

So you know that these are all subcontracts because there's a pound sign listed in the Specific Funding Source column.

In this example, Donegan is a PI at your Center. And Donegan received a subcontract. The grant went from NHLBI to Dartmouth, and then is subcontracted to your cancer center.

In the Donegan example, \$50,000 of the annual direct costs are cancer relevant. However, only 20%, or \$10,000 of them, are allocated into Research Program 3.

The next example, so Farber and Jones combine both what we talked about in the Donegan example, as well as some elements of a SPORE example.

In the Farber line, the middle line here, the P01 went from NHLBI to Case and then came on to your center.

In this example \$80,000 of the subcontract dollars are cancer-relevant. However, only 40% of them, or \$32,000, fit into Research Program 3.

The final line talks about how you would manage a core. In the same P01 that went from NHLBI to Case Western, and then to your center, Jones is the leader of the Biostat Core. Because it's a core, \$40,000 of the cancer-relevant funds, or 100%, are coded ZY to indicate that this is a core resource.

Again, if you have any questions we'd be happy to take them at the end of Data Table 2 presentation.

So Example 6 shows us how to account for grants that utilize the multiple PI mechanisms.

In this example, both Isaac and News are PIs at your center. Since they're both investigators at your center, they both require an entry into Data Table 2.

So if we look at Isaac, Isaac's grant is from NIAID. Here's the grant number, the start and end data as well as the project title. So of the cancer-relevant costs for this grant, \$480,000 were awarded to Isaac and 100% of these costs fit into Research Program 2.

In the same award the cancer-relevant costs that were allocated to News, were \$320,000. And 100% of these annual direct costs fit into Research Program 3.

Let's alter the complexity of this a little bit and take a look at the Birmann and Glick examples that are shown here for Number 7.

This is the way that you should handle a multi-investigator project grant where not all of the principal investigators are members of your cancer center.

In the Birmann and Glick example, Birmann is a member of your center and Glick is a member of UAB. You know this is a multiple PI grant because there's an ampersand [&] listed in the PI column.

So in this example \$140,000 of the dollars are cancer-relevant. However, only 20% of them fit into Research Program 3.

Again in the Newton and Fish example, this was an R01 that went to both Newton and Fish and \$480,000 cancer-relevant dollars were awarded to Newton and 100% of these costs fit into Research Program 4.

Let's take a look at how to use the non-programmatically aligned code when filling out Data Table 2. There are many, many instances that you'll use in non-programmatically aligned code.

The first instance here is for the regular P30.

So if you look in the first entry, the PI is K. Smith. And this is a P30, Cancer Center Support Grant. 100% of these funds are allocated into the ZY are non-programmatically aligned category.

You also use ZY for supplements to the P30 grant. For example, the next line shows Smith as the PI of a CURE supplement. The next line, to Murphy, shows a Community Health Educator supplement to the P30. 100% of the funding to P30 supplements is cancer-relevant, and they should all be coded as ZY.

Other things that get categorized as ZY include things like contracts for the SEER program.

The Gordon example here shows the SEER program that came to the center, \$400,000 of annual direct costs, and 100% of them are coded for ZY.

So you remember earlier that we talked in Example 4 about a SPORE example. Lee was the PI of the SPORE and Grant was the Director of the Administrative and Patient Advocacy Core.

Since we've already accounted for these costs earlier, the project direct and total cost column are left blank. However, we will include the \$4000 of this core and 100% of these dollars are coded for ZY.

The Birman / Glick example we just spoke about, what you saw before is that although \$140,000 were awarded to Birman, I believe only 20% of them fit within one research program. You can account for the remaining 80% that was non-programmatically aligned by using the ZY category.

The last example that we're going to include is how do you account for accrual-based industry-funded projects?

So in this example, the annual total project and total program costs should be based on the actual or estimated number of patients that are accrued during the reporting period.

In this example the descriptive data is included. The PI is Pope. The specific funding source is Vical. The project number in this case was left blank. There's a start and end date and the project title is listed.

There are \$250,000 in cancer-relevant annual direct costs, and 100% of them fit within Research Program 4.

Once you've entered all of the data into Data Table 2, it rolls up really nicely into Data Table 2B.

Data Table 2B really presents a summary of the total number of projects and their annual direct and total costs and is organized by funding agencies.

So you can look across here and see, for example, the number of NCI peer-reviewed research projects or the number of industry non-peer reviewed research projects. And then, of course, the total of all projects, both in terms of dollars and number of projects that are awarded to your center.

And with that, I'm happy to take any questions.

Dr. Henry Ciolino: Okay Shannon, we have several questions. Could you go back to Example 4?

Dr. Shannon Silkensen: Sure. This is the SPORE example.

Dr. Henry Ciolino: Right.

Dr. Shannon Silkensen: Yes, multi-investigator grant.

Dr. Henry Ciolino: So each project in a SPORE has both a clinical and a basic science leader or a PI.

Dr. Shannon Silkensen: Yes.

Dr. Henry Ciolino: Do you list those two names or you just list the overall PI?

Dr. Shannon Silkensen: So that's a great question, Henry. We accounted for that. If you look at the bottom line here, the Lee / Sherman example. So Lee is the PI of the SPORE, and then Sherman is the example of the leader for Project 1. If Sherman and Smith were co-leaders of Project 1 you could list them both here.

Dr. Henry Ciolino: Okay. You list a scientific core associated with a SPORE under ZY. What if the center feels like the core should be in a particular program?

Dr. Shannon Silkensen: So I can understand that centers may feel that a core is associated with a research program. However, for the purpose of this CCSG all cores need to be coded ZY.

Dr. Henry Ciolino: Okay. In Example 4 you list Grant as a core PI.

Dr. Shannon Silkensen: Yes.

Dr. Henry Ciolino: If Grant is not a cancer center member, would you still list this core under Lee or Grant in the ZY program code?

Dr. Shannon Silkensen: Yes, because this is a cancer-relevant core.

Dr. Henry Ciolino: Could you clarify, please, under project direct costs and project total costs? That is annual, that's not for total project?

Dr. Shannon Silkensen: Yes, those are the annual, cancer-relevant costs.

Dr. Henry Ciolino: Okay. In Data Table 2B, for project totals, you only have project totals, you don't have program totals.

Dr. Shannon Silkensen: Yes.

Dr. Henry Ciolino: Is there a problem with that? Could some of the dollars in that data field be from non-cancer-relevant grants?

Dr. Shannon Silkensen: Data Table 2 only reports cancer-relevant funding. So if you had a grant that was \$1 million, but only \$800,000 of it was cancer relevant, you would only include the \$800,000 in the project direct cost column, and then you would allocate those \$800,000 appropriately into programs, whether it was all for one program or split among several programs.

Dr. Henry Ciolino: Okay. Do you want to answer the question now as to how to identify multi-PI grants? Or do we present that later in the...

Dr. Shannon Silkensen: So I'm not sure what the question is specifically asking. But one way that you would identify them actually by inspection in Table Data 2 is there's an ampersand [&] after the PI's name in Data Table 2.

Dr. Henry Ciolino: I'm not sure if that was the question or whether how they could identify multi-PI grants at their institutions.

Dr. Shannon Silkensen: I think there are going to be 67 unique answers to that...

One way that you can do is you can use the NIH RePORTER function. That has a checkbox that, allows you to search for grants that utilize the NIH's multi-PI mechanism. It also allows you to identify sub-projects within a multi-component grant, be it a P01 or a SPORE P50.

Dr. Henry Ciolino: Okay. Could you go to Example 5, please?

Dr. Shannon Silkensen: Sure.

Dr. Henry Ciolino: Let's see, in this example, how do you determine with the percentage — the 20% is? Is that based on the annual dollar amounts or the total parent grant budget?

Dr. Shannon Silkensen: So thanks for this question. It seems like I must've been unclear.

So in this example, like all, we take the top line, which is Donegan. So in this example, \$50,000 of their annual direct costs are cancer-relevant. This is a heart, lung, and blood grant, so one could imagine that the dollars for the grant are actually greater than \$50,000.

Of those \$50,000, 20% of them fit into Research Program 3 and the remaining 80% of this grant should be coded ZY because those are cancer relevant, non-programmatically aligned dollars.

Dr. Henry Ciolino: In Data Table 2B, you have a listing of the number of projects.

Dr. Shannon Silkensen: Yes.

Dr. Henry Ciolino: How do account a program project grant that might have four individual projects, but is one program project?

Dr. Shannon Silkensen: I would count each project individually, Henry.

OK, so I think this is just a semantic question. For those on the phone, the question reads, "In Example 4, the table requests, project direct, and project total cost, if the examples and directions request annual costs, is there any way to change the table headings to reflect the budget direct and total cost?"

I think it's really just a space concern. We'll work with our data people to see if we can maybe add an "AN" before direct to indicate annual direct and annual total cost, also annual program direct and total cost as well.

Sorry for the confusion.

Dr. Henry Ciolino: Okay. Could you go to Example 9, I believe it is?

Dr. Shannon Silkensen: Sure.

Dr. Henry Ciolino: This is the clinical trial funding.

Dr. Shannon Silkensen: Yes.

Dr. Henry Ciolino: So are you supposed to report a single date in time or do you report for the entire year?

Dr. Shannon Silkensen: You report for a single date in time. So for Data Table 2, and all, the data tables, you'll report data from a center-chosen date.

So somebody has a question about formatting for subcontracts (Example 5). Which column does the pound sign [#] go in?

The pound sign goes in the specific Funding Source column; not the Complete Project number column.

Dr. Henry Ciolino: How do you report grants that are in a no-cost extension?

Dr. Shannon Silkensen: So that's a really good question. I'm sorry we didn't include an example; that was a lack of foresight on our part.

Include grants that are on a no-cost extension. The project date has already been started. Include the project end date and estimate of the dollars that remain on the award.

Dr. Henry Ciolino: Okay. Suppose a cancer center has a subcontract from another institution or cancer center. How does that cancer center report the dollar amount in Table 2B?

Dr. Shannon Silkensen: So are you talking about the recipient of the subcontract or the sender of the subcontract?

Dr. Henry Ciolino: I think the question regards the recipient.

Dr. Shannon Silkensen: So the recipient of the subcontract is shown here, and we can use the Donegan example again. Again, Donegan has received a \$50,000 subcontract from Dartmouth. Or we don't actually know the total cost of the subcontract. What we know is that \$50,000 of the subcontract funds are cancer-relevant, so they're reported here.

Dr. Henry Ciolino: Okay. If it's the institution that's sending out the subcontract, do they still report the dollars?

Dr. Shannon Silkensen: Yes, the institution should count the money in the Project columns before they send it.

Dr. Henry Ciolino: Right. We have a question as to when these data tables will be implemented.

Dr. Shannon Silkensen: So implementation, Henry, you spoke a little bit about this at the introduction. We are hopeful that centers will begin making the changes they can with their FY13 data submission. And we're hopeful that everyone will be onboard by FY14.

Dr. Henry Ciolino: Okay.

Dr. Shannon Silkensen: So I'm a little bit confused by this question. It reads, "When reporting on a specific program funding, is it acceptable to include individual grants in those totals even though they are reported on Data Table 2A?"

Dr. Henry Ciolino: I'm not clear.

Dr. Shannon Silkensen: Yes, I'm sorry, please resend your question, we're happy to answer it.

I think we should move on to Data Table 3.

If you have additional questions, please send them and we'll do our best to answer them after the webinar.

Dr. Henry Ciolino: So Data Table 3 hasn't changed all that significantly. What we've done is clarify some of the definitions of the things that go into it.

Data Table 3 provides reviewers with an overview organized by anatomic sight of two things, the number of new cancer cases seen at the center and the participation of the center's patients in interventional treatment trials.

This is an example of Data Table 3. There are three columns. The reporting source is at the top of the first column.

It's very important that you fill this in with the proper consortium partner or affiliate that's a formal part of the cancer center because some of you are going to be submitting multiple Data Table 3s in the future. We're going to discuss that in a little bit.

You have 43 different anatomic sites. We believe that all the cancer types that you see at your centers can be fit into these sites. It does not include all cancer sites because this is supposed to be an overview for the convenience of the reviewers.

If you are seeing a particular cancer type at your center that you think is important enough to add to this list, please contact your Program Director and we will consult with the folks in the SEER Program to decide whether we should add another cancer site to this.

Column 2 is your newly registered patients and Column 3 is the patients enrolled in interventional treatment trials during this center-defined reporting period.

So newly registered patients are patients that you see face-to-face and are reported through your center's cancer registry for that diagnosis for the first time.

This includes both analytic cases where you're diagnosing and treating for the first time. It also includes non-analytic cases, patients that are referred to the center for further evaluation and treatment.

If you have a patient that has more than one type of malignancy during a reporting period, you count them twice.

You do not include in newly registered patients consults, new patient appointments, or follow-up appointments for the purposes of rehabilitation.

You also do not report patients that are seen only at satellite institutions that do not report through the center's registry.

At some of our centers, center staff help set up clinical trials that occur only amongst community practitioners, not at the center. Those patients are not included amongst the newly registered patients at the center.

The interventional treatment trial protocols are those designed to evaluate one or more interventions. This includes behavioral interventions. These were previously called Therapeutic Trials.

Most centers will still submit one Data Table 3. However, if you have an affiliated institution that is a formal part of your cancer center — an example of this would be a pediatric hospital that's a formal part of your cancer center — but that maintains a separate cancer registry, you will submit two Data Table 3s. And that's why it's important to get the reporting source at the top of Column 1.

Consortium Centers should submit one Data Table 3 for each formal consortium partner that's carrying out clinical trials and also for an affiliated institution that's a formal part of the cancer center that maintains a separate cancer registry. So some of the consortium centers will have multiple Data Table 3s.

If you have any questions, I'd be happy to try to answer them.

Dr. Shannon Silkensen: Thanks, Henry that was a really great walkthrough on Data Table 3.

One of the questions that we received is, "Does the 10%, you know, sort of hypothetical benchmark still exist for total enrollment versus newly diagnosed patients?"

Dr. Henry Ciolino: We have attempted in this version of the guidelines to remove benchmarks of this type

Dr. Shannon Silkensen: There's no benchmark at this point.

Dr. Henry Ciolino: And quite frankly I have not seen at any of the site visits that I have attended where people have looked at Data Table 3 that closely by disease site to see if 10% of the patients that the cancer center has seen — they have not drilled down that far.

Dr. Shannon Silkensen: Somebody else had a question about cooperative group studies. So for cooperative group grants where the centers receive dollars per patient per accrual, is it appropriate to estimate annual dollars?

Yikes, this is a Data Table 2 question. Yes, for cooperative group studies where the centers receive dollars per patient, follow Example 9.

Dr. Henry Ciolino: So we have a question, “How do you define a consortium?” And you can find this information in the new guidelines.

A consortium partner must bring to the table several things, including its own portfolio of peer-reviewed research. I suggest you read the guidelines to get a more detailed answer for that and consult with your program director.

Dr. Shannon Silkensen: So somebody asked us about supportive care accrual. So, Henry, should supportive care accrual be included in the “newly enrolled” column? For example patients with colorectal cancer are on a drug study for nausea and/or vomiting.

Dr. Henry Ciolino: No, only patients that are newly diagnosed and treated for the first time that go into the newly registered category. Newly treated patients.

Dr. Shannon Silkensen: So this question is on a similar issue. The questioner asks, “The use of the word treatment implies that this is an intervention intended to treat the cancer. Is that the case?”

Dr. Henry Ciolino: Yes that is our intent for a Data Table 3. Do not include trials for rehabilitation purposes or supportive care.

Dr. Shannon Silkensen: So, Henry, enrolling patients from an affiliated VA, are Centers required to include the registry numbers on a separate Data Table 3? So if the VA is affiliated with your cancer center, do they submit a separate Data Table 3 or would we expect to receive the combined Data Table 3 for the cancer center and the affiliated VA?

Dr. Henry Ciolino: If the affiliated VA is a formal part of the cancer center and it maintains a separate cancer registry, then you’d want a separate Data Table 3 for it. If it reports through the registry of the cancer center, then you would combine those patients into the cancer center Data Table 3.

Dr. Shannon Silkensen: Henry, does interventional include prevention and supportive care trials?

Dr. Henry Ciolino: No, it's only protocols that are devoted to specific interventions, devices, drugs, behavioral interventions for treatment.

Dr. Shannon Silkensen: Can diagnostics or imagining studies be considered an intervention??

Dr. Henry Ciolino: No, diagnostics or imagining studies are not treatments.

Dr. Shannon Silkensen: I think we have one more question coming.

Melissa Glim: Yes, we actually have four or five.

Dr. Shannon Silkensen: Okay.

Dr. Henry Ciolino: Why don't you push on with Summary 4 and I will review these questions afterwards.

Dr. Shannon Silkensen: Perfect. I'm happy to go on with Data Table 4.

All right so let's step back for a minute and think about the data that actually go into Data Table 4 and what Data Table 4 shows us.

So Data Table 4 really shows us five things. The first three are I think kind of evident. Number 1 it shows the types of clinical research that are being supported — be they interventional, observational, ancillary, correlative.

The second thing Data Table 4 shows us is the source of support — is it funded nationally by externally peer-reviewed mechanisms, institutional or industry.

And third, it drills down a little bit more. It shows you the specific funding source. It actually names the institution, the institute, or the specific pharmaceutical company that is supporting the study.

The last two points that Data Table 4 shows us are a little bit nuanced. It shows whether the trials at your center are multi-site and it also shows if the center is able to accrue to the trials that it has open.

So the data are organized in Data Table 4 in the following way. You're going to begin with an alphabetized list of all the clinical research studies at your center. These are alphabetized by the PI's last name.

And then you're going to parse the data through a three-way filter and divide it into bins — whether it's an interventional study, an observational study, or an ancillary or correlative study.

These three bins — interventional, observational and ancillary/correlative — cleanly map to the previous clinical research categories. The mapping is shown here and it's also listed in the data guide.

So once you have taken your alphabetized list of clinical research studies and bin them into either interventional, observational, or ancillary and correlative studies, you'll need to separate them further by their source of support.

The four potential sources of support categories are shown here in grey. Are the clinical researches studies supported by national efforts to the NCTN, by externally peer-reviewed mechanisms such as R01s or P01s? Are the studies supported with institutional funds or with industry dollars?

One thing that I'd like to emphasize is that observational and ancillary/correlative studies need a source of support be it national externally peer-reviewed, institutional or industrial.

So before we get into the examples, I'd like to review a few definitions with you.

First off, for Data Table 4, the specific funding source refers to the specific name of the financial sponsor for the clinical research study. For example your institution, like NYU, or the NCI or a pharmaceutical company, like GSK.

Second, the protocol ID or IRB number is a unique identifier for each clinical research study. For example this identifier is used by all sides participating in an NCTN trial. It is a common protocol number used by centers participating in a multi-site trial or it can be an internal protocol ID or IRB number for institutional-supported studies.

Here are just a few examples. You can have something like NYU 1054 or NCI 06-8-01, RTOG 07112.

So every clinical researches study has a primary purpose. This has not changed with the new data guide, but what has changed is the list of valid purpose types that you're able to enter.

The right-hand column on the list here shows the eight valid primary purposes accepted into Data Table 4. Try to enter something sneaky like an outcomes study and you risk the chance of having your dataset returned to you for noncompliance.

Total targeted accrual: so accrual is one of those seven-letter words that brings up a lot of discussion.

The CCSG defines accrual as the number of participants that have completed or are actively in the process of completing the study. This number includes dropouts. It does not include screen failures.

Total targeted accrual therefore is the total number of participants needed for the entire study. For multi-site trials, this includes participants at all participating sites.

Targeted accrual at your center is the total number of study participants your center expects to accrue during the entire study period.

Yes for single-site studies conducted at your center, the total targeted accrual and the targeted accrual for your center values will be the same.

However for multi-site studies led by your center, the total targeted accrual for your center will always be less than the total targeted accrual for the entire study.

Lastly, let's review what the CCSG defines as a multi-site clinical research study. These are studies that recruit participants from two or more geometrically distinct cancer center or moment sites that are not affiliated with your cancer center. For example NYU could lead a multi-site clinical research study with MUSC and Baylor.

So accrual sites, as we're talking about Data Table 4, let's talk a little bit about what accrual should be captured in the cancer center's primary accrual site columns.

These columns show the number of enrolled participants in your center and its formal consortium partner. Participants from nearby community hospitals or other centers that are participating in multi-site trials led by your cancer center are reported in the other accrual site column.

So accrual timeframe — Data Table 4 asks for two timeframes. One, how many participants have been accrued to this clinical research study in the past 12-month reporting period. And, two, how participants have been accrued to this clinical research study to date.

It would stand to reason that the number of participants accrued to the clinical research study to date would always be greater than the number of participants that have been accrued during the last 12-month reporting period.

So let's get into the examples. So Example 1 is probably the most straightforward example. In this example, the entire clinical research study takes place at your cancer center and its formal consortium partners.

In this example, it's an institutional clinical research study. The specific funding source is NYU. It addresses more than one anatomical site, so it's listed as "multiple" in the site column. The protocol ID is listed. And since this is an institutional trial, the protocol ID number references the institution. The PI's name is included and the clinical research study is associated with Research Program 10.

The date the study opened is included. And since the study is still open, no close date is listed.

This is a Phase 2 study and its primary purpose is supportive care.

The title of the study is Enbrel in Patients with Idiopathic Pneumonia Syndrome Following Going to a Donor SCT

So now is where it gets interesting, the right-hand side of this table. Since the study takes place only at your center and its formal consortium partners, you're going to include an N in the "is multi-site trial" column. I just noticed that the N didn't show on the slide, but there should be an N right before number 105. Again, I'm sorry for that.

Since the study takes place only at your center and its formal consortium partners, the "total targeted accrual" numbers are identical for the entire study and for your center.

In Example 1, ten patients have accrued to the study in the last 12-month reporting period and 30 participants have been accrued to date. The other accrual site columns are left blank since this study takes place only at your center and its formal consortium partners.

Let's move on and look at Example 2. Example 2 is an example of an externally peer-reviewed study. It is supported by both NYU and the NCI. It's a multi-site trial and its common protocol ID number is listed in the protocol ID column. It's NCI 1109.

The name of the PI at your center — Mack in this case — is included. And this study is associated with Research Program 3.

This is another example of a study whose primary purpose is supportive care.

So let's take a look at how the accrual data are actually reported. Since this is a multi-site trial, yes or Y is included in this column.

The PI expects to accrue 400 participants in the entire study — 60 of them at your center. Remember the total number of participants expected to be accrued at your center will be less than the total targeted accrual for the entire clinical research study.

Your center has accrued 22 participants during the last 12 months and 46 participants to date. The other accrual sites have accrued 70 participants during the last 12 months and 240 participants to date.

Does this make sense? Is everybody clear on how these data need to be entered? If not, please ask us a question at the end of this presentation.

In this final example — Example 3 — your center is participating in a multi-institutional, national clinical research center. Follow this example if you are reporting a study was initiated by another institution.

So we've used an old cooperative group study as an example here. The source of support is national and the specific funding source is listed as COG.

The protocol ID reflects a common protocol number — COG 08H9 — and the primary purpose column shows us this is a treatment study.

And here it gets interesting. Let's look at the right-hand side of this column. This is a multi-site trial, not one initiated by your center. Therefore the multi-site column is checked yes.

The total targeted accrual column for the entire study is left blank since the study did not originate at your center.

In this example, your center is expected to accrue six participants. In the last 12 months reporting period, you have not accrued any patients. However, you have accrued four patients to date.

Since your center is participating in another center's study, you do not need to document any accruals in the other accrual sites column.

Well that really concludes our brief review of Data Table 4. I'm happy to take any questions at this time.

Dr. Henry Ciolino: Okay, Shannon, let's see. I'm trying to organize these by So in Summary 2A...

Dr. Shannon Silkensen: Yes.

- Dr. Henry Ciolino:** If you have an industrially sponsored clinical trial that doesn't have a clear end date, what do you put in the project end date column?
- Dr. Shannon Silkensen:** Please just leave it empty. Please do not insert a blank character in the column.
- Dr. Henry Ciolino:** Okay. Would national cooperative group trials be considered a multi-site trial?
- Dr. Shannon Silkensen:** Yes, Henry, national cooperative group trials are considered multi-site trials.
- Dr. Henry Ciolino:** Okay a few questions on Data Table 3.
- Dr. Shannon Silkensen:** Ah yes.
- Dr. Henry Ciolino:** Can patients that you enroll in diagnostic trials be included in Data Table 3 since the primary purpose of those trials is to identify not to treat?
- You should not include these patients in Data Table 3 because the intent of Data Table 3 is for those patients that you intend to treat and change the course of the disease.
- We have a question about a VA hospital that's not a formal part of the cancer center but does accrue patients onto trials, "Do you prepare a separate Data Table 3?"
- Well if it's not a formal part of the cancer center, then you do not report these patients at all on Data Table 3 — either the centers or a separate Data Table 3.
- You do include these patients in Data Table 4 however.
- Dr. Shannon Silkensen:** So, Henry, in Data Table 4, my understanding is that the VA would count as another accrual site, so you would include them in the far right-hand column. In the VA in this example here, they would have accrued 70 participants in the last 12-month reporting period and perhaps 240 to date.
- Dr. Henry Ciolino:** Okay. For centers that are having site visits in 2013, do you go back and recode the Data Table 4 categories and definitions?
- Dr. Shannon Silkensen:** I think that's going to be very individual. Each of the centers should contact their program director and we'll move forward with a solution that's right for you.

Dr. Henry Ciolino: We have a question about Data Table 3, “If a patient is brought in, do you code them for the anatomic site under the site of the original malignancy or what you’re actually seeing the patient for at that point — say metastasis to bone?”

And the answer is that you code them under the primary diagnosis.

So the question is about subcontracts and how they should be listed in Summary 2 — how the primary institution should list that?

Dr. Shannon Silkensen: So the primary institution can claim the dollars that are subcontracted to a second institution. And an example that we - a way that we can show that is actually through the Lee lung cancer score that’s part of Example 4.

So if you look at Example 4, let’s for this example a million dollars of annual direct costs cancer relevant for the SPORE flowed to this center. However if you sum up the dollars that flowed to the research programs at the center, you’ll see that it’s less than a million dollars.

So the center would account for the \$1M in the project column and then apply the appropriate dollars into the program columns. Keep in mind that the sum of the dollars allocated to the Research Program will usually [but not always] equal the total project dollar amount.

Dr. Henry Ciolino: The silences you hear are us digesting your question, so don’t want you to think we’ve signed off or anything just yet.

Dr. Henry Ciolino: Well I think we’ll now push on to the electronic data format and our new IT specialist chief will discuss that. New as of a year ago.

Dr. Shannon Silkensen: Give us just a minute to get there with the slides. All right.

Chi Dinh: Thank you, Henry, and thank you, Shannon. Hello everyone and thank you so much for being here.

I would like to take a few more minutes of your time to share with you data migration process and touch a little bit on the electronic data table format.

After more than ten years, our office finally has a centralized database that can store and manage data in one location. I would like to briefly walk you through how the data currently get in to our system.

As we receive the Data Table Files 1 through 4 from each of your center, most of these data are in Excel and some in Access format. First, we validate the data and for every misformatted file from 67 centers we have

to modify the structure into a uniform format. Each file must have the same column names and consistent data type.

We organize the data before we import it into Access and then migrate it into SQL server database — which we called OCCdb. The data are further aggregated and forecasted on our website.

We want to make certain that the data in our database is accurately representing the activity at your center. This is why we like to request that you follow the eData guide when submitting these Data Tables to us.

And to make this data submission more efficient for the centers, we are continuing to find ways to improve this process internally.

Let's take a look at Data Table 1. From a SQL server 2008 database perspective, these are what the data fields look like.

The CCSG grant number is defined as an integer — which only accepts numeric value. For instance whereas a full grant number may be something like 5P30CA123456, for this purpose of the eData, please include only the numeric piece 123456.

The isNew is one character field. It indicates whether this is a new leader. Use Y for yes and N for no.

The rest of fields are defined as VARCHAR or character string with various length. Please note the last name, first name and degrees have been broken down into individual fields. This is a change. Previously these fields were lumped together.

I don't plan to go over field by field in every Data Table, but for your convenience I have include all the fields in Data Tables 1 through 4 at the end of this presentation. Please note that the changes are emphasized and highlighted in yellow.

Let's skip to Data Table 3. This is an example of how we would like the data to be submitted to us. Currently there are 43 predefined primary site categories as listed. Altering the list will make the data process less efficient. If the data is not available or applicable, please enter zero.

The latest ICD code list can be found on our website.

And we would like to take this opportunity to thank many of you for helping us and for you folks in identifying the errors and discrepancies in this list. This list will updated in advance once it goes in effect in 2014.

There are many varieties in how the Centers report Data Table 4. We would appreciate if you use only the defined codes and values — especially in these following four fields — the Clinical Research Category, which is previous known as the Section, it is a text field and can only accept three abbreviated value:
interventional (INT),
observational (OBS) or
ancillary or correlative (ANC/COR) studies.

The Study Source, which is previous known as Sponsor Category, is defined as one character and valid entry for this field is N, E, I and D.
N for national,
E for externally peer review,
I for institutional and
D for industry.

Please note the proper date field format — two-digit month, two-digit day and four-digit year.

A blank is considered a character, therefore please don't enter a space or blank in this date time field.

Phase, for interventional studies acceptable entries include pilots, feasibility, 0, I, II, III, IV or combination. For other studies, enter 'NA'. Please do not include a blank space before or between words.

Primary Purpose, which is previous known as Study Type, is a text field and only accept the following eight three-character valid values:
treatment (TRE), prevention (PRE), supportive care (SUP), screening (SCR), diagnostic (DIA), health services research (HSR), basic science (BAS), and other (OTH).

We would like to emphasize, please know that you are our primary audiences for our website. We encourage you to use our site as a tool to get the latest and relevant information. These include the Guidelines, the Data Guide, the eData, the ICD codes, FAQs, and we have quite a number of webinars posted in our website and this presentation will be posted on our website shortly.

We also would like to bring the RePORTER to your attention. This is an NIH database reporting tool. You can use this tool to retrieve data for Data Table 2A. It has many useful features and one of the features is to identify multi-PI grants.

To ease on the data submission process for the Centers, eight Excel Data Table templates will be created and available for download from our website.

We are planning to attend the CCAF in March setting up a workshop on the data tables. We welcome any suggestion that you may have for this workshop and we hope to see all of you there.

So please let us know if you have any questions at this point and again thank you so much for joining us.

Dr. Henry Ciolino: Thank you, Chi. We do have a couple of questions. In Table 4 where they're listing the title of the protocol, their understanding is that Excel is limited to 254 characters in a field. What if the title runs longer than that?

Chi Dinh: In Excel 2010, the total number of characters that a cell can contain is 32,767 characters; however the Project Title in the OCCdb is defines as VARCHAR(8000) . It accepts up to 8000 characters.

Dr. Henry Ciolino: Okay. And in Data Table 3, do you need to provide the exact text for the anatomic disease site or are there codes to use?

Chi Dinh: We will provide Data Table 3 template

Dr. Henry Ciolino: Okay. We have some questions about the other data tables. Where should clinical prevention studies be reported?

Clinical prevention studies should be reported in Data Table 4 but not Data Table 3 because they're not intended to treat.

In Data Table 3, newly enrolled patients aren't necessarily newly registered patients.

And also from Data Table 3, if a patient develops a subsequent malignancy to a prior one, does that patient count as a new patient in the reporting period? Yes.

Dr. Shannon Silkensen: Thanks, Henry. One straggling question about Data Table 2, reads, "If a study is sponsored by the institution but also has industry support in the form of funds or drug only, should both be listed under the funding source?" And the answer is yes please if it's — it sounds like it's an institutional trial and then you would list both the industry and the institution in the specific funding source category.

Dr. Shannon Silkensen: The next two questions we received deal with Data Table 4. In Example 2 on Data Table 4, the questioner asks, "Is this representing a multi-site

study that the institution reports as a lead site or is it part of a national trial?”

This is not a national trial. Example 2 was intended to be a multi-site trial led by your institution. In this example, you would report the accruals that you expected for the entire study in the total targeted accrual column and then only those for your center in your center accrual column.

Dr. Shannon Silkensen: Another question we received about Data Table 4 is if we have affiliates through a cooperative group and they open studies which we do not participate in; do we also need to report these studies in Data Table 4?

And the answer is no. If you're not participating in the study, you do not need to report it in Data Table 4.

Dr. Henry Ciolino: Okay one more thing about Data Table 3. If a cancer center has a formal partner that is reporting through the center registry, do you include the newly enrolled cases? And the answer to that is yes you do.

Dr. Henry Ciolino: We also had a question if there were additional seminars — webinars — being scheduled about the new guidelines. The answer to that is no, but the program directors are always happy to take questions from the centers about the new guidelines and update the FAQ list as we get important questions.

Dr. Linda Weiss: And the workshop.

Dr. Henry Ciolino: And there's also a workshop in March at the next CCAF meeting devoted to the data tables themselves. Chi and some of the program directors here in the OCC will be attending.

If we have not answered your questions, the reason was because we had a little trouble understanding it. Please don't hesitate to send further questions to either Shannon Silkensen, Chi Dinh, or me, Henry Ciolino. Our e-mail addresses on the slide that you see in front of you right now and we'll be happy to answer them. [henry.ciolino@nih.gov, chi.dinh@nih.gov, shannon.silkensen@nih.gov]

Dr. Shannon Silkensen: Thank you all for attending today. We've really gone through a lot of dramatic change — both in terms of the guidelines and the data tables.

We're happy to work with you and look forward to hearing from you. Thank you so much.

Coordinator: That concludes today's conference. You may disconnect at this time.

END