SC Minutes from 9.11.14

Present: Vanita Aroda, Irwin Brodsky, Ranee Chatterjee, Chhavi Chadha, Cyrus Desouza, Karen Johnson, Sangeeta Kashyap, Sun Kim, Erin LeBlanc, Anne Peters, Anastassios Pittas, Philip Raskin, Patricia Sheehan

Ancillary Studies

No AS has been successfully funded
3 applications going back in this cycle
PIs and junior staff continue should continue to like about potential ancillary studies

Dr. Dawson-Hughes (AS14-04)

This application proposes to investigate the difference between free and total 25OHD in the role of predicting diabetes risk.

Burden: Minimal burden to sites. No real time collection of data

Action: [CC] send out follow-up email for SC votes

Dr. Gunstad (AS14-05)

This application proposes to assess the impact of prediabetes on neurological disorders and the effect of vitamin D in attenuating cognitive decline.

Burden – provide brochure to participants who then go online to agree and complete 2-3 questionnaires, no collection of data in real time.
Cross section protocol – baseline, 12, 24, etc. (12 month intervals)

Action: [CC] will ask Dr. Gunstad to better explain study and clarify on committee's questions

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Responses to Ancillary Study Questions

1. The PHQ-9 has questions regarding suicidal ideation. There is a legal responsibility of the test administer to respond to this. A D2d investigator suggested you consider the PHQ-8 instead. The investigators were concerned that they would have added responsibility to deal with any findings? You had mentioned letting the investigators know about evidence of cognitive impairment. How would you do so and what would this mean to the D2d study investigators.

We completely agree about the depression measure and will switch to the PHQ-8. The grant application will be updated to highlight this information.

In terms of cognitive impairment, we propose to use an approach utilized in past NIH studies that minimizes both risk and burden. First, the consent form will inform participants that the cognitive testing does not constitute a clinical evaluation but that we will notify them if their test performance encourages the need for further evaluation. Most individuals will seek this type of evaluation at the same facility that is conducting the D2d trial, so team members would only need to have contact information for that service handy (e.g. either a handout or just have the phone numbers for the neuropsychology service).

In terms of contacting the D2d investigators, we are happy to implement either of the two below options based on feedback from D2d:

1. *More information but increased responsibility.* We include information in the consent form that allows us to inform D2d staff that the individual has suspected cognitive impairment. Our staff would be able to provide that info in a timely way.
2. *Decreased information but less responsibility*. We inform the participant of their poor performance, but not D2d investigators. Most likely, staff will get a few easy questions about that feedback (e.g. how do I schedule an evaluation, etc.) that could be handled at a low level.

Of these, I'd recommend option #2. It is easier for everyone and still meets the ethical requirements.

2. In follow-up of participants, what role would the sites play? Will they be responsible for reminding participants?

No – sites will not have any additional burden after recruitment/referral to the ancillary study. We will contact them for follow-up visits, any missing data, etc.

3. If you were to use D2d Screen failures as controls who would be responsible for reminding them to do the follow-up assessments (note the sites will not be in contact with these people)?

The ancillary team would do all the reminding for this group as well. After the initial recruitment/referral, we would manage all the remaining activities for the ancillary study.

Task/Responsibility	D2d Clinical Sites	Ancillary	D2d DCC
IRB documentation for site	X		
Initial contact/refer to ancillary	X		
Coordinate/conduct assessments		X	
Contact participant if impaired		X	
Reminders/Initiate follow-up		X	
Coordinate follow-up visits		X	
Participant payment		X	
Extract D2d study data			X

Outline of study activities

Procedures

D2d patients that agreed to be contacted regarding additional studies will be approached for the proposed study by research staff at their respective clinical site. Research staff from the clinical site will briefly describe the ancillary study and obtain assent for the ancillary study team to contact them. They will then be contacted by the ancillary study team to learn more about the project, including all activities, possible risks/benefits, compensation, and time commitments.

D2d patients that agree to take part after this introduction will be emailed a link to the study website that will activate their participation. These individuals will be asked to read a short introduction to the study and the informed consent form. A link within this section will allow them to contact the ancillary study team to ask any follow up questions prior to initiating their participation.

At that point, they will review the online informed consent form. However, prior to completing the online consent form, all participants will be required to pass a short "quiz" on the key information within the informed consent form to ensure adequate comprehension. They will then complete the online questionnaires and computerized cognitive test battery.

Performance during testing will be monitored using the ProctorU system, an online service that is used to ensure the validity of remote testing. The ProctorU system is widely used for a variety of purposes. For example, many colleges and universities utilize it for online placement testing and Kent State University has used this service >5000 times in the past year alone. We have successfully pilot tested the use of ProctorU with the proposed measures below.

The ancillary study team will be responsible for all reminding activities and will contact individuals for their follow-up assessments. Those assessments will be identical to the above, with the exception of the consenting procedures.

Matched Controls will be enrolled using a similar set of procedures and recruited from persons that fail the D2d screening criteria. Research staff from the clinical site will briefly describe the ancillary study and obtain assent for the ancillary study team to contact them. They will then be contacted by ancillary study staff and proceed through the above steps for enrollment and participation.

Action: [CC] send out follow-up email for SC votes

Recruitment update

530 randomized

Some sites really ramped up recruitment. We have a few sites close to 90% of their cumulative goal.

August was a disappointing month. September has been much better, 27 randomized to date.

Vanita – RRS is trying to empower sites with resources, (GDM, retention, social media) next month's meeting will focus on recruiting minorities, especially Hispanics.

ADA Collaboration

Taso and Patty spoke with the liaison for research at the ADA. ADA is eager to help D2d and has offered to do the following:

- Add D2d to the Clinical Trials Resources page on the ADA website
- Advertise D2d in the Diabetes Awareness Campaign (2x/year)
- Include D2d in the Diabetes Pro Smart Brief email (1x/week)
- Post on Facebook and Twitter (2x/month)
- Mention D2d in the Diabetes Forecast Newsletter in an article on research the ADA is supporting

The national office has informed local chapters that D2d is an ADA supported study.

Action: [Sites] need to reach out to their local ADA chapter to find 'free' ways they are able to offer support.

Reminder: Find out when your local ADA – Step Out Walk is and how you can promote D2d. Sites that plan organize a D2d team for the walk should notify the CC as soon as possible. The CC will try to order D2d t-shirts for sites participating at their local events.

Publications

Diabetes Care published D2d's Rationale and Design paper. The link is available on the D2d website under News → Publications. You should have also received the link by email.

Investigator Meeting

Registration is open.
SC suggestions for meeting:

- Awards
- True Blue
- RC Training