D2d Publication and Presentation Proposal Submission Form

Office Use
Submission Number PR16-01 Date Submitted (MM/DD/YYYY) 03/18/2016

To: D2d Publications and Presentations Subcommittee

Re: D2d Publications and Presentations Preliminary Concept Proposal

Title of Proposal *(81 character limit)*: The Role of Electronic Health Records in Current Age of Clinical Trial Enrollment: Data from The D2d Study

Lead Author: Aroda, Vanita
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If Lead Author is not a member of the D2d study group, please specify:
D2d Co-Investigator: n/a
Institutional Affiliation: n/a

Proposed Writing Group (name and D2d role)

List one author per line. Indicate who will do the statistical analysis.

Order and author list is subject to change.
Aroda, Pittas, Vickery, Brodsky, Ouellette, Cook, Chadha, Serafin-Dokhan, Staten, Sheehan

Statistical analyses: D2d CC (Nelson/Ware)

Scope of Project Proposal

- (•) D2d-wide
- ( ) Site-specific
- ( ) Other, specify

Publication Tier Designation (see D2d Publications and Presentations Policy)

- ( ) Tier 1
- (•) Tier 2
- ( ) Tier 3

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Significance, proposed central hypothesis and specific aims of analysis/preliminary abstract

Clinical trial enrollment in multi-center studies has traditionally relied on outreach to potential participants from the overall community through various avenues (advertisement, informational mailers and communications, referrals from providers). The robustness of current electronic health record data and information potentially allows an efficient approach to dissemination of clinical trial opportunities to patients affected by the condition of study. Optimal methods of incorporating the electronic health record (EHR) in clinical trial recruitment are not well established.

The D2d Study is an NIH-funded multicenter clinical trial evaluating the prevention of diabetes with vitamin D supplementation in over 2,000 adults at high risk of diabetes. High risk of diabetes in D2d is defined as meeting 2 out of 3 ADA-defined criteria for prediabetes (FPG 100-125 mg/dl, 2-hour post-challenge glucose 140-199 mg/dl, HbA1c 5.7-6.4%) while not meeting any criteria for diabetes. Sources for participant recruitment in the D2d study have been systematically collected and categorized as non-EHR methods (e.g. general communications, advertisement, referrals) versus EHR-based approaches, which include IRB-approved query of the EHR, outreach to individuals meeting prescreening criteria, followed by refinement of the EHR query based on ongoing review of enrollment data (ie identification of 'sweet spot' targets for each study site).

This proposal aims to describe and evaluate the use of the EHR in clinical trial enrollment for the D2d study, with the hypothesis that EHR-based approaches offer an effective and efficient means of enrollment for a study of this nature. Further, we propose that EHR-based approaches for clinical trial recruitment are scalable across multiple sites, resulting in effective widespread dissemination of information about current diabetes prevention research opportunities directly to patients at risk.

Identify variables to be used in the analyses

Recruitment metrics from EDC - e.g. Categories of recruitment that are being collected in the EHR, for both screening and randomization, across the different sites and by time
-EHR-based approaches
-non-EHR based approaches (e.g. general communications, advertisement, referrals)
-screen failure rates based on approach for recruitment
-uptake of EHR based approaches across the different sites over time and correlation of EHR uptake with recruitment efficiency
-demographics, as a whole, and by recruitment (EHR vs non-EHR) approach
-Site descriptions and locations - uptake and efficiancy of EHR approaches
-Laboratory data for main inclusion/exclusion criteria at screening, baseline, and randomization

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Description of analysis plan (if desired, may include envisioned tables, figures)

Description of analysis by proposed results:

Figure: Screening numbers, EHR vs non-EHR approaches (pie or chart)
Figure: Qualified (Randomized) numbers, EHR vs non-EHR approaches (pie or chart)
Figure: Change in recruitment efficiency over time (Randomization:Screening Ratio) based on incorporation of EHR approaches (a pre-post for each site and overall for D2d)
Table: Baseline Descriptive characteristics: Enrolled: entire cohort vs. EHR-vs non-EHR; age, ethnicity, qualifying glycemic parameters; geographic location

Proposal Type

Type of proposal (check all that apply)

- [x] Manuscript – analysis
- [x] Manuscript – methodology
- [ ] Manuscript – validation
- [ ] Manuscript – other
- [ ] Letter to the Editor
- [ ] Abstract/Extended Abstract
- [ ] Oral Presentation (e.g. Powerpoint)
- [ ] Poster Presentation

Abstract and Presentations only

Intended meeting: ADA 2016
Submission due date: 12/01/2015
Meeting date: 06/01/2015

Publications only

Intended journal: JAMA (alt. Annals, Lancet Diabetes Endo, Diabetes Care, Clinical Trials)

Describe timeline for submission

manuscript to be developed in conjunction with approved ADA poster (June, 2016)

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Acknowledgement of D2d Publications and Presentations Policy

I have read and agree to abide by the policies and procedures for D2d Publications and Presentations as described in the document titled: *D2d Publication and Presentation Policy*.

Lead Author Signature Vanita Aroda Digitally signed by Vanita Aroda DN: cn=Vanita Aroda, o, ou, email=vanita.aroda@medstar.net, c=US Date: 2016.03.18 14:00:10 -04'00' Date _____
(e-signature accepted)

Note: After a proposal is submitted to the PPS and if approved, the lead author has nine months to submit a draft to the subcommittee for review. Should the lead author fail to submit a draft within nine months, the subcommittee may assign the proposal to other members of the D2d Research Group for completion.

Final steps to submission:
Save a copy of this form to your computer.
Click on the "Submit" button and follow the directions to submit electronically. Alternatively, you may attach the file manually to an email and send to: D2d@TuftsMedicalCenter.org.

Submit