PREPARING FOR SUCCESS

CCSG CLINICAL PROTOCOL & DATA MANAGEMENT REVIEW

HURON

Preparing for Success: CCSG Clinical Protocol & Data Management Review

1. Introductions & Information
2. Clinical Protocol & Data Management
3. Site Visit Preparation & Other Helpful Tips
4. Site Perspective
5. Q&A

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INTRODUCTIONS & INFORMATION

TODAY'S MODERATOR

ELLEN MCLAUGHLIN
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- 25 years of health care and cancer center experience
- Director, Research Administration
  - Georgetown University, Lombardi Comprehensive Cancer Center
- Certified Research Administrator
- Interim director of clinical trials office for NCI-designated center
- Oversight and delivery of CCSG submissions for multiple centers
- Oncology Nurse, Gynecologic/Women's Health

Today's Presenters

ANITA L. HARRISON
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- 27 years of clinical research and cancer center experience
- Associate Director, Administration
  - Medical University of South Carolina, Hollings Cancer Center
  - Washington University, Siteman Cancer Center
- Clinical Trials Administrator
  - UCSF
  - Wake Forest University Comprehensive Cancer Center
- NCI CCSG reviewer since 2001
- Founding leadership team, SoCRA

Today's Presenters

TERRI L. MATSON

MANAGER

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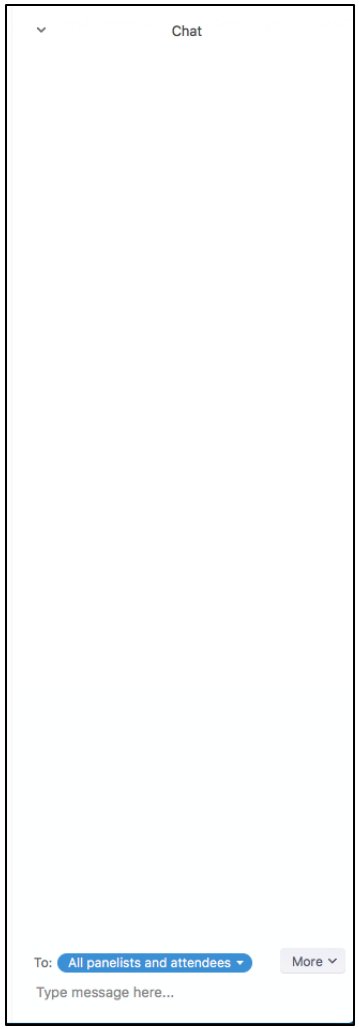
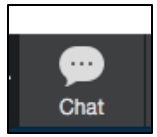
- 22 years of progressive clinical research management roles in industry and academia
- Administrative Director, Clinical Trials Office
  - Medical University of South Carolina, Hollings Cancer Center
  - Multiple interim directorships for emerging NCI-designated centers
- Inaugural member, AACI Clinical Research Initiative
- SoCRA member since 2000

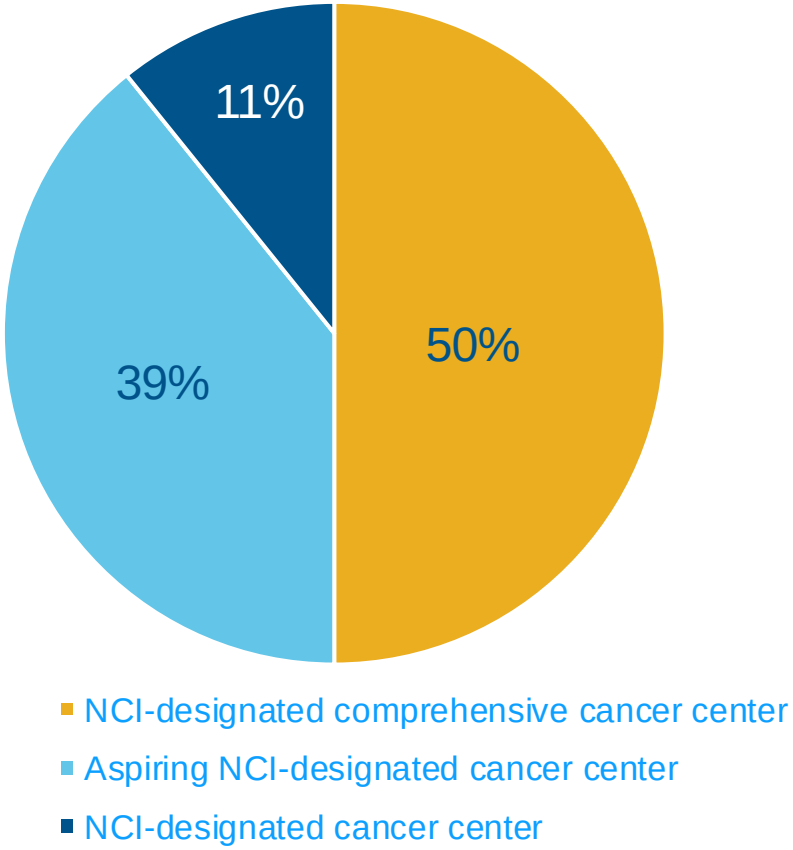
Ask Us Your Questions Through the Chat Feature



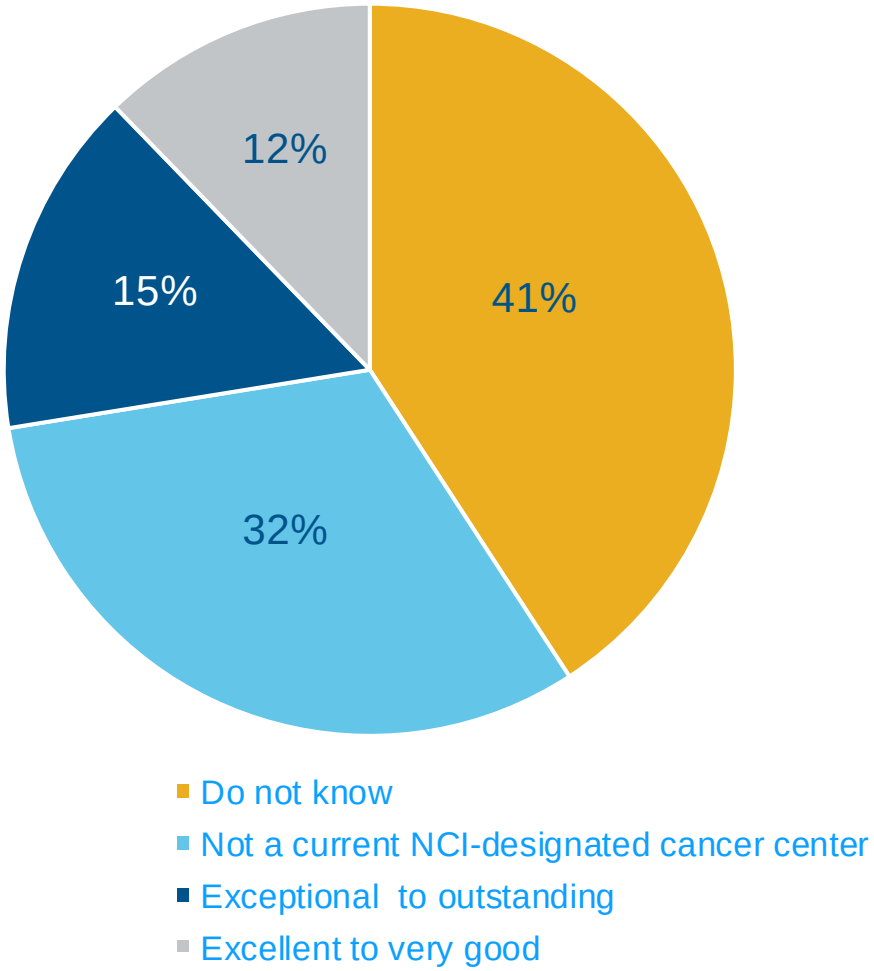
Enter a question in this dialog area at any time



Types of Cancer Centers Represented Today



Previous CPDM Merit Rating of Participating Centers



Disclaimer

The material presented today is based upon our current understanding of the Cancer Center Support Grant funding opportunity announcement (FOA) as outlined in PAR-17-095.

https://grants.nih.gov/grants/guide/pa-files/PAR-17-095.html

Terminology

Terms	Definition
CPDM	Clinical Protocol and Data Management. Centers often rename their CPDM functional unit as “CTO”, “CRO”, “CRS”, “CTSU”
CCSG	Cancer Center Support Grant
CTMS	Clinical Trials Management System
CTRP	Clinical Trials Reporting Program
DSM, DSMC, DSMP	Data and Safety Monitoring, Committee, Plan
EDC	Electronic Data Capture
FOA	Funding Opportunity Announcement
IIS	Investigator-Initiated Study
NCTN	National Clinical Trials Network
PRMS	Protocol Review and Monitoring System

Resources

- **Office of Cancer Centers Webpage**
  - https://cancercenters.cancer.gov/GrantsFunding/GrantsFunding
    - CCSG Funding Opportunity Announcement
    - Data and Safety Monitoring Plan examples
    - Data Table Guides

- **Listing of Approved Peer Review Funding Organizations**
  - https://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf

- **Communicate with Your Cancer Center Administration**
  - Review the prior CCSG review Summary Statement
  - Discuss proposed CCSG CPDM budget
  - Review Research Program changes that may impact accrual reporting
  - Verify center's geographic catchment area
  - Outline draft/review/submission deadlines as well as site visit schedule and preparation

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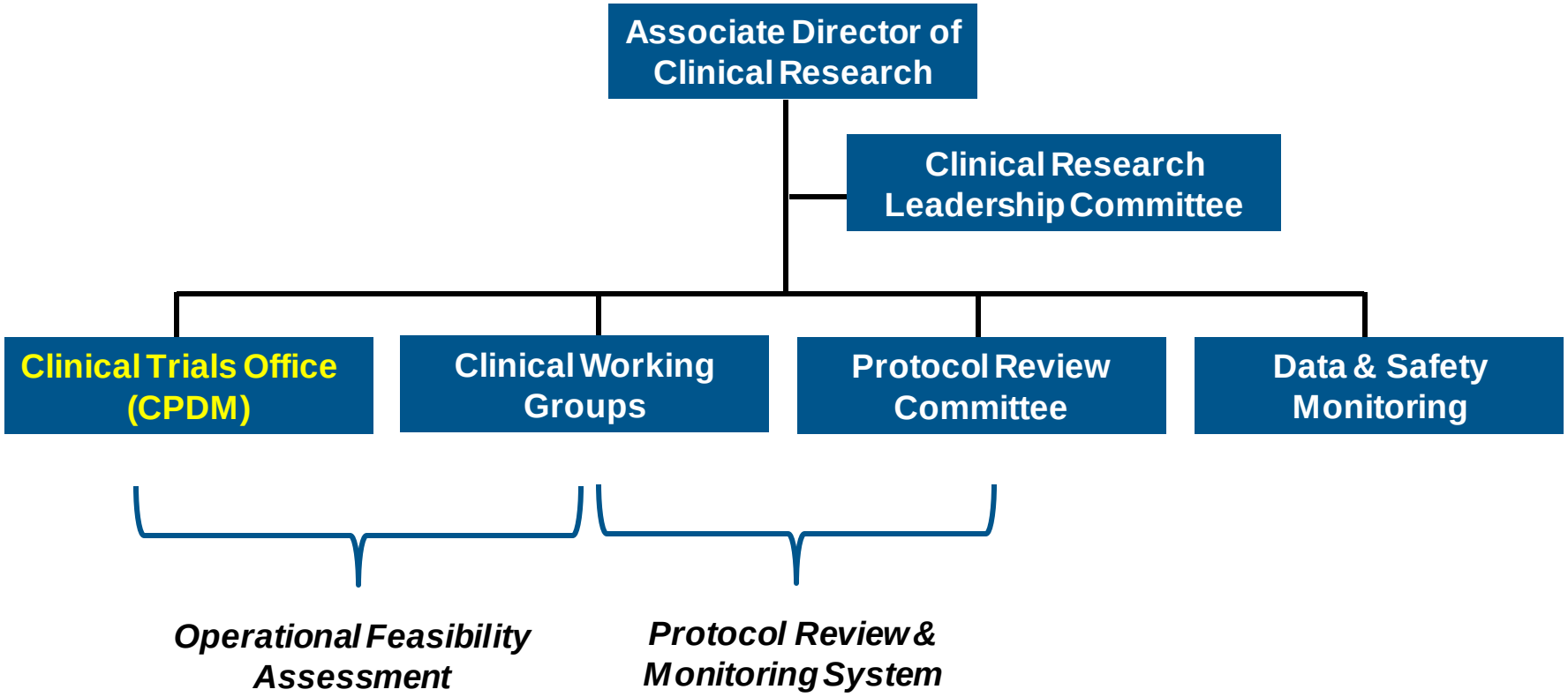
CLINICAL PROTOCOL & DATA MANAGEMENT

Typical Cancer Center Clinical Research Infrastructure



Expectations of the CTO/CPDM

- **Provides *central* management and oversight functions for coordinating, facilitating, and reporting on cancer-relevant clinical studies for the institutions that define the center**
- **Serves as the *central* location of all cancer protocols and maintains a centralized database of study-specific data (CTMS)**
  - Accrual reports on the inclusion of minority, women, children
  - Data Table 4 – Clinical Research Protocols
- **Oversees quality control functions (staff compliance monitoring and trial auditing)**
- **Delivers education and training services for clinical research support staff**
- **Facilitates submission of study data to CTRP**
- **Supports the PRMS and DSMC but is separate and distinct in its function**

CPDM Written Section

Required Attachments

Budget/Justification

Abstract

Specific Aims

Research Strategy

Part I. CPDM

Part II. Data and Safety Monitoring

Part III. Inclusion of Women and Minorities

Part IV. Inclusion of Children in Clinical Research

Sample Format Attachment

ACCRUAL TO CLINICAL RESEARCH STUDIES 2013-2017

Table 1. ACCRUAL TO ALL INTERVENTIONAL CLINICAL RESEARCH STUDIES 2013-2017

Calendar Year	2013	2014	2015	2016	2017
National Group	114	137	125	135	114
External Peer Review	7,737	6,335	416	1,469	508
Institutional (investigator-initiated)	533	456	246	535	274
Industry	172	210	251	209	208
Total Interventional Accrual	**8,556**	**7,138**	**1,038**	**2,348**	**1,104**

Table 2. ACCRUAL TO INTERVENTIONAL TREATMENT STUDIES 2013-2017

Calendar Year	2013	2014	2015	2016	2017
National Group	96	123	106	106	106
External Peer Review	33	25	35	58	33
Institutional (investigator-initiated)	147	139	220	213	231
Industry	157	202	248	206	203
Total Interventional Treatment Accrual	**433**	**489**	**609**	**583**	**573**

Table 3. ACCRUAL TO NON-INTERVENTIONAL STUDIES 2013-2017

Calendar Year	2013	2014	2015	2016	2017
National Group	236	287	259	304	118
External Peer Review	883	1,047	5,805	981	607
Institutional (investigator-initiated)	2,122	5,454	5,671	3,547	883
Industry	32	11	32	52	17
Total Non-Interventional Accrual	**3,273**	**6,799**	**11,767**	**4,884**	**1,625**

Sample Format Attachment 2A

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

Table 4. Demographics - Cancer Incidence in CENTER'S Catchment Area & Cancer Patient Population

		Demographics for CENTER Catchment Area 2016 (N=3,317,749*)		Demographics for Persons Newly Diagnosed with Cancer in CENTER Catchment Area 2014 (N=13,625**)		Newly Diagnosed Cancer Patients at CENTER 2017 (N=4,088***)	
Gender							
	Male	1,668,828	50%	6,604	49%	1,979	48%
	Female	1,648,921	50%	7,021	51%	2,109	52%
	Unknown	0	0%	0	0%	0	0%
Ethnicity							
	Hispanic or Latino (of any race)	1,111,446	34%	2,425	18%	958	23%
	Non-Hispanic	2,206,303	66%	11,200	82%	3,100	76%
	Unknown	0	0%	0	0%	30	<1%
Race							
	White	2,521,489	76%	11,786	87%	3,476	85%
	African American	182,476	6%	545	4%	171	4%
	Native American/ Alaskan Native	43,131	1%	136	<1%	17	<1%
	Asian	404,765	12%	1,090	8%	234	6%
	Hawaiian/Pacific Islander	19,907	<1%	68	<1%	142	3%
	More Than One Race	145,981	4%	0	0%	40	<1%
	Unknown	0	0%	0	0%	8	<1%

*Source
**Source
***Source

Sample Format Attachment 2B

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

Table 5. Accrual to CENTER Clinical Research Studies (2017)

	Interventional Treatment Accrual (N=573)		Interventional Non-Treatment Accrual (N=531)		Non-Interventional Accrual (N=1,625)	
Gender						
Male	288	50%	229	43%	610	38%
Female	285	50%	302	57%	1,014	62%
Unknown	0	0%	0	0%	1	<1%
Ethnicity						
Hispanic or Latino (of any race)	131	23%	355	67%	592	36%
Non-Hispanic or Latino	438	76%	175	33%	1,004	62%
Unknown	4	<1%	1	<1%	29	2%
Race						
White	461	80%	160	30%	1,078	66%
African American	15	3%	7	1%	42	3%
American Indian/Alaskan Native	2	<1%	1	<1%	10	<1%
Asian	45	8%	12	2%	90	6%
Hawaiian/Pacific Islander	1	<1%	1	<1%	10	<1%
More Than One Race	46	8%	11	2%	235	14%
Unknown	3	<1%	339	64%	160	10%

CPDM Budget/Justification

- **Appropriate Cost Inclusions:**
  - CTO medical and administrative leadership effort
  - CTO staff positions that speed protocol preparation, revision, and activation:
    - Dedicated trial activation staff
    - Staff within the legal and/or contracting office devoted to negotiating Center's clinical trial agreements
  - Staff with responsibilities relevant to NCI CTRP
  - CTO IT support for the generation of CCSG-relevant data
  - Staff providing education and quality control for the Center's study portfolio
  - DSMC chair and administrative coordinator effort

- **Inappropriate Cost Inclusions:**
  - Staff supporting clinical coordination, data entry, etc.
  - Patient care costs
  - Staff supporting pre/post award budget management and coverage analysis

CPDM Budget/Justification

Centers may consider including a table demonstrating the breakdown of the CPDM budget

Clinical Trials Office Budget and CCSG Request

Income Source	CCSG Year 05 (FY18)	Percent of Total	Proposed CCSG Year 06 (FY19)	Proposed Percent of Total
CCSG	$300,379	2%	$419,576	3%
Institutional	$550,000	4%	$550,000	4%
Cost Recovery	$11,190,897	88%	$11,526,624	88%
Other Grants	$669,893	6%	$720,889	5%
Total Operating Budget	$12,741,166	100%	$13,217,087	100%

Of note, the cost recovery category consists of the fees received from industry-supported studies as well as per-subject accrual reimbursement rates provided by various NCTN groups that are recovered by the Center to offset operational budget expenses. The Center funds the costs that are not covered by these chargebacks.

CPDM Abstract & Specific Aims

- **Abstract**
  - Limit: 30 lines
  - Summary of Parts I-IV

- **Specific Aims**
  - Limit: 1 page
  - Include aims for Parts I-IV

CPDM Written Section

Required Attachments

Budget/Justification

Abstract

Specific Aims

Research Strategy (12 pages)

Part I. CPDM (~8 pgs)

Part II. Data and Safety Monitoring (~2 pgs)

Part III. Inclusion of Women and Minorities (~1-1.5 pgs)

Part IV. Inclusion of Children in Clinical Research (~0.5 pg)

Typical Content
Part I. CPDM

- **CPDM achievements during CCSG project period (or last 3 years for new centers)**
- **Itemized response to previous CCSG reviewer critiques**
- **Characterization of the Center's clinical research activity, examples may include (utilize impactful graphics):**
  - Reduced time to study activation
  - Increase in volume of IIS trials/accrual demonstrating center's prioritization (IIS > NCTN > Industry)
  - Growth in early phase trial activity
  - Increase in accrual of minorities
  - Increase to interventional treatment studies

Typical Content Part I. CPDM

- **Organization and Management Structure**
  - Include organization chart outlining functional units within CTO including FTE counts
  - Characterize each functional unit
  - Describe qualifications and responsibilities of CTO medical director and administrator

- **Services**
  - Regulatory and study activation (operational feasibility assessments, clinical working group admin support, PRMS, IRB, budget, and contract support)
  - IIS protocol development and study management (including multi-site) support
  - Patient screening, enrollment, and coordination of study-related patient care and data management
  - Quality control functions (e.g., monitoring and auditing)
  - Training and education
  - Communications (internal and external)

Typical Content Part I. CPDM

- **Environment**
  - CTO location(s)
  - IT capabilities (e.g., CTMS, eRegulatory, EDC)

- **Policies**
  - Standard operating procedures
  - Research billing compliance
  - Data and safety monitoring

- **Governance, Oversight, Strategic Planning, and Evaluation**
  - Describe relevant Center leadership committees (*i.e.,* Clinical Research Leadership Committee)

- **Future Plans**

CPDM Review Criteria

1. How effective is CPDM in centralizing, managing, and reporting on the cancer clinical trials of the Center?

2. How effective are the quality control functions and training services offered by the CPDM?

3. Does the CPDM successfully identify impediments to successful accrual of patients to the Center's clinical trials and provide remedies?

4. How reasonable is overall accrual, based on the nature/type of the individual trials supported?

5. To what extent does CPDM help to assure timely initiation and completion of clinical trial activities?

Typical Content Part II. DSM

- This section summarizes (~2 pages) the formal DSMP, including the DSMC that is charged with overseeing all Center-driven IIS, which should be submitted and approved (reapproved) prior to CCSG submission

- DSM will be the focus of a future Huron webinar

Typical Content Parts III & IV. Women, Minorities, & Children

- These sections summarize (~1.5-2 pgs) data presented in the 2A & 2B attachments
- Area(s) with deficiencies need to have a detailed plan outlined
- Inclusion of Minorities, Women, and Children will be the focus of a future Huron webinar

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SITE VISIT PREPARATION & OTHER HELPFUL TIPS

Site Visit (4-6 Months Post Submission)

- **Meet with Center leaders to confirm site visit agenda and time allotments**
  - CPDM presentation typically 10 min with 10 min Q&A; presented by CTO Medical Director or Associate Director of Clinical Research
  - CPDM may be presented in combination with PRMS, DSMC, and/or Inclusion of Women, Minorities, and Children for up to 20 mins with 20-min Q&A
- **Plan for a 30-min breakout session with selected CCSG reviewers to discuss CPDM, PRMS, and DSM in greater detail. Nearby conference space will need to be secured.**

Site Visit (4-6 Months Post Submission)

- Centers often include CTO poster
- Have available biosketches for PRMS, DSMC, and CTO leadership; SOPs; and supporting materials demonstrating CPDM services (*e.g.*, IT solution demonstration, external communications)
- Updated clinical research data including accrual since what was reported in written application and updated Data Table 4


Q&A
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Future Thought Leadership Opportunities

- Data and Safety Monitoring
- Protocol Review and Monitoring System
- Inclusion of Minorities, Women, and Children in Clinical Research
- Data Tables 3 & 4

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THANK YOU!
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