



A CENTRALIZED AND AUTOMATED PROCESS TO COLLABORATIVELY MANAGE ACTION ITEM FOLLOW UP IN MULTI-SITE CLINICAL TRIALS

Moderator: Carmen Rosa, MS, National Institute on Drug Abuse, Center for Clinical Trials Network

Presenters: Mitra Lewis, Phoebe Gauthier, Dagmar Salazar, Ashley Case

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Disclosures

No relevant disclosures

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Introduction



National Drug Abuse Treatment Clinical Trial Network (CTN)

- Clinical research in prevention, treatment and implementation interventions for individuals and communities impacted by substance use
- Collaboration between investigators, clinicians and health systems across the US
- Manage a large portfolio of multi-site studies in >100 sites
- Contracts to Emmes as Clinical Coordinating Center (CCC) and Data and Statistics Center (DSC)

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Clinical Trial Network (CTN)



Appalachian Node
 University of Pittsburgh
 West Virginia University

Big South/West Node
 UT Southwestern Medical Center
 UT Health Science Center at San Antonio
 University of California, Los Angeles

Clinical Coordinating Center
 The Emmes Corporation

Data & Statistics Center
 The Emmes Corporation

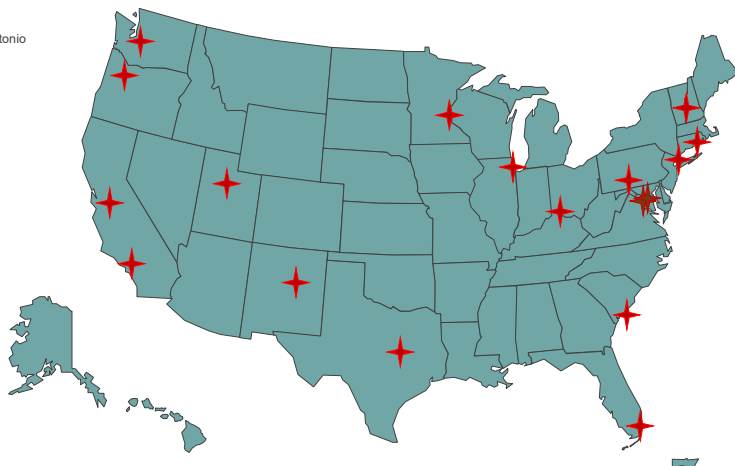
Florida Node Alliance
 University of Miami
 Columbia University

Great Lakes Node
 University of Illinois Chicago
 RTI International

Greater Intermountain Node
 University of Utah

Greater Southern California Node
 University of California, Los Angeles

Health Systems Node
 Kaiser Foundation Hospitals



New England Consortium
 Yale University
 McLean Hospital

New York Node
 New York University
 New York State Psychiatric Institute

Northeast Node
 Dartmouth College

Northstar Node
 Hennepin Healthcare Research Institute

Ohio Valley Node
 University of Cincinnati

Pacific Northwest Node
 University of Washington
 Washington State University

Southwest Node
 University of New Mexico

Southern Consortium Node
 Medical University of South Carolina

Western States Node
 Oregon Health & Science University
 Stanford University

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CTN Research Portfolio



Studies that address:

- Prevention & treatment strategies
- Enhancing/increasing treatment capacities/access
- Implementation & Health Services Research
- Data science
- Optimize effective interventions
- Ancillary/platform studies, secondary data analysis

~ 26,800 participants recruited

27%	African American
15%	Hispanic
10%	Multi-race/Other
3%	Asian American
1%	American Indian/Alaska Native
40%	Female

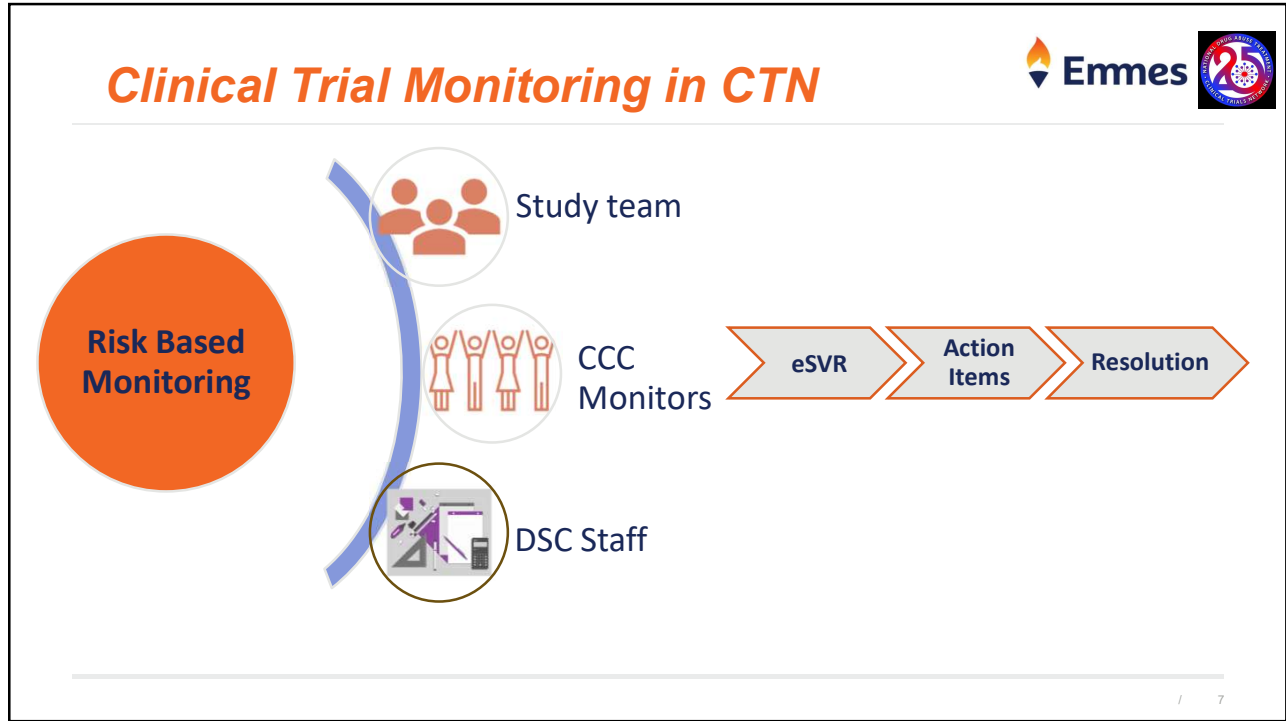
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Trial Oversight



- Monitoring trial performance for protection of participants and quality data is central to CTN
- Identification and resolution of action items (AIs) is key aspect
- Need for corrective actions to prevent re-occurrences
 - Collaboration between CCC, DSC, study leadership, sites, and managers
 - Reporting to NIDA and study DSMB that oversee study progress
- A risk-based monitoring approach works well
 - Centralized, include remote and in-person monitoring
 - Automated process to identify and follow up AIs


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Presenters/Panelists

- **Dagmar Salazar, MS (The Emmes Company – CCC)**

 - Initial development of centralized process
- **Ashley Case (The Emmes Company – DSC)**

 - Development of automated eSVR with action items
- **Phoebe Gauthier, MA, MPH (The Emmes Company – CCC/DSC)**

 - Site performance monitoring by study leadership team
- **Mitra Lewis, MS (The Emmes Company – CCC)**

 - Centralized action items follow up and staff responsibilities

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 Emmes




DAGMAR SALAZAR, MS

Initial Development of Centralized Process

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Site Visit Reports - Background



Prior to 2014 used MS Word templates for visit reports and action items

eSVR was launched in August 2014

 Emmes

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eSVR Project Review



- Conducted review in 2017, 3 yrs post launch

Asked ourselves 3 core questions



1. What is going well?
2. What areas could be improved?
3. What should we be doing differently and why?

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eSVR Project Review



Core Q1: What was going well?

- Met primary goals for implementing eSVR*
- Increased efficiency with writing, reviewing, approving, and distributing site visit reports*



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eSVR Project Review



Core Q2: What areas could be improved?

- Despite use of eSVR, a manual process was used for action items.
- Issues Encountered:
 - Coordinating center staff were noncompliant with timeline for distribution of action item memos
 - Delayed resolution of action items by the site

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eSVR Project Review



Core Q3: What should we be doing differently and why?

Proposal: Leverage data entered in eSVR to develop an automated monthly AI report to be distributed to sites including:

- *All outstanding action items*
- *All action items resolved in the past month*





Passing of the Opioid Crisis Legislation

- *Anticipating an expansion of portfolio (x2-3), which would exacerbate issues encountered*


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Action Item Tracking – Revamp



- Working Group Assembled
- In 2018, a series of meetings with various stakeholders, met to:
 - Develop specifications for the monthly Action Item report
 - Draft email text for automated email report
 - Outline distribution list for internal and external staff
 - Develop workflow for the Action Item Tracking Procedures



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Action Item Tracking – Revamp

- Evaluated the MS Word Action Item Memo Template
 - Separated memo into 3 parts
 - Distribution list
 - Instruction to site
 - List of Action Items

MEMORANDUM
Via e-mail

TO: ██████████ Principal Investigator
██████████ Research Coordinators

FROM: Dagmar Salazar, MS, CCC Protocol Specialist

SUBJECT: Status of Action Items Identified at ██████████ on CTN Protocol ██████████

The purpose of this memorandum is to provide the status of the action items identified during the interim monitoring visit(s).

The table below indicates the status of action items noted as "Pending" on the site visit report(s). Please complete any unresolved action items within 2 weeks of this memo. Items noted as "pending next visit" do not need attention at this time and will be verified on-site at the next monitoring visit. Thank you for your attention to this matter.

#	Date Action Item Identified	Description of Action Item	Details of the Resolution	Current Status	Verified by CCC (Date/Staff Initials)
1.	3/24/2016	Site staff to recontact participant 0123 at the next scheduled visit, if participant is still active in the study.	To be reviewed on-site by CCC monitor	Pending, Next Visit	5/11/2015 DS
2.	3/24/2016	Also, site staff is to report recontact error as a protocol deviation in the EDC and to their local IRB, as applicable.	Protocol Deviation entered in EDC	Resolved	5/11/2015 DS

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Action Item Tracking – Revamp



- Evaluated action item data in eSVR

Report Section	Item Number	Responsible Party	Action	Date Identified	Action Item Due Date	Date Resolved	Memo Due Date
Data-CRF - Source Document Review	A1	Site Staff	The CRA identified 24 data discrepancies during the visit conducted on 07/13-14/2023. No discrepancies	07/14/2023	09/11/2023	09/18/2023	8/28/2023
Data-CRF - Source Document Review	B4	Site Staff	The CRA identified twenty-four data discrepancies and entered seven manual queries during the visit	07/14/2023	09/11/2023	07/26/2023	8/28/2023

- Action items identified by monitor at each site visit & recorded in the eSVR
- Each action item in the eSVR includes:
 - a description of the finding and/or observation
 - corrective action
 - a responsible party
 - due date

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Action Item Tracking – Revamp



- Created mock-up of action item report/listing including
 - Columns needed
 - Specification for excel layout
- Provided to the data management group

Site	Protocol	Report Section	Item Number	Responsible Party	Action	Monitor 1	Date Identified	Action Item Due Date	Date Resolved
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Original specifications for listing of AIs for the monthly report

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Action Item Tracking – Revamp



- Email text for inclusion with automated monthly action item email report
- Aim: include concise total summary of unresolved vs closed action items, with instruction for closing action items and filing documentation

Sample Report

Hello [REDACTED]

The purpose of this monthly NIDA CTN-0 [REDACTED] Action Item Summary Report is to provide you with the status of action items that were identified at past site monitoring visit(s).

Currently your site has:

- 2 Unresolved Action Items,
- 30 Closed Action Items.

The CCC instructs the site staff to complete any Unresolved Action Items as soon as possible.

If you have any questions or concerns, please contact the assigned Protocol Specialist or Beth Jeffries at bjeffries@emmes.com of the Clinical Coordinating Center.

Reminder: A copy of this report should be filed in section 10.5 (Sponsor Monitor Reports) of your site's regulatory binder.

Thank you,
NIDA Clinical Coordinating Center (CCC)



Action Item Tracking – Revamp



- **REFINED** email text by improving site instruction (Reply all) to communicate completion of Action Items

Hello [REDACTED]

The purpose of this monthly NIDA CTN-0 [REDACTED] Action Item Summary Report is to provide the status of action items that were identified at past site monitoring visit(s).

Currently your site has:

- 0 Unresolved action items
- 79 Closed action items

Each Action Item identified at a site is assigned a "Responsible Party" (e.g., site staff, Emmes staff). The Clinical Coordinating Center (CCC) instructs the site staff to complete any Unresolved Action Items assigned to "site staff" as soon as possible and **Reply All** to this email when complete.



Next, the CCC will add a resolution date for item(s) confirmed complete. If you have any questions, concerns, or note a discrepancy in the attached report, please **Reply All** to this email.

Reminder: Please file a copy of this report in the Sponsor Monitor Reports section of your site's regulatory binder.

Thank you,
NIDA Clinical Coordinating Center (CCC)



Internal Action Item Status Review Timeline

Developed internal workflow for the action item tracking procedures



Action	Protocols assigned to the 2 nd Friday	Protocols assigned to the 4 th Friday
Step 1: DSC generates the Excel reports for internal review daily	Reports updated daily	Reports updated daily
Step 2: AIC will begin the Action Item review process	30 th – 2 nd	14 th –16 th
Step 3: AIC will email internal staff with the AI Excel link	By the 3 rd	By the 17 th
Step 4: Internal review of AI status must be completed	By the 9 th	By the 23 rd
Step 5: AIC will review DSC reports against Action Item summary email sent to internal staff	By the 10 th	By the 24 th
Step 6: Automated email/report distributed	On the 11 th	On the 25 th

S	M	T	W	T	F	S
29	30	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

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Conclusions

Importance of Project Reviews

- **Assess if goal(s) are being met**
 - ✓ *Implementation of an eSVR within an EDC increased efficiency with writing, reviewing, approving, and distributing site visit reports*
- **Identify areas that can be improved**
 - ❖ *Non-compliance (CCC & Sites) with Action Item Resolution*
- **Develop new goals to increase the success of the project**
 - ❑ *Automated monthly Action Item report*

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ASHLEY CASE

Leveraging Electronic Data Capture System to Automate Notifications

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Existing electronic record of Action Items



Site monitored: [redacted]
Protocol monitored: [redacted]
Visit start date: 05/01/2024

Executive Summary Facilities and Staffing Regulatory Site Status Data-CRF - Source Document

Clinical/Research Laboratory Area Study Investigational Product Study Investigational Product 2 SI

Safety was not reviewed at this visit.

A. Reported SAEs
1 Protocol defined, SAEs reviewed at this visit.
If *Yes* [List Here](#)
a All SAEs accurately reported in Advantage eClinical.

B. Reported AEs
1 Protocol defined adverse events reviewed at this visit.
If *Yes* [List Here](#)
a All AEs accurately reported in Advantage eClinical.

Delete	Action #	Item Number	Report Section	Responsible Party	Action	Date Identified	Due Date
<input type="checkbox"/>	1	SAE#4	Safety	Site Staff	Split SAE into 2 separate SAEs	05/01/2024	05/10/2024
<input type="checkbox"/>	2	SAE#9	Safety	Other- (specify)	Medical monitor to provide guidance on how to list outcome	05/01/2024	05/30/2024

[Add](#) [Save](#) [Cancel](#)

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Existing electronic record of Action Items



Report Section	Item Number	Responsible Party	Action	Date Identified	Action Item Due Date	Date Resolved	Memo Due Date
Clinical/Research Laboratory Area	#2	Site Staff	Expired dipsticks must be removed for supplies	05/01/2024	05/02/2024	05/02/2024	5/16/2024
Clinical/Research Laboratory Area	Log1	Site Staff	Updated temp log needed on Freezer 1	05/01/2024	05/02/2024		5/16/2024
Clinical/Research Laboratory Area	SOP#7	Site Staff	Specimen SOP is missing approval signature	05/01/2024	05/03/2024		5/17/2024
Data-CRF - Source Document Review	Form1	Site Staff	Form A was captured on paper and needs to be	05/01/2024	05/02/2024		5/16/2024
Safety	SAE#4	Site Staff	Split SAE into 2 separate SAEs	05/01/2024	05/10/2024		5/24/2024
Safety	SAE#9	Other- (specify)	Medical monitor to provide guidance on how to list	05/01/2024	05/30/2024		6/13/2024
Safety							

Save Cancel

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Specifications for Development





- **Studies and sites**
- **Email specifics**
- **Manipulating EDC report into 'paper' report**
- **Internal Action Item Report**



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Specifications for Development

- Studies and sites
- Email specifics
- Manipulating EDC report into 'paper' report
- Internal Action Item Report

From: mlewis@emmes.com <mlewis@emmes.com>
Sent: Friday, April 26, 2024 5:17 AM
To:
Cc:
Subject: NIDA CTN- [redacted] Action Item Summary Report – [redacted]

Hello [redacted]

The purpose of this monthly NIDA CTN- [redacted] Action Item Summary Report is to provide the status of action items that were identified at past site monitoring visit(s).

Currently your site has:
 12 Unresolved action items
 149 Closed action items

Each Action Item identified at a site is assigned a "Responsible Party" (e.g., site staff, Emmes staff). The Clinical Coordinating Center (CCC) instructs the site staff to complete any Unresolved Action Items assigned to "site staff" as soon as possible and **Reply All** to this email when complete.

Next, the CCC will add a resolution date for item(s) confirmed complete. If you have any questions, concerns, or note a discrepancy in the attached report, please **Reply All** to this email.



Reminder: Please file a copy of this report in the Sponsor Monitor Reports section of your site's regulatory binder.

Thank you,
 NIDA Clinical Coordinating Center (CCC)

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Specifications for Development

Group	Protocol	SiteNum	FullName	Email
Site	ABC	99999	Jane Smith	jane.smith@demo.com
Site	ABC	99999	Rob Robinson	RRobinson@demo.com
Site	ABC	98888	Jane Smith	jane.smith@demo.com
Site	ABC	98888	John Johnson	jjohnson@demo.com
Site	ABC	98888	Bob Roberts	broberts@demo.com
Site	XYZ	97777	Will Williams	will.williams@demo.com
Site	XYZ	97777	John Johnson	John@demo.com

Site Contacts (TO) Study Leadership (CC) +

Group	Protocol	SiteNum	FullName	Email
Emmes	ABC	All Sites	Ashley Case	acase@demo.com
Emmes	ABC	All Sites	Dagmar Salazar	dsalazar@demo.com
Study Leadership	ABC	All Sites	Mitra Lewis	mlewis@demo.com
Emmes	XYZ	All Sites	Carmen Rosa	croso@demo.com
Study Leadership	XYZ	All Sites	Pheobe Gauthier	pgauthier@demo.com

Site Contacts (TO) Study Leadership (CC) +

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Specifications for Development

- Studies and sites
- Email specifics
- **Manipulating EDC report into 'paper' report**
- Internal Action Item Report








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Specifications for Development

DEMO SITE
Action Items (AIs) Monthly Report
01MAY2024
SITE #: Demo Site
Unresolved AIs: 3; Resolved AIs: 3
Total AIs Issued: 6

Date Action Item Identified	Action Item Description	Responsible Party	Action Item Due Date	Status	Date Verified as Resolved by CCC
05/01/24	Updated temp log needed on Freezer 1	Site Staff	05/02/24	Unresolved	
05/01/24	Specimen SOP is missing approval signature	Site Staff	05/30/24	Unresolved	
10/02/23	Review corrected source at next visit	CCC – Site Monitor	10/30/23	Unresolved	
05/01/24	Expired dipsticks must be removed for supplies	Site Staff	05/02/24	Resolved	05/02/24
10/02/23	Submit updated FWA to Emmes	Site Staff	10/15/23	Resolved	02/01/24
10/02/23	Send more urine cups	CCC – Protocol Specialist	10/30/23	Resolved	01/18/24

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Specifications for Development



- Studies and sites
- Email specifics
- Manipulating EDC report into 'paper' report
- **Internal Action Item Report**

CTN-0xxx
Action Item Listing Report
Generated: Thursday, May 16, 2024 12:34 PM
Site: ABC SITE

Protocol	Site	Report Section	Item Number	Responsible Party	Action	Monitor 1	Date Identified	Action Item Due Date	Report Locked Status	Date Resolved
ABC	12345	Facilities and Staffing	6	Site Staff	The Staff Delegation of Responsibilities and Signature Log is currently incomplete and missing the endorsement date. The site staff will fill in the date upon endorsement, submit the updated log to the CCC for upload to Veeva Vault and file it in the site regulatory binder. This action item is not required to be completed prior to site endorsement.	Sally Smith	04/22/24	05/13/24	Locked	
ABC	12345	Regulatory	5	Site Staff	The final Site Initiation/Endorsement Readiness Checklist has not yet been received by the CCC. The site staff have been instructed to submit checklist to the CCC upon completion and file it in the site regulatory binder. This action item is not required to be completed prior to site endorsement.	Sally Smith	04/22/24	05/13/24	Locked	
ABC	12345	Regulatory	5	Site Staff	During the review of the regulatory file, the CRA noted that a copy of the CV for Dr. Bart (PI) was not filed in the the site regulatory file but was submitted to the CCC. The CRA instructed the site staff to file a copy of the CV in the site regulatory binder. This action item is not required to be completed prior to site endorsement.	Sally Smith	04/22/24	05/13/24	Locked	04/24/2024

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Testing and Development



- **Refinement of report**
- Testing the automation



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Testing and Development



CTN-0
Action Items (AIs) Monthly Report
26APR2024 ET

Unresolved AIs: 12; Resolved AIs: 149
Total AIs Issued: 161

Date Action Item Identified	Action Item Description	Responsible Party	Action Item Due Date	Status	Date Verified as Resolved by CCC
		Site Staff		Unresolved	

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Testing and Development



Date Action Item Identified	Action Item Description	Responsible Party	Action Item Due Date	Status	Date Verified as Resolved by CCC
05/01/24	Updated temp log needed on Freezer 1	Site Staff	05/02/24	Unresolved	
05/01/24	Specimen SOP is missing approval signature	Site Staff	05/30/24	Unresolved	
05/01/24	Expired dipsticks must be removed for supplies	Site Staff	05/02/24	Resolved	05/02/24
10/02/23	Submit updated FWA to Emmes	Site Staff	10/15/23	Resolved	02/01/24
10/02/23	Review corrected source at next visit	CCC - Site Monitor	10/30/23	Unresolved	
10/02/23	Send more urine cups	CCC - Protocol Specialist	10/30/23	Resolved	

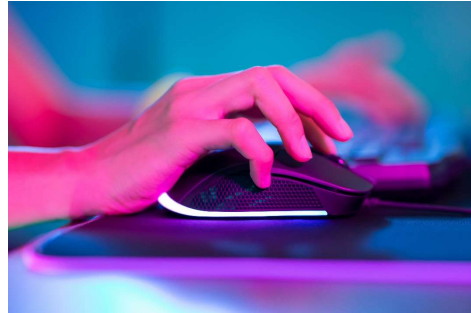
Date Action Item Identified	Action Item Description	Responsible Party	Action Item Due Date	Status	Date Verified as Resolved by CCC
05/01/24	Updated temp log needed on Freezer 1	Site Staff	05/02/24	Unresolved	
05/01/24	Specimen SOP is missing approval signature	Site Staff	05/30/24	Unresolved	
10/02/23	Review corrected source at next visit	CCC - Site Monitor	10/30/23	Unresolved	
05/01/24	Expired dipsticks must be removed for supplies	Site Staff	05/02/24	Resolved	05/02/24
10/02/23	Submit updated FWA to Emmes	Site Staff	10/15/23	Resolved	02/01/24
10/02/23	Send more urine cups	CCC - Protocol Specialist	10/30/23	Resolved	01/18/24

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Testing and Development



- Refinement of report
- **Testing the automation**



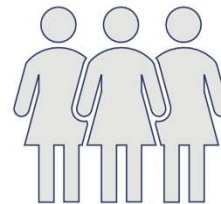
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Limitations of Automated Process




- **Staffing changes at site and/or coordinating center still relied on manual input from study managers**




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Limitations of Automated Process

Emmes 


- Staffing changes
- eSVR delayed resolution





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Limitations of Automated Process

Emmes 

- Staffing changes
- eSVR delayed resolution
- Program doesn't fire



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Conclusions



 

- **Using technology to...**
 - Increase efficiencies
 - Reminders to site staff
- **More studies**



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PHOEBE GAUTHIER, MA, MPH

SITE AND STUDY LEADERSHIP PERSPECTIVES ON AN AUTOMATED ACTION ITEM PROCESS

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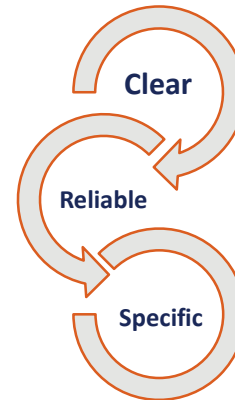
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Needs of Sites and Study Leadership



- Expanding portfolio of substance use disorder studies increases demands on sites and study leadership teams
- Increased demands = increased need for efficiency

Action Item process must be:



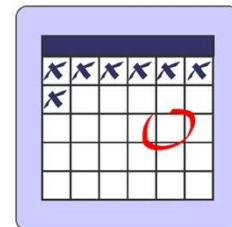
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Participating Sites



- **Need for timely communication of action items**
 - Timing is critical during study activation phase
 - Motivation to launch stemming from institution, study leadership team, and Sponsor expectations
- **Automation allows for a faster turnaround of vital information**
- **Expected and predictable timing for action item report**



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Impact of Automation – Sites



- **No benefits are lost that may have been present in a manual approach**
 - Automatic emails are addressed from Study Manager
 - Email arrives in inbox (not “other” folder, or blocked)
 - Distribution list is consistently updated to ensure comprehensive communication to all team members
- **Site teams may be unaware of the switch to automation**
 - Action items are specific, detailed, and highly individualized to the site
 - No change in level of content communicated

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Sample Action Item Email



From: mlewis@emmes.com <mlewis@emmes.com>
Sent: Friday, April 26, 2024 5:17 AM
To:
Cc: Mitra Lewis <mlewis@emmes.com>; nidaccadmin <nidaccadmin@emmes.com>; ctmonitors <ctmonitors@emmes.com>; crosa_at_nida.nih.gov <crosa@nida.nih.gov>
Subject: NIDA CTN-~~0000~~ Action Item Summary Report - [REDACTED]

Hello [REDACTED]

The purpose of this monthly NIDA CTN-~~0000~~ Action Item Summary Report is to provide the status of action items that were identified at past site monitoring visit(s).

Currently your site has:

- 12 Unresolved action items
- 149 Closed action items

Each Action Item identified at a site is assigned a "Responsible Party" (e.g., site staff, Emmes staff). The Clinical Coordinating Center (CCC) instructs the site staff to complete any Unresolved Action Items assigned to "site staff" as soon as possible and **Reply All** to this email when complete.

Next, the CCC will add a resolution date for item(s) confirmed complete. If you have any questions, concerns, or note a discrepancy in the attached report, please **Reply All** to this email.

Reminder: Please file a copy of this report in the Sponsor Monitor Reports section of your site's regulatory binder.

Thank you,
 NIDA Clinical Coordinating Center (CCC)

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Sample Action Item Report



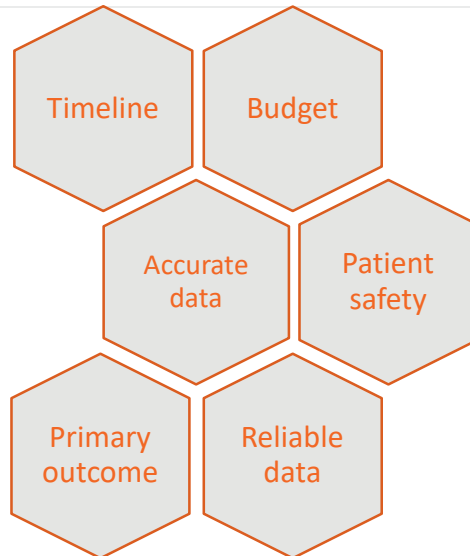
Date Action Item Identified	Action Item Description	Responsible Party	Action Item Due Date	Status	Date Verified as Resolved by CCC
08/31/23	The temperature logs for the [REDACTED] storage area are only provided on a monthly basis so the CRA was unable to review the temperature logs from 08/01/2023 through 08/30/2023. The site staff was instructed to provide the August temperature logs for the [REDACTED] storage area when they become available.	Site Staff	09/28/23	Unresolved	
08/31/23	The CRA noted that injection site T was used at visit M02 and visit M04 for participant 00014. The site staff is to enter a protocol deviation in Advantage eClinical for the repeat use of an injection site within an 8-week timeframe, and report to the IRB if required.	Site Staff	09/28/23	Unresolved	
05/22/20	Evidence of [REDACTED] IRB site approval letter for version 6.0 of the protocol is missing from Veeva Vault. The site staff have been instructed to upload a copy of the letter to Veeva Vault. This action is required to be completed prior to site endorsement.	Site Staff	06/19/20	Resolved	05/26/20

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Study Leadership Team



- Highly invested in site performance
- Action item reports provide needed insight into study operations on the ground



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Impact of Automation – Leadership Team



- **Many benefits experienced by sites are extended to study leadership**
 - Recognized, known sender
 - Timely, accurate, specific
 - Communication to all parties
- **Added benefit:**
 - All site reports across a given protocol received on same day
 - Allows for cross-site comparison
 - *Understanding of what is “normal”*

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Action Items Across the Study Lifecycle



Site Activation

- Staff experience, institutional support, physical resources
- Gaps in training

Implementation

- Feasibility of planned procedures
- Site performance

Site Closure

- Data completeness
- Regulatory compliance

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Conclusions



- Participating sites and study leadership teams have increasing demands as the network portfolio expands
- Increased need for efficiency amid timeline, budget, and resource constraints
- Action items remain critical to success of each trial
- Automation improves reliability, timeliness, and communication
- Increases the utility of the report, especially for study leadership

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MITRA LEWIS, MS

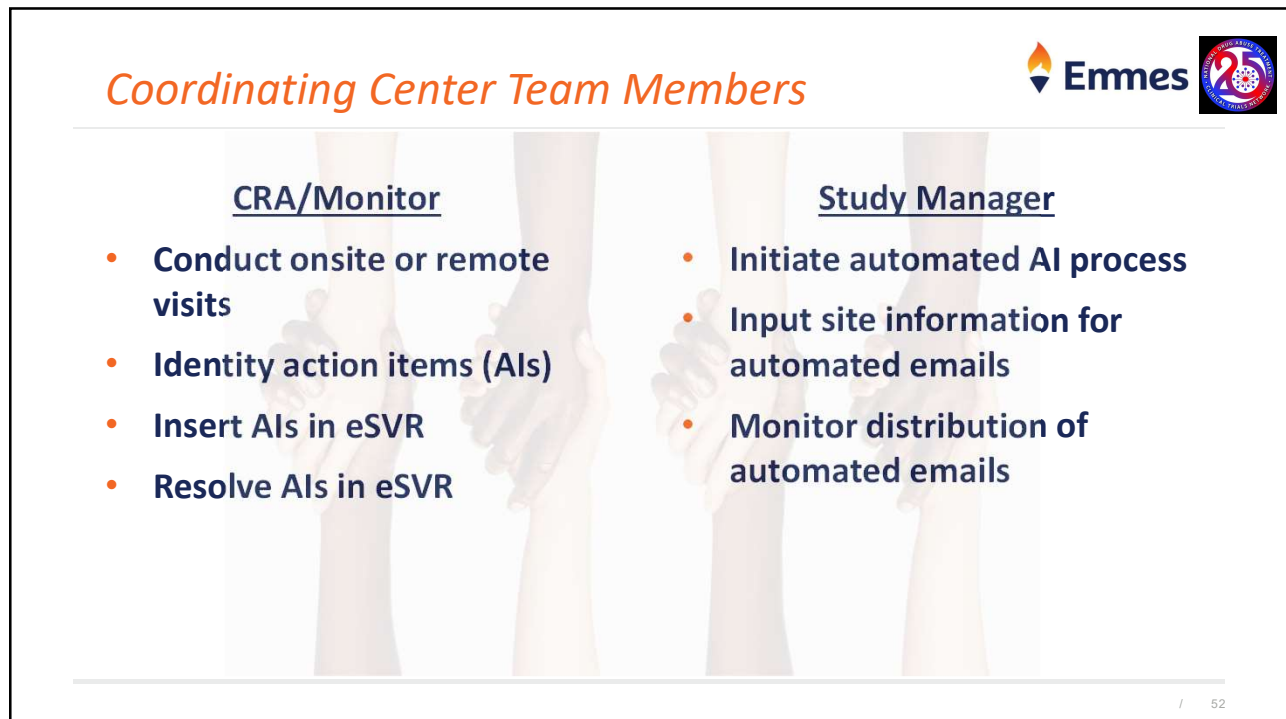
THE ROLE OF THE CLINICAL COORDINATING CENTER

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Coordinating Center Team Members



The Action Item Coordinator

- Central staff member for all studies using automated process
- Facilitate the overall process for automated action item follow up
- Communicates with both study managers and monitors
- Reviews action item reports for all active studies
- Distributes reminder email to CCC staff with summary of open action items, by site, for each active study

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Study Start Up



Step 1 Email Monitoring Manager

- Protocol name and number
- Number of sites

Step 2 Manager will assign to 2nd or 4th Friday

Step 3 Study Manager will

- submit request to data center to initiate action item reports and emails
- inform Action Item Coordinator of protocol and Friday assignment
- populate email distribution list

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Email Distribution List



- **Site contacts (TO) tab will appear on the “To” line of the email**
 - Site staff: Principal Investigator and RC/RA
- **Staff listed within the “Leadership Contacts (CC)” will appear on the “CC” line of the email**
 - Coordinating Center staff: study manager, monitors, study team alias, TMF staff, administrative staff
 - CTN Network staff: Scientific Officer(s)
 - Leadership team: Lead Investigator, Project Coordinator
- **Broken out by protocol and site**

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Internal Action Item Status Review Process



save a copy of the report to the specified folder and add file extension

use the report to tabulate the summary using the filter feature within Excel

email the link to the internal team for review, along with a summary of report status and action item status

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Internal Action Item Status Review Process



Protocol ABCD
Action Item Listing Report
Generated: Monday, April 22, 2024 9:28 AM
Site: 12345

Protocol	Site	Report Section	Item Number	Responsible Party	Action	Monitor 1	Date Identified	Action Item Due Date	Report Locked Status	Date Resolved
ABCD	12345	Site Status	C4	Site Staff	The CRA noted that PATID 00027 signed the unstamped version of the consent addendum. Site staff were instructed to have the participant re-sign on the IRB-stamped version during the next study visit.	Monitor Name	10/12/23	11/09/23	Locked	
ABCD	12345	Data-CRF - Source Document Review	B4	Site Staff	The CRA noted that previously identified monitoring data discrepancies have not been resolved. The site staff were instructed to resolve all outstanding monitoring data discrepancies, as appropriate.	Monitor Name	10/12/23	11/09/23	Locked	
ABCD	12345	Site Status	C4a	Site Staff	The CRA noted PATID 00013 did not sign the stamped version of the consent addendum. Site staff were instructed to have the participant re-consent on the stamped version during the next visit.	Monitor Name	08/17/23	09/14/23	Locked	
ABCD	12345	Facilities and Staffing	2	Site Staff	The Site Visitor Log was not signed at the SIV as the visit was conducted remotely. The Site Visitor Log was emailed to the CCC CRA on 05/27/2021. The Site Visitor Log will be signed by the CCC CRA and then sent to the site to sign and maintain in the site regulatory binder. This action item is not required to be completed prior to site endorsement.	Monitor Name	05/27/21	06/24/21	Not locked	
ABCD	12345	Regulatory	5	Site Staff	The CCC CRA noted that a fully executed revised subcontract between the site and XXX, for the receipt of the medication, was missing from the site regulatory binder. Site staff were directed to file the fully executed subcontract in their site regulatory binder once it has been received. This action item is required to be completed prior to endorsement.	Monitor Name	05/27/21	06/24/21	Locked	06/02/2021

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Internal Action Item Status Review Process



Sample Initial Email to the protocol CRA(s)

"Hello All,

We are looking to distribute the automated AI email/report to sites on **Friday [enter date]**. Please follow the link for the current listing of Action items to assess the status of the unresolved action items.

Once you have assessed the status of all respective unresolved action items you are responsible for, please enter the resolution date directly into eClinical and reply to this email for confirmation.

Study #1 →

CTN-0xxx [CRA name(s)]: "G:\NIDACCC\MONITORING\Action Item Follow Reports\file_name_of_AIC_Excel report"

No AIs unresolved. @[CRA name] Can you confirm?

Study #2 →

CTN-0xxx [CRA name(s)]: "G:\NIDACCC\MONITORING\Action Item Follow Reports\file_name_of_AIC_Excel report"

- Unlocked cells for sites xxxxx and xxxxx @[CRA Manager name]

Study #3 →

CTN-0xxx [CRA name(s)]: "G:\NIDACCC\MONITORING\Action Item Follow Reports\file_name_of_AIC_Excel report"



15 AIs unresolved. []

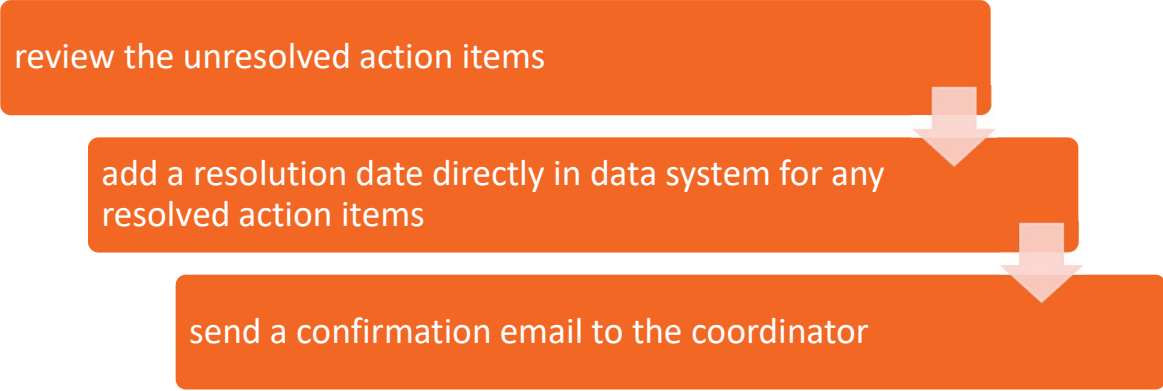
If possible, please complete or respond to this email before COB Wednesday [enter date]. Please let us know if you have any questions.

Thank you,
[AIC]"

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Internal Action Item Status Review Process





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graph TD
    A[review the unresolved action items] --> B[add a resolution date directly in data system for any resolved action items]
    B --> C[send a confirmation email to the coordinator]
  
```

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QC Monitoring the Action Item Process

Action Item Coordination will monitor process by:

- Comparing the original reports against the summary email to ensure that resolution dates have been added.
- Ensuring that reports have been locked.
- Ensuring that the monitor has confirmed that no updates are warranted.
- Following up with the monitor and manager by email if no response has been received to confirm no unresolved action items or no updates to the report have been made.



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QC Monitoring the Action Item Process



- **Study Managers will monitor process by:**
 - Ensuring that the automated emails are distributed to the appropriate sites on the assigned Friday.
 - Following up with the action item coordinator if resolution dates were not added to the report.
 - Following up with the data system team if the emails were not fired on the appropriate Friday.



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Progress to Date



- **eSVR launch in 2014 for electronic visit reports**
- **Automated process for action items launched in 2017**
 - now in its 7th year
- **Approximately 25 studies supported thus far**
- **Next steps**

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THANK YOU AND QUESTIONS?

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