

# Welcome to the NACC Session!

Topic	Speaker Names
Welcome	Walter Kukull, PhD (NACC)
UDSv4 Launch	Sarah Biber, PhD (NACC) Jess Welsch, MBA (NACC) Cindy Carlsson, PhD (Wisconsin ADRC) Sudeshna Das, PhD (Massachusetts ADRC)
NACC Data Platform	Sarah Biber, PhD (NACC)
Becoming More Multimodal and Expanding Interoperability	Kristen Russ, PhD (NCRAD) Gil Rabinovici, PhD (UCSF ADRC) Rhoda Au, PhD (Boston University ADRC) Bill Jagust, PhD (UC Berkeley ADRC)



# UDSv4 Plan

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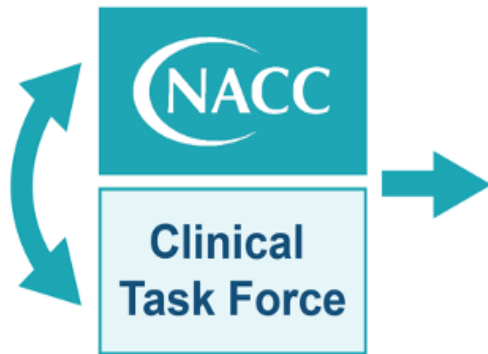
**Sarah Biber, PhD – NACC Executive Director**  
**Thursday, October 17, 2024**  
**2024 Fall ADRC Meeting**

A network diagram background consisting of a complex web of light blue lines connecting various nodes. Some nodes are represented by solid teal circles, while others are smaller, semi-transparent light blue circles. The connections form a dense, interconnected structure that spans the entire width and height of the slide.

# **UDSv4: Collaborating to create a new gold-standard for clinical phenotypic data collection in AD/ADRD**

# UDSv4: Defining a new standard for the field

## Aligned with key scientific advances



### ADRD Disease Modifying Drugs


**Form A4a: ADRD-Specific Treatments**



LEQEMBI (lecanemab) injection  
200 mg/2 mL (100 mg/mL)

### Social Determinants of Health

**A1a: Social Determinants of Health**



### ATN

- **A: Amyloid**
- **T: Tau**
- **N: Neurodegeneration**

### New Concepts

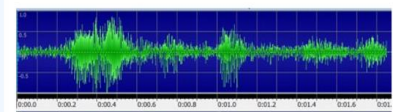
- **Subjective Cognitive Decline**
- **Mild Behavioral Impairment**
- **Addition of the new verbal learning test**

### More Inclusive

- **More inclusive gender and sexual orientation questions**
- **Captures multi-racial identity**

### Digital Voice

- **Neuropsychological exam**



# Completed UDSv4 Content, PDFs, and REDCap Forms

100% UDSv4 content complete!

## Approved by CTF

- Form A1
- **Form A1a: SDOH**
- Form A2
- Form A3
- Form A4
- **Form A4a: ADRD-Specific Drugs**
- Form A5/D2
- Form B1
- **Form B3: UPDRS**
- \*Form B4
- \*Form B5
- \*Form B6
- \*Form B7
- Form B8
- Form B9
- Form D1a
- Form D1b
- Form C2/C2t

### **New forms**

*\*No changes from UDSv3*



100% of UDSv4 REDCap forms developed

A network diagram background consisting of a complex web of light blue lines connecting various nodes. Some nodes are represented by solid teal circles, while others are smaller, semi-transparent light blue circles. The network is dense and spans the entire width of the slide.

# Data-Informed Timeline, Tools, and Strategies

# NACC UDSv4 Pilot Complete!

**3-month UDSv4 Pilot:** end of May – end of August 2024

## Benefits

- NACC, the CTF, and the EDC Workgroup obtained actionable feedback on UDSv4 resources, tools, and timelines
- ADRCs practiced:
  - Obtaining IRB approval for Administering the new UDSv4 forms content to participants across cognitive categories
  - Collecting UDSv4 data with new EDC tools
  - Submitting UDSv4 data to the NACC Data Platform via new submission options
  - Leveraging UDSv4 documentation and training materials

# NACC UDSv4 Pilot Complete!

**3-month UDSv4 Pilot:** end of May – end of August 2024

## 23 ADRCs Participated

16

ADRCs tested clinical core participants

1

ADRC tested mock participants

6

ADRCs did not administer to participants

## 55 Subjects

51

ADRC Participants

4

Mock Participants (ADRC staff)

Spanning all cognitive diagnoses

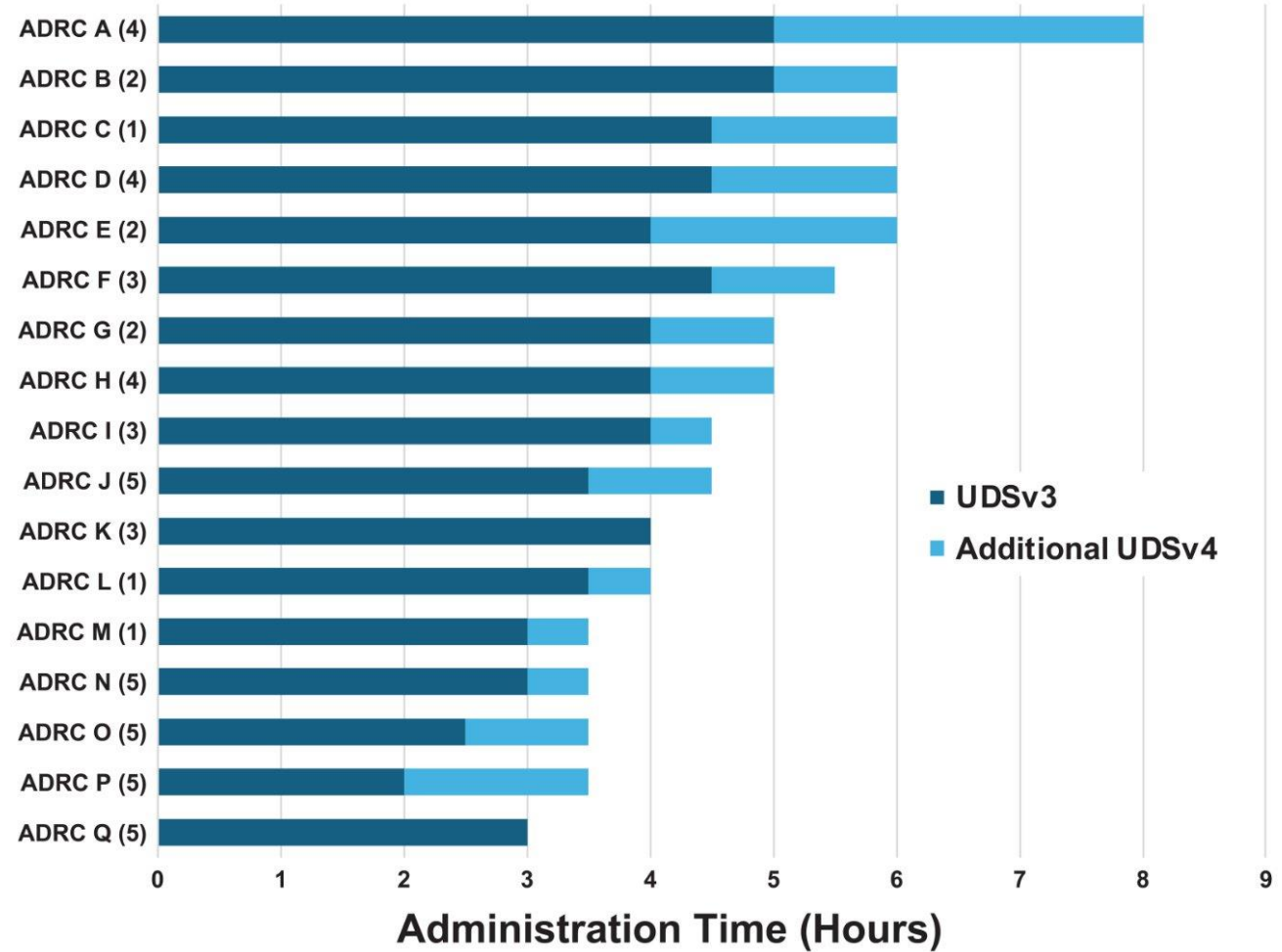


# ADRCs Vary in Their Degree of Readiness to Transition to UDSv4

# UDSv4 Pilot Survey Results

**UDSv4  
Administration  
Time Varies**

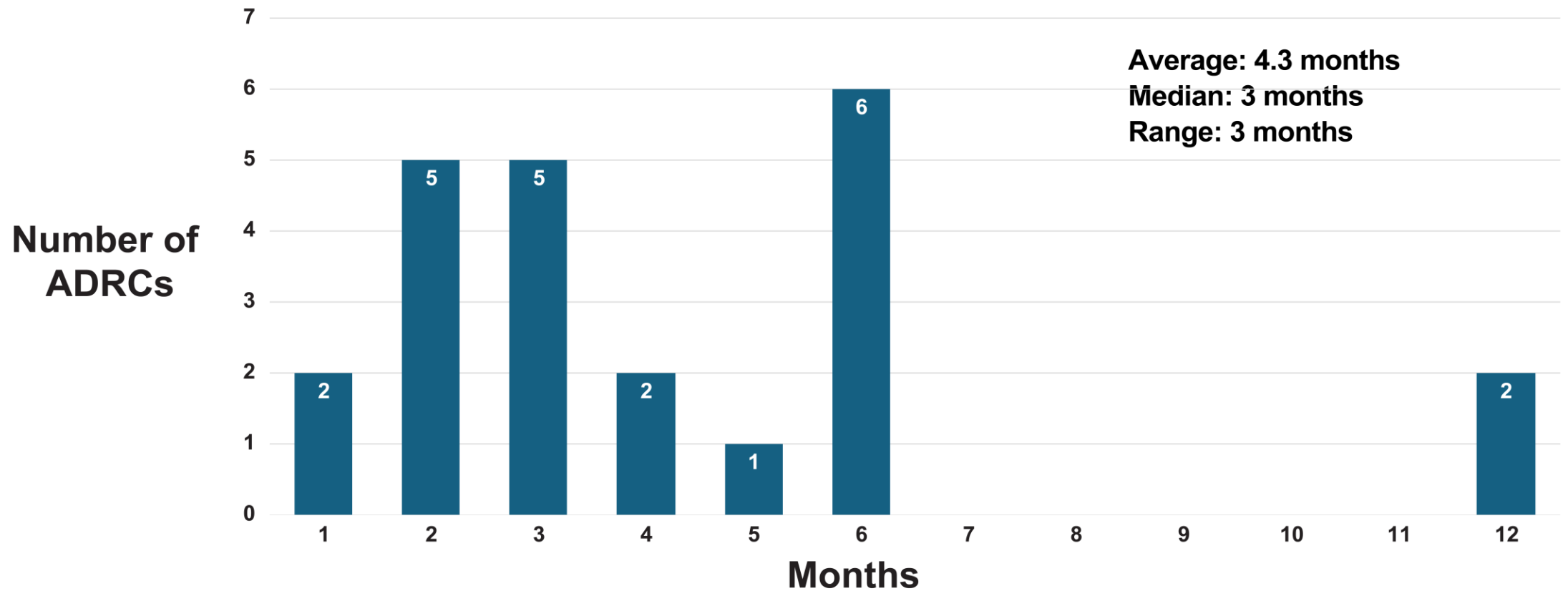
**ADRCs  
(Number of  
pilot participants)**



Average additional administration time for UDSv4: 1 hour

# UDSv4 Pilot Survey Results

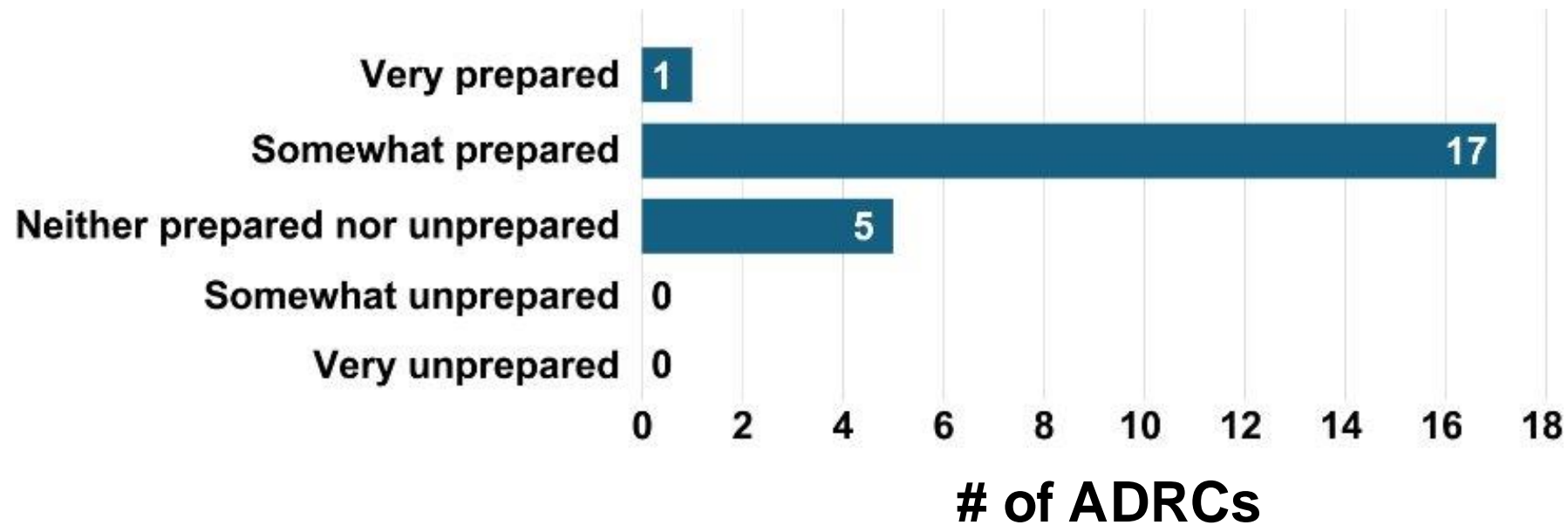
Anticipated time needed to transition to UDSv4  
for all prospective data collection varies



# UDSv4 Pilot Survey Results

**Pilot ADRCs are making progress towards preparing for the UDSv4 transition**

*In general, how prepared do you think your site is for the transition to UDSv4?*



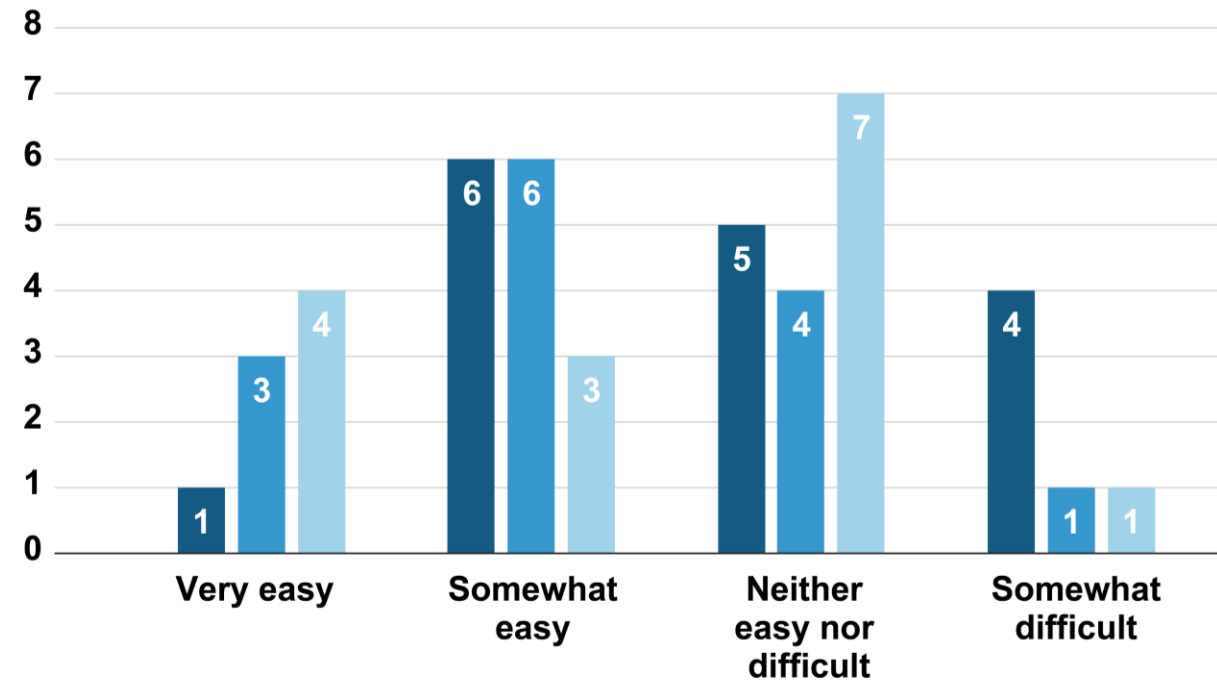
# UDSv4 Pilot Survey Results

Pilot ADRCs are off to a great start leveraging the new NACC electronic data capture and submission system

*How easy was it to use the new REDCap forms and submission system?*

# ADRC Responses

- New UDSv4 form content
- New REDCap forms for UDSv4 data collection
- New submission options for UDSv4



August 2024 Survey

# Responding to your Pilot Feedback

A collaboration between NACC, CTF, and the EDC Workgroup

- **General**

- Website with centralized resources
- Additional implementation time

- **Clinical**

- Updating some forms and clinical guidance documentation
- Additional clinical trainings and webinars
- Boiler plate language for IRBs
- Clinical support via the ADRC Community Forum
- Recommend forms that can be sent to participants in advance

- **Technical**

- Changes to REDCap form logic and rules
- More accessible API documentation
- Hosting a sandbox environment where ADRC can practice data submission

## General



Onboarding Checklist



Community Forums



Office Hours



FAQs



UDSv4 Website

## Clinical



Forms & Coding Guidebooks



Training Webinars and Videos

## Technical



REDCap Forms and Resources



dVoice Forms and Guidelines



UDSv4 GitHub Library



Data Collection Options



UDSv3 to UDSv4 Crosswalk



Data Submission Options



NACC Data Platform Sandbox



Training Webinars and Videos

# How to get your site ready for UDSv4

All UDSv4 Resources  
Accessible on the NACC Website

[bit.ly/UDSv4Updates](https://bit.ly/UDSv4Updates)





**When are we transitioning to UDSv4?**





## ADRC Sites

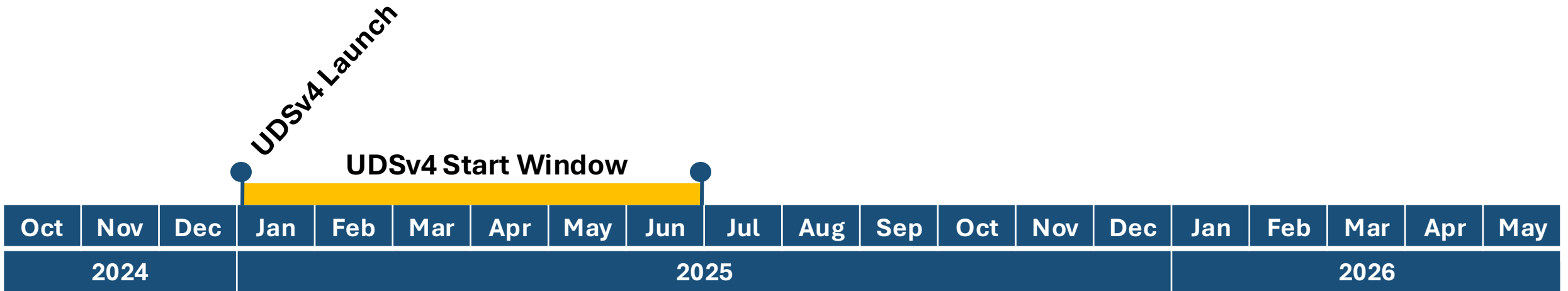


Final UDSv4 Forms  
Documentation Available

End of NACC  
Grant Cycle



## ADRC Sites

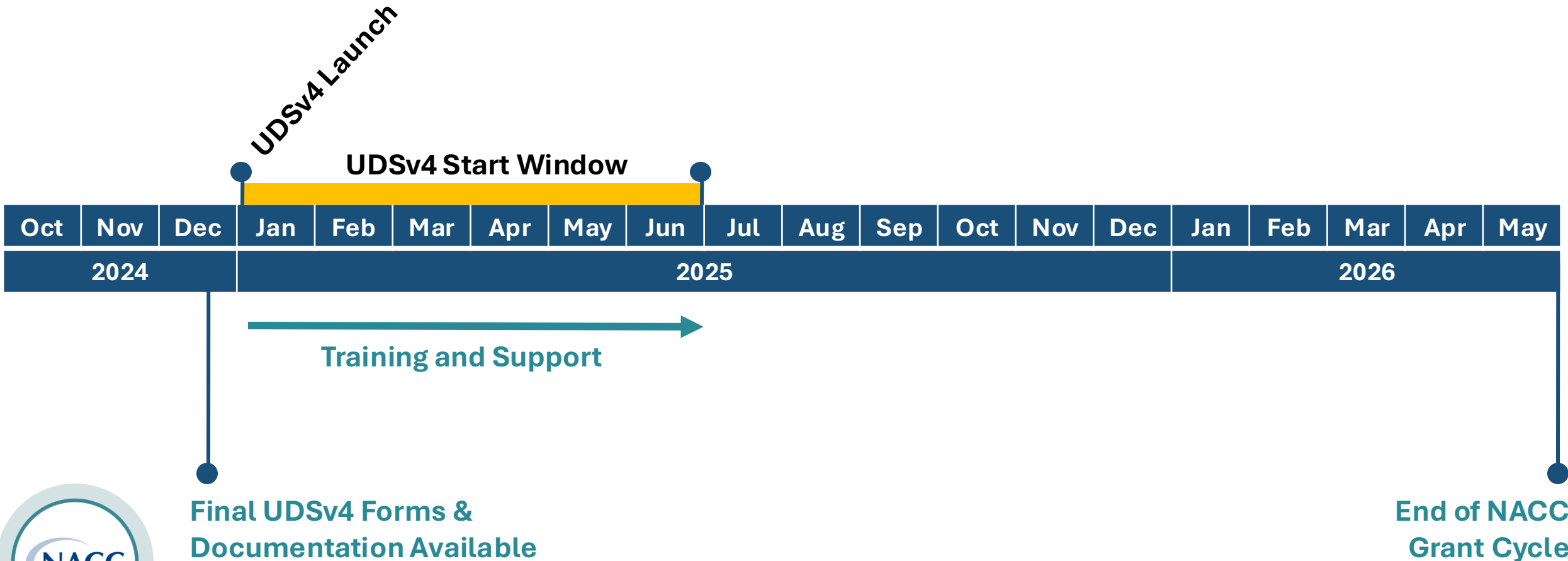


Final UDSv4 Forms & Documentation Available

End of NACC Grant Cycle



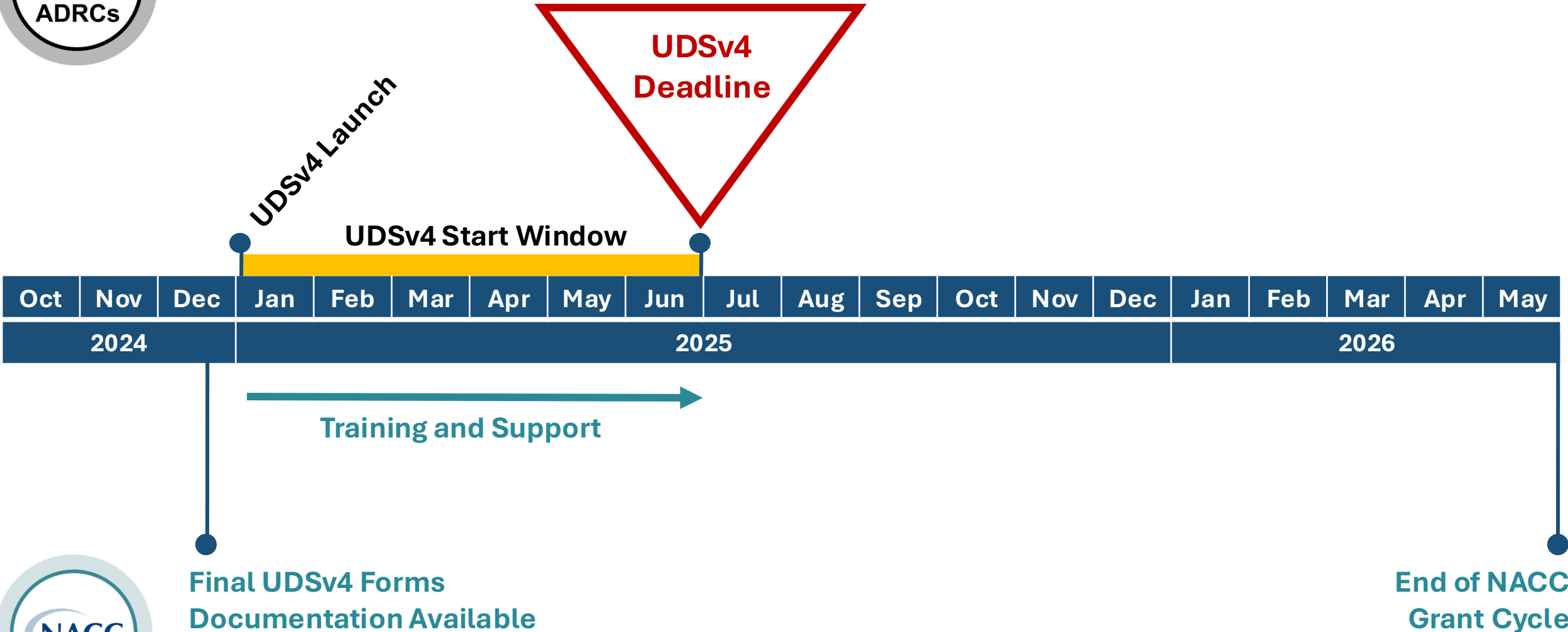
## ADRC Sites



## ADRC Sites



ADRCs

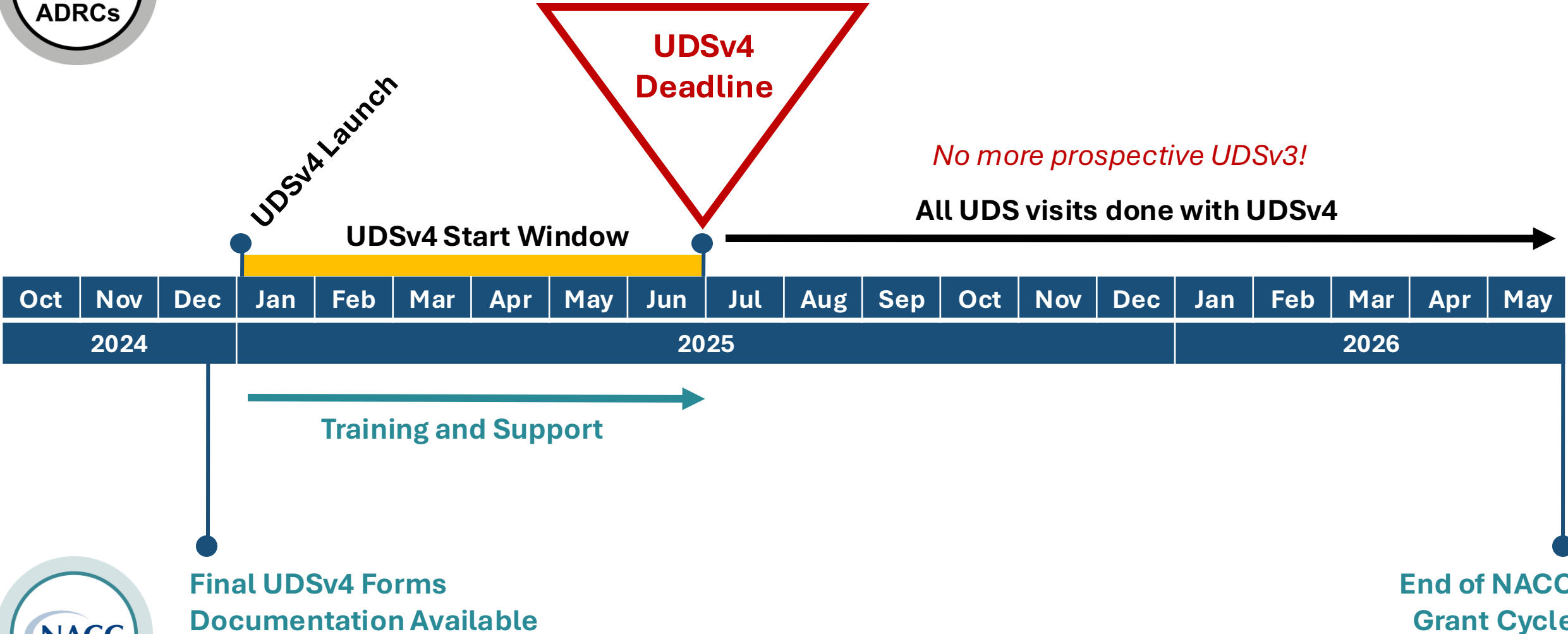


NACC

## ADRC Sites



ADRCs

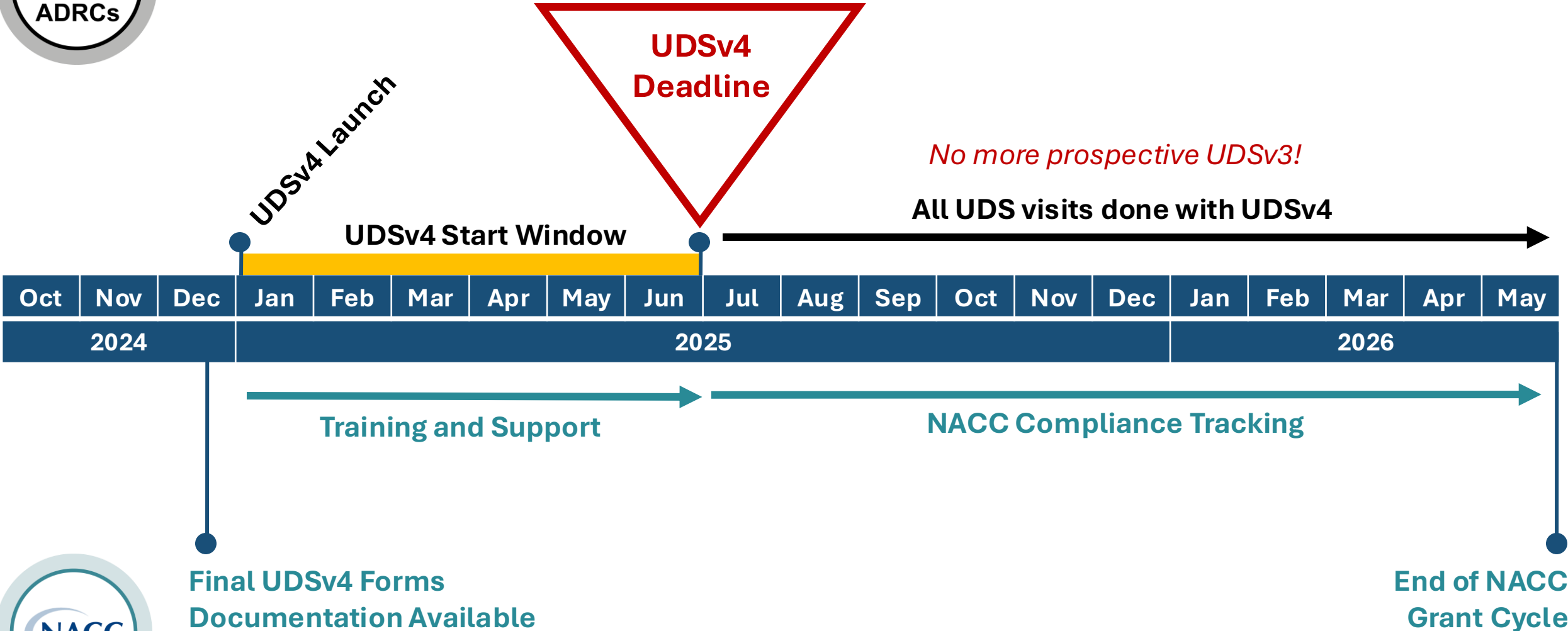




## ADRC Sites



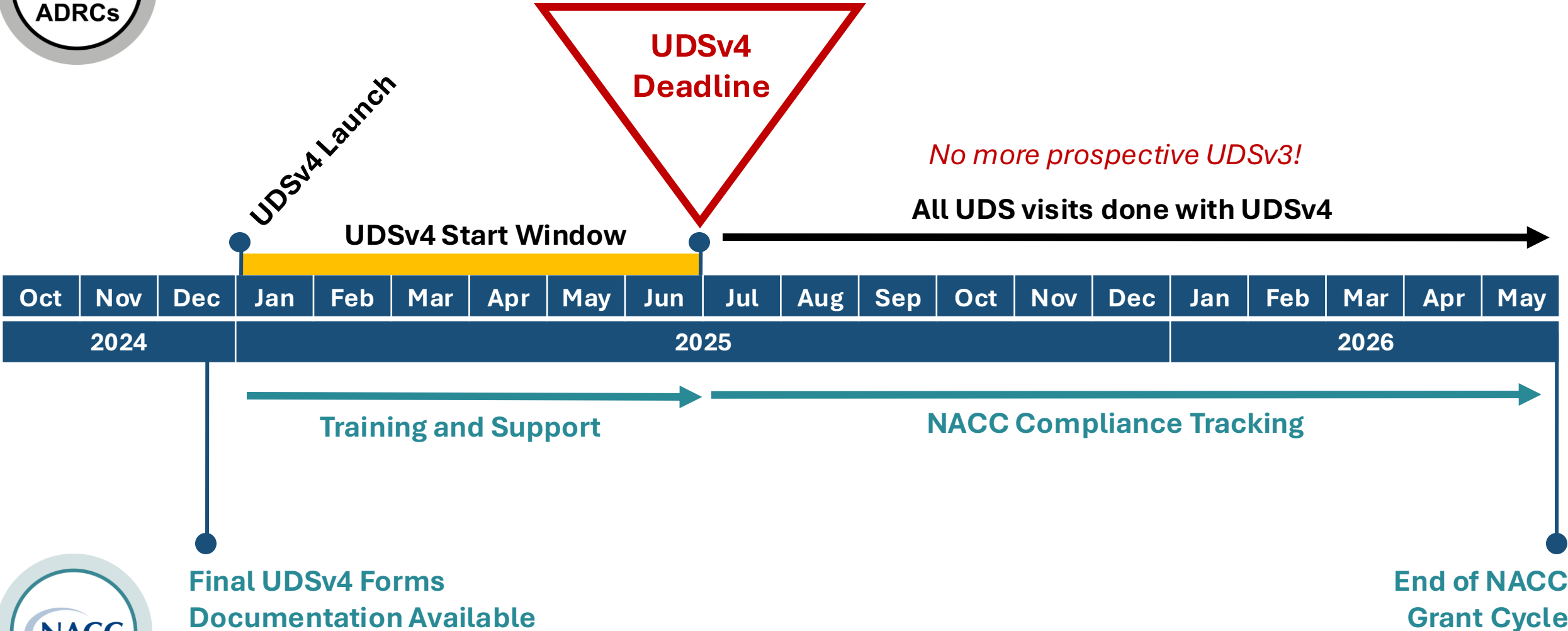
ADRCs



## ADRC Sites



ADRCs



Final UDSv4 Forms  
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End of NACC  
Grant Cycle



## ADRC Sites



**UDSv3 Exceptions:**  
- Spanish and Chinese translations

ADRCs

**UDSv4  
Deadline**

**UDSv4 Launch**

*No more prospective UDSv3!*

**All UDS visits done with UDSv4**

**UDSv4 Start Window**



**Training and Support**

**NACC Compliance Tracking**

**Final UDSv4 Forms  
Documentation Available**

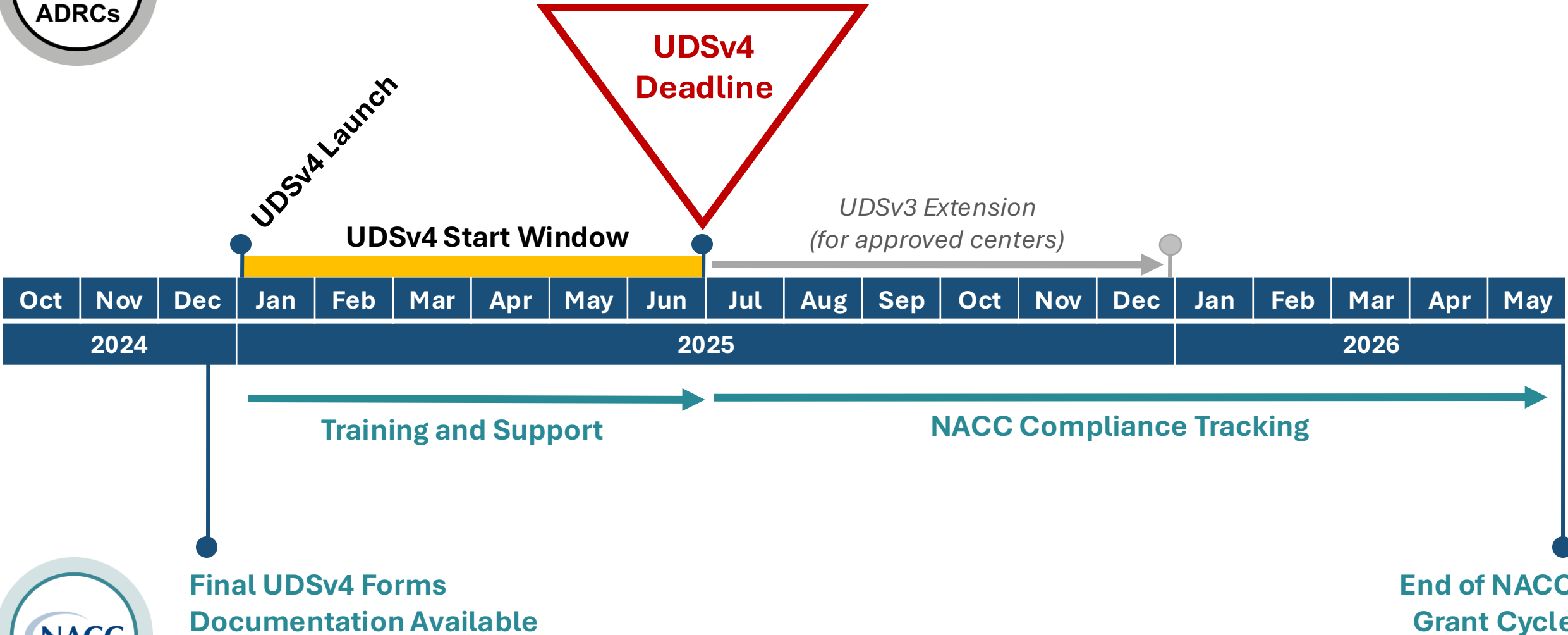
**End of NACC  
Grant Cycle**



## ADRC Sites



ADRCs



Final UDSv4 Forms  
Documentation Available

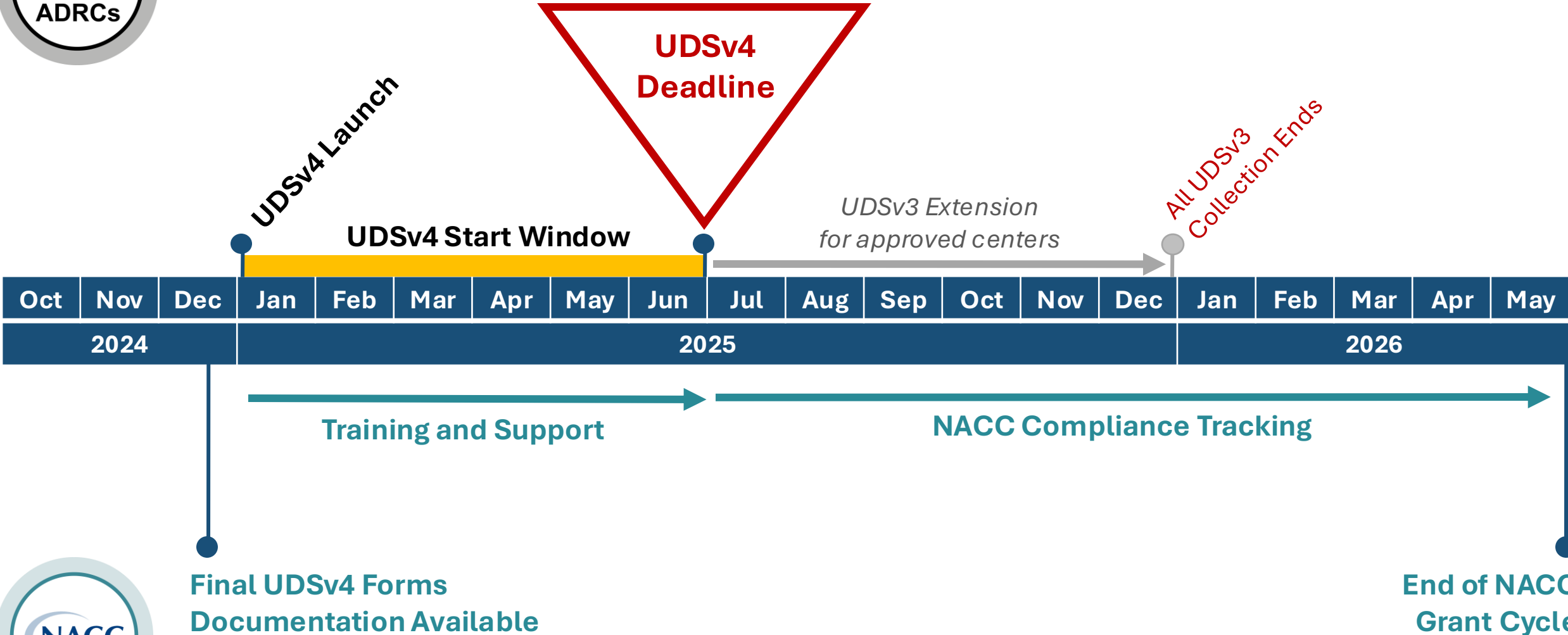
End of NACC  
Grant Cycle



## ADRC Sites



ADRCs



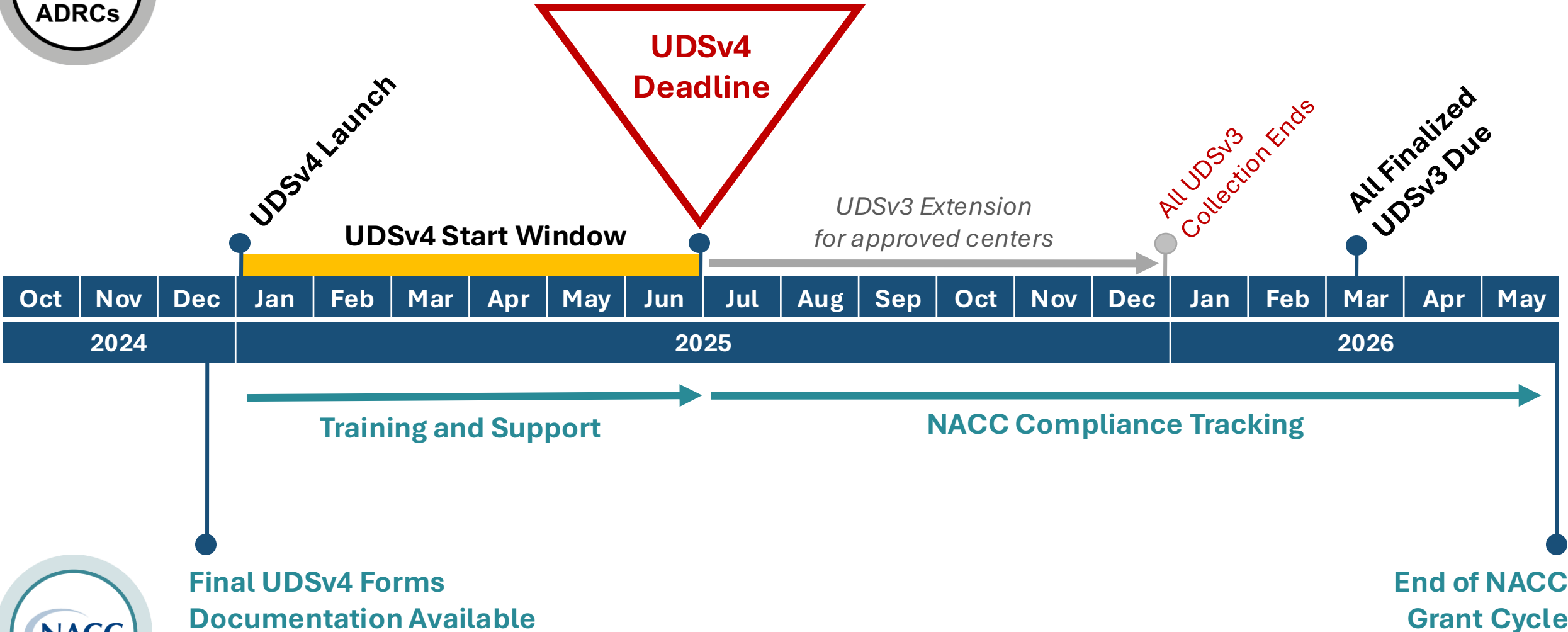
Final UDSv4 Forms Documentation Available

End of NACC Grant Cycle

## ADRC Sites



ADRCs



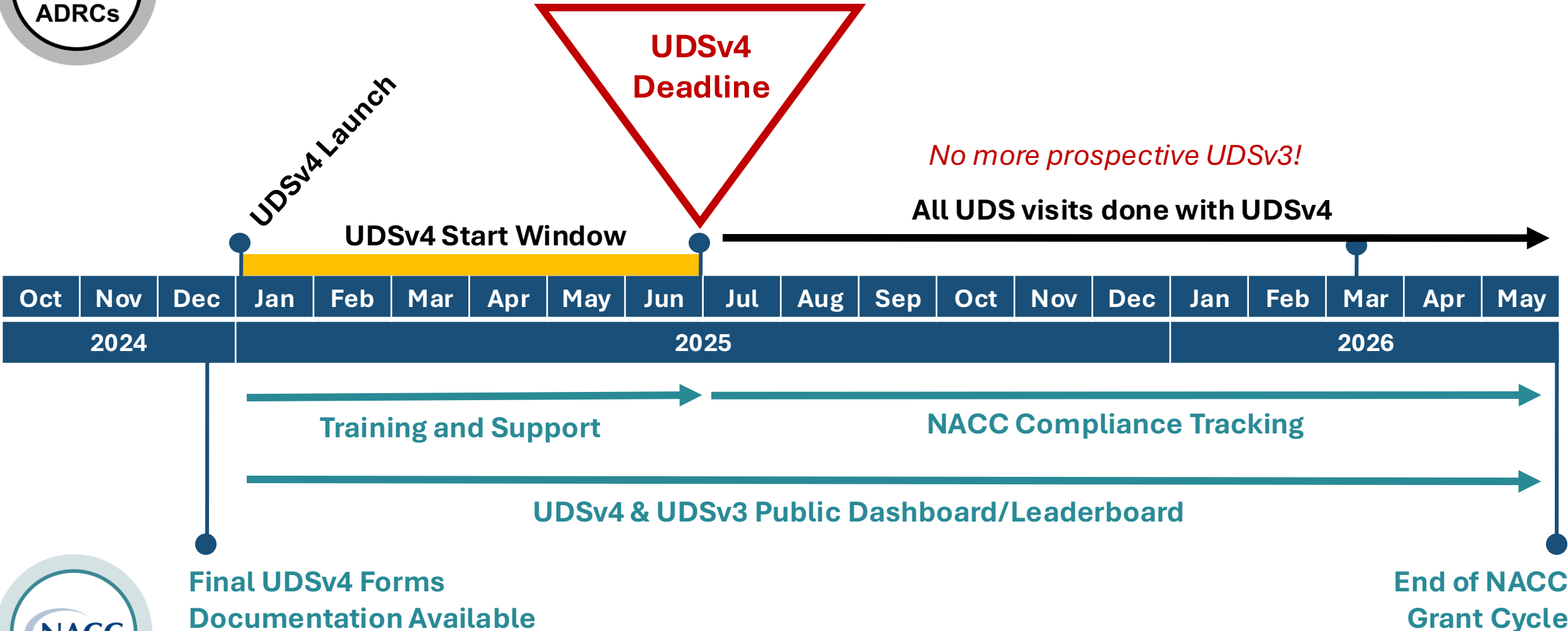
Final UDSv4 Forms Documentation Available

End of NACC Grant Cycle

## ADRC Sites



ADRCs



Final UDSv4 Forms  
Documentation Available

End of NACC  
Grant Cycle





## UDS Public Dashboard

Download PDF

Export CSV

Last Updated Wed 2, Oct 2024 12:30 AM

52.5K

Total number of participants

19K

Number of active participants

4.9K

Number of participants with available UDSv4 data

	Total # Submitted	Total # Finalized	% Finalized
UDSv4	6.2K	4.9K	79 %
UDSv3	112K	85K	76 %

### UDS v4 Submissions

### UDS v3 Submissions

ADRC	#Packets Submitted	#Packets Finalized	% Finalized	#Packets Submitted	#Packets Finalized	% Finalized
<a href="#">ADRC - A</a>	304	297	97.69 %	4.7K	3.9K	82.97 %
<a href="#">ADRC - B</a>	293	244	82.99 %	4.2K	3.78K	90 %
<a href="#">ADRC - C</a>	290	190	65.51 %	3.9K	3.1K	79.48 %
<a href="#">ADRC - D</a>	263	185	70.34 %	3.4K	2.75K	80.87 %
<a href="#">ADRC - E</a>	242	175	72.31 %	2.7K	1.57K	58.14 %
<a href="#">ADRC - F</a>	220	167	75.90 %	2.3K	1.53K	66.52 %
<a href="#">ADRC - G</a>	198	154	77.71 %	2.15K	1.51K	70.23 %
<a href="#">ADRC - H</a>	175	123	70.28 %	1.98K	900	45.46 %



# Thank you to the CTF!

## Clinical Task Force



**ALLAN LEVEY, MD, PHD**  
Emory ADRC



**RHODA AU, PHD**  
Boston U ADRC



**LISA BARNES, PHD**  
Rush U ADRC



**BRAD BOEVE, MD**  
Mayo Clinic ADRC



**JEFFREY BURNS, MD, MS**  
U of Kansas ADRC



**SUZANNE SCHINDLER, MD, PHD**  
WashU Knight ADRC



**CINDY CARLSSON, MD, MS**  
UW Madison ADRC



**GREG JICHA, MD, PHD**  
U of Kentucky ADRC



**ANDY SAYKIN, PSYD**  
Indiana U ADRC



**MARY SANO, PHD**  
Mount Sinai ADRC



**SANDRA WEINTRAUB, PHD**  
Northwestern ADRC



**SUZANNE CRAFT, PHD**  
Wake Forest ADRC



**MEGAN ZUELSDORFF, PHD**  
UW Madison ADRC



**HOWIE ROSEN, MD**  
UCSF ADRC



**KOSTAS LYKETSOS MD**  
John Hopkins ADRC



**TERESA GOMEZ-ISLA, MD, PHD**  
Massachusetts ADRC



**AIMEE PIERCE, MD**  
OHSU ADRC



**LIANA APOSTOLOVA, MD, MS**  
Indiana ADRC

Thank you Jessica Culhane and Kathryn Gauthreaux!

# Thank you EDC Workgroup Leads & Co-leads!

## Workgroup Leads:

Leads the EDC Workgroup All Hands Meetings and oversees the EDC Workgroup leads meetings with the subgroup co-leads.



**SUDESHNA DAS, PHD**  
Massachusetts ADRC



**SARAH BIBER, PHD**  
NACC

## Development Subgroup:

Design, build and test EDC technologies including data quality validation.



**JON READER, MS**  
Michigan ADRC



**DEBBIE ZEMLOCK, MS**  
Northwestern  
University



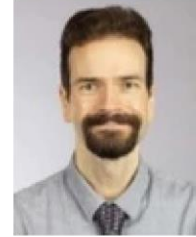
**KATHRYN  
GAUTHREAU, MS**  
NACC

## Requirements Subgroup:

Identify and recommend best practices for EDC/REDCap data capture and requirements for data collection, data quality checking and data transformation from ADRC's to NACC.



**MEREDITH ZOZUS, PHD**  
South Texas ADRC



**CHAD MURCHISON, PHD**  
UAB ADRC



**KARI STEPHENS, PHD**  
NACC

## Documentation & Training Subgroup:

Design and develop training materials and SOPs for EDC (REDCap, in particular) at ADRCs and make existing resources more readily available to the community.



**NIRANJANA  
SHASHIKUMAR, MS**  
Vanderbilt Exploratory  
ADRC



**LAURA MCLEOD, BBA**  
NACC

## Coordination:

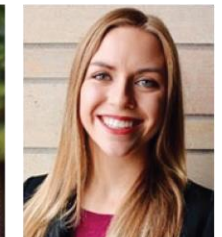


**JESSICA WELSCH, MBA**  
NACC

## Alumni:



**SARAH GOTHARD, BS**  
OHSU ADRC



**HANNAH ROSENRETER**  
NACC

*Not Pictured*

**LEAH REUTER** - Wisconsin ADRC

**ALICE SPALITTA** - Wisconsin ADRC

# Connect with me

**Sarah Biber, PhD – NACC**

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