National Institute of Diabetes and Digestive and Kidney Diseases

Data Readiness for Timely ClinicalTrials.gov Reporting

From Primary Completion Date to Public Reporting

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National Institute of Diabetes and Digestive and Kidney Diseases

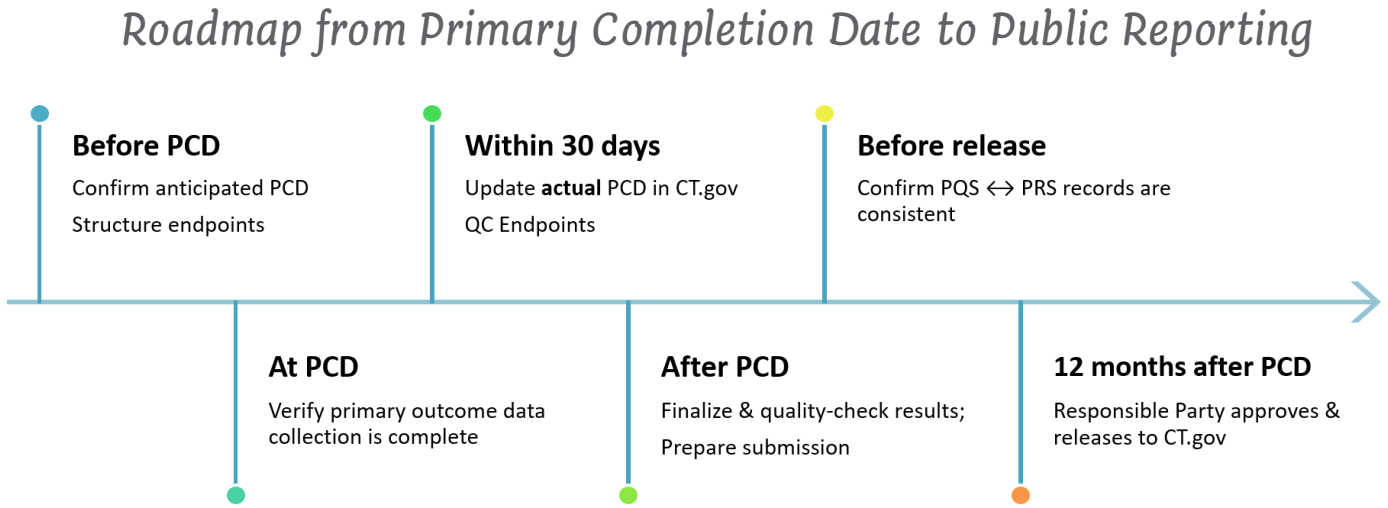
AGENDA

Objective

Apply practical strategies for timely and compliant reporting of clinical data in CT.gov

You will learn to

- Identify the Actual Primary Completion Date (PCD)
- Structure Study Endpoints
- Understand PRS, PQS, and ClinicalTrials.gov processes



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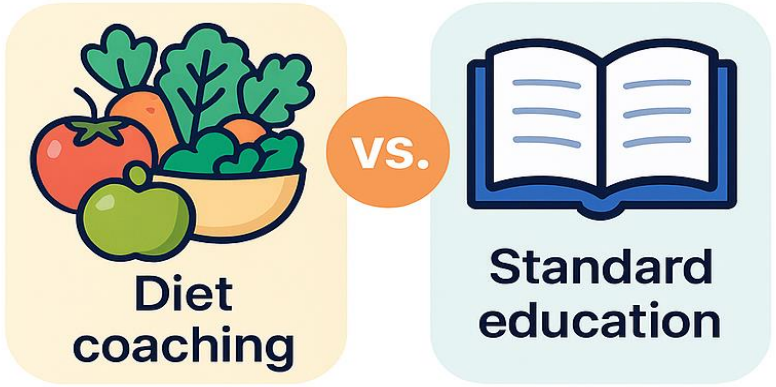
DASH-DK Trial

Randomized trial

Compares diet coaching vs. standard education in adults with chronic kidney disease and hypertension



Decrease in systolic blood pressure from baseline to Week 24

History

Slow enrollment

CT.gov non-compliance

Goal

Enter results ~3 months before CT.gov due date

Three Major Resources

Protrak Query System (PQS)

- Maintains protocol-related info
- Researcher enters registration data, including **endpoints titles and time frames**

Sends basic registration data nightly

Protocol Registration and Results System (PRS)

- Review, release, and quality control of protocol & results
- Researcher completes & validates registration data and **results**

Responsible Parties approve and release

ClinicalTrials.gov (CT.gov)

- Displays public record

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Before PCD

Track Actual Primary Completion Date (PCD)

<u>Primary</u> Completion Date (PCD)

Date the final participant completed data collection for all **<u>primary</u>** outcome measures.

<u>Study</u> Completion Date

Date the final participant completed data collection for all **<u>study</u>** outcome measures, including adverse events.

Researcher Action: Know Anticipated vs. Actual PCD.

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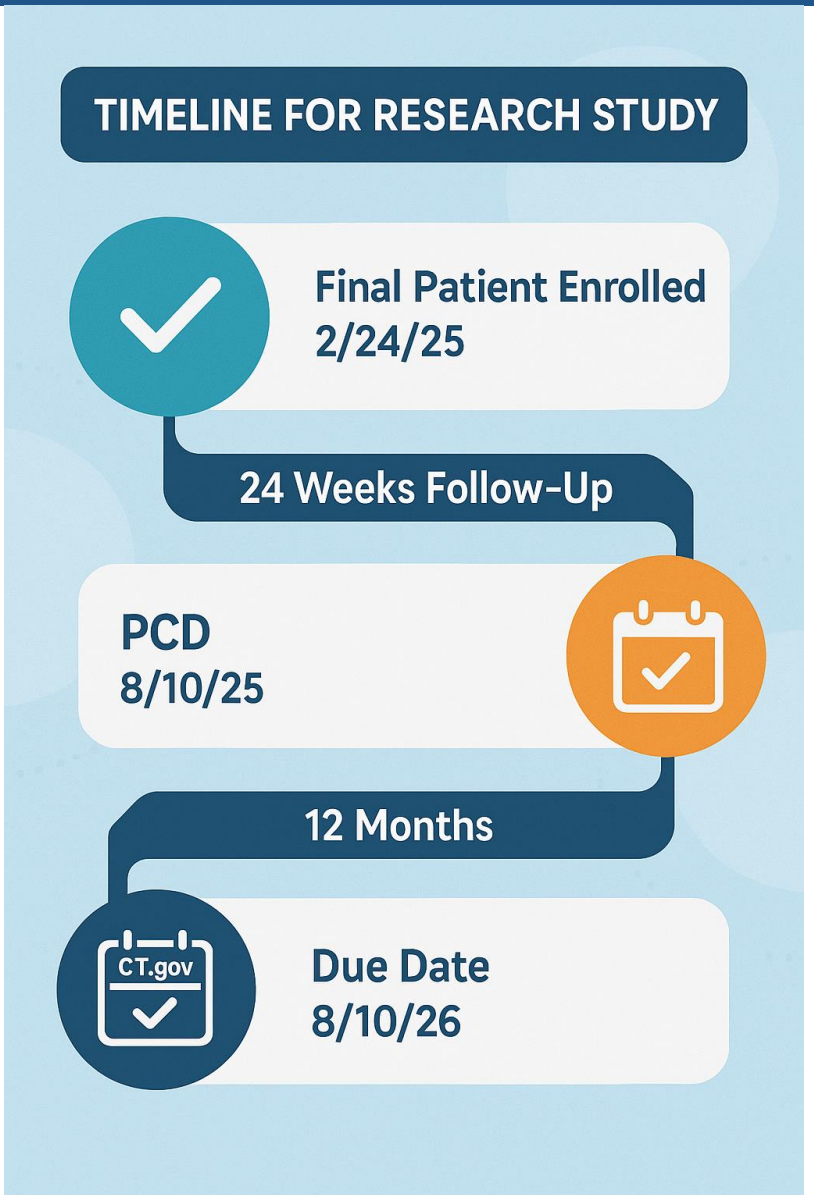
Within 30 days PCD

Update Actual Primary Completion Date (PCD)

1. Update the Actual PCD and any associated study information in PRS

2. Results generally due in CT.gov within 12 months after PCD
   - Applicable Clinical Trials (ACTs): FDAAA 801 / 42 CFR Part 11
   - NIH-funded clinical trials (NIH Policy) regardless of ACT status

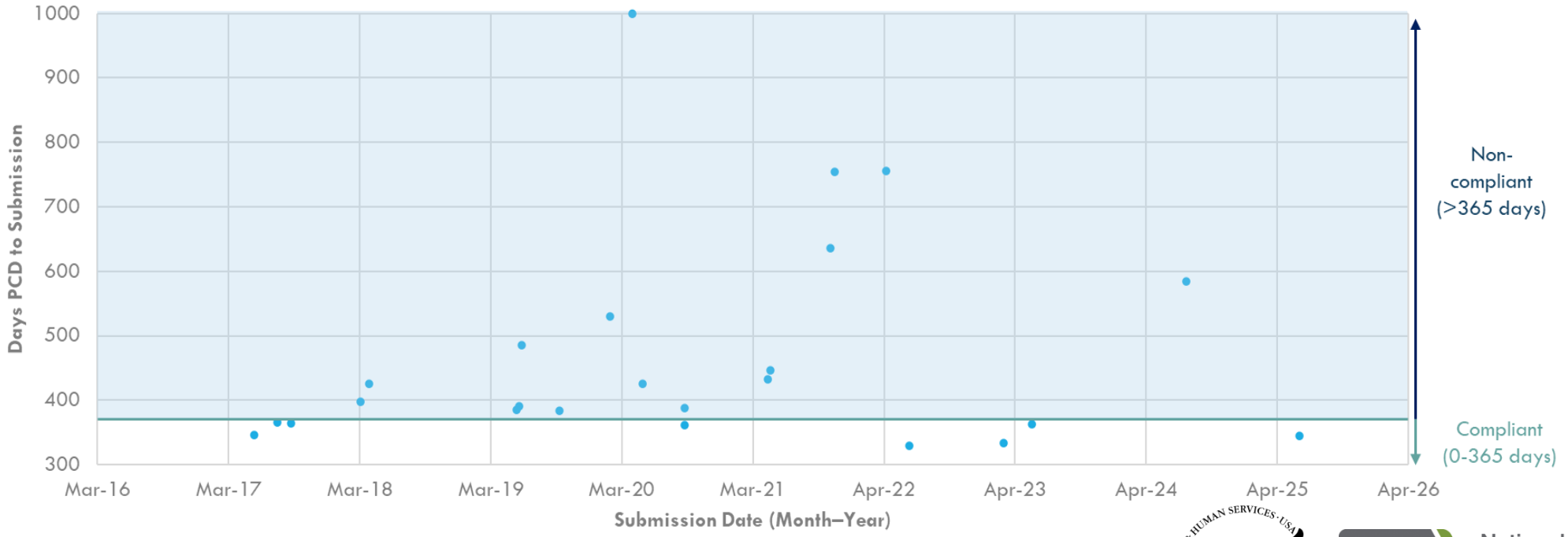


Main Reason for CT.gov Noncompliance?

Updating the Primary Completion Date late

*Ex: On 6/12/2024, PCD updated from 2/2/2025 to the **actual date 12/17/2022**.*

*Update was 543 days post-PCD. CT.gov reporting was **584 days post-PCD**.*



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Within 30 days PCD

Format the Study Endpoints like CT.gov Outcome Measures

- **CT.gov Outcome Measure Requirements**
  - Primary and/or secondary
  - What was measured
  - Unit of measurement
  - Range, direction, & category for scales
  - Participant-based time fames
  - No hypotheses or directions

- Researcher Action: Detail the study endpoints using CT.gov requirements for outcome measures.

- *Original*: Decrease in systolic blood pressure from baseline to Week 24

✓ *Revised*: Difference in the change from baseline to 24-weeks in mean systolic blood pressure (mmHg) between the diet and education groups

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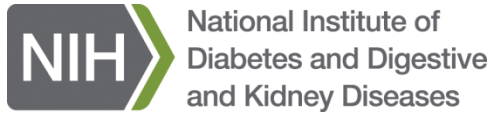
Within 30 days PCD

Use PQS as an Internal Quality Check

- **PQS:** NIH repository of study-related information, entered by PIs/study teams, to meet mandatory reporting requirements to federal agencies and to register trials on CT.gov

- **Confirm alignment before nightly release to PRS**
  - Actual Primary Completion Date
  - Endpoint descriptions and time frames
  - Final enrollment
  - Arms and groups
  - Analysis populations
  - Protocol and Statistical Analysis Plan

- Researcher Action: Use PQS to catch readiness gaps before PRS catches compliance gaps.



After PCD

Study Results are Entered in PRS

- **PRS:** System by National Library of Medicine (NLM) used by study sponsors and investigators to register clinical trials and submit trial results publicly to CT.gov

- **Results sections must tell the same story throughout**
  - Participant Flow
  - Baseline Characteristics
  - Outcome Measures and Statistical Analyses
  - Adverse Events
  - Protocol and SAP uploads

ClinicalTrials.gov PRS
Protocol Registration and Results System

- Researcher Action: Designate Responsible Party for PRS (i.e. PN). Review, approve, and release for posting.

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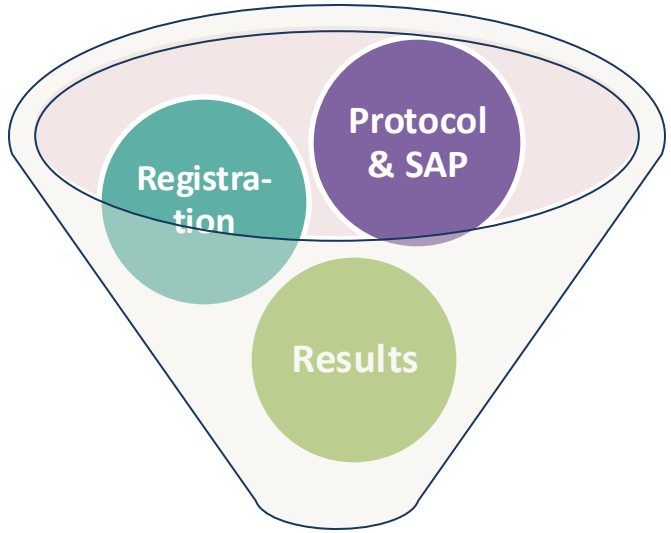
Before Release

PRS Reviews & Releases to CT.gov

- **PRS Review may take up to 30 days**
  - Validity
  - Meaningful data entry
  - Logic
  - Internal consistency
  - Formatting

- PRS may issue comments before release to CT.gov
  - Major comments delay public posting
  - Advisory comments allow posting with comments noted

- Researcher Action: Address PRS comments w/in 25 days.



NIH National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov

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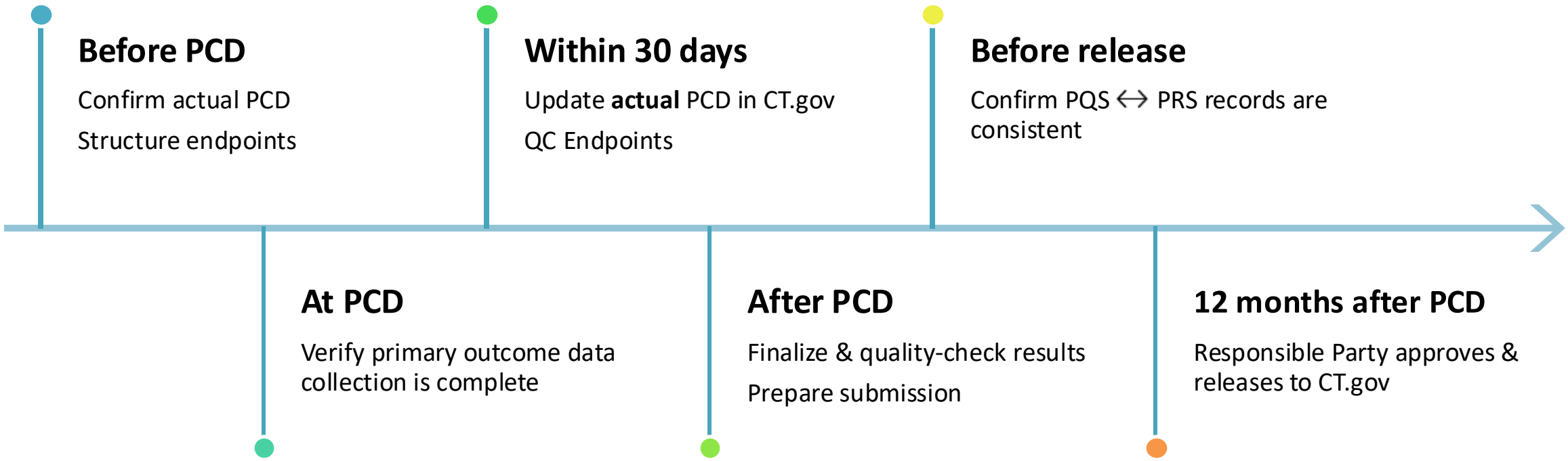
Reporting Timeline: Your Roadmap



Researcher Action: Know the PCD. Structure the endpoints. Align the data. Submit on time.

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Reporting Timeline: DASH-DK Roadmap

Before PCD: 7/1/25

Confirm actual PCD

Structure endpoints

Within 30 days: 9/9/25

Update **actual** PCD in CT.gov

QC Endpoints

Before release: 3/20/26

Confirm PQS ↔ PRS records are consistent

At PCD: 8/10/25

Verify primary outcome data collection is complete

After PCD: 2/20/25

Finalize & quality-check results

Prepare submission

~~12~~ *9* months after PCD: 5/20/26

Responsible Party approves & releases to CT.gov

Researcher Action: Know the PCD. Structure the endpoints. Align the data. Submit on time.

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Take Away Message

ClinicalTrials.gov reporting is easier when the team treats PCD confirmation, endpoint design, PQS review, and PRS entry as one connected workflow.

- ✓ Update the Actual Primary Completion Date
- ✓ Detail the Study Endpoints

Thank You

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