



Implementation of NINDS CDEs: Lessons Learned

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Purpose

- Outline our process for implementing the CDEs.
- Review lessons learned
- Review limitations
- Demonstrate how we incorporated CDEs into our system and untimely into the PUDs

StrokeNet = NINDS CDE + NINDS
Repository

SIREN = NINDS CDE + FITBIR Repository

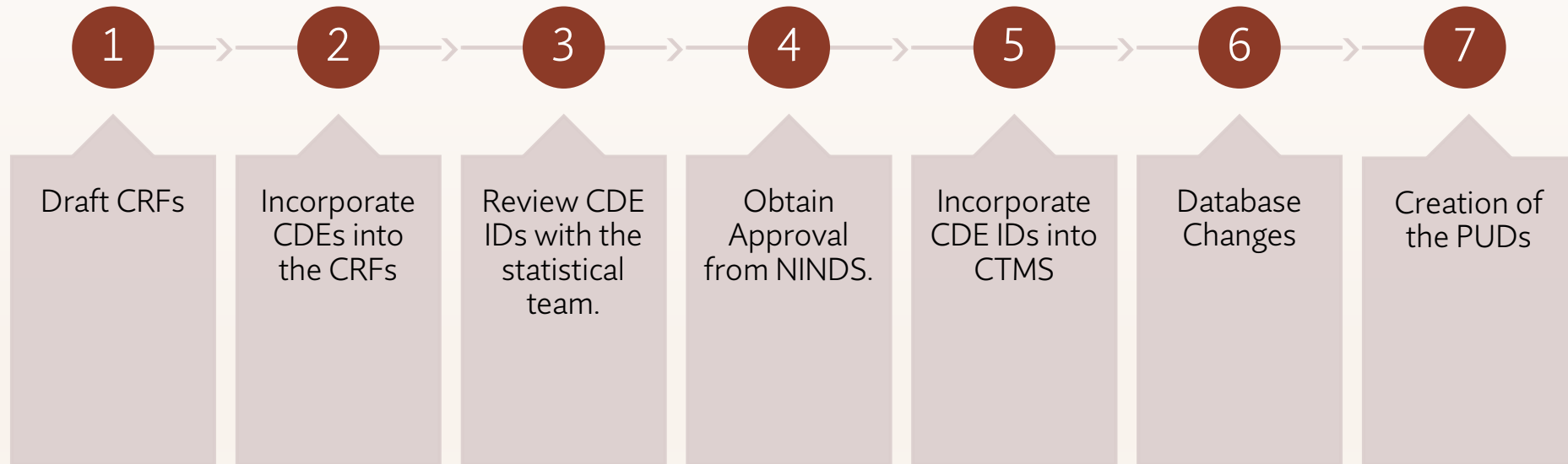


NIH SIREN
Emergency
Trials
Network



StrokeNet
PREVENTION | TREATMENT | RECOVERY

Our Process



Direct vs. Indirect Mapping

Direct Mapping Example:

- Adverse Event Grade: CDE ID: C02305
 - DCU Permissible Values

| | |
|-------|-----------------------------------|
| Grade | <input type="radio"/> (1) Grade 1 |
| | <input type="radio"/> (2) Grade 2 |
| | <input type="radio"/> (3) Grade 3 |
| | <input type="radio"/> (4) Grade 4 |
| | <input type="radio"/> (5) Grade 5 |

- NINDS CDE Permissible Values

| permissible_values |
|--|
| Grade 1; Grade 2; Grade 3; Grade 4; Grade 5; |

Indirect Mapping Example:

- Drug abuse / Drug current illicit use indicator: CDE ID: C00713
 - DCU Permissible Values

| | | | |
|------------|------------------------------|----------------------------------|------------------------------------|
| Drug abuse | <input type="radio"/> (1) No | <input type="radio"/> (2) Active | <input type="radio"/> (3) Inactive |
|------------|------------------------------|----------------------------------|------------------------------------|

- NINDS CDE Permissible /values

| crf_id | cde_id | variable_name | cde_name | permissible_values |
|--------|--------|-----------------------------|---|--------------------|
| F0303 | C00713 | DrgSubstCurrntIllicitUseInd | Drug or substance current illicit use indicator | Yes; No; Unknown; |
| | | | | |

Incorporating CDEs in CTMS

| # | Form name | CRF number | List order | Database column name | User interface field name | Data type | Code Group ID | Is required | Derived | Included in PUD | NINDS CDE ID | NINDS CDE name | Definition |
|----|-----------|------------|------------|----------------------|---|----------------------|---------------|-------------|---------|---|--------------|--|------------|
| 1 | 104 | 104 | 10 | Q01 | Adverse Event Name | Text | | | Not | Include | C02307 | AdvrsEvtVerbatimTermText | Local |
| 2 | 104 | 104 | 20 | Q02 | Grade | Radio button options | 67 | | Not | Include | C02305 | AdvrsEvtSeverScale | Local |
| 3 | 104 | 104 | 30 | Q03 | Serious | Radio button options | 51 | | Not | Include | C02309 | SeriousAdvrsEvtInd | Local |
| 4 | 104 | 104 | 40 | Q04 | Relatedness to study intervention | Radio button options | 533 | | Not | Include | C02304 | AdvrsEvtRelatednessScale | Local |
| 5 | 104 | 104 | 50 | Q05 | Date of onset | Date/Time | | | Not | Days from project-specific Day-Zero based on Local Time | C02306 | AdvrsEvtStartDateTime | Local |
| 6 | 104 | 104 | 60 | Q06 | Time of onset | Date/Time | | | Not | Minutes from project-specific Time-Zero based on UTC Time | C02306 | AdvrsEvtStartDateTime | Local |
| 7 | 104 | 104 | 70 | Q07 | Outcome | Radio button options | 534 | | Not | Include | C02303 | AdvrsEvtOutcomStatus | Local |
| 8 | 104 | 104 | 80 | Q08 | Date of resolution | Date/Time | | | Not | Days from project-specific Day-Zero based on Local Time | C02301 | AdverseEvtEndDateTime | Local |
| 9 | 104 | 104 | 100 | Q09 | Study intervention interrupted | Radio button options | 51 | | Not | Include | C02300 | AdvEvtStdyIntrvntActTakenTyp_StudyInterventionInterrupted | Local |
| 10 | 104 | 104 | 110 | Q10 | Study intervention discontinued | Radio button options | 51 | | Not | Include | C02300 | AdvEvtStdyIntrvntActTakenTyp_StudyInterventionDiscontinued | Local |
| 11 | 104 | 104 | 120 | Q11 | Study intervention modified | Radio button options | 51 | | Not | Include | C02300 | AdvEvtStdyIntrvntActTakenTyp_StudyInterventionModified | Local |
| 12 | 104 | 104 | 190 | Q12 | Describe event or problem | Text | | No | Not | Not included | C17447 | | Local |
| 13 | 104 | 104 | 200 | Q13 | Relevant tests/ laboratory data, including dates | Text | | No | Not | Not included | | | Local |
| 14 | 104 | 104 | 210 | Q14 | Other relevant history, including pre-existing medical conditions | Text | | No | Not | Not included | | | Local |

PUDS



Built from BRICS



National Institute of
Neurological Disorders
and Stroke

Suggestions?

1. NINDS CDE Website Usability

- Bring the search function to the top of the page, rather than the side.
- Make it easier to find the CDE definitions and answer choices without needing to download them.

1. FITBIR WebDCU Usability

- Filter already applied on the side of the page.

2. FITBIR Two-Factor Requirements

Summary of Limitations and Lessons Learned

1. Begin adding CDE IDs after CRFs have been fully finalized
2. Keep a summary of the common CDE used for standard questions.
3. Review the CDEs with statisticians before sending them for approval.
4. Be mindful of indirect mapping
5. Send the CDE for approval early.
6. Add CDEs to CTMS after approval – don't wait.
7. Be careful when adding or adjusting CDEs after data additions, removals or changes since there is no re-approval of CDEs.
8. Be attentive to CDE changes or updates.
9. Incorporation on CDEs into the study database streamlines PUDS creation.
10. Be cautious of differences between repositories



Thank you