PRE Clinical Interagency reSearch resourcE-TBI

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CELEBRATING LANDMARKS OF NEUROTRAUMA
40th
Annual Symposium
National Neurotrauma Society
AANS/CNS Joint Section on
Neurotrauma and Critical Care
35
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Common Data Elements (CDEs): What? Why? How?

Michelle LaPlaca, Neil Harris

Atlanta VA Medical Center

PRECISE-TBI

VA GREATER LOS ANGELES
HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

WHAT is a CDE?

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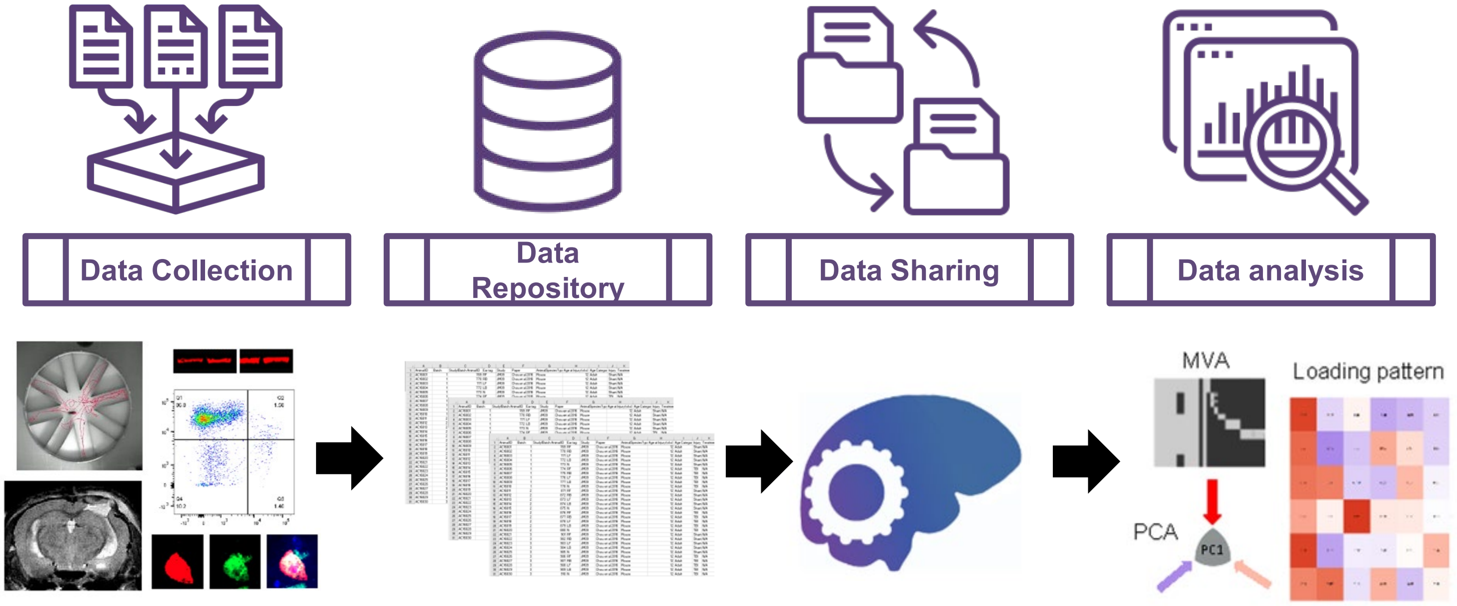
CDEs are concepts related to units of data expressed as content standards, variables, or terms that enable investigators to systematically collect, analyze, and share data across the research community



Data Collection

Data Repository

Data Sharing

Data analysis

adapted from Chou et al. 2022 *Neurotrauma Reports*

WHAT is a Data Dictionary?

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CDEs for a study are assembled into a data dictionary

CDE Level	Variable Name	Title	Description
Core	AgeVal	Age of the animal at the time of procedure	Age of the animal at the time of procedure in minutes, hours, days, weeks, months, or years.

cont'd

Datatype	Maximum character quantity	Input restriction	Minimum value	Maximum value	Permissible values	Unit of measure
Numeric	1000	Free-Form Entry	0	1000		minutes; hours; days; weeks; months; years

cont'd

Guidelines/instructions	Notes	Keywords	CDE origination
Specify the age of the subject. Indicate in your final study data dictionary which unit of measure is used in the dataset.			NIH/CIT/BRICS

WHY do we need CDEs?

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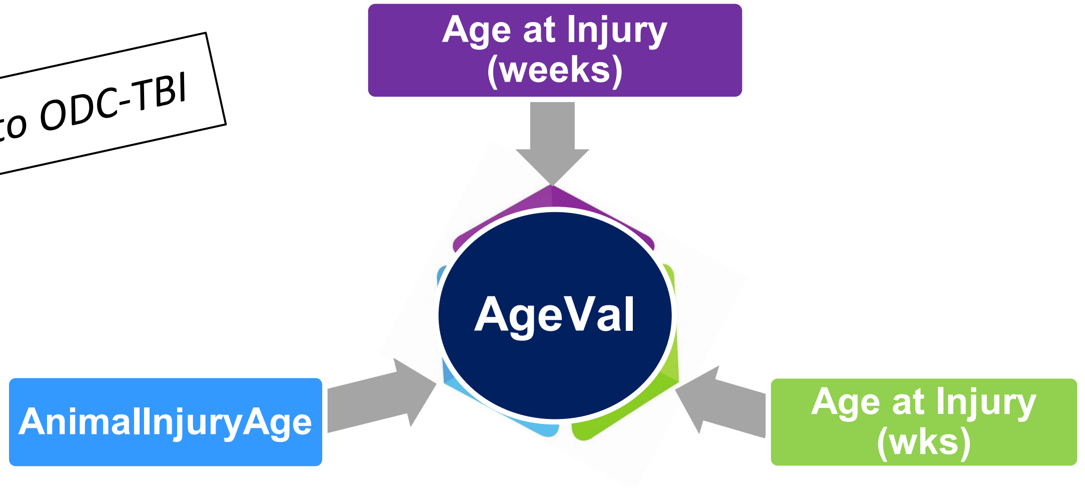
Data submitted to ODC-TBI


Age at Injury (weeks)

AgeVal

AnimalInjuryAge

Age at Injury (wks)

Variable names not consistent
Data not reported evenly

Poor reproducibility
Difficult mapping & sharing

PRECISE CDEs v1.0 (23 CDEs) used to map variable names in 11 datasets from ODC-TBI.

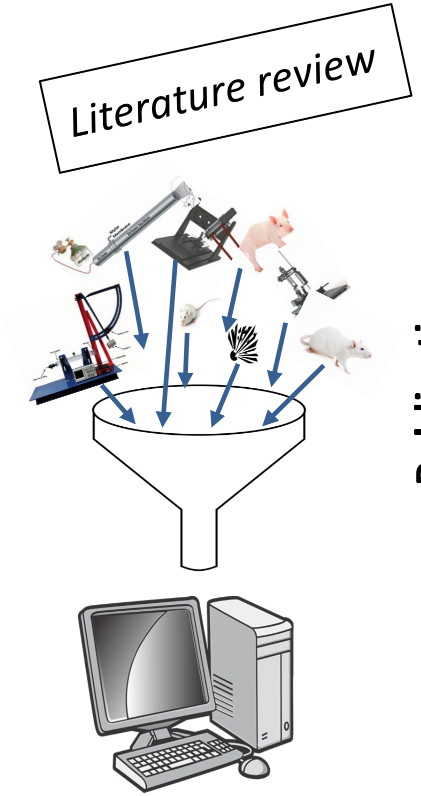
- Best mapping: *Species*, *Breed* (no distinction between breed or strain), *GeneModtxt*, *AgeVal*, *Sex*
- Age not provided for each timepoint; reported at the time of injury
- Units not homogeneous across datasets or in a single dataset

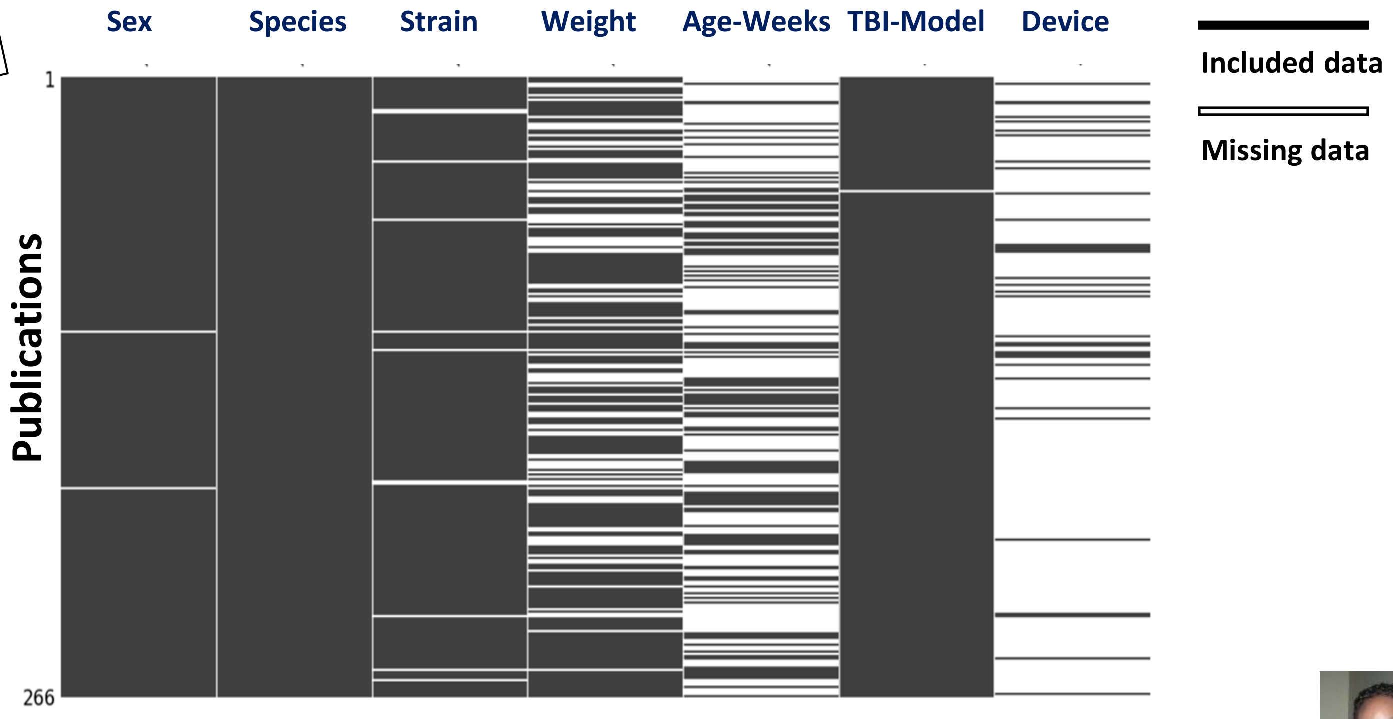
Abel Torres-Espín, Ph.D. UCSF

WHY do we need CDEs?

Missing Information

Poor reproducibility
Difficult mapping & sharing





Monique Surles-Zeigler
Ph.D. UCSD

WHY should I use CDEs?

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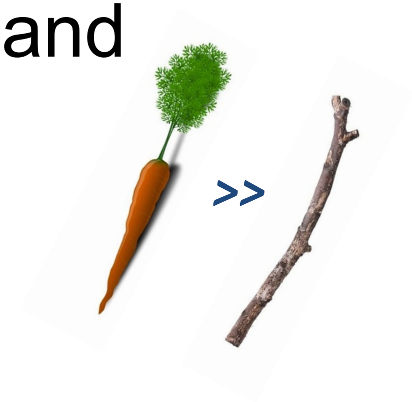
- Facilitate mandatory data management and sharing policies
- Improve data management and quality: ***rigor & transparency***
- Facilitate data sharing among labs & studies: ***reproducibility***
- Enable data pooling to increase statistical power & compare data across labs



HOW are CDEs developed and used?

STEPS for PRECISE-TBI

1. Form working groups of stakeholders and experts to develop / refine CDEs
2. Identify variables that are in common use by the research community
3. Create data dictionary templates and CDE priorities
4. Release to research community for input; enable consensus; update and iterate
5. Endorse for publication and use

STEPS for the Investigator

1. Use existing CDE Data Dictionaries to create study-specific data dictionary
2. Create new CDEs as needed for your study
3. Existing data: map your variables to existing / new CDEs
4. Prospective studies: design data collection instruments to match study-specific data dictionary

e.g., TOP-NT

HOW are CDEs developed and used?

PRINCIPLES

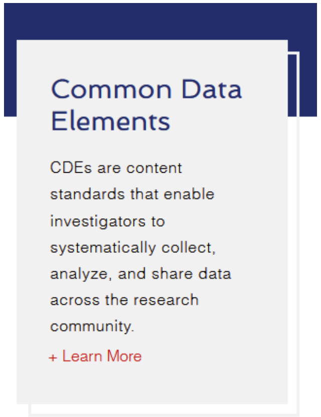
- CDEs are intended to be dynamic and can evolve over time
- PRECISE-TBI will establish a minimal CORE set of CDEs
    - CORE
    - RECOMMENDED
    - SUPPLEMENTAL
- PRECISE-TBI is agnostic to the study
- Each study should have a study-specific data dictionary
- Data sharing does not currently require CDEs
- Informatics tools will make process easier in the future

WHERE do I find CDEs?

https://www.precise-tbi.org/

PRE Clinical Interagency reSearch resourcE-TBI

Elevating Rigor, Reproducibility, Transparency, & Translation in TBI Research


Common Data Elements

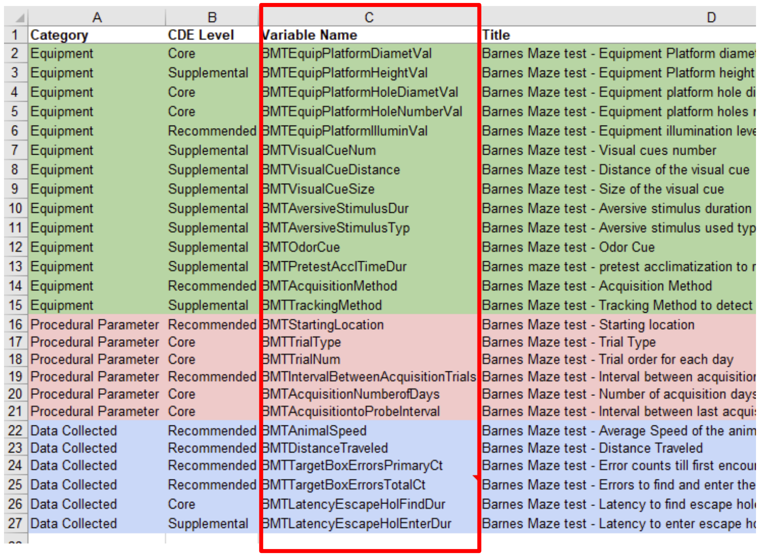
CDEs are content standards that enable investigators to systematically collect, analyze, and share data across the research community.

+ Learn More

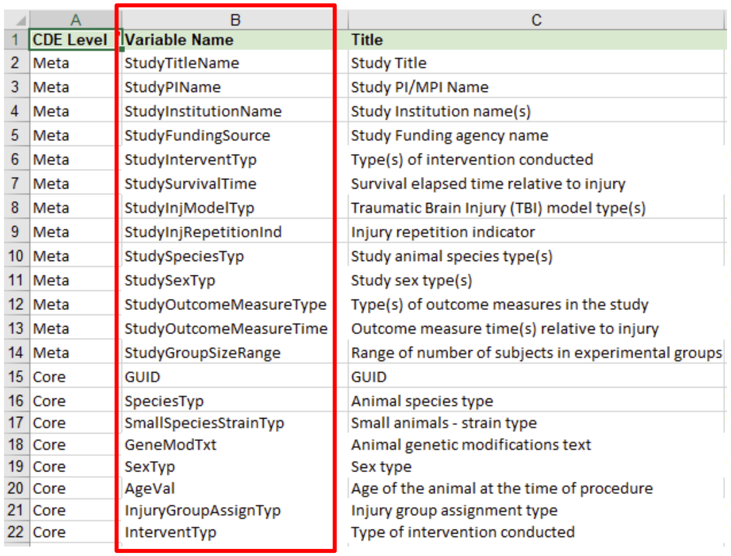
PRECISE CDEs v001.0

PRECISE CDEs v001.1

Check out the latest PRECISE-TBI CDEs by clicking the name on the list to access spreadsheets.



	A	B	C	D
1	**Category**	**CDE Level**	**Variable Name**	**Title**
2	Equipment	Core	BMTEquipPlatformDiametVal	Barnes Maze test - Equipment Platform diame
3	Equipment	Supplemental	BMTEquipPlatformHeightVal	Barnes Maze test - Equipment Platform height
4	Equipment	Core	BMTEquipPlatformHoleDiametVal	Barnes Maze test - Equipment platform hole di
5	Equipment	Core	BMTEquipPlatformHoleNumberVal	Barnes Maze test - Equipment platform holes
6	Equipment	Recommended	BMTEquipPlatformIlluminVal	Barnes Maze test - Equipment illumination leve
7	Equipment	Supplemental	BMTVisualCueNum	Barnes Maze test - Visual cues number
8	Equipment	Supplemental	BMTVisualCueDistance	Barnes Maze test - Distance of the visual cue
9	Equipment	Supplemental	BMTVisualCueSize	Barnes Maze test - Size of the visual cue
10	Equipment	Supplemental	BMTAversiveStimulusDur	Barnes Maze test - Aversive stimulus duration
11	Equipment	Supplemental	BMTAversiveStimulusTyp	Barnes Maze test - Aversive stimulus used typ
12	Equipment	Supplemental	BMTOdorCue	Barnes Maze test - Odor Cue
13	Equipment	Supplemental	BMTPretestAcclTimeDur	Barnes maze test - pretest acclimatization to
14	Equipment	Recommended	BMTAcquisitionMethod	Barnes Maze test - Acquisition Method
15	Equipment	Supplemental	BMTTrackingMethod	Barnes Maze test - Tracking Method to detect
16	Procedural Parameter	Recommended	BMTStartingLocation	Barnes Maze test - Starting location
17	Procedural Parameter	Core	BMTTrialType	Barnes Maze test - Trial Type
18	Procedural Parameter	Core	BMTTrialNum	Barnes Maze test - Trial order for each day
19	Procedural Parameter	Recommended	BMTIntervalBetweenAcquisitionTrials	Barnes Maze test - Interval between acquisitio
20	Procedural Parameter	Core	BMTAcquisitionNumberofDays	Barnes Maze test - Number of acquisition days
21	Procedural Parameter	Core	BMTAcquisitiontoProbeInterval	Barnes Maze test - Interval between last acqui
22	Data Collected	Recommended	BMTAnimalSpeed	Barnes Maze test - Average Speed of the anim
23	Data Collected	Recommended	BMTDistanceTraveled	Barnes Maze test - Distance Traveled
24	Data Collected	Recommended	BMTTargetBoxErrorsPrimaryCt	Barnes Maze test - Error counts till first encou
25	Data Collected	Recommended	BMTTargetBoxErrorsTotalCt	Barnes Maze test - Errors to find and enter the
26	Data Collected	Core	BMTLatencyEscapeHolFindDur	Barnes Maze test - Latency to find escape hol
27	Data Collected	Supplemental	BMTLatencyEscapeHolEnterDur	Barnes Maze test - Latency to enter escape h



	A	B	C
1	**CDE Level**	**Variable Name**	**Title**
2	Meta	StudyTitleName	Study Title
3	Meta	StudyPIName	Study PI/MPI Name
4	Meta	StudyInstitutionName	Study Institution name(s)
5	Meta	StudyFundingSource	Study Funding agency name
6	Meta	StudyInterventTyp	Type(s) of intervention conducted
7	Meta	StudySurvivalTime	Survival elapsed time relative to injury
8	Meta	StudyInjModelTyp	Traumatic Brain Injury (TBI) model type(s)
9	Meta	StudyInjRepetitionInd	Injury repetition indicator
10	Meta	StudySpeciesTyp	Study animal species type(s)
11	Meta	StudySexTyp	Study sex type(s)
12	Meta	StudyOutcomeMeasureType	Type(s) of outcome measures in the study
13	Meta	StudyOutcomeMeasureTime	Outcome measure time(s) relative to injury
14	Meta	StudyGroupSizeRange	Range of number of subjects in experimental groups
15	Core	GUID	GUID
16	Core	SpeciesTyp	Animal species type
17	Core	SmallSpeciesStrainTyp	Small animals - strain type
18	Core	GeneModTxt	Animal genetic modifications text
19	Core	SexTyp	Sex type
20	Core	AgeVal	Age of the animal at the time of procedure
21	Core	InjuryGroupAssignTyp	Injury group assignment type
22	Core	InterventTyp	Type of intervention conducted

HOW do I use CDEs?

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Study-specific CDEs are added to the datasheet

e.g., injury parameters, behavioral outcomes

GUID	SpeciesTyp	SmallSpeciesStrainTyp	GeneModTxt	SexTyp	AgeVal	InjuryGroupAssignTyp	InterventTyp
BS_1001	rat	Sprague Dawley	wild type	male	3	sham	vehicle
BS_1002	rat	Sprague Dawley	wild type	female	3	sham	vehicle
BS_1003	rat	Sprague Dawley	wild type	male	3	sham	vehicle
BS_1004	rat	Sprague Dawley	wild type	female	3	sham	vehicle
BS_1005	rat	Sprague Dawley	wild type	male	3	sham	vehicle
BS_1006	rat	Sprague Dawley	wild type	female	3	sham	vehicle
BS_1007	rat	Sprague Dawley	wild type	male	3	TBI	Drug A
BS_1008	rat	Sprague Dawley	wild type	female	3	TBI	Drug A
BS_1009	rat	Sprague Dawley	wild type	male	3	TBI	Drug A
BS_1010	rat	Sprague Dawley	wild type	female	3	TBI	Drug A
BS_1011	rat	Sprague Dawley	wild type	male	3	TBI	Drug A
BS_1012	rat	Sprague Dawley	wild type	female	3	TBI	Drug A

BS_1012
BS_1012
BS_1012
BS_1012

Each time point or trial for the same animal is indicated on a separate row

Next Steps for CDE Development

❖ **Continue to survey existing CDEs**

- NIH/CIT/BRICS (FITBIR Preclinical)
- TOP-NT
- Epilepsy → PTE

❖ **Widen CDE development** to include **histopathology**, **fluid biomarkers**, **injury models**, and **imaging** as well as priority domains from the community and literature

❖ **Consider end-to-end use of CDEs**

- Data collection tools
- Informatics submission tools – e.g., ODC-TBI

❖ Understand **data sharing requirements** and compatibility with CDE tools

❖ Comply with **National Library of Medicine** governance to **endorse PRECISE-TBI CDEs** for research community use

PRECISE-TBI COMMON DATA ELEMENTS

CDE Committee: _*PRECISE-TBI_

Corina Bondi, Univ Pitt

Fiona Crawford, Roskamp Institute

*Ed Dixon, Univ Pitt

Scott Ferguson, Roskamp Institute

*Jeffrey Grethe, UCSD

*Gene Gurkoff, UC Davis, VA Northern CA Health System

*Neil Harris, UCLA, LA VAMC

*Russell Huie, UCSF, San Francisco VA Health Care System

*Catherine Johnson, Missouri S&T, Truman Memorial Veteran Hospital

*Michelle LaPlaca, Georgia Tech, Emory, Atlanta VAMC

Jonny Lifshitz, Univ Arizona

Bruce Lyeth, UC Davis

Deborah Shear, WRAIR

*Monique Surles-Zeigler, UCSD, San Francisco VA Health Care System

*Abel Torres Espin, UCSF, San Francisco VA Health Care System

*Pam VandeVord, Virginia Tech, Salem VAMC

Cheryl Wellington, UBC

Awwad, Hibah (NIH/NINDS) (at-large)

Coleen Atkins, Miami

Tiffany Greco, UCLA

Annie Hoffman, UCLA

Asla Pitkänen, Univ East Finland

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