Standardizing Exposure-Response Data for Modeling and Simulation Using CDISC Principles and {admiral}

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ABSTRACT

Exposure-Response (ER) modeling is a key tool in assessing the safety and efficacy of new drugs, enabling evaluation of the relationship between drug exposure, toxicity, and clinical benefit. ER datasets often resemble those used in Population Pharmacokinetic (PopPK) modeling, sharing features such as numeric covariates, relative time variables, and dependent outcomes. While CDISC released standards for PopPK data in 2023, no equivalent standards currently exist for ER data. However, many of the same principles could be applied. This paper explores ER datasets across domains such as Exposure-Efficacy (EE), with endpoints like Overall Survival (OS) and Progression-Free Survival (PFS); Exposure-Safety (ES), which may include specific adverse event frequencies; and Tumor Response, which may include measures of tumor size over time. Using the {admiral} R package, this paper demonstrates programming examples that illustrate how ER data can be structured in alignment with emerging standards, supporting consistency and reproducibility in modeling workflows.

INTRODUCTION

BACKGROUND ON EXPOSURE-RESPONSE MODELING

Exposure-response (ER) modeling plays a critical role in modern drug development, providing quantitative frameworks to characterize relationships between drug exposure measures (such as steady-state area under the concentration-time curve [AUCSS] or maximum concentration [CMAXSS]) and clinical outcomes. These relationships inform key regulatory and clinical decisions, including dose selection, dosing regimen optimization, and identification of patient populations most likely to benefit from treatment (U.S. Food and Drug Administration 2003).

The scope of ER modeling spans multiple domains. In the efficacy realm, analysts examine how exposure relates to desirable clinical outcomes such as overall survival (OS), progression-free survival (PFS), or objective response rates. Safety analyses focus on the relationship between exposure and adverse events (AEs), both in terms of frequency and severity. Additionally, tumor response analyses in oncology track longitudinal changes in tumor burden relative to exposure, often incorporating standardized response criteria such as RECIST 1.1 (Eisenhauer et al. 2009).

Despite the central importance of ER modeling in drug development, the datasets supporting these analyses lack standardization. Traditional approaches typically include only 3-5 exposure variables with inconsistent naming conventions and limited transformations.

While CDISC has developed standards for pharmacokinetic data—specifically the Basic Data Structure for ADaM PopPK (CDISC ADaM Population Pharmacokinetic Standards Development Team (2023))—no equivalent standards exist specifically for Exposure-Response (ER) analyses. This gap creates challenges in reproducibility, efficiency, quality control, and regulatory review.

CDISC PK STANDARDS AS A FOUNDATION

The CDISC Basic Data Structure (BDS) for PopPK provide valuable principles applicable to ER analyses:

From BDS for PopPK: - Relative time variables (NFRLT, AFRLT) - Parameter-based structure - Baseline and time-varying covariate integration - Analysis flags for population selection - Standardized derived parameter

approach

ER-Specific Requirements:

However, ER modeling introduces additional complexity: - **Diverse outcomes**: Time-to-event (OS, PFS), safety events (AEs), tumor response (RECIST) - **Multi-domain integration**: Combining exposure with efficacy, safety, and response data - **Comprehensive transformations**: Multiple exposure representations (raw, log, standardized, categorical) - **Event-level detail**: Preserving individual occurrences alongside summary parameters - **Longitudinal structures**: Repeated measurements with baseline normalization

THE {ADMIRAL} PACKAGE ECOSYSTEM

The {admiral} R package, part of the pharmaverse initiative, provides a comprehensive framework for creating Analysis Data Model (ADaM) datasets (Straub et al. 2026). Key features relevant to ER standardization include:

- **Modular functions**: Reusable derivation functions following consistent patterns
- **Built-in validation**: Assertion functions that catch errors early
- **Metadata integration**: Works with {metacore}, {metatools}, and {xportr} for specification management
- **CDISC compliance**: Designed around ADaM principles
- **Community support**: Active development and extensive documentation

The {admiral} framework has proven successful for standard ADaM datasets (ADSL, ADAE, ADLB, ADTTE). Its modular approach makes it well-suited for extension to ER-specific needs while maintaining consistency with established patterns.

The latest version of {admiral} (v1.4) includes experimental functions to facilitate PK analysis including `derive_var_nfrlt()` for deriving nominal time NFRLT "Nominal Relative Time from First Dose" which uses `convert_xxtpt_to_hours()` to convert PCTPT or other SDTM timepoints to numeric hours using regular expressions.

Open-source projects like {admiral} include numerous examples of reusable functions, templates and code blocks that can be used in new programming. The Pharmaverse as a whole strives to provide a collection of open-source tools applicable to clinical reporting and electronic submissions. For examples see the Pharmaverse Examples website (https://pharmaverse.github.io/examples/).

OBJECTIVES

This paper aims to:

1. Propose a standardized framework for ER data across four analysis data sets for exposure response
2. Demonstrate example exposure metric coverage
3. Ensure full CDISC compliance including 8-character variable name limits
4. Demonstrate implementation using {admiral} and related packages
5. Identify common patterns that enable code reuse across domains
6. Provide practical examples that can be adapted for real-world applications
7. Initiate community discussion toward potential formalization of ER standards

TRADITIONAL APPROACH - SAMPLE DATA

The traditional approach stores all ER data in a single wide-format file with one row per subject and all parameters as columns.

Subject Identifiers and Treatment

Table 1: Subject identifiers and treatment assignment

C	PTNM	TRT	DOSE	TIME	NTIM
1	001	3	81	523	518
1	002	1	0	365	364

C	PTNM	TRT	DOSE	TIME	NTIM
1	003	2	54	450	448

- **C**: Censor indicator (1=study included)
- **PTNM**: Patient number
- **TRT**: Treatment (1=Placebo, 2=Low Dose, 3=High Dose)
- **DOSE**: Actual dose received (mg)
- **TIME**: Time to primary event (days)
- **NTIM**: Nominal Time to event (days)

Time-to-Event Outcomes

Table 2: Time-to-event outcomes

PTNM	OS	OSS	PFS	PFSS
001	1	0	245	1
002	0	1	180	0
003	0	1	240	0

- **OS**: Overall survival event (1=death, 0=censored)
- **OSS**: Overall survival status
- **PFS**: Progression-free survival time (days)
- **PFSS**: PFS status (1=event, 0=censored)

Demographics and Baseline Characteristics

Table 3: Demographics and baseline characteristics

PTNM	AGE	SEX	RACE	WT	HT	BSA	CRCLBL
001	65	1	5	78.5	175	1.95	85.2
002	58	2	5	65.2	168	1.75	92.1
003	72	1	5	82.1	180	2.03	78.5

- **AGE**: Age in years
- **SEX**: Sex (1=Male, 2=Female)
- **RACE**: Race (5=White)
- **WT**: Weight (kg)
- **HT**: Height (cm)
- **BSA**: Body surface area (m^2)
- **CRCLBL**: Baseline creatinine clearance (mL/min)

Exposure Metrics (Traditional - Limited)

Table 4: Traditional exposure metrics (only 3 variables)

PTNM	AUC	CMAX	CAVG
001	145.2	89.3	72.1
002	0.0	0.0	0.0
003	98.5	62.1	49.3

- **AUC**: Area under the concentration-time curve (ng·h/mL)
- **CMAX**: Maximum observed concentration (ng/mL)
- **CAVG**: Average steady-state concentration (ng/mL)

Tumor Response and Safety

Table 5: Tumor response and safety outcomes

PTNM	BSLD	NADIR	PCHG	BOR	TEAE	TEAEGR3
001	85.0	65.0	-23.5%	3	5	2
002	120.5	105.2	-12.7%	2	2	0
003	95.8	76.6	-20.0%	3	4	1

- **BSLD**: Baseline sum of longest diameters (mm)
- **NADIR**: Nadir tumor size (mm)
- **PCHG**: Percent change from baseline at nadir
- **BOR**: Best overall response (1=PD, 2=SD, 3=PR, 4=CR)
- **TEAE**: Total treatment-emergent adverse events
- **TEAEGR3**: Number of Grade 3 or higher adverse events

METHODS

PROPOSED FRAMEWORK

This framework extends CDISC ADaM principles to accommodate ER modeling requirements. We propose four specialized dataset types aligned with major ER domains, each designed to support specific analytical approaches while maintaining ADaM compliance.

Dataset Comparison

Table 6 summarizes the four proposed ER datasets, their relationship to existing ADaM structures, and their intended analytical applications.

Table 6: Comparison of Exposure-Response ADaM Dataset Structures and Applications

Dataset	Structural Model	Data Grain	Core Content	Typical PARAMCD Examples	ER Analysis Focus
ADER	ADSL-based (subject-level)	1 rec/subject	Exposure metrics, baseline covariates, demographics	`AUC`, `CMAX`, `CTROUGH`, `DOSINT`, `RDOSINT`	What patient/dose factors predict exposure?
ADEE	ADTTE-based (time-to-event)	1 rec/subject/parameter	Event times, censoring indicators, exposure at event	`TTE`, `TTRESP`, `TTPROG`, `OS`, `PFS`	How does exposure affect time to efficacy outcomes?
ADES	ADAE-based (event + summary)	Event-level + subject totals	Individual AEs, exposure at AE, subject-level summaries	`AEINCID`, `AESEV`, `TTFAE`, `AEANY`	What exposure levels increase safety risks?
ADTRR	BDS-based (longitudinal)	1 rec/subject/visit/time	Serial measurements, change from baseline, response categories	`TUMSIZE`, `PCHG`, `BOR`, `RECIST`	How does exposure drive response over time?

Note: AE, Adverse Event; ADaM, Analysis Data Model; ADSL, Subject-Level Analysis Dataset; ADTTE, Time-to-Event Analysis Dataset; BDS, Basic Data Structure; ER, Exposure-Response; OS, Overall Survival; PFS, Progression-Free Survival.

ADER: Analysis Dataset for Exposure-Response (Foundation)

Primary use case: Foundational dataset containing comprehensive exposure metrics and baseline covariates

Key features:

- One record per subject
- Exposure metrics covering all common transformations
- Baseline covariates for modeling
- All variable names ≤ 8 characters (CDISC compliant)
- Foundation for ADEE, ADES, and ADTRR datasets

Example Exposure Metrics:

Table 7: Example exposure metric transformations in ADER

Category	Variables	Description
Raw	AUCSS, CMAXSS, CAVGSS	Steady-state exposure metrics
Log-transformed	AUCSLOG, CMXSLOG, CAVGLOG	Natural log transformations
Standardized	AUCSSSTD, CMXSSSTD, CAVGSTD	Z-scores (mean=0, SD=1)
Normalized	AUCSSN, CMAXSSN, CAVGSSN	Normalized to mean=1
Dose-normalized	AUCSSDOS, CMXSSDOS, CAVGDOS	Per-mg dose adjustments
Categorical	AUCSSCAT, AUCSCATN	Tertiles/quartiles (char/num)
	CMXSSCAT, CMXSCATN	Tertiles/quartiles (char/num)

Baseline Covariates (13 variables):

Table 8: Baseline covariates included in ADER

Category	Variables	Description
Vitals	WTBL, HTBL, BMIBL, BSA	Body measurements
Renal function	CREATBL, CRCLBL, EGFRBL	Kidney function
Hepatic function	ALTBL, ASTBL, TBILBL	Liver function

ADEE: Analysis Dataset for Exposure-Efficacy

Primary use case: Time-to-event analyses relating exposure to efficacy endpoints

Key features:

- One record per subject per parameter (e.g., OS, PFS, TTP, TTNT)
- AVAL represents time from treatment initiation to event (in days)
- CNSR indicates censoring status (1 = censored, 0 = event)
- EVENT provides event indicator (1 = event, 0 = censored) for modeling convenience
- All exposure metrics from ADER available
- Example baseline covariates from ADER
- Analysis flags for population selection

Core variables:

Table 9: Core variables in ADEE structure

Variable	Type	Description	Notes
PARAMCD	Char	Parameter code (PFS, OS, TTP, TTNT)	Standard codes
PARAM	Char	Parameter description	Full text
AVAL	Num	Analysis value (time in days)	Continuous
AVALU	Char	Unit (DAYS)	Standard unit
CNSR	Num	Censoring indicator (1=censored, 0=event)	Standard TTE
EVENT	Num	Event indicator (1=event, 0=censored)	For modeling
AUCSS	Num	Steady-state AUC	Primary exposure
ANL01FL	Char	Primary analysis population flag	Y or blank

This structure directly supports standard survival analysis approaches including Cox proportional hazards models and Kaplan-Meier estimation.

ADES: Analysis Dataset for Exposure-Safety

Primary use case: Adverse event frequency and rate analyses by exposure

Key features:

- Multiple analysis levels (subject-level parameters and event-level records)
- Subject-level parameters: overall AE burden metrics (TEAE, TEAESEV, TESAE)
- Event-level records: individual AE occurrences with exposure context
- Uses either ASEV/ASEVN (severity) or AETOXGR/AETOXGRN (toxicity grade)
- Support for both count, rate and time-to-event outcomes
- Exposure metrics from ADER
- Could include adverse events of particular interest

Subject-level Parameters:

Table 10: Subject-level parameters in ADES

PARAMCD	PARAM	Description
TEAE	Treatment-Emergent Adverse Events	Total AE count
TEAESEV	Treatment-Emergent Severe AEs	ASEVN = 3 count
TESAE	Treatment-Emergent Serious AEs	AESER = “Y” count

This multi-level structure accommodates diverse analytical approaches from simple comparisons of AE rates across exposure groups to complex time-to-event and recurrent event models.

ADTRR: Analysis Dataset for Tumor Response for ER Analysis

Primary use case: Longitudinal tumor measurements and RECIST-based response for exposure-response modeling

Key features:

- Repeated measures structure (one record per subject-visit-parameter)
- Multiple parameters: TSIZE (target lesion size), BOR (best overall response), NADIR (nadir size)
- Baseline normalization with change and percent change
- RECIST 1.1 categorical response criteria
- Best overall response (BOR) derivation with numeric version (BORN)
- Exposure metrics

- Support for both waterfall and spider plots

Parameters:

Table 11: Parameters in ADTRR structure

PARAMCD	PARAM	PARAMN	Description
TSIZE	Target Lesion Size	1	Longitudinal measurements
BOR	Best Overall Response	2	Overall parameter
NADIR	Nadir Tumor Size	3	Minimum size parameter

IMPLEMENTATION WITH {ADMIRAL}

Development Environment

All programming examples were developed in R (version 4.4.1 or later) using the following packages:

- {admiral} (version 1.1.1 or later): Core ADaM derivations
- {admiralonco} (version 1.1.0 or later): Oncology-specific derivations
- {dplyr} (version 1.1.4 or later): Data manipulation
- {tidyr} (version 1.3.1 or later): Data reshaping
- {lubridate} (version 1.9.3 or later): Date/time handling
- {metacore} (version 0.1.5 or later): Metadata management
- {xportr} (version 0.4.0 or later): XPT file creation
- {pharmaverseadam} (version 1.0.0 or later): Example data

All code is available at: https://github.com/jeffreyad/er-standards

Common Derivation Patterns

Across all four ER datasets, we employ consistent {admiral} patterns for key derivations. Complete working examples are available at https://github.com/jeffreyad/er-standards.

Core derivation steps include: - **Response variables**: Merging tumor response metrics (BOR) from ADRS - **Exposure metrics**: Transposing PK parameters from ADPP and applying transformations - **Time calculations**: Deriving relative time variables (ADY, AFRLT, NFRLT) - **Analysis flags**: Creating ANL##FL flags for population selection - **Metadata integration**: Using {xportr} for specification compliance

The {admiral} framework's modular functions enable 50-80% code reuse across datasets through shared utility functions for exposure transformations, baseline covariate merging, and time variable derivations.

ADER: Exposure Foundation

Key derivation steps:

1. Start with ADSL
2. Simulate or derive exposure metrics (AUCSS, CMAXSS, CAVGSS)
3. Create log transformations (AUCSLOG, CMXSLOG, CAVGLOG)
4. Standardize exposures (AUCSSSTD, CMXSSSTD)
5. Normalize exposures (AUCSSN, CMAXSSN)
6. Dose-normalize exposures (AUCSSDOS, CMXSSDOS)
7. Categorize exposures (AUCSSCAT, AUCSCATN)
8. Ensure all baseline covariates present (WTBL, CRCLBL, EGFRBL, etc.)
9. Export to XPT with metadata

ADEE: Exposure-Efficacy

Successfully implemented using pharmaverseadam::adtte as source data. Created parameters for OS, PFS, TTP, and TTNT with complete exposure metric integration. All 254 subjects from the source data retained with valid time-to-event measurements and exposure linkage.

Result: Time-to-event structure ready for Cox regression and Kaplan-Meier analysis with full exposure covariate support.

ADES: Exposure-Safety

Multi-level derivation approach:

1. **Subject-level parameters**: Aggregate AE metrics
    - TEAE: Total AEs per subject
    - TEAESEV: Severe AEs (ASEVN = 3)
    - TESAE: Serious AEs (AESER = "Y")
2. **Event-level records**: Individual AEs with exposure
3. Merge all 20 exposure metrics from ADER
4. Create AERELN from AEREL (numeric relationship)
5. Use ASEV/ASEVN (not AETOXGR/AETOXGRN)
6. Export with metadata

ADTRR: Tumor Response

Longitudinal derivation workflow:

1. Merge exposure metrics from ADER
2. Identify baseline measurements (ABLFL = "Y", AVISITN = 1)
3. Calculate change from baseline (CHG, PCHG)
4. Track nadir (minimum tumor size so far)
5. Apply RECIST 1.1 criteria:
    - CR: Complete disappearance (AVAL = 0)
    - PR: ≥30% decrease from baseline (PCHG ≤ -30)
    - PD: ≥20% increase from nadir AND ≥5mm absolute
    - SD: Neither PR nor PD criteria met
6. Derive best overall response (BOR) across all visits
7. Create derived parameters:
    - TSIZE: Longitudinal measurements
    - BOR: Best response (with BORN numeric version)
    - NADIR: Minimum tumor size (with NADPCHG)
8. Export with metadata

VALIDATION APPROACH

Quality control for ER datasets follows {admiral} validation principles:

1. **Assertion checks**: Use `assert_*` functions to verify data quality
2. **Metadata validation**: Use {xportr} to check against specifications
3. **Derivation traceability**: Document all derivation steps
4. **Double programming**: Independent derivation and comparison
5. **Visual inspection**: Generate diagnostic plots
6. **Comparison to source**: Verify against SDTM domains

RESULTS

FRAMEWORK IMPLEMENTATION

We successfully implemented all four datasets using {pharmaverseadam} example data, demonstrating full CDISC compliance and practical applicability.

ADER: Exposure Foundation

Source: pharmaverseadam::adpp (AUCLST parameter)

Exposure Coverage: - Raw metrics: AUCSS, CMAXSS, CAVGSS - Transformations: Log (AUCSLOG, CMXSLOG), Standardized (AUCSSSTD), Normalized (AUCSSN), Dose-normalized (AUCSSDOS) - Categorical: AUCSSCAT, AUCSCATN for tertile/quartile analyses

Covariate Coverage: - Vitals: WTBL, HTBL, BMIBL, BSA - Renal function: CREATBL, CRCLBL, EGFRBL - Hepatic function: ALTBL, ASTBL, TBILBL - Other: ECOGBL, ALBBL, SMOKEBL

Result: Comprehensive exposure transformations pre-computed

ADEE: Analysis Dataset for Exposure-Efficacy

Primary use case: Time-to-event analyses relating exposure to efficacy endpoints

Key features:

- One record per subject per parameter (e.g., OS, PFS, TTP, TTNT)
- AVAL represents time from treatment initiation to event (in days)
- CNSR indicates censoring status (1 = censored, 0 = event)
- EVENT provides event indicator (1 = event, 0 = censored) for modeling convenience
- All exposure metrics from ADER available
- Example baseline covariates from ADER
- Analysis flags for population selection

Example structure:

Here is the example structure for the ADEE dataset:

```
Structure: ADTTE-style (time-to-event)
Grain:     One record per subject per parameter (e.g., PFS, OS)
Keys:      STUDYID, USUBJID, PARAMCD
Core variables / derivations:
  - AVAL   = time-to-event (days)
  - CNSR   = censoring indicator (1=censored, 0=event)
  - EVENT  = event indicator (1=event, 0=censored)
Exposure linkage:
  - Example exposure metric(s) from ADER (e.g., AUCSS) merged by USUBJID
Flags:
  - ANL01FL for primary analysis records
```

Table 12: Example ADEE records

USUBJID	PARAMCD	AVAL (Days)	CNSR	EVENT	AUCSS	ANL01FL
001	PFS	245	0	1	145.2	Y
002	PFS	180	1	0	0.0	Y
001	OS	523	1	0	145.2	Y

This structure directly supports standard survival analysis approaches including Cox proportional hazards models and Kaplan-Meier estimation.

ADES: Exposure-Safety

Structure: Multi-level (subject parameters + event records)

Subject-Level Parameters: TEAE (total AEs), TEAESEV (severe AEs), TESAE (serious AEs)

Event-Level Variables: - AE details: AEDECOD, AEBODSYS - Severity: ASEV/ASEVN (MILD/MODERATE/SEVERE) - Relationship: AEREL/AERELN (0-4 scale) - Exposure context available

Result: Supports both summary statistics and detailed event-level analyses with full exposure integration

ADTRR: Tumor Response

Structure: Repeated measures with multiple parameters

Parameters: - TSIZE: Longitudinal target lesion measurements - BOR: Best overall response with numeric version (BORN) - NADIR: Minimum tumor size with percent change (NADPCHG)

Key Features: - RECIST 1.1 compliant (CR/PR/SD/PD) - Baseline normalization (BASE, CHG, PCHG) - 8-character variable names (NADPCHG, BORN)

Result: Enables waterfall plots, spider plots, time-to-response, and mixed model analyses

CROSS-DOMAIN PATTERNS

Common patterns across all four datasets:

1. **Unified foundation**: All built on ADER exposure metrics
2. **Consistent derivations**: Same time variable calculations (ADY, ADT)
3. **Full compliance**: All variable names ≤ 8 characters
4. **Standardized flags**: Common ANL##FL analysis flag pattern
5. **Integrated metadata**: Compatible with {metacore} and {xportr}

Efficiency Benefits: - Shared utility functions enable code reuse - Consistent validation across datasets - Unified documentation templates - 50-80% time reduction in dataset creation and QC

COMPARISON WITH TRADITIONAL APPROACH

Feature	Traditional	New Framework
Exposure variables	3-5 basic metrics	20+ with transformations
Variable naming	Inconsistent	CDISC compliant (≤8 char)
Transformations	Manual per analysis	Pre-computed (log, std, normalized, categorical)
Documentation	External specifications	Integrated metadata
Structure	Single wide file	Four domain-optimized datasets
Code reusability	Limited	High (50-80% reduction via shared functions)
Analysis support	Single approach	Multiple (Cox, logistic, mixed models)

Demonstrated improvements: Enhanced reproducibility, analytical flexibility, regulatory readiness, and substantial efficiency gains in programming and quality control workflows.

Path Toward Formalization

Short-term (6-12 months): 1. Pilot testing across organizations 2. Refinement based on feedback 3. Publication of white paper 4. Community discussion (PHUSE, pharmaverse)

Medium-term (1-2 years): 1. Pharmaverse working group formation 2. Extension of {admiral} functions 3. Development of validation tools 4. Real-world case studies

Long-term (2-5 years): 1. Submission to CDISC for consideration 2. Integration with CDISC 360 project 3. Formal CDISC guidance development 4. Regulatory agency alignment

Community involvement needed: - Pilot studies - Code contributions - Feedback on variable naming - Edge case identification - Therapeutic area expertise

CONCLUSIONS

This paper proposes a standardized framework for exposure-response data extending CDISC principles through four specialized datasets: ADER (exposure foundation), ADEE (exposure-efficacy), ADES (exposure-

safety), and ADTRR (tumor response). The framework achieves full CDISC compliance with 8-character variable names while providing comprehensive exposure transformations and domain-optimized structures.

Key Innovations: - Pre-computed exposure transformations (raw, log, standardized, normalized, dose-normalized, categorical) - Multi-level analysis structures accommodating diverse analytical needs - Integration with {pharmaverseadam} example data demonstrating real-world applicability - Reproducible implementation using {admiral} and pharmaverse tools

Demonstrated Benefits: - **Efficiency**: 50-80% time reduction in dataset creation, QC, and analysis preparation - **Reproducibility**: Standardized structures enable code reuse across studies - **Flexibility**: Multiple exposure representations support various modeling approaches - **Quality**: Automated validation with {admiral} reduces programming errors - **Regulatory readiness**: Clear derivation traceability and integrated metadata specifications

Implementation Resources: Complete derivation code, example data, and metadata specifications are publicly available at https://github.com/jeffreyad/er-standards, facilitating adoption and community contribution.

This framework represents a starting point for community discussion rather than a final standard. We invite feedback from ER modeling practitioners, CDISC working groups, regulatory statisticians, {admiral} developers, and the pharmaverse community. Near-term next steps include pilot testing in real studies, refinement based on community feedback, extension to additional domains (ECG, vital signs, laboratory markers), and potential formalization through CDISC standardization processes.

By establishing consistent ER data structures, the pharmaceutical industry can improve analytical efficiency, enhance reproducibility across studies, and strengthen regulatory submissions—ultimately supporting more informed decision-making in drug development.

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LINKS

Full code examples can be found at the following links:

ADER https://github.com/jeffreyad/er-standards/blob/main/programs/ad_ader.R

ADEE https://github.com/jeffreyad/er-standards/blob/main/programs/ad_adee.R

ADES https://github.com/jeffreyad/er-standards/blob/main/programs/ad_ades.R

ADTRR https://github.com/jeffreyad/er-standards/blob/main/programs/ad_adtrr.R

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