DTS PRE-UAT AUDIT

Independent Pre-UAT Review of a Data Transfer Specification

Sponsor	LRC Pharmaceuticals
Protocol	LRC-2026-001
DTS reviewed	Version 1.0, dated 01-JUN-2026
RTSM platform	RTSM / IRT
EDC platform	Medidata Rave EDC
Integration	One-way, out of RTSM into EDC; Rave Web Services (REST)
Audit date	01-JUN-2026
Prepared by	Luis Rodriguez Consulting

SAMPLE DELIVERABLE

This is a sanitized sample of the report a client receives from a DTS Pre-UAT Audit. The sponsor name, protocol, and study details are fictitious and used only to illustrate format and depth. No real sponsor, compound, or study is represented.

Contents

1. Executive Summary

This report presents the findings of an independent pre-UAT review of the Data Transfer Specification (DTS) governing the one-way integration from the RTSM system into Medidata Rave EDC for protocol LRC-2026-001. The review evaluated the specification against five dimensions: completeness, technical feasibility, data mapping accuracy, error handling and edge cases, and regulatory and audit-trail readiness.

Overall readiness: Conditional. The DTS is well-structured and covers the core transfer scenarios, but it is not yet ready for UAT entry. Three Critical findings concern unblinding protection, emergency-unblinding scope, and retry cadence for supply-critical notifications, and should be resolved before UAT begins. The Major findings should be closed before UAT entry or scheduled with owners and dates.

Findings by severity

Critical	Major	Minor	Observation
3	10	6	4

The three risks that matter most

- Unblinding could leak at the EDC layer. Treatment arm and drug code are sent as unblinded data, but the forms that carry them do not record the access restriction or name the restricted form. A blinded user could potentially see treatment assignment. (Finding M-1.)
- A failed supply or randomization message could go uncorrected for a week. The default retry cadence after three failed attempts is weekly, applied to all transaction types alike, including dispensation and randomization. (Finding E-1.)
- Emergency unblinding has no defined path. Unblinded data flows exist, but there is no trigger or form for an emergency or manual unblinding event, leaving a safety-critical action unrepresented in EDC. (Finding C-1.)

Recommended next step: Resolve the three Critical findings and confirm owners and target dates for the Major findings before entering UAT. The Minor findings and Observations can be addressed in parallel during UAT preparation. A one-hour debrief call is available to walk through the findings and prioritization.

2. Scope & Methodology

This audit is an independent document review of the DTS identified on the title page. It does not include UAT execution, system configuration or build, EDC form design, or regulatory submission support; those are available as separate engagements. The review is based solely on the specification as written and on standard RTSM-EDC integration practice; it does not assume access to the live systems.

Evaluation dimensions

- Completeness — coverage of the integration data points and scenarios the study requires, including the transactions and events implied by the protocol.
- Technical feasibility — whether the transfer method, environment handling, and identifiers are consistent and workable for the stated platforms.
- Data mapping accuracy — consistency and completeness of field mappings, code lists, OID alignment, stratification handling, and cross-references between RTSM and EDC.
- Error handling and edge cases — defined behavior for failed transfers, retries, backouts, manual intervention, and reconciliation.
- Regulatory and audit trail — conformance with 21 CFR Part 11, ICH E6(R3), and GAMP 5 expectations for data integrity, traceability, and defensibility.

Severity definitions

Severity	Definition
Critical	Could compromise patient safety, blinding, or randomization integrity, or will block go-live. Resolve before UAT entry.
Major	Likely to surface as a UAT defect or a data-reconciliation problem. Resolve before UAT entry or schedule with an owner and date.
Minor	Quality, clarity, or consistency issue with low operational risk. Resolve before DTS approval.
Observation	Best-practice recommendation. Non-blocking; addresses durability and defensibility.

3. Findings Summary

The table below lists all findings in priority order. Detailed findings follow in Section 4, grouped by evaluation dimension.

ID	Dimension	Severity	Finding
C-1	Completeness	**Critical**	No emergency or manual unblinding event defined despite unblinded data in scope
M-1	Data Mapping Accuracy	**Critical**	Unblinding-sensitive fields are not flagged at the form level
E-1	Error Handling & Edge Cases	**Critical**	Weekly retry cadence is too slow for supply and randomization-critical notifications
C-2	Completeness	**Major**	Re-randomization trigger declared but not specified
C-3	Completeness	**Major**	Ancillary drug allocation named as critical but not mapped
M-2	Data Mapping Accuracy	**Major**	Stratification factors are undefined
M-3	Data Mapping Accuracy	**Major**	Competing date concepts across two forms
M-4	Data Mapping Accuracy	**Major**	AGE field-ownership conflict
T-1	Technical Feasibility	**Major**	MetaDataVersionOID is hardcoded to “1” in all examples
T-2	Technical Feasibility	**Major**	StudyOID shows the Production value in all examples, including test contexts
E-2	Error Handling & Edge Cases	**Major**	Orphaned accountability records on dispensation backout are not addressed
E-3	Error Handling & Edge Cases	**Major**	Screening and rescreening backouts are handled outside the transfer
R-1	Regulatory & Audit Trail	**Major**	Audit trail for manual interventions is unspecified
C-4	Completeness	**Minor**	Trigger matrix omits the Enrollment transaction
M-5	Data Mapping Accuracy	**Minor**	Date-of-birth format is ambiguous
M-6	Data Mapping Accuracy	**Minor**	Randomization XML example does not demonstrate the sensitive transfer

ID	Dimension	Severity	Finding
T-3	Technical Feasibility	**Minor**	Satellite-site truncation could collide with an existing site ID
E-4	Error Handling & Edge Cases	**Minor**	No triage mapping for EDC ReasonCodes
R-2	Regulatory & Audit Trail	**Minor**	Approval signatures are not executed
C-5	Completeness	**Observation**	No data flow diagram included
T-4	Technical Feasibility	**Observation**	Two-account credential policy is sound; confirm Production provisioning before go-live
E-5	Error Handling & Edge Cases	**Observation**	Reconciliation capability is generation-only
R-3	Regulatory & Audit Trail	**Observation**	No documented UAT validation of blinded/unblinded segregation

4. Detailed Findings

Completeness

C-1 CRITICAL No emergency or manual unblinding event defined despite unblinded data in scope

Observation. The DTS declares Unblinded Data Points = Yes and transfers Treatment Arm, Drug Code, and Drug Unit ID (Kit ID), but no trigger, form, or notification is defined for an emergency or manual unblinding event. Emergency unblinding is a standard RTSM transaction and a Part 11 audit-trail-sensitive event.

Risk & impact. If unblinding occurs in RTSM but is not represented in EDC, the two systems disagree on a safety-critical fact, and the unblinding action may not be traceable in the EDC audit trail. If unblinding is intended to flow to EDC and is simply unspecified, it may surface as a late UAT defect or a post-go-live gap.

Recommendation. Confirm with the sponsor and RTSM vendor whether emergency unblinding is in scope for this integration. If in scope, add the trigger, target form, transaction type, and restricted-access handling. If out of scope, state so explicitly and document the manual process and its audit trail.

DTS reference: *Data Transfer Overview; IRT Form Triggers (Section 5.3)*

C-2 MAJOR Re-randomization trigger declared but not specified

Observation. The Randomization form lists “Re-randomization (if applicable)” as a trigger, but no row appears in any trigger matrix, and the transaction-type behavior (Insert vs. Update on a re-randomization) and downstream impact on dispensation and accountability are not defined.

Risk & impact. An undefined re-randomization path is a common source of UAT defects and of duplicated or conflicting randomization records in EDC.

Recommendation. Either remove the re-randomization trigger if the protocol does not permit it, or fully specify the transaction sequence, including how a re-randomization updates TRTARM/STRAT and whether prior dispensation/accountability records are affected.

DTS reference: *Randomization Form*

C-3 MAJOR Ancillary drug allocation named as critical but not mapped

Observation. The Critical Data Points note references Treatment Arm and dispensed Drug Code / Kit ID “used for ancillary drug allocation,” yet no form or field mapping in the specification covers ancillary supply.

Risk & impact. A data point the DTS itself flags as critical has no defined transfer, creating ambiguity about whether ancillary allocation is in scope and how it reaches EDC.

Recommendation. Clarify whether ancillary drug allocation is part of this integration. If so, add the corresponding form and mappings; if not, remove it from the Critical Data Points list to avoid implying coverage that does not exist.

DTS reference: *Data Transfer Overview (Critical Data Points)*

C-4 MINOR Trigger matrix omits the Enrollment transaction

Observation. The Screening form lists “Enrollment” among its triggers, but the IRT Form Triggers matrix contains no Enrollment row, so the narrative and the matrix disagree.

Risk & impact. Inconsistency between the form narrative and the trigger matrix invites differing build and test interpretations.

Recommendation. Reconcile the two. Add an Enrollment row to the trigger matrix or remove Enrollment from the Screening form trigger list, whichever matches the intended design.

DTS reference: *Screening Form; IRT Form Triggers (continued)*

C-5 OBSERVATION No data flow diagram included

Observation. The DTS does not include a data flow diagram mapping the RTSM-to-EDC interface and its data points.

Risk & impact. ICH E6(R3) data-governance expectations and the ACRO/TransCelerate adoption tools recommend a data flow diagram for connected systems; its absence is a documentation gap rather than a defect.

Recommendation. Add a one-page data flow diagram showing each transaction, its triggering event, the target form, and direction of flow. It also accelerates stakeholder review and UAT planning.

DTS reference: *Document-level*

Data Mapping Accuracy

M-1 CRITICAL Unblinding-sensitive fields are not flagged at the form level

Observation. Treatment Arm (TRTARM) and Drug Code (DRUGCODE) are declared unblinded data points routed to “a Rave EDC form restricted to unblinded users,” but neither the Randomization form nor the Dispensation form spec records the restricted-access designation, names the target restricted form, or describes how blinded study-team users are prevented from viewing these values.

Risk & impact. Without an explicit form-level restriction, an unblinding leak at the EDC layer becomes possible — blinded users could see treatment assignment or drug code. This is the highest-consequence failure mode for a blinded study.

Recommendation. For every form carrying an unblinded field, record the EDC access restriction, name the restricted form/role, and add an explicit UAT test case proving blinded roles cannot view TRTARM, DRUGCODE, or KITID. Confirm the EDC-side role configuration with the EDC team before UAT.

DTS reference: *Randomization Form; Dispensation Form; Data Transfer Overview*

M-2 MAJOR Stratification factors are undefined

Observation. STRAT maps to “Stratification factor combinations” as a single coded list, with no definition of the individual stratification factors, no code list, and no confirmation that stratum codes align between RTSM and EDC.

Risk & impact. Mismatched or undefined stratum codes are among the most common randomization-integration defects and can corrupt stratified analyses.

Recommendation. Define each stratification factor and its levels, provide the full code list, and confirm code-value and OID alignment between RTSM and the EDC field. Add UAT cases covering each stratum combination.

DTS reference: *Randomization Form*

M-3 MAJOR Competing date concepts across two forms

Observation. ENRDAT (“Date subject was enrolled/randomized”) sits on the Screening form, while RANDDT (“Date of randomization”) sits on the Randomization form. Both can represent the randomization date.

Risk & impact. Two sources for one underlying concept create a reconciliation discrepancy and ambiguity about which field is authoritative for analysis.

Recommendation. Define each date precisely and confirm they are intended to differ (e.g., enrollment vs. randomization). If they represent the same event, consolidate to a single authoritative field.

DTS reference: *Screening Form; Randomization Form*

M-4 MAJOR AGE field-ownership conflict

Observation. AGE is transferred from RTSM as an integer while DOB (BRTHDTC) is also transferred. If the EDC derives age from date of birth, the RTSM-supplied AGE may conflict with the EDC-derived value.

Risk & impact. Two systems writing or deriving the same value produces edit-check failures or silent data discrepancies.

Recommendation. Confirm whether AGE is EDC-derived. If it is, do not transfer AGE from RTSM; if it is a direct-entry field, confirm the derivation rules match. Document the single owner of the value.

DTS reference: *Demographics Form*

M-5 MINOR Date-of-birth format is ambiguous

Observation. The BRTHDTC data format allows “yyyy or yyyy-mm-dd,” and the RTSM mapping reads “Year of Birth / Date of Birth.” The EDC field will accept one defined format.

Risk & impact. Format ambiguity risks edit-check rejection or inconsistent data capture across sites.

Recommendation. Specify a single expected format for the EDC field and confirm RTSM emits exactly that format.

DTS reference: *Demographics Form*

M-6 MINOR Randomization XML example does not demonstrate the sensitive transfer

Observation. The Randomization form example transmits only RANDNUM and omits TRTARM and STRAT — the very fields the specification treats as unblinding-sensitive and analytically critical.

Risk & impact. The example does not illustrate the highest-risk part of the transfer, reducing its usefulness as a build and test reference.

Recommendation. Extend the example to include TRTARM and STRAT, with values that exercise the restricted-access handling.

DTS reference: *Randomization Form Example*

Technical Feasibility

T-1 MAJOR MetaDataVersionOID is hardcoded to "1" in all examples

Observation. Every ODM XML example uses MetaDataVersionOID="1". In Rave, this value is expected to correspond to the active CRF/draft version in the target URL, which can differ across environments and over the study lifecycle.

Risk & impact. If the emitted MetaDataVersionOID does not match the deployed CRF version, transactions may be rejected. Hardcoding it removes the flexibility to track CRF versioning.

Recommendation. Confirm with the EDC vendor how MetaDataVersionOID is expected to be sourced for this study, and specify whether RTSM parameterizes it per environment and CRF version rather than emitting a constant. (Stated as a verification item, not an assertion of platform behavior.)

DTS reference: *Form Specifications (all XML examples)*

T-2 MAJOR StudyOID shows the Production value in all examples, including test contexts

Observation. The IRT Variable Table correctly parameterizes StudyOID by environment (UAT vs. Prod), but every XML example uses StudyOID="LRC-2026-001(Prod)", including examples that would occur in a test environment.

Risk & impact. If examples are used as build references without adjustment, transactions could be posted against the wrong environment.

Recommendation. Confirm StudyOID is environment-driven at runtime and update at least one example to show the UAT value, so the examples reinforce the variable-table rule rather than contradict it.

DTS reference: *IRT Variable Table; Web Service Call Specification*

T-3 MINOR Satellite-site truncation could collide with an existing site ID

Observation. The LocationOID rule strips extra characters from satellite site IDs (e.g., 999a becomes 999). If a numeric site 999 also exists, the truncation produces a collision.

Risk & impact. Two distinct RTSM sites could map to one EDC LocationOID, misrouting subject data.

Recommendation. Confirm against the site list that no satellite-site truncation collides with an existing numeric site, and document the rule for resolving any collision.

DTS reference: *IRT Variable Table (LocationOID)*

T-4 OBSERVATION Two-account credential policy is sound; confirm Production provisioning before go-live

Observation. The dual-account policy (separate test and Production credentials, no overlap) follows good practice for limiting Production access.

Risk & impact. Low. The only risk is operational: a Production account not provisioned in time for the UAT-to-Prod migration could delay go-live.

Recommendation. Confirm the Production account is provisioned and validated ahead of the migration window. No change to the policy is needed.

DTS reference: *Data Transfer Credentials*

Error Handling & Edge Cases

E-1 CRITICAL Weekly retry cadence is too slow for supply- and randomization-critical notifications

Observation. After the maximum failed send attempts (default 3), the system re-sends failed files at a configurable but default-weekly cadence. The same cadence applies regardless of transaction type.

Risk & impact. A failed dispensation, randomization, or accountability notification could leave EDC out of sync with drug accountability and treatment assignment for up to a week, undermining safety monitoring and reconciliation.

Recommendation. Define an expedited retry and alerting path for safety- and supply-critical notification types (randomization, dispensation, accountability), distinct from the default cadence used for lower-risk transactions.

DTS reference: *Import Error Handling*

E-2 MAJOR Orphaned accountability records on dispensation backout are not addressed

Observation. Accountability repeat keys are matched to dispensation repeat keys. When a dispensation repeat key is removed during a visit backout (TransactionType=Remove), the specification does not define what happens to a previously sent accountability record tied to that key.

Risk & impact. An accountability record could remain in EDC referencing a removed dispensation, producing an internally inconsistent casebook.

Recommendation. Define the cascade behavior: whether a dispensation backout triggers removal or nullification of the linked accountability record, and how that is transmitted.

DTS reference: *Dispensation Form; Subject Accountability Form; Subject Visit Backouts*

E-3 MAJOR Screening and rescreening backouts are handled outside the transfer

Observation. The specification states that screening and rescreening backouts are managed outside the integration. No automated correction or reconciliation step is defined.

Risk & impact. Manual handling can leave stale subject/screening data in EDC with no automated correction and an unclear audit trail.

Recommendation. Document the manual reconciliation procedure, the responsible role, and how the manual change is captured in the EDC audit trail, so the carve-out is controlled rather than implicit.

DTS reference: *Subject Visit Backouts*

E-4 MINOR No triage mapping for EDC ReasonCodes

Observation. The failed-response example returns ReasonCode RWS00041 (“Field does not exist”), but the DTS provides no mapping of common ReasonCodes to triage or remediation actions. The designated study-team contact receives the error without a defined response path.

Risk & impact. Without a triage map, error resolution depends on individual knowledge and may be slow or inconsistent.

Recommendation. Add a short table mapping the most common ReasonCodes to likely cause and first-response action, with the escalation path to vendor support.

DTS reference: *Import Error Handling; Failed Response Message*

E-5 OBSERVATION Reconciliation capability is generation-only

Observation. The job that generates files for existing subjects and visits supports re-sending but is not a true two-way reconciliation between RTSM and EDC record counts.

Risk & impact. Low to moderate. Undetected drift between systems could persist until manually noticed.

Recommendation. Consider a periodic reconciliation check comparing key record counts (subjects, randomizations, dispensations) between RTSM and EDC, with a discrepancy report.

DTS reference: *File Transport and Data Transfer Assumptions*

Regulatory & Audit Trail

R-1 MAJOR Audit trail for manual interventions is unspecified

Observation. Self-Support and support-driven manual data changes (Demographic Data Change, Visit Data Change, Visit Backout, Drug Data Change) update data outside the automated flow. The DTS does not state how these manual changes are captured in an audit trail for 21 CFR Part 11 traceability.

Risk & impact. Manual changes that are not traceable undermine data integrity and defensibility under Part 11 and ICH E6(R3).

Recommendation. State how each manual-change function is logged and audit-trailed, and confirm that the resulting EDC update carries traceable attribution.

DTS reference: *IRT Database Change Management*

R-2 MINOR Approval signatures are not executed

Observation. The approval matrix for RTSM vendor and sponsor roles is present but unsigned.

Risk & impact. An unexecuted DTS should not gate UAT entry. (Expected for a template or draft; noted for completeness.)

Recommendation. Obtain all required signatures and finalize at version 1.0 before UAT entry.

DTS reference: *Document Approvals; Version Summary*

R-3 OBSERVATION No documented UAT validation of blinded/unblinded segregation

Observation. The specification does not include a UAT test case proving that blinded EDC roles cannot view unblinded fields delivered by the integration.

Risk & impact. Without an explicit test, the access restriction central to Finding M-1 is asserted but not verified.

Recommendation. Add a UAT test case that confirms blinded roles cannot view TRTARM, DRUGCODE, and KITID in EDC, and that unblinded roles can.

DTS reference: *Data Transfer Overview; UAT planning*

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5. Risk Assessment

The Critical and Major findings are mapped below to their primary risk category and to the trial milestone at which the risk would most likely materialize if unaddressed. Likelihood reflects how often this class of issue surfaces in practice when left unresolved in a specification of this kind.

ID	Risk	Likelihood	Surfaces at
M-1	Unblinding leak to blinded EDC users	Medium-High	UAT / post go-live
E-1	EDC out of sync after a failed supply/randomization message	Medium	Production
C-1	Emergency unblinding not represented in EDC	Medium	Production
C-2	Conflicting randomization records on re-randomization	Medium	UAT
C-3	Ambiguous scope for ancillary drug allocation	Medium	UAT
M-2	Stratum code mismatch corrupts stratified data	Medium-High	UAT
M-3	Reconciliation discrepancy from duplicate date concepts	Medium	Data review
M-4	AGE vs. DOB derivation conflict	Medium	UAT
T-1	Transactions rejected on CRF version mismatch	Medium	UAT
T-2	Posting against the wrong environment	Low-Medium	UAT
E-2	Orphaned accountability after dispensation backout	Medium	Data review
E-3	Stale screening data from manual backout	Medium	Data review
R-1	Manual changes not traceable under Part 11	Medium	Audit / inspection

6. Pre-UAT Action List

The actions below are ordered by priority. Items in the first group should be closed before UAT entry; the second group before DTS approval; the third group strengthens durability and defensibility and can proceed in parallel.

Must resolve before UAT entry

- ☐ Record the EDC access restriction on every form carrying an unblinded field; name the restricted form/role and confirm the configuration with the EDC team (M-1).
- ☐ Define an expedited retry and alerting path for randomization, dispensation, and accountability notifications, separate from the default cadence (E-1).
- ☐ Confirm whether emergency/manual unblinding is in scope; specify the trigger, form, and restricted handling or document the manual process (C-1).
- ☐ Fully specify or remove the re-randomization trigger, including transaction type and downstream effects (C-2).
- ☐ Clarify and map, or remove, ancillary drug allocation (C-3).
- ☐ Define stratification factors, levels, and code lists, and confirm RTSM-EDC code alignment (M-2).
- ☐ Resolve the ENRDAT vs. RANDDT date concepts; designate the authoritative field (M-3).
- ☐ Confirm AGE ownership relative to EDC-derived age and remove the conflict (M-4).
- ☐ Confirm MetaDataVersionOID sourcing per environment and CRF version with the EDC vendor (T-1).
- ☐ Confirm StudyOID is environment-driven at runtime and correct the examples (T-2).
- ☐ Define cascade behavior for accountability records when a dispensation repeat key is removed (E-2).
- ☐ Document the manual screening/rescreening backout reconciliation step and its audit trail (E-3).
- ☐ Specify how manual-change functions are logged and audit-trailed for Part 11 traceability (R-1).

Resolve before DTS approval

- ☐ Reconcile the Enrollment trigger between the form narrative and the trigger matrix (C-4).
- ☐ Specify a single date-of-birth format and confirm RTSM emits it (M-5).
- ☐ Extend the randomization example to include TRTARM and STRAT (M-6).
- ☐ Confirm no satellite-site truncation collides with an existing numeric site (T-3).
- ☐ Add a ReasonCode-to-remediation triage table (E-4).
- ☐ Execute all required approval signatures and finalize at v1.0 (R-2).

Recommended (non-blocking)

- ☐ Add a one-page data flow diagram of the RTSM-EDC interface (C-5).

- □ Confirm Production credential provisioning ahead of the migration window (T-4).
- □ Add a periodic RTSM-vs-EDC reconciliation check with a discrepancy report (E-5).
- □ Add a UAT test case validating blinded/unblinded segregation in EDC (R-3).

About this engagement

The DTS Pre-UAT Audit is an independent, fixed-fee review of a Data Transfer Specification before UAT. It is delivered as a written report with prioritized findings, a risk assessment, and a pre-UAT action list, with an optional one-hour debrief call. Turnaround is typically five to seven business days from receipt of the DTS.

Luis Rodriguez Consulting specializes exclusively in RTSM-EDC integration for clinical trials, with five years of vendor-side experience at Suvoda across oncology, CNS, and rare disease. The practice is vendor-neutral: findings reflect the study's needs, not a platform relationship.

Luis Rodriguez Consulting · A Tacmacu, LLC Company · luis@luisrodriguezconsulting.com · www.luisrodriguezconsulting.com

This sample report is illustrative. The findings demonstrate the depth and format of a real audit but describe a fictitious study. No real sponsor, compound, therapeutic area, or platform combination is represented.