IMMUNE TOLERANCE NETWORK

REQUEST FOR PROPOSAL

Specimen Tracking System

Issued By:
Immune Tolerance Network
Benaroya Research Institute
1201 Ninth Avenue
Seattle, WA 98101

Issued: August 10, 2026
Response Deadline: September 14, 2026

Version	Issue Date	Modifications
1.0	July 22, 2026	Final draft
1.1	August 10, 2026	Updated timelines

Contents

1 Introduction and Background

The Immune Tolerance Network (ITN) is a National Institute of Allergy and Infectious Diseases (NIAID)-funded clinical research program led by the Benaroya Research Institute (BRI). Through a global network of investigators and advisors, ITN develops and conducts clinical trials to advance immune tolerance therapies, integrating hypothesis-driven, mechanism-based research into every study.

The ITN is seeking proposals for a new Specimen Tracking System (STS) to support end-to-end tracking of mechanistic biospecimens across all active ITN studies, from collection at clinical sites through processing, aliquoting, shipping, and receipt at laboratories and the biorepository. The system serves clinical site users, core laboratory users, and ITN operations staff.

The primary requirements for the new STS are:

A. A user-friendly, web-based application with configurable, role-based workflows for specimen data entry, editing, review, and full chain-of-custody tracking.
B. Study configuration via import of the ITN's current Kit Production File (KPF) or equivalent structured file to define expected specimens, barcodes, tube types, and visit-level collections.
C. Robust data export and integration capabilities supporting the ITN's downstream data warehouse and reporting infrastructure.
D. A demonstrated track record of strong security practices, responsive customer support, and a scalable, transparent licensing model.
E. Support for a live transition from the current system with minimal disruption to active studies.

2 Administrative

2.1 Technical Contact

Questions concerning technical specifications or Statement of Work requirements should be directed to:

Name	Jared Hennessy
Address	1201 Ninth Avenue, Seattle, WA 98101
Phone	206-413-7234
Email	jhennessy@immunetolerance.org

2.2 Contractual Contact

Questions regarding contractual terms and conditions or proposal format should be directed to:

Name	Mary Roy
Address	1201 Ninth Avenue, Seattle, WA 98101
Phone	206-413-6010
Email	mroy@immunetolerance.org

2.3 Due Dates

Initial responses are due by September 14th, 2026. Responses may be in the form of a preliminary proposal to be refined after discussions with the ITN. All final proposals are due by October 9th, 2026. Late proposals will not be evaluated.

2.4 Schedule of Events

Event	Date
1. RFP Distribution to Vendors	Aug 10, 2026
2. Initial Response Due	Sep 14, 2026
3. Questions / Demos from Vendors	Sep 30, 2026
4. Final Proposal Due Date	Oct 9, 2026
5. Anticipated Decision and Selection of Vendor(s)	Oct 23, 2026
6. Anticipated Contract Commencement	Nov 6, 2026
7. New System in Production	Q1 2027

3 Evaluation Factors for Award

Any award pursuant to this RFP will be based upon the proposal most advantageous to the ITN, considering the following criteria:

- Functional fit: the extent to which the proposed solution satisfies the stated functional, technical, and integration requirements in Section 4 and Appendix C.
- Security posture: demonstrated security architecture, vulnerability management history, third-party audit practices, and compliance with applicable federal data security standards, including FedRAMP for any cloud-hosted components.
- Pricing transparency and scalability: a clear, itemized 5-year total cost of ownership that does not impose hard concurrent-user caps or per-seat fees that penalize growth.
- Migration and transition approach: demonstrated ability to deliver a live transition from a production system with minimal disruption to active studies.
- Vendor stability, experience, and references: track record with comparable clinical research organizations, academic medical centers, or federally sponsored research networks.
- Customization and support responsiveness: a well-defined enhancement request and development process with committed turnaround targets.

The ITN reserves the right to reject any or all offers, accept other than the lowest-priced offer, award based on initial proposals without further discussion, or award more than one contract.

4 Statement of Work

4.1 Operating Context and Scale

The figures below reflect actual ITN operations and provide the baseline for scalability requirements.

Parameter	Current / Projected
Active users (current)	~161 total: 146 external across 69 sites and labs, plus 15 internal ITN staff

Active studies (current)	12 active studies; over 63,000 samples managed in a recent 9-month period
Largest single study	~50 users across 12 sites, managing over 53,000 samples; one or more studies of similar or larger scale than the current largest are anticipated
Projected growth	~400 users, ~100 clinical sites, ~35 labs, ~20 active studies, ~80,000 specimen events/year
Geography	Primarily domestic currently; GDPR/local data-protection requirements are to be considered

4.2 Hosting and Deployment

The ITN is open to vendor-hosted, ITN-hosted (on-premises), or hybrid deployment models, provided security, data-access, and compliance requirements are met. Proposals for on-premises or hybrid deployments are explicitly welcomed and will be evaluated on equal footing with cloud-hosted solutions.

Any cloud-hosted component must be FedRAMP-compliant. The ITN prefers a deployment architecture in which the database back-end is on-premises or otherwise directly and efficiently accessible to the ITN, to support high-volume bulk data transfer to the ITN's SQL Server data warehouse. Architectures that impede efficient bulk extract/load are disfavored.

4.3 Requirements

Full requirements are provided in Appendix C, which vendors must complete and return with their proposal; each is tagged Must-have [M], Should-have [S], or Could-have [C]. Appendix C's detailed sections are organized into seven requirement groups (A–G). The summaries below describe each group and cite the Appendix C groups that it contains. Scale, hosting, and timeline are expanded in Sections 4.1, 4.2, and 4.4, and vendors respond to all requirements in Section 5.

The requirements below and in Appendix C represent the ITN's operational floor, i.e. the capabilities any replacement system must deliver to maintain specimen data quality, chain of custody, and regulatory compliance across clinical studies. Where the ITN describes a current workflow in detail, it is intended to give vendors sufficient context to scope development and pricing accurately, not to prescribe a specific implementation. The Kit Production File (KPF), for example, is documented in Appendix D as a concrete reference for the study configuration import requirement; vendors may propose equivalent or superior mechanisms. The ITN welcomes proposals that improve existing workflows through modern interface design, intelligent automation, or architectural innovations that reduce user burden, provided the stated functional outcomes are met.

4.3.1 Group A: Access, Configuration & Data Governance

The system must enforce role-based, study-scoped access control per the roles and visibility model in Appendix B, with users assignable to multiple studies (role evaluated per study) and administrators managing roles and ITN-managed provisioning of external site and lab users without vendor involvement. ITN staff must define studies, sites, visits, and expected specimen collections (versionable and seeded from a Kit Production File) without vendor development for routine changes. Participant management must use study-assigned pseudonymous identifiers (no direct identifying information stored in the STS), support cross-site transfers with the identifier retained, and provide dual-site visibility during and after transfer. Data-entry constraints must be configurable by role and context (e.g. controlled lists for Clinical Site Users, free text for Core Lab Users), with data-hygiene safeguards — format validation, warn-on-nonstandard, and administrator alerts on circumvention — applying even to free-text lab fields.

4.3.2 Group B: Specimen Collection & Processing

Collection must support pre-specified expected collections, efficient barcode-scanning entry (including 2D/DataMatrix), recording of missed and unexpected collections, and on-demand label printing at sites.

Aliquoting must capture parent–child lineage and processing metadata, enforce configured allowable derivative types, propagate parent metadata to child specimens, and support on-demand label printing at labs. A study-specific catalog of orderable supplies (collection kits, airbills) must route orders for ITN review. Optional mobile / electronic-source capture (low priority) with barcode scanning, multi-user completion, and store-and-forward is desirable for future use.

4.3.3 Group C: Shipping, Receipt & Chain of Custody

Before shipment, Clinical Site Users must file specimens into virtual storage locations organized by temperature condition and destination, with current location visible per specimen and only appropriately filed specimens eligible to join a matching package. Shipping must support virtual containers, configurable allowable destinations, printed and automatically emailed manifests, airbill/tracking capture, and reopen/unship corrections. Receiving labs mark packages received then scan to accession, flagging missing, damaged, or discrepant specimens; on receipt confirmation, custody transitions automatically: the shipping site's access becomes read-only and the receiving site gains edit, dispose, and aliquot rights. A complete, auditable chain of custody must be maintained across all events, with disposition/disposal events (reason capture, confirmation, audit trail) and configurable notifications for key custody events, including receipt confirmation to the shipping site.

4.3.4 Group D: Reporting & Data Integration

Integration is central to ITN operations and data lock-in is a primary risk to avoid. Basic operational reports (work list, sample custody, collection status) are required for site and lab users, and all STS data must be exposed for downstream business intelligence via the ITN data warehouse; ad-hoc reporting and in-STS dashboards are desirable but not required. ITN technical staff must have full database access (read-only or read/write) and at least one robust programmatic/bulk method (linked server, REST or Java/.NET API, or scheduled/on-demand delimited or ITN-specified XML export), with efficient, high-volume, bidirectional bulk transfer to the ITN's on-premises SQL Server warehouse. Integration must include ingestion of the kit/barcode seed data currently delivered via the Kit Production File (KPF, Appendix D) or an equivalent vendor-proposed mechanism, automated study-configuration import, bulk insert/query/update, and a nightly biorepository metadata exchange that reflects repository-side status (received, accessioned, stored).

4.3.5 Group E: Security, Compliance & Auditability

Vendors must demonstrate a modern security posture (documented secure-development lifecycle, regular third-party penetration testing, timely vulnerability management), single sign-on with one credential across all vendor-provided components (MFA desired), encryption in transit and at rest, and a published, auditable security and password policy. A full audit trail of configuration and specimen-data changes, controlled corrections with change-control records, and 21 CFR Part 11 controls (audit trails, electronic signatures, record integrity) are required; vendors should document the Part 11 controls provided and any gaps relative to ITN workflows. FedRAMP compliance is required for any cloud-hosted component, and GDPR / local data-protection support is desired.

4.3.6 Group F: Platform, Performance & Operations

The system must scale to the ITN's current and projected load (Section 4.1) with transparent, scale-tolerant pricing that avoids per-seat fees and hard concurrent-user caps (cost detail in Section 5.7). ITN staff must configure the system and manage users directly, supported by a costed, responsive vendor enhancement process. The platform must meet availability, backup, and disaster-recovery targets — including outage-resilient operation and efficient retrospective/bulk entry to reconcile records after downtime — provide a usable, browser-based interface with configurable branding as the “ITN Specimen Tracking System (STS),” and provide Production, Training, and Development/QA environments, with the Training environment refreshable from Production and able to support end-to-end new-user certification. Hosting and deployment options are defined in Section 4.2.

4.3.7 Group G: Program: Migration, Support & Commercial

The vendor must migrate open/active studies and their configuration from the current system (closed studies excluded; the ITN will provide a full export) with minimal disruption, following a documented

phased plan toward full operation by March 2027 (Section 4.4). Ongoing requirements include a defined support and service model (business-hours support, documented escalation and bug handling), training for ITN configuration, data-management, and administrator staff, workflow-structured end-user documentation the ITN can adapt into study lab manuals, and contracting flexibility (monthly invoicing, termination without cause). Detailed vendor-response, pricing, and qualification content is provided by the vendor in Section 5.

4.4 Deliverables Timeline

Work is structured in two phases:

Phase 1: Initial development (if applicable), configuration, data migration, and go-live. Proposals must include a high-level timeline for: requirements capture and verification, development (if applicable), testing and validation, deployment, data migration and conversion, training, documentation, and contingencies for missed milestones.

Phase 2: Ongoing maintenance, version-controlled development, documentation updates, and a support and service plan that includes defined policies for bug resolution, security vulnerability management, and enhancement requests.

Target: all migrations complete and system fully operational by March 2027. New studies should be able to onboard onto the new STS earlier where feasible.

5 Proposal Requirements

Requirements are defined in Section 4.3 and Appendix C. This section defines the structure and content of the vendor's response. Do not restate requirements; describe your approach and cross-reference the relevant Appendix C group.

5.1 Executive Summary

A brief overview of the proposed solution and services, identifying the main features and benefits relative to the ITN's stated requirements.

5.2 System Capabilities

For each requirement in Appendix C, use the compliance options defined in that appendix (Fully Compliant, Partially Compliant, Compliant via Configuration, Compliant via Custom Development, or Not Compliant). For items requiring development, provide an estimated level of effort. Vendors must return a completed copy of Appendix C as part of their proposal.

5.3 User Experience and Workflow Innovation

Beyond satisfying the functional requirements in Appendix C, the ITN seeks a system that meaningfully improves the daily experience for clinical site personnel, core lab staff, and operations managers. The following are priority goals for any replacement solution:

- A modern, simplified, and intuitive interface that reduces the learning curve for site personnel who interact with the system infrequently or across multiple concurrent studies.
- Barcode-first workflows that minimize manual data entry at every stage of the specimen lifecycle.
- Reduced interaction steps for common tasks, with particular attention to collection entry, shipment packing, and accessioning workflows.
- Drag-and-drop or other intuitive methods for organizing specimens and shipments where appropriate.
- Intelligent automation to reduce transcription errors and catch discrepancies at the point of entry, e.g. auto-population of expected values, inline validation, and workflow guidance.
- Context-sensitive help and clear navigation to reduce formal training requirements.

Vendors are encouraged to include screenshots, annotated workflow diagrams, or links to recorded demonstrations that illustrate their UX approach for at least two of the following scenarios: specimen collection entry at a clinical site, shipment creation and manifest generation, and laboratory receipt and accessioning. Responses that address only the Appendix C compliance matrix without demonstrating workflow experience will be evaluated as less competitive on the user experience criterion.

5.4 Security and Compliance

Describe your security architecture, vulnerability-management program, incident history over the past three years, and any third-party audits or certifications. State the FedRAMP authorization status of any cloud-hosted components, and document which 21 CFR Part 11 controls your system provides and any gaps relative to the requirements in Group E.

5.5 Data Access and Integration

Provide documentation or examples of the APIs, export formats, and database-access options described in Group D, including how bidirectional bulk transfer to the ITN's on-premises SQL Server warehouse would be supported.

5.6 Migration and Transition

Describe the approach to transitioning from an existing production STS, including migration of active study specimen and configuration data, parallel system operation during transition, and management of active studies during cutover. The ITN will provide a complete export from the current system to support migration. (See Group G for detailed migration requirements.)

5.7 Hosting and Infrastructure

Describe your proposed hosting model and how it satisfies the deployment, availability, and hosting requirements in RFP Section 4.2 and Appendix C Group F — including FedRAMP authorization status for any cloud-hosted components, on-premises infrastructure requirements (if applicable), how database access to the ITN's data warehouse would be supported, and your backup, archive, and disaster-recovery plan.

5.8 Licensing and Pricing Model

Provide a complete, itemized cost breakdown including:

- All Year 1 costs (implementation, configuration, development if applicable, training, licensing, and infrastructure).
- All recurring annual costs for Years 2–5, broken out by category.
- One-time costs associated with data migration or transition.
- Any additional costs anticipated for the ITN (e.g., third-party identity management, audit services, infrastructure).
- Separate cost lines for each environment (Production, QA, Training/Demo).
- Cost implications of adding active studies, users, or data volume beyond the baseline in Section 4.1.
- Cost structure for enhancements or customizations beyond the base scope.

Pricing must satisfy the scalability and commercial requirements in Group F and the contracting-flexibility requirements in Group G.

5.9 Vendor Customization and Development Process

Describe the process by which the ITN can request, scope, prioritize, and contract for system customizations or new feature development. Include typical timelines for enhancement delivery and how the ITN would be kept informed of development progress. (See Group E and Group F for related requirements.)

5.10 Project Management Approach

Describe the project management methodology for this engagement, including:

- Proposed project team structure and key roles, with named individuals where possible.
- Communication plans: meeting cadence, status reporting, and escalation procedures.
- Risk management approach, specifically addressing risks associated with migrating an active production system.
- Approach to managing the ITN's participation and time commitments during transition.
- Proposed milestones and success criteria for Phase 1 (go-live) and ongoing Phase 2 operations.

5.11 Deliverables List

Provide a complete list of all work products and deliverables, including:

- Fully configured, operational STS in Production and all required additional environments.
- Migrated active study specimen and configuration data from the current system.
- System user guide and data dictionary.
- Training materials and training sessions for ITN configuration staff, data management staff, and administrators.
- Documented backup and recovery plan and initial test results.
- Documented security and user access policies.
- API documentation or data export specifications.

5.12 Appendix: References

Provide a minimum of three (3) references from current or recent clients, preferably from organizations with operational profiles similar to the ITN (clinical research networks, academic medical centers, NIAID-funded consortia, or comparable organizations). For each reference, provide organization name, contact name and title, phone and email, brief description of services provided, and contract period.

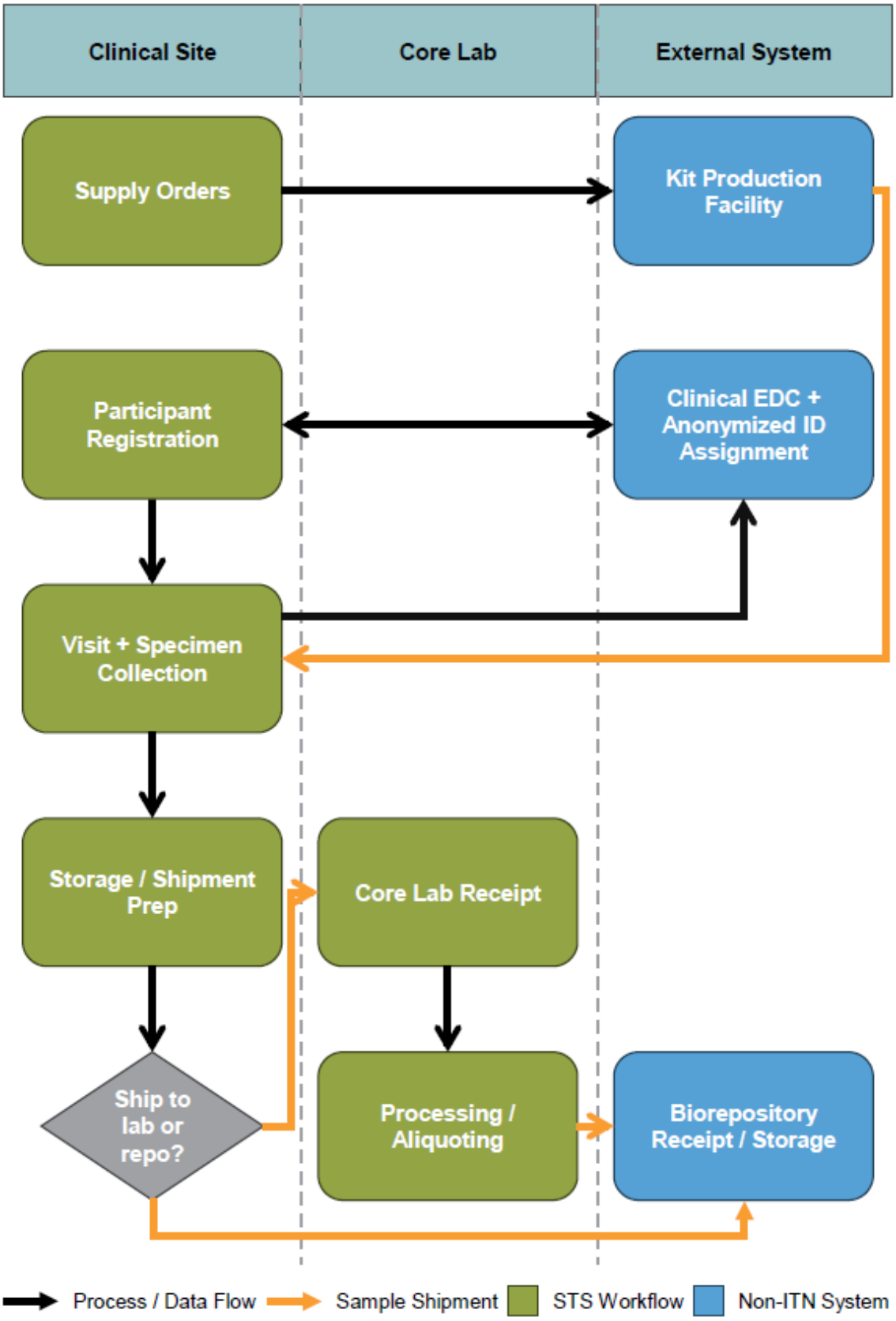
5.13 Appendix: Project Team Staffing

Provide an organizational chart and brief biographical summaries for all key personnel proposed for this engagement: Project Manager, Lead Technical/Implementation Consultant, Configuration and Training Lead, and Ongoing Support Contact(s). Describe the extent to which proposed personnel are dedicated to the ITN versus shared across multiple client engagements.

5.14 Appendix: Company Overview

Provide a brief overview of the vendor organization, including company history, founding date, and ownership structure; number of full-time employees; current client base (particularly clinical research or federally sponsored research); summary of financial stability; and product roadmap and long-term commitment to the proposed STS.

Appendix A: Specimen Lifecycle



Appendix B: Operating Scale and User Role Definitions

B.1 Current Operating Scale

The figures below are the basis for scalability and performance requirements (REQ-F.1).

Parameter	Value
Reference period	September 10, 2025 – June 9, 2026
Total active users	~161 (146 external across 69 sites/labs; 15 internal ITN staff)
Active studies	12
Samples managed (period)	Over 63,000
Largest study (current)	50 users, 12 sites, over 53,000 samples
Projected growth target	~400 users, ~100 sites, ~35 labs, ~20 studies, ~80,000 specimen events/year

Critical pricing constraint: the pricing model must not impose a hard concurrent-user cap or per-seat fee structure that makes scaling cost-prohibitive.

B.2 User Role Definitions

Role	Responsibilities	Data Visibility
Clinical Site User	Sample collection entry; shipment packing and dispatch	Samples collected at or shipped from their assigned site, within assigned study
Core Lab User	Sample receipt; processing and aliquoting	Samples received at or aliquoted at their assigned lab, within assigned study
Clinical Operations Manager (COM)	All site and lab user tasks across all sites/labs within a selected study	All sites and labs within the selected study
Administrator	All above, plus study configuration and user/role management	Full, within scope of administration
Read-Only / Auditor	View and reporting access only; no edit rights	Configurable; typically study-wide

Users may be assigned to multiple studies with different roles per study. Role and data scope are evaluated independently per study. Administrators assign users to roles directly, without vendor involvement.

Appendix C: Requirements Compliance Matrix

Vendors must complete the Compliance and Vendor Response columns for every requirement and return this appendix as part of their proposal.

Priority codes: [M] Must-have — failure to meet disqualifies the proposal. [S] Should-have — strongly desired; explain any gap. [C] Could-have — nice to have; not required.

Compliance options: Fully Compliant / Partially Compliant / Compliant via Configuration / Compliant via Custom Development / Not Compliant.

Req ID	Requirement	Pri.	Compliance	Vendor Response
Group A – Access, Configuration & Data Governance				
Group A.1 — User Roles and Access Control				
REQ-A.1.1	Enforce role- and study-scoped (and site/lab-scoped) data visibility per the role definitions in Appendix B.	M		
REQ-A.1.2	Support users assigned to multiple studies, with role and data scope evaluated independently per study.	M		
REQ-A.1.3	Administrators assign users to roles and permissions directly, without vendor involvement.	S		
REQ-A.1.4	Provide a read-only / auditor capability for view and reporting access without edit rights.	S		
Group A.2 — Study Configuration and Setup				
REQ-A.2.1	ITN configuration staff define and update studies, sites, visits/timepoints, expected specimen types collected per visit without vendor development for routine changes.	M		
REQ-A.2.2	Ingest a study's expected-specimen definitions from a Kit Production File (KPF) or equivalent structured file (CSV/XLSX) to seed specimen barcodes with their associated visits and tube/sample types (see Appendix D).	M		
REQ-A.2.3	Version all study configuration details.	C		
REQ-A.2.4	Support automated import of study configuration from a structured file to reduce manual entry.	C		
Group A.3 — Participant Management				
REQ-A.3.1	Allow site users to register participant identifiers via free-text field with study-specific formatting rules.	M		
REQ-A.3.2	Move a participant between sites while retaining the same identifier, with visibility to both originating and receiving sites.	M		
REQ-A.3.3	Bulk import list of Participant IDs for a given study.	S		
Group A.4 — Data Entry Controls and Validation				

REQ-A.4.1	Per-study configurable value lists for user selection, populated manually and/or via file upload, e.g. KPF (visit numbers, specimen types, tube types, barcode suffixes).	M		
REQ-A.4.2	Free-text fields block or warn (configurable per field) when an entry does not match an expected format.	M		
REQ-A.4.3	Alert system administrators when a user circumvents a data-entry validation rule.	M		
REQ-A.4.4	Validation rules configurable by ITN staff per study/field without vendor development.	S		
REQ-A.4.5	Data-entry constraints configurable by role/context: a field may be a controlled list for Clinical Site Users and free text for Core Lab Users (e.g., barcode suffixes, shipping destinations).	M		
REQ-A.4.6	Apply data-hygiene safeguards (format validation, warn-on-nonstandard-value, admin alerts) even where free text is permitted for lab roles.	M		
Group B – Specimen Collection & Processing				
Group B.1 — Specimen Collection Workflow				
REQ-B.1.1	Pre-specify expected specimen collection per study, participant, and visit by loading configuration (including expected barcodes).	M		
REQ-B.1.2	Provide an efficient collection-entry workflow, including recording specimens NOT collected.	M		
REQ-B.1.3	Support barcode scanning for specimen entry (multiple formats, including 2D/DataMatrix).	M		
REQ-B.1.4	Record missed visits, missed collections, unexpected/unscheduled collections, and free-text annotations.	S		
REQ-B.1.5	Provide a calendar/visit view for site users to track participants and scheduled visits.	C		
REQ-B.1.6	Support on-demand printing of additional/replacement specimen and kit barcode labels at clinical sites.	S		
REQ-B.1.7	Support efficient retrospective/bulk entry of specimen records (collection through shipment) to reconcile activity recorded on paper during a period of system unavailability.	M		
Group B.2 — Processing and Aliquoting				
REQ-B.2.1	Pre-specify allowable processing steps per study configuration.	M		
REQ-B.2.2	Provide a user-friendly aliquoting/processing workflow for collected specimens.	M		

REQ-B.2.3	Capture parent-child relationships and processing metadata (timepoint, stimulant, volume, additional label text).	M		
REQ-B.2.4	Support processing recorded at both clinical sites and labs (e.g., on-site PBMC isolation vs. central processing).	S		
REQ-B.2.5	Restrict child/derivative specimen types that can be produced to a configured allowed set for that parent tube and study.	S		
REQ-B.2.6	Child aliquots/derivatives inherit and preserve all parent-tube metadata, maintaining full parent-child lineage.	M		
REQ-B.2.7	Lab processing/aliquoting workflow mirrors the site collection workflow but applies the role-aware, more flexible data-entry constraints in REQ-A.4.5 and REQ-A.4.6.	M		
REQ-B.2.8	Support on-demand printing of barcode labels at labs, especially for aliquots/derivatives produced during processing.	M		
REQ-B.2.9	Labels printed on demand at sites or labs must match the biorepository's barcode symbology (2D DataMatrix), orientation, and cryolabel stock so they scan reliably at downstream receipt and accessioning.	M		
Group B.3 — Supply Ordering				
REQ-B.3.1	Define a study-specific catalog of orderable supplies (primarily collection kits, plus airbills).	M		
REQ-B.3.2	Notify designated ITN personnel by email and in-system notification to review submitted orders.	M		
REQ-B.3.3	Support exception handling for urgent/rush requests and provide ordering visibility to help reduce rush orders.	S		
Group B.4 — Mobile / Electronic Source Capture				
REQ-B.4.1	Optional mobile capture of requisition-form data as an electronic source document, with barcode scanning (incl. 2D), multi-user completion, and store-and-forward for intermittent connectivity.	C		
REQ-B.4.2	If implemented, mobile capture should support the 21 CFR Part 11 controls described in REQ-E.3.2.	C		
Group C – Shipping, Receipt & Chain of Custody				
Group C.1 — Pre-Shipment Storage				
REQ-C.1.1	Support a virtual storage location hierarchy (at minimum: storage unit → box → position) at clinical sites, organized by temperature condition and shipping destination, configured per study.	M		
REQ-C.1.2	Allow Clinical Site Users to file collected and/or processed specimens into virtual storage boxes prior to package creation, by scanning barcodes or selecting from a sample	M		

	list; a specimen's current storage location must be visible in its record at all times.			
REQ-C.1.3	Enforce that only specimens filed in an appropriate storage location (matching temperature and destination) can be added to a shipping package for that destination, or provide a clear workflow warning when a mismatch is detected.	M		
REQ-C.1.4	Allow bulk selection of all specimens in a virtual storage box for rapid addition to a shipping package.	S		
Group C.2 — Shipping and Manifests				
REQ-C.2.1	Bulk-select samples and place them into a virtual shipping container.	M		
REQ-C.2.2	Pre-specify allowable shipping destinations per study, visit, and specimen type based on configuration.	M		
REQ-C.2.3	Print and automatically email manifest to destination contacts and the ITN upon shipment.	M		
REQ-C.2.4	Allow shipping sites to mark packages as packed and shipped, and to reopen/unship packages to make corrections.	M		
REQ-C.2.5	Capture shipping conditions/airbill type (ambient, dry ice, liquid nitrogen) and allowable shipping days, consistent with study lab-manual rules.	S		
REQ-C.2.6	Capture/record courier tracking and airbill numbers against shipments.	M		
REQ-C.2.7	Courier API integration (e.g., FedEx) to retrieve tracking status automatically.	C		
REQ-C.2.8	Support an optional shipper attestation / electronic signature at ship confirmation of the manifest, consistent with 21 CFR Part 11.	S		
Group C.3 — Receipt and Accessioning				
REQ-C.3.1	Receiving site/lab marks a package received then unpacked, scanning barcodes to accession specimens.	M		
REQ-C.3.2	During unpacking, mark samples missing, damaged, or discrepant, with comments/deviations.	M		
REQ-C.3.3	On receipt, custody transitions automatically: shipping site's access becomes read-only; receiving site gains edit/dispose/aliquot rights.	M		
REQ-C.3.4	Support a discrepancy/query-management workflow so manifest-vs-physical mismatches are recorded, tracked, and resolved before accessioning.	S		
REQ-C.3.5	Provide configurable notifications for key custody events, including shipment dispatched, receipt confirmation	S		

	returned to the shipping site, and discrepancies flagged at receipt.			
Group C.4 — Chain of Custody and Disposition				
REQ-C.4.1	Maintain a complete, auditable chain of custody for every specimen and aliquot across all events.	M		
REQ-C.4.2	Reflect repository-side status (package received, accessioned, stored) on STS samples via nightly update (see REQ-D.6.1); STS does not manage repository storage.	S		
REQ-C.4.3	Support disposition/disposal events for STS-tracked samples (e.g., damaged/discrepant, uncollected) with reason capture, confirmation workflow, and audit trail.	M		
Group D – Reporting & Data Integration				
Group D.1 — Reporting and Data Export				
REQ-D.1.1	Standard operational reports for site and lab users: at minimum work list, sample custody, and sample collection status.	M		
REQ-D.1.2	Expose all STS data for downstream warehousing and reporting via the access/export methods in REQ-D.2.1 and REQ-D.2.2.	M		
REQ-D.1.3	Configurable/ad-hoc reporting and custom queries within STS.	C		
REQ-D.1.4	Dashboards within STS with visibility into participant/visit tracking and supply ordering.	C		
Group D.2 — Data Access and Bulk Transfer				
REQ-D.2.1	Provide ITN technical staff read-only (or read/write) access to the entire underlying database (configuration and specimen data).	M		
REQ-D.2.2	Provide at least one robust programmatic/bulk access method: linked-server or direct DB access, a documented REST or Java/.NET API, and/or scheduled and on-demand exports to delimited files or ITN-specified XML.	M		
REQ-D.2.3	Support efficient, high-volume, bidirectional bulk transfer of all sample activity into and out of the ITN's on-premises Microsoft SQL Server reporting warehouse (DIVE).	M		
Group D.3 — Bulk Data Operations				
REQ-D.3.1	Insert, query, and update records in bulk, including KPF-based study seeding, bulk marking of shipped packages as received, and bulk corrections.	M		
Group D.4 — Study Configuration Integration				

REQ-D.4.1	Support automated import of study configuration from a structured flat file exported from ITN systems.	S		
Group D.5 — Supply-Chain / Kit Data Ingestion				
REQ-D.5.1	Ingest kit/barcode seed data currently delivered via the KPF (or an equivalent mechanism proposed by the vendor) to seed study value lists (barcode trunk, specimen type, tube type).	M		
REQ-D.5.2	Accept the full KPF field set as described in Appendix D.	M		
REQ-D.5.3	Validate/screen inbound KPF files for format errors before import and route success/error notifications appropriately.	S		
Group D.6 — Biorepository Nightly Metadata Exchange				
REQ-D.6.1	Support nightly metadata exchange with the biorepository LIMS: STS provides shipment/manifest and specimen metadata; STS ingests repository-side status updates (received, accessioned, stored) for reconciliation in DIVE.	M		
REQ-D.6.2	Maintain alignment on key identifiers: Study Number, Site Code, Visit Number, Participant ID, Specimen Type, Tube Type, Collection Date, Barcode.	M		
Group E – Security, Compliance & Auditability				
Group E.1 — Auditing and Change Control				
REQ-E.1.1	Full audit trail of all configuration and specimen-data changes (who, what, when, old/new value, reason).	M		
REQ-E.1.2	Controlled correction of previously submitted entries with change control (reason capture, timestamp, user identity).	M		
REQ-E.1.3	Electronic-signature support for regulated actions where required, consistent with 21 CFR Part 11 (see REQ-E.3.2).	M		
Group E.2 — Security				
REQ-E.2.1	Demonstrable modern security posture: documented secure-development lifecycle, regular third-party penetration testing, and timely patching/vulnerability management, with results available to the ITN.	M		
REQ-E.2.2	Role- and group-based access control; least-privilege; ITN-authorized users only.	M		
REQ-E.2.3	Single sign-on with one credential valid across all vendor-provided system components.	M		
REQ-E.2.4	Self-service password reset/recovery, with a fallback toll-free telephone recovery path if self-service is unavailable.	M		
REQ-E.2.5	Encryption of data in transit and at rest.	M		

REQ-E.2.6	Published, auditable user-security and password policy.	M		
REQ-E.2.7	Multi-factor authentication.	S		
REQ-E.2.8	Single sign-on via Microsoft Active Directory for internal ITN staff.	S		
REQ-E.2.9	Option to enable SSO via Microsoft Active Directory for external site and lab users.	C		
Group E.3 — Regulatory and Compliance				
REQ-E.3.1	Data storage compliant with applicable federal security regulations and policies.	M		
REQ-E.3.2	Support 21 CFR Part 11 controls (audit trails, electronic signatures, record integrity and retention) sufficient for the ITN to operate Part 11-compliant workflows. Vendors should document which Part 11 controls their system does and does not provide.	M		
REQ-E.3.3	FedRAMP compliance for any cloud-hosted component.	M		
REQ-E.3.4	Support GDPR / local-equivalent data-protection requirements; required when international sites are active.	S		
Group F – Platform, Performance & Operations				
Group F.1 — Scalability, Performance, and Pricing				
REQ-F.1.1	Transparent, predictable pricing that does not penalize growth. Provide a fully itemized 5-year TCO (license/subscription, per-user/study/specimen fees if any, storage, support, environments, enhancement rates).	M		
REQ-F.1.2	No hard concurrent-user cap and no per-seat pricing structure that makes scaling cost-prohibitive. The pricing model must support growth from ~161 to ~400+ users without step-change cost.	M		
REQ-F.1.3	Scale to current load and projected growth (Appendix B) without performance degradation.	M		
REQ-F.1.4	Maintain acceptable interactive performance for collection, shipping, and accessioning under concurrent multi-site load.	M		
REQ-F.1.5	Provide published performance benchmarks and capacity assumptions.	S		
Group F.2 — Configurability and Customization				
REQ-F.2.1	ITN staff perform routine study setup, configuration, and user management themselves after transition, with limited vendor involvement.	M		

REQ-F.2.2	Vendor provides a clear, costed, responsive process for custom enhancements with committed turnaround targets.	S		
REQ-F.2.3	Favor declarative/admin configuration tooling over code changes wherever possible.	S		
Group F.3 — Availability, Reliability, Backup, and Recovery				
REQ-F.3.1	Target 24x7 availability with only limited, pre-scheduled outages outside business hours; document an SLA. Unplanned downtime of more than a few business hours is unacceptable without prior ITN approval.	M		
REQ-F.3.2	Documented backup, archive, and disaster-recovery plan, demonstrated sufficient at least annually and open to ITN audit/testing.	M		
REQ-F.3.3	Archived data restorable within 1 business day.	M		
REQ-F.3.4	Minimize the operational impact of outages: publish planned-maintenance windows outside business hours and describe system behavior and recovery procedures during unplanned downtime.	M		
Group F.4 — Usability				
REQ-F.4.1	Intuitive, visually clear navigation; views configurable by permission.	S		
REQ-F.4.2	Vendor provides usability metrics (learnability, efficiency, memorability, error rate/recovery, satisfaction).	S		
REQ-F.4.3	In-system contextual help available to end users.	S		
REQ-F.4.4	Browser-based; support for current mainstream browsers with backward compatibility, kept current at no additional cost.	S		
Group F.5 — Environments				
REQ-F.5.1	Provide at minimum Production, QA/Validation, and Training/Demo environments.	M		
REQ-F.5.2	Training/Demo environment readily refreshable from Production on the ITN's direction.	M		
REQ-F.5.3	The Training/Demo environment must support an end-to-end new-user certification workflow (practice collection, aliquoting, and demo shipments) without affecting production data.	M		
Group F.6 — Deployment and Hosting				
REQ-F.6.1	ITN is open to vendor-hosted, ITN-hosted (on-premises), or hybrid deployment, provided security, data-access, and compliance requirements are met. On-premises proposals are explicitly welcomed.	M		

REQ-F.6.2	Any cloud-based hosting must be FedRAMP-compliant.	M		
REQ-F.6.3	The ITN prefers the database back-end on-premises or directly and efficiently accessible to the ITN to support high-volume bulk transfer to DIVE (REQ-D.2.3). Architectures that hinder bulk extract/load are disfavored.	S		
REQ-F.6.4	If vendor-hosted, vendor provides servers, secure access, archival, and backup/restore.	M		
Group G – Program: Migration, Support & Commercial				
Group G.1 — Data Migration and Transition				
REQ-G.1.1	Provide a documented migration plan to move open/active studies and specimen records from the current system, with data-integrity verification. Closed studies are out of scope.	M		
REQ-G.1.2	Maintain current operations with minimal disruption during transition; a parallel/overlap period is expected.	M		
REQ-G.1.3	Configure active studies during transition in consultation with ITN subject-matter experts; the ITN will provide a full export from the current system.	M		
REQ-G.1.4	Provide a phased plan covering: requirement capture/verification, development (if any), testing/validation, deployment, data conversion, training, documentation, and contingencies for missed milestones.	M		
REQ-G.1.5	Provide a complete data dictionary for all exports, tables, and views as part of transition deliverables.	S		
REQ-G.1.6	Meet the ITN's target timeline: all migrations complete and system fully operational by March 2027; new studies may onboard onto the new STS earlier where feasible.	M		
Group G.2 — Vendor, Support, and Service Requirements				
REQ-G.2.1	Technical support to the ITN staff at minimum 9am–5pm Pacific, Mon–Fri, via email and phone; documented escalation and bug-handling procedures.	M		
REQ-G.2.2	Training for: (a) data-management staff on data access/use, (b) configuration staff on system configuration, (c) administrators on user management.	M		
REQ-G.2.3	Comprehensive system user guide including data dictionary; in-system contextual help.	M		
REQ-G.2.4	Act as an active partner with ITN Clinical Operations and Data Collaboration teams.	S		
REQ-G.2.5	Documented, costed, SLA-backed process for ongoing maintenance, version-controlled enhancements, and documentation updates.	M		

REQ-G.2.6	Strong references from comparable biorepository or clinical-research deployments.	S		
REQ-G.2.7	Contracting flexibility: ability to terminate without cause on short notice; monthly (not annual) invoicing preferred.	M		
REQ-G.2.8	Provide end-user documentation structured by role and workflow (site collection, lab processing, shipping, receipt, supply ordering, disposition) that the ITN can adapt into study-specific lab manuals, maintained and versioned as the system changes.	M		

Appendix D: Kit Production File (KPF) Example

The Kit Production File (KPF) is a structured data file produced by the ITN's sample collection kit supplier. It is the mechanism ITN's current system uses to seed expected specimen collections (barcodes, tube types, specimen types, and visit assignments) for each manufactured collection kit; files are delivered daily from the Kit Production Facility. This appendix documents the KPF as a concrete reference for the study-configuration import requirement (REQ-A.2.2, REQ-D.5.1–D.5.3). Vendors are encouraged to propose alternative or more efficient mechanisms for consuming this data, provided the underlying fields and functional outcomes described here are supported.

The KPF contains the following fields:

Field	Description
Request_num	Supply order request number
Study_ID	ITN study identifier (e.g., ITN093AI)
Site_ID	Numeric identifier for the clinical site
Visit_Num	Study visit number (may be blank; visit encoded in Kit_Type)
Kit_Type	Human-readable kit description, including study ID and visit label
Tube_Type	Physical tube type (e.g., "10 ml Na Heparin," "1.8 ml cryovial")
Specimen_Type	Type of biological specimen (e.g., "Whole Blood," "Plasma-Na Citr," "DNA")
Barcode	Full specimen barcode printed on label (format: [6-digit KitID]-[suffix])
KitID	Six-digit kit identifier (barcode trunk)
TimePoint	Study timepoint, if applicable
Stimulant	Stimulant used, if applicable (e.g., for immunological assay kits)
additional_label_text	Any additional text printed on the specimen label
total_number_tubes	Number of tubes of this type in the kit
ShipDate	Date the kit was shipped to the clinical site
ExpDate	Expiration date of the kit