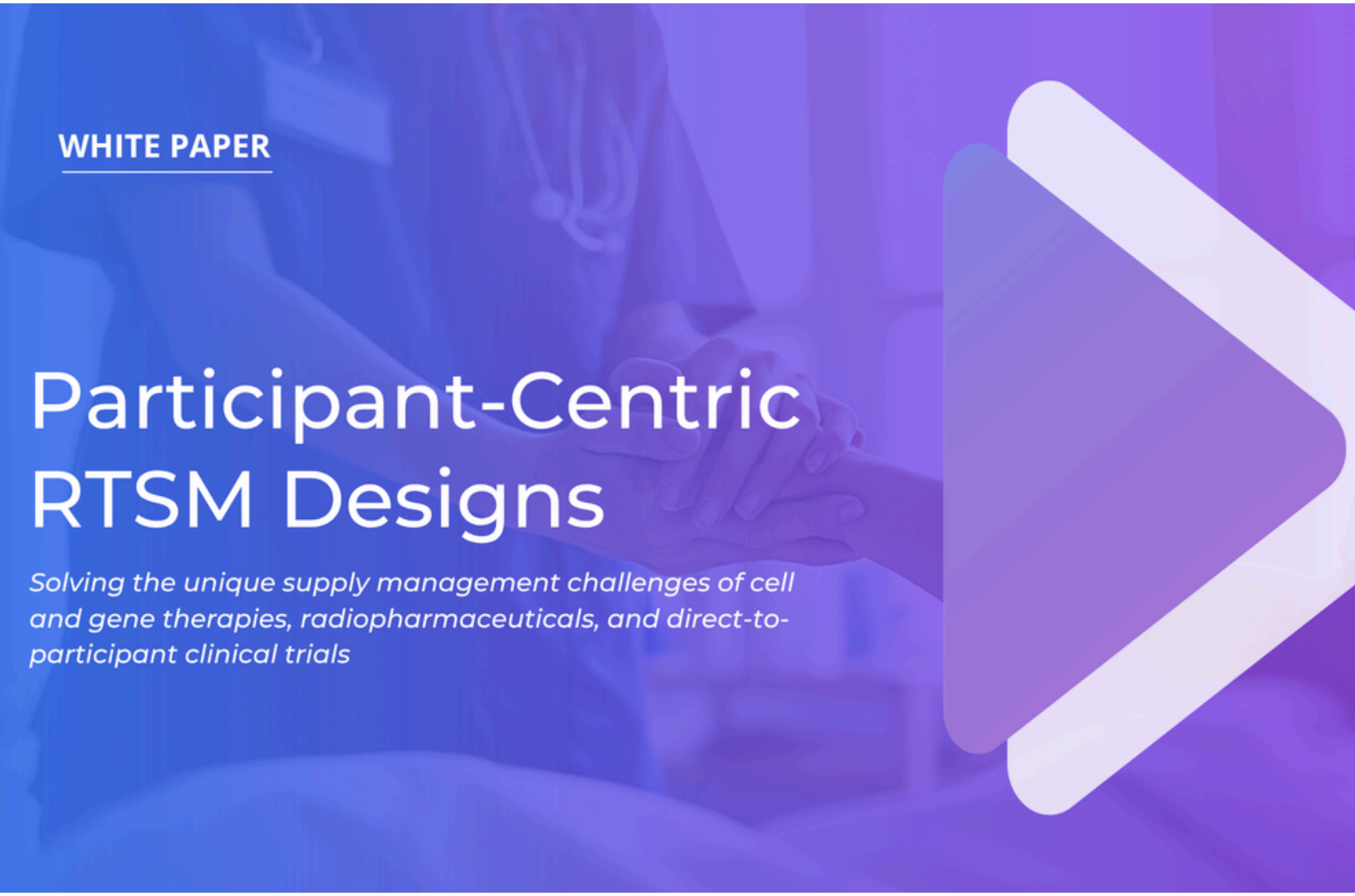


WHITE PAPER

Participant-Centric RTSM Designs

Solving the unique supply management challenges of cell and gene therapies, radiopharmaceuticals, and direct-to-participant clinical trials

Endpoint®

Executive Summary

Participant-centric supply management is moving from a specialized operational consideration to a core requirement for modern clinical development. Cell and gene therapies, radiopharmaceuticals, and direct-to-participant trial designs are creating study environments where supply must be linked to the individual participant, governed across more handoffs, and responsive to change as it happens.

Traditional RTSM models were built primarily around site-centric workflows, pooled inventory, and conventional resupply logic. Those models can become strained when a treatment is manufactured for one participant, when usability is measured in hours or days, or when delivery extends into the participant's home while protecting personally identifiable information.

This white paper examines the market conditions and operational requirements shaping participant-centric RTSM: participant-specific manufacturing, time-critical usability windows, temperature-controlled logistics, direct-to-participant coordination, privacy protection, country and site barriers, and full lifecycle accountability. The goal is not to suggest that technology removes uncertainty from participant-centric supply. It is to show how purpose-built RTSM capabilities can help teams preserve identity, usability, privacy, and accountability from order through destruction.

The Participant-Centric Market Landscape

Advanced therapies and participant-centric study designs are expanding faster than traditional supply models can comfortably support. This shift is being shaped by three market forces: continued growth in cell and gene therapy, momentum in radiopharmaceuticals, and the expansion of decentralized and direct-to-participant models.

Cell and gene therapy is projected to grow from approximately $19B to $82B by 2030, radiopharmaceuticals from approximately $6B to $13B by 2030, and the decentralized/direct-to-participant market from approximately $9B to $20B by 2030. More than 65% of new advanced-therapy studies require identity-locked, time-critical, or direct-to-participant supply models.

These trends converge around a common operational reality: **participant-centric trials require systems that can manage per-participant manufacturing, sub-day or short-window usability, privacy-protected delivery workflows, and traceable accountability across sites, depots, manufacturers, couriers, home health partners, and study teams**. When these requirements are handled through retrofitted systems or manual workarounds, sponsors may absorb the cost through amendments, excursions, lost doses, delays, and additional operational risk.

Participant-Specific Manufacturing

In participant-specific manufacturing, supply is not treated as interchangeable inventory. For cell and gene therapies, especially autologous and allogeneic therapies, manufacturing can be tied to a biological harvest event associated with a specific individual. Standard lot logic does not apply when each treatment is uniquely manufactured for one participant.

Radiopharmaceuticals introduce a related set of operational constraints. Production windows may be fixed, dosing may be calculated by body weight, and scheduling must align to isotope decay timelines measured in hours. In both cases, product creation and product use are tightly bound to the individual participant's clinical journey.

The resulting operational requirements are significant: manufacturing cannot begin until enrollment is confirmed, each lot may be identity-locked to a single participant, batch records must follow the participant rather than conventional stock management, manufacturing failures may require urgent re-initiation, and regulatory documentation must trace participant identity end to end.

Purpose-built RTSM can support these requirements by triggering manufacturing orders from enrollment confirmation events, linking lot records to the correct participant, maintaining chain-of-identity controls from harvest collection through administration, supporting re-manufacture workflows with identity continuity, and preserving GxP-ready documentation across the participant-specific supply record.

Chain of Identity and Usability

The participant-specific supply lifecycle typically moves through enrollment, harvest or collection, manufacture, QC release, dispatch, and administration. Each step is gated by participant-specific event confirmation. The result is an identity-locked supply chain in which manufacturing events define when and how supply becomes usable.

In this model, usability is not simply a function of inventory availability. It is conditional on manufacturing completion, release confirmation, custodial handoffs, and identity verification at each critical point. Supply intended for Participant A cannot be dispensed to Participant B. A break in chain of identity may render the therapy clinically unusable.

In this environment, RTSM should act as more than an inventory system. **It should provide event-driven usability gates, identity verification checkpoints at dispatch and receipt, system-level identity locks that prevent cross-participant assignment, chain-of-identity breach alerts, and participant-centric supply records designed for identity-locked workflows.**



"Endpoint helps make participant-centric supply visible, controlled, and actionable from order through destruction."

Half-Life, Expiration, and Usability Windows



For time-critical therapies, time is not a logistics variable. It is a clinical safety constraint. From manufacture release to optimal administration window, expiry warning, hard expiration, and destruction, each milestone depends on precise usability control.

Radiopharmaceuticals may decay within hours, requiring administration to be precisely timed. Cell therapy viability windows may be measured in days rather than weeks. Standard expiry logic may not be sufficient for sub-day half-life calculations, and a missed administration window can mean a wasted or difficult-to-replace manufacturing cycle. Replacement logistics must therefore be triggered before expiry, not reactively after product loss.

Purpose-built RTSM can help govern these windows through configurable half-life and expiry rules by product, usability calculations based on manufacturing release timestamps, real-time expiry alerts to sites, coordinators, and logistics teams, pre-expiry replacement triggers with defined lead times, and system blocks that help prevent dispensing outside the calculated usability window.

Temperature Profiles and Cold Chain Management



Many participant-centric and advanced therapy supply models require strict temperature management across a complex, multi-leg cold chain. Relevant profiles may include cryogenic, ultra-low, frozen, refrigerated, and controlled room temperature conditions.

For cell and gene therapies, temperature excursions during transit may permanently compromise therapy viability. Each handoff between manufacturer, depot, courier, site, or participant home introduces risk. Temperature data must be captured, validated, and linked to the product record. When an excursion occurs, use-or-discard decisions may need to be made quickly and documented appropriately.

RTSM can support cold-chain decision-making by configuring temperature profiles at the study, country, and shipment level; connecting temperature-monitoring data to shipment records; routing excursions through review and override workflows with documented approval; notifying appropriate site and sponsor roles; and requiring temperature acceptance before administration is recorded.

Bespoke Logistics

Participant-centric supply rarely follows a single predictable route. Logistics may move from manufacturer to specialty courier, depot or hub, last-mile distribution, and ultimately to the site or participant. Each leg requires independent tracking, temperature management, and identity verification.

Logistics providers capable of supporting cell and gene therapies may be limited. Country-specific import and export regulations vary by therapy type and site location. Chain-of-custody documentation must remain unbroken across all logistics legs. Contingency routing may be required if a primary logistics path becomes unavailable, and timing must synchronize manufacturing release with participant readiness.

RTSM can help coordinate these movements through configurable logistics-provider assignments at the study, country, and site level; country-specific routing rules; regulatory documentation templates; digital chain-of-custody records; contingency shipment workflows; automated re-routing and notification logic; and manufacturing-to-dispatch coordination aligned with participant visit scheduling.

Direct-to-Participant Supply Management

Direct-to-participant models bring the clinical trial to the participant rather than asking the participant to travel to the trial. This creates a broader coordination network involving site coordinators, specialty pharmacies, manufacturers, logistics providers, sponsors, monitors, home health nurses, regulatory or audit stakeholders, and the participant's home.

Participant home address data is sensitive PII and must be protected from sponsor visibility. Coordination between site, pharmacy, nurse, and logistics teams must be precise. Participant unavailability may require rescheduling without breaking the supply chain. Home delivery requires special handling, confirmation, and regulatory oversight without compromising privacy.

DTP capabilities should be designed around encrypted and segregated address handling, sponsor-blind data visibility, multi-party coordination workflows triggered by visit scheduling events, flexible rescheduling with supply-chain impact assessment and re-trigger logic, home delivery confirmation workflows, participant-signed receipt capture where appropriate, and audit trails that preserve accountability without exposing PII to unauthorized system roles.

Privacy and Logistical Coordination

Effective DTP execution requires role-based data visibility. Each participant in the supply ecosystem needs access to the information required for their function, and no more.

Sponsors and monitors may receive study-level aggregate data without PII or participant address information. Site coordinators may access full participant data within assigned and activated sites. Logistics providers may receive delivery address information without clinical identity linkage. Home health nurses may access assigned participant visit data for scheduled appointments. Manufacturers may receive lot IDs and manufacturing specifications without personal data. Regulatory and audit roles may access full audit trails, with PII access governed by protocol and jurisdiction.

Privacy is not only a policy requirement. In participant-centric supply, it must be embedded into the RTSM architecture through role-based visibility and data-point-level controls configured by study, country, and site.

Oversight, Accountability, and Country/Site Barriers

Participant-centric trials must operate within varied country, site, and regulatory environments. Import restrictions, site infrastructure limitations, full accountability requirements, privacy laws such as GDPR and HIPAA, local QP release, local storage, and destruction documentation are all critical considerations.

These variables can create barriers to access if they are not managed within the supply management configuration. Some countries may prohibit certain therapy types. Some sites may lack qualified cold chain infrastructure or logistics capability. Gaps in accountability can halt entire programs.

RTSM can help teams manage these barriers through country-level configuration for import and export restrictions, approved logistics providers, site capability profiles, digital order-to-destruction accountability, e-signature support, regional compliance rule sets, legal review checkpoints where required, local QP release workflows, destruction confirmation, and import documentation templates.

Compliance and Accountability: Full Lifecycle Tracking

A participant-centric supply model must capture every touchpoint from first order to final destruction. A complete accountability lifecycle includes Order, Manufacture, Fulfill, Release, Dispatch, Delivery, Receipt and Temperature Acceptance, Replacement, Administration, Return, Accountability, and Destruction.

This lifecycle reflects the operational reality that advanced therapy and DTP supply cannot be governed through isolated milestones. Each step should be confirmed, attributed, timestamped, and auditable so teams can preserve product integrity, participant safety, regulatory compliance, and operational visibility across the full journey.

The Cost of Getting It Wrong

Participant-centric supply failures can carry clinical, financial, operational, and regulatory consequences. Key categories of value at risk include high per-dose therapy value, autologous CAR-T manufacturing failure rates, temperature excursions in biologics shipments, protocol amendment costs, and the compound impact of avoidable supply-driven delays or errors.

CAR-T list prices can range from $373K–$475K, with Casgevy priced at $2.2M. Autologous CAR-T batch failure rates may fall in the 5–10% range, and approximately 20% of biologics shipments experience a temperature event in transit. Substantial protocol amendments can cost $500K–$1M and create potential delays of three to six months. In a mid-size Phase II cell therapy program, avoidable supply-driven costs can reach $4M–$8M when workflows, identity control, and cold-chain logic are not purpose-built.

These figures should be treated as directional risk indicators rather than guaranteed outcomes. The larger point is that participant-centric supply failures can have consequences far beyond inventory. They can affect treatment continuity, participant experience, study timelines, regulatory readiness, and the integrity of the supply record.

Predictability in this context is not proving the original plan correct. It is recognizing when reality has changed, understanding the consequence, and responding through governed workflows before supply risk becomes participant or study risk.

RTSM as Part of a Connected Decision Architecture

The platform advantage is not simply a longer list of features. It is the ability to connect protected data, operational events, identity controls, logistics workflows, usability gates, and audit-ready accountability across the participant-centric supply lifecycle.

Core capabilities include protected PII storage, communication flows, chain of custody and identity, temperature and logistics management, expiration and usability controls, and resupply or replacement management. Together, these capabilities help convert supply-relevant signals into context, consequence, decision, and response.

In practice, this means protecting sensitive participant data, coordinating role-aware communications, preserving chain of identity, monitoring temperature and logistics events, governing expiry and usability, and enabling replacement workflows when participant-specific need, manufacturing failure, or timing risk requires action.

> “Purpose-built RTSM helps convert supply-relevant signals into context, consequence, decision, and response.”

DTP Configuration Across the Study Hierarchy

DTP configuration can be structured as a hierarchy across study, country, site, visit, and participant levels. At the study level, a global DTP flag enables capability across the program, with lower levels inheriting unless overridden.

At the country level, DTP rules address import regulations, approved logistics providers, and privacy compliance requirements. At the site level, capability profiles determine whether a site is qualified and activated for DTP pathways. At the visit level, specific visits can be designated for home delivery workflows. At the participant level, individual DTP preferences, encrypted home address data, and scheduling or rescheduling configuration take final precedence.

This hierarchy allows participant-centric supply to remain both configurable and governed, giving sponsors the ability to tailor DTP execution without losing control over compliance, privacy, or operational accountability.

Benefits Across Stakeholders

Purpose-built participant-centric RTSM creates value across sponsors, sites, and participants, but those benefits should be framed as directional and protocol-dependent rather than guaranteed.

For sponsors, participant-centric RTSM can support faster startup for complex supply designs, lower amendment risk through configurable rules, and stronger compliance by design through GxP-ready audit trails, role-based PII controls, and country-level regulatory rule sets.
For sites, the value is focused on event-driven coordination, identity-safe workflows, and reduced manual reconciliation. Digital chain of custody, e-signature support, and verification gates can help study teams move from manual multi-party handoffs toward more controlled execution.

For participants, the value is practical and human: fewer unnecessary site visits where DTP is appropriate, better coordination around scheduled visits, privacy-aware home delivery pathways, and stronger controls around the supply intended for them. Directional benchmarks for decentralized models point to fewer site visits and lower dropout, though individual results vary by protocol.



Conclusion:

Participant-centric clinical trials require participant-centric supply management. As cell and gene therapies, radiopharmaceuticals, and DTP models expand, sponsors need RTSM capabilities that can support identity-locked products, time-critical usability controls, privacy-aware workflows, bespoke logistics, and full lifecycle accountability.

The goal is not to remove uncertainty from clinical development. It is to build a better system for responding to it. When RTSM is configured around participant-specific manufacturing, usability windows, cold-chain realities, privacy requirements, and order-to-destruction accountability, teams can recognize issues earlier, understand their implications faster, and act through governed workflows.

The future of clinical supply is not simply site-based or inventory-based. It is participant-linked, event-driven, privacy-aware, and accountable from order through destruction. RTSM should help make that model visible, controlled, and actionable across the full participant journey.

Contact us today to learn more or request a personalized demo.
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