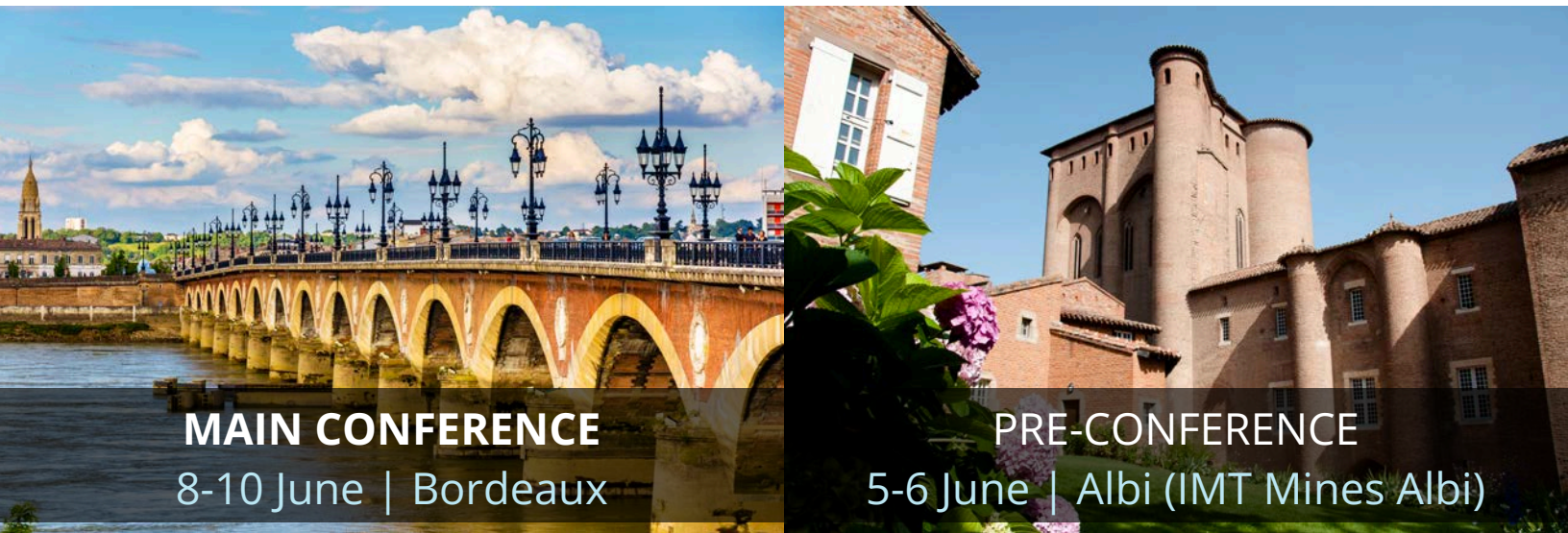


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The TREATMENT project: a Physical-Internet-enabled reference architecture for end-to-end visibility in direct-to-patient clinical trial logistics

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Abstract: *Clinical trials are increasingly adopting decentralized and direct-to-patient delivery models, but these models intensify the need for auditable chain-of-custody, condition control, and coordinated execution across heterogeneous logistics actors. This paper presents TREATMENT as a Physical-Internet-enabled reference architecture for regulated direct-to-patient clinical trial logistics. The contribution does not lie in standards adoption alone, but in the integration of connected logistics units, a neutral multi-tenant cooperation platform, a single-trace interoperability mechanism combining GS1 EPCIS 2.0 events and GS1 EDI documents, and an explicit milestone-driven rule-based logic for road-drone synchronization. The evaluation is structured around trace completeness, chain-of-custody integrity, document-event correlation, telemetry timeliness, condition monitoring, route integrity, and intermodal synchronization. Results show complete capture of planned custody milestones, successful correlation of shipment documents and physical events across heterogeneous providers, near-real-time telemetry availability, correct alert generation for conservation and route anomalies, and event-governed release of the downstream drone leg from validated upstream milestones. The paper also discusses transferability conditions, architectural limits, and the broader relevance of the approach for regulated multimodal healthcare logistics.*

Keywords: *Physical Internet; clinical trial logistics; direct-to-patient; road-drone cooperation; GS1 EPCIS; interoperability; end-to-end visibility; connected logistics unit*

Physical Internet (PI) Roadmap Fitness: [X] Transportation Equipment [X]
Logistics/Commercial Data Platform [X] Governance [X] PI Networks [X] Access and Adoption

Targeted Delivery Modes: [X] Paper [] Poster [] Flash Video [X] In-Person presentation

1. Introduction

Clinical trial supply chains are designed around stringent requirements for product integrity, subject safety, protocol compliance, and audit readiness. These requirements become harder to satisfy when investigational medicinal products move beyond the clinical site and are delivered directly to participants, as happens in decentralized and hybrid trial models. Recent reviews and regulatory guidance highlight both the promise and the operational fragility of decentralized clinical trials: remote participation can reduce participant burden and improve access, but it also creates new challenges for investigational product supply, temperature control, role allocation, and evidence continuity (Rogers et al., 2022; FDA, 2024; EMA, 2022).

The logistics problem is therefore not limited to transport efficiency. In regulated direct-to-patient operations, the central question is whether multiple actors and modes can produce a continuous, trustworthy, and machine-readable record linking what was shipped, where it moved, under which conditions it was handled, and when it was received. GS1 has long provided identification and messaging standards (based on GS1 EDI) for clinical trials (GS1,

2022b), but in practice, direct-to-patient clinical trial logistics still suffers from fragmented data ownership, provider-specific interfaces, and limited correlation between shipment documents and physical events. This paper addresses that gap through the TREATMENT¹ project. The research contribution is not presented as a generic "digitalization" case, nor as a simple implementation of existing standards. Instead, it proposes and critically discusses a Physical-Internet-enabled reference architecture that combines: (i) connected logistics units at item and aggregation level; (ii) a neutral multi-tenant cooperation platform for cross-actor visibility and governance; (iii) a single-trace mechanism that correlates GS1 EPCIS 2.0 (GS1, 2022a) events and GS1 EDI documents, going beyond the GS1 white-paper in (GS1, 2022b); and (iv) an explicit rule-based synchronization logic for activating the drone leg after validated road-leg milestones. The empirical scope of the paper is deliberately bounded: it includes device- and platform-level validation and two integrated demonstrations conducted in July and October 2025, while larger-scale and comparative benefits remain part of the research agenda rather than claimed outcomes.

2. Related work and research gap

Physical Internet research has established the value of modular logistics units, open networks, interoperable interfaces, and neutral coordination mechanisms for improving logistics performance at ecosystem level (Montreuil, 2011; Montreuil et al., 2013; Ballot et al., 2014; Crainic and Montreuil, 2016; Pan et al., 2017). In this literature, visibility is not just a tracking feature: it is the informational infrastructure that makes shared assets, pull-based orchestration, and synchromodal reconfiguration feasible. In parallel, the decentralized clinical trial literature has shown that investigational product distribution to participants is feasible but operationally demanding. The systematic review by Rogers et al. (2022) showed that decentralized methods are expanding across trial activities, while recent operational work from the Trials@Home RADIAL proof-of-concept trial reported that direct-to-participant shipment is feasible only when responsibilities, temperature control, participant availability, and contingencies are explicitly managed (Heath et al., 2025). Regulatory bodies have converged on a similar point: decentralized trial elements can be used, but sponsor oversight, investigator responsibility, data integrity, and participant protection must remain demonstrable (FDA, 2024; EMA, 2022). On the transport side, healthcare drone studies document growing technical maturity and clear potential for reducing response times in selected medical logistics scenarios, especially in constrained or remote geographies (Lin et al., 2018; Stierlin et al., 2024). However, most road-drone or drone-healthcare studies focus on routing, feasibility, safety, or service economics. Much less attention has been devoted to the regulated traceability problem that arises when an investigational product changes custody across organizations and modes while remaining subject to protocol-specific conservation, documentation, and audit requirements.

The research gap addressed here is therefore specific: existing work does not adequately explain how a regulated direct-to-patient clinical trial flow can be orchestrated as a Physical Internet service while preserving trace completeness, chain-of-custody integrity, selective data visibility, and auditable handover between road and aerial legs. TREATMENT contributes a reference architecture and an evaluation framing for exactly this problem.

3. Research contribution and system architecture

This paper makes the following scientific contributions: (i) it formalizes TREATMENT as a Physical-Internet-enabled reference architecture for regulated direct-to-patient clinical trial

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logistics; (ii) it defines a single-trace interoperability mechanism that correlates GS1 EPCIS 2.0 events and GS1 EDI documents around the same shipment objects and custody milestones; (iii) it makes the road–drone decision logic explicit as a rule-based, milestone-driven orchestration mechanism rather than leaving last-mile activation implicit; (iv) it proposes an evaluation framing for auditable intermodal coordination under regulated conditions, covering trace completeness, chain-of-custody integrity, document-event correlation, telemetry timeliness, exception visibility, and intermodal synchronization.

The architecture, depicted in Figure 1, is centred on two connected logistics units and one neutral cooperation layer. At item level, the smart box (a tertiary packaging containing the medicines) acts as a connected logistics unit attached to the investigational product package. It emits item-level events related to location, conservation conditions, and proof-of-delivery evidence. At aggregation level, the smart capsule acts as a reusable connected logistics unit designed for modal handover and last-mile mission execution. It aggregates one or more item-level units, exposes additional mission and environmental telemetry, and supports coupling with the drone leg.



Figure 1: Proposed TREATMENT reference architecture

Above these assets sits a neutral multi-tenant cooperation platform. The platform ingests operational data from heterogeneous providers, validates messages, normalizes them into a canonical model, enforces policy-based visibility, and stores the resulting evidence in an auditable repository. The platform does not replace provider-specific execution systems; instead, it separates coordination from execution, which is consistent with Physical Internet thinking about open networks and neutral interoperability layers.

The single-trace mechanism is achieved through shared identifiers and complementary message semantics. GS1 identifiers provide the stable references needed to connect item, logistic unit, location, and shipment semantics. GS1 EPCIS 2.0 captures the event history of association, aggregation, transport, receipt, and exception states. GS1 EDI captures business commitments and shipment documents such as despatch and receipt notices. The innovation is in their correlation: rather than treating documents and events as parallel but disconnected channels, the architecture binds them to the same shipment objects and custody milestones.

3.1. PI mapping of the architecture

Table 1 makes the mapping to core Physical Internet principles explicit. The aim is not to force an abstract PI vocabulary onto the case, but to show where the architecture genuinely instantiates PI concepts and where it remains a domain-specific adaptation for regulated healthcare logistics.

Table 1: Explicit mapping between TREATMENT and core Physical Internet principles

PI principle	TREATMENT implementation	Research relevance
Modular connected units	Smart box at item level; smart capsule as reusable aggregation unit for last mile and modal handover.	Moves the PI container idea into regulated healthcare and preserves modular handover semantics.
Open interoperable networks	GS1 identifiers, EPCIS 2.0 events, and GS1 EDI documents across heterogeneous providers	Shows interoperability across organizations rather than within a single proprietary platform.
Neutral data platform	Multi-tenant cooperation platform with canonical model, validation, routing, and audit trail.	Separates coordination from provider-specific execution systems.
Pull-based orchestration	Last-mile activation triggered by validated receipt, patient slot, and exception status.	Replaces purely push release with event-driven service activation.
Synchromodal coordination	Road-to-drone handover documented through aggregation, association, despatch, receipt, and deconsolidation events.	Extends PI thinking to controlled intermodal handover in clinical trials.
Selective trust and governance	Policy-based visibility, role-aware access, and transaction-level document-event correlation.	Addresses the governance layer often missing in conceptual PI deployments.

3.2. Rule-based road-drone synchronization

The current implementation uses rule-based orchestration rather than optimization. This design choice is deliberate. In regulated clinical settings, accountability, explainability, and auditability are often more critical than the global efficiency gains that might be achieved by an opaquer dispatcher. The synchronization mechanism therefore relies on milestone-driven heuristics anchored in observable events and auditable state transitions.

The drone leg can be activated only when five conditions are simultaneously satisfied: (1) a validated receipt event confirms that the shipment is physically available at the handover node; (2) the patient-selected delivery window is still valid; (3) the destination passes address validation and geofencing checks; (4) no unresolved conservation or integrity alert is open; and (5) an eligible service provider confirms execution within the required timeout and operational envelope. If any of these conditions is not satisfied, the request is not silently forced through the network. Instead, it is rescheduled, corrected manually, placed on hold for investigation, or reallocated to another provider or to a ground-based alternative. The main point is that the drone leg is not released by a static plan, but by the verified operational state of the network.

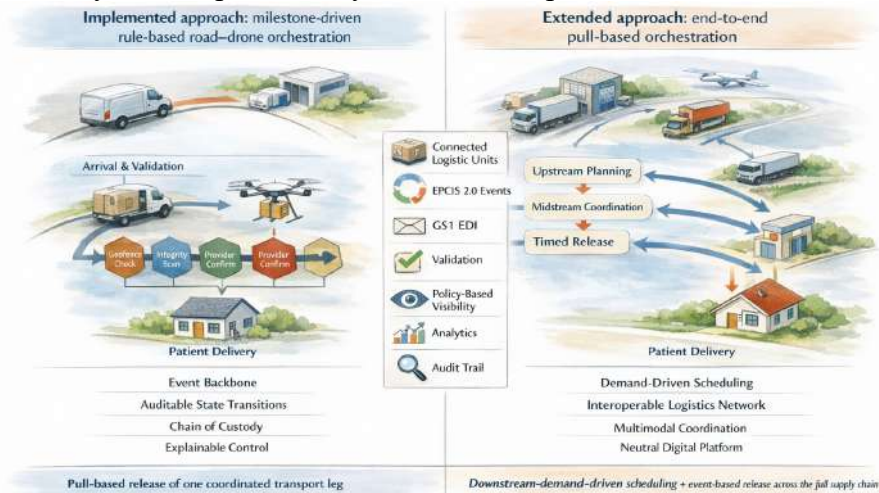


Figure 2: Implemented approach vs extended end-to-end pull approach

This logic is academically relevant because it shows how road–drone cooperation can be expressed as pull-based orchestration rather than as a static pre-planned itinerary. The triggering signal is not a planner’s prior assumption that the shipment should be available at a certain time, but a validated milestone generated by the event backbone. In this sense, the drone leg is released by the verified state of the network rather than by the inertia of an upstream schedule. Its broader end-to-end generalization is discussed in Section 6.

4. Evaluation design

The evaluation is organized as a design-oriented case study with three empirical layers. The first layer covers component and interface level validations for connected logistics units and the neutral cooperation platform. The second layer, covered in the July 2025 field pilot, which validated the hospital-to-patient drone-enabled last-mile flow with two smart boxes, one smart capsule, one drone leg, and two heterogeneous digital providers. The third layer, covered in the end-of-project October 2025 demonstration scenario, which extends the scope upstream by including the road leg from depot to hospital and its synchronization with the subsequent direct-to-patient drone segment. In that scenario, two smart boxes are managed across two destinations, and the hospital receipt milestone triggers the pull-based activation of the downstream drone service through standardized EDI/EPCIS interactions.

In this study, the architecture is evaluated along seven dimensions: trace completeness, chain-of-custody integrity, document-event correlation, telemetry timeliness, condition monitoring, route integrity, and intermodal synchronization. These dimensions were selected because they are directly relevant to regulated direct-to-patient clinical trial logistics and because they can be supported by the evidence currently documented without overstating comparative performance claims, as shown in Table 2.

Table 2: Evaluated empirical dimensions and observed evidence

Dimension	Operationalization	Observed evidence
Trace completeness	Presence of all planned milestone types in machine-readable form across road, hospital handover, drone, and delivery phases.	The documented pilots cover milestone capture from logistic-unit creation and road-leg tracking to hospital receipt, shipment request, provider notification/confirmation, drone delivery, and proof of delivery.
Chain-of-custody integrity	Unambiguous link between packaging, aggregation, transport, receipt, deconsolidation, and delivery evidence.	Validated through EPCIS aggregation and association events, receipt messages, and delivery/deconsolidation evidence across the July and October scenarios.
Document-event correlation	Business documents linked to the same shipment objects as field events.	GS1 EDI despatch, receipt, shipment request, shipping notification, and shipping confirmation messages are correlated to shipment objects through EPCIS transaction events across heterogeneous providers.
Telemetry timeliness	Ability of smart capsule / drone telemetry to reach the cooperation platform at the required refresh rate.	The project KPI for data transfer at least once per minute is reported as achieved; the smart-capsule posting interval is described as exceeding the minimum requirement.
Condition monitoring	Ability to detect and report conservation anomalies through pre-alarm and alarm logic.	Positive tests are reported for threshold-based alert generation related to environmental conditions.

Route integrity	Ability to detect and report deviations from the expected path or geofence.	Positive tests are reported for pre-alarm and alarm generation under path-deviation or geofencing anomalies; geofencing checks are also part of operational validation in the transport flow.
Intermodal synchronization	Ability to release the drone leg based on validated upstream milestones rather than fixed pre-planning.	Road-leg events and hospital receipt are captured first; the validated receipt then triggers automatic pull-based booking of the drone service via Shipment Request, followed by provider notification, confirmation, and replicated drone delivery sequences for two destinations.

The purpose of this section is therefore to assess what has been empirically evidenced in terms of interoperability, auditable orchestration, and event-governed intermodal coordination under regulated conditions. Potential service impacts associated with the drone-enabled leg are addressed separately in Section 4.1.

4.1. Drone-enabled operational impact

While the previous section focuses on demonstrated evidence, the drone-enabled leg is also relevant because it addresses a broader set of operational impacts that are particularly meaningful in geographically constrained direct-to-patient settings. In this respect, the drone is not introduced merely as an additional transport mode, but as a service enabler for time-sensitive, accessibility-constrained, and territorially fragile delivery contexts.

This subsection therefore captures the main impact dimensions associated with the drone-enabled extension. The aim is to make the expected impact dimensions explicit and measurable, while keeping them analytically separate from the empirically validated interoperability and orchestration results presented above. The quantitative impact of the drone-enabled leg is detailed in Table 3 (Pirri et al., 2024).

Table 3: *Quantitative impact dimensions of the drone-enabled leg*

Impact dimension	Operationalization	Quantitative indicator	Results
Transport time reduction	Difference between conventional last-mile delivery time and drone-enabled coordinated delivery time.	Average delivery time reduction (%) or minutes saved per mission.	Estimated 35–55% reduction.
Reduced traffic and environmental burden	Reduction in road-based vehicle movement due to partial substitution of the last-mile ground segment with the drone leg.	Vehicle-km avoided; estimated CO2 emissions avoided; reduction in local road traffic burden.	1.2–2.5 kg of CO2 emissions saved per mission
Improved accessibility in constrained territories	Ability to maintain or improve service to remote or hard-to-reach destinations	Increased service coverage.	Up to 100% for remote or hard-to-reach areas

5. Results and discussion

The July 2025 pilot demonstrated that the planned custody milestones could be captured in machine-readable form across the hospital-to-patient drone-enabled last-mile flow, from logistic-unit creation and aggregation to despatch, receipt, deconsolidation, and proof of delivery. From a Physical Internet perspective, this is important because the system did not merely generate isolated sensor readings; it produced a coherent event history with operational and business meaning. The cooperation platform also validated the correlation between GS1 EDI despatch and receipt messages and the corresponding EPCIS transaction history across heterogeneous digital providers.

The October 2025 integrated multimodal demonstration extended this evidence upstream by including the road leg from depot to hospital and its synchronization with the subsequent drone-enabled direct-to-patient segment. This broader scenario showed that the hospital receipt milestone could act as a validated release condition for the downstream drone service through standardized EDI/EPCIS interactions. As a result, the architecture moved beyond simple multimodal visibility and demonstrated a concrete form of intermodal synchronization, in which upstream physical availability and downstream service activation were linked through auditable event-based control.

Device and integration levels validation also produced concrete evidence on operational behaviour. Smart-capsule telemetry reached the cooperation platform at a rate exceeding the minimum project threshold of one update per minute, showing that the architecture can support near-real-time situational awareness. Threshold-based pre-alarm and alarm generation for conservation anomalies and route deviation also worked as intended, indicating that the event backbone supports exception visibility rather than only retrospective traceability. In addition, the smart-box autonomy observed under the relevant monitoring profile was approximately five months, which is compatible with the intended monitoring horizon of the proposed logistics configuration.

Taken together, these results support four main claims: (i) the architecture improves evidence continuity: physical movements, logistic-unit transformations, and shipment documents can be inspected as one trace rather than as fragmented records; (ii) it preserves chain-of-custody integrity across packaging, aggregation, handover, transport, receipt, and delivery through explicit EPCIS events and linked business documents; (iii) it shows that a neutral cooperation platform can coordinate heterogeneous actors without collapsing interoperability into a single-provider information silo, (iv) it demonstrates that road–drone cooperation can be governed through validated milestones and pull-based release logic rather than through a purely static pre-planned itinerary.

More broadly, the results suggest that the main scientific contribution of the work lies not only in combining connected logistics units, EPCIS-based traceability, and drone-enabled delivery, but in showing how these elements can be integrated into a governance-aware orchestration architecture. In this sense, the study contributes a transferable design logic for regulated multimodal healthcare logistics: downstream service execution is not released by schedule alone, but by validated network state, shared events, and auditable control rules. The main result is therefore not only traceability, but auditable release coordination across heterogeneous actors and modes.

From a Physical Internet perspective, this suggests a broader research direction: moving from the pull-based activation of a single transport leg to a network-wide pull architecture in which connected logistics units, neutral event-sharing platforms, and interoperable service interfaces collectively govern when operations are released, postponed, rerouted, or recomposed. In regulated healthcare logistics, such an approach may be especially valuable because it combines flexibility with explicit control points, thereby preserving traceability, chain-of-custody integrity, and compliance evidence while still enabling adaptive multimodal coordination.

At the same time, this generalization should be interpreted with caution. The current work validates the feasibility and relevance of milestone-based release logic in coordinated road–drone execution, but it does not yet demonstrate a fully implemented end-to-end pull architecture across the entire clinical trial supply chain. Extending the mechanism upstream would require additional coordination rules, broader partner participation, and further validation under heterogeneous clinical pathways, geographical contexts, and service

configurations. For this reason, the present study should be understood as a validated step toward full pull orchestration rather than as its complete operational realization.

Still, generalization is conditional rather than automatic. Operational envelope limits for drones, local aviation rules, hospital landing or handover infrastructure, and the willingness of stakeholders to share standardized data all shape feasibility. The architecture should therefore be read as a transferable blueprint with domain-specific adaptation points, not as a universally plug-and-play solution. From a failure-mode perspective, the available evidence covers threshold exceedance and route-deviation alerts, as well as asynchronous ingestion and cross-provider document-event correlation. What remains to be documented more systematically are stress cases such as repeated provider non-confirmation, first-message loss during a critical handover, large-scale exception bursts, or contested custody evidence. These represent priority topics for the next validation cycle.

6. Generalizability and limitations

The main result is therefore not only traceability, but auditable release coordination across heterogeneous actors and modes. This is the case for three main reasons: (i) the connected logistic unit abstraction is not drone-specific; (ii) the neutral cooperation platform is provider-agnostic, provided that participating actors can expose shared identifiers and machine-readable events or documents; and (iii) the orchestration logic is grounded in validated milestones, patient constraints, and auditable release conditions that remain relevant across multiple trial designs, geographical contexts, and service configurations.

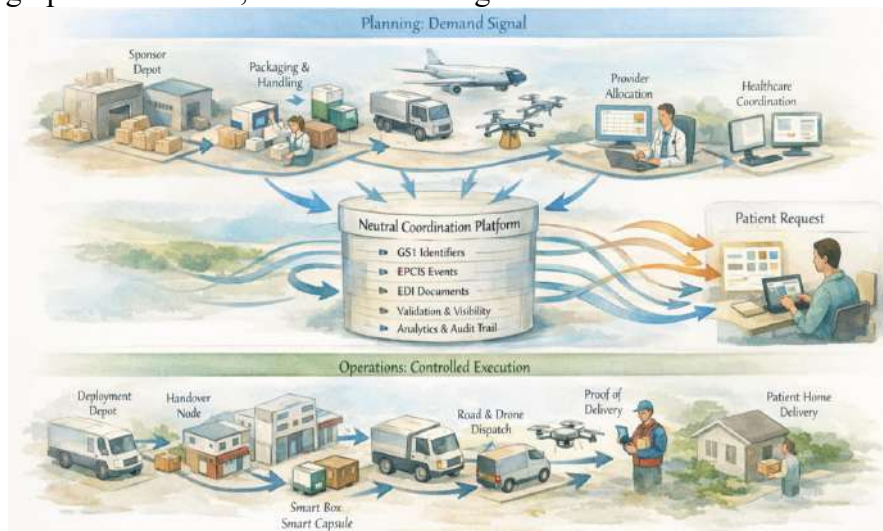


Figure 3: Patient-driven, end-to-end pull orchestration across the supply chain

More importantly, the same principle can be extended beyond the last-mile drone leg to the broader end-to-end clinical trial supply chain. In such a scenario, the pull signal would originate when a patient delivery request is confirmed, and a delivery slot is selected that is compatible with supply chain response times and operational constraints. Figure 4 illustrates this broader generalization perspective, in which the validated road–drone synchronization logic is interpreted as one instance of a wider patient-driven and event-governed pull orchestration model. This downstream commitment would then structure the organization of upstream and midstream activities, allowing routes, handovers, and service allocations to be scheduled according to pull principles around an actual delivery need rather than around forecast-based pre-positioning alone. Within this architecture, planning still plays an important role, but it is activated by a real demand commitment and subsequently governed through milestone validation, custody continuity checks, and condition-monitoring events. Road–drone

synchronization therefore becomes one instance of a broader principle: a supply chain that is scheduled from downstream demand and released through auditable event-based control. More importantly, the same principle can be extended beyond the last-mile drone leg to the broader end-to-end clinical trial supply chain. In such a scenario, the pull signal would originate when a patient delivery request is confirmed, and a delivery slot is selected that is compatible with supply chain response times and operational constraints. Figure 4 illustrates this broader generalization perspective, in which the validated road–drone synchronization logic is interpreted as one instance of a wider patient-driven and event-governed pull orchestration model. This downstream commitment would then structure the organization of upstream and midstream activities, allowing routes, handovers, and service allocations to be scheduled according to pull principles around an actual delivery need rather than around forecast-based pre-positioning alone. Within this architecture, planning still plays an important role, but it is activated by a real demand commitment and subsequently governed through milestone validation, custody continuity checks, and condition-monitoring events. Road–drone synchronization therefore becomes one instance of a broader principle: a supply chain that is scheduled from downstream demand and released through auditable event-based control.

7. Conclusion

This paper presented TREATMENT as a Physical-Internet-enabled architecture for regulated direct-to-patient clinical trial logistics. The core contribution is not the use of standards per se, but their integration into a coherent orchestration model that combines connected logistic units, a neutral multi-tenant cooperation platform, GS1 EPCIS 2.0 event sharing, GS1 EDI document exchange, and milestone-driven road–drone synchronization.

The reported evidence shows that this architecture can deliver more than fragmented tracking. It can generate a single auditable trace across packaging, aggregation, transport, handover, receipt, and delivery, while preserving chain-of-custody integrity and correlating business documents with field events across heterogeneous providers. The October integrated demonstration further indicates that upstream road-leg evidence and hospital receipt can act as validated release conditions for the downstream drone leg, thereby moving from simple multimodal visibility toward event-governed intermodal coordination.

From a Physical Internet perspective, the relevance of the study lies in showing how a regulated healthcare logistics system can be organized around shared identifiers, interoperable event semantics, modular connected units, and neutral coordination mechanisms. In this sense, TREATMENT contributes a governance-aware interoperability model for direct-to-patient logistics: execution is not released by schedule alone, but by validated network state, auditable milestones, and explicit control rules.

At the same time, the present results should be interpreted within their current evidential boundary. The paper demonstrates interoperability and explainable coordination under regulated conditions, but it does not yet establish controlled comparative gains over conventional delivery configurations in terms of lead time, cost, or emissions. Likewise, the broader end-to-end pull interpretation should be read as a credible architectural extension rather than as a fully implemented supply-chain capability.

Overall, TREATMENT provides both a validated field case and a transferable research direction. It shows that milestone-based, standards-enabled, and provider-agnostic orchestration is feasible in a demanding direct-to-patient setting, and it opens a clear path toward broader pull-based, multimodal, and patient-driven healthcare logistics architectures.

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