Demonstrating GS1 Clinical Trials Interoperability

A Site Centric Proof-of-Concept (PoC) by Pfizer, 4G Clinical, and McCreadie Group

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Proof-of-Concept Objective

The proof-of-concept was conducted to demonstrate that the GS1 Clinical Supply Identification standard and the GS1 Clinical Supply EDI XML standard can be deployed across systems and stakeholders to increase clinical supply chain efficiency and supply management integrity.

Executive Summary

This proof-of-concept, conducted by Pfizer, 4G Clinical (Prancer RTSM Software), and McCreadie Group (Vestigo Investigational Drug Accountability Software), used a mock study modeled after a live protocol to evaluate practical adoption of the GS1 Clinical Trials standards. Multiple transactions, including shipment receiving and dispense events, were triggered by the RTSM with manual activities performed to mimic site supply receipts and patient dispensing in interlinked systems. GS1 barcode scanning for supply identification and EDI XML messaging was leveraged to keep system data aligned.

The pilot was set up to accommodate both bulk and serialized inventory, with the focus on serialized inventory workflows.

Two primary site-facing processes were optimized:

- **Site Shipment Receipt:** Automated messages sent from Prancer populated Vestigo workflows with shipment and inventory details, minimizing manual data entry. Barcode scanning was used by sites to validate and verify material identity against the electronic shipment record.
- **Barcode Validated Dispense in Vestigo:** Barcode scanning was implemented at the point of dispense, with new application logic to parse the GS1 Data Matrix barcode directly into the web application. Vestigo displayed protocol, Global Trade Item Number (GTIN), lot, and item/serial information from the scan and compared it to internal inventory records for immediate verification.

A key objective was to enable both receipt and dispense workflows using existing barcode scanners already deployed in research pharmacies without having to customize the configuration of the installed devices. This was critical to minimizing administrative burden and avoiding the need for custom hardware.

This proof-of-concept demonstrates that GS1 standards can be smoothly adopted in clinical trial operations, reducing manual data entry and administrative burden through standardized barcoding and automated data exchange. Industry-wide adoption would streamline workflows, improve accuracy, and support real-time accountability, paving the way for safer and more efficient research.

GS1 EDI XML Messaging

GS1 developed a specification for clinical supply electronic data interchange (EDI) messaging. The current set of available messages covers the span of material management actions from initiation of shipments through dispensing of drug to patients. It is an XML messaging standard based on broader GS1 EDI standards used for linking trading partners.

For more on information on the clinical supply EDI standard. Reference **EDI - Clinical Trials | GS1**

Scope and Limitations

This pilot focused on tracking kits from receipt to dispensing. Return flows and two-way messaging (e.g., for returns or recalls) were not included, as the goal was to validate barcode scanning and data exchange.

Future work will explore using the dispatch method to alert sites of incoming shipments in advance and implementing kit status change messages to support two-way accountability for returns.

For site identification, sponsor-assigned proxy Global Location Numbers (GLNs) were used during the pilot. Exception flows for damaged and lost kits were tested to ensure robust handling of real-world scenarios.

This targeted approach demonstrates that GS1 standards can be layered onto existing RTSM and site pharmacy systems to streamline accountability, improve data accuracy, and reduce site workload—while preserving familiar equipment and workflows.

Drug Accountability and Returns

When study drug is dispensed to patients, the patients consume some or all the drug. Any unused drug must be returned to the investigator site for accountability and disposal purposes. The drug return process is part of the sponsor's drug accountability requirements.

- Clinical study drug accountability refers to the systematic tracking of investigational products from their receipt at the research site through dispensing to participants, ensuring accurate records for compliance and audit readiness.
- All drug movements—including receipt, storage, dispensing, return, and destruction—must be recorded in detailed accountability logs, with discrepancies promptly reported and resolved.
- Sponsors must maintain oversight, monitor compliance, and ensure that all processes protect participant safety and data integrity.

This PoC explored a part of the process, and the reader can intuitively see how GS1 standards can provide efficiency gains in all aspects of the supply accountability process.

Brief History: GS1 Standards in Clinical Research

Since the advent of Randomization and Trial Supply Management software systems (RTSM – also known as Interactive Response Technology or IRT), investigational products have been serialized via assignment of unique kit numbers to dispensable units (DUs). As the contract manufacturing organizations (CMOs) that performed clinical supply packaging on behalf of the Pharma industry became larger and improved their material handling infrastructure, it became common practice to barcode the DUs to support their pick / pack operations. Although the CMO barcodes uniquely identified the supplies within their facilities, the barcode content was not globally unique, and it was proprietary to the CMO packaging the supplies. Therefore, systems at other organizations including clinical sites would need to reconfigure their systems to read barcodes generated by the individual CMOs.

In 2016, a white paper was published that proposed use of GS1 data standards to create globally agreed and readable barcode content for clinical study supplies. GS1 put their support behind the effort, and created a working group chaired by Hans von Steiger (Pfizer), Pierre Fernandez-Barbereau (Sanofi) and Olivia Chauvel (CH Victor Dupouy) to create a GS1 clinical supply identification standard that was issued by GS1 in September of 2019.

Upon completion of GS1 identification standards, the GS1 clinical supply standards team then created a GS1 electronic data interchange (GS1 EDI) XML standard for clinical supplies systems. This was a natural next step as Pharma companies and RTSM providers are using proprietary EDI XML messaging standards to manage distribution of clinical supplies via their CMOs.

The GS1 EDI XML standards were issued in March of 2023. Since that time, the Clinical Supply Leadership Forum (CSLF) created a GS1 Community of Practice led by Asim Khan (Amgen) and Hans von Steiger (Pfizer) to support and drive further implementation of the standards across the industry.

GS1 Clinical Supply Standards Building Blocks

The GS1 identification standards relies on assignment of Global Trade Item Numbers (GTINs) to DUs. The GTINs are a fundamental data element embedded in the barcode to provide the barcodes with their global identification property through assignment of a globally unique ID number. The adoption of the GS1 identification standard within clinical supply barcodes promises interoperability, efficiency, and improved patient safety.

GS1 EDI standards are based on the accepted XML communication standards developed for commercial trading partners. They rely on the use of both GTINs and Global Location Numbers (GLNs). The GLNs are globally unique numbers that identify the parties involved in the inventory transactions such as the shipper and receiving organization.

Site and Sponsor challenges

Clinical sites typically use specialized drug accountability software to manage investigational product inventory, track shipments, and document dispensing to participants. These systems often connect with sponsor-provided randomization and Clinical Trial Management (CTMS) platforms. There is currently a lack of integration between site and sponsor systems due to the challenges associated with connecting hundreds of sponsor systems with thousands of clinical site systems.

- **Site Burden:** Sites face duplicate entry across RTSM and site supply management systems, e.g., Vestigo, manual reconciliation, and inconsistent barcode formats. Sites cannot support custom equipment for different sponsors and trials as they are an undue administrative burden with increased risk of errors.
- **Sponsor Challenges:** Sponsors struggle with missing accountability data, varied SOPs, and lack of standardization in reporting. The absence of a common language for product and site identification leads to inefficiencies and data silos.

The Proof-of-Concept

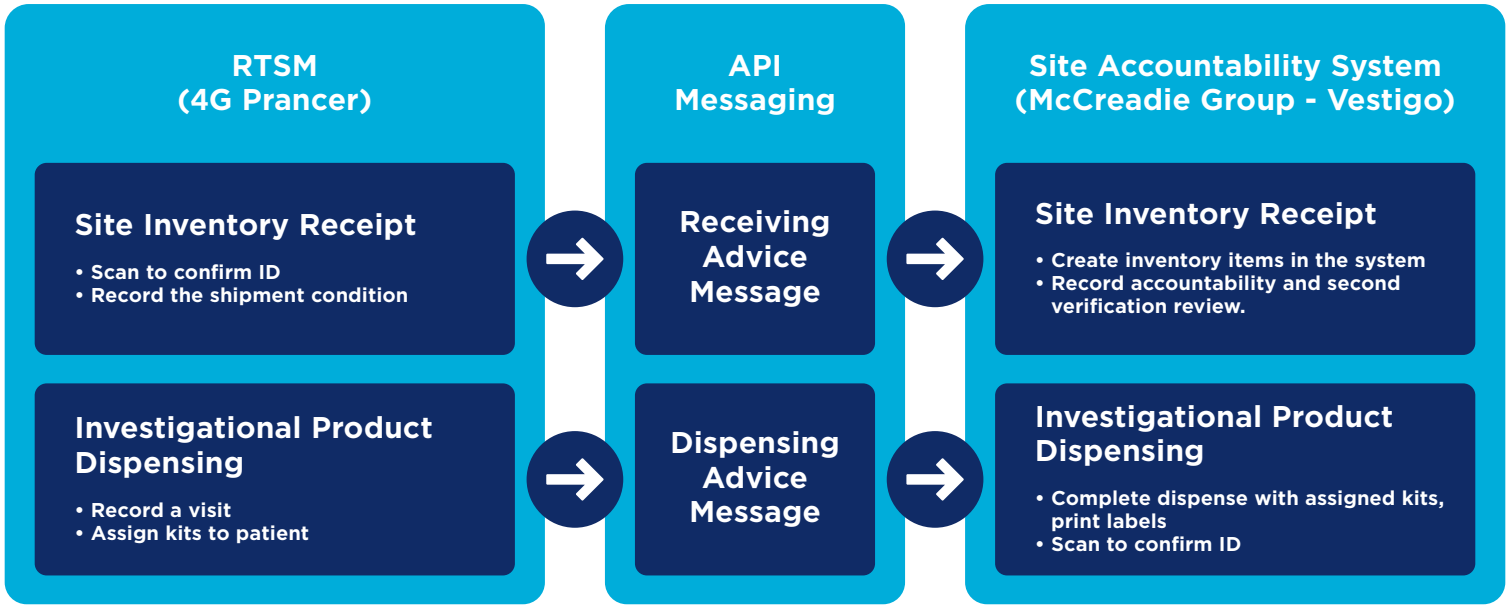

Figure 1

Project Scope and Objectives

The pilot linked Pfizer's sponsor operations, 4G Clinical's RTSM (Prancer), and McCreadie Group's Vestigo drug accountability system (Figure 1). The goal was to:

1. Standardize barcode scanning and data messaging across RTSM and Site systems.
2. Reduce manual data entry and duplicate effort at sites.
3. Enable real-time inventory tracking and accountability.
4. Demonstrate technical integration using GS1 EDI XML schemas.

Technical Implementation

- The GS1 Data Matrix barcodes and associated messages included Application Identifiers (AIs) for 01 (GTIN), 10 (Batch/Lot), 21 (Serial), and 7240 (Protocol), all encoded in the barcode and presented on-label as human-readable information (HRI).
- **Barcode Generation and Scanning:** GS1-compliant barcodes were generated at the sponsor level and applied to investigational product labeling. Sites used existing scanning equipment (e.g., Zebra scanners) to read these barcodes during inventory receipt and dispensing, validating GTIN, Lot, Serial, and Protocol Number.
- **GS1 EDI XML Messaging:** Two Vestigo API endpoints received GS1 EDI XML messages from 4G Clinical—one for shipment receipt and one for treatment visits. Messages used GS1's Receiving Advice and Dispensing Advice schemas.

  Note: No patient Personally Identifiable Information (PII) is exchanged between site systems and sponsor/RTSM platforms as part of the GS1 Clinical Trials workflow. The only patient-related identifier transmitted is the Patient Study Number, which is assigned by the sponsor or RTSM system for trial management purposes. This number does not contain any PII and is used solely for study tracking and kit allocation.
- **Barcode Parsing:** Web applications aren't designed to parse (extract from a text string) control characters in GS1 compliant barcodes, so application logic was updated to interpret these characters instead of relying on custom scanner configurations, which aren't practical for sites. The solution improves compatibility and scalability across locations. Site barcode scanners must support 2D imaging and read GS1 DataMatrix symbols.

Site Experience: Real-World Impact

Pharmacist / Pharmacy Staff

- **Role:** Responsible for receiving investigational inventory, verifying shipments, dispensing study medication, and maintaining accurate accountability records.

- **Workflow Impact** (Ref. Figure 1)**:**
  - When inventory arrives, the pharmacist accesses RTSM (Prancer), scans each barcode to confirm receipt, after which Vestigo displays the receiving advice message to finalize receipt, thus removing redundant entry steps. Using GS1 barcodes, each kit is scanned with the pharmacy's barcode scanner.
  - The Vestigo system automatically populates key fields (protocol, GTIN, lot, serial) from the scan, reducing manual data entry and minimizing transcription errors.
  - Exception flows upon receipt (e.g., damaged or lost kits) are handled within the RTSM, streamlining documentation and accountability into Vestigo. If a kit is damaged or lost, the system records this event, like how a warehouse logs damaged goods and updates inventory.
  - At the time of dispensing, the pharmacist completes and verifies the prescription in Vestigo, scans the kit barcode, and instantly validates that the dispensed kit matches the inventory record.
  - Each investigational product kit is assigned to a single patient and tracked from receipt through dispensing. Kits that are partially used (e.g., opened for dose rounding or split dosing) are not reallocated to another patient. Once a kit has been dispensed, any unused portion remains assigned to the original patient and is managed according to site SOPs for accountability and disposition (e.g., destruction, return, or quarantine if required).

Study Coordinator

- **Role:** Manages patient enrollment, randomization, and kit allocation in the RTSM.

- **Workflow Impact:**
  - The coordinator logs into the RTSM to randomize the patient and process a treatment visit to obtain kit allocation details.
  - The treatment allocation is transmitted to the pharmacy directly into a Vestigo queue using a REST API endpoint and XML Dispense Advice messaging, supporting seamless handoff and communication between coordinators and pharmacy staff; and supporting accuracy in identifying the kit to be dispensed.
  - The GS1 standard ensures that kit identifiers are consistent across systems, ensuring the correct kit is dispensed.

Non-Compliance Codes

List of Non-compliance Codes used in the PoC

01 - Lost

02 - Damaged

03 - Temperature Excursion

Tangible Benefits Realized

- **Efficiency:** Automated barcode scanning and data exchange reduce duplicate entry and manual reconciliation at both receipt and dispense.
- **Accuracy:** Real-time validation of kit details minimizes risk of dispensing errors and improves compliance.
- **Usability:** Familiar equipment and workflows are preserved—no need for custom hardware or retraining.
- **Accountability:** Exception flows for damaged or lost kits are integrated, supporting robust inventory management and regulatory documentation.

Key Findings

- **Technical Feasibility:** The pilot successfully demonstrated end-to-end integration—shipment receipt in Prancer, message transmission to Vestigo, and barcode validation within Vestigo at dispense. Real barcodes were printed and scanned using off-the-shelf equipment, confirming that site-friendly integration is possible without custom hardware.

- **Challenges Observed:** Schema mismatches, expiry dating is not available in the Receiving Advice standard, and inconsistent terminology prompted manual fixes and work arounds. Early alignment on field definitions and message formats is critical. Organizations leveraging the standard will need clear onboarding guides.

- **Site Equipment:** The pilot emphasized the importance of leveraging existing site scanning equipment and coding applications. Custom configurations (e.g., replacing FNC1 with a visible character) were dismissed as a scalable solution; instead, application logic was adapted to ensure compatibility.

Technical Issues and Solutions

Problem	Resolution
Missing ExpiryDate and Quantity in Receiving Advice	The team extended the Receiving Advice schema to include ExpiryDate and Quantity fields, ensuring sites received all necessary information for automated inventory addition. This information is available in the Dispatch Advice and consideration should be given to copying site inventory systems on the Dispatch Advice upon supply shipment.
No Published List of Non-Compliant Codes	The Receiving Advice message has a field for "Non-Compliance Codes" to communicate if the material is received in a condition that calls into question its usability. At the writing of this paper, a list of non-compliance codes for clinical supplies was not available. A pilot specific list of codes was created based on observed codes in test messages and direct communications with sponsors. This pilot team is working with GS1 and clinical supply discipline peers to assemble a list of non-compliance codes.
Misspelled XML Tags (<reasonOfNonCopliance>)	The misspelled tag was corrected to <reasonOfNonCompliance> in all outbound and inbound messages. Schema validation scripts were updated to flag similar issues early.
Schema vs. Message Naming are purposefully inconsistent (clinicalTrialReceivingAdvice vs. clinicalTrialsReceivingAdvice)	In this pilot, message generators and parsers were updated to match the XSD schema's naming (clinicalTrialsReceivingAdvice). Manual reconciliation was performed for legacy messages, and documentation was updated to reflect the pilot specific change. Pilot team has received further instruction from GS1 technical team to maintain naming convention specification based on GS1 messaging architecture.
Event Identifier Not Present in Dispensing Advice	This is not a current problem but a recommendation for future improvement. The team identified that including an event identifier (such as visit, cycle, or day of treatment) would help differentiate patient visits, especially in rapid succession. No workaround was implemented.
Document Status Code Requirements	Guidance was established internally to use ORIGINAL for initial transmissions and ADDITIONAL_TRANSMISSION for rebroadcasts or corrections, pending further clarification from GS1. GS1 provided to industry peers

GLN Management

GLN	GLN Type	Entity Name
0863772000001	Legal Entity	Pfizer Inc
0194108000021	Physical Location	Pfizer Inc (shipper address)
0194108000038	Legal Entity	Dr. Cherish Lallone Clinical Investigator
0194108000045	Physical Location	Dr. Lallone (Receiving Address)
0194108000052	Legal Entity	4G Clinical

Use of GLNs with a Pfizer company prefix is a workaround because sites should have their own GS1 registered company prefixes. Like the pilot, many real-world sites will not be GS1 members or the sites will be part of larger research institutions and not have or know their GLN.

At some point, this will become a barrier to widespread adoption of the GS1 EDI XML Clinical Trials standard. The pilot team asserts that the solution to this is the creation of a mechanism for the issuance of GLNs to smaller investigator centers and a GLN registry to allow ready access to site GLNs. Establishing a global or regional GLN repository would be instrumental in streamlining site identification, reducing manual effort, and supporting scalable adoption of GS1 standards.

Moving Forward Together: Establishing a Collaborative Steering Committee

To ensure successful adoption and continuous improvement of the GS1 Clinical Trials standard, the pilot team recommends forming a steering committee composed of:

- **Sponsors (pharmaceutical companies)**
- **RTSM vendors**
- **Site software providers**
- **Site representatives**

This committee will:

- **Encourage ownership and shared knowledge** across the supply chain.
- **Collect and review ideas and findings** from real-world implementations.
- **Make recommendations back to GS1** for standard updates and clarifications.
- **Share best practices and lessons** learned from successful projects.

By fostering collaboration and transparency, this group can address technical gaps, promote consistent adoption, and drive innovation in clinical trial data management.

Conclusion

The proof-of-concept project between Pfizer, 4G Clinical, and McCreadie Group demonstrates that GS1 Clinical Trials standards can be successfully implemented in real-world workflows. While technical and operational challenges remain, the pilot provides a roadmap for scalable, site-centric adoption. Standardization, collaboration, and leveraging existing site infrastructure are critical to realizing the full benefits of GS1 in clinical research.

Glossary and Appendices

- **Clinical Trial Site (or Research Site):** The location where a clinical trial is conducted.
- **Investigational products (IP):** the study drug or placebo.
- **Kits:** pre assembled packages labeled for use in the trial (often serialized—each kit has a unique identifier).
- **Randomization and Trial Supply Management (RTSM)** – Software provided by the Sponsor for a study and used by clinical trial sites to receive and enter data; also referred to as Interactive Response Technology (IRT) systems.
- **Site Drug Accountability software** – Software procured by a research site to manage Investigational product and the Investigational Drug Service across all protocols
- **Protocol Number** – The alphanumeric identifier assigned by the Sponsor to a clinical study.

Who is McCreadie Group and What is Vestigo®?

McCreadie Group is a trusted leader in pharmacy innovation, committed to advancing the pharmacy profession and clinical research through cutting-edge software solutions and expert consultative support. Founded in Ann Arbor, Michigan in 2004, our mission is to drive improvements in quality, efficiency, safety, and compliance for research sites and academic medical centers. They are committed to enhancing interoperability and monitoring capabilities within the clinical trial space, ensuring excellence and reliability in healthcare, education, and research worldwide.

Vestigo® is McCreadie Group's flagship platform for investigational drug management. Vestigo streamlines drug accountability, standardizes clinical trial workflows, and enhances compliance through digital solutions. Designed to integrate seamlessly with existing systems and workflows, Vestigo enables research pharmacies to manage site clinical trial supply and local investigator patient supply management.

McCreadie group is committed to innovation, reliability, and customer partnerships that empower research teams to focus on what matters most: enhancing patient safety, improving operational efficiency, and advancing clinical research.

Who is 4G Clinical and What is Prancer?

4G Clinical is an RTSM provider with Prancer as their flagship product. The Prancer RTSM is responsible for executing randomization, managing blinded supply and resupply to depots and sites, and most importantly, dispensing drug to patients. Our work doesn't stop at go-live. In fact, that is where it really begins.

4G mission is to **NEVER** mis-randomize, stock-out, mis-dose or compromise the blind.

Who is Pfizer?

Pfizer applies science and global resources to bring therapies to people that extend and significantly improve their lives. Pfizer strives to set the standard for quality, safety, and value in the discovery, development, and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments, and cures that challenge the most feared diseases of our time. For 175 years, Pfizer worked to make a difference for all that rely on its medicines.

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