



Clinical Trial Shipment Management

File Specification for RTSM E-Packing Slip

Summary

Clinical trial sites rely on investigational product (IP) accountability systems for safety, compliance, standardization of protocol and inventory management. These systems ensure meticulous tracking of investigational drugs throughout all points in the accountability cycle – from receipt through use by each participant. This minimizes errors, safeguards patients, and meets the strict requirements set by regulatory bodies.

Manually entering investigational product inventory data is a consistent pain point and complaint for clinical trial sites due to packing slips with limited information, and inaccuracies from repetitive data entry. This is time-consuming for staff and can lead to delays. Manual entry makes it difficult to track inventory levels in real-time, which can disrupt studies if there's insufficient or unusable product on hand.

This document provides a simple and standard file format that can be adopted by RTSM systems to provide sites with a downloadable file describing a shipment's context and IP inventory data. This file can be downloaded by users to aid in eliminating manual entry of items into subsequent systems such as McCreadie Group's Vestigo drug accountability software. Vestigo will provide a tool to intake this standardized file as part of the shipment receipt process and populate the contents of the shipment receipt for the user for review and confirmation.

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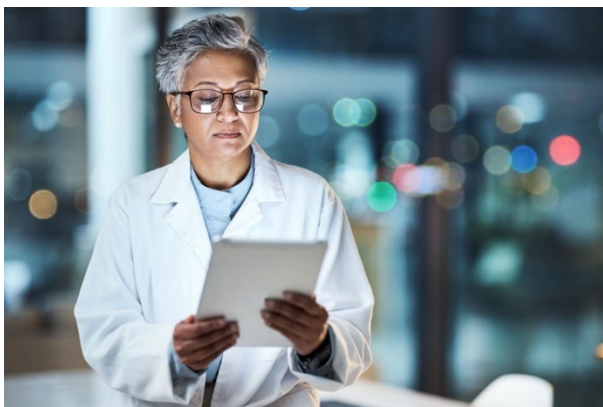
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This will reduce duplicate entry by increasing automation of the shipment receipt process, saving valuable time for site staff, maintaining consistent processes, and reducing risks of transcription errors in the accountability record.

The basis of this standard file format is a set of pre-defined fields that align with the GS1 clinical trials standard for data exchange of investigational drug information. This format recognizes that GS1 clinical trials standard is not yet widely adopted and thus maintains the intention of consistently defined fields across drug shipments. The format uses JSON rather than XML for faster data transfer, better adaptability for system integration and improved readability of end users. To ensure data integrity, there needs to be consistency between the definitions of fields between the RTSM and the drug accountability system used by the site, and those fields must be easily interpreted by an end user reading the file.

The benefits of supporting this standard are:

- Reduced duplication of data entry
- Improved data integrity and validation
- Consistent data format
- Reduction of protocol deviations
- Reduced time with study monitors
- Minimal training to use
- Increased site satisfaction



File Specifications

The basis of this project is the provision of a standard data file to users within an RTSM system upon dispatch of an investigational drug shipment to a clinical research site. The file will be downloaded by the user when receiving a shipment in the RTSM system.

All timestamps used in this specification follow an ISO format of YYYY-MM-DDTHH:MM:SS with data being sent in the UTC time zone.

A standard file naming convention that clearly identifies the Sponsor, Sponsor Protocol Number, Site Number, and Shipment Number is highly recommended. For example: SponsorABC_ABC-00200_0201_Shipment0132.json

Shipment General Data

Each message must contain a General Data segment to uniquely identify the message, sponsor, and protocol.

Field	Purpose	Requirement	Data Type
MessageID	Identifies the download of the shipment receipt. If the site downloads the file twice, the MessageID will be different.	Required	Unique GUID
Sponsor Name	The Sponsor's name. This ensures data integrity when loading files and can be displayed in the application for visual confirmation.	Required	NVarchar(500)
SponsorProtocolNumber	The Sponsor's protocol number for the study. This ensures data integrity when loading files and can be displayed in the application for visual confirmation.	Required	NVarchar(100)

Shipment Dispatch Data

Field	Purpose	Requirement	Data Type
SiteNumber	The assigned site number for the protocol at the study site.	Required	NVarchar(50)
SiteName	The site name associated with the site number. This is used to visually ensure the message is associated with the correct site.	Optional, but useful for quality control	NVarchar(300)
ShipmentNumber	An internal Shipment Number/packing slip number identifying the shipment.	Optional, but highly recommended for quality control and reduction in manual entry	NVarchar(200)
ShipmentTracking	The tracking number from the transportation provider associated with the shipment. This should be formatted with Tracking Number and Vendor separated by a pipe (1Z12345 UPS) Ex: AWB Airway Bill Number	Optional	NVarchar(200)

ShipmentDepotName	The depot information where the dispatch originated.	Optional	NVarchar(200)
ShipmentDispatchDate	The date the shipment was dispatched to the site.	Optional	DateTime

Kit Number Manifest

Field	Purpose	Requirement	Data Type
DrugID	An optional unique identifier of the drug for the RTSM. This allows a drug to be uniquely identified and aligned with how the inventory will be stored and tracked.	Optional	NVarchar(200)
DrugDescription	The human-readable drug description. For blinded studies, ex: "Treatment Bottles" For open-label, full description of drug and strength.	Required	NVarchar(100)
UnitofMeasure	The RTSM's designated unit of measure for shipment. Example: Bottles, Tablets, Kits	Optional	NVarchar(50)
ItemQuantity	The quantity of items affected by the transaction.	Required	Numeric
LotNumber	The Lot Number of the inventory	Required	NVarchar(50)
KitNumber	The Kit Number/Item Number of the inventory	Optional, as inventory may not be kit-specific	NVarchar(30)
ExpirationDate	The expiration date of the inventory	Required	DateTime
StorageConditions	The storage conditions for how the drug should be stored.	Optional	NVarchar(200)

Sample Message

The message below illustrates a shipment sent to Site Number 1001 containing two items of drug "Apple 50mg." A total of 2 kits (items 123A and 456A) of Lot BLN1, expiring December 31, 2026, were received.

```
{
  "shipmentDispatchEvent": {
    "generalData": {
      "messageId": "CEA17F1C-B9CD-4908-8B66-952A049BB080",
      "sponsorName": "SponsorABC",
      "sponsorProtocolNumber": "ABC-00200"
    },
    "shipmentDispatchData": {
      "siteNumber": "1001",
      "siteName": "Site Name",
      "shipmentNumber": "0120003400258",
      "shipmentTracking": "XT2234 | UPS",
      "shipmentDepotName": "Depot Name",
      "shipmentDispatchDate": "2024-05-20T00:00:00.000Z",
      "kitNumberManifest": {
        "kitData": [
          {
            "drugID": "123456",
            "drugDescription": "APPLE 50mg",
            "unitofMeasure": "KIT",
            "itemQuantity": 1,
            "lotNumber": "BLN1",
            "kitNumber": "123A",
            "storageConditions": "Ambient",
            "expirationDate": "2026-12-31T00:00:00.000Z"
          },
          {
            "drugID": "123456",
            "drugDescription": "APPLE",
            "unitofMeasure": "KIT",
            "itemQuantity": 1,
            "lotNumber": "BLN1",
            "kitNumber": "456A",
            "storageConditions": "Ambient",
            "expirationDate": "2026-12-31T00:00:00.000Z"
          }
        ]
      }
    }
  }
}
```

