



Automated Sample Retention Solution

Problem:

Bioavailability and Bioequivalence (BA/BE) studies require samples of the investigational product retained. Typically, this is performed manually and overseen by clinical monitors during the site initiation. This manual approach is feasible for a limited number of sites. However, for studies with a large number of sites, the manual retention becomes less feasible, as it requires additional monitoring visits and physical presence of study personnel.

In traditional manual BA/BE retention, there is no system audit trail generated, as this retention and review action occurs outside the system.

Additionally complicating the traditional scenario, this manual retention step must be re-executed upon re-shipment of additional quantities of Investigational Product (IP). In the traditional BA/BE retention plan, these resupply site shipments would necessitate additional corresponding monitor site visits.

It should also be noted that when pursuing traditional manual retention workflows, the initial shipments must be timed with upcoming monitoring visits. For large BA/BE studies, coordination of clinical monitoring staff, site, and depots to time clinical monitor presence requires very careful planning and diligence. In a traditional manual retention workflow, failure to time these site visits in conjunction with IP arrival can result in unnecessary risks to patient enrollment and generate other delays.

Finally, BA/BE manual retention requires the on-site reviewer to have awareness of the IP treatment types selected for retention, essentially requiring the clinical monitor be unblinded to the treatment.

In a recent study, Pharm-Olam conducted a BA/BE trial that had over 50 active sites with 800 subjects. For a study of this size, traditional manual retention practices are not cost effective and incur significant risks of delays.

Benefits of Alternative Solutions:

Pharm-Olam recognized that the Inventory Management system could be used to guide the site personnel to retain the kits in a blinded and controlled fashion.

By utilizing the capabilities of the system, and working with the Electronic Data Capture (EDC) vendor to customize additional integrated Inventory Management (IM) functionality, Pharm-Olam and its customer could save a significant amount of time and resources. This would also result in strengthening the blind of the study, and allowing for the custody and status of the retained IP to be captured within the system's audit trail.

Solution:

Pharm-Olam currently uses a traditional web based EDC system that includes Interactive Web Response and Inventory Management (IWR/IM) functionality embedded in the product. This system did not innately possess the functionality required to signal to the site staff what items to retain, nor did it possess the ability to signal to the reviewer which items to cross-reference.

Working with the EDC vendor, Pharm-Olam Data Management and Data System’s personnel devised a solution that allows the retention personnel at the site to pick from a random list of codes.

Requisition ID S0146

Required Fields*

Please select two items from each of the following groups:

☐ i76NzD

☐ BTdA17

☐ Onw9mZ

☐ EgP0BF

☐ HvqJvw

☐ J2aOoV

☐ gxFMjY

☐ QKYTEt

☐ zY1c4o

☐ XkgWOM

☐ Jnpcfl

☐ EoSVsb

☐ OiKq06

☐ katYz4

☐ y11qle

Submit

Back

These codes are subsequently linked to bottles from the three different treatment groups. The system guides the user to select a quantity from each treatment type (in this case two bottles) for retention, but does so in a manner that obscures the bottle number and random code from the treatment type category.

Once the user selects the six random codes (two from each of the three treatment types) the system directs the user to preserve six bottles.

The shipment has been confirmed as being received. Please retain the following containers (do not dispense to subjects):

9915

9902

9918

9905

9908

9887

OK

The system preserves the confirmation screen above in a listing which can be viewed at any time by site personnel and site CRA's.

Shipment Confirmed On:

11-Nov-2014 17:28:02

by: Renner, Benjamin

9918

9902

9915

9908

9887

9905

This relationship between the random codes and the bottle numbers is also preserved in an audit trail, which is obscured from blinded personnel, and allows subsequent reviews by unblinded Data Systems.

Kit Label	Random Label	Selected
9918	HvqJvw	Yes
9916	EgP0BF	
9902	XkgWOM	Yes
9890	OiKq06	
9909	katYz4	
9915	gxFMjY	Yes
9908	Onw9mZ	Yes
9892	EoSVsb	
9893	BTdA17	
9889	J2aOoV	
9906	zY1c4o	
9887	y11qle	Yes
9894	QKYTEt	
9888	i76nzD	
9905	Jnpcfl	Yes

While the process outlined above allows for an organized, blinded retention, Pharm-Olam recognized the need to allow for oversight. Additionally, the interactions above resulted in a lot of instructional information concerning the retention to the data entry operator at the site; instructions that would be useful for a site pharmacist.

As a work-around, Pharm-Olam devised a special email to be distributed that contained a blinded list of the kit numbers, the retention sample selection codes (with the selection highlighted) and subsequent retained kits.

This email allowed for:

- The site, clinical team, and project team to be signaled that a retention action has occurred
- Direct QC staff to the relevant inventory that has been retained
- Provide site staff with a succinct message to provide directly to site pharmacists

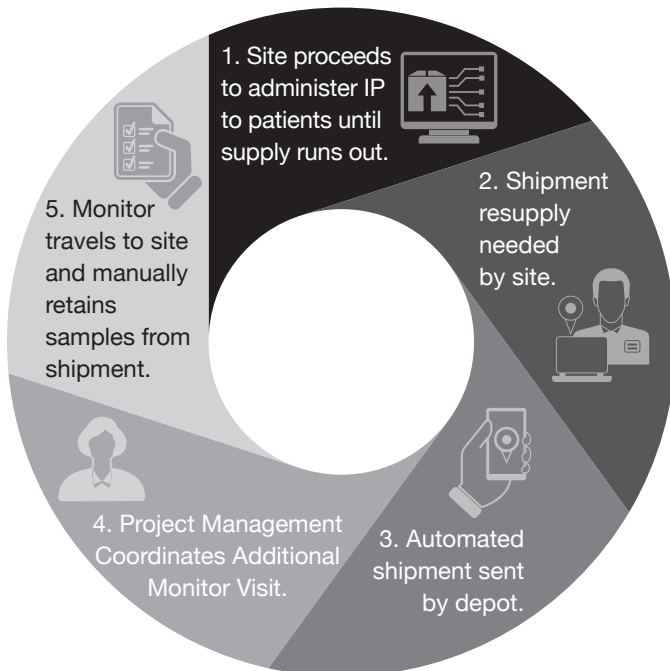


Figure 1: Traditional Workflow

Requires additional monitor travel, unblinding site monitor, additional project management oversight, and does not allow for a system audit trail.

Results:

The net result of the implementation of this solution resulted in an improved, less resource-intensive workflow (see flow charts below).

Factoring initial and re-supply monitoring visits needed in a typical 50-site study, implementing an automated retention plan has relieved the study of the need for over 70 unnecessary monitoring visits, saving considerable resources.

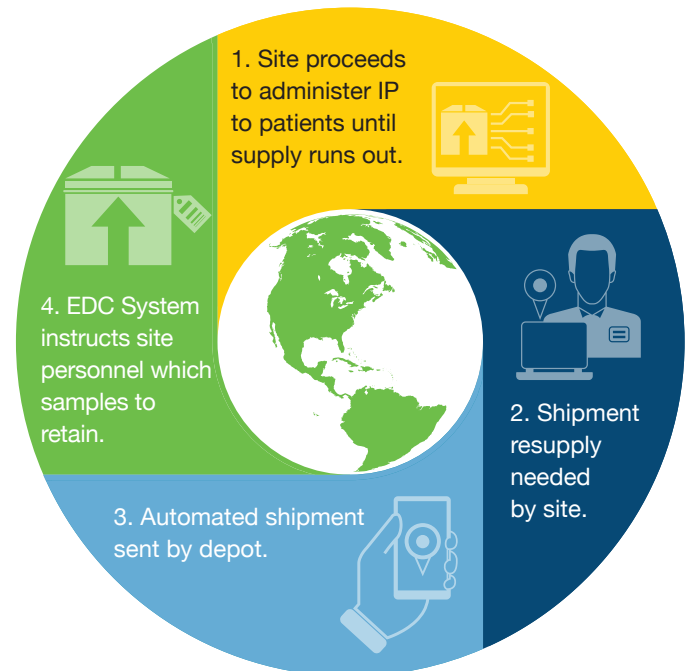


Figure 2: Automated Workflow

Pharm-Olam's solution relieves the need for unneeded additional monitor travel, allows the monitor to remain blinded to treatment, and allows for a system audit trail.

To learn more about how Pharm-Olam Data Management solutions can help your study, please visit www.pharm-olam.com.



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