

Methods for Deploying eSignatures in Trip Reporting and Clinical Supply Management for CTMS



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Acknowledgements

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- ❑ Thanks to the OCUG Planning and Review Committee and Siebel Clinical CTMS Focus Group Chairs for their patience in receiving and reviewing this presentation



Business Case for E-Signatures

- ❑ CTMS is first and foremost a management and tracking tool
- ❑ Identify data and processes with regulatory impact
- ❑ Is CTMS the “System of Record” ?



The Moment of Truth

- ❑ Select **business process**
 - ❑ Trip Reports
 - ❑ Decision Points (e.g. Remove Subject)
 - ❑ Site Communication Package

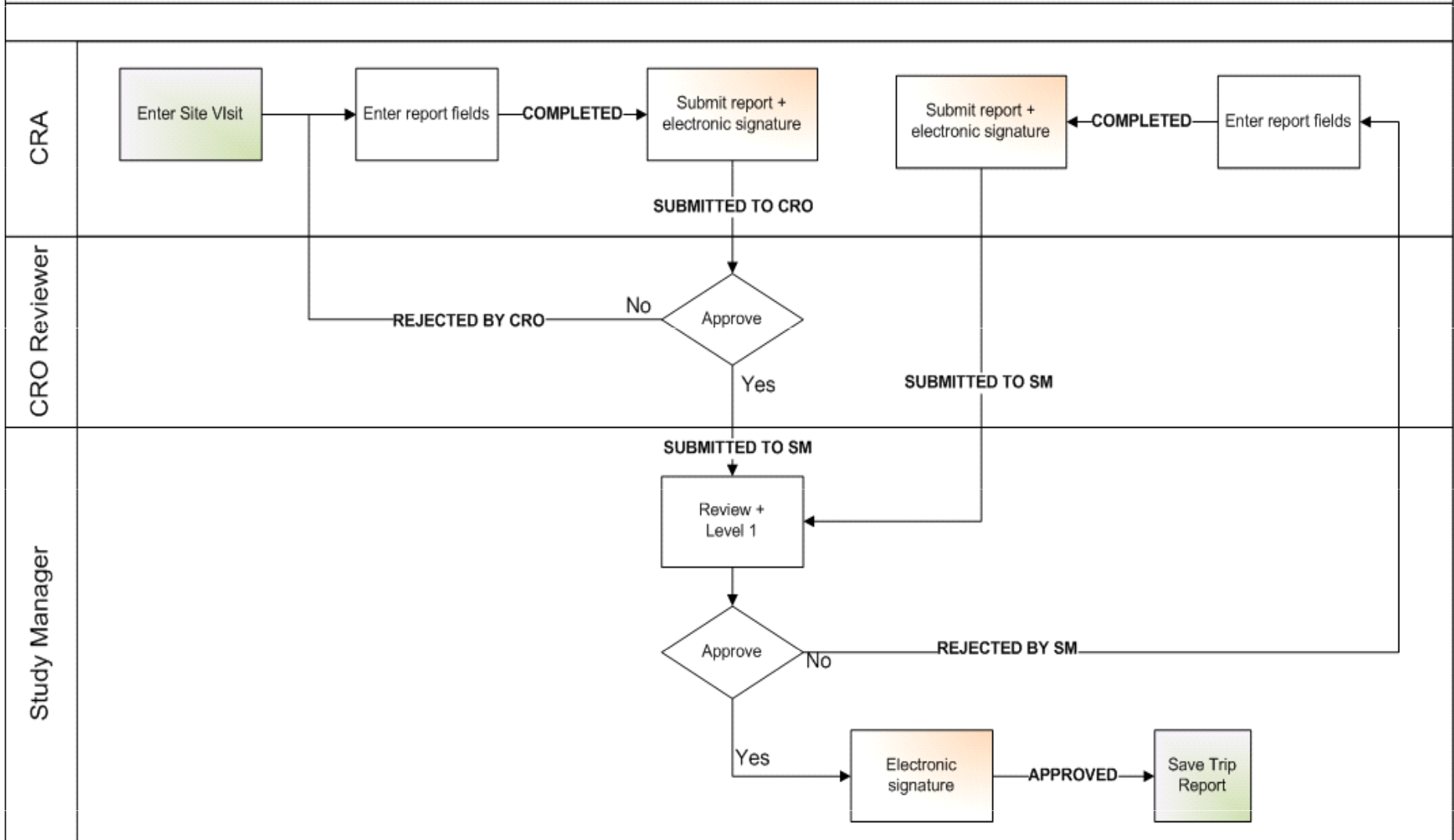
- ❑ Select an **approach**
 - ❑ Typewriter Rule vs.
Electronic Record / Electronic Signature



Scenario for E-Signatures

- ❑ Trip Report Approval Workflow:
 - ❑ CRA to sign on submitting
 - ❑ Study Manager to sign on approval

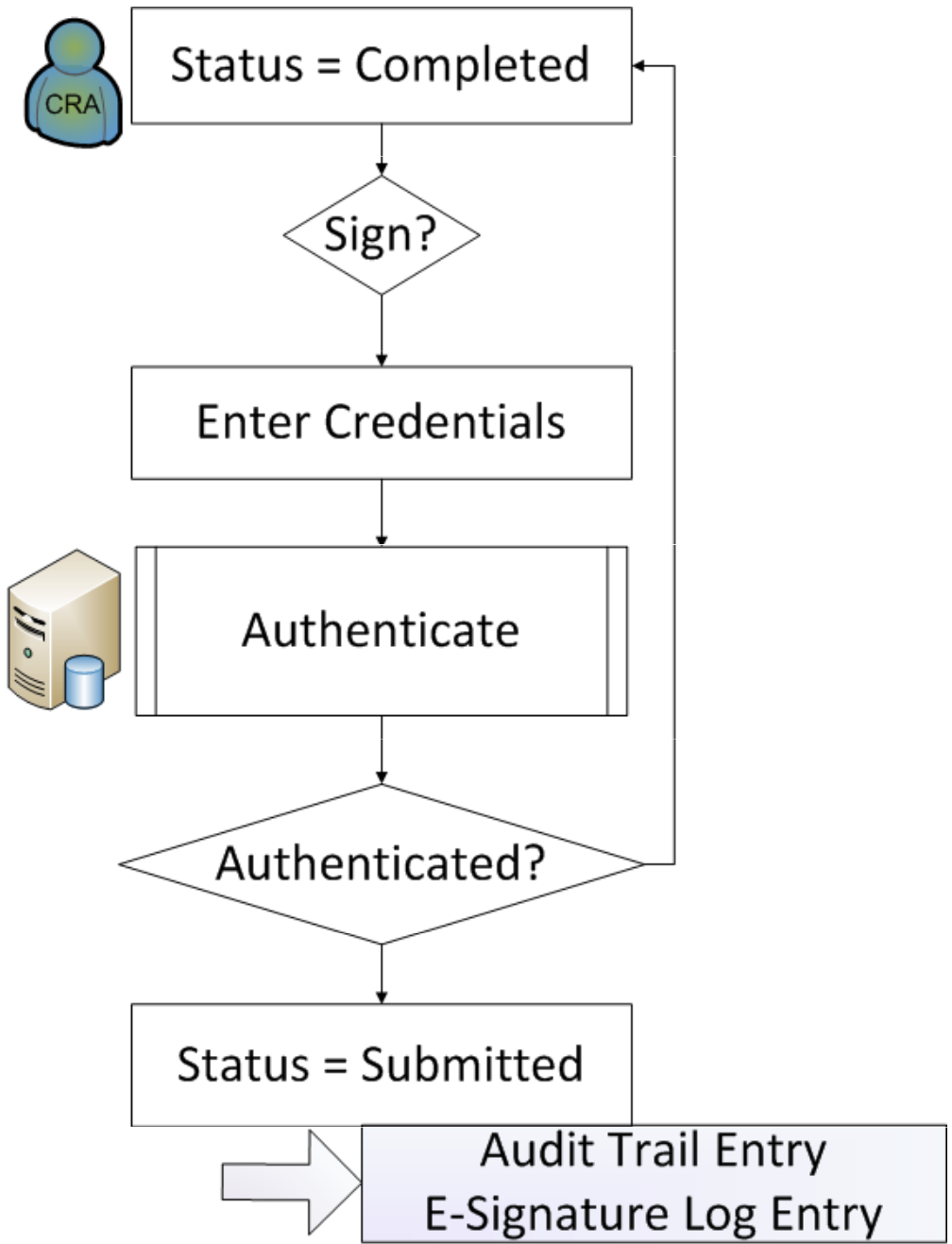
Trip Report Workflow

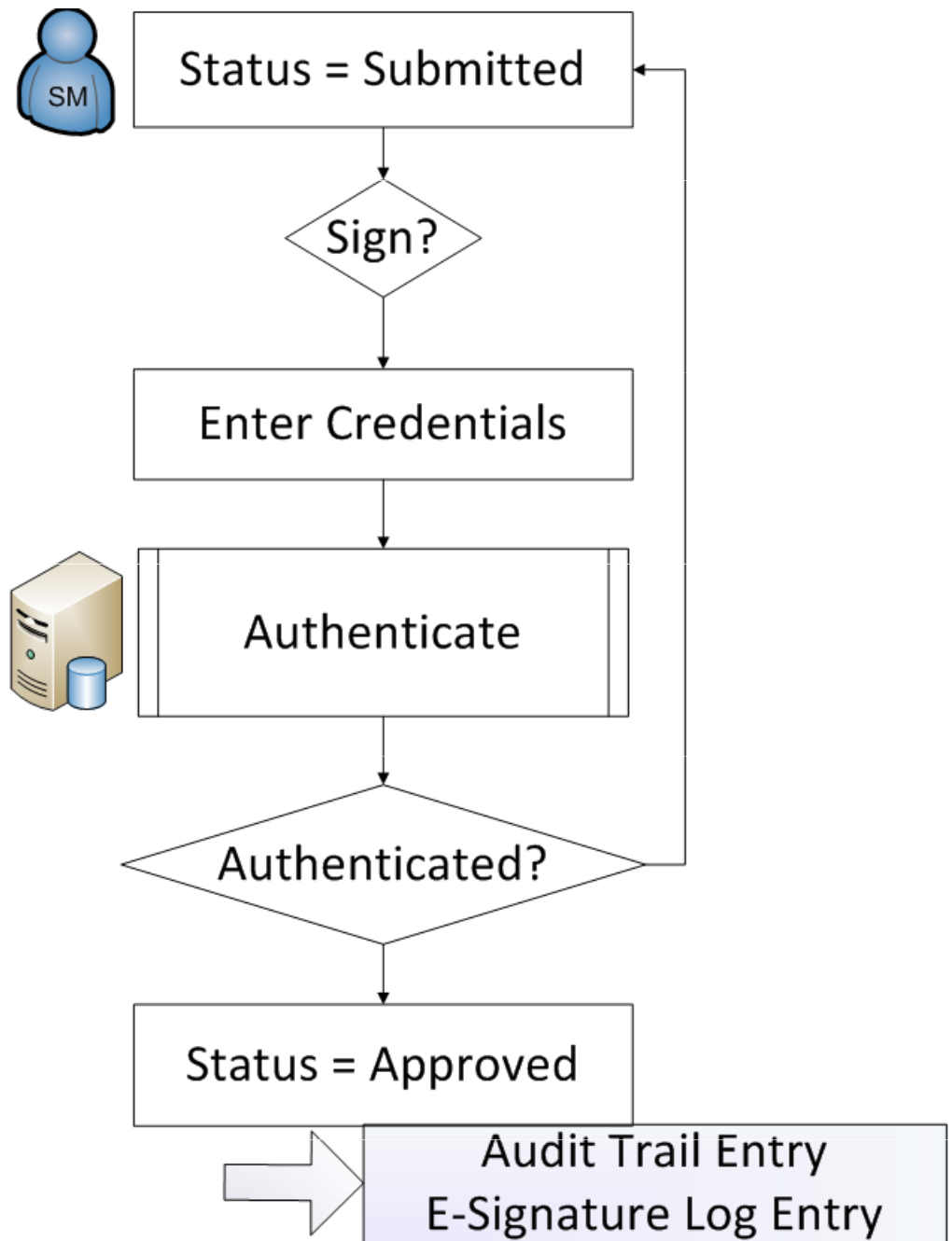




Authentication

- ❑ Components of e-signature per 21 CFR Part 11
- ❑ Authenticate user
- ❑ Siebel authentication context





File Edit View Navigate Query Tools Help

Site:Site # 1 > Site Visit:

Home Contacts Accounts Calendar Activities Site Management Record Of Initiation

Protocol Site List | Charts

Trip Report

Menu | New Delete eSign & Approve Query

Protocol: * Protocol # 1 Visit Name: * Site Visit Demo Attendees: DEVUSER2 Protocol Title: Protocol # 1

Account: Account 1 Visit Type: * Site Initiation Template: Trip Report Status: Submitted

Start: 5/1/2009 12:19:37 F PI Last Name: DEVUSER2 Comments: Trip Report Completed: 5/1/2009

Completed: 5/2/2009 Manager Comments:

Visit Status: * Done

More Info | Activities

Current Trip Follow-Up Items

Menu | New Query

Activity	Activity	Signed To	Created By

eSignature - Microsoft Internet Explorer

eSignature

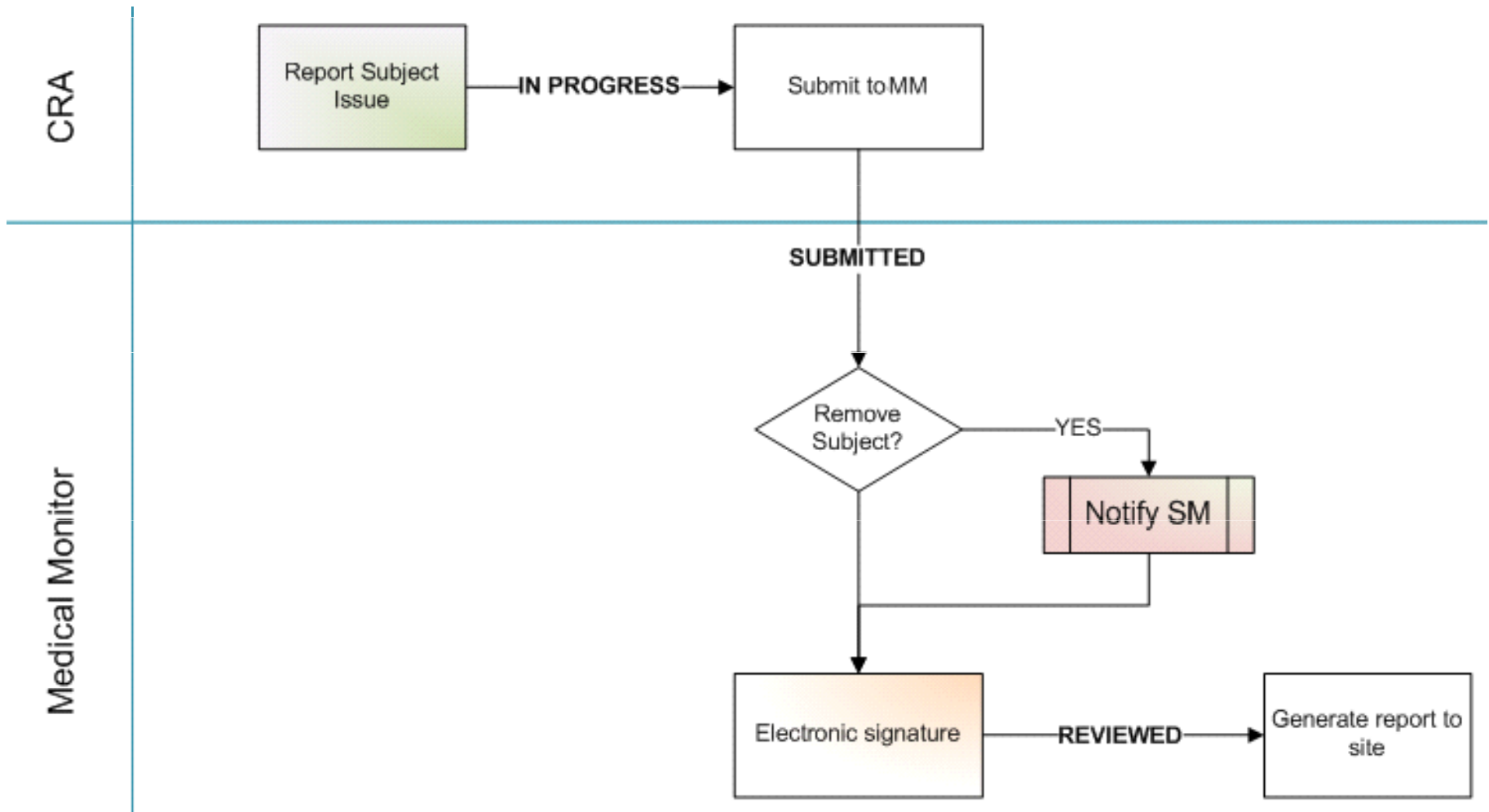
Last Name: * DEVUSER2

First Name: * DEVUSER2

Login Name: * DEVUSER2

Password:

Submit Cancel





Audit Trail

- ❑ What data is audit trailed
- ❑ Components of audit trail per 21 CFR Part 11

10	5.1.2 Clinical Study Agreement between Principal Investigator/Site/Institution
11	5.2 Sponsor Documents
12	5.2.1 IRB approved Protocol and Amendments. (Comment on Version date and IRB approval date)
> 13	5.2.2 Investigator's Brochure (IB) and Amendments. (Comment on version and issue date of brochure)

Audit Trail Changes | Menu ▾ | Query

	Employee Login	Operation	Old Value	New Value	Date ▾
>	SM		No	Yes	7/9/2009 06:52:06 PM
	SM	Modify		No	7/9/2009 06:51:52 PM

Signature Log

- ❑ Record all signature events, name, date, values
- ❑ Audit Trail for signature data (metadata)

Attendees: Trip Report Status:

Site # - PI Name:

[More Info](#) | [Activities](#) | [Deviations](#) | [Communications](#) | [Activity Plans](#) | [Attachments](#) | [Calendar](#) | [Cc](#)

[Trip Report](#) | **[eSign Log](#)** | [Current Trip Follow-Up Items](#) | [All Follow-Up Items](#)

|

Employee Login	Operation	Old Value	New Value	Date
> CRA	Modify	Submitted SM	Approved	5/20/2009 07:42:04 AM
CRA	Modify	Completed For PR	Submitted PR	5/20/2009 07:41:42 AM
DEVUSER2	Modify	Completed For SM	Submitted SM	5/18/2009 07:28:37 AM
DEVUSER2	Modify	Completed For PR	Submitted PR	5/18/2009 07:28:30 AM



Part II: Supply Management



Supply Management Scenarios

- ❑ Business processes incorporated into CTMS
- ❑ IP distribution and tracking
- ❑ Managing product availability (warehouse inventory)
- ❑ Managing site inventory
- ❑ IVRS/IWRS interface



Serialized Asset Model

- ❑ Use Product–Asset hierarchy already in Siebel
- ❑ Kit-level control at depot and site
- ❑ Evaluate ROI (Return on Investment)
- ❑ Next steps (progress towards tracking solution?)

Serialized Asset Model

- ❑ Leverage Product>Asset Hierarchy

The screenshot shows a web application interface with two main sections. The top section is titled 'Products' and contains a table with the following data:

Name	Part #	Type	Description
> Bottles	Bottles	Product	

The bottom section is titled 'All Assets' and contains a table with the following data:

Asset #	Serial #	Type	Serialized	Product	Batch Number	Expiry Date
> 1-922514						
1-576947	#123	Product	✓	Bottles		2/4/2009
1-588570	1-588570	Product	✓	Bottles		8/21/2015
1-588702	1-588702	Product	✓	Bottles		8/17/2010

A blue arrow points from the 'Bottles' product in the top table to the 'Serialized' column header in the bottom table. A red box highlights the 'Serialized' column header.

Transaction Records

Inventory Transactions:

Home | Contacts | Accounts | Calendar | Activities | Investigators | Assets | Administration - Product | Supplies Management

Transaction #	Source Location	Destination Location	Transaction Date	Type	Product	Part #	Qty	Expiry Date	Batch Number
1-638185	Location	External Location	2/3/2009 11:50:03	De-Allocate	BOX	BOX	10	2/10/2009	22
1-638191	Location	External Location	2/3/2009 11:51:38	De-Allocate	BOX	BOX	10	2/27/2009	44
1-638197	Inventory	External Location	2/3/2009 11:53:04	De-Allocate	BOX	BOX	10	2/27/2009	44
1-336193	External Location	Inventory	1/8/2009 05:17:57	Receive Other	Bottles	Bottles	80		
> 1-588552	External Location	Location	1/29/2009 01:15:47	Ship Internal	Bottles	Bottles	1		
1-588565	Location	Location	1/29/2009 01:16:56	Ship Internal	Bottles	Bottles	1		
1-588584	External Location	Location	1/29/2009 01:19:05	Ship Internal	Bottles	Bottles	1		

1-588552

Menu | New | Delete | Cancel | Query

Inventory Transaction

Type: * Ship Internal
 Organization: Default Organization
 Product: * Bottles
 Part #: Bottles
 Qty: * 1
 Serialized:
 Commit:
 Transaction Date/Time: 1/29/2009 01:15:47
 Comments:

Source & Destination

Source Location: * External Location
 Source Availability: * On Hand
 Source Status: * Good
 Destination Location: * Location
 Destination Availability: * On Hand
 Destination Status: * Good

Picked And Shipped By

Name:
 Date:

Inspected By

Name:
 Date:

Transaction Detail

1-588584

Menu | New Delete Cancel Query

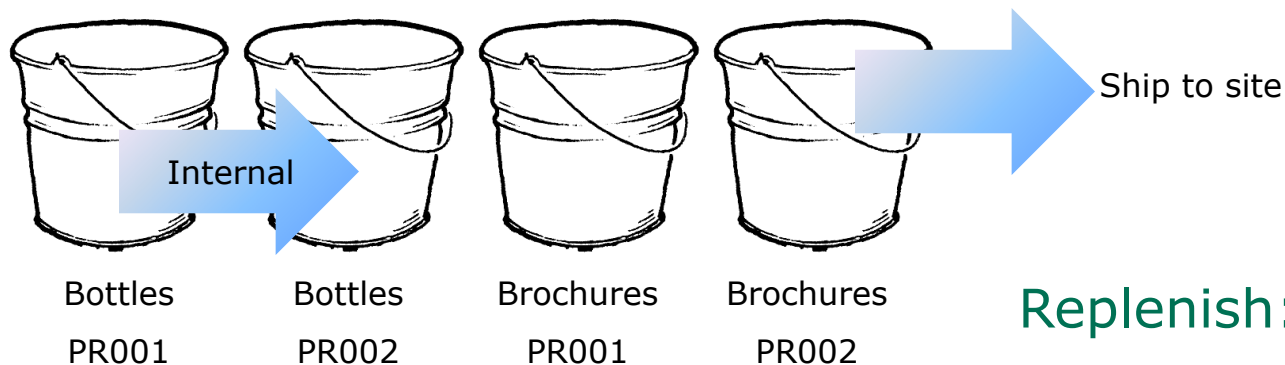
Inventory Transaction		Source & Destination	
Type: * Ship Internal	Organization: Default Organization	Source Location: * External Location	
Product: * Bottles	Part #: Bottles	Source Availability: * On Hand	
Qty: * 1	Serialized: <input checked="" type="checkbox"/>	Source Status: * Good	
Commit: <input checked="" type="checkbox"/>	Transaction Date/Time: 1/29/2009 01:19:05	Destination Location: * Location	
Comments:		Destination Availability: * On Hand	
		Destination Status: * Good	

Reference			
Order ID:	Repair ID:	Transaction #:	1-588584
	Activity ID:	Cycle Count ID:	

Asset		
Menu New Delete Query		
Asset #	Serial #	Asset Description
> 1-588570	1-588570	

Batch Accounting

- ❑ No serializing: keep track of batch -> product
- ❑ Manage available inventory for each protocol
- ❑ Replenish, ship, and re-allocate transactions



Replenish: pour into bucket
 Batch expiry: spill bucket

Managing Inventory at Site

- ❑ Example: When to deliver CRFs to sites, and how much
- ❑ Objective: send small amount each time, in keeping with newly enrolled subjects



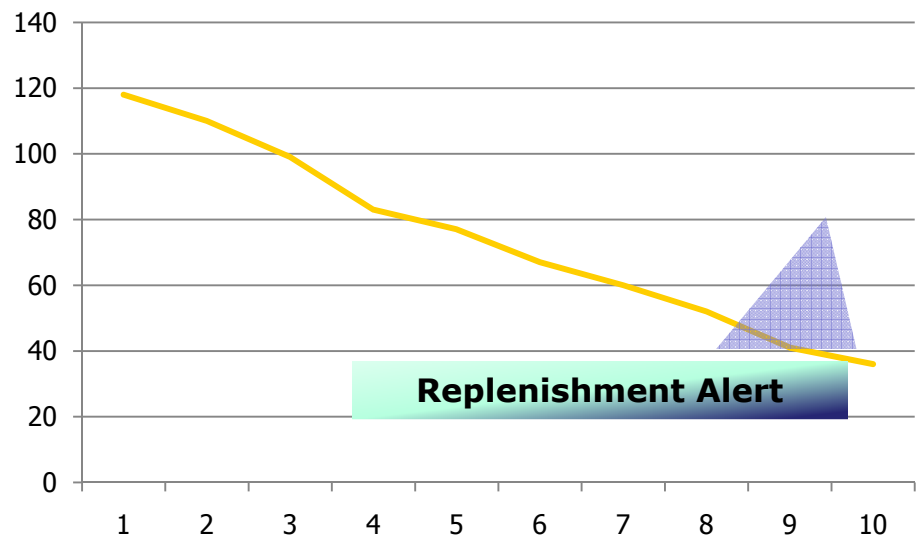
Depletion and Replenishment

- Also: model ancillary products consumption

Formula:

$$\text{Inventory (N+1)} = \text{Inventory(N)} + \text{Supply(N)} - \text{SubjectsActive(N)} \times \text{PerSubjectRate}$$

Replenish at pre-defined amount





Case Study

- ❑ Batch Accounting Scenario
- ❑ Shipment Authorization to trigger shipment by third party
- ❑ Shipment Authorization to trigger update of inventory per protocol
- ❑ E-Signature for the Shipment Authorization



Shipment Authorization Record

Shipment Authorization | Menu ▾ | New Delete Query eSign & Approve Query Results

Form ID	Form Date	Site ID	Protocol	Account	Last Name	First Name	Status
> 1-8KGR	6/24/2009 05:36:44	161- Paulina P	PR02-1		Peron	Paulina	Approved

- ❑ System record to issue report (authorization)
- ❑ Note the “Approved” status
- ❑ Subtract shipped amount from relevant Protocol-Product-Batch combo bucket



Shipment Authorization Record

To: Associated Shippers of Mississauga

Attn: KEMAL ILGAZ

Ship the below products to:

Maria de Fatima Hospital
 22225 Dundas St. West
 Toronto, M3M3M5 ON, Canada

Contact:

Joaquim Furtado
 (416) 555 0977
jfurtado@mdfh.on.ca

Product	Batch	Quantity	Unit	Kit #	Rcp Ack
Cotton Balls	MCB01	2	Kit	1801, 1802	<input type="checkbox"/>
Momyx Moisturizer	MCMM33	6	Box		<input type="checkbox"/>
Momyx Formula Box	MMFB21	4	Kit	2104, 2105, 2106, 2107	<input type="checkbox"/>
Cat-AADD Brochure	AADD1	24	Brochure		<input type="checkbox"/>

ELECTRONICALLY SIGNED BY:

Beatrix Knopf, Director of Clinical Supplies, 15/SEP/2008 15:08:23 EDT

UserID: ROP RowID: F-4476229 Timestamp: 15/SEP/2008 19:08:23 GMT



Question and Answers

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Biography

Alex Platkin, Senior OLS/RDC/CTMS Global Deployment Specialist, DBMS Consulting, Inc.

- Alex is a Senior OLS/RDC/CTMS Global Deployment Specialist DBMS Consulting, with several years of Siebel business analysis and deployment experience.

Jason Essig, Senior Siebel Architect Expert, DBMS Consulting, Inc.

- Jason is a Senior Siebel Architect Expert for DBMS Consulting, with 10+ years of Siebel configuration and architecture experience.