

# Managing Research Compliance Utilizing an Electronic Compliance Database System

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## Disclosure

- I have no financial relationships to disclose
- The electronic compliance manager tool I will be highlighting was developed by the Department of Pharmacy Services for Intermountain Healthcare, Inc., and is a copyright of Intermountain Healthcare, Inc.
  - Electronic database is currently active in use for pharmacy compliance
  - Conceptually applicable to the research setting... medication research in proposal
  - Presentation is to highlight conceptually how an electronic compliance manager can be used in a research compliance environment.

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## Why is compliance so important to research?

- Protect and provide safety
  - Public / Patient Safety
  - Investigator Safety
    - Ex., drug study involving hazardous medication
    - Standing as a reputable investigator
  - Protect the data
    - Integrity of the study
    - Increases the impact of the research outcome
- Regulatory
  - Controlled substances
  - Government and regulatory oversight (FDA, JC, HHS, etc.)
- Cost control

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## Common Reasons for Research Non-Compliance

- Pre-study Related
  - Failure to conduct complete literature research, prior literature reports
  - Failure to have a detailed, written and vetted protocol
    - sample size analysis
    - statistical assumptions to be made
    - identify limitations of measurement methods
    - identify adequate bias control measures
    - failure to determine and write a detailed time line
- IRB Approval
  - Adherence to responsibilities as clinical investigator
  - No approval obtained, lapse in IRB, no continuing review
- Study Related
  - Informed Consent (improper/outdated consent)
  - Protocol Deviations / Violations (changes made with no approval)
  - Drug and Device Accountability (record keeping inadequate)
  - Inadequate Medical Records (trial data not recorded (e.g., adverse events))

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## Compliance in Research: It's About Coordination

- Manual Oversight
  - Costly
  - Time consuming
  - Accuracy lower
    - data collection errors
    - competency of staff
    - study integrity harder to control
  - Bulky
    - paperwork and amount of filing
    - ability to retrieve more difficult
- Electronic Oversight
  - Less costly
  - Increased efficiency
    - Real time
  - Compliance assessment and controls improved

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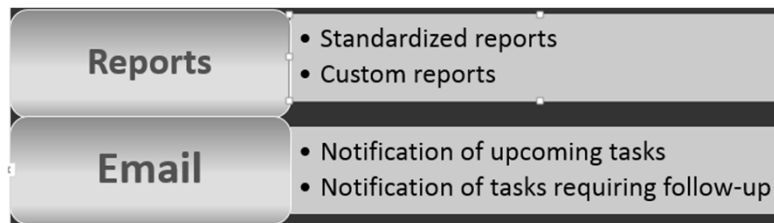
## RxCM: Electronic Compliance Manager

- Stores Documents associated with task completion and documents compliance.
  - Attachments can be added to each task for documentation, retrieval, verification
  - Demonstrate compliance with internal policies as well as State/Federal laws
- Dashboard function provides timeline alerts for task completion
  - Organizes workflow daily/weekly/monthly for staff
- Provides both corporate/local levels a method for managing compliance
  - Status assessment in real time
  - Ensures completion of required job functions for category compliance
- Provides validation tool for compliance audits/inspections.
  - Internal (Internal Process Control, Corporate Compliance, Internal Quality)
  - External (State DOPL, DEA, FDA, JC, etc.)

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## RxCM: Electronic Compliance Manager

- RxCM Functionality



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## RxCM: Electronic Compliance Manager

- Maintains Task Lists by category to complete/perform in compliance with the required category
  - Corporate Assigned Tasks
    - Controls/organizes compliance for categories of focus system wide
  - Local Pharmacy Assigned Tasks (created by the pharmacy)
    - Controls/organizes workflow for task completion by staff
- Organizes required categories of compliance in the workplace
  - Controlled Substances
  - Compounding USP 797/795
  - Pharmacy Licensing
  - 340B
  - Utah State DOPL Readiness
  - Medication Management (JC)
  - Medication Research ?
    - In 2017, 640 medication research studies**

Task List

Pharmacy IPC Testing From 12/09/2014 To

Assigned To All Pharmacy Tasks Not Complete Completed All Tasks

Category Controlled Substance Monitoring Frequency All Frequencies

Search Rows 15

Category	Status	Title
Controlled Substance Monitoring	OVERDUE	Check Manual Issues from NarcStation (present on patient care units)
	Due Today	Check Manual Issues from NarcStation (present on patient care units)
	Due Today	Controlled Substances Inventory Returned from Will-Call Area to Inventory Stock
	Due Today	For CII's returned to stock, verify that a paper inventory log sheets are updated
	Due Soon	Expired or Recalled Controlled Substances

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## Medication Research

- Next Steps for Pharmacy Compliance → Medication Research Compliance
- Food and Drug Administration Good Clinical Practice Guidelines state:
  - 4.6** Investigational Product(s)
  - 4.6.1** Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.
  - 4.6.2** Where allowed/required, the investigator/institution **may/should assign some or all of the investigator's/institution's duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist** or another appropriate individual who is under the supervision of the investigator/institution.
- The Joint Commission Medication Management Standard : MM.06.01.05

Rationale: The hospital safely manages investigational medications

**A 1.** The hospital has a written process addressing the use of investigational medications that **includes review, approval, supervision, and monitoring.**

**A 2.** The hospital's written process for the use of investigational medications specifies that the **pharmacy controls the storage, dispensing, labeling, and distribution of investigational medications.**

Good Clinical Practice: Consolidated Guideline. Federal Register, 1997, Vol. 62, No. 90.

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## RxCM: Electronic Compliance Manager

- © 2017 Intermountain Healthcare, All rights reserved A Central APEX Application, version: 1.92

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## Login



### Sign in to Application

Username:

Password:

**Sign in**

Pharmacy Compliance Manager is a tool created to track compliance with Intermountain Policy as well as State and Federal laws.

- How can I get access to this application?
- Who do I call for help?

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## Main Screen

Task List									
Task List									
<div> <div>Pharmacy</div> <div>Research Compliance</div> <div>From 03/12/2017 To</div> </div> <div> <div>Assigned To</div> <div>All Pharmacy Tasks</div> <div>Not Complete</div> <div>Completed</div> <div>All Tasks</div> </div> <div> <div>Category</div> <div>Research and Development</div> <div>Frequency</div> <div>All Frequencies</div> </div> <div> <div>Search</div> <div>Rows</div> <div>100</div> </div>									
Category	Status	Title	Assigned To	Due	Frequency	Type	A	Spread Sheet	
Research and Development	OVERDUE	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/10/2017	Just Once	Corporate	-		
	OVERDUE	Regulatory Documentation is complete (all aspects must be complete and accounted for to complete the task).	Unassigned	04/10/2017	Just Once	Corporate	-		
	OVERDUE	Site Operations have been approved/inspected, found to be appropriate for the study protocol (all aspects must be complete and accounted for to complete the task)?	Unassigned	04/10/2017	Just Once	Corporate	-		
	Due Today	Regulatory Review completed and uploaded into IDCM	Unassigned	04/11/2017	Just Once	Corporate	-		
	Due Today	Study protocol and application submitted for IRB review and approval?	Unassigned	04/11/2017	Just Once	Corporate	-		
	Due Soon	Study approved by IRB?	Unassigned	04/12/2017	Just Once	Corporate	-		
	Due Soon	Study protocol and application reviewed by Pharmacy Services for pharmacy oversight determination?	Unassigned	04/12/2017	Just Once	Corporate	-		
	Due Soon	Drug/Device accountability compliance has been developed in compliance with IRB requirements and or Pharmacy oversight (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/12/2017	Monthly	Corporate	-		
	Due Soon	Regulatory Documentation is complete (all aspects must be complete and accounted for to complete the task).	Unassigned	04/18/2017	Just Once	Corporate	-		
	Due Soon	Regulatory Review completed and uploaded into IDCM	Unassigned	04/24/2017	Just Once	Corporate	-		
	Due Soon	Drug/Device accountability compliance has been developed in compliance with IRB requirements and or Pharmacy oversight (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/28/2017	Just Once	Corporate	-		
	Due Soon	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/28/2017	Just Once	Corporate	-		
	Due Soon	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/28/2017	Just Once	Corporate	-		
	Due Soon	Regulatory Review completed and uploaded into IDCM	Unassigned	04/28/2017	Just Once	Corporate	-		

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## Task List Function

Task List   Manage Tasks   Maintenance   Dashboard   Reports

Task List

Task List

Pharmacy: Cindy's Test Pharmacy   From: 02/28/2017   To:

Assigned To: All Pharmacy Tasks   ☐ Not Complete   ☐ Completed   ☒ All Tasks

Category: Shadi stuff   Frequency: All Frequencies

Search:    Rows: 100

Pharmacy ( Research location/facility )

- select pharmacy -  
 340B Heber Valley Medical Center  
 340B Pharmacies  
 797 Compounding Pharmacies  
 Bear River Valley Hospital  
 Central Lab  
 Cindy's Test Pharmacy  
 Community Pharmacy  
 Demonstration Pharmacy  
 Dev Pharmacy  
 Email Testing  
 Fillmore Pharmacy  
 GP Test  
 GP View Test  
 Glen's New Test  
 Homecare  
 IMC Pharmacy  
 IPC Testing  
 LDS Pharmacy  
 Matt's Awesome Pharmacy  
 Medical Group  
 Mikes  
 New People Testing  
 OIOG Corporate  
 Research Development Demo  
 Riverton Lab  
 Specialty Pharmacy  
 Supply Chain Center  
 TESTAmerican Fork Hospital Pharmacy  
 TESTCassia Regional Medical Center

Assigned to

All Pharmacy Tasks  
 Unassigned  
 CS Techs  
 Group name-rename  
Jensen, Michael  
 Shoe, Jim  
 Water, April  
 Doe, John  
 Doe, Jane

Category ( Study )

All Categories  
 340B Auditing  
 Acu-Dose Tracking  
 CS Monitoring  
 Canada  
 Cindy's Test Category  
 Cindy's Test Category  
 Controlled Substance Monitoring  
 Delta  
 Directory Verification  
 General  
 Homecare CS Monitoring  
 Matt's Test Category  
 Medical Group  
 Outdates/Inspections  
 Research and Development  
 Rx Specific Category  
 Shadi stuff  
 Test  
 Training Pharmacy Task Categories  
 compounding

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## Task List Function

Task List   Manage Tasks   Maintenance   Dashboard   Reports

Task List

Task List

Pharmacy: Research Compliance   From: 03/08/2017   To:

Assigned To: Unassigned   ☐ Not Complete   ☐ Completed   ☒ All Tasks

Category: Research and Development   Frequency: All Frequencies

Search:    Rows: 100

Category	Status	Title	Assigned To	Due Date	Completed	Frequency	Type	Last Updated By
Research and Development	Due Soon	Regulatory Documentation is complete (all aspects must be complete and accounted for to complete the task).	Unassigned	04/19/2017	-	Just Once	Corporate	-
	Due Soon	Drug/Device accountability compliance has been developed in compliance with IRB requirements and or Pharmacy oversight (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/28/2017	-	Just Once	Corporate	-
	Due Soon	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/29/2017	-	Just Once	Corporate	-
	Due Soon	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/29/2017	-	Just Once	Corporate	-
	Due Soon	Regulatory Review completed and uploaded into ISCM	Unassigned	04/29/2017	-	Just Once	Corporate	-
	Due Soon	Study protocol and application submitted for IRB review and approval?	Unassigned	04/29/2017	-	Just Once	Corporate	-
	Due Soon	Study protocol and application reviewed by Pharmacy Services for pharmacy oversight determination?	Unassigned	04/29/2017	-	Monthly	Corporate	-
	Due Soon	Site Operations have been approved/inspected, found to be appropriate for the study protocol (all aspects must be complete and accounted for to complete the task)?	Unassigned	04/30/2017	-	Just Once	Corporate	-
	Due Soon	Study approved by IRB?	Unassigned	04/30/2017	-	Just Once	Corporate	-

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## Main Screen

Task List   Manage Tasks   Maintenance   Dashboard   Reports

Task List

♥ Task updated.

Task List

Pharmacy: Research Compliance   From: 03/12/2017   To:

Assigned To: All Pharmacy Tasks   ☐ Not Complete   ☒ Completed   ☐ All Tasks

Category: Research and Development   Frequency: All Frequencies

Search:    Rows: 100

Category	Status	Title	Assigned To	Due	Completed	Frequency	Type	A	Last Updated By
Research and Development	Completed Late	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/10/2017	04/11/2017	Just Once	Corporate	-	Jensen, Michael
	Completed Late	Regulatory Documentation is complete (all aspects must be complete and accounted for to complete the task).	Unassigned	04/10/2017	04/11/2017	Just Once	Corporate	-	Jensen, Michael
	Completed Late	Site Operations have been approved/inspected, found to be appropriate for the study protocol (all aspects must be complete and accounted for to complete the task)?	Unassigned	04/10/2017	04/11/2017	Just Once	Corporate	-	Jensen, Michael
	Completed On-Time	Regulatory Riview completed and uploaded into IdCM	Unassigned	04/11/2017	04/11/2017	Just Once	Corporate	-	Jensen, Michael
	Completed On-Time	Study protocol and application submitted for IRB review and approval?	Unassigned	04/11/2017	04/11/2017	Just Once	Corporate	-	Jensen, Michael

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## Main Screen

Task List   Manage Tasks   Maintenance   Dashboard   Reports

Task List

♥ Task updated.

Task List

Pharmacy: Research Compliance   From: 03/12/2017   To:

Assigned To: All Pharmacy Tasks   ☐ Not Complete   ☒ Completed   ☐ All Tasks

Category: Research and Development   Frequency: All Frequencies

Search:    Rows: 100

Category	Status	Title	Assigned To	Due	Completed	Frequency	Type	A	Last Updated By
Research and Development	Completed Late	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/10/2017	04/11/2017	Just Once	Corporate	-	Jensen, Michael
	Completed Late	Regulatory Documentation is complete (all aspects must be complete and accounted for to complete the task).	Unassigned	04/10/2017	04/11/2017	Just Once	Corporate	-	Jensen, Michael
	Completed Late	Site Operations have been approved/inspected, found to be appropriate for the study protocol (all aspects must be complete and accounted for to complete the task)?	Unassigned	04/10/2017	04/11/2017	Just Once	Corporate	-	Jensen, Michael
	Completed On-Time	Regulatory Riview completed and uploaded into IdCM	Unassigned	04/11/2017	04/11/2017	Just Once	Corporate	-	Jensen, Michael
	Completed On-Time	Study protocol and application submitted for IRB review and approval?	Unassigned	04/11/2017	04/11/2017	Just Once	Corporate	-	Jensen, Michael
	Due Soon	Study approved by IRB?	Unassigned	04/12/2017	-	Just Once	Corporate	-	-
	Due Soon	Study protocol and application reviewed by Pharmacy Services for pharmacy oversight determination?	Unassigned	04/12/2017	-	Just Once	Corporate	-	-
	Due Soon	Drug/Device accountability compliance has been developed in compliance with IRB requirements and or Pharmacy oversight (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/12/2017	-	Monthly	Corporate	-	-
	Due Soon	Regulatory Documentation is complete (all aspects must be complete and accounted for to complete the task).	Unassigned	04/18/2017	-	Just Once	Corporate	-	-
	Due Soon	Regulatory Riview completed and uploaded into IdCM	Unassigned	04/24/2017	-	Just Once	Corporate	-	-
	Due Soon	Drug/Device accountability compliance has been developed in compliance with IRB requirements and or Pharmacy oversight (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/28/2017	-	Just Once	Corporate	-	-
	Due Soon	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	Unassigned	04/28/2017	-	Just Once	Corporate	-	-

[Spread Sheet](#)

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## Manage Tasks Function

Task List   Manage Tasks   Maintenance   Dashboard   Reports

Manage Tasks

**Task Maintenance**

Corporate Tasks

Pharmacy Tasks

Assigned To: Research Compliance

Category: All Categories   Frequency: All Frequencies

Search:   Rows: 15

Master Task

Create

Category	Edit	Title	Next Load	Due	End	Frequency	Last Updated	Assigned To
Research and Development	Edit	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?				Just Once	04/10/2017 09:23	Research Compliance
	Edit	Regulatory Documentation is complete (all aspects must be complete and accounted for to complete the task).				Just Once	04/10/2017 09:24	Research Compliance
	Edit	Regulatory Review completed and uploaded into ICDM				Just Once	04/10/2017 09:42	Research Compliance
	Edit	Site Operations have been approved/inspected, found to be appropriate for the study protocol (all aspects must be complete and accounted for to complete the task)?				Just Once	04/10/2017 09:46	Research Compliance
	Edit	Study approved by IRB?				Just Once	04/10/2017 09:47	Research Compliance
	Edit	Study protocol and application reviewed by Pharmacy Services for pharmacy oversight determination?				Just Once	04/10/2017 09:47	Research Compliance
	Edit	Study protocol and application submitted for IRB review and approval?				Just Once	04/10/2017 09:48	Research Compliance
	Edit	Drug/Device accountability compliance has been developed in compliance with IRB requirements and or Pharmacy oversight (all aspects must be complete and accounted for to complete the task, any variations are to be reported)?	04/13/2017	05/04/2017	04/30/2017	Monthly	04/10/2017 09:51	Research Compliance

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## Manage Tasks Function

### • Create Task

Master Task

Create   Load Now   Cancel

Task Type: Corporate Assign To: Research Compliance   Attachment Required

Title

Task

Category: - select category -   Schedule Available Starting:   Ending:

Task Schedule

Schedule: ☐ Daily ☐ Weekdays ☐ Weekly ☐ Monthly ☐ Quarterly ☐ Yearly ☐ Just Once

Can start task:   day(s) before task is due

Next Load Due

Entered By

Master Task

Apply Changes   Delete   Load Now   Cancel

Task Type: Corporate Assign To: Research Compliance   Attachment Required

Title

Task

Category: Research and Development   Schedule Available Starting: 04/28/2017   Ending:

Task Schedule

Schedule: ☐ Daily ☐ Weekdays ☐ Weekly ☐ Monthly ☐ Quarterly ☐ Yearly ☒ Just Once

Can start task: 21 day(s) before task is due

Next Load Due

Entered By: Michael Jensen   Entered: 04/06/2017

Updated By: Michael Jensen   Updated: 04/10/2017

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## Maintenance Function

Task List Manage Tasks Maintenance Dashboard Reports

Maintenance > Pharmacies [Add New](#)

**Maintenance**

- Pharmacies
- Task Categories
- Admin Users
- Scanners
- Holidays

Edit	Pharmacy	Start Date	End Date
<a href="#">Edit</a>	Research Compliance Post Audit	04/06/2017	05/31/2017
<a href="#">Edit</a>	Research Development Demo	04/01/2017	06/30/2017
<a href="#">Edit</a>	340B Heber Valley Medical Center	02/12/2015	
<a href="#">Edit</a>	340B Pharmacies	10/15/2014	
<a href="#">Edit</a>	797 Compounding Pharmacies	10/15/2014	
<a href="#">Edit</a>	Bear River Valley Hospital	08/27/2014	
<a href="#">Edit</a>	Central Lab	06/15/2015	
<a href="#">Edit</a>	Cindy's Test Pharmacy	08/05/2014	
<a href="#">Edit</a>	Community Pharmacy	10/14/2014	
<a href="#">Edit</a>	Demonstration Pharmacy	11/05/2015	
<a href="#">Edit</a>	Dev Pharmacy	04/20/2016	
<a href="#">Edit</a>	Email Testing	03/03/2017	
<a href="#">Edit</a>	Fillmore Pharmacy	08/14/2014	
<a href="#">Edit</a>	GP Test	08/25/2014	
<a href="#">Edit</a>	GP View Test	12/29/2016	
<a href="#">Edit</a>	Glen's New Test	03/11/2015	
<a href="#">Edit</a>	Homecare	12/23/2014	
<a href="#">Edit</a>	IMC Pharmacy	07/11/2014	
<a href="#">Edit</a>	IPC Testing	08/01/2014	
<a href="#">Edit</a>	LDS Pharmacy	07/10/2014	
<a href="#">Edit</a>	Matts Awesome Pharmacy	07/27/2016	
<a href="#">Edit</a>	Medical Group	04/01/2015	
<a href="#">Edit</a>	Mikes	08/01/2014	
<a href="#">Edit</a>	New People Testing	08/22/2014	
<a href="#">Edit</a>	OIOO Corporate	06/12/2015	
<a href="#">Edit</a>	Research Compliance	04/03/2017	
<a href="#">Edit</a>	Riverton Lab	06/22/2015	
<a href="#">Edit</a>	Specialty Pharmacy	02/27/2015	
<a href="#">Edit</a>	Supply Chain Center	10/14/2014	
<a href="#">Edit</a>	TESTAmerican Fork Hospital Pharmacy	07/02/2014	

Task List Manage Tasks Maintenance Dashboard Reports

Maintenance > Task Categories [Add Category](#)

**Maintenance**

- Pharmacies
- Task Categories
- Admin Users
- Scanners
- Holidays

Task Category	Start	End
340B Auditing	10/15/2014	
Acu-Dose Tracking	08/05/2014	
CS Monitoring	07/31/2014	
Cindy's Test Category	08/05/2014	
Controlled Substance Monitoring	08/13/2014	
Delta	08/27/2014	
Directory Verification	08/05/2014	
Fillmore task list	08/27/2014	09/01/2021
General	08/05/2014	
Homecare CS Monitoring	12/23/2014	
Matts Test Category	08/01/2016	
Medical Group	09/04/2014	
Outdates/Inspections	07/28/2014	
Research and Development	04/01/2017	06/30/2017
Shadi stuff	09/16/2014	

row(s) 1 - 15 of 18 [Next](#)

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## Maintenance Function

• Add New

[Add New](#)

Edit

[Edit](#)

Pharmacy [Create](#) [Cancel](#)

■ Pharmacy

■ Start Date  End Date

Pharmacy [Apply Changes](#) [Cancel](#)

■ Pharmacy

■ Start Date  End Date

People [Add Group](#) Categories [Add Category](#)

Last name	First Name	Groups
Jensen	Mike	Add
Shoe	Jim	Add
Water	April	Add
Doe	John	Add
Doe,	Jane	Add
Nilly	Willey	Add

Task Category	Owner
Cindy's Test Category	Pharmacy
Rx Specific Category	Pharmacy
Canada	Pharmacy
340B Auditing	Corporate
Acu-Dose Tracking	Corporate
CS Monitoring	Corporate
Cindy's Test Category	Corporate
Controlled Substance Monitoring	Corporate
Delta	Corporate
Directory Verification	Corporate
Fillmore task list	Corporate
General	Corporate
Homecare CS Monitoring	Corporate
Matts Test Category	Corporate
Medical Group	Corporate

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## Dashboard Function

### • Dashboard

Task List   Manage Tasks   Maintenance   Dashboard   Reports

Task List

Pharmacy  Due

Assigned To  ☒ Not Complete ☐ Completed ☐ All Tasks

Category  Frequency

Search  Rows

Category	Status	Title	Assigned To	Due	Frequency	Type
AcuDose Compliance	Due Soon	AcuDose Compliance Checklist(s)	CS Techs	02/10/2017	Daily	Corporate
Controlled Substance Monitoring	Due Soon	Perform Narcotic Diversion Detection Auditing Activities	CS Techs	02/11/2017	Daily	Corporate
	Due Soon	Pharmacy Access Review (Including the Narc Room and Satellites)	CS Techs	02/17/2017	Daily	Corporate
	Due Soon	Validate the Receiving Process	CS Techs	02/12/2017	Daily	Corporate
	Due Soon	Perform AcuDose Discrepancy by Station review	CS Techs	02/05/2017	Daily	Corporate
	Due Soon	Perform NarcStation Open Transaction Review/F-util-Fx Open Transaction Review	CS Techs	02/21/2017	Daily	Corporate
	Due Soon	Using a weekly Aesynt Performance Analytics (ADS) report to highlight possible diversion	CS Techs	02/13/2017	Daily	Corporate
PCH Operations	Due Today	TPN pump (EM2400) test solution - lab value verification (PM TPN)	CS Techs	02/06/2017	Daily	Corporate
	Due Today	WAVE #1 - IV batch pre-scan/barcode validation	CS Techs	02/03/2017	Daily	Corporate
	Due Today	WAVE #2 - IV batch pre-scan/barcode validation	CS Techs	02/07/2017	Daily	Corporate
	Due Today	WAVE #3 - IV batch pre-scan/barcode validation	CS Techs	02/04/2017	Daily	Corporate
	Due Today	WAVE #4 - IV batch pre-scan/barcode validation	CS Techs	03/08/2017	Daily	Corporate
	Due Soon	EM2400 pump database backup	CS Techs	03/05/2017	Daily	Corporate
Sterile Compounding	Due Today	#1 Baxter Repeater Pump (Vanco)	CS Techs	03/02/2017	Daily	Corporate
	OVERDUE	#1 Compounding Aseptic Containment Isolator (CACI) Hazardous	CS Techs	03/07/2017	Daily	Corporate
	Due Today	#1 Compounding Aseptic Containment Isolator (CACI) Hazardous	CS Techs	03/06/2017	Daily	Corporate
	Due Today	#1 Laminar Airflow Workbench (LAFW) Narc Hood	CS Techs	03/04/2017	Daily	Corporate
	Due Today	#2 Baxter Repeater Pump (Lipid)	CS Techs	03/03/2017	Daily	Corporate
	OVERDUE	#2 Compounding Aseptic Containment Isolator (CACI) Hazardous	CS Techs	02/22/2017	Daily	Corporate
	Due Today	#2 Compounding Aseptic Containment Isolator (CACI) Hazardous	CS Techs	03/10/2017	Daily	Corporate

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## Reports Function

Task List   Manage Tasks   Maintenance   Dashboard   Reports

Reports

Pharmacy Compliance

Type ☒ Corporate ☐ Pharmacy From  To

Category  Frequency

Spread Sheet

Pharmacy	Late	Total	Compliance
340B Heber Valley Medical Center	485	485	0%
340B Pharmacies	548	548	0%
797 Compounding Pharmacies	485	485	0%
Bear River Valley Hospital	531	531	0%
Central Lab	485	485	0%
Cindy's Test Pharmacy	579	579	0%
Community Pharmacy	485	485	0%
Demonstration Pharmacy	543	543	0%
Dev Pharmacy	485	485	0%
Email Testing	480	480	0%
Filmore Pharmacy	487	487	0%
GP Test	587	587	0%
GP View Test	485	485	0%
Glen's New Test	509	509	0%
Homecare	529	529	0%
IAC Pharmacy	487	487	0%
IPC Testing	610	610	0%
LDS Pharmacy	488	488	0%
Matts Awesome Pharmacy	551	551	0%
Medical Group	519	519	0%
Mikes	590	590	0%
New People Testing	487	487	0%
OIOG Corporate	485	485	0%
Research Compliance	40	40	0%
Research Development Demo	485	485	0%
Riverton Lab	485	485	0%
Specialty Pharmacy	485	485	0%
Supply Chain Center	485	485	0%
TESTAmerican Fork Hospital Pharmacy	488	488	0%
TESTCassia Regional Medical Center	493	493	0%
Training Pharmacy	488	488	0%

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Spread Sheet

Task Compliance

Pharmacy

Type ☒ Corporate ☐ Pharmacy From  To

Category  Frequency

Search  Rows

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## Reports Function

Task List   Manage Tasks   Maintenance   Dashboard   Reports

**Reports**

☒

Pharmacy	Category	Status	Title	Assigned To	Due	Frequency	Type	Completed	Attachment	Attachment Req	Last Updated	Comments/Notes
Training Pharmacy	CS Monitoring	Completed Late	Check Manual Issues from NarcStation (present on patient care units)	Unassigned	06/20/2014	Daily	Corporate	06/28/2014	-	-	Jensen, Michael	gfhahgh
Mikes	Acu-Dose Tracking	Completed Late	Test Weekdays	Unassigned	06/31/2014	Daily	Corporate	09/05/2014	-	-	Jensen, Michael	-
Training Pharmacy	CS Monitoring	Completed Late	Preform NarcStation Open Transaction Review	Jensen, Michael	09/01/2014	Weekdays	Corporate	09/04/2014	-	-	Jensen, Michael	-
Mikes	Acu-Dose Tracking	Completed Late	Test Weekdays	Unassigned	08/29/2014	Daily	Corporate	09/04/2014	-	-	Jensen, Michael	-
Training Pharmacy	Acu-Dose Tracking	Completed On-Time	test Monthly test Monthly	Unassigned	09/30/2014	Monthly	Corporate	09/11/2014	-	-	Jensen, Michael	-
Training Pharmacy	Acu-Dose Tracking	Completed Late	Test Weekdays	Unassigned	08/24/2014	Daily	Corporate	09/04/2014	-	-	Jensen, Michael	-
Training Pharmacy	CS Monitoring	Completed On-Time	Reconciling Manual Admits to the ADT	Unassigned	08/28/2014	Daily	Corporate	08/28/2014	-	-	Jensen, Michael	-
Training Pharmacy	Acu-Dose Tracking	Completed Late	Test Weekdays	Unassigned	09/29/2014	Daily	Corporate	09/04/2014	Attachment	-	Jensen, Michael	-
Training Pharmacy	CS Monitoring	Completed Late	Preform NarcStation Open Transaction Review	Jensen, Michael	08/29/2014	Weekdays	Corporate	09/04/2014	-	-	Jensen, Michael	hjsdfjasklaskdjklfjaskdjfkljaskdjfkl
Training Pharmacy	CS Monitoring	OVERDUE	Preform NarcStation Open Transaction Review	Unassigned	08/27/2014	Weekdays	Corporate	-	-	-	Jensen, Michael	-
Training Pharmacy	Acu-Dose Tracking	Completed Late	Test Weekdays	Unassigned	08/27/2014	Daily	Corporate	09/04/2014	-	-	Jensen, Michael	-
Training Pharmacy	CS Monitoring	Completed Late	Preform NarcStation Open Transaction Review	Jensen, Michael	08/26/2014	Weekdays	Corporate	08/27/2014	-	-	Jensen, Michael	done
Training Pharmacy	Acu-Dose Tracking	Completed Late	Test Weekdays	Unassigned	08/26/2014	Daily	Corporate	08/27/2014	-	-	Jensen, Michael	-
Mikes	CS Monitoring	OVERDUE	Check Manual Issues from NarcStation (present on patient care units)	Unassigned	08/28/2014	Daily	Corporate	-	-	-	Jensen, Michael	Identified error, needkkkkkkkkkk
Training Pharmacy	CS Monitoring	OVERDUE	Perform AcuDose-Rx Access User List Maintenance - Current Employees	Nemati, Simin	08/29/2014	Weekly	Corporate	-	-	-	Jensen, Michael	-

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Intermountain Healthcare

## Reports Function

- Raw Data Spreadsheet Sample

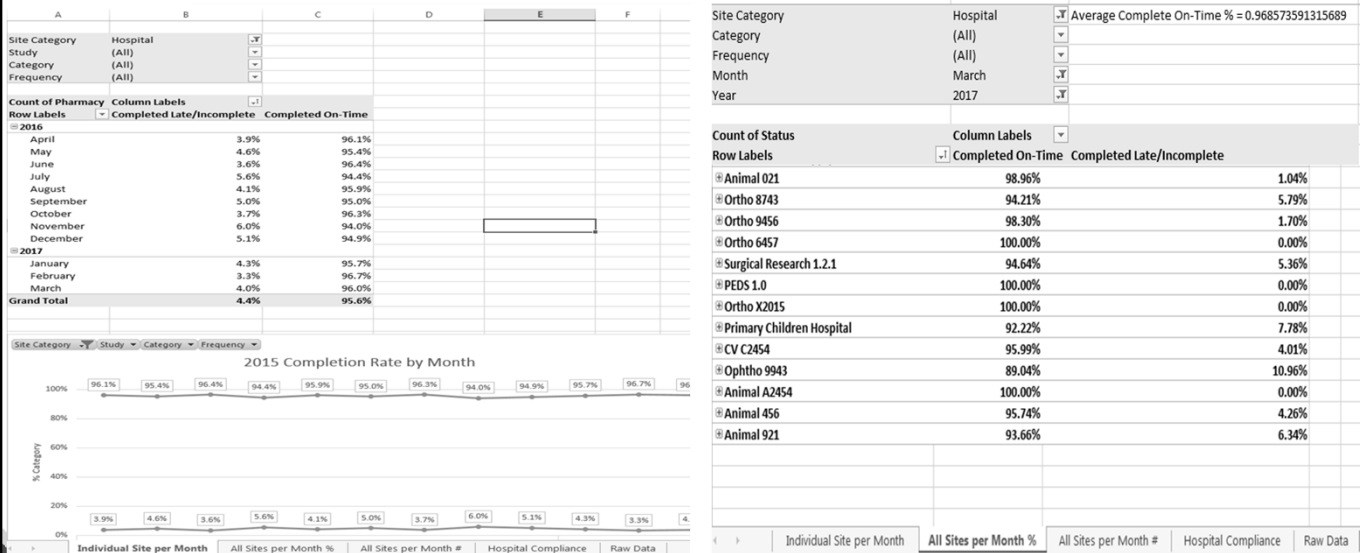
Title	Status	Frequen	Category	Due	Completi	Month	Site Category	Year
*PM* #1 Laminar Airflow Workbench (LAFW)	Completed On-Time	Daily	Sterile Compounding	3/14/2017	3/14/2017	March	Hospital	2017
Sterile inner gloves	Completed On-Time	Daily	Sterile Compounding	3/14/2017	3/14/2017	March	Hospital	2017
Perform Split Billing Automatic and Manual Accumulation Accuracy.	Completed On-Time	Monthly	340B	3/10/2017	3/9/2017	March	Hospital	2017
Perform Split Billing Automatic and Manual Accumulation Accuracy	Completed On-Time	Monthly	340B	3/10/2017	3/10/2017	March	Hospital	2017
Verify all 340B Audit Reports (Appendix 2-4) for previous month have been confirmed and sub	Completed On-Time	Monthly	340B	3/10/2017	3/1/2017	March	Hospital	2017
All counters, pass-through windows, work surfaces, sink areas are disinfected daily	Completed Late/Incomplete	Weekdays	Sterile Compounding	3/1/2017	3/2/2017	March	Medical Group	2017
Pressure controls are recorded	Completed Late/Incomplete	Weekdays	Sterile Compounding	3/1/2017	3/2/2017	March	Medical Group	2017
Compounding Aseptic Isolator (CAI)	Completed On-Time	Daily	Sterile Compounding	3/1/2017	3/1/2017	March	Hospital	2017
*Chemo* Floor mopping performed from cleanest room (buffer) to less clean area (anteroom)	Completed On-Time	Weekdays	Sterile Compounding	3/1/2017	3/1/2017	March	Hospital	2017
*Chemo* Pressure gauge or velocity meter	Completed On-Time	Weekdays	Sterile Compounding	3/1/2017	3/1/2017	March	Hospital	2017
*PM* Laminar Airflow Workbench (LAFW)	Completed On-Time	Daily	Sterile Compounding	3/1/2017	3/1/2017	March	Hospital	2017
Reconciling Controlled Substance Waste Discrepancies in AcuDose-Rx	Completed On-Time	Weekdays	Controlled Substance Monitoring	3/1/2017	3/1/2017	March	Hospital	2017
Reconciling Manual Admits to the ADT	Completed On-Time	Weekdays	Controlled Substance Monitoring	3/1/2017	3/1/2017	March	Hospital	2017

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Intermountain Healthcare

## Reports Function

- Individual Study Reports



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## Reports Function

- Overall Compliance Report by Study

B	C	D	E	F	G	H	M	N	O	P
Research Compliance by Study	Funding Source	Q1 2017				IRB	Site Study Task Performance Reports			Completion Status
	G = Grant, P = Private, I = Industry	Pre-Study Review/Task Completion				Review	Weekday	Weekly	Monthly	
Surgical Research 1.2.1	G	65.0	91.5	100.0	100.0	Hold	NA	NA	NA	NA
PEDS research Study 1.0	P	92.0	100.0	100.0	100.0	Approve	83.0	84.0	100.0	NA
Ortho Study X2015	G	97.4	100.0	100.0	100.0	Approve	91.0	100.0	100.0	Submitted
Cardiovascular Study C2454	G	98.3	95.0	100.0	100.0	Approve	97.0	98.0	98.0	NA
Ophthalmology Study O9943	I	100.0	100.0	83.3	100.0	Approve	100.0	100.0	100.0	NA
Animal Study A254	I	87.0	99.0	100.0	100.0	Review	95.0	68.0	85.0	NA
Animal Study A456	G	87.0	100.0	100.0	100.0	Review	NA	NA	NA	NA
Animal Study A921	G	87.0	100.0	100.0	100.0	Approve	NA	NA	NA	NA
Animal Study A021	G	33.0	54.0	82.0	100.0	Deny	0.0	0.0	0.0	0.0
Ortho Study X8743	I	100.0	100.0	100.0	100.0	Approve	98.0	100.0	100.0	Published
Ortho Study X9456	P	100.0	100.0	100.0	100.0	Approve	NA	100.0	100.0	Submitted
Ortho Study X6587	P	97.0	100.0	100.0	100.0	Review	NA	NA	NA	NA
System Average	#NAME?	87	95	97	100	#DIV/0!	81	81	85	0
Red Level	<85	<85	<100	<100	<100	<85	<85	<100	<100	<85

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## Conclusion

- The use of an electronic compliance database manager provides an efficient method for coordinating, managing, and documenting aspects of compliance for related activities in the health-care setting.
- An electronic compliance database manager provides a tool to organize activities of compliance, tailored to the demands required based on the setting or project being conducted.
- The use of an electronic compliance database manager provides the compliance specialist the ability to organize, validate, audit, report, trend, and assess all research compliance requirements in a healthcare setting.

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## Questions ?

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