

## General Overview of Vestigo Verify

---

Vestigo is an application to support investigation drug services for the management of the drug therapy used as part of a research protocol. Vestigo features tools to assist with protocol management, full electronic virtual inventories with drug accountability, dispensing and labeling of prescriptions, protocol billing management and reporting.

Vestigo is an application to manage the Investigational Drug Service. As such, it performs record-keeping functions subject to the statutes found in 21 CFR Part 11. The regulations require electronic features and controls as well as user policies and practices.

Vestigo undergoes rigorous internal validation for all development activities in order to ensure compliance with applicable regulations. Full compliance with 21 CFR Part 11 requires that the application be used in an environment with internal controls, local policies and procedures to ensure the application is used correctly. Please see the document "Statement of Compliance with 21 CFR Part 11" for further information.

Depending on your login and permissions some of the functions outlined in this document may not be available to you.

Access to Vestigo is granted by the facility and the facility maintains control of who accesses the system and when they access the system. To change access date, time or to get additional access please contact the site contact who granted you access.

While monitors may be defaulted to use certain browser(s), we recommend Chrome, Firefox, and Edge as these options are more user-friendly.

Vestigo and Vestigo Verify may contain patient health information (PHI). Users should take appropriate precautions to ensure PHI is not exposed to unauthorized individuals.

Vestigo is a web-based application brought to you by the McCreadie Group. If you have questions about Vestigo, please email us at [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com) or 734-548-9007 option 2.

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreadie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreadie Group, Inc

## Verify Account Information

The Vestigo Verify Home Screen has various functionality for protocol(s) in Vestigo.

Monitors can only enter studies where access is current. If access is closed, the monitor can contact the site to open access. Visits that are current and access is granted will be shaded green.

### Account Information

In the top right corner of the screen, the monitor can access information about their account, Vestigo Verify, and the Help Center.

My Account is the monitor's demographic information. Monitors can update their password here. Monitors will be required to confirm their information. Monitors can change their name, company, and phone number. If a different email address is needed, the site can add a new account for the monitor.

The Help Center will allow the monitor to access manuals and documentation. Please note, pop up blockers must be off to access the Help Center.

The "About" link will provide information about Vestigo, 21 CFR Part 11 compliance, and support.

Select "View Protocols" to see protocol details. If access is current, the monitor will be able to access the protocol on the next screen.

Site	Visit #	Status	Scheduled Visit	Access Granted	Visit Purpose	Visit Type
Testing - IDS Pharmacy 12345 University Drive Room BA325 MyCity, OH 99887	#826	Scheduled	10/13/2020 14:00-10/13/2020 15:00EDT	10/12/2020 20:00- 10/13/2020 20:00EDT	Interim	Fully Remote

### Account Functionality

Across the top of the screen, the monitor has the ability to review details about their upcoming visits, protocols and sites, and communications between site and monitor. The five tabs allow the monitor to do the following:

**My Visits:** The monitor can visualize their visit and access dates and times at each site. A visit with current access will be shaded green to make it easier to locate.

My Account | Help Center | About | Log Out  
Andrew Jonathan (andrewjonathan@gmail.coz) 2137721232 here

My Visits | My Protocols | My Calendar | My Visit Notes | My Communication History

Home

Visit Date: 09/12/2020 Through: 11/12/2020 [Search](#)

If you do not see the visit, please confirm that you are using the correct email address or contact the site to confirm the email address that was used.

Site	Visit #	Status	Scheduled Visit	Access Granted	Visit Purpose	Visit Type	
Testing - IDS Pharmacy 12345 University Drive Room BA325 MyCity, OH 99887	#826	In Progress	10/13/2020 14:00-10/13/2020 15:00EDT	10/12/2020 16:00-10/13/2020 20:00EDT	Interim	Fully Remote	<a href="#">View Protocols</a>
Testing - IDS Pharmacy 12345 University Drive Room BA325 MyCity, OH 99887	#814	Scheduled	10/14/2020 8:00-10/14/2020 9:00EDT	10/14/2020 18:00-10/15/2020 19:00EDT	Interim	Fully Remote	<a href="#">View Protocols</a>

**My Protocols:** Monitors can review a list of protocols and sites where they are established as the monitor. Per site and protocol, the monitor can:

Contact a Site: Question about Upcoming Visit, No Longer on Protocol, Request Availability. All Contact a Site options will trigger an alert on the Vestigo side for the client (Vestigo side alert called “Monitor Site Requests to be Resolved”). Any replies by the site to the monitor will be emailed to the monitor as well as seen on their My Communications tab.

Request a Visit: **Only available** if the site has set availability in their calendar.

When “Request a Visit” is selected, a calendar will display below. If availability is set up, the monitor will see day(s) and time noted with “Availability”. Select the timeslot and enter details.

If “Availability” is not displayed, the Vestigo client is not using the availability feature or all of the available “slots” are taken. The monitor can use Contact a Site: Request Availability and provide the date and time they are requesting. Either way, the site can schedule the visit or reject. The monitor will receive information about their request (availability: accepted or rejected; via contact a site: response) in an email as well as on their My Communications tab.

My Visits: Review a list of previous visit/access, View Protocol to download Visit Summary Report, and cancel upcoming visits/access.

My Account | Help Center | About | Log Out  
Andrew Jonathan (andrewjonathan@gmail.coz) 2137721232 here

My Visits | **My Protocols** | My Calendar | My Visit Notes | My Communication History

Site	Protocol	Title	Lead Sponsor			
Testing - IDS Pharmacy 12345 University Drive Room BA325 MyCity, OH 99887	B7841003   2017-001255-31   P277	A MULTICENTER, OPEN-LABEL STUDY TO EVALUATE THE LONG-TERM SAFETY, TOLERABILITY AND EFFICACY OF SUBCUTANEOUS PF-06741086 IN SUBJECTS WITH SEVERE HEMOPHILIA	Pfizer	<a href="#">Request a Visit</a>	<a href="#">My Visits (1)</a>	<a href="#">Contact Site</a>
Testing - IDS Pharmacy 12345 University Drive Room BA325 MyCity, OH 99887	CAAE: 33109220.7.0000.0068   P694	A Pragmatic Randomized Controlled Trial of Therapeutic Anticoagulation Versus Standard Care as a Rapid Response to COVID-19 Pandemic	University of Sao Paulo General Hospital	<a href="#">Request a Visit</a>	<a href="#">My Visits (1)</a>	<a href="#">Contact Site</a>

**My Calendar:** Calendar layout of visits with site details.

**My Visit Notes:** Detailed list of Visit Comments and Action Items entered by site and visit number across protocols and status.

**My Communication History:** View all emails sent from the site to monitor and monitor to site.

## Protocol Visit Header

Once the monitor selects to View Protocol, the following screen will provide more information about that visit:

- Access dates and times
- Who to contact at the site with any questions or to change and/or to extend access.
- The protocol(s) that are available during the specified visit.

During access date and time window, the monitor can select View Protocol to review study details.

After access date and time window has passed, the View Protocol link will allow the monitor to review Visit Notes on the specified visit and download a Visit Summary report.

**Visit #826: IDS Pharmacy**  
 Access Dates/Times: 10/12/2020 16:00 - 10/13/2020 20:00EDT (Ends in a day)  
 For Assistance for this visit, contact [IDS@IDS.csv](mailto:IDS@IDS.csv)

**Notes:** -Per SOP (reference IDS Pharmacy Policy 1.2: On-Site Monitor Visits), all pharmacy documentation will occur electronically in Vestigo. You must ensure you can log into Vestigo Verify, maintain your account, and bring your own computer to an off-site visit (if applicable) -Any drug returns or destructions should be authorized in Vestigo Verify to serve as an electronic signature for our records. -All IDS Pharmacy Policies were provided in at the time of SIV. They can be found underneath the Documents > Facility Documents of any protocol to which you have been granted access. They will not be re-distributed by e-mail or any other means.

**Logistic Notes:** \*\*As of March 2020, all monitoring visits will be conducted remotely. You will be given access to Vestigo for the business day (8am to 5pm) of your visit. If you require more time, please contact via e-mail or use the Contact Site option in Vestigo Verify. \*\*Temperature logs are uploaded at the end of the month, only. Partial temperature logs are not available, per Policy (see Facility Documents).

Protocol	Title	Lead Sponsor
97641003 - P277	A MULTICENTER, OPEN-LABEL STUDY TO EVALUATE THE LONG-TERM SAFETY, TOLERABILITY AND EFFICACY OF SUBCUTANEOUS PF-06741086 IN SUBJECTS WITH SEVERE HEMOPHILIA	Pfizer <a href="#">View Protocol</a>

Visit Date:  Through:  [Search](#)

If you do not see the visit, please confirm that you are using the correct email address or contact the site to confirm the email address that was used.

Site	Visit #	Status	Scheduled Visit	Access Granted	Visit Purpose	Visit Type
Testing - Barrie IDS 127 Main St This I changed AnyTown, MI 48109	#844	Requested	10/16/2020 12:00-10/16/2020 19:00EDT	No Access Granted	Interim	Fully Remote <a href="#">View Protocols</a>
Testing - IDS Pharmacy 12345 University Drive Room BA325 MyCity, OH 99887	#843	In Progress	10/15/2020 11:00-10/15/2020 12:00EDT	10/15/2020 11:00- 10/16/2020 12:00EDT	Interim	Fully Remote <a href="#">View Protocols</a>
Testing - IDS Pharmacy 12345 University Drive Room BA325 MyCity, OH 99887	#842	Completed	10/14/2020 17:00-10/14/2020 18:00EDT	10/14/2020 17:00- 10/14/2020 18:00EDT	Not Set	Not Set <a href="#">View Protocols</a>

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreadie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreadie Group, Inc

## Verify Monitor Review

Monitors can select transactions and indicate they have reviewed them. They can do this for transactions that have been previously reviewed as well. In the dropdown, select the drug, and then select the other parameters to generate specific details. You can click “More Filters” to specify additional variables.

**Protocol Numbers:** STRA-BLU-2020 | P496 **PI:** Chad Adams

**Title:** An open-label, randomized trial to assess the effects of freeze-dried strawberry and blueberry tablets vs. intravenous Gatorade on time to re-hydration in athletes ages 18 to 21

---

[Protocol](#)
[Inventory](#)
[Returns](#)
[Documents](#)
[Accountability](#)
[Visit Notes](#)
[Monitor Review](#)
[AuditLog](#)
[Temperature Logs](#)
[Reports](#)

**Drug**  [More Filters](#)

**Status**  All  Transactions Needing Review  Transactions Previously Reviewed

**Date:**  **To**

---

**Transactions**

Records Per Page

<input type="checkbox"/>	<input checked="" type="checkbox"/> Date	Transaction Type	<input checked="" type="checkbox"/> Lot Number	<input checked="" type="checkbox"/> Item Number	<input checked="" type="checkbox"/> Subject	<input checked="" type="checkbox"/> Patient ID	Quantity Dispensed or Received	Dose	Reviewed By
--------------------------	--	------------------	--	---	---	--	--------------------------------	------	-------------

A monitor can specify a date range, specific inventory or transactions types, locations, and subjects, or they can select all.

Other filters are as shown below

[Protocol](#)
[Inventory](#)
[Returns](#)
[Documents](#)
[Accountability](#)
[Visit Notes](#)
[Monitor Review](#)
[AuditLog](#)
[Temperature Logs](#)
[Reports](#)

**Drug**

**Status**  All  Transactions Needing Review  Transactions Previously Reviewed

**Date:**  **To**

**Inventory**  **Transaction Type**

**Subject**  **Location**

Select “Search” will produce a menu of the transactions that meet the parameters selected.

Checking the box on the right and clicking “Mark as Reviewed” will serve as an indicator that the monitor has reviewed and agrees with the transaction. The system will user/date/time stamp the screen with this as well as the Monitor Review Report (a format when generating a DARF) will indicate this in the far-right column under Reviewed.

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreadie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreadie Group, Inc

## Verify Monitor Email Template Examples

---

This is a list of examples of emails sent to a monitor. A monitor will receive an email:

- When a Monitor Account is created by a Site
- When a Visit is Scheduled by a Site
- When a Visit is Modified by a Site
- Reminder 48 hours before a Visit
- Follow-up 48 hours after a Visit when Action Items Exist
- Weekly Summary of Upcoming Visits
- When a Site responds to a Monitor Site Request

The emails are structured so the first part of the email message has the relevant information related to the email subject. The second part of the email is a standardized message for monitor reference. Sites can create a template of information to use when scheduling monitor visits in Protocol Management > Manage Templates. Templates can be made for:

- Template for Notes to Send to Monitors
- Template for Logistic Notes to Send to Monitors

There are several instances where a monitor may not receive emails sent via Vestigo:

- This may be due to using an incorrect email address. Monitors can work with the sites or support to correct incorrect email accounts.
- Emails may not deliver due to their firewall blocking the emails. There are a couple of actions that can be done to help prevent this from happening:

Please make sure monitors contact their IT with this information below.

If you are having issues receiving emails, please contact your IT and request that support@mccreadiegroup.com and support@vestigo.biz are whitelisted. There may be an add-on to the @vestigo.biz email showing up as an email from "email-od.com". You can advise their IT to whitelist using our friendly from address "support@vestigo.biz" plus the Source IP for the email delivery service should be: Source IP: s1-ba2f.socketlabs.email-od.com[142.0.186.47] or create a "rule" or "exception" that if the firewall sees email.od.com plus the @vestigo.biz, to whitelist it.



## Welcome Email – Creation of the account



Monitor: Jonathan Andrew (Company Name) - jonathanandrew@gmail.coz  
IDS Monitor Contact: Demo3 (IDS@IDS.gov)

A new account to Vestigo Verify has been created for you. When a visit is scheduled, you will receive a separate e-mail notification outlining the date, time, and details of your visit and access period.

A Vestigo site has created this account. You may have accounts under different email addresses if you work across companies.

Your UserName	Your Password	Added By	Link
jonathanandrew@gmail.coz	UE.uK2pj	Barrie L Gura	<a href="https://monitor.vestigo.biz">https://monitor.vestigo.biz</a>

### About Vestigo

Vestigo is a software solution used by leading Investigational Drug Services to help maintain their records, track inventory, and record dispensing of investigational drugs.

### About Vestigo Verify

Vestigo Verify is the monitoring module of Vestigo. With Vestigo Verify you will be able to:

- Review the pharmacy records for approved protocol(s)
- Acknowledge inventory and dispense transactions
- Generate Drug Accountability Records
- Authorize returns and destructions, co-sign destructions
- Create Action Items and notes
- View documents

### Vestigo Verify Link

<https://monitor.vestigo.biz>

### Access to Vestigo Verify:

- Sites will grant you access for a designated time period and may terminate your access prior to the end date. Please contact the site if you have any questions or concerns about your access.
- Your username is the email address you provide to the site across all Vestigo clients. Your email will be attached to all actions completed and serves as your electronic signature.
- Generate Drug Accountability Records
- An initial password will be assigned to you. By logging in, you can manage your information, account settings, and password in "My Account."
- For forgotten passwords, click the "Reset Password" link at the login screen and enter your email address.

### Help and Assistance

- For more details on the full functionality of Vestigo Verify, please visit the Vestigo Verify Help Center and refer to the User Manuals. Vestigo Verify support is also available at [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com).



## Protocol Added to a Monitor Account



Monitor: Jonathan Andrew (Company Name) - jonathanandrew@gmail.coz  
IDS Monitor Contact: Demo3 (IDS@IDS.cov)

You have been designated as a monitor in Vestigo Verify for Demo3 for PALABA 2017-004543-20|P3225. You will receive an email notification when access is granted. You may request a visit/access for this protocol in Vestigo Verify under the My Protocols tab.

### About Vestigo

Vestigo is a software solution used by leading Investigational Drug Services to help maintain their records, track inventory, and record dispensing of investigational drugs.

### About Vestigo Verify

Vestigo Verify is the monitoring module of Vestigo. With Vestigo Verify you will be able to:

- Review the pharmacy records for approved protocol(s)
- Acknowledge inventory and dispense transactions
- Generate Drug Accountability Records
- Authorize returns and destructions, co-sign destructions
- Create Action Items and notes
- View documents

Vestigo Verify Link

<https://monitor.vestigo.biz>

### Access to Vestigo Verify:

- Sites will grant you access for a designated time period and may terminate your access prior to the end date. Please contact the site if you have any questions or concerns about your access.
- Your username is the email address you provide to the site across all Vestigo clients. Your email will be attached to all actions completed and serves as your electronic signature.
- Generate Drug Accountability Records
- An initial password will be assigned to you. By logging in, you can manage your information, account settings, and password in "My Account."
- For forgotten passwords, click the "Reset Password" link at the login screen and enter your email address.

### Help and Assistance

- For more details on the full functionality of Vestigo Verify, please visit the Vestigo Verify Help Center and refer to the User Manuals. Vestigo Verify support is also available at [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com).



## Monitor Visit Scheduled Without Access



Monitor: Jonathan Andrew (Company Name) - jonathanandrew@gmail.coz  
 IDS Monitor Contact: Demo3 (IDS@IDS.cov)

You have been scheduled but no access has been granted for a monitor visit in Vestigo Verify at IDS Pharmacy for Protocols:

- PALABA 2017-004543-20 | P3225

Your UserName	Visit Type / Purpose	Added By	Visit Start and End	Access Begin and End
jonathanandrew@gmail.coz	Fully Remote - Close Out Visit	Barrie Gura	10/16/2020 1:00:00 PM through 10/16/2020 2:00:00 PM	No Access Granted

### About Vestigo

Vestigo is a software solution used by leading Investigational Drug Services to help maintain their records, track inventory, and record dispensing of investigational drugs.

### About Vestigo Verify

Vestigo Verify is the monitoring module of Vestigo. With Vestigo Verify you will be able to:

- Review the pharmacy records for approved protocol(s)
- Acknowledge inventory and dispense transactions
- Generate Drug Accountability Records
- Authorize returns and destructions, co-sign destructions
- Create Action Items and notes
- View documents

### Vestigo Verify Link

<https://monitor.vestigo.biz>

### Access to Vestigo Verify:

- Sites will grant you access for a designated time period and may terminate your access prior to the end date. Please contact the site if you have any questions or concerns about your access.
- Your username is the email address you provide to the site across all Vestigo clients. Your email will be attached to all actions completed and serves as your electronic signature.
- Generate Drug Accountability Records
- An initial password will be assigned to you. By logging in, you can manage your information, account settings, and password in "My Account."
- For forgotten passwords, click the "Reset Password" link at the login screen and enter your email address.

### Help and Assistance

- For more details on the full functionality of Vestigo Verify, please visit the Vestigo Verify Help Center and refer to the User Manuals. Vestigo Verify support is also available at [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com).



## Monitor Granted Visit and Access Using the Custom Access option



Monitor: Jonathan Andrew (Company Name) - jonathanandrew@gmail.coz  
 IDS Monitor Contact: Demo3 (IDS@IDS.gov)

You have been scheduled and granted access for a monitor visit in Vestigo Verify at IDS Pharmacy for Protocols:

- PALABA 2017-004543-20 | P3225

Your Username	Visit Type / Purpose	Added By	Visit Start and End	Access Begin and End
jonathanandrew@gmail.coz	Fully Remote - Other	Barrie Gura	10/20/2020 10:00:00 AM through 10/20/2020 11:00:00 AM	10/20/2020 8:00:00 PM through 10/21/2020 8:00:00 PM

-Per SOP (reference IDS Pharmacy Policy 1.2: On-Site Monitor Visits), all pharmacy documentation will occur electronically in Vestigo. You must ensure you can log into Vestigo Verify, maintain your account, and bring your own computer to an off-site visit (if applicable). Any drug returns or destructions should be authorized in Vestigo Verify to serve as an electronic signature for our records. All IDS Pharmacy Policies were provided in at the time of SIV. They can be found underneath the Documents > Facility Documents of any protocol to which you have been granted access. They will not be re-distributed by e-mail or any other means.

\*\*As of March 2020, all monitoring visits will be conducted remotely. You will be given access to Vestigo for the business day (8am to 5pm) of your visit. If you require more time, please contact via e-mail or use the Contact Site option in Vestigo Verify. \*\*Temperature logs are uploaded at the end of the month, only. Partial temperature logs are not available, per Policy (see Facility Documents).

### About Vestigo

Vestigo is a software solution used by leading Investigational Drug Services to help maintain their records, track inventory, and record dispensing of investigational drugs.

### About Vestigo Verify

Vestigo Verify is the monitoring module of Vestigo. With Vestigo Verify you will be able to:

- Review the pharmacy records for approved protocol(s)
- Acknowledge inventory and dispense transactions
- Generate Drug Accountability Records
- Authorize/Cosign IP for Destruction or Return to Sponsor
- Create Action Items and Comments
- View documents

Vestigo Verify Link	<a href="https://monitor.vestigo.biz">https://monitor.vestigo.biz</a>
---------------------	---

### Access to Vestigo Verify:

- Sites will grant you access for a designated time period and may terminate your access prior to the end date. Please contact the site if you have any questions or concerns about your access.
- Your username is the email address you provide to the site across all Vestigo clients. Your email will be attached to all actions completed and serves as your electronic signature.
- Generate Drug Accountability Records
- An initial password will be assigned to you. By logging in, you can manage your information, account settings, and password in "My Account."
- For forgotten passwords, click the "Reset Password" link at the login screen and enter your email address.

### Help and Assistance

- For more details on the full functionality of Vestigo Verify, please visit the Vestigo Verify Help Center and refer to the User Manuals. Vestigo Verify support is also available at [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com).



## Monitor Requested Visit Via Site Availability: Accepted



Monitor: Andrew Jonathan (here) - andrewjonathan@gmail.coz  
 IDS Monitor Contact: Testing (IDS@IDS.cov)

You have been scheduled and granted access for a monitor visit in Vestigo Verify at Barrie IDS for Protocols:

- CL-Paxerol-002|P789

Your UserName	Visit Type / Purpose	Added By	Visit Start and End	Access Begin and End
andrewjonathan@gmail.coz	Remote with Assistance - Close Out Visit	Barrie Gura	10/26/2020 10:00:00 AM through 10/26/2020 1:00:00 PM	10/20/2020 8:00:00 AM through 10/21/2020 10:00:00 AM

-Per SOP (reference IDS Pharmacy Policy 1.2: On-Site Monitor Visits), all pharmacy documentation will occur electronically in Vestigo. You must ensure you can log into Vestigo Verify, maintain your account, and bring your own computer to an off-site visit (if applicable) -Any drug returns or destructions should be authorized in Vestigo Verify to serve as an electronic signature for our records. -All IDS Pharmacy Policies were provided in at the time of SIV. They can be found underneath the Documents > Facility Documents of any protocol to which you have been granted access. They will not be re-distributed by e-mail or any other means.

\*\*As of March 2020, all monitoring visits will be conducted remotely. You will be given access to Vestigo for the business day (8am to 5pm) of your visit. If you require more time, please contact via e-mail or use the Contact Site option in Vestigo Verify. \*\*Temperature logs are uploaded at the end of the month, only. Partial temperature logs are not available, per Policy (see Facility Documents).

### About Vestigo

Vestigo is a software solution used by leading Investigational Drug Services to help maintain their records, track inventory, and record dispensing of investigational drugs.

### About Vestigo Verify

Vestigo Verify is the monitoring module of Vestigo. With Vestigo Verify you will be able to:

- Review the pharmacy records for approved protocol(s)
- Acknowledge inventory and dispense transactions
- Generate Drug Accountability Records
- Authorize/Cosign IP for Destruction or Return to Sponsor
- Create Action Items and Comments
- View documents

### Vestigo Verify Link

<https://monitor.vestigo.biz>

### Access to Vestigo Verify:

- Sites will grant you access for a designated time period and may terminate your access prior to the end date. Please contact the site if you have any questions or concerns about your access.
- Your username is the email address you provide to the site across all Vestigo clients. Your email will be attached to all actions completed and serves as your electronic signature.
- Generate Drug Accountability Records
- An initial password will be assigned to you. By logging in, you can manage your information, account settings, and password in "My Account."
- For forgotten passwords, click the "Reset Password" link at the login screen and enter your email address.

### Help and Assistance

- For more details on the full functionality of Vestigo Verify, please visit the Vestigo Verify Help Center and refer to the User Manuals. Vestigo Verify support is also available at [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com).



## Monitor Requested Visit Via Site Availability: Rejected



Monitor: Jonathan Andrew (Company Name) - jonathanandrew@gmail.com  
IDS Monitor Contact: Demo3 (IDS@IDS.gov)

Your visit request to Demo3 for Protocol PALABA 2017-004543-20|P3225 has been rejected.

The site has responded with:

"We will follow up with you about a future date and time for access. Thank you"

### About Vestigo

Vestigo is a software solution used by leading Investigational Drug Services to help maintain their records, track inventory, and record dispensing of investigational drugs.

### About Vestigo Verify

Vestigo Verify is the monitoring module of Vestigo. With Vestigo Verify you will be able to:

- Review the pharmacy records for approved protocol(s)
- Acknowledge inventory and dispense transactions
- Generate Drug Accountability Records
- Authorize/Cosign IP for Destruction or Return to Sponsor
- Create Action Items and Comments
- View documents

Vestigo Verify Link

<https://monitor.vestigo.biz>

### Access to Vestigo Verify:

- Sites will grant you access for a designated time period and may terminate your access prior to the end date. Please contact the site if you have any questions or concerns about your access.
- Your username is the email address you provide to the site across all Vestigo clients. Your email will be attached to all actions completed and serves as your electronic signature.
- Generate Drug Accountability Records
- An initial password will be assigned to you. By logging in, you can manage your information, account settings, and password in "My Account."
- For forgotten passwords, click the "Reset Password" link at the login screen and enter your email address.

### Help and Assistance

- For more details on the full functionality of Vestigo Verify, please visit the Vestigo Verify Help Center and refer to the User Manuals. Vestigo Verify support is also available at [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com).



The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreadie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreadie Group, Inc.

## Verify: Logging In and Out

---

A monitor can see all of their protocol visits at one site <https://monitor.vestigo.biz>.

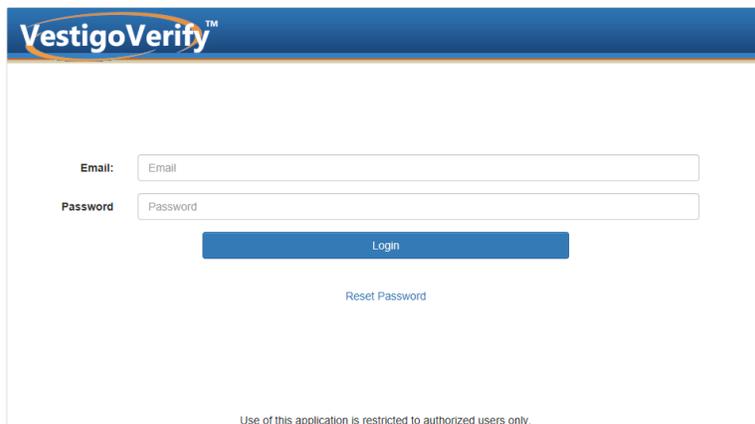
An External monitor's login will be their email address.

Vestigo will generate a random password. This password can be changed by going to the My Account link.

This username and password will grant access for the monitor to login at any time to view details such as past and upcoming visits.

Access to a protocol is only granted by a site and will only be available during the dates and times set by the site. When access ends, either by the site or expired, the monitor will no longer access the protocol.

Access can be extended by contacting the site directly. The McCreddie Group (support) does not grant access to monitors.



The screenshot shows the login interface for VestigoVerify. At the top left is the VestigoVerify logo. Below it, there are two input fields: one labeled 'Email:' with 'Email' as a placeholder, and another labeled 'Password' with 'Password' as a placeholder. A blue 'Login' button is positioned below the password field. Below the button is a blue link labeled 'Reset Password'. At the bottom of the page, there is a small disclaimer: 'Use of this application is restricted to authorized users only.'

When you are finished using Vestigo, be sure to click the Log Out on the menu bar (upper right-hand corner).

Logging out will prevent anyone else from using your session.

The organization will close the visit/access session which will revoke the access granted.

If you are an internal reviewer/auditor, your access granted is whatever is determined by the organization.

## External Monitors: Resetting a Password

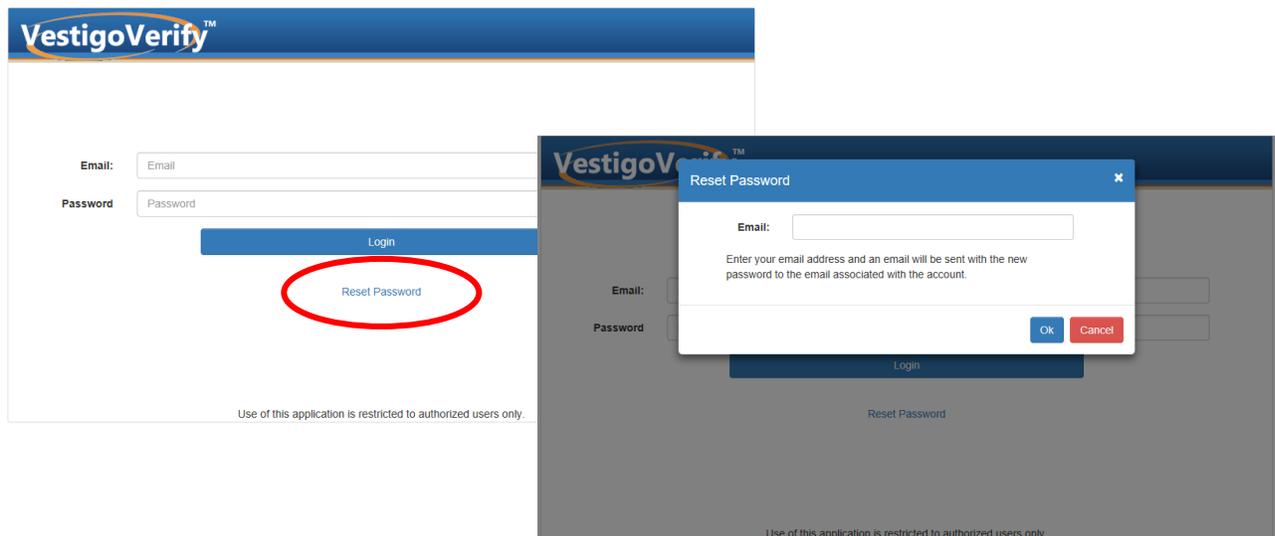
To reset your password (forgot your password) select the “Reset Password” link found on the login screen. Enter the email address associated with your account.

The system will generate a random password and send it to the users email address. To change the system generated password to My Account. If the email with the reset password is not received, see the section “Receiving McCreddie Group Emails” below.

When the email with the password is received, we suggest closing the browser, locate the link to the website in the email, and select that link to open Vestigo Verify. This will ensure the link is not cached with old or prior information.

Users can also clear the cache and/or do not use previously created favorites or links if the password has been changed.

While monitors may be defaulted to use certain browser(s), we recommend Chrome, Firefox, and Edge as these options are more user-friendly.



## Receiving McCreadie Group Emails

---

If emails from Vestigo are not received there may be a few reasons why this is occurring. Emails are automatically sent via support@mccreadiegroup.com and support@vestigo.biz. These may need to be added to organizations list of acceptable email domains (“whitelisted”).

If you are having issues receiving emails, please contact your IT and request that support@mccreadiegroup.com and support@vestigo.biz are whitelisted. There may be an add-on to the @vestigo.biz email showing up as an email from "email-od.com". You can advise their IT to whitelist using our friendly from address "support@vestigo.biz" plus the Source IP for the email delivery service should be: Source IP: s1-ba2f.socketlabs.email-od.com[142.0.186.47] or create a "rule" or "exception" that if the firewall sees email.od.com plus the @vestigo.biz, to whitelist it.

The McCreadie Group will work with the appropriate IT resources to get these emails recognized as “safe” emails.

If the email associated with the visit/access is incorrect, please contact the site, they can add a new account with the correct email address.

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreadie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreadie Group, Inc

## Verify Tabs

When the monitor logs in, they are provided a view of their past, current and future visits.

Once you have selected a protocol, the Protocol Header contains the Protocol Title, the Primary Investigator, and the Protocol Numbers.

**VestigoVerify** My Account | Help Center | About | Log Out  
Jonathan Andrew (jonathanandrew@gmail.coz) 213-908-8333  
Company Name

My Visits | My Protocols | My Calendar | My Visit Notes | My Communication History

Home / Visit

**Visit #41068: Springfield General Hospital**  
 Access Dates/Times: 10/23/2020 9:48 - 10/30/2020 20:00EDT (Ends in 2 days)  
 For Assistance for this visit, contact bgura@mccreadiegroup.coz

**Notes:** -Per SOP (reference IDS Pharmacy Policy 1.2: On-Site Monitor Visits), all pharmacy documentation will occur electronically in Vestigo. You must ensure you can log into Vestigo Verify, maintain your account, and bring your own computer to an off-site visit (if applicable) -Any drug returns or destructions should be authorized in Vestigo Verify to serve as an electronic signature for our records. -All IDS Pharmacy Policies were provided in at the time of SIV. They can be found underneath the Documents > Facility Documents of any protocol to which you have been granted access. They will not be re-distributed by e-mail or any other means.

**Logistic Notes:** \*\*As of March 2020, all monitoring visits will be conducted remotely. You will be given access to Vestigo for the business day (8am to 5pm) of your visit. If you require more time, please contact via e-mail or use the Contact Site option in Vestigo Verify. \*\*Temperature logs are uploaded at the end of the month, only. Partial temperature logs are not available, per Policy (see Facility Documents).

Protocol	Title	Lead Sponsor	
10-27-29 - P3231	FLUAD vs. FLUZONE HD Influenza Vaccine in Residents of Long Term Care	David H. Canaday	<a href="#">View Protocol</a>

**VestigoVerify** My Account | Help Center | About | Log Out  
Jonathan Andrew (jonathanandrew@gmail.coz) 213-908-8333  
Company Name

My Visits | My Protocols | My Calendar | My Visit Notes | My Communication History

Home / Visit / Protocol

**Protocol Numbers:** 10-27-29 | P3231 **PI:** Test User

**Title:** FLUAD vs. FLUZONE HD Influenza Vaccine in Residents of Long Term Care

**Visit Summary Report:** Visit #41068 - Visit Start: 10/23/2020 - Monitor: Andrew, Jonathan [View](#)

Protocol | **Inventory** | Returns | Documents | Accountability | Visit Notes | Monitor Review | AuditLog | Temperature Documents | Reports

<b>Protocol Status:</b>	Recruiting
<b>Lead Sponsor:</b>	David H. Canaday
<b>Phase:</b>	Phase 4
<b>Intervention Type:</b>	Drug
<b>Study Design:</b>	Observational Model: Allocation: Randomized Intervention Model: Parallel Assignment Primary Purpose: Treatment Masking: Single (Outcomes Assessor)
<b>Facilities:</b>	Cancer Center Pharmacy, IDS Pharmacy
<b>Summary:</b>	Adjuvanted flu vaccine, Fluad, is not immunologically inferior to HD influenza vaccine in older persons living in long-term care.

This is the main view of the protocol which consists of eight pieces of information:

- Protocol Status
- Lead Sponsor
- Phase



Intervention Type  
Study Design  
Facilities  
Summary

To review the data, you may select any of the following tabs:

1. Protocol
2. Inventory
3. Returns
4. Documents (sectioned as is Vestigo)
5. Accountability
6. Visit Notes
7. Monitor Review
8. Audit Log
9. Temperature Documents
10. Reports

The reports generate as a PDF document.

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreadie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreadie Group, Inc

## Verify Accountability Logs (DARF)

Vestigo manages the inventory electronically and creates drug accountability records automatically. There are multiple accountability form layouts.

To generate an accountability form, select the drug, then the format you wish to use. The IDS can preselect the format to generate the DARF, however, the format can still be changed.

The DARF selected will determine which fields are filterable and will display on the DARF. While one can select these filters, it is not necessary to generate the DARF.

The Monitor Review DARF will have the monitor's username in the verification column on the far right.

The site can pre-select some filters including blinding PSNs and to include cycle counts and temperature excursions. A few things to note:

- 1) Blinding the PSNs on the DARF does NOT fully blind a monitor; they can still potentially see PSN on another screen or report
- 2) Depending on other settings established by the site, pre-selecting or checking to include temperature excursions and cycle count may or may not display these transactions. If these do not show, please note, this is not an error but determined by these other settings.
- 3) If selections are pre-set by the site, the monitor cannot uncheck certain boxes.

Monitors can contact the site to discuss any questions.

Protocol Numbers: STRA-BLU-2020 | P496 PI: Chad Adams  
Title: An open-label, randomized trial to assess the effects of freeze-dried strawberry and blueberry tablets vs. intravenous Gatorade on time to re-hydration in athletes ages 18 to 21

Protocol Inventory Returns Documents **Accountability** Visit Notes Monitor Review AuditLog Temperature Logs Reports

Drug Strawberry 100mg Tablets (#30 tablets/bottle) v  
Form IDS Oral v  
Date: 04/06/2020 To 07/01/2020  
Subject None selected v Inventory None selected v  
Location All selected (3) v  
Include Temperature Excursions  Include Subject and Inventory Returns   
Blind PSNs  Include Cycle Counts   
Generate Accountability Record

We do not recommend selecting a patient if the inventory is not patient specific. If you do select a patient, and the inventory is general inventory, the balance/balance forward will be blank. This will also be true if the drug is a dispense only drug.

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreadie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreadie Group, Inc

## Verify Inventory

The inventory tab displays the drug(s) in the protocol. All Inventory transaction detail can be viewed for all drugs with Full inventory tracking selected on the drug build.

On these screens, please use the arrows located in the blue banner to the left of the header title to navigate and switch options.

[My Account](#) | [Help Center](#) | [About](#) | [Log Out](#)  
 Jonathan Andrew (jonathanandrew@gmail.coz) 213-908-8333  
 Company Name

My Visits
My Protocols
My Calendar
My Visit Notes
My Communication History

[Home](#) / [Visit](#) / [Protocol](#)

**Protocol Numbers:** 10-27-29 | P3231
PI: Test User

**Title:** FLUAD vs. FLUZONE HD Influenza Vaccine in Residents of Long Term Care

**Visit Summary Report:**

Visit #41089 - Visit Start: 10/26/2020 - Monitor: Andrew, Jonathan

View

Protocol
Inventory
Returns
Documents
Accountability
Visit Notes
Monitor Review
AuditLog
Temperature Documents
Reports

▼
Drugs

Drug	Dose Amt/Units	Inventory Units	QOH	
Fluad	0.5 ML	SYRINGE	9	<a href="#">Add Visit Note</a> <span style="float: right;"><a href="#">Show Visit Notes (1)</a></span>
Fluzone HD	0.5 ML	SYRINGE	6	<a href="#">Add Visit Note</a>

Select the drug name for which you want to view all inventory. To return to the list of drugs on the protocol, select the arrow next to Drugs.

**Protocol Numbers:** 10-27-29 | P3231
PI: Test User

**Title:** FLUAD vs. FLUZONE HD Influenza Vaccine in Residents of Long Term Care

**Visit Summary Report:**

Visit #41095 - Visit Start: 10/27/2020 - Monitor: Andrew, Jonathan

View

Protocol
Inventory
Returns
Documents
Accountability
Visit Notes
Monitor Review
AuditLog
Temperature Documents
Reports

▶
Drugs

Drug	Dose Amt/Units	Inventory Units	QOH	
Fluad	0.5 ML	SYRINGE	9	<a href="#">Add Visit Note</a> <span style="float: right;"><a href="#">Show Visit Notes (1)</a></span>

▼
Inventory for Fluad
▼

Show only inventory with a QOH greater than zero

ID	Location	←Lot Number	←Item	QOH	Expiration	Manufacturer	Unit	Patient-Specific
5433	Refrigerator A	H724032		9	1/1/2025	Genlabs	SYRINGE	<a href="#">Add Visit Note</a> <span style="float: right;"><a href="#">Show Visit Notes (3)</a></span> <span style="float: right; font-size: 0.8em;"><a href="#">View Transactions</a></span>

### Inventory with a quantity on hand (QOH) of 0

To only see inventory on hand that is greater than 0, click the funnel on the right side, and then check the box to see only inventory on hand greater than 0.

Inventory for Fluvad

Show only inventory with a QOH greater than zero

### Viewing transactions at an inventory specific level

To view transactions at an inventory level (lot specific or lot/item specific), select the link “View Transactions” on the right. The transaction detail will display below the Inventory field with the details such as date, transaction type, prescription details, comments, and user who completed that transaction.

Protocol | Inventory | Returns | Documents | Accountability | Visit Notes | Monitor Review | AuditLog | Temperature Documents | Reports

Drugs

Drug	Dose Amt/Units	Inventory Units	QOH
Fluvad	0.5 ML	SYRINGE	9

Inventory for Fluvad

Show only inventory with a QOH greater than zero

ID	Location	Lot Number	Item	QOH	Expiration	Manufacturer	Unit	Patient-Specific
5433	Refrigerator A	H724032		9	1/1/2025	Genlabs	SYRINGE	

View Transactions

Transactions for Refrigerator A - H724032

Service Date	Txn ID	Quantity	Transaction	Prescription	Reason	Comments	User
10/23/2020 5:40	9370	12	Receive				bgura
10/23/2020 6:26	9372	-1	Dispense	4064-0			bgura
10/26/2020 13:56	9378	-1	Dispense	4066-0			bgura
10/26/2020 14:42	9379	-1	Dispense	4067-0			techb

### To View Other Inventory

To view other inventory of that drug, click the arrow next to Inventory for that drug, and other inventory will present.

Protocol | Inventory | Returns | Documents | Accountability | Visit Notes | Monitor Review | AuditLog | Temperature Documents | Reports

Drugs

Drug	Dose Amt/Units	Inventory Units	QOH
Fluvad	0.5 ML	SYRINGE	9
Fluzone HD	0.5 ML	SYRINGE	6

Inventory for Fluvad

Show only inventory with a QOH greater than zero

ID	Location	Lot Number	Item	QOH	Expiration	Manufacturer	Unit	Patient-Specific
5433	Refrigerator A	H724032		9	1/1/2025	Genlabs	SYRINGE	

## To View Other Drugs on the Protocol

To view transactions on another drug on the protocol, click the arrow next to Drugs.

Protocol **Inventory** Returns Documents Accountability Visit Notes Monitor Review AuditLog Temperature Documents Reports

▼ Drugs

Drug	Dose Amt/Units	Inventory Units	QOH		
Fluad	0.5 ML	SYRINGE	9	<a href="#">Add Visit Note</a>	<a href="#">Show Visit Notes (1)</a>
Fluzone HD	0.5 ML	SYRINGE	6	<a href="#">Add Visit Note</a>	

▼ Inventory for Fluad

Show only inventory with a QOH greater than zero

ID	Location	Lot Number	Item	QOH	Expiration	Manufacturer	Unit	Patient-Specific
5433	Refrigerator A	H724032		9	1/1/2025	Genlabs	SYRINGE	<a href="#">Add Visit Note</a> <a href="#">Show Visit Notes (3)</a> <a href="#">View Transactions</a>

## Adding a Visit Note

To do this, select the Add Visit Note at the drug or inventory level. Enter the Note using one of two options:

1. Visit Action Item
2. Visit Comment

Please see our manual “Verify Comments and Action Items” for more information.

Any old DARF Notes entered will still display on the DARF.

About | My Account | Log Out

VestigoVerify

Home / Visit / Protocol

Protocol Numbers: 2012-4181 | P127  
Title: Asenapine for Bipolar Depression

Save Cancel

Protocol Inventory Returns Documents Accountability Visit Notes Monitor Review AuditLog

Drugs

Drug	Dose Amt/Units	Inventory Units	QOH	
Asenapine 10 mg	10 MG	BOX	26	Add DARF Note
Asenapine 5 mg	5 MG	TAB	0	Add DARF Note

Inventory for Asenapine 10 mg

10 Records Per Page < 1 2 >

ID	Location	Lot Number	Item	QOH	Expiration	Supplier	Unit	Patient-Specific	
3384	Barries shelf 123	A123456	1	0	12/30/2017	Abbott Laboratories	BOX		Add DARF Note View Transactions
3388	Barries shelf 123	B123456	1	1	12/30/2017	Abbott Laboratories	BOX		Add DARF Note View Transactions

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreddie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreddie Group, Inc

## Verify Returns

Drug returns is a special virtual inventory location that is used to manage drug return data. There are two sources of returns. The first is returns from patients where the pharmacy is tracking those returns for the monitor. The second source is from inventory adjustments which allow inventory that is expired or otherwise unused to be managed in drug returns. Inventory that are quarantined will also be displayed on this screen.

There are two functions of returns for a monitor –

- Authorizing a destruction or return to sponsor on a returned/quarantined item
- Cosigning a completed destruction or return to sponsor on a returned/quarantined item.

The Returns tab provides the monitor with four dispositions of item:

- Returns
- Quarantine
- Destroyed
- Returned to Sponsor

### Authorizing a destruction or return to sponsor

A monitor can authorize returned or quarantined item(s) to be destroyed or returned to the sponsor. When an item is authorized for destruction or return to sponsor, the authorization username/time/date stamp will appear on the pharmacy’s Manage Drugs screen stating the action authorized. The pharmacy does the final disposition of the drug. Once they have completed the action, the item will move from returns or quarantine to either “Destroyed” or “Returned to Sponsor” tab on both the pharmacy and monitor view. Destructions can also be witnessed by a pharmacy member and a Certificate of Destruction can be created by the pharmacy team. This information will appear on the DARF as well.

To begin, select a drug from the dropdown

Protocol Numbers: STRA-BLU-2020 | P496      PI: Chad Adams  
**Title:** An open-label, randomized trial to assess the effects of freeze-dried strawberry and blueberry tablets vs. intravenous Gatorade on time to re-hydration in athletes ages 18 to 21

Protocol   Inventory   **Returns**   Documents   Accountability   Visit Notes   Monitor Review   AuditLog   Temperature Logs   Reports

Drug

Select Drug  
 Strawberry 100mg Tablets (#30 tablets/bottle)  
 Blueberry 50mg Tablets (#100 tablets/bottle)  
 Gatorade 100mg/10mL Vial

If there is no inventory in that disposition, the screen will indicate “Sorry your search returned no results”.

Returns   Quarantine   Destroyed   Returned to Sponsor

Transactions

<input type="checkbox"/>	Return Date	<input checked="" type="checkbox"/> Lot	<input checked="" type="checkbox"/> Item	Qty	Unit	Source	Return Comments	Returned	Authorized
Sorry your search returned no results									

If there is inventory, the screen will display that data.

Returns **Quarantine** Destroyed Returned to Sponsor

Transactions									
<input type="checkbox"/>	Quarantined Date	<input checked="" type="checkbox"/> Lot	<input checked="" type="checkbox"/> Item	Qty	Unit	Source	Return Comments	Quarantined	Authorized
<input type="checkbox"/>	5/18/2020	873AN	X1	1	BOTL	Inventory		bgura 5/18/2020 16:00EDT	

After selecting a drug from the dropdown list, select the “Returns” or “Quarantine” tab to view specific items to authorize an action. Select the inventory (check the boxes next to the piece of inventory) and select either Authorize Destruction or Authorize Return to Sponsor. Doing this will trigger a new window to add comments and/or an authorization number for that action. If no comment is needed, select save.

To make finding items in returns easier, lot and item number columns are sortable. There is also a limit to the number of transactions on each page. The user can navigate from page to page as well determine how many transactions can be displayed on each screen.

**Add Authorize Destruction Information** ✕

**Destruction Authorization Number:**

Enter the Site Destruction Number or leave blank if none. Click Save.

**Notes:**

Enter your notes or leave blank. Click Save.

**Add Return to Sponsor Information** ✕

**Return Shipment Number:**

Enter the Return Shipment Number or leave blank. Click Save.

**Notes:**

Enter your notes or leave blank. Click Save.

### Cosigning a completed destruction or item returned to sponsor

When the pharmacy has completed the action on the item to destroy or return to sponsor, the item will move from the return or quarantine tab to either the Destroyed or Returned to Sponsor tab. At this time, the monitor can select the item(s) and cosign the appropriate action has been completed.

If the pharmacy has placed an item into destroyed or returned to sponsor without authorization from a monitor, the monitor cannot perform an authorization, but can cosign the action has been completed.

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreddie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreddie Group, Inc

## Verify Documents

Documents can be attached to protocols by the IDS and can be made available to view in the monitor module.

The monitor view of documents is broken down by groupings like the Vestigo side is.

The screenshot shows a navigation bar with 'Home / Visit / Protocol'. Below it, protocol details are listed: 'Protocol Numbers: STRA-BLU-2020 | P496' and 'PI: Chad Adams'. The title describes a trial on freeze-dried strawberry and blueberry tablets. A menu is open over the 'Documents' tab, listing 'Protocol Documents', 'Transaction Documents', 'Facility Documents', and 'Competency Documents'. Below the menu, 'Facilities' and 'Summary' are visible, including 'Cancer Center Pharmacy, IDS Pharmacy' and a study description.

If a document is not visible, please contact the site directly. The site can assist in this matter.

For receive documents uploaded prior to July 2020:

- If the document source was “Transaction” (uploaded directly on the Receive screen), the document is now housed in Transaction Documents > Historical Shipment Receipts.
- If the document source was “Protocol” (uploaded via Edit Protocol > Documents), the document is now housed in Protocol Documents > Historical Shipment Receipts.

Documents added to a Receive as of July 2020, are housed on the Transaction Documents tab in Shipment Receipts.

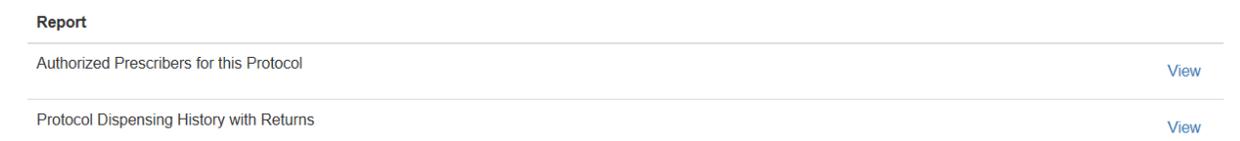
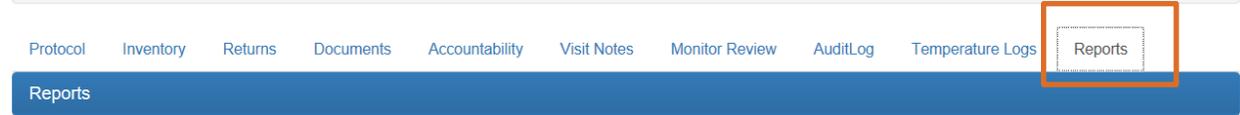
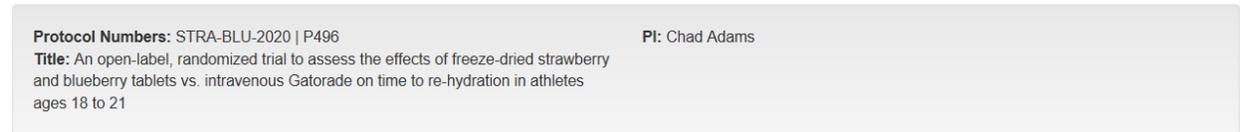
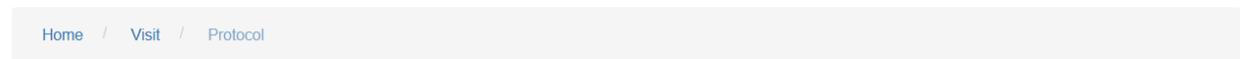
Temperature Documents are available on the tab labelled, Temperature Documents. This section will include any temperature documents have been uploaded by the site for the inventory locations where inventory for your study has been stored.

In order to see temperature documents, you may need to open the beginning date field to that date the site has used when uploading documents.

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreddie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreddie Group, Inc

## Verify Monitor Reports

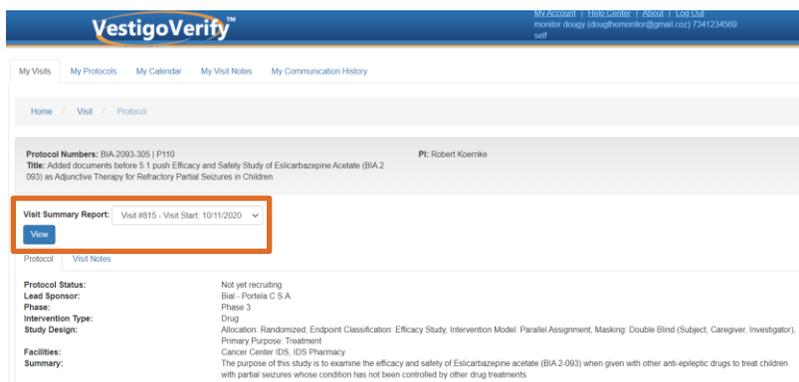
Once you have selected a protocol, the Protocol Header contains the Protocol Title, the Primary Investigator, and the Protocol Numbers.



On the Verify Reports tab, monitors can download two reports: Authorized Prescribers for the Protocol and Protocol Dispensing History with Returns. The reports generate as a PDF document.

We have also added a Visit Summary Report which includes:

1. Returns that have been authorized and/or cosigned by the monitor
2. Any Action Items entered by the monitor
3. Any Comments entered by the monitor



The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreadie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreadie Group, Inc

## Verify Temperature Documents

Sites have the ability to upload temperature related documents associated with a date and inventory location. These documents include Logs, Calibration Certificates, Communications, Temperature Excursions, and Other.

The system will automatically provide access to the monitor and other reviewers without additional steps by the user or site.

If the study has inventory in an inventory location and there is a temperature document associated with that location, the monitor will have access to those documents. This is also true for any locations where inventory was stored, but not currently.

Documents will be stored by a date range and location.

Select the View link to download the document. Once downloaded, monitors and read only users can save or print them.

Protocol   Inventory   Returns   Documents   Accountability   Visit Notes   Monitor Review   AuditLog   **Temperature Logs**   Reports

Date:  To:

Location:

Temperature Logs				
	Temp Log Start Date	Temp Log End Date	Location	Last Modified
<a href="#">View Files</a>	January 1, 2020 12:00 am	December 31, 2020 12:00 am	IDS Drawer A	rasystem (April 30, 2020 1:57 pm EDT)
<a href="#">View Files</a>	January 1, 2020 12:00 am	December 31, 2020 12:00 am	IDS Drawer B	rasystem (April 23, 2020 2:18 pm EDT)
<a href="#">View Files</a>	January 1, 2020 12:00 am	December 31, 2020 12:00 am	IDS Drawer A	rasystem (April 23, 2020 2:17 pm EDT)

File Name	Certified	File Create User/Date	
2020.04.docx		rasystem (April 23, 2020 2:18 pm EDT)	<a href="#">View</a>

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreadie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreadie Group, Inc

## Verify Comments and Action Items

The COVID pandemic has accelerated remote monitoring of investigational drug products. Communication of action items is more critical than ever since face to face meetings are less frequent.

To help streamline communications from monitor to site, and site to monitor, Vestigo Verify provides the monitor the ability to document Comments and Action Items which require pharmacy follow up.

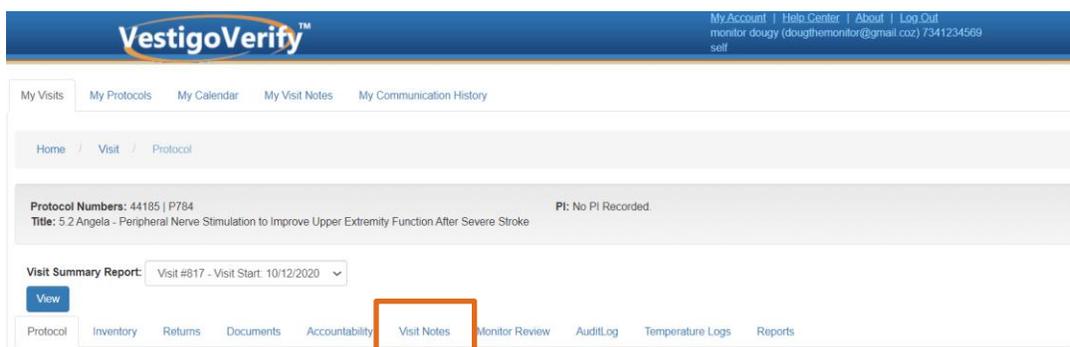
During access to the protocol, the monitor can enter:

- Comments: A narrative message regarding the visit
- Action Item: A question or request the site must respond to

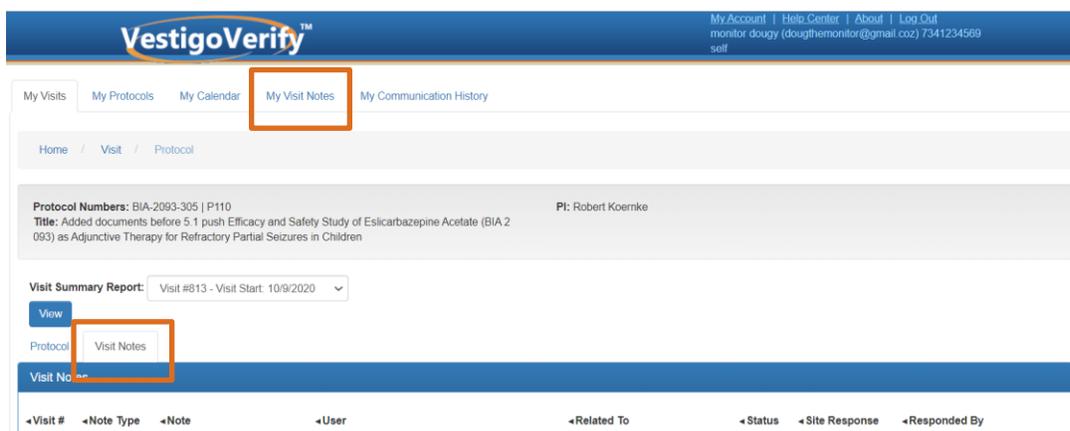
Once an Action Item is entered by the monitor, the pharmacy will be alerted to the action item in their alert queue (corresponding with the Main Facility listed on the protocol). Users can reply through the alert or on the protocol Monitor Visit tab about the requested documentation or information.

In Vestigo Verify, an ongoing list of items and comments can be found in two places:

1. During access window, the monitor can view study specific items and comments on the protocol tabs, Visit Notes.



2. After access window, the monitor can review items and comments through the Visit Summary and/or on the My Visit Notes. The Visit Summary Report will also have this information.



If the access is still open, the monitor can complete Action Items on the protocol Visit Notes tab. If the access is ended, the monitor can review and complete on the My Visits tab (top of the screen). If



additional action is needed, the site will need to extend the existing visit or open a new visit and access for the monitor to respond or enter a new Action Item.

With access open, the monitor can edit the Action Item and change the status to "Removed" as long as the site has not responded to it.

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreddie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreddie Group, Inc

## Verify Audit Log

The Audit Log tab provides the monitor with a date range specific detail of any changes on the protocol related to 21 CFR Part 11 Regulation. These changes can be viewed in their entirety or by selecting a particular section.

**Protocol Numbers:** STRA-BLU-2020 | P496 **PI:** Chad Adams

**Title:** An open-label, randomized trial to assess the effects of freeze-dried strawberry and blueberry tablets vs. intravenous Gatorade on time to re-hydration in athletes ages 18 to 21

Protocol   Inventory   Returns   Documents   Accountability   Visit Notes   Monitor Review   **AuditLog**   Temperature Logs   Reports

**Section:** All    **Start Date:** 04/01/2020    **Through:** 07/01/2020

There are four sections of the Audit Log

- Inventory
- Patients
- Prescriptions/Fills
- Protocols/Arms/Drugs

There is also a Monitor Activity Audit Log available to the site. This provides the site visibility to the monitors activities and actions.

The information in this document is confidential for use by the Vestigo client and monitors who are granted access to Vestigo and should not be disclosed to any other person. The information contained therein may not be disclosed without the prior consent of the McCreddie Group, Inc. A recipient may not solicit, directly or indirectly (whether through an agent or otherwise) the participation of another institution or person without the prior approval of the McCreddie Group, Inc

## FAQ'S for Monitor Access and Troubleshooting – January 2017

---

### Tips for Monitor Access OR Log-In Questions

Here are a few tips for monitor access or log in questions.

Q. What is the Vestigo Verify™ URL for monitors?

A. <https://monitor.vestigo.biz>

Q. Who should use this URL?

A. External Monitors should use this URL. All other Vestigo Users should use their site specific URL. Read Only users will be redirected to the Monitor URL after they log in.

Q. What URL should an internal reviewer use?

A. Internal Reviewers should use the same URL as the IDS. The read only user will be redirected the Monitor URL.

Q. What is a monitor's User Name?

A. The monitor's user name is their email address.

Q. What is an Internal Reviewer or Study Coordinator's User Name?

A. The Internal Review/Study Coordinator (read only access) user name is assigned by the site administrator.

Q. I am using Forgot Password/Reset Password but not receiving an email with a new password.

A. Vestigo Verify™ has a "Reset Password" link. The Vestigo® product has a link called "Forgot Password". Monitors need to use the URL to Vestigo Verify™, <https://monitor.vestigo.biz> for all sites, protocols, and visits.

If they are using Reset Password from the monitor URL and they are not receiving an email, three things may be happening:

- 1) They may be using the wrong email address to login/reset (do not use their old username)  
Please verify they are using the email address you used to set up their visit/access.
- 2) Their organization firewall maybe blocking our emails  
For more information about this, please see the answer for the next question: I am a monitor, why am I not receiving emails when the site opens a visit/access for me?  
If they do receive all emails, see #3
- 3) Their account may be locked  
Please have them call or email support at [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com) with their email address for us to check on the account. Only McCreadie Group Support can unlock monitor accounts. Future functionality will allow for monitor accounts to auto unlock after 5 minutes.

Q. I am a monitor, why am I not receiving emails when the site opens a visit/access for me?



A. Monitors must receive our emails. If they are not receiving emails, they need to contact their IT department. Here is some information for their IT department, however McCreadie Group support can assist if needed.

Emails are automatically sent through the system when a site opens the visit/access. The visit/access email comes from [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com). Reset password emails come from [support@vestigo.biz](mailto:support@vestigo.biz). The most common reason monitors do not receive our emails, is a monitor's company firewall is blocking our emails. The monitor must ask their IT to "whitelist" [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com) and [support@vestigo.biz](mailto:support@vestigo.biz). For [support@vestigo.biz](mailto:support@vestigo.biz) emails, there may be an add-on showing up as an email from "email-od.com". The monitor can advise their IT to whitelist using our friendly from address [support@vestigo.biz](mailto:support@vestigo.biz) plus the Source IP for the email delivery service should be: Source IP: s1-ba2f.socketlabs.email-od.com[142.0.186.47] or create a "rule" or "exception" that if the firewall sees email.od.com plus the @vestigo.biz, to whitelist it.

Q. I received the email from the site about my visit/access, but did not receive a password.

A. The only time an email will contain a password is a monitor's very first visit to Vestigo or when they do a reset password. Even if they never logged in, only the first set up email will contain a password. If you recall the password or can find that email, please use that password. If not, go to <https://monitor.vestigo.biz> and use "Reset Password". A new password will be emailed to the email address. The password in the email is not site, visit, or protocol specific. You can keep the system generated password or when you log in, change it under "My Account". This will continue to be the password you use to login.

Q. Are there any requirements when changing my password?

A. Please use at least 8 characters consisting of at least 1 uppercase and at least 1 special character

Q. I am a monitor, I can log in and see the link to View Protocols, but why do I not see a link to access the protocol(s)?

A. When the link to access a protocol is not available, one of two things may be happening:

- 1) Vestigo Verify™, requires Internet Explorer 9 or above or the most updated version of Chrome or Firefox.
- 2) The monitor access may not be current. Please ask the site to check the access date/time. If it is correct, is the computer the monitor is using on the same time zone as the Vestigo® site. If not, the visit access needs to be adjusted or the computer changed to the same time zone as the Vestigo® site.

Q. How does a monitor update their email address, phone number and company name?

A. For email address changes, please add the monitor with a new account with their new email address. Please email [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com) with the old and new email addresses, monitor's name, and indicate if this is a new company or a change to their existing email address. Because the monitor's email address is their user name and the user name is printed on documents, a change to the email address will change these documents. Future functionality will allow sites to edit email addresses.

A monitor can update their phone number under “My Account” (top right corner). This new phone number will display on the IDS side as well.

For company names, please email support with monitors name, email address and company change information. Future functionality will allow monitors to change their company name under “My Account”.

Q. How do I find documentation to understand the functionality and workflow/screens?

A. On the monitor view, under “About” (top right corner) or on the IDS view under “Help and Support” (top right corner) is a document called “Protocol Reviewer Guide”. You or the monitor can download and/or print this document. This guide is the same for Internal Reviewers and Study Coordinators, however, they have read-only access only.

If you or they continue to have issues, please contact us at *McCreadie Group Contact:*  
[support@mccreadiegroup.com](mailto:support@mccreadiegroup.com)