**User Guide**

Genomic Information System for Integrated Science 2 (Genisis2) Technical Services

Release 3



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**Artifact Rationale**

Per the Veteran-focused Integrated Process (VIP) Guide, the User’s Guide is required to be completed prior to Critical Decision Point #2 (CD2), with the expectation that it will be updated as needed. The User Guide is a technical communication document intended to give assistance to people using a particular system, such as VistA end users. It is usually written by a technical writer, although it can also be written by programmers, product or project managers, or other technical staff. Most user guides contain both a written guide and the associated images. In the case of computer applications, it is usual to include screenshots of the human-machine interfaces, and hardware manuals often include clear, simplified diagrams. The language used is matched to the intended audience, with jargon kept to a minimum or explained thoroughly. The User Guide is a mandatory, build-level document and should be updated to reflect the contents of the most recently deployed build. The sections documented herein are required if applicable to your product.

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# Introduction

## Purpose

The purpose of this guide is to familiarize users with the important features and navigational elements of Genisis2*.*

## Organization of the Manual

The User Guide provides an overview of the data management process supported by the Genisis2 application. It addresses the multiple User Roles, and describes how a user assigned to each role navigates and interacts with the application.

### Assumptions

This guide was written with the following assumed experience/skills of the audience:

Users have basic understanding of the Study Approval process, and have been assigned to at least one Approved Study in the system.

### Disclaimers

#### Software Disclaimer

*This software was developed at the Department of Veterans Affairs (VA) by employees of the Federal Government in the course of their official duties. Pursuant to title 17 Section 105 of the United States Code this software is not subject to copyright protection and is in the public domain. VA assumes no responsibility whatsoever for its use by other parties, and makes no guarantees, expressed or implied, about its quality, reliability, or any other characteristic. We would appreciate acknowledgement if the software is used. This software can be redistributed and/or modified freely if any derivative works bear some notice that they are derived from it, and any modified versions bear some notice that they have been modified.*

#### Documentation Disclaimer

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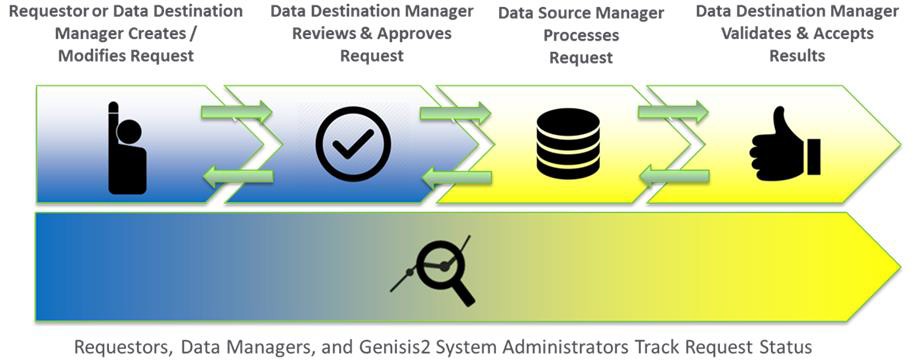
# System Summary

The Department of Veterans Affairs (VA) has established leadership in genomic medicine through the undertaking of a groundbreaking program called the Million Veteran Program (MVP). Launched in 2011, MVP invites users of the VA healthcare system nationwide to participate in a longitudinal study with the aim of better understanding the inter-relation of genetic characteristics, behaviors and environmental factors, and Veteran’s health. Today, MVP is the largest genomic research database in the world. The MVP data consists of blood samples from consenting Veterans that is used to generate genomic data, data from questionnaires and the electronic health record data. This resource is made available to VA researchers and VA- approved affiliates to pursue genomic discoveries and validation studies that can lead to personalized healthcare for Veterans. Ultimately, validated scientific findings will be returned to

the Veteran and incorporated into their medical record to fulfill the potential of personalized medicine – delivery of optimal interventions to patients based on their biological characteristics.

The primary component of the project is the Genomic Information System for Integrative Science 2 (Genisis2) platform. Genisis 1.0, implemented between 2011 and 2015, features a series of modular applications to facilitate recruitment and enrollment of MVP participants, automating most study-related logistics including study enrollment, clinical study data capture, consent, blood sample tracking, and genomic data storage. Genisis 1.0 also provides the secure analytical infrastructure necessary to conduct robust genomic and bioinformatics-related data management and data analysis. This remotely accessible analysis environment features a high performance-computing cluster with significant storage capacity and tools for scientific analysis of combined genotypic and phenotypic data.

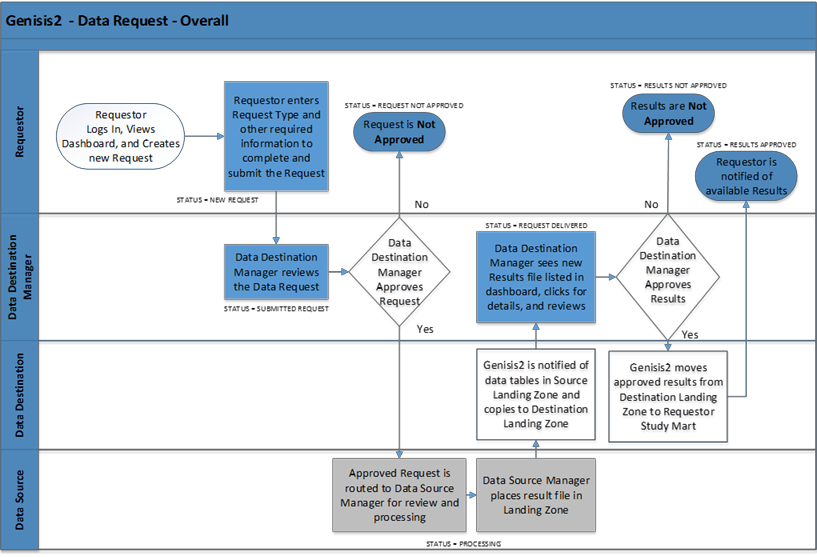
Genisis2 will provide additional functionality to the Genisis 1.0 platform by automating data processing, data request transactions, and data request tracking for integrating VA Informatics and Computing Infrastructure (VINCI) clinical data into Genisis2, as well as providing enhanced system administration.



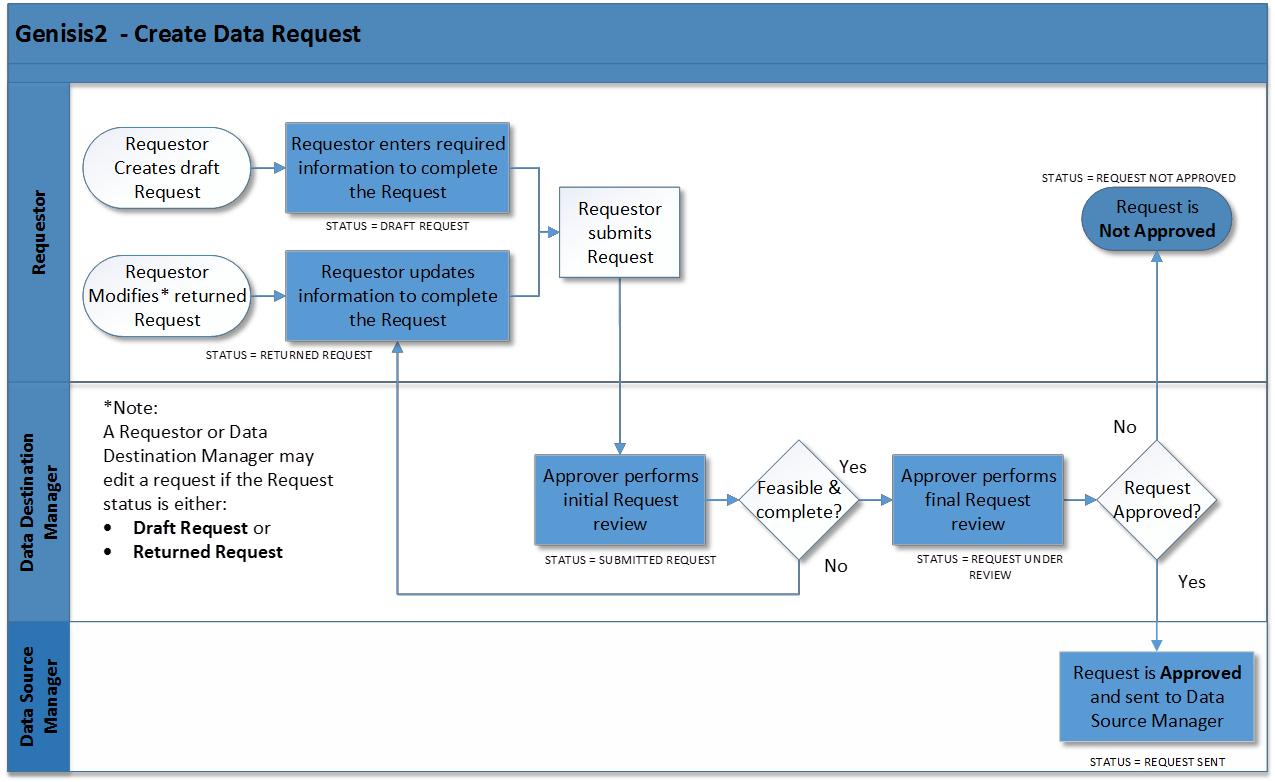
**Figure 1: High Level Genisis2 Process Flow**

## Work Flows

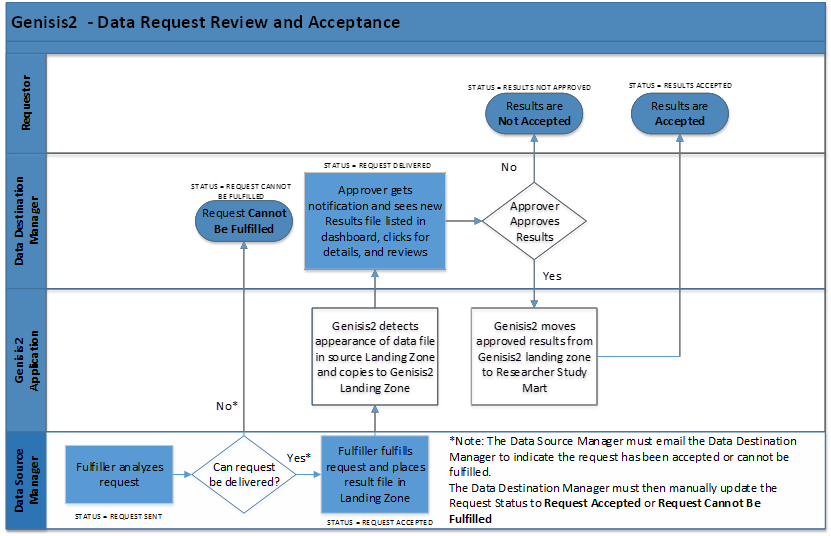
The data requests are managed, fulfilled, and tracked using a workflow management system. Figures 2, 3 and 4 depict the detailed workflow steps. Figure 5 illustrates the workflow summary.



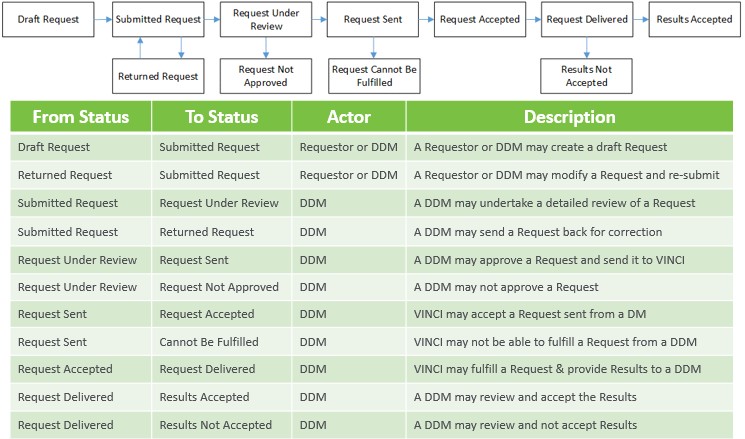
**Figure 2: Genisis2 Data Request – Overall**



**Figure 3: Genisis2 Create Data Request**



**Figure 4: Genisis2 Create Data Request Review and Acceptance**



**Figure 5: Genisis2 Work Flow Summary**

## System Configuration

The Genisis2 server architecture is shown in Figure 6.

**LDAP**

**Apache Webserver**

**SQL**

**Server 2012**

**Red Hat Enterprise Linux (RHEL)**

**Red Hat Enterprise Linux (RHEL)**

**Microsoft Windows Server**

**2008 R2**

**8080**

**REST**

**8080**

**Wildfly**

**REST**

**Wildfly**

**Services**

**JBPM**

**8080**

**REST**

**REST**

**JBPM**

**KIE REST**

**Engine**

**1433**

**8085**

**REST**

**1433**

**REST**

**10636**

**Figure 6: Genisis2 Server Architecture**

The Genisis2 Server architecture consists of the following components:

* Apache Webserver running on RHEL using Angular JS as the User Interface (UI) framework.
* Wildfly Application Server running on RHEL
* Microsoft SQL Server Database running on Microsoft Windows 2008 R2
* OpenLDAP server running on the same Microsoft Windows 2008 R2 as the SQL server above.

## User Access Levels

Genisis2 supports the following user types:

1. Requestor
2. Data Destination Manager (DDM)
3. Data Source Manager (DSM)
4. Genisis2 System Administrator (planned for a future release)

The Requestor has the minimum set of activities they can access and perform in the application. For example, the Requestor can generate and track their own data requests.

The Data Destination Manager has all the capabilities of a Requestor, but can review and approve requests, review and approve data results, and track requests more broadly.

The Data Source Manager addresses any questions about the data that they may have with the Requestor (through the Data Destination Manager and not directly), prepares and places the data in a Source landing zone database, and notifies the Data Destination Manager of its location.

The Data Destination Manager will then copy the data over from the Source landing zone database to the Destination landing zone database, extract the data to a flat file, and perform any additional cleanup that may be required. Personally Identifiable Information (PII) and Protected Health Information (PHI) information is then removed from this data and copied over to the specific Study Mart set up for the Requestor.

The Genisis2 System Administrator is a super user that has access to all of the functions that the Requestor and the Data Destination Manager have; and in addition, the Genisis2 System Administrator can Create, Modify, or Delete users. The Genisis2 System Administrator is responsible for creating a user account within Genisis2 and assigning one of the roles. The Genisis2 application then coordinates with the VA LDAP server to create and store the role information.

## Logging On

User Names and Passwords are controlled by a centralized VA LDAP access control process. Password expiration and other administrative processes are controlled by that group. Genisis2 coordinates with the local OpenLDAP server for username and password authentication.

Genisis2 user types are managed within a Genisis Local LDAP server to provide the user some functions and hide others from them. For example, a user is recognized as a Requestor, Data Destination Manager, Data Source Manager or Genisis2 System Administrator and are afforded different levels of functionality within the application.

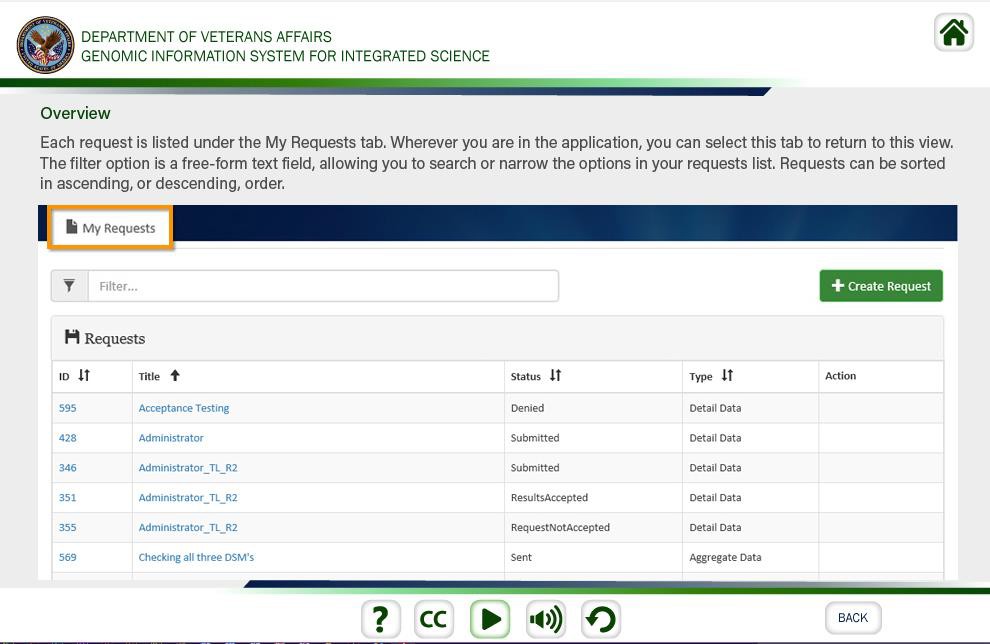
# Using the Software

This User Guide presents excerpts from the online help system that highlight screen features and explain the steps for each user type (either Requestor, Data Destination Manager, or Data Source Manager) to create, manage, and/or track a data request.

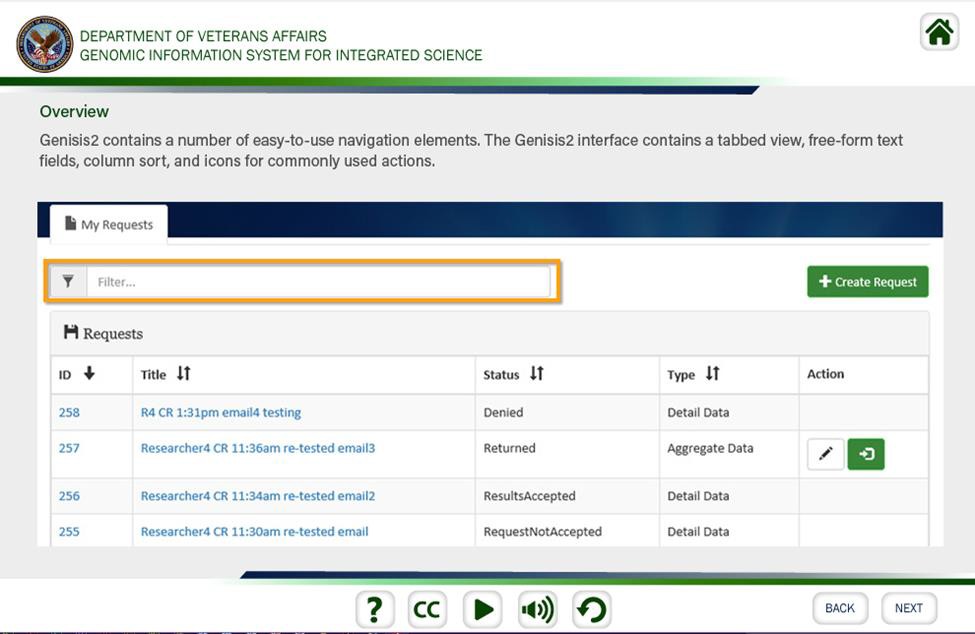
## General Overview

This section shows a general overview of screen user interface features.

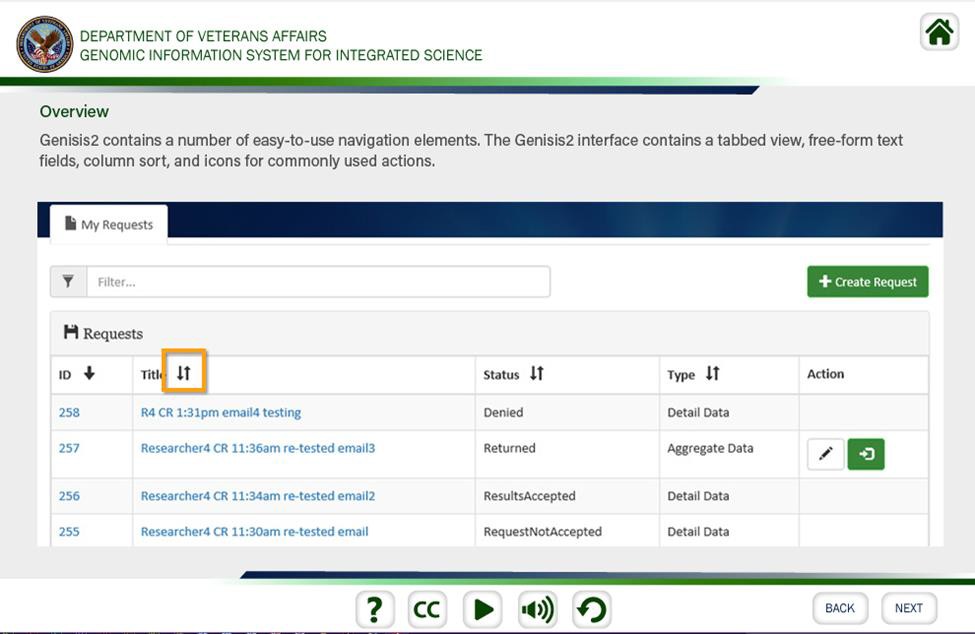
### Requestor Overview



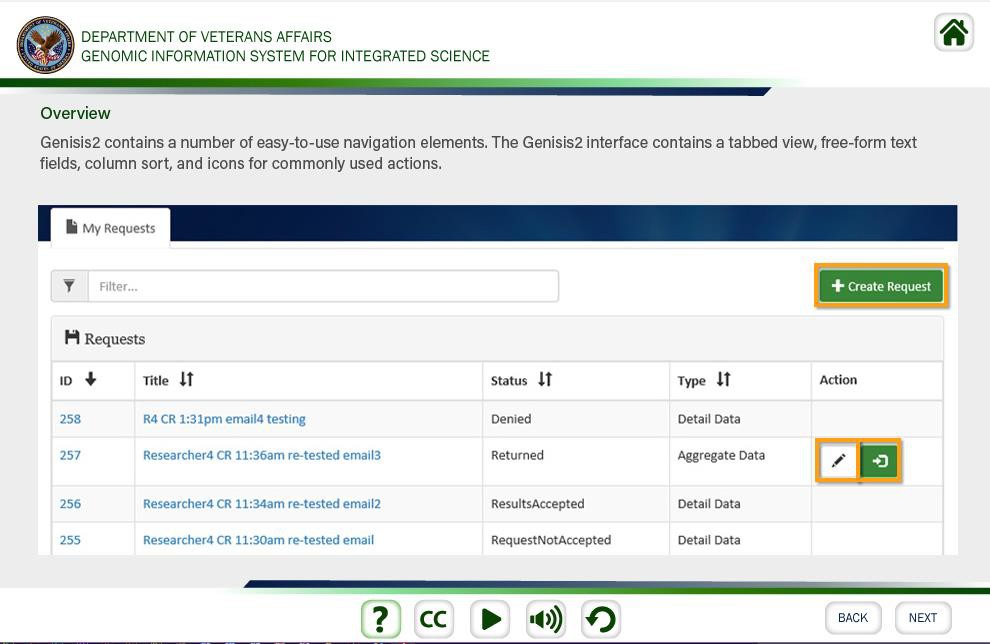
**Figure 7: Genisis2 User Interface Requestor – My Request Tab**



**Figure 8: Genisis2 User Interface Requestor – Filter**

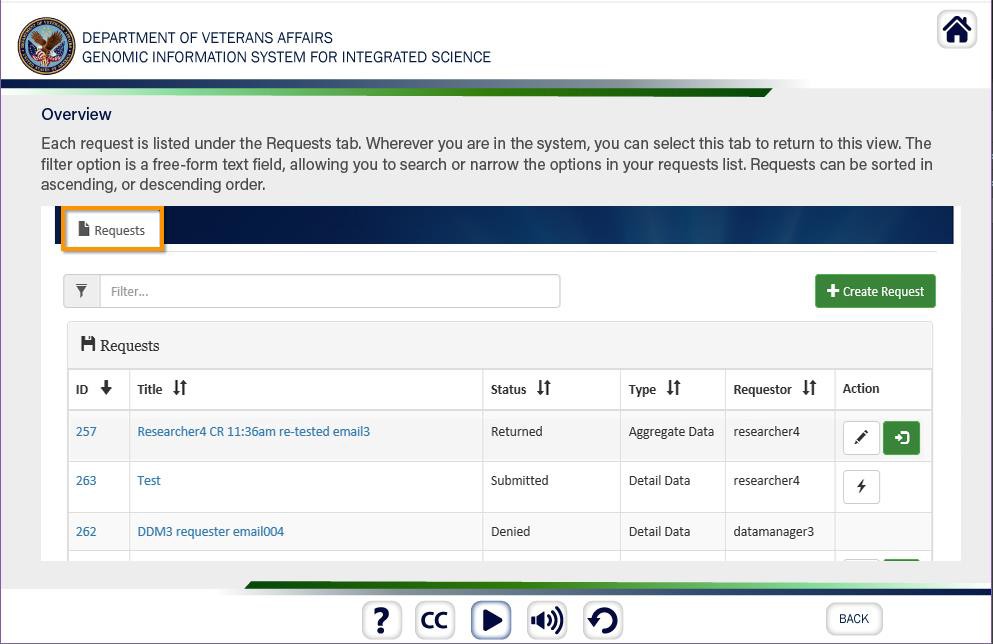


**Figure 9: Genisis2 User Interface Requestor – Column Sorting**

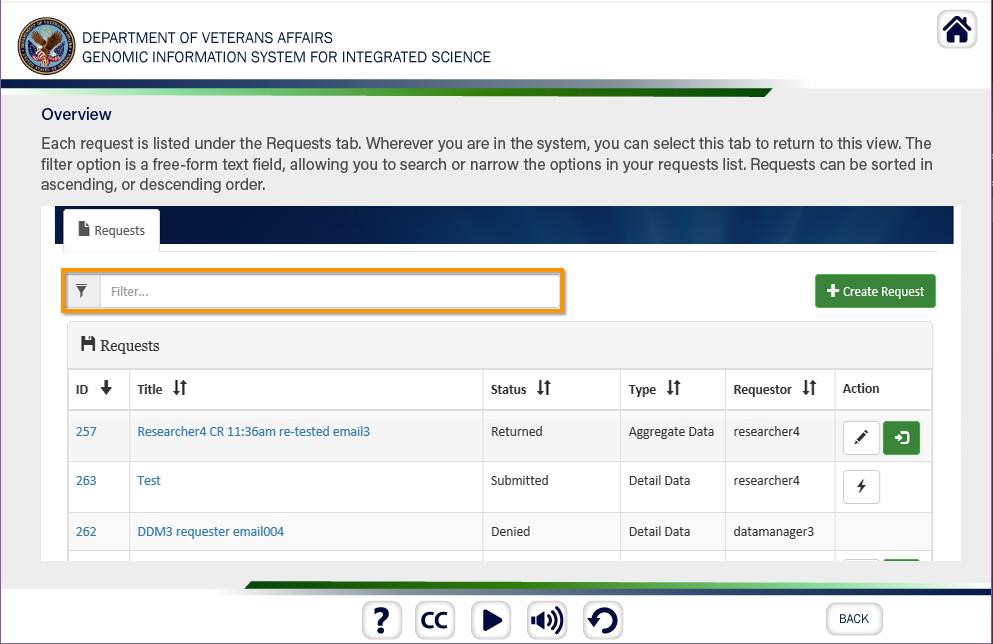


**Figure 10: Genisis2 User Interface Requestor – Action Items and Create Request**

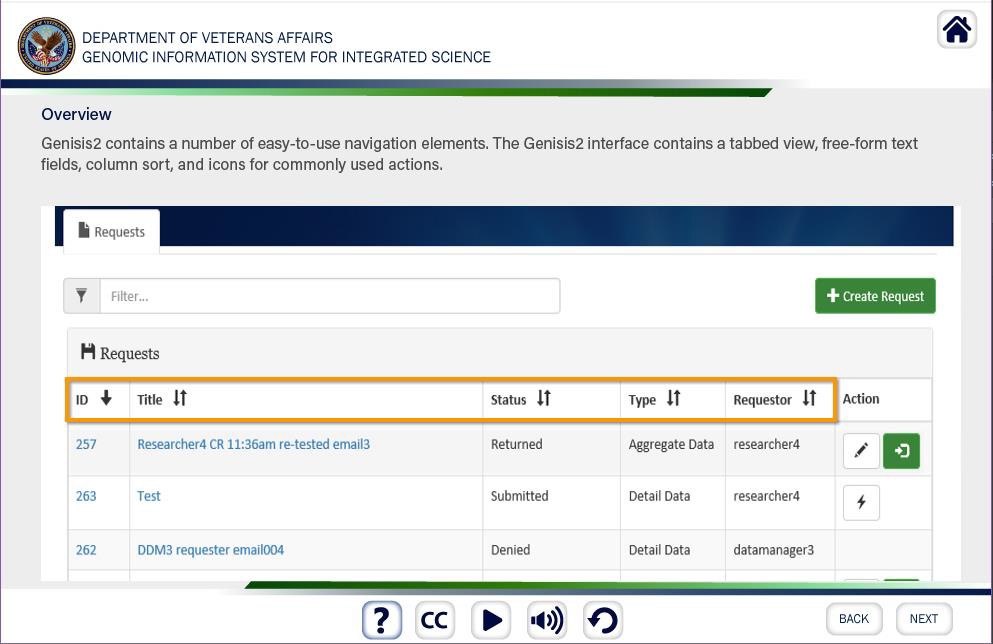
### Data Destination Manager and Data Source Manager Overview



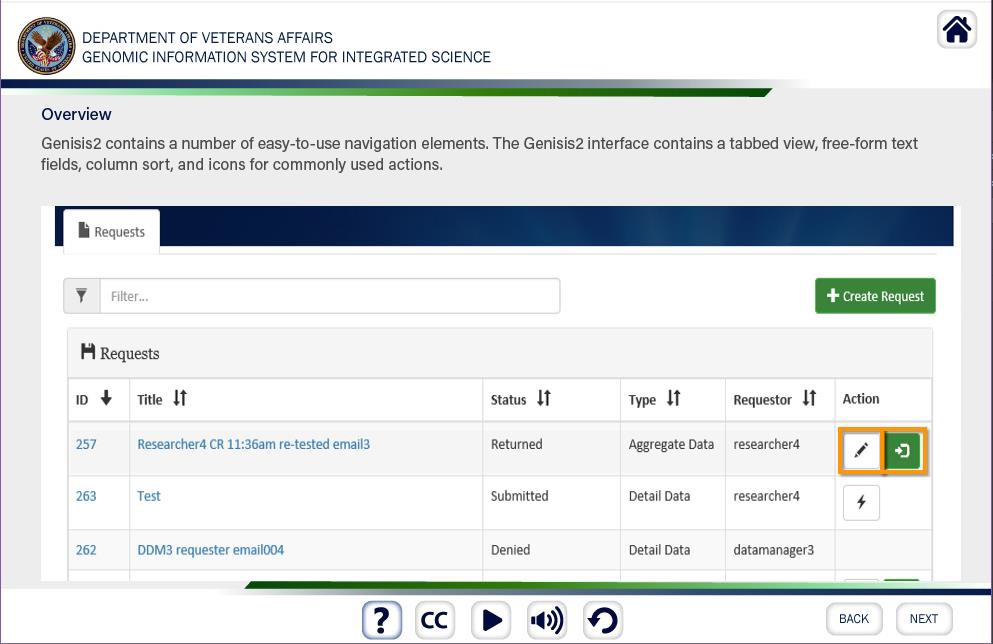
**Figure 11: Genisis2 User Interface Data Destination Manager – Request Tab**



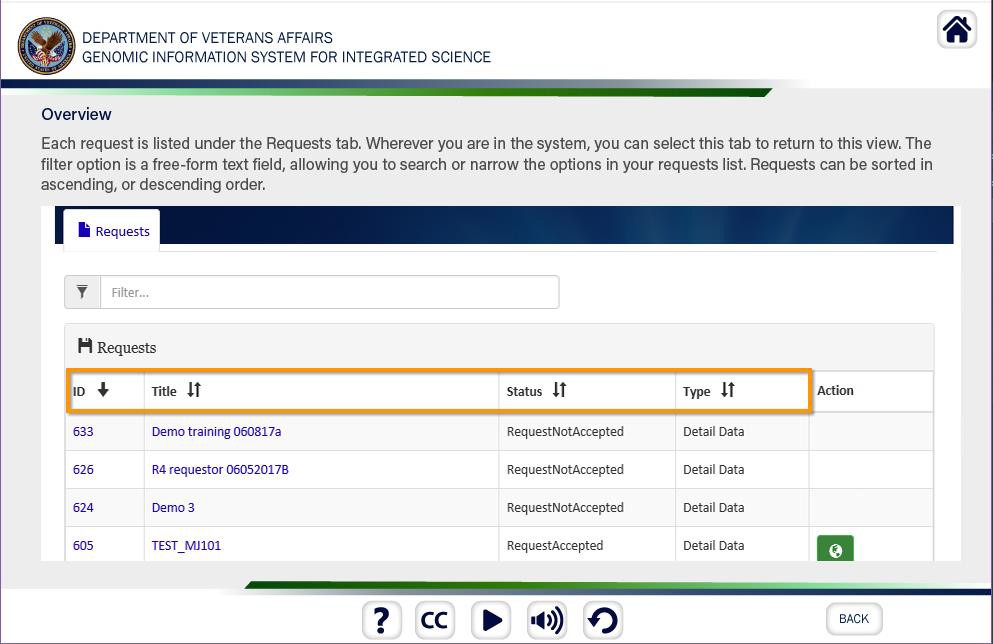
**Figure 12: Genisis2 User Interface Data Destination Manager – Filter**



**Figure 13: Genisis2 User Interface Data Destination Manager – Column Sorting**



**Figure 14: Genisis2 User Interface Data Destination Manager – Action Button**

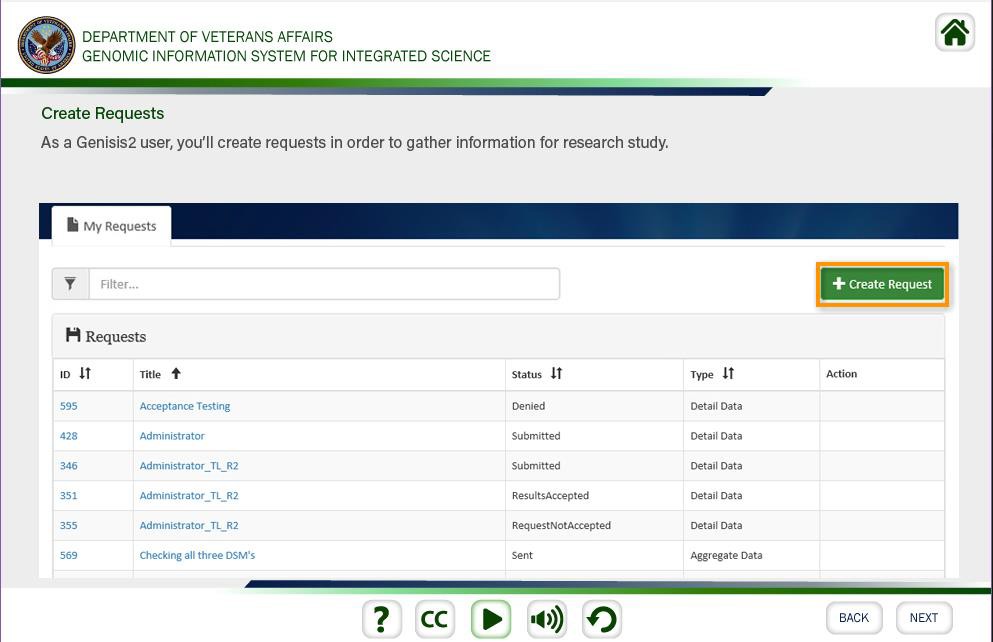


**Figure 15: Genisis2 User Interface Data Source Manager – Column Sorting (NOTE: DSM does not have the ability to CREATE a Request)**

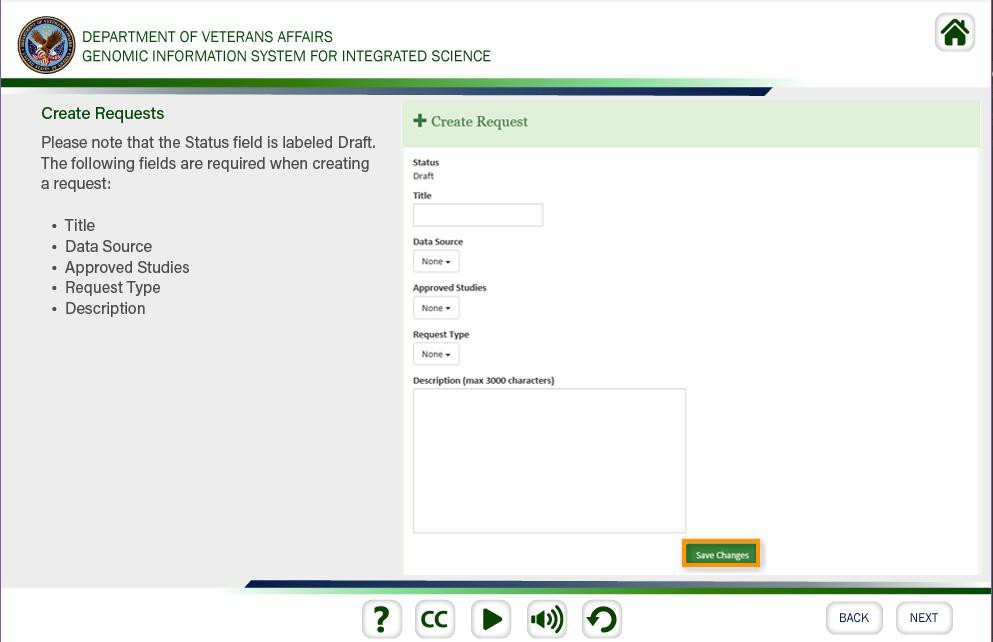
## Requestor Scenarios

As noted above, the Requestor may create a request and track their own requests. This section shows those Requestor capabilities.

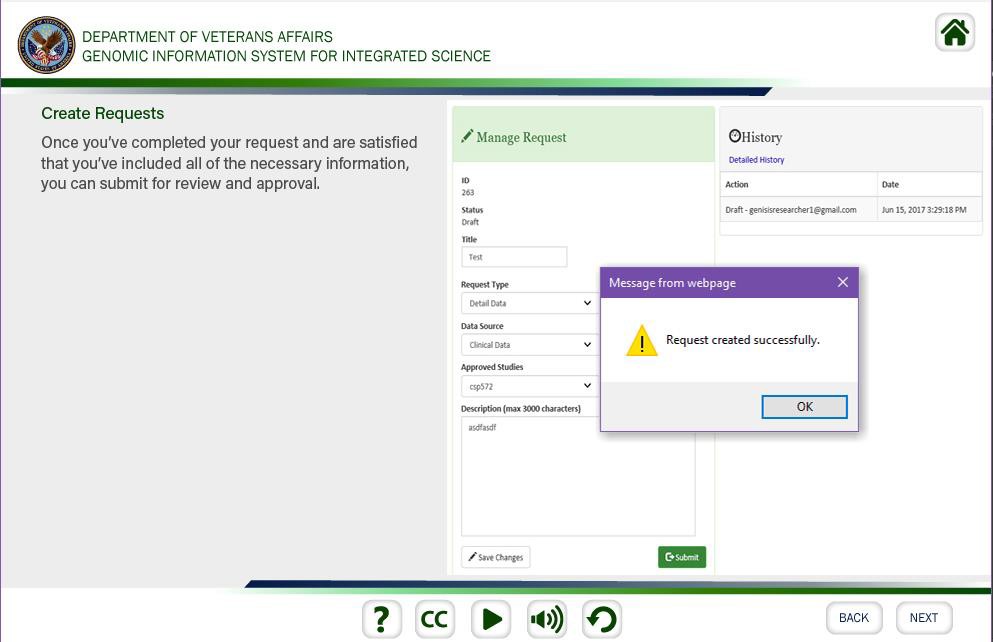
### Create a Request



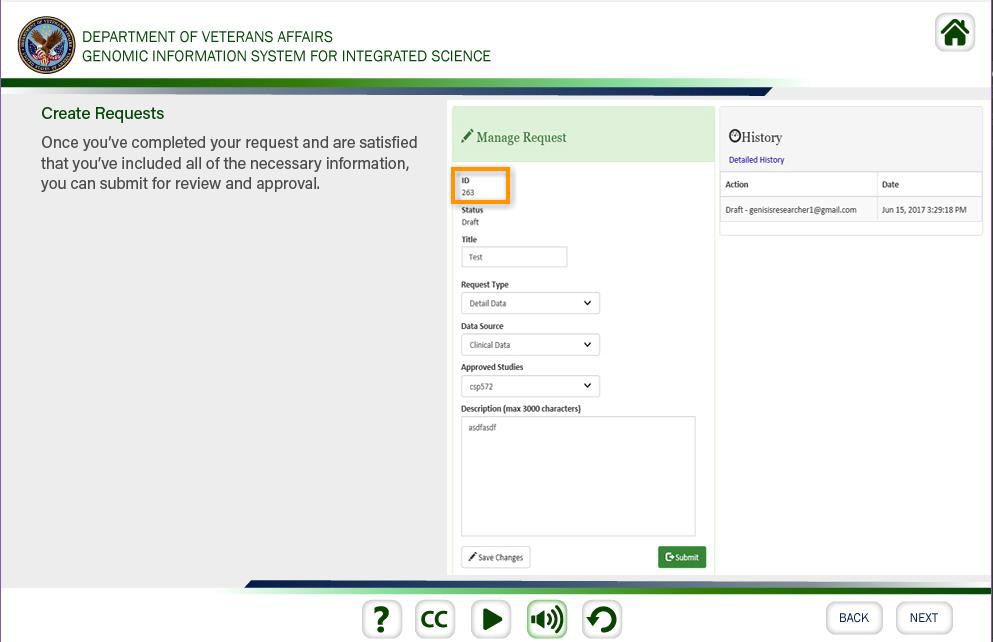
**Figure 16: Genisis2 User Interface Requestor - Create Request**



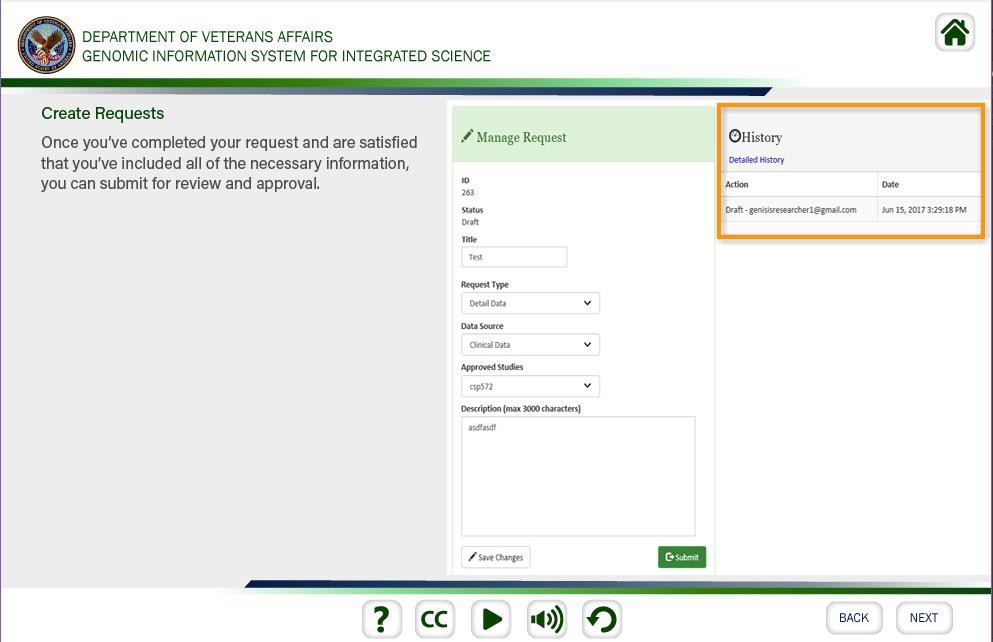
**Figure 17: Genisis2 User Interface Requestor - Request Save Changes**



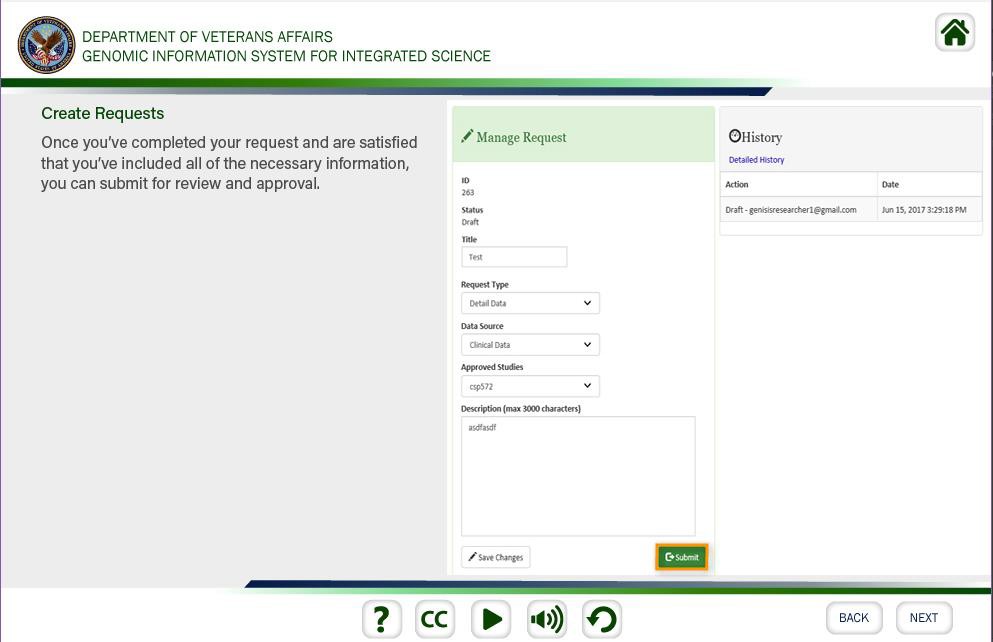
**Figure 18: Genisis2 User Interface Requestor – Request Created Successfully Notification**



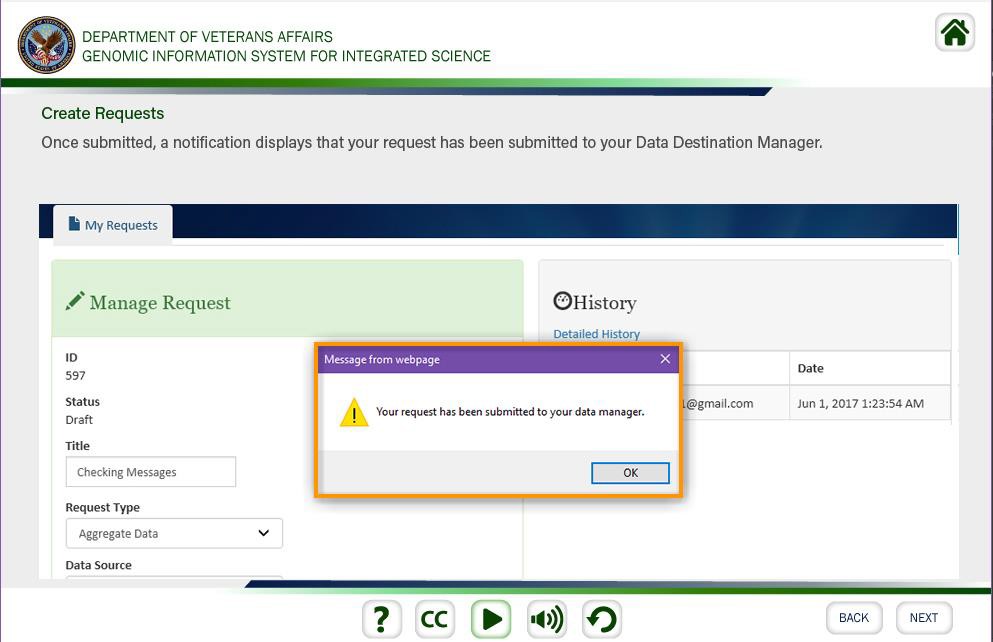
**Figure 19: Genisis2 User Interface Requestor – Request ID Number**



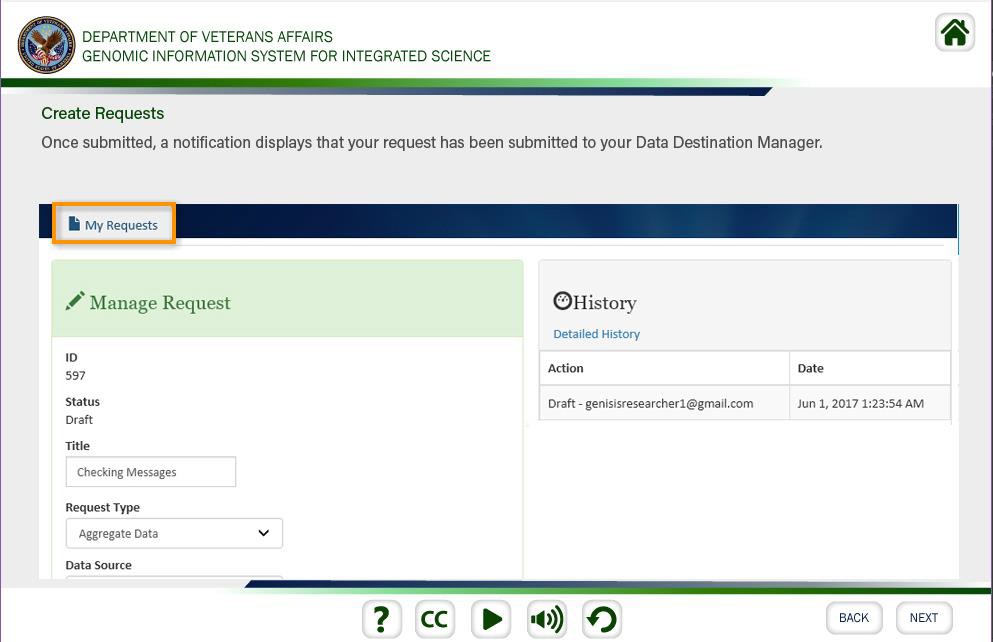
**Figure 20: Genisis2 User Interface Requestor – History and Detailed History Box**



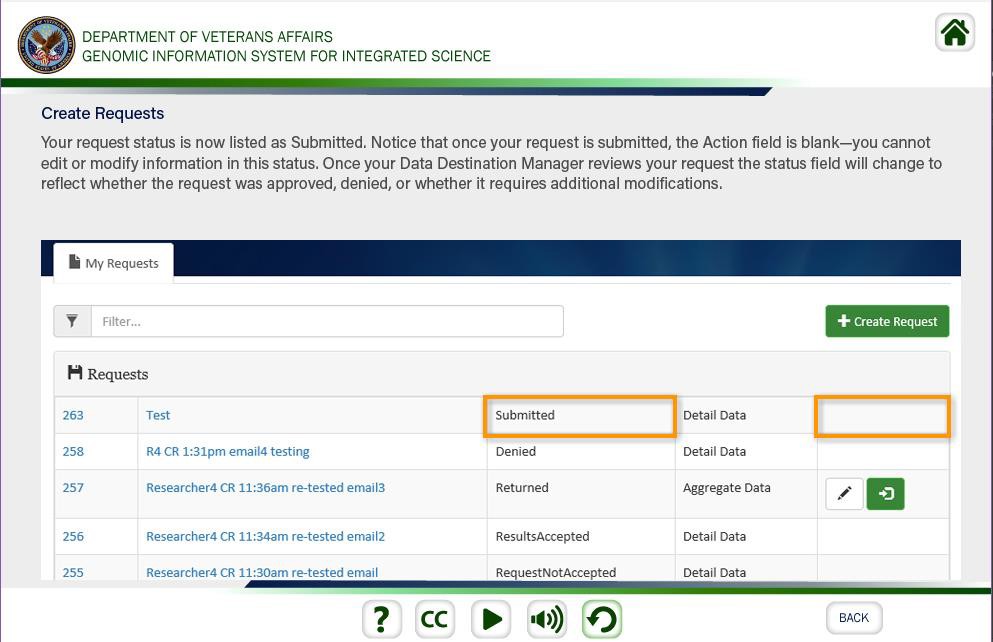
**Figure 21: Genisis2 User Interface Requestor – Submit Request Button**



**Figure 22: Genisis2 User Interface Requestor – Request submitted to Data Manager Notification**

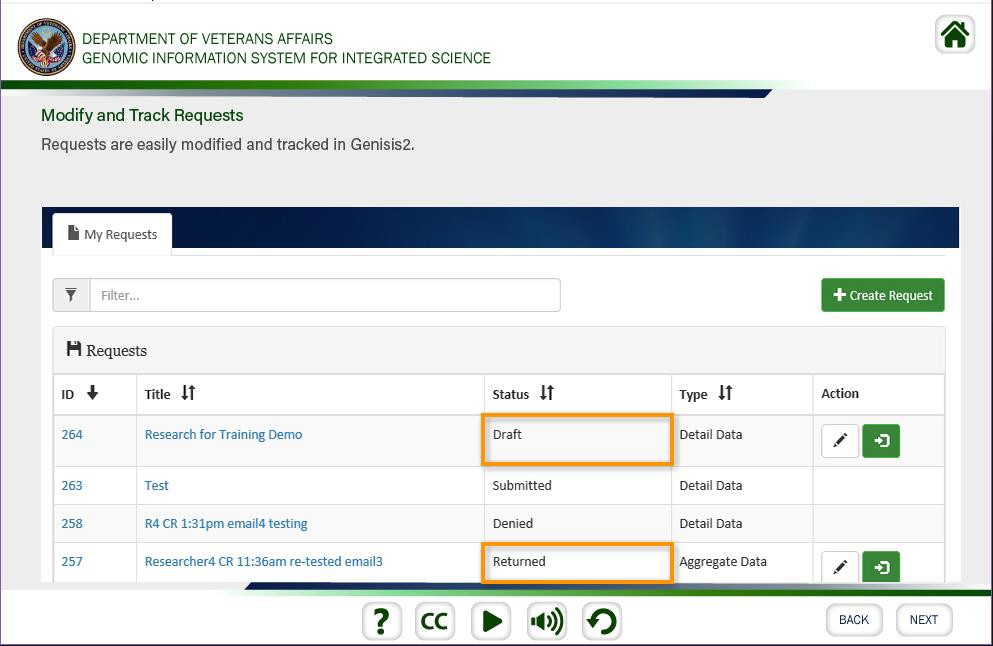


**Figure 23: Genisis2 User Interface Requestor – My Requests Tab to Return to List**

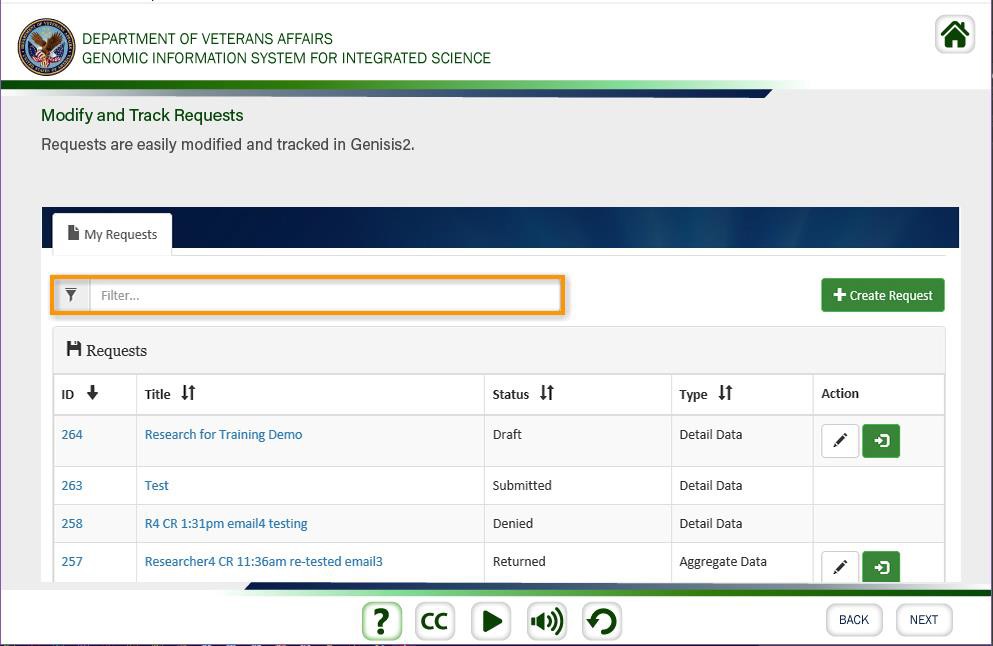


**Figure 24: Genisis2 User Interface Requestor – Request Status Updated to Submitted with No Actions Available**

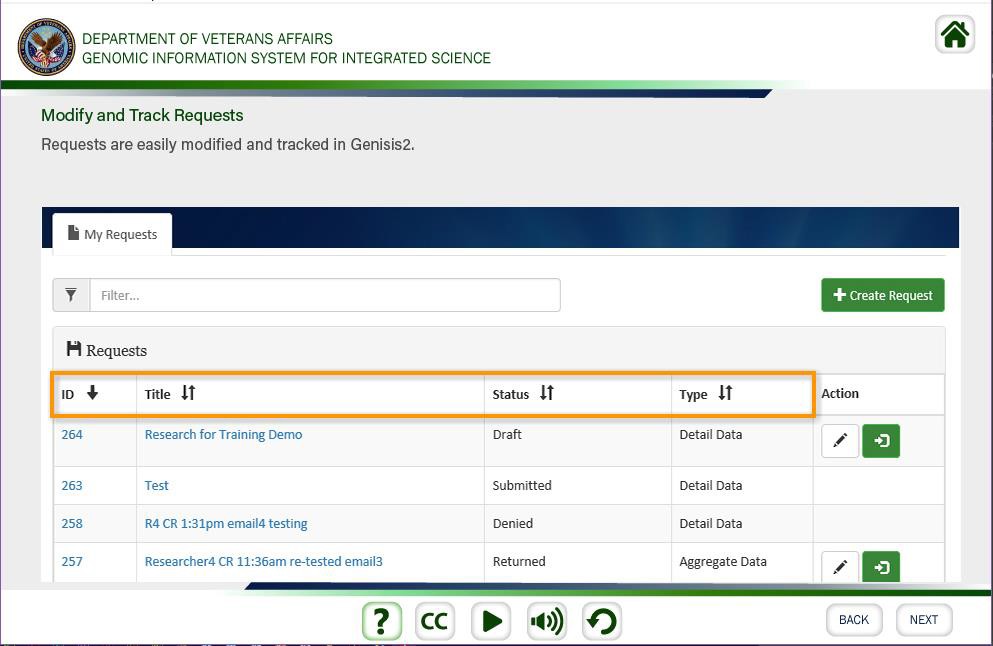
### Modify and Track a Request



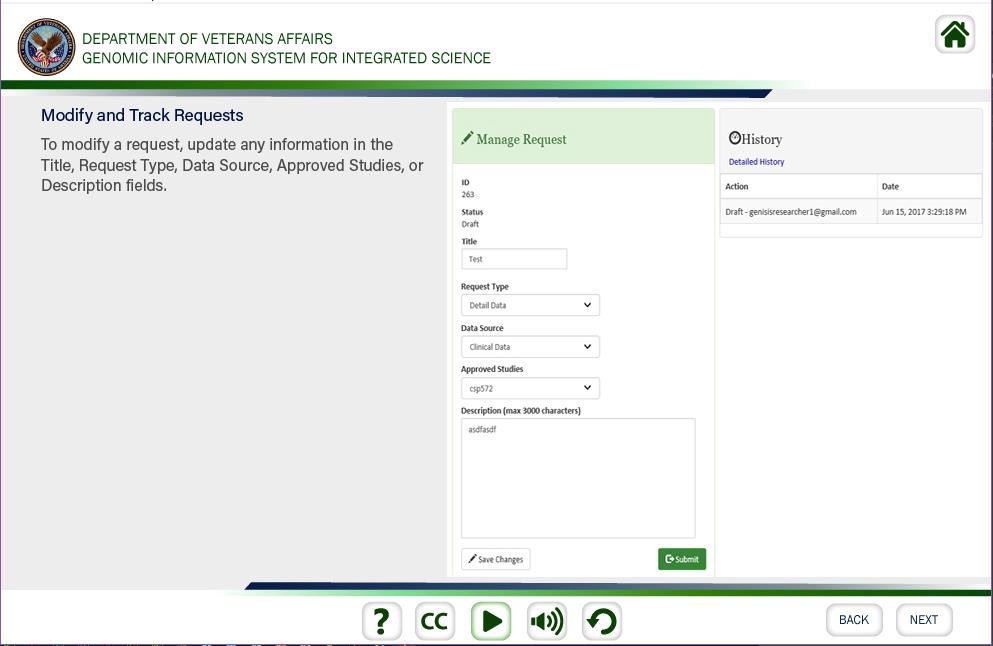
**Figure 25: Genisis2 User Interface Requestor – Tracking Requests (Only Available in Draft or Returned Status)**



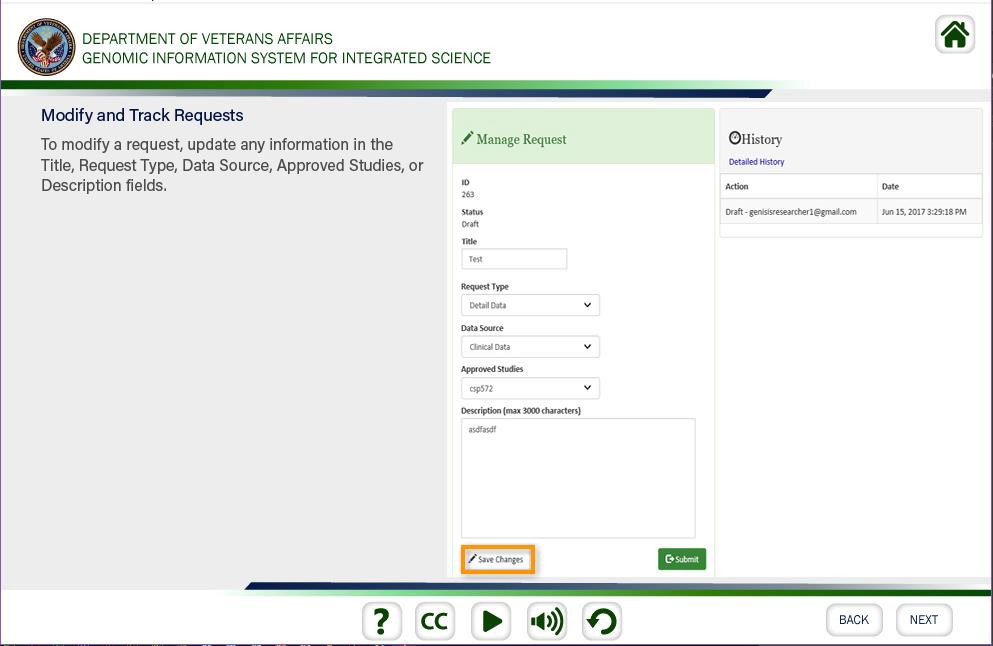
**Figure 26: Genisis2 User Interface Requestor – Modify and Track using Filter**



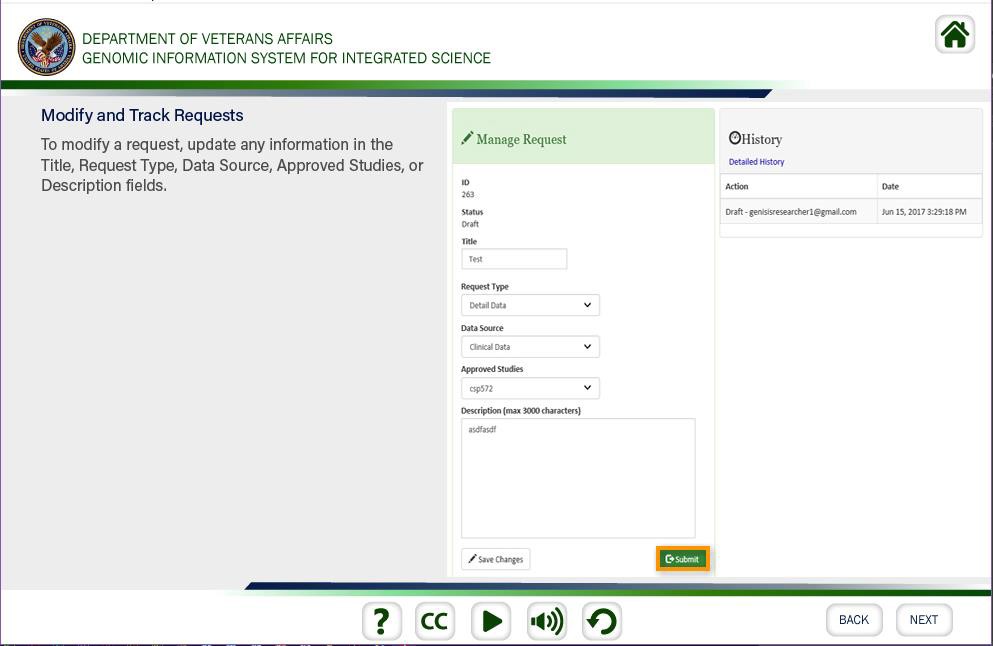
**Figure 27: Genisis2 User Interface Requestor – Request Sorting Columns. Select by ID or Title to Modify Request**



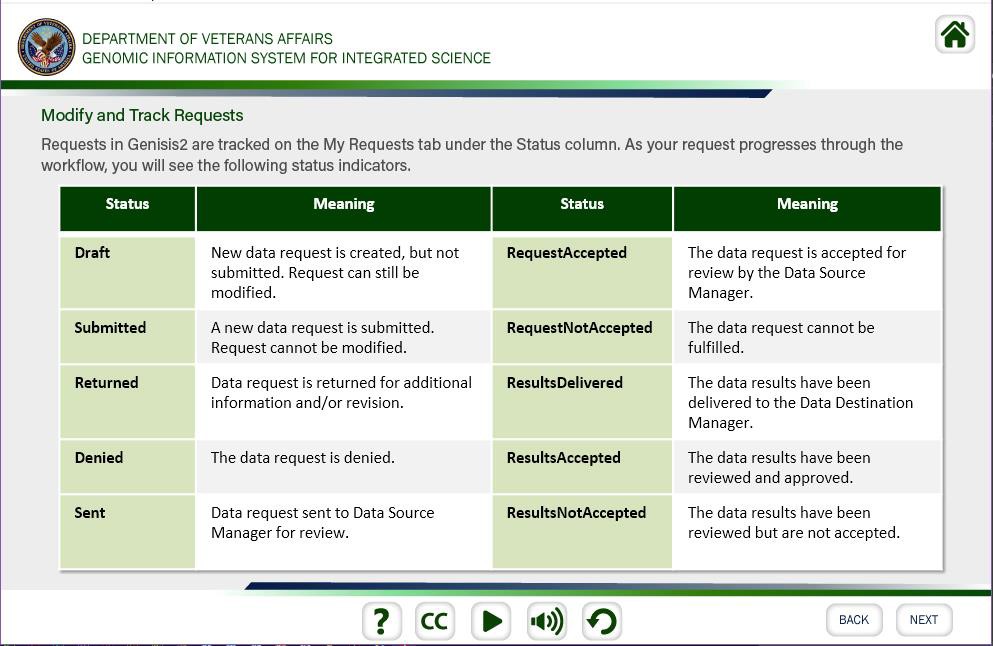
**Figure 28: Genisis2 User Interface Requestor – Modify a Request**



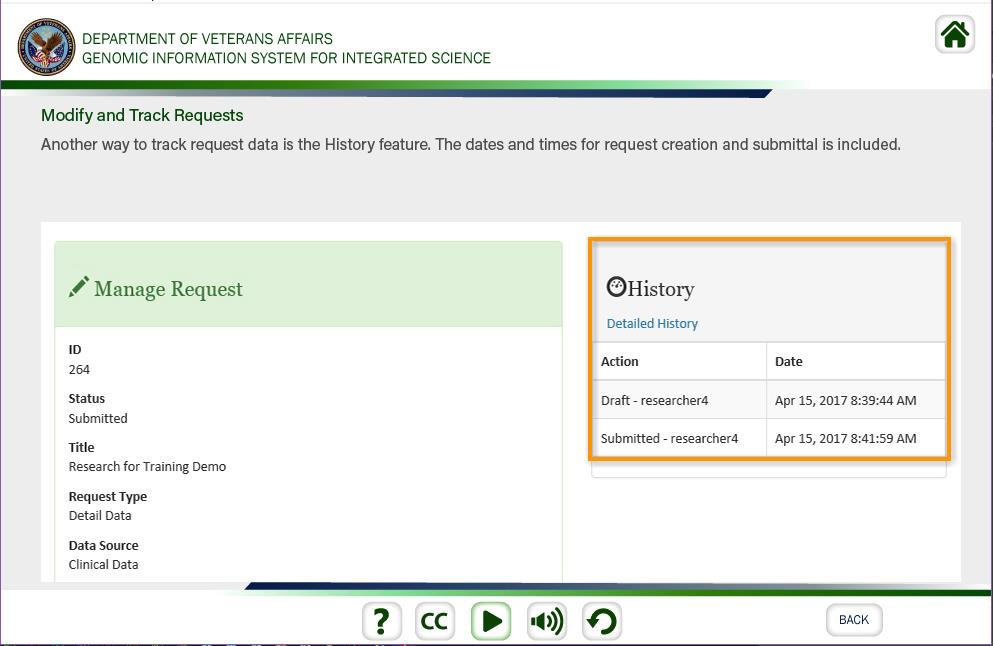
**Figure 29: Genisis2 User Interface Requestor – Save Modified Request**



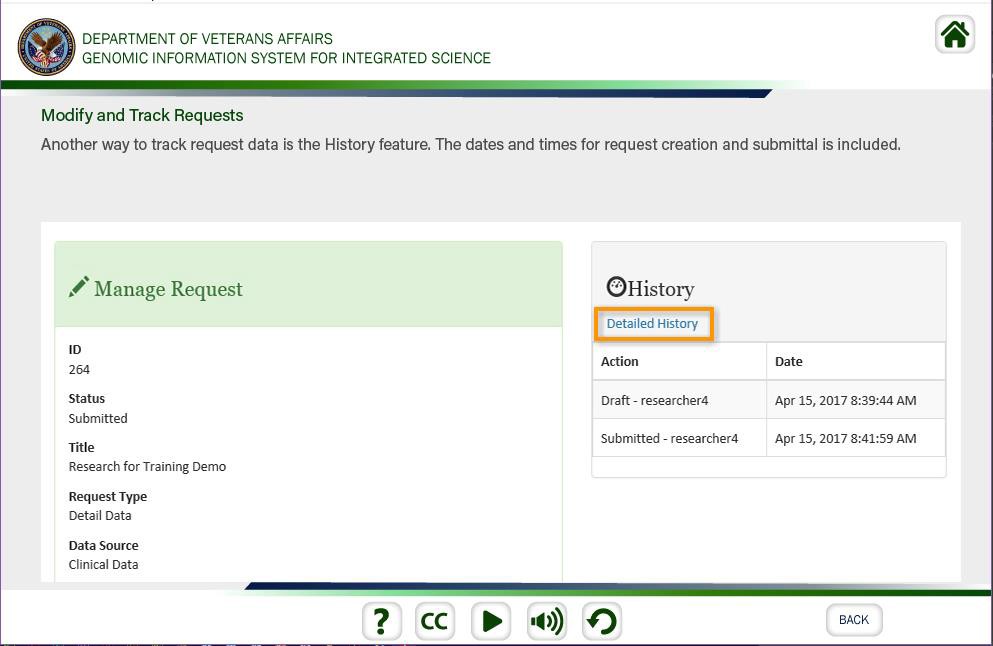
**Figure 30: Genisis2 User Interface Requestor – Submit Modified Request**



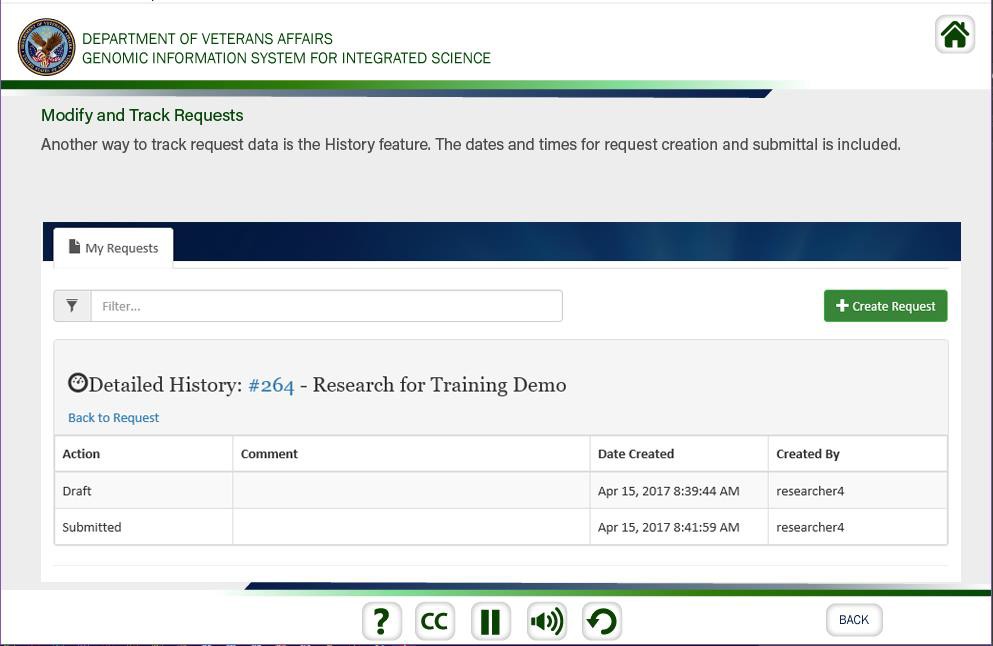
**Figure 31: Genisis2 User Interface Requestor – Status Indicators**



**Figure 32: Genisis2 User Interface Requestor – History Feature**



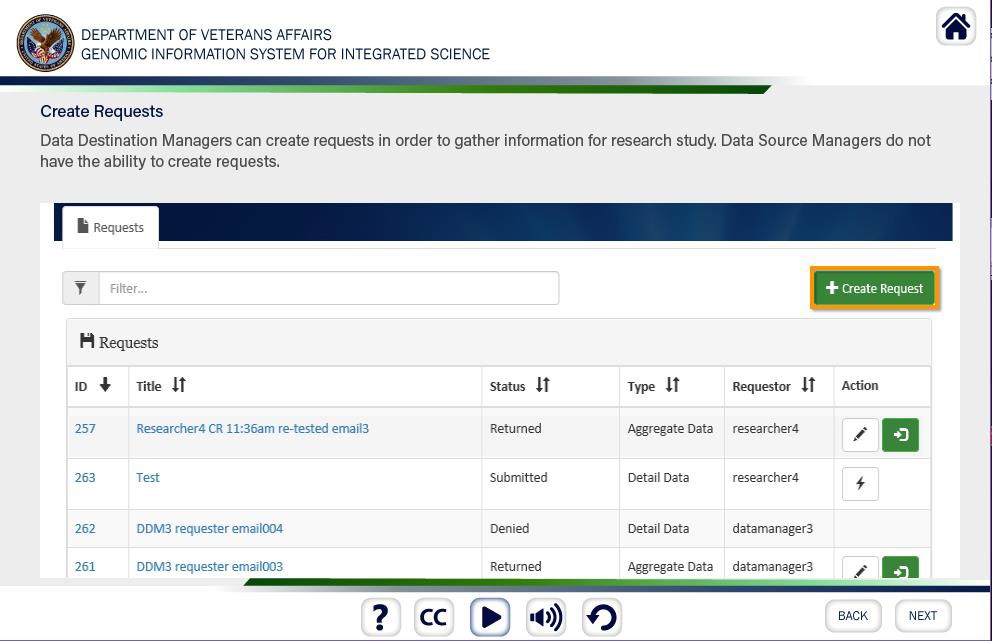
**Figure 33: Genisis2 User Interface Requestor – Detailed History Feature**



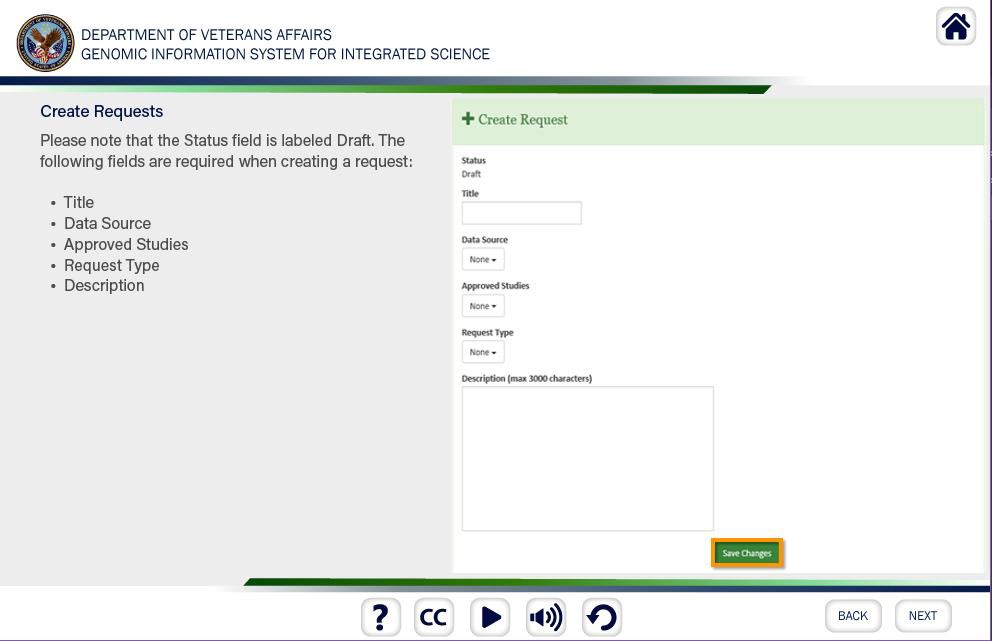
**Figure 34: Genisis2 User Interface Requestor – Detailed History Feature View**

## Data Destination Manager and Data Source Manager Scenarios

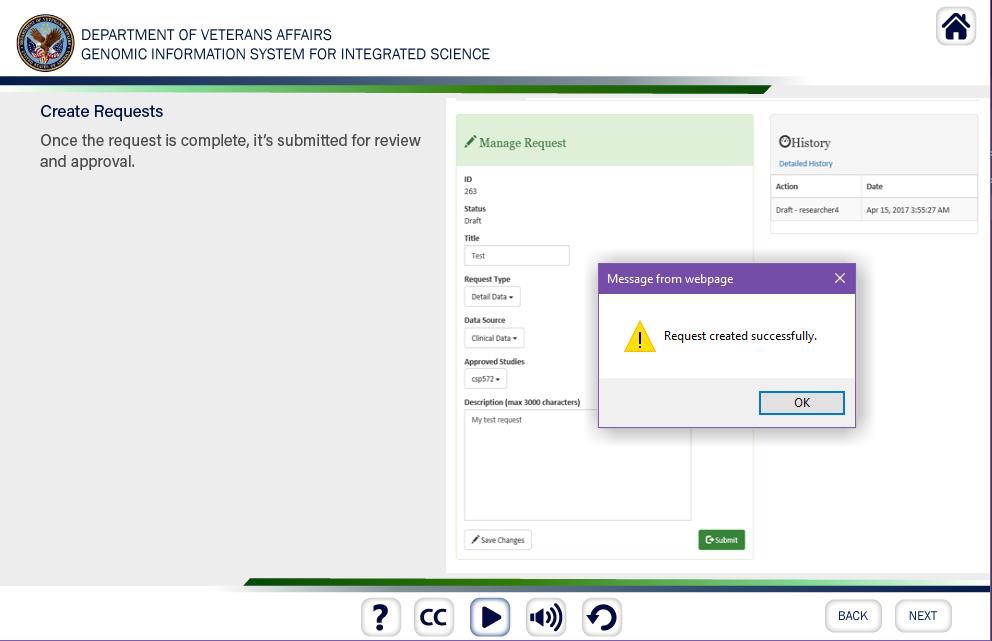
### Create a Request



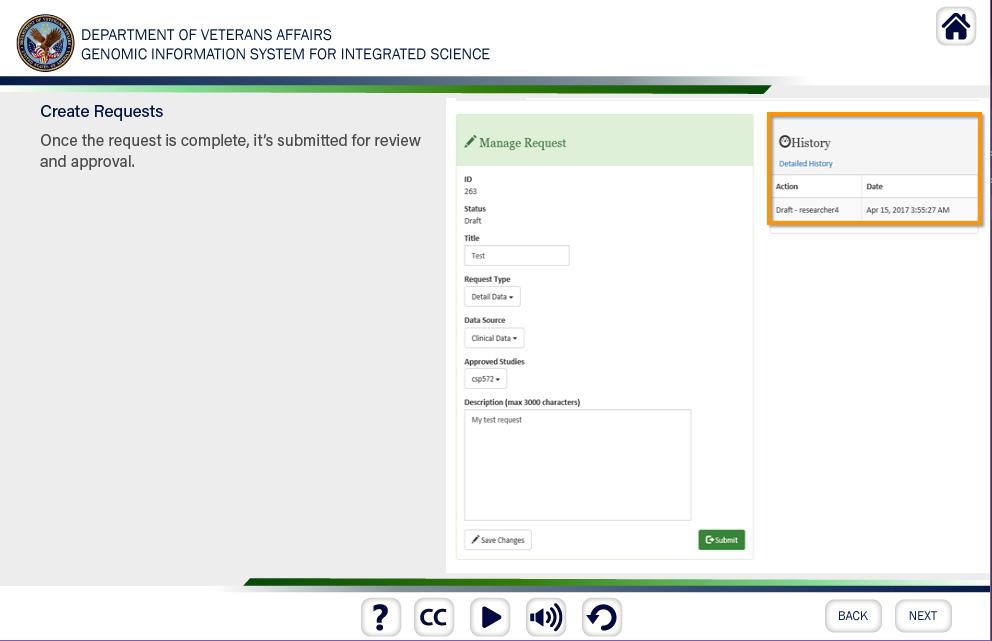
**Figure 35: Genisis2 User Interface Data Destination Manager – Create Request (DSM Cannot Create Request)**



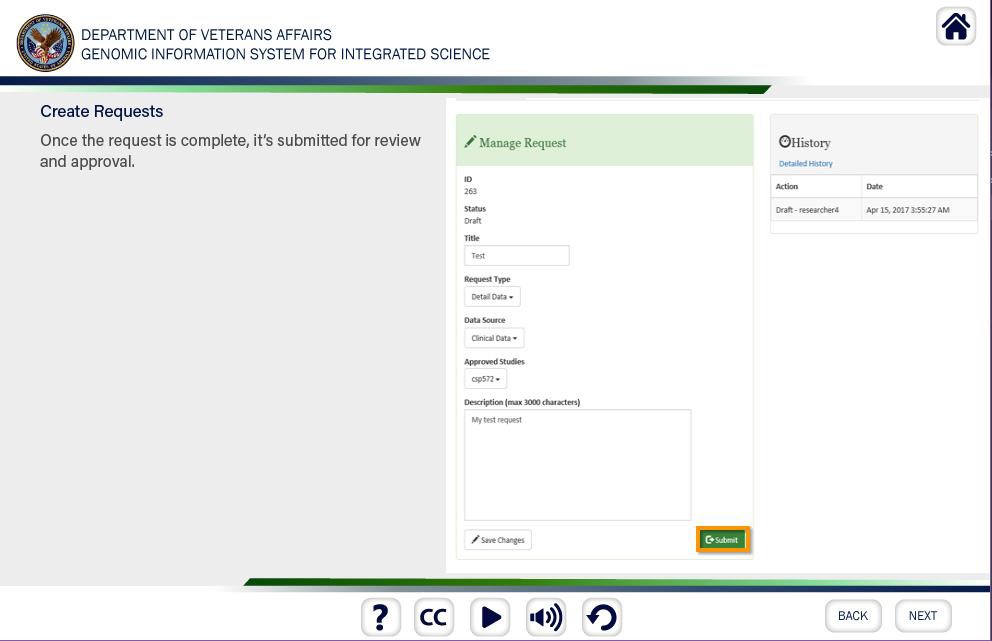
**Figure 36: Genisis2 User Interface Data Destination Manager – Request Save Changes**



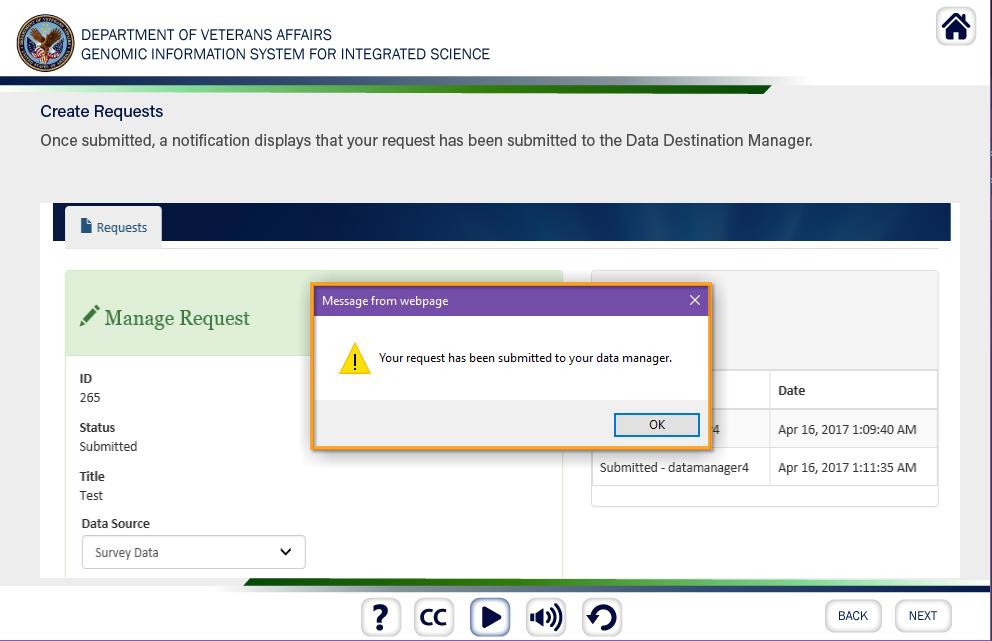
**Figure 37: Genisis2 User Interface Data Destination Manager – Request Created Successfully Notification**



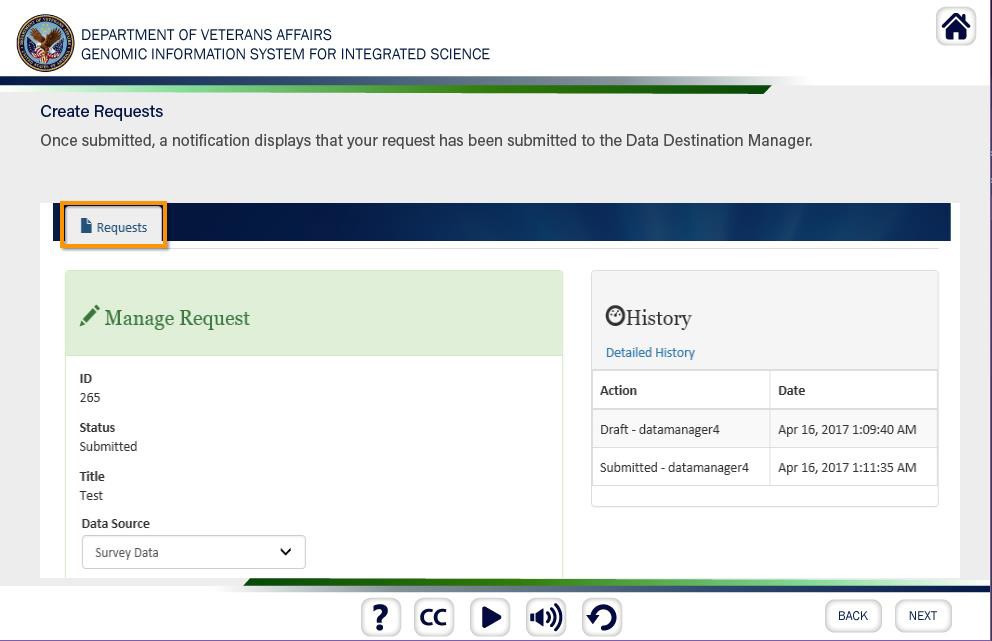
**Figure 38: Genisis2 User Interface Data Destination Manager – History Feature**



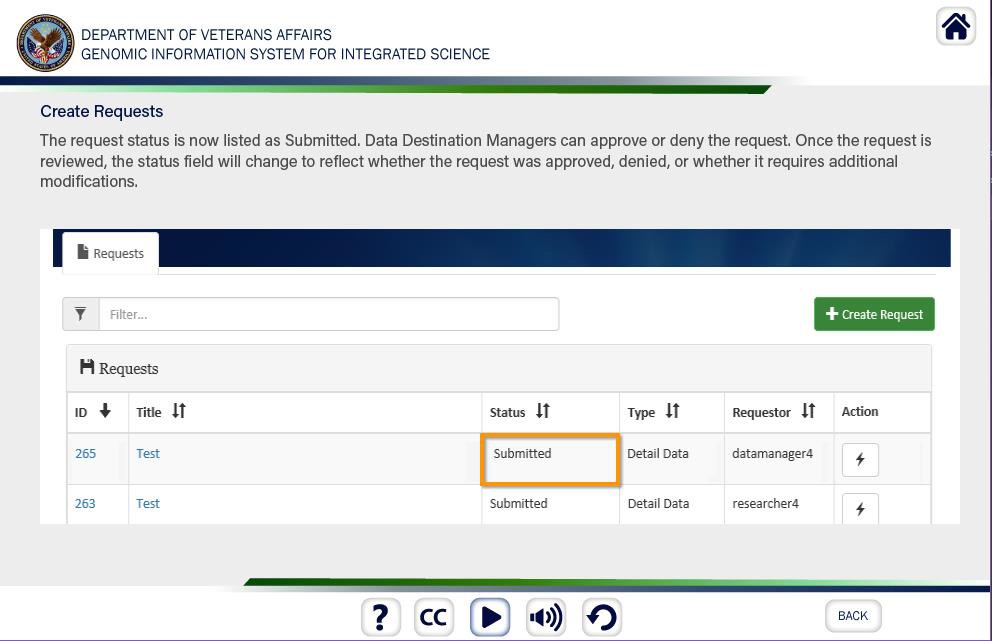
**Figure 39: Genisis2 User Interface Data Destination Manager – Submit Request**



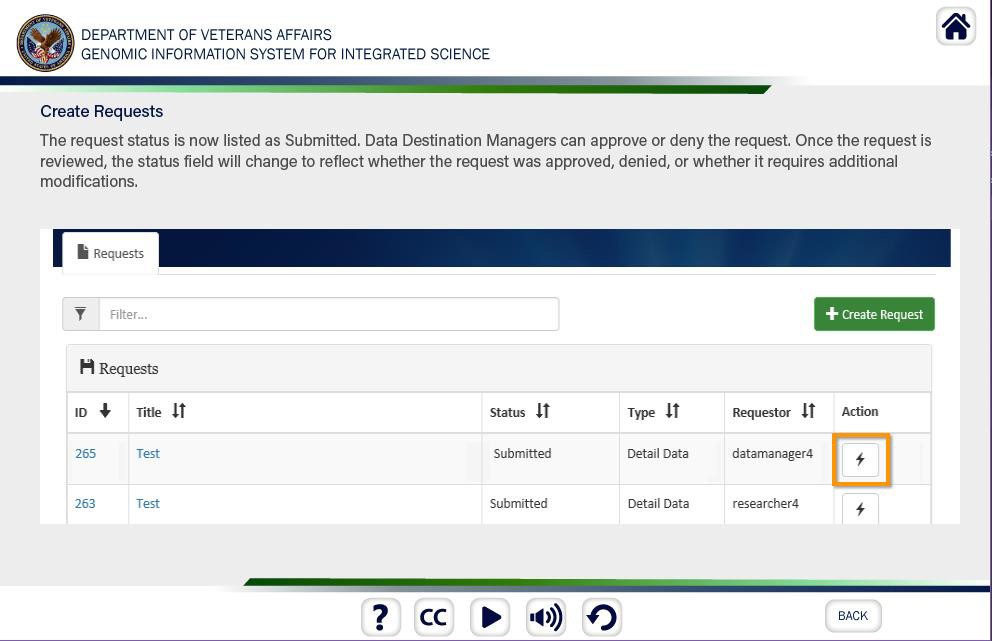
**Figure 40: Genisis2 User Interface Data Destination Manager – Submit Request Notification**



**Figure 41: Genisis2 User Interface Data Destination Manager – Click Requests Tab to Return to List**

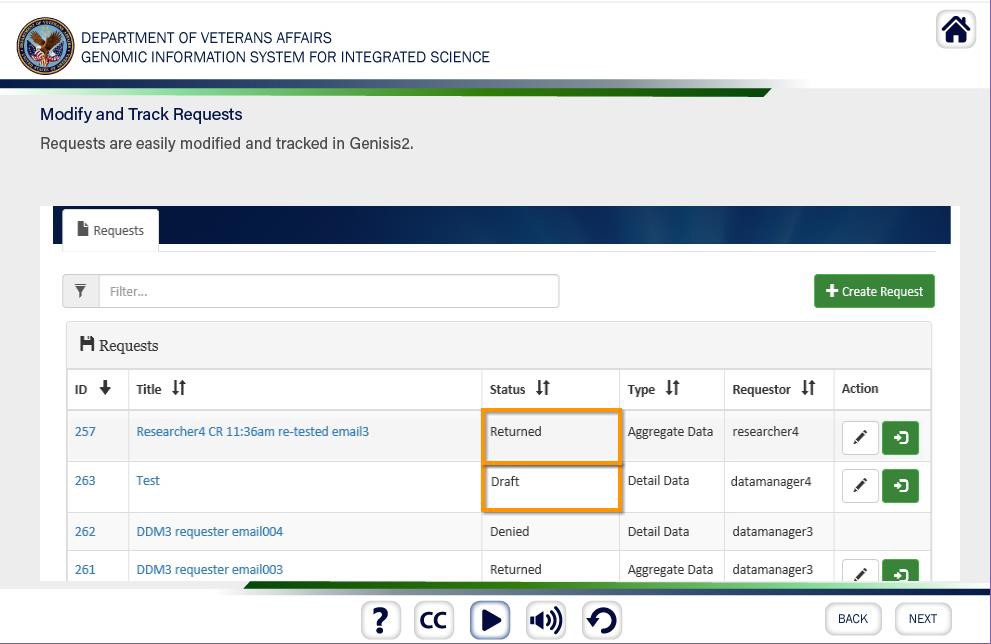


**Figure 42: Genisis2 User Interface Data Destination Manager – Status Field**

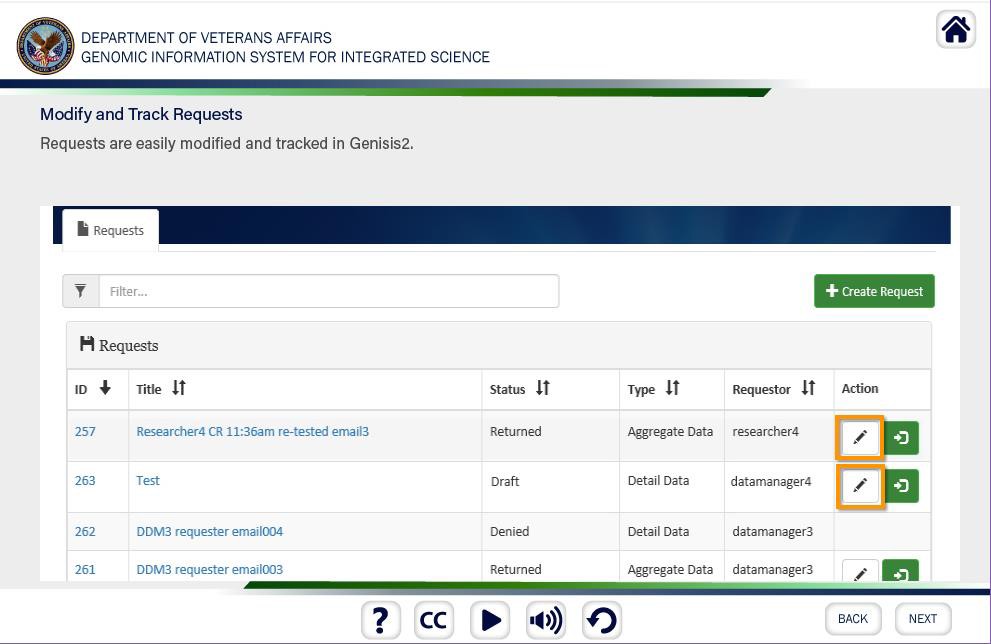


**Figure 43: Genisis2 User Interface Data Destination Manager – Action Button**

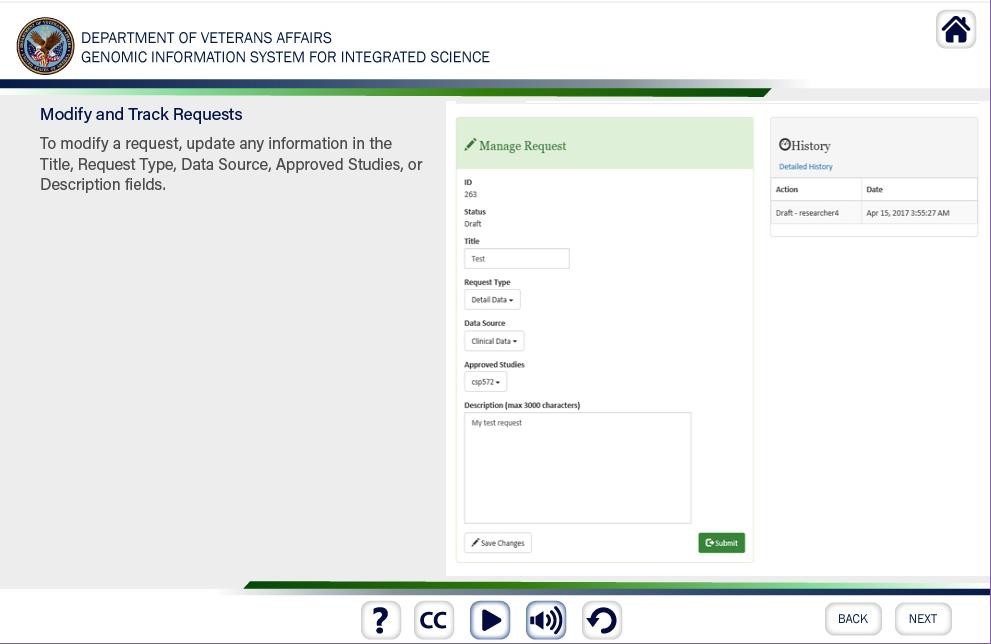
### Modify and Track a Request



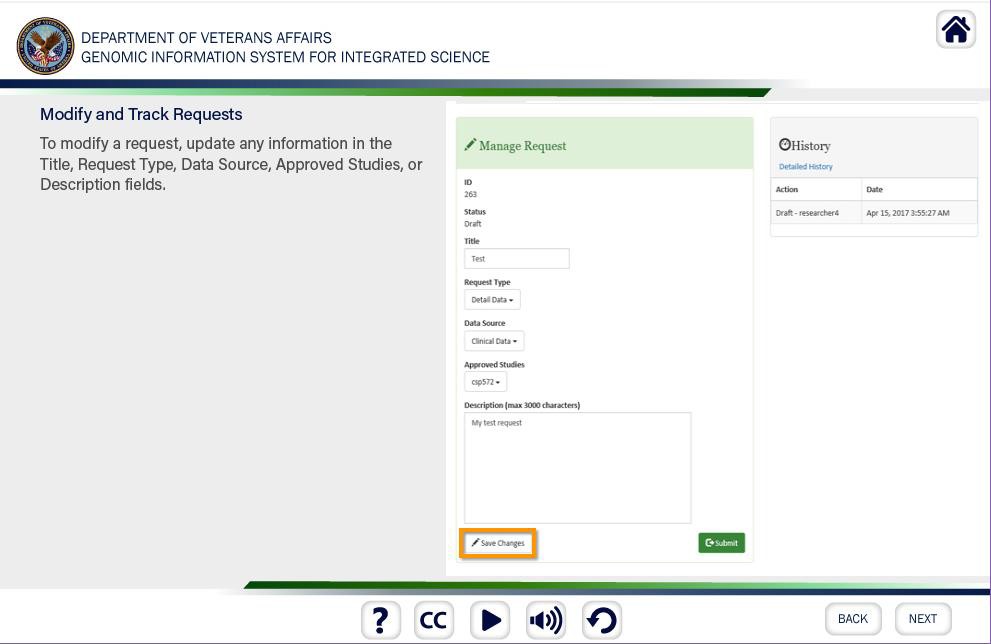
**Figure 44: Genisis2 User Interface Data Destination Manager – Tracking Requests (Only Available in Draft or Returned Status)**



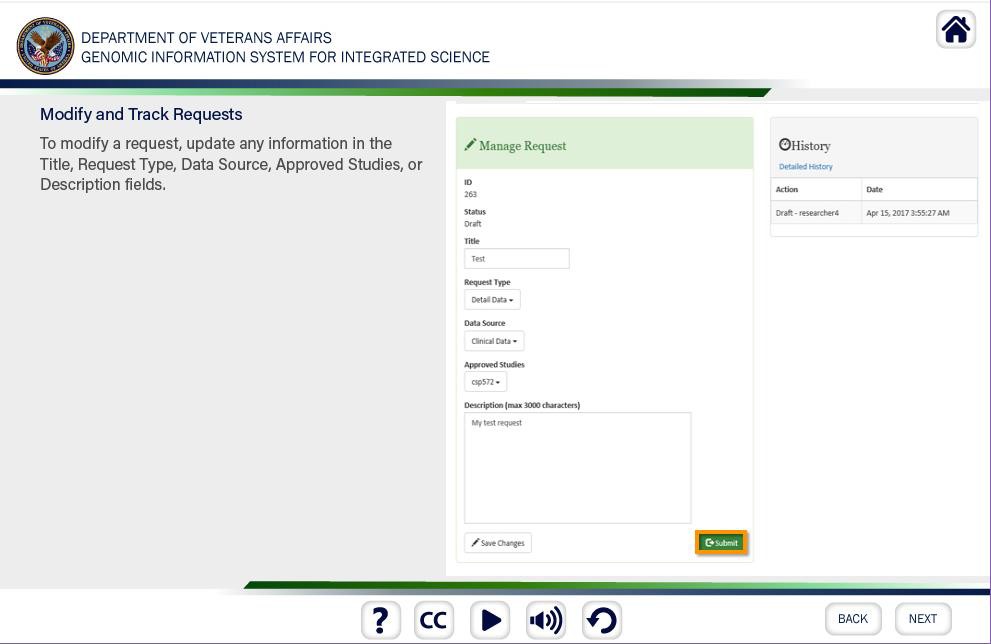
**Figure 45: Genisis2 User Interface Data Destination Manager – Action Button to Modify a Request**



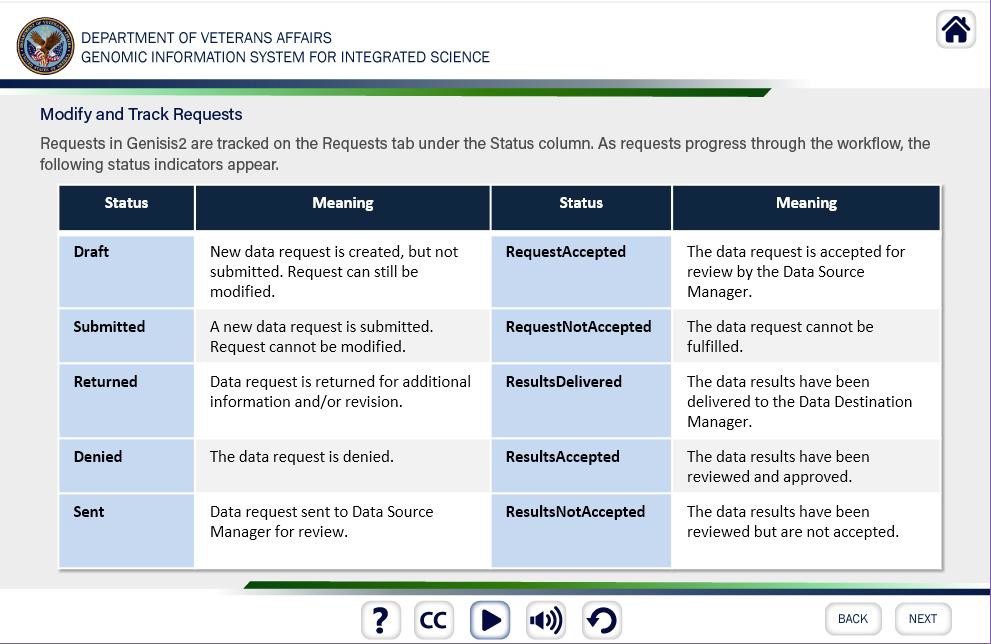
**Figure 46: Genisis2 User Interface Data Destination Manager – Modify a Request (DSM Can ONLY View Request Details)**



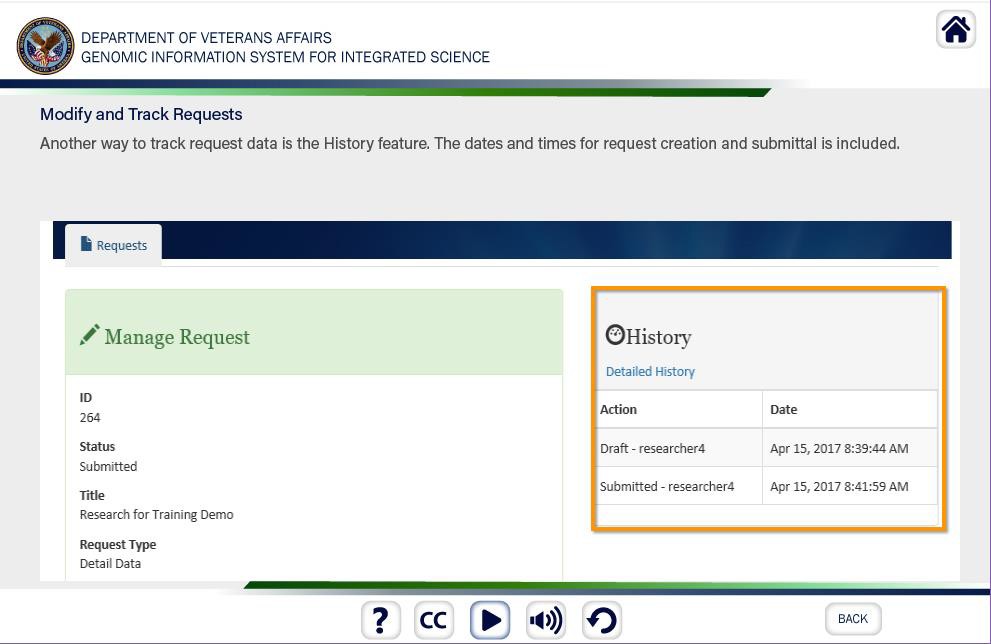
**Figure 47: Genisis2 User Interface Data Destination Manager – Save Modified Request (DSM Can ONLY View Request Details)**



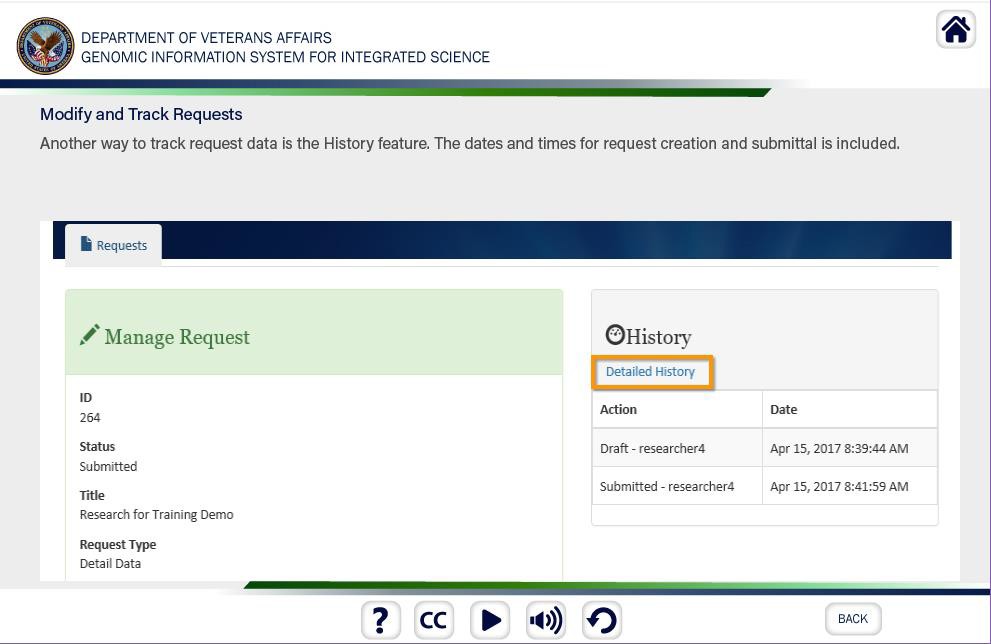
**Figure 48: Genisis2 User Interface Data Destination Manager – Submit Modified Request (DSM Can ONLY View Request Details)**



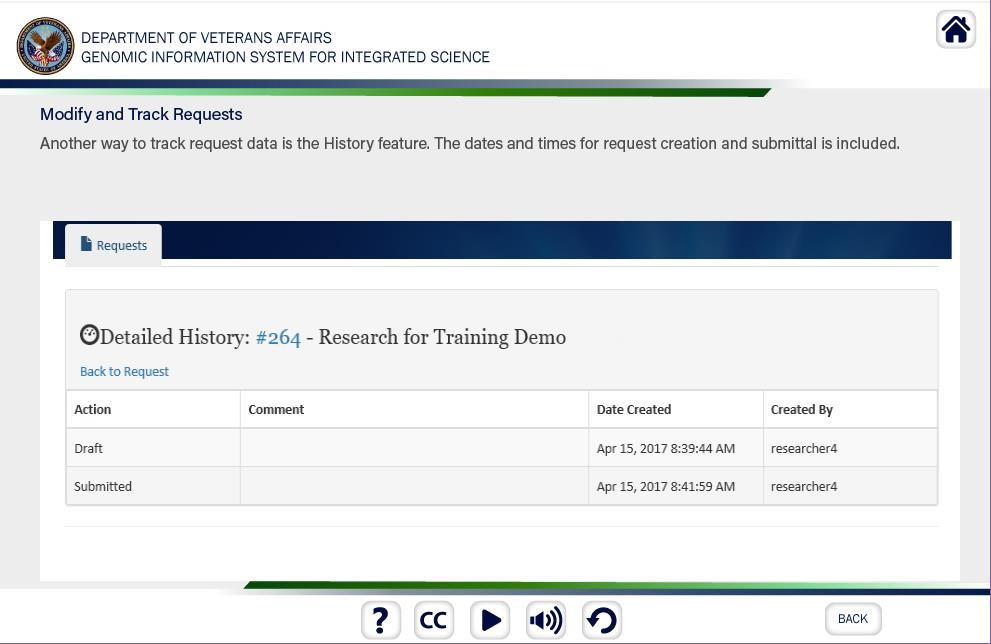
**Figure 49: Genisis2 User Interface Data Manager – Status Indicators**



**Figure 50: Genisis2 User Interface Data Destination Manager/Data Source Manger – History Feature**

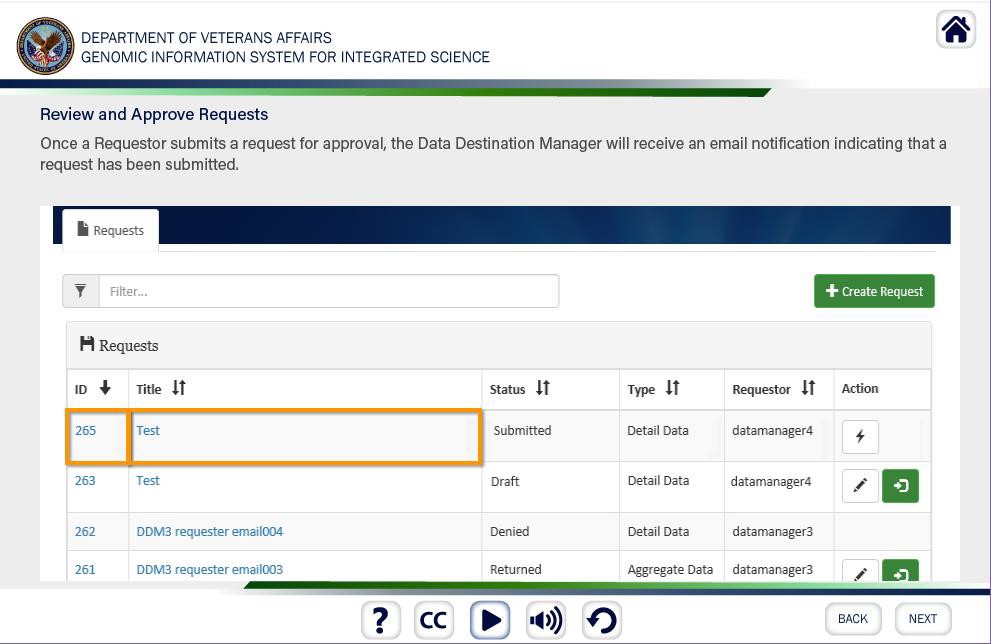


**Figure 51: Genisis2 User Interface Data Destination Manager/Data Source Manger – Detailed History Feature**

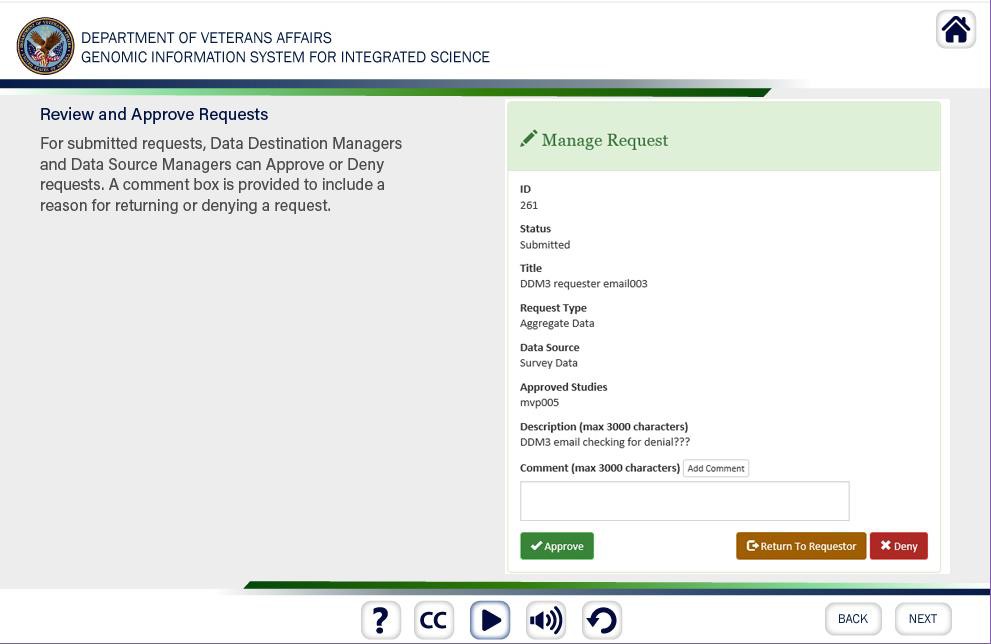


**Figure 52: Genisis2 User Interface Data Destination Manager/Data Source Manger – Detailed History View**

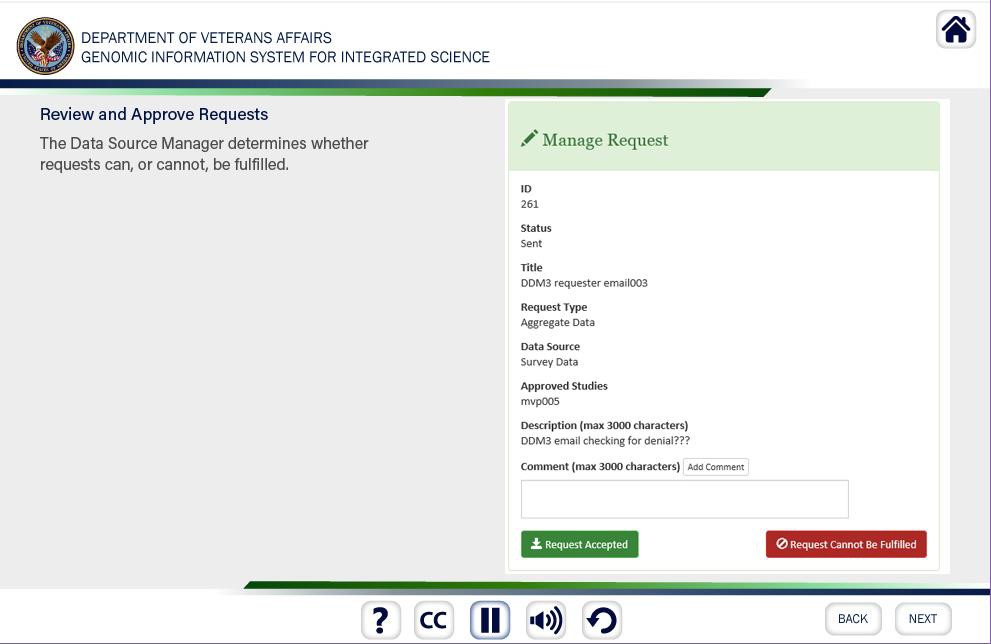
### Review and Approve a Request



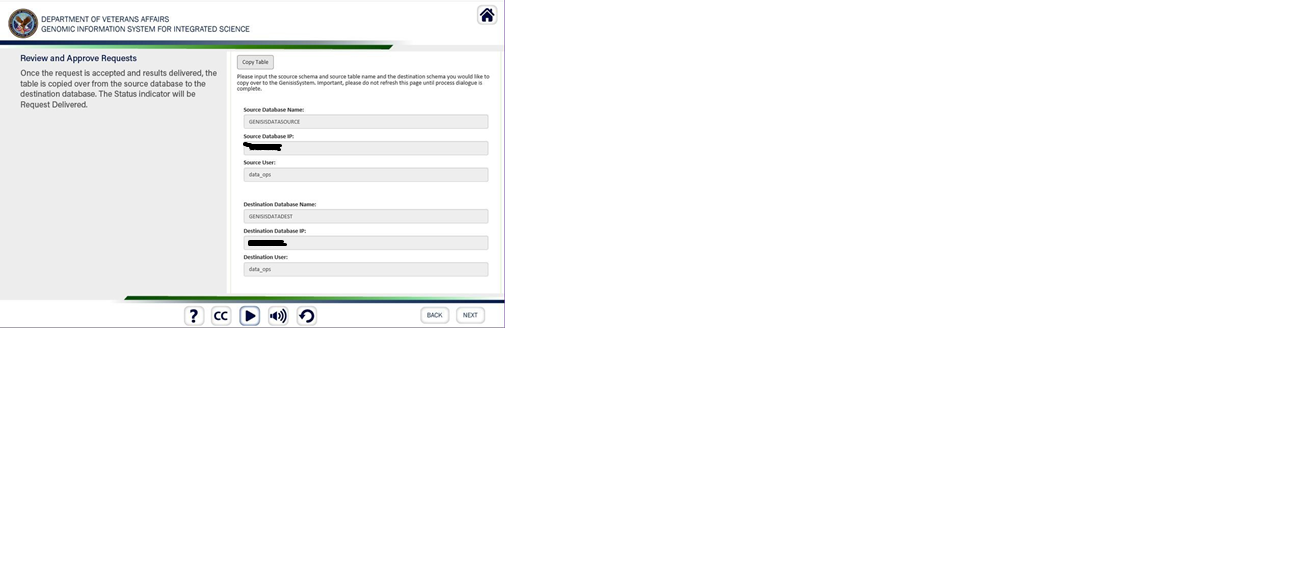
**Figure 53: Genisis2 User Interface Data Destination Manager/Data Source Manger – Request Submitted for Review. Click ID or Title to Review or Approve**



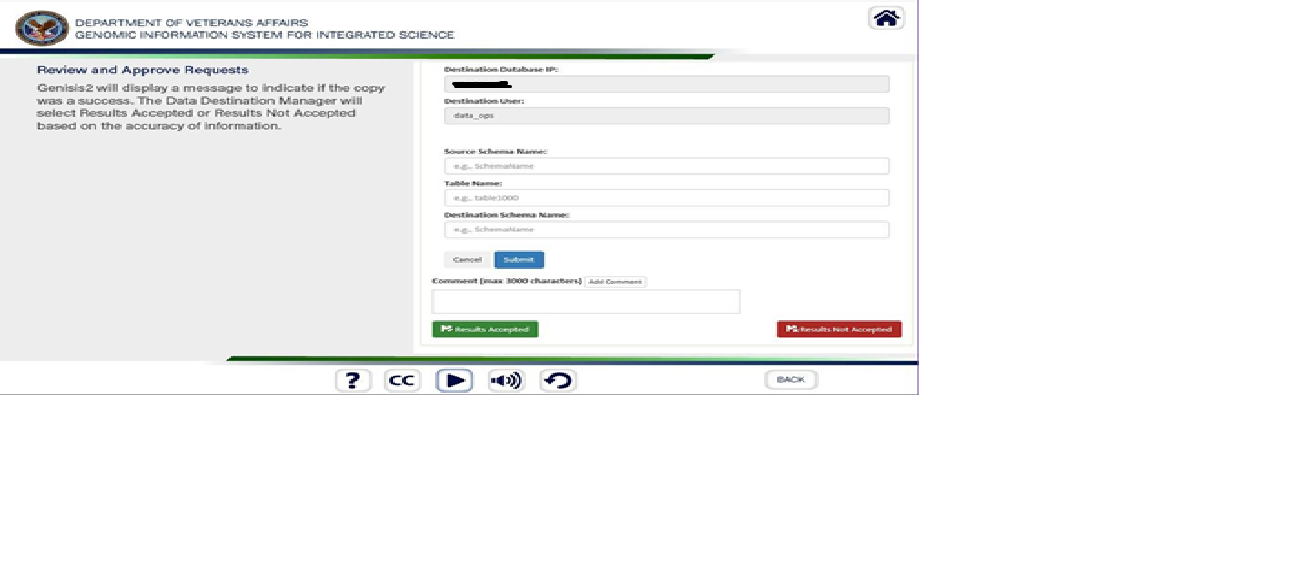
**Figure 54: Genisis2 User Interface Data Destination Manager/Data Source Manager – Approve, Return or Deny Request.**



**Figure 55: Genisis2 User Interface Data Source Manager – Request Accepted or Cannot Be Fulfilled**



**Figure 56: Genisis2 User Interface Data Destination Manager – Copy Table**



**Figure 57: Genisis2 User Interface Data Destination Manager – Copy Table Accepted or Not Accepted**