# Oracle® Life Sciences InForm DECS Manager User Guide



Release 7.0.1 F56803-01 March 2024

ORACLE

Oracle Life Sciences InForm DECS Manager User Guide, Release 7.0.1

F56803-01

Copyright © 2019, 2024, Oracle and/or its affiliates.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software, software documentation, data (as defined in the Federal Acquisition Regulation), or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, then the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs) and Oracle computer documentation or other Oracle data delivered to or accessed by U.S. Government end users are "commercial computer software," "commercial computer software documentation," or "limited rights data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, reproduction, duplication, release, display, disclosure, modification, preparation of derivative works, and/or adaptation of i) Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs), ii) Oracle computer documentation and/or iii) other Oracle data, is subject to the rights and limitations specified in the license contained in the applicable contract. The terms governing the U.S. Government's use of Oracle cloud services are defined by the applicable contract for such services. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle®, Java, MySQL, and NetSuite are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Inside are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Epyc, and the AMD logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information about content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services unless otherwise set forth in an applicable agreement between you and Oracle. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services, except as set forth in an applicable agreement between you and Oracle.

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <a href="http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc">http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc</a>.

## Contents

#### Preface

Documentation accessibility	iv
Diversity and Inclusion	iv
Related resources	iv
Access to Oracle Support	iv
Additional copyright information	v

#### 1 Manage studies

Add a study	1-1
Start or stop a study	1-1
Install study MeML	1-2
Check database connectivity	1-2
Update database statistics	1-2
Remove a study	1-2
Assign rights to users	1-3

#### 2 Troubleshooting

#### 3 Frequently asked questions

How many studies can I add?	3-1
What happens when I add a study?	3-1
What happens when I remove a study?	3-1
How can I see the URLs associated with a study?	3-2



#### Preface

This preface contains the following sections:

- Documentation accessibility
- Diversity and Inclusion
- Related resources
- Access to Oracle Support
- Additional copyright information

#### Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup? ctx=acc&id=docacc.

#### **Diversity and Inclusion**

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

#### **Related resources**

All documentation and other supporting materials are available on the Oracle Help Center.

#### Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

 English interface of Oracle Health Sciences Customer Support Portal (https:// hsgbu.custhelp.com/)



 Japanese interface of Oracle Health Sciences Customer Support Portal (https://hsgbujp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit http://www.oracle.com/us/support/ contact/health-sciences-cloud-support/index.html or visit http://www.oracle.com/pls/topic/ lookup?ctx=acc&id=trs if you are hearing impaired.

## Additional copyright information

This documentation may include references to materials, offerings, or products that were previously offered by Phase Forward Inc. Certain materials, offerings, services, or products may no longer be offered or provided. Oracle and its affiliates cannot be held responsible for any such references should they appear in the text provided.



## 1 Manage studies

#### In this chapter:

- Add a study
- Start or stop a study
- Install study MeML
- Check database connectivity
- Update database statistics
- Remove a study
- Assign rights to users

### Add a study

- 1. Click Home.
- 2. Click
- 3. Enter a study name that:
  - Has between 3 and 16 characters.
  - Does not contain spaces or non-alphanumeric characters other than underscore.
  - Does not start with a digit or underscore.
  - Is not used by another study.
- 4. Enter a system user password that contains:
  - A minimum of eight characters.
  - At least one upper case character, and at least one number or special character.
- 5. Click Submit.

When the study setup is completed, a new study card appears on the Studies page. You manage the study using the buttons and icons on the study card.

The study type is Dev and approval is set to FALSE for all studies.

#### Note:

Adding a study could take up to 30 minutes to complete.

#### Start or stop a study

1. Click Home.



2. On the study card, click  $\bigcirc$  to start a study that is not running, or to stop a study that is running.

### Install study MeML

- 1. Click Home.
- 2. Click  $\stackrel{1}{\frown}$  on the study card.
- 3. Click Click to add or drag your XML files here.
- 4. Select one or more XML files, and click **Open**.

Alternatively, you can select and drag the files directly to the **Click to add or drag your XML files here** box.

- 5. If you selected multiple files, click the up and down arrows next to the files to set the order in which to install them.
- 6. Click Install.

#### Note:

Only files with .xml extension will be allowed by DECS. The .xml extension is case sensitive.

### Check database connectivity

Click Home.

On each study card:

indicates a successful connection between the application server and database server.

indicates the application server and the database server are not connected.

### Update database statistics

- 1. Click Home.
- 2. Click O on the study card.

Oracle recommends that you update database statistics after you add a large amount of data or metadata to a study.

#### Remove a study

- 1. Click Home.
- 2. Click X on the study card, and click OK to confirm.



## Assign rights to users

- 1. Click Admin.
- 2. On the left side, select a user.
- 3. Select one or more user rights, and click Update.

The following user rights exist in DECS Manager:

- Admin—Access the Admin page and assign rights to users.
- Add/Remove Study—Add and remove studies.
- Start/Stop Study—Start and stop studies.
- Update database stats—Update database statistics.
- Install MedML—Install study MedML.
- View event log—View the events added by InForm to the event log on the application server.



# 2 Troubleshooting

To get useful information when troubleshooting errors:

- Click **Event Log** to view the 1000 most recent events added by InForm to the event log on the InForm application server.
  - To view more details about an event, select it in the table.
  - To refresh the Event Log, click 2 above the table.
- When a study deployment or MedML installation fails, the status Failed and a View Log link appear on the study card.
  Click the link to view the error message generated when the failure occurred.



# 3 Frequently asked questions

#### In this section:

- How many studies can I add?
- What happens when I add a study?
- What happens when I remove a study?
- How can I see the URLs associated with a study?

#### How many studies can I add?

You can add up to 10 studies. If 10 studies have been added, you can add a new study only after you remove an existing study.

#### What happens when I add a study?

DECS Manager performs the following tasks when you add a study:

1. Create a new InForm server and a new study (pfadmin command).

The server name is the same as the study name.

- 2. Configure the study to support automated deployment from Oracle Health Sciences Central Designer (pfadmin command).
- 3. Add the new study in Oracle Health Sciences InForm Adapter (RegisterTrialTool SetServer and SetTrial commands).
- Install the base components of the Oracle Health Sciences InForm application for the study (dbsetup command).
- 5. Set the system user password (pfadmin command).
- 6. Enable the ODMSubmitService (pfadmin command).

#### Note:

Adding a study could take up to 30 minutes to complete.

## What happens when I remove a study?

DECS Manager performs the following tasks when you remove a study:

- 1. Remove the study from Oracle Health Sciences InForm Adapter (RemoveServer and RemoveTrial commands).
- Disable the Deployment and Clinical Data API web services for the study (pfadmin command).



- **3.** Remove the Oracle Health Sciences InForm server and study (pfadmin command).
- 4. Remove study virtual directories from IIS (pfadmin command).
- 5. Remove from ODBC data source administration (pfadmin command).
- 6. Remove the study user from the database (pfadmin command).

## How can I see the URLs associated with a study?

Click 🕕 on the study card.

A dialog box appears listing the study, Oracle Health Sciences InForm Adapter, Clinical API, and Deployment URLs.

