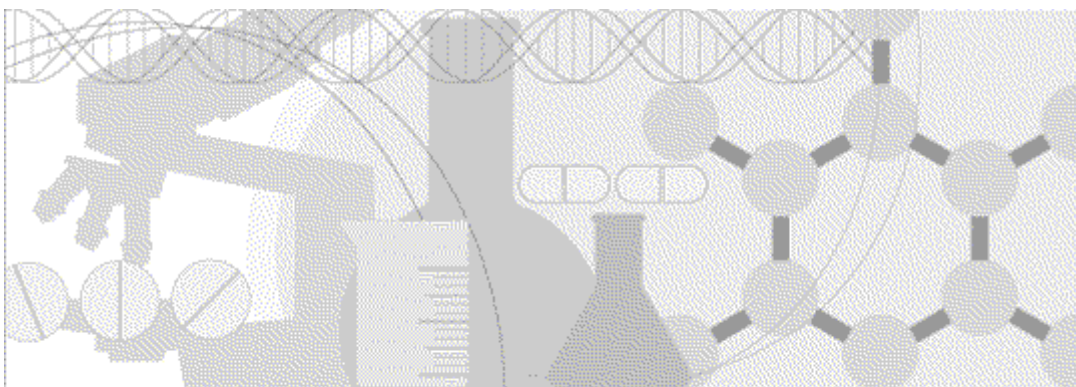


Release Notes

Oracle[®] Health Sciences InForm 6.0



ORACLE[®]

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Contents

About this release vii

About the InForm GTM 6.0 release	viii
Additional software	viii
InForm 6.0 documentation.....	ix
If you need assistance.....	xiii

Chapter 1 Hardware and software requirements 1

Client requirements	2
Client computers—Microsoft Windows	2
Client computers—Macintosh	2
Client computers—Tablets.....	3
Server requirements.....	4
Minimum hardware requirements	4
Software requirements	5
Hardware recommendations for enhanced performance.....	9
Windows patch recommendations for the InForm software	10
English Windows operating system patches for the InForm and Cognos application servers.....	10
Japanese Windows operating system patches for the InForm and Cognos application servers.....	14
Oracle client component and patch requirements for the InForm application server.....	18
Minimum Oracle client software components required for the InForm application server and Cognos 8 Business Intelligence application servers.....	18
Minimum Oracle client patches required for the InForm application servers.....	19
Minimum Oracle client patches required for the Cognos 8 Business Intelligence application servers ..	19
Oracle database server component and patch requirements for the InForm study database and Reporting and Analysis database servers.....	20
Minimum Oracle database server components required for the InForm study database and Reporting and Analysis database servers.....	20
Minimum Oracle database server patches required for the InForm study database and Reporting and Analysis database servers.....	20
InForm 6.0 compatibility with other Oracle Health Sciences products	22
Considerations for configuring email notifications	23

Chapter 2 Changes in this release 25

Enhancements in InForm release 6.0.....	26
Enhancements: System requirements	26
Enhancements: Authentication and Passwords	27
Enhancements: Data Viewer	28
Enhancements: Forms, Visits, Items, and Itemsets	31
Enhancements: InForm Portal	35
Enhancements: Installation and Configuration	36
Enhancements: Rules.....	36
Enhancements: Source verification.....	37
Enhancements: System configuration.....	38
Enhancements: Clinical Data API.....	39
Fixes: Authentication and Passwords.....	40
INF-13168	40
Fixes: Cross-Product and Integration	41
INF-12618	41
INF-13742	41
Fixes: Data Viewer.....	42

INF-12421	42
INF-13209	42
INF-13210	42
INF-13307	43
INF-13770	43
INF-13931	43
INF-14158	44
INF-14184	44
INF-14239	45
Fixes: Forms, Visits, Items, and Itemsets	46
INF-5450	46
INF-12607	46
INF-12866	46
INF-13143	47
INF-13144	47
INF-13190	47
INF-13361	48
INF-13362	48
INF-13675	48
INF-13842	49
INF-14107	49
INF-14300	49
Fixes: InForm Portal	50
INF-12994	50
INF-13081	50
INF-13083	50
INF-13218	51
Fixes: Installation and Configuration	52
INF-12643	52
INF-13365	52
INF-13461	53
INF-13932	53
Fixes: Queries	54
INF-13214	54
INF-13364	54
Fixes: Reporting—General	55
INF-13455	55
INF-13457	55
Fixes: Reporting—Ad Hoc Reports	56
INF-13335	56
INF-13452	56
INF-13504	57
INF-13957	57
INF-14172	58
INF-14180	58
Fixes: Reporting—Database	59
INF-12639	59
INF-13237	59
INF-13288	59
INF-13324	60
INF-13325	60
INF-13326	60
INF-13327	60
INF-13333	61
INF-13383	61
INF-13450	61
INF-13451	62

INF-14131	62
INF-14247	62
INF-14252	63
Fixes: Reporting—Standard Reports	64
INF-13207	64
Fixes: Source Verification	65
INF-13208	65
INF-13460	65
INF-13768	65
INF-13771	66
Fixes: Subject Transfers	67
INF-13380	67
Fixes: Utilities	68
INF-13929	68
INF-13930	68
Documentation updates	69
Updates to the Release Notes	69
Updates to the Upgrade and Migration Guide	69
Updates to the Installation Guide	69
Updates to the Study and Reporting Setup Guide	69
Updates to the User Guide	70
Updates to the Reporting and Analysis Guide	70
Updates to the Reporting Database Schema Guide	70
Updates to the Utilities Guide	71
Updates to the Portal Administration Guide	71

Chapter 3 Installing or upgrading to this release 73

Before installing or upgrading to this release	74
Installing the InForm 6.0 software for the first time	75
Upgrading or migrating to the InForm 6.0 release	76

About this release

In this preface

About the InForm GTM 6.0 release.....	viii
InForm 6.0 documentation	ix
If you need assistance.....	xiii

About the InForm GTM 6.0 release

The InForm GTM 6.0 release includes the following components.

- InForm GTM 6.0 product CD.
- InForm GTM 6.0 documentation CD—English.
- InForm GTM 6.0 documentation CD—Japanese.

Note: The Japanese documentation CD contains the most current translation of every document. For the documents that are available from both the user interface and the documentation CD, Oracle recommends using the PDF version of the document on the documentation CD.

Before beginning the installation, check the Oracle Software Delivery Cloud (<https://edelivery.oracle.com>) or the Download Center (<https://extranet.phaseforward.com>) for the latest service packs and hot fixes, as well as the accompanying *Release Notes* and *Known Issues* documents, and the latest versions of the documentation.

Additional software

- Cognos 8 Business Intelligence installation files:
 - BiReportingWin64_CZAG2ML.tar.gz (Cognos 8.4.1 Business Intelligence installation).
 - C8_BI_8_4_1_Win64_FP004.tar.gz (Cognos 8.4.1 Business Intelligence FP4 upgrade).
 - Cognos 8.4.1 Hotsites:
 - up_c8bisrvr_winx64_8.4.105.1076_ml.tar.gz
 - up_c8bisrvr_winx64_8.4.105.1100_ml.tar.gz

InForm 6.0 documentation

The InForm 6.0 documentation includes the documents in the following table. All documentation is available from the Oracle Software Delivery Cloud (<https://edelivery.oracle.com>) and the Download Center (<https://extranet.phaseforward.com>).

All documents may not be updated for every InForm release. Therefore, the version numbers for the documents in a release may differ.

Document	Description	Part number	Last updated
<i>Release Notes</i>	The <i>Release Notes</i> document describes enhancements and issues fixed in the current release, and other late-breaking information.	E37405-2	6.0
<i>Known Issues</i>	<p>The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available.</p> <p>Note: The most current list of known issues is available on the Extranet. To sign in to the Extranet, go to https://extranet.phaseforward.com.</p>	E37406-1	6.0
<i>Upgrade and Migration Guide</i>	The <i>Upgrade and Migration Guide</i> provides instructions for upgrading and migrating the InForm software and InForm Portal software to the current InForm release, and for upgrading the Cognos 8 Business Intelligence software for use with the Reporting and Analysis module. The guide also describes any changes and additions made to the database schema, MedML, and resource files.	E37407-1	6.0
<i>Secure Configuration Guide</i>	The <i>Secure Configuration Guide</i> provides an overview of the security features provided with the Oracle® Health Sciences InForm application, including details about the general principles of application security, and how to install, configure, and use the InForm application securely.	E37408-1	6.0
<i>Installation Guide</i>	<p>The <i>Installation Guide</i> describes how to install the software and configure the environment for the InForm application and Cognos 8 Business Intelligence software.</p> <p>This document is also available from the Documentation CD.</p>	E37409-2	6.0

Document	Description	Part number	Last updated
<i>Study and Reporting Setup Guide</i>	<p>The <i>Study and Reporting Setup Guide</i> describes how to perform the tasks that are required to set up an InForm study and configure the Reporting and Analysis module for the study.</p> <p>This document is also available from the Documentation CD.</p>	E37410-1	6.0
<i>User Guide</i>	<p>The <i>User Guide</i> provides an overview of the InForm application including details on multilingual studies, how to navigate through the user interface, and how to use the application to accomplish typical tasks you perform while running a clinical study.</p> <p>This document is also available from the Documentation CD and the InForm user interface.</p>	E37411-1	6.0
<i>Reporting and Analysis Guide</i>	<p>The <i>Reporting and Analysis Guide</i> provides an overview of the Reporting and Analysis module. It includes a brief overview of the Reporting and Analysis interface, illustrates how to access the Ad Hoc Reporting workspace, and describes the study management and clinical data packages available for creating reports. It also provides detailed descriptions of each standard report that is included with your installation.</p>	E37412-1	6.0
<i>Reporting Database Schema Guide</i>	<p>The <i>Reporting Database Schema Guide</i> describes the Reporting and Analysis database schema, and provides information on creating Reporting Database Extracts (RDEs).</p>	E37415-1	6.0
<i>Portal Administration Guide</i>	<p>The <i>Portal Administration Guide</i> provides step-by-step instructions for setting up the InForm Portal software, and configuring and managing the InForm Portal application.</p> <p>This document is also available from the Documentation CD.</p>	E37416-1	6.0

Document	Description	Part number	Last updated
<i>Utilities Guide</i>	<p>The <i>Utilities Guide</i> provides information about and step-by-step instructions for using the following utilities:</p> <ul style="list-style-type: none"> • PFCConsole utility • MedML Installer utility • InForm Data Import utility • InForm Data Export utility • InForm Performance Monitor utility • InForm Report Folder Maintenance utility <p>This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.</p> <p>This document is also available from the Documentation CD.</p>	E37413-1	6.0
MedML Installer utility online Help	<p>The MedML Installer utility online Help provides information about, and step-by-step instructions for using, the MedML Installer utility, which is used to load XML that defines study components into the InForm database.</p> <p>This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.</p> <p>This document is also available from the user interface.</p>	NA	NA
InForm Data Export utility online Help	<p>The InForm Data Export utility online Help provides information about and step-by-step instructions for using the InForm Data Export utility, which is used to export data from the InForm application to the following output formats:</p> <ul style="list-style-type: none"> • Customer-defined database (CDD). • Name value pairs. <p>This document is also available from the user interface.</p>	NA	NA

Document	Description	Part number	Last updated
InForm Data Import utility online Help	<p>The InForm Data Import utility online Help provides information about and step-by-step instructions for using the InForm Data Import utility, which is used to import data into the InForm application.</p> <p>This document is also available from the user interface.</p>	NA	NA

If you need assistance

Oracle customers have access to support through My Oracle Support. For information, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info>, or if you are hearing impaired, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs>.

CHAPTER 1

Hardware and software requirements

In this chapter

Client requirements.....2

Server requirements.....4

Hardware recommendations for enhanced performance.....9

Windows patch recommendations for the InForm software10

Oracle client component and patch requirements for the InForm application server.....18

Oracle database server component and patch requirements for the InForm study database
and Reporting and Analysis database servers20

InForm 6.0 compatibility with other Oracle Health Sciences products22

Considerations for configuring email notifications23

Client requirements

Client computers—Microsoft Windows

You can access the InForm application from any computer that has a Microsoft Windows operating system that supports Microsoft Internet Explorer 7.0, 8.0, or 9.0, Firefox 3.5 or higher, or Google Chrome 19 or higher.

Note: Cognos 8.4.1 does not support Internet Explorer 9.0, Google Chrome, or Apple Safari.

- Display resolution must be a minimum of 800 x 600.
- Recommended display resolution is 1024 x 768 or higher.
- The Data Viewer requires a resolution of 1024 x 768.
- To view files that you export from the Data Viewer, you must install a version of Microsoft Excel that is compatible with your operating system.
- To view reports that you export from the Reporting and Analysis module, you must install a version of Microsoft Excel that is compatible with your operating system.
- To view reports in PDF format, you must install Adobe Acrobat Reader 7.0 or higher.

The InForm 6.0 client was validated using Microsoft Windows XP, Windows Vista, and Windows 7.

For more information, see the *Installation Guide*.

Client computers—Macintosh

You can access the InForm application from Macintosh computers running OS X 10.5 or higher, using Apple Safari 3.2.1 or higher.

- Display resolution must be a minimum of 800 x 600.
- Recommended display resolution is 1024 x 768 or higher.
- The Data Viewer requires a resolution of 1024 x 768.
- Apple Safari is not supported for the Reporting and Analysis module.
- To view files that you export from the Data Viewer, you must install a version of Microsoft Excel that is compatible with your operating system.
- To view reports that you export from the Reporting and Analysis module, you must install a version of Microsoft Excel that is compatible with your operating system.
- To view reports in PDF format, you must install Adobe Acrobat Reader 7.0 or higher.

For more information, see the *Installation Guide*.

Client computers—Tablets

You can access the InForm application from the following tablets:

- **iPad 2**—Running iOS 5.1 or higher.
- **Android**—Running Android 4.0.x (Ice Cream Sandwich) or higher.

Tablets are not supported for the Reporting and Analysis module.

Server requirements

Minimum hardware requirements

The following tables identify the minimum hardware requirements for an InForm server environment, with the Reporting and Analysis module, that supports a single, small-study deployment or a study test environment. The environment consists of three servers: an InForm application server, a Cognos 8 Business Intelligence application server, and a combined Oracle database server.

For additional information on sizing guidelines and recommendations, see the *Installation Guide*.

InForm application server

Component	Description
Processor	2.0 GHz or higher Intel or AMD x86 processor (two or more processor cores).
Memory	4 GB RAM.
Disk storage	2 GB minimum free space for the InForm application and Oracle client files.

Cognos 8 Business Intelligence application server

Component	Description
Processor	2.0 GHz or higher Intel or AMD x86 processor (two or more processor cores).
Memory	4 GB RAM.
Disk storage	10 GB minimum free space for the Cognos 8 Business Intelligence application, Cognos 8 Business Intelligence Temp space, and Oracle client files.

Oracle database servers

Component	Description
Processor	2.0 GHz or higher Intel or AMD x86 processor (two or more processor cores).
Memory	4 GB RAM.
Disk storage	5 GB minimum free space for the Oracle database application files, plus sufficient storage capacity for the study and Reporting and Analysis database (dependent on the study size).

Software requirements

The InForm 6.0 release supports the Oracle 11g release.

InForm application server

Component	Description
Operating system	<p>Supported Microsoft Windows platforms:</p> <p>2008 R2 Standard Edition or Enterprise Edition with Service Pack 1 (64-bit).</p> <p>Note: The InForm 6.0 application server was validated using the Microsoft Windows 2008 R2 Standard Edition.</p> <p>For the recommended patches for Windows operating systems, see <i>Windows patch recommendations for the InForm software</i> (on page 10).</p>
Web server	<p>Microsoft Internet Information Server 7.5 (IIS 7.5).</p> <p>Note: The IIS configuration must include the following:</p> <ul style="list-style-type: none"> • The DefaultAppPool Managed Pipeline Mode is set to Integrated. • IIS 6.0 Compatibility is Enabled. <p>Note: ASP.NET must be installed as a separate operating system component before you install the InForm software.</p>
Database client (64-bit)	<p>Supported Oracle versions:</p> <p>Oracle 11g database servers: 11.2.0.3 and 11.2.0.2.</p> <p>The Oracle Standard Edition database and client are not supported for the InForm software. The InForm software requires functionality that exists in the Enterprise Edition.</p> <p>Note: The InForm 6.0 application server was validated using Oracle Enterprise Edition 11.2.0.3.</p> <p>For details on required components and patchsets, see <i>Oracle client component and patch requirements for the InForm application server</i> (on page 18).</p>

Component	Description
Other	<ul style="list-style-type: none">• Microsoft MSXML 6.0 SP3.• .NET 4.0.• .NET 3.5 SP1• ODP.NET 2.0.• ASP.MVC 2.0• Web Services Enhancements (WSE) 2.0 SP3 (only if using the InForm Server Adapter application).• Microsoft Visual C++ 2008 Redistributable - x64 9.0.x• Microsoft Access Database Engine 2010 Redistributable (AccessDatabaseEngine_x64)• Configured SMTP server. <p>Note: The SMTP server sends email notifications from the study server. These emails send Password Reset notifications and links to report outputs from the Reporting and Analysis module. For these features to work as expected, you must configure the SMTP server.</p>

Cognos 8 Business Intelligence servers

Component	Description
Operating systems	<p>Supported Microsoft Windows platforms:</p> <p>2008 R2 Standard Edition or Enterprise Edition with Service Pack 1 (64-bit).</p> <p>Note: The InForm 6.0 Cognos 8 Business Intelligence application server was validated using the Microsoft Windows 2008 R2 Standard Edition.</p> <p>For the recommended patches for Windows operating systems, see <i>Windows patch recommendations for the InForm software</i> (on page 10).</p>
Reporting	<p>Cognos Business Intelligence 8.4.1 64-bit with Fix Pack 4 and the following Hotsites:</p> <ul style="list-style-type: none"> up_c8bisrvr_winx64_8.4.105.1076_ml.tar.gz up_c8bisrvr_winx64_8.4.105.1100_ml.tar.gz <p>Cognos requires the following Oracle JDBC driver:</p> <ul style="list-style-type: none"> ojdbc6.jar <p>The OJDBC driver is a requirement for the Cognos Report Server and the Cognos Content Manager.</p>
LDAP	Oracle Directory Server Enterprise Edition 11g. Release 1 (11.1.1.5.0).
Database client (32-bit)	<p>Supported Oracle versions:</p> <p>Oracle 11g database servers: 11.2.0.3 and 11.2.0.2.</p> <p>For details on required components and patchsets, see <i>Oracle client component and patch requirements for the InForm application server</i> (on page 18).</p> <p>The Oracle database client is a requirement for the Cognos Report Server and the Cognos Content Manager.</p> <p>Note: The Cognos 8 Business Intelligence application server was validated using Oracle Enterprise Edition 11.2.0.3.</p>
Other	<ul style="list-style-type: none"> .NET 3.5 SP1. <p>.NET is a requirement for the Cognos Report Server and the Cognos Content Manager.</p> <ul style="list-style-type: none"> ASP <p>ASP is a requirement for the Cognos Gateway Server</p> <ul style="list-style-type: none"> Java Runtime Environment 6 (JRE 1.6 winx64) <p>Note: The Cognos 8 Business Intelligence application server was validated using Oracle Java Runtime Environment (JRE) 1.6.0_35.</p>

Oracle database servers

Component	Description
Operating system	<p>Supported Windows platforms:</p> <ul style="list-style-type: none">• Microsoft Windows Server 2008 R2 Standard Edition or Enterprise Edition Service Pack 1 (64-bit). <p>Supported Unix platforms:</p> <p>See your Oracle database documentation for the supported versions of the following operating systems for the Oracle database:</p> <ul style="list-style-type: none">• Sun Solaris 10 (64-bit).• Oracle Enterprise Linux 5 (OEL 5.8 with Unbreakable Enterprise Kernel R2).• HP-UX 11 PA-RISC (v1 and v2) (64-bit).• IBM AIX 5L (64-bit).• Red Hat Enterprise Linux AS/ES 3, 4 and 5 (x86-64). <p>Note: The InForm 6.0 Oracle database servers were validated using the Oracle Enterprise Linux 5.</p>
Database	<p>Supported Oracle versions:</p> <p>Oracle 11g database servers: 11.2.0.3 and 11.2.0.2.</p> <p>For details on required components and patchsets, see <i>Oracle database server component and patch requirements for the InForm database and Reporting and Analysis database servers</i> (on page 20).</p> <p>Note: The database servers were validated using the Oracle Enterprise Edition 11.2.0.3.</p>

Hardware recommendations for enhanced performance

In practice, an appropriate hardware architecture must be developed based on the workload that will be generated by the studies that are hosted in the environment. This often means allocating additional memory, processor cores, and appropriate storage infrastructure to each server.

For multi-study environments, the study and Reporting and Analysis databases may be segmented onto independent, appropriately scaled Oracle database servers. Depending on Reporting and Analysis usage and requirements, the Cognos 8 Business Intelligence application components (Content Manager, Report Server, and Gateway Server) may also be segmented onto independent, appropriately scaled application servers.

For additional information on sizing guidelines and recommendations, see the *Installation Guide*.

Windows patch recommendations for the InForm software

English Windows operating system patches for the InForm and Cognos application servers

The recommended Windows patch list applies to Microsoft Windows Server 2008 R2 Standard Edition 64-bit-English with Service Pack 1. InForm and Cognos 8 Business Intelligence servers with the recommended patches were used for validation of the InForm 6.0 software.

English Windows operating system	
Hot Fix ID	Description
KB2425227	Security Update
KB2484033	Update
KB2488113	Update
KB2492386	Update
KB2505438	Update
KB2506014	Update
KB2506212	Security Update
KB2506928	Update
KB2507618	Security Update
KB2509553	Security Update
KB2510531	Security Update
KB2511250	Update
KB2511455	Security Update
KB2515325	Update
KB2522422	Update
KB2529073	Update
KB2533552	Update
KB2536275	Security Update
KB2536276	Security Update
KB2541014	Update
KB2544521	Security Update
KB2544893	Security Update
KB2545698	Update
KB2547666	Update

English Windows operating system	
Hot Fix ID	Description
KB2552343	Update
KB2560656	Security Update
KB2563227	Update
KB2564958	Security Update
KB2567680	Security Update
KB2570947	Security Update
KB2584146	Security Update
KB2585542	Security Update
KB2598845	Update
KB2603229	Update
KB2604115	Security Update
KB2607047	Update
KB2607576	Update
KB2608658	Update
KB2618451	Security Update
KB2620704	Security Update
KB2620712	Security Update
KB2621440	Security Update
KB2631813	Security Update
KB2632503	Update
KB2633952	Update
KB2636573	Update
KB2640148	Update
KB2641690	Update
KB2643719	Security Update
KB2644615	Security Update
KB2645640	Security Update
KB2647753	Update
KB2653956	Security Update
KB2654428	Security Update
KB2655992	Security Update
KB2656356	Security Update

English Windows operating system	
Hot Fix ID	Description
KB2656373	Security Update
KB2656411	Security Update
KB2658846	Security Update
KB2659262	Security Update
KB2660075	Update
KB2661254	Update
KB2667402	Security Update
KB2675157	Security Update
KB2676562	Security Update
KB2677070	Update
KB2679255	Hotfix
KB2685939	Security Update
KB2686831	Security Update
KB2688338	Security Update
KB2690533	Security Update
KB2691442	Security Update
KB2695962	Security Update
KB2698365	Security Update
KB2699779	Update
KB2699988	Security Update
KB2703157	Update
KB2705219	Security Update
KB2706045	Security Update
KB2709630	Update
KB2709715	Security Update
KB2712808	Security Update
KB2718523	Security Update
KB2718704	Update
KB2719857	Update
KB2719985	Security Update
KB2724197	Security Update
KB2729094	Update

English Windows operating system	
Hot Fix ID	Description
KB2731771	Update
KB2731847	Security Update
KB2732059	Update
KB2735855	Update
KB2736233	Update
KB2739159	Update
KB2743555	Security Update
KB2744842	Security Update
KB2749655	Update
KB2756822	Update
KB958488	Update
KB976902	Update
KB976932	Service Pack
KB982018	Update

Japanese Windows operating system patches for the InForm and Cognos application servers

This recommended Windows patch list applies to Microsoft Windows 2008 R2 Standard Edition 64-bit-Japanese with Service Pack 1. The InForm and Cognos 8 Business Intelligence servers with the recommended patches were used for validation of the InForm 6.0 software.

Japanese Windows operating system	
Hot Fix ID	Description
KB2425227	Security Update
KB2484033	Update
KB2488113	Update
KB2492386	Update
KB2505438	Update
KB2506014	Update
KB2506212	Security Update
KB2506928	Update
KB2507618	Security Update
KB2509553	Security Update
KB2510531	Security Update
KB2511250	Update
KB2511455	Security Update
KB2515325	Update
KB2522422	Update
KB2529073	Update
KB2533552	Update
KB2536275	Security Update
KB2536276	Security Update
KB2541014	Update
KB2544521	Security Update
KB2544893	Security Update
KB2545698	Update
KB2547666	Update
KB2552343	Update
KB2560656	Security Update

Japanese Windows operating system	
Hot Fix ID	Description
KB2563227	Update
KB2564958	Security Update
KB2567680	Security Update
KB2570947	Security Update
KB2584146	Security Update
KB2585542	Security Update
KB2598845	Update
KB2603229	Update
KB2604115	Security Update
KB2607047	Update
KB2607576	Update
KB2608658	Update
KB2618451	Security Update
KB2620704	Security Update
KB2620712	Security Update
KB2621440	Security Update
KB2631813	Security Update
KB2632503	Update
KB2633952	Update
KB2636573	Update
KB2640148	Update
KB2641690	Update
KB2643719	Security Update
KB2644615	Security Update
KB2645640	Security Update
KB2647753	Update
KB2653956	Security Update
KB2654428	Security Update
KB2655992	Security Update
KB2656356	Security Update
KB2656373	Security Update
KB2656411	Security Update

Japanese Windows operating system	
Hot Fix ID	Description
KB2658846	Security Update
KB2659262	Security Update
KB2660075	Update
KB2661254	Update
KB2667402	Security Update
KB2675157	Security Update
KB2676562	Security Update
KB2677070	Update
KB2679255	Hotfix
KB2685939	Security Update
KB2686831	Security Update
KB2688338	Security Update
KB2690533	Security Update
KB2691442	Security Update
KB2695962	Security Update
KB2698365	Security Update
KB2699779	Update
KB2699988	Security Update
KB2703157	Update
KB2705219	Security Update
KB2706045	Security Update
KB2709630	Update
KB2709715	Security Update
KB2712808	Security Update
KB2718523	Security Update
KB2718704	Update
KB2719857	Update
KB2719985	Security Update
KB2724197	Security Update
KB2729094	Update
KB2731771	Update
KB2731847	Security Update

Japanese Windows operating system	
Hot Fix ID	Description
KB2732059	Update
KB2735855	Update
KB2736233	Update
KB2739159	Update
KB2743555	Security Update
KB2744842	Security Update
KB2749655	Update
KB2756822	Update
KB958488	Update
KB976902	Update
KB976932	Service Pack
KB982018	Update

Oracle client component and patch requirements for the InForm application server

The Oracle database patches apply to the InForm study database and the Reporting and Analysis database. The client patches apply to the Oracle client for the core InForm application.

Note: The patches for the Oracle database server and the Oracle client are set so that both the database and the client use the same version of TSTZ (timestamp/timezone) files. The version of these files should always match. Take this into consideration when applying future patches to the database or client.

If a future patch for either the database or client changes the version of these files, you must review the patches for both the client and database.

Oracle Windows patches

When a physical machine is more than one type of server, you need all the patches that are required for each type of server. For example, in a single-tier InForm installation, the machine that is both the InForm server and the database server requires all the patches listed under both the Oracle database and the Oracle client.

For more information, see *Software requirements* (on page 5).

Minimum Oracle client software components required for the InForm application server and Cognos 8 Business Intelligence application servers

When the base release of Oracle software (11.2.0.2 or 11.2.0.3) is installed, select the following components:

Oracle Client:

- Oracle Database Utilities.
- Oracle Java Client.
- SQL*Plus.
- Oracle Windows Interfaces:
 - Oracle Services for Microsoft Transaction Server.
 - Oracle Objects for OLE.
 - Oracle ODBC Driver.
 - Oracle Provider for OLE DB.
- Oracle Data Provider for .NET.
- Oracle Net.

Minimum Oracle client patches required for the InForm application servers

Oracle 11.2.0.3 for Windows 64-bit

Oracle version	Patch number	Patch application order	Notes
11.2.0.3	13413168	1	Patch set/Base install Oracle 11.2.0.3
11.2.0.3	14613223	2	11.2.0.3 Patch 11

Oracle 11.2.0.2 for Windows 64-bit

Oracle version	Patch number	Patch application order	Notes
11.2.0.2	10098816	1	Patch set/Base install Oracle 11.2.0.2
11.2.0.2	14672268	2	Patch 22

Minimum Oracle client patches required for the Cognos 8 Business Intelligence application servers

Note: The Cognos 8 Business Intelligence application servers require the 32-bit version of the Oracle client.

Oracle 11.2.0.3 for Windows 32-bit

Oracle version	Patch number	Patch application order	Notes
11.2.0.3	13413168	1	Patch set/Base install Oracle 11.2.0.3
11.2.0.3	14613222	2	11.2.0.3 Patch 11

Oracle 11.2.0.2 for Windows 32-bit

Oracle version	Patch number	Patch application order	Notes
11.2.0.2	10098816	1	Patch set/Base install Oracle 11.2.0.2
11.2.0.2	14672267	2	Patch 22

Oracle database server component and patch requirements for the InForm study database and Reporting and Analysis database servers

Minimum Oracle database server components required for the InForm study database and Reporting and Analysis database servers

When the base release of Oracle software (11.2.0.2 or 11.2.0.3) is installed, the following components must be selected:

- Oracle Database
- Oracle Call Interface
- Oracle Net Services
- Oracle Net Listener

Minimum Oracle database server patches required for the InForm study database and Reporting and Analysis database servers

Oracle 11.2.0.3 for Windows 64-bit and Red Hat Linux AS 4 x86-64

Oracle 11.2.0.3 for Windows 64-bit

Oracle version	Patch number	Patch application order	Notes
11.2.0.3	13413168	1	Patch set/Base install Oracle 11.2.0.3
11.2.0.3	14613223	2	11.2.0.3 Patch 11

Oracle 11.2.0.3 for Red Hat Linux AS 4 x86-64

Oracle version	Patch number	Patch application order	Notes
11.2.0.3	13466801	1	Patch set/Base install Oracle 11.2.0.3
11.2.0.3.4	14275605	2	Patch Set Update 11.2.0.3.4

Oracle 11.2.0.2 for Windows 64-bit and Red Hat Linux AS 4 x86-64

Oracle 11.2.0.2 for Windows 64-bit

Oracle version	Patch number	Patch application order	Notes
11.2.0.2	10098816	1	Patch set/Base install Oracle 11.2.0.2
11.2.0.2	14672268	2	Patch 22

Oracle 11.2.0.2 for Red Hat Linux AS 4 x86-64

Oracle version	Patch number	Patch application order	Notes
11.2.0.2	10098816	1	Patch set/Base install Oracle 11.2.0.2
11.2.0.2.8	14275621	2	Patch Set Update 11.2.0.2.8

InForm 6.0 compatibility with other Oracle Health Sciences products

The *Products Compatibility Matrix*, which identifies InForm compatibility with other Oracle Health Sciences products, can be downloaded from <https://extranet.phaseforward.com>.

To sign in, click **Customer Login**. Enter your email address and password, and navigate to the **Bulletins** section.

Considerations for configuring email notifications

Although the InForm application can be configured to send emails from the trial server, the emails are not able to be encrypted. Customers must consider this fact when designing email notifications, and should not include any data in an email that is required to be encrypted.

CHAPTER 2

Changes in this release

In this chapter

Enhancements in InForm release 6.0.....	26
Fixes: Authentication and Passwords.....	40
Fixes: Cross-Product and Integration.....	41
Fixes: Data Viewer.....	42
Fixes: Forms, Visits, Items, and Itemsets	46
Fixes: InForm Portal	50
Fixes: Installation and Configuration.....	52
Fixes: Queries	54
Fixes: Reporting—General.....	55
Fixes: Reporting—Ad Hoc Reports	56
Fixes: Reporting—Database	59
Fixes: Reporting—Standard Reports	64
Fixes: Source Verification.....	65
Fixes: Subject Transfers	67
Fixes: Utilities	68
Documentation updates.....	69

Enhancements in InForm release 6.0

Enhancements: System requirements

Federal Information Processing Standard (FIPS) compliance

INF-12966—The InForm software is compliant with the FIPS 140-1 and FIPS 140-2 computer security standards. You can now install the InForm software on a FIPS enabled server.

Support for 64-bit application server and Cognos 8 Business Intelligence servers

The InForm application server and Cognos 8 Business Intelligence servers now support 64-bit platforms only. For more information, see the software requirements in ***InForm application server*** (on page 5) and ***Cognos 8 Business Intelligence servers*** (on page 7).

In previous InForm releases, the InForm application server and Cognos 8 Business Intelligence servers supported 32-bit platforms.

Support for iPad and Android tablets

You can now access the InForm application from the following tablets:

- **iPad 2**—Running iOS 5.1 or higher.
- **Android**—Running Android 4.0.x (Ice Cream Sandwich) or higher.

Tablets are not supported for the Reporting and Analysis module.

Enhancements: Authentication and Passwords

Improved password reset functionality

New features in the InForm 6.0 release improve security and make the password reset tasks easier to use.

You are now required to answer two different security questions when changing or resetting your password; the security questions are pre-defined by Oracle. Free format questions are no longer allowed.

In addition, the terminology that describes your account status and the information in the email sent by the InForm application after a successful password change are improved.

The following pages in the user interface have been updated to support these improvements:

- Login page
- Reset Your Password page
- Reset Your Password Confirmation page
- Change Expired Password page
- Password Recovery Information—Change Password page
- External Reporting Login page

For more information, see the *User Guide* and the *Study and Reporting Setup Guide*.

Improvements in the email message after a password change

The information in the email sent by the InForm application after a successful password change has been improved.

- The email addresses of the sender and receiver now appear in the body of the email with a temporary password.
- The maximum email address length is now 255 characters.
- When you reset your password, the email from the InForm application includes a temporary password and instructions on how to access your account.

The information in the email can be customized by a study administrator. For more information, see the *Study and Reporting Setup Guide*.

Login pages support customized support and contact information

A study administrator can now add support and contact information to the InForm Login page and the External Reporting Login page. By default, support and contact information does not appear on the login pages.

For more information, see the *Study and Reporting Setup Guide*.

Enhancements: Data Viewer

Data Viewer has five new Custom Review States rights

INF-11792—There are now five Assign Review State rights that allow you to assign custom review states in the Data Viewer.

- Assign Review State 1
- Assign Review State 2
- Assign Review State 3
- Assign Review State 4
- Assign Review State 5

The five new rights, one for each custom review state, can be assigned to any rights group. Members of the rights groups inherit the assigned rights accordingly. You can assign only those custom review states for which you have the rights to do so.

When you have any of the Assign Review State rights, you automatically also have the View Review States right to view all the custom review states.

In the InForm 5.5 releases, there was one Assign Review States right. If you migrate from an InForm 5.5 release to the InForm 6.0 release, the original Assign Review States right is mapped to the five new Assign Review State rights. Therefore, if you were assigned the Assign Review States right in an InForm 5.5 release, after migrating to the InForm 6.0 release, you will be assigned all five of the new Assign Review State rights.

Data Viewer Detail Pane now displays item status icons

INF-12176—In the Data Viewer Record Listing View, the Detail Pane now displays status icons for items.

In the InForm 5.5 releases, when you selected an item in the Detail Pane, the status icon that appeared was for the form the item was on; it was not the status icon for the item. This may have, for example, misled users to think that the data item contained a query when it did not.

Data Viewer filters on change of query status

INF-12178—In the Data Viewer, you can now filter forms to see if they have a change of query status, such as whether a form has new, opened, or answered queries.

In the InForm 5.5 releases, in the Data Viewer user interface, the **Data changed since date** filter and the **Data changed since review** filter displayed only forms that had clinical data changes after the selected date. Because a query is not considered to be clinical data, forms with query state changes were not included as part of the filtering criteria.

The following options in the Filters pane in the Data Viewer user interface have been updated:

- The **Data changed since date** filter has been renamed to **Updated since date**.
- The **Data changed since review** filter has been renamed to **Updated since review**.

These two filters now include forms with clinical data changes and forms with query status changes of opened or answered after the selected date. Changes to other query statuses (such as Candidate, Close, or Delete) are not counted as an update.

Data Viewer highlights new or updated data

INF-12596—The Data Viewer now highlights new or updated data.

When you filter data in the Data Viewer using the **Updated since date** filter and **Updated since review** filter, the Data Viewer highlights the cells that belong to an item that contains data that has been changed since the selected date for filtering.

For example, if a blood pressure group control changes from 120/80 to 120/81, both the 120 and the 81 are highlighted because they belong to the same item.

Data Viewer allows single column filtering on some clinical data values

INF-12433—In the Data Viewer Record Listing View and Record Comparison View, you can now perform single column filtering on clinical data values. You can filter on any one column at a time, except for the columns for the review states, site, subject, and visit.

- Columns that contain entered values are filtered by the normalized value.
- For each column you filter, you can select up to five filtering criteria that are appropriate for the column type (for example, numeric, case-insensitive alphanumeric, or date).
- Column filtering is applied only in the current view. All column filtering selections are lost when you navigate away from the current view.

Data Viewer provides a way to mark comments as reviewed

INF-12434—The Data Viewer Comments View now provides a way to mark comments as reviewed. Marking a comment as reviewed is not considered to be a clinical data change.

The Comments View dialog box in the Data Viewer user interface now includes a column of check boxes that are associated with each comment.

When you select a checkbox to mark a comment as reviewed:

- The Data Viewer saves the user name and date and time that the comment was marked as reviewed to the database immediately.
- After you mark a comment as reviewed, the comment and its review status are shown to all reviewers.
- Any update to a comment in the InForm application unmarks the comment within the Data Viewer.

The Data Viewer displays the user name and date of review as a tooltip when you hover over the checkbox within the Comments View dialog box.

- The date and time is the local date and time.
- The date format is determined for each user by the setting in the Date Format field on the User details page in the Admin user interface.

Data Viewer provides the ability to view data from multiple forms in one view

INF-12631—The Data Viewer now provides a way to view data from multiple forms in one view. Columns from multiple clinical forms can be put together into a single view on which you can create queries, verify items, and export the data to Excel. For example, you can now view the subject's height from the Demographic form and the subject's weight and BMI from the Vital Signs form at the same time.

This improvement affects only the Data Viewer detail views, and has no effect on any other part of the InForm application.

In the InForm 5.5 releases, the Data Viewer Record Listings View showed only the records for a single form. This may not have been effective when reviewing related items that spread across multiple forms.

Enhancements: Forms, Visits, Items, and Itemsets

Dynamic child controls

INF-13350—Child controls are now visible or hidden depending on whether their parent controls are selected.

Study designers specify this behavior by defining a property on a control that is set in the Central Designer application during the study design. For more information, see ***Study design considerations*** (on page 32).

A parent control may be either a radio button or a checkbox. When you do not select a parent control in the InForm application, this functionality allows the child control to be visible or hidden.

- **Visible**—As in previous InForm releases.
- **Hidden**—Values in the child control are cleared, and the control does not occupy space on the InForm form.

In previous InForm releases, child controls were always visible and active even when their parent controls were not selected.

How dynamic controls affect the InForm application

Dynamic controls:

- Can be configured on all InForm forms created in the Central Designer application on which users can enter data.
- Are hidden in the sample case report book if they are set to be hidden (collapsed) on a form.
- Do not affect the Data Viewer.

Data Viewer columns corresponding to hidden child controls remain visible in the Data Viewer user interface.

- Do not affect the InForm Data Import utility functionality; the utility works the same way as in previous InForm releases.

Study design considerations

When study designers create or edit a form using the Central Designer application, they can specify whether a child control should be visible or hidden in the InForm application when its parent control is not selected.

Study designers must set the COLLAPSIBLE property for child items in the Central Designer application. This property controls the behavior of child controls in the InForm application. The property can have a value of true or false. For more information, see the Central Designer *InForm Design Guide*.

- **false (visible)**—When the COLLAPSIBLE property for a child item is set to false in the Central Designer application, and the parent control is not selected in the InForm application:
 - Child controls are always visible and active in the InForm application. This is the default behavior.
 - If the COLLAPSIBLE property for a child item is not defined in the Central Designer application, the child controls work in the InForm application as if the property is set to false.
- **true (hidden)**—When the COLLAPSIBLE property for a child item is set to true in the Central Designer application, and the parent control is not selected in the InForm application:
 - Child controls are hidden in the InForm application, and they do not occupy space on the InForm form.
 - The values of all hidden child controls are cleared.

New itemset types: Add Entry itemsets and Repeating Data itemsets

Two types of itemsets are now available for submitting multiple rows of data on a form at one time: Add Entry itemsets and Repeating Data itemsets.

These itemsets have attributes that are configured during study design. The display and behavior of the itemsets differ in the InForm application depending on the type. Both itemset types can appear on the same form.

Itemsets created in previous InForm releases behave as Add Entry itemsets in the InForm 6.0 release.

Feature comparison: Add Entry itemsets and Repeating Data itemsets

	Add Entry itemset	Repeating Data itemset
New features		
Variable rows	Yes	No
Fixed rows	No	Yes
Grid display of not started rows.	No	Yes
Predefined items	No	Yes Predefined items and values appear in a static display with a light grey background to distinguish them from items that allow data entry.
Display an asterisk (*) in the column header for required items.	Yes	Yes
Enter items from the grid view.	Yes Click the Add Entry button to add a new row to the itemset or to enter items.	Yes Click on or tab through the controls.
Blank items	No	Yes Cells for blank items appear with a light grey background. The associated item has no value, and the cell is not editable. Blank items are defined during study design.

	Add Entry itemset	Repeating Data itemset
New features		
Row comments	No	Yes Click the Add Item Comment icon to the right of the itemset. Use as a shortcut to apply the same comment to all items in the itemset that are not pre-defined or blank.
Existing features		
Allow new entries/rows	Yes	No No Add Entry button on the form.
Column sorting	Yes	No
Row hyperlinks	Yes After the first row submission. Click the underlined number at the beginning of the row to view each item in the Detailed view. In the Detailed view, you can enter comments, queries, and rules for individual items within an itemset row and display audit trail information on an item-by-item basis.	Yes For every row after the form is started. Click the underlined number at the beginning of the row to view each item in the Detailed view. In the Detailed view, you can enter comments, queries, and rules for individual items within an itemset row and display audit trail information on an item-by-item basis.
Row delete/undelete actions	Yes	No

Reporting changes for repeating data itemsets

Reporting changes due to the new repeating data itemset feature include:

- Repeating data itemsets are represented by separate report topics just like Add Entry itemsets.
- Pre-defined items are not reflected in the Reporting and Analysis module.
- Data for blank items appears in the operational model, clinical model, and RDEs.
 - Operational model—The new Sections: Properties report topic contains new report elements Grid Itemset (Y/N) and Initial Row Count.
 - Clinical model—The Reason Incomplete folder for repeating data itemset report topics contains a report element that indicates whether an item is blank.
 - RD_ views in RDEs contain new columns that identify whether an item in a repeating data itemset is blank.

For more information, see the *Reporting and Analysis Guide*.

Enhancements: InForm Portal

New InForm Portal Administration right

INF-12993—A new InForm Portal Config Admin right is now available.

This right:

- Allows a rights group to be dedicated to InForm Portal administration tasks; users no longer need to have extra rights to perform these tasks.
- Can be assigned to an existing rights group so that you do not need to create a new rights group for InForm Portal administration tasks.

This may reduce the additional user accounts required specifically for InForm Portal administration.

In previous releases, a user had to be in a specific rights group (for example, InForm Portal Admin) to perform InForm Portal administration tasks.

Size of the InForm Portal RefName database column is increased

INF-13177—The size of the RefName column in the InForm Portal database PF_DOC_REF table has been increased to 150 bytes. You can now upload documents in the InForm Portal application that have a RefName of up to 150 English characters, or up to 40 Japanese characters.

Enhancements: Installation and Configuration

Reporting customization wizards are available in silent mode

You can now run the two Reporting customization wizards from the command line in silent mode. In silent mode, the wizards run non-interactively, using the information you supply in a response file (setup.iss). The two wizards are:

- **Cognos Customization for InForm wizard (CRNConfig\setup.exe)**—This wizard is run on the Cognos Content Manager Server and the Cognos Report Server.
- **Cognos Gateway Customization for InForm wizard (CRNGatewayConfig\setup.exe)**—This wizard is run on the Cognos Gateway Server.

For more information, see the *Installation Guide*.

Cognos Application Firewall (CAF) is enabled during installation

INF-13560—The Cognos Customization for InForm wizard (CRNConfig\setup.exe) has been updated so that the Cognos Application Firewall (CAF) on the Cognos Content Manager Server and Cognos Report Server is enabled during the installation.

A new field now appears on the Cognos Content Store and Application Firewall page in the Cognos Customization for InForm wizard where you must supply a valid domain or host name for the Cognos Application Firewall.

For more information, see the *Installation Guide*.

Enhancements: Rules

Calculation rules can be run in batch mode

INF-6163— You can now run calculation rules manually in batch mode. In previous InForm releases, you could run only form rules manually in batch mode.

To support this improvement, the following pages in the Admin user interface have been updated and added.

- Rules page
- Select Rules to Run page
- Batch Run Rules Status page (new)
- Subject—Rules Status page (new)

For more information, see the *User Guide*.

Calculation rules with dependencies now run on initial submission of the Screening form

INF-14244—Calculation rules triggered by a dependency are now run on the initial submission of the Screening form.

Enhancements: Source verification

Item-level partial source verification

Individual items and itemsets on a form can now be designated for source verification.

In the InForm application, an item or itemset is identified as requiring source verification when it has been designated as SV Required, and optionally as critical, in the Central Designer application. Only items or itemsets that are SV Required can be designated as critical. Not all items on a form need to be critical.

In the InForm application, you can override the criticality defined for an item or itemset in the Central Designer application.

Items or itemsets can be designated as critical in three ways.

- **In the Central Designer application**—The study designer specifies a property of an item or itemset to be SV Required and SV Critical.

For more information, see the Central Designer *InForm Design Guide*.

- **With MedML in the InForm application**—A system administrator can use MedML to manually override the SV Critical property for an item or itemset that was defined in the Central Designer application. MedML can be used to apply overrides for one site or across all sites.

For more information, see the *Utilities Guide*.

- **With the Set SV Settings dialog box in the InForm user interface**—If you have the proper rights, you can use the Set SV Settings dialog box to manually override the SV Critical property for an item or itemset that was defined in the Central Designer application. The user interface can be used to apply overrides for one site.

You can choose one of the following override options.

- **Study Default**—Use the criticality set for the item during the study design in the Central Designer application.
- **This Form**—Set the item to critical for only the selected form.
- **All Forms**—Set the item to critical for all forms. All instances of the item must be verified, not just the items on the form on which you set the override.
- **Not Critical**—Set the item to not critical for only the selected form.

For more information, see the *User Guide*.

If an itemset is designated as critical, all items within the itemset are critical. However, because the InForm application verifies itemsets at the row level, and not by individual items, setting an item within an itemset as critical has no effect.

When item-level source verification takes effect

The critical property for an item takes effect in the InForm application only when the form that the item is on will not otherwise be verified, due to the Partial SV settings for subjects and forms.

By default, all subjects are verified. However, if you use the InForm user interface to limit the set of subjects and forms to be verified, all subject and forms no longer need to be verified.

- If a subject or form is selected to be verified, every SV Required item for those subjects and forms must be verified.
- On all other forms that are not selected to be verified, only the items that are designated as critical (not all the SV Required items) must be verified.

Reporting changes for item-level source verification

Reporting changes due to the new item-level source verification feature include:

- Operational model changes:
 - Items report topics:
 - Added new properties and counts to identify critical items.
 - Changed the meaning of existing report elements and report topics for critical items.
 - Forms report topics:
 - Changed the meaning of existing report elements and report topics for critical items.
- Standard report changes:
 - The Source Verification Listing and CRF Item Listing reports contain new filter options for critical items.
 - Columns in all Case Report Form (CRF) reports have been modified due to the new item-level source verification feature.

For more information, see the *Reporting and Analysis Guide*.

Enhancements: System configuration

Changed default value for the Post a query for conflict resolution System Configuration option

INF-14240—In the Admin user interface, the default value for the Post a query for conflict resolution option on the System Configuration page has been changed from Yes to No.

This option is used when the InForm application communicates with the Central Coding application. Setting the Post a query for conflict resolution option to No may help reduce the number of conflict queries that are created unnecessarily when some Adverse Event items are coded by the Central Coding application. For more information, see Known Issue INF-9391.

Enhancements: Clinical Data API

Clinical data can be submitted in ODM format with InForm-specific extensions

You can now import clinical data into the InForm application by submitting an XML file in ODM format with InForm-specific extensions. The InForm application provides the following tools that support importing clinical data:

- ODM Submit utility—Command line tool that allows a local user to execute an import file in ODM format with InForm-specific extensions using the command line.
- Clinical Data API—Web service interface that allows a remote InForm user to import clinical data using an API.

These new tools are available in addition to the InForm Data Import utility. They provide many of the same features, as well as additional features, while leveraging standard ODM XML.

For more information, see the *Clinical Data API Guide*.

New ODM Submit right

INF-14132—A new ODM Submit right is now available.

This right provides the ability to submit ODM data through the Clinical Data API.

- To access the Clinical Data API, a separate user account must be created and assigned this right. This user account, which should have no other rights or sites associated with it, can be used by multiple users for the same customer without sharing any credentials that could impact clinical data.
- Standard user accounts should not have the ODM Submit right.

For more information, see the *Clinical Data API Guide*.

Fixes: Authentication and Passwords

INF-13168

Summary: When you reset your password, if you enter certain non-alphanumeric characters in the Question field, an error no longer occurs, and the browser displays the InForm application.

Description: In previous releases, the following non-alphanumeric characters caused an error to occur when you entered them in the Question field:

- Apostrophe (')
- Quotation mark (")
- Less than symbol (<)
- Greater than symbol (>)
- Left parenthesis (()
- Right parenthesis ())

Solution: The software has been updated so that the InForm application now supports the non-alphanumeric characters listed in the Description.

Impact: Issue resolved. Previously reported Known Issue. This change affects all InForm users.

Fixes: Cross-Product and Integration

INF-12618

Summary: The InForm application now correctly processes MESSAGEEDIT elements in transactions from the CIS application.

Description: In previous releases, the InForm application failed to process MESSAGEEDIT transactions, which are created by the CIS application when you need to manually edit transactions so they can be processed by the CIS application.

The following issues occurred with the transaction:

- The InForm application misread the TIME attribute in the MESSAGEEDIT element, which caused an error to occur.
- The InForm application used the database column INF_MSGEDIT_HISTORY.RANSACTIONCONTENT instead of INF_MSGEDIT_HISTORY.TRANSACTIONCONTENT.

The InForm application inserted improper strings into most columns in the INF_MSGEDIT_HISTORY database table.

Solution: The software has been updated so that the InForm application now correctly processes MESSAGEEDIT elements in transactions from the CIS application.

Impact: Issue resolved. This change affects studies that use the InForm application with the CIS application.

INF-13742

Summary: Reissuing an open InForm query from the Central Coding application no longer causes a conflict query in the InForm application.

Description: In previous releases, the InForm application created a conflict query if an open InForm query was reissued from the Central Coding application, and the same action was performed two times on the query (for example, if the query was answered, re-opened, and answered again).

The InForm application uses revision numbers to track query actions. The conflict query was created because when the same action was performed two times on the query, the check on the revision numbers failed.

Solution: The software has been updated so that when the InForm application checks the revision numbers for queries with multiple actions from the Central Coding application, the check on the revision numbers no longer fails, and a conflict query is no longer created.

Impact: Issue resolved. This change affects users who work with queries and studies integrated with the Central Coding application.

Fixes: Data Viewer

INF-12421

Summary: The data value for a group control now appears in the Data Viewer audit trail after the initial entry.

Description: Data values should appear the same in the audit trail in the Data Viewer and in the audit trail for a form.

In previous releases, data from group controls did not appear in the Data Viewer audit trail unless the data was changed after the initial entry. Examples of group controls are the Sitting Blood Pressure on a Vital Signs form, the Time to onset from last dose on an Adverse Event form, or Lab data on a Baseline form.

Solution: The software has been updated so that the initial values from group controls now appear the audit trail in the Data Viewer and in the audit trail for a form.

Impact: Issue resolved. This change affects users who work with the Data Viewer and users who review study activity using the audit trails.

INF-13209

Summary: In the Data Viewer Record Listing View, you can now filter on any review state mnemonic regardless of its format.

Description: In previous releases, in the Data Viewer Record Listing View, if you filtered on a review state mnemonic that was not in the format of one letter and one digit (for example, R1), an error occurred.

Solution: The software has been updated so that so that you can now filter review state mnemonics in any format.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with the Data Viewer.

INF-13210

Summary: If your study has only one custom review state, you can now open the Data Viewer.

Description: In previous releases, if only one review state was defined, an error occurred when you clicked the Review button in the navigation toolbar to open the Data Viewer. As a result, you could not access the Data Viewer.

Solution: The software has been updated so that an error no longer occurs when you try to open the Data Viewer if your study has only one review state.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with the Data Viewer.

INF-13307

Summary: In the Data Viewer Record Listing View, the Open Query (red dot) icon no longer appears in an item cell when you create a candidate query.

Description: In previous releases, when you created a candidate query from the Data Viewer Record Listing View, the red dot icon that indicates there is an open query on the item incorrectly appeared in the item cell. The icon should have appeared only if you created an open query.

Solution: The software has been updated so that when you create a candidate query in the Data Viewer, the software now properly checks the status of the newly created candidate query, and it no longer displays the red dot icon.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with the Data Viewer and users who create queries.

INF-13770

Summary: Data values from items in nested controls now appear in the same order in the audit trail in the Data Viewer and in the audit trail for a form.

Description: In previous releases, data from a complex control (that is, a control that contains nested lists), may have appeared in a different order in the audit trail in the Data Viewer and in the audit trail for a form.

Solution: The software has been updated so that the Data Viewer audit trail components now display the same information as the audit trail for a form.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with the Data Viewer and users who review study activity using the audit trails.

INF-13931

Summary: The data value for an item in a group control no longer appears differently in the audit trail in the Data Viewer than in the audit trail for a form.

Description: In previous releases, data from a group control (for example, a blood pressure control) may have appeared differently in the audit trail in the Data Viewer and in the audit trail for a form.

For example, if the value for a Sitting Blood Pressure item on a Vital Signs form was 120/90 mmHg:

- In the audit trail for the form, the value appeared as 120/90 mmHg.
- In the audit trail in the Data Viewer, the data value may have appeared on separate lines, and the units may not have appeared.

Solution: The software has been updated so that the Data Viewer audit trail components now display the same information as the audit trail for a form.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with the Data Viewer and users who review study activity using the audit trails.

INF-14158

Summary: In the Data Viewer, the correct count for complete forms now appears in all views.

Description: In previous releases, if your study had a combination of fully enrolled subjects, and subjects that were screened but not enrolled, an incorrect count for complete forms could have appeared in two places in the Data Viewer. This occurred because when the form status counts were calculated, the counts for both fully enrolled subjects, and subjects that were screened but not enrolled, were considered.

If you did not filter on any subject, the incorrect count appeared in the following locations:

- Summary by Visits view > Summary Data Table > Form State section > Complete column
- Record Listing View > Summary Data pane > Form Status section > Complete row

However, if you filtered on a fully enrolled subject, the correct form status count appeared in both locations.

Solution: The software has been updated so that when form status counts are calculated for the Data Viewer, subjects that are not fully enrolled are now excluded.

Impact: Issue resolved. This change affects users who work with the Data Viewer.

INF-14184

Summary: Hidden items in an itemset no longer appear in the Data Viewer.

Description: In previous releases, if a blinded item was in an itemset, the item appeared in the Data Viewer.

Solution: The software has been updated so that all blinded items in itemsets are correctly hidden in the Data Viewer.

Impact: Issue resolved. This change affects users who work with the Data Viewer.

INF-14239

Summary: The data values for items on a form no longer display differently in the audit trail in the Data Viewer than in the audit trail for a form when you enter and then delete an entry in the Reason incomplete section in a comment before entering the item values.

Description: Data values should appear the same in the audit trail in the Data Viewer and in the audit trail for a form.

In previous releases, although the data values were correct in both the Data Viewer audit trail and the form audit trail, when you entered and then deleted an entry in the Reason incomplete section for an item-level or a form-level comment for a form, and then entered values in the form items, the values were displayed differently in the Data Viewer audit trail.

Solution: The software has been updated so that data values for items on a form now display the same in the audit trails for the Data Viewer and the form after you enter and then delete an entry in the Reason incomplete section for an item-level or form-level comment before entering values in the form items.

Impact: Issue resolved. This change affects users who work with the Data Viewer and users who review study activity using the audit trails.

Fixes: Forms, Visits, Items, and Itemsets

INF-5450

Summary: When you perform data entry in a new visit by using more than one browser session and submit the forms, the visit is no longer started two times.

Description: In previous releases, when you entered and submitted data on a regular form in an unstarted visit using more than one browser session, the visit was started two times in the database. As a result, there were duplicate rows for the started visit in the PF_SUBJECTVECHAPTER view in the InForm database. This could cause errors while running ad hoc reports.

Solution: The software has been updated so that when you enter and submit data on a regular form in an unstarted visit, and then enter data on the same form in the same visit and submit it, the visit is no longer started two times. Only one row for the started visit appears in the PF_SUBJECTVECHAPTER view in the InForm database.

Impact: Issue resolved. This change affects all InForm users.

INF-12607

Summary: Form submission times are improved for subjects with thousands of data points.

Description: In previous releases, in some cases, form submission times for subjects with thousands of data points could be very slow or could fail because when the InForm application processed rules, it loaded the entire case report book for the subject. This occurred when rules had cross-visit dependencies, and may also have occurred in other cases as well.

Solution: The software has been updated so that rules processing no longer loads the entire case report book.

Impact: Issue resolved. Performance improvement. This change affects all InForm users.

INF-12866

Summary: HTML tags in CRF control captions now render correctly in the InForm user interface.

Description: In previous releases, when a study designer inserted an HTML tag into the caption for a CRF control (for example, a textbox, pulldown, or group control), the text appeared in the InForm user interface, but the formatting was not applied.

For example, if the HTML tags for a line break (
) and for italics (<i>) were inserted into a textbox control caption, the text appeared, however:

- The text following the line break tag did not move to the next line.
- The text following the italics tag was not italicized.

Solution: The software has been updated so that HTML tags for CRF control captions now render correctly, and the intended formatting is applied to the text in the InForm user interface.

Impact: Issue resolved. This change affects study designers and all InForm users.

INF-13143

Summary: You can now edit or delete an item from an itemset when any item value within the itemset contains a special character.

Description: In previous releases, if you tried to edit or delete an item from an itemset and any item value within the itemset contained a special character, an error occurred and the item was not updated or marked as deleted.

Solution: The software has been updated so that you can now edit or delete an item from an itemset when any item value within the itemset contains a special character.

Impact: Issue resolved. This change affects all InForm users.

INF-13144

Summary: You can now enter a Reason for Change when you remove the association between two forms.

Description: In previous releases, when you navigated to a form and removed its association to another form, the Reason for Change section did not appear.

Solution: The software has been updated so that when you remove an association between two forms, the Reason for Change section now appears.

Impact: Issue resolved. This change affects all InForm users.

INF-13190

Summary: The Query Listing page and forms that contain queries now render properly if they contain query text with a carriage return or new line feed character.

Description: In previous releases, if the Query Listing page or a form contained an item with a query, and the query text contained a carriage return or new line feed character, the page did not load and a blank page appeared in the user interface.

Solution: The software has been updated so that the Query Listing page and forms now load properly when they contain an item with a query, and the query text contains a carriage return or new line feed character.

Impact: Issue resolved. This change affects all InForm users.

INF-13361

Summary: A query link on an itemset summary now appears for an item when the item is a nested control and the inner control contains data.

Description: In previous releases, direct query access from an itemset summary was not available for an item in an itemset if the item was a nested control, and the inner control contained data.

Solution: The software has been updated so that a query link now appears in an itemset summary for an item with a nested control in which an inner control contains data.

Impact: Issue resolved. This change affects users who work with queries.

INF-13362

Summary: A nested control with a query in an itemset summary now provides a direct link to the query.

Description: In previous releases, a nested control with a query in an itemset summary did not provide a link to the query. The itemset row showed there was a query, but only simple controls provided direct links to queries.

Solution: The software has been updated so that nested controls with a query in an itemset summary now correctly provide a link to the query.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with queries.

INF-13675

Summary: Form updates now appear correctly in the user interface when a form contains the same item in both a non-repeating section and an itemset.

Description: In previous releases, if forms contained the same item in both a non-repeating section and an itemset, edits to the item may not have appeared in the user interface, or may have caused an error when you submitted the form. The form updates, however, were saved in the database.

Solution: The software has been updated so that when a form contains the same item in both a non-repeating section and an itemset, edits to the item are now processed correctly so that the updates display in the user interface, and submission errors no longer occur.

Impact: Issue resolved. This change affects all InForm users.

INF-13842

Summary: Data for values with the same timestamps is now consistent in all views of the audit trail.

Description: In previous releases, if data was entered into an itemset so that two values were submitted at the same time (for example, from a data import using the InForm Data Import utility or from a Central Coding import), they correctly appeared individually in the audit trail. However, the data could have appeared in a different order in the Audit Trail field on the Data Value(s) page, in the audit trail for the form items that appeared when clicking the audit trail icon on a form, and in the Audit Trail page when viewing form item details.

Solution: The software has been updated so that when multiple items have the same timestamps, the audit trail data now appears consistently in all views of the audit trail.

Impact: Issue resolved. This change affects all InForm users.

INF-14107

Summary: You can now successfully access forms after adding items to them using revising without reversioning.

Description: In previous releases, when you added items to a form sequentially using revising without reversioning, an error occurred when you tried to access the form after each addition. As a result, you could not verify that the item was successfully added to the form.

Solution: The software has been updated so that you can now successfully access forms after adding items to them using revising without reversioning. An error no longer occurs, and you can verify that the items have been successfully added to the form.

Impact: Issue resolved. This change affects InForm users who install study versions and who perform revising without reversioning.

INF-14300

Summary: When you try to submit data in a retriggered dynamic form with a new item, the originally activated version of the form is used, and an error no longer occurs.

Description: In previous releases, when a dynamic form was activated by calculations, and then the form was de-activated, if a study version was applied to a site that had a newer version of the form, and then the form was activated again by calculations, the InForm application was unsure about which version of the form to use when you tried to submit data, and an error occurred.

Solution: The software has been updated so that when a dynamic form is activated by calculations, and then the form is de-activated, if a study version is applied to a site that has a newer version of the form, and then the form is activated again by calculations, the form uses the originally activated version of the form, and an error no longer occurs.

Impact: Issue resolved. This change affects all InForm users.

Fixes: InForm Portal

INF-12994

Summary: The InForm Portal Home page created by the Portal Configuration Wizard now displays correctly in the browser window.

Description: In previous releases, when you set up the InForm Portal using the Portal Configuration Wizard, the InForm Portal Home page might not have fit the browser window. In some cases, the Home page height and width settings did not fill the entire browser window. A vertical scroll bar appeared to the right of the Home page, and you had to scroll to see the data on the page.

Solution: The software has been updated so that the default height and width settings for the InForm Portal Home page now ensure that the Home page displays correctly in the browser window.

Impact: Issue resolved. This change affects all InForm Portal users.

INF-13081

Summary: In the InForm Portal application, non-administrative users can now access and read files.

Description: In previous releases, when a non-administrative user clicked a document to view, access was denied, and an error appeared in the event log.

Solution: The software has been updated so that non-administrative users can now access documents, but cannot edit them.

Impact: Issue resolved. This change affects all InForm Portal users.

INF-13083

Summary: If the DSN you enter during the InForm Portal installation has more than 50 characters, an error no longer occurs.

Description: In previous releases, if you used a DSN with more than 50 characters, an error occurred because the entry was larger than the default length of the database column.

Solution: The software has been updated so that the database column length is now 255 characters.

Impact: Issue resolved. Previously reported Known Issue. This change affects all InForm Portal users.

INF-13218

Summary: The default InForm Portal Home page now contains Oracle contact information.

Description: In previous releases, the default InForm Portal Home page (homedefault.html) was blank.

Solution: The software has been updated so that the Home page now includes contact information for Oracle support, and can be customized as necessary.

Impact: Issue resolved. This change affects all InForm Portal users.

Fixes: Installation and Configuration

INF-12643

Summary: The MedML Installer utility now prevents you from installing multiple sub-controls with the same value.

Description: The InForm application does not allow you to have multiple sub-controls with the same value.

In previous releases, however, the MedML Installer utility did not prevent you from installing MedML with duplicate values for the sub-controls during revising without reversioning. When you installed the MedML with duplicate values, an error did not occur during the installation.

Solution: The software has been updated so that when you try to install the MedML with duplicate values, an error now occurs, and you cannot continue with the installation.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who perform revising without reversioning.

INF-13365

Summary: You can now grant database execute rights to the pfdbadmin user on the Oracle 11.2.0.3 database.

Description: In previous releases, when you tried to grant database execute rights to the pfdbadmin user on the Oracle 11.2.0.3 database, the command completed without error. However, due to an known issue in the 11.2.0.3 database, the pfdbadmin user would not be able to successfully execute commands.

Solution: The software has been updated so that when one of the following patch sets is applied to the 11.2.0.3 database, you can grant execute rights to database users:

- 13885389—11.2.0.3 Patch 5 for Windows 2008 (64-bit).
- 13696216—11.2.0.3.2 Patchset Update for Linux.

Impact: Issue resolved. This change affects users who install and configure the InForm application.

INF-13461

Summary: For InForm installations on Windows 2008, historical time stamps now render in the InForm user interface using historical daylight savings time information.

Description: In previous releases, the InForm application correctly rendered time stamps in the user interface in the local timezone for a site. However, when you reviewed historical time stamps for the audit trails, queries, comments, signatures, and so on, the time was rendered in the InForm user interface using the most recent daylight savings time information known to the operating system. The InForm application did not account for historical daylight savings time adjustments.

Note: All data in the InForm database is stored in Greenwich Mean Time (GMT). This issue affected only the historical time stamps that rendered in the user interface.

Solution: The software has been updated so that for Windows 2008 installations, the InForm application now uses historical daylight savings time adjustments. As a result, historical time stamps now render correctly in the user interface.

Impact: Issue resolved. This change affects all users who use the InForm application on Windows 2008.

INF-13932

Summary: When you migrate from the InForm 4.6 software, extraneous log files are no longer created.

Description: In previous releases, when you ran UpdateTrialSchema.cmd during the migration, a log file (named 1) was created. The file contained an error message stating that the core_SystemUserStudyLocale_en-US.xml file could not be found.

This message occurred when the script attempted to delete a file that did not exist; it did not affect the success of the migration.

Solution: The software has been updated so that all messages are now recorded in the correct log file for UpdateTrialSchema.cmd.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who install or migrate the InForm application.

Fixes: Queries

INF-13214

Summary: On the Query Listing page, when you click on the Issuer drop-down list, the resulting list of usernames now appears in a specific order.

Description: In previous releases, the list of names in the Issuer drop-down list on the Query Listing page appeared in random order except for the entries All and Autoquery, which always appeared first in the list.

Solution: The software has been updated so that the names in the Issuer drop-down list are now sorted as follows:

- 1 Special characters
- 2 Numerals
- 3 Uppercase (in alphabetical order)
- 4 Lowercase (in alphabetical order)

Impact: Issue resolved. This change affects users who work with queries. This change affects only the order of the entries in the Issuer drop-down list. This change makes it easier to find issuer usernames.

INF-13364

Summary: Query links now appear for itemset items defined with a simple control when the text contains a line break.

Description: In previous releases, on the summary page for itemsets, query links should have appeared for all items defined with a simple control that had open queries. However, if the item text contained a line break, the query link did not appear.

Solution: The software has been updated so that query links now appear for itemset items defined with a simple control regardless of whether the text contains a line break.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with queries.

Fixes: Reporting—General

INF-13455

Summary: Information about the group associated with the user who issued a query now appears in reports for autoqueries.

Description: In previous releases, if you created an ad hoc report that contained query data, or ran a standard report that contained query data, columns that contained data about the group associated with the user who issued the query were not populated for autoqueries. As a result, you could not sort reports by group name for autoqueries.

Solution: The software has been updated so that columns that contain data about the group associated with the user who issue a query are now populated for autoqueries. You no longer need to hardcode a group name to associate with autoqueries in the Reporting and Analysis database.

Impact: Issue resolved. Previously reported Known Issue. This change affects all Reporting and Analysis users.

INF-13457

Summary: You can now create accurate reports with data about the form lock state and the case report book signature status.

Description: In previous releases, reports that contained data about the form lock state and the case report book signature status that were generated from the IRV_CRF_STATUS_REPORT database table may have contained inaccurate case report book signature information. When you modified the lock state of a form, the case report book signature status may have been incorrectly modified in reports.

Note: The signature status appeared correctly in the InForm application.

Solution: The software has been updated so that reports that contain data about the form lock state and the case report book signature status now contain accurate case report book signature information.

The IRV_CRF_STATUS_REPORT database table no longer modifies the signature status when you modify the lock state of a form, and as a result reports accurate case report book signature information.

Impact: Issue resolved. Previously reported Known Issue. This change affects all Reporting and Analysis users.

Fixes: Reporting—Ad Hoc Reports

INF-13335

Summary: Visits that contain repeating forms and appear with the Complete status in the InForm application now appear as complete in the Reporting and Analysis module.

Description: In previous releases, in some cases, when a visit contained a repeating form, the required items in one or more instances of the repeating form that were complete in the InForm application appeared as incomplete in the Reporting and Analysis module. As a result, the form and the visit in which it existed were also considered incomplete.

This could cause a discrepancy in status counts and other data related to the complete status of visits, forms, and items.

Solution: The software has been updated so that the Reporting and Analysis module now gathers data for the completion status of a repeating form from the correct database table column. As a result, the completion status for the form and the visit in which it exists is accurate in the Reporting and Analysis module and matches the status that appears in the InForm application.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with ad hoc reports.

INF-13452

Summary: When you click a query link in a report, an error no longer occurs.

Description: When an ad hoc report contains the INFORMPARTIALURL_QUERY report element, the report output includes a link to the query.

In previous releases, an error occurred when you clicked the link if the item on which the query exists was in an itemset.

Solution: The software has been updated so that an error no longer occurs when you click the link to the query. You no longer have to manually navigate to the item on which the query exists to see the query.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with ad hoc reports.

INF-13504

Summary: When you deploy a new study version, form status information and counts for started forms that no longer exist in the new study version now appear in reports.

Description: In previous releases, when you removed a form from a study by deploying a new study version, if instances of the form were started in the previous study version, the form data should have appeared in all standard and ad hoc reports in the Reporting and Analysis module. However, form status data, including counts, did not appear for started forms that existed in previous study versions.

The clinical data collected for the forms appeared correctly in reports.

Solution: The software has been updated so that form status information and counts for forms that were started in one study version and subsequently removed in a new study version now appear in reports.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with ad hoc reports.

INF-13957

Summary: In ad hoc reports, data for items with a Display Override setting of HIDDEN now appears correctly.

Description: In previous releases, in some cases, when an item had a Display Override setting of HIDDEN, and you added the report element for that item to an ad hoc report in the Reporting and Analysis module, instead of displaying N/A to indicate that the item was blank by design, the cell that corresponded to the hidden item was empty. This incorrectly indicated that data was not entered for the item.

Solution: The software has been updated so that when an item has a Display Override setting of HIDDEN, and you add the report element for that item to an ad hoc report in the Reporting and Analysis module, the cell that corresponds to the hidden item now correctly displays N/A.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with ad hoc reports.

INF-14172

Summary: Data for blinded items that exist in itemsets no longer appears in ad hoc reports for users for whom the items are blinded.

Description: In previous releases, if an item existed in an itemset and was blinded for a user, when the user generated an ad hoc report, data for the blinded item incorrectly appeared in the report.

This issue occurred because the RT_CV_MODELDICTIONARY table was incorrectly populated with the ID for the itemset in which the item existed, instead of the item ID. The itemset ID was subsequently used in the clinical model to determine whether to apply blinding.

Solution: The software has been updated so that the RT_CV_MODELDICTIONARY table now retrieves the correct ID for items in itemsets. As a result, data for blinded items that exist in itemsets no longer appears in ad hoc reports for users for whom the items are blinded.

Impact: Issue resolved. This change affects users who work with ad hoc reports.

INF-14180

Summary: Items with display override settings of Hidden are no longer visible in ad hoc reports and the Data Viewer to users who should not be able to see the items.

Description: In previous releases, if the display override setting for an item was set to Hidden, then to Editable, and then to Hidden again, data for the item incorrectly appeared in ad hoc reports and in the Data Viewer for users who should not have been able to see the item.

Solution: The software has been updated so that data for items now correctly appears in ad hoc reports and in the Data Viewer to users according to the display override settings for the items.

Impact: Issue resolved. This change affects users who work with ad hoc reports and the Data Viewer.

Fixes: Reporting—Database

INF-12639

Summary: Data for screening and enrollment forms now appears in the IRV_ACTIVATED_FORMS Reporting and Analysis database view.

Description: In previous releases, data for screening and enrollment forms did not appear in the IRV_ACTIVATED_FORMS Reporting and Analysis database view. As a result, screening and enrollment form data did not appear in the CRF Item Listing standard report.

Solution: The software has been updated so that data for screening and enrollment forms is now propagated to the IRV_ACTIVATED_FORMS Reporting and Analysis database view, and the screening and enrollment form data appears in the CRF Item Listing standard report.

Impact: Issue resolved. This change affects users who run standard reports.

INF-13237

Summary: When you run the Model Updater Service to update the Reporting and Analysis clinical model for a study, the service now continues to update the clinical model for other studies in the queue after encountering an error.

Description: In previous releases, when the Model Updater Service encountered an error while updating the Reporting and Analysis clinical model for a study, the service stopped processing. As a result, the clinical models for studies in the queue that did not contain errors were not updated.

Solution: The software has been updated so that when the Model Updater Service encounters an error while updating the clinical model for a study, it logs the error in the event log and continues to process the remaining studies in the queue.

Impact: Issue resolved. This change affects users who use the Model Updater Service to update the clinical model for studies.

INF-13288

Summary: The RD_ views now use the correct ISO format for year only, or month only date controls.

Description: In previous releases, if a date control included only the year or the month, the _DTS column in the RD_ view incorrectly displayed yyyy-nul-nul or mm-nul-nul, instead of displaying just the year or month (for example, yyyy or mm).

Solution: The software has been updated so that the RDE date-related logic now creates the correct date columns in the database, and they contain the correct value and format for date-related content.

Impact: Issue resolved. This change affects users who work with RDEs.

INF-13324

Summary: The TM_ and TMS_ columns in RD_ views are now updated when you submit a form.

Description: In previous releases, date and time controls were not working correctly. As a result, the TM_ and TMS_ columns were not in the RT_MD_DATADictionary, and the columns were not updated when you submitted a form.

Solution: The software has been updated so that the RDE date-related logic now creates the correct date columns in the database, and they contain the correct value and format for date-related content.

Impact: Issue resolved. This change affects users who work with RDEs.

INF-13325

Summary: The _DTR column now appears in the RD_ views when a date control has a time part that allows an Unknown entry.

Description: In previous releases, if a date control had date and time parts, and only the time parts allowed an Unknown entry, the _DTR column was missing from the RD_ view. The _DTS column appeared as expected in the RD_view.

Solution: The software has been updated so that if a date control has date and time parts, and only the time parts allow the Unknown entry, the _DTR column is no longer missing from the RD_ view.

Impact: Issue resolved. This change affects users who work with RDEs.

INF-13326

Summary: Values in the _TMS columns in RD_ views are no longer missing.

Description: In previous releases, _TMS columns, which display string data for time controls, did not appear in the corresponding database tables for the controls. However, _TMS columns appeared in the RD_ views for the controls. Because the RD_ views are populated by the database tables, the time strings for the controls that appeared in the InForm application did not appear in RDEs.

Solution: The software has been updated so that the RDE date-related logic now creates the correct date columns in the database, and they contain the correct value and format for date-related content.

Impact: Issue resolved. This change affects users who work with RDEs.

INF-13327

Summary: Time values are no longer missing in the _DTS column in the RD_ views.

Description: In previous releases, if a date control had both date and time parts, and allowed an Unknown entry, the DTS_ column generated from the CT_ table only contained date values from this control. As a result, the time value was missing from the _DTS column.

Solution: The software has been updated so that if a date control has date and time parts, and allows the Unknown entry, time values are no longer missing from the _DTR column in the RD_ views.

Impact: Issue resolved. This change affects users who work with RDEs.

INF-13333

Summary: All the proper unit columns for text controls that have only a single unit of measure defined are now created in the CV_ views, and are available in the Reporting and Analysis database.

Description: In some previous releases, for text controls with a single unit of measure, three unit-specific columns for normalized data, entered unit, and unit code were not generated within the CV_ views. As a result, you could not access the unit information within the Reporting and Analysis database. These columns were created for text controls with more than one unit of measure defined.

This issue occurred in InForm releases prior to InForm 4.6 SP0, and in InForm releases 4.6 SP3, 4.6 SP3a, and 4.6 SP3b.

Solution: The software has been updated so that all the unit columns are now created in the CV_ views for text controls with only a single unit defined.

Impact: Issue resolved. This change affects users who work with the Reporting and Analysis database.

INF-13383

Summary: Rows are no longer added to the IRV_SV_SUBJECTVISITS Reporting and Analysis database view for dynamic visits that are not activated or triggered in the InForm application.

Description: In previous releases, rows were added to the IRV_SV_SUBJECTVISITS Reporting and Analysis database view for dynamic visits that were not activated or triggered in the InForm application. As a result, data for dynamic visits that were not activated appeared in standard reports.

Solution: The software has been updated so that system visits and non-started dynamic visits no longer appear in the IRV_ database views. As a result, data for dynamic visits that are not activated in the InForm application no longer appears in the IRV_SV_SUBJECTVISITS Reporting and Analysis database view, and does not appear in standard reports.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who work with the Reporting and Analysis database.

INF-13450

Summary: The instructions for RDE customizations are improved.

Description: In previous releases, RDE customizations were not working properly. Assistance and additional steps to those documented in the *InForm 5.5 SP0 Reporting Database Extracts Guide* were required from Oracle Global Support.

Solution: Updates and improvements to the customization steps are now available, and are documented in the *InForm 6.0 Reporting Database Schema Guide*. RDE customizations can now be performed without assistance by Oracle Global Support.

Impact: Issue resolved. This change affects users who work with RDEs.

INF-13451

Summary: All columns now appear in the RD_ views when a group control with multiple child date time controls has a part that allows an Unknown entry.

Description: In previous releases, if a group control with multiple child date time controls allowed an Unknown entry, some columns that were used to generate RDE datasets were missing in the RD_ views.

Solution: The software has been updated so that if a group control with multiple child date time controls has a part that allows an Unknown entry, the review schema CT_ tables are now populated correctly, and they are no longer missing in the RD_ views.

Impact: Issue resolved. This change affects users who work with RDEs.

INF-14131

Summary: Review schema creation no longer fails for a study that includes a form with a large number of items.

Description: In previous releases, when you deployed a study that contained a form with a large number of items, the review schema could not be created because the SQL that was required to create the DV_ view and CV_ view for the form exceeded the size of the variable in PL/SQL designated to hold the view SQL. The variable was limited to hold 32K of data.

Solution: The software has been updated so that DV_ views and CV_ views now use the datatype CLOB. As a result, review schema creation no longer fails when you attempt to deploy a study that includes a form with a large number of items.

Impact: Issue resolved. This change affects users who work with the Reporting and Analysis database.

INF-14247

Summary: Subject numbers are no longer truncated to 10 multi-byte characters in CV_ and RD_ views.

Description: In previous releases, subject numbers were truncated to 10 multi-byte characters in CV_ and RD_ views. As a result, the subject number may have been truncated in ad hoc reports as well.

Solution: The software has been updated so that character limits for CV_ views are now 63 characters (255 bytes) and character limits for RD_ views are now 20 characters (80 bytes). As a result, subject numbers are no longer truncated to 10 multi-byte characters.

Impact: Issue resolved. This change affects users who work with RDEs and ad hoc reports.

INF-14252

Summary: Data is now streamed to the PF_HEARTBEAT table successfully.

Description: In previous releases, in some cases, a streaming error occurred and the PF_HEARTBEAT table was not updated. As a result, you could not determine whether the streaming process for other tables and views was successful.

Solution: The software has been updated so that data is now streamed to the PF_HEARTBEAT table successfully.

Impact: Issue resolved. This change affects database administrators who work with streams.

Fixes: Reporting—Standard Reports

INF-13207

Summary: The Audit Trail Report and the Historical Login Report now only appear in the Reporting and Analysis module for users who are members of the User Admin Info Data Users reporting rights group.

Description: In previous releases, the Audit Trail Report and the Historical Login Report were visible to all users. However, you could only successfully run the reports if you were a member of the User Admin Info Data Users reporting rights group. If you were not a member of the User Admin Info Data Users reporting rights group, an error occurred when you attempted to run the reports.

Solution: The software has been updated so that the Audit Trail Report and the Historical Login Report now only appear in the Reporting and Analysis module for users who are members of the User Admin Info Data Users reporting rights group. As a result, users who cannot run the reports cannot see them in the application.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who run the Audit Trail Report or the Historical Login Report.

Fixes: Source Verification

INF-13208

Summary: When you try to source verify a form with multiple instances from the Summary view after navigating to it from the Source Verification Listing page, an error no longer occurs.

Description: In previous releases, this error could occur when there were multiple instances of the form, and you navigated to the Summary view of the form by clicking Monitor in the navigation toolbar to open the Source Verification Listing page.

Solution: The software has been updated so that you can now navigate to a form with multiple instances from the Source Verification Listing page.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who perform source verification.

INF-13460

Summary: The Verified data column now correctly appears on the Time and Events Schedule only for sponsor users with the Monitor right.

Description: In previous releases, if a sponsor user had the Monitor right, the Visit view in the Time and Events Schedule displayed the Verified column heading and data as expected. However, if a sponsor user did not have the Monitor right, the Verified data column incorrectly appeared on the page; however, the Verified column heading did not appear.

Solution: The software has been updated so that if the sponsor user does not have the Monitor right, the Verified data column no longer appears on the Time and Events Schedule.

Impact: Issue resolved. This change affects all sponsor users.

INF-13768

Summary: Site users with the Mark and Unmark a CRF as SVed right are no longer able to source verify forms.

Description: Site users should not have any access to source verification information, regardless of their rights.

In previous releases, however, if a site user had the Mark and Unmark a CRF as SVed right, the Verify button incorrectly appeared on all started forms, and the user could verify a form by clicking the Verify button. The icons did not change to show that the form was verified, so the icons were correctly hiding the SV information.

Solution: The software has been updated so that if a site user has the Mark and Unmark a CRF as SVed right, the Verify button no longer appears on all started forms.

Impact: Issue resolved. Previously reported Known Issue. This change affects all site users.

INF-13771

Summary: If you are using Internet Explorer 9.0, when you configure Partial SV, extra numbers no longer appear with the subject numbers in the Set SV Settings dialog box.

Description: When you are configuring Partial SV, the list of subjects selected for source verification and their method of selection appear in the Subjects selected for source verification list box in the Set SV Settings dialog box.

In previous releases, if you were using Internet Explorer 9.0, an extra column of numbers appeared with the subject numbers and method of selection.

Summary: The software has been updated so that if you are using Internet Explorer 9.0, the extra column of numbers no longer appears with the subject numbers and method of selection.

Impact: Issue resolved. Previously reported Known Issue. This change affects users who configure the Partial SV settings.

Fixes: Subject Transfers

INF-13380

Summary: You can now successfully transfer subject data when it contains more than 100 itemset entries in one form.

Description: In previous releases, when you tried to transfer subject data that contained more than 100 itemset entries in one form, an error occurred, and the data was not transferred. Subject transfers were a single long running transaction; you had to wait until it was complete to perform other actions.

Solution: The software has been updated so that the performance of transferring subject data is improved, and you can now successfully transfer subject data that contains more than 100 itemset entries in one form. Subject transfers are now managed as multiple short transactions that run as a background process.

Impact: Issue resolved. Performance improvement. This change affects users who transfer subject data.

Fixes: Utilities

INF-13929

Summary: Importing MedML to change the selection of a radio button now properly updates the content of a text control associated with the radio button.

Description: In the InForm application, when you select a radio button that has an associated text control, you can enter additional information in the text control. If you change the selection to another radio button, the content of the text control associated with the first radio button is deleted.

In previous releases, however, under certain conditions, if you used the InForm Data Import utility to import MedML that changed the selection from a radio button that had data in an associated text control to another radio button, the content of the text control was not deleted.

Solution: The software has been updated so that if you use the InForm Data Import utility to import MedML that changes the selection from a radio button that has data in an associated text control to another radio button, the content of the text control is now deleted.

Impact: Issue resolved. Previously reported Known Issue. This change affects InForm Data Import utility users.

INF-13930

Summary: The InForm Data Import utility now prevents you from importing data for an item if the item path specified in the import file is incorrect.

Description: In previous releases, when you used the InForm Data Import utility to import data for an item that did not exist in an itemset, but you included a valid itemsetindex number with the EDITPATIENTDATA tag in the import file, the import was successful. However, you were not able to source verify the form on which the item existed.

Solution: The software has been updated so that the InForm Data Import utility only imports items with valid paths. If you attempt to use the InForm Data Import utility to import data for an item that does not exist in an itemset, but you include an itemsetindex number in the item path in the import file, the import is unsuccessful and an error occurs.

Impact: Issue resolved. This change affects InForm Data Import utility users.

Documentation updates

Updates to the Release Notes

Issue	Description
INF-12926	<p>The <i>Release Notes</i> now include the version of the Oracle Directory Server required by the Cognos 8 Business Intelligence server —Enterprise Edition 11g Release 1 (11.1.1.5.0).</p> <p>This information is in the System Requirements > Cognos 8 Business Intelligence servers topic.</p>

Updates to the Upgrade and Migration Guide

Issue	Description
INF-12431	<p>The <i>Upgrade and Migration Guide</i> now includes information on reviewing the rights assigned to each rights group before you upgrade, and verifying the rights assigned to each rights group after the upgrade is complete.</p>

Updates to the Installation Guide

Issue	Description
INF-13015	<p>The <i>Installation Guide</i> and the <i>Study and Reporting Setup Guide</i> now include information about the PUBLISHREVIEWSCHEMA pfadmin command, which you can use to publish the review schema and update all of its clinical tables after you install a new study version.</p>

Updates to the Study and Reporting Setup Guide

Issue	Description
INF-13015	<p>The <i>Installation Guide</i> and the <i>Study and Reporting Setup Guide</i> now include information about the PUBLISHREVIEWSCHEMA pfadmin command, which you can use to publish the review schema and update all of its clinical tables after you install a new study version.</p>

Updates to the User Guide

Issue	Description
INF-12880	<p>The <i>User Guide</i> now documents all the rights needed to configure and submit Partial SV settings.</p> <p>This information appears in the InForm administration chapter in the following topics:</p> <ul style="list-style-type: none">• InForm administration tasks• System administration rights• CRF rights

Updates to the Reporting and Analysis Guide

Issue	Description
INF-13348	The <i>Reporting and Analysis Guide</i> now includes a list of reserved words for the Itemset Column Header property, and indicates that use of a reserved word causes the clinical model creation to fail.

Updates to the Reporting Database Schema Guide

Issue	Description
INF-12432	The <i>Reporting Database Schema Guide</i> now includes information about RDEs, including RD view descriptions and instructions for creating and requesting a custom RDE. In previous releases, information about RDEs appeared in the <i>Reporting Database Extracts Guide</i> . The <i>Reporting Database Extracts Guide</i> is no longer available.
INF-12833	The <i>Reporting Database Schema Guide</i> now includes the correct decoded values for the subject states that appear in the SUBJECTSTATE and SUBJECTSTATETEXT columns in the IRV_CUR_SUBJECT and IRV_CUR_SUBJECTDIM views.
INF-12902	<p>The <i>Reporting Database Schema Guide</i> now includes descriptions for the following columns, which appear in CV_ views:</p> <ul style="list-style-type: none">• CREATEDBYUSERID• CREATEDBYDATETIME• MODIFIEDBYUSERID• MODIFIEDDATETIME

Updates to the Utilities Guide

Issue	Description
INF-13001	The <i>Utilities Guide</i> now includes more detailed and accurate information describing the way key items work for forms, items, and itemsets.

Updates to the Portal Administration Guide

Issue	Description
INF-13194	<p>The Portal <i>Administration Guide</i> now includes updated information about localizing the InForm Portal Home page.</p> <p>Information about using JavaScript to evaluate the browser locale and displaying the locale-specific content is documented in the Setting up the InForm Portal application > Localizing the InForm Portal Home page topic.</p>

CHAPTER 3

Installing or upgrading to this release

In this chapter

Before installing or upgrading to this release74

Installing the InForm 6.0 software for the first time75

Upgrading or migrating to the InForm 6.0 release.....76

Before installing or upgrading to this release

Before installing or upgrading to the InForm 6.0 release, carefully review the hardware and software requirements detailed in ***Hardware and software requirements*** (on page 1).

Installing the InForm 6.0 software for the first time

To install the InForm 6.0 software for the first time, follow the instructions in the *Installation Guide*.

Upgrading or migrating to the InForm 6.0 release

To upgrade or migrate to the InForm 6.0 release from a previous release, follow the instructions in the *Upgrade and Migration Guide*.