bCRM

Tessella Project Number 3760

System Installation Guide

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Revision History

Issue	Author	Date	Description
V1.R1.M0	Geraint Lloyd	17-Mar-2005	1 st version for release v1.0.0
V1.R2.M0	Robert Nelson	28-Jul-2005	Version for release v1.0.1

References

Ref.	Document	Date	Details and Version
[Goodman]	"Some practical improvements in the continual reassessment method for phase I studies", S.N.Goodman, M.L.Zahurak, S.Piantadosi	Statistics in Medicine 14:1149-1161, 1995	Paper describing a practical application of the CRM to phase I studies
[Braun]	"The bivariate continual reassessment method: extending the CRM to phase I trials of two competing outcomes", T.M.Braun	Controlled Clinical Trials 23:240-256, 2002	Original paper describing the bivariate continual reassessment method
[SUG-S]	"bCRM – Defining and Running Simulations" – System User Guide	27-Jul-05	NPD/3670/SUG "bCRM – Defining and Running Simulations" V1.R2.M0
[SUG-T]	"bCRM – Running A Trial", System User Guide	27-Jul-05	NPD/3760/SUG "bCRM– Running a Trial" V1.R2.M0

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1 Introduction

1.1 Purpose of this document

This document describes how to install bCRM. Users should refer to the System User Guides (bCRM Simulation and Running a bCRM Trial) on how to use the system once installed, and they are encouraged to read the 1995 [Goodman] paper and the original bCRM paper [Braun] before using the bCRM application.

1.2 Scope of this document

This guide only describes installation of bCRM, it does not cover its usage.

1.3 Context of this Issue

This issue documents version 1.0.1 of the system.

1.4 Definition of Terms

bCRM

refers to the computer programs that implement the bivariate continual reassessment method dose-finding algorithm, simulate and run phase 1 clinical trials using the bivariate continual reassessment method design and provide charts and graphs of the results.

2 Installation / Uninstall.

2.1 Installation

bCRM is distributed on CD and is downloadable from the bCRM website. If you have a distribution CD go straight to section 2.1.2. The application is packaged as a single executable Windows installer.

2.1.1 Downloading

To download bCRM from the website, click on a link to download one of the release installers. You will see a message along the lines of:

File Dowr	ile Download			
?	Some files can harm your computer. If the file information below looks suspicious, or you do not fully trust the source, do not open or save this file.			
	File name: bCRM_v1_0_1.exe			
	File type: Application			
	From: trials2.ct-alert.com			
	This type of file could harm your computer if it contains malicious code.			
	Would you like to open the file or save it to your computer?			
	<u>O</u> pen <u>Save</u> Cancel <u>M</u> ore Info			
	Always ask before opening this type of file			

The installer can either be run from the website (click **Open**) or saved locally before being run. (click **Save**).

2.1.2 Installing

The software is packaged as an executable file. It is installed as follows:

1. Execute the installer file (bCRM_v1_0_1.exe).



The installer checks for a compatible Java installation on your system. If no suitable Java installation can be found the bCRM install is terminated:



bCRM requires Java version 1.4 or later to run. Java 1.4.2_01 is included on the bCRM CD and is available on the bCRM website. The very latest version of Java can be down loaded from Sun Microsystems's website: <u>http://java.sun.com/j2se/</u>.



2. When the pre-install checks are complete the Welcome screen is displayed:



Click Next to continue.

3. bCRM uses charting components which are distributed with licences.

뤻 bCRM Setup	_ 🗆 ×
License Agreement You must agree with the license agreements below which relate to components used by bCRM to proceed.	5
SUMMENDER * BCRM * SUMMENDER	-
The bCRM application utilises one open source visualisation toolkit:	
JFreeChart (http://www.jfree.org/jfreechart/)	
The complete text of the licence is included below.	
/2010/00/00/00/00/00/00/00/00/00/00/00/00/	•
C I accept the license agreement C I do not accept the license agreement Wise Installation Wizard®	
<u>R</u> eset <u>Back</u> <u>N</u> ext>	Cancel

Select 'I accept the license agreement' and click Next.

4. Change the destination folder if you do not want to use the default installation directory ("c:\Program Files\bCRM\").

🔂 bCRM Setup		
Destination Folder Select a folder where the application will be installed.	5	
The Wise Installation Wizard will install the files for bCRM in the following folder.		
To install into a different folder, click the Browse button, and select another folder.		
You can choose not to install bCRM by clicking Cancel to exit the Wise Installation Wizard.		
C Destination Folder		
C:\Program Files\bCRM\ Browse		
Wise Installation Wizard®	Cancel	

Click Browse to display a file chooser:

🛃 bCRM Setu	p	×
Look in:	🗀 ЬСВМ	• 🗈 💣
Config		
ib log		
<u>F</u> older name:	C:\Program Files\bCRM\	ОК
		Cancel

OK sets the chosen installation path, **Cancel** leaves the path unchanged. Click **Next** twice to start the installation.

5. Click **Next** to begin the installation

🖶 bCRM Setup	_ 🗆 🗙
Ready to Install the Application Click Next to begin installation.	ſ
Click the Back button to reenter the installation information or click Cancel to exit the wizard.	
Wise Installation Wizard®	Cancel

6. A progress bar monitors the installation.

🤯 bCRM Setup	
Updating System The features you selected are currently being installed.	5
	i
Wise Installation Wizard®	Cancel

The installer will place a shortcut on the Start menu and on your desktop.

7. Click Finish to exit the installer.



You should now have an (optional) shortcut on your desktop to the just installed version of bCRM:



You should also have an entry in your list of programs accessible from the Windows Start menu.

All Programs 🜔	🖮 bCRM Apps 🔹 🕨	📩 Uninstall bCRM 1.0.1
	🔎 Log Off 🚺 Shut Dow	💋 bCRM 1.0.1

The bCRM entry has a:

- 1. Link to run the application
- 2. A link to uninstall bCRM

2.2 Uninstallation

There are three ways to uninstall bCRM:

1. Execute the uninstaller shortcut created in the Start Menu. Click **Yes** at the confirmation dialog.

Windows Installer	×
Are you sure you want to uninstall this produc	st?
Yes <u>N</u> o	

2. Re-run the bCRM installer. This will launch the installer in 'Maintenance' mode.

🛃 bCRM Setup		_ 🗆 🗙
Application Mainten Select the maintena	nance Ince operation to perform.	5
© Modify	Change which application features are installed. Displays the Select Features dialog, which lets you configure individual features.	
C R <u>e</u> move	Uninstall bCRM from this computer.	
Wise Installation Wizard®		incel

Select 'Remove' and click **Next** twice. A progress bar is displayed during the uninstallation procedure.

3. Through the Add/Remove Program dialog of the Control Panel.

3 Installation Verification Procedure

To verify the correct installation of bCRM, carry out the following procedure:

- 1. Start bCRM by double clicking the bCRM shortcut created by the installer.
- 2. The following splash screen should appear.



- 3. Select About from the Help menu.
- 4. Check that the version information displayed in the dialog box corresponds to the versions of the bCRM application and executable installed.
- 5. Close the **About** dialog box.
- 6. Exit bCRM.

Read the original [Goodman] and [Braun] to understand more about the model and the two other user guides [SUG-S], [SUG-T] for detailed instructions on how to use the software.