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# bCRM

Tessella Project Number 3760

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## System Installation Guide

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### Tessella Support Services plc

**e-mail: [post@tessella.com](mailto:post@tessella.com)**

**[www.tessella.com](http://www.tessella.com)**

**Head Office: Abingdon**

3 Vineyard Chambers, Abingdon, Oxfordshire OX14 3PX,  
England  
Tel: +44 (0)1235 555511  
Fax: +44 (0)1235 553301

## Document Control

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### Contributors

Person	Role	Company	Contribution
Geraint Lloyd	Author	Tessella	
Tom Parke	Reviewer	Tessella	

### Document Approval

Person	Role	Company

### Distribution

Person	Role	Company
Notes Projects Database 3760		Tessella

### Revision History

Issue	Author	Date	Description
V1.R1.M0	Geraint Lloyd	17-Mar-2005	1 <sup>st</sup> 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/3760/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

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### 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.

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### 1.2 Scope of this document

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

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### 1.3 Context of this Issue

This issue documents version 1.0.1 of the system.

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### 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.

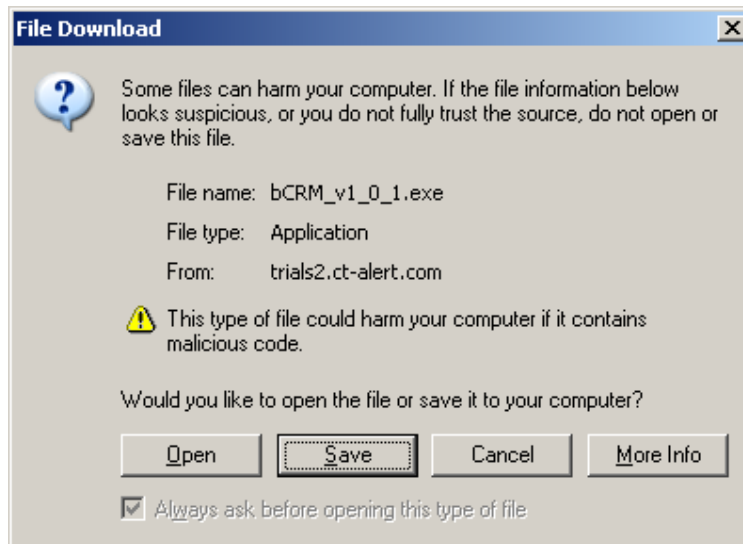
## 2 Installation / Uninstall.

### 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:



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

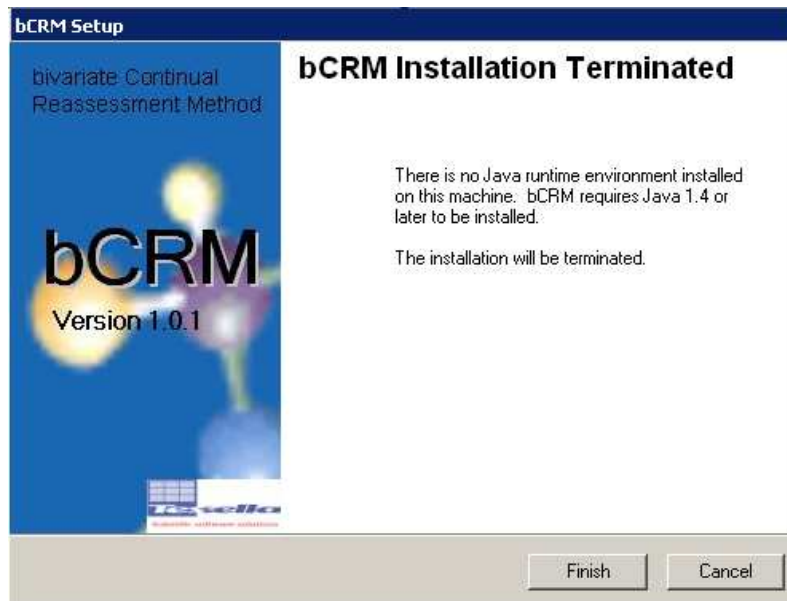
## 2.1.2 Installing

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 downloaded from Sun Microsystems's website: <http://java.sun.com/j2se/>.

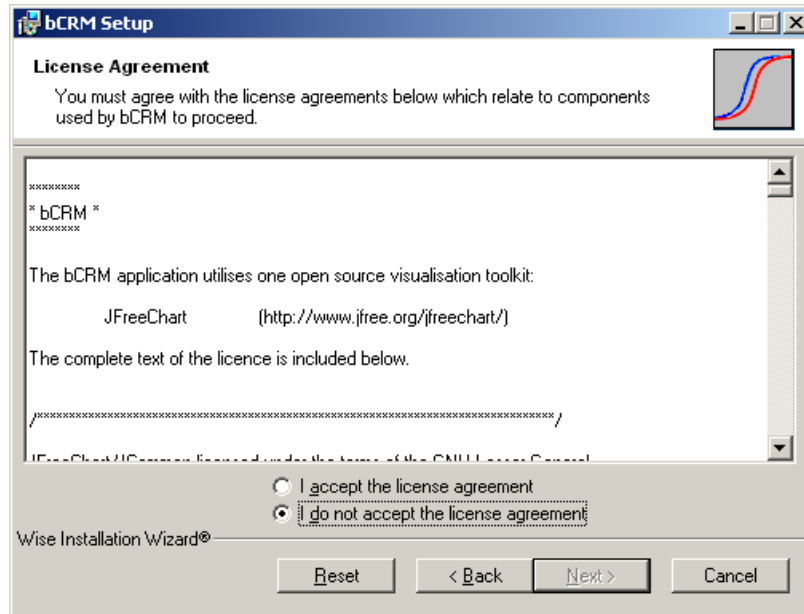


2. When the pre-install checks are complete the Welcome screen is displayed:



Click **Next** to continue.

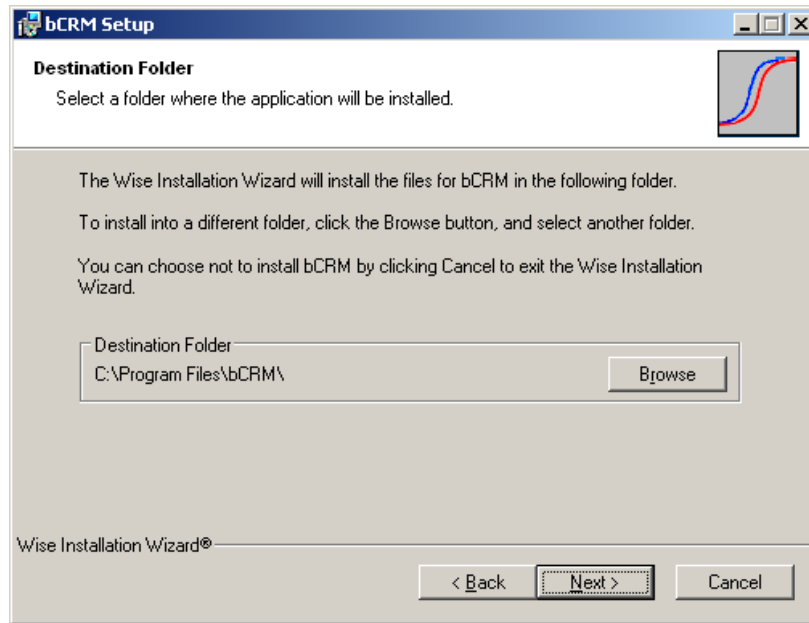
3. bCRM uses charting components which are distributed with licences.



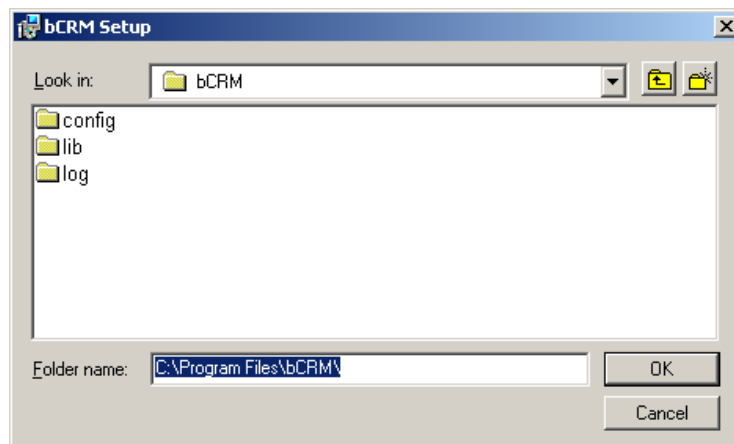
Select 'I accept the license agreement' and click **Next**.



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

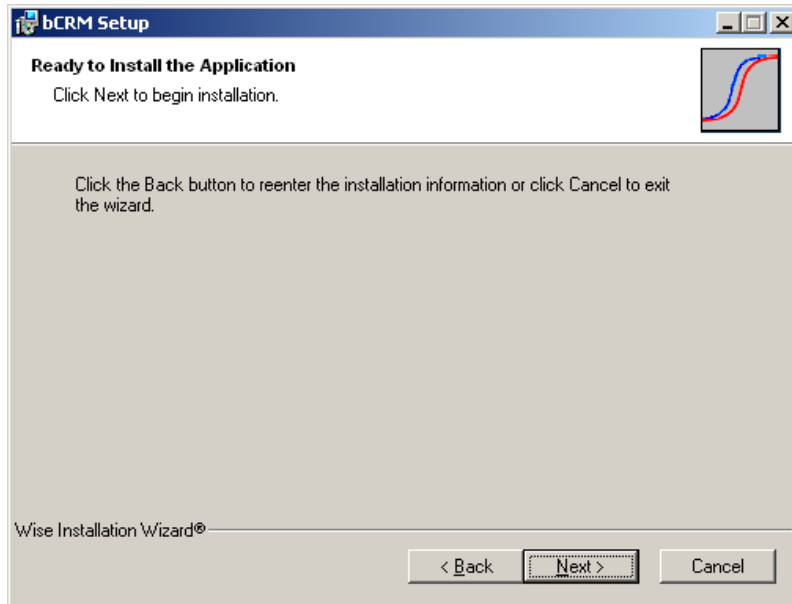


Click **Browse** to display a file chooser:

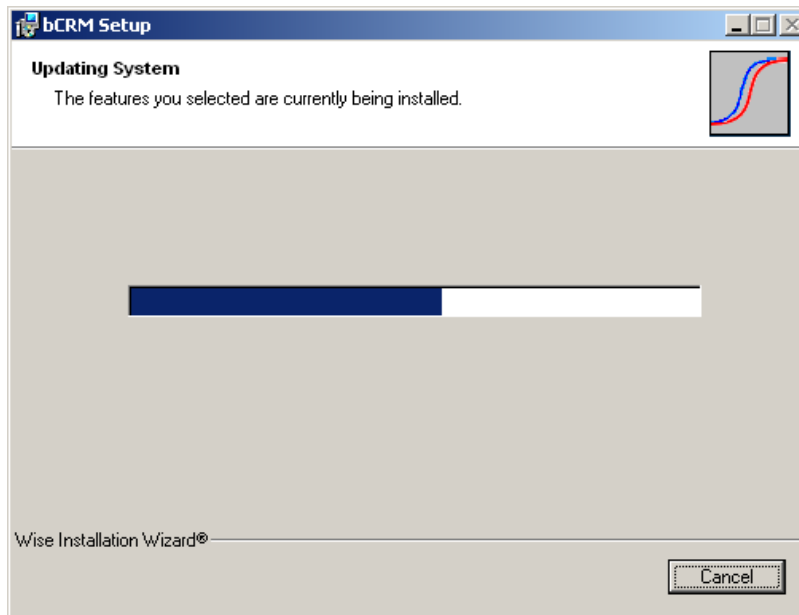


**OK** sets the chosen installation path, **Cancel** leaves the path unchanged. Click **Next** twice to start the installation.

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



6. A progress bar monitors the installation.



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.



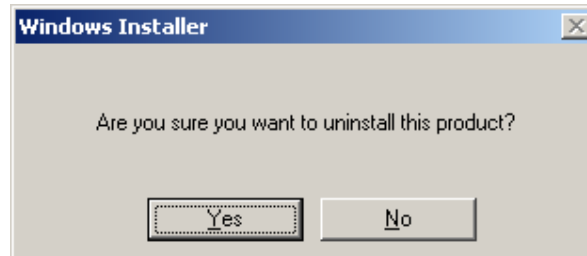
The bCRM entry has a:

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

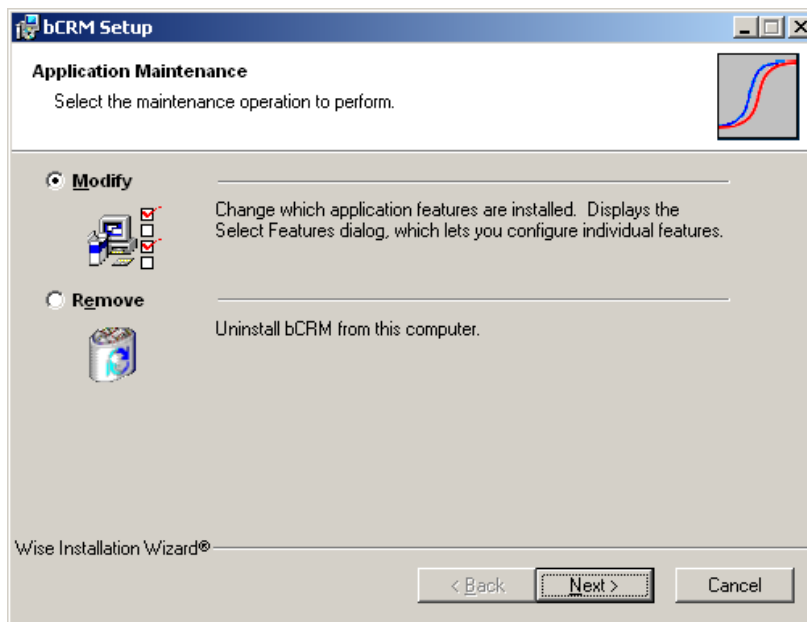
## 2.2 Uninstallation

There are three ways to uninstall bCRM:

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



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



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

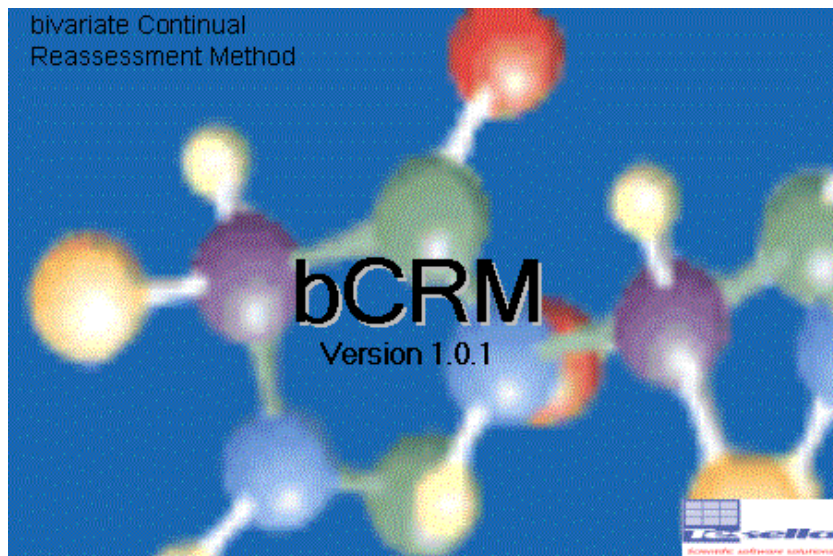
3. Through the Add/Remove Program dialog of the Control Panel.

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## 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.