



# **TrialSense System Installation Guide**

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## **Part I. TrialSense Overview**

## Overview of TrialSense System

TrialSense™ means clinical trials automation. Featuring intelligent case report forms, task workflow sequencing, and robust security, TrialSense offers a comprehensive solution for the administration of multiple trials within a single integrated environment. Its user-friendly, Web-based data collection interface is the portal to a powerful and flexible software engine that continuously monitors the complete clinical trial process. TrialSense empowers clinical researchers to achieve accurate, efficient, effective clinical trials.

### TrialSense Server

The TrialSense Server surrounds a database engine designed specifically to scale from single-user environments up to large, multi-user distributed environments containing vast amounts of data. Its robust and versatile structure permits the storage and synchronization of widely varying information without expensive and time-consuming database changes. The TrialSense Server has been designed to work with any ANSI SQL-92 compliant database management system (DBMS) and is certified to work with MySQL Database Server 5.0 (or later).

### TrialSense Server Minimum System Requirements

Operating System: Windows 2000/XP Professional  
 Processor: Pentium V 2.0 GHz  
 Memory: 2 GB  
 Free Hard Drive Space: 100 MB  
 Network: 10 Mbps Ethernet

### TrialSense Console

The TrialSense Console is the main administrative interface into the TrialSense System. As such, the Control Center supports plug-in components for form design, security settings and user management, synchronization configuration, conflict resolution, and system auditing.

- **User Management:** The user management task takes care of creating user accounts in the TrialSense System, configuring the users' permissions, and managing each user's profile, including signing certificate and system settings.
- **System Auditing:** The system-auditing task provides the means of easily analyzing the audit information of the TrialSense System. Additionally, the system-auditing task includes an interface to customize the amount of auditing information to collect within the TrialSense System.

**TrialSense Overview**

- **Form Design:** If installed, the TrialSense Form Developer provides for the creation and management of portable electronic form definitions to be used throughout the TrialSense System.
- **Protocol Design:** If installed, the TrialSense Protocol Developer provides for the creation and management of electronic clinical trial protocols to be used throughout the TrialSense System.



The TrialSense Console is normally installed along with the TrialSense Server.

**TrialSense Collection Station**

The TrialSense Collection Station provides a unique and highly intuitive electronic form assessment environment, designed to easily enter clinical trial data. The TrialSense Collection Station is a Web browser based interface to the TrialSense system.

**TrialSense Collection Station Minimum System Requirements**

- Web Browser: Internet Explorer 7, Firefox 3
- Processor: Pentium 4 1.0 GHz
- Memory: 512 MB
- Free Hard Drive Space: 50 MB
- Network: Modem or 10 Mbps Ethernet or 802.11x Wireless



In order for TrialSense Collection Stations to connect to the TrialSense Server, the TrialSense Collection Station must be able to connect to the network. For more information about configuring Windows settings, see *Part IV. Configuring Windows Settings*.



The TrialSense Collection Station is accessed through a Web-browser. On the TrialSense Server computer, the TrialSense Collection Station can be accessed by typing <http://localhost/TrialSense> into the browser. Remote clients would replace “localhost” with the name or IP address of the server computer.

## **Part II. Installation Prerequisites**

## **Setup Prerequisites**

Depending on the version and component of the TrialSense System that you are installing, there may be one or more software packages that must be installed prior to installing the TrialSense component. In most cases, the prerequisite software will be included on your installation CD and installed automatically, if not already installed on your computer. However, certain versions of the TrialSense System may not bundle prerequisite software with the installation CD, or you may want to install alternate software, in which case you should install the prerequisite software prior to installing the TrialSense component.

## **TrialSense System Hardware Setup**

The TrialSense System can be configured as an independent network, as part of a campus network, or as systems distributed across the Internet. In all cases, **the TrialSense computer must have a static IP** in order for the clients to connect and access data.

## **Sample Hardware for the TrialSense System**

The following chart lists examples of available computers and network equipment that meet the minimum requirements of the TrialSense System.

<u>Function</u>	<u>Minimum Requirements</u>	<u>Example</u>
Server/Console	2GB RAM, 30 GB hard drive, 10/100 Ethernet	Desktop: Dell Dimension 2400
Collection Station	1GB RAM, 10 GB hard drive, 10/100 Ethernet	Tablet: HP tc1100, Motion M1300 Laptop: Dell Latitude 100L Desktop: Dell Dimension 2400
Network Switch	4-Port 100 Mbps	Netgear 10/100 4-port switch, Gigafast 10/100 8-port switch, 3Com 10/100 4-port switch

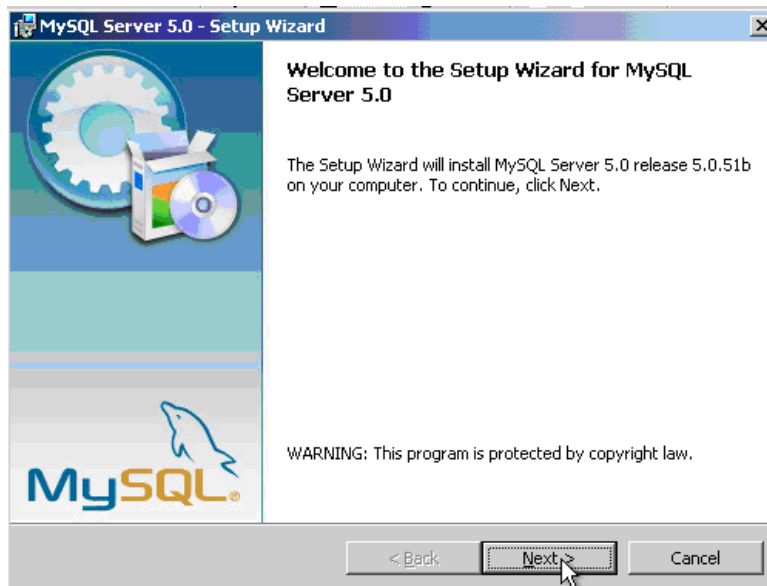
**Note:** *If Collection Station computers are installed outside of the campus network, the TrialSense Server computer must have a public IP address, that is, the computer can be connected to from the Internet.*

**Note:** *TrialSense Server uses port 80 to provide access to Collection Stations. Make sure this port is not blocked by your campus network firewall*



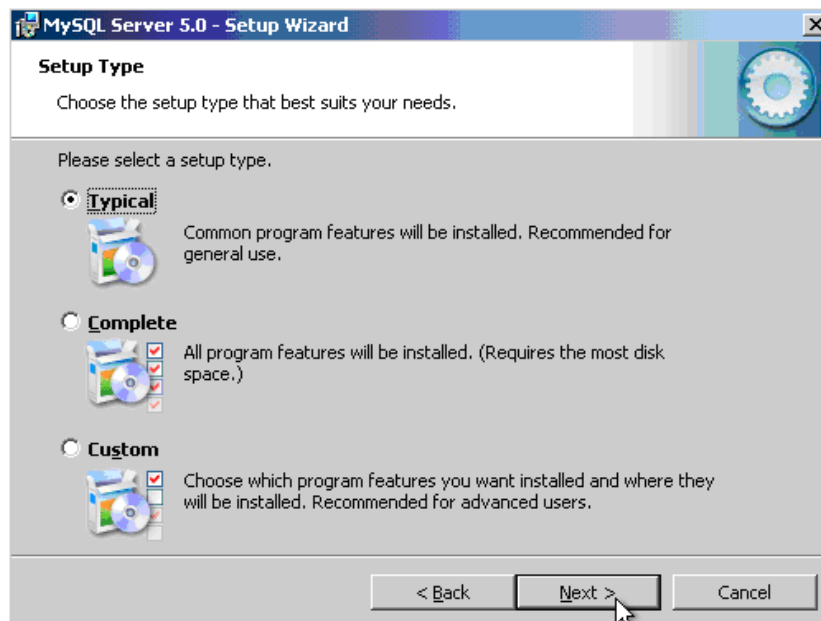
## MySQL Database Server, Version 5.0 or later

The TrialSense Data Source is designed to work with any ANSI SQL-92 compliant database management system (DBMS). It is certified to work with MySQL Database Server 5.0 and later. It is recommended that you install the latest version of MySQL available from MySQL.com.



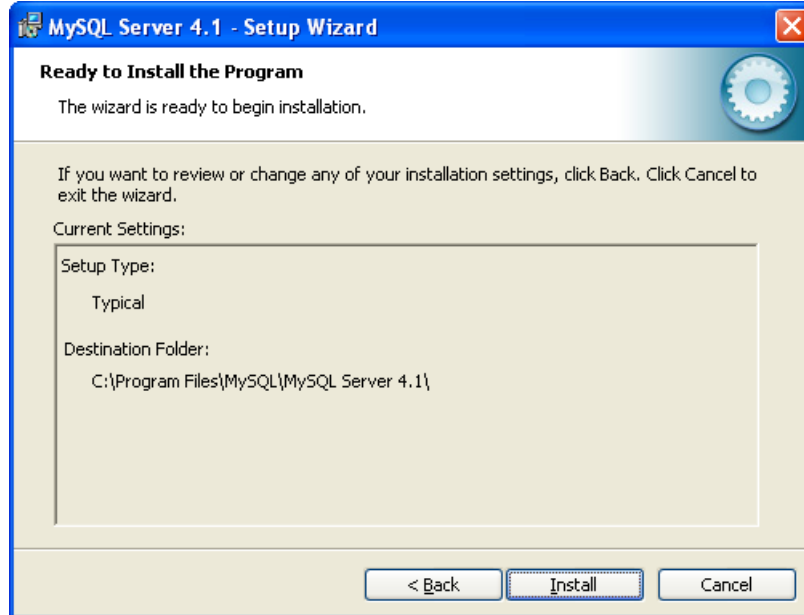
## MySQL Installation Setup Type

For most users, the typical installation setup will work without modification. If you need to change the installation location or would like to include additional documentation with the installation, select *complete* or *custom* installation.



### Installation Prerequisites

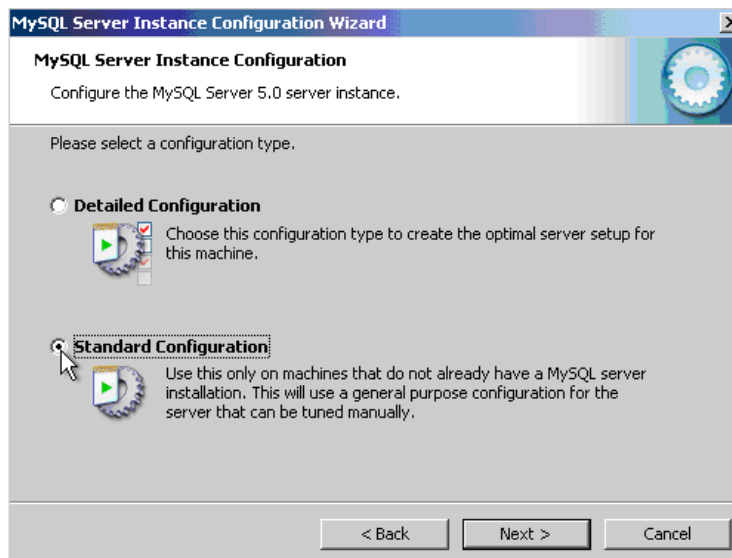
Once you have made your selection, you are presented with a summary of the installation settings. Click on *Back* to modify the installation settings or *Install* to begin the MySQL installation.



After the MySQL installation, you may be asked to sign up for a MySQL.com account. This will provide you with an account on the MySQL.com website to access user documentation, discussion groups, and other MySQL content. Signing up for a MySQL.com account is optional, and you may skip this step.

## MySQL Server Instance Configuration

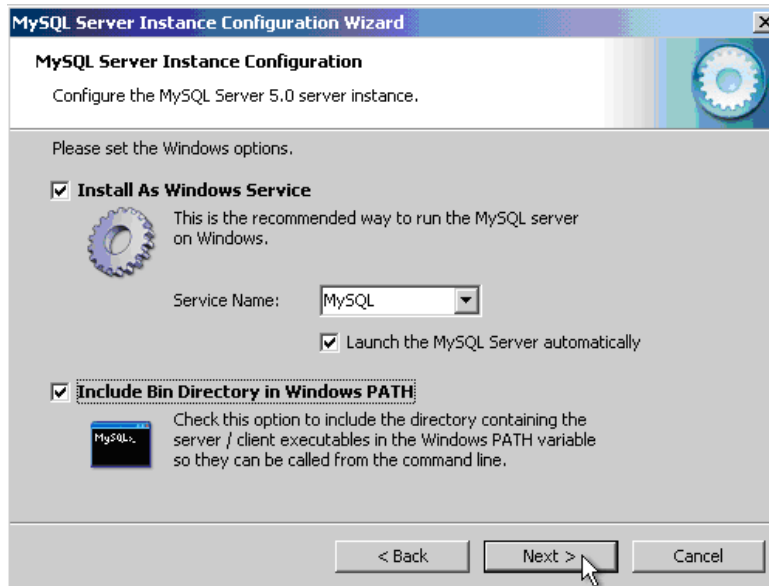
In order for the TrialSense System to utilize the MySQL database, it must be configured and running as a Windows service. At the end of the MySQL installation, you will be asked if you want to *Configure the MySQL Server now*. You can either do it now, or start the configuration wizard later through the *Start* menu.



It is recommended that you select *Standard Configuration*, as the detailed configuration requires additional steps be completed during the setup of a MySQL database.



The TrialSense System needs to be able to connect to the MySQL database automatically without user interaction. If MySQL is not started as a Windows service, TrialSense may not function properly.

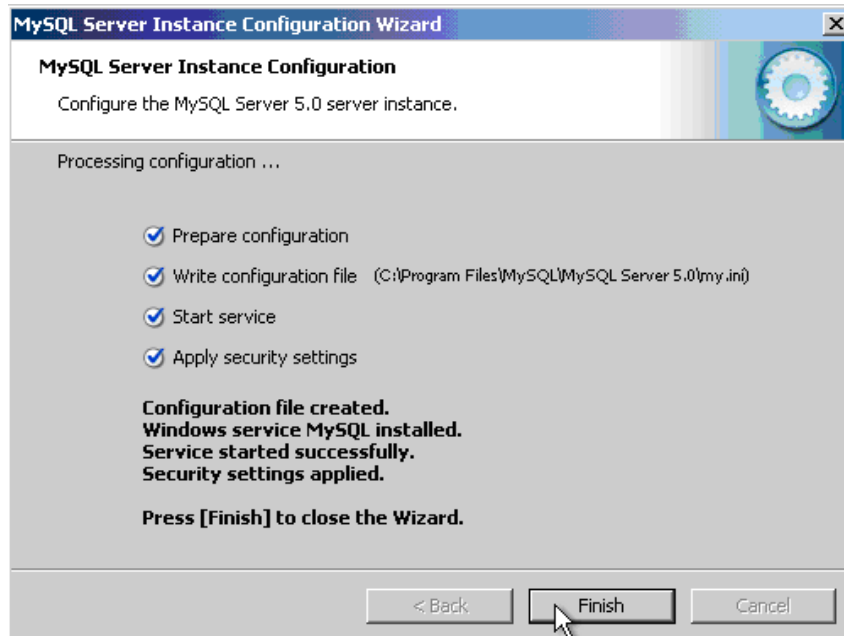


### MySQL Security Settings

At this point, you are presented with the option to modify the default security settings and *Anonymous* account.



The default administrator account is *root* with no password. It is strongly recommended that you set the root password.

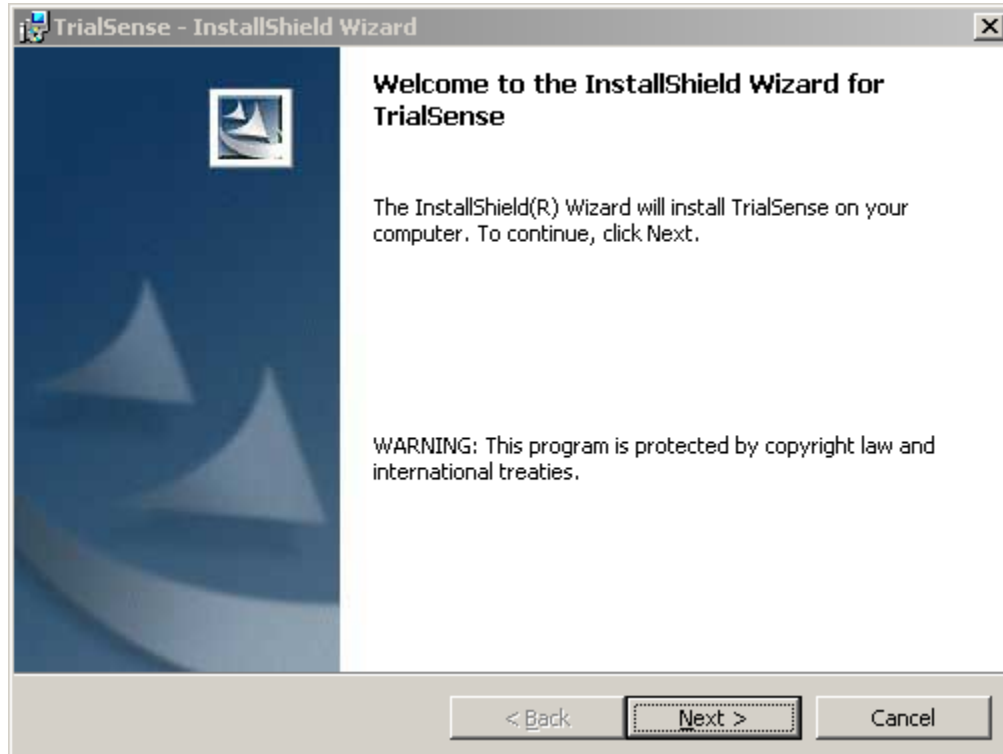


If the MySQL database is not installed and configured properly, the TrialSense Data Source, TrialSense Console, and TrialSense Collection Station will not work.

## **Part III. Installing TrialSense**

## Installing TrialSense

The TrialSense installer is preconfigured to install the TrialSense software to the *Program Files* folder in Windows. The TrialSense installer will not let you remove critical components of the TrialSense System.



In order to complete the TrialSense Console installation, you must be logged in to Windows using an administrator account.



TrialSense uses MySQL Server 5.0 or later as the default database, you will need to install the MySQL software prior to installing the TrialSense Console. See *Part II Installation Prerequisites* for more information about installing prerequisite software.

**Step 1:** After opening the trial sense installation program, choose “Next” to continue to the next screen.

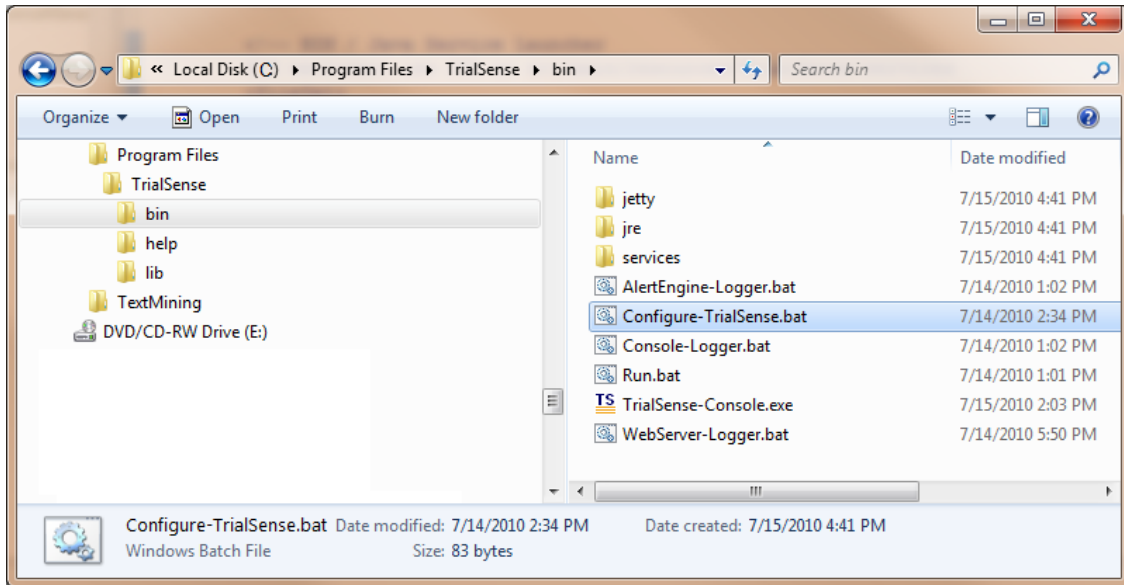
**Step 2:** Press “Install” on the following screen to begin the installation

**Step 3:** Click “Finish” to complete the installation.

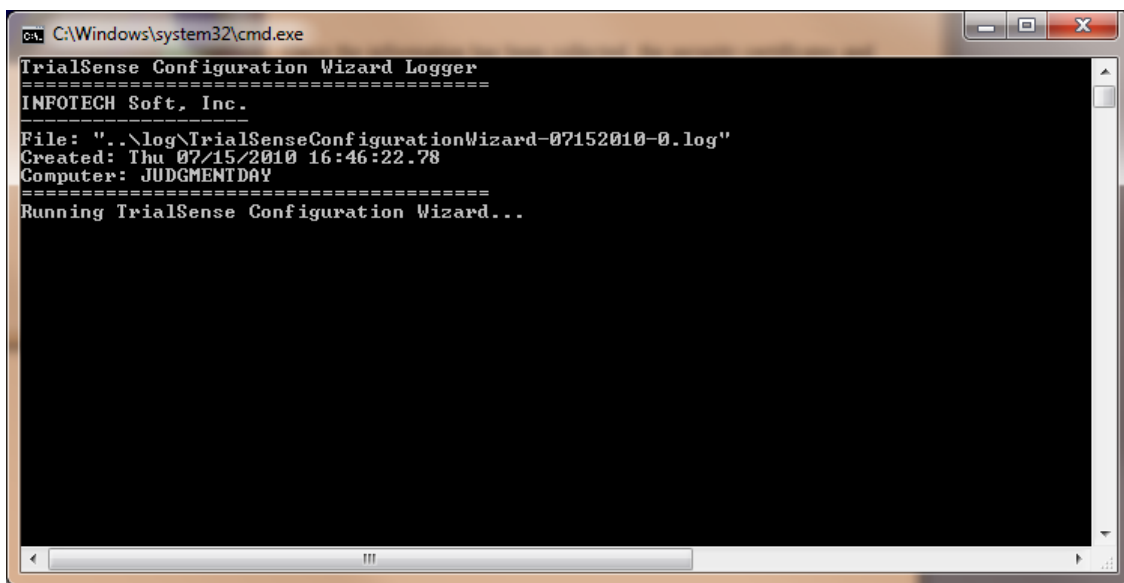
## Configuring TrialSense

Open a Windows File Explorer and navigate to where you installed the TrialSense software.

Right-click on the “Configure-TrialSense.exe” program in the TrialSense \bin directory and select ‘Run as Administrator...’.

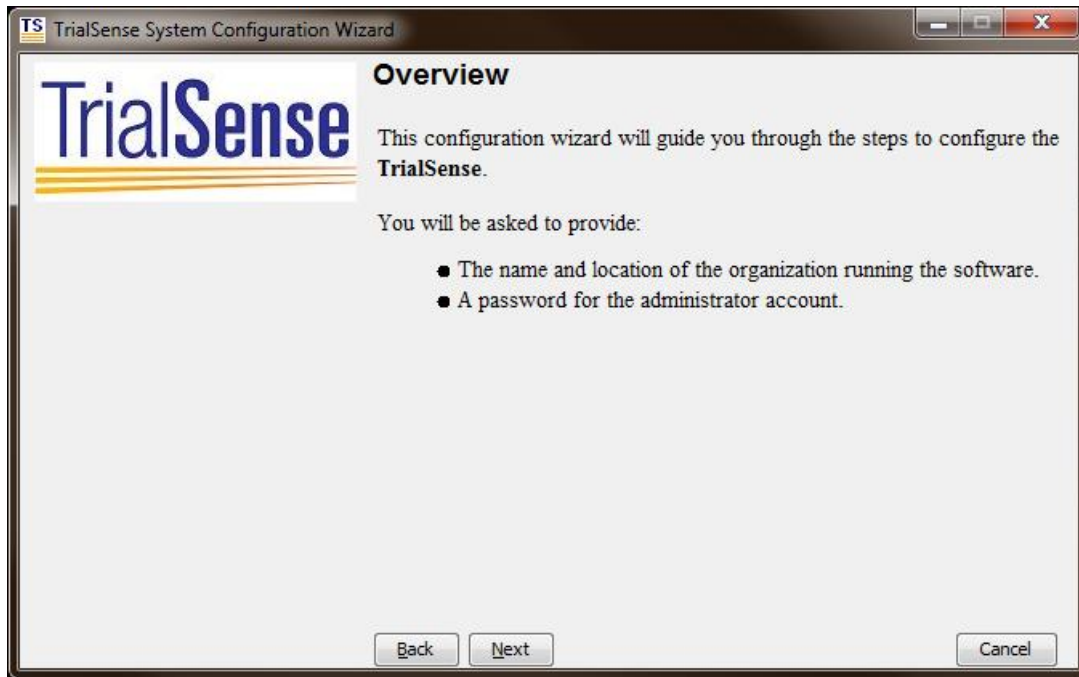


A window will pop-up indicating that the TrialSense Configuration Wizard is starting.

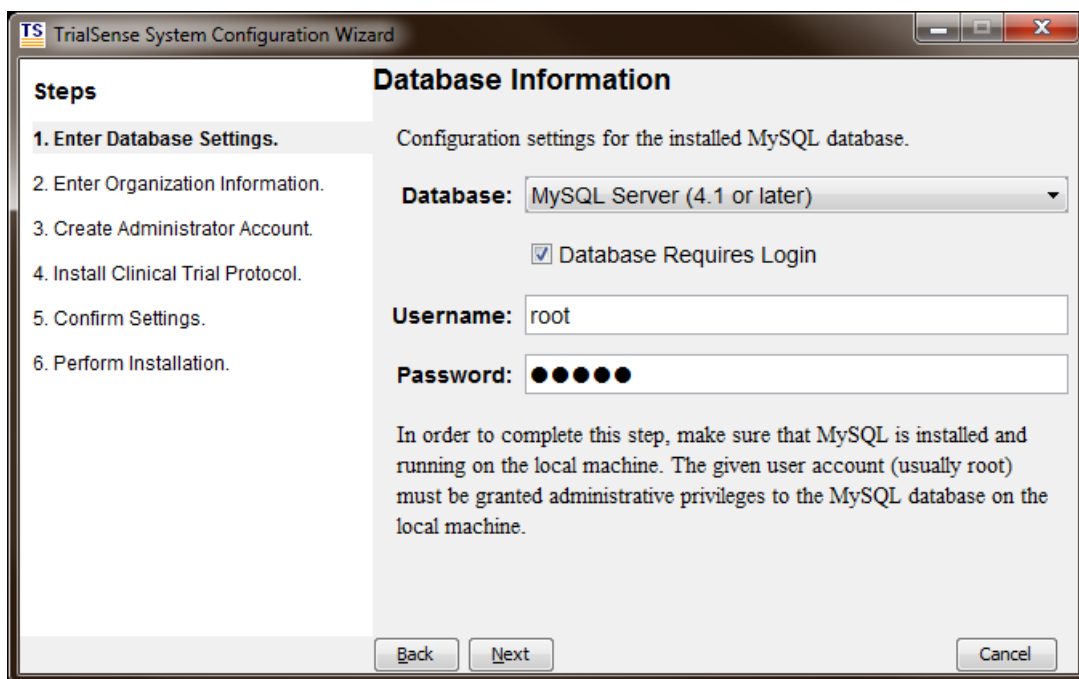




After a few seconds the TrialSense Configuration Wizard will open. Click Next.

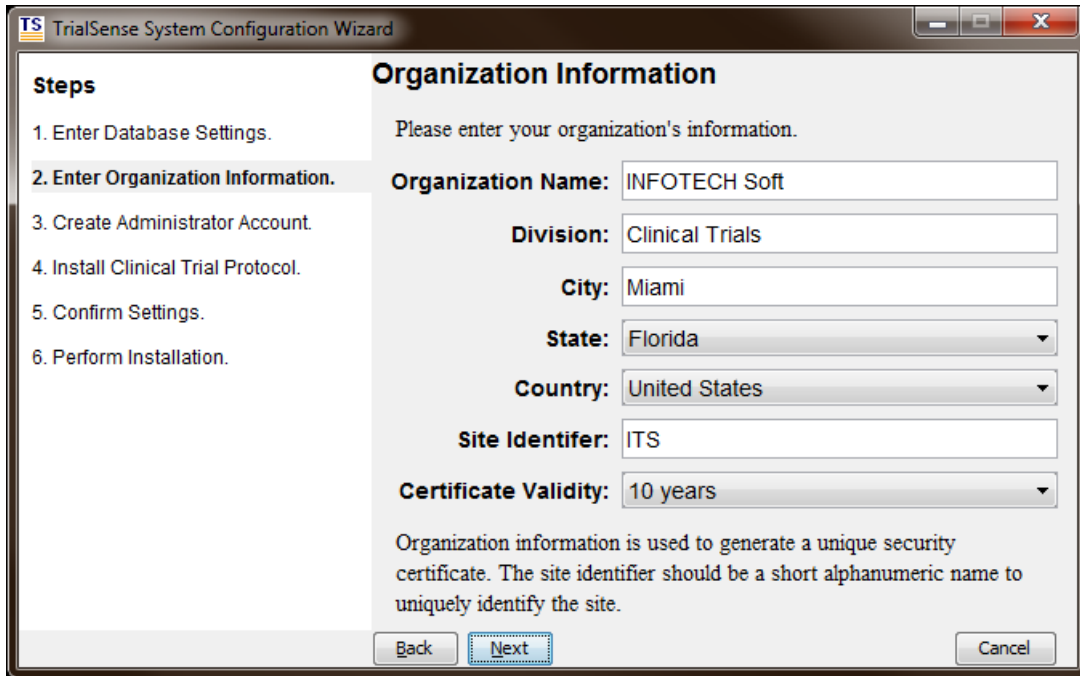


On the Database Information screen, select “Database Requires Login” and enter the username and password you selected for MySQL. **The Next button will remain disabled until the TrialSense Configuration Wizard is able to connect to the MySQL database.** For more information about installing and configuring the MySQL database, see Part II. Installation Prerequisites.

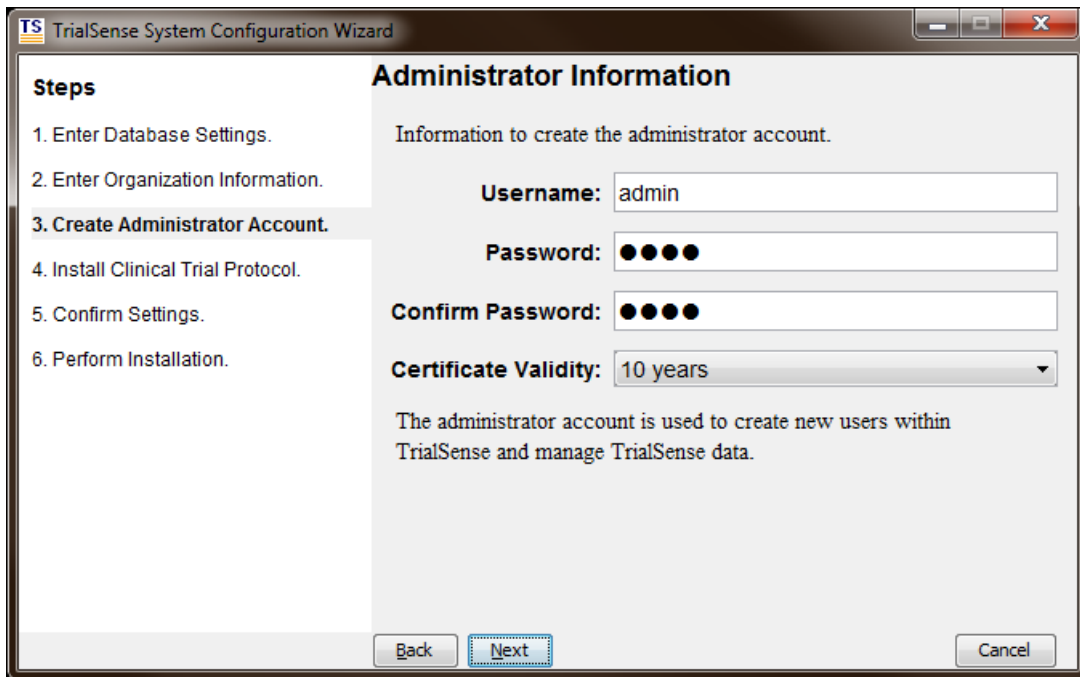


## Installing TrialSense

On the Organization Information screen, enter the Name, City, and State of your institution. Specify a short 3-4 character Site Identifier to uniquely identify your institution.

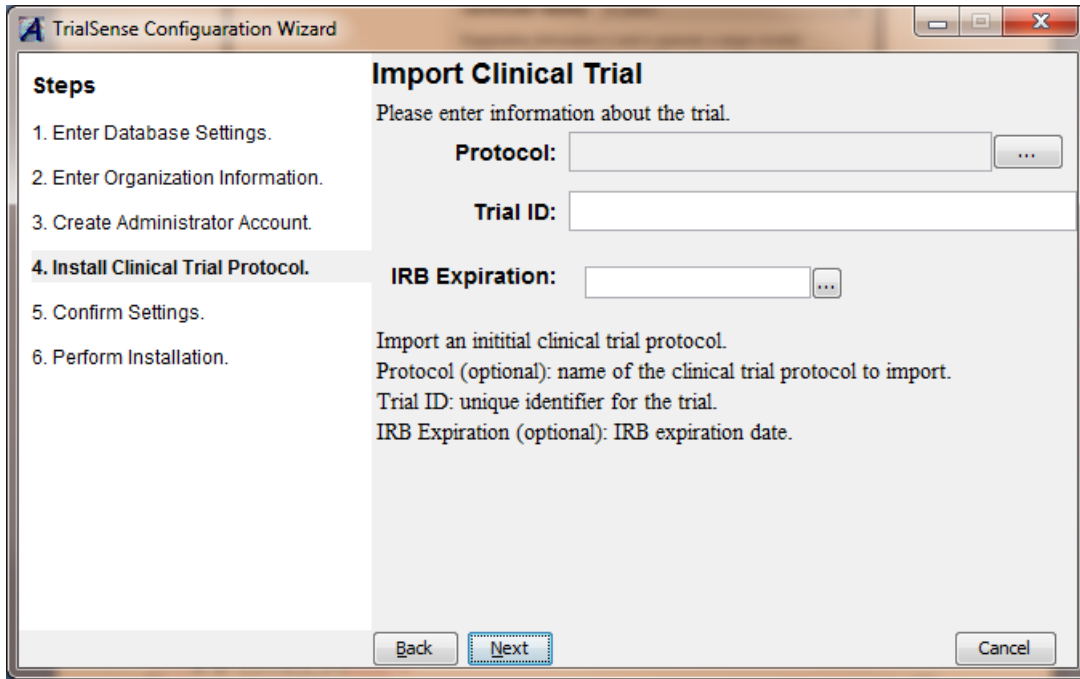


On the Administrator Information screen, enter a password that will be used for the TrialSense Administrator account.

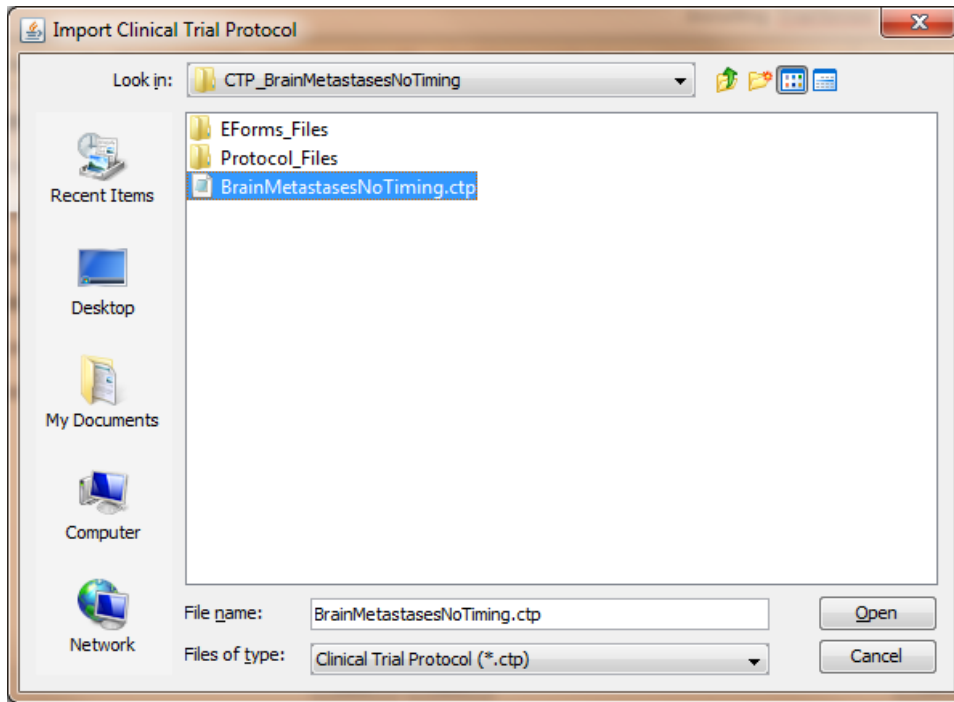


**Installing TrialSense**

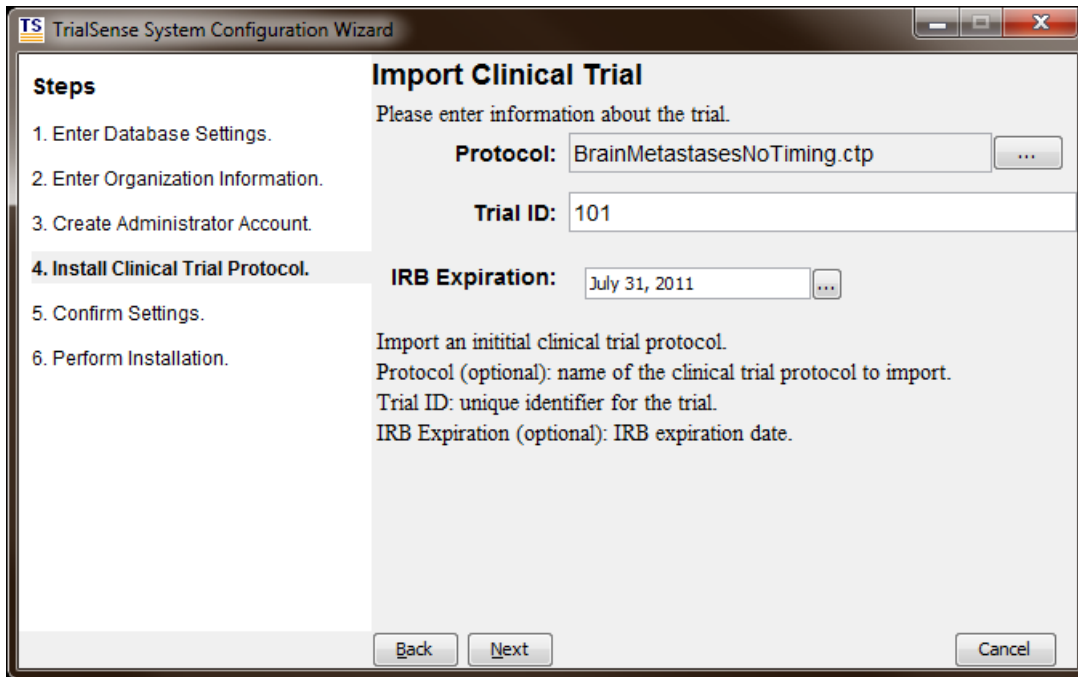
(Optional) If you were provided with a TrialSense protocol you can import it here or you can import it later through the TrialSense Console.



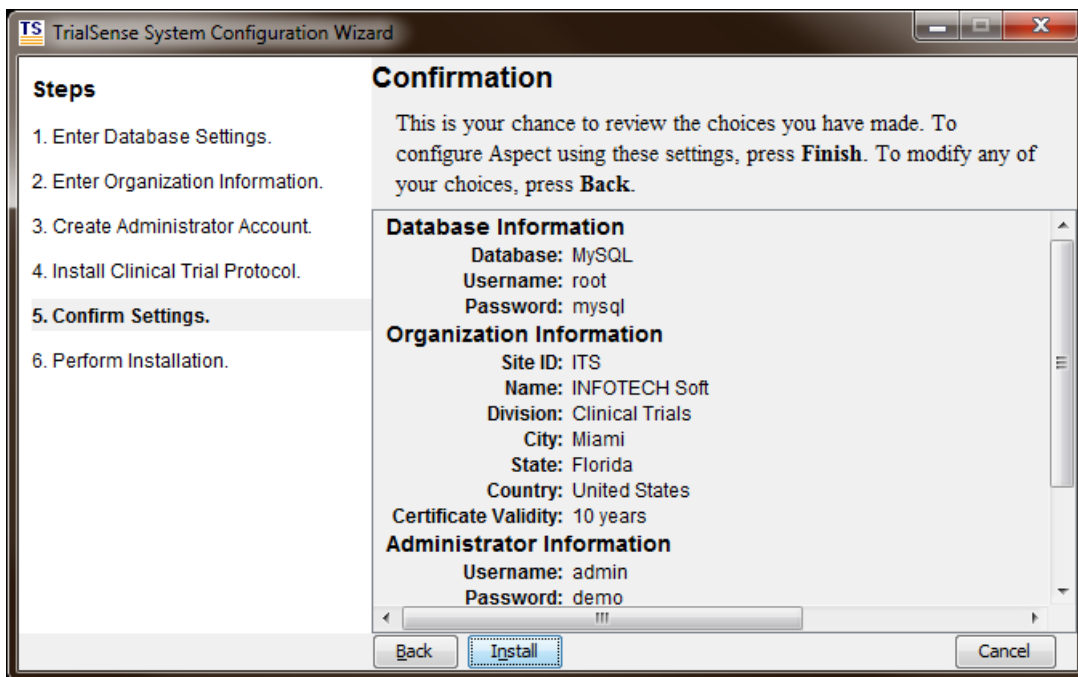
On the Import Clinical Trial screen, click on the browse ‘...’ button to locate your TrialSense clinical trial protocol (.ctp file).



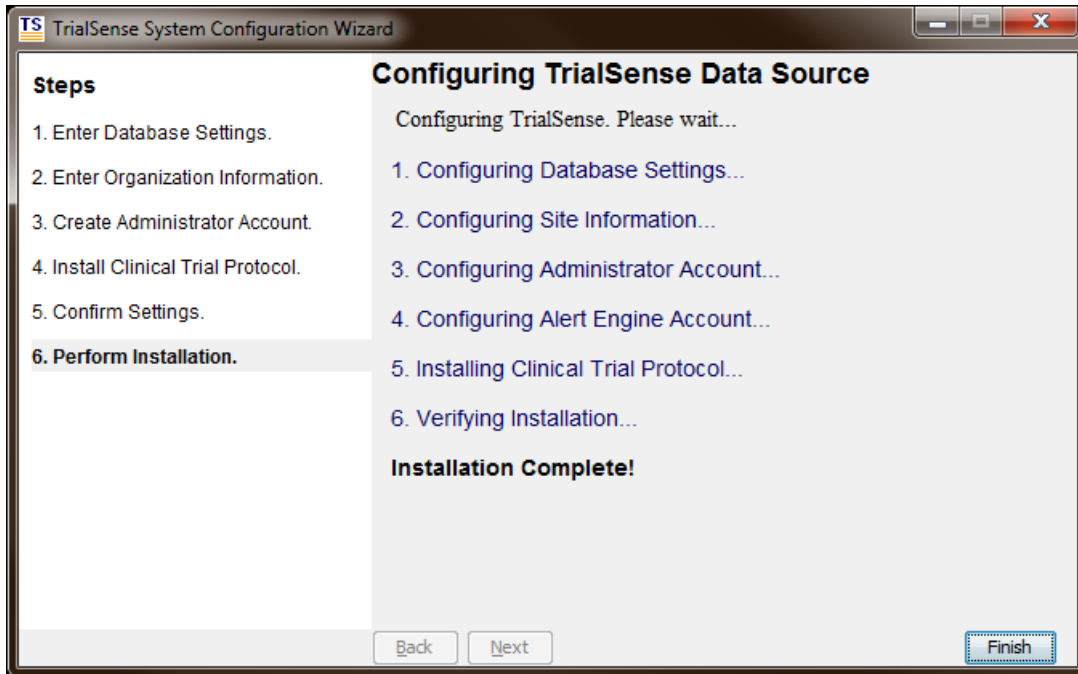
Enter a short identifier for the trial. Optionally, select an IRB Expiration date for the trial.



On the Confirmation screen, verify that the information you entered is correct. If you see a mistake, click on the 'Back' button to return to a previous screen to make the correction. Click 'Install' to start configuring TrialSense.



The TrialSense Configuration Wizard will configure the MySQL database, create the Administrator user account and install the clinical trial protocol.



Once the TrialSense Configuration Wizard has completed, you must reboot your computer to start the TrialSense Windows services.

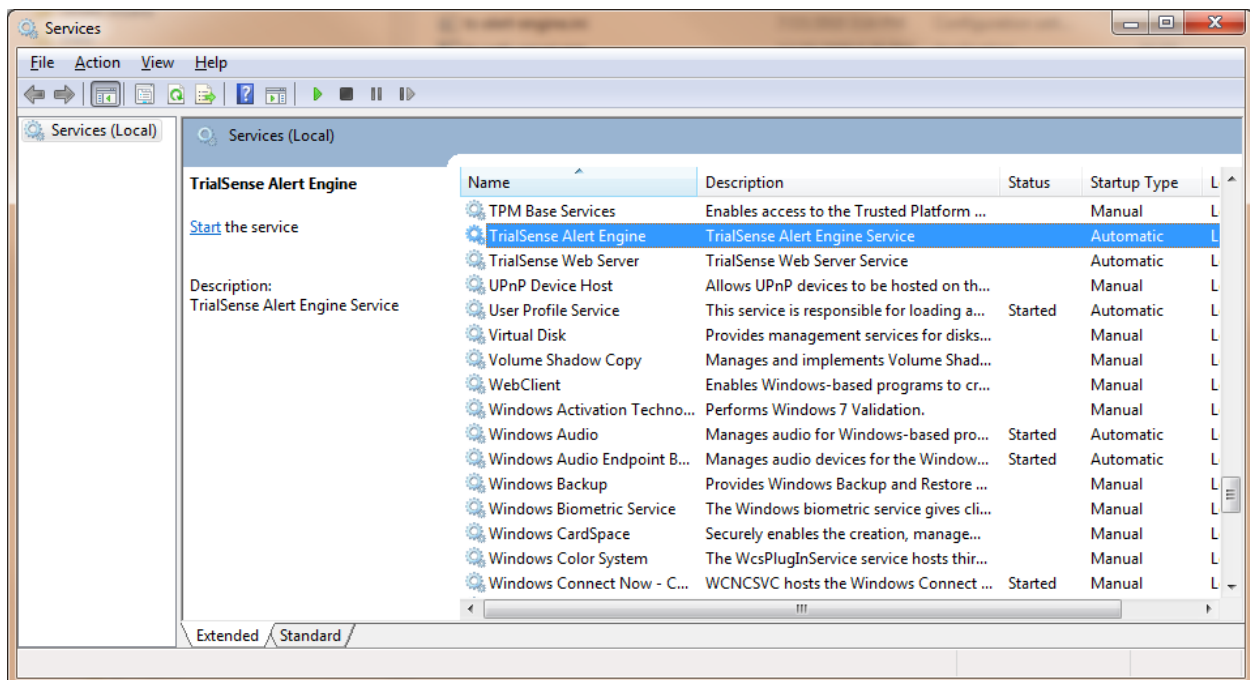
## Starting Windows Services

### TrialSense Alert Engine Service

During the installation process, the TrialSense AlertEngine is installed as a Windows service. In order for TrialSense to automate the clinical trial process, this service must be started *after* the configuration wizard has run.

### TrialSense Web Server Service

During the installation process, the TrialSense Web Server is installed as a Windows service. In order for users to access the TrialSense Web Interface, this service must be started *after* the configuration wizard has run.



The TrialSense Alert Engine and Web Server services start automatically when Windows starts. You can manually start the service the first time by opening the *Administrator Tools* in the *Control Panel* and starting the TrialSense Alert Engine and TrialSense Web Server services. Alternately, you can reboot the computer to have the service started automatically.