

Children's Hospital and Regional Medical Center

Seattle Children's Hospital Research Institute

StudyManager User Guide Coordinator Edition

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I. General Information

A. StudyManager Description

StudyManager is a widely used and proven Clinical Trials Management System (CTMS). A CTMS helps researchers manage all aspects of clinical trials planning, tracking and reporting. StudyManager has been deployed at Children's Hospital as a major tool for monitoring billing compliance related to research activity.

StudyManager is being used by investigators, research staff and research support staff to develop budgets and track all study events for all new clinical research since January 1, 2007.

StudyManager is a web-based database that requires no installation on desktop computers. Study information can be accessed from anywhere using Internet Explorer and a Children's Hospital StudyManager account.

B. Requirements

Clinical Trial Management policy CTM-100, "**StudyManager Utilization and Compliance Policy,**" outlines requirements for StudyManager utilization at Children's. All new Industry studies need to be entered in StudyManager as of January 1, 2007. All other studies with new funding awarded after January 1, 2007 will also be entered, regardless of funding source. Investigators and research team members will be notified by the Office of Sponsored Research (OSR) regarding their studies that have been entered.

Patients and patient study visit data must be entered into StudyManager within 2 business days of signing the study Informed Consent Form and study visit occurrence. For visit procedures completed at another date other than the main study visit date, that data must be entered within 2 business days of completion. Patient status must be changed to reflect current status of study participation within 2 business days of any study participation change.

C. Charge Direction (Research vs. Standard of Care)

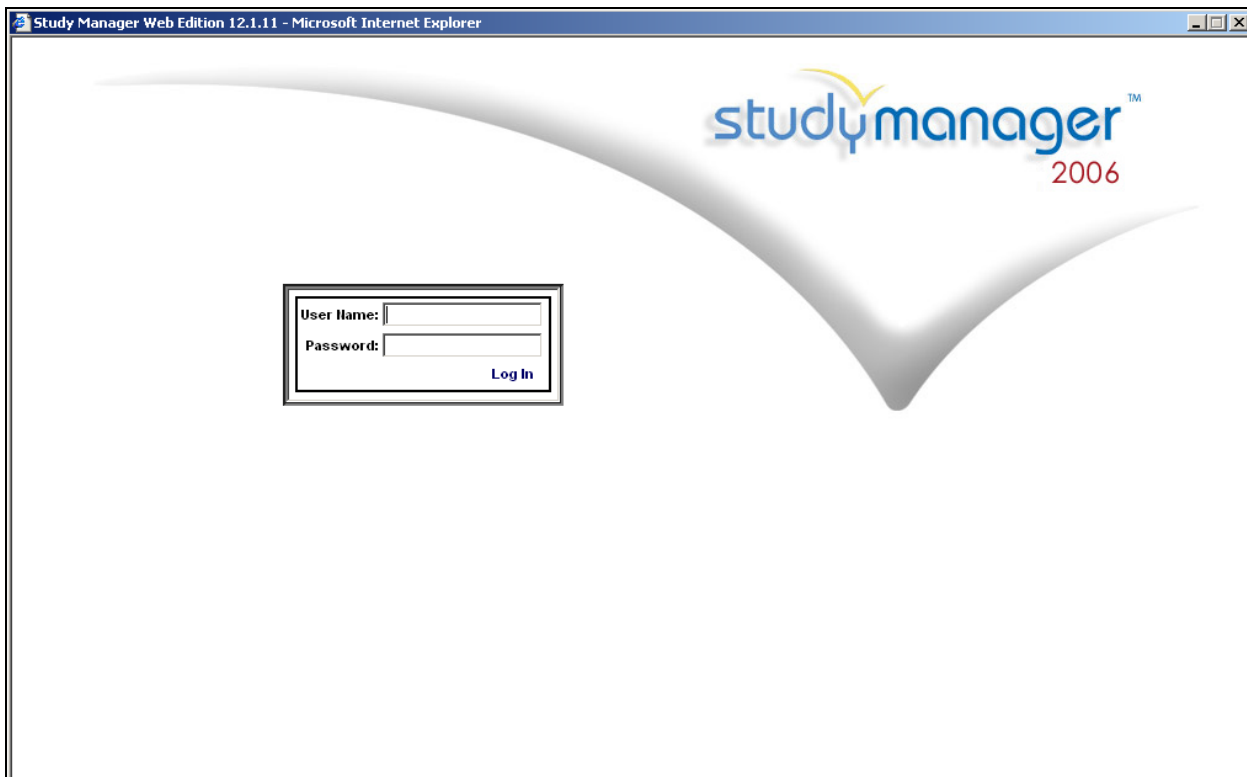
StudyManager tracks all study events as "Research" or "Standard of Care" according to a mutually agreed upon designation, between Principal Investigator and Clinical Research Budget Analyst, set during financial responsibility analysis and budget development. These study events or "procedures" are tagged in the StudyManager field "Financial Type." When this data is displayed for investigators, coordinators, other study team members, business services or other hospital billing staff, it is displayed in the "Provider" field so that the data in Financial Type cannot be altered. The information in the "Provider" field should never be changed. Changing this information does not alter the Financial Type data which will be used for all audits of research billing data.

D. StudyManager Account Set Up and Training

All authorized StudyManager users will be trained prior to gaining StudyManager access. If a new study team member requires StudyManager access, submit a StudyManager Account Request Form or contact the StudyManager Administrator for assistance. Never share login information with anyone. If additional training is ever needed, contact the StudyManager Administrator. Users experiencing technical difficulties with StudyManager should contact Research IT or the StudyManager Administrator.

II. Navigating StudyManager

With a StudyManager account, users can access StudyManager from anywhere, by going to <https://resweb.seattlechildrens.org/studymanager> in Internet Explorer.

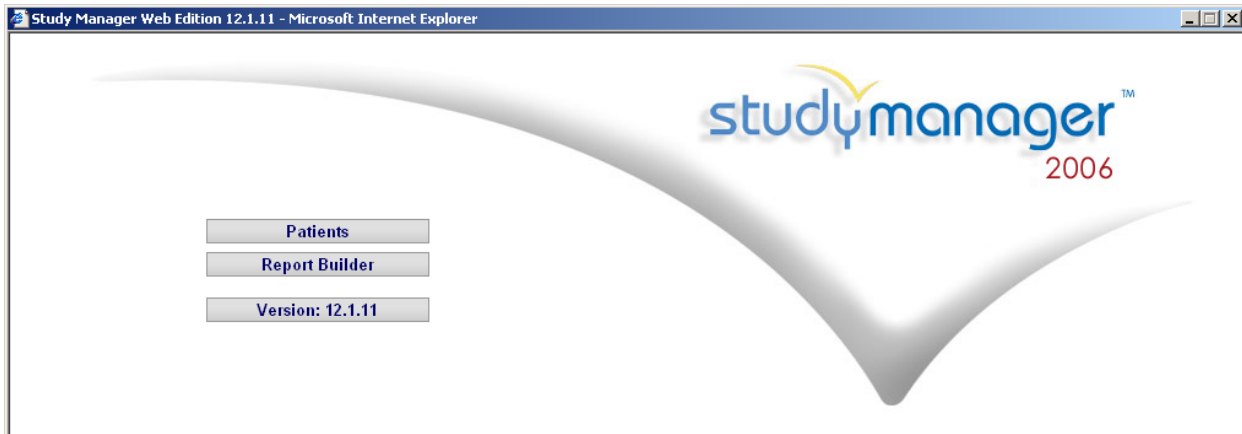


Enter User Name and Password.

Note: Do not share login information. If a team member requires access, they should complete a **StudyManager Account Request Form**.

Do not choose to have the computer remember login information. This is a security violation and passwords should be manually entered every time StudyManager is accessed.

From the Home Screen menu, select either "Patients" or "Report Builder" as necessary.

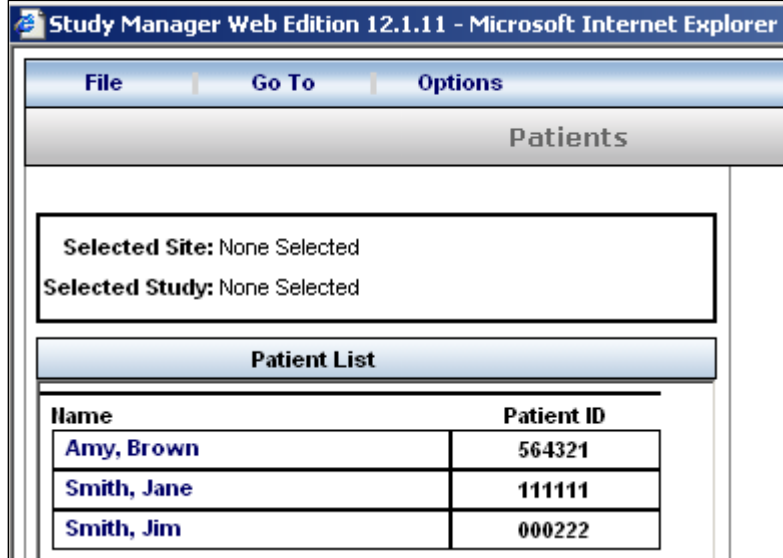


Once an area is initially selected during a StudyManager session, navigate to other areas by using the “Go To” menu as shown below.

 A screenshot of the "Go To" menu in the Study Manager interface. The menu is open, showing options: "Patients", "Report Builder", and "Home Screen". Below the menu, there are sections for "Selected Site: None Selected", "Selected Study: None Selected", and a "Patient Filter" section. The "Patient Filter" section includes input fields for "Site:", "First Name:", "Last Name:", "Patient ID:", and "Additional ID:", along with a "Study Patients:" checkbox and a "Clear Filter" button.

A. Using Filters and Lists

Some filters are integrated as a section of a screen, allowing the user to submit criteria to search for groups of records. In the image above is an example of the *Filter* section for the *Patients* screen. Once the user has entered and/or selected criteria, clicking **Submit Filter** displays a list of patients meeting the criteria.



B. Filtered Lists

A filter results in a list of data. For example, if a filter is submitted to locate all “Study X” patients, StudyManager will return a list of all those patients. A patient can then be selected from the list. Submitting a blank filter will result in a list of all data the user has access to in StudyManager.

C. Entering and Saving Data

Entering and saving data in StudyManager typically involves adding a new record, or selecting a record to edit and then *Submitting* changes.

*Note: In StudyManager, to **Submit** data is the same thing as saving data.*

Adding a Patient to the StudyManager Database

Before adding a patient to a study and tracking study visits, first add the patient to the StudyManager database from the *Patients* screen. If the patient has already been added, skip to *Enrolling a Patient in StudyManager*.

*Note: A list of all patients entered in StudyManager can be viewed by clearing the patient filter and clicking **Patient List**.*

1. Click **New Patient**. The following displays in the right hand side of the screen:

The screenshot shows a web form for adding a patient. At the top, it displays 'Date Updated: 12/27/2006 Updated By: RC201'. Below this is a legend '* = Required'. The form fields are:

- * First Name: [text box]
- MI: [text box]
- * Last Name: [text box]
- * Site: [dropdown menu]
- Patient ID: [text box]
- Additional ID: [text box]
- Street: [text box]
- Apt/ Suite: [text box]
- City: [text box]
- State: [text box]
- Zip: [text box]
- Phone 1: [text box]
- Phone 2: [text box]
- Email: [text box]
- Availability: [dropdown menu, set to 'Available for Studies']
- Gender: [dropdown menu]
- Birth Date: [MM/DD/YYYY format]
- Age: [text box]

2. Fill in the General/Demographic information. Instructions for completing the fields are provided below.

Field Name	Field Description
First Name	Enter patient's first name.
MI	Enter patient's middle initial.
Last Name	Enter patient's last name.
Site	Select "Children's Hospital" from the drop down menu. The specific division/clinic where the patient is a study participant will be selected later when enrolling the patient to the study.
Patient ID	Enter patient's medical record number at Children's Hospital.
Additional ID	Leave blank.
Street, Apt/Suite, City, State, Zip, Phone 1, Phone 2, Email	Entering the address is not required. Leave blank.
Availability	Leave this set at the default, "Available for Studies."
Gender	Select the gender.
Birth Date	Enter the birth date in MM/DD/YYYY format.
Age	Age will automatically calculate.

3. Click **Submit** to save the patient to the database. Click **Cancel** to exit without saving.

Enrolling a Patient in StudyManager

1. Select the patient to enroll by using the *Patient List* filters.
2. Once the patient is selected, click **Add Patient to Study**. The *Add Patient to Study* box displays.
3. Select a **study** from the drop down list.
4. **Select investigator** from the drop down list.
5. Select **coordinator** from the drop down list.
6. Select a **site** from the drop down list. This is the site the study patient will be associated with, when enrolled in the study. This will be different from the site, “Children’s Hospital” which is associated to the general patient record on the *Patients* screen.
7. Select **hospital** from the drop down list. This should be “Children’s Hospital” unless tracking patients enrolled at another hospital participating in the study.
8. **Multi-Arm studies only – Select arm.** If the study the patient is enrolled into is designated as a “Multi-Arm” study, specify which arm to associate the study patient with.
9. By default, the patient’s initials are used for the **alias**. Input another alias if desired. If two patients on the same study have the same alias, one must be changed. One way this can be done is by adding a “2” to the end of the alias.
10. Select an **initial status** for the patient. All study patients are assigned a current status when enrolled in studies, i.e. screening, randomized, dropped, failed. This status may be changed in *Patient Visits*, but an initial status must be assigned when adding a patient to a study:
 - **Pre-Screening** – Patients who have not started officially screening for the study can be entered in StudyManager and set with the initial status “Pre-Screening.”
Note: This is optional as only consented patients are required to be entered.
 - **Screening** – Patients who have consented to a study and are in the process of screening to confirm eligibility and meet baseline requirements can be set with the status “Screening.”
 - **Randomized** – Patients who take part in a multi-arm study and have been randomized according to protocol guidelines can be set with the status “Randomized.”
 - **On Study** – Patients who are on single arm studies, and thus not randomized, can be tracked with the status “On study” when they are enrolled.

Add patient to study

Select study:

Select investigator:

Select coordinator:

Select site:

Select hospital:

Alias:

Patient's initial status:

Pre-Screening Screening
 Randomized On Study

|

11. If “Screening,” “Randomized” or “On Study” is selected, enter a Screening Date and Screening Number. These dates and numbers are required. Screening Number is assigned by the user, and must be unique for each patient in the study.
12. If “Randomized” is selected, you must enter a Screening Date and Screening Number, as well as a Randomization Date and Randomization Number. These dates and numbers are required. These dates and numbers are assigned by the user, and must be unique for each patient in the study.
13. Click **Submit** when finished. Click **Cancel** to exit the screen without saving.

Once a patient is added to the study, the *Patient Visits* screen displays on the right hand side of the screen. From here, visits may be added or edited and the patient status can be changed.

Tracking Patient Visits

After a patient has been added to a study, use *Patient Visits* to manage visits and other enrollment data. To reach the *Patient Visits* screen from the *Patients Screen*, select a patient, and click **Patient Visits**.

Patient visits for study: WA201-RC201									
Patient Info		Visit Info							
Alias: J-S Status: Screening Screen Num: 1 Rand Num:		<table border="1"> <thead> <tr> <th>Visit</th> <th>Visit Date</th> </tr> </thead> <tbody> <tr> <td>1 / Visit 1</td> <td>04/18/2007</td> </tr> <tr> <td>1.5 / Fever follow-up</td> <td>05/09/2007</td> </tr> </tbody> </table>	Visit	Visit Date	1 / Visit 1	04/18/2007	1.5 / Fever follow-up	05/09/2007	
Visit	Visit Date								
1 / Visit 1	04/18/2007								
1.5 / Fever follow-up	05/09/2007								
Procedure	Provider	Type	Comp.						
ALT	Standard of Care,	Protocol-Required	Yes						
AST	Standard of Care,	Protocol-Required	Yes						
C-reactive protein	Standard of Care,	Protocol-Required	Yes						
CBC with differential	Standard of Care,	Protocol-Required	Yes						
Echo doppler pro-fee	Standard of Care,	Protocol-Required	Yes						
Echocardiogram	Standard of Care,	Protocol-Required	Yes						
Electrocardiogram (ECG) (EKG)	Standard of Care,	Protocol-Required	Yes						
Erythrocyte Sedimentation Rate (ESR)	Standard of Care,	Protocol-Required	Yes						
Informed Consent	Research,	Protocol-Required	Yes						
Pharmacokinetics, serum	Research,	Protocol-Required	Yes						
Physical Exam	Standard of Care,	Protocol-Required	Yes						
Res. RII Case Report Form CRF Completion/Submission	Research,	Protocol-Required	Yes						
Add Visit Edit Visit Manage Patient									

New Patient	Patient Info	Patient Visits
Add Patient to Study	Patient Studies	

- The top left contains patient enrollment info that was set when adding the patient to the study, and can be edited by clicking **Manage Patient**.
- The *Visit Info* section contains completed visits and dates.
- Selecting an individual visit displays details of that visit below.
- Further visit information can be viewed or changed by clicking **Edit Visit**.

A. Add Visit

Select the patient with the *Patient List* filters, and click **Patient Visits**. The patient and visit information displays.

1. Click **Add Visit**. The *Add Visit* box displays:

Add Visit (Study: WA201-RC201)

Select a visit: Visit Date: / /

[Submit](#) | [Cancel](#)

2. From here, select the visit number and enter the correct date for the visit.
3. Click **Submit**, the *Visit Check List* displays.

Study Manager Web Edition 12.1.11 - Microsoft Internet Explorer

Add Visit / Visit Check List

Patient: Clint Vickers **Alias:** C-V2 **Patient Status:** Screening
Study: WA201-RC201 **Visit:** 1.08 / Cycle 1 Day 8 **Screen Num:** 4 **Rand Num:**

Visit Date: 05/29/2007 [Set Visit Date](#) | [Set All Providers](#) | [Complete All Procedures](#)

Visit Procedures							
	Procedure Date	Procedure	Provider	Complete	Qty	Type	Procedure Notes
1	<input type="text" value="05"/> / <input type="text" value="29"/> / <input type="text" value="2007"/>	Vital Signs	<input type="text" value="Standard of Care,"/> ▾	<input type="checkbox"/>	<input type="text" value="1"/>	Protocol-Required	Click to enter notes
* Vital signs will be assessed prior to study drug administration and before the subject leaves the hospital. Vital signs include respiration rate, Note: blood pressure, pulse and temperature.							
2	<input type="text" value="05"/> / <input type="text" value="29"/> / <input type="text" value="2007"/>	Study Medication Administration	<input type="text" value="Research,"/> ▾	<input type="checkbox"/>	<input type="text" value="1"/>	Protocol-Required	Click to enter notes
* Note: Study drug will be administered once weekly for 6 months. The first dose must be given within 2 business days of randomization.							
3	<input type="text" value="05"/> / <input type="text" value="29"/> / <input type="text" value="2007"/>	Adverse Events Review	<input type="text" value="Research,"/> ▾	<input type="checkbox"/>	<input type="text" value="1"/>	Protocol-Required	Click to enter notes
4	<input type="text" value="05"/> / <input type="text" value="29"/> / <input type="text" value="2007"/>	Concomitant Medications Review	<input type="text" value="Research,"/> ▾	<input type="checkbox"/>	<input type="text" value="1"/>	Protocol-Required	Click to enter notes
5	<input type="text" value="05"/> / <input type="text" value="29"/> / <input type="text" value="2007"/>	CBC with differential	<input type="text" value="Standard of Care,"/> ▾	<input type="checkbox"/>	<input type="text" value="1"/>	Protocol-Required	Click to enter notes
* Note: Tests must be done within 72 hours prior to study drug administration.							

Additional Procedures				
Date	Procedure	Provider	Qty	Procedure Notes
There are no additional procedures assigned to this visit.				

[Add Procedure](#) | [Edit Procedure](#) | [Remove Procedure](#)

[Submit Visit](#) | [Cancel](#) | [Visit Notes](#)

4. Use the *Visit Check List* to check off procedures as complete, enter procedure specific notes, adjust the quantity, change the provider, and add additional procedures as needed.
5. If a procedure is not checked as complete, procedure notes are required:
6. If the *procedure notes* window displays, enter notes stating why the procedure was not completed, and then click **Store Info**. Or, click **Cancel** to return to the visit checklist to mark the procedure as complete. Even if a procedure is marked as complete, procedure notes may still be entered. Click the **Click to enter notes** link.
7. Click **Submit Visit** when finished entering visit data. Click **Cancel** to exit without saving. When you submit the visit, all the data related to the *Visit Checklist* is saved. The visit will display on the *Patient Visits* screen. From this point, use **Edit Visit** to modify existing information.

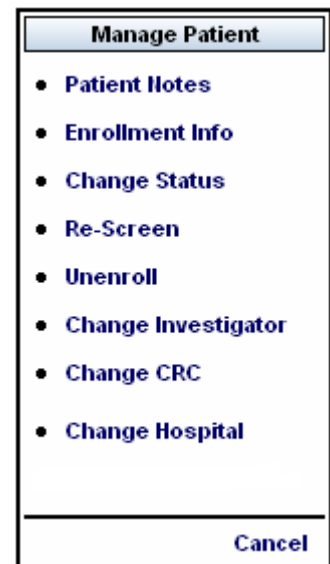
Notes:

- *Change the entire visit date by using “Set Visit Date”, or change the date of individual procedures by typing directly into the Procedure Date field.*
- *To mark all procedures as completed in one step, click **Complete All Procedures**.*
- *To add general visit notes for a particular visit, click **Visit Notes**.*

B. Manage Patient

The **Manage Patient** link allows patient study information to be edited:

- **Patient Notes** - Click **Patient Notes** to enter any general information about this patient in relation to the study. Click **Save Notes** to save the information or **Cancel** to exit without saving.
- **Enrollment Info** - This link allows viewing and editing of screening and randomization numbers, as well as the status change dates, alias, etc.
- **Change Status** – Use this to manually change a patient’s status in the study. Patient status is the designation assigned to a patient that provides information about their study activity and progress.
 - **Pre-Screening** – Patients who have not started officially screening for the study can be entered in StudyManager and set with the initial status “Pre-Screening.”
 - *Note: This is optional as only consented patients are required to be entered.*
 - **Screening** – Patients who have consented to a study and are in the process of screening to confirm eligibility and meet baseline requirements can be set with the status “Screening.”



- **Randomized** – Patients who take part in a multi-arm study and have been randomized according to protocol guidelines can be set with the status “Randomized.”
 - **On Study** – Patients who are on single arm studies, and thus not randomized, can be tracked with the status “On study” when they are enrolled.
 - **Pre-Screening** – Patients who have not started officially screening for the study can be entered in StudyManager and set with the initial status “Pre-Screening.”
 - **Screening** – Patients who have consented to a study and are in the process of screening to confirm eligibility and meet baseline requirements can be set with the status “Screening.”
 - **Randomized** – Patients who take part in a multi-arm study and have been randomized according to protocol guidelines can be set with the status “Randomized.”
 - **Follow-up** – Patients who have completed the active phase of a study and are only being followed for adverse events can be set with the status “Follow-up.”
 - **On Study** – Patients who are on single arm studies, and thus not randomized, can be tracked with the status “On study” when they are enrolled.
 - **Failed** – Patients who enter screening but do not meet all the study entry criteria can be set with a status of “Failed” to signify a screen fail.
 - **Dropped** – Patients who are enrolled to a study but either withdraw consent or are taken off study for other reasons such as non-compliance, can be set with a status of “Dropped.”
 - **Completed** – Patients who have met all the requirements of a study and are at the point where they are no longer subject to any further study interventions or follow-up and for whom no more study data will be collected can be set with a status of “Completed.”
 - **No Show** – If a patient is scheduled for a study visit, during any point of the study, and does not keep their appointment, the patient can be set with the status “No show” to track the reason for not completing that visit.
 - **Did Not Qualify** – To compile recruitment data, patients who are not screened because they do not meet an initial assessment for study consideration can be tracked with the status “Did not qualify.”
- **Re-Screen** - If a patient has a status of failed, there is the option to “re-screen” them into the study. Doing this is different from simply changing their status back to screening. Using **re-screen** retains the record of the failed patient, and creates a new patient enrollment, with a status of screening. If a patient is re-screened, enter a new screening number for them, and their alias will automatically have a “-2” added to it, i.e. “FML-2.” To re-screen a patient, click **Re-Screen** and a prompt to re-enroll the patient into the study will display.

- **Change Investigator** - Use this link to set or change the Investigator assigned to the study patient.
- **Change CRC** – Use this link to change the patient’s study coordinator.
- **Change Study Arm** (Multi-arm studies only) – Allows the study arm for a patient to be changed.
- **Change Arm Cycle** (Multi-arm studies only) – Allows a patient to be assigned to subsequent “cycles” in the study.
- **Change Hospital** – Change hospital data for patient.
- **Change Disease Site** (NCI Reporting Studies only) – Set the disease site, which the patient will accrue towards on NCI reports.

Printing a Visit Checklist

While not required, it may often be helpful to print a visit checklist in preparation for a patient study visit. This checklist displays all the procedures and other study events for a visit and marks each as Standard of Care or Research.

- 1. Select a study and a study site from the drop down menus.
- 2. Select one or more visits from the *Study Visits* menu.
- 3. Print either a checklist for a specific patient or a blank checklist.
- 4. After making a selection, click **Continue**.
- 5. If printing a checklist for specific patient, select the patient name.
- 6. The checklist will then load and display in Adobe PDF format. (The example below is a blank visit checklist, not specific to a patient.)

Visit Checklist

Patient: WA201-RC201 Alias: Status:
Study: WA201-RC201 Visit: 1 / Screening/Baseline
Screen Number: Randomization Number:
Visit Date:

Visit Procedures

Procedure Date	Procedure	Provider	Complete	Qty	Type
1 <input type="text"/>	Informed Consent	Research	<input type="checkbox"/>	1	Protocol-Required
Procedure Notes:					
2 <input type="text"/>	Demographics & Medical History	Research	<input type="checkbox"/>	1	Protocol-Required
Procedure Notes:					
3 <input type="text"/>	Physical Exam	Research	<input type="checkbox"/>	1	Protocol-Required
Procedure Notes:					
4 <input type="text"/>	Vital Signs	Research	<input type="checkbox"/>	1	Protocol-Required
Procedure Notes:					
Vital signs include respiration rate, blood pressure, pulse and temperature.					
5 <input type="text"/>	Height & Weight	Research	<input type="checkbox"/>	1	Protocol-Required
Procedure Notes:					

- 7. View the visit checklist on screen, save it to a computer drive/network folder, or print by choosing the appropriate icon.
- 8. On the last page of a visit checklist, there is a signature line if the printed checklist is to be used as a source document.

Additional Procedures					
Procedure	Date	Procedure	Provider	Complete	Qty Type
1	<input type="text"/>	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
Additional Procedure Notes:					
2	<input type="text"/>	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
Additional Procedure Notes:					
3	<input type="text"/>	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
Additional Procedure Notes:					
Visit Notes:					

Coordinator / Physician Signature					

Using Reports

A. Overview

StudyManager provides some reports that may be helpful to coordinators and others involved in clinical research at Children's Hospital. Running reports is not mandatory. When the Report Builder screen is first viewed, select the patient module and then any of the templates.

Once a template is selected, any user-customized reports saved under that template will display.

After selecting a new or saved report, the fields of that report will display on the right hand side of the screen. Other fields can be added, and existing fields can be removed. Many fields on reports can also be filtered for specific data, i.e. a date range, a study, a group of patients, a sponsor, etc. Once the filtering information is selected, run the report. The report will come up as a preview, which can be further formatted, saved, printed, or exported to a text file.

The screenshot shows a software interface with a menu bar containing 'File' and 'Go To'. Below the menu bar, there are two dropdown menus: 'Select Module:' with 'Patients' selected, and 'Select Template:' which is open, showing a list of saved reports. The list includes: CRF Report, Patient Visit Detail, Study Patient Totals, Study Patients by Name, Study Patients by Status, Study Summary by Arm: Visit, Study Summary: Visit, and Visit Checklist.

Report Fields and Filters		
Field	Type	Filter
Study ID	Core	(not set)
Site ID	Core	(not set)
Site Name	Optional	(not set)
Patient Name	Optional	(not set)
Alias	Core	(not set)
Visit Date	Optional	(not set)
Visit Name	Optional	(not set)
Visit Number	Optional	(not set)
Show Off-Protocol Visits Only [filter only]	Core	(not set)
Procedure Name	Core	(not set)
Provider	Optional	(not set)
Procedure Notes	Optional	(not set)

B. Patient Report Descriptions

Patient Visit Detail

This report provides information specific to a patient study visit. It shows: the Study ID; Site ID and Name; Patient Name and Alias; Visit Date, Name and Number; and the Procedures, Provider and Notes. This report may be helpful when reporting on what happened at a specific patient visit.

Study Patient Totals

This report can provide the accrual numbers for every patient status (Screening, Failed, Randomized, On Study, Completed...), both current totals or for a specific date range (reporting period), as well as a grand total of all patients entered. If this is more information than needed, the report can be customized to provide more focused data. It is similar to a study patient enrollment log.

Study Patients by Name

This report provides a patient roster for the studies selected. It lists the patients by name and displays their study number, status, and most recent visit completed (name of visit and date).

Study Patients by Status

This report is similar to the Study Patients by Name report, but is formatted for easier review of status.

Study Summary by Arm: Visit

For multi-arm studies, this report provides a more detailed view than either the Study Patients by Name or by Status reports. It provides the dates that each study patient completed each study visit for each arm of the study. It is similar to a study patient tracking log.

Study Summary: Visit

For single arm studies, this report provides a more detailed view than either the Study Patients by Name or by Status reports. It provides the dates that each study patient completed each study visit. It is similar to a study patient tracking log.

Visit Checklist

The visit checklist can be printed out both from the Patient Module and the Report Builder module. The Visit Checklist report provides information for completed patient visits only. If the visit checklist is to be used for recording completion of procedures during a patient visit or for a source document for that visit, the report should not be used. Instead print out the checklist from the Patient Module, which provides space for recording information and a signature line.

