

STANDARDS FOR THE USE OF STUDY MANAGER™

Clinical Research Policy/Procedure

Approved: October 2008

Next Review: October 2009

Purpose

To define the standards and usage requirements for Study Manager™.

Responsible Persons

Research Managers, Research Coordination Staff (who have been granted permission rights), Grants and Contracts Data Coordinator, Grants and Contracts Analysts, Clinical Trials Budget & Claims Analysts, and Regulatory Affairs Coordinators.

Policy

Study Manager™ is the management information system program used by the Research Division to track census (e.g., enrollment and status), workload (e.g., visits and procedures), and earnings (total of income generated by completed patient visits) for sponsored clinical studies. Data entered into Study Manager provides a centralized access point for assessing study progress and for auditing billing (procedures performed) and earnings (visit revenue).

Responsible Persons are required to maintain a Minimum Data Set (MDS) (see Appendix) in Study Manager consisting of: (i) patient information, (ii) patient status in treatment, (iii) study visits and protocol-required research-paid procedures for which a hospital or outside services bill will be generated, (iv) completion dates of visits and procedures, (v) earnings receivable per patient visit (i.e., Visit Support by Sponsor), (vi) additional procedures generating reimbursement not covered by the "Visit Support by Sponsor" amounts, and (vii) uploads of IRB approved original and modified Protocols and Informed Consents for each trial. Responsible Persons *may* maintain additional data other than the minimum data set described above.

Procedure

1. At the time that an administrative file is established for a proposed clinical study, the Grants and Contracts Data Coordinator creates a study shell record in Study Manager (SM). The study shell serves as the *envelope* for the study in SM and contains study information and data including the study sponsor, study title, protocol number, and investigator. See *also* Clinical Research Policy/Procedure: RESEARCH STUDY INITIATION PROCEDURES – ADMINISTRATION.

2. **Visits.** For each study shell entered in SM, the Research Manager supervising the study is responsible for insuring input and naming of Visits for the study in SM [Studies > (Select Study) > Visit Information > Add Visits]. Add one (1) Visit for each scheduled study visit or research encounter per the study protocol, and include three (3) “Unscheduled” placeholder (e.g. “A”, “B”, “C”) visits. Record a Visit # and Visit Name (e.g., “Screening”) associated with each respective Visit. Visit name must be consistent with Budget and Billing Matrix (BBM).
3. **Visit Procedures.** The Research Manager and/or the Reimbursement and Claims Analyst is responsible for insuring input of Visit Procedures for each Visit in SM [Studies > Visit Information > Visit Procedures > Add Procedure > Protocol Procedures]. Include all protocol-required research-paid procedures for which a hospital or outside services bill will be generated, including procedures which are identified as possible and billable depending upon other certain conditions in the protocol. The generic name of the procedure should be included, but the internal cost or price is not necessary, as it is covered on the BBM.
4. **Visit Support by Sponsor.** The Research Manager and/or the Clinical Trials Budget & Claims Analyst is responsible for insuring input of (1) “Visit Support by Sponsor” for each Visit. [Studies > Visit Information > Visit Procedures > Add Procedure.
 - a. **Amount Due.** Include the total amount due from the sponsor (including indirect) that the sponsor has agreed to reimburse for the Visit under the assumption that all procedures for the visit are completed. [Financials > Budgeting > (Select Study) > View One Procedure Across All Visits > Visit Support by Sponsor > Edit].
 - ➔ **NOTE:** The Amount Due should equal the “Sponsor Offer Payment per Visit” row in the Budget and Billing Matrix. The Total Protocol Revenue should equal the “Total Amount Due” column on the Combined Budget in the SM Report Builder Module.
 - A Grants and Contracts Analyst or the Clinical Trials Reimbursement and Claims Analyst will verify the Amount Due/Visit Support by Sponsor for each Visit against the Contract and BBM for the study.
5. **Patient Quota.** The Research Manager is responsible for ensuring input of the patient quota for the study [Studies > Study Sites > Select Site > Study Sites General Information > Patient Quota > Submit] as well as in the [Studies > Edit Study] sections.
6. **Patients.** The Research Coordinator or designee enters new patients in SM [Patients > New Patient] and their associated patient information [Patients > Patient Info].
 - a. **Alias; Screen Number; Randomization Number.** If and when the sponsor assigns a subject ID (e.g., screening number, randomization number,) promptly input the identifier in SM [Patients > Patient Visits > Manage Patient > Enrollment Info]. Screening numbers and randomization numbers must match those used by the Sponsor.
7. **Patient Visits.** The Research Coordinator or designee adds patients to a study [Patients > Add Patient to Study] and enters patient visits [Patients > Patient Visits] each time a patient comes to the site for a study visit.

- a. **Visit Checklist.** When a patient comes to the site for a study visit, indicate the visit procedures the patient completes in SM [Patients > Patient Visits > Edit Visit > Complete checkbox].

➔ **Patient Visits and the Visit Checklist must be entered and completed in SM within five (5) business days of the patient visit.**

- b. **NOTE:** “Unscheduled” study visits or procedures (e.g., safety visit or “ad-hoc” procedure) should be updated in SM by the Research Coordinator at the time they occur, using one of the three placeholder Unscheduled Visits. Include the Visit Procedures. See Steps 2-3 above.
- c. **Invoiceable Items:** If an Item is “Invoiceable” in one of the Unscheduled Visits, and the GC staff are going to be asked to generate a special Invoice to the Sponsor, then there should be no reference to Amount Due or Visit Support \$\$ in Study Manager, just the fact that the procedure or visit is checked off as “done.”
8. **Patient Status.** The Research Coordinator or designee updates a patient’s status as needed as patients move through a protocol. The following Status Indicators are in use: Screening, Randomized, On Study, Dropped, Completed, Follow-Up, Did Not Qualify, and Failed. [Patients > Patient Visits > Manage Patient > Change Status].
9. **Completion of Study:** Once a study is completed or terminated and the decision has been made to archive the records, Grants and Contracts Staff label the study shell record with a “ZDELETE” in front of the title and set the “Active” flag to null.

Forms

- ◆ Budget and Billing Matrix

Supplemental Information

- Study Manager Reference Manual

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References

Clinical Research Policy/Procedure: CLINICAL RESEARCH BUDGETING AND COVERAGE ANALYSIS

Clinical Research Policy/Procedure: RESEARCH STUDY INITIATION PROCEDURES – ADMINISTRATION

Addendum

1. Budget and Billing Matrix
2. Minimum Data Set (MDS) for Study Manager
3. Study Manager Process Steps

pk:Standards for the Use of Study Manager – v. 2.0.doc (10/13/08)

STANDARDS FOR THE USE OF STUDY MANAGER

ADDENDUM 1

Budget and Billing Matrix

STANDARDS FOR THE USE OF STUDY MANAGER

ADDENDUM 2

Minimum Data Set (MDS) for Study Manager

Appendix

MINIMUM DATA SET (MDS) for STUDY MANAGER™

Section	Item	Description
REQUIRED		
<u>Studies</u>	Shell	Study Id Site Protocol Sponsor Title Investigator
<u>Procedures</u>	Generic Name	This refers to our Excel ChargeMaster for Research: CPT__NAME__LOC__PROV__OUR COST__ CHARGES__COMMENTS__ASSOC CPT CODES __LAST UPDATE (DATE/WHO)
<u>Protocol</u> (Visits and Procedures) Note: Internal Costs no longer necessary in SM, only Visit Support	Visits	All Visits Visit Name (Needs to match BBM and Protocol) Research-paid procedures for which a hospital or outside services bill will be generated Possible Procedures Depending on Outcome (Listed as Optional Procedures on Checklist) Visit Support by Sponsor and \$\$ Amount Three Additional Visits for "Unscheduled" Procedures
<u>Patients</u>	All Patients	Enroll Patient Patient Identification Number Date of Birth (Required to ID in EPIC) Study Visit Checklist for Each Visit Ad-hoc procedures added to SM via the addition of an unscheduled visit (for auditing purposes)
<u>Status</u>	All Patients	Screening, On Study, Dropped, Completed, Follow-Up, Did Not Qualify, Failed
<u>Regulatory</u>	Document Packet for Ea Study	IRB Approved Original and Modified Protocols IRB Approved Original and Modified Informed Consents
OPTIONAL		
<u>Internal Financial Auditing</u>	Internal Costs No Longer Required in SM	Internal Cost for the Procedure is on BBM now.
DO NOT USE		
<u>One-Time Fees</u>	Financial Events	Study Setup Pharmacy Setup Advertising
<u>Staff Costs</u>	Coordinator Time	
<u>Payment</u>	Checks	Posting Check Assigning to Cost Center (Study)

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ADDENDUM 3

Study Manager Process Steps

