

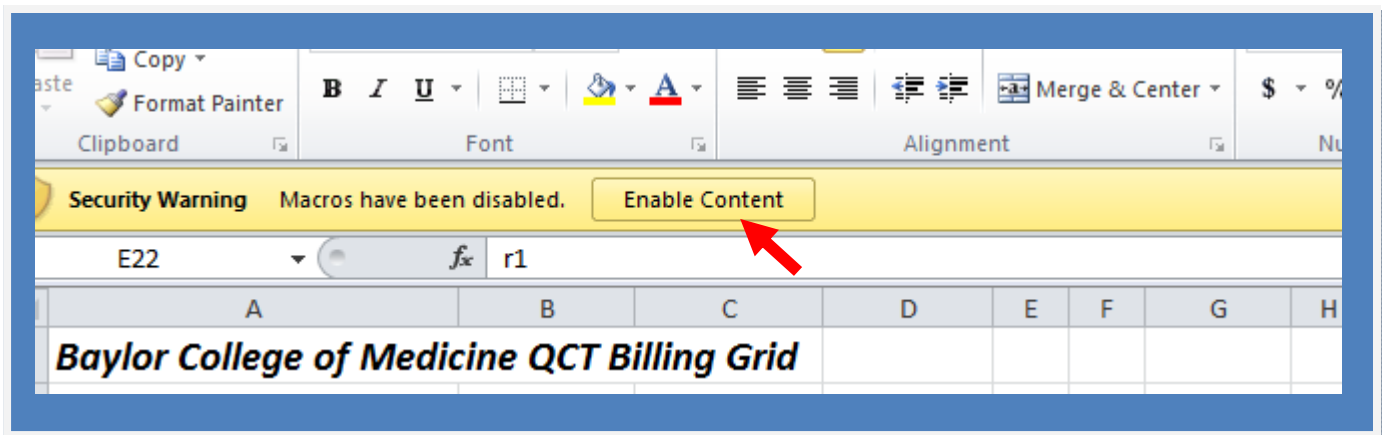
# Billing Grid Instructions Version 1.0

**Updated : January 10, 2015**

BCM's billing grid is a required component that must accompany the online submission for qualifying clinical trials (QCT). During Phase 1 of the online QCT rollout, the billing grid is an Excel-based spreadsheet with macros (programs) and formulas used to facilitate the budget and coverage analysis for QCTs. In Phase 2 (3rd quarter 2015) the billing grid will be generated online. The billing grid is an internal budget that is utilized in negotiating the clinical trial budget with outside entities providing extramural funding (e.g., pharmaceutical company, foundation or federal/state entity) or intramural use for trials that are funded by the department. The coverage analysis information provided by the billing grid serves as the basis for clinical billing compliance and facilitates appropriate billing and reimbursement from third party payers (e.g., Medicare/Medicaid or private insurance companies).

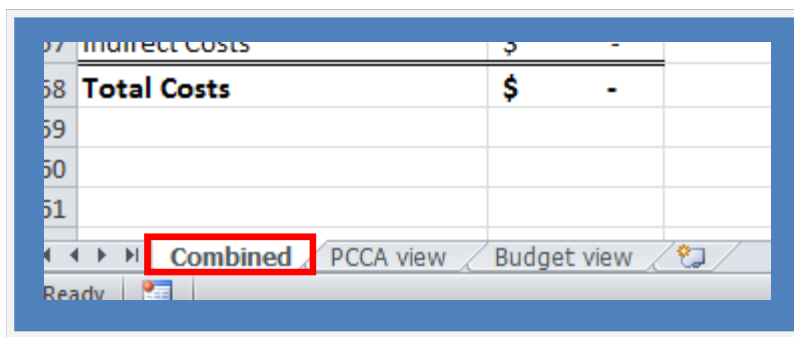
Excel 2010 on the MS Windows platform is required for the macros in the billing grid to function appropriately. The billing grid template can be accessed via the following link: <https://ictr.research.bcm.edu/ICTR/QCT/Billing%20Grid%20Template%201126.xlsm>

- **Open the Billing Grid Template**
- **Click on "Enable Content" button (shown below) to allow the macros to run correctly.** This will need to be done each time the grid is opened.



Note: There are three (3) different worksheets within the billing template: (1) Combined, (2) PCCA view and (3) Budget view. These sheets serve different purposes that will be described in the instructions that follow.

- **Select the worksheet named "Combined"** in the bottom left hand corner of the Excel workbook. This worksheet serves as the main entry point for information pertaining to the study, visits, procedures and budgetary items.



- **Complete the Demographic Information** section of the worksheet.

- ⇒ Sponsor Protocol Number - if applicable
- ⇒ clinicaltrials.gov number - if study has been registered with the clinicaltrial.gov website, enter the 8 digit number assigned. Note: this number is required prior to contract execution for industry-sponsored clinical trials and prior to patient enrollment for all trials.
- ⇒ Recruitment Goal - if there is a target recruitment goal for the site, then enter here; otherwise enter the estimated number of participants to be enrolled at BCM (this number is used to calculate the study budget).
- ⇒ Overhead - enter the institution's overhead rate based on sponsor type
- ⇒ Status - the status is for study team/PI purposes and intended to identify the status of the budget/coverage analysis process:
  - ⇒ Draft - budget and coverage analysis is under development
  - ⇒ With Sponsor - study budget is being negotiated with sponsor
  - ⇒ Final - study budget and coverage analysis has been finalized and approved by the sponsor
  - ⇒ Amendment - the study budget and/or coverage analysis is undergoing an amendment

Demographic Information	Update CA and Budget	Status: <b>Draft</b>
<i>Principal Investigator:</i> Dr. John Investigator		
<i>Study Title:</i> Phase III study of xyz in patients with abc.		
<i>Sponsor Protocol Number:</i> XYZ-120		
<i>Sponsor:</i> Pharma, Inc		
<i>H Number:</i> H-12345		
<i>clinicaltrials.gov # (NCTN):</i> CT12345678		
<i>Recruitment Goal:</i>	5	
<i>Overhead</i>	35%	

A set of instructions is located to the right of the demographics section.

<p><b>Instructions:</b> Enter all information on this worksheet (Combined). Add a new procedure row: click on the "Add new procedure" button. Add new visit columns: click on the "Add new visit" button. <b>Do not cut and paste cells.</b> To update the PCCA and Budget view worksheets click "Upate CA and Budget" button. Hover over cells with red corners for additional information.</p>
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- **Complete the “On Study” section of the worksheet.** This section contains information about study-related procedures and time points.

- ⇒ **Procedures Column:** the name of each procedure is entered in a separate row in the first column
- ⇒ **CPT Column:** (Common Procedure Terminology™), which are 5 digit codes assigned by the American Medical Association (AMA) for most patient care items and services, are entered in the second column. To find the relevant CPT code for an item or service, please visit; <https://ocm.ama-assn.org/OCM/CPTRelativeValueSearch.do?submitbutton=accept> (the website allows a limited number of searches). You may use a search engine by prefixing a search with “Find CPT”. Alternatively, AMA’s CPT Standard Edition Manual can be purchased. For procedures that do not have a CPT code, enter N/A or leave the cell blank. Please note: Some affiliate institutions prefer to work directly with the study-team in assigning the CPT codes.
- ⇒ **Cost Type Column:** enter the cost type category associated with each procedure (e.g. personnel, patient care, etc.) in the cost type column (3rd column)
- ⇒ **Rate Column:** Enter the rate negotiated with sponsor or provider for reimbursement of the specific procedure. Please note that the investigator/department is responsible for covering the cost if the sponsor’s reimbursement for a procedure is less than the affiliate charge for the procedure. Thus, the investigator should follow the affiliate institution process/procedures for budget approval prior to submission to ICTR or OOR.

On Study				
Add new procedure		Add new visit		
Procedure	CPT	Cost Type	Rate	Mod
Informed Consent	N/A	Personnel	\$ 100.00	N
Radomization	N/A	Personnel	\$ 75.00	
Physical Exam	99215	Patient Care	\$ 150.00	q
Lab-CBC	85025	Patient Care	\$ 50.00	q
EKG	93000	Patient Care	\$ 120.00	r1
Investigational Drug	N/A	Drug	\$ -	
PI Effort	N/A	Personnel	\$ 250.00	N
Stipend	N/A	Stipend	\$ 50.00	N
<b>Visit Direct Costs</b>				
<b>Visit Indirect Costs</b>				
<b>Visit Total</b>				

- **Study time points** are represented in the next set of columns. Each visits should be labeled according to the protocol and study schedule (e.g., screening, week 1, etc). Three columns are grouped with each visit; Mod (modifier), Qty (quantity) and Amount.
- **Add the modifiers.** The modifier cell is a drop down menu consisting of four (4) possibilities.
  - ⇒ **NB (Non Billable)** items are those that are non patient care related and cover expenses such as personnel time, informed consent fee, patient stipend, etc. These items are billed to the trial sponsor.
  - ⇒ **R1 (Research Patient Care)** patient care item or services that are paid for by the study sponsor, if sponsor is paying for the entire study, all patient care items and services would have a R1 modifier
  - ⇒ **Q1 (Routine Cost of a QCT)** patient care item or service that is a routine cost in a QCT and will be billed to Medicare or patient’s insurance, these include routine lab tests, imaging, office visits, administration costs of the study drug, etc.
  - ⇒ **Q0 (Billable object of investigation of a QCT)** item that is the object of the investigation for a QCT that is billable to Medicare or patient’s insurance—typically Q0 items are the drug or device being studied.

	Screening			Baseline			Visit 1			Visit 2			Visit 3		
Rate	Mod	Qty	Amount	Mod	Qty	Amount	Mod	Qty	Amount	Mod	Qty	Amount	Mod	Qty	Amou
100.00	NB	1	\$ 100.00												

**Add the Quantity.** The next column in the time point triad is quantity. Enter the number of times the item or service occurs for the specific time point. This number is frequently one (1); however, if a triplicate EKG is required then a three (3) would be entered or if a lab procedure is required before and after treatment then a two (2) would be appropriate.

Notes: The final column (amount) will auto calculate (a formula is already in place) the total number by multiplying the cost rate by the quantity entered.

The amount column formula takes into account the type of modifier and adjusts the number that is displayed. For example, if the modifier selected is a Q1 or a Q0, the amount cell will be blank (see below). Since Q1's and Q0's are routine costs that will be billed to the patient or thier insurance/Medicare/Medicaid. As such the item does not show up as a cost that needs to be covered by the sponsor, grant or other funding entity for the research cost. When the modifier is NB or R1 (see below) the items are reflected in the study budget.

q1	1	\$ -	← Q1 or Q0 = blank, patient or 3rd party payer is charged
r1	1	\$ 120.00	← R1 or NB = amount that must be covered by the study budget

The number of visits and procedures you can enter in the “On Study” section is not limited by those listed when the template is first opened. More procedures and visits can be added with the simple push of the “Add new procedure” button. Similarly, the number of visits can be modified by clicking on the “Add new visit” button.

**New Procedures:** Below the “On Study” dark blue bar a gray button “Add new procedure” is located (see below). Once you start entering the procedures associated with the protocol and you’ve used all the rows available, you can add more by clicking on this button. A new row will be added below the last procedure for additional entry, all the formulas needed for the billing grid are automatically added to the correct cells in the new row, there is no need to copy and paste these.

**New Visits:** Above the Cost Type column a gray button “Add New Visit” exists (see below). Once you have entered visits found on your protocol or study schedule and you’ve used all the available ones, you can add more by clicking on the Add New visit button. A new set of columns will be added after the last visit set. All three columns associated with the visit time point are added along with the formulas needed for the billing grid, again there is not need to copy and paste the formulas.

On Study				
Procedure	CPT	Cost Type	Rate	M
Informed Consent	N/A	Personnel	\$ 100.00	N
Radomization	N/A	Personnel	\$ 75.00	
Physical Exam	99215	Patient Care	\$ 150.00	q
Lab-CBC	85025	Patient Care	\$ 50.00	q
EKG	93000	Patient Care	\$ 120.00	r1

The next section calculates the “Visit Totals” costs (directs plus indirects) and the per-patient “On Study Totals” based on the total accrual goal (these formulas are already part of the grid and will update as information are entered).

<b>Visit Direct Costs</b>						<b>\$ 520.00</b>
<b>Visit Indirect Costs</b>						<b>\$ 182.00</b>
<b>Visit Total</b>						<b>\$ 702.00</b>

	<b>Direct</b>	<b>Indirect</b>	<b>Total</b>
<b>On Study - Per Patient</b>	\$ 2,320.00	\$ 812.00	\$ 812.00
<b>On Study - Total Accrual</b>	\$ 11,600.00	\$ 4,060.00	\$ 4,060.00

- **Administrative costs.** The final sections of the billing grid is for entry of fees related to the start up, additional or invoice items and study close out. Formulas for calculating the totals are in place for each of these items. To include indirect costs, select “Y” for “yes” from the drop down menu in the “Include Indirect” column. If indirect costs are not applicable to the item then select “N” for “no”.

<b>Start Up</b>	<b>Direct</b>	<b>Indirect</b>	<b>Total</b>	<b>Include Indirect?</b>
IRB Initial Fee	\$ 2,500.00	\$ -	\$ 2,500.00	N
Pharmacy Set Up	\$ 2,000.00	\$ 700.00	\$ 2,700.00	Y
Protocol Review/Feasibility		\$ -	\$ -	
Site Visit		\$ -	\$ -	
Administrative/Contract Development		\$ -	\$ -	
<b>Start Up Total</b>	<b>\$ 4,500.00</b>	<b>\$ 700.00</b>	<b>\$ 5,200.00</b>	
<b>Additional/Invoice Items</b>	<b>Direct</b>	<b>Indirect</b>	<b>Total</b>	<b>Include Indirect?</b>
IRB fee		\$ -	\$ -	
Start Up Fee		\$ -	\$ -	
Pharmacy Fee		\$ -	\$ -	
EKG Invoice		\$ -	\$ -	
<b>Additional Invoice Total</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	
<b>Close Out</b>	<b>Direct</b>	<b>Indirect</b>	<b>Total</b>	<b>Include Indirect?</b>
Regulatory Close Out		\$ -	\$ -	
Financial Close Out		\$ -	\$ -	
Record Storage		\$ -	\$ -	
<b>Close Out Total</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	

To add additional rows in this section (Start up, Additional/Invoice Items or Close Out), click on the appropriate button to add the required rows (shown below). All formulas are copied into the new row, no need to cut and paste.

Add new start up fee

Add new invoice item

Add new close out fee

**Patient Care Coverage Analysis (PCCA) and Budget Spreadsheet.** After completion of the fields in the “Combined” spreadsheet in the billing grid, the PCCA view and Budget view spreadsheet can be automatically updated by clicking on the button labeled “Update CA and Budget”. The button is located in the demographics information section of the workbook.

Update CA and Budget

**PCCA view Spreadsheet** - The Patient Care Coverage Analysis spreadsheet that is part of the billing grid shows the patient care item and services with a R1, Q1 or Q0 modifier. It does not include the financial/budget information. This sheet can be used as a resource that provides an overview of study specific items and services that routine costs that can be charged to the patient or their insurance provider and those that are research related and paid for by the trial budget. Study coordinators and scheduling teams should have access to this sheet to facilitate billing compliance.

<b>Patient Care Coverage Analysis</b>														
Demographic Information												Status: Draft		
<i>Principal Investigator:</i> Dr. John Investigator														
<i>Study Title:</i> Phase III study of xyz in patients with abc.														
<i>Sponsor Protocol Number:</i> XYZ-120														
<i>Sponsor:</i> Pharma, Inc														
<i>H Number:</i> H-12345														
<i>clinicaltrials.gov # (NCTN):</i> CT12345678														
<i>Recruitment Goal:</i>												5		
<i>Overhead</i>												35%		
On Study														
Procedure	CPT	Cost Type	Screening		Baseline		Visit 1		Visit 2		Visit 3		EOT	
			Mod	Qty	Mod	Qty	Mod	Qty	Mod	Qty	Mod	Qty	Mod	Qty
Physical Exam	99215	Patient Care	q1	1			r1	1					r1	1
Lab-CBC	85025	Patient Care	q1	1			r1	1					r1	1
EKG	93000	Patient Care	r1	1										
Investigational Drug	N/A	Drug					q0	1	q0	1	q0	1		

Combined **PCCA view** Budget view

**Budget view Spreadsheet** - The budget view tab provides a summary of the financial information that was entered in the "Combined" worksheet. It excludes items and services with a q1 or q0 modifier (routine costs billed to insurance or the patient) and strips the modifiers. This worksheet can be used to negotiate the study budget with the sponsor of the study. It should be used by the financial analyst or personnel reconciling and managing the financial aspects of the study.

<b>Budget Grid</b>								
<b>Demographic Information</b>								<b>Status: Draft</b>
Principal Investigator: Dr. John Investigator								
Study Title: Phase III study of xyz in patients with abc.								
Sponsor Protocol Number: XYZ-120								
Sponsor: Pharma, Inc								
H Number: H-12345								
clinicaltrials.gov # (NCTN): CT12345678								
Recruitment Goal: 5								
Overhead 35%								
<b>On Study</b>								
Procedure	CPT	Cost Type	Rate	Screening		Baseline		V
				Qty	Amount	Qty	Amount	
Informed Consent	N/A	Personnel	\$ 100.00	1	\$ 100.00			
Radomization	N/A	Personnel	\$ 75.00			1	\$ 75.00	
Physical Exam	99215	Patient Care	\$ 150.00					1
Lab-CBC	85025	Patient Care	\$ 50.00					1
EKG	93000	Patient Care	\$ 120.00	1	\$ 120.00			
PI Effort	N/A	Personnel	\$ 250.00	1	\$ 250.00	1	\$ 250.00	1
Stipend	N/A	Stipend	\$ 50.00	1	\$ 50.00	1	\$ 50.00	1
<b>Visit Direct Costs</b>					<b>\$ 520.00</b>		<b>\$ 375.00</b>	
<b>Visit Indirect Costs</b>					<b>\$ 182.00</b>		<b>\$ 131.25</b>	
<b>Visit Total</b>					<b>\$ 702.00</b>		<b>\$ 506.25</b>	
		<b>Direct</b>	<b>Indirect</b>	<b>Total</b>				
<b>On Study - Per Patient</b>		\$ 2,445.00	\$ 855.75	\$ 3,300.75				
<b>On Study - Total Accrual</b>		\$ 12,225.00	\$ 4,278.75	\$ 16,503.75				
<b>Start Up</b>								
		<b>Direct</b>	<b>Indirect</b>	<b>Total</b>	<b>Include Indirect?</b>			
IRB Initial Fee		\$ 2,500.00	\$ -	\$ 2,500.00	N			
Pharmacy Set Up		\$ 2,000.00	\$ 700.00	\$ 2,700.00	Y			
<span>Combined</span> <span>PCCA view</span> <span><b>Budget view</b></span>								