Budgeting and Billing for Clinical Research

Kate Marusina, Manager, Clinical Trials, CTSC
September 2011
Clinical Trials Resource Group

- **We Provide:**
  - logistical support to clinical research,
  - education and training of investigators and staff, and
  - clinical trials monitoring

- **Main Website:**

- **CT newsletters**
How to navigate Clinical Trial Process at UCD

- **Process Maps**
  - [http://intranet.ucdmc.ucdavis.edu/ctsc/area/clinicaltrials/processmaps.shtml](http://intranet.ucdmc.ucdavis.edu/ctsc/area/clinicaltrials/processmaps.shtml)
UCDHS Process Map – Industry Sponsored Trials
Post-Approval
Draft: May, 2011

Subject Recruitment
- Identify Prospective subjects using PHI data (IRB approval required)
- Advertise (IRB approval required)
- Obtain and Document Informed Consent
- Confirm Eligibility per study protocol and enroll (record the date)

Scheduling and Documentation
- Outpatients
  - Invision: Create 47 acct., schedule pt on 47-acct
  - EMR: Add v70.7 to pt problem list
  - EMR: create and edit Overview notes for v70.7 code to add study information
  - EMR: associate orders with v70.7 code
  - How to place Radiology orders
  - How to place Lab orders
  - EMR: Physician releases the orders
  - EMR: EMR physician provides documentation per P&P 2382
  - Submit research records to HIM
- E-mail MSA unit
- In-patients, Short Stays and Emergency (this SOP is under construction)
- Dispersing Drugs for Inpatients
- Emergency Treatment use in a life-threatening situation
- EMR: Physician provides documentation per P&P 2382
- Submit research records to HIM

Investigational Drug Pharmacy
- Arrive for distribution and maintenance of the inv prod
- Dispersing Drugs for Outpatients
- CRC/PI submits protocol modifications to IRB and Sponsor reports to IRB
- CRC/PI maintain Regulatory Binder

Regulatory Requirements
- CRC/PI notifies IRB and Sponsor about AEs
- CRC maintains log of completed study procedures for billing reference
- CRC/PI prepares protocol deviations to IRB and Sponsor

Billing and Payments
- CRC prepares documentation for the invoice
- CRC prepares protocol deviations to IRB and Sponsor
- Financial Analyst creates Accounts Receivable in Kuali
- If there is an invoicing event: CRC submits invoice to sponsor
- Financial Analyst checks the final payment against invoice and contract
- Financial Analyst forwards check to cashier's office
- Financial Analyst closes DaFIS acct

Study Closure
- CRC prepares documentation for the final invoice
- CRC submits final invoice to sponsor
- Financial Analyst checks the final payment against invoice and contract
- Financial Analyst forwards check to cashier's office
- CRC notifies HS Contracts
- CRC notifies Patient Accounting (to close the bulk acct)
- CRC notifies IRB and files the permanent study closure paperwork

Documents archived (21 CFR 54.6)

Trial closure visit with the Sponsor
- Resolve Sponsor queries
- IDS is notified, unused drug returned or destroyed
- All collaborating depts notified
- CRC/PI notifies IRB

Study closed
Main Component of B&B process

- **Financial Considerations** permeate the entire clinical trials process
- **Support by:**
  - HS Contracts (Budgets),
  - Clinical Trials Office (Coverage Analysis),
  - Amb Operations (47 accounts)
  - Patient Financial Services (Bulks),
  - Extramural Acct (DaFIS)
  - Dept (Accts Receivable)

- Coverage Analysis (what is paid by insurance, what is paid by the study)
- Budgets based on Coverage Analysis
- Sponsor negotiations, Contract
- DaFIS and Bulk Accounts
- Consenting the patient for financial implications of their participation
- Invoicing and Accounts Receivable
- Billing reconciliation
- 47 -accounts
Coverage Analysis = QCT+ Billing Grid

- Determines what is payable by insurance and what is payable by the study

- Qualified Clinical Trials Form
- Billing Grid
Coverage Analysis: QCT

- Required for ALL Full Committee and Expedited human subject studies
- Irrespective of the sponsor (yes, for NIH too)
- For many of you this is the only form to fill out
- Kept on record at the dept and CTSC
QCT form is harmonized with the Consent form

The Consent Form:
- there are no charges to the participant and insurer
- the sponsor/department is paying for the research, and the participant/insurer is paying for standard of care costs

The Qualifying Clinical Trials Form:

If answered “no”, must go through the rest of the QCT Tool to determine eligibility to bill insurance/Medicare for “other routine costs” on the study
Patient’s Financial Obligations

1. The investigational item or service itself, unless otherwise covered outside of the clinical trial.

2. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., additional blood draws for biomarker discovery).

3. Items and services customarily provided by the sponsors free of charge for any enrollee in the trial.

1. Items or services required solely for the provision of the investigational item or service (e.g., administration of an investigational chemotherapeutic agent).

2. The clinically appropriate monitoring of the effects of the item or service (e.g., extra blood draws for signs of liver failure), or prevention of complications.

3. Items or services that are needed for reasonable and necessary care arising from the provision of an investigational item or service, in particular, for the diagnosis or treatment of complications.

1. Items or services that are typically provided absent a clinical trial.
Patient’s financial obligations as Billing Grid

- Keep QCT on file; Billing Grid is required;
  Who pays for procedures and services required by protocol?

- Conventional Care Costs
  - Patient has Medicare/Insurance
  - Patient is Uninsured

- Other Routine Costs*
  - Medicare/Insurance Or Sponsor, if agreed in CTA or if indigent
  - Self-pay Or Sponsor, if agreed in CTA or if indigent

- Research Costs
  - Sponsor

*What are “Other Routine Costs”?

- Administration of Investigational item
- Clinical Appropriate Monitoring
- *Prevention, diagnosis and treatment of complications
### Part 2: Billing Grid

| Study Procedure/Labs                                      | CPT Code                          | Q0/Q1 | Screening | C1 | C2 | C3 | C4 | C5 | C6 | C7 | C8 | C9 | C10 | C13 | C16 | C19 | C22 | C25 | EOT | Short-term FU | Long-term FU | Notes                                                                                                                                                                                                 |
|-----------------------------------------------------------|-----------------------------------|-------|-----------|----|----|----|----|----|----|----|----|----|-----|-----|-----|-----|-----|-----|-----|-----|----------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Complete Physical Examination (includes vital signs/height/weight at screening) | 99201-99205, 99211-99205          | Q1    | P         |    |    |    |    |    |    |    |    |    |     |     |     |     |     |     |     | P         |              | Complete physical exam at screening and end of treatment are reasonable and necessary for work-up prior to treatment and for assessment of potential complications upon completion of treatment.                                                                                           |
| Physical Examination (includes vital signs/weight)[SOC]   | 99201-99205, 99211-99205          | Q1    | P         | P  | P  | P  | P  | P  | P  | P  | P  | P  | P   |     |     |     |     |     |     | P         |              | Physical exam each cycle is reasonable and necessary for assessment of potential complications and/or clinical signs of disease progression during treatment.                                                                                                    |
| Vital Signs/Weight                                       | 99211                             | Q1    | P         |    |    |    |    |    |    |    |    |    |     |     |     |     |     |     |     |     | P         |              | Vital signs prior to treatment with study medication is reasonable and necessary for patient safety.                                                                                                                                 |
| ECOG Performance Status                                  | N/A                               | N/A   | S         | S  | S  | S  | S  | S  | S  | S  | S  | S  | S   | S   | S   | S   | S   | S   | S   | S   | S         |              | This is a data collection activity and is payed for by the sponsor.                                                                                                                                                                                                 |
| MUGA Scan (or ECHO if MUGA not available)                | 78472 (93306)                     |       | S         | S  | S  | S  | S  | S  | S  | S  | S  | S  | S   | S   | S   | S   | S   | S   | S   | S         |              | Sponsor to pay for this activity. MUGA not billable to 3rd party for screening purposes and in the absence an abnormal ECG (LCD L28246 01/01/2010).                                                                                                     |
Other Financial Obligations of the subject

- Can the study pay co-pays and deductible?
- Can the study pay for travel?
- Can the study pay stipends?
- Difference between Medicare and Medicare Advantage patients
- What is the patient is not insured? Can the study pay for their costs?
Protocol, Funding, ICF, Budget and CA are related!
Budgets

- **Based on**
  - Coverage Analysis
  - Sponsor Contract (primary)

- **Final budgets are included in the signed sponsor contract (can be amended)**

- **Close relationship with the Consent Form**
UBT: principles

Start Up
- Categories of tasks
  - Protocol-related tasks
  - Budget-related tasks
  - IRB Docs
  - Training
  - Pharmacy communication
  - Communications w/Sponsor

- FEES
  - Advertisement
  - Office supplies
  - Pharmacy fees
  - Translation of Informed Consent

Tasks
- Complete Feasibility Questionnaire from Sponsor
- Review protocol & study flow
- Review by Scientific Review Committee (Cancer Ctr)
- Preparation and return of Sponsor/Site documents
- Pre-Study Site Selection visit, prepare for & attend
- Prepare, distribute, collect and copy financial disclosures
- Obtain and copy CV’s
- Preparatory Research
- CMS determination
Each task is given a time bracket

<table>
<thead>
<tr>
<th>Protocol</th>
<th>CRC</th>
<th>PI</th>
<th>Actuals</th>
<th>Guidelines</th>
</tr>
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<tbody>
<tr>
<td>Complete Feasibility Questionnaire from Sponsor</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
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<tr>
<td>Review protocol &amp; study flow</td>
<td>5</td>
<td>1</td>
<td>2-10</td>
<td>1-2</td>
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<tr>
<td>Review by Scientific Review Committee (Cancer Ctr)</td>
<td>2</td>
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<td>2</td>
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<tr>
<td>Preparation and return of Sponsor/Site documents</td>
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<td>0.5</td>
<td>2-5</td>
<td>0.5-1</td>
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<tr>
<td>Pre-Study Site Selection visit, prepare for &amp; attend</td>
<td>6</td>
<td>1</td>
<td>4-6</td>
<td>1</td>
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<tr>
<td>Prepare, distribute, collect and copy financial disclosures</td>
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<td>0.5</td>
<td>2-3</td>
<td>0.5-1</td>
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<tr>
<td>Obtain and copy CV's</td>
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<td></td>
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<td>2-6</td>
<td>0.5-1</td>
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<tr>
<td>CMS determination</td>
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<td>0</td>
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<td>TOTAL Hrs</td>
<td>27.5</td>
<td>4.5</td>
<td>16-30</td>
<td>7-10</td>
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</table>

Recommended guidelines* - not set in stone
Per patient

Start Up | Close Out | Invoicables | Per Patient

Hospital procedures
CRC tasks
PI tasks

Assistance with the Procedure
Inclusion/Exclusion
Informed Consent
Demographics
Randomization
Med history
Medication history
Vital signs
Serum Pregnancy test

Less rigid structure, highly depends on the protocol and the unit performing the study.
We did not assign specific time brackets for these tasks
## Study Procedure

<table>
<thead>
<tr>
<th>Study Procedure</th>
<th>Service Code</th>
<th>CPT Code</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th># of occurrences</th>
<th>Per Patient</th>
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<tbody>
<tr>
<td>CT scan (CT head w/o contrast)</td>
<td>7190323</td>
<td>70450</td>
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<td>1</td>
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<td></td>
<td>2</td>
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<td>Serum Chemistry (Chem-2)</td>
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<td>80002</td>
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<td></td>
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<td>2</td>
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<td>CBC</td>
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<td>Urinalysis</td>
<td>6850605</td>
<td>85027</td>
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<td>1</td>
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<td></td>
<td>2</td>
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<td>Arterial Blood gases (Critical care ABG)</td>
<td>3810303</td>
<td>81002</td>
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<td>1.00</td>
<td>1.00</td>
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<td>CRC</td>
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<td></td>
<td>0.50</td>
<td></td>
<td>1.00</td>
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<tr>
<td>Informed Consent</td>
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<td>CRC</td>
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<td></td>
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<td></td>
<td>1.00</td>
<td>$14.63</td>
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<td>CRC</td>
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<td></td>
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<td></td>
<td>1.00</td>
<td>$29.25</td>
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<td>PI</td>
<td>PI</td>
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<td></td>
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<td>$14.63</td>
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<td></td>
<td>1.00</td>
<td>$29.25</td>
</tr>
</tbody>
</table>

**Per patient** $691.21

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- **From Coverage Analysis and Contract**
- **Add to other time commitments**
- **On-line Query tool with research prices**
Monetize the time

- **Start Up**
  - CRC: 100 hrs
  - PI: 30 hrs
  - Fees: $2500

- **Close Out**
  - CRC: 40 hrs
  - PI: 4 hrs

- **Invoicables**
  - CRC: 270 hrs
  - PI: 12 hrs

- **Per Patient**
  - CRC: 6 hrs
  - PI: 1 hrs
  - Procedures: $200
  - 10 patients
### ACTUAL STUDY COSTS

<table>
<thead>
<tr>
<th>Occurrences</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Startup total</td>
<td>$13,272.50</td>
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<tr>
<td>Closeout</td>
<td>$2,860.00</td>
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</table>

**Invoicables:**

<table>
<thead>
<tr>
<th>Occurrences</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>adverse event</td>
<td>$2,392.00</td>
</tr>
<tr>
<td>site monitoring</td>
<td>$3,237.00</td>
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<tr>
<td>annual renewal</td>
<td>$1,170.00</td>
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<tr>
<td>IRB docs</td>
<td>$2,600.00</td>
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<tr>
<td>administrative tasks</td>
<td>$819.00</td>
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<tr>
<td>screen failures</td>
<td>$7,020.00</td>
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</table>

**Per Patient costs:**

<table>
<thead>
<tr>
<th>Occurrences</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>$6,912.05</td>
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<table>
<thead>
<tr>
<th>SPONSOR BUDGET</th>
<th>Anticipated Gain/Loss</th>
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<tbody>
<tr>
<td>Total Direct</td>
<td>$40,282.55</td>
</tr>
<tr>
<td>Total Indirect</td>
<td>$10,473.46</td>
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<tr>
<td>IRB Fees</td>
<td>$6,800.00</td>
</tr>
<tr>
<td><strong>Total for the project</strong></td>
<td><strong>$57,556.01</strong></td>
</tr>
</tbody>
</table>
Internet Tools

- UCDHS Cost Query Tool
- EMR Orderables for LAB
- EMR Orderables for RAD
  - [http://intranet.ucdmc.ucdavis.edu/researchbudgeting/](http://intranet.ucdmc.ucdavis.edu/researchbudgeting/)
  - (try CBC and PAP)
Negotiations with Sponsors

- **Start-up costs are critically important**
- **Tools:**
  - Coverage Analysis
  - Dear Sponsor letter
- **We show sponsor our labor involvement**
  - Enable the sponsor to eliminate/substitute optional tasks (i.e. invest mtg by phone instead of in person)
- **Julie Calahan (HS Contracts)**
Cost of under enrollment

Effect of increasing per patient cost to $15,000
Effect of increasing start up fee to $8,000
Break-even, 8 patients
Cost if only 5 patients enrolled

Actual study

PP start 9/1/2010
PP end 5/31/2012
Contract Start up cost 4000
Internal start up cost 6334
Internal close out costs 2280
Internal maintenance costs 5257
Contract Patient cost 10580
Internal Patient cost 9160
Projected patient enrollment 8
Identifying patients in the electronic systems

- UC Davis designated a special financial class to research outpatients
- We use this financial class ("47-account") to schedule research patients
- Using this path enables correct routing of the charges to the study accounts
- Additional training is available from Ambulatory Operations (Peter Walsh)
- E-Learning piece
Dec 2010 – May 2011: >700 pts registered with 47-accts
Bulk account becomes the policy number
47-cases in EMR

<table>
<thead>
<tr>
<th>Date</th>
<th>Type</th>
<th>Department</th>
<th>Specialty</th>
<th>Provider</th>
<th>Description</th>
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<td>10/04/2010</td>
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<td>AIMSER</td>
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<td>Ucdhall, Jason Hbcmd</td>
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<tr>
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<td>DERM</td>
<td>Derm</td>
<td>Ucdmonroe, Ryan Fa...</td>
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<td>IM</td>
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<td>PCNTRN</td>
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<td>Ucdbeamer, Jeanette...</td>
<td>Research Patient/Ophthalmo...</td>
</tr>
</tbody>
</table>

Research Encounter in Chart Review
Important role of V70.7

1) Title of the study.
2) IRB identification number.
3) Phone contact number.
4) One or two sentences explaining any information that a clinician should be aware of in the event of an emergency.

Per policy 2317
Placing RAD and LAB research Orders

- Process Maps
Billing reconciliation

- Monthly statements from professional and hospital side
  - Need to compare with your own records
  - Resolve issues of incorrect billing

- Prepare invoice
  - Or track the patients/procedures

- Financial Analysts in the department will prepare Accounts Receivable based on the invoice
  - To know what our outstanding balance is
Life of a charge

**PATIENT MANAGEMENT (PMS)** (front-end)
- Appt Scheduling - flags
- Registration – flags
- Clinic Charge Entry – CCE
- Pharmacy Charge Entry
- Vision Charge Entry
- Charge Desc Master (CDM)
- Transaction Master (TM)

**Cheryl White 4-7347**
- Lab Information System (LIS)
- Pre-Processor/Recirc Error File (RCE)

**Gennell King 4-3411**
- Radiology System (IDX)
- Pre-Processor/Recirc Error File (RCE)

**Robert Lewis 4-9273**
- PATIENT ACCOUNTING (Facility Fees/Hospital Chgs, Technical Chgs) (FMS or PFS or PA) (back-end)

**Sadia Ramay 4-9119**
- SIGNATURE (Pro Fees) (SIG or PBG) (back-end)

**ACCOUNT SERVICES (FMS & Signature)**
- Patient Complaints
- Collection Agencies
- Charge Reversals
- Work in both back-end systems

**EMR**
- Problem List P&P 2317

**Lab Charges**
- Bulk Account -90 acct
- Patient’s Account
- Charges Rec’d from PM/LIS/IDX
- Charge Reversals
- Hospital Service Code
- CDM
- GL/Proc Codes/Service Cds
- CPT Codes
- Bill Generation
- DaFIS Transfer Accounting

**Radiology Charges**
- Bulk Account – 90 acct
- Patient’s Account
- Charges Rec’d from PM/LIS/IDX
- Charge Reversals
- TM
- Transaction Master ID Codes (TMID)
- CPT Codes
- Bill Generation
- DaFIS Transfer Accounting
Questions?

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