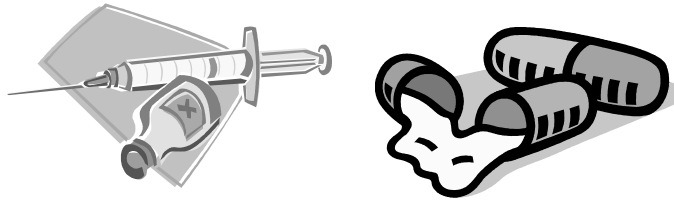


Investigational Drugs for CALGB Studies

Susan Tuttle, R.N.
Audit Committee Vice-Chair



CALGB Audit Preparation Workshop, November 2008

For CALGB Participants Only

Ordering Investigational Drugs

- The Division of Cancer Treatment and Diagnosis (DCTD) of NCI supplies INDs (as well as pharmaceutical companies)
- NCI INDs shipped from Pharmaceutical Management Branch (PMB)

Ordering Investigational Drugs

- Shipped directly to institution or site where drug will be prepared and administered
- Refer to drug information section of the protocol to identify the supplier

NCI Clinical Drug Request

- Need Investigator name, NCI # and signature
- Person ordering IND and phone #
- Fax #
- Date order sent and date needed
- NCI protocol number
- Drug name, NSC #, strength and dose, and quantity ordered

Emergency Supply

- Fax Clinical Drug Request directly to NCI at 301-480-4612 prior to noon eastern time for next day delivery
- Include express courier name and account number
- Follow-up telephone call to 301-496-5725 is highly recommended
- Rush orders done only in emergency situations

Receiving INDs



Receiving Protocol INDs

- Drug shipments accompanied by drug receipts or shipment invoices
- Verify for accurate amount or damage to shipment
- File invoices or receipts and provide as source documentation at audit
- Initial and date day drug received

Storage



Handling INDs

- FDA recommends the pharmacy department, whenever possible, be responsible for drug receipt, storage, accountability, and preparation of INDs
- Keep in secure, limited-access storage area

Handling INDs

- Label drug container with protocol #, drug name and drug strength
- Separate storage container for each IND and strength
- Store separately from commercial supplies of medicines
- Daily temperature log should be kept for refrigerator and freezer

Drug Accountability Record Form (DARF)



DARFs

- Drug Accountability Record Form
- Utilize the most current NCI DARF
- Current form can be located and completed with protocol information at:
<http://ctep.info.nih.gov/forms/index.html>
(bookmark this page)

Completing DARFs

- Each protocol should have individual DARF
- Separate DARF for each supplied drug in the protocol
- Separate DARF for each dose strength of medicine, i.e.; 100mg, 200mg and 500mg
- All study drug received from NCI or other supplier should be noted

Completing DARFs

- Maintain patient specific DARF for double blind study drug – note patient initials and patient ID # at top of DARF
- Record lot #s for each shipment – if multiple lot #s, enter separately on DARF
- Utilize “Julian date” if lot # is not provided on vial/bottle of drug or on shipping invoice

DARFs

- Designate if control or satellite record
- Use only for receipts from NCI/supplier and for drug dispensed to patients
- Do NOT enter patient returned drug unless instructed in protocol
- HINT: Utilize a generic destruction log for patient returned drug

DARFs - Transfers

- Control DARFs
Note # of vials/bottles/pills transferred to satellite clinic/hospital – do NOT note mg or units dispensed to pt
- Satellite DARFs
Note # of vials/bottles/pills transferred
Note mg or units dispensed to patient

National Institutes of Health National Cancer Institute		Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program		PAGE NO. 1		CONTROL RECORD <input checked="" type="checkbox"/>		SATELLITE RECORD <input type="checkbox"/>	
Investigational Agent Accountability Record									
Name of Institution: Southeast Cancer Control Consortium				NCI Protocol No.: CALGB 50602					
Agent Name: Galiximab Refrigerate				Dose Form and Strength: 100 mg vials - 2 ml (50mg/ml)					
Protocol Title: A Phase II Study of Galiximab (Anti-CD80) for Patients with Relapsed/Refractory Hodgkin Lymphoma				Dispensing Area: Chemotherapy/Pharmacy Supplies by Biogen Idec, Inc. provided in kits of 6 vials					
Investigator Name: James N. Atkins, MD				NCI Investigator No.: 012345					
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward	Manufacturer and Lot No.	Recorder's Initials	
						Balance			
1.	2/4/08	Rec'd	from Biogen		+12	12	ABC 789	ST	
2.	2/7/08	TAT	192441	880 mg	-4	8	ABC 789	ST	
3.	2/14/08	TAT	192441	880 mg	-4	4	ABC 789	ST	
4.	2/19/08	Rec'd	from Biogen		+12	16	ABC 789	ST	
5.	2/21/08	TAT	192441	880 mg	-4	12	ABC 789	ST	
6.	2/28/08	TAT	192441	860 mg	-4	8	ABC 789	ST	
7.	3/27/08	TAT	192441	860 mg	-4	4	ABC 789	ST	
8.	4/24/08	TAT	192441	800 mg	-3	1	ABC 789	ST	
9.	4/30/08	Rec'd	from Biogen		+12	13	ABC 789	ST	
10.	4/16/08	Transfer to Mt Airy Clinic			-5	8	ABC 789	ST	
11.	9/2/08	Transfer to Mt Airy Clinic			-4	4	ABC 789	ST	
12.	9/2/08	Transfer from Mt Airy to SCC			+3	7	ABC 789	ST	
13.									

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Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward	Manufacturer and Lot No.	Recorder's Initials	
						Balance			
1.	6/16/08	Transfer from SCC			+5	5	ABC 789	ST	
2.	6/16/08	MEC	201666	1100 mg	-1	4	ABC 789	ST	
3.	6/23/08	MEC	201666	1100 mg	-1	3	ABC 789	ST	
4.	6/30/08	MEC	201666	1100 mg	-1	2	ABC 789	ST	
5.	7/7/08	MEC	201666	1100 mg	-1	1	ABC 789	ST	
6.	8/4/08	MEC	201666	1100 mg	-1	0	ABC 789	ST	
7.	9/2/08	Transfer from SCC			+4	4	ABC 789	ST	
8.	9/2/08	MEC	201666	1100 mg	-1	3	ABC 789	ST	
9.	9/2/08	Transfer to SCC			-3	0	ABC 789	ST	
10.									

Return of IND

- Return to NCI/supplier within 90 days:
 - Study completed/discontinued
 - Drug is outdated/expired
 - Obvious excess in inventory
 - Drug is damaged (loss of refrigeration)
 - When last pt has received their last treatment

Return of IND

- Use traceable mail and package drugs securely to prevent breakage
- Return to NCI/ supplier at room temperature
- Complete Return Drug List Form
- Provide Return Drug forms for audit – should have PMB noted as received
- Subtract vials/bottles returned to NCI/supplier from DARF balance

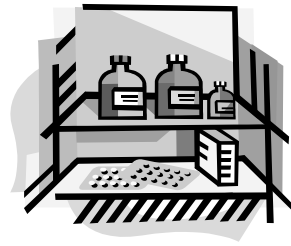
Transfer of INDs

- Transfer from one active protocol to another DCTD approved protocol
- If protocol closes and another protocol utilizes the same IND and formulation
- Requires NCI approval by phone 301-496-5725 and in writing – use form provided on NCI website

Pharmacy Non-Compliance

- Replace commercial with IND drug
- Replace IND with commercial drug
- Replace blinded study drugs
- Borrowing of study drug from one protocol to another
- Transfer between satellites

Pharmacy Audit



Pharmacy

- Review 1-5 drug logs and inventory for investigational drugs
- Review unannounced patient on protocol utilizing investigational drug
- Make sure investigational pharmacist is available day of audit for drug audit
- Prevention – internally audit your pharmacy every 3-4 months

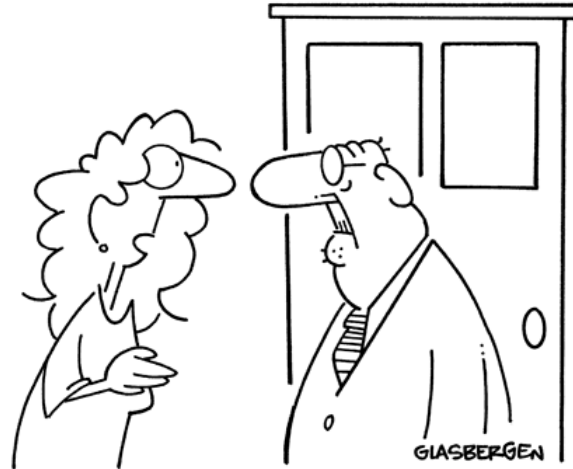
Pearls of Wisdom for Pharmacy

- No “Whiteout” or “Mark-Overs” or “Black-Outs” on DARFs
- Insert notation for drug received and dispensed on DARFs
- Shipping invoices kept for audit
- Shelf supply matches balance on DARF
- Drug used ONLY for protocol patients

Pharmacy

- Commercial drug should **NOT** be used for protocol patients when drug supplied
- Drug in secure location with limited access
- NCI Approval prior to transfer of drug from one protocol to another
- Return of drug to NCI on closed studies **PROMPTLY** – within 3 months of closure

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**"Honey, when you left for the office this morning,
you were a happy, enthusiastic, vibrant 25 year old!
Do you want to talk about it?"**



**Cancer and Leukemia Group B
Fall Group Meeting
2008 Tampa, FL
November 13-16**