Oncology Pharmacy
Investigational Drug Services

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QUIZ: Name These Acronyms

- NCI
- CTEP
- DCTD
- DARF (NOT DWARF)
- CDR
- IND
- NDA
- FDA
- PMB
- ODAC
- PI
What is an Investigational Drug?

- **Official Definition:**
  A drug that is being studied and that has not yet received permission from the U.S. Food and Drug Administration to be legally marketed and sold in the United States.
Our Current Investigational Drugs:

- Sorafenib
- Lenalidomide
- Forodesine
- Cloretazine
- Clofarabine
- SU
- Phenoxodiol
- AMD3100
- PS341 (Velcade)
- Azacytidine
- Herceptin
- Docetaxel
- Irinotecan
- Bevacizumab
- C225 (Cetuximab)
Can a commercial drug be considered investigational?

Yes, when it is being studied for a new indication for which the FDA has not yet approved it.
In our terms what do we consider an Investigational Drug?

• **Working Definition:**
  – A chemical or biological drug that is used in a clinical investigation.
  – A new chemical compound not yet FDA approved
  – An approved drug that is being studied for an approved or unapproved use, dose, dosage form, administration schedule, or being used in an IND application in a controlled, randomized, or blinded clinical trial.
Sponsors of Investigational Drugs

• National Cancer Institute (NCI)
  – drugs supplied directly from NCI

• Industrial Sponsors (pharmaceutical companies)
  – delivery varies by protocol, companies usually send a start up supply once all documents have been completed. Safe lead time is for most studies is 10 days.
Sponsors of Investigational Drugs

• **Cooperative Groups** (ECOG, CALGB, SWOG, GOG, COG)
  – **MULTIPLE DELIVERY SCENARIOS**
    • NCI
    • Via the cooperative group
    • Via Pharmaceutical Companies
    • No drugs supplied at all.
What ways can a patient gain access to an investigational drug?

- Clinical Trial under an Investigational New Drug Application
- Expanded Access Protocols
  - making investigational drugs with activity available to select patients prior to FDA approval
    - lenalidomide
    - VEGF-trap
What are the criteria?

• Special Exception/Compassionate Use
  – Unsuccessful standard therapy
  – Ineligible for Clinical Trials
  – An available Investigational agent for the
disease that is currently under investigation in
Phase 2 and 3 trials with demonstrated activity.
  • Ferriprox
  • Dasatinib
What is required from the investigator?

• Special Exception/Compassionate Use
  – IRB approval for use
  – Informed Consent
  – Approval from the Sponsor to provide the drug
True or False?

- All investigational agents are provided to patients free of charge?
  - True - IF it is not an FDA approved drug
  - True - IF it is a approved drug but not for the indication for which it is being studied.
  - False if it is an approved drug( or in the compendia) for the specific disease used in combination with another investigational therapy
• THIS DOES NOT MEAN ALL CARE IS FREE OF CHARGE!
Who is responsible for Investigational Drugs in any institution?

• The principal investigator is ultimately responsible for all drugs shipped in his/her name! The responsibility can be delegated to the pharmacist - which is the preferred individual to manage the drug component of any study.

• CAN YOU TRUST YOUR PHARMACIST???
Pharmacist Role

• Protocol Review/Study start up
  – assure protocol is feasible from a pharmacy perspective (timing, stability, weekend dosing, etc)
  – assure equipment is available or supplied
  – assure costs are evaluated

• Dispensing

• Closure (return or destroy drug)
Pharmacist Role

• Drug Ordering
  – Fill out CDR - clinical drug request form
  • Investigator number, Investigational agent number,
  • Correct shipping address :
    Attn : Nancy Beaulieu, RPh
    Yale Medical Oncology
    Yale Physicians Building 2nd floor Rm 237
    800 Howard Avenue
    New Haven, Ct 06511
Pharmacist Role

• Drug Ordering
  – NCI -PMB (pharmaceutical management branch) drug usually delivers drug via FedEx or other courier - they ship Monday - Thursday with a 2 working day lead time
  – Urgent/Emergency requests required in by 2pm for next day delivery
  – Specified designee signature
Pharmacist Role

• Receiving/Accountability
  – Assure appropriate storage conditions (temp monitoring, product integrity)
  – Assure quantity and correct product (I am not joking!!)
  – Log in drug on DARF - drug accountability record form.
  – NCI form or company sponsor form
Pharmacist Role

• Receiving/Accountability
  – Determine whether or not drug supply is patient specific.
  – Keep on-going accountability, reorder as necessary
  – Keeping blinded studies blinded
Communication

• Please make us aware of any protocol that is approved or any drug that we may be expecting to receive.

• We should have a protocol copy prior to receiving drug.
Pharmacist Role

- Closure (return or destroy drug)
  - NCI drug must be returned to the NCI clinical repository
Pharmacist Role

- Attend site initiation visits
- Monitoring visits
- Maintain drug supply at appropriate storage conditions in locked environment with minimal access
- Assure order verification, appropriate dosing, dose modifications for
- Compliance checks
- Dispensing (Manufacturing verification, Proper labeling)
Requirements Prior to Dispensing

• Copy of the most current protocol
• Copy of the signed patient consent
• Accurate order designated as a HIC protocol.
  – NO abbreviations, complete orders including HIC #, drug, dose, dosage, administration guidelines, frequency.
• Order signed by the Principle investigator or co-investigator. (not a fellow)
Drug Storage and Security

- Investigational drugs must be stored in a secured location - double locked
- Limited access
Drug Transfer

• It is reasonable to transfer the same drug in the same vial size and concentration to another study that utilizes the product?

• Borrowing of investigational agents is allowed from one study to another.
Drug Transfer

• DCTD supplied investigational agents may be transferred within an institution from a completed DCTD sponsored protocol to another DCTD approved protocol that utilized the same agent and formulation
Drug Transfer Guidelines

• Transfer form must be submitted within 72 hours of transfer
• Prior approval required if transferring from active protocol
  – excessive inventory, short dating, medical emergency
  – No transfer allowed to non- DCTD studies