Investigational Drug Services

Mary Miller-Bell, PharmD, RPh
June 14, 2016
Investigational Drug Services
Duke Hospital

• IDRP: Infectious Disease / HIV
• ICS: Investigational Chemotherapy Service
• IDS – Investigational Drug Service

• FTE’s dedicated to research:
  – 6 RPhs (2.8-IDS, 1-ICS, 1-HIV, 1-Manager)
  – 6 Support Staff (3-IDS, 2-ICS, 1-HIV)
  – 1 Accounting Clerk
The Investigational Drug Service

- **Staff:**
  - Mary Miller-Bell, PharmD, RPh
  - Cathy Sampey, PharmD, RPh
  - Barbara Wiernek, MPharm, MBiotech, PhD
  - Lindsey Muller, CRC, MS, PhT
  - Malphus Stroud, Clinical Research Specialist, CPhT
  - Maude Menesah-Simpson, CPhT
  - Bethelehem Girmai, Accounting Clerk II

- **Contact Information:**
  - Phone: 919.684.3543
  - Functional Pager: 919.970.8392
  - Group Email: Pharmacy-Grp_IDS@dm.duke.edu

- **Scope of Service:**
  - Manage ~170 studies
    - 60% outpatient / 40% inpatient
Lindsey Muller, MSPS

• Clinical Research Coordinator - Investigational Drug Services
• Department of Pharmacy
• Email: lindsey.muller@dm.duke.edu
• IDS group email: Pharmacy-Grp_IDS@dm.duke.edu
• IDS Pharmacy: (919)-684-3543
• Pager: (919)-970-4159
• IDS On-call pager: (919)-970-8392
• Fax: (919)-681-2740
Investigational Chemotherapy Service (ICS)

- **Staff:**
  - Martin Kowalsky, PharmD, RPh
  - Cheryl Morgan Maxey, Clinical Research Coordinator
  - William “Bo” Morrissey, Clinical Research Specialist

- **Contact Information:**
  - Phone: 919.668.0657

- **Location:**
  - Duke Cancer Center Infusion Pharmacy

- **Scope of Service:**
  - Manage ~220 studies
    - Majority outpatient – via Cancer Infusion Center
Infectious Disease Clinic Research Pharmacy

• **Staff:**
  – Kenneth Shipp, BSPharm, RPh
  – Shelly Wilkins, PhT, Patient Assistant Specialist

• **Contact Information:**
  – Phone: 919.681.1788

• **Scope of Service:**
  – Manage ~25 studies
  – International Maternal Pediatric Adolescent AIDS Clinical Trial Group (IMPAACT), AIDS Clinical Trial Group (ACTG), Investigator and Industry Sponsored Projects
  – Majority outpatient
  – Ambulatory clinical services to HIV/AIDS patients – counseling and prescription filling
Duke University Hospital Policy

• The Department of Pharmacy is responsible for the control of investigational drugs within Duke Hospital.

• The Investigational Drug Services are responsible for establishing study-specific procedures for safe and appropriate - investigational drug accountability, procurement, storage, preparation, dispensing, destruction of investigational drugs and billing within Duke Hospital.

• Investigational drugs administered to patients by Patient Care Service nurses are dispensed from the Department of Pharmacy.
**IDSs Operations**

- **Protocol-Specific Services:**
  - Randomization, secure storage, accountability, blinding, preparation / compounding, patient counseling, staff education, records management
  - Prepare online pharmacy procedures / drug data sheets
  - Facilitate creation of pharmacy order drug builds for EPIC
  - Audits (CTQA, Sponsor)
  - Inspections (FDA)
  - Ensure adherence with USP <797> standards
Maestro Care Builds

• Change in work and work flow

• No more paper orders
  – Maestro Care (MC) order required
  – MC Order considered the source document

• IDS acquired new position – CRC
  – Manage Maestro Care build process
    • Create priority build list from DOCR Red cap database
    • Build Study drug orderable for pharmacist review
  – Responsible for conducting monitoring visits
    • Adherence to IDS P&Ps
Maestro Care Builds

- Timely builds of eRx’s needed for study ordersets
- IDS to collect metrics to document areas to address for improvement

How can the study team help?

- Request Pharmacy Manual
- Request picture of study drug label
- Help us think through how the drug needs to be ordered during the DOCR Initiation meeting
VESTIGO™

Web-Based Software for IDS Practice – 21 CFR Part 11 Compliant

• Safety
  • Product selection is limited to drugs used for the current protocol
  • Automated checks for expired products and IRB approvals
  • Patient management functions prevent dispensing to patients who are not enrolled in a specific study.

• Efficiency
  • Single process to record dispensing, inventory used, print labels / forms and writes charges
  • Reports to track workload and financials included
  • Automated billing

• Economics
  • Reduced manual operations and increased efficiency of staff
  • Improved billing capture rate compared to manual logs
Vestigo Labels

- Name of area product is dispensed and phone number
- Date
- Name of prescriber
- Protocol number
- Name of subject
- Subject Medical Record Number
- Subject ID number
- Name and strength of study drug
- Directions for use
- Appropriate cautionary statements
- Full last name of dispensing pharmacist
 Billing with Vestigo

• Monthly Invoicing
• Fully Itemized Invoice
• Ability to track Grant Fund Code expiration dates
• Ability to track IRB expiration dates
• Funds transferred automatically
• Maintenance Fees
  – Fees are accrued and billed monthly
  – Once study is closed, fees will continue to accrue until drug is removed
Vestigo Invoice

- Fully Itemized Invoice
- Emailed PDF
- Monthly Billing
IDS Fees: Creation of set fees

- Set-up Fee
- Maintenance fee
  - Monitor time
  - Study drug storage / space needed / satellite/ temperature monitoring
- Dispensing Fee
  - IV (hazardous vs non-hazardous / Gene therapy) / blinding
  - Controlled substance
  - Over-encapsulation
IDS Updates

• No discounts for government sponsored or investigator initiated studies
  – Most up-front time
  – Resource – intensive
    • Highest risk to Duke

• Follow Duke / IDS policies
  – Use Temp Trak for all monitoring
  – Use Vestigo as the DAR
  – Keep monitoring visits to a one-hour meeting per month as requested
Constructing a Budget Estimate
<table>
<thead>
<tr>
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**TOTAL SCORE**

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*Assign Set-up Fee for Government sponsored (G) ~ 33% or IIT studies ~ 50% discount based on typical fees

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<td>Open-label extension study for existing protocols</td>
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<td>1-4</td>
<td>$1750</td>
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<tr>
<td>5-8</td>
<td>$2000</td>
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<tr>
<td>9+</td>
<td>$2250 or as negotiated</td>
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<td>Gene therapy or stem cell research study</td>
<td>As negotiated</td>
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**Set-Up Fee:**

**Quarterly Maintenance Fee:**

**Close-Out Fee:** $300

**Dispensing/Preparation Fees:**

**Drug & Packaging Fees:**

**Shipping Fee:** $25/shipment + courier's account information
## Set-Up Fee Budget Elements

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**TOTAL SCORE**
### Maintenance Fee Budget Elements

Assign a quarterly maintenance fee as follows:

| Will multiple pharmacy satellites be involved? If known, how many? [IDS = 1 unit] | Yes (1 unit) | No (0 units) | Number Applicable |
| Will subjects receive multiple doses? | | | |
| Will used items be returned to IDS? | | | |
| Will used items be stored by IDS? | | | |
| Is 2-8°C storage required? | | | |
| Is freezer storage required? [-20°C = 2 units; -80°C = 4 units] | | | |
| Will monitoring visits be scheduled more frequently than once per quarter? | | | |

For number of subjects expected to enroll at Duke, assign a score as follows:

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<th>Number of subject</th>
<th>Score</th>
<th>Score Assigned</th>
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<td>1</td>
<td></td>
</tr>
<tr>
<td>11-25</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>26-50</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>51-75</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>76-100</td>
<td>5</td>
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<td>&gt; 100</td>
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<td>G: $100 ITT: $75</td>
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<td>5-8</td>
<td>$225</td>
<td>G: $150 ITT: $110</td>
</tr>
<tr>
<td>9-12</td>
<td>$300</td>
<td>G: $200 ITT: $150</td>
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<td>&gt;12</td>
<td>$375 or as negotiated</td>
<td>G: $250 ITT: $190</td>
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Role of IDS for Investigators and Coordinators

Relationship / Role to Pharmacy Services

- Consolidate activities and skills:
  Design → Implementation → Closeout

- Integrate research into patient care activities

- Off-hour Enrollment:
  - IDS sets up study drugs to be successfully prepared for most studies that will enroll during early morning, evening and weekend hours.
    - The pharmacy team is inserviced
    - IDS provides just in time preparation sheets to ensure consistent preparation
    - IDS Team member on-call 24/7 to assist with randomization and coordination of study drug preparation

- Comply with laws and standards
- Educate pharmacy staff on the specifics of research projects
What else does IDS do for research?

Compliance:
- TJC
- FDA/DEA
- AAHRPP
  - (Association for the Accreditation of Human Research Protection Programs)
- USP <797>
- NC Board of Pharmacy
- Duke University Hospital Policy

"How long do we have to get in compliance?"
End Results

• Integration of the IDS into clinical practice and adherence to Good Clinical Practice:
  - Enhances Subject SAFETY
  - Increases Study INTEGRITY
  - Improves Audit / Inspection results

• Supports Duke University Hospital’s Vision

• To discover, develop and deliver a healthier tomorrow
Questions?

mary.miller.bell@duke.edu