IDS Primer

An open Q & A session

Presentation by Jason Mills, PharmD, MBA
Quick Introduction

- IDS compliment:
  - 3 FT pharmacists
  - 3 FT technicians

- Location – 1st Floor, MH room 161 (distribution center)

- MUSC involvement
  - IRB member, PRC member, pharmacy products committee member, technician council member, to name a few...
Objectives

- What is an IDS?
- What does an IDS do?
- The MUSC IDS process
- IDS FAQs
What is an IDS?

- “Effectively support and establish a patient-centered focus for a hospital pharmacy department in supporting innovation and new knowledge in medication use.” (Mark & Weber)

- Jason’s definition: A specialized pharmacy trained to manage both non-FDA and FDA approved agents for use within a clinical trial
What does an IDS do?

• “...ensure that the storage, security, packaging, labeling, and inventory maintenance of investigational drugs comply with federal, state, and institutional standards that govern medication-use processes.” (Shehab & Tamer)

• “... assist investigators performing drug studies by taking responsibility for the receipt, appropriate storage, inventory, dispensing, and return of study drugs; facilitating the sponsors’ monitoring visits; and processing the documentation associated with these tasks.” (McDonagh, Miller & Naden)
What does an IDS do?

“The benefits of a pharmacy IDS include improved accountability for study drugs used within the institution, the ability to provide 24-hour services for study drug dispensing and drug information, input on protocol design, improved patient teaching, facilitation of the coordination of nonstudy and study procedures and treatments, and ensuring limited access to study drugs.” (McDonagh, Miller & Naden)
What does an IDS do?

- All the before mentioned items
- Assist in Access
- Actively provide cost avoidance
- Assist in recruitment of studies
The MUSC IDS process

- Planning
  - Info gathering → idspharm@musc.edu
  - Usual Suspects – Protocol/Pharm Manual/IB
  - MUSC involvement (ie. How many patients?)
  - Investigational agents IDS is responsible for?
  - Outpatient vs. Inpatient – IDS scope
  - Timelines – Budget due date, IRB review date, anticipated “active” date, enrollment start dates, etc.
The MUSC IDS process

- Planning Continued
  - Evaluation – resources needed vs. supplied
  - Budget assistance
  - Q & A between pharmacy and study staff
  - “Holding Pattern”
  - SIV
  - Pharmacy Binder Setup – Audit Friendly (2 week setup time minimum)
The MUSC IDS process

- Planning Continued
  - IV-/IWRS registration – 6 envelopes/accesses needed
  - Drug procurement/replenishment processes
    - Additional Supplies? (special tubing, lines, syringes, blinding material, etc.)
Cost

- Revenue generated from study specific activities charged to the investigator
  - Variation of costs based on study design and features
- IDS fee schedule summary
  - Old vs. New (release date YTD)
Cost

- Challenges
  - Similar to every university based IDS in the country...
    - Revenue insufficient to cover overhead (i.e. Personnel, materials, etc.)
    - Perceived costs too high
    - Unknown costs (e.g. multiple strengths)
    - Study inadequately budgeted
      - Budget created at initiation/planning stage
      - Underestimate task time*

*www.projectsmart.com/project-management/defining-the-budget
The MUSC IDS process

- Execution
  - Entry into electronic systems – current vs. future state (multi-disciplinary)
  - Receipt of Drug(s)
  - Training of Satellite site staff (if applicable)
  - Preparing/Dispensing/Documenting
  - Keeping track of Updates
    - Amendments
    - Drug formulation and/or exp time changes
The MUSC IDS process

- Termination
  - Close-out Visit (if applicable)
  - Destruction/Return of investigational products
  - Warehouse storage (Warning! cost associated with retrieval)
FAQ’s

When is a drug considered Investigational?
- Non-commercially available, non-FDA approved drug with IND filed. Currently only available in clinical trials
- Commercially available, FDA approved being used in post-marketing surveillance (phase IV); new indication, new dosage form, new method of administration, new combo product, new component (e.g. excipient, coating, etc.)
- Here at MUSC – An agent provided by study sponsor to avoid charging the patient, study gets charged
FAQ’s

- Who dispenses investigational drugs?
  - Inpatient
    - IDS pharmacy or MUSC satellite pharmacy
  - Outpatient
    - Outpatient studies may use the IDS for drug management. Studies not utilizing IDS need to have adequate storage and control over supplies. Physician to carry out dispensation.
FAQ’s

What happens if an outpatient study patient is admitted?

- Standard home medication procedures apply:
  - Inpatient orders written to continue study medication or stop study medication
  - If continued, identification and labeling procedures followed
References

Questions