

The Betsy Poon Pharmacy Education Series

Investigational Drug Services
Panel Discussion

Spring 2025



Speaker Welcome



Panelist: Micha Koentz, PharmD, CCRP
Investigational Pharmacy Supervisor
Cook Childrens, Fort Worth, TX



Panelist: Jennifer Murphy, PharmD, BCOP
Senior Oncology Investigational Drug Service Pharmacist
UC Davis Health, Sacramento, CA



Panelist: Camille Smith, PharmD, DPLA, CCRP
Sr. Clinical Pharmacy Specialist – Investigational Studies
St. Jude Children’s Research Hospital, Memphis, TN

Conflicts of Interest/Disclosures

NAME	COMPANY	RELATIONSHIP
Micha Koentz, PharmD, CCRP	None	None
Jennifer Murphy, PharmD, BCOP	HOPA, McCreadie, CME Horizons	Speaker's Bureau
Camille Smith, PharmD, DPLA, CCRP	None	None

Learning Objectives

- Discuss fee scheduling set up at various Investigational Drug Services (IDS) practice sites especially given the budgetary constraints of consortium trials
- Discuss processes for study start-up and new patient starts
- Review the implications of adopting electronic accountability platforms and the impact it has on daily operations
- Characterize different electronic health records (EHR) and how drug build impacts study start up
- Compare the process for Investigational Drug Service drug transfers across different practice sites

ARS Question #1

Investigational Pharmacy is revenue generating.

A. True

B. False

IDS Fee Schedule

	Cook Children's	St. Jude	UC Davis Health
Standard Fees	Start-up Maintenance Dispensing fees Close-out		
Unique Fees	<ul style="list-style-type: none">N/A	<ul style="list-style-type: none">N/A	<ul style="list-style-type: none">ProcurementHazardous assessmentModificationShipping

IDS Fee Schedules

	Cook Children's	St. Jude	UC Davis Health
Fees Charged for COG Studies	<ul style="list-style-type: none">Flat fee (COG) vs. separate fees	<ul style="list-style-type: none">Dispensing fees	<ul style="list-style-type: none">None

IDS Fee Schedule

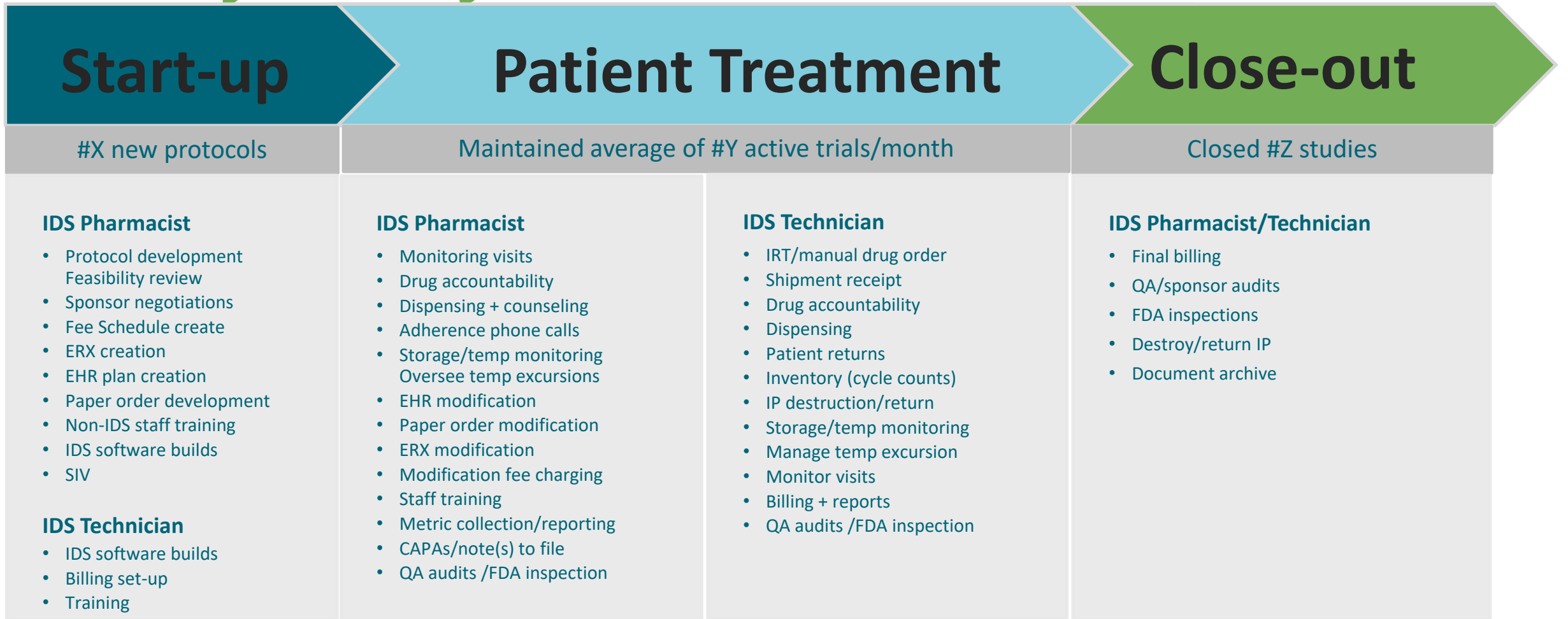
How do your fee charges impact your service line?

ARS Question #2

Do you charge for COG studies at your site?

- A. Yes, full fees
- B. Yes, reduced fees
- C. No fees charged

Study Lifecycle Overview



Study Lifecycle

Start-up

#X new protocols

IDS Pharmacist

- Protocol development Feasibility review
- Sponsor negotiations
- Fee Schedule create
- ERX creation
- EHR plan creation
- Paper order development
- Non-IDS staff training
- IDS software builds
- SIV

IDS Technician

- IDS software builds
- Billing set-up
- Training

Study Lifecycle

Patient Treatment

Maintained average of #Y active trials/month

IDS Pharmacist

- Monitoring visits
- Drug accountability
- Dispensing + counseling
- Adherence phone calls
- Storage/temp monitoring Oversee temp excursions
- EHR modification
- Paper order modification
- ERX modification
- Modification fee charging
- Staff training
- Metric collection/reporting
- CAPAs/note(s) to file
- QA audits /FDA inspection

IDS Technician

- IRT/manual drug order
- Shipment receipt
- Drug accountability
- Dispensing
- Patient returns
- Inventory (cycle counts)
- IP destruction/return
- Storage/temp monitoring
- Manage temp excursion
- Monitor visits
- Billing + reports
- QA audits /FDA inspection

Study Lifecycle

Close-out

Closed #Z studies

IDS Pharmacist/Technician

- Final billing
- QA/sponsor audits
- FDA inspections
- Destroy/return IP
- Document archive

Study Start-Up

	Cook Children's	St. Jude	UC Davis Health
Feasibility	<ul style="list-style-type: none">• Questionnaire by every team• Group feasibility meeting• Review protocol, IB, pharmacy manual	<ul style="list-style-type: none">• Protocol review, manuals, IB• Discussion with sponsor via email or phone if further questions	<ul style="list-style-type: none">• Protocol, manual, IB review• Questionnaire completed by sponsor

Study Start-Up

	Cook Children's	St. Jude	UC Davis Health
Operationalizing Trials	<ul style="list-style-type: none"> • CPOE build • Electronic system build • IP Ordering • IP storage • Training for nurses or pharmacists 	<ul style="list-style-type: none"> • Protocol vs. local, state, federal regulations • EHR and eRX builds • Electronic inventory system build • Pharmacy specific educational document • IP ordering (at enrollment?) • Any nursing implications? 	<ul style="list-style-type: none"> • Protocol vs. local, state, federal regulations • Production label = master formula record for IP • CPOE order set builds • EMR study drug entries • Electronic inventory system builds • CTMS • IP ordering • Inventory/ cycle counts • Patient dispenses

New Patients and Drug Supply

	Cook Children's	St. Jude	UC Davis Health
IP Management/ Ordering	IDS managed (for non-COG, can be automatic)	IDS managed	IDS managed

Electronic Inventory Systems

Benefits	<ul style="list-style-type: none">• Virtual access to eDARFs• Document storage and archive• Transparency• Satellite access & dispenses• CTMS interface• Billing• Non-billable/ charity work tracking• Metrics• Consolidation of protocols/IDS competency training• SOP integration
Challenges	<ul style="list-style-type: none">• Double documenting (EMR vs eDARF)• Limited access – IDS• Initial and recurring costs
Future State	<ul style="list-style-type: none">• IRT integration?

Electronic Inventory Systems

	Cook Children's	St. Jude	UC Davis Health
Electronic Inventory System	<ul style="list-style-type: none">• Yes	<ul style="list-style-type: none">• Yes	<ul style="list-style-type: none">• Yes
Integration into Daily IDS Operations	<ul style="list-style-type: none">• Upload documents: Packing lists, Temp logs, prescriptions, IRT• Every movement is done in this system	<ul style="list-style-type: none">• Upload documents• Temp logs• Packing slips• Every movement is done in this system	<ul style="list-style-type: none">• Upload documents• Temp logs• Packing slips

Electronic Inventory System

	Cook Children's	St. Jude	UC Davis Health
System Utilization	<ul style="list-style-type: none"> • In-person or Remote monitor visits • Dispensing • Document upload • Metrics 	<ul style="list-style-type: none"> • Monitor visits • Dispensing • Document upload • Metrics 	<ul style="list-style-type: none"> • Monitor visits • Dispensing • Billing • Document upload • Monitor visits • Satellite dispenses • Metrics
Document Retention	<ul style="list-style-type: none"> • Everything saved in electronic inventory system 	<ul style="list-style-type: none"> • Everything saved in electronic inventory system • "pharmacy binder" kept with study team if physical needed 	<ul style="list-style-type: none"> • S: drive • Electronic regulatory system • Electronic inventory system

ARS Question #3

Does your site leverage your electronic system for document retention?

- A. Yes
- B. Only for certain studies
- C. No, and no future plans
- D. No, but future plans exist

Electronic Health Record Utilization

	Cook Children's	St. Jude	UC Davis Health
Study Drug Builds	<ul style="list-style-type: none">• “INV (protocol mnemonic) Drug name”• No charges for IP (\$0 for “INV” drugs)• EHR builds include “INV” drugs	<ul style="list-style-type: none">• “INV (protocol mnemonic) Drug name”• No charges for IP• eRx team builds from IT ticket entered by IDS• Limitations especially with rounding doses (dose banding)	<ul style="list-style-type: none">• “Study drug–XYZ”• No charges dropped for IP• Limited by EMR functionality

Electronic Health Record Utilization

	Cook Children's	St. Jude	UC Davis Health
Order Templates <ul style="list-style-type: none">• Paper• Electronic	<ul style="list-style-type: none">• Electronic; treatment plans are built with INV drugs• All IV chemo is CPOE• PO chemo for outpatient is on Paper Rx	<ul style="list-style-type: none">• Electronic• "Protocol Orders Group" prepares template for all therapeutic studies• EHR build team uses the template for the EHR build	<ul style="list-style-type: none">• Hybrid model• Adult<ul style="list-style-type: none">• CPOE order set Go Live: 8/2021• Peds<ul style="list-style-type: none">• Only PO IP on paper

IP Transfer Process

	Cook Children's	St. Jude	UC Davis Health
On-campus Satellites	<ul style="list-style-type: none">• Not current state• New hospital 60 miles away in future	<ul style="list-style-type: none">• Not current state• New IDS area planned in future	<ul style="list-style-type: none">• IDS Cancer Center• Cancer Center Infusion• Inpatient Oncology
Off-campus Satellites	<ul style="list-style-type: none">• None	<ul style="list-style-type: none">• None	<ul style="list-style-type: none">• None
Affiliate/Regional Sites	<ul style="list-style-type: none">• None	<ul style="list-style-type: none">• Affiliate sites but we do not transfer drug there	Cancer Care Network <ul style="list-style-type: none">• Independent NCI sites

Question & Answer Session

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