

Research Pharmacy in COVID-19

Introduction

Research Pharmacy :
A specialized area that facilitates the conduct of clinical trials using research medications in human subjects
Each campus has a Research pharmacy

- West Campus:
Non-oncology trials, primarily inpatient studies
Outpatient ambulatory clinics
- East Campus:
Both Oncology and Non-Oncology trials
Ambulatory clinics
Clinical Research Center (CRC)

Introduction

A typical clinical trial life-cycle (non-COVID):
Pre-review prior to IRB submission (3-5 business days)
Review during the IRB process
Preparation for activation/dispensing (2 weeks post IRB approval)
Typical process (non-COVID-19):
A couple months from pre-review to patient dispensing
**During COVID: Average turnaround time 24 hours for pre-review
Dispensing to patients in less than a week (typically within 24 hours of research medication receipt)**

Research Pharmacy Responsibilities

To provide preliminary pharmacy review and approval prior to IRB submission:

- Feasibility
- Potential benefit outweighs risk to human subjects
- Accuracy of application to protocol

Preparation and Dispensing:

- To facilitate research medication dispensing and accountability to ensure compliance with the protocol and all applicable regulations, policies, and procedures
- Protocols are dissected by the pharmacists for preparation and dispensation details
- Guidelines are created prior to enrollment to ensure safe and accurate preparation and dispensing for the entirety of the protocol
- There is a USP <797> compliant cleanroom for preparation of sterile products including Chemo/hazardous medications
- Pharmacists create example order templates (POE) for the providers to use
- Pharmacists build the protocol in the pharmacy system/POE
- Provide prompt review of protocol amendments to ensure compliance throughout the study
- Facilitate audits by sponsors and regulatory agencies

Inventory control :

- Strict adherence to inventory control procedures
- Internal ordering and receipt of supplies for each trial
- Protocol built in Vestigo (inventory /accountability)
- Inventory management to ensure adequate supplies for study subjects
- Perpetual accountability (every vial/bottle/tablet)
- Strict temperature monitoring for storage conditions
- Internal destruction of expired/unused materials

Results

26 Therapeutic trials opened

Including:
Remdesivir (NCT04292899/NCT04292730)
Sarilumab
Alteplase (NCT04357730)
Hydroxychloroquine (NCT04332991)
Leronlimab (NCT04347239)
Various platform studies
Compassionate use

119 patients (796 dispensings)

3 vaccine trials opened
(NCT04611802/NCT04436276)
181 patients (551 dispensings)

Conclusion

We are not done yet!
3 therapeutic trials still open
ACTIV-3 (NCT04501978)
HIBISCUS (NCT04860518)
ACTIV-2 (NCT04518410)
More in the pipeline
Additional vaccine trials in the pipeline

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