



DESMOND TUTU
HEALTH FOUNDATION

Inspection Preparedness

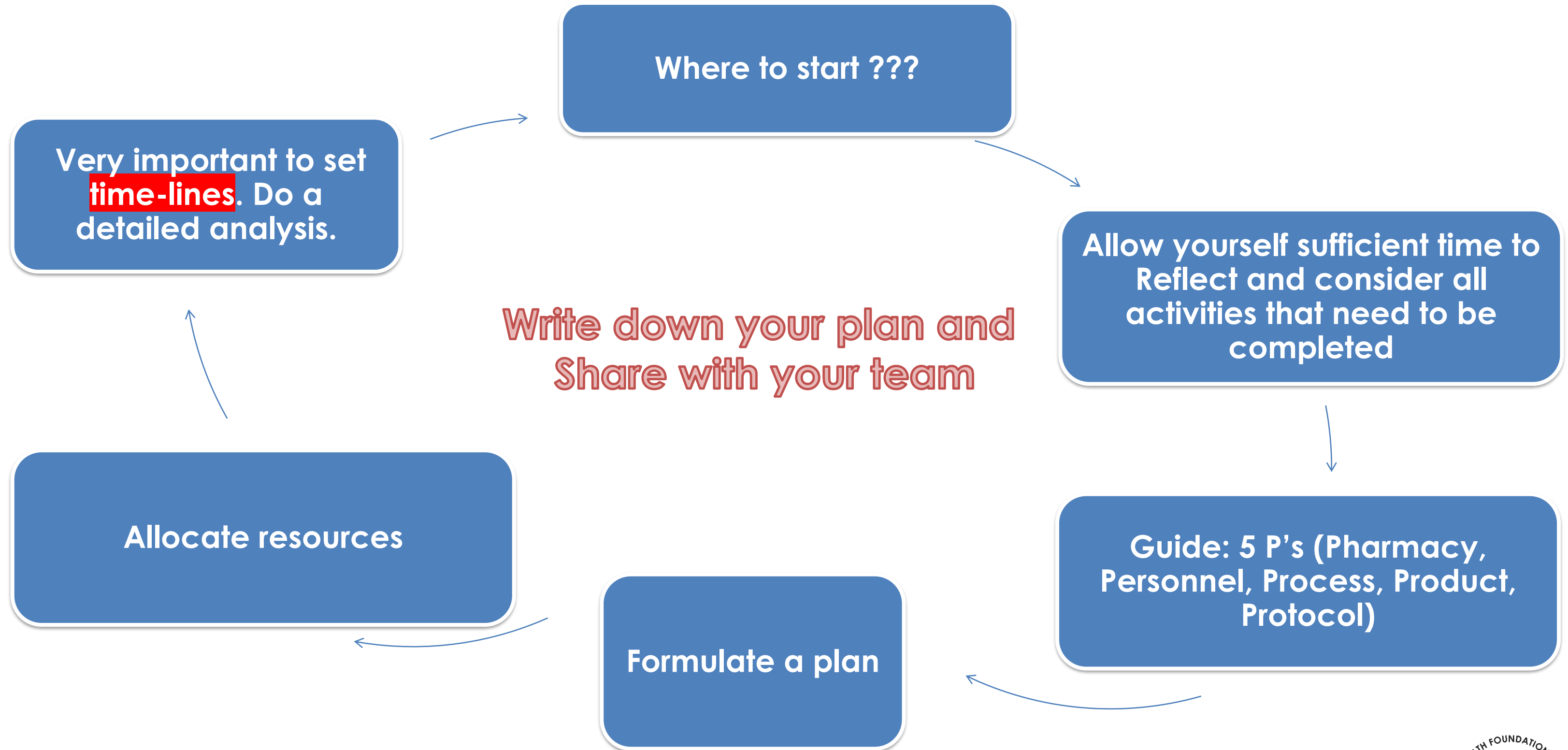
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Pharmacist of Record HPTN 084

Emavundleni CRS

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Inspection Notification – Getting Started!



Pharmacy

Pharmacy local regulatory approvals (licensing, fees, etc.)

Access control SOP; All pharmacy keys must be kept by the pharmacists

Neat and tidy appearance of pharmacy at all times

Servicing and calibration

Storage cupboards

Review your PEP – make sure information is correct and all communication with PAB is on file

Personnel and Training

CV's, Fees, Indemnity/Malpractice insurance - All pharmacy staff involved at any time during the course of the study

TRAINING RECORDS are very important

Pharmacists signature list present and verify start and end dates Similar with authorized prescriber's list

Pharmacy general SOPs are available with training logs

GCP training, HSP training, DAIDS training, Aseptic technique training, Handling of hazardous Substances training – all these must be on file and valid

Process

Study product management SOP

1. The process of selecting the IP

2. How it was labelled

3. What details were on the label

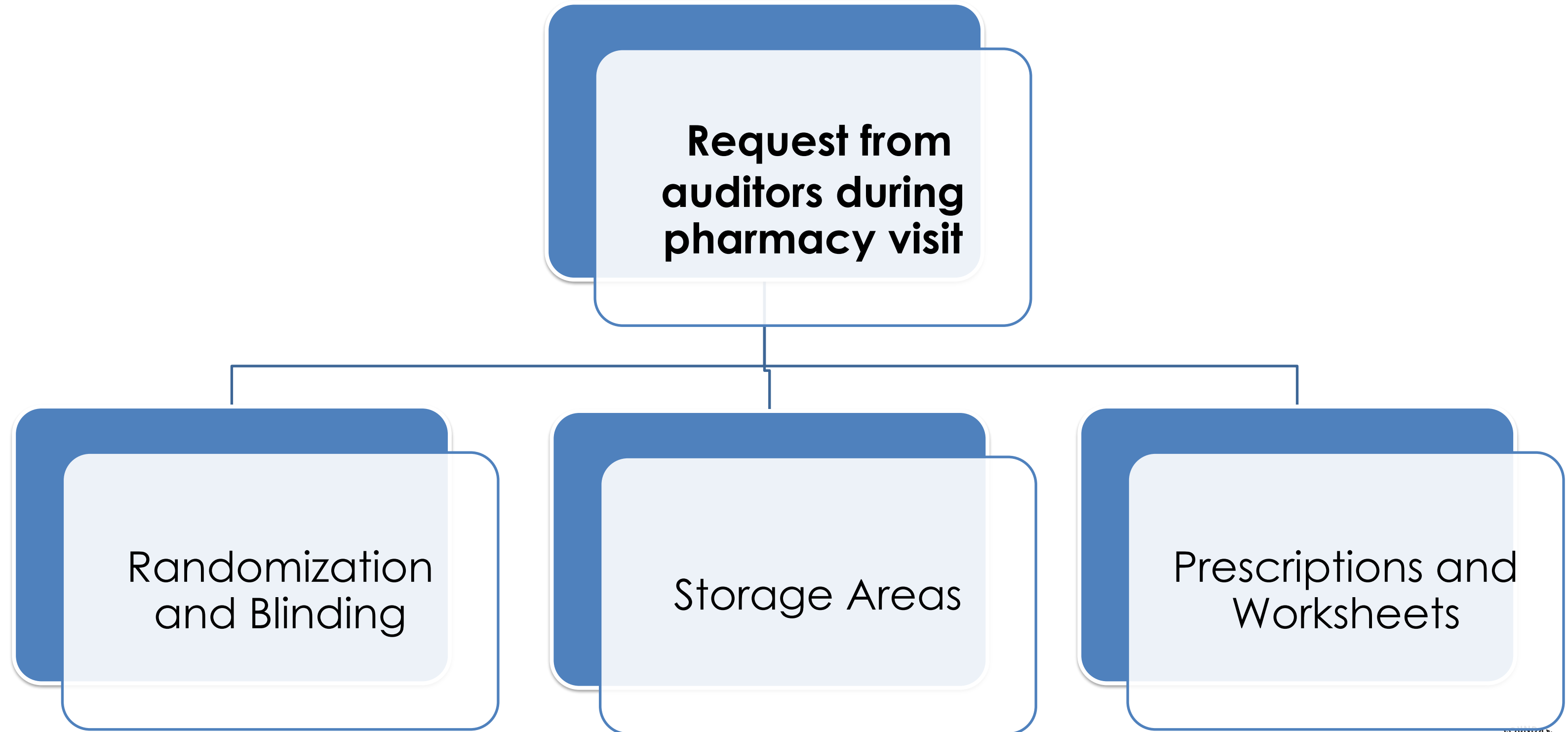
4. Accountability records

So, it's important to thoroughly review your dispensing records, including all accountability records

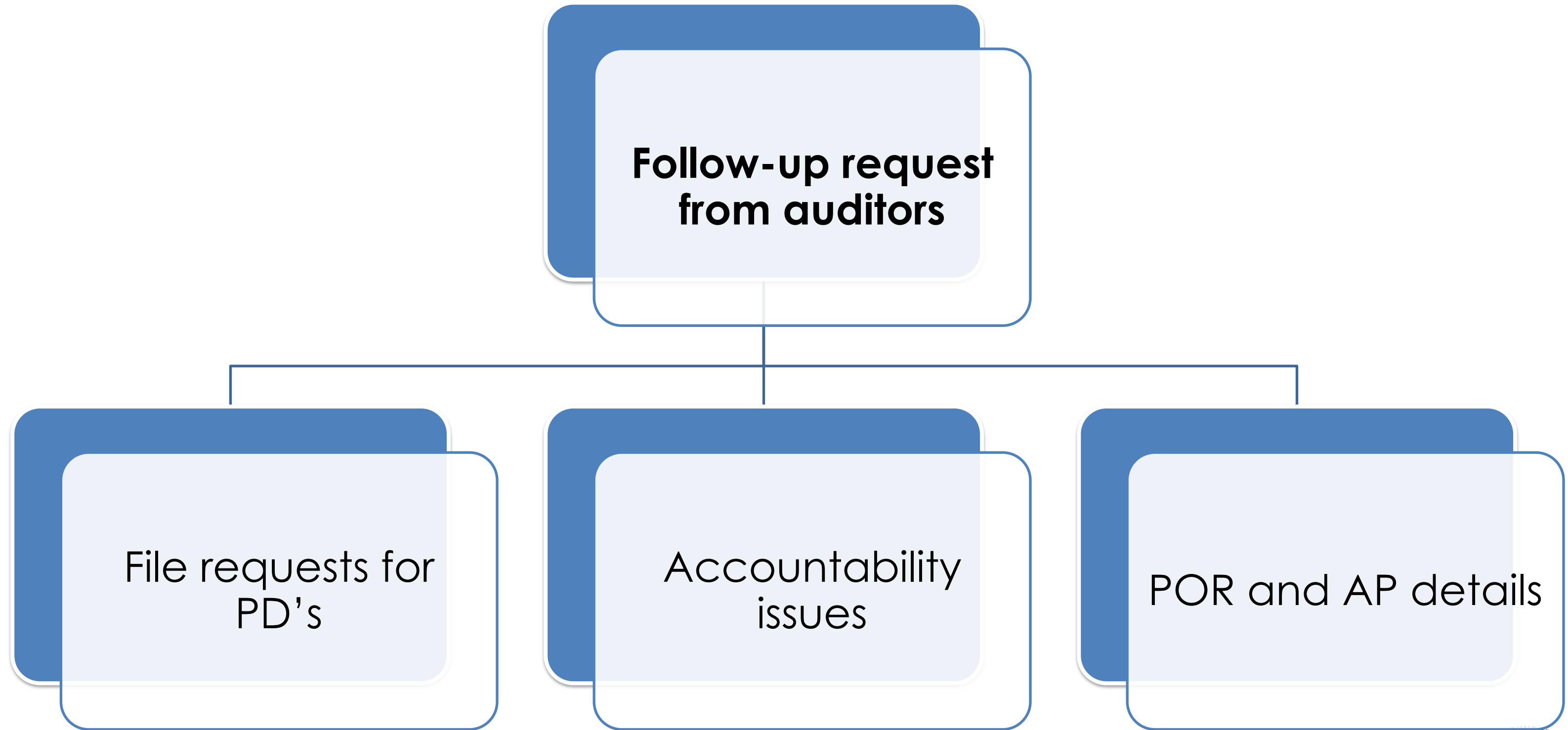
Process - continued

- The Randomization process
- Blinding and Chain of Custody
- Accountability records
 - batch numbers/kit numbers
 - expiry dates
 - date IP dispensed
 - date IP quarantined (have a dedicated quarantine area)
- Deviations/ Errors/ CAPA's/ All TERF's/ IRF's for the entire study period available
- Temperature charts for the study period - missing data, excursions, etc

Audit



Audit - continued



Learning Outcomes Post Inspection

Time Management
Delegation Skills
Storyboards
Quality Assurance
Collaboration

Overwhelming and Anxious
Stay Calm
Trust your plan and processes
Debrief
Reassure your Team

Thank You