CLINICAL EXCELLENCE CONSULTING

Investigational Product (IP) Management in Clinical Research

Patient Safety • IP Lifecycle • Site Responsibilities • Monitoring • Accountability • Best Practices I Presenter: Khurram Shah

Patient Safety

Monitoring IPs closely ensures participant safety and data integrity throughout trials.

Regulatory Compliance

Proper IP handling ensures compliance with regulatory guidelines and standards.

Data Integrity

Accurate reporting of IP usage ensures valid results for research conclusions.

Supply Chain

Efficient supply chain management ensures availability and integrity of IPs.

Investigational Product Lifecycle

01	Identify need for a new investigational product.
02	Develop the IP formulation, design, and composition.
03	Conduct preclinical studies to assess safety and efficacy.
04	Submit IND application for regulatory approval.
05	Conduct clinical trials to evaluate product in human subjects.
06	Perform continuous monitoring for safety and data integrity.
07	Analyze trial data for efficacy and safety outcomes.
08	Obtain marketing authorization post successful trial results.

Site Responsibilities for IP Management

RECEIPT	Confirm all IPs are received correctly per shipment documentation.
STORAGE	Store IPs according to manufacturer specifications; monitor temperature.
INVENTORY	Maintain accurate, up-to-date inventory of all IPs on-site.
DISPENSING	Dispense IPs only to authorized trial participants per protocol.
ACCOUNTABILITY	Document all IP usage, returns, and accountability meticulously.

Role of Monitors in IP Oversight

MONITOR CHECKS	Ensure proper storage conditions for IPs are maintained at all sites.
INVENTORY MGMT	Review inventory logs regularly for accuracy and protocol compliance.
PROTOCOL	Verify site follows IP administration and handling guidelines.
DOCUMENTATION	Conduct audits of IP accountability documentation and records.

Essential Checks for Investigational Products

- Confirm IP status, storage conditions, and expiration dates at every visit.
- Review inventory records and dispensing procedures for protocol compliance.
- Verify IP accountability is maintained and all documentation is complete.
- Establish clear procedures for the return of all unused investigational products.

IP Receipt, Best Practices & Accountability

- On receipt: verify delivery, inspect condition, confirm quantity, label accuracy, sign-off.
- Train staff on IP handling; label clearly; conduct frequent inventory checks.
- Perform compliance audits; review incident reports; keep accountability logs current.
- Careful IP lifecycle tracking from production to administration minimizes errors.