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LESSONS LEARNED FROM REGULATORY INSPECTIONS: Preparedness is the Best Guarantee for Peace

MODERATOR

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What type of
Clinical Research Trials
may experience
Regulatory Assessments?

What type of Clinical Research Trials may experience Regulatory Assessments?

ALL Clinical Research Trials!

Clinical Trials Funded by:

- ✓ Industry Sponsors
- ✓ Federal Dollars (NIH, CDC, etc.)
- ✓ Internal Research Grants
- ✓ Non-profit or Foundation Grants

Types of Inspections/Regulatory Assessments

- **FDA Inspection** – Clinical trials with an IND* or IDE**
- **Industry Sponsor Audit** (i.e. pharmaceutical, medical device, etc.)
- **NIH or Cooperative Group** (i.e. COG, SWOG, etc.) **Audit**
- **Internal Compliance Audit/Inspection**
- **etC...**financial audits (beyond scope for today; *Coordinators - know your billing grids!*)

***IND = Investigational New Drug** (allows use of an investigational drug or biologic in a clinical trial)

****IDE = Investigational Device Exemption** (allows use of an investigational device in a clinical study)

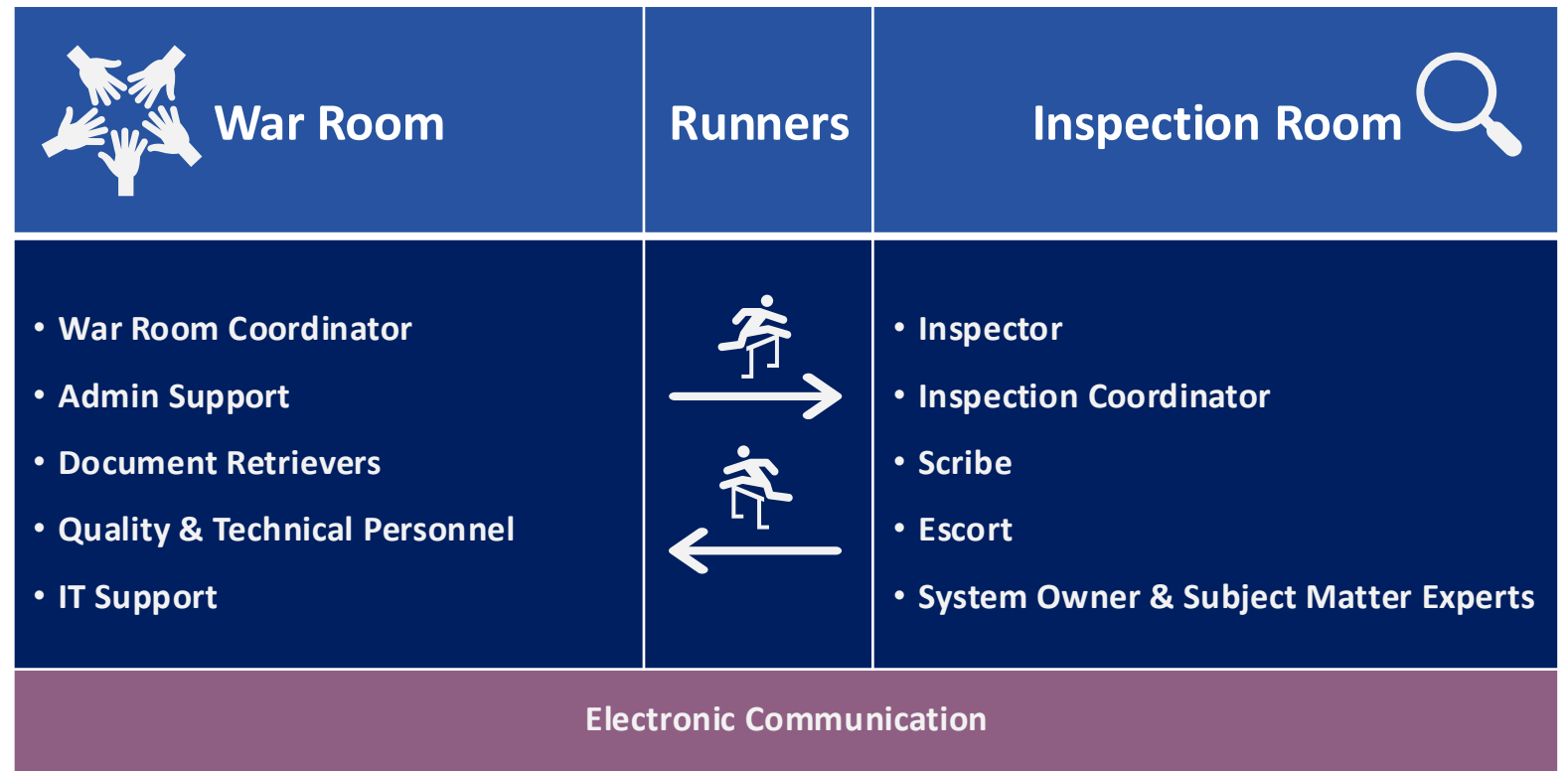
Types of Inspections/Regulatory Assessments

Type	Focus	Objective
Routine	<ul style="list-style-type: none"> • High-enrolling research sites • High number of SAEs at research site • Unusually low number of SAEs at high-enrolling research site compared to other sites • High number of deaths of study subjects at high-enrolling site • Geographical Area 	<ul style="list-style-type: none"> • Inspect pivotal studies <ul style="list-style-type: none"> ◦ <u>FDA</u>: Phase III studies • Confirm that data is substantiated by research records <ul style="list-style-type: none"> ◦ <u>FDA</u>: does data meets requirements for approving a new drug or device? • Assure data integrity & reliability - Check for adherence to GCP guidelines • Confirm adequate protection of human rights and welfare • Assure clinical investigators comply with the IRB regulations, policies, and findings
For Cause	<ul style="list-style-type: none"> • Investigator conducts research outside of his/her therapeutic area. • Suspicious Data: Investigator reports few or no AEs compared to other sites. • Investigator reports higher efficacy results than other investigators. • Received complaint: Patient, Employee, Sponsor, CRO, IRB, etc. submits complaint. 	<ul style="list-style-type: none"> • <i>Assess same items as in routine inspections</i> • <i>Can be an extension of a study-oriented inspection</i> • Based on specific instruction/complaint will assess: <ul style="list-style-type: none"> • Study team operations: <ul style="list-style-type: none"> • PI & staff training on protocol and procedures • PI involvement/oversight • Study Team SOPs • Data manipulation/falsification • Subject safety (UAPs/AEs/SAEs) • Adequacy of Informed Consent Process • Adherence to Eligibility/Enrollment Criteria

What to Expect

The type of inspection will determine how the inspection proceeds

- **Ask yourself:**
 - What type of inspection is this?
 - *Routine vs. For Cause*
 - What are the inspector's objectives?
- Study team roles and responsibilities



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QUESTIONS?

How to Prepare for Regulatory Assessments

- **Maintain Clear Roles and Responsibilities (WHO is in charge?)**
- **Follow Good Documentation Practices (GDP)**
- **Maintain Good Clinical Practice (GCP)**
- **Follow the Protocol!**



THANK YOU!