U.S. FOOD & DRUG ADMINISTRATION

# International Clinical Trials: GCP Perspective

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# Disclaimer

The views expressed in this presentation are those of the speaker and not necessarily those of the Food and Drug Administration

# Objectives

To share information about international clinical trials from GCP perspective

To provide you information on how to comply with FDA's regulatory requirements for international clinical trials

# International Clinical Trials

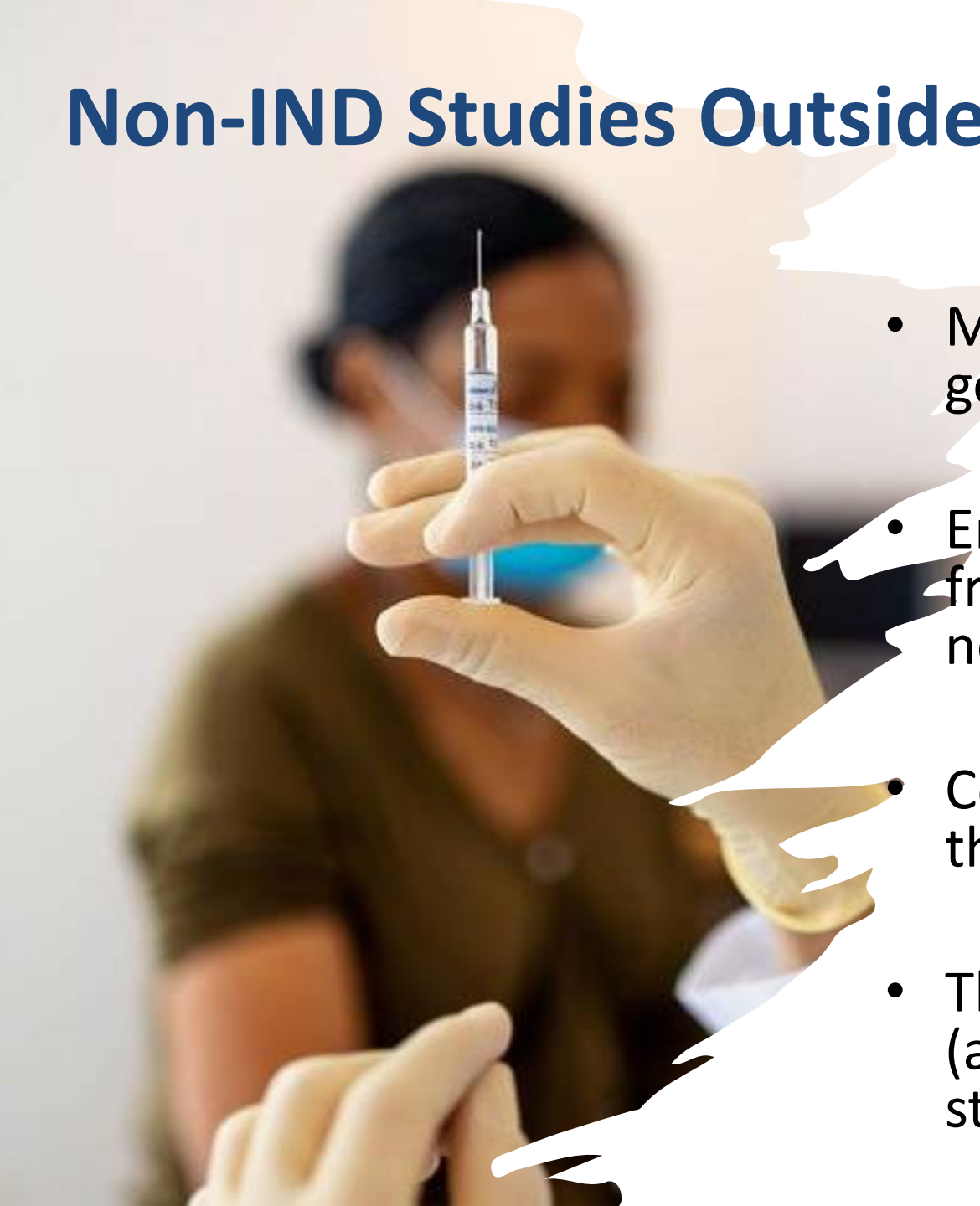
- Clinical trails are increasingly global
- They are conducted under a variety of scenarios
- Some trials are based solely on foreign clinical data

# Conducting Clinical Trials Outside United States

- Investigational New Drug (IND) is not required
- If a clinical trial is conducted under an IND, IND requirements must be met unless waived
- If a clinical trial is not conducted under IND, one must ensure that the trial complies with the requirements in 21 CFR 312.120


An IND is a request for FDA authorization to ship an investigational drug across state lines for use in human clinical trials.

# Non-IND Studies Outside the United States



- Must conduct the study in accordance with good clinical practice (GCP)
- Ensuring that FDA is able to validate the data from the study through an onsite inspection, if necessary
- Conducting studies in a manner comparable to that required for IND studies
- The GCP requirements encompass both ethical (approval by IEC/IC) and data integrity standards for clinical studies.

# How are Clinical Trials Conducted in the United States

- In the United states investigators are required to submit an IND to FDA if they intend to conduct a clinical investigation unless studies meet specific regulatory exemption criteria.

- When a clinical study is conducted under an IND, all FDA IND requirements (21CFR 312) must be met unless waived.

# Investigator Responsibilities for IND Studies

**1)** Ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations. 312.60

**2)** Ensuring control of drugs under investigation; including storage of the investigational drug . 312.61

**3)** Maintaining adequate records of the disposition of the drug, accurate case histories. 312.62

**4)** Providing investigator reports: progress reports, safety reports, final. 312.64

**5)** Ensuring IRB review, approval and reporting requirements. 312.66

**6)** Ensuring FDA has access to inspect investigator's records and reports. 312.68

**7)** Ensuring that informed consent is adequately obtained.312.60

**8)** Providing financial disclosure to sponsor. 312.64

The investigator responsibilities are covered under Part 312.60 to 312.70 Investigational New Drug Application Regulations

# Exemptions from IND Requirements

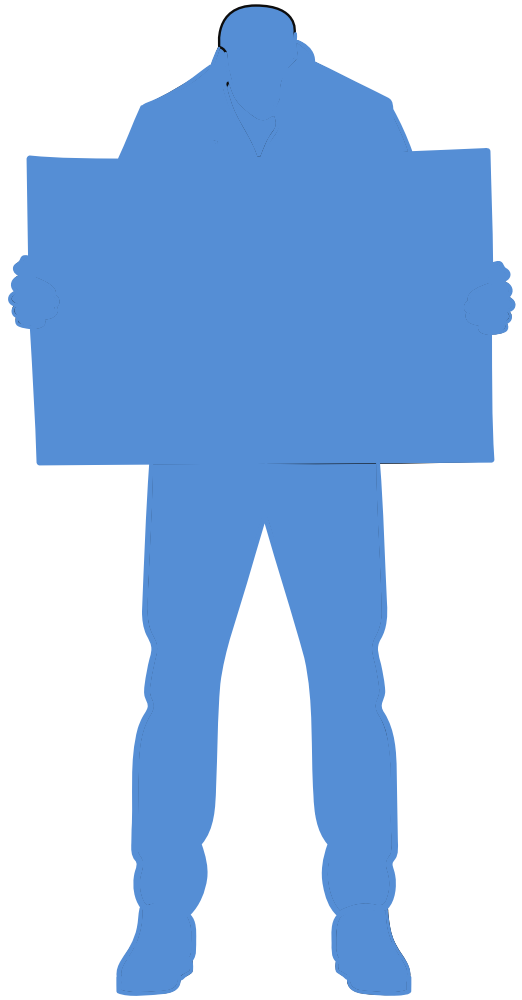
## Exemption from IND will be granted if **all of** the following requirements are met:

| | | | | |
|---|---|---|---|---|
| The drug product for the planned investigation is **lawfully marketed** in the U.S. | The planned investigation is **not intended to support new indication**/or significant change in labeling | The planned investigation does not involve a route of administration or dosage level or use in a patient population or other factor that **significantly increases risk** | The investigation is conducted in compliance with part 56 (**Institutional Review Board**) and part 50 (**Informed Consent**) regulations | The investigation is conducted in compliance with 21 CFR 312.7 (**promotion and commercial distribution** of an investigational new drug) regulations |

# Acceptance of Foreign Data from Non-IND Trials

**Foreign data should be:**

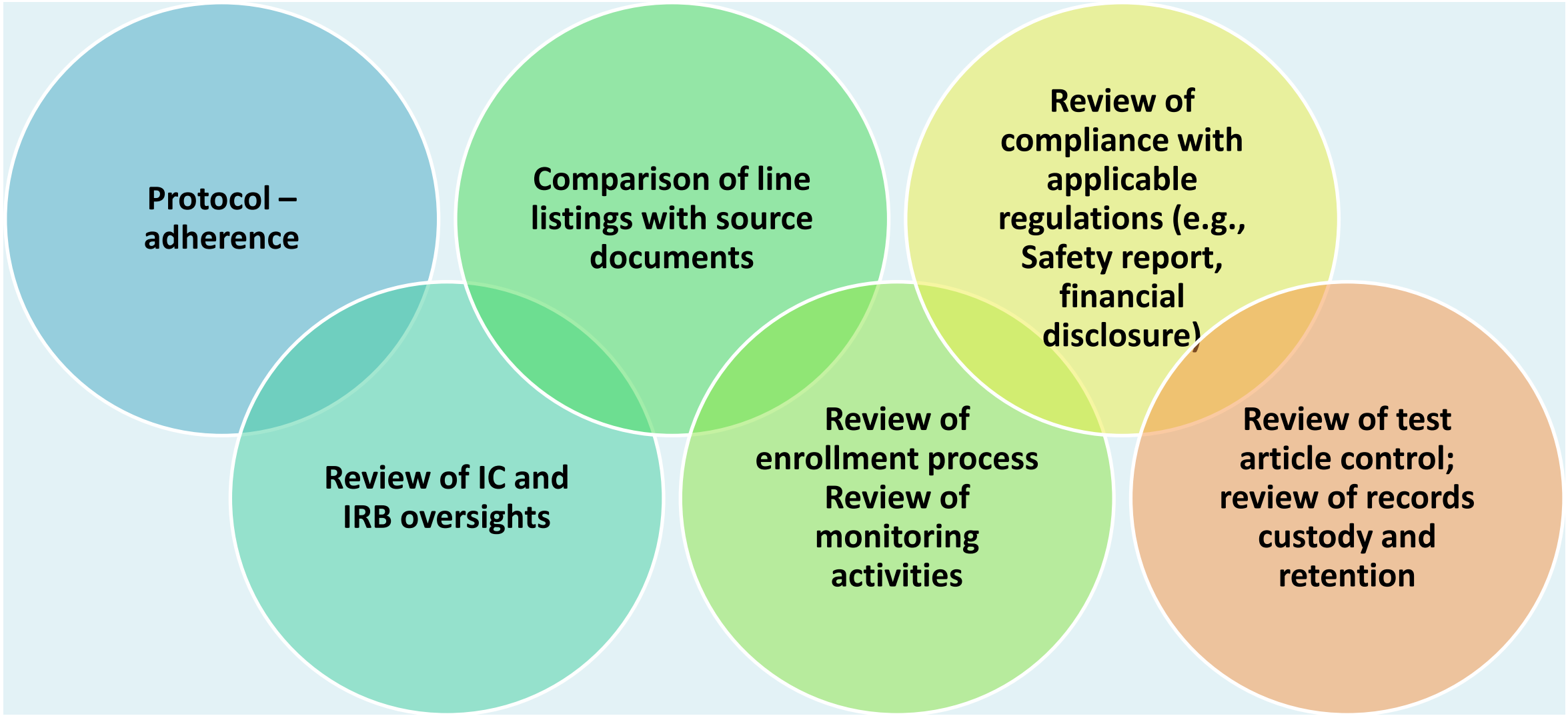
1. Applicable to the **U.S. population** and medical practice
2. Generated by **investigators** of recognized competence
3. Considered **valid** without an inspection
4. Validated through **inspection** when it deems necessary



# Inspection of Clinical Investigator

- Knowledge of Clinical Investigator regulations and important guidances
- Understanding of Clinical Investigator responsibilities and complying with regulatory expectations
- Adherence to Code of Federal Regulations

# Inspection Areas of Focus



# Sponsor / CRO Inspection Focus

Organization and Personnel

Registration of Trials

Selection and Communication with Investigators

Monitors and Monitoring

Quality Assurance (Auditing)

Adverse Event Reporting

Data Handling/Data Audit

Control of Investigational Product(s)

Review of Automated (Computerized) Processes

Electronic Records and Electronic Signatures

Recordkeeping and Record Retention

Financial Disclosure

# Take Home Point

Wherever clinical trials are conducted, it is important to have drug development programs that reliably produce high quality data acquired in a manner that will not jeopardize the rights, safety, or welfare of trial participants

FDA's Principal Deputy Commissioner, Janet Woodcock, M.D.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