PRACTICAL EXPERIENCE IN GCP INSPECTION, NON EU/EEA COUNTRIES INDONESIA

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INTRODUCTION

Directorate of Drug and Biological Product Evaluation

Sub Directorate of New Drug Evaluation

- New Registration of Chemical Entity:
  - NCE
  - Extended line
- Variation Registration of Chemical Entity (Innovator drug products)

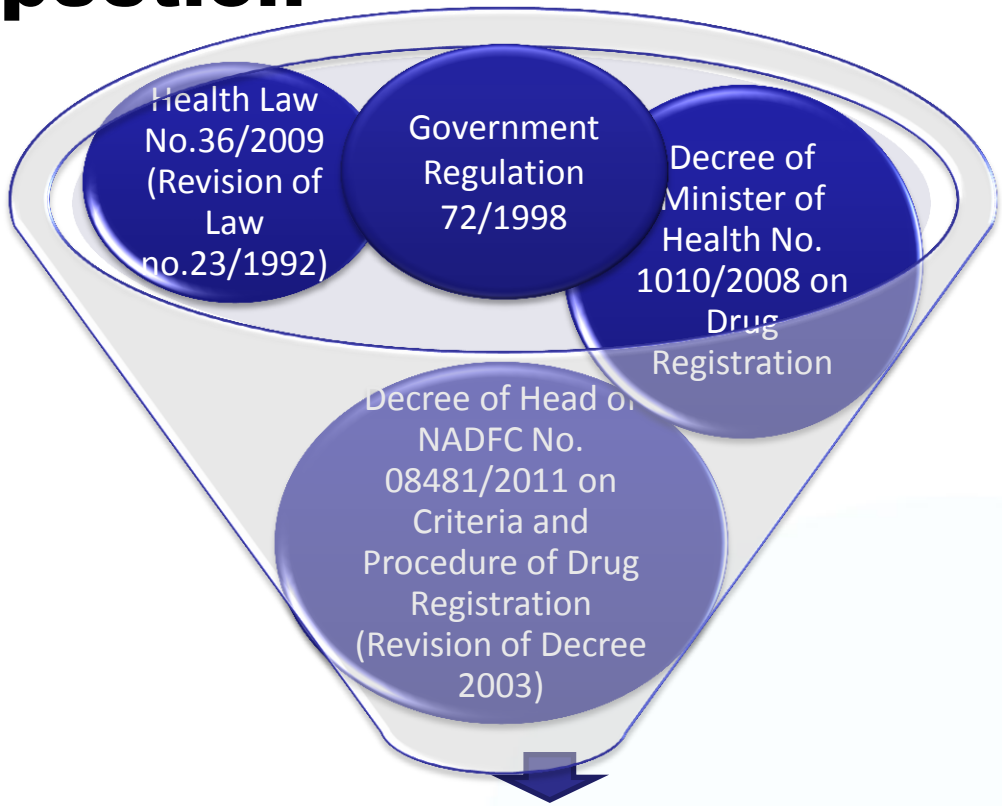
Sub Directorate of Copy Drug and Biological Product Evaluation

- New Registration of Chemical Entity: Generic Drug Products
- Variation Registration of Biological Entity & Chemical Entity (Generic drug products)
- New Registration of Biological Entity:
  - NBE
  - Biosimilar
  - Extended line

Sub Directorate of Evaluation on Product Therapeutic for Special Purpose

- Clinical Trial. Christine Siagian, Head of Clinical Trial Section: Clinical Trial Authorization including IP importation, GCP Inspection, SAE reporting
- Special Access Scheme (SAS)
- Operational General Affair

The National Agency of Drug and Food Control (NADFC) Indonesia to perform a GCP Inspection



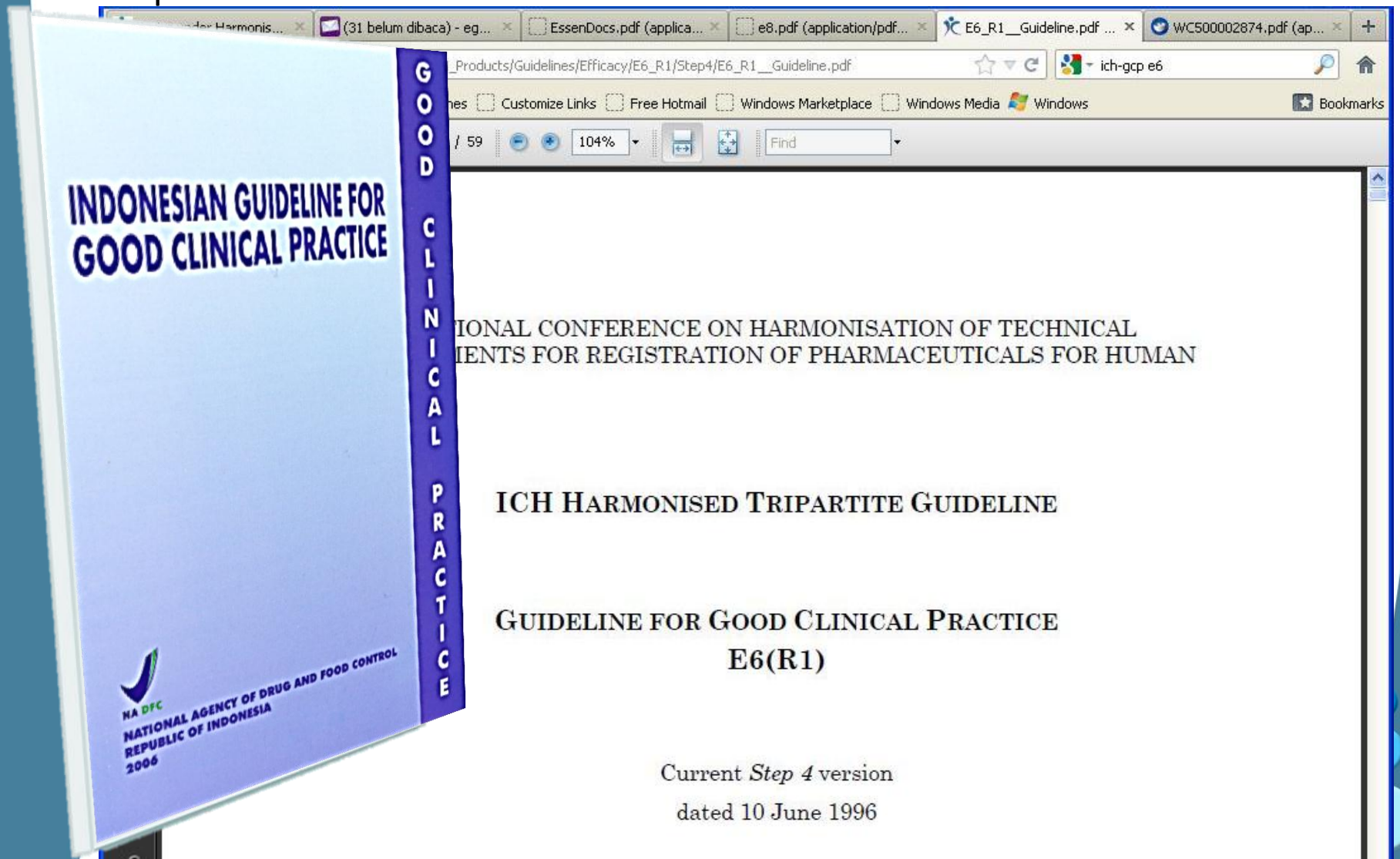
Good Clinical Practice in Indonesia → Adopted from ICH GCP (E6)

Decree of Head of NADFC 02002/SK/KBPOM, 2001 on Clinical Trial Procedure

Decree of Head of NADFC No. HK.00.05.3.4991 dated 30 Nov 2004 on GCP Inspections

Indonesian Guidelines for Good Clinical Practice

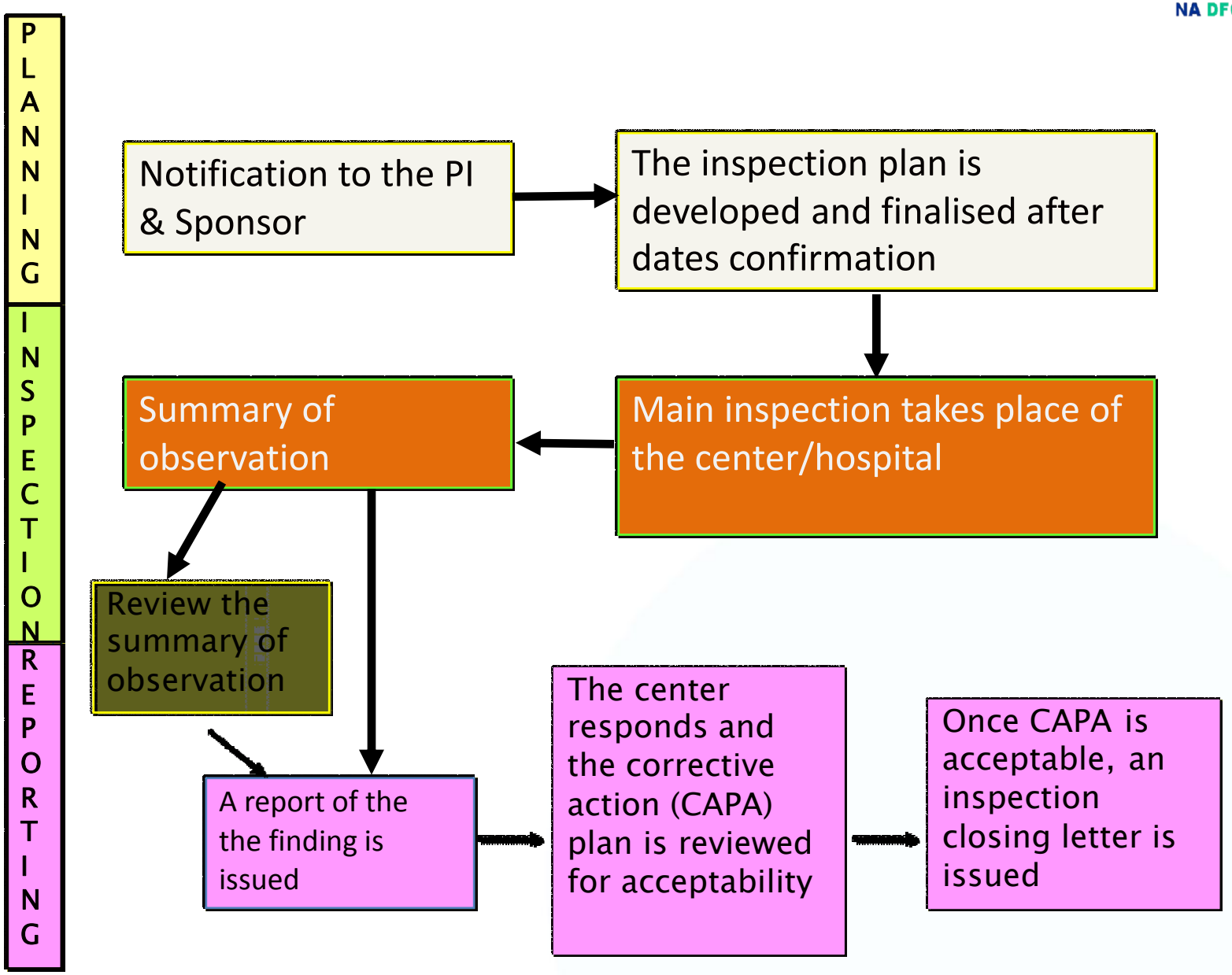
Adopted from ICH – GCP E6



Sites most commonly inspected are CLINICAL INVESTIGATOR

- Sites which are involved in clinical trial
- Area inspected

GCP Inspection



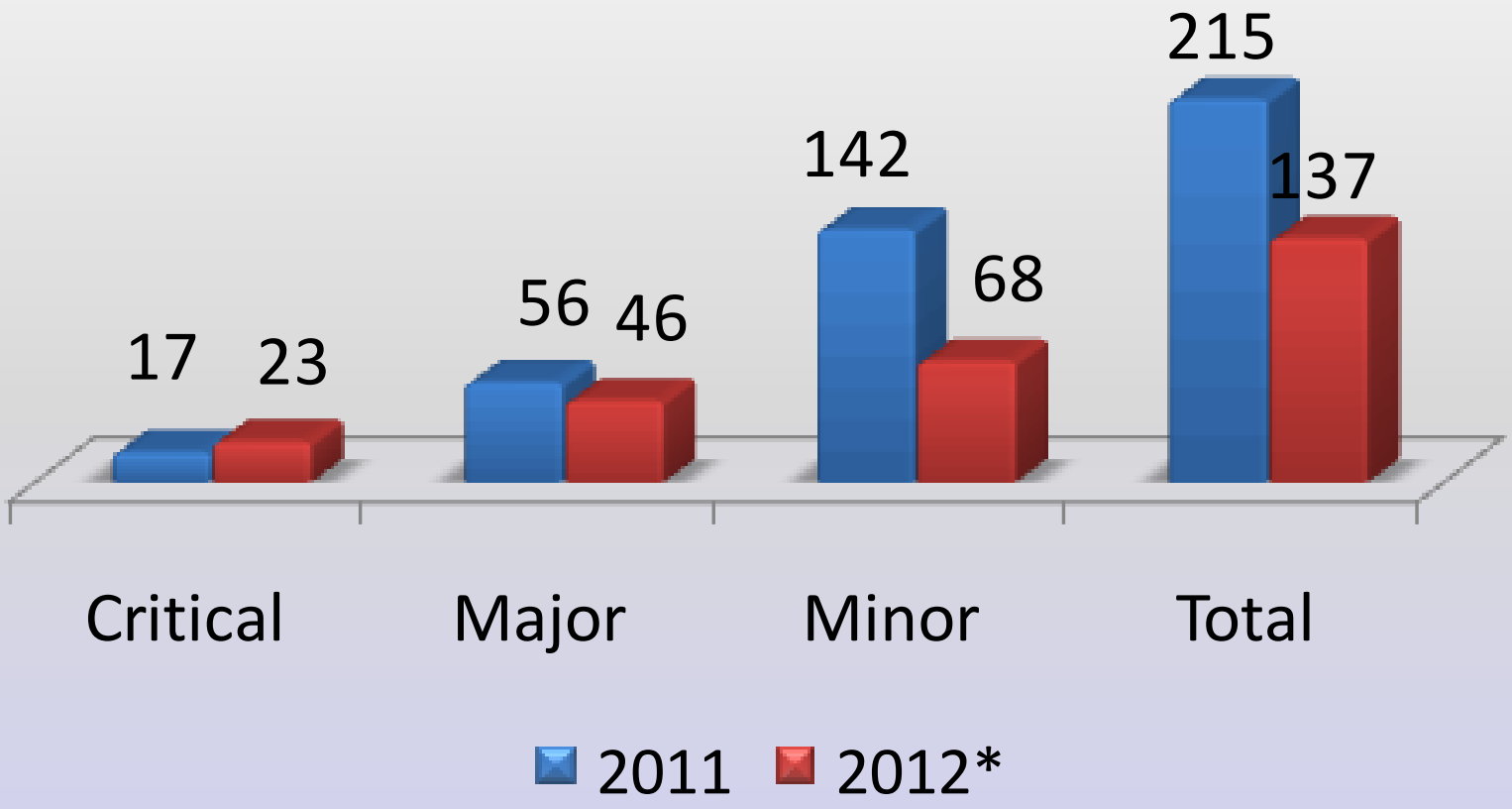
CLASSIFICATION OF FINDING

Critical finding: direct subject safety implications or regulatory offence or directly casts doubt on validity of data

Major finding : non-compliance with regulations that could have impact on the patient or validity of data.

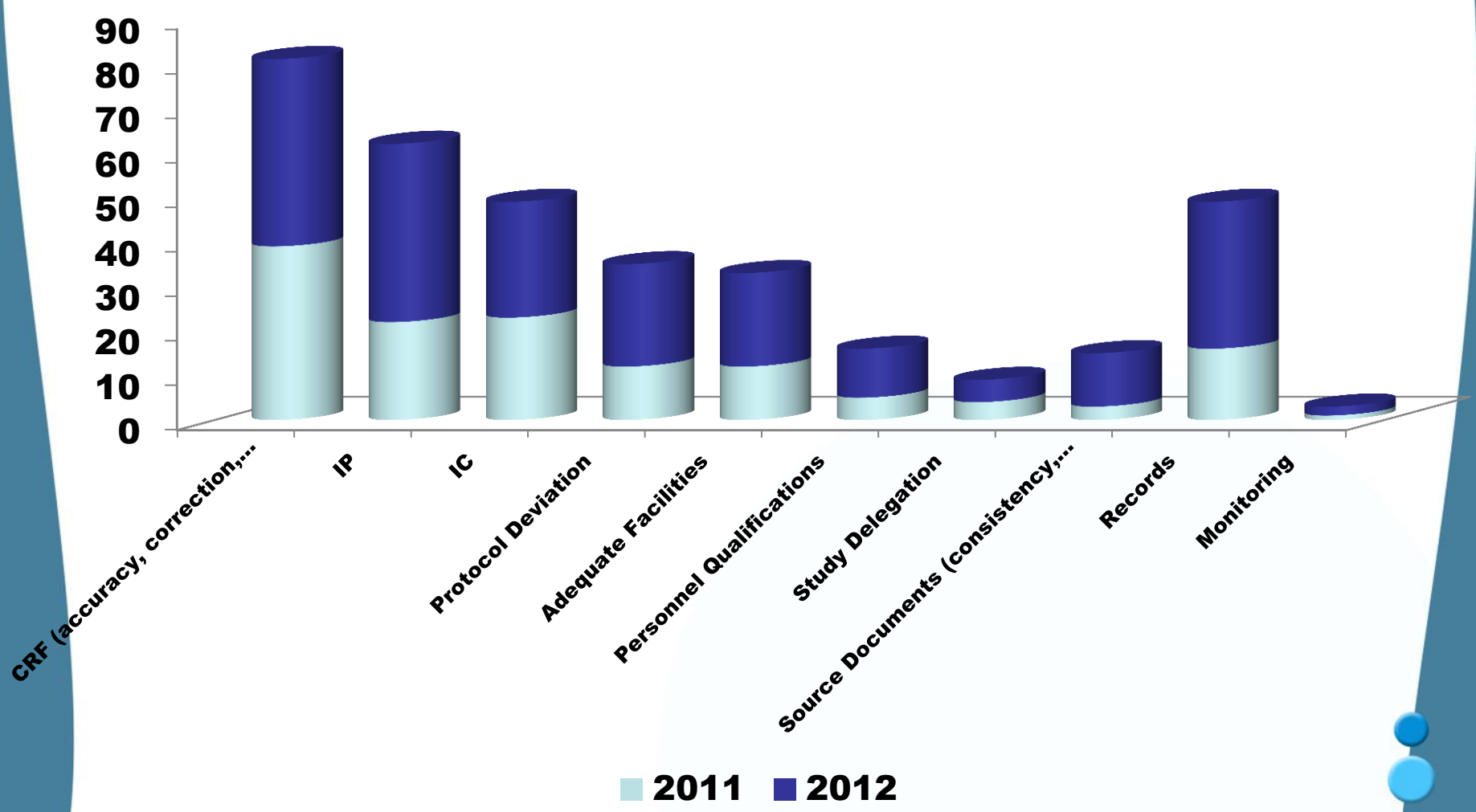
Other : Minor non-compliance. Lots of minor non-compliance may add up to a major non-compliance

Classification of GCP Inspection Finding in last 2 years



* Until October 2012

Area of findings



GCP Inspection
THREE MOST COMMON FINDINGS

Inspection FINDING 1

- **Accuracy, Correction, Completeness of CRF**
  - **Most Clinical Trials use paper-CRF which needs to be verified regularly. These also need a lot of work to complete the data in the specified time. The system is not paperless. Everything should be recorded in writing, therefore, paper – CRF is completed or verified over the specified time. The investigator has overall responsibility for ensuring the accuracy and completeness of data entry (Reference: ICH GCP 4.9.1, WHO-GCP 8.1)**
  - **The impact of the finding: Impact on quality and integrity of data**
    - **By not recording the data into CRF at the time the activity occurs, there is no evidence of what has occurred or has been observed, therefore, no data to be submitted to the sponsor for further handling. Data Quality and integrity are essential for data to be relied. Monitor should conduct more intensive monitoring and Record of each visit in CRF must be verified by the responsible person designated in the protocol**

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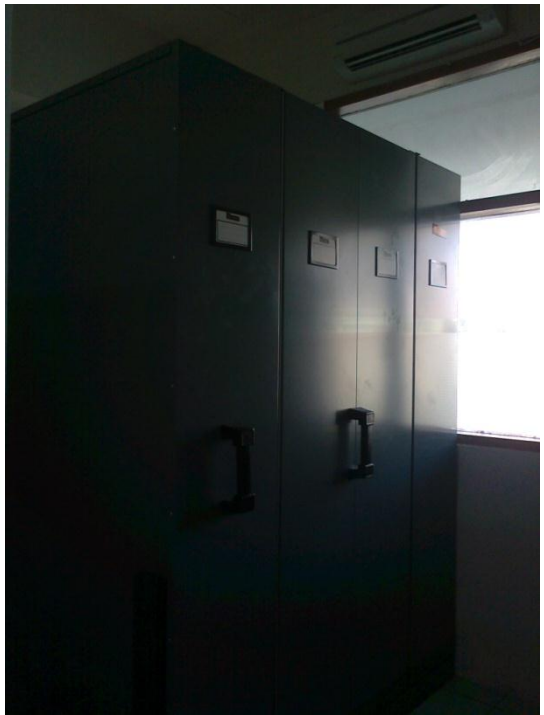


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Inspection FINDING 2

- **Informed Consent Form**
  - **Copy of ICF is not given to participants. This happens because many participants refuse to keep the ICF due to afraid to make it lost. (Ref: ICH-GCP 4.8.11, WHO-GCP 3.3, 4.5)**
  - **Investigators tend to conduct pre-screening, however, they do too much therefore the pre-screening is actually a screening. Therefore, ICF is obtained after screening (Ref:ICH-GCP 4.8.8, WHO-GCP 3.3)**
  - **The impact of the finding:**
    - **Impact on safety and wellbeing of the participants. Participants have to know thorough information about their participation and information about contact person to contact in an emergency situation. Participants have to understand their decision to participate in trial after having explained about the study and comprehension.**

Inspection FINDING 3

- **Investigational Products**
  - **Inadequate storage or handling controls for IP.**
    - **Miss to record the temperature (especially during week-end). Some records show deviation in storage temperature (Ref: ICH GCP 4.6.4)**
    - **Unlocked refrigerator / drug storage, therefore, the storage is also used for daily / routine drug storage. (Ref: ICH-GCP 4.6.5)**
- **Impact of this finding: impact on safety of the subjects.**
  - **Participants should be protected from poor-quality products resulting from how to handle and store IP (contamination / cross – contamination, unacceptable storage temperature). The stability of drug upon unacceptable storage temperature has to be assessed. In this stage, drug has to be quarantined until sponsor decides.**
  - **The access to storage room should be limited to protect the use of IP from other purpose than trial.**


VAKSIN BCG KERING
FREEZE DRIED BCG VACCINE
10 ampoules

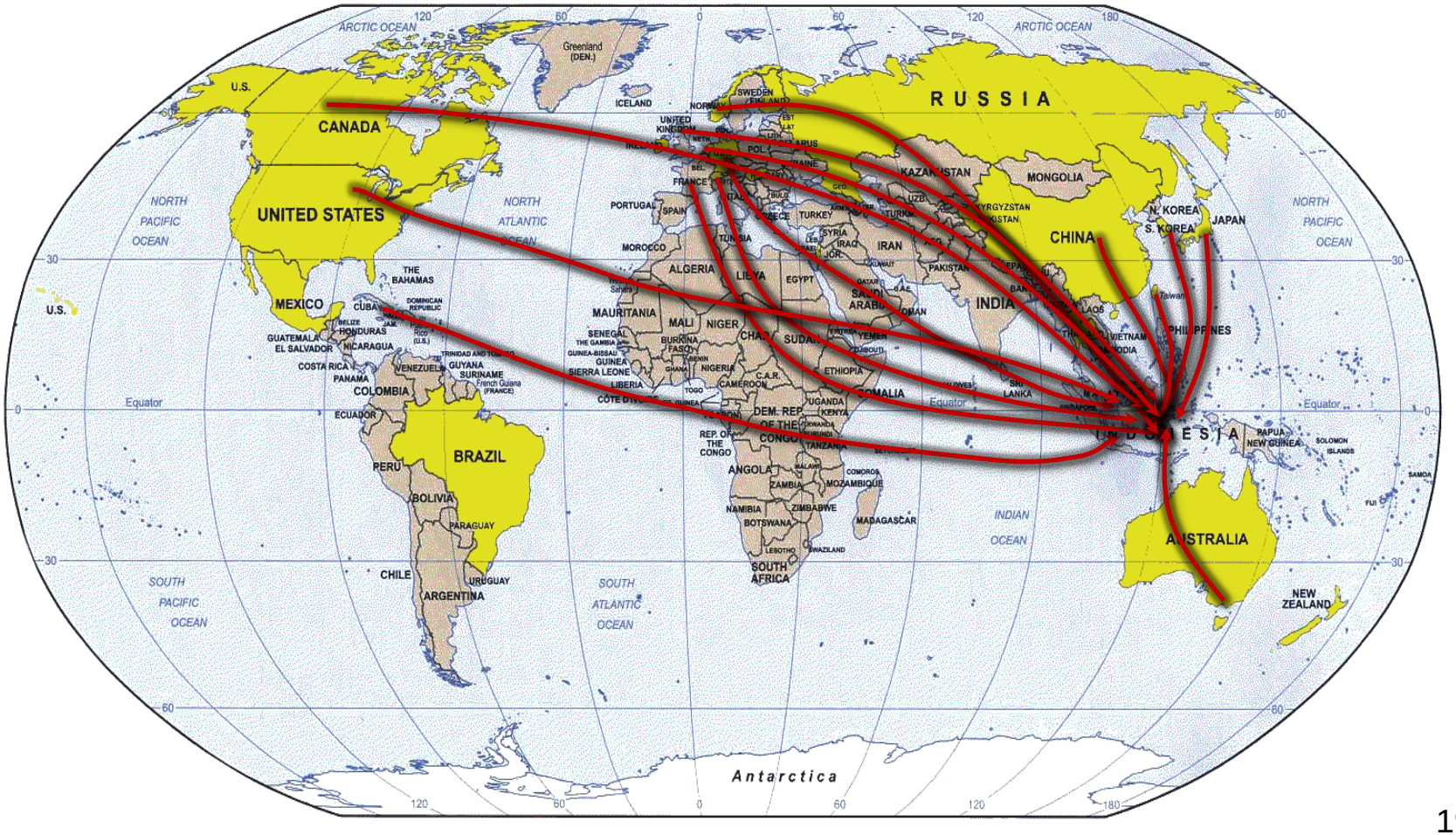
CHALLENGES

Data Sources – Electronic

Data Sources - Traditional

Electronic Clinical System for all sites → electronic consenting, electronic signatures, electronic medical records, electronic trial master file

- **Increasing GCP compliance among all clinical trial players therefore increasing the global clinical trial.**



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