Challenges in implementation of guidelines

□ Challenges are of two types:

1. Technical Barriers for implementation of ICH-GCP regulations
2. Political Barriers for implementation of ICH-GCP regulation

1. Technical challenges:

• Four major categories of players can be identified in the ICH-GCP area:

i- The health authorities
ii- The academic institution
iii- The clinical investigators
iv the pharmaceutical industry

Patients and the public, as the ultimate recipients of the benefits (or failures) of the ICH GCP process constitute an important 5th party, although not directly participating in the implementation or control of the process.

• Some of these common barriers are personnel's

knowledge, facility, equipment and finances.

- The most common and consistent barrier to different degree across countries is the lack of sufficient personnel in all player categories. Health authorities usually complain about the shortage of competent medical and paramedical professionals to evaluate protocols and related documentation, the shortage of quality compliance inspectors, and the scarcity of auxiliary personnel.

- lack of insufficient knowledge/know-how and training at academic and clinical investigators levels (ethic committee, institutional review board), cumbersome, bureaucratic implementation process in starting/conducting clinical studies, and lack of GCP training program.

2. Political challenges:

i- lack of or insufficient legislative/regulatory framework

ii- The most frequent areas of noncompliance

include: ethics committee, institutional review board (IRBs, composition and practices), informed consent issued (content, process, signature and dating), investigator dedication of authority (unreliable, excessive dedication), clinical monitoring (non existing adequate reporting of ADR, infrequent, and/or inefficient).