CLINICAL STUDIES IN JORDAN
POINTS OF STRENGTH & CHALLENGES

1st Mena Regulatory Conference on Bioequivalence, Biowaivers, Bioanalysis and Dissolution.
Outline

JFDA

CLINICAL STUDIES LAW

CLINICAL STUDIES DIVISION

CLINICAL STUDIES COMMITTEE
Jordan Food and Drug Administration (JFDA) has been established in 2003 as the sole national competent authority for drug safety & efficacy and food safety and quality. Current Number of Employees: 624
Clinical Studies Division (CSD)

- Clinical studies division has been established on August 2004 for the purpose of monitoring all clinical studies conducted in Jordan.

- Number of Employees: 4
  (Head of division, Two pharmacists, Secretary)
Tasks of CSD

- Review the applications for accreditation of centers hospitals, laboratories, that will conduct studies.

- Inspection of the sites before granting accreditation for clinical studies.

- Periodic inspections to make sure continuous adhering to standards & requirements.

- Review therapeutic & non therapeutic protocols to ensure compliance to requirements.
Tasks of CSD

- Follow up clinical studies during conduction to safeguard the participants & ensure compliance with international guidelines.

- Holding seminars & lectures to raise awareness of participants and local community in this field.
<table>
<thead>
<tr>
<th>Year</th>
<th>No. of Bioequivalence Studies approved</th>
<th>No. of clinical Studies approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>131</td>
<td>2</td>
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<tr>
<td>2006</td>
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<td>2007</td>
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<td>2012</td>
<td>153</td>
<td>16</td>
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<td>until 20/9/2013</td>
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</table>
Main articles in clinical studies law #2 year 2011

- Definitions of different types of studies (as per article # 2)
- Can’t carry out any clinical study on human without informed consent signed by the participant & undergoing the necessary tests to ensure his safety (as per article 5-a).
- Insurance contract with an insurance company to cover any damage that may result from the clinical study (as per article 5-b)
- The need to form IRB in each institution that conduct clinical studies , consisting of at least five members of both sexes including legal & member of local community (as per article 7)
Clinical studies law 2011

- Any clinical study require the approval of CSC based on the recommendations of IRB (as per article # 10)

- Each institution conduct CS must adhere to the approved protocol & Helsinki declaration (as per article 11)
Clinical studies law # 2- Year 2011

- Clinical studies have to be conducted in sites accredited for clinical studies (as per article # 4)
  1. Public hospitals.
  2. Private hospitals.
  3. University academic institutions.
  4. Scientific research institutions.
  5. Pharmaceutical manufacturing companies.
The Clinical Studies Committee is formed under article # 12 in Clinical Studies Law – Jordan (law # 02 Year 2011)
Consist of 12 members

- General Director of JFDA
- Drug Directorate Director
- Head of Clinical Studies Division
A Pharmacist from the Drug Directorate delegated by the Drug Directorate Director

Two Clinicians: One named by the Minister of Health and an internist named by the Physicians Labor Board in Jordan
Clinical Studies Committee/JFDA

- Head of Pharmacy in the Department of Royal Medical services

-Five representatives of Academics and Private Sector:
  Specialists in Pharmacokinetics, Analytical Chemistry, Biostatistics, Clinical Pharmacy and Pharmacology, The membership is 2 years and can be renewed after the approval of the Minister of Health
As per article # 13 of the law, the committee has the following responsibilities:

- Accreditation of IRBs
- Evaluation of any submitted documents
- (protocols, reports, etc.,…)
- Ensuring that the studies are being conducted according to the applicable laws and regulations
Regulatory Submission Process

- **Clinical Trial Application:**
  1. Submit an **appointment request**
  2. Fill one of the three templates:
     - **BE / BA study**
     - **Phases I-III Study**
     - **Phase IV (Observational) Study**
Regulatory Submission Process

- Complete the application by submitting all the required Documents:
  - IRB approved Protocol / Protocol Amendments
  - Investigator Brochure
  - IRB approved informed consent form (ICF)
  - IRB approval Letter
Regulatory Submission Process

- Local Insurance Policy.
- Accepted GMP Certificate.
- Investigational Medicinal Product Available data.
- Samples of the approved labels according to JFDA guidelines.
Regulatory Submission Process

- IRB, Sites, Labs Accreditation by JFDA
- GLP / accreditation of Laboratories
- Investigators Resumes
- Certificate(s) of analysis of investigational product(s)
- Normal Ranges / Reference Ranges for the diagnostic tests
Regulatory Submission Process

- Sample of Case Report Form (CRF).
- Clarification of the relationship between different parties in the trial
- Others as required
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<tr>
<th>Part 1:</th>
<th>YES</th>
<th>NO</th>
<th>NA</th>
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<tr>
<td>Part 2 Protocol and Amendments</td>
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<tr>
<td>Investigator’s Brochure (IB)</td>
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<tr>
<td>Informations given to trial Subject:</td>
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<tr>
<td>a- ICF &quot;Arabic and English language&quot;</td>
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<td>b- Any other written information</td>
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<tr>
<td>c- Advertisements for subject recruitment (if used)</td>
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<tr>
<td>Dated, documented approval /favorable of IRB</td>
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<td>C.V. and/or other relevant documents evidencing qualifications of investigator(s) and sub investigator(s)</td>
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<tr>
<td>Normal values/ ranges</td>
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<tr>
<td>Sample of label(s) attached to investigational product container(s)</td>
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<td>Instructions for handling of investigational product(s) and trial-related materials (if not included in protocol or IB)</td>
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<tr>
<td>Certificate(s) of analysis of investigational product(s)</td>
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<td>Shipping records for investigational product(s) and trial-related materials</td>
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<td>Master randomization list</td>
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<td>Pre- trial monitoring report (to be provided upon request)</td>
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<td>Trial initiation monitoring report (to be provided upon request)</td>
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<td>Financial aspects of the trial(to be provided upon request)</td>
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<tr>
<td>Case report form</td>
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</table>
Regulatory Submission Process

Sponsor → PI → Protocol submission → IRB

Accredited sites/LCS Article 4 B

Public hospitals, Private hospitals, University academic institutions, Scientific research institutions, Pharmaceutical manufacturing companies

Protocol submission → CSD- JFDA
Regulatory Submission Process

After receiving the application the timeline to give approval/disapproval

- One week for Bioequivalence studies.
- 4-6 weeks for clinical studies (phase 1-111).
- 2-3 weeks for clinical studies (phase 1V).
Points of Strengths

1. Law No. (2), For the Year 2011, Law of Clinical Studies (amending Law No. 67 for the year 2001) which embraces “The Declaration of Helsinki” & ICH-GCP.

2. Institutional Review Board Committee (IRB)

3. Clinical Studies Committee

4. Licensing hospitals, laboratories & Contract Research Organization (CROs)

5. Advanced volunteers Data Base.
Points of Strengths

6. Conducting regular inspections to ensure adherence to ICH/GCP rules & maintaining a close relationship with the CROs/sites.

7. Signed consent form.

8. Adhering to inclusion-exclusion criteria.

9. Insurance contract within the Kingdom.

10. Promoting educational workshops and lectures for healthcare professionals.
Points of Strengths

11. Enhancing public awareness about the importance and the need to participate in medical research (multimedia workshop).

12. Maintaining ongoing communication with international regulatory authorities to keep up with best practices.

13. Issuing timeline charts for the process of clinical & bioequivalence protocol approval.
Challenges facing clinical studies in Jordan

- To keep and maintain the followings:
  - Jordan as a site of excellence in the field of science & technology including clinical studies.
  - Conduct clinical studies at the highest level of accuracy & transparency.
  - Achieve the highest level of security, safety & awareness of the participants in clinical studies.
  - Raise awareness of the local community in the field of clinical studies.
  - High adherence with GCP & local regulations.
What’s Next?

- Ethical Conducting according to applicable laws and Regulations
- Emphasis on Progress Reporting.
- Routine Inspections.
- Continuous Training.
The Most Precious Possession is Human

His Majesty King Hussien Bin Talal
Thank you

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