Biostatistics
Consideration on
Clinical Trials in China

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Disclaimer

- The views expressed in this talk are only those of the speaker and do not necessarily represent those of State Food and Drug Administration (SFDA)
Outline

- Statistical requirements of clinical trial
- Current problems of biostatistics in China
- Chinese biostatistics in future
Statistical Requirements of Clinical Trial

• ICH E9
  √ Consideration for overall clinical development
  √ Trial design consideration
  √ Trial conduct consideration
  √ Data analysis consideration
Statistical Requirements of Clinical Trial

- Biostatistics Guidelines In China (Adopted by 2005)
- Consideration for overall clinical development
- Trial design consideration
- Trial conduct consideration
- Data management
- Data analysis consideration
Why biostatistics is important to clinical trials?

- Scientific hypotheses need the statistics to realize them
- Technical support for design and conduct of clinical trials
- Evidence-based medicine for new drugs on the market
- To infer new drugs’ efficacy and safety in the more unknown population from the less known population’s data
Statistical Requirements of Clinical Trial

- Blinding, randomization and multicenter design
- Right hypotheses according to the current therapies of the relevant indications
- Enough sample size
- The proper representative population of the patients
- 2 pivotal trials on the stage of confirmation
Current Problems of Biostatistics in China

- The regulator
  • Absence of independent biostatistics reviewers
  • No criteria to code the ADEs or ADRs
- The investigators
  • Not to design clinical protocols according to statistical views effectively
  • Statistical Analysis Plans (SAPs) not predefined
  • Incorrect Statistical analysis methods
  • Improper statistical inference
# Current Main Differences of Clinical Trials between China and ICH

<table>
<thead>
<tr>
<th>Items</th>
<th>China</th>
<th>ICH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III (generally)</td>
<td>1 trial</td>
<td>More than 2 trials</td>
</tr>
<tr>
<td>Statistical Analysis Plans (SAPs)</td>
<td>Not predefined</td>
<td>Predefined</td>
</tr>
<tr>
<td>Primary Endpoints</td>
<td>Not clear</td>
<td>Clear</td>
</tr>
<tr>
<td>Sample Size</td>
<td>200～600</td>
<td>1500</td>
</tr>
<tr>
<td></td>
<td></td>
<td>300～600 (6 months)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100 (1 year)</td>
</tr>
<tr>
<td>Data Management Manners</td>
<td>p-CRF, p-CTD</td>
<td>e-CRF, e-CTD</td>
</tr>
<tr>
<td>Multiple comparison</td>
<td>No Statistical Penalty</td>
<td>YES</td>
</tr>
</tbody>
</table>
Present Actions in China

• To enhance the international communication and cooperation further
• To track the latest development of the international biostatistics
• To train and to recruit the persons with statistical ability
• To investigate the status quo of clinical trials and data management in China deep and widely
Chinese Biostatistics in Future

- To establish the independent office of biostatistics evaluation
- To emphasize to review the protocols and SAPs when the sponsors apply the clinical trials
- To supervise the course of the data collection further
- To set up e-sub system
What should we do next?

• To share the respective experience with other regulators in time

• Facing the globalization of the clinical trials, we need more data or information to establish the special mechanism whether to accept clinical studies in the different regions or not
Overall Goal

• To ensure the efficacy and safety of new drugs on the market
  ✓ Drugs on the market must be based on the adequate and well-controlled clinical studies
  ✓ Drug evaluation must reveal something concealed behind the data well and objectively
  ✓ To impulse clinical trials in China actively, including international multicentre study
Thanks for your attention

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