Drug Development in Developing Countries: A Pharmaceutical Company’s Perspective

Michael Dunne, MD
Vice President, Clinical Development
Therapeutic Head, Infectious Diseases
Pfizer Global Research and Development

Why would pharmaceutical companies do trials in developing countries?

- Helps overall development of the drug
- Performs trials where the patients are
- No reason, per se, to exclude people from developing nations
- Defines utility of new drugs in ethnic/racial populations
  - Human physiology varies with race
  - Cultural practices potentially influence drug efficacy/safety
- Provides service to the community
  - Especially with unique local diseases
  - Trachoma, onchocerciasis, kala-azar

Clinical trials with antibiotics: the challenges

- Study design
  - Comparator agents
  - Standard of care
  - Methods of evaluation
- Implementation
  - Informed consent
  - Follow up
  - Regulatory review and approval
  - Logistical support

Challenges around study implementation

<table>
<thead>
<tr>
<th>Informed consent</th>
<th>Enabling</th>
<th>Hindrance</th>
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</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Established</td>
<td>Evolving</td>
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<tr>
<td>Ethical committees</td>
<td>Established</td>
<td>Evolving</td>
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<tr>
<td>Follow up evaluations</td>
<td>Select for compliance</td>
<td>Logistics preclude full follow up</td>
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<tr>
<td>Regulatory review</td>
<td>Established</td>
<td>Evolving</td>
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<tr>
<td>Logistical support (power/transport/phone)</td>
<td>No issue</td>
<td>Situational</td>
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<tr>
<td>Standards of Good Clinical Practice</td>
<td>In place</td>
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Pharmaceutical research in developing countries

Strengths

- Global infrastructure
  - Source materials from many regions
  - Personnel on the ground to navigate local customs and rules
- Strong sense of purpose
- Stable, long term enterprise
- Sufficient resource to ensure expertise in the scientific issues
  - Efficiency and productivity primary focus of pharma efforts
  - “all components of research effort under one roof”
  - Optimizes transition to manufacturing processes
Research in Developing Countries: The Added Value

- Allows for medical improvements for local community members
  - Treatment of endemic diseases
  - Trachoma, river blindness
- Epidemiologic information gained during trials helps direct scarce resources
- Enhances appropriate use of new medicines
  - Subtleties around safety/efficacy defined in trials

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Pharmaceutical research in developing countries

Weakness
- Stretches home office resources
- When oversight from developed country is needed
- Difficult to justify research without return on investment
  - Return on investment does not resonate with general public
- Though public encourages more charitable work
- Shareholder concerns about charitable work
- Public relations difficult to maintain
  - Lack of trust to be resolved
  - Compliance with local regulatory/ethical committee guidance often insufficient

Research in Developing Countries: The Added Value

- Technology transfer
  - Knowledge of clinical trial process
    - Training in ‘good clinical practice’
    - Rigor can be applied to tackling other community issues
  - Equipment can donated to institutions for future studies
    - Computers, fax machines
    - Freezers
  - Exposure of the local researchers to global opinion leaders
    - Presentation of data at international meetings

Clinical Trials: the challenges of global development programs

- In the best interest of companies to have global capabilities
- In the best interest of communities to have research performed locally
- Significant challenges are faced while introducing new technologies
- Continued dialogue on the value of global research and development programs could further enable appropriate relationships to evolve between public and private sectors
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