The IRB Ecosystem of a Busy Clinical Research Institution

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Agenda

- The IRBs and your HRPP
- What is an IRB Ecosystem?
- Why & when an IRB Ecosystem?
- How to work with outside IRBs

Human Research Protection Program (HRPP)

A shared responsibility
An HRPP is a shared responsibility

Components of the HRPP

1. Institution
2. IRBs
3. Investigators
4. Organizational Official
5. Employees
6. Legal counsel
7. Grants and Contracts Office
8. Investigators and research staff
9. IRBs
10. IRB
11. IRB
12. IRB
# Authorities

<table>
<thead>
<tr>
<th>IRB</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approve research</td>
<td>Disapprove research</td>
</tr>
<tr>
<td>Modify research</td>
<td>Non-compliance</td>
</tr>
<tr>
<td>Disapprove research</td>
<td>Select IRBs</td>
</tr>
<tr>
<td>Suspend research</td>
<td>Restrict investigators</td>
</tr>
<tr>
<td>Terminate research</td>
<td>Hire/fire staff</td>
</tr>
<tr>
<td>Observe research</td>
<td>Allocate funds</td>
</tr>
</tbody>
</table>

**Acts on research**

**Acts on individuals and systems**

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# IRB Ecosystem

- A set of co-existing, human research review units integrated with an institution’s HRPP.
  - Based on trust
  - Efficient, with non-duplicative activities
  - Partners in human research protections
    - Open communication
    - Honesty
    - Single-minded focus
    - Integrated with institution’s HRPP
Simple IRB Ecosystem

- Captive IRB
- NCI CIRB
- HRPP
- NeuroNext or StrokeNet
- Independent IRB

Partners in Human Research Protections
Teammates in Overcoming Obstacles

Why Rely on Outside IRBs?

- By requirement:
  - Sponsor
  - Funding Agency
Why Rely on Outside IRBs? Continued

- By Choice:
  - Captive IRB workload
  - Multi-campus institution wants to consolidate IRBs
  - Desire to focus on IIR
  - Desire for more clinical trials

Changing Landscape of Clinical Research
Serious decline in federal research dollars for US institutions

Pharma: Urgent Need To Change

90% of R&D expenditures result in NO new drug approvals

FDA Approved Drugs

Global Pharma R&D Budget ($bn)

Total Cost Per New Drug ($mm)
**Globally dispersed clinical trial activity**
Offshoring means fewer activities for US investigators

**Global research snapshot & forecast**

<table>
<thead>
<tr>
<th>Region</th>
<th>Market size ($bn)</th>
<th>Global share (%)</th>
<th>Growth 2010 (%)</th>
<th>CAGR 2012-16 (%)</th>
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</thead>
<tbody>
<tr>
<td>North America</td>
<td>347.1</td>
<td>36.3</td>
<td>3.0</td>
<td>1-4</td>
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<tr>
<td>Europe</td>
<td>265.4</td>
<td>27.8</td>
<td>2.4</td>
<td>0-3</td>
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<tr>
<td>Japan</td>
<td>111.2</td>
<td>11.6</td>
<td>0.1</td>
<td>1-4</td>
</tr>
<tr>
<td>Latin America</td>
<td>66.7</td>
<td>7.0</td>
<td>12.7</td>
<td>10-13</td>
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<tr>
<td>Asia and ROW</td>
<td>165.2</td>
<td>17.3</td>
<td>14.0</td>
<td>10-13</td>
</tr>
<tr>
<td>Total</td>
<td>955.5</td>
<td>100</td>
<td>5.1</td>
<td>3-6</td>
</tr>
</tbody>
</table>

*Table 1. Global and regional pharmaceutical markets 2011 and growth forecasts to 2016. The Asian market grew by 14% during 2010 and is forecast to continue double-digit growth through 2016.*

In an environment of research budget cuts, can clinical trials provide alternate research funding opportunities?

Time for a change

AMCs vying to better compete for industry trials

Working to conquer study start-up delays, IRB review process

By Ronald Rosenberg
Staff Writer

Academic Medical Centers (AMCs)—facing major financial pressures on their educational and clinical care capabilities—are making a greater effort to improve the efficiency of their clinical trials, despite declines in National Institutes of Health funding and stiff competition from for-profit investigative sites.

AMCs remain sought-after sites for clinical study conduct, largely for their institutional prestige and the integrity of its Principal Investigators, who sponsors often seek to cultivate as key opinion leaders in a particular indication. Located in large metropolitan areas, many AMCs also have access to huge numbers of potential patient participants for trials. Yet, despite their perceived value, AMCs continue to face challenges for sponsors ranging from time-consuming lags of internal study review and intellectual property issues to slower enrollment and longer IRB turnaround.

Now, many AMCs are taking the steps necessary to remedy these issues, become more competitive and, ultimately, win the trust of industry sponsors.

Study start-up challenges

The myriad challenges facing AMCs often start with a labyrinth of bureaucratic layers see AMCs on page 12

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transition

Transition is in your future.

When?

NOW ☑

LATER ☐
How to work with outside IRBs

Decision-making
Choosing IRB Partner(s)

- Some may be chosen for you
  - NCI-CIRB
  - Novartis Signature
  - StrokeNet, etc

Choosing IRB Partner(s) – continued

- You get to choose others
  - Your needs
  - Your desires
  - Your expectations
  - Your limitations
Careful Transition Management

- Regulatory notifications/filing
- Communication
  - Internal stakeholders
  - External stakeholders
- Integration with institutional workflows & eIRB software
- Policy adjustments
- Informed consent templates
- Gatekeepers
- Costs & invoicing

Key Issues to Manage
Key Issues to Manage – continued

- Contract or MSA
  - Required by IRB?
  - Required by institution?
  - Terms & conditions?

- Single point of contact
- Performance expectations
- Redacted minutes
- Reports
- Management of noncompliance

Ongoing Relationship Management
Thank You!

For more information please email us at:

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