**Bacterial Pneumonia (HABP/VABP) Phase Three Clinical Trials**

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**METHODS**

Tufts CSDD, in collaboration with CTTI developed a comprehensive, detailed mapping of direct and indirect cost elements. Primary cost elements include per-patient direct costs, per-trial and per-site costs.

**PER-PATIENT COST ELEMENTS**

- Patient Recruitment/Site Activation (i.e. compensation)
- Clinical Trial Insurance
- Screen Fails
- Procedures
- Lab tests
- Quay Resolution
- Data Entry

**PER-TRIAL AND PER-SITE COST ELEMENTS**

- Site and Clinical Supply Costs
- Printing/Paper/Document Costs
- Personnel Costs
- Other Costs

**SITE DISTRIBUTION ASSUMPTIONS**

- Data provided by electronic data capture (EDC) systems. Clinical trial sites were evenly distributed across 32 countries in the US and 32 countries outside the US.

**RESULTS**

- **HABP/VABP** is defined as an acute infection of the pulmonary parenchyma that is associated with clinical signs and symptoms, such as fever, hypothermia, chills, rigors, cough, or chest pain accompanied by the presence of a new or progressive infiltrate on a chest radiograph in a patient hospitalized for more than 48 hours or developing within 7 days after discharge from a hospital.

**STUDY ASSUMPTIONS**

- Tufts CSDD determined the fully-loaded cost of a HABP/VABP phase III clinical trial with 1,000 patients and 200 global sites to be $78,000 per patient.

**LIMITATIONS**

- The cost of screen failure rates are the main drivers of cost for a phase III HABP/VABP clinical trial.

**CONCLUSIONS**

- Opportunities to lower the high costs of HABP/VABP clinical trials exist.

**REFERENCES**


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**ACKNOWLEDGEMENTS**

- Tufts CSDD developed the fully-loaded cost of a HABP/VABP phase III clinical trial with 1,000 patients and 200 global sites to be $78,000 per patient.

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**SUMMARY**

- **Tufts CSDD** determined the fully-loaded cost of a HABP/VABP phase III clinical trial with 1,000 patients and 200 global sites to be $78,000 per patient.

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**TABLES**

**TABLE 1**

<table>
<thead>
<tr>
<th>Variable</th>
<th>HABP/VABP</th>
<th>Oncology</th>
<th>Endocrine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Sites (all locations)</td>
<td>201 sites</td>
<td>278 sites</td>
<td>123 sites</td>
</tr>
<tr>
<td>Total Subjects (all locations)</td>
<td>1,000 subjects</td>
<td>446 subjects</td>
<td>562 subjects</td>
</tr>
<tr>
<td>Total Number of Countries</td>
<td>30 countries</td>
<td>81 countries</td>
<td>131 countries</td>
</tr>
<tr>
<td>Randomization Rate</td>
<td>1 patient randomized per 100 screened</td>
<td>25 patients randomized per 100 screened</td>
<td>45 patients randomized per 100 screened</td>
</tr>
</tbody>
</table>

**TABLE 2**

<table>
<thead>
<tr>
<th>Variable</th>
<th>HABP/VABP</th>
<th>Oncology</th>
<th>Endocrine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Cost Element</td>
<td>$30</td>
<td>$39</td>
<td>$45</td>
</tr>
<tr>
<td>Per-Patient</td>
<td>$20</td>
<td>$29</td>
<td>$34</td>
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<tr>
<td>Per-Trial and Per-Site</td>
<td>$55</td>
<td>$66</td>
<td>$75</td>
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<tr>
<td>Indirect</td>
<td>$3</td>
<td>$5</td>
<td>$7</td>
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<tr>
<td>Total Cost</td>
<td>$78</td>
<td>$99</td>
<td>$117</td>
</tr>
</tbody>
</table>

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**FIGURES**

- Figure 1: The Primary Cost Elements
- Figure 2: A list of Per-Trial and Per-Site Cost Elements
- Figure 3: Average cost-per-patient for a Phase III Endocrine, HABP/VABP, and Oncology trials by primary therapeutic area
- Figure 4: Study Assumptions
- Figure 5: Cost Drivers: Changing One Driver
- Figure 6: Cost Drivers: Changing One Driver
- Figure 7: Average cost-per-patient for a Phase III HABP/VABP trial by primary cost element.