Clinical Trial 'Metrics': Benchmarking Australia’s Performance

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Chairman, Medicines Australia

Clinical Trials Advisory Committee Meeting
20 February 2014
Overview

1. Essential KPIs
2. Local Experience
3. Case Study (Company Data)
## Essential KPIs

<table>
<thead>
<tr>
<th>Process</th>
<th>KPI</th>
<th>Definition</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Up</td>
<td><strong>Start up time</strong></td>
<td>Document submission to initiation (HREC approval, RGO approval, CTN complete, contact signed)</td>
<td>12 Weeks (84 Calendar Days)</td>
</tr>
<tr>
<td>Recruitment</td>
<td><strong>Recruitment target</strong></td>
<td>Studies meeting overall recruitment target</td>
<td>Non- / Under-recruiting sites: &lt; 10%</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td><strong>Site quality</strong></td>
<td>For any internal or external site audits during current year, no critical audit findings and any other audit findings would be proactively address and a Corrective and Preventive Action (CAPA) plan put in place</td>
<td>0 critical audit findings; CAPA in place for all other audit findings within 3 months of adverse finding</td>
</tr>
<tr>
<td>Cost</td>
<td><strong>Cost containment</strong></td>
<td>Full cost of running a clinical trial (start up, HREC, per patient and pharmacy fees, etc.)</td>
<td>Cost of running clinical trials in Australia is equal to or lower than the median compared to other countries of similar economic profile (Canada, France, Germany, UK)</td>
</tr>
</tbody>
</table>
Study Start Up – Local Experience

HREC Approval (HREC Approval Letter) to SSA Completion (Last Contract Signature) – Calendar Days
Source: Medicines Australia Survey

<table>
<thead>
<tr>
<th></th>
<th>25th Percentile</th>
<th>Median</th>
<th>Average</th>
<th>75th Percentile</th>
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</thead>
<tbody>
<tr>
<td>National (n=271)</td>
<td>8.5</td>
<td>49</td>
<td>33</td>
<td>49</td>
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<tr>
<td>S1 (n=91)</td>
<td>66</td>
<td>49</td>
<td>43</td>
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<tr>
<td>S2 (n=82)</td>
<td>72</td>
<td>59</td>
<td>43</td>
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<tr>
<td>S3 (n=44)</td>
<td>58.25</td>
<td>36</td>
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<td>28</td>
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<tr>
<td>S4 (n=23)</td>
<td>64.5</td>
<td>45</td>
<td>37</td>
<td>37</td>
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<tr>
<td>S5 (n=24)</td>
<td>48.25</td>
<td>45</td>
<td>37</td>
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</tbody>
</table>

Key:
- S1: Victoria
- S2: New South Wales
- S3: Queensland
- S4: South Australia
- S5: Western Australia

Average Study Start Up Times: Australia v. Global
Source: Medicines Australia Survey

- **Slower**: 43%
- **Faster**: 14%
- **Same**: 22%
- **Much Faster**: 7%
- **Much slower**: 7%
- **N/A**: 7%
Recruitment – Local Experience

Average Recruitment Rate: Australia v. Global
Source: Medicines Australia Survey

Phase I
- Below Average: 0%
- On Par: 50%
- Above Average: 50%

Phase II
- Below Average: 25%
- On Par: 50%
- Above Average: 25%

Phase III
- Below Average: 41%
- On Par: 42%
- Above Average: 17%

Phase IV
- Below Average: 10%
- On Par: 70%
- Above Average: 20%

Average Recruitment Rate: Australia v. Global
Source: Medicines Australia Survey
## Per Patient Cost – Median (Standardised; excl. tax concessions; AUS$1 = US$0.82)

### Phase I
Source: Medicines Australia Analysis

<table>
<thead>
<tr>
<th>Country</th>
<th>Cost</th>
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</thead>
<tbody>
<tr>
<td>Japan</td>
<td>1.38</td>
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<tr>
<td>United States</td>
<td>1.26</td>
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<tr>
<td>Canada</td>
<td>1.09</td>
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<td>Australia</td>
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### Phase III
Source: Medicines Australia Analysis

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<tr>
<td>India</td>
<td>0.27</td>
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</tbody>
</table>
Case Study (Company Data) – Start Up

Study Start Up Times (Individual Trials, Australia), 2014
Calendar Days
Source: Company Data

Study Start Up Times, 2014 – Calendar Days
Source: Company Data
Case Study (Company Data) – Recruitment

New Patients – All Regions
Clinical Trials (All Phases), 2014
Source: Company Data

- W. Europe, 41%
- N. America, 28%
- ME/Africa, 2%
- Latin America, 3%
- Asia Pac (excl. AUS), 15%
- E. Europe, 1%
- C. Europe, 9%

Australia, 1%

New Patients – Asia-Pac
Clinical Trials (All Phases), 2014
Source: Company Data

- South Korea, 32%
- China, 24%
- Taiwan, 13%
- Singapore, 12%
- Hong Kong, 2%
- New Zealand, 3%

Australia, 7%
Case Study (Company Data) – Recruitment

(Average) Patients Per Site, Clinical Trials (All Phases), 2014
Source: Company Data

<table>
<thead>
<tr>
<th>Country</th>
<th>Average Patients</th>
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Questions