Promoting Profile Adoption by Clinical Trialists

Annual Meeting
Thursday, 13 June 2019

Agenda

<table>
<thead>
<tr>
<th>time [min]</th>
<th>item</th>
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<tbody>
<tr>
<td>T₀ + 00-05</td>
<td>Mozley: review specific aims for panel discussion, etc.</td>
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<tr>
<td>T₀ + 05-10</td>
<td>Siegelman: What has worked and why. What hasn’t.</td>
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<tr>
<td>T₀ + 15-20</td>
<td>Panel: Comparison of what has worked and what hasn’t.</td>
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<td>T₀ + 25-30</td>
<td>open microphone: audience suggestions for new action items.</td>
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Specific Aims

• To critically review adoption of profiles by trialists
  – identify factors that have led to success, including
    • easily understandable use cases
    • How major decisions could be based on outcome:
      – business decisions
      – regulatory decisions
    – review missed opportunities
      • disinclination to move beyond status quo
      • inability to see how profiles would change decisions
• To identify new strategies for promoting adoption

Specific Questions

• Are profiles written in the best language for trialists to understand?
• Are executive summaries written for the decision makers, e.g., busy pharmaceutical division managers?
• Are management decisions that can be based on the profile clearly stated?