**Clinical Trial Data – Reducing The Time To Submission**

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**Abstract**

Objectives:

- For patients and physicians to view faster of the latest clinical trial findings.
- For industry to improve its ability to provide timely and comprehensive clinical trial results.

**Research Design and Methods:**

- The plan is to describe the times from PCD to submission, all primary manuscripts in one therapeutic area for a PCD between 2008 and 2011, and a journal submission date. The primary manuscripts were found by searching PubMed and Medline for all studies in one therapeutic area (TA) that had PCD between 2008 and 2011, and a journal submission date. The primary manuscripts were then reviewed for the following information: start date, PCD, and submission date. The data were collected in a database and analyzed. Statistical analyses were performed.

**Results:**

- The results from the pilot study are shown in the next graphic. (Phase 2: Methods to minimize delays were implemented. This streamlined process resulted in significantly faster manuscript submission with the process variables: 3rd draft, mean and median weeks). The pilot study had a number of individuals who were excited to work on this paper and would do it again. The results from the pilot study are shown in the next graphic. The company’s SOP is described below.

**Conclusions:**

- The results from the pilot study are shown in the next graphic. The company’s SOP is described below. The second goal of the project was to map the existing processes to identify potential improvements, and finally assess impact of changes to the process. The results from the pilot study are shown in the next graphic. The pilot study was a success, and the changes made to the process variables: manuscript submission, mean and median weeks.

**Future Directions:**

- Plan ahead.
- Peer reviewed trial data must be made public quickly.
- The results from the pilot study are shown in the next graphic. The company’s SOP is described below. The second goal of the project was to map the existing processes to identify potential improvements, and finally assess impact of changes to the process. The results from the pilot study are shown in the next graphic. The pilot study was a success, and the changes made to the process variables: manuscript submission, mean and median weeks.

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**Keyhole Agenda:**

1. **Plan Ahead**
   - Facilitate the process
   - In order to facilitate the process, there were often multiple reviews for each draft. Frequently more than 3 drafts. The authors’ responses were not coordinated in time.

2. **Identify Key Points**
   - Identify authors for intellectual contributions
   - Generate first draft

3. **Incorporate Comments**
   - Prepare to incorporate comments
   - Incorporate comments

4. **Review Data Critically**
   - Review data critically

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**Sample Agenda for Manuscript kickoff Call**

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Agenda Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5</td>
<td>Introduction to process and goals</td>
</tr>
<tr>
<td>5-10</td>
<td>Review of existing processes</td>
</tr>
<tr>
<td>10-15</td>
<td>Identify authors for intellectual contributions</td>
</tr>
<tr>
<td>15-20</td>
<td>Generate first draft</td>
</tr>
<tr>
<td>20-25</td>
<td>Prepare to incorporate comments</td>
</tr>
<tr>
<td>25-30</td>
<td>Incorporate comments</td>
</tr>
<tr>
<td>30-35</td>
<td>Review data critically</td>
</tr>
</tbody>
</table>

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**Data Collection:**

- The frequency of multiple reviews is shown in the next graphic. There were often multiple reviews for each draft. Frequently more than 3 drafts. The authors’ responses were not coordinated in time.

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**Results:**

- The results from the pilot study are shown in the next graphic. The company’s SOP is described below. The second goal of the project was to map the existing processes to identify potential improvements, and finally assess impact of changes to the process. The results from the pilot study are shown in the next graphic. The pilot study was a success, and the changes made to the process variables: manuscript submission, mean and median weeks.

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**Suggested times for draft submissions:**

<table>
<thead>
<tr>
<th>Draft</th>
<th>Suggested times for submission (weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
<td>1-2</td>
</tr>
<tr>
<td>2nd</td>
<td>2-4</td>
</tr>
<tr>
<td>3rd</td>
<td>3-5</td>
</tr>
</tbody>
</table>

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**Conclusion from Phase 1:**

- The pilot study was successful and published a manuscripts date within 3 months of the pilot study.

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**Learning:**

- The parallel process is aligned and supports ICMJE guidance that all authors should be involved at stages of manuscript development.

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**References:**


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**Acknowledgments:**

- I am very happy with the process to invite all the authors for intellectual contributions. Your effort to finalize the manuscript has been an important and critical component in the successful completion of the project.

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**Authors:**

- The second goal of the project was to map the existing processes to identify potential improvements, and finally assess impact of changes to the process. The results from the pilot study are shown in the next graphic. The pilot study was a success, and the changes made to the process variables: manuscript submission, mean and median weeks.