Project Standard Implementation
Yun Ma, Boehringer Ingelheim
Contents

I. Project Centric Approach (PCA) concept

II. PCA Process Flow

III. Interaction and communication

IV. PSAP and TSAP: Relationship and workflow
Section 1: PCA concept
Challenge at Project Peak Time

Multi-critical timeline
Multi-tasking with all team members
Data integration process
ISS/ISE SAP preparation
Medra/whodra dictionary alignment
Art of Programming Work
Project Centric Approach

- Working concept implemented by project team

1. Centralisation and harmonisation of project standard covering all trial and project deliverables and used for implementation with the end in mind

2. Shift of tasks, resources and effort from trial to project level
Section 2: PCA Process Flow
Programming Flow Chart

- Central ADS
  - ADS are maintained by the same programmers with high expertise;
- Central TFL templates
  - Company standard display plus project/trial specific TFL programs is standardized and easy to re-use;
- Standardized Result Datasets
  - Reduce efforts in validation and review of results
Interaction and communication
Issue – Strategy – Implementation considering example of Statistics

- Many people might work on project level
  - Unclear responsibilities
  - Complex communication

- PSTAT: Statistical project accountability and oversight
- Task responsibility assigned to STAT
- PSTAT confirms decisions

- Clear and transparent assignment of tasks
- Task assignment matrix
- Specialists for certain types of tasks

<table>
<thead>
<tr>
<th>Task</th>
<th>Name1</th>
<th>Name2</th>
<th>Name …</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task 1</td>
<td>Responsible</td>
<td>Associate</td>
<td></td>
</tr>
<tr>
<td>Task 2</td>
<td>Responsible</td>
<td>Associate</td>
<td></td>
</tr>
<tr>
<td>Task …</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Name: Yun Ma
Organization: Boehringer Ingelheim (China) Investment Co., Ltd.
Address: 南京西路1601号越洋广场29楼
City, State ZIP: Shanghai
Work Phone: 52883979
Fax:
E-mail: yun_1.ma@boehringer-ingelheim.com
Web:
Twitter: