Clinical Trials to the Clinic

CLINICAL INFORMATICS NEWS

Conducted December 2013

Study Demographics

Participants reported they were from the following countries:

- **USA**: 76%
- **Europe**: 8%
- **Asia**: 6%
- **Rest of World**: 9%

BioClinica Software Survey

BioClinica and Clinical Informatics News conducted this survey in December 2013 to explore what types of software tools clinical CROs use to forecast clinical supply demand. In this two part survey download, learn about different software used, and whether the software is meeting study participants’ needs. Part I of the survey asks questions of Microsoft Excel users, and Part II digs deeper into the other options available to CROs today.

With 119 respondents, the study is projected to carry a margin-of-error under 2%.

Study Background & Purpose

BioClinica and Clinical Informatics News conducted this survey in December 2013 to explore what types of software tools clinical CROs use to forecast clinical supply demand. In this two part survey download, learn about different software used, and whether the software is meeting study participants’ needs. Part I of the survey asks questions of Microsoft Excel users, and Part II digs deeper into the other options available to CROs today.

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Study Demographics

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BioClinica.com
Does your organization currently use software other than Microsoft Excel to forecast your clinical supply demand?

Part I:
The following data is based on the respondents who answered No to the above question...

Is Excel meeting your needs for forecasting demand?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>64%</td>
<td>36%</td>
</tr>
</tbody>
</table>

If Excel is not meeting your needs for forecasting demand, why not?

- Protocol complexity: 47%
- Difficult to quickly reassess forecast due to study assumptions: 47%
- Difficult to account for REAL subject/inventory activity: 33%
- Unable to capture distribution requirements (i.e. lead times, IRT resupply values, etc.): 30%
- Difficult to plan budgets: 30%
- Error prone: 27%
- All the above: 20%
- Other: 7%
Are you or your organization interested in utilizing a software tool to forecast demand?

The respondents that answered No to the above question, were asked:

Why are you or your organization not interested in utilizing a tool to forecast demand?

The respondents that answered Yes to the above question, were asked:

What is important to you or your organization in a software's capability?

- Ability to forecast multiple study scenarios (i.e. country changes, enrollment rates, etc.)
  - 71%
- Budget Forecasting/Mgmt
  - 61%
- Ability to quickly re-forecast due to study changes
  - 59%
- Ability to forecast based off of REAL subject/inventory data
  - 57%
- Manufacturing planning
  - 23%
- Ability to forecast depot shipments
  - 21%
- Ability to determine best resupply settings for an IRT setup
  - 21%
- All of the above
  - 16%
How important is it for you to have the ability to forecast off of REAL subject and inventory information after a study starts?

- Least Important: 0%
- Somewhat Important: 6%
- Important: 32%
- Very Important: 44%
- Most Important: 18%

How much overage do you on average plan for?

- 10-20%: 29%
- 20-30%: 35%
- 30-40%: 9%
- 40-50%: 15%
- 50-75%: 12%
- Greater than 75%: 0%

How many protocols are you responsible for?

- 1-5: 65%
- 6-10: 18%
- 11-20: 12%
- Greater than 20: 6%
Rate the complexity of the majority of your studies.

<table>
<thead>
<tr>
<th>Complexity</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Simple</td>
<td>0%</td>
</tr>
<tr>
<td>Simple</td>
<td>9%</td>
</tr>
<tr>
<td>Somewhat Complex</td>
<td>53%</td>
</tr>
<tr>
<td>Complex</td>
<td>38%</td>
</tr>
<tr>
<td>Very Complex</td>
<td>0%</td>
</tr>
</tbody>
</table>

How many of your protocols utilize an IRT system?

<table>
<thead>
<tr>
<th>Range</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5</td>
<td>82%</td>
</tr>
<tr>
<td>6-10</td>
<td>12%</td>
</tr>
<tr>
<td>11-20</td>
<td>6%</td>
</tr>
<tr>
<td>Greater than 20</td>
<td>0%</td>
</tr>
</tbody>
</table>

At what point in the protocol process do you begin forecasting efforts?

<table>
<thead>
<tr>
<th>Point</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft protocol</td>
<td>41%</td>
</tr>
<tr>
<td>Protocol concept</td>
<td>38%</td>
</tr>
<tr>
<td>Final protocol</td>
<td>18%</td>
</tr>
<tr>
<td>Other</td>
<td>3%</td>
</tr>
</tbody>
</table>
On average, how often do your major study assumptions (country list, country start dates, enrollment rates, etc.) change prior to first patient in?

<table>
<thead>
<tr>
<th>Frequency</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>18%</td>
</tr>
<tr>
<td>2</td>
<td>38%</td>
</tr>
<tr>
<td>3</td>
<td>32%</td>
</tr>
<tr>
<td>4</td>
<td>0%</td>
</tr>
<tr>
<td>More than 4</td>
<td>12%</td>
</tr>
</tbody>
</table>

How often do you reassess your supply budget?

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily</td>
<td>0%</td>
</tr>
<tr>
<td>Weekly</td>
<td>27%</td>
</tr>
<tr>
<td>Monthly</td>
<td>41%</td>
</tr>
<tr>
<td>Quarterly</td>
<td>27%</td>
</tr>
<tr>
<td>Yearly</td>
<td>0%</td>
</tr>
<tr>
<td>When notified of a study change</td>
<td>6%</td>
</tr>
</tbody>
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How often do you reassess your supply forecast?

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<tr>
<td>Daily</td>
<td>0%</td>
</tr>
<tr>
<td>Weekly</td>
<td>29%</td>
</tr>
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<td>Monthly</td>
<td>50%</td>
</tr>
<tr>
<td>Quarterly</td>
<td>18%</td>
</tr>
<tr>
<td>Yearly</td>
<td>0%</td>
</tr>
<tr>
<td>When notified of a study change</td>
<td>3%</td>
</tr>
</tbody>
</table>
How many hours do you spend monthly forecasting demand?

- 1-3: 27%
- 4-6: 24%
- 7-10: 29%
- 11-13: 9%
- 14-17: 3%
- Greater than 17: 9%
Does your organization currently use software other than Microsoft Excel to forecast your clinical supply demand?

Part II:

The following data is based on the respondents who answered Yes to the above question...

Which of the following software products are used by your company for forecasting clinical supply demand?

- ClinApps: 40%
- CT-Fast: 28%
- Med Sim: 21%
- Optimizer: 3%
- We outsourced to a vendor: 1%
- Other: 0%

Respondents were asked to rate the effectiveness of the following software products or outsourced services that their company uses:

ClinApps

- Very ineffective: 3%
- Somewhat ineffective: 10%
- Effective: 47%
- Very effective: 33%
- Most effective: 7%
Respondents were asked to rate the effectiveness of the following software products or outsourced services that their company uses: (cont’d)
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Outsourced Services

<table>
<thead>
<tr>
<th>Effectiveness</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very ineffective</td>
<td>5%</td>
</tr>
<tr>
<td>Somewhat ineffective</td>
<td>13%</td>
</tr>
<tr>
<td>Effective</td>
<td>49%</td>
</tr>
<tr>
<td>Very effective</td>
<td>28%</td>
</tr>
<tr>
<td>Most effective</td>
<td>5%</td>
</tr>
</tbody>
</table>

What are the features you like about the software that your company uses to forecast clinical supply demand?

Ability to forecast complex studies

<table>
<thead>
<tr>
<th>Software</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>ClinApps</td>
<td>35%</td>
</tr>
<tr>
<td>CT-Fast</td>
<td>10%</td>
</tr>
<tr>
<td>Med Sim</td>
<td>5%</td>
</tr>
<tr>
<td>Optimizer</td>
<td>8%</td>
</tr>
<tr>
<td>Outsourced Vendor</td>
<td>43%</td>
</tr>
</tbody>
</table>

Budget Planning/Mgmt

<table>
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</tr>
<tr>
<td>Optimizer</td>
<td>10%</td>
</tr>
<tr>
<td>Outsourced Vendor</td>
<td>45%</td>
</tr>
</tbody>
</table>
What are the features you like about the software that your company uses to forecast clinical supply demand? (cont’d)

Ability to quickly re-forecast due to study changes

- ClinApps: 31%
- CT-Fast: 5%
- Med Sim: 7%
- Optimizer: 17%
- Outsourced Vendor: 40%

Ability to forecast multiple study scenarios (i.e., country changes, enrollment rates, etc.)

- ClinApps: 33%
- CT-Fast: 5%
- Med Sim: 8%
- Optimizer: 15%
- Outsourced Vendor: 40%

Ability to forecast based off of REAL subject/inventory data

- ClinApps: 27%
- CT-Fast: 7%
- Med Sim: 12%
- Optimizer: 5%
- Outsourced Vendor: 49%
What are the features you like about the software that your company uses to forecast clinical supply demand? (cont’d)

**Ability to determine best resupply settings for an IRT setup manufacturing planning**
- ClinApps: 29%
- CT-Fast: 3%
- Med Sim: 12%
- Optimizer: 12%
- Outsourced Vendor: 44%

**Ability to forecast depot shipments**
- ClinApps: 34%
- CT-Fast: 5%
- Med Sim: 11%
- Optimizer: 8%
- Outsourced Vendor: 42%

**Ability to forecast based off of REAL subject/inventory data**
- ClinApps: 28%
- CT-Fast: 3%
- Med Sim: 5%
- Optimizer: 15%
- Outsourced Vendor: 50%
What do you not like about the software that your company uses to forecast clinical supply demand?

**Inability to forecast complex studies**
- ClinApps: 27%
- CT-Fast: 20%
- Med Sim: 13%
- Optimizer: 7%
- Outsourced Vendor: 33%

**Inability to Budget Plan**
- ClinApps: 18%
- CT-Fast: 29%
- Med Sim: 0%
- Optimizer: 12%
- Outsourced Vendor: 41%

**Inability to quickly re-forecast due to study changes**
- ClinApps: 13%
- CT-Fast: 13%
- Med Sim: 20%
- Optimizer: 7%
- Outsourced Vendor: 47%
What do you **not like** about the software that your company uses to forecast clinical supply demand? *(cont’d)*

**Inability to forecast multiple study scenarios (i.e., country changes, enrollment rates, etc.):**
- ClinApps: 24%
- CT-Fast: 18%
- Med Sim: 6%
- Optimizer: 18%
- Outsourced Vendor: 35%

**Inability to forecast based off of REAL subject/inventory data:**
- ClinApps: 27%
- CT-Fast: 20%
- Med Sim: 7%
- Optimizer: 7%
- Outsourced Vendor: 40%

**Inability to forecast depot shipments:**
- ClinApps: 8%
- CT-Fast: 23%
- Med Sim: 15%
- Optimizer: 31%
- Outsourced Vendor: 23%
What do you not like about the software that your company uses to forecast clinical supply demand? (cont’d)

Inability to determine best resupply settings for an IRT setup, manufacturing planning

- ClinApps: 24%
- CT-Fast: 18%
- Med Sim: 12%
- Optimizer: 0%
- Outsourced Vendor: 47%

Difficult User Interface

- ClinApps: 16%
- CT-Fast: 16%
- Med Sim: 0%
- Optimizer: 16%
- Outsourced Vendor: 53%

Cost

- ClinApps: 30%
- CT-Fast: 15%
- Med Sim: 11%
- Optimizer: 4%
- Outsourced Vendor: 41%
How important is it for you to have the ability to forecast off of REAL subject and inventory information after a study starts?

- Least Important: 0%
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- Important: 36%
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How many protocols are you responsible for?

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Rate the complexity of the majority of your studies.

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