Tufts – Veeva 2017 eClinical Landscape Study

- Assessing Data Management Practices, Performance, and Challenges
- Usage of Data Sources, Management Applications, and their Challenges
About the Tufts – Veeva 2017 eClinical Landscape Study

- Conducted online between May – July 2017
- 257 Unique Companies Responded
- Respondent Years of Experience in Clinical Data Management
  - Mean of 16.5 (Median 16 years)
- 87.9% of Respondents Located in the U.S.

Clinical Data Management Responsibility*

- Frequent User, 26%
- Primary Person Responsible, 32%
- One of Several Responsible, 41%
3 Subgroup Stratifications

• Company Type*
  • Sponsors (N=193)
  • CROs (N=56)

• Company Size (Total Clinical Trial Volume Annually)**
  • Low: < 5 trials, median = 2 (N=84)
  • Medium: 5-15 trials, median = 8 (N=80)
  • High: > 15 trials, median = 50 (N=93)

• Primary EDC Provider***
  • Industry Leaders (Medidata & Oracle) (N=149)
  • All Others (N=108)

*What is the primary role of the organization you represent?
**How many clinical trials (studies) does your organization initiate each year across all phases?
***What is the primary EDC application your organization uses for the majority of your studies today?
Clinical Data Management Applications Used

Do the clinical studies your organization executes (directly or through a service partner) utilize any of the following applications? Please indicate all that are currently used.
**Average Number of Clinical Trial Applications Used by Company Size**

<table>
<thead>
<tr>
<th>Volume of Clinical Trials Initiated Annually</th>
<th>Average Number of Applications Used*</th>
<th>Coefficient of Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>4.2</td>
<td>.40</td>
</tr>
<tr>
<td>Medium</td>
<td>5.5</td>
<td>.42</td>
</tr>
<tr>
<td>High</td>
<td>6.5</td>
<td>.33</td>
</tr>
</tbody>
</table>

*Subgroup differences are significant (p<.05)

Do the clinical studies your organization executes (directly or through a service partner) utilize any of the following applications? Please indicate all that are currently used.
Specific Clinical Data Management Applications Used by Company Size

Percent of companies using either proprietary or commercial applications

- Electronic Data Capture (EDC)
  - Low Trial Volume (<5 Trials Initiated Annually): 100%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 100%
  - High Trial Volume (>15 Trials Initiated Annually): 100%

- Safety/Pharmacovigilance
  - Low Trial Volume (<5 Trials Initiated Annually): 65%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 65%
  - High Trial Volume (>15 Trials Initiated Annually): 80%

- Electronic Trial Master File (eTMF)
  - Low Trial Volume (<5 Trials Initiated Annually): 60%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 65%
  - High Trial Volume (>15 Trials Initiated Annually): 83%

- Randomization and Trial Supply Management
  - Low Trial Volume (<5 Trials Initiated Annually): 60%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 60%
  - High Trial Volume (>15 Trials Initiated Annually): 80%

- Clinical Trial Management System (CTMS)
  - Low Trial Volume (<5 Trials Initiated Annually): 43%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 63%
  - High Trial Volume (>15 Trials Initiated Annually): 76%

- eCOA / ePRO
  - Low Trial Volume (<5 Trials Initiated Annually): 25%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 50%
  - High Trial Volume (>15 Trials Initiated Annually): 71%

- Paper CRF
  - Low Trial Volume (<5 Trials Initiated Annually): 24%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 36%
  - High Trial Volume (>15 Trials Initiated Annually): 37%

- Investor Grant Payments
  - Low Trial Volume (<5 Trials Initiated Annually): 17%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 29%
  - High Trial Volume (>15 Trials Initiated Annually): 29%

- Electronic Medical Record (EHR/EMR)
  - Low Trial Volume (<5 Trials Initiated Annually): 14%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 24%
  - High Trial Volume (>15 Trials Initiated Annually): 33%

- Electronic source data capture (eSource)
  - Low Trial Volume (<5 Trials Initiated Annually): 5%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 18%
  - High Trial Volume (>15 Trials Initiated Annually): 31%

- Study start-up
  - Low Trial Volume (<5 Trials Initiated Annually): 2%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 20%
  - High Trial Volume (>15 Trials Initiated Annually): 19%

- Other (please specify)
  - Low Trial Volume (<5 Trials Initiated Annually): 1%
  - Medium Trial Volume (5-15 Trials Initiated Annually): 4%
  - High Trial Volume (>15 Trials Initiated Annually): 4%

*Differences are significant (p<.05)*

Do the clinical studies your organization executes (directly or through a service partner) utilize any of the following applications? Please indicate all that are currently used.
Specific Clinical Data Management Applications Used by Company Type

Percent of companies using either proprietary or commercial applications

- **Electronic Data Capture (EDC)**
  - Sponsor: 100%
  - CRO: 100%

- **Randomization and Trial Supply Management**
  - Sponsor: 76%
  - CRO: 88%

- **Electronic Trial Master File (eTMF)**
  - Sponsor: 64%
  - CRO: 72%

- **Clinical Trial Management System (CTMS)**
  - Sponsor: 61%
  - CRO: 64%

- **Safety/Pharmacovigilance**
  - Sponsor: 63%
  - CRO: 75%

- **eCOA / ePRO**
  - Sponsor: 48%
  - CRO: 55%

- **Paper CRF**
  - Sponsor: 26%
  - CRO: 52%

- **Electronic source data capture (eSource)**
  - Sponsor: 14%
  - CRO: 32%

- **Investor Grant Payments**
  - Sponsor: 25%
  - CRO: 32%

- **Electronic Medical Record (EHR/EMR)**
  - Sponsor: 18%
  - CRO: 27%

- **Study start-up**
  - Sponsor: 13%
  - CRO: 20%

- **Other (please specify)**
  - Sponsor: 3%
  - CRO: 4%

* Differences are significant (p<.05)

Do the clinical studies your organization executes (directly or through a service partner) utilize any of the following applications? Please indicate all that are currently used.
Types of Data Companies Manage in Their Primary EDC

Percent of companies

- eCRF Data: 100.0%
- Local Lab Data: 59.5%
- QoL Data: 59.5%
- Central Lab Data: 56.8%
- ePRO Data: 34.2%
- Pharmacokinetic Data: 33.9%
- Biomarker Data: 28.0%
- PharmacoDynamic Data: 21.4%
- eCOA Data: 20.6%
- Medical Images: 20.2%
- Mobile Health Data: 9.7%
- Genomic Data: 9.7%

What data does your organization manage in their primary EDC application? Select all that apply.
Volume of Data Companies Manage in Their Primary EDC

Average reported volume of data managed in primary EDC

- eCRF Data: 77.5%
- Central Lab Data: 4.8%
- Local Lab Data: 4.7%
- QoL Data: 3.9%
- ePRO Data: 3.3%
- Pharmacokinetic Data: 1.3%
- Medical Images: 1.2%
- eCOA Data: 1.1%
- Biomarker Data: 0.8%
- PharmacoDynamic Data: 0.5%
- Genomic Data: 0.4%
- Mobile Health Data: 0.3%

What data does your organization manage in their primary EDC application? Select all that apply and specify the percentage of the total data attributed to each.
Types of Data Companies Manage in Their Primary EDC vs. Volume of Data Reported

What data does your organization manage in their primary EDC application? Select all that apply and specify the percentage of the total data attributed to each.
Select the frequency with which your organization utilizes data from the following sources currently and estimate the frequency of utilization in three years. (Data source utilization corresponds to frequencies of “always”, “often”, or “sometimes”)

- **EDC**
  - Data Used Currently: 100.0%
  - Projected Data Usage in 3 Years: 100.0%

- **eInformed Consent**
  - Data Used Currently: 92.7%
  - Projected Data Usage in 3 Years: 92.6%

- **eCOA / ePRO**
  - Data Used Currently: 69.6%
  - Projected Data Usage in 3 Years: 91.6%

- **Smart Phone**
  - Data Used Currently: 44.8%
  - Projected Data Usage in 3 Years: 84.1%

- **eSource**
  - Data Used Currently: 38.4%
  - Projected Data Usage in 3 Years: 82.7%

- **Custom Apps**
  - Data Used Currently: 29.2%
  - Projected Data Usage in 3 Years: 76.3%

- **mHealth**
  - Data Used Currently: 32.1%
  - Projected Data Usage in 3 Years: 61.8%

- **Personal Cardiac Monitoring**
  - Data Used Currently: 31.9%
  - Projected Data Usage in 3 Years: 55.4%

- **Blood Glucose Monitoring**
  - Data Used Currently: 0%
  - Projected Data Usage in 3 Years: 0%
Percent of Respondents Increasing Use of Any Data Source Over 3 Years

- Increasing Use of Any Data Source Over 3 Years: 97.2%
- Neither Increasing Nor Decreasing Use of Any Data Source Over 3 Years: 2.8%

Select the frequency with which your organization utilizes data from the following sources currently and estimate the frequency of utilization in three years.
Proportion of Companies Projecting Change in Total Data Sources Used in 3 Years

- Increasing Number of Data Sources in 3 Years: 69.7%
- Decreasing Number of Sources in 3 Years: 4.5%
- No Change in Number of Sources in 3 Years: 25.8%

Select the frequency with which your organization utilizes data from the following sources currently and estimate the frequency of utilization in three years. (Data source utilization corresponds to frequencies of “always”, “often”, or “sometimes”)
# Magnitude of Projected Change in Data Sources Used

<table>
<thead>
<tr>
<th>Data Source</th>
<th>Difference between reported data usage and projected usage in 3 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDC</td>
<td>0.0%</td>
</tr>
<tr>
<td>eInformed Consent</td>
<td>61.9%</td>
</tr>
<tr>
<td>mHealth</td>
<td>47.1%</td>
</tr>
<tr>
<td>Smart Phone</td>
<td>46.8%</td>
</tr>
<tr>
<td>eSource</td>
<td>45.7%</td>
</tr>
<tr>
<td>Custom Apps</td>
<td>42.3%</td>
</tr>
<tr>
<td>Personal Cardiac Monitoring</td>
<td>29.7%</td>
</tr>
<tr>
<td>Blood Glucose Monitoring</td>
<td>23.5%</td>
</tr>
<tr>
<td>eCOA / ePRO</td>
<td>23.0%</td>
</tr>
</tbody>
</table>

Select the frequency with which your organization utilizes data from the following sources currently and estimate the frequency of utilization in three years. (Data source utilization corresponds to frequencies of “always”, “often”, or “sometimes”)

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*Image of a table showing the magnitude of projected change in data sources used.*
Projected Data Sources Used in 3 Years by Company Type

Select the frequency with which your organization utilizes data from the following sources currently and estimate the frequency of utilization in three years. (Data source utilization corresponds to frequencies of “always”, “often”, or “sometimes”)

*Differences are significant (p<.05)
### Projected Data Sources Used in 3 Years by Company Size

<table>
<thead>
<tr>
<th>Source</th>
<th>Low Clinical Trial Volume</th>
<th>Medium Clinical Trial Volume</th>
<th>High Clinical Trial Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>eInformed Consent*</td>
<td>84.4%</td>
<td>87.5%</td>
<td>88.0%</td>
</tr>
<tr>
<td>Smart Phone</td>
<td>91.1%</td>
<td>96.6%</td>
<td>95.1%</td>
</tr>
<tr>
<td>eCOA / ePRO</td>
<td>88.0%</td>
<td>91.3%</td>
<td>95.1%</td>
</tr>
<tr>
<td>mHealth*</td>
<td>79.5%</td>
<td>79.5%</td>
<td>79.5%</td>
</tr>
<tr>
<td>Custom Apps*</td>
<td>52.4%</td>
<td>70.7%</td>
<td>79.6%</td>
</tr>
<tr>
<td>eSource</td>
<td>85.0%</td>
<td>91.2%</td>
<td>89.1%</td>
</tr>
<tr>
<td>Personal Cardiac Monitoring*</td>
<td>68.2%</td>
<td>79.6%</td>
<td>68.2%</td>
</tr>
<tr>
<td>Blood Glucose Monitoring</td>
<td>37.0%</td>
<td>30.0%</td>
<td>57.9%</td>
</tr>
</tbody>
</table>

*Percent of companies

Differences are significant (p<.05)

Select the frequency with which your organization utilizes data from the following sources currently and estimate the frequency of utilization in three years. (Data source utilization corresponds to frequencies of “always”, “often”, or “sometimes”)

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* Differences are significant (p<.05)
*With specific reference to your organization's clinical data management systems, what is the biggest challenge you face today?
### Biggest Single Reported CDMS Challenge (1 of 2)

<table>
<thead>
<tr>
<th>Percent Rate the Biggest Challenge</th>
<th>Overall (N=257)</th>
<th>CRO (N=56)</th>
<th>Sponsor (N=193)</th>
<th>Leading EDC (N=149)</th>
<th>Other EDC (N=108)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle Time Challenges (Time from Protocol – FPFV or Time from LPLV – Database Lock)</td>
<td>29.7%</td>
<td>31.5%</td>
<td>29.4%</td>
<td>29.0%</td>
<td>30.7%</td>
</tr>
<tr>
<td>Costs in Clinical R&amp;D</td>
<td>29.3%</td>
<td>20.4%</td>
<td>31.0%</td>
<td>30.3%</td>
<td>27.7%</td>
</tr>
<tr>
<td>Number of Systems in Clinical R&amp;D</td>
<td>17.5%</td>
<td>22.2%</td>
<td>16.9%</td>
<td>20.0%</td>
<td>13.9%</td>
</tr>
<tr>
<td>Volume of Source Data Verification</td>
<td>17.1%</td>
<td>16.7%</td>
<td>17.4%</td>
<td>16.6%</td>
<td>17.8%</td>
</tr>
<tr>
<td>Other (Protocol Related, System Related, etc.)</td>
<td>4.9%</td>
<td>3.7%</td>
<td>5.4%</td>
<td>3.5%</td>
<td>6.9%</td>
</tr>
<tr>
<td>No CDMS Challenges</td>
<td>1.6%</td>
<td>5.6%</td>
<td>0%</td>
<td>0.7%</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

With specific reference to your organization's clinical data management systems, what is the biggest challenge you face today? (select one)
### Biggest Single Reported CDMS Challenge (2 of 2)

<table>
<thead>
<tr>
<th>Percent Rate the Biggest Challenge</th>
<th>Overall (N=257)</th>
<th>Low Trial Volume (N=84)</th>
<th>Medium Trial Volume (N=80)</th>
<th>High Trial Volume (N=93)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle Time Challenges (Time from Protocol – FPFV or Time from LPLV – Database Lock)</td>
<td>29.7%</td>
<td>29.1%</td>
<td>29.0%</td>
<td>30.8%</td>
</tr>
<tr>
<td>Costs in Clinical R&amp;D*</td>
<td>29.3%</td>
<td>40.5%</td>
<td>31.6%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Number of Systems in Clinical R&amp;D*</td>
<td>17.5%</td>
<td>8.9%</td>
<td>14.5%</td>
<td>27.5%</td>
</tr>
<tr>
<td>Volume of Source Data Verification</td>
<td>17.1%</td>
<td>16.5%</td>
<td>17.1%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Other (Protocol Related, System Related, etc.)</td>
<td>4.9%</td>
<td>5.1%</td>
<td>2.6%</td>
<td>6.6%</td>
</tr>
<tr>
<td>No CDMS Challenges*</td>
<td>1.6%</td>
<td>0%</td>
<td>5.3%</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Differences are significant (p<.05)

With specific reference to your organization's clinical data management systems, what is the biggest challenge you face today? (select one)
Data Management Cycle Time
(In Days)

- **Time to Build and Release Study Database (N=220)**: 68.3 days (CoV = .48)
- **Time from Patient Visit to Data Entered into the EDC (N=230)**: 8.1 days (CoV = .93)
- **Time from Study’s Last Patient Last Visit to Database Lock (N=236)**: 36.3 days (CoV = .91)

*On average, how many weeks does it take for your company to build and release a study database, including all edit checks?*

**On average, how many days do you estimate it takes from the patient visit to when the patient’s data is entered into the EDC application?**

***On average for phase II and III trials, how many days do you estimate it takes from the study’s last patient out (LPO)/last patient last visit (LPLV) to database lock (all data)?**
Average Time to Build and Release a Study Database
(in Days)

- **Overall**: 68.3 days, CoV = 0.48
- **CRO**: 52.8 days, CoV = 0.45
- **Sponsor**: 73.4 days, CoV = 0.46
- **Low Trial Volume**: 72.8 days, CoV = 0.40
- **Medium Trial Volume**: 60.2 days, CoV = 0.62
- **High Trial Volume**: 71.4 days, CoV = 0.43
- **Industry Leading EDC**: 75 days, CoV = 0.38
- **Other EDC**: 60.2 days, CoV = 0.60

On average, how many weeks does it take for your company to build and release a study database, including all edit checks?
Average Time for Site Staff to Enter Patient Data
(in Days)

<table>
<thead>
<tr>
<th>Category</th>
<th>Average Time</th>
<th>CoV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>8.1</td>
<td>.93</td>
</tr>
<tr>
<td>CRO</td>
<td>6.8</td>
<td>.66</td>
</tr>
<tr>
<td>Sponsor</td>
<td>8.4</td>
<td>.92</td>
</tr>
<tr>
<td>Low Trial Volume</td>
<td>8.2</td>
<td>.95</td>
</tr>
<tr>
<td>Medium Trial Volume</td>
<td>7.7</td>
<td>1.0</td>
</tr>
<tr>
<td>High Trial Volume</td>
<td>8.4</td>
<td>.87</td>
</tr>
<tr>
<td>Industry Leading EDC</td>
<td>9</td>
<td>1.18</td>
</tr>
<tr>
<td>Other EDC</td>
<td>6.8</td>
<td>.78</td>
</tr>
</tbody>
</table>

On average, how many days do you estimate it takes from the patient visit to when the patient's data is entered into the EDC application?
Average Time to Lock a Study Database (in Days)

<table>
<thead>
<tr>
<th>Category</th>
<th>Average Time (Days)</th>
<th>CoV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>36.3</td>
<td>.91</td>
</tr>
<tr>
<td>CRO</td>
<td>27.7</td>
<td>.75</td>
</tr>
<tr>
<td>Sponsor</td>
<td>38.7</td>
<td>.91</td>
</tr>
<tr>
<td>Low Trial Volume</td>
<td>42.7</td>
<td>.75</td>
</tr>
<tr>
<td>Medium Trial Volume</td>
<td>33.7</td>
<td>.67</td>
</tr>
<tr>
<td>High Trial Volume</td>
<td>33.7</td>
<td>1.19</td>
</tr>
<tr>
<td>Industry Leading EDC</td>
<td>39.4</td>
<td>.92</td>
</tr>
<tr>
<td>Other EDC</td>
<td>31.8</td>
<td>.85</td>
</tr>
</tbody>
</table>

On average for phase II and III trials, how many days do you estimate it takes from the study's last patient out (LPO)/last patient last visit (LPLV) to database lock (all data)?
## Top Causes of Database Build Delays

<table>
<thead>
<tr>
<th>Cause</th>
<th>Percent of Total (N=257)</th>
<th>CROs (N=56)</th>
<th>Sponsors (N=193)</th>
<th>Industry Leaders (N=149)</th>
<th>Other EDC (N=115)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Changes</td>
<td>45.1%</td>
<td>51.8%</td>
<td>43.5%</td>
<td>47.0%</td>
<td>42.6%</td>
</tr>
<tr>
<td>User Acceptance Testing (Including Review and Approvals)</td>
<td>16.7%</td>
<td>12.5%</td>
<td>17.6%</td>
<td>14.1%</td>
<td>20.4%</td>
</tr>
<tr>
<td>Database Design Functionality</td>
<td>15.2%</td>
<td>7.1%</td>
<td>17.6%</td>
<td>12.1%</td>
<td>19.4%</td>
</tr>
<tr>
<td>Study Database Move from Development into Production</td>
<td>8.2%</td>
<td>7.1%</td>
<td>8.8%</td>
<td>10.7%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Standards Management</td>
<td>4.3%</td>
<td>0%</td>
<td>5.7%</td>
<td>6.7%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Ethics Approval Delays/Changes</td>
<td>1.2%</td>
<td>1.8%</td>
<td>1.0%</td>
<td>1.3%</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

To the best of your knowledge, what is the most common cause for delays when your organization is building clinical trial databases?
## Association Between Causes of Delays and Cycle Times

<table>
<thead>
<tr>
<th></th>
<th>Percent of Total (N=257)</th>
<th>*Time from LPLV to DB Lock</th>
<th>Coefficient of Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Changes</td>
<td>45.1%</td>
<td>31.8 Days</td>
<td>.73</td>
</tr>
<tr>
<td>User Acceptance Testing</td>
<td>16.7%</td>
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<td>.90</td>
</tr>
<tr>
<td>Database Design Functionality</td>
<td>15.2%</td>
<td>50.4 Days</td>
<td>1.15</td>
</tr>
<tr>
<td>Study Database Move</td>
<td>8.2%</td>
<td>39 Days</td>
<td>.57</td>
</tr>
<tr>
<td>Standards Management</td>
<td>4.3%</td>
<td>37.5 Days</td>
<td>.51</td>
</tr>
<tr>
<td>Ethics Approval Delays/Changes</td>
<td>1.2%</td>
<td>33.3 Days</td>
<td>.46</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td><strong>100%</strong></td>
<td><strong>36.3 Days</strong></td>
<td><strong>.91</strong></td>
</tr>
</tbody>
</table>

To the best of your knowledge, what is the most common cause for delays when your organization is building clinical trial databases?

*On average for phase II and III trials, how many days do you estimate it takes from the study's last patient out (LPO)/last patient last visit (LPLV) to database lock (all data)?
Challenges Loading Data into Primary EDC

- Loading Issues, 77%
- No Loading Issues, 23%
- Integration Issues, 34%
- EDC System Limitations, 32%
- Technical Demands on Support Staff, 29%
- Other, 5%

What, if anything, prevents your company from loading data into your organization's primary EDC application?
Specific Factors Preventing Respondents from Loading Data into Their Primary EDC

Factors Selected (Multiple)

- Cost/Effort of Integration: 34.3%
- EDC System Limitation: 18.8%
- Technical Demands with Internal Support Staff: 15.5%
- Technical Demands with External Support Staff: 13.9%
- EDC System Financial Penalty: 7.5%
- EDC System Performance Penalty: 5.2%
- Other: 4.9%

What, if anything, prevents your company from loading data into your organization's primary EDC application?
## Downstream Impact of EDC Release after FPFV

<table>
<thead>
<tr>
<th>Incidence</th>
<th>Percent</th>
<th>Time from Patient Visit to Data Entry **</th>
<th>Coefficient of Variation</th>
<th>Time from LPLV to DB Lock ***</th>
<th>Coefficient of Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never (N=39)</td>
<td>15.2%</td>
<td>5.4 Days</td>
<td>.87</td>
<td>31.4 Days</td>
<td>.72</td>
</tr>
<tr>
<td>Rarely (N=135)</td>
<td>52.5%</td>
<td>7.8 Days</td>
<td>.89</td>
<td>34.4 Days</td>
<td>1.06</td>
</tr>
<tr>
<td>Often (N=70)</td>
<td>27.2%</td>
<td>10.1 Days</td>
<td>.94</td>
<td>41.7 Days</td>
<td>.75</td>
</tr>
<tr>
<td>Always (N=7)</td>
<td>2.7%</td>
<td>10.2 Days</td>
<td>.66</td>
<td>53.8 Days</td>
<td>.58</td>
</tr>
</tbody>
</table>

*In general, how often does first patient first visit occur before EDC is fully released (i.e. the production release of all screens, all validation checks, and all data processing requirements)?

**On average, how many days do you estimate it takes from the patient visit to when the patient's data is entered into the EDC application?

***On average for phase II and III trials, how many days do you estimate it takes from the study's last patient out (LPO)/last patient last visit (LPLV) to database lock (all data)?
In general, how often does first patient first visit occur before EDC is fully released (i.e. the production release of all screens, all validation checks, and all data processing requirements)?
Incidence of EDC Release After FPFV

In general, how often does first patient first visit occur before EDC is fully released (i.e. the production release of all screens, all validation checks, and all data processing requirements)?
About

• About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums.

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