Clinical Trial Management Systems Survey

Conducted: January 2013

Study Background & Purpose

In January 2013, eCliniqua and BioClinica conducted a survey within the biotechnology and pharmaceutical sector on Clinical Trial Management Systems. The purpose of the study was to determine how clinical trial management systems are used, what types, and for which purposes as well as the processes used within the organizations of the respondents.

With 525 respondents the study is projected to carry a margin-of-error under 2%.

BIOCLINICA is a global provider of integrated, technology-enhanced clinical trial management solutions. BioClinica operates regulatory-body-compliant imaging core labs on two continents, and supports worldwide eClinical and data management services from offices in the United States and Europe. As an Imaging Core Lab and Electronic Data Capture pioneer, BioClinica offers clinical trial management solutions, technology and expertise resulting from more than 20 years of experience.
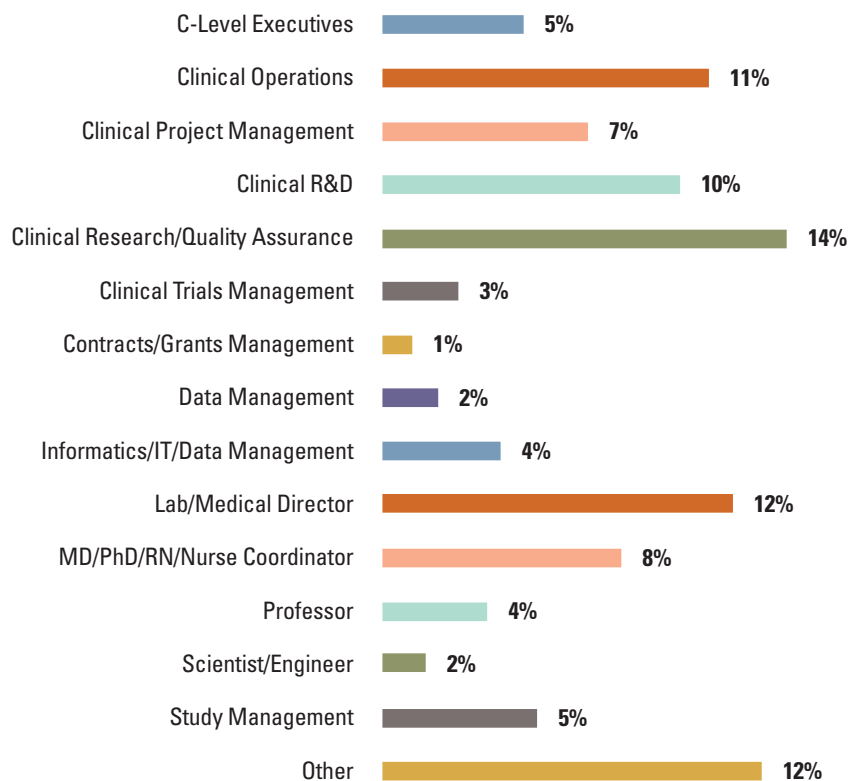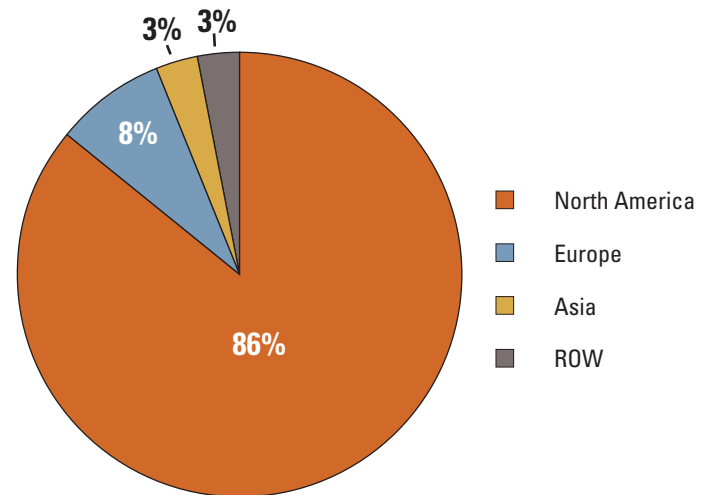**BioClinica.com**

eCliniqua is an online publication that focuses on innovative technologies to manage clinical trials and enable drug discovery. Areas of regular coverage: electronic data capture; patient recruitment; technologies and practices; clinical trial informatics including ePRO (patient reported outcomes), clinical trial management software, trial master files, and case report forms; trial design; adaptive clinical trials; contract and clinical research organizations; regulatory issues; site selection and site monitoring.
**eCliniqua.com**

Study Audience

Participants were from the following countries and reported the following job functions:

Pie chart: North America 86%, Europe 8%, Asia 3%, ROW 3%

- C-Level Executives 5%
- Clinical Operations 11%
- Clinical Project Management 7%
- Clinical R&D 10%
- Clinical Research/Quality Assurance 14%
- Clinical Trials Management 3%
- Contracts/Grants Management 1%
- Data Management 2%
- Informatics/IT/Data Management 4%
- Lab/Medical Director 12%
- MD/PhD/RN/Nurse Coordinator 8%
- Professor 4%
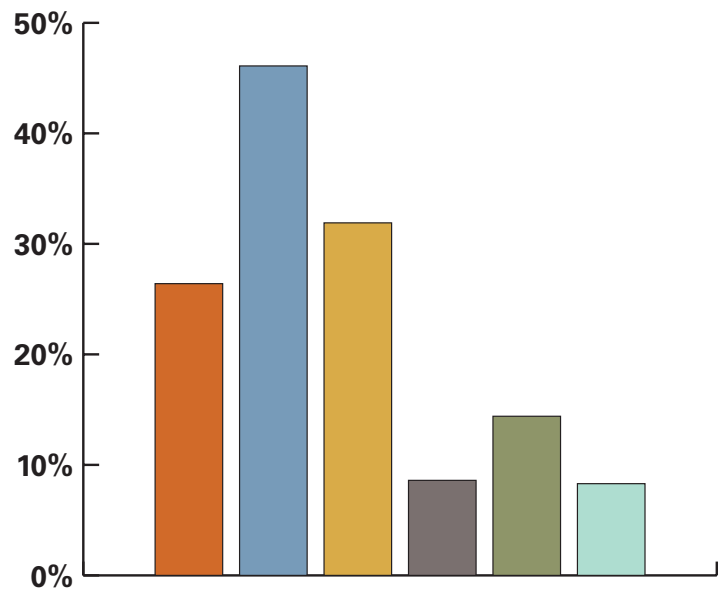- Scientist/Engineer 2%
- Study Management 5%
- Other 12%

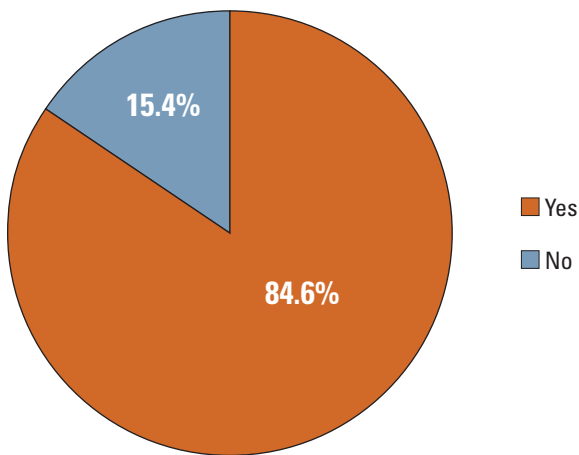# Use of Digital Software

Overall Sample Size: 525

1. Does your organization currently use digital software to manage clinical trials, even if it is not specifically labeled as a clinical trial management system (CTMS)?

- 40.1%
- 59.9%
- Yes
- No
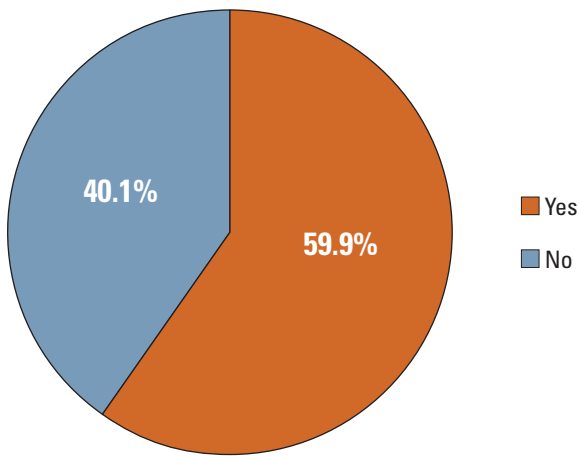
2. Of the respondents that answered yes, participants were asked to select from the following regarding which type of CTMS they use:

- A traditional CTMS product
- A web-based CTMS product
- An in-house built system
- A collection of non-CTMS clinical systems to provide CTMS functions
- Spreadsheets and unconnected calendars
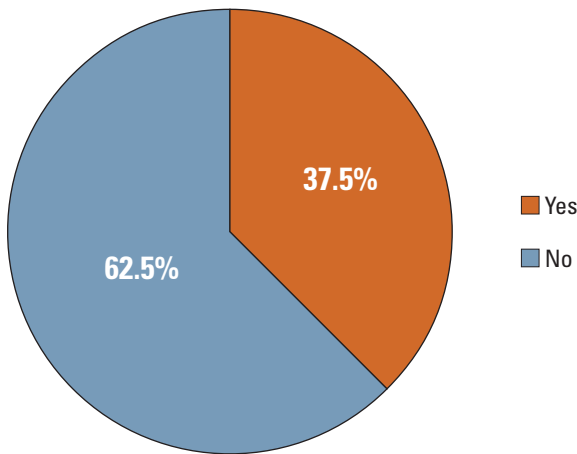- Another solution not listed above

3. Do you personally feel it is necessary for an organization managing clinical trials to use a CTMS or similar digital-based software (as opposed to manual paper-based processes)?

- 15.4%
- 84.6%
- Yes
- No

Outsource of CTMS Functions

4. Does your organization outsource CTMS functions to vendors such as CROs and/or SMOs?


- 37.5% Yes
- 62.5% No

5. Of the respondents that answered yes, participants were asked to select from the following regarding which of the following functions are outsourced:
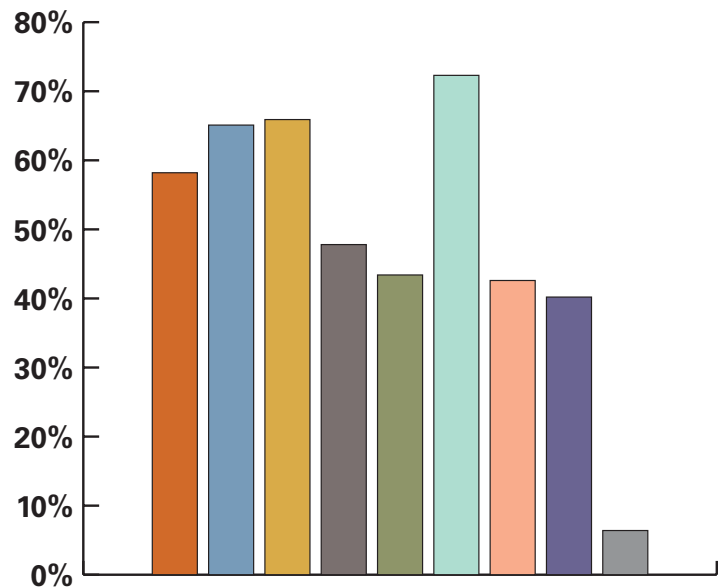

- Site assessment and qualification
- Site initiation and management
- Subject enrollment and schedule tracking
- Regulatory document tracking
- Safety and pharmacovigilance
- Site monitoring
- Site payments
- Inventory and shipment tracking
- Other

Management of Site Payments
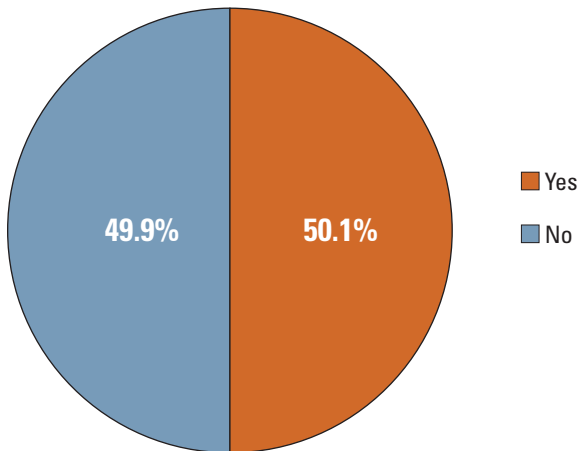
6. Does your organization manage site payments directly?

43.4% | 56.6%
Yes
No
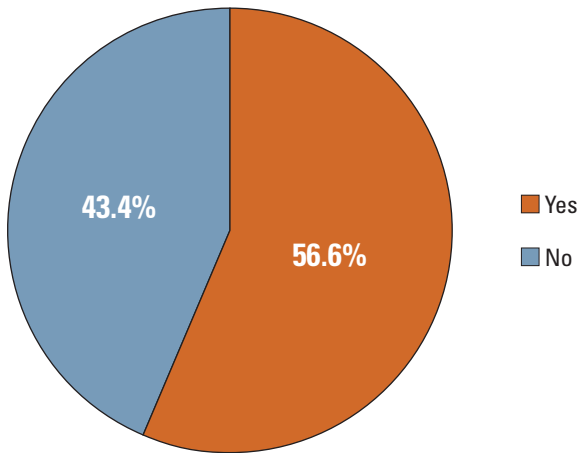
7. Of the respondents that answered yes, participants were asked if their organization uses their CTMS to manage site payments?

23.1%
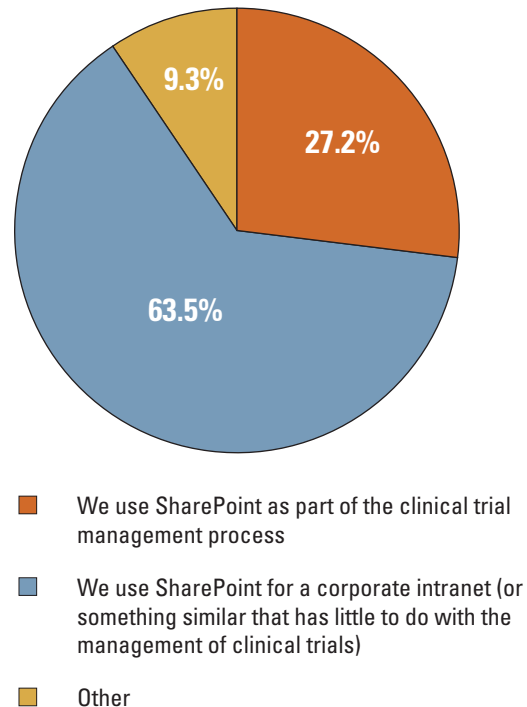76.9%
Yes
No, use another type of management system
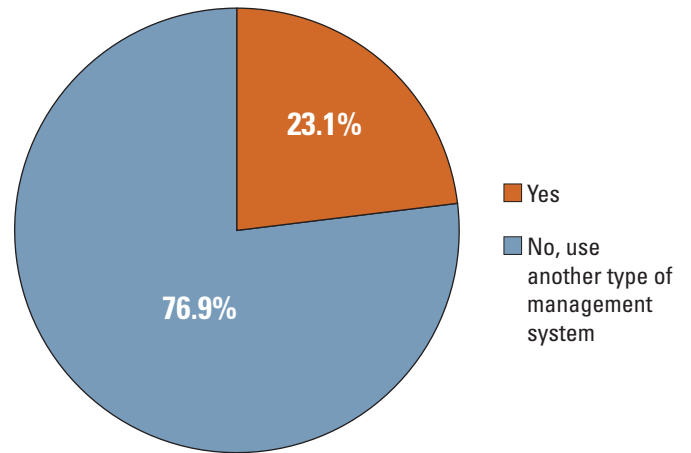
Usage of Microsoft SharePoint

8. Does your organization use Microsoft SharePoint?

49.9% | 50.1%
Yes
No

9. Of the respondents that answered yes, participants were asked how they use SharePoint.

9.3%
27.2%
63.5%

■ We use SharePoint as part of the clinical trial management process

■ We use SharePoint for a corporate intranet (or something similar that has little to do with the management of clinical trials)

■ Other

Usage of Microsoft Outlook

10. Does your organization use Microsoft Outlook?
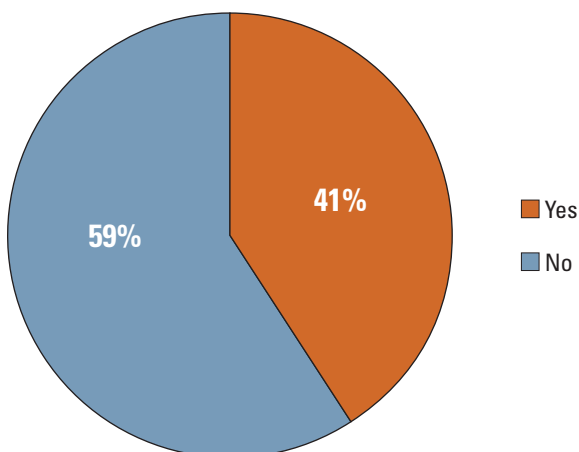

- 10.8% No
- 89.2% Yes

■ Yes
■ No
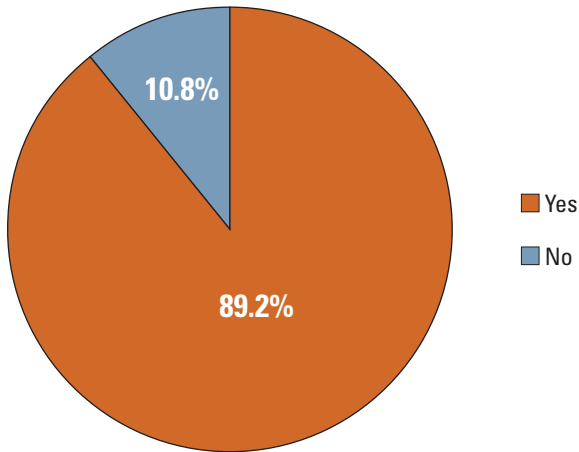
11. Of the respondents that answered yes, participants were asked if employees with permission can synchronize the appropriate CTMS calendars and contacts with Outlook?


- 59.1% No
- 40.9% Yes

■ Yes
■ No
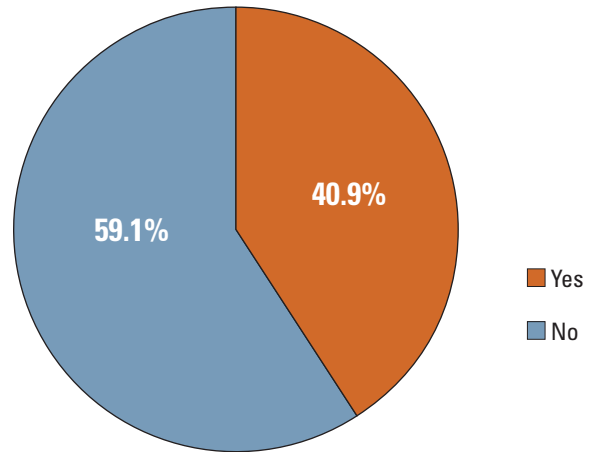
Usage of Microsoft Project

12. Does your organization use Microsoft Project to manage clinical trial project plans?
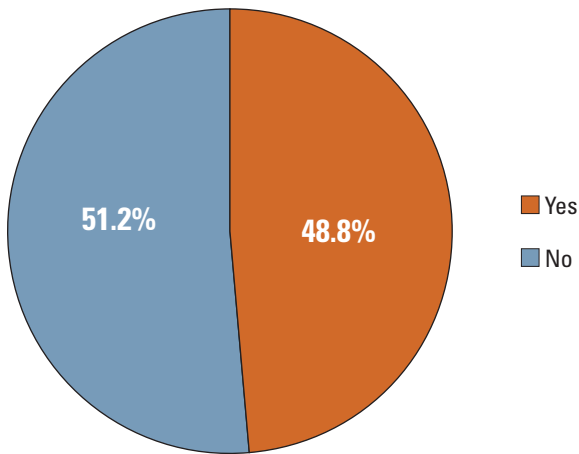

- 59% No
- 41% Yes

■ Yes
■ No

13. Of the respondents that answered yes, participants were asked if employees with permission can synchronize the appropriate CTMS study milestones and/or site visit dates with their Microsoft Project plans?
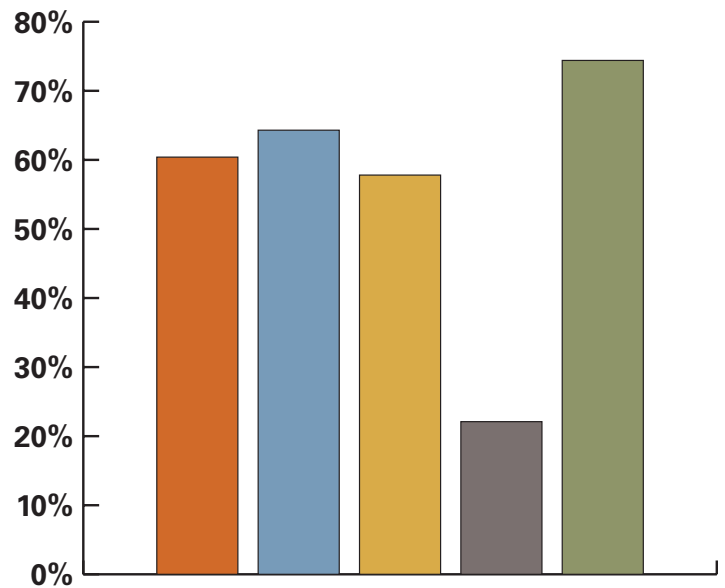

- 54.9% No
- 45.1% Yes

■ Yes
■ No
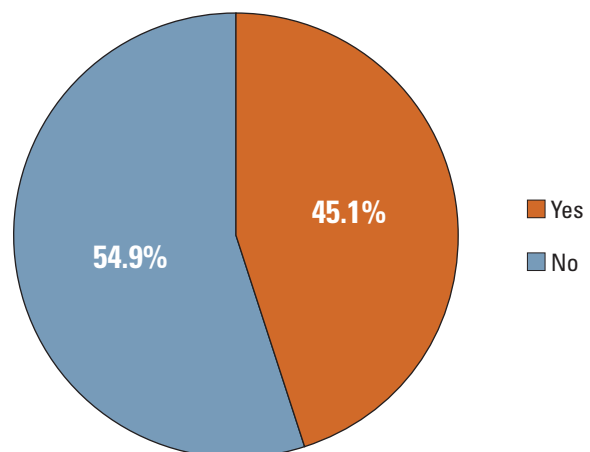
CTMS Reporting

14. Does your organization use CTMS for reporting purposes?


51.2% 48.8%

■ Yes
■ No

15. Of the respondents that answered yes, participants were asked to select all features that their CTMS reports support:


■ KPIs and metrics (library of common operational benchmarks)

■ Drill-down capability (ability to select on summary information to get more details)

■ Interactive selection capability (to re-render the report based on the user's selection)

■ Mobile connectivity (get reports on your smart phone or tablet device)

■ Easy export to the standard Microsoft Office products such as Excel and Access

CTMS & Site Monitoring

**16. Does your organization use CTMS to manage site monitoring?**
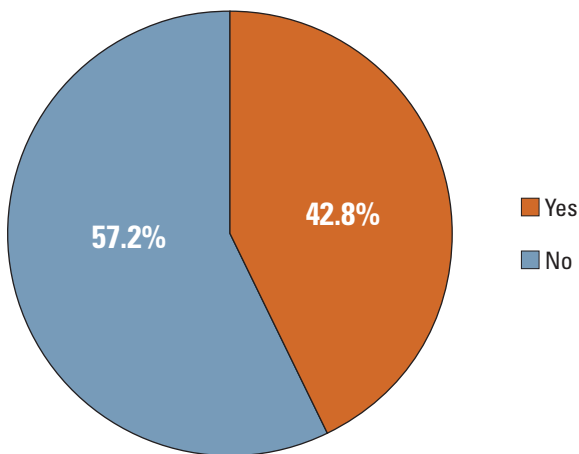
17. Of the respondents that answered yes, participants were asked if they use custom site report templates rather than a generic one provided by the CTMS vendor?

42.8%

57.2%

■ Yes
■ No

19.9%

80.1%

■ We use custom site visit report templates

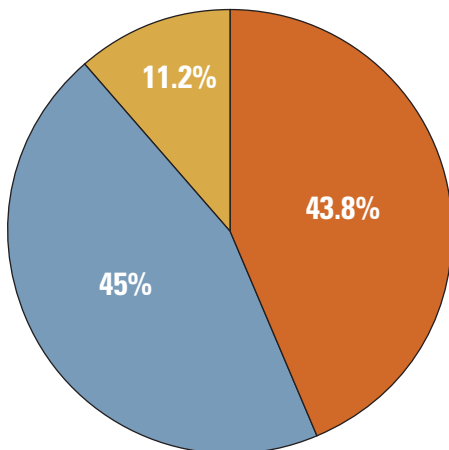■ We use a generic one provided by the CTMS vendor
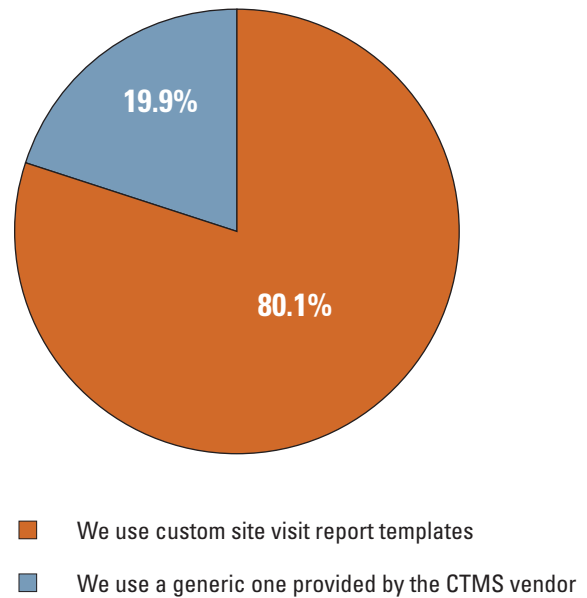
General CTMS

18. Are monitors ever forced to enter the same information into multiple places (such as a site visit report document and then the CTMS later)?

- Yes
- No
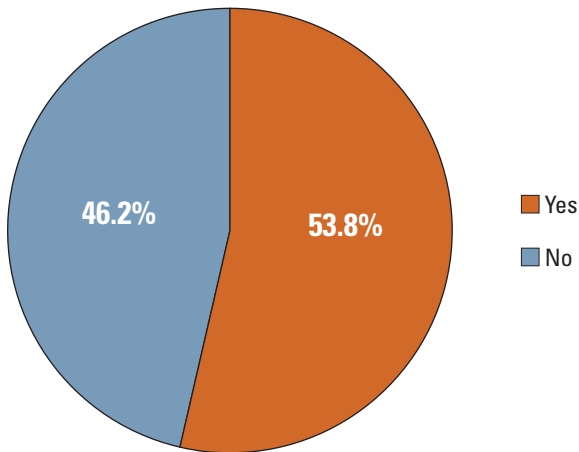
19. Are electronic signatures supported and easy to use?

- Yes, supported and easy to use
- Yes, supported but not easy to use
- No, not supported
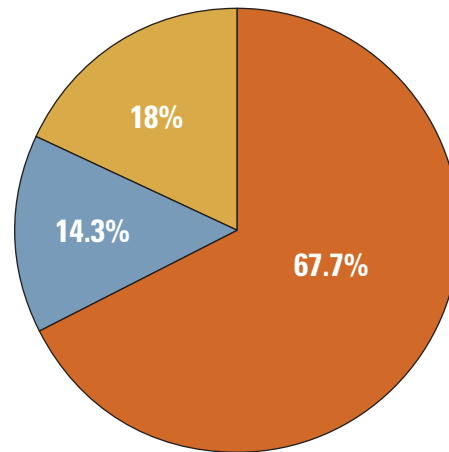
20. How important is it to you that your CTMS support and align with common industry standards (as applicable)?

- Extremely Important
- Important
- Not Important

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