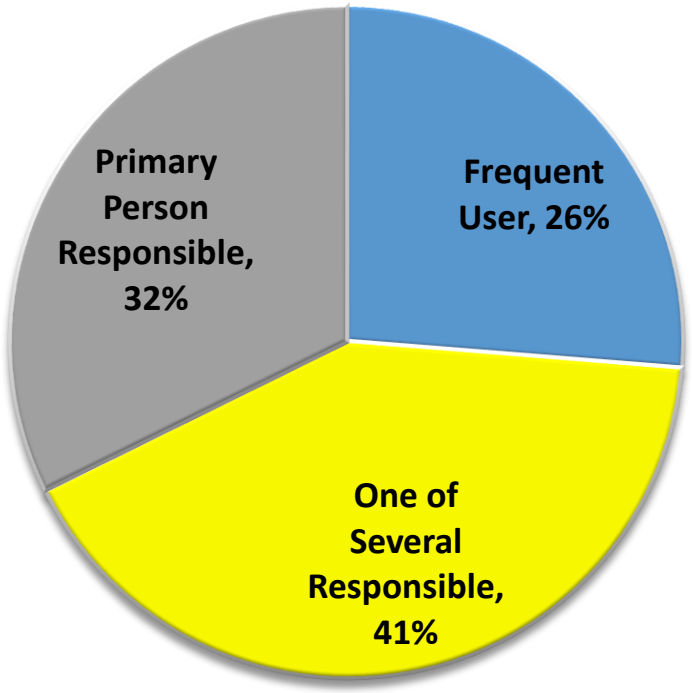
Tufts – Veeva 2017 eClinical Landscape Study

- **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*



3 Subgroup Stratifications

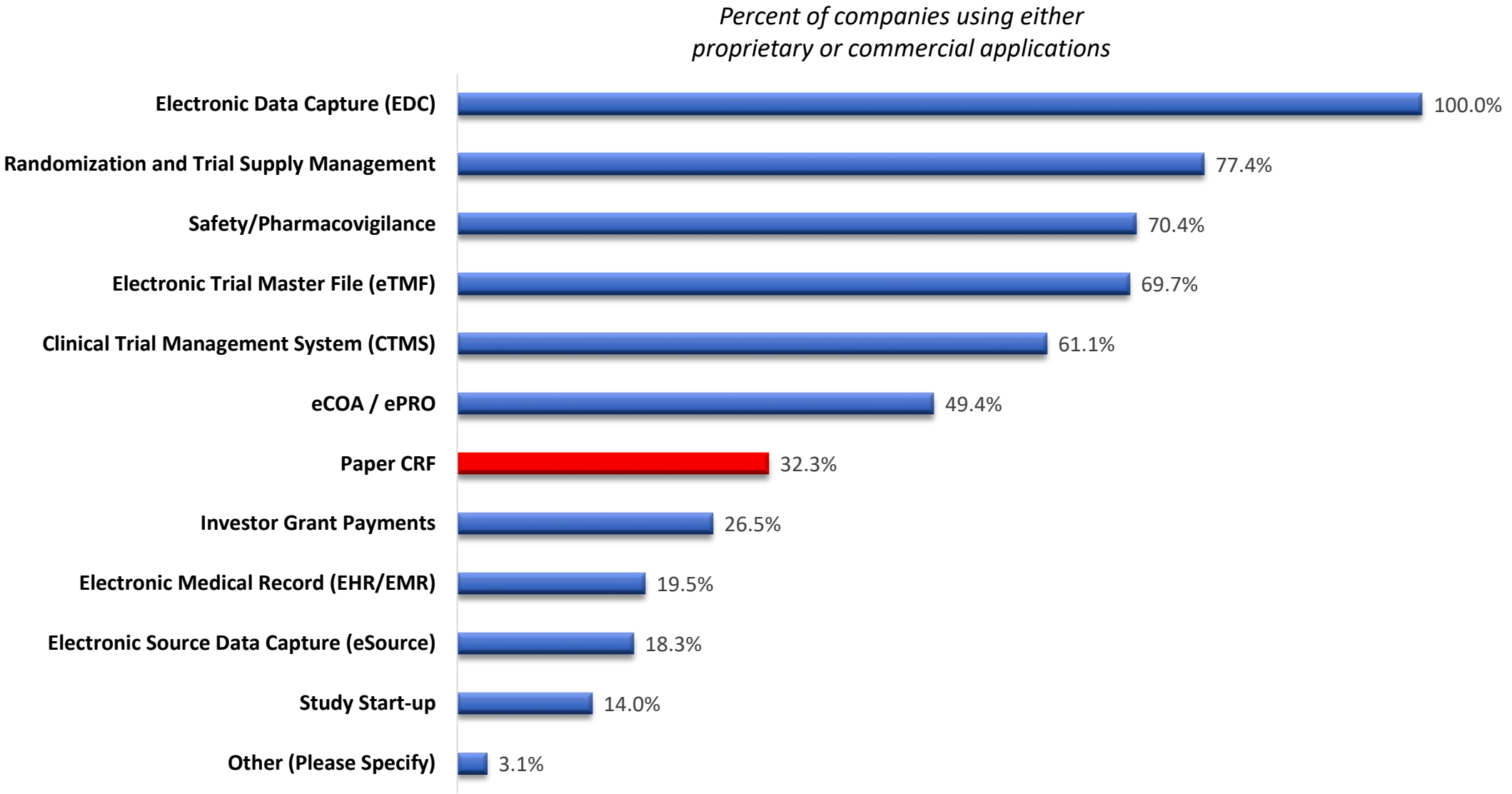
- **Company Type***
  - *Sponsors (N=193)*
  - *CROs (N=56)*

- **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

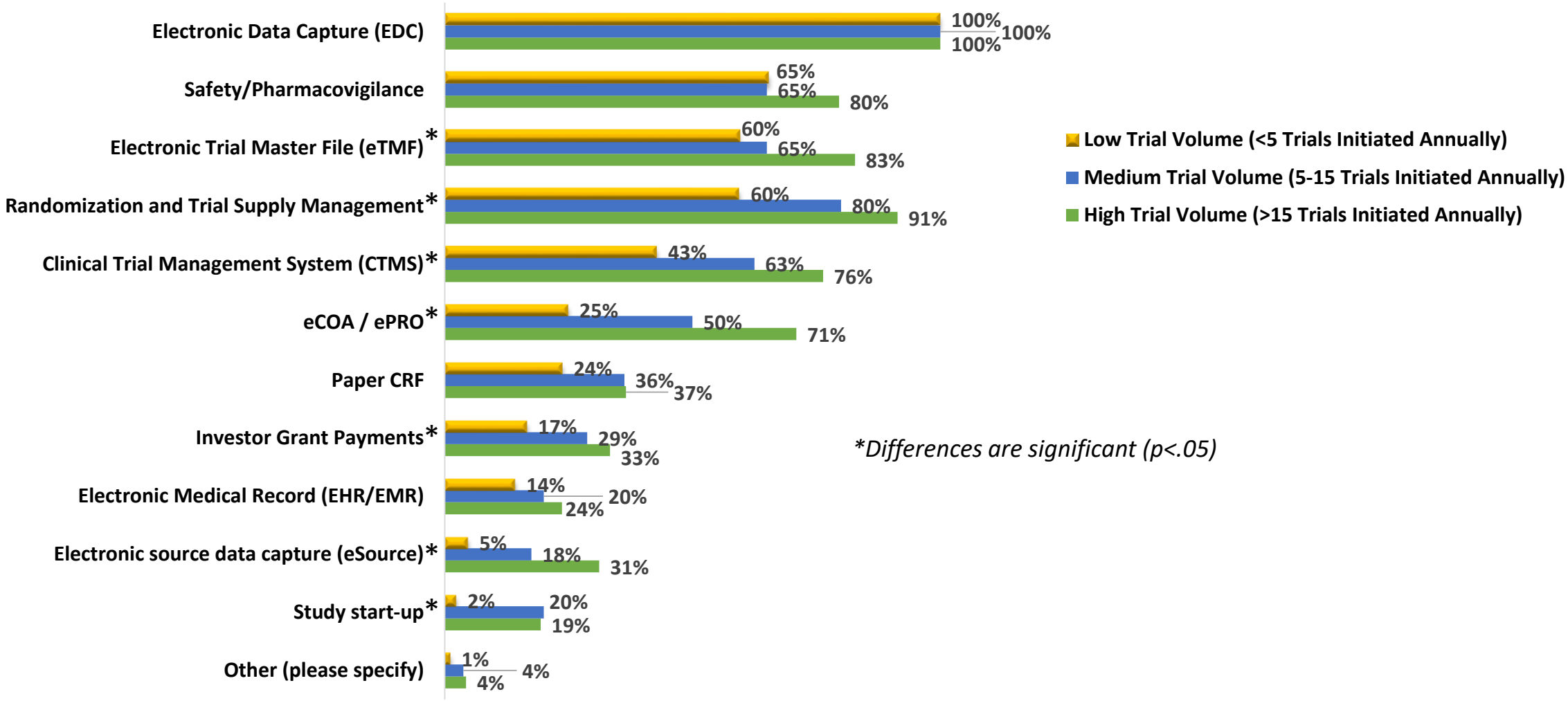
Volume of Clinical Trials Initiated Annually	Average Number of Applications Used*	Coefficient of Variation
Low	**4.2**	**.40**
Medium	**5.5**	**.42**
High	**6.5**	**.33**

**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



**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.

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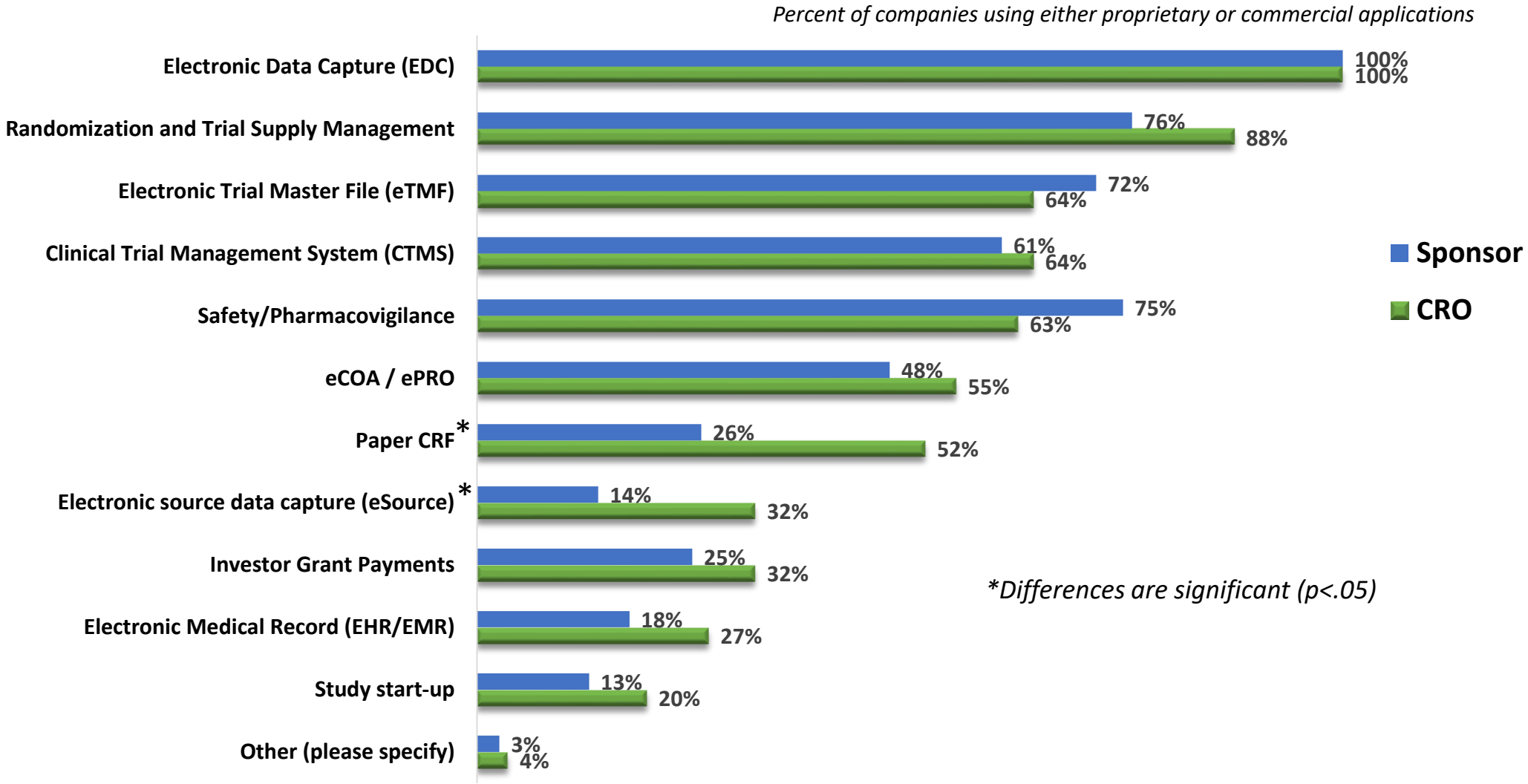
Specific Clinical Data Management Applications Used by Company Type



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.

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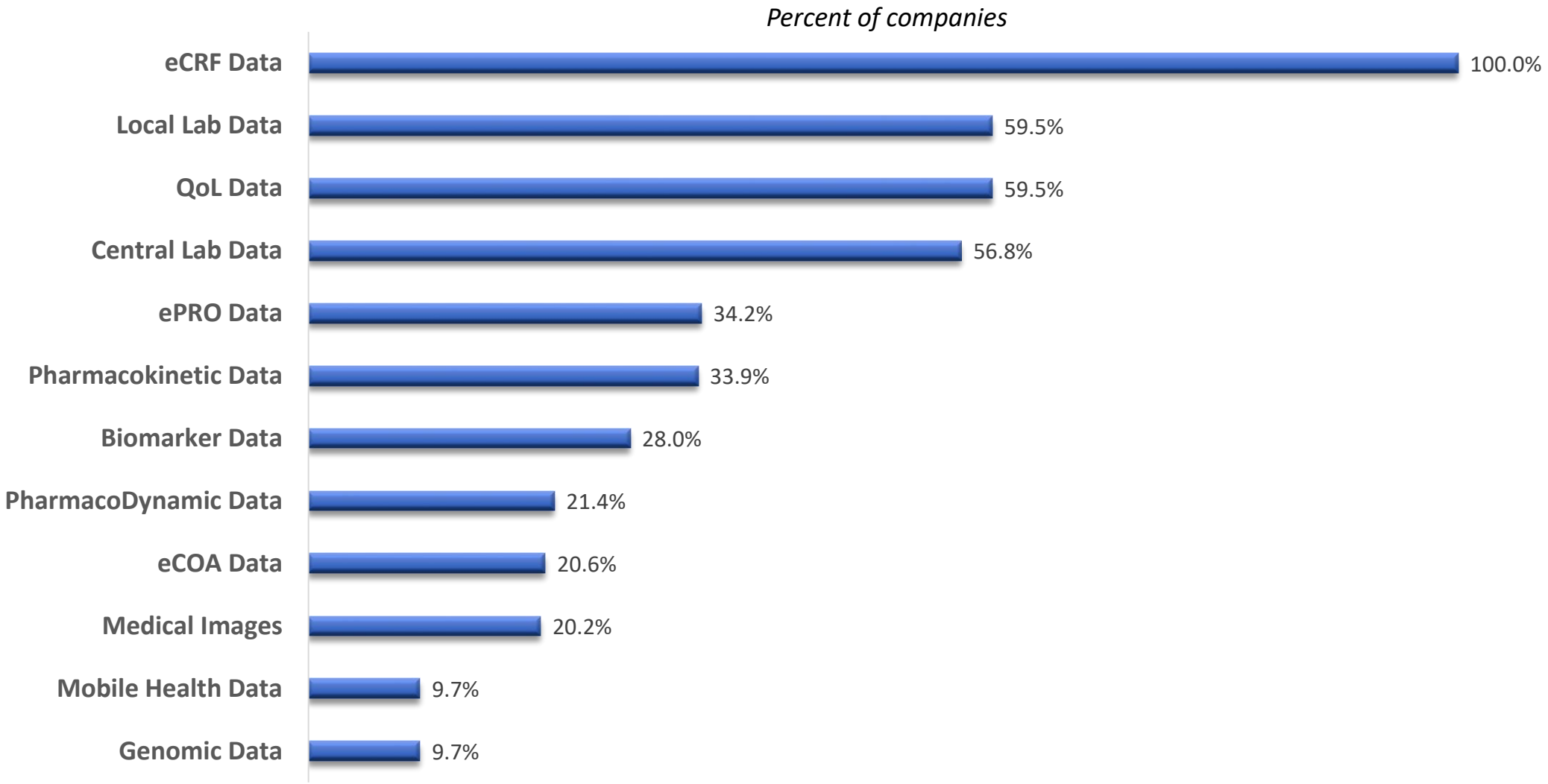
Types of Data Companies Manage in Their Primary EDC



What data does your organization manage in their primary EDC application? Select all that apply.

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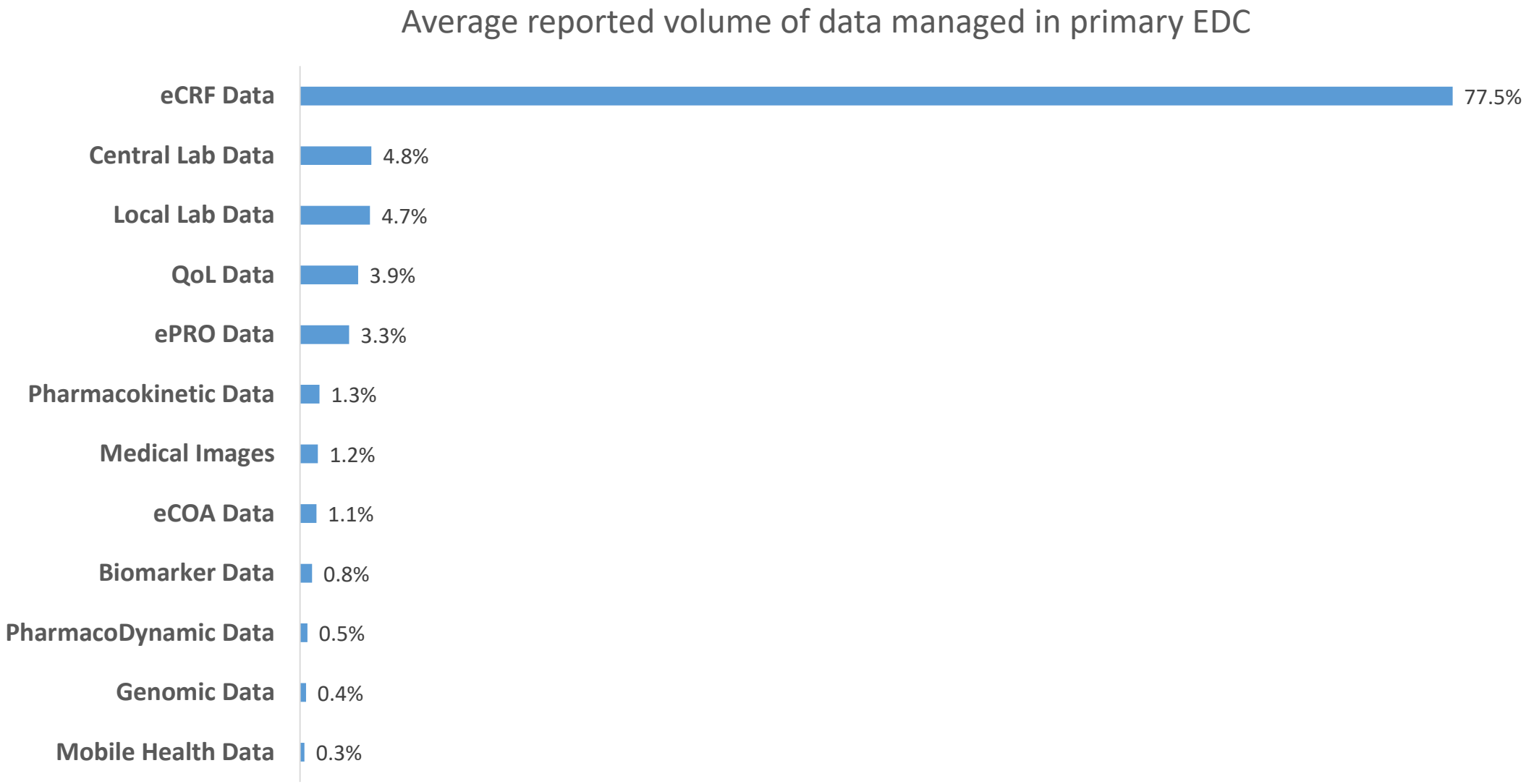
Volume of Data Companies Manage in Their Primary EDC



N= 169 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.

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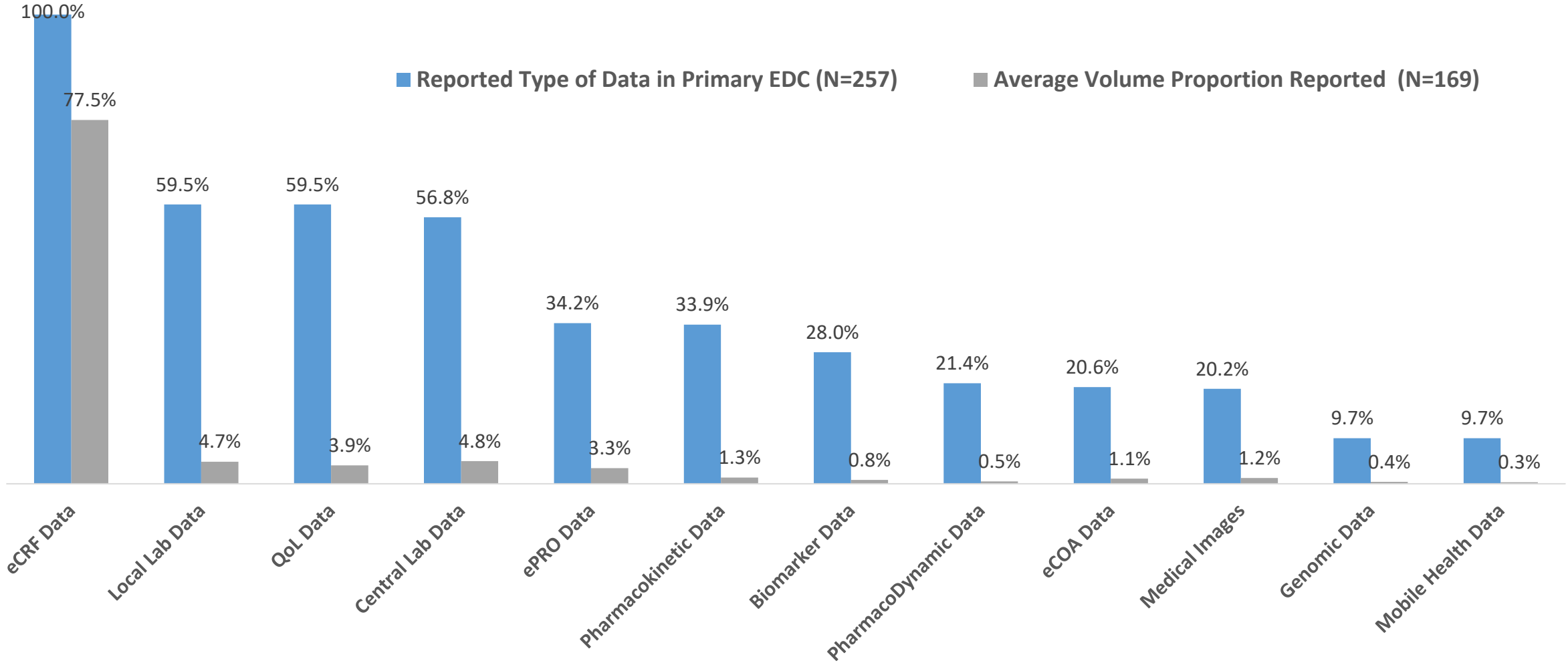
Types of Data Companies Manage in Their Primary EDC vs. Volume of Data Reported



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.

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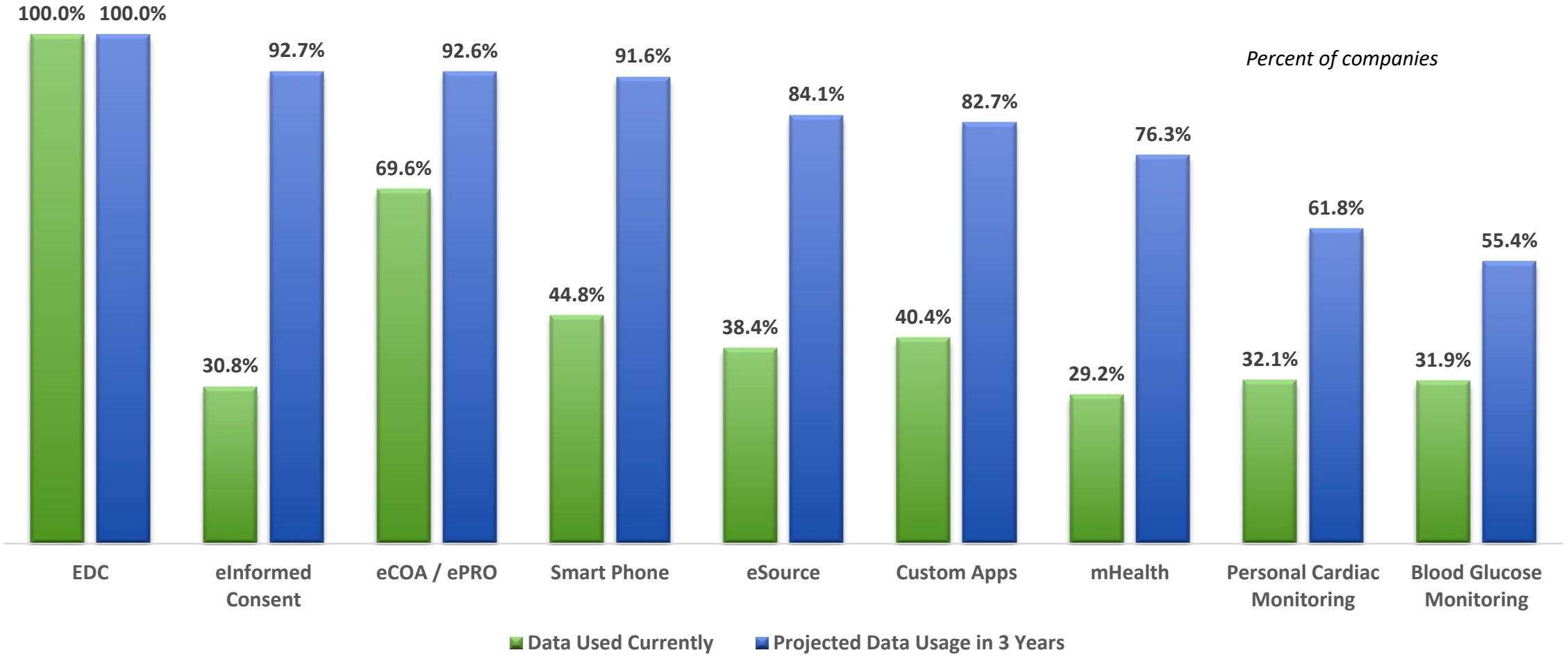
Data Sources Used Currently and Projected Use in 3 Years



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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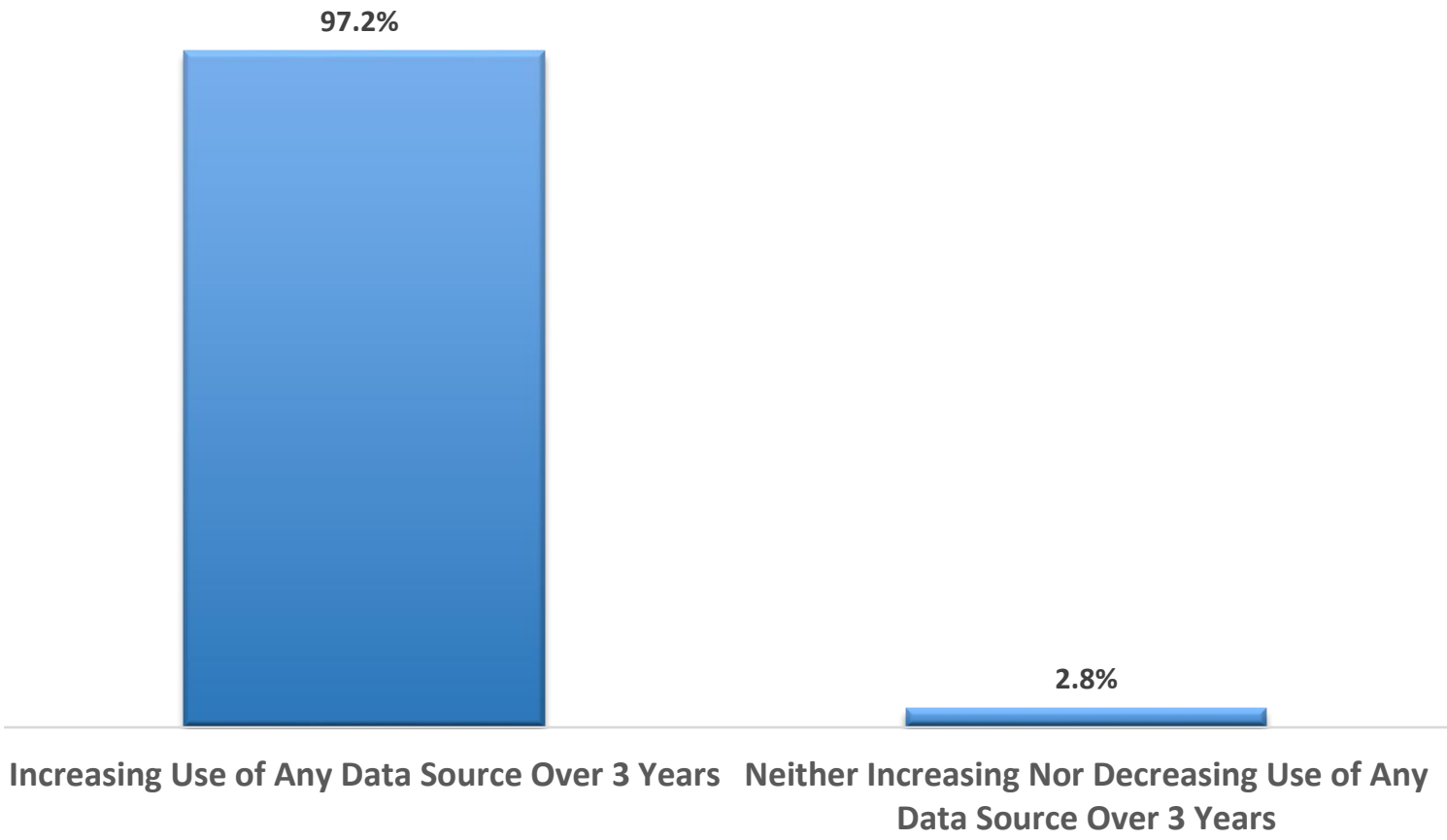
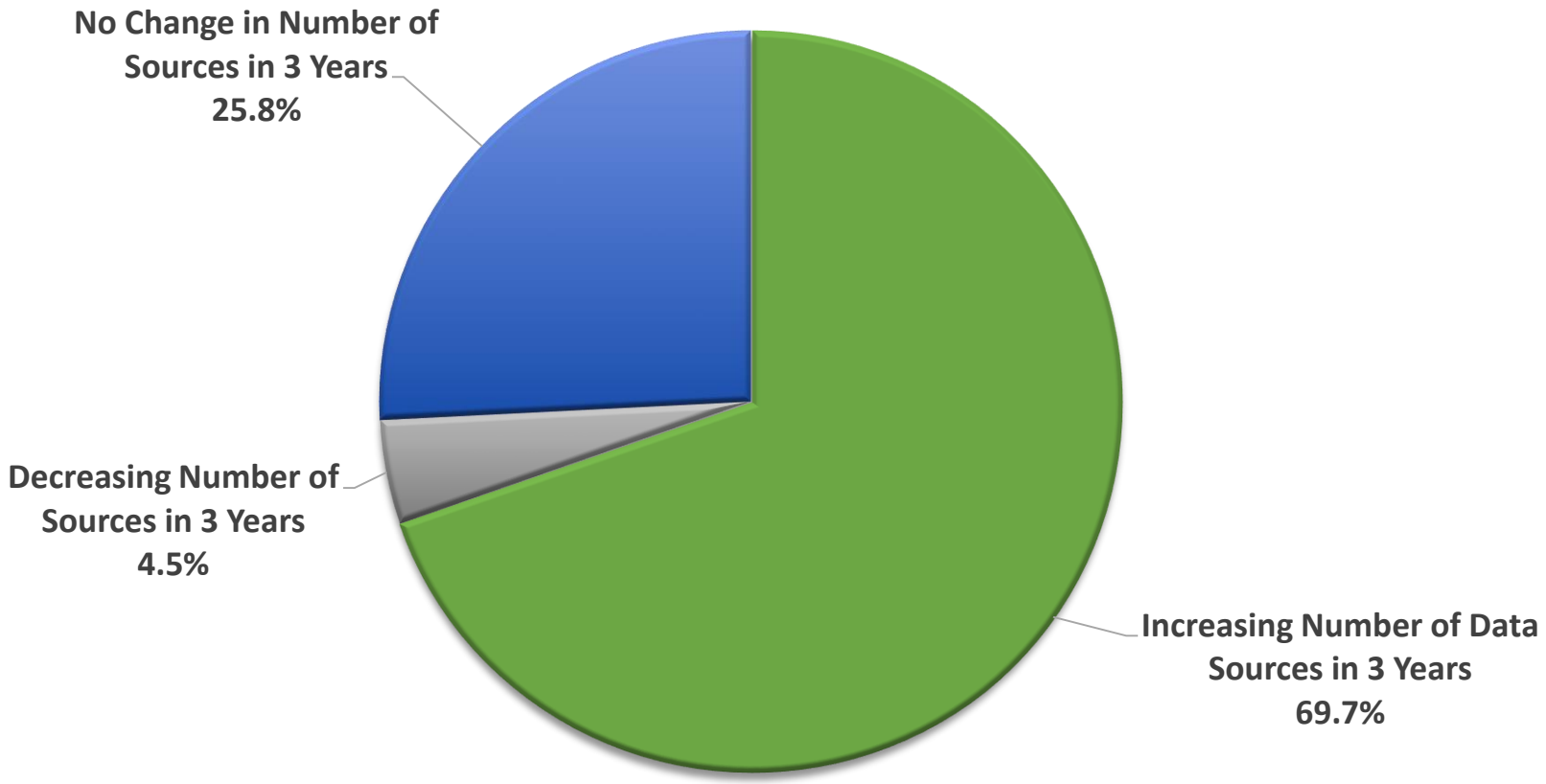
Percent of Respondents Increasing Use of Any Data Source Over 3 Years



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



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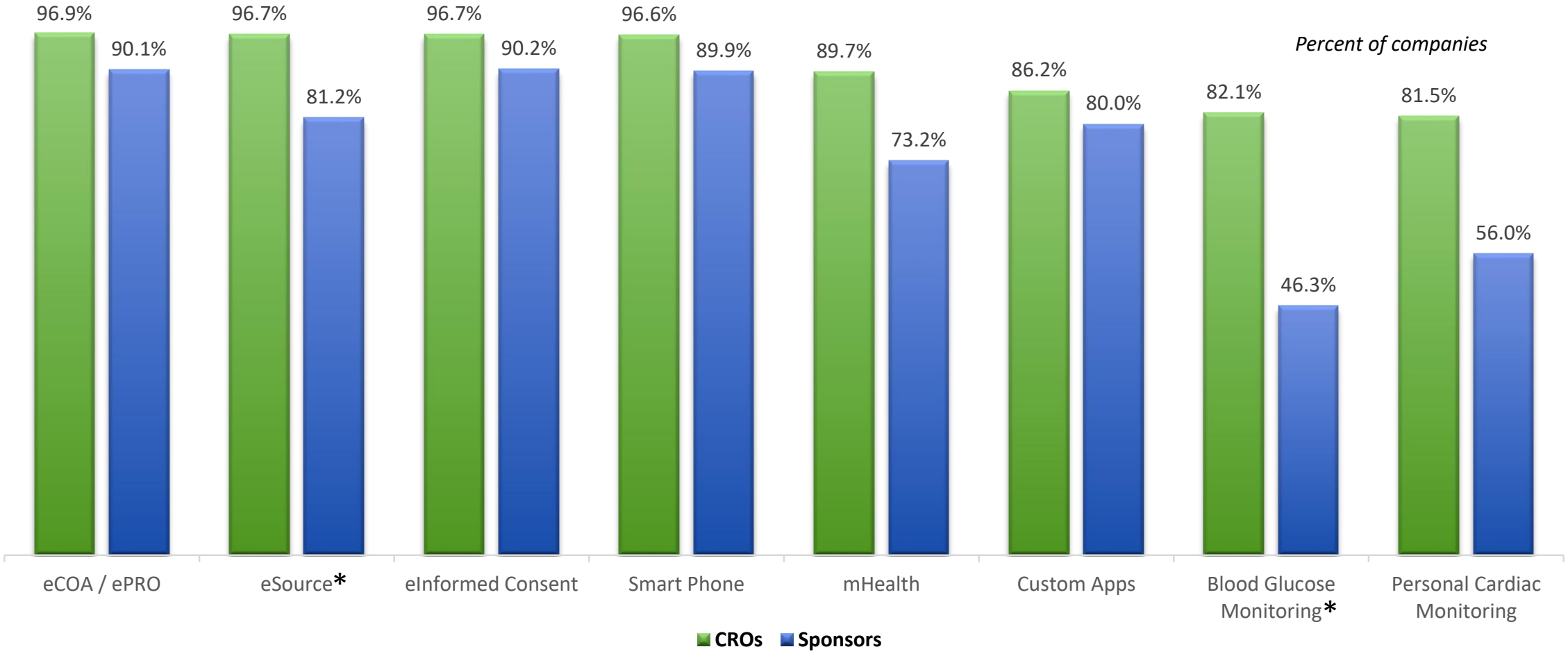
Magnitude of Projected Change in Data Sources Used

	Difference between reported data usage and projected usage in 3 Years
EDC	0.0%
eInformed Consent	61.9%
mHealth	47.1%
Smart Phone	46.8%
eSource	45.7%
Custom Apps	42.3%
Personal Cardiac Monitoring	29.7%
Blood Glucose Monitoring	23.5%
eCOA / ePRO	23.0%

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”)

Projected Data Sources Used in 3 Years by Company Type



*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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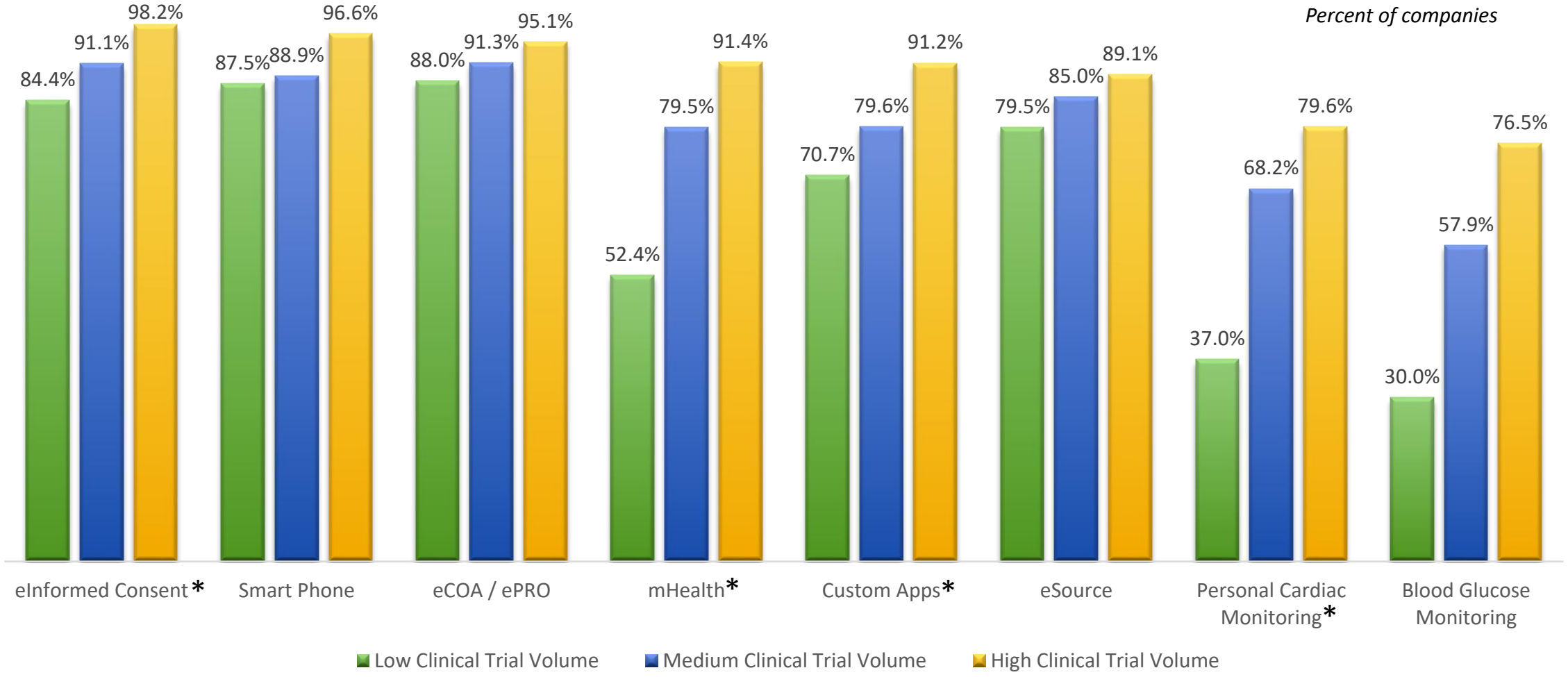
Projected Data Sources Used in 3 Years by Company Size



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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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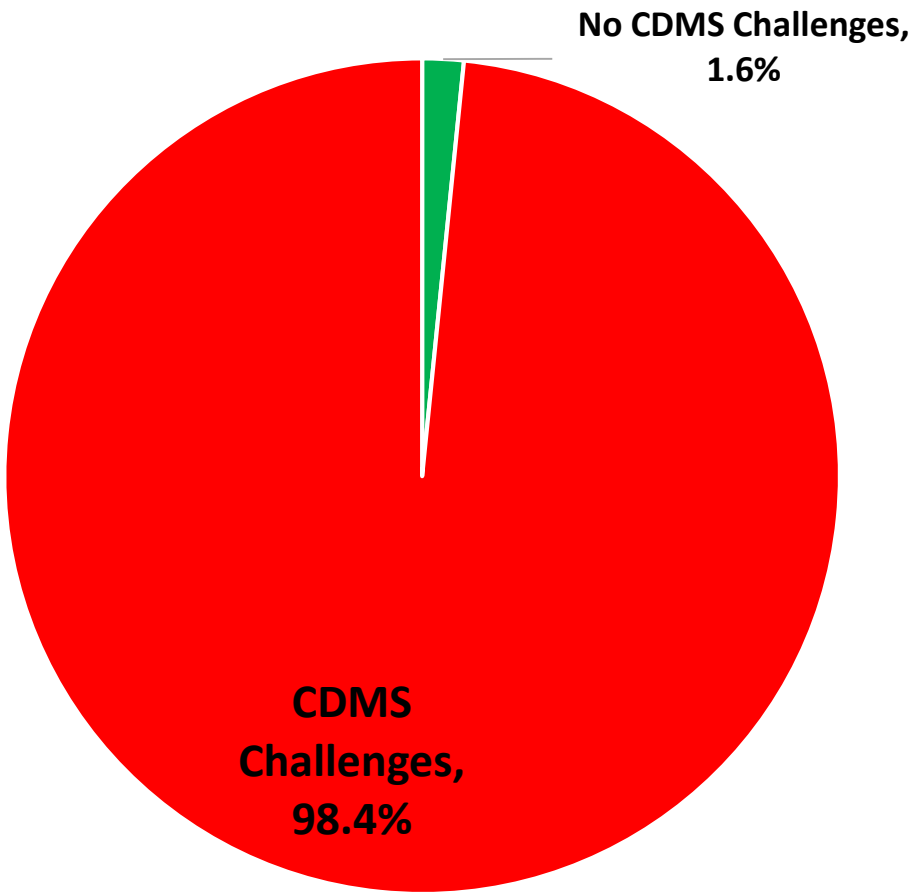
Proportion of Respondents Reporting CDMS Challenges



*With specific reference to your organization's clinical data management systems, what is the biggest challenge you face today?

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Biggest Single Reported CDMS Challenge (1 of 2)

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

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

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Biggest Single Reported CDMS Challenge (2 of 2)

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

**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)

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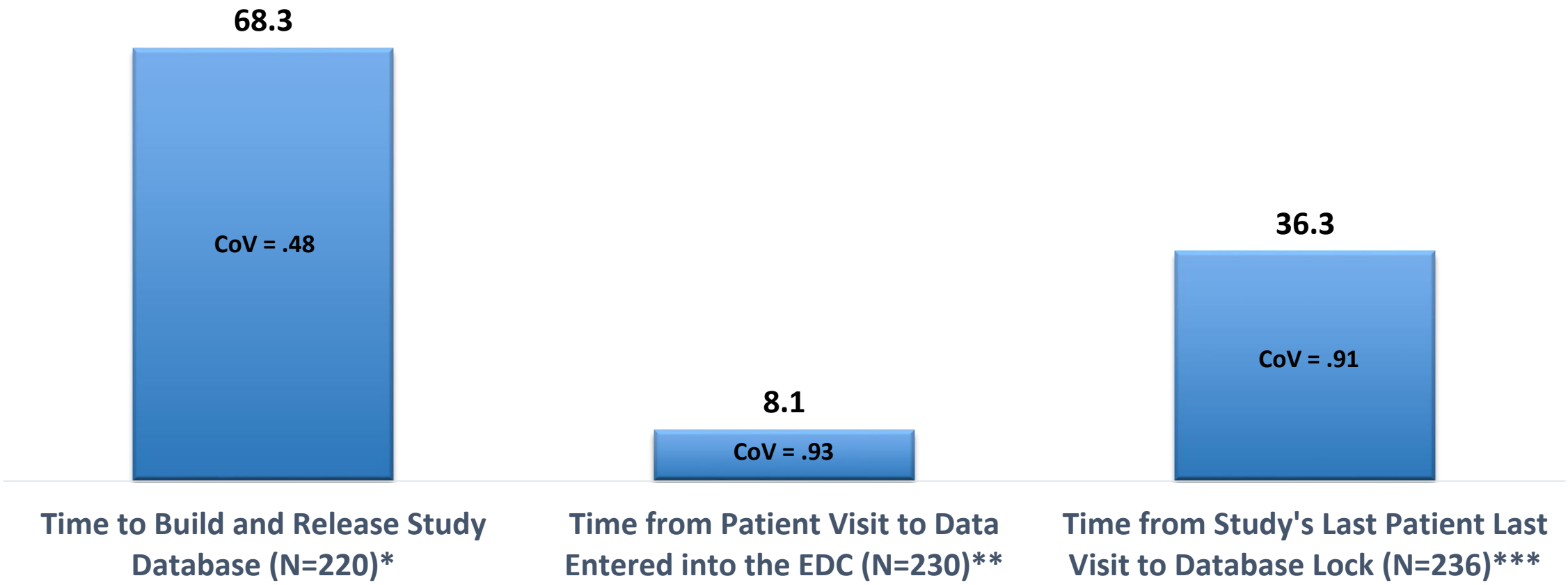
Data Management Cycle Time

(In Days)



*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)?

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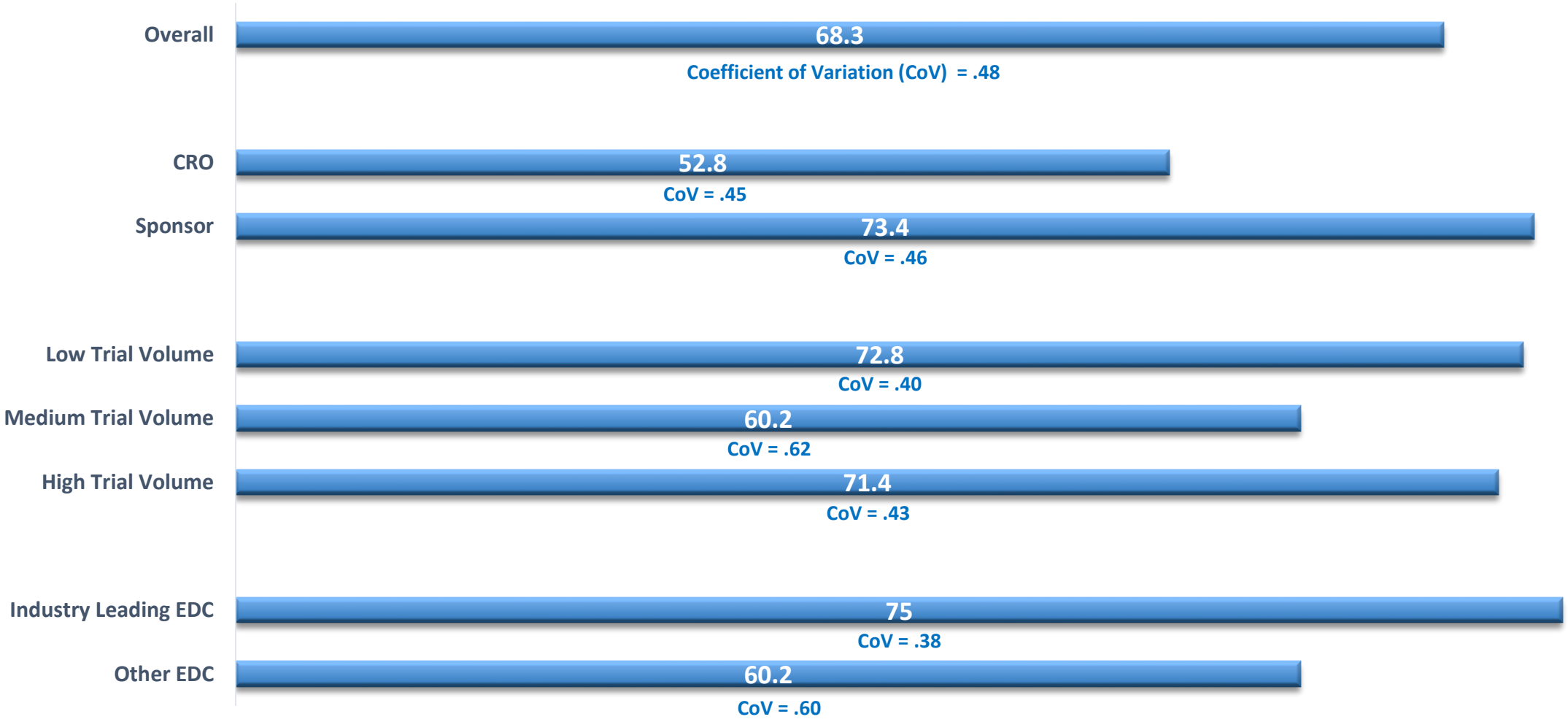
Average Time to Build and Release a Study Database

(in Days)



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

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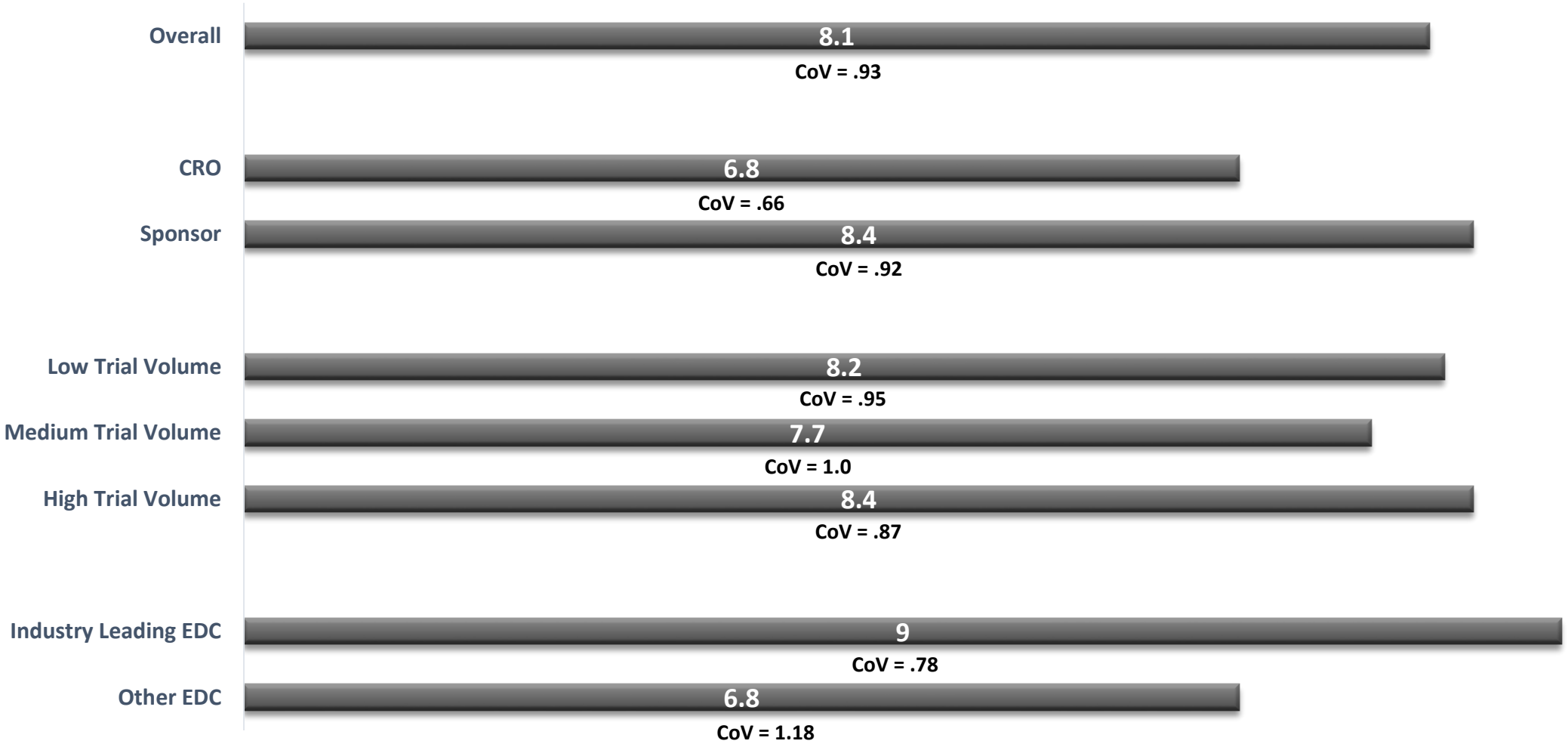
Average Time for Site Staff to Enter Patient Data

(in Days)



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?

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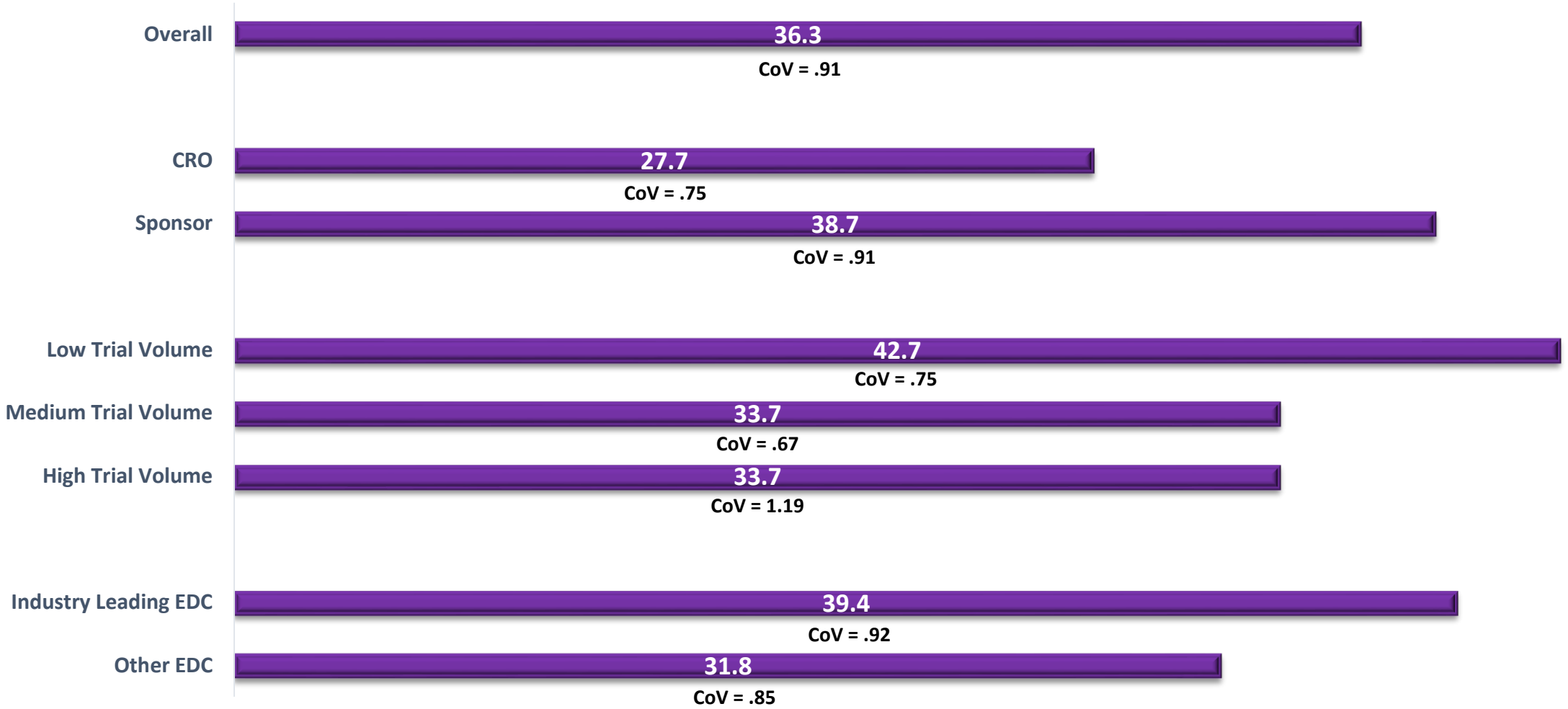
Average Time to Lock a Study Database

(in Days)



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

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

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

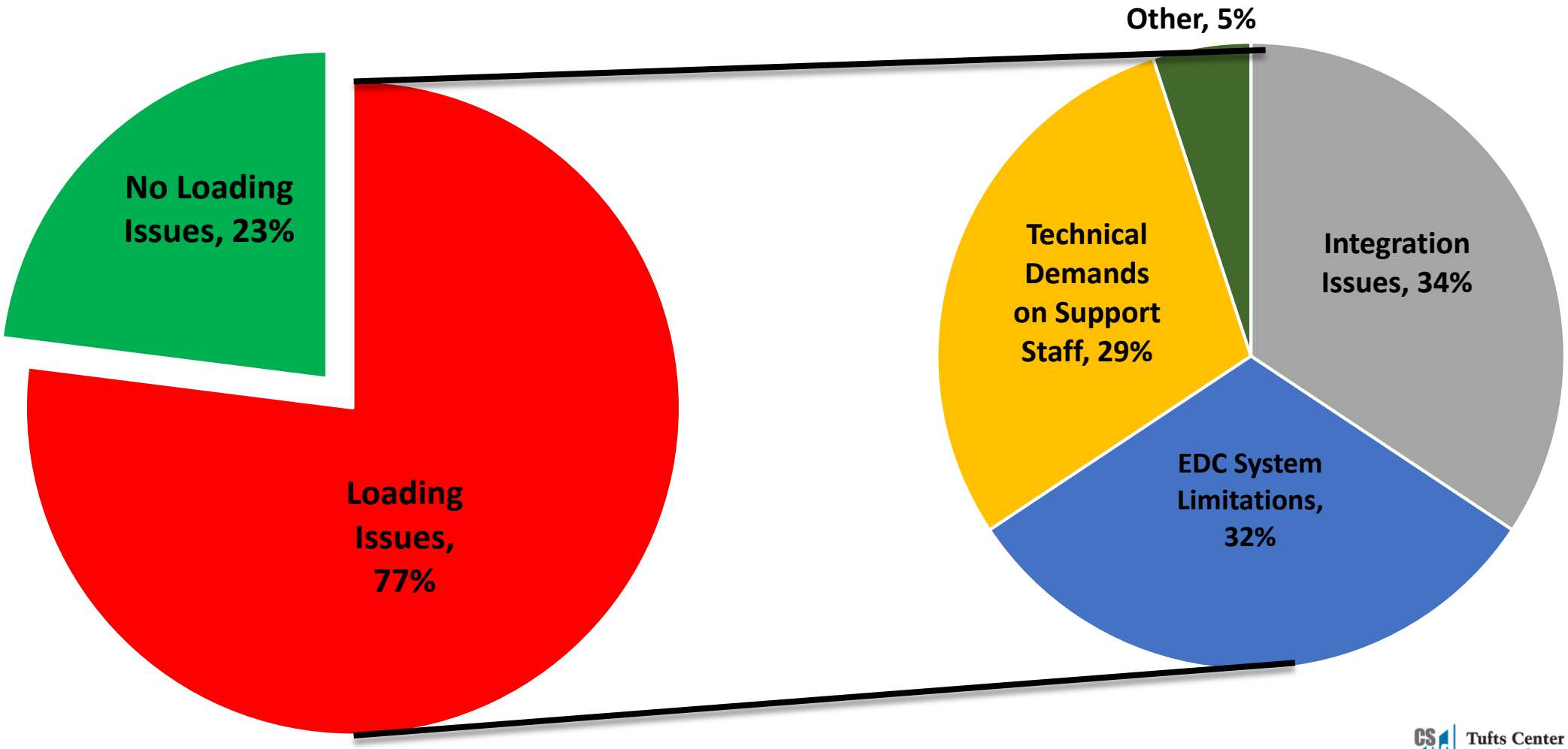
Association Between Causes of Delays and Cycle Times

	Percent of Total (N=257)	*Time from LPLV to DB Lock	Coefficient of Variation
Protocol Changes	45.1%	31.8 Days	.73
User Acceptance Testing (Including Review and Approvals)	16.7%	34.2 Days	.90
Database Design Functionality	15.2%	50.4 Days	1.15
Study Database Move from Development into Production	8.2%	39 Days	.57
Standards Management	4.3%	37.5 Days	.51
Ethics Approval Delays/Changes	1.2%	33.3 Days	.46
Overall	100%	36.3 Days	.91

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

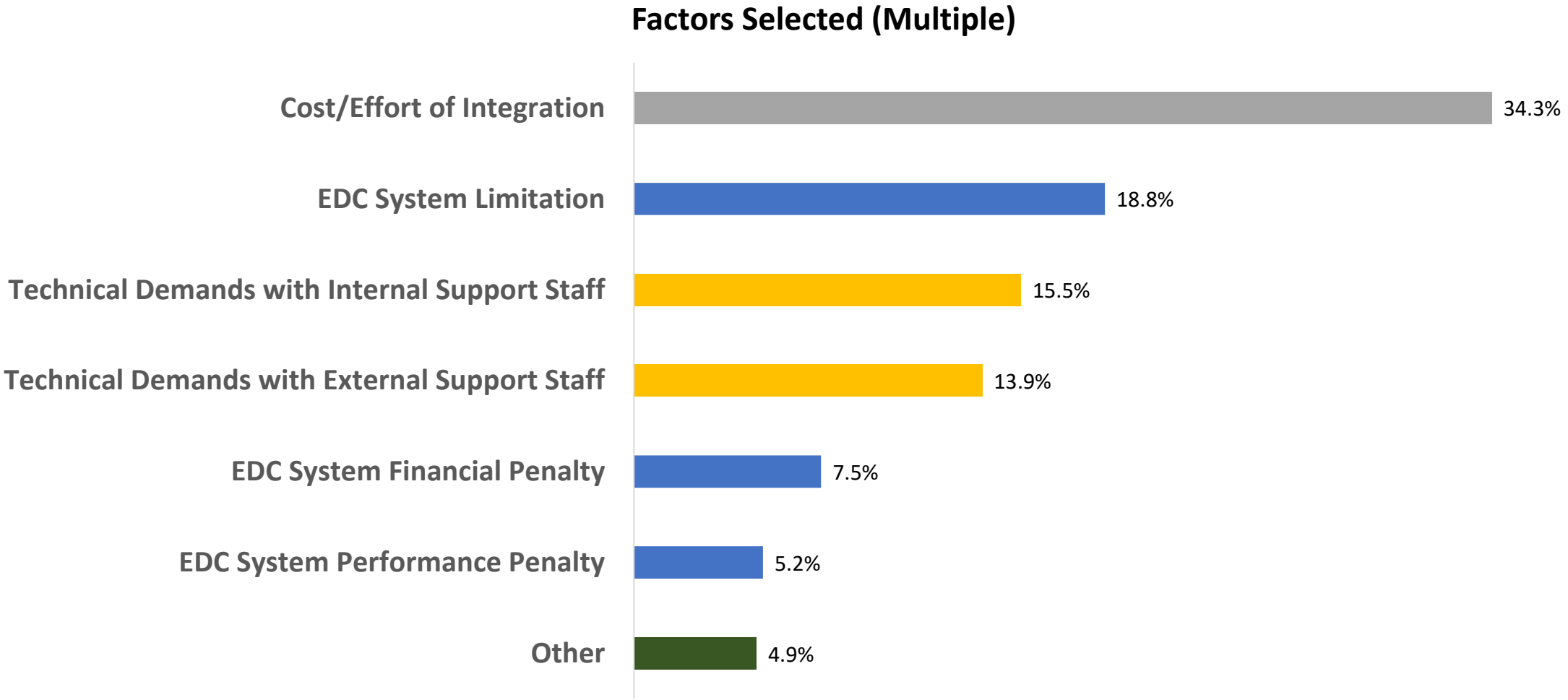
*On average for phase II and III trials, how many days do you estimate it takes from the study's last patient out (LPO)/last patient last visit (LPLV) to database lock (all data)?

Challenges Loading Data into Primary EDC



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



What, if anything, prevents your company from loading data into your organization's primary EDC application?

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Downstream Impact of EDC Release after FPFV

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

*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?
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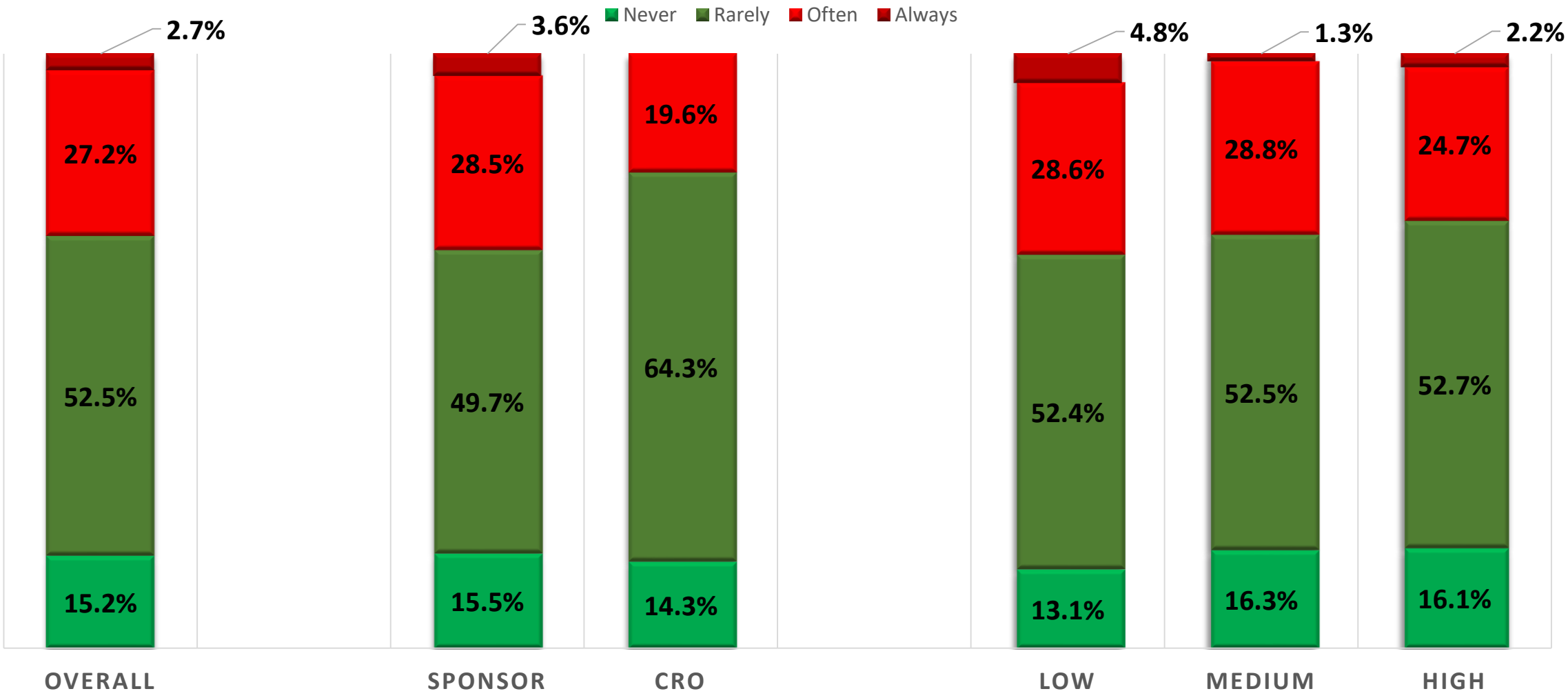
Incidence of EDC Release After FPFV



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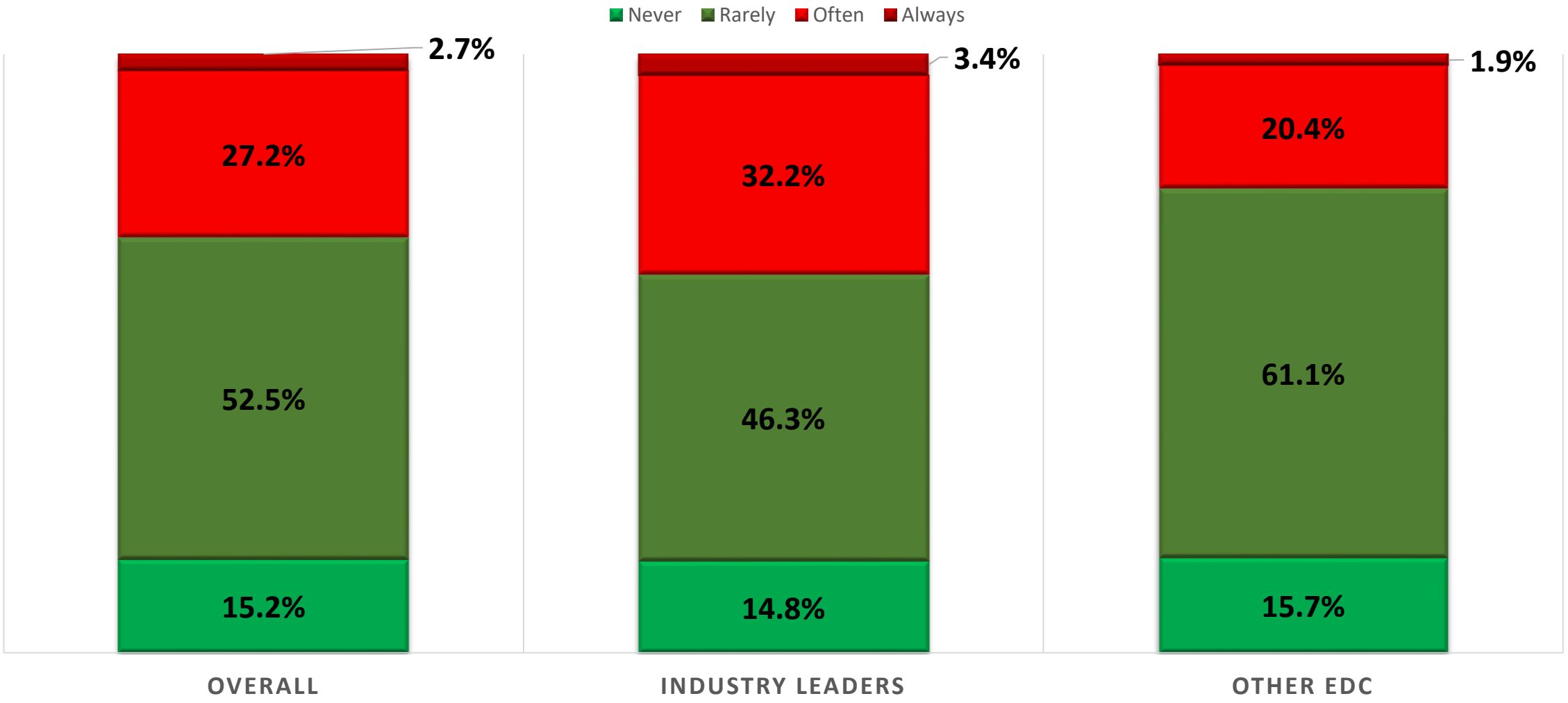
Incidence of EDC Release After FPFV



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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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- **About Veeva:**

Veeva Systems Inc. is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 550 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices in Europe, Asia, and Latin America. For more information, visit veeva.com.

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