Tufts – Veeva 2017 eClinical Landscape Study

Assessing Data Management Practices, Performance, and Challenges

Tufts Center for the Study of Drug Development
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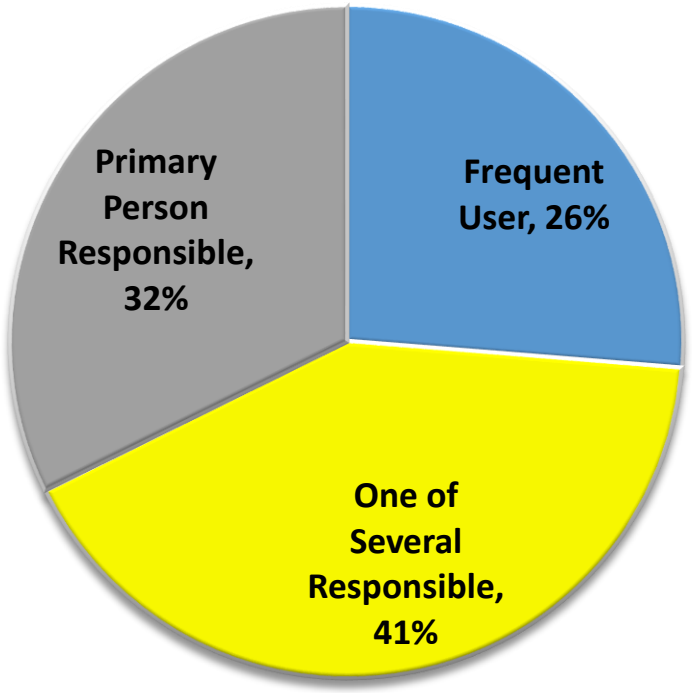
About the Tufts – Veeva 2017 eClinical Landscape Study

- **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

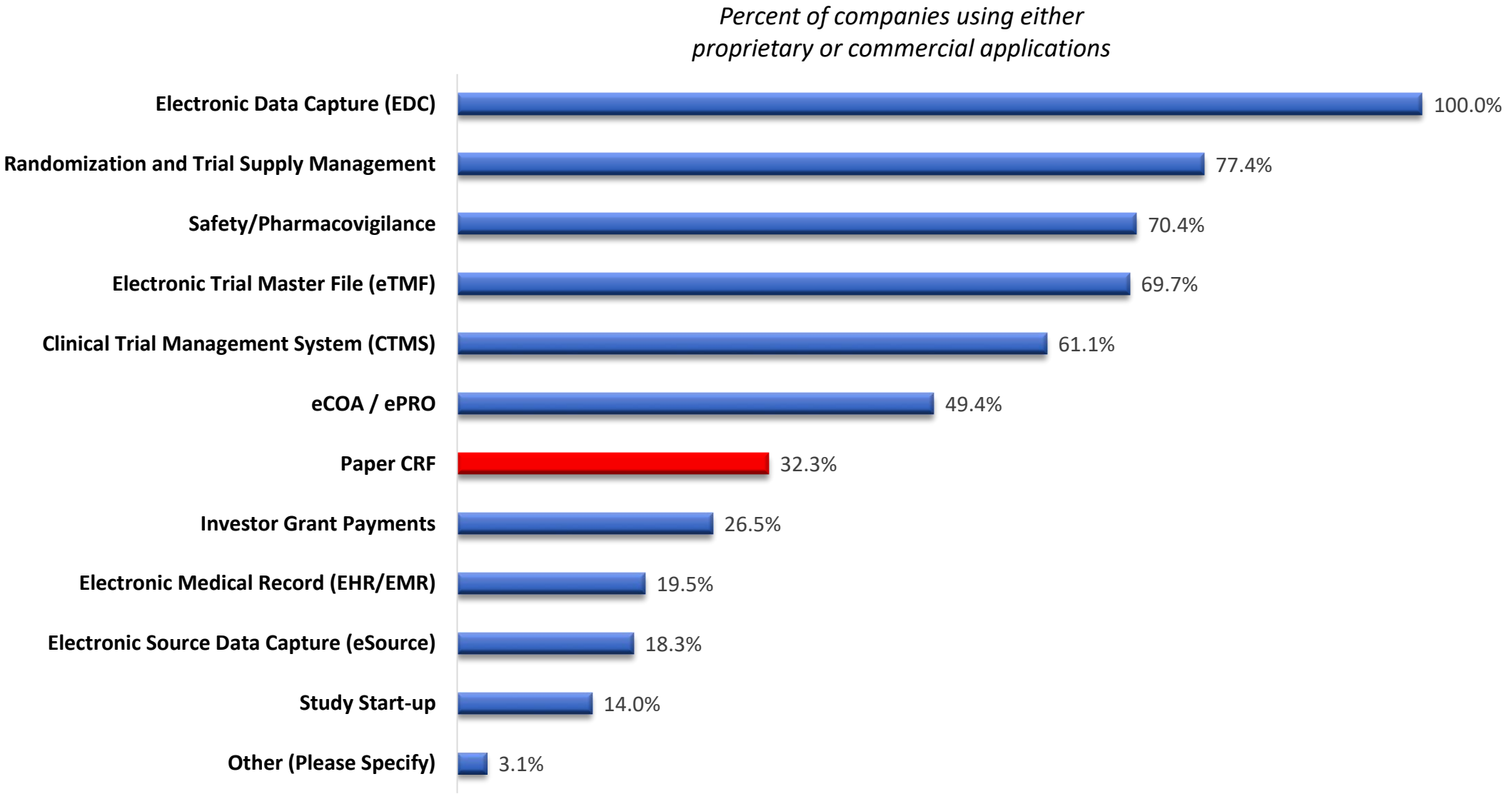
- **Company Type***
  - *Sponsors (N=193)*
  - *CROs (N=56)*

- **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)*

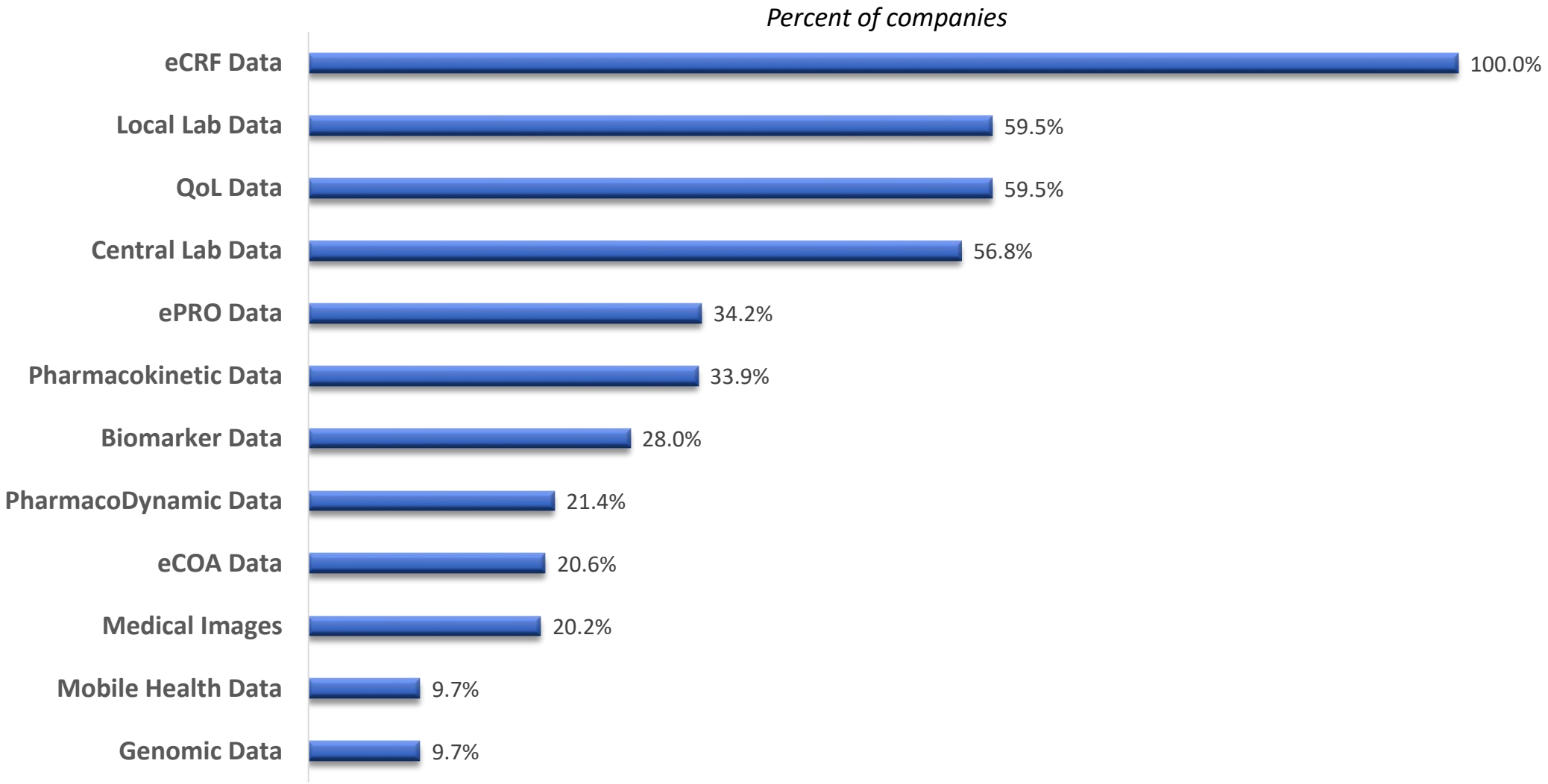
*What is the primary role of the organization you represent?
**How many clinical trials (studies) does your organization initiate each year across all phases?
***What is the primary EDC application your organization uses for the majority of your studies today?

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.

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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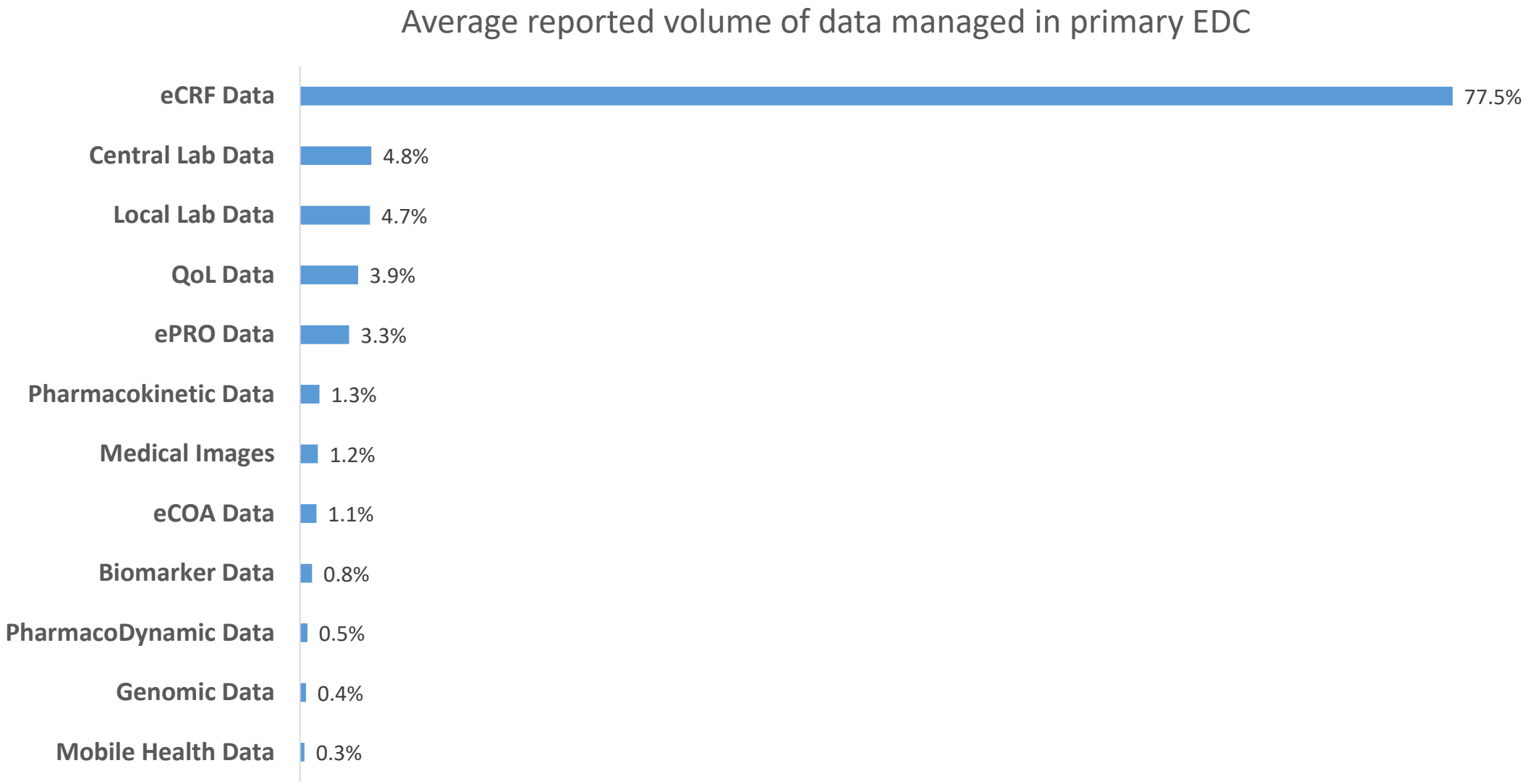
Volume of Data Companies Manage in Their Primary EDC



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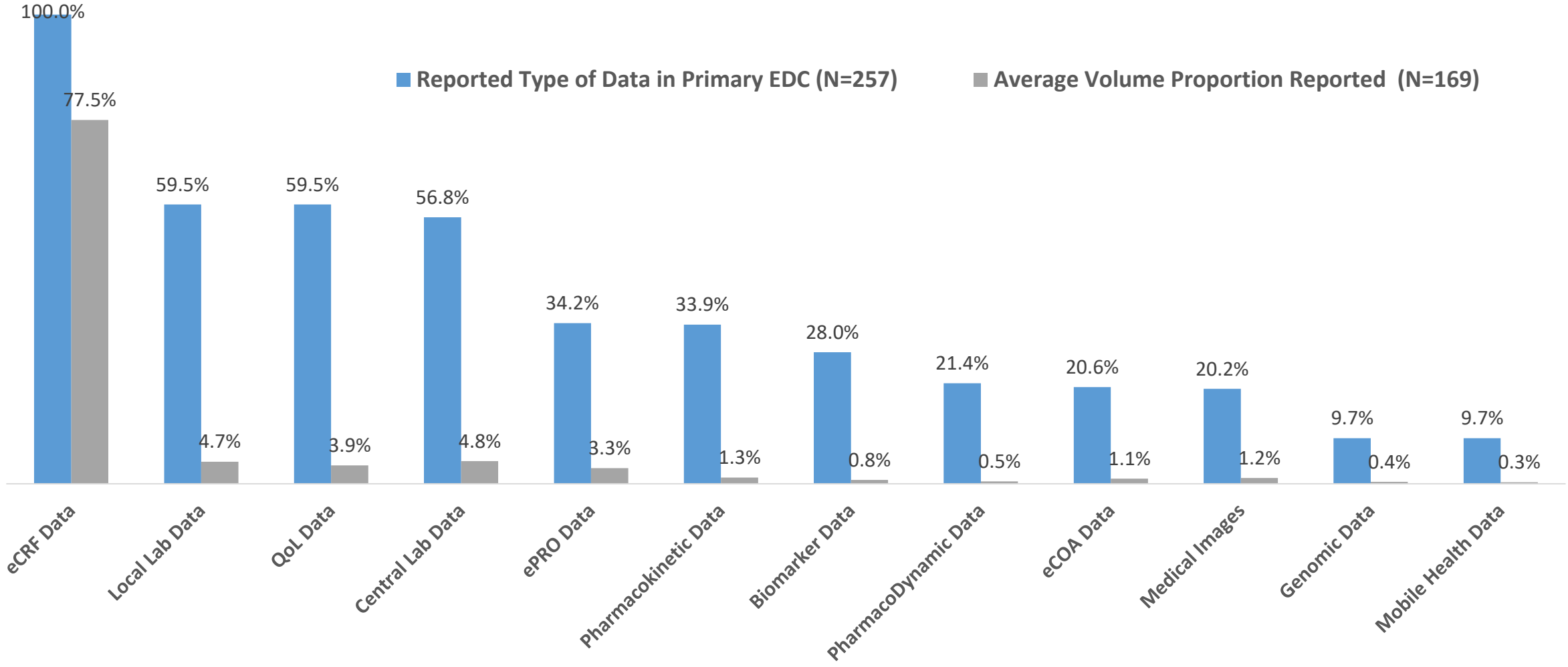
Types of Data Companies Manage in Their Primary EDC vs. Volume of Data Reported



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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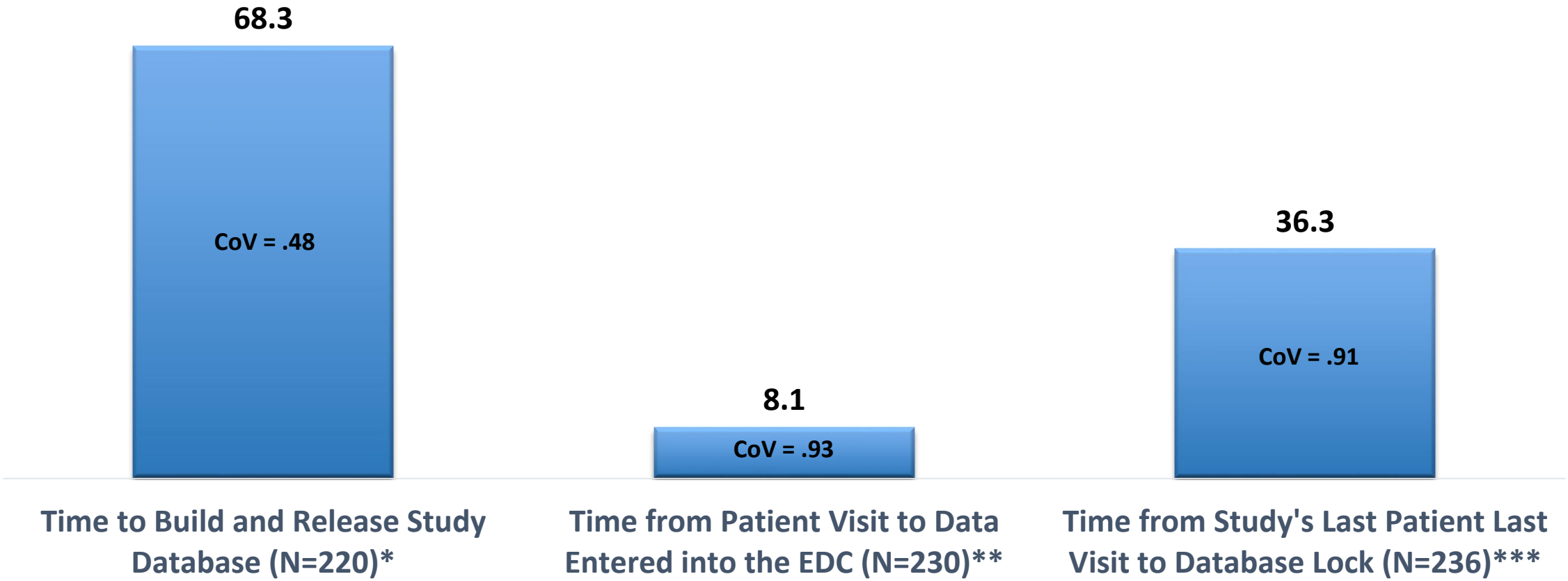
Data Management Cycle Time

(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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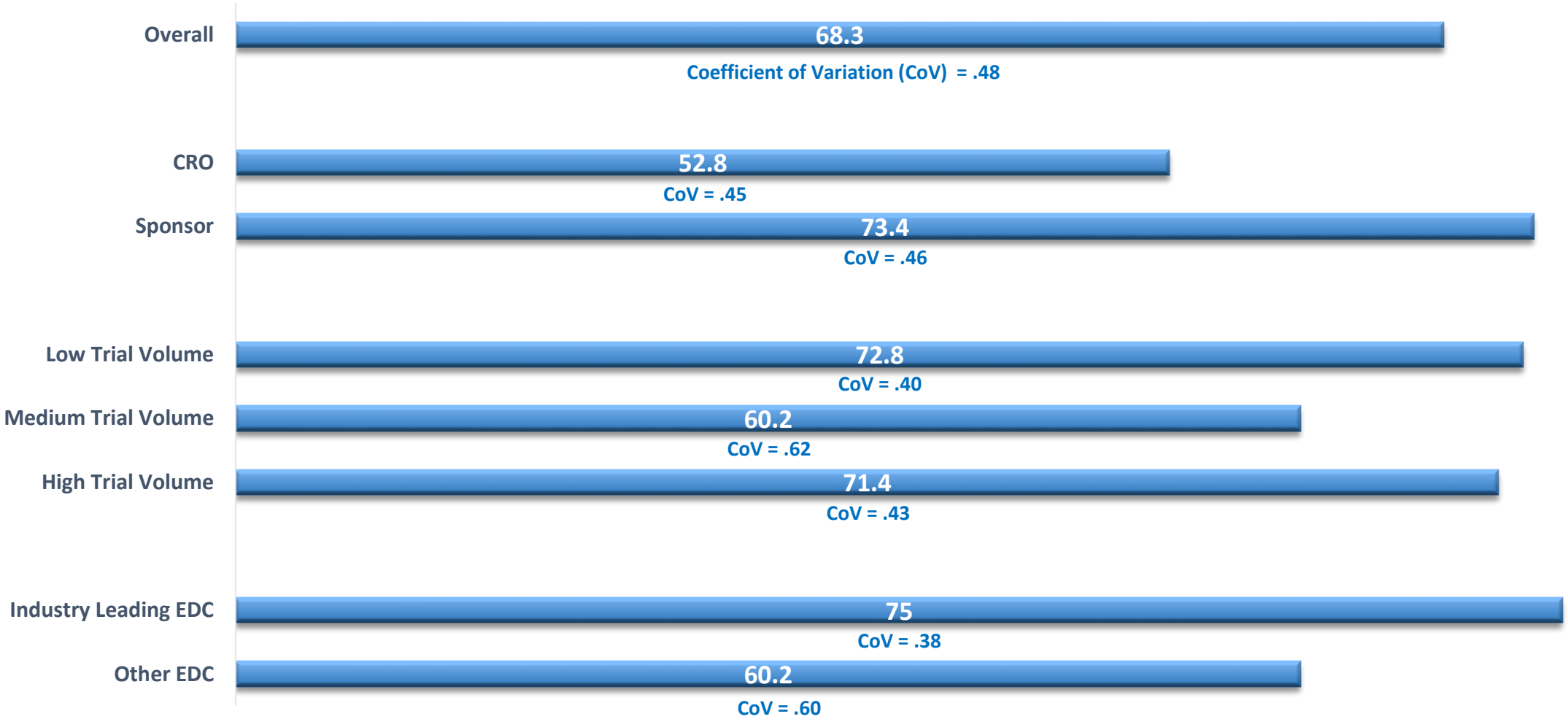
Average Time to Build and Release a Study Database

(in Days)



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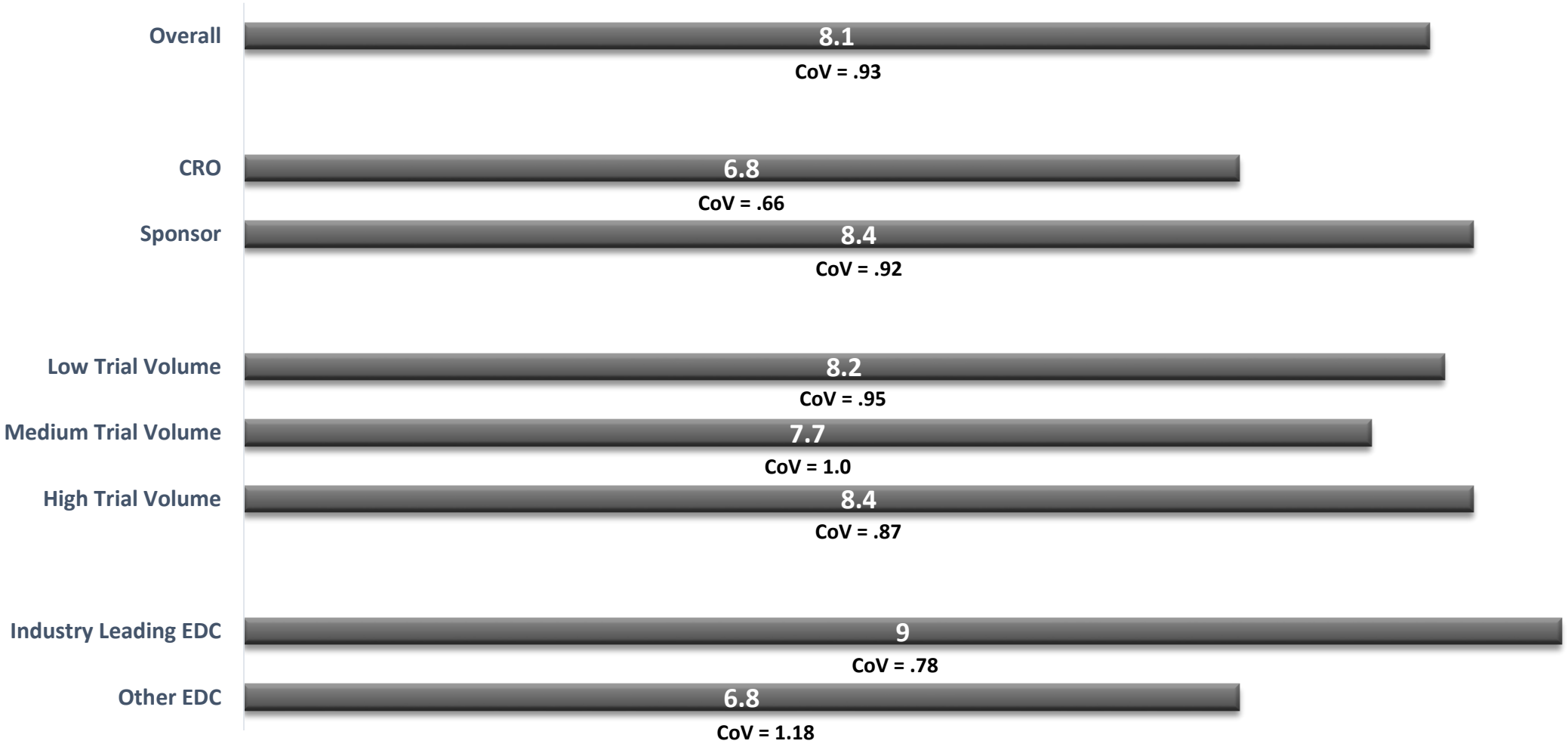
Average Time for Site Staff to Enter Patient Data

(in Days)



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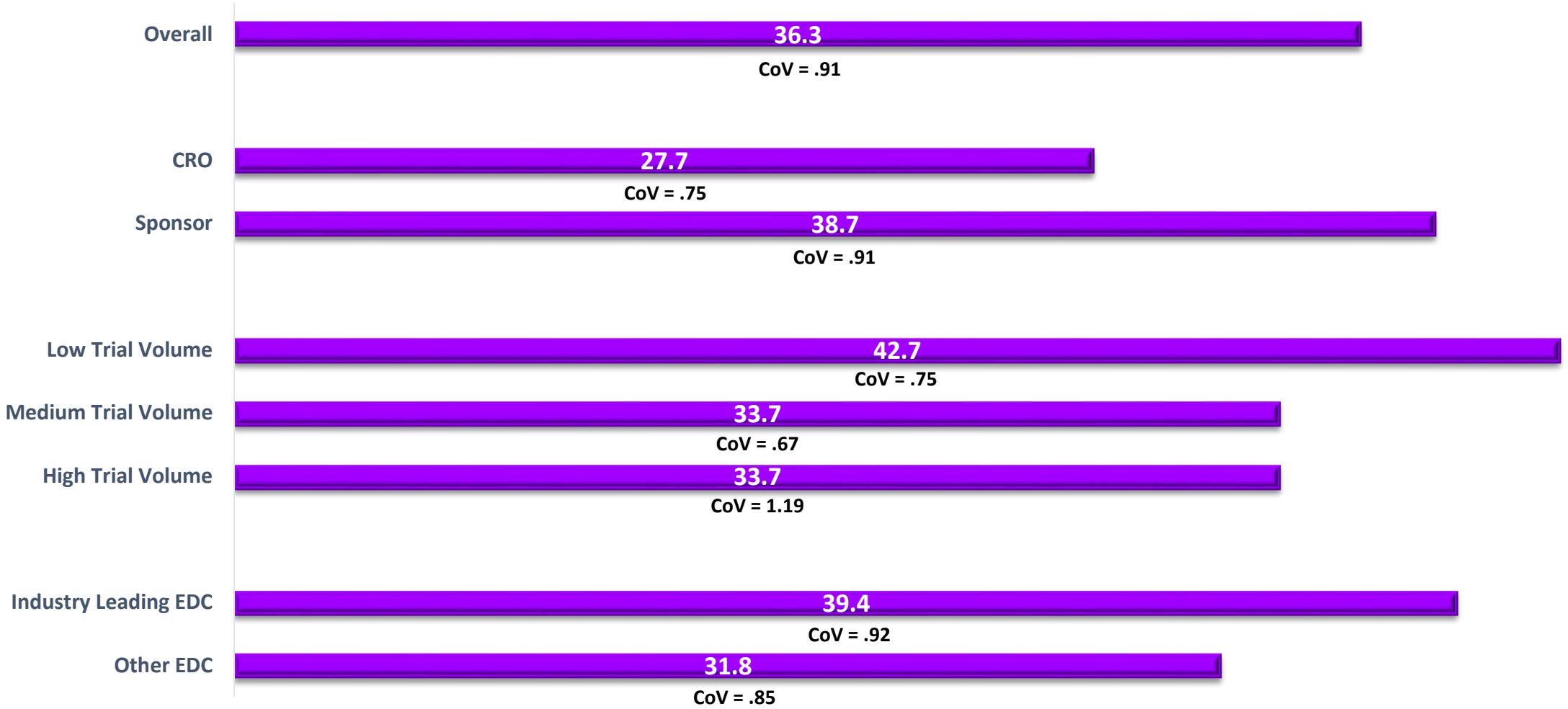
Average Time to Lock a Study Database

(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)?

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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?

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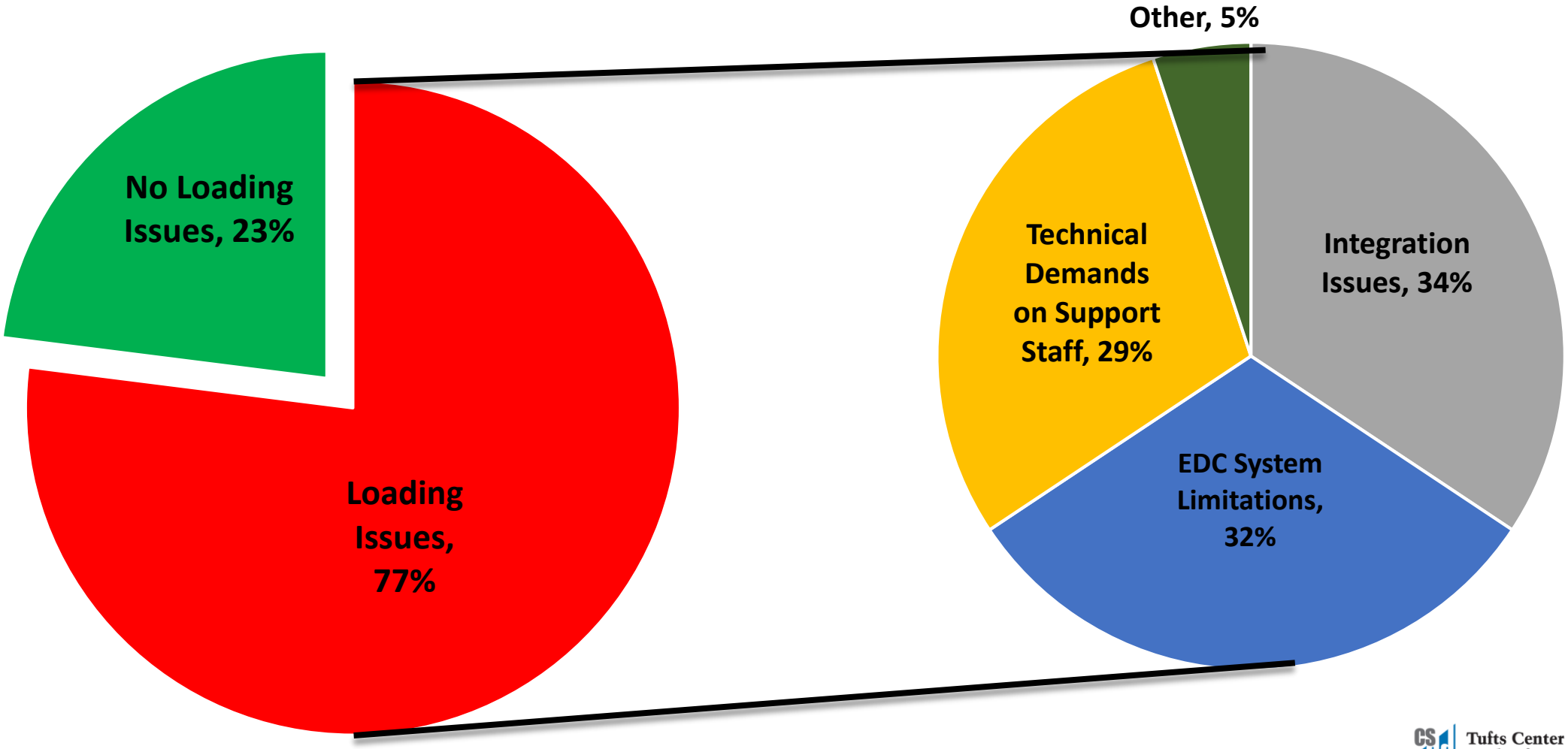
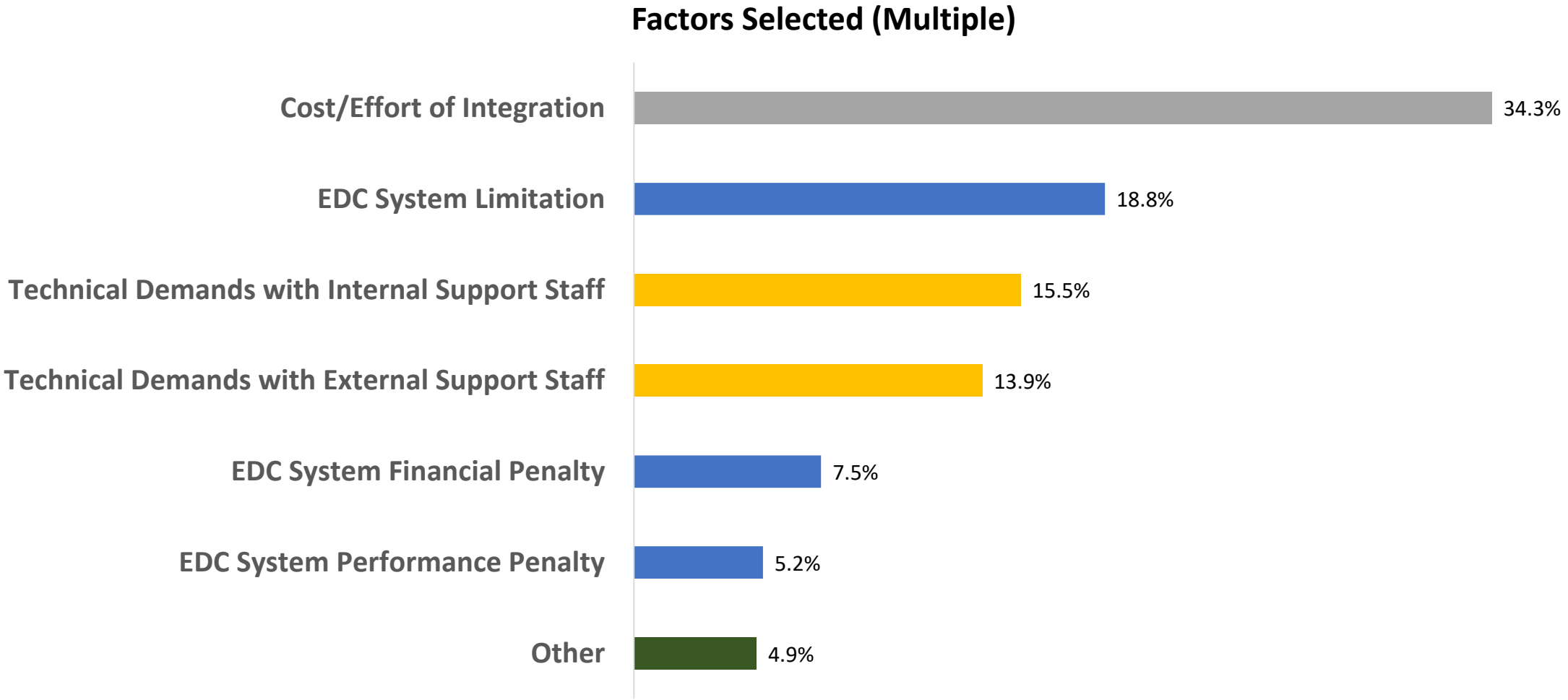
Challenges Loading Data into Primary EDC



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



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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)?
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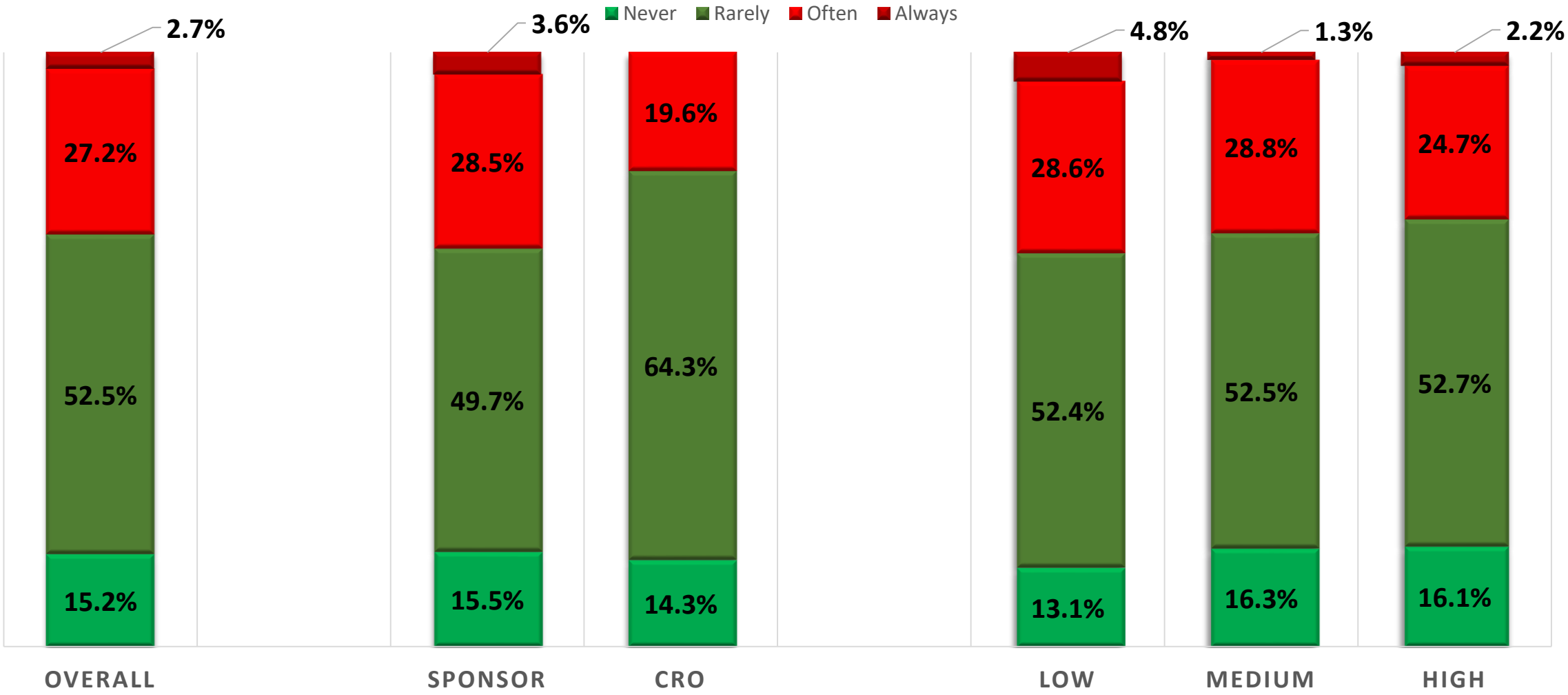
Incidence of EDC Release After FPFV



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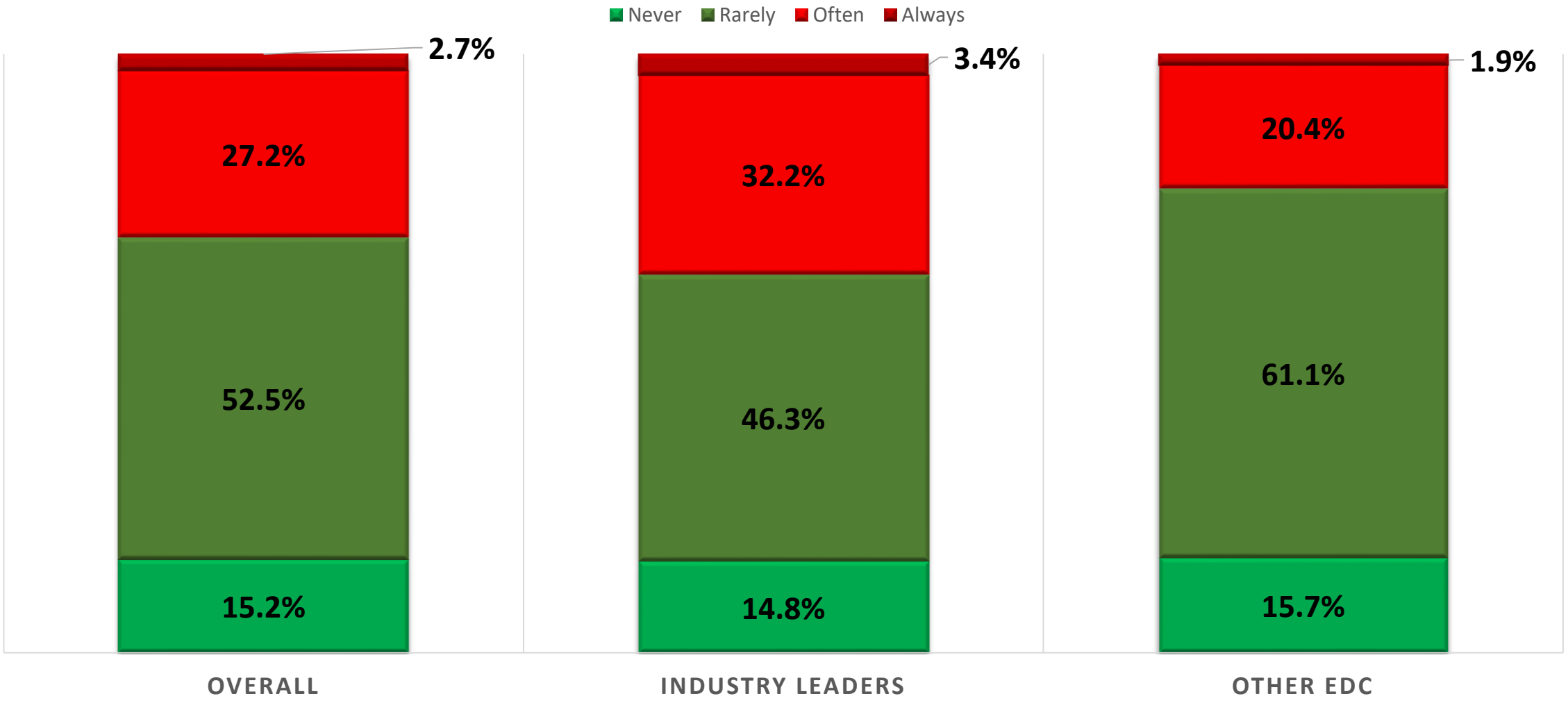

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About

- **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.

Tel: 617-636-2170
Fax: 617-636-2425
Email: csdd@tufts.edu
Web: http://csdd.tufts.edu

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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.

Tel: (925) 452-6500
Email: EDCsurvey@veeva.com
Web: https://www.veeva.com