Tufts CSDD-Veeva eClinical Study CRO Report

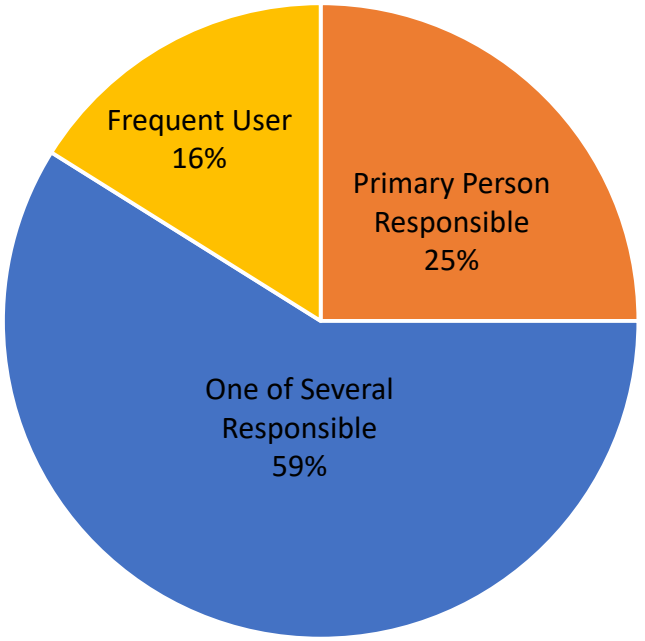
- **Assessing Data Management Practices, Performance, and Challenges**
- **Usage of Data Sources, Management Applications, and their Challenges**

About the Tufts-Veeva 2017 eClinical Landscape Study

CRO Report

- **Conducted online between May – July 2017**
- **257 Unique Companies Responded**
  - 56 unique CROs responded
- **CRO Respondent Years of Experience in Clinical Data Management**
  - Mean of 18.2 (median 20 years)
- **87.9% of Respondents Located in the U.S.**
  - 78.6% of CROs located in U.S.

CRO Clinical Data Management Responsibility*



3 Subgroup Stratifications

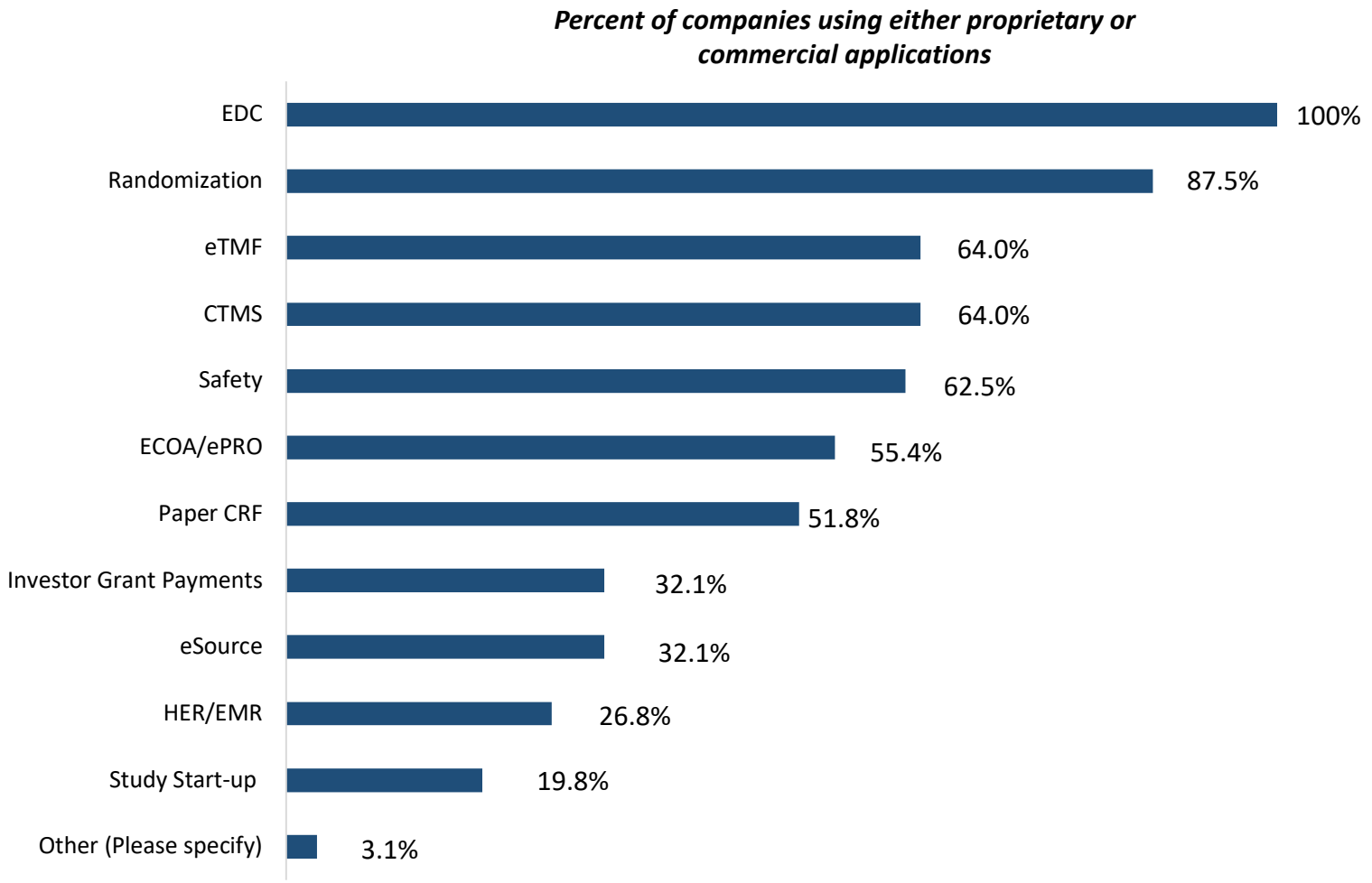
- **Company Type***
  - Sponsors (N=193)
  - CROs (N=56)

- **Company Size (Total Clinical Trial Volume Annually)****
  - Low: <5 trials, median=2 (N=56)
  - Medium: 5-15 trials, median= 25 (N=56)
  - High: >15 trials, median = 29 (N=56)

- **Primary EDC Provider *****
  - Industry Leaders (Medidata & Oracle) (N=56)
  - All Others (N= 201)

*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 by CROs



N=56

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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Average Number of Clinical Trial Applications Used by CRO Size

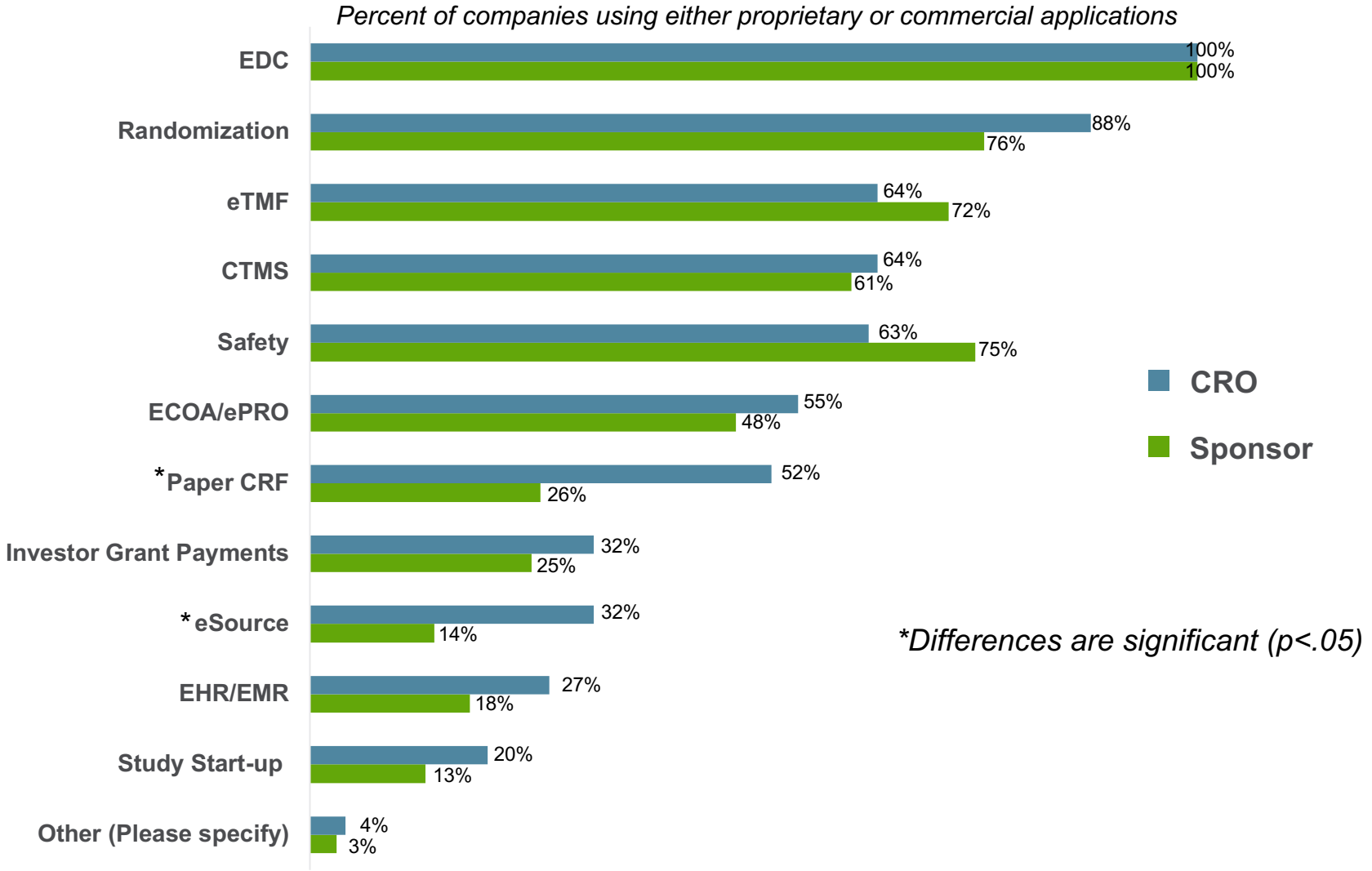
Volume of Clinical Trials Initiated Annually	Average Number of Applications Used*	Coefficient of Variation
Low	5.0	0.28
Medium	5.0	0.50
High	6.9	0.36

*Subgroup differences are significant (p=.025)

N=56

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.
How many clinical trials (studies) does your organization initiate each year across all phases?

Specific Clinical Data Management Applications Used by Company Type



N=249

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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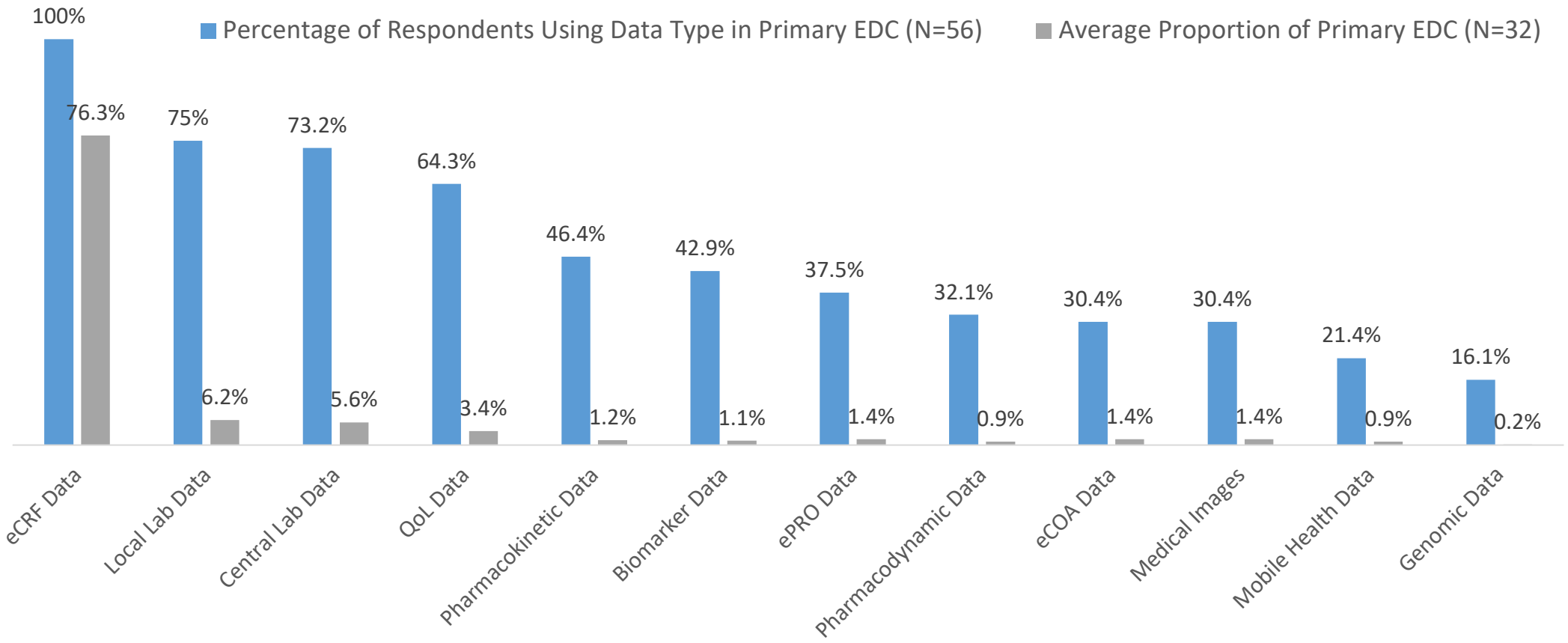
Types of Data CROs Manage in their Primary EDC vs Volume of Data Reported



N=56

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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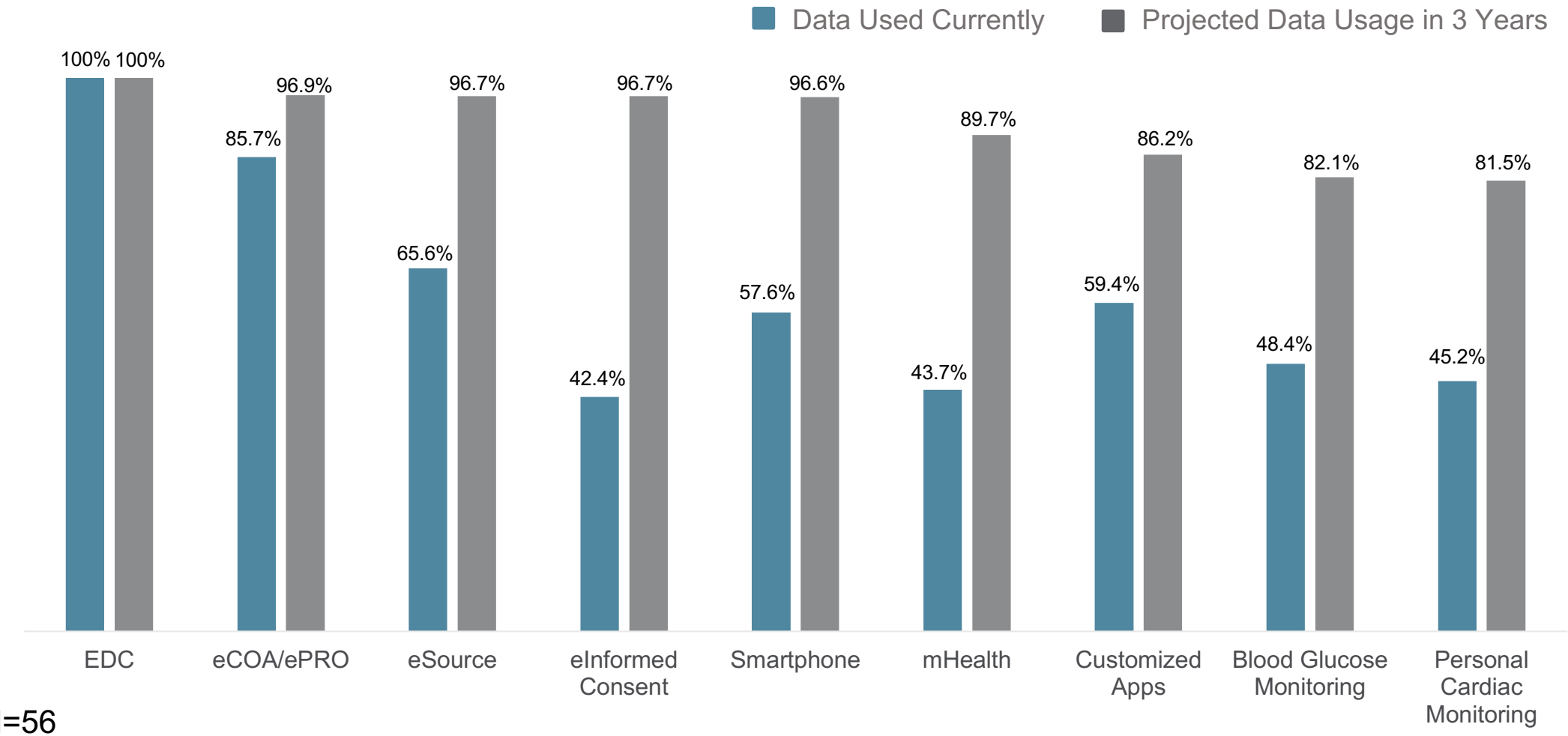
Data Sources Used by CROs Currently and Projected Use in 3 Years



N=56

Select the frequency with which your organization utilizes data from the following sources currently and estimate the frequency of utilization in three years

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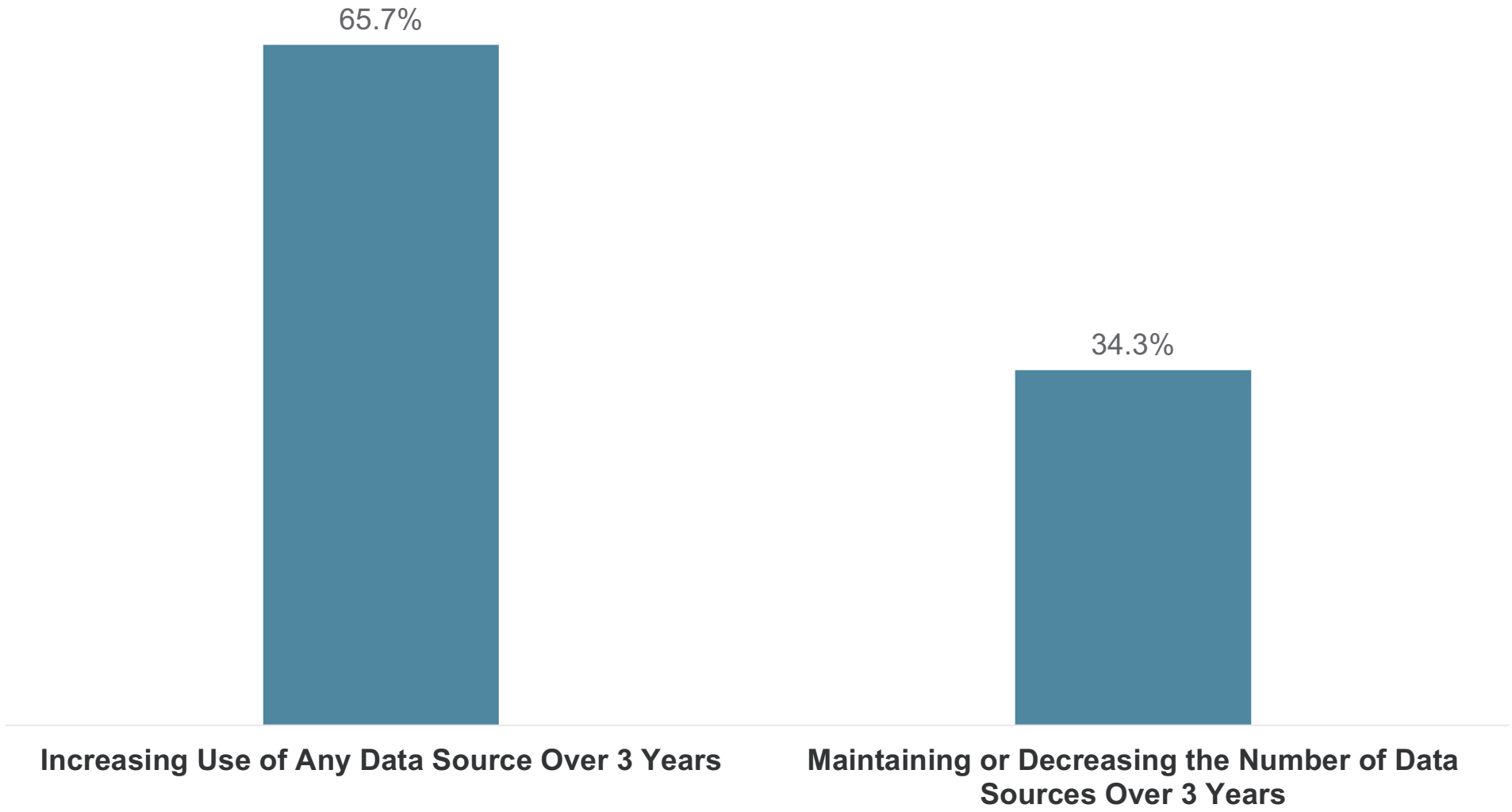
Percent of CRO Respondents Increasing Use of Any Data Source Over 3 Years



N=56

Select the frequency with which your organization utilizes data from the following sources currently and estimate the frequency of utilization in three years

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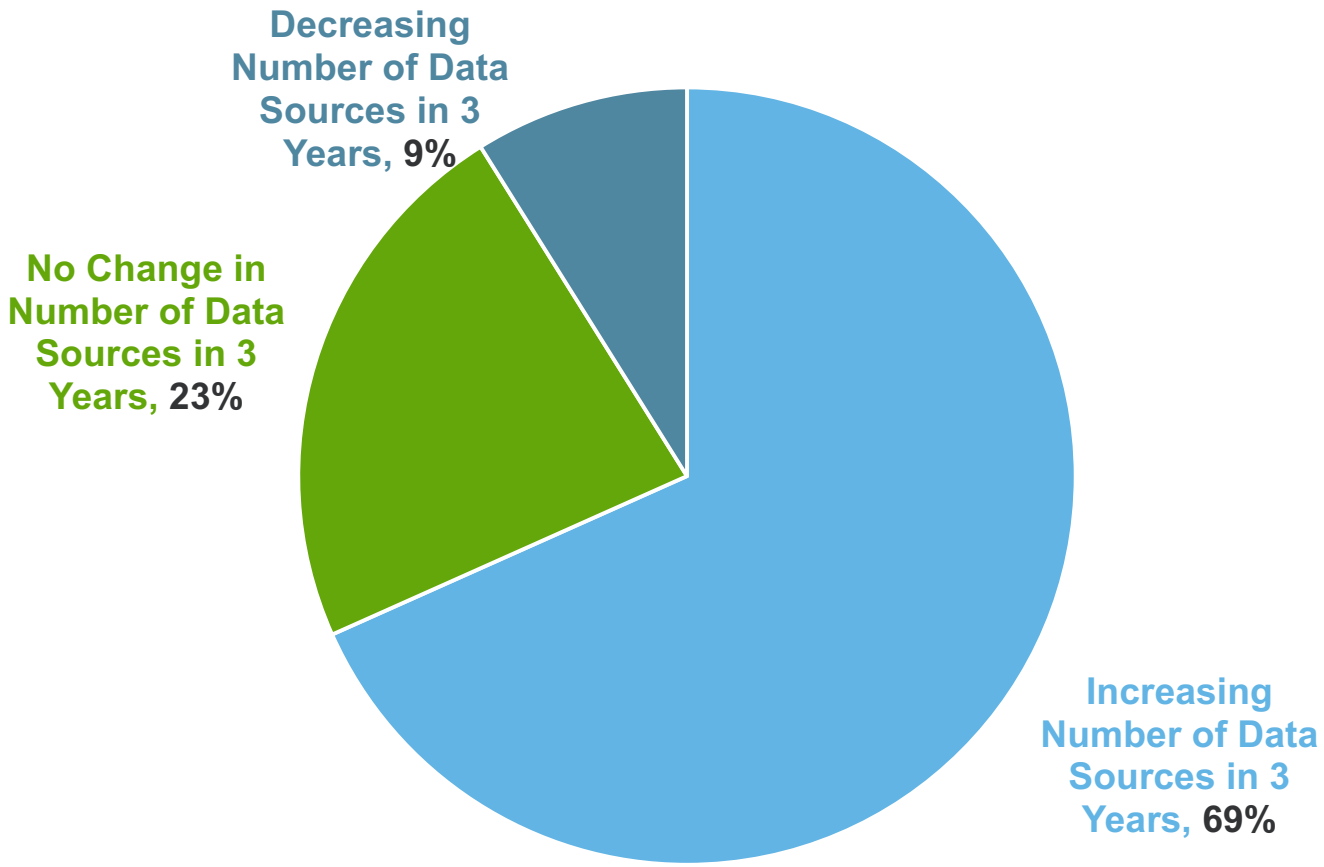
Proportion of CRO Companies Projecting Change in Total Data Sources Used in 3 years



N=56

Select the frequency with which your organization utilizes data from the following sources currently and estimate the frequency of utilization in three years

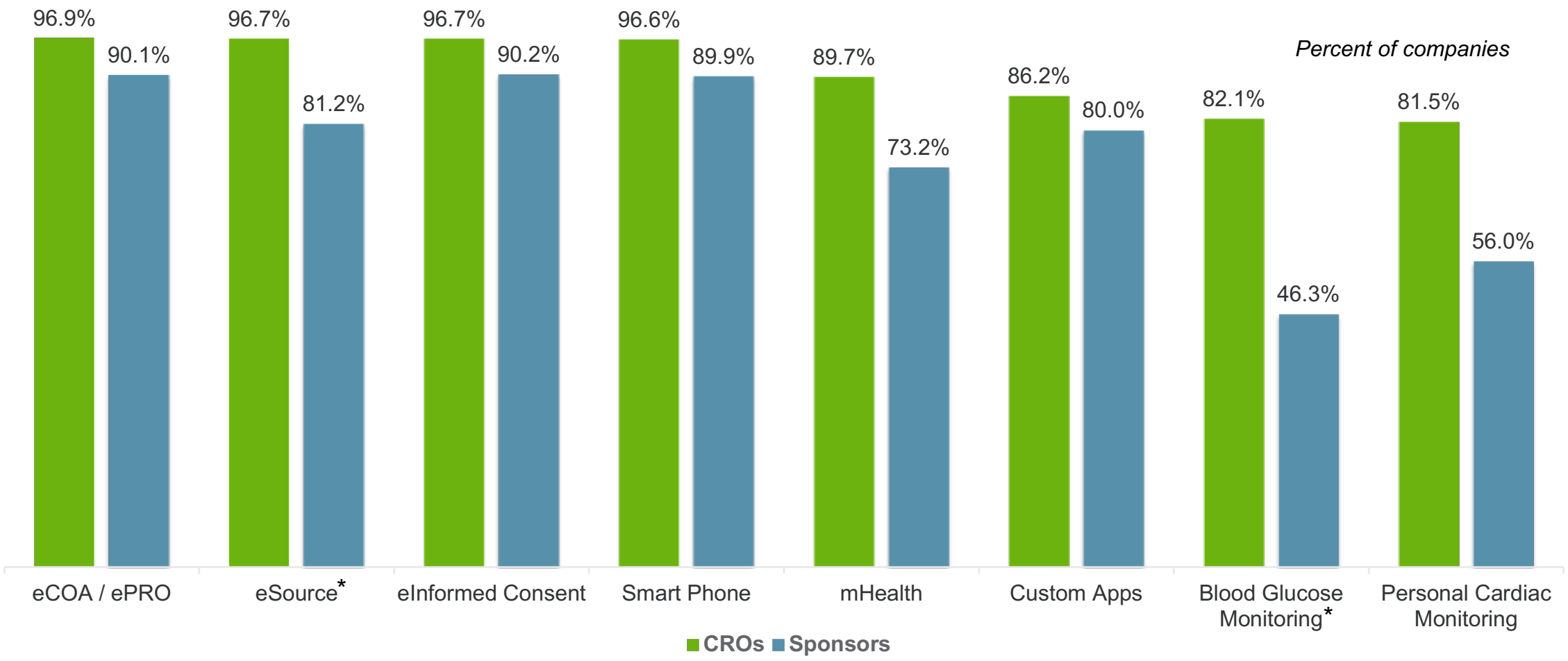
Magnitude of Projected Change in Data Sources Used by CROs

	Difference between reported data usage and projected usage in 3 years
EDC	0%
eCOA/ePRO	11.2%
eSource	31.1%
Informed Consent	54.3%
Smart Phone	39.0%
mHealth	46.0%
Customized Apps	26.8%
Blood Glucose Monitoring	33.7%
Personal Cardiac Monitoring	36.3%

N=56

Select the frequency with which your organization utilizes data from the following sources currently and estimate the frequency of utilization in three years

Projected Data Sources Used in 3 Years by Company Type



*Differences are significant (p<.05)

N=249

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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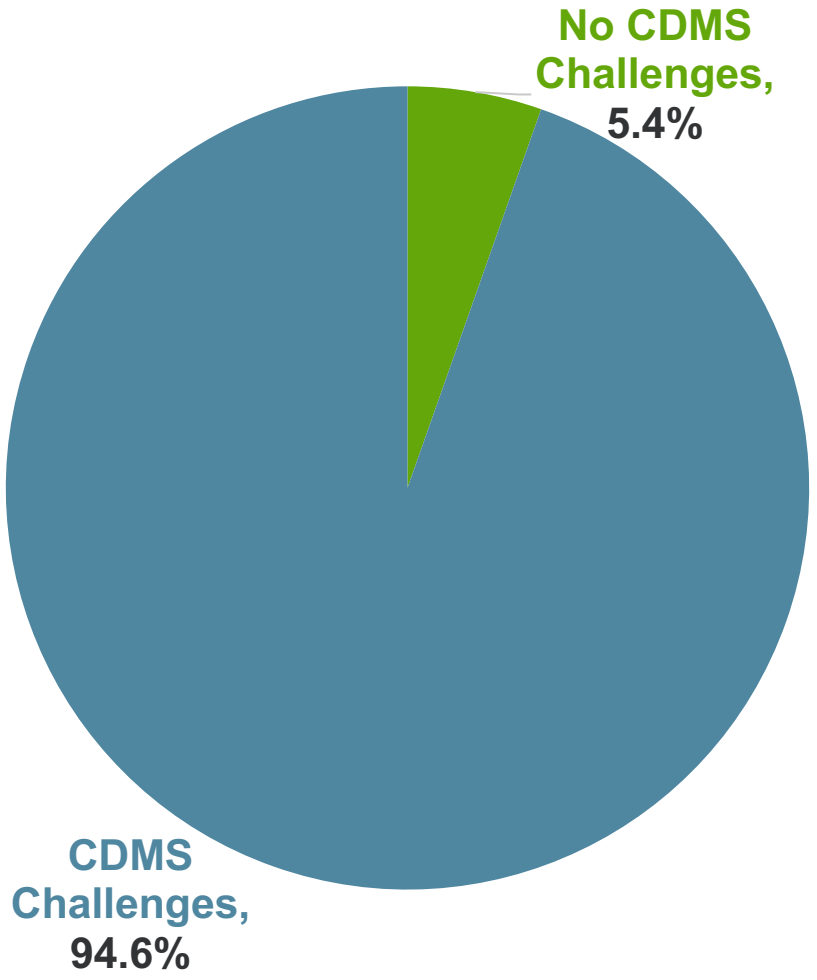
Proportion of CROs Reporting CDMS Challenges



N=56

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 by Company Type

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

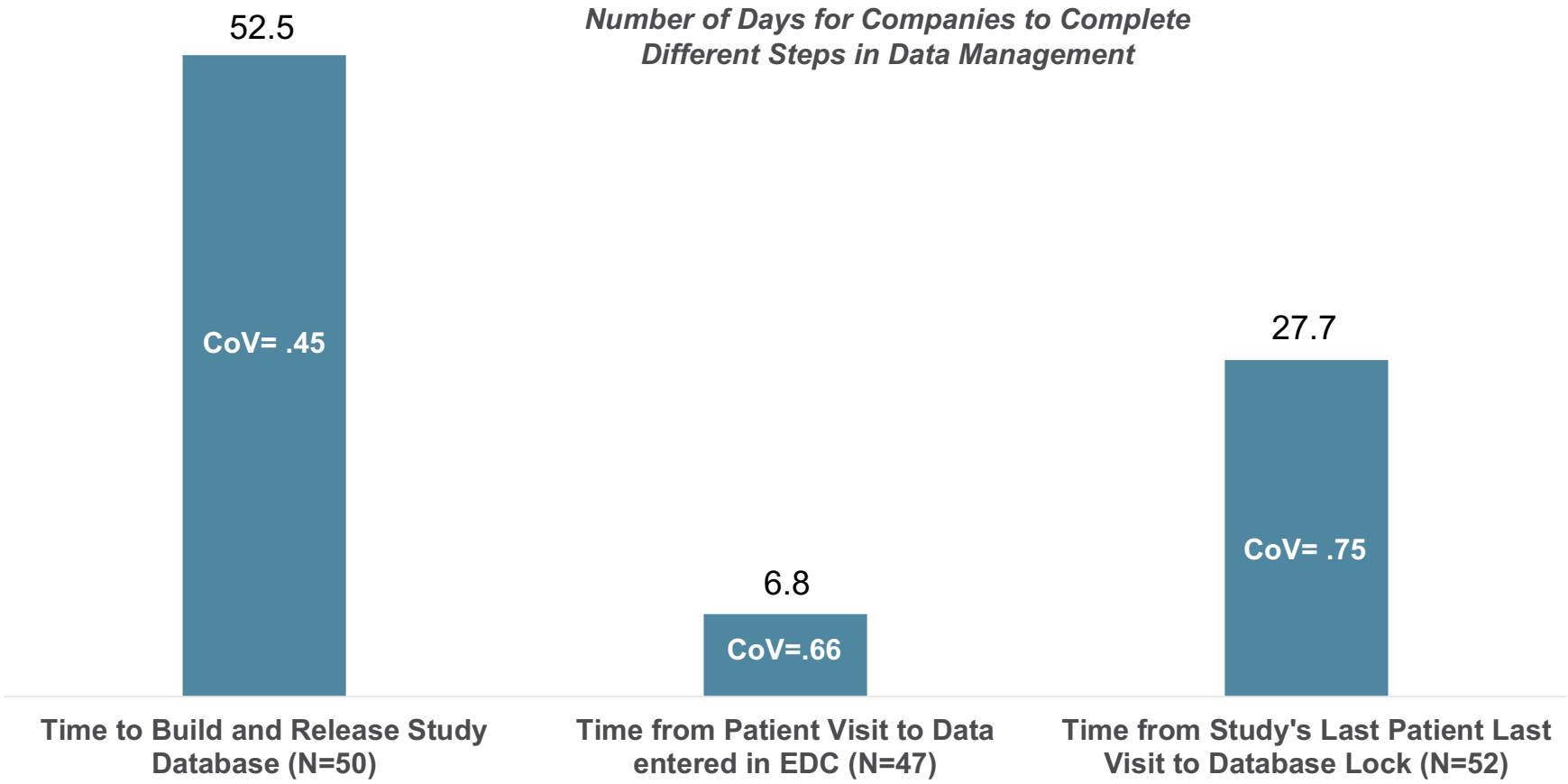
With specific reference to your organization's clinical data management systems, what is the biggest challenge you face today? (select one)

Biggest Single Reported CDMS Challenge by CRO Size

Percent Rate the Biggest Challenge	CRO (N=56)	Low Trial Volume	Medium Trial Volume	High Trial Volume
Cycle Time Challenges (Time from Protocol – FPFV or Time from LPLV – Database Lock)	31.5%	12.0%	20.6%	19.0%
Costs in Clinical R&D	20.4%	48.0%	35.3%	9.5%
Number of Systems in Clinical R&D	22.2%	8.0%	8.8%	26.2%
Volume of Source Data Verification	16.7%	12.0%	17.6%	21.4%
Other (Protocol related, system related)	3.7%	8.0%	2.9%	2.4%
No CDMS Challenges	5.6%	0.0%	5.9%	0.0%

With specific reference to your organization's clinical data management systems, what is the biggest challenge you face today?
How many clinical trials (studies) does your organization initiate each year across all phases?

Data Management Cycle Time for CROs



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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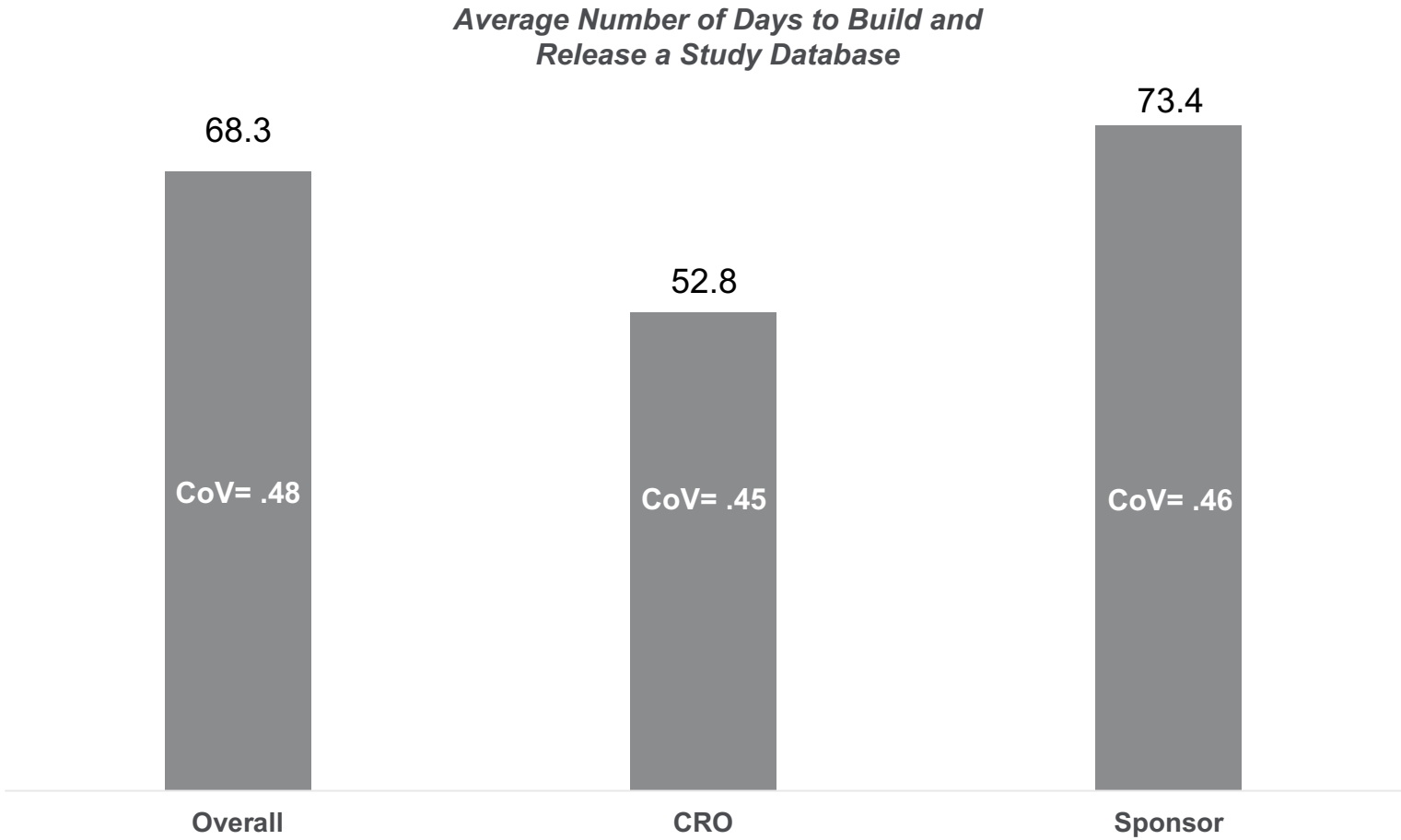
Average Time to Build and Release a Study Database by Company Type



N=257

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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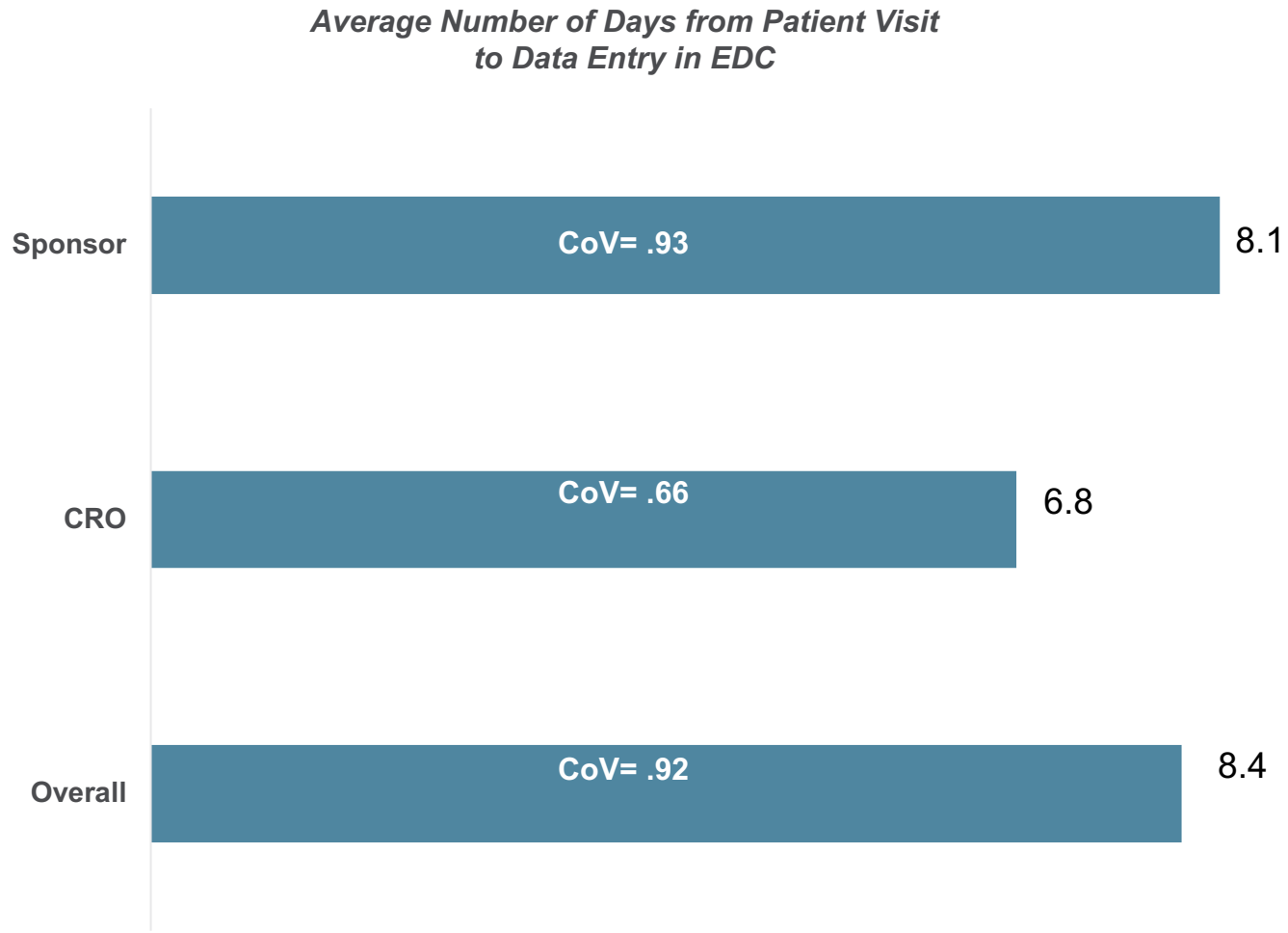
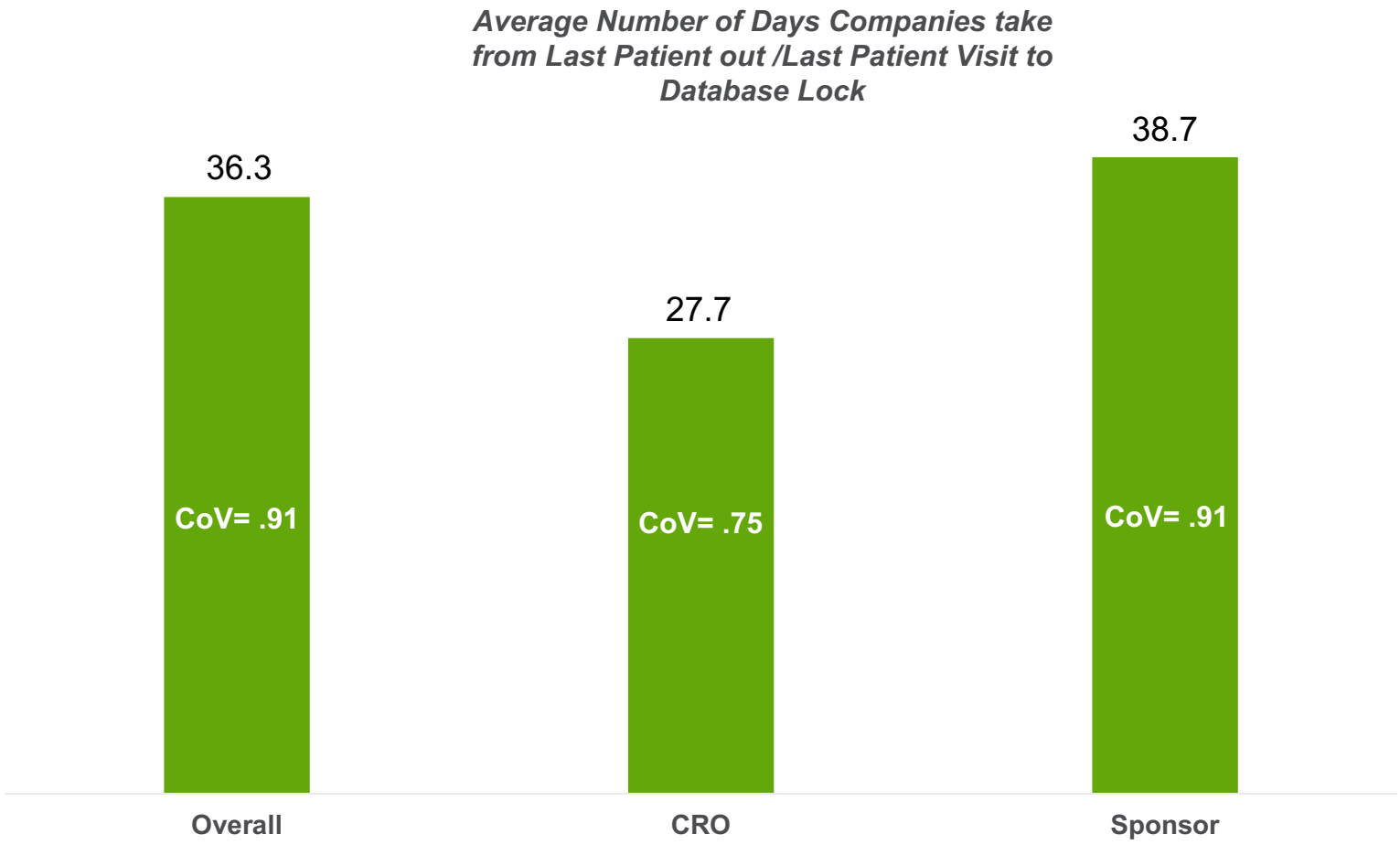
Average Time for Site Staff to Enter Patient Data by Company Type



N=257

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 by Company Type



N=257

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 by Company Type

	Percent of Total (N=257)	CROs (N=56)	Sponsors (N=193)
Protocol Changes	45.1%	51.8%	43.5%
User Acceptance Testing (Including Review and Approvals)	16.7%	12.5%	17.6%
Database Design Functionality	15.2%	7.1%	17.6%
Study Database Move from Development into Production	8.2%	7.1%	8.8%
Standards Management	4.3%	0%	5.7%
Ethics Approval Delays/Changes	1.2%	1.8%	1.0%

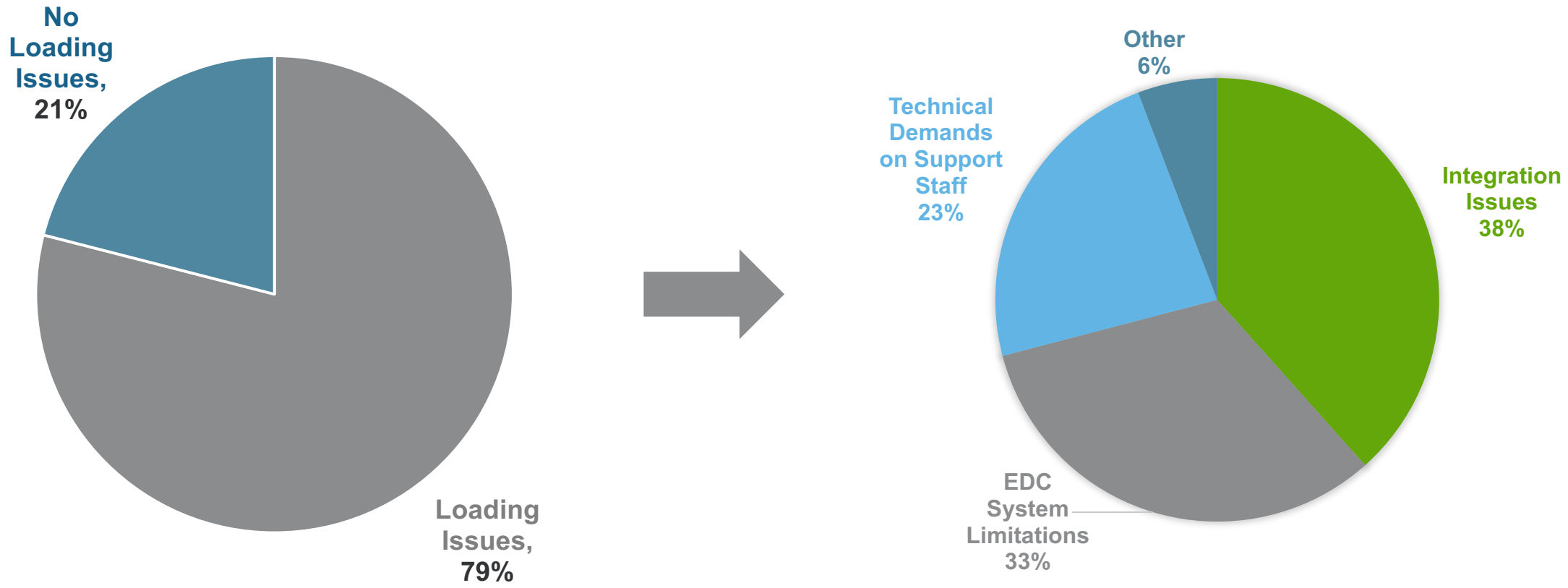
To the best of your knowledge, what is the most common cause for delays when your organization is building clinical trial databases?

Association Between Causes of Delays and Cycle Times for CROs

	CROs (N=56)	*Time from LPV to DB Lock	Coefficient of Variation
Protocol Changes	51.8%	34.3 Days	.69
User Acceptance Testing	12.5%	36.8 Days	1.08
Database Design Functionality	7.1%	59.6 Days	1.51
Study Database Move from Development into Production	7.1%	48.4 Days	.69
Standards Management	0%	44.0 Days	.34
Ethics Approval Delays/ Changes	1.8%	21.0 Days	0
Overall	100%	39.3 Days	1.11

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)?

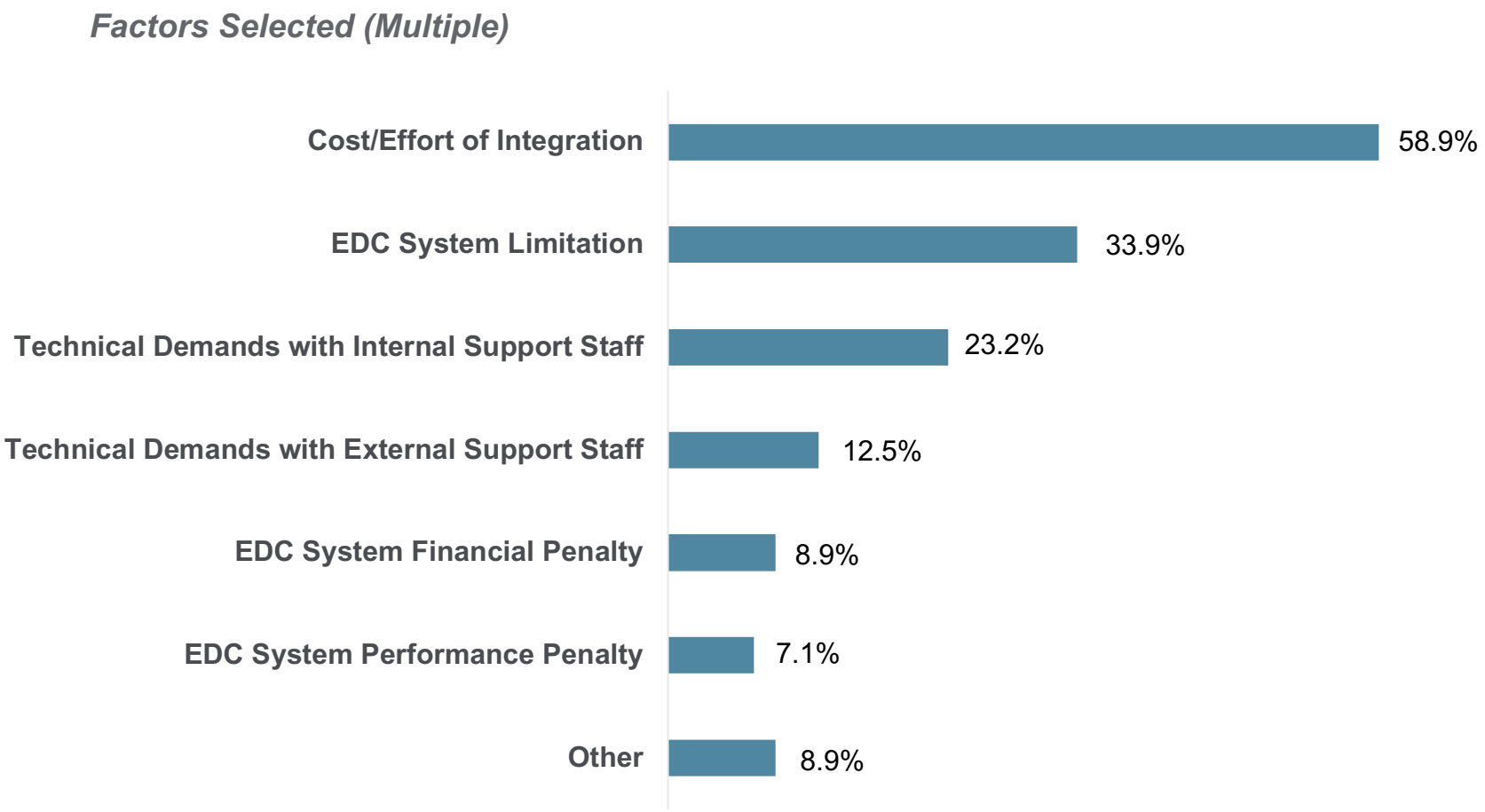
Challenges CROs Face When Loading Data into Primary EDC



N=56

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

Specific Factors Preventing CROs from Loading Data into their Primary EDC



N=56

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

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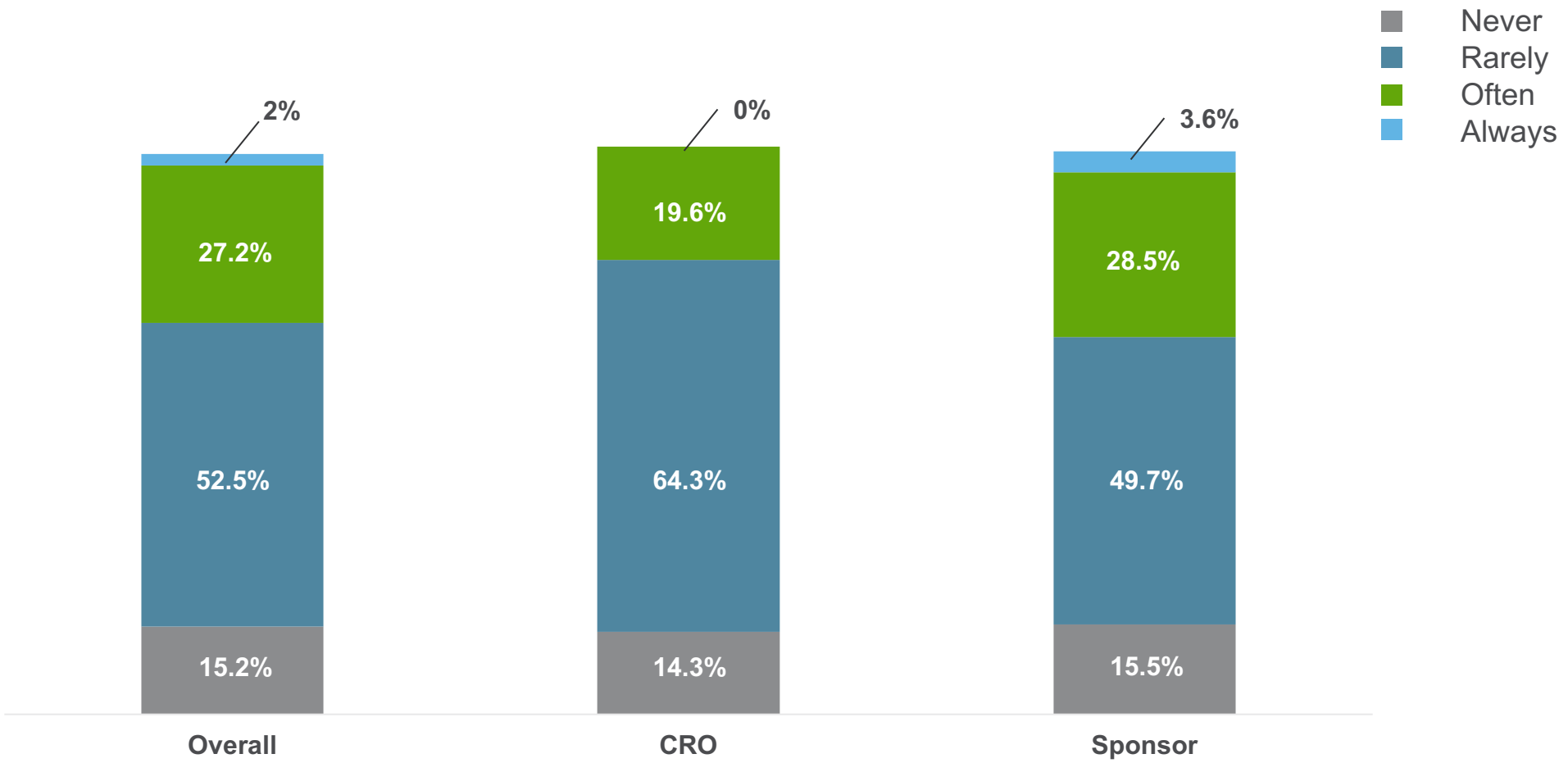
Incidence of EDC Release After FPFV by Company Type



N=257

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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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

- 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.

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