

Data Standards Governance and Implementation Across Industry: Key Challenges and Benefits

- Presented by: Gayathri Mahadevan (gayathri.Mahadevan@cytel.com)
Matt Baldwin (mbaldw01@amgen.com)
- With Support from ODS Working group members for the project “Best practices in data standards implementation governance”

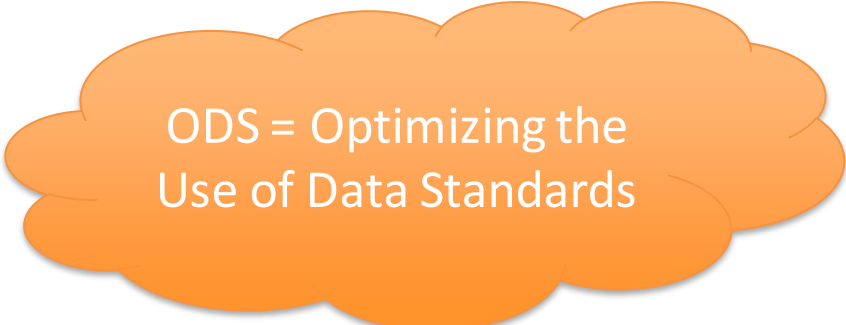
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Introduction

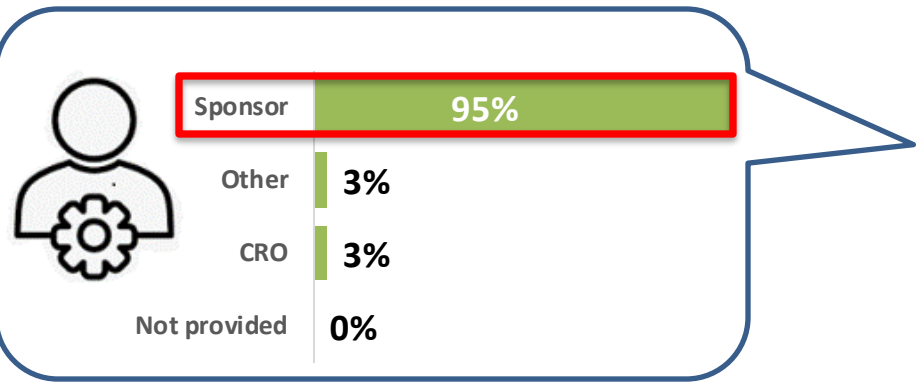
- PHUSE ODS working group created and released a survey “[Best Practices for Data Standards Governance Implementation](#)” on February 14, 2022.
- Entries were accepted through March 15, 2022. 171 individual responses were received.
- Responses were requested from anyone who is involved in data standards governance or is a user of data standards, from any functional role
- The purpose of the survey was to gather insight into:
 - how organizations are currently governing data standards
 - scope of standards governed
 - how governance is organized
 - key challenges and pain points experienced by organizations when implementing and governing the standards
 - key benefits of a standards library
- This presentation provides details on select survey demographics, challenges & benefits



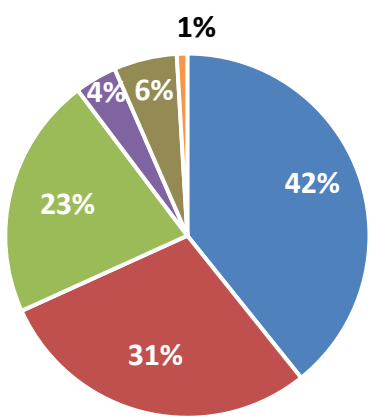
ODS = Optimizing the
Use of Data Standards

Survey Demographics

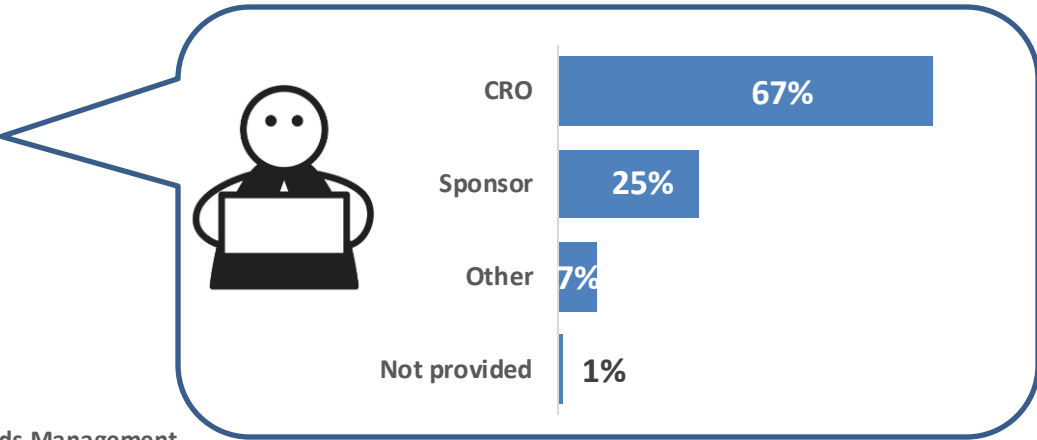
N=171



Standards Management

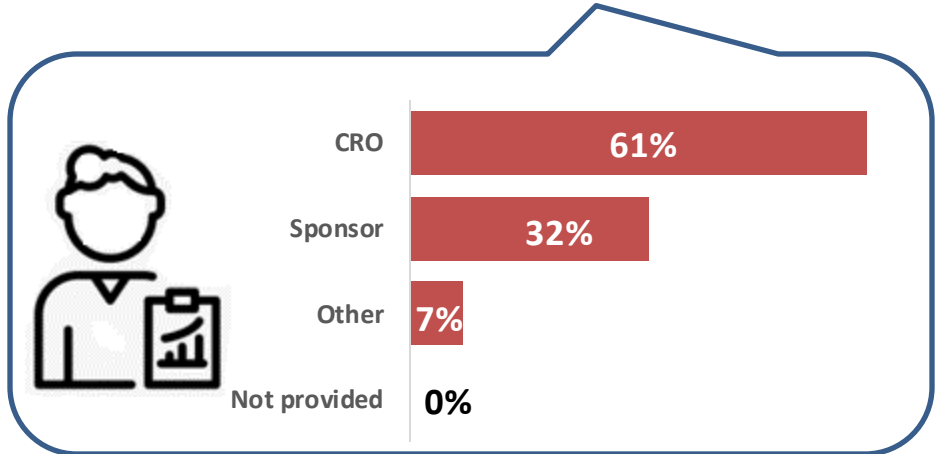


- Programmer
- Statistician
- Standards Management
- Data Management
- Other
- Not Provided



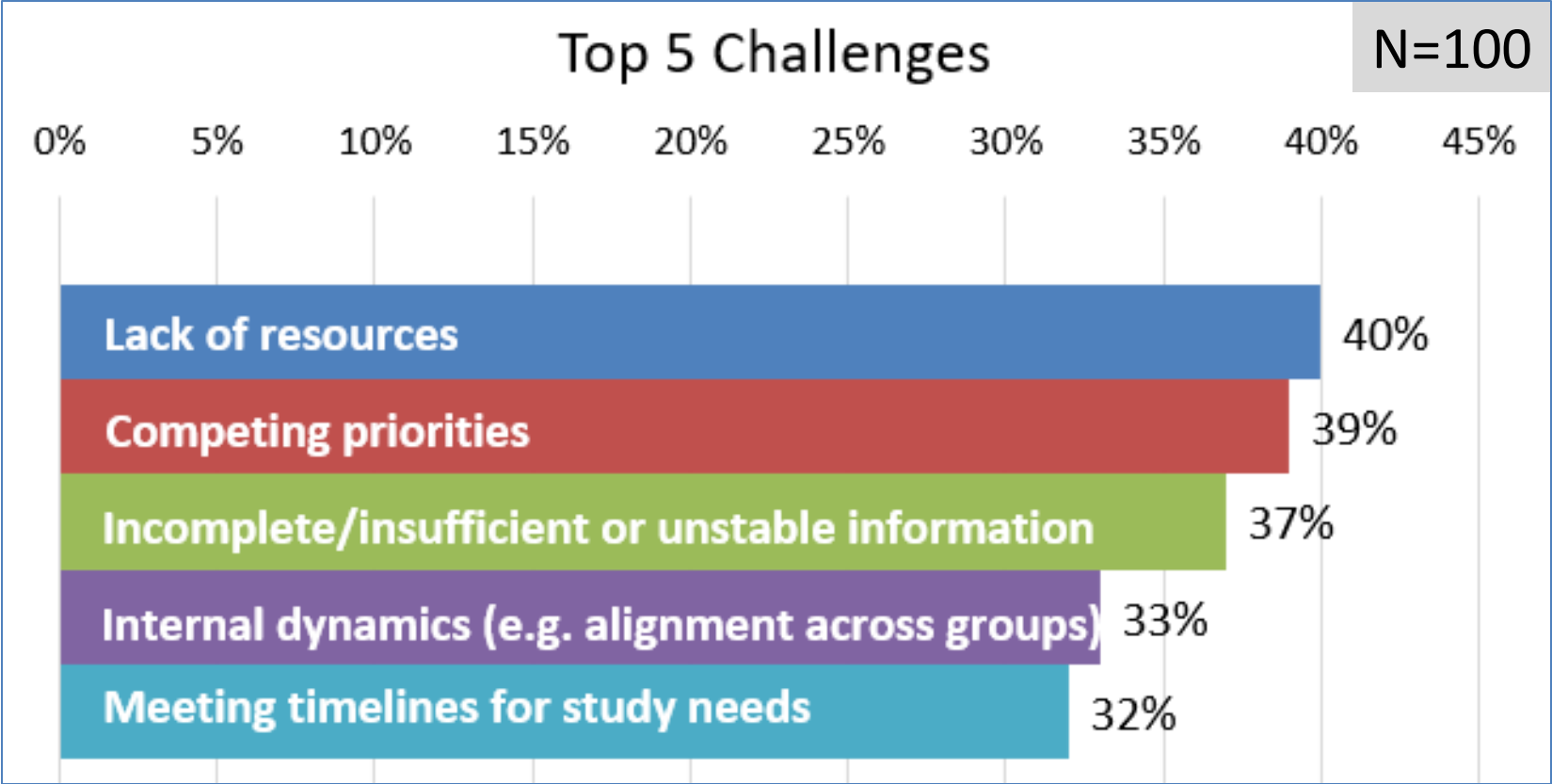
Programmer

Statistician

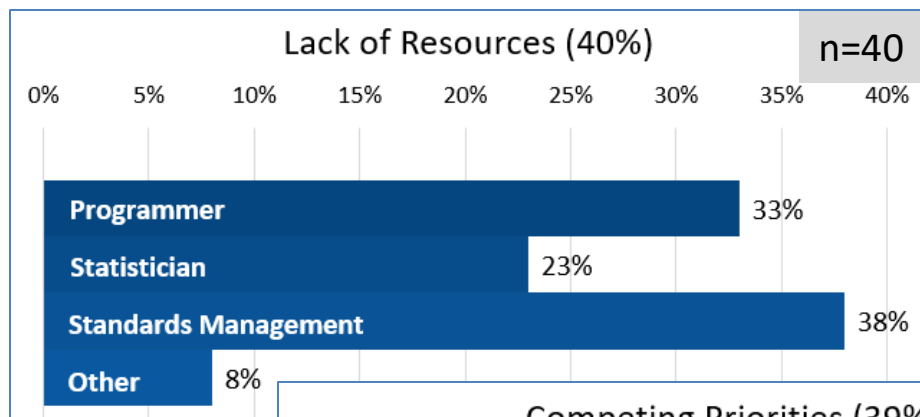


* Both Pharmaceutical and Biotech sponsors are combined as sponsor
* 98% of respondents expressed their views on clinical data

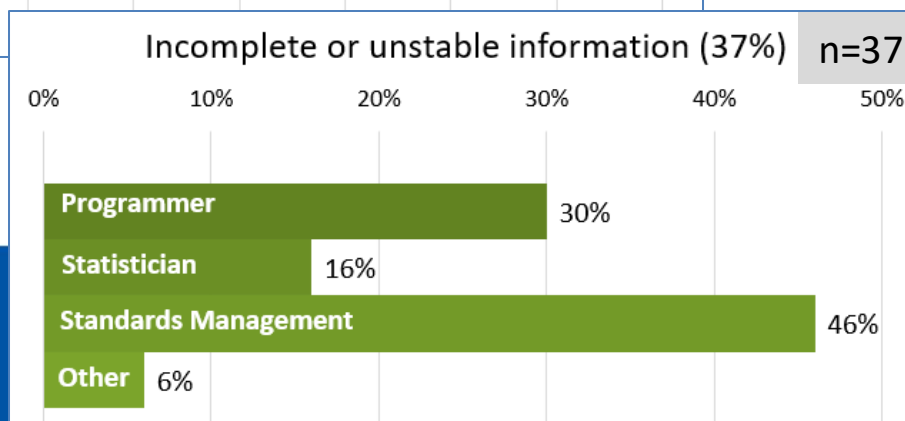
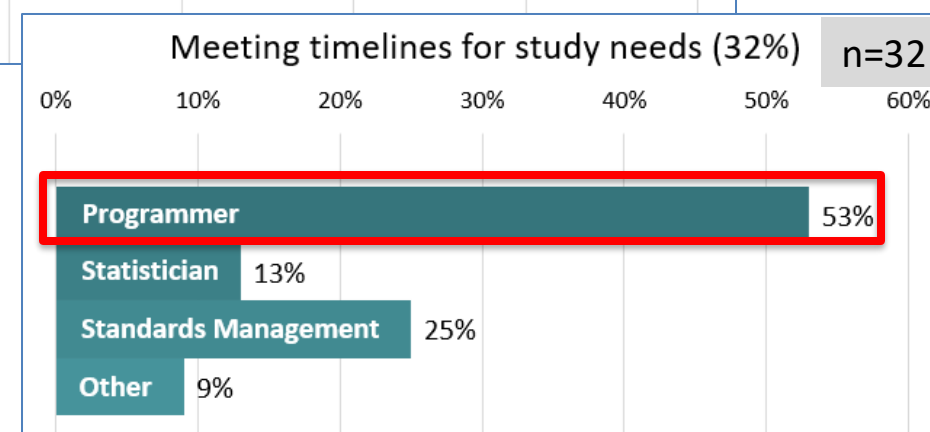
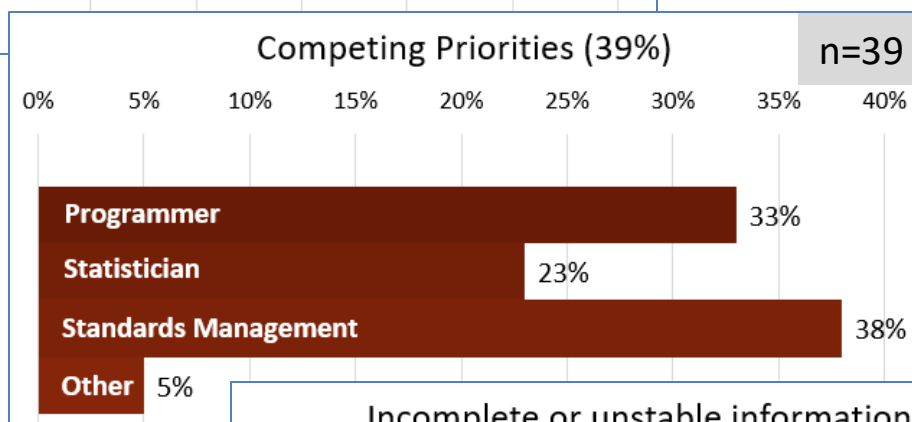
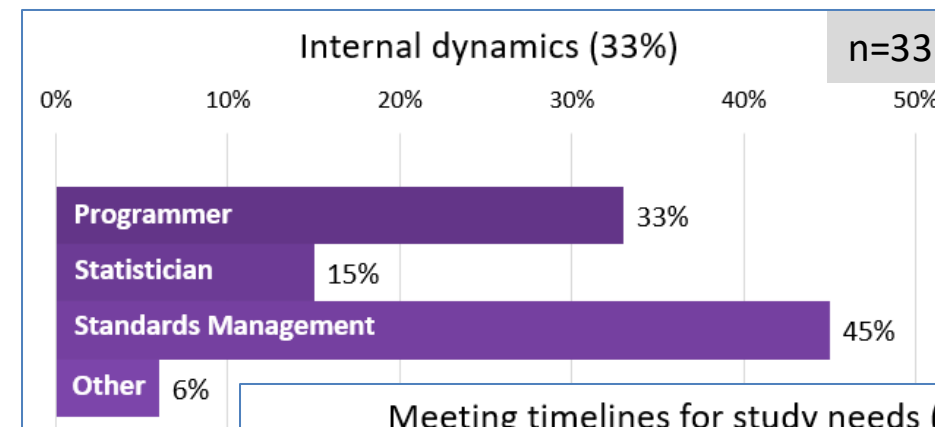
What are your biggest challenges in developing standards? (Q11)



What are your biggest challenges in developing standards? (Q11)



N=100



What are your biggest challenges in developing standards? (Q11)

Notable Observations:

N=100



Programmer
➤ Top response at 45%

- Meeting timelines for study needs

n=38



Challenge	
Meeting timelines for study needs	45%
Competing priorities	34%
Lack of resources	34%



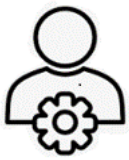
Statistician
➤ Tie for top two responses at 43%

- Lack of resources
- Competing priorities

n=21



Challenge	
Competing priorities	43%
Lack of resources	43%
Incomplete or unstable information	29%



Standards Management
➤ Top response at 53%

- Incomplete/insufficient or unstable information

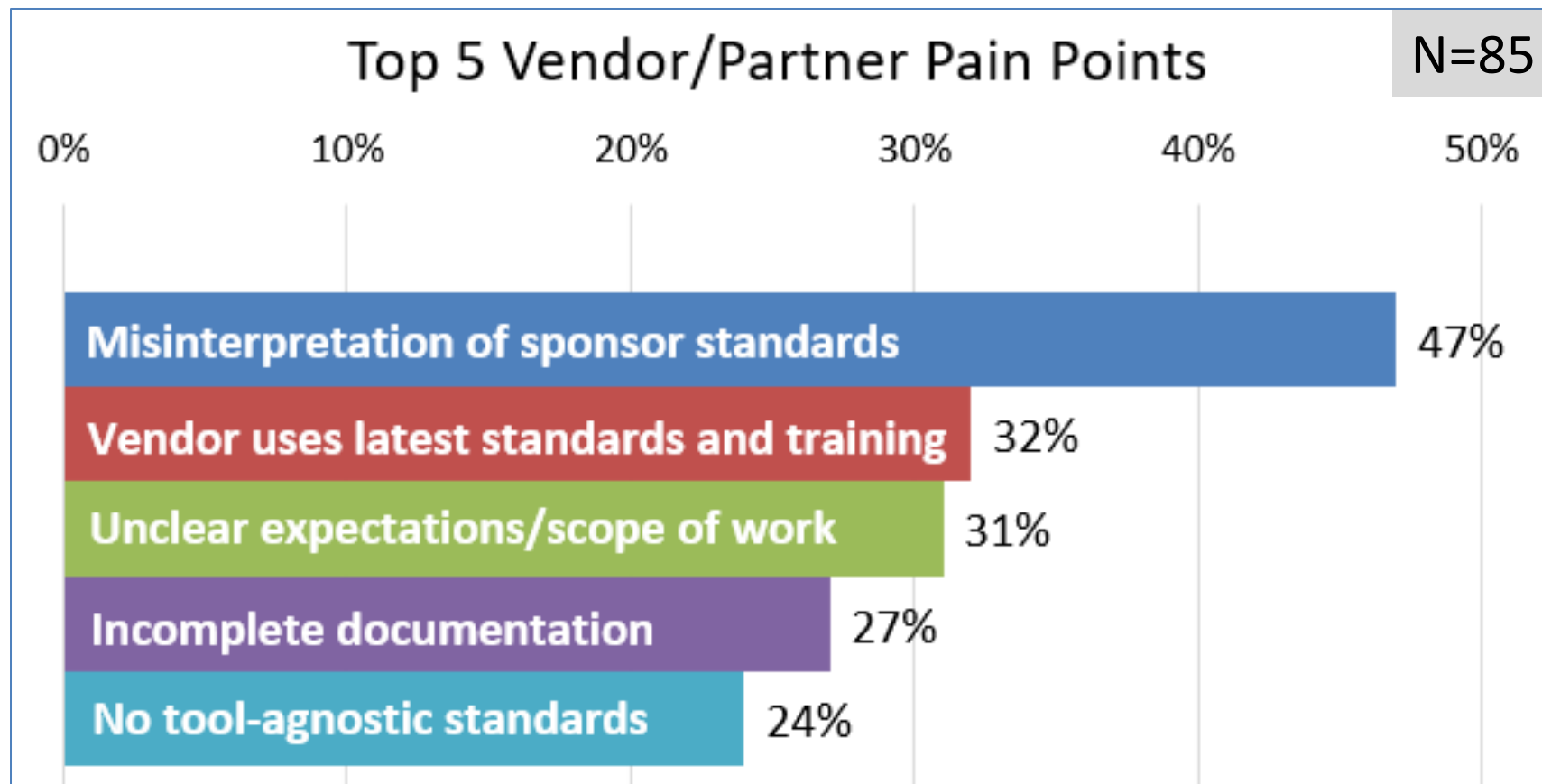
➤ Five responses above 40%

n=32

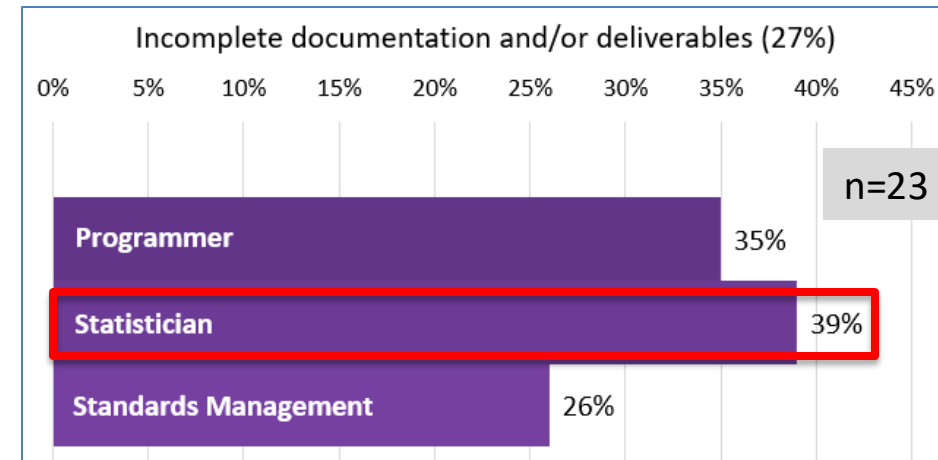
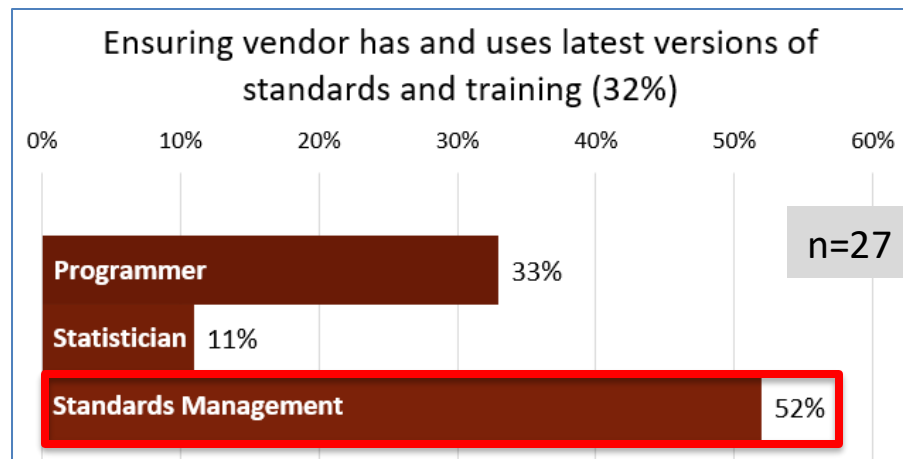
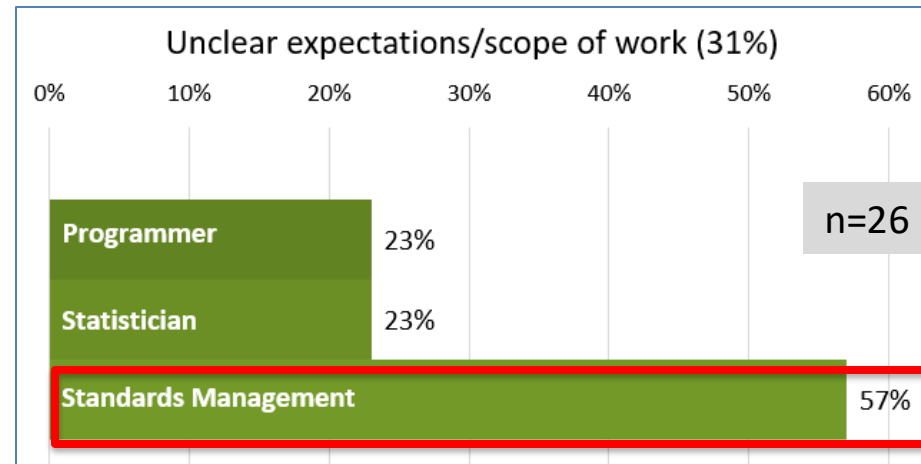
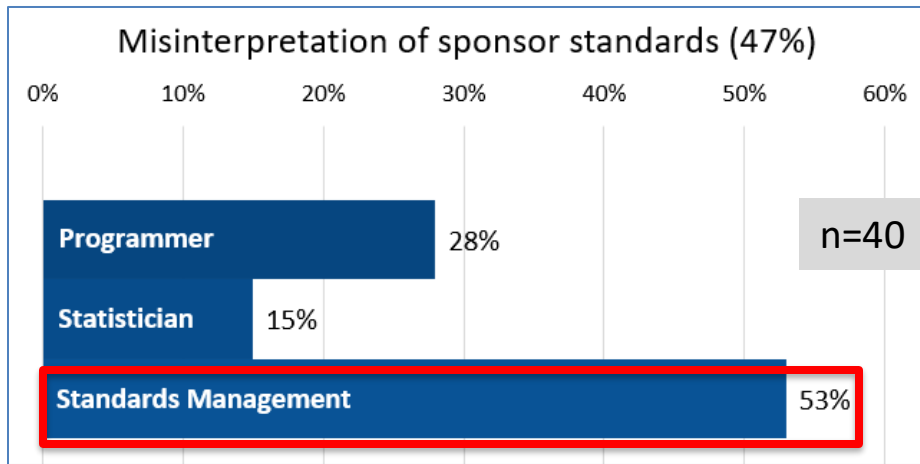


Challenge	
Incomplete or unstable information	53%
Internal dynamics	47%
Competing priorities	47%
Lack of resources	47%
Standards not covered by CDISC	41%

What are the pain points for implementing and governing standards between sponsors and vendors/partners? (Q22)



What are the pain points for implementing and governing standards between sponsors and vendors/partners? (Q22)



N=85

What are the pain points for implementing and governing standards between sponsors and vendors/partners? (Q22)

Notable Observations:

N=85



Programmer

n=34

- Top response at 35%
 - Traceability
- Unknown / Not applicable at 32%

Pain Point

Traceability	35%
Misinterpretation of sponsor standards	32%
Unknown/Not applicable	32%
Vendor uses latest standards and training	26%



Statistician

n=17

- Top response at 53%
 - Incomplete documentation and/or deliverables
- Unknown / Not applicable at 47%

Pain Point

Incomplete documentation and/or deliverables	53%
Unknown/Not applicable	47%
Misinterpretation of sponsor standards	35%
Unclear expectations/scope of work	35%



Standards Management

n=27

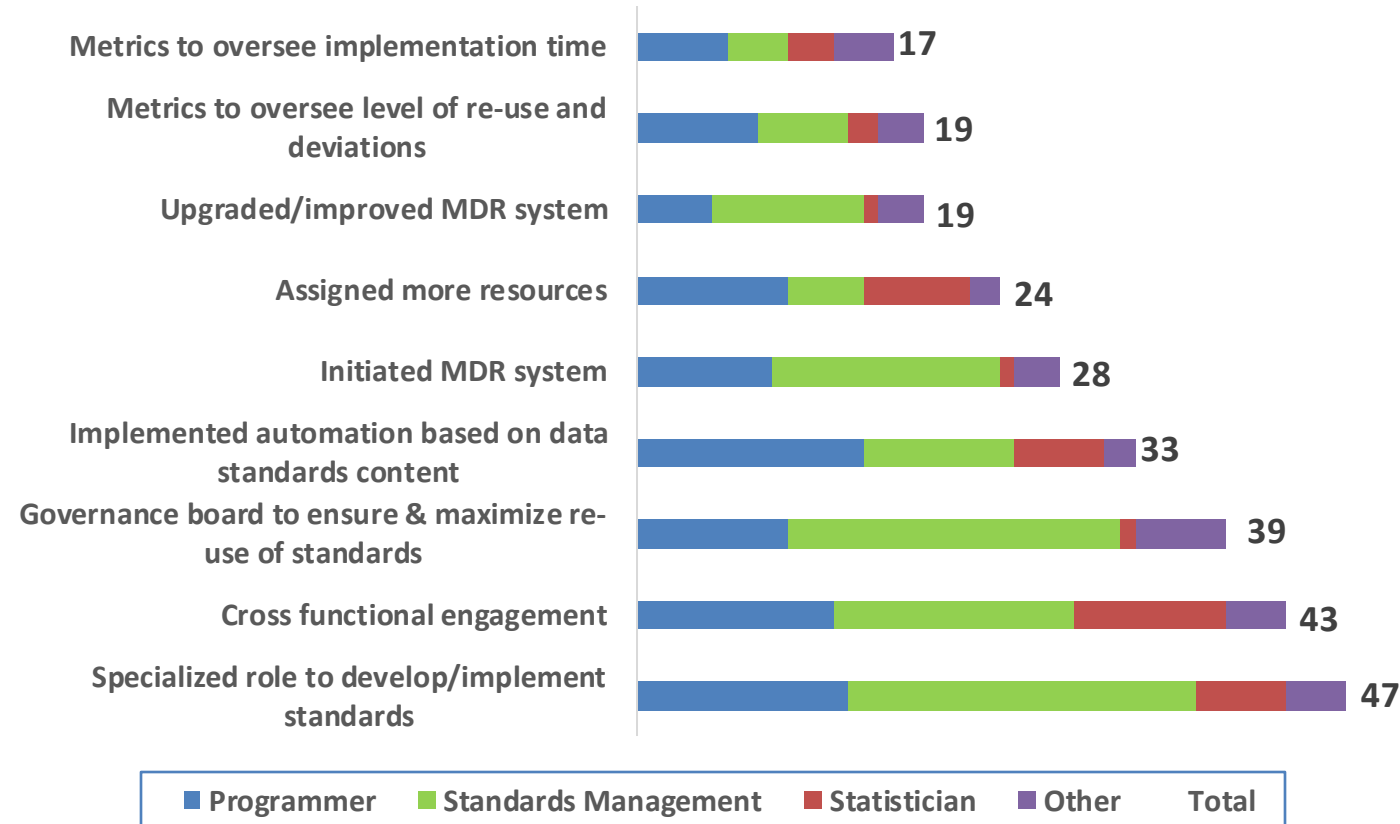
- Top response at 78%
 - Misinterpretation of sponsor standards
- Unknown / Not applicable at 4%

Pain Point

Misinterpretation of sponsor standards	78%
Vendor uses latest standards and training	52%
Unclear expectations/scope of work	48%

Actions That Improved Development / Implementation Time (Q12)

N=83



Top three actions as selected by our focus roles:

Programmer

- Implementation of automation based on data standards content
- Specialized role to develop/ implement standards
- Cross functional engagement

Statistician

- Cross functional engagement
- Assigning more resources
- Specialized role to develop/ implement standards

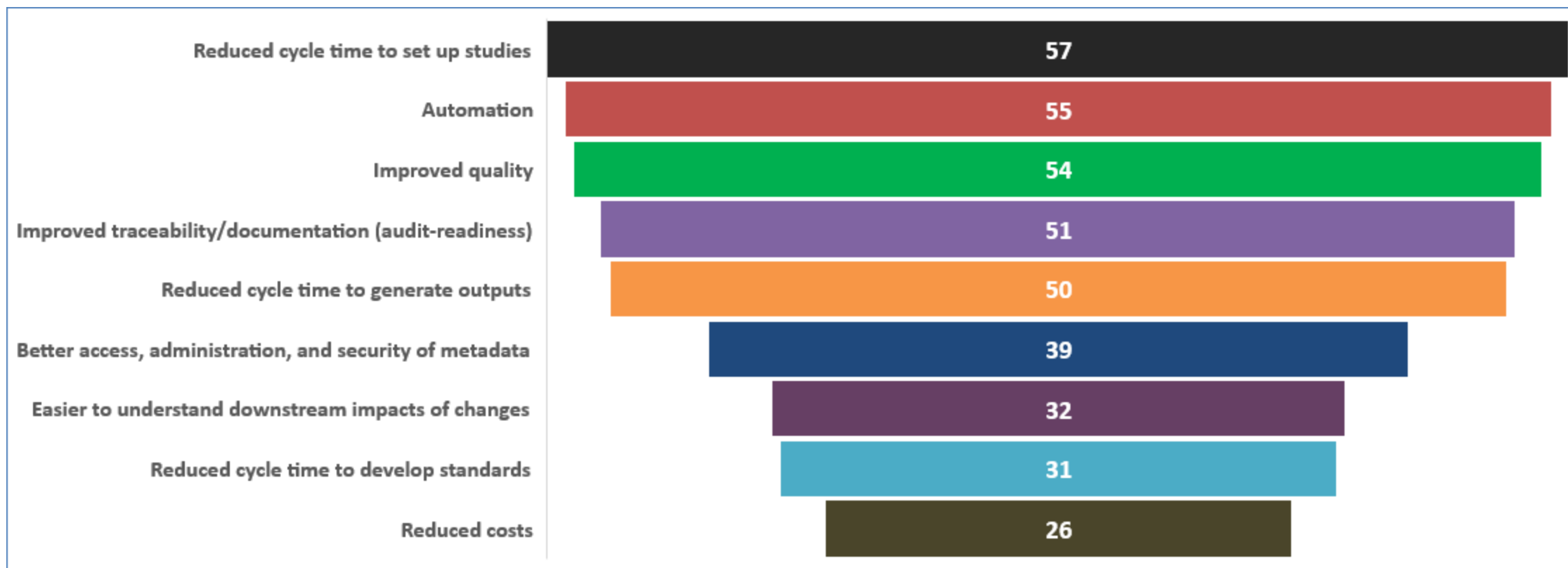
Standards Management

- Specialized role to develop/ implement standards
- Governance board to ensure and maximize re-use of existing standards
- Cross functional engagement

* Respondents could select more than one action. Figure excludes "NA", "Unknown" and "Other" action

N=81

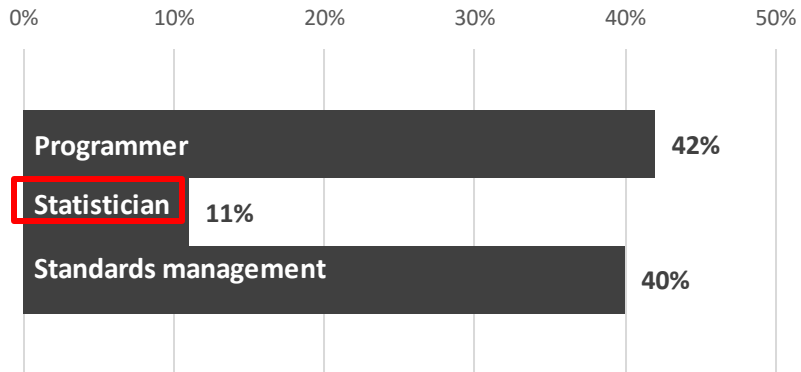
Benefits of Standards Library (Q16)



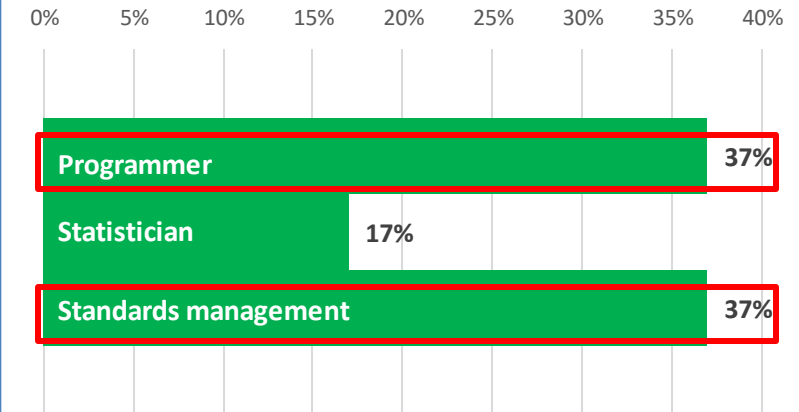
- Select all that apply question.
- Figure represents all selections excluding “Other”, “Not Applicable” and “Unknown”

Benefits of Standards Library (Q16)

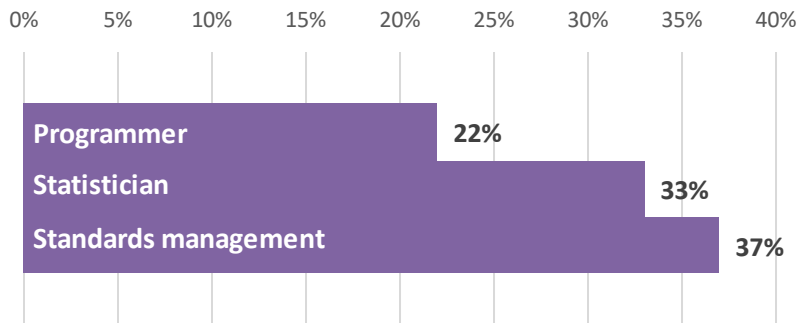
Reduced cycle times to set up studies
(N=57)



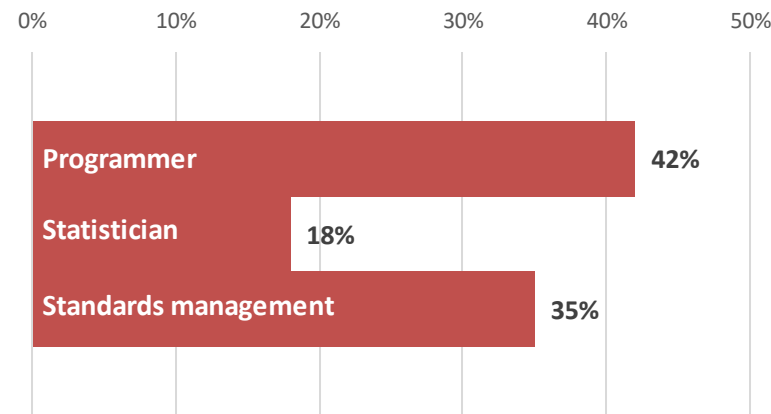
Improved quality (N=54)



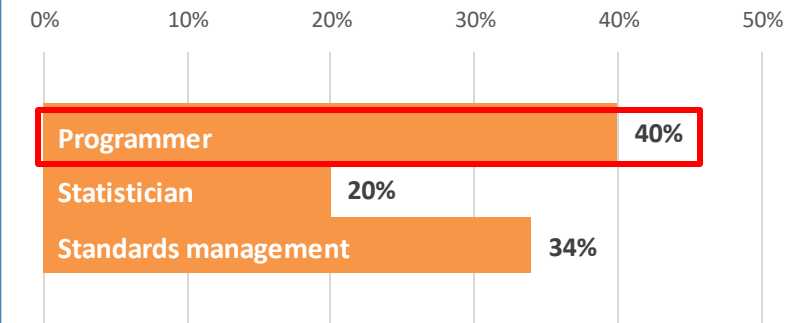
Improved traceability/ documentation
(audit- readiness) (N=51)



Automation (N=55)

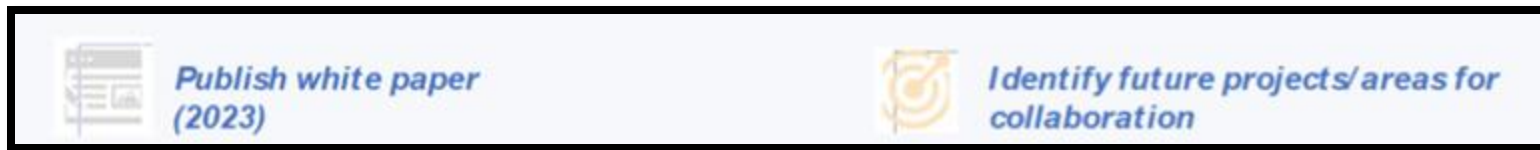


Reduced cycle time to generate outputs
(N=50)



Conclusion and Next Steps

- While most companies have some level of standards governance, there are currently no clear best practices across industry
- Additionally, most functional roles are experiencing similar types of challenges and pain points
- The survey shows the need for further exploration and information sharing, to help shed light on issues and potential solutions
- Next steps for “[*Best Practices for Data Standards Governance Implementation*](#)” project are as below:



- More information on the PHUSE project can be found at: [PHUSE Page](#)
- Poster presented for PHUSE CSS 2022 is also available within PHUSE archives
- Please email us at: workinggroups@phuse.global for volunteering opportunities

THANK YOU



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Groups**

