

PP07 Data Standards Governance: Current State and Challenges

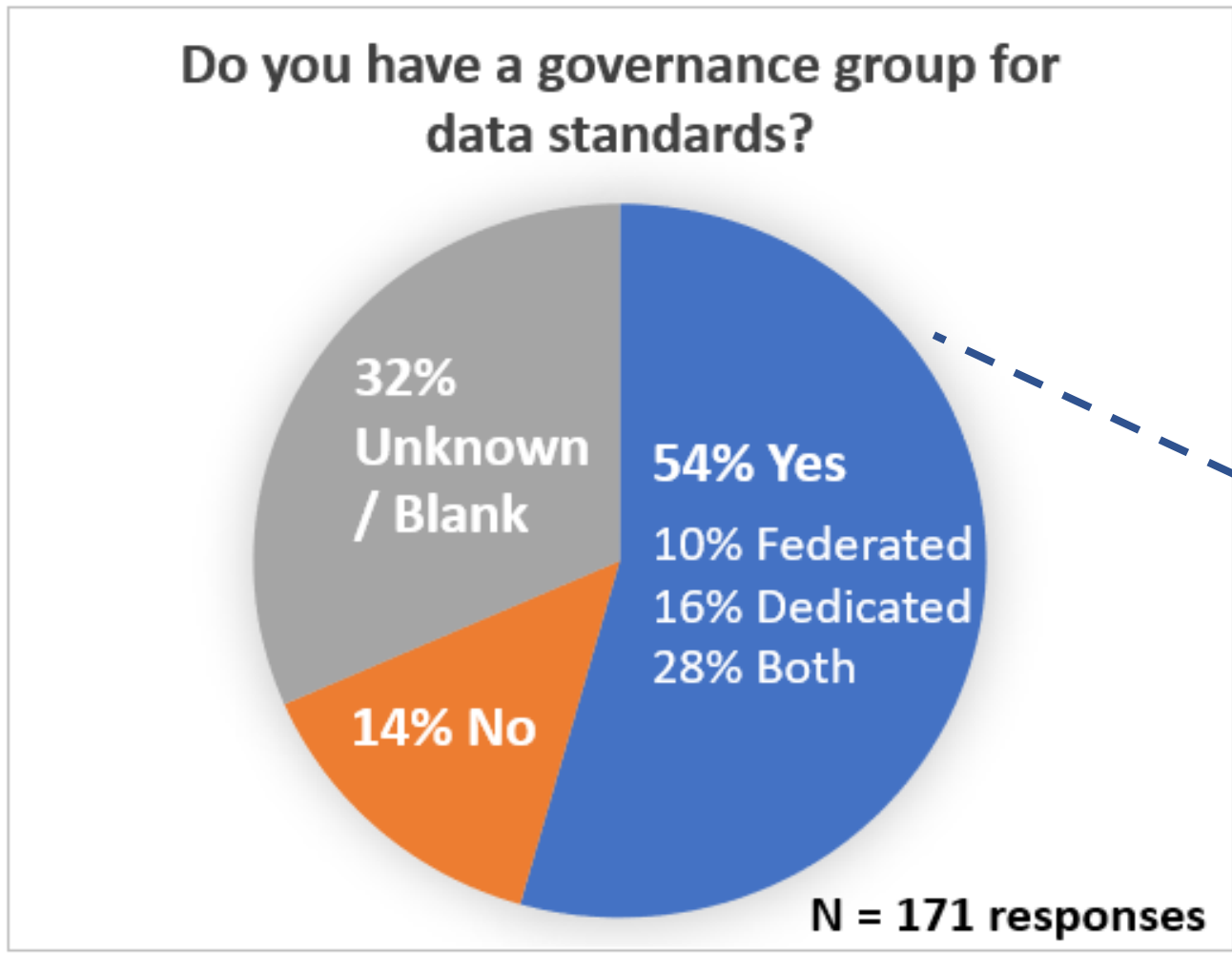
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Abstract: With the quickly evolving science of drug development and clinical research, increasing pace of innovation, and wide variety of therapeutic areas and indications being researched, published data standards cannot cover all possible data scenarios. Sponsors must decide how to interpret and implement available standards and extend upon those standards to fill in the gaps. These decisions are often inconsistent across organizations, but also can be inconsistent within an organization without appropriate governance. This poster presents some high-level results and trends from a survey which was distributed by the PHUSE Best Practices for Data Standards Governance Implementation project in February-March 2022, with a focus on how organizations are currently governing data standards and what particular challenges and pain points organizations are experiencing when implementing and governing their standards.

Responder Demographics

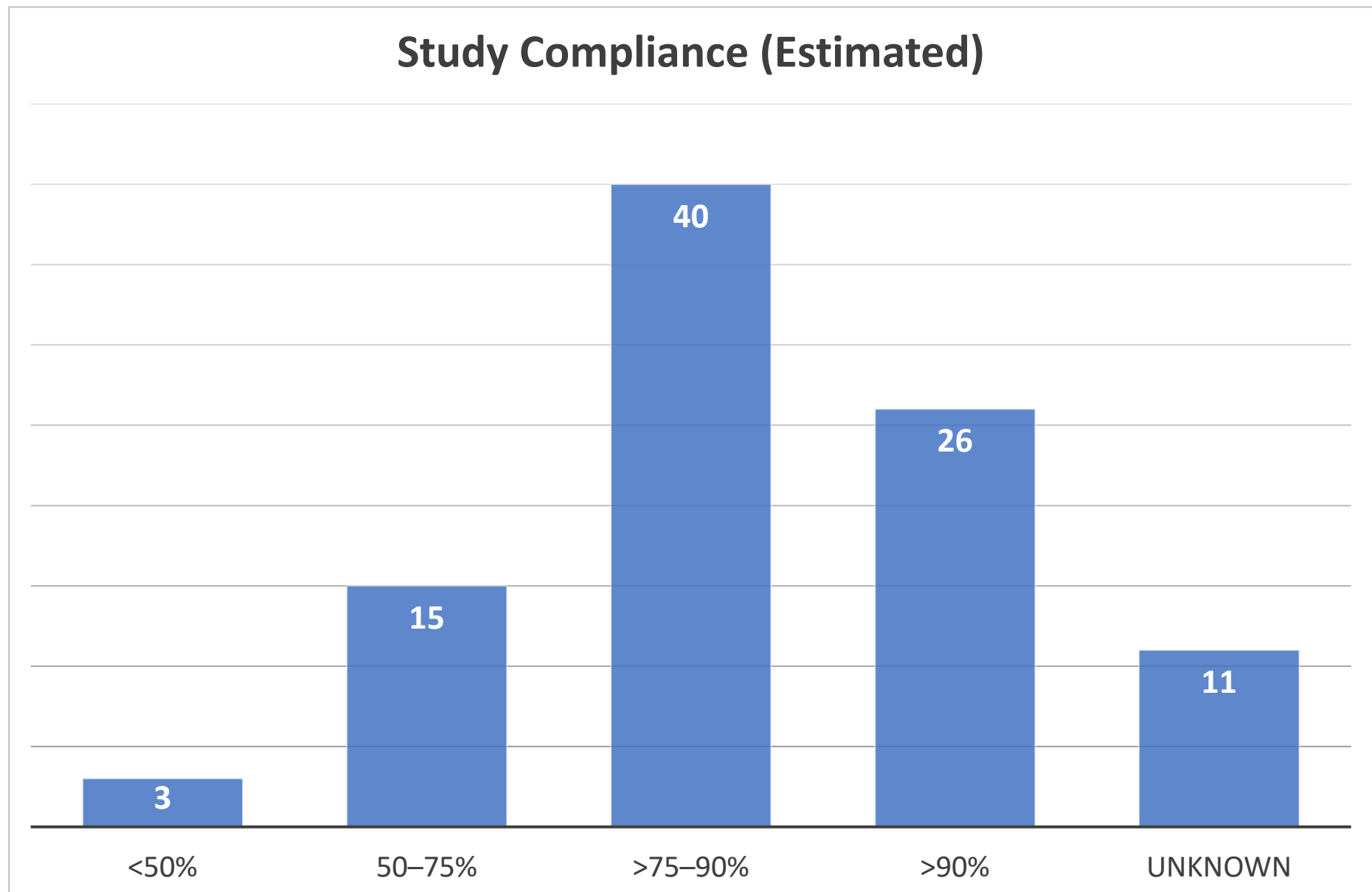
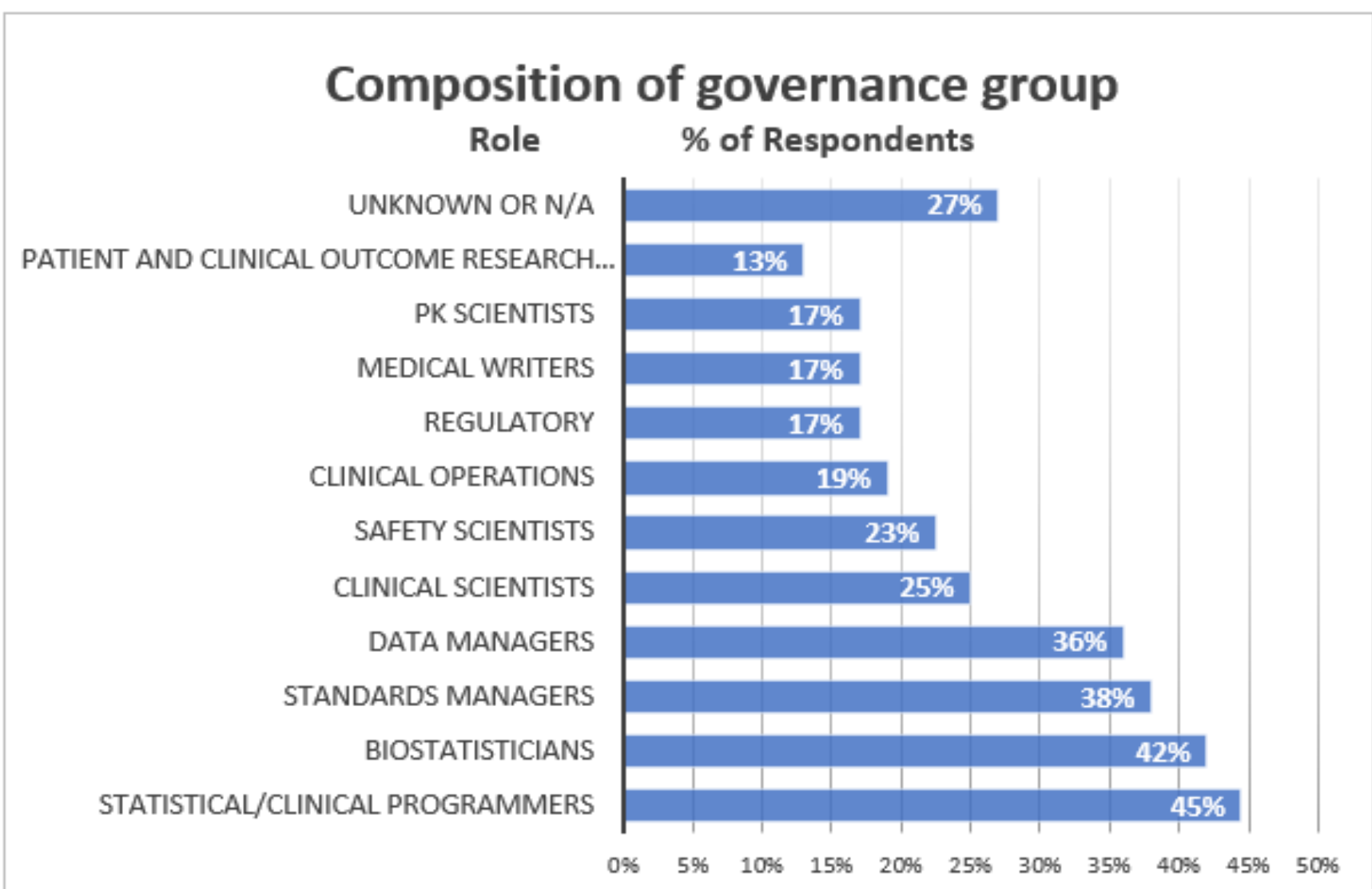
- **171 Responses**
- **79% from pharma/CROs**
- **98% Clinical data focus (vs Non-Clinical)**
- **69% involved with standards governance**
- **Most Common Roles Responding:**
 - 1. Statistical/Clinical Programmer (43%)**
 - 2. Statistician (24%)**
 - 3. Standards Manager (23%)**

Current State

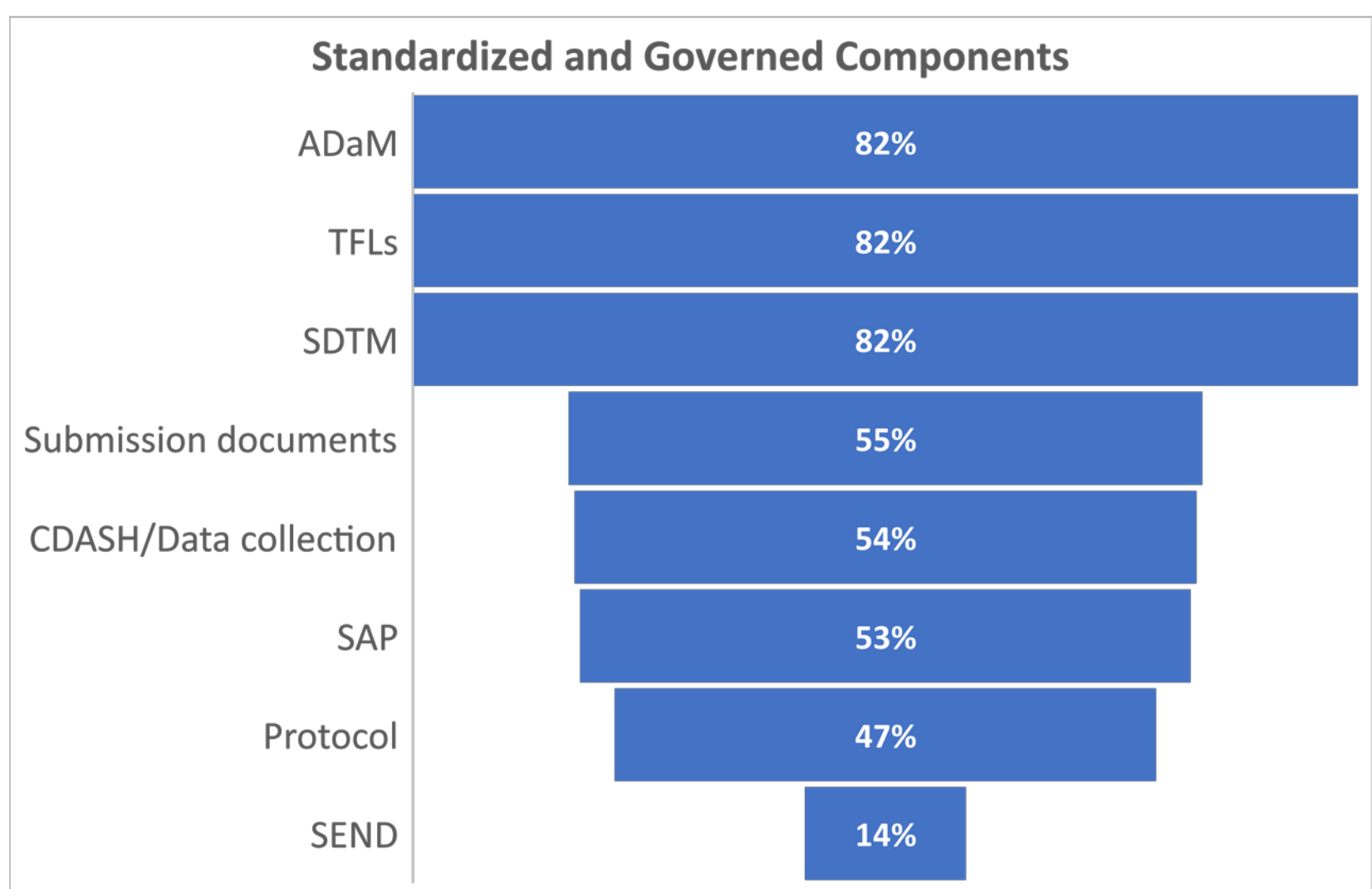


Federated: group of employees who support data standards along with other functional responsibilities
Dedicated: group of employees who exclusively work on data standards

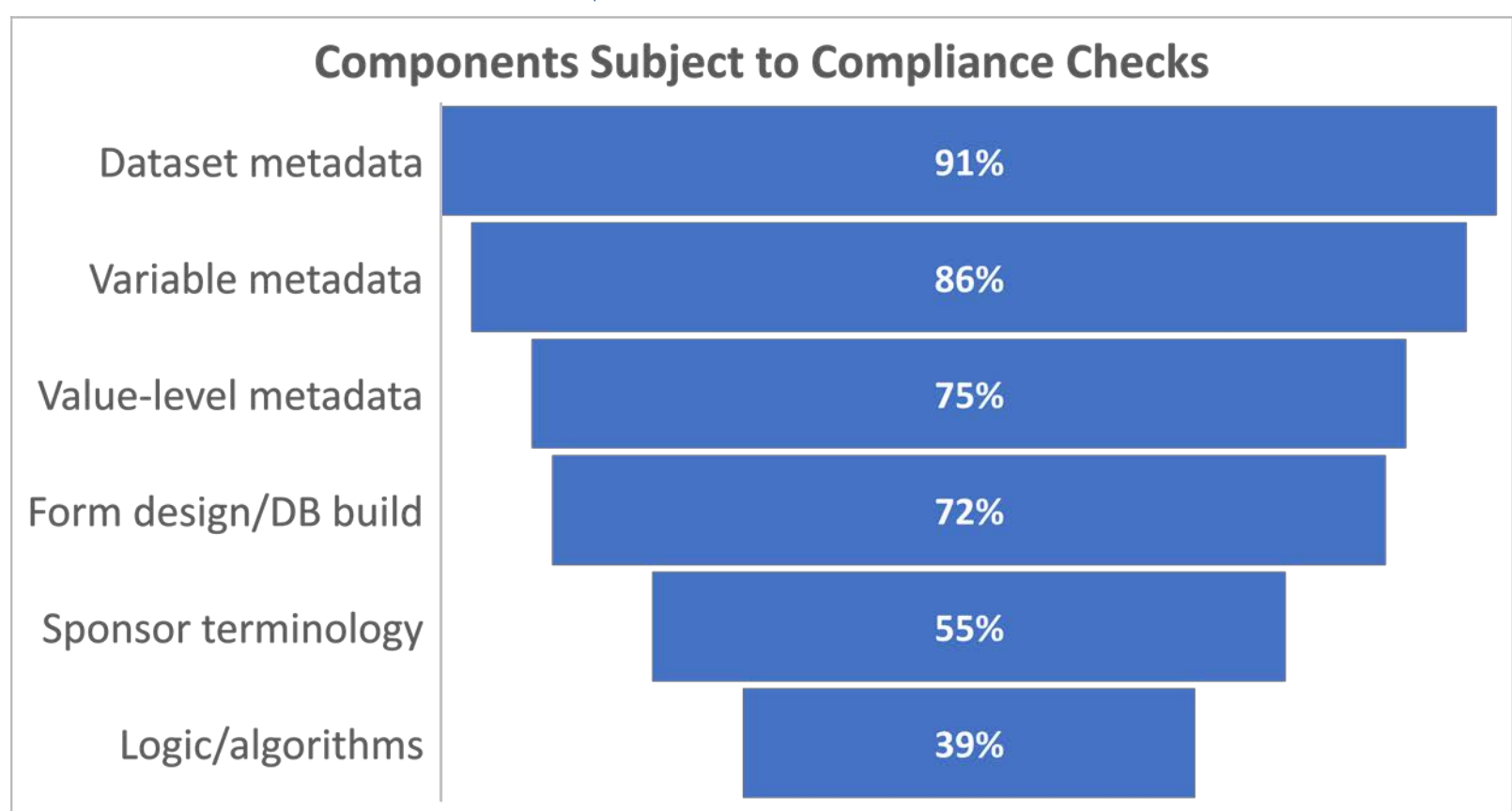
% Respondents	Data Standards Governed
52%	Only core/global & therapeutic area standards
22%	Only core/global standards for common forms
12%	Core/global by centralized group & therapeutic area standards by individual function or molecule
14%	Other, NA, Blank, Unknown



Average # roles = 5.7 (for 84 respondents who answered with role details)

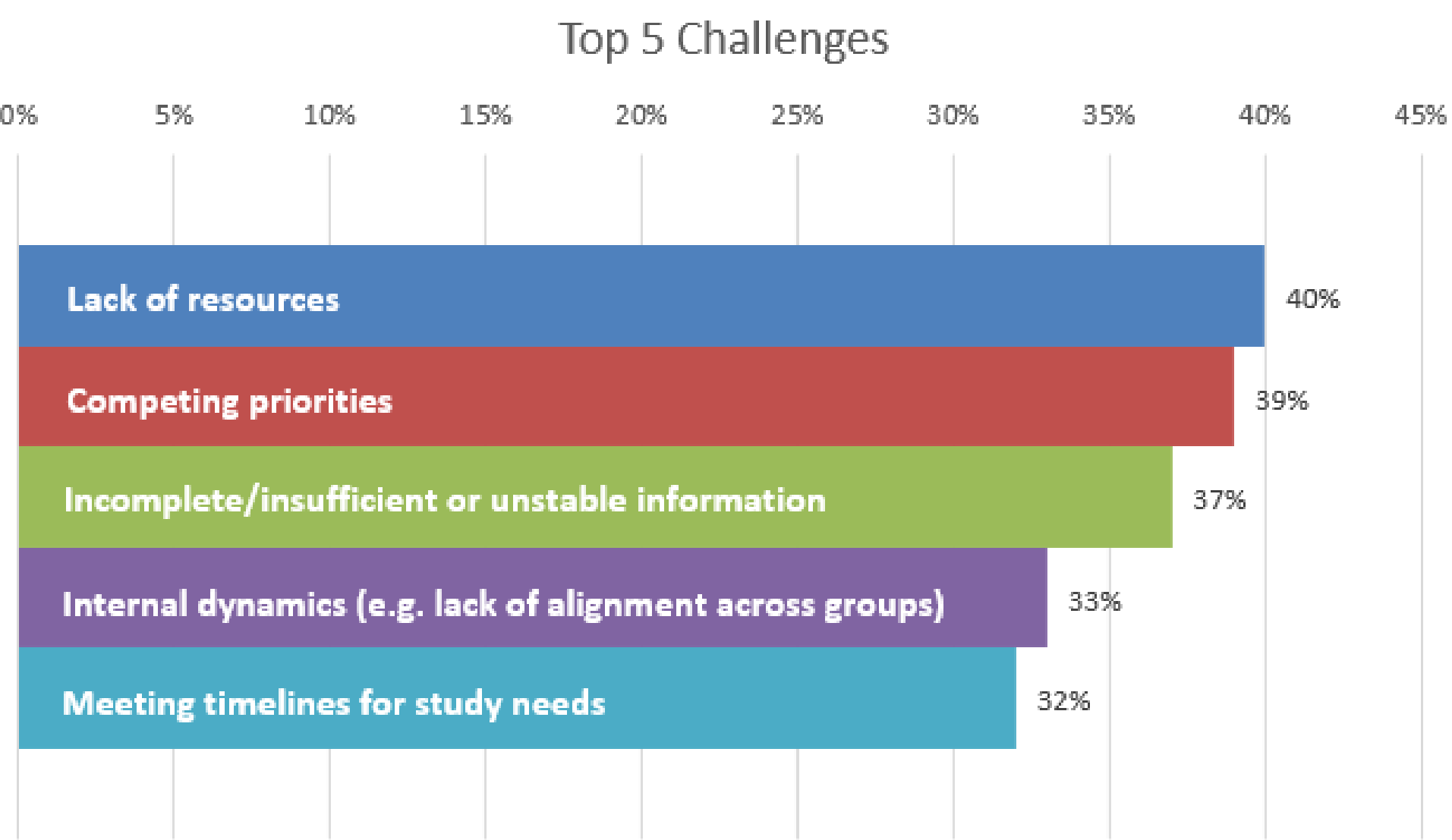


SDTM/ADaM datasets are most likely to be governed & checked for compliance

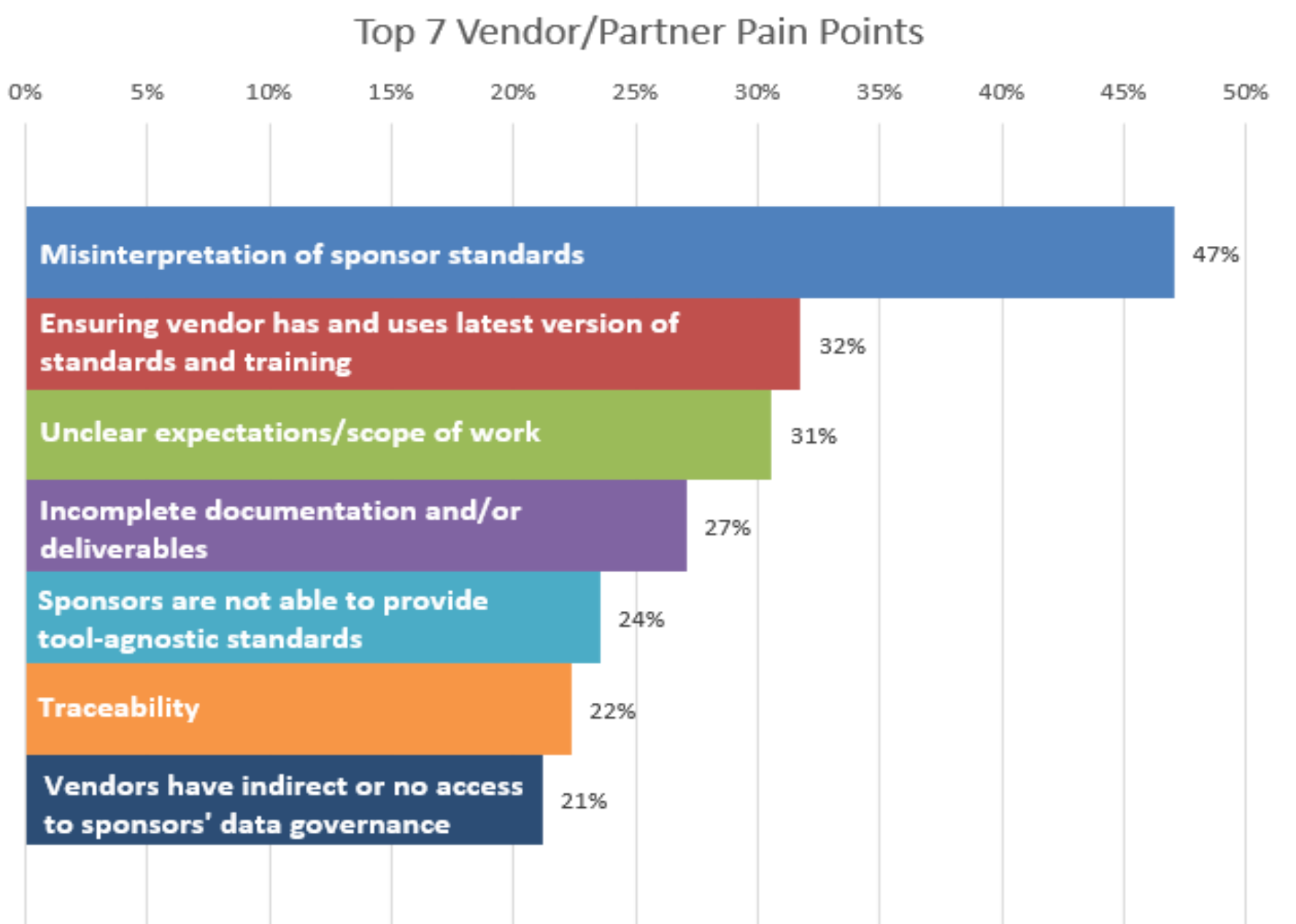


- Compliance Checking Methods**
- 91% check data to their organization's standards
 - 86% use in-house tools to check compliance (alone or with other tools)
 - 64% use a combination of commercial tools, in-house tools, and/or manual review

Challenges



- Additional Notes**
- Users were asked to select top 3 challenges in developing standards
 - Additional feedback noted challenges with:
 - MDRs and automation
 - CDISC changes, new versions, and new terminology
 - Additional pain points using vendor/partner resources to support study work:
 - High employee turnover within vendors
 - Lack of sufficient experience/training



Initial Insights: While most companies have some level of internal standards governance, there are currently no clear best practices across industry, suggesting the need for further exploration and information sharing. However, when there is a Standards Development Organization influence (e.g., CDISC-managed standards) and particularly for standards mentioned in the FDA Data Standards Catalog, the data suggests that industry is more likely to implement and govern those standards. Additionally, most companies are experiencing the same types of challenges and pain points. Further collaboration should help to shed light on issues and potential solutions.

Next Steps:



Complete survey data analysis (2022)



Publish white paper (2023)



Identify future projects/areas for collaboration