ACRP
Northern California Chapter
(San Francisco Bay Area)

Welcome
Mar 23, 2017 Educational Event

6:00 - 6:40 PM Registration Sign-in, Networking, Buffet
6:40 - 7:20 PM Sponsor Appreciation, About ACRP & our N CA Chapter, Metrics Survey Summary
7:20 - 8:20 PM Educational Presentation with Q & A
8:20 - 8:45 PM Raffle, Open Mic, Networking, 1:1 with Speaker

Bonnie Miller, RN MS
Chapter President
ACRP Chapters Advisory Group, Pacific West Region
Clinical Research Consultant
Certified Trainer, Certified Business Management
Bonnie.miller@comcast.net

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Tonight's Sponsors

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UCSC Silicon Valley Extension

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About ACRP

ACRP
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Mission: To promote excellence in clinical research
Vision: Clinical research is performed ethically, responsibly, and professionally everywhere in the world
How: Develop & promote professional standards, core competencies, training

Association of Clinical Research Professionals (ACRP)

Twitter, Facebook, LinkedIn

Academy of Clinical Research Professionals (The Academy) CCRA®, CCRC®, CPI®

Some ACRP Affiliates & Partners

ACPU Association of Clinical Pharmacology Units — Supporting early stage clinical research
Consortium of Academic Programs in Clinical Research
IAOCR
ACRES Alliance for Clinical Research Excellence and Safety
Clinical Trials Transformation Initiative
CTIN Clinical Trials for Better Health
CenterWatch
European Centre for Clinical Research Training
MRCT Multi-Regional Clinical Trials — The MRCT Center at Harvard
CISCRP The Center for Information & Study on Clinical Research Participation
Volunteers Advancing Health greater gift initiative
PhRMA Research • Progress • Hope

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About ACRP

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- Join 13,000 global clinical research peers
- Be informed: Peer reviewed award winning *Clinical Researcher,* Interest Groups, Online Communities, White Papers, Annual Meeting eLibrary, GCP*Partner* App
- Chapters: Local networking & educational events
- Discounts: Student membership, ACRP & partners educational offerings, annual meeting, certification
- Career Center
- Awards Programs
- Contact hours: CME, CBRN, and ACRP
- Contribute to the profession
- Volunteer: Build your network, showcase & grow leadership and expertise, contribute to the profession
  - ❑ Publish – Clinical Researcher
  - ❑ Present – Webinar, Classroom, Annual Meeting
  - ❑ Lead an Interest Group
  - ❑ Contribute to the Online Community
  - ❑ Northern CA Chapter – present, volunteer, host, sponsor
  - ❑ Global Committees
  - ❑ Board of Trustees: ACRP, Academy

Annual Meeting & Expo: Seattle, WA April 29 to May 2, 2017

- ***N CA Chapter, Pacific NW, and Canada Chapters are co-hosting a networking event for our members – invites coming soon***
- ***Online Sessions Library -free with registration or purchase***

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ACRP Certification

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Who tonight would like to share?

- Validate competence:
  - ✓ Impartial endorsement of understanding of international clinical research standards and ability to apply that knowledge on the job
- Commit to quality standards:
  - ✓ Ensure the core tenants of ethical, responsible clinical research. human subject protection, data quality, and regulatory compliance
- Promote professionalism of the role:
  - ✓ A core body of knowledge, ongoing professional development, code of ethics
- Employment advantage
  - ✓ 62.5 % Employers prefer or require ACRP Certification for employment
- Income advantage
  - ✓ Certificants earn an average of $10,000 more than their non-certified counterparts; 15.3% increase pay or get bonus

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ACRP Chapters

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Northern California Chapter
(San Francisco Bay Area)

- ~4,300 Chapter members (1/3 of ACRP members)
- ~60 Chapters
- Local opportunities
  - Professional development, contact hours, network with colleagues & friends
  - Build and showcase leadership and other skills
  - Make a difference
  - Have fun

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N CA (SF Bay Area) Chapter

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Mission: To serve Northern California clinical research professionals by providing educational, professional development and networking opportunities in support of human subject protections in clinical research

~275 Members

~1400 Distribution

501 (c)(3) non-profit

http://community.acrpnet.org/communities/community-home?communitykey=ec0f114b-f234-4c59-a9af-a659a6b1e8b8&tab=groupdetails

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About SF Biotech Bay

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- *American Medical Writers Association*
- *Association of Women in Science*
- *Bay Area Biomedical Consultants Network*
- *BioMedical Device Group*
- *BioPharma Consortium*
- *BioScience Forum*
- *CA Life Sciences Organization*
- *ClinOps ToolKit*
- *ClinPulse PRC-Clinical*
- *Health Care Business Women's Association*
- IRBs
- *Model Agreements and Guidelines International*
- *Northern California Science Writers Association*
- Patient Advocacy Groups
- *Society of Quality Assurance*
- *Regulatory Affairs Professional Society*
- *Society of Clinical Research Associates*
- Sponsors - Biotech, Device, Pharma
- Study Sites - Medical Centers & Community
- University Biosciences Certificate Programs: San Francisco State College of Extended Learning, University of CA Berkeley Extension, University of CA Santa Cruz Extension
- University Biotechnology Masters Program, San Jose State
- Vendors- Consultants, CROs, Recruiters/Staffing Agencies, Service Providers

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N CA Chapter Volunteers

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N CA Chapter Board

Elected Board

Bonnie Miller - President
Patricia Kasper - Vice President
Heather Brown - Secretary
Amanda Whalen -Treasurer

Appointed Board / Committee Chairs

Kathleen Tam - Budget
Sean Gerstenlauer - Bylaws
Emily Troutner - Communications
Peter Gompper - Education
Gina Hashem, Caroline Cooper, and Victoria Millward - Event Management Co-Chairs
Peter Hegedus - Membership
Bonnie Miller - Nominating
Patricia Kasper - Sponsorship
Heather Brown - Volunteer

N CA Chapter Appointed Leadership

Communications Committee Members:
Eron Villarreal, Koen De Lombaert, Martin Zydek, Xin Zhao

Education Committee Members: Bev Assman *and TBD*

Event Management Committee:
East Bay Manager: Kakali Hossain
North Bay Manager: *TBD*
Peninsula Manager: Victoria Millward
Sacramento Manager: *TBD*
South Bay Manager: *TBD*
Event Crew: *Join the crew*

Membership Committee Member: Xin Zhao

Sponsorship Committee Members:
Sean Gerstenlauer *and TBD*

Volunteer Committee Member: Narinder Bolaria

Join our ~30 Volunteers - must be N CA Chapter ACRP member

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Tonight's Event Volunteers

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2017 Program

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Confirmed Proposed

Jan	Annual Planning Meeting	2016 Annual Report, 2016 Plans, New & Renewing Volunteer Orientation	Crowne Plaza, Foster City
March	Peninsula Educational Event	Navigating Clinical Data Technology Outsourcing John Fontenault, SVP Operations OmniComm Systems, Inc.	Genentech, South San Francisco
May	East Bay Educational Event	Hot Topic Expert, Organization	XOMA, Berkeley
June	North Bay Educational Event	Hot Topic Expert, Organization	Ultragenyx, Novato
July	Peninsula Networking Event *Collaboration with RAPS SF Chapter?*		Westin Hotel, Palo Alto
Sept	South Bay Educational Event *Collaboration with B2DG?*	Hot Topic Expert, Organization	Cepheid, Sunnyvale
Oct	East Bay Networking Event		Scott's Seafood Restaurant, Oakland
Nov	Annual Holiday Educational Event	Hot Topic Expert, Organization	Veterans Administration Health Care, Palo Alto

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Tonight's Educational Event

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Survey Results: "How do you use study metrics in your job?"
Please see the handout

Approved for 1 contact hour - BRN, ACRP, CME
Purchase online up to 14 days after the event; sign-in & attend event;
1-30 days after event: logon (member/guest) *http://www.acrpnet.org/*
then go to *Learning Portal* to complete the evaluation and receive the certificate
Questions: chapters@acrpnet.org

Introducing our Speaker

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Raffle

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Open Mic

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FIND a job or FILL a job

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Networking & 1:1 with Speaker

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Thank You!

- ***Attendee Feedback Form***

- ***Badge recycle***

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Survey: How do you use study metrics in your job?

Thank you for participating in our survey!

The survey was designed to gain an understanding of how metrics are used in SF Bay Area clinical research organizations

For over a decade several organizations (i.e., Tufts CSDD, MCC, SCRS, CI4CC, AAHRPP, etc.) have reported on the importance of using peer-vetted standardized performance metrics to evaluate clinical research activities.

Common aim of each initiative; establish meaningful indicators of success of processes or functions. Taken together, the overall 'health status' of a project is gauged, and risks/opportunities of projects identified.

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Survey Questions

1. What is your primary role?
2. What is the size of your organization (in number of personnel)?
3. What is your organization's core business?
4. How important are metrics to your work?
5. Choose the following areas in which the use of metrics is important to you or your organization?
6. Which of the following apply to your organization's use of metrics?
7. Does your organization use peer-reviewed/industry standardized metrics?
8. Select the areas in which industry standardized metrics are used by you or your organization: (Protocol design, study performance, site/sponsor/CRO performance, data management, Quality and risk management, endpoint assessment, lab management, personnel performance, other, N/A)
9. In your experience, do metrics successfully capture critical study risks in the following areas?
10. Do you use metrics as risk assessment tools to mitigate risk (e.g. variation in error rates, compliance, patient safety)?

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Survey Questions

11. Have you uncovered unknown or unexpected study risks by using metrics?
12. Does your organization operate on a retroactive or proactive approach to risk management?
13. Does your organization have a quality management system?
14. Does your organization/department incorporate business processes and/or SOPs based on the analysis of metrics?
15. How often do metrics fail to detect issues critical to the success and efficient operation of clinical trials at your organization?
16. To what extent is the collection and application of meaningful and relevant metrics made easy within your organization?
17. Do you use a data technology system to aggregate data into an accessible repository and efficiently generate metrics for your clinical trials?
18. Do you use data analytics (e.g. correlation) of metrics to assess the status, health, and strategy of your clinical trials?

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Survey Questions

19. In your experience, is performance data transparency important to developing expectations, relationship management and incentive tracking?
20. Are metrics commonly shared with team members of your projects?
21. Are metrics are a part of your communication plan?
22. Have the use of metrics reduced ambiguity in your past projects (e.g. milestones)?
23. Have metrics created ambiguity in your past projects?

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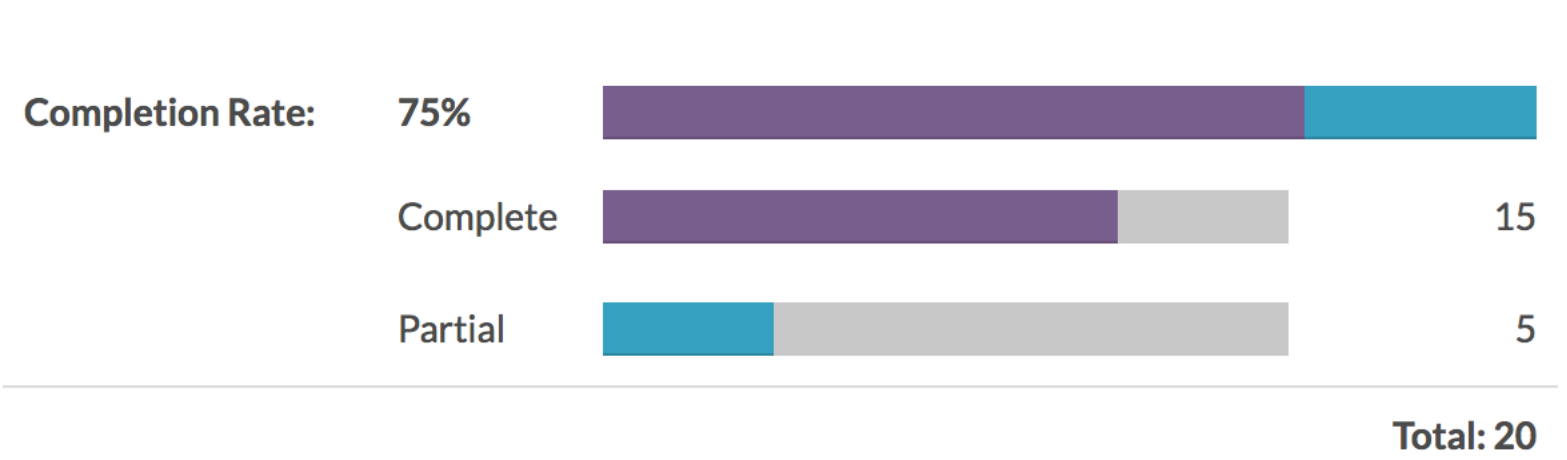
Response counts



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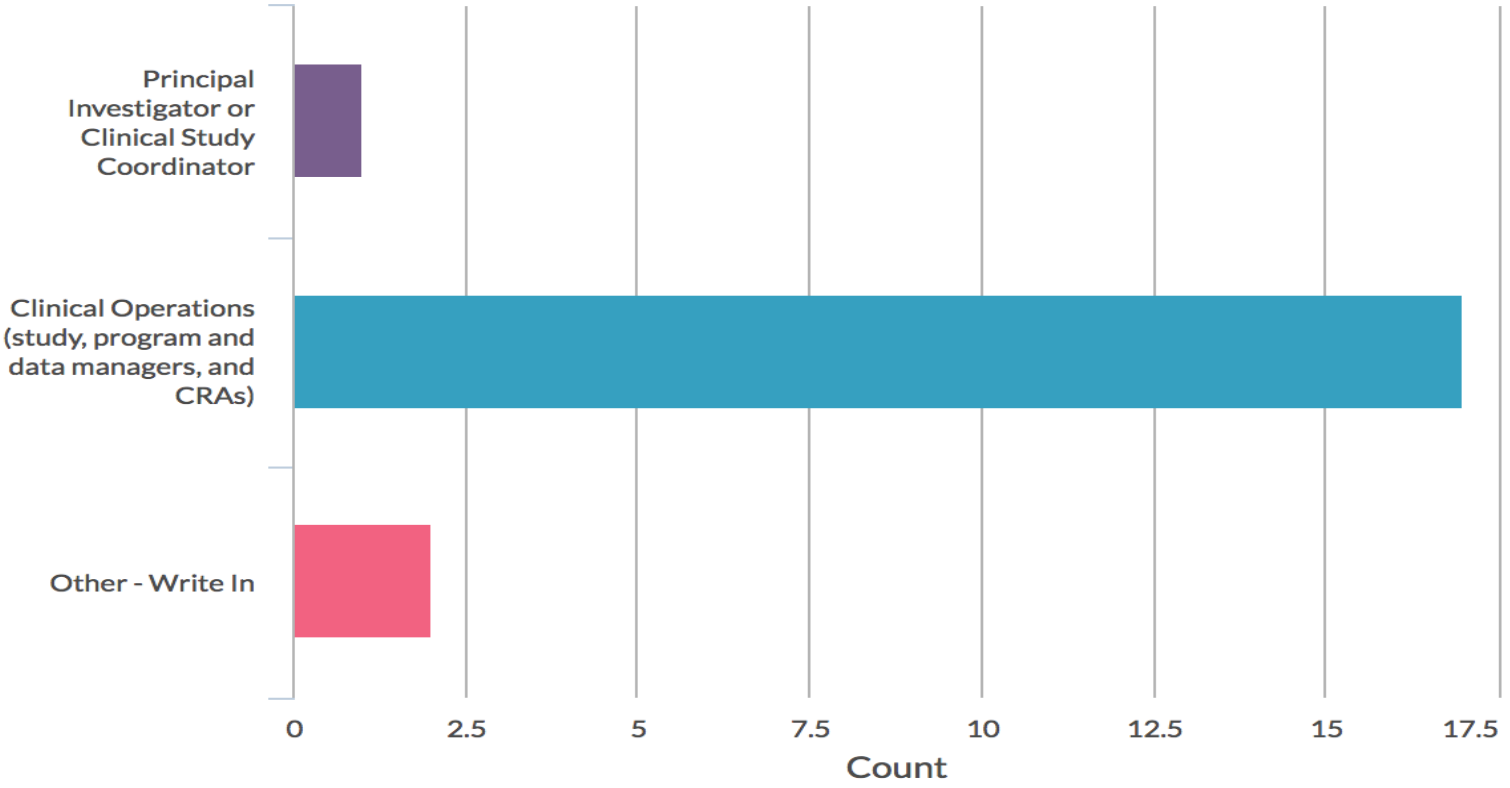
1. What is your primary role?



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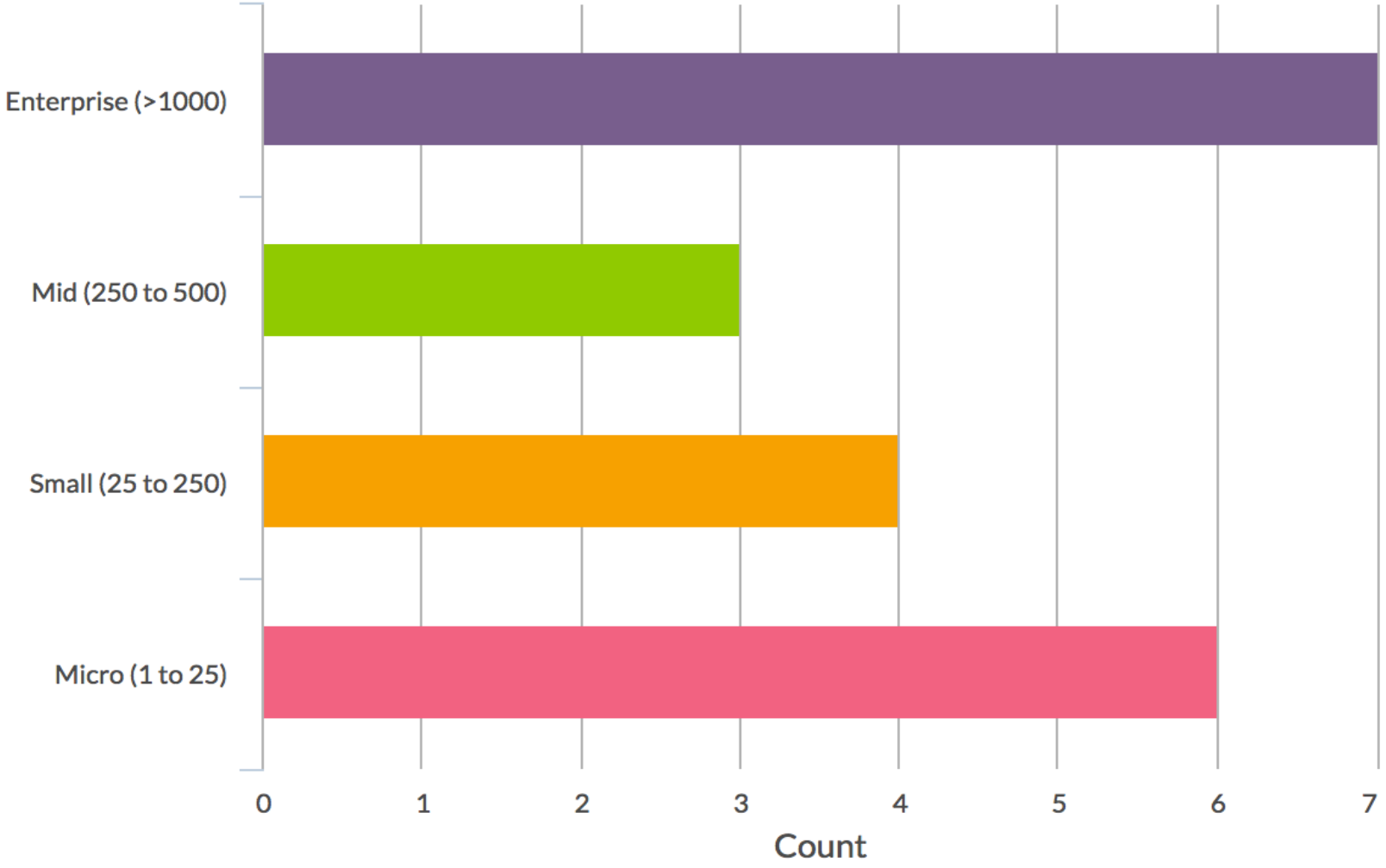
2. What is the size of your organization (#personnel)?



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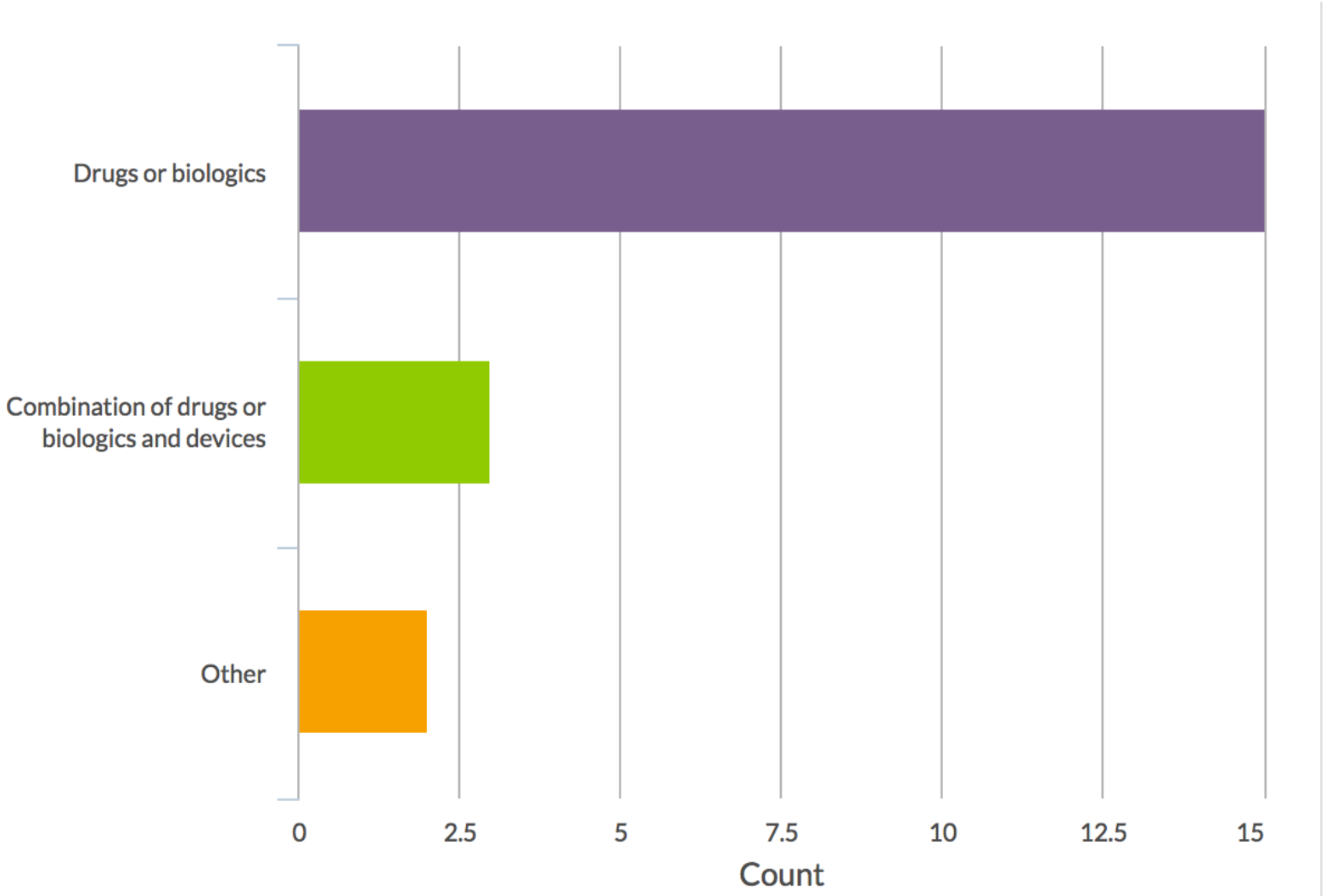
3. What is your organization's core business?



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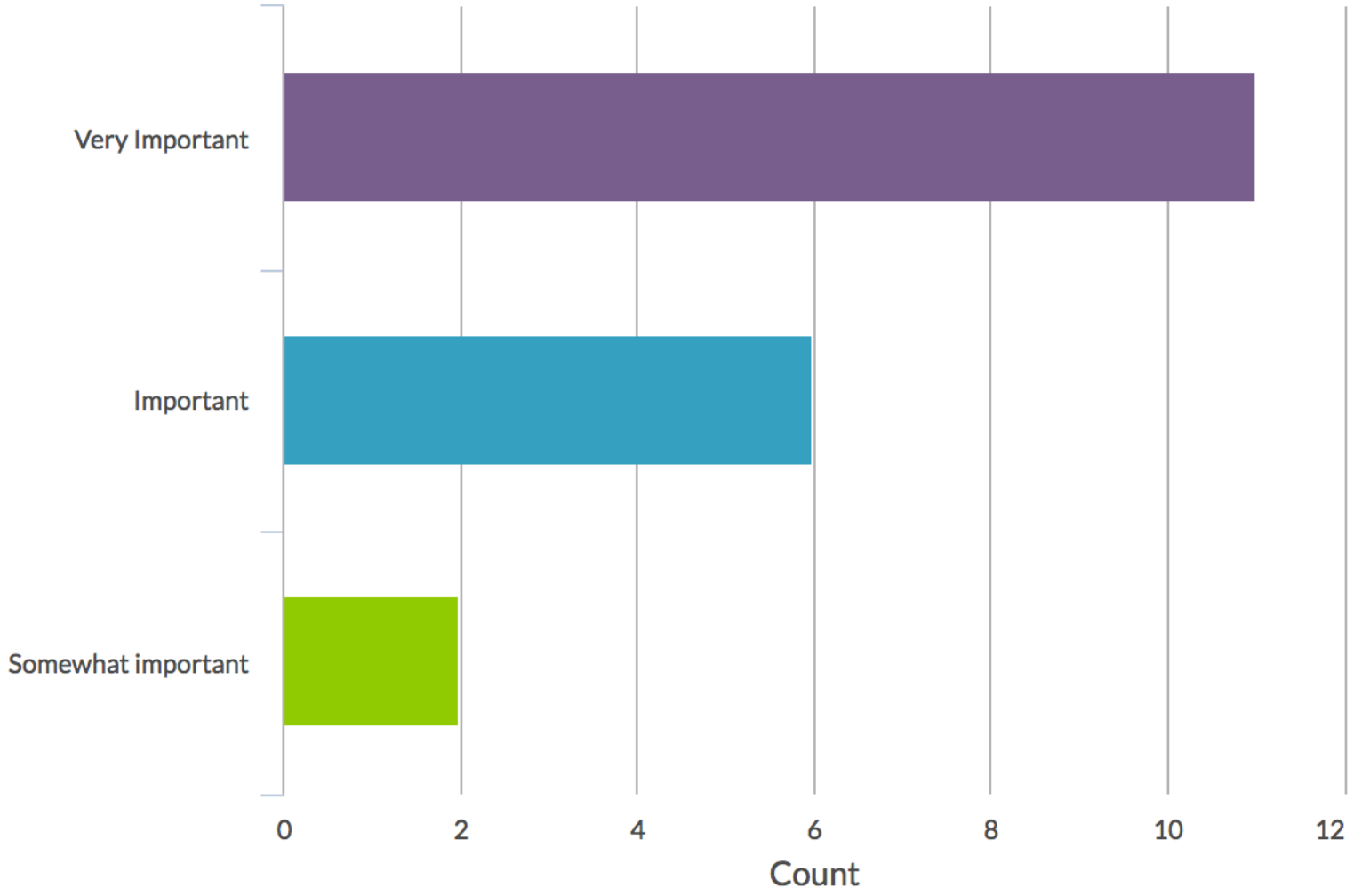
4. How important are metrics to your work?



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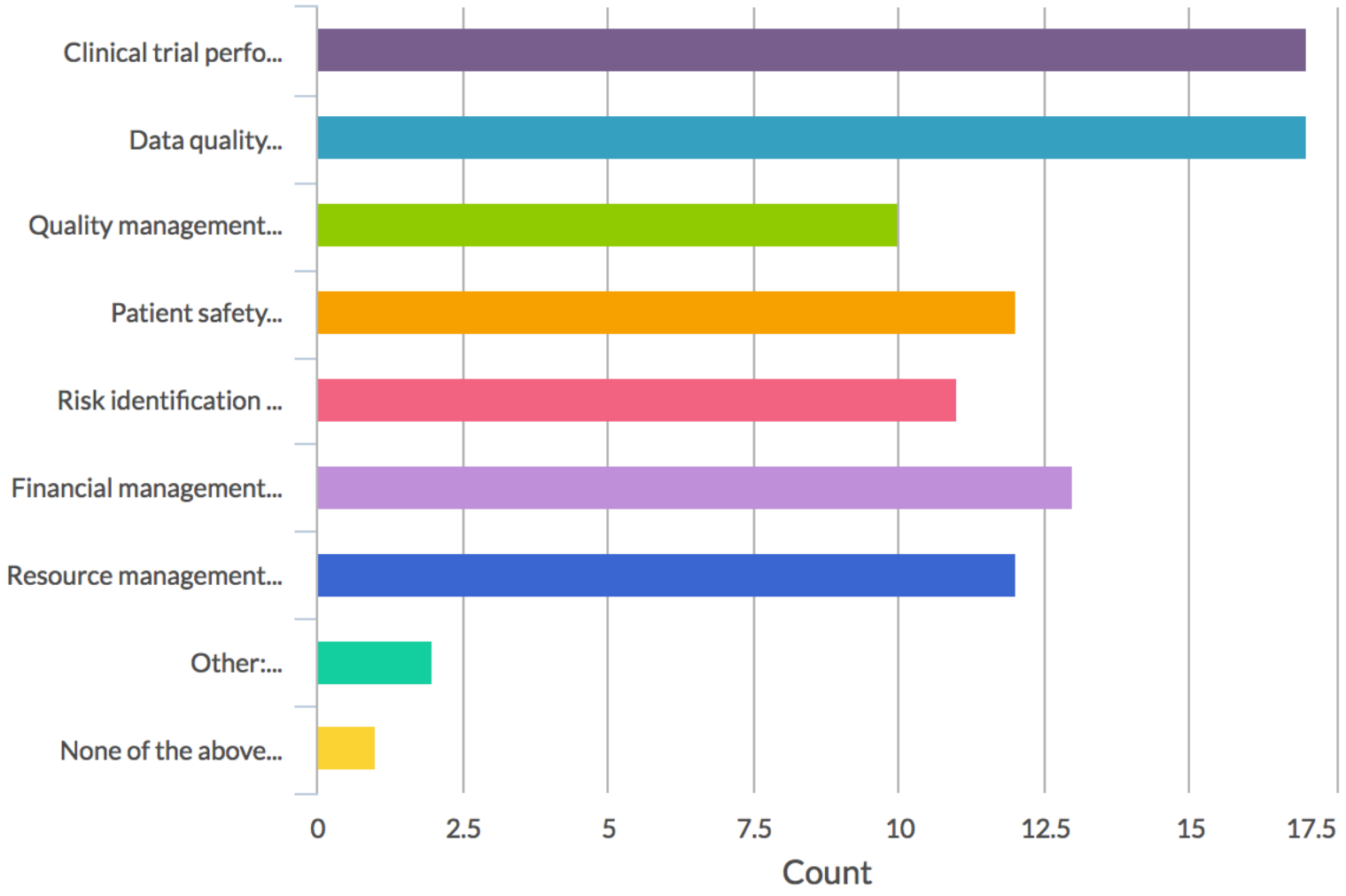
5. Metrics are important:



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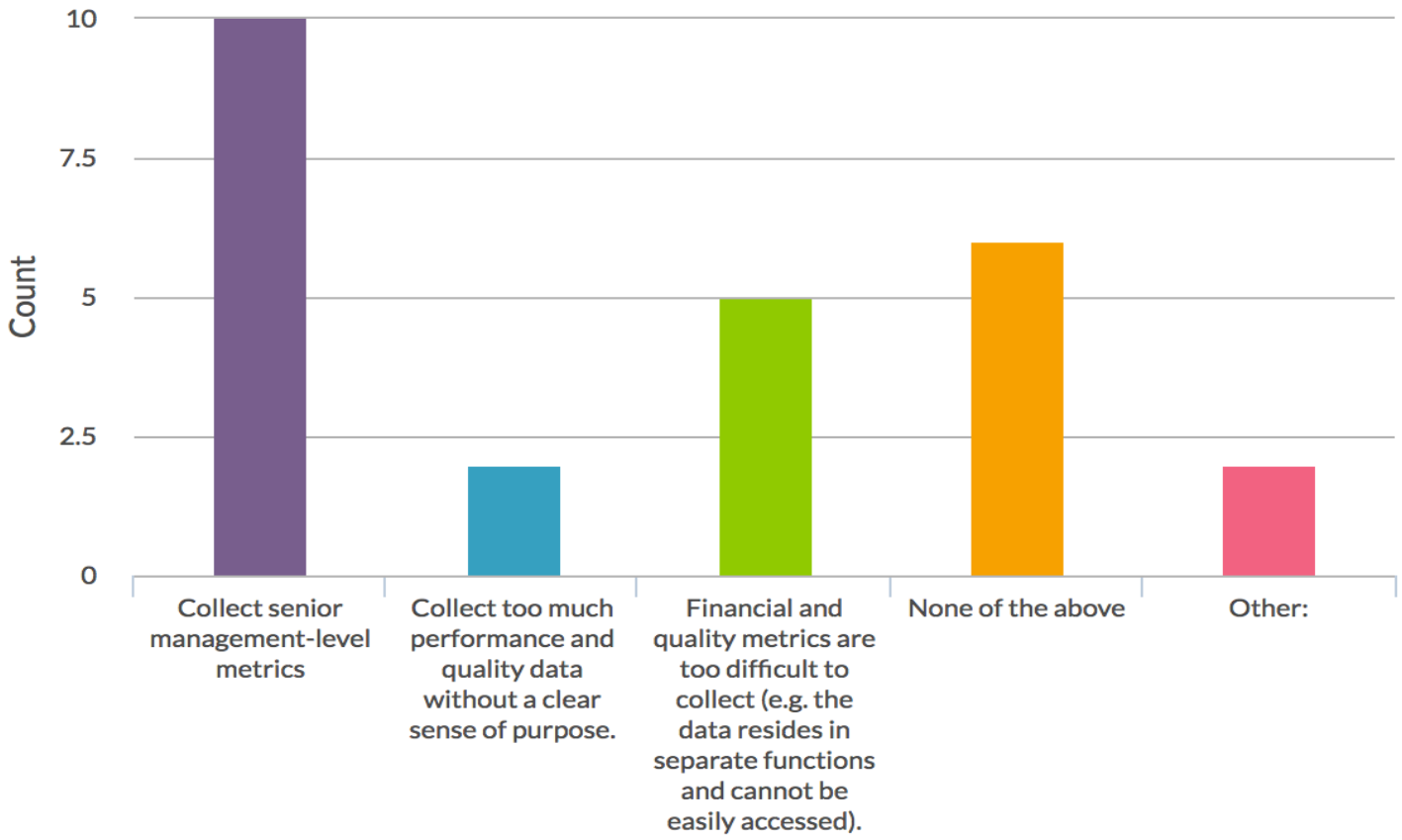
6. Organization's use of metrics:



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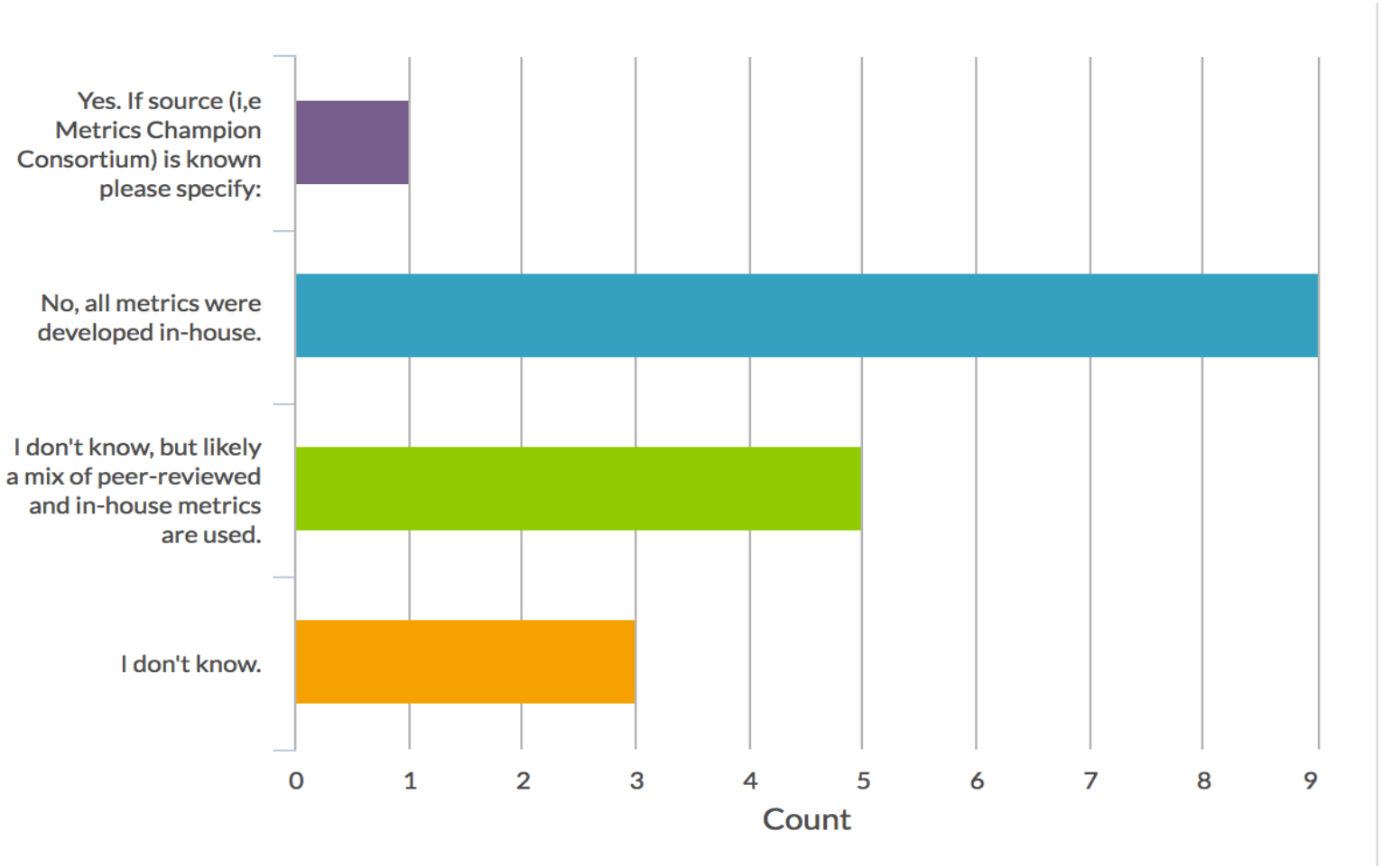
7. Use peer-reviewed industry standardized metrics?



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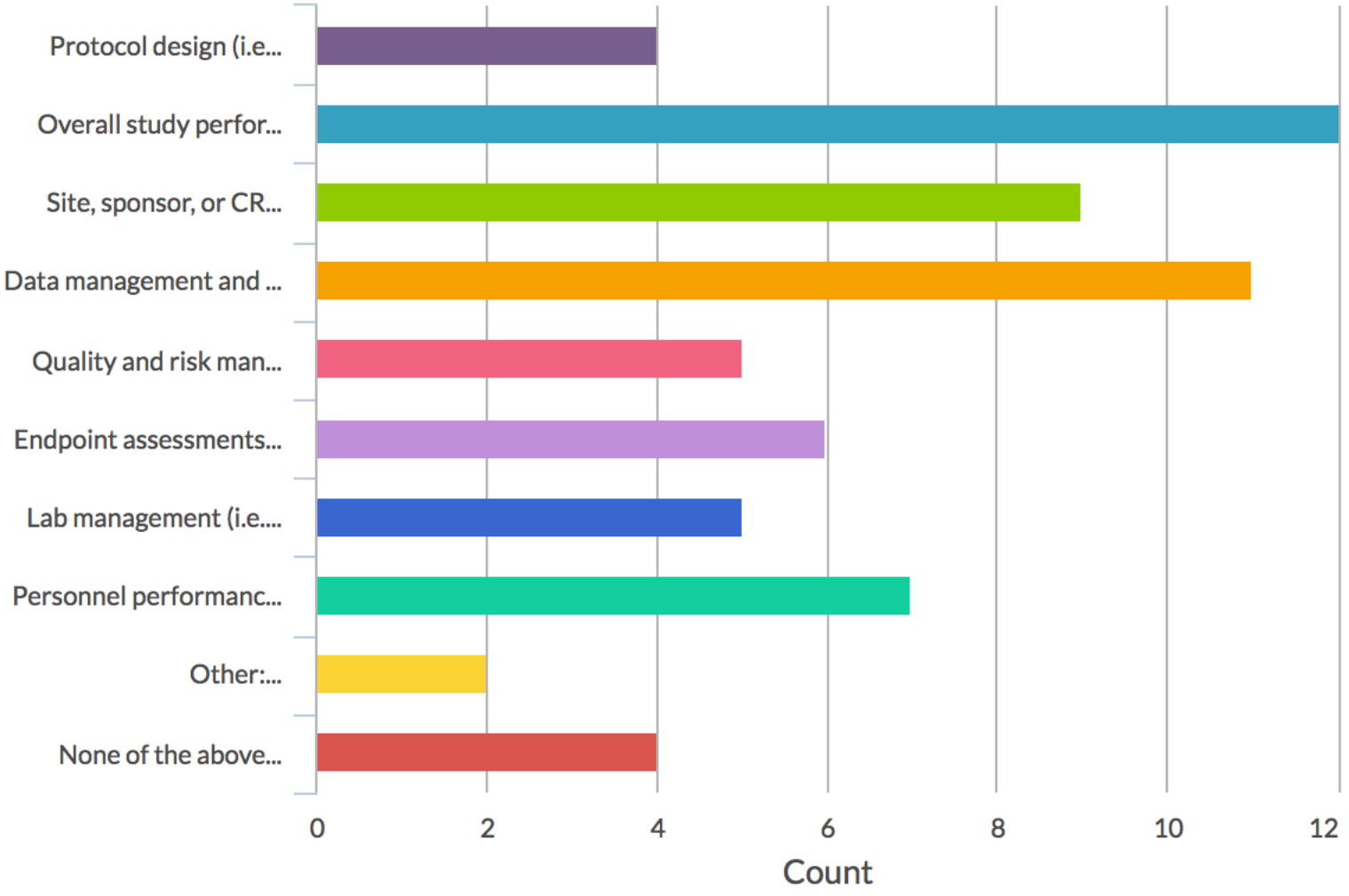
8. Industry standardized metrics are used for:



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9. Metrics successfully capture critical study risks for:

	Often	Sometimes	Rarely
Disease indication Count	3	10	4
Study design Count	7	9	1
Patient safety Count	4	12	1
Study phase Count	3	9	5
Patient Satisfaction Count	0	1	0
Site Selection & Recruitment Count	1	0	0
physician resource Count	1	0	0

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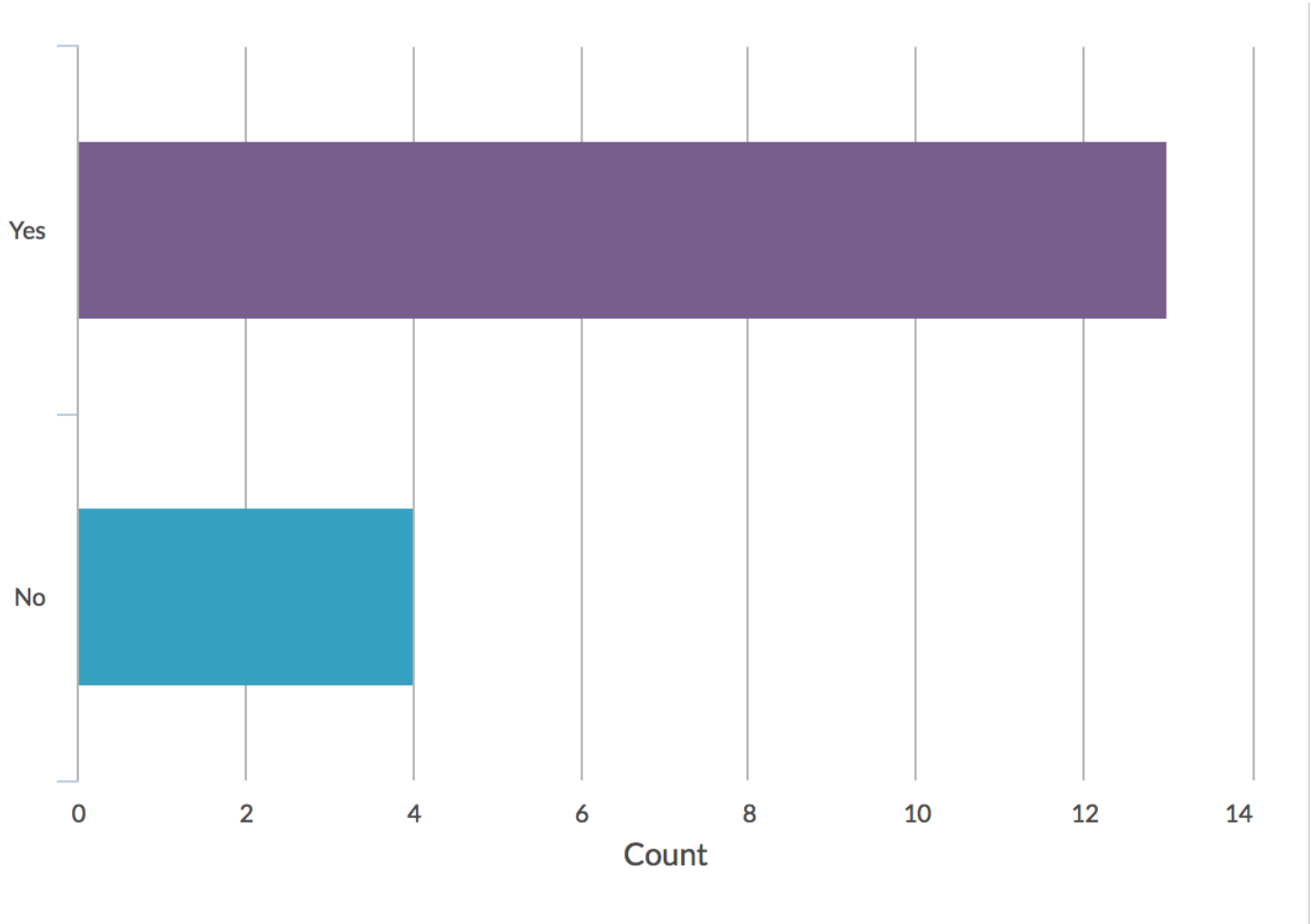
10. Metrics used as risk assessment tools:



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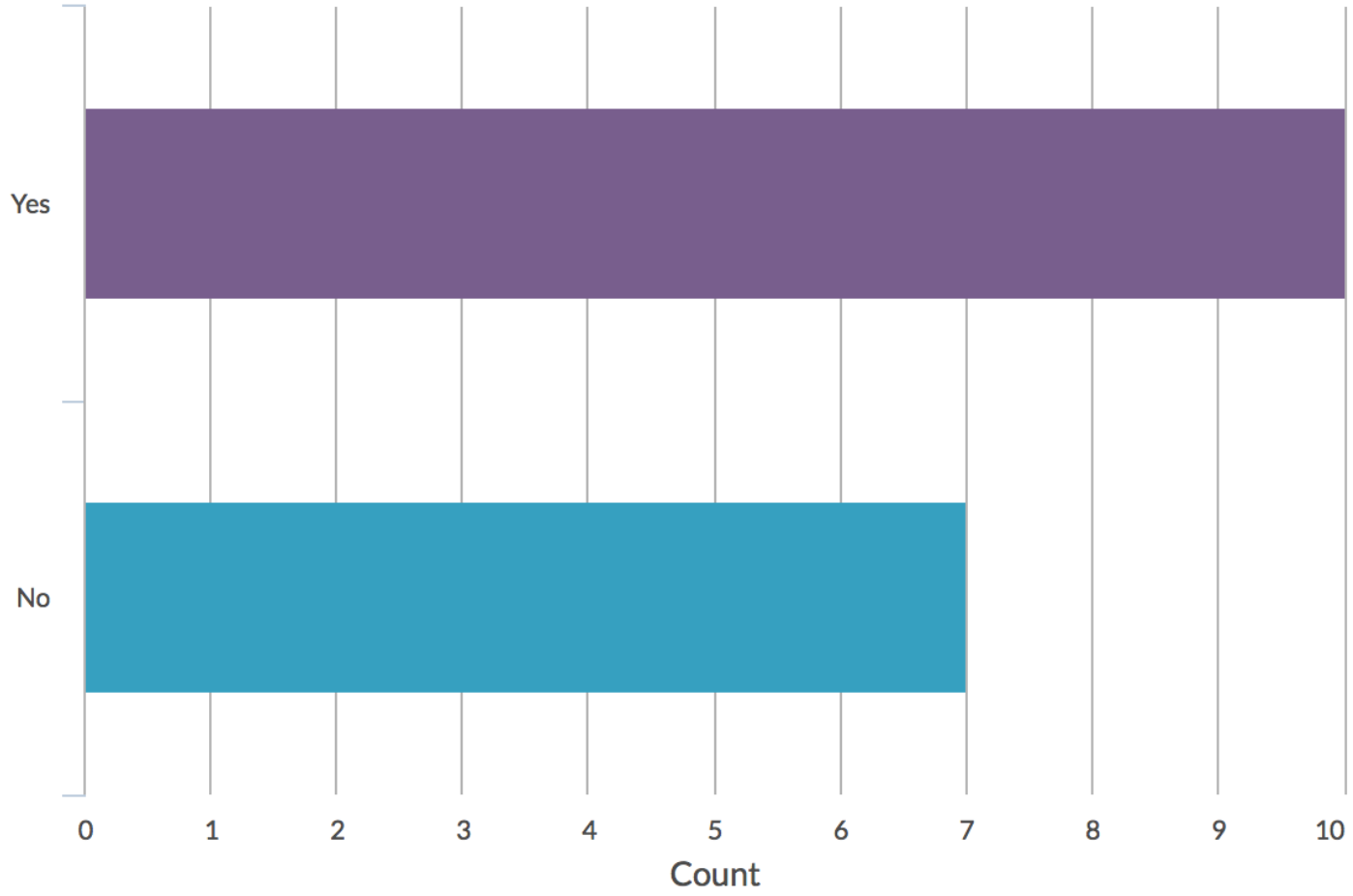
11. Unknown/unexpected risks found using metrics:



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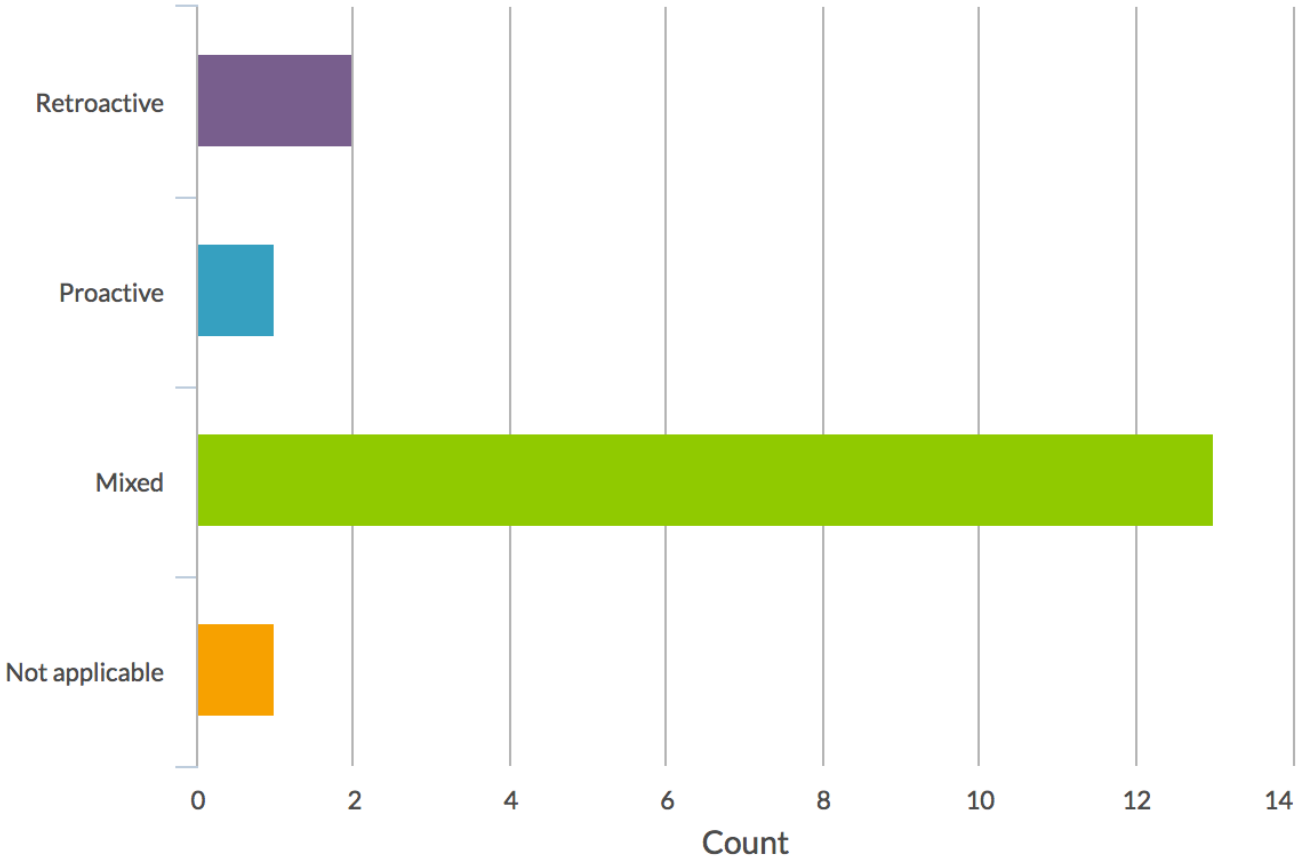
12. Risk management is retroactive or proactive?



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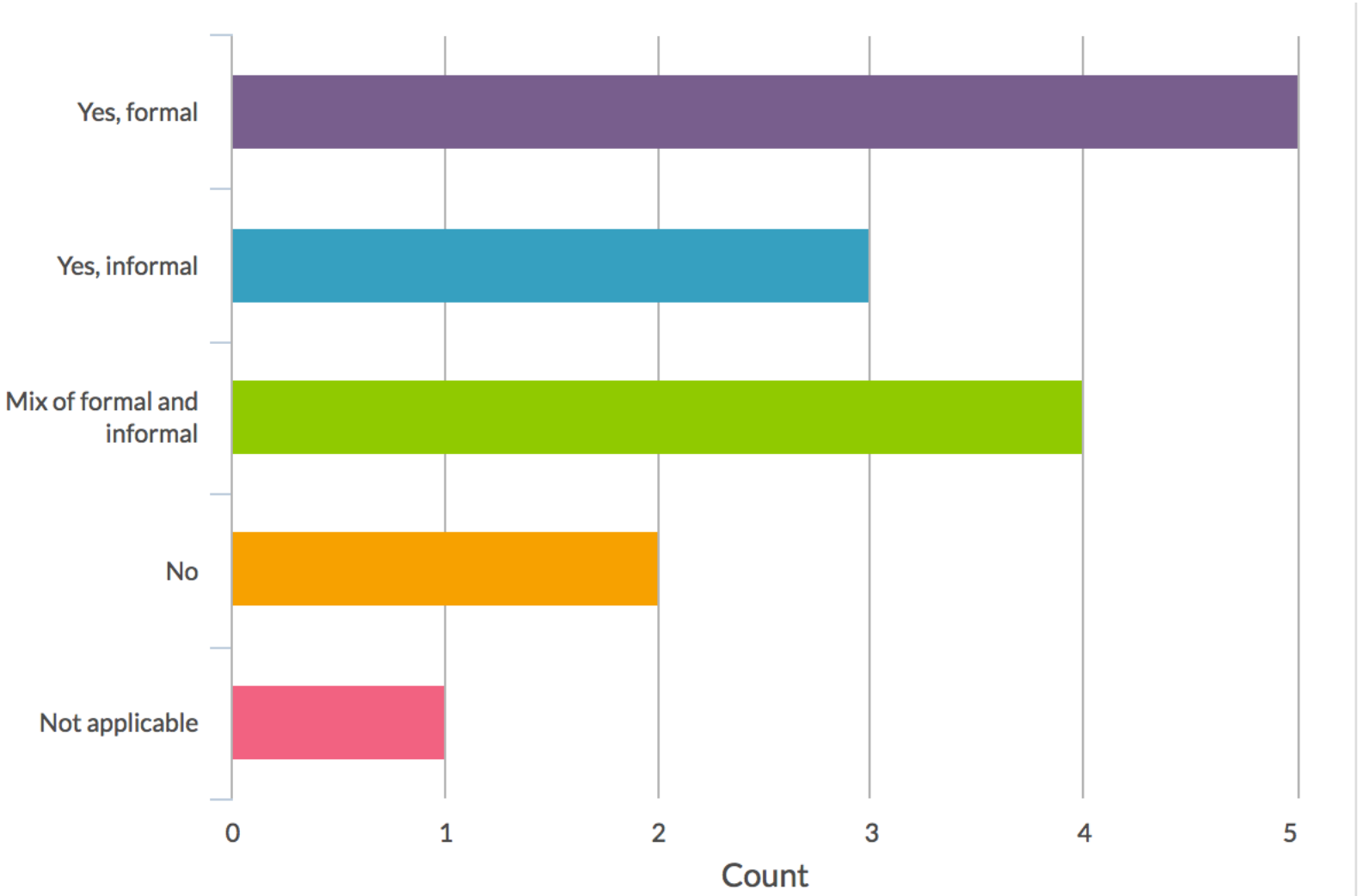
13. Organization has a quality management system:



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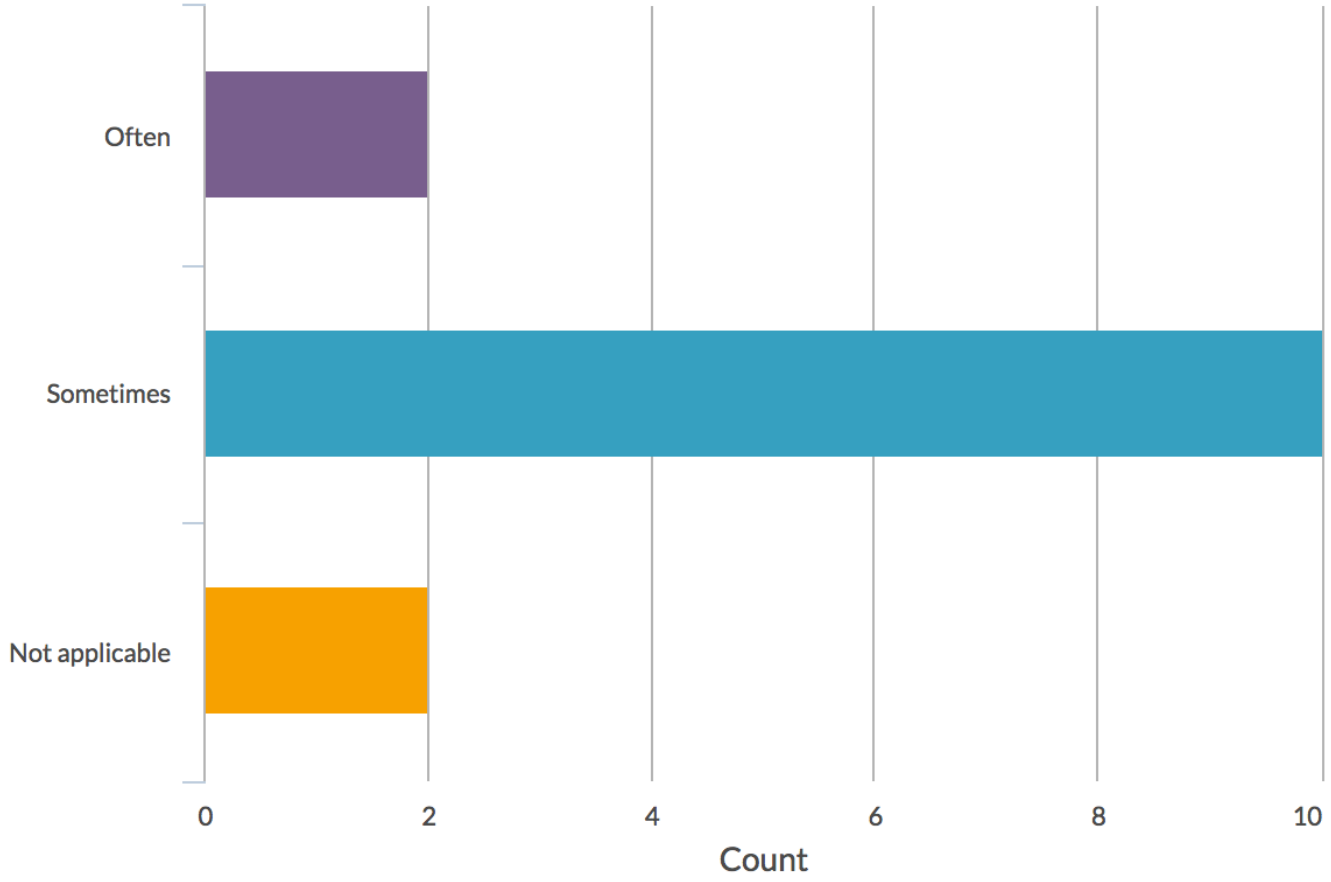
14. Incorporated SOPs based on analysis of metrics:



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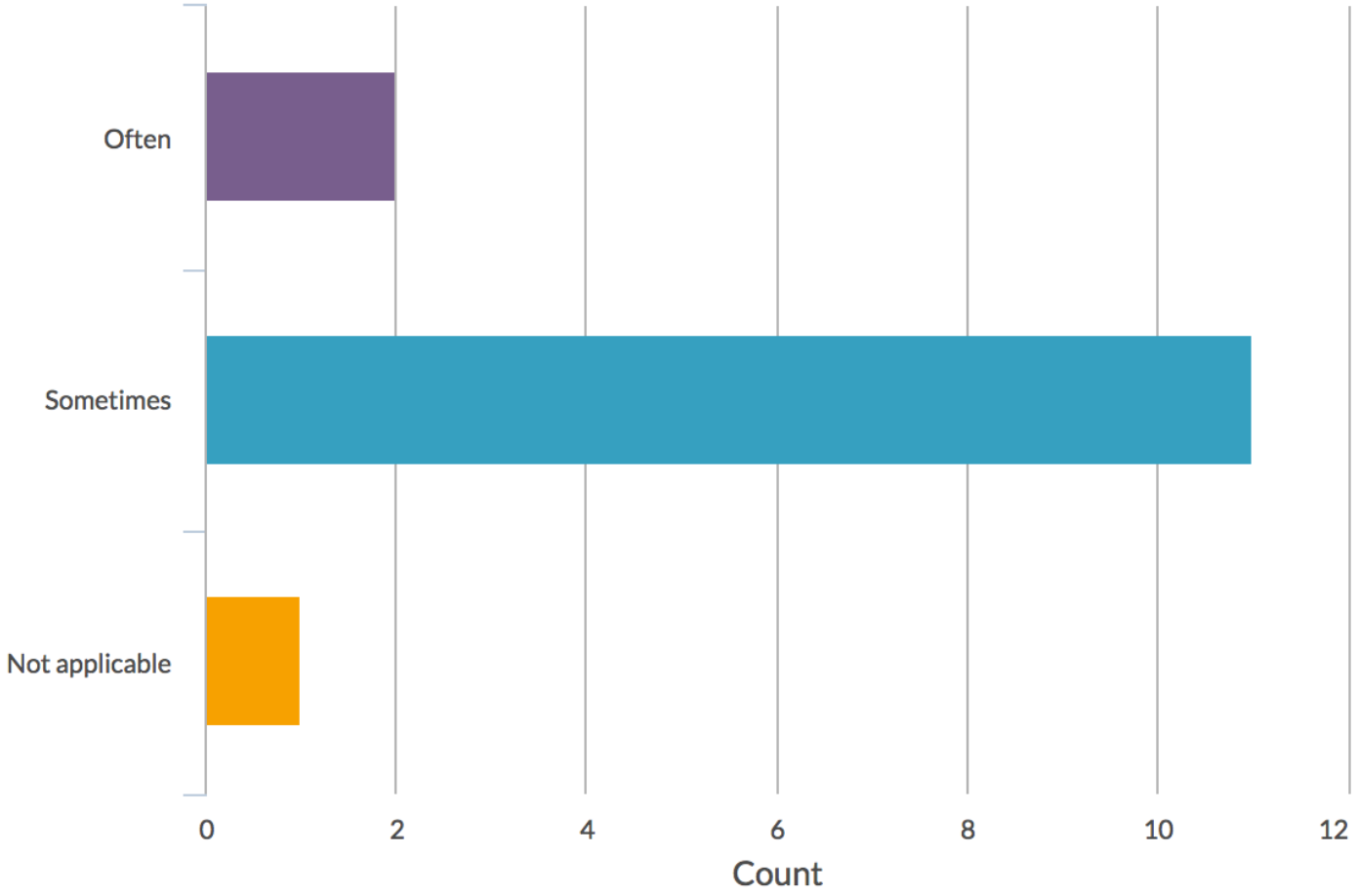
15. Metrics fail to detect issues critical to success:



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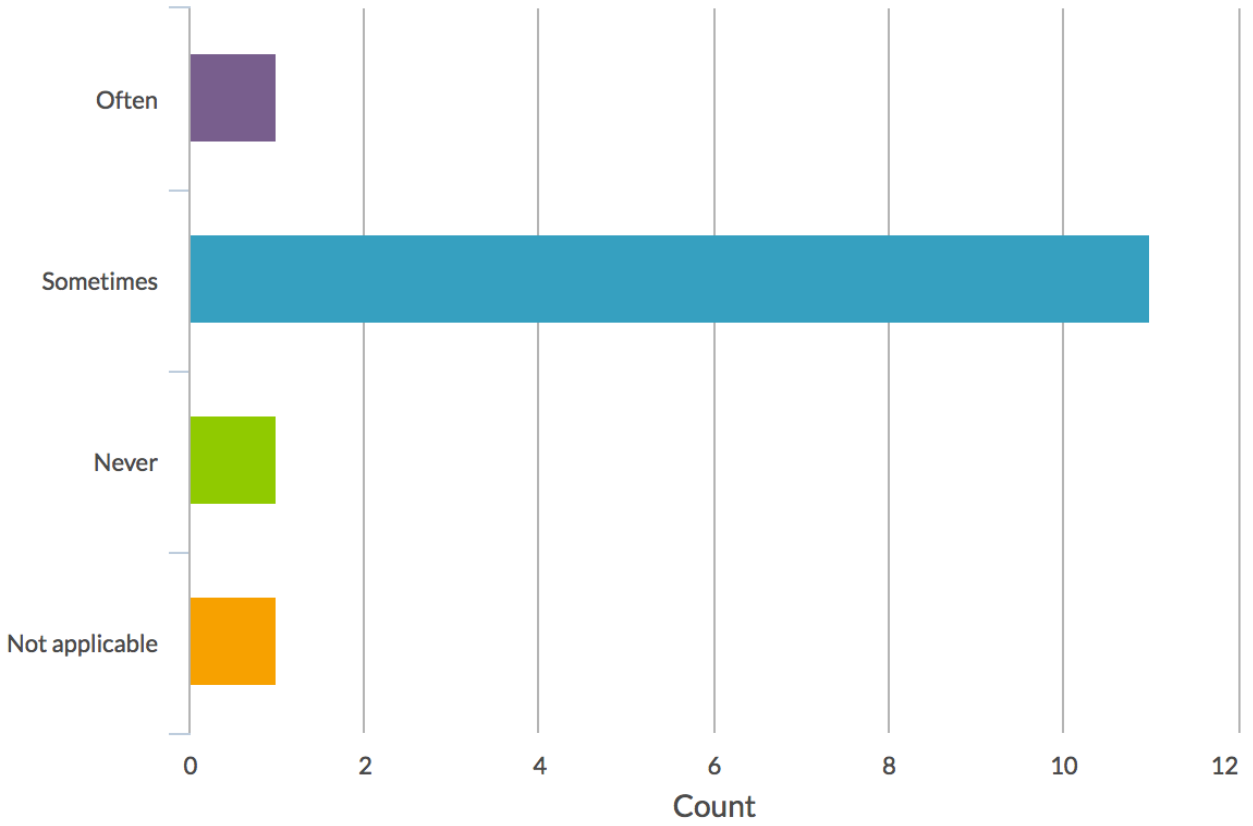
16: Access to meaningful metrics are made easy:



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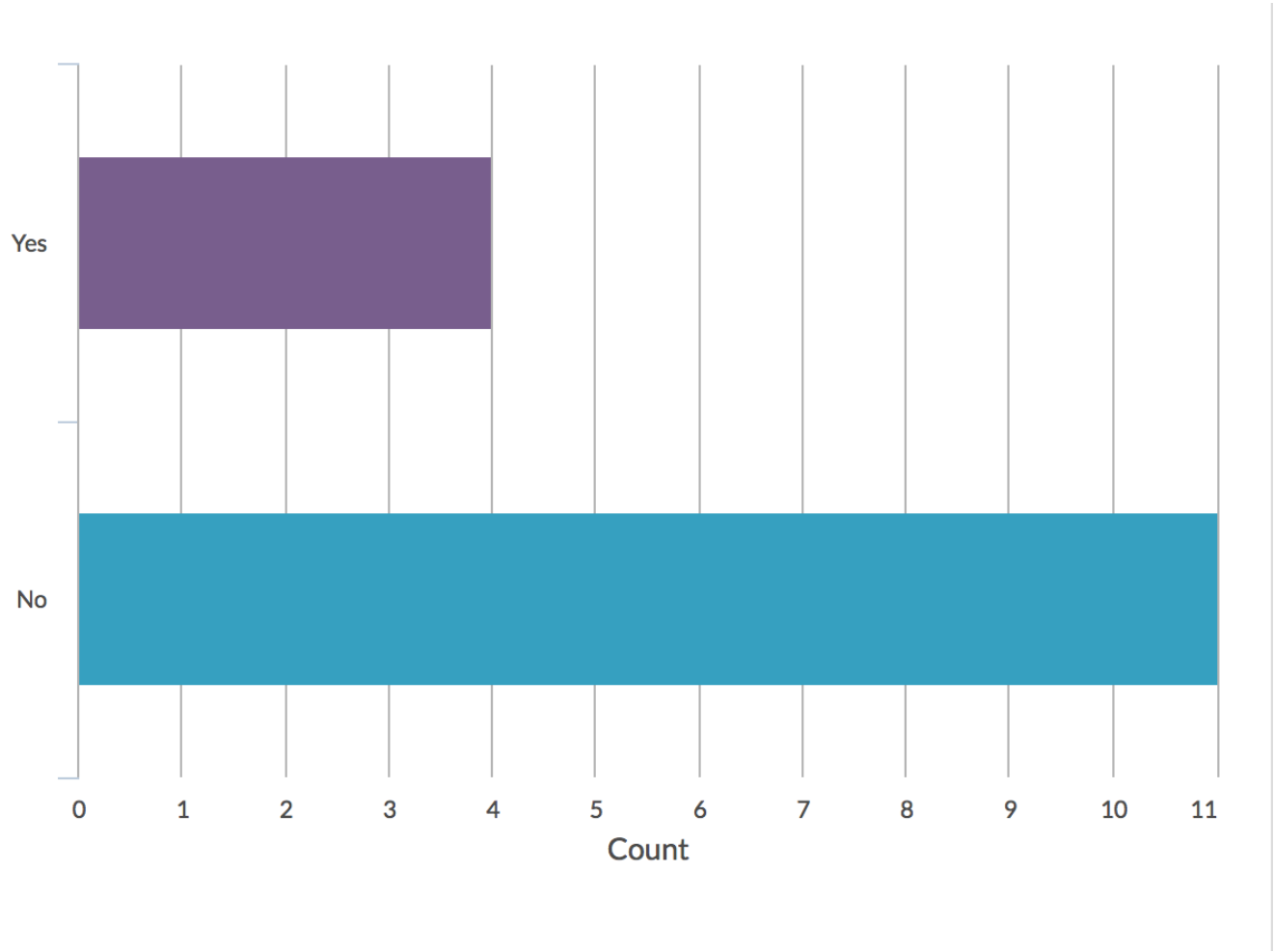
17. Use a data system is used for metrics generation:



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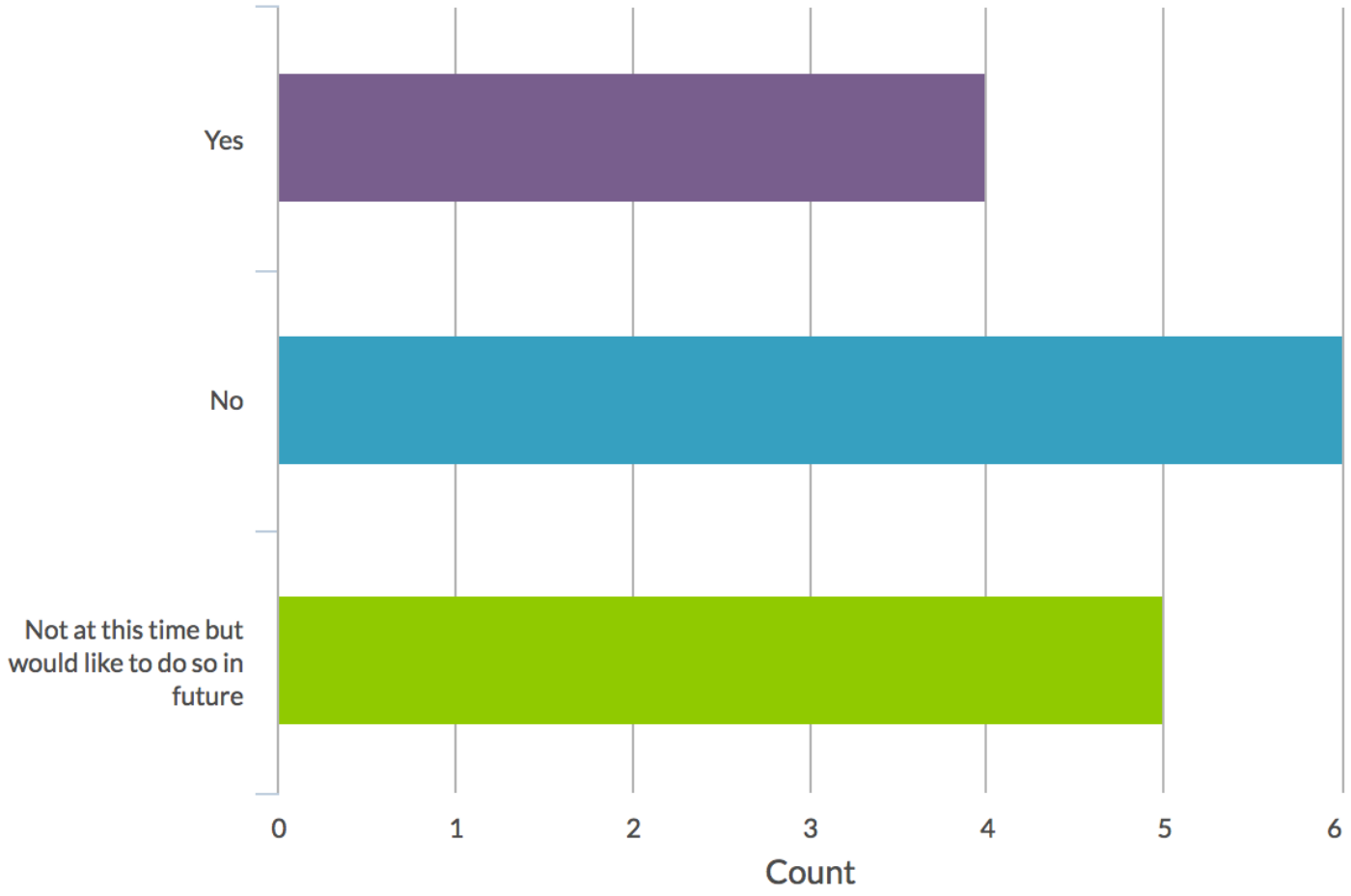
18. Data analytics is used to assess clinical trial status:



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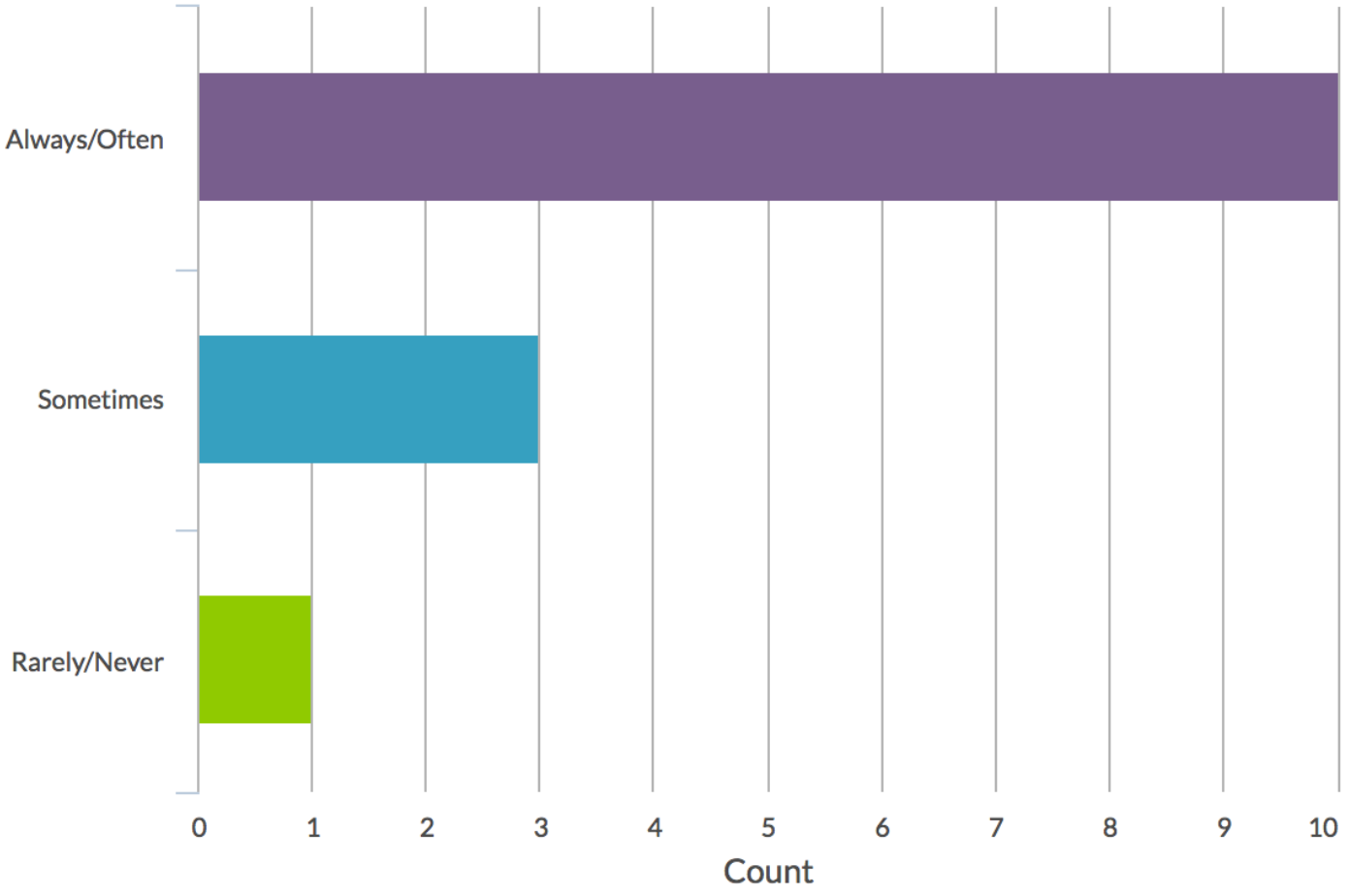
19. Performance data transparency is important:



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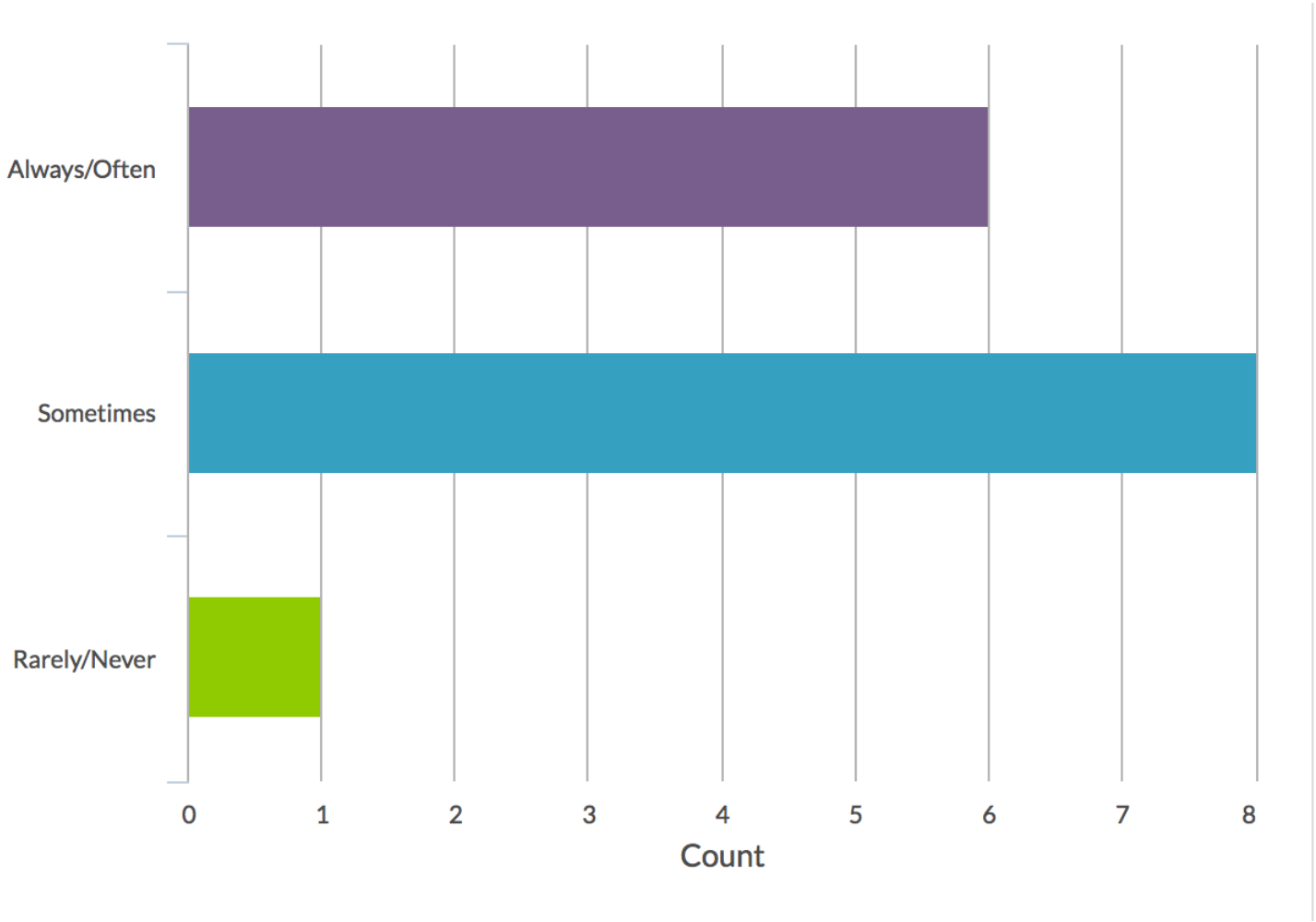
20. Metrics are shared with project team members:



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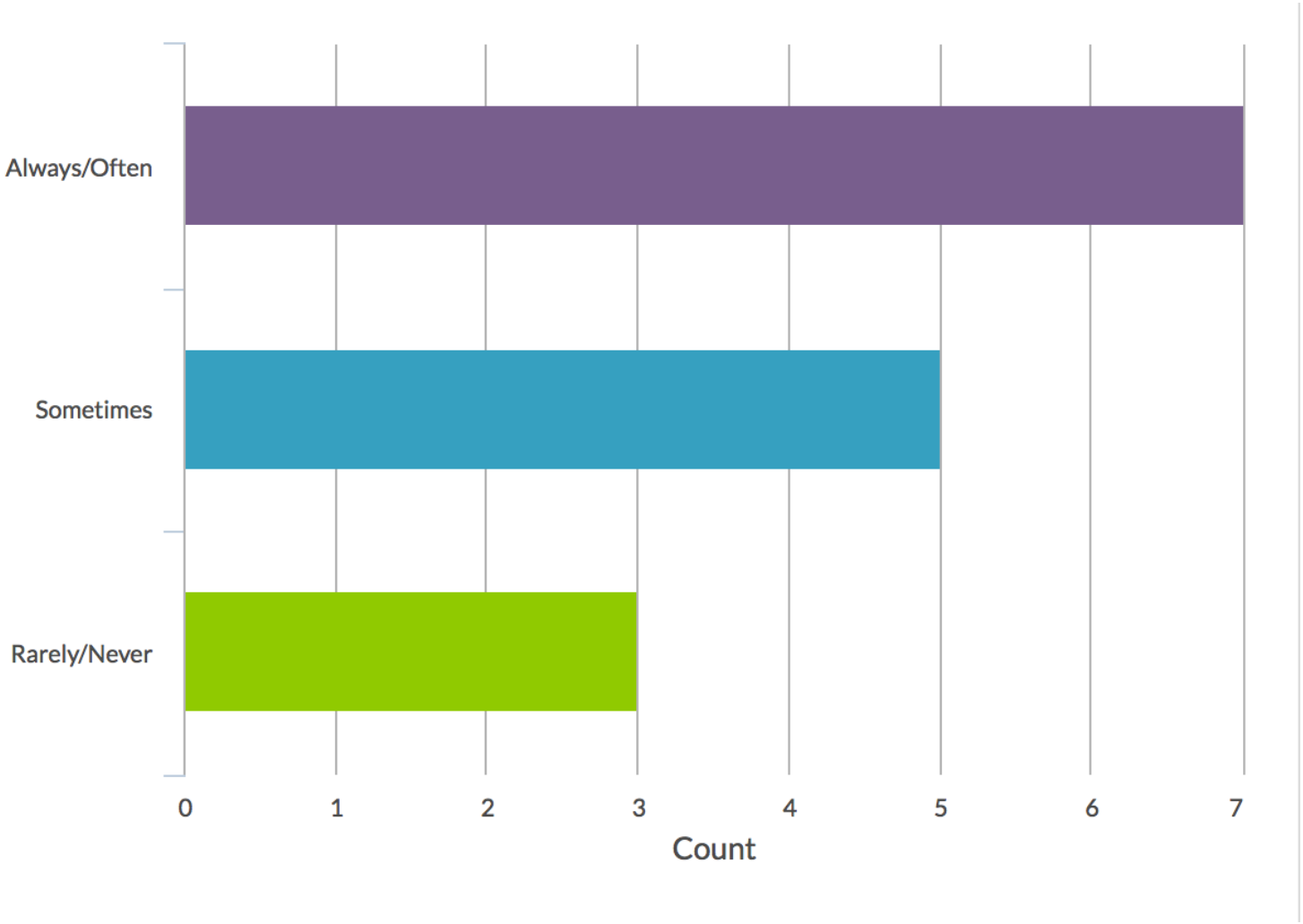
21. Metrics are a part of communication planning:



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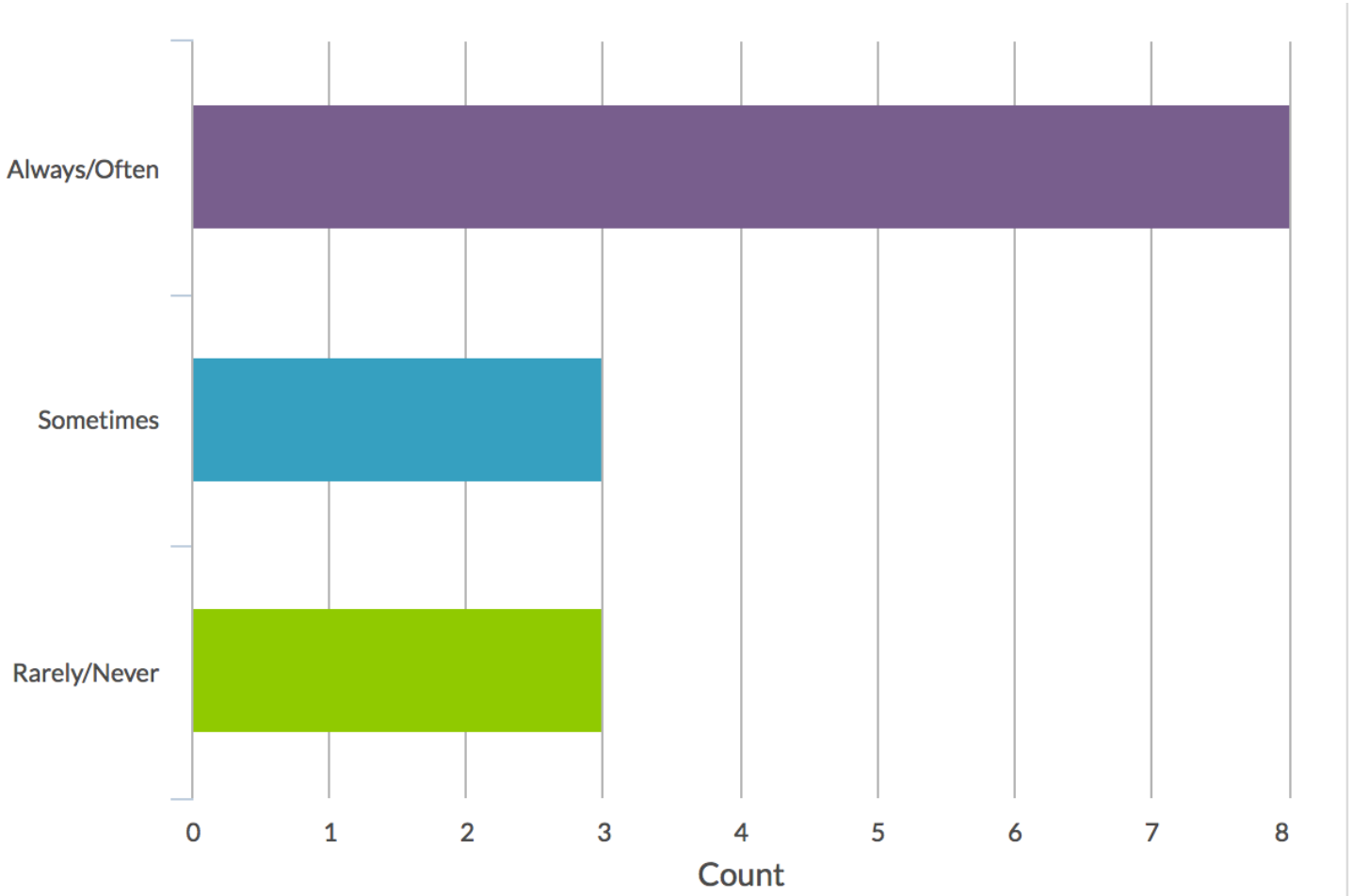
22. Metrics reduced ambiguity in past projects:



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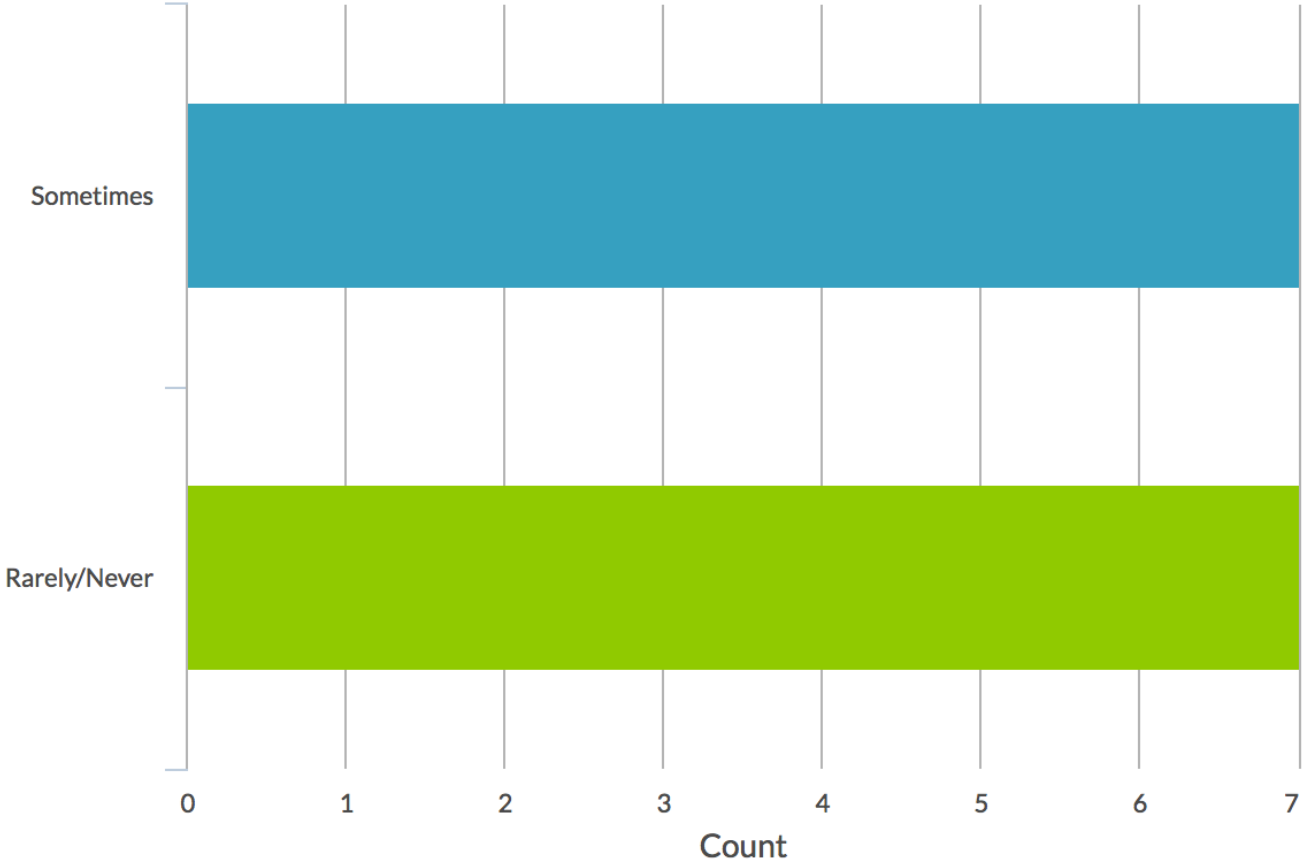
23. Metrics created ambiguity in past projects:



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