

The Research Compliance Network (RCN) is a national consortium of representatives from academic medical centers, universities, and hospitals. RCN members are professionals whose role involves quality assurance and quality improvement activities (QA/QI) related to organization-wide human subjects research compliance, including post-approval auditing. The network currently includes over 300 members representing various institutions, large and small.

Introduction

Unlike the IRBs, QA/QI criteria are not outlined in the regulations and QA/QI functions vary between organizations. To better define the characteristics, scope, and time trends of these functions, a national consortium representing more than 100 institutions conducted surveys in 2019 and 2022. This poster will highlight some findings.

Methods

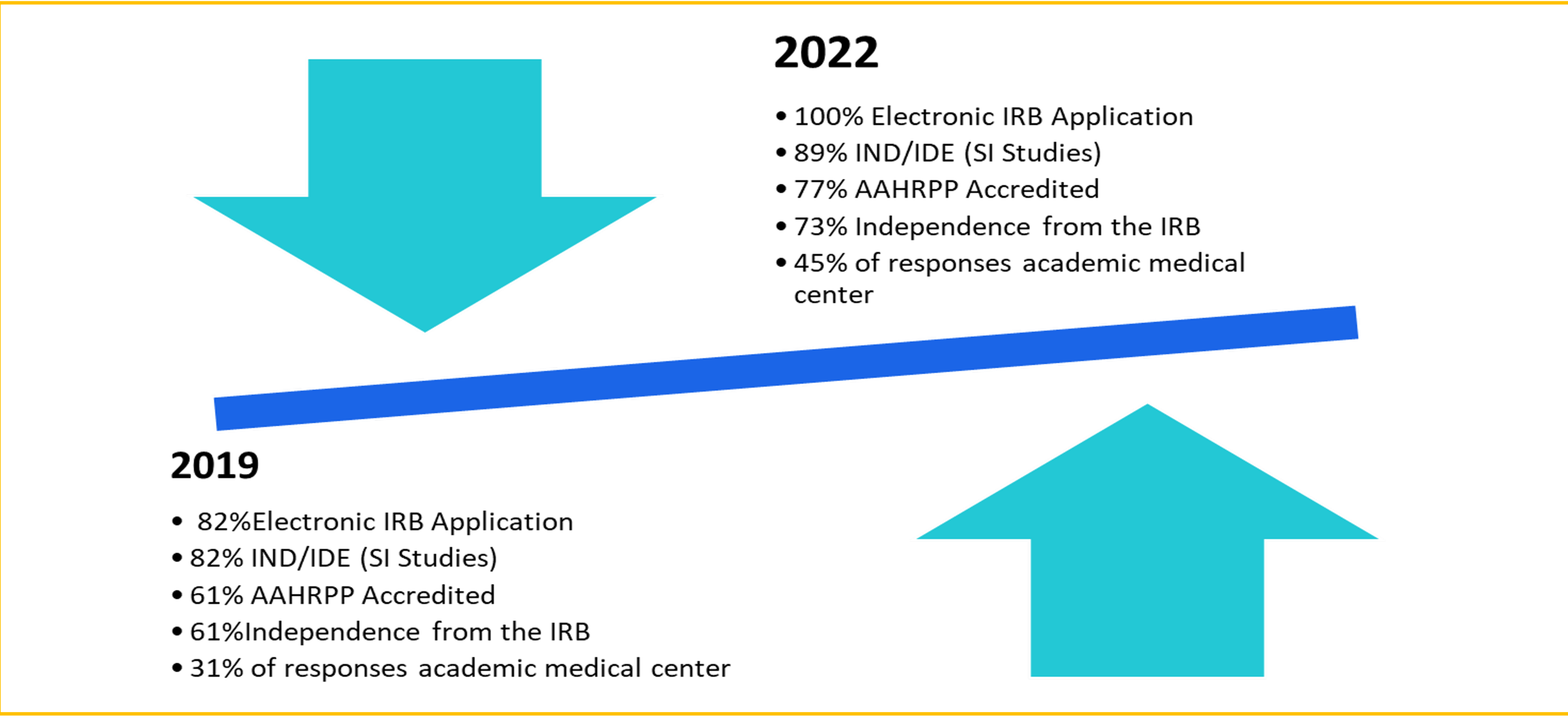
An online survey was distributed to all members of the consortium via the Qualtrics platform. The survey included 74 closed-ended questions organized in five sections including: organizational characteristics, QA/QI program scope, policy and procedures, single IRB issues, and resources.

Ten business days were provided to complete the survey with two reminders. The survey was anonymous, and members were instructed to submit one response per organization.

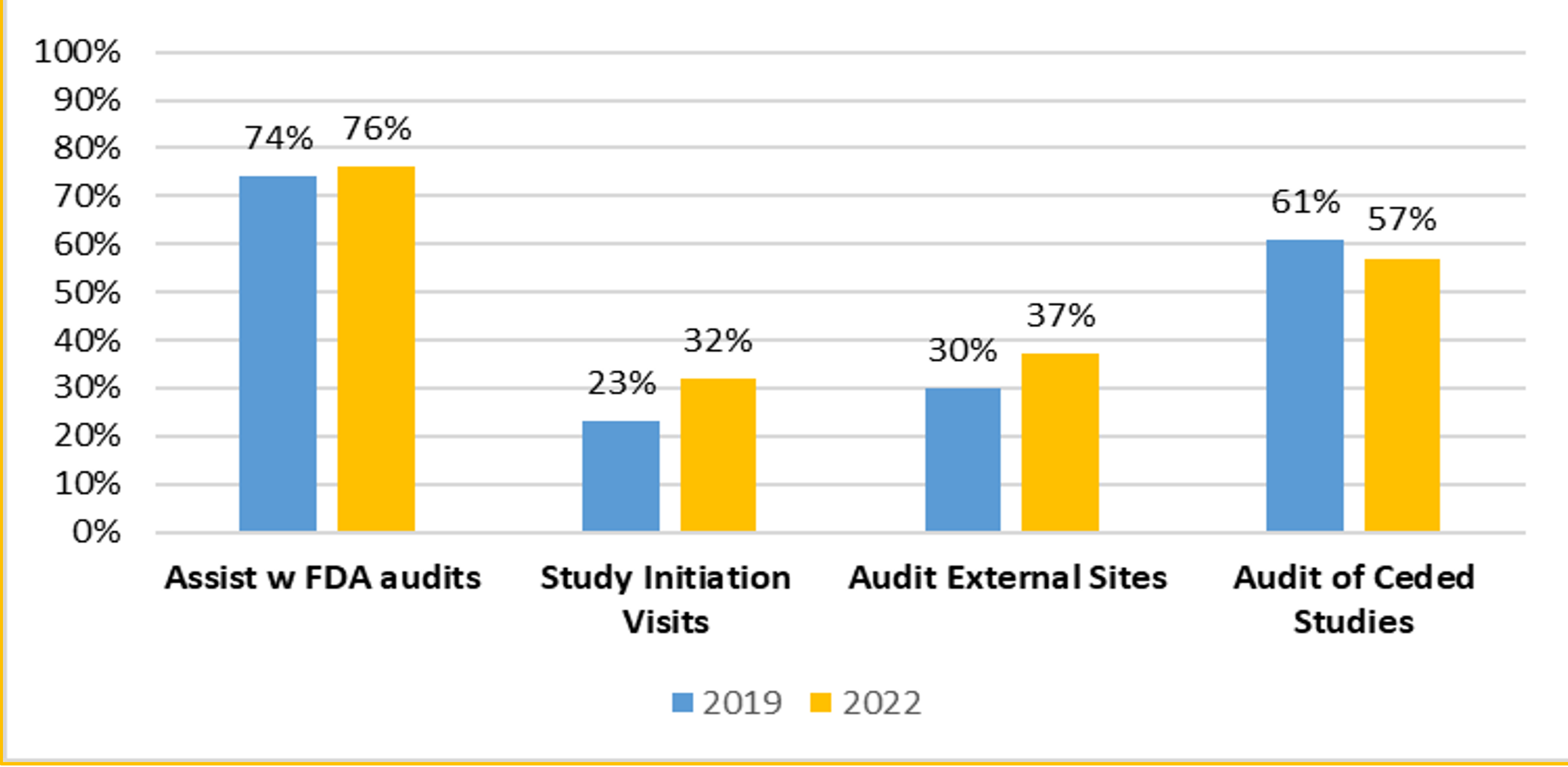
Minor modifications were made to the survey in 2022 to evaluate the impact of the pandemic on QA/QI work arrangements and workload. However, the core questions were similar in order to identify time trends.

Results

Organizational Characteristics



Program Scope-Select QA Activities



Disclaimer: The findings presented represent a portion of the survey results. This information continues to be reviewed and evaluated.

Key Findings

The scope of QA/QI Programs, i.e., select QA activities, has increased in since 2019. Additionally, QA/QI Programs have achieved greater autonomy with 73% of institutions reporting independence from the IRB. Interestingly, the 2022 results demonstrated a decline in audits of ceded studies perhaps as a result of settling into the 2018 Final Rule and/or the pandemic focusing other priorities.

Discussion

Further research is warranted to better understand how best to structure, organize, and support QA/QI Programs in an evolving research landscape. In particular, monitoring how, if at all, QA/QI Programs audit ceded studies may yield best practice recommendations.

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