

Registry and Biorepository Working Group Call

Co-Chaired by:

Melissa Rawley-Payne

Biobank Operations Manager
Lupus Research Alliance

Angela Dobes, MPH

Vice President, IBD Plexus
Crohn's & Colitis Foundation

August 26, 2020

HRA 2020 Registry Working Group Meeting – August 2020

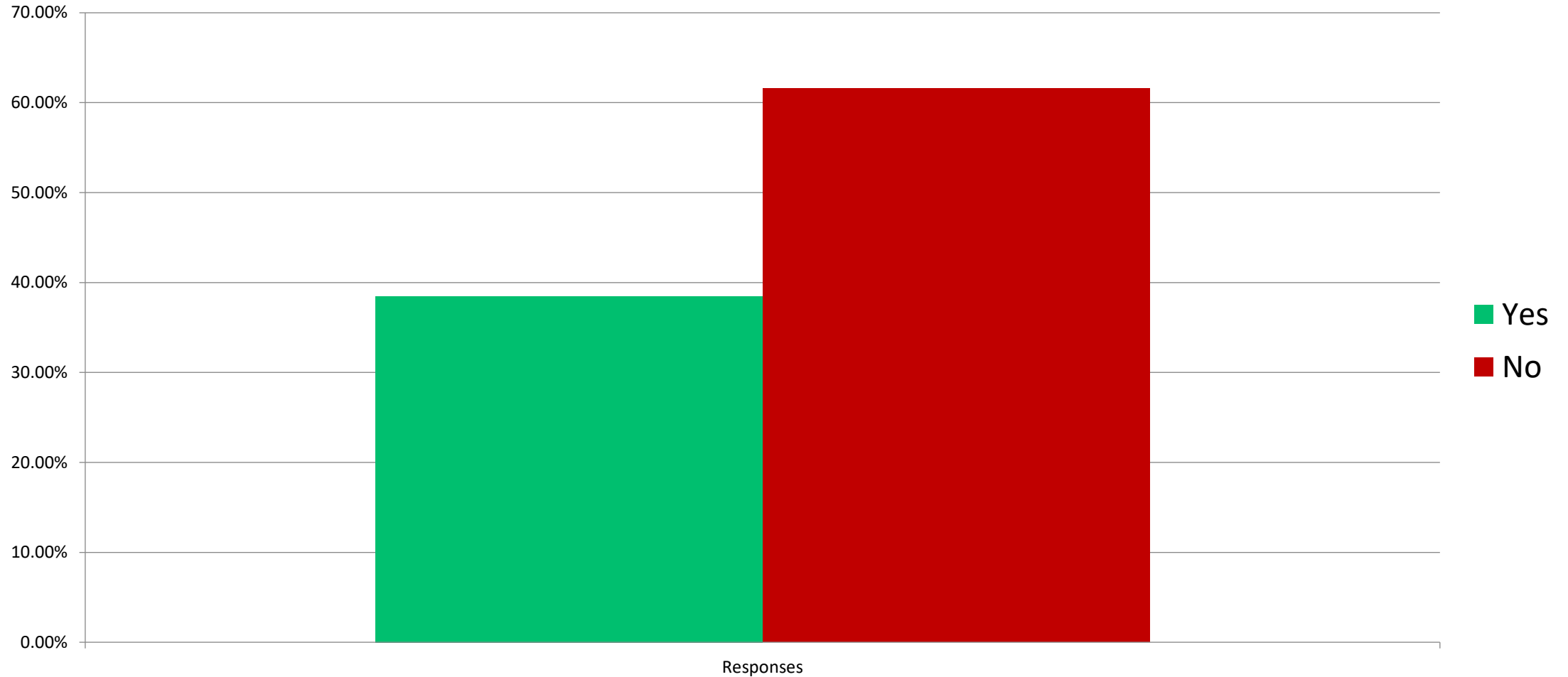
- Introductions by any new attendees
- Snapshot of Survey Results
- Business Plan Development
 - Purpose and Role of Business Plan (*Melissa, LRA*)
 - Components of Business Plan (*Melissa, LRA*)
 - Operational Structure and Governance Model Examples and Discussion (*Angela, Crohn's & Colitis Foundation*)
 - Focus on Governance and Data Sharing
- Confirm next meeting's topic of interest

General Survey Result Summary

Questions focused on capabilities of existing or planned registries /
biorepositories

- 13 unique responses

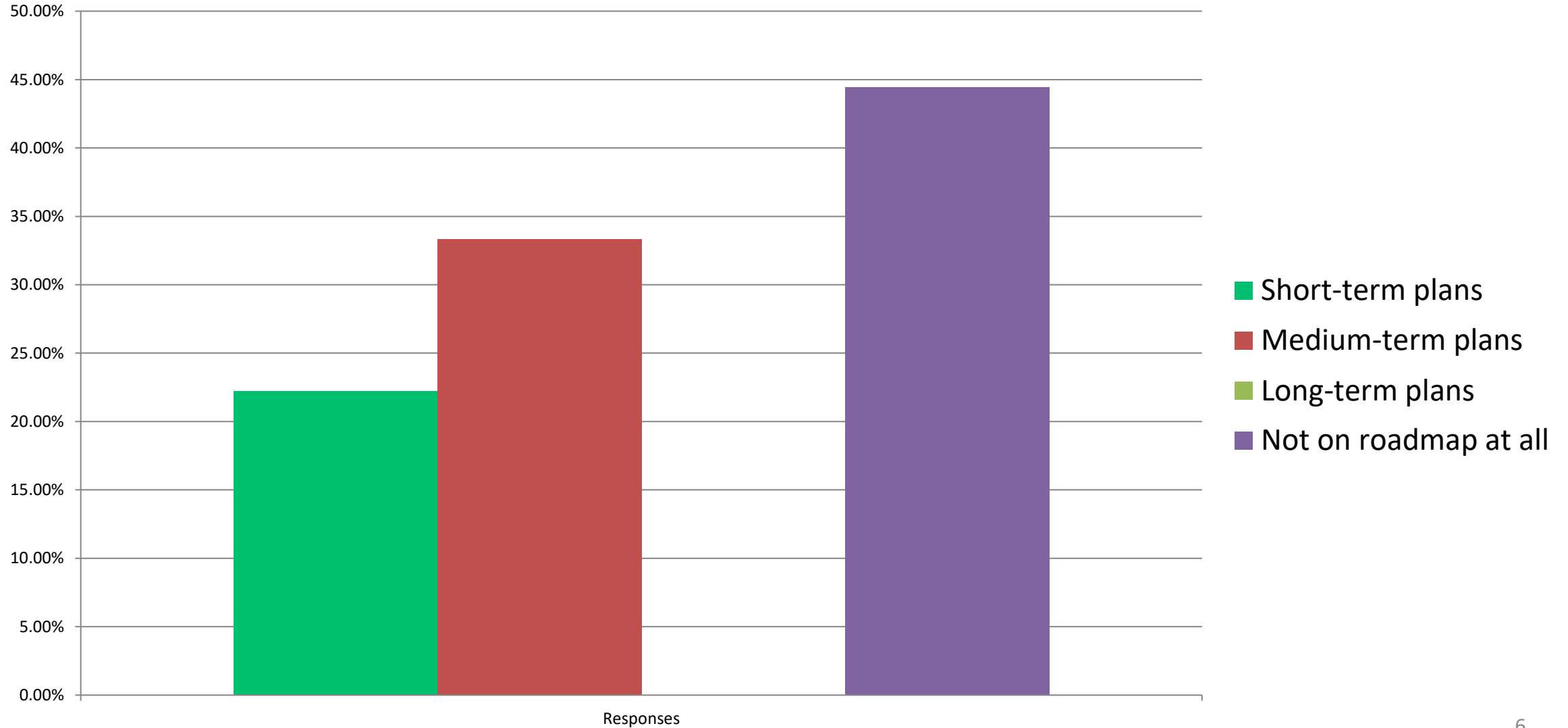
Does your organization currently use/maintain a registry?



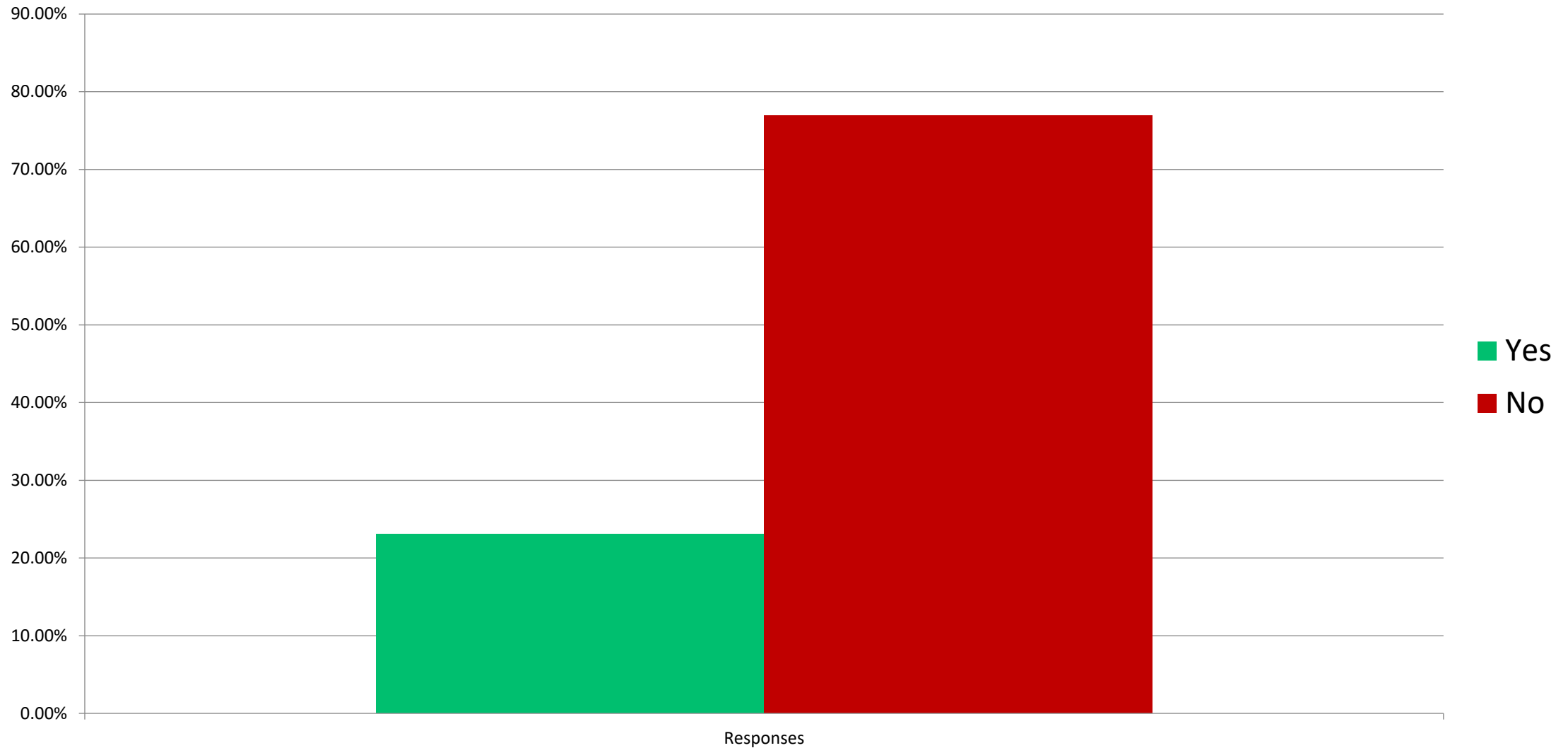
For organizations with a registry, please indicate the platform(s) used

- PEER through Genetic Alliance (soon to be LunaPEER, in collaboration with Genetic Alliance and LunaPBC)
- Proprietary
- Redcap (2)
- IQVIA

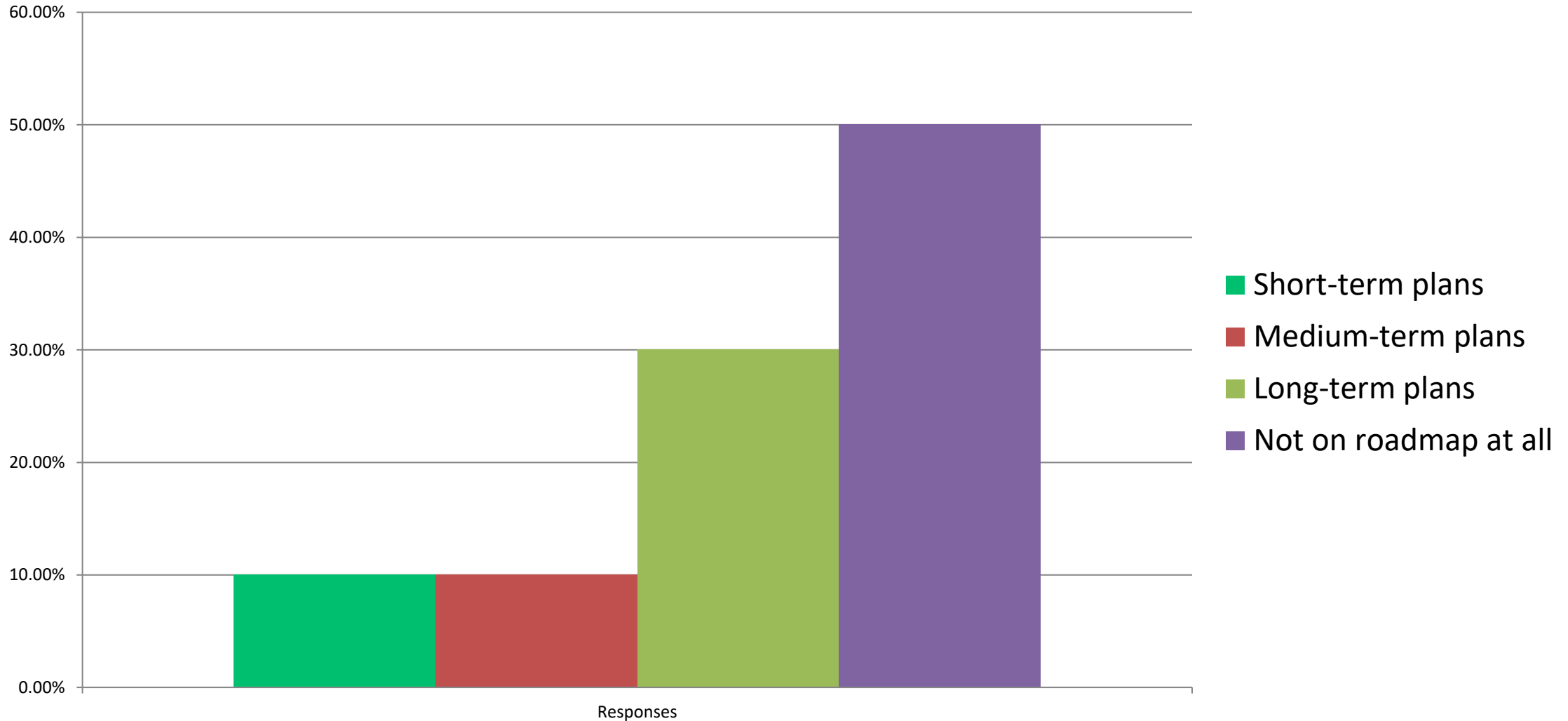
If No Current Registry, is building a patient registry on your roadmap?



Does your organization currently use/maintain a biorepository?



If No Current Biorepository, is building one on your roadmap?



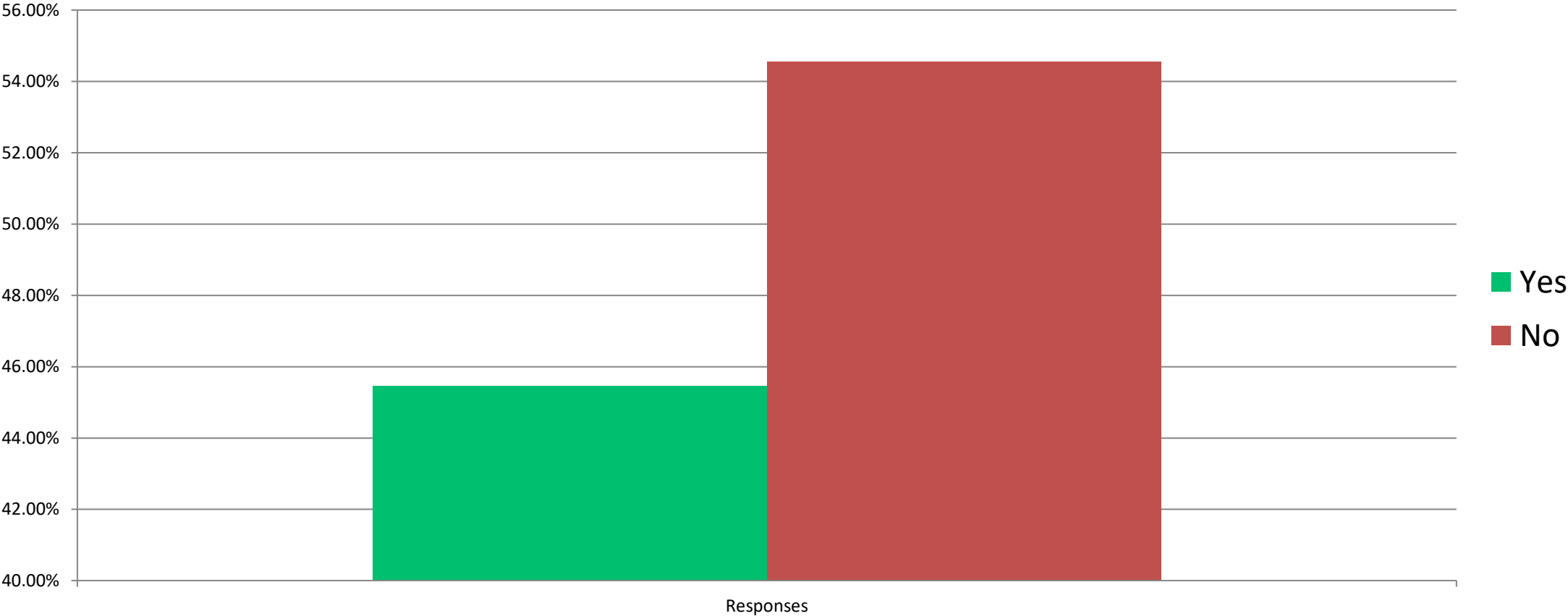
For organizations with a biorepository, please indicate the platform(s) used

- Komen Tissue Bank at Indiana University
- Brooks Life Sciences
- University of Washington in St. Louis

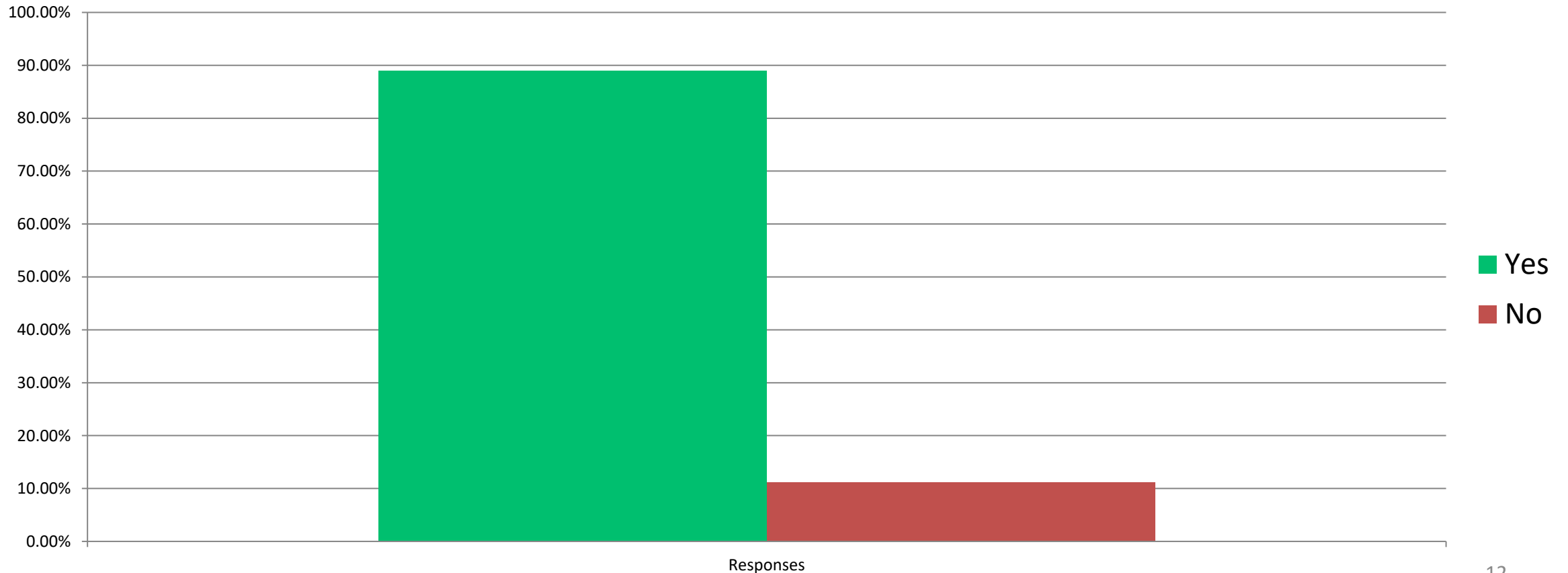
Please indicate if the registry and/or biorepository your organization uses offers one or more of the following capabilities

Recruitment of affected individuals for clinical studies	75.00%
Recruitment of unaffected individuals (controls) for clinical studies	25.00%
Recontact of individuals for activities such as recruitment into external clinical trials	58.33%
Industry partnerships (i.e., pharmaceutical company, payer, etc.)	75.00%
Data-sharing with industry	75.00%
Data-sharing with academic researchers to advance your organizations' research field	91.67%
Data-sharing with organizations beyond your immediate research field	41.67%

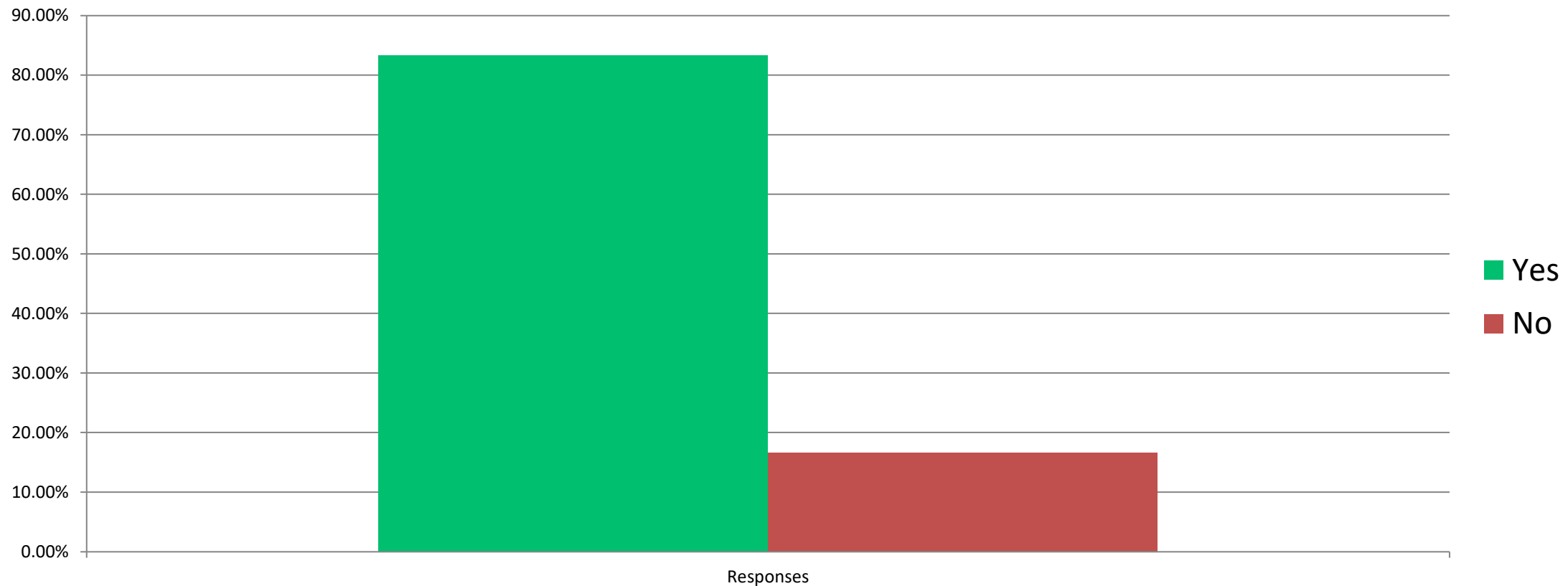
Do you have a business plan or any other relevant documents you can share with other working group members?



For your organization, has the investment of time, effort, and dollars been worth it, either in the short term or hoping that it will in the long term?



We would like working group meetings to be interactive and provide opportunities for members to share best practices and lessons learned. Would you be interested in presenting at a future meeting?



General Business Plan Development – References

- Non-profits
 - ❖ <https://www.propelnonprofits.org/resources/social-enterprise-business-plan/>
- Registries
 - ❖ <https://cdn.ymaws.com/www.thepcpi.org/resource/resmgr/nqr-n-registry-business-case-.pdf>
- Biobanking
 - ❖ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5327055/>

Purpose of a Business Plan

- Commonly used tool for starting or growing a business endeavor
- Important planning document to assist with developing and ensuring the success of a business
- Contains organization-level information used to help raise capital for business development and outlines a plan for long-term sustainability
- Outlines aspects such as the specific purpose of the business, the anticipated benefits and how those benefits will drive revenue to support the development and ongoing operation of the business, how the goals outlined will be achieved and financially sustained
- Must include input from senior management
- Should be reviewed regularly and updated as needed

General Business Plan Considerations

- Determine the content of to be included to meet the specific needs by evaluating relevant references
- Determine if there are resources internally to assist with development
 - If not, determine if there are funds available to leverage an external vendor to support
- Plan for at least 10-12 weeks for business plan development

Business Plan Table of Contents

- Executive Summary
- Mission
- Operational Structure and Governance Model
- Business Description
- SWOT analysis
- Market Analysis/Research
- Competitive Analysis
- Marketing Strategy
- Financial Plan

Note: The recommended sections to be included in a business plan will vary across available references but most highlight similar areas of content focus

IBD Plexus Use Case: *GOVERNANCE & DATA SHARING*

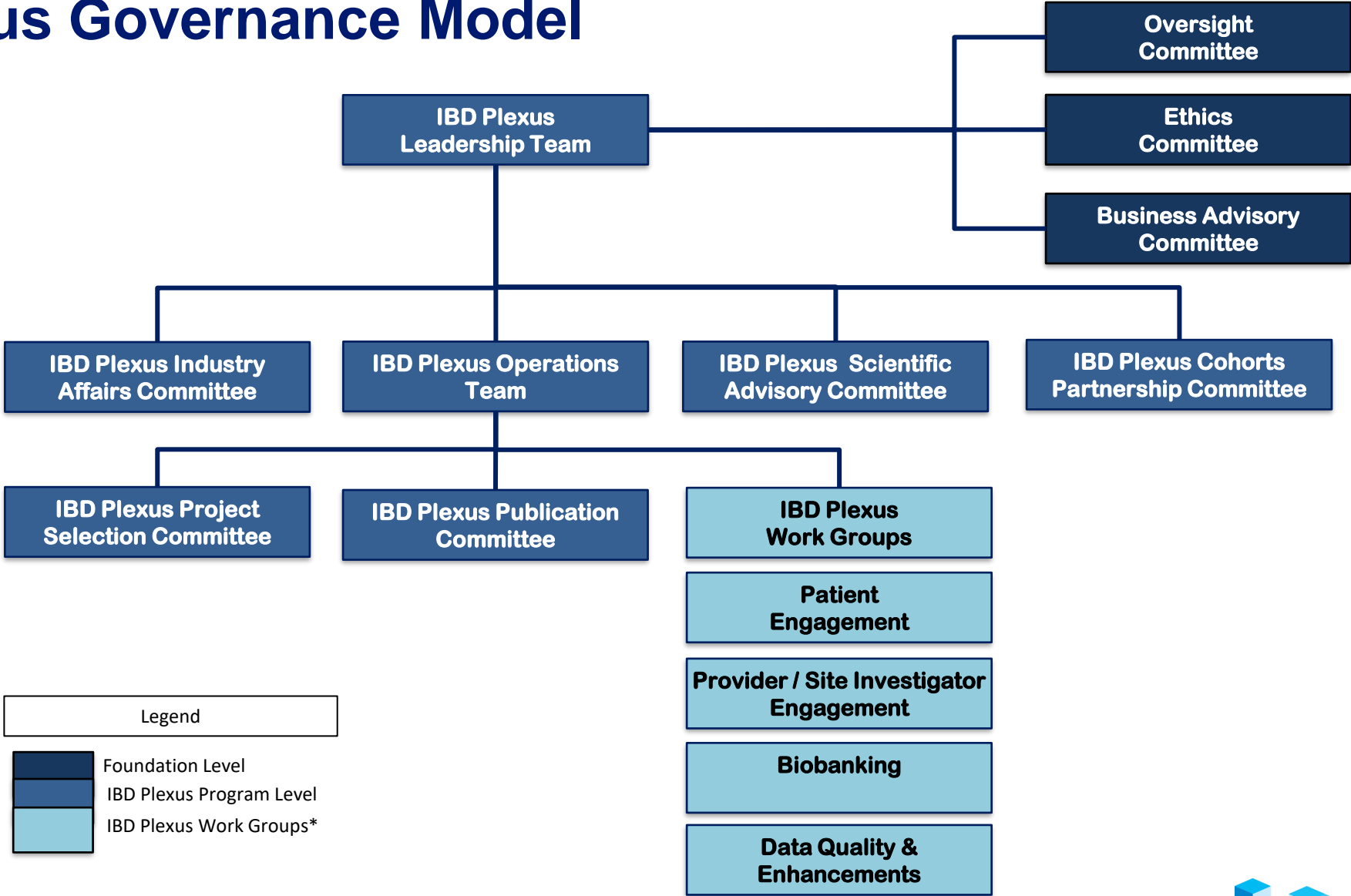
Angela Dobes, MPH
Vice President, IBD Plexus



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Governance and Operations

IBD Plexus Governance Model



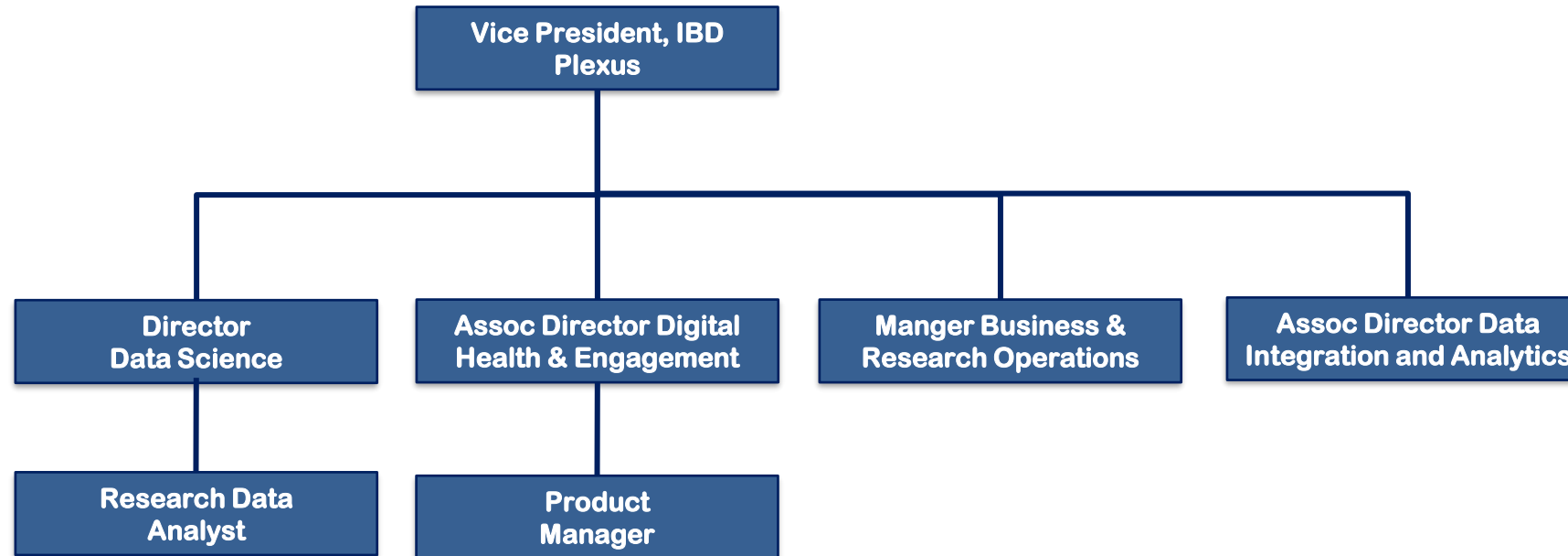
Legend

- Foundation Level
- IBD Plexus Program Level
- IBD Plexus Work Groups*

*work group topic areas can change based on need



IBD Plexus Operations Team



IP, Royalties, New Resources & Data Sharing

IP, Royalties & New Resources

General Guidelines:

- Inventorship and ownership of any patentable invention shall be determined in accordance with United States and any applicable state law
 - Company / Institution conducting research will own IP
 - Neither Site nor PI shall claim IP for solely contributing data and samples to IBD Plexus
- Foundation will not have a right to any royalties
- Any new resources generated should be provided to the Foundation at cost and without markup, for at cost distribution to scientists at non-commercial organizations

Note: Research projects funded by the Foundation have different IP / royalty policies

Data Use Terms

- Only de-identified data is transferred to members
 - If limited dataset (as defined by HIPAA) is required, researcher needs to get additional IRB approval
- Company agrees to safeguard storage of the data and prevent attempts to re-identify the individuals
- Data cannot be used for product promotion, marketing, targeting segments of the physician IBD landscape to understand prescribing patterns
- Foundation and IBD Plexus must be acknowledged on all abstracts, posters and publications
- Accommodates need to abide by journals and funders data sharing requirements
 - If required, to post data to a 3rd party database
 - Only limited, required clinical data should be posted
 - Data can only be used for validation or reproduction of the research results
 - Data is subject to a Creative Commons license with all of the attribution non-commercial and share alike features or their equivalent.

Project-generated Raw Data

Raw data generated for a project, such as data derived from biosamples, must come back into IBD Plexus once data exclusivity terms expire.

Exclusivity Types

- Non-targeted data
 - Data that is not directed at a particular hypothesis but rather is a preliminary exploration of the data
 - 6 months exclusivity
- Targeted data
 - Data that has been generated to answer a focused hypothesis
 - Data that has been generated using a non-commercially available assay
 - 18 months exclusivity and opportunity for additional 12-month extension

Business Plan Section Content Details

Business Plan Section Content

- **Executive Summary**
 - Founder
 - Organizational Description including
 - How the project aligns with the goals/objectives of the organization
 - Project Description including
 - Purpose of the Registry
 - Need or Problem to be Addressed
 - Value Proposition/Competitive Advantage
 - Stakeholders
 - Key Success Factors
- **Mission**
- **Operational Structure and Governance Model**

Business Plan Section Content

- **Business Description**
 - Goals and Objectives
 - Registry Population
 - Products/Services
 - Pricing Structure
 - Intellectual Property (IP) Rights
 - Performance Metrics
 - Risk Mitigation Strategies
- **SWOT Analysis**
 - Internal Strengths/Weaknesses
 - External Opportunities/Threats
- **Market Analysis/Research**
 - Industry context
 - Target Market/Customers
 - Market Needs and Gaps
 - New Market Opportunities

Business Plan Section Content

- **Competitive Analysis**
 - Primary Competitors
 - Competitive Products/Services
 - Risks & Opportunities in the Competitive Market
 - Recent or Emerging Changes in the Industry
 - Competitive Advantages/Value of Proposed Product/Services
- **Marketing Strategy**
 - Marketing and Growth Strategy
 - Performance Metrics
- **Financial Plan**
 - Costs
 - Funding Mechanisms
 - Revenues
 - Return on Investment
 - Partner Collaboration Model