Registry and Biorepository Working Group Call

Co-Chaired by:

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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?

- Yes: 40.00%
- No: 60.00%

Responses
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?

- Short-term plans
- Medium-term plans
- Long-term plans
- Not on roadmap at all
Does your organization currently use/maintain a biorepository?

Responses

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<th>Yes</th>
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If No Current Biorepository, is building one on your roadmap?

- **Short-term plans**
- **Medium-term plans**
- **Long-term plans**
- **Not on roadmap at all**
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

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

Yes

No
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?

[Graph showing responses]

- Yes: 90.00%
- No: 10.00%
General Business Plan Development – References

• Non-profits
  ❖ https://www.propelnonprofits.org/resources/social-enterprise-business-plan/

• Registries

• Biobanking
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
Governance and Operations
IBD Plexus Governance Model

IBD Plexus Leadership Team

IBD Plexus Industry Affairs Committee

IBD Plexus Operations Team

IBD Plexus Scientific Advisory Committee

IBD Plexus Cohorts Partnership Committee

Oversight Committee

Ethics Committee

Business Advisory Committee

IBD Plexus Project Selection Committee

IBD Plexus Publication Committee

IBD Plexus Work Groups

Patient Engagement

Provider / Site Investigator Engagement

Biobanking

Data Quality & Enhancements

Legend

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

*work group topic areas can change based on need
IBD Plexus Operations Team

Vice President, IBD Plexus

Director Data Science

Assoc Director Digital Health & Engagement

Manager Business & Research Operations

Assoc Director Data Integration and Analytics

Research Data Analyst

Product Manager
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