Making Your Organizations Registry and or Biobank a Reality

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http://www.resourcerepository.org/documents/2032/makingyourorganizationsregistryandorbiobankareality/
Registry & Repository Overview

Genetic Alliance BioBank Webinar
August 11, 2010
Why do we need a registry & repository?

**Data**
- Characterizing PMS
- Natural history
- Verifying animal models
- Identifying clinical endpoints

**Samples**
- In-vitro studies

• Genotype-phenotype studies
• Cohort development
Objectives of the R&R

<table>
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<tr>
<th>Objective</th>
<th>To centralize PMS data and samples</th>
<th>To support a wide range of PMS-related research projects</th>
<th>To understand the PMS phenotype</th>
<th>To make family participation easy</th>
<th>To facilitate clinical trials</th>
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<tr>
<td>To improve researchers’ interest in and access to PMS data and samples</td>
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<td>To support natural history studies</td>
<td>To improve clinical care guidelines</td>
<td>To increase the numbers of families participating in research</td>
<td>To identify meaningful endpoints</td>
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<td>To generate publishable findings which increase awareness of PMS and its problems and to create greater statistical power</td>
<td>To develop useful research cohorts</td>
<td>To draw attention to currently unaddressed medical conditions</td>
<td>To prevent participation fatigue across the board by limiting researchers’ direct access to families</td>
<td>To encourage long-term participation</td>
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<td>To validate animal models</td>
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Our process

Learned about registries and repositories

Attended Workshops
Read the Executive Summary of AHRQ’s “User’s Guide to Registries Evaluating Patient Outcomes

Identified vendors to evaluate

5 registry vendors
4 repository vendors

Interviews

Contacted other disease groups to learn what vendors and procedures they used.
Contacted vendor clients for feedback
Contacted stakeholders in related areas to find out what resources already exist

Vendor Site Visits

Reviewed all vendors using set criteria (see next slide for criteria)
Our Criteria for Evaluating Vendors

**Technological Performance**
- web-based format with extensive data mining capability
- emergency backup protocols
- privacy guards and legacy data collection.

**Quality Assurance**
- chain of custody information
- audit tracking
- testing of repository samples to verify quality

**Customer Support**
- templates for consent forms
- institutional review board (IRB) oversight
- experience designing questionnaires
- experience distributing data and samples

**Customer Usability**
- customize the registry questionnaire
- customize the layout and presentation of results

**Regulatory Compliance**
- operating under **Good Laboratory Practice (GLP) compliant standards** and in accordance with all applicable state and federal regulations.
Our Conclusions

- Vendors (independent and not attached to any other medical or pharmaceutical entity) have only been offering registry services to rare disease groups for the past few years.
- Very few disease groups our size have made creating a R&R a priority.
- Disease groups that have “done their own” registry have either spent a great deal of money on the development of them or utilize a simple spreadsheet.
- PMSF would like to retain ownership /control of our data and samples.
- PMSF would rather pay a vendor than having Foundation volunteers responsible for creating and managing a registry.
- PMSF must be committed annually to the financial cost of building the R&R.
- PMSF will prioritize the acquisition of samples based on input from the research community.
Major Issues for Patient Group to Consider

**Foundation’s Individual Needs**
- Capacity - is the group large enough to warrant a vendor run R&R?
- Financial capacity – can the group sustain the R&R annually?
- Internal support – does the group leadership support the R&R and understand the value of it?

**Ownership**
- Data – does the group need to retain ownership of registry data?
- Bio Samples – does the group need to retain ownership of all bio samples?
- If ownership is not retained do participants understand the repercussions?

**Donor (Patient) Consent**
- Must understand who will have access to the data and bio samples.
- Must understand what type of research will be done for what reasons, now and in the future.

**Distribution**
- Who Gets Access? (all researchers, only those doing specific research, etc.)
- What do they have to do in return? (purchase samples, publish results, share info.)
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