Core Facilities and Biomedical ‘Omics: what’s what, what?

BORG:
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George Grills: EB Liaison
BORG

Resistance is futile
Biomedical ‘Omics Research Group

• Current Members
  – Lisa D White (Chair) - Baylor College of Medicine
  – Nicholas P. AKAlos (Co-Chair) - Univ of Maryland Sch of Med
  – Seth Crosby - Washington University School of Medicine
  – Chris Turck - Max Planck Institute of Psychiatry
  – Kevin L. Knudtson - Univ of Iowa
  – Katia Sol-Church - AI duPont Hospital for Children
  – Lauren Bechel – Baylor College of Medicine

The goal of the BORG is to be a resource for core laboratory directors interested in, or in the process of, converting or expanding academic core facility resources into clinical diagnostic resources (e.g., CLIA certified), including genomics, proteomics, metabolomics, flow cytometry and imaging resources.
The BORG Survey – Prelude to Assimilation

- Demographic information
- Gauge interest and need
- How we can help
So...the survey

Demographics

• Respondents

• Location of Facility

Results

<table>
<thead>
<tr>
<th>Sent to:</th>
<th>Responded</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>467</td>
<td>113</td>
<td>24.2</td>
</tr>
</tbody>
</table>

Bar chart showing the distribution of responses by region:
- United States: 91.9%
- Canada: 1.8%
- Europe: 3.6%
- Asia: 1.8%
- Africa: 1.8%
- Australia/South Pacific: 1.8%
- Other (please specify): 1.8%
So...the survey

- **Facility Affiliation**

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>University</td>
<td>46.36%</td>
</tr>
<tr>
<td>Medical School</td>
<td>26.36%</td>
</tr>
<tr>
<td>Veterinary School</td>
<td>0.00%</td>
</tr>
<tr>
<td>Hospital</td>
<td>7.27%</td>
</tr>
<tr>
<td>Biotech Company</td>
<td>1.82%</td>
</tr>
<tr>
<td>Private Laboratory or Diagnostic Group</td>
<td>0.91%</td>
</tr>
<tr>
<td>Research Institute</td>
<td>11.82%</td>
</tr>
<tr>
<td>Zoo</td>
<td>0.00%</td>
</tr>
<tr>
<td>Museum</td>
<td>0.00%</td>
</tr>
<tr>
<td>Government</td>
<td>2.73%</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>2.73%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>110</strong></td>
</tr>
</tbody>
</table>
So...the survey

Samples tested in your lab?

<table>
<thead>
<tr>
<th></th>
<th>Human Clinical/Research</th>
<th>Non-Human Mammalian</th>
<th>Insects</th>
<th>Birds</th>
<th>Reptiles</th>
<th>Water</th>
<th>Air</th>
<th>Soil</th>
<th>Total Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Facility (Shared Resource)</td>
<td>78.00% 78</td>
<td>95.00% 95</td>
<td>39.00% 39</td>
<td>16.00% 16</td>
<td>21.00% 21</td>
<td>16.00% 16</td>
<td>5.00% 5</td>
<td>20.00% 20</td>
<td>100</td>
</tr>
<tr>
<td>Diagnostic Laboratory</td>
<td>100.00% 6</td>
<td>16.67% 1</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>6</td>
</tr>
<tr>
<td>Survey Laboratory</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>0</td>
</tr>
<tr>
<td>Research Laboratory</td>
<td>75.00% 18</td>
<td>83.33% 20</td>
<td>16.67% 4</td>
<td>0.00% 0</td>
<td>0.00% 0</td>
<td>4.17% 1</td>
<td>0.00% 0</td>
<td>12.50% 3</td>
<td>24</td>
</tr>
</tbody>
</table>

Plants, Marine Organisms (including fish, sea urchins and other invertebrates), C. Elegans, Bacteria, Yeast, Fungi, Virus
So...the survey

Q4 What is the technological focus of your laboratory? (Check all that apply)

- Development of mouse monoclonal antibodies
- Histopathology
- Chemical synthesis, drug discovery
- Lipidomics
- Electron Microscopy, Bio-Nano Research, Micro/Nano Processing (Cleanrooms), Materials characterization (all sorts) - all shared facilities.
- Cancer genomics
- Epigenetics
- DNA sequence data
So...the survey

**Q5** Is your laboratory currently certified by a regulatory organization such as CLIA, CAP, State, FDA, ISO, etc?

Answered: 112  Skipped: 1
Q7 If you are not certified, are you planning to get your laboratory certified by a regulatory agency?

Answered: 92   Skipped: 21
Survey Nitty Gritty

Why?

- Standardization of procedures
- New Source of samples/users
- To process clinical trial samples
- Keep our instrument busy
- Uh?...
Q10 Please indicate the tests that you intend to offer in your certified laboratory:

Answered: 63    Skipped: 50

- Laboratory Developed Tests
- FDA approved
- Both
- N/A
Survey Nitty Gritty

What kind of help do you expect from your institution

What obstacles/hurdles have you or do you expect to be formidable?

- all of the above were challenging!

- Getting clinicians to use our test versus a test they are already familiar and comfortable with.

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have absolutely No Idea!</td>
<td>20</td>
</tr>
<tr>
<td>Cost</td>
<td>18</td>
</tr>
<tr>
<td>Logistics</td>
<td>15</td>
</tr>
<tr>
<td>Documentation</td>
<td>23</td>
</tr>
<tr>
<td>Compliance</td>
<td>18</td>
</tr>
<tr>
<td>Standardization</td>
<td>17</td>
</tr>
<tr>
<td>Validation</td>
<td>15</td>
</tr>
<tr>
<td>Proficiency Testing</td>
<td>12</td>
</tr>
<tr>
<td>Data Analysis/Reporting</td>
<td>8</td>
</tr>
<tr>
<td>Lack of familiarity with regulatory processes</td>
<td>20</td>
</tr>
<tr>
<td>Providing a test that will continue to be competitive with similar tests on the market</td>
<td>9</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>5</td>
</tr>
</tbody>
</table>

Responses
Q13 What do you feel is single most important thing that the BORG can do to help you succeed at gaining clinical/other regulatory certification? (Check all that apply)

Answered: 63  Skipped: 50

Education on the process,...
Development of Standards
Assay Development
QA/QC
I don't think that the BOR...
Other (please specify)
Take Home Messages

• Well, at least we (ABRF respondents) know what we don't know and that we want to know more!

• At least 40% of all respondents interested in learning more.

• Education of the ABRF community is a priority of the BORG and what is needed from users.
  • Examples of accreditation/certification agencies
  • What you need to do to prepare
  • Business models and considerations for sustainability
• Best practices
  • Particularly available checklists and standards organizations
  • Not just for humans, but also environmental and plant
Future Directions

• Work with other RGs to recommend and make available general reference standards
• Draft guidelines and educational materials for cores
• Work with other societies like ISAC and ISBER to gain consensus around guidelines
• Provide pointers to service providers who might come review a core prior to CAP/CLIA/FDA review
• A series of papers in JBT outlining working models for certified core facilities in various biomedical and other biological subdomains
Discussion?