Genetic Alliance Registry Bootcamp – Winter 2021

Genetic Alliance supports advocacy organizations and communities in their quest to improve the lives of their members, primarily by helping them build their capacity for research. We recognize that recruitment, retention, engagement, data collection, and community building are all activities that are often best done in advocacy organizations or other community-based groups. Collection of real-world evidence and patient reported outcomes are more robust when done by these communities, so it is critical they have appropriate resources readily available. To support these efforts Genetic Alliance offers many services and programs, ranging from the Genetic Alliance BioBank and Genetic Alliance IRB (an established IRB with more than 125 approvals) to Genetic Alliance’s registry offering, the Promise for Engaging Everyone Responsibly (PEER). Genetic Alliance’s Registry Bootcamp takes these offerings a step further, by providing communities with the guidance and support necessary to plan and launch a registry and/or study.

Registry Bootcamp offers communities a deep dive into the world of registries. The Bootcamp is appropriate for any organization and/or community group seeking to build a condition- and/or community-specific research registry, natural history study, observational study, or other clinical study. While the program is first and foremost designed for those who are starting from scratch, many of the resources in Registry Bootcamp will bring value to those seeking to further develop an existing registry – for instance, resources to develop and/or deepen your registry or study’s engagement strategy. The course is platform-agnostic and will not go into the specifics of launching a registry with Genetic Alliance’s PEER program, though we do offer a PEER-specific Bootcamp module for those onboarding to PEER.

Participants in Registry Bootcamp will engage in peer-to-peer learning and receive educational materials and mentorship from Genetic Alliance staff and partners. Genetic Alliance has been working in and with communities to build registries for more than 25 years, and this lived experience informs both the course materials and live sessions. At the culmination of the program participants will have all the background needed to embark on the process of launching a registry and/or study and will have begun much of the planning necessary for success. The program is one month long (November 9th, 2021 through December 9th, 2021) and consists of four one-week modules (see syllabus at end of this document) and three live meetings (required; see syllabus for dates). Live meetings will include presentations from Genetic Alliance staff/partners as well as time for us to connect and engage in discussion as a class. Optional office hours with Genetic Alliance staff are also offered throughout the course. The course modules typically consist of 2-4 hours of readings and/or video instruction, combined with recommended worksheets and exercises (typically another 2-4 hours per week, though this can vary depending on the extent to which you wish to explore these activities within your organization). Additional resources that allow you to dive deeper are also available. Communities who choose to use PEER have the option to add the PEER module, as well, which takes communities through the process of launching a PEER registry or study. The PEER module is asynchronous, and completion time will vary depending on the needs and timeline for your community’s registry or study.
Registry Bootcamp is made possible through the generous funding of the following sponsors. There is no cost to communities to participate. Additional fees may apply for communities seeking to use the Genetic Alliance Biobank or Institutional Review Board, for those who become a member of the PEER program, or for those who wish to contract with Genetic Alliance for additional services and/or guidance beyond the scope of this course.

About the Promise for Engaging Everyone Responsibly:

Genetic Alliance established the Promise for Engaging Everyone Responsibly (PEER) to enable communities to build registries. PEER is a membership-based program that provides the support, guidance, and required infrastructure (e.g., IRB application writing assistance, in-house IRB review, the data platform, EHR connectivity, etc.) needed to successfully create and launch a registry and/or study. Since its establishment in 1995, PEER has evolved steadily to meet the needs of various communities through consistent policy and technology advancements. The inherent values that guide its development – community engagement, data collection across conditions, participant control of data, and a design that asks and answers the questions most critical to those participants – remain front and center today. We enable the best and most efficacious means to generate data and research opportunities from within a community.

For additional questions about Registry Bootcamp or the Promise for Engaging Everyone Responsibly:

Please contact us over email at bootcamp@geneticalliance.org.
<table>
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<tr>
<th>Week</th>
<th>Module Information</th>
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| **Week 1: Laying the Groundwork** | - Learn about the benefits of iterative planning  
- Define what you want to accomplish  
- Understand the importance of engagement  
- Consider values guiding engagement in your community  
- Identify key stakeholders for your community  
- Learn about different methods for stakeholder engagement  
- Review key considerations for successful collaboration with diverse stakeholders  
**Outcomes:** Identify registry goals and begin to develop your engagement plan |
| **Week 2: The Devil's in the Data** | - Understand different data types  
- Identify the data types needed to support your registry goals  
- Explore different types of data analysis  
- Learn about your responsibilities as they relate to data collection, data privacy, and relevant regulations (e.g., HIPAA, GDPR)  
- Continued work on engagement: begin to develop metrics for engagement in your community  
**Outcomes:** Identify needed data types for your registry and/or study. Continue developing engagement plan. |
| **Week 3: Pulling it All Together** | - Explore different business models for registries  
- Estimate registry and staffing costs  
- Learn about the importance of IRB review  
- Understand the elements of an IRB protocol  
- Introduction to platform assessment tools  
- Continued work on engagement: continue to develop metrics for engagement in your community  
**Outcomes:** Articulate a possible "five-year plan" for your registry, based on what you know about your community's needs so far. If you have not already
done so, begin estimating registry costs and assessing platform features. Continue work on engagement plan.

December 3rd, 2021 to December 9th, 2021

Week 4: Building for the Future
- Understand possible paths forward for your registry
  - Conducting natural history studies and/or clinical trials
  - Registry growth over time
- Revisit key considerations for successful collaboration with diverse stakeholders
- Explore additional strategies for activating your community and expanding your reach
- Begin developing your IRB protocol
- Continued work on engagement: continue to develop metrics for engagement in your community

Outcomes: Finish drafting your “five-year plan”. Finish any outstanding-activities, including revisiting your engagement plan. Begin working on IRB protocol elements.

Course Meetings

<table>
<thead>
<tr>
<th>Date</th>
<th>Activity</th>
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<tbody>
<tr>
<td>November 9, 2021 (10-11:30am PT / 1-2:30pm ET)</td>
<td>Kick-off meeting (required)</td>
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<tr>
<td>November 12, 2021 (11am-1pm PT / 2-4pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>November 16, 2021 (1-3pm PT / 4-6pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>November 19, 2021 (10am-12pm PT / 1-3pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>November 23, 2021 (10am-12pm PT / 1-3pm ET)</td>
<td>Midpoint check-ins (required)</td>
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All times are listed in PT and ET.
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<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>November 30, 2021 (1-3pm PT / 4-6pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>December 3, 2021 (10am-12pm PT / 1-3pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>December 7, 2021 (1-3p PT / 4-6pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>December 9, 2021 (9am-11am PT / 12-2pm ET)</td>
<td>Closing check-ins (required)</td>
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Additional office hours may be scheduled upon request.