Genetic Alliance Registry Bootcamp – Fall 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, training, and support necessary to plan and launch a registry and/or study.

Registry Bootcamp is appropriate for any organization or community group seeking to build a condition- 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, a number of the resources in Registry Bootcamp will bring value to those seeking to further develop an existing registry. The course is platform-agnostic and will not go into the specifics of launching a registry or study with Genetic Alliance’s PEER program, though we do offer an optional, PEER-specific module for those who choose to use PEER.

Participants in Registry Bootcamp will engage in peer-to-peer learning and receive educational materials and mentorship from Genetic Alliance staff, who bring with them their 25+ years of experience in registry development, and from our partners. At the culmination of the program participants will have all the background needed to launch a registry and/or study and will have begun much of the planning and design necessary for success. This is a month-long program (September 21, 2021 through October 19, 2021) which consists of four one-week modules (see syllabus at end of this document) and three live meetings (required; see syllabus for dates). Optional office hours with Genetic Alliance staff are also offered throughout the course. The course modules typically consist of 2-4 hours of video instruction and/or readings, 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 participants to dive deeper are also available. Communities who choose to use PEER have the option to add on the PEER-specific 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 Katherine Lambertson (klambertson@geneticalliance.org).
## Genetic Alliance Registry Bootcamp Syllabus – Fall 2021

### Course Modules

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<thead>
<tr>
<th>Week</th>
<th>Module Information</th>
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| **September 21, 2021 to September 27, 2021** | **Week 1: Laying the Groundwork**  
  - Define what you want to accomplish  
  - Learn about the importance of engagement  
  - Choose engagement strategies  
  - Begin to develop metrics for engagement in your community  
  - Explore key considerations for successful collaboration with diverse stakeholders  

**Outcomes:** Identify registry goals and begin to develop your engagement plan. |
| **September 28, 2021 to October 4, 2021** | **Week 2: The Devil’s in the Data**  
  - Understand different data types  
  - Identify the data types needed to support your registry goals  
  - Understand different types of data analysis  
  - Understand your responsibilities as they relate to data collection, HIPAA and GDPR  

**Outcomes:** Finish drafting engagement plan. Identify needed data types for your registry and/or study. |
| **October 5, 2021 to October 11, 2021** | **Week 3: Pulling it All Together**  
  - Learn about different business models for registries  
  - Estimate registry and staffing costs  
  - Learn about the benefits of iterative planning in registry development  
  - Learn about the importance of IRB review  
  - Begin planning for your IRB protocol submission  
  - Introduction to platform assessment tools  

**Outcomes:** Estimate registry costs if you have not already done so. Begin drafting key IRB protocol elements. Articulate a possible "five-year plan" for your registry, based on what you know about your community's needs so far. Begin assessing platforms if you have not already done so. |
| **October 12, 2021 to October 18, 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
- Additional strategies for activating your community and expanding your reach

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

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**Course Meetings**

*All times are listed in PT and ET.*

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<thead>
<tr>
<th>Date</th>
<th>Activity</th>
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<tbody>
<tr>
<td>September 21, 2021 (11am-12:30pm PT / 2-3:30pm ET)</td>
<td>Kick-off meeting (required)</td>
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<tr>
<td>September 24, 2021 (11am-1pm PT / 2-4pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>September 28, 2021 (1-3pm PT / 4-6pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>September 30, 2021 (11am-1pm PT / 2-4pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>October 5, 2021 (9am-11am PT / 12-2pm ET)</td>
<td>Midpoint check-ins (required)</td>
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<td>October 8, 2021 (11am-1pm PT / 2-4pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>October 12, 2021 (1-3pm PT / 4-6pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>October 14, 2021 (11am-1pm PT / 2-4pm ET)</td>
<td>Drop-in office hours (optional)</td>
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<tr>
<td>October 19, 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.