Implementing GeNomics In pracTicE II (IGNITE II): Pragmatic Clinical Trials

Pre-Application Informational Webinar

IGNITE Goals

- Conduct pragmatic clinical trials to measure the clinical utility and cost-effectiveness of genomic medicine interventions
- Assess approaches for real-world application of genomic medicine in diverse clinical settings
- Produce generalizable knowledge on the types of genomic medicine interventions requiring randomized clinical trials and effective methods for conducting them

IGNITE II Components

- 4-6 multi-site Clinical Groups (CGs) and Enhanced Diversity Clinical Groups (EDCGs)
- Coordinating Center
- 2-4 pragmatic clinical trials of genomic medicine interventions

Proposed Pragmatic Clinical Trial Protocols

- Should:
  - Be adaptable to wide range of settings, including resource-limited sites
  - Propose an intervention with preliminary evidence of improved health outcomes and cost effectiveness
  - Be able to be expanded network-wide
  - Be relevant to racial/ethnic minority participants and resource-limited sites
  - Address conditions of high public health impact
  - Be feasible to enroll patients within 12 months of initiation of the trial
  - Have the power to detect clinically meaningful differences within 12 months of randomization

Trials evaluating tumor sequencing will be considered non-responsive

Also, trials evaluating germline cancer susceptibility as a major component will be considered a low priority for NHGRI funding

Applicants are strongly encouraged to contact NHGRI to discuss their proposed trial and patient population well in advance of the submission date

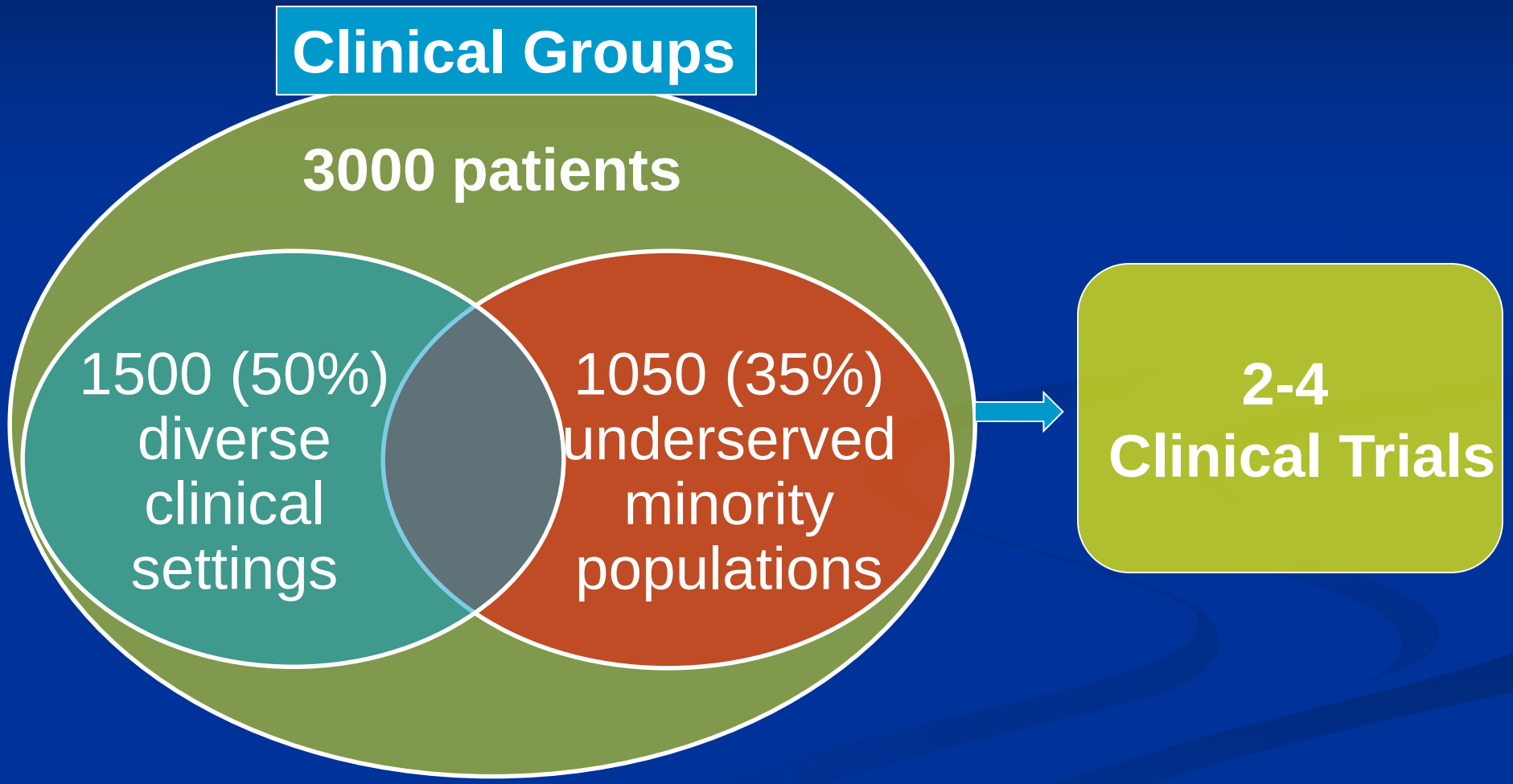
IGNITE II – CG RFA

- Demonstrated ability to implement agreed upon genomic medicine protocols and potential ELSI research study
- Evidence of institutional support and success in participant recruitment and retention
- Genomic testing in a CLIA-certified environment
- Plan for integrating genomic results and harmonizing CDS into patients' EHRs
- Ability to enroll at least 3,000 patients
- At least 50% of patients should be recruited from diverse clinical settings
- At least 35% of patients from racial and ethnic minority populations

IGNITE II – EDCG RFA

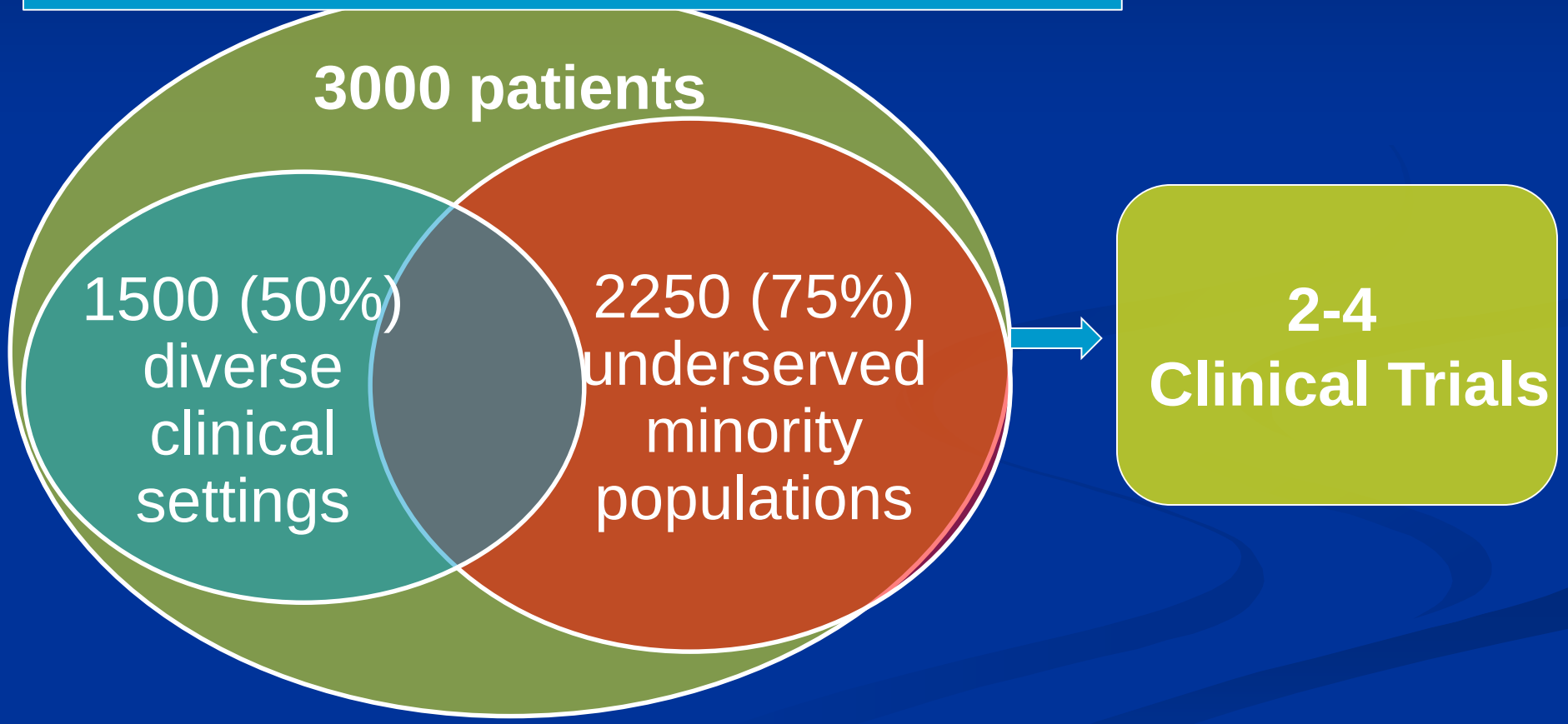
- Demonstrated ability to implement agreed upon genomic medicine protocols and potential ELSI research study
- Evidence of institutional support and success in participant recruitment and retention
- Genomic testing in a CLIA-certified environment
- Plan for integrating genomic results and harmonizing CDS into patients' EHRs
- Ability to enroll at least 3,000 patients
- At least 50% of patients should be recruited from diverse clinical settings
- At least 75% of patients from racial and ethnic minority populations

Patient Enrollment
RFA-HG-17-008

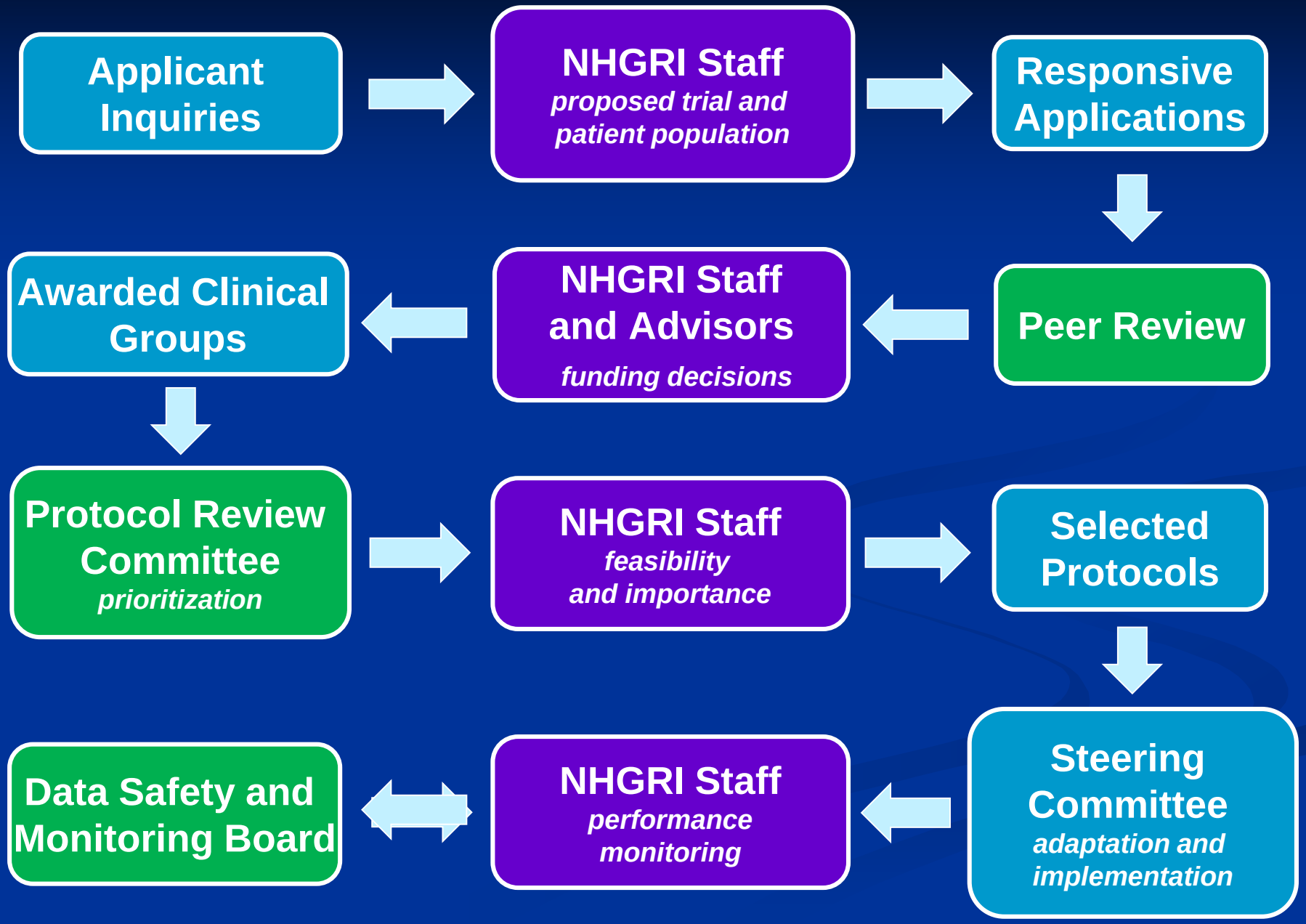


Patient Enrollment
RFA-HG-17-009

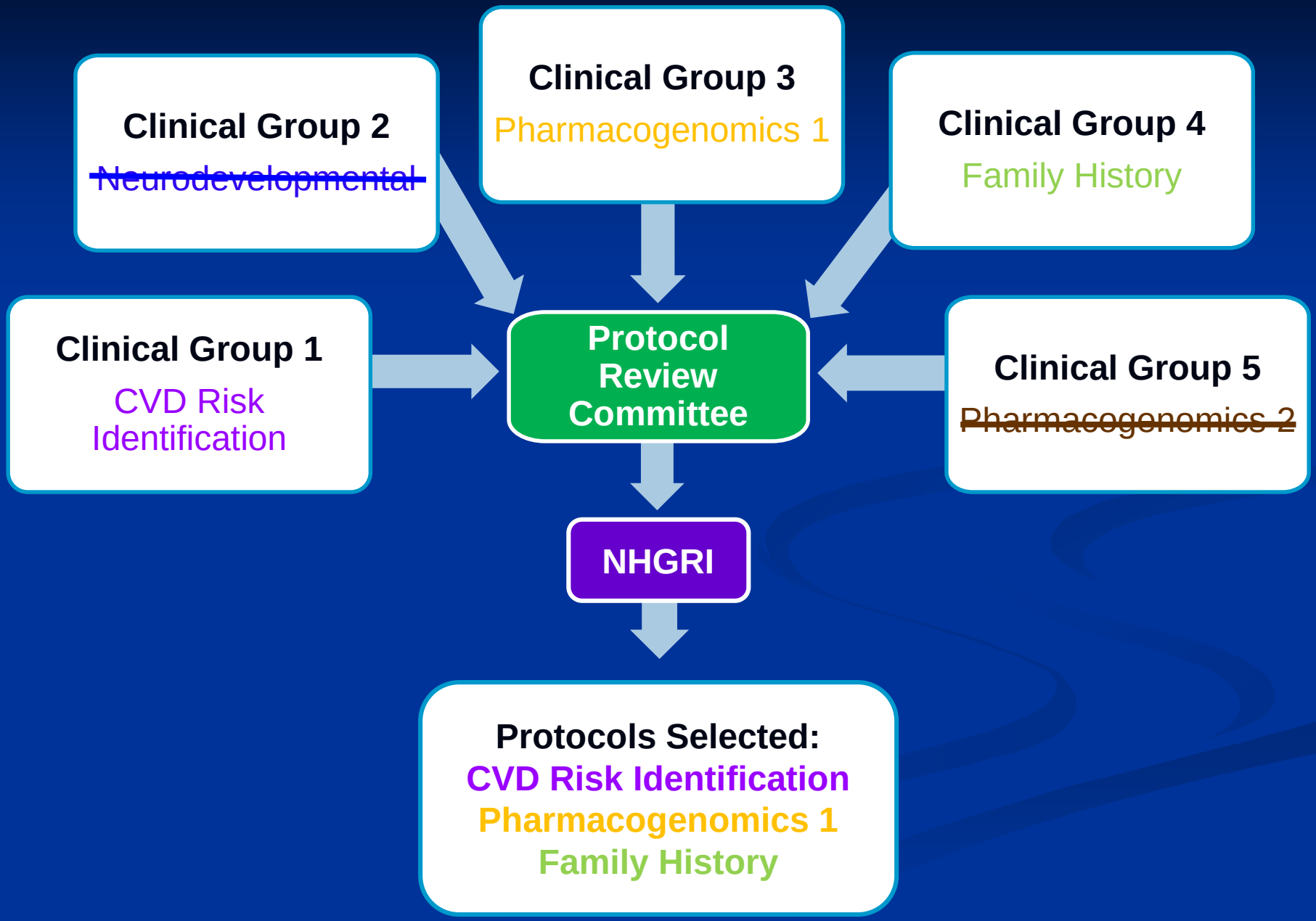
Enhanced Diversity Clinical Groups



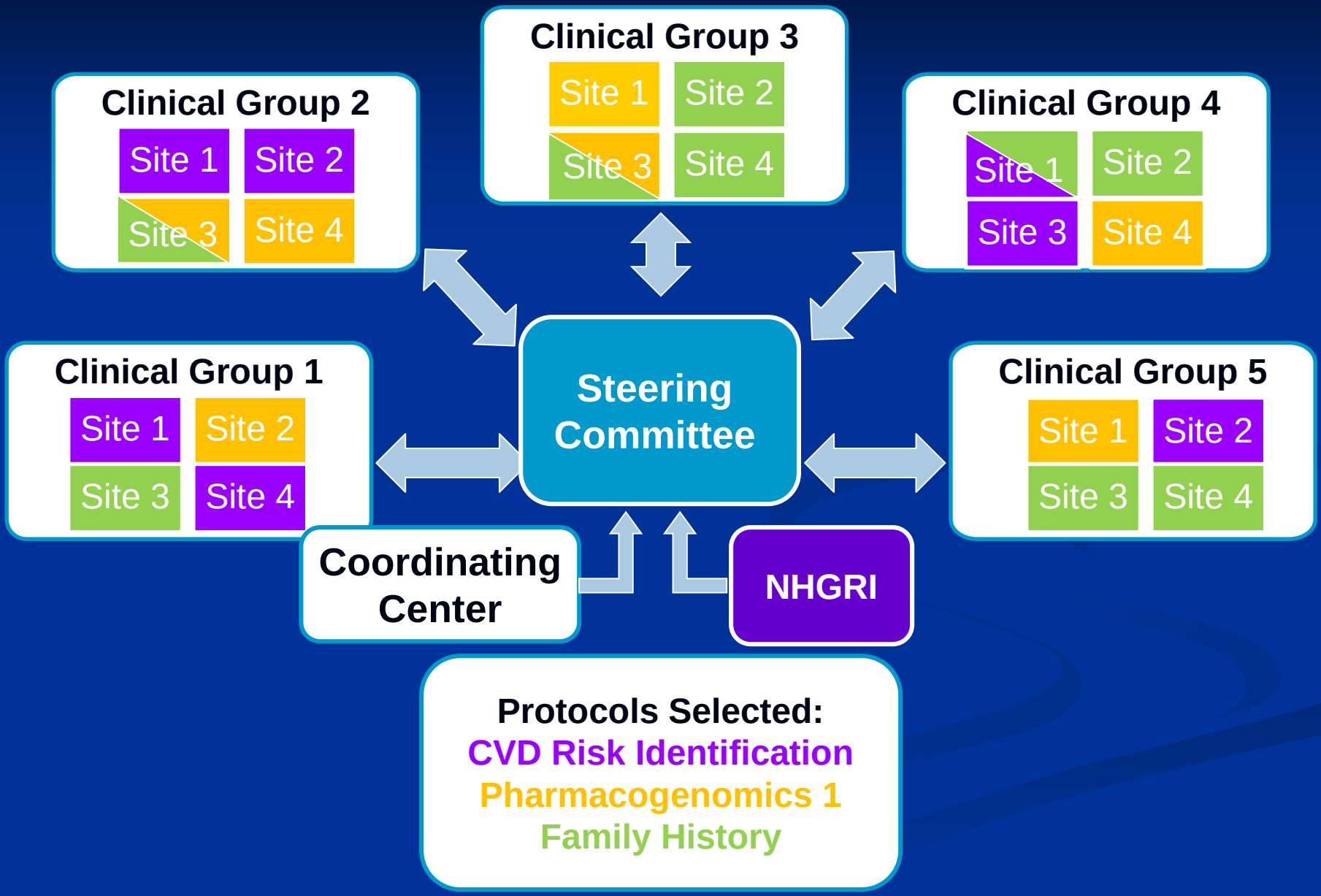
Protocol Selection and Monitoring



Protocol Prioritization



Protocol Adaptation



ELSI Research

- IGNITE II may include a single ELSI research study implemented across all funded IGNITE clinical groups
- The ELSI research study will be funded separately through a supplement
- The ELSI research study will be collaboratively developed by the CGs after award and should **not** be proposed in the current application
- Applicants should describe strengths of their research team, including experience conducting ELSI research
- The CC will facilitate the ELSI study

Coordinating Center

- Participate in the planning and development of the network infrastructure and committee structure
- Participate in adaptation of protocols
- Develop manual of operations and reporting forms
- Receive and disseminate recruitment and other monitoring reports
- Receive data from CG sites for data analysis
- Lead network-wide protocol adaptation, execution, and analyses, development and statistical modeling, and final analysis of primary and secondary network-wide clinical trial outcomes in collaboration with the CGs
- Help in preparation and writing of reports and manuscripts for publication

Open Competition

- IGNITE I grantees should describe their performance and collaboration in the IGNITE I Network as well as experience and capabilities in pragmatic clinical trials
- New applicants to IGNITE should describe experience and capabilities in working in multi-site research networks, genomic medicine implementation, and pragmatic clinical trials

IGNITE II Timeline

- If you haven't already done so – Contact us to discuss your proposed trial and patient population
- October 3rd – Letter of Intent due date
- November 3rd – Application due date
- February/March 2018 – Scientific Merit Review
- May 2018 – Advisory Council Review
- Mid-to-late summer 2018 – IGNITE II grants funded

Overview of Budget

Questions

Frequently Asked Questions

https://www.genome.gov/27569241/

Questions about the Peer Review Process

Additional Questions