Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes

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Board of Scientific Advisors

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Blue Ribbon Panel Recommendation:
Cancer Prevention and Early Detection in Individuals at High Risk for Cancer

Recommendation:

- Sponsor initiatives to improve the current state of genetic counseling and testing, prevention, early detection, and knowledge landscape for those with an inherited predisposition.

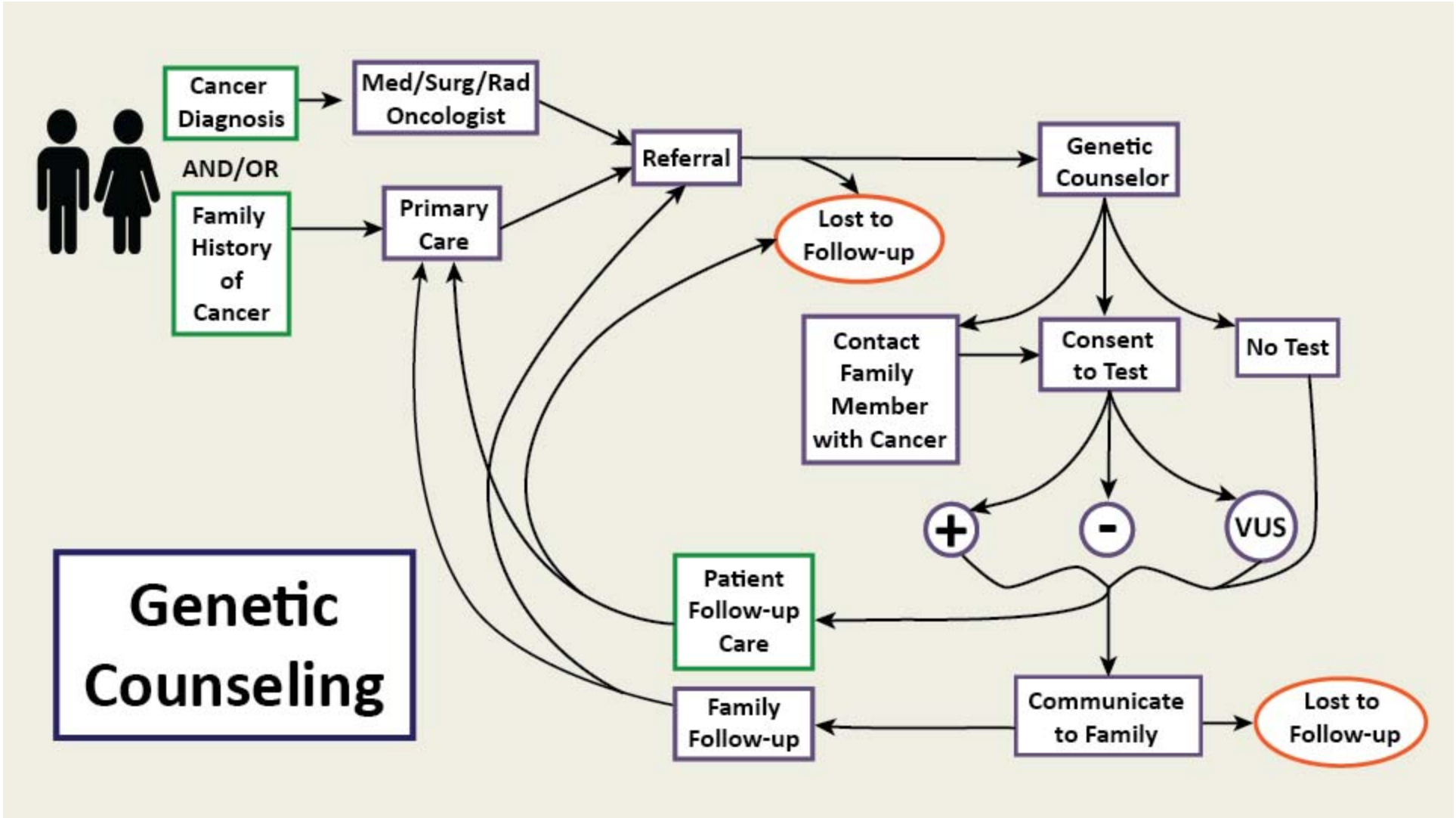
Goals:

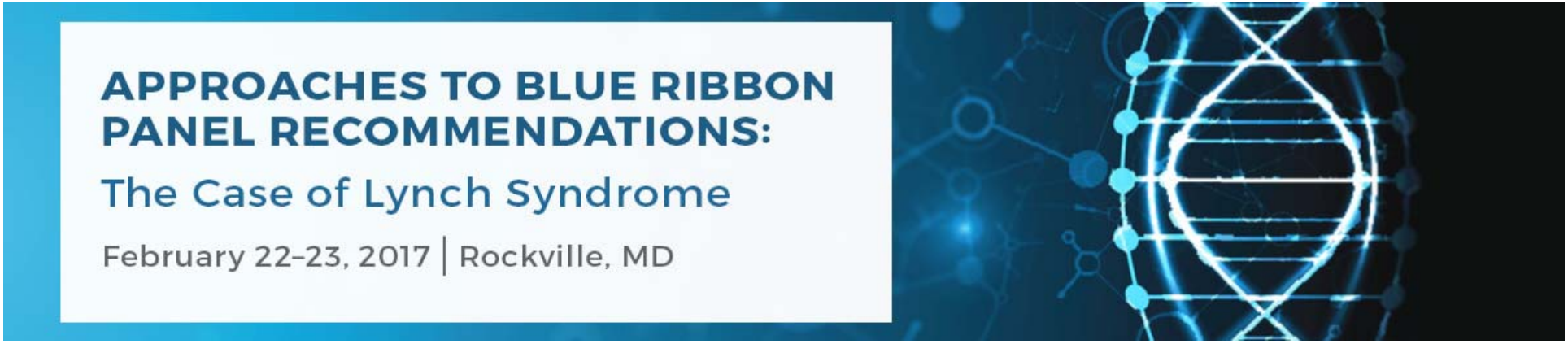
- Increase case ascertainment for proband and at-risk relatives
- Improve the delivery of evidence-based services
  - Genetic counseling
  - Preventive & early detection services
  - On-going surveillance

Blue Ribbon Panel Recommendation:
Cancer Prevention and Early Detection in Individuals at High Risk for Cancer

Background:

- Inherited susceptibility to cancer ~ 10% of all cancers
- Under-utilization of cancer genetic counseling & testing
- Cancers associated with multiple genetic syndromes
- Increasing complexity of genetic testing over the past 2 decades
  - From single gene to multi-gene panel tests and tumor sequencing


Cancer Diagnosis
Med/Surg/Rad Oncologist
AND/OR
Family History of Cancer
Primary Care
Referral
Lost to Follow-up
Genetic Counselor
Contact Family Member with Cancer
Consent to Test
No Test
+
-
VUS
Genetic Counseling
Patient Follow-up Care
Family Follow-up
Communicate to Family
Lost to Follow-up



Workshop Take-Away Messages

- Requirements:
  - Broad-based screening approach for hereditary cancers
  - Multiple paths for ascertainment
  - Sustainable care delivery processes (ascertainment & follow-up care)
  - Multiple approaches required to meet the needs for variety of healthcare settings and diverse populations
- Lynch Syndrome demonstration projects conducted
  - Statewide program (Ohio)
  - Integrative health care systems (Kaiser, Geisinger)
- Gaps noted: follow-up care, sustainability, and implementation in diverse health care settings, real-world approaches

RFA: Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes

AIMS:

1. Develop and test strategies to increase case ascertainment of hereditary cancers through different approaches.
2. Develop and adopt evidence-based health care delivery models for cancer prevention and detection, cascade testing of relatives and follow-up care.
3. Test sustainable strategies to improve implementation across diverse health care settings and populations.
4. Identify demonstration metrics for successful and sustainable ascertainment, consultation and interpretation of genetic testing.

RFA: Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes

- **Research Interests – Including but not limited to:**
  - Variety of health care delivery settings
  - Address spectrum of hereditary cancer syndromes
  - Focus on continuum of care – determine best strategies for coordinated and sustainable care from ascertainment through follow-up
  - Outreach to diverse communities – racial/ethnic minorities, low socioeconomic communities, rural, etc.
  - Examine behavioral/psychological impact on patients and families
  - Care transitions

RFA: Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes

- **Solicits multi-PI U01 application**
  - Requires multidisciplinary expertise to cover the multifaceted challenges of care coordination in this patient population.
  - NCI expertise across inherited cancer syndromes, genomics, health care delivery and consortia will facilitate work across studies.
- **Funded investigators will meet annually**
  - Share study implementation challenges/successes and findings
- **Required data sharing with existing NIH resources**
- **Requested funding**
  - $4M per year (total $20M) to fund up to 4 applications

RFA Evaluation Criteria

- Data sharing across the funded sites and more broadly to the general research community as measured by enhancement of existing data repositories
- Evidence of research productivity and impact
- Increase in implementation science applications addressing the totality of clinical care
- Evidence of increased and sustained clinically justified referrals to genetic counseling and outreach to a diverse patient population

Portfolio Analysis

NCI-wide portfolio analysis focused on case ascertainment in hereditary cancers and syndromes and health care delivery

1R01CA197784 Comparison of 3 Modes of Genetic Counseling in High-Risk Public Hospital Patient	**U01HG007282 (co-funded) Implementation, Adoption, and Utility of Family History in Diverse Care Settings**
▪ Study the integration of a clinic-based tool into the electronic health record ▪ Hereditary Breast and Ovarian ▪ Goal: improve accuracy of risk perception, facilitate referrals for specialized risk counseling, and increase chemoprevention uptake in patients at risk for breast cancer	▪ Study the integration of patient-driven and electronic collection of family health history for risk stratification ▪ Heart disease and selected cancers ▪ Goal: promote informed decision making by patients and providers in diverse care settings and improve adherence to risk-stratified preventive care guidelines

Summary

- **Blue Ribbon Panel Recommendation and Workshop**
  - Improve the current state of genetic counseling and testing
  - Emphasized sustainability and follow-up care for high-risk individuals in a variety of care settings
- **RFA**
  - Aims to test and disseminate methods to improve ascertainment and delivery of evidence-based services for those with hereditary cancer syndromes
  - Encourages the development of sustainable approaches in diverse care settings and populations

Investment will support scalable approaches for a variety of practice settings

BSA Subcommittee Recommendations

- **Research emphasis**
  - Emphasize the broad approach to inherited syndromes
  - Transition points in care in vulnerable periods (e.g. peds to adults)
  - Human behavior component: Include investigations of impact of counseling and testing on patient and family and how responses may differ across populations
- **Mechanism**
  - Consider stagger RFA release with 1-2 grants funded in Year 1 and remainder in Year 2
  - Budget

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