HMO Cancer Research Network (CRN) Research Resource Concept

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NCI Board of Scientific Advisors

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Presentation Outline

- Need for National Research Resource

- Unique Qualities of CRN to Serve as National Resource

- Proposed Areas of Scientific Excellence

- Components of New RFA / Budget

- Metrics of Success
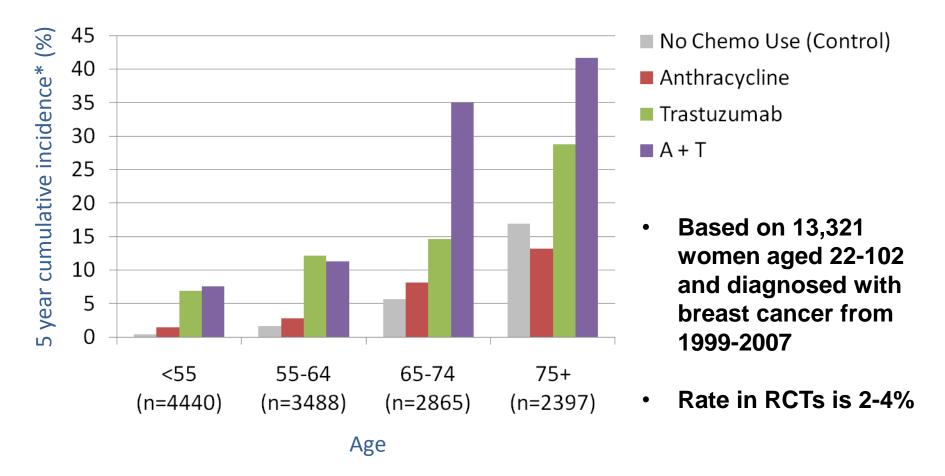
- Other NIH HMORN initiatives

Need for National Research Resource within Health Care Delivery Systems

- Rapid expansion in complexity and cost of cancer diagnostic technologies and treatment
  - Lack of research on the interactions among treatments or outcomes of expanded diagnosis
- No other initiative can support diverse multilevel research designs to examine these issues within context of clinical care

- Innovations in EMRs and patient portals have changed landscape of research within the context of care delivery

CRN: Unique Strengths and Opportunities

- Size, scope, and network of research quality data from EHR/VDW
  - Millions of patients with longitudinal clinical care data

- Capacity to evaluate natural experiments that influence cancer care and determine if results from research in controlled settings lead to same outcomes in clinical practice
  - E.g.: Post-market evaluation of drug outcomes or extent of variation in care for recommended therapies

- Provides unique platform for conduct CER as drugs and diagnostic procedures multiple and evolve

  - E.g. Examine drug interactions in complex patients treated with multiple drugs, clinical trials focused on practice questions, and longitudinal studies on health outcomes

- Enables research on how to best provide high quality, targeted care while reducing inefficiencies and cost

Chemotherapy Induced Heart Failure is High in Clinical Practice Compared to RCTs

- **Based on 13,321 women aged 22-102 and diagnosed with breast cancer from 1999-2007**

- **Rate in RCTs is 2-4%**

*Adjusted for: health plan, age, Charlson score, summary stage, year of diagnosis, radiation treatment

Bowles EA et al. In preparation for publication

Radiation Exposure has Increased Dramatically: Data from 5 CRN HMOs

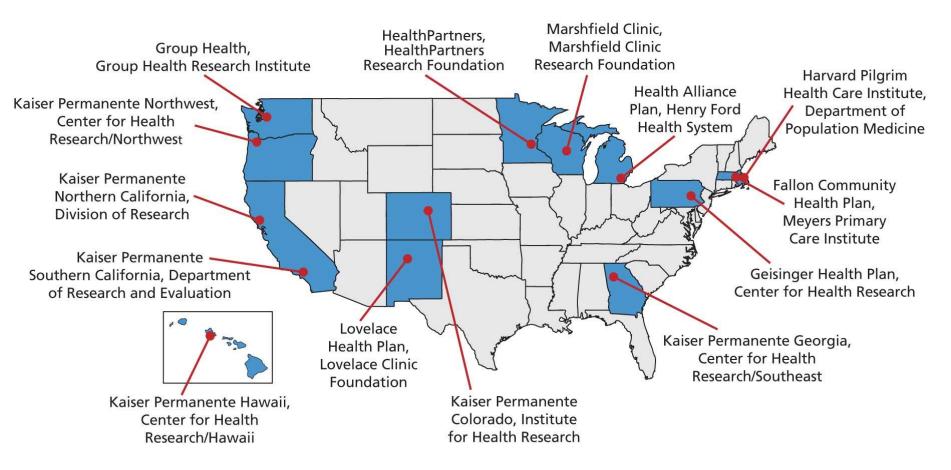

Mean Annual Effective Dose and Dose Incured by the Highest 1% and and 10% of Patients

For each patient in each year, radiation from all imaging examinations was summed

Smith-Bindman R et al. In preparation for publication

Cancer Research Network Sites

Group Health, Group Health Research Institute

Kaiser Permanente Northwest, Center for Health Research/Northwest

Kaiser Permanente Northern California, Division of Research

Kaiser Permanente Southern California, Department of Research and Evaluation

HealthPartners, HealthPartners Research Foundation

Marshfield Clinic, Marshfield Clinic Research Foundation

Health Alliance Plan, Henry Ford Health System

Harvard Pilgrim Health Care Institute, Department of Population Medicine

Fallon Community Health Plan, Meyers Primary Care Institute

Geisinger Health Plan, Center for Health Research

Kaiser Permanente Georgia, Center for Health Research/Southeast

Lovelace Health Plan, Lovelace Clinic Foundation

Kaiser Permanente Colorado, Institute for Health Research
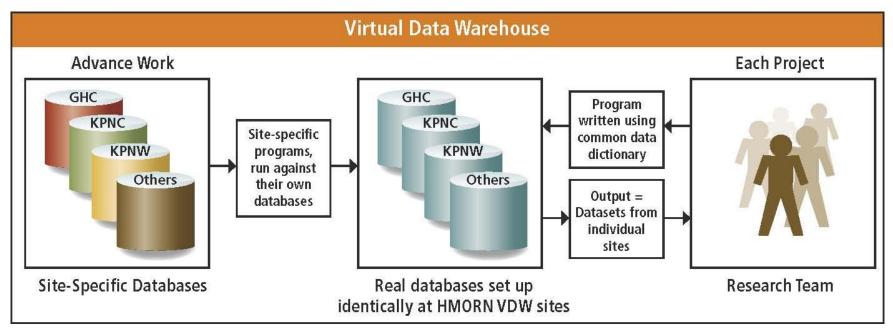
Kaiser Permanente Hawaii, Center for Health Research/Hawaii

CRN consists of 14 research centers (U19), affiliated with HMOs that provide care for 11 million individuals

Nature of CRN Data

- Patient-specific clinical care data documented in context of regular practice are transformed into standardized, high quality data that can be used for cancer research

- Retention rate for cancer survivors is nearly 85% at five years post-diagnosis

- Longitudinal clinical care data are unique to the CRN

- CRN is well suited for studies of cancer quality of care, survivorship, and long-term outcomes

- Can address issues in patients with rare cancer or complex medical conditions that cannot be well studied with existing clinical trial systems
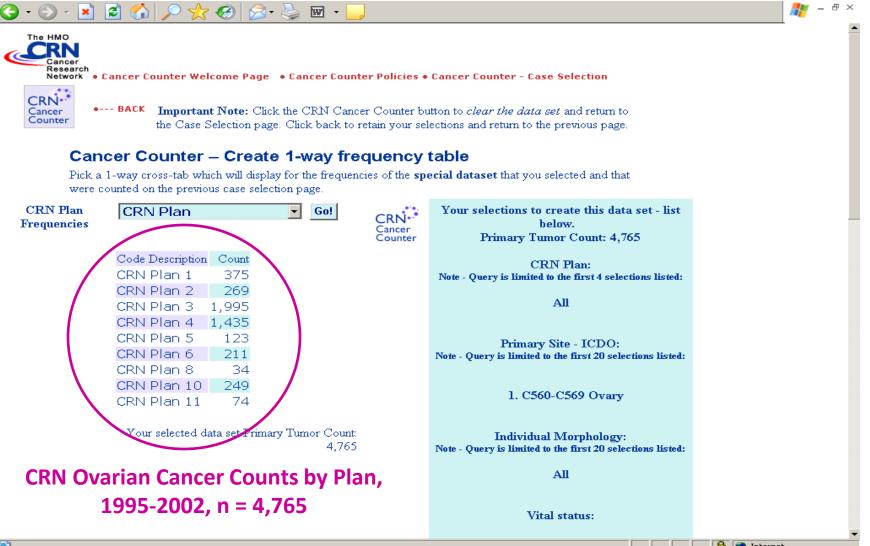
Virtual Data Warehouse (VDW)

The VDW is populated by automated data from the following sources:

- ~11,000,000 total enrollees
- ~100,000 incident cancers/year
- ~69,000,000 Rx fills/year
- 505 clinic sites
- 8 affiliations with cancer centers

- Tumor registry
- Enrollment
- Demographics
- Geocoding
- Utilization

- Laboratory
- Pharmacy
- Chemotherapy
- Radiology
- Pathology

Cancer Counter Enables Rapid Assessment of Power for Specific Research Questions
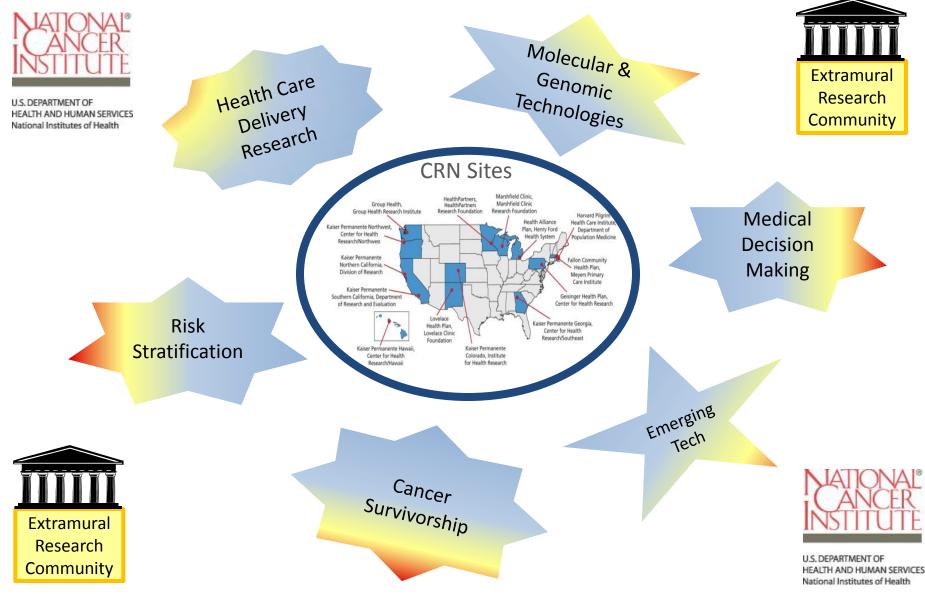

CRN Ovarian Cancer Counts by Plan, 1995-2002, n = 4,765

Recommendations from External Evaluation

D. Ransohoff, K. Kerlikowske, D. Schrag, T. Tosteson

"CRN provides unique data and has capacity to serve as a national resource that should be preserved and strengthened"

- Support infrastructure and collaboration rather than specific scientific projects

- Develop and maximize mechanisms and interfaces to facilitate collaboration of external researchers with CRN

- Formulate strongest scientific questions by cultivating expertise from CRN and external investigators

- Develop governance structure to target areas of scientific excellence

Key Areas of Scientific Excellence
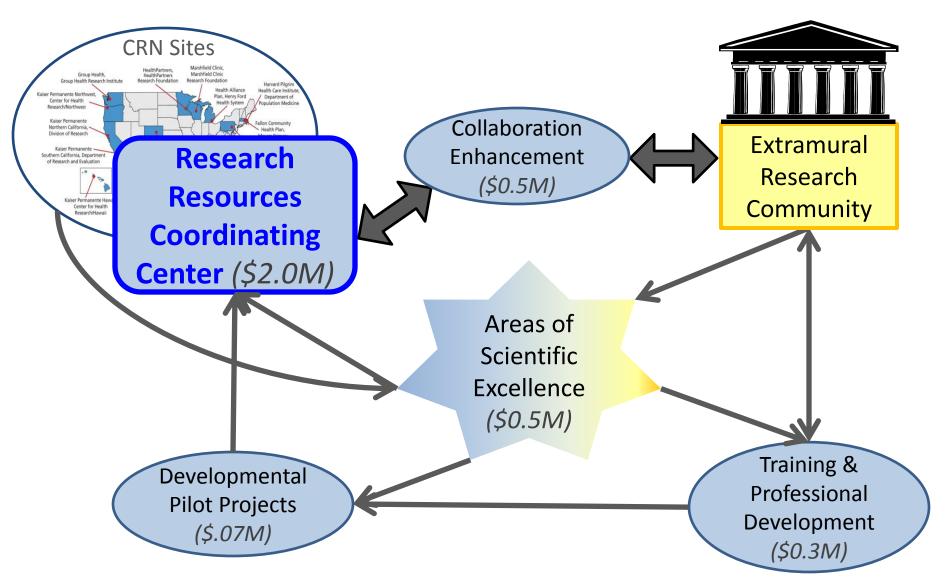
Key Areas of Scientific Excellence

- Use of **molecular and genomic technologies** in community practice
  - Which patient groups experience improved outcomes from treated tailored on clinical characteristics and molecular ? (i.e. Do colorectal cancer patients receive KRAS /BRAF testing, and does it alter care and improve outcomes?)

- **Health care delivery research**, including multi-level systems and comparative effectiveness research of cancer services
  - Can EMR-based outreach be combined with pharmacy data to identify women non-adherent to adjuvant hormonal treatment (i.e., tamoxifen, raloxifene) and interventions be developed to improve treatment adherence and outcomes?
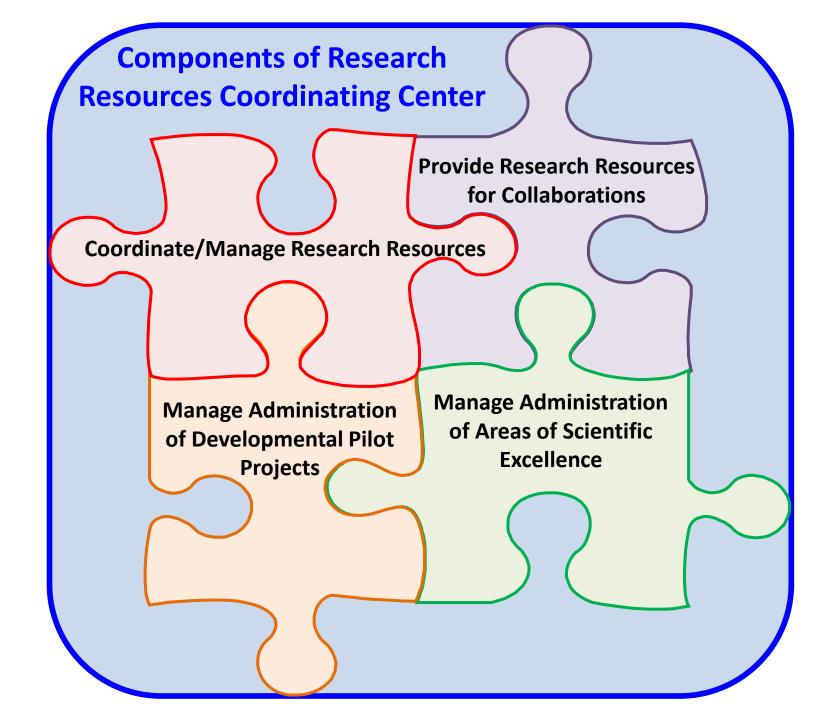
Key Areas of Scientific Excellence

- Quantification of **risk stratification** though large-scale epidemiologic studies that utilize data on molecular, biologic, behavioral, lifestyle, pharmacologic, radiologic, and other risk (and protective) factors

  – What is the long-term cancer risk/benefit associated with common drugs, such as NSAIDS or statins, or cumulative radiation exposure from common imaging studies?

- Increased understanding of **medical decision making**, and development / evaluation of tools to enhance physician-patient cancer communication and improve care quality

  – Can physician and patient web portals, informed by data from EMRs, improve continuity of care for cancer patients to enhance treatment decision making and increase adherence to guideline-consistent care?

Key Areas of Scientific Excellence

- **Cancer survivorship**, including long-term consequences of cancer treatment, surveillance, supportive care, care coordination, recurrence, quality of life, and family burden
  - Which breast cancer patients treated with anthracyclines and/or trastuzumab are at greater risk of cardiotoxicity than similar patients treated with no chemotherapy?

- Validation, dissemination, and implementation research on **emerging technologies** including risk prediction, diagnostic and prognostic, and informatics / communications technologies
  - Is it possible to determine clinical and molecular markers that reliably predict low risk of breast cancer recurrence in women diagnosed with ductal carcinoma in situ?

National Cancer Institute

Components of New Research Resource RFA

CRN Sites

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Research Resources Coordinating Center *($2.0M)*

Collaboration Enhancement *($0.5M)*

Extramural Research Community

Areas of Scientific Excellence *($0.5M)*

Developmental Pilot Projects *($.07M)*

Training & Professional Development *($0.3M)*

Total budget = $4.0M per year for 5 years

Components of Research Resources Coordinating Center

Coordinate/Manage Research Resources

Provide Research Resources for Collaborations

Manage Administration of Developmental Pilot Projects

Manage Administration of Areas of Scientific Excellence
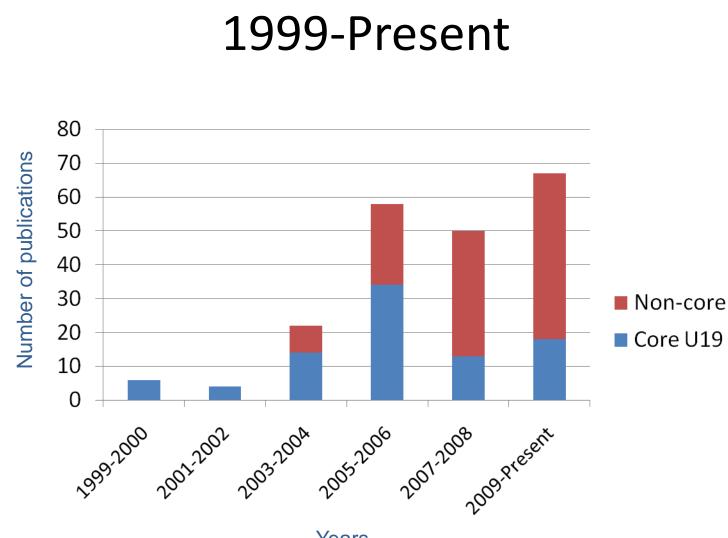
CRN Has Demonstrated Capacity to Serve as a National Resource

- Increased use of the HMORN for national research
  - Recognized by AHRQ, FDA, NIH OD, and other NIH institutes

- Successful competition for competitive funding
  - Increase in number of funded grants using CRN as a resource since 2006
  - 50% of these collaborative grants awarded to PIs outside the CRN

- Growth in rate of scientific publications
  - At least 210 publications in peer-reviewed scientific journals; over 100 published in last 4 years

- Professional development of junior investigators
  - Over 40 investigators have interfaced with the CRN in their training; CRN Scholars Program was implemented in 2007

Growth in Funded* Research Projects Using the CRN, 1999-Present

*Includes NCI-funded grants and contracts as well as projects funded by AHRQ, CDC, DoD, ACS, IOM, and NHGRI that used the CRN; http://crn.cancer.gov/projects/projects.php

Growth in CRN Publication Rate, 1999-Present

What Will Be Lost if CRN U24 RFA is Not Funded?

- Cancer-directed resource within community practice for CER and other PCORI-related research

- Potential for rapidly evaluating the effects of new cancer discoveries within clinical practice

- Further enhancement and development of VDW with data elements in cancer domains
  - Examples: chemotherapy agents; radiation; prognostic biomarkers; biospecimen linkage; recurrence; adverse events; screening; risk factors; co-morbidities

- Proactive facilitation of ongoing engagement with Cancer Centers and cooperative groups

- Engagement of external researchers in developing cancer specific areas of scientific excellence and related collaborative research

Issues Addressed with Change to U24

- Develop focused and limited set of areas of scientific excellence with membership from CRN sites that can contribute substantively . Incorporate extramural researchers as key members of these teams.
  - **Issue: Lack of focused scientific agenda, especially in cancer treatment related research**

- Mandate specific performance criteria in RFA that will be evaluated annually; failure to meet requirements will result in improvement plans, adjustments to funding, and other relevant actions.
  - **Issue: Variable capacity across sites to engage in meaningful research**

- Formalize relationships between CRN oncologists, other CRN researchers, and NCI cooperative groups; enhance existing relationships between CRN sites and cancer centers; increase visibility of CRN to the entire extramural research community
  - **Issue: Limited targeted engagement of external investigators with expertise in cancer**

Issues Addressed with Change to U24

- Provide dedicated resources to "navigate" inception and development of new collaborative research projects with external collaborators.
  - **Issue: Less than optimal process for conceptualizing and implementing collaborative research projects**

- Engage more cancer expertise and more closely monitor CRN site and project performance. Based on maturation of infrastructure, increased recent grant funding, and engagement of more clinical experts, the increase in research publications is expected to continue and improve further.
  - **Issue: Less than optimal utilization of the CRN resource in terms of timely scientific publication and dissemination of research results into practice and policy**

More Rapid Engagement of Extramural Investigators

- Trans-NCI Program Announcement
  - Approach for highlighting unique areas of scientific excellence and key questions within those areas

- Competitive funding mechanism
  - Could bring specialized expertise and technical resources into collaboration with CRN
  - Enhance more timely and efficient examination of selected research priorities
  - Supplement existing NCI initiatives, such as cancer centers, cooperative groups and other grant mechanisms

Metrics of Success

- Use of CRN as a "real world" population test-bed for cancer care innovations

- Research capacity
  - Durable, robust, validated resource that can be re-used for multiple projects across multiple domains
  - Ability to rapidly establish retrospective cohorts and prospective accrual to multi-level intervention studies or pragmatic trials

- Success in developing focused scientific areas of excellence

- Increased scientific research productivity (e.g. grant funded research projects) with outcomes disseminated into practice

- Others: Collaborative success; Develop future research leaders

Other NIH HMORN Initiatives

- HMO Research Network Collaboratory (NIH Common Fund)
  - Will not address diseases covered by other larger NIH ICs (cancer, heart disease)
  - Designed to address research questions for less common diseases (smaller NIH institutes) or research needs common to many diseases

- Larger disease specific IC efforts are continuing
  - Cardiovascular Research Network (NHLBI)
  - Mental Health Data Resource (NIMH)

- Synergy and coordination with NCI initiatives and other initiatives across HHS

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