

ADVANCING CANCER RESEARCH THROUGH A VIRTUAL POOLED REGISTRY

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THE OPPORTUNITY

- ▶ Cancer epidemiology cohort studies may have participants living in all U.S. states
- ▶ Determining cancer occurrence through linkages with all population-based cancer registries has never been accomplished
- ▶ Can we solve this with a Virtual Pooled Registry?

WHAT DOES A VIRTUAL POOLED REGISTRY DO?

- ▶ Capacity to readily and efficiently link with central cancer registries to
 - Identify cancer patients
 - Identify cancer outcomes
- ▶ Through a process that can be performed
 - Repeatedly over time
 - Identifies which registries have matches to reduce the work required when there is no match

BENEFICIARIES OF VIRTUAL POOLED REGISTRY

- ▶ Many Federal and non-Federal entities require long term follow up of individuals to
 - Identify new cancer cases
 - Determine survival and cause of death
- ▶ Key audiences for a Virtual Pooled Registry
 - The Surveillance Community (cancer registries)
 - Cohort studies
 - Clinical trials groups
 - FDA and pharmaceutical companies

VALUE OF A VIRTUAL POOLED REGISTRY

- ▶ Potential efficiencies of such a centralized process would likely
 - Reduce cost of follow up
 - Provide more complete and accurate data
 - Reduce the lengthy time required for such efforts

OPPORTUNITIES FOR COST/ TIME SAVINGS WITH VPR: SURVEILLANCE COMMUNITY

▶ Early

- De-duplication of cases
- Enhance follow up information

▶ Later

- Provide for more detailed & complete treatment information for patients treated in more than one state
- As we move to capture recurrence and disease progression data sharing would provide another source to identify this outcome.

OPPORTUNITIES FOR COST AND TIME SAVINGS WITH VPR: COHORT STUDIES

- ▶ NCI and others spend large \$\$\$ to
 - support follow-up for cancer cohorts
 - to identify cancer cases among existing cohorts
- ▶ VPR would
 - simultaneously increase accuracy and completeness of information
 - markedly reduce costs
 - markedly reduce time and effort.

CANCER SURVEILLANCE SYSTEMS OFFER EXCELLENT PLATFORM FOR MULTI-STATE STUDIES

- ▶ Increase statistical power
- ▶ Support study of rare exposures
- ▶ Support study of rare cancers
- ▶ Improve representativeness
- ▶ Expand geographical coverage

PROBLEM: LINKAGE STUDIES REQUIRE PATIENT IDENTIFIERS

- ▶ Research conducted in multiple states require as many as 50 separate approvals and linkages!

SO WHAT IS “VIRTUAL” ABOUT IT?

- ▶ Goal is to create capacity similar to National Death Index but without aggregating patient data
 - One research application process
 - One research file submission
 - One standardized linkage process occurring simultaneously at multiple registries
 - **Registry data remains behind separate security firewalls at each participating registry**
 - **Registry data release controlled by registry**

Childhood Cancer Survivor Study

Resource for Research

Greg Armstrong, MD, MSCE
Principal Investigator
Childhood Cancer Survivor Study (CCSS)

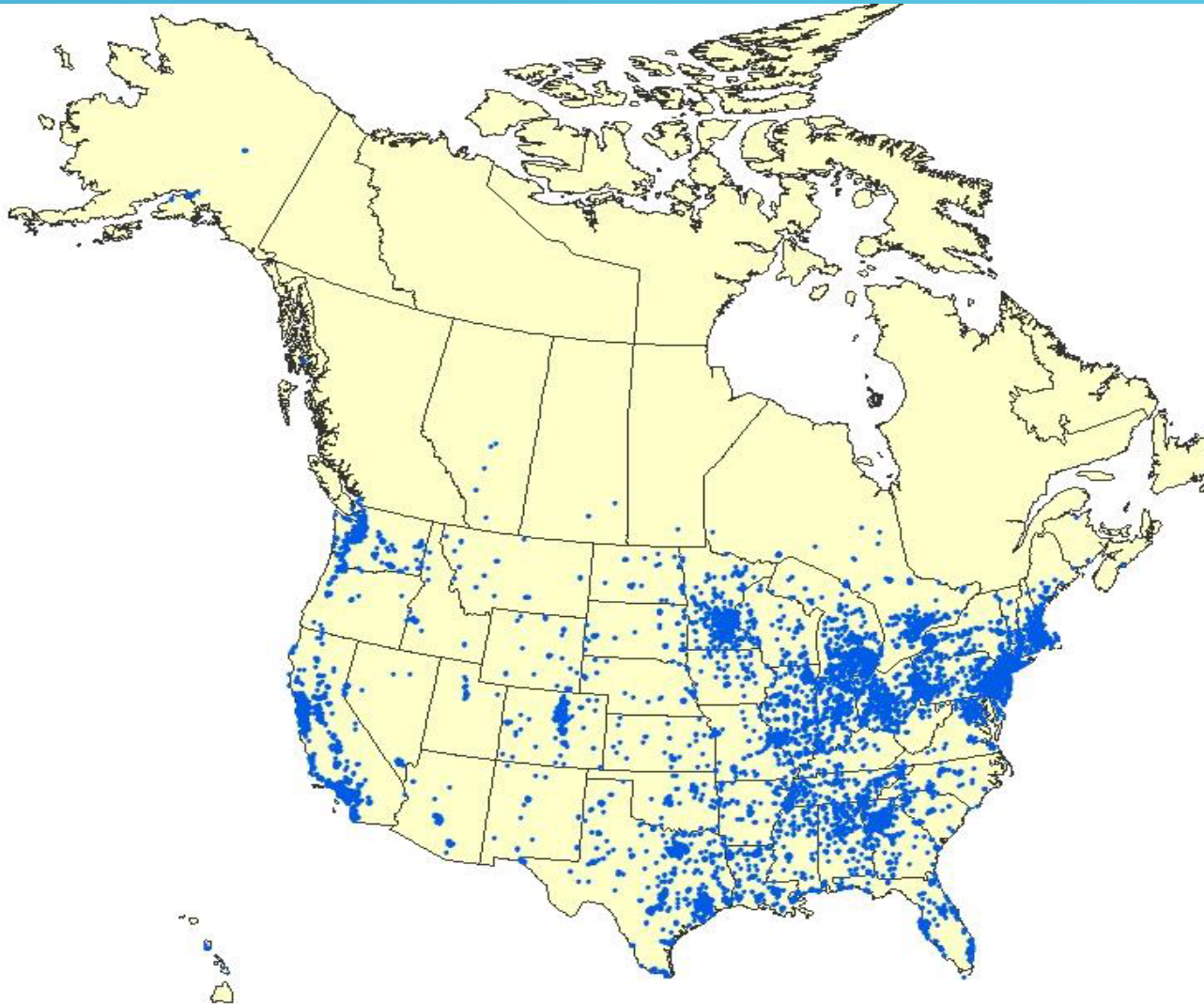


Department of Epidemiology and Cancer Control

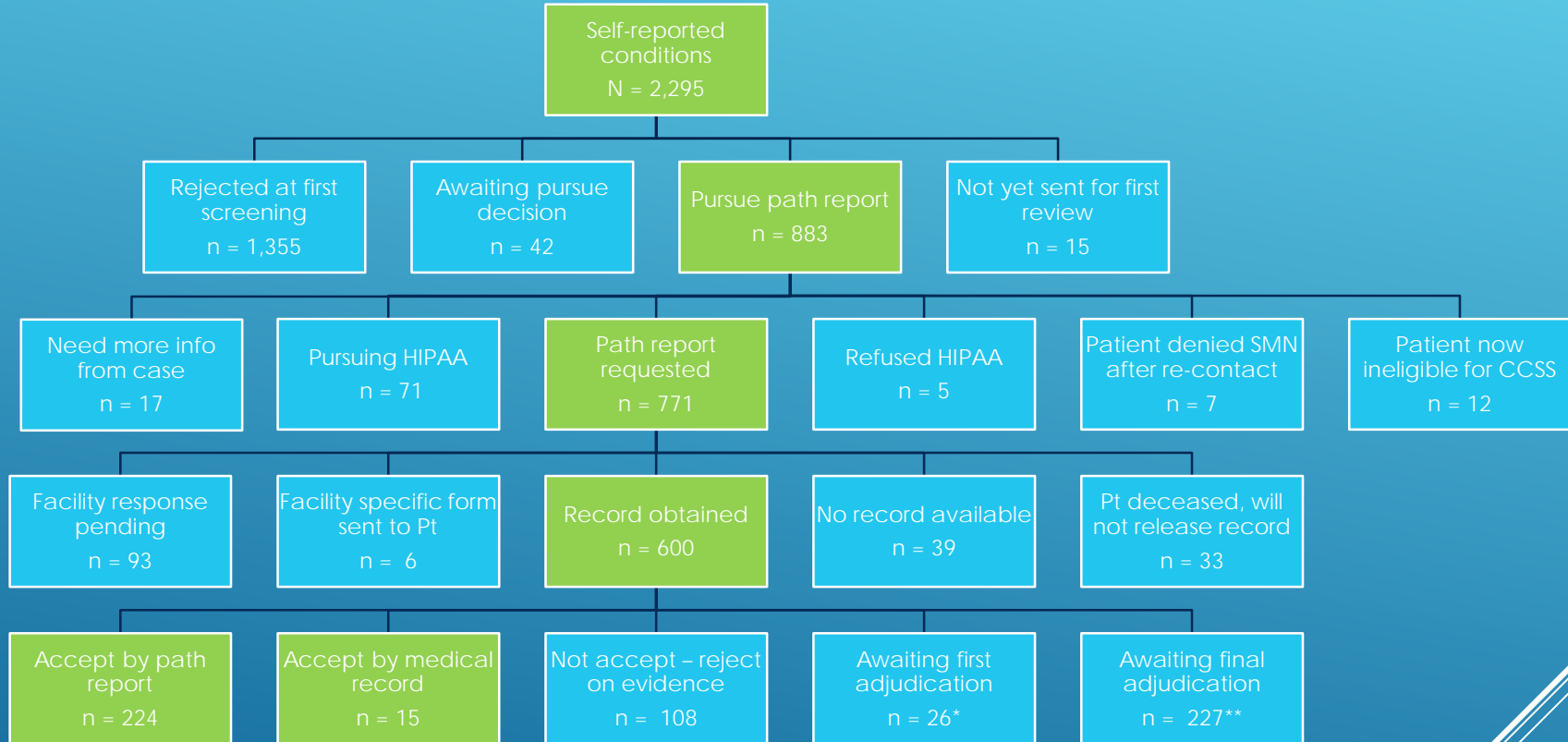
GOALS

Nation's leading study of late effects/survivorship among childhood cancer survivors

Childhood Cancer Survivor Study (U24 CA 55727) Study Participants



Process for Confirming 2nd Primaries



QUESTION (IF POSSIBLE, JUST ONE RESPONSE PER REGISTRY):

Has your registry ever performed a record linkage for an external research study?

1. YES, once
2. Yes, a few times
3. Yes, many times
4. No, haven't been asked
5. No, it is not permitted

VIRTUAL POOLED REGISTRY

- ▶ Modeled after elements of the Cancer Research Network
- ▶ NCI-funded consortium of providers to develop standardized methods for studies of cancer:
 - prevention
 - early detection
 - treatment
 - survivorship
 - surveillance
 - end of life care

CANCER RESEARCH NETWORK (CRN) MODEL



CRN CANCER RESEARCH NETWORK

- ▶ **The Virtual Data Warehouse (VDW)**
 - HMO patient data (including living patients)
 - **patient data stored behind separate security firewalls at each participating CRN site**
 - standardized linkage datasets
 - supported by set of informatics tools

VPR MAJOR STEPS

1. Demonstration project
2. Automation development
3. Model review and approvals process
4. Availability of centralized process
5. Additional registry enrollment

1. MAJOR STEPS: DEMONSTRATION PROJECT

- ▶ 7 states volunteered for demonstration project
 - Linkage with real cohort study
- ▶ Adventist Health Study volunteered
- ▶ Workgroup meeting by phone
 - Volunteer state IT and directors
 - IMS, Inc. (SEER/NAACCR funding)
 - NPCR informatics (Registry Plus)

MAJOR STEPS: 1. DEMONSTRATION PROJECT

Workgroup developing basic tools

- ✓ Protocol
- ✓ Data use agreement
- ✓ Researcher input file specs
- ✓ Researcher input file edits
- ✓ Registry file specs

MAJOR STEPS: 1. DEMONSTRATION PROJECT: PROGRESS TO DATE

- ▶ Replication of actual cohort study linkage with 3 state cancer registries
 - Idaho, Michigan, North Carolina
 - done with excellent results
 - 4 additional state registries have volunteered
 - California, New Jersey, Utah, Kentucky

MAJOR STEPS

1. Demonstration project
2. Automation development
3. Model review and approvals process
4. Additional registry enrollment
5. Sustainable Funding

MAJOR STEPS: 2. AUTOMATION DEVELOPMENT

1. Protocol for assuring proper formatting, standardizing and editing of researcher input file
2. Standardization of registry linkage files behind registry firewalls
3. Standardization of linkage software protocol including match counts table
4. Development of file transfer protocol to cancer registries

MAJOR STEPS

1. Demonstration project
2. Automation development
3. Model review and approvals process
4. Additional registry enrollment
5. Sustainable Funding

MAJOR STEPS: 3. MODEL REVIEW AND APPROVALS

1. Establish advisory/review committee
2. Identify “best practices” for research use and privacy protection of registry data
3. Develop model processes for review and approvals
4. Explore existing central NCI IRBs
 - ▶ Adult Late Phase Central IRB, 2001
 - ▶ Pediatric Central IRB, 2004
 - ▶ Adult Early Phase Central IRB, 2013
 - ▶ Cancer Prevention and Control, 2015

MAJOR STEPS

1. Demonstration project
2. Automation development
3. Model review and approvals process
4. Additional registry enrollment
5. Sustainable Funding

MAJOR STEPS: 4. ADDITIONAL REGISTRY ENROLLMENT

1. Voluntary basis
2. Technical assistance available
 - ▶ Review and approvals process improvement
 - ▶ Linkage process

MAJOR STEPS

1. Demonstration project
2. Automation development
3. Model review and approvals process
4. Additional registry enrollment
5. Sustainable Funding

MAJOR STEPS: 5. SUSTAINABLE FUNDING

- ▶ Cohort follow-up and cancer outcomes and confirmation are a large portion of NCI's funding for cancer cohorts
- ▶ Epidemiology and Genomics Research Program alone has >1,000,000 patients followed annually
- ▶ Similar costs of cohort follow up for
 - Division of Cancer Epidemiology Genetics
 - Division of Cancer Prevention
- ▶ Clinical Trials Follow up
 - Division of Cancer Treatment and Diagnosis
 - Division of Cancer Prevention
- ▶ FDA requires long-term cancer monitoring as part of some post-marketing approvals

MAJOR STEPS: 5. SUSTAINABLE FUNDING

- ▶ Costs of operating VPR are expected to be far less than current NCI expenses
- ▶ Budget to provide annual funding to each participating registry

THE OPPORTUNITY

- ▶ Findings from cancer epidemiology cohorts are critical in many areas of transdisciplinary and translational research:
 - environmental, lifestyle, clinical, and genetic determinants of cancer and its outcomes
 - risk prediction analyses and models
 - prevention strategies.
- ▶ Cancer survivor cohorts can provide information on
 - genetic
 - clinical
 - environmental
 - lifestyle factors.
- ▶ The NAACCR community can make major contributions to achieving these goals.