

# Methods and Strategies Working Group II

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# WG2 Methodological Challenges

- Rare vs. very rare
- Data collection/standardization
  - CASES
    - Population-based resources like NAACCR could be better exploited, rapid ascertainment improving (electronic path submission in progress)
    - When population-based ascertainment is not feasible:
      - Cases may be largely captured at tertiary care facilities, reduces costs
      - May need to be more flexible about ascertainment of very rare cancer cases: loose interest groups (web-based)
    - Consider case-only designs, especially for very rare cancer
      - Can start with molecular pathogenesis or genetics and go backwards
      - If effect is strong (i.e. vinyl chloride and liver angiosarcoma), may see a signal
  - CONTROLS
    - Relatives
    - Spouses
    - Controls from ongoing cohorts with standardized data
  - SOURCES
    - DOD, VA, access limited but possible, HMO sources
  - SOLUTION:
    - NCI could support infrastructure for ascertainment of cases and control selection

# WG2: Methodological Issues

- Data pooling
  - Expensive for individual centers to prepare data for pooling- no support
  - Solution:
    - NIH grants to cover data pooling preparation activity; structured for multiple institutions..
    - Consider NIEHS / private foundations
  - Start with core data collection instrument, then subgroups of additional data
  - NCI Intramural or IARC doing pooling- need to be sensitive to ownership
- Biospecimens
  - Lack of funds for storage long-term
  - Saliva test kits improve participation, could help with very rare cancers
  - Material transfer agreements and intellectual property becoming entwined
  - Tumor tissue may be useful for case only studies
- Human subjects issues
  - Difficult to coordinate multiple IRBs, especially internationally
  - HIPAA: was a problem initially, less now
  - Solution:
    - IRB Infrastructure funding from NIH Roadmap, form networks of IRB's to facilitate approval of protocols approved by other IRB's, takes work and trust (HMOs)
    - NCI funding to help coordinate IRBs for consortia, especially international

## WG2: Improvements on Coordination/implementation and Types of Consortia Models

### Dissemination of findings

#### Intra-consortia:

No real problems with data sharing

Problems with equal opportunity for publication for very rare cancers

#### Solution:

- publication and authorship policy up front
- facilitate opportunities for junior investigators

#### Public data sharing

- May be difficult when working with international collaborators

### Avoiding Duplicate studies

- Problem: Depletion of specimens ... BUT replication is good
  - Website announcements of ongoing studies with data details
  - "Owner" of specimens can control in cases of material scarcity.
  - Steering committees coordinate and facilitate

### Multi- Institution/international/PI/author

- IRB difficulties, add budget item to grants for addressing IRB issues, especially long-term international projects or consortia

### Advocacy groups role

- Help with data access under HIPAA, IRB by lobbying congress
- Place for consortia of advocacy groups