

National Academies of Sciences, Engineering, and Medicine

National Cancer Policy Forum

November 14-15, 2016

Washington, DC

***Cancer Care in Low-Resource Areas:
Cancer Treatment, Palliative Care, and Survivorship Care***

Session 3: Models and Strategies to Deliver cancer Care in Low-resource Settings

***Improving Patient Access to Cancer Care:
The Role of Clinical Trials and Implementation Science***



Academic and Community Collaboration for Cancer Clinical Trials: One State's Perspective



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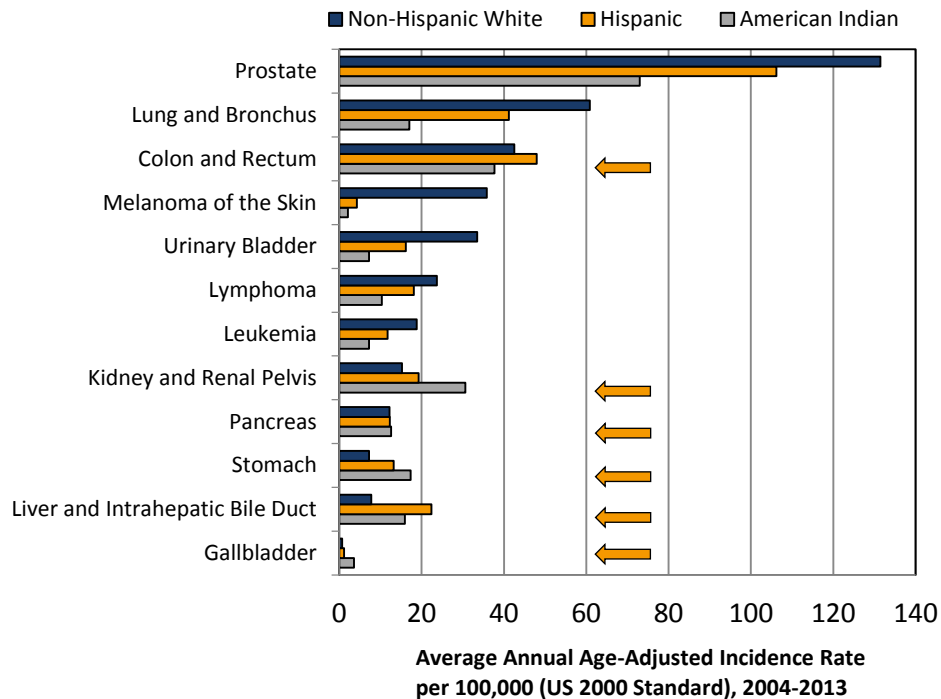
University of New Mexico Comprehensive Cancer Center

The State of New Mexico

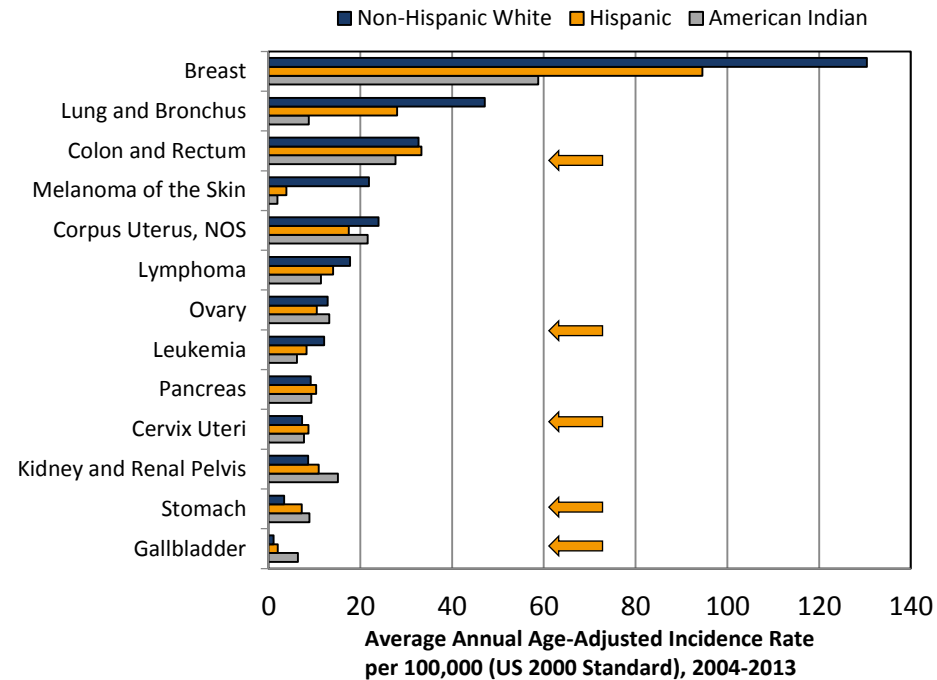
- **Rich multiethnic diversity**
- **Population: 2,059,179**
 - 47.3% Hispanic
 - 39.4% Non Hispanic white
 - 8.6% American Indian
 - 3.3% Other Minorities
 - 1.5% Multiple
- **Tremendous Disparity:**
 - Per Capita Income: ranked 48th
 - 20% below national level
 - Uninsured: 10.9% (19.6)*
- **Distinct Cancer Patterns**

Cancer Incidence, New Mexico (2004-2013)

Males

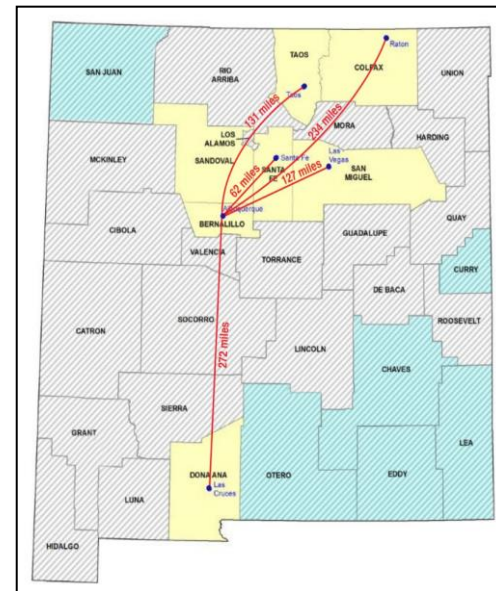
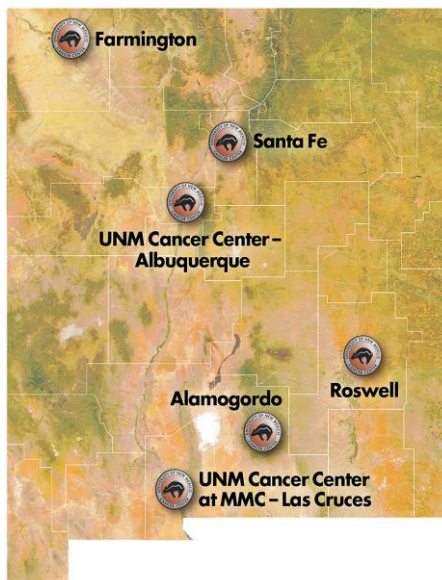


Females



Courtesy of NM Tumor Registry, C. Wiggins (PI)

A Statewide Cancer Clinical Trials Network



New Mexico Cancer Care Alliance

- Non-profit (501c3) public-private joint venture: UNMCCC, 5 health systems, virtually all NM community-based oncologists
- Governed by constitution and bylaws creating a single statewide cancer IRB and integrated infrastructure for the management and oversight of cancer clinical interventions and trials
- Based at UNM Comprehensive Cancer Center (UNMCCC); UNMCCC Director is the Board Chair with authority over all NMCCA trials
- Financial support: UNMCCC, NM Health Systems, and specific Participants.

Why was NMCCA created?

- Increase access to clinical trials in NM.
 - Provides expanded access to clinical trials
- Improve the efficiency in how trials are conducted, and improve overall cancer care in the state.
 - Provides research support for community practices & hospitals
 - Provides education to patients & families

NMCCA: Background

- Established February 2002
- New Mexico not for profit 501c (3)
- Independent Board of Directors
- By-laws and Articles of Incorporation
- Application to the IRS for a not-for-profit determination

What does it mean to be a Participant?

- Participant Class/categories → dictate board seats and voting for super majority items:
 - Class A are physicians
 - Class B, C and D are institutional → Institutional Participants pay an annual participation fee:
 - B – Government entities, Founding Hospitals
 - C – Founding Community Based Hospitals
 - D – Community Based Hospitals
 - Affiliate Participants

What does it mean to be a Participant?

- Class A, B, C & D Participants: agree to provide the NMCCA the first right of refusal prior to opening a clinical trial at their practice/facilities
- Institutional Participants
 - B & C provided cash and/or in-kind contributions
 - D did not provide cash contribution

Agreements

- Research Services Agreement:
 - Appoints NMCCA as its representative for the purpose of entering into clinical trials with sponsors.
 - Identifies duties and responsibilities of NMCCA and each Participant
- IRB Authorization Agreements:
 - Authorize use of UNM IRB, NCI CIRB and WIRB for review of trials opened under the auspices of the NMCCA

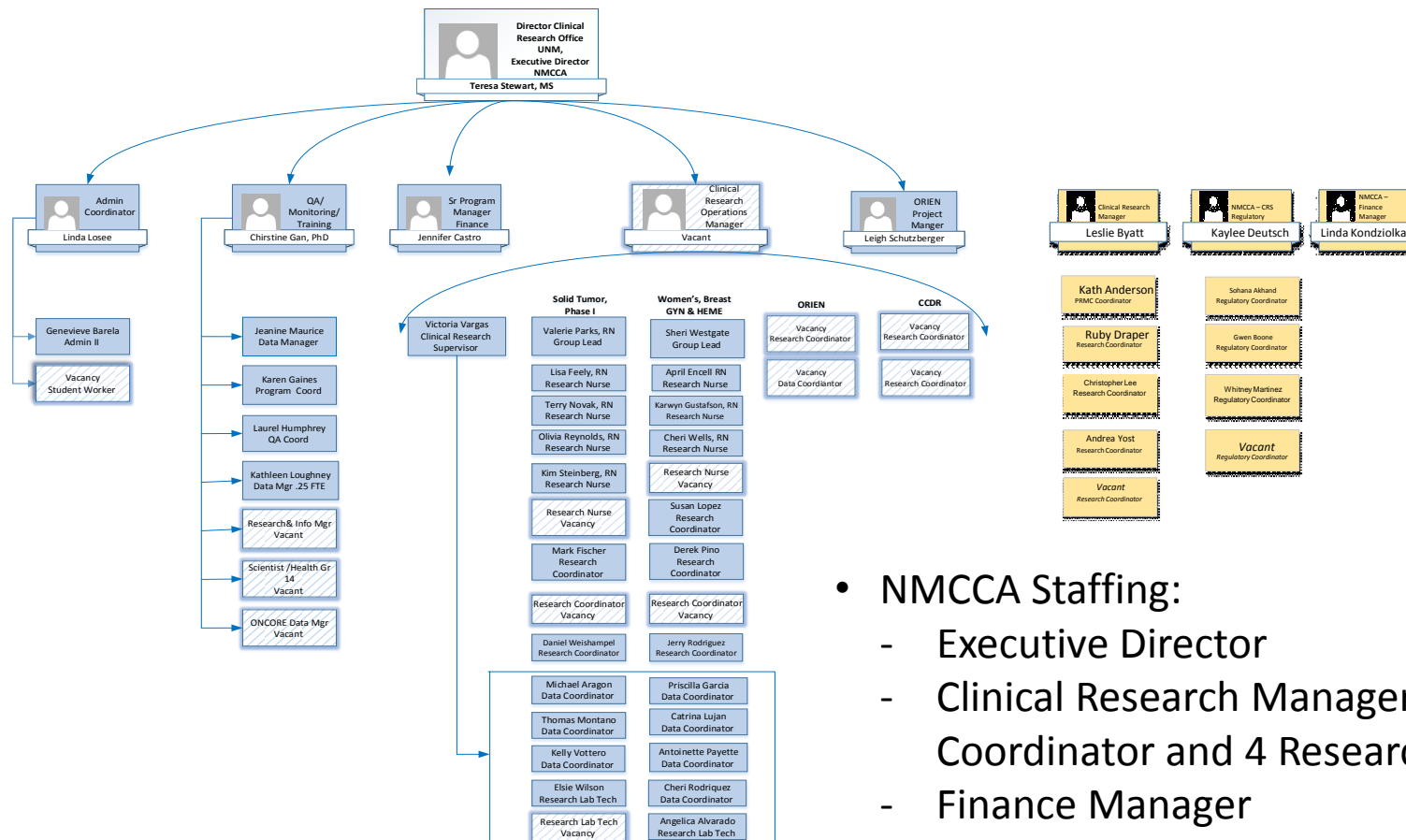
Process for Activation of a New Site

- New Sites are approved by the NMCCA Board and contracts signed.
 - When new physicians join a site, the individual PI is approved but no additional contracts are executed
 - Paperwork submitted to NCI, including training investigators and staff
- NMCCA notified by NCI when components are added to each NCI Research Base (SWOG, NRG, etc)
- Update any FWA and IRB authorization
- Contacts for pharmacy, laboratory and imaging, ancillary depts, (like cardiology, ophthalmology), etc.

Process to identify, approve & open studies

- NMCCA executes Confidentiality Agreement
- Obtain protocol & send to disease specific Clinical Working Group
- If disease specific CWG approves, sent to PRMC for approval.
- PRMC approval, NMCCA regulatory Coordinators submit to IRB, obtain Medicare Coverage Analysis for industry sponsored trials and NMCCA executes contract & budget.
- NMCCA is responsible for ongoing continuing review, amendments and external adverse event reporting

UNMCCC/NMCCA Integrated Clinical Research Structure



- NMCCA Staffing:
 - Executive Director
 - Clinical Research Manager, PRMC Coordinator and 4 Research Coordinators
 - Finance Manager
- NMCCA sites employ & fund their research staff

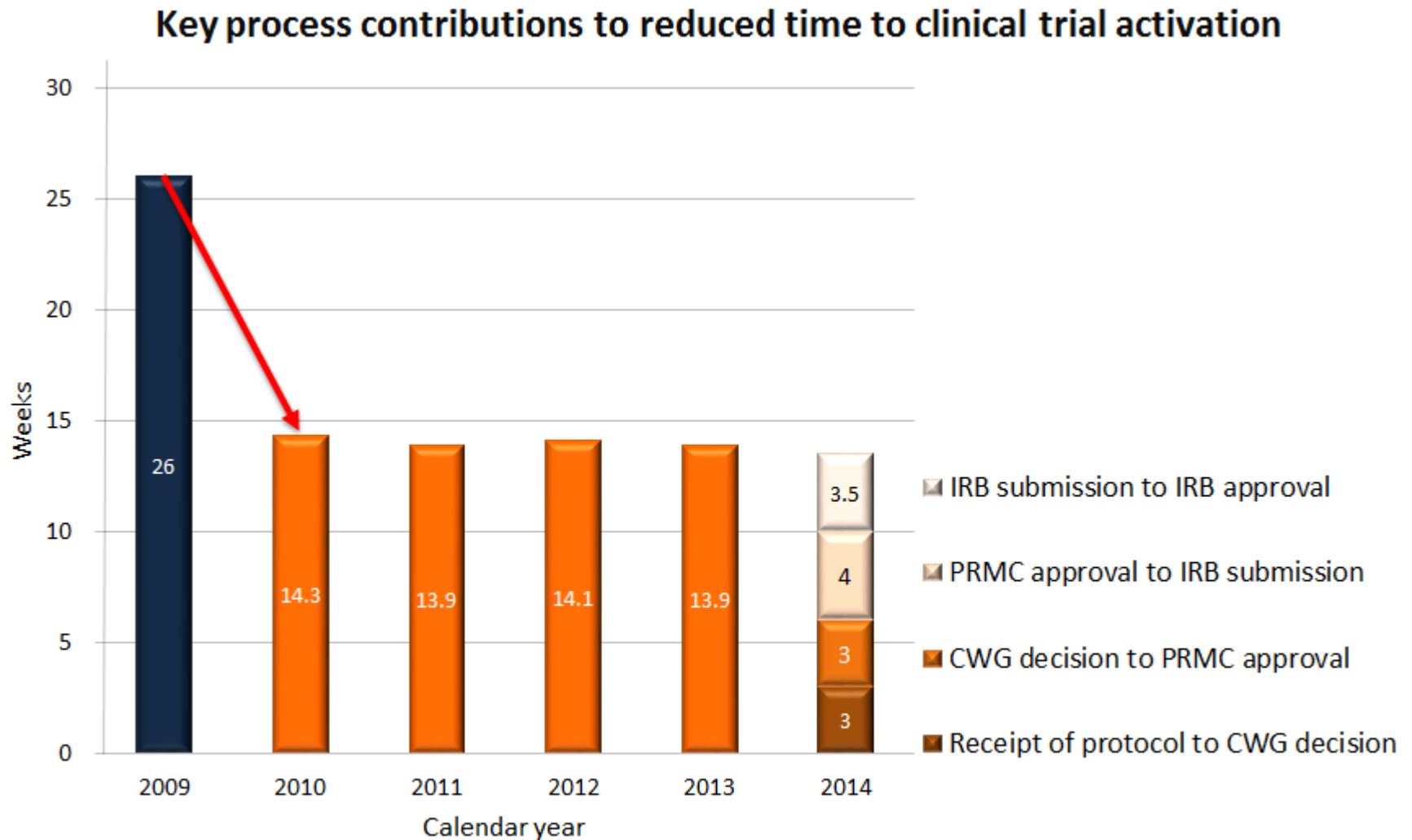
Clinical Research Operations: Study Management

- Regulatory Coordinators – NMCCA staff assigned to submit study to the IRB for all NMCCA sites.
 - They manage each study assigned for all sites participating in the trial.
 - Assigned by disease CWG.
- NMCCA staff manage Site, PI and Staff records centrally
 - Training, NCI #s, CVs, CLIAs, Normal Values, etc

Clinical Research Operations: Contracting/Budgeting

- One contract and budget/study with NMCCA and sponsor. NMCCA,
 - invoices sponsor
 - distributes funds to site for patient enrollments
 - reimburses third party vendors
- NMCCA develops the Medicare Coverage Analysis for the network

Time to Activate Clinical Trials: 14 weeks



Clinical Research Operations: Quality Assurance & Auditing

- All sites within the NMCCA fall under the UNMCCC DSMP
 - Staffed and led by UNMCCC
- Research Nurses, Research Coordinators, Data Coordinators and Lab techs.
 - Employed by each site to manage the site workload with a dotted line to NMCCA CRM.
 - NMCCA employs Research Coordinators for sites with limited resources and accruals.

Goals, Metrics & Performance Indicators

- We measure the network, sites, investigators, staff, sponsor, IRB, etc...
- Important to involve all stakeholders in the identification and measurement of metrics
- Communicate the findings



"For starters, I think we should find out who made the coffee that day!"

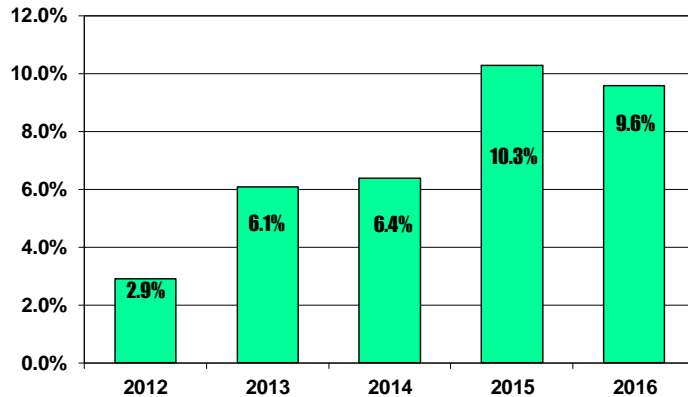
New Mexico Model Governance & Communication

- Board of Directors – Quarterly
- Executive Committee – Quarterly
- Finance Committee – Annually
- CWG- Monthly
- PRMC – twice/month
- Staff Meetings – Quarterly
- Scientific Retreats of PIs – 3x/year
- Staff Training - annually
- Quality Assurance Committee (Staff) – Quarterly → Identifies expectations and requirements of key stake holders (ex. Impact budget)
 - Accrual requirements, external: NCORP grant, NCI CCSG, Community Hospitals CoC, & individual site accrual goals.
 - Accrual requirements, internal: investigator, research coordinator, CWG, site & overall accrual/ research FTE (NMCCA network)

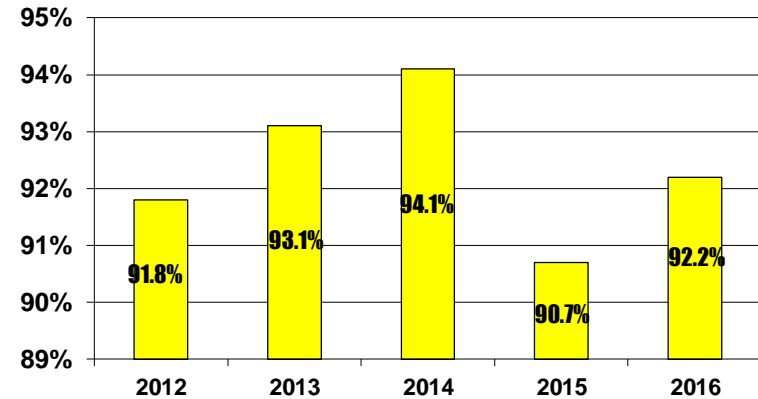


NMCCA Audit Report

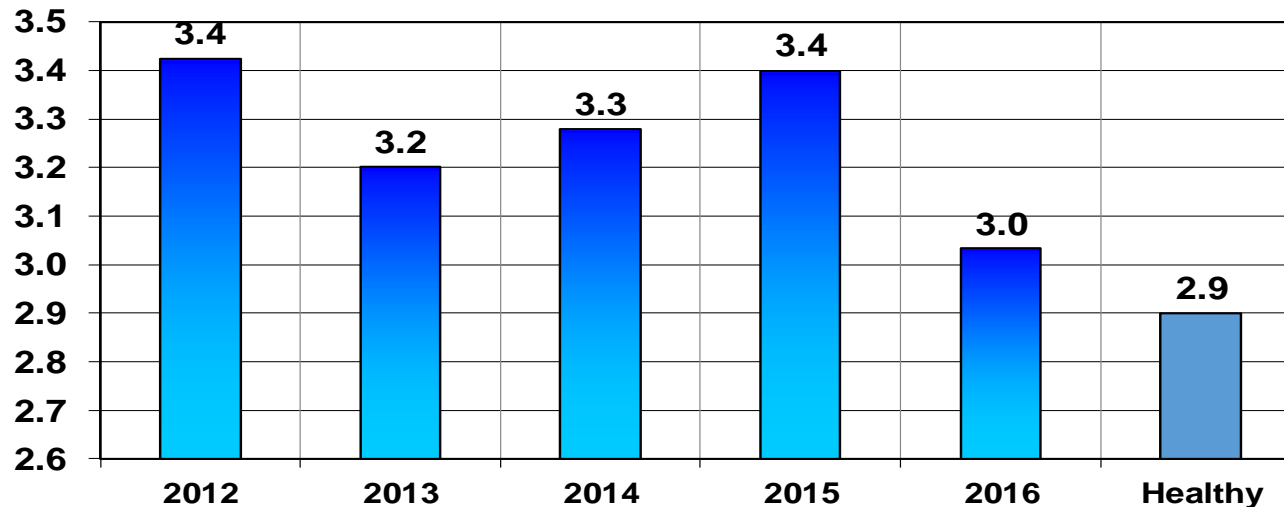
Operating margin



Program efficiency



Altman Z ratio



Legislative Wins

- SB requiring insurance companies to cover the routine procedures associated with cancer clinical trials (2003)
- Funding from state via NMDOH to NMCCA for patient and healthcare provider education and training
- Other state funding: NMDOH to support the online resources for cancer patients through the Albuquerque Cancer Coalition (also on the NMCCA website)

Lessons Learned

- **FLEXIBILITY**

- One size does not fit all.

- **AUTOMATION/IT solutions**

- Consider e-Regulatory Binders, use WebEx for meetings and interactions, etc.
- The sooner you implement automation/IT solutions, the sooner your staff gets efficient

- **COMMUNICATION**

- Do not overlook this important task.
- Relationship management & establishment of shared expectations provides clarity when complexity of trials increase & problems occur.

Thank you

Questions?

