



Walking Forward  
June 2010 RTOG Update

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# Objectives: Walking Forward Update

- Survey results
- Patient navigation
  - New model using health navigator
- ATM study complete
- Clinical trials
- Submitted EGFR lung cancer proposal with UW-Madison

# Key Elements of Walking Forward

- Phase II/III Clinical Trials

- Prostate brachytherapy
- Breast brachytherapy
- IMRT / Tomotherapy
- Phase II/III cooperative group trials
- **WON / SBRT**

- Surveys

- Address barriers to health care
- General population
- Cancer population
- **Patient Navigation**

- Patient Navigator Program

- Community education
- Assistance with service and access issues
- documentation and data collection
- **Health Navigator**

- ATM analysis

- To determine association between ATM heterozygosity and sensitivity to radiation
- **Completed**

# Patient Navigation Program

## Two Navigation Programs

### 1. Community Navigation Program

- Community research representatives live each on each reservation
- Assessment of barriers to early cancer detection
- Goal: promote education, outreach, networking
- Expansion: health navigator

### 2. Cancer Navigation Program

- Goal: assist cancer patients during cancer treatment (case worker, patient advocate)
- Assessment of barriers to early cancer detection

- Networking
- Lays foundation & trust for entire project

# Medical mistrust and satisfaction with health care (cancer survey)

- 52 Native Americans, 113 non-Natives
- Native Americans expressed significantly higher levels of mistrust ( $p=0.0001$ ) and lower levels of satisfaction with health care ( $p = 0.0001$ ) compared to non-Natives
- In multivariable analyses, NA race was the only factor found to be significantly predictive of higher mistrust ( $p=0.001$ ) and lower satisfaction with healthcare ( $p=0.0001$ ), even when adjusting for income, education, and geographic remoteness.
- Guadagnolo A, Petereit D, et al. Medical mistrust and less satisfaction with health care among Native Americans presenting for cancer treatment. *Journal of Health Care for the Poor and Underserved*. Feb;20(1):210-26, 2009.

# Patient Navigation Survey

- Pre-post survey study of cohort receiving patient navigation during cancer treatment
- One of the few studies assessing the impact of PN during cancer treatment
- 52 adult NA cancer patients undergoing treatment at a regional care center in Rapid City, SD

## Mean scale scores for mistrust and satisfaction pre- and post- navigation

<u>Scale</u>	<u>pre</u>	<u>post</u>	<u>p-value</u> †
Satisfaction*	4.12	4.53	<0.0001
Change in mean score (95% CI)		+0.41 (0.22-0.60)	
Medical mistrust**	2.38	2.23	0.13
Change in mean score (95% CI)		-0.13 (-0.28-0.03)	

† Wilcoxon signed ranks test (non-parametric)

\* a higher score corresponds to higher level of satisfaction

\*\*a higher score corresponds to a higher level of medical mistrust

Guadagnolo, B A; Boylan, Petereit, D G. Patient Navigation for Patients Undergoing Cancer Treatment: Utilization and Impact on Care Delivery in a Regional Health Care Center

## Cancer Survey: Persistent Stage Disparity

- Americans Indians presented with more advanced-stage screen detectable cancers than non-NAs (breast, cervix, colorectal, prostate) 45% vs. 24%,  $p=0.04$ .
- Of patients with screen-detectable cancer, the identifying diagnostic was a screening test for 68% of white vs. 37% of Native American patients. ( $p=0.006$ ).
- Implications for new strategies



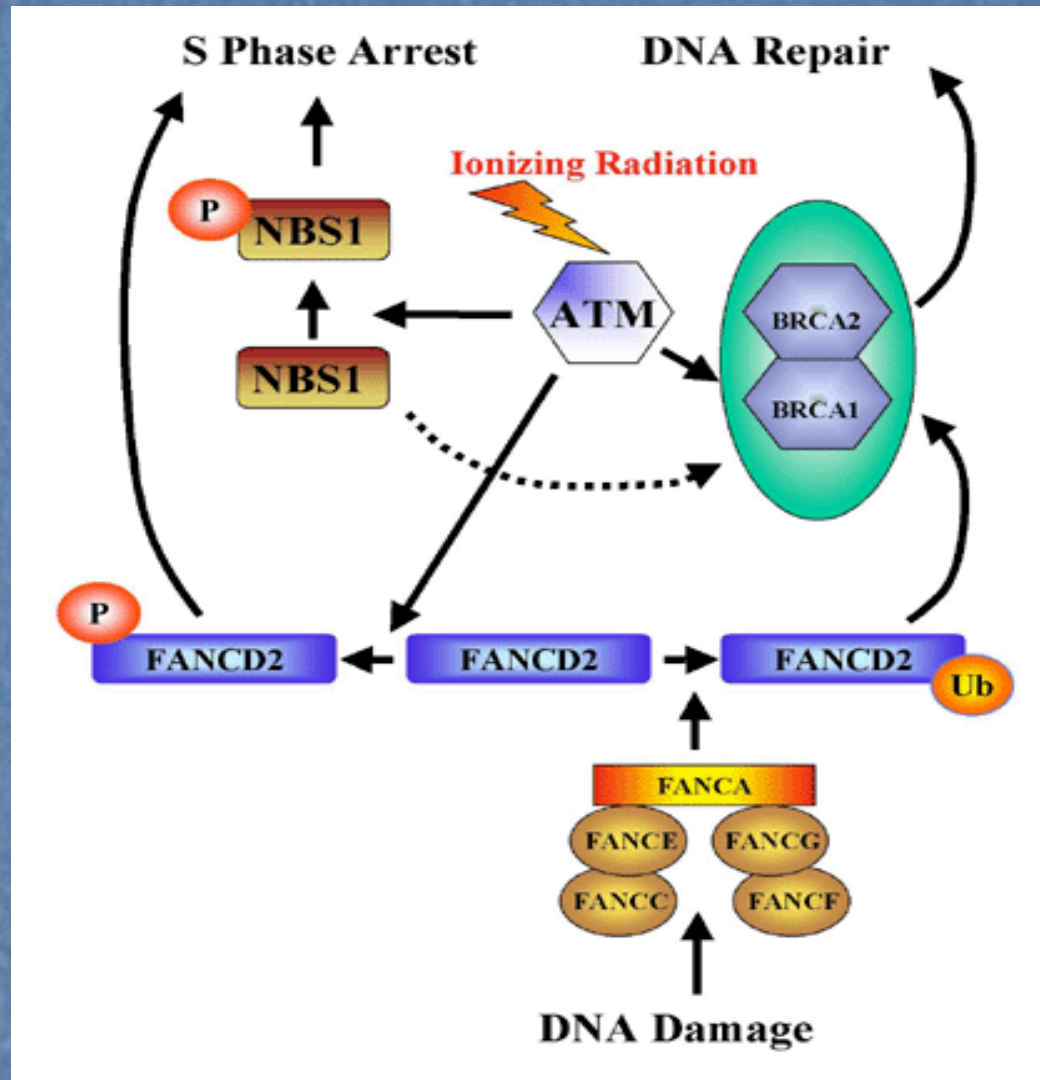
# Community Survey

- Survey of 975 individuals in 2004-2006 from three reservations and among the urban Native American community in the service region of the Rapid City Regional Hospital.
- Examined the rates and determinants of cancer screening in a large sample of Native Americans from this region.

## Conclusions from the Community Survey

- Cancer screening was markedly underutilized in this sample.
- Only forty-four percent of individuals reported ever receiving cancer screening.
- Strongest determinant of receiving cancer screening overall or for a specific cancer site was a screening recommendation by a doctor or nurse.
- Planned interventions: to be discussed

# Mechanism of Radiation Injury



# IS ATM heterozygosity related to radiation induced skin toxicities in American Indians?

- Sequenced all 61 exons of 200 samples (100 Natives and 100 non Natives)
- No statistically significant differences for total prevalence of SNPs among AI (40%) and non-AI (48%) patients ( $p=0.32$ ) were identified.
  - Five SNPs had a prevalence of  $>2\%$ , of which 4 occurred at a rate of  $>5\%$  in one or both groups.
  - The only statistically significant difference among the groups was the c.4138C>T SNP seen in 8% of AI versus 0% of non-AI patients ( $P=0.007$ ). However, this SNP is predicted using the Polyphen software tool not to affect protein function.
- The prevalence of those SNPs predicted to result in potentially deleterious missense mutations, was 28% among non-AI and 18% among AI ( $p= 0.13$ ).
  - Of particular interest is SNP c.5557G>A, which had a prevalence of 25% in non-AIs versus 14% in AIs ( $p= 0.07$ ). Three homozygous patients were identified for this SNP, all in the non-AI group.
- Accepted for oral presentation 2010 ASTRO

# Patients Entered on Research Trials During the Walking Forward Era (2002-2010)

Research Study	Als	Non-Als	Total
CDRP treatment trials	10	91	101
Cooperative Group Trials	19	307	326
ATM	102	52	154
Patient Navigation	362	0	362
Community Survey	984	0	984
Cancer Survey	225	150	375
Navigation Survey	94	0	94
Stock Show Prostate Survey	1	26	27
Cheyenne River Screening	27	0	27
Educational Module Screening	410	0	410
Coordination(EMSC)			
GRAND TOTAL	2234	626	2860

# Accrual Research Trials (2002-2010)

## ■ Phase II/III clinical trials (427)

- Prostate brachytherapy (1AI, 7 other)
- Breast brachytherapy (4AI, 37 other)
- Tomotherapy Prostate (4AI, 39 other)
- Tomotherapy Prostate (high risk)
  - (1AI, 8 other)
- 65 other clinical trials (phase II&III)  
19AI, 2 Hisp, 1 Asian, 304 Caucasian  
326 total

## ■ Surveys (1890)

- General population
- Cancer population (225 AI, 150 other)
- Male population eligible for screening
- Navigator participants
- EMSC (410)

## ■ Patient Navigator Program (362)

- Community education
- Assistance with service and access issues
- Documentation and data collection

## ■ ATM analysis (154) (102AI, 52 other)

- Assessment of radiosensitivity
- Establish baseline for ATM mutation

## ■ Cheyenne River Screening (27)

- Prostate and colo-rectal screening event on the Cheyenne River Reservation May 2007

**As of June 2010, data has been collected on 2860 participants**

# Clinical Trial Accrual (2002-2010)

## Cooperative Group Clinical Trials (326)

- RTOG – 36 Patients
- CTSU – 126 Patients
- MCCRC – 3 Patients
- NCCTG – 97 Patients
  - GOG – 38 Patients
  - ECOG – 6 Patients
  - NSABP – 20 Patients

September 2009 – June 2010

## Phase II/III Clinical trials (34)

- Breast brachytherapy (6 Caucasian)
  - Tomotherapy Prostate (high risk)  
(1 Caucasian)
- Cooperative Group Clinical Trials(phase II&III)
  - GOG – 3 Caucasian, 1 Asian
  - ECOG 1 AI
  - NCCTG 9 Caucasian
  - CTSU 6 Caucasian, 1 AI
  - SWOG 5 Caucasian
  - RTOG 1 Caucasian



# Continuation of Walking Forward (U 54)

*Specific Aim 1:* Expand the current patient navigation program using hospital and community-based navigators.

*Specific Aim 2:* Expand the scope of NCI sponsored clinical trials.

**Wisconsin Oncology Network (WON)**

**RTOG SBRT TRIALS: Michael Swartz, MD (RTOG PI)**

**-Tomotherapy credentialed RPC**

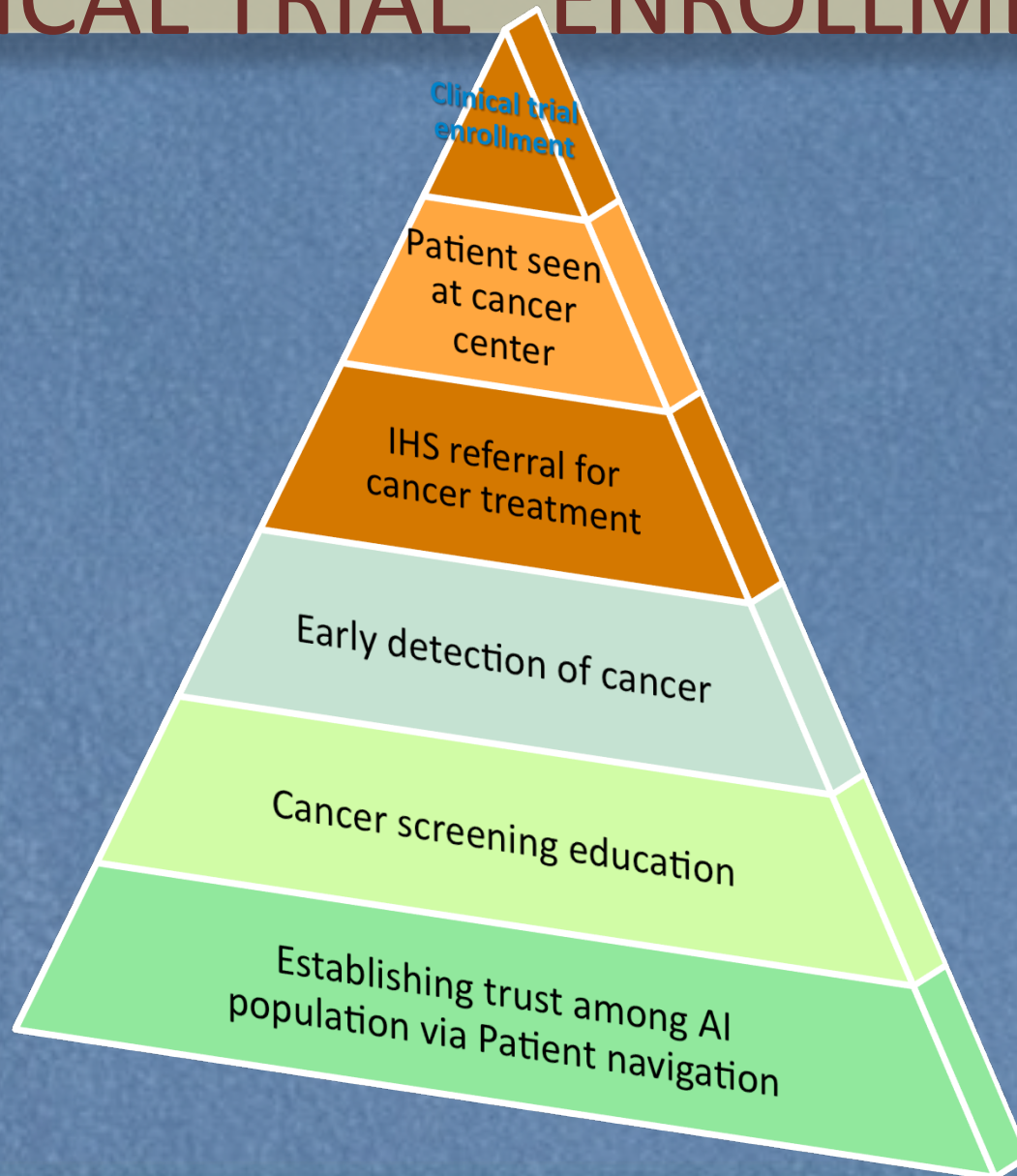
*Specific Aim 3:* Identify genetic responses to radiation that could be predictive of adverse responses *in vivo*.

# Successful Recruitment Clinical Trials

- 21% AIs who underwent patient navigation during radiation were enrolled on a clinical trial
- Reasons for non-participation in clinical treatment trials for AIs
  - advanced stage and/or poor performance status (29%)
  - no trial available for cancer site (16%)
  - and other reasons for ineligibility after evaluation (15%)

Guadagnolo B, Petereit D, Helbig P, et al:  
Involving American Indians and Medically Underserved  
populations in Cancer Clinical Trials. *Clinical Trials: Journal  
of the Society for Clinical Trial*, 6(6), Dec 2009; 610-617.

# CLINICAL TRIAL ENROLLMENT



# Increasing Clinical Trial Accrual



*Rapid City Regional Hospital  
Rapid City, South Dakota*



*Rapid City Regional Hospital  
John T. Vucurevich Cancer Care Institute  
Rapid City, South Dakota*



**Cheyenne River Sioux**



# Walking Forward Navigator-Driven Community Education and Screening

- Goal: Expand and enhance a Navigator-driven cancer education and screening program with American Indians (AIs) in the Northern Plains
- Aim: Increase AI screening for breast, cervix, colorectal, and prostate cancers by 20%
- Educational modules using audience response systems

## Screening workshops by Community Navigators

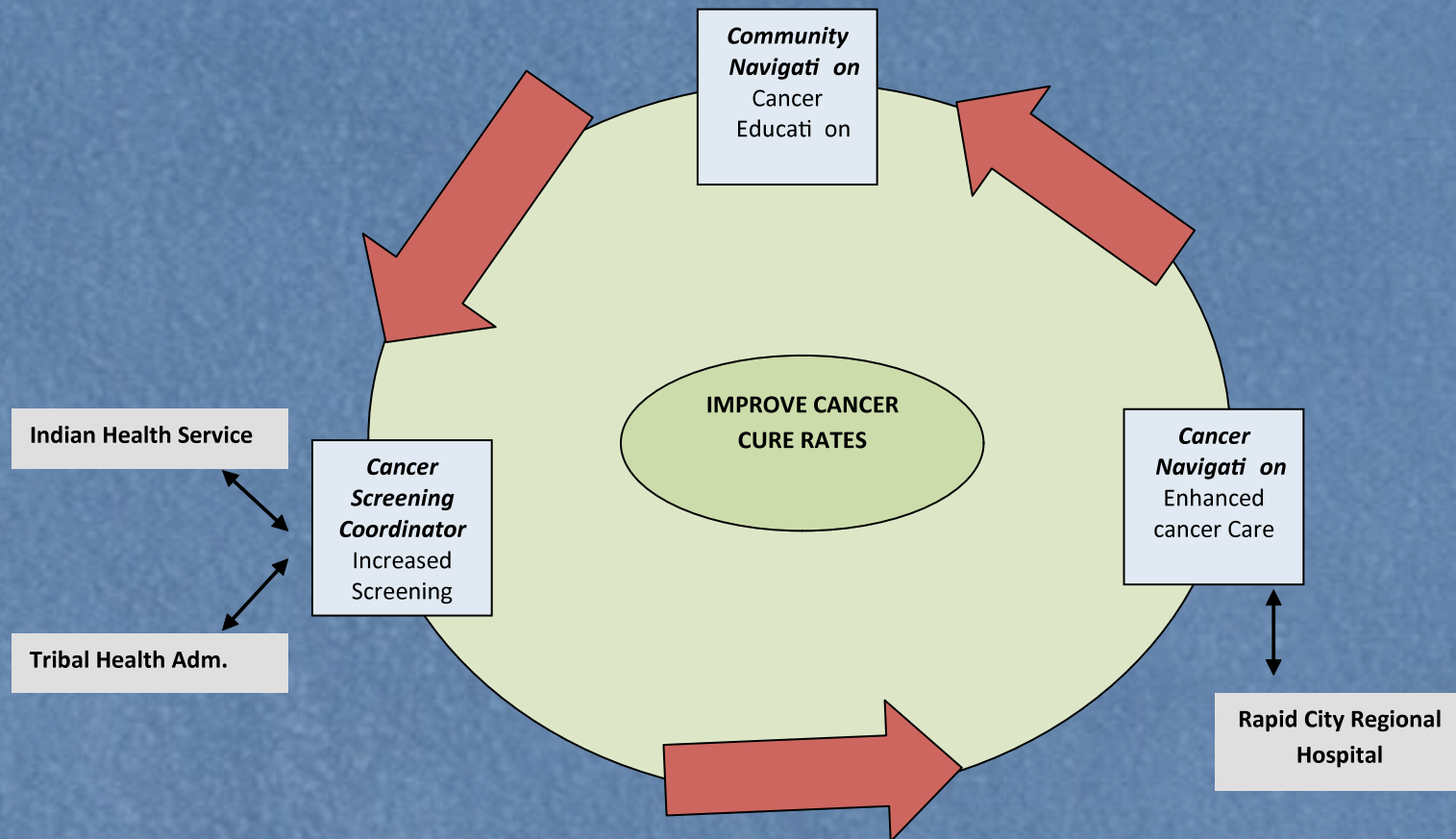
- Educational intervention- 2-hour cancer screening workshops coordinated and implemented by community navigators in the tribal communities.
- Pre- and post-test were administered to assess cancer/screening knowledge through use of an audience response system.
- 403 community member participants
- Data collected on baseline screening rates revealed pre-workshop screening prevalence among participants was lower than the national average.

# Screening workshops by Community Navigators (N=410)

- Pre- and post-testing revealed significant increase in cancer screening knowledge after workshops.
- Increase in knowledge quiz score:
  - 21% for cervical cancer ( $p < 0.001$ )
  - 24% for breast cancer ( $p < 0.001$ )
  - 21% for prostate cancer ( $p < 0.001$ )
  - 22% for colo-rectal cancer ( $p < 0.001$ )
- 94% of participants would recommend workshop to a friend, and 73% rated quality of information as high.
- Subrahmanian, K; Petereit, D G; Kanekar, S; Burhansstipanov, L; Esmond, S; Miner, R; Spotted Tail, C; Guadagnolo, B A. Community-based participatory development, implementation, and evaluation of a cancer screening educational intervention among American Indians in the Northern Plains.



# Model For Expanding Patient Navigation



# *Pine Ridge IHS Hospital*



# WF Publications 2002-2010

- 21 peer reviewed manuscripts published
- 5 Manuscripts pending
- 4 book chapters
- 77 abstracts and presentations at national and international meetings

# WF Publications U54 Grant

- Guadagnolo, BA, Petereit, DG, Helbig, P, Koop, D, Kussman, P, Fox, E, Patnaik, A. Involving American Indians and Medically Underserved populations in Cancer Clinical Trials. *Clinical Trials: Journal of the Society for Clinical Trial*, 6(6), Dec 2009; 610-617. PMID 19933720
- Pandhi, N, Guadagnolo, B A, Kanekar, S, Petereit, D G, Smith, M A. Cancer Screening in Native Americans from the Northern Plains. *American Journal of Preventive Medicine*. 38(4), Apr 2010. (PMCID 2851544)
- Swartz, MJ, Petereit, DG. The Role of Radiation Therapy in the Management of Breast Cancer in South Dakota. *South Dakota Medicine. Special Issue 2010*; 38-40. (PMID 20401984)
- Swartz, MJ, Petereit, DG. The Role of Radiation Therapy in the Management of Lung, Prostate and Colorectal Cancer in South Dakota. *South Dakota Medicine. Special Issue 2010*; 60-66.(PMID 20397493)

# Manuscripts (submitted)

1. Guadagnolo, B A; Cina, K; Koop, D; Brunette, D; Petereit, D G. Does patient navigation improve satisfaction with health care and reduce medical mistrust among American Indian cancer patients in the Northern Plains? (Pending IRB Review)
2. IAEA Guidelines for the Management of Cervical Cancer: A Guide for Radiation Oncologists. Vienna, Austria. In press, 2010.
3. Pandhi, N; Guadagnolo, B A; Kanekar, S ; Petereit, D G; Karki, C; Smith, M A. Intention to Receive Cancer Screening in Native Americans from the Northern Plains. (Pending AAIRB Approval)
4. Guadagnolo, B A; Boylan, A; Sargent, M; Koop, D; Brunette, D; Kanekar, S; Short Bull, V; Molloy, K; Petereit, D G. Patient Navigation for Patients Undergoing Cancer Treatment: Utilization and Impact on Care Delivery in a Regional Health Care Center. (Pending Letters of Support and IRB Approval)
5. Subrahmanian, K; Petereit, D G; Kanekar, S; Burhansstipanov, L; Esmond, S; Miner, R; Spotted Tail, C; Guadagnolo, B A. Community-based participatory development, implementation, and evaluation of a cancer screening educational intervention among American Indians in the Northern Plains. (Pending Letters of Support)

# IRB Approval Process

## Includes Manuscripts (Need Help!)

- 1. Rapid City Regional Hospital IRB Approval (meets monthly)
- 2. Letters of Support from three different Tribes
- 3. OST (Pine Ridge) Research Review Board Approval
- **4. Aberdeen Area IRB Approval Requires:**
  - RCRH Approval
  - Letters of Support
  - OST (Pine Ridge) Approval

### Approval Delays Related To:

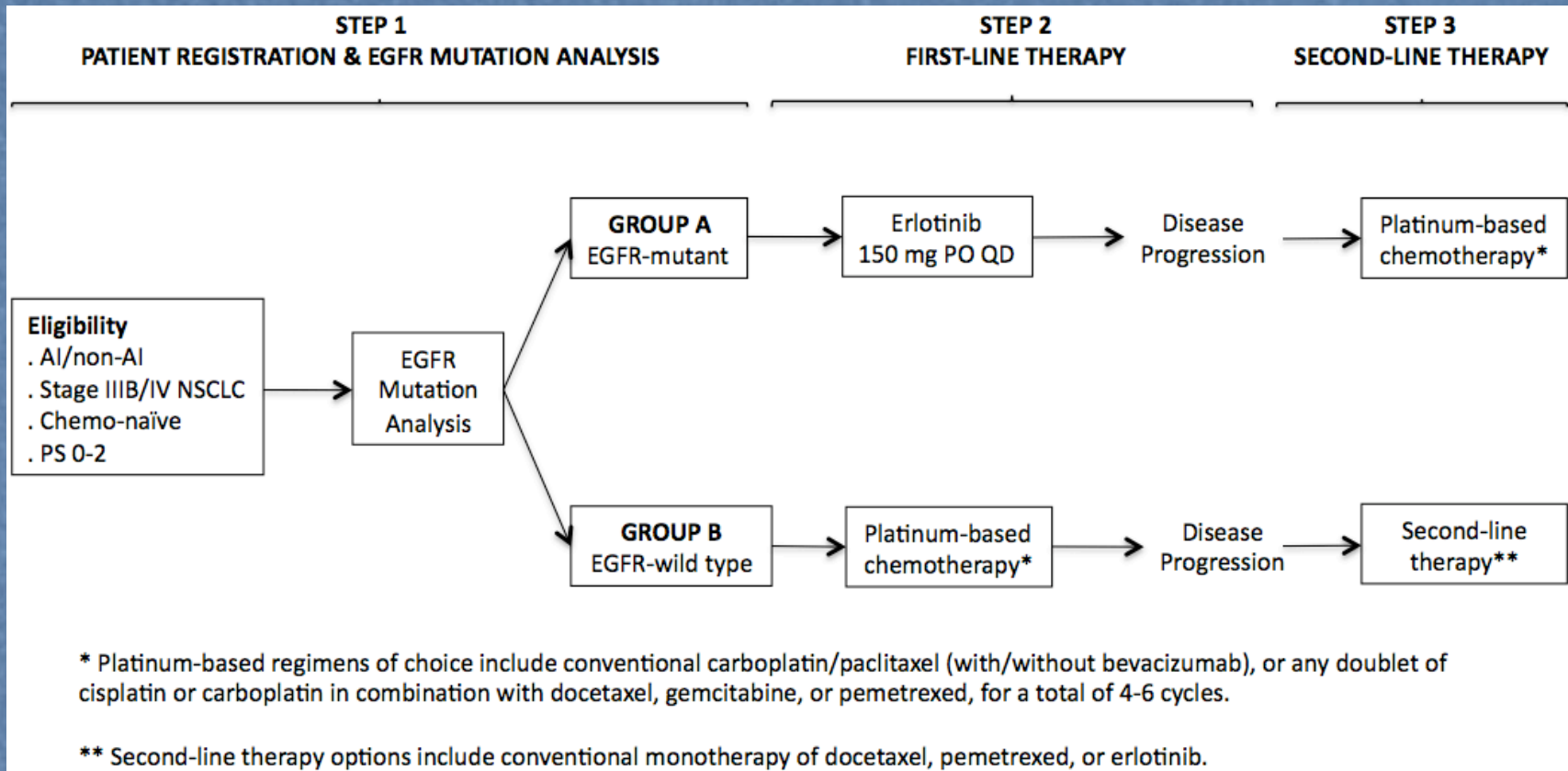
- Meetings lack quorum
- Weather delays
- Change in tribal leadership which delays Letters of Support
- If one delay occurs, the entire process is delayed

**CAN TAKE 6 TO 12 MONTHS  
THESE DELAYS COULD COMPROMISE FUTURE FUNDING  
NEED HELP FROM NATIONAL IHS AND NCI!!!**

# Walking Forward: Critical Outcomes

- Accrual rate of 10% of AIs to clinical trials
- Over 2,200 American Indians enrolled research studies
- Significant reduction in the number of missed treatment days among navigated AI cancer patients undergoing cancer treatment
- Improved satisfaction with health care system after PN
- Identification of specific barriers to effective cancer screening and cancer care
- Establishment of trusting partnerships with AI communities
- Creation of research infrastructure to address new ?s

# NSCLC EGFR TRIAL



PIs: Paul M Harari, MD (UW), Tien Hoang, MD (UW), Daniel G Petereit, MD



# Collaborators

- University of Wisconsin
  - Minesh Mehta, MD
  - Mark Ritter, MD, PhD
  - Amy Moser, PhD
  - Paul Harari, MD
  - Richard Steeves, MD PhD
  - Sarah Esmond, MA
  - Rebecca Koscik, PhD
  - Anne Traynor, MD
  - Tien Huang, MD
- MD Anderson
  - Ashleigh Guadagnolo, MD