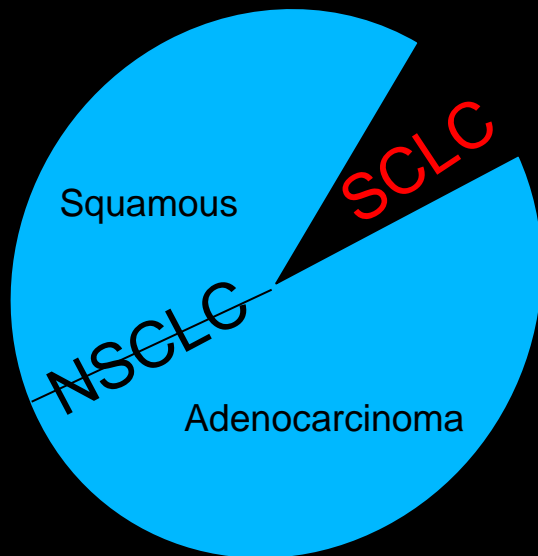
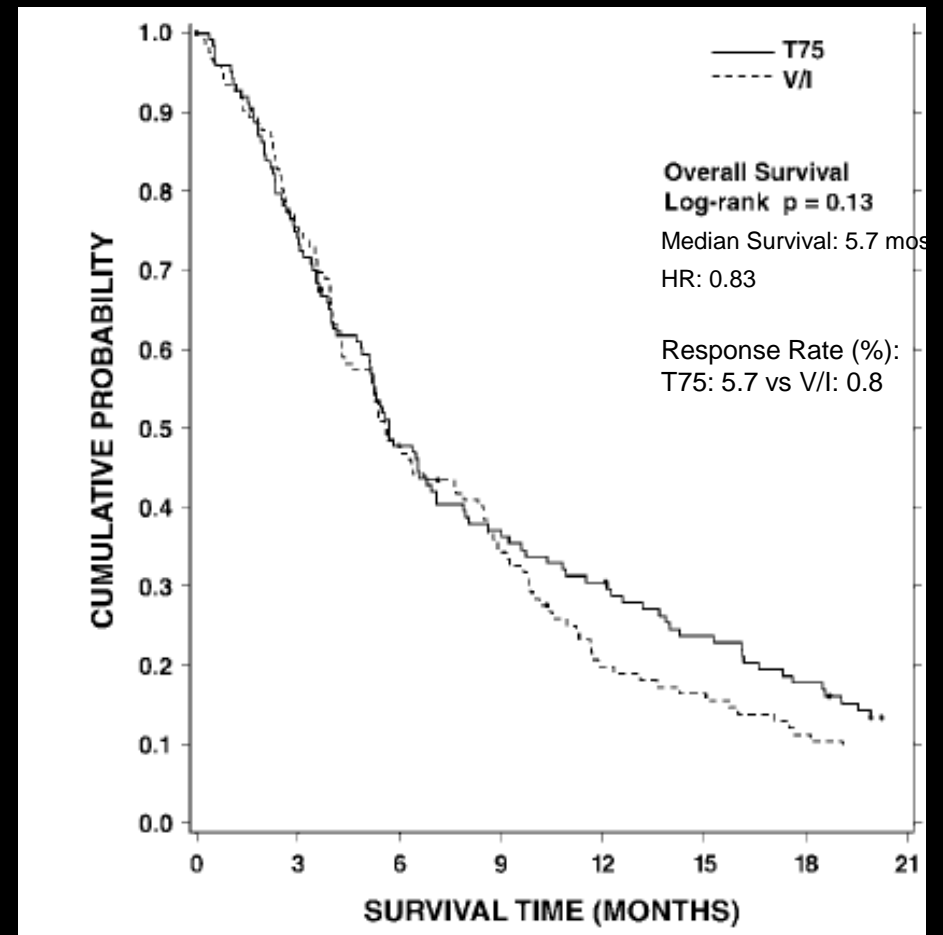


Lung Cancer Status (circa 2000)

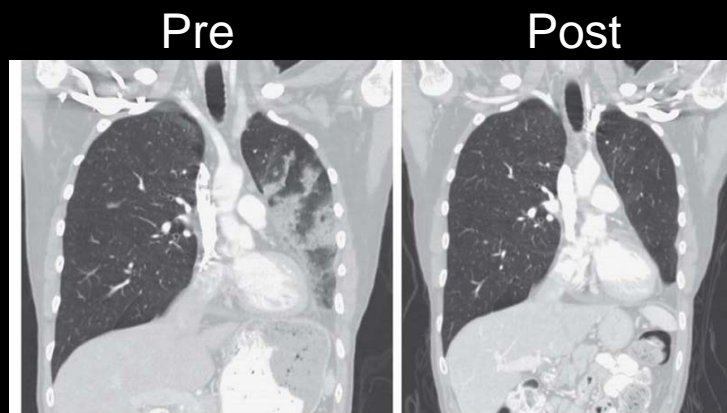
Lung cancer (circa 2000)



TAX 320: 2L NSCLC—Taxotere (T75)
vs Vinorelbine or Ifosfamide (V/I)

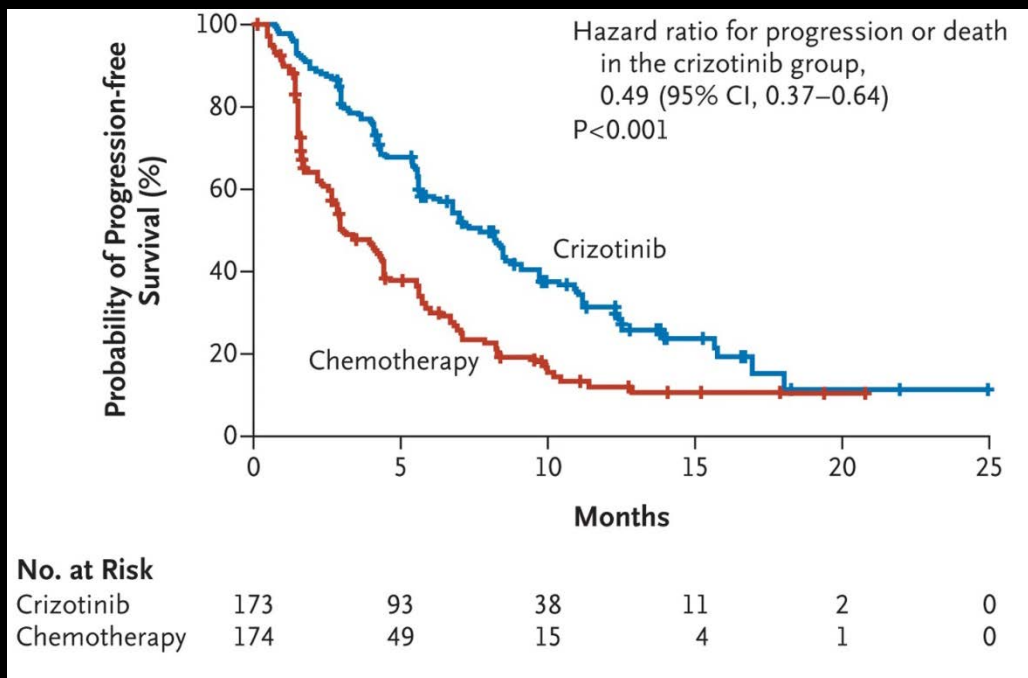


Antitumor effects of TKI in NSCLC ALK+



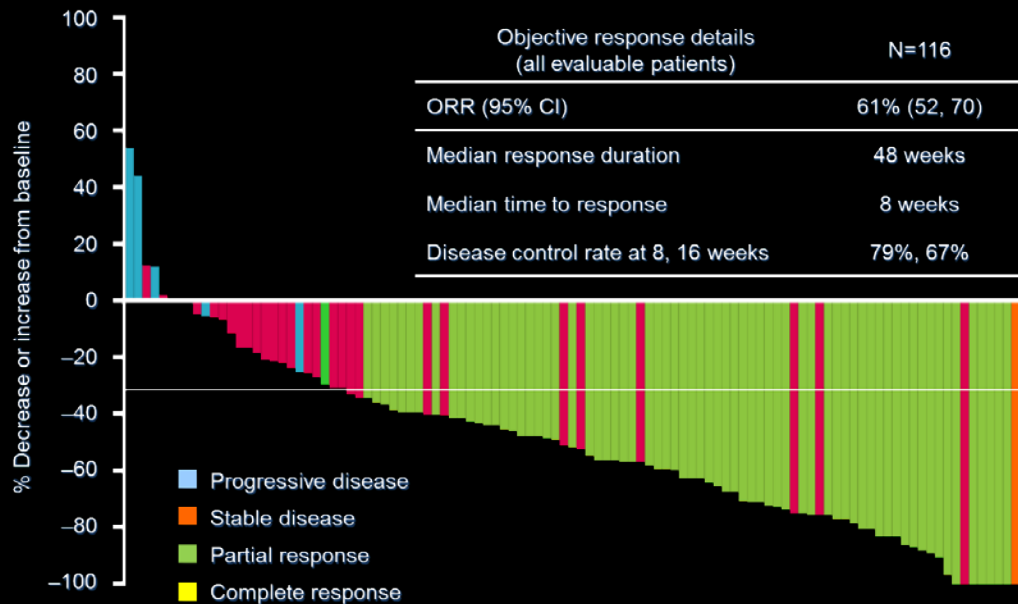
Kwak EL et al. N Engl J Med 2010;363:1693-1703

PFS



Shaw AT et al. N Engl J Med 2013;368:2385-2394

Waterfall Plot

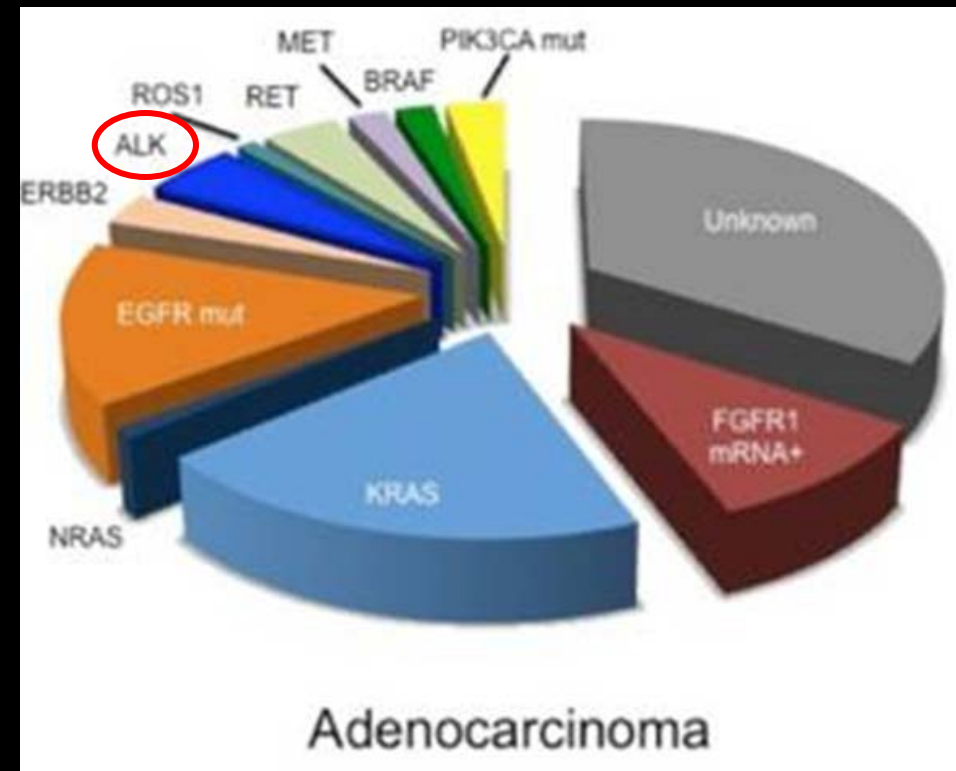
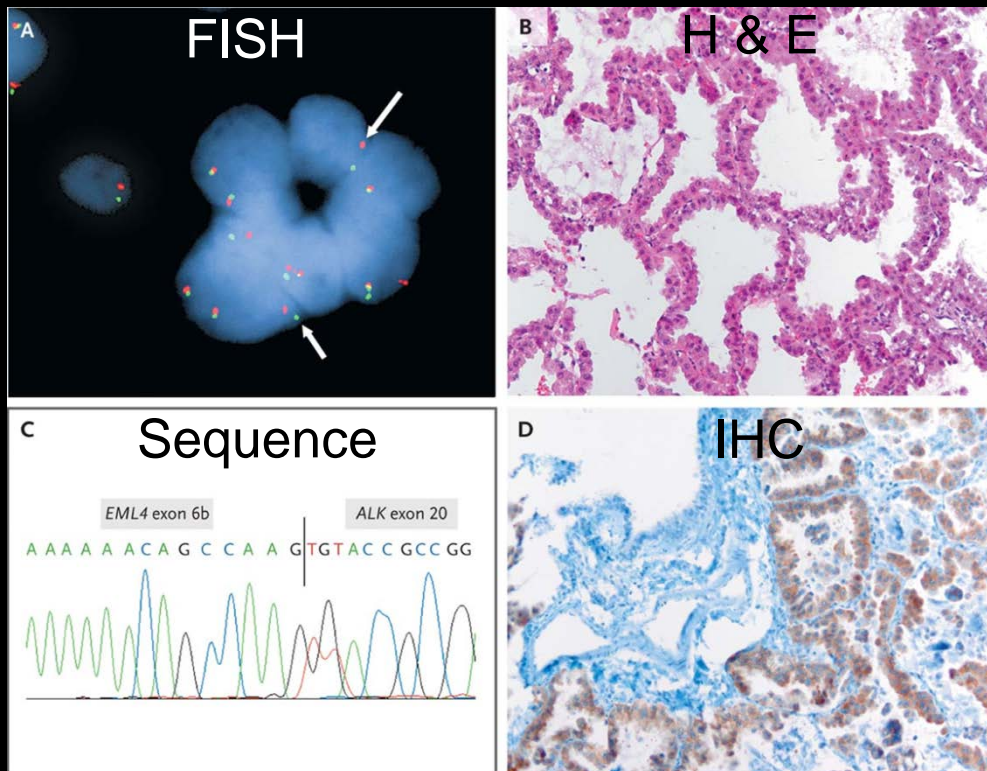


Camidge et al, TLO 2012

Why TKIs have such incredible responses in specific populations?

ALK Rearrangement as Example

EML4-ALK-Positive NSCLC



DX EML4-ALK-Positive NSCLC:

A: break-apart FISH Vysis LSI ALK Dual Color, Break Apart Rearrangement Probe (Abbott Molecular). B: H&E. C: sequence of a RT/PCR assay of *EML4-ALK*.

Panel D: IHC analysis of ALK protein expression.

Kwak EL et al. *N Engl J Med* 2010;363:1693-1703

National Cancer Policy Forum Workshop Agenda: Policy Issues in the Development and Adoption of Molecularly Targeted Therapies for Cancer (day 1)

- Overview of the Workshop
- Session 1: Challenges in developing clinical biomarker tests
 - Single analyte tests
 - NGS
 - Circulating tumor DNA
 - RNAseq test
- Break
- Session 2A: Evidentiary Standards: Regulatory Science
 - Overview of FDA Regulations for Diagnostics
 - Evolving paradigm for Companion Diagnostics and other Diagnostic Tests at FDA
 - Clinical Utility of Diagnostic Tests
- Lunch Break

National Cancer Policy Forum Workshop Agenda: Policy Issues in the Development and Adoption of Molecularly Targeted Therapies for Cancer (day 1, cont'd)

- Session 2B: Evidentiary Standards: Reimbursement
 - MolDX approach
 - Payers Perspectives
- Session 3A: Generating Evidence: Clinical Trial Designs
 - LungMap
 - Evaluation of NGS for companion diagnostics use
- Break
- Session 3B: Generating Evidence: Other Mechanisms
 - Actionable Genome Consortium
 - Coverage with evidence development
 - Facilitated drug access program and registry
 - Benefits and limitations/challenges of registries/databases
- Wrap up Day 1 and Adjourn

National Cancer Policy Forum Workshop Agenda: Policy Issues in the Development and Adoption of Molecularly Targeted Therapies for Cancer (day 2)

- Session 4: Practice Guidelines & Implementation into Clinical Practice
 - Guidelines Development
 - Treatment Pathways
 - Adoption of genomics in oncology care
 - Return of sequencing results to patients
- Break
- Session 5: The business model for test development
 - Examples
- Workshop Wrap Up
- Adjourn