Diffusion of ClonoSEQ Technology into the Clinic

Consulting Project for Adaptive Biotechnologies
As part of the coursework for MGMT 522

June 5, 2013

Road map

- Front slide
- Biz model/ canvass
- Our Data 1 (Research)
- Our Data 2 (Research)
- Gaining Traction – Moore's Technology Adoption Curve
- (1, 2, 3, 4)
  - 1st step
  - 2nd Step
  - 3rd Step
  - 4th Step….
- Cost
- Reimbursement
- Thank you

Business Model

KEY PARTNERS

- Cancer Care Hospitals
- Insurance companies
- In future if they want to contract it out, to device manufacturer
- Delivery service for assays, specimen transfer
- Key opinion leaders

KEY ACTIVITIES

- NGS for ALL
- Publish peer-reviewed studies
- Present at conferences
- Include influencers in research
- Get phase 3 clinical research trials and build database

KEY RESOURCES

- NGS for clinic
- Staff/researchers
- Partnership with labs/hospitals etc.

VALUE PROPOSITION

- More accurate than current standard of care
- Less invasive than current standard
- Lower cost of investment
- Reduce customer pain with blood testing – more frequent testing possible
- Future efficient prediction of diseases
- More beneficial for patients with more treatment options

CUSTOMER RELATIONSHIPS

- Website for quickly checking individual results
- Can be tailored to specific levels of accuracy

CHANNELS

- Website for collective data
- Storage and Transportation for specimens

CUSTOMER SEGMENTS

- Clinical Research Labs
- Clinics – SCCA (Childrens, Fred Hutch, UW Meical, SCCA)
- Clinical Trials
- Cancer centers (cancercenters.cancer.gov)

COST STRUCTURES

- Shipping, researchers, own lab staff, facility/building
- Advertisement, funding clinical trials
- Training staff

REVENUE STREAMS

- Grants
- Reimbursement from Insurance or patients

Secondary Research

Industrial Analysis	Flow Cytometry
	PCR based Tests
	Next Generation Sequencing
	Reimbursement

Primary Research - Interviews

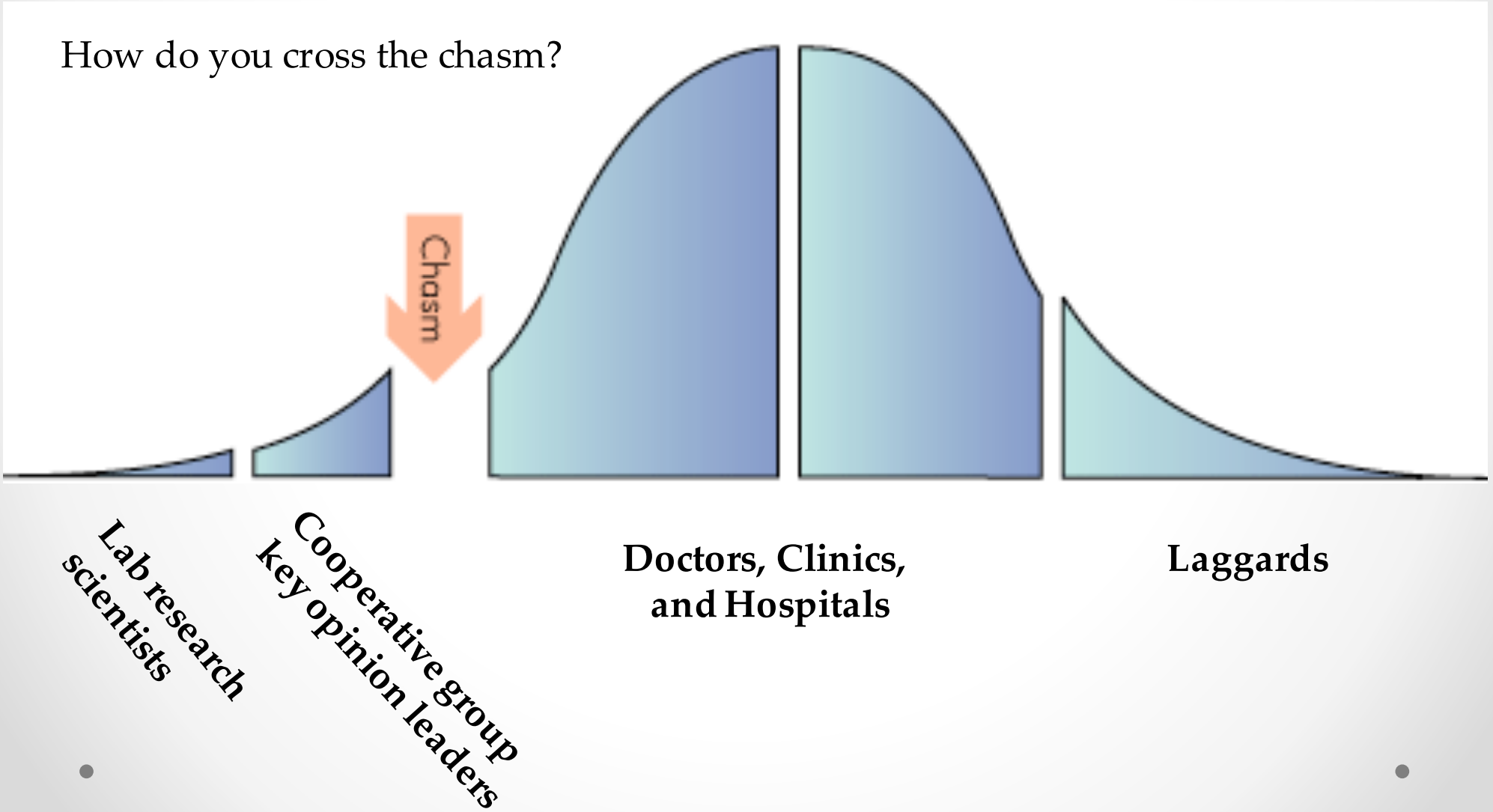
Interviewed :

- Doctors (Oncologists)
- Research Lab Scientist
- People from Corporate Groups

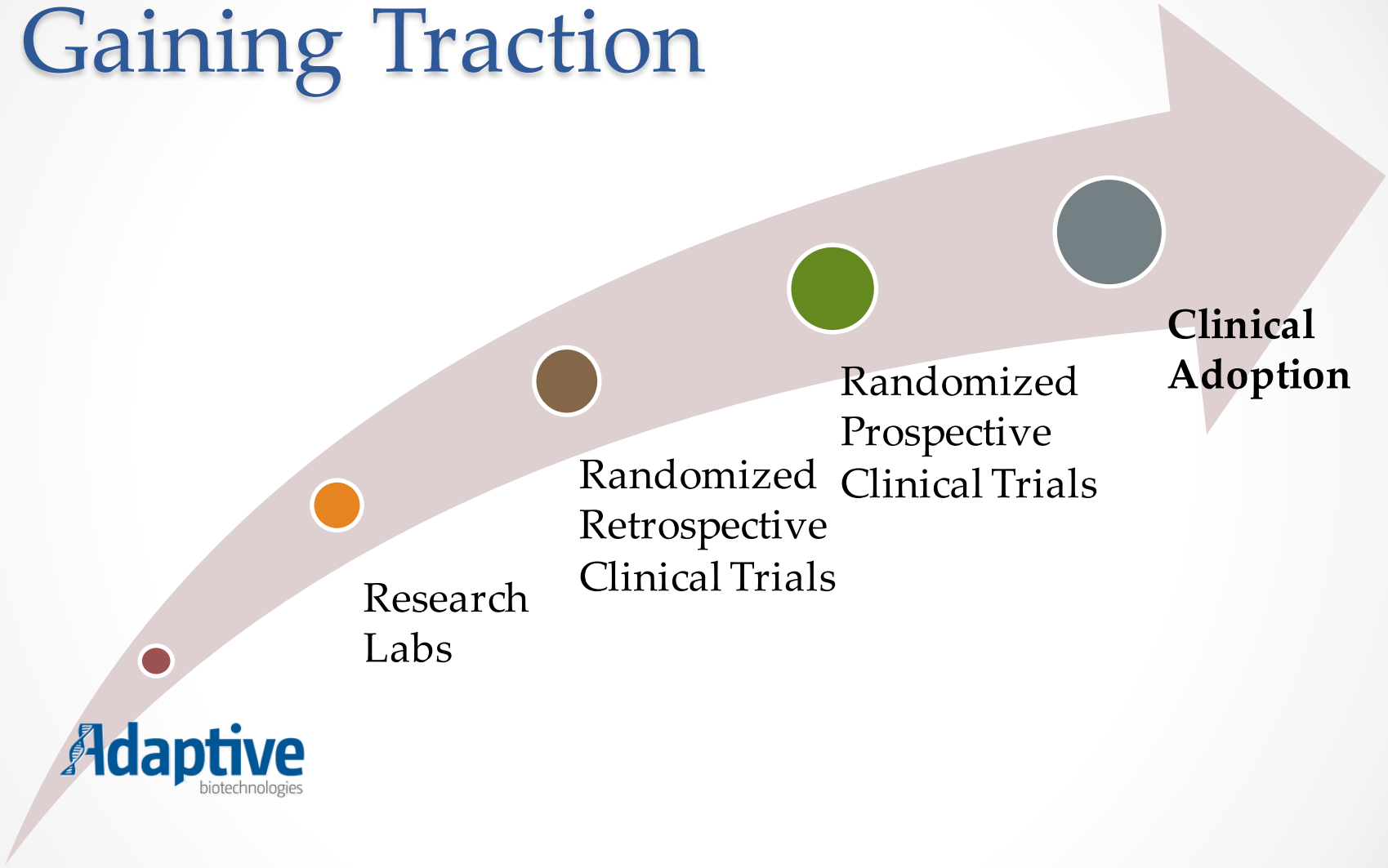
Main Aspects:

- Clinical Trials
- Price
- Timely return of results
- Interpretable results

Moore's Technology Adoption Curve



Gaining Traction



Adaptive biotechnologies

Research Labs: Innovators

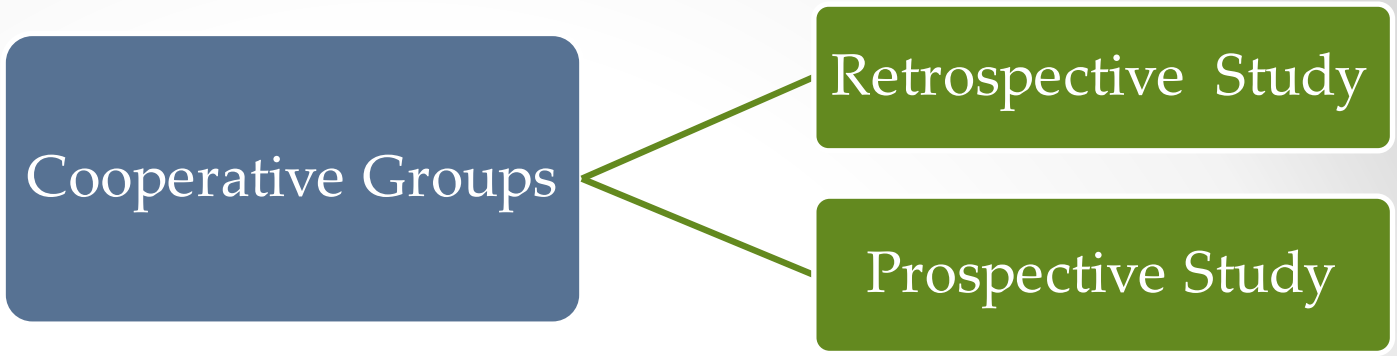
Certifications

Publications

Presentations

How to encourage adoption?	• Show the effectiveness • Discuss in person • Offer free testing
Key Players:	• Brent Wood and David Wu.

Early Adopters



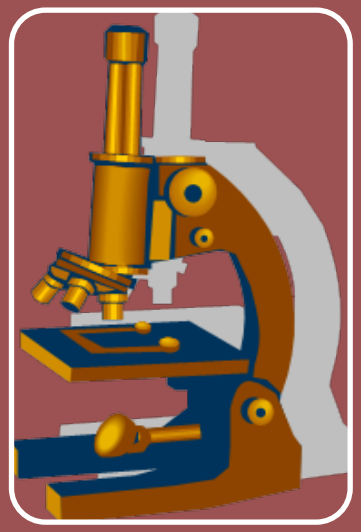
How to encourage adoption?

- Demonstrate improved sensitivity and specificity
- Show clinical correlation, if possible
- Contact the clinical trial biology chairs
- Work with researchers who are members of cooperative groups

Key Players:

- Dr. Mignon Loh at UCSF - Pediatric ALL clinical trials
- Dr. Soheil Meshinchi - UW - Pediatric AML clinical trials
- Dr. Jerry Radich at SCCA - Adult Clinical Trials with SWOG
- Dr. Pheonix Ho - Attending Physician at FHCRC, trained with Soheil Meshinchi
- MD Anderson, Memorial Sloan Kettering, MCI, John's Hopkins, St

Retrospective Clinical Trials



For access to Children's Oncology Group's tissue repository:

- ALL - Dr. Mignon Loh at UCSF
- AML - Dr. Soheil Meshinchi at UW

Prospective Clinical Trials

Institution Level - SCCA, MD Anderson

National Cooperative Groups Level - Children's Oncology Group

Advantages:

- Gain access to a large amount of patients through one organization
- Will avoid a decent amount of red tape
- Build momentum
- Increase awareness in the leukemia treatment community

Later : SCCA, Children's, Fred Hutch

Clinical Adoption

How to encourage adoption?	Complete phase three trials
	Publish results
	Present at conferences (e.g. ASH)
	Reduce price to $500-700
	Return results in 3-4 days or less
	Make results easily interpretable
	Demonstrate that results should change treatment options
	Hire product evangelists for hospitals and insurance companies
Key players:	http://cancercenters.cancer.gov/cancer_centers/index.html

Key Partners / Opinion Leaders at a glance…

- Research scientists involved in clinical trials
- Leukemia society, Foundations interested in diagnosis and treatment
- Research Labs - David Wu (Brent Wood Lab)
- Pediatric ALL - Mignon Loh at UCSF
- Pediatric AML - Soheil Meshinchi – UW
- Adult Clinical Trials - SWOG - Dr. Jerry Radich
- Dako and Genomic Health

Cost

Flow Cytometry: $300 - $500

$$$...

People think Adaptive costs $1000 - $1500

Reimbursement

Initially – invest own money

Look into Grants

Then, Insurance.

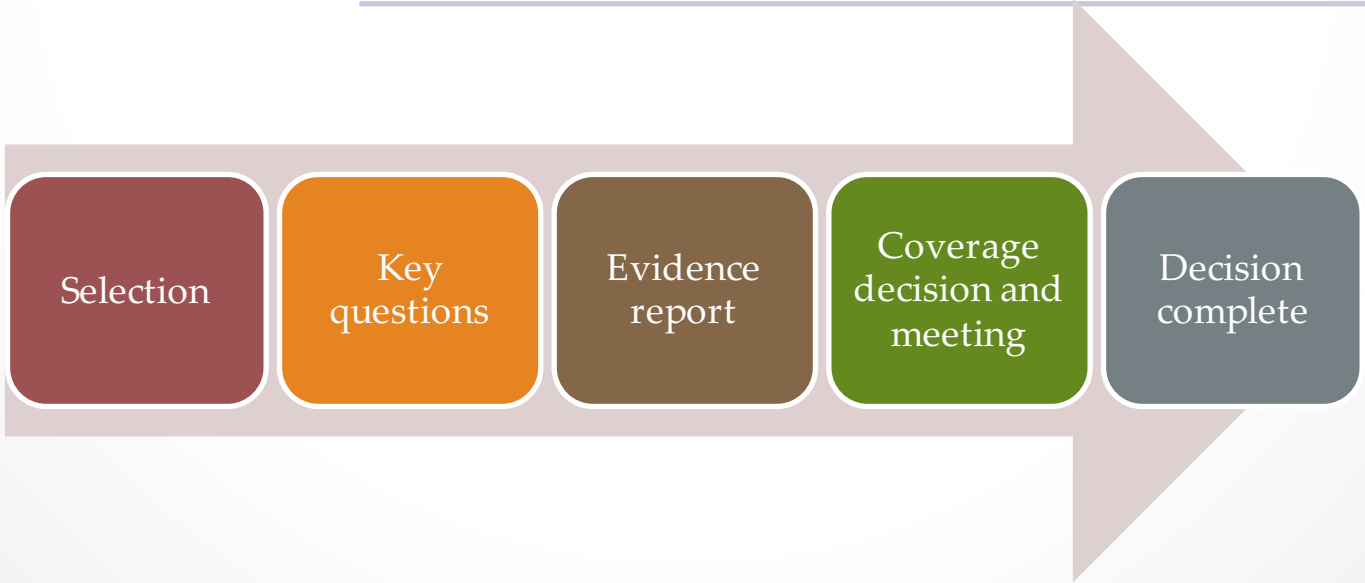
Adults vs children – sympathetic nature

Insurance Coverage

Health Technology Assessment Program (HTA), WA State Health Care Authority

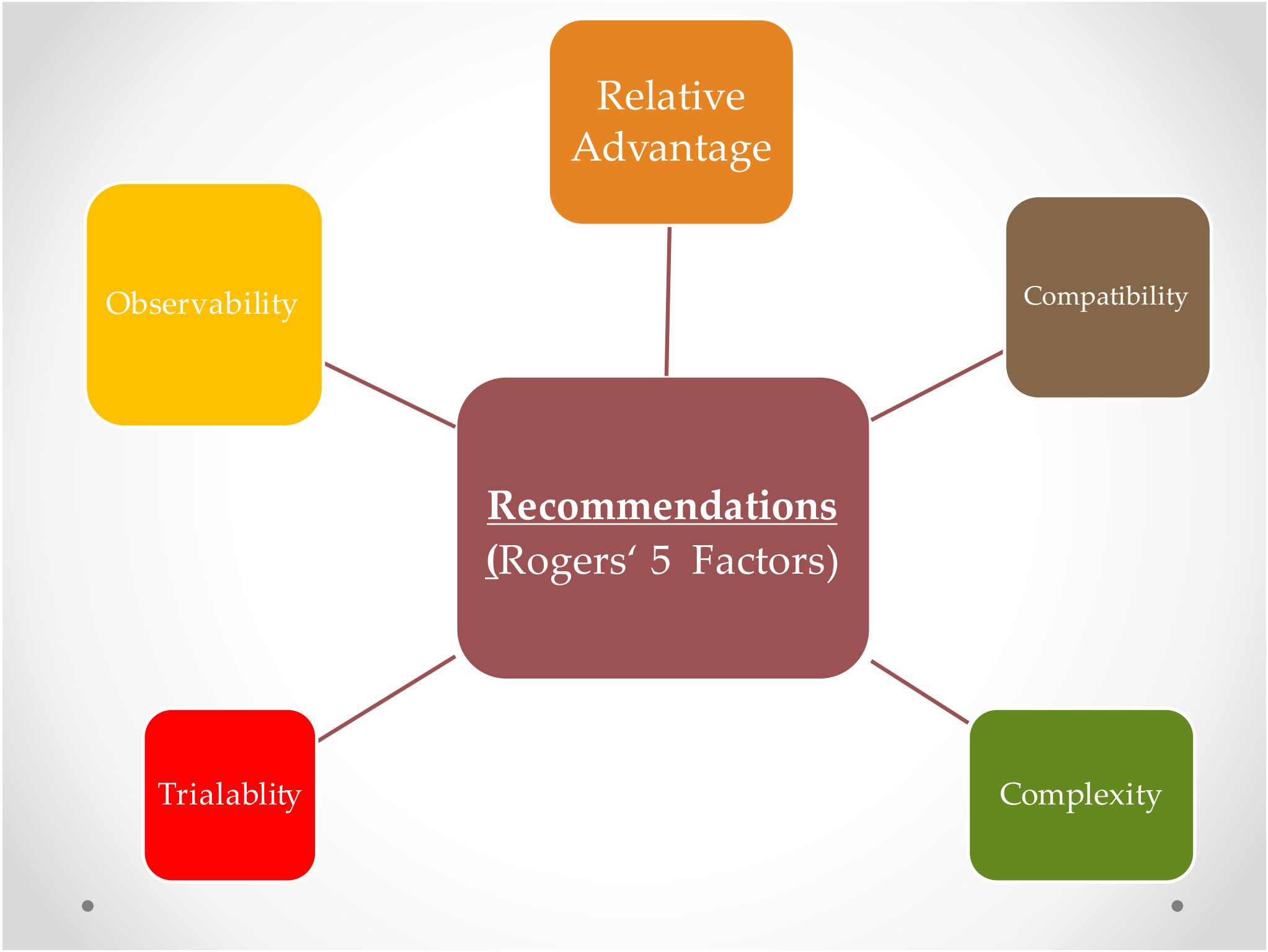
Three main assessment criteria HTA considers:

- Safety
- Efficacy
- Cost-effectiveness

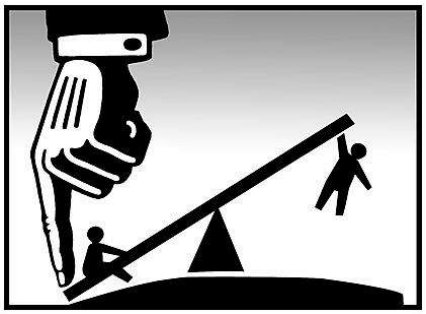


Insurance Coverage

U.S. Preventive Services Task Force	**Assessment criteria**	Effectiveness, measured by the balance of benefits and harms
		Cost-effectiveness of preventive services will not be evaluated


Relative Advantage
Observability
Compatibility
Recommendations (Rogers' 5 Factors)
Trialablity
Complexity

Relative advantage

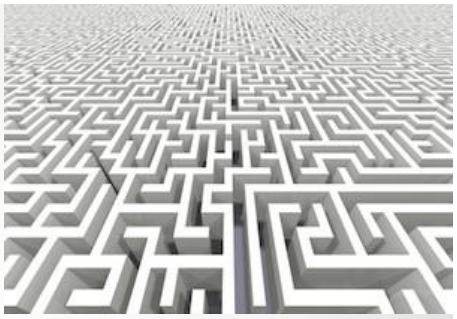


- Publications, clinical trials, and medical correlation
- Prove that MRD test can be done on only blood
- Cost needs to be $500-700
- Return of results in 3-4 days or less

Compatibility

- Workflows exist for sending out samples for testing
- Additional bone marrow will NOT need to be extracted
- Include other prognostic genetic testing along with clonoSEQ results.

Complexity



- Convincing doctors of the relative advantage
- Data analysis and result interpretation needs to be extremely straightforward

Trialability

- Provide testing to research labs for free
- Pay for clinical trials testing
- Offer deals to hospitals to gain customers with little risk to them
- Apply for research grants to make this more affordable

Observability

- Advertise through conferences, presentations, publications, and clinical trials
- Quickly win over key opinion leaders within national cooperative groups
- Provide access to the database of immuno-profiles

Additional Considerations, Risks and Pitfalls

What aspects of Adaptive's technology requires FDA approval?

Will clinicians and technicians need to be trained to interpret results?

Cancers with relatively high survival rates, like ALL, may not be a priority moving forward for researchers that are constrained by the sequester.

Clinical trials is a slow process and SEQUENTA has already performed ~10 clinical trials last year.

The cost must be comparable to flow cytometry.

Clinicians are not likely to stop using flow cytometry for the initial diagnosis of the cancer, because doctors want the results back in under 24 hours.

However, in order for ClonoSEQ to be useful for MRD on day 29 and beyond, clinicians will need to order it on Day 1 in addition to flow cytometry.

References

Flow Cytometry Test Details, Requirement and Turnaround Time;	http://pathlabs.ufl.edu/tests/flow-cytometry-on-aspirate-with-or-without-bone-marrow-biopsy http://www.uams.edu/clinlab/flow.htm
Limited Resources for ALL Research (Section D, implementation, barriers to entry)	http://onlinelibrary.wiley.com/doi/10.1002/pbc.24399/full
Insurance Coverage	www.hta.hca.wa.gov www.uspreventiveservicestaskforce.org
Leukemia Misdiagnosis Rate	http://www.mdanderson.org/patient-and-cancer-information/cancer-information/cancer-types/leukemia/index.html
Cancer Prevalence	http://www.asuragen.com/Diagnostics/US/Educational_pages/leukemia.aspx http://www.lls.org/diseaseinformation/leukemia/
Sequenta clinical trials	http://sequentainc.com/sequenta-launches-clonosight-first-sequencing-based-minimal-residual-disease-test-for-leukemia-and-lymphoma/

Thank you!