





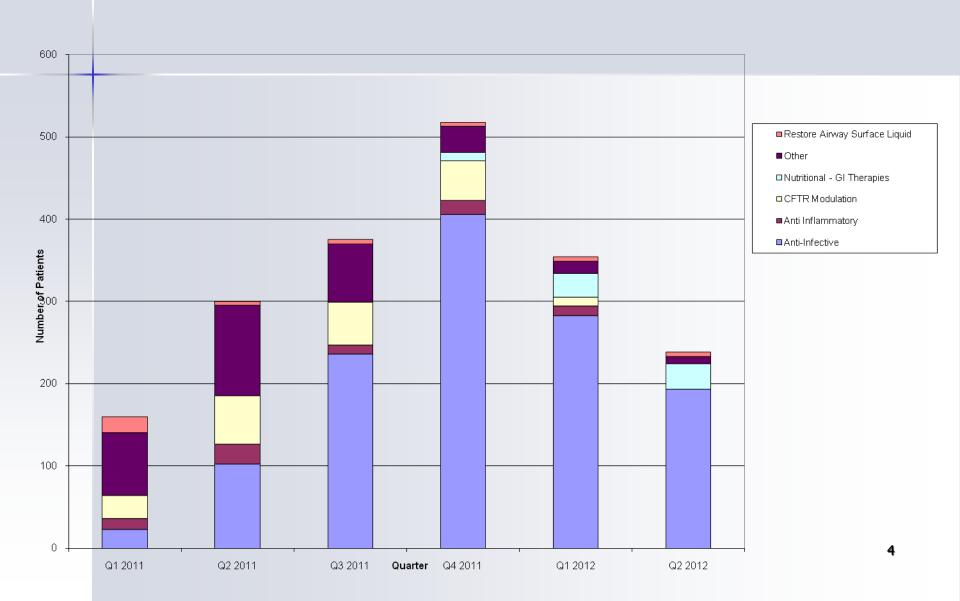
Davies, Zoe; Dunn, Colleen; Hernandez, Cathy; Zirbes, Jacquelyn; Milla, Carlos; Moss, Richard.

Therapeutics Development Network

- Established in 1998
- 7 sites
- 1999 Stanford
- 2009 77 total
- Translational Research Center
 - 12 sites

Cystic Fibrosis Foundation Therapeutics Pipeline Gene Therapy COMPACTED DNA POTENTIATOR VX-7 **CFTR** Modulation CORRECTOR VX-809 HYPERTONIC SALINE DENUFOSOL **Restore Airway** BRONCHITOL **Surface Liquid** MOLI 1901 GS9411 Mucus PULMOZYME Alteration **IBUPROFEN** ORAL N-ACETYLCYSTEINE Anti-INHALED GLUTATHIONE Inflammatory **KB001** SILDENAFIL GSK SB 656 933 TOB AZITHROMYCIN CAYSTON TIP (TOBRAMYCIN INHALED POYDER **Anti-Infective** MP-376 ARIKACE GS 9310/11 BAY Q3939 **Transplantation** INHALED CYCLOSPORINE AquADEKs Nutrition PANCRELIPASE PRODUCTS LIPROTAMASE PHASE 3 **AVAILABLE PRE-CLINICAL** PHASE 1 PHASE 2 **Initial Testing in Laboratory Human Safety** Human Safety & **Definitive Trial** TO Trial **Efficacy Trial PATIENTS** February 10, 2011

Current Projections



Background Information

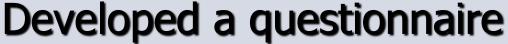
- Seasoned research team
- Good reputation
- Mentors
- What's our secret?
- How can we improve?

Success Hypothesis:

Participants enjoy their research experience

Why?

- Relationship
- Close follow up
- Easy access to the team
- Early access to drugs
- Altruism
- Money



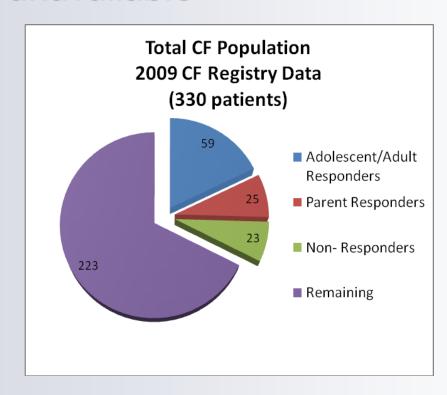
- 28 questions
- 5 categories:
 - Overall Research Experience
 - Research Process
 - Research Procedures
 - Research Environment
 - RC Professionalism
- Several open ended questions
- General comments



Stanford Database Search: 330 Stanford CF patients 107 patients eligible to participate

- 84 completed
 - 25 parent, 59 adolescent/adult
- 23 unavailable







Overall Results:

Stanford Study Subjects:

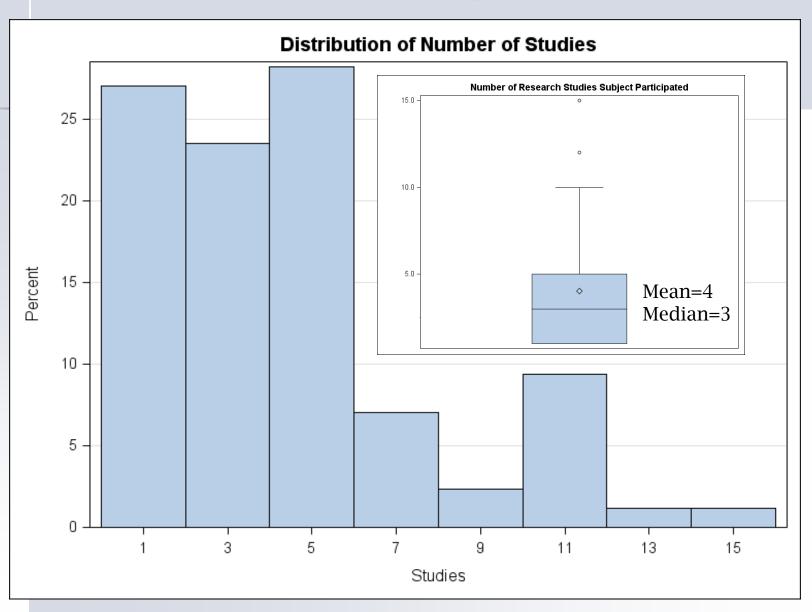
- satisfied
- safe



- well cared for
- experience was worthwhile



Stanford Research "Repeat Offenders"



How satisfied subject was with research experience correlated with repeated research participation



Factors that Correlated the Strongest with Level of Satisfaction with Research Experience

- Time to consider participation
- No pressure felt during enrollment
- Adequately compensated
- Center fosters research awareness and participation
- Working with research coordinators as an incentive

All Spearman's $\rho > 0.4$ p < 0.001

Factors also correlated with level of satisfaction but less strongly

- Well cared for
- Worthwhile experience
- Adequately informed
- Questions addressed
- Thank you letter
- Studies were available quickly
- Visits accommodating
- Time well utilized
- Knowledgeable RC's

Areas for Improvement

- Adequate compensation
 - Education of patients/families.
- Clinic staff to foster research participation
 - Continuing education of clinic staff.
- Studies to open for enrollment in a timely manner
 - Continue efforts to streamline contract/budget process.
- Some recruitment strategies found not helpful
 - Develop new recruitment strategies.

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