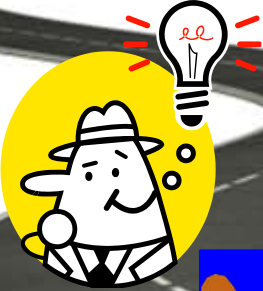


A Road Map for Conducting Clinical Research

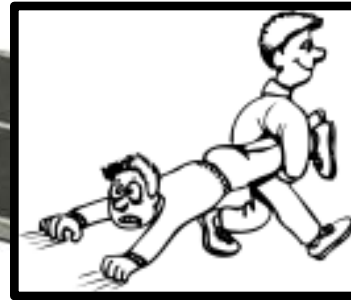
Alexandra L. Quittner, PhD
University of Miami

Road Map for Conducting Clinical Research

1. Good Idea!



2. Planning 3. Training



4. Recruitment



5. Implementation & Quality Control



6. Marathon vs. Sprint



The iCARE Study

I Change Adherence & Raise Expectations



Planning

- Identifying funding sources
- Feasibility
 - Sample size calculations



- <http://department.obg.cuhk.edu.hk/researchsupport/statstesthome.asp>

- Personnel
- Equipment
- Pilot all procedures
- Manual of Procedures (MOP)
- IRB / Ethics submissions



The iCARE Study

I Change Adherence & Raise Expectations

Alexandra L. Quittner & Kristin Riekert



Planning & Funding Phase

- Pis had each planned a large scale adherence intervention trial
- CF Foundation was interested in both;
 - concerned about competition for pts.
 - confusion amongst centers
- Partnered to test both interventions in a cluster design
- Now we had 3 sources of funding!

Study Design

- **PI' s: Quittner & Riekert**
- **Sponsors: CFF, Genentech, Novartis**
- **RCT**
- **Translational Study**
- **Cluster design – 21 CF centers**
- **2 groups – enroll 720 adolescents**
 - **iCARE Adherence Dashboard**
 - **Comprehensive Adherence Program (CAP)**
 - **iCARE Adherence Dashboard**
 - **Training in behavioral, Problem-Solving intervention**

Study Design

Sites with IRB approval
(n = 21)

Randomized

Site drop
out

CAP Sites

Dashboard Sites

Site drop
out

Baseline Assessment

Baseline Assessment

12-month Assessment

12-month Assessment

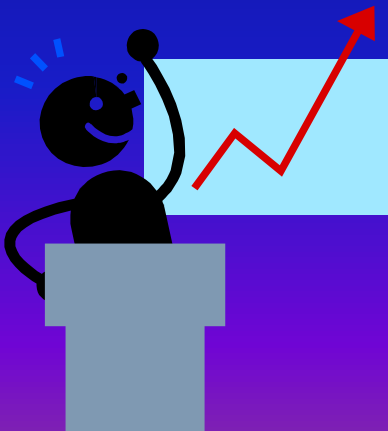
24-month Assessment

24-month Assessment



Training

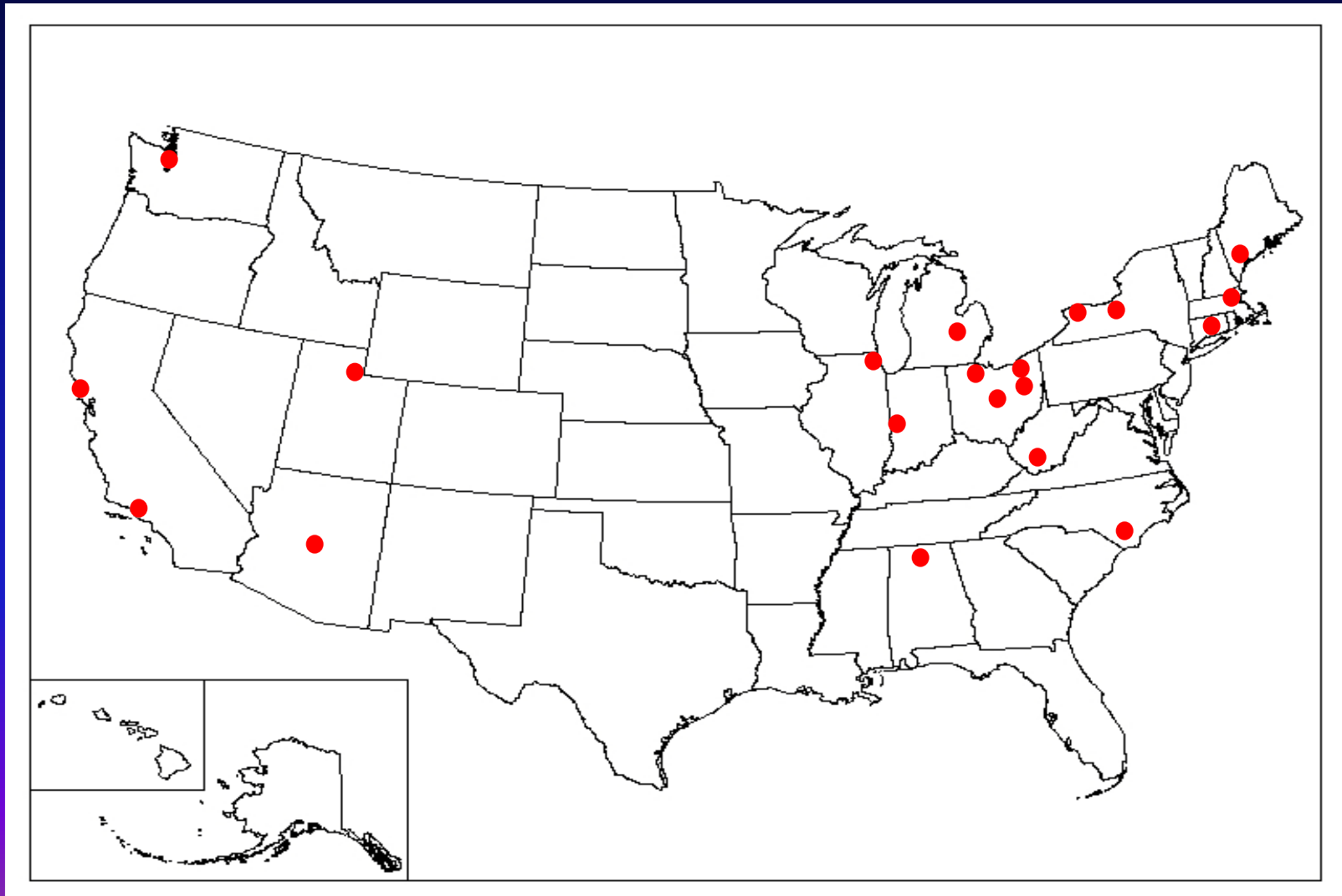
- Group meeting
- Motivate & excite!
- Establish collaborative relationships
- Revise MOP
- Amendments to IRB



Training

- **First kick-off meeting—luncheon @ NACF**
 - Sponsored by CFF (also covered night in hotel)
- **Provided 20 CF Centers with training on procedures**
- **MOPs for each sites**
- **2 laptops programmed with measures**

Nationally Representative Sample



Training in Problem-Solving

- **Personal visit to each CAP center**
 - Meet with entire team for 1.5 hours
 - Overview of rationale for study
 - Evidence-base for intervention
 - Study Design & Procedures
 - *We want “buy in” to change clinical care*
- **2 hour training with “adherence champions” —those who will do PS**
 - Videos, role-plays, discussion

Recruitment

- “Buy In” from clinics, CF Teams, patients
- Creative strategies
 - Logo for study
 - Newsletters
 - Website announcements
 - Social media
 - Clinic email list
 - Incentives



Picture of clinic



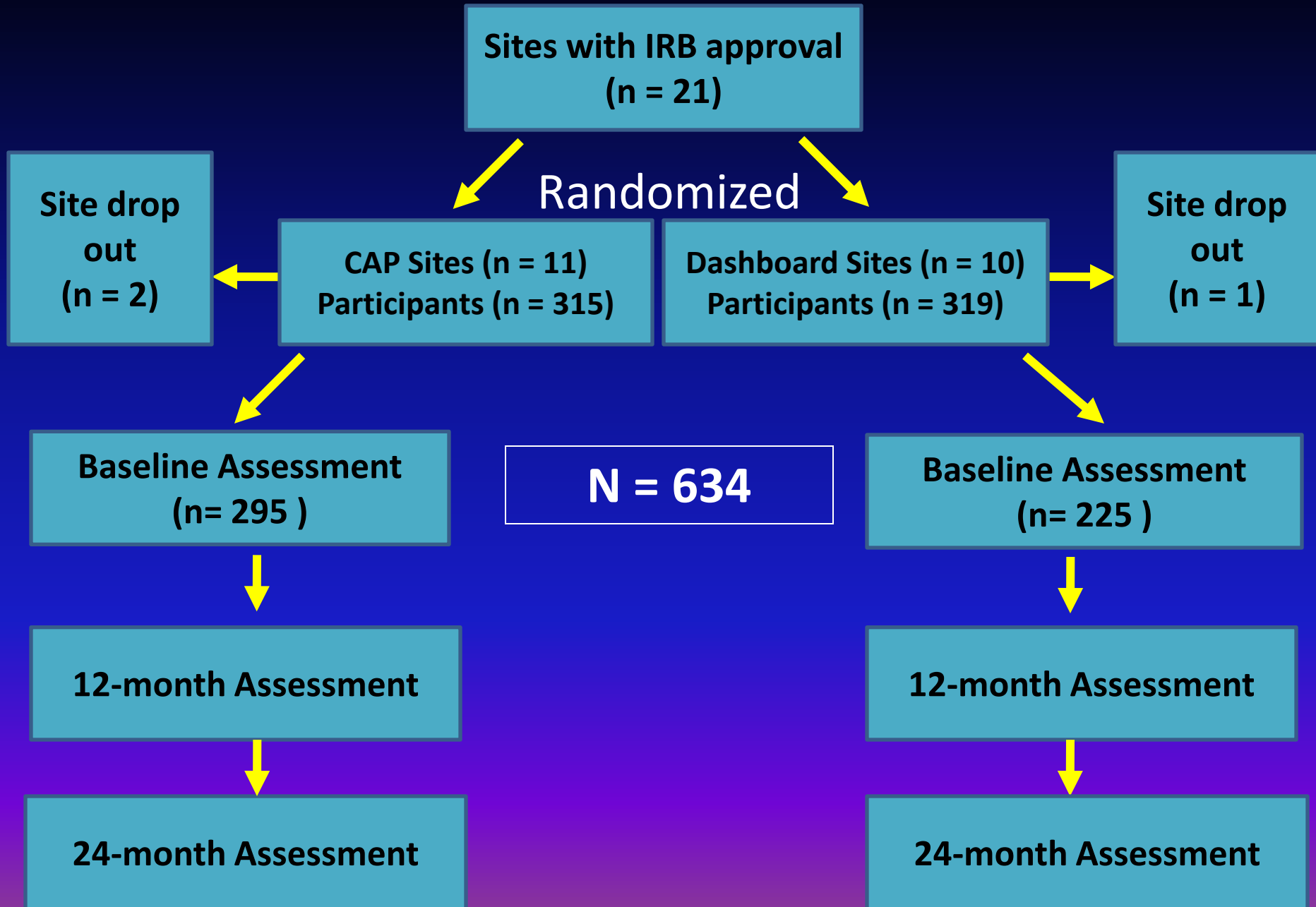
My Reason:
Helping patients
become more adherent

My Way:
Not interrupting
this private session

 My Way

FOUNDATION

Study Design



Patient Characteristics (*n* = 513)

	<i>n</i>	%	M (SD)	Range
Age (years)	513		14.49 (2.6)	11-21
Sex				
Female	278	54.1%		
Male	230	44.7%		
Missing	6	1.2%		
Race				
White	459	89%		
African American	18	3.5%		
American Indian	11	2.1%		
Alaska Native	2	0.4%		
Other	6	1.2%		
Refused	4	0.8%		
FEV₁ % predicted	403		85.18 (22.11)	21-141
BMI %ile	417		46.78 (26.75)	<1-98.5

Knowledge of Disease Management

Adolescents % correct

Domains	<i>N</i>	<i>M (SD)</i>	Range
Lung health	513	85.13 (14.30)	36.36-100.00
General health	513	78.52 (18.74)	20.00-100.00
Treatments	513	77.83 (17.57)	28.57-100.00
Nutrition	513	68.76 (15.47)	13.33-100.00

Knowledge of Disease Management: *Adolescents*

Question

% incorrect

14. The foods that contain the most energy are:

89%

- a. Fats
- b. Carbohydrates
- c. Proteins

Parents

30. Foods that contain the most energy are:

85%

- a. Fats
- b. Carbohydrates
- c. Proteins

Treatment Skills: % correct

(n = 1-488 based on prescription)

<u>Medication/treatment</u>	<u>n</u>	<u>M (SD)</u>	<u>Range</u>
Turbuhaler®	14	94.64 (7.74)	83.30-100.00
Enzymes	439	94.21 (12.40)	0.00-100.00
DPI	73	89.91 (14.02)	36.36-100.00
PEP	4	88.89 (15.71)	66.67-100.00
CPT	33	86.01 (19.27)	30.77-100.00
Vest	424	80.87 (16.22)	0.00-100.00
Nebulizer	488	80.01 (18.37)	0.00-100.00
MDI with spacer	272	78.14 (19.56)	0.00-100.00
MDI	149	68.56 (19.67)	0.00-100.00
Acapella®	118	67.60 (22.82)	0.00-100.00
FLUTTER®	58	50.82 (29.78)	4.76-100.00

Implementation & Quality Control

- Database creation
- Periodic checks of data quality
 - Missing data
 - Errors collecting data (e.g., skipping pages)
 - Tracking data collection
 - Supervision



We Monitor & Change Things all the Time!

- Ceiling effects in one measure @ Baseline updated those items to ensure better measurement properties
- Sending postcards with fun pictures to remind centers to do PS sessions during Generalization Phase

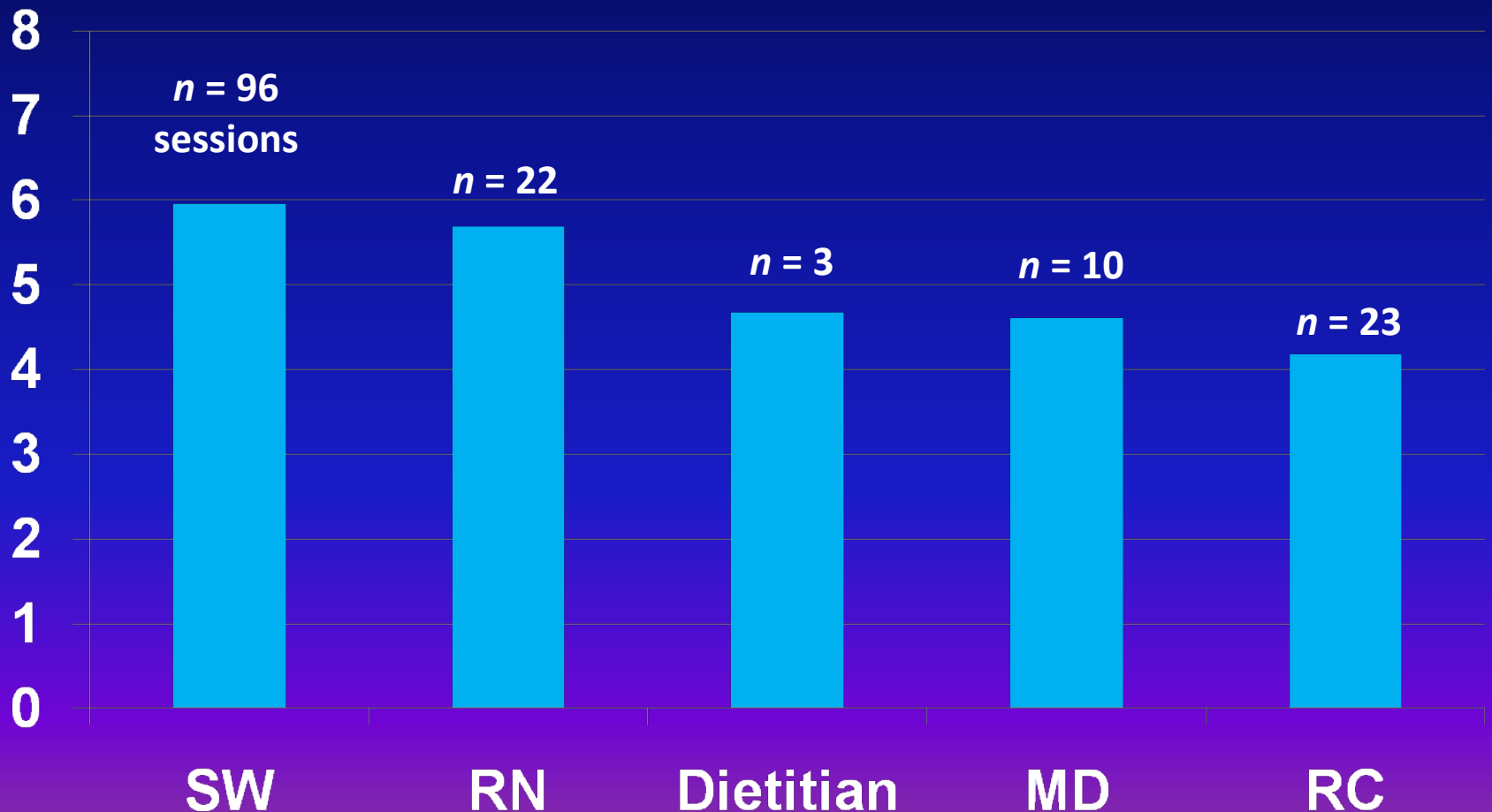


Supervision & Fidelity of PS

- **Behavioral interventionist videotapes 1st PS session with each teen/parent**
- **Tape is sent to University of Miami & reviewed by PhD**
- **Tape is coded for treatment fidelity**
- **Phone supervision scheduled**
- **Supervision provided for each taped PS session**

Fidelity Implementing PS Intervention

Average Fidelity Score



Finish Line

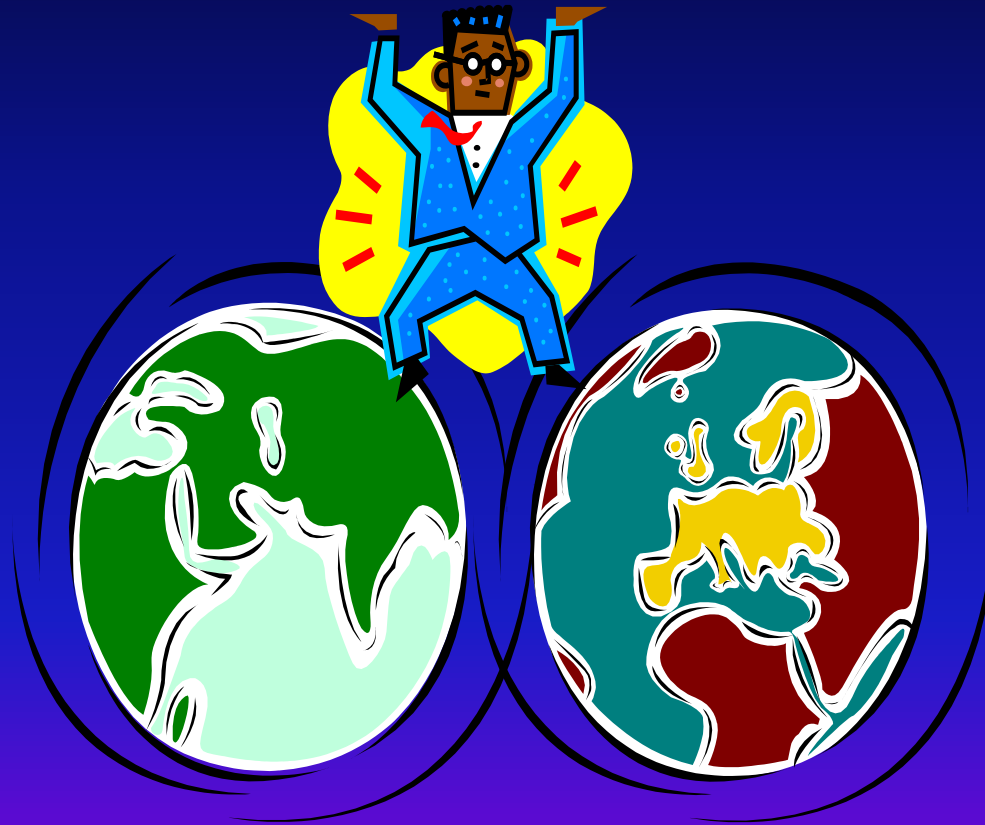
- Complete data collection
- Clean data
- Run Analyses
- Dissemination
 - Conferences
 - Publications
 - Translate to clinical care



VS.



Important Differences between Behavioral & Medical Research



Need More \$ Than You Think!

- Interventions delivered in-clinic are time-intensive, personnel-intensive
- Most medical centers are earning \$ on pharma studies; this was a fraction (1/10) of usual \$
- Medical Team has to be invested and care about their patients (“buy in”)

Behavioral Studies—Not Easier!

- Medical centers are practiced in drug studies
- Assumption that *behavioral* studies are easier (no blood draws)
- *Does* require their time & effort
- Clinic space & “flow” (\$\$)
- Clearly less profitable
- Myth that all HCPs know how to *change* behavior!

Falling Off the Cliff of Translational Research—



Translational Does Not Mean *Just* the Setting!

- We are conducting PS sessions with 315 teens in Year 1-2, and 315 teens in Years 2-3 (PhD too expensive!)
- Must train HCPs to deliver intervention (MSWs, MDs, RNs, RTs, etc)
- Variable training in their specialties
- Limited counseling skills (rapport, empathy)
- Almost no formal training in how to ***change behavior***

Positive Comments!

- RTs renamed study “eye-opener” and have convened national discussion about poor skills in airway clearance and inhaled meds
- CF Teams reporting that adolescents come to clinic asking, “Do I get to do a problem-solving session today?”
- Physician at Boston called about teen and her vitamin levels!!
- Many lessons learned.....and more coming!

Thank You!
It works better with a team!



People with CF and their families!