



# **Leveraging the Internet to Extend Capabilities and Reduce Costs in Health-related Research**

**H Timothy Bunnell**  
**11/6/2013**

# Overview – Three Case Studies

- **Streamlining Clinical Trials**

- NIH-funded project to compare a streamlined procedure to standard clinical trial procedures

- **Facilitating Healthcare Delivery**

- Nemours internally-funded project to use web-based services and dashboards to enhance care of obese pediatric patients

- **Enhancing Assistive Technology**

- NIH (STTR) project to commercialize lab-developed personalized speech synthesis technology

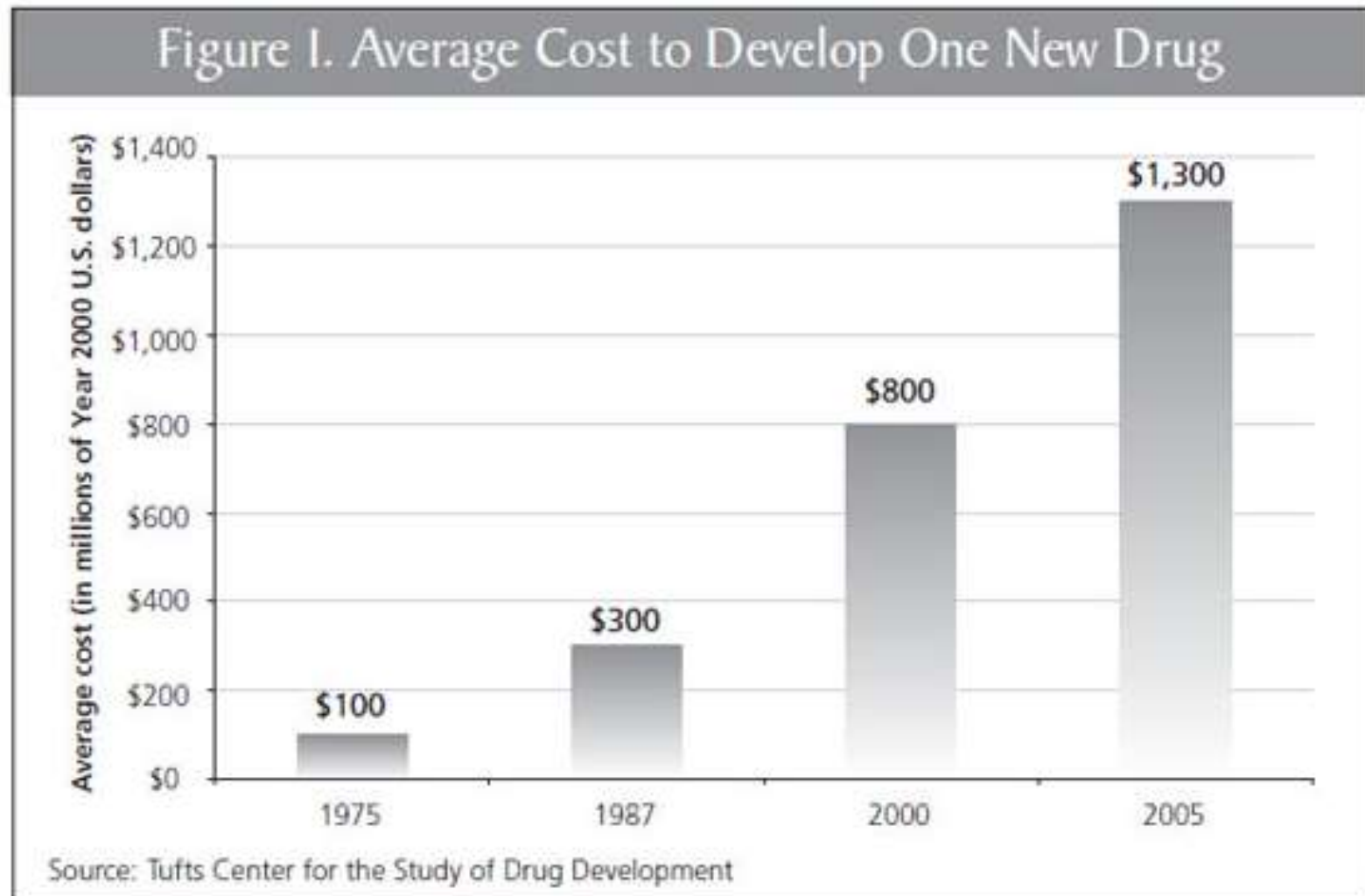
# **Use of Mobile Devices and the Internet to Streamline an Asthma Clinical Trial**

**Kathryn Blake, PharmD  
Principal Investigator**

# **In Response to an NIH RFA:**

## **Pilot Studies to Develop and Test Novel, Low- Cost Methods for the Conduct of Clinical Trials (R01) RFA-HL-12\_019**

# High Costs of Clinical Trials



# And it gets worse...

- **2011 - \$5.8 Billion per drug**
- **Largely due to Clinical Trial costs**
  - 350% Increase since 2005
  - \$47,000 per participant in a trial
  - 83% Increase since 2008

# Challenges Being Addressed

## ■ Focus

- ✓ minimize specialized infrastructure
- ✓ minimize visits
- ✓ explore novel methods of obtaining patient consent
- ✓ employ low-cost methods of monitoring study conduct such as adherence
- ✓ test the feasibility of the design in a clinical trial

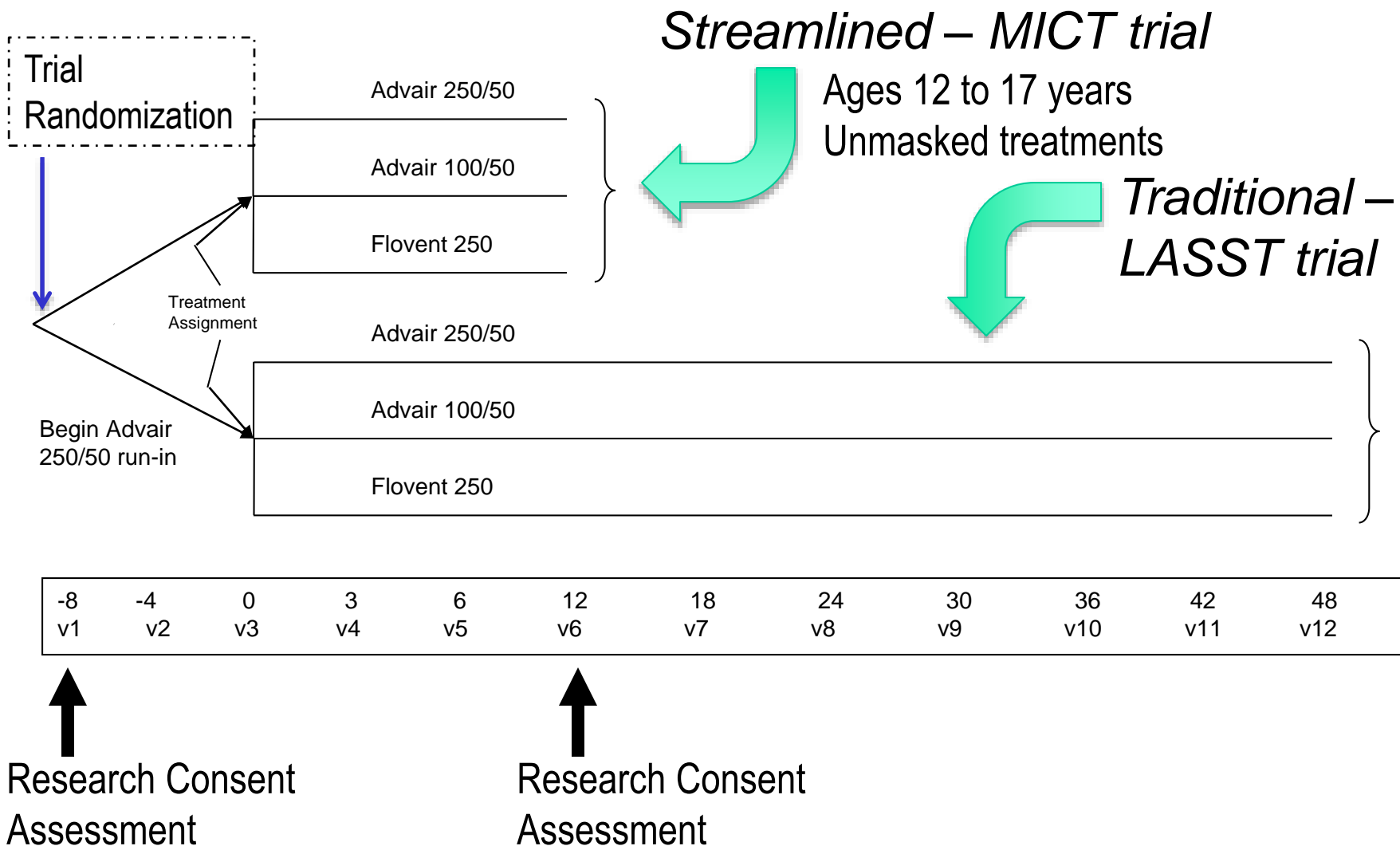
Investigators are encouraged to utilize a team approach: expertise in clinical trials, systems engineering, bioinformatics, computer programming as well as disease experts.

# Goals

- **Long-range goal**
  - transform the paradigm of clinical research by capitalizing upon widely used mobile electronic means of communication and information transfer
- **Immediate goal**
  - to compare a streamlined approach to conducting a clinical trial with a traditional multi-center clinical trial conducted concurrently by the American Lung Association Asthma Clinical Research Centers network



# Design



# MICT Trial: Streamlined Design

Advair 250/50

Advair 250/50

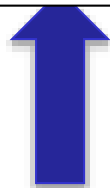
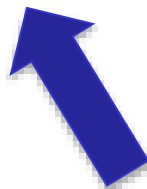
Advair 100/50

Flovent 250

|          |          |         |         |         |                |
|----------|----------|---------|---------|---------|----------------|
| -8<br>v1 | -4<br>v2 | 0<br>v3 | 3<br>v4 | 6<br>v5 | 12 weeks<br>v6 |
|----------|----------|---------|---------|---------|----------------|



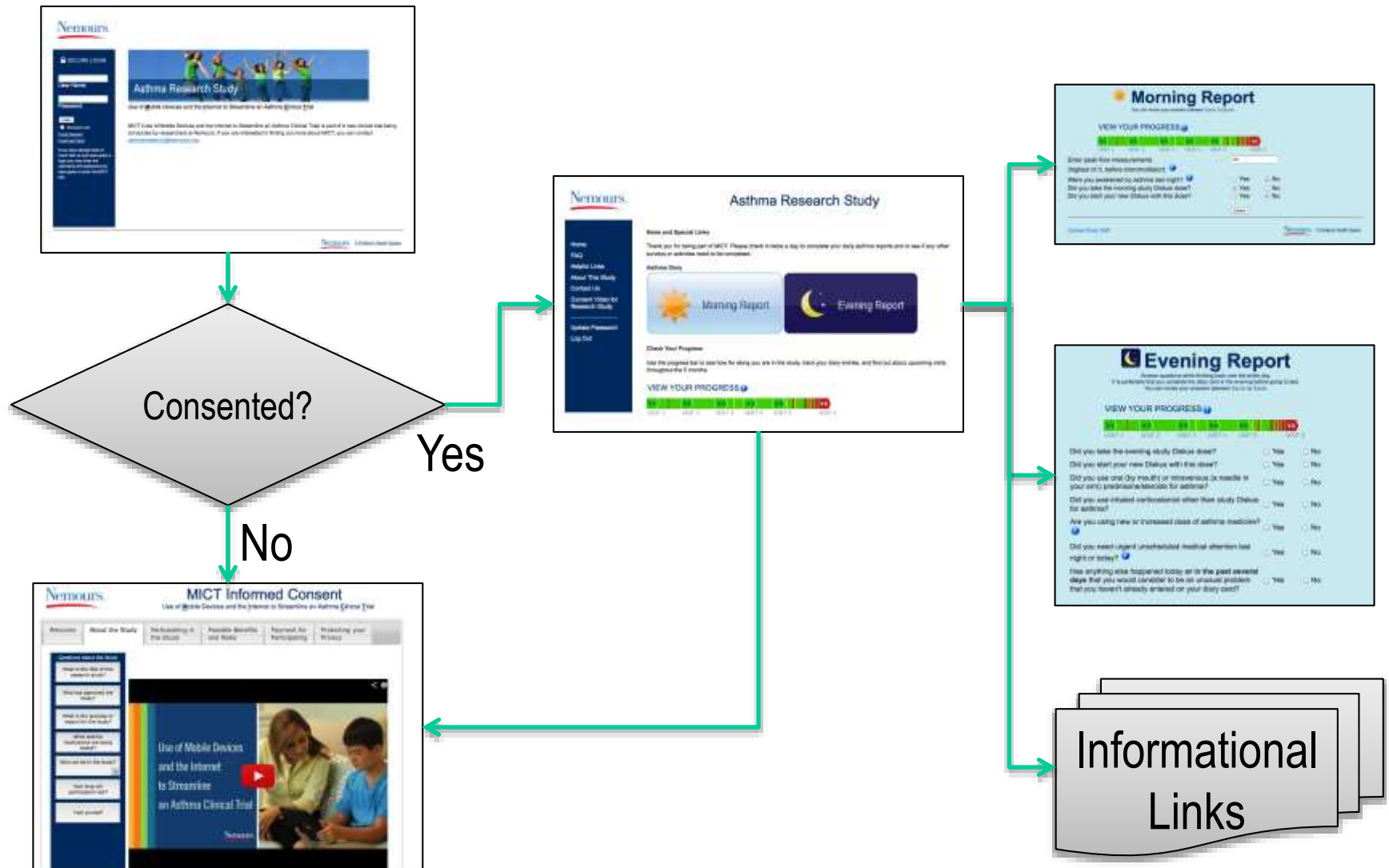
Clinic Visit



Clinic Visit

Virtual Visits using  
iPad with Face Time

# The whole process



# Behavior Triggers

- **For morning report:**

1. less than 10 of the last 14 days have been completed
2. not completed 2 days in a row
3. dose not taken 2 days in a row

- **For evening report:**

1. completed less than 10 of the last 14 days
2. not completed 2 days in a row
3. dose not taken 2 days in a row
4. missed 7 or more doses in the last 28 days

# Study Site



## Asthma Research Study

Use of Mobile Devices and the Internet to Streamline An Asthma Clinical Trial

 SECURE LOGIN

User Name

Password

Login

☐ Remember me?

[Forgot Password](#)

[Forgot User Name](#)



This study is part of a new clinical trial being conducted by researchers at Nemours.

For more information contact:

800-SOS-KIDS (800-767-5437) extension 55-3925

904-697-3925

[asthmaresearch@nemours.org](mailto:asthmaresearch@nemours.org)

 A Children's Health System

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# Challenges

- **Not everyone has home internet connection**
  - We are supplying in this study
- **Authentication process is cumbersome**
  - Must work with separate site to “Sign” Consent
  - Our IRB is pleased with the solution
  - Users may be less so.

# Collaborators

## Overall Project

- Tim Wysocki, PhD
- Mary Ward, RN
- Janet Holbrook, PhD (JHU)
- Dave Shade, PhD (JHU)

## Web & Informatics

- Suzanne, McCahan, PhD
- Chris Pennington, MS
- Yang Li, MS
- Kathleen Norton
- Ferdie Martinez
- Terri McAninch

# **Guiding Care of Pediatric Obesity Patients**

**Sandra Hassink, MD**  
**Principal Investigator**



# Broad Objectives

- **Provide real-time role-specific access to healthcare data in the context of a specific area of care (pediatric obesity):**
  - Provide treatment outcome measures and decision support for physicians
  - Provide individualized feedback and encouragement to support patient participation and compliance
  - Provide tools for physicians assistants or health coaches to interact frequently with large numbers of patients.
- **Serve as a model for utilizing technology to leverage large-scale (population level) data views for improved individual-level care.**

# Implementation

- **Provide a central database that integrates information from multiple sources (EMR, patient, physician, health coach)**
- **Create ‘dashboards’ to present views of these data that are tailored to the needs of the patient, physician, and health coach.**
- **For research purposes, provide extensive usage tracking, allowing us to:**
  1. Identify usage patterns for participants and data elements
  2. Relate usage to outcomes
  3. Inform future development.

## Nemours.



# Obesity Study Physician Dashboard

User: Sandra Hassink  
Date: January 7, 2013

[Logout](#)

# of Patients: 6  
# of Visits: 11

- Hover over a Subject ID in the legend to highlight that subject's data.
- Hover the mouse over a data point or bar to see information about it.
- Click on a line or legend to see detailed data for that Patient

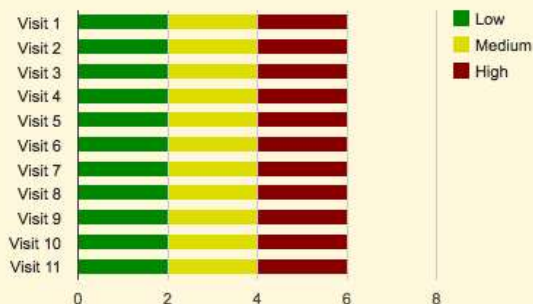
BMI at Each Visit



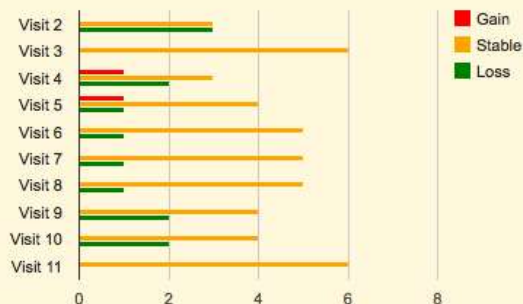
Charts show detail when the mouse hovers on a data point.

Clicking on a patient's data brings up an extended patient detail screen as shown in the next slide.

Number of Patients in each Risk Group



Number of Pts with BMI Gain, Stable, or Loss



Change over time for population of pts under this PCP's care.

MOVE CLOSE

## Dashboard

[Logout](#)

Participant: Patient Eight

Last visit: 2011-10-20

Next visit: 2011-11-20

Risk group: High

Goal 1: Eat less take-out, restaurant, or fast food

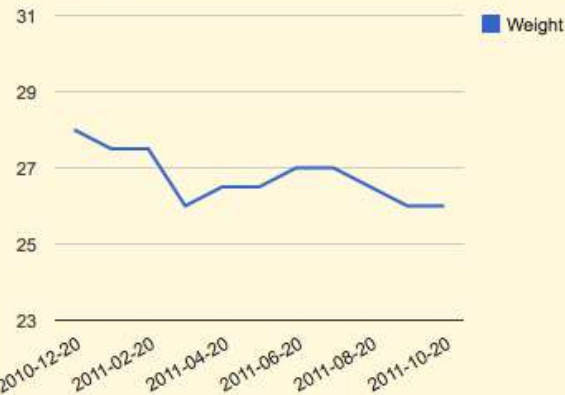
Goal 2: Eat meals at regular times

Goal 3: Be physically active at least 1 hour a day

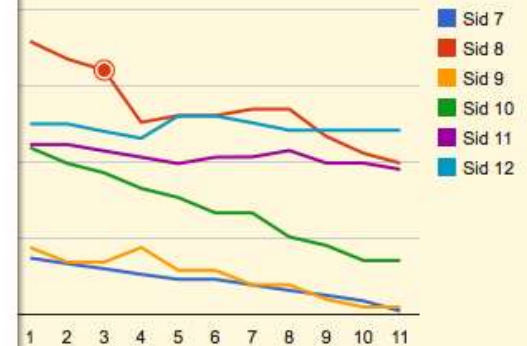
## Select Chart

☒ Weight
 ☐ Blood Pressure
 ☐ BMI
 ☐ A1C

## Weight



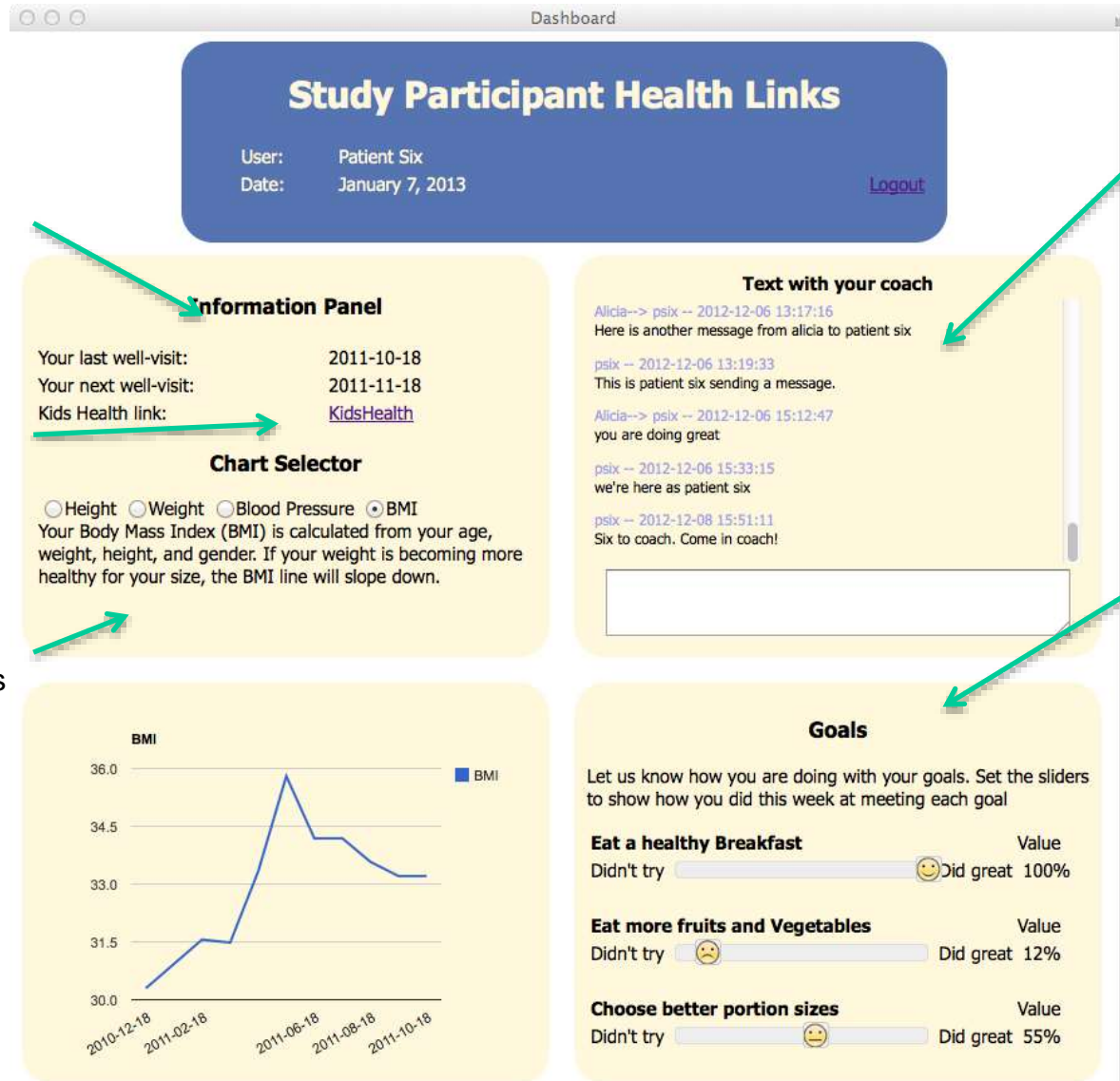
## BMI at Each Visit



## Number of Pts with BMI Gain, Stable, or Loss



# Participant Dashboard



Real-time chat/messaging with health coach.

Self reporting goal progress on goals set by PCP.

General Information, status updates, and useful web links

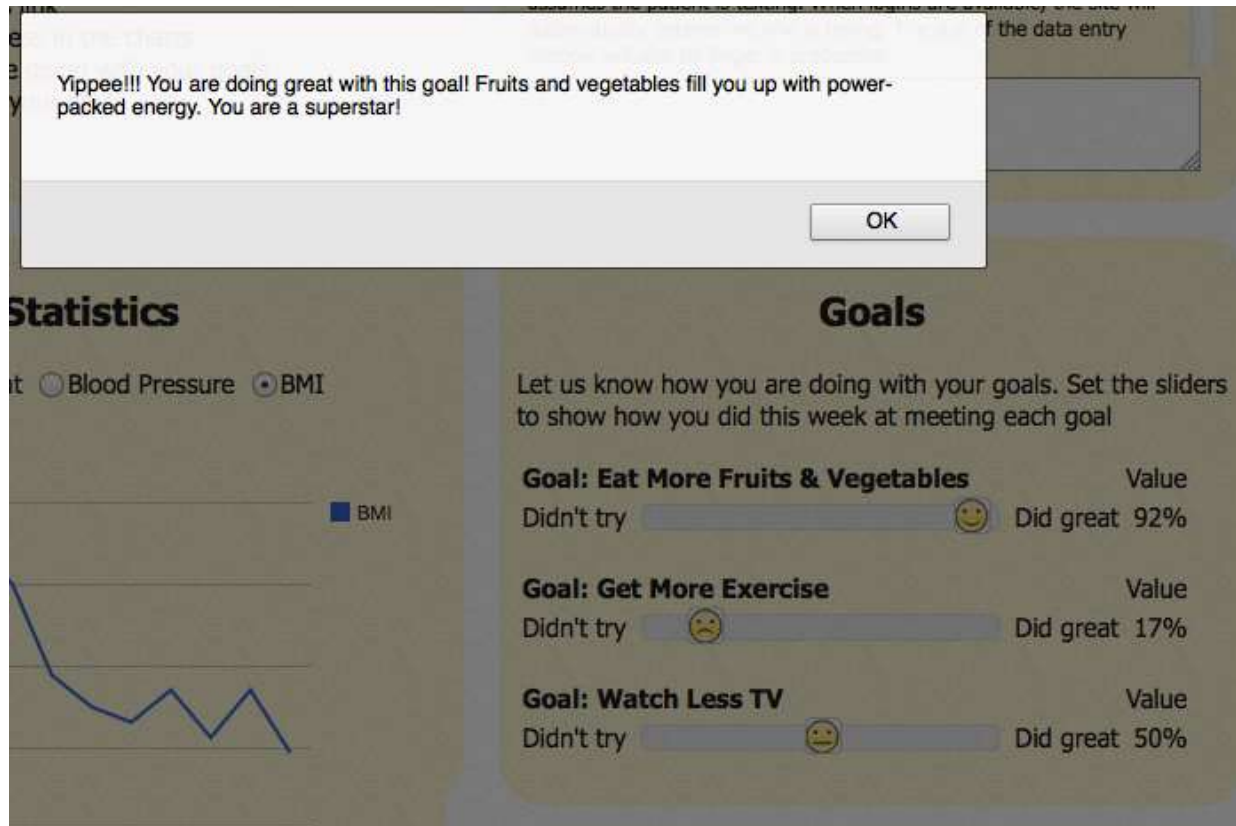
KidsHealth link goes directly to weight management content for teens.

Chart selection with explanations of charts

Individual line charts



# Goal-setting Feedback



Setting a goal slider brings a pop-up with reinforcement when positive progress is reported or helpful suggestions and advice when poor progress is reported.

Messages drawn randomly from a goal-specific message database.

# Challenges

- **Physicians need to be convinced that benefits outweigh the costs in terms of their time**
- **Placing barriers such as an extra login weighs against the project**
  - Single sign-on could help
- **Mingling data sources (teen user, family diary data, EMR data) challenging**
  - Making sure non-validated data does not impact medical decisions
  - Making sure medical data is understandable to lay users
- **Bandwidth limits media**
  - Could use video chat instead of text message passing
- **In this study can only recruit users with home PC or tablet and internet connection**



# Collaborators

## Overall Project

- Sandra Hassink, MD
- Lloyd Werk, MD
- Diane Abatemarco, PhD
- Babu Balagopal, PhD
- Katryn Furuya, MD

## Informatics

- David Milov, MD
- Suzanne, McCahan, PhD
- Chris Pennington, MS
- Saverio Rinaldi

# Personalized Synthetic Voices

**H Timothy Bunnell, PhD**  
**Principal Investigator**

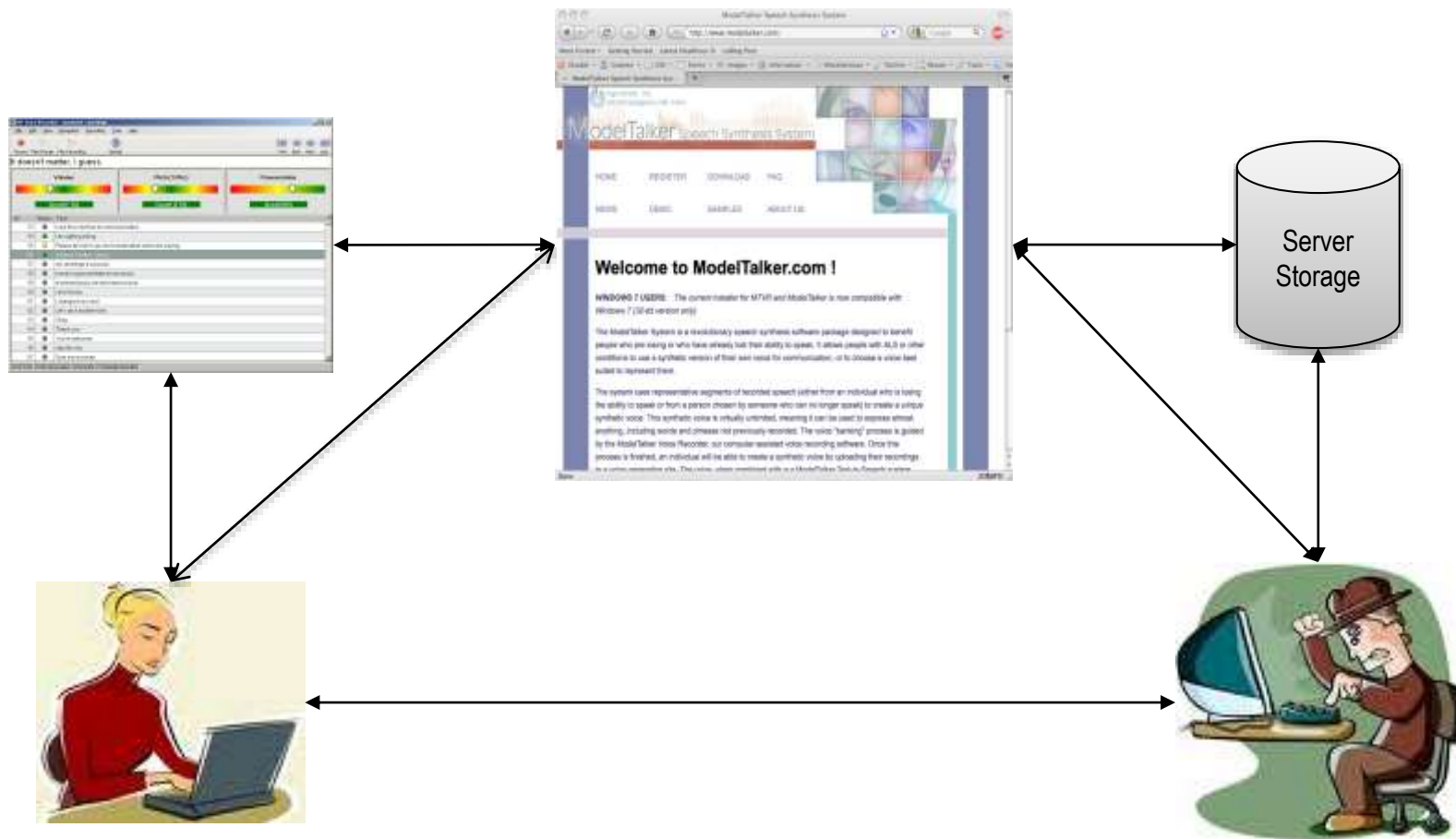
# Background

- **Augmentative Communication (AAC) devices allow non-vocal users to communicate**
  - Input ranging from typing to single switch scanning
  - Output increasingly in the form of Text to Speech (TTS)
- **2.5 Million Americans require, or could use AAC technology**
- **In some cases, the need for AAC is foreseeable**
  - ALS
  - Parkinson's
- **Use of generic TTS systems in AAC devices means loss of 'vocal identity' for users who acquire need for AAC**
- **Technology allows for construction and delivery of personal TTS voices based on the speech of an individual.**
- **ModelTalker project aims to deploy personal voice construction technology for users with neurodegenerative disorders.**

# ModelTalker System and Project Overview

- **Combines tools for recording, database construction, TTS**
- **Primarily intended for construction of small-database voices recorded by novice users**
- **New versions of all components under development**
  - ModelTalker Voice Recorder (MTVR)
    - In beta release
    - Available from MT website ([www.modeltalker.com](http://www.modeltalker.com))
  - ModelTalker Voice Constructor (MTVC)
    - Lab use & evaluation study
  - ModelTalker TTS (MTv2)
    - Lab use & evaluation study

# Process



# MTVR Interface

MT Voice Recorder - test72710c - polikoff

File Edit View Navigation Recording Tools Help

Record Play Prompt Play Recording Upload First Back Next Last

It comes up like that.

Volume

Too Loud! (0)

Pitch (108hz)

Good! (127)

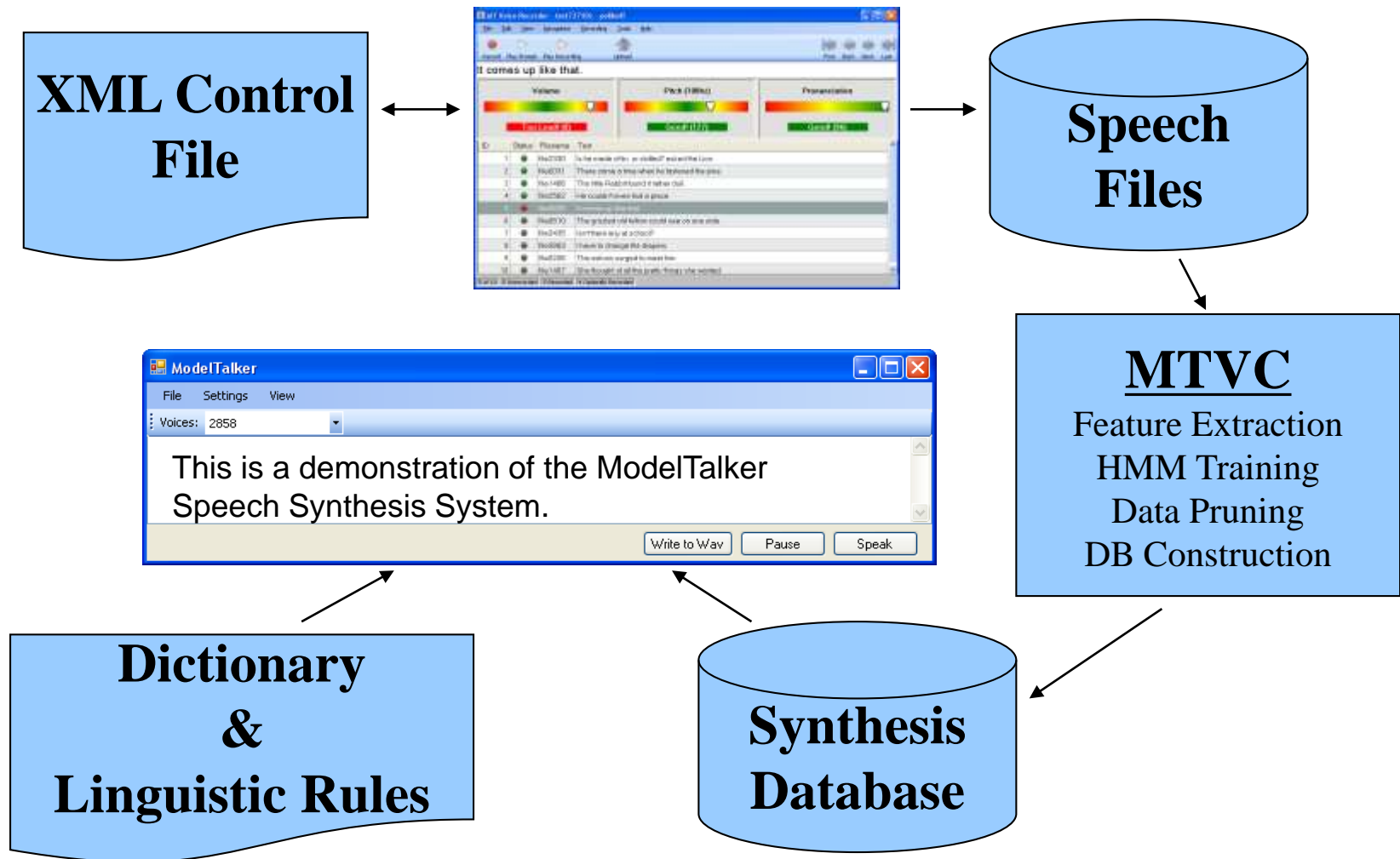
Pronunciation

Good! (96)

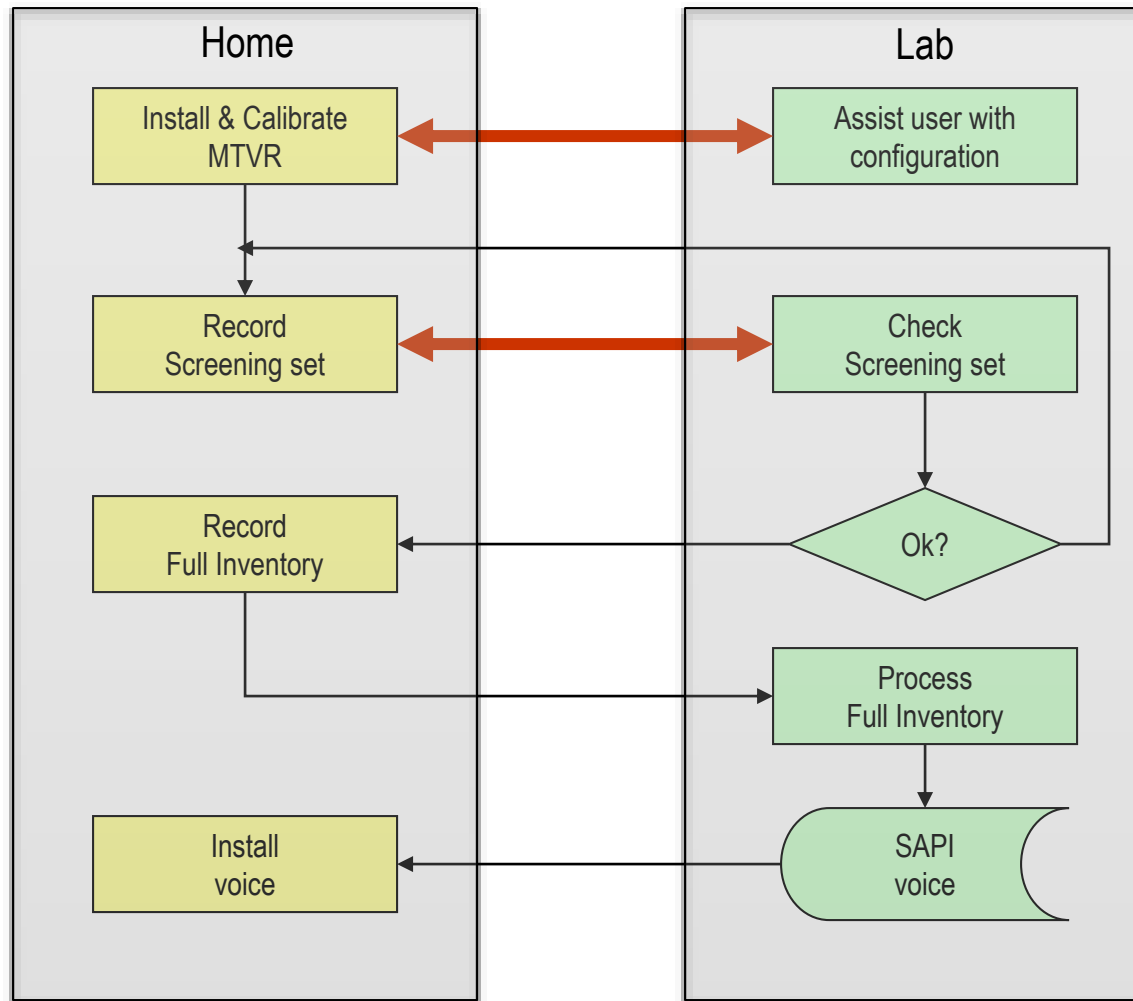
| ID | Status | Filename | Text   |
|----|--------|----------|--|
| 1  | ●      | file2330 | Is he made of tin, or stuffed? asked the Lion.   |
| 2  | ●      | file0031 | There came a time when he fastened the pine.     |
| 3  | ●      | file1486 | The little Rabbit found it rather dull.          |
| 4  | ●      | file2562 | He couldn't even find a place.                   |
| 5  | ●      | file3835 | It comes up like that.                           |
| 6  | ●      | file0610 | The grizzled old fellow could see on one side.   |
| 7  | ●      | file3435 | Isn't there any at school?                       |
| 8  | ●      | file3863 | I have to change the diapers.                    |
| 9  | ●      | file0206 | The wolves surged to meet him.                   |
| 10 | ●      | file1467 | She thought of all the pretty things she wanted. |

5 of 10 5 Unrecorded 5 Recorded 4 Optimally Recorded

# System Structure



# Data Flow





# Challenges

- **Remote users need better coaching**
  - Difficult to help debug problems when we can't see what the environment looks like
  - Face-to-face interaction more 'user-friendly'
- **Must install platform-specific application on user's PC**
  - Frequent problems with incompatibility from one version of Windows to next
  - Increasing number of Mac users!
- **No incremental feedback**
  - Cannot catch problems as they develop
  - Cannot provide basis for deciding when to stop

# Contributors

## Research

- Steve Hoskins, PhD
- Debra Yarrington, PhD
- Jason Lilley, PhD
- Kyoko Nagao, PhD
- James Polikoff, MS
- Chris Pennington, MS
- And many more...

## Implementation & Service

- Bill Moyers
- John Gray
- Betsy Warren