



**BIGHEALTH**  
CONSORTIUM™

***“Linking Research and Care to Make  
Personalized Medicine a Reality”***

**Project Action Group**

*January 23, 2009*

# Project Action Group: Charter & Goals



## Charter

- The Project Action Group focuses on identifying the process, activities, and participants needed to successfully evolve concepts into BIG Health Consortium™ Projects

## Goals

- Ensure that BIG Health ideas and concepts are clearly defined and communicated
- Ensure that all actions required to successfully evolve a concept into a BIG Health Consortium™ Project are identified and tracked
- Ensure that BIG Health Consortium™ participants are informed of evolving projects and understand how they may contribute to, or leverage those projects
- Provide a process and venue for discussing BIG Health concepts and capabilities. PAG Discussion Forums give all parties, whether directly or moderately interested, an opportunity to discuss concepts with the people closest to the concept, the initiators.

# Today's PAG Discussion Forum

- **Purpose:** To introduce the Patient Reported Outcomes (PRO) concept to the community and solicit feedback and participation.
- **Results:** At the conclusion of today's discussion we would like to identify actionable next steps for evolving this concept into a BIG Health Consortium™ Project.

# BIG Health Project Evolution Framework

A **BIG HEALTH PROJECT** is a project or collection of projects purposefully designed to demonstrate or prove a desired outcome that will advance, enable, or support BIG Health's mission in its efforts to promote and accelerate personalized and translational medicine. The results of the BIG Health Project must be quantifiable and tangible.

A **PROPOSAL** is one or more concepts that have been taken to a deeper level of detail and planning. It involves taking the concept and proposing how it could be achieved and who would be involved to help accomplish the project and documenting this in a formal proposal.

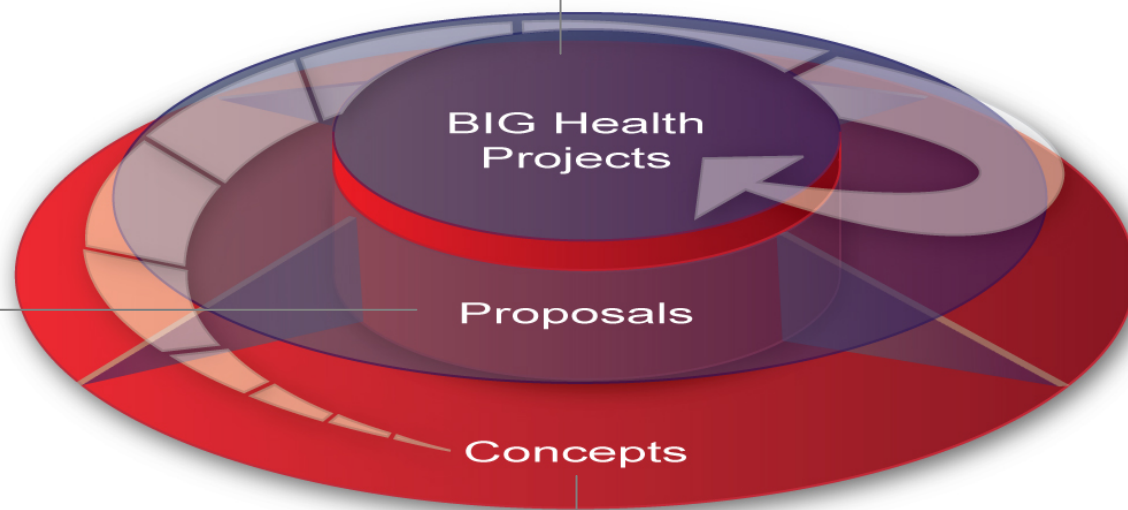


*Proposal  
Submission Form  
(Template)*

A **CONCEPT** is simply an idea that has been collected during a BIG Health meeting or submitted by a BIG Health Community member. The concept doesn't necessarily have any detail or depth. Think of this as if someone were to say, "wouldn't it be great if..."



*Concept Submission  
Document  
(Template)*



# What defines a BIG Health Consortium™ Project ?



- Multi-stakeholder community
- Multi-institutional engagement
- Regional/National/International in scope
- Extensible
- Pathway to sustainability





# ***Patient Reported Outcomes (PRO) Concept Overview***

**Project Action Group Discussion Forum**

*January 23, 2009*

# Discussion Forum Agenda

- Introduction of Initiator
- Review of Concept
  - The Challenge
  - Concept Description
    - *Overview*
    - *Background*
    - *Reporting*
    - *Feasibility*
    - *Cornerstones*
  - From Identification to Improvement
  - Incorporating Innovation
  - Concept Components
  - Required Capabilities
  - Current Concept Participants
- Q&A
- Next Steps



# **Improving patient-centered care via Patient Reported Outcomes (PRO) data:**

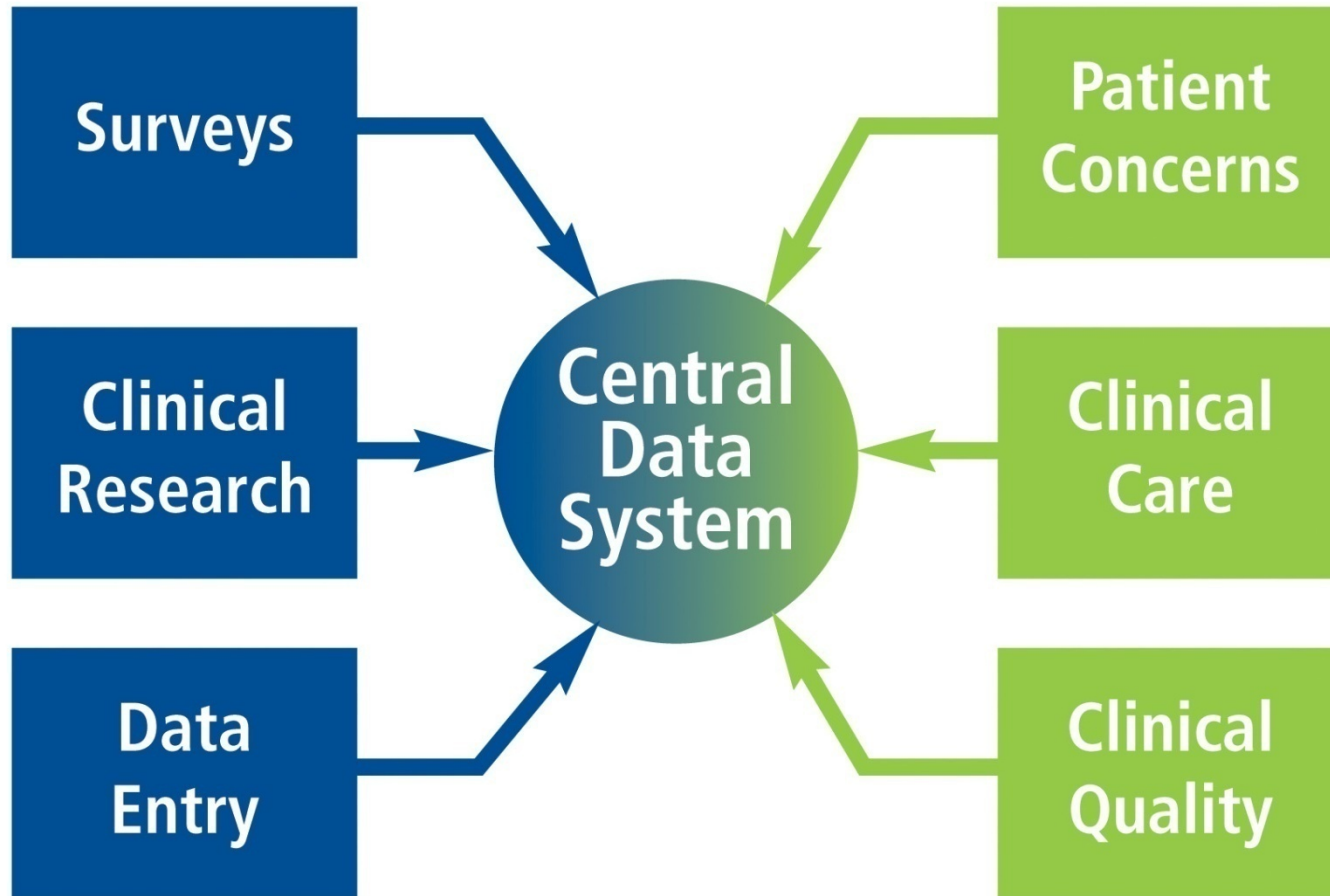
**A systematic approach to evidence  
development and implementation**



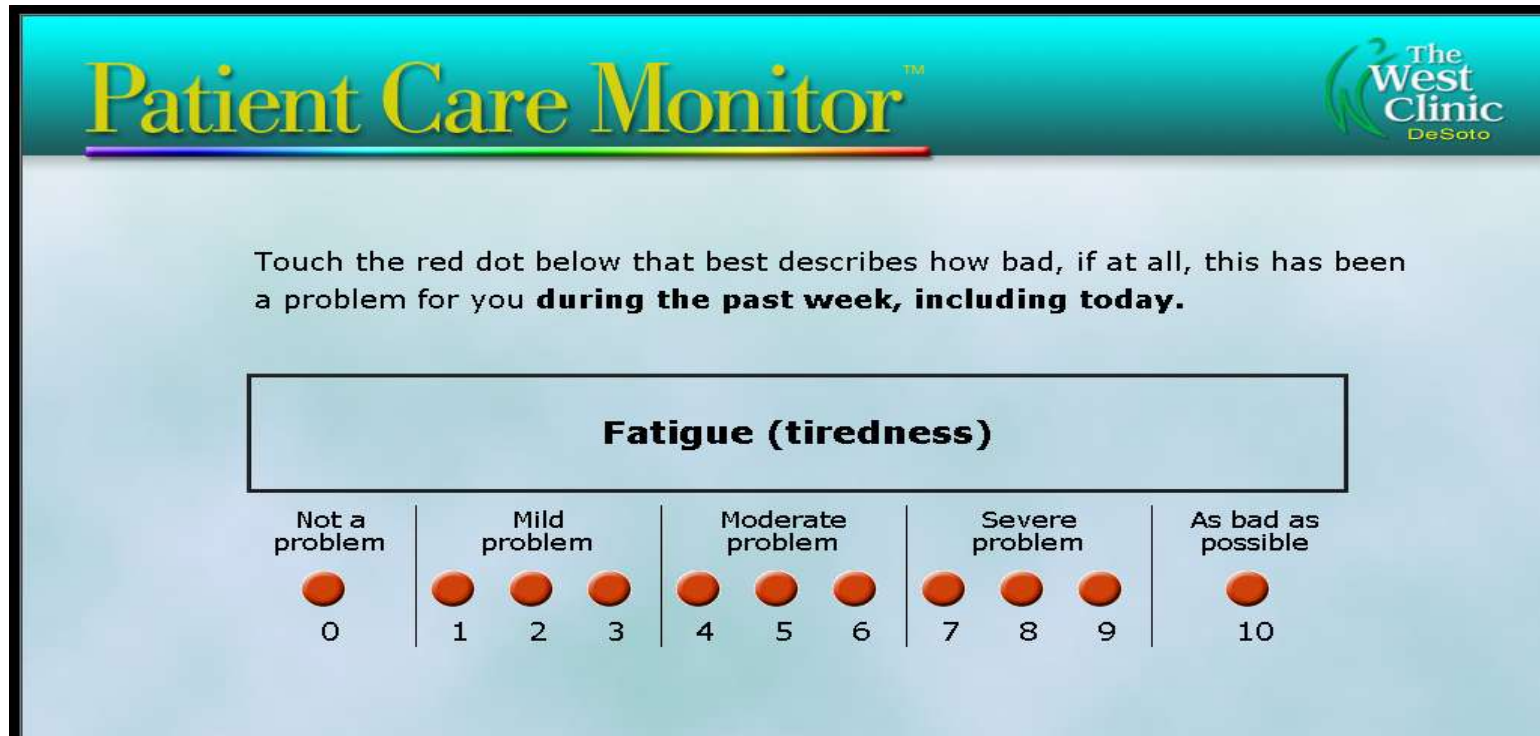
# The Challenge

- Cancer care providers are often unaware of their patient's concerns, symptoms, or psychosocial distress
- Cannot implement new evidence if providers are unaware of the problems
- Need clinical surveillance system that highlights patient concerns
- Should feed into research in an iterative manner
- Provides an opportunity to create a PRO phenotype that can be linked to “-omic”, administrative, EHR, radiology and other data to inform personalized health

# Patient Reported Outcomes (PRO): Concept Overview



# PRO: Concept Background



**Patient Care Monitor™**

The West Clinic  
DeSoto

Touch the red dot below that best describes how bad, if at all, this has been a problem for you **during the past week, including today.**

**Fatigue (tiredness)**

Not a problem	Mild problem	Moderate problem	Severe problem	As bad as possible
0	1 2 3	4 5 6	7 8 9	10

- ***Adapted the PACE System***
- ***Developed in the community oncology setting***
- ***Review of systems data and practice efficiency***



# PRO: Concept Background

## Patient Care Monitor™

Press the red bar containing the survey name for each survey you want to issue to this patient. An "X" will appear in front of each survey you select. Use the scroll bar to the right of the survey list to view more choices.

Press the **Continue** bar below to proceed with the first survey.

Patient AMY E ABERNETHY, born on 08-26-1967 (ID = AAE670826)

<input type="checkbox"/>	PCM Screener
<input type="checkbox"/>	FACT-G-4
<input type="checkbox"/>	FACT-B-4
<input type="checkbox"/>	FACIT-F-4
<input type="checkbox"/>	FACT-C-4
<input type="checkbox"/>	FACT/GOG-NTX-4
<input type="checkbox"/>	MDASI-1999
<input type="checkbox"/>	Self Efficacy
<input type="checkbox"/>	Duke Private Diagnostic Clinic
<input type="checkbox"/>	NCCN Distress Management

***Programmed a menu of well-validated questionnaires that would be credible in any research study (e.g. FACT-B, MDASI)***

# PRO: Concept Background

## Patient Care Monitor™



### M.D. Anderson Symptom Inventory (MDASI) Core Items

**Part I.** How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. In the following questions, we ask you to rate how severe the following symptoms have been **in the last 24 hours**.

Please press the **Continue** bar below.

- *Modular survey system*
- *Concatenated and presented seamlessly*



# PRO: Reporting



**PATIENT CARE MONITOR REPORT**  
**Patient Name:** kafdkfjakfjdafikjdaifdfakfj  
**DOB/Age/Sex:** dljlfajfdlrfajdaikdfjlfakfjdljl  
**Doctor:** kkjddajfalkajdfajldfjalfjldf  
 ajfdalkjfdlafjldjafjldjalfjldkj

**MR #:**  
**Survey Date/Time:** Apr 26 2006 (Wed) / 9:17AM  
**Version:** English  
**Dx/Dx Date:**

Review of Systems	Current 4/26/06	First 4/12/06	Review of Systems	Current 4/26/06	First 4/12/06
<b>1. Allergic/Immunologic</b>			<b>12. Neurological</b>		
Sinus problems	3	-	Daytime sleepiness	5	-
Hives (welts)	0	-	Trouble thinking (concentrating)	3	-
<b>2. Constitutional</b>			Memory loss	3	-
Fatigue	8	-	Trouble sleeping at night	0	-
Chills	5	-	Burning in hands/feet	0	-
Fever	4	-	Dizziness/lightheadedness	0	-
Weight gain	0	-	Numbness/tingling	0	-
Weight loss	0	-	<b>13. Endocrine</b>		
<b>3. Eyes</b>			Sexual problems	7	-
Dry eyes	6	-	Hot flashes/flushes	3	-
Trouble seeing	5	-	Night sweat	0	-
Eyes tearing (watery eyes)	2	-	Day sweat	0	-
<b>4. ENT/Mouth</b>			<b>14. Hematologic/Lymphatic</b>		
Change in taste of food	9	-	New lump/mass	0	-
Dry mouth	8	-	Easy bleeding	0	-
Sore throat	6	-	Bruising	0	-
Mouth sores/ulcers	6	-	<b>15. Psychiatric</b>		
Trouble swallowing	4	-	Crying/feeling like crying	6	-
Difficulty hearing	0	-	Nervous, tense, anxious	6	-
<b>5. Pain</b>			Worry	6	-
Headache	6	-	Feeling hopeless	5	-
Physical pain	0	-	Sad (depressed)	5	-
<b>6. Cardiovascular</b>			Feeling helpless	5	-
Chest pain	2	-	Lost interest in people	4	-
Rapid heart beat	0	-	I would be better off dead	2	-
Swelling	0	-	Absence of pleasure	2	-
<b>7. Respiratory</b>			Feeling worthless	2	-
Coughing	1	-	Feeling guilty	0	-
Wheezing	0	-	<b>16. T-Scores</b>		
Difficulty breathing	0	-	Distress	67.1	-
<b>8. Gastrointestinal</b>			Despair/Depression	65.1	-
Constipation	5	-	<b>17. Physical Functioning</b>		
Diarrhea	5	-	Hard work or activity	9	-
Nausea (queasy feeling)	5	-	Attend paid job	9	-
Heartburn (indigestion)	3	-	Household work	9	-
Vomiting	0	-	Run errands	7	-
Increased appetite	0	-	Run	7	-
Decreased appetite	0	-	Function normally	6	-
<b>9. Genitourinary</b>			Light work or activity	6	-
Vaginal dryness	5	-	Walk	5	-
Problems with urination	0	-	Attend social activities	5	-
Menstrual pain/cramping	0	-	Bathe or dress	4	-
Vaginal itching	0	-	Driving	4	-
Vaginal bleeding	0	-	Cook for self	4	-
Vaginal discharge	0	-	Stay out of bed	2	-
<b>10. Musculoskeletal</b>			Sit up	0	-
Weakness of body parts	7	-			
Joint pain	2	-			
Muscle aches	0	-			
<b>11. Integumentary (skin, breast)</b>					
Rash	7	-			
Dry skin	5	-			
Itching	5	-			
Hair loss	5	-			
Breast tenderness	2	-			
Nipple discharge	0	-			
Nail changes	0	-			

Symptom scores & severity: 0=none; 1-3=mild; 4-6=moderate; 7-10=severe; ↑ = worse by ≥ 3 points; ↓ = better by ≥ 3 points; □ = severe; = moderate; ISQ = skipped; - not asked; (?) = referral suggested;

**Notes:**

History	Alerts/Changes

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## PRO: Feasibility

- 66 consenting breast cancer patients
  - Mean age 55 (SD 12) with 38% over age 60
  - 22% non-white
  - 49% did not have a Bachelor's degree
- Used e/Tablets on 4 visits to the Duke Breast Cancer clinic
- Completed paper and electronic versions of standard symptom and quality of life instruments commonly used in cancer research
- Allowed patients to use the educational library available on the tablet computer

# PRO: Feasibility

<i>Question</i>		<i># (%)</i>	
Easy to read?	Very easy	57 (89%)	94%
	Somewhat easy	3 (5%)	
Easy to respond?	Very easy	59 (92%)	98%
	Somewhat easy	4 (6%)	
Easy to navigate?	Very easy	60 (94%)	99%
	Somewhat easy	3 (5%)	
Weight comfortable?	Very comfortable	49 (77%)	100%
	Somewhat	9 (13%)	

# PRO: Feasibility

<i>Question</i>		# (%)	
Satisfied with e-tablets?	Very satisfied	22 (34%)	<b>75%</b>
	Satisfied	26 (41%)	
Recommend use?	Yes	54 (84%)	<b>84%</b>
	No	0 (0%)	
	Don't know/Skipped	10 (16%)	
E-tablet help patient to remember symptoms?	Yes	42 (66%)	<b>66+%</b>
	No	9 (14%)	
	Don't know/Skipped	8 (12%)	
	Haven't seen doctor	5 (8%)	

# PRO: Equivalence

	N	Paper Mean	Electronic mean	P (DIFF)
FACT-G Physical	58	20.41	20.49	0.7763
FACT-G Emotional	58	18.39	18.66	0.3526
FACT-G Functional	58	17.98	17.64	-0.3112
FACT-B	55	24.98	24.49	-0.1955
FACIT-Fatigue	59	34.12	34.47	0.3291
MDASI Global Symptom	50	1.96	1.82	0.3291
MDASI Global Interference	50	2.30	2.22	0.5286

***No difference between paper and electronic for main surveys studied***



# Feasibility – Main Findings

- **Easy to use, navigate, and read**
- **Patients satisfied with the PRO system, and would recommend them to other patients.**
- **Help patients recall symptoms to report.**
- **The PRO system can be used to collect research-quality data using common, validated instruments in an academic oncology clinic.**

Improving Health Care Efficiency and Quality Using Tablet Personal Computers to Collect Research-Quality, Patient-Reported Data

*Amy P. Abernethy, James E. Herndon, Jane L. Wheeler, Meenal Patwardhan, Heather Shaw, H. Kim Lyerly, and Kevin Weinfurt*

# PRO: Concept Cornerstones

Clinical  
Research

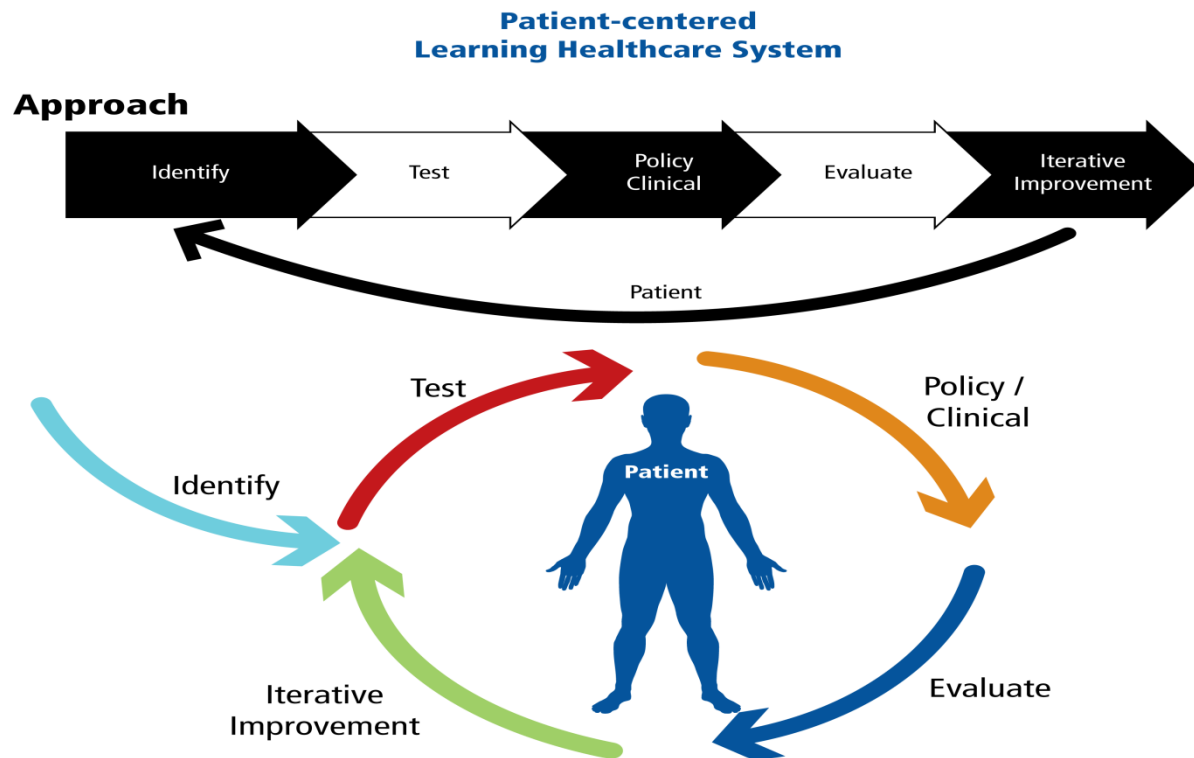
Care Models

The Patient  
& Family

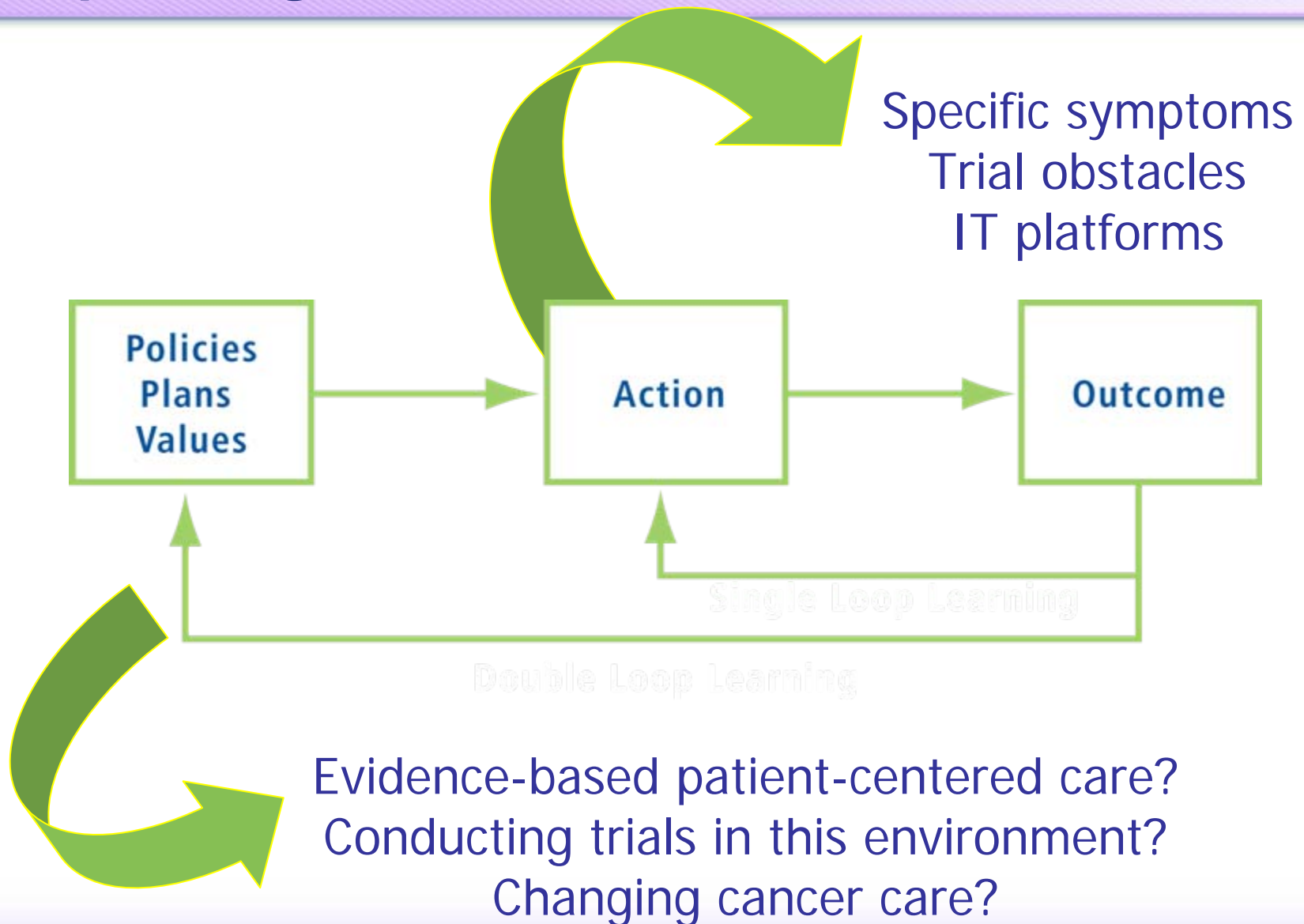
Technology

Iterative  
Innovation

# From Outcome Identification to Healthcare Improvement



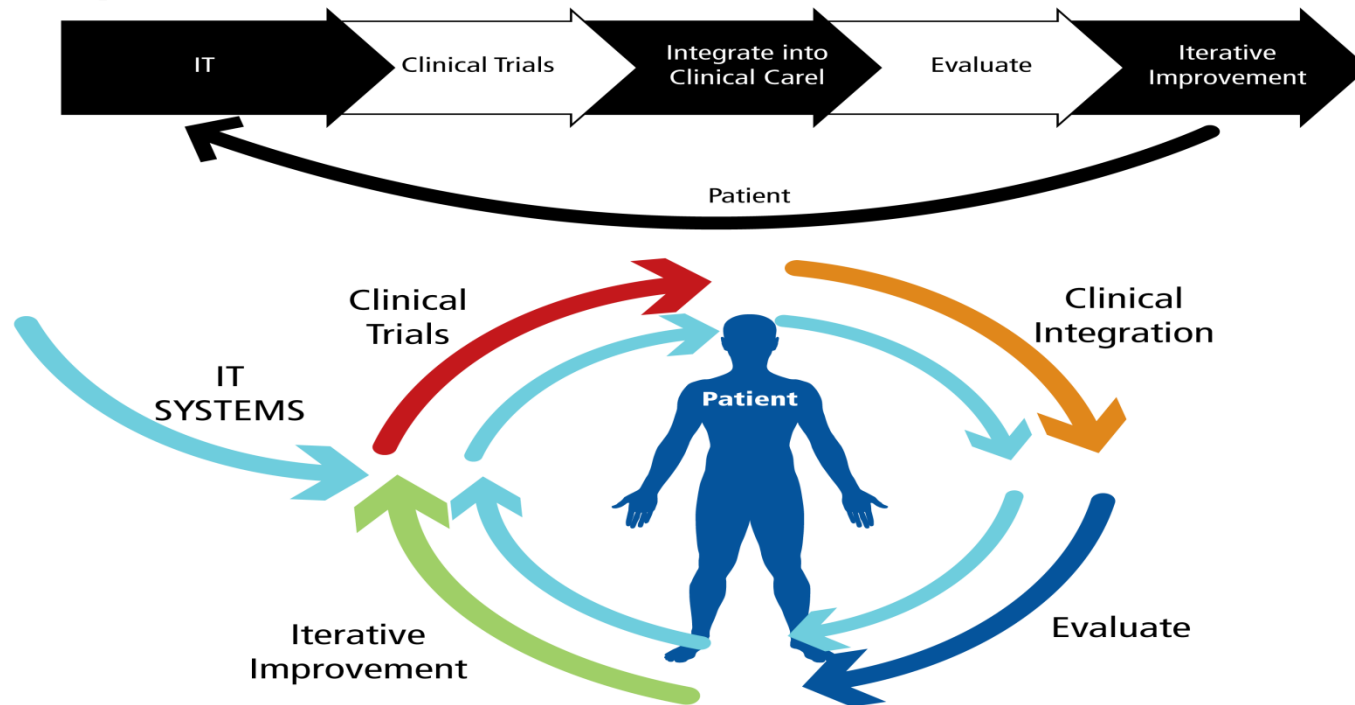
# Incorporating Innovation



# PRO: Concept Components

## Patient-centered Learning Healthcare System

### Components





## Next Steps

- **Understand difference between paper and electronic on various instruments, and impact of survey order**
- **Extend to additional populations**
- **Extend to additional oncology settings including community and academia**
- **Integrate with therapeutic and non-therapeutic clinical trials**
- **Integrate with basic science information and risk models**
- **Quality improvement, satisfaction, and health resource utilization evaluation studies**
- **Interoperability with caBIG<sup>®</sup> Tools (ePRO CTCAE)**

# Q & A

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# Required Ecosystem Capabilities

<b>Services</b>	<b>Resources</b>	<b>Tools</b>
System Integration	Phenotypic data repository	CTRP
Patient Education Content Development / Harmonization	Genotypic data repository	CTCAE system
Patient ROS Training development		POC Data Collection tool
Participant Recruitment		Outcomes Reporting Tool
FDA Compliance Evaluation		
SOP Development		
Data Sharing Policy Development		

# Targeted Concept Participants



## Targeted Participants

Organization	Role	Contact	Notes
UNC	Care Provider		Local, national (interest from Australia & UK)
UAB	Care Provider		Health disparities data
Semantic Bits	System Integrator		
NCI / caBIG	Tool Provider		CTRP and AE system
UCSF	Care Provider		
Microsoft	EHR Provider		
Google	Tool Provider		
SAS	Tool Provider		Dashboard development
Oracle	Tool Provider		eBusiness tools
PACE / Memphis			
SDS/Acorn West Clinic			
NCCCP			Health disparities data
National Call to Action (NCTA)			



# Current Concept Participants

## Confirmed Participants

Name / Org	Role	Contact	Notes
Duke Cancer Care Research Program	Initiator	Amy Abernethy	



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**[www.bighealthconsortium.org](http://www.bighealthconsortium.org)**

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