

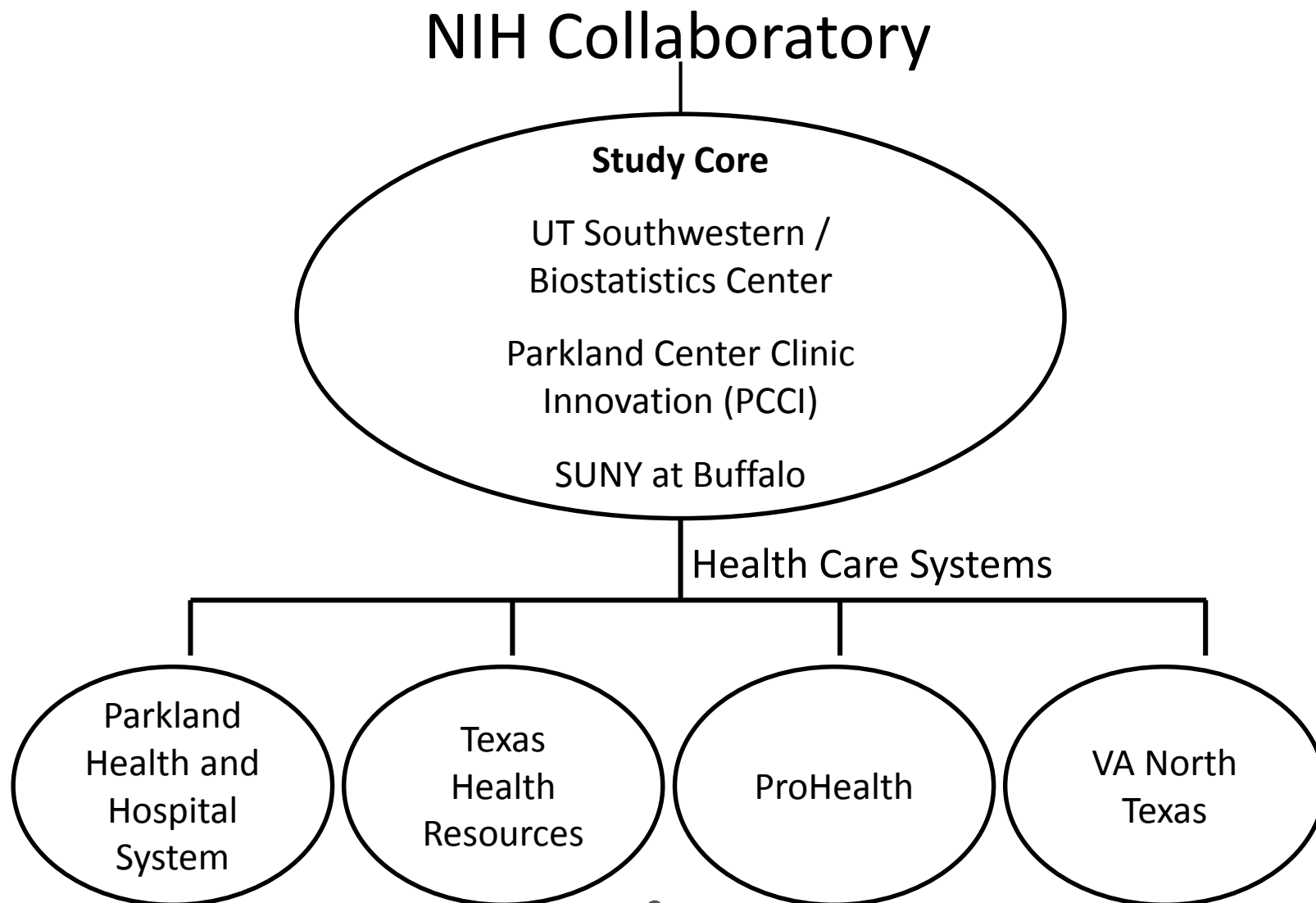
Improving Chronic Disease Management with Pieces

*A Pragmatic Trial to Improve Care of Patients with CKD,
Diabetes and Hypertension*

Friday, January 09, 2015



ICD-Pieces Pragmatic Trial Organization



Clinical Relevance

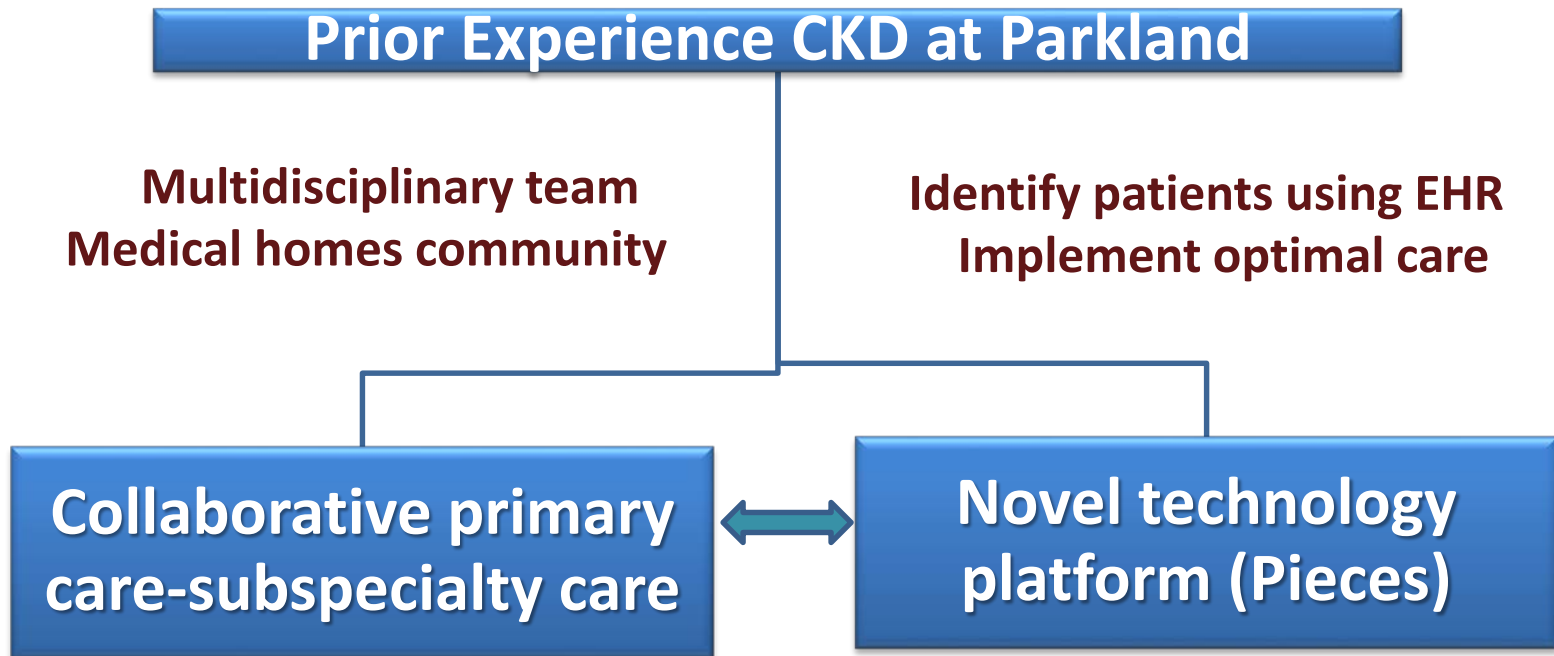
- **Chronic kidney disease (CKD)**
 - Increasing prevalence
 - Gaps between evidence-based care and practice
- **Diabetes and hypertension:**
 - Frequently coexist
 - Leading causes of CKD in the United States
- **Kidney disease and diabetes are very costly**
- **CKD,HTN,DM Comorbidity:** Higher than individual disease risks
- **How to improve outcomes?**
 - Identify patients and risks for adverse outcomes
 - Develop and implement best practices

Improving Care in CKD

Bringing best care to practice

- Early diagnosis
- Slowing progression
- Treatment associated complications
- Preparation for renal replacement therapy

CKD Pilot Implementation Study*



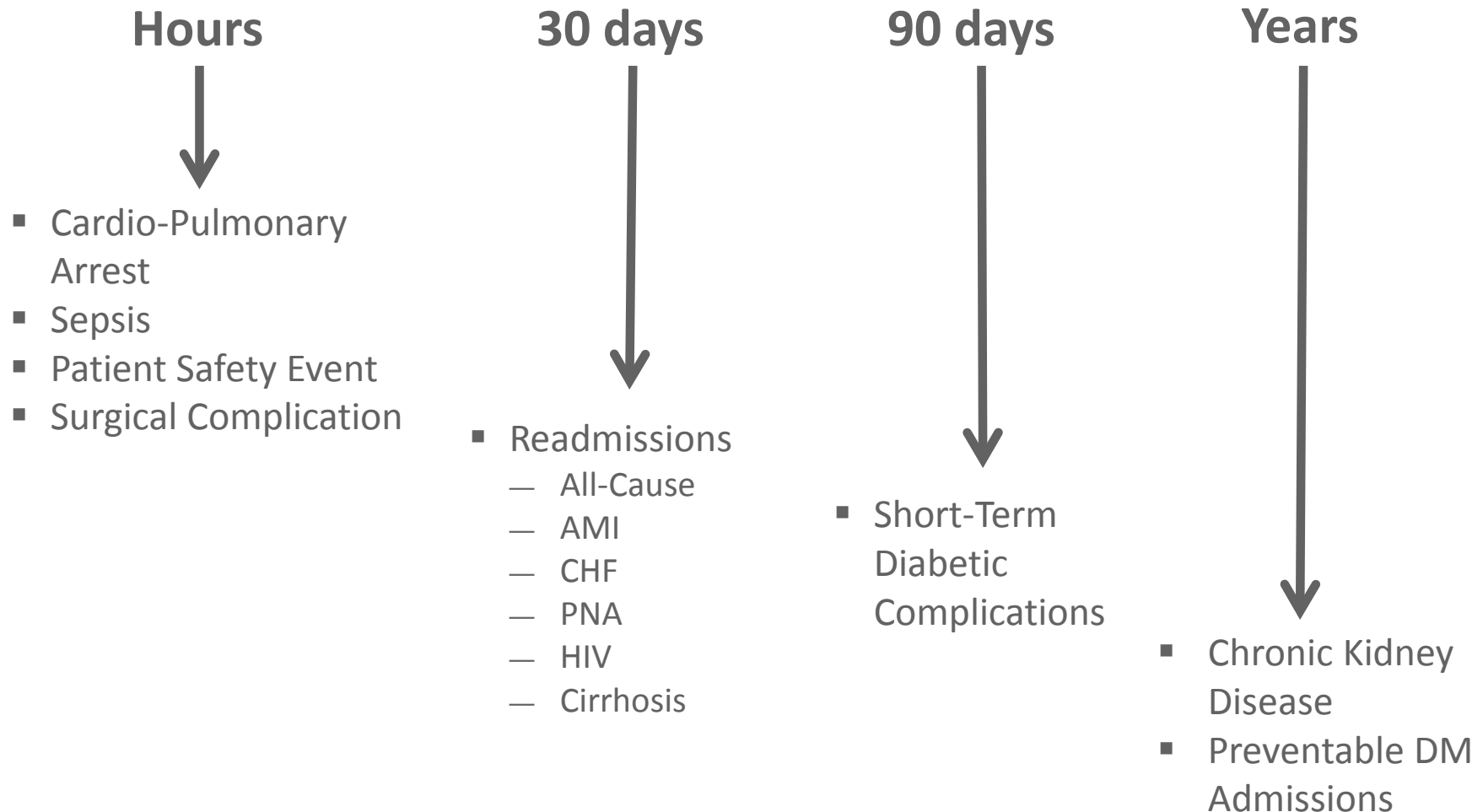
*Pilot study supported by NIDDK

What is Pieces™?

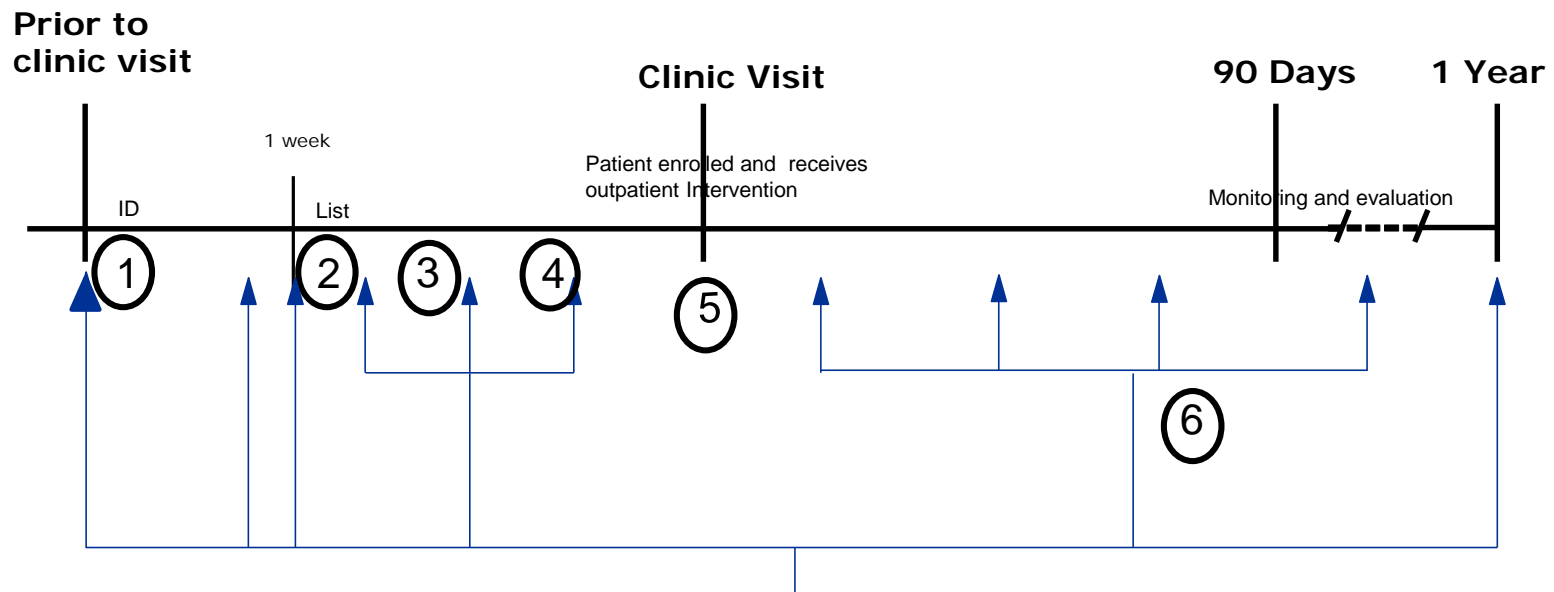
Parkland Intelligent e-Coordination and Evaluation System

- Sits on top of EHR/EPIC
- Natural language processing to read EHR
- Near real-time risk stratification
- Automated protocol activation
- Patient-tailored interventions
- Electronic ascertainment of outcomes

Predictive Model Expansion to Focus on Other Clinical Quality & Performance Metrics



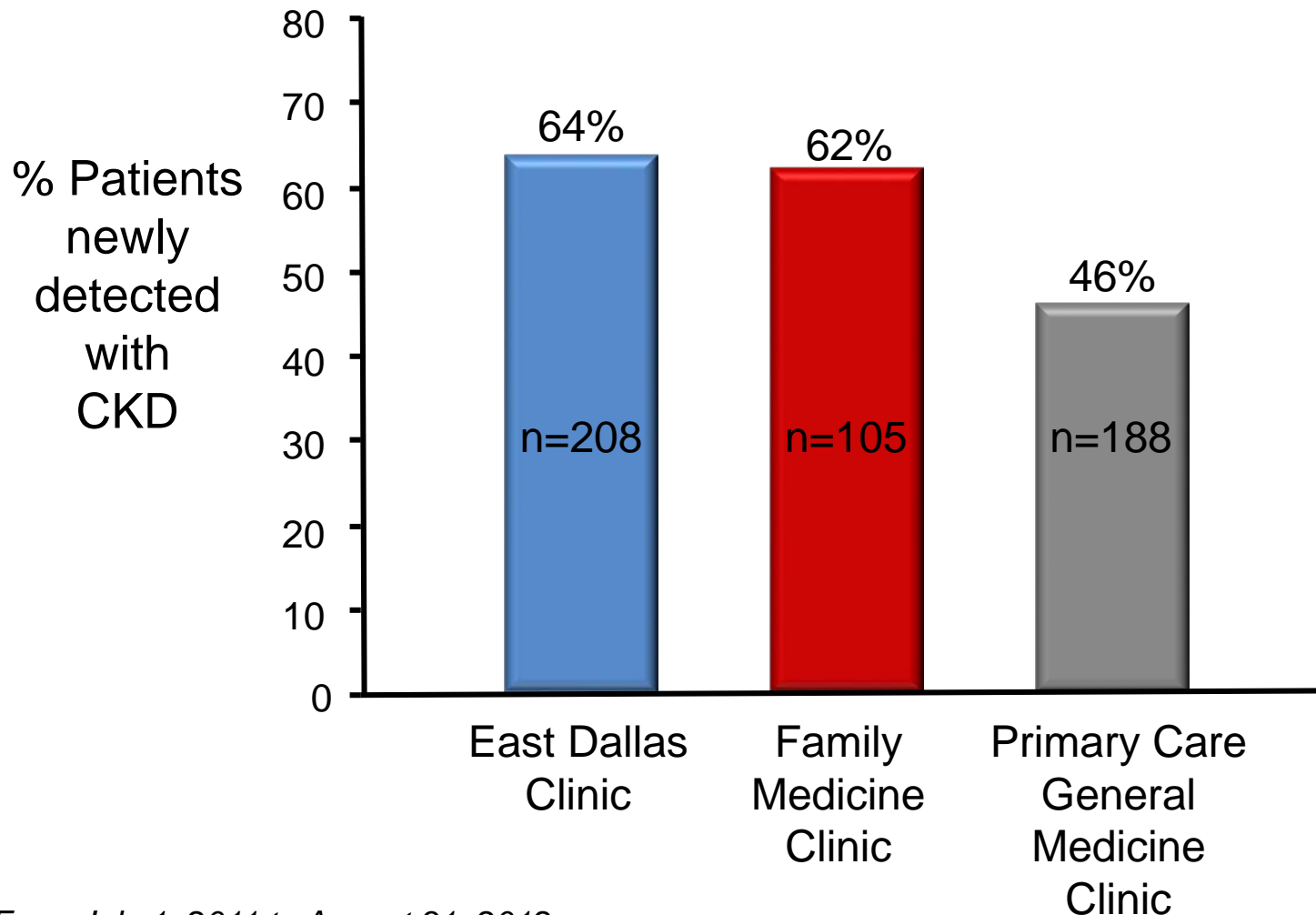
Pieces™ -CKD Detection and Care Pilot study



PIECES™

- ① System identifies patients with $eGFR < 60 \text{ ml/min/1.73m}^2$ or with proteinuria/ albuminuria
- ② System provides list of patients to intervention team
- ③ Patient confirmed to have CKD by intervention team
- ④ Patient contacted by intervention team and scheduled for a PCP clinic visit
- ⑤ Patient receives recommended intervention from PCP
- ⑥ System continues to monitor treatment compliance and track outcome variables

CKD Pilot Study: Patients Newly Detected with CKD by Pieces™



From July 1, 2011 to August 31, 2012

Achievement of CKD Pieces Study Goals

	Screening	Last follow-up visit	
Clinical Measurement	% at Goal	% at Goal	
	n=107	n=107	P-value (McNemar's test)
Follow-up duration, month <i>median [range]</i>		11.2 [0.2 – 21.5]	
Systolic blood pressure	34.6%	44.0%	0.14
Diastolic blood pressure	57.9%	66.1%	0.17
ACEI/ARB	57.8%	87.2	<.0001
Statin	45.0%	79.8	<.0001

*if positive test for proteinuria or albuminuria, then goal BP <130/80;
Otherwise goal BP < 140/90).*

ICD-Pieces Pragmatic Clinical Trial

Multiple Chronic Conditions

CKD

Diabetes

Hypertension

Public health implications
Progression to End Stage Renal Disease(ESRD)
Excessive Cardiovascular morbidity/mortality
High risk population
Gaps in clinical practice

ICD-Pieces Study Hypothesis

- Patients who receive care with a collaborative model of primary care-subspecialty care enhanced by novel information technology (Pieces) will have fewer hospitalizations, readmissions, CV events and deaths than patients receiving standard medical care.

Specific Aims UH2

1. Establish a Health Care Systems Collaboratory to conduct a pragmatic trial to improve care of patients with three chronic coexistent medical conditions: CKD, diabetes and hypertension
2. Establish functionality across the 4 participating health care systems of a technology-enhanced model of collaborative care by primary care practitioners for patients with CKD, diabetes and hypertension.

Specific Aims UH3

1. Conduct a randomized pragmatic clinical trial of management of patients with CKD, diabetes and hypertension with a clinician support model enhanced by technology support (Pieces) compared with standard of care
2. Develop and validate predictive models for risks of hospitalizations, cardiovascular events and deaths for all patients with coexistent CKD, diabetes and hypertension and to predict risk of 30 day readmissions for patients who are hospitalized

ICD - Pieces™ Collaboratory

Miguel Vazquez, MD, PI
Robert Toto, MD, Co-PI
Ruben Amarasingham, MD
Adeola Jaiyeola, MD
George Oliver, MD PhD

PCCI

(Drs. Amarasingham, Jaiyeola, Oliver)

Biostatistics Core (Dr. Chul Ahn and Dr. Song Zhang)
Diabetes Core (Dr. Perry Bickel)
SUNY (Dr. Chet Fox and Dr. Linda Khan)
NIH (Dr Andrew Narva and Dr Barbara Wells)

Dr. Ruben Amarasingham

Parkland

Dr. Susan Hedayati

THR

VA

ProHealth

Dr. Ferdinand Velasco

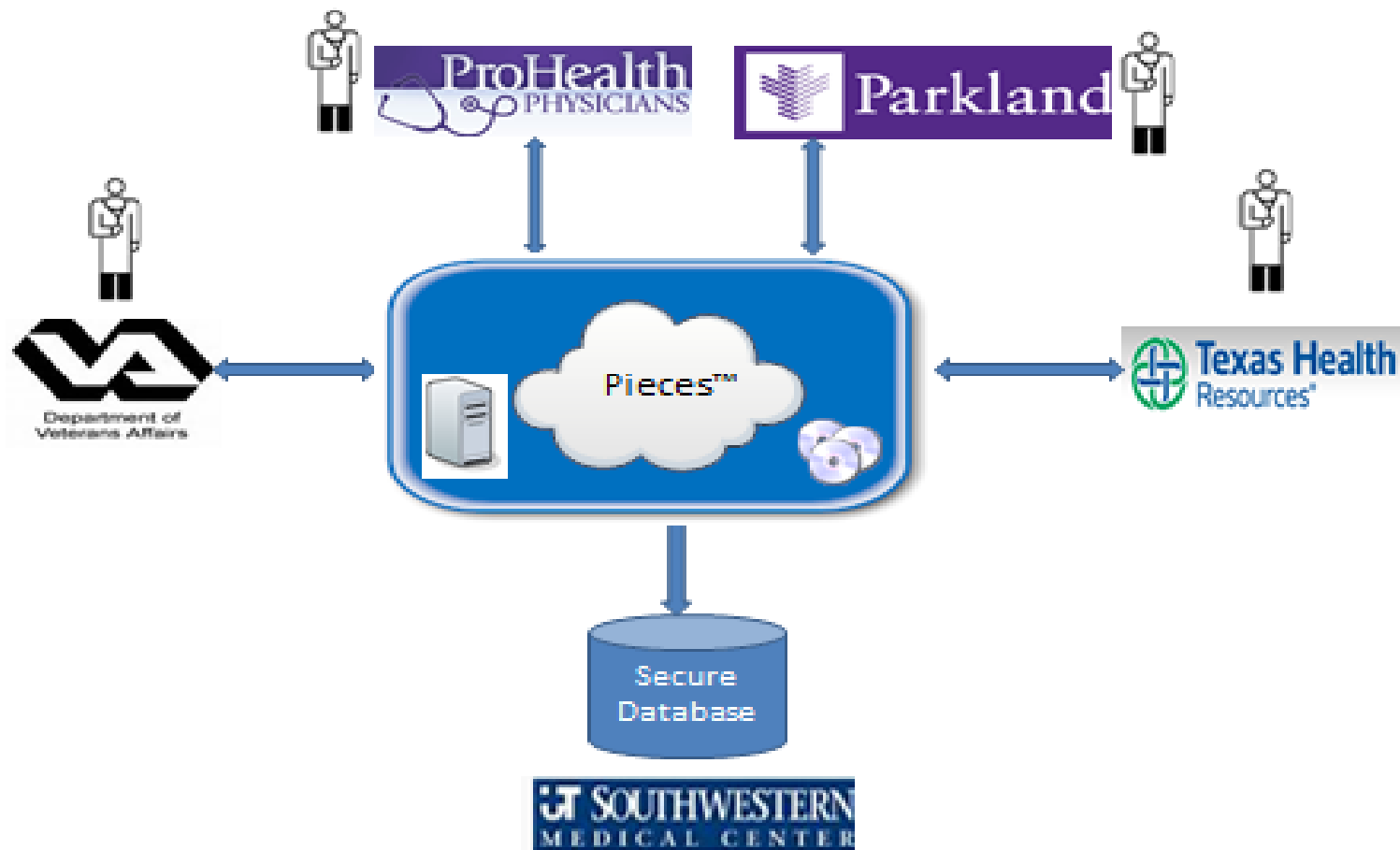
Mr. John Lynch

Diverse Participatory Healthcare Systems and EHRs

HCS	Description	Location	EHR
Parkland	Safety-net public	Dallas County	EPIC
Texas Health Resources	Private non-profit	North Texas	EPIC/All Scripts
ProHealth	Private non-profit	Connecticut	All Scripts
VA North Texas	Federal	North Texas	CPRS

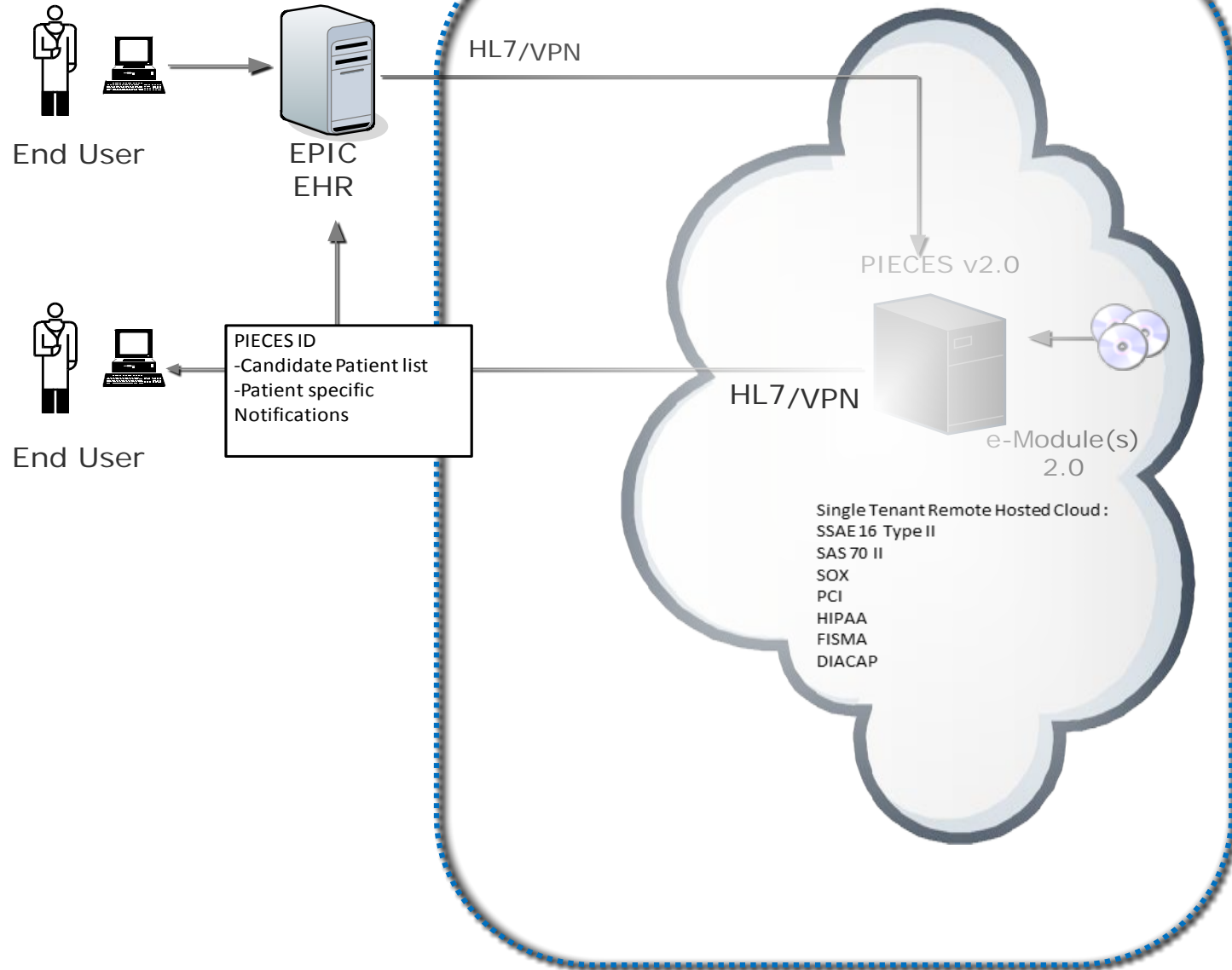
Study Sites

Pieces™ Connects with Implementation Sites





Draft ICD PIECES Architecture



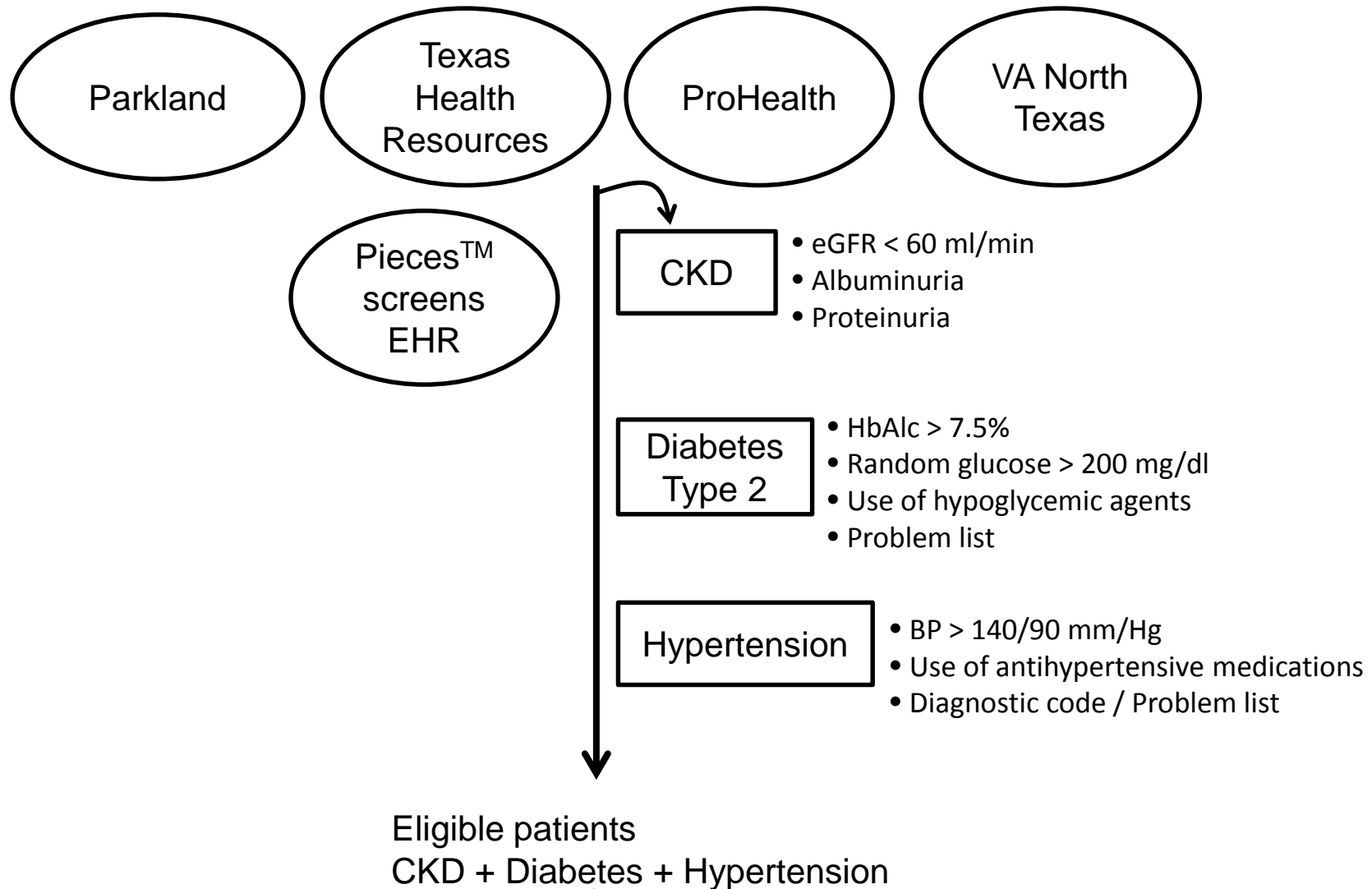
What happens in the study?

- **Patients with triad of CKD, diabetes and hypertension are identified**
 - Objective and reproducible criteria
 - Leverage data EHR
- **Clinicians notified of eligible patients**
- **Pieces provides clinician support for implementation**
 - Primary care provider in medical home
 - Practice facilitator is key to facilitate implementation
- **Monitoring clinical measures and adjustments treatment**
- **Pieces facilitates ascertainment outcomes electronically**

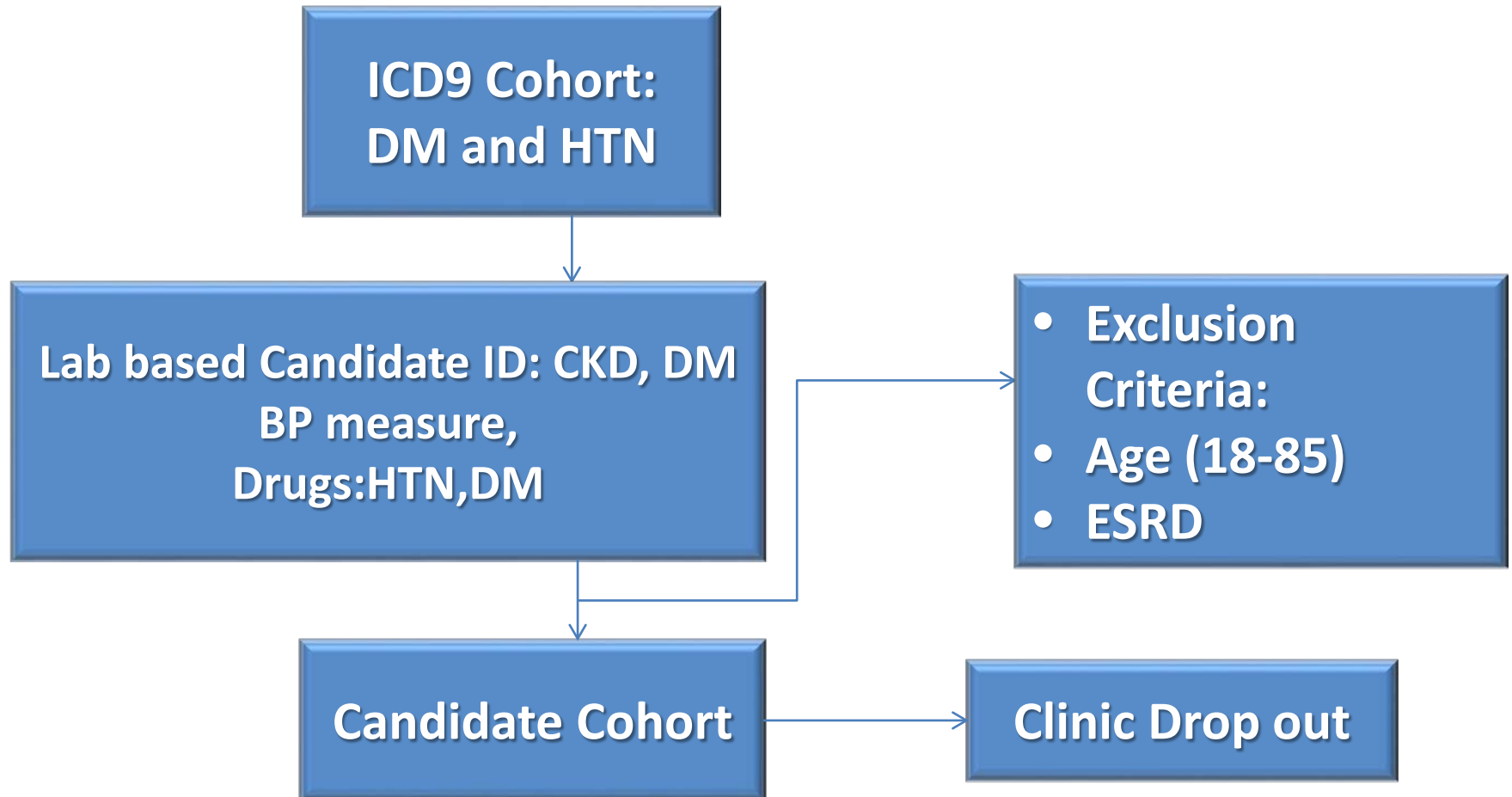
Design of the study

- Stratified Cluster Randomization
- Stratum: Healthcare System
- Randomization Unit: Clinic or Practice Site
- Within each hospital system, clinics or practice sites will be randomized to either ICD-PIECES or standard care group.
- Every patient assigned to each clinic or practice site will receive the same intervention.

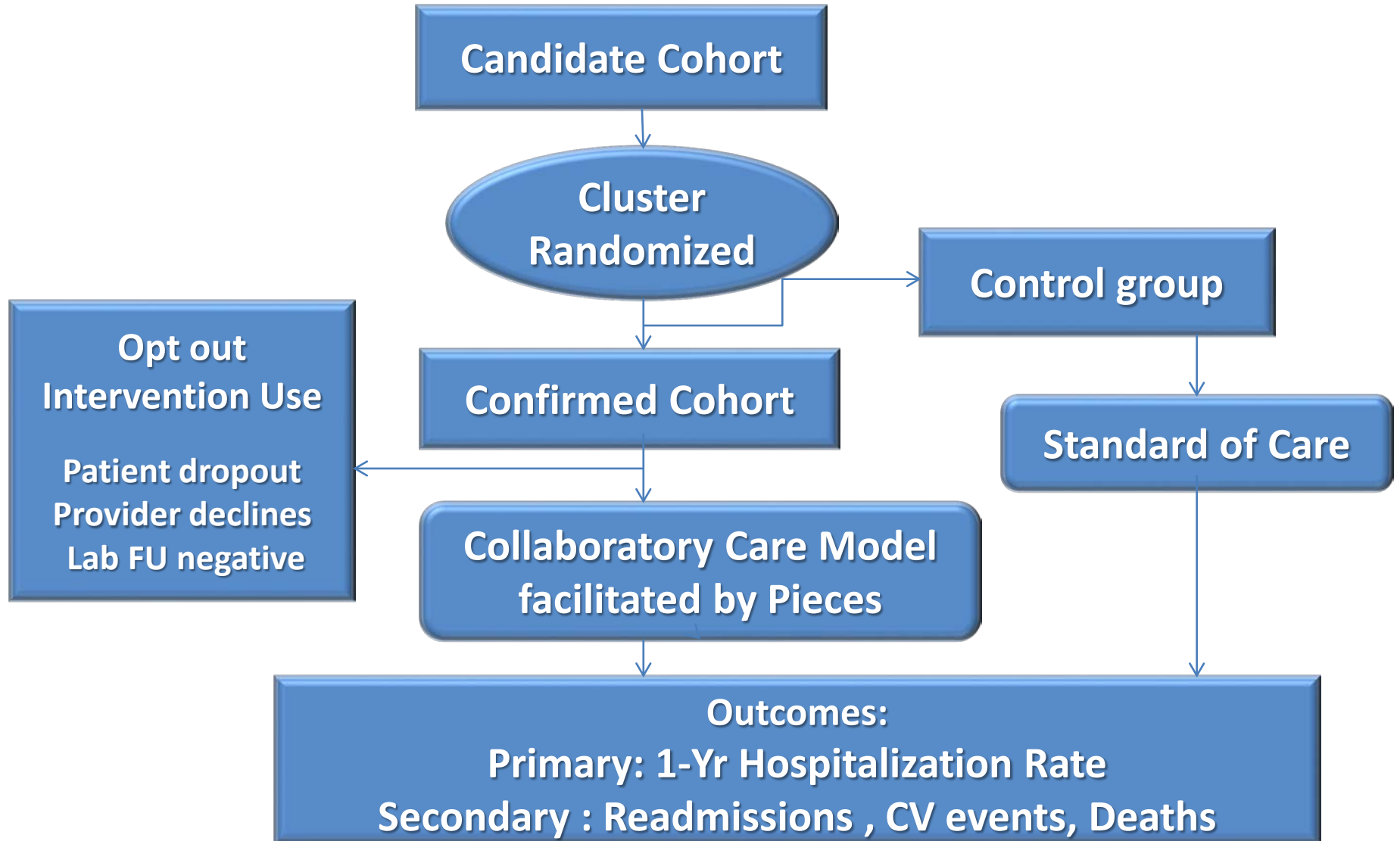
Detection CKD, Diabetes and Hypertension



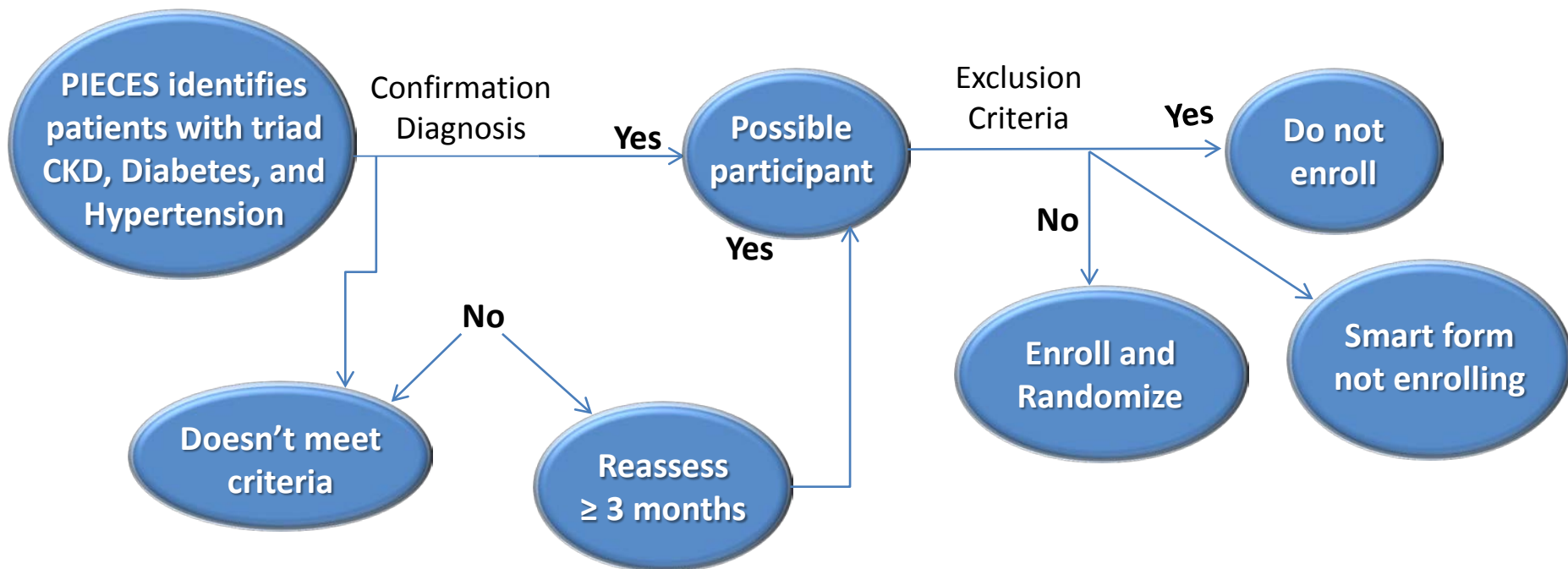
ICD-Pieces Participant Selection Work Flow



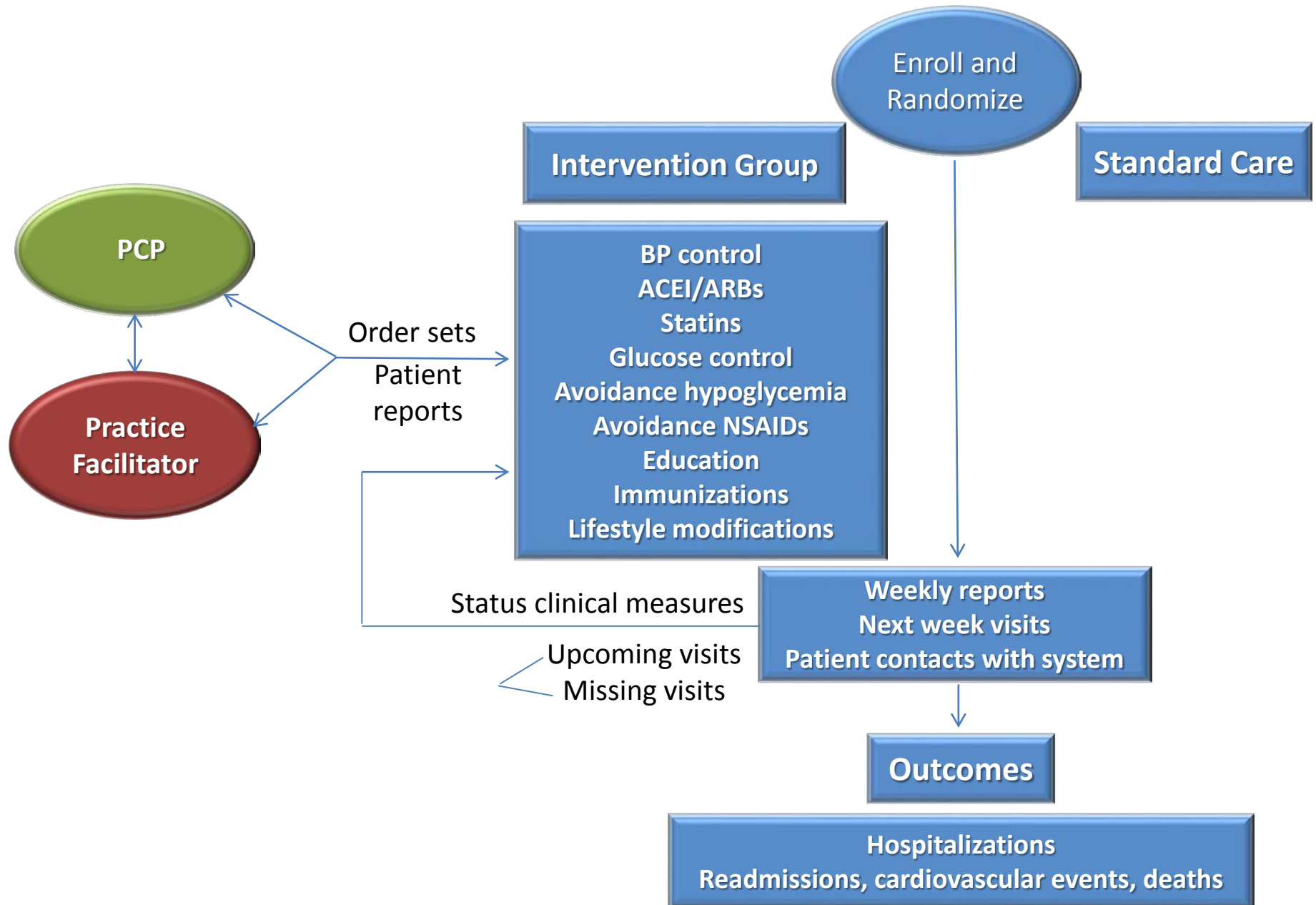
ICD-Pieces Implementation Work Flow



ICD-Pieces Patient Identification Work Flow



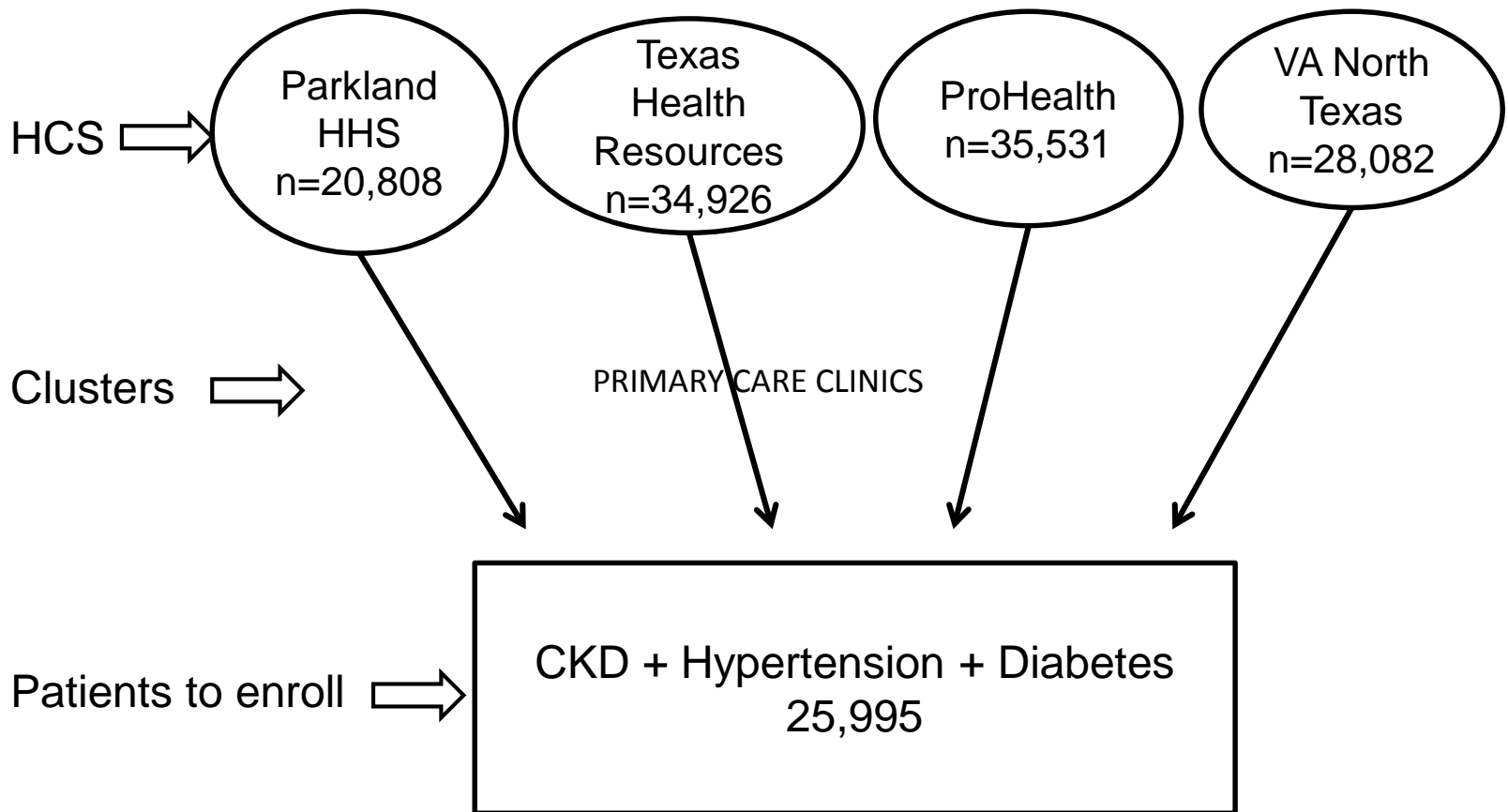
ICD-Pieces Patient Care Work Flow



Role of Practice Facilitator

- Designated staff on site at each clinic – RN/NP, PA, Nutritionist, Pharmacist, etc.
- Receives list of eligible patients scheduled for clinic visit weekly through the EHR
- Activates the site-specific enrollment protocol
- Triggers order set in the EHR to enroll patients in the study
- Reviews weekly updates on enrolled patients and adjusts management according to site specific-protocol

Proposed Patient Enrollment



Proposed Consenting Process

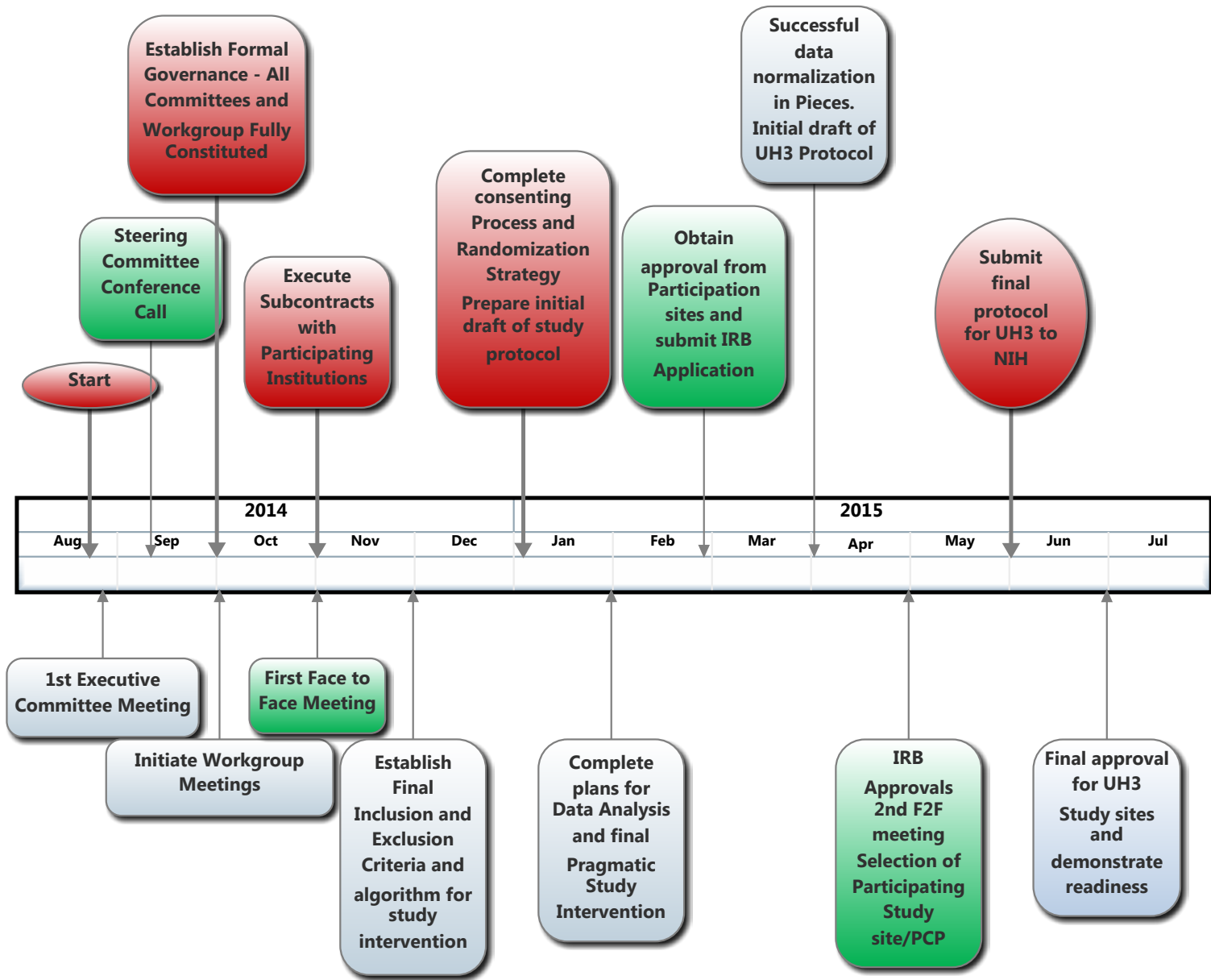
- Submission to IRB each individual health care system
- No plans to obtain individual consent
- Patients will be informed health care teams using PHI
 - Study focusing on CKD, diabetes and hypertension
 - Data from EHR
 - Study goal is to learn/ facilitate primary care providers delivering best care interventions
- Patients informed by print and electronic media
 - Culturally sensitive
 - Language appropriate
- Primary care providers can decide whether to follow recommendations

General Task for Year 1 Planning Period

- Regulatory
- Clinical
- Informatics
- Pragmatic Study

Improving Chronic Disease Management with Pieces

- Important public health problem
- Collaboration 4 large health care systems
 - Socioeconomic and ethnic diversity
 - Diverse geographic distribution
 - Different EHR
- Novel technology platform
- Prior experience with chronic conditions
- Potential for application to other diseases



Acknowledgements

Name	Institutional Affiliation	Role in the Study
Robert Toto, MD	UT Southwestern	Co-Investigator
Ruben Amarasingham, MD, MBA	PCCI	Co-Investigator/Parkland Site PI
George “Holt” Oliver, MD, PhD	PCCI	Co-Investigator
Adeola Jaiyeola, MD, MHSc	PCCI	Project Manager
Andrew Narva, MD	NIDDK/ NIH	Project Officer
Barbara Wells, PhD	NHLBI/ NIH	Scientific Officer
Ferdinand Velasco, MD	Texas Health Resources	THR Site PI
John Lynch, MHA	Pro Health Physicians Connecticut	Pro Health Site PI
Susan Hedayati, MD, MHS	VA North Texas Healthcare System	VA Site PI
Chul Ahn, PhD	UT Southwestern	Biostatistician
Song Zhang, PhD	UT Southwestern	Biostatistician
Brett Moran, MD	UT Southwestern	EHR Consultant
Perry Bickel, MD	UT Southwestern	Endocrinology Consultant
Chester Fox, MD	SUNY in Buffalo	Family Med Consultant
Linda Khan, PhD	SUNY in Buffalo	Co-Investigator