



NIH PRAGMATIC TRIALS
COLLABORATORY

Rethinking Clinical Trials®

NOHARM

PHASE ZERO

Andrea L. Cheville, MD, MSCE

Mayo Clinic, Rochester MN



2019 CONTEXT

MARCH “GO LIVE” WITH E2C2 TRIAL INTERVENTION

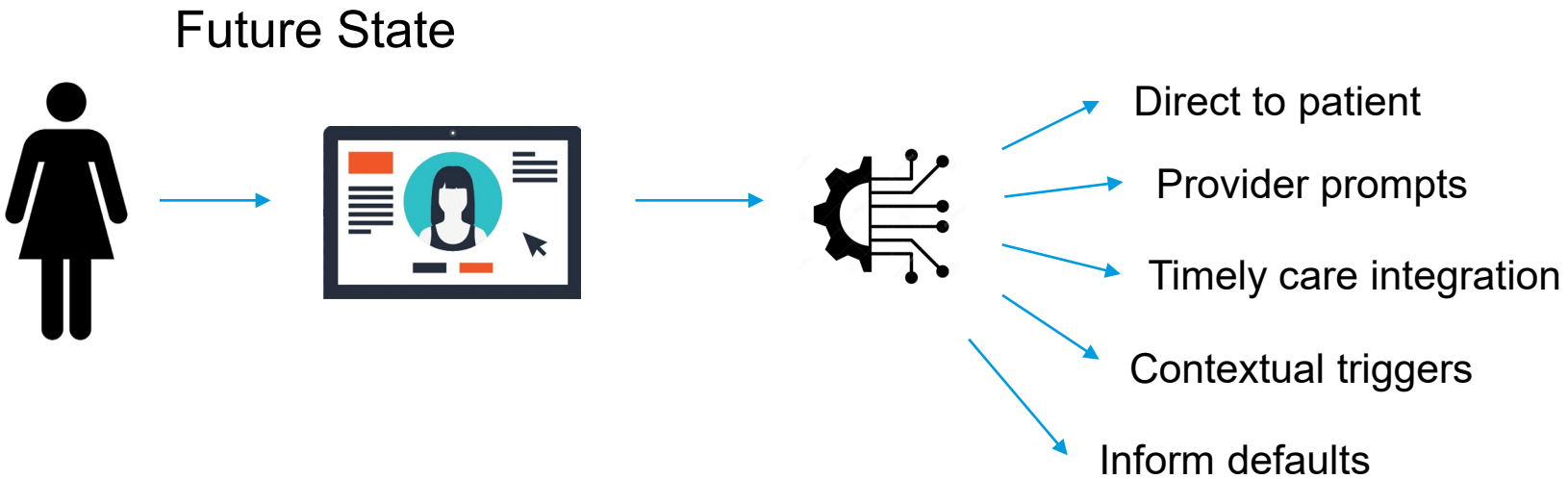
- Systematized ePROM symptom screening
- Automated EHR responses to actionable scores
 - Align with patient preferences
- High reach – population level
- Limited provider engagement
- Patients wanted more personalization

RFA CATALYST

GALVANIZED TEAM TO CONSIDER NEXT STEPS

- Relevant to our program's focus
- Bandwidth
- Interest & enjoyment
- Fundable opportunity to advance the state of the science

THE IDEA



TRANSLATION TO A TESTABLE HYPOTHESIS

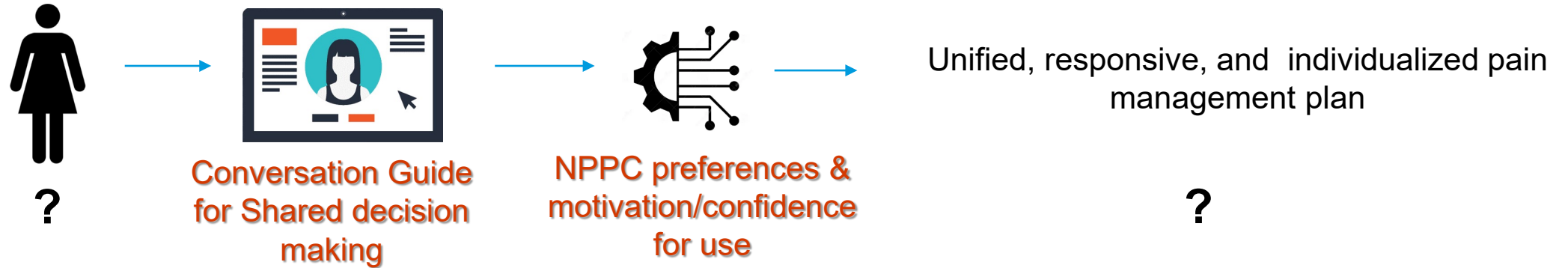
Assets

- High throughput destination medical center
- High rural representation
- Geographic range
- E2C2 trial
 - Population-level enrollment
 - EHR CDS

Limitations

- Primary care longitudinal follow up
- Ethnic and racial diversity
- Clinician engagement
- ↑ EHR build resources

STRATEGY – Team & Intervention



Skills

- EHR build
- Shared decision making
- Integrative medicine
- User-centered e-design
- Rehabilitation approaches to pain
- Telerehabilitation for pain control

Empirical Support



Innovation



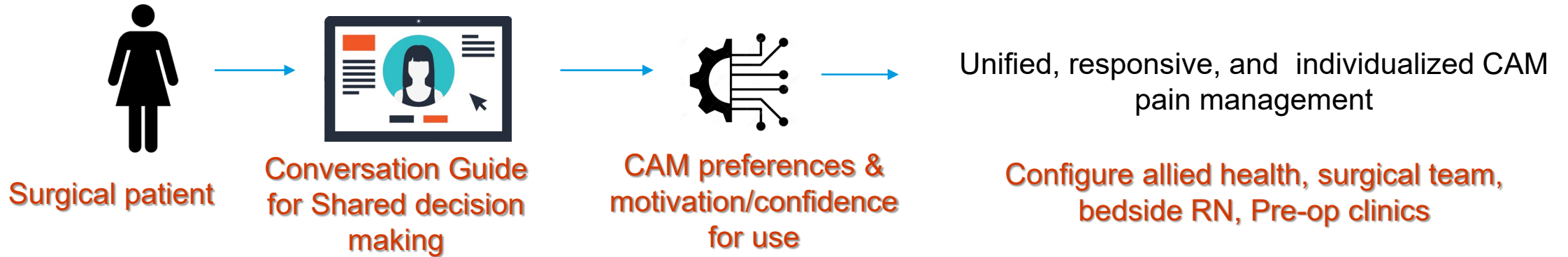
Resources



Team



STRATEGY – Population & Context



Available populations

- Cancer
- Back pain
- MSK
- Surgical*
- Chronic pain
- Transplant

Contexts

- Non-Mayo health system(s)
- Mayo Midwest
- Mayo Enterprise*

Empirical Support



Innovation



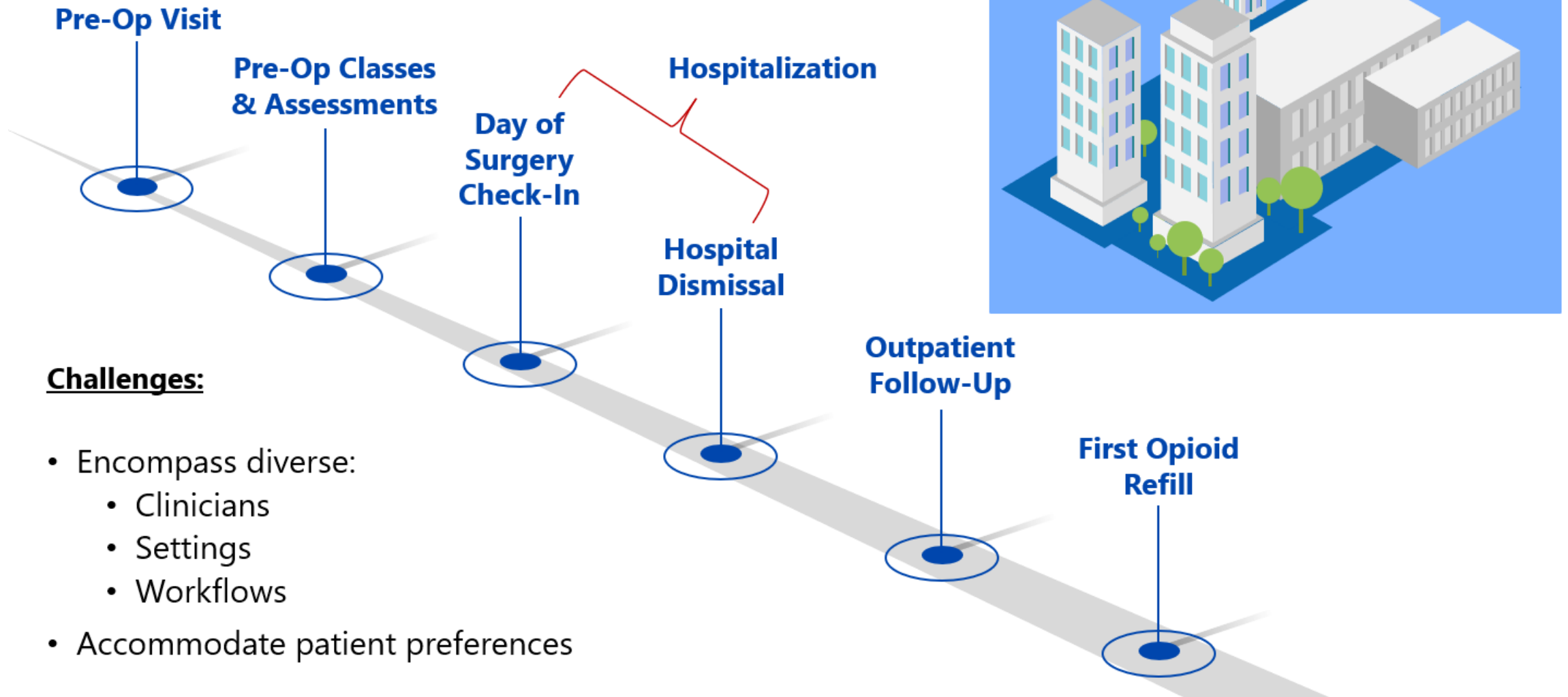
Resources



Team



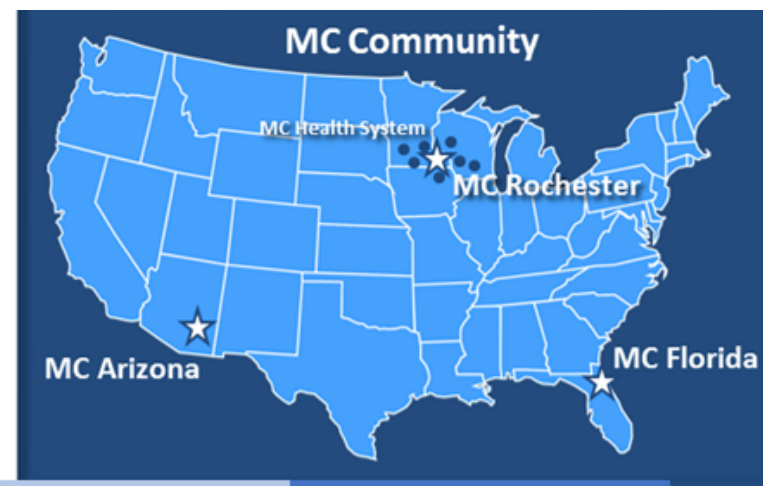
THE NOHARM TRIAL TESTED A CLINICALLY INTEGRATED EHR SYSTEM TO INCREASE USE OF VALIDATED NONPHARMACOLOGIC PAIN CARE (NPPC).



Challenges:

- Encompass diverse:
 - Clinicians
 - Settings
 - Workflows
- Accommodate patient preferences

NOHARM Population-level, Stepped Wedge, Cluster-randomized Pragmatic Trial



	Tranche 1 Rochester Cardiac, C-Section Florida Ortho Eau Claire Ortho, Colorectal, Gyn, C-Section La Crosse Gyn, C-Section	Tranche 2 Rochester Ortho, Gyn, Lung Arizona Lung, Cardia Mankato Colorectal	Tranche 3 Rochester Colorectal Florida Transplant Arizona Colorectal, Gyn, Transplant	Tranche 4 Florida Colorectal, Gyn, Lung, Cardiac Eau Claire Lung, Cardiac Mankato C-Section	Tranche 5 Rochester Transplant Arizona Ortho Mankato Ortho La Crosse Ortho, Colorectal
Control Condition	Data Collection 10/16/2020				
Step 1	Go Live 3/1/2021				
Step 2		Go Live 10/1/2021			
Step 3			Go Live 5/1/2022		
Step 4				Go Live 12/1/2022	
Step 5					Go Live 7/1/2023

THANK YOU