



NOHARM

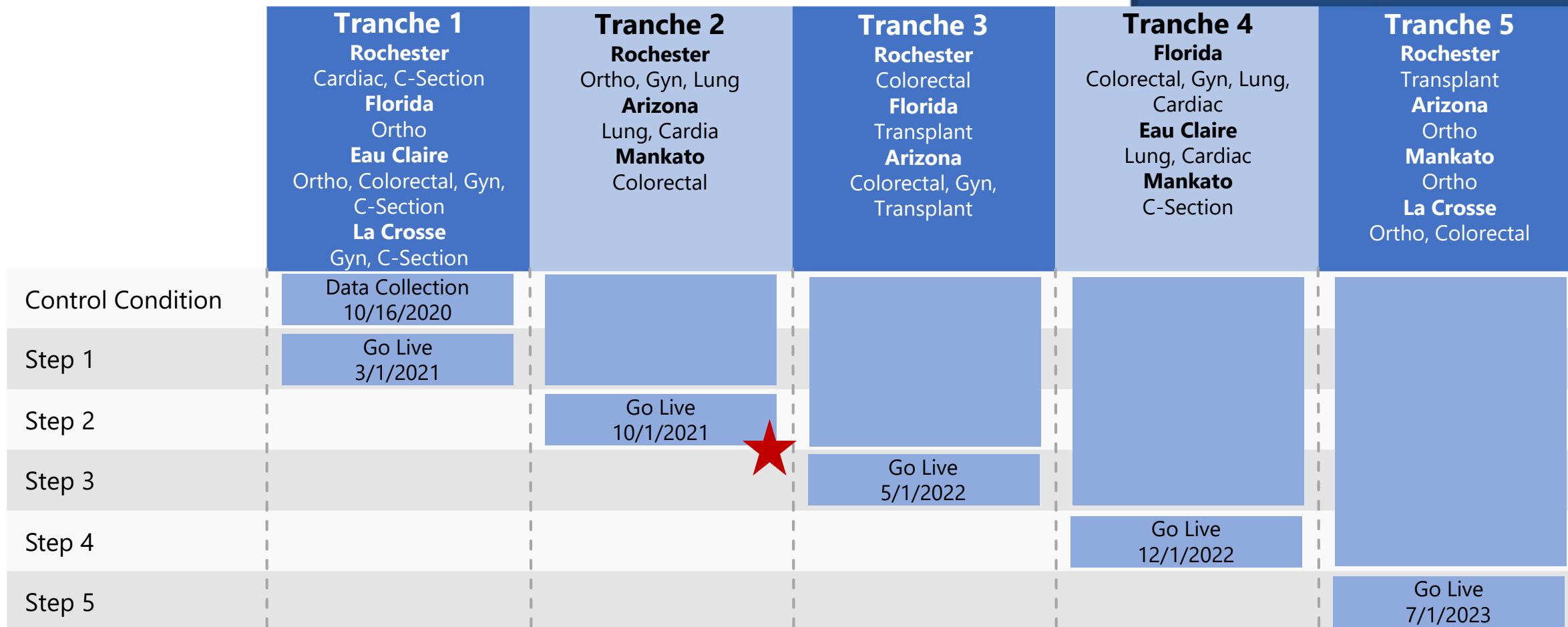
Non-pharmacological Options in post-operative Hospital-based And Rehabilitation pain Management pragmatic trial -

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Stepped wedge, cluster-randomized trial

- Population-level
- Waiver of consent
- Target enrollment 80K with ~38K accrued

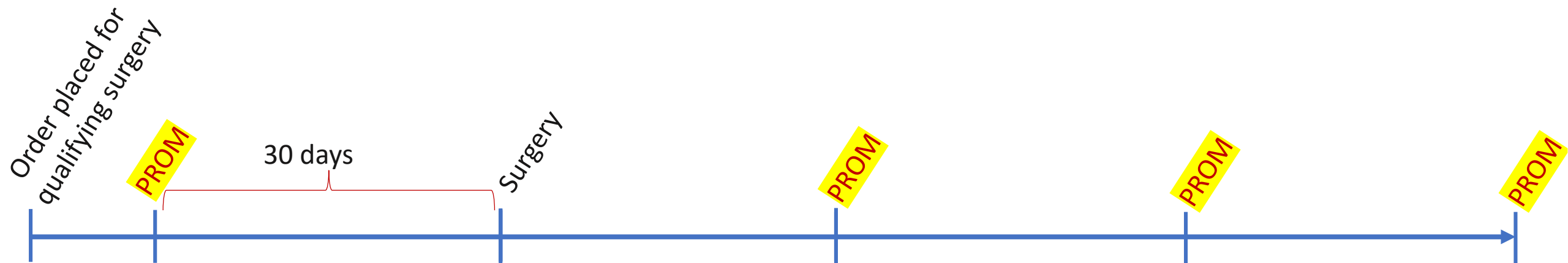


Outcomes:

- EHR assessment at baseline, and 1, 2, and 3 months post-surgery
- Primary
 - Pain interference – PROMIS CAT
 - Physical function – PROMIS CAT
- Secondary
 - Opioid consumption
 - Anxiety – PROMIS CAT
 - Healthcare utilization

EHR PROM collection for clinical trials

- Potential access to any patient, anywhere, at any time
- Requires careful specification of the right person, time, and PROM
 - Assignment triggered by event and/or characteristic(s)
 - Appropriate cadence
- Avoid competing with clinical PROMs and PROMs from other studies
- Timely discontinuation as required



PROM collection via the EHR: Challenge

- Complex assignment logic
 - Trigger events
 - Require precise parameterization
 - Robust to rescheduling, cancellations, deaths
 - Sync to ensure “lock out” rules function appropriately
 - Vulnerable to EHR perturbations
 - Trial-related build advancements
 - Cluster “go lives”
 - EHR updates

PROM collection via the EHR: Solution

- Include informaticists and expert EHR builders on trial team
- Ensure that entire trial team appreciates mission critical research needs to:
 - Minimize bias
 - Complete data collection
 - Reduce contamination
- Regular proxy and outcome monitoring

PROM collection via the EHR: Challenge

- Lower response rates among portal non-users
 - Demographically distinct subgroup(s)
 - More frequent point-of-care PROM collection
 - Altered cadence

PROM collection via the EHR: Solutions

- Optimize site-specific POC PROM assessment modes
- PROM collection at all POC encounters
- “Scavenge” PROMs collected by other studies/clinicians
- Augment EHR-collection with mailed print, IVR, etc. PROM collection

EHRs for PCT intervention delivery: Opportunity

Explanatory trials tell you what is true. PCTs tell you what to do.
Ideally, when, how often, to whom, etc...

- Automate capture of intervention delivery specifics, variations, and dose
 - Anticipate and parameterize process variables
 - Leverage/adapt existing data elements
 - Create new data elements
 - “Silently” embed in clinical workflows

Thank you for your kind attention!

We wish to extend heartfelt thanks to our partners within the HEAL Initiative, NIA, NICHD, and NIH Clinical Trials Collaboratory, as well as our patient participants.